Unicompartmental Knee Arthroplasty with Use of Novel Patient-Specific Resurfacing Implants and Personalized Jigs

By Wolfgang Fitz, MD

This paper describes the surgical technique with a patient-specific resurfacing unicompartmental knee arthroplasty. The patient-specific implant is currently designed on the basis of data from preoperative computed tomography. The implant is provided with a set of patient-specific, disposable cutting jigs. Biomechanical and anatomic axes are factored into jigs from a scan obtained through the hip, knee, and ankle, effectively achieving pre-navigation of the cut planes without the need for a navigation system. The surgical technique is reduced to five simple, reproducible steps. After removing the articular cartilage, the knee is balanced to determine the correct amount of tibial resection; this is followed by femoral preparation, verification of balancing and tibial preparation, and trial and cementing of the implant. The introduction of personalized three-dimensional image-derived resurfacing implants, as well as personalized single-use instrumentation, has the potential to change the common surgical practice of unicompartmental knee arthroplasty. Patient-specific resurfacing implants enable a femoral bone-preserving approach and enhance cortical bone support on the tibia, overcoming critical design limitations of commercial off-the-shelf implants. Patient-specific resurfacing implants can restore normal anatomy, the position of the joint line, and normal joint function, with the potential to result in more normal knee kinematics.

Osteoarthritis of the knee is a growing epidemic affecting increasingly younger patients[1]. The rate of unicompartmental knee arthroplasty is growing three times faster than that of total knee arthroplasty[1]. Excellent, dependable clinical results in the first decade of its use have encouraged surgeons to expand the indication for unicompartmental knee arthroplasty to younger and more active patients[2]. There are several key benefits of unicompartmental knee arthroplasty as compared with total knee arthroplasty. Postoperative range of motion is better; the knee feels more normal[3,4]; and the prevalence of postoperative complications, such as deep venous thrombosis, pulmonary embolism, and infection, is lower[5-8].

Of all knee arthroplasties performed in 2007 in the U.S., only 8% were unicompartmental[1]. The prevalence of unicompartmental osteoarthritis of the knee with preservation of the other two compartments is, however, reported to range between 6% and 40%[9,10]. A major reason why unicompartmental knee arthroplasty is used in only a small percentage of patients is that it is technically more demanding than total knee arthroplasty, with a surgical technique that is considered to be less reproducible. There are also major limitations to current implant designs. The implants do not match the anatomy accurately; some implants are narrower than others. High early failure rates have been reported in obese patients for designs with an inset or narrow tibia[6], while early results with a wider tibial component have had lower early failure rates in obese patients[11]. Most systems are gradually changing to asymmetric femoral components to improve implant fit and to reduce the risk of edge-loading.

Design flaws also persist on the lateral side. The lateral tibial plateau is rounder as compared with the medial side. The tibial components do not match the anterior-posterior and/or medial-lateral ratio of the tibial plateau. Experienced surgeons use tricks to compensate for these shortcomings. The tibial component is moved more medially, not covering the most lateral aspect of the tibial plateau, and the femoral component is intentionally moved as lateral as possible. The lateral condyle is smaller, and oversizing of the femoral component can result in femoropatellar impingement.

Personalized, patient-specific implants can address the shortcomings of current off-the-shelf implants and can im-

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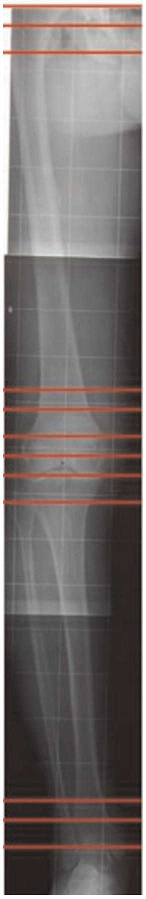

Fig. 1
Implants and instrumentation are derived from computed tomographic scans and full-length radiographs of the limb. Single-use instrumentation is pre-navigated through use of the mechanical axis information of the hip and ankle.

prove osseous coverage on the tibial as well as on the femoral side. An anatomic femoral design can resurface the femoral condyle, eliminate femoral chamfer cuts, and restore knee kinematics as closely as possible to the normal anatomy. The tibial component can cover the entire tibial cortex, with expected improvements in the rates of tibial implant subsidence and loosening. This is not only beneficial on the medial side but can be particularly helpful in the lateral compartment, preempting the design limitations of current implant designs.

