

REVIEW ARTICLE

Patient-Specific Orthopaedic Implants

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Patient-specific orthopaedic implants are emerging as a clinically promising treatment option for a growing number of conditions to better match an individual's anatomy. Patient-specific implant (PSI) technology aims to reduce overall procedural costs, minimize surgical time, and maximize patient outcomes by achieving better biomechanical implant fit. With this commercially-available technology, computed tomography or magnetic resonance images can be used in conjunction with specialized computer programs to create preoperative patient-specific surgical plans and to develop custom cutting guides from 3-D reconstructed images of patient anatomy. Surgeons can then place these temporary guides or "jigs" during the procedure, allowing them to better recreate the exact resections of the computer-generated surgical plan. Over the past decade, patient-specific implants have seen increased use in orthopaedics and they have been widely indicated in total knee arthroplasty, total hip arthroplasty, and corrective osteotomies. Patient-specific implants have also been explored for use in total shoulder arthroplasty and spinal surgery. Despite their increasing popularity, significant support for PSI use in orthopaedics has been lacking in the literature and it is currently uncertain whether the theoretical biomechanical advantages of patient-specific orthopaedic implants carry true advantages in surgical outcomes when compared to standard procedures. The purpose of this review was to assess the current status of patient-specific orthopaedic implants, to explore their future direction, and to summarize any comparative published studies that measure definitive surgical characteristics of patient-specific orthopaedic implant use such as patient outcomes, biomechanical implant alignment, surgical cost, patient blood loss, or patient recovery.

Key words: Custom implants; Orthopaedic surgery; Patient-specific implants

Introduction

Surgical implant devices have been used worldwide in orthopaedic surgery for over 100 years¹. Today, modern implants are commonly used in joint arthroplasties, spine fixation, tissue reconstruction, as well as for fracture fixation². The clinical need for such orthopaedic implants will continue to increase, as projections have demonstrated that the demand for total knee arthroplasties (TKAs) in the USA will grow by 484%, from 719,000 annual TKA procedures in 2015 to 3.48 million by 2030, while the demand for total hip arthroplasties (THAs) will grow by 172%, from 332,000 to 572,000 annual THA procedures over the same time period³. This is in part due to THAs and TKAs becoming increasingly common in younger patients, as joint arthroplasty procedures in patients under 65 years increased by 109% between 2000 and 2007, compared to an increase of just 46% over the same time period for patients over 65 years⁴.

This rise in joint arthroplasty coupled with a trend toward younger patients is noteworthy, as Harrysson *et al.* cite that over a preliminary 10-year period, younger patients face a significantly higher risk of implant failure in undergoing a total joint arthroplasty (TJA)⁵. Several factors contribute to this joint arthroplasty failure, most notably micro-motions of the implant due to uneven stress distribution on the bone surface⁶. This is primarily a concern in the increasingly prevalent younger and more active patient populations. The uneven stress distribution existing at the bone-implant interface is a result of the rigid bone preparation at the implant site in a conventional TJA⁷. In a traditional total joint arthroplasty, bones are uniformly prepared for implant component fit, resulting in a "squared-off" bone end that lacks the roundness of the natural periarticular osseous anatomy⁷. This bone contouring can have a dramatic effect on weight distribution and can lead to the "corners" of the bone-implant interface taking on a disproportionate

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amount of stress, resulting in harmful bone remodeling and eventual loosening of the implant⁷.

In light of these insights, there has been increased attention paid to patient-specific implants (PSIs) in an attempt to increase implant durability, while maintaining or decreasing associated implant costs⁸. PSIs utilize magnetic resonance imaging (MRI) or computed tomography (CT) scans of a joint or bone to create an alignment guide for each component of the implant that is specific to a patient's unique anatomy⁸. This improves implant fit and load distribution while minimizing the inefficiency and cost associated with sizing implants in the operating room⁷. Stress concentrations shown in Fig. 1 demonstrate the disproportionately localized stress along the sharp edges of a bone surface prepared for conventional implant (Fig. 1A), while bone surfaces of a PSI showed a more uniform stress distribution due to the pre-planned surgical cuts, which better recreate the patient's natural contoured anatomy (Fig. 1B)⁷. The balanced load distribution of PSIs is consistent across implant types when compared to their conventional standardized counterparts. Despite this evidence for improved fit and load distribution, the assumed efficacy of patient-specific implants is still controversial. According to a 2014 survey of nearly 15,000 AAOS (American Academy of Orthopaedic Surgeons) orthopaedic health professionals, only 47% of them see a benefit to using patient-specific implants over traditional implants in orthopaedic surgery⁹. Given this divide in opinion in the field, further investigation into the biomechanics, patient recovery, cost, and true efficacy of PSI surgical options is essential.

