Patient-Specific Surgical Guidance System for Intelligent Orthopaedics

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Abstract

Clinical benefits for image-guided orthopaedic surgical systems are often measured in improved accuracy and precision of tool trajectories, prosthesis component positions and/or reduction of revision rate. However, with an ever-increasing demand for orthopaedic procedures, especially joint replacements, the ability to increase the number of surgeries, as well as lowering the costs per surgery, is generating a similar interest in the evaluation of image-guided orthopaedic systems. Patient-specific instrument guidance has recently gained popularity in various orthopaedic applications. Studies have shown that these guides are comparable to traditional image-guided systems with respect to accuracy and precision of the navigation of tool trajectories and/or prosthesis component positioning. Additionally, reports have shown that these single-use instruments also improve operating room management and reduce surgical time and costs. In this chapter, we discuss how patient-specific instrument guidance provides benefits to patients as well as to the health-care community for various orthopaedic applications.

Keywords

Patient-specific instrument guidance · Total knee arthroplasty (TKA) · Computer-assisted surgery (CAS) · Cartilage defect repair · Planning

18.1 Introduction

The introduction of x-ray technology as a medical image modality by William Conrad Röntgen in 1895 marked the beginning of image-guided surgery. Within months of Prof. Röntgen publishing his findings, x-ray images were not only used as a diagnostic tool but also to navigate surgical procedures [1, 2]. One of the first reported cases was performed by Dr. Robert Jones in Liverpool to remove a small bullet which was embedded in a boy's wrist [2]. In this case, x-ray images of the affected anatomy allowed the surgeon to better understand the complex anatomy of the patient,

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G. Zheng et al. (eds.), *Intelligent Orthopaedics*, Advances in Experimental Medicine and Biology 1093, https://doi.org/10.1007/978-981-13-1396-7_18

plan a suitable approach and help to transfer this plan into their surgical actions [3]. This basic workflow for an image-guided intervention is still used today in many orthopaedic interventions.

In general, image-guided surgery provides a link between a plan based on an image of the affected anatomy and the intraoperative action of the surgeon. The challenge in every image-guided procedure is to link the intraoperative situation to the medical image of the affected anatomy. This step requires a registration of the real anatomy to the representation of the anatomy in the image. In traditional image-guided interventions, this 2D (x-ray) to 3D (anatomy) registration is performed by the surgeon and relies on his or her clinical expertise.

In the early 1990s, computer-assisted surgery (CAS) systems were introduced for orthopaedic applications. CAS systems are image-guided surgery systems in which the link between image and anatomy is created using a navigator. CAS systems can be classified as freehand systems or instrument-guided systems. This characterization is based on the style of the instrument handling. In freehand systems the surgeon is guiding the surgical instrument, and the CAS system is providing visual feedback to navigate the instrument position and trajectory. In instrument-guided systems, the surgical tool is physically guided by the CAS system. Robotic-assisted systems are one example of such instrument-guided CAS systems.

A novel method of instrument-guided computer-assisted surgery was introduced in 1998 by Prof. Rademacher [4]. Patient-specific instrument guides, also known as patient-specific guides, or patient-specific instrumentations, provide a unique way of registration. While "conventional" CAS systems registration is performed by applying computer algorithms intraoperatively to virtually align the image with the anatomy, in patient-specific instrument guides, the registration is structurally integrated into a physical component of an instrument guide.

The basic steps for the patient-specific instrument-guided procedure are image acquisition, surgical planning, surgical guide design and creation, registration and instrument tracking.

In the image acquisition step, a 3D image (computed tomography (CT) or magnetic resonance imaging (MRI)) of the affected anatomy is obtained, and image analysis methods are applied to create 3D isosurface models of the anatomy (Fig. 18.1a). Using these 3D models, a surgical plan is generated. Depending on the surgical intervention, this plan may contain entrance point, trajectory and/or insertion depth of one or more surgical instruments. Furthermore, for arthroplasty cases, the type and size of prosthesis components may be planned (Fig. 18.1b). Surgical planning and 3D isosurface anatomical models are then used to design a patient-specific instrument guide. Each guide contains one or more registration components, as well as one or more tool guidance components. The registration component(s) are shaped to fit uniquely onto areas of the 3D anatomical model which will be accessible during the surgical intervention. To ensure a stable and unique registration, anatomical areas with distinct features are chosen, such as bone protuberances or unique curvatures. Instrument guidance components (such as cylinders or slots) are integrated into the guide in such a way to reproduce the surgical planning (Fig. 18.1c). A physical model of the patient-specific instrument guide is created using prototyping technology. The majority of patient-specific instrument guides are currently produced using an additive manufacturing process, also referred to as 3D printing, in which a part is created by depositing material, layer-by-layer [5]. These guides are then packaged, and sterilized, and sent to the surgery room. During the surgery, a surgical exposure is performed, and the guide is fitted to the corresponding anatomical surface (Fig. 18.1d). With the guide in the predefined (registered) position on the anatomy, surgical instruments are navigated using the guidance components in the guide (Fig. 18.1e). After all tools are navigated, the guide is removed from the anatomy and discarded.

