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SCHOLARENA

Journal of Orthopaedics and Bone Research

RESEARCH ARTICLE

ISSN: 2643-9956

Knee Unloader Orthosis with Optimal Transitional Mechanism with Three Degrees of Freedom Joint Design in Subjects with Medial Compartment Knee Osteoarthritis

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Citation: : Baghaei Roodsari Roshanak (2023) Knee Unloader Orthosis with Optimal Transitional Mechanism with Three Degrees of Freedom Joint Design in Subjects with Medial Compartment Knee Osteoarthritis. J Orthop Bone Res 4: 101

Abstract

Background: Patients with knee osteoarthritis (OA) suffer from progressive inability to stand and walk. orthosis is considered as a conservative treatment that uses corrective forces in all of stages of walking and standing. In this study, we aimed to design and manufacture a new orthosis to tackle this problem. For this purpose, a new knee joint is designed which can apply alternative corrective forces on the knee in the stance phase.

Materials and Methods: Patients with medial knee osteoarthritis who met the inclusion criteria were enrolled. The new knee joint mechanism was designed and manufactured. Then, braces were made. The effect of the new brace was assessed on gait parameters in five conditions. The data were analyzed by motion analysis.

Results: The new brace improved the knee adduction angle in the frontal plane and decrease knee flexion angle in the stance phase. but it did not affect the swing phase. The evaluation of the impact of the new brace on OA showed spatiotemporal variable were increased in the patients but double support time and stance phase were decreased.

Conclusion: Our results indicated that the new brace improved the kinematics and spatiotemporal parameters of gait in patients with OA.

Keywords: Knee osteoarthritis, knee orthoses, function, gait kinematics parameters, spatiotemporal parameters

Introduction

Knee osteoarthritis (OA) is a common age-related disorder in the elderly impairing their gait [1-3]. Since approximately 62% of the bodyweight passes through the medial side of the knee joint, medial compartment knee OA is more prevalent than the lateral side [4]. People with OA of the medial compartment commonly have an increase in knee adduction angle and the load-bearing passes through the medial compartment during initial stance to the mid stance phase of gait, which creates severe knee pain[5] .

The use of knee braces is a common conservative treatment of the medial compartment of the knee OA [6]. Any conservative treatment should demonstrate a positive effect on the reduction of knee adduction angle [7]. Unloader knee orthoses are alternative conservative methods of treating knee OA using direct application of forces to alter frontal plane knee alignment whilst simultaneously reducing the excessive, knee adduction angle [6]. It has also been shown that these orthoses can improve knee confidence, function, and joint stiffness [5, 8-10]

Although knee orthosis is considered the most suitable solution to improve malalignment but traditional braces act with permanent corrective forces by using several approaches, consisting of straps, adjustable superstructures, or inflatable bladders[11-15]. Current braces put permanent correction force on the knee joint in both stance and swing phases of gait [16], while, requirement for such pressure in the swing phases is unnecessary[17, 18]. This has caused complaints that are the main problem in the use of knee orthosis (KO) [19]

Therefore, it seems unnecessary to apply knee valgus force at all the stages of walking, which is the case when using KO. Since in sound limb the full varus angle and moment in the knee joint happens only between heel strikes to 30% of the stance phase and not permanently [18] [20]the varus angle and moment was decreased to release the locking mechanism on the knee between pre-swing and terminal swing. Thus, it can be concluded that applying a constant force brace on the knee can affect the function of the knee and apply unnecessary loads on the affected knee [18, 20].

It seems that designing an orthosis capable of automatically correct the knee alignment only during the stance phase seems essential. Moreover, KOs usually has movement along one or two axes, while the anatomical knee joint movements have three dimensions with six degrees of freedom [21]. Hence, there is a lack of coordination between orthotic and anatomical knee joints [19, 22].

According to the explanations above, it can be considered that three factors are affecting the performance of KOs including lack of compliance of motion of the brace joint with the knee joint, lack of coordination between knee joint orthoses with the anterior-posterior movement of the tibia on the femur in knee flexion/extension, and the application of constant corrective force on the knee joint at all the stages of gait [18, 21, 23]

Thus, the aim of this study was to develop an OA knee unloader orthosis incorporating a new-mechanism orthotic knee joint and a corrected position for the knee. We also investigated the effect of a frame made of different available materials for knee brace on transition correction knee adduction angle in patients with medial compartment knee OA and their gait characteristics were evaluated [24].

Design Considerations and Functional Mechanism for the New Knee Orthosis

A new design of knee unloader orthosis consists of a new mechanical knee joint with a lateral sidebar design. Indeed, this brace is composed of four main parts, including the new mechanical knee joint (along with a mechanical part to provide convert movement from sagittal plane to frontal plane and the part of providing sliding movement tibia on the femur in flexion movement), thigh, calf shells and straps [24].