Methods

For this review of the literature, related published reports were found via searches of PubMed using the following subject terminology: "Orthopaedic PSI," "patient-specific orthopaedic implants," and "patient-specific orthopaedic instruments". In total, these searches returned 397 published articles. Of these, 11 non-English articles were preliminarily

excluded. Then, abstracts of all remaining articles were browsed for relevancy to the study and 279 non-related publications were excluded. This left 107 articles for final review. Each article was strictly screened for quality via review of proper methodology, acceptable research design, and the reputability of its journal. Twenty-seven articles were screened out due to unclear or improper study methodology, leaving 80 research articles for inclusion in this review. This entire process is depicted in Fig. 2.

Current Applications

Total Knee Arthroplasty

With the increasing popularity of TKA treatment for debilitating knee osteoarthritis and loss of joint function, investigating methods to improve the efficacy, accuracy, and reproducibility of TKAs has become an important goal in contemporary orthopaedic research, with patient-specific TKA holding potential¹⁰. Biomechanical analysis cites correct implant component alignment as one of the most important features of a successful TKA¹¹. TKA implant malpositioning relative to a patient's natural knee anatomy can lead to patellofemoral pain, knee instability, stiffness, inferior function, inferior range of motion, and wear and loosening of components: all precursors for implant failure (Fig. 3)^{13–15}. Similarly, proper anatomical alignment correlates with better knee function, faster rehabilitation and recovery, less pain, increased TKA implant longevity, and improved quality of life^{12,14,16–20}.

Despite the importance of proper TKA implant alignment, conventional TKA surgical techniques have been associated with a high incidence of implant malalignment (20%–30%) independent of surgeon experience or *US News and World Report* hospital ranking^{21–24}. One of the primary objectives of PSI design is to reduce this malalignment in an effort to reduce associated complications or implant failure. In a PSI TKA, a commercial PSI program uses a MRI or CT scan to take patient-specific measurements of the complete

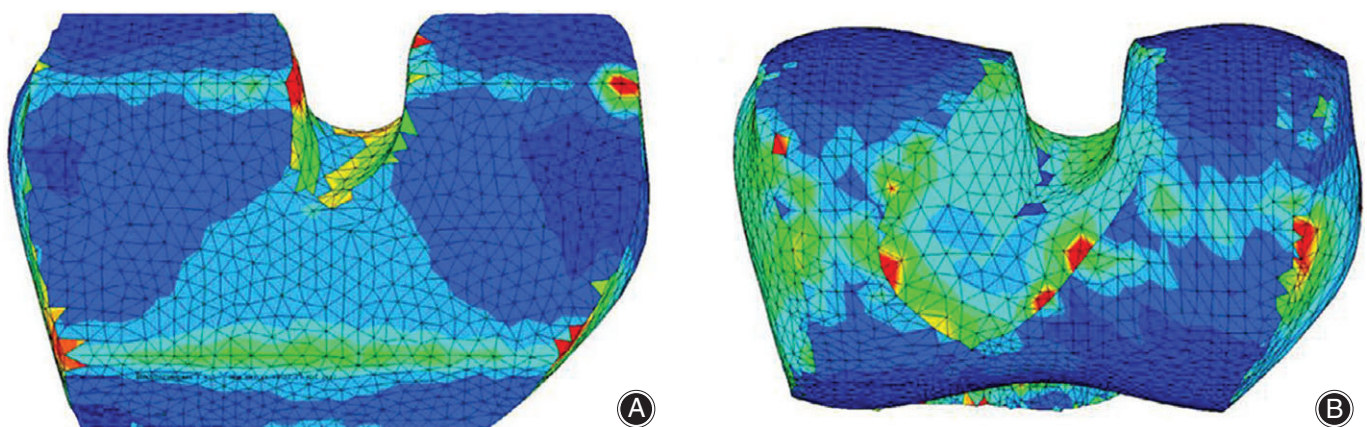


Fig. 1 Representation of the stress distribution of bone surface for conventional (A) and patient-specific (B) implant with both loading and reaction force applied in the center. Maximum stresses are shown in red color at a level of 5 MPa. Green contour stress levels are 2.5 MPa⁷.

