A review of the efficacy of lower-limb orthoses used for cerebral palsy

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Authors' objectives
To assess the efficacy of lower limb orthoses used for children with cerebral palsy (CP).

Searching
The Cochrane Library (Issue 3, 2000), RECAL Information Services, MEDLINE, CINAHL, EMBASE, SIGLE, AMED and Inspec were searched from 1994 to 2000. Unpublished studies were sought in the UK National Research Register, through the National Health Service Research and Development website, ASLIB Index to Theses (UK theses) and Dissertation Abstracts (including North America). The Internet was also searched and the websites of organisations such as the CanChild Centre for Childhood Disability Research were located. Handsearches were conducted in journals that publish abstracts from relevant European and North American conference proceedings such as Gait and Posture, and Developmental Medicine and Child Neurology (1994 to 2000). The consensus conference document (see Other Publications of Related Interest no.3), colleagues, researchers in the field and librarians were contacted for additional material. Abstracts were eligible for inclusion.

Study selection
Study designs of evaluations included in the review
Controlled clinical trials were eligible. Randomised controlled trials (RCTs) and non-randomised controlled trials (prospective, cross-sectional and retrospective) in which the participant acted as their own control were included.

Specific interventions included in the review
Studies that compared any lower limb orthosis with an alternative, a control intervention, or no orthoses were eligible. The following types of orthoses were included: hybrid hinged; rigid tone reducing footplate; daytime ankle foot orthoses (AFO), including rigid and hinged; rigid; supramalleolar orthoses (temporary applications of casts were excluded), with and without a tone reducing footplate; hinged tone reducing footplate; supramalleolar dynamic AFO; metal Klenzack; posterior leaf spring AFO; dynamic AFO with plantarflexion stop; spiral graphite and hinged AFO, with and without tone reducing footplate and calf cut out. The control interventions predominantly involved measuring an activity barefoot or with shoes only.

Participants included in the review
Studies of children with CP were eligible. Studies that examined heterogeneous diagnoses, such as adults or children with head injuries, were excluded. The characteristics of the children were generally described as perambulatory, spastic CP (including diplegia and hemiplegia), and equinus (including dynamic equinus and users of orthoses). Most of the included children had spastic type CP.

Outcomes assessed in the review
The inclusion criteria were not defined in terms of outcomes. Most of the included studies assessed the outcomes using the Activity dimension of the International Classification of Impairment, Disability and Handicap (ICIDH-2; see Other Publications of Related Interest no.1). Other outcomes were also assessed: gait analysis, used to examine parameters of walking; standing balance; movement from sitting to standing; stair climbing; changes in Gross Motor Function Measure (see Other Publications of Related Interest no.2); a standardised walking obstacle course; range of joint movement; and X-rays to monitor foot and ankle alignment in orthoses.

How were decisions on the relevance of primary studies made?
The author did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality
Validity was not formally addressed, but aspects of validity were discussed in the text of the review, e.g. study design,
adequacy of description of the interventions and the methods used to assess the outcomes.

**Data extraction**
The author did not state how the data were extracted for the review, or how many reviewers performed the data extraction. The tabulated information included: author and year of publication, study design, sample size, characteristics of the participants, type of orthoses, ICIDH-2 and key outcomes.

**Methods of synthesis**
How were the studies combined?
A narrative synthesis of the studies was undertaken.

How were differences between studies investigated?
Some differences were discussed in the text of the review.

**Results of the review**
One RCT (34 children) and 26 within-participant comparisons (403 children in total) were included. The non-randomised trials comprised 5 prospective studies (49 participants), 17 cross-sectional studies (266 participants) and 4 retrospective studies (88 participants).

Of the 27 included studies, 11 were journal publications and 15 were abstracts. The sample size ranged from 1 to 47 (mean 16).

The descriptions of orthoses were inconsistent and it was unclear which movements were permitted or restricted.

The RCT (34 preambulatory children) found no significant difference between hybrid hinged AFOs and no orthoses in gross motor function at 6 months.

In the within-participant comparison studies, improvement was commonly reported using any orthoses compared with the barefoot condition.

**Authors' conclusions**
The author's conclusion appears to state that only orthoses that extend to the knee and have either a rigid ankle, leaf spring, or hinged design with plantarflexion stop were found to prevent equinus deformity; that supramalleolar orthoses with a tone reducing feature or Dynamic AFOs were not found to prevent equinus; and that preventing plantarflexion (or equinus) improves parameters of gait for the majority of children. The author also stated that further research was required.

A: The author concludes that only lower limb orthoses which prevent equinus during gait improve gait efficiency, that is rigid or solid, leaf spring or hinged AFOs with plantarflexion stop; supramalleolar orthoses do not prevent equinus. Preventing plantarflexion has been shown to improve stability in stance phase, clearance in swing phase, pre-positioning in terminal swing, and increase step length and walking speed. There is a suggestion that preventing plantarflexion also improves energy expenditure. There is no evidence to support any tone reducing effect on gait from orthoses that incorporated specially moulded footplates.

**CRD commentary**
The aims of the review were stated and the inclusion criteria were defined in terms of the intervention, study design, participants and outcome. Many relevant sources of trials were searched and attempts were made to locate unpublished material. It was not stated whether any language restrictions were applied and the methods used to select the studies were not reported. Validity was not formally assessed, although some aspects of validity were discussed in the text. Some relevant data were extracted and tabulated, but the methods used to extract the data were not described and the results were not presented with values or levels of statistical significance.

A narrative review was appropriate given the clinical heterogeneity among the studies. The critical appraisal of the
evidence on specific orthoses was lacking. In addition, it was not mentioned whether the studies were adequately powered to detect a difference between the treatments and, given that only 10 studies included more than 16 patients, this could seriously affect the validity of the results. Conclusions were based on limited evidence from poor quality studies with small sample sizes and may not be reliable. The authors’ conclusions about the need for further research were supported by the evidence presented.

Implications of the review for practice and research
Practice: The author did not state any implications for practice.

Research: The author stated that strong evidence is only likely to come from RCTs that ensure baseline similarity between the treatment groups using the diagnostic classification produced by the Surveillance of Cerebral Palsy in Europe, and that monitor outcomes using the Gross Motor Function Classification System (see Other Publications of Related Interest no.2).

Bibliographic details

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12005323

Other publications of related interest

Indexing Status
Subject indexing assigned by NLM

MeSH
Cerebral Palsy /physiopathology /rehabilitation /therapy; Cross-Sectional Studies; Equinus Deformity /prevention & control; Humans; Leg /physiopathology; Orthotic Devices /classification /statistics & numerical data; Prospective Studies; Randomized Controlled Trials as Topic; Retrospective Studies; Treatment Outcome

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Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.