South African Orthopaedic Journal
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An intra-operative device for parallel drilling and femoral landmark estimation during medial patellofemoral ligament reconstructive surgery

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Abstract

Background: The aim of this study was to design and test a device to guide medial patellofemoral reconstruction surgeries.

Materials and methods: A three-dimensional (3D) printed, modular and cost-effective medial patellofemoral ligament (MPFL) reconstruction guide, Pat-Rig, was designed with parallel holes running in the medio-lateral direction. This device was manufactured using a commercial additive manufacturing facility, and bench tested using a custom-built test rig. CT scans of patella bones were reconstructed, and the device was tested on four 3D-printed patellas of various sizes.

Results: The device was successful in guiding the surgical drill into the patella to drill parallel holes adhering to the current surgical requirements and specifications. The device was augmented with an innovative radiopaque scale which can allow the surgeon to accurately predict the landmarks to drill and measure the drill depth of the tunnels.

Conclusion: There are no devices on the market that accurately predict the drill locations on the patella during MPFL reconstruction surgeries. The device, Pat-Rig, was found to overcome the current limitations of the MPFL surgeries and was able to provide satisfactory surgical guidance during the reconstruction.

Level of evidence: Level 5

Keywords: knee surgery, patella, orthopaedic, MPFL reconstruction, 3D-printed, novel surgical device

Citation: Dey R, Patnaik S, Nair G, Steiner S, Sivarasu S. An intra-operative device for parallel drilling and femoral landmark estimation during medial patellofemoral ligament reconstructive surgery *SA Orthop J* 2020;**19**(4):212-217. http://dx.doi.org/10.17159/2309-8309/2020/v19n4a3

Editor: Dr Michael Held, University of Cape Town, South Africa

Received: May 2019 *Accepted*: February 2020 *Published*: November 2020

Funding: This study was funded by the National Research Foundation (NRF) – NRF grant no: CSUR13082630873. The funding sources had no influence on the reported study and the decision to submit the study for publication.

Conflict of interest: The authors declare they have no conflicts of interest that are directly or indirectly related to the research.

Introduction

The current global trend towards becoming fit and healthy has led to an increase in the number of soft tissue injuries of the lower limbs due to the additional stress of the related activities. The medial patellofemoral ligament (MPFL) attaches the medial aspect of the patella to the medial epicondyle of the femur.[1,2] Patella dislocation is a common knee joint pathology. Apart from active individuals, people having soft tissue defects since birth also suffer from patellar dislocations.[3] As the MPFL plays a very important part in keeping the patella in its place, microscopic tears have been observed in the ligament, post-acute patellar dislocations.[3,4] While the incidence rate of primary dislocation is relatively low (6 to 80 per 100 000 individuals), one in every two of these patients suffers from re-dislocation of patella and lives with their knee pain until they have their knee re-operated. Repetitive patellar dislocations cause microscopic tears in the MPFL which results in complete MPFL rupture in 94% of patients.[3-7]

Over 130 techniques exist to treat patella-femoral instability and none of these completely alleviates the post-surgical pain and trauma.[8] MPFL reconstruction surgeries replace the anatomic ligament with a 0.18–0.2 m long ligament graft.[9] There are two major surgical procedures that are performed to reinstate the MPFL in its anatomic position:

a. the single-bundle procedure,[10] and
b. the double-bundle procedure.[10,11]

The double-bundle surgical procedure (*Figure 1*) requires two holes to be drilled on the medial aspect of the patella with the knee in 30° of flexion. These holes house the patellar end of the graft and also allow the graft to have a converging fan-shaped structure, which closely mimics the original structure of the MPFL.[12] The single-bundle technique requires drilling of one hole into the patella. Studies have demonstrated that there is no significant difference in the forces acting on the patella, post a single-bundle or a double-bundle MPFL reconstruction surgery.[10] For both the procedures, the graft is inserted into the lateral femoral condyle through a single hole.[13-15] With the exact point of insertion into the femur under debate, studies have shown that current MPFL reconstruction surgeries have a radial error of 0.004 m.[16]

There are no existing methods for locating the anatomic insertion points of the MPFL graft into the medial patella. The current best practice involves taking intra-operative X-rays, from which the surgeon makes an estimate of the location for the drills. Moreover, there are no means to ensure that the drilled holes are parallel to each other. Non-parallel drills might exert unequal forces on the bone bridge between the drills, which can lead to fracture of the patella.[17,18]

Pat-Rig[8,19-20] is a drill-guiding medical device, designed by the authors, which can assist the surgeon in accurately locating the graft insertion locations on the patella and guide the surgeon when drilling parallel holes into the bone. The device is designed for single use and is made from a three-dimensional (3D) printed component. It can be made available to the surgeon within a few hours, in case of emergency. The additive manufacturing technique also makes the device low cost compared to the available surgical guides on the market.[20] This is a bench study describing the design and development of a low-cost MPFL reconstruction guiding device, not previously described.

