Evaluation of the Influence of a New Design of Orthosis on the Loads Applied on the Knee Joint

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Received: February 01, 2019
Accepted: March 04, 2019
Version of Record Online: March 16, 2019

Abstract

Background: Knee osteoarthritis influences the ability of the subjects during standing and walking. Although knee offloading orthosis reduces the loads applied on the knee joint and decrease knee pain, most of the subjects discontinue brace use due to stretching the ligaments structure of the knee joints, and tendency of the brace to migrate distally. Therefore, a new type of orthosis was developed to overcome the aforementioned problem. The aim of this research was to check the influence of this orthosis on reducing the loads applied on the knee joint.

Method: A group of normal subjects was recruited in this study to walk with and without the orthosis. A Kistler force plate and Qualisys motion analysis system were used to collect the kinetic and kinematic parameters. The difference between walking parameters under two conditions was evaluated by paired t test. The p-value of difference was set at 0.05.

Results: There was no difference between spatiotemporal gait parameters during walking with and without the orthosis (P-value>0.05). The adductor moment applied on the knee joint was 0.433±0.138 and 0.478±0.143 N.m/BW while walking with and without the orthosis, respectively (P-value=0.006). There was a slight increase in the hip adductor moment while walking with orthosis.

Conclusion: The new design of the orthosis reduces the loads applied on the knee joint through the hip joint. The new orthosis decreases the loads applied on the knee joint without any negative influences on the walking performance.

Keywords
Adductor Moment; Gait; Knee OA; Orthosis

Introduction

Osteoarthritis is one of the most common joint disorder which influences the human joints especially hip, knee and ankle joints [1,2]. Although it has been reported that the prevalence of this disease varies between 19.2% and 28.2%, it will become the fourth leading cause of disability by 2020 [2,3]. It has been shown that more than 13% of American aged 55-64 and more than 18% with 65-74 years have knee OA [1,2]. Based on the results of various studies, knee OA influences the kinetic of the knee joint [4-6]. Subjects with knee OA
have reduced knee flexion/extension and increased range of abduction/adduction. Moreover, altered Ground Reaction Force (GRF) transmitted through knee, altered activity pattern of the key lower extremity muscles are the other problems associated with knee OA [4,6,7].

The force applied on the knee joint is not transmitted equally between the medial and lateral components while walking [8]. It has been shown that force augmentation is a key factor in development of knee OA. The force applied on the medial side of the knee joint in the subjects with OA in the medial compartment of the knee joint is 100% of total body weight, compared to 60 to 75% in normal subjects [8-10]. Based on the results of various research studies, adductor moment (applied on the knee joint in the mediolateral direction) plays a significant role in this regard [8]. In OA subjects, the peak of adductor moment increases significantly, compared to the normal subjects [4,7,11]. Moreover, there is a significant correlation between severity of knee OA (based on Lawrence grade) and adduction moment [12].

Basically, there are two main approaches for treatment of the patients with knee OA including surgery (total knee arthroplasty and wedge osteotomy) and conservative treatment [13-15]. Conservative treatment approaches include exercise, use of offloading knee braces, lateral wedge insole and a combination of lateral wedge and subtalar strap [16-19].

For 12 N.m (Newton Meter) valgus moments applied by offloading knee brace 228 N or 0.3 N/BM (Newton/body mass) reduction of vertical force occurred [20,21]. During gait, valgus brace reduces the knee adductor moment by an average of 13% (7.1 N.m) and therefore decreases the loads applied on the medial compartment of the knee joint [13]. Although use of offloading knee orthoses improves knee joint stability, reduce the applied load, and decrease knee pain, they have some problems prevent to be used efficiently. Stretching the ligaments structure of the knee joint, and tendency of the brace to migrate distally as a result of muscle contraction are two most important problems associated with the use of the knee orthosis [17,22,23]. Based on the results of the research done by Wilson et al., 59% of the 30 patients who received offloading knee orthoses had discontinued brace use after 2.7 years, compared to 100% after 11.2 years [17]. Most of fatty subjects cannot use these orthoses due to restriction of knee joint motion during walking as a result of immigration of the orthosis distally [23]. Long term compliance is another drawback of brace work. As in most of the available orthoses, three-point pressure systems have been employed. In this system some portion of pressure applied on the distal part of tibia which creates discomfort, due to abrasions on the skin [15,24].

