Comparison the effect of lateral wedge insole and acupuncture in medial compartment knee osteoarthritis: A randomized controlled trial

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Background: There is lack of well-designed trials evaluating structural benefits of non-pharmacologic therapies in knee osteoarthritis (OA). In this parallel-group randomized controlled trial, we aim to compare the possible advantages of lateral wedge insole and acupuncture in patients with medial knee OA.

Method: Patients with grade two or three of medial knee OA were randomly allocated to group one who received an in shoe lateral wedge and group two who underwent acupuncture. We assessed patients’ pain, function and their safety and efficacy.

Results: Twenty patients in each group were recruited in the study. Pain significantly decreased after therapy in both groups one and two (paired t test, P = 0.001, 95% CI: 1.62–2.35 and 1.58–2.20 respectively). Function improved in each group (paired t test, P = 0.001, 95% CI of 0.94–2.38 in group one and 0.97–2.43 in group two). A non-clinically statistically significant difference regarding the femoral and tibial cartilage thickness was obtained in both groups one (P = 0.005, CI: −0.43–0.82 and P = 0.037, CI: −0.44–0.80 respectively) and two (P = 0.025, CI: −0.45–0.79 and P = 0.035, CI: −0.29–0.96 respectively). Between groups analysis showed no significant difference regarding abovementioned measures.

Conclusion: Both lateral wedge insole and acupuncture can be effective in the treatment of medial knee osteoarthritis without any superiority of one over the other.

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1. Introduction

Knee osteoarthritis (OA), which most commonly affects the medial compartment [1], is one of the major causes of pain and physical disability in the elderly and it is estimated that it involves almost 10–13% of those over 65 years with a consequent major healthcare burden [2,3]. Although the role of biomechanical factors in the pathogenesis of knee OA has been well described [4], according to the findings of a meta-analysis conducted in 2000, about 86% of OA trials evaluate drug treatments or assess surgical procedures [5]. This has prepared lucrative opportunities for the development of drug therapies, in the absence of sufficient evidences to support rehabilitation and physical therapy techniques [6,7], in spite of the fact that probably, overall there is no, at least statistically, considerable disparity between non-pharmacological therapies and pharmacological therapies [8]. Bearing the adverse effects of the most frequently used existing medications in mind, we should aspire to increase the use of rehabilitation therapies if we are to prove their safety and efficacy.

Previous observational studies were suggestive for the advantageous effect of lateral wedge insoles for patients with medial tibio-femoral compartment OA [9–12]; yet, these findings have not been supported by conducted randomized clinical trials and no structural protection pursuing the utilization of lateral wedge insoles has been observed [6,13–16]. Nevertheless, the use of lateral wedge insoles for patients with medial knee OA is recommended in most of existing guidelines for the management of knee OA [8]. Acupuncture is also a suggested modality for symptomatic treatment of patients with knee OA in many guidelines [8]; nonetheless, a systematic review of the evidence for the efficacy of acupuncture in knee OA which included seven RCTs.
and 393 patients recommended that observed improvement in function of patients after acupuncture was inconclusive [17]. Also a very recent RCT in 352 patients with knee OA has shown very small, statistically significant, improvements in pain severity in patients, two and six weeks after acupuncture [18]. Synopsis of the evidences has suggested that a minimum number needed to treat with acupuncture for clinically significant relief of pain in patients with knee OA is four [8].

To the best of our knowledge, most of the previously conducted studies regarding the effects of acupuncture and laterally wedge insoles were mainly based on subjective variables such as gained score using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) or visual analog scale (VAS), other than objective variables such as measurement of knee articular cartilage thickness by magnetic resonance imaging (MRI). As a result, their findings may be inconclusive and not reliable. So, we presume to perform a study, to assess and compare the effects of lateral wedge insoles and true acupuncture on subjective and objective findings of the patients with medial knee OA.

2. Material and methods

2.1. Design and participants

We designed a parallel randomized controlled trial with the allocation ratio of 1:1 and recruited participants from the individuals seeking care at the physical medicine and rehabilitation clinics of hospitals affiliated to our university who said that they were interested in participating in research. The trial was conducted from May 2012 to January 2013.

