THA with Use of Patient-Specific Resurfacing Jigs and a Novel Customized Implant Design

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Abstract

» Conventional total hip arthroplasty (THA) largely remains an unguided procedure dependent on the ability and experience of the surgeon. New technologies, such as patient-specific instrumentation and robotics, have shown promising results in improving implant positioning, which has the potential to improve patient outcomes.

» The use of off-the-shelf (OTS) implant designs, however, limits the success of the technological advances since they are unable to recreate the native anatomy of the joint. The inability to restore femoral offset and version or the presence of implant-related leg-length discrepancies often lead to suboptimal surgical results that increase the risk of dislocation, fractures, and component wear, compromising postoperative functional outcomes and implant longevity.

» A customized THA system, whereby the femoral stem is designed to restore patient anatomy, has recently been introduced. The THA system uses computed tomography (CT)-derived 3D imaging to create a custom stem, patient-specific component placement, and patient-specific instrumentation that matches the patient's native anatomy.

» The purpose of this article is to provide information on the design and manufacturing process of this new THA implant, to illustrate the associated preoperative planning, and to describe the surgical technique; 3 surgical cases are presented.

Since Sir John Charnley pioneered the operation, total hip arthroplasty (THA) has been one of the most successful orthopaedic procedures. Despite this success, patient dissatisfaction and litigation do still exist[1,2]. Studies have shown an 89% patient-satisfaction rate post-THA, but with >370,000 operations performed annually in the United States, >40,000 people are unsatisfied with the procedure[3,4]. Additionally, >75% of arthroplasty surgeons have been named in a malpractice suit, with infection, nerve damage, and leg-length discrepancy (LLD) the leading causes[5,6].

While the factors that contribute to patient dissatisfaction are not clearly elucidated, the current issues of LLD, inaccurate restoration of femoral offset, and acetabular cup malpositioning have been associated with poor outcomes[7,8]. Traditional THA has 3 primary shortcomings. First, preoperative planning can be compromised by the limitations of 2-dimensional (2D) imaging, with studies showing more accurate results using computed tomography (CT) scans[9]. Intraoperatively, the

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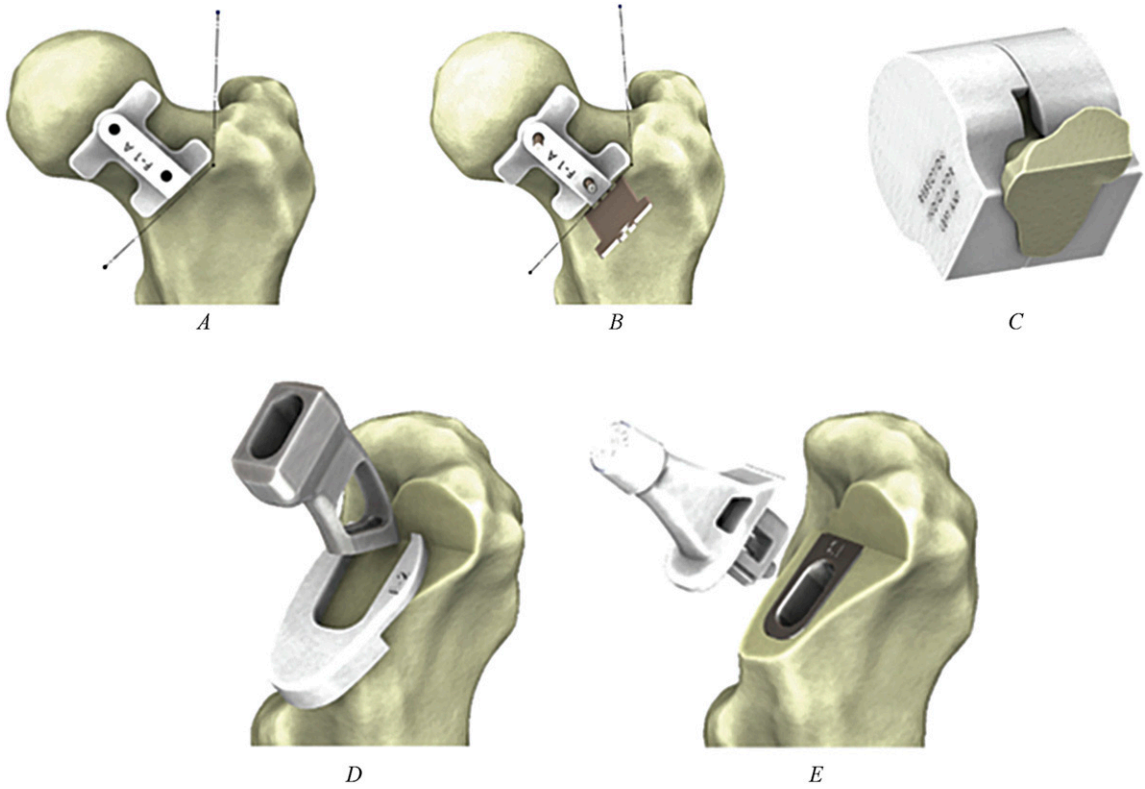


