Application of an Unloader Knee Brace in the Treatment of Osteoarthritis

Alexander J. Friedman
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Abstract

BACKGROUND

Osteoarthritis (OA) is a debilitating condition that affects a large and diverse cross-section of American society. Historically, treatments for OA have focused on providing symptomatic relief and improving ability to complete activities of daily living (ADLs). These treatments range from NSAID use and physical therapy, to total knee arthroplasty, an invasive and expensive procedure. Although firm data is lacking, many OA patients report subjective symptomatic improvement in symptoms by wearing a knee brace on the affected joint. Recently, several manufacturers have developed a new knee brace designed to reposition the knee in such a way as to “unload” the medial compartment. For patients with OA of the medial compartment, can an unloader knee brace reduce pain and improve function?

METHODS

An exhaustive search using MEDLINE-Ovid, Web of Science, and Google Scholar was performed using keywords: brace, osteoarthritis, knee, unload, and unloader. These were screened with eligibility criteria. The resulting studies were then appraised and assessed for quality with GRADE.

RESULTS

Current clinical trials were found to include two studies relating to the use of an Unloader Knee brace to treat OA. One open-label prospective study of 20 patients with symptomatic medial knee OA showed that 76% of patients were able to achieve a reduction in pain and improvement in function in activities of daily living (ADLs) at 1 year using the PROTEOR unloader brace. A second prospective cohort study examined the effects of the Bespoke unloader Knee Brace for 7 patients with knee OA. This study demonstrated that through the use of the Bespoke unloader knee brace patients found their external knee adduction moment was significantly reduced, speed of walking significantly increased, knee ROM was reduced, and an increase in step length was also observed. However, this study used evidence from prior research to infer that their results should equate to improvements in pain and improved ADLs.

CONCLUSION

Unloader knee braces are a viable treatment option for patients with OA of the medial compartment of the knee. Better studies are needed to confirm if this treatment option will provide long-term relief. Although strong data is still lacking to confirm the complete success of this treatment, it is low risk and low cost. Therefore, it is recommended that they be used in clinical practice for patients with knee OA refractory to acetaminophen and NSAIDS.

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Application of an Unloader Knee Brace in the Treatment of Osteoarthritis

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A Clinical Graduate Project Submitted to the Faculty of the

School of Physician Assistant Studies

Pacific University

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Alexander Friedman is originally from Milwaukee Wisconsin, but spent much of his formative years in Ventura County, California. He completed his Bachelors degree in Philosophy from the University of California Santa Cruz in 2007. After finishing his undergraduate coursework he completed a certificate program for Emergency Medical Technicians and worked in the field for over 5 years. Since arriving at Pacific University, Alex has completed a Masters of Health Care Administration and the didactic portion of the Physician’s Assistant Masters Program. After graduation Alex hopes to serve his community through providing primary or emergency medical care.
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Unloader knee braces are a viable treatment option for patients with OA of the medial compartment of the knee. Better studies are needed to confirm if this treatment option will provide long-term relief. Although strong data is still lacking to confirm the complete success of this treatment, it is low risk and low cost. Therefore, it is recommended that they be used in clinical practice for patients with knee OA refractory to acetaminophen and NSAIDS.

**Keywords:** Brace, Osteoarthritis, and Unloader Knee Brace.
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Figure I: Osteoarthritis of the knee

List of Abbreviations

OA ................................................................................................................. Osteoarthritis
ADLs ............................................................................................................. Activities of Daily Living
VAS .............................................................................................................. Visual Analog Scale
KOOS ................................................................. Knee injury and Osteoarthritis Outcome Score
NSAIDs ............................................................. Non Steroidal Anti-Inflammatory Drugs
SL ............................................................................................................... Sport and Leisure Activities
QoL .............................................................................................................. Quality of Life
ES ............................................................................................................... Effect Size
FDA ............................................................................................................ Food and Drug Administration
Application of an Unloader Knee Brace in the Treatment of Osteoarthritis

