**Title:**

Proof-of-concept prototype drill-guide for use in medial patello-femoral ligament (MPFL) reconstruction surgery

**Key words:** MPFL, Knee, MPFL reconstruction, patella dislocation

**Authorship:**

**van Duren BH**, BEng MBCHB DPhil CEng MIMechE MRCS
Academic Clinical Lecturer (Trauma & Orthopaedics)
Leeds Institute of Rheumatic & Musculoskeletal Medicine
University of Leeds

**Lebe M,** MRCS
Senior House Officer
Royal National Orthopaedic Hospital
Stanmore

**Davies DC**
Professor of Anatomy
Department of Surgery and Cancer
Imperial College London

**Pandit H FRCS** (Trauma and Orth), DPhil (Oxon)
Professor of Elective Orthopaedics
Leeds Institute of Rheumatic & Musculoskeletal Medicine
University of Leeds

**Somashekar N**, FRCS
Consultant Orthopaedic Surgeon
Hillingdon Hospitals Trust
Uxbridge

**Abstract:**

Surgical reconstruction of the medial patello-femoral ligament (MPFL) has become increasingly popular over the last few years for managing patella instability and/or dislocation. A variety of techniques are used for fixation of the graft to the medial border of the patella. The bone bridge or V-shaped tunnel technique utilises two tunnels drilled from the medial aspect of the patella that converge centrally creating a tunnel through which the graft is threaded. This technique has advantages: it avoids hardware (bone anchors) and their associated complications, creates a broad attachment of the ligament approximating normal anatomy and the tunnel does not breach the lateral cortex of the patella theoretically reducing the risk of patella fracture.

In current practice the bony tunnels are created using techniques requiring freehand targeting and alignment of the two tunnels, which has potential disadvantages. This technique relies on estimation of the patella centre by the surgeon and is subject to wide variation. Additionally this technique can be inefficient, inaccurate and time consuming. To address these disadvantages a new drill-guide device was developed. This paper describes the design and testing of a drill-guide device that enables accurate, reproducible, and efficient construction of the v-shaped bone tunnel.

A prototype drill-guide was constructed using CAD and 3D printing methods. The device has asymmetric arms with one side designed to grip the lateral aspect of the patella and the other to guide the two drill trajectories to meet in the middle of the patella. The drill guide sleeves are chamfered to a sharp edge to improve grip on the patella preventing the jig from moving when drilling the tunnel. The contact surface of the lateral jaw is designed with both a coronal and transverse curvature to prevent the lateral aspect of the patella from moving during drilling. The drill-guide has guide holes for Kirschner-wire placement (2 medial and 1 lateral), to allow the surgeon to secure the drill-guide in cases where it is difficult to maintain a secure grip on the patella.

To assess the efficacy of the prototype drill guide, an experiment designed to assess a group of ten surgeons with an average of 4.2 years experience performing the task of creating a v-shaped bone tunnel using a free-hand technique and the drill-guide. To determine the accuracy of the tunnel placement, the angle between drill holes, distance from centre of the patella and the amount of over-drill were measured. Procedure duration was also compared.

The results revealed that the prototype drill-guide created a much more accurate bone bridge than the traditional free hand method. The root mean square error for the distance from centre was 0.50mm vs 2.12mm and the angle between tunnels was $2.6^{O}$ vs $15.9^{O}$ for the prototype and traditional methods respectively. There was a mean of 8.9mm over-drill with the traditional method, which was negated when using the guide. Surgeons using the guide were approximately 25%

faster than using the traditional free-hand technique.

Therefore, the use of the prototype drill-guide improved the accuracy with which the patella bone bridge was constructed, reduced the variability in the resulting construction and reduced procedure duration compared to the traditional free-hand technique.

**Introduction:**

Patella instability and lateral dislocation is a common pathology with a reported incidence of 5.8 cases per 100,000(1). Studies have shown that the medial patello-femoral ligament (MPFL) is always injured after lateral patella dislocation (2–4) and there is a recurrence rate of 44% after non-operative management of an acute injury (5). The highest risk of lateral patella dislocation occurs between 30 degrees of knee flexion and full extension, when the patella is least constrained in the trochlea (1). The MPFL acts as a patella stabiliser between 30 degrees of knee flexion and full extension and accounts for 50-60% soft tissue forces controlling patella lateralisation (4).