Mechanical Knee Joint

The idea behind this design was based on movement from knee extension to abduction for preventing knee joint varus in the gait cycle [18]. This knee orthosis has a new joint mechanism which comprises three parts as follows.

1- The new joint mechanism applies sagittal plane movement to frontal, that is, this mechanism converts the knee extension movement at terminal swing to knee abduction movement at initial stance until mid-stance.

2- There is a translational of movement of approximately 10 to 15 mm in this new knee joint mechanism, which is an up-down movement in lateral upright through a drawer mechanism. This mechanism was considered to accommodate the femur gliding movement on the tibia during knee flexion.

3- This new knee joint also simulated screw home mechanism, which occurs in physiologic knee joint. It has movements in three planes so that this joint is combined of three in one joint by three axes. A flexible steel wire was located in chamber in a way that it produces a special abduction as a result of knee extension and the amount of abduction is adjustable by screwing [24].

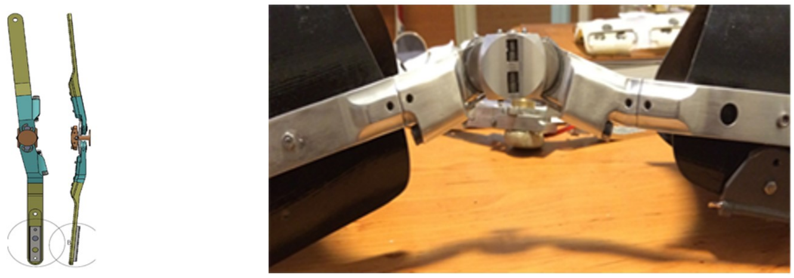


Figure1: structures and specifications other

The brace was attached to the thigh and calf shells by using a uni-direction lateral aluminum joint. Two important characteristics of the frame are its' high resistance and low weight. The first characteristic is necessary for preventing deformation of the frame and transition movement to the patient's limb. The second characteristic increases the patient's limb orthosis adaptation [5, 10, 25].

To achieve these characteristics, two available materials were considered for fabricating two shells of this knee orthosis. The new orthosis was custom-molded individually and constructed from a lower extremity cast of patients. The semi-hard aluminum thigh and calf shells were formed onto the positive mold and attached to the joint as the first available material. The laminating resin shells were fabricated from the same positive mold of the subjects by a vacuum apparatus as the second material. In order to construct a hard resin brace frame, carbon fiber sheets were used between layers of stockinet. These resin shells were also attached separately to the new joint mechanism. As described above, the joint was designed to transform extension to abduction and was capable of regulating the excessive adduction angle produced in the OA knee in stance phase of the gait cycle. In addition, a translational axis for tibia motion and two rotational axes in the transverse plane were considered to reach an appropriate brace function in providing translational motion of femur on tibia. The straps served as suspensions in this orthosis.

Table 1: 2-Maximum value of knee flexion and adduction angle (Kinematic variable) in stance and swing phases and spatiotemporal parameter of the gait cycle in different brace conditions in five tests

Maximum value of knee flexion and adduction angle in stance and swing phases (Kinematic variable) (degree)				New jointCorrection mechanism	Shell	Experiment
swing		stance				
Maximum flexion	Maximum adduction	Maximum flexion	Maximum adduction			
73.38	6.00	48.55	5.36	**with**	**Resin**	**With brace**
72.87	6.01	51.37	4.04	**without**		
69.99	4.28	48.57	4.92	**with**	**Aluminum**	
69.33	4.54	48.42	4.54	**without**		
72.57	6.4	51.41	6.47	**Without brace**		

Spatial temporal gait parameters						New jointCorrection mechanism	Shell	Experiment
Double stance time (s)	StrideTime (s)	Stride length(m)	Stance phase %	cadence	Velocity(m/s)			
0.14	2.00	1.10	61.10	60.60	0.79	**with**	**Resin**	**With brace**
0.17	1.81	0.96	62.70	58.25	0.57	**without**		
0.14	1.84	1.02	66.30	57.69	0.63	**with**	**Aluminum**	
0.18	1.77	0.97	67.06	55.40	0.56	**without**		
0.21	1.76	0.937	68.18	56.60	0.55	**Without brace**		

Participants

This study was conducted at the biomechanics laboratory of University of social welfares and rehabilitation Sciences in Tehran, Iran from 2016 to October 2018. In the Quasi experimental Study by analyzing the standard deviation of each variable, the adduction angle of the affected knee in the stance phase was considered [7, 18]. Sample size was determined seven using the following formula and 95% confidence interval, 80% power, and minimal clinically important difference of 3; however, 10 patients were enrolled. Samples were selected by convenience sampling method; hence, each eligible subject was voluntarily enrolled.

