Hand and wrist orthoses for adults with rheumatological conditions

Practice guideline for occupational therapists

College of Occupational Therapists
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Hand and wrist orthoses for adults with rheumatological conditions

Practice guideline for occupational therapists

College of Occupational Therapists

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Specialist Section Rheumatology
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NICE has accredited the process used by the College of Occupational Therapists to produce its practice guidelines. Accreditation is valid for five years from January 2013 and is applicable to guidance produced using the processes described in the Practice guidelines development manual 2nd edition (2011). More information on accreditation can be viewed at www.nice.org.uk/accreditation.
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Notes: The term ‘service user’ is used within this document to refer to adults with rheumatological conditions.

This guideline was developed using the processes defined within the Practice guidelines development manual (College of Occupational Therapists [COT] 2011a).

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

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 2013a) 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 service user.

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 College of Occupational Therapists’ Practice guidelines development manual (COT 2011a). 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). It is strongly advised that readers study section 10 to understand the guideline methodology, together with the evidence tables in Appendix 5, to be fully aware of the outcome of the literature search 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.

It is important to note that while the evidence includes research published since 2004, participants with rheumatoid arthritis recruited to some of these studies may not have had access to current biological therapies. While only that proportion of service users 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 service user outcomes.
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 systematic 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 service users.

While the recommendations for rheumatoid arthritis and osteoarthritis cannot be extrapolated to other inflammatory conditions, the recommendations for optimising service user outcomes 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 service users 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 service user values and preferences; the majority of service users 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**

<table>
<thead>
<tr>
<th>Functional wrist orthoses</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. It is recommended that a functional wrist orthosis should be prescribed for service users experiencing wrist pain as a result of rheumatoid arthritis. (Haskett et al 2004 [B]; Pagnotta et al 2005 [C]; Ramsey et al 2014 [A]; Thiele et al 2009 [C]; Veehof et al 2008a [B])</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Resting/night orthoses</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. It is suggested that where a night or resting orthosis is being considered as potentially beneficial to reduce symptoms for a service user 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])</td>
</tr>
</tbody>
</table>

**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. (Spicka et al 2009 [D]; van der Giesen et al 2010 [D]; van der Giesen et al 2009 [C]; Zijlstra et al 2004 [C]) |
### Key recommendations

**Osteoarthritis: base of thumb orthoses**

#### Orthoses to reduce pain and/or improve function

4. **It is recommended** that an orthosis should be prescribed for service users 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.


**Optimising service user outcomes**

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


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 service user choice.


8. **It is recommended** that to optimise adherence to wearing a prescribed orthosis, the occupational therapist should discuss with the service user 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.

(de Boer et al 2008 [C]; Gooberman-Hill et al 2013 [D]; McKee and Rivard 2004 [D]; Veehof et al 2008b [C])

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). Chronic pain, experienced as a result of musculoskeletal conditions, can have a significant impact on an individual including their activities of daily living, work, social and leisure activities (Hammond et al 2008, p158).

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. The National Audit Office in 2009 reported that rheumatoid arthritis costs the NHS an estimated £5.6 billion a year in healthcare costs, with the majority of this in the acute sector (National Audit Office [NAO] 2009, p5). Similar estimates (£5.2 billion) have been identified for osteoarthritis, reflecting particularly the cost of hip and knee joint replacements (Oxford Economics 2010, p15). The report ‘The economic costs of arthritis for the UK economy’ estimates that the indirect costs of arthritis (osteoarthritis and rheumatoid arthritis) on society are £14.8 billion. This includes the cost of permanent retirement, absenteeism, reduced productivity and informal care (Oxford Economics 2010, p24). When indirect costs are added to direct costs (hospital and other medical care), and ‘quality of life’ costs, the total cost of arthritis is estimated at £30.7 billion per annum (Oxford Economics 2010, p28).

This 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. Intervention provided by occupational therapists working in rheumatology, therefore, commonly includes the consideration of wrist and hand-based orthoses.

The College of Occupational Therapists Specialist Section-Rheumatology (COTSS-Rheumatology), formerly called the National Association of Rheumatology Occupational Therapists (NAROT), developed a series of clinical guidelines in 2003, including one on 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.

COTSS-Rheumatology carried out a membership survey in 2007 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 service users' 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 College of Occupational Therapists’ NICE accredited process (COT 2011a).

1.2 Topic identification process

The COTSS-Rheumatology 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 COTSS-Rheumatology newsletter.

NICE has accredited the process used by the College of Occupational Therapists to produce its practice guidelines. Accreditation is valid for five years from January 2013 and is applicable to guidance produced using the processes described in the Practice guidelines development manual 2nd edition (COT 2011a).

A guideline project proposal was developed by COTSS-Rheumatology and this was subsequently approved by the College of Occupational Therapists’ Practice Publications Group in November 2013.

1.3 National context: rheumatology statistics

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 2015).

Osteoarthritis is the most common form of arthritis, and 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 National Audit Office estimated in 2009 that 580,000 people had rheumatoid arthritis (NAO 2009, p5) which, when extrapolated, is approximately 690,000 people in the UK population. Rheumatoid arthritis is the most common inflammatory arthritis, with prevalence being two to four times greater in women (1.16%) than men (0.44%) (Symmons et al 2002). The involvement of the wrist and metacarpophalangeal joints is approximately 90% and 95% respectively (Smith 2013).
1.4 Context of service delivery

The number of people aged 60 years or over in the UK is expected to exceed 20 million by 2030, with the number of people aged 65 and over being projected to rise by 48.7% in the next 20 years to over 16 million. Furthermore, the number of people over 85 years of age in the UK is predicted to double in the next 20 years and nearly treble in the next 30 years (Age UK 2014, Office for National Statistics 2013). Prevalence of long-term/chronic conditions increases with age, and the growth in the number of people with long-term conditions impacts further on the health and social care systems across the UK (Department of Health 2013, Department of Health, Social Services and Public Safety [DHSSPSNI] 2012, Scotland. Scottish Government 2013, Wales Audit Office 2014).

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 a number of clinical pathways, one of which is for musculoskeletal conditions. The musculoskeletal pathway identifies a number of sub-pathways, and there are NICE pathways for both rheumatoid arthritis and osteoarthritis (NICE 2014a).

The commissioning and delivery of services in England and Wales is expected to take into account the clinical guideline (NICE 2013a) and quality standard for rheumatoid arthritis (NICE 2013b), and the clinical guideline for osteoarthritis (NICE 2014b). 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 takes into account factors such as comorbidities, and risks and benefits of treatment options, are also pertinent to this guideline.

The rheumatoid arthritis clinical guideline (NICE 2013a) highlights the importance of the multidisciplinary team, with a recommendation that:

*People with RA 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 1.3.1.1] (NICE 2013a, p10)

The NICE quality standard for rheumatoid arthritis further states that a rheumatology service comprises a specialist multidisciplinary team including consultant rheumatologists, nurse specialists, physiotherapists, occupational therapists, podiatrists and orthotists, all with expertise in managing rheumatoid arthritis (NICE 2013b, p11).
The Scottish Intercollegiate Guideline Network (SIGN 2011) highlights the importance of the multidisciplinary team, and a useful perspective on the context of service delivery for rheumatoid arthritis was summarised in a needs assessment undertaken by the Scottish Public Health Network:

*Scotland needs to prioritise specialist early management of RA given the current evidence that this improves outcomes. This needs to be balanced with ensuring that the needs of those with ongoing chronic disease are met and ensuring that the needs of an ageing population are met. Whilst the costs of investing in the development of RA services can be seen as high, the current cost pressures are unlikely to be contained without the application of the 'invest to save' principle.*

(Scottish Public Health Network 2012, p16)

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 departments across the country take on large numbers of referrals per year and a significant proportion are specifically for orthotic interventions (Benharoch 2013, Tougher 2013). Orthotic intervention continues to be a core element of rheumatology occupational therapy practice (Mountain 2007).

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 as a consequence 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.

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 (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 (Arthritis Research UK 2012).

A systemic disease, rheumatoid arthritis can affect the whole body, including the lungs, heart and eyes (NICE 2013a), and the person may also be more susceptible to neurological conditions, such as carpal tunnel syndrome (Smith 2013).

A key symptom of rheumatoid arthritis is joint pain; this may be worse at night and early in the morning or after periods of prolonged or intense activity. Swelling and stiffness are also features, and general malaise and fatigue may also be present (Luqmani et al 2009). 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).

People with long-standing rheumatoid arthritis, or those who present late to clinical services, may develop joint deformities including wrist fusion, deviation of the carpometacarpal and metacarpophalangeal joints, and finger deformities, namely Boutonnière and swan neck. Thumbs may also become Z-shaped (Smith 2013).

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.

Newer biological therapies, such as anti-tumour necrosis factor drugs [Anti-TNFα], have made an impact on rheumatoid arthritis and, for some people who have not responded well to other pharmacological treatments, these have ‘revolutionised the disease pathway’ (McArthur et al 2013). Functional improvement may not, however, be without challenges, and research has highlighted the need for the availability of focused occupational therapy involvement to maximise the potential for occupational gain (McArthur et al 2014).
2 The occupational therapy role

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

*Occupational therapists view people as occupational beings. As occupational beings, people are intrinsically active and creative, needing to engage in a balanced range of activities in their daily lives in order to sustain health and wellbeing. People shape, and are shaped by, their experiences and interactions with their environments. They create identity, purpose and meaning through what they do and have the capacity to transform themselves through conscious and autonomous action.*

*The purpose of occupational therapy is to enable people to fulfil, or to work towards fulfilling, their potential as occupational beings. Occupational therapists promote activity, quality of life and the realisation of potential in people who are experiencing occupational disruption, deprivation, imbalance or isolation. We believe that activity can be an effective medium for remediation, facilitating adaptation and re-creating identity.*

*(College of Occupational Therapists 2014a, p2)*

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.* (National Clinical Guideline Centre 2014, Section 8.6.5)

The NICE clinical guideline for rheumatoid arthritis (NICE 2013a) likewise 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 1.3.1.4)

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. A review of the literature on the use of hand and wrist static orthoses for individuals with rheumatoid arthritis (Adams et al 2005, p85) identified that the rationale for orthotic prescription was based on a range of potential outcomes:

- To rest and immobilise weakened joint structures and decrease local inflammation.
- To position joints correctly.
- To minimise contractures of the joint.
- To increase joint stability.
- To relieve pain.
- To improve hand function.

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, service user management, 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 service users with multiple pathologies, or those with cognitive or emotional disorders, dementia and learning disabilities. Where a service user requires assistance to understand the potential benefits, risks and wearing regimen, or assistance to don/doff their recommended orthosis, the occupational therapist, with the service user’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 provision of services (Marmot 2010, p15). Inequalities may be present in accessing services (e.g. referral systems); provision of orthoses (e.g. self-purchase requirements); accessible service user information (e.g. language used); ensuring a service-user-focused approach to 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 a service user 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 Advisory Fitness to Work Report (Allied Health Professions Federation 2014), and/or the service user 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 service user 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 Arthritis Research UK, the National Rheumatoid Arthritis Society and Arthritis Care. These include user-friendly leaflets on the role of occupational therapy in overcoming everyday difficulties; for example, *Independent living and arthritis* (Arthritis Care 2010) and *Splints for arthritis of the wrist and hand* (Arthritis Research UK 2011).

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 service user.

Occupational therapy staff must work alongside other professionals in accordance with local service arrangements to ensure the needs of the service user 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 a service user’s journey along the rheumatology care pathway.

It is intended that occupational therapists use this guideline to inform their work with service users, 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] 2012).
- Code of ethics and professional conduct (COT 2015a).
- Professional standards for occupational therapy practice (COT 2011b).

Occupational therapists should also be familiar with their relevant country-specific policy documents and performance measures, and cognisant of the following guidelines (note the clinical guideline development processes for the National Institute for Health and Care Excellence (NICE) and the Scottish Intercollegiate Guideline Network (SIGN) have been NICE Accredited):

- Osteoarthritis. Care and management in adults (NICE 2014b).
- Rheumatoid arthritis. The management of rheumatoid arthritis in adults (NICE 2013a).
- Quality standard for rheumatoid arthritis (NICE 2013b).
- Top ten quality standards for RA (British Society for Rheumatology 2012).
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 service user’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 tables in Appendix 5 adopt, however, 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 service user. A person-centred perspective underpins occupational therapy practice, and
intervention must be compatible with the service user’s preferred outcomes or, where appropriate, in their best 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 service user 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:
• Service user satisfaction.
• 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 service user specific, 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 are 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.
• There are no exclusions for severity of the rheumatological condition or for comorbidities; however, each service user 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 (Helders 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.

