Hand and wrist orthoses for adults with rheumatological conditions

Practice guideline

Second edition

Royal College of Occupational Therapists

Please note: New text and key changes included in this second edition are highlighted in yellow.
Other RCOT practice guidelines available:


Occupational therapy in neonatal services and early intervention (2017)


Hand and wrist orthoses for adults with rheumatological conditions (2015)

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NICE has accredited the process used by the Royal College of Occupational Therapists to produce its practice guidelines. Accreditation is valid for five years from January 2018 and is applicable to guidance produced using the processes described in the Practice guidelines development manual 3rd edition (2017a). More information on accreditation can be viewed at www.nice.org.uk/accreditation.
This guideline was developed using the processes defined within the Practice guidelines development manual (College of Occupational Therapists [COT] 2017a).

Readers are referred to the manual to obtain further details of specific stages within the guideline development process.

The manual is available at: https://www.rcot.co.uk/sites/default/files/Practice-guidelines-development-manual-Third-edition%20update%202018.pdf
Effective self-management, in conjunction with collaborative multidisciplinary team management in rheumatoid arthritis and osteoarthritis, requires clients to make multiple changes and teams to provide multiple interventions. To maximise effective service delivery, these must be evidence-based.

The College of Occupational Therapists Specialist Section-Rheumatology has commenced major work to update and expand Rheumatology Occupational Therapy Clinical Guidelines, to contribute further to evidence-based practice. This first updated guideline, on orthoses, was prioritised by both rheumatology clients and occupational therapists in a survey conducted by the Specialist Section, as well as being the most popular topic in the previous guidelines, published in 2003.

Even with changing medical management, orthoses are still a core intervention for many people with arthritis, to reduce hand symptoms and improve hand function, alongside hand exercises and joint protection. This guideline is an impressive, well-referenced contribution to rheumatology occupational therapy. It is well conducted; the method and article reviews are thoroughly explained and it follows GRADE and NICE accredited processes and standards. It is thus an authoritative body of work, which occupational therapists and clients with arthritis can use with confidence.

The authors are to be congratulated on their commitment to developing this guideline for hand and wrist orthoses, and thus to our speciality and our profession. Much of this work has been completed in their own time. Although some of the guideline group were already very experienced in systematic reviewing, others had to develop these skills, and the guideline thus represents a truly collaborative venture.

The guideline group has taken great care to develop evidence-based recommendations using the available research. They identify clearly the limitations of current research as, in the main, evidence is only available related to wrist, resting and swan neck orthoses in rheumatoid arthritis and orthoses for base of thumb osteoarthritis. They have addressed orthotic provision, including clear recommendations for standardised assessment and patient education, combined with other hand interventions. The authors highlight the lack of research into long-term effectiveness, cost-effectiveness and the lack of recent research evaluating other common orthoses, such as compression gloves. Further investigation is still needed and thus the authors identify a number of areas for research which clinicians and researchers can take up the challenge to address.

Publishing guidelines does not necessarily mean they will be used in practice. The authors address dissemination and implementation, by providing standardised continuing professional development (CPD) materials about the guideline and an audit tool for use in clinical practice. As rheumatology occupational therapists it is now our responsibility to ensure the guideline is understood and implemented into practice.

Alison Hammond PhD, FCOT
Professor in Rheumatology Rehabilitation
I am delighted that the College of Occupational Therapists has published this practice guideline for the use of hand and wrist orthoses in rheumatology by occupational therapists. This document provides specific evidence-based recommendations which describe the most appropriate care or action to be taken by therapists working with adults who may benefit from a hand or wrist orthosis as an intervention for a rheumatological condition. At Arthritis Care, we encounter many people who struggle daily with this painful and debilitating condition, so we welcome any guidance that can improve the treatment, and thus the lives, of the millions of people living with arthritis. As a membership organisation supporting people living with arthritis, we are particularly pleased to see the involvement of service users in this process.

The guideline team is to be congratulated on producing this thorough practice guideline, which will surely result in more effective and much better informed treatments for people with hand or wrist arthritis. Occupational therapists have a key role to play in advising and assisting people living with arthritis, so that they can live their lives to the full and retain independence. This document provides an important step forward in enabling therapists to determine the most appropriate interventions for people with a rheumatological condition, based on the available evidence. As such, it contributes to the advancement of effective therapy in this field, which Arthritis Care wholeheartedly welcomes. I hope it will be widely circulated and considered, and I would urge the profession to respond to the suggested recommendations.

Judi Rhys
Chief Executive
Arthritis Care

The impact of long-term rheumatic and musculoskeletal disease on both the individual and society is staggering, yet often trivialised and overlooked (Murray et al 2013). Although long-term conditions are now rising up the healthcare agenda, this is unfortunately outpaced by the rise in clinical demand, which shows no sign of abating (NHS England 2014). These complex conditions can have a dramatic impact on a person’s quality of life, and while pharmacological therapy can alter disease processes and reduce pain, optimal management requires input from multiple professionals with access to a range of pharmacological and non-pharmacological therapies. Indeed, access to the wider multidisciplinary team, and specifically occupational therapy, is recommended by both NICE (NICE 2018) and SIGN (SIGN 2011). Hand involvement is almost ubiquitous in rheumatoid arthritis and although patients clearly value occupational therapy, only 40% of patients access such services (National Audit Office 2009). Clearly there is still much to do before all patients can receive the care they require, but I am confident this guideline will play an important role in achieving this goal.

The authors should be congratulated on the substantial work conducted to produce this robust and pragmatic guideline. Similarly, the College and wider profession should also be acknowledged for obtaining accreditation to produce NICE-endorsed guidelines, and for developing the evidence base to inform the specific recommendations within. Such a guideline could not be produced by all AHPs (allied health professions), and occupational therapists should be justifiably proud. I sincerely hope that this guideline is used to improve individual patient care, and that it is used on a wider level to increase the provision of this much needed service.

Dr Michael Backhouse
National Institute for Health Research (NIHR) Fellow
President of British Health Professionals in Rheumatology
Key recommendations for implementation

The aim of this practice guideline is to provide specific evidence-based recommendations which describe the most appropriate care or action to be taken by occupational therapists working with adults who may benefit from a hand or wrist orthosis as an intervention for a rheumatological condition. Physiotherapists, hand therapists, orthotists and others who prescribe or use orthoses may also wish to refer to the guideline to inform their practice.

An orthotic intervention prescribed by an occupational therapist is usually one component of a more comprehensive joint protection and self-management programme (Hammond 2014). The recommendations are intended to be used alongside the therapist’s clinical expertise in their assessment of need and implementation of interventions. The practitioner is, therefore, ultimately responsible for the interpretation of this evidence-based guideline in the context of their specific circumstances and each individual.

Recommendation statements should not be taken in isolation and must be considered in conjunction with the contextual information provided in this document, together with the details on the strength and quality of the recommendations. The statements are graded based on the Grading of Recommendations Assessment, Development and Evaluation (GRADE) process (GRADE Working Group 2004) as described in the Royal College of Occupational Therapists’ Practice guidelines development manual (COT 2017a). The strength of the recommendations is identified via a scoring of 1 (strong) or 2 (conditional), and the quality of the supporting evidence via a grading on a scale of A (high) to D (very low). This revised edition of the guideline strengthens the previous recommendations. It is strongly advised that readers study sections 10 and 11 to understand the guideline methodology, together with the evidence tables in Appendix 6, to be fully aware of the outcome of the literature searches and overall available evidence.

The guideline aims to support the occupational therapist’s decision-making and clinical reasoning and, being based on evidence, cannot cover all aspects of occupational therapy practice with respect to the prescription of orthoses for rheumatological conditions. It is also not intended to be a guide on assessment or orthosis fabrication.

The evidence includes research published since 2004, and participants with rheumatoid arthritis recruited to some of these studies may not have had access to current biological therapies. While only that proportion of people who have more aggressive forms of the disease will meet the eligibility criteria to receive such medication, the improved outcomes that have been reported may have influenced the findings of more recent studies. More dated research may not, therefore, necessarily be representative of the current population living with rheumatoid arthritis.

The recommendations, based on the best available evidence to date, are set out in three categories:

i. Rheumatoid arthritis: orthoses for activity and rest.
ii. Osteoarthritis: base of thumb orthoses.
iii. Optimising outcomes for people who access services.
Recommendations could not be developed, due to insufficient evidence, for a number of presentations of rheumatoid arthritis (e.g. ulnar deviation, Boutonnière deformity); trigger finger; carpal tunnel syndrome (CTS) (where there is an underlying inflammatory pathology); the use of compression gloves; or for conditions such as psoriatic arthritis or systemic lupus erythematosus. Orthoses may, however, be prescribed for these other inflammatory conditions, and the absence of published evidence does not mean that an orthotic intervention may not be effective for those people.

It is important to highlight that this guideline is based on the best available evidence to date and subsequently the recommendations cannot explicitly address all clinical, health and social care areas or outcomes identified within the scope. The guideline does not therefore reflect the full range of orthotic interventions used in practice by occupational therapists. While the recommendations for rheumatoid arthritis and osteoarthritis cannot be extrapolated to other inflammatory conditions, the recommendations for optimising outcomes for people who access services provide overarching principles that can be considered as part of the prescription of any hand or wrist orthosis for adults with rheumatological conditions.

**Recommendations by category**

The recommendations are not presented in any order of priority or relative importance. The overall quality of evidence grade reflects the robustness or type of research supporting a recommendation, but not necessarily the recommendation’s significance to occupational therapy practice.

‘**It is recommended.** . . .’ benefits appear to outweigh the risks (or vice versa) for the majority of the target group; most people would want or should receive this course of intervention or action.

‘**It is suggested.** . . .’ Risks and benefits are more closely balanced, or there is more uncertainty in likely values and preferences of people who access services; the majority of people would want this intervention but not all, and therefore they should be supported to arrive at a decision for intervention consistent with the benefits and their values and preferences.
### Rheumatoid arthritis: orthoses for activity and rest

#### Functional wrist orthoses
1. **It is recommended** that a functional wrist orthosis should be prescribed for **people** experiencing wrist pain as a result of rheumatoid arthritis.
   

#### Resting/night orthoses
2. **It is suggested** that where a night or resting orthosis is being considered as potentially beneficial to reduce symptoms for a **person** with rheumatoid arthritis, both subjective and objective measures are used for the monitoring and review of effectiveness.
   
   (Adams et al 2008 [B]; Silva et al 2008 [A])

#### Orthoses for swan neck deformity
3. **It is suggested**, when considering an orthosis for swan neck deformity, that a potential positive effect on dexterity should be balanced by possible adverse effects such as pressure and paraesthesia.
   
   (Giesen et al 2010 [D]; Giesen et al 2009 [C]; Spicka et al 2009 [D]; Zijlstra et al 2004 [C])

### Osteoarthritis: base of thumb orthoses

#### Orthoses to reduce pain and/or improve function
4. **It is recommended** that an orthosis should be prescribed for **people** experiencing pain and/or functional difficulties with activities of daily living as a result of thumb base osteoarthritis.
   

#### Orthoses to improve grip and pinch strength
5. **It is suggested** that an orthosis can improve the grip/pinch strength for some people with thumb base osteoarthritis.
   

[New evidence 2020]
### Optimising outcomes for people accessing services

**6. It is recommended** that validated, standardised assessment and outcome measures are used pre- and post-provision of an orthosis to monitor progress, evaluate effectiveness, assess functional outcomes and understand individual satisfaction.


[Statement amended and new evidence 2020]

**7. It is suggested** that, given the inconsistent evidence of a superior orthosis fabrication/design or wearing regimen, the orthosis selected should maximise occupational performance and **individual choice**.


[New evidence 2020]

**8. It is recommended** that to optimise adherence to wearing a prescribed orthosis, the occupational therapist should discuss with the **person** the potential benefits and limitations; practicalities of use and comfort; provide the opportunity to try on orthoses prior to issue; and routinely arrange follow-up review of the intervention.


[New evidence 2020]

It is additionally recommended that occupational therapists use the audit tool that is available to support this guideline (see section 7) to undertake audit against the above recommendations.
Pain and disability are a key focus for the management of rheumatological conditions. Arthritis Research UK in their parliamentary guide to musculoskeletal conditions state that ‘untreated arthritis, regardless of the cause, can lead to pain, disability and lost quality of life’ (Arthritis Research UK 2012, p4). Pain experienced as a result of musculoskeletal conditions can have a significant impact on an individual’s ‘ability to participate in family, social and working life’ (Public Health England 2019).

The rheumatological conditions covered by this guideline are considered to be long-term conditions with impact on the individual and on the health and social care systems. Versus Arthritis reports that treating the most common forms of arthritis, osteoarthritis and rheumatoid arthritis cost the NHS and wider healthcare system in 2017 £10.2 billion in direct costs (York Health Economics 2017, cited in Versus Arthritis 2019a, p17). They also estimate that lost working days due to osteoarthritis and rheumatoid arthritis cost the UK economy £2.58 billion in 2017 (York Health Economics 2017, cited in Versus Arthritis 2019a, p17).

This review of the practice guideline focuses on the contribution that orthotic interventions can make to the health and wellbeing of individuals with rheumatological conditions.

1.1 Practice requirement for the guideline

Occupational therapy is a key intervention for individuals who have a rheumatological condition, especially when there is wrist and hand involvement. Pain in these areas often has an impact on an individual’s occupational performance. Interventions provided by occupational therapists working in rheumatology, therefore, commonly include the consideration of wrist and hand-based orthoses.

The Royal College of Occupational Therapists Specialist Section – Trauma and Musculoskeletal Health (RCOTSS-Trauma and Musculoskeletal Health), previously called the Royal College of Occupational Therapists Specialist Section-Rheumatology (RCOTSS-Rheumatology) and formerly called the National Association of Rheumatology Occupational Therapists (NAROT), developed a series of clinical guidelines in 2003, including splinting (NAROT 2003a). These aimed to support occupational therapy staff to deliver evidence-based practice. The clinical guidelines were accessed, used and valued by practitioners, indicative of a continuing need for information to support evidence-informed best practice. The guidelines, of which splinting was the most frequently downloaded in the series, were withdrawn in 2013.

In 2007, RCOTSS-Trauma and Musculoskeletal Health carried out a membership survey to identify the main research priorities among practitioners (McArthur 2007a). Results showed that research evidence for the use of orthoses was the second most requested area for clinicians, and hand therapy was third on people who accessed services' priority list, with pain relief at the top of the priority list (McArthur 2007b).

Recognising that the original guidelines published by NAROT (2003b) were dated, the Specialist Section’s National Executive Committee made a commitment to support the development of more specific and targeted practice guidelines produced in line with
The occupational therapy role

the Royal College of Occupational Therapists’ NICE accredited process (COT 2017a).

1.2 Topic identification process

RCOTSS-Trauma and Musculoskeletal Health identified from the literature, and from discussions taking place within their study days and conferences, a wide variation in the prescription of hand orthoses within rheumatology occupational therapy practice (Doherty et al 2009). Hand and wrist orthoses for rheumatological conditions were identified as the topic for this occupational therapy practice guideline. Specialist Section members were alerted to the proposal via the section’s newsletter.

A guideline project proposal was developed by RCOTSS-Trauma and Musculoskeletal Health and this was subsequently approved by the Royal College of Occupational Therapists’ Practice Publications Group in November 2013.

1.3 National context

Musculoskeletal conditions is an umbrella term for a range of conditions, including inflammatory conditions such as rheumatoid arthritis, conditions that cause musculoskeletal pain such as osteoarthritis, and osteoporosis and fragility fractures (Versus Arthritis 2019a). This guideline focuses on rheumatoid arthritis and osteoarthritis.

Rheumatology involves the investigation, diagnosis and management of conditions which include inflammatory arthropathies (for example, rheumatoid arthritis); degenerative arthropathies (for example, osteoarthritis); systemic conditions and connective tissue disease; and soft tissue rheumatism (British Society for Rheumatology 2019).

Over 5 million people have arthritis of the hand. Osteoarthritis is the most common form, with rheumatoid arthritis the next most common (Versus Arthritis 2013).

Osteoarthritis is normally associated with later life. Data collected by the Arthritis Research UK Primary Care Centre at Keele University identified the prevalence of consultation, with a general practitioner, for osteoarthritis in those aged 45 years or over in the UK as 33%. Hand and wrist consultation prevalence is estimated at 6%, representing 1.56 million people. Women aged 45–64 years are more than twice as likely as men in that age group to have consulted their general practitioner regarding hand or wrist osteoarthritis – an estimated 620,000 women aged 45–64 years in the UK (Arthritis Research UK 2013, p31).

Rheumatoid arthritis is the second most common form of arthritis, and can affect adults of any age, although 40–60 years of age is the most common for rheumatoid arthritis to develop (Scott and Bosworth 2014). The Global Burden of Disease Study estimated that over 460,000 UK adults had rheumatoid arthritis in 2017 (Institute for Health Metrics and Evaluation 2019). Rheumatoid arthritis is the most common inflammatory arthritis, with prevalence being two to three times greater in women than men (Versus Arthritis 2019a).
1.4 Context of service delivery

The UK population is ageing. The number of people aged 65 or over is growing faster than the number of people under 65 in the UK. The number of people aged 65 to 85 rose by 23% to 10.6 million between 2008 and 2018. The number of people aged over 85 increased by 22.8% to 1.6 million in the same period (Office for National Statistics 2018). Looking ahead, it is predicted that in the next twenty years in England alone there will be an increase of around 49% in the 65 and older age group, to around 4.75 million people. The fastest growing age group is those aged over 85 where the expected increase is almost 114% or 2.8 million people (Age UK 2017).

The impact of arthritis on individuals can be significant; it is estimated that one third of the population over 50 have some form of arthritis that is troublesome enough to interfere with everyday activities.

Service delivery must, therefore, be seen in the context of the prevalence of osteoarthritis and rheumatoid arthritis, a rising older population, an increase in those with long-term or multiple conditions, and the associated increase in need for care and support (Great Britain. Parliament. Select Committee on Public Service and Demographic Change 2013).

The National Institute for Health and Care Excellence (NICE) defines several clinical pathways, one of which is for musculoskeletal conditions. The musculoskeletal pathway identifies a number of sub-pathways, including pathways for both rheumatoid arthritis (NICE 2018) and osteoarthritis (NICE 2014a).

The commissioning and delivery of services in England and Wales is expected to consider the clinical guideline (NICE 2014b) for osteoarthritis and the clinical guideline (NICE 2018) and quality standard (NICE 2013) for rheumatoid arthritis. In Scotland there is a clinical guideline for the management of early rheumatoid arthritis (SIGN 2011).

The NICE guideline for the care and management of osteoarthritis identifies both pharmacological and non-pharmacological management and treatment options (NICE 2014b). A key recommendation refers to holistic assessment and management; this states:

Assess the effect of osteoarthritis on the person’s function, quality of life, occupation, mood, relationships and leisure activities. [Recommendation 1.2.1] (NICE 2014b, p10)

NICE recommendations that refer to the need to agree an individualised plan that considers factors such as comorbidities, and risks and benefits of treatment options, are also pertinent to this guideline.

The rheumatoid arthritis clinical guideline (NICE 2018) highlights the importance of the multidisciplinary team, with a recommendation that:

Adults with rheumatoid arthritis should have ongoing access to a multidisciplinary team. This should provide the opportunity for periodic assessments of the effect of the disease on their lives (such as pain, fatigue, everyday activities, mobility, ability to work or take part in social or leisure activities, quality of life, mood, impact on sexual relationships) and help to manage the condition. [Recommendation 1.7.1] (NICE 2018, p10-11)
The recognition of the contribution of different members of the multidisciplinary team in the provision of rheumatology services is essential. Orthoses, for example, may be prescribed by occupational therapists, physiotherapists, orthotists or hand therapists, and the health professional(s) involved will reflect local service delivery pathways.

Many occupational therapy services across the country continue to receive large numbers of referrals per year and a significant proportion is for splinting interventions (Benharoch 2013, Tougher 2013). Splinting remains a core intervention offered to people with arthritis and aligns well with joint protection education. The challenge for occupational therapy researchers is to produce substantive evidence on the efficacy and effectiveness of splint provision: for example, future research questions should focus on which splint designs are the most effective and at which stage of the disease process splints should be considered (Adams 2010, Ekelman et al 2014).

### 1.5 Background to clinical conditions

The recommendations within this guideline focus on osteoarthritis and rheumatoid arthritis. This reflects findings from the literature search for evidence that support the use of hand and wrist orthoses for adults with rheumatological conditions. A brief outline of these two particular conditions is therefore provided.

#### 1.5.1 Osteoarthritis

A range of factors are understood to increase the risk of osteoarthritis, and it may develop because of a combination of factors, such as damage to the joints (excessive loading, i.e. stress over time); injury or disease; occupation; joint abnormalities and genetic factors (Versus Arthritis 2019a).

Osteoarthritis develops as a consequence of joint breakdown, combined with the body’s attempted repair process (Arthritis Research UK 2013, p6), and may affect multiple joints. It is mainly degenerative in aetiology and is characterised by roughening and thinning of cartilage, thickening of underlying bone with the formation of ‘bony spurs’, and resultant narrowing of the gap between the bones (joint space). Additionally, swelling may result from excess fluid in the joint (caused by thickening of the synovium in the joint capsule), inflammation from the joint surfaces rubbing together, and the capsule and ligament around the joint may thicken and contract, resulting in reduced range of motion. The loss of cartilage, in severe cases, can lead to bone surfaces rubbing together and wearing away.

Osteoarthritis results in a reduction in joint movement, and the main symptom of pain. While it can affect any joint, it most commonly affects the knee and hip, where intervention focuses on physical activity and pain management. Additionally the foot, ankle, hand and wrist may be affected. Hand osteoarthritis commonly presents in the base of the thumb, but may affect any joint, with characteristics of deformity, lasting pain, work disability, reduction in quality of life and overall function (Kloppenburg et al 2019, Gooberman-Hill et al 2013).

The management of osteoarthritis is set out in the NICE clinical guideline (NICE 2014b) but there is, as yet, no disease-modifying anti-rheumatic drug (DMARD) therapy available.
1.5.2 Rheumatoid arthritis

Rheumatoid arthritis is an inflammatory arthritis and may affect multiple joints. It affects the body symmetrically and typically begins in the small joints of the hands and feet and spreads proximally over time. The synovium of the joint becomes inflamed and thickened, and forms a pannus that erodes both the cartilage and the underlying bone. Genetics and smoking have been identified as risk factors (Versus Arthritis 2019b).

A systemic disease, rheumatoid arthritis can affect the whole body, including the lungs, heart and eyes (NICE 2018), and can include neurological complications, such as carpal tunnel syndrome (NICE 2019). Fatigue is a common feature and is reported to have an impact on functional ability (McArthur et al 2015).

Key symptoms of rheumatoid arthritis in the upper limb include pain, joint swelling, stiffness and muscle weakness. These can lead to impairment in hand function (Hammond et al 2018). People with long-standing rheumatoid arthritis, or those who present late to clinical services, may present with tendon and joint problems. Joint deformities may affect the wrist and hand as a result of disease damage to intrinsic and extrinsic structures. Typical presentations include ulnar drift of the metacarpophalangeal joints and boutonniere and swan-neck deformities in the fingers (Wu and Talwalker 2019).

The occupational therapy needs of those with early rheumatoid arthritis are different from those of individuals with more long-standing disease. Both may have loss of function due to joint pain but the aetiology of symptoms is different: that is, inadequately controlled disease activity is typically the main factor for joint pain in early disease; in disease of long duration there is also potential for pain due to altered body mechanics secondary to joint damage, with or without disease activity. Clinical interventions focus on ‘controlling pain and inflammation, reducing joint damage and maintaining or improving physical function and quality of life’ (McArthur et al 2013, p457).

Both earlier diagnosis and biological therapies, such as anti-tumour necrosis factor drugs (Anti-TNFα), have made a significant impact on the management of rheumatoid arthritis (Siegel et al 2017). For some the use of these disease modifying treatments ‘has enabled people to move from a trajectory of long term decline to one of maintenance and potential improvement’ (McArthur et al 2015, p854). Evidence supports the use of a range of occupational therapy interventions for adults with rheumatoid arthritis; however research has highlighted an increased need for the availability of occupationally focused interventions (Siegel et al 2017).
The occupational therapy role

2 The occupational therapy role

The person-centred and holistic philosophy of occupational therapy underpins the recommendations within this guideline.

Occupational therapists believe that the ability to engage in meaningful occupation is fundamental to the facilitation and maintenance of health and wellbeing. By engaging with occupations (activities we have to, need to, or want to do), we gain a sense of our own being. It is not enough, however, to just ‘do and be’, we also need to engage in meaningful occupations in order to become something in the future. (Royal College of Occupational Therapists 2019, p2-3)

Occupational therapy interventions should take into account national clinical guidelines.

The NICE osteoarthritis clinical guideline (NICE 2014b) recommends a holistic assessment and, within the context of non-pharmacological management, there are two recommendations that are particularly pertinent to health professionals who prescribe orthoses or assistive devices:

People with osteoarthritis who have biomechanical joint pain or instability should be considered for assessment for bracing/joint supports/insoles as an adjunct to their core treatments. (Recommendation 1.4.8)

Assistive devices (for example, walking sticks and tap turners) should be considered as adjunct to core treatment for people with osteoarthritis who have specific problems with activities of daily living. If needed, seek expert advice in this context (for example from occupational therapists or Disability Equipment Centres). (Recommendation 1.4.9)

Referral to occupational therapy services is recommended for people with hand osteoarthritis:

This evidence suggests that those people with hand pain, difficulty and frustration with performing daily activities and work tasks should be referred to occupational therapy for splinting, joint protection training and assistive device provision. This may be combined with hand exercise training. People should be referred early particularly if work abilities are affected. (NICE 2014a, Section 8.6.5)

The NICE clinical guideline for rheumatoid arthritis (NICE 2018) makes direct reference to occupational therapy:

People with RA should have access to specialist occupational therapy, with periodic review if they have:

- Difficulties with any of their everyday activities, or
- Problems with hand function. (Recommendation 1.8.2)

The SIGN rheumatoid arthritis guideline (SIGN 2011) also includes a recommendation for occupational therapy; however, the specific recommendation for ‘splinting’ is actually
included within a section on physiotherapy rather than indicating that this intervention
may be provided by a range of other health professionals (including occupational
therapists, hand therapists and orthotists):

Skilled occupational therapy advice should be available to those experiencing
limitations in function. (Recommendation 7.1.1)

Resting and working splints can be used to provide pain relief. (Recommendation 7.2.4)

The role of occupational therapy within rheumatology includes a variety of
interventions to support self-management, enhance function and facilitate
independence. The occupational therapy clinical guidelines for rheumatology
(NAROT 2003b) identified key areas for intervention of joint protection and energy
conservation; psychological wellbeing and self-management; sexuality, parenting and
family relationships; employment and splinting.

Orthotics is a conservative intervention for wrists and hands that are affected by either
primary inflammation (e.g. rheumatoid arthritis) or degenerative processes
(e.g. osteoarthritis) with secondary inflammation (Bradley and Adams 2013). Daily
activities that require lifting or grabbing items may increase pain; therefore, support for
joints may decrease pain and improve function.

Assessment for, and provision of, wrist and hand orthoses is frequently used as part of
occupational therapy intervention when addressing the consequences of osteoarthritis
or rheumatoid arthritis on the hand and wrist. The use of orthotics for people with
arthritis has been identified as the following (Deshayes 2018):

- To reduce inflammation.
- To decrease pain.
- To support unstable joints.
- To properly positioning joints.
- To limit undesired motion.
- To increase range of movement.

The evidence for prescribing an orthosis is, however, variable and prescription should
therefore be underpinned by clinical reasoning based on ‘biomechanical and anatomical
knowledge’ (Bradley and Adams 2013, p191). Occupational therapists gain their
experience and expertise in the provision of an orthosis largely as a post-graduate and,
therefore, therapists must ensure they work within their scope of practice and
competence (COT 2015a).

The occupational therapist is advised to consider three areas within their clinical
decision-making: disease management, management of people who access services, and
management of mechanical function/dysfunction (Bradley and Adams 2013, p193).

An orthosis for the hand and wrist may include one or more of the following joints:

- The carpal joints, including the radiocarpal and distal radioulnar joints – wrist.
- Carpometacarpal joint (CMCJ) – base of the thumb (or trapeziometacarpal joint).
- Metacarpophalangeal joint (MCPJ) – between the distal ends of the metacarpal bones
  and proximal phalanges of the fingers and thumb (the large knuckles of the hand).
- Proximal interphalangeal joint (PIPJ) – middle joint of the fingers.
- Distal interphalangeal joint (DIPJ) – end joint of the fingers.
- Interphalangeal joint (IPJ) – distal joint of the thumb.
Hand function is a global term but includes range of movement; sensation and proprioception; dexterity/coordination; strength of grip; and a range of grip types. Where any of these elements of function are affected, this can impact on the individual’s occupational performance. An orthosis needs to support the joint being treated, but fabrication and design should only immobilise or restrict joints that are the target of the intervention and minimise restriction of other movements and of hand function.

Orthotic prescription must take account of individual preferences and needs, including the complexities of treating people with multiple pathologies, or those with cognitive or emotional disorders, dementia and learning disabilities. Where an individual requires assistance to understand the potential benefits, risks and wearing regimen, or assistance to don/doff their recommended orthosis, the occupational therapist, with the person’s agreement, may need to liaise with family and/or paid carers. Any written information provided should be fully accessible and/or clear and ‘easy to read’.

Occupational therapists should also take into account potential health inequalities and any social determinants of health that may be appropriate to the people who access occupational therapy services (Marmot 2010, p15). Inequalities may be present for those accessing services for example; through referral systems; provision of orthoses (e.g. self-purchase requirements); accessible information (e.g. language used); and the approach to the provision of an orthosis and impact on work capacity (health and safety perspectives of orthosis wearing).

If an orthosis is required to be worn by an individual in the context of their paid employment, additional factors may need to be considered, including health and safety, hygiene and infection control issues. These will vary from one situation to another, depending on the working environment and duties. The occupational therapist may provide advice via an Allied Health Professional Health and Work Report (Allied Health Professions Federation 2019), and/or the individual may need to be advised to seek guidance from their employer and/or occupational health advisor before wearing the orthosis at work. The occupational therapist may need to consider offering alternative designs, materials and strapping to assist the individual in achieving adherence to the relevant requirements of their employment.

This practice guideline focuses on orthoses, but this is just one intervention that occupational therapists can offer individuals with rheumatological conditions involving the hand and wrist. The prescription of an orthosis should not be seen in isolation but within the context of a comprehensive assessment and individually tailored intervention plan. Information provided as part of an individualised care plan may include signposting to publicly available resources, such as those available from Versus Arthritis and the National Rheumatoid Arthritis Society. These third sector agencies provide online information and user-friendly leaflets on the role of occupational therapy in overcoming everyday difficulties; for example, Living better with rheumatoid arthritis (National Rheumatoid Arthritis Society 2018) and What are wrist and hand splints? (Versus Arthritis 2018).

Ongoing access to a multidisciplinary team and a holistic assessment is an important part of the management of arthritis pathways (NICE 2014a). It is recognised that in a multidisciplinary team, there may be some key areas of occupational therapy assessment and intervention that overlap with the role of other health and social care personnel. Where an occupational therapist is unable to provide the required intervention, they should discuss the options for onward referral, to an appropriate service, with the individual.

Occupational therapy staff must work alongside other professionals in accordance with local service arrangements to ensure the needs of the individual are met. Good
communication across the primary/secondary care interface, and between health, social care, the independent and voluntary sector, is imperative.

A valuable overview and discussion of the changing role of occupational therapy practice and research within the field of rheumatology over the past 30 years; self-management and joint protection programmes; and how therapists might need to change to implement evidence-based practice can be read in the Elizabeth Casson Memorial Lecture 2014 (Hammond 2014).
3 Objective of the guideline

The guideline objective is:

To provide evidence-based recommendations that inform the practice of occupational therapists working with adults over 16 years of age who have rheumatological conditions, and who may benefit from a custom-made or prefabricated hand or wrist orthosis.

The inflammatory and degenerative processes associated with rheumatological conditions can impact on hand and wrist structures. Clinical reasoning enables a practitioner to determine if the prescription of a hand or wrist orthosis may have the potential to improve symptoms, such as pain and reduced function (Bradley and Adams 2013).

The objective addresses occupational therapy intervention at any point during an individual’s journey along the rheumatology care pathway.

It is intended that occupational therapists use this guideline to inform their work, with a particular focus on empowering the person to fully engage and take responsibility for achieving their individual goals.

The application of the guideline will also inform the delivery of evidence-based services.

This guideline should be used in conjunction with the current versions of the following professional practice documents, of which knowledge and adherence is assumed:

- Standards of conduct, performance and ethics (Health and Care Professions Council [HCPC] 2016).
- Code of ethics and professional conduct (COT 2015a).
- Professional standards for occupational therapy practice (COT 2017b).

Occupational therapists should also be familiar with their relevant country-specific policy documents and performance measures, and cognisant of the following guidelines:

- Osteoarthritis. Care and management in adults (NICE 2014b).
- Rheumatoid arthritis in adults: management (NICE 2018).
- Quality standard for rheumatoid arthritis (NICE 2013, updated 2018).
- 2018 update of the EULAR recommendations for the management of hand osteoarthritis (Kloppenburg et al 2018).
The occupational therapist prescribing an orthosis must also give due consideration to any guidance from the Medicine and Healthcare Products Regulatory Agency on prosthetic and orthotic devices.

Occupational therapists must only ‘provide services and use techniques for which [they] are qualified by education, training and/or experience’, and within their professional competence (COT 2015a, p32). This guideline should be used in conjunction with the therapist’s clinical expertise and, as such, the clinician is ultimately responsible for the interpretation of the evidence-based recommendations in the context of their specific circumstances and the person’s individual needs.
4 Guideline scope

4.1 Clinical questions

The key questions identified in the scope for this guideline were:

- **Is there evidence to support the use of hand and wrist orthoses as an intervention for adults living with rheumatological conditions?**
- **Is there any evidence of harm arising from the use of an orthosis that practitioners should be aware of?**

Egan et al (2001), in their Cochrane review of splints and orthoses for treating rheumatoid arthritis, referred to both commonly used terms – splint and orthosis. The guideline development group recognised that occupational therapists may potentially use either term but agreed that, for consistency, ‘orthosis’ rather than ‘splint’ would be the terminology used in the guideline. The evidence review in Section 5 and evidence tables in Appendix 6, however, adopt the terminology of the published article reviewed.

An **orthosis or orthotic device** is an:

‘Externally applied device used to modify the structural and functional characteristics of the neuromuscular and skeletal systems’. (International Organization for Standardization 1989)

4.1.1 Key outcomes

The guideline development group members identified key outcomes for orthotic intervention, from their knowledge of the evidence base and clinical expertise.

Optimising an individual’s occupational performance by improving:

- Pain.
- Swelling.
- Deformity (including hand appearance).
- Self-efficacy.
- Dexterity.
- Sensory symptoms.
- Grip strength.
- Range of movement (ROM).
- Quality of life.
- Self-management strategies.

The heterogeneity of the population means that it can be difficult to identify the specific outcomes that will be the most important to an individual. A person-centred perspective underpins occupational therapy practice, and intervention must be compatible with the person’s preferred outcomes or, where appropriate, in their best
Guideline scope

interest (considering lack of capacity and conditions such as dementia).

4.1.2 Key areas for inclusion in the guideline scope

Orthotic interventions as an objective experience, including:

- The clinical reasoning of the therapist and rationale for orthotic interventions.
- The physical outcomes, such as biomechanical/structural support and symptom relief.
- Provision of information to the person accessing services regarding wear and care of an orthosis.
- Contraindications and/or risks.
- Difficulties with the application of an orthosis, wear, care and functional ability.

Orthotic interventions as a subjective experience, including:

- Satisfaction of the person accessing services.
- Therapeutic contextual factors, such as self-management strategies.

4.1.3 Key areas for exclusion from the guideline scope

The scope also clarified areas which would not be covered:

- How to fabricate an orthosis due to the wide range of available materials and designs which are specific to the person, as well as being dependent on the skill mix of the therapist.
- Post-operative orthoses for the hand and wrist, due to the specialised nature of this area of practice, which is often provided within an orthopaedic service.
- Orthotic interventions for the hand and wrist outside the specialism of rheumatology; for example, splinting for adults with neurological conditions (COT 2015b).
- Hand assessment, as the focus of the guideline is on the intervention and not on biomechanical assessment.