BACKGROUND

Osteoarthritis of the knee is common after 50 years of age and can develop for many reasons, including: aging, previous trauma, high impact activities, misalignment, and genetic predisposition. Cartilage is a firm, smooth tissue that permits very low friction joint movement. In osteoarthritis, when the slick surface of the cartilage deteriorates, it becomes rough. After a period of time the cartilage may wear down completely leaving bone rubbing on bone. Osteoarthritis usually causes pain in the affected joint, when it is loaded (joint load refers to the force put on a weight-bearing or load-bearing joint during activity) or at the extremes of motion. Symptoms such as swelling, grinding, catching, and locking suggest internal derangement which means there may be damaged cartilage or bone fragments disrupting the smooth range of motion expected in a healthy knee. Knee pain can also cause muscle inhibition. Muscle inhibition may lead to the additional sensations of “buckling” or “giving way”. As the joint degeneration becomes more severe, the knee loses active range of motion and potentially some passive range of motion as well.

As knee OA becomes more advanced, patient’s ability to walk becomes more and more limited. Motions such as bending or twisting, and going up and down stairs often becomes excruciating in the latter stages of OA. Other common symptoms include swelling, limping, and pain while sleeping.

Changes in articular cartilage are permanent. Consequently, there are no treatments or procedures available to cure an arthritic joint. Therefore, OA treatments focus on alleviating symptoms and maintaining function. Conservative treatment for all patients with OA includes activity modification, physical therapy, and weight loss. For example, it is important for knee
OA patients to use proper footwear and avoid high impact activities such as running. The initial drugs of choice for the treatment of pain in knee osteoarthritis are oral acetaminophen and topical capsaicin.\textsuperscript{1} NSAIDs are often indicated as well, but their tendency to cause ulcerations and GI bleeds make them a poor choice for long term use. There may be even more reason to seek conservative options other than NSAIDS due to recent developments by the FDA. According to Troy Brown of Medscape, “The US Food and Drug Administration (FDA) has strengthened an existing label warning that nonaspirin nonsteroidal anti-inflammatory drugs (NSAIDs) may increase the risk for heart attack or stroke, according to an agency alert sent [July 9\textsuperscript{th}, 2015]”.\textsuperscript{5} This recent development adds credence to the notion that NSAIDS are not a good long term option for OA treatment. Opioids can be used appropriately in patients with severe osteoarthritis, but again, their dependence forming characteristics make them a poor choice for long term management. Other conservative OA treatment options include corticosteroid injections and hyaluronic acid injections or “viscosupplementation”. While these options have shown modest improvement in symptoms, their effects tend to be short term.\textsuperscript{1}

After these conservative measures have been exhausted, providers are left with a more invasive and expensive option to perform surgery. However, according to doctors Stephen McPhee and Maxine Papadakis, authors of Current Medical Diagnosis and Treatment, “Two published randomized trials demonstrate that arthroscopy does not improve outcomes at 1 year over placebo or routine conservative treatment of osteoarthritis”.\textsuperscript{1} Arthroscopic surgery is indicated in OA patients if they have mechanical symptoms and internal derangement symptoms, rather than pain. Joint replacement surgeries may be a good option for patients that have reached the most advanced and debilitating stages of OA. According to doctors McPhee and Papadakis, “[total knee replacement surgeries] are effective and cost-effective for patients with significant
symptoms or functional limitations, providing improvements in pain, function, and quality of life.”

In the United States, Osteoarthritis is one of the most common causes of disability among adults. OA causes a significant loss of productivity via chronic disability and affects nearly 25% of people over age 18, and 68% of adults over age 65. This is a significant problem for the American population. As the number of people over age 65 years double to more than 70 million by 2030, OA will become even more ubiquitous than it is today. Currently, the incidence of knee OA in the United States is 240 per 100,000 person-years.

Given these statistics, combined with the fact that many patients fail conservative treatment with acetaminophen and NSAIDs, leaving only opioids and more invasive procedures as options, it may be prudent to investigate other conservative treatment options. Knee sleeves or braces are known to alleviate some subjective pain symptoms possibly due to improvements in neuromuscular function. For patients with unicompartmental OA in the medial or lateral compartment, unloader knee braces are designed to offload the degenerative compartment. For patients with mild to moderate OA affecting only the medial compartment, can an unloader knee brace reduce pain and improve function enough to avoid using higher risk options?

