Patient-specific Total Knee Arthroplasty: A Novel Technique and Implant

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Abstract: Although total knee arthroplasty (TKA) is an increasingly successful procedure, technical methods to improve implant alignment continue to evolve. Patient-specific jigs are gaining popularity as an efficient means to improve alignment and provide an alternative to conventional jigs and computer navigation. Patient-specific TKA implants combine use of these jigs with an implant, based on computed tomography imaging that tightly conforms to the patient's unique 3-dimensional topography. Proposed benefits include decreased incidence of implant overhang and sizing issues, better approximation of osseous geometries, and improved soft-tissue tensioning with the theoretical benefit of more natural knee kinematics. We describe a technique for implantation of a novel patient-specific jig and TKA implant system and discuss benefits and potential critiques of its use.

Key Words: total knee arthroplasty (TKA), patient-specific implants, patient-specific instrumentation, ITotal, computer tomography (CT)

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HISTORICAL PERSPECTIVE

Since its genesis in the early 1970s, total knee arthroplasty (TKA) has evolved into an exceedingly successful procedure, effectively reducing pain and improving function for arthritic patients.[1–5] Conventional implant geometries are based on anthropometric population norms that accommodate most knees and a broad spectrum of subtle anatomic variations. Although in most cases an adequate fit can be achieved, mismatch occurs with some frequency and can impact clinical outcome. Mahoney and Kinsey[6] evaluated 437 TKAs and found that femoral overhang of at 3 mm occurred in 57% of cases. This was associated with clinically significant knee pain 2 years postoperatively and was related to use of larger implants, short stature, and female sex. Conventional TKA geometries do not accommodate all ethnic anthropometric variations. Korean patients have a different mediolateral/anteroposterior (ML/AP) ratio compared with the whites. In this population, smaller knees have been shown to have a larger ML/AP ratio and larger knees have a smaller ML/AP ratio. This may result in ML undercoverage and overcoverage, respectively, when using TKA components based on white femora.[7] Individualized implants based upon preoperative computed tomography (CT) not only match individualized j-curves but also the varied femoral and tibial osseous geometries observed in different sexes and/or ethnicities.[8] Restoring patient's natural geometries may impact soft-tissue balancing and tensions posing a theoretical benefit of reapproximating natural knee kinematics and subsequently, proprioception; an intriguing although unproven hypothesis.

Use of conventional jigs for TKA is a reliable, yet gross method to restore mechanical and anatomic lower extremity alignment.[9] Critics argue that use of these jigs relies on the surgeon's subjective discretion in defining the orientation of the osseous cuts that leads to an inherent degree of inaccuracy and imprecision. Such issues are clearly impacted by the particular system and the technical prowess and experience of the operator. Because of the profound societal impact of hip and knee arthroplasty and the associated rising incidence of revisions and escalating economic burden, many believe that a more accurate system is necessary to negate the long-term sequelae of implant malalignment. A method to improve alignment has been long sought for in the arthroplasty profession and is evident by the emergence of technologies such as computer-assisted navigation (CAN), robotic assisted surgery, and custom cutting jigs. CAN is supported by some authors to improve accuracy and decrease the incidence of malaligned "outliers." Critics of this technique cite high monetary costs for navigation equipment and software as well as increased operative time[10] with uncertain clinical outcome benefits. Patient-specific instruments (PSIs) have emerged over the past several years as a viable competitor to CAN. PSIs are based on CT or magnetic resonance imaging and are fabricated before the operation; obviating the need for intraoperative preparation that is required for CAN. Only the jigs required for the operation are included in the surgical kit, limiting the equipment and time necessary for preparation; potentially improving operating room turnover time[11] (Fig. 1). Early reports of PSI are promising with some series reporting excellent accuracy and precision, reduced blood loss, and decreased operative times.[12–14] One criticism of this technology is the added cost of the CT or magnetic resonance imaging required for jig fabrication. Long-term clinical outcome and survivorship data are necessary to determine if the improved precision gained with PSI results in a lower revision rates that offset the added cost of advanced imaging to fabricate these jigs.