The focus is on orthotic interventions to manage the signs and symptoms of the underlying pathology, and address the functional impairments within the hand. This guideline should, however, be considered alongside global treatment strategies for facilitating improved hand function and occupational performance.

4.2 Target population

The population to whom this practice guideline applies is those adults with rheumatological conditions who may benefit from an orthosis for the hand or wrist.

To further define the target population:

- Adults are defined as any person aged 16 years and over.
- Underlying pathologies are inflammatory arthropathies, with either primary inflammation (e.g. rheumatoid arthritis) or secondary inflammation (e.g. osteoarthritis).
- There are no restrictions/limitations on gender, ethnicity or cultural background.
Guideline scope

- There are no exclusions for severity of the rheumatological condition or for comorbidities; however, each person should be assessed individually (taking into account relevant comorbidities) when determining appropriate care or action specific to the guideline recommendations.

Children under the age of 16 years are excluded, given the variation in clinical rationale and service provision compared to provision for adults. Orthotic intervention for this age group is different, due to the developmental implications, and may have different presentations to adult arthritis (e.g. juvenile idiopathic arthritis) and there is a scant evidence base to support the use of orthoses with children (Dunbar et al 2017, Holder et al 2002).

Specific conditions where the provision of an orthosis is a rarity, such as crystal arthropathy, are also excluded from the guideline scope.

4.3 Target audience

The principal audience for this practice guideline is occupational therapists who prescribe orthoses as an intervention for adults with a rheumatological condition.

This guideline is applicable to occupational therapy staff delivering services to adults in a range of settings, including community occupational therapy services, and rheumatology outpatients, inpatients, and day care units.

This practice guideline will also be relevant to a wider audience:

- Hand therapists, physiotherapists and orthotists who prescribe orthoses, who may wish to refer to the guideline to inform their practice.

- Managers and commissioners: to provide evidence of the role of occupational therapy with adults who may benefit from an orthosis in terms of their health and wellbeing outcomes, and thus inform business planning and commissioning of services.

- Members of the multidisciplinary team: to provide a greater understanding of the role of the occupational therapist in prescribing orthoses. This will promote closer working between disciplines (including nursing, medical and other multidisciplinary team staff), with the potential for improved outcomes for people who access services.

- Education providers: as an educational tool, orientating individuals to an evidence-based resource to support orthotic interventions, and the role of occupational therapy in providing orthoses for rheumatological conditions (e.g. occupational therapy and physiotherapy students, student orthotists, technical instructors).

- **People who access services** and their carers: providing information to enable them to be more informed about the occupational therapy process and orthotic interventions.
5 Recommendations and supporting evidence

The recommendations developed by the guideline development group are underpinned by the evidence available to date which supports the use of hand and wrist orthoses as an intervention for adults with rheumatological conditions. They also take into account evidence on risks or harm from the use of an orthosis (see section 4.1, Clinical questions). Details of the guideline methodology, including the literature search strategy and the development process, are set out in sections 9, 10 and 11.

Synthesis of the evidence resulted in the emergence of recommendations for orthotic prescription in the context of three core areas:

- Rheumatoid arthritis: orthoses for activity and rest.
- Osteoarthritis: base of thumb orthoses.
- Optimising outcomes for people who access services.

The three themes cut across the desired outcomes identified (see section 4.1) but, while the recommendation statements have been set out within three categories, it is essential to recognise that there are overlaps. Individual recommendations should not be considered in isolation, but in the wider context.

Where available, qualitative feedback from people who accessed services obtained during the guideline consultation has been used to provide a user perspective as an adjunct to the published evidence.

The strength of the recommendations is identified via a scoring of 1 (strong) or 2 (conditional), and the quality of the supporting evidence via a grading on a scale of A (high quality) to D (very low quality). A recommendation grading takes into account the consistency in the direction of the outcomes from the individual items of evidence used to support that recommendation.

Four of the eight recommendations were agreed by the guideline development group as being strong; that is, most individuals would want to, or should, receive the course of intervention or action stated. The other four recommendations were conditional; that is, the majority of individuals would want the intervention, but not all would, with the risks and benefits being more closely balanced.

Additional details on individual studies (for example, on study design, methodological limitations, recruitment numbers and statistical significance) can be accessed in the evidence tables (Appendix 6).

Outcomes desired, risks, generalisability and social determinants of health associated with the recommendations are outlined in section 5.4. Potential financial and organisational barriers are discussed in section 7.2.

This guideline focuses specifically on the prescription of orthoses, as defined in the scope, and does not set out to compare orthoses with other interventions. This is in line
with the PICO framework (Huang et al 2006, Richardson et al 1995) which, for this guideline, did not specify a comparative intervention (section 10.1). Alternative management options are therefore not explicitly reviewed or discussed. Occupational therapists should, however, be aware of the range of other interventions that they may provide, or that may be within the remit of other members of the multidisciplinary team.

Recommendations are based on a synthesis of the best available evidence (sourced from English language publications). It should, therefore, be noted that the guideline is not able to reflect the full range of orthotic interventions for rheumatological conditions that can be provided by occupational therapists.

5.1 Rheumatoid arthritis: orthoses for activity and rest

**Rheumatoid arthritis: orthoses for activity and rest**

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5.1.1 Introduction

Orthoses for rheumatoid arthritis are prescribed for a number of reasons. They can be used to ‘provide support, reduce pain, prevent undesirable motion during occupational performance, increase range of movement or prevent deformity and position joints for occupational performance’ (Yasuda 2008, p1226-1227).

An orthosis provided for an individual for use at night, or during rest, is based on the premise that this will maintain the hand in an anatomical position of rest, with the potential to reduce both localised pain and inflammation. The orthosis should support the joints in a rested position that ‘place[s] the least internal pressure on them and are opposite that of the potential deformity’ (Deshaires 2018, p962).

People with rheumatoid arthritis may also be prescribed and provided with functional...
Recommendations and supporting evidence

Wrist orthoses. These orthoses are designed to be worn while active, as opposed to rest, and aim to provide stability, decrease pain and improve function (Deshaies 2018).

Swan neck deformity with hyperextension at the proximal interphalangeal joint and flexion at the distal interphalangeal joint is the result of muscle imbalance, which may include intrinsic tightness with associated metacarpophalangeal flexion. The deformity may be caused by the destructive effects of synovitis and initiated at any one of the digital joints (Deshaies 2018). Proximal interphalangeal joint motion can become limited, resulting in significant loss of digital function. The provision of an orthosis (for one or more fingers) to position the proximal interphalangeal joint in approximately 5° of flexion aims to make it easier for the person to activate the flexor digitorum superficialis tendon and initiate flexion of the proximal interphalangeal joint. The orthosis may be a mass-produced or custom-made thermoplastic (figure-of-eight) design, or sterling silver (commonly called a silver ring splint) typically custom-made by a jeweller or available from some suppliers.

The medical management of rheumatoid arthritis has changed, however, with modern biologic treatment regimens resulting in more effective control of inflammation for some individuals. Earlier diagnosis, with the advent of tight control disease-modifying anti-rheumatic drug regimens, has also improved outcomes (Chakravarty et al 2008, Siegel et al 2017). Occupational therapists will work with individuals who may have a range of symptom presentation: those whose symptoms are more effectively controlled and those, often older people, whose joint deformity and instability pre-date more recent management options (Bradley and Adams 2013).

### 5.1.2 Functional wrist orthoses

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A mixed methods systematic review (Ramsey et al 2014) addressed the effectiveness of functional wrist orthoses used by people with rheumatoid arthritis. A total of 23 studies were included in the review and the data analysis indicated that pain was reduced by the use of functional wrist orthoses. The qualitative study synthesis provided additional evidence for this benefit by identifying that pain reduction and decreasing swelling were a primary reason for orthosis use from the individual’s perspective. The other key outcomes considered were grip, function and dexterity. While there may be moderate improvement in grip, evidence of the effect on function was inconclusive, and that on dexterity indicated that it could be negatively affected. The need for dexterous manipulation is likely to result in non-use for those tasks; indeed, impact on function was suggested as being task-specific.

An important finding of the review was the heterogeneous nature of the variables described in the studies; for example, disease duration, orthosis type, wearing regimen and intervention period. As a result of this variation, definitive recommendations on orthosis type and wearing regimen could not be developed.

**Thiele et al’s (2009)** Australian cross-over trial explored the effectiveness of a leather wrist orthosis compared to a fabric wrist orthosis. This study recruited 25 participants,
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with a two-week follow-up and a one-week washout period. Outcomes included were pain, function and stiffness (using the Australian/Canadian Osteoarthritis Hand Index), and grip strength. Additionally, self-reported occupational performance in activities of daily living was measured via the Canadian Occupational Performance Measure (COPM). Between baseline and follow-up, both orthosis design groups showed statistically significant reduced pain, improved function and grip strength (all p<0.05) with no increase in wrist stiffness.

Veehof et al's (2008a) randomised controlled trial in the Netherlands investigated the effectiveness of functional wrist orthoses. Thirty-three participants were recruited, 17 of whom were allocated to an intervention group. Participants were randomised to receive either usual care (n=16) or a choice of one of four different prefabricated orthoses. The orthosis was worn as much as possible during the day for four weeks. The primary outcome was a reduction in wrist pain, with secondary outcomes of improved grip strength and functional ability.

Pain scores reduced by 32% in the orthosis group compared to 17% in the control group, a significant difference. There was no significant change between the groups in grip or functional ability. The study suggests that prefabricated wrist orthoses are highly effective in reducing wrist pain, after four weeks of wearing, for people with rheumatoid arthritis.

A Canadian cohort study carried out by Pagnotta et al (2005) aimed to determine the influence of a wrist orthosis on pain, work performance, perceived task difficulty and orthosis benefit. Impact was measured using a work simulator to assess work performance and endurance with the orthosis both on and off.

Thirty participants wore a prefabricated wrist orthosis to undertake 14 tasks, the work simulator generating computer readouts for performance and endurance. Pain was rated before and after each task. Wearing the orthosis did not interfere with work performance, improved or did not change pain levels, and increased or maintained endurance. The perceived difficulty for completing most tasks did not increase as a result of wearing the orthosis.

Haskett et al (2004) compared the effect of three different orthoses in a randomised controlled trial in Canada. Forty-five participants were randomly assigned to wear either a Rolyan® wrist extensor orthosis, a custom-made leather wrist orthosis or an Anatomical Technologies elastic wrist support. Each orthosis, fitted by an occupational therapist, was to be worn for activities during the day that caused pain or discomfort, for four weeks. There was a washout period of one week between wearing each orthosis.

The primary outcome was to reduce pain, and all three orthoses reduced pain compared with baseline (p=0.007), although the leather wrist orthosis demonstrated a greater benefit in terms of pain reduction. The researchers considered this may be related to the custom-fitting of the leather orthosis, although there is no comment on the possible contribution that the material of the leather orthosis (which would be stiffer), or the wrist positioning (noted at 5° ulnar deviation), may also have had on achieving greater pain reduction. After the four-week intervention period, grip and pinch strength were improved in all groups, although the clinical significance of the very small change recorded is uncertain. The orthosis did not appear to compromise dexterity.

The cost of the leather wrist orthosis (including fitting and participant instruction) was two to three times greater than for the other two orthoses. The superiority of the leather wrist orthosis for pain relief supports the Thiele et al (2009) trial. However, while pain reduction and participant preference favoured the leather orthosis, the
Recommendations and supporting evidence

differences between it and the Rolyan® wrist extensor orthosis were considered not significant enough to warrant the cost of the custom-made version.

Evidence overview

The evidence for the use of functional wrist orthoses for people with rheumatoid arthritis is strong with respect to the reduction of pain, as particularly evidenced by the systematic review undertaken by Ramsey et al (2014). A decrease in pain was a consistent outcome across the studies, as measured using visual analogue scales. The reduction of symptoms, such as pain, is also a key motivator for adherence to wearing an orthosis.

Risks associated with wearing a functional wrist orthosis were not specifically reported in the studies, but a potential negative impact on dexterity was highlighted.

5.1.3 Resting/night orthoses

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The effectiveness of a static resting orthosis was evaluated in a UK randomised controlled trial undertaken by Adams et al (2008). The participants included in this research had a confirmed diagnosis of rheumatoid arthritis, with a disease duration of less than five years. A static resting thermoplastic orthosis and standardised occupational therapy intervention were provided to the intervention group (n=60) while the control group (n=60) received the standardised occupational therapy intervention only.

The orthosis in this study was worn during the day when resting (and when hands were warm, red, tender or swollen), with incremental increase in wearing time per day. Participants were also encouraged to wear the orthosis on alternate nights.

Measures were taken at baseline and at the 12-month period by a blinded assessor. At 12 months there was no statistically or clinically significant difference in the change in grip strength, hand deformity or pain between the control group and the intervention group. There was an indication that the static orthosis might provide some benefit in the occurrence of early morning hand stiffness, but not in its duration. The control group improved in almost all outcomes compared to the intervention group.

Participants’ self-reported views on effectiveness, however, contradicted those of the outcome measures. In the intervention group 84% (n=47) perceived the orthosis to be effective, although 24% (n=12) of the group reported they had never worn the orthosis, and a further 20.4% (n=10) wore the orthosis for less than five hours per week.
The research raises an interesting discrepancy between the outcomes of objective and subjective measures, but the outcomes appeared to suggest that adding a static resting hand orthosis to standardised occupational therapy intervention is not indicated for people with early rheumatoid arthritis.

**Silva et al (2008)** conducted a randomised controlled trial, in Brazil, to evaluate the effectiveness of using a night-time positioning orthosis for the hand. The focus was on the impact of the orthosis on pain, grip, pinch strength, upper limb function and also on the individual’s satisfaction. The intervention group (n=25) wore a night-positioning orthosis, while the control group (n=25) only wore the orthosis during the evaluations at baseline, at 45 and 90 days. The thermoplastic orthosis was custom-made, by an occupational therapist, and the material could be readjusted after fabrication if any discomfort was caused by pressure points. The mean disease duration for participants in this study was 9–10 years. No other upper limb therapy was provided during the course of the three-month study period.

The intervention group demonstrated a significant improvement compared to the control group (p<0.005) across all domains measured. The authors’ belief was that a reduction in the inflammatory process resulted in a decrease in pain, enabling an individual to use his/her strength to best effect. As a consequence, improved performance in activities of daily living was reported.

The perspective of participants in the intervention group, established through a Likert satisfaction scale, was that at three months 44% indicated they felt ‘better’ and 44% felt ‘much better’ with the use of the orthosis. The reasons for satisfaction levels expressed were not reported.

The authors concluded that a night-time resting hand orthosis, compared to no intervention, reduced pain in the hand, improved grip and pinch strength, and increased upper limb function and functional status, as determined after wearing the orthosis for three months.

**Evidence overview**

The effectiveness of a resting or night-positioning orthosis is not definitive. While the outcomes from the two studies are potentially divergent in direction of benefit, it is important to note the different inclusion criteria and any variations in orthosis design and hand positioning.

A positive impact on hand pain, grip and pinch strength, upper limb function and functional status was reported for participants with a mean of 9-10 years’ disease duration, although the benefits beyond three months use were not researched.

The evidence reviewed does not enable a specific recommendation to be made with respect to the prescription of a resting or night-positioning orthosis for service users with rheumatoid arthritis. The two studies do, however, identify the importance of using subjective service user perspectives and objective outcome measures to monitor progress and effectiveness of any orthosis prescribed.
### 5.1.4 Orthoses for swan neck deformity

#### Rheumatoid arthritis: orthoses for activity and rest

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A qualitative study performed by [Giesen et al (2010)](https://doi.org/10.1080/17407740903237568) explored hand function difficulties and influences on the selection of either the silver ring splint or the commercial thermoplastic orthosis. Two questions were asked: one about the participant's main difficulties experienced because of the swan neck deformity(ies) and the second about the reasons for their orthosis preference. Positive categories for orthosis choice focused on its effect on hand function or pain, the ease of use, appearance and comfort. Categories that reflected negative reasons influencing choice were side effects; sharp edges; sweating; pain in adjacent finger due to friction; paraesthesia of splinted fingertip; slipping off and change of fit during wear. The range of factors potentially influencing choice needs to be considered as part of the process of orthotic prescription.

A randomised cross-over trial also undertaken in the Netherlands by [Giesen et al (2009)](https://doi.org/10.1080/17407740903237568) with 50 participants with swan neck deformity compared the effectiveness of a silver ring splint with a commercial thermoplastic orthosis (Oval-8®). The participants used each orthosis for a period of four weeks, with a washout period of two weeks. Participants subsequently used their preferred orthosis for another 12 weeks; satisfaction and preferences were also investigated.

Dexterity was the primary outcome, measured using the Sequential Occupational Dexterity Assessment (SODA), and results indicated that both orthoses increased dexterity to a similar extent, and both reduced dexterity-related pain. The presence of a nodule causing interference, or more frequently a minor skin problem, was reported by a small number of participants. Both orthoses were found to be acceptable to the participants, although overall the satisfaction scores for the silver ring splint were higher after four weeks, and were significantly higher for three satisfaction items after the 12-week preferred orthosis period.

[Spicka et al (2009)](https://doi.org/10.1080/17407740903237568) conducted an observational pilot study to investigate how silver ring splints (three-point ring orthosis) might impact on grip strength and dexterity of the hand in participants with deformity of the proximal interphalangeal joints. While this small-scale UK study (n=8) provided only tentative findings because it was not powered to detect significant differences, it suggested that hand dexterity and grip may show a trend towards improvement when silver ring splints are worn.

The effect of silver ring splints on hand function for individuals with rheumatoid arthritis was studied over the course of a year in the Netherlands by [Zijlstra et al (2004)](https://doi.org/10.1080/17407740903237568). One or more silver ring splints were fitted to proximal and distal interphalangeal joints of affected fingers and interphalangeal joint of thumbs of 17 participants. Data analysis identified a statistically significant improvement in dexterity, as measured by the Sequential Occupational Dexterity Assessment (SODA); there were no statistically significant changes in pain, grip and pinch strength, and only slight improvement in hand and finger function at one month.
Further conditional recommendations are made in the context of individuals with hand carpometacarpal (trapeziometacarpal) joint should be provided with an orthosis.  

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Osteoarthritis being assessed by healthcare professionals, including occupational therapists. Of particular relevance to occupational therapy, people with osteoarthritis should be assessed for their ability to perform activities of daily living, receive instruction in joint protection techniques, and be offered assistive devices as required. Thermal agents are also identified as being appropriate considerations for the relief of pain and stiffness.

The European League Against Rheumatism (EULAR) makes 10 recommendations for the treatment of hand osteoarthritis based on a combination of research-based evidence and clinical expertise (Kloppenburg et al 2019). One of these recommendations states that ‘orthoses should be considered for symptom relief in patients with thumb base osteoarthritis’ and that long term use (greater than three months) is advocated (Kloppenburg et al 2019, p17).

The term ‘thumb base osteoarthritis’, or ‘base of thumb osteoarthritis’, is used in this guideline. Studies include those which referred to the first carpometacarpal joint or trapeziometacarpal joint, although these did not always differentiate whether this involvement was ‘with or without scapho-trapezoid joint osteoarthritis’ (Zhang et al 2009, p9). Primary research studies of orthoses for thumb base osteoarthritis include those investigating a single orthosis, comparisons between two orthoses of different design, and those studies in which other interventions are provided alongside an orthosis. It is also relevant to note emerging findings from a pilot randomised controlled trial in which it was found that placebo orthoses were credible (Adams et al 2014, Adams et al in press).

### 5.2.2 Orthoses to reduce pain and improve function, grip and pinch strength

<table>
<thead>
<tr>
<th>Osteoarthritis: base of thumb orthoses</th>
<th>Orthoses to reduce pain and/or improve function</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>4. It is recommended</strong> that an orthosis should be prescribed for people experiencing pain and/or functional difficulties with activities of daily living as a result of thumb base osteoarthritis.</td>
<td>1A</td>
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<tr>
<td><strong>5. It is suggested</strong> that an orthosis can improve the grip/pinch strength for some people with thumb base osteoarthritis.</td>
<td>2C</td>
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**Cantero-Téllez et al** (2018) compared the short-term effect of an orthosis on 66 participants with thumb carpometacarpal osteoarthritis where the thermoplastic
material included the metacarpophalangeal joint with an orthosis that did not include the metacarpophalangeal joint. Participants were randomly assigned to each orthosis group and instructed to wear it at night and 3-4 hours a day during activities of daily living. Pain (measured via a visual analogue scale) and hand function (measured via the Quick Disabilities of the Shoulder and Hand [QuickDASH]) recordings were taken at baseline and one week after the start. Pain scores in both groups reduced significantly (from 77 to 46 in the group whose orthoses included the metacarpophalangeal joint and from 77 to 48 in the other group, p<0.001 for both). A significant improvement in function was also seen, with QuickDASH scores decreasing from 40.2 to 36.1 in the group whose orthoses included the metacarpophalangeal joint and from 41.7 to 35.7 in the other group (p<0.001 for both).

A crossover randomised controlled trial undertaken by Vegt et al (2017) investigated differences in outcomes between the Push Ortho Thumb Brace CMC and a custom-made orthosis for participants with osteoarthritis of the carpometacarpal joint of the thumb. The Push Ortho Thumb Brace CMC is an off-the-shelf, semi-rigid orthosis that immobilises the carpometacarpal joint. The custom-made orthosis was rigid and immobilised the carpometacarpal and metacarpophalangeal joints. Sixty-three participants used each orthosis for two weeks with a two-week washout period. Both orthoses reduced pain and improved hand function, but the Push Ortho Thumb Brace CMC reduced pain significantly more (p=0.008) while the custom-made orthosis increased hand function (as measured via the Nine Hole Peg Test) significantly more (p<0.001). Key grip strength was significantly reduced with both orthoses, but significantly more with the custom-made orthosis (p=0.001).

A cohort study was conducted by Bani et al (2014) using a custom-made neoprene carpometacarpal joint orthosis with thermoplastic stabilisation. Eleven participants were recruited, and the prescribed orthosis left the wrist and metacarpophalangeal joints free. Results demonstrated a reduction in pain and an improvement in function, grip strength and pinch strength.

Hamann et al (2014) compared four different types of orthoses for thumb carpometacarpal osteoarthritis in an attempt to identify the stabilisation and functionality of each. They tested the Rhizo Forte V/2013, the Ortho CMC Push Brace, the Rhizo-Hit® and the Rhizomed. Eighteen female participants wore each orthosis during a series of tests to measure stabilisation and hand function. The study found that all types of orthoses restricted motion, though hand function (assessed via the Sollerman test) was highest with the Ortho CMC Push Brace and lowest with the Rhizomed. Both differed significantly from the other orthoses (p<0.05). The authors conclude that the Ortho CMC Push Brace provides the greatest hand functionality.

A soft prefabricated thumb orthosis, combined with exercise, was used by the intervention group (n=30) in a randomised controlled trial in which the control group (n=29) carried out an exercise programme only (Hermann et al 2014). This Norwegian study identified an immediate positive impact on pain during grip (significant for three pain measures) when wearing the orthosis, but no sustained general effect when not worn. A trend towards an increase in pinch grip was identified but, unlike some of the other studies, Hermann et al found that grip was decreased when the orthosis was worn. Function was self-reported and participants described a range of activities during which they had worn the orthosis, from resting or sleeping to driving and writing by hand. Satisfaction with the orthosis design was mixed, with additional support for the carpometacarpal joint being identified as needed by 11 participants in the intervention group. A total of 82% (n=23) stated that they would, however, continue to use the orthosis after the study.

Maddali-Bongi et al (2014) used a cohort study to evaluate the use of an orthosis for individuals with symptomatic thumb carpometacarpal joint osteoarthritis. The focus was
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on pain, grip and pinch strength and hand disability, and participants were manual workers (n=27) and non-manual workers (n=23) in Italy. All participants had a ‘butterfly’ thermoplastic short opponens custom-made orthosis, and additionally received an educational programme of two sessions (two hours each).

Pain was significantly reduced at 30 days post-intervention in both groups, and this was maintained at the 12-month follow-up point. Manual and non-manual workers had significant improvements in grip and pinch strength at 30 days; hand function and ability improved in the whole group, and in manual workers, but was not significant in non-manual workers. During the 30-day period the wearing regimen was 16 hours a day; during the follow-up period the orthosis was intended to be worn only as required, on pain exacerbation. The findings add to the evidence that pain relief can be gained from use of an orthosis for thumb base osteoarthritis, but it should be noted that an education programme (which included ergonomic principles about how to prevent thumb carpometacarpal overuse) was also a part of this intervention.

Bani et al’s (2013a) cohort study, undertaken in Iran, involved 18 participants with osteoarthritis and pain in the base of the thumb. A custom-made low temperature mouldable thermoplastic orthosis was worn for 90 days and measures were completed at baseline, 30, 60 and 90 days. A significant improvement was detected in pain scores after 30 days of wearing. Grip, pinch and function also improved significantly after 90 days of wearing the orthosis.

A comparison of a prefabricated neoprene splint and custom-made thumb splint for first carpometacarpal joint osteoarthritis was carried out by Bani et al (2013b) in a small randomised cross-over trial involving 35 participants. Splints were worn during routine activities of daily living for four weeks with a two-week washout before changing over, while a control group did not wear a splint. The evaluation demonstrated a significant improvement in pain, function and pinch compared to baseline and the control group. Grip strength changes were positive but not significant. The custom-made splint was found to give better results in terms of pain reduction, but there was no significant difference between the two orthoses for any of the other measures.

The comparison between a prefabricated neoprene orthosis and custom-made thumb orthosis was the subject of a study by Becker et al (2013). One hundred and nineteen individuals were randomised. Sixty-two participants completed the trial, having worn one of the two orthoses over a period of 5–15 weeks for daily activities, and at night if wanted. Pain, grip and pinch strength were found to improve with both orthoses, but there was no change in arm-specific hand function, as measured by the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire. The only significant difference between the two orthoses was in relation to comfort, with the prefabricated neoprene orthosis being preferred.

Kjeken et al (2011a) examined the use of an orthosis, but as part of a broader assistive technology intervention which included other small devices to assist with personal care, housework and leisure activities (e.g. ergonomic handles). The focus of this three-month Norwegian randomised controlled trial (n=70) was the primary outcome of occupational performance and satisfaction using the Canadian Occupational Performance Measure (COPM). Secondary measures included the Australian/Canadian Osteoarthritis Hand Index, and pain and fatigue. A total of 26 of the 35 participants in the assistive technology group received an orthosis, although no additional information was provided about design or wearing regimen. COPM scores identified a significant positive change in performance and satisfaction scores in the assistive technology group at three months, and there was also significant improvement for the AUSCAN hand function score. There was minimal but non-significant improvement reported for other secondary outcomes measured, including pain. The
A systematic review was undertaken by Kjeken et al (2011b) which considered the effect of orthoses and exercise programmes, separately and combined, on hand osteoarthritis. Nine studies were identified which involved orthoses, two with low risk of bias. Meta-analysis demonstrated that an orthosis (for thumb support) significantly reduced hand pain, but there was no consensus on when it would be most usefully worn. Subluxation could also be reduced but whereas improvement in function and pain could be amplified with a prefabricated semi-rigid orthosis, a rigid orthosis gave better effect for subluxation. The review also identified that combining an orthosis and daily exercises may reduce pain and stiffness, and improve function.

A comparison of two orthoses, a prefabricated neoprene Comfort Cool™ orthosis and a custom-made thermoplastic hybrid orthosis (1.6 mm Rolyan® Aquaplast Watercolors), was conducted using a cross-over trial in Canada (Sillem et al 2011). Participants (n=56) were randomly allocated to one of the orthoses, which was worn at night for four weeks, prior to a two-week washout period and a change to the alternative orthosis. The improvements in pinch and grip were minimal and had an equivalent effect between the two orthoses. Pain and function were improved by the use of either orthosis, although the hybrid orthosis reached statistical significance in the change from baseline and achieved a greater treatment effect on pain reduction.

The use of a functional orthosis for osteoarthritis of the thumb carpometacarpal joint was investigated in a Brazilian randomised controlled trial (Gomes Carreira et al 2010) in which an orthosis was provided for all participants (n=40). The intervention group was given the orthosis for the full 180 days of the study for activities of daily living and work activities, whereas the control group was given the orthosis only from days 90–180. Pain was improved in both groups, but the intervention group experienced improvement as early as 45 days, which was maintained throughout. The control group only experienced improvement once they started using the orthosis. The study found, however, that the orthosis had minimal impact on functional capacity and did not alter grip strength, pinch strength or dexterity.

Boustedt et al’s (2009) randomised controlled trial (n=40) investigated the impact of an orthosis and exercise when added to a standard joint protection programme for individuals with thumb base osteoarthritis. They participated in a joint protection programme consisting of group educational/behavioural sessions, trying out grip assistive devices and an elastic thumb orthosis during the day at clinic and home and, during the session, paraffin wax heat treatment and hand exercise with paraffin dough. In the orthosis and exercise intervention group two different orthoses were worn by the 20 female participants: a custom-made thermoplastic forearm orthosis worn at night, and a prefabricated elastic thumb orthosis and/or custom-made thermoplastic thumb orthosis worn at all times during the day. Hand exercise was also performed at home. The control consisted of the joint protection programme only.

Measures were taken at baseline, one week after the five-week joint protection programme and at one-year follow-up. The analysis identified that, compared to the control group, the participants in the intervention group had a significant decrease in pain and stiffness, and an improvement in daily activities, directly after the intervention and at one-year follow-up. Grip force also improved in the intervention group, but this was not significantly different from the control group.

Moe et al’s (2009) systematic review included other systematic reviews to summarise the evidence on the effectiveness of non-pharmacological and non-surgical interventions for hand osteoarthritis. Orthoses were included in three of the four reviews which met...
Recommendations and supporting evidence

The overarching view was that there was evidence, albeit limited, for the use of an orthosis to reduce pain, but no recommendation on design or materials could be made due to the absence of sufficient evidence.

A randomised controlled trial conducted in France aimed to examine the provision of a night-time custom-made neoprene orthosis on thumb base osteoarthritis (Rannou et al 2009). The intervention group of 57 participants were fitted with an orthosis by an occupational therapist, while the control group (n=55) received the usual care (not defined). A statistically and clinically significant change was determined for the reduction of pain, reduction in disability (Cochin Hand Function Scale) and participant-perceived disability at 12 months. While there was some improvement at one month, this was not significant. Concordance and satisfaction were high, and no adverse effects were reported.

A systematic review (Egan and Brouseau 2007) examined the evidence on the effectiveness of orthoses for carpometacarpal osteoarthritis. The review identified some evidence for the use of an orthosis, not only for its potential positive impact on pain relief, but in reducing subluxation on pinch in participants with early osteoarthritis. This study focused on the clinical implications for occupational therapists emerging from the evidence. While agreeing with other studies that there is a lack of superiority with respect to orthosis design, the authors considered that wearing an orthosis at least for painful or heavy activities, and for longer periods during the day and at night for an initial period of three to four weeks, may be beneficial. Encouraging the use of an orthosis during activities promoting carpometacarpal subluxation for individuals with Stage I and II osteoarthritis was also suggested.

Wajon and Ada (2005) compared two different orthosis and exercise regimens in their randomised controlled trial. A custom-made thermoplastic strap orthosis was worn by the intervention group (n=19) for two weeks, followed by a further four-week period with the addition of abduction exercises. The control group (n=21) wore a short opponens thumb orthosis and after their two-week period continued to wear the orthosis but began a pinch grip exercise regimen. In both groups the orthosis was to be worn full time and removed only for personal hygiene. Outcomes measured were pain, pinch strength and hand function (Sollerman Test of Hand Function). While improvements were recorded for both groups, neither intervention was superior to the other.

A comparative cross-over randomised trial was undertaken by Weiss et al (2004) comparing the effect of a prefabricated neoprene orthosis and a custom-made thermoplastic orthosis. The treatment was short, with participants asked to wear the first orthosis for one week immediately followed by wearing the second orthosis. There was no washout period included. Both orthoses were effective at relieving pain, allowing function and reducing subluxation, but participants preferred the prefabricated neoprene orthosis, and the effects on pain, function and pinch pain were superior.
Evidence overview

A number of studies have been undertaken to explore the impact of orthoses on the symptoms of base of thumb osteoarthritis. The studies, while not all high quality, frequently considered pain as the primary outcome measure, with function, grip and pinch strength often as secondary outcome measures.

The evidence that orthoses have an impact on pain has been consistent in terms of direction of the outcomes, with an improvement being reported in 17 of the 19 studies described (9 of those statistically significant). Only one study identified no change in pain. The impact of an orthosis on function was considered in 13 studies, six of which (46%) were statistically significant in favour of an improvement in function, with one identifying no change. Risks or adverse outcomes associated with these orthoses were rarely reported in the studies.

Changes in grip and pinch strength outcomes have been less consistent, with two studies identifying a decrease in grip, and statistical significance being rare for both measures.

5.3 Optimising outcomes of people who access services

Optimising outcomes of people who access services

6. **It is recommended** that validated, standardised assessment and outcome measures are used pre- and post-provision of an orthosis to monitor progress, evaluate effectiveness, assess functional outcomes and understand individual satisfaction.


(Statement amended and new evidence 2020)

7. **It is suggested** that, given the inconsistent evidence of a superior orthosis fabrication/design or wearing regimen, the orthosis selected should maximise occupational performance and **individual** choice.


(New evidence 2020)
8. **It is recommended** that to optimise adherence to wearing a prescribed orthosis, the occupational therapist should discuss with the person the potential benefits and limitations; practicalities of use and comfort; provide the opportunity to try on orthoses prior to issue; and routinely arrange follow-up review of the intervention.


Occupational therapists, working in partnership with people with rheumatological conditions, should evaluate the effectiveness of their intervention. This means ensuring that appropriate standardised assessment tools are used as a baseline from which change can be measured; seeking the views of individuals regarding the effectiveness of their intervention; and documenting the process and results of assessments and interventions. Standardised outcome measures should be used to provide credible and reliable justification for the intervention that is delivered and ensure that what is recorded is measured objectively with as little error as possible, and the highest level of reliability and validity.

The principle of involving the public and people who access services in research, and the full engagement of individuals in their assessment and treatment, is essential in individually focused interventions. The involvement of people who access services is integral to an intervention such as orthotics, where concordance is ultimately within the person’s control.

This section includes evidence from studies that included participants with either rheumatoid arthritis or osteoarthritis. The recommendations for optimising outcomes for people who access services provide overarching principles that can be considered as part of the prescription of any hand or wrist orthosis for adults with rheumatological conditions.

5.3.1 Measuring outcomes

**Optimising outcomes of people who access services**

6. **It is recommended** that validated, standardised assessment and outcome measures are used pre- and post-provision of an orthosis to monitor progress, evaluate effectiveness, assess functional outcomes and understand individual satisfaction.


A range of assessments and outcome measures have been used within the appraised primary research and, where validated for use with the guideline population, these may also be applicable to practice.
The key primary and secondary outcomes reported in the evidence supporting this guideline were pain, function, grip and pinch strength. Self-report measures were frequently used for pain and function, with some objective measures, mostly for grip and pinch strength.

Pain intensity was self-reported most frequently using a visual analogue scale (VAS) or the Numeric Rating Scale for Pain (NRS Pain). The VAS consists of a single line, usually 100 millimetres (mm) in length, against which the participant makes a line perpendicular to the 100 mm line to reflect their intensity of pain. Pain is normally what is currently being experienced or which has been experienced over a specified time period, such as the past 24 hours. A score of 0 refers to no pain, with the score of 100 referring to the worst pain imaginable (Bani et al 2014, Bani et al 2013a, Bani et al 2013b, Boustedt et al 2009, de Boer et al 2008, Gomes Carreira et al 2010, Haskett et al 2004, Kjeken et al 2011a, Pagnotta et al 2005, Rannou et al 2009, Silva et al 2008, Veehof et al 2008a, Wajon and Ada 2005, Weiss et al 2004). The NRS Pain is a comparable measure using a single 11-point numeric scale in which the participant self-reports a whole number (0–10) that reflects the intensity of pain (Hermann et al 2014, Maddalí-Bongi et al 2014).

“I am 79 – all my working life I was a draughtsman and the ‘splints’ did help reduce pain.”