Surgical reconstruction of the MPFL has become increasingly popular over the last few years (6) and has shown good results in clinical studies (7–10). A large variety of techniques for the reconstruction of the MPFL are currently being used in clinical practice (6). A number of ways of fixing a graft to the medial border of the patella have been reported: fixation using interference screws, use of bone anchors, trans-patella tunnels, trans-osseous Ethibond sutures, and fixation using a medial bone bridge (6). There are advantages and disadvantages to all the techniques listed above. The use of screws and anchors can cause pain and irritation at the site of insertion. Shah et al. reported that 1.1% of MPFL revisions can be attributed to symptoms related to symptomatic hardware (11). They also found that the risk of recurrent dislocation/subluxation and apprehension/hyper-mobility was greater with techniques employing sutures and anchors, compared to bone tunnel methods (11). However, methods using patella bone tunnels increase the risk of patella fracture (6,11–15).

The bone bridge or v-shaped tunnel technique utilises two tunnels drilled from the medial aspect of the patella to converge in the middle of the patella to create a tunnel through which the graft is threaded (15). This technique has advantages in that it avoids the use of hardware and associated complications, allows for a broader attachment of the ligament more closely replicating normal anatomy and the tunnel does not breach the lateral cortex of the patella, theoretically reducing the risk of patella fracture associated with trans-patella bone tunnels (15). However, there is potential risk of tunnel “blowout” in the event of bone bridge failure (6, 15). The risk of tunnel “blowout” can be minimised by ensuring that the bone bridge is of adequate size; Ahmad et al. suggested that a bone bridge of at least 10mm between tunnel openings should be maintained (15).

In current practice, a V-shaped tunnel in the patella is created by inserting two K-wires that meet in the centre of the patella. This is performed free-hand before subsequently creating the tunnels using a 5mm cannulated drill. Placing the K-wires free-hand has a number of potential disadvantages. Ahmad et al. described the technique of inserting the k-wires, in particular the second K-wire as follows: “*aiming to meet the first K-wire in the middle of the patella. When the second K-wire meets the first K-wire inside the patella, the first K-wire is seen to vibrate, confirming* *that the ends of the 2 wires are in contact*” (15). It may require several attempts to achieve the desired position, thereby creating multiple channels within the patella, risking compromising the integrity of the tunnel. This technique relies solely on estimation of the location of the centre of the patella (the described confluence of the tunnels) and is subject to a wide variation. Additionally, this technique requires a number of manoeuvres that can be inefficient and are time consuming. The end-result can be inaccurate tunnel placement with a potential impact on the final success (or failure) of the MPFL reconstruction.

In order to overcome the problems associated with the free-hand construction of a bone tunnel for MPFL reconstruction, we have developed a drill-guide device that allows accurate and reproducible construction of the v-shaped bone tunnel, while dispensing with the use of K-wires and cannulated drill. The design considerations and methodology are described and a proof-of-concept prototype and the results of early pre-clinical tests of the device are presented.

**Methods:**

Design:

The aim was to design a drill guide that will improve the accuracy and efficiency of creating the V-shaped bone tunnel used in MPFL reconstruction. The drill guide was designed to meet the following criteria:

1. Create a bone tunnel to the specifications described in the literature (15): A minimum bone bridge distance of 10mm between tunnel holes, approximate tunnel angles of 40 degrees from the midline, and confluence of the two drill holes in the middle of the patella.

2. Ease of use: the device should offer a distinct advantage over the current technique using k-wires and cannulated drill. Ease of execution, the number of handling actions required, and the time to complete the task were considered.

To meet the criteria above the drill-guide design was based on a two arm grasping principle (see *Figure 1*). The device has asymmetric arms with one side designed to grip the lateral aspect of the patella and the other to guide the two drill trajectories to meet in the middle of the patella. The medial (drill-guide) arm has two drill guides placed at 80 degrees to each other and orientated to meet at a pre-specified radius (see sizing considerations described below) from the entry point. The tips of the drill guide sleeves are chamfered to lead to a sharp edge to improve grip on the patella preventing the drill-guide from moving when drilling the tunnel. The lateral jaw is attached to the lateral arm using a ball and socket joint to allow for a degree of conformity to achieve a good fit to the lateral aspect of the patella. Additionally, the contact surface has both a coronal and transverse curvature to prevent the lateral aspect of the patella from moving during drilling.

The design incorporates a locking mechanism to maintain grip on the patella, facilitating a single person drilling technique. In addition to the locking mechanism, guide holes for K-wire placement (two on the medial arm and one through mid-point of lateral jaw) are present, to allow the surgeon to secure the drill-guide with 2mm K-wires in cases where it is difficult to maintain a secure grip on the patella. The device is designed to be used with a collared or graduated drill to prevent unnecessary over drilling. The prototype device was drafted using computer aided design (CAD) software (FreeCAD; www.FreeCAD.org).

