Advances in Science and Technology Research Journal

Advances in Science and Technology Research Journal, 2025, 19(6), 108–120
https://doi.org/10.12913/22998624/202883
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Received: 2025.02.11
Accepted: 2025.04.15
Published: 2025.05.01

Enhancing mobility with knee orthoses: Design considerations and patient needs through case study

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ABSTRACT

Knee orthoses are critical in many conditions from pain due to arthritis to knee instability during sports. However, there are very serious challenges regarding usability, comfort, and aesthetics in designing knee orthoses. This paper takes a design approach for the knee orthosis specifically targeted toward arthritis patients and young athletes. From these requirements, it became imperative to have a lightweight, skin-friendly device capable of providing real-time feedback through embedded sensors. A bi-modal methodology was adopted: theoretically, the leg and spring fixtures were modeled in SOLIDWORKS to compute muscle forces with and without the use of orthosis; experimentally, three sets of springs and a brace were manufactured and tested. Kinematic and kinetic data were captured using the G-Walk system; EMG measurements were used to evaluate upper leg muscle activity in controlled tests. This study compared knee braces with spring wires of diameters 1.6 mm, 2.0 mm, and 2.25 mm against an unbraced condition during the Squat Jump Test performed with the G-Walk system. All braced conditions reduced dynamic performance; flight height, center of mass, and average concentric speed was reduced by up to 15%, 20%, and 40% respectively. Kinetic analysis indicated stable takeoff force, lower impact force by 10%, and coupled reduction of eccentric phase rate by 80% with increase in concentric phase by 300%. Increased brace stiffness resulted in lower Quadriceps and Patella forces; EMG data indicated the 2.0 mm brace as providing the optimal balance. Some discrepancies were noted against theoretical models.

Keywords: knee orthosis, back shell, squat jump, G-walk, EMG.

INTRODUCTION

Knee problems can go from slight aches to situations where their pain is unbearable and influences everyday activity significantly. Solutions to this issue include medical devices such as orthotics, knee braces, and sleeves; in severe situations, surgery is necessary. Early diagnosis and treatment are crucial in averting any long-term disability [1–3]. Osteoarthritis, which is currently the main cause of disability in an estimated more than 527 million persons from all parts of the world, also attacks young persons. Factors that aggravate such issues are the type of sport, genetic inheritance, injury history, working conditions, and abnormalities in the joints [4].

Patellofemoral pain syndrome (PFPS) is another common knee condition with pain centered around the knee, worsened by climbing and squatting. In PFPS, the major finding is reduced gluteal medius and maximus activation which in turn increases the angle of hip adduction and dynamic knee valgus. Additionally, decreased quadriceps and hamstring activity may cause excessive knee flexion, placing more strain on the joint. While the underlying causes remain unclear, strength training targeting the knee, core, and hip muscles is widely recognized as an effective treatment, significantly reducing pain and improving knee function by correcting abnormal biomechanical patterns [5–6]. Knee orthoses significantly improve mobility among persons with limited hand function hence the requirement that they be easy to wear, comfortable, and made from very light yet tough materials such as carbon fiber and advanced polymers. With a custom fit, they can take into consideration any abnormality in the functioning of the joint or changes in the course of the disease, hence increasing support while at the same time reducing possibilities of skin irritation. A good look also matters, certainly, young athletes [7-8]. Smart orthoses with sensors for feedback and support in postoperative rehabilitation and adjustments to the orthosis have come with technological advances. Personalized design based on 3D printing can be used to correct the alignment path, reduce pain, and enhance the performance path [9]. Even as these innovate, there still remain cost, access, and patient education challenges.

A 3D-printed or smart orthosis would indeed be very expensive, thus unapproved for use by many people in many different parts of the world. Such patients would also not understand what to do with them properly; therefore, they would more commonly wear them less frequently with less enjoyment. There should be collaboration between healthcare professionals, manufacturers, and policymakers as an approach to ensure equity in access to good-quality orthoses. Patient education should also be included in the benefits and proper use to improve long-term outcomes [10]. Orthoses assist or restrict movement, while prostheses replace the lost function. Their major functions include protection, alignment, support in mobility, and load distribution, thus calling for the need to distinguish between orthoses and prostheses in prescribing for optimal treatment [11–12]. Esrafilian et al. (2012) designed a modular knee orthosis for patients suffering from osteoarthritis by attempting to decrease their knee adduction moment. They used a motion analysis system to assess the foot forces, knee joint moments, and parameters of gait analysis. The findings suggested that the orthosis was successful in partially relieving the joint stress while enhancing the patient's walking posture [13]. In order to assist patients with a weak quadriceps muscle, Spring et al. (2012) designed a knee-extension assist (KEA) as an innovative assistive device that facilitates an individual's daily activities. The integrated KEA can be incorporated into other existing orthoses and provides knee extension moment on them at different angles. The biomechanical analysis noted that the KEA appliances delivered 82 and 75 percent of the necessary knee-extension moment during standing-to-standing movement, 56 and 50 percent of the moment during the sit-to-stand movement, thus helping in the control and ease of movement [14]. Ma et al. (2013) constructed a powered knee orthosis to assist the ambulation of the elderly and people with knee dysfunctions. Gait studies conducted with healthy subjects who role played having mobility restrictions showed that the powered orthosis provided assistive torque, which helped to sustain proper movement patterns, during walking [15]. Kim et al. (2013) worked on a pneumatically powered knee orthosis that utilizes muscle stiffness torque feedback to aid knee extension. The results from 20 subjects revealed that peak muscle activity of the rectus femoris and biceps femoris decreased by 25.62% and 29.82% respectively while peak knee extension torque increased by 17.68% [16]. Brand et al. (2017) studied a lightweight knee unloader orthosis to determine its effectiveness on pain relief and reduction of adduction moments of the knee joint. Their study reported 16% reduction of pain perception and during the measurements, a decrease of up to 20% of knee adduction moments was noted which showed the orthosis was beneficial in medial knee osteoarthritis sufferers [17]. Kamada et al. (2017) evaluated a knee orthosis with elastic element in terms of the damping effect when the user is walking. It was shown that this knee orthosis is superior in providing knee support compared to conventional knee orthoses, particularly when the patient is walking up and down slopes and also when walking on the flat surface at varying speeds [18].