• 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 service users.

• 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.

• 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).

• Service users 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 and 10.

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 service user outcomes.

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 service user feedback obtained during the guideline consultation has been used to provide a user perspective as an adjunct to the published evidence (see section 5.3).

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 service users would want to, or should, receive the course of intervention or action stated. The other four recommendations were conditional; that is, the majority of service users 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 5).

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
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

5.1.1 Introduction
The National Association of Rheumatology Occupational Therapists (NAROT) (2003a) splinting clinical guideline provided some key contextual information, much from seminal texts, about the prescription of orthoses for rheumatoid arthritis.

Falconer (1991) stated ‘the rationale for splinting an acutely inflamed joint is both biomechanical and physiological. By externally supporting, positioning and restricting the motion of the inflamed joint, the splinting reduces pain, stress, and deformity caused by abnormal muscle action, positional factors and external loads’ (NAROT 2003a, p2).

An orthosis provided for an individual 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. Melvin (1989) described a resting orthosis as ‘a static volar orthosis that restricts motion by preventing flexion of the wrist, thumb and fingers and maintains the joints in a functional position’ (NAROT 2003a, p2).

People with rheumatoid arthritis are also prescribed and provided with functional wrist orthoses. ‘In contrast to resting splints, these are designed to enable the user to continue to function, while reducing pain and providing support for the wrist’ (NAROT 2003a, p22).

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 (NAROT 2003a, p11). 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 service user 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). Occupational therapists will work with service users who may have a range of symptom presentation: those whose symptoms are more effectively controlled and those, often
Recommendations and supporting evidence

older people, whose joint deformity and instability pre-date more recent management options (Bradley and Adams 2013, pp194–195).

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

<table>
<thead>
<tr>
<th>Functional wrist orthoses</th>
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<tbody>
<tr>
<td><strong>1. It is recommended</strong> that a functional wrist orthosis should be prescribed for service users experiencing wrist pain as a result of rheumatoid arthritis.</td>
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<tr>
<th>Resting/night orthoses</th>
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<tr>
<td><strong>2. It is suggested</strong> that where a night or resting orthosis is being considered as potentially beneficial to reduce symptoms for a service user with rheumatoid arthritis, both subjective and objective measures are used for the monitoring and review of effectiveness.</td>
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<tr>
<td><em>(Adams et al 2008 [B]; Silva et al 2008 [A])</em></td>
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<tr>
<th>Orthoses for swan neck deformity</th>
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<td><strong>3. It is suggested</strong>, 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.</td>
</tr>
<tr>
<td><em>(Spicka et al 2009 [D]; van der Giesen et al 2010 [D]; van der Giesen et al 2009 [C]; Zijlstra et al 2004 [C])</em></td>
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5.1.2 Functional wrist orthoses

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.

This study, in which participants reported a preference for any of the orthoses over no orthosis, also demonstrated improvements being maintained at six months. The cost of the leather wrist orthosis (including fitting and participant instruction) was two to three times greater than for the other two orthoses. While pain reduction and participant
Recommendations and supporting evidence

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

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.

The study 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 service user their individual occupational performance needs and
 activities, to ensure that the prescription of an orthosis and daily wearing regimen
 ‘maximises benefit and minimises inconvenience’.

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. Strategies previously developed to increase adherence
 to wearing regimens (Veehof et al 2008b) were incorporated into this study.

There was a clinically significant improvement in pain reduction in favour of the
 intervention group. Pain scores reduced by 32% in the orthosis group compared to 17%
 in the control group. 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.

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,
 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. The superiority of the leather wrist orthosis for pain relief

A recent 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 a service user 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.

**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
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 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 were not researched. Participants with early rheumatoid arthritis did not, however, obtain the same improvement in outcomes as determined by objective measures, although where the orthosis was used there was perceived effectiveness by participants.

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

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). 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.

Adverse effects were highlighted in the study: two participants dropped out, while 33% of the silver ring splints were discarded after one year. Reasons included intolerance of the orthosis, pressure of the splints on bony edges, rheumatoid nodules and paraesthesia. Silver ring splints were identified as being potentially less acceptable for long-standing finger deformities due to the degree of force needed to correct them, but had the ability to improve dexterity in selected individuals. It should also be noted that, given the publication date of 2004, the participants are unlikely to have had the opportunity to receive many of the current biological therapies, so they may not be fully representative of the current rheumatoid arthritis population.

Spicka et al (2009) 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. This small-scale UK study (n=8) provided only tentative findings but, while not powered to detect significant differences, suggested that hand dexterity and grip may show a trend towards improvement when silver ring splints are worn.

A randomised cross-over trial undertaken in the Netherlands with 50 participants with swan neck deformity (van der Giesen et al 2009) 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. The researchers suggested the decision regarding orthosis prescription can be based on preference and/or cost, given the comparable effectiveness of both orthoses on dexterity and dexterity-related pain.

Van der Giesen et al also performed a qualitative study to further explore hand function difficulties and influences on the selection of either the silver ring splint or the commercial thermoplastic orthosis (van der Giesen et al 2010). 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.

**Evidence overview**
Some evidence exists to support prescription of an orthosis to improve dexterity where correctable swan neck deformity exists for people with rheumatoid arthritis. Impact on other dimensions, such as dexterity-related pain and function, is weaker.

Inherent with the use of silver ring splints or Oval-8® ring orthoses is the potential for some adverse side effects, and the range of both positive and negative factors influencing choice should be considered as part of the orthotic prescription process. The recipients of an orthosis for swan neck deformity need to be carefully selected, as factors such as long-standing deformity may mean an orthosis is not tolerated.

### 5.2 Osteoarthritis: base of thumb orthoses

#### 5.2.1 Introduction
The American College of Rheumatology (ACR) guideline for osteoarthritis (Hochberg et al 2012) recommends that individuals with osteoarthritis involving the thumb carpometacarpal (trapeziometacarpal) joint should be provided with an orthosis. Further conditional recommendations are made in the context of individuals with hand 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 11 recommendations for the treatment of hand osteoarthritis based on a combination of research-based evidence and clinical expertise (Zhang et al 2007). The recommendation specific to orthoses is that ‘splints for thumb base osteoarthritis to prevent/correct lateral angulation and flexion deformity are recommended’ (Zhang et al 2007, p382).

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).
Osteoarthritis: base of thumb orthoses

### Orthoses to reduce pain and/or improve function

4. **It is recommended** that an orthosis should be prescribed for service users 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.


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

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.

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, highlighting that it is therefore realistic to take into account the individual’s occupational needs and perceptions when making a decision about the specific choice of orthosis or exercise regimen.

A systematic review (Egan and Brousseau 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
Recommendations and supporting evidence

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.

**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. The 40 participants all 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 the inclusion criteria. 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, in 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. Adherence and satisfaction were high, and no adverse effects were reported.

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.
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 (AUSCAN) 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 contributory impact of thumb orthoses cannot be isolated or identified within this study, but it does provide some indicative contributory evidence of improvement on function.

A systematic review was also 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 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.

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, that improvement having been continuous and significant throughout the measurement period. 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; there was also a control group. 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.

A study, with a comparable methodology to the earlier Bani et al (2013a) cohort investigation, 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.

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 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. The study did not measure grip, pinch or hand function at the 12-month follow-up but the core intervention period was the 30-day period, when the wearing regimen was 16 hours a day; the orthosis was intended to be worn only as required, on pain exacerbation, for the follow-up period. 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.
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, have 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 94% of the studies described (50% of those being statistically significant). One study identified no change in pain. The impact of an orthosis on function was considered in 11 studies, 5 (45%) of which 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 referred to in the studies.

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

5.3 Optimising service user outcomes

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 (COT 2014b); 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 (COT 2013) and ensure that what is recorded is measured objectively with as little error as possible, and the highest level of reliability and validity.

The principles of public and patient involvement in research, and the full engagement of service users in their assessment and treatment, are essential to user-focused interventions. Service user involvement is integral to an intervention such as orthotics, where adherence is ultimately within the service user’s control.

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

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<th>Optimising service user outcomes</th>
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<td><strong>6. It is recommended</strong> that validated, standardised assessment and outcome measures are used pre- and post-provision of an orthosis to monitor progress and evaluate effectiveness.</td>
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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 service user choice.

8. **It is recommended** that to optimise adherence to wearing a prescribed orthosis, the occupational therapist should discuss with the service user 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.
   (de Boer et al 2008 [C]; Gooberman-Hill et al 2013 [D]; McKee and Rivard 2004 [D]; Veehof et al 2008b [C])

5.3.1 Measuring outcomes
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, Maddali-Bongi et al 2014).

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

Service user – 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 (van der 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.

### 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.

### 5.3.2 Orthosis design and wearing regimen
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.

Orthosis design for osteoarthritis was examined by Bani et al (2013b). 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. 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)**. 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 **van der 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.

Wearing regimens, as identified within the evidence for rheumatoid arthritis and osteoarthritis, has been highly variable (see evidence tables in Appendix 5). 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 the evidence.

**5.3.3 Service user experiences**
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 service user’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.”

Service user – consultation feedback
De 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 service user in the prescription of an orthosis.

“The 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.”

Service user – consultation feedback

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

“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?”

Service user – consultation feedback

Gooberman-Hill et al (2013) involved service users 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
Recommendations and supporting evidence

design features for the proposed placebo orthosis with a focus on wearability and support.

“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.”

Service user – consultation feedback

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 service user perspectives on the characteristics and experiences of wearing an orthosis. 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 on adherence.

Evidence overview
Research that involves service user perspectives 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 adherence of wearing.

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 are more likely to result in effective outcomes for service users and, by association, more efficient use of occupational therapy service resources.

5.4 Potential impact of the recommendations
5.4.1 Desired outcomes
1. Service users perceive 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 service user's individual 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, service users with diabetes may have less tolerance for an orthosis due to impaired sensation or circulatory impairment. Cognitive ability should also be considered, including the service user'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 adherence 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-adherence with a 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 service users. Potential side effects should, therefore, be discussed with the service user and monitored during the period of intervention.

The service user 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 adherence.

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 service user and carefully assessed and monitored following orthotic prescription (van der 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 service user 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 all service users with differing literacy levels.

It is good practice to not only 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 to the service user.

Difficulty experienced in the ability to don (put on) and doff (take off again) an orthosis is a factor which may contribute to poor adherence to wearing and outcomes. Service users who live alone may have difficulty managing the donning and doffing, 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 service user 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 ring orthosis may only be available for those service users 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 Service user perspectives

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

Service user perspectives are integral to the guideline development process and involvement took place through consultation on the draft scope and draft guideline (see section 9.3).

Service user perspectives were received from five individual ‘expert service users’ and from Arthritis Care Scotland on the draft guideline. Service users 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 service user 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 clumsy. 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/tryed 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.]
“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 by the service user. 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.”
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 service user with a rheumatological condition.

Familiarity with the 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 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 College of Occupational Therapists’ website, and can additionally be accessed via the College of Occupational Therapists’ Specialist Section-Rheumatology webpages.

The guideline has been 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 service user, 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), 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.
Implementation of the guideline

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 service users 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 adherence to wearing regimens, with studies reporting on service user 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 service user 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, 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 (van der 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 guide

The quick reference guide is intended to be used by practitioners as an easily accessible reminder of the recommendations for intervention. 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 guide includes the following:

- Introduction.
- List of the recommendations, their strength, and the quality of the evidence leading to their development.
- Evidence overview.
- Background to the clinical condition.
- Potential impact of the recommendations.

#### 7.3.2 Audit form

It is recommended that occupational therapists use the 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 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 College of Occupational Therapists.

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**Accessing the implementation resources**

The quick reference 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 COT publications section (Practice guidelines) of the College of Occupational Therapists’ website:


The resources can also be accessed via the web pages of the College of Occupational Therapists Specialist Section-Rheumatology (http://www.cot.co.uk/cotss-rheumatology/cot-ss-rheumatology).
8 Recommendations for future research

The review of the evidence within the guideline scope identified a small body of occupational therapy primary research, but confirmed a need for further intervention studies.

‘The effectiveness of occupation-focused interventions continues to be the major priority identified by occupational therapists for research activity’ (COT 2007, p12).

Establishing effectiveness is closely linked to the use of standardised assessments and outcome measures in the provision of services, and to cost-effectiveness studies which support the commissioning of occupation-focused services (COT 2013).

Future research topics identified from the evidence and from the expertise of the guideline development group include:

Economic evaluation

Economic evaluations and health economic data are needed to establish the cost-effectiveness of orthotic interventions, provided by occupational therapists, for adults with rheumatological conditions.