Although the implementation of tool navigation in patient-specific instrument guides is very different to the above-mentioned robotic CAS systems, both systems can be classified as instrument-guided CAS systems. In both meth-

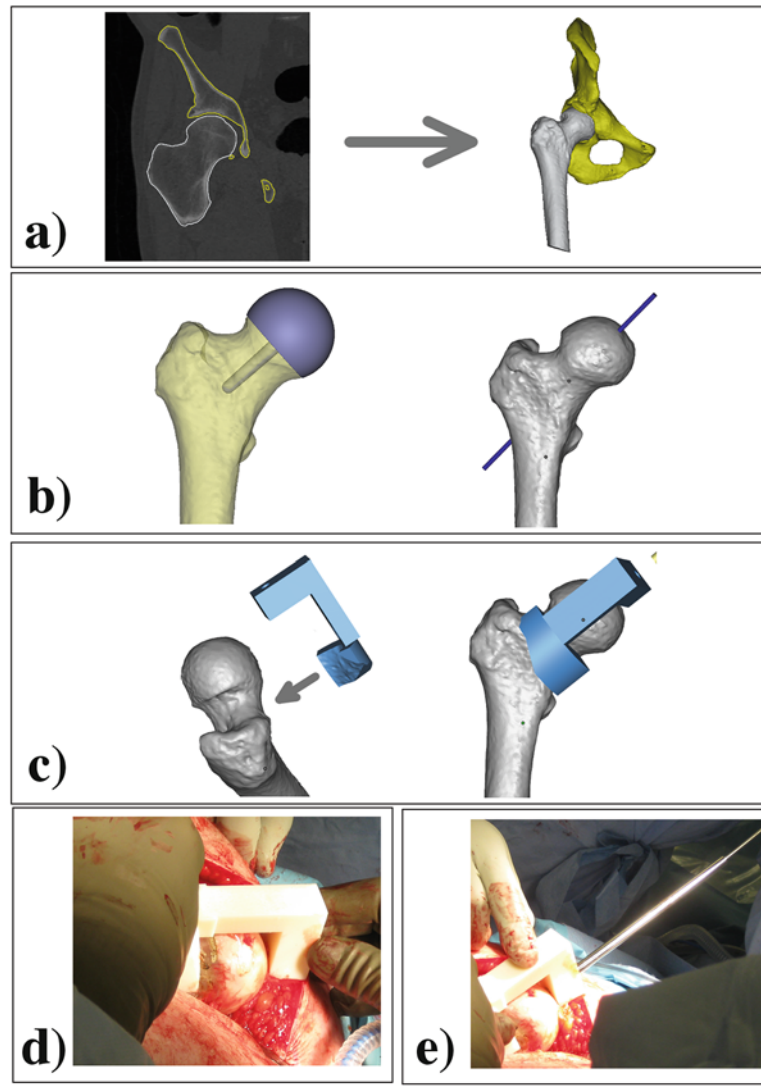

Fig. 18.1 Basic steps for patient-specific instrument-guided procedures. This example shows a patient-specific guide for the femoral central pin placement during a hip resurfacing procedure: (**a**) segmentation and 3D model generation from a preoperative CT scan; (**b**) surgical planning of component size and central pin alignment; (**c**) guide design, surface area around the femoral neck is used to register the guide to the anatomy; (**d**) intraoperative registration of the patient-specific instrument guides; (**e**) a medially attached guidance component is used to drill the pin into the bone following the preoperative planned central pin trajectory

ods, the surgeon manually performs the registration: in robotic-CAS systems, by selecting and digitizing appropriate anatomical features; in patient-specific instrument guides, by fitting the guide to the corresponding anatomical surface. Following registration, in both systems, the surgical tool(s) are guided along a preoperatively defined tool trajectory.

Currently, the majority of applications for patient-specific guides are in total knee arthroplasty. Other applications include hip and shoulder arthroplasty, osteotomies, and cartilage repair. In the following sections, we will focus on knee applications. We will also examine the effect of patient-specific instrument guides on operating room efficiency, costs and infection rates. We will conclude this chapter with a discussion of challenges and future developments in the area of patient-specific instrument guides.

18.2 Patient-Specific Instrument Guides for Total Knee Arthroplasty

Total knee arthroplasty (TKA) is a well-established surgical treatment for patients with advanced knee osteoarthritis. It is predicted

that the number of primary TKA cases in the USA will be over 1.3 Million in 2020, which reflects a 300% increase compared to 2005 [6]. Other countries predict a similar increase in demand for this procedure [7, 8]. Although the complication rate for the procedure is considered low, due to the number of procedures performed, revision surgeries are still a burden for healthcare systems.

The malalignment of prosthesis components during the surgical intervention is considered a major factor for implant failure. In particular, outliers in the overall coronal leg alignment are associated with a higher rate of revisions compared to well-aligned knees [9]. Computer-assisted surgery systems are applied to TKA procedures with the goal of increasing the accuracy and reliability in prosthesis component alignment. CAS systems for TKA procedures were introduced by Delp et al. in 1998 [10]. Although many studies have shown an improvement in component alignment using CAS as compared to conventional TKA procedures [10], their effect on the long-term success of the procedure has prompted controversial discussion for many years. However, in 2016, the Australian National Joint Registry reviewed their long-term results and reported a significant decrease in revisions for the CAS-TKA system relative to conventional TKA procedures [11], indicating that the improved component alignment resulted in a better long-term clinical outcome.

The application of patient-specific instrument guides for TKA has seen rapid growth in recent years. Various commercial products implement the concept of patient-specific instrument guides for TKA cases. The current leading products on the market are the PSI Knee System and the Signature System from Zimmer Biomet (Warsaw, IN, USA), the TruMatch Personalized Solution from DePuy Synthes (Warsaw, IN, USA) and the Visionaire Patient Matched Instrumentation from Smith & Nephew (London, UK).