In order to increase back drivability, Zhu et al. (2019) created a quasi-direct drive actuator integrated with a low ratio gearbox for a partial-assist knee orthosis. The human trials demonstrated the decrease of quadriceps activation, suggesting a reduction in muscle strain and an improvement in mobility [19]. Lee et al. (2020) studied a motorized knee exoskeleton meant to assist with knee extension during early stance phases of gait cycles. Some participants exhibited biomechanical compensatory movements in the non-assisted leg to mitigate metabolic costs, showing that the device still requires improvement [20]. Zhu et al. (2021) developed a powered knee orthosis that was back-drivable and powered which reduced quad activity in a range of daily activities such as lifting-lowering, sit-to-stand transitions, and stair climbing. Bench testing of the actuator exhibited low noise levels with reliable torque assistance [21]. Zhou et al. (2024) introduced a modified orthosis designed using four points bending which, in human trials, reduced lateral foot pressures by 22% [22]. The knee orthosis that was created by Liu et al. (2024) has a rehabilitation motion rotation center that attempts to mirror the human knee's natural movements for better recovery results [23]. Karimi et al. (2024) examined a knee orthosis for patients with osteoarthritis and were able to determine that it significantly lowered the knee joint contact forces while maintaining walking speed, proving it to be a helpful conservative treatment option [24]. The aim of this work is to design, develop, and evaluate a knee orthosis that enhances mobility, reduces discomfort, and improves joint support for individuals suffering from knee conditions such as patellofemoral pain syndrome.

METHODOLOGY

The work was divided into experimental procedures and theoretical part. the experimental work was based on the case study that the orthosis designed for. The theoretical part starts by modeling the case leg in order to design a suitable orthosis. Later the spring fixture was modeled using SOLIDWORKS software. The second part of theoretical part is concerned in finding the muscles forces with and without the orthosis. The experimental work includes manufacture of three springs sets, spring tests, manufacture of the brace, EMG measuring for the upper leg muscles during controlled test, and the measure of the kinematics and kinetics data of the hip and knee joints using G-Walk device.

Case study

The case study a male suffering from pain in the patellofemoral joint or the soft tissues around it are said to have patellofemoral pain syndrome (PFPS). This chronic issue tends to become worse when you sit, squat, climb stairs, or run with your knee bent (flex) [25]. He weighs 95 kg, is 186 cm tall, and is 26 years. To help support and lessen the stress on his knee, a brace will be provided, as shown in Figure 1. The tests were carried out under the approval of the ethical procedures at Al-Nahrain University with reference No. of 01/2025.

The leg measurement was taken, in order to manufacture an orthosis that suits the case's measurements, a scan (CR scan 01) of the patient's leg is taken to get the knee's measurements. The total length is 87 cm (from hip to ankle joint), the length of thigh is 44 cm (from hip to knee joint) and the length of leg is 43 cm (from knee to ankle joint), as shown in Figure 2.

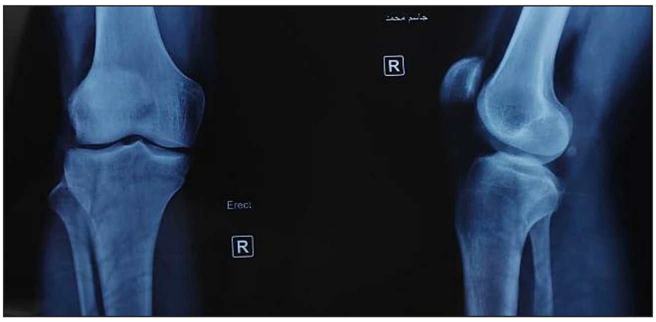

Figure 1. The x-ray of the patient's knee showing patellofemoral pain syndrome

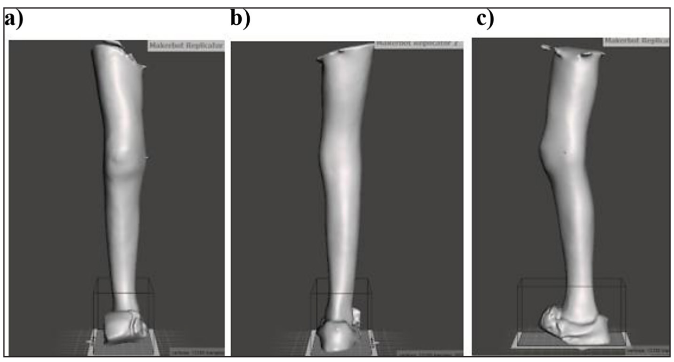

Figure 2. Case study leg scan: (a) front view, (b) back view, (c) side view

Design the brace, the dimensions of the orthosis (back shell orthosis) are drawn in SOLIDWORKS 2022, which consists of two parts, a large part and a small part. The large part is on the thigh and the small part is on the leg and is articulated at the knee location, as shown in Figure 3. Each brace contain three torsional springs.

Drawing of a torsional spring, Figure 4, fixture to fix the spring when performing a torque test using SOLIDWORKS 2022 as shown in the figure. This step was carried out in order to assure correct functioning of the fixture before manufacturing process.