This paper presents and discusses a novel surgical technique that utilizes patient-specific unicompartmental resurfacing implants paired with patient-specific personalized jigs.

Materials and Methods

The individualized iUni (ConforMIS, Burlington, Massachusetts) implant has been cleared under the 510(k) process (i.e., pre-market notification) by the United States Food and Drug Administration. The implant is designed for medial or lateral tibiofemoral compartment repair. The device is completely patient specific. Each device is made on the basis of data from a preoperative computed tomographic scan or, in the future, a magnetic resonance imaging scan. Preoperative imaging includes the long-leg axis information through the femoral head and the center of the talus to measure the mechanical axis (Fig. 1). The biomechanical and anatomic axes are accurately defined for implant and jig design by acquiring a scan through the hip and ankle joints as well as the knee.

Each device is optimized on both the femoral and the tibial surface for optimal fit. Design features of the iUni implant include: (1) an anatomically shaped femoral component that exactly matches the patient's anatomy, thereby minimizing the amount of bone removal; (2) matching anatomy of the tibial component to closely follow the patient's individualized shape, achieving 100% cortical bone support; and (3) (unlike the fit provided by off-the-shelf devices) an accurate anatomic fit in the lateral compartment.

The implant is accompanied by a set of patient-specific, disposable, and pre-navigated cutting jigs (iJigs; ConforMIS). The iJig is produced from the same computed tomography or magnetic resonance imaging data that are used to design and manufacture the iUni implant. The iJig is thus a unique positioning and alignment device that fits the condyle in only one position. Biomechanical and anatomic axes are factored into the iJig from the scan, effectively achieving pre-navigation of cut planes without the need for a navigation system. The instrument set is disposable and comes with the implants in

Fig. 2
Instrumentation and implants are delivered in one sterile box.

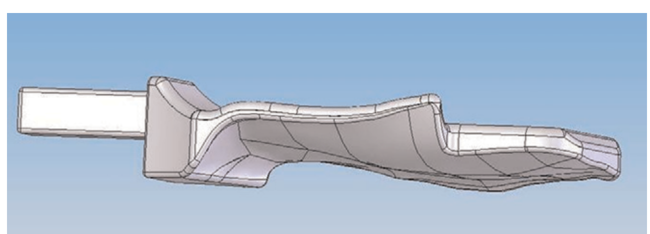

Fig. 3
The patient-specific navigation and balancing block matches the tibial surface and comes in 1-mm increments. For every 1-mm increase in thickness, 1 mm less bone is resected from the tibia. This allows precise balancing before the tibia is resected.