In general, patient-specific instrumentations for the TKA procedure contain a set of two patient-specific guides: one femur and one tibial guide. These guides are designed to be used with standard surgical approaches, such as medial parapatellar arthrotomy. The registration surface of the femur guides contains part of the anterior ridge as well as part of the distal condyles. The tibia guides are fitted to the anterior medial tibial cortex and medial and/or lateral plateaus.

Patient-specific instrument guides in TKA are employed to navigate the femoral and tibial bony resections. The guidance components contain either slots to directly navigate the saw to perform these bony cuts or contain cylinders to navigate the insertion of pins. These pins are then used to position a standard prosthesis cutting block onto the bone, which subsequently guides the saw for the bony resections.

In recent years, various studies have reported on the short- and midterm outcomes of patient-specific guided TKAs compared to conventional TKA procedures. So far, there is no common conclusion as to whether the guides provide higher accuracy and/or precision in achieving optimal prosthesis component alignment. While some studies found that patient-specific instrument guided cases had a significantly better and/or more reliable overall leg alignment [12–17], other studies did not find a significant difference in the neutral leg alignment [18–24]. Similarly, some studies found that the use of patient-specific instrument guides increased the accuracy and/or reliability for femoral component rotation [25–27], while other studies did not see a significant difference in femoral component rotation between the use of patient-specific instrument guides and the conventional technique [28, 29]. Some studies have found that the application of patient-specific instrument guides might result in less accurate and reliable alignment for the tibial component [21, 30]. On the other hand, Heyse et al. found that the use of patient-specific instrument guides improved the tibial component rotation significantly compared to conventional technique [31]. Sliva et al. and Ng et al. found significantly smaller deviations for tibial component rotation using patient-specific guides [25, 32].

Notably, only a minority of the above-mentioned studies used a 3D image modality, such as CT or MRI, for the postoperative evaluation of the alignment errors [14, 15, 22,

25, 27, 31, 32]. More often, the measurements were performed on plain radiographs and might be affected by projection errors.

The majority of studies have reported no significant differences in patient-reported short- or midterm clinical outcomes. However, Nabavi et al. published significantly higher Oxford Knee Scores in the 1-year postoperative follow-up for patients treated with patient-specific instrument guides compared to conventional instruments [33].

Unlike conventional TKA instrumentations, patient-specific instrument guides do not require the opening of the femoral intramedullary canal. This, together with the reduced surgery time discussed below, is believed to be the reason for significantly reduced blood loss, which some researchers observed when comparing conventional and patient-specific guided procedures [33–36].

Commercial patient-specific instrument guide systems for TKA procedures use either MRI or CT scans as preoperative image modalities. The authors of a recently published meta-analysis concluded that CT-based guides had a slightly but significantly higher incidence rate of outliers in the coronal overall limb alignment compared to MRI-based guides [37].

Many authors of the above-mentioned studies discussed limitations, including low case numbers, single-surgeon observations and absent long-term evaluations. Further studies are required to fully evaluate the effect of patient-specific instrument guides on the clinical outcome for total knee arthroplasties.

18.3 Operating Room Efficiency, Cost and Infections

Although the effect of patient-specific instrument guides on postoperative alignment of prosthesis components is still uncertain, there is less controversy about the effect of these guides on the operating room efficiency.

Studies have shown a significant decrease of surgical time compared to conventional procedures [12, 13, 23, 24, 35, 38–41]. The average decrease in surgical time varied between 3 min [23] and 18.5 min [12]. Some authors also reported a significant decrease in the overall operating room time, ranging between 8.6 min [13] and 20.4 min [38].

In contrast, Hamilton et al. did not find a significant decrease in surgical time, but did report a significant decrease in the number of surgical trays opened during the procedure. The group measured the average number of trays opened during a conventional procedure as 7.3, which was significantly reduced to 2.5 using patient-specific guides [42]. Significant reductions of opened trays during the surgery were also found by other researchers [13, 17, 29].

Conventional instrumentations for performing bone resections during TKA procedures adapt to differences between patients by accommodating instruments and instrument parts of various sizes, angles, distances etc. Often, these instruments are modular, requiring assembly in the operating room. Patient-specific instrument guides make many of the conventional instruments obsolete, simplifying and streamlining the intraoperative procedure. These changes are reflected in the published reduction in surgical time and number of trays opened during the procedure.

The correlation between the number of opened trays during the surgery and a faster room turnover time was measured in a study by DeHaan et al. [38]. The authors of this study found that the average turnover time for conventional TKA surgery was significantly reduced from 21.6 min to 15.2 min using patient-specific instrument guides. DeHaan and co-authors also analysed the costs and savings associated with patient-specific instrument guides for TKA surgeries in a single US institution. Added costs for patient-specific guides, including preoperative imaging and the guide itself, were documented to be in a range of $930–$1860. The average cost saving was calculated as $1566 per case, which included the savings from reduced operating room time and sterilization of fewer trays. The authors concluded that, depending upon which

imaging centre is used, the use of patient-specific instrument guides for TKA procedures can result in significant cost savings.

A more comprehensive cost analysis was performed by Tibesku et al. using an activity-based costing model [43]. The authors of this study also concluded that the additional costs per case for the guide and the preoperative imaging were offset by an increase in the efficiency of the procedure which led to cost savings due to reduction in OR time and reduced surgical tray utilization. The activity-based cost model applied by the authors of this study showed an annual OR time savings of 10,500 min. By utilizing these gains in OR time to perform surgeries other than TKA, the model estimated the additional gross margin for the hospital per year as 78,240 Euros. The study concluded that if saved OR time can be used effectively to perform additional procedures, the use of patient-specific instrument guides can result in incremental revenue for the hospital.

