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Designing a Novel Device for Femoral Socket Preparation in ACL Reconstruction

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Abstract

ACL reconstruction is one of the most commonly performed orthopedic operations in the United States. However, graft failure following primary surgery has been observed in up to 10% of patients. Studies have implicated surgical errors as the largest cause of graft failure, with femoral tunnel malposition as the most commonly cited error. Henceforth, this investigation serves to develop and test the feasibility of a novel surgical guide for femoral socket preparation in ACL reconstruction with the intended goal of improving femoral drilling accuracy. The device is inserted via a conventional anterolateral (AL) incision under anteromedial (AM) visualization. It then marks the desired location on the femoral condyle for tunnel drilling accounting for an AM drilling trajectory. The device is then withdrawn and standard AM drilling is performed in accordance with the femoral marking. The prototype device was found to appropriately mark the femoral site drilling in 90% of trials (n=30). These results generally confirm the feasibility of such a surgical guide (AL marking for AM drilling), although future work must be dedicated to specifically delineating its efficiency and efficacy relative to other drilling techniques in a cadaveric setting.

Keywords: anterior cruciate ligament, anteromedial, transtibial, outside-in, femoral tunnel

Introduction

Background & Research Aims

Approximately 200,000 ACL ruptures occur annually within the United States with numbers rising due to an increasingly active population.[1,3,4] Given that up to 10% of patients will require revision at some point and revision surgeries result in significantly lower patient satisfaction ratings relative to primary surgeries, failure of primary reconstruction is of great concern to orthopedic surgeons.[1,3] Literature has historically approximated that nearly 70% of primary reconstruction failures can be attributed to technical errors.[1] Femoral tunnel malposition has been reported to be the most common technical failure, with an incidence rate of 80% among graft failures.[2] Consequently, our long-term goal is to reduce instances of ACL revision surgeries by optimizing primary ACL reconstruction via increased femoral tunnel drilling accuracy. The implications of such improvement would dramatically increase patient satisfaction, maximize the operative capacity of surgeons, and increase hospital revenue from elective procedures.

Metrics of Failure

While the etiologic classification of failure of ACL reconstruction remains complex and multifactorial, Noyes and Barber-Westin have presented specific, quantitative indications of revision surgery: (1) a complete graft tear with > 6 mm of anterior tibial displacement as compared to the healthy knee; (2) a positive pivot shift test graded +2 or +3 compared to the healthy knee, with or without knee pain or inflammation.[1 5] Alfred and Bach have also proposed a definition of ACL failure contingent on >3mm difference of anteroposterior knee laxity relative to healthy knee and >10mm absolute displacement assessed through KT-1000 arthorometer. For the purposes of this investigation, failure will be understood according to the aforementioned standards (anterior tibial displacement, anteroposterior laxity, or absolute displacement).

Mechanisms of Failure

There are generally 3 mechanisms of ACL graft failure: biological causes (~0.5%), chronic or acute traumatisms (~5-10%), and technical errors (~70%).[1] The decision to focus specifically on technical errors was thus made given immense asymmetry as to their contribution to graft failure. Among technical errors, femoral tunnel malposition has been found to account for the vast majority of graft failure (~80%).[1,2] This occurs because even small changes in the placement of the femoral tunnel towards the tibial center of rotation may impact the kinematics of the knee.[1,17-20] With regards to the sagittal plane, overly anterior femoral tunnels may lead to tightened grafts during flexion, either reducing a patient's range of motion or causing graft stretching and resultant laxity.[21-23] By contrast, when the femoral tunnel is too posterior, the graft may tighten in knee extension and have laxity on flexion, similarly leading to failure. If, however, the graft does not break, then the knee may adapt to this circumstance by creating a knee flexion contracture with a deficit of complete extension.[1] The biomechanical effect of this could impair the gait and cause anterior knee pain due to overload of the patello-femoral joint.[1] With regards to the coronal plane, a centered and overly-vertical femoral tunnel may restore anteroposterior stability but produce a rotational instability with a positive pivot shift test; thereby increasing the biomechanical demand during rehabilitation and contribute to damage of the meniscus, articular cartilage, and development of degenerative osteoarthritis.[4,8,24,25] The placement of the femoral tunnel too anterior in the sagittal plane is the most common technical error observed.[6]

