PRAXIM ACL Navigation System using Bone Morphing

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Introduction

Primary Anterior Cruciate Ligament (ACL) reconstruction is the sixth-most common procedure in orthopedic surgery with nearly 75,000–125,000 procedures performed per year. While the procedure remains highly successful, there remains a 10–15% failure rate in most series. The etiology of ACL failure can be classified as failures due to a) surgical technique b) graft incorporation and c) trauma [5].

Background

Among failures due to surgical techniques, the most common technical error is poor tunnel placement [6, 13]. Anisometric graft positioning can cause graft stretch and poor control of knee rotational or translational stability. For example, anterior femoral tunnel placement produces strain in flexion and laxity in extension while posterior femoral tunnel placement produces strain in extension and laxity in flexion and risks back wall »blow out«. Anterior tibial tunnel placement results in strain in flexion and possible impingement in extension. Posterior tibial tunnel placement places strain on the graft in extension and possible PCL impingement. Medial or lateral tibial tunnel positioning can cause impingement conflicts with the PCL and femoral condyles.

Current surgical techniques rely on anatomic criteria, intra-operative fluoroscopy, and alignment jigs to create an isometric, non-impinging, and appropriately positioned graft. However, arthroscopic landmarks may be variable and inaccurate, fluoroscopic monitoring is cumbersome, and conventional transtibial approaches jigs such as the over-the-top guide can affect the femoral and tibial positioning (femoral tunnel tends to be anterior and vertical and tibial tunnel tends to be posterior) [5].

Surgical navigation offers an additional means of supervising tunnel positioning. In addition to anatomic criteria, quantitative isometric and impingement criteria can be used to plan tunnel positioning. This provides the surgeon with increased control in choosing tunnel position to optimize graft placement for the individual knee anatomy.

This chapter represents a summary of some recent research and clinical experience carried out at our institutes with the PRAXIM ACL navigation system. Below, a brief history and detailed description of the system is provided. Three recent studies related to the technical and clinical evaluation of the system, as well as to its use in revision procedures, are then presented, followed by a brief discussion.

History of the Praxim ACL Navigation System

ACL reconstruction surgery aims to restore normal knee stability and function, for a patient population that is typically young and active. Since our early studies performed in 1992, the development of our computer assisted ACL system focused on:

1. Improving joint function with precise measurement of knee kinematics,

2. Implementing an accurate registration procedure without exposing the patient to pre- or per-operative radiation,
3. Providing an effective and convenient procedure for use in clinical routine.

The resulting system does not require the use of any pre- or intra-operative imaging modalities such as CT, C-Arm fluoroscopy, radiography, or MRI, and it can be used without changing the surgical approach or the instrumentation. This unique technique of CT-less navigation for orthopedics was developed, patented and published for the first time in 1993 [8]. In 1994, Dr R. Julliard performed the first computer-assisted ACL surgery. This technique was first reported by Dessenne et al. in 1995 [3].

This early experience revealed that three major criteria had to be considered to correctly place the graft:
1. the joint anatomy,
2. the ligament isometry, and
3. impingement in the notch.

The results of this work were commercialized in an efficient Computer-Assisted Surgical Protocol on the Praxim platform. The system included tunnel-placement navigation based on the above criteria, and immediately appeared to be a significant help for the surgeon. More recent improvements to the system included accurate knee stability evaluation, a bendable 3D ligament model to simulate realistic graft behavior, and refinement of the protocol for increased safety, convenience and flexibility [1]. The system is now recognized as a comprehensive, accurate and proven solution for ACL reconstruction surgery [10, 11].

Methods

System Description

The Praxim surgical system is an image-free system that integrates *Bone Morphing*® technology to reconstruct the anatomy of the patient under arthroscopy. The ACL navigation system includes: a station, a small set of instruments and image-free per-operative software.

Station and Instruments

The Praxim *Surgetics*® station, an open platform system independent of implant companies, is a proven standard which has supported more than 10,000 surgeries. For added convenience, the ACL application is also supported by the portable Praxim NANO station, and the integrated digital operating room platform, which allows side-by-side placement and picture-in-picture integration of the arthroscopic video display and the navigation screen directly in front of the surgeon for optimal ergonomics.

