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Biomechanical evaluation of a novel dynamic posterior cruciate ligament brace

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ABSTRACT

Background: Use of a rigid brace or cast immobilization is recommended in conservative treatment or postoperative rehabilitation after a posterior cruciate ligament injury. To prevent the loss of knee joint function and muscle activity often associated with this, a flexible knee brace has been developed that allows an adjustable anteriorly directed force to be applied to the calf in order to prevent posterior tibial translation. The purpose of this biomechanical study was to evaluate the impact of this novel dynamic brace on posterior tibial translation after posterior cruciate ligament injury and reconstruction.

Methods: A Telos stress device was used to provoke posterior tibial translation in seven human lower limb specimens, and stress radiographs were taken at 90° of knee flexion. Posterior tibial translation was measured in the native knees with an intact posterior cruciate ligament; after arthroscopic posterior cruciate ligament dissection with and without a brace; and after posterior cruciate ligament reconstruction with and without a brace. The force applied with the brace was measured using a pressure sensor.

Findings: Posterior tibial translation was significantly reduced ($P = 0.032$) after application of the brace with an anteriorly directed force of 50 N to the knees with the dissected posterior cruciate ligament. The brace also significantly reduced posterior tibial translation after posterior cruciate ligament reconstruction in comparison with reconstructed knees without a brace ($P = 0.005$).

Interpretation: Posterior tibial translation was reduced to physiological values using this dynamic brace system that allows an anteriorly directed force to be applied to the calf.

1. Introduction

The incidence of posterior cruciate ligament (PCL) ruptures reported in the literature is 5–20% of all acute knee ligament injuries with almost 50% of PCL injuries being isolated (Kowalczuk et al., 2015; Schulz et al., 2003). The PCL acts as the primary stabilizer preventing posterior translation of the tibia relative to the femur (Butler et al., 1980). Gravity and dynamic loads caused by the hamstring muscles provoke posterior tibial translation (PTT) when the PCL is insufficient and the patient is lying in a supine position (Lopez-Vidriero et al., 2010; Strobel et al., 2002). It is therefore recommended that PTT should be kept to a minimum or at the pre-injury level during the ligament healing phase after PCL injury and during the graft incorporation phase after PCL reconstruction (Pierce et al., 2013). To achieve this position, the recommended treatment algorithm uses a rigid brace or cast immobilization with a posterior tibial splint for the first 5–8 weeks (Edson et al., 2010; Jung et al., 2008; Kim et al., 2013), since applying an anteriorly directed force to the tibia during PCL healing has been reported to improve the clinical outcome (Strobel et al., 2002; Ahn et al., 2011; Jacobi et al., 2010). After this initial healing period, a 6- to 8-week period follows with a second brace that allows an adjustable range of motion (Edson et al., 2010; Jung et al., 2008; Yoon et al., 2013). Initial prolonged rigid brace or cast immobilization during the healing period can cause knee joint stiffness, reduce muscle strength, and result in impairment of knee joint function. This can prolong the rehabilitation process and delay the patient's return to work, thereby increasing costs to the healthcare system.

To overcome these limitations, a novel flexible PCL brace has been developed that makes it possible to apply an adjustable anteriorly directed force to the calf in order to reduce PTT after PCL injury, or to prevent PTT after PCL reconstruction. The novel flexible PCL brace is intended to allow conservative treatment or postoperative rehabilitation using a single brace, with a potential for early mobilization in the knee joint. Currently, none of the available PCL braces has been evaluated biomechanically in relation to whether or not they are able to prevent or reduce PTT

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(Jansson et al., 2013). In addition, the amount of anteriorly directed force that needs to be applied to the calf is still unknown.

The purpose of this biomechanical study was to evaluate the impact of a novel dynamic brace with free degrees of flexion on PTT after PCL injury and reconstruction. It was hypothesized that the brace, which applies an anteriorly directed force to the calf, can reduce PTT after PCL injury and prevent PTT after PCL reconstruction. It was also evaluated whether increasing the anteriorly directed force to the calf can further affect PTT.