KineSpring implant system is also a new implant used to reduce the loads applied on the medial compartment of the knee joint in young patient with mild to moderate OA [14,25]. There is not enough evidence to support the effective of this method of treatment. Based on available literature, although use of offloading knee brace reduces the load applied on the knee joint but most of the patients prefer to not use knee brace due to aforementioned problems. As there was no suitable and effective knee orthosis for patient with knee OA, therefore, the aim of this study was to design an orthosis to reduce the loads applied on the hip joint indirectly. The design of this orthosis was based on the influence of hip joint alignment on reducing the loads applied on the knee joint and decreasing [26]. The new orthosis was also designed to decrease the distal migration of the orthosis and to be easy to be used.

**Methods**

A new type of orthosis was designed with nearly the same structure as Scottish rite orthosis without medial thigh bar. It consists of three main parts. Hip joint (adjustable flexion/extension) the trunk and thigh shells. The trunk and thigh sell in both right and left sides were attached to each other by adjustable hip joints. Figure 1 shows the structure of the new orthosis.

The hip joint of the orthosis was a single axis hip joint with special screws to change flexion/extension. The hip joints of the orthosis were aligned in 5 degrees of abduction.

**Subjects:** A group of normal subjects with history of no neuromuscular disorder were asked to participate in this study (10 subjects). Table 1 shows the characteristics of the subjects participated in this study. An ethical approval was obtained from Isfahan University of Medical Sciences Ethical Committee. A consent form was signed by each participant before data collection. The main inclusion criterion to select the subjects was having no musculoskeletal and neurological disorders which influence the ability of the Subjects to stand and walk. Some parameters such as spatiotemporal gait parameters, force applied on the leg, adductor moment of the knee and hip joints and three dimensional kinematic of the hip and knee joints while walking were the parameters selected in this study.
Figure 1: The new developed orthosis, anterior view with subject (A); posterior view with subject (B); posterior view of the orthosis (C); Donjoy knee brace (D).

| Parameters     | Age (year) | Weight (Kg) | Height (m) |
|----------------|------------|-------------|------------|
| Mean value     | 21±1.2     | 60±5.9      | 1.75±0.15  |

Table 1: The characteristics of the subjects participated in this study.

Equipment: A Kistler force plate was used to analyze the force applied on the leg while the subjects walked with and without the orthosis. A motion analysis system with 7 high speed cameras was used to collect the motion of the body and especially lower extremity during walking. Eighteen markers (with 14 mm diameters) were attached to right and left anterior superior Iliac spine, right and left posterior superior Iliac spine, right and left medial and lateral malleolus, right and left medial and lateral sides of the knee joint, right and left metatarsal head, and right and left greater trochanters. Moreover, four marker clusters, compressing of four markers were affixed to rhomboid plates, were attached to the anterolateral surface of the leg and thighs. The locations of the markers were recorded by Qualisys track manager software. The foot, shank, thigh and pelvic components were reconstructed by visual 3D software produced by C Motion Company. The data were collected with 100 Hzr frequencies. The outputs were filtered with a Butterworth low pass filter with cut off frequency of 10 Hzr and split out to gait cycle interval using heel strike data. The subjects were asked to walk along a 5-meter walkway. The walking tests were repeated to collect 5 successful trials. It should be emphasized that the analysis of the results was blind. Some parameters such as spatiotemporal gait parameters, the range of motions of hip and knee joints in three planes, ground reaction force components and the moments applied on hip and knee joints were evaluated in this study. The normal distribution of the parameters was evaluated by Shapiro Wilk test. Since they had normal distribution, paired sample t test was used to compare the effects of the orthosis on the gait parameters (significant point was set at 0.05).
Results

The mean values of spatiotemporal gait parameters during walking with and without the orthosis are shown in table 2. The mean value of walking speed during walking with and without the orthosis was 55.9±3.77 m/min and 55.6±5.4 m/min, respectively (P-value of the difference was 0.42).

