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Design and Evaluation of a New Type of Knee Orthosis for Improving the Performance of Subjects with Knee Osteoarthritis

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Abstract. Knee joint osteoarthritis is a disease which influences the performance of the joint during walking. Various types of knee orthosis have been designed to improve the performance of the subjects, however they are not without problems. The aim of this paper is to design an orthosis which is easy to use and more economically efficient.Two subjects with knee osteoarthritis were recruited in this research study. The gait performance of the subjects and their stability while standing, were evaluated by use of motion analysis system and a force plate (Kistler). The mediolateral excursion of the knee joint decreased while walking with the knee orthosis in contrast to normal walking. Moreover, the adduction moment applied on the knee joint decreased significantly (p-value<0.05). The new design of the orthosis improves the performance of the subjects during walking. Moreover, it is more cosmesis, easy to use and more economically efficient.

Key words: knee orthosis, gait, stability, osteoarthritis

1. Introduction

Knee osteoarthritis (OA) is a disease which influences joint articular surfaces. As a result the smooth motion of the joint is distributed and the patients suffer from pain associated with the knee motion [1, 2]. It has been reported that knee OA affects more than 13% of American aged 55-64 and more than 70% with age of 65-74[1]. Patients with knee OA usually demonstrate major involvement in medial compartment. There are some alternations associated with knee OA which include decreasing knee joint excursion, altered ground reaction force applied on the leg and altered the pattern of the leg lower extremity muscles involved in gait[3-9].

One of the important contributing factors mentioned regarding the development of knee OA is force applied on the knee joint[8]. The force applied on the knee joint is not transmitted equally between the medial and lateral compartments while walking. In healthy subjects, between 71% and 91% of total knee force is transmitted through the medial compartment of the knee joint, compared to 100% in OA subjects[9, 10]. There are various types of treatments used to decrease pain during walking, to align the mechanical axis of the joint and to decrease the mediolateral instability of the joint, which include using various kinds of knee brace, lateral wedge insole, subtalar strap and tibia wedge osteotomy [2, 9-24]. Tibia osteotomy associated with numerous sever complications, such as maluninion of tibia, intraoperative injury to popliteal artery and tibial nerve, vein thrombosis and pain tract infection[25, 26]. Therefore, most clinicians attempt to use conservative treatment instead. Two most common types of conservative treatment for knee OA are use of knee brace and lateral wedge insole. However the results of various research studies showed that use of lateral wedge insole was neither statistically significant nor clinically important[18, 27]. In contrast knee brace has been proved to have some benefits for the patients such as reducing knee joint varus moment, improving the configuration of the loads applied on the knee and decreasing pain during walking[22, 27, 28].

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Various types of knee braces such as Generation II brace, medial unloading Monarch brace and Vista CA brace have being used for the patients with knee OA. However patients experience some problems which include tendency of the brace to migrate distally as a result of muscles contraction[2]. The weight of the orthosis and the cost of the device were the other important problems. Moreover, changing the alignment of the orthosis is a big issue which needs to be resolved. Therefore, the aim of this research was to design a new type of orthosis which is easy to be used and is as efficient as the knee brace, which overcome the aforementioned problems. Moreover, it was aimed that the new orthosis improves the performance of the subjects with a reasonable cost.

2. Material

2.1. Orthosis

A new type of the knee orthosis has been designed which consists of some straps and a soft knee orthosis. The new type of knee orthosis was designed to reduce the force and adducting moment applied on the medial side of the knee joint. It was designed to realign the knee joint by applying a downward directed force on the lateral side of the knee joint as is shown in figure 1. The lateral directed force is applied through a lateral strap extended between the knee and ankle joints. The proximal part of the lateral strap is attached to the lateral side of knee soft orthosis, as is shown in figure 2, to increase the lever arm of the orthosis. The distal part of the lateral strap is attached to a corset encircles the foot, figures 1 and 2.