Diagnosis of osteoarthritis was made by an expert physiatrist with regards to the American College of Rheumatology criteria for the classification and reporting of osteoarthritis of the knee joint [7,19]. The eligibility criteria for inclusion in the study were as follows: age between 38 and 65 years, successive knee pain unresponsive to conventional treatments for at least three months, and radiological findings are consistent with medial compartment knee OA, grade two (small osteophytes, possible narrowing of the joint), or grade three (multiple, moderately sized osteophytes, definite joint space narrowing, some sclerotic areas, possible deformation of bone ends) of the Kellgren–Lawrence classification system.

Patients were excluded if they had undergone initiation of other medical therapies with possible effects on the volume of knee articular cartilage (for example glucosamine and/or chondroitin); had symptomatic comorbid disease that limited walking more than knee pain limited walking (diabetic neuropathies, inflammatory arthritis, foot ulcers or sores, experienced pain emanating more from the back or hip than from the knee, vasculitis); had undergone amputation of or previous major trauma to a foot, raising apprehensions that using an insoles may deteriorate the pain; had any previous knee surgery; were chairbound or usually used an ambulation aid to walk; had been using oral or parenteral steroids; had contraindications to magnetic resonance imaging or had undergone surgical treatments for any condition of the knee, vasculitis); had undergone amputation of or previous major trauma to a foot, raising apprehensions that using insoles may deteriorate the pain; had any previous knee surgery; were chairbound or usually used an ambulation aid to walk; had been using oral or parenteral steroids; had contraindications to magnetic resonance imaging or had severe knee joint osteoarthritis.

Every patient signed an informed consent form and the study protocol was approved by our university’s ethics committee (no. ct-90-2690).

2.2. Interventions and measurements

Every patient in group one; for the side of the affected knee; received an in shoe wedge with the maximum of 5 mm (millimeter) thickness in the lateral heel which was tapering to the 2 mm thickness towards the anterior and medial sides of the sole and continued up to the metatarsal heads. Patients in this group were instructed to use the wedge in an appropriate shoe (not high heels or narrow-toed shoes) 1 h a day during the first week. The duration of use gradually increased to the minimum of 8 h a day. Patients were followed with telephone calls every 45 days during the study period. The patients’ convenience was assessed and reported throughout the study (Table 1).

Acupuncture was performed for patients in group two with eight needle insertions per patient per session for total duration of 10 sessions using 0.25 × 25 mm stainless steel needles. We selected the acupuncture points based on Traditional Chinese Medicine meridian theory as following [20]:

1) EX.31 (Heding): above the knee in the depression of the midpoint of the superior patellar border
2) EX.32 (xiyan): below the patella in the hollow at medial side of the patellar tendon
3) ST.35 (Dub): lower border of the patella in the depression lateral to the patellar ligament
4) ST.36 (Zusanli): 3 cm below the knee, about one fingerbreadth from the tibial tuberosity
5) ST.44 (Neiting): on the dorsum of the foot, proximal to the web margin between the second and third toes
6) GB.34 (Yanglingquan): in the lateral side of the leg in the hollow anterior and below the capitulum of the fibula, 2 cm below the knee
7) DU.20 (Baihui): at the intersection of the median line at the vertex of the head with a line drawn from the tip of one ear to the other
8) BL.60 (Kunlun): in the depression between the apex of the lateral malleolus and Achilles tendon.

Acupuncture was done by a trained physical medicine and rehabilitation resident with a two-year practice and during all sessions, the depth of insertion, and the intensity of stimulation (manipulation) were kept identical. The needles remained in the patients’ body for 30 min in each session.

