Design, Implementation and Testing of a Novel Prototype Orthotic Knee Joint with Two Degrees of Freedom in a Patient with Medial Knee Osteoarthritis

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ABSTRACT: Knee braces are a conservative treatment option for patients with knee osteoarthritis (KOA). However, no commercially available orthotic knee joint currently reflects natural knee movements. A prototype orthotic knee joint with two degrees of freedom (DOF) in the sagittal and transverse planes was developed to more closely simulate the natural motion of the knee joint. The prototype was tested on a male subject with medial KOA during a sit-to-stand task. The efficacy of the transverse plane DOF was assessed by comparing the limb-orthosis interaction force when the transverse plane was locked to mimic a one-DOF setting versus when it was unlocked. Unlocking the transverse plane eliminated the 45-Newton shearing force produced with the one-DOF setting at wide angles of flexion. The two-DOF orthotic knee joint prototype demonstrated greater conformity to natural knee movements, allowing the wearer to better tolerate bracing-related difficulties.

Keywords: Knee Joint; Knee Osteoarthritis; Orthotic Devices; Braces; Rotation; Movement; Materials Testing.

الملخص: دعامة الركبة هي خيار علاجي محافظ للمرضى الذين يعانون من التهاب مفصل الركبة. ومع ذلك، لا يوجد أي جهاز تقويمي لمفصل ركبة متوفر تجاريا في الوقت الحالي يوفر حركات الركبة الطبيعية. تم تطوير نموذج جديد لداعم تقويمي للركبة مع درجتي حرية حركة في المستوىين السهميّ و العرضي من أجل محاكاة الحركة الطبيعية لمفصل الركبة بشكل أكثر قربًا. تم اختبار النموذج الأولي على ذكر مريض مصاب بالتهاب مفصل الركبة الأنسي خلال الحركة الطبيعية لمفصل الركبة بشكل أكثر قربًا. تم اختبار النموذج الأولي على العرضي من خلال مقارنة قوة تفاعل أطراف الأطراف عندما تم قفل المستوى العرضي لتقليد الحركة الطبيعية لمفصل الركبة والأغلاق. فتح المستوى العرضي ألغي قوة القص⁴ لنويتن المنتجة بإعداد مجال حركي واحد في زوايا انثناء واسعة. أظهر النموذج ثنائي الحرضي من خلال مقارنة قوة تفاعل أطراف عندما تم قفل المستوى العرضي لتقليد الحركة الطبيعية لمفصل الركبة عند الفتح والأغلاق. فتح المستوى العرضي ألغي قوة القص⁴ نيوتن المنتجة بإعداد مجال حركي واحد في زوايا انثناء واسعة. أظهر النموذج ثنائي الحركة للداعم التقويمي للركبة قدرًا أكبر من التوافق مع حركات الركبة الطبيعية، مما أتاح لمرتديه أن يتحملوا بشكل أفضل المعوبات

الكلمات المفتاحية: مفصل الركبة؛ التهاب مفصل الركبة؛ أجهزة تقويم العظام؛ أجهزة داعمة؛ داعمدوران؛ حركة؛ اختبار المواد.

NEE BRACES ARE A CONSERVATIVE TREATment option for patients with medial knee osteoarthritis (KOA).¹⁻³ Nevertheless, despite the positive effects of various types of knee braces, they limit the motion of the joint in all directions.^{4,5} This is partly due to the structural design of these orthotic devices, which generally follow simpler kinematic pathways than those of the natural anatomic knee joint. This mismatch can result in the pistoning of the brace components over the lower limb, constraining the wearer's normal range of motion with the subsequent distal movement and potentially leading to misalignment of the brace and uncomfortable pressure on the skin.⁶ Furthermore, axial misalignment causes unnecessary reaction forces

at skin and joint attachment points, resulting in discomfort and even outright injury.⁷

Currently available orthotic knee joints, including both single-axis or polycentric devices, have one degree of freedom (DOF) in the sagittal plane and therefore can only mimic the range of flexion and extension of the anatomic knee, thus restricting the joint's natural movement.⁸⁹ As such, the incorporation of an additional DOF in the transverse plane would allow the brace to more closely imitate the natural motion of the knee by allowing internal and external rotation.

To the best of the authors' knowledge, no commercially available orthotic knee joint with more than one DOF is currently available.^{8,9} As such, a prototype orth-

¹Rehabilitation Research Center, Department of Orthotics & Prosthetics, School of Rehabilitation Sciences, Iran University of Medical Sciences, Tehran, Iran; ²Department of Mechanical Engineering, Sharif University of Technology, Tehran, Iran; ³Department of Biomechanics, Djavad Mowafaghian Research Centre of Intelligent Neuro-Rehabilitation Technologies, Tehran, Iran *Corresponding Author's e-mail: saeedi.h@iums.ac.ir otic knee joint was developed with two DOF in both the sagittal (i.e. flexion/extension) and transverse (i.e. internal/external rotation) planes. The prototype was tested to determine its efficacy in more closely simulating the natural motion of the knee joint by assessing the limb-orthosis interaction force when the transverse plane DOF was locked versus when it was unlocked.