Person who accessed services – consultation feedback

The Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire (Hudak et al 1996) was used in a number of the research studies to measure upper limb function (Bani et al 2014, Bani et al 2013a, Bani et al 2013b, Boustedt et al 2009, Gomes Carreira et al 2010, Silva et al 2008, Veehof et al 2008a). The DASH is a self-report questionnaire of physical function, symptoms, confidence and social participation relating to conditions affecting any part of the upper extremity. It assesses overall upper limb function (bilateral), irrespective of the hand affected, and consists of 30 items, 24 of which are focused on function, including fine motor hand functions. There are also optional additional modules relating to paid or unpaid work and to performance of a sport or playing a musical instrument. The scoring of items is on a Likert scale of 1 (no difficulty) to 5 (unable to do), with an algorithm transforming the score to a range from 1 to 100, with a higher score indicating greater disability.

The method used in two studies (Kjeken et al 2011a, Sillem et al 2011) to measure function was AUSCAN, the Australian/Canadian Osteoarthritis Hand Index (Bellamy et al 2002). Again a self-reported measure of overall hand function, this measure has three scales to assess hand pain, stiffness and hand function where there is the presence of osteoarthritis.

An objective measure of bilateral dexterity used in three studies included in the evidence (Giesen et al 2009, Veehof et al 2008a, Zijlstra et al 2004) was the Sequential Occupational Dexterity Assessment (SODA) (van Lankveld et al 1996). The SODA, designed to measure hand function in rheumatoid arthritis, consists of standardised hand-related daily activities that are assessed in terms of ability to perform the tasks; a higher score indicates better hand function.

The measurement of grip and pinch strength generally involved a dynamometer and pinch gauge, using recognised standardised measurement tools such as the Jamar® Hydraulic Hand Dynamometer.

A number of systematic reviews further support the use of validated, standardised
Recommendations and supporting evidence

assessments and outcome measures to monitor progress and effectiveness (Duong et al 2018; Healey et al 2018; Aebischer et al 2016; Hammond et al 2016; Bertozzi et al 2015; Nasir et al 2014). The authors noted the difficulty in comparing research evidence because of a lack of standardised assessments and outcome measures and the wide variety of assessments and measures used.

Evidence overview
The evidence across the studies indicated that pain and function outcomes can be determined using self-reported measures such as the VAS or NRS for pain, and the DASH or AUSCAN for function. Measures can also be used to objectively determine performance for dexterity, grip and pinch strength. The combination of subjective (self-reported) and objective performance measures can provide reliable, valid and responsive information about the outcomes of orthotic intervention, and contribute to evidence of effectiveness. This would greatly increase the comparability of systematic reviews of the evidence around orthoses.

5.3.2 Orthosis design and wearing regimen

Optimising service user outcomes

7. It is suggested that, given the inconsistent evidence of a superior orthosis fabrication/design or wearing regimen, the orthosis selected should maximise occupational performance and individual choice.


Research into the effectiveness of one orthosis design compared to another has been the focus of a number of studies, as reported in the evidence on orthoses for rheumatoid arthritis and for osteoarthritis.

Cantero-Téllez et al (2018) compared two orthoses for thumb carpometacarpal osteoarthritis, one that immobilised the metacarpophalangeal joint and one that did not. Overall no difference was found between the two orthoses design in terms of pain reduction and improved hand function. Bani et al (2013b) also investigated orthoses for osteoarthritis. The custom-made orthosis was found to give better results in terms of pain reduction, but there was no significant difference between that and the neoprene orthosis on any other measures. Orthoses were worn for routine activities of daily living for four weeks. Similarly, Vegt et al’s (2017) study found varying results, with participants reporting less pain and better key grip strength with an off-the-shelf design that immobilised the carpometacarpal joint compared to a custom-made design that immobilised both the carpometacarpal and metacarpophalangeal joints. However, the study found that hand function improved significantly with the custom-made design (p<0.001).

Additionally, in Vegt et al participants reported which orthoses they preferred. Two-thirds (66%) preferred the off-the-shelf orthosis, 13% the custom-made orthosis and 19% said they were satisfied with either.
A literature review by Almeida et al (2017) investigated differences between orthoses design and found inconclusive evidence to recommend any one particular design. Four studies did not show significant differences in pain reduction; two studies found significant pain reduction with a custom-made design only involving the carpometacarpal joint compared to a pre-fabricated neoprene design; one study showed better pain reduction with a pre-fabricated neoprene design compared to a rigid thermoplastic design. Inconclusive results were also found in a systematic review of orthoses for thumb base osteoarthritis by Spaans et al (2015). Of six randomised controlled trials comparing different orthoses, two studies found that a custom-made orthosis reduced pain significantly more than a pre-fabricated design, but all other randomised controlled trials found no evidence of a superior design.

Becker et al (2013) compared a prefabricated neoprene orthosis and custom-made thumb orthosis worn for daily activities and at night if wanted, over a period of 5–15 weeks. The only significant difference between the two orthoses was in relation to comfort, with the prefabricated neoprene orthosis being preferred. A greater effect on pain reduction was evidenced in a custom-made thermoplastic hybrid orthosis compared with a prefabricated neoprene orthosis, worn at night for four weeks, in Sillem et al’s study (2011). Wajon and Ada’s (2005) randomised controlled trial, however, found neither a custom-made thermoplastic strap orthosis (plus abduction exercises) nor a short opponens thumb orthosis (plus pinch exercise) was superior to the other. Orthoses were worn for a total of six weeks full time. Weiss et al (2004) compared a prefabricated neoprene orthosis with a custom-made thermoplastic orthosis worn for a one-week period in a cross-over trial; participants preferred the prefabricated neoprene orthosis, and the effects on pain, function and pinch pain were superior.

Studies comparing orthosis design for rheumatoid arthritis included two investigations comparing leather wrist splints with one or more other prefabricated wrist orthoses. The superiority of the leather wrist orthosis (not commonly available in the UK) for pain relief was found by both Thiele et al (2009) and Haskett et al (2004), though Haskett et al concluded that the difference compared to the other orthosis was not significant enough to warrant the cost of the custom-made leather orthosis. The intervention period for Thiele et al’s study was two weeks (wearing regimen not specified), and for Haskett et al’s study an orthosis was worn for activities during the day that caused pain or discomfort, for four weeks.

Orthosis design for swan neck deformity was compared by Giesen et al (2009) for a silver ring splint and a commercial thermoplastic orthosis. Participants found both orthoses to be acceptable but preferred the silver ring splint, while the researchers said given both were comparably effective orthoses, the prescription could be based on individual choice or cost.

Wearing regimens, as identified within the evidence for rheumatoid arthritis and osteoarthritis, has been highly variable (see evidence tables in Appendix 6). These have covered a wide range of time periods for wearing, and guidance on when to wear the orthosis (for example, during the day, at night, or for activities).

**Evidence overview**
A wide range of prefabricated orthoses are available commercially; others are custom-made. These may be fabricated from a variety of materials, including thermoplastics, neoprene, leather and hybrid combinations. Research studies have compared a number of these orthoses, for both osteoarthritis and rheumatoid arthritis. While some orthoses showed a greater effect on pain reduction, and others were preferred by participants, there is no consistent evidence of a superior orthosis design. Furthermore, the variance of wearing regimen is particularly evident within
5.3.3 Experiences of people who access services

### Optimising outcomes of people who access services

8. **It is recommended** that to optimise adherence to wearing a prescribed orthosis, the occupational therapist should discuss with the person the potential benefits and limitations; practicalities of use and comfort; provide the opportunity to try on orthoses prior to issue; and routinely arrange follow-up review of the intervention.


[New evidence 2020]

A prospective study by Tada et al (2018) attempted to design an effective, attractive and easy to wear splint. It found that the splint was not only effective at reducing pain, participants reported satisfaction related to usability of 8.9 (±0.3) out of ten, and satisfaction with appearance 7.6 (±0.4) out of ten.

Almeida et al’s (2017) literature review noted that although there is not enough evidence to recommend a specific orthosis design, the choice of orthosis should therefore be based on the occupations and activities of daily living of the person. The authors recommended that future studies should keep a client-centred perspective while examining the impact of the orthosis on the person’s goals, their performance while wearing the orthosis and whether they follow the clinician’s recommendations.

Shankland et al (2017) investigated reasons for not wearing an orthosis, and found the most common reasons were; food hygiene issues, the orthosis making the hand too hot, or finding the orthosis too rigid. Some said a reduction in pain levels meant they did not feel the need to wear the orthosis.

A systematic review of eight articles considering compression gloves by Nasir et al (2014) highlighted the need for consultation with the person about comfort and fit in order to help with the wearing regime. This review noted that comfort and fit are important to encourage motivation to wear the gloves regularly, and may influence outcomes such as hand function.

Gooberman-Hill et al (2013) involved people who had a diagnosis of arthritis in the design of a proposed future clinical trial evaluating orthoses for thumb base osteoarthritis. Eight participants from two sites in the UK were engaged in interactive discussion fora to discuss their experiences of osteoarthritis and of their own thumb orthosis; to try on and evaluate a number of alternative orthoses; to express their view on the acceptability of a placebo arm in a future trial; and to consider the acceptable and unacceptable design features for the proposed placebo orthosis with a focus on wearability and support.
Recommendations and supporting evidence

“Consideration should be given to including the evaluation of ease of use, comfort and acceptable appearance. Collating information from patients for all areas will improve [the] evidence base.”

The evaluation of their existing orthoses highlighted some key factors from their own experiences, such as neoprene is too hot in summer; the beige colour is too medical and not practical; dislike of hard plastic moulded orthoses; hook and loop fastenings easy to don/doff but catch on clothing; concerns about washing orthoses; and stigma about wearing an orthosis, as it makes disability obvious. An important factor highlighted was that an orthosis should offer support in painful areas and immobilisation, and conversely that a placebo orthosis should not offer any ‘real’ support for the joint at the base of the thumb. This study provided perspectives on the characteristics and experiences of wearing an orthosis by the people who wore them. These may offer the occupational therapist insight into the treatment burden associated with orthotic intervention, and inform their consideration of how the process of service delivery can positively impact adoption of the orthosis.

“I have had splints now for 30 years. This week, while enquiring about boots to be made, I found out that there are not only beige wrist splints but black as well. There is no cost difference but because more people want beige there is no choice. I would have gladly worn [sic] black in my younger years, and intend to ask if I can get it next time. Not all people are able to accept orthosis, but if there is no extra cost incurred, could we have a little choice?”

Boer et al (2008) examined the possession and use of a functional wrist orthosis in a Dutch population with rheumatoid arthritis (n=240). The multicentre cross-sectional study identified, from interviews and questionnaires, that the main reason for using an orthosis was for relief of pain and joint protection. Use was significantly associated with the presence of wrist and hand complaints, worse physical functioning and greater satisfaction with comfort. A large proportion of participants had not, however, been wearing their orthosis in the three months prior to the study; 42% (n=54) had not used the orthosis at all. Reasons for non-use included a perception there was no need, difficulties with comfort or fit and perceived harmful effect. This study highlights the importance of the active engagement of the person in the prescription of an orthosis.

The usage of functional wrist orthoses was also explored via semi-structured interviews in a Dutch qualitative study involving 18 participants with rheumatoid arthritis (Veehof et al 2008b). This research aimed to gain insight into participants’ motivations for, and perceived barriers to, wearing an orthosis.

Orthosis use was found to be dependent on symptoms and their seriousness; notably pain, swelling or tingling feelings. Reducing those symptoms, and the provision of support or immobilisation of the wrist, were reported to be important reasons for orthosis wear. A decrease in functional ability, activities that were wet or dirty, and other reasons such as poor comfort and fit were identified as some of the potential...
Recommendations and supporting evidence

barriers to wearing an orthosis. The study highlighted the importance of the individual person’s perceived benefits and barriers in influencing concordance to orthotic prescription. An outcome of the study was a list of strategies to increase accordance with wearing regimens.

“I suspect I am no different to many service users in wanting to know what are the benefits and potential risks of any intervention to me personally. Therefore from a service user’s perspective I would suggest that strengthening or highlighting the perceived benefit of the recommendation to the user is fundamental in achieving compliance.”

Pagnotta et al (2005) identified that most participants did not use the orthosis for their daily activities, commenting that the orthosis got in the way and was ‘cumbersome’. When they did use it, the primary purpose was for pain management. This finding emphasises the importance of the occupational therapist considering treatment burden and discussing with the person their individual occupational performance needs and activities, to ensure that the prescription of an orthosis and daily wearing regimen ‘maximises benefit and minimises inconvenience’.

The application of a client-centred occupation-based framework for orthotic intervention was the focus of a case studies report by McKee and Rivard (2004). Three case studies were reported, two of whom were individuals with hand osteoarthritis. The Canadian Model of Occupational Performance underpinned the intervention approach, with satisfaction and performance measured by the Canadian Occupational Performance Measure (COPM). The importance of six factors was delineated: client-centredness; orthosis comfort; cosmesis; convenience; ‘less is more’ orthosis design; and follow-up, indicating that these must equally be considered as well as efficacy, for example in improving pain. An ‘interactive consultation process and a collaborative approach’ can maximise the success of the person’s outcomes.

“I would also say that the patient has to be ready to accept there is a problem and, while not a magic wand, something might be improved. I would think, though, that provision for follow-up appointment(s) would be advised to check for compliance.”

Evidence overview

Research that involves the perspectives of people who access services can provide a richness which, when taken into account, can have the potential to enhance wearing of an orthosis in practice and, as such, can improve the outcomes sought by the individual. Views expressed that were common to the studies included the importance of the support provided by the orthosis, its comfort and appearance, and ease of use, with ‘perceived need’ being a key driver for deciding to wear the orthosis.

The range of potential issues influencing wearing of an orthosis implies that follow-up review of an orthosis is necessary to enable these to be addressed.

Orthoses that are worn regularly are more likely to result in effective outcomes for those who wear them and, by association, more efficient use of occupational therapy service resources.
5.4 Potential impact of the recommendations

5.4.1 Desired outcomes

1. People who access services’ perspectives on the benefits of wearing an orthosis.
2. Measurable effectiveness determined by benefits and outcomes which may include:
   - Reduced pain.
   - Improved grip.
   - Improved pinch strength.
   - Improved function.
   - Improved dexterity.

5.4.2 Risk management

A comprehensive assessment:
The evidence reviewed did not indicate when it might be inappropriate to prescribe an orthosis; however, the prescription of any orthosis must be based on a comprehensive assessment, taking into account the nature of the individual’s clinical condition – that is, ‘the underlying disease process and the possible associated hand impairment and functional limitations’ (Bradley and Adams 2013, p203) and their occupational performance needs. The individual’s general medical status may also impact on orthosis prescription: for example, a person with diabetes may have less tolerance for an orthosis due to impaired sensation or circulatory impairment. Cognitive ability should also be considered, including the person’s capacity for understanding how to use the orthosis correctly and how to recognise and respond to discomfort or other indications of possible adverse effects in a timely and appropriate manner.

An orthosis as part of a comprehensive intervention programme:
The potential impact of an orthosis in the re-direction of force to other joints unconstrained within the orthosis, especially if they are also affected by the underlying pathology, must also be taken into account. Orthoses should not, therefore, be considered in isolation. A more comprehensive occupational therapy programme, including joint protection techniques and education, may be required (Bradley and Adams 2013, p192).

Appropriate orthosis assessment and fitting:
The provision and fitting of an orthosis is a specific skill which requires clinical expertise with respect to anatomy and biomechanics of the wrist and hand. To optimise user concordance and functionality, there is a need for appropriate assessment and fitting. An inappropriately selected and fitted orthosis may be ineffectual and increase the risks. Individuals who may benefit from an orthosis should therefore be referred to an appropriately trained health professional.

In the context of prescribing an orthosis, factors such as skin condition, correct fitting, and environment where the orthosis will be used (particularly in relation to environmental or work hazards) all need to be part of the decision-making process.

Monitoring for side effects:
Clinical reasoning is essential to determine the balance of expected outcomes with potential risks or possible adverse effects. This is particularly important given that the nature of the evidence does not support routine provision, and non-concordance with a
Recommendations and supporting evidence

Prescribed wearing regimen was reported in a number of the studies included in the evidence.

Adverse outcomes from orthotic prescription/use were minimal in the studies reviewed, but orthoses were not without side effects, as reported by people who wore them. Potential side effects should, therefore, be discussed with the person and monitored during the period of intervention.

The person’s perspectives established in one functional wrist orthosis study, for example, made reference to side effects: unpleasant feelings such as tingling, or pressure points due to tight fit (Veehof 2008b). The importance of reducing any risks was identified in the Veehof et al study (2008b), stating that orthosis use should be reviewed one week after prescription to evaluate the perceived benefits and barriers to orthosis wearing, including comfort, fit and concordance.

Silver ring splints and Oval-8® orthoses may have side effects for some individuals (intolerance of the orthosis, pressure of the orthosis on bony edges, rheumatoid nodules and paraesthesia), and the risk of these should be discussed with the person and carefully assessed and monitored following orthotic prescription (Giesen et al 2010, Zijlstra et al 2004).

Other considerations:

Additional considerations which were not necessarily identified within the evidence, but should be taken into account, are the durability of an orthosis over time, and the responsibility of maintenance and replacement of an orthosis in the long term, particularly if the person is no longer being seen for review or has been discharged from the service.

5.4.3 Generalisability

The studies conducted on orthoses were heterogeneous with variations in sample populations, and in the nature of an individual orthosis, its wearing regimen and concurrent treatments and interventions. This variation has been taken into account in the development of the recommendations, to ensure that findings have not been over-generalised.

The studies have reflected the core population affected by arthritis; that is, there is a higher prevalence in women and in people aged 45 years and over, and can therefore, in the main, be applied to the guideline population.

5.4.4 Social determinants of health

Occupational therapists need to consider the accessibility of self-reported outcome measures so that these are inclusive for those with differing literacy levels.

It is good practice not only to discuss, but also provide, accessible, easy to understand, clearly written information and instructions (including therapist contact details) as part of the provision of an orthosis. If possible, the inclusion of photographs or clear illustrations may be helpful.

Difficulty experienced in the ability to put on and take off again an orthosis is a factor which may contribute to poor concordance to wearing and outcomes. People who live alone may have difficulty managing this, and this must therefore be taken into account in terms of the orthosis design and wearing regimen, and where there is bilateral presentation.

The financial circumstances of a person may have an impact on choice. Silver ring splints, for example, are not routinely available via NHS providers. Preference, therefore, for a silver ring splint rather than a thermoplastic commercial figure-of-eight
Recommendations and supporting evidence

ing orthosis may only be available for those who can afford to self-purchase. This may disadvantage those who cannot afford a silver ring orthosis, which is reported as a more cosmetically and psychologically acceptable orthosis.
6 Perspectives of people who accessed services

The target audience of the full guideline document is primarily occupational therapists who prescribe orthoses. While of potential interest to people who access services, the guideline development group acknowledged that it was not written specifically for a lay audience.

The perspectives of people who access services are integral to the guideline development and review processes and involvement took place through consultation on the draft scope and draft guidelines (see sections 9.3 and 11.4).

In the first edition of the guideline, perspectives were received from five individual ‘experts’ who had accessed services and from Arthritis Care Scotland on the draft guideline. They were asked to take into account and provide views on five consultation questions (designed by the guideline development group to prompt opinions particularly on benefits, risks and outcomes), and any other areas they considered pertinent. The responses provided invaluable insights and comments and led to amendments, and the inclusion of specific quotes, within this final guideline.

Q1 – Did you find the overview of the evidence useful to refer to when reading the recommendations?

All six of the respondents felt that the overview sections of the evidence were useful, although one respondent indicated that not all “service users will have the capacity to do the intellectual gymnastics required to benefit from the statistical information”.

“Yes, the overview was useful in expanding the reasoning behind the recommendations.”

“Yes, because it legitimises the points and aids understanding of the outcomes in a bigger setting.”

Q2 – Do you think the recommendations and information take into account both the benefits and potential risks of an orthosis?

One valuable comment was made that information about risks was more evident for orthoses for swan neck deformity. The evidence overview in two sections was revisited and subsequently amended to reflect this observation.

“I really don’t understand ‘potential risks’. Benefits – yes! Risks – don’t wear it!”

“. . . Try to get the therapist to underline that the outcome might not be clear if only restricted to a two- to four-week review, and maybe underline the longer-term benefits to the patient. I know from personal experience that it has taken even four to six weeks to get the full benefit of the splints.”
Q3 – Do you think these recommendations will help people understand how an orthosis may assist them?

A specific comment was given on the format of one recommendation, which was subsequently revisited and revised by the guideline group, but the key theme from the responses to this question was that the recommendations will help in understanding. Responses to this question highlighted the importance of face-to-face interaction with the occupational therapist, and the significance of discussions about the possible prescription of an orthosis to meet their individual needs. This included that explanations from the occupational therapist should convey their confidence in an orthosis, together with the pros and cons of wearing an orthosis.

“I think I learned more from the O. [occupational] therapist than from leaflets.”

“If the OT takes time to say that there are proven studies which show some benefits and if the person has run out of options – pain gels, tablets, hot/cold compresses et al – and that it might be of use, even if it looks dumpy. It could let patients also understand more as there are facts to look at.”

Q4 – Do you think the recommendations and information will help people understand some of the issues an occupational therapist needs to take into account when deciding if an orthosis may assist a service user?

The guideline was considered as being beneficial, more so for members of the multidisciplinary team than the target audience.

“I think it will be of greater benefit to other members of the multidisciplinary team and wider healthcare team members, such as commissioners and purchasers, than actual service users, as I think the language used is not specifically targeted at the service users. An overview of the issues written specifically for service users may be beneficial.”

“Yes, but although every orthosis, depending on type, is person-oriented, may the orthosis be shown/ tried on while the problems are discussed? Also gives patient a chance to see if they can open/close splints unaided or where an alternative way needs to be provided. I got wrist splints but the design was tweaked a bit, causing me problems as my fingers were not able to easily open the longer/stronger [replacement] Velcro® strips.”

Q5 – Are the desired outcomes listed important from a service user perspective?

All respondents clearly stated that all the outcomes were important, with some comments reflecting the importance of the occupational therapist explaining the pros and cons, and that what was available would assist daily activities.

“Yes. I would further suggest that potentially reducing deformity and thereby improving the appearance of one’s hands is important to service users. Having said that, I acknowledge that the document is evidence-based and this may not have come out in the evidence reviewed.”

[Outcomes were identified from the clinical expertise as part of the scope development: therefore the appearance of hands was added, for clarity, to deformity.]
Service user perspectives

“Yes, recommendation no. 8 highlights the need to involve the service user in finding what would suit their particular needs and improve their understanding of the potential benefits or limitations.”

“The desired outcome list covers the most obvious things that a patient would expect from using [an] orthosis. There comes a point where you know without the orthosis there is no longer a functioning joint/limb and then you are ready to accept the need for [an orthosis] and also try to accept the orthosis's limitations.”

The consultation form also provided two additional sections for any other comments to be recorded. Some additional points were provided, a number of which have been included as quotes in section 5.3. The quote below is valuable in highlighting the importance of guidelines to the delivery of services.

“Feedback from individuals who have RA [Rheumatoid Arthritis] confirm that any support available to maximise function and reduce pain is to be welcomed. These guidelines should ensure that consideration of the use of orthoses is available to all individuals with rheumatological conditions.”
7 Implementation of the guideline

This practice guideline aims to assist occupational therapists to take the most appropriate evidence-based action when prescribing an orthosis for a person with a rheumatological condition.

Familiarity with the revised guideline document will be an important first step for both individual practitioners and their managers. It is therefore imperative that occupational therapists and managers working in this clinical area take responsibility for reviewing the guideline recommendations within the context of their practice.

Bringing the guideline to the attention of colleagues within the multidisciplinary team and service commissioners should also be a priority.

A further action to facilitate implementation must be for lead therapists to consider the ‘levers’ and ‘barriers’ within their local organisation and culture that may have an impact on any changes that may be necessary to practice. Section 7.2 identifies potential barriers that may be applicable, while section 7.3 describes resources to facilitate implementation.

7.1 Dissemination and promotion

Awareness and implementation of this revised practice guideline are important if it is to influence and have an impact on occupational therapy practice.

Following publication, the full practice guideline has been made available to download freely from the Royal College of Occupational Therapists’ website, and can additionally be accessed via the Royal College of Occupational Therapists’ Specialist Section-Trauma and Musculoskeletal Health webpages.

The guideline will be promoted to its key target audience of occupational therapists and to relevant others using professional networks and publications, internet and social media channels.

7.2 Organisational and financial barriers

The recommendations stated within this guideline document are intended to help occupational therapy staff to contribute effectively to those outcomes important to the person accessing services, and to the provision of orthoses within occupational therapy services.

The occupational therapist’s individualised approach, which takes into account the person, the environment and their occupation (Law et al 1996, Duncan 2011), is an important facilitator in the effective implementation of the recommendations.

It is recognised, however, that there will be potential barriers, both organisational and financial, that may influence application of the recommendations. It is important that occupational therapists take these into account when implementing this guideline. The most likely barriers, described below, were identified via consensus agreement of the clinical experts in the guideline development group.
The underpinning critical resource required to implement these guideline recommendations is the inclusion of appropriately trained practitioners within the multidisciplinary team (NICE 2014a). Commissioners, providers and managers should ensure that occupational therapists are core team members, giving full recognition to their contribution to care planning and musculoskeletal health and, thus, the health and wellbeing of people with rheumatological conditions (Arthritis Research UK 2014).

The use of some standardised assessment and outcome measures may have financial costs and implications as some, for example the Australian/Canadian Osteoarthritis Hand Index, are not free to download or use.

The evidence reviewed has not provided definitive guidance about the superiority of particular designs of orthoses. Choice of design has, however, been identified as one of the potential factors likely to influence concordance to wearing regimens, with studies reporting on personal preferences. The therapist should therefore, ideally, be able to choose the most appropriate orthosis and design, which reflects the clinical and occupational needs of the individual and, where possible, their preference. There is a wide variety of commercially available prefabricated orthoses of different designs and fabrics. Where an orthosis is custom-made, rather than prefabricated, there may be a cost implication for the necessary equipment, materials and fabrication process, including staff time.

The cost or source of a specific orthosis may be a potential barrier. An occupational therapist may be limited in choice due to their organisation’s preferred supplier contracts. As identified in the evaluation, orthoses used in research, such as a leather functional wrist orthosis (Haskett et al 2004), may not be available to occupational therapists within UK healthcare provision. Silver ring splint provision, which is likely to require importation from the supplier in the USA, or links with local jewellers for custom fabrication, may also prove to be prohibitively expensive or inaccessible and the occupational therapist may, therefore, only be able to advise and support the individual to self-purchase.

The feasibility of follow-up appointments within organisational systems and workloads may provide a barrier to the review of an orthosis prescribed. Access to a replacement or subsequent orthosis may also be subject to financial restrictions.

Cost-effectiveness: the literature search strategy for this guideline included economic and cost-effectiveness search terms, and the NHS Economic Evaluation Database was included as a core database.

Despite this, no cost-effectiveness studies or economic evaluations specific to hand and wrist orthoses were identified in the development or review of the guideline, and the costs associated with orthoses have not been a feature of most of the studies reviewed for the guideline.

Two studies used to support the recommendations in this guideline compared the benefits of two orthoses and considered financial implications alongside the outcomes of the intervention. In a comparison of three orthoses Haskett et al (2004) identified that the most expensive of the three (taking into account the orthosis itself, fitting time and instructions) was the leather functional wrist orthosis, which demonstrated some superiority in terms of degree of pain reduction and participant preference. Clinical differences alone were not considered significant enough to warrant the prescription of the more expensive custom-made leather orthosis.
Cost is a potential issue for the prescription of orthoses for swan neck deformity. Research participants have expressed a preference for silver ring splints compared to a thermoplastic orthosis, but the effects of both orthoses on dexterity and dexterity-related pain have been shown to be comparable (Giesen et al 2009).

The implication from those two studies is that the evidence base does not consistently identify one orthosis as superior to another with respect to effectiveness on key primary and secondary outcomes. Cost may therefore be a factor that influences decision-making.

The prescription of an orthosis has not been specifically compared to alternative treatments in this guideline. In practice, however, an orthosis may be recommended by commissioners or trusts, prior to other treatments being provided, as a low-cost and potentially effective option.

### 7.3 Implementation resources

Three core implementation resources are available to support this practice guideline.

#### 7.3.1 Quick reference and implementation guide

The quick reference and implementation guide is intended to be used by practitioners as an easily accessible reminder of the recommendations for intervention and suggestions for implementing them. It should ideally be used once the practitioner has read the full guideline document. This is important to ensure an appreciation and understanding of how the recommendations were developed, and their context.

The quick reference and implementation guide includes the following:

- **Introduction.**
- **List of the recommendations, their strength, and the quality of the evidence leading to their development.**
- **Policy and service delivery context**
- **Background to the clinical condition.**
- **The occupational therapy role**
- **Potential impact of the recommendations.**
- **Tips for implementing the recommendations.**

#### 7.3.2 Audit form

It is recommended that occupational therapists use the Royal College of Occupational Therapists’ audit tool that supports this guideline.

The audit form for this guideline provides a standard template for individual occupational therapists or services to audit and review their current interventions against the individual recommendations. The aim is to encourage a reflection on current practice and to consider, where this does not follow the recommendations, the clinical reasoning in place to support decisions.

A baseline assessment conducted using the audit tool can be repeated to enable review of progress on actions identified from the audit. It can be useful to undertake a routine audit every one or two years to monitor ongoing compliance.

The audit form, while initially providing a tool for use within an individual/service
context, offers the potential for future benchmarking.

7.3.3 Continuing professional development session

A set of PowerPoint slides, with notes and interactive activities, provides the resources for an individual or service to conduct a continuing professional development session focused on the practice guideline.

The learning outcomes for the session are:

- Explore aspects of the evidence-based guideline/recommendations in relation to current practice.
- Develop an understanding of the importance of using an evidence-based guideline to inform practice.
- Explore and develop an understanding of how to use the Royal College of Occupational Therapists’ audit tool for the evidence-based recommendations.

The slide set can also be valuable in increasing awareness about the guideline, and can be tailored to meet local needs.

In addition to the audit form, which is most likely to be used by services, a reflective practice template is available for occupational therapists to review their own practice.

A feedback form is available to provide comment on the guideline and implementation resources to the Royal College of Occupational Therapists.

**Accessing the implementation resources**

The quick reference and implementation guide, audit form and continuing professional development session resources are available as separate documents.

These can be downloaded, together with the full guideline document, from the RCOT practice resources section (Practice guidelines) of the Royal College of Occupational Therapists’ website: [https://www.rcot.co.uk/practice-resources/rcot-practice-guidelines](https://www.rcot.co.uk/practice-resources/rcot-practice-guidelines).

The resources can also be accessed via the web pages of the Royal College of Occupational Therapists Specialist Section-Trauma and Musculoskeletal Health by members of the Specialist Section ([https://www.rcot.co.uk/about-us/specialist-sections/trauma-and-musculoskeletal-rcot-ss/member-resources](https://www.rcot.co.uk/about-us/specialist-sections/trauma-and-musculoskeletal-rcot-ss/member-resources)).
8 Recommendations for future research

The Royal College of Occupational Therapists commenced a research Priority Setting Partnership with the James Lind Alliance in 2019. This brings together people who access occupational therapy services, carers, occupational therapists and others working in the health and care environment in Priority Setting Partnerships to identify and prioritise ‘uncertainties’ or ‘unanswered questions’ about treatments or interventions that they agree are most important in a particular area. Once the high level Top 10 research priorities for occupational therapy research in the UK are available, an important piece of follow-on work will be supporting the translation of the priorities into more targeted and focused research priorities within the context of specific clinical areas.

In this review of the practice guideline some of the recommendations lacked any new supporting evidence which had not already been considered within the original guideline. For example, there were no new studies on rheumatoid arthritis and wrist braces or night resting splints. As discussed in previous sections there may be many factors influencing this lack of recent research focus, such as the change of interventions that occupational therapists are using in practice with the impact of biological therapies in rheumatoid arthritis. Therefore, an important area of future research for occupational therapists working in rheumatology should be exploring the changing nature of their role due to recent medical advances.

Another large gap in the evidence is around the economic evaluation of orthotics as an intervention in rheumatology occupational therapy. Given that occupational therapists are delivering healthcare in an environment of finite resources, it was agreed by the guideline review group that the production of statistics and health economics data would be invaluable in helping occupational therapists maintain current working practice.

Other areas for future research that were agreed by the guideline review group from the recent evidence are identified below.

**Occupational therapy interventions in rheumatology:**
- Identification of the current role of rheumatology occupational therapy in inflammatory arthritis, including the setting in which they are working, with a shift towards primary care.
- Emphasis on the importance of early preventative interventions in inflammatory arthritis, specifically the importance of work related interventions, and self/lifestyle management techniques and their effectiveness.
- More multimodal studies which are reflective of clinical practice and that seek to establish the effectiveness of a range of interventions and their outcomes.
- Exploration of occupational therapy interventions for people with hypermobility and the effectiveness of these interventions.
- Establishing best orthosis design and wearing regimens, taking into account satisfaction of the wearer (e.g. joint positioning and parameters, movement versus stability, technical properties of materials, fabrication intensity, day/night/as required, duration of intervention, concordance, risks, adverse outcomes).
- Long-term effects of orthoses versus alternative treatments (e.g. steroid...
Outcomes and Economic evaluation:

- Identification of the volume and cost of prescribing an orthosis for people accessing services, along with the related health benefits, psychological impact and desired outcomes, particularly in osteoarthritis of the thumb.
- Investigation into the application of outcome measurement in clinical practice for the measurement of effectiveness of orthoses, and other occupational therapy interventions.
9 Guideline development process

Sections 9 and 10 provide the details of the development process and methodology for the first edition of the guideline. Section 11 outlines the review process and update for this second edition. Detailed information on the following steps in the guideline development process can be found in the Practice guidelines development manual (COT 2017a).

9.1 Guideline development group

The membership of the core guideline development group comprised six occupational therapists with expertise in the field of rheumatology, and/or experience of developing guidelines. A seventh member was co-opted for the second half of the project (see Appendix 1).

The core group members were all practising therapists, educators or researchers, who undertook guideline development work in their own time, with some support from employers (for example, to attend meetings). To facilitate timely progression of the guideline development, much of the liaison and activity was carried out using email correspondence.

Two members of the Research and Development Team at the Royal College of Occupational Therapists were co-opted as additional critical appraisers, together with four individuals who were involved in rheumatology practice or research.

The Research and Development Manager at the Royal College of Occupational Therapists was co-opted as Editorial Lead.

Given the very specific occupational therapy nature of this practice guideline, it was determined that the core group would be profession-specific, with wider expertise from other stakeholders and people who access services obtained outside core group meetings, via consultation with a virtual reference group.

All comments received from stakeholders, people who access services and occupational therapists on the draft scope and draft guideline document were reviewed by the guideline development group. Where appropriate, revisions were incorporated into the scope form or guideline document prior to submission to the College’s Practice Publications Group, for approval. Conflict of interest declarations were noted and reviewed for any necessary action.

In the interests of openness and transparency, details of the comments submitted as part of the consultation activities are available on request from the Royal College of Occupational Therapists.

9.2 Stakeholder involvement

Stakeholders expected to have an interest in the guideline topic were identified by the core group membership at the preliminary guideline meeting. Specific attention was paid to identifying professional colleagues who may be working as part of a multidisciplinary team, and national charitable or voluntary organisations that may
9.2.1 Scope consultation with stakeholders
A core group of stakeholders were approached to comment on an initial draft of the scope, which was provided in the form of a Stakeholder Information Document (together with a comments proforma and conflict of interest declaration form).

The following stakeholders were invited to comment on the scope document:

- British Health Professionals in Rheumatology/British Society of Rheumatologists (BHPR/BSR)
- National Rheumatoid Arthritis Society
- Chartered Society of Physiotherapy
- Royal College of Nursing
- British Association of Hand Therapists.

Comments received were reviewed by the guideline development group and, where these could be endorsed, the scope amended accordingly.

9.2.2 Draft guideline consultation with stakeholders
The draft guideline was sent to each of the stakeholders who had been contacted as part of the scope consultation (see section 9.2.1), for their review and comment.

Feedback from additional stakeholders was also invited:

- Arthritis Research UK
- European League against Rheumatism
- British Association of Prosthetists and Orthotists.

A number of individuals who were in contact with guideline development group members via professional or local networks, and who expressed an interest in the consultation, were also invited to participate.

The guideline document and consultation form were placed in the public domain, for a one-month consultation period, on the RCOT-SS Trauma and Musculoskeletal Health website page (from 19/01/15 to 13/02/15).

All comments were discussed at a meeting of the guideline development group and taken into account during the revision of the final guideline.