Mathematical model for muscles force

Movement is greatly aided by biarticular muscles, which operate across two joints. A good example are the three muscles that make up the hamstrings. These muscles connect to the lower leg bones after emerging from the hipbone's ischial tuberosity. Their primary roles include extending the hip by moving the thigh, flexing the knee when the thigh and hip are stabilized, and lifting the trunk from a flexed position while maintaining an upright posture. The quadriceps, which serve as the leg's primary extensors, are another example of a biarticular muscle.

The model for hamstrings and quadriceps muscles are used [26] with modifications to include the passive orthosis effect. It was assumed that the legs and the feet are weightless and that the entire weight is lumped into a single weight P acting at a distance c from the hip joint as shown in Figure 5. The moment created by force P about A should be equal to the moment produced by the calf muscle at A:

$$-b\,sin\phi\,F^c + c\,P = 0 \;\Rightarrow\; F^c = c\frac{P}{b\,sin\phi} \tag{1}$$

where: F^c denotes the force produced by the calf muscle group. Because of symmetry in the idealized structure, the calf muscle will produce the same tension as the hamstrings. The moment of all external forces with respect to the knee joint must be equal to zero, including the orthosis effect:

$$-(L\,cos\phi - c)P - 2d^k F^c sin\phi + d^q F^q + T_s = 0 \tag{2}$$

a) b)

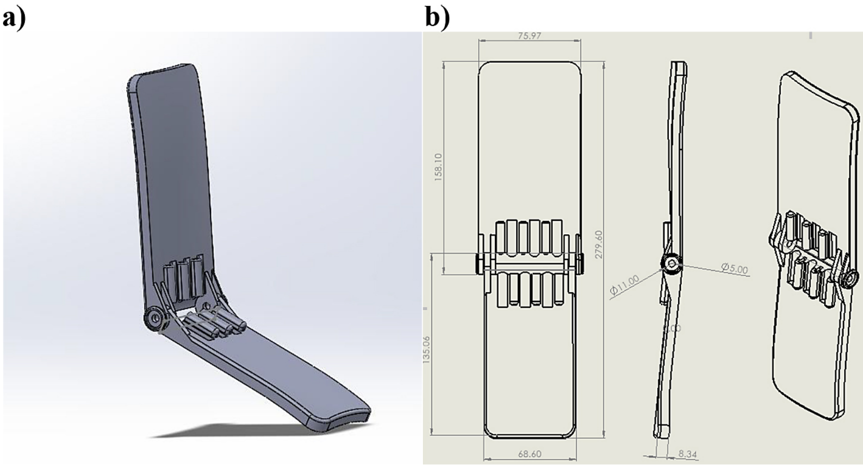

Figure 3. Brace modeling: (a) final 3D assembly, (b) dimensions of the assembly

a) b) c) d)

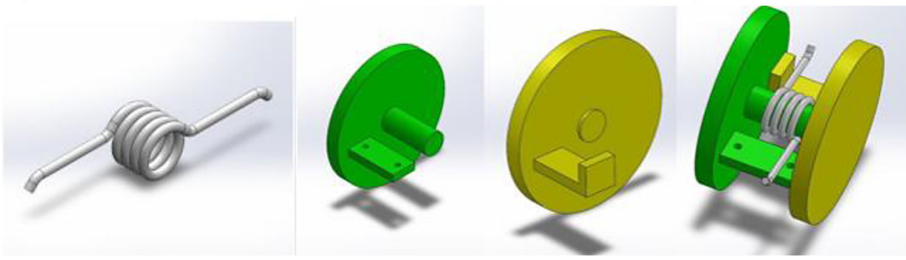

Figure 4. Torsional spring fixture: (a) torsion spring, (b) spring fixture part 1, (c) spring fixture part 2, (d) assembly of the spring fixture

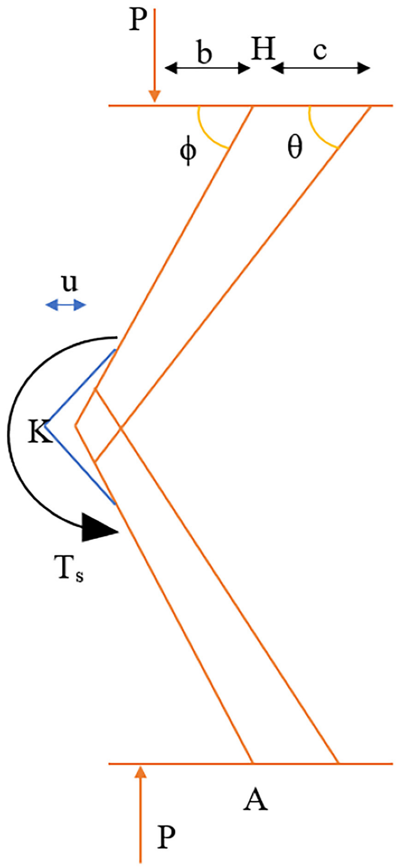

Figure 5. The presentation of the human leg under squat test

the moment arm dk and the angle ϕ can be shown to be given by the relations:

$$d^k = \left(b + L\cos\theta - L\,sin\theta\,\frac{cos\phi}{sin\phi}\right) \tag{3}$$

$$\tan\phi = (L+h)\frac{sin\theta}{b+(L-h)cos\theta} \tag{4}$$

The next step is the determination of the moment arm d^q of the quad muscle group, which can be determined from the following equations:

$$s^2 = \left(\frac{L}{3}\right)^2 + u^2 - \left(\frac{2L}{3}\right)u\cos(\pi-\theta) \tag{5}$$

$$\left(\frac{L}{3}\right)^2 = s^2 + u^2 - 2\,s\,u\cos\alpha \tag{6}$$

$$d^q = u\sin\alpha \tag{7}$$

The compressive force acting on the quads and the knee joint can be found by considering:

$$F^p = 2\,F^q\,cos\alpha \tag{8}$$

where: F^p represents the patellofemoral compressive force. The three forces were found for the four cases.

