

Orthotics for Knee InStability

Orthotic management of instability of the knee related to neuromuscular and central nervous system disorders: systematic review, qualitative study, survey and costing analysis

What our research found:

- There is limited evidence on the effectiveness of the various types of orthoses used within the NHS to manage patients with neuromuscular and central nervous system conditions
- Orthotic devices are essential for 'normal' daily activities, such as helping users of devices to work, support their family and take part in social and community activities
- A core set of outcome measures is needed. Important to patients are: reduction in pain, falls and trips, improved balance and stability as well as participation in paid employment, outdoor activities (such as gardening), family visits and social events
- Future research needs to examine the extent to which devices help patients when they are used in real-life settings and take account of patient goals
- We also need to know how best to deliver orthotic services to ensure cost effective delivery of care that meets the needs of patients



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About knee orthoses

Weakness or joint laxity of the knee in neuro-muscular disease (NMD) and central nervous system (CNS) conditions can cause problems such as pain, falls and mobility issues. Lower limb orthoses may be prescribed to improve the ability and quality of walking, and protect, stabilise and improve function.¹

There is a wide variety of lower limb orthoses available, some of which can be used in combination, such as an ankle-foot-orthosis (AFO) or knee-ankle-foot orthosis (KAFO). The devices can be made from metal and leather or more modern thermoplastics or carbon fibre composites which are lighter and fit more closely, potentially giving better control of the limb.² The knee hinge mechanisms also vary, and whether the device is entirely locked or entirely unlocked at the knee will alter the way the wearer walks.³ Recently new mechanisms have been introduced, where mechanical or microprocessor controlled knee joints give a more normal walking pattern.

Orthotic devices can be fully custom-made or pre-fabricated/off-the-shelf, some of which may be customised to suit individual needs. The cause and extent of knee instability and rehabilitation goals are personal to the individual and ought to be the driver for orthosis design. In addition to stability and safety, the clinician fitting the device needs to understand the patient's living and working circumstances and their preferences and expectations.⁴

Orthotic services are normally provided in secondary care hospital trusts; but the way in which orthotics services are delivered varies⁵ as does involvement of relevant healthcare professions.⁶

What research did we do and why?

We were commissioned to try and address some uncertainties around the use of orthotics for knee instability.⁷ We undertook:

- a qualitative study to explore the perspectives of users of orthoses on what makes a device acceptable, how much prescribed devices are used, what factors influence whether or not devices are used, and the outcomes important to patients
- a systematic review to assess how well the various orthotic options for knee instability actually perform in research studies
- a survey of healthcare professionals to identify types of orthotic devices currently provided by the NHS
- we also gathered information about costs.

The research was commissioned by NIHR HTA programme and the full report is available via the project website: www.nets.nihr.ac.uk/projects/hta/133002

What did the users of orthoses tell us?

We held in-depth interviews that explored peoples' experiences of using orthoses, perceptions of the treatment received, and views on treatment goals and outcomes. Twenty-four people with a NMD or CNS condition who had been offered an orthotic device for knee instability took part. Participants came from across England and some were recruited directly via the NHS while others were recruited through patient support groups. Their ages ranged from 36 to 80. Half the sample had been diagnosed as having polio; the other half had multiple sclerosis, Charcot-Marie-Tooth disease, spinal injury, spina bifida or had experienced a stroke. Half were engaged in either full or part-time paid employment, half indicated they were retired.

- Orthotic devices are vital for users to live as normal a life as possible, engage in daily activities and have independence for as long as possible.

"...they give me my independence to go out on my own which without them I haven't got..."

- Usefulness of an orthotic was measured by its ability to let the wearer lead as normal a life as possible and any malfunction of the device could have serious consequences for the wearer.

"...one of the hinges just failed without warning. So that's an immediate demobilisation..."

- The main desired outcome for those wearing orthoses was a reduction in pain, falls or trips, with improved balance and stability.
- Effectiveness, reliability, comfort and durability were the most valued features of orthoses.
- Many expressed frustration with perceived deficiencies in service provision relating to appointment and administrative systems and referral pathways.

"...each time I want to go back I have to go to my GP to refer me back to the orthotics . . . it's quite a long-winded process."

Further patient views are given in Box 1.

What did the healthcare professionals say?

An email invitation letter and link to our web survey was sent out by the relevant professional bodies. The 238 healthcare professionals who responded included orthotists, physiotherapists and rehabilitation medicine physicians who managed patients across a range of NMD and/or CNS conditions.

