Prototype Development of Offloading Knee Brace for Management of Knee Osteoarthritis: A Case Study

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ABSTRACT

Background: Osteoarthritis (OA) of the knee is a degenerative joint condition characterized by the gradual deterioration of the cartilage in the knee joint commonly affecting the medial compartment of knee joint due to the increased load bearing during various activities. As the cartilage diminishes, the bones in the medial compartment may start rubbing against each other, causing discomfort, pain, stiffness in the joints, reduced range of motion, quadriceps muscle weakness, joint instability which may cause a feeling of wobbliness or unsteadiness, making it more difficult for individuals to maintain balance and stability during movement and changes in proprioception. Different types of knee orthosis can be beneficial in the management of OA. The currently available knee orthoses are useful for offloading the medial compartment of the knee, but are highly expensive, unaffordable for most people in developing nations like India. Hence the study aims to develop an effective intervention that does not involve surgery or pharmaceuticals, providing alternatives for those who may prefer or cannot undergo more invasive treatments. A new offloading knee brace was developed at Indian Spinal Injuries Centre, which was designed appropriately providing potential to reduce symptoms, improve joint function, improve balance and enhance overall well-being. The developed new offloading knee brace is an economical solution for the patients as well as the findings of the study will help the orthotist to have an option for an appropriate knee brace for successful treatment of person with medial knee osteoarthritis.

Objective: To develop a light weight and cost – effective offloading knee brace to assess the effects on balance and strength in patients suffering from medial osteoarthritis.

Study design: Case report

Significance: Unfortunately, the braces available are costly and unaffordable for Indian population, therefore the attempt was made to reduce the cost of the brace and the spiral design in new offloading brace resolve the balancing issues and improve the muscle strength of knee osteoarthritis.

Method: A 45-year-old male with osteo knee arthritis of medial compartment of grade 2 (mild) was assessed and pre – test reading for balance and strength was done. The subject was then provided with new offloading knee brace for a period of 1 week, post – test for balance and strength was recorded.

Result: The result shows a significant improvement in five – time sit to stand test, stair climb test, 6 - minute walk test, timed up and go test and lift and carry test thereby indicating improvement in balance and strength after the use of the brace.
Conclusion: The offloading knee brace was effective in improving the balance and strength in person with medial knee osteoarthritis.

Keywords: Osteoarthritis, Balance, Strength, Knee orthosis, Offloading knee brace.

INTRODUCTION
Osteoarthritis is a chronic degenerative joint disease that affects the cartilage, bone, and other structures in the joint and has complex aetiology. The symptoms of OA include loss of articular cartilage, hypertrophy of bone at the margins, subchondral sclerosis, and a variety of biochemical and morphological changes to the synovial membrane and joint capsule. Radiographic joint space constriction, stiffness, instability in the joints, and chronic pain are major clinical signs. OA can affect the hands, hips, shoulders, and knees and it is affecting more than 25% of the population over the age of 18 years. Knee OA was found to be the most prevalent among all joint sites affected by OA, with a prevalence of up to 32.7% in urban areas and 37.8% in town areas and majorly seen in 45-65 years of age group. In India, Osteoarthritis is the most frequent joint disease with a prevalence of 22% to 39%. Knee osteoarthritis (OA) generally show severe involvement in the medial compartment, which is marked by higher stresses across this compartment, joint inflammation and cartilage, joint space loss, changes in muscle control and interferes with balance and postural control. Treatment for knee OA is targeted to reduces all the symptoms, to correct mechanical malalignment and addressing knee joint manifestation. There are currently no effective therapeutic therapies for osteoarthritis (OA), apart from pain management and end-stage surgical intervention. As a result, there is an unmet clinical need for alternate OA treatment options. Most people in underdeveloped nations like India cannot afford the current knee orthoses due to expensiveness and bulkiness, which are an excellent way to offload the medial compartment of the knee in patients with knee osteoarthritis. Thus, this study aims to develop a light weight and cost – effective offloading knee brace which can meet the unmet needs of the patients with OA knee.

MATERIALS & METHODS
Detail of the patient: A 45-year-old male subject with medial knee osteoarthritis of grade 2 participated in the study, with height (cm) of 157.48, weight (kg) 55 and BMI 22.2.

Study design: Case report.