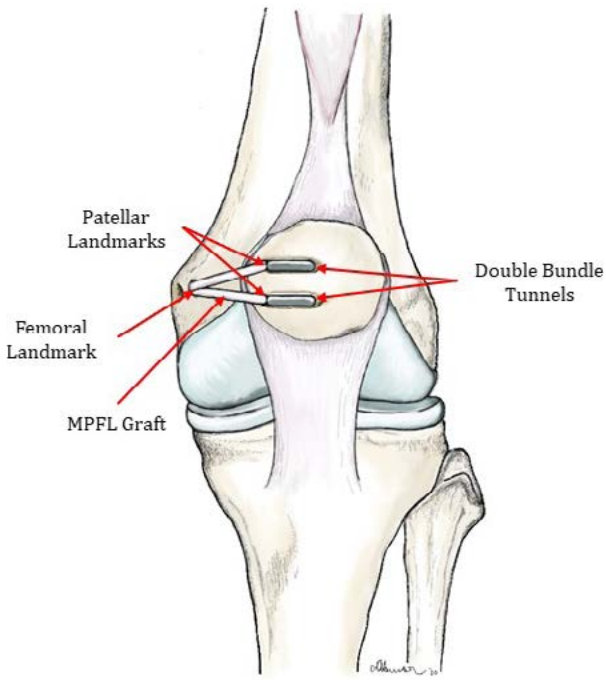

Figure 1. Schematic representation of the double-bundle MPFL reconstruction technique. Currently, there are no reliable guidance devices available for the orthopaedic surgeon, which increases the graft insertion landmarking error on the patella and the femur.

Materials and methods

Design considerations for the patellar landmarks

A pre-design study was conducted, which helped the authors to understand the clinician's requirement for the MPFL reconstruction surgery. The study revealed that the location for the first drill point must, on average, be 0.01 m from the superior surface of the patella. Furthermore, it was also realised that the second parallel drill should be at a distance of 0.01–0.015 m from the first drill point.

The initial prototype (*Figure 2*) included fixed drill holes on the medial and the lateral sides of the device, with the goal of providing the surgeon with a single device which can be used for both the left and the right knee. With the aim to accommodate patellas of different shapes and sizes, it was realised that the drill-guide system should be movable. To achieve that goal, a separate drill-guide housing was designed having two parallel 0.0045 m drill guides cut into it, at a distance of 0.015 m from each other. The design of the

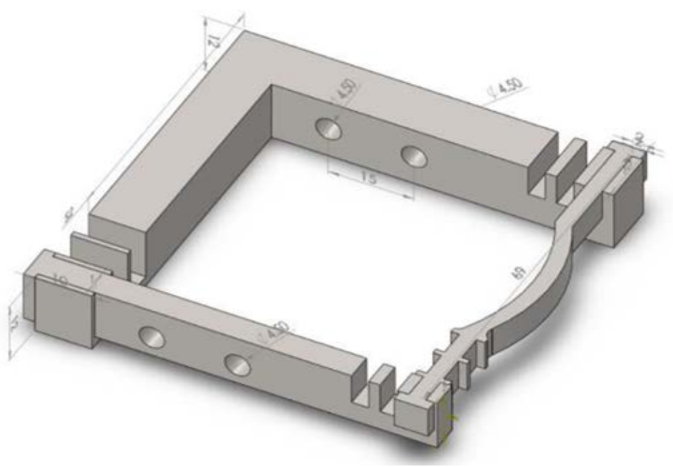

Figure 2. Initial iteration of the Pat-Rig. The parallel holes are to guide the surgeon to drill parallel holes on the medial aspect of the patellar bone. The design was created to accommodate different sizes of patella.
(source: Sivarasu S, Patnaik S. Accessory for conducting patella surgery [Pat-Rig]. British Patent Application No GB1511597.5, 2015)