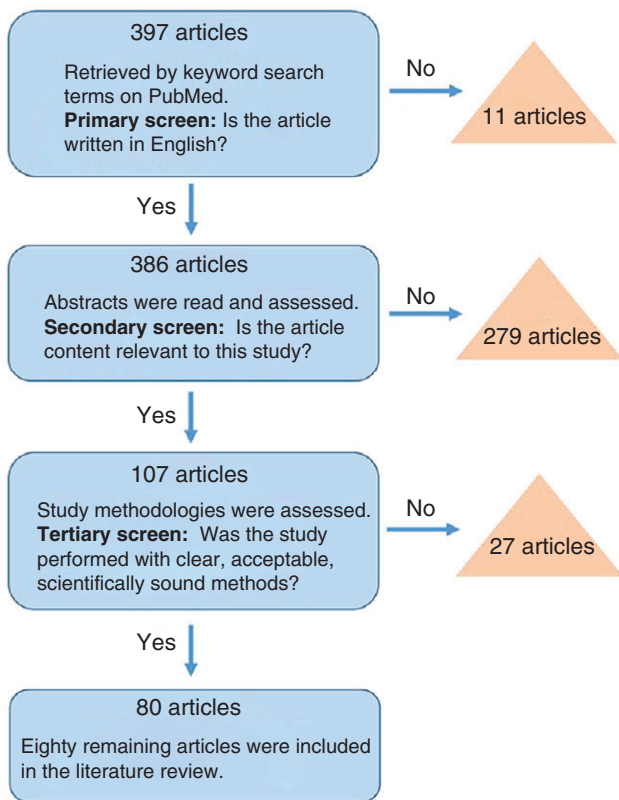


Fig. 2 Flowchart depicting the selection process for articles included in this review.

joint space in order to optimally guide the operative plan and the surgeon's specific bone cuts¹¹. Ideal joint alignment theoretically results from the patient's postoperative mechanical leg axis, femoral component coronal alignment, tibial component coronal alignment, femoral component sagittal alignment, and tibial component sagittal alignment¹¹. This includes the distal and posterior cutting planes for the femur and the proximal cutting plane for the tibia as well as the shape, size, and fit of the implant, which is displayed in a 3-D anatomic model¹⁰. The program also provides the surgeon with on-screen warnings if a cutting plane will result in an undesirable outcome such as "notching" (Fig. 4). After the surgeon reviews the preoperative plan, custom-made jigs are manufactured based on the preoperatively planned bone resections (Fig. 5). These jigs act as temporary guidance to precisely reflect the preoperative plan and allow the surgeon to make the appropriate resections⁹.

Despite the theoretical advantages of PSIs in TKA, there is controversy regarding the clinical advantage of PSI use over traditional implants for TKA procedures. Currently, there is no reported clinical advantage of PSI use over traditional implants for outcomes in regards to blood loss, range of motion, length of hospital stay, postoperative Oxford knee score at 3 months, or postoperative UCLA activity score at 2 years^{8,25-35}. However, Ng *et al.* demonstrated that PSIs