(See Figure 1)

METHODS

An exhaustive search using MEDLINE-Ovid, Web of Science, and Google Scholar was performed using keywords: brace, osteoarthritis, knee, unload, and unloader. These results were screened with eligibility criteria. The resulting studies were then appraised and assessed for quality with GRADE.

Eligibility criteria was determined using PICO criteria for inclusion. For this systematic review, studies needed to relate to the question “For patients with mild to moderate OA affecting
the medial compartment, can an unloader knee brace reduce pain and/or improve function?”

Studies that examined braces for joints other than the knee, examined braces with mechanisms other than unloading the medial compartment (e.g. knee sleeves), examined conditions other than OA (such as MCL tears), and are more than 5 years old were excluded.

RESULTS

The initial search yielded 25 articles for review. After comparing the results to inclusion and exclusion criteria, two studies were included in this systematic review. One open-label prospective study\textsuperscript{10} of 20 patients with symptomatic medial knee OA studied the efficacy of the PROTEOR unloader brace. One prospective cohort study\textsuperscript{11} examined the effects of the Bespoke Unloader Knee Brace for 7 patients with Knee OA. See Table I.

Ornetti et al

This very recent study\textsuperscript{10} was an open-label prospective study of 20 patients with symptomatic medial knee OA published in March 2015. The authors’ objective was to evaluate the clinical effectiveness and safety of Proteor group’s new custom-made OdrA valgus knee brace in medial knee osteoarthritis in terms of pain and secondary symptoms. The principle outcome assessed in this study was improvement in pain at week six compared with pain measurements assessed at the time of inclusion. Pain was measured at rest using a visual analog scale (VAS) measuring from 0-100.\textsuperscript{10}

In addition to this primary outcome, secondary outcomes measured included improvement in pain at week 52 measured by a VAS (0-100), overall self-evaluation of disease severity measured by a VAS (0-100), function was measured by the Knee injury and Osteoarthritis Outcome Score (KOOS) consisting of 42 questions covering 5 domains, each scored from 0 (worst) to 100 (best): pain, other symptoms, function in activities of daily living (ADLs), function in sports and leisure activities (SL), and quality of life (QoL). Consumption of
nonsteroidal anti-inflammatory drugs (NSAIDs) and analgesics were evaluated by the number of days per week each class of drug was taken. Disease severity at week 6 and week 52 was measured by a semi-quantitative Likert scale: 1 = severely worsened, 2 = worsened, 3 = stable, 4 = improved, 5 = much improved. Tolerance to wearing the brace and compliance were evaluated by recording adverse effects in a patient diary and by measuring the average amount of time the brace was worn in hours per day and days per week.\textsuperscript{10}

Patients were recruited to participate in this study through referrals from the Department of Rheumatology and Physical Medicine of Dijon University Hospital over six a month period. Inclusion criteria consisted of patients that were 40 to 80 years old who had unilateral medial compartment knee OA. To meet this criteria patients needed to achieve a score of medial compartment pain at rest > 4 on a 0-10 VAS, and have radiological evidence of disease stage II, III or IV according to the Kellgren and Lawrence classification within the previous six months. In addition, patients needed to have no change in pharmacological treatment in the previous six months and no injections of hyaluronic acid or corticosteroids during this period. Exclusion criteria were the presence of a disease that could interfere with gait analysis or inflammatory or rapidly destructive knee OA. Patients with an indication for surgery or other diseases likely to cause knee pain or modify gait were also excluded. After inclusion and custom molding of the OdrA brace, patients were instructed to wear the brace for at least 6 hours per day, 5 days per week.\textsuperscript{10}

Twenty patients that met all inclusion and exclusion criteria were included in this study. This included 16 female patients and 4 male patients. One patient was forced to withdraw from the study at week 6 due to “venous intolerance” leaving 19 patients evaluated at week 6. Eighteen patients were reassessed at week 52 due to one additional loss to follow up.\textsuperscript{10}