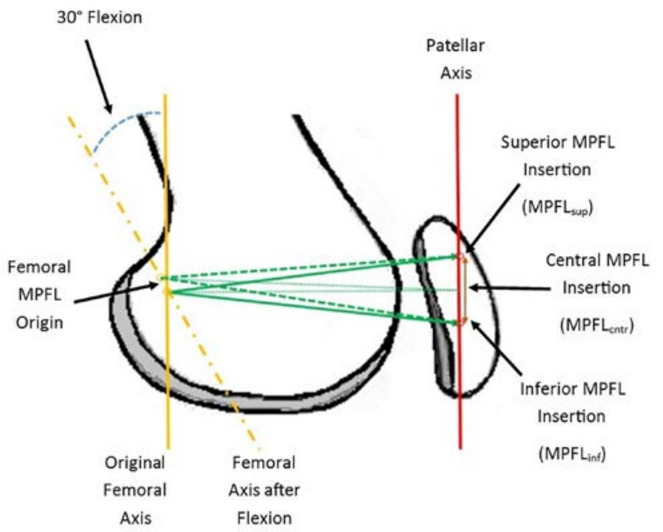

Figure 3. Schematic representation of the positional change of the medial patellofemoral ligament from 0° to 30° of knee flexion. This position is an important design parameter for the femoral landmark prediction device as the MPFL reconstruction surgery requires the knee to be flexed at that angle.

(source: Dey R, Patnaik S, Sivarasu S. Novel device to accurately locate femoral insertion landmark in medial patellofemoral ligament (MPFL) reconstruction. *Proceedings of the 2017 Design of Medical Devices Conference*. 2017 Design of Medical Devices Conference. Minneapolis, Minnesota, USA. April 10–13, 2017. V001T11A019. ASME. https://doi.org/10.1115/DMD2017-3500)

device was further altered to make it right or left knee specific. The final prototype was designed around a 3D reconstructed model of a 0.046 m × 0.049 m male patella, which is bigger than the average size of the bone.[21] This enabled a new design for the device which could accommodate every size of patella.

Design considerations for the femoral landmarks

The MPFL is a fan-shaped soft tissue attaching the medial patella to the medial femur.[1,7,22] If the superior and inferior edges of the soft tissue are considered, then at 30° of knee flexion the superior landmark of the MPFL ($MPFL_{sup}$) has an average length of 0.0575 m, and the average length of the inferior landmark of the MPFL ($MPFL_{inf}$) measures to 0.0555 m.[23] Past studies have shown that the length of the central aspect of the MPFL changes negligibly, when compared to the changes in $MPFL_{sup}$ and $MPFL_{inf}$, during the flexion of the knee from 0° to 30°.[23] To design the device, therefore, trigonometric principles were applied to establish the angle of attachment between the fan-shaped ligament and the patella at the superior and inferior edges (*Figure 3*).

The average length of the central landmark of the MPFL ($MPFL_{cntr}$) is 0.055 m during the first 30° of knee flexion.[23] Neglecting the angular change in length of the central aspect of the ligament, using the formulae shown below, it can be established that the angle suspension of the inferior edge of the MPFL is 8° and the superior edge is 17° when the femur is flexed at 30°.

$$\text{Inferior attachment angle} = \cos^{-1}(MPFL_{inf}/MPFL_{cntr}) \quad (1)$$

$$\text{Superior attachment angle} = \cos^{-1}(MPFL_{sup}/MPFL_{cntr}) \quad (2)$$

The other design aspect of this device was the converging angle of the fan on the femur. To calculate the angle subtended by the superior and inferior borders of the MPFL, the law of cosines was applied, and the angle was established to be 15.1°. The equation applied for this calculation is as follows:

$$\text{Convergence angle} = \cos^{-1}(15^2 - MPFL_{inf} - MPFL_{sup}/2*MPFL_{inf}*MPFL_{sup}) \quad (3)$$

The design was made in such a way that it fits into the drill-guide housing of the Pat-Rig. This fits well with the surgical practice of the double-bundle procedure as the drill-guide housing will not be in use during the second part of the surgery where the surgeon drills the tunnel into the femoral landmark.

Design considerations for the radiopaque scale

To provide the surgeon with an option to view the depth of the drill and the distance of the drill landmarks on the patella, a radiopaque scale was designed. The material of choice was transparent, and the scale had markings every 0.025 m for the surgeon's reference.

Design of the test rig

To test the functionality of Pat-Rig, a test rig was designed to hold the 3D-printed patella and the drill-guiding device in place. The test rig was developed to function as a substitute for the quadriceps tendon, which is generally intact and holds the patella in place during the MPFL reconstruction surgery. The test rig was designed around the dimensions of the Pat-Rig, except for the height. The rig enabled the authors to drill holes into the patella through the drill-guiding device and thereby assess the functionality of the Pat-Rig.

