A comparative study on the effect of the insole materials with subtalar strapping in patients with medial compartment osteoarthritis of the knee

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Abstract This study was conducted to assess the symptomatic effects of the insole with an elevation of 12 mm composed of urethane (urethane insole) or of sponge rubber (rubber insole) with subtalar strapping in patients with medial compartment osteoarthritis of the knee (knee OA). The setting was an outpatient clinic. Eighty-four patients with knee OA were prospectively randomized, and evaluated and treated with the urethane or rubber insole for 4 weeks. Randomization was performed according to birth date and each participant was categorized into the urethane group or the rubber group. The percentage of remission of Lequesne index of severity for knee OA was compared between urethane and rubber insole groups at the conclusion of the study. Participants were asked to report adverse effects of use of the respective insoles. The percentage of remission was significantly improved in the urethane insole group \( (n = 42) \) compared with the rubber insole group \( (n = 42) \) \( (P = 0.001) \). Adverse effects were more common in the rubber insole group (17 out of 42, 40.5\%) than in the urethane insole group (8 out of 42, 19.0\%), and this was statistically significant \( (P = 0.028) \). The inserted insole in combination with subtalar strapping had a more natural form-fit to the sole than the insole insert alone. In our study of the subtalar strapping insole, an insole composed of urethane, was more comfortable than that of rubber sponge.

Key words Insole · Knee · Material · Orthotic device · Osteoarthritis

Introduction

Osteoarthritis of the knee (knee OA), which occurs symptomatically in approximately 6\% of adults 30 years of age and older and in 11\% of adults 65 years of age and older, accounts for more mobility disability in the elderly than any other disease.\(^1\) Patients with knee OA usually present with major involvement in only one compartment, with the medial compartment involved nearly 10 times more often than the lateral compartment.\(^2\)

While surgeons have made remarkable progress in techniques such as high tibial osteotomy and total knee arthroplasty for treatment of medial compartment knee OA, the vast majority of patients are hesitant to undergo surgical treatment. One of the first forms of conservative mechanical treatment for patients with medial compartment knee OA was the use of lateral wedged inserted insoles. Yasuda and Sasaki\(^3\) reported, however, that the inserted insole failed to correct the femorotibial angle in patients with varus deformity and medial compartment knee OA. It is plausible that, with the inserted insole, movement of the talus may prevent calcaneal valgus correction, thereby preventing femorotibial valgus correction. Thus, the effect of the inserted insole is fundamentally different from surgical correction of the femorotibial angle with high tibial osteotomy.

In research conducted on conservative alternatives to surgical correction of the femorotibial angle, this limitation of the inserted insoles was addressed through the development of a novel lateral wedged insole with elastic strapping of the subtalar joint. The subtalar strapping insole resulted in a significant change in the talocalcaneal angle, the talar tilt angle, and the femorotibial angle, while the inserted insole alone produced a significant change only in the talocalcaneal angle on standing radiographs.\(^4\) The insole with subtalar strapping produced the desired realignment. This
led to the conclusion that an insole with elastic fixation obtained with tension of a subtalar and ankle joint band leads to valgus angulation of the talus. This corrects the femorotibial angle in patients with varus deformity knee OA, and may have a therapeutic effect similar to that of high tibial osteotomy.

Further studies suggested that the subtalar strapping increased the effectiveness of the insole in treating the symptoms of OA of the knee measured as increased maximum distance of ambulation and for pain reduction while asleep, upon awakening, and upon standing up from a seated position. A significant correlation was observed between lower extremity lean body mass per body weight and symptomatic relief of knee OA by treatment with the subtalar strapping insole. Without muscular support of the anatomic realignment, patients may retain their previous varus stance and gait, negating the effect of insole therapy. In another study, we assessed the optimal tilt of the lateral wedged insole with subtalar strapping. Patients with knee OA were treated with a lateral wedge with elevations of 8, 12, or 16 mm with subtalar strapping. We concluded from the results that the 12-mm wedge is best suited for routine and regular use.

