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Design and Evaluation of a New Type of Knee Orthosis to Align the Mediolateral Angle of the Knee Joint with Osteoarthritis

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Abstract. Osteoarthritis (OA) is a disease which influences the performance of the knee joint. Moreover, the force and moments applied on the joint increase in contrast to normal subjects. Various types of knee orthoses have been designed to solve the mentioned problems. However, there are other problems in terms of distal migration during walking and the alignment of the orthosis which cannot be changed following the use of brace. Therefore, the main aim of the research was to design an orthosis to solve the aforementioned problems. A new type of knee orthosis was designed with a modular structure. Ten patients with knee OA participated in this research project. The force applied on the foot, moment transmitted through the knee joint and spatiotemporal gait parameters were measured by use of a motion analysis system.The results of the research showed that the loads applied on the knee joint decreased following the use of new-designed knee orthosis. Moreover, it allows alignment of the components when the subject used the brace.The new design of the knee brace can be used as an effective treatment to decrease the loads applied on the knee joint and to improve the alignment whilst walking. It is recommended that other parameters such as pain severity and the quality of life should be measured in further studies.

Key words: Knee osteoarthritis, orthosis, gait

1. Introduction

Osteoarthritis (OA) is a disease which influences the body joints. In this disease the articular surface of the joint is damaged and the smooth motion of the joint is disturbed. It is the most common type of arthritis which affects more than 13% of the American people aged 55-64 and more than 70% with the age of 65-74. By the year 2020, an estimated 18.2%of the population will be affected in the United States of America [1, 2]. Patients with knee OA usually demonstrate major involvement in medial compartment. The most common types of alteration include decreasing knee joint excursion, altered ground reaction force applied on the leg and altered the pattern of key lower extremity muscles involved in gait [2].

The two most common types of conservative treatment for patients with OA are various kinds of knee braces and lateral wedge insole, which have been used to reduce knee pain, to improve knee alignment and to increase the knee joint range of motion during walking [3].Using lateral wedge insole is another conservative treatment used in this regard. Sazaki and Yasuda (1987) showed that lateral wedge alters the mechanical alignment of the lower limb and reduces the loads applied on the medial compartment of the knee . On the contrary, it was defined from the results of the double- blind randomized crossover trial in 90 patients with knee OA that the effect of lateral wedge insole was neither statistically significant nor clinically important . Knee brace has been proved to have some benefits for the patients, such as reducing the knee joint varus moments, improving the configuration of the loads applied on the knee and decreasing pain during walking [4]. Valgus braces attempt to reduce excessive compartmental loading and improve the performance of the subjects. The braces unload the painful compartment by applying a three-point pressure

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system. Various kinds of knee braces, such as Generation II brace, medial unloading Monarch brace and Vista CA brace have been used for patients with knee OA [4-8]. However, patients experience some problems with use of knee orthoses such as tendency of the brace to migrate distally as a result of muscles contraction [4-7, 9]. Moreover, it is not possible to change the alignment of the brace during follow-up period. Therefore, the aim of this project was to design and evaluate an orthosis to overcome the aforementioned problems.

2. Method

A new type of knee orthosis has been designed which has a modular structure to change the alignment based on the patients' need. The components of the orthosis were designed so that they can be aligned with respect to each other. It allows alignment adjustment while the user wears the orthosis. The orthosis was made of three main components which include the upper shell, the lower shell and the knee joint.

The upper shell of the orthosis was made of polyethylene (high density) vacuumed on the positive cast of the patients' limb. It had two elastic straps which secured the orthosis on the leg (figure 1). The upper shell of the orthosis workedas the third component of three-point pressure system. The lower shell of the orthosis consisted of two layers. The first layer was made of low density polyethylene which was vacuumed over the positive cast. It was trimmed to cover the upper lateral and the lower medial parts of the leg. These areas were the locations of corrective forces used to align the limb. The second layer, which was made of high density polyethylene, was vacuumed on the first layer. The first layer could be moved inside the second one by aligning screws in the upper lateral and lower medial sides of the leg. Therefore, the magnitude of the force could be adjusted according to the patient's need. The lower shell was secured on the leg by three elastic straps, figure 1.

