12

Patient Specific Instruments: Past, Present and Future

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Chapter Outline

INTRODUCTION

Patient specific instrumentation is a new concept that exploits different aspects of computer-assisted technologies to perform virtual surgery and produce patient specific instruments (PSI) based on preoperative imaging. Thus, shifting several operative steps to the preoperative stage, saving operative time and making the procedure easier and potentially less complicated. This concept started with total knee arthroplasty (TKA) in the early 2000s and can be applied to similar procedures that require planning and has complex conventional instrumentation system. The technique of PSI for TKA involves preoperative planning of surgery, including sizing, alignment and bone cutting, based on imaging (CT or MRI) and then the designing and production of femoral and tibial templates that can act as pin guides or cutting blocks. These instruments can replace part or all of the conventional instruments for TKA. Acting as patient-specific guides, these instruments should be placed accurately over the distal femur and the proximal tibia following a unique surface matching. The technique is time saving and less invasive as it eliminates the use of intramedullary (IM) guides. Figure 12.1 illustrates the technical steps of this technique.

THE PAST

Conventional Total Knee Arthroplasty: The Challenges

The development of TKA was secondary to total hip arthroplasty (THA) as it was hindered by several factors. The anatomy of the knee is complex and its kinematics is not fully understood. The almost monoplanar motion of the knee subjects the prostheses to more stresses increasing the risk of loosening as the forces resulted from the motion in other planes (e.g. rotation) will be transmitted to the implant-bone interfaces. These interfaces may be implant-cement or cement-bone in case of cemented prosthesis or implant-bone in case of cementless prosthesis. The knee joint is superficial