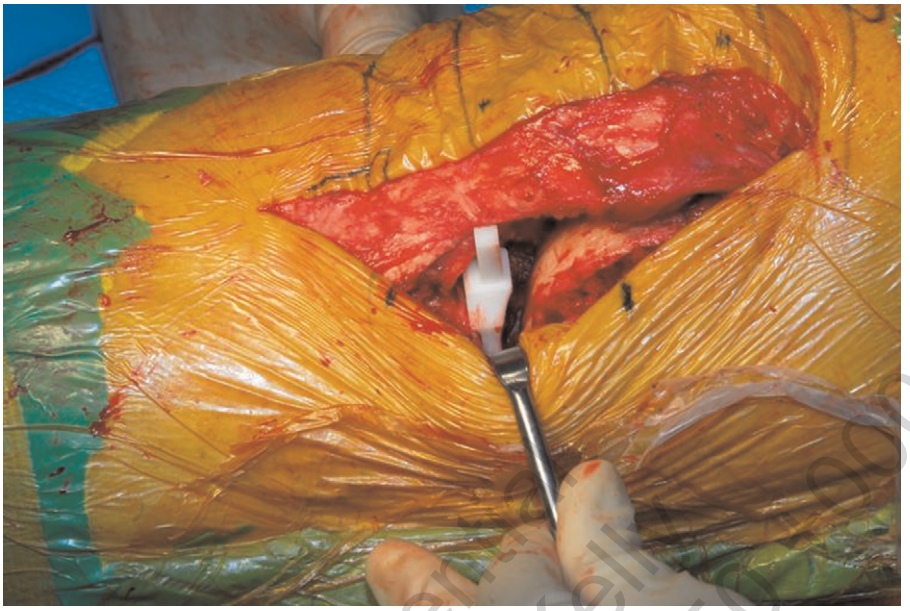

Fig. 4-A

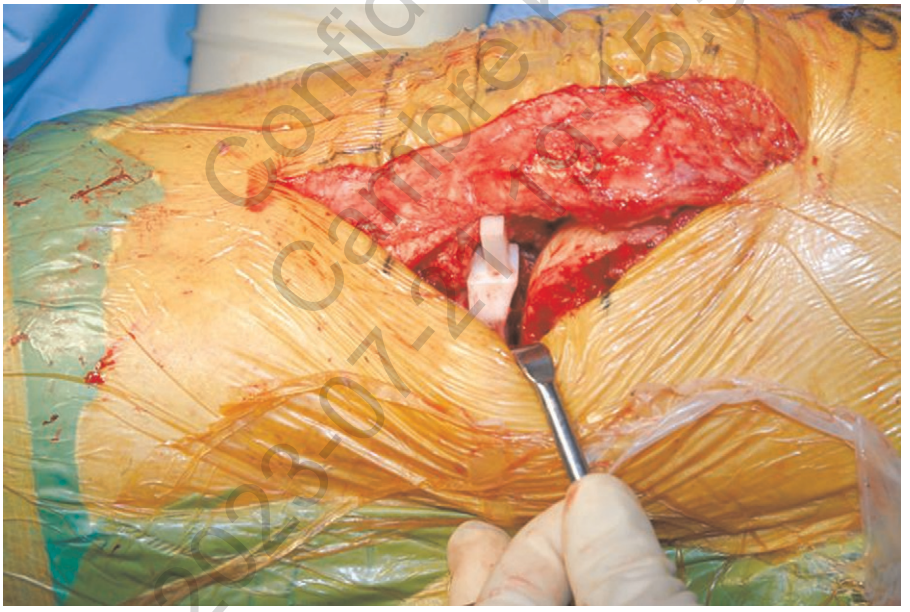

Fig. 4-B

Figs. 4-A and 4-B Navigation chips are placed on the tibia, and valgus and varus stresses are applied with the knee positioned in slight flexion until the desired laxity is achieved. If the laxity is too great (Fig. 4-A), a thicker chip is inserted (Fig. 4-B) to achieve appropriate chip thickness.

one sterile box (Fig. 2). The advantages of the iJig instrumentation include: (1) easy positioning of the implant in the exact anatomic position in which the femoral component will be placed; (2) precise alignment with both the anatomic and the biomechanical axis by referencing against the hip and ankle joints; (3) replacement of the usual multitray instrument set with a small number of disposable self-positioning cutting guides; and (4) facilitation of precise positioning of the implant in either the medial or lateral compartment.

Surgical Technique

The surgical approach is based on the principles used with current unicompartmental knee arthroplasty systems. Through a midline skin incision, a short medial or lateral parapatellar arthrotomy is performed. The knee is brought into extension and the linea terminalis is marked. It is important to preserve the medial collateral ligament to avoid overcorrection. The meniscofemoral and meniscotibial ligaments are released, and all osteophytes along the femoral

