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The Immediate Effect of Medial Wedge Insole and Neoprene Brace on the Pain, Knee Valgus and Gait in Patients with Patellofemoral Pain Syndrome: Randomized Cross-Over Clinical Trial

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Review Article

Abstract

Introduction: Patellofemoral pain syndrome (PFPS) is a common problem that particularly affects active young people. In these patients, dynamic knee valgus causes hip and knee kinematic changes. Therefore, the reduction of dynamic valgus angle is one of the rehabilitation strategies in people with PFPS. The objective of this study was to evaluate the immediate effect of a medial wedge insole and knee orthosis on the knee pain and knee movement during walking and squat on involved side in people with PFPS.

Materials and Methods: 15 volunteers with PFPS participated in this crossover clinical study. All participants signed the consent form and then were evaluated in four random conditions (without orthosis, medial wedge, medial wedge in combination with knee brace, and knee brace). The kinematics and kinetics of the lower limb were studied during walking and single-leg squat. Data analysis was performed using repeated measures statistical analysis of variance (ANOVA).

Results: The knee brace, knee brace with medial wedge, and medial wedge significantly reduced the pain of affected leg after single-leg squat ($P = 0.001$). The walking speed ($P = 0.067$) and dynamic knee valgus angle ($P = 0.490$) did not significantly change in four different modalities of intervention. The peak moment of the knee in frontal plane was significantly increased in three conditions [medial wedge ($P = 0.001$), knee brace ($P = 0.008$), and knee brace in combination with medial wedge ($P = 0.033$)] compared with the control condition.

Conclusion: Use of medial wedge and neoprene knee brace can decrease pain and improve the biomechanical performance of people with PFPS. The use of these interventions can cause positive biomechanical effects on the lower limb.

Keywords: Patellofemoral pain syndrome; Dynamic knee valgus; Neoprene knee brace; Medial wedge

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Introduction

Patellofemoral Pain Syndrome (PFPS) is a common musculoskeletal disorder (MSD) of the knee joint (1) that is more common in young people or people with high levels of activity such as runners, basketball players, and military personnel (2). The pain is exacerbated by increasing force on the patellofemoral joint during activities such as squatting, going up and down stairs, running, and jumping that require the quadriceps muscle activity (3). Investigations indicate that factors such as quadriceps angle change, muscle weakness, especially the Vastus Medialis Oblique (VMO), hip muscle weakness, muscle imbalance, stiffness of lateral structures, abnormal lower limb biomechanics, and overactivity of the patellofemoral joint are involved in the development of this complication (2).

Among the biomechanical disorders of the lower

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extremities that aggravate the process of this complication, genu valgum, excessive rotation of the leg inward, and foot pronation can be mentioned (4). In general, it can be stated that any factor that causes abnormal deviation of the patella from the femoral groove, leads to increased stress and pressure on the patella surface (3). Since the patella is confined between the tibia and femur, kinematic changes in the hip and knee theoretically increase the quadriceps angle (Q-angle), thereby reducing the contact surface in the patellofemoral joint and increasing the pressure on the joint surfaces (5). Kinematic changes including increased adduction and internal rotation of the hip and increased abduction and external rotation of the distal tibia are collectively called dynamic knee valgus (DKV) (6). Among the causes of DKV may be a decrease in the strength of the hip abductors or an abnormal backward eversion of the foot (Pes Pronatus Valgus) (7). Therefore, prevention of DKV (as one of the underlying causes of PFPS) can be an important part of rehabilitation programs for subjects with this complication.

There are many treatment plans for PFPS. The medical community agrees that conservative therapies, including medication, physiotherapy, and orthosis, may be appropriate for this complication (8-10). Based on the results of most previous studies, a significant decrease in pain intensity and an increase in daily physical activity due to the use of leg (foot) orthosis and knee orthosis have been reported (2,11-13); However, in some studies, no change in pain was observed using knee orthosis (14). In another study, pain changes were assessed using only leg (foot) orthosis during single-leg squats (SLSs), which showed a reduction in pain (12). The results of previous studies suggest that people with PFPS show changes in gait in the transverse and frontal planes in the stance phase (1,15,16). In a study, the kinematics of the lower limb joints in patients with DKV and PFPS during SLS were examined in two modes of normal movement correction pattern and DKV correction, with no significant results obtained in the frontal plane of the knee (17). However, in a study to examine the knee biomechanics during going down stairs using braces and taping in people with PFPS, a reduction in knee range of motion (ROM) in the coronal plane was confirmed (18). The diversity in the implementation of previous studies and various interventions can cause disagreement on the effects of orthosis in this complication.