9.3 Involvement of people who access services
9.3.1 Scope consultation with people who access services
Three organisations/groups with links to people who access services and fora were invited to comment on the scope:

- Arthritis Care Northern Ireland
- Arthritis Care Scotland
- Patient Representatives Group (North Bristol NHS Trust).
These groups were selected for their ability to provide a perspective from organisations representing people who access services, and/or views of individual experts who have access services. A copy of the scope Stakeholder Information Document was sent to the group contacts.

Comments received were reviewed by the guideline development group and, where these could be endorsed, the scope amended accordingly.

### 9.3.2 Draft guideline consultation with people who access services

Consultation activities with people who access services were undertaken to obtain views on the guideline recommendations and document.

Arthritis Care Scotland and Arthritis Care Northern Ireland were again invited for their views and comments.

Additional consultation took place with:
- Individual(s) engaged in patient involvement opportunities via email networks.
- Managed Clinical Network Patient Engagement Group (Greater Glasgow and Clyde Health Board).

To facilitate different levels of involvement and engagement activities, extractions from the draft guideline were made available in addition to the full draft. An abbreviated document was produced to include the recommendation statements summary, evidence summaries, and the section on optimising outcomes for people who access services and the potential impact of the recommendations. The document was made available to individuals identified within networks, fora or organisations for people who access services / have rheumatological conditions, together with a consultation form which, while providing the opportunity for open comments, asked five specific consultation questions (see section 6).

The guideline development group recognised that the groups engaging in the consultation process would not necessarily be representative of all individuals living with a rheumatological condition, in terms of experiences and cultural and ethnic diversity. It was determined, however, that individuals from these identified populations could take on a valuable role in the guideline development process, particularly by providing their perspectives as individuals who access services / lay representatives.

All comments were duly considered for inclusion within the final guideline.

Qualitative feedback from these representatives is quoted alongside the recommendations where applicable. This approach aims to enhance the individual’s perspective as an adjunct to the published evidence.

### 9.4 Occupational therapists consultation

The primary audience of the guideline is occupational therapists and, specifically, those working with people with rheumatological conditions. Ongoing awareness of the progress of the guideline development project was communicated to the members of RCOTSS-Trauma and Musculoskeletal Health via their e-newsletter and website. An article authored by the guideline development group was also published in the Specialist Section’s journal (Squire et al 2014).
Guideline development process

9.4.1 Scope consultation with occupational therapists
Members of RCOTSS-Trauma and Musculoskeletal Health were invited to participate in the scope consultation by the Specialist Section Chair via the membership email network. A copy of the scope documentation was provided, with a request for feedback and comment.

Other Specialist Sections of the Royal College of Occupational Therapists were invited to comment, namely Specialist Sections Trauma and Orthopaedics (as it was known at the time); Older People; Work; and Independent Practice.

Comments received were reviewed by the guideline development group and, where these could be endorsed, the scope amended accordingly.

9.4.2 Draft guideline consultation with occupational therapists
A one-month consultation period enabled members of the RCOTSS-Trauma and Musculoskeletal Health to comment on a draft of the full guideline. The Specialist Section’s National Conference took place during the consultation period and delegates were therefore alerted to the opportunity to comment on the guideline draft as part of a presentation providing an update on the progress of the guideline development project.

The consultation was additionally open to any member of the British Association of Occupational Therapists and was promoted via the monthly professional magazine, Occupational Therapy News. The draft guideline and a consultation feedback and conflicts of interest form were made available to members (and the public) via the College’s website.

All comments were duly considered for inclusion within the final guideline.

9.5 External peer review
Four independent peer reviewers were invited by the guideline development group to critically appraise a draft of the full guideline. Reviewers were selected for their known clinical and research expertise in the field, and/or their guideline development experience or knowledge. The external peer reviewer form asked for comment on both the presentation and content of the draft guideline, taking into account factors such as its purpose, robustness, and unbiased nature. The detailed views and expert opinions received were discussed by the guideline development group and used to inform the content of the final guideline.

9.6 Conflicts of interest
All guideline development group members (core group and co-opted), stakeholders, occupational therapists and external peer reviewers were required to declare any pecuniary or non-pecuniary conflicts of interest, in line with the guideline development procedures (COT 2017a). People who access services were also asked to declare any conflicts of interest.

The nature of the potential or actual conflicts made in the declarations (see Appendix 3) were not determined as being a risk to the transparency or impartiality of the guideline development.

The editorial lead for the guideline was a member of staff at the Royal College of Occupational Therapists, who attended guideline meetings as an ‘officer in attendance’.
The recommendation statements and guideline content were, however, developed and finalised by the guideline development group with the involvement of stakeholders, representatives of people who access services, and occupational therapists, and were externally peer reviewed. The views of the Royal College of Occupational Therapists have not, therefore, unduly influenced the final recommendations in this guideline.

9.7 Declaration of funding for the guideline development

This practice guideline was developed by a group led by a Specialist Section of the Royal College of Occupational Therapists. Specialist Sections are official branches of the College with specialist interests who, through their membership, are able to engage expert practitioners, educators and researchers in the development of guidelines, and access the required clinical and research expertise.

As a membership organisation, the major source of funding for the Royal College of Occupational Therapists and its Specialist Sections is obtained from membership. Other sources of income are primarily from advertising and events.

The development and publication of the first edition of the practice guideline was funded by the Royal College of Occupational Therapists and the RCOTSS-Trauma and Musculoskeletal Health. The Royal College of Occupational Therapists provided specific resources to cover the meeting venue, travel expenses, literature search, editorial and publication support. A small ring-fenced allocation was made by the National Executive Committee of the Specialist Section to fund any other costs associated with the development and promotion of the practice guideline.

Manufacturers and distributors of orthoses and materials for fabrication were viewed by the guideline development group as being stakeholders, but a decision was made not to include them in the project to avoid any potential for commercial bias or influence.

There were no external sources of funding.

The project lead, who chaired meetings, was a member of the RCOTSS-Trauma and Musculoskeletal Health, but was not a National Executive Committee member so had no direct decision-making relationship with the allocated funding for the project.

9.8 Royal College of Occupational Therapists’ appraisal and ratification process

The guideline proposal, scope and final document were all reviewed and subsequently ratified by the Royal College of Occupational Therapists’ Practice Publications Group, in line with the requirements of the Practice guidelines development manual (COT 2017a).

The scope was approved by the Practice Publications Group in March 2014 and the final version of this guideline was approved by the Practice Publications Group in May 2015.
10 Guideline methodology

10.1 Guideline questions

- Is there evidence to support the use of hand and wrist orthoses as an intervention for adults living with a rheumatological condition?
- Is there any evidence of harm arising from the use of an orthosis that practitioners should be aware of?

The PICO framework (Huang et al 2006, Richardson et al 1995) was used to assist in developing the specific practice question further (see Table 1). PICO describes the specific care group or condition being studied, and the nature of the intervention to be investigated.

A comparative treatment can be specified where applicable, together with the anticipated outcomes (the desired/undesired or expected results of the intervention). This level of specificity is important in developing the question so that it addresses the requirements of the scope (COT 2017a).

Table 1: PICO framework

<table>
<thead>
<tr>
<th>Patient (person who accessed services), Population or Problem/circumstance</th>
<th>Adults, 16 years and over, who have a rheumatological condition involving the hand or wrist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention under investigation or action</td>
<td>Orthoses</td>
</tr>
<tr>
<td>Comparison, which is an alternative intervention or action</td>
<td>None</td>
</tr>
</tbody>
</table>

10.2 Literature search strategy and outcomes

The literature search was carried out by Royal College of Occupational Therapists’ Librarians, experts in the field of occupational therapy literature, using a search strategy defined following discussion and agreement with the guideline development group.
10.2.1 Key terms
The strategy involved combining concept groups of key words. Six key categories or concepts and their related terms were identified: condition/problem; alternative conditions; limb-related terms; intervention; occupational therapy terms; and cost-related terms (see Appendix 4, Table A1).

Specific exclusions identified were: material published pre-2004, individuals under 16 years of age, and language other than English (due to lack of resources for translation). All study designs were considered potentially relevant.

10.2.2 Databases
The databases searched reflected the most likely sources of published peer reviewed occupational therapy rheumatology evidence. Seven core databases were searched from 1 January 2004 to the dates the individual searches were carried out (in 2014), as detailed in Table 2.

Table 2: Database searches

<table>
<thead>
<tr>
<th>Core databases</th>
<th>Search date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cumulative Index to Nursing and Health Literature (CINAHL)</td>
<td>Federated search</td>
</tr>
<tr>
<td>MEDLINE</td>
<td>20/05/14</td>
</tr>
<tr>
<td>Allied and Complementary Medicine (AMED)</td>
<td>Federated search</td>
</tr>
<tr>
<td>PsycINFO</td>
<td>16/05/14</td>
</tr>
<tr>
<td>Social Policy and Practice</td>
<td></td>
</tr>
<tr>
<td>Health Management Information Consortium (HMIC)</td>
<td></td>
</tr>
<tr>
<td>PubMed</td>
<td>15/05/14</td>
</tr>
</tbody>
</table>

Additional specialist databases were also searched: OTDBASE; OT SEARCH; OTseeker; the Cochrane Library (including the NHS Economic Evaluation Database – NHS EED); Ethos; ProQuest; and the Royal College of Occupational Therapists’ Library catalogue. Hand-searching of the Journal of Rheumatology Occupational Therapy and relevant websites was also undertaken.

Searches included title, abstract or descriptor fields. The date of each search, search fields and search result numbers are detailed in Appendix 4 (Tables A2 and A3). A ten-year time frame was identified as appropriate for the search period.

Full search histories are available on request from the Royal College of Occupational Therapists.

10.2.3 Search results
The search identified a total of 2,069 results. These were scrutinised for duplicates, both within database searches and cross-database search returns, by the Royal College of Occupational Therapists’ Research and Development Manager. A total of 1,404 duplicates were removed. The unique results list was provided to the project lead and guideline development group members undertaking the screening activity.
10.3 Criteria for inclusion and exclusion of evidence

The resultant 665 search findings (title and abstracts) were each independently screened by two different members of the guideline development group against an eligibility checklist:

**Inclusion criteria:**
- Adults aged over 16 years.
- Orthoses.
- Rheumatological condition.
- Hand/wrist.

**Exclusion criteria:**
- Crystal arthropathy.
- Fibromyalgia.
- Hypermobility.
- Neurological conditions.
- Elbow, knee, foot or neck orthoses.
- Post-operative orthoses.
- Hand assessment.
- Fabrication of orthoses.

The allocation process ensured that guideline development group members did not screen any evidence that they had authored or co-authored. Where two screeners had a yes/no variation in opinion as to whether an abstract should be included or excluded for appraisal, the abstract was further reviewed against the eligibility criteria by the reviewers to make a consensus decision. If consensus could not be reached, this was referred to a guideline development group meeting for a consensus decision.

This process enabled the identification of abstracts that would be potentially relevant to the practice guideline and should therefore be included within the critical appraisal process.

Following the screening, 490 items were further excluded, resulting in a total of 175 items identified for full paper review and critical appraisal.

A total of 175 articles were critically appraised and details transferred into evidence tables (see section 10.4); 31 items of evidence were subsequently used in developing the recommendations (see section 10.5).

An overview of the literature search outcomes is provided in Figure 10.1.
10.4 Strengths and limitations of body of evidence

Each of the 175 articles identified as potential evidence was critically appraised by two independent reviewers. Appraisals were undertaken by all members of the guideline development group, with additional support provided by co-opted members. The allocation process ensured that reviewers did not appraise any evidence that they had authored or co-authored. Any discrepancy in grading was discussed, and the final grading agreed and confirmed by the two original reviewers or via group consensus.

The quality of the evidence was initially assessed and recorded using forms based on the Critical Appraisal Skills Programme (CASP) checklists (CASP 2013). Assessment took into account factors such as the appropriateness of the study design and recruitment strategy; procedural rigour in data collection and analysis; confounding factors and potential biases; transferability; precision of results; and the value of the findings.

A quality of evidence grade was then assigned to each individual article using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach, as defined within the Practice guidelines development manual (COT 2017a). The grading reflects the research design and the confidence in the research findings.
Guideline methodology

The initial grading was allocated as follows:
- Randomised controlled trial (RCT)/systematic review = High.
- Observational study = Low.
- Any other evidence = Very Low.

Limitations in the design of a study or its implementation may, however, bias the estimates of the treatment effect. If there were serious limitations, then downgrading of the quality of the evidence was considered, as in Table 3.

**Table 3: Grading evidence up or down** (after GRADE Working Group 2004)

<table>
<thead>
<tr>
<th>Decrease* grade if</th>
<th>Increase grade if</th>
</tr>
</thead>
<tbody>
<tr>
<td>* Each quality criterion can reduce the quality by one or, if very serious, by two levels</td>
<td></td>
</tr>
<tr>
<td>- Serious or very serious limitation to study quality.</td>
<td>- Magnitude of the treatment effect is very large and consistent.</td>
</tr>
<tr>
<td>- Important inconsistencies in results.</td>
<td>- Evidence of a large dose-response relation.</td>
</tr>
<tr>
<td>- Some or major uncertainty about directness of the evidence.</td>
<td>- All plausible confounders/biases would have decreased the magnitude of an apparent treatment effect.</td>
</tr>
<tr>
<td>- Imprecise or sparse data (relatively few participants and/or events).</td>
<td>Only studies with no major threats to validity should be upgraded.</td>
</tr>
<tr>
<td>- High probability of reporting bias.</td>
<td></td>
</tr>
</tbody>
</table>

A decision to increase or decrease the initial grade of the evidence was recorded and justified on the critical appraisal forms. A moderate category only became relevant if there was a suggested change in the initial grading of an article due to up- or downgrading. Evidence was ultimately graded in one of four categories, as detailed in Table 4.

If there was no reason to up- or downgrade the evidence, then the original grading remained.

**Table 4: GRADE quality of evidence grading** (after GRADE Working Group 2004)

<table>
<thead>
<tr>
<th>Quality of evidence</th>
<th>Grading</th>
<th>Characteristics</th>
<th>Confidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>A</td>
<td>Based on consistent results from well-performed randomised controlled trials, or overwhelming evidence of an alternative source, e.g. well-executed observational studies with strong effects.</td>
<td>True effect lies close to that of the estimate of the effect. Further research is very unlikely to change confidence in the estimate of the effect.</td>
</tr>
</tbody>
</table>
Once the methodological quality of each piece of evidence had been assessed, details for each item of evidence were collated, from the two independent appraisals, into an evidence table (Appendix 6).

### 10.5 Method used to arrive at recommendations

The evidence tables were used by the guideline development group to synthesise the evidence available, and as the basis to evaluate and judge the potential contribution of each item of evidence to the development of the guideline recommendations.

The identified outcomes (section 10.1) were used as the starting point, in conjunction with condition and orthosis types identified from the appraised evidence. Where evidence was identified to support an outcome or theme, this was reviewed. Each individual group member contributed their expert views to the discussion to develop recommendation options.
Guideline methodology

Where a number of items of evidence supported an identified outcome and subsequent recommendation, an overall quality of evidence rating was determined. This overall rating was established as follows:

- Where the evidence outcomes pointed in different directions towards benefit and towards harm, the lowest quality of evidence determined the overall quality grade of evidence.

- Where the outcomes pointed in the same direction towards either benefit or harm, the highest quality of evidence was appropriate to recommend an intervention and determined the overall quality of evidence.

- In circumstances where the balance of benefits and harm was uncertain, the lowest grade of quality of evidence was assigned.

Strength of recommendation was the second element of the GRADE system applied using the categories, strong or conditional, to reflect the strength (Table 6).

**Table 6: Strength of grade** (after Guyatt et al 2008)

<table>
<thead>
<tr>
<th>Strength</th>
<th>Grade</th>
<th>Benefits and risks</th>
<th>Implications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strong</td>
<td>1</td>
<td>Benefits appear to outweigh the risks (or vice versa) for the majority of the target group.</td>
<td>Most people would want or should receive this course of intervention or action.</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Risks and benefits are more closely balanced, or there is more uncertainty in likely values and preferences of the person.</td>
<td>The majority of people would want this intervention, but not all, and therefore they should be supported to arrive at a decision for intervention consistent with the benefits and their values and preferences.</td>
</tr>
</tbody>
</table>

The development of the recommendations, including assignment of the overall quality and strength grading, was a consensus decision obtained at the guideline development group meeting, and by subsequent email correspondence as required for any revisions. There were no recommendations which were not agreed by all members, so that no formal voting system or use of the nominal group technique was required. Thirty-one items of evidence were used to develop the recommendations.

A recommendation decision form was completed for each recommendation developed. This recorded key information about the evidence used to form the basis of that recommendation, the overall allocation of the quality of evidence and strength of the recommendation. The form also facilitated discussion and recording of any specific or associated risks and benefits, and this was reflected in the final strength of recommendation. Any judgement by the guideline development group was documented as part of this decision-making process (the forms are available on request from the Royal College of Occupational Therapists).
11 Guideline review process - 2\textsuperscript{nd} edition

The guideline review commenced in 2018, three years after publication of the guideline and followed the review process as outlined in the Practice guideline development manual (COT 2017a, Section 3.14).

The guideline question, objective and scope were unchanged, as were the criteria for inclusion or exclusion of evidence. This section outlines the process followed and, where necessary, cross-references to the first edition development process and methodology.

11.1 Guideline review group established

The guideline review group consisted of one member of the original guideline development group and seven new members. All were occupational therapists with expertise and specialist interest in rheumatological conditions and orthoses. Conflicts of interest were declared in line with the guideline development process requirements.

11.2 Identification of new evidence

Monitoring searches were carried out in 2016 and 2017 to ensure no significant studies were published which would require an immediate change to the recommendations or withdrawal of the guideline. All searches were undertaken by the Royal College’s Library and Information Service.

11.2.1 Key search terms

The monitoring search (2015-2016) and full review search strategies replicated the 1\textsuperscript{st} edition guideline search terms across the databases and platforms. These searches involved combining groups of search terms from six categories or concepts and their related terms: two sets of conditions, limb-related terms, interventions, occupational therapy and related terms, and finance/value terms (Appendix 5 Tables A5, A7 and A8).

The monthly monitoring searches (from 2016) used a reduced set of terms and combinations (Appendix 5 Table A6).

11.2.2 Databases

The monthly monitoring searches were only carried out on the EBSCOHOST and OVID platforms. For the full review search, core and specialist databases were searched from the last date of the 1\textsuperscript{st} edition guideline search (May 2014) to October 2018. The databases accessed were: EBSCOHOST platform (MEDLINE, CINAHL); OVID platform (AMED, HMIC, PsycINFO, Social Policy and Practice); OTseeker; OTDBASE; OT SEARCH; Cochrane Library; NHS EED, PubMed, PubMed Central, ETHOS (now part of the British Library) and RCOT Library online catalogue. Relevant websites were also searched.

Details for the specific database searches are provided in Appendix 5 Tables A5 – A8.
11.2.3 Search results

The monitoring searches returned 135 results (EBSCOHOST platform n=126 and OVID platform n=9). The College Officer cleansed for duplicates and anomalies within and across databases, resulting in 11 articles for screening. No articles were identified as presenting evidence that any recommendations should be changed to prevent harm.

For the full search, the core and specialist searches produced a total of 1,116 results (EBSCOHOST platform n=230; OVID platform n=48 and specialist databases/websites n=838). Following cleansing, by the College Officer, 291 abstracts were suitable for screening.

11.2.4 Screening and appraisal of evidence

A total of 291 abstracts were independently screened by two members of the guideline review group against criteria identified in the guideline development process (Section 10.3). This resulted in 230 items being excluded, and 61 items of evidence being selected for independent appraisal by two group members.

An overview of the full literature search is provided in Figure 11.1.
Figure 11.1: Review full literature search
11.3 Assessment of update requirements

A total of 13 articles were agreed by consensus as providing new evidence for inclusion in an update of the guideline to support four existing recommendation statements. Additionally, one article from the 1st edition guideline was used to add support to an existing recommendation. To note, systematic reviews that only discussed articles used as evidence in the first edition of the guideline were discounted.

The 13 new items of evidence were mostly graded as Moderate (Grade B, n=7), with three each graded Low (Grade C, n=3) or Very low (Grade D, n=3).

The guideline review group’s discussions focused on the update required for the 2nd edition in terms of:

- New evidence appraised.
- Development of recommendations where indicated by new evidence or knowledge.
- Consideration of any original material that was no longer appropriate and how this might need to be replaced or withdrawn.
- Consideration of any relevant feedback and comments received since the publication of the guideline.

11.4 External review

To be added.

11.5 College appraisal and ratification process

To be added.

11.6 Overview of limitations and any potential bias of the guideline

Evidence included in the development and review of the guideline recommendations was sourced from published, peer reviewed journal articles. Relevant policy documents have been referenced within the contextual information where applicable, but it is acknowledged that grey literature has not been included in the evidence.

The literature search identified a body of primary research, relating predominantly to the provision of an orthosis for thumb base osteoarthritis, functional wrist orthoses for rheumatoid arthritis, and some studies that researched the use of silver ring splints or Oval-8® orthoses for swan neck deformity as a consequence of rheumatoid arthritis. The review of the literature for the first and second editions of the guideline combined identified 44 items of evidence from which recommendations were developed.

A total of 52.3% of the evidence was derived from high or moderate quality studies:

Grade A = 18.2% (n=8)
Grade B = 34.1% (n=15)
Grade C = 31.2% (n=14)
Grade D = 15.9% (n=7)

A number of studies in the 1st edition guideline literature search were appraised which
considered orthoses as an intervention for carpal tunnel syndrome. These resulted in discussion by the guideline development group, as many were viewed to fall outside the scope of the guideline, in that the populations involved excluded those with inflammatory or rheumatoid conditions. A consensus was reached regarding their exclusion. In the review for the 2nd edition, the literature search also found articles related to carpal tunnel syndrome, but as per the development of the guideline, all were excluded due to the exclusion of the guideline’s target population.

As in the first guideline literature search, limited evidence was identified with respect to orthoses for trigger finger, Boutonnière deformity, ulnar deviation, or for osteoarthritis of the distal interphalangeal joints. This evidence was insufficient to develop a specific recommendation, either to support or refute the prescription of an orthosis. There was limited literature on the use of compression gloves in rheumatological conditions. Additional information is provided in Appendix 7.

The evidence did provide a number of higher quality studies from a design and methodological perspective. The guideline development and review groups downgraded 15 of the potential grade A studies due to limitations identified from the appraisal and a resultant lack of confidence in the estimate of the research effect. Systematic reviews were mainly graded as A or B, which was based on the robustness of the review methodology and reported outcomes. This did not necessarily reflect, however, the quality of the individual studies included within the review.

The evidence identified did have some overarching limitations. While there have been a number of research studies undertaken, the majority of these were small-scale, underpowered, and of limited follow-up duration. Study populations were mostly heterogeneous and the nature of the orthosis design and the wearing regimens used in international research can differ from UK practices. Only a small proportion of the primary research was conducted in the UK, and therefore there may be medical management differences and orthotic prescription factors that could influence generalisation.

Additionally:

• Not all studies provided adequate information on the orthosis being investigated, which would make reproduction of the intervention a challenge. Many commercially available prefabricated wrist and hand orthoses are described in papers by their tradename, which can be country-specific. A full description of the orthosis, with the inclusion of a photograph, would be needed to enable the replication of the intervention / study.

• A number of papers failed to explicitly state the wrist angle of the orthosis, and/or there appeared to be no attempt to determine if the wrist was held in a predetermined position during task performance, or to see if the orthosis maintained the angle of wrist extension after a period of use.

• There appeared to be little or no attempt to quantify ‘fit’, which underpins optimal orthotic treatment. This will impact not only on function but, importantly, comfort, both of which will influence compliance. Information on fitting complications and rejection rates was rarely provided.

Details on specific limitations of individual studies are noted in the evidence tables in Appendix 6.

Table 11.1: Summary of evidence used to develop the recommendations

<table>
<thead>
<tr>
<th>Category</th>
<th>Author</th>
<th>Year</th>
<th>Evidence quality</th>
</tr>
</thead>
</table>

Royal College of Occupational Therapists
<table>
<thead>
<tr>
<th>Condition</th>
<th>Study Details</th>
<th>Year</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rheumatoid arthritis: orthoses for activity and rest</td>
<td>Ramsey et al</td>
<td>2014</td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>Giesen et al</td>
<td>2014</td>
<td>D</td>
</tr>
<tr>
<td></td>
<td>Giesen et al</td>
<td>2010</td>
<td>D</td>
</tr>
<tr>
<td></td>
<td>Spicka et al</td>
<td>2009</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>Thiele et al</td>
<td>2009</td>
<td>D</td>
</tr>
<tr>
<td></td>
<td>Adams et al</td>
<td>2008</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>Silva et al</td>
<td>2008</td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>Veelhoven et al</td>
<td>2008</td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>Pagnotta et al</td>
<td>2005</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>Haskett et al</td>
<td>2004</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>Zijlstra et al</td>
<td>2004</td>
<td>C</td>
</tr>
<tr>
<td>Osteoarthritis: base of thumb orthoses</td>
<td>Cantero-Téllez et al</td>
<td>2018</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>Vegt et al</td>
<td>2017</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>Bani et al</td>
<td>2014</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>Hamman et al</td>
<td>2014</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>Hermann et al</td>
<td>2014</td>
<td>D</td>
</tr>
<tr>
<td></td>
<td>Maddali-Bongi et al</td>
<td>2014</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>Bani et al</td>
<td>2013</td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>Becker et al</td>
<td>2013</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>Kjeken et al</td>
<td>2011</td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>Kjeken et al</td>
<td>2011</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>Sillem et al</td>
<td>2011</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>Gomes Carreiral et al</td>
<td>2010</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>Boustedt et al</td>
<td>2009</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>Moe et al</td>
<td>2009</td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>Rannou et al</td>
<td>2009</td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>Egan and Brousseau</td>
<td>2007</td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>Wajon and Ada</td>
<td>2005</td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>Weiss et al</td>
<td>2004</td>
<td>C</td>
</tr>
<tr>
<td>Optimising individual outcomes</td>
<td>Cantero-Téllez et al</td>
<td>2018</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>Duong et al</td>
<td>2018</td>
<td>D</td>
</tr>
<tr>
<td></td>
<td>Healey et al</td>
<td>2018</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>Tada et al</td>
<td>2018</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>Almeida et al</td>
<td>2017</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>Shankland et al</td>
<td>2017</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>Vegt et al</td>
<td>2017</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>Aebischer et al</td>
<td>2016</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>Hammond et al</td>
<td>2016</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>Bertozzi et al</td>
<td>2015</td>
<td>D</td>
</tr>
<tr>
<td></td>
<td>Spaans et al</td>
<td>2015</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>Bani et al</td>
<td>2014</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>Nasir et al</td>
<td>2014</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>Bani et al</td>
<td>2013</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>Bani et al</td>
<td>2013</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>Becker et al</td>
<td>2013</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>Gooberman-Hill et al</td>
<td>2013</td>
<td>D</td>
</tr>
<tr>
<td></td>
<td>Kjeken et al</td>
<td>2011</td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>Sillem et al</td>
<td>2011</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>Gomes Carreira et al</td>
<td>2010</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>Boustedt et al</td>
<td>2009</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>Giesen et al</td>
<td>2009</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>Rannou et al</td>
<td>2009</td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>Thiele et al</td>
<td>2009</td>
<td>C</td>
</tr>
<tr>
<td>Reference</td>
<td>Year</td>
<td>Grade</td>
<td></td>
</tr>
<tr>
<td>-----------------</td>
<td>------</td>
<td>-------</td>
<td></td>
</tr>
<tr>
<td>Boer et al</td>
<td>2008</td>
<td>C</td>
<td></td>
</tr>
<tr>
<td>Silva et al</td>
<td>2008</td>
<td>A</td>
<td></td>
</tr>
<tr>
<td>Veehof et al</td>
<td>2008a</td>
<td>B</td>
<td></td>
</tr>
<tr>
<td>Veehof et al</td>
<td>2008b</td>
<td>C</td>
<td></td>
</tr>
<tr>
<td>Pagnotta et al</td>
<td>2005</td>
<td>C</td>
<td></td>
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<tr>
<td>Wajon and Ada</td>
<td>2005</td>
<td>A</td>
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<tr>
<td>Haskett et al</td>
<td>2004</td>
<td>B</td>
<td></td>
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<tr>
<td>McKee and Rivard</td>
<td>2004</td>
<td>D</td>
<td></td>
</tr>
<tr>
<td>Weiss et al</td>
<td>2004</td>
<td>C</td>
<td></td>
</tr>
<tr>
<td>Zijlstra et al</td>
<td>2004</td>
<td>C</td>
<td></td>
</tr>
</tbody>
</table>

The involvement of the Royal College and the Specialist Section in the development, authoring and funding of this practice guideline, is fully acknowledged (section 9.6). Involvement is inherent because of the organisational structure of the professional body and its relationship with its members.

The potential for any bias in development and authoring was, however, minimised through the rigorous nature of the guideline development process. This was achieved through the systematic methodology adopted, the contributions of stakeholders and people who access services, the valued opinions of the independent peer reviewers and occupational therapists, and the judicious management of any potential or actual conflicts of interest.
Updating the 2nd edition of the guideline

The National Executive Committee of the Royal College of Occupational Therapists Specialist Section - Trauma and Musculoskeletal Health is responsible for monitoring new evidence over the next five-year period and will provide a focal point for feedback received following publication of the 2nd edition of the guideline.

In line with College procedures, this reviewed guideline will be available until 2025 and then withdrawn; however, relevant literature will be monitored regularly to detect new evidence that may have a significant impact on the recommendations. If this occurs, the guideline may be withdrawn earlier, depending on the strength of the evidence.
Appendix 1: Guideline development and review groups

Guideline Development Group, 2013-2015

Ruth Squire (Project Lead)
- MSc, DipCOT
- Lecturer in Occupational Therapy, Cardiff University, Wales
- Member of: Royal College of Occupational Therapists Specialist Section - Rheumatology; British Health Professionals in Rheumatology – Education Officer

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- Member of: Royal College of Occupational Therapists Specialist Section - Rheumatology; British Health Professionals in Rheumatology

Sarah Bradley
- MSc Hand Therapy, DipCOT
- Advanced Practitioner in Hand Therapy, Poole Hospital, Dorset
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Lucia Ramsey
- BSc(Hons) Occupational Therapy, PgCHEP, AHT
- Lecturer in Occupational Therapy, Ulster University, Jordanstown, Northern Ireland
- Member of: Royal College of Occupational Therapists Specialist Section - Rheumatology; British Health Professionals in Rheumatology; Irish Rheumatology Health Professionals Society; British Association of Hand Therapists; and Fellow of the Higher Education Academy

Co-opted member to group (from September 2014)

Cathy Ball
- MSc Health Sciences (University of East Anglia), DipCOT
- Research Clinical Specialist in Hand Therapy, Kennedy Institute of Rheumatology, University of Oxford
- Member of: Royal College of Occupational Therapists Specialist Section - Rheumatology; British Health Professionals in Rheumatology; British Association of Hand Therapists
Guideline Review Group, 2018-2020

Ruth Squire (Project Lead)
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- Senior Lecturer in Occupational Therapy, Cardiff University, Wales
- Member of: Royal College of Occupational Therapists Specialist Section – Trauma and Musculoskeletal Health; British Society of Rheumatology

Patricia Bisset
- Occupational therapist practitioner, Greater Glasgow and Clyde NHS
- Member of: Royal College of Occupational Therapists Specialist Section – Trauma and Musculoskeletal Health; Royal College of Occupational Therapists Specialist Section – Older People; Scottish Society of Rheumatology

Elizabeth Doherty
- Occupational therapist practitioner, East Lancashire Hospitals NHS Trust
- Member of: Royal College of Occupational Therapists Specialist Section – Trauma and Musculoskeletal Health; North West Rheumatology Occupational Therapist Group

Kerry Edwards
- Senior Lecturer, York St John University
- Member of: Royal College of Occupational Therapists

Jo Harness
- Occupational therapy practitioner, North Devon NHS Healthcare Trust
- Member of: Royal College of Occupational Therapists Specialist Section – Trauma and Musculoskeletal Health; British Society of Rheumatology; British Association of Hand Therapists

Laura Ingham
- Occupational therapy practitioner, Swansea Bay University Health Board; Associate Lecturer in Occupational Therapy, Cardiff University, Wales
- Member of: Royal College of Occupational Therapists Specialist Section – Independent Practice; British Association of Hand Therapists

Katharine Noel
- Occupational Therapist, Norfolk and Norwich University Hospital
- Member of: Royal College of Occupational Therapists; British Association of Hand Therapists, British Health Professionals in Rheumatology

Ebby Sigmund
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- Member of: Royal College of Occupational Therapists Specialist Section – Trauma and Musculoskeletal Health; Royal College of Occupational Therapists Specialist Section – Older People; Royal College of Occupational Therapists Specialist Section – Independent Practice; British Association of Hand Therapists; British Society of Rheumatology; Scottish Society of Rheumatology
- Associate with Somek and Associates and The OT Practice
Appendix 2: Acknowledgements

The guideline development group would like to thank all those who have contributed to the development of this practice guideline.

1. **People who access services** reference groups and individuals
   - Arthritis Care Scotland – Maureen McAllister, Joint Working Project Manager
   - Arthritis Care Northern Ireland
   - Patient Representative Group (North Bristol NHS Trust)
   - Managed Clinical Network Patient Engagement Group (Greater Glasgow and Clyde Health Board)

   Five individuals (**experts who access services**) responded to the draft guideline consultation:
   - Miss Wendy Spencer
   - Mr William McGinn, Patient and Carer Forum Member
   - Three people who preferred to remain anonymous

2. **Stakeholders**
   - Jill Firth, Consultant Nurse in Rheumatology, Pennine Musculoskeletal Partnership; Honorary Secretary of British Health Professionals in Rheumatology
   - Margaret Hayden, Occupational Therapist specialising in hand therapy, British Association of Hand Therapists
   - Dr Anne McEntegart, Consultant Rheumatologist, Stobhill Hospital, Glasgow; Chair of the Managed Clinical Network in Greater Glasgow and Clyde Health Board
   - Scott McNab, Orthotist, Peacocks Medical Group, British Association of Prosthetists and Orthotists Professional Affairs Committee
   - Dr Joseph McVeigh, Lecturer in Physiotherapy, Ulster University/Chartered Society of Physiotherapy
   - National Rheumatoid Arthritis Society
   - Michaela Stoffer, Head of Degree Programme Occupational Therapy, University of Applied Sciences for Health Professions Upper Austria; Member of the Health Professional Scientific Subcommittee of the European League Against Rheumatism (EULAR); Liaison Officer to EULAR for the Austrian Association for Health Professionals in Rheumatology

3. **External peer reviewers**
   - Dr Jenny Lewis, Senior Clinical Research Occupational Therapist and NIHR Lecturer, Royal National Hospital for Rheumatic Diseases NHS Foundation Trust and University for West of England
   - Dr Margaret McArthur, Honorary Fellow, School of Health Sciences, University of East Anglia, Norwich
Appendix 2: Acknowledgements

- Dr Elaine Morrison, Consultant Physician and Rheumatologist, NHS Greater Glasgow and Clyde
- Karyn Ross, Teaching Fellow, National Centre for Prosthetics and Orthotics, Department of Biomedical Engineering, University of Strathclyde, Glasgow

4. Co-opted critical appraisers

- Naomi Algeo BSc Occupational Therapy, Research Intern, Arthritis Research UK: Centre for Sport, Exercise and Osteoarthritis
- Lisa Newington MSc Physiotherapy, BSc (Hons), Health Education Wessex; Allied Health Professional Research Intern and Clinical Specialist Hand Therapist, London Hand and Wrist Unit
- Mandy Sainty MSc, DipCOT, Research and Development Manager, Royal College of Occupational Therapists
- Caroline Spicka MSc Health and Rehabilitation, OT degree, Occupational Therapist, University Hospitals Trust Southampton
- Dr Elizabeth White PhD, Head of Research and Development, Royal College of Occupational Therapists

5. Occupational therapists and physiotherapists

Eighteen occupational therapists and physiotherapists responded to the draft guideline consultation. Those who wished to be acknowledged are listed below:

- Kirsty Bancroft, Hand Occupational Therapist, Poole Hospital NHS Foundation Trust
- Bridget Ellis, Clinical Specialist Physiotherapist – Hand Therapy, Poole Hospital NHS Foundation Trust
- Janet Harkess, Head Occupational Therapist, NHS Fife
- Jo Harness, Advanced OT Practitioner – Rheumatology, Northern Devon Healthcare Trust
- Charlie Laver, Specialist Occupational Therapist, Pennine MSK Partnership Ltd
- Alison Leiper, AHP Coordinator for Rheumatology for Greater Glasgow and Clyde
- Rhoda Mackay, Occupational Therapist, NHS Western Isles
- Christina Macleod, Occupational Therapist, Hampshire Hospital Foundation Trust
- Caroline Mountain, Occupational Therapist, Portsmouth Hospitals NHS Trust
- Lisa Newington, Health Education Wessex, Allied Health Professional Research Intern and Clinical Specialist Hand Therapist, London Hand and Wrist Unit
- Ebby Sigmund, Occupational Therapist, Rheumatology Outpatients, NHS Dumfries and Galloway
- Caroline Spicka, Occupational Therapist, University Hospitals Trust, Southampton
- Nicola Walker, Team Manager/Advanced Clinical Specialist Rheumatology, East Cheshire Trust/Mid Cheshire Hospitals Trust
- Julie Weeks, Freelance Occupational Therapist and Complementary Practitioner

Scope consultation respondents included COTSS-Rheumatology members, and a representative from COTSS-Trauma and Orthopaedics and COTSS-Older People.
6. The guideline development group would additionally like to thank the following:

- The Royal College of Occupational Therapists Library Service
- The Royal College of Occupational Therapists' Practice Publications Group and supporting Officers Julia Roberts, Quality Programme Manager, and Tessa Fincham, Publications Manager
- Shona MacNeilage, NHS Library Manager, Greater Glasgow and Clyde Health Board
Appendix 3: Conflicts of interest declarations

Declarations were made in line with the conflict of interest procedures (section 9.6), as follows:

- All members of the core guideline development group and five members of the guideline review group were members of the Royal College of Occupational Therapists Specialist Section-Musculoskeletal Health.