At week 6, mean pain score had decreased by more than 50\% from inclusion, dropping
from 63.1 to 29.8 on VAS (see Table IIa). This significant improvement was maintained throughout the 52-week follow up period when the mean pain score was measured at 38.1. Substantial benefits were also measured in all 5 domains of the KOOS survey including pain, other symptoms, function of ADLs, function of SL, and QoL at both 6 and 52 week intervals (see Table IIa). Furthermore, the domains of pain, other symptoms and function of ADL were significantly decreased between week 6 and week 52. There were 85% of patients who believed that their knee OA had “improved” or “much improved” at week 6, and this figure only declined to 76% at week 52.10

Another extremely promising benefit of the use of this unloader knee brace was a substantial decrease in consumption of NSAIDs and analgesics. At the beginning of the study at week 0, patients were consuming analgesics at a mean of 4.5 days per week. By week 52, the consumption of analgesics had decreased to a mean of 1.3 days per week with 1/3 of patients discontinuing analgesic use entirely. By week 52 only one patient continued to use NSAIDs at least once a week, compared to six at the start of the study. Another additional benefit observed through the use of the unloader knee brace was an economic benefit of the ability to return to work. At the beginning of the study, three patients were on sick leave due to their knee OA. By week 52, two of those three were able to return to work in some capacity.10

In general the brace was very well tolerated. However, some adverse reactions were documented. One female patient had to stop the study early because her lower-limb varicose veins were aggravated while wearing the brace. However, Doppler ultrasonography revealed no deep vein thrombosis. The authors suggest that lower limb varicose veins may be a contraindication to using this type of brace. Six other patients described one or more superficial adverse effects concerning the skin in their patient diaries. Those adverse effects included two patients reporting local heat, four patients reporting moderate irritation, and five patients reported
a “zone of excessive weight bearing at the front of the tibia”. The patients wore the knee brace for a mean of more than 8 hours per day and more than 6 days per week at week 6. These statistics decreased to a mean of 6 hours per day and 4.7 days per week, by week 52. Most patients were able to put on and take off the brace without difficulty, but five patients had difficulties in getting dressed because of the lateral hinges.\textsuperscript{10}

Based on these findings the authors concluded, “this new unloader brace appeared to have good effect on medial knee OA, with an acceptable safety profile and good patient compliance”. The authors acknowledged that due to their small sample size and lack of control group to measure the possible placebo effect, a larger randomized study comparing the effects of this unloader brace to a neutral brace is necessary to confirm their results. Based upon the fact that pain and function were substantially improved with the brace, as shown by the effect size >0.8 and the high rate of satisfaction among patients over 75% at one year, in addition to the reduced consumption of drugs achieved by wearing the brace, further studies on this type of brace are clearly warranted\textsuperscript{10}.

\textbf{Arazpour et al}

This prospective cohort study,\textsuperscript{11} examining the effects of the Bespoke unloader knee Brace for 7 patients with knee OA, was published in February of 2014. The objective of the authors of this study was to, “identify the effects of a new design of knee unloader orthosis on specific gait parameters in patients with mild-to-moderate medial knee osteoarthritis”. The reason for the design of the unloader knee brace described in this study was to improve brace compliance by offering design features to reduce discomfort. However, the authors felt it was necessary to undertake a pilot study in a small patient group to establish its effect on gait parameters before conducting a longitudinal study to determine its function and compliance in a larger population. Therefore, the principal outcomes measured in this study were knee ROM
(°), external knee adduction moment (Nm/kg), speed of walking (m/s), step length (m), and cadence (steps/min), rather than the subjective measurements of pain and function.¹¹

Seven volunteer patients participated in this study. Patients were referred to the Orthotics & Prosthetics Clinic of University of Social Welfare and Rehabilitation Sciences in Tehran, Iran. These patients were selected based on non-probability judgment sampling, where the researchers selected subjects to be sampled based on their knowledge and professional judgment. The referring clinicians believed that the seven patients selected to participate in this study were, “representative of typical cases seen in their clinical caseload”. Inclusion criteria to participate in the study consisted of pain in one or both knees, with grade 1 or 2 knee medial compartment OA according to the Kellgren–Lawrence scale, which ranges from a severity of 0-4. Patients who had a recent history of trauma, had invasive treatment including injection therapy for the knee during the prior 6 months, neurological disease, lower back pain, hip, ankle or foot disease, skin problems or any disease that made it difficult to apply a brace were excluded from the study.¹¹