Although the use of both knee and insole orthosis interventions is recommended for patients with PFPS (10,19,20), further studies on the mechanism of PFPS, the interaction of orthoses on joints, the biomechanical effect of orthoses on lower limb joints, and the effect of these orthoses on reducing pain and increasing function, both biomechanically and clinically, seems necessary. Given that little research was conducted on the effects of orthoses on the frontal and transverse planes (1,16,21) and the DKV changes were not specifically studied in patients with PFPS, the present study is carried out with the aim to examine medial wedge insole and knee braces on pain, DKV, and gait in patients with PFPS. Additionally, two simultaneous interventions on the knee joint and foot that had not been studied in previous studies, are explored.

Materials and Methods

This study was a randomized crossover clinical trial conducted from October 2015 to June 2016 at the Musculoskeletal Research Center, School of Rehabilitation Sciences, Isfahan University of Medical Sciences, Isfahan, Iran. The ethical research permits (IR.MUI.REC.1394.3.452) and Iranian Registry of Clinical Trials (IRCT) code (IRCT20150210021034N4) were obtained before the start of the study.

The number of samples was estimated using G*Power software (Version 3.1, University of Dusseldorf, Germany). Considering the maximum knee torque in the wedge-free state (0.60 ± 0.21 Nm/kg) and with medial wedge (0.62 ± 0.23 Nm/kg) which was reported in the study of Boldt et al., 90% confidence level for small studies, and 55% power for experimental studies, 15 participants were considered as the optimal sample size. Accordingly, 15 individuals with PFPS (9 females and 6 males) participated in the study voluntarily who were selected using the convenience nonprobability sampling method. The study inclusion criteria included being in the age range of 18 to 35 years, positive DKV test in SLSs, no history of surgery, joint pain and crepitus sound during the patellafemoral grinding test (positive for patellafemoral grinding test), at least 4 months of pain, having at least a 30 mm visual analogue scale (VAS) score, and not using other therapies during the study (22). Have a history of knee ligament injury, patellar tendon or cartilage injury, traumatic patellar dislocation, patellar instability, meniscus injury, pregnancy, neurological interventions, and neurological problems that affect coordination or balance during the test, and a history of lower limb surgery (23) were also considered as the exclusion criteria. The inclusion and exclusion criteria were checked by an examiner. To prevent bias, the cases of the subjects were reviewed by another examiner.

After obtaining written consent and completing the demographic information form (including age, gender, and weight), all test steps were carefully described to the participants by the examiner. Biomechanical measurements were performed in four different modes of intervention including “medial wedge insole, knee brace, combination of knee brace and medial wedge insole, and without orthosis (control)”. These interventions were performed during the two positions of walking and SLS on the affected leg. To reduce error, each gait test was repeated seven times and the SLS test on the affected leg three times (24). All measurements were performed by one tester in one session. The order of the tests and orthoses at each stage was determined randomly by taking the closed envelopes from a bag. To prevent participants from getting tired during the test, similar time intervals of about 10 minutes were considered for people to rest.

For the gait test, after marking, the person was asked to walk a specific 6-meter path. Twenty six reflective markers (14mm diameter) were placed on the iliac crest, anterior superior iliac spine (ASIS), posterior superior iliac spine(PSIS), greater trochanter of femur, femur inner and outer condyles, patella center, tibial tuberosity, malleoluses and ankles, heel center, and the first and fifth metatarsals in the two left and right sides (14,25) (Figure 1).

