Design and Evaluation of a Patellar Tendon-Bearing Brace with Off-Loading Mechanism on Tibia

Vahid Chamani (PhD Candidate)[1], Mahmood Bahramizahed (PhD)[1], Mobina Khosravi (PhD)[2], Akbar Biglarian (PhD)[3], Gholamreza Ghorbani Amjad (PhD)[4], Seyyed Mohammad Ebrahim Mousavi (PhD)[1], Mokhtar Arazpour (PhD)[1]*

[1]Department of Orthotics and Prosthetics, University of Social Welfare and Rehabilitation Sciences, Tehran, Iran
[2]Physiotherapy Research Center, School of Rehabilitation, Shahid Beheshti University of Medical Sciences, Tehran, Iran
[3]Department of Biostatistics and Epidemiology, Social Departments of Health Research Institute, University of Social Welfare and Rehabilitation Sciences, Tehran, Iran
[4]Department of Orthopedics, School of Medicine, Hamadan University of Medical Sciences, Hamadan, Iran

ABSTRACT

The current study aimed to design a patellar-tendon-bearing (PTB) brace capable of measuring and quantifying weight offloading on the tibia. The PTB brace was designed with off-loading mechanism on the tibia with features, including ankle joint, vertical sliding adaptor, vertical sliding piece, and upper connector of load cells to PTB brace. Also, the present study investigated the effect of brace on 20 healthy individuals under 8 different off-loading conditions, based on measuring the vertical distance between the calf shells and foot plate through a sliding adapter at 0.5, 1, 1.5, 2, 2.5, 3, and 3.5 cm. The Pedar device and load cells embedded in PTB brace were used to determine the extent of offloading and assess the reliability and validity of brace. Increasing the vertical distance between the calf shells and the footplate can lead to a greater amount of offloading. Accordingly, off-loading ranged from a minimum of 16.5% at 0 cm position to a maximum of 60.48% at 3.5 cm position of sliding adapter. Percentage values of tibia off-loading in 8 conditions were not significantly different in Padar devices and PTB brace. Therefore, PTB brace load cells, as a valid method, can measure off-loading levels. When fabricating a PTB brace, a monitoring system with load cells is essential to measure the amount of tibial offloading, leading to readjustment if limb slides down inside the brace. Additionally, a component is needed to correctly position limb in off-loading condition. In the current study, sliding adapter of brace can provide that capability.

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Keywords

Patellar Tendon Bearing; Braces; Tibial Fractures; Tibia; Off-Loading; Load Cell

Introduction

Fractures of the tibia and fibula are common in lower limb injuries [1], and conservative treatments include closed reduction, immobilization, and gradual weight bearing. The treating tibia shaft fractures aimed to achieve bone union for a fully functional and pain-free limb. Casting and bracing are widely used non-surgical methods for treating tibia fractures [2]. Among these, the Patellar Tendon-bearing (PTB) brace is commonly employed [3], designed to transfer axial forces from the tibia to the ground using lateral bars, thereby maintaining alignment, controlling movement at the fracture site, and promoting healing [4]. It also supports partial body weight, enabling weight

*Corresponding author: Mokhtar Arazpour
Department of Orthotics and Prosthetics, University of Social Welfare and Rehabilitation Sciences, Tehran, Iran
E-mail: m.arazpour@gmail.com

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bearing on the injured limb [5, 6].

However, this brace has been used in the healing of fractures, there has still remained uncertainty and conflicting results regarding its effectiveness in offloading the lower limb. Current functional braces for tibia fractures currently lack a mechanism to measure tibia offloading. Orthotists increase leg flexion angle [7] and the longitudinal distance of calf shells and footplates to provide tibia offloading [8-11]. However, there is no clinical device to measure and continuously adjust offloading in the PTB brace, the Pedar device has been used to measure plantar pressures and single scan devices and to find maximum plantar pressure in different areas of the foot inside the PTB brace [12-16]. However, these instruments are costly and impractical for clinical application, restricting their availability to well-equipped research centers.