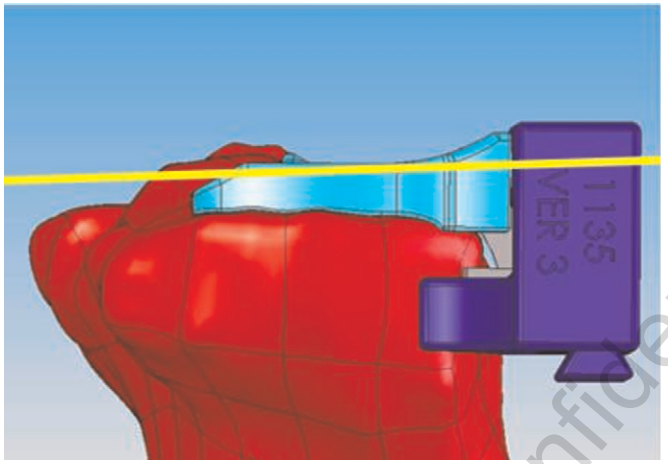

Fig. 5-A

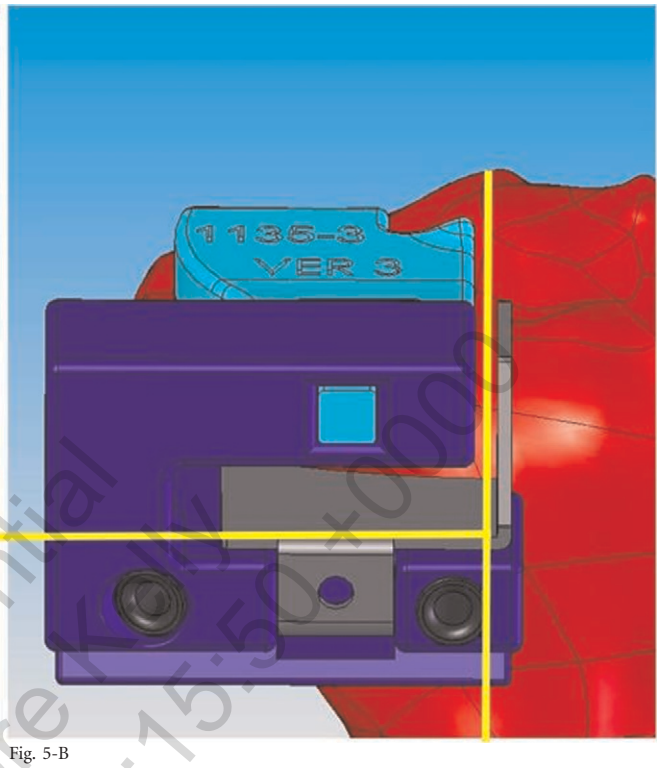

Fig. 5-B

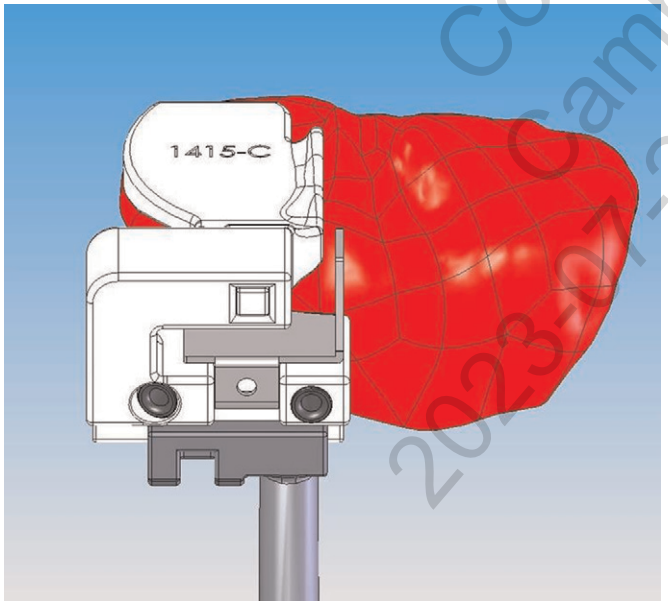

Fig. 5-C

Figs. 5-A, 5-B, and 5-C The cutting block is attached to the navigation chip, which contains the mechanical information of all three planes—the posterior slope (Fig. 5-A), the sagittal cut (Figs. 5-B and 5-C), and the horizontal cut 90° relative to the tibial mechanical axis (Fig. 5-B).

condyle and the tibial plateau are removed. Since the implant is designed to the surface of the femoral subchondral bone and has a maximal thickness of 3.5 mm, it basically replaces the hyaline cartilage. All cartilage inferior to the linea terminalis is removed. This is facilitated with use of a curved elevator, an osteotome, or a ring curette. A notchplasty is performed and the femoral iJig is placed on the condyle. The femoral iJig is used to verify complete removal of all osteophytes. The surgeon confirms that the femoral iJig conforms to the individual subchondral surface of the condyle after the cartilage has been completely removed.