The system is based on an accurate infrared optical tracking system. There is no keyboard or mouse; the main interaction is performed by the surgeon, pressing a blue foot pedal to go forward and a yellow foot pedal to go backward in a linear protocol. A tactile screen is used to enter patient demographics and to select options at the beginning of the procedure, such as particular stability tests to be performed. Patient information can be recorded and stored in the post-operative report on the individual patient's CD-ROM.

The set of instruments include 6 rigid bodies (or reference markers), 2 universal fixations for the instruments and 2 bone fixation devices. Wireless passive reference markers are constructed in shapes that are easily differentiable (Fig. 40.1), and are tracked by the optical localization system.

The system has been designed for easy integration into the classical clinic and normally does not require any significant changes in the routine procedure or in the instrumentation. To ensure the accuracy of the system, the instruments and the pointer are calibrated at the beginning of the protocol using a calibrator reference marker.

Fig. 40.1. Surgetics station and instruments set. F and T reference markers respectively fixed on the femur and on the tibia, 1 and 2 rigidly attached to the classical drill guides

Image-Free Per-Operative Software

In ACL reconstruction, a universally optimal position for the femoral tunnel has not yet been determined. More often than not, it is placed deep and high in the notch, far from the center of the anatomical attachment site. There is general agreement that the aim of ACL reconstructive surgery is to stabilize the knee by obtaining correct isometry and absence of impingement.

- Anisometry is defined as the maximal variation of distance between the tibial and femoral attachment sites during flexion of the knee. The anisometry profile is the curve of this distance with respect to the flexion angle, from extension to flexion. Therefore, a decreasing profile will result in a tight knee in extension and a lax knee in flexion.
- Impingement is defined as contact between the graft and the notch in extension. A virtual graft is drawn between the insertion sites. If there is impingement, the distance of penetration of this cylinder into the notch defines the impingement values.

The image-free software uses bone-morphing® technology to reconstruct the exact anatomy of the patient in 3D. The resulting models are used to (1) display in real-time a bendable graft model, (2) evaluate the impingement, and (3) construct the ligament anisometry profile for a planned set of tunnel placements.

Surgical Protocol

The following surgical protocol for ACL reconstruction surgery has been designed based on surgeon practice and experience. This system is designed to be integrated and adapted to most of the classical approaches and instrumentation, including most innovative procedures.

Installation

The navigation system does not require any specific arrangement in the operating room. The Praxim station is installed next to the arthroscopic tower so that the surgeon can see both screens at the same time, and the optical cameras can have an unobstructed view of the reference markers.

Once the patient's leg is washed and draped, the surgeon installs the reference markers on the tibia and on the femur. Fixation requires the use of either a one or a two pin external fixation device. The one pin fixation is a triangular shaped pin which has been specifically designed for this surgery by one of the authors. The pin can be preset and installed quickly and percutaneously for minimum invasiveness. The preparation of the graft and the arthroscopic examination of the notch are then performed.

Data Acquisition

Anatomical Points

The acquisition sequence is performed arthroscopically and on the patient skin (depending on the landmark) using the specially designed pointer (reference marker P). On the tibia:

- the center of the ankle is determined by computing a point between the skin over the lateral and medial malleoli,
- the medial and lateral tibial spines are acquired to constitute an anatomical reference,
- the middle of the medial and lateral tibial plateaus are digitized in order to quantify the translational laxity in each compartment,
- the middle of the anterior inter-meniscus ligament is used as a reference for the pivot shift test measurements

Kinematic Acquisition

The reference markers F and T on the femur and tibia are used to acquire the specific kinematics of the patient.

- A passive flexion-extension motion is performed by the surgeon. This dynamic acquisition is aimed at calculating the anisometry values and profiles of the graft.
- If requested by the surgeon, it is possible to acquire the centre of the femoral head by performing a conic movement in order to calculate a true hip-knee-ankle angle in the sagittal plane [12]. This option is useful in cases of knee flexion contracture.