Fig. 1

Patient-specific preparation of the femoral shaft is facilitated by anatomical bone-resection jigs. The F-1A jig (**Figs. 1-A and 1-B**) is designed to fit the patient-specific anatomy of the femoral neck to ensure the planned bone-resection height. The resected bone should be flush when placed in the resection indicator model (**Fig. 1-C**) for collared stems, whereas a slightly divergent neck resection is allowable for non-collared stems. The F-2 jig is placed flush against the resected neck surface and against the remaining medial neck. It serves as a guide for femoral broaching to ensure the planned shaft version of the implant (**Fig. 1-D**). The final broach size corresponding to the implant size, and a patient-specific trial neck can be used to check leg length and stability through full range of motion prior to placing the patient-specific femoral stem component (**Fig. 1-E**). (Reproduced with permission from Conformis, Inc.)

procedure remains unguided, potentially leading to difficulties achieving the preoperative plan[10,11]. Finally, the use of off-the-shelf (OTS) implants may limit the surgeon's ability to consistently recreate patient-specific anatomy.

As new technology has emerged, results have shown that CT imaging is superior for predicting implant size when compared with traditional 2D methods[12-14]. Studies have also shown that 3D planning is significantly more accurate in planning leg length and offset[15]. The use of CT has also been shown to improve the results of less experienced surgeons[11,12].

Unlike total knee arthroplasty (TKA), conventional THA largely

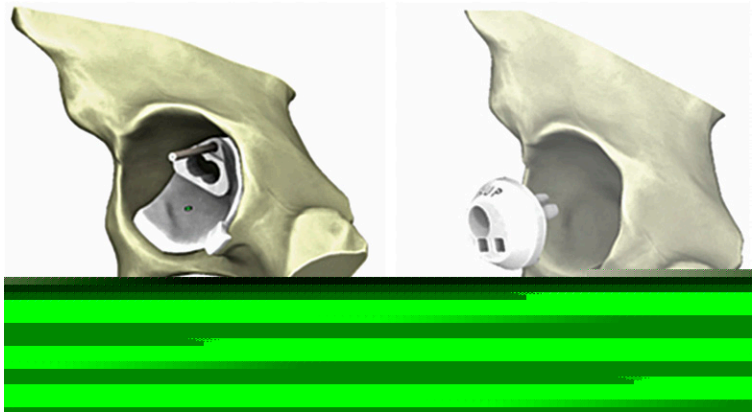


Fig. 2

To control acetabular reaming depth and prevent excessive medialization of the acetabular cup, the patient-specific A1 jig (**Fig. 2-A**) facilitates accurate placement of the A2 jig (**Fig. 2-B**), which serves as a position guide and depth stop for the stage-1 reamer. (Reproduced with permission from Conformis, Inc.)

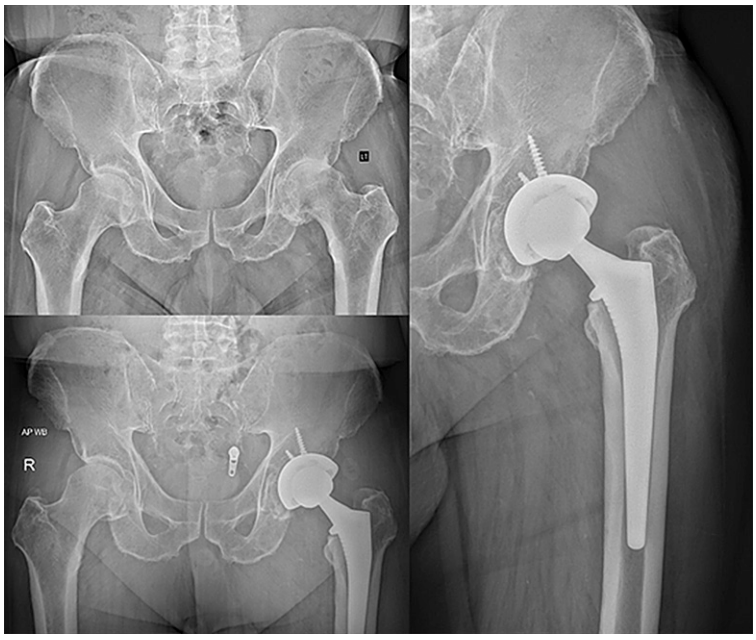


Fig. 6-A

Figs. 6-A, 6-B, and 6-C Case 2. **Fig. 6-A** Anteroposterior radiographs of the hip revealed severe osteoarthritic changes of the left hip joint. Patient-specific THA was performed, restoring a long femoral-neck length in slight varus position.

specific jig for additional stability. The A1 jig, when fit inside the acetabulum, is utilized to drill 2 lug holes and a pilot hole into the patient's acetabulum. The A1 guide is then removed.

The A2 jig, with 2 pegs, is then placed in the acetabulum based on the position of the 2 lug holes (Fig. 2-B). This jig serves as a depth control to prevent over-reaming and excessive medialization and as a centering position guide for the stage-1 reamer.

The stage-1 reamer only prepares the rim of the acetabulum; that is, the cutting edges of the reamer are not fully distributed around the hemisphere but only along the peripheral half of the acetabular cup surface (Fig. 3-A). Then the A2 jig is removed from the acetabulum, and the stage-2 reamer is used. This reamer only has cutting surfaces on the dome section (Fig. 3-B). The lack of cutting edges on the rim is intended to avoid eccentric reaming and to provide depth control to prevent over-medialization.