| Parameter                  | Stride length (m) | Cadence (steps/min) | Velocity (m/min) | Knee flexion/extension (degree) | Knee abduction/adduction (degree) | Knee rotation (degree) |
|----------------------------|-------------------|---------------------|------------------|---------------------------------|----------------------------------|------------------------|
| Walking with orthosis      | 1.19±0.063        | 94.4±4.56           | 55.99±3.77       | 59.35±6                         | 14.86±4.5                        | 21.57±8.4              |
| Walking without orthosis   | 1.23±0.056        | 90.89±7.02          | 55.6±5.4         | 62.86±5.2                       | 13.07±5.74                       | 19.55±5.6              |
| P-value                    | 0.06              | 0.028               | 0.42             | 0.045                           | 0.233                            | 0.29                   |

Table 2: The mean values of spatiotemporal gait parameters and kinematic of the knee joint while walking with and without the orthosis.

The first peak of the anteroposterior force applied on the leg was 0.132±0.033 N/BW during walking with orthosis, compared to 0.127±0.026 in walking without orthosis. There was a significant difference between the peak of the mediolateral force applied on the foot while walking with and without the orthosis. The peak of the vertical force applied on the leg increased significantly while using the orthosis (it was 1.08±0.053 compared to 1.03±0.0496 N/BW). The adduction moment applied on the leg was the other parameter selected in this research study. The adductor moment applied on the leg was 0.43±0.138 and 0.478±0.143 N.M/BM, in walking with and without the orthosis, respectively (P-value of the difference was 0.006). Table 3 summarizes the mean values of the loads (forces and moments) applied on the leg in two conditions.

| Parameter                  | Fx1 (N/BW) | Fx2 (N/BW) | Fy (N/BW) | Fz1 (N/BW) | Fz2 (N/BW) | Fz3 (N/BW) | Moment (N/BM) |
|----------------------------|------------|------------|-----------|------------|------------|------------|---------------|
| Walking with orthosis      | 0.132±0.033| 0.158±0.016| 0.12±0.028| 1.08±0.053 | 0.866±0.041| 1.077±0.038| 0.433±0.138   |
| Walking without orthosis   | 0.127±0.026| 0.159±0.011| 0.0926±0.017| 1.03±0.05  | 0.879±0.051| 1.066±0.023| 0.478±0.143   |
| P-value                    | 0.35       | 0.39       | 0.002     | 0.023      | 0.35       | 0.4        | 0.006         |

Table 3: The mean values of the loads applied on the leg and adductor moment applied on knee joint while walking with and without the orthosis.

The kinematics parameters of the knee joints are represented in table 2. The range of flexion/extension of the knee joint while walking without the orthosis was nearly the same as that of walking with the orthosis (p-value >0.05). The range of the motion of the knee joint in frontal plane was 14.86±4.5 in walking with new device compared to 13.07±5.74 in normal walking. The range of flexion/extension of the hip joint was 29.49±8.38 during walking with the orthosis, compared to 34.33±3.21 degree while walking without the orthosis (p-value=0.01). The mean values of adductor moment applied on the hip joint were 1.16±0.47 and 1.01±0.32 Nm/BM, during walking with and without the orthosis, respectively. Table 4 shows the kinematic and kinetic parameters of the hip joint in both conditions. Figure 2 shows the moment applied on the knee joint of a normal subject while walking with and without the orthosis.

Discussion

The numbers of the subjects suffer from knee joint osteoarthritis is increasing. It has been estimated that in 2012 more than 18% of USA population will suffer from symptoms of the knee joint OA [1,2]. There are various treatment approaches used for subjects with knee OA, including conservative treatment and surgical operation (total knee arthroplasty, wedge osteotomy and use of KineSpring knee implant system) [15,18,27].

The most common used conservative treatment for knee OA include use of knee offloading brace, lateral wedge insole and lateral wedge insole with subtalar strap [27]. Based on the available literature some patients with knee OA prefer to not use knee orthoses or remove them after a while, due to distal immigration of the orthosis and force applied on the knee joint [15,22-24,28,29]. Therefore, the aim of this research was to design and evaluate an orthosis to solve these problems. It was aimed to design an orthosis which indirectly influence the
loads applied on the knee joint.