Furthermore, it is speculated that the preoperative planning of prosthesis component sizes might result in decreased storage and loaner costs for instruments, which, in turn, might also result in additional cost savings for the hospital and health-care system.

Due to their individualized character, patient-specific instrument guides are single-use instruments. In general, single-use instruments are considered safer with respect to infection control compared to reusable instruments, since cross-contamination can be avoided [44–46]. The effect of using patient-specific instruments during TKA procedures on the postoperative infection rate should be investigated further, as surgical site contamination can lead to periprosthetic infections, a serious complication with prolonged and expensive treatment [47]. It stands to reason that lowering the infection rate can not only have a huge benefit for the patient but can also result in significant lowering of costs for hospitals and health-care systems.

18.4 Patient-Specific Instrument Guides for Large Osteochondral Cartilage Defect Repair

Clinical studies have demonstrated superior outcomes for osteochondral autologous transplantations (OAT) as a treatment option for osteochondral cartilage defects [48, 49]. In this procedure, one or more autologous osteochondral cylindrical grafts are harvested from minimal weight-bearing areas in the joint and transplanted in a weight-bearing area where cartilage is damaged. Unlike alternative treatment options, OAT is a single-stage treatment with restoration of mature hyaline cartilage and fast native bone-to-bone subchondral healing. On the other hand, various studies have demonstrated the importance of creating a congruent, continuous joint surface when using OAT to optimize outcomes [50, 51]. Donor site accessibility and the variation in the radius of the femoral condyle curvature make re-creation of a congruent joint surface challenging when using multiple small grafts. Furthermore, the limited donor site availability often restricts conventional OAT treatment to lesions less than 4 cm^2 [49]. However, the combination of advances in 3D preoperative planning and accurate and reliable intraoperative guidance also makes this preferred treatment option available for larger defects.

Here we describe a case of a 17-year old woman with a 6.9 cm^2 full-thickness cartilage defect in the medial femoral condyle of her right knee, who was treated with a patient-specific instrument-guided OAT procedure. Prior to the surgery, a CT arthrogram scan of the treatment knee was obtained. Three-dimensional surface models of the bony anatomy and the cartilage were created (Fig. 18.2).

These models were imported into our custom-designed image-guided planning software [52]. In consultation with the orthopaedic surgeon, a

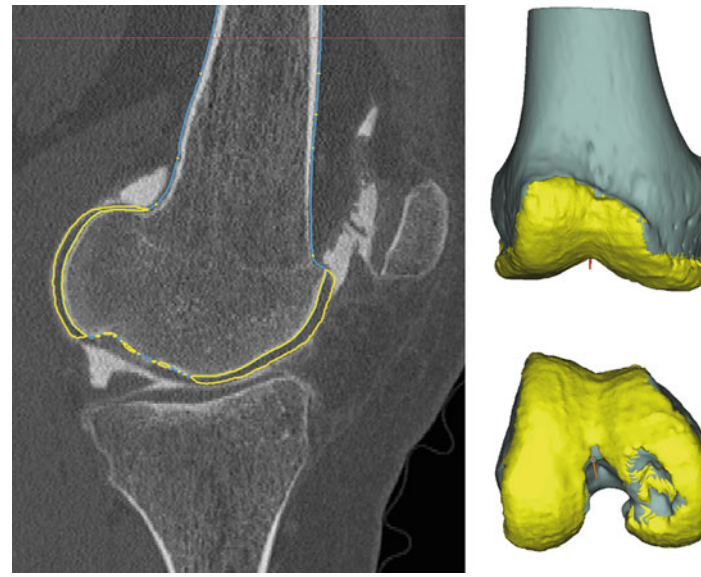

Fig. 18.2 Left side shows a sagittal CT arthrogram slice of the medial condyle. Blue contours mark the outline of bone; yellow contours mark the outline of cartilage. Right side shows the isosurface models for bone and cartilage created from the segmented CT arthrogram

patient-specific surgical plan was developed. The surgical plan consisted of a set of five osteochondral grafts (plugs) positioned in the defect site and their corresponding harvest sites. The plugs could be rotated axially allowing the sloped surface at the harvest site to match that of the defect site. Furthermore, by displaying the bone and/or cartilage 3D model transparently, the bone plug interference in the recipient and harvest sites could be identified and corrected. Based on the intraoperatively available harvest and delivery tools, plug diameters were planned with three plugs with a diameter of 10 mm and two plugs with an 8 mm diameter. Figure 18.3 shows the final surgical plan.

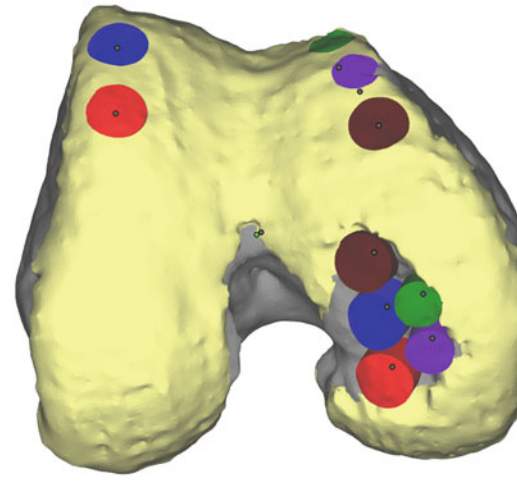

Fig. 18.3 A set of 3 × 10 mm and 2 × 8 mm grafts were planned. For each graft, the planned harvest site and corresponding recipient site are marked with the identical colour

Using the patient's surgical plan, a set of individualized guides were designed and prototype printed using a thermoplastic ABS material. For each osteochondral graft in the surgical plan, a guide was constructed containing the following three components: a positioning template, a harvest guide cylinder and a delivery guide cylinder (Fig. 18.4).

