3D-printed Patient-specific Guides for Hip Arthroplasty

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Abstract

Surgeons and engineers constantly search for methods to improve the surgical positioning of implants used for joint arthroplasty. Rapid prototyping is being used to develop patient-specific instrumentation (PSI) and has already been successfully translated into large-scale clinical use for knee arthroplasty. PSI has been used in shoulder arthroplasty; however, it is not yet known whether PSI provides improved accuracy and outcomes compared with conventional methods in either shoulder arthroplasty or knee arthroplasty. In the hip, PSI has been limited to the positioning of custom-manufactured implants and a small number of surgeons testing the emerging solutions from different manufacturers. Early results indicate consistent accurate positioning of implants with the use of PSI in hip arthroplasty but with added costs and uncertain effect on clinical outcomes.

Introduction

The clinical function of a hip ar- throplasty depends on surgical, implant, and patient factors. Surgical factors include component position- ing,¹ which is a modifiable risk factor and is known to contribute to patient dissatisfaction,² dislocation, wear, impingement, decreased range of motion, and leg length discrepancy.³⁻⁷ Acetabular loosening occurs in up to 50% of cases after hip arthroplasty.⁸

Computer-aided surgery and robot- ics have been used to improve the accuracy of component positioning in hip arthroplasty but have had limited uptake because of high costs, increased operating times, and other logistic issues.^{9,10} Reports of image-guided hip arthroplasty are encouraging, but data from the National Joint Registry show that conventional instrumented sur- gery remains the standard treatment.¹¹

More recently, patient-specific in- strumentation (PSI) has been developed to guide the positioning of components during hip arthroplasty. This technique uses imaging techniques such as CT and MRI to plan surgery in a virtual three- dimensional (3D) environment. The

surgeon can then plan prosthesis ori- entation and position in relation to a chosen standard frame of reference and execute the plan using simple intra- operative patient-specific guides.

Here, we present the currently commercially available guides and summarize the relevant literature regarding PSI for hip arthroplasty in order to provide an overview of PSI and describe the evidence regarding its use in clinical practice.

Rapid prototyping was initially de- veloped in the mid 1980s for the production of toys and household machinery and has been used for a wide variety of medical and nonmedical purposes since that time.¹² PSI has evolved out of this and has been taken up in numerous fields of surgery. The first reported use in orthopaedics was in the spine in 1998 for producing guides to aid in the placement of

pedicle screws¹³ and has since spread to include guides for shoulder, hip, knee, and ankle elective and trauma surgery.

PSI has been increasingly commer- cially used in total knee arthroplasty to produce custommade pinning and cutting guides;¹⁴ however, recent lit- erature has questioned whether the use of PSI improves the accuracy of im- plant alignment or clinical outcomes compared with standard instrumenta- tion.^{15,16} Studies using PSI for shoulder and ankle arthroplasty show promis- ing early results in terms of the accu- racy of implant placement; however, commercial applications have not been developed and no study has demon- strated improved clinical outcomes in shoulder or ankle arthroplasty.¹⁷⁻²¹

Clinical Application in Hip Arthroplasty

PSI is being used in hip arthroplasty to improve the accuracy of acetabular and femoral component position- ing.²²⁻²⁴ Acetabular guidance systems aim to optimize the cup size, implant medialization, anteversion, and incli- nation. Femoral guidance systems aim to optimize the stem size and positioning, offset, leg length (height of neck cut), and stem version. Four commercial systems are currently available internationally (Table 1 and Figures 1–3). In addition, a number of patents have been registered on devices that have been modified with the intent to improve on current designs. The Signature Hip (Zimmer Biomet), OPS (Corin Group), and MyHip (Medacta) are currently available for use in the United States and Europe, whereas the Hip Plan (Symbios) is currently avail- able for use only in Europe.

