

Offloader knee braces for knee osteoarthritis

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Abstract

Introduction

Knee osteoarthritis is a relevant health problem given its high prevalence and associated disability. Within the non-pharmacological management alternatives, the use of offloader knee braces has been proposed, however, there is no consensus in the literature regarding its indication.

Methods

We searched in Epistemonikos, the largest database of systematic reviews in health, which is maintained by screening multiple information sources, including MEDLINE, EMBASE, Cochrane, among others. We extracted data from the systematic reviews, reanalyzed data of primary studies, conducted a meta-analysis and generated a summary of findings table using the GRADE approach.

Results and conclusions

We identified 14 systematic reviews including nine studies overall, all of which were randomized trials. We conclude that the use of offloader knee braces in patients with knee osteoarthritis probably increases physical function through walking distance. However, its use may make little or no difference to physical function measured with the Hospital for Special Surgery Knee score, it may slightly worsen the quality of life and increase adverse events, but the certainty of the evidence is low. In addition, we are uncertain whether the use of offloader knee braces reduces pain as the certainty of the evidence has been assessed as very low.

Problem

Osteoarthritis is a relevant health problem, with hip and knee osteoarthritis being the eleventh leading cause of global disability, the thirty-eighth in years of life adjusted for disability [1], and an important reason for consultation in both primary and specialist care.

Conservative management is the first line of treatment, within which the use of knee braces has been considered. There are five main types of knee orthoses: prophylactic, which protects the knee from injury; functional, supporting the injured knee; rehabilitation, which limits harmful movement after injury or surgery; patellofemoral, which helps the patella move smoothly; and offloader knee braces. This last one is used in knee osteoarthritis since it allows to partially offset the misalignment of varus or valgus deformities, which increases the degenerative process and symptoms in the femorotibial compartments of the knee.

The use of this type of orthosis is intended to reduce pain, improve physical function and possibly delay the progression of the disease, however, its mechanisms and effects are not clear and its clinical use is highly variable, so there is no consensus in the literature on its indication.

Key messages

- We are uncertain whether the use of offloader knee braces reduces pain as the certainty of the evidence has been assessed as very low.
- Use of offloader knee braces may make little or no difference to physical function measured with the Hospital for Special Surgery Knee score (low certainty evidence).
- Use of offloader knee braces probably increases physical function measured with walking distance.
- Use of offloader knee braces may slightly worsen the quality of life and increase adverse effects (low certainty evidence).

About the body of evidence for this question

<p>What is the evidence. See evidence matrix in Epistemonikos later</p>	<p>We identified 14 systematic reviews [2], [3], [4], [5], [6], [7], [8], [9], [10], [11], [12], [13], [14], [15] including nine primary studies [16], [17], [18], [19], [20], [21], [22], [23], [24], all of which corresponds to randomized trials.</p> <p>This table and the summary in general are based on six randomized trials [17], [18], [20], [22], [23], [24], since three trials [16], [19], [21] were excluded from the analysis due to their study design (cross-over).</p>
<p>What types of patients were included*</p>	<p>All trials [17], [18], [20], [22], [23], [24] included adult patients with diagnosis of symptomatic knee osteoarthritis (pain).</p> <p>The average age ranged from 46 to 63.1 years and on average, 57.1% of the included patients were men.</p> <p>Three trials [17], [22], [23] reported the average body mass index of their patients, which varied between 27.2 and 29.8 Kg/m².</p> <p>Regarding the severity of osteoarthritis on radiography, one trial [22] evaluated patients with knee osteoarthritis graded 1 to 4 in Kellgren-Lawrence scale and two trials [18], [24] only patients with Kellgren-Lawrence 3 and 4.</p> <p>All trials included patients with osteoarthritis of the medial compartment and two trials [17], [18] also included patients with osteoarthritis of the lateral compartment.</p>
<p>What types of interventions were included*</p>	<p>All trials [17], [18], [20], [22], [23], [24] evaluated the use of an offloader knee brace.</p> <p>All trials [17], [18], [20], [22], [23], [24] had a parallel design, comparing against a control group with knee osteoarthritis that did not receive the treatment.</p>
<p>What types of outcomes were measured</p>	<p>The trials evaluated multiple outcomes, which were grouped by the systematic reviews as follows:</p> <ul style="list-style-type: none"> • Pain measured by visual analog scale (VAS) • Functionality reported by patients with Hospital for Special Surgery Knee score (HSS) and Knee injury and Osteoarthritis Outcome Score (KOOS) • Quality of life reported by EQ-5D, Western Ontario and McMaster Universities Arthritis Index