Outcomes and effectiveness

Studies to determine the effectiveness of the use of orthoses across the range of rheumatological conditions and splint types, taking into account factors such as:

• Early versus late stage arthritis.
• Predictive factors.
• Wearing regimen (e.g. intensity, day/night/as required, duration of intervention, adherence, risks, adverse outcomes).
• Orthosis design (e.g. joint positioning and parameters, movement versus stability, technical properties of materials, fabrication).
• Long-term effects of orthoses versus alternative treatments (e.g. steroid injection, surgical intervention, placebo orthoses).
• Standardised assessment tools and outcome measures.
• Review procedures.

Service user perspectives

Exploration of the service user’s experiences, including health benefits, psychological impact and desired outcomes.

The guideline recommendations were developed from evidence where the clinical diagnosis was osteoarthritis or rheumatoid arthritis. Further research is required for
Recommendations for future research

orthotic interventions for those conditions (including trigger finger, Boutonnière and ulnar deviation deformities), but also for other rheumatological conditions, including psoriatic arthritis, systematic lupus erythematosus, scleroderma and carpal tunnel syndrome (where there is an underlying inflammatory pathology). High-quality studies are also required across the range of orthosis types.
9 Guideline development process

Detailed information on the following steps in the guideline development process can be found in the *Practice guidelines development manual* (COT 2011a).

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 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 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 service users obtained outside core group meetings, via consultation with a virtual reference group.

All comments received from stakeholders, service users and end users 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 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 represent service users.
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 COTSS-Rheumatology 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 Service user involvement
9.3.1 Scope consultation with service users
Three organisations/groups with service user links 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 service users, and/or individual expert service user views. 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 service users**

Service user/lay person consultation activities 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, to enhance inclusion of expert service user perspectives, with:

- Individual service user(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 service user outcomes and potential impact of the recommendations. The document was made available to individuals identified within the service user networks, fora or service user organisations, 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 expert service users/lay representatives.

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

Qualitative feedback from service user representatives is quoted alongside the recommendations where applicable. This approach aims to enhance the user perspective as an adjunct to the published evidence.

**9.4 End user consultation**

The primary target group of end users of the guideline are 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 COTSS-Rheumatology via their e-newsletter and website. An article authored by the guideline development group was also published in the COTSS-Rheumatology journal (Squire et al 2014).
9.4.1 Scope consultation with end users
Members of COTSS-Rheumatology 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 College of Occupational Therapists were invited to comment, namely Specialist Sections Trauma and Orthopaedics; 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 end users
A one-month consultation period enabled members of the COTSS-Rheumatology to comment on a draft of the full guideline. The COTSS-Rheumatology 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, end users and external peer reviewers were required to declare any pecuniary or non-pecuniary conflicts of interest, in line with the guideline development procedures (COT 2011a). Service users 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.
9.7 Declaration of funding for the guideline development

This practice guideline was developed by a group led by a Specialist Section of the 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 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 this practice guideline was funded by the College of Occupational Therapists and the College of Occupational Therapists Specialist Section-Rheumatology. The 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 College of Occupational Therapists Specialist Section-Rheumatology 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 College of Occupational Therapists Specialist Section-Rheumatology, but was not a National Executive Committee member so had no direct decision-making relationship with the allocated funding for the project.

The editorial lead for the guideline was a member of staff at the 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, service user representatives, and end users, and were externally peer reviewed. The views of the College of Occupational Therapists have not, therefore, unduly influenced the final recommendations in this guideline.

9.8 College of Occupational Therapists’ appraisal and ratification process

The guideline proposal, scope and final document were all reviewed and subsequently ratified by the College of Occupational Therapists’ Practice Publications Group, in line with the requirements of the Practice guidelines development manual (COT 2011a).

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 (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 2011a).

Table 1: PICO framework

<table>
<thead>
<tr>
<th>Patient (service user), 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>
<tr>
<td>Outcome desired</td>
<td>Optimising occupational performance by improving:</td>
</tr>
<tr>
<td></td>
<td>• Pain.</td>
</tr>
<tr>
<td></td>
<td>• Swelling.</td>
</tr>
<tr>
<td></td>
<td>• Deformity (including hand appearance).</td>
</tr>
<tr>
<td></td>
<td>• Self-efficacy.</td>
</tr>
<tr>
<td></td>
<td>• Dexterity.</td>
</tr>
<tr>
<td></td>
<td>• Sensory symptoms.</td>
</tr>
<tr>
<td></td>
<td>• Grip strength.</td>
</tr>
<tr>
<td></td>
<td>• Range of movement (ROM).</td>
</tr>
<tr>
<td></td>
<td>• Quality of life.</td>
</tr>
<tr>
<td></td>
<td>• Self-management strategies.</td>
</tr>
</tbody>
</table>

10.2 Literature search strategy and outcomes

The literature search was carried out by 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).

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>Federated search</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cumulative Index to Nursing and Health Literature (CINAHL)</td>
<td>20/05/14</td>
</tr>
<tr>
<td>MEDLINE</td>
<td></td>
</tr>
<tr>
<td>Allied and Complementary Medicine (AMED)</td>
<td>Federated search 16/05/14</td>
</tr>
<tr>
<td>PsycINFO</td>
<td></td>
</tr>
<tr>
<td>Social Policy and Practice</td>
<td>15/05/14</td>
</tr>
<tr>
<td>Health Management Information Consortium (HMIC)</td>
<td></td>
</tr>
<tr>
<td>PubMed</td>
<td></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 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 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 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 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 2011a). The grading reflects the research design and the confidence in the research findings.
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>Serous or very serious limitation to study quality.</td>
</tr>
<tr>
<td></td>
<td>Important inconsistencies in results.</td>
</tr>
<tr>
<td></td>
<td>Some or major uncertainty about directness of the evidence.</td>
</tr>
<tr>
<td></td>
<td>Imprecise or sparse data (relatively few participants and/or events).</td>
</tr>
<tr>
<td></td>
<td>High probability of reporting bias.</td>
</tr>
<tr>
<td></td>
<td>Magnitude of the treatment effect is very large and consistent.</td>
</tr>
<tr>
<td></td>
<td>Evidence of a large dose–response relation.</td>
</tr>
<tr>
<td></td>
<td>All plausible confounders/biases would have decreased the magnitude of an apparent treatment effect.</td>
</tr>
<tr>
<td></td>
<td>Only studies with no major threats to validity should be upgraded.</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>
Guideline methodology

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 5).

A summary of the evidence used to develop the recommendations is provided in Table 5.

Table 5: Summary of evidence used to develop the recommendations

<table>
<thead>
<tr>
<th>Quality of evidence</th>
<th>Grading</th>
<th>Characteristics</th>
<th>Confidence</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Moderate</strong></td>
<td>B</td>
<td>Based on randomised controlled trials where there are serious flaws in conduct, inconsistency, indirectness, imprecise estimates, reporting bias or some other combination of these limitations, or from other study designs with special strengths.</td>
<td>True effect likely to be close to the estimate of the effect but there is a possibility that there could be a substantial difference. Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.</td>
</tr>
<tr>
<td><strong>Low</strong></td>
<td>C</td>
<td>Based on observational evidence, or from controlled trials with several very serious limitations.</td>
<td>True effect may be substantially different from the estimate of the effect. Further research is very likely to have an important impact on confidence in the estimate of the effect and is likely to change the estimate.</td>
</tr>
<tr>
<td><strong>Very Low</strong></td>
<td>D</td>
<td>Based on case studies or expert opinion.</td>
<td>Any estimate of effect is very uncertain and may be far from the true effect.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Wrist/hand</th>
<th>Condition</th>
<th>Orthosis</th>
<th>Author</th>
<th>Year</th>
<th>Evidence quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrist</td>
<td>Rheumatoid arthritis</td>
<td>Functional</td>
<td>de Boer et al</td>
<td>2008</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Haskett et al</td>
<td>2004</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Pagnotta et al</td>
<td>2005</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Ramsey et al</td>
<td>2014</td>
<td>A</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Veehof et al</td>
<td>2008a</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Veehof et al</td>
<td>2008b</td>
<td>C</td>
</tr>
<tr>
<td>Wrist</td>
<td>Rheumatoid arthritis and osteoarthritis</td>
<td>Functional</td>
<td>Thiele et al</td>
<td>2009</td>
<td>C</td>
</tr>
</tbody>
</table>
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.
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 service users would want or should receive this course of intervention or action.</td>
</tr>
<tr>
<td>Conditional</td>
<td>2</td>
<td>Risks and benefits are more closely balanced, or there is more uncertainty in likely service user values and preferences.</td>
<td>The majority of service users 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 College of Occupational Therapists).
10.6 Limitations and any potential bias of the guideline

Evidence included in the development of the guideline recommendations was sourced from published, peer reviewed journal articles. Relevant policy documents or grey literature have been referenced within the contextual information where applicable.

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 outcome of the literature search, appraisal, and synthesis of the evidence resulted in 31 papers being used to support the guideline recommendations.

A total of 51.6% of the evidence was derived from high or moderate quality studies:

- Grade A = 25.8% \((n=8)\)
- Grade B = 25.8% \((n=8)\)
- Grade C = 35.5% \((n=11)\)
- Grade D = 12.9% \((n=4)\)

The guideline development group downgraded eight of the studies, initially graded A, due to limitations identified from the appraisal and a resultant lack of confidence in the estimate of the research effect. These decisions and comments on individual studies are noted in the evidence tables (Appendix 5).

A number of studies were appraised which considered orthoses as an intervention for carpal tunnel syndrome. These resulted in some 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. There was also limited evidence identified with respect to orthoses for trigger finger, Boutonnière, ulnar deviation, or for the distal interphalangeal joints in osteoarthritis. This evidence was insufficient to develop a specific recommendation, either to support or refute the prescription of an orthosis. There was limited literature on compression gloves in rheumatological conditions and those known studies fell outside the time limits of this guideline (Hammond et al 2015). Additional information is provided in Appendix 6.

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. Many of the studies were conducted when biological therapies had only just been introduced and, therefore, the impact of these new therapeutics on outcomes in relation to orthotics had not been fully explored.

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 trade
name, 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.

- 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 actually 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, service user comfort, both of which will influence compliance. Information on fitting complications and rejection rates was rarely provided.

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.

The role of the College of Occupational Therapists, and the COTSS-Rheumatology, in the development, authoring and funding of this practice guideline is fully acknowledged (section 9.7). Involvement is inherent because of the organisational structure of the professional body and its relationship with members of the British Association of Occupational Therapists.

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 service users, the valued opinions of the external peer reviewers and occupational therapy end users, and the judicious management of any potential or actual conflicts of interest.
11 Updating the guideline

The National Executive Committee of the College of Occupational Therapists Specialist Section-Rheumatology is responsible for ensuring future review of this guideline, and will provide a focal point for any feedback received on the guideline following its publication.

Occupational therapists have a continuous personal responsibility to keep abreast of occupational therapy specific evidence.

Members of the College of Occupational Therapists Specialist Section-Rheumatology National Executive Committee should discuss any significant developments in evidence relevant to the guideline, which may be identified in the period prior to its formal review.

This practice guideline is scheduled for update by September 2020. The review date may be brought forward, however, if there is significant new evidence which may impact on practice or the guideline recommendations.

Dissemination of information updates will primarily be achieved via the Specialist Section website, newsletter distributions, and any updates on the evidence base presented at the Specialist Section’s national conference.

The wider membership of the British Association of Occupational Therapists will be made aware of any significant developments in the evidence base via the publication OTnews.