INDICATIONS AND CONTRAINDICATIONS

The indications for patient-specific TKA are similar to those for conventional cruciate retaining implants. Patients should have a diagnosis of osteoarthritis, posttraumatic arthritis, osteonecrosis, or a systemic inflammatory arthropathy affecting the knee. All conservative measures should be trialed first including activity modification, walking assistive devices (cane, crutches, etc.), oral anti-inflammatories, and injectable agents such as viscosupplementation and corticosteroids. Absolute contraindications to individualized TKA (iTKA) include an active knee infection, significant soft-tissue deficiencies, femoral and/or tibial osseous deficiencies, knee instability, varus or valgus deformity exceeding 15 degrees, and posterior cruciate incompetence.

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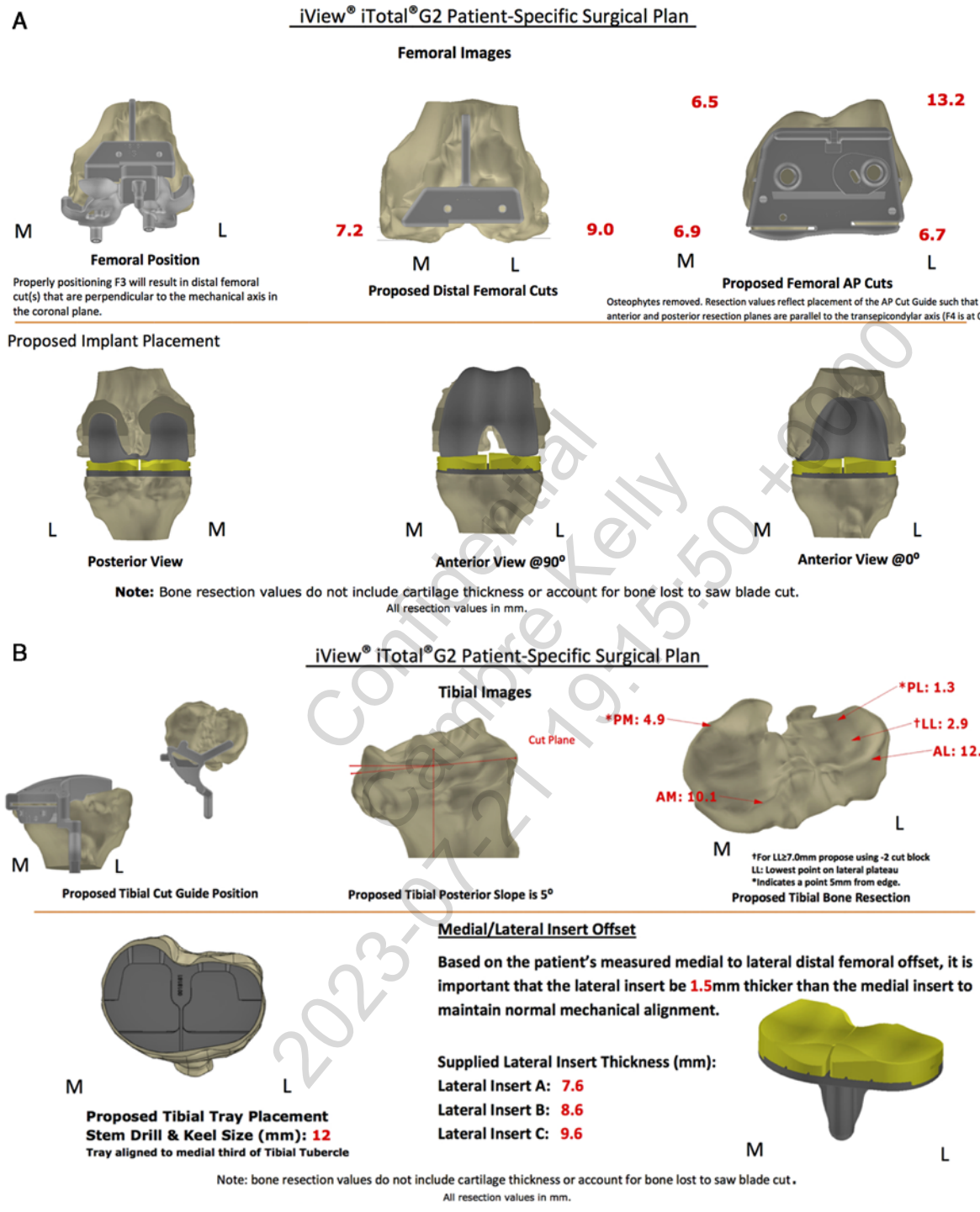

FIGURE 1. Computer-aided design of patient-specific cutting jigs and individualized total knee arthroplasty femoral (A) and tibial (B) implants.