Next, the A3 jig is latched onto the rim of the acetabulum. To assure correct positioning, the A3 jig has pegs like the A2 jig that can fit into the lug holes that were prepared by the A1 jig. Its purpose is to highlight the true dimensions of the acetabulum, and it serves as a cup-positioning guide (Fig. 4-A). The A3 jig functions to highlight extraneous bone that may lead to impingement and dislocation. Three holes in this jig, matching the position of the screw holes on the acetabular component, may be utilized to mark the acetabulum for accurate screw placement and subsequent implant cup placement based on the preoperative plan. The final component can then be impacted in place. (Fig. 4-B)

A nylon trial liner can then be inserted and will allow the surgeon to test reduction before accepting the final component (Fig. 4-C). Once satisfied, standard ceramic or cobalt-chromium heads and several options of liners can be placed.

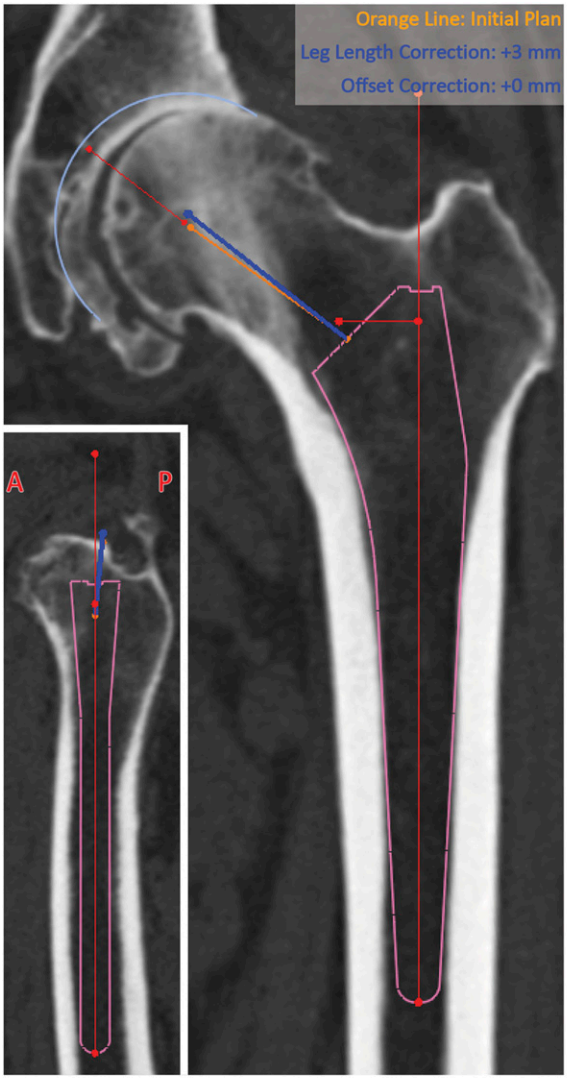
Case Presentation

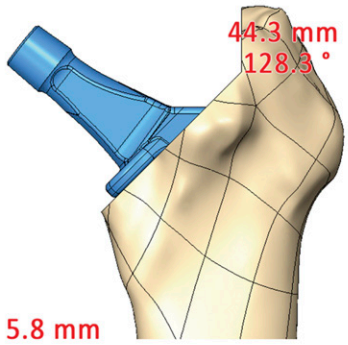
Case 1

A 68-year-old woman was indicated for right THA because of osteoarthritis uncontrolled by conservative management. Patient-specific implantation was chosen because of the patient's large CCD angle and short femoral-neck length. The iView surgical plan is described and is shown along with pre- and postoperative radiographs in Figures 5-A, 5-B, and 5-C. The procedure was performed via a direct anterior approach utilizing the C-THA system. The patient-specific stem (size 13 with a neck angle of 145°) was used along with a 50-mm acetabular cup secured by two 6.5-mm cancellous screws. A ceramic femoral head with a diameter of 36 mm and a femoral head length of 0 mm was selected to restore appropriate offset and leg length on the basis of intraoperative fluoroscopy and soft-tissue tension. The iView surgical plan templated this head size to increase offset by 2.3 mm and leg length by 3.3 mm. The arthroplasty components also included a 36-mm neutral liner. Postoperatively, the patient did well without any documented complications at the most recent follow-up of 3 months.

Case 2

A 77-year-old man was indicated for left THA because of chronic hip pain secondary to osteoarthritis. Patient-specific implantation was chosen because of a varus neck angle with a long neck length. The iView surgical plan is described and is shown along with pre- and postoperative radiographs in Figures 6-A, 6-B, and 6-C. The procedure was also performed via a direct anterior approach utilizing the press-fit C-THA. A patient-specific stem in size 14 with a neck angle of





FEMORAL VERSION MEASUREMENTS
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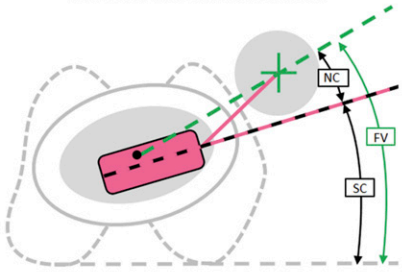
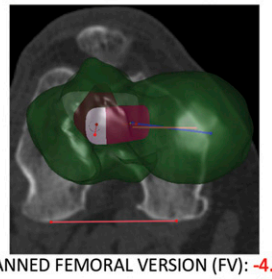