2. Methods

2.1. Specimen preparation

Seven fresh frozen lower limb specimens from four female donors (average age = 75, range = 52–88 years) were used for testing. Quantitative computed tomography scans (qCT; Lightspeed VCT 64, General Electric, Milwaukee, WI, USA) were performed for each specimen to rule out any relevant pathology, such as previous fractures. The lower limbs were cut in the middle of the femur. Soft tissues and muscles were retained. The specimens were kept frozen at −20 °C, thawed 24 h before testing at 4 °C, and prepared at room temperature prior to testing. After thawing, diagnostic arthroscopy was performed to ensure that central stabilizers such as cruciate ligaments and menisci were intact. Brass rods (diameter 4 mm, length 50 mm) were implanted in a standardized fashion under fluoroscopic control into the tibia and femur at 90° of knee flexion so that they were axially aligned to each other in order to serve as radiological landmarks for measuring PTT.

2.2. Brace

The novel dynamic knee brace (M4PCL knee brace, medi GmbH, Bayreuth, Germany) is composed of a femoral and a tibial leg frame (Fig. 1a). Polycentric physiological hinge joints connect the two frames, using the principle of four-chain linkage, and allow constrained or free flexion and extension movements. An anteriorly directed force can be applied to the calf from a posterior pressure pad attached to the tibial frame. The amount of force applied by the posterior pressure pad is variable and can be adjusted using a wire traction wheel (Fig. 1b).

Fig. 1. (a) The M4PCL knee brace. (b) A variable anteriorly directed force can be applied to the calf by turning the wire traction wheel on the posterior pressure pad.

2.3. Posterior tibial translation measurements

A Telos stress device (Metax GmbH, Hungen-Obbornhofen, Germany) was used to provoke PTT by applying a standardized posteriorly directed force of 150 N at 90° of knee flexion (Schulz et al., 2003; Jung et al., 2006; Schulz et al., 2005; Shelbourne et al., 1999). After two preloading cycles in which the knee was moved between 0° and 90° of flexion, the specimens were positioned in the stress device at 90° of knee flexion, as recommended by the manufacturer. The proximal end of the femur and the ankle of the specimen were fixed to the stress device in order to standardize knee positioning in the device and minimize rotational error. Lateral stress radiographs (Siremobil 2000, Siemens Healthcare, Erlangen, Germany) were taken in five states per specimen:

1) Native knee with an intact PCL (native)
2) After arthroscopic total dissection of the PCL (dPCL) without a brace
3) After arthroscopic total dissection of the PCL (dPCL) with a brace applied
4) After arthroscopic reconstruction of the PCL (rPCL) without a brace
5) After arthroscopic reconstruction of the PCL (rPCL) with a brace applied

The distance between the radiation source and the fixed knee in the stress device was kept at a constant maximum. Care was taken to ensure that the center of the knee was located in the center of the image intensifier, to minimize measurement errors in the repeated measurements of each specimen.

In the first part of the biomechanical tests, the brace was applied with an anteriorly directed force of 50 N, representing approximately the lower leg mass of a person weighing 80 kg. For quantification of the anteriorly directed force, a pressure sensor (Sensor 5101, Tekscan Inc., South Boston, MA, USA) was positioned in a standardized fashion between the calf and the posterior pressure pad. The pressure sensor, 0.102 mm thick, has a matrix dimension of 112 × 112 mm, which is larger than the surface of the pressure pad. The total number of sensels is 1963, resulting in a spatial resolution of 15.5 sensels per square centimeter. The net force between the calf and the pressure pad was calculated as the sum of each sensel force. The pressure pad's wire traction wheel was turned until the pressure sensor measured a net force of 50 N before testing started.

In the second part of the biomechanical tests, the anteriorly directed force was further increased by turning the pressure pad's wire traction wheel by one full turn and two full turns (360°, 720°) in order to examine whether increasing the anteriorly directed force alters PTT further. Maximum force values from the pressure sensor were documented after the wire traction wheel was turned before testing started.

PTT was measured using an image processing program (Gimp 2.8.4, GNU) and consisted of three steps (Fig. 2):

- The long axis of the tibial and femoral brass rods was marked.
- At the proximal end of the tibial brass rod, a line was drawn perpendicular to the long axis of the tibial brass rod.