PREOPERATIVE PLANNING

The Conformis patient-specific total knee system utilizes a proprietary individualized fit (iFit) technology that converts CT data into an iTKA implant that uniquely conforms to the 3-dimensional topography of the patient's knee. At least 6 weeks before the operation, a CT scan of the affected knee is obtained using community available CT scanners according to the Conformis protocol. Proprietary algorithms, which take into account the hip and ankle, convert the CT data to an implant and jigs that restore the patient's mechanical axis. A computer-aided design file (Figs. 1A, B) is created. The jigs are constructed of a high-grade plastic, and the implants are

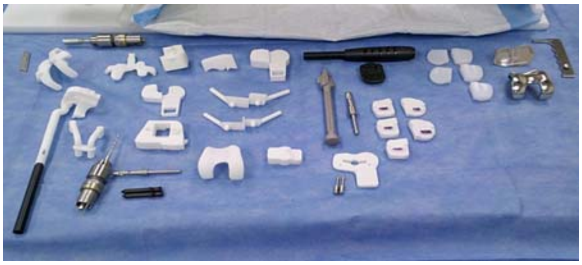

FIGURE 2. Patient-specific jig and implant operative set-up before a individualized total knee arthroplasty case.

constructed of cobalt-chromium-molybdenum using direct digital processing.

The individualized jig PSIs are disposable, custom jigs fabricated using the same technology used to create the iTKA implants. The jigs are created to tightly conform to the patient's anatomy thereby improving the precision of the osseous cuts. They are delivered with the implant in a sterile package therefore, limiting the complexity and time required for preoperative set-up and postoperative maintenance; improving the efficiency of the hospital staff. The implant kit is delivered to the respective hospital the weeks before the date of surgery and includes the individualized jigs and iTKA; all the components needed to perform the operation (Fig. 2). Three medial and lateral polyethylene components (medial size—6, 7, and 8 mm; lateral—A, B, and C) are included in the kit and provide the ability adjust balancing of the final implant.

SURGICAL TECHNIQUE

Surgical Approach

Implantation of custom TKA implants can be accomplished according to conventional TKA approaches including medial parapatella, subvastus, midvastus, and trivector approaches. The patient is positioned supinely with a leg support so that it can be flexed to 90 degrees during the operation. We utilize a trivector approach that involves a midline knee incision 4 cm proximal to the patella down to the medial aspect of the tibial tubercle. A vertical arthrotomy is made starting a half-centimeter medial to the quadriceps tendon down distally around the medial aspect of the patella and to the tibial tubercle. Appropriate medial and lateral soft-tissue releases are performed to adequately expose the knee.

Distal Femoral Resection

Femoral osteophytes are not removed because they are crucial for the appropriate fit of the femoral jigs. The femoral positioning jig (F1) is positioned on the distal femur and a coring is used to remove the cartilage in the center of both condyles (Fig. 1). F2, which is attached to the distal femoral cutting block F3 is placed referencing the distal femur off these 2 circular areas without cartilage (Fig. 2) and seated securely on bone within the cartilage voids. Two pins for the distal cutting block F3 are placed, and additional 2 pin holes are drilled using F2 which later will be utilized to place the AP cutting block F4. F2 is removed and the distal femur cut (Figs. 3A, B). In patients with a larger varus or valgus condylar angle a small step cut of 2 to 4 mm is required to reduce the amount of bone resection to match the distal femur anatomically.

Tibial Resection

The leg is flexed to 90 degrees and the tibial jig assembly (T1) is positioned against the anterior tibia. The outline is marked on the tibial and using a curette the cartilage is removed. The inner surface of this extramedullary jig contours to the tibia and a tibial stylus provides additional contact points to verify the planned amount of bone resection of medial and lateral tibial plateaus. Once jig alignment is verified with an alignment rod, 2 Steinmann pins are inserted through T1 into the anterior tibia (Fig. 4). The proximal tibial resection is made with an oscillating saw with care to preserve the posterior cruciate.