3D Anatomy Reconstruction

Bone morphing consists in computing the accurate morphology of the patient's knee from a deformable statistical model, without use of CT, radiography or fluoroscopy. Several hundred scattered points are acquired quickly by the surgeon, by »painting« the cartilage and bone surface with the probe. These points are matched with the statistical model using a 3D/3D registration algorithm [4]. The

Fig. 40.2. Clinical set-up of the system. Surgeon acquiring the femoral bone morphing area. Visualization of the arthroscopic view and the Surgetics at the same time

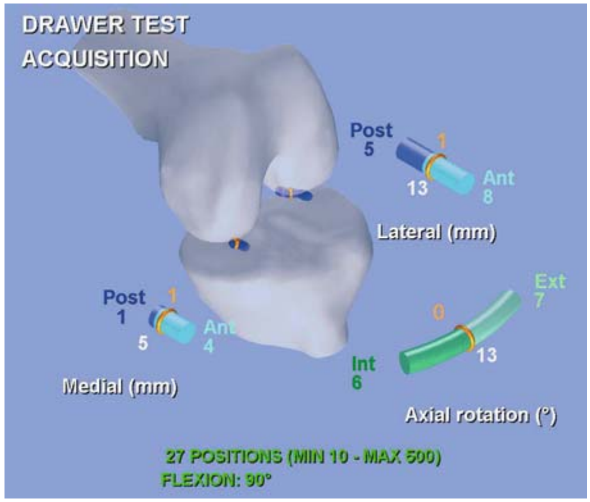

Fig. 40.3. Display of the medial and lateral translation laxity and rotation during a drawer test. The stability for each compartment can be assessed in real-time

bone model displayed on the screen is formed in real-time, to adapt to the knee of the patient.

Through this procedure the femoral notch and the tibial inter-spinal areas are reconstructed. The intra-operative 3D anatomy allows real customization of the procedure to each patient as shown on Fig. 40.2.

Pre- and Post-Operative Stability Evaluation

Although various clinical tests exist for assessing the integrity and function of the ligaments in the knee, objectively incorporating clinical test results into the surgical plan can be illusive. We have therefore been working to effectively integrate knee instability measurements into the protocol for guiding both intra-articular and extra-articular ligament reconstructions. The quantitative laxity measurements can be performed at various stages in the procedure, for pre- as well as post-reconstruction evaluation. Upon review of the various clinical tests for assessing knee injuries and instabilities, we selected four protocols for intra-operative evaluation:

- Drawer test,
- Varus-Valgus stability test,
- Lachman test,
- Pivot shift test.

For each test, the landmarks previously acquired are used to determine the rotation and translation of the medial and lateral compartment individually. Figure 40.3 shows the screen during the acquisition.

The system guides the surgeon in performing each test by displaying the 3D anatomical models in real-time, along with the flexion angle, the landmark point trajectories and their maximum displacements in the relevant planes/directions.

At the end of the stability exam, the summary screen gives a global appreciation of the knee stability in three dimensions at 0, 30 and 90 degrees of flexion. With this unique tool the instability of the knee can be objectively characterized and interpreted, and the knee properly reconstructed [2].

Interactive Planning and Navigation

Anatomical References

The radiological features of the tunnels are well known by the surgeon, and their positions are defined in relations with different landmarks such as the Blumensaat's line, the over the top limit and the tibial spines. The projection of the femoral notch on the tibia in the direction of the Blumensaat's line helps the surgeon to position the tibial tunnel as anterior as possible while avoiding notch impingement whereas the tibial spines displayed on the tibia gives a conventional arthroscopic reference.

The over the top limit display allows the surgeon to make the compromise between anatomical and isometric placement of the femoral tunnel.

Graft Simulation and Notch Impingement

In order to correctly guide graft placement, an advanced graft-simulation algorithm has been integrated into the system. A bendable ligament model is calculated and displayed in real-time as a function of the position and shape of the femoral notch and the planned fixation points. The simulation is based on a non-linear energy criterion that monitors collisions with the 3D bone surface during the kinematics measurements. The renderings aid visualization of the ligament trajectory, by depicting how the virtual ligament glides overtop of the 3D bone surface models as the knee is flexed and extended.

Using this graft simulation, any notch impingement can be identified and its intensity evaluated dynamically. A red zone appearing on the femoral surface reveals the presence of potential impingement between the virtual graft and the notch. The displayed distance represents the maximum penetration distance of the virtual ligament inside the notch for the entire range of flexion measured (Fig. 40.4).