2.2. Subjects

Two patients with knee OA without any other reported musculoskeletal disorders participated in this study. The mean values of their mass, height and age were 72 Kg, 1.72 meter and 52 year, respectively. The subjects were evaluated as having a medial compartment knee OA according to the American College of Rheumatology criteria for a diagnosis of Knee OA, medial knee pain and radiographic osteophyte at the medial joint space [29]. The severity of knee OA was defined by use of the Kellgren and Lawrence grade (K-L grade) based on X-ray of the knee as was described in atlas of standard radiology [6]. The subjects were asked to walk with and without orthosis. Before running the tests, an Ethical approval was obtained from Ethics Committee of Isfahan University of Medical Sciences. The subjects were asked to sign a constant form before data collection. The following parameters were evaluated in this research study:

- Spatiotemporal gait parameters
- The mediolateral and vertical forces applied on the foot
- The excursions of the knee joint in the frontal and sagittal planes
- The adducting moment of the knee joint

2.3. Procedure

For tracing the movement of the subjects an array of 7 high speed cameras produced by Qualysis Company was used. Moreover, the force applied on the leg was measured by a Kistler force plate. The analyse space for cameras was calibrated by moving and rotating a rod with reflective markers in space. The motions of the markers and the force plate data were recorded by use of Track – Manager Software produced by Qualysis Company. The markers were labelled and defined in Track Manager and export as 3D files. 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, knee and ankle joints during walking. Force plate data was also processed with 3D to calculate the resulting moments of the lower limb joints.

The marker set was based on six degrees of freedom principles, primarily using marker cluster for tracing, based on CAST/ISB recommendations[30]. Sixteen markers (with 14 mm diameter) were attached to the right and left anterior superior iliac spines (ASIS), right and left posterior superior iliac spines (PSIS), right and left medial and lateral malleolus, right and left medial and lateral sides of the knee joints and first and fifth metatarsal heads. Knee markers were attached on the skin of the medial and lateral sides of the knee joint while the subjects wore the orthosis. Moreover, four marker clusters comprising of four markers attached on the rhomboid plates were attached to the anterolateral surfaces of the legs and thighs by use of extensible Velcro straps. The subjects were asked to walk along a level surface to collect five successful trials. The collected data were filtered (Woltring filter with a cut off frequency of 10 Hz) and split to gait cycle interval using heel strike data.

The parametric statistical test was used to evaluate the difference between the mean values. The two sample t-test with a significance level of 0.05 was used for the final analysis to compare the performance of each subject while walking with and without orthosis.

3. Results

The gait parameters during walking with and without orthosis are shown in table 1. The walking speed of subject 1 varied between93.9 and 92.2 m/min, respectively. In contrast in subject 2 the walking speed improved significantly during walking with orthosis (p-value=0). Although the stride length of the first subject decreased while walking with the orthosis compared to normal walking (1.38 and 1.32 m, respectively), the cadence increased significantly follow the use of orthosis (p-value<0.05). The mediolateral stability of the knee joint was measured by evaluation of the knee angle in the mediolateral direction. Based on this parameter the stability of the knee joint improved by use of knee orthosis (p-value=0.05). The mediolateral knee joint moments were 51.9 and 38.6 Nm in walking without and with the knee orthosis, respectively. The vertical force applied on the foot increased by 23N follow the use of the knee brace.
In contrast to subject 1, the walking speed of second subject increased follows the use of the knee orthosis (it was 71.1 and 113.82 m/min in walking without and with knee orthosis, respectively). The excursion of the knee joint in the mediolateral direction was 9.9 degree in normal walking compared to 5.6 degree in walking with the device (p-value=0.0). Last but not least the mediolateral moment applied on the knee decreased by use of the brace, table 1.

Table 1: The gait parameters of the subjects while walking with and without orthoses (the comparison was done between normal walking and walking with each orthosis)

Parameters	Subject 1		Subject 2	
	Normal walking	Walking with the new orthosis	Normal walking	Walking with the new orthosis
Walking speed (m/min)	93.9±9.8	92.2±4.2	71.1±14.5	113.82±10.07
	P-value=0.366		P-value = 0	
Stride length (m)	1.38±0.062	1.32±0.09	1.12±0.08	1.34±0.04
	P-value=0.06		P-value= 0.005	
Cadence (steps/min)	81.43±7.2	90.9±7.3	86.2 ±7.2	115.4±6.26
	P-value=0.036		P-value=0	
Knee flexion (degree)	62.11± 0.9	59.6± 1.7	55.2±6.2	56.8±1.2
	P- value = 0.06		P-value= 0.56	
Knee adduction (degree)	11.26±1.3	9.3±1.5	9.9±1.07	5.6±0.556
	P- value = 0.05		P-value= 0	
Knee moment (N.m)	51.9±8.5	38.6±5.6	38.6±2.5	34.2±1.5
	P-value = 0.027		P-value=0.04	
Vertical force (N)	797± 11.6	820±33.8	678.8±45	672.3±21.1
	P- value = 0.23		P-value=0.5	
Mediolateral force (N)	37.4±11.1	35.9±0.8	38.9±6.8	43.5±13
	P-value = 0.77		P-value= 0.07	