Current Outcomes

At the present time, there exist 3 commonly used drilling techniques, each with distinct advantages and disadvantages in regards to femoral tunnel placement: transtibial (TT), anteromedial (AM), and outside-in (OI). While benefits and drawbacks of each technique are numerous, they can be briefly summarized as the following: (1) TT- surgical familiarity, but increased risk of nonanatomic femoral tunnel placement due to constrained tibial drilling; (2) AM- unconstrained anatomic placement, but technically demanding due to poor visualization with risk of posterior-wall blowout; (3) OI- unconstrained anatomic placement with favorable visualization, but surgically inefficient with long hospital stays with greater abrasion of the graft at the intra-articular edges of the tunnel.[7] Tunnel misalignment has been observed in all techniques.[1] Our device will address these shortcomings by allowing for AL marking for AM drilling. It will therefore benefit from the visualization of an OI technique in marking the femoral condyle and the favorable drilling trajectory of the AM technique while mitigating the difficulties of visualization of the AM technique as there already exist a footprint for the surgeon to follow.

Results

Identification of Design Constraints

In order to design a device that offered a novel value proposition relative to other techniques, an in-depth review of contemporary ACL reconstruction strategies was performed. The benefits and drawbacks of each technique were then leveraged to identify the design constraints of the novel prototype.

Transtibial Technique

The TT technique has been a standard surgical option for femoral tunnel drilling for over a decade as endoscopic drilling requires a single incision and is thus less invasive and time-consuming relative to two-incision techniques.[5] Additionally, TT has been observed to exhibit decreased surgical pain and morbidity, better cosmesis (due to the lack of a lateral incision) and decreased screw divergence.[5,8] The technique is performed with conventional AL and AM portals for introducing an arthroscope and surgical instruments (Fig. 1). A channel is then drilled diagonally from the tibia through the femur (Fig. 2). Usually, the extra-articular landmark of the tibial tunnel is located 1 cm above the insertion of the pes anserinus and 1.5 cm medial to the tibial tuberosity, allowing for an oblique orientation of the tibial tunnel guide of approximately 50°.[8] However, this focus on isometric rather than anatomic reconstruction has presented several problems over time. Notably, the position of the tibial tunnel dictates the location of the femoral tunnel as the femoral tunnel inherently must be collinear with its tibial counterpart. This orientation subsequently leaves the surgeon susceptible to extremely vertical and anterior graft placement, the consequences of which have already been described. Additionally, the TT has been observed to produce greater anterior femoral translation in swing phase, graft–tunnel length mismatch, potential violations of the posterior cortical wall, posterior cruciate ligament impingement.[5,8]

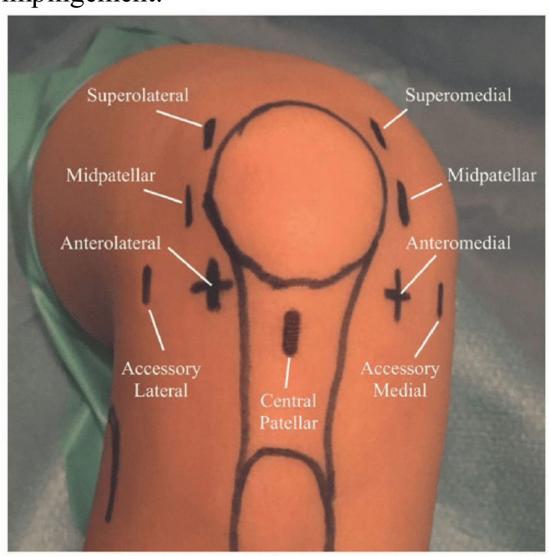

Figure 1: Visualization of all portals utilized in ACL reconstruction. Note superomedial/lateral & patellar incisions are typically not utilized.[11]