FV = FEMORAL VERSION
SC = STEM CONTRIBUTION TO FV
NC = NECK CONTRIBUTION TO FV



PLANNED FEMORAL VERSION (FV): -4.1 °
STEM CONTRIBUTION TO FV (SC): 0.4 °
NECK CONTRIBUTION TO FV (NC): -4.5 °

Resection Above Lesser Trochanter: 5.8 mm
Neck Version Compensation: -3.0 °
Neck/Head Length: 44.3 mm
Neck Angle: 128.3 °

Head Length Range: mm	25-29	29-40.5	40.5-44.5	44.5-48.5
Head Size: 36 mm	36 SH (-4)	36 MD (0)	36 LG (+4)	36 XL (+8)
Leg Length Correction: 3 mm	-5.0 mm	-2.5 mm	0.0 mm	2.5 mm
Femoral Offset: 50.5 mm	-6.3 mm	-3.1 mm	0.0 mm	3.1 mm

Fig. 6-B

The iView surgical plan for the femoral component determined a neck angle of 128.3° with a long neck length (44.3 mm). On the basis of the patient's anatomy and the determined individual anatomical stem and neck contributions to overall femoral version, a neck version compensation of −3° was incorporated in the femoral component.

128.3° was used along with a 57-mm acetabular cup secured by two 6.5-mm cancellous screws. A ceramic femoral head with a diameter of 36 mm and a length of +4 mm was selected on the basis of intraoperative fluoroscopy and soft-tissue tension. The iView surgical plan templated this head size to increase offset by 0 mm and leg length by +3 mm. The arthroplasty components also included a 36-mm neutral +2 liner. Postoperatively, the patient did well without any documented complications at the most recent follow-up of 4 months.

Case 3

A 75-year-old woman with chronic right hip pain secondary to osteoarthritis was indicated for right THA. Patient-specific implantation was chosen because of a varus neck angle with a short neck length. The iView surgical plan is described and is shown along with pre- and postoperative radiographs in Figures 7-A, 7-B, and 7-C. The procedure was again performed via a direct anterior approach utilizing the C-THA press-fit implants. A patient-specific stem in size 10 with a neck angle of 125.7° was used along with a 47-mm acetabular cup secured by a single 6.5-mm cancellous screw. A ceramic femoral head with a diameter of 32 mm and length of 0 mm was selected on the basis of intraoperative fluoroscopy and soft-tissue