$$n = \frac{\left(z_{1-\beta} + z_{1-\frac{\alpha}{2}}\right)^2 ({\sigma_1}^2 + {\sigma_2}^2)}{(\mu_1 - \mu_2)^2}$$

Sample size calculation formula

Patients with mild to moderate osteoarthritis were clinically identified by physical examinations and radiography evaluations. High risk patients were diagnosed by orthopedic surgeons and physiotherapists by the means of using conventional X-ray imaging and magnetic resonance imaging (MRI), based on Age ≥ 40 yrs, obesity and body mass index ≥ 30, vitamin D insufficiency. Osteoarthritis was diagnosed based on radiographic findings such as sharpening of the bone edges and narrowing of the inner parts of the knee joint and the formation of osteophytes and sclerosis below the condyle head in the standing position in the front of view [26].

Patients whom were enrolled in the study all had clinical symptoms for more than six months such as pain existence in one or both knees in stage 2 (moderate) and stage 3 (severe) of based on Kellgren-Lawrence scale and moderate swelling and tenderness to palpation, crepitation, and joint stiffness in the morning for < 30 min or after prolonged immobility, muscle weakness and lack of knee confidence in standing position.

The exclusion criteria were sustaining any injuries, Patients with ligament problems, and meniscus tear, knee osteotomy undergoing any invasive treatments including injection therapy for the knee during the past six months, the patients whom were candidates for arthroplasty and having a symptomatic spine, hip, or ankle or having neurological foot, or skin diseases or any other disease making it difficult to apply a brace (e.g., due to arthritis in the hand or difficulty in bending) [27].

All patients were evaluated and subjects a total of 10 individuals (eight females and two males) participated. The subjects wore a knee orthosis on the affected side. The effect of the new modified brace was evaluated on Kinematic and spatio-temporal gait parameters of patients with medial compartment knee osteoarthritis by a gait analyzer coupled with a force plate. The subjects' mean age was 61.50±10.513 years, the mean weight was 73.7±8.354 kg, and the mean height was 158.2±10.465 cm.

According to Table 3, the study subjects, particularly females, were classified as overweight in terms of the body mass index.

Table 3: Descriptive characteristics of 10 subjects

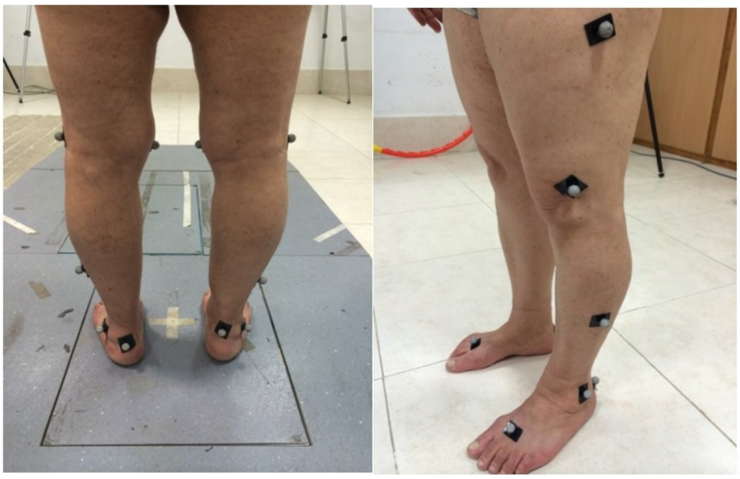
Gender	patient	Age (years)		Height (cm)		Weight (kg)		BMI (kg/m²)	
		mean	SD	mean	SD	mean	SD	mean	SD
woman	8	58.38	5.502	156.75	8.301	74.88	8.983	30.461	2.84
man	2	74.00	19.799	164.00	21.213	69.00	2.828	26.168	5.67
total	10	61.50	10.512	158.20	10.465	73.7	8.354	29.603	3.625

Prior to the outset of the study, we obtained the approval of the Ethics Committee of the University of Social Welfare and Rehabilitation Sciences.

Testing Procedure

An advanced gait analyzer coupled with a force plate was used to evaluate the impact of the new brace. For this purpose, 16 patients were selected of which six were excluded due to obesity, osteoarthritis in the left knee, and increased pain sensitivity. The patient's joint space width and the weight-bearing line extending from the center of the femoral head to the center of the ankle joint and the knee joint loosening in the frontal plane were assessed. Patients were asked to attend a biomechanics laboratory to measure the body sizes and record disease information. All testing and information collection procedures as well as the devices were explained to patients. Patients were also assured about the safety of devices and familiarized with the lab environment. Patients' information and written consent were obtained immediately after enrollment. According to the ethical protocol, the study objectives and stages were explained to all patients. The new brace-shell was precisely designed for each patient.