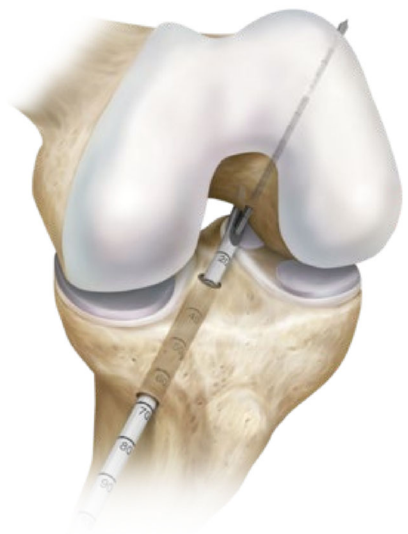

Figure 2: Representation of TT reaming. Note that only one incision is made by the tibia, which therefore constrains the drilling of the femoral tunnel. Consequently, anatomic femoral portals can compromise the tibial tunnel.[10]

Anteromedial Technique

A more contemporary approach is the AM technique, where the femoral tunnel is drilled independently of the tibial tunnel for more anatomic graft construction as originally described by Bottoni et al. (Fig. 3).[30] An arthroscope is introduced through the standard AM portal to visualize the femoral footprint. However, drilling through this portal does not always allow favorable visualization of the ACL, and thus the possibility of creating a short femoral tunnel may increase.[8] Therefore, an accessory AM portal is also made slightly lower on the medial wall of the lateral femoral condyle specifically for the purposes of drilling (Fig. 1). The accessory AM portal is usually 1 to 2 cm medial and 5 mm inferior to the standard AM portal.[8] With the knee in maximum flexion, an arthroscopic awl is then used to make a hole at the center of the ACL footprint and the Beath pin is drilled into the hole through the lateral femoral condyle.[8] The tibial tunnel is drilled in the same fashion as the TT technique, however, the tibial starting point can be closer to the tibial tuberosity and the drill can be inserted at a steeper angle relative to the TT technique, preventing iatrogenic injury to the medial collateral ligament.[31,32] While this technique allows for anatomical placement of the femoral tunnel, it has been noted that visualization during hyperflexion is very difficult, potentially leading to iatrogenic chondral injury.[9-15] Moreover, the technique has been cited as very technically demanding for surgeons with increased risk of posterior-wall blowout, potential damage to posterior articular cartilage, risk of articular cartilage injury of the medial femoral condyle during reaming of the hyperflexed knee, distal/inferior Beath pin exit with potential damage to common peroneal nerve, difficulty seating endoscopic aimer, as well as difficulty visualizing and passing the reamer due to intra-articular debris.[3,8]

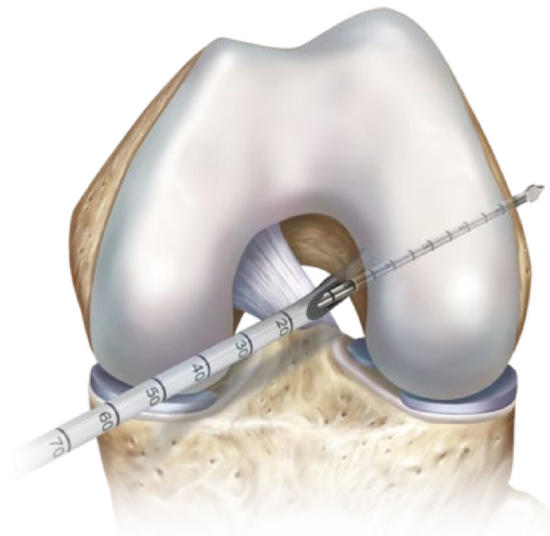

Figure 3: Medial portal (AM) femoral socket preparation.[38]