The undersides of the positioning templates were shaped to the surface of the femoral condyles surrounding the defect as well as the patellar groove and were designed to fit into a conventional surgical exposure of the knee (Fig. 18.4-1). For the preparation of the delivery site, a guide cylinder was positioned directly over the planned recipient site (Fig. 18.4-2), which guided a chisel tool to prepare the cylindrical recipient hole. A harvest guide cylinder was integrated into the template to allow positioning and orienting of a conventional harvester over the planned harvest site (Fig. 18.4-3). The delivery of the harvested graft plug was guided through the delivery guide cylinder (Fig. 18.4-4). Small

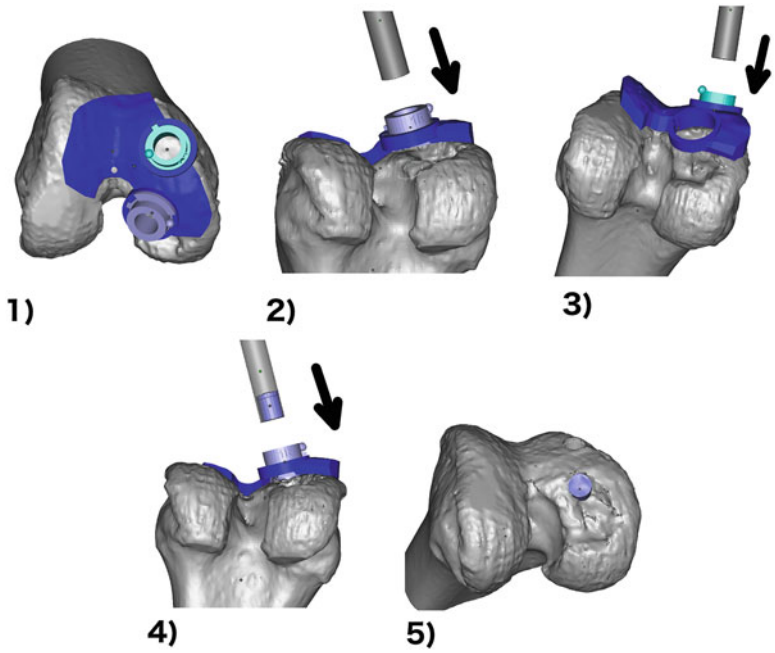

Fig. 18.4 Patient-specific instrument-guided harvesting and delivery of one osteochondral graft

spherical rotation marks attached to the harvest cylinder, as well as the delivery cylinder, allowed insertion of the graft following the planned rotation and ensured that the slope of the graft consistent with the medial condyle curvature. To ensure that the prepared delivery hole and the height of the cylinder matched, the depth of the chisel insertion was navigated using a predefined mark on the chisel tool. The planned depth of tool insertion was reached when this mark was aligned with the top of the guidance cylinder.

After delivery of the graft, the patient-specific instrument guide was removed (Fig. 18.4-5). The same procedure was repeated for the remaining four grafts, each with their own specific guide tool.

Preoperatively, as well as 3 months, 6 months and 1 year postoperatively, the patient documented pain and function using the Knee Injury and Osteoarthritis Outcome Score (KOOS) and the Western Ontario and McMaster Universities Osteoarthritis index (WOMAC). Figure 18.5 shows the KOOS sub-scores for symptoms, knee-related quality of life, pain, function in daily living (ADL) and function in sports and recreation (Sportsrec). Overall, the sub-scores showed a continuous improvement during the follow-up period. Similarly, the WOMAC sub-scores[1] for pain, stiffness and function showed a steady improvement over the 1-year postoperative follow-up time.

Using conventional surgical techniques, OAT is considered technically demanding for larger lesions due to the potential for incongruous surface, gapping between the plugs with fibrocartilaginous fill and donor site morbidity [49]. Therefore, it is often only used to treat defects which can be filled with two to three plugs. By using accurate and high-resolution 3D preoperative images, combined with medical image analysis methods, a precise and careful preoperative planning of plug position, orientation and optimal harvest sides can be performed.

Such virtual planning can provide unique features, such as investigation of graft intersections, and measurements for defect coverage. Furthermore, a preoperative planning allows for a trial-and-repeat process to establish an optimal graft pattern, which is impossible in an ad hoc surgical approach. We have shown in an earlier study that our preoperative planning

[1] Sub-scores were transformed to a 0–100 scale, with higher scores reflecting better quality of life.