*Information about the College of Occupational Therapists Specialist Section-Rheumatology is available at: http://www.cot.co.uk/cotss-rheumatology/cot-ss-rheumatology.*
Appendix 1: Guideline development group

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

Katie McAlarey
- DipCOT
- Clinical Specialist Occupational Therapist in Rheumatology, New Victoria Hospital, Glasgow, Scotland
- Member of: College of Occupational Therapists Specialist Section-Rheumatology; British Health Professionals in Rheumatology; Scottish Society of Rheumatology

Professor Jo Adams
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- Professor of Musculoskeletal Health; Professional Lead for Occupational Therapy, Southampton University
- Member of: College of Occupational Therapists Specialist Section-Rheumatology; British Health Professionals in Rheumatology

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- Clinical Specialist in Rheumatology and Lead Occupational Therapist, North Bristol NHS Trust
- Member of: College of Occupational Therapists Specialist Section-Rheumatology; British Health Professionals in Rheumatology

Sarah Bradley
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- Advanced Practitioner in Hand Therapy, Poole Hospital, Dorset
- Member of: College of Occupational Therapists Specialist Section-Rheumatology; British Health Professionals in Rheumatology; British Association of Hand Therapists

Lucia Ramsey
- BSc(Hons) Occupational Therapy, PgCHEP, AHT
- Lecturer in Occupational Therapy, Ulster University, Jordanstown, Northern Ireland
- Member of: 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: College of Occupational Therapists Specialist Section-Rheumatology; British Health Professionals in Rheumatology; British Association of Hand Therapists
Appendix 2: Acknowledgements

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

1. **Service user 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 (expert service users) responded to the draft guideline consultation:
   - Miss Wendy Spencer
   - Mr William McGinn, Patient and Carer Forum Member
   - Three service users 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, 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, College of Occupational Therapists

5. End users

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 College of Occupational Therapists Library Service
- The College of Occupational Therapists' Practice Publications Group and supporting Officers Julia Roberts, Quality Programme Manager, and Tessa Woodfine, 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, COT 2011a), as follows:

- All members of the core guideline development group were members of the College of Occupational Therapists Specialist Section-Rheumatology.
- 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.
- The co-opted Editorial Lead was an Officer of the College of Occupational Therapists.
- Two of the co-opted critical appraisers were officers of the 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 end users involved in the consultation activity identified their membership of one or more professional organisations or specialist rheumatology-related fora, which included the British Association of Occupational Therapists; College of Occupational Therapists Specialist Section-Rheumatology; 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 service user conflicts of interest declared, other than personal experience of a rheumatological condition(s).

No commercial or financial interests were declared.

The adherence to the 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

### 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>rheumato* OR rheumatism OR arthrit* OR osteoarthritis OR psoriatic arthritis 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 TFCC OR triangular fibrocartilage complex</td>
<td>splint* OR brace* OR bracing OR thermoplastic* OR lycra 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* hand therap*</td>
<td>econom* OR cost* OR financ* OR money OR monies OR saving* OR resource* OR staff*</td>
</tr>
</tbody>
</table>
Table A2: Core databases or platforms

A title/abstractdescriptor 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

<table>
<thead>
<tr>
<th>Database or platform and search date</th>
<th>Cochrane</th>
<th>EBSCO</th>
<th>Ovid</th>
<th>PubMed</th>
</tr>
</thead>
<tbody>
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<td>22/05/14</td>
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<table>
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<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>
</tr>
</thead>
<tbody>
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<td>27</td>
<td>4</td>
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<tr>
<td>Strings: 1 AND 3 AND 4 AND 5</td>
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<td>92</td>
<td>35</td>
<td>198</td>
</tr>
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<td>Strings: 1 AND 2 AND 3 AND 4 AND 6</td>
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<td>10</td>
</tr>
<tr>
<td>Strings: 1 AND 3 AND 4 AND 6</td>
<td>6</td>
<td>21</td>
<td>5</td>
<td>27</td>
</tr>
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<td>Strings: 1 AND 2 AND 4</td>
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<td>295</td>
<td>83</td>
<td>635</td>
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<td>Strings: 1 AND 2 AND 3 AND 4</td>
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<td>22</td>
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</tr>
<tr>
<td>Strings: 1 AND 3 AND 4</td>
<td>45</td>
<td>330</td>
<td>88</td>
<td>599</td>
</tr>
<tr>
<td>Strings: (1 AND 4) OR (2 AND 4) OR (4 AND 5) *</td>
<td>6</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total results</td>
<td>184</td>
<td>871</td>
<td>239</td>
<td>1738</td>
</tr>
<tr>
<td>Removed via platform de-duping and/or filter options (date/language)</td>
<td></td>
<td></td>
<td>412</td>
<td>96</td>
</tr>
<tr>
<td>Total for cleansing/screening</td>
<td><strong>184</strong></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 'cross-reference checking' 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 databases or platforms

<table>
<thead>
<tr>
<th>Database or platform</th>
<th>Fields</th>
<th>Terms</th>
<th>Number retrieved</th>
<th>Date of search</th>
</tr>
</thead>
<tbody>
<tr>
<td>OT SEARCH</td>
<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 ti</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>
</tr>
</tbody>
</table>
| OTDBASE              | Topic search and subtopic terms ti | • 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] | 408 | 13/05/14 14/05/14 |
| ProQuest             | ti OR su                        | String 4 – intervention individual term searches                     | 44               | 10/06/14       |
| Ethos                | ti OR secondary title fields    | String 4 – intervention individual term searches                     | 66               | 02/06/14       |
| Handsearch           | N/A                             | Terms from strings 2, 3, 4                                            | 27               | 15/07/14       |
| COT Library          | All fields                      | String 4 – intervention individual term searches                     | 47               | 13/05/14       |
| Websites             | N/A                             | String 4 – intervention terms and browsing of identified sites  
                     |                                                                  | String 3 – limb-related terms and browsing of identified sites | 73 | 30/04/14 |
# 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>Adams et al (2008)</td>
<td>Randomised controlled trial</td>
<td>Intervention group: static resting splint plus standard occupational therapy intervention</td>
<td>Measures taken at baseline prior to randomisation and at 12 months</td>
<td>Analysis included 56 in intervention group and 60 in control group 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 &gt;48 hours/week 47 (84%) participants perceived splint to be effective; 12 (25.5%) viewed not effective at all Grip: no significant difference in grip strength data between groups or in percentage of change over 12 months Ulnar deformity: no significant differences between groups detected Pain: over 12-month follow-up, ordinal pain levels showed no significant differences. Both groups had identical final pain levels 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 lowered</td>
<td>Grade B — Moderate Downgraded from A due to limitations: • Cannot say that further research is unlikely to change confidence in the treatment effect size and direction Comments: • 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 • 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 • Unexplained discrepancy between high level of participant-perceived effectiveness in those who wore splints and objective outcome measures • Design of splint used in trial ‘followed a moderate intrinsic plus position’ • Results of effectiveness may be confounded by compliance.</td>
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<tr>
<td></td>
<td>Aim: to evaluate the effectiveness of static resting splints in early RA Prospective multicentre single blinded design Eight participating centres, occupational therapy department referrals Inclusion: over 18 years, confirmed diagnosis of RA, duration &lt;5 years Exclusion: hemiparesis, from a vulnerable group, severe cognitive difficulties 120 participants randomised into 2 groups Splinted group data for 56 (97%) Male: female ratio = 14:42 Mean age (standard deviation – SD) = 59.61 years (12.35) Mean disease duration (SD) = 8.64 months (8.96) Control group data for 60 (97%) Male: female ratio = 18:42 Mean age (SD) = 55.22 years (14.62) Mean disease duration (SD) = 12.37 months (13.12) United Kingdom.</td>
<td>Static resting splint of low temperature thermoplastic: Forearm prone position Wrist neutral MCPJ flexion maximum 60° IPJ flexion 30° Thumb mid position, palmar abducted</td>
<td>Control group: standard occupational therapy intervention Written and verbal instruction given regarding wearing times and care of splint Advised to wear during day when resting and when hands are warm, red, tender or swollen, increasing wear by 15 minutes per day. Alternative night wear encouraged to start. Follow-up telephone calls made at 1 week and 1 month by occupational therapist 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.</td>
<td>Secondary outcomes: • Structural impairment—summary scores of the dominant hand MCPJ ulnar deviation deformity (goniometry readings) • Hand function—applied dexterity test (button board) from the Arthritis Hand Function Test • Michigan Hand Outcomes Questionnaire (MHQ) – 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 Compliance – 7-point ordinal questionnaire for estimated hours splint worn per week Perceived effectiveness – 5-point ordinal scale (where 1 = not at all and 5 = very).</td>
<td>•  Grade B — Moderate Downgraded from A due to limitations: • Cannot say that further research is unlikely to change confidence in the treatment effect size and direction Comments: • 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 • 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 • Unexplained discrepancy between high level of participant-perceived effectiveness in those who wore splints and objective outcome measures • Design of splint used in trial ‘followed a moderate intrinsic plus position’ • Results of effectiveness may be confounded by compliance.</td>
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| Bani et al (2014) | Cohort study                                                                           | 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. Wrist and MCP joints left free. Participants were instructed to use orthosis when they experienced symptoms and for ADLs. Orthosis used for maximum of 3 months. | Measures completed at baseline, 30, 60 and 90 days. Pain: VAS (100 mm) Function: Disability of the Arm, Shoulder and Hand (DASH) questionnaire Grip and pinch strength: Jamar® Hydraulic Dynamometer and pinch gauge – average of three scores. | Mean orthosis use: 7.9 hours per day. Pain: decrease observed after 30 days (p=0.003), and continued to improve during treatment with the splint (at 90 days p<0.001). Function: DASH scores significantly improved between baseline and each of the 30-, 60- and 90-day periods (at 90 days <0.001). Grip and pinch strength: after 90 days of using the splint, grip strength and pinch strength were improved compared to baseline (p<0.001). 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. | Grade C – Low Comment:  
• Unclear sampling methods – no information provided on recruitment, therefore unable to make a judgement as to representation and inclusion  
• Small sample size  
• No control group  
• No hand function assessment  
• Limited statistical analysis of results  
• No reference to grade of OA for each participant – could this affect levels of pain, grip strength, level of function?  
• Specific wearing regimens not outlined (e.g. for how long, how often)  
• No discussion of how they measured splint use over the study period, e.g. splint diary  
• Neither subjects nor assessor blinded – unable to, as only one cohort and subjects knew they were using the splint  
• Did not look at any harmful effects/contraindications  
• No mention of any other interventions during this period which may have affected outcomes  
• No reference to compliance, comfort, feedback on splint from participants. |
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<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 Pain: VAS (10 cm) Function: Disability of the Arm, Shoulder and Hand (DASH) Grip strength: Jamar® dynamometer Lateral pinch: Jamar® pinch gauge.</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 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 Grip strength: significant difference compared to baseline after 60 days but not at 30 days Pinch strength: demonstrated significant improvement at all timelines compared with baseline Improvement in pain scores 30 days post wearing of splint and continuous improvement throughout measurement period Grip, pinch and function all improved after 90 days of wearing of orthosis.</td>
<td>Grade C – Low Comments: • No control • Small sample size with no power calculation related to selection of assessments • Irregular presentation of results in tables (p=0.000) compared to text (p&lt;0.001) • No loss to follow-up or data in a study is unusual, but possible with small sample size • Volunteers and no description of how this may affect characteristics • Highly customised splint design, which would be difficult to replicate.</td>
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**Source Design and participants**

Cohort repeated measure study

**Intervention**

- 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
- 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.

**Outcomes**

- Measures completed at baseline, 30, 60 and 90 days
- Pain: VAS (10 cm)
- Function: Disability of the Arm, Shoulder and Hand (DASH)
- Grip strength: Jamar® dynamometer
- Lateral pinch: Jamar® pinch gauge.

**Results**

- Pain: reduced at 30 days (p<0.001), and continued to reduce at 60 days (p<0.001) and 90 days (p<0.001) compared with baseline
- Function: improved at 30 days (p<0.001), and DASH score continued to reduce at 60 days (p<0.001) and 90 days (p<0.001) compared with baseline
- Grip strength: significant difference compared to baseline after 60 days but not at 30 days
- Pinch strength: demonstrated significant improvement at all timelines compared with baseline
- Improvement in pain scores 30 days post wearing of splint and continuous improvement throughout measurement period
- Grip, pinch and function all improved after 90 days of wearing of orthosis.