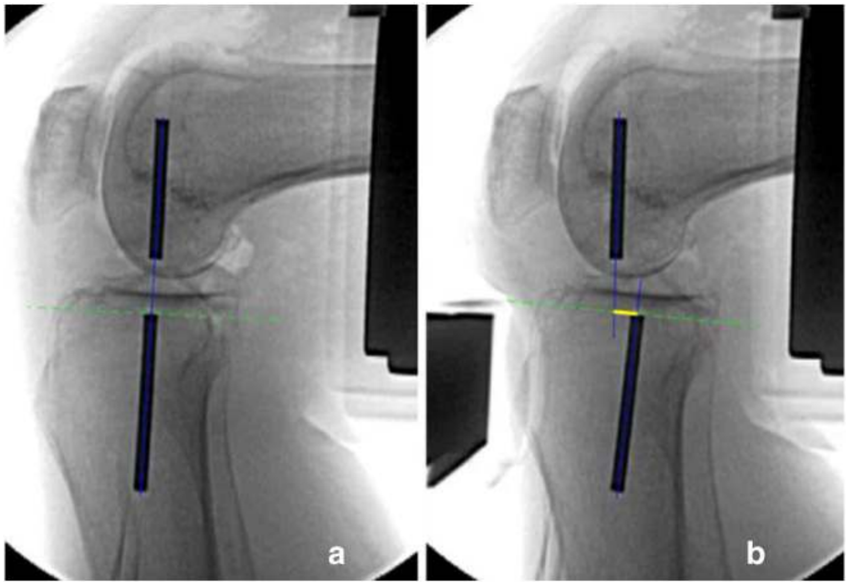

Fig. 2. The method used to measure posterior tibial translation.(a) Two brass rods (diameter 4 mm, length 50 mm) were implanted into the tibia and femur at 90° of knee flexion and aligned to each other axially to serve as landmarks.(b) The posterior tibial translation (yellow bold line) was measured as the distance between the long axes of the brass rods (blue lines) at the level of the tibial perpendicular line (dashed green line).

- PTT was measured as the distance between the long axes of the two brass rods at the level of the tibial perpendicular line.

2.4. PCL reconstruction

All of the surgical procedures were performed by the same surgeon (RM) under the guidance of the senior consultants (RA, PBS). The all-inside TightRope (Arthrex Inc., Naples, FL, USA) hamstring graft link technique was used for the arthroscopic PCL reconstruction (Adler, 2013). Bovine extensor digitorum tendon grafts were used as hamstring substitutes due to their similar structural, material, and viscoelastic properties (Donahue et al., 2001). The tendon grafts were sharply trimmed in line with the fiber orientation using a graft-sizing block to achieve a graft adjusted to a diameter of 9 mm. The tendon grafts were folded over two TightRope reverse tensions (Arthrex Inc.) in order to obtain a four-stranded graft with a length of approximately 90 mm. The tendon grafts were secured with four buried-knot sutures (two sutures on both ends of the graft).

2.5. Statistical analysis

Statistical analyses were performed using IBM SPSS Statistics, version 21 (IBM Corporation, Armonk, NY, USA). Data are reported as means with standard deviation (SD). The box plots show the median and 25–75 interquartile range. Distribution was tested using the Shapiro–Wilk test. Normally distributed data were compared using repeated-measures analysis of variance (ANOVA), followed by a post hoc comparison with Bonferroni correction. A significance level of $P < 0.05$ was set.

3. Results

Measurements of PTT in the native knees in the Telos stress device were used as the baseline values, and all subsequent measurements reported represent changes relative to the baseline. Negative values for PTT indicate anterior tibial translation in comparison with the baseline measurement.

3.1. Brace with an anteriorly directed force of 50 N

After complete dissection of the PCL, the mean PTT increased significantly to 8.4 mm (SD = 2.0 mm) in comparison with the native state ($P < 0.001$). Applying the brace to the PCL-dissected knee significantly reduced PTT to 7.8 mm (SD = 2.1 mm) in comparison with the dissected state ($P = 0.032$).