Balancing the Knee

All hyaline cartilage is removed from the tibial plateau to prepare for the placement of the individualized tibial navigation chip (Fig. 3) and to balance the knee. The minimum thickness is 3.5 mm, representing the thickness of the femoral component, with 1-mm increments. The blocks contain the

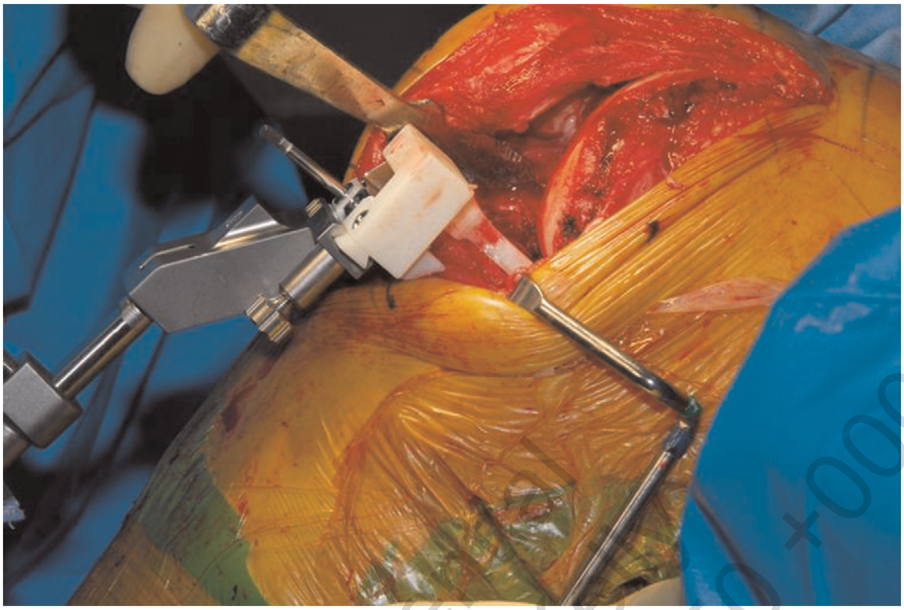

Fig. 6
The cutting block is attached to the extramedullary alignment guide and, while protecting the medial collateral ligament with a retractor, the horizontal tibial cut is completed.

information from all three planes relative to the tibial mechanical axis and determine the amount of tibial resection. The thicker the block, the less tibial bone is resected. The square docking block of the navigation chip (Fig. 3), which attaches to the tibial cutting block, moves 1 mm superiorly in 1-mm increments; for each 1-mm increase, 1 mm less bone is resected from the tibia. The minimum tibial component composite thickness (metal-backed tray plus polyethylene insert) is 8 mm.

Assuming that the tibial cartilage thickness is 3 mm, a maximum tibial resection of 5 mm is required for the 8-mm tibial component. Frequently, less resection is required. The navigation chips are placed and the knee is held in 15° to 30° of flexion to assess its laxity. This process is repeated until the surgeon determines the ideal laxity (Figs. 4-A and 4-B). If osteophytes have not been properly resected, the joint may not widen sufficiently with stress and, as a consequence, excessive tibial resection may occur. Since the navigation chip is based on the osseous tibial surface, the surgeon needs to ensure that all cartilage has been removed to avoid deviation from the pre-planned navigation. The laxity of the joint should be approximately 1 mm medially and 1 to 2 mm laterally when the knee is in slight flexion. If the laxity is too great (Fig. 4-A), thicker chips are inserted (Fig. 4-B); if too loose, thinner chips are inserted to complete the balancing step.

Axial and Sagittal Tibial Cuts

Once the appropriate chip has been selected, the knee is held in 90° of flexion and the tibial cutting block is attached to the navigation chip and the extramedullary alignment guide (Figs. 5-A, 5-B, and 5-C). The alignment guide is placed on the leg (Fig. 6) and attaches the tibial iJig to the navigation chip. The tibial iJig sits flush to the anterior portion of the tibia, preferably with use of only the medial pin hole. The surgeon then performs the sagittal tibial cut. The reciprocating saw blade can be left in place to protect the anterior cruciate ligament while the axial cut is made. The horizontal tibial cut is completed, and the tibial iJig is removed.