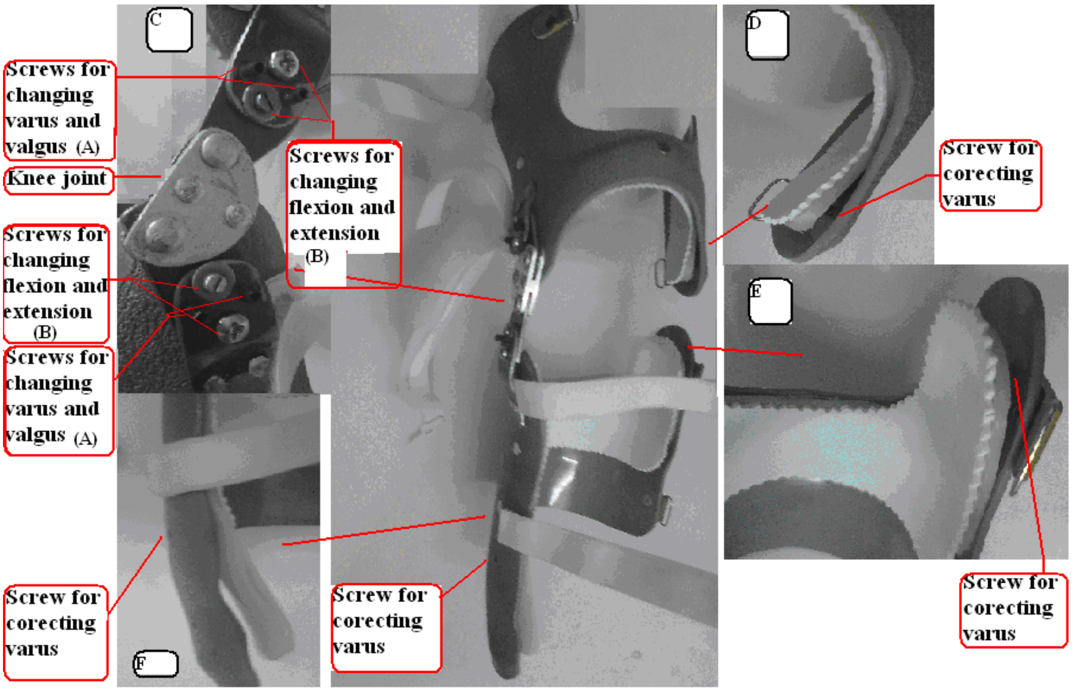

Fig. 1: The new design of the knee orthosis designed for patients with knee OA, C: the knee joint, D: the lower medial part of thigh shell, E: the upper lateral part of shank shell with the aligning screw, F: the lower medial part of the orthosis with the aligning screw

The knee joint of the orthosis was a polycentric type with special components to align the orthosis in the anteroposterior and mediolateral directions. The screws A in figure 1, allowedorthotists to change abduction/adduction alignment of the orthosis. The screws B, helpedorthotists to change the alignment of the orthosis in the sagittal plane.

2.1. Subjects

Ten patients with knee OA without any other reported musculoskeletal disorders participated in this research project. The mean values of their mass, height and age were 60±2.8 kg, 1.63± 0.12 meter and 55±3.7 year, respectively. Subjects were diagnosed with medial compartment knee OA according to the American College of Rheumatology criteria for the diagnose of knee OA, medial knee pain and radiographic osteophyte at the medial joint space of the knee [10]. The severity of knee OA was defined by use of the Kellgren and Lawrence grade (K-L grade) based on the X-ray of the knee, as it was described in the Atlas of Standard Radiography [11]. The subjects were asked to walk on a level surface with and without orthosis to investigate the influence of orthosis on the knee alignment. Ethics approval was received from XXXXX University Ethics Committee before starting the data collection. The subjects were asked to sign a consent form.

2.2. Parameters

Somespatio-temporal gait parameters, knee joint angle in sagittal and frontal planes, the mediolateral moment applied to the knee joint, vertical and mediolateral forces transmitted through the knee, and the hip joint flexion/extension angles were evaluated during walking with and without the knee orthosis.

2.3. Procedure

For tracing the movement of the subjects an array of 7 high speed cameras (Qualisys Medical, 2003)by Qualysis Company was used. Moreover, the force applied on the leg was measured by a Kistler force plate. The subjects lower body anatomy was reconstructed by Visual 3D software produced by C Motion Company. This programme was also used for calculation of angle change of the hip and knee joints during walking. Force plate data was also processed with 3D to calculate resulting moments of the lower limb joints.