Outside-In Technique

The outside-in technique similarly allows for anatomical and independent placement of the femoral tunnel and is performed utilizing the same AL and AM portals as with the AM technique.[16] A 2 to 3 cm longitudinal skin incision is made just posterior to the lateral epicondyle of the femur (Fig. 4).[8] The iliotibial band is split longitudinally, and the distal femoral cortex posterior to the lateral epicondyle is exposed.[8] The arthroscope is inserted through the AM portal while the femoral tunnel guide is inserted through the AL portal.[8] The femoral tunnel is then reamed with a cannulated reamer corresponding to the measured diameter of the graft. Consequently, OI is especially useful in cases where the leg cannot be flexed more than 130° to drill an accessory AM portal.[33] Whereas AM requires hyperflexion for reaming, the outside-in technique provides an anatomic femoral tunnel aperture that can be reliably reproduced without hyperflexion of the knee.[8,34] However, this technique is not efficient for the surgeon as it requires multiple incisions resulting in longer operative times and hospital stays.[3] Additionally, the OI technique has been observed to cause greater surgical morbidity with the lateral incision, femoral tunnel widening, graft migration, jamming in the tunnel, and soft tissue interposition between the fixation device and the femoral cortex.[8,24]

Figure 4: Outside in femoral socket preparation.[39]

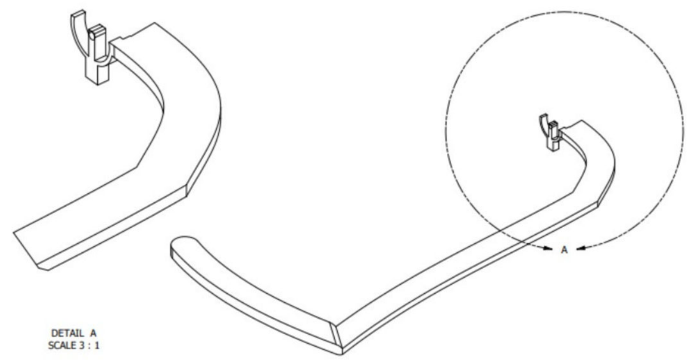

Figure 5: Prototype blueprint. Note the prong of the semicircular region surrounding the centered drill mechanism. This was constructed so that the surgeon can orient themselves anterior to the back of the femoral condyle. The rectangular portion protruding from semicircular is where the miniature guide drill would reside

Figure 6: 3D Prototype

Design Specifications

The current device prototype leverages the favorable visualization of the OI technique while allowing for the drilling trajectory of the AM technique. It therefore compensates for the difficulties in visualization of the AM technique by having the AL landmark. The guide thus resembles contemporary OI guides but includes a mechanism (i.e. small mechanical drill) with which to mark the femoral site of drilling on the guide itself that converts the AL angle into an AM–compliant marking (Fig. 5). Since the guide is positioned off the back wall of the femur, external "prongs" represent a circle of diameter 6mm that would be oriented anterior to the back wall to allow sufficient clearance of a 10mm tunnel without causing posterior wall blowout. After marking drilling position, the guide would then be withdrawn and conventional medial portal drilling would ensue via an accessory incision (Fig. 1). The benefit of such a device is that it allows for AM visualization of the guide mark (since the guide is inserted in the AL portal and the arthroscope in the AM portal), which is generally considered a more favorable viewpoint.[3] However, this tool would also allow for the horizontal drilling trajectory of the AM technique (the guide is withdrawn from the AL portal, the camera remains in the AM portal, and femoral drilling occurs through the accessory AM portal). Surgeons cannot currently insert an arthroscope in the AM portal and drill with an accessory portal as the positioning becomes very technically demanding to maintain.[3] Essentially, this tool allows for AM drilling without the operation becoming technically demanding.