Fifteen markers reflecting infrared light were placed on each patient's lower limb using bilateral adhesive. Marking was performed by the Helen-Hayes technique on the sacrum, great left and right trochanter, outer thigh, outer knee, outer leg, outer ankle, calcaneus, and second leg metatarsus. The markers were mounted on the patient's body to delineate the anatomical coordinate system and calculate the kinematic parameters of all four lower limb segments over a complete gait cycle. The knee joint center was defined to the gait analyzer, based on the patient's height and circumference, and marker was attached to the inner knee to record the data.



a b

Figure 2: A-Marking on the lower limbs of the patient, B-internal knee marker to find the center of the knee

To record patient gait parameters while using the brace made of carbon composite shells and a new joint, the advanced gait analyzer was used to quantify normal and pathological walking patterns, and force plate was utilized to determine the beginning and end of the stance phase. Three-dimensional kinematics of the lower limb recorded with an advanced Vicon motion analysis 460 (Oxford Metrics, the UK) with five infrared cameras, a Work Station software, and 100 Hz frequency, Two force platforms (Kistler 9286BA, Switzerland), on a 5-m walkway.

a b

Figure 3: Biomechanics Laboratory

Kinematic data were obtained using an advanced gait analyzer. The parameters were normalized to body weight ratio. The maximum adduction angle in the frontal plate was studied in static and dynamic states with and without brace as the main parameter of the study along with other Spatio-Temporal parameters [2, 7, 17, 28]. To analysis data, force plate data were first filtered by Matlab software using a 4th order Butterworth 10-Hz low-pass filter. The subjects were asked to walk barefoot at her self-selected speed on the 5-m walk-way of the force plate for five times in order to record the acceptable data. Data were recorded since initial touch of the heel to the force plate, and the subjects were asked to walk at their normal speed and take appropriate steps on two force plates to record the data walked. An average of five valid trials per condition was used for analysis. A trial was considered valid if all the markers were recognized by the motion capture system. The subjects performed some familiarization trials before data collection to achieve a natural gait pattern

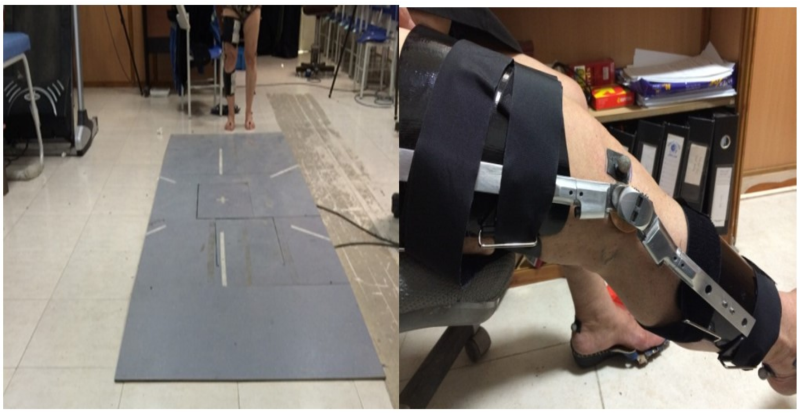


Figure 4: Wearing a brace and a 5-meter walk-way on the force plate

In the next step, patients' knees were covered by the functional brace and the patients were asked to walk again five times. Kinematic parameters in sagittal and frontal planes in hip and knee joints were calculated based on the position of light reflective markers. To determine the spatio-temporal parameters of the gait, the heel coordinates were used. Also, maximum and average knee flexion and adduction angle and hip and knee range of motion at the frontal plane was recorded from the initial contact heel to the ground during the stance phases. The collected data, as well as the information obtained from each camera, were used to create a three-dimensional motion model on the computer called reconstruction. Using the gait graph of each experiment, the gait cycle was completed and the required information was recorded. To determine the parameters' values, data were entered into Excel software. The code specified in Matlab software was run on the data sorted in Excel. Values of the study parameters were extracted for all 10 patients.

Two force platforms were set apart and positioned to capture a left and right heel strike.

Data Analysis

Results

The repeatability of the motion analysis device was assessed using intra-class correlation coefficient for the study variables and Paired t-test was used to investigate the intra-group variations of the parameters studied. Paired t-test was used for paired comparison of mean response parameters in two measurements with and without brace.

Table 4: Evaluation of intragroup changes in kinematic parameters of gait in patients with osteoarthritis of the medial compartment knee

Frontal plane				**Sagittal plane**				
Maximum adduction angle knee(degree)Stance phase		**Maximum adduction angle knee(degree)Swing phase**		**Maximum flexion knee(degree)Stance phase**		**Maximum flexion knee(degree)Swing phase**		
Without brace	With brace	Without brace	With brace	Without brace	With brace	Without brace	With brace	**brace**
-8.466	-5.519	-6.903	-6.953	44.4905	40.634	60.164	62.002	**mean**
2.151	1.419	1.39	1.543	5.055	5.786	8.0369	10.643	**SD**
0.000		0.581		0.000		0.408		**P-value**

According to Table 4 there was a significant difference in the knee adduction angle in the stance phase with and without brace (P = 0.000), but in the swing phase, no significant difference was observed in the knee adduction angle with and without brace (P = 0.581); thus, brace could significantly modify knee adduction angle in stance phase.