The device was also tested in silico on a 3D-reconstructed model of the patella using SolidWorks (Dassault Systemes, Velizy, France). The test involved drilling parallel holes into the medial aspect of the

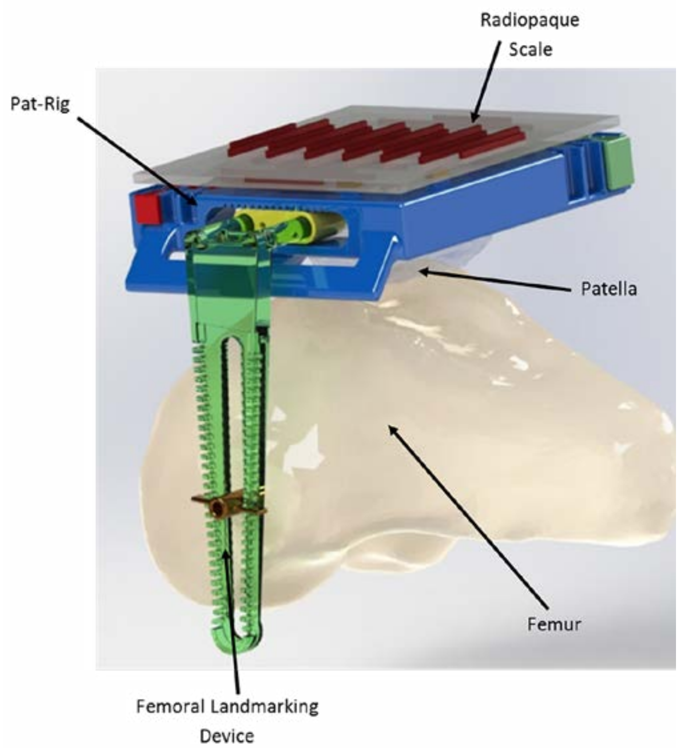

Figure 4. Schematic representation of the final design of the Pat-Rig overlaid on the 3D-reconstructed patella and the femur. The radiopaque scale and the Pat-Rig were overlaid on the entire set-up. In silico tests were performed on this set-up and the graft insertion landmarks were accurately marked.

(source: Dey R, Patnaik S, Sivarasu S. Novel device to accurately locate femoral insertion landmark in medial patellofemoral ligament (MPFL) reconstruction. *Proceedings of the 2017 Design of Medical Devices Conference.* 2017 Design of Medical Devices Conference. Minneapolis, Minnesota, USA. April 10–13, 2017. V001T11A019. ASME. https://doi.org/10.1115/DMD2017-3500)

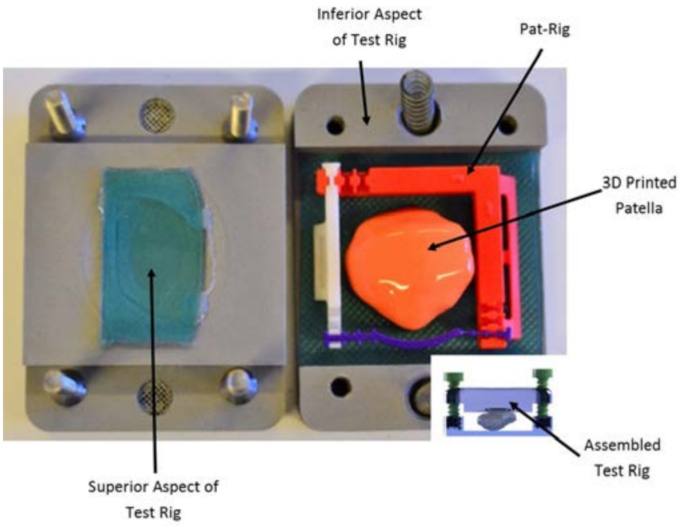

Figure 5. Schematic representation of the 3D-manufactured test rig for the Pat-Rig. The device and the 3D-printed patella were stuck together in place using silicone double-sided adhesive. A mechanical drill was used to drill into the patella through the device.

patella. Along with the drilling of parallel holes into the patella, the clearance distance, i.e. the distance between the outer edges of the patella and the inner edges of the device, was measured.

Results

Pat-Rig: The novel drill-guide device

The designed device (*Figure 4*) was modular and had four detachable parts. The medial and the superior components were fused together. The medial component had an ellipsoid gap, 0.036 m long, to house the drill-guide component. The gap had teeth on the top to hold the drill guide in place during the drilling process.