All systems required preoperative imaging with either CT or MRI to cre- ate the patientspecific model and tem- plate the guides and implants required. CT provides well-defined bony anat- omy with low levels of artifact; however, it has limitations in demonstrating soft tissue. The commercial systems available use a low-dose radiation protocol, delivering slightly higher radiation exposure compared with conventional radiographs, with a 2011 study reporting a scan time of 11 minutes and a direct per-patient cost of V52.80 (\$54.94).²⁵ Although MRI is better for visualizing detail within the soft tissues, it offers less well-defined soft tissue—bone boundaries compared with CT. For example, it is difficult to differentiate osteophytes from soft tisues on MRI. Neither imaging modaility has been proved to be superior for PSI in total hip arthroplasty (THA), and which is used depends on the system chosen (Table 1). It is as yet uncertain which is the optimal imag- ing modality for creation of PSI in total hip replacement and both are currently available depending on the commercial system chosen (Table 1).

PSI requires 3D preoperative plan- ning and therefore incorporates the known and obvious advantages of 3D compared with 2D planning.²⁶ Three- dimensional reconstruction software is used to create a 3D computer model. This 3D model is used to virtually plan the positioning and sizing of the prostheses. The frames of reference and target positioning/orientation of the implants can be tailored to the surgeon's preference. Two of the commercially available models include kinematic simulation to take into account the influence of pelvic tilt and assess the potential functional effect of a chosen implant position in terms of bony and implant impingement (ie, MyHip, OPS). The guide is de- signed to fit and complement the patient's native anatomy using bony and soft-tissue landmarks on the CT

or MRI scan. The physical 3D guide is created and produced using a number of methods, including selective laser sintering and additive materials manufacturing (3D printing) and sterilized before delivery to the surgeon's center. The whole process can take as little as 3 weeks from start to finish;²⁷ however, there is typically a lead time of approximately 6 to 8 weeks while the PSI guide is created.

Of the commercially available hip PSI systems, all four offer guides for the acetabular component orientation, but only two of the systems offer a guide for femoral component orientation (ie, MyHip, OPS). The surgical technique varies between products, with anterior, posterior, and lateral surgical approaches available depending on the system chosen (Table 1).

The depth of acetabular reaming and therefore planning for accurate medialization of the implant are still determined by hand and clinical judgment, although future models may include a guidance feature. Pins can be used to guide alignment of the reamer if desired. Preoperative 3D printed acetabular models are avail- able to help with understanding the patient's unique anatomy and how the guide/implant should fit before attempting insertion into the patient (Figure 4).

Insertion guides come in two broad categories: constrained and nonconstrained, depending on whether the guide simply shows the correct direction of implantation or physically guides insertion. Accurate insertion of the guides depends on bony (ie, acetabular dome, rim, notch) and soft- tissue (ie, transverse acetabular ligament) landmarks, which are used to place a custom jig into the acetabulum. As with conventionally guided surgery, the surgical exposure is important in getting this step right. The positioning of the implants is then guided by either pins or lasers. All require care when preparing the surgical site, particularly with soft-tissue removal so that land- marks used in planning are not removed; this is of particular importance in cases in which osteophytes are removed.²⁸

Only the MyHip and OPS systems include a femoral component guide. Posterior and anterior cutting guides are offered so that the surgeon can choose the guide best suited to the preferred surgical approach. This guides the neck cut level and angle but does not guide stem version.

Does Patient-specific Instrumentation Improve the Accuracy of Cup Orientation?

Buller et al²⁹ undertook a dry bone simulation study, with seven sur- geons performing THA performed with standard instrumentation, fol- lowed by PSI-guided THA. The surgical goal was to accurately place the acetabular implant in 22 \square of anteversion and 40 \square of inclination as per a preoperative plan. In the standard instrumentation group, six of seven acetabular components were placed in an unacceptable position with regard to inclination). In the PSI group, three of seven acetabu- lar components were malpositioned with regard to version, and none was malpositioned with regard to inclination.

Shandiz et al³⁰ undertook a cadaver study in which they implanted PSI- guided acetabular components into 12 hips. Preoperative CT scans were used in surgical planning, and post-operative CT scans were used to measure implant positioning and ori- entation. This demonstrated the ability to accurately position the component using the PSI guide to within $2.5\Box$ of planned, with a maximum deviation from planned of $4.7\Box$.