**Quality and comment**

Grade C – Low

Comments:

- No control
- Small sample size with no power calculation related to selection of assessments
- Irregular presentation of results in tables (p=0.000) compared to text (p<0.001)
- No loss to follow-up or data in a study is unusual, but possible with small sample size
- Volunteers and no description of how this may affect characteristics
- Highly customised splint design, which would be difficult to replicate.
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<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>Measured at baseline and 4, 6 and 10 weeks</td>
<td>Pain: significantly reduced (p=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=0.000) 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 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=0.000) compared to control group. No significant difference between two splints identified 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 Pinch: increased at end of 4 weeks for both prefabricated (p=0.000) and custom-made splint (p=0.001), and also at end of 10 weeks (both p=0.000). No significant difference determined between the two splints In the control group, pain increased and pinch strength decreased, but no statistically significant differences were found in function and grip strength The prefabricated and custom-made splints both reduced pain, with the custom-made splint being more effective. Function and pinch strength also increased, but grip strength was not improved.</td>
<td>Grade A – High 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</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>(2013)</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>
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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></td>
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<tr>
<td></td>
<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>
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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 (PASS)</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>
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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>
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<td></td>
<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>
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<td>119 participants with 62 completing: Male: female ratio = 14:48</td>
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<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>
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<td>Mean age (SD) = 63 years (8.1)</td>
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<td>• Pinch – B&amp;L Engineering® pinch gauge</td>
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<td></td>
<td>United States of America.</td>
<td></td>
<td>• Grip strength – Jamar® dynamometer</td>
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<td>• Ordinal Scale for pain – 0 (no pain) to 10 (worst pain you ever had)</td>
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<td>Satisfaction scale for splint – six 11-point ordinal satisfaction scales asked at follow-up for:</td>
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<td></td>
<td>1) Satisfaction with the splint</td>
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<td>2) How the splint helped in terms of pain</td>
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<td>3) How the splint helped in keeping active, doing daily living activities</td>
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<td>4) If the splint improved quality of life</td>
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<td>5) How comfortable wearing the splint was</td>
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<td>6) How easy it was to follow the hand therapist’s instructions regarding splint use</td>
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<td>A higher score indicated greater satisfaction or help.</td>
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• Baseline (1 week before start of the intervention)  
• 1 week after the 5 week JP programme  
• Follow-up (1 year after the intervention)  
Primary outcome  
• Grip force – Grippit™  
Secondary outcome:  
• ADL difficulties – DASH (work and leisure items not used)  
• Pain and stiffness – VAS (100 mm) for most recent week. | Five dropouts at follow-up so analysis data for 35 participants  
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  
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  
Suggests that adding splinting and exercise to a joint protection programme gives greater improvement of pain, stiffness, grip force and daily activities. | Grade C – Low  
Comments:  
• Not randomised study and no control group/non-splinted group  
• Study does not provide evidence for use of particular splints in thumb OA, but does provide context for their use  
• DASH does not identify fine motor activity problems – common in base of thumb OA  
• Not all constructs of the DASH used, even though 21 women worked and assume all participated in leisure activities  
• SE group had slightly shorter duration of diagnosis  
• Splinting in evaluation group appears to have been day and night except for exercise regimen, but no information apparent regarding compliance or any issues with this regimen  
• Both groups tried elastic thumb spicas during the day as part of the JP programme. |
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- Hand and wrist complaints, ADL, pain, swelling and tingling in the wrist and hand  
- Possession and prescription process  
- Usage – category on 8-point scale of never to always  
- Activities undertaken when wearing the splint (6 categories)  
- Individual reasons for usage and for non-usage  
Questionnaire and clinical assessment:  
- Disease characteristics – Dutch Arthritis Impact Measurement Scale II (AIMS II), Disease Activity Score (DAS28), VAS (100 mm) for pain and fatigue  
- Physical and mental functioning – RAND-36 Health Survey  
- Coping – Coping with Rheumatic Stressors (CORS)  
- Participant satisfaction: Dutch version of Quebec User Evaluation of Satisfaction with Assistive Technology (D-QUEST). | 128 participants possessed a functional wrist splint  
58% (n=74) were using the splint  
54 participants (42%) had not used the orthoses at all  
Activity use: housekeeping activities (39%), cycling/driving (30%), resting (28%), always (20%), work and leisure activities (varying between 2% and 8%)  
Rates of prescription varied among three centres but did not reach statistical significance  
Reasons for use: relief of pain/swelling (n=65/74) and joint protection (n=49/74)  
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)  
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. | Grade C – Low  
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. |
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<td>Egan and Brousseau (2007)</td>
<td>Systematic review&lt;br&gt;Aim: to review the evidence regarding the effectiveness of splinting for CMC OA&lt;br&gt;Inclusion: experimental or observational studies that examined the effects of splinting for OA of the CMC joint in adults&lt;br&gt;Exclusion: splinting post-operatively, splinting used as an adjunct to medical treatments, e.g. corticosteroid injections&lt;br&gt;Wide range of timescales applied from databases used (1962–2006)&lt;br&gt;Seven studies were found to meet the inclusion criteria&lt;br&gt;Used evidence tables to record level of evidence, sample, treatment, dosage, outcome, effect size and threat to internal validity&lt;br&gt;Number of participants varied from 10 to 114, but only one study with above 37&lt;br&gt;Male: female ratio not always stated, but majority or all women&lt;br&gt;Mean age: varied 53.8 to 67.2 years.</td>
<td>Splinting for CMCJ OA.</td>
<td>Depending on the study concerned, the outcomes examined included:&lt;br&gt;• Subsequent need for surgery&lt;br&gt;• Level of pain&lt;br&gt;• Compliance with splint wear&lt;br&gt;• Restriction on activity during splint use&lt;br&gt;• Comparison of different types of splint&lt;br&gt;• Reduction of CMC subluxation&lt;br&gt;• Pinch strength&lt;br&gt;• Participant preference.</td>
<td>Clinical interpretations of the evidence include that splint use appears to:&lt;br&gt;• Decrease pain for many participants&lt;br&gt;• Reduce subluxation on pinch in participants with early OA, so should be encouraged to wear splints during ADLs that cause subluxation&lt;br&gt;• Have no impact on decreasing the eventual need for surgery&lt;br&gt;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&lt;br&gt;An initial period of continual 3–4 weeks of splinting may be beneficial. Splinting can then be according to aggravating ADLs&lt;br&gt;The use of splints during activities promoting CMC subluxation should be encouraged for individuals with Stage I and II OA&lt;br&gt;Effectiveness of intervention for pain relief, alongside its conservative nature and low cost, would indicate splint provision is warranted.</td>
<td>Grade B – Moderate&lt;br&gt;Downgraded from A due to limitations:&lt;br&gt;• 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&lt;br&gt;• Brief description only of each study&lt;br&gt;• Variety of study designs, four with reasonable methodological quality&lt;br&gt;• 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&lt;br&gt;Comments:&lt;br&gt;• All relevant studies were included due to the small number likely to be available in this topic area&lt;br&gt;• 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.</td>
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| Gomes Carreira et al (2010) | Randomised controlled trial  
  Aim: to assess the effectiveness of splinting for the trapeziometacarpal joint in Grades II and III OA  
  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)  
  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, tendonitis, chronic inflammatory arthropathy  
  40 participants from Rheumatology department randomised into intervention or control group  
  Intervention group:  
  Male: female ratio = 0:20  
  Mean age (SD) = 62.8 years (8.5)  
  Mean disease duration (SD) = 6.3 years (3.4)  
  Control group:  
  Male: female ratio = 2:18  
  Mean age (SD) = 65.1 years (10.1)  
  Mean disease duration (SD) = 7.7 (6.1)  
  Brazil. | Custom-made functional thermoplastic splint for trapeziometacarpal stabilisation, made by an occupational therapist, for all participants in both groups  
  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  
  Control group (CG): Splint used only during evaluations for first 90 days, then during ADL for second 90 days. | Measures at baseline, 45, 90 and 180 days (measured while wearing splint and without)  
  Primary outcome:  
  • Pain – VAS (10 cm)  
  Secondary outcomes:  
  • Functional capacity – DASH  
  • Grip strength – Jamar® dynamometer  
  • Pinch strength – pinch gauge  
  • Upper limb dexterity – O’Connor test (with and without splint). | All participants completed trial with no loss to follow-up  
  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  
  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  
  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  
  Function: improvement but not statistically significant in DASH scores  
  Manual dexterity: no statistically significant differences found between groups. IG participants completed the O’Connor test in a shorter time with the splint  
  Concluded that splint use during ADL for this service user group reduces pain, has minimal impact on functional capacity and does not alter grip strength, pinch strength or dexterity. | Grade B – Moderate  
  Downgraded from A due to limitations:  
  • 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)  
  • Only states that the evaluations were carried out by blinded assessor; not clear if the occupational therapist was blind to the treatment  
  Comments:  
  • DASH may not have been responsive enough as a measure  
  • Study population almost entirely female – may limit generalisability of findings  
  • Information not collected on splint adherence, adverse effects, participant experience and opinions of splint wear. |
<table>
<thead>
<tr>
<th>Source</th>
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</thead>
<tbody>
<tr>
<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</td>
<td>• Acceptability of splints</td>
<td>• Use of placebo arm is acceptable</td>
<td>Grade D – Very Low</td>
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<tr>
<td>Recruitment source: service users known to clinical occupational therapists; authors describe service users as research partners, rather than participants</td>
<td>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 service users and project staff</td>
<td>• Wearability – defined by materials, warmth, colour, type of fastenings, appearance</td>
<td>• Findings will inform design of subsequent Delphi exercise and RCT</td>
<td>Comments:</td>
<td></td>
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<tr>
<td>Bristol 6 participants</td>
<td>Interactive discussion between service users and research staff, and the opportunity to try on a range of splints</td>
<td>• Support gained from thumb splints with/without immobilisation</td>
<td>• Future trial will include investigation of acceptability of placebo splint</td>
<td>• Service user project which will inform a Delphi exercise and randomised controlled trial</td>
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<tr>
<td>Male: female ratio = 0:6</td>
<td>Topics covered in session:</td>
<td>• Whether or not placebo arm is an acceptable feature of future trial</td>
<td>• 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</td>
<td>• Small numbers of participants</td>
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<td>Keele 2 participants</td>
<td>• Service users’ experience of OA and of their own thumb splints</td>
<td>• Input to potential design of placebo splint.</td>
<td>• Future trial will include investigation of acceptability of placebo splint</td>
<td>• Limited recruitment sources</td>
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<td>Male: female ratio = 1:1</td>
<td>• Exposure to a number of alternative splints during the session, which they tried on and evaluated</td>
<td></td>
<td>• 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</td>
<td>The two groups were very different sizes and this affects dynamics – one forum contained only two service users</td>
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<td>Age range: 56–72 years</td>
<td>• Service users’ view of the acceptability of placebo arm in future trial</td>
<td></td>
<td>• Future trial will include investigation of acceptability of placebo splint</td>
<td>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</td>
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<td>Disease duration: 9 months to 28 years</td>
<td>• Acceptable and unacceptable design features for proposed placebo splint, with focus on wearability and support.</td>
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<td>• Use of placebo arm is acceptable</td>
<td>Facilitators were not independent, and this may have influenced the service users.</td>
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<td>Inclusion criteria: thumb base OA, thumb splints already prescribed</td>
<td>United Kingdom.</td>
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<td>• Findings will inform design of subsequent Delphi exercise and RCT</td>
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<td>Exclusion criteria: none stated</td>
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<td></td>
<td>• Future trial will include investigation of acceptability of placebo splint</td>
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<tr>
<td>Haskett et al (2004)</td>
<td>Randomised controlled trial</td>
<td>Total trial period 14 weeks plus follow-up visit at 6 months</td>
<td>Assessment at baseline, after each splint phase and washout period, and at 6-month follow-up</td>
<td>Splint wear – average 29 hours per week</td>
<td>Grade B – Moderate</td>
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<td>Aim: to compare the effect of three types of wrist splint on perceived wrist pain, hand function and perceived upper extremity function</td>
<td>Three splint types:</td>
<td>Primary outcome:</td>
<td>Pain: all splints reduced pain (p=0.007) compared with baseline</td>
<td>Downgraded from A due to limitations:</td>
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<td>Recruitment via referral to occupational therapy department in a specialised arthritis treatment centre</td>
<td>• Rolyan® wrist extensor orthosis (RWS prefabricated)</td>
<td>• Pain – VAS (10 cm)</td>
<td>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)</td>
<td>• True blinding not stated and biases may have affected outcomes</td>
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<td>45 participants randomly assigned to treatment in three-phase cross-over trial</td>
<td>• Custom-made leather wrist splint (LWS) Wrist extension 15–20° Ulnar deviation 5°</td>
<td>Secondary outcome:</td>
<td>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&lt;0.02). Pegboard dexterity and lifting were not improved with splint use</td>
<td>Comments:</td>
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<td>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</td>
<td>• Anatomical Technologies elastic wrist support (AWS prefabricated)</td>
<td>• Hand function – Arthritis Hand Function Test (AHFT) – hand strength and dexterity</td>
<td>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</td>
<td>• Small sample size</td>
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<td>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</td>
<td>Each of the splints worn for 4 weeks with separation by one-week washouts</td>
<td>• Perceptions of function – McMaster Toronto Arthritis Patient Function Preference questionnaire</td>
<td>Preference: ranked LWS (most preferred), RWS, AWS</td>
<td>• No confidence levels presented</td>
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<td>Male: female ratio = 6:39 Mean age (SD) = 49.1 years (13.0) Mean disease duration (SD) = 8.6 years (9.2) 78% participants – RA Canada.</td>
<td>Splint to be worn during activities during the day that cause pain or discomfort; minimum of 10 hours per week</td>
<td>Splint use – daily diary record</td>
<td>RWS $58 Canadian dollars (CAD) LWS $100 CAD AWS $30 CAD.</td>
<td>• Large variation at baseline on number of variables</td>
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<td>All splints were fitted by an occupational therapist.</td>
<td>Costs considered: splint, fitting time and service user instructions.</td>
<td>Costs (splint, fitting time and instructions): RWS $58 Canadian dollars (CAD) LWS $100 CAD AWS $30 CAD.</td>
<td>Outcome assessors were independent but unclear if blind</td>
<td>• Not possible to blind participants or practitioners</td>
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<td>• Practical significance of the grip improvements not measured</td>
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<td>• Repeated measures used at assessment at regular intervals (smallest gap 1 week), therefore there may have been a practice effect</td>
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<td>• By the time the third splint was applied there may have been a degree of functional adaptation that could have influenced the results.</td>
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<td>Hermann et al (2014)</td>
<td>Randomised controlled trial</td>
<td>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</td>
<td>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</td>
<td>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.</td>
<td>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/sleep, 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.</td>
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<td>Kjeken et al (2011a)</td>
<td>Randomised controlled trial</td>
<td>Intervention – assistive technology, which includes assistive devices and orthoses or splints</td>
<td>Assessed at baseline (before allocation) and after 3 months</td>
<td>AT group: 34/35 received assistive technology devices, 26 received splints</td>
<td>Grade A – High</td>
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<td></td>
<td>Aim: to evaluate the effect of assistive technology on OA of the hand</td>
<td>Intervention group (AT): received information and assistive devices and/or splints</td>
<td>Primary outcome:</td>
<td>Self-reported assistive technology usage: 92% in the AT group</td>
<td>Comments:</td>
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<td>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</td>
<td>Control group (CG): received information only</td>
<td>• Activity performance and satisfaction with performance – COPM (Canadian Occupational Performance Measure)</td>
<td>Comfort with usage rated as high</td>
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<td>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</td>
<td>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>Secondary outcomes:</td>
<td>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)</td>
<td>• Only two males in the population studied</td>
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<td>Compliance measured via questionnaire as well as including questions re comfort.</td>
<td>The control group had a significant negative effect on COPM performance scores (p=0.005)</td>
<td>The control group had a significant negative effect on COPM performance scores (p=0.005)</td>
<td>• Short-term follow-up only 3 months</td>
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<td>Consecutively recruited via outpatient clinic</td>
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<td>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)</td>
<td>• Occupational therapist carried out the evaluations and participants were not ‘blind’ to treatment but observer was ‘blinded’</td>
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<td>70 participants randomised to either intervention group or control group</td>
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<td>The other secondary outcomes, such as pain and fatigue, demonstrated small and non-significant change.</td>