A drill-guide device must accommodate inter-patient variation in patella size. The device sizing options were based on the results of studies of the patella morphology (16–18), using the mean medial-lateral and superior-inferior dimensions of the patella (with associated ranges) reported in the literature. Based on a fitted circle of diameter corresponding to the mean patella sizes described in the literature, it was determined that three sizes, small, medium and large corresponding to 35mm, 45mm, and 55mm respectively, would accommodate the expected variation in patella size.

Device Testing:

A prototype drill-guide device (*Figure 2*) was produced using a 3D printer (XYZprinting Da Vinci Junior 3D) and used to carry out a functional assessment of the device. Due to the limited size of print space of the 3D printer, only a prototype of the small (35mm) size was produced.

To assess the effect of the drill-guide on accuracy and procedure duration, an experiment was designed to compare the performance of ten trainee surgeons (with an average of 4.2 years; range: 2-12 years of experience) creating a V-shaped bone tunnel using 1) the method described by Ahmad et al.(15) using K-wires and a cannulated drill and 2) the prototype drill-guide. The surgeons were divided into two groups (5 in each): *group A* were asked to perform the task using the traditional method first and the drill-guide second, *group B* performed the task using the drill-guide first, followed by the traditional method.

The experimental set-up is shown in *Figure 3*. A model patella was mounted on a platform simulating a femur and tibia at 30 degrees of knee flexion. The patella was constructed from a 3D printed outer shell filled with a polyurethane foam (Polycraft LD40 Expanding Polyurethane Foam), to simulate cortical and cancellous bone composition respectively. The patella was attached to the platform using 15mm elasticated material under tension. The surgeon was then asked to create a v-shaped tunnel based on the description by Ahmad et al. (15). The surgeons were given the scientific paper with the relevant description highlighted to read' to ensure that they understood the ideal v-tunnel shape required. The surgeons were also given a brief description of the prototype drill guide and its features. The time taken to complete each task was recorded.

In order to perform the required measurements, the patellae were divided in the coronal plane. To determine the accuracy of the tunnel placement the angle between drill holes, the distance from the centre of the patella, and the length of over-drill were measured from digital images of the divided patellae (*Figure 4*). The images were processed using (Open Source Computer Vision Library & Python 2.7.10). The digital images were loaded and a circle was fitted to the outer diameter of the patella. Each image was calibrated using the patella diameter. The two drill trajectories were then templated for both direction and length and the over-drill distance, distance of confluence from centre of patella, and tunnel angles were calculated.

In addition to the simulation tests the prototype drill-guide was also tested on two cadaveric patellae. The cadavers were donated and the cadaveric study performed at the Human Anatomy Unit, Imperial College London, in compliance with the provisions of the UK Human Tissue Act (2004). The medial border of the patella was exposed using a longitudinal skin incision. The drill guide was then positioned and fixed in place whilst the tunnels were drilled. The patellae were then divided in the coronal plane in the same way as the model patellae in the simulation tests, to allow examination of the constructed bone bridge.

**Results:**

In the simulation tests, the prototype drill-guide created a more accurate bone bridge than the traditional free hand method. The root mean square error for the distance from the centre of the patella was 2.12mm using the traditional method compared to 0.50mm using the drill-guide. The root mean square error for the angle between tunnels was $15.9^{O}$ (range: $5.2^{O}$ – $28.0^{O}$) and $2.6^{O}$ (range: $1.3^{O}$ – $5.6^{O}$) for the traditional method and guide respectively. There was a mean of 8.9mm over-drill with the traditional method, compared to no over-drill using the guide in conjunction with a collared drill. Use of the drill-guide resulted in an approximately 25% faster completion of the procedure (44 seconds vs. 61 seconds) than the traditional method.

The prototype device exhibited good grip and facilitated accurate drilling of both cadaveric patellae. A clean and accurate bone tunnel was made with the use of the drill-guide resulting in a good bone bridge (*Figure 5*).

**Discussion:**

The results of the current study have demonstrated as a proof-of-concept the use of a drill-guide designed for the construction of a v-shaped tunnel during MPFL surgery with the bone bridge method resulted in improved accuracy and reproducibility while reducing the procedure duration, compare to a traditional free-hand method.