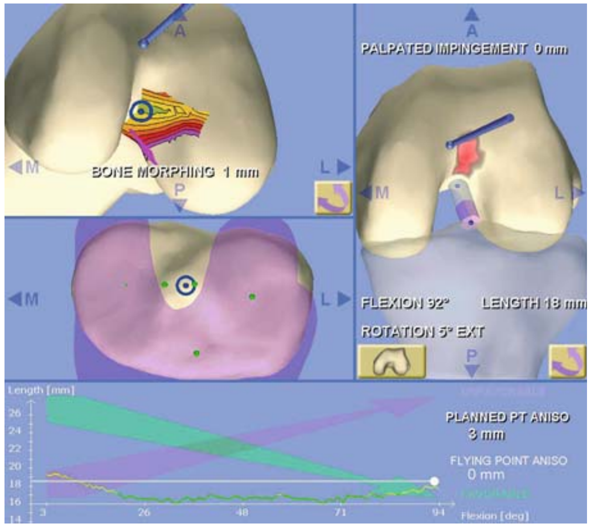

Fig. 40.4. Interactive planning on tibia and femur. The blue circles correspond to the insertion points of the tunnels – the red area on the right image of the femur shows the potential impingement area between the graft and the notch for the selected centre of the tunnels. The anisometry map on the femur is color-coded: green indicates an anisometry value less than 2 mm; yellow, 2–4 mm; orange, 4–6 mm; and red more than 6 mm. Blumensaat's line is represented by a dotted line. The over-the-top limit is represented by a pink line on the femur. The anisometry curve is illustrated in green; it is computed in real time as the surgeon selects new insertion sites

Graft Anisometry Profile Description

The anisometry is globally defined as the maximal variation of the graft fiber length during flexion-extension. A single value of anisometry displayed on the screen for a single graft fiber would make the tunnel placement process long and non intuitive. The system therefore computes for a given tibial point an anisometry color map painted directly on the external femoral notch surface. The locations corresponding to minimum anisometry are displayed in green and the maximum value is represented in red. The resulting map is superimposed in the femoral bone model as presented in Fig. 40.4. While moving the pointer on the bone, the potential graft insertion point is displayed as a circle and the surgeon can check at the same time the anisometry of the anterior, central and posterior fibers.

For any given pair of Femoral and Tibial insertion sites (F and T) selected by the surgeon, an anisometry curve is represented and defines the graft profile. A favorable profile characterizes a fiber that loses tension during flexion, whereas a non-favorable profile characterizes a fiber that stretches in flexion.

Optimization Strategy

A possible strategy for the planning consists in

1. First choosing a point on the tibia with respect to the anatomical references given by the system;
2. The system displays the anisometry map for the given tibial point on the femur. The anisometry curve is represented in real-time as the pointer is moved on the potential femoral insertion point. If it can't be ideal, the anisometry must be positive but not too high as that would leave a pathological laxity in flexion;
3. The surgeon adjusts the tibial point to prevent any conflict for the given femoral point, and checks the corresponding anisometry profile.

Navigation of Tunnels

Currently different surgical approaches on placement of the tunnel as well as fixation of the graft exist. As such a tool should respond to most of these techniques, the system has been designed to be very flexible, interactive but also intuitive for the surgeon. Using any standard instrumentation for drilling the tunnels, one reference marker is fixed on the conventional tibial guide and one on the femoral guide, and the guides are calibrated. The navigation of the tibial tunnel consists in placing the guide on the tibia and follows the virtual guide on the screen in order to reach the target previously recorded. During this part of the navigation the axis of the guide is projected on the femur in order to have a preview of the final trajectory of the graft.

The operation for the femoral tunnel is similar and the femoral tunnel may be navigated and drilled inside-out (through the medial arthroscopic portal or through the tibial tunnel) or outside-in.

After the fixation of the graft, individual fibers of the graft are checked in order to validate the isometry and impingement.

Results

Technical Validation Study Using a 6 Degree-of-Freedom Robot

One of the exciting aspects of the Surgetics navigation system is the ability to quantify multiplanar knee translations and rotations (coupled motions) during knee stability examination. Traditionally, clinical examination, the cornerstone of clinical decision making in knee instability, remains empirical and may be confusing in the setting of multiplanar knee instability. We have assessed the accuracy of a navigated knee stability examination in cadaveric knees subjected to varus loading with and without external rotation loading in intact and posterolateral corner deficient knees. In this injury pattern, there is multiplanar instability with an increase in both varus and external rotation.