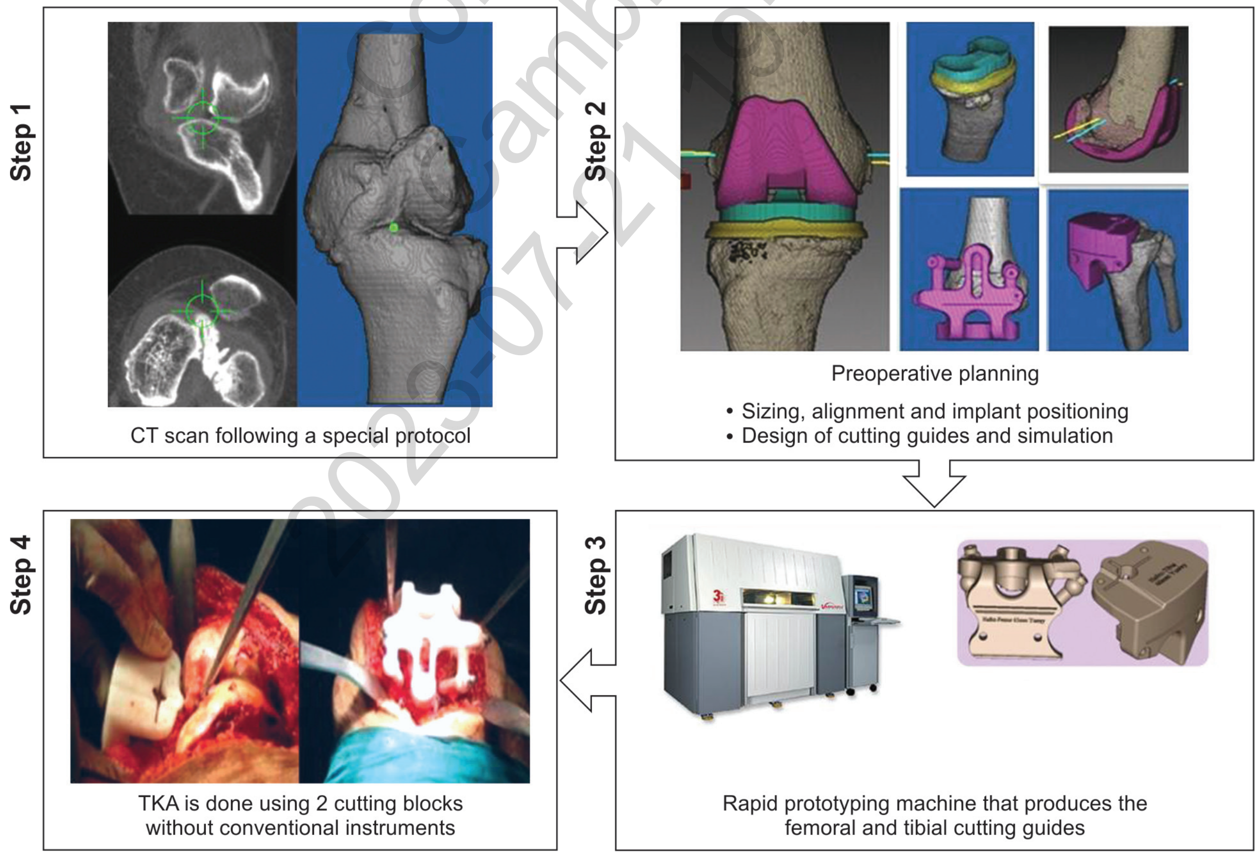

Figure 12.1 Patient specific instruments (PSI)

and although this makes the surgical approach easier it subjects the joint to higher risk of wound complications and infection. Placement of the prosthesis is very critical and must be accurate as a few degrees of malalignment can lead to failure. Complication rates are higher in THA, and salvage procedures are less successful. While excision arthroplasty can successfully salvage a failed THA it produces a very poor result in the case of TKA, and amputation is still a recognized complication for TKA but not for THA.

In addition, knee arthroplasties are becoming more complicated over time with the introduction of new and more demanding techniques. Knee arthroplasties include TKA, unicompartmental, bicompartmental, unispacer and patellofemoral arthroplasty. TKA could be a primary procedure (using an unconstrained or a hinged prosthesis) or a revision procedure. The primary procedure has many options; fixed-bearing, mobile-bearing, cruciate substituting, cruciate retaining, non-modular tibial component, cemented or uncemented.

Each implant has its own instrumentation system with a particular sequence of technical steps resulting in an increased cost, complexity, operative time, inventory, load on sterilization and learning curve for surgeons and nurses. The new techniques of minimally invasive surgery (MIS) for TKA made the procedure more difficult and increased the potential risk of complications. The indications for TKA have been extended to include difficult cases of arthrodesed knees, post patellectomy, bone deformities, HIV, hemophilia and others. These cases again require highly skilled and experienced surgeons and are usually done in specialized centers. Some of these cases require meticulous preoperative planning and very precise surgical performance.

The outcome of TKA in general is dependent on the technical success of the procedure.[15,16,68] Component malalignment may lead to early failure and revision surgery.[38,63,77] Bone cutting and alignment should be performed in three dimensional (3D) planes, but the accuracy of performance may vary as surgeons have different abilities in correlating the (2D) data from preoperative radiographs to the complex 3D anatomy during surgery. Surgeons may not be able to recognize up to 10° of knee flexion secondary to flexed femoral and tibial components and surgeons have tendency to internally rotate the femoral implant.[72]

Accuracy of Conventional Total Knee Arthroplasty

Is There a Need to Improve Accuracy in Total Knee Arthroplasty?

The answer could be no considering that the outcome of TKA is satisfactory and it is considered to be one of the most successful surgical procedures with consistent increase in the number of operations performed per year all over the world. The survival rate is more than 95% at 15 years.[32,37,40,63,66] In a recent report,[58] the importance of accuracy of implant alignment and restoration of mechanical axes were challenged. In this retrospective review of 398 primary cemented TKA with 15 years follow-up, there were 292 knees in the mechanically aligned group (with a mechanical axis of 0° ± 3°) and 106 knees with malalignment (with a mechanical axis of beyond 0° ± 3°). The revision rate was 15.4% in the aligned group and 13% in the maligned group. The revision of implants in 9.2% of the aligned as compared to 7.5% of the other group was due to aseptic loosening, mechanical failure, wear, or patellar problems. The author stated that "describing alignment as a dichotomous variable (aligned versus malaligned) on the basis of a mechanical axis goal of 0° ± 3° is of little practical value for predicting the durability of modern TKA implants". The conclusion from this study is that a mechanical axis of 0° ± 3° did not improve the survival rate at 15-year follow-up. Although, this conclusion does not accord with the results of previous studies, it supports the argument "we do not need to improve accuracy of TKA beyond the 0° ± 3°".