EXPERMENTAL METHODOLOGY

Torsional spring fixture was installed on the torsion test device, Figure 6, so the device can support the torsion spring in order to determine the spring constant by giving a specific angular displacement starting from zero and going up to a limit within the elastic limit, the amount of torque was measured by the device for each angular displacement and the torque angular deflection diagram was drawn to obtain the spring constant.

A pair of brace was manufactured using a 3D printing method by fused deposition modeling technology. A K1Max printer with high speed PETG (polyethylene terephthalate glycol) filement where used to print two parts (shell) and it took four and half hours. Then the parts were cleaned of excesses. The patient wears the brace after assembling and fixing it on the piece of cloth that was sewn to contain the brace and it contains two straps, a strap around the thigh and a strap around the leg, as shown in Figure 7. In our research, three steel springs with different wire diameters 1.6 mm, 2 mm, and 2.25 mm were used in sequence. The tests is performed 4 times,

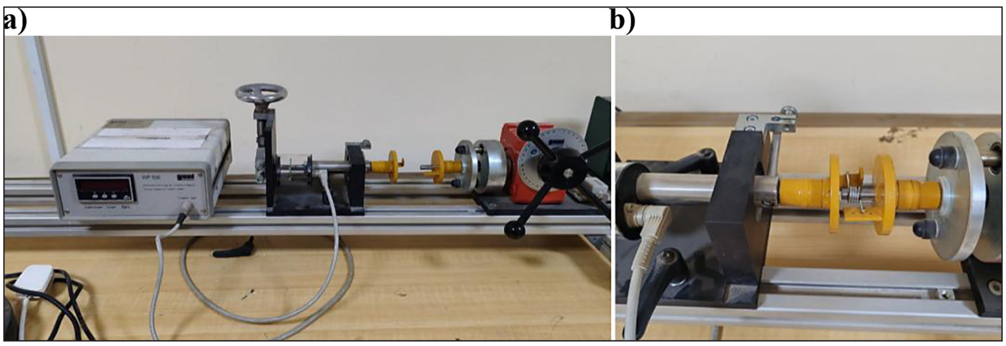

Figure 6. Torsion test: (a) device, (b) torsional spring fixture mounted

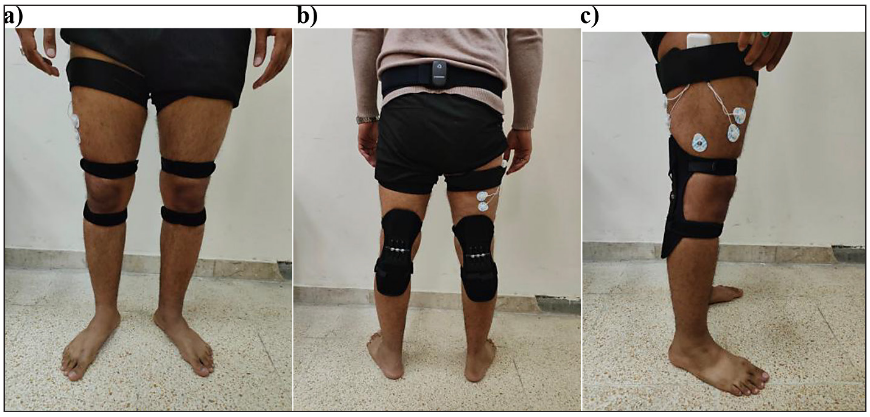

Figure 7. The case study after wearing the brace: (a) front view, (b) back view, (c) side view

Figure 8. The manufactured parts of the brace

once without a brace and once using a brace with 1.6 mm wire diameter spring, 2 mm wire diameter spring and 2.25 mm wire diameter spring, as shown in Figure 8.

G-walk device

The sensor needs to be positioned correctly on the topic to be assessed in order to provide accurate and reproducible data throughout test execution. The sensor for the 'Jumps' protocol has to be placed underneath the line that joins the two dimples of Venus—the lumbosacral passage—which is equivalent to the S1–S2 vertebrae as shown in Figure 11. With the flat side facing the rear of the pocket, the sensor was inserted into the belt and positioned it in the middle of the previously determined column point [27-29]. To

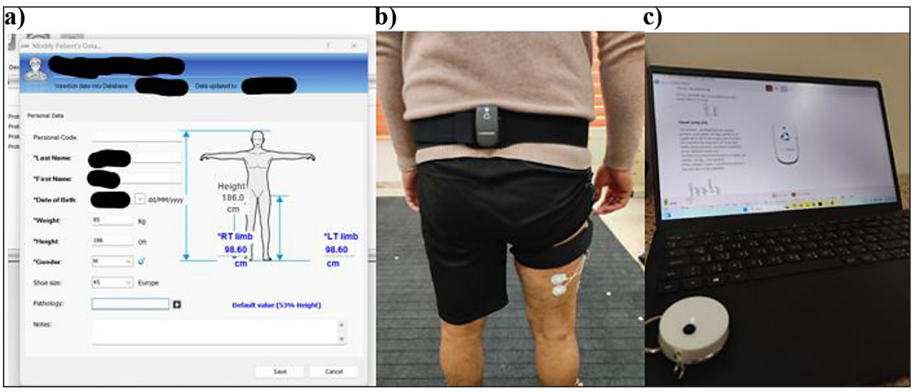

Figure 9. G-Walk configuration: (a) case study details in device software, (b) device mounting on the case study, (c) bluetooth connection between device and software

make the belt as supportive as possible for the body and to prevent it from moving while the test is being administered, it was advised to tighten it securely, as shown in figure. After installing the device, the patient's information was recorded, as shown in Figure 9.