The device was designed such that the minimum distance between the superior component and the first drill-guide hole was 0.01 m. The distance between the two drill-guiding holes were kept constant at 0.015 m. The inferior component was made to curve outwards to accommodate the convex inferior apex of the patellar bone. If the surgeon chooses the option of inserting a guidewire into the patella, an optional 0.0025 m plug-in drill-guide hole was designed. This guide hole can be inserted into the existing 0.0045 m drill hole using the fan-blade shaped protrusion.

To make the device modular, slots were created into the lateral, medial and superior components. The slots enabled the dimensions of the device to be altered from 0.54–0.48 m in the superior-inferior axis and 0.54–0.43 m in the anterior-posterior axis.

To fasten the device to the patient's knee, loop-and-hook fasteners (Velcro®), were used. To attach the fasteners to the Pat-Rig, two protruding appendages were designed on the medial and lateral sides.

A radiopaque scale was designed to mount onto the Pat-Rig. Two upward-facing protrusions on the Pat-Rig were used to mount the scale on the top of the device. The purpose of the scale was to assist the surgeons with accurately locating the initial points for drilling onto the patella. The scale could also be used to measure the depth of the drill into the patella.

It would be possible to sterilise the whole device by using a gas sterilisation process; however, the device was designed to be disposable in order to reduce the risks of inter-patient infection.

The test rig for testing the novel device

The designed test rig (*Figure 5*) was divided into superior and inferior segments. The superior segments of the rig could be collapsed onto the inferior one with the help of long screws. A spring was introduced in between the compartments to make the collapsing mechanism easy. This enabled the test rig to accommodate patellas of different heights. Normally, the anterior aspect of a patella has a convex shape; keeping that in mind, an elliptical groove was cut into the floor of the superior component. The respective roof and floor of the inferior and superior compartments were layered with a