- Three members of the guideline development group and one co-opted critical appraiser were authors or co-authors of evidence, or contextual grey literature, included within the guideline. Careful allocation of abstracts and articles for screening and critical appraisal, and the consensus approach taken in the guideline development meetings, meant there was no undue bias from any authorship.

- Two members of the guideline review group identified their roles in research activities.

- The co-opted Editorial Lead in the 1st and 2nd editions was an Officer of the Royal College of Occupational Therapists.

- Two of the co-opted critical appraisers in the 1st edition were officers of the Royal College of Occupational Therapists. All evidence was appraised by two individuals, and allocations ensured that these officers were ‘paired’ with an appraiser not employed by the College.

- Guideline group members, co-opted critical appraisers, and occupational therapists involved in the consultation activity identified their membership of one or more professional organisations or specialist rheumatology-related fora, which included the Royal College of Occupational Therapists; Royal College of Occupational Therapists Specialist Section-Musculoskeletal Health; British Association of Hand Therapists; Association of Occupational Therapists of Ireland; Scottish Society of Rheumatology; British Health Professionals in Rheumatology; and the Chartered Society of Physiotherapy.

- Stakeholder and peer reviewer declarations included involvement in rheumatology related fora or specialist interest groups, research activities, and authorship of publications pertinent to the guideline topic.

The nature of declarations, made by all those involved in the guideline development, was related to professional interests and expertise in clinical practice, education or research.

There were nil conflicts of interest declared by people who access services, other than personal experience of a rheumatological condition(s).

No commercial or financial interests were declared.

The adherence to the Royal College of Occupational Therapists’ conflicts of interest policy, and the nature and management of the above declarations, together with the robust guideline development methodology, mean that the potential for any bias has been taken into account and mitigated.
Appendix 4: Literature search strategy (1st edition)

Table A1: Search terms and strings

<table>
<thead>
<tr>
<th>Term string set 1: Condition/problem</th>
<th>Term string set 2: Alternative conditions to be searched only with Term string set 1</th>
<th>Term string set 3: Limb-related terms</th>
<th>Term string set 4: Intervention</th>
<th>Term string set 5: Occupational Therapy terms</th>
<th>Term string set 6: Additional terms to narrow specifically for cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>rheumatoid* OR rheumatism OR arthrit* OR osteoarthritis OR psoriatic arthrit* OR inflammatory arthropath* OR degenerative arthropath* OR inflammatory arthrit* OR degenerative arthrit* OR rheumatoid arthrit* OR lupus erythematosus OR joint inflammation</td>
<td>synov* OR trigger finger* OR trigger thumb* OR carpal tunnel syndrome OR dactylitis OR sausage finger* OR swan neck OR Boutonniere OR mallet finger* OR ulnar deviation OR Z-thumb OR Z-thumb OR tendon rupture* OR de Quervain* OR tendinopathy* OR sublux* OR deform*</td>
<td>hand* OR wrist* OR thumb* OR finger* OR digit* OR carpal* OR metacarpal* OR radiocarpal OR distal radioulnar OR phalangeal OR interphalangeal OR inter-phalangeal OR TFCC OR triangular fibrocartilage complex</td>
<td>splint* OR brace* OR bracing OR thermoplastic* OR lycra OR neoprene OR edema glove* OR edema glove* OR orthos* OR orthotic* OR compression glove* OR isotoner glove* OR prefabricated OR pre-fabricated OR elastic* OR comfortprene OR off the shelf OR off-the-shelf OR wrist wrap* OR thumb wrap* OR wrist cuff* OR oval 8 OR oval-8 OR futuro OR spica</td>
<td>occupational therap* OR physiotherap* OR orthotist* OR physical therapist* OR ergotherapist* OR hand therap*</td>
<td>econom* OR cost* OR financ* OR money OR monies OR saving* OR resource* OR staff*</td>
</tr>
</tbody>
</table>
### Appendix 4: Literature search strategy

#### Table A2: Database search strategy

A title/abstract(descriptor search was undertaken for the various search string combinations.

**Key:**

- Ab  = abstract
- de  = descriptors
- hw  = heading words
- id  = key words
- kw  = keyword
- sh  = subject heading
- su  = subject
- ti  = title

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<thead>
<tr>
<th>Database or platform and search date</th>
<th>Cochrane</th>
<th>EBSCO</th>
<th>Ovid</th>
<th>PubMed</th>
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</thead>
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<td>20/05/14</td>
<td>16/05/14</td>
<td>15/05/14</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Search term strings (below) and fields searched (right)</th>
<th>ti, ab, kw</th>
<th>Ti, AB, SU</th>
<th>ti, ab, de, hw, id, sh</th>
<th>ti, ab</th>
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</thead>
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<tr>
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<td>2</td>
<td>10</td>
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<tr>
<td>Strings: 1 AND 3 AND 4 AND 6</td>
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<td>21</td>
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<tr>
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<td>83</td>
<td>635</td>
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<td>15</td>
<td>98</td>
<td>22</td>
<td>204</td>
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<tr>
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<td>88</td>
<td>599</td>
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<td></td>
<td></td>
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<td>871</td>
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<tr>
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<td>412</td>
<td>96</td>
<td>1317</td>
</tr>
<tr>
<td><strong>Total for cleansing/screening</strong></td>
<td>184</td>
<td>459</td>
<td>143</td>
<td>421</td>
</tr>
</tbody>
</table>

*These broad searches were not used as a default during searching as too many non-relevant results would have been returned, but were used for the Cochrane Database results.

MEDLINE, CINAHL – accessed via EBSCOHOST platform
AMED, HMIC, PsycINFO, Social Policy and Practice – accessed via Ovid platform
## Table A3: Specialist searches

<table>
<thead>
<tr>
<th>Database or platform</th>
<th>Fields</th>
<th>Terms</th>
<th>Number retrieved</th>
<th>Date of search</th>
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<td>ti OR su</td>
<td>String 4 – intervention terms</td>
<td>39</td>
<td>21/05/14</td>
</tr>
<tr>
<td>OTseeker</td>
<td>ti AND kw</td>
<td>Individual terms from: String 4 [ti] AND (string 1 [kw] OR string 2 [kw] OR string 3 [kw] OR (string 5 [kw] OR string 6 [kw])) String 5 [ti]</td>
<td>158</td>
<td>16/05/14</td>
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<tr>
<td>OTDBASE</td>
<td>Topic search and subtopic terms ti</td>
<td>• Orthotics (AND terms finger; hand; wrist; arm; theory/research) • Physical condition (AND terms arthritis; finger) • Hands (AND function; theory/research; –therapy) String 4 – individual terms [ti]</td>
<td>408</td>
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<td>ProQuest</td>
<td>ti OR su</td>
<td>String 4 – intervention individual term searches</td>
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<td>10/06/14</td>
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<tr>
<td>Ethos</td>
<td>ti OR secondary title fields</td>
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<td>66</td>
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<td>String 4 – intervention terms and browsing of identified sites String 3 – limb-related terms and browsing of identified sites</td>
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<td>30/04/14</td>
</tr>
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</table>
Appendix 5: Literature search strategy (2nd edition)

Table A4: Monitoring search and full review search terms and strings

For the monitoring searches, Ovid was searched in the descriptor / subject heading, while EBSCO was searched in the title, abstract and subject.

For the full review search, Ovid and EBSCO platform terms were searched in title, descriptor / subject heading fields and abstract.

<table>
<thead>
<tr>
<th>Term string set 1: Condition/problem</th>
<th>Term string set 2: Alt conditions to be searched only with Term string set 1</th>
<th>Term string set 3: Limb related terms</th>
<th>Term string set 4: Intervention</th>
<th>Term string set 5: Occupational Therapy terms</th>
<th>Term string set 6: Additional terms to narrow specifically for cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rheumato* OR Rheumatism OR Arthritis* OR Osteoarthritis* OR Psoriatic arthritis* OR Inflammatory arthropathy* OR Degenerative arthropathy* OR Inflammatory arthrit* OR Degenerative arthrit* OR Rheumatoid arthrit* OR Lupus erythematosus OR Joint inflammation</td>
<td>Synov* OR Trigger finger* OR Trigger thumb* OR Carpal tunnel syndrome OR Dactylitis OR Sausage finger* OR Swan neck OR Boutonniere OR Mallet finger* OR Ulnar deviation OR Z thumb OR Z thumb OR Tendon rupture* OR De Quervain* OR Tendinopathy* OR Sublux* OR deform*</td>
<td>Hand* OR Wrist* OR Thumb* OR Finger* OR Digit* OR Carpal* OR Metacarpal* OR Radiocarpal OR Distal radioulnar OR Phalangeal OR Interphalangeal OR TFCC OR Triangular fibrocartilage complex</td>
<td>Splint* OR Brace* OR Bracing OR Thermoplastic OR Lyra OR Neoprene OR Oedema glove* OR Edema glove* OR Orthos* OR Orthotic* OR Compression glove* OR Isotoner glove* OR Prefabricated OR Pre-fabricated OR Elastic* OR Comfortprene OR Off the shelf OR Off-the-shelf OR Wrist wrap* OR Thumb wrap* OR Wrist cuff* OR Oval 8 OR Oval-8 OR Futuro OR Spica</td>
<td>Occupational therap* OR Physiotherap* OR Orthotist* OR Physical therapist* OR Ergotherapist* OR Hand therap*</td>
<td>econom* OR cost* OR financ* OR Money OR Monies OR Saving* OR Resource* OR Staff*</td>
</tr>
</tbody>
</table>
Tables A5 and A6: Monitoring search strategy

The following table shows EBSCO (Medline, CINAHL) and Ovid (AM ED, HMIC, PsycINFO, Social Policy and Practice) platform searches from monitoring searches, which covered the periods from 2014-2017. The first monitoring search (2015-2016) replicated the 1st edition full guideline search, while the second set of monitoring searches (from 2016) used a condensed approach to ensure no studies were published that required an immediate change to the recommendations. A full review search, which covered the period from 2014-2018, replicated the 1st edition guideline literature search.

Table A5: Monitoring search (2015-2016)

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<th>Search strings</th>
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<tr>
<td>1 AND 3 AND 4</td>
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<td>Total</td>
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</tbody>
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Table A6: Monthly monitoring searches (from 2016)

<table>
<thead>
<tr>
<th>Search strings</th>
<th>Ebsco – monthly from 2016</th>
<th>Ovid – monthly from 2016</th>
</tr>
</thead>
<tbody>
<tr>
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<tr>
<td>Total</td>
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<td>2</td>
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</tbody>
</table>

Tables A7 and A8: Full review search strategy

Tables A7 and A8 show the search strings and platforms/databases used in the full review search, which covered the period from 2014-2018 and replicated the original 1st edition guideline literature search.

Medline and CINAHL were accessed via the EBSCO platform while AMED, HMIC, PsycINFO, Social Policy and Practice were accessed via Ovid.
### Table A7: Full review search - Database searches

<table>
<thead>
<tr>
<th>Search strings (below) and fields searched (right)</th>
<th>Platform and search date</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
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<td>Cochrane - 01.10.18 and 03.10.18</td>
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<td>Ovid – 01.10.18</td>
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<td>1 AND 2 AND 3 AND 4</td>
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<td>(1 AND 4) OR (2 AND 4) OR (4 AND 5)*</td>
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<td><strong>Total</strong></td>
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<td><strong>230</strong></td>
<td><strong>48</strong></td>
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</tbody>
</table>

* These broad searches were not used as a default as too many non-relevant results would have been returned across all databases, but were used for searching the Cochrane Database.
<table>
<thead>
<tr>
<th>Database or platform</th>
<th>Fields</th>
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<th>Number retrieved</th>
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<td>Title or subject</td>
<td>String 4 – intervention terms</td>
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<td>OTseeker</td>
<td>Title, abstract, keywords</td>
<td>Individual terms from: Strings 2, 3, 4, and 5</td>
<td>218</td>
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</table>
| OTDBASE             | Topic search and title | • Orthotics (AND terms finger; hand; wrist; arm; theory/research)  
• Physical condition (AND terms arthritis; finger)  
• Hands (AND function; theory/research; –therapy)  
String 4 – individual terms in title | 94 | 04.10.18 |
| RCOT newsletters    | All fields | String 4 – intervention individual search terms | 6 | 04.10.18 |
| UK National PhD Theses | Title | String 4 – intervention individual term searches  
String 1 – condition individual term searches (Rheumatoid arthritis, rheumatism OR rheumatological, arthritis) | 5 | 05.10.18 |
| Handsearch of the RCOT library catalogue | All fields | Terms from strings 1, 3, 4 | 7 | 03.10.18 |
| NHS EED             | Title | String 4 | 49 | 03.10.18 |
| Medicines and Healthcare products Regulatory Agency | Keywords | String 4 | 2 | 08.10.18 |
| Websites            | N/A | String 4, and Strings 3 and 4 for NIHR website | 65 | 05.10.18 |
# Appendix 6: Evidence tables

<table>
<thead>
<tr>
<th>Source</th>
<th>Design and participants</th>
<th>Intervention</th>
<th>Outcomes</th>
<th>Results</th>
<th>Quality and comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aebischer et al (2016)</td>
<td>Systematic review Aim: to review the evidence on the effectiveness of physiotherapy and occupational therapy on pain, function and quality of life Inclusion: randomised and quasi-randomised controlled trials (RCTs), systematic reviews, observational, pragmatic and case control studies in English, German, French or Dutch, participants had diagnosis of primary trapeziometacarpal osteoarthritis (TMC OA) Exclusion: studies with participants under 18 years old, not having physiotherapy or occupational therapy interventions No date limitations 27 studies included 10 RCTs 7 parallel group studies 5 cross-sectional design studies 3 observational studies 2 retrospective studies</td>
<td>Splints Exercise Multimodal Interventions Joint protection Laser Acupuncture Nettle sting Neurodynamic mobilisation Manual therapy</td>
<td>Pain Function No studies examined quality of life</td>
<td>Narrative analysis showed the following: Pain reduction seen in 26 studies, with all splints effective regardless of make or design Function improved in 24 studies. One study using a custom-made thermoplastic splint and one using long custom-made thermoplastic splint did not show function improvement Interventions that included exercises with or without splints, multimodal intervention and nettle sting improved both outcomes. Joint protection, neurodynamic mobilisation, manual therapy and acupuncture improved pain. Laser did not improve pain</td>
<td>Grade B - Moderate Downgraded due to: Most studies were of poor quality and heterogeneity was high across studies Comments: Data were missing or contradictory to conclusions in some studies and there were indications of reporting bias in some Elevate risk of bias in the studies means results should be interpreted conservatively Meta-analysis was conducted where studies had enough homogeneity in key factors Limitations included not systematically searching for unpublished trials and language restrictions</td>
</tr>
<tr>
<td>Source</td>
<td>Design and participants</td>
<td>Intervention</td>
<td>Outcomes</td>
<td>Results</td>
<td>Quality and comment</td>
</tr>
<tr>
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</tbody>
</table>
| Adams et al (2008) | Randomised controlled trial | Intervention group: static resting splint plus standard occupational therapy intervention<br>Static resting splint of low temperature thermostatic:
Forearm pronation position
Wrist neutral
MCP flexion maximum 60°
IP flexion 30°
Thumb mid position, palmar abducted<br>Control group: standard occupational therapy intervention<br>Written and verbal instruction given regarding wearing times and care of splint<br>Advised to wear during day when resting and when hands are warm, red, tender or swollen, increasing wear by 15 minutes a day. Alternative night wear encouraged to start. Follow-up telephone calls made at 1 week and 1 month by occupational therapist<br>Standardised occupational therapy intervention: 1:1 education and practice of joint protection plus hand and wrist exercises with provision of written booklets, ADL assessment, provision of assistive devices as required, plus provision of other wrist or hand splints as indicated. | Measures taken at baseline prior to randomisation and at 12 months<br>Primary outcome: Grip strength – MIE digital grip analyser<br>Secondary outcomes: Structural impairment summary scores of the dominant hand MCP ulnar deviation deformity (goniometry readings)<br>Hand function – applied dexterity test (button board) from the Arthritis Hand Function Test<br>Michigan Hand Outcomes Questionnaire (MHO) – self-report pain and stiffness using 5-point rating scale for pain, and a 6-point scale for early morning wrist and hand joint stiffness<br>Compliance – 7-point ordinal questionnaire for estimated hours splint worn per week<br>Perceived effectiveness – 5-point ordinal scale (where 1 = not at all and 5 = very). | Analysis included 56 in intervention group and 60 in control group<br>Adherence to splint wear was self-reported and moderate. Ranged from 12 participants (24%) who never wore splint to 12 (24.5%) who wore splint >48 hours/week<br>47 (84%) participants perceived splint to be effective; 12 (25.5%) viewed not effective at all<br>Grip: no significant difference in grip strength data between groups or in percentage of change over 12 months<br>Ulnar deformity: no significant differences between groups detected<br>Pain: over 12-month follow-up, ordinal pain levels showed no significant differences. Both groups had identical final pain levels<br>Hand stiffness: splint appeared to contribute towards reducing early morning stiffness; however, where participants reported early morning stiffness still present after 12 months, the control group showed duration was significantly lower<br>Control group improved in almost all outcomes compared to intervention group<br>Use of a resting splint in early RA did not show improvement in grip, pain, function or deformity of the hand. | Grade B – Moderate<br>Downgraded from A due to limitations:<br>• Cannot say that further research is unlikely to change confidence in the treatment effect size and direction<br>Comments:<br>• Targeted participants with early RA – may have been too early for participants to have adjusted to diagnosis and be ready to commit to self-management behaviours, e.g. wearing splints<br>• Follow-up at 12 months may be too short to show some longer-term beneficial effects, and lack of follow-up before 12 months may have failed to capture immediate or short-term effects<br>• Unexplained discrepancy between high level of participant-perceived effectiveness in those who wore splints and objective outcome measures<br>• Design of splint used in trial ‘followed a moderate intrinsic plus position’<br>• Results of effectiveness may be confounded by compliance. |
<table>
<thead>
<tr>
<th>Source</th>
<th>Design and participants</th>
<th>Intervention</th>
<th>Outcomes</th>
<th>Results</th>
<th>Quality and comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almeida et al (2017)</td>
<td>Literature review</td>
<td>8 randomised controlled trials (RCTs) and 6 controlled clinical trials</td>
<td>All evaluated hand function (via the Disabilities of the Arm, Shoulder and Hand [DASH, 6 studies], other standardised questionnaire [6 studies], and questionnaire written by authors [2 studies]) and pain (via visual analogue scale [11 studies], numeric rate scale [2 studies], Australian/Canadian Hand Osteoarthritis Index [1 study], Pain Anxiety Symptoms Scale [1 study] and Pain Catastrophizing Scale [1 study])</td>
<td>12 studies showed significant improvement in hand function</td>
<td>Grade B - Moderate</td>
</tr>
<tr>
<td></td>
<td>Aim: to understand impact of different thumb orthosis designs on pain, hand strength and hand function on people with carpometacarpal osteoarthritis (CMC OA)</td>
<td>7 examined only custom-made orthosis, 5 compared custom-made with prefabricated models, and 2 look at off-the-shelf orthotics</td>
<td>9 evaluated hand grasp and 14 evaluated pinch strength (both via the JAMAR and/or pinch gauge dynamometers [9 studies], Grippit Electronic Instrument [2 studies], Greenleaf Solo System Pinchmeter [2 studies], non-described electronic dynamometer [1 study])</td>
<td>1 study showed better hand function results with a pre-fabricated, hand-based neoprene orthosis compared to a custom-made, thermoplastic one, 2 studies showed better results with short, hand-based orthosis compared to a long, forearm-based one, and 1 study showed better results with a soft orthosis compared to a rigid one</td>
<td></td>
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<tr>
<td></td>
<td>Inclusion: use of orthotics on people aged 18 and older with diagnosed thumb CMC OA, reported at least one functional outcome via a standardised assessment, had a description of the chosen orthotic design, published in English</td>
<td>5 RCTs had control groups with alternative treatments or no treatment, while 3 RCTs and 4 clinical controlled trials had 2 or more orthoses in independent groups, and 2 studies had different orthoses in the same group at different times</td>
<td>Orthotic use ranged from 7.7 to 13 hours a day, with total duration ranging from 2 weeks to 12 months</td>
<td>12 studies found orthoses significantly decreased pain at the CMC joint, 1 did not and 1 study did not report a comparison</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exclusion: studies reporting on people who underwent surgery</td>
<td>Wearing instructions varied across studies</td>
<td>Orthotic design comparisons were inconclusive: 4 studies did not show significant differences in pain modification</td>
<td>Orthotic design comparisons were inconclusive: 2 found better results with hand-based, custom-made designs only involving the CMC joint compared to a prefabricated, neoprene orthosis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>14 studies</td>
<td></td>
<td>1 study showed less pain with a pre-fabricated, neoprene orthosis compared to a rigid thermoplastic design</td>
<td>1 study showed less pain with a pre-fabricated, neoprene orthosis compared to a rigid thermoplastic design</td>
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<td></td>
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<td></td>
<td>7 studies reported improvements in hand grip and pinch strength while 6 showed no difference and 1 showed a decrease in strength</td>
<td>7 studies reported improvements in hand grip and pinch strength while 6 showed no difference and 1 showed a decrease in strength</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Wearing instructions did not influence functional outcome</td>
<td>Wearing instructions did not influence functional outcome</td>
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<td></td>
<td>Comments:</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Authors suggest short, hand-based orthoses providing adequate stabilisation to the CMC without immobilising adjacent joints may best reduce pain</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Limitations include only including studies published in English and not evaluating the quality of each study.</td>
<td></td>
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</tr>
<tr>
<td>Source</td>
<td>Design and participants</td>
<td>Intervention</td>
<td>Outcomes</td>
<td>Results</td>
<td>Quality and comment</td>
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</tr>
<tr>
<td>Bani et al (2014)</td>
<td>Cohort study</td>
<td>Custom-made short neoprene thumb CMCJ orthosis fabricated with neoprene material reinforced with a thermoplastic component formed in a ‘U’ shape around the CMCJ for stabilisation of the joint</td>
<td>Measures completed at baseline, 30, 60 and 90 days</td>
<td>Mean orthosis use: 7.9 hours per day</td>
<td>Grade C – Low</td>
</tr>
<tr>
<td></td>
<td>Aim: to analyse the effect of a custom-made neoprene thumb carpometacarpal orthosis with thermoplastic stabilisation on pain, function, grip strength and key pinch</td>
<td>Thermoelastic splint reinforced with a thermoplastic component formed in a ‘U’ shape around the CMCJ for stabilisation of the joint</td>
<td>Pain: VAS (100 mm)</td>
<td>Pain: decrease observed after 30 days (p&lt;0.003), and continued to improve during treatment with the splint (at 90 days p&lt;0.001)</td>
<td>Comment:</td>
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<tr>
<td></td>
<td>Mild to moderate OA of carpometacarpal (CMC) joints of the thumb (Grade 1 or Grade 2) with joint pain</td>
<td>Wrist and MCP joints left free</td>
<td>Function: Disability of the Arm, Shoulder and Hand (DASH) questionnaire</td>
<td>Function: DASH scores significantly improved between baseline and each of the 30-, 60- and 90-day periods (at 90 days p&lt;0.001)</td>
<td>• Undeclared sampling methods – no information provided on recruitment, therefore unable to make a judgement as to representation and inclusion</td>
</tr>
<tr>
<td></td>
<td>Inclusion: no deformity of affected hand, no previous surgery or injection during preceding 6 months, no allergy to splint materials</td>
<td>Participants were instructed to use orthosis when they experienced symptoms and for ADLs</td>
<td>Grip and pinch strength: Jamar® Hydraulic Dynamometer and pinch gauge – average of three scores</td>
<td>Grip and pinch strength: after 90 days of using the splint, grip strength and pinch strength were improved compared to baseline (p&lt;0.001)</td>
<td>• Small sample size</td>
</tr>
<tr>
<td></td>
<td>Exclusion: other disease that might cause similar pain (such as carpal tunnel syndrome (CTS), De Quervain’s syndrome, Dupuytren’s contracture, arthritis, or fifth/sixth cervical disk herniation), no pain or stiffness in the shoulders or glenohumeral joint</td>
<td>Orthosis used for maximum of 3 months</td>
<td>Pain, function and pinch strength maintained significant differences between 30 and 60 days, and between 60 and 90 days. Although it was initially improved, no significant difference was demonstrated for grip strength for the duration of the use of the orthosis.</td>
<td></td>
<td>• No control group</td>
</tr>
<tr>
<td></td>
<td>11 participants</td>
<td></td>
<td></td>
<td></td>
<td>• No hand function assessment</td>
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<tr>
<td></td>
<td>Male: female ratio = 2:9</td>
<td></td>
<td></td>
<td></td>
<td>• Limited statistical analysis of results</td>
</tr>
<tr>
<td></td>
<td>Mean age = 55.35 years Iran.</td>
<td></td>
<td></td>
<td></td>
<td>• No reference to grade of OA for each participant – could this affect levels of pain, grip strength, level of function?</td>
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<tr>
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<td>• Specific wearing regimen not outlined (e.g. for how long, how often)</td>
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<td></td>
<td>• No discussion of how they measured splint use over the study period, e.g. splint diary</td>
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<tr>
<td></td>
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<td></td>
<td>• Neither subjects nor assessor blinded – unable to, as only one cohort and subjects knew they were using the splint</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td>• Did not look at any harmful effects/contraindications</td>
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<tr>
<td></td>
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<td></td>
<td></td>
<td>• No mention of any other interventions during this period which may have affected outcomes</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td>• No reference to compliance, comfort, feedback on splint from participants.</td>
</tr>
<tr>
<td>Source</td>
<td>Design and participants</td>
<td>Intervention</td>
<td>Outcomes</td>
<td>Results</td>
<td>Quality and comment</td>
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<tr>
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</tr>
<tr>
<td>Bani et al. (2013a)</td>
<td>Cohort repeated measure study</td>
<td>Splint to stabilise the first CMC joint, maintain pulp of distal phalange of index finger free for gripping with other fingers, leave thumb in functional position</td>
<td>Measures completed at baseline, 30, 60 and 90 days</td>
<td>Pain: reduced at 30 days (p&lt;0.001), and continued to reduce at 60 days (p&lt;0.001) and 90 days (p&lt;0.001) compared with baseline</td>
<td>Grade C – Low</td>
</tr>
<tr>
<td></td>
<td>Aim: evaluation of the effect of custom-made splint for the thumb (OA first metacarpal joint) on pain, grip, strength and key pinch</td>
<td>Custom-made, low temperature mouldable thermoplastic material (1.6 mm thickness, inside lined with Plastazote 1.6 mm) Use during routine ADL; remove to sleep, bath, exposure to heat, etc</td>
<td>Pain: VAS (10 cm)</td>
<td>Function: improved at 30 days (p&lt;0.001), and DASH score continued to reduce at 60 days (p&lt;0.001) and 90 days (p&lt;0.001) compared with baseline</td>
<td>Comments:</td>
</tr>
<tr>
<td></td>
<td>Referrals to Orthotics and Prosthetics department</td>
<td></td>
<td></td>
<td>Grip strength: Jamar® dynamometer</td>
<td>• No control</td>
</tr>
<tr>
<td></td>
<td>Inclusion: clinical and radiological diagnosis of thumb carpometacarpal joint, OA Grade 1 and 2, with pain in the base of the thumb</td>
<td>Lateral pinch: Jamar® pinch gauge.</td>
<td>Grip strength: significant difference compared to baseline after 60 days but not at 30 days</td>
<td>Pinch strength: demonstrated significant improvement at all timelines compared with baseline</td>
<td>• Small sample size with no power calculation related to selection of assessments</td>
</tr>
<tr>
<td></td>
<td>Exclusion: other deformities of the affected hand; deformities of the distal interphalangeal joint of the thumb; use of a splint on the affected thumb during the previous 6 months; surgery on the studied hand during the previous 6 months; potential allergy to the splint material; an inability to respond to a questionnaire due to communication difficulties or to perform the tests; evidence of injection therapy in the studied hand in the previous 6 months; presence of additional disease affecting the ipsilateral upper limb (e.g. carpal tunnel syndrome, De Quervain’s tenosynovitis, Dupuytren’s contracture, arthritis, and fifth and sixth cervical vertebral disk herniation)</td>
<td></td>
<td>Improvement in pain scores 30 days post wearing of splint and continuous improvement throughout measurement period</td>
<td>Grip, pinch and function all improved after 90 days of wearing of orthosis.</td>
<td>• Irregular presentation of results in tables (p&lt;0.000) compared to text (p&lt;0.001)</td>
</tr>
<tr>
<td></td>
<td>18 participants Male: female ratio = 3:1</td>
<td></td>
<td></td>
<td></td>
<td>• No loss to follow-up or data in a study is unusual, but possible with small sample size</td>
</tr>
<tr>
<td></td>
<td>Mean age = 56.06 years Iran</td>
<td></td>
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<td></td>
<td>• Volunteers and no description of how this may affect characteristics</td>
</tr>
<tr>
<td></td>
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<td>• Highly customised splint design, which would be difficult to replicate.</td>
</tr>
</tbody>
</table>
### Appendix 5: Evidence tables