In comparison with the dissected state, PCL reconstruction without the brace significantly reduced PTT from 8.4 mm to 1.2 mm (SD = 3.8 mm; $P = 0.023$). Applying the brace to the PCL-reconstructed knee further reduced PTT to −1.2 mm (SD = 3.8 mm). This reduction was significant in comparison with both the dissected state ($P = 0.003$) and the reconstructed state without the brace ($P = 0.005$) (Fig. 3).

3.2. Brace with increased anteriorly directed force

In the PCL-dissected state, increasing the anteriorly directed force on the posterior pressure pad by further turning the wire traction wheel with one and two full turns significantly reduced PTT from 8.4 mm to 6.9 mm (SD = 2.0 mm; $P = 0.018$) and 5.1 mm (SD = 2.6 mm; $P = 0.019$), respectively.

After PCL reconstruction, one full turn on the wire traction wheel of the pressure pad did not significantly alter PTT in comparison with the applied brace with an anteriorly directed force of 50 N (−1.2 mm, SD = 3.9 mm; $P = 1.000$). Two full turns resulted in a PTT of −1.8 mm (SD = 3.7 mm; $P = 0.298$).

For the dissected state, one full turn on the wire traction wheel resulted in a mean net force at the posterior pressure pad of 97 N (SD = 14 N) and 81 N (SD = 15 N) in the PCL-reconstructed knee. In comparison with the net force after the first full turn on the wire traction wheel, a second full turn significantly increased the mean net force at the posterior pressure pad to 162 N (SD = 24 N; $P = 0.005$) and 124 N (SD = 19 N; $P = 0.006$), respectively (Fig. 4).

4. Discussion

The present in vitro study shows that PTT was reduced using the novel dynamic brace that allows an adjustable anteriorly directed

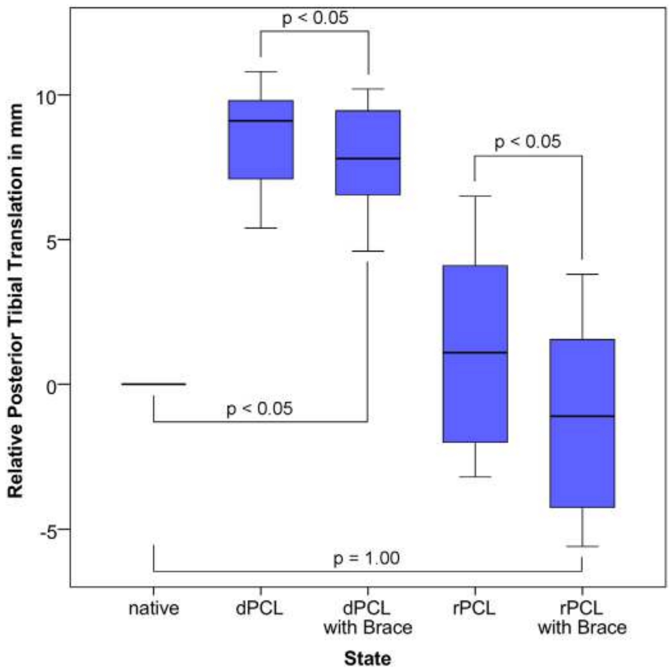

Fig. 3. Changes in the posterior tibial translation measurements relative to the native knee using the brace with an applied anteriorly directed force of 50 N. dPCL, dissected posterior cruciate ligament; rPCL, reconstructed posterior cruciate ligament.

force to be applied to the calf. PTT was significantly reduced after the brace had been applied to the PCL-dissected knee. However, the PTT values for the uninjured knee were not restored. The PCL reconstruction almost restored the native PTT, and application of the brace significantly reduced PTT in comparison with the PCL-reconstructed knee without a brace.

Stress radiography has been described as the most accurate technique for quantifying posterior laxity in PCL-injured knees, and it makes it possible to differentiate between isolated PCL injuries and combined posterior instabilities (Schulz et al., 2003; Jung et al., 2006; Schulz et al., 2005; Garavaglia et al., 2007; Hewett et al., 1997). In clinical practice, PTT is usually evaluated as a side-to-side difference (SSD) measurement between the injured knee and the contralateral side using peripheral bony landmarks, as described by Jacobsen (Jacobsen, 1976). It has been reported that an SSD larger than 8 mm indicates complete PCL rupture (Kowalczuk et al., 2015; Hewett et al., 1997; Schulz et al., 2007). In the present study, PTT was assessed relative to the native state of the knee and was measured using two implanted brass rods. Complete PCL dissection resulted in a mean PTT of 8.4 mm, which is comparable with reported SSD values for complete PCL ruptures using the stress radiographic method (Jung et al., 2006; Shelbourne et al., 1999; Garavaglia et al., 2007; Schulz et al., 2007).