The proposed drill-guide offers a number of advantages over the currently used technique. Its use can significantly increase the accuracy with which the v-shaped tunnel is drilled. The use of a guide will also limit variability in the tunnel shape and particularly prevent the formation of an inadequate bone bridge (15). A bone bridge can only can only resist a limited amount of force before failing (6), therefore it is of the utmost importance that the tunnel is drilled in such a way as to maximise the strength of the bone bridge. Avoiding over-drill by using a collared drill also minimises the amount of bone loss and therefore, minimise weakening effect of drilling the patella.

The duration of the procedure to create the v-shaped bone tunnel using the prototype device was approximately 25% less than that using the traditional method, because of the requirement for less estimation, fewer surgical steps and fewer tool changes.

The use of the drill-guide device described in the current study has a few potential weaknesses. In some cases it may not be possible to maximise the size of the bone bridge. This could be addressed by making the device fully adjustable,but this would make it complicated, which would be detrimental to time efficiency and could possibly introduce errors and undersizing. The use of circular patella models rather than anatomically shaped sawbone patellae in the simulation tests may not have accurately reflected the surgical situation, but the use of the prototype drill-guide on cadaveric patellae suggests that this was not the case. Moreover, the use of patella models highlighted the difficulty of creating an accurate bone tunnel 'freehand' in a symmetrical circular patella, which should presumably be less challenging than in an asymmetrical patella of a patient.

The prototype drill-guide used in the current study was manufactured using a 3D printer as a proof of concept. With commercial production in mind, a similar device could be manufactured from stainless steel to safely undergo sterilisation, as is the case with other surgical instruments. In this instance a range of sizes would be need to be provided for the surgeon (e.g. small, medium, large) in order to make the most suitable tunnel. Alternatively, it may be an option to produce the drill guide as a single use device that is patient specific. Three dimensional printing would allow the use of patient specific imaging to plan bone tunnels and customise the drill-guide for the individual patient. Whether such customisation would be of benefit has not been explored in this study. Single use devices have become increasingly popular, because they may be more cost effective than having to sterilise conventional instrument trays with the associated logistics. The choice of commercialisation strategy for the drill guide will be dependant on cost analysis and surgeon requirements with regards to the possibilities discussed above.

**Conclusions:**

In summary we have shown that the use of a well-designed drill-guide to produce the v-shaped bone tunnel required in MPFL reconstruction surgery using the “bone block” technique can reliably produce an accurately constructed tunnel with minimal bone loss and in a shorter time than a traditional ‘freehand’ technique.

**Figures:**

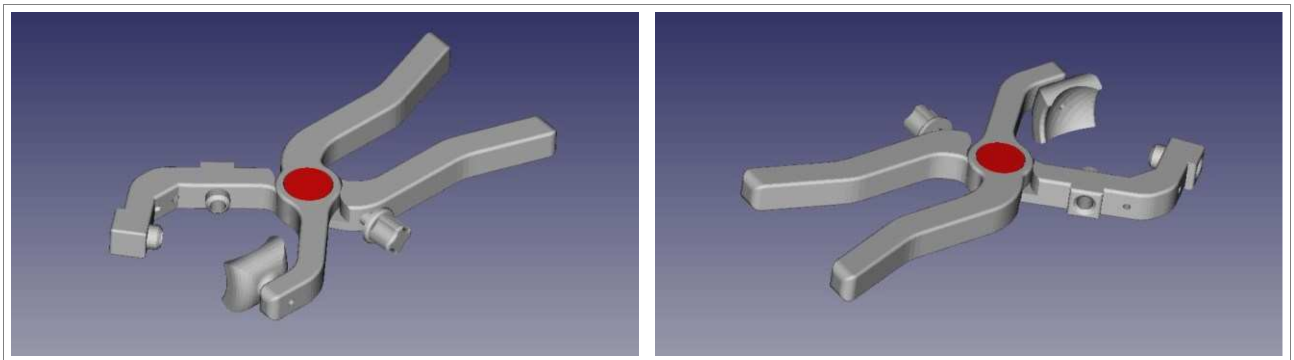

***Figure 1:*** *Three dimensional CAD (FeeCAD version 0.16, www.freecad.org) representation of the prototype drill guide. The design features described are illustrated. Two 5mm drill guide-sleeves at 80 degrees on the medial arm, dual curvature lateral jaw, three k-wire guide-holes (2 on the medial arm and 1 on the lateral through axis of lateral jaw), and a locking mechanism (tightening this clamps the pivot axis by means of friction).*