Methods

We searched in Epistemonikos, the largest database of systematic reviews in health, which is maintained by screening multiple information sources, including MEDLINE, EMBASE, Cochrane, among others, to identify systematic reviews and their included primary studies. We extracted data from the identified reviews and reanalyzed data from primary studies included in those reviews. With this information, we generated a structured summary denominated FRISBEE (Friendly Summary of Body of Evidence using Epistemonikos) using a pre-established format, which includes key messages, a summary of the body of evidence (presented as an evidence matrix in Epistemonikos), meta-analysis of the total of studies when it is possible, a summary of findings table following the GRADE approach and a table of other considerations for decision-making.

	<p>(WOMAC) and McMaster Toronto Arthritis Patient Preference Disability Questionnaire (MACTAR)</p> <ul style="list-style-type: none"> Parameters of gait kinematics: walking distance, walk test of 6 minutes and a stair climb in 30 seconds Adverse effects <p>The average follow-up of the trials was 6.7 months with a range between 3 and 12 months.</p>
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* Information about primary studies is not extracted directly from primary studies but from identified systematic reviews, unless otherwise stated.

Summary of findings

The information on the effects of the use of offloader knee braces in knee osteoarthritis is based on two trials [17], [24] including 177 patients, since there was not sufficient information to include the remaining trials [18], [20], [22], [23] in the analyses.

Two trials [17], [24] measured pain (177 patients), one trial [17] measured physical function with the Hospital for Special Surgery Knee score and quality of life (117 patients), two trials [17], [24] measured physical function through walking distance (177 patients) and one trial [17] measured adverse effects (117 patients).

The summary of findings is the following:

- We are uncertain whether the use of offloader knee braces reduces pain as the certainty of the evidence has been assessed as very low.
- Use of offloader knee braces may make little or no difference to physical function measured with the Hospital for Special Surgery Knee score (low certainty evidence).
- Use of offloader knee braces probably improves physical function evaluated through walking distance (moderate certainty evidence).
- Use of offloader knee braces may slightly worsen quality of life (low certainty evidence).
- Use of offloader knee braces may slightly increase adverse effects (low certainty evidence).

Offloader knee braces for knee osteoarthritis				
Patients	Knee osteoarthritis			
Intervention	Offloader knee braces			
Comparison	Without knee braces			
Outcome	Absolute effect*		Relative effect (95% CI)	Certainty of evidence (GRADE)
	WITHOUT knee braces	WITH knee braces		
	Difference: patients per 1000			
Pain**	4.97 cm	3.57 cm	--	⊕○○○ ^{1,2,3} Very Low
	MD: 1.4 cm more (Margin of error: 1.34 less to 4.15 more)			
Physical function (HSS)***	69 points	70 points	--	⊕⊕○○ ^{1,3} Low
	MD: 1.0 more (Margin of error: 2.98 less to 4.98 more)			
Physical function (walking distance -km)	2.35	3.4	--	⊕⊕⊕○ ¹ Moderate
	MD: 1.05 more (Margin of error: 0.44 to 1.66 more)			
Quality of life****	0.6 points	0.56 points	--	⊕⊕○○ ^{1,3} Low
	MD: 0,04 less (Margin of error: 0.12 less to 0.04 more)			
Adverse effects*****	246	400	RR 1.63 (0.95 - 2.82)	⊕⊕○○ ^{1,3} Low
	Difference: 154 patients more per 1000 (Margin of error: 7 less to 448 more)			

Margin of error: 95% confidence interval (CI).
RR: Risk ratio.
MD: Mean difference.
GRADE: Evidence grades of the GRADE Working Group (see later).