We assessed patients’ pain and function in addition to knee joint cartilage thickness before and after each intervention. The total duration of intervention was three months for group one and three weeks for group two (three sessions per week) and outcome measurement was done in another session immediately after the end of each intervention predetermined period. Pains during movement over the past week were measured by the visual analog scale (VAS) from zero to 10 in 1 cm intervals (zero: no pain, 10: greatest pain imaginable). The WOMAC scale was used to investigate functional status. This scale evaluates patients’ function during different activities like sitting, standing and walking and consists of five questions regarding the level of pain experienced during a particular activity over the past 48 h. Every question can have five different answers that take different scores from zero to four (zero: no pain, one: mild pain, two: moderate pain, three: severe pain, four: very severe pain). Final score for each patient is calculated through summation of all five parts’ scores.

Patients’ joint cartilage thickness before and after each therapeutic intervention was measured by a Siemens Avanto magnetic resonance imaging (MRI) scanner with Tim 32 × 8 with proton density-weighted imaging with a slice thickness of 3 mm, field of view of 14 cm, matrix of 358 × 512, TR: 2700, TE: 36, slice gap: 0.6, signal average: 2, bandwidth: 191 and Turbo faster: 10. This measurement was done in the medial compartment of the posterior inferior portion of the femoral condyle and posterior portion of the tibial plateau simultaneously.

### Table 1

The scoring system for reporting patients’ convenience regarding the use of lateral wedge insole.

<table>
<thead>
<tr>
<th>Score</th>
<th>Level of discomfort</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>None</td>
</tr>
<tr>
<td>1</td>
<td>Mild</td>
</tr>
<tr>
<td>2</td>
<td>Moderate</td>
</tr>
<tr>
<td>3</td>
<td>Severe</td>
</tr>
<tr>
<td>4</td>
<td>Very severe</td>
</tr>
</tbody>
</table>
2.3. Sample size

The sample size calculation for this study was based on the detection of a one-point difference in each group for the outcome pain intensity measured by the visual analog scale (VAS) (estimated standard deviation of 1.5). With a two-sided 5% significance level, a power of 80% and correlation of 70%, and a sample size of 20 patients per group (total: 40) were necessary.

2.4. Randomization

For allocation of the participants to either a lateral sole wedge group or an acupuncture group a computer-generated list of random numbers was used. Blocking was used to ensure that comparison groups will be generated according to a predetermined ratio with the block size of two. The allocation sequence was concealed from the researcher enrolling and assessing participants in sequentially numbered, opaque, sealed and stapled envelopes.

2.5. Blinding

The patients and the physiatrist who measured outcomes were aware of the allocated arm but the radiologists who reported participants’ knee magnetic resonance imaging (MRI) and the statistical specialist who analyzed data were blinded.

2.6. Statistical methods

All analyses were on an intention-to-treat basis with all randomized patients included in the analyses conducted by SPSS version 16. Missing data from patients who withdrew after the initial visit were adjusted by means of the “last observation carried forward” technique. We assessed normality using normal distribution histogram, q–q plots and p–p plots. Also, Kolmogorov–Smirnov test and Skewness & Kurtosis test confirmed normality. All demographic characteristics except age were analyzed using the Chi-Square test. We used paired t-test for comparing all outcomes with initial data in each group and independent sample t-test for between groups analysis. T-test also was used for assessing whether there is any difference between groups regarding the age. P values of less than 0.05 were considered to be significant. Also we determined 95% Confidence Intervals in order to assess the clinical significance of outcomes.

3. Results

Among 40 patients finally recruited; 20 persons in the wedge group and 20 patients in the acupuncture group; 35 completed the trial (Fig. 1). None of them crossed over to the other treatment group. Twenty seven and half percent of all 40 patients were males. Patients were aged between 39 and 65 years old with the mean age of 56.02 ± 6.32. Most of the cases (45%) were uneducated and also most of them (72.5%) were employed as a housekeeper. There was no significant difference between the two groups regarding the age, gender, education and job (Table 2).

VAS score significantly improved after therapy in both groups (paired t test, P = 0.001, 95% CI of 1.62–3.25 in group one and 1.58–3.20 in group two). Also, the WOMAC score significantly decreased after each intervention (paired t test, P = 0.001, 95% CI of 0.94–2.38 in group one and 0.97–2.43 in group two). Between groups analysis showed no significant difference regarding the function and pain (Tables 3 and 4, P = 0.908 and 0.304 respectively). Therefore, patients’ function and pain improved both statistically and clinically after the therapy independent to the type of intervention.