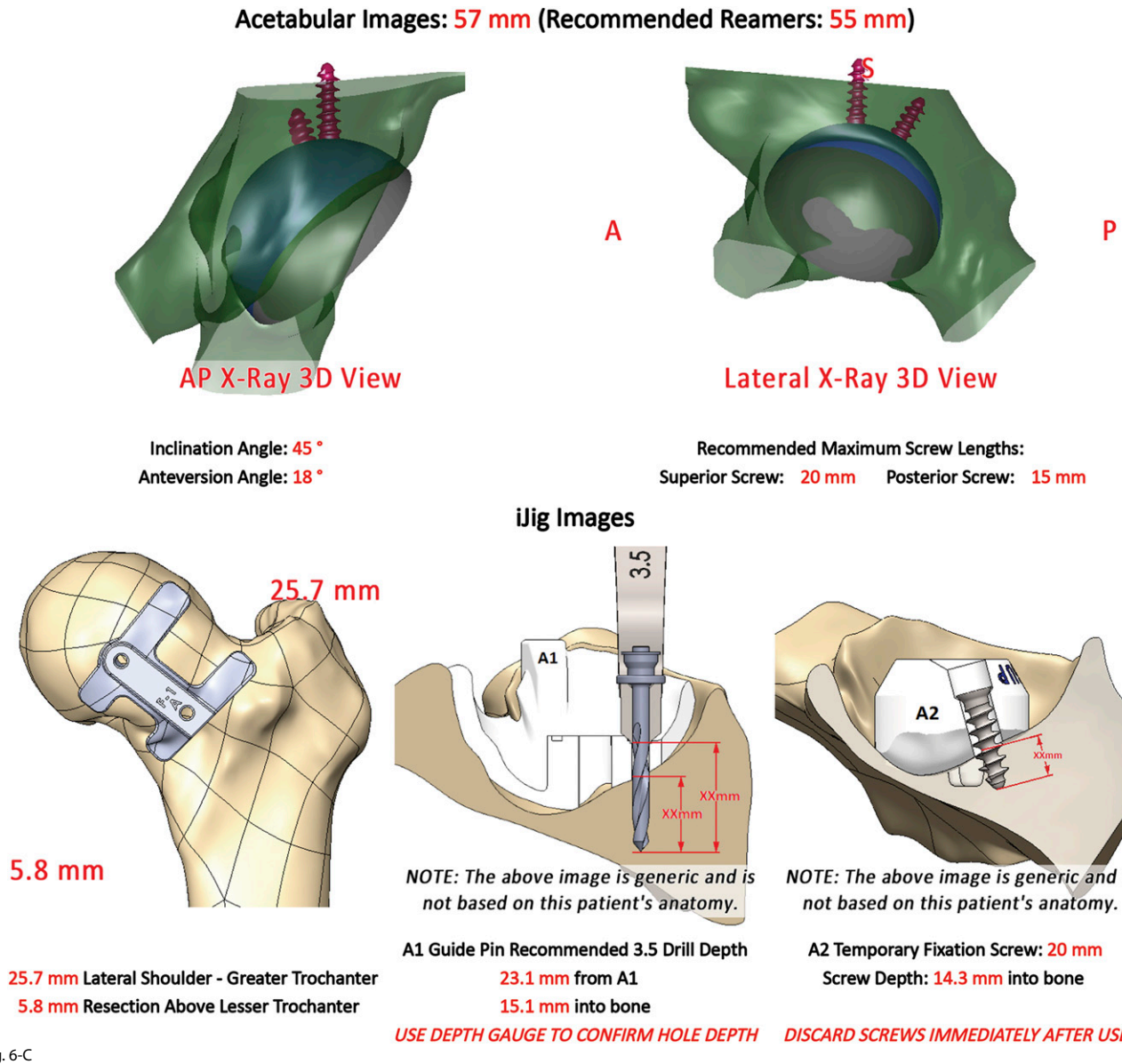


Fig. 6-C

For the orientation of the acetabular cup, an inclination angle of 45° and an anteversion angle of 18° were determined on the basis of the preoperative 3D reconstruction of the patient's anatomy.

tension. The iView surgical plan templated this head size to increase offset by 0 mm and leg length by 0 mm. The arthroplasty components also included a 32-mm neutral liner. At the most recent follow-up, 14 weeks postoperatively, the patient was doing well without any documented complications.

Source of Funding

Conformis, Inc. was the manufacturer of the implants used in this study. No funding was received.

Discussion

The accurate restoration of leg length and femoral offset and accurate acetabular cup positioning are essential to the outcome of THA. Therefore, preoperative planning is vital to the high success rates of THA[34]. However, repeated studies have shown that 3D CT-guided preoperative planning is significantly more accurate in correctly predicting femoral stem and acetabular cup size than traditional 2D radiographic templating and therefore leads to more reliable predictions of leg-length and offset[12-15].

There are several reasons for the relatively low accuracy of 2D templating, including inaccuracy in radiographic magnification, difficulties based on variation caused by the patient's position, and incorrect placement of scaling objects due to technical error[14,35,36].

The potential drawbacks of CT imaging include increased cost and higher patient radiation exposure. However, recent studies have shown that those fears may be overstated and

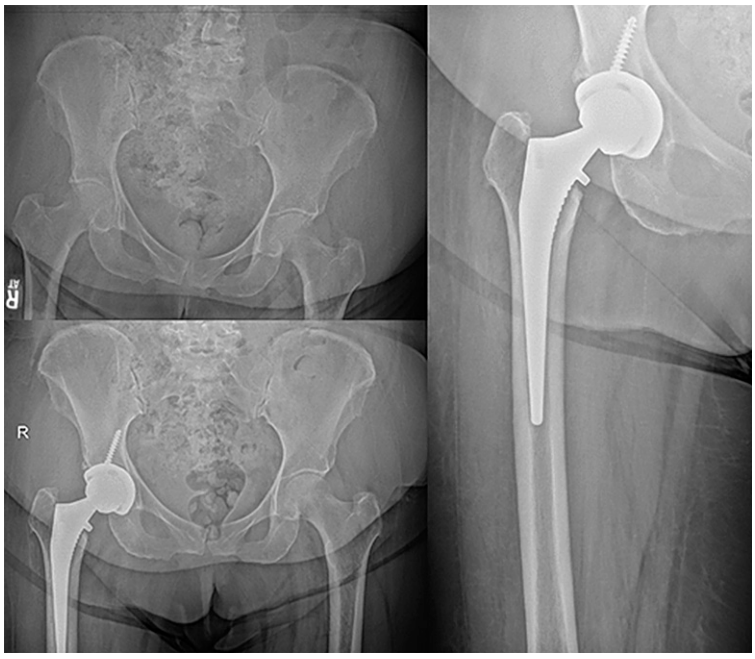


Fig. 7-A

Figs. 7-A, 7-B, and 7-C Case 3. **Fig. 7-A** Symptomatic osteoarthritis of the right hip was treated with the customized THA. A short anatomical femoral neck length was incorporated into the implant design to restore the patient-specific femoral anatomy.