3. Results

The mean values of the gait parameters are shown in table 1. As can be seen, the mean values of the moments applied on the knee joint during walking with orthosis was significantly less than that of normal walking (p-value<0.05). The instability of the knee joint, which was represented as the excursion of the knee joint motion in the frontal plane,also decreased significantly during walking with orthosis in contrast to that in normal walking. The values were 12.9±7.8 and 7.5±4.56 degreewhile walking without and with the knee orthosis, respectively (p-value=0.037).

Table 1: The values (mean and ±SD) of the gait parameters during walking with and without knee orthosis

Parameter	Flexion angle (knee)	Adduction angle (knee)	Flex/ Ext angle (hip)	[1]Force 1 (N)	[2]Force 2 (N)	[3]Moment (Nm)
Walking without orthosis	59.3±6.2	12.9±7.8	38.26±4.9	1.03±0.125	0.063±0.014	0.867±0.49
Walking with orthosis	49.33±8.8	7.5±4.56	43.46±3.5	1±0.13	0.064±0.009	0.72±0.36
P-value	0.0105	0.037	0.032	0.25	0.4	0.05

[1] vertical force
[2] mediolateral force
[3] mediolateral (adductor) moment

The mediolateral force applied on the limb did not differed significantly during walking with orthosis (p-value<0.05). The mean value of the vertical force transmitted through the knee joint in walking with orthosis was 1± 0.135 N/BW, compared to 1.03±0.125 N/BW in normal walking. Figures 2, 3, 4 and 5 show the abduction/adduction angle of the knee joint, mediolateral force applied on the knee joint, mediolateral moment (adduction moment), and vertical force applied on the knee joint during walking with and without orthosis, respectively.

4. Discussion

It is somewhat controversial whether using knee orthosis reduces the mediolateral moment applied to the knee joint or not [12]. It has been expressed by some researchers that the main influence of unloader brace in most cases is compensation for a portion of the external load [12]. However, the results of this research showed that the adduction moment applied to the knee joint decreased significantly following the use of a new design of knee brace. It is clear that the two important parameters which influence the moment applied on the knee are the magnitude of the mediolateral force and its moment arm. As can be seen from table 1 the mediolateral force decreased following use of the knee orthosis. Moreover, improvement of the knee joint alignment in the mediolateral direction is the other important findingof this research.

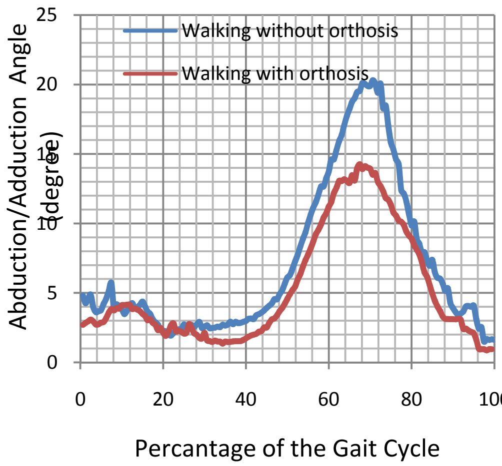

Figure 2: Abduction/adduction angle of the knee joint while walking with and without orthosis (subject 1)

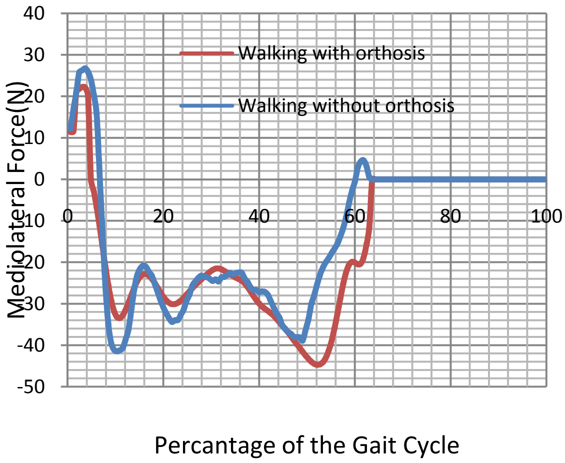

Figure 3: Mediolateral force applied on the limb while walking with and without orthosis (subject 1)