To the best of our knowledge, no study has quantitatively calculated the distance between the calf shells and footplate of the PTB brace based on the required off-loading amount. Most studies have simply aimed to create the maximum distance between these two components [16, 17]. However, a maximum distance on one side requires compensating for limb length discrepancy and increasing the maximum height of the shoe heel on the opposite side, this adjustment can reduce walking stability, necessitating customized orthopedic shoes and potentially raising the risk of falls and complications for patients. Furthermore, there is currently no tool available to continuously measure weight distribution during the use of the brace. This is particularly crucial given the variability in off-loading amount, depending on how the brace is worn and the placement of the limb [17]. This issue is especially pertinent for elderly individuals, who may struggle to correctly wear the PTB brace for offloading the heel in diabetic foot cases [15]. Consequently, an off-loading PTB brace is needed, which can be adjusted with each use and show the tibia offloading in real-time.

Therefore, the present study aimed to design a PTB brace equipped with the capability to measure and quantify off-loading, and to continuously adjust tibial pressure clinically during patient use in various conditions. The hypotheses of the current study were, as follows: 1) the PTB brace, with its various settings for off-loading on healthy individuals, is a valid and reliable device for evaluating its off-loading effectiveness, and 2) there is a measurable relationship between different heights in the vertical distance between the calf shells and the footplate, and the off-loading effectiveness of the brace.

Material and Methods

Design considerations for PTB brace

The design features of the PTB brace were as follows: 1) The PTB brace features adjustable calf shell height, leading to the vertical movement of the lateral bars, which can be locked at any desired position (Figure 1), 2) the maximum adjustability of the height should cause the footplate to be positioned 3.5 cm away from the person's heel when bearing weight, 3) the lateral bars can bear a maximum weight of 100 kg, and 4) the brace is equipped with a

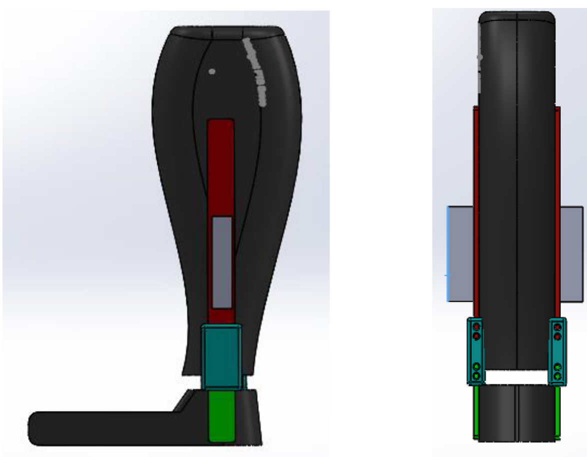

Figure 1: Schematic placement of bars on the patellar tendon-bearing (PTB) brace

force sensor system using two S-shaped load cells (Kelly brand DEE C3) connected to the lateral bars. The output of these load cells is connected to a processor system that displays the maximum and minimum vertical loads applied to the lateral bars. Table 1 presents the specifications of the load cells.

In this study, two load cells on the sides of the brace were used to measure the force exerted. By adjusting the brace height, the force on the leg can be altered as needed. The PTB brace, designed to meet clinical standards for offloading, was created using SolidWorks software and manufactured using a CNC cutting machine. Its components include an ankle joint designed for mobility and adjustability, a vertical sliding adaptor for continual adjustability, a vertical sliding piece with a printed ruler, and an upper connector linking the load cell to the PTB brace.

Based on the guidelines of PTB below-knee prosthesis [18], two 4-millimeter polypropylene sheets were used to create anterior-posterior calf shells in a clamshell configuration after casting and rectifying each person's limb. These shells were designed to accommodate limb volume and prevent limb movement within the PTB brace. The tension of the shell straps was excessive, preventing vertical movement of the limb inside the brace. Additionally, a 5-millimeter polypropylene sheet was used to construct the footplate (Figure 2).

Table 1: Characteristic of load cells of patellar tendon-bearing (PTB) brace used in the study

Model	DEE
Capacity (E_{max})	500 kg
Accuracy according to OIML R-60	C3
Material	Alloy steel
Degree of sealing	IP65
Maximum number of internal partitions	3000
Minimum number of internal partitions	3500
Total error (FS%)	±0.030≥
Creep failure in 30 minutes (FS%)	±0.020≥
Effect of temperature on sensitivity (FS/10 ºC%)	±0.020≥
Zero balance (FS%)	±1.0≥
Excitation voltage (V)	10 ~ 12
Ratio of output voltage to excitation voltage	2.0±0.003 mV/V
Input resistance (Ω)	20±400
Output resistance (Ω)	352±3
Maximum allowed load (E_{max}%)	120%
Maximum safe final load (E_{max}%)	150%
Optimal temperature range (ºC)	-10 ~ +40
Working temperature range (ºC)	-30 ~ +70
Dimensions (mm)	Length: 51, width: 19.1, height: 76.2