<td>• Some participants had already had AT devices and splints at baseline</td>
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<td>Intervention (AT) group:</td>
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<td>• Possible harmful effects of assistive technology not investigated.</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 CMCJ 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 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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| 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<0.001), 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<0.001 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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<td>McKee and Rivard (2004)</td>
<td>Case studies</td>
<td>Provision of an orthosis as part of an occupation-focused occupational therapy intervention programme</td>
<td>Self-reported narrative accounts of usefulness</td>
<td>An orthosis must fit into a person's lifestyle. Six essential considerations:</td>
<td>Grade D – Very Low Comments:</td>
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<tr>
<td></td>
<td>Aim: to demonstrate and discuss application of a client-centred, occupation-based practice framework for orthotic intervention</td>
<td>Both orthoses were individually made by the occupational therapist</td>
<td>Client satisfaction and performance by use of Canadian Occupational Performance Measure (COPM).</td>
<td>• 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</td>
<td>• 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.</td>
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<td>All female (3 case studies)</td>
<td>Mildred: ulnar-based thumb interphalangeal orthosis, thermoplastic, Plastazote lining, Velcro® straps and modified glove</td>
<td>Carol: CMC thumb orthosis.</td>
<td>Splinting can improve pain, but author suggests that as well as efficacy of splinting, a client-centred approach is important</td>
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<td></td>
<td>Mildred – 75 years, OA IPJ dominant thumb, pain affecting activities</td>
<td>Use of Canadian Model of Occupational Performance for intervention planning and the associated outcome measure Canada.</td>
<td>Report supported the use of the COPM for intervention planning and outcome measure and encourages use of this tool.</td>
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<td>Lynn – 26 years, spina bifida, foot orthosis</td>
<td>Canada.</td>
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<td>Carol – 60 years, bilateral OA thumb CMCJ</td>
<td>Provision of an orthosis as part of an occupation-focused occupational therapy intervention programme</td>
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<td>Carol: CMC thumb orthosis.</td>
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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 reviews/evidence found  
- Methodological/reporting issues or conflict between some 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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| Pagnotta et al (2005) | Cohort study  
Aim: to identify the influence of wearing a wrist splint on pain, work performance, endurance, perceived task difficulty and perceived splint benefit during the performance of upper limb tasks  
A consecutive sample of individuals admitted for inpatient or outpatient treatment in a Rheumatic Disease Unit  
Inclusion: diagnosis of RA, recently used a prefabricated and commercially available circumferential fabric-type wrist working splint with a palmar metal insert  
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. | 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  
Used the Baltimore Therapeutic Equipment Company work simulator. | • 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)  
• Splint wearing: questionnaire indicating a list of common reasons for wearing or not wearing splint. Each participant was asked to indicate their reasons for wearing the splint and to rank the two most important reasons  
• Disease activity: 4-point rating scale  
• Tenderness: 4-point scale  
• Crepitus: present or absent  
• ROM: Treuhaft hand assessment. | 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)  
Results revealed that for most tasks, there was generally a positive effect of splint use on hand function; however, perceived splint benefit was marginal. The task with greatest overall perceived splint benefit was ‘chopping with a knife’  
Splint use:  
• Improved or did not change pain levels  
• Did not interfere with work performance  
• Increased or maintained endurance  
• Did not increase perceived task difficulty for most tasks  
Subjective reports: in daily use the splint often ‘got in the way’ or made movement ‘cumbersome’. The majority reported not wearing the splint regularly during daily activities  
The primary reason for those who ‘sometimes’ or ‘often’ wore a splint was pain management, but the majority did not use their splints regularly. | 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. |
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<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: • 9 randomised controlled trials • 4 experimental • 3 observational • 5 survey/questionnaire • 2 qualitative studies</td>
<td>Effectiveness defined via most frequently occurring outcomes: • Function • Strength • Pain • Dexterity</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 Moderate evidence that grip strength is improved ($d=0.3-0.4$) but dexterity is impaired Insufficient evidence for the effect on function</td>
<td>Grade A – High Comments: • Wide variation of definitions of ‘function’ across the literature makes comparison difficult • Diversity of outcome measures – and use of standardised and non-standardised outcomes – made comparisons more difficult • Uses informal methods to detect publication bias within results • Caution needed regarding over-interpretation of the results due to use of a narrative analysis • 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>Aim: evaluate effectiveness of working wrist splints in adults with RA 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 Inclusion: qualitative and quantitative studies; effectiveness of working wrist splints in people with RA or the experiences and/or perceptions of service users and/or therapists or carers involved in the provision of working wrist splints to people with diagnosed RA; English language only 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 Participants = 1,492 adults with diagnosed RA Mean age (from 16/23 studies) = 55.5 years Male: female ratio – not stated in all studies Mean disease duration (from 12/23 studies) = 9.3 years Countries of study: not stated.</td>
<td>Meta-analysis could not be carried out due to heterogeneity of studies Used the Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) guidelines, across 10 databases.</td>
<td>Analysis of the data: Narrative approach to synthesis of the data was taken as opposed to a meta-analysis, due to too many differences in the studies regarding settings, interventions and outcomes used Where possible the strength of the effect of change between groups was reported using Cohen’s $d$ effect, with $d=0.2$ small effect size, $d=0.5$ medium effect and $d=0.8$ large effect Meta-ethnographical approach taken to analysing the qualitative data Both approaches then combined in order to compare and contrast the interventions from the quantitative evidence with the qualitative data.</td>
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<td>Rannou et al (2009)</td>
<td>Randomised controlled trial</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. Splints made by occupational therapists and adjustments could be made as required. Control group: usual care.</td>
<td>Primary outcome: • Pain – VAS (0–100 mm) – change from baseline to 1 month • Clinical variables: • Hand disability – Cochin Hand Function Scale – change at 1 month • Perceived disability scores • Perceived global assessment • Pinch strength and pain during pinch – electric dynamometer • Range of motion • Thumb mobility – Kapandji index thumb opposition and counter opposition subscales • Adherence and tolerance Change in pain level and measures of disability measured at 12 months 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 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 ($p=0.003$) 54% of the intervention group and 11% of the control group reported that they had improved ($p=0.001$) at 12 months There were no differences between groups in radiographic progression, or adduction deformity 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 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 90% satisfied with splint at 12 months No adverse effects directly attributed to the splint were reported.</td>
<td>Grade A – High Comments: • Risk of bias associated with lack of blinding, especially participants and assessing therapists • Trial was conducted in a specialist centre using custom-made splints by specialist occupational therapists, so results may not be generalisable to other settings • Cochin Hand Function Scale may lack sensitivity • Neoprene splint looks like x-lite splint in the illustration.</td>
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<td>Sillem 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). 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. Results showed equivalent therapeutic effect on function, grip and lateral pinch. Pain relief was better in the custom-made hybrid splint group. Participants preferred the Comfort Cool™ splint.</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. 30/56 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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| Silva et al (2008) | Randomised controlled trial  
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 service user satisfaction  
Participants recruited sequentially from rheumatology outpatient clinics  
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 >3 and <7 on a visual analogue scale for pain in the more affected hand  
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  
50 participants with RA were randomly divided into 2 groups (25 in each group)  
Intervention group:  
Male: female ratio = 5:20  
Mean age (SD) = 51.64 years (11.4)  
Mean disease duration (SD) = 10.12 years (7.39)  
Control group:  
Male: female ratio = 4:21  
Mean age (SD) = 50.72 years (10.51)  
Mean disease duration (SD) = 9.02 years (6.8)  
Brazil. | Night-time positioning splint, custom-made from thermoplastic and fixed with hook and loop straps  
More affected hand  
Wrist dorsiflexion 10°  
MCPJ flexion 25–30°  
PIPJ flexion 30° and thumb abduction  
Intervention group: night-positioning splint prescribed for use while sleeping  
Control group: the splint was only used during evaluation. | Assessments undertaken at baseline, 45 days and 90 days  
Primary outcome:  
• Pain – VAS (0–10 cm)  
Secondary outcomes:  
• Functional status – Health Assessment Questionnaire (HAQ) in interview form  
• Upper limb disability and symptoms – Disabilities of the Arm, Shoulder and Hand (DASH) administered in interview form  
• Pinch strength – pinch gauge  
• Grip strength – Jamar® dynamometer mean of three measurements was used for analysis  
• Service user satisfaction – Likert scale consisting of 5 answers (much worse, worse, same, better and much better)  
• Diary to record hours of use of splint. | Total of 47 participants included at final assessment  
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<0.001)  
HAQ scores: decreased in the intervention group but remained constant in the control group. A significant difference between groups was shown over time (p<0.005)  
DASH (work): decrease in scores in the intervention group and constant scores in the control group. A significant difference was detected (p=0.011)  
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<0.010)  
Grip strength: intervention group increased strength, while control group decreased. Over the 3 months, the difference between the groups was significant (p=0.04)  
Pinch (key, palmar and tip): showed significant improvement in the intervention group in intra-group analysis compared to the control group  
Mean use of splint: 8 hours per night (SD 1.57). | Grade A – High  
Comments:  
• Control group received no intervention  
• Follow-up for 3 months only, so long-term effects not studied  
• 1 participant at end of 3 months admitted did not use splint correctly  
• No analysis for participant satisfaction outcomes  
• Duration of RA, 9–10 years  
• Functional outcome measure used only two of the three DASH modules. |
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<td>Spicka et al (2009)</td>
<td>Pilot observational study Aim: to assess the impact of proximal interphalangeal joint (PIPJ) silver ring splints (SRS) on measurements of hand dexterity and grip strength in individuals who were already routinely wearing these splints Recruitment via Occupational Therapy Department and Rheumatology Clinic (secondary care) Inclusion: people with RA referred by a rheumatology consultant to occupational therapy, who had been assessed for, and had already purchased, silver ring splints Exclusion: individuals deemed to be from a vulnerable group, and who were unable to understand English 8 participants Male: female ratio = 1:7 Mean age = 63 years (range not given) Hand dominance: right (100%) All participants had already been wearing the splints for at least 18 months United Kingdom.</td>
<td>Silver ring splints – custom-made by jeweller Highly localised splints that are not widely available on NHS.</td>
<td>Measures taken with and without the SRS worn: 1. Hand dexterity, measured by the Nine Hole Peg Test (NHPT) 2. Grip strength, measured by the MIE digital grip analyser (three consecutive efforts recorded).</td>
<td>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&gt;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.</td>
<td>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. day/night 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.</td>
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<td>Thiele et al (2009)</td>
<td>Cross-over trial</td>
<td>Use of a custom-made leather splint versus a commercially available fabric splint</td>
<td>Assessed at baseline and after each two-week splint phase by observer blinded to treatment allocation</td>
<td>Pain: statistically significant decrease in pain for both splints but more so for leather splint</td>
<td>Grade C – Low</td>
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<td>Wrist extension 15–20° Splint fitted by occupational therapist</td>
<td>Hand function, stiffness and pain:</td>
<td>Stiffness: leather splint demonstrated significant reduction in stiffness but fabric splint did not; no significant difference in effect between the splints</td>
<td>Downgraded from A due to limitations:</td>
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<td>Each splint worn for 2 weeks with one-week washout period</td>
<td>• Australian/Canadian Osteoarthritis Hand Index (AUSCAN) – VAS (10 cm) – reference to previous 48 hours</td>
<td>Function: both splints produced a statistically significant improvement in function, with little difference between the splints</td>
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<td>Total trial duration 5 weeks.</td>
<td>Self-perceived occupational performance in ADL:</td>
<td>Grip strength: noted as achieving a statistically significant increase for both groups (p&lt;0.001)</td>
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<td>• COPM</td>
<td>Indicated that for the short-term relief of pain and dysfunction the leather wrist splint was superior to a commercially available fabric splint.</td>
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<td>Power grip strength:</td>
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<td></td>
<td></td>
<td></td>
<td>• Jamar® dynamometer</td>
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<td>Splint preference.</td>
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- **Source Design and participants**: Thiele et al (2009)
- **Intervention**: Use of a custom-made leather splint versus a commercially available fabric splint
- **Outcomes**: Assessed at baseline and after each two-week splint phase by observer blinded to treatment allocation
- **Results**: Pain: statistically significant decrease in pain for both splints but more so for leather splint
- **Quality and comment**: 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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<td>van der Giesen et al (2010)</td>
<td>Qualitative</td>
<td>Two types of splint: Silver ring splint (SRS) and Oval-8® commercially prefabricated thermoplastic splint (PTS)</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)</td>
<td>Hand function difficulties were identified in seven sub-concepts:</td>
<td>Grade D – Very Low</td>
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<td>[Cross-reference with van der Giesen et al 2009]</td>
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<td>Each splint was worn for 4 weeks, with a two-week washout.</td>
<td>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>• Difficulty initiating finger flexion</td>
<td>Comments:</td>
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<td>• Painful PIP joint hyperextension</td>
<td>• Participant responses to questions were only handwritten verbatim and not recorded on audio tape for accuracy</td>
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<td>Qualitative study carried out adjunct to a randomised cross-over trial comparing silver ring and Oval-8® finger splints</td>
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<td>• Dislike of appearance</td>
<td>• No mention of saturation of data</td>
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<td>Multicentre study carried out in three rheumatology outpatient clinics</td>
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<td>• Functional difficulties associated with poor pinch or tripod grip</td>
<td>• Only the main functional difficulty for each participant was recorded, therefore some data were lost</td>
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<td>Consecutively selected and included in a randomised cross-over trial</td>
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<td>• Large grip</td>
<td>• 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</td>
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<td>Inclusion: RA; mobile swan neck deformity manually correctable to ≥45° of PIPJ 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</td>
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<td>• Applying pressure with fingertips</td>
<td>• Assessors not independent, so potential source of bias</td>
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<td>Exclusion: condition other than RA or other severe finger deformities interfering with hand function or use of finger splints</td>
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<td>• Hand function requiring multiple grips (dexterity)</td>
<td>• 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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<td>50 participants</td>
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<td>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)</td>
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<td>Male: female ratio = 9:41</td>
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<td>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</td>
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<td>Median age (SD) = 53.8 years (21.6)</td>
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<td>Positive aspect categories:</td>
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<td>Mean disease duration (SD) = 13.7 years (11.5)</td>
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<td>• Effect (on hand function or pain)</td>
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<td>Netherlands.</td>
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<td>• Ease of use</td>
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<td>• Appearance</td>
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<td>Negative aspect categories:</td>
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<td>• Side effects</td>
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<td>• Sharp edges</td>
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<td>• Sweating</td>
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<td></td>
<td>• Pain in adjacent finger due to friction</td>
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<td></td>
<td>• Paraesthesia of splinted fingertip</td>
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<td>• Splint slipping off</td>
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<td></td>
<td>• Change of fit during wear</td>
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<td></td>
<td>The positive and negative aspects of the SRS and PTS demonstrated no distinguishable pattern.</td>
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<tr>
<td>Source</td>
<td>Design and participants</td>
<td>Intervention</td>
<td>Outcomes</td>
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<tr>
<td>van der Giesen et al (2009)</td>
<td>Randomised cross-over trial</td>
<td>Two types of splint: Silver ring splint (SRS) and Oval-8® commercially prefabricated thermoplastic splint (PTS)</td>
<td>Measures collected at baseline, after the first splint period, after the washout period, after the second splint wearing and at the 12-week follow-up period</td>
<td>Dexterity: both splints improved dexterity as reported by the SODA scores, and dexterity-related pain was also decreased</td>
<td>Grade C – Low Comments: • Not controlled • Cross-over design • Not fully blinded therefore potential for bias • No power calculations due to small numbers • Dropout rate not calculated into proposed sample size • Satisfaction questionnaire not validated • Sample included participant with early swan neck deformity and excluded people with other hand deformities, which may not be a typical presentation in contemporary practice.</td>
</tr>
</tbody>
</table>