Schwarzkopf et al³¹ undertook a cadaver study of 14 acetabuli using the Bullseye Hip Replacement In- struments (Bullseye Hip Replace- ment) PSI for acetabular preparation and cup placement. CT and MRI were used preoperatively to deter- mine the surgical plan and create the PSI. Postoperative CT scans were used to demonstrate the accuracy of the placement of implants. The ace- tabular cup inclination and ante- version angles were within the target range, and all implanted sizes matched the preoperative surgical planned implant size.

In a prospective randomized con- trolled trial, Small et al³² compared 18 patients undergoing THA with conventional instrumentation and 18 patients undergoing THA with PSI. Pre- and post-operative CT scans were used to evaluate planned versus actual results. Results demonstrated a statistically significant difference in version of the acetabu- lar component between standard instrumentation and PSI (P = 0.018; mean difference from planned versus actual anteversion of 26.9 \Box 6 8.9 \Box for standard instrumentation and 20.2 \Box 6 6.9 \Box for PSI cases). The difference for inclination was not statistically significant (mean differ- ence in abduction from planned versus actual of 1.3 \Box 6 9.1 \Box for standard instrumentation and 22.0 \Box 6 7.3 \Box for PSI cases).

In a nonrandomized prospective study, Hananouchi et al³³ compared 38 patients undergoing THA with traditional instrumentation to 31 patients undergoing THA with PSI. The planned versus actual position of the acetabular component was eval- uated with pre- and postoperative CT scans, determining the incidence of outliers beyond 10^{\Box} from planned placement in each group. The study authors reported that the use of PSI reduced the number of outliers compared with the use of standard instrumentation (zero versus 23.7%, respectively). This trend was statis- tically significant for mean inclina- tion (P = 0.01) but not for mean anteversion (P = 0.08).

In a prospective study, Spencer- Gardner et al²⁷ treated 100 patients using the OPS PSI for cup placement. They used 3D CT planning software to preoperatively choose the optimal acetabular inclination and version for each patient. A posterolateral surgical approach was used for each patient, and the PSI laser guidance system was used for the accurate placement of the acetabular implants. The accuracy of implant placement was evaluated using 3D CT to compare the actual position with the preoperative plan. They demonstrated accurate placement to within $5\square$ in 54% of patients and to within $10\square$ in 91% of patients. These results are comparable with robotic and computer-navigated techniques and superior to reported freehand techniques.

Ito et al³⁴ prospectively evaluated 10 patients in whom PSI was used for femoral stem placement. CT scans were used for preoperative planning. In all patients, noncemented implants were placed via the posterior surgical approach. Postoperative CT scans were used to demonstrate the accuracy of the placement of im- plants. Results demonstrated a mean accuracy of stem tilt of $2.1 \square 6 4.1 \square$, varus/valgus of $1.0 \square 6 0.7 \square$, and anteversion of $4.7 \square 6 1.2 \square$.

Some pitfalls to accurate cup implantation have been highlighted, including errors made during the impaction process of cup implantation. Extra care should be taken at this stage. In addition, the presence of osteo- phytes can sometimes pose a challenge to the accurate placement of the PSI guide and must be taken into account when executing the surgical plan.²⁸

PSI for the placement of the femoral component of hip resurfacing has also been investigated, with promis- ing early results in terms of stem-shaft angle and version.³⁵

Does the Use of Patient- specific Instrumentation Affect the Duration of Surgery?

Hananouchi et al³³ reported a mean surgical time of 106.1 minutes with PSI, compared with 116.3 minutes with standard instrumentation. This difference was not significant. In the PSI group, the mean time to use the surgical guide was 3.6 minutes.