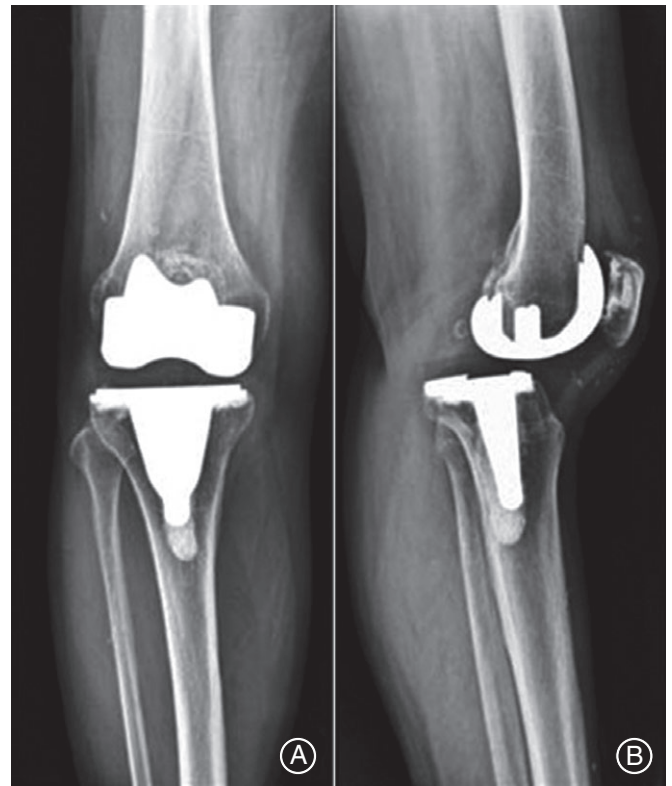


Fig. 3 Anterior (A) and lateral (B) radiographs of knee, 2 years after TKA using a traditional cruciate-retaining implant with notable loosening and polyethylene wear of the implant¹².

result in improved accuracy of biomechanical implant alignment when compared to standard TKA implants³⁰. Furthermore, a 2015 cadaver study by Patil *et al.* showed that PSI TKAs allow for better knee kinematic function when compared to a standard TKA³⁶. This was shown by testing active femoral rollback, active tibiofemoral adduction, and passive varus-valgus laxity in cadaver knees that had either been implanted with patient-specific implants using patient-specific cutting guides, or with a standard implant using traditional intramedullary alignment cutting guides. The study concluded that PSI TKAs resulted in knee kinematics significantly closer to normal than the standard TKA implants were able to achieve, potentially suggesting improved function and patient satisfaction after a PSI TKA with the enhanced restoration of knee kinematics that PSIs allow for³⁶. Patient-specific TKA implants also carry a potential economic advantage, as DeHaan *et al.* found that a patient-specific TKA carries a shorter average operating room time by 20.4 min and an average of four fewer instrument trays utilized per operation when compared to a traditional TKA procedure³⁷. They argue that the shorter operating time and fewer instrument trays result in a net savings of US\$736 per operation when compared to traditional TKA, even when they accounted for the additional cost of PSI imaging³⁷. With the potential cost savings and improved alignment, PSI