Emg device

The device sensors (due+ pro wireless electromyography bipolar device -from one to eight 2 channel probes with integrate Inertial measurement unit) are in the form of channels, and each channel consists of a positive electrode and a negative electrode. Two channels were used to measure the electrical activity of the muscle of two main muscles related to the squat jump. The first channel was placed on the body of the rectus femoris muscle, which is considered the main muscle in the anterior thigh muscle group and the main contributor in the squat jump, while the second channel was placed on the body of the hamstring muscle because it is the main muscle of the posterior thigh muscles and an important muscle for the squat jump, as shown in Figure 10.

The purpose of the Squat Jump test is to assess the explosive force of lower limb athletes. The test begins with the subject standing upright with their feet shoulder-width apart and their hands on their hips. After the operator gives the order to begin, the subject squats by bending their knees by 90 degrees and holds that position for one second. From this static squat position, the subject jumps vertically down without making any counter movements to maintain elasticity; if the subject makes a countermovement, the test will not be valid, as shown in Figure 11. During the test, the maximal flexion in the joint is determined by

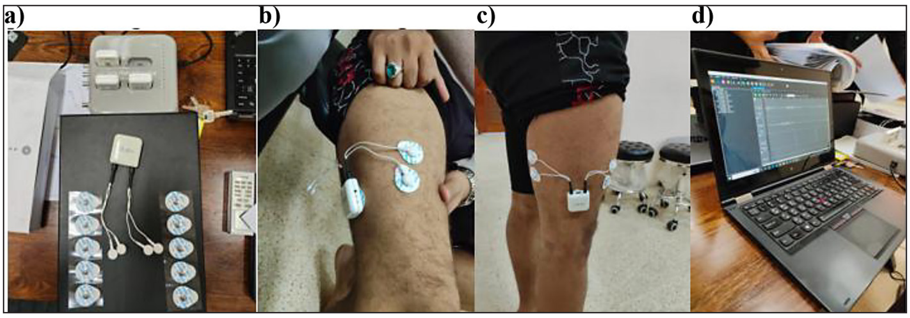

Figure 10. Electromyography sensor's fixation: a) the sensor and electrode, b) front electrode position, c) back and front electrode position, d) recording data through device software

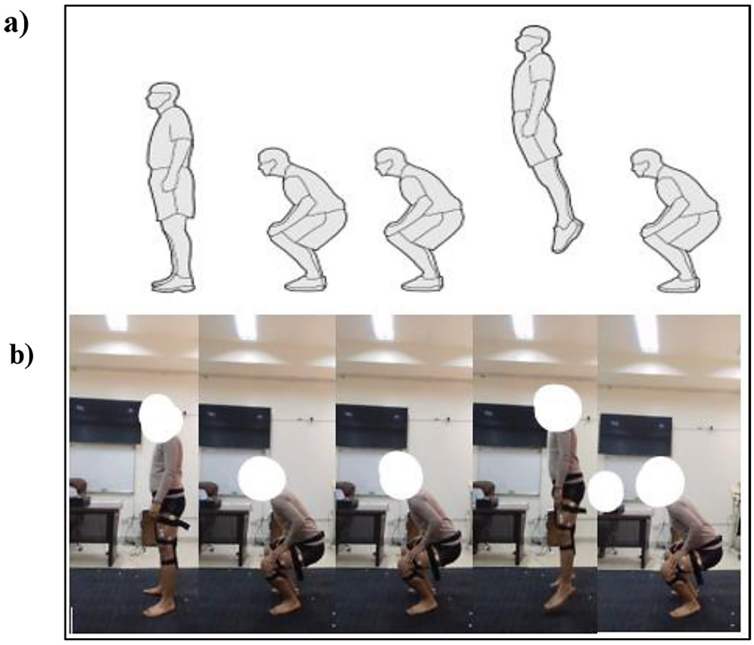

Figure 11. The squat jump sequence (starting from right): (a) in software protocol, (b) in real action.

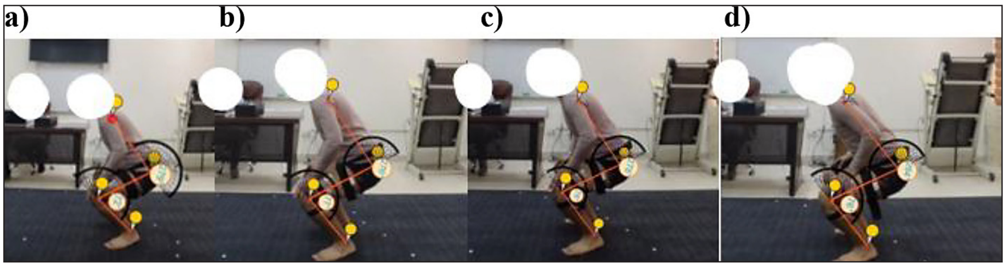

Figure 12. Defining the knee joint angles: (a) original, (b) 2 mm, (c) 2.25 mm, (d) 1.6 mm

calculating the angles of the knee joint using the Kenova software, as shown in Figures 12

RESULTS AND DISCUSSION

The G-Walk system was used to assess the patient's performance under four conditions: (i) without the brace (Case 1) and (ii) with the brace incorporating spring wire diameters of 1.6 mm (Case 2), 2.0 mm (Case 3), and 2.25 mm (Case 4). A squat jump test was conducted in all cases.