<table>
<thead>
<tr>
<th>Source</th>
<th>Design and participants</th>
<th>Intervention</th>
<th>Outcomes</th>
<th>Results</th>
<th>Quality and comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bani et al (2013b)</td>
<td>Randomised controlled trial</td>
<td>Intervention group: splint to stabilise the first CMC joint, maintain pulp of distal phalange of index finger free for gripping with other fingers, leave thumb in functional position</td>
<td></td>
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<tr>
<td></td>
<td>Aim: to compare the effect of prefabricated and custom-made thumb splints on pain, function, grip strength and key pinch in basilar joint OA</td>
<td>Intervention splint 1: prefabricated thumb CMC splint (covered first CMC and metacarpophalangeal joints allowing full range of motion in other fingers, material thickness 3.5 mm)</td>
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<td></td>
<td>Recruitment from Tehran Orthotics and Prosthetics department, referred by orthopaedic surgeon. Assigned randomly to 3 groups—cross-over study with a control group</td>
<td>Intervention splint 2: custom-made CMC thumb splint (low temperature moulding material, 1.6 mm thickness, inside lined with Plastazote 1.6 mm)</td>
<td>Measured at baseline and 4, 6 and 10 weeks</td>
<td>Pain: significantly reduced (p&lt;0.000) at end of week 4, whether wearing prefabricated splint or custom-made splint. Prefabricated splint and the custom-made splint both significantly reduced pain compared to the control group at the end of the tenth week (both p&lt;0.000)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Inclusion: clinical and radiological diagnosis of OA Grade 1 and 2 first CMC joint, evidence of pain in the base of the thumb</td>
<td>Use during routine ADL: remove to sleep, bath, exposure to heat, etc. One splint was worn for 4 weeks, followed by a two-week washout period, and then the 2nd type of splint was worn for 4 weeks</td>
<td>Function: Disability of the Arm, Shoulder and Hand (DASH) Grip strength: Jamar® dynamometer Lateral pinch: Jamar® pinch gauge</td>
<td>Comparing the two splints, significant differences were noted in pain levels (p=0.024) at 10 weeks: a better performance in pain reduction was reported for the custom-made splint at the end of the study period</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exclusion: other hand deformities of the affected hand; deformity of thumb IP joint; use of a splint on the thumb during the previous 6 months; evidence of surgery on the studied hand in the previous 6 months; allergy to the splint material; inability to respond to a questionnaire or to perform the functional tests; evidence of injection therapy in the studied hand during the previous 6 months; evidence of other disease affecting the thumb or wrist</td>
<td>Control group: Follow-up period of 10 weeks</td>
<td>Function: at the end of week 4, prefabricated splint demonstrated increase in DASH score (p=0.018) but custom-made splint had no significant improvement compared to control group. Both splints significantly increased function at end of tenth week (p&lt;0.000) compared to control group. No significant difference between two splints identified</td>
<td>Grip strength: positive effect from both splints but neither demonstrated significant improvement at end of 4 weeks or end of 10 weeks, and no significant difference between the two splints</td>
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<tr>
<td></td>
<td>35 volunteer participants (11 in control group and 12 in each of the other intervention groups)</td>
<td>Male: female ratio per group: • Prefabricated splint = 4:8 • Custom = 3:9 • Control = 3:8</td>
<td>Pain: significantly reduced (p&lt;0.000) at end of 4 weeks for both prefabricated (p&lt;0.000) and custom-made splint (p&lt;0.001), and also at end of 10 weeks (both p&lt;0.000). No significant difference determined between the two splints</td>
<td>Pinch: increased at end of 4 weeks for both prefabricated (p&lt;0.000) and custom-made splint (p&lt;0.001), and also at end of 10 weeks (both p&lt;0.000). No significant difference determined between the two splints</td>
<td></td>
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<td></td>
<td>Age range average per group: • Prefabricated splint – 53.42 years • Custom – 54.91 years • Control – 58.64 years</td>
<td>Pain: significantly reduced (p&lt;0.000) at end of 4 weeks, whether wearing prefabricated splint or custom-made splint. Prefabricated splint and the custom-made splint both significantly reduced pain compared to the control group at the end of the tenth week (both p&lt;0.000)</td>
<td>In the control group, pain increased and pinch strength decreased, but no statistically significant differences were found in function and grip strength</td>
<td>The prefabricated and custom-made splints both reduced pain, with the custom-made splinting being more effective. Function and pinch strength also increased, but grip strength was not improved.</td>
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<td></td>
<td>Iran.</td>
<td>Control group: Follow-up period of 10 weeks</td>
<td>Pain: significantly reduced (p&lt;0.000) at end of 4 weeks, whether wearing prefabricated splint or custom-made splint. Prefabricated splint and the custom-made splint both significantly reduced pain compared to the control group at the end of the tenth week (both p&lt;0.000)</td>
<td></td>
<td>Grade A – High</td>
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<td>Ongoing care during the intervention period was the same in all groups. Therapists were given ample time to cut and fit the splints to the participants. The splints were not weighed, as the prefabricated splint is made of low-density material. No carryover effects were observed.</td>
<td></td>
<td>Comments: • Cross-over design – issues around carryover effects • No sample size calculation • Small study • Limited follow-up period • Limited details of the splints • No reports on any harmful effects • No costing given re splint, therapist time • No blinding – participants or therapists or evaluator.</td>
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<tr>
<td>Becker et al (2013)</td>
<td>Randomised controlled trial</td>
<td>Splint provided by an occupational therapist</td>
<td>Measures at baseline, and the majority also at 5–15 weeks</td>
<td>62 completed the study: 32 neoprene splint and 30 thermoplastic splint</td>
<td>Grade B – Moderate</td>
</tr>
<tr>
<td></td>
<td>Aim: to compare two splints for trapeziometacarpal arthrosis; a neoprene and a thermoplastic hand-based thumb spica splint</td>
<td>Splint 1: prefabricated neoprene Comfort Cool™ Thumb CMC Restriction Splint (North Coast Medical)</td>
<td>Primary outcome</td>
<td>51 participants did not return for the second visit and 6 did not complete the protocol for other reasons</td>
<td>Downgraded from A due to limitations:</td>
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<td>Null hypothesis: no difference in arm-specific disability 5–15 weeks after prescription of a prefabricated neoprene splint or a similar custom-made thumb spica made from thermoplastic</td>
<td>Splint 2: customised 3.2 mm thick thermoplastic hand-based thumb spica splint with metacarpophalangeal included and the IP joint and wrist free</td>
<td>Other outcome measures:</td>
<td>Similar improvements seen between the two groups for pain, grip and pinch strength</td>
<td>• Superiority trial – cannot conclude that splints are equivalent, only that there is no evidence that one is better than the other</td>
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<td>Outpatient office of two hand surgeons at a tertiary care hospital</td>
<td>Regimen: wear the splint as needed for pain relief with daily activities and at night if it helped them sleep</td>
<td>• Arm-specific disability – DASH</td>
<td>Average arm-specific function did not change</td>
<td>• Reliance on clinical rather than radiological diagnosis</td>
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<td>Equally randomised (1:1) to wear either splint</td>
<td>Splint adjustments were allowed.</td>
<td>• Pain Anxiety Symptoms Scale (PAS)</td>
<td>There were no detectable differences in DASH score, change in DASH, pain, satisfaction, pinch or grip strength between the two splint types in the sample</td>
<td>• Research assistant not blinded to randomisation</td>
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<td>Inclusion: 18 years or older, clinically diagnosed with trapeziometacarpal arthrosis by the hand surgeon, English-speaking</td>
<td></td>
<td>• Pain Catastrophising Scale (PCS)</td>
<td>Neoprene group rated comfort higher (p=0.048) – this was the only significant difference between the two splints</td>
<td>• Large dropout numbers (n=57)</td>
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<td>Exclusion: history of surgically treated trapeziometacarpal arthrosis</td>
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<td>• Centre for Epidemiological Studies Depression Scale (CES-D)</td>
<td>Satisfaction appeared high</td>
<td>• Some participants received other splints or changed from one type to the other</td>
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<td></td>
<td>119 participants with 62 completing:</td>
<td></td>
<td>• Whiteley Index</td>
<td>Suggestion that prefabricated neoprene thumb spica splints were on average cheaper (but no costs provided), more comfortable and as effective as a custom-made thermoplastic splint.</td>
<td>• DASH scores included even if greater than 3 items missing</td>
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<td>Male: female ratio = 14:48</td>
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<td>• Pinch – B&amp;L Engineering® pinch gauge</td>
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<td>• Three participants completed protocol later than the accepted timeframe</td>
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<td>Mean age (SD) = 63 years (8.1)</td>
<td></td>
<td>• Grip strength – Jamar® dynamometer</td>
<td></td>
<td>• No specific information given on how, when the participants actually used the splints, or if any harmful effects were reported.</td>
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<td></td>
<td>United States of America</td>
<td></td>
<td>• Ordinal Scale for pain – 0 (no pain) to 10 (worst pain you ever had)</td>
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<tr>
<td>Bertozzi et al (2015)</td>
<td>Systematic review</td>
<td>Interventions focused on:</td>
<td>Outcome measures included:</td>
<td>Results for interventions focused on splints included:</td>
<td>Grade B - Moderate</td>
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<td></td>
<td>Aim: to review evidence from randomised controlled trials (RCTs) on the effect of conservative interventions on pain and function in those with thumb carpometacarpal (CMC) osteoarthritis (OA)</td>
<td>Therapeutic exercise (n=4)</td>
<td>Pain (n=16)</td>
<td>Moderate quality evidence (n=3) indicates that splints can improve function at long-term follow-up</td>
<td>Downgraded due to:</td>
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<td>Inclusion: published RCTs with participants diagnosed with CMC OA, symptomatic and 18 years or older using common rehabilitative interventions and assessed at least one primary outcome</td>
<td>Manual therapy (n=4)</td>
<td>Hand strength (n=11)</td>
<td>Low quality evidence (n=2) that splints did not significantly improve function at short-term follow-up</td>
<td>Low quality evidence in regard to splints</td>
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<td></td>
<td>Exclusion: quasi-RCTs, non-randomised trials, evaluations of surgical or pharmacological interventions</td>
<td>Therapeutic exercise and manual therapy (n=1)</td>
<td>Function (n=7)</td>
<td>Low quality evidence (n=2) that splints provide no significant improvement at short- and long-term follow-ups</td>
<td>Comments</td>
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<td></td>
<td>Databases were searched from inception to May 2014</td>
<td>Laser therapy (n=1)</td>
<td>Stiffness (n=6)</td>
<td>Moderate quality evidence (n=2) that splints provide significant improvement in hand strength at short-term follow-up, but low quality evidence (n=2) for significant improvement at long-term follow-up</td>
<td>Much of the evidence was low quality.</td>
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<td>16 studies included.</td>
<td>Magneto therapy (n=1)</td>
<td>Range of motion (n=4)</td>
<td>Low quality evidence (n=1) that splints did not significantly improve range of motion in long-term follow-up</td>
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<td></td>
<td>Splints (n=3)</td>
<td></td>
<td>Low quality evidence (n=1) that splints did not significantly improve range of motion in long-term follow-up</td>
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<td></td>
<td>Multidisciplinary treatment programme (n=1)</td>
<td></td>
<td>Low quality evidence (n=1) that splints did not significantly improve range of motion in long-term follow-up</td>
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<td>Control groups consisted of no treatment, sham protocol, normal activities, placebo and joint protection and education-only programme.</td>
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<td>Low quality evidence (n=1) that splints did not significantly improve range of motion in long-term follow-up</td>
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<td>Aim: to examine the effect of an extended joint protection programme with splint and exercise (SE group) compared with the standard joint protection programme (control group)</td>
<td>Regimen: splints 24 hours per day combined with daily home exercise, as well as the JP programme</td>
<td>• Baseline (1 week before start of the intervention)</td>
<td>Intervention group wearing splint had significant decrease in pain, stiffness and an improvement in daily activities directly after the intervention (p=0.034; p=0.014; p=0.007) and at 1-year follow-up (p=0.012; p=0.012; p=0.003) compared to the control group</td>
<td>Comments:</td>
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<td>Referred by a physician</td>
<td>Night: custom-made thermoplastic forearm splint</td>
<td>Primary outcome</td>
<td>Control group decreased in pain on motion and improved in daily activities just after the intervention, but not at 1-year follow-up in the splint intervention group pain at night, pain on motion, and stiffness decreased. Grip force increased and daily activities improved</td>
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<td>Inclusion: women with either clinically and/or X-ray diagnosed hand OA, who had experienced any kind of pain in the CMC-1 joints, not specified to a certain level of pain, and not been in a JP programme group earlier</td>
<td>Day: prefabricated elastic thumb splint and/or custom-made thermoplastic thumb splint at all times, using a hot pack for 15 minutes before hand exercise at home, carrying out the same hand exercise with paraffin dough as in the JP programme once a day</td>
<td>Secondary outcome:</td>
<td>In the splint intervention group pain at night, pain on motion, and stiffness decreased. Grip force increased and daily activities improved</td>
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<td>Exclusion: women with evidence of RA or any rheumatic disease other than OA, and women with carpal tunnel syndrome</td>
<td>Control group: joint protection programme only</td>
<td>• ADL difficulties – DASH (work and leisure items not used)</td>
<td>Suggests that adding splinting and exercise to a joint protection programme gives greater improvement of pain, stiffness, grip force and daily activities.</td>
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<td>42 participants</td>
<td>All participants received standard joint protection programme provided by occupational therapists. 10 group educational/behavioural sessions over a period of 5 weeks (groups of 4-8 participants), included trying out grip assistive devices and elastic thumb splints during the day at clinic and home. Also included paraffin wax heat treatment and hand exercise with paraffin dough.</td>
<td>Pain and stiffness – VAS (100 mm) for most recent week.</td>
<td>Both groups tried elastic thumb spicas during the day as part of the JP programme.</td>
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<td>Two dropped out, so 20 in each intervention group</td>
<td>Control group:</td>
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<td></td>
<td>All female</td>
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<td>Extended programme and splint group</td>
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<td>Median age (range) = 61 years (40–76)</td>
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<td>Median disease duration (range) = 2 years (1–23)</td>
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<td>Control standard programme group</td>
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<td></td>
<td>Median age (range) = 61 years (50–76)</td>
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<td>Median disease duration (range) = 5 years (1–18)</td>
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<td>Sweden.</td>
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<td>Boer et al (2008)</td>
<td>Multicentre cross-sectional study&lt;br&gt;Aim: to examine possession and usage of functional wrist orthoses in a Dutch population&lt;br&gt;Random selection of participants from outpatient clinics at three rheumatology centres&lt;br&gt;Inclusion: clinical diagnosis of RA according to the 1987 American College of Rheumatology (ACR) criteria from medical records; fluent in Dutch&lt;br&gt;Exclusion: not stated&lt;br&gt;240 participants out of 362 eligible&lt;br&gt;Male: female ratio = 55:185&lt;br&gt;Median age (interquartile range): 63 years (18)&lt;br&gt;Netherlands.</td>
<td>Functional wrist orthoses (custom-made thermoplastic or commercial fabric with steel reinforcement).</td>
<td>Semi-structured interview:&lt;br&gt;- Hand and wrist complaints, ADL, pain, swelling and tingling in the wrist and hand&lt;br&gt;- Possession and prescription process&lt;br&gt;- Usage – category on 8-point scale of never to always&lt;br&gt;- Activities undertaken when wearing the splint (6 categories)&lt;br&gt;- Individual reasons for usage and for non-use&lt;br&gt;Questionnaire and clinical assessment:&lt;br&gt;- Disease characteristics – Dutch Arthritis Impact Measurement Scale II (AIMS II), Disease Activity Score (DAS28), VAS (100 mm) for pain and fatigue&lt;br&gt;- Physical and mental functioning – RAND-36 Health Survey&lt;br&gt;- Coping – Coping with Rheumatic Stressors (CORS)&lt;br&gt;- Participant satisfaction: Dutch version of Quebec User Evaluation of Satisfaction with Assistive Technology (D-QUEST).</td>
<td>128 participants possessed a functional wrist splint&lt;br&gt;58% (n=74) were using the splint&lt;br&gt;54 participants (42%) had not used the orthoses at all&lt;br&gt;Activity use: housekeeping activities (39%), cycling/driving (30%), resting (28%), always (20%), work and leisure activities (varying between 2% and 8%)&lt;br&gt;Rates of prescription varied among three centres but did not reach statistical significance&lt;br&gt;Reasons for use: relief of pain/swelling (n=65/74) and joint protection (n=49/74)&lt;br&gt;Reasons for non-use: no need; problems with ease of use; plus comments on lack of fit or comfort; potential ‘harmful effect’ of a wrist orthosis (not defined)&lt;br&gt;Factors significantly associated with usage included the presence of wrist and hand complaints, worse physical functioning (RAND-36) and greater satisfaction with comfort of the wrist orthoses.</td>
<td>Grade C – Low&lt;br&gt;Comments: Results are convincing due to large effect reported; however, questionnaire design not a recognised and validated source; cultural differences with activities chosen to ask about, e.g. cycling, may not apply to guideline population; 90% of participants had costs reimbursed by insurance company, with significant differences between the three locations; Recruitment bias possible.</td>
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Aim: to compare the short-term effect of 2 thumb orthotic designs on pain and hand function  
Recruitment: referral by orthopaedic hand surgeon to hand therapy clinic  
Inclusion: diagnosis of thumb carpometacarpal osteoarthritis (CMC OA) in the dominant hand and classified as Grade 2 or 3 according to Eaton and Littler radiological staging protocol, had pain intensity during activities of daily living (ADL) >40/100 on the visual analogue scale (VAS)  
Exclusion: neurological disorder affecting the upper limb, received treatment/surgery for hand in past 6 months, received intra-articular joint injection to the wrist, fingers or thumb, exhibited thumb metacarpophalangeal (MCP) hyperextension, scored >4 on the Beck Depression Inventory, >30 in the State Trait Anxiety Inventor, did not complete the Quick Disabilities of the Arm, Shoulder and Hand (QuickDASH) or previously received any type of hand orthosis for this problem  
66 participants  
Male:female ratio=1:4  
Mean age=63.7 years  
Spain. | Randomly allocated into 2 groups  
33 participants fitted with an orthosis where the thermoplastic material included the MCP joint  
33 participants fitted with a CMC joint immobilisation orthosis that does not included the MCP joint  
All orthoses were custom fabricated and participants received identical wearing instructions: use at night and during daytime ADL for 3-4 hours per day  
Participants asked to record treatment adherence and any discomfort  
No other treatment intervention. | Pain (primary outcome) measured by VAS  
Hand function (secondary outcome) measured by QuickDASH  
Both completed 1 day prior to beginning the intervention and 1 week after start of intervention. | Mean pain scores reduced from 77 to 46 in the group whose splint included the MCP joint, and from 77 to 48 in the group whose splint excluded the MCP joint. Both are significant effects (p<0.001), but there are not significant differences between the two.  
Mean QuickDASH scores reduced from 40.2 to 36.1 in the group whose splint included the MCP joint, and from 41.7 to 35.7 in the group excluding the MCP joint. These were significant effects (p<0.001), but not significantly different between groups. | Grade B - Moderate  
Downgraded due to: The sample is small with little information about the participants, who was excluded, randomisation and does not discuss blinding of the assessors. Outcomes measured after only one week of splint wearing. |
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<tr>
<td>Duong et al (2018)</td>
<td>Survey of hand therapists</td>
<td>Survey adapted from one used to assess the management of knee OA by physiotherapists in the United Kingdom.</td>
<td>Survey collected demographics, experience, expertise and attitude and beliefs about exercise and orthosis prescription for base of thumb OA, then presented a case study after which asked about clinical assessment and treatment of hypothetical person.</td>
<td>Three-quarters of respondents had 6+ years of experience in hand therapy. A majority completed postgraduate training in hand therapy and specific training in manufacturing orthoses. 74% said they would refer the person in the case study for radiographs of the first carpometacarpal joint. The most commonly used physical measures were palpitation, range of motion, grind test and pain provoked by opposition of the thumb across the palm. 65% would use questionnaires in their assessment, with the most common being the Disabilities of the Arm, Shoulder, Hand (DASH) and the Patient-Related Wrist and Hand Evaluation (PRWHE). Most common treatments were orthoses (92%), pain education (78%), heat (75%) and exercise therapy (74%). 97% thought pain is reduced by an orthosis, and 11% said they gave everyone the same splint, and 53% said they asked their patients to sleep with their splints on in the first 2 weeks.</td>
<td>Grade D – Very low</td>
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| Egan and Brousseau (2007) | Systematic review | Splinting for CMC OA. | Depending on the study concerned, the outcomes examined included:  
- Subsequent need for surgery  
- Level of pain  
- Compliance with splint wear  
- Restriction on activity during splint use  
- Comparison of different types of splint  
- Reduction of CMC subluxation  
- Pinch strength  
- Participant preference. | Clinical interpretations of the evidence include that splint use appears to:  
- Decrease pain for many participants  
- Reduce subluxation on pinch in participants with early OA, so should be encouraged to wear splints during ADLs that cause subluxation  
- Have no impact on decreasing the eventual need for surgery  
There were no specific indications for splint type selection (e.g. short or long opponens design) so participants’ preference and functional needs are key when discussing splint characteristics.  
An initial period of continual 3–4 weeks of splinting may be beneficial. Splinting can then be according to aggravating ADLs.  
The use of splints during activities promoting CMC subluxation should be encouraged for individuals with Stage I and II OA  
Effectiveness of intervention for pain relief, alongside its conservative nature and low cost, would indicate splint provision is warranted. | Grade B – Moderate  
Downgraded from A due to limitations:  
- Risk of bias due to lack of independent assessment of literature and its inclusion in the review (one reviewer only); a second assessor would have improved validity  
- Brief description only of each study  
- Variety of study designs, four with reasonable methodological quality  
- No information about the limitations of these studies, although it was noted that the researchers’ calculations for pain relief varied from those of the authors for one study  
Comments:  
- All relevant studies were included due to the small number likely to be available in this topic area  
- Comment was made on the design of the studies concerned and none were found to lead to strong evidence. A recommendation was made for a high-quality RCT. |
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<td>Giesen et al (2010) [Cross-reference with Giesen et al 2009]</td>
<td>Qualitative</td>
<td>Two types of splint: Silver ring splint (SRS) and Oval-8® commercially prefabricated thermoplastic splint (PTS) Each splint was worn for 4 weeks, with a two-week washout.</td>
<td>Open-ended questions about perception of hand function problems (at baseline) and reason for choosing splints (at 10 weeks, when the participants had trialled both splints) The International Classification of Functioning, Disability and Health (ICF) was used to help analyse the data into ‘meaning units’ relating to hand function difficulties</td>
<td>Hand function difficulties were identified in seven sub-concepts - Difficulty initiating finger flexion - Painful PIP joint hyperextension - Dislike of appearance - Functional difficulties associated with poor pinch or tripod grip - Large grip - Applying pressure with fingertips - Hand function requiring multiple grips (dexterity) Splint wear/adherence was similar for both splints. Mean (SD) adherence rates: SRS = 15.3 hours per week (7.4) PTS = 15.4 hours per week (7.4) Splint preference: no overall clear preference. After wearing each splint for 4 weeks, 24 participants chose SRS and 21 chose PTS, and 2 were unable to choose between them Positive aspect categories: - Effect (on hand function or pain) - Ease of use - Appearance - Comfort Negative aspect categories: - Side effects - Sharp edges - Sweating - Pain in adjacent finger due to friction - Paraesthesia of splinted fingertip - Splint slipping off - Change of fit during wear The positive and negative aspects of the SRS and PTS demonstrated no distinguishable pattern</td>
<td>Grade D – Very Low Comments: - Participant responses to questions were only handwritten verbatim and not recorded on audio tape for accuracy - No mention of saturation of data - Only the main functional difficulty for each participant was recorded, therefore some data were lost - Authors state recruitment process not based on inclusion of maximum variation of participants, so findings cannot be generalised to all people with RA with swan neck deformities - Assessors not independent, so potential source of bias - Questions asked about positive and negative experiences with either splint. If these had been rephrased in relation to both splints, may have elicited more/different responses.</td>
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<tr>
<td>Giesen et al (2010) [Cross-reference with Giesen et al 2009]</td>
<td>Qualitative&lt;br&gt; Aim: identification of problems people had with hand function due to the deformity and the reasons for selecting particular types of splints&lt;br&gt; Qualitative study carried out adjunct to a randomised cross-over trial comparing silver ring and Oval-8® finger splints&lt;br&gt; Multicentre study carried out in three rheumatology outpatient clinics&lt;br&gt; Consecutively selected and included in a randomised cross-over trial&lt;br&gt; Inclusion: RA; mobile swan neck deformity manually correctable to ≥45° of PIP flexion of index and/or middle finger; stable disease activity; no corticosteroid injection for previous 3 months; no planned surgery; no treatment with swan neck splints in past&lt;br&gt; Exclusion: condition other than RA or other severe finger deformities interfering with hand function or use of finger splints&lt;br&gt; 50 participants&lt;br&gt; Male: female ratio = 9:41&lt;br&gt; Median age (SD) = 53.8 years (21.6)&lt;br&gt; Mean disease duration (SD) = 13.7 years (11.5)&lt;br&gt; Netherlands.</td>
<td>Two types of splint:&lt;br&gt; Silver ring splint (SRS) and Oval-8® commercially prefabricated thermoplastic splint (PTS)&lt;br&gt; Each splint was worn for 4 weeks, with a two-week washout.</td>
<td>Open-ended questions about perception of hand function problems (at baseline) and reason for choosing splints (at 10 weeks, when the participants had trialled both splints)&lt;br&gt; The International Classification of Functioning, Disability and Health (ICF) was used to help analyse the data into ‘meaning units’ relating to hand function difficulties</td>
<td>Hand function difficulties were identified in seven sub-concepts&lt;br&gt; • Difficulty initiating finger flexion&lt;br&gt; • Painful PIP joint hyperextension&lt;br&gt; • Dislike of appearance&lt;br&gt; • Functional difficulties associated with poor pinch or tripod grip&lt;br&gt; • Large grip&lt;br&gt; • Applying pressure with fingertips&lt;br&gt; • Hand function requiring multiple grips (dexterity)&lt;br&gt; Splint wear/adherence was similar for both splints; Mean (SD) adherence rates SRS – 15.3 hours per week (7.4) PTS – 15.4 hours per week (7.4)&lt;br&gt; Splint preference: no overall clear preference. After wearing each splint for 4 weeks, 24 participants chose SRS and 21 chose PTS, and 2 were unable to choose between them&lt;br&gt; Positive aspect categories:• Effect (on hand function or pain)&lt;br&gt; • Ease of use&lt;br&gt; • Appearance&lt;br&gt; • Comfort&lt;br&gt; Negative aspect categories:• Side effects&lt;br&gt; • Sharp edges&lt;br&gt; • Sweating&lt;br&gt; • Pain in adjacent finger due to friction&lt;br&gt; • Paraesthesia of splinted fingertip&lt;br&gt; • Splint slipping off&lt;br&gt; • Change of fit during wear&lt;br&gt; The positive and negative aspects of the SRS and PTS demonstrated no distinguishable pattern.</td>
<td>Grade D – Very Low&lt;br&gt; Comments: Participant responses to questions were only handwritten verbatim and not recorded on audio tape for accuracy&lt;br&gt; • No mention of saturation of data&lt;br&gt; • Only the main functional difficulty for each participant was recorded, therefore some data were lost&lt;br&gt; • Authors state recruitment process not based on inclusion of maximum variation of participants, so findings cannot be generalised to all people with RA with swan neck deformities&lt;br&gt; • Assessors not independent, so potential source of bias&lt;br&gt; • Questions asked about positive and negative experiences with either splint. If these had been rephrased in relation to both splints, may have elicited more/different responses.</td>
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<tr>
<td>Gomes Carreira et al (2010)</td>
<td>Randomised controlled trial &lt;br&gt; Aim: to assess the effectiveness of splinting for the trapeziometacarpal joint in Grades II and III OA &lt;br&gt; Inclusion: clinical and radiological diagnosis of idiopathic Grade II and III OA of the trapeziometacarpal joint; dominant hand; over 40 years of age; dominant hand thumb base pain between 3 and 7 on 0–10 cm visual analogue scale (VAS) &lt;br&gt; Exclusion: severe deformities of the dominant hand that prevented gripping between 1st, 2nd and 3rd fingers; deformities of the distal interphalangeal joint (DIP); use of thumb splint in previous 6 months; allergy to the splint material; surgery on the hand studied in the previous 6 months or scheduled in the upcoming 6 months; injections in the hand under study in the previous 6 months; changes in use of anti-inflammatory medication and analgesics in the previous 3 months; incapacity to respond to the questionnaire and perform the tests; geographical inaccessibility; other associated diseases, e.g. carpal tunnel syndrome, fractures in the carpus, tendinitis, chronic inflammatory arthropathy &lt;br&gt; 40 participants from Rheumatology department randomised into intervention or control group &lt;br&gt; Intervention group: &lt;br&gt; Male: female ratio = 0:20 &lt;br&gt; Mean age (SD) = 62.8 years (8.5) &lt;br&gt; Mean disease duration (SD) = 6.3 years (3.4) &lt;br&gt; Control group: &lt;br&gt; Male: female ratio = 2:18 &lt;br&gt; Mean age (SD) = 65.1 years (10.1) &lt;br&gt; Mean disease duration (SD) = 7.7 (6.1) &lt;br&gt; Brazil.</td>
<td>Custom-made functional thermoplastic splint for trapeziometacarpal stabilisation, made by an occupational therapist, for all participants in both groups &lt;br&gt; Intervention group (IG): Splint used during ADL, including work activities, for 180 days. Instructed to remove it for sleeping, bathing and ADL with contact with heat &lt;br&gt; Control group (CG): Splint used only during evaluations for first 90 days, then during ADL for second 90 days.</td>
<td>Measures at baseline, 45, 90 and 180 days (measured while wearing splint and without) &lt;br&gt; Primary outcome: &lt;br&gt; Pain – VAS (10 cm) &lt;br&gt; Secondary outcomes: &lt;br&gt; Functional capacity – DASH &lt;br&gt; Grip strength – Jamar® dynamometer &lt;br&gt; Pinch strength – pinch gauge &lt;br&gt; Upper limb dexterity – O’Connor test (with and without splint).</td>
<td>All participants completed trial with no loss to follow-up &lt;br&gt; Pain: splinting effectively reduced pain in both groups, but IG showed improvement as early as 45 days, maintained at 90 and 180 days. CG only improved after 90 days when these participants also started to use the splint for ADL &lt;br&gt; At 180 days the improvement in pain was significantly different between the IG and CG (p=0.003), demonstrating an additional gain from longer use of the splint &lt;br&gt; Grip strength: no significant changes in power or pinch grip strength with use of splint. Key grip strength was reduced with splint wear in both IG and CG &lt;br&gt; Function: improvement but not statistically significant in DASH scores &lt;br&gt; Manual dexterity: no statistically significant differences found between groups. IG participants completed the O’Connor test in a shorter time with the splint &lt;br&gt; Concluded that splint use during ADL for this group reduces pain, has minimal impact on functional capacity and does not alter grip strength, pinch strength or dexterity.</td>
<td>Grade B – Moderate &lt;br&gt; Downgraded from A due to limitations: &lt;br&gt; • Sample size appears small – 40 participants in total, 20 in each arm, although author reports only needed a minimum of 17 per group to demonstrate 2 cm improvement in VAS for pain, and that numbers recruited allow for possible loss to follow-up of 20% (which didn’t materialise) &lt;br&gt; • Only states that the evaluations were carried out by blinded assessor; not clear if the occupational therapist was blind to the treatment &lt;br&gt; Comments: &lt;br&gt; • DASH may not have been responsive enough as a measure &lt;br&gt; • Study population almost entirely female – may limit generalisability of findings &lt;br&gt; • Information not collected on splint adherence, adverse effects, participant experience and opinions of splint wear.</td>
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<td>Gooberman-Hill et al (2013)</td>
<td>Participatory design</td>
<td>Two interactive discussion fora, one in Bristol and one at Keele, each of 3 hours duration Groups facilitated by research staff, including two project research fellows, two clinical research fellows (one an occupational therapist) and designed to encourage discussion and collaboration between participants and project staff Interactive discussion between participants and research staff, and the opportunity to try on a range of splints Topics covered in session: • Experience of OA and of their own thumb splints • Exposure to a number of alternative splints during the session, which they tried on and evaluated • Views of the acceptability of placebo arm in future trial • Acceptable and unacceptable design features for proposed placebo splint, with focus on wearability and support.</td>
<td>• Acceptability of splints • Wearability – defined by materials, warmth, colour, type of fastenings, appearance • Support gained from thumb splints with/without immobilisation • Whether or not placebo arm is an acceptable feature of future trial • Input to potential design of placebo splint.</td>
<td>• Use of placebo arm is acceptable • Findings will inform design of subsequent Delphi exercise and RCT • Future trial will include investigation of acceptability of placebo splint • Evaluation of existing splints included views that: neoprene too hot in summer, beige colour too medical and not practical, dislike of hard plastic moulded splints, hook and loop fastenings easy to don/doff but catch on clothing, concerns re washing splints, stigma re wearing (makes disability obvious). Support from splint was viewed as essential • Recommended placebo splint design: ➢Must not offer 'real' support for carpometacarpal (CMC) joint ➢Colour: beige ➢To incorporate elastic fabric and hard plastic element ➢Hook and loop fastenings ➢Blinding: those wearing placebo splints should not mix with those wearing active splint, e.g. at clinic.</td>
<td>Grade D – Very Low Comments: • Will inform a Delphi exercise and randomised controlled trial • Small numbers of participants • Limited recruitment sources • The two groups were very different sizes and this affects dynamics – one forum contained only two participants • Acknowledged that study did not discuss results of previous RCT with the fora members as they had already concluded that placebo would have a beneficial effect • Facilitators were not independent, and this may have influenced the participants.</td>
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<td>Hamann et al (2014)</td>
<td>Cohort study</td>
<td>4 orthoses were used: BSN medical, Push braces, Sporlastic, and MEDI</td>
<td>Range of motion of the thumb CMC and metacarpophalangeal (MCP) while using the 4 orthoses and without orthosis via three repetitions of maximum opposition reposition</td>
<td>All orthoses restricted motion in all directions. CMC joint stabilisation was largest with MEDI and BSN medical, and lowest with Push braces. For the MCP joint, the largest restriction of motion was with MEDI followed by BSN medical, while Sporlastic and Push braces restrained very little motion</td>
<td>Grade D – Very low</td>
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<td>Hand function via the Sollerman test</td>
<td>Hand function was greatest with the Push braces (average Sollerman test sum score of 78/80) and lowest with MEDI (46/80) (significantly different to the other orthoses, p&lt;0.05). The BSN score was 72/80 and Sporlastic was 75/80</td>
<td>Downgraded due to: Need to replicate the study to understand if the splint can still provide functionality and stability, and could have addressed areas around pain and compliance</td>
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<td>• Limitations included the possibility that increased pain during range of motion measurements influenced outcomes, participants were women only</td>
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<td>• Pain levels were not tested, so unable to conclude which orthosis provided the best pain relief with minimum loss of function</td>
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<td>Hammond et al (2016)</td>
<td>Systematic review</td>
<td>All studies were randomised controlled crossover trials</td>
<td>Proximal interphalangeal joint circumference</td>
<td>3 studies were moderate quality and 1 study low quality</td>
<td>Grade C - Low</td>
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<td>Aim: to review the evidence on the effects of compression gloves on adults with rheumatoid arthritis (RA) and osteoarthritis (OA)</td>
<td>Nylon/elastane and thermal compression gloves were tested (though 3 of those used are no longer manufactured)</td>
<td>Pain, Stiffness, Swelling, Numbness, Night throbbing, Health status, Grip strength, Pinch strength, Range of motion, Dexterity, Hand volume, Number of tender joints</td>
<td>Significant reductions in proximal interphalangeal joint circumference, though not accompanied by reduced finger stiffness, improved flexion or dexterity</td>
<td>Downgraded due to: dated studies and outcome measures with inconclusive findings</td>
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<td>Inclusion: randomised controlled trials (RCTs), quasi-RCTs and randomised crossover controlled trials published in English using compression gloves to manage RA or hand OA that had been diagnosed by a physician, gloves were provided by health professionals</td>
<td>All wore gloves at night.</td>
<td>Inconclusive results for pain, stiffness, numbness, night throbbing and health status</td>
<td>No significant differences between compression gloves and placebo gloves for grip strength, pinch strength, range of motion, dexterity, hand volume or number of tender joints</td>
<td>Comments: Limitations include the poor reporting of baseline and follow-up data and the age of the studies Because of the age of the studies, some outcome measures used are now infrequently employed</td>
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<td>Exclusion: studies that evaluated 2 types of gloves without a control group or phase as a comparison, case studies, observational studies or reported only in abstracts, poster presentations or conference proceedings</td>
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<td>4 studies</td>
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<td>Published between 1970 and 1990</td>
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<td>Methodological quality assessed by PEDro scale.</td>
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| Haskett et al (2004) | Randomised controlled trial Aim: to compare the effect of three types of wrist splint on perceived wrist pain, hand function and perceived upper extremity function Recruitment via referral to occupational therapy department in a specialised arthritis treatment centre 45 participants randomly assigned to treatment in three-phase cross-over trial Inclusion: inflammatory arthritis affecting wrist with any two other symptoms (palpable swelling, pain on direct pressure, pain on motion, wrist ROM restricted by ≥20%) and aged ≥20 years Exclusion: previous splints not willing to participate in a two-week washout period pre-trial; required combination wrist splint (i.e. with thumb); post-operative; excessive subluxation; unstable medication regimen Male: female ratio = 6:39 Mean age (SD) = 49.1 years (13.0) Mean disease duration (SD) = 8.6 years (9.2) | Total trial period 14 weeks plus follow-up visit at 6 months Three splint types:  
  - Rolyan® wrist extensor orthosis (RWS prefabricated)  
  - Custom-made leather wrist splint (LWS) Wrist extension 15–20°  
  - Ulnar deviation 5° Anatomical Technologies elastic wrist support (AWS prefabricated) Each of the splints worn for 4 weeks with separation by one-week washouts Splint to be worn during activities during the day that cause pain or discomfort; minimum of 10 hours per week All splints were fitted by an occupational therapist. | Assessment at baseline, after each splint phase and washout period, and at 6-month follow-up Primary outcome:  
  - Pain – VAS (10 cm) Secondary outcome:  
  - Hand function – Arthritis Hand Function Test (AHFT) – hand strength and dexterity  
  - Perceptions of function – McMaster Arthritis Patient Function Preference questionnaire Splint use – daily diary record Costs considered: splint, fitting time and participant’s instructions | Splint wear – average 29 hours per week  
  Pain: all splints reduced pain (p=0.007) compared with baseline Custom LWS was more effective in reducing pain than the AWS, although differences between LWS and RWS, and RWS and AWS, were not statistically significant. Comparing with baseline, all three improved perceived wrist pain; however, only the change with the LWS was statistically significant (LWS p=0.001; RWS p=0.06; AWS p=0.38) Hand function: regardless of splint type, grip strength, 2-point pinch strength, 3-point pinch strength, aggregate applied dexterity, and pouring water were significantly improved over baseline (p<0.02). Pegboard dexterity and lifting were not improved with splint use A significantly stronger grip resulted with the RWS compared to the AWS (p=0.04); the LWS compromised pegboard dexterity marginally more than the AWS (p=0.03). There were no differences between the LWS and RWS on any of the AHFT items Preference: ranked LWS (most preferred), RWS, AWS Wrist splints reduced pain, improved strength and did not compromise dexterity after 4 weeks’ use Improvements maintained at 6 months and no harm was identified Costs (splint, fitting time and instructions):  
  - RWS $58 Canadian dollars (CAD)  
  - LWS $100 CAD  
  - AWS $30 CAD. | Grade B – Moderate Downgraded from A due to limitations:  
  - True blinding not stated and biases may have affected outcomes Comments:  
  - Small sample size  
  - No confidence levels presented  
  - Large variation at baseline on number of variables  
  - Not possible to blind participants or practitioners  
  - Outcome assessors were independent but unclear if blind  
  - Practical significance of the grip improvements not measured  
  - Repeated measures used at assessment at regular intervals (smallest gap 1 week), therefore there may have been a practice effect  
  - By the time the third splint was applied there may have been a degree of functional adaptation that could have influenced the results. |

Appendix 5: Evidence tables
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<th>Source</th>
<th>Design and participants</th>
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<tr>
<td>Healy et al (2018)</td>
<td>Systematic review</td>
<td>43 RCTs examined use of orthoses for arthritis treatment – 4 studied orthoses for the hand for osteoarthritis, 2 studied orthoses for the hand and wrist for rheumatoid and juvenile idiopathic arthritis and 2 for the hand only</td>
<td>Osteoarthritis: 2 of these compared thumb orthoses to a control condition while 2 compared thumb splint interventions</td>
<td>Osteoarthritis: Significant small effect size found between orthoses and control group for thumb opposition score in 1 study Those who used thumb splint for 90 days had better pain reduction than those who used it for evaluation only in 1 study (effect size: -1.1 (95% CI -1.90 to -0.30)) All other outcome measures showed no significant differences</td>
<td>Grade B - Moderate Downgraded due to: Limited studies and not specific to one disease or condition Comments Limitation included limiting analysis to baseline versus final assessment, potentially missing significant differences in between Not able to make a strong conclusion on the effectiveness or cost-effectiveness of orthoses Most outcome measures were self-reported and at risk for bias It was not always possible to blind participants due to the nature of the intervention An extensive range of outcome measures were used across studies</td>
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Aim: to assess the effectiveness and cost-effectiveness of prosthetic and orthotic interventions

Inclusion: randomised controlled trials (RCTs) published between 1995 and 2015 that provided devices for a clinical problem for use during activities of daily living (ADLs), involved all ages and any medical conditions, and used validated outcome measures

Exclusion: involving healthy participants, examining devices for prevention of injuries and within therapy / training sessions, examining new / research devices, not published in English

323 RCTs

319 examined orthotic interventions

4 examined prosthetic interventions

Osteoarthritis: 2 of these compared thumb orthoses to a control condition while 2 compared thumb splint interventions

Rheumatoid and juvenile idiopathic arthritis: 2 compared wrist splints to control condition, 1 compared hand splints to a control group and 1 compared 2 hand splint interventions

Osteoarthritis: Grip strength

Pinch strength

Pain

Thumb opposition score (Kapandji index)

Thumb counter-opposition score (Kapandji index)

Cochin hand functional scale

Closure of the first web

Kallman score

Disabilities of the Arm, Shoulder and Hand instruments (DASH)

Rheumatoid and juvenile idiopathic arthritis:

DASH

Grip strength

Dexterity

Ulnar deviation

Stiffness

Michigan Hand Outcomes Questionnaire

Pain

Pinch strength

Stanford Health Assessment Questionnaire

No other outcome measures showed significant differences
### Source
Hermann et al (2014)

### Design and participants
Randomised controlled trial  
Aim: to explore the feasibility and assess the effect of a prefabricated soft thumb-based orthosis on pain, hand strength and activity performance in persons with OA of the CMC joint  
Department of Rheumatology referrals  
Inclusion: hand OA diagnosed by a physician according to the American College of Rheumatology, thumb pain on palpation and ability to communicate well in Norwegian  
Exclusion: previous thumb surgery; cortisone injection during the past 2 weeks before inclusion; other diseases that could have an impact on hand function; cognitive deficits  
59 participants (from eligible sample of 116) randomised to intervention ‘orthosis’ group (30 participants) or control group (29 participants)  
Male: female ratio = 1:58  
Mean age (SD) = 70.5 years (6.7)  
Disease duration (median, range) = 15.2 years (5, 41)  
Norway.