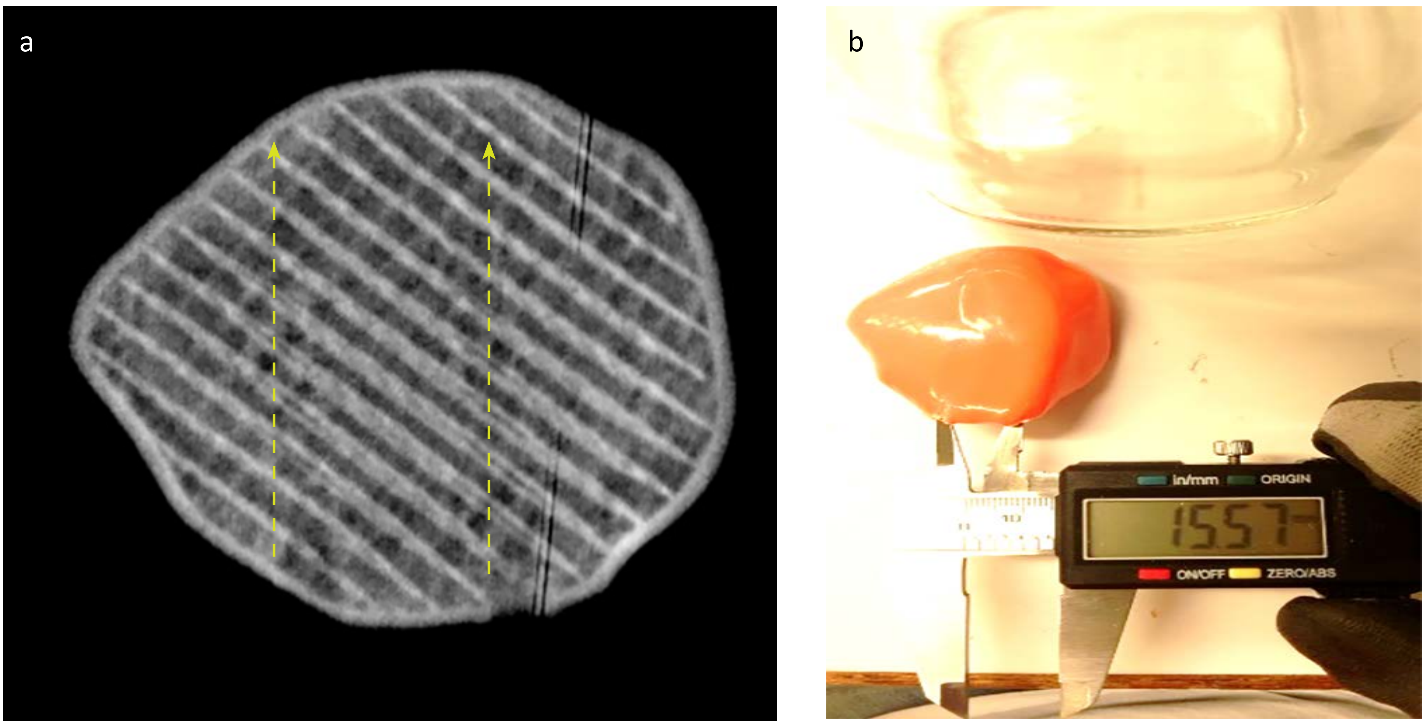

Figure 6. (a) X-ray images showing the parallel holes drilled into the 3D-printed patella during bench testing using the test rig. (b) The parallel holes were observed to lie at surgically acceptable distances from each other.

silicon anti-slip pad. These design features kept the Pat-Rig and the patella in their respective positions.

The drills were made into the medial aspect of four 3D-printed patellas, using the Pat-Rig. The drilled holes were found to be in a straight line and parallel to each other (*Figure 6a*) and about 0.015 m apart (*Figure 6b*). The test rig was able to withstand the drilling force and keep the components of the drill-guiding device and the patella fixed in their respective places.

The in silico tests provided the proof of concept for the device. The holes drilled on the medial aspect of the patella were straight and parallel to each other. The average measured clearance distances were 0.00132 m. This suggested that the device will be able to accommodate the soft tissues around the knee joint space.

Discussion

The Pat-Rig was designed, manufactured and tested at the University of Cape Town. Traditional MPFL reconstruction surgical guide tools cost thousands of dollars, whereas the Pat-Rig can be manufactured for the equivalent of less than $20. This significant decrease in the cost of the device gives it the edge over the available devices on the market. As the results show, the device decreases the chances of misaligning the parallel holes and assists the surgeon to accurately predict the two points of drill during the double-bundle MPFL reconstruction surgery.

MPFL is one of the major ligaments that holds the patella in place, articulating the femur. A weak or torn MPFL can give rise to pain in the knee and/or can make the patella 'wobble' in the available joint space. The Pat-Rig enables the surgeon to accurately fix the MPFL into its anatomical orientation and restore patella-femoral biomechanics and range of motion.

After the successful in silico and bench tests of the Pat-Rig, the device will be tested in a real surgical setting on cadavers. Following the cadaver trials, a clinical trial with the device will be conducted. To make the device a complete stand-alone device for the MPFL reconstruction surgery, a scale will also be developed, which would help the surgeons to accurately locate the femoral landmark for the MPFL graft insertion.

This study was limited to developing a low-cost device to improve transosseus patellar fixations. This would possibly reduce post-surgical complication rates for the MPFL double-bundle procedure. Future research is needed to validate this device's ability to accurately predict the femoral and the patellar insertion points using cadaver tests and further adapt the design of Pat-Rig for different variations of the MPFL reconstruction surgery.

Conclusion

The current study describes the design and development of a 3D-printed surgical guide. This device, Pat-Rig, addresses one of the current limitations of the MPFL reconstruction surgery. Locating graft insertion points on the patella and the femur was found to be more intuitive and efficient with Pat-Rig. Due to its significantly low cost of production, this device fits into the surgical set-up of any developing country, such as South Africa.

Acknowledgements

The authors would like to acknowledge Dr Tinashe Mutsvangwa, Charles Harris and Ms Leanne Haworth for their assistance. The authors would also like to thank the National Research Foundation (NRF) for funding this study. NRF grant no: CSUR13082630873.

Ethics statement

This submission is in accordance with the principles laid down by the Responsible Research Publication Position Statements as developed at the 2nd World Conference on Research Integrity in Singapore, 2010. Prior to commencement of the study ethical approval was obtained from the following ethical review board: Human Research Ethics Committee, HREC ref: 707/2016. This article does not contain any studies with human participants or animals performed by any of the authors.

Declaration

The authors declare authorship of this article and that they have followed sound scientific research practice. This research is original and does not transgress plagiarism policies.

Author contributions

RD: Study conceptualisation, data capture, data analysis, first draft preparation and manuscript revision.
SP: Co-inventor of the device, manuscript preparation and revision.
GN: Study design, design of testing set-up and manuscript preparation.
SSt: Manuscript preparation and manuscript revision.
SSiv: Co-inventor of the device, study supervisor, manuscript preparation and manuscript revision.

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