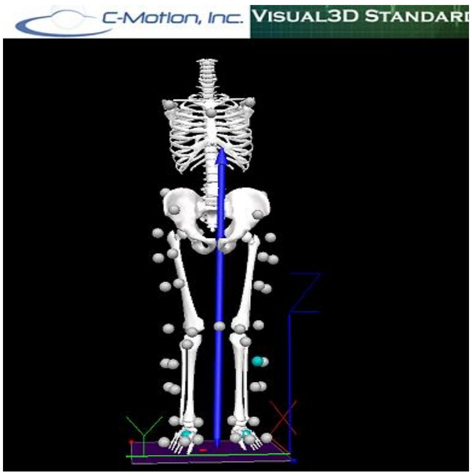

Figure 1. Modeling in Visual3D software

4 cluster markers attached to a semicircular plate were attached to the outer lateral part of the leg and thigh on both the left and right sides. In each position, first in the standing position (static test) the three-dimensional position of the markers were recorded by cameras to define the desired segment (foot, leg, and thigh). The individuals then walked at their normal walking speed along a 6-meter path (so that the affected side was in full contact with the force plate during the stance phase). In the SLS on the affected leg, after randomly selecting one of the four intervention modes and performing the gait test, the person performed the test on the force plate. After completing the tests for each random intervention (7 gait tests and 3 squat tests on the affected leg), the patient determined the severity of his pain in the VAS and his movements were recorded by motion analysis cameras including 7 infrared cameras (Qualysis Motion Capture System, 41113, Packhusgatan 6, Qualisys AB, Gothenburg, Sweden) with a frequency of 100 Hz (24). The position of the markers was then named and recorded using Qualisys Track Manager (QTM) (Qualysis motion analysis, 41113, Packhusgatan 6, Qualisys AB, Gothenburg, Sweden). The body parts including feet, legs, thighs, hips, and trunk were reconstructed by Visual3D (Visual3DTM, C-motion Inc., Germantown, MD, USA). The output data was filtered using a low-pass filter (LPF) (Butterworth) and a cut-off frequency of 15 Hz for force (1,25). In order to eliminate the effect of the body weight confounding factor, the torque was normalized to body weight. The data of the gait variables and the angle and torque variables were extracted using the QTM software and Visual 3D software, respectively.

The insole used in the present study had a full-length medial wedge made of high-density ethylene-vinyl acetate (EVA) to prevent excessive compression while walking (13,25). The wedge slope was considered to be zero degrees transverse for healthy feet and 6 degrees transverse for feet with PFPS (1,26). The insoles were made in the School of Rehabilitation Sciences, Isfahan University of Medical Sciences, and to make each insole, the wedge slope was normalized with the foot length.

The knee brace used in this test was made of neoprene with four springs (Technotan Company, Tehran, Iran) with the patella part open. Despite the different sizes, each participant received a knee brace tailored to their knee circumference to create fewer restrictions for them. To measure the ROM and the range of torque of the knee on the frontal plane while walking, the stance range was considered from Heel Contact to Push Off and in the squat position on the affected leg, from the time the center of pressure of the body was between the two feet to the maximum flexion that each person did during 12 squats on the affected leg, which were then analyzed (1,27,28). The average walking speed was obtained by dividing the step length by step time. Finally, all data were entered into Excel software (Microsoft Corp. Released 2016. Microsoft Office for Windows, Redmond, WA, USA) and for statistical analysis, the mean repetitions were calculated for each individual data, which was performed by a technical orthopedic expert.

Repeated measures analysis of variance (ANOVA) was used to compare different intervention modes in each of the tests (for comparison of four dependent groups). Moreover, Bonferroni post hoc test was utilized to determine the significance level of the difference between the interventions. Using G*Power software and based on maximum knee torque in the orthosis-free case and with orthosis and internal wedge and 90% confidence level for small studies, the power of the present study was calculated to be about 60%. Finally, the data were analyzed in SPSS software (version 16.0, SPSS Inc., Chicago, IL, USA). $P < 0.05$ was considered as the significance level.

Results

The participants consisted of 15 people with PFPS (6 males and 9 females). Figure 2 demonstrates the process of entering the study and the rate of sample loss. All subjects underwent all stages of the study and due to lack of dropouts, the intention-to-treat (ITT) analysis was not possible.

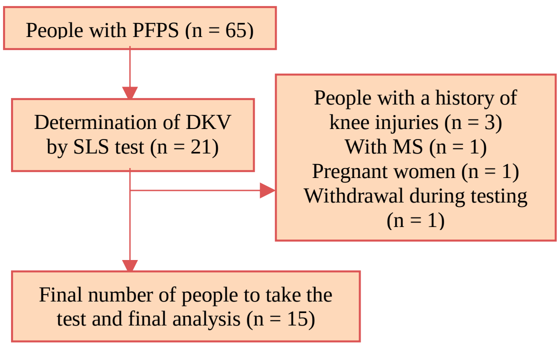

Figure 2. Process of entering the study and sample dropout rate

PFPS: Patellofemoral Pain Syndrome; SLS: Single-leg squat; DKV: Dynamic knee valgus

Table 1 presents the demographic information of the participants. PFPS involvement was in the dominant leg in 11 patients and in the non-dominant leg in 4 patients.