Assess Extension and Flexion Balance

After the distal femoral and proximal tibial cuts are made, femoral and tibial osteophytes are removed and the extensor spacer block (T3) is positioned between the distal femur and proximal tibia (Fig. 5A). The knee is assessed for appropriate balance while valgus and varus loads are applied. An alignment rod can be attached to T3 to assess coronal alignment. The knee is positioned in 90 degrees of flexion and the flexion spacer (T4) is positioned between the tibial plateau and posterior femoral condyles. Appropriate tension is assessed while applying varus and valgus loads to the knee (Fig. 5B) in flexion and surgeon should assess, whether flexion gap is stable medial and lateral. If the lateral flexion gap is loose, more external rotation of the femoral component can be added later to decrease laxity.

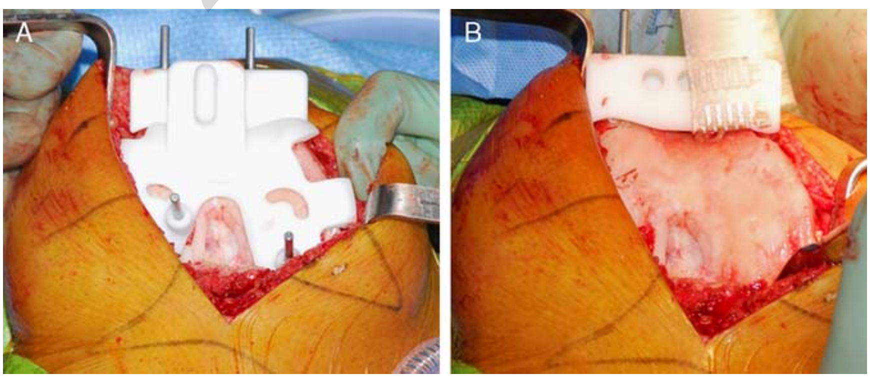

FIGURE 3. The distal femoral jig (F1) has been positioned and secured into place with pins (A) and the distal femoral resection being performed (B).