As can be seen from the results of the research presented in tables 2 and 3, the adductor moment applied on the knee joint decreased significantly while walking with the new orthosis with no negative effects on walking speed and kinematic of the knee joint. The orthosis did not immigrate distally as it was restricted by pelvic bony tubercles.

Based on the results of various studies there was a significant correlation between severity of osteoarthritis (KL grade) and the magnitude of adductor moment applied on knee joint [8,30,31]. It means that in subjects with sever OA the adductor moment increased significantly. The results of this research showed that the peak of adductor moments applied on the knee joint decreased follow the use of the new orthosis. The orthosis put the leg (through the hip joint) in some degrees of abduction (nearly 5 degree) and decreased the medial angulation of the leg. As can be seen from figure 3, the momentum arm of the vertical component of ground reaction force decreases by putting the leg in 5 degree of abduction.

The spatiotemporal gait parameters of the subject while walking with two conditions are shown in table 2. As can be seen the walking speed of the subjects while using the orthosis was nearly the same as that during normal walking. It means that the orthosis did not influence the abilities of the subjects in order to walk efficiently.

| Parameter                  | Hip flexion moment (N/BM) | Hip extension moment (N/BM) | Hip adductor moment (N/BM) | Hip Int rotation moment (N/BW) | Hip Ext rotation moment (N/BW) | Hip flexion/extension (degree) | Hip abduction/adduction (degree) | Hip rotation (degree) |
|----------------------------|---------------------------|-----------------------------|----------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|----------------------|
| Walking with orthosis      | 0.79+0.48                 | 0.21+0.10                   | 1.16+0.47                  | 0.27+0.35                     | 0.10+0.07                     | 29.49+8.38                    | 8.12+2.43                     | 7.12+3.36            |
| Walking without orthosis   | 0.54+0.11                 | 0.23+0.11                   | 1.01+0.32                  | 0.10+0.05                     | 0.11+0.05                     | 34.33+3.21                    | 11.02+4.52                    | 8.74+2.99            |
| P-value                    | 0.014                     | 0.265                       | 0.122                      | 0.019                         | 0.268                         | 0.01                          | 0.011                         | 0.059                |

Table 4: The mean values of the loads applied on the hip joint and kinematic of the hip joint while walking with and without the orthosis.
Based on the results of the research done by Chang et al., the greater hip internal abduction moment (external adductor moment) during gait plays a significant role against ipsilateral knee medial OA progression and reduces the knee joint adductor moment [26]. The results of this study also showed that adductor moment applied on the knee joint decreased due to a slight increase in hip joint adductor moment (internal abductor moment).

The kinematic of the knee and hip joints and force applied on the leg were the other parameters collected in this research study. As can be seen from tables 4 using the orthosis influenced the kinematic of the hip joint significantly. Although the range of motion of the hip joint decreased while walking with the orthosis, it did not influence the performance of subjects, based on walking speed.

Although this research was done on normal subjects, it can be concluded that the new orthosis could decrease the loads applied on the knee joint and decrease the pain of the knee joint. This conclusion was based on the correlation between the severity of knee OA, pain and magnitude of adductor moments [15,24]. The new orthosis aligned the leg in some degrees of abduction (5 degrees) and reduced the adductor moment of the knee joint without restriction the ability of the subjects during walking. Moreover, it does not have distal immigration as it was fixed on the pelvic. However, there were some limitations which should be mentioned here. The main limitation of this study was that this research was done on normal subjects. The second limitation was related to small number of the subjects. Therefore, it is recommended that the new device will be tested on subjects with knee OA (obese and non-obese subjects) and with a big number of subjects. It is also recommended to compare the output of the studies done on normal and those with knee OA.

**Conclusion**

The new device presented in this study seems to decrease the loads applied on the knee joint and is easier to be used for the obese subjects due to less distal immigration. The alignments of the leg improved follow the use of the orthosis. It is recommended that the new device be tested on OA subjects, with bigger number of subjects.
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