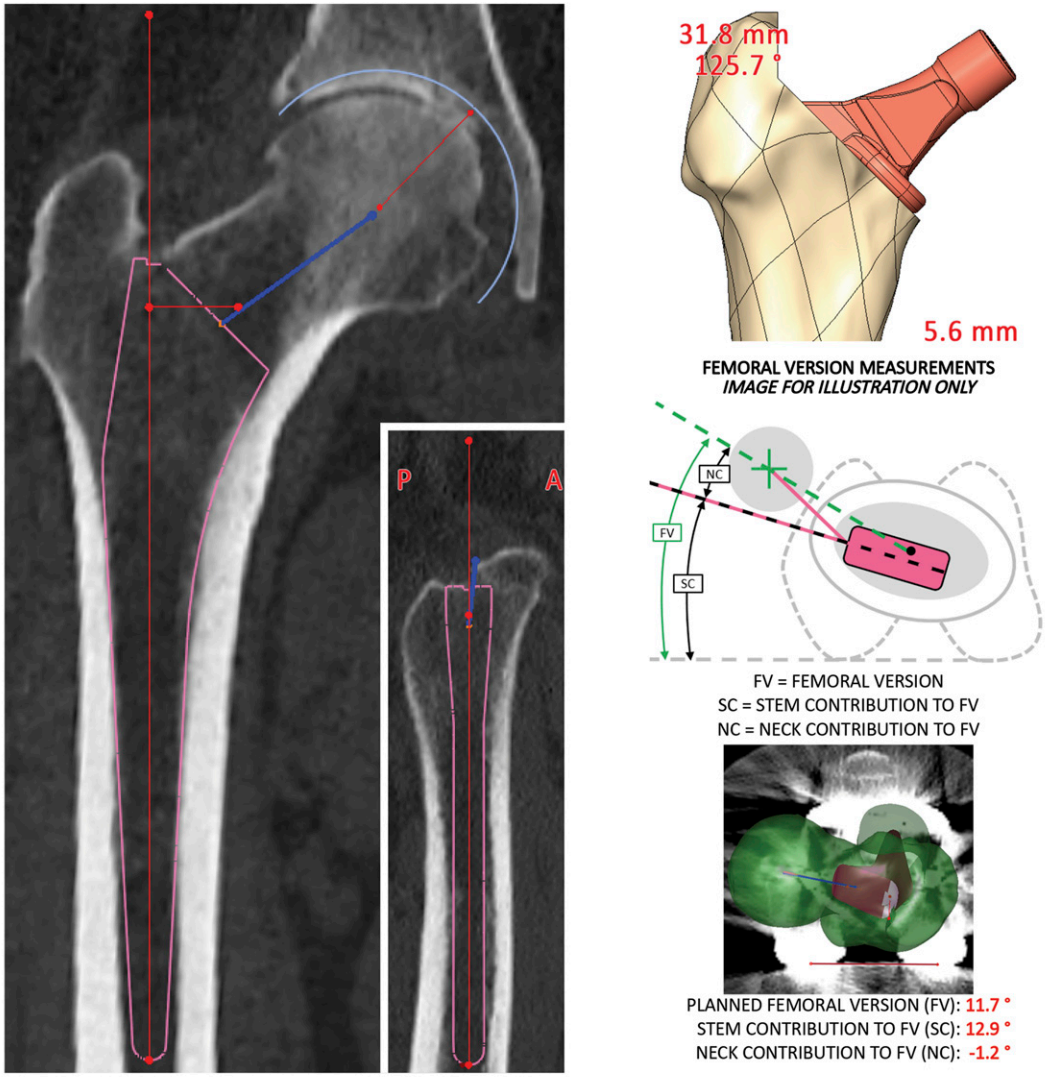
are justified by the demonstrated superiority of CT imaging for preoperative planning[37]. Overall, the precision of 3D CT imaging helps to ensure that implant components are accurately templated and a precise preoperative plan is generated, making it a key strength of this hip system.

While other orthopaedic procedures such as TKA have become guided procedures, THA largely remains unguided. This is a potential source of error, with Bosker et al. reporting that only 70.5% of acetabular cups are placed within the Lewinnek "safe zone" using freehand placement techniques. When limiting the margin of error to within 5° of the target, freehand is only successful 21.5% of the time[17].

One emerging method for utilizing guidance in THA is robotic-assisted surgery. Domb et al.[19] recently analyzed the results of robotic-assisted THA (rTHA) versus manual THA (mTHA) in a propensity score-matched comparison, with 66 patients in each group. They found that 97% of acetabular components were within the Lewinnek safe zone and 90.9% in the Callanan safe zone for rTHA compared with only 73.8% and 56.9% in the respective zones for mTHA. This meant that patients undergoing rTHA had a 9 and 4.7-fold reduced risk of acetabular cup placement outside of the Lewinnek and Callanan safe zones, respectively. The study also demonstrated significantly higher patient-reported outcomes for the rTHA group in terms of the Harris hip score, Forgotten Joint Score-12, Veterans RAND-12 physical component, and Short Form-12 physical component. The authors attributed the better patient-reported outcomes to the technology's ability to "customize the hip implant to the patient anatomy for offset and leg length."[19]

While robotic-assisted THA has demonstrated positive results as detailed above, there remain drawbacks to the technology. The main limitations of robotics include the cost, the substantial training required for surgeons and staff to operate the machines, and increased operative time[38]. Furthermore, robotic guidance is limited to the use of OTS implants with fixed version, angles, and lengths of components. Having said that, the cost to the health-care system of the patient-specific hip system described in this paper has yet to be completely understood. At most hospitals, the patient-specific system is categorized within the existing pricing structure available to manufacturers. A cost analysis of the episode-of-care costs when utilizing this system is currently being planned. Similar studies of the customized knee platform marketed by the same manufacturer have shown it to save the hospital and insurance $900 to $1,700 per episode of care[39,40]. A final determination on the potential savings of using this technology when compared with other guided approaches has yet to be made.