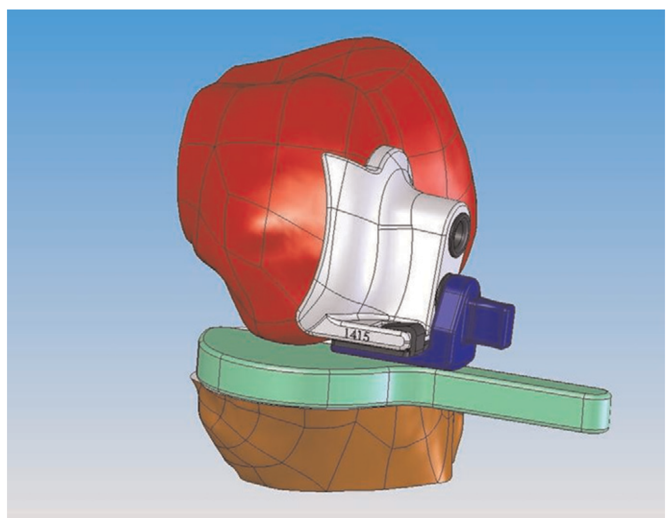

Fig. 7
After complete removal of all cartilage and osteophytes, the femoral iJig is placed on the condyle. The pin holes are drilled, and the posterior condylar resection is completed. The thickness of the L-guide (blue) represents the amount of bone to be removed from the posterior femoral condyle.

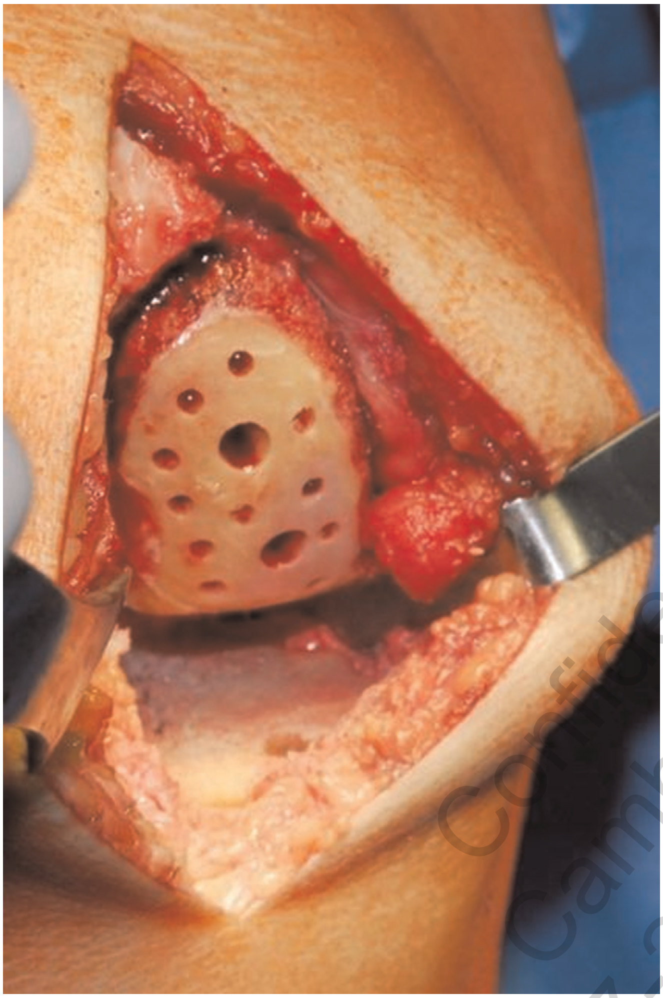

Fig. 8
Final femoral preparation: preparation of the anterior recess; rounding of the edge, transitioning to the flat posterior cut; and drilling multiple small holes for cement interdigitation.

Femoral Preparation

The femoral iJig (Fig. 7) is placed on the distal part of the femur, and complete removal of all cartilage and all osteophytes is verified. Two important considerations are that the peg holes are drilled with the knee positioned in 15° of flexion relative to the sagittal anatomic femoral axis (Fig. 1) and the amount of bone to be removed from the posterior condyle is 3 to 5 mm (Fig. 7). The thickness of the L-guide represents the amount of bone to be removed and helps the surgeon to ensure appropriate posterior condylar resection. The pin holes are drilled, and the posterior condylar resection is completed. The superior edge of the femoral drill is then marked. The femoral preparation is completed by preparing an anterior recess with use of a curved osteotome or a 5-mm burr (Fig. 8). The anteriormost edge of the component submerges 3.5 mm below the subchondral bone plate. The taper starts 10 mm inferior to the anteriormost edge. The transition from the subchondral bone to the flat posterior cut should be rounded with use of a file, burr, or osteotome. Smoothing of the edge and the placement and depth of the recess are verified with the femoral trial component. For better cement interdigitation, multiple 1.5 to 2-mm holes are drilled.