The Bespoke unloader knee brace used in this study were custom molded from a cast of each patient’s lower limb. An experienced expert in the field performed valgus correction manually during the casting process. The knee was corrected to the maximal corrected position in the frontal plane to a less varus position, which was still comfortable for the patient. This procedure was manually performed while the plaster cast was set, following an initial assessment prior to casting.¹¹

Patients were assessed to confirm the fit and comfort of their custom unloader knee brace before they began regimented gait analysis. Once this had occurred, patients were randomly assigned into two groups by blindly picking either the letter ‘A’ or ‘B’, which designated them into a with or without brace group for their first walking condition. Patients wore identically styled footwear for each gait analysis session. To assess the patient’s gait, they walked along the
gait laboratory at a comfortable self-selected speed in each test condition to collect five data sets. Kinematics and kinetics data were gathered by a Vicon digital motion capture system using six infrared cameras and two force platforms positioned to capture a left and right heel strike. Using this system, the authors of this study were able to interpret sagittal plane knee ROM, maximum externally applied knee adduction moment, walking speed, cadence, and step length. The knee joint adduction moment was calculated using an inverse dynamics model and reported in the units of Nm/kg.\textsuperscript{11}

The external knee adduction moment was significantly reduced ($p = 0.001$) (Table IIb), and walking speed was significantly increased ($p < 0.001$) when wearing the Bespoke unloader knee brace. A reduction in the knee ROM ($p = 0.002$) and an increase in step length ($p = 0.001$) were also observed while wearing the brace. Cadence was not significantly altered while wearing the brace ($p = 0.504$). The authors of this study concluded that the unloader knee braces used in this study applied a corrective force to the knee joint and reduced the external knee adduction moment in these patients. According to the authors of this study, “this reduction in the external knee adduction moment is thought to be the main biomechanical mechanism in reducing knee pain, providing functional improvement and a more symmetrical gait pattern in patients with knee OA at early and middle stages of OA”.\textsuperscript{11}

Although the external knee adduction moment was significantly reduced in this study, the percentage reduction found in this study appears to be much less (3\%) than results found in previous studies. Furthermore, the reduction of 0.02 Nm/kg in this knee adduction moment may not be clinically relevant. The authors hypothesize that the smaller reduction in adduction moment may have been due to the volunteer subjects having mild (grade 1 and 2 only) OA. Therefore, the authors plan to execute a larger study to include all grades of OA severity.\textsuperscript{11}

The authors of this study freely admit that external knee adduction moment alone cannot
completely capture the true loading, or compression force on the joint surfaces of the knee. Therefore, the clinical benefit of this brace needs to be confirmed in a future study. There were some other limitations to this study that need to be discussed. Only the immediate effects of ambulating with the knee brace were analyzed and the effect on pain scores could not be assessed. Furthermore, this study did not have a placebo control group and the patients acted as their own controls. Given their results as well as the limitations of this study the authors concluded that, “this pilot study demonstrated the potential of a new design of knee unloader orthosis as a conservative treatment approach for patients with mild medial compartment OA. [This] unloader knee orthosis … is shown to have immediate benefits in patients with mild medial knee OA”.