Descriptive statistics of the studied variables are presented in table 2.

Given the results of multivariate tests, there was a significant difference of the interventions in the four test positions in the pain variable ($P = 0.001$). Therefore, for pairwise comparison of the groups in the ANOVA output, the Bonferroni post-hoc test was used, the results of which are presented in table 3.

The results obtained from the knee ROM in the frontal plane while walking and SLS on the affected leg as well as the walking speed in four different modes of intervention did not show a significant difference between the interventions in the four test positions on the basis of the results of the multivariate tests ($P < 0.050$). There was a significant difference in the first peak of knee torque in the frontal plane while walking during the stance phase in four test positions based on the results of the multivariate tests ($P = 0.002$). Therefore, the Bonferroni post-hoc test was employed for pairwise comparison of the groups in the ANOVA output (Table 4).

Discussion

The aim of this study was to evaluate the effect of medial wedge insole and neoprene knee brace orthoses on the knee pain, angle, and torque in the frontal plane and gait in people with PFPS. The results indicated that the medial wedge insole and knee brace had a significant effect on knee pain and torque in the frontal plane, but had no effect on the knee ROM in the frontal plane (while walking and squatting on the affected leg) and walking speed of the patients with PFPS. The use of the medial wedge and neoprene knee brace could show an immediate effect on reducing pain.

Effect of orthosis on pain in patients with PFPS while squatting on the affected leg: Based on the findings, pain in the orthosis-free state was significantly higher than the other three conditions, including with the knee brace, medial wedge insole, and with knee brace and medial wedge insole. However, no significant difference was found among the interventions themselves. The mechanism of pain relief using orthosis may be the result of its effect on increasing proprioception and joint position (11). Salsich et al. examined pain in 20 women with PFPS and DKV and concluded that pain increased with increasing internal hip rotation and external knee rotation as the DKV increased (6). The results of a study by Barton et al. suggested that the use of prefabricated foot orthoses reduced pain when completing SLS (11).

Table 1. Descriptive statistics of participants

Gender	Age (years)	Weight (kg)	Height (cm)	BMI (kg/m^2)
Female	24.11 ± 2.20	57.66 ±7.22	1.62 ±0.07	21.88 ±1.99
Male	21.50 ± 1.37	63.25 ±13.15	1.74 ± 0.06	20.65 ±3.69

BMI: Body mass index; Data are reported based on mean ± standard deviation (SD).

Table 2. Mean values of the indicators studied in the four test situations

Variable	Group				
	Control (without orthosis)	Knee brace	Medial wedge insole	Brace and medial wedge insole	P
Pain (mm)	45.6 ± 10.45	28.53 ±8.28	29.80 ±9.74	27.13 ± 7.90	0.001
Knee ROM in frontal plane (degree)	5.43 ± 2.31	4.61 ± 2.32	5.59 ±2.20	4.69 ± 2.21	0.490
Knee ROM during SLS test on frontal plane (degree)	7.39 ± 3.29	7.25 ± 3.99	7.82 ±3.31	8.17 ± 4.60	0.340
Walking speed (meters per second)	1.12 ± 0.13	1.10 ± 0.14	1.10 ±0.13	1.110±0.15	0.067
First maximum knee abductor torque (Nm)	0.40 ±0.12	0.40 ± 0.12	0.40 ±0.13	0.46 ±0.12	0.002

Data are reported based on mean ± standard deviation (SD).
SLS: Single-leg squat; ROM: Range of motion

In another study, Barton et al. addressed the immediate effect of a pre-fabricated foot orthosis with a four-degree varus wedge and supporting arch on pain changes when step descending, single-leg lifting from a sitting position, and completing SLS, with the results showing reduced pain in the functions mentioned (12). Ghasemi and Dehghan reported pain relief using two types of knee braces after three weeks of follow-up (8). Studies similar to the present study on pain have reported similar outcomes, but the results of Powers et al. (14) were different. In their study on patellar braces, they did not find a significant reduction in pain and gait parameters in both with and without braces (14). The reason for the discrepancy in the results can be due to the variety of interventions, follow-up period, and test conditions. In the present study, the effect of orthosis on the knee ROM in the frontal plane in walking and while squatting on the affected leg and the knee ROM in the frontal plane in the stance phase of walking and during the squat on the affected leg were examined in four different modes of intervention which did not show significant changes.