**[Cross-reference with van der Giesen et al 2010]**

Consecutively selected and included in a randomised cross-over trial

Inclusion: RA, mobile swan neck deformity manually correctable to ≥45° of PIPJ 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

Exclusion: condition other than RA or other severe finger deformities interfering with hand function, or use of finger splints

Fifty participants from 83 screened; 47 (94%) of those completed the study

Male: female ratio = 9:41
Median age (SD) = 53.8 years (21.6)
Mean disease duration (SD) = 13.7 years (11.5)
Netherlands.

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<tr>
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<th>Intervention</th>
<th>Outcomes</th>
<th>Results</th>
<th>Quality and comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Veehof et al (2008a)</td>
<td>Randomised controlled trial</td>
<td>Intervention group: commercially available prefabricated wrist splint fitted for more affected wrist by an occupational therapist</td>
<td>Baseline and after 4 weeks</td>
<td>Mean duration of wear (SD) = 11.4 hours per day (2.5)</td>
<td>Grade B – Moderate</td>
</tr>
<tr>
<td></td>
<td>Aim: to investigate the efficacy of wrist working splints after a period of splinting in people with RA</td>
<td></td>
<td>Primary outcome:</td>
<td>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)</td>
<td>Downgraded from A due to limitations:</td>
</tr>
<tr>
<td></td>
<td>Four-week RCT among 33 people with RA with wrist arthritis</td>
<td>Wrist extension 10–20° Choice of four different splints, all with fabric gauntlet and removable volar metal stay – choice provided to enhance fit</td>
<td>Secondary outcome:</td>
<td>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’ gs=−0.45)</td>
<td>• Sample size too small to offer statistical significance and did not meet the required power calculations for the primary outcome measure selected</td>
</tr>
<tr>
<td></td>
<td>Single outpatient clinic and selected by the rheumatologist</td>
<td>Requirement to wear the splint as much as possible, especially during activities, and to keep a daily diary Educational and behavioural strategies were applied</td>
<td>Tests for performance were conducted without the splint</td>
<td>Grip strength: no significant differences and small treatment effect. Mean grip strength scores slightly increased in intervention group</td>
<td>• Selection of wrist with more symptoms was interesting – but hand dominance could be important in relation to the outcomes measured</td>
</tr>
<tr>
<td></td>
<td>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</td>
<td>Control group: received usual care, though were offered a splint on conclusion of the study.</td>
<td>Participants’ perceived changes: 5-point scale, at end of the four-week trial period.</td>
<td>Functional ability: DASH and SODA-S slightly improved in both groups; no significant differences and treatment effect small (Hedges’ gs=0.34)</td>
<td>• Selection by the rheumatologist for trial participation could have introduced bias</td>
</tr>
<tr>
<td></td>
<td>Exclusion: recent injection of corticosteroid; severe deformities; wearing a pre-existing splint; carpal tunnel syndrome or other neurological deficit</td>
<td></td>
<td></td>
<td>Participant-perceived changes: significant difference in splinted group, who perceived their pain and function to have improved compared to the control group (p=0.01)</td>
<td>• Non-blinded trial</td>
</tr>
<tr>
<td></td>
<td>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></td>
<td></td>
<td>Little harm likely; low-cost intervention.</td>
<td>• ‘Usual care’ not defined.</td>
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<tr>
<td>Veehof et al (2008b)</td>
<td>Qualitative study – semi-structured interviews</td>
<td>Fabric working wrist splints</td>
<td>Factors that influence reasons for using splints and limitations regarding them</td>
<td>Factors influencing splint use: majority of participants indicated dependence on the seriousness of their symptoms (pain, swelling, or tingling feelings)</td>
<td>Grade C – Low</td>
</tr>
<tr>
<td></td>
<td>Aim: to evaluate service user motivations for and perceived barriers to using their wrist working splint</td>
<td>Interview at home by an independent researcher</td>
<td>Service users’ motivations for, and perceived barriers to, using working wrist splints for RA</td>
<td>Reasons to wear splint: reduction of symptoms, wrist support, and immobilisation of the wrist</td>
<td>Comments:</td>
</tr>
<tr>
<td></td>
<td>Identified through hospital files and contacted by Consultant Rheumatologist</td>
<td>Mean interval between splint prescription and interview (SD) = 6.0 months (3.5)</td>
<td>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</td>
<td>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</td>
<td>No ethical approval sought/mentioned</td>
</tr>
<tr>
<td></td>
<td>20 of the 57 contacted consented to be interviewed. Two interviews were used as pilot interviews and were excluded from further analysis</td>
<td>Fabric wrist splints – two types used</td>
<td>Reference was made to side effects: unpleasant feelings such as tingling, or pressure points due to tight fit</td>
<td>Reference was made to side effects: unpleasant feelings such as tingling, or pressure points due to tight fit</td>
<td>No triangulation of results or respondent validation mentioned</td>
</tr>
<tr>
<td></td>
<td>Inclusion: adult, RA, in receipt of a fabric wrist working splint between 1 and 12 months previously because of pain from wrist arthritis</td>
<td>16 received a Rolyan® D-ring and 2 participants received a Futuro™ splint.</td>
<td>Themes in results:</td>
<td>Themes in results:</td>
<td>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</td>
</tr>
<tr>
<td></td>
<td>Participants = 18</td>
<td>The interview transcripts were analysed using the framework approach.</td>
<td>• Prescription and knowledge</td>
<td>• Prescription and knowledge</td>
<td>• Length of time the splint had been prescribed before the interview varied from 1–12 months.</td>
</tr>
<tr>
<td></td>
<td>Male: female ratio = 4:14</td>
<td></td>
<td>• Splint use</td>
<td>• Splint use</td>
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<tr>
<td></td>
<td>Mean age (SD) = 56.3 years (16.4)</td>
<td></td>
<td>• Advantages</td>
<td>• Advantages</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Netherlands.</td>
<td></td>
<td>• Disadvantages</td>
<td>• Disadvantages</td>
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<td></td>
<td></td>
<td></td>
<td>• Expectations</td>
<td>• Expectations</td>
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<td></td>
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<td></td>
<td>• Appearance, comfort and fit</td>
<td>• Appearance, comfort and fit</td>
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<td></td>
<td></td>
<td></td>
<td>• Social environment</td>
<td>• Social environment</td>
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<td></td>
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<td></td>
<td>Decisions by individuals whether to wear or not wear a working splint are intentional</td>
<td>Decisions by individuals whether to wear or not wear a working splint are intentional</td>
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<td></td>
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<td></td>
<td>Authors have developed educational and behavioural strategies with the aim of increasing adherence to wearing splints.</td>
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<tr>
<td>Source</td>
<td>Design and participants</td>
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</table>
| Wajon and Ada (2005) | Randomised controlled trial
Aim: to compare the effects of two six-week splint and exercise regimens for individuals with trapeziometacarpal OA
Referred to hand physiotherapy practice
Inclusion: pain at base of thumb, Stage I–III trapeziometacarpal OA
Exclusion: De Quervain’s tendonitis; carpal tunnel syndrome; scapholunate instability; trigger thumb; steroid in preceding 6 weeks; previous surgery
40 participants
Intervention group: Male: female ratio 5:14
Mean age (SD) = 59.7 years (9.0)
Mean disease duration (SD) = 3.9 years (5.2)
Control group: Male: female ratio 4:17
Mean age (SD) = 61.2 years (12.5)
Mean disease duration (SD) = 3.3 years (3.6)
Australia. | Intervention group: custom-made thermoplastic thumb strap splint plus abduction exercises
Control group: short opponens thumb splint including MCPJ and pinch exercises
Two-week period of splinting followed by a four-week period of wearing the splint and incorporating the addition of exercise
Instructed to wear splint full time and remove for personal hygiene only. | Measured by a blinded assessor at weeks 0, 2, and 6
• Pain: VAS (10 cm) at rest
• Strength: tip pinch in kilograms – pinch gauge
• Hand function: Sollerman Test of Hand Function scored out of 80. | 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<0.01)
• Strength had increased for tip pinch by a mean of 0.6 kg (p<0.01)
• Hand function improved by a mean of 6.5 points on the Sollerman Test of Hand Function (p>0.01) | 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. |

**Design and participants**
- Randomised trial/cross-over design
- Aim: to assess the level of pain, pinch strength, CMCJ 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 4:21
  - 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.