*The risks/average **WITHOUT knee braces** are based on the risks/average in the control group of the trials. The risk/average **WITH knee braces** (and its margin of error) is calculated from the relative effect/mean difference (and its margin of error).
** Pain: measured on a 10 cm visual analog scale (VAS).
*** Hospital for Special Surgery Knee score (HSS): a scale from 0 to 100 points, where a higher score means better physical function. One study [25] reported a minimally clinically important difference (MCID) of 8.29 points in patients who underwent primary total knee arthroplasty.
**** EQ-5D Scale: Quality of life scale from 0 to 1 points where a higher score means better quality of life. Although no minimally clinically important difference (MCID) was found in this condition, a review [26] that evaluated this scale in different populations indicated that the MCID would vary between 0.03 and 0.52 points.
***** Adverse effects such as local irritation, problems related to poor fitting of the orthosis and local volume increase were reported.

¹ The certainty of evidence was downgraded in one level for risk of bias, since the trials presented detection, performance, and incomplete information bias in general.
² The certainty of evidence was downgraded in one level for inconsistency, since the trials reached different conclusions (I2 of 91%).
³ The certainty of evidence was downgraded in one level for imprecision, as each end of the confidence interval leads to a different decision.

Follow the link to access the interactive version of this table ([Interactive Summary of Findings – iSoF](#))

About the certainty of the evidence (GRADE)*

⊕⊕⊕⊕

High: This research provides a very good indication of the likely effect. The likelihood that the effect will be substantially different† is low.

⊕⊕⊕○

Moderate: This research provides a good indication of the likely effect. The likelihood that the effect will be substantially different† is moderate.

⊕⊕○○

Low: This research provides some indication of the likely effect. However, the likelihood that it will be substantially different† is high.

⊕○○○

Very low: This research does not provide a reliable indication of the likely effect. The likelihood that the effect will be substantially different† is very high.

* This concept is also called 'quality of the evidence' or 'confidence in effect estimates'.

† Substantially different = a large enough difference that it might affect a decision

Other considerations for decision-making

To whom this evidence does and does not apply

The evidence contained in this summary is applicable to adult patients with symptomatic knee osteoarthritis.

It is not applicable to patients with acute or chronic knee pain from another cause, or to patients with symptomatic osteoarthritis of other joints.

About the outcomes included in this summary

The outcomes included in the summary of findings table are those considered critical for decision-making, according to the opinion of the authors of this summary, and in general coincide with the systematic reviews identified.

In relation to the outcomes, functionality and quality of life, we choose the Hospital for Special Surgery Knee score (HSS) and EQ-5D scale, respectively, because they were used by the trial with the largest sample size.

In relation to the gait kinematics parameters, which are predictors of symptomatology, progression and are related to the patient's functionality, we selected the walking distance parameter as it was reported in most of the studies.

Even though the maximum knee abduction moment (peak KAM) has been reported as a predictor of the presence of osteoarthritis in the medial compartment, the severity of the radiographic disease, the rate of progression and the presence of symptoms of osteoarthritis [27], none of the included trials analyzed this parameter. Thus, it would be relevant to have trials assessing this in the future.

Balance between benefits and risks, and certainty of the evidence

It is not possible to clearly establish whether the use of knee orthoses reduces pain, as the certainty of the existing evidence has been assessed as very low.

Regarding functionality, although there is probably a benefit in the distance walked with the use of knee orthoses, the available evidence is not conclusive when considering other elements such as strength, range of motion and instability, among others, which are evaluated with the Hospital for Special Surgery Knee score (HSS).

Furthermore, the evidence indicates that the intervention could slightly worsen the quality of life and could increase adverse effects such as local irritation, problems related to poor fitting of the orthosis and local volume increase, but the certainty of the evidence is low.

In consequence, it is not possible to make an adequate balance between risks and benefits.

Resource considerations

A systematic review [28] that evaluates cost-effectiveness reported that the use of knee orthoses generates less quality-adjusted life years (QALYs) and its costs are equal to or higher than other interventions, concluding that they probably are not profitable and should not be a priority in health services.

However, the review suggests as a limitation the use of low-quality randomized clinical trials, so it would be reasonable to carry out more studies in this regard to evaluate the relation between costs and benefits.

What would patients and their doctors think about this intervention

Faced with the available evidence, it is expected to find variability in the decision of patients and clinicians. Although there might be a decrease in pain and there are clinical guidelines that recommend its use, the current evidence that favors its use is scarce.