- A range of orthoses are prescribed for knee instability related to NMD or CNS conditions: KAFOs (75%), AFOs (94%) and knee braces (89%).
- A substantial proportion of participants also prescribed shoe adaptations (66%) and insoles (70%).
- Approximately half the devices prescribed or fitted were reported to be custom-made (range 0 to 100%).
- At least half of the healthcare professionals thought comfort and confidence in mobility were extremely important outcomes from treatment.
- Just over one quarter reported that no formal outcome measure was used to assess the effectiveness of the devices provided. No single outcome measure was used by the remaining respondents: the most commonly used measures were the Visual Analogue Scale, the Ten-metre Walk Test and the Timed Up and Go Test.
- One third said they formally assessed patient satisfaction.
- Over 75% thought that improvements could be made to care pathways. Suggestions included: greater awareness of the role of orthotic services; reduced waiting times; better communication between all the professionals providing care to an individual.

“More time available for orthotic treatment, and more clinicians and funding to enable faster treatment. Earlier referral to orthotics. MDT [multi-disciplinary team] assessment sessions rather than multiple individual assessments. More standardised outcome measurement.”

What are the estimated costs?

The estimated cost of individual KAFOs was highly variable, influenced by the length of assessment, fitting and review appointments, the healthcare professionals seen, and whether the device was off the shelf, or custom-made. Cost estimates ranged from £73 to £3,553.

BOX 1: WHAT USERS FELT ABOUT:

Wearing orthotic devices

- Orthotic devices are essential for ‘normal’ daily activities, such as working, driving, using public transport, outdoor activities and taking part in social events and gatherings
- Orthoses and mobility aids (sticks, crutches, wheelchairs, mobility scooters), are ‘mixed and matched’ for maximum comfort and independence
- A ‘spare’ device is needed in case the currently used device requires adjustment or repair or fails unexpectedly
- The characteristics of footwear associated with an orthosis are important

Desired outcomes from wearing a device

- The most desired outcomes are reduction in pain, falls or trips, with improved balance and stability
- Effectiveness, reliability, comfort and durability are the most valued features of orthoses
- Goals for mobility focus on pursuit of different desired daily activities
- Success of treatment is judged by the extent to which their orthosis enabled participants to engage in paid employment, outdoor activities (such as gardening), family visits and social events
- Participation in these activities is important for both physical and mental well-being

Delivery of orthotic services

- Referral routes into orthotic services channelled through GPs and orthopaedic services result in treatment delays
- Consultants in rehabilitation medicine provide co-ordinated care and monitoring of condition, while making proactive and timely decisions to refer patients to orthotics and other specialist services
- There are deficiencies in the appointment systems in orthotic services causing delays in receiving treatment, inconvenience and expense
- Workshops within orthotics departments for the manufacture, adjustment and repair of orthoses are associated with delivery of timely, good quality orthotic care, particularly for minor or emergency repairs to devices

What does the existing evidence say?

A systematic review of studies of adults using orthosis in a real-life setting identified twenty-one studies (which included 478 patients): two RCTs; two non-randomised controlled studies; one cohort study and 16 case series. The number of patients in individual studies was small, ranging from 5 to 67 participants. One hundred and fifty three of the patients who participated in the studies had a NMD, including post-polio and inclusion body myositis. Three hundred and twenty five patients had knee instability from CNS causes, either post stroke or spinal cord injury. The devices evaluated were KAFOs (mainly carbon fibre), stance control KAFOs and hip KAFOs. In general reporting was poor and all the studies were at risk of bias, meaning the findings need to be viewed with caution.

It is not possible to tell from existing literature how effective the devices are as few studies examined how devices help patients in everyday life. The studies assessed mostly mechanical outcomes such as gait analysis and energy consumption, rather than those important to wearers.

Implications for healthcare

Given the lack of evidence it is not appropriate to draw conclusions about the effectiveness of specific orthotic devices for knee instability related to NMD or CNS disorders.

Better understanding of models of service delivery that ensure maximum benefit for patients and best value for money is needed.

Use of a core set of patient reported outcome measures in the clinical setting would help provide a more patient relevant assessment of the impact of any change in device or management strategy on individual patients. It would also help with audit of service delivery.

Recommendations for research

Research is required on the effectiveness of orthoses in managing knee instability related to NMD and CNS conditions and using outcome measures relevant to patients' everyday lives. Due to challenges identified during this research it is suggested that any future trial be informed by a feasibility study. Given the relative rarity of some of the populations and the personalised nature of the intervention, particularly for custom-made devices, a national registry may be an

appropriate way forward.

Development of a core set of outcome measures would be beneficial. Reduction in pain, falls and trips, improved balance and stability as well as participation in paid employment, outdoor activities (such as gardening), family visits and social events were all identified as important to patients.

To date there is little evidence about the views and experiences of people who are given orthoses for knee instability, and further studies are required to investigate in depth some of the issues raised in our qualitative research.

We suggest that future research should explore different models of delivery of orthotic service for people with NMD and CNS conditions to identify best practice in terms of greatest benefit to patients and value for money.

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Additional information about the project can be found at our blog site: Orthotics for Knee Instability
www.kneeorthotics.blogspot.co.uk

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