Kinematic parameters

The results showed (Figures 13–14) a reduction in maximum flight height with the brace, averaging about 15% lower than the unbraced condition. Center of mass height exhibited a similar tendency, decreasing by as much as 20% in the

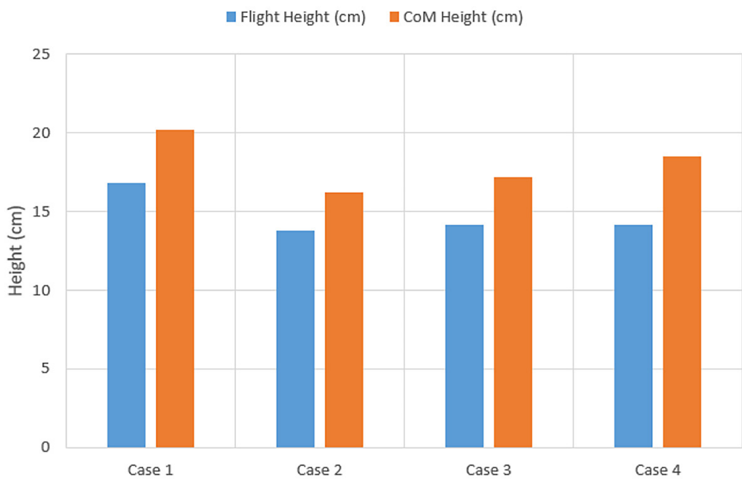

Figure 13. Flight height and center of mass for squat jump test for all cases

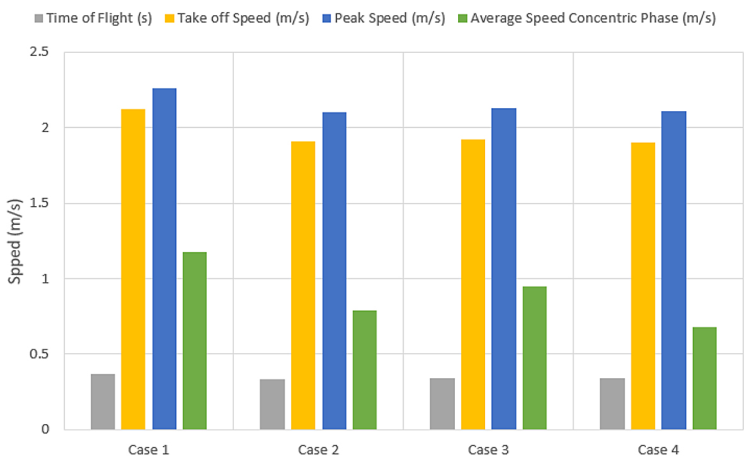

Figure 14. Speed and time for squat jump test for all cases

braced cases. Flight time experienced a slight reduction, around 8%. Takeoff velocity and peak velocity were diminished by roughly 10% and 7% respectively. Average velocity during concentric phases showed the largest reduction, going down by nearly 40% with the brace; this points towards a critical effect on explosive movement.

Kinetic parameters

Throughout the experiments, calipers seemed to do little to aid in the increase of takeoff force, which experienced less than a 4% change across all conditions. However, use of the brace did produce a decrease of approximately 10% in the impact force, showing some degree of effectiveness as a cushioning device. Similarly, the force at the countermovement height in the 2. 25 mm spring condition exhibited a very large decrease, close to 30%. The propulsive peak force, on the other hand, only changed on the order of 5%. The peak rate of force development in the eccentric phase experienced about an 80% greater reduction of force within the 2.25 mm brace condition, which clearly illustrates the limitations regarding rapid force generation. Inversely, the concentric phase rate of force development rose over 300% in the same condition, showing clear evidence of a compensatory effect. Concerning average concentric power, a considerable drop was noticed, having a maximum reduction of 47%, within the most restricting base condition, as shown in Figures 15 and 16.

Impact on performance

Of the parameters studied, the mean concentric velocity and peak eccentric rate of force development showed the most telling decline which underlines their greater sensitivity to bracing. These results indicate that the brace is able to provide