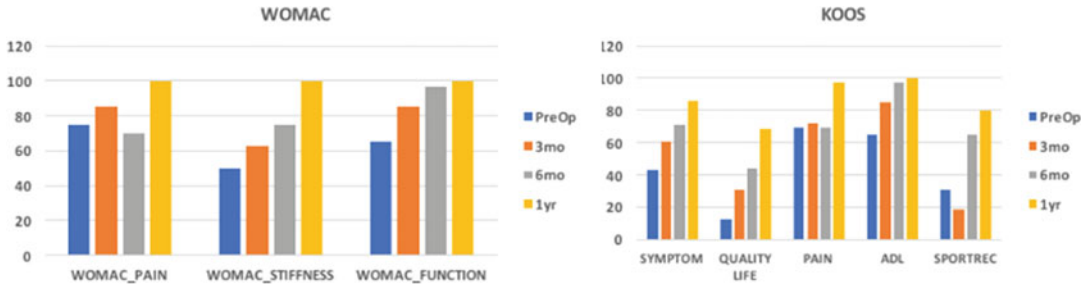

Fig. 18.5 WOMAC and KOOS sub-scores for preoperative, 3-month, 6-month and 1-year postoperative evaluations

can achieve reproduction of natural cartilage curvature with an Root Mean Square (RMS) error of 0.31 mm, a defect coverage of 84% and an overlap between the graft plugs of 16% [52]. In the same study, we were also able to show that large parts of the planning procedure can be performed automatically with similar or better results than those of a human operator with substantially faster planning time.

After creating a preoperative plan which optimizes the use of available harvest areas, patient-specific instrument guides were employed to precisely transfer this plan into the intraoperative situation. By using guidance cylinders, combined with rotational marks and depth navigation, it was possible to guide tool trajectories with 6 degrees of freedom. Accuracy and precision of this patient-specific instrument-guided technique was investigated in a laboratory study [53]. By using patient-specific guides, it was found that the surgeons were able to significantly more accurately reconstruct surface congruency over the defect, have better coverage of the defect area and reduce the number of grafts which were proud or recessed compared to using the conventional surgical technique. Furthermore, the patient-specific instrument-guided procedures were significantly faster, not only compared to the conventional technique but also compared to a freehand CAS method. An animal trial showed that this higher accuracy and precision during the intraoperative procedure directly related to a better short-term healing response in the transplanted cartilage [54]. Both of these studies have shown that the patient-specific instrument-guided methods were comparable to freehand CAS methods with respect to accurate reconstruction of the cartilage surface over the defect. However, differences between the two CAS systems were seen with respect to procedure time, which was significantly longer for the freehand CAS system. Furthermore, the animal trial revealed a significantly smaller cyst volume in the patient-specific instrument-guided group compared to the conventional, a difference which was not observed for the freehand CAS group. It is considered that subchondral cysts might be the result of synovial fluid penetrating into the gap between the graft and the subchondral bone. Since patient-specific instrument guides are an instrument-guided CAS system, which holds the chisel tool or drill in a steady trajectory during the preparation of the delivery hole, it may provide a more tightly fitting plug, reducing the fluid penetration. With the conventional and freehand CAS-guided techniques, the tools are hand-held without external support and can result in a hole that is less cylindrical.

A unique combination of preoperative planning and easy-to-use and precise intraoperative guidance provides the ability to extend the technically demanding procedure of OAT to patients with larger defects of over 4 cm^2.

18.5 Other Applications for Patient-Specific Instrument Guides for Orthopaedic Interventions

About 10 years ago, rapid prototype technology started to be more widely available, which

accelerated the research and development in patient-specific instrument guides. Around the same time, newly developed materials proved to significantly increase the long-term survival rate of hip resurfacing implants, which created a renewed interest in using hip resurfacing arthroplasty (HRA) as a treatment option for hip osteoarthritis. However, HRA is deemed a technically challenging procedure with a significant learning curve [55], and interest in image-guided methods for HRA procedures were soon expressed. Consequentially, researchers saw the opportunity to introduce patient-specific instrument guides for HRA procedures. The preparation of the proximal femur and the resulting alignment of the femur component allow for only a small margin of error, and the majority of patient-specific instrument guides in hip resurfacing are designed to navigate femoral component placement. In hip resurfacing systems, the placement of the femoral central pin (also known as the guide wire) is a crucial step for the accuracy of femoral component alignment since it identifies the final femoral component orientation, as well as 2 of the 3 degrees of freedom for femoral component positioning. Various research groups have published methods and results for patient-specific femoral central pin guidance tools. Figure 18.1 shows a patient-specific guide for the femoral central pin placement. We tested the accuracy of this patient-specific guide design in various studies [56, 57] and found in the most recent study that the alignment error for the central pin was 0.05° in the frontal plane and 2.8° in the transverse plane. We found errors in the entrance point for the central pin of 0.47 mm in the frontal plane and 2.6 mm in the transverse plane. Other research groups have compared similar patient-specific instrument-guided solutions to conventional central pin placements techniques and found significantly improved accuracy for the patient-specific guided pins [58–60].

Recently, researchers have also proposed and evaluated solutions for patient-specific instrument guides for total hip replacement (THR). Various groups developed and tested patient-specific instrument guides for acetabular cup placement [61–65]. When compared with conventional surgical methods, these guides have shown to significantly improve acetabulum cup alignment [61, 62, 65]. Similarly, patient-specific instrument guides which were developed to navigate the femoral stem placement showed improved precision compared to conventional methods [66, 67].

Other joint arthroplasty applications for patient-specific instrument guides include total shoulder arthroplasty [68–71] and total ankle arthroplasty [72].