FS: Full Scale

Participants

The PTB brace prototype was created by an experienced orthotist for 20 healthy individuals with normal body mass index (between 20-25), no neuromuscular diseases, no history of surgery or plaques in the lower limbs, no wounds or skin diseases, no allergies, and no use of any walking aids, as inclusion criteria.

During this phase, a Pedar sensor device was positioned on the footplate of the brace. The obtained readings, including the difference between the injured side and the contralateral leg, as well as those recorded by the PTB brace, were compared under the following conditions: a) walking with the brace without off-loading conditions (a Pedar sensor device was placed on the footplate of the brace simultaneously with the measurement of the vertical distance between the calf shells and foot plat), b) recording the numerical values of the load cell in the condition of without off-loading and different conditions of off-loading while standing, c) walking with the brace in the off-loading condition while using the Pedar sensor to compare the values obtained from the brace and the difference measured by the Pedar device.

Each participant underwent three trials,

Figure 2: Patellar tendon-bearing (PTB) brace with indicator of off-loading amount on tibia

adjusting the brace for off-loading by incrementally increasing the vertical distance between the calf shells and foot plate using the sliding adapter. Measurements started from 0 cm and increased in 0.5 cm increments up to 3.5 cm for each trial. Posterior-anterior wedges were placed on the contralateral shoe to match the increased vertical distance to accommodate differences in lower limb lengths.

Each participant walked on a treadmill at a constant speed of 2-2.4 m/s for 60 seconds (approximately 50 steps) in eight different off-loading conditions with three reparations in each condition. During this process, data was recorded from each individual, capturing fifty gait cycles to measure the maximum plantar pressure on the foot (off-loading effect), divided into three regions: hind-foot (heel), mid-foot, and forefoot. Moreover, the maximum plantar force values were obtained for each region, which were then averaged to calculate the overall plantar pressure of the foot. To determine the degree of off-loading, these values were converted into percentages and subtracted from the contralateral foot, displaying the off-loading values as percentages.

Statistical analysis

The reliability of the PTB brace and Pedar device was checked in eight different off-loading conditions using Cronbach's alpha test (SPSS software 26). To evaluate the off-loading percentages of the PTB brace and the Pedar device, we first employed the Shapiro-Wilk test to check the normal distribution of the data. Subsequently, we used the independent t-test and Mann-Whitney U test to compare the off-loading percentages of the PTB brace and Pedar device in off-loading conditions with normal and non-normal distributions, respectively.

Results

The reliability of the PTB brace and Pedar device in eight different conditions was checked using Cronbach's alpha, resulting in values of 0.901 and 0.900, respectively, which are statistically acceptable [19].

Table 2 presents the percentage of off-loading with the PTB brace in eight conditions, showing that offloading increases with incremental vertical distance between the calf shells and footplate. The minimum average off-loading was 16.5% with a 0 cm sliding adapter, while the maximum average was 60.48% with a 3.5 cm sliding adapter. However, in conditions of 1.5 cm and 2 cm, the range of off-loading percentages changed from 15.3-52.4 to

Table 2: Summary of off-loading percentage values in 8 different conditions

	Maximum	Minimum	Mean	Standard deviation
Percentage 0	31.0	9.4	16.505	6.1083
Percentage 0.5	40.0	11.5	19.270	7.3412
Percentage 1	44.0	11.3	26.170	6.9230
Percentage 1.5	52.4	15.3	34.535	11.6135
Percentage 2	71.1	12.7	45,800	17.0167
Percentage 2.5	77.9	19.4	50.670	18.9201
Percentage 3	85.1	18.6	53.275	22.5033
Percentage 3.5	92.2	25.0	60.480	19.1917

12.7-71.71, respectively, with a reduction in the minimum percentage in the 2 cm condition. The average percentage difference in leg off-loading was from 0 to 0.5 cm: 2.7%, 0.5 to 1 cm: 3.1%, 1 to 1.5 cm: 8.35%, 1.5 to 2 cm: 11.26%, 2 to 2.5 cm: 4.87%, 2.5 to 3 cm: 2.6%, and 3 to 3.5 cm: 7.2%, showing the maximum and minimum off-loading differences between 1.5 and 2 cm, and 2.5 and 3 cm, respectively.