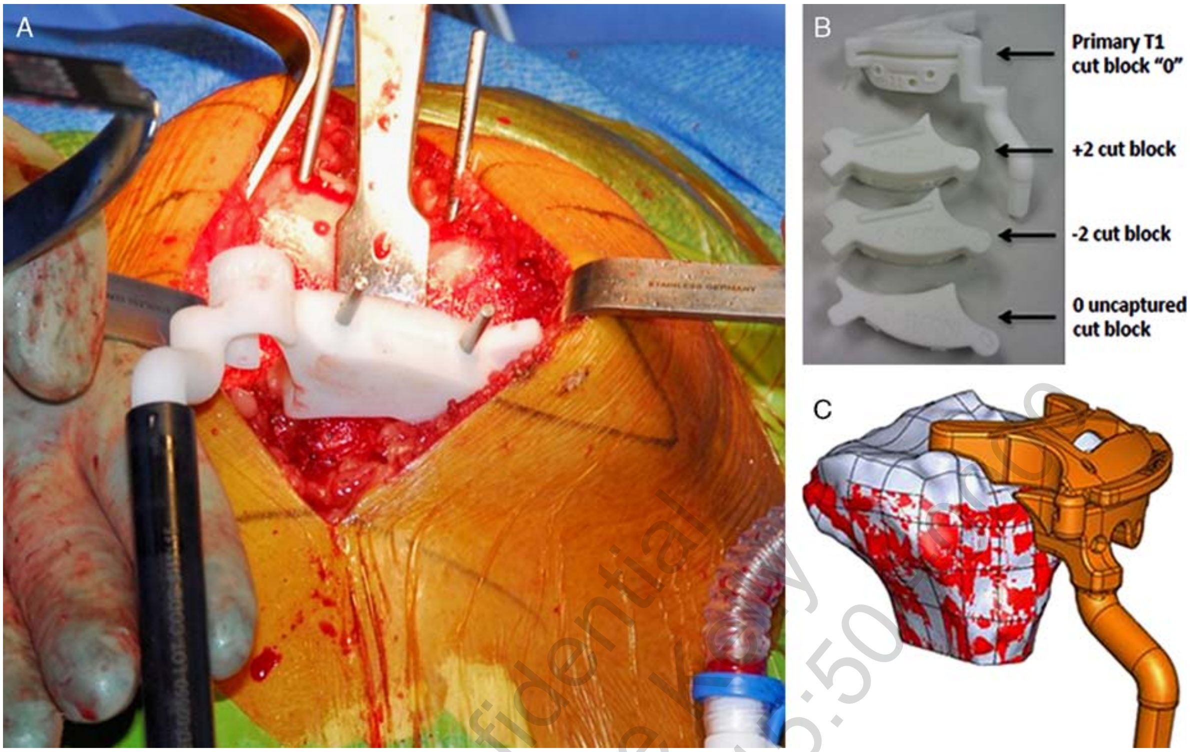

FIGURE 4. A, The tibial resection cutting guide (T1) is secured to the proximal tibia in preparation for the tibial resection. B, Different T1 cutting attachments provides versatility of the proximal tibial resection. C, Computer-aided design image demonstrating placement of the T1 jig placed on the proximal tibia.

Tension Algorithm

Tight in Flexion and Extension

Resect an additional 2 mm from the tibia using the T1 jig with the "recut" clip removed.

Tight in Extension and Balanced in Flexion

Resect an additional 2 mm from the distal femur using the +2 F4 jig.

Tight in Flexion and Balanced in Extension

Place the T1 jig in its original position and recut the posterior tibia thereby increasing the tibial slope.

Loose in Flexion and Extension

Thicker polyethylene inserts are available if the joint is loose in this scenario.

Anterior and Posterior Femoral Resection

For the placement of the AP cutting block (F4) 2 different techniques are used: measured resection or a gap balancing technique. For the measured resection technique, the 2 pin holes which were drilled using (F2) are placed and the (F4) cutting block is seated. There is the option to place the AP block (F4) either neutral (0 degrees) or up to 5 degrees of external rotation (Fig. 8). For the gap balancing technique, the AP cutting block (F4) is placed on the flexion spacer block.

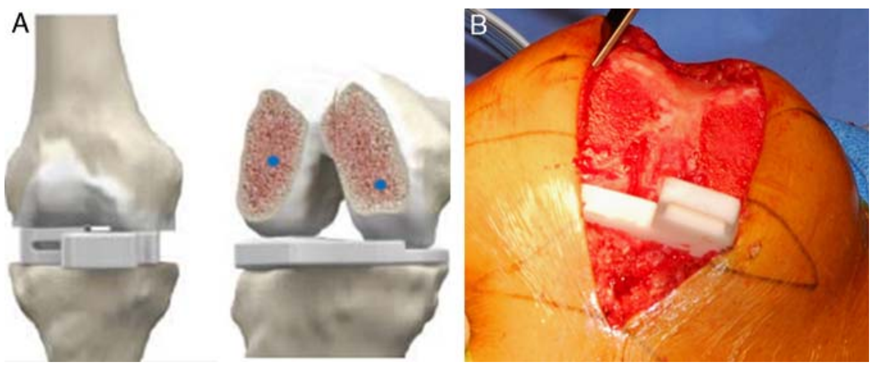

FIGURE 5. Soft-tissue balancing is assessed in extension (A) and flexion (B) with the T3 and T4 spacer blocks, respectively.

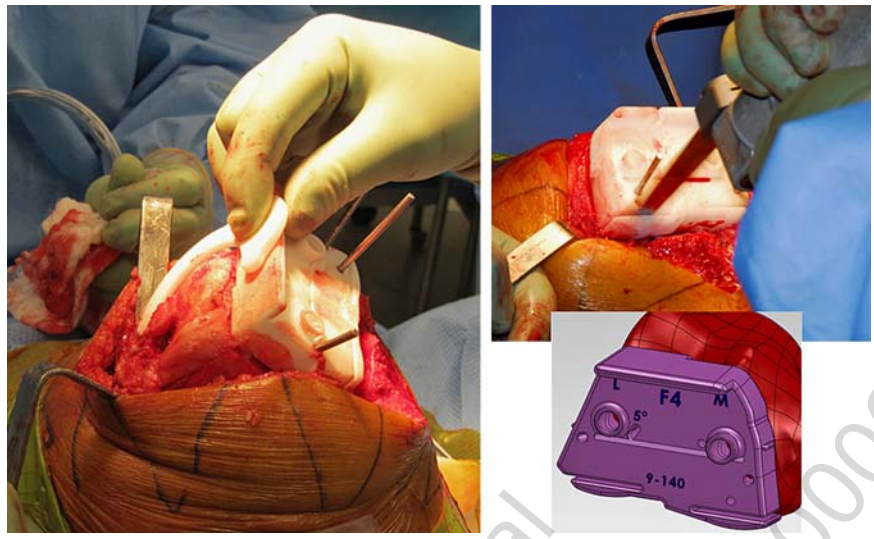

FIGURE 6. Placement of the F4 anteroposterior femoral cutting jig.