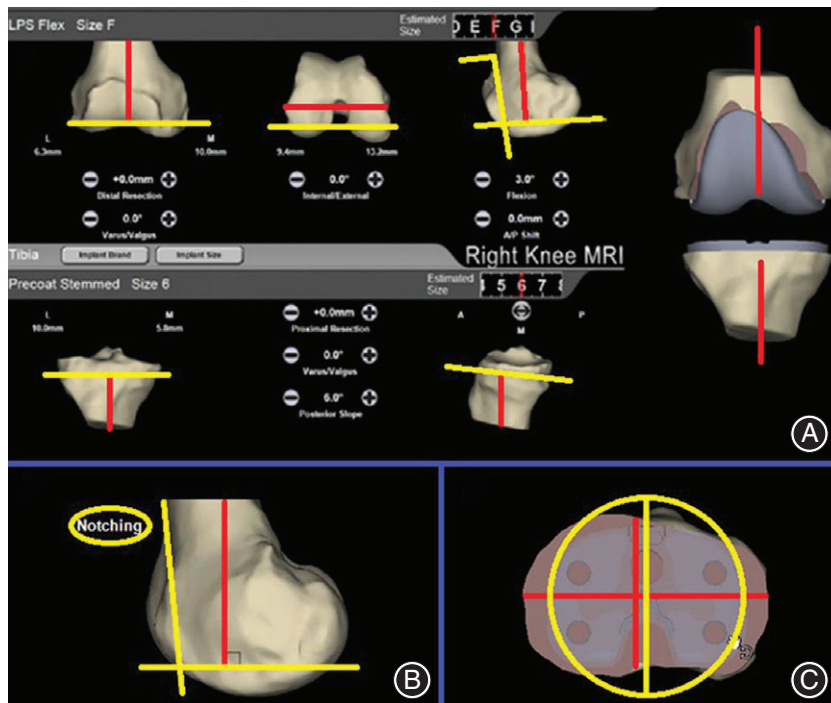


Fig. 4 Adapted user interface showing the data necessary for preoperative planning of a patient-specific total knee arthroplasty: (A) This image displays the distal and posterior cutting planes and the sagittal alignment of the femur (yellow lines), and the proximal cutting plane of the tibia with its slope (yellow lines). Red lines display the mechanical axis of the femur and tibia as well as the transepicondylar axis of the knee. The software displays a warning (B) if the anterior cutting plane exits the femoral cortical bone or (C) if tibial overhang occurs¹⁰.

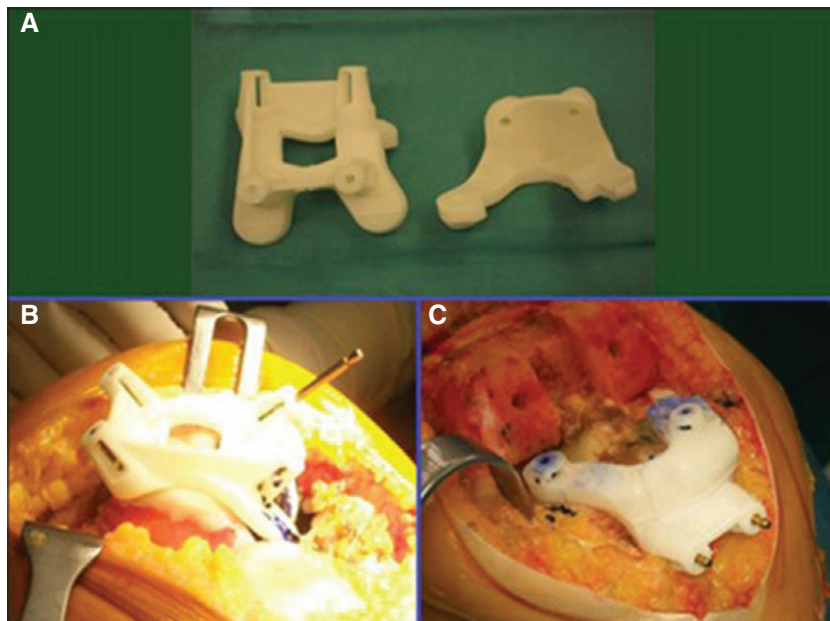


Fig. 5 Femoral and tibial custom-made jigs (A) used to guide the surgeon's cuts in the femur (B) and tibia (C).

TKAs could be an advantageous treatment option in the future. However, studies are needed to assess long-term PSI TKA patient outcomes at 10 or more years before definitive conclusions can be made.

Total Hip Arthroplasty

Traditional total hip arthroplasty (THA) consistently improves patient range of motion, decreases patient pain, and improves patients' quality of life³⁸⁻⁴⁰. In a traditional

THA, modular implants are placed using basic instrumentation and the surgeon's intraoperative assessment of anatomical landmarks in the patient⁴⁰. One of two strategies is typically employed for a traditional THA: cemented or uncemented fixation of the femoral stem (Fig. 6)⁴². Figure 6 shows a comparison of cemented (Fig. 6A) fixation and press-fit (Fig. 6B) fixation⁴¹. Without a clear advantage of using one fixation method over the other, orthopaedic surgeons are exploring PSIs as an alternative to traditional