We measured cartilage thickness of the femur and tibia before and after therapeutic intervention in both groups and after in group data analysis we found a significant statistical but not clinical change in each group regarding both femoral and tibial cartilage thickness after therapy (Tables 5 and 6, P = 0.005, CI: −0.63–0.82 and P = 0.037, CI: −0.44–0.80 respectively in group one; P = 0.025, CI: −0.45–0.79 and P = 0.035, CI: −0.29–0.96 in group two). But, there was no significant difference regarding femoral and tibial cartilage thickness between two groups (Tables 5, 6, P = 0.563 and 0.448 respectively). So, joint cartilage thickness increased with either lateral wedge insole prescription or acupuncture but this change was not clinically important in our relatively small sample and there was no definite difference between these two modalities.

We screened all participants for probable adverse events, but no serious adverse event was reported by the patients in any group during the study.

4. Discussion

We could find positive results from both wedge prescription and performing acupuncture in patients with medial knee osteoarthritis for pain reduction and improvement of function. Although we could find statistically significant improvement of joint cartilage thickness as

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Table 2

Distribution of patients’ demographic characteristics in two groups.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group 1 (number, percent)</th>
<th>Group 2 (number, percent)</th>
<th>P value</th>
<th>Statistical indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (male/female)</td>
<td>4/16 (20%/80%)</td>
<td>7/13 (35%/65%)</td>
<td>0.288</td>
<td>1.12</td>
</tr>
<tr>
<td>Age 55.2 ± 7.15</td>
<td>11/9 (55%/45%)</td>
<td>12/8 (60%/40%)</td>
<td>0.480</td>
<td>0.712</td>
</tr>
<tr>
<td>Education (uneducated or elementary/more than elementary)</td>
<td>13/7 (65%/35%)</td>
<td>16/4 (80%/20%)</td>
<td>0.288</td>
<td>1.12</td>
</tr>
</tbody>
</table>

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Fig. 1. Patient recruitment, randomization and follow up.
a result of these non-pharmacologic interventions, this improvement was not clinically important according to the 95% CI calculation. Also, none of these methods had any priority in comparison to the other.

Most of the studies performed to evaluate clinical utility of either lateral wedge insoles or acupuncture in the management of knee OA have not documented their results with magnetic resonance imaging; a precise paraclinic diagnostic technique. Also no research has been done to compare the efficacy of these two therapeutic options up to now.

Some of the previous studies obtained good results for lateral wedge prescription and found much benefit including decrease in VAS score, femorotibial angle and talar tilt angle in patients with knee OA with varus deformity [13], reducing the varus torque [19,21], reducing loading of the medial compartment in persons with medial knee osteoarthritis [19] and reducing the knee adduction moment [12] and walking pain in a large group of patients with medial knee OA [12]. In contrast to the abovementioned advantages and our results, a systematic review conducted by Reilly et al. [22] in 2006 could not find major or long-term beneficial effects with the use of lateral wedges.

In 2007 Baker et al. [6] conducted a double-blind, randomized, crossover trial that participants received a 5° lateral-wedge insole or a neutral insole for six weeks. Following a four-week washout period, patients crossed over to the other treatment for six weeks. The effect of treatment with a lateral-wedge insole for knee OA was neither statistically significant nor clinically important. Considering the study design and its difference with our research method can explain the discordance in results. We prescribed lateral wedge for a more prolonged duration (three months) and at least 8 h a day which might be the reason of better outcome. Bennell and colleagues [16] in 2011 studied 200 people with clinical and radiographic diagnosis of mild to moderately severe medial knee osteoarthritis to compare the effect of full length 5° lateral wedge insoles with flat control insoles worn inside the shoes daily for 12 months. Outcomes were change in volume of medial tibial cartilage from magnetic resonance imaging scans and changes in measures of pain, function, stiffness, and health related quality of life. In contrast to our study, they found no symptomatic or structural benefit for lateral wedge insoles and suggested that it could be due to encouraging the participants to wear the insoles in their usual shoes which might be non-standardized ones. Different shoe types can influence the biomechanical and clinical effectiveness of insoles, and in particular shoes with heels can attenuate their effects. We measured femoral and tibial cartilage thickness in the posteromedial aspect of the knee for evaluating the effect of wedge but Bennell et al. used volume of cartilage in the medial tibial compartment on magnetic resonance imaging for outcome measurement. Therefore, it may not be rational to compare these techniques. Also, studying patients for a long time (one year) might influence their adherence and proper use of the lateral wedge.