However, this answer should be yes due to three reasons: (1) the outcome of TKA is not as successful as reported, (2) the outcome of TKA is dependent on accuracy and (3) the accuracy of the conventional techniques are questionable. These reasons are explained in more details herein.

The outcome of total knee arthroplasty: Some authors cast doubts in the reported high rate of success of TKA. In one report[26] surgeon's assessment was rated higher in comparison to patient's self-assessment. Traditionally surgeons used revision as an endpoint while reporting success rate of TKA, missing all other causes of failure and all patients who are indicated for revision, but did not have surgery because of medical reasons. In one study[53,54] of 1,429 TKAs, the survival rate was 97.5% when revision was used as endpoint, but it was significantly reduced to 72% when pain was used as an endpoint.[54] The outcome results of TKA will be affected by the percentage of patients who lost to follow up; the outcome of the lost to follow up patients should be considered as failure (worst case analysis).

The outcome measures used for TKA are not standardized.[3] Many of the published studies on survival reported the results of one surgeon using a particular prosthesis in one center, these results cannot be generalized. Also, the reports of senior surgeons and centers of excellence are not representative. On the other hand, the survival rate of TKA in arthroplasty registers is worse than what is reported by other studies. Significant number of TKA procedures is done by occasional surgeons who perform less than 10 procedures per year.[46] Literature is scarce in reporting results of junior surgeons or surgeons who have had no formal training in arthroplasty. In addition, the success rate of TKA in developing countries is not known. In some places a high rate of complications and failures has been observed, but not reported. Most knee prostheses are repeatedly modified by manufacturers, so the reported results are for designs, which are no longer available. "There has been a failure to recognize that minor modifications to design, material, surface finish or fixation techniques can dramatically alter the performance of a knee replacement."[3] The majority of outcome studies of TKA used short knee radiographs and few of them used long-leg radiographs for assessment of alignment and loosening. The accuracy of plane radiographs is limited and may lead to clinically significant measurement errors that affect the overall outcome results. Recent studies used CT scanning specially to assess computer-assisted TKA.[7,45,57]

The high survival rate in outcome studies is related to elderly patients who, in most cases, have low demand and limited activities of daily living (ADLs). Therefore, their TKA procedures are not subjected to the actual demands of ADLs as found in younger patients. These patients usually do well even in the presence of malalignment or other technical errors. They are usually satisfied because their main expectation is pain relief rather than function. Many of them die before the manifestations of technical failures of TKA. Younger and active patients have lower survival rate. In one study,[62] the 10 years survival rate for young patients less than 50 years was 83% while for patients older than 70 years it was 94%. Results for complicated cases are poor as examples; deformities, hemophilia, following patellectomy, osteotomy, arthrodesed knees, etc. Revision TKA is more difficult, has more complications and the success rate is lower. Diduch et al. published the survivorship analysis of 108 TKA procedures for patients under the age of 55. The overall survival rate was 87% at 18 years.[13] For all the above reasons it is believed that the success rate of TKA is lower than what is reported.

The outcome of total knee arthroplasty is dependent on accuracy: Many authors stressed on the importance of surgical techniques for TKA and the adverse effects of malalignment on the survival rate of TKA.[15,16,68] Laboratory studies showed that as little as 3° of varus/valgus angulation can significantly change the pressure distribution of total load and hence the pressure distribution in the medial and lateral compartments of the tibial component.[77]