Fig. 40.5. Setting of the 6 degrees of freedom robot with the knee mounted and the Surgetics system on the side

Methods. Six cadaveric knees were mounted on a 6 Degree-of-Freedom (DOF) robotic manipulator/positional sensor (Kawasaki ZX 165U, Kawasaki Heavy Industries, Japan). The knees were taken through a full range of motion and then subjected to 9 Nm of varus stress at 0°, 30° and 60°. The procedure was then repeated with the 9 Nm varus stress and 4 Nm external rotation force at the same flexion angles. This protocol was used in both intact knees and the same knees after sectioning of the postero-lateral corner.

The testing system, composed of a 6-DOF robotic manipulator and a 6-DOF universal force-moment sensor (ATI DAQ F/T Multi-Axis Force-Torque Sensor System, ATI Apex, North Carolina), allowed for quantification of unidirectional knee translations and rotations. This surgical navigation system was used to quantify coupled knee motion and characterize translation and rotation in both the medial and lateral compartments of the knee (Fig. 40.5).

Accuracy of the surgical navigation system compared to the robot was assessed using the intraclass correlation coefficient. Wilcoxon Rank Sum Test (paired nonparametric test) was used to determine differences in knee rotations.

Results. Intraclass Correlation Coefficients (ICCs) between the robotic sensor and the navigation system for varus and external rotation at 0, 30, and 60 degrees were all statistically significant at <0.01. The overall ICC for all tests was 0.99 ($p<0.0001$).

This study demonstrated Praxim ACL navigation system is a highly accurate means of dynamically quantifying knee stability examination and may help identify pathologic multiplanar or coupled knee motions, particularly in the setting of complex instability patterns [11].

Clinical experience

Comparative Study on 96 Patients

In 2000, Menetrey et al. [9] proposed an innovative method for comparing the positioning of the tibial and femoral tunnel using computer assisted ACL surgery as a gold standard. The study compared the accuracy and reproducibility of 5 different conventional guides on 5 cadaveric knees looking at the positioning with respect to the anatomical original position, the notch impingement, and the elongation of the graft. The »Aimer« and transtibial guides appeared the more reproducible and reliable positioning.

Today about 300 ACL reconstructions were performed using this system in our center. Based on this study and our previous experience [10], we compared in-vivo in a group of 96 patients the placement using manual instrumentation with the result given by the system.

Methods. All patients received a ligament reconstructive surgery using the same technique: semi-tendinosus tendon using BioRCI tibial screw fixation (Smith and Nephew, Andover, MA USA) and femoral endo-button. The manual guides used: Acufex PCL related (Smith and Nephew, Andover, MA USA) for the tibia and In/Out femoral guides.

The positioning given by the ancillary was first blindly chosen by the operator and recorded using the navigation system. The reconstruction objectives were to get a tibial tunnel as anterior as possible avoiding notch impingement, and which minimize the anisometry with a favorable curve.

Results. The operating time was increased by 17 min (10–30); no per or post operative complications were noticed. On the tibia, the tunnel selected using the manual instrumentation appears too posterior in all cases. The navigation tool changed the positioning of the tibial tunnel giving a more anterior and medial. These modifications were possible and secured in all case by the visualization of the projection of the notch on the tibia and the real-time display of the conflict. On the femur the manual instrumentation proposed a good position with respect to the anisometry in 60% of the cases, a favorable anisometry curve in 15% of the case, and a non-favorable position for the other cases. The operator changed the original position proposed by the manual guides in 40% of the case avoiding 15% of femoral tunnel misplacement.

This system allowed to safety place the tibial tunnel more anterior increasing the anterior stability of the knee. The navigation tool was also useful in 40% of the case helping the positioning of the femoral tunnel.

Clinical Study of 30 ACL Revision Reconstructions

The clinical utility of the navigation system has also been evaluated for ACL revision procedures.

Methods. The study included 30 patients with previous history of ACL repairs (2 synthetical grafts, 17 semi-tendinosus grafts and 11 patella tendons). The repairs consisted in 13 quadrupled semi-tendinosus grafts and 17 patella tendon reconstructions.

The failed center position of the tibial and the femoral tunnel were analyzed and recorded using the system: the anisometry curve of the initial plasty were computed. The operator reconstructed the ACL following standard navigation (◘ Fig. 40.6).

Results. In 20 knees, the authors reported an initial mal-positioning of the tunnels (66% of the cases). 8 tibial tunnels were positioned too anterior leading to anterior conflict with the femoral notch, 10 tibial tunnels were too posterior with an anisometry superior to 8 mm and only 12 tunnels was reported correctly placed. In 60% of the cases (18 knees), the defavorable anisometry curve were due to the mal-positioning of the femoral tunnel.