Verification of Balancing and Tibial Preparation

The trial femur and tibial spacer blocks are inserted (Fig. 9), and joint play is assessed throughout range of motion. It is important to avoid knee tightness to prevent overcorrection. If joint laxity is not sufficient, an additional amount of bone is removed from the tibia by mounting the tibial cutting block on the alignment guide. If the joint is too loose, the surgeon may insert the 10-mm spacer block, which corresponds to the thicker 8-mm polyethylene insert for the tibial trial, and evaluate balance in flexion and extension.

Trial and Cementing of Implants

The final tibial preparation is then completed. The tibial template is placed on the tibia and both holes are drilled, pinning the anterior hole only to accommodate instruments for the upcoming pin-hole preparation (Fig. 10). The position for the posterior pin is marked. The template is removed and the pin inset is created with use of a 5-mm osteotome. The tibial implant is designed to match the patient's anatomy and cover the tibial cortex without overhang or underhang. The outline of the tibial template provides visual confirmation of the match. The tibial trial component is used, and complete seating of the real component is verified. The surgeon performs a final trial with use of the trial femoral component and the trial tibial insert.

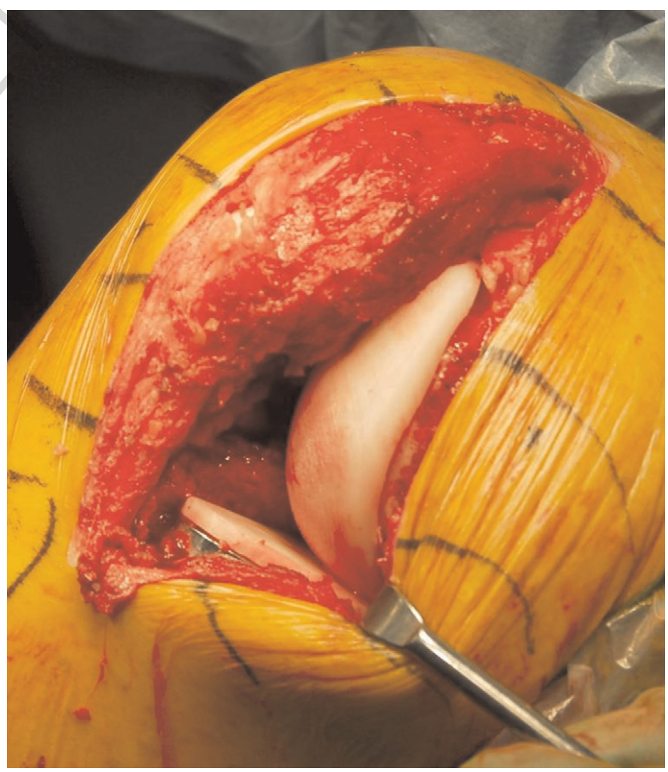

Fig. 9
Trial components are inserted for a final assessment.

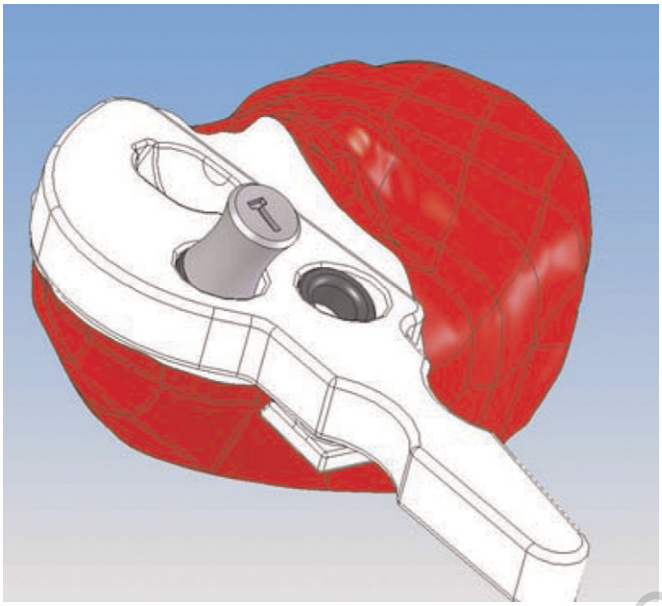

Fig. 10
An individualized tibial template is used to complete the tibial preparation.