Clinical studies have also shown that component malpositioning may lead to wear and loosening, or patellar instability resulting in early failure and revision surgery.[38,63,77] As little as 3° of varus/valgus angulation can significantly change the pressure distribution and total load in the medial and lateral compartments of the tibial component.[77] Other authors attributed the better functional results to the improved accuracy. Lehnen et al. prospectively compared the clinical outcome of 43 patients with navigated TKA with 122 patients with conventional TKA.[47] The patient outcome scores WOMAC score ($P = 0.002$) and Knee Society Score ($P = 0.040$) at 1 year follow-up was significantly improved in the navigated TKA group with 91% (extremely or very satisfied) as compared to 70% in the conventional TKA group ($P = 0.007$). In a randomized prospective controlled trial by Choong et al. compared the alignment, function and patient quality of life (QOL) outcomes between 60 patients with navigated versus 55 patients with conventional TKA.[10] The mechanical axis was within 3° of neutral ($P = 0.003$) in 88% in the navigated group as compared to 61% in the conventional. Patients with coronal alignment within 3° of neutral had superior International Knee Society and short-form twelve physical scores at 6 weeks, 3 months, 6 months and 12 months after surgery. The authors hence concluded "computer assisted TKA achieves greater accuracy in implant alignment and this correlates with better knee function and improved quality of life".

The limited accuracy of conventional techniques: Current surgical techniques rely on plain radiographs for preoperative planning and standardized conventional instrumentation for performing the procedure. Yet, plain radiographs have limited accuracy.[5,42,48] The position of the leg (e.g. 10° of knee flexion and 20° of external to 25° of internal rotation) may significantly alter the measurements of knee alignment.[48] The accuracy of conventional instrumentation systems is limited and can affect the result of surgery, especially bone cutting and implant alignment.[1,2,4,9,18,34,49,76] The use of conventional instrumentation involves measuring different parameters, such as sizes of implants, alignment and inclination, and level of bone cutting. These measurements may not be exact and they usually require "eyeballing" and personal judgment that adds to the complexity of conventional surgery. Significant malalignment errors (> 3°) may result from using either extramedullary or intramedullary rods.[52,72,74] The entry point of the IM guide is not exact and may lead to inaccurate bone cutting and alignment of the prosthesis. In one report, an anterior starting point of IM guides resulted in recurvatum and a posterior one resulted in 4° of flexion, this could significantly affect alignment.[52] The sizing of implants using conventional instrumentation is not accurate.[35] Conventional instruments are based on average bone geometry of Caucasians that is not representative of all patients. Reports from Far East showed significant anatomical variations from Caucasians.[55] The use of these systems involves several technical steps of sizing, measurements of alignment and rotation, in addition to bone cutting. These steps are dependent on each other and may lead to accumulation of errors.

Other Problems of Conventional Techniques

Although accuracy and reproducibility are important limitations of conventional techniques, there are other important limitations that can affect the survival, function, patient satisfaction and may even lead to increased morbidity and mortality. As discussed above the accuracy issue is somewhat controversial, but some of these limitations are not.

Conventional Instrumentation Limitations

Complexity: Conventional instrumentation systems are complex tools comprising of numerous pieces of jigs and fixtures that need assembling and attachment to bone (followed by detachment) during the operative procedure. As an example, a demonstration kit for a standard size three primary TKA (DePuy PFC Sigma) has 84 different pieces. Most of primary prostheses have various options; fixed-bearing, mobile-bearing, cruciate substituting, cruciate retaining, cemented and uncemented. There are new instruments, which have been recently introduced for MIS surgery. There are different sizes (on average six sizes) of implants for each of these options. There are additional pieces of instruments to fit the different sizes and the different options. Conventional instrumentation systems are frequently modified over time and it is not uncommon to have several instrumentation systems (old and new) for a single TKA prosthesis. Hospitals may have different prostheses from various manufacturers. Theater spaces are usually limited and the complexity of this instrumentation is increasing with new instruments added every now and then. The option of storing these instruments away from the operating room (OR) is not convenient and prolongs the operative time. The cost of conventional instruments may be as high as $ 100,000. In high volume hospitals, instruments are given free, but the cost is offset toward the cost of the prostheses. For low volume surgeons and hospitals, implant companies cannot provide instrumentation systems for free; they rather provide the instruments as a loan on a case per case basis. The cost of transportation and supply chain management is not to be considered as zero either.