### Intervention
Intervention ‘orthosis’ group: prefabricated Thumb Support 202 orthosis and hand exercises as per the control group  
Regimen: wear splint as much as wanted, especially when symptomatic and when performing heavy manual tasks  
Control group: Hand exercise programme of 4 hand exercises, 2 sessions per day with 10 repetitions of each exercise in the study period  
Medical treatment provided for all participants as usual during the study period, including use of symptomatic medication for hand OA.

### Outcomes
Participants were assessed at baseline (before group allocation) and after 2 months  
**Primary outcome:**  
- Pain – Numeric Rating Scale 0–10 (level of pain following measures of grip and pinch strength)  
**Secondary outcomes:**  
- Grip and pinch strength – Grippit™  
- Self-reported hand symptoms and activity performance – Australian/Canadian Hand Osteoarthritis Index (AUSCAN)  
- Self-reported frequency of hand exercises: a 5-point scale used by all participants at 2 months  
- Self-reported splint wear: 5-point scale  
- Experience of wearing splint – semi-structured interviews conducted by an occupational therapist.

### Results
55 participants completed the trial.  
Pain: Orthosis group reported significantly less pain when wearing the orthosis for three measures:  
- Pain during R grip \( p = 0.01 \)  
- Pain during L grip \( p = 0.02 \)  
- Pain during L pinch \( p = 0.04 \)  
A soft orthosis appears to have an immediate pain-relieving effect when worn. There were no significant differences between the two groups in the pain measures  
Pinch strength: trend towards increase in strength  
Grip strength: trend towards decreased grip in orthosis group when wearing orthosis (significantly for right hand grip strength)  
There were no significant differences between the groups in the secondary outcomes at follow-up  
Orthosis was reported most frequently as useful for rest/deep, dressing, gardening, washing floors, vacuum cleaning, driving, and writing by hand  
Satisfaction: 17 participants satisfied with the orthosis design; 11 reported that they would like more support to the CMC joint  
23 would continue to use the orthosis after the study, 3 would not, and 2 were uncertain because of difficulties putting the orthosis on.

### Quality and comment
Grade B – Moderate  
Downgraded from A due to limitations:  
- Small numbers in each group and very small proportion of men  
- Could not be double-blinded  
- Retrospective questions used for frequency/use of splint – likely recall bias  
- A weakness in the orthosis material was discovered partway through the trial: this was corrected in the remaining two-thirds of the orthosis group but may have influenced the support given and the frequency of use of the splint  
- No consistency in wearing across the intervention group  
- Synergic effects may have been present with the combination of hand exercises and orthoses in the orthosis group.
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<td>Kjeken et al (2011a)</td>
<td>Randomised controlled trial Aim: to evaluate the effect of assistive technology on OA of the hand Inclusion: adults with hand OA diagnosed by a rheumatologist or orthopaedic surgeon according to criteria of American College of Rheumatology; minimum of two self-reported activity limitations secondary to hand OA; aged &lt;80 years and able to communicate in Norwegian Exclusion: hand surgery within the past 6 months or medication changes in the past month; functional impairment due to trauma or other diseases cognitive or mental impairment. Participants who had hand surgery during the trial or changed medication in the past month were excluded from the three-month follow-up evaluations Consecutively recruited via outpatient clinic 70 participants randomised to either intervention group or control group Intervention (AT) group: Male: female ratio = 1:34 Mean age (SD) = 61.1 years (6.0) Mean disease duration (SD) = 11.5 (8.3) Control group: Male: female ratio = 1:34 Mean age (SD) = 59.9 years (7.5) Mean disease duration (SD) = 10.0 years (8.0) Norway.</td>
<td>Intervention – assistive technology, which includes assistive devices and orthoses or splints Intervention group (AT): received information and assistive devices and/or splints Control group (CG): received information only Information consisted of details about hand OA and a leaflet containing three hand exercises and five suggestions for alternative working methods to improve hand function and ADL performance.</td>
<td>Assessed at baseline (before allocation) and after 3 months Primary outcome: • Activity performance and satisfaction with performance – COPM (Canadian Occupational Performance Measure) Secondary outcomes: • Disease activity (modified health questionnaire) • Pain, fatigue – VAS • Function – AUSCAN hand index function score • Clinical observations of the hands by joint counts was carried out by the occupational therapist to determine severity • Radiological OA of CMC joints Compliance measured via questionnaire as well as including questions re comfort.</td>
<td>AT group: 34/35 received assistive technology devices, 26 received splints Self-reported assistive technology usage: 92% in the AT group Comfort with usage rated as high Activity performance and satisfaction: COPM scores identified significant positive change in performance (p=0.003) and satisfaction scores (p&gt;0.001) in the AT group at 3 months. High confidence levels (95% CI) indicated moderate to large treatment effect (effect sizes 0.9) The control group had a significant negative effect on COPM performance scores (p=0.005) Function: AUSCAN hand index function score showed significant improvement in AT group at 3 months (p&lt;0.001). Adjusted mean difference between AT and control group of −0.3 (p=0.06, effect size −0.5) The other secondary outcomes, such as pain and fatigue, demonstrated small and non-significant change.</td>
<td>Grade A – High Comments • Only two males in the population studied • Short-term follow-up only 3 months • Occupational therapist carried out the evaluations and participants were not ‘blind’ to treatment but observer was ‘blinded’ • Some participants had already had AT devices and splints at baseline • Possible harmful effects of assistive technology not investigated.</td>
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<tr>
<td>Source</td>
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<td>Kjeken et al (2011b)</td>
<td>Systematic review</td>
<td>Splint classified according to location, primary anatomic parts included, direction and purpose, number of joints included and material used (rigid, semi-rigid, soft) Design and effects of both splinting and hand exercises, separately and together: • Design of splints • Effects of splints • Design of exercise programmes • Effects of exercise programmes</td>
<td>Main outcome measures: • Pain • Need for surgery • Pinch strength • Function Dexterity and splint satisfaction also looked at in a small number of papers.</td>
<td>12 studies, 7 of which assessed the effectiveness of splints and 2 a combination of splints and exercises in people with hand OA. Three considered exercise alone Broad variety of designs for both splints and exercise programmes Meta-analysis of effect of splints demonstrated that splints significantly reduce hand pain. All splints designed to support thumb joint Splint use effects: 2 RCTs had low risk of bias – showed that splints have a significant effect on decreasing pain at short-term (&lt;3 months) and long-term (≥3 months) follow-up; some uncertainty about heterogeneous effects for short-term follow-up and confidence interval was large for long-term follow-up A long and rigid splint well tolerated at night giving pain relief; shorter splint significantly reduced pain during ADL 7 high-risk papers: no significant effects of the splint in one paper; another showed soft splints to be more comfortable and conducive to function CMJ subluxation can be corrected by splinting in early stage OA, especially rigid splints Splints are prescribed for function and pain relief with no consensus on when it is most useful to wear them Single trials: • Hand exercises may reduce pain and increase range of movement and strength, but evidence is limited • Splints and daily exercises combined may reduce pain and stiffness, and improve function.</td>
<td>Grade A – High</td>
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<td>Aim: to describe and evaluate the design and effects of splints and exercise programmes in hand OA Search included randomised controlled trials, controlled clinical trials, controlled before and after studies, interrupted time series. Mixed population papers were excluded (1994–2010) Inclusion: hand OA Exclusion: pharmacological and surgical intervention 311 participants overall Male/females in studies not detailed consistently, but appears there were more women, which is consistent with other literature and the disease incidence English, German, French and Scandinavian language papers only.</td>
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<td>Comments: Despite searching for good-quality literature, mostly papers with a high risk of bias were sourced Variation in materials used in splint design Did not state a number of demographic characteristics, e.g. male: female ratio, setting and countries of studies, therefore may be difficult to generalise results.</td>
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Appendix 5: Evidence tables
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<th>Source</th>
<th>Design and participants</th>
<th>Intervention</th>
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| Maddali-Bongi et al (2014) | Cohort study  
Aim: to evaluate the usefulness of a custom-made splint and educational programme for symptomatic trapeziometacarpal (TMC) joint OA  
Outpatient setting  
Inclusion: symptomatic TMC joint OA in Stages I–III confirmed by hand X-ray  
Exclusion: previous surgery or infiltrative treatment of TMC joint; inflammatory arthritis; neuropathies and De Quervain’s tenosynovitis  
Participants: 50 (12 bilateral OA TMC joints)  
Male: female ratio = 6:44  
Mean age (SD) = 60.72 years (10.63)  
Manual workers:  
Male: female ratio = 1:26  
Non-manual workers:  
Male: female ratio = 5:18  
Italy. | TMC joint OA butterfly thermoplastic short opponens custom-made splint  
Worn 16 hours a day for 30 days and then when required up to 12 months  
Plus an educational programme of two 2-hour sessions. | Measures evaluated at baseline, first month (end of treatment period) and 12 months  
Primary outcome  
• Pain – Numeric Rating Scale 0–10 (non-standardised) evaluated at all three points  
Secondary outcomes (at baseline and 1 month):  
• Hand strength – Jamar® dynamometer  
• Pinch strength – pinch gauge  
• Hand disability – Dreiser test (questionnaire)  
Compliance: participant diary  
Safety: adverse effects leading to dropouts  
Satisfaction: single question rated on scale of 0–10. | Pain: significantly reduced at 30 days post-intervention in both manual workers (p<0.0001) and non-manual workers (p<0.0001), and combined results showed significant improvement in pain at 30 days (p<0.0001)  
12-month follow-up – this reduction in pain was maintained; total scores (p<0.0001), manual workers (p<0.0001) and non-manual workers (p<0.0001)  
Grip and pinch strength – at 30 days the whole group improved significantly (p<0.0001)  
Manual and non-manual workers had significant improvements in grip strength (both p<0.0001) and in pinch strength (p<0.0001 and p<0.05 respectively)  
Hand function (Dreiser): at 30 days whole group improved significantly (p<0.0001) and in the manual workers (p<0.05), but no significant difference in the non-manual workers  
Adherence/compliance with splint wear hours reported as high and no dropouts or adverse effects reported. Splints were not reported as needing any modification over study time. | Grade C – Low  
Comments:  
• Bias towards the positive effects of the intervention – i.e. does not report the results of all outcomes at 12 months (only reported pain results)  
• No control, and there could be significant bias with the outcomes (analysis of bilateral participant data) and fact that the assessor was not blinded  
• Combines splinting with education, yet does not extrapolate the effects of these on each other  
• Elements of the results do fit with other studies on TMC joint splinting in OA  
• Some data analysis information gaps  
• Results not solely attributable to splinting  
• No power calculations for numbers needed to treat. |
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| McKee and Rivard (2004) | Case studies  
  Aim: to demonstrate and discuss application of a client-centred, occupation-based practice framework for orthotic intervention  
  All female (3 case studies)  
  Mildred – 75 years, OA IPJ dominant thumb, pain affecting activities  
  Lynn – 26 years, spina bifida, foot orthosis  
  Carol – 60 years, bilateral OA thumb CMCJ  
  Use of Canadian Model of Occupational Performance for intervention planning and the associated outcome measure Canada. | Provision of an orthosis as part of an occupation-focused occupational therapy intervention programme  
  Both orthoses were individually made by the occupational therapist  
  Mildred: ulnar-based thumb interphalangeal orthosis, thermoplastic, Plastazote lining, Velcro® straps and modified glove  
  Carol: CMC thumb orthosis. | Self-reported narrative accounts of usefulness  
  Client satisfaction and performance by use of Canadian Occupational Performance Measure (COPM). | An orthosis must fit into a person's lifestyle. Six essential considerations:  
  - Client-centredness  
  - Comfort  
  - Cosmesis  
  - Convenience  
  - Less is more (minimalistic design, number of restricted joints, thickness, complexity of straps, ease of maintenance, visibility, amount of skin enclosed)  
  - Follow-up  
  Splinting can improve pain, but author suggests that as well as efficacy of splinting, a client-centred approach is important  
  Report supported the use of the COPM for intervention planning and outcome measure and encourages use of this tool. | Grade D – Very Low  
  Comments:  
  - Case study presentation  
  - Three client stories – no information as to how the selection was made  
  - Only two of the three examples were for hand orthoses  
  - Narrative accounts. |
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  - Pain  
  - Stiffness  
  - Function – as defined by International Classification of Functioning, Disability and Health (ICF)  
  - Desire for surgery. | 173 reviews on hand OA identified. After eligibility and quality screening, four systematic reviews were included in this study. Splinting included in three out of four reviews  
  1. Splinting (3 × RCTs) and pressure gloves versus no gloves (1 × RCT): intervention, control/duration and outcomes not reported  
  2. Splint design: conflicting results between two systematic reviews re effect size and direction in relation to splint design; one concluding more pain relief from full, compared to half splint, and the other reporting no clear evidence of one type of splint being superior to another for pain relief, comfort or function. Studies comparing different designs of thumb splint, different materials, and custom-made versus prefabricated, marred by small sample sizes and unclear/conflicting effect sizes. Authors report it is reasonable to conclude that there is limited evidence that splints can relieve CMC joint pain in people with OA, but not enough evidence to give recommendations regarding design or materials  
  3. Splint versus no treatment (1 RCT): study suggested that evidence was ‘fair’ for the effectiveness of splinting to relieve pain and improve function  
  4. Desire for surgery (1 RCT, splint versus no treatment): approximately 1/3 of each group desired surgery; study authors’ conclusion is that splinting did not affect this outcome  
  Suggests limited evidence that splinting of the thumb CMC joint reduces pain. | Grade A – High  
  Comments:  
  - Paucity of high-quality systematic review’s evidence found  
  - Methodological/reporting issues or conflict between some of systematic reviews studied  
  - Search targeted hand OA – may have missed some titles specific to thumb or fingers  
  - May have missed some relevant studies – limited languages included in search, no conference proceedings or expert opinion accessed  
  - Absence of participant experience/opinion. |
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| Nasir et al (2014) | Literature review                                                                       | 5 clinical crossover trials, 2 clinical trials and 1 case study. | • Grip strength  
• Pinch strength  
• Range of motion  
• Dexterity  
• Hand pain  
• Finger swelling  
• Joint stiffness | 3 studies rated on the PEDro scale as low or moderate quality  
Grip strength improved in all studies, but in only 2 significantly so  
Pinch strength was only measured in 1 study and no effect was found  
Range of motion measured in 4 studies; 1 study found self-reported improvement, and 2 studies reported no significant improvement  
Dexterity was measured by 3 studies and all 3 found improvement, though only 1 significantly so (p<0.05)  
Finger swelling was measured by 7 studies, with 6 reporting significant improvement, and 1 finding no significant improvement  
Pain was measured by 7 studies, with 4 finding significant improvement and 2 finding improvement with no statistical indicators  
Joint stiffness was measured by 7 studies, and 6 saw self-reported improvement, 1 significantly so, and 1 study saw no improvement | Grade C - Low  
Downgraded due to:  
• Dated studies  
Comments:  
• Limitations include the use of outdated outcome measurement tools in some studies, lack of methodological quality rating, no correlation between pain and stiffness relief and diminished swelling of the proximal interphalangeal joints  
• Unclear how compression gloves improve outcomes (i.e. the mechanics of how they work). |
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<tr>
<td>Pagnotta et al (2005)</td>
<td>Cohort study</td>
<td>Prefabricated wrist splint (Wrist extension 10–15°) Using a work simulator participants performed 14 tasks, 10 assessing work performance and 4 assessing endurance with splint on and off.</td>
<td>• Pain: VAS (10 cm) measured before and after the performance of each task, both with splint on and with splint off. • Work performance and endurance: Baltimore Therapeutic Equipment Company work simulator – computerised readouts were generated for each task. • Perceived difficulty: VAS (10 cm) • Perceived splint benefit: VAS (10 cm)</td>
<td>Pain: with the splint on, pain was significantly lower in 5 tasks, i.e. 3 work performance tasks (placing/turning key or knob/driving) and 2 endurance tasks (chopping with knife/placing). Perceived difficulty in task performance: difficulty less for 13 of 14 tasks when wearing splint (5 significantly). Work performance: did not differ significantly with the splint on versus off. Endurance: mean scores were always better with the splint on; differences reached significance on only one task (pull electric cord).</td>
<td>Grade C – Low Comments: • Small sample size • Participants were allowed to practise the task prior to testing situation • Subjective judgement of cut-off (20%) and classification of VAS score ≥7 as strong perceived benefit • Homogeneity within participants • Use of a work simulator for the tasks may not allow for adaptations the participants already make to tasks • No apparent follow-up • Some participants could not complete the task due to fatigue or pain, and so 5 work performance tasks and 2 endurance tasks had less than a full sample of participants.</td>
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Exclusion: unable to wear a prefabricated elasticised wrist splint because of advanced wrist and hand deformities rash; allergies; altered sensation; skin breakdown; received an injection of corticosteroid medication in the wrist or any small joints of the hand or flexor tendon sheath of the hand within the preceding 2 months; diagnosed as having carpal tunnel syndrome associated with persistent numbness; severe finger deformities limiting grip of the tools; clinical fusion of the radiocarpal joint; wrist and/or hand surgery in the past 6 months. | | | | | |

Male: female ratio = 4:26 Mean age (SD) = 56.7 years (14.2) Mean disease duration (SD) = 9.2 years (8.73) Canada.
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<tr>
<td>Ramsey et al (2014)</td>
<td>Mixed methods systematic review, registered with the Centre for Reviews and Dissemination (CRD42012001946)</td>
<td>Working wrist splints - Reports 23 studies, comprising:</td>
<td>Effectiveness defined via most frequently occurring outcomes:</td>
<td>Strong quantitative evidence, (including 9 RCTs) (using Cohen’s $d$ effect $d=0.7-0.8$), backed up by qualitative literature that working wrist splints reduce pain</td>
<td>Grade A – High</td>
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<td></td>
<td>Aim: evaluate effectiveness of working wrist splints in adults with RA</td>
<td>9 randomised controlled trials</td>
<td>• Function</td>
<td>Moderate evidence that grip strength is improved ($d=0.3-0.4$) but dexterity is impaired</td>
<td>Comments:</td>
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<td></td>
<td>10 databases searched from inception to September 2012 for quantitative and qualitative studies of the effectiveness of working wrist splints, plus hand-searching of article references and relevant print and electronic journals</td>
<td>4 experimental</td>
<td>• Strength</td>
<td>Insufficient evidence for the effect on function</td>
<td>• Wide variation of definitions of ‘function’ across the literature makes comparison difficult</td>
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<td>Inclusion: qualitative and quantitative studies; effectiveness of working wrist splints in people with RA or the experiences and/or perceptions of people who access services and/or therapists or carers involved in the provision of working wrist splints to people with diagnosed RA; English language only</td>
<td>3 observational</td>
<td>• Pain</td>
<td>Working wrist splints reduce pain</td>
<td>• Diversity of outcome measures – and use of standardised and non-standardised outcomes – made comparisons more difficult</td>
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<td>Exclusion: where &lt;50% participants had RA; including children with juvenile RA; where splinting was included as part of an extensive occupational therapy treatment programme; splints used post-operatively; studies addressing splints for the finger, thumb or pressure gloves (not wrist splints); conference proceedings</td>
<td>2 qualitative studies</td>
<td>• Dexterity</td>
<td></td>
<td>• Uses informal methods to detect publication bias within results</td>
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<td></td>
<td>Participants = 1,492 adults with diagnosed RA Mean age (from 16/23 studies) = 55.5 years</td>
<td>Meta-analysis could not be carried out due to heterogeneity of studies</td>
<td>Other outcomes were included in the study but not presented in this paper:</td>
<td></td>
<td>• Caution needed regarding over-interpretation of the results due to use of a narrative analysis</td>
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<td>Male: female ratio – not stated in all studies Mean disease duration (from 12/23 studies) = 9.3 years</td>
<td>Used the Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) guidelines, across 10 databases.</td>
<td>swelling, deformity, ROM and quality of life</td>
<td></td>
<td>• Includes cross-over studies which author states may lead to inconclusive/biased results because these compare effects within subjects rather than between groups</td>
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<td></td>
<td>Countries of study: not stated.</td>
<td>Analyses were small compared to the effect observed in the studies.</td>
<td>Analysis of the data:</td>
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<td>Rannou et al (2009)</td>
<td>Randomised controlled trial&lt;br&gt;Aim: to assess the efficacy of splinting for thumb base OA at 1 month and the efficacy, safety and effects on disability at 12 months&lt;br&gt;Parallel group multicentred – two tertiary care hospitals&lt;br&gt;Inclusion: pain &gt;30 mm on VAS; 45-75 years of age; radiologic evidence of OA; and either CMC enlargement or closure of 1st web space&lt;br&gt;Exclusion: post-traumatic arthritis; gout; inflammatory arthritis; neurological condition affecting the upper limb; hand/wrist trauma in the past 2 months; previous hand surgery; collagen diseases; skin conditions affecting splint wear; steroid injection (referred to as infiltration) within 2 months; previous splinting; psychiatric disorder; inability to speak or write French; pregnant&lt;br&gt;112 participants randomised to intervention group (57 participants) or control group (55 participants)</td>
<td>Intervention group: custom-made neoprene splint to be worn at night. Covered the base of the thumb and thenar eminence but not the wrist.&lt;br&gt;Splints made by occupational therapists and adjustments could be made as required&lt;br&gt;Control group: usual care.</td>
<td>Primary outcome:&lt;br&gt;- Pain – VAS (0-100 mm) – change from baseline to 1 month&lt;br&gt;Clinical variables:&lt;br&gt;- Hand disability – Cochin Hand Function Scale – change at 1 month&lt;br&gt;- Perceived disability scores&lt;br&gt;- Perceived global assessment&lt;br&gt;- Pinch strength and pain during pinch – electric dynamometer&lt;br&gt;- Range of motion&lt;br&gt;- Thumb mobility – Kapandji index thumb opposition and counter opposition subscales&lt;br&gt;- Adherence and tolerance&lt;br&gt;Change in pain level and measures of disability measured at 12 months&lt;br&gt;Co-interventions were also assessed and radiographic evidence of base of thumb OA as possible influencing variables.</td>
<td>Pain: no differences between groups at 1 month. Both groups improved from baseline but the differences were not statistically significant&lt;br&gt;Reduction in pain was greater in the intervention group than controls at 12 months (p=0.002), as was reduction in disability by Cochin Hand Function Scale score (p=0.008) and participant-perceived disability (p=0.003)&lt;br&gt;54% of the intervention group and 11% of the control group reported that they had improved (p=0.001) at 12 months&lt;br&gt;There were no differences between groups in radiographic progression, or adduction deformity&lt;br&gt;The results show that a rigid splint used at night did not influence pain levels in the first month of use, but there was improvement in pain and function at 12 months&lt;br&gt;Treatment adherence in intervention group was high: 93% reported wearing splints 5-7 nights a week at 1 month, 81% at 6 months, 86% at 12 months and 75% during the whole year of follow-up&lt;br&gt;90% satisfied with splint at 12 months&lt;br&gt;No adverse effects directly attributed to the splint were reported.</td>
<td>Grade A – High&lt;br&gt;Comments:&lt;br&gt;- Risk of bias associated with lack of blinding, especially participants and assessing therapists&lt;br&gt;- Trial was conducted in a specialist centre using custom-made splints by specialist occupational therapists, so results may not be generalisable to other settings&lt;br&gt;- Cochin Hand Function Scale may lack sensitivity&lt;br&gt;- Neoprene splint looks like x-lite splint in the illustration.</td>
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<tr>
<td>Shankland et al (2017)</td>
<td>Pre-post design</td>
<td>First clinic visit collected demographics, history of condition, home and work environment, and occupational performance issues, upper extremity activity and participation, and baseline physical measurements</td>
<td>Upper extremity activity and participation via the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire (primary outcome measure)</td>
<td>19 had right hands treated, 15 had left hands treated and 26 had both hands treated</td>
<td>Grade C - Low</td>
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<td>Intervention consisted of education about joint protection, assistive devices and fabrication of an orthosis, and instruction on a standard set of exercises to facilitate joint stability and pinch strength (frequency and intensity individualised). The therapist and participant jointly agreed which orthotic design, wearing schedule and materials best fit with the participant’s occupational needs. Participants asked to record the length per day they wore the orthosis</td>
<td>Occupational performance issues via the Canadian Occupational Performance Measure (COPM)</td>
<td>Pain via the visual analog scale (VAS)</td>
<td>Mean hours per day of orthotic use was 9.3</td>
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<td>3 week visit to encourage adherence and discuss problems</td>
<td>Thumb total active range of motion (TAROM), flexion and extension via a finger goniometer</td>
<td>COPM Performance Scale increased 2.5 points (p&lt;0.0001)</td>
<td>All outcome measures showed significant changes</td>
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<td>6 week visit collected data logs and outcome data.</td>
<td>Lateral pinch strength via a calibrated B&amp;L pinch gauge.</td>
<td>COPM Satisfaction Scale increased by 2.8 points (p&lt;0.0001)</td>
<td>DASH decreased by 9.3 (p&lt;0.0001)</td>
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<td>Pain improved by 1.9cm (p=0.0001)</td>
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<td>TAROM (left hand) increased 8.4 degrees (p=0.0001)</td>
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<td>TAROM (right hand) increased 7.9 degrees (p=0.003)</td>
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<td>Later pinch strength increased 1.5lbs (p=0.001)</td>
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Comments:
- Limitations included grade of OA unknown, potential bias in adherence data because relied on self-reporting, no control group, no measurement of tripod pinch and grip strength, assessments carried about by one of the authors, confounding variables may have influenced the results (e.g. medication), and as it is a multi-modal intervention it is difficult to say definitively what caused findings.
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<tr>
<td>Silem et al (2011)</td>
<td>Multicentre cross-over equivalence trial</td>
<td>Two thumb splints: Neoprene Comfort Cool™ prefabricated (fit according to size)</td>
<td>Data collection at baseline, at week 4, after the washout week and after use of second splint</td>
<td>Hand function (AUSCAN): improvement in both groups at 4 weeks but the hybrid splint showed statistically significant improvement over baseline (p=0.02). No significant difference between splints. Pain: improvement in pain for both groups at 4 weeks, but hybrid splint produced statistically significant improvement (p&lt;0.001)</td>
<td>Grade B – Moderate Downgraded from A due to limitations: Therapists not blinded and acted as assessors, also therefore risk of bias if therapist has strong opinions/preferences. Short follow-up. 3056 reported using analgesics, which may have increased the effects of splints. Therapists were not blinded to the outcome measures as they measured grip and pinch strength. Cross-over designs can have limitations, i.e. exposure to other interventions. Severity of OA not assessed.</td>
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<td>Aim: to determine if two splints had an equivalent effect on self-reported hand function, pain and hand strength after 4 weeks of use</td>
<td>Custom-made thermoplastic hybrid splint fabricated from neoprene and 1.6 mm Rolyan Aquaplast Watercolors</td>
<td>Primary outcome: • Hand function – AUSCAN functional subscale</td>
<td>Grip and pinch strength: very small improvement in both groups but not at a level of significance after wearing splints for 4 weeks Follow-up at 3 months did not show a significant difference between measures at 4 weeks and 3 months for AUSCAN pain and function scores. Statistically significant difference between baseline and three-month follow-up for both splints</td>
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<td>Hypothesis: both splints will have a similar effect on function, pain and strength in those with OA of the CMC J</td>
<td>The two four-week treatment periods were separated by a one-week washout period</td>
<td>Secondary outcomes • Pain – AUSCAN pain subscale</td>
<td>Results showed equivalent therapeutic effect on function, grip and lateral pinch</td>
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<td>Recruit from three outpatient hand therapy departments</td>
<td>Instructed to wear splints when symptomatic, during heavier manual tasks and at night-time if desired</td>
<td>• Grip – Jamar® dynamometer</td>
<td>Pain relief was better in the custom-made hybrid splint group</td>
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<td>Inclusion: clinical diagnosis of OA, i.e. not confirmed on X-ray; age over 45 years; able to communicate in English</td>
<td>Total duration of the study was 9 weeks plus a follow-up phone call 3 months after initial baseline assessment.</td>
<td>• Lateral pinch – Preston pinch gauge</td>
<td>Participants preferred the Comfort Cool™ splint.</td>
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<tr>
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<td>Exclusion: previous thumb surgery, neurological diagnosis or OA extending into wrist</td>
<td>Satisfaction: with splint’s comfort, appearance, convenience and durability on a 5-point Likert scale Daily log of hours worn.</td>
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<td>Random assignment of 56 participants</td>
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<td></td>
<td>Male: female ratio = 5:51 Mean age (SD) = 64 years (8.61) Mean disease duration (SD) = 2.99 years (4.68) Canada.</td>
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<tr>
<td>Silva et al (2008)</td>
<td>Randomised controlled trial</td>
<td>Night-time positioning splint, custom-made from thermoplastic and fixed with hook and loop straps</td>
<td>Assessments undertaken at baseline, 45 days and 90 days</td>
<td>Total of 47 participants included at final assessment</td>
<td>Grade A – High</td>
</tr>
<tr>
<td></td>
<td>Aim: to evaluate the effectiveness of a night-time positioning hand splint in people with RA in terms of pain, grip and pinch strength, upper limb function and participant satisfaction</td>
<td>More affected hand Wrist dorsiflexion 10° MCP flexion 25–30° PIP flexion 30° and thumb abduction</td>
<td>Primary outcome: • Pain – VAS (0-10 cm)</td>
<td>Pain: decrease observed in the more affected hand in the intervention group, while pain remained constant in the control group. A significant difference was detected between groups over time (p&lt;0.001)</td>
<td>Comments:</td>
</tr>
<tr>
<td></td>
<td>Participants recruited sequentially from rheumatology outpatient clinics</td>
<td>Intervention group: night-positioning splint prescribed for use while sleeping</td>
<td>Secondary outcomes: • Functional status – Health Assessment Questionnaire (HAQ) in interview form</td>
<td>HAQ scores decreased in the intervention group but remained constant in the control group. A significant difference was detected between groups over time (p&lt;0.005)</td>
<td>Control group received no intervention</td>
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<td>Inclusion: 18 to 65 years with RA as classified according to American College of Rheumatology (ACR); use of the same DMARDs for at least 6 months prior to intervention; same doses of corticosteroids and NSAIDs for at least 1 month prior to the study; a score of &gt;3 and ≤7 on a visual analogue scale for pain in the more affected hand</td>
<td>Control group: the splint was only used during evaluation.</td>
<td>• Upper limb disability and symptoms – Disabilities of the Arm, Shoulder and Hand (DASH) administered in interview form</td>
<td>DASH (work): decrease in scores in the intervention group and constant scores in the control group. A significant difference was detected (p=0.011)</td>
<td>Follow-up for 3 months only, so long-term effects not studied</td>
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<td>Exclusion: deformities that prevented fabrication of the splint; use of any other upper limb splint; surgery scheduled within 6 months following the study; allergies to the splint material; living in inaccessible areas with difficult access to transportation</td>
<td>Intervention group:</td>
<td>• Pinch strength – pinch gauge</td>
<td>DASH (upper limb symptoms): intervention group showed improvement in scores after 45 days; control group scores were constant. A significant difference was detected over time (p&lt;0.010)</td>
<td>1 participant at end of 3 months admitted did not use splint correctly</td>
</tr>
<tr>
<td></td>
<td>50 participants with RA were randomly divided into 2 groups (25 in each group)</td>
<td>Intervention group:</td>
<td>• Grip strength – Jamar® dynamometer mean of three measurements was used for analysis</td>
<td>Grip strength: intervention group increased strength, while control group decreased. Over the 3 months, the difference between the groups was significant (p&lt;0.04)</td>
<td>No analysis for participant satisfaction outcomes</td>
</tr>
<tr>
<td></td>
<td>Intervention group: Male: female ratio = 5:20</td>
<td>Intervention group:</td>
<td>• Participant satisfaction – Likert scale consisting of 5 answers (much worse, worse, same, better and much better)</td>
<td>Pinch (key, palmar and tip): showed significant improvement in the intervention group in intra-group analysis compared to the control group</td>
<td>Duration of RA, 9-10 years</td>
</tr>
<tr>
<td></td>
<td>Mean age (SD) = 51.64 years (11.4)</td>
<td>Intervention group:</td>
<td>• Diary to record hours of use of splint.</td>
<td>Mean use of splint: 8 hours per night (SD 1.57).</td>
<td>Functional outcome measure used only two of the three DASH modules.</td>
</tr>
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<tr>
<td>Spaans et al (2015)</td>
<td>Systematic review</td>
<td>Hand therapy, intra-articular injections with hyaluronate or steroid, various orthoses, transdermal steroid delivery and leech therapy.</td>
<td>Pain</td>
<td>9 RCTs looked at orthoses: 2 found that orthoses, compared to no orthoses, reduced pain but did not impact functional capacity, grip or pinch strength. 6 RCTs compared various orthoses: 2 studies found both prefabricated and custom-made orthoses reduced pain, but custom-made did so significantly more. 1 RCT compared a short and long prefabricated opponens orthosis and a short custom-made one. They found significant pain reduction in all groups. 1 RCT found no significant pain reduction differences between 3 orthoses. 1 RCT compared a thumb strap orthosis and abduction exercises on one hand to a short opponens orthosis and pinch exercises in the other hand. Both showed reduced pain and increased strength and hand function, but no significant differences between the two groups. 1 RCT compared an orthosis with hand exercises to hand exercises only. Concluded orthosis provided pain relief only when worn. 1 RCT compared the supply of technical accessories, technical accessories and a semistable orthosis, and technical accessories and a nonstabilising orthosis in patients waiting joint replacement arthroplasty. These prevented over 70% of patients from requiring surgery.</td>
<td>Grade B - Moderate. Downgraded due to: Risk of imprecise findings with lack of statistical analysis, small sample sizes with no justification and no demographic information included making generalising difficult. Comments: Orthoses studies were heterogeneous in nature, making comparisons difficult. No evidence that a custom-made orthosis is superior to a prefabricated orthosis, that a certain length is superior, or that constant use is more effective.</td>
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</table>
| Spicka et al (2009) | Pilot observational study                                         | Silver ring splints – custom-made by jeweller                                | Measures taken with and without the SRS worn:                                                                                   | 40 eligible participants invited to join study. 8/40 (20%) consented and participated. The difference in dexterity and grip strength was not statistically significant (p>0.05), for either hand, either when the SRS was worn or not worn. A trend was apparent towards improved performance when the SRS was worn:  
  - Participants were quicker with respect to dexterity when SRS was worn; the effect was greater in the non-dominant hand than the dominant  
  - Grip strength was greater when SRS was worn. | Grade D – Very Low  
 Downgraded from C due to:  
 - Small effect  
 - Findings not statistically significant  
 - Missing baseline data  
 - Only 8 participants (32 non-responders out of those deemed eligible and invited to join study)  
 - Authors’ acknowledgement of the possibility of Type II error  
 Comments:  
 - Participants had been wearing the SRS for 18 months prior to study and therefore effect on original deformity is unknown  
 - Did not measure the PIPJ deformity  
 - Immediate impact of splints only and not long-term  
 - Mean duration of splint wear given as 18 hours/day (SD 10) but no further breakdown, e.g. daynight use, so cannot tell if exposure is similar or not for all participants  
 - No indication of how much time elapsed after removal of the SRS before measurements were taken, nor if/how long possible benefits of SRS may endure after removal. |