On the other hand, a significant difference was also observed in knee flexion in stance phase with and without brace (P = 0.000); but in swing phase, no significant difference was observed in knee flexion with and without brace (P = 0.408). According to Table 4, the knee flexion angle significantly reduced with brace in the stance phase, while it was increased in the swing phase.

Table 5: Evaluation of intragroup changes in spatio-temporal parameters of gait in people with osteoarthritis knee

Speed(m/s)		**Cadence(steps/min)**		**Stance phase(% of cycle)**		**Stride length(m)**		**Stride time(sec)**		**Double limb SupportTime(Sec)**		
Without Brace	With Brace	Without Brace	With Brace	Without Brace	With Brace	Without Brace	With Brace	Without Brace	With Brace	Without Brace	With Brace	**Brace**
0.541	0.636	66.807	74.641	68.618	65.811	0.842	0.976	1.796	1.557	0.319	0.213	**Mean**
0.192	0.211	11.139	11.311	7.153	6.101	0.244	0.353	0.372	0.266	0.208	0.113	**SD**
0.000		0.001		0.000		0.038		0.002		0.018		**P-value**

According to Table 5, there was a significant difference in spatio-temporal gait parameters with and without brace. Data showed the desired alterations in patient's gait while using brace

The results of fitting a linear mixed model were calculated by changing the parameters of the additional group. Experiments were repeated five times for each patient in each measurement step (with and without brace). Therefore, by fitting the linear mixed model, changes in five repetitions and changes caused by brace were investigated in the present study. Since the measurements in each state were performed with and without a functional brace- in other words, each measurement was specific to the moment the subject used or did not use the brace- repetitions in the model were defined with and without brace and entered into the model as repeated brace.The average result of repeated (five times) measurements were compared for each parameter with and without brace. The mixed model modified the model and its results by considering the repetitions for the two interventions (with and without brace). Compared to the paired t-test method, the correlation was entered into the model and modified the results.

Kinematic gait parameters of patients with knee osteoarthritis

Table 6: Measurements of 5 repetition steps in conditions with and without brace

With brace						**Without brace**						
Total (men±SD)	5	4	3	2	1	Total (men±SD)	5	4	3	2	1	**Repetition**
40/633±5/551	40/672	40/647	40/791	40/516	40/539	44/490±5/2519	44/31	44/43	44/66	44/44	44/60	**knee flexion** in the **stance phase**
10/202±001/62	61/914	62/033	62/055	62/02	61/984	7/709±416/60	60/134	60/274	60/192	59/967	60/251	**knee flexion** in the **swing phase**
391/1±538/5-	503/5-	668/5-	607/5-	489/5-	424/5-	0868/2±465/8-	579/8-	587/8-	359/8-	506/8-	295/8-	**Knee adduction** angle in the **stance phase**
682/4±953/6-	941/6-	001/7-	927/6-	975/6-	920/6-	669/4±902/6-	884/6-	869/6-	954/6-	953/6-	853/6-	**Knee adduction** angle in the **swing phase** of gait

Table 7: Evaluation of fixed effects of affected knee variable

Knee adduction angle in theswing phase		Knee adduction angle in thestance phase		knee flexion in theswing phase		knee flexion in thestance phase		Source
p-value	F	p-value	F	p-value	F	p-value	F	
01/0	161/20	000/0	788/156	0/000	*465/657*	0/000	588/202	**Width of origin**
802/0	063/0	000/0	432/86	0/167	**1/945**	/0000	80/471	**brace**
0/950	336/0	760/0	618/0	1/000	0/028	836/0	0/523	**Repeat (brace)**

Table 6 shows the mean knee flexion in the stance phase of the affected limbs for the study participants by measurement rank (1 to 5) and brace usage. It was observed that the mean knee flexion with brace was about 40° in the stance phase for all the subjects in five repetitions. However, knee flexion was 44° without brace in the same phase. Hence, the new brace reduced knee flexion in the affected limb by 4° in the stance phase.

According to Table 7 in five-time repeated measurements, use of brace had significant effect on mean knee flexion in stance phase (P = 0.000). Since there was no significant difference between repeated measurements (P = 0.836), it can be said that repeated use of brace did not effect on the knee flexion change in the stance phase.

Also there was a significant difference in the mean knee flexion in the stance phase between using and not using the brace. It was also observed that there was no significant difference among repeated measurements (five times) in terms of using and not using the brace; i e, the obtained values were reliable.