Another guided technique used in THA is C-arm fluoroscopy. The use of fluoroscopic guidance has been shown to lead to better component positioning. Nishikubo et al. reported that the acetabular component was placed in the target zone in 84.3% of hips using fluoroscopy compared with 69% in the control group[41]. Jennings et al. noted similar results, with 80% of implants in the fluoroscopy group being in the combined (acetabular cup abduction 2and anteversion) safe zone compared with 63% in the non-fluoroscopy group[42]. Other studies, however, failed to demonstrate a significant difference between fluoroscopy and control groups[18,43]. Additionally, the use of C-arm fluoroscopy may lead to increased radiation exposure to the patient and surgical team and represent



Resection Above Lesser Trochanter: 5.6 mm
Neck Version Compensation: 3.0 °
Neck/Head Length: 31.8 mm
Neck Angle: 125.7 °

Head Length Range: mm	25-29	29-36.5	36.5-40.5	40.5-43.5
Head Size: 32 mm	32 SH (-4)	32 MD (0)	32 LG (+4)	32 XL (+7)
Leg Length Correction: 0 mm	-2.3 mm	0.0 mm	2.3 mm	4.1 mm
Femoral Offset: 38.2 mm	-3.2 mm	0.0 mm	3.2 mm	5.7 mm

Fig. 7-B

The surgical iView for the femoral component showed a femoral neck angle of 125.7° and a need for neck version compensation of 3° that was incorporated into the C-THA implant design.

an additional potential contaminant in the operative field[44,45].

The use of patient-specific instrumentation has also been studied as a potential improvement to the intraoperative technique of THA. Small et al.[21] reported significant improvements in accuracy of achieving targeted anteversion, with a deviation of −0.2° for the patient-specific instrumentation group versus −6.9° for control group ($p = 0.018$). The patient-specific instrumentation relied solely on the osseous anatomy of the acetabulum, thus eliminating common sources of error for cup malpositioning, such as patient BMI, morphology, and patient position as long as the acetabulum was exposed[21]. Buller et al.[46] found a significant improvement in offset (3.1 versus 8.5 mm; $p < 0.0001$), version (5.2° versus 14.9°; $p = 0.0149$), and inclination (1.4° versus 10.4°; $p = 0.0013$) when comparing the planned values in the patient-specific instrumentation group and the standard group. The patient-specific instrumentation group also had significantly fewer clinically relevant perforations ($p = 0.002$) compared with the standard group, reducing the risk of compromising the external iliac artery and vein or obturator nerve[46].

Patient-specific instrumentation has shown promising results in terms of achieving the accurate placement of