The influence of using knee orthosis on the mediolateral and anteroposterior stability was not significant (p-value>0.05). Figures 3, 4 and 5 show the pattern of the mediolateral force, the anteroposterior force and the adducting moment applied on the knee joint while walking with and without orthosis.Figures 6 and 7 show the pattern of the knee joint flexion and adduction, respectively. Table 2 shows the stability of the subjects while standing with and without orthosis. As can be seen from this table the use of orthosis did not influence the stability of the subjects.

Table 2: The stability of the subjects while standing with and without orthosis

Parameters	Subject 1		Subject 2		
	Normal standing	Standing with the new orthosis	Normal standing	Standing with the knee cage	Standing with the new orthosis
Anteroposterior COP sway (mm)	21.71±4.7	22.34±6.7	31.47±8.4	30.4±7.2	29.6±6.8
	P-value= 0.44		P-value= 0.8		P-value= 0.4
Mediolateral COP sway (mm)	10.6±3.3	9.82±2.46	19.35±4.7	19±8	18.6±6.3
	P-value=0.3		P-value= 0.76		P-value= 0.3

4. Discussion

It is a little controversial that using knee orthosis reduces the mediolateral moment applied on the knee joint. However, based on the results of variousresearch studies, the mediolateral moment applied on the knee joint increases in patients suffering from knee OA [4, 5, 10, 31]. Therefore, it is important and practical to decrease the moment applied on the knee joint by use of some orthotic interventions. As can be seen from the results of this research, the mean values of the mediolateral moment applied on the knee joint decreased significantly (table 1) while walking with the new design of the orthosis in contrast to normal walking. It is clear that two parameters influence the mediolateral moments applied on the knee joint, which include the magnitude of the mediolateral force and its moment arm. Since there is no significant difference between the force applied on the knee joint while walking with and without orthosis (table 1),therefore, it can be concluded that the moment arm of the mediolateral force decreased follow the use of the orthosis.

The same as results of other research studies, the results of this study also showed that the difference between the stability of the subjects in standing with the knee orthosis is the same as that in normal standing, table 2. The main problem of the subjects with the knee OA is related to single limb support not double limbs support. One of the main parameters which represents the stability of the subject while walking is the excursion of the knee joint in the mediolateral plane (abduction/adduction angle). The higher the mediolateral excursions of the knee joint, the higher knee joint instability. As can be seen from table 1, the excursion of the knee joint decreased significantly following the use of the knee orthosis. As the stability of the knee joint improves, the subjects do not need to move their trunk sideway to enhance stability.

The knee joint range of motion did not differ in normal walking and walking with the new design of the orthosis. Therefore, it can be concluded that the use of the device did not influence the range of motion of the knee in the sagittal plane. Moreover the new design has some advantages compared with the knee cage which include:

a) The weight of the new orthosis is less than the knee cage orthosis (0.4 kg compared to 1.1kg)
b) The performance of the subjects improved while walking with the new orthosis
c) The new orthosis is more economically efficient than the knee cage
d) The new orthosis dose not restrict the knee joint motion in Sagittal plane
e) The amount of protrusion of the orthosis under cloth is less than that of knee cage orthosis

There were some limitations regarding this research study which is needed to be acknowledged.
a) The number of participants was too small
b) The follow up period was short

Therefore, it is recommended that the performance of the new orthosis will be evaluated in another study on more knee OA patients. Moreover it is recommended that the other parameters such as, the energy consumption during walking and quality of life follow the use of the orthosis be measured.

5. Conclusion

The performance of the subjects improved while walking with the new orthosis. However it did not influence the stability of the subjects during quiet standing. It is recommended to evaluate the performance of the new orthosis on more patients with knee OA. Moreover, it is recommended to evaluate the other parameters such as oxygen consumption while walking and also the quality of life follow use of the new design of knee orthosis.

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