Self et al. conducted a study to investigate the biomechanics of the knee during step descending using braces and taping in patients with PFPS, concluding that the knee ROM in the coronal plane was reduced by using tapes and braces (18). The results of the present study were consistent with the findings of studies by Mills et al. (25) and Boldt et al. (1). In their study, Mills et al. examined the effect of foot orthoses with three different degrees of stiffness on lower joint kinematics and muscle electromyography (EMG). They examined the maximum, minimum, and distance traveled by the knee angle on the frontal plane, with no significant difference observed in the kinematics of the knee on the frontal plane (25).

The results of the study by Boldt et al. showed no difference in the maximum knee angle in the frontal plane using the medial wedge insole (1). Graci and Salsich examined the kinematics of the lower limb joints in 20 women with DKV and PFPS during SLS in both normal movement pattern and DKV correction, with no significant results obtained on the knee frontal plane (17).

Effect of orthosis on walking speed: In the present study, walking speed was calculated for each step and the results indicated that walking speed did not change significantly after immediate use of the medial wedge insole and neoprene knee brace. In this study, individuals walked at the desired speed and their level of activity may not have been such as to impair their gait pattern. Research suggest a tendency to slow walking in people with PFPS (14,29-31). In the study by Powers et al., a decrease in speed was observed in patients with PFPS during brisk walking, climbing and descending stairs, and going up and down ramps. Additionally, no significant differences in pain, torque, and gate indices were observed in the immediate patellar brace examination in women with PFPS (14). Bek et al. conducted a study on the immediate effect of infrapatellar strap on 18 women with unilateral patellofemoral pain. Then, the gait parameters were measured with and without infrapatellar strap by scanning the soles, which showed no significant difference (3).

Table 3. Comparison of pain changes during squats on the affected leg in different intervention situations

Comparisons	Mean difference (mm)	95% confidence interval (mm)	P
Without orthosis-knee brace	17.06	10.15-23.98	≤ 0.001*
Without orthosis-medial wedge insole	15.80	9.89-21.70	0.023*
Without orthosis-knee brace and medial wedge insole	18.46	12.02-24.91	0.007*
Knee brace-medial wedge insole	1.26	(-8.28)-5.74	> 0.999
Knee braces-Knee braces and medial wedge insole	1.40	(-4.78)-7.58	> 0.999
Medial wedge insole-knee brace and medial wedge insole	2.66	(-3.65)-8.98	> 0.999

*Significant difference at the level of P < 0.050

Table 4. Comparison of the first maximum knee torque in the frontal plane during the stance phase in different intervention modes

Comparisons	Mean difference	95% confidence interval	P
Control-knee brace	0.006	(-0.020)-0.400	> 0.999
Control-medial wedge insole	-0.037	(-0.059)-(-0.015)	≤ 0.001*
Control-knee brace and medial wedge insole	-0.060	(-0.091)-(-0.028)	0.033*
Knee brace-medial wedge insole	-0.043	(-0.091)-0.004	0.080
Knee brace-knee brace and medial wedge insole	-0.065	(-0.100)-(-0.003)	0.008*
Medial wedge insole-knee brace and medial wedge insole	-0.022	(-0.064)-0.020	0.750

*Significant difference at the level of P < 0.050

Arazpour et al., meanwhile, measured spatio-temporal indices six weeks after wearing the knee flexion brace, and the results showed decreased pain, increased mean cadence, improved speed and step length, and knee flexion (29). The results of the present study were in line with the findings of the studies of Powers et al. (14) and Bek et al. (3) who also examined the immediate effect, but the study of Arazpour et al., who studied the long-term effects, had better results.

Effect of orthosis on knee torque in the frontal plane: The results of the present study showed that the maximum adductor torque of the knee was increased by the orthosis interventions of the medial wedge insole and the medial wedge insole combined with the knee brace. Prospective research has identified biomechanical risk factors for PFPS including increased knee adduction torque, increased knee adduction torque impulses, and increased femoral anteversion (6). Based on the previous studies, individuals with PFPS showed an increase in the area below the knee abductor torque diagram relative to the stance phase compared to healthy individuals while running (32). Therefore, a therapeutic strategy aims to reduce the knee adduction torque and create varus torque in the knee to prevent the onset and progression of PFPS (6,26). The results of the present study were in agreement with the goal of reducing the adductor torque, but the results of Boldt et al. (1) contradicted the findings of the present study. In his study, he examined the effect of the medial wedge on the mechanism of running in people with PFPS compared to healthy individuals, observing an increase in the internal adductor torque of the knee and a decrease in hip adductor rotation in both groups and concluded that the medial wedge had little effect on the kinematic mechanism of the knee and hip during running in subjects with PFPS (1).