Methods

The first step in developing the two-DOF orthotic knee joint prototype involved sketching potential designs in order to choose a realistic option for bracing the knee joint. Secondly, currently available polycentric knee joints were examined, modified and tested following the addition of a rotary component. A computer-aided design was then created digitally using SolidWorks[®], Version 5 (Dassault Systèmes, Paris, France) and CATIA[™] software, Version 5 (Dassault Systèmes). This allowed for more detailed conceptual input and to assess whether the orthotic knee joint could be manufactured. The design and construction of the prototype was performed concurrently in the Djavad Mowafaghian Research Center of Intelligent Neuro-Rehabilitation Technologies and the Department of Orthotics & Prosthetics of the Iran University of Medical Sciences, Tehran, Iran.

The final design of the prototype consisted of a polycentric hinge with a hyperextension stop to allow flexion/extension and a drawer joint above the polycentric hinge for transverse rotation [Figures 1A and B]. The transverse plane motion of the drawer joint could be locked by a screw and plate, hindering the joint's movement in the transverse plane and mimicking one-DOF products currently available in the market.^{8,9} When unscrewed and detached, the joint was released and the device returned to its original two-DOF configuration [Figure 1C]. Overall, the range of motion of the proto-type in the sagittal and transverse planes was 140 and 20 degrees, respectively [Table 1].

The drawer joint measured $60 \times 47 \times 15$ mm, weighed 300 g and was made from stainless steel. The aluminium sidebars (20×5 mm) attached proximally to the drawer joint as femoral components and distally to the polycentric hinge as tibial components. The hinge was mediolaterally attached to a knee brace consisting of white copolymer polypropylene and 4-mm-thick anterior thigh and tibial shells lined with a 5-mm-thick ethylene vinyl acetate (EVA) copolymer closed cell foam for comfort. Four 5-mm-wide nylon straps with hook and loop closures were attached around the outside of the device to allow the wearer to adjust the fit. Each strap had a protective pad made from a 5-mm-thick EVA copolymerclosed cell foam positioned to protect the posterior leg skin [Figures 1D–F].

Subsequently, the testing phase was initiated to assess the performance of the prototype. A 45-year-old male subject with grade II medial KOA according to Kellgren and Lawrence classifications was recruited to perform a sit-to-stand task.¹⁰ Briefly, the subject was asked to rise from sitting in a chair and, after a short pause, sit down again without support at a self-selected speed. The chair had no arms and was adjusted to the subject's height to ensure that the thighs lay parallel



Figure 1: Computer-aided designs (CADs) and photographs of a novel prototype orthotic knee joint with two degrees of freedom. A: CAD showing the polycentric hinge (red arrow) and drawer joint (yellow arrow) in a neutral position. B: CAD showing the joint components in a flexed and rotated position in the sagittal and transverse planes, respectively. C: CAD showing the position of the upper (red arrow) and lower (yellow arrow) joint components and miniature tension load cell (arrowhead). The transverse plane motion of the drawer joint could be locked and unlocked using a screw and plate (asterisk). D–F: Photographs of the (D) anterior, (E) medial and (F) posterior views of the prototype.

Table 1: Manufacturing characteristics of a novel prototype orthotic knee joint with two degrees of freedom

| Characteristic | Measurement |
|------------------------------|-------------|
| Aluminium polycentric hinge | |
| Weight in g | 100 |
| Height in mm | 50 |
| Width in mm | 33 |
| Thickness in mm | 18 |
| Range of motion in degrees | 140 |
| Stainless steel drawer joint | |
| Weight in g | 300 |
| Height in mm | 47 |
| Width in mm | 60 |
| Thickness in mm | 15 |
| Range of motion in degrees | 20 |
| Aluminium sidebars | |
| Thickness in mm | 5 |
| Width in mm | 20 |

to the seat when the subject was in a sitting position. The feet were kept parallel to one another on the ground while the arms were placed against the chest. A miniature tension load cell (UMMA[®] 100 kg-force model, DACELL Co. Ltd., Nami-myeon, Cheongwon-gun, South Korea) was used to measure the interactive shearing force between the limb and orthosis in the shell area during knee joint motions. The load cell was embedded between the posterior aspect of the orthotic joint in the medial side and the detachable aluminium plate [Figure 1C]. In order to measure the angle of knee flexion at the moment of lowest and highest interactive shearing force between the limb and orthosis, an incremental rotary encoder (E30S series, AUTONICS

Co. Ltd., Busan, South Korea) allowing 1,000 pulses/ revolution was installed co-axially at the centre of the orthotic joint on the lateral side. After three practice sit-to-stand trials, the mean values were calculated for the final analysis.