Ergonomics: There is a growing need to introduce ergonomics in the surgical workplace,[71] which is more difficult to achieve with the current technique. Conventional instrumentation is supplied in many trays (at least four, but can go up to ten) that require an additional table or two. Revision procedures or other options for primary (mobile-bearing, cruciate retaining, etc.) may require additional trays. These tables and trays need to be positioned as close to the surgeon and the nurse as possible, but the environment is often not ergonomically efficient. The tables usually are in the way of surgical assistant(s). There is usually a lack of space and these trays may cross the zone of the laminar flow.

Theater spaces are usually limited and cannot cope with the increasing number of instruments added every now and then.

Invasiveness: Intramedullary guides are relatively invasive and carry higher risk of bleeding, fat embolism, infection and fractures. Excessive bleeding is a known complication following the violation of IM canal[7,44] and may result in excessive use of suction drains, delayed recovery and higher risk of infection. Bleeding may lead to hematoma, which in turn can delay recovery and increase the risk of infection. In addition, excessive bleeding may necessitate blood transfusion. In a review of 17,644 TKA procedures, Claus et al. found that allogeneic blood transfusion raised the risk of infection by a factor of 3.17 and increased the risk of cardiovascular complication risk by a factor of 3.9.[11]

Fat embolization syndrome has also been correlated to the placement of IM guides during TKA.[41] Fat embolism can be mild and undiagnosed or fatal. There are several reports in the literature of diagnosed cases of fat embolism and some of these cases were fatal. Chauhan et al. in a randomized control trial, showed that the incidence of confusion was significantly reduced in navigated TKA as compared to conventional technique where IM guides are used. Confusion is one of the symptoms of minor fat embolism that might be caused by IM guides. The incidence of fat embolism is higher in bilateral simultaneous TKA, 12% compared with 4% for unilateral TKA.[14,41] The medullary canals have also been found to be the most common site to yield a positive intraoperative culture following TKA.[51] Periprosthetic fractures intraoperatively and postoperatively have also been related to the use of IM guides.[12,19] The numerous pieces of conventional instrumentation are metallic and some have sharp edges, spokes or pins. They may require drilling to attach them to the bone at different steps of the procedure. These metallic edges and pins require careful handling and can potentially cause sharp injuries to the operator or the patient.

Sterilization of instruments: After every TKA surgery, the numerous pieces of conventional instruments need washing, cleaning, packing and sterilization. The required time, personnel and materials are very costly (at least $ 200 as a rough estimate). More importantly, is the quality of sterilization especially for pieces that have narrow holes and canals. Certain microorganisms, such as the infective agents of Variant Creutzfeldt-Jakob Disease (vCJD), are highly resistant to ordinary measures of sterilization. The disease has a long incubation period and there may be many other people who are infective carriers. There are many uncertainties about this subject to the extent that experts in the field are unable to make straightforward pronouncements. The disease was of high concern in UK in the last 2 decades and the Department of Health in UK, has issued a document on the risk of transmission of vCJD through the reuse of surgical instruments.[75] It was emphasized that the risk of surgical transmission of vCJD cannot be ruled out and high quality decontamination and sterilization of all surgical instruments is the key to reducing the risk and single-use instruments should be encouraged where this is practical. In the past, it was understandable that the practicality and cost effectiveness of the wide introduction of single-use surgical instruments in orthopedics was not feasible. The best example here is the conventional instrumentation for TKA, which are very expensive to be treated as single-use instruments. The alternative approach to single-use instruments is to improve the sterilization services. The UK Government has invested £ 200 million over 2 years on a major program of modernization of decontamination facilities. It seems reasonable to draw one conclusion from all the above. Single-use instruments are preferable to reusable ones, especially if they are affordable and do not compromise the quality of surgical performance, such as PSI for TKA.