PROCEDURE
A subject diagnosed with medial knee osteoarthritis took part in this study. Detailed information was given to the subjects about the procedure. The subject consenting to participate in the study had signed the consent form. Then, the measurement and casting of patient was processed. It took around 2 days to complete the brace with the full procedure. After that the patient was asked to come for completion of protocol. The subject was asked to perform five – time sit to stand test, stair climb test, timed up and go test, lift and carry test and 6-minute test without the brace for initial readings and 5 minutes resting period was given to the patient between each of the above-mentioned test. Then, balance and strength were measured using these tests. After providing 1 week of intervention, the patient was asked to perform five – time sit to stand test, stair climb test, timed up and go test, lift and carry test and 6-minute test with brace with 5 minutes of resting period was given to the patient between each of the above-mentioned test. Then, balance and strength were measured using these tests. The image of the Offloading knee brace and the procedure performed with the subject are depicted below.
The results of every test, by examining the pre-test and post-test data of five times sit to stand test (FTSST), the stair climb test (SCT), six-minute walk test (6MWT), timed up and go test (TUG), and lift and carry test (LCT) demonstrate that the brace is beneficial for patients with osteoarthritis in the knees because it improves balance and strength.
**Table – 1: Comparison of pre – test and post – test scores of FTSST**

<table>
<thead>
<tr>
<th>Time (in seconds)</th>
<th>Pre – test</th>
<th>Post – test</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.178</td>
<td>2.358</td>
<td></td>
</tr>
</tbody>
</table>

**Table – 2: Comparison of scores of pre – test and post – test of SCT**

<table>
<thead>
<tr>
<th>Time (in seconds)</th>
<th>Pre – test</th>
<th>Post – test</th>
</tr>
</thead>
<tbody>
<tr>
<td>13.9</td>
<td>12.3</td>
<td></td>
</tr>
</tbody>
</table>

**Table – 3: Comparison of pre – test and post – test scores of 6MWT**

<table>
<thead>
<tr>
<th>Distance covered (in meter)</th>
<th>Pre – test</th>
<th>Post – test</th>
</tr>
</thead>
<tbody>
<tr>
<td>336.6</td>
<td>343</td>
<td></td>
</tr>
</tbody>
</table>
DISCUSSION
The scores of all the tests i.e. Five times sit to stand test (FTSST), 6 – minute walk test (6MWT), Stair climb test (SCT), Timed up and go test (TUG), Lift and carry test (LCT) shows that the brace is effective for the patients with knee osteoarthritis as it improved their strength, endurance and walking ability. The possible reasons could be the combination of the several underlying mechanisms, including changes in various neuromuscular factors such as proprioception, muscular strength and atrophy along with mechanical factors such as altered moments of the knee and comprehensive joint loads, supported by the findings of Raja K et.al. The knee orthosis must have applied a corrective force to the knee joint and reduced the external knee adduction moment in the patient, as said by Arazpour M et.al in their study. Also, Schmalz et.al in their study had demonstrated that valgus inducing knee brace can reduce approximately 10% of the produced external genu varus moment in the knee joint. This reduction is thought to be the main biomechanical mechanism in providing functional improvement and a more symmetrical gait patterns in patients with knee OA.

Studies have also shown that lower limb
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malalignment and an increase adduction moment reduce the levels of mobility in the affected subjects. Furthermore, studies have also demonstrated that for each 1Nm increase in valgus moment created by brace, a corresponding 3% reduction in adduction moment is created and a sequent 1% reduction in loads on the medial compartment of the knee. These results support our hypothesis that the offloading knee brace have improved the functional ability of the patient by a subsequent reduction in the knee adduction moment. Dwarakanathan R et al. in their study had said that the Centre of pressure (COP) trajectory shows a larger sway area in bipedal standing in baseline assessment, which reduced with orthotic intervention, especially with the use of the unloading knee orthosis. This supports our result that the patient has an improved balance and stability with customized offloading knee orthosis in our study.

Despite the strong association of knee moments with OA progression, these moments do not directly cause OA alone. Malalignment along with joint space narrowing is the crucial factor, with a lack of biomechanical evidence showing a significant change following bracing. The positive outcomes of the bracing may depend on the patient’s maintenance of the treatment duration and consistency.

CONCLUSION
The present study supports that with the use of offloading knee brace there was a significant improvement in the balance and strength in person with medial knee osteoarthritis.

The offloading knee brace shows that the use of appropriate biomechanical force system helps in improving the alignment of knee joint and enhances the muscular strength and joint stability. Hence, it can be concluded that the developed prototype of the offloading knee brace tends to show immediate benefits in the patients with mild medial knee OA.

Declaration by Authors
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Conflict of Interest: None.

REFERENCES
7. Bennell, K., Dobson, F., & Hinman, R. (2011). Measures of physical performance assessments: Self-Paced Walk Test (SPWT), Stair Climb Test (SCT), Six-Minute Walk Test (6MWT), Chair Stand Test (CST), Timed Up & Go (TUG), Sock Test, Lift and Carry Test (LCT), and Car Task. Arthritis Care and Research,
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