Spencer-Gardner et al²⁷ found that the total operating time increases by 3 to 5 minutes with use of PSI. This compares to time increases in navi- gated THA of 8 to 58 minutes. Ito et al³⁴ used PSI for femoral component insertion and demonstrated a mean surgical time of 111 minutes. Small et al³² demonstrated a mean surgical time of 95 minutes for the PSI group versus 88 minutes for the standard instrumentation group; this trend was not found to be statistically significant.

Is Patient-specific Instrumentation Useful in Cases With Massive Bone Defects and Abnormal Anatomy?

Substantial deformity and insufficient bone structure or quality are contra- indications for the use of currently available PSI guides for hip arthro- plasty. The dynamic modeling used preoperatively with PSI requires nor- mal anatomy and sites of rigid attachment for guiding instruments intraoperatively. Further develop- ments in the design of these guides may result in the ability to use these systems in patients with more severe deformity.

How Much Does Patient- Specific Instrumentation Add to the Operating Costs?

Most surgeons would use the cur- rently available commercial PSIs, which in our experience add ap- proximately \$371 to each surgical case. For individual hospital pro- duction of PSI, in 2010 Hananouchi et al³³ reported startup costs of up to \$150,000, including \$15,000 to \$30,000 for software and \$120,000 for the rapid prototyping machine itself, along with a material cost per case of \$50 to \$100. The long-term effect of these guides in reducing the need for future medical treatment for early failures of poorly positioned implants is not yet known, but the potential financial implications of this may well out- weigh the added initial costs.

Does the Use of Patient- Specific Instrumentation Have Any Other Intraoperative Effects?

Blood Loss: Hananouchi et al³³ demonstrated a mean blood loss of 655.9 mL for PSI versus 683.9 mL for standard instrumentation; this difference was not statistically significant. Ito et al³⁴ reported a mean estimated blood loss of 356 mL using PSI for the femoral component. Small et al³² demon- strated mean estimated blood loss of 200 mL in the PSI group compared with 150 mL in the traditional in- strumented group; this trend was not found to be statistically significant.

Complications: Spencer-Gardner et al²⁷ reported one complication in a series of 100 patients in whom PSI was used for cup placement—a fractured ceramic liner due to

incomplete seating requiring revision liner exchange. Ito et al³⁴ reported no complications or revision surgeries in a series of 10 patients in which patient-specific instruments were used for femoral stem placement. In a randomized controlled trial of 18 PSI versus 18 standard instrumentation cases, Small et al³² demonstrated no com- plications in the PSI group and one complication in the standard instru- mentation group (anterior dislocation).

How Does Patient-specific Instrumentation Compare With Robotic and Computer-Navigated Systems?

Robotic-assisted hip arthroplasty surgery is also based on 3D CT scans, allowing preoperative planning of positioning and sizing of implants. Robotic-assisted systems are designed to either physically prepare the bone (active) or prevent the surgeon from reaming outside the predefined boundaries (semiactive).36 Although robotic-assisted surgery has been shown to be an accurate surgical tool, its acceptance has been limited because of concerns about its ease of use and costs.37

Computer-navigated hip arthro- plasty surgery is a passive system using CT, fluoroscopy, or imageless naviga- tion techniques. CT navigation is rela- tively unaffected by minimal access approaches38 and has shown good long-term clinical results.39 Issues related to cost and radiation expo- sure for CT navigation and concerns regarding accuracy with fluoro- scopic and imageless navigation have limited surgeon acceptance of the technology.37

PSI for hip arthroplasty is still in its early phases of clinical use; although studies determining the accuracy of implant positioning seem promising, longer term clinical data have not been published. PSI also increases the overall costs of the operation, while potentially adding time to the surgery duration depending on the complexity of the case and surgeon experience.

Summary

PSI hip guides have been shown to improve the accuracy of implant positioning and may have a role to play in reconstructing complex anat- omy, particularly in revision surgery. However, it is unknown whether the use of PSI in hip arthroplasty has any effect on longterm functional out- comes or survival. More clinical outcomes data are required to convince the surgeon that the benefits of PSI in terms of accuracy are worth the challenges of the learning curve involved and the increased costs.