The anterior femoral cut can be assessed with an angel wing to ensure anterior femoral notching does not occur (Fig. 6). Also, appropriate position of F4 is verified by ensuring that the profile of the jig matches the profile of the posterior femoral condyles. F4 is secured with 2 pins, the lugholes are drilled, anterior, posterior femoral resections and the anterior chamfer cuts are performed. F4 is then removed and F5 and F6 positioned on the distal femur to complete the chamfer cuts.

Tibial Preparation

After ensuring, proximal tibia osteophytes are removed, the tibial and femoral trials are inserted, and balancing verified. The tibial trial is then placed anatomically on the tibia, pinned, and the final preparation completed using a drill and a keel punch (Fig. 7).

Patella Resection and Preparation

The patella can be prepared before preparation of the tibia and femur to facilitate exposure or afterwards. Before resection, a caliper is used to measure the native thickness and the amount of bone to be resected. The resection can be performed free hand or using the resection guide included in the set. Implant sizes include 32, 35, 38, and 41 mm and correlate with 6, 7, 8.5, and 10 mm of polyethylene thickness, respectively. After the patella resection, the patella clamp is used to prepare the peg holes.

Trialing

The femoral and tibial trials are positioned and the "A" lateral trial insert (6 mm + the distal femoral resection thickness) and 6-mm medial polyethylene trial insert is inserted. Femoral and tibial ostephytes are no longer needed and can be removed as needed to ensure adequate soft-tissue tensioning. The femoral, tibial, and polyethylene trials are positioned and knee tension can be assessed with varus and valgus loads throughout the range of motion. An 8-mm medial trial insert and B and C lateral inserts (each add 1 mm to thickness) are available if needed to increase

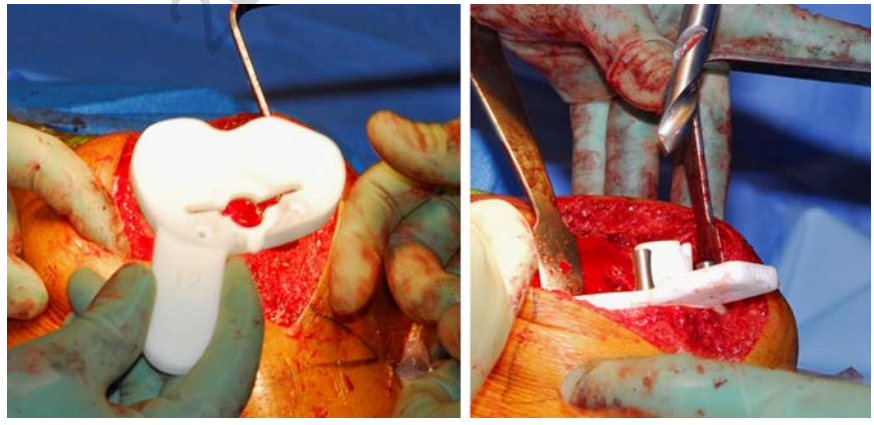

FIGURE 7. The T5 tibial preparation jig is positioned appropriately covering the tibial plateau, and the proximal tibia is prepared with 12-mm drill and keel punch.

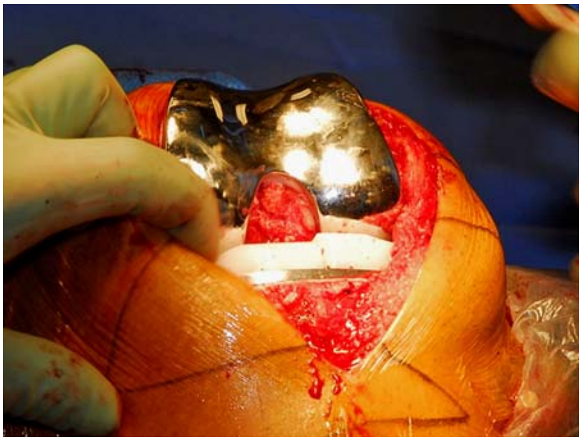

FIGURE 8. Image after implantation of final individualized total knee arthroplasty components.