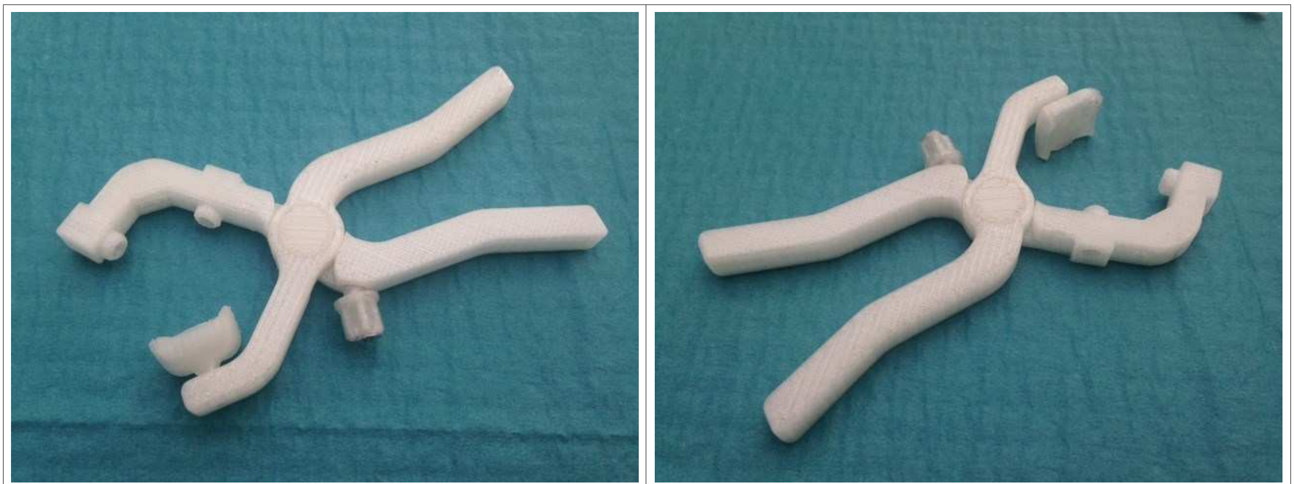

***Figure 2:*** *Images showing the prototype drill-guide manufactured using a 3-dimensional printer (XYZprinting Da Vinci Junior 3D).*