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<tr>
<td>Tada et al (2018)</td>
<td>Prospective study</td>
<td>A ring-like tin splint that restricted the motion of the DIP joint was worn by participants</td>
<td>Participants were measured at baseline and after 1, 3 and 6 months of splint use</td>
<td>Pain decreased at all measurement points, but significantly so after 1 month (p&lt;0.001, 95% CI=+/−4.5)</td>
<td>Grade D – Very low</td>
</tr>
<tr>
<td></td>
<td>Aim: to test effectiveness and participant satisfaction of a tin ring splint</td>
<td>Frequency or duration of use was not specified, except to say to wear or remove it freely depending on pain severity</td>
<td>Pain was measured via the Numeric Pain Scale (NPS)</td>
<td>Active arc of motion did not change significantly, though it did increase</td>
<td>Downgraded due to:</td>
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<tr>
<td></td>
<td>Inclusion: people with painful osteoarthritis (OA) of the distal interphalangeal (DIP) joint</td>
<td>Active arc of motion of the DIP joint</td>
<td>Function of the upper extremity was measured through the Hand 20</td>
<td>Function increased, with significant improvement seen at 6 months (p&lt;0.001, 95% CI=+/−3.2)</td>
<td>• Risk of bias due to not specifying how participants recruited nor who took the measurements and how the follow-up data was obtained.</td>
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<td></td>
<td>Exclusion: people with secondary joint deformation due to comorbid conditions or severe deformations with joint subluxation, or those who received intra-articular injections of steroids or hyaluronic acid formulations within the last 6 months</td>
<td>Treatment satisfaction was rated on a 10 point scale (10=completely satisfied)</td>
<td>Treatment satisfaction ranged from 7.8 at months 1 and 6 to 7.7 at 3 months</td>
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<td>Comments:</td>
</tr>
<tr>
<td></td>
<td>30 participants</td>
<td>Satisfaction with ease of wearing the splint and its cosmetic appeal was rated on a 10 point scale (10=completely satisfied) after 1 month of wear</td>
<td>Participants rated usability 8.9/10 and cosmetic appeal 7.6/10</td>
<td>Participants wore the splint for an average of 6.2 days/week at 1 month, 4.7 days/week at 3 months and 3.8 days/week at 6 months</td>
<td>• Limitations include no control group, not examining the influence of the severity and duration of OA on the treatment outcome, small number of cases.</td>
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<td></td>
<td>Male:female ratio=1:14</td>
<td>Frequency of wearing the splint was asked in the last week of wear</td>
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<td>Mean age=68 years</td>
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<td>Japan</td>
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| Thiele et al (2009) | Cross-over trial                | Use of a custom-made leather splint versus a commercially available fabric splint | Assessed at baseline and after each two-week splint phase by observer blinded to treatment allocation | Pain: statistically significant decrease in pain for both splints but more so for leather splint  
Stiffness: leather splint demonstrated significant reduction in stiffness but fabric splint did not; no significant difference in effect between the splints  
Function: both splints produced a statistically significant improvement in function, with little difference between the splints  
Grip strength: noted as achieving a statistically significant increase for both groups ($p<0.001$)  
Indicated that for the short-term relief of pain and dysfunction the leather wrist splint was superior to a commercially available fabric splint. | Grade C – Low  
Downgraded from A due to limitations:  
• No information provided about period of recruitment or issue of power calculation to guide numbers needed to treat  
• Many variables – e.g. length of wearing time variable not accounted for  
• Used AUSCAN, which has been validated for use with people with OA; however, this trial includes a high percentage of participants with RA, therefore the results from AUSCAN outcome measure could be considered not to be as valid  
• No control group, therefore unable to ascertain true treatment effects e.g. no wearing times included, i.e. participants controlled this variable  
• Effect sizes are given but not confidence levels  
• No outcomes measured after first arm of cross-over trial, which limited the ability to account for carryover effect  
• Not large enough sample to generalise the analysis of comparative data between the two splints  
• No mention of aesthetic preference, though the custom moulding of the leather splint may have led to its higher rating with participants. |

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<tr>
<td>Veehof et al (2008a)</td>
<td>Randomised controlled trial Aim: to investigate the efficacy of wrist working splints after a period of splinting in people with RA Four-week RCT among 33 people with RA and wrist arthritis Single outpatient clinic and selected by the rheumatologist Inclusion: recognised diagnosis of RA; signs of active arthritis of wrist due to RA; painful wrist; stable drug regimen and no anticipated changes in four-week period Exclusion: recent injection of corticosteroid; severe deformities; wearing a pre-existing splint; carpal tunnel syndrome or other neurological deficit Intervention group of 17 participants Male: female ratio = 5:12 Mean age (SD) = 60.3 years (10.8) Mean disease duration = 8.2 years (6.8) Control group of 16 participants Male: female ratio = 5:11 Mean age (SD) = 55.1 years (12.8) Mean disease duration = 5.0 years (4.6) Netherlands.</td>
<td>Intervention group: commercially available prefabricated wrist splint fitted for more affected wrist by an occupational therapist Wrist extension 10–20° Choice of four different splints, all with fabric gauntlet and removable volar metal stay – choice provided to enhance fit Requirement to wear the splint as much as possible, especially during activities, and to keep a daily diary Educational and behavioural strategies were applied Control group: received usual care, though were offered a splint on conclusion of the study.</td>
<td>Baseline and after 4 weeks Primary outcome: Wrist pain – VAS (100 mm) Secondary outcome: Grip strength – dynamometer (Vigorimeter) Functional ability – DASH and short version of SODA (SODA-S) Tests for performance were conducted without the splint Participants’ perceived changes: 5-point scale, at end of the four-week trial period.</td>
<td>Mean duration of wear (SD) = 11.4 hours per day (2.5) Pain: intervention group score decreased by 32% after 4 weeks but increased by 17% in the control group. The effect size (Hedges’ g = 1.24) indicated a large treatment effect on VAS-measured pain (p = 0.002) Pain on function: SODA-S results found activities painful to undertake decreased by 30% in the intervention group compared to 6% in the control group. This was not significantly different in the two groups, therefore small treatment effect (Hedges’ g = 0.45) Grip strength: no significant differences and small treatment effect. Mean grip strength scores slightly increased in intervention group Functional ability: DASH and SODA-S slightly improved in both groups; no significant differences and treatment effect small (Hedges’ g ≤ 0.34) Participant-perceived changes: significant difference in splinted group, who perceived their pain and function to have improved compared to the control group (p &lt; 0.01) Little harm likely; low-cost intervention.</td>
<td>Grade B – Moderate Downgraded from A due to limitations: Sample size too small to offer statistical significance and did not meet the required power calculations for the primary outcome measure selected Selection of wrist with more symptoms was interesting – but hand dominance could be important in relation to the outcomes measured Selection by the rheumatologist for trial participation could have introduced bias Non-blinded trial ‘Usual care’ not defined.</td>
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</table>
| Veehof et al (2008b)   | Qualitative study – semi-structured interviews                                             | Fabric working wrist splints interview at home by an independent researcher  | Factors that influence reasons for using splints and limitations regarding them | Factors influencing splint use: majority of participants indicated dependence on the seriousness of their symptoms (pain, swelling, or tingling feelings) | Grade C – Low  
Comments:  
- No ethical approval sought/mentioned  
- No triangulation of results or respondent validation mentioned  
- Splints were provided by rheumatologists, which is usual practice in the Netherlands. May not be usual practice in United Kingdom as splints can be provided by a range of healthcare professionals  
- Length of time the splint had been prescribed before the interview varied from 1–12 months. |
|                        | Aim: to evaluate participant motivations for and perceived barriers to using their wrist working splint |
|                        | Identified through hospital files and contacted by Consultant Rheumatologist               | Mean interval between splint prescription and interview (SD) = 6.0 months (3.5) | Participants’ motivations for, and perceived barriers to, using working wrist splints for RA  
The interview transcripts were analysed using the framework approach. | Reasons to wear splint: reduction of symptoms, wrist support, and immobilisation of the wrist  
Reasons not to wear splint included: reduced functional abilities, activity-related, e.g.: wet or dirty tasks, inconvenience, long drying time, sweating, wear and tear  
Reference was made to side effects: unpleasant feelings such as tingling, or pressure points due to tight fit  
Themes in results:  
- Prescription and knowledge  
- Splint use  
- Advantages  
- Disadvantages  
- Expectations  
- Appearance, comfort and fit  
- Social environment  
Decisions by individuals whether to wear or not wear a working splint are intentional  
Authors have developed educational and behavioural strategies with the aim of increasing adherence to wearing splints. |  |
|                        | 20 of the 57 contacted consented to be interviewed. Two interviews were used as pilot interviews and were excluded from further analysis | Fabric wrist splints – two types used  
16 received a Rolyan® D-ring and 2 participants received a Futuro™ splint. |                                                                                       |                                                                                                                                   |  |
|                        | Inclusion: adult, RA, in receipt of a fabric wrist working splint between 1 and 12 months previously because of pain from wrist arthritis |                                                                                       |                                                                                       |                                                                                                                                   |  |
|                        | Participants = 18                                                                        |                                                                                       |                                                                                       |                                                                                                                                   |  |
|                        | Male: female ratio = 4:14                                                                 |                                                                                       |                                                                                       |                                                                                                                                   |  |
|                        | Mean age (SD) = 56.3 years (16.4)                                                         |                                                                                       |                                                                                       |                                                                                                                                   |  |
|                        | Netherlands.                                                                             |                                                                                       |                                                                                       |                                                                                                                                   |  |

Appendix 5: Evidence tables
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<tr>
<td>Vegt et al (2017)</td>
<td>Multicentre, crossover randomised controlled trial</td>
<td>One orthosis was off-the-shelf, semi-rigid and immobilises the CMC-1 joint (PB)</td>
<td>• Pain measured via a 10-cm visual analogue scale</td>
<td>59 participants completed the study</td>
<td>Grade B - Moderate</td>
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<td>Vect: to compare the Push Ortho Thumb Brace CMC and a custom made orthosis for treatment of primary osteoarthritis of the carpometacarpal joint of the thumb (CMCOA)</td>
<td>Second orthosis was custom-made, rigid and immobilised both the CMC-1 and MCP-1 joint</td>
<td>• Hand function assessed using the Jebsen Taylor Hand Function test, Nine Hole Peg Test (NHPT), key grip, pinch grip and functional Index for Hand Osteoarthritis</td>
<td>There was no significant difference in pain reduction between the two orthoses. Participants reported less pain with both, though it was more significant with the off-the-shelf orthosis (p=0.008)</td>
<td>Downgraded due to: Insufficient washout effects for 2 of the outcome measures, potential recruitment bias, that only people with symptomatic CMCOA who requested treatment were studied, meaning results may not be applicable to all people with CMCOA, and stopping recruitment early on because power calculations suggested large numbers required to detect a difference between the two orthoses.</td>
</tr>
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<td>Recruitment via rehabilitation physicians, plastic and orthopaedic surgeons, rheumatologists and hand therapists across three sites from Sept 2013 – Nov 2014</td>
<td>Participants stratified by radiographic stage, and all used both orthoses for two weeks with a washout period of two weeks</td>
<td>• Satisfaction and preference measured via the Dutch version of the Quebec User Evaluation of Satisfaction with Assistive Technology score</td>
<td>NHPT times improved with both orthoses, but this reduction was significantly greater with the custom made orthosis (2 seconds versus .6 seconds, p&lt;0.001)</td>
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<td>Inclusion: over 18 years of age, diagnosis of primary CMCOA confirmed by clinical history, examination and radiograph of the hand</td>
<td>Coin toss determined which orthosis was worn first</td>
<td>Key grip strength was reduced significantly more with the custom made orthosis (0.9kg versus 0.4kg, p=0.001)</td>
<td>68% preferred the off-the-shelf orthosis, 13% the custom-made and 19% either</td>
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<td></td>
<td>Exclusion: secondary CMCOA, previous surgery for CMCOA, corticosteroid injection in the CMC-1 joint in the preceding 6 months, other local medical conditions that might interfere with the study results, such as rheumatoid arthritis</td>
<td>Neither assessors nor patients were blind to treatment.</td>
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<td></td>
<td>63 participants Male:female ratio=5:11 Mean age=60.1 The Netherlands.</td>
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<td>Wajon and Ada (2005)</td>
<td>Randomised controlled trial</td>
<td>Intervention group: custom-made thermoplastic thumb strap splint plus abduction exercises</td>
<td>Measured by a blinded assessor at weeks 0, 2, and 6</td>
<td>No difference was found between the intervention and control groups in the extent of mean improvement at 2 weeks or 6 weeks for pain, pinch strength or hand function. After 6 weeks of intervention, outcomes had improved with both splint groups. Considered together: Pain had decreased on the VAS by a mean of 2.1 cm (p&lt;0.01). Strength had increased for tip pinch by a mean of 0.6 kg (p&lt;0.01). Hand function improved by a mean of 6.5 points on the Sollerman Test of Hand Function (p&gt;0.01). While both groups improved, neither splint or exercise regimen was superior to the other in participants with trapeziometacarpal OA. Splint and exercise choice may therefore take into account individual requirements such as occupational needs. One participant had to stop the trial as their splint was too painful to wear, but this was not discussed.</td>
<td></td>
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</table>

Grade A – High

Comments:
- No record of compliance during the trial
- Lack of statistical power in the numbers in trial means that results need to be interpreted with caution
- Not long-term enough – only six-week follow-up; a relatively short duration of splint use to draw conclusions of effects of splint alone, but pragmatic to include effect of exercises as well
- Data analysis did not include assessing for normal distribution
- Sollerman Test of Hand Function has a degree of assessor judgement in assigning a score, as tasks have to be achieved using the correct hand grip. |
<table>
<thead>
<tr>
<th>Source</th>
<th>Design and participants</th>
<th>Intervention</th>
<th>Outcomes</th>
<th>Results</th>
<th>Quality and comment</th>
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</table>
  Aim: to assess the level of pain, pinch strength, CMC stability, functional effects, satisfaction and preference after the use of both a prefabricated neoprene splint and a custom-made thermoplastic splint  
  Participants acted as ‘own controls’  
  Inclusion: Stage 1 or 2 OA base of thumb according to Eaton-Littler classification  
  Exclusion: concomitant diagnoses  
  25 participants  
  Male: female ratio 4:2  
  Age range not provided but 21 working and 4 retired  
  Symptoms experienced: 48% less than 6 months  
  20% 6 months–1 year  
  32% 1–5 years  
  United States of America. | Two types of thumb splint:  
  Prefabricated neoprene splint that included the CMC and metacarpophalangeal joint (PFN)  
  Custom-made short opponens thermoplastic (CMT) supporting the CMC joint  
  Worn for one week each, then subjects swapped splints and used for another week  
  Regimen – when symptoms felt in thumb, day or night. | Pain with splint usage (VAS)  
  Pain with pinch testing (VAS)  
  Functional abilities while wearing each splint (self-report rating scale devised by the authors)  
  Satisfaction with splints – splint preference (VAS)  
  CMC joint stability using radiographic imaging techniques in variety of options – i.e. not loaded and no splint, to loaded and wearing both types of splint. | Splints worn on average 8.3 hours per day for the CMT and 9.1 hours per day for the PFN  
  Pain at rest: statistically significant results reached for pain improvement at rest after using PFN compared to the CMT (p=0.019), but both splints provided significant thumb pain relief after wearing (CMC p=0.002, PFN p<0.001)  
  Pinch strength: improvement in strength and pain reduction during pinch greater with the PFN splint (p=0.012 and p<0.002)  
  ADLs: easier with the PFN; more than twice as many participants reported activities were harder with the CMT than the PFN  
  Splint satisfaction: PFN rated higher (p<0.001) on VAS; 72% would prefer PFN for long-term use  
  Radiological: subluxation was better reduced with the CMT (p<0.001) but both better when compared with unsplinted views  
  Splints examined are commonly in use in occupational therapy in United Kingdom  
  Both splints were effective at relieving pain, allowing function and reducing subluxation  
  Participants preferred the PFN splint, and the effects on pain, function and pinch pain were superior. | Grade C – Low  
  Downgraded from A due to limitations:  
  • Potential of reporting bias and imprecise treatment effects due to small sample with short follow-up period  
  • Small population: cross-over design has some benefits but a three-arm trial might have produced more reliable results  
  • Splint order may have influenced splint preference  
  • One splint did not include the MCP, which influenced splint preference  
  • Longer-term use of the splint might have influenced preference  
  • Four pinch trials when examining subluxation may have induced fatigue/pain  
  • Not clear if functional abilities scale was valid for use in OA  
  • Unclear if assessors independent of treatment  
  • Non-controlled study  
  • Small number of participants (25); no power calculations  
  • Very short wearing period of one week and no washout period. |
<table>
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<tr>
<th>Source</th>
<th>Design and participants</th>
<th>Intervention</th>
<th>Outcomes</th>
<th>Results</th>
<th>Quality and comment</th>
</tr>
</thead>
</table>
| Zijlstra et al (2004)  | Cohort study                                                                                                                                                                                                          | Mass-produced silver ring splints (SRS) from the Silver Ring Splint Company in USA | Primary outcome:  
- Dexterity – Sequential Occupational Dexterity Assessment (SODA) 
- Grip strength (air bulb manometer), tip pinch strength (pinch gauge) – only for hands where SRS worn 
- Disease Activity Score (DAS 28) 
- Self-reported hand function – Dutch Arthritis Impact Measurement Scale 2 (AIMS 2) 
- SODA pain score 
Recording of number of hours used in 1st month, and at 3 and 12 months, to report if stopped using and reasons. Satisfaction questionnaire also at 3 months. 
- Measured at baseline (T0), 1 month (T1), 3 months (T2) and 12 months (T3) of SRS use. | Total of 72 SRS supplied: 64 for (PIP) joints and 5 for (DIP) joints of fingers, 3 for IP joint of thumb. Both hands splinted for most patients. Unable to fit satisfactory SRS for 1 or more fingers in 4 participants 
2 participants dropped out because unable to tolerate adverse effects (1 × finger paraesthesia, 1 × rheumatoid nodules). 15 completed 
Dexterity: SODA scores improved by a mean of 9 points. The difference from baseline was statistically significant for participants still wearing their SRS at 3 and 12 months (Wilcoxon’s signed rank test 3 months p=0.005 and 12 months p=0.026) 
Pain: SODA scores showed no significant change 
Grip and pinch: showed no significant change 
Hand and finger function: Dutch AIMS 2 subscale showed slight improvement at 1 month, but this was not statistically significant at 3 and 12 months 
33% of SRS were discarded after 1 year for a number of reasons: inability to tolerate the SRS, paraesthesia, pressure of the splints on bony edges or rheumatoid nodules 
At study conclusion, 11 participants would continue using splint, 2 said not and 2 didn’t know 
Participant satisfaction rating (0-5) of splints: mean score = 3 (indifferent). | Grade C – Low 
Comments:  
- Pilot study only, so small sample size 
- Single centre, single assessor 
- Does not give a breakdown of the medications that participants took over the period of the study, but did include the DAS 28 
- No blinding of assessors 
- No controls or alternative intervention arm. |
Appendix 7: Outline of other evidence for orthoses

The following section outlines some of the other evidence found, but for which the quality or volume did not enable a specific recommendation to be made about the prescription and use of orthoses.

A7.1 Carpal tunnel syndrome

Carpal tunnel syndrome was included as an alternative condition search term in the search strategy, as an adjunct to a rheumatological condition. Twenty-one articles in the first edition’s literature search and 12 in the second edition’s were identified but many specified an inflammatory condition as an exclusion criterion.

The presentation of carpal tunnel syndrome can be short-lived, in which case as inflammation settles, so do carpal tunnel syndrome symptoms. Medication management can be more appropriate, for example the short-term use of non-steroidal anti-inflammatory drugs, or surgical decompression to preserve nerve and muscle function in the long term. Carpal tunnel syndrome pathology in rheumatoid arthritis is due to inflammation in the wrist or flexor synovitis, both of which present a mechanical pressure on the median nerve.

Insufficient evidence was identified regarding the impact of orthoses in carpal tunnel syndrome where there is an underlying inflammatory pathology. A recommendation could not therefore be made. There is evidence that supports the use of wrist orthoses in idiopathic carpal tunnel syndrome, and therefore therapists must make a decision regarding prescription on an individual basis.

A7.2 Trigger finger

The use of orthoses for trigger finger was investigated in studies by Tarbhai et al (2012) and Colbourn et al (2008), both of which were graded as low quality (Grade C).

Tarbhai’s study was a small randomised controlled trial which compared two orthosis designs: one metacarpophalangeal joint (MCPJ) based and one distal interphalangeal joint based. The 28 participants had a variety of underlying pathology, and seven individuals had osteoarthritis. After six weeks there was a statistically significant improvement in pain, and in the severity and frequency of triggering in both groups, but function was not improved. There was no significant difference between the two splints, although the metacarpophalangeal joint orthosis was reported to be more comfortable.

Colbourn’s cohort study involved 28 participants who wore a custom-made thermoplastic splint to limit MCPJ flexion, day and night, for a period of six weeks. Improvements were found in stages of stenosing tenosynovitis, pain and number of triggering events. Grip strength did not significantly change. Adherence was an issue, in that 57% of participants reported that they did not wear the orthosis continuously, and only 35.7% completed the exercises prescribed.

In practice, orthoses may be prescribed prior to other treatments such as steroid injections or surgery.
A7.3 Boutonnière deformity and ulnar deviation

There was insufficient published evidence identified to develop any recommendations with respect to orthotic prescription for the treatment of Boutonnière deformity or ulnar deviation. Some evidence was included in the 2003 splinting clinical guideline (NAROT 2003a), but the limited more recent research findings may reflect changes in the pharmacological management and subsequent reduction in the presentation of these deformities seen as a result of rheumatoid arthritis.
## Appendix 8: Glossary and abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition/Description</th>
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| **ACR**      | **American College of Rheumatology**  
ACR represents over 9,400 rheumatologists and rheumatology health professionals around the world. The ACR offers its members the support they need to ensure that they are able to continue their innovative work by providing programmes of education, research, advocacy and practice support.  
http://www.rheumatology.org/ACR/about/ |
| **ADL**      | Activities of daily living. |
| **Assistive devices** | ‘A variety of implements or equipment used to aid patients/clients in performing tasks or movements.’  
Quick reference dictionary for occupational therapy: Jacobs and Jacobs 2009 |
| **AUSCAN**   | **Australian/Canadian Osteoarthritis Hand Index**  
http://womac.com/auscan  
Information re measures of hand function: Poole 2011 |
| **BAHT**     | **British Association of Hand Therapists**  
BAHT is a registered UK charity and clinical interest group for anyone interested in the rehabilitation of hands. BAHT aims to support members in their professional development as hand therapists, including the progression of specialist knowledge, clinical skills and their understanding of the profession.  
http://www.hand-therapy.co.uk |
| **BAOT**     | **British Association of Occupational Therapists**  
BAOT is the professional body for all occupational therapy staff in the UK.  
http://www.rcot.co.uk |
| **BAPO**     | **British Association of Prosthetists and Orthotists**  
BAPO is the ‘only UK body that represents the interests of prosthetic and orthotic professionals and associate members to their employers, colleague Allied Health Professionals and all groups that are involved in the field of prosthetics and orthotics’.  
Prosthetists are ‘autonomous registered practitioners who provide gait analysis and engineering solutions to patients with limb loss’.  
Orthotists are ‘autonomous registered practitioners who provide gait analysis and engineering solutions to patients with problems of the neuro, muscular and skeletal systems’.  
http://www.bapo.com |
| BHPR Section Council | **British Health Professionals in Rheumatology Section Council**  
BHPR is a committee of the British Society for Rheumatology (BSR) and brings together all the health professions whose major interest lies in the care of people with musculoskeletal conditions. Members come from many professions: nursing, physiotherapy, occupational therapy, podiatry, psychology, social work, medicine, pharmacy and others.  
https://www.rheumatology.org.uk/about-bsr/who-we-are/committees/bhpr-section-council |
|---|---|
| Biologics | Biologics are drugs that have been developed in recent years that can target individual molecules and generally work more quickly than conventional DMARDs. Biologics are prescribed for those individuals who have not responded well to other treatments suitable for their condition.  
Anti-TNF drugs are an example of biologics. The protein, tumour necrosis factor, increases inflammation when excess amounts are present in blood or joints, and therefore anti-TNF drugs target this protein.  
https://www.versusarthritis.org/about-arthritis/treatments/drugs/disease-modifying-anti-rheumatic-drugs-dmards/ |
| Boutonnière | **Boutonnière deformity**  
Condition of the finger characterised by flexion of the PIP joint and hyperextension of the DIP joint.  
Bradley and Adams 2013 |
| CASP | **Critical Appraisal Skills Programme**  
The Critical Appraisal Skills Programme supports the development of skills in the critical appraisal of scientific research, and provides a number of critical appraisal tools to support this activity (CASP 2013).  
http://www.casp-uk.net |
| CI | **Confidence interval**  
‘A way of expressing how certain we are about the findings from a study, using statistics. It gives a range of results that is likely to include the ‘true’ value for the population. A wide confidence interval indicates a lack of certainty about the true effect of the test or treatment - often because a small group of patients has been studied. A narrow confidence interval indicates a more precise estimate (for example, if a large number of patients have been studied).  
The confidence interval is usually stated as ‘95% CI’, which means that the range of values has a 95 in a 100 chance of including the ‘true’ value. For example, a study may state that ‘based on our sample findings, we are 95% certain that the ‘true’ population blood pressure is not higher than 150 and not lower than 110’. In such a case the 95% CI would be 110 to 150.’  
Glossary: http://www.nice.org.uk/website/glossary/glossary.jsp |
<table>
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<tr>
<th>Abbreviation</th>
<th>Definition</th>
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<tbody>
<tr>
<td>CMCJ/TMJC</td>
<td>Carpometacarpal joint/trapeziometacarpal joint.</td>
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<tr>
<td>COPM</td>
<td><strong>Canadian Occupational Performance Measure</strong>&lt;br&gt;The COPM is an evidence-based outcome measure designed to capture a client's self-perception of performance in everyday living, over time.&lt;br&gt;<a href="http://www.thecopm.ca">http://www.thecopm.ca</a></td>
</tr>
<tr>
<td>CTS</td>
<td>Carpal tunnel syndrome.</td>
</tr>
<tr>
<td>Custom-made</td>
<td>An orthosis that is made to individual specifications.</td>
</tr>
<tr>
<td>DASH</td>
<td><strong>Disabilities of the Arm, Shoulder and Hand questionnaire</strong>&lt;br&gt;<a href="http://dash.iwh.on.ca">http://dash.iwh.on.ca</a>&lt;br&gt;Information re measures of adult shoulder function: Angst et al 2011</td>
</tr>
<tr>
<td>DIPJ</td>
<td>Distal interphalangeal joint.</td>
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<tr>
<td>DMARDs</td>
<td><strong>Disease-modifying anti-rheumatic drugs</strong>&lt;br&gt;Pharmacological intervention that alters the underlying disease rather than treating the symptoms. DMARDs slow down the disease and its effect on the joints, with the result that pain, swelling and stiffness are reduced over a period of weeks or months.&lt;br&gt;Conventional DMARDs are a group of drugs which are slow-acting and can take several weeks to work (see also Biologics).&lt;br&gt;<a href="https://www.versusarthritis.org/about-arthritis/treatments/drugs/disease-modifying-anti-rheumatic-drugs-dmards/">https://www.versusarthritis.org/about-arthritis/treatments/drugs/disease-modifying-anti-rheumatic-drugs-dmards/</a></td>
</tr>
<tr>
<td>Dynamometer</td>
<td>An instrument used to measure the maximum isometric strength of the hand and forearm muscles.</td>
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<tr>
<td>EULAR</td>
<td><strong>European League Against Rheumatism</strong>&lt;br&gt;EULAR is the organisation which represents the patient, health professional and scientific societies of rheumatology of all the European nations. EULAR endeavours to stimulate, promote and support the research, prevention, treatment and rehabilitation of rheumatic diseases.&lt;br&gt;<a href="http://www.eular.org">http://www.eular.org</a></td>
</tr>
<tr>
<td>GRADE</td>
<td><strong>Grading of Recommendations Assessment, Development and Evaluation</strong>&lt;br&gt;GRADE is a systematic and explicit methodology to assist in the judgement of the quality and strength of guideline recommendations.&lt;br&gt;<a href="http://www.gradeworkinggroup.org">http://www.gradeworkinggroup.org</a></td>
</tr>
<tr>
<td>Hand function</td>
<td>The ability to use the hand in daily activities.&lt;br&gt;Fowler and Nicol 2001</td>
</tr>
<tr>
<td>HCPC</td>
<td><strong>Health and Care Professions Council</strong>&lt;br&gt;HCPC is the regulator for 16 health professions, including occupational therapists.&lt;br&gt;<a href="http://www.hcpc-uk.org">http://www.hcpc-uk.org</a></td>
</tr>
<tr>
<td><strong>MCPj</strong></td>
<td>Metacarpophalangeal joint</td>
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| **NAROT** | National Association of Rheumatology Occupational Therapists  
NAROT became known as the College of Occupational Therapists Specialist Section-Rheumatology, and more recently the RCOTSS Rheumatology Clinical Forum |
| **Neoprene** | A synthetic rubber with elastic properties that is covered by fabric when used for orthosis fabrication. |
| **NHS** | National Health Service  
The NHS refers to the publicly funded healthcare systems in the UK. |
| **NICE** | National Institute for Health and Care Excellence  
NICE (formerly the National Institute for Health and Clinical Excellence) provides national guidance and advice to improve health and social care.  
http://www.nice.org.uk |
| **NRAS** | National Rheumatoid Arthritis Society  
NRAS provides information and support for people with rheumatoid arthritis and juvenile idiopathic arthritis, their families, friends and carers, and health professionals with an interest in rheumatoid arthritis.  
http://www.nras.org.uk |
| **NRS** | Numeric Rating Scale – Pain  
Gives information on measures of adult pain.  
Hawker et al 2011 |
| **NSAIDs** | Non-steroidal anti-inflammatory drugs. |
| **OA** | Osteoarthritis. |
| **Orthoses** | Plural term for orthosis. |
| **Orthosis** | Externally applied device used to modify the structural and functional characteristics of the neuromuscular and skeletal systems.  
International Organization for Standardization 1989 |
| **Orthotic** | Term used as an adjunctive/descriptive term; i.e. an orthotic department, an orthotic intervention. |
| **Oval-8®** | Thermoplastic three-point orthosis used as an intervention for swan neck deformity.  
Bradley and Adams 2013, p202 |
### p values

**Probability**

‘The p value is a statistical measure that indicates whether or not an effect is statistically significant.

For example, if a study comparing two treatments found that one seems more effective than the other, the p value is the probability of obtaining these results by chance. By convention, if the p value is below 0.05 (that is, there is less than a 5% probability that the results occurred by chance), it is considered that there probably is a real difference between treatments. If the p value is 0.001 or less (less than a 1% probability that the results occurred by chance), the result is seen as highly significant.

If the p value shows that there is likely to be a difference between treatments, the confidence interval describes how big the difference in effect might be.’

Glossary: [http://www.nice.org.uk/website/glossary/glossary.jsp](http://www.nice.org.uk/website/glossary/glossary.jsp)

### Pinch gauge

An instrument that measures finger pinch strength.

### PIPJ

Proximal interphalangeal joint.

### Prefabricated

An orthosis manufactured in advance and ready to be fitted to an individual.

### RA

Rheumatoid arthritis.

### RCT

**Randomised controlled trial**

‘A study in which a number of similar people are randomly assigned to two (or more) groups to test a specific drug or treatment. One group (the experimental group) receives the treatment being tested, the other (the comparison or control group) receives an alternative treatment, a dummy treatment (placebo) or no treatment at all. The groups are followed up to see how effective the experimental treatment was.

Outcomes are measured at specific times and any difference in response between the groups is assessed statistically. This method is also used to reduce bias.’

Glossary: [http://www.nice.org.uk/website/glossary/glossary.jsp](http://www.nice.org.uk/website/glossary/glossary.jsp)

### RCOT

**Royal College of Occupational Therapists**

The College of Occupational Therapists is a wholly owned subsidiary of BAOT and operates as a registered charity. The College sets the professional and educational standards for the occupational therapy profession and represents the profession at the national and international levels.

[https://www.rcot.co.uk/about-us/governance/how-we-are-run](https://www.rcot.co.uk/about-us/governance/how-we-are-run)

### RCOT Rheumatology Clinical Forum

**Royal College of Occupational Therapists Rheumatological Clinical Forum**

The Rheumatology Clinical Forum is part of the RCOTSS—Trauma and Musculoskeletal Health and is the forum for occupational therapists working in or with an interest in Rheumatology and musculoskeletal health.

<table>
<thead>
<tr>
<th><strong>RCOTSS-Trauma and Musculoskeletal Health</strong></th>
<th><strong>Royal College of Occupational Therapists Specialist Section-Trauma and Musculoskeletal Health</strong></th>
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<tr>
<td>RCOSS-Trauma and Musculoskeletal Health is a branch of the College. It provides professional and clinical information on all aspects of occupational therapy practice related to trauma, orthopaedics and rehabilitation, including amputees.</td>
<td><a href="https://www.rcot.co.uk/about-us/specialist-sections/trauma-and-musculoskeletal-rcot-ss">https://www.rcot.co.uk/about-us/specialist-sections/trauma-and-musculoskeletal-rcot-ss</a></td>
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</tbody>
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| **ROM** | **Range of movement.** |
| **SIGN** | **Scottish Intercollegiate Guideline Network** |
| SIGN develops evidence-based clinical practice guidelines for the National Health Service (NHS) in Scotland. | [http://www.sign.ac.uk](http://www.sign.ac.uk) |

| **SODA/SODA-S** | **Sequential Occupational Dexterity Assessment** |
| SODA-S is the shortened version of this assessment. | Lankweld et al 1996 |

| **Spica orthosis** | **Orthosis used to immobilise the thumb and/or wrist.** |
| **Splint** | **See orthosis.** |

| **SRS** | **Silver ring splint** |
| A bespoke orthosis made of silver as an intervention for swan neck deformity. | Bradley and Adams 2013, p197 |

| **Swan neck deformity** | **Condition of the finger characterised by hyperextension of the PIP joint and flexion of the DIP joint.** |
| Bradley and Adams 2013 | |

| **Thermoplastic** | **A material that becomes soft when heated, can be moulded and becomes hard when cooled.** |

| **Thumb base OA** | **First carpometacarpal joint with or without scapho-trapezoid joint osteoarthritis.** |
| Zhang et al 2009 | |

| **Trigger finger** | ‘A phenomenon in which the movement of a finger is halted momentarily in flexion or extension and then continues with a jerk.’ |
| Anderson 2002 | |

| **Ulnar deviation** | **Deviation of the MCPJ due to capsular attenuation and joint destruction.** |
| Bradley and Adams 2013, p196 | |

| **VAS** | **Visual Analogue Scale** |
| A VAS is a continuous scale, consisting of a horizontal or vertical line (usually 10cm in length), which is anchored by two verbal descriptors that describe extremes of a symptom, for example pain intensity. | Hawker et al 2011 |
| **Versus Arthritis** | **Versus Arthritis, formed in 2018, is a charity that funds high-quality research, educates healthcare professionals, lobbies government, and provides information to people with arthritis, and their carers. It builds upon the legacies of Arthritis Research UK and Arthritis Care.**  
**https://www.versusarthritis.org** |
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<tr>
<td><strong>Washout period</strong></td>
<td><strong>The period during a clinical study when the participants do not receive any treatment that is under investigation.</strong></td>
</tr>
<tr>
<td><strong>Wearing regimen</strong></td>
<td><strong>The frequency and duration of suggested orthosis wear.</strong></td>
</tr>
</tbody>
</table>

All websites in the glossary were accessed on 01.08.19.
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All websites in these references were accessed on 13.08.2019 unless otherwise indicated.