Regarding patients' opinion, one study [29] evaluated the use of knee orthoses in patients with osteoarthritis over time. At two years, 25% used knee braces regularly. No clinical or radiographic factors were found to be associated with their use or suspension. Patients

who reported substantial improvement in the comfortable walking range and fewer difficulties with the brace, such as skin irritation or difficulties wearing the brace with clothing, were more likely to continue wearing it.

Regarding the physicians opinions, a study [30] that surveyed French general practitioners in 2005, showed that only 10.5% of them usually prescribe knee braces for patients with osteoarthritis.

Differences between this summary and other sources

The identified systematic reviews coincide in that available evidence is scarce and more studies are required to be able to draw conclusions, which is consistent with the results obtained in this summary.

The International Society for the Study of Osteoarthritis (OARSI) [31] recommends the use of biomechanical interventions such as knee orthoses and insoles in patients with osteoarthritis of the knee. They base their recommendation on a systematic review [14] that was included in this summary. The American Academy of Orthopedic Surgery (AAOS) reports that it is not possible to make a recommendation regarding the use of a valgus directing force brace due to a lack of evidence in this regard [32].

Could this evidence change in the future?

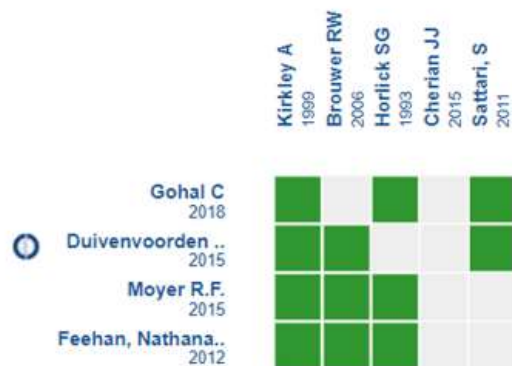
It is likely that the conclusions about pain, physical function measured with the Hospital for Special Surgery Knee score, quality of life and adverse effects change in the future, given the uncertainty of the existing evidence.

Two ongoing systematic reviews were identified in the International prospective register of systematic reviews (PROSPERO): one assesses changes in the moment of maximum knee abduction from interventions that modify gait, including the use of knee braces with reinforcement in discharge [33] and the second evaluates physical treatments to relieve knee osteoarthritis pain, including knee braces [34].

Four ongoing randomized clinical trials were identified in the International Clinical Trials Registry Platform of the World Health Organization evaluating the use of knee braces, which evaluate quality of life [35], physical function [36], [37] and pain [35], [38].

How we conducted this summary

Using automated and collaborative means, we compiled all the relevant evidence for the question of interest and we present it as a matrix of evidence.



An evidence matrix is a table that compares systematic reviews that answer the same question. Rows represent systematic reviews, and columns show primary studies. The boxes in green correspond to studies included in the respective revisions. The system automatically detects new systematic reviews including any of the primary studies in the matrix, which will be added if they actually answer the same question.

Follow the link to access the [interactive version Offloader knee bracing for knee osteoarthritis.](#)

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Notes

The upper portion of the matrix of evidence will display a warning of “new evidence” if new systematic reviews are published after the publication of this summary. Even though the project considers the periodical update of these summaries, users are invited to comment in *Medwave* or to contact the authors through email if they find new evidence and the summary should be updated earlier.

After creating an account in Epistemonikos, users will be able to save the matrixes and to receive automated notifications any time new evidence potentially relevant for the question appears.

This article is part of the Epistemonikos Evidence Synthesis project. It is elaborated with a pre-established methodology, following rigorous methodological standards and internal peer review process. Each of these articles corresponds to a summary, denominated FRISBEE (Friendly Summary of Body of Evidence using Epistemonikos), whose main objective is to synthesize the body of evidence for a specific question, with a friendly format to clinical professionals. Its main resources are based on the evidence matrix of Epistemonikos and analysis of results using GRADE methodology. Further details of the methods for developing this FRISBEE are described here (<http://dx.doi.org/10.5867/medwave.2014.06.5997>)

Epistemonikos foundation is a non-for-profit organization aiming to bring information closer to health decision-makers with technology. Its main development is Epistemonikos database

www.epistemonikos.org.

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