Discussion. The main difficulty appeared to us in the analysis of the failure and the realization of new tunnels. The system allowed us to understand the reason of the first failure and to avoid reproducing any mal-positioning of the new tunnels. The use of the Praxim ACL navigation system appeared to be a valuable tool but also essential as medicolegal justification. The multiple ACL reconstruction methods and the choice of the fixation system associated with the use of the navigation greatly simplified the ACL revision surgery in our practice.

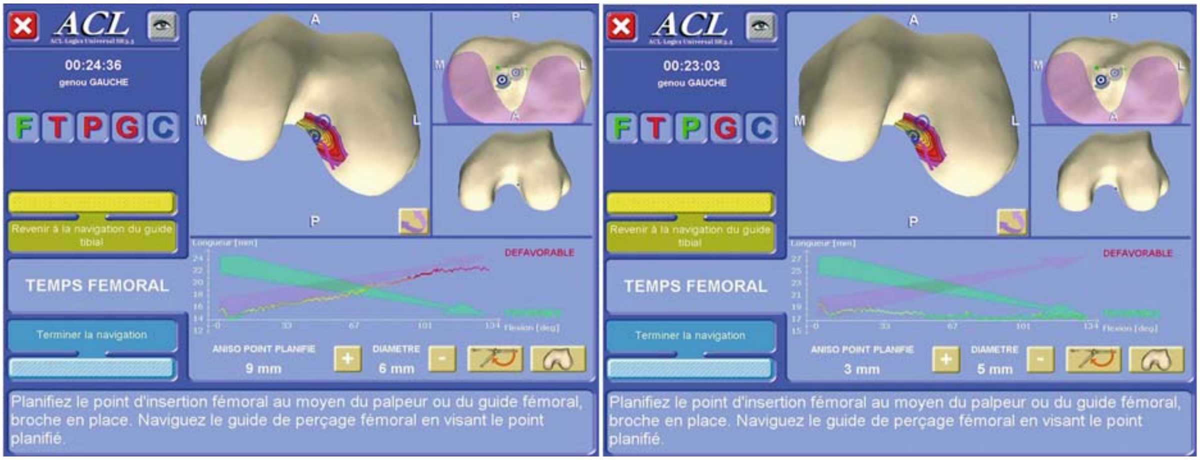

Fig. 40.6. Example of ACL revision. *Left image*, the first stage: The femoral tunnel is located in non-favorable anisometry area and the tibial tunnel is positioned too anterior: The anisometry is 9 mm with a non-favorable curve profile. *Right image*, the second stage: The chosen femoral point is in a favorable area with an anisometry of 3 mm. The tibial tunnel center point is more anterior without notch conflict. The anisometry curve is horizontal

Discussion

Anterior Cruciate Ligament (ACL) reconstruction is the treatment of choice for young, active individuals with an ACL deficient knee and symptoms of instability. While this procedure is widely performed, estimated rates of revision surgery are as high as 10–20%, which has prompted a search for modified techniques such as the double bundle ACL reconstruction. While failure to recreate knee stability may result in early failures, ACL reconstruction is also associated with a late risk of the development of osteoarthritis. Both modes of failure may be associated with the surgeon's inability to properly recreate the normal knee kinematics. Surgical navigation offers the potential to not only navigate the position of the graft by supervising the placement of graft tunnels, but also the opportunity to interrogate the multiplanar kinematics of the knee before, during, and after ACL reconstruction.

While we have demonstrated that navigated knee examination is accurate and provides real-time multiplanar visualization and kinematic data, inter and intra-observer variation in the application of clinical tests remains problematic. In addition, standard pitfalls of surgical navigation systems, such as landmark and mechanical errors, increased surgical time, and line-of-site issues, must be recognized when applying this technology clinically [7].

Surgical navigation offers the opportunity to monitor multiple aspects of knee ligament reconstructions dynamically. An inherent difficulty in ACL reconstruction is choosing the correct position for the placement of the graft so as to create an isometric graft that best reproduces the knee's normal kinematics. Navigated knee stability examination may help surgeons tailor the knee reconstruction to the patient's particular pattern of knee instability. In addition, the ability to integrate isometry and impingement criteria with arthroscopic landmark criteria allows the surgeon to refine the planning and execution of tunnel placement in accordance with the individual pattern of knee instability.

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