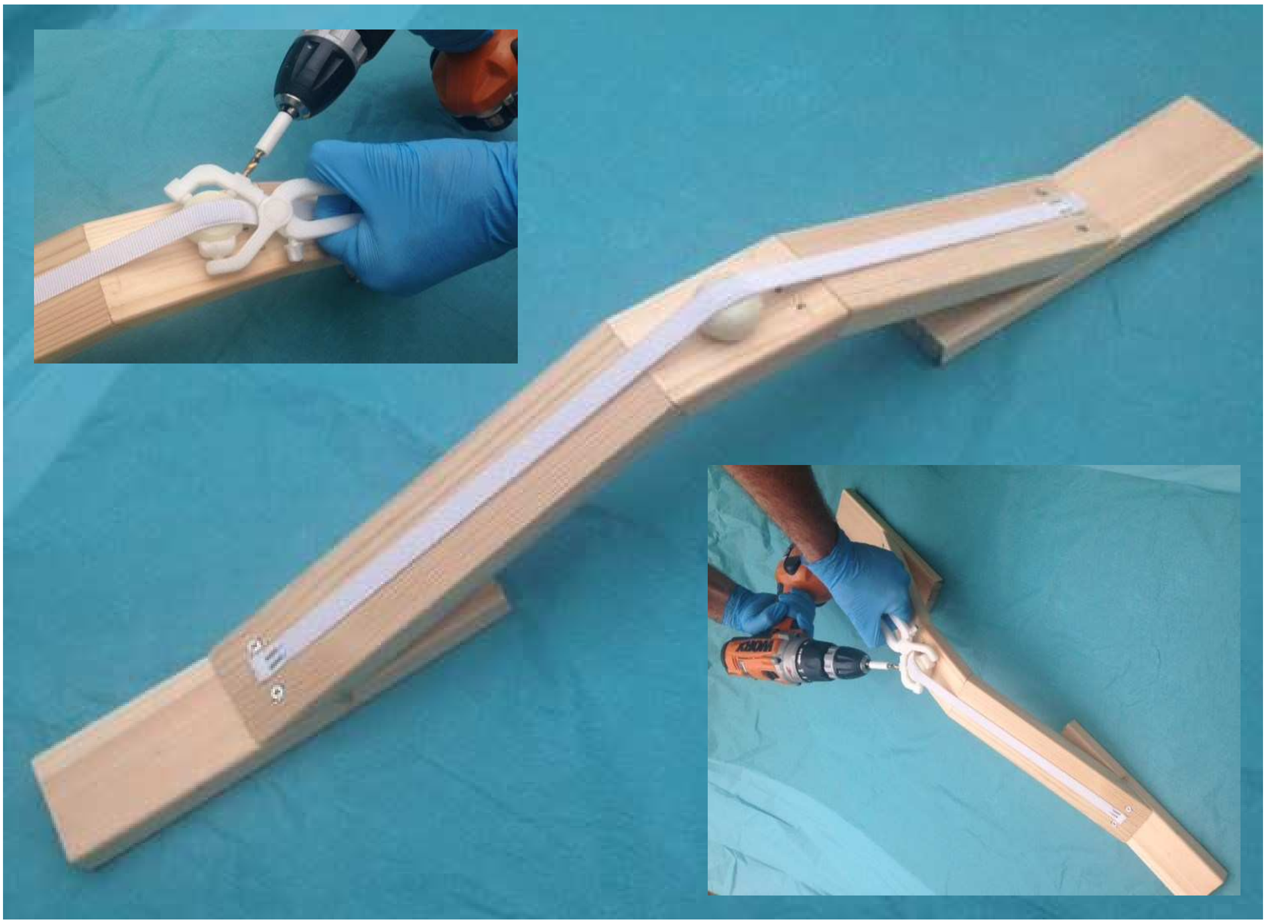

***Figure 3:*** *Image showing the experimental setup used to mount the patellae for the comparison of the prototype drill-guide to conventional techniques. Insets show the prototype drill-guide in use. Note the collar mounted on the drill bil.*


***Figure 4:*** *Image showing patellae divided in the coronal plane drilled by a single surgeon. Left*

*shows a bone tunnel made using the 'freehand' technique (with extensive overdrill) and right, a tunnel made using the prototype drill-guide device.*