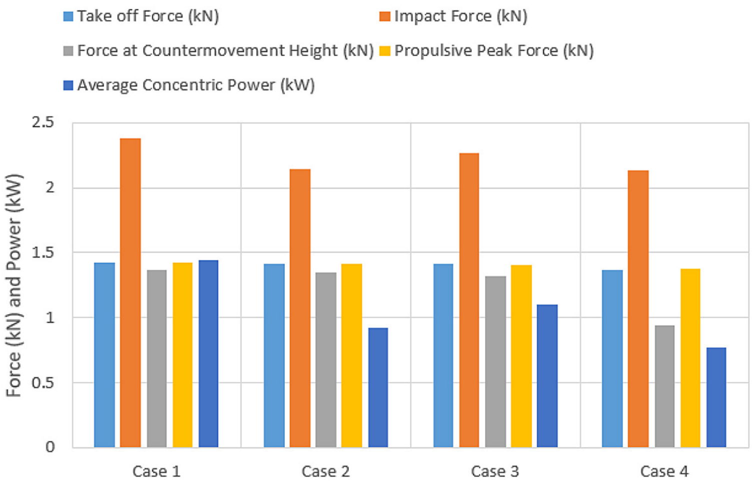

Figure 15. Forces for squat jump test for all cases

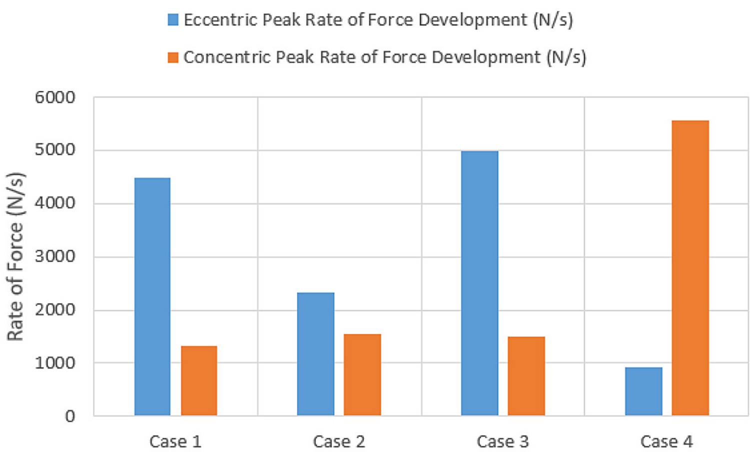

Figure 16. Force rate for squat jump test for all cases

longitudinal stability, but at the expense of some dynamic functional capacity, especially with respect to the speed of force production and application.

Muscles forces

In Figure 17, it can be observed that, with the stiffer brace, there were marked reductions in the Patella and Quadriceps forces. The Quadriceps maximum force per unit weight of 73.23 was registered while the patient was not using the brace and was lowered to 69.09, 65.68, and 63.99 after bracing with the 1.6 mm, 2.0 mm, and 2.25 mm braces. These changes correspond to reductions of 5.64%, 10.31%, and 12.59%, indicating that a stiffer brace effectively reduces Quadriceps loading. The Patella forces also lowered from 139.91 without the brace to 132.01, 125.45, and 122.25 with the respective changes in the brace, resulting in a reduction of 5.65%, 10.34%, and 12.62%. The Hamstring force did not change from 6.54 in all conditions, which means that the brace has very little effect on posterior muscle loading. These results suggest that a knee brace is effective in lessening the tension on the Quadriceps and Patella, thereby reducing muscle fatigue and stress to the joint. This is important for improving brace design especially for rehabilitation and prevention of injuries since, on the one hand, greater support means greater muscle effort is unwanted and, on the other, bracing stiffness needs to be increased for better load transfer. This is partly corroborated by the constant Hamstring force, which indicates that the brace comes into effect on the anterior muscle. In all probability, these changes will design better braces for increased comfort and performance during recovery.

Electromyography

Muscle activity was evaluated in a patient under four conditions; without a brace (Case 1) and with the braces having different spring wire diameters of 1.6 mm (Case 2), 2.0 mm (Case 3), and 2.25 mm (Case 4), using the Squat Jump Test. For the rectus femoris, recorded maximal activity was 2.47 mV, 1.29 mV, 0.842 mV, and 0.816 mV, respectively, implying reductions of 47.8%, 65.9%, and 66.9% when wearing the brace. For the RMS values, similar patterns were established with the following respective reductions: 26.8%, 56.8%, and 58.5%. Hamstrings recorded 2.067 mV, 0.922 mV, 1.41 mV, and 2.967 mV for maximal activation with corresponding RMS values of 0.121 mV, 0.077 mV, 0.134 mV, and 0.162 mV. The 2.0 mm spring wire brace (Case 3) achieved the best compromise between rectus femoris strain reduction at 65.9% and optimal maintenance of hamstring activation; this points to effective support without excessive compensatory activation. Conversely, the 2.25 mm brace (Case 4) was excessive regarding hamstring activation above baseline (43.5% increase), suggesting stiffness, thus leading to severe compensatory responses. The 2.0 mm brace remained the most efficient in reducing muscle strain while keeping muscle function in balance, as depicted in Figure 18.

RMS values in this study are significative measures combining effort the muscle exerts under each condition. The decrease in RMS from the rectus femoris indicates that the brace is effective in reducing the overall muscle load, while changes that appear in the hamstring indicate whether the brace does indeed induce unwanted compensatory activation. Even though