DISCUSSION

In synthesizing the data from these two small studies,\textsuperscript{10,11} there is a consensus that utilizing an unloader knee brace can provide both subjective improvements in pain and function as well as beneficial physiologic changes for patients with mild to moderate medial compartment OA. Looking at these two studies\textsuperscript{10,11} simultaneously provides insight from two very different points of view. Ornetti et al\textsuperscript{10} sought to demonstrate the benefits of reduced pain and improved function over a period of 1 year. While Arazpour et al\textsuperscript{11} sought to demonstrate that knee adduction moment, ROM, and other physiologic changes were objectively modified through the use of the unloader knee brace. These studies significantly elevate the quality of the other’s research. Looking only at subjective outcomes, it is very difficult to separate placebo effect and potential improvements in neuromuscular function from true benefits of unloading the medial compartment. However, once it is understood that a significant reduction in the external knee adduction moment can be achieved through the same device that provides improvements in pain and function, then one can build a stronger argument for the benefits of unloader knee braces.
Although both of these studies contribute to building a strong case for the use of unloader knee braces for patients with mild to moderate medial compartment OA, there are significant limitations to both studies\textsuperscript{10,11} that warrant much more extensive research to be done before a truly evidence based recommendation can be made. In the case of the Ornetti et al study, there were severe limitations, including small sample size (n=20), lack of blinding, and lack of follow up beyond one year. Due to the chronic and degenerative nature of OA, long-term follow up is essential to understanding the viability of a treatment. Patients are not going to cease needing OA treatment after one year, so providers must know how something like an unloader knee brace will continue to perform several years down the line. Due to these substantial limitations the Ornetti et al study has received a GRADE of “very low” quality of evidence. In the case of the Arazpour et al study\textsuperscript{11}, this research was designed and implemented to be a preliminary pilot study. This means that they were attempting to provide a foundation on which to build further research. Limitations to this study include very small sample size (n=7), severe lack of follow up, lack of blinding, and lack of a control group that is separate from the experimental group. When these limitations are taken into account using GRADE criteria, the quality of evidence for this study becomes designated “very low”.

In general, unloader knee braces were very well tolerated by the patients involved in these studies. Most complaints involved mild skin irritation or a “zone of excessive weight bearing at the front of the tibia”\textsuperscript{10}. However, venous insufficiency caused or aggravated by circumferential bracing could be a serious problem that needs to be specifically address if this technology were to be widely implemented. Especially because the population that tends to have problems with venous insufficiency and the population that has the greatest instances of OA are one in the same, older adults.
These studies\textsuperscript{10,11} have certainly shown enough to warrant funding for more extensive randomized controlled trials for the treatment of mild to moderate medial compartment OA with an unloader knee brace. Furthermore, based on the low cost ($75-$1,000 dollars US), the low risk of adverse effects, and the subjective short term improvements in pain and function, unloader knee braces may be a good option for conservative treatment of OA. Especially for patients that have failed acetaminophen and NSAID therapy, but are not yet severely debilitated enough to warrant surgery. In addition to patients that have failed NSAID therapy, patients that are currently relying on NSAIDS may benefit the most from the addition of an unloader knee brace as part of their treatment plan. For these patients, unloader knee braces may actually be able to lower their risk of heart attack and stroke by reducing their reliance on NSAIDS.\textsuperscript{6}

**CONCLUSION**

Based on current evidence, an unloader knee brace should be considered in the treatment of mild to moderate knee OA of the medial compartment for anecdotal improvements in pain and function. There is a growing population of patients in need of additional conservative OA treatment and unloader knee braces appear to be relatively safe, inexpensive, and effective. More research is needed to confirm the preliminary findings of the Ornetti et al and Arazpour et al studies and to see if unloader knee braces can indeed provide a safe, long term treatment that patients are likely to comply with. Funding for further research is warranted based on these findings. Future research should focus on long-term compliance, affects on venous insufficiency, and the possibility of unloader knee braces delaying the need for surgery. Providing a conservative treatment option for OA patients that does not rely on pharmaceuticals or invasive procedures may significantly impact quality of life for the better. By using an unloader knee brace OA patients may be able to reduce pain, improve function, engage in more sports and leisure activities, and even reduce dangerous cardiovascular risk factors.
References


Table I. Characteristics of Reviewed Studies

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<td>Ornetti et al&lt;sup&gt;10&lt;/sup&gt;</td>
<td>Open-label prospective study</td>
<td>Serious&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Not serious&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Serious&lt;sup&gt;c&lt;/sup&gt;</td>
<td>Not serious&lt;sup&gt;d&lt;/sup&gt;</td>
<td>No</td>
<td>Very Low</td>
</tr>
<tr>
<td>Arazpour et al&lt;sup&gt;11&lt;/sup&gt;</td>
<td>prospective cohort study</td>
<td>Serious&lt;sup&gt;e&lt;/sup&gt;</td>
<td>Not serious&lt;sup&gt;f&lt;/sup&gt;</td>
<td>Serious&lt;sup&gt;g&lt;/sup&gt;</td>
<td>Not Serious&lt;sup&gt;h&lt;/sup&gt;</td>
<td>No</td>
<td>Very Low</td>
</tr>
</tbody>
</table>