Design Evaluation

Device feasibility was tested by measuring instances of deviation of prototype markings from conventional AM markings on the femoral cortex in an adult male femur model. The AM drilling area (Fig. 7) denotes the portion of the condyle where a centered marking would yield an acceptable tunnel of diameter 10mm (i.e. a marking on the edge of the brown circle would yield a femoral tunnel centered at that location, which is just barely an acceptable tunnel position without leading to posterior-wall blowout). This region was chosen under the guidance of an orthopedic surgeon. The prototype was then used to mark the femoral condyle utilizing a pen, and markings outside of the acceptable region were recorded (Fig. 7). This process was independently repeated 30 times. The number of prototype markings (i.e. blue dots) that resided beyond the acceptable region was recorded. It was found that 90% of prototype markings resided within an acceptable region for AM drilling. Given that the purpose of this investigation was to test the anatomical feasibility of this approach, no robust statistical analyses were performed on the data. Analyzing the deviation within the control area is not useful as no single marking within the control area results in a better tunnel than another (there does not exist a single, absolute best location for femoral drilling so long as the femoral tunnel resides within a relatively confined area. As such, noting the deviation between the markings within the control does not yield useful information. In this regard, results were binary, with markings either being in an acceptable location as determined by a consulting surgeon or not). As such, although it is not possible to conclude that this prototype is more accurate or efficient than other guides/techniques, it can be concluded that anterolateral marking for AM drilling within the knee compartment is possible and shows promise as a novel technique.

Figure 7: Results of prototype marking on the femoral condyle. Control area (left) was determined under the guidance of an orthopedic surgeon. This area denotes the ideal region wherein the center of a 10mm femoral tunnel could be placed without causing graft impingement/failure. Prototype markings (right) were made utilizing the device to test the feasibility of an AL approach to generate AM markings. It was observed that the AL prototype placed 90% of markings within an acceptable region (n=30).

Discussion

Significance

As discussed, it is impossible to comment on the efficiency or efficacy of utilizing this device relative to other techniques. This investigation was fundamentally designed with the sole intention of testing the feasibility of the guide. Henceforth, these results do not necessarily suggest a more accurate approach to femoral socket preparation. Rather, they are significant in that they demonstrate that AL marking of the femoral condyle for AM drilling shows promise as a novel strategy with the potential to be more precise than current methods contingent upon future investigations. This is in turn significant as it could optimize patient satisfaction by reducing instances of graft failure should the guide device be proven to be more accurate than contemporary tools. Moreover, should the device be shown to demonstrate to more efficient than current alternatives, this technique would have the additional benefit of optimizing elective surgeries within hospitals, which are a critical source of revenue for such institutions, earning an estimated $48-64 billion in the US alone.[45] However, as discussed, such findings are predicated on a more rigorous future work of the device with a functional drill component relative to alternatives techniques.

Limitations & Future Work

The largest limitation of this study was the inability to produce a guide with a drill compartment to be tested on cadavers. The initial proposal of this research described developing a surgical-grade guide with a drill component that would make the femoral marking. Throughout the design process, it was discovered that such a device would require far more resources than previously anticipated. As such, the deliverable of this project had to be scaled down slightly to develop a similar device that lacked the mechanical drill properties as was intended (but still serve the same functional purpose). As such, a fully functional drill-guide could not be delivered, hence cadaveric testing could not occur and therefore data could not be collected to compare the proposed technique to contemporary techniques. This would be the aim of future work, using the design proposed in this paper to construct a surgical-grade guide with the functional drill component and testing the drill in a cadaver lab to quantitatively determine its practicality as a surgical tool.

Materials and Methods

Fabrication of Device Prototypes

The current prototype was designed utilizing the CAD software: Autodesk Inventor. Measurements of the average adult male right femoral condyle were utilized to inform the dimensions of the guide-head as previously discussed. The prototype was subsequently printed with ABS plastic. ABS plastic was utilized as it is a relatively durable and easily accessible resource for preliminary testing. Moreover, since it was decided that cadaveric tests would not be feasible, surgical grade material and subsequently Direct Metal Laser Sintering (DMLS) was not required.

Data Collection

Data were collected utilizing a model of an average adult male right femur as previously described. AM control region was marked under the guidance of consulting surgeon. Fine-point pens (0.5mm) were utilized to mark the femur model from prototype measurements. Such was chosen to allow the most precision possible when collecting data. ImageJ was utilized following each trial to confirm which markings were beyond the control region.

End Matter

Author Contributions and Notes

P.C.C designed research, performed research, & wrote the paper.
The author declares no conflicts of interest.

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