In their study, Self et al. did not observe a significant difference in knee torque on the frontal plane using braces and taping while descending the step of 20 cm height (18). Although the statistical reports of motor effects differed from those of previous studies (1,3,6,11,14,25,27,32), the effect values in each case are unlikely to exceed the measurement errors. The reason for these differences may be explained by the different conditions of the tests and interventions.

In the present study, a change was observed in the knee adduction torque. The change in torque often depends on a change in the two components of the magnitude of the surface reaction force and the distance of this force from the center of rotation of the joint (34,35). Assuming that the surface reaction force is the same in different repetitions, it seems that the change in the resulting adduction torque can be related to the change in the vertical distance of the force vector to the center of the joint. The change in the vertical distance of the force vector to the center of rotation of the joint can take place both by moving the knee joint in the frontal plane and by moving the point of action of the surface reaction force by changing the center of pressure in the sole. The results of the present study revealed that knee movement in the frontal plane was not significant. Therefore, the resulting change in the torque size can be attributed to a change in the center of pressure of the sole. In this way, the center of pressure may be pushed to the side edge of the foot due to the use of the medial wedge, and the surface reaction force vector may approach the axis of rotation of the knee joint center. Therefore, it is suggested that in future studies, the level of displacement of the center of pressure be also investigated, but in general, given the results obtained (decrease of pain and increase of the first knee torque peak in the frontal plane), the knee and insole application can be considered as an effective treatment strategy in the treatment of people with PFPS.

Limitations

One of the limitations of the present study was the lack of follow-up of participants in time intervals. Therefore, it is not possible to comment definitively on the long-term effect of these orthoses.

Recommendations

Given that the DKV is the result of biomechanical changes of the knee and hip in the frontal and transverse planes, and in this study only one part of it (kinetic and kinematic changes of the knee in the frontal plane) was discussed, it is suggested that the knee movement on the transverse plane, as well as the biomechanics of the hip joint be investigated in future studies.

Conclusion

During activities such as SLS that exert pressure on the patellofemoral joint, orthosis interventions can help reduce pain and pressure on the joint. In the present study, the orthosis interventions did not show an immediate effect on gait speed and ROM of the knee in the frontal plane, but the maximum knee torque in the frontal plane increased, which could help reduce DKV in individuals with PFPS.

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Authors' Contribution

Ameneh Abedian-Aval: study design and ideation, study support, executive, and scientific studies, providing study equipment and samples, data collection, analysis and interpretation of results, specialized statistics services, manuscript preparation, specialized evaluation of the manuscript in terms of scientific concepts, final manuscript approval to be submitted to the journal office, responsibility of maintaining the integrity of the study process from the beginning to the publication, and responding to the reviewers' comments; Niloufar Fereshtenejad: study support, executive, and scientific studies, providing study equipment and samples, data collection, analysis and interpretation of results, manuscript preparation, specialized evaluation of the manuscript in terms of scientific concepts, final manuscript approval to be submitted to the journal office, responsibility of maintaining the integrity of the study process from the beginning to the publication, and responding to the referees' comments; Ebrahim Sadeghi-Demneh: study design and ideation, attracting financial resources for the study, providing study equipment and samples, analysis and interpretation of results, specialized statistics services, manuscript preparation, specialized evaluation of the manuscript in terms of scientific concepts, final manuscript approval to be submitted to the journal office, responsibility of maintaining the integrity of the study process from the beginning to the publication, and responding to the reviewers' comments.

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Conflict of Interest

The authors declare no conflict of interest. Dr. Ebrahim Sadeghi attracted funding for the basic studies related to this article from Isfahan University of Medical Sciences and is working as an associate professor of technical orthopedics at this university. The present study was prepared based on the information
extracted from a dissertation on the master's degree in artificial limbs with the design number 394452 and with the financial support of Isfahan University of Medical Sciences.

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