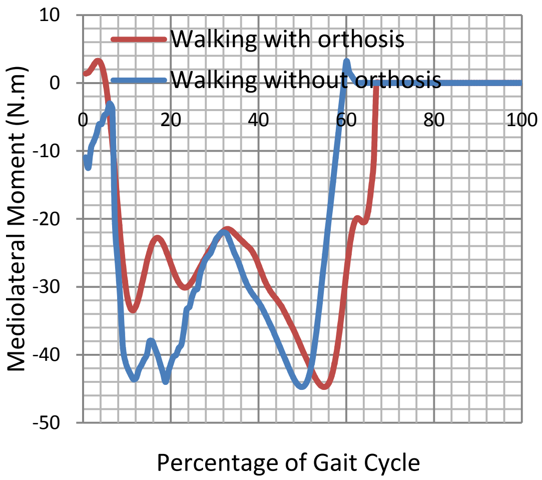

Figure 4: Mediolateral moment applied on the knee joint while walking with and without orthosis (subject 1)

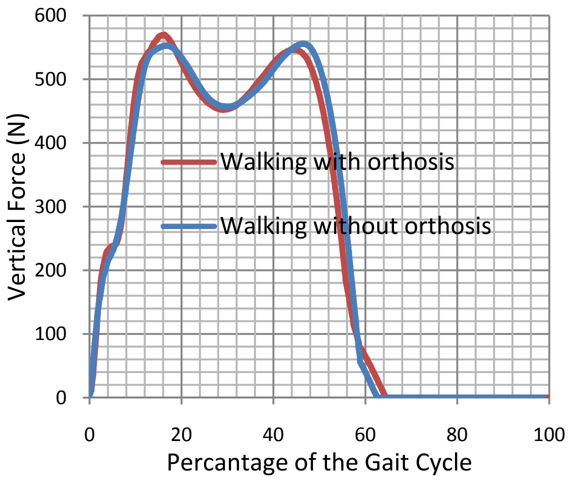

Figure 5: The vertical force applied on the foot while walking with and without knee orthosis (subject 1)

The mediolateral and vertical forces transmitted through the knee joint did not differed significantly while walking with orthosis (table 1). The main reason is that the orthosis did not transmit some portions of the loads during walking. It means that the whole part of the forces is transmitted by the leg. The results of the current research is the same as the results of the research undertaken by Schmaltz et al. (2011) which showed that using the knee orthosis did not influence the adduction force applied to the foot [5].

Most studies reported only a few degrees of varus angle reduction during gait [12]. The results of the current research study also showed that the valgus angle of the knee joint decreased, particularly during the last part of the stance phase. Therefore, it might be concluded that even though the angular change was small, it seems reasonable that the valgus angle reduction would lead to the decreases in the loads (adduction moment) transmitted through the knee joint in the mediolateral plane. To the authors' knowledge, the tibiofemoral angle has been measured in some research studies by use of X-ray in a static quiet standing position. However, we measured the angle of the knee joint in the mediolateral direction during walking, which might be a good alternative method in this regard.

The magnitude of orthosis distal migration was not directly measured in this study. It is clear that the congruency of the anatomical and mechanical knee joints influences the performance of the orthosis. If the orthosis migrates distally during walking, it will decrease the knee joint range of motion in the sagittal plane and the patient will have problems during walking. However, in the current research the range of motion of the knee joint was nearly the same while walking with and without orthosis. Therefore, it might be indirectly concluded that the distal migration of our new orthosis was not too much to influence the performance of the subject.

The new design of the orthosis might have the following advantages over the other designs

a) It has a modular structure to allow changing the alignment of the components with respect to each other
b) The distal migration of the orthosis is not too much to influence the function of the orthosis
c) The magnitude of the corrective force can be changed according to the patient's needs.

The followings are some limitations of this research study which need to be acknowledged.

a) The quality of life of the subjects following the use of orthosis was not evaluated.
b) The knee joint pain severity was not evaluated.

Finally, it is recommended that other parameters such as stability of the subjects, energy consumption during walking and severity of the knee pain be measured in future studies.

5. Conclusion

The mediolateral force transmitted through the knee joint was decreased following the use of a new design of knee brace. Moreover, the moment applied to the knee joint declined which influenced the pain associated with Knee OA. Distal brace migration on the leg is often a compliant of the patients, especially during extension. It was solved in the current designed orthosis by use of the elastic straps.

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