Bone abnormalities as a result of trauma or disease may result in pain and limited mobility of the adjacent joints. Osteotomy, a surgical procedure in which a reduction of bone towards a healthy anatomy is performed, is a joint-preserving treatment option for such cases. Osteotomy not only allows for angular correction in three different planes (varus/valgus, extension/flexion and internal/external rotation) but also for displacement correction in three directions (lengthening/shortening, medial/lateral, dorsal/ventral). This 3D complexity means these procedures profit greatly from a 3D planning [73]. Since the misalignments (as a result of fractures or deformities) are unique, each patient also has a unique osteotomy resection(s). It is, therefore, very difficult to provide any “standard guidance” instruments, and conventional procedures rely heavily on intraoperative imaging and surgeon experience. Instead, various research groups have suggested navigating these complex procedures using patient-specific instrument guides and have published promising results in early studies. So far, the suggested applications for patient-specific instrument guides range from lower limb osteotomies [74–76] and upper limb osteotomies [77–79], to osteotomies to improve joint functions [80–85]. Furthermore, patient-specific instrument guides are utilized to navigate pelvic tumour resections to ensure sufficient margin resections as well as to avoid unnecessary loss of joint function [86–89].

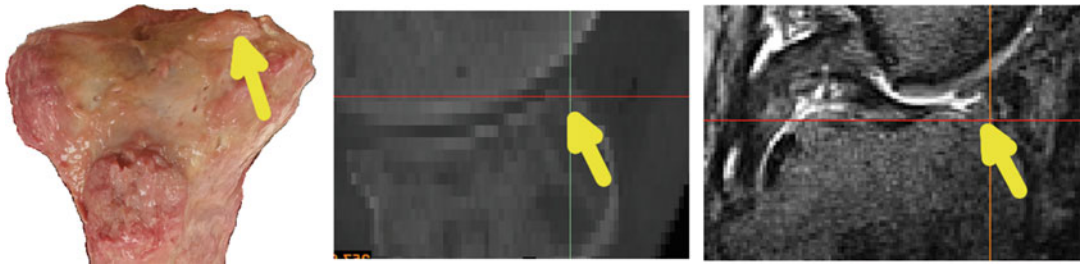

Fig. 18.6 Depiction of a proximal tibia with a partly cartilaginous osteophyte (yellow arrow). Left: dissection of the proximal tibia. Middle: CT slice in sagittal view with 120 KvP voltage and 2.5 mm slice distance. Right: Sagittal T1-weighted MRI slice

18.6 Challenges and Future Work

Patient-specific instrument guides are a relatively newly developed computer-assisted technology, and their application for orthopaedic surgical interventions is in the beginning phase. As with many new developments, patient-specific guides still have some challenges to overcome to achieve a full transition into routine clinical use. In this section, we will discuss some of these limitations and some future and current work which may overcome these challenges.

18.7 Preoperative Image Modalities

Patient-specific instrument guides rely on a preoperative 3D model of the affected anatomy which accurately represents the patient's anatomy, especially in the registration areas. The bases for such accurate models are medical images of the anatomy which depict the anatomical surface exactly. Particularly in patients with osteoarthritis, this consideration might be critical, because the disease is characterized by the breakdown of articular cartilage accompanied by the changing of local bone anatomy [90]. One example of such bone alterations is the development of osteophytes – abnormal osteocartilaginous tissue that grows along joint borders [91]. Their high variability in density and composition might interfere with an accurate depiction in medical image modalities. Figure 18.6 shows the depiction of a partly cartilaginous osteophyte on a proximal tibia (left), in a CT scan (middle), and a MRI scan (right).

Various studies have hypothesized that osteophytes may be related to increased postoperative errors for image-guided interventions. In an accuracy study for patient-specific instrument-guided total knee arthroplasties, Seon et al. suggested that outliers resulted from large osteophytes which interfered with the fit of the guide [92]. An observational study on patient-specific guides for hip resurfacing procedures found that osteophytes, not accurately identified in a preoperative CT scan with standard segmentation protocols, could potentially result in errors up to 2.8° between the planned and final achieved tool trajectories [93]. Results for this study also showed that 78% of the surface points collected from osteophytes were depicted in the CT scan with a Hounsfield unit below the usual bone threshold and would therefore be missed with segmentation methods using the standard threshold.

In addition to osteophytes, motion artefacts during image acquisition might result in insufficient image quality. Kosse et al. reported that 4% of the patients had visible motion artefacts in the preoperatively acquired MRIs and needed to be excluded from the study [28]. All of these studies indicate that future work in the careful selection of image modalities, custom-made imaging protocols, as well as improved segmentation protocols might improve the reliability of patient-specific instrument guides. It can be speculated that inaccurate depiction of the anatomy might

be the reason for some of the reported outliers in the above-mentioned clinical follow-up studies.

Some researchers have raised concerns about the requirement of preoperative CT or MRI scans due to the additional cost, time and radiation exposure [18, 94]. Cerveri et al. published early results of a feasibility study to replace the preoperative 3D image with 2 to 5 x-rays [95]. The authors proposed a method in which these x-ray images of a patient are used to morph a statistical shape atlas for a distal femur with severe cartilage damage into a patient-specific model. The results of this feasibility study are promising, and future work in this area might eliminate or reduce the need for costly and/or invasive preoperative imaging.

18.8 Preoperative Planning

Patient-specific instrument guides are a tool to transfer preoperatively planned resections into the surgical situation. As such, the quality of the preoperative planning plays an important role in the postoperative outcome of the procedure and should be performed with great care by the surgeon. Although many commercial systems provide an "initial plan" based on image analysis for tibial and femoral resection, these plans might not reflect optimal outcome from a clinical point of view. A study found that 91.1% of initial plans for patient-specific instrument-guided TKA procedures required at least one correction by the surgeon [96]. A similar study found that surgeons corrected the initial plan for the size of the femoral component in 16% of the cases and the size of the tibial component in 48% of the cases. The initial planned rotation for the tibial component was changed by the surgeon in all of the 50 investigated cases (100%), and the initial planned flexion of the femoral component was manipulated by the surgeon in 46% of cases [97]. Goyal and Stulberg evaluated the precision of surgical planning systems for patient-specific instrumented TKA by comparing plans from two different commercial systems and found significant differences in the determination of the mechanical axis, in the planning of femoral and tibial component sizes, as well as in the resection heights of four of the six bone resections [98].