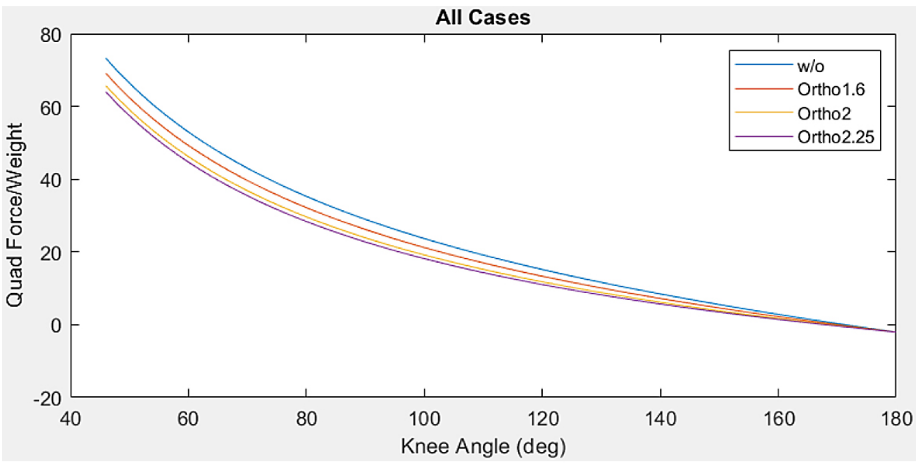

Figure 17. Quadricep (rectus femoris) forces for all cases

the maximum is interesting to see a peak effort moment, RMS provides a bigger picture in terms of the braces that influence muscle efficiency and fatigue. Experimental RMS values of muscle activity are then compared with the theoretical forces predicted by the mathematical model for the Quadriceps, Hamstring, and Patella. Both the RMS value and the theoretical quadriceps force display a decrease as the brace stiffness increases. However, the RMS decrease is much greater than the decrease in theoretical force, indicating that muscle activation is influenced more by brace support than predicted by the theoretical force model. Case 3 (2.0 mm) shows the most efficient results with a 56.8% RMS reduction accompanied by a 10.3% decrease in force. Theoretical hamstring force remains the same (6.54 N/unit weight) in all check cases, which does not match with the experimental RMS results. According to the RMS results, hamstrings activation decreases initially (Case 2) and then increases significantly again (Case 3, Case 4). Case 4 (2.25 mm) shows excessive hamstring activation with a 33.8% RMS increase, indicating overcompensation that is not captured by the theoretical model of force. Case 3 (2.0 mm) shows a minor increase (10.7%), indicating support that is well balanced without excessive compensation. Quadriceps – both experimental RMS and theoretical forces confirm that Case 3 (2.0 mm brace) provides the best efficiency with significantly reduced muscle activation and controlled force reduction. Hamstring – theoretical force model does not capture compensatory muscle activation, particularly in case 4, where the excessive involvement of the hamstring indicates that a stiff brace tends to overcompensate. Patella force – similar behavior to quadriceps force, confirming that the brace plays a role in limiting knee joint stress.

Study limitations

The study highlights potential long-term effects of orthosis use, including both benefits and risks. The key benefits include reduced joint stress, which may slow osteoarthritis progression, decreased muscle fatigue leading to prolonged mobility, and improved knee stability, which can help prevent further injuries, especially in those with instability or post-surgery recovery.

The study also highlights potential risks of long-term orthosis use. These include muscle deconditioning due to reduced activation, altered movement patterns that may lead to secondary injuries, and compliance issues caused by discomfort or movement restrictions. To fully understand the long-term impact, future research should track biomechanical and physiological changes through patient monitoring, muscle strength assessments, and gait analysis.

The study offers practical insights for physicians, physical therapists, and orthosis manufacturers to optimize knee orthosis use and improve patient outcomes. For physicians – personalized orthosis prescriptions should consider brace stiffness to balance support and muscle activation. The orthosis can help reduce joint stress in arthritis patients and should be monitored for long-term effects like muscle deconditioning.

For physical therapists – rehabilitation programs should include strength training alongside bracing to prevent muscle atrophy. Gait retraining is necessary to counteract altered movement patterns, and patient education ensures proper orthosis use. For manufacturers – optimizing brace stiffness (with 2.0 mm spring proving most effective), improving material comfort, and developing smart orthoses with sensor-based feedback can enhance compliance and performance.

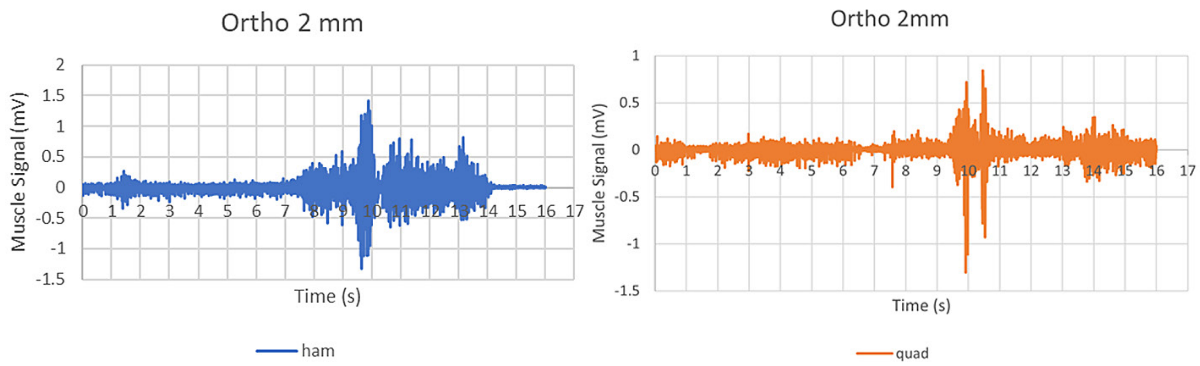

Figure 18. EMG for rectus femoris and hamstring (Case 3)

Overall, the study underscores the need for tailored brace selection, integration with therapy, and continuous design innovation.

CONCLUSIONS

The knee brace greatly affected explosive movement metrics with a reduction of 40% from normal concentric speeds along with a decrease in jump height and CoM height; thus, while the brace is said to provide stability, it limits the dynamic performance of the user. Sufficient increases in brace stiffness demonstrated 12.6% reduction in Quadriceps and Patella forces, implying that the brace competently distributes load and thus reduces stress in these structures anteriorly. Based on EMG readings, a 2 mm spring wire brace supported the best combination of a significant increase in the reduction of rectus femoris activation and did not cause an undue compensation in hamstring activation, while the stiffest (2.25 mm) brace caused overcompensation in hamstring activity. The experimental activation of the muscles (as judged by RMS values) was more sensitive to brace support than theoretical force models predicted, indicating limitations in the ability of current models in providing full characterization of compensatory muscle behavior.

Acknowledgments

Approval was obtained from the local ethics committee and the tests were carried out under the approval of the ethical committee at Al-Nahrain University. The patient had legally authorized publisher and corresponding author and provided a written informed consent for the publication of patient information in the present manuscript.

All authors have accepted responsibility for the entire content of this manuscript and consented to its submission to the journal, reviewed all the results and approved the final version of the manuscript. The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request.

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