Despite advances in our understanding of the lower extremity valgus realignment and symptomatic improvement induced by the insole with subtalar strapping, and its indication and optimal tilt, the optimal material of the lateral wedge has not yet been elucidated. Therefore, this study was designed to assess lower extremity valgus realignment, symptomatic relief, and adverse effects in patients treated with the insole composed of sponge rubber or urethane with subtalar strapping.

**Materials and methods**

This study was accomplished through prospective, randomized evaluation of patients with knee OA treated with the lateral wedged insole composed of sponge rubber with subtalar strapping, as well as those treated with the insole composed of urethane with subtalar strapping. The principal outcome measures considered were pain improvement using a clinical index and the radiographic bony alignment. Additionally, side effects and complications of the use of these insoles were measured. The procedures outlined in the Helsinki Declaration were followed.

Subjects were defined as patients with medial compartment OA knee, according to the American College of Rheumatology criteria, and a standing femorotibial angle greater than 176° by X-ray (the standard value of femorotibial angle in standing radiographs is 176° in healthy Japanese adult females). Exclusion criteria following the report by Maillerfert et al. were functional class of IV (Steinbrocker), radiographic grade of IV according to Kellgren and Lawrence, greater or similar reduction in lateral than medial femorotibial joint space width (concomitance with lateral knee OA) on plain posteroanterior X-rays, bilateral knee OA, secondary knee OA, hip OA, ankle OA, hallux rigidus, valgus deformity of the midfoot, other symptomatic deformity of the foot, advanced arthroplasty of the hindfoot, any disease treated with insoles, previous ankle arthrodesis, tibial osteotomy, and intra-articular corticosteroid injection within 1 month.

After providing informed consent, 84 new female outpatients with knee OA (>45 years old, mean age 63.4, standard deviation 8.9) seen in our Orthopedic Outcome Clinic from May to July in 2003 and January in 2004 were treated with the insole with subtalar strapping for 4 weeks. All participants were also treated with a nonsteroidal anti-inflammatory drug (NSAID) (acemetacine, 30 mg) orally twice a day as adjunctive therapy. All other adjunctive therapies were discontinued, including intra-articular hyaluronan injections and physical therapy.

Each symptom relating to knee OA was evaluated according to the Lequesne index for OA knee including: (1) pain during nocturnal bed rest with full extension of the knee, (2) duration of morning stiffness or pain after getting up, (3) increased pain with standing for 30 min. (4) pain on walking, (5) pain when getting up from sitting position without the help of arms, (6) maximum distance walked, (7) ability to climb stairs, (8) ability to descend stairs, (9) ability to squat, and (10) ability to walk on uneven ground. Items (1) and (2) concerning pain during nocturnal bed rest and pain after awakening were evaluated by patient self-report, as patients could not be observed at night or early in the morning. All other items were assessed under stable conditions by research nurses who were uninformed of the objective of the study at the commencement of treatment and then again at the fourth week thereafter.

Disease duration was based upon patients’ recollection of the onset of their knee pain. Height was measured to the nearest 1 cm using a stadiometer and weight was measured to the nearest 0.1 kg with subjects standing erect, wearing underwear and robes without shoes. A research nurse who was blinded to the objectives of the study asked participants to assess their level of pain using the Lequesne index of severity for knee OA. Radiographs were evaluated for changes characteristic of OA in anteroposterior views using the Kellgren and Lawrence grade (K-L grade), as described in the Atlas of Standard Radiographs. The age, disease duration, height, weight, index of severity for knee OA, and K-L grade were evaluated at baseline.

Two types of materials were prepared: urethane was made from PORON L-24 (Rogers Corp., Rogers, CT, USA), with a density of 240 kg/m³, 0.54 MPa pull strength, 115% stretch rate, and 8.1 N/mm rip strength; and sponge rubber was made from PORON MO-48 (Rogers Corp.), with a density of 480 kg/m³, 2.92 MPa pull strength, 153% stretch rate, and 8.1 N/mm rip strength. The urethane (PORON L-24) was suitable as a cushion material under the buttons of a cellular phone. The sponge rubber (PORON MO-48) was usually used as skid material inside shoes.

The urethane and sponge rubber were both manufactured into a lateral wedged insole with an elevation of 12 mm. The insole was wrapped and fixed to the