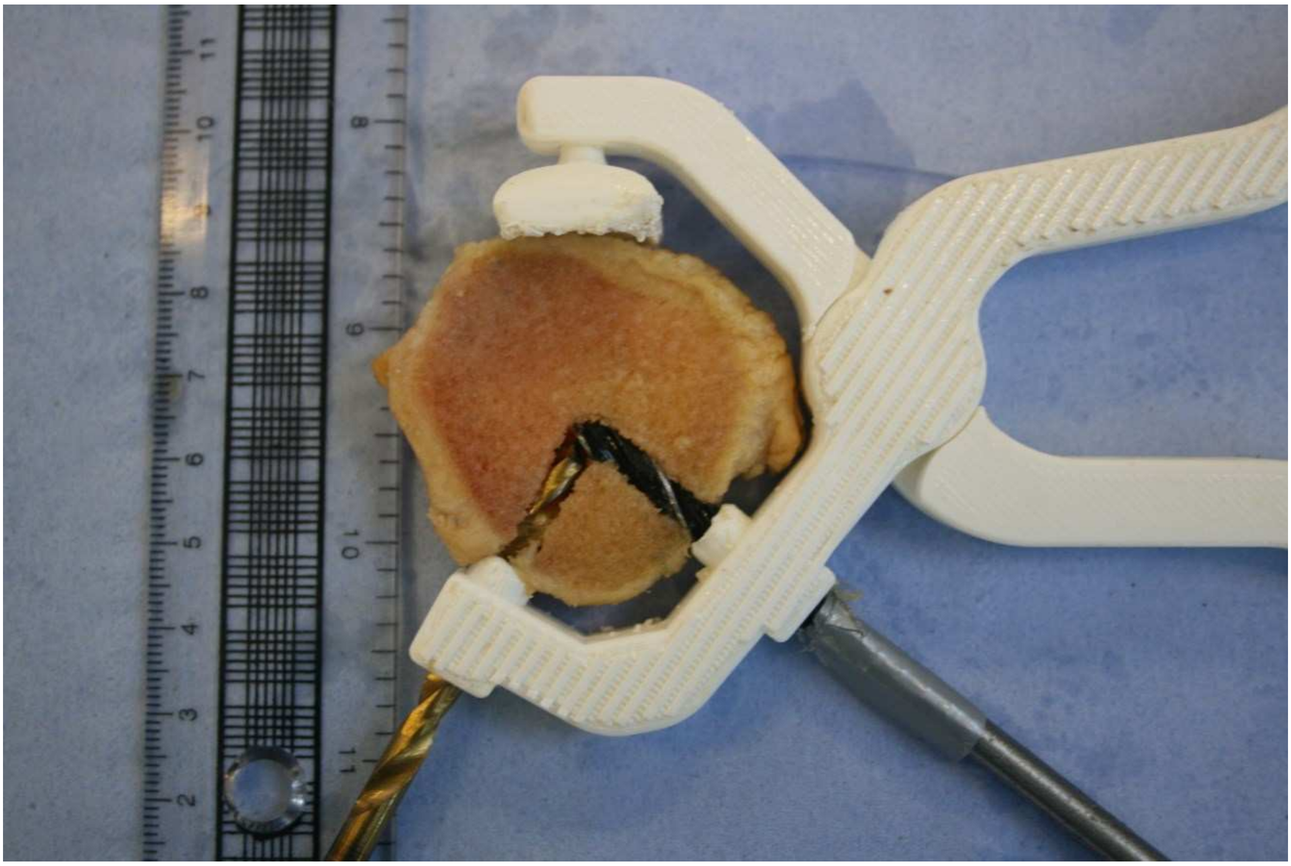

***Figure 5:*** *Image showing a cadaveric patella divided in the coronal plane with the MPFL drill guide and two drill bits in situ for illustration purposes. Note that owing to limitation in 3D printer size we only had a small drill guide available, when for this particular patella a larger size would have been more appropriate.*

| | | time T | time G | Centre T | Centre G | Angle T | Angle G | Over-drill T | Over-drill G |
|---|---|---|---|---|---|---|---|---|---|
| | | Time (min:sec) | | RMS Error (mm) \|\| (degrees) | | | | | |
| **Group 1 (TF)** | 1 | 01:19 | 00:42 | 0.51 | 0.47 | 5.22 | 1.44 | 7.42 | 0.00 |
| | 2 | 01:25 | 00:42 | 1.57 | 0.91 | 18.94 | 1.27 | 13.21 | 0.00 |
| | 3 | 00:38 | 00:48 | 5.28 | 0.33 | 22.08 | 2.69 | 1.44 | 0.00 |
| | 4 | 01:21 | 00:31 | 2.10 | 0.84 | 10.83 | 2.93 | 16.33 | 0.00 |
| | 5 | 02:00 | 01:07:31 | 2.45 | 0.24 | 11.44 | 2.7 | 13.9 | 0.00 |
| Av. TF | | 01:21 | 00:46 | 2.38 | 0.56 | 13.70 | 2.21 | 10.46 | 0.00 |
| Range TF | | 00:38–02:00 | 00:31–01:07 | 0.51-5.28 | 0.33-0.91 | 5.22-22.08 | 1.27-2.93 | 1.44-16.33 | 0.00 |
| **Group 2 (GF)** | 1 | 00:36 | 00:31 | 1.88 | 0.35 | 16.68 | 1.31 | 2.00 | 0.00 |
| | 2 | 00:56 | 00:42 | 1.78 | 0.53 | 17.07 | 3.41 | 11.80 | 0.00 |
| | 3 | 00:26 | 00:35 | 2.79 | 0.64 | 5.39 | 1.51 | 14.74 | 0.00 |
| | 4 | 00:33 | 00:36 | 0.54 | 0.15 | 28.04 | 2.70 | 0.00 | 0.00 |
| | 5 | 00:52:00 | 01:04:28 | 2.26 | 0.58 | 23.19 | 5.6 | 7.94 | 0.00 |
| Av. GF | | 00:40 | 00:41 | 1.85 | 0.45 | 18.07 | 2.91 | 7.30 | 0.00 |
| Range GF | | 00:26-00:56 | 00:31-01:04 | 1.78-2.79 | 0.35-0.64 | 5.39-28.04 | 1.31-3.41 | 2.00-14.74 | 0.00 |
| **Av. Tot** | | **01:01** | **00:44** | **2.12** | **0.50** | **15.89** | **2.56** | **8.88** | **0.00** |
| **Range Tot** | | **00:26–02:00** | **00:31–01:07** | **0.51-5.28** | **0.33-0.91** | **5.22-28.04** | **1.27-3.41** | **1.44-16.33** | **0.00** |

***Table 1:*** *Table showing the data of ten surgeons making bone tunnels using both the traditional technique (T) and the Guide (G). The surgeons were split into two groups of five with half using the traditional technique first (TF) and the other half the guide first (GF).*

**References:**


1. Colvin AC, West RV. Patellar instability. J Bone Joint Surg Am. 2008 Dec;90(12):2751–62.

2. Nomura E, Inoue M. Surgical technique and rationale for medial patellofemoral ligament reconstruction for recurrent patellar dislocation. Arthrosc J Arthrosc Relat Surg Off Publ Arthrosc Assoc N Am Int Arthrosc Assoc. 2003 Jun;19(5):E47.