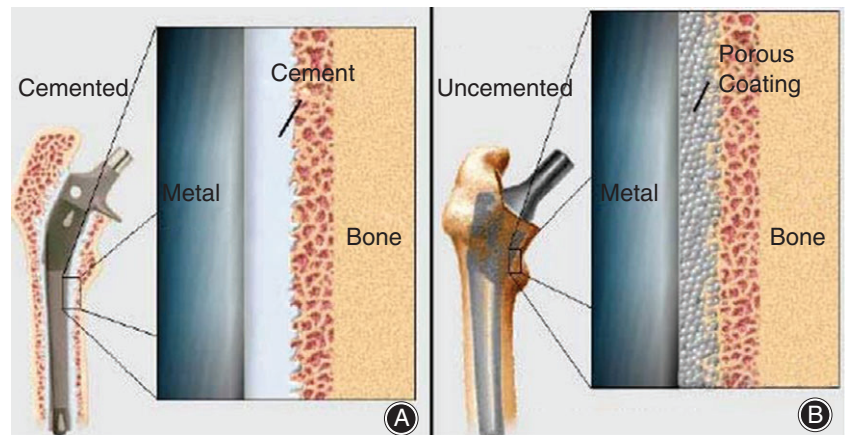


Fig. 6 (A) A cemented implant is held by cement, which attaches the metal implant directly to the femur bone. (B) A press-fit implant has a porous meshing between the implant and bone, allowing for the ingrowth of bone into the mesh⁴¹.

implants in THA^{43–45}. Particular interest has been given to the improvement of acetabular cup alignment, as acetabular cup malpositioning has been demonstrated to be the most common cause of THA revision⁴⁶. Accurate acetabular cup positioning in THA has been demonstrated to decrease the risk of dislocation, impingement, and implant wear rate^{47–55}. Accurate acetabular cup placement could be an important advantage for using PSIs in THA procedures. In a PSI THA, preoperative computer-assisted surgical planning software is used to plan the procedure and to fabricate patient-specific instruments for use in guiding the procedure^{42,56} (Fig. 7). The temporary PSI acetabular cup is placed within and around the acetabulum of the patient⁴² (Fig. 8). A peripheral guide-wire is then drilled through the acetabular PSI cup, eventually serving as a reference for the

trajectory of acetabular reaming. Then, the temporary PSI guide cup is removed, and an appropriately sized permanent acetabular component is chosen and inserted with the reference of the residual guide-wire⁴². The PSIs are designed based on a CT scan or MRI of the patient's hip, with great attention given to the patient's unique bony morphologic features of the acetabulum and proximal femur⁴². This methodology theoretically minimizes the sources of error associated with conventional THA methodology, which has a much higher dependence on appropriate patient positioning, pelvis orientation, exposure, and surgeon experience^{42,57–60}.

Similar to PSI usage in TKA procedures, there is a lack of literature comparing clinical outcomes of PSIs and conventional THAs. However, PSIs have been demonstrated to