The output signal of the miniature tension load cell was filtered through a low pass filter and amplified 1,000 times using a DN-AM100[®] dynamic load cell amplifier (DACELL Co. Ltd.). The amplified voltage was then digitised using a 3.3-V 84-MHz Arduino Du e[®] ARM core data acquisition board (Arduino, Turin, Italy). The microcontroller in the data acquisition board was programmed with custom software and the recorded data were uploaded to a computer from a secure digital card. The results were input into an Excel spreadsheet, Version 2013 (Microsoft Corp., Redmond, Washington, USA) and presented in the form of a line chart.

All procedures and components involved in the design, implementation and testing of the prototype were approved by the Ethics Committee of the Iran University of Medical Sciences (#92-11-50-3209). Voluntary informed consent was provided by the subject prior to the testing of the prototype.

Results

When the transverse plane of the orthotic knee joint was locked (i.e. providing only one DOF), the orthotic joint only partially mimicked the path of the anatomic knee during the sit-to-stand task, allowing only flexion and extension movement. Furthermore, the miniature tension load cell mounted behind the joint detected a mean shearing force load of 45 Newtons (N) between the limb and orthosis in the shell area when the subject sat down and flexed his knee to approximately 90 degrees. The amount of force increased as the flexion angle exceeded 40 degrees, with the maximum amount of force occurring in the final phase of the sitting move-



Figure 2: Line graph showing the interactive shearing force load between the limb and orthosis in the shell area during a sit-to-stand task using a novel prototype orthotic knee joint with two degrees of freedom (DOF) compared to one DOF alone.

N = Newtons; DOF = degrees of freedom.



Figure 3: Photographs showing the displacement of the upper and lower components of the drawer joint of a novel prototype orthotic knee joint with two degrees of freedom. During a sit-to-stand test, these two components were displaced by 15 mm when the subjects flexed his knees from (A) full extension to (B) approximately 90 degrees, representing movement in the transverse plane.

ment, when the knees were flexed at approximately 90 degrees. This interactive shearing force was transmitted through the sidebars into the orthotic joint.

However, when the task was repeated with the transverse plane unlocked (i.e. providing two DOF), the orthotic joint was able to more closely mimic natural knee joint movements. In addition, the miniature tension load cell detected almost no load when the subject sat down and flexed his knee to approximately 90 degrees [Figure 2]. The subject also declared that he was more comfortable while seated when the transverse plane was unlocked. The maximum displacement of the rotary part of the orthotic joint in the transverse plane (i.e. the drawer joint) between the two sliding components was 15 mm. This occurred just after the subject had begun to sit down from a standing position [Figure 3].

Discussion

Patients often report discomfort, poor fit and skin irritation as reasons for poor compliance with or discontinuation of the use of knee braces.^{11,12} Furthermore, previous research indicates that KOA patients wear their braces for less than four hours a day.^{13,14} There is therefore a need to redesign knee orthotic devices in order to increase wear time, more closely mimic natural movement and reduce patient discomfort.¹² Accordingly, a novel prototype orthotic knee joint with two DOF in both the sagittal and transverse planes was designed and tested on a subject with medial KOA.

When the transverse plane of the two-DOF prototype was locked into a one-DOF setting, the mounted load cell behind the joint detected a mean shearing force load of 45 N. This could be due to mismatch between the movement of the orthotic and anatomic joints as the orthosis attempted to force the knee to follow a simplified movement pattern, thereby preventing natural rotary motion. As a result, unwanted constraint force (i.e. interactive shear force) was generated between the orthosis and the limb in contact areas. As the flexion angle exceeded 40 degrees, the amount of force increased. The maximum amount of force was recorded in the very last phase of movement into a seated position, when the subject flexed his knees to approximately 90 degrees. This is understandable considering that the limb volume increases as the knee joint moves into deep flexion.¹⁵ In other words, as the motion of the orthotic joint does not accurately reflect natural knee kinematics, the tightly fitting interface magnifies the pistoning constraint, leading to a high load.

However, when the transverse plane of the prototype was unlocked to allow two DOF, there were fewer limitations in the path of the anatomic knee joint. As such, the subject was able to both flex and rotate his knee, allowing for a much freer range of motion. The internal and external rotation decreased the extra shearing force between the limb and orthosis, resulting in increased comfort for the wearer when sitting and standing, which are movements which require deep flexion and among the most routinely practiced activities in daily living.¹⁶

Conclusion

A novel prototype orthotic knee joint with two DOF was designed to more accurately reflect natural knee movements by allowing motion in both the sagittal and transverse planes. When compared with the one-DOF setting, the two-DOF mechanism allowed the subject to move his knee more freely and complete the range of motion with a lower constraint force when sitting and standing. Such devices are recommended to mitigate the inconvenience and discomfort associated with traditional one-DOF knee braces, thereby improving the quality of life of patients with KOA.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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