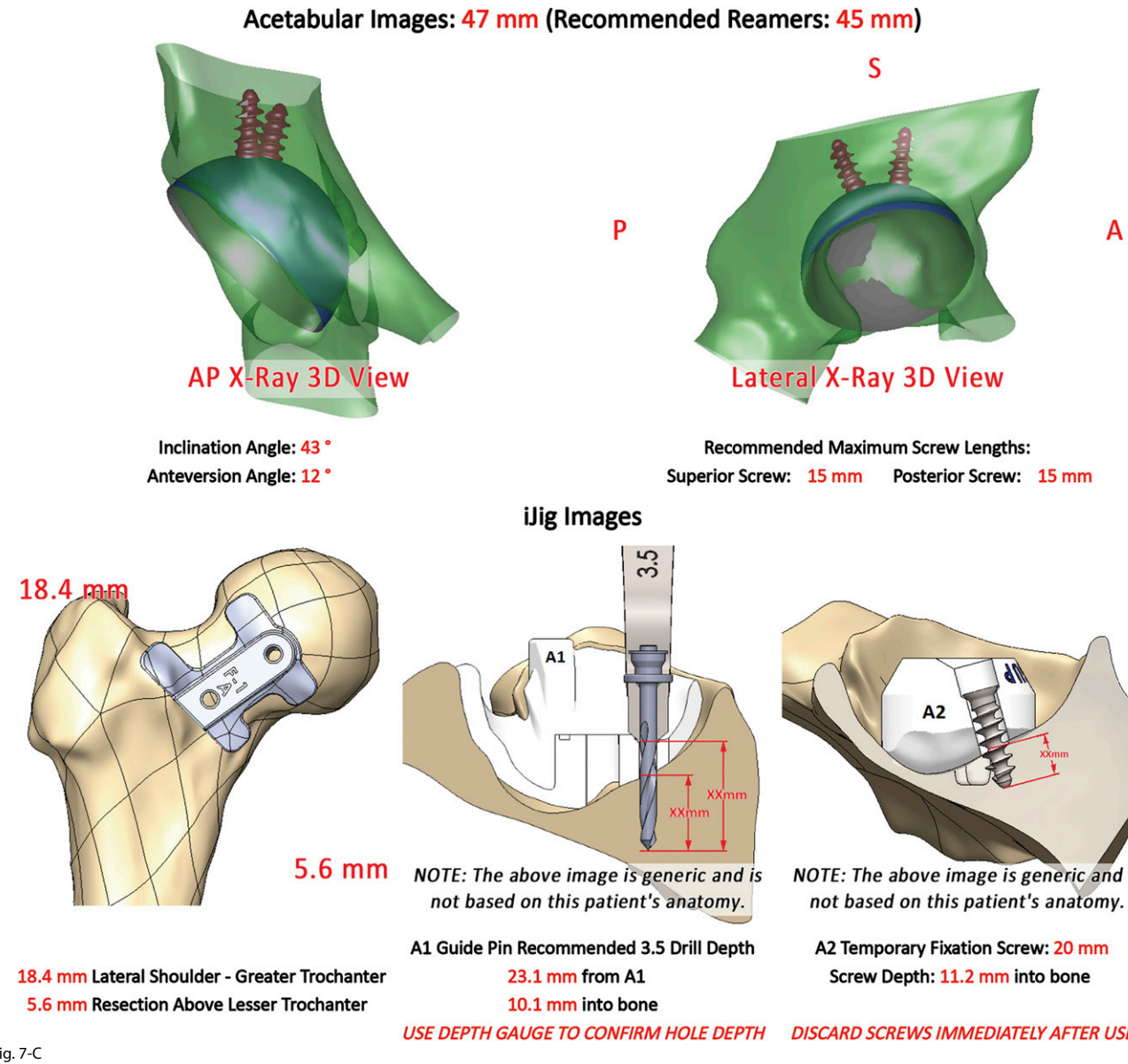


Fig. 7-C

The iView surgical plan for the acetabular cup demonstrated a 47-mm cup size based on the patient's anatomy, with an inclination angle of 43° and an anteversion angle of 12°.

components and executing the preoperative plan, but the technology remains limited by OTS implants. While the importance of restoring leg length, femoral offset, and acetabular version and inclination are essential to achieving favorable results in THA, OTS implants present a hurdle in some cases. In fact, in up to 32% of cases, femoral offset and leg length may not be restored simultaneously[47].

Charles et al. wrote about the importance of reproducing normal femoral offset during THA, and they list benefits including improved abductor strength, enhanced stability, greater range of motion, reduced aseptic loosening, and lesser rates of polyethylene wear. The complications of failing to restore femoral offset include increased rates of limping, fatigue, and reliance on walking aids[33]. Despite the well-known importance of achieving the correct femoral offset, in some studies, femoral offset was only properly restored 40% of the time[31]. The limitations of OTS implants have been suggested as possible causes of reduced offset, with the use of femoral components with less offset than the patient's native hip and with short-necked modular heads specifically cited[33]. The inability of OTS implants to capture the wide range of patient-specific anatomies has been described in articles going back more than 30 years and was the theoretical basis for modular femoral neck implants[26]. The modular-neck stems allow for the adjustment of leg length, femoral anteversion, and femoral offset independent of stem size. This flexibility gives the surgeon the ability to recreate the patient-specific anatomy in order to

improve range of motion, stability, abductor strength, and leg length[28]. Despite the theoretical benefits of the modular components, multiple issues have derailed their widespread adaptation. Mechanical failure, component dissociation, and mechanically assisted crevice corrosion have all been reported, with the latter leading to a recall due to adverse soft-tissue reactions[29].

The hip system described in the present paper may be able to provide the flexibility necessary to capture these patient-specific anatomies without the drawbacks of modular components. It was designed to address the leg-length or offset compromises that sometimes must be made with OTS implants in anatomical outliers, in an effort to provide consistent restoration of anatomy for all patients. The 3 surgical cases described are examples of using the system when notable variance outside the norm of both neck length and neck angle is present.

The primary concern regarding this hip system is that of all new technologies: cost. While the initial cost of the system may be higher, this is mitigated by several factors. Traditional THA often requires the use of 10 trays that must be resterilized between each procedure. This hip system utilizes single-use instruments and only 1 or 2 trays, reducing the number of trays required to be sterilized and thus decreasing the cost and time associated with the system. Additionally, the preoperative planning of implant sizes and optimizing the use of reaming devices may further decrease intraoperative time and thus contribute to lower overall cost. Finally, the use of CT-based 3D planning may identify patients who do not "require" customized implants, and lower-cost OTS implants may be utilized in such cases.

In some aspects, this new system does not depart from the traditional methods of performing THA. The surgeon still must prepare the acetabulum so that the instrumentation can be properly placed. In femora with proximal-distal mismatch, the need to ream the femur to address the underlying anatomical condition remains. This system also does not eliminate the need for adequate soft-tissue management. However, the implementation of appropriate femoral version, neck length, and implant position with the C-THA design addresses limitations that have been attributed to OTS implants and may therefore contribute to a more individualized surgical procedure.

Conclusions

The novel hip system utilized in this case series addresses 3 key areas of potential refinement in THA technique. The utilization of 3D CT imaging allows for the generation of a more accurate and predictable preoperative plan than that provided by traditional radiography. The use of patient-specific instrumentation allows for a guided procedure with many of the benefits of robotic-assisted and fluoroscopy-guided techniques without some of the drawbacks. Finally, the use of 3D-printed jigs and customized implants to match the patient-specific anatomy will offer the same theoretical benefits as the modular-neck implants without the junctional issues. At this point in time, the clinical benefits of these improvements have not been established, and further studies should be undertaken to compare the hip system to traditional approaches.

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