However, Figure 3A shows the average maximum pressure values, Figure 3B indicates the average maximum force values in the eight off-loading conditions. Additionally, Figure 4A and B display the maximum values of the contact surface and plantar force of the foot compared to the off-loading amount of the leg by the PTB brace, respectively.

The normality results revealed that off-loading conditions of 0, 0.5, 1, and 2 cm did not present a normal distribution, while the other conditions (1.5, 2.5, 3, 2, and 3.5 cm) showed a normal distribution. The average percentage values of the maximum plantar force and leg off-loading in the conditions of 0, 0.5, 1, and 2 cm were not significantly different (Table 3, *P*-value>0.05). Similarly, the comparison of off-loading conditions in the range of 2.5, 3, and 3.5 cm for Pedar devices and PTB brace also showed no significant difference (*P*-value>0.05). Therefore, the load cells integrated into the PTB brace are regarded as a reliable method for measuring the amount of off-loading.

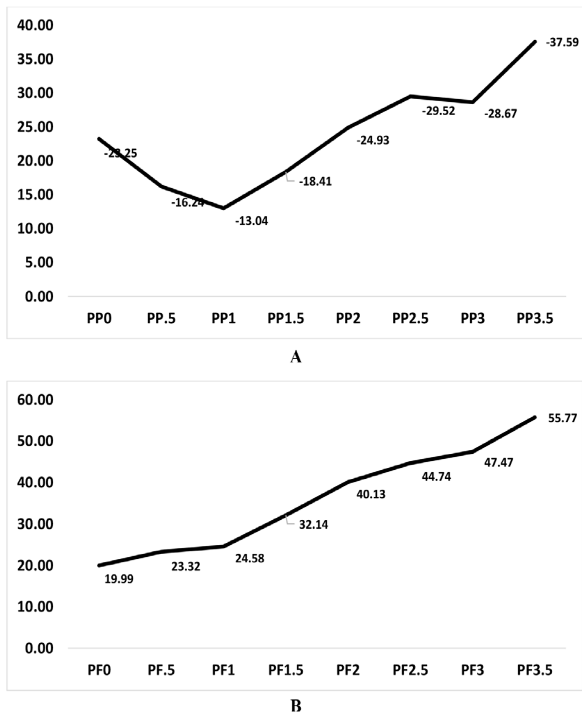

Figure 3: **A:** average maximum pressure, PP (peak pressure). **B:** average maximum force in eight off-loading conditions, PF (peak force)

Discussion

When comparing the off-loading percentages between the foot plantar and the leg, the

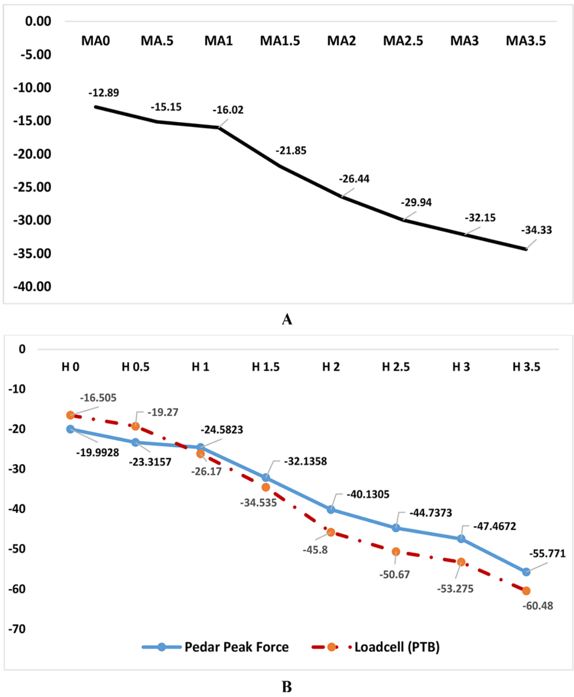

Figure 4: A: maximum values of the contact surface, MA (maximum area). **B:** maximum plantar force of foot compared to the off-loading amount of leg by the patellar tendon-bearing (PTB) brace in eight off-loading conditions, H (height) (vertical distance of the calf shells with the foot plate)

results showed no significant differences in the percentage values across all eight off-loading conditions for the Pedar devices and the PTB brace. The trend depicted in Figure 4B was consistent across these points, with aligned values. Therefore, the average total percentage of the maximum force exerted on the foot plantar at all points can serve as a representative measure of leg off-loading. Further, it was determined that the load cells integrated into the PTB brace are reliable for accurately measuring the amount of leg off-loading.