3. Nomura E, Inoue M. Hybrid medial patellofemoral ligament reconstruction using the semitendinous tendon for recurrent patellar dislocation: minimum 3 years' follow-up. Arthrosc J Arthrosc Relat Surg Off Publ Arthrosc Assoc N Am Int Arthrosc Assoc. 2006 Jul;22(7):787–93.

4. Criscenti G, De Maria C, Sebastiani E, Tei M, Placella G, Speziali A, et al. Reconstruction of medial patello-femoral ligament: Comparison of two surgical techniques. J Mech Behav Biomed Mater. 2016 Jun;59:272–8.

5. Hawkins RJ, Bell RH, Anisette G. Acute patellar dislocations. The natural history. Am J Sports Med. 1986 Apr;14(2):117–20.

6. Lenschow S, Schliemann B, Gestring J, Herbort M, Schulze M, Kösters C. Medial patellofemoral ligament reconstruction: fixation strength of 5 different techniques for graft fixation at the patella. Arthrosc J Arthrosc Relat Surg Off Publ Arthrosc Assoc N Am Int Arthrosc Assoc. 2013 Apr;29(4):766–73.

7. Arendt EA, Moeller A, Agel J. Clinical outcomes of medial patellofemoral ligament repair in recurrent (chronic) lateral patella dislocations. Knee Surg Sports Traumatol Arthrosc Off J ESSKA. 2011 Nov;19(11):1909–14.

8. Ahmad CS, Brown GD, Stein BS. The docking technique for medial patellofemoral ligament reconstruction: surgical technique and clinical outcome. Am J Sports Med. 2009 Oct;37(10):2021–7.

9. Han H, Xia Y, Yun X, Wu M. Anatomical transverse patella double tunnel reconstruction of medial patellofemoral ligament with a hamstring tendon autograft for recurrent patellar dislocation. Arch Orthop Trauma Surg. 2011 Mar;131(3):343–51.

10. Panagopoulos A, van Niekerk L, Triantafillopoulos IK. MPFL reconstruction for recurrent patella dislocation: a new surgical technique and review of the literature. Int J Sports Med. 2008 May;29(5):359–65.

11. Shah JN, Howard JS, Flanigan DC, Brophy RH, Carey JL, Lattermann C. A systematic review of complications and failures associated with medial patellofemoral ligament reconstruction for recurrent patellar dislocation. Am J Sports Med. 2012 Aug;40(8):1916–23.

12. Thienpont E, Druez V. Patellar fracture following combined proximal and distal patella realignment. Acta Orthop Belg. 2007 Oct;73(5):658–60.

13. Lippacher S, Reichel H, Nelitz M. [Patellar fracture after patellar stabilization]. Orthop. 2010 May;39(5):516–8.

14. Panni AS, Alam M, Cerciello S, Vasso M, Maffulli N. Medial patellofemoral ligament reconstruction with a divergent patellar transverse 2-tunnel technique. Am J Sports Med. 2011 Dec;39(12):2647–55.

15. Ahmad R, Jayasekera N, Schranz P, Mandalia V. Medial patellofemoral ligament reconstruction: a technique with a 'v'-shaped patellar tunnel. Arthrosc Tech. 2014 Oct;3(5):e589-592.

16. Kim TK, Chung BJ, Kang YG, Chang CB, Seong SC. Clinical implications of anthropometric patellar dimensions for TKA in Asians. Clin Orthop. 2009 Apr;467(4):1007–14.

17. Placella G, Tei MM, Sebastiani E, Criscenti G, Speziali A, Mazzola C, et al. Shape and size of the medial patellofemoral ligament for the best surgical reconstruction: a human cadaveric study. Knee Surg Sports Traumatol Arthrosc Off J ESSKA. 2014 Oct;22(10):2327–33.

18. Baldwin JL, House CK. Anatomic dimensions of the patella measured during total knee arthroplasty. J Arthroplasty. 2005 Feb;20(2):250–7.