**Intervention**
- 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.

**Outcomes**
- 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.

**Results**
- 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 (CMT 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.

**Quality and comment**
- 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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<th>Results</th>
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</thead>
</table>
Aim: to study the effect of silver ring splints in hand function in people with RA  
One-year duration intervention pilot study undertaken in a single rheumatologist’s practice  
Inclusion: RA, stable disease; finger deformities eligible for splinting  
Exclusion: not stated  
17 participants  
Male: female ratio = 3:14  
Median age = 65 years (range 37–74 years)  
Disease duration median 21 years (range 3–41 years)  
Hand dominance: all but 1 = right-handed. Medication did not change during study period  
Netherlands. | Mass-produced silver ring splints (SRS) from the Silver Ring Splint Company in USA  
One or more splints fitted to proximal (PIP) and distal (DIP) interphalangeal joints of fingers and IP joint of thumbs. | Primary outcome:  
Dexterity – Sequential Occupational Dexterity Assessment (SODA)  
Secondary outcomes:  
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 6: 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 of orthoses.

A6.1 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 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 service user basis.

A6.2 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.
A6.3 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 7: Glossary and abbreviations

| 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. |
| Arthritis Care | Arthritis Care supports people with arthritis and is the UK’s largest charity working with, and for, people who have arthritis.  
http://www.arthritiscare.org.uk |
| Arthritis Research UK | Arthritis Research UK is a charity that funds high-class research, educates healthcare professionals, and provides information to people with arthritis, and their carers.  
http://www.arthritisresearchuk.org |
| 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.cot.co.uk/people-structure/about-baotcot |
| 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’. |
<table>
<thead>
<tr>
<th>BAPO (contd.)</th>
<th>Orthotists are ‘autonomous registered practitioners who provide gait analysis and engineering solutions to patients with problems of the neuro, muscular and skeletal systems’. <a href="http://www.bapo.com">http://www.bapo.com</a></th>
</tr>
</thead>
<tbody>
<tr>
<td>BHPR</td>
<td><strong>British Health Professionals in Rheumatology</strong>&lt;br&gt; 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. <a href="http://www.rheumatology.org.uk/BHPR">http://www.rheumatology.org.uk/BHPR</a></td>
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<tr>
<td>Biologics</td>
<td>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 to, or who have had side effects from, conventional DMARDs. 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. <a href="http://www.arthritisresearchuk.org/arthritis-information/drugs/dmards.aspx">http://www.arthritisresearchuk.org/arthritis-information/drugs/dmards.aspx</a></td>
</tr>
<tr>
<td>Boutonnière</td>
<td><strong>Boutonnière deformity</strong>&lt;br&gt; Condition of the finger characterised by flexion of the PIP joint and hyperextension of the DIP joint. <a href="#">Bradley and Adams 2013</a></td>
</tr>
<tr>
<td>CASP</td>
<td><strong>Critical Appraisal Skills Programme</strong>&lt;br&gt; 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). <a href="http://www.casp-uk.net">http://www.casp-uk.net</a></td>
</tr>
</tbody>
</table>
| CI          | **Confidence interval**<br> ‘There is always some uncertainty in research. This is because a small group of patients is studied to predict the effects of a treatment on the wider population. The confidence interval is 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.’<br> ‘The CI 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.’<br> ‘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
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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</table>
| CI (contd.)        | confidence interval indicates a more precise estimate (for example, if a large number of patients has been studied).’
Glossary: [http://www.nice.org.uk/website/glossary/glossary.jsp](http://www.nice.org.uk/website/glossary/glossary.jsp) |
| CMCJ/TMCJ          | Carpometacarpal joint/trapeziometacarpal joint.                                                                                                                                                    |
| COPM               | **Canadian Occupational Performance Measure**  
The COPM is an evidence-based outcome measure designed to capture a client’s self-perception of performance in everyday living, over time.  
[http://www.thecopm.ca](http://www.thecopm.ca)                                |
| COT                | **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.  
[http://www.cot.co.uk/people-structure/about-baotcot](http://www.cot.co.uk/people-structure/about-baotcot) |
| COTSS-Rheumatology | **College of Occupational Therapists Specialist Section-Rheumatology**  
COTSS-Rheumatology is a branch of the College. It provides professional and clinical information on all aspects of occupational therapy practice related to rheumatology.  
It has a responsibility to keep abreast of relevant professional, practice, policy and legislative developments and issues.  
[http://www.cot.co.uk/cotss-rheumatology/cot-ss-rheumatology](http://www.cot.co.uk/cotss-rheumatology/cot-ss-rheumatology) |
| CTS                | Carpal tunnel syndrome.                                                                                                                                                                                   |
| Custom-made        | An orthosis that is made to individual specifications.                                                                                                                                                  |
| DASH               | **Disabilities of the Arm, Shoulder and Hand questionnaire**  
[http://dash.iwh.on.ca](http://dash.iwh.on.ca)  
*Information re measures of adult shoulder function: Angst et al 2011*                                                          |
| DIPJ               | Distal interphalangeal joint.                                                                                                                                                                              |
| DMARDs             | **Disease-modifying anti-rheumatic drugs**  
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.  
Conventional DMARDs are a group of drugs which are slow-acting and can take several weeks to work (see also Biologics).  
| Dynamometer        | An instrument used to measure the maximum isometric strength of the hand and forearm muscles.                                                                                                            |
| EULAR | European League Against Rheumatism  
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.  
http://www.eular.org |
| --- | --- |
| GRADE | Grading of Recommendations Assessment, Development and Evaluation  
GRADE is a systematic and explicit methodology to assist in the judgement of the quality and strength of guideline recommendations.  
http://www.gradeworkinggroup.org |
| Hand function | The ability to use the hand in daily activities.  
Fowler and Nicol 2001 |
| HCPC | Health and Care Professions Council  
HCPC is the regulator for 16 health professions, including occupational therapists.  
http://www.hcpc-uk.org |
| MCPJ | Metacarpophalangeal joint |
| NAROT | National Association of Rheumatology Occupational Therapists  
NAROT is now known as the College of Occupational Therapists Specialist Section-Rheumatology. |
| 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 |
<p>| NSAIDs | Non-steroidal anti-inflammatory drugs. |
| OA | Osteoarthritis. |
| Orthoses | Plural term for orthosis. |</p>
<table>
<thead>
<tr>
<th><strong>Orthosis</strong></th>
<th>Externally applied device used to modify the structural and functional characteristics of the neuromuscular and skeletal systems. <em>International Organization for Standardization 1989</em></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Orthotic</strong></td>
<td>Term used as an adjunctive DESC</td>
</tr>
<tr>
<td><strong>Oval-8®</strong></td>
<td>Thermoplastic three-point orthosis used as an intervention for swan neck deformity. <em>Bradley and Adams 2013, p202</em></td>
</tr>
<tr>
<td><strong>p values</strong></td>
<td>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: <a href="http://www.nice.org.uk/website/glossary/glossary.jsp">http://www.nice.org.uk/website/glossary/glossary.jsp</a></td>
</tr>
<tr>
<td><strong>Pinch gauge</strong></td>
<td>An instrument that measures finger pinch strength.</td>
</tr>
<tr>
<td><strong>PIPJ</strong></td>
<td>Proximal interphalangeal joint.</td>
</tr>
<tr>
<td><strong>Prefabricated</strong></td>
<td>An orthosis manufactured in advance and ready to be fitted to an individual.</td>
</tr>
<tr>
<td><strong>RA</strong></td>
<td>Rheumatoid arthritis.</td>
</tr>
<tr>
<td><strong>RCT</strong></td>
<td>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: <a href="http://www.nice.org.uk/website/glossary/glossary.jsp">http://www.nice.org.uk/website/glossary/glossary.jsp</a></td>
</tr>
<tr>
<td><strong>ROM</strong></td>
<td>Range of movement.</td>
</tr>
<tr>
<td><strong>SIGN</strong></td>
<td>Scottish Intercollegiate Guideline Network SIGN develops evidence-based clinical practice guidelines for the National Health Service (NHS) in Scotland. <a href="http://www.sign.ac.uk">http://www.sign.ac.uk</a></td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
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<tr>
<td>SODA/SODA-S</td>
<td><strong>Sequential Occupational Dexterity Assessment</strong>&lt;br&gt;SODA-S is the shortened version of this assessment. <em>van Lankweld et al 1996</em></td>
</tr>
<tr>
<td>Spica orthosis</td>
<td>Orthosis used to immobilise the thumb and/or wrist.</td>
</tr>
<tr>
<td>Splint</td>
<td>See orthosis.</td>
</tr>
<tr>
<td>SRS</td>
<td><strong>Silver ring splint</strong>&lt;br&gt;A bespoke orthosis made of silver as an intervention for swan neck deformity. <em>Bradley and Adams 2013, p197</em></td>
</tr>
<tr>
<td>Swan neck deformity</td>
<td>Condition of the finger characterised by hyperextension of the PIP joint and flexion of the DIP joint. <em>Bradley and Adams 2013</em></td>
</tr>
<tr>
<td>Thermoplastic</td>
<td>A material that becomes soft when heated, can be moulded and becomes hard when cooled.</td>
</tr>
<tr>
<td>Thumb base OA</td>
<td>First carpometacarpal joint with or without scapho-trapezoid joint osteoarthritis. <em>Zhang et al 2009</em></td>
</tr>
<tr>
<td>Trigger finger</td>
<td>‘A phenomenon in which the movement of a finger is halted momentarily in flexion or extension and then continues with a jerk.’ <em>Mosby’s medical, nursing and allied health dictionary: Anderson 2002</em></td>
</tr>
<tr>
<td>Ulnar deviation</td>
<td>Deviation of the MCPJ due to capsular attenuation and joint destruction. <em>Bradley and Adams 2013, p196</em></td>
</tr>
<tr>
<td>VAS</td>
<td><strong>Visual Analogue Scale</strong>&lt;br&gt;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. <em>Hawker et al 2011</em></td>
</tr>
<tr>
<td>Washout period</td>
<td>The period during a clinical study when the participants do not receive any treatment that is under investigation.</td>
</tr>
<tr>
<td>Wearing regimen</td>
<td>The frequency and duration of suggested orthosis wear.</td>
</tr>
</tbody>
</table>

All websites in the glossary were accessed on 05.05.15.
References

Evidence references


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Hand and wrist orthoses for adults with rheumatological conditions


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### Supporting information references


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Shoulder Disability Questionnaire (SDQ), and Western Ontario Shoulder Instability Index (WOSI). *Arthritis Care & Research*, 63 (Supplement S11), S174–S188.


Accessed on 22.06.15.


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Poole JL (2011) Measures of hand function: Arthritis Hand Function Test (AHFT), Australian Canadian Osteoarthritis Hand Index (AUSCAN), Cochin Hand Function Scale, Functional Index for Hand Osteoarthritis (FIHOA), Grip Ability Test (GAT), Jebsen Hand Function Test (JHFT), and Michigan Hand Outcomes Questionnaire (MHQ). Arthritis Care & Research, 63 (Supplement 11), S189–S199.


All websites in these references were accessed on 05.05.15 unless otherwise indicated.
Hand and wrist orthoses for adults with rheumatological conditions

*Practice guideline for occupational therapists*

This publication provides 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.