- Lack of control group
- Lack of blinding
- Small sample size
- Lack of follow up beyond 1 year
Table II. Summary of Findings from Ornetti et al Study\(^{10}\)

<table>
<thead>
<tr>
<th>Clinical variables</th>
<th>W0 n=20</th>
<th>W6 n=19</th>
<th>W52 n=18</th>
<th>ES (95% CI) W6</th>
<th>ES (95% CI) W52</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain, VAS (0–100)</td>
<td>63.1 ± 12.8</td>
<td>29.8 ± 14.2*</td>
<td>38.1 ± 17.4*§</td>
<td>2.6 (1.6–3.6)</td>
<td>1.9 (1.0–2.8)</td>
</tr>
<tr>
<td>Disease severity, VAS (0-100)</td>
<td>64.2 ± 16.5</td>
<td>34.1 ± 16.8*</td>
<td>36.9 ± 15.9*§</td>
<td>1.9 (1.1–2.7)</td>
<td>1.7 (1.0–2.4)</td>
</tr>
<tr>
<td>KOOS (0–100)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>42.6 ± 12.5</td>
<td>66.0 ± 13.6*</td>
<td>54.3 ± 13.2*§</td>
<td>1.9 (1.4–2.4)</td>
<td>0.9 (0.5–1.3)</td>
</tr>
<tr>
<td>Symptoms</td>
<td>54.4 ± 17.3</td>
<td>75.7 ± 17.5*</td>
<td>60.2 ± 16.2*§</td>
<td>1.2 (0.4–2.0)</td>
<td>0.4 (0.05–0.9)</td>
</tr>
<tr>
<td>ADL</td>
<td>44.5 ± 12.6</td>
<td>67.8 ± 11.9*</td>
<td>58.5 ± 12.7*§</td>
<td>1.8 (1.4–2.2)</td>
<td>1.1 (0.6–1.6)</td>
</tr>
<tr>
<td>SL</td>
<td>14.5 ± 13.4</td>
<td>37.3 ± 12.9*</td>
<td>34.0 ± 12.4*</td>
<td>1.7 (1.2–2.2)</td>
<td>1.5 (0.7–2.2)</td>
</tr>
<tr>
<td>QoL</td>
<td>28.6 ± 17.4</td>
<td>45.9 ± 23.3*</td>
<td>45.7 ± 16.5*</td>
<td>1.0 (0.3–1.7)</td>
<td>0.9 (0.3–1.5)</td>
</tr>
</tbody>
</table>

Data are mean ± SD unless indicated. KOOS: Knee injury and Osteoarthritis Outcome Score (0–100, 0, worst, to 100, best); ADL: activities of daily living; SL: sport and leisure activities; QoL: quality of life; ES: effect size; 95% CI: 95% confidence interval. *P < 0.05 comparing W6 vs. W0 and W52 vs. W0. §P < 0.05 comparing W6 vs. W52.
### Table III. Summary of Findings from Arazpour et al Study\textsuperscript{11}

<table>
<thead>
<tr>
<th>Variable Measured</th>
<th>Without Orthosis</th>
<th>With Orthosis</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knee ROM (°)</td>
<td>44 ± 1.86</td>
<td>39 ± 1.61</td>
<td>0.002</td>
</tr>
<tr>
<td>External knee adduction moment (Nm/kg)</td>
<td>0.55 ± 0.027</td>
<td>0.53 ± 0.021</td>
<td>0.001</td>
</tr>
<tr>
<td>Speed of walking (m/s)</td>
<td>0.90 ± 0.020</td>
<td>0.95 ± 0.022</td>
<td>0.001</td>
</tr>
<tr>
<td>Step length (m)</td>
<td>0.53 ± 0.038</td>
<td>0.56 ± 0.048</td>
<td>0.001</td>
</tr>
<tr>
<td>Cadence (steps/min)</td>
<td>102 ± 8</td>
<td>100 ± 7</td>
<td>0.504</td>
</tr>
</tbody>
</table>
Figure I: Osteoarthritis of the Knee