The tibial tray is cemented first. All extruded cement is removed, and the femoral component is inserted. The knee is brought into 45° of flexion and the trial tibial insert is placed, allowing equal pressurization of the femoral component in flexion and in extension during polymerization. The trial insert is taken out, residual extruded cement is removed, and the final polyethylene insert is inserted. As another option, the surgeon may also insert the final polyethylene insert before inserting the femoral component. The arthrotomy and wound is closed in a standard fashion.

Discussion

The indications for unicompartmental knee arthroplasty have been outlined by several authors[4,12,13]. Surgeons have been offering unicompartmental knee arthroplasty to younger and more active patients as a more conservative treatment option for unicompartmental knee arthritis. Pennington et al.[14] reported excellent results in younger and more active patients, with a survivorship of 92% over an average follow-up period of eleven years. Patients in that study had an average weight of 90 kg (range, 50 to 116 kg), but weight restrictions are controversial in the literature. Tabor et al.[15,16] found no change in survivorship with use of a Marmor-styled resurfacing femur and an all-polyethylene tibia, regardless of weight. Murray et al.[17] and Argenson et al.[18] did not believe that weight is a contraindication for unicompartmental knee arthroplasty, and, recently, Swienckowski and Pennington[19] recommended no weight restrictions up to a body mass index of 45.

It remains unclear whether these limitations are related to surgical technique or implant design, such as lack of optimal coverage of the entire cortical rim. Fitzpatrick et al.[20] showed that two commercially available unicompartmental implants can cover at best 67% of the cortical bone and concluded that there is room for improvement in the current designs for both the medial and lateral compartments. However, after calculating a theoretical implant design, they concluded that the maximum cortical coverage achievable with an optimized off-the-shelf design would be only 75%. These shortcomings can be resolved with a personalized component that is designed to cover the entire tibial cortex. Cortical bone is forty times stronger than cancellous bone[21], and this is likely to be the reason why some components[4] have higher failure rates in heavier patients, since they lack coverage of the majority of the cortex.

Resurfacing the femur and removing the appropriate amount of bone from the tibia for a 9-mm all-polyethylene tibial component has been shown to result in excellent long-term results, and it restores the anatomic joint line. Cartier et al. reported a 93% survival rate with a follow-up of between ten and twelve years[22]. The concept of the patient-specific unicompartmental arthroplasty reported here is similar. Since the femoral component thickness (3.5 mm) matches the average cartilage thickness, the femoral surface is anatomically restored. This can require a tibial resection that may be 1 to 2 mm more in selected patients with little joint laxity as compared with a technique in which a minimal tibial cut is made[4,13] by moving the femoral component farther in the superior and anterior position and by resecting more bone from the posterior and distal femoral condyles. Moving the joint line superiorly with this technique may change normal knee kinematics, and its impact on long-term results remains unclear.

Both short-term and long-term follow-up studies of this implant are needed to estimate the impact of surgical technique on early failure modes and the potential benefit on long-term survivorship. Long-term results using an off-the-shelf resurfacing femoral component have shown excellent results at a minimum follow-up of ten years[22].

This new technique requires an additional computed tomographic scan with slices through the hip and ankle, adding additional radiation exposure. Magnetic resonance-based imaging, which will be available very soon, will avoid the additional radiation exposure. Another disadvantage of this implant is a manufacturing time of six weeks. However, we currently accept a similar delay for dental crowns, other implants, and transplant surgery. In most joint practices, surgery is not scheduled immediately, but rather within a period of six to eight weeks after the initial office visit, within the time frame for the production and delivery of the implants and instruments.

This new approach needs to be compared with computer-assisted surgical techniques. The potential benefit of the pre-navigated jigs lies in addressing the disadvantages of computer-assisted techniques: eliminating the potential risk of creating tibial or femoral fractures during the placement of guides, and shortening surgical time by eliminating the data-referencing step. However, the accuracy of the pre-navigated jigs remains to be determined.

In conclusion, the introduction of personalized three-dimensional image-derived resurfacing implants as well as personalized single-use instrumentation has the potential to change common surgical practice for unicompartmental knee arthroplasty. Patient-specific resurfacing implants enable a femoral bone-preserving approach with enhanced cortical bone support on the tibia, overcoming critical design limitations of commercial off-the-shelf implants. Patient-specific resurfacing implants may restore normal anatomy and joint function and may improve the clinical results. ■

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