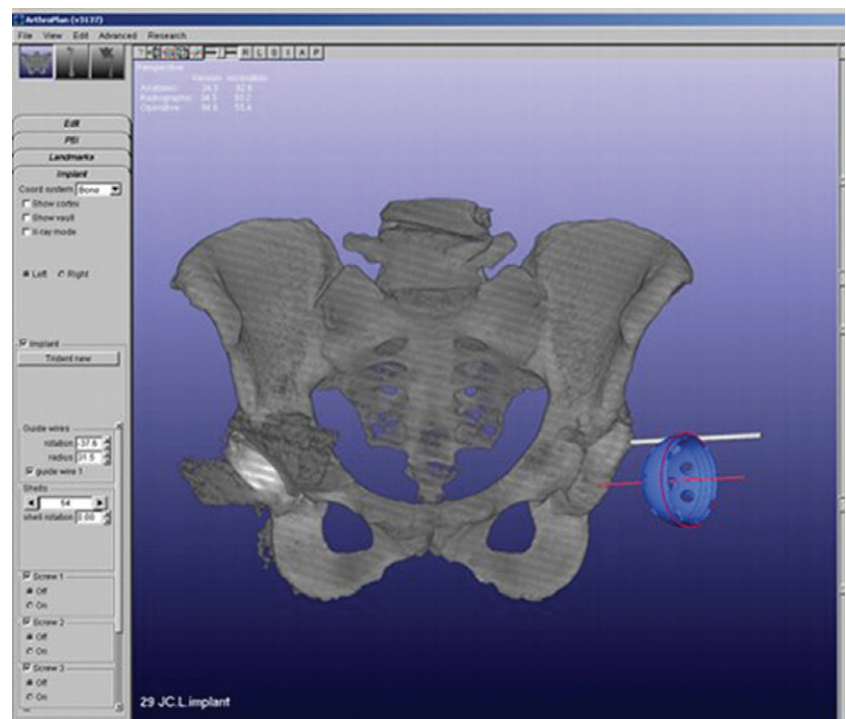


Fig. 7 Screen shot of a surgical simulator software program used for preoperative planning and manufacturing of a 3D printed patient-specific implant (PSI) acetabular cup⁴².



Fig. 8 A 3D printed patient-specific implant (PSI) right acetabular cup placed in a native acetabulum/pelvis patient-specific model. Both the model and implant were manufactured based on a patient computed tomography (CT) scan, and were printed with an SLA 5000 3D printer from 3D systems using Watershed XC11122 resin⁴².

be more accurate at placing acetabular THA implants in their intended position and alignment, theoretically reducing the risk of implant wear, dislocations, impingement, and revision^{42,61–65}. PSI THA technology could also carry advantages for treating patients with a high body mass index (BMI) or unique morphologies. A higher BMI correlates with malpositioned acetabular cups in THAs, yet Small *et al.* found no difference in positioning for those patients with high BMI in patient-specific THAs^{42,66}. This is attributed to the fact that traditional THA operative plans are impacted by soft tissue, patient positioning, and the degree of pathology. In comparison, PSI THA technology primarily relies on the imaging of the bony anatomy, allowing for objective measurements and preoperative customization⁴². Despite this benefit of PSIs, long-term outcomes and cost analysis data for PSI THAs are required before a recommendation regarding the use of PSIs for hip arthroplasty can be made.



Fig. 9 Outline of a computer-assisted planning approach for a corrective osteotomy with plate fixation. (A) First the degree of malunion is quantified by superimposing the proximal misaligned bone (orange) with the mirrored contralateral bone (green). (B) The distal fragment of bone is then reduced through simulation (violet) and the planned positioning of the patient-specific fixation plate is calculated and displayed⁷⁵.

Bone Plates

A recently emerging indication for PSI use is in corrective osteotomies. 3-D bone models are developed from CT scans, and a planned correctional osteotomy is simulated by manipulating the virtual bone models in computerized 3-D space^{67–74}. Measurements are taken for the development of patient-specific cutting guides and a patient-specific osteosynthesis plate to stabilize postoperative bone healing (Fig. 9)^{75,76}. Accuracy in preoperative quantification of the surgical reconstruction is critical, as over-correction and under-correction in the correctional osteotomy is associated with loss of range-of-motion and muscle strength⁷⁷. Therefore, computerized modeling, planning, and manufacturing of implants have seen increasing popularity⁷⁵. Laboratory studies using patient-specific guides have reported average residual errors less than 1° and 1 mm for simulated osteotomies, much lower than the 2.4° average error associated with a standard corrective osteotomy^{78,79}. However, as with joint arthroplasties, clinical outcome and cost studies are necessary prior to justifying the increased cost of PSIs for this application.

Future Applications

With its increasing popularity in total knee arthroplasties, total hip arthroplasties, and corrective osteotomies, moving forward PSI technology has potential indications in many orthopaedic procedures. The idea of improved patient-specific implants for spinal surgery is currently being explored, with Amendia, a provider of spinal technologies, recently acquiring Custom Spine and the rights to its 41 patents relating to patient-specific spinal technologies⁸⁰. The orthopaedic department at Cleveland Clinic has also explored the use of patient-specific instruments in glenoid implant positioning in shoulder arthroplasty. Their results suggest that patient-specific guiding instruments allow for a significant decrease in the average deviation of implant position for inclination and medial-lateral offset in such procedures⁸¹.

There is controversy regarding the efficacy of patient-specific orthopaedic implants, yet the theoretical alignment and precision of PSI methodology provide potential advantages when compared to standard procedures. However, the long-term clinical efficacy of this custom technology must be demonstrated in further clinical study before the widespread application of PSI technology is fully supported and indicated for patient care.

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