According to Tables 6, 7 there was no significant difference between using and not using the brace in the swing phase (P = 0.167). In other words, there was no significant difference in mean response when using and not using the brace. However, according with table 6, the flexion angle of the affected knee (P = 62.001) increased when the subjects used the brace compared to the condition they did not use it (p = 60.164) in the swing phase.

According to Tables 7, Repeated knee flexion measures in the swing phase also had no significant difference (P = 1.000); in other words, repeated use of the brace did not affect the knee flexion change. According to table 6 there was no significant difference regarding the mean knee flexion in the swing phase when the subjects used the brace and the average number of times they did not. It also showed that there was no significant difference in repeated measurements (five times) between using and not using the brace; i e, the obtained measures were reliable.

According to table 7, the use of the brace had significant effect on Knee adduction angle at the frontal plane in the stance phase (P = 0.000). In other words, there was a significant difference in the mean Knee adduction angle at the frontal plane between using and not using the brace.

Repeated measures of brace effect on Knee adduction angle at the frontal plane in the stance phase were not significantly different In other words, repeated use of brace had no effects on Knee adduction angle. There was a significant difference in the mean knee adduction angle in the stance phase when the subjects used the brace and the average number of times they did not use it. There was no significant difference in repeated measurements (five times) between using and not using the brace; i e, the measures were reliable.

According to tables 6, the use of the brace had not significant effect on knee adduction angle at the frontal plane in the swing phase (P = 0.802). There was no significant difference in repeated measures in terms of brace effect on knee adduction angle in the swing phase (P = 0.950). In other words, repeated use of brace did not influence knee adduction angle in the swing phase.

The Effect of Average Measures of Five Repetitions with and Without Brace on Spatial-Temporal Gait Parameters of Patients With Knee Osteoarthritis

Table 8: Measurements of 5 repetition steps in conditions with and without braces

With brace						Without brace						
Total (men±SD)	5	4	3	2	1	Total (men±SD)	5	4	3	2	1	**Repetition**
6363/02040/0±	6298/0	6223/0	6445/0	6475/0	6378/0	5404/01873/0±	5466/0	5405/0	5404/0	5352/0	5395/0	Speed(m/s)
64/748643/10±	7651/74	54/74	9215/74	53/74	442/74	808/66696/10±	425/66	704/66	017/67	6644/66	2304/67	**Cadence(steps/min)**
811/65855/5-±	765/65	706/65	838/65	901/65	845/65	609/68862/6±	607/68	612/68	765/68	479/68	581/68	**Stance phase(% of cycle)**
976/0338/0±	968/0	979/0	984/0	978/0	972/0	842/00/234±	8401/0	8416/0	849/0	845/0	836/0	**Stride length(m)**
557/1256/0±	551/1	556/1	553/1	565/1	562/1	796/1358/0±	801/1	7912/1	8021/1	795/1	792/1	Stride time(sec)
212/0109/0±	219/0	215/0	213/0	204/0	211/0	319/02/0±	316/0	314/0	320/0	326/0	321/0	Double limbSupport time (Sec)

Table 9: Evaluation of fixed effects of affected knee variable

Double limb Support time (Sec)		Stride time (sec)		Stride length (m)		Stance phase **(% of cycle)**		Cadence (steps/min)		Speed (m/s)		**Source**
p-value	F	p-value	F	p-value	F	p-value	F	p-value	F	p-value	F	
001/0	605/26	000/0	440/295	000/0	211/95	000/0	114/1073	000/0	399/417	000/0	55/87	Width of origin
000/0	325/18	000/0	358/31	000/0	069/15	000/0	128/42	000/0	238/42	000/0	978/20	**brace**
997/0	138/0	999/0	096/0	998/0	128/0	967/0	291/0	974/0	269/0	716/0	671/0	**Repeat (brace)**

According to table 9 Use of brace had a significant effect on gait velocity in patients with knee osteoarthritis (P = 0.000). In other words, gait velocity significantly increased in patients when they used the brace compared to the time they did not.The repeated measures of brace effect on gait velocity in patients with knee osteoarthritis did not significant difference (p = 0.716)

Also, Use of brace had a significant effect on the Cadence in patients with knee osteoarthritis (P = 0.000). i e, there was a significant difference between Cadence when the subjects used the brace and did not use it. There was no significant difference in repeated measures of brace effect on Cadence in patients with knee osteoarthritis (p = 0.974). In other words, time did not affect cadence.

Another hand use of brace had a significant effect on the percentage of stance phase in patients with knee osteoarthritis (P = 0.000); i e, the percentage of stance phase significantly decreased in patients with knee osteoarthritis when they used the brace compared to the time they did not. There was no significant difference in repeated measures of brace effect on the percentage of stance phase in patients with knee osteoarthritis (p = 0.967); i e, time did not affect the stance phase changes.

