Effectiveness of an insole with a lateral wedge for idiopathic osteonecrosis of the knee

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For the purpose of investigating the effect of an insole with a lateral wedge, we studied 30 patients (31 knees) aged from 46 to 78 years with idiopathic osteonecrosis of the knee for at least three years. The 18 knees treated with an insole (group I) were matched by age, gender, obesity index, area of lesion, femorotibial angle, stage, and clinical evaluation with 13 treated conservatively without an insole (group II).

The clinical results, as rated by a knee score, improved significantly more in group I than in group II. Radiologically, the necrotic area and ratio decreased in group I, whereas in group II they increased. In advanced cases, with stage 4 or a femorotibial angle of more than 180°, the use of an insole did not improve the clinical or radiological findings. The insole is a valuable method of conservative treatment for the early stages of osteonecrosis of the medial femoral condyle.

Patients and Methods

From 1990 to 1996, we studied 41 knees in 39 patients with osteonecrosis, clinically and radiologically diagnosed at Shimane Medical University. Nine patients (10 knees) were excluded as the condition was thought to be secondary to systemic lupus erythematosus, renal transplantation or steroid medication. This left a total of 31 knees in 30 patients in the study. All were ‘idiopathic’. The mean age of the patients was 69 years (46 to 78). Twenty-seven were women and one woman was bilaterally affected. All lesions were situated in the medial femoral condyle.

The insoles, silicone rubber soles (Fig. 1a) with two velcro bands, were specifically designed for each patient. The exterior height of the insole was 7 mm. The patient was able to insert the insole into an ordinary shoe or use it without a shoe indoors (Fig. 1b).

The patients were randomly divided into two groups. Seventeen (18 knees) in group I were treated with the insole for the observation period and 13 (13 knees) in group II were treated conservatively without the insole, but with...
analgesics or physiotherapy. The mean duration from the onset of pain to the initial visit was 18.6 months (1 to 60) in group I and 12.5 months (1 to 60) in group II. All patients were initially given analgesics or anti-inflammatory agents. Both groups were well matched for age, gender, obesity index, initial clinical and radiological evaluation, and follow-up period (Table I). The obesity index was calculated according to the formula:

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\text{obesity index} = \frac{\text{body-weight}}{\text{height} - 100} \times 0.9
\]

All patients were followed up for at least 36 months (36 to 183).

Clinical and radiological assessment. The clinical outcome was graded according to the Hospital for Special Surgery (HSS) knee scoring system which has a 100 point scale, of which 30 are for pain, 22 for function, 18 for range of movement, ten for flexion deformity, ten for muscle strength, and ten for instability.

For radiological evaluation, the initial and final follow-up radiographs were reviewed in terms of necrotic area (cm²), ratio (%), femorotibial angle (FTA) in the one-foot standing position, and the stage of osteonecrosis. The necrotic area was calculated as the maximum width of the lesion on the anteroposterior radiograph multiplied by the maximum length in the lateral view. The necrotic ratio was calculated as the ratio of the maximum width of the lesion to the width of the condyle on the anteroposterior radiograph. The radiological changes in the knee were classified according to Koshino’s staging of osteonecrosis.

Statistical analysis. ANOVA tests and chi-squared (Fisher’s exact) tests were used to determine if differences in the clinical and radiological values between the two groups were significant. A p value of <0.05 was accepted as significant.

Results

Compared with the initial visit, the clinical results at the final follow-up, as rated by the total HSS knee score, were significantly better in group I (58.6 ± 4.6 vs 69.9 ± 11.5; p = 0.002) than in group II (60.8 ± 7.6 vs 57.8 ± 8.8);

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<tr>
<th>Stage</th>
<th>Group 1 Initial</th>
<th>Final</th>
<th>Group 2 Initial</th>
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* two knees had an FTA of more than 180° at the initial visit

Radiological changes in the two groups showing a) the necrotic area, and b) the necrotic ratio before and after treatment (*: p < 0.05; NS, not significant).
p = 0.21). In particular, the pain score (the combination of the score of pain on walking and that of pain at rest) improved significantly more in group I (5.5 ± 3.4 vs 14.3 ± 9.1; p = 0.002) than in group II (6.8 ± 4.0 vs 4.0 ± 3.9; p = 0.23). No patients using an insole complained of pain or discomfort around the ankle or other joints.

Radiologically, in group I the necrotic area (2.3 ± 1.8 vs 1.3 ± 0.8 cm²; p = 0.048) and ratio (46.9 ± 17.4% vs 34.8 ± 15.7%; p = 0.01) significantly improved (Figs 2 and 3). By contrast, group II (Fig. 2) showed a relatively large increase in area (2.4 ± 2.0 vs 3.1 ± 3.2 cm²; p = 0.42) and ratio (42.2 ± 23.6% vs 44.4 ± 24.9%; p = 0.87).

In group I none of the knees at stage 1 or stage 2 changed at follow-up. In group II, one knee advanced from stage 2 to stage 3, and three from stage 2 to stage 4 (Table II). Although two of the seven knees initially at stage 3 in group I, advanced to stage 4, all of their initial FTAs were more than 180°.

When comparing the 23 patients with an FTA of less than 180°, the incidence of stage 4 (degenerative stage) was less for those in group I (14%) than for those in group II (78%). By contrast, with the knees which had an FTA of more than 180°, there was no significant difference in the occurrence of stage 4 between the two groups.

Discussion

We have described the effect of an insole with a lateral wedge in the treatment of osteonecrosis of the medial femoral condyle. Various surgical procedures with high rates of success have been documented including arthroscopic debridement,11 core decompression,12,13 high tibial osteotomy,14,15 osteochondral graft,16-18 and unicondylar19 or total condylar replacement.20,21 There have been few accounts of the outcome after conservative treatment and of the indications for each surgical procedure. Muheim and Bohne9 have noted that smaller lesions, averaging 2.4 cm², did not collapse quickly, while larger defects, averaging 10.4 cm², fragmented rapidly. Lotke et al10 have suggested surgical treatment for those knees which have lesions with a transverse diameter greater than 50% of that of the medial femoral condyle. The incidence of osteoarthritis after conservative treatment ranges from 33% to 90%.9,22,23 Our results showed a similar prevalence of osteoarthritis (stage 4; 54%) in group II. We hoped that the use of an insole might give lasting symptomatic relief.

The extent of the lesion in the medial femoral condyle may be limited by altering the mechanical axis of the knee. High tibial osteotomy, by altering the mechanical axis, may give good results.14,15 Biomechanical studies have shown that the contact force within the normal knee is ten times greater on the medial than on the lateral tibial plateau.26,27 In a varus knee, the compression force is wholly applied on the medial plateau.28 Biomechanically, Yasuda and Sasaki29 showed that the use of an insole with a lateral wedge changes the spatial position of the femur, tibia, and calcaneus and decreases the tensile force in the lateral collateral ligament and iliotibial tract, thereby reducing the resultant compression force affecting the medial compartment of the joint. They showed that the use of an insole reduced the loading force on the medial compartment by 16 ± 6% of body-weight and that patients with medial osteoarthritis of the knee who wore insoles, improved clinically and radiologically.25 It has also been suggested that changing the mechanical axis affects bone density30 with reduction of osteosclerosis of the medial condyle after high tibial osteotomy.31 By changing the mechanical axis of the knee with an insole with a lateral wedge, reduction of the medial compression force prevents the collapse of the osteonecrotic lesion. An insole did not affect the outcome in knees with advanced osteonecrosis or with an FTA which was more than 180°. An insole with a lateral wedge, however,
gives good results as conservative treatment for early idiopathic osteonecrosis of the knee.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

References