The findings of these studies show that future developments into more advanced preoperative planning methods might help to improve the clinical translation for patient-specific instrument guides.

18.9 Intraoperative Validation

An important step for every computer-assisted surgery system is the registration between the intraoperative instrument position and the medical image used for planning. In patient-specific instrument guides, this registration is achieved by fitting the guide to the corresponding anatomical surface during the surgical intervention. An accurate fit between guide and anatomy depends on many factors, including the accuracy of the preoperative images of the anatomy as discussed above. Furthermore, the design of the registration component might influence the fit of the guide. The selected anatomical registration areas need to be not only accurately depicted but also must have a sufficient number of registration features. Kwon et al. published the results of a comparison study between two different patient-specific instrument guide designs for TKA and found that minor expansions of the registration area for both guides (femur and tibia) resulted in an improved rotational stability of these guides. This improved fit directly translated into better alignment of the prosthesis components and shorter surgery times [12]. However, an expansion to a larger registration area is not always clinically feasible or desired. For example, increasing the registration area of a tibial cutting guide during a TKA procedure would require removal of larger parts of the tuberosity. Such increase in invasiveness could directly affect the recovery time of the patient. Furthermore, larger registration areas do not necessarily guarantee improved fit of the guide. A study on patient-specific guides for hip resurfacing showed an improvement in tool guidance accuracy when the registration surface of the guide was reduced [57]. In this study, articular surface and osteophyte-prone areas were removed, which

resulted in a decrease of depiction uncertainty. Selection of the optimal registration surface is currently made by researchers and technicians manually. However, promising research in this area could provide mathematical methods to support this part of the guide design process. Van den Broeck et al. published an algorithm to analyse the registration stability of guides based on the anatomical geometry [99]. Such methods might help to optimize guide designs preoperatively in the future.

18.10 Summary and Conclusions

Patient-specific instrument guides are a unique way of performing computer-assisted orthopaedic surgeries, in which a prototype-printed part is the navigator which links a preoperative plan to surgical action. Similar to other CAS systems, the guides rely on an accurate 3D preoperative image of the affected anatomy, a clinically optimal surgical plan, a reliable registration procedure and a precise tool guidance method.

Prototype technologies are currently one of the most rapidly advancing new technologies. Patient-specific instrument guides take advantage of these innovations without the need to bring new technology into the surgery room. This simplifies clinical transition for these guides. For a hospital, no great initial investments are required to purchase equipment and/or hire technical staff.

Unlike other CAS solutions, patient-specific instrument guides have shown to improve efficiency in the surgery room, and there are good indications that these guides can achieve cost savings. In a time where health-care costs are steadily rising and the number of orthopaedic procedures is expected to multiply in coming years, it is sensible to also evaluate the economic benefit of new technologies.

Orthopaedic surgery and computer-assisted orthopaedic surgery are rapidly evolving fields, with new developments and discoveries frequently improving current methods and standards. Such developments include novel prosthesis designs, new recommendations for component positioning and new and improved algorithms for segmentation or registration. An advantage of patient-specific instrument guides is a seamless integration of changes into the clinical routine. While freehand and robotic CAS systems often require software and/or hardware updates to implement new or improved features, for users of patient-specific instrument guides, no update procedure is necessary. For these users, evidence of change is having an improved guide delivered to the surgery room.

Patient-specific instrument guides require sufficient access to the registration area of the anatomy. Therefore, for minimally invasive procedures, patient-specific instrument guides are not the optimal image-guided technology. For example, the articular cartilage repair case we presented above was chosen because of the very large defect size. Large defects require extensive access to harvest sites and are therefore not candidates for arthroscopic procedures. Consequently, patient-specific guides were an optimal navigation method. Smaller cartilage defects are more likely treated in an arthroscopic manner, and freehand or robotic CAS systems are better options for intraoperative navigation for these cases. Another limitation in the use of patient-specific instrument guides is the requirement of a final preoperative planning of instrument trajectories. In contrast, freehand CAS systems can provide intraoperative planning methods, which might allow the surgeon to adapt to a situation which can only be sufficiently judged intraoperatively.

In general, we believe that the easy integration of patient-specific instrument guides into operating room procedures as discussed above is a major advantage of this CAS method. However, it also makes this relatively new technology vulnerable to an insufficient research period. Many hospitals have adapted the technology for TKA procedures and have published early results. Although motivation to integrate this new method into clinical practice is encouraging, results should be seen as possible input into further improvements and not necessarily as “make-or-break” validation studies. Kwon et al. described their experiences with patient-specific instrument

guides for TKA procedures before and after small modifications were made to the guides' designs and found that these small changes in the second generation of guides significantly improved axis alignment and surgical time [12]. Similarly, we found that changes in the guide design for hip resurfacing procedures improved our accuracy from 4.5° [56] in the transverse plane to 2.8° [57]. There might not be much of a learning curve in the application of the guide for the surgeon and operating room team, but there might be a learning curve for researchers and technicians in the design of the guides. Effects of this learning curve might only be evident in a delayed reaction in the clinical outcome.

In conclusion, patient-specific instrument guides provide a method to 3D plan a surgical intervention and transfer this plan into the surgical field in an effective, user-friendly and time- and instrument-efficient way.

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