Another hand Use of brace had a significant effect on Stride length in patients with knee osteoarthritis (P = 0.000). In other words, Stride length increased significantly in patients with knee osteoarthritis when they used the brace compared to the time they did not. There was no significant difference in repeated measures of brace effect on Stride length in patients with knee osteoarthritis (P = 0.998); hence, time did not affect patients' Stride length.

Use of brace had a significant effect on Stride time in patients with knee osteoarthritis (P = 0.000); hence, the Stride time increased significantly in patients with knee osteoarthritis when they used the brace compared to the time they did not. There was no significant difference in repeated measures of brace effect on Stride time in patients with knee osteoarthritis (P = 0.999). In other words, time did not affect Stride time changes in the studied patients.

Use of brace had a significant effect double stance time in patients with knee osteoarthritis (P = 0.000). In other words, there was a significant difference in the double stance time in patients with knee osteoarthritis when they used and did not use the brace; i e, use of the brace decreased double stance time. There was no significant difference in repeated measures of brace effect on double stance time in patients with knee osteoarthritis (p = 0.997); i e, time had no effects on double stance time in the studied patients.

Discussion

The aim of this study was to assess the effect of a newly designed joint orthosis with different structural materials on the gait characteristics of OA patients in five conditions and to determine which condition yields better results in terms of reducing peak knee adduction angle in the stance and maximum knee flexion angles in the swing phases of the gait cycle.

Modification of knee adduction angle in the frontal plane in the middle of the stance phase and synchronization with knee joint kinematics during the swing phase

According to the results of the study by N Foroughi et [17] the knee adduction moment and angle increases by 30% in stance phase of the gait cycle. Accordingly, knee joint alignment will be corrected due to the screw home mechanism. Therefore, it seems that an attempt to correct knee mal alignment during the first 30% of the stance phase is reasonable. More satisfactory results of the brace with corrective mechanism are due to the mechanical transformation of knee extension in the sagittal plane at the initial stance (i.e., heel strike) to abduction in the frontal plane near mid stance. This corrective function of the brace prevents knee adduction position (due to body weight bearing) and maintains the knee in the abduction position. In addition, in this mechanism, the application of the inhibitory force from the deviation to the knee joint does not continue until the end of the gait cycle and is reduced after the stance phase. The new joint mechanism has the dual function of knee adduction angle modification at the frontal plane at its peak in the middle stance phase and synchronization with knee joint kinematics during the swing phase. The brace with a new articular mechanism prevents the development of knee adduction angle from the early to middle of the stance phase and to prevent any problems in normal knee movements, cooperates with knee kinematics during the rest of the walking phases.

According to the gait analysis results of the current study, the new joint mechanism reduced the knee adduction angle in the stance phase by preventing genu varum. However, the new joint mechanism did not change the knee adduction angle in the swing phase. In fact, it can be said that the knee adduction angle on the frontal plane decreased in the stance phase and did not change in the swing phase. These results were observed in the replications of each test in the laboratory. It is important to note that this finding was inconsistent with the results of the study by M Toriyama [29] study since the knee adduction angle increased while using the brace at 46% to 55% of the stance phase compared to not using it in his study. This may depend on the flexible shell of the Össur unloader brace and the incompatibility of the brace with joint motion in the study by M Toriyama According to findings of the study by NA Segal [30]; improved knee alignment during walking confirmed the positive biomechanical effects of the brace."

In addition, in agreement with the results of the present study, the knee flexion rate in the stance phase decreased with the use of a new brace and helped to achieve a complete limb flexion in the swing phase that was in accordance with the required gait modification in the patients as noted in the study by da Silva[31], This can be achieved by producing compatibility between joint motion and the new brace, adhering to the lock and release soft switch mechanism of the knee, helping to achieve complete extension at the stance loading phase, and providing complete limb flexion while walking in the swing phase using the traction wire.

In patients with severe osteoarthritis, there is less extension in mid stance, which is accompanied by a delay in the peak knee flexion angle in the swing phase. In the study by L Sharma [32], changes in knee flexion angle during gait were introduced as determinants of the disease severity.

The results of the present study contradict the findings of the studies by Richard [33], Davidson [34], and RDA Gaasbeek [35] on knee angles modification in sagittal plane. In the study by Richard, valgus brace did not change knee flexion in the swing phase; but in the study by Davidson & RDA Gaasbeek, the range of motion of the knee reduced in the sagittal plane while using the brace, since it prevented complete extension at the end of the swing phase and reduced the swing phase duration. In the study by Davidson, brace could prevent complete knee extension in the stance phase by applying the constant valgus-producing forces in the frontal plane. However, the new articular mechanism, due to synchronization with knee kinematics, was at least dependent on the strap pressure to stabilize the brace on the limb. Hence, it did not cause restrictions on knee movements in the sagittal plane.