knee tension. In the event that the knee is tight in extension, flexion, or both, standard soft-tissue releases can be performed to appropriately balance the knee. Once appropriate balancing is achieved, the trials are removed and the osseous beds are irrigated of marrow and blood in preparation for cementation. Cement should be prepared according to standard manufacturer recommendations and applied to the osseous bed and implants. The components are implanted and impacted to ensure cement interdigitation (Figs. 8, 9). Inspection of the entire surgical bed is performed to ensure that all excess cement is removed. The wound is irrigated and closed in layers.

Postoperative Protocol

We utilize a multimodal pain protocol consisting of oral and parenteral anti-inflammatories and analgesics. Patients weight bear immediately, start physical therapy, including active and passive range of motion and start walking 100 feet on the day of surgery. The vast majority is discharged home on POD#2, return to clinic at 1 week postoperatively for a wound check and then 12 weeks to ensure they are progressing well with their motion and strength and to document any surgery-related complications.

FUTURE OF THE TECHNIQUE

The Conformis iTKA is a novel, custom knee arthroplasty system that provides an efficient and effective method to successfully treat knee arthritis. Certain benefits of this system include the ease of use, reduced bleeding due to the all-extramedullary technique, complete coverage of cancellous bone, reduced operative set-up time, and tight conformity of the implant with the patient's anatomy. There are reasonable critiques of this concept that must be addressed in order for it to be successfully integrated into common orthopedic practice. First, the implant itself has only been in existence for 2 years and clinical studies are necessary to prove its long-term effectiveness and longevity. In addition, the excess costs of advanced imaging must be justified. Long-term studies with adequate power are needed to demonstrate a significant increase in implant survival and outcomes compared with conventional methods. Measures accounting for financial benefits of improved case set-up time and operative times should be included in analyses to more precisely define potential cost benefits. Despite these critiques, patient-specific jigs and implants do offer certain, inherent benefits that prompt clinical interest and warrant further investigation.

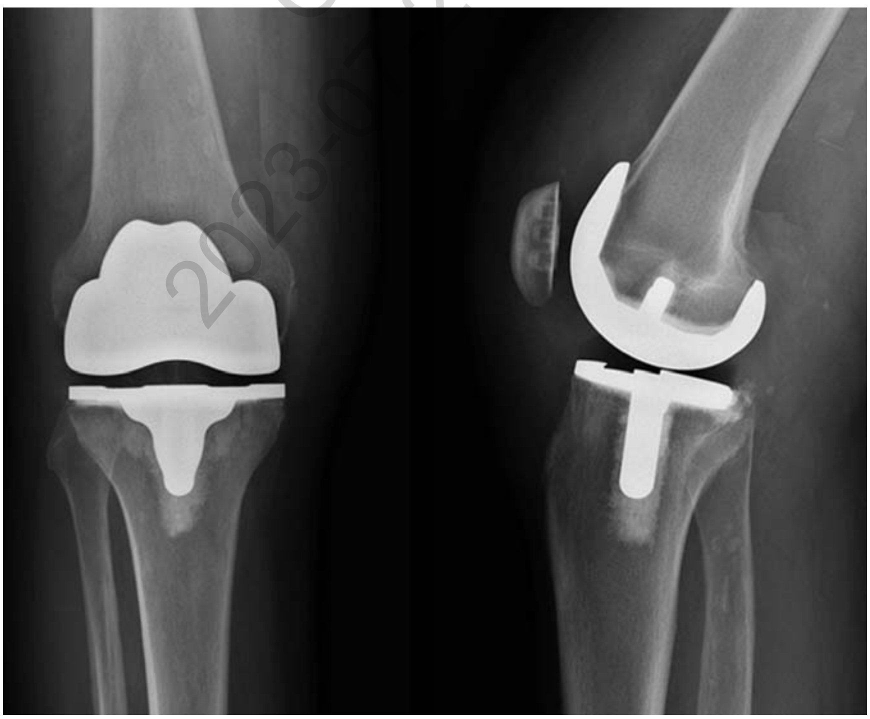

FIGURE 9. Postoperative anteroposterior and lateral radiograph of individualized total knee arthroplasty implant.

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