In trials where the sliding adapter was positioned at a height of 0 cm, the load cells were recorded with an average off-loading of 16.5% on the tibia across 20 participants. The Pedar device also indicated an average reduction of 19.99% in force and 23.25% in overall plantar pressure of the foot. These findings are consistent with Shereff et al.'s study, which demonstrated a decrease in weight-bearing pressure on the sole of the foot when using a short-leg walking cast [19].

Table 3: Results of independent t-test and Mann-Whitney U test for eight off-loading conditions

Conditions		*P*-value
Offloading Perc 0	Loadcell	0.429
	Pedar	
Offloading Perc 0.5	Loadcell	0.201
	Pedar	
Offloading Perc 1	Loadcell	0.923
	Pedar	
Offloading Perc 1.5	Loadcell	0.745
	Pedar	
Offloading Perc 2	Loadcell	0.253
	Pedar	
Offloading Perc 2.5	Loadcell	0.075
	Pedar	
Offloading Perc 3	Loadcell	0.844
	Pedar	
Offloading Perc 3.5	Loadcell	0.583
	Pedar	

The results of the present study showed that increasing the vertical distance between the calf shell and footplate with the sliding adapter led to increasing weight offloading. However, at distances of 1.5 cm and 2 cm, the range of off-loading percentages changed from 15.3-52.4 to 12.7-71.71 respectively, with the minimum percentage decreasing at 2 cm, showing that the leg slides down inside the PTB brace. Accordingly, the monitoring system can help track off-loading amounts and alert patients and therapists for needed adjustments. Additionally, the obtained findings revealed that differences in average leg off-loading percentages were not significant from 2.5 cm onwards, possibly due to leg movement and sliding in the 2.5 to 3 cm range.

Under all tested off-loading conditions, neither the Pedar device nor the load cells of the PTB brace indicated a complete 100% off-loading rate, likely due to the active engagement of leg muscles, which play a role during the mid-stance and pre-swing phases of walking. While the Pedar device showed 100% offloading in the heel region, it did not demonstrate the same level of offloading in the overall plantar part of the foot. Additionally, the maximum off-loading amount among all participants occurred when using a 3.5-centimeter sliding adapter, reaching a maximum of 92.2%. The application of the PTB brace significantly decreased overall plantar pressure and contact area; although both plantar pressure and contact area were significantly reduced in the hindfoot and midfoot, plantar pressure increased in the forefoot region [16]. According to the study, which was conducted on PTB brace in four conditions: with a locked or free ankle and with 1 or 2 cm of heel clearance, excessive lifting of the heel minimizes the contact area, leading to increasing focal pressure in the forefoot [16].

Conclusion

Despite the maximum friction between the calf's clamshell and the skin, incorporating a monitoring system with load cells is needed in PTB brace fabrication, monitoring tibia offloading, and necessary adjustments if the limb slides down inside the brace. Additionally, a component is required to correctly position the limb during off-loading. The sliding adapter of the PTB brace utilized in this study effectively meets this requirement.

Authors' Contribution

Conceptualization was done by M. Arazpour and M. Bahramizahed. Methodology was handled by V. Chamani and Gh. Ghorbani Amjad. Investigation was carried out by V. Chamani and M. Khosravi. Data analysis was performed by A. Biglarian. The original draft was written by SME. Mousavi and M. Arazpour. Writing, review, and editing were completed by M. Arazpour and V. Chamani. All the authors read, modified, and approved the final version of the manuscri.

Ethical Approval

This study was approved by the Ethics Committee of University of Social Welfare and Rehabilitation Sciences (Code: IR.USWR.REC.1400.266).

Informed Consent

The participants were informed about the study objectives and were assured that their information would remain confidential. They all signed a written consent form.

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Conflict of Interest

None

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