It seems that the new joint by using the articulated accelerator and locking mechanisms in the swing and stance phases, coupling to the knee kinematics in the transverse plane and trans cellular segment in the sagittal plane, preventing the longitudinal displacement and sliding of the brace during motion, and avoiding knee disruption during flexion motion can modify knee alignment in the frontal and sagittal planes. The reduction of knee adduction angle in the middle of the stance phase while using the brace, compared to not using it, and no changes in the knee adduction angle in the swing phase in the frontal plane, may emphasize the dual function of the articular mechanism. Increasing knee flexion in the swing phase and decreasing knee flexion in the stance phase in the sagittal plane can support improved knee biomechanical function in patients.

A significant increase in gait Speed, stride length, and Stride time was observed during the stance phase in the present study. However, a significant decrease was observed in double limb Support time and step time during the gait phases. These results were obtained from the gait analyzer while walking on a straight path for each patient while using and not using the brace. These results were consistent with those of the study by M Toriyama [29] on gait speed, cadence, stride length, and Stride time obtained from the gait analyzer, but they were inconsistent with those of the study by JD Richards [33].

Since in the current study, the brace joint was in Synchronization with the knee joint, and the results showed the control of the adduction angle in the stance phase, and improvement of the flexion angle in the swing phase, the brace could increase gait speed by increasing stride length, and Stride time and cadence. However, the study by Richards [33] emphasized changes in cadence and gait speed in the studied patients while using the brace. But walking symmetry was improved with the longer stance phase. Improvement in gait speed and other spatio-temporal variables confirmed improvement in knee joint functional abilities [2]. It can be deduced that by increasing gait speed the integral of speed and the stride length also increase, so cadence and the stride length also increase with the new brace; the information obtained from gait analyzer also confirm the findings.

Conclusion

Understanding the complexity of knee osteoarthritis and the development of treatments require extensive investigations. Investigating patients' walking patterns to achieve the most desirable type of intervention is very important. Although other non-mechanical treatments such as physiotherapy, osteotomy surgery, and lateral wedge placement are available for OA patients, these treatments have some drawbacks that prevent them from being completely accepted by OA patients [19, 25, 36-39]. Thus, a mechanical treatment capable of minimizing excessive misaligned load on the knee joint while allowing OA patients to perform their daily activities could be highly beneficial. Brace sleeves, used as knee osteoarthritis modifiers, are very effective during activities of daily living such as walking [20]. Although studies introduce brace as the knee osteoarthritis modifier, synchronizing the brace joint to the knee joint and modify positioning of the brace on the limb is the main factor for maximum efficiency [21]. An appropriate brace joint can reduce all unwanted forces on the joint and shear forces on the knee tissue.

With the help of a knee-fit brace, the knee angle in the frontal plane, the direction of the knee adduction angle, and the compressive load applied to the medial compartment of the joint can be reduced during loading [40-42]. Likewise, patients' walking patterns may be modified. Valgus brace applies a constant and permanent modifying force to the knee throughout the walking process. However, the peak of knee adduction angle occurs in the middle of the stance phase [18, 43]. Valgus brace significantly reduces knee adduction angle, but it is unnecessary to apply a constant bending force to the knee during walking. Also, common valgus braces reduce the knee flexion angle in the swing phase and shorten the stride length [31]. This is due to limited movement in the knee due to the force of ordinary braces, or due to the inconsistency that the patients feel between the movement of the brace joint and the knee joint. In the new articular mechanism, by maximizing the synchronization of brace joint with knee kinematics, the motion limitation was not created in the sagittal plane during the swing phase, so knee flexion rate increased in the swing phase [24].

The results of the study showed knee adduction angle modification in the middle of the stance phase, knee flexion improvement in the swing phase, and knee flexion reduction in the stance phase, while no changes were observed in knee adduction angle in the swing phase. Likewise, brace can be adjusted with the patient's gait by discontinuing shaving; so that there is no need for excessive straps to apply shaving to the brace. Since knee alignments provided by traction wire from initial stages of the swing phase to the end of the stance phase, there is no additional force on the knee. Also, due to transitional force of tibia on femur in the transverse plane, the brace does not have a longitudinal displacement by mounting the transducer piece on the load connected to the leg shell [24].

A limitation of this study was the limited number of participants because of the nature of this study. Only a single participant was recruited for the evaluation of the new brace.

Study Application

This brace can be considered as a solution for modifying knee adduction angle and controlling the symptoms of medial compartment knee osteoarthritis with further investigations and overcoming the possible problems. With this brace, it may be possible to eliminate the need of patients, especially the youth, to undergo painful and expensive surgical procedures to reduce the symptoms of osteoarthritis.

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