An SSD of less than 10 mm is an accepted indication for conservative treatment after PCL injury (Lopez-Vidriero et al., 2010; Wind et al., 2004). For conservative treatment, cast immobilization or a full-extension brace is frequently used, followed by a second brace that allows an adjustable range of motion. However, the clinical benefit and effects of cast immobilization and brace application after PCL injury or reconstruction are matters of controversy, and no uniform recommendations are available (Pierce et al., 2013; Kim et al., 2013; Watsend et al., 2009).

Clinical follow-up studies after isolated PCL injuries that were treated conservatively have shown that the SSD improved between 1.5 mm and 4.3 mm in comparison with the SSD measured after the injury (Strobel et al., 2002; Jung et al., 2008; Ahn et al., 2011). To date, one clinical study has reported results with conservative treatment using a flexible PCL brace (PCL-Jack, Albrecht GmbH, Stephanskirchen, Germany) for 4 months after an acute PCL injury. The brace used in the study allowed an anteriorly directed force of up to 70 N to be applied to the calf via inbuilt springs (Jacobi et al., 2010). The SSD was measured using a Rolimeter arthrometer in 70° of knee flexion. After 24 months, the initial SSD of 7.1 mm was reduced to 3.2 mm (Jacobi et al., 2010). In the present study, the brace with an anteriorly directed force of 50 N was insufficient to restore PTT to physiological values after complete dissection of the PCL. Wearing a dynamic PCL brace for a prolonged time might have a reinforcing effect, as measured in the present in vitro study. However, it should be borne in mind that most complete PCL ruptures are likely to undergo surgical treatment, as conservative treatment has only a limited ability to restore the PTT (Strobel et al., 2002; Jung et al., 2008; Ahn et al., 2011).

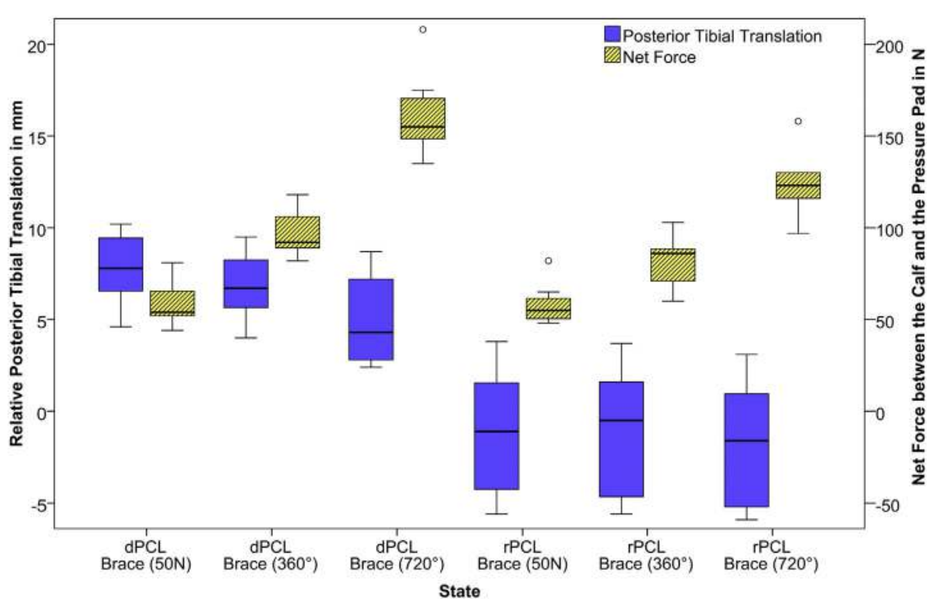

Fig. 4. Comparison of posterior tibial translation (blue boxes) relative to the native knee and the net force between the calf and the posterior pressure pad (hatched yellow boxes) using the brace with an initial anteriorly directed force applied (50 N) and increased anteriorly directed forces by turning the wire traction wheel of the pressure pad by one and two full turns (360°, 720°). dPCL, dissected posterior cruciate ligament; rPCL, reconstructed posterior cruciate ligament.