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Table 1

Characteristics of the Commercially Available Patient-specific Instrumentation Hip Systems

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Trade Name (Manufacturer)	Approach	Landmarks	Acetabular Guide	Femoral Guide	Alignment	Imaging	Kinematic Simulation	Insertion Guide	Implant
Signature Hip (Zimmer Biomet)	Posterior, lateral	Bony and soft- tissue	Yes	No	Pins	MRI	No	Yes	Brand- specific
MyHip (Medacta)	Anterior, posterior	Bony	Yes	Yes	Pins	CT or MRI	Yes	Yes	Brand- specific
Hip Plan (Symbios)	Posterior	Bony	Yes	No	Pins	СТ	No	Yes	Brand- specific
OPS (Corin Group)	Any	Bony	Yes	Yes	Lasers	СТ	Yes	Yes	Brand- specific

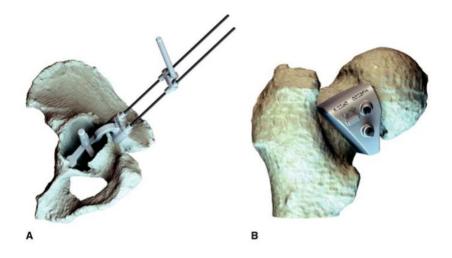


Figure 1: Images showing the MyHip system (Medacta). A, The acetabular guide is seated into the acetabulum, and two pins are inserted through attached drill sleeves. The guide is removed, leaving the two pins to act as either a constrained or unconstrained guide to reaming and component placement. B, The femoral guide has a contoured fit to the femoral neck/head and is kept in place for the neck cut by two intraosseous pins. (Courtesy of Medacta, Chicago, IL.)



Figure 2: Image showing the OPS system (Corin Group). A guide and acetabular model are created for each patient. The soft tissue in the acetabular fossa is excised, and the guide is inserted and compared with the 3D printed model to confirm accurate seating in the acetabulum. A laser handle is attached to the guide to focus a laser onto the operating room wall. A second, pelvic-mounted laser is then directed to match this point on the wall. Use of this second laser allows for maintenance of the laser point while reaming the acetabulum. The implant introducer has a laser attachment, which has to line up with the pelvic-fixed laser on the wall to ascertain the correct inclination and anteversion of the implant. The 3D printed model can also be used to demonstrate the expected overhang of native bone as a second check of correct implant placement. (Courtesy of Corin Group, Pymble, NSW, Australia.)



Figure 3: Image showing the Signature Hip system (Zimmer Biomet). The 3D printed Primary Acetabular Guide is seated into the acetabulum, and pins are placed into the rim of the acetabulum through attached drill sleeves. The pins are left in place, and the guide is removed. These pins can act as either a constrained or nonconstrained guide to reaming of the acetabulum and placement of the implant. (Courtesy of Zimmer Biomet, Warsaw, IN.)

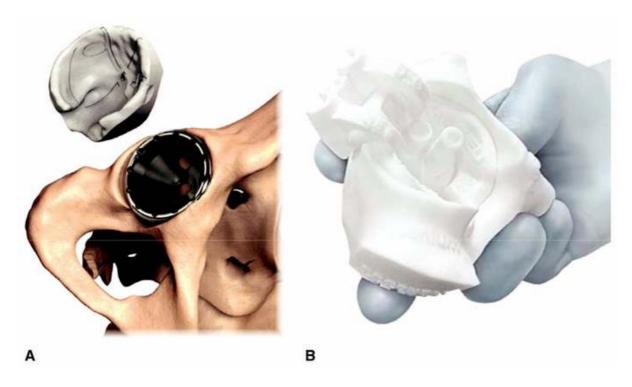


Figure 4: Images of models based on bony landmarks. These models are used to help appreciate the threedimensional anatomy and the manner in which the jig and final implant should seat in the acetabulum. A, OPS. B, Signature. (Panel A courtesy of Corin Group, Pymble, NSW, Australia. Panel B courtesy of Zimmer Biomet, Warsaw, IN.)