Operative time: Total knee arthroplasty has to be done within specific time limits guided by the constraint of the tourniquet time and anesthetic considerations. The operative time is dependent on the experience and skills of the surgeons. However, the surgeon is limited by the time required for the utilization of conventional instrumentation as well as the setting time of the cement. Even with uncemented techniques and with the fastest surgeon TKA is unlikely to be done in less than 30–40 minutes. This time is required to assemble and attach the different pieces of jigs and fixtures, perforation of IM canal and measurements for sizing, alignment, rotation and the level of bone resection. Additional time may be spent on evaluation and decision-making, especially in difficult or unforeseen circumstances. The longer the operative time, the higher the risk of contamination as the wound is exposed to non-physiological atmosphere including the heat from theater lights, air and operators' hands. The longer time of disturbed normal anatomy, such as the dislocation of the patella and subluxation of the knee joint, is another concern. Longer non-physiological and non-anatomical exposure leads to longer rehabilitation time and longer hospital stay. Furthermore, the longer the operative time the longer the tourniquet time and the higher the risk of infection and vascular complications, the longer the anesthetic time and the longer the recovery with more potential anesthetic complications. A technically successful operation that exceeds the tourniquet time limit may predispose to complications (e.g. infection) and subsequent failure. Claus et al. analyzed the postoperative complications of 17,644 TKA procedures and found that extended surgery time increased the rate of hematoma and infection.[11] Shortening of operative time can have significant impact on health care economics as it reduces theater time. It can be very useful in avoiding the above-mentioned complications associated with longer operative times. Shorter operative time may extend the indications of TKA or allow procedures that otherwise cannot be performed, such as cases of bilateral simultaneous, day surgery, bleeding tendencies, potential risk of infection, high anesthetic risk, due to associated medical problems.

Complications: The success of TKA has to be assessed in the light of the possible complications. The reported incidence of complications following primary TKA is variable possibly because the documentation and reporting of complications is not standardized. Some authors who followed a comprehensive method in reporting found that complications could be as high as 23% and wound infection was the most common complication. While Scuderi et al[65] reported a nearly similar rate of complications (26%), but following revision TKA. In addition to technical errors explained above, there are other complications that are related to the limitations of conventional techniques and could be improved by alternative techniques.

Infection: Infection is the most devastating complication in TKA and in the worst case scenario, it may lead to amputation. Infection is one of the main causes of early failure of TKA.[16,17,68] The risk of infection of primary TKA is 2.5%, nearly double that of THA and infection following revision TKA is more than double that of primary TKA. This rate may increase by up to 17% in certain conditions such as psoriasis.[30] This rate could be even underestimated as it has been reported from specialist centers with strict aseptic techniques and where operations were done by very experienced surgeons. There are cases of infection that could be missed either because they are low-grade infection with minimal symptoms, medically unfit patients or patients who have been lost to follow-up. Literature from developing countries on the incidence of infection following TKA is scarce and infection rates are probably much higher than the reported figures from developed countries. Causes of infection could be related to the wound, operative technique, OR environment and patient-related factors (host). The potential risk of contamination and infection from the current technique of TKA could be attributed to one or more of the following situations. Failed or imperfect sterilization of the numerous reusable instruments that has multiple holes, canals and deep cavities. IM perforation as IM canals were found to be the most common site to yield a positive intraoperative culture following revision TKA,[51] as bacteria tend to gravitate toward the medullary canals due to restricted metabolic activity there. Bleeding due to IM perforation or long operative time. Intraoperative contamination of the numerous instruments, trays or table that may come outside the zone of the laminar flow. Long operative time with long non-physiological exposure of tissues and ischemia from longer tourniquet time.

Infection following TKA has not been significantly reduced during the last 30 years in spite of the improvement in antibiotic prophylaxis, operative techniques and OR environment.[30] Conventional instrumentation could be a potential culprit, as there have been no radical changes to conventional instrumentation for the last 30 years. Although they have been repeatedly modified for the purpose of improving accuracy they maintained the features that may still predispose to contamination such as IM guides, numerous metallic pieces with multiple holes and reusability. Short-term complications are important especially from patients' point of view. These complications can influence the functional recovery and the patients' satisfaction. They