Our findings about the positive effect of acupuncture were concordant with previous results. According to a meta-analysis in 2006, Sham-controlled RCTs suggest specific effects of acupuncture for pain control in patients with peripheral joint osteoarthritis and it seems a safe and good option particularly for knee OA [23].

In another review conducted by Selfe and Taylor in 2008 all 10 of the studies which were included; measured pain, and six of these also measured physical function. Nine studies concluded that acupuncture was effective. So, authors declared that acupuncture should be considered an adjunct or alternative treatment of knee pain and dysfunction associated with osteoarthritis of the knee [24].

Cao and colleagues in the most recent meta-analysis in 2012 found significantly better relief from knee osteoarthritis pain and a larger improvement in function (both short term and long term) by acupuncture than sham acupuncture, standard care treatment, or waiting for further treatment [25]. None of the surveys have studied the possible structural benefit of acupuncture in knee osteoarthritis. This structural improvement may be explainable by two mechanisms. First, mechanical

### Table 3
Comparison the wedge group with acupuncture group regarding the WOMAC score.

<table>
<thead>
<tr>
<th></th>
<th>WOMAC score before intervention</th>
<th>WOMAC score after intervention</th>
<th>Effect size</th>
<th>95% CI</th>
<th>Power</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1 (lateral wedge insole)</td>
<td>54.5 ± 11.43</td>
<td>37.75 ± 8.04</td>
<td>1.70</td>
<td>0.94–2.38</td>
<td>100</td>
<td>0.001</td>
</tr>
<tr>
<td>Group 2 (acupuncture)</td>
<td>49.65 ± 8.57</td>
<td>35.05 ± 8.32</td>
<td>1.73</td>
<td>0.97–2.43</td>
<td>100</td>
<td>0.001</td>
</tr>
<tr>
<td>P value</td>
<td>0.137</td>
<td>0.304</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Table 4
Comparison the wedge group with acupuncture group regarding the VAS score.

<table>
<thead>
<tr>
<th></th>
<th>VAS score before intervention</th>
<th>VAS score after intervention</th>
<th>Effect size</th>
<th>95% CI</th>
<th>Power</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1 (lateral wedge insole)</td>
<td>7.2 ± 1</td>
<td>4.15 ± 1.42</td>
<td>2.48</td>
<td>1.62–3.25</td>
<td>100</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Group 2 (acupuncture)</td>
<td>7.05 ± 1.05</td>
<td>4.2 ± 1.28</td>
<td>2.43</td>
<td>1.58–3.20</td>
<td>100</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>P value</td>
<td>0.647</td>
<td>0.908</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Table 5
Comparison the wedge group with acupuncture group regarding the femoral cartilage thickness.

<table>
<thead>
<tr>
<th></th>
<th>Femur cartilage thickness before intervention</th>
<th>Femur cartilage thickness after intervention</th>
<th>Effect size</th>
<th>95% CI</th>
<th>Power</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1 (lateral wedge insole)</td>
<td>1.47 ± 0.41</td>
<td>1.55 ± 0.39</td>
<td>0.20</td>
<td>−0.43–0.82</td>
<td>0.84</td>
<td>0.005</td>
</tr>
<tr>
<td>Group 2 (acupuncture)</td>
<td>1.55 ± 0.41</td>
<td>1.62 ± 0.41</td>
<td>0.17</td>
<td>−0.45–0.79</td>
<td>0.76</td>
<td>0.025</td>
</tr>
<tr>
<td>P value</td>
<td>0.591</td>
<td>0.563</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Table 6
Comparison the wedge group with acupuncture group regarding the tibial cartilage thickness.

<table>
<thead>
<tr>
<th></th>
<th>Tibial cartilage thickness before intervention</th>
<th>Tibial cartilage thickness after intervention</th>
<th>Effect size</th>
<th>95% CI</th>
<th>Power</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1 (lateral wedge insole)</td>
<td>1.33 ± 0.35</td>
<td>1.4 ± 0.42</td>
<td>0.18</td>
<td>−0.44–0.80</td>
<td>0.76</td>
<td>0.037</td>
</tr>
<tr>
<td>Group 2 (acupuncture)</td>
<td>1.41 ± 0.23</td>
<td>1.49 ± 0.24</td>
<td>0.34</td>
<td>−0.29–0.56</td>
<td>0.72</td>
<td>0.035</td>
</tr>
<tr>
<td>P value</td>
<td>0.378</td>
<td>0.448</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
signaling through connective tissue created by acupuncture needle manipulation can induce intracellular cytoskeletal reorganization in fibroblasts and possibly in other cells present within connective tissue. This rearrangement has been shown to induce cell contraction, migration, and protein synthesis [26]. Zhu et al. in 2011 suggested that proper mechanical stimulation in the early and middle stages of osteoarthritis can affect the function of chondrocytes, repair the damaged chondrocytes and delay the articular cartilage degeneration by regulation of the expression of integrins which are one of the mechanoreceptors on the surface of cells [27]. Second, based on a survey by Bao and colleagues, acupuncture can down-regulate the expression of matrix metalloproteinase-1, 3 (MMP-1, MMP-3) and tissue inhibitor of metalloproteinase-1 (TIMP-1) in the cartilage of rats thus it may have a protective effect on cartilage from OA [28]. We measured and compared joint cartilage thickness before and after acupuncture in a group of patients with knee OA for the first time and could not observe a clinically significant improvement.

4.1. Study limitations

We should note that we faced some limitations during this study. First, patients and the person who assessed pain and functional outcomes were not blinded about the intervention. Second, although a resident of physical medicine followed the patients in group one regarding their compliance through phone calls, it might not be as effective as regular visits for acupuncture conducted by him in group two. Third, acupuncture was done by a resident of physical medicine and rehabilitation not an expert acupuncturist. According to previous researches the acupuncturist’s experience can strongly affect the results. Therefore, our findings regarding the acupuncture advantages might be underestimated even with proper acupuncture teaching to the residents in our institution. Fourth, therapeutic response was monitored three weeks after acupuncture but three months after lateral wedge usage. Finding no significant difference between these two methods cannot disclaim the probable faster onset of therapeutic response with acupuncture. Investigating the effect of lateral wedge in knee OA needs its long term use by the patients and even three months follow up seems to be inadequate. On the other hand, some patients may refuse acupuncture as a non-pharmacologic therapy because of pain or discomfort. Bearing in mind the more convenience, less pain and no need for frequent visits advantages with using lateral wedge in contrast to the acupuncture may enhance the value of this safe noninvasive treatment regardless of the no statistically significant difference between these two interventions observed in this study.

Having a small sample size is another important limitation of this study which might influence the ability to find statistically significant differences between groups.

5. Conclusion

Both wedge prescription and acupuncture in patients with knee osteoarthritis can reduce pain and improve function, however, we could not find sufficient evidence supporting the structural benefits of these therapeutic interventions. There was no significant statistical difference between these methods. We suggest conducting further well designed RCTs with larger sample size and long term follow up to assess certain benefits of non-pharmacologic treatments (in particular structural changes) such as lateral wedge and acupuncture.

6. Conflict of interest statement

On behalf of all authors, there are no known conflicts of interest associated with this publication and there has been no significant financial support for this work that could have influenced its outcome.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at http://dx.doi.org/10.1016/j.knee.2013.12.002.

References