Increasing the anteriorly directed force by turning the wire traction wheel on the pressure pad by two turns resulted in a PTT reduction of 3.4 mm and a mean force at the posterior pressure pad of 162 N. The anteriorly directed force to the calf required in order to prevent PTT has not yet been investigated. In a study including healthy volunteers performing activities such as knee flexion and squatting, LaPrade et al. (2014) investigated a dynamic loading brace that increases the anteriorly directed force with increased flexion. A maximum mean force of 153 N was measured at 90° of flexion (LaPrade et al., 2014). However, it can be assumed that patients might not be able to tolerate that amount of force being applied to the calf for a prolonged period of time.

In the present study, reconstruction of the PCL with an applied brace with an anteriorly directed force of 50 N was necessary in order to restore PTT to physiological values. The PCL-reconstructed knee with an applied brace showed a 9.6 mm reduction in PTT in comparison with the dissected state without a brace. Several clinical follow-up studies have evaluated different reconstruction techniques and postoperative rehabilitation programs using stress radiography (Yoon et al., 2013; Ahn et al., 2013; Chuang et al., 2011; Seon and Song, 2006). After a minimum 2 years of postoperative follow-up, the SSD was reported to have improved between 7.7 mm and 10.2 mm in comparison with the preoperative SSD.

Any comparison of the present data with published clinical follow-up results needs to be cautious due to the lack of standardized measurement techniques for quantifying posterior laxity in PCL and the absence of any effects of the ligament healing phase after PCL injury or the graft incorporation phase after PCL reconstruction. To the best of the authors' knowledge, this is the first biomechanical study that has evaluated a PCL knee brace that allows the application of an anteriorly directed force to the calf.

Limitations of the study include the small number of specimens used, as well as the use of paired specimens (left and right) as independent samples in the statistical analysis. This might influence the statistical results, as paired specimens treated as independent samples in the statistical analysis might reduce the variation in the generated data, due to potentially similar behavior. Using only right-sided specimens in the statistical analysis reduced the overall number of specimens to four, with a similar mean effect of the brace in PTT reduction in absolute values, while the effect of the brace was no longer significant. Including paired specimens might therefore tend to bias the statistical results towards a type I error. For this type of investigation, it is recommended that left- and right-sided specimens should not be used, in order to rule out type I statistical errors. The data were based on specimens from elderly female donors, and the findings can only be extrapolated with caution to young patients with PCL injuries. There are also certain differences between the present in vitro setting and the clinical implementation of the brace. The effects of muscle tension and weight bearing in vivo by patients were not investigated in the present in vitro experiment. The brace was fitted in a standardized way in accordance with the manufacturer's recommendations. Repeated placement and removal of the brace by patients themselves might lead to variations in the anteriorly directed force. A further limitation of the study is that only complete PCL rupture was investigated. Statements on the effectiveness of the dynamic brace for conservative treatment of partial PCL ruptures are therefore only speculative. The effectiveness of this novel dynamic knee brace needs to be investigated in further clinical studies.

5. Conclusions

The novel dynamic knee brace presented here, with an anteriorly directed force applied to the calf, can reduce PTT after PCL rupture. After the brace was applied to the PCL-reconstructed knee, PTT was restored completely in comparison with the native state. This type of PCL brace can therefore be used after PCL reconstruction to overcome the drawback of initial knee immobilization and allow an earlier return to work. However, the in vitro laboratory results presented here need to be confirmed in a clinical investigation evaluating the effectiveness of the brace.

Conflicts of interest

The laboratory costs of this study were supported by medi GmbH; the surgical equipment for PCL dissection and arthroscopic reconstruction was provided by Arthrex Inc. free of charge. The sponsors were not involved in the design, execution, or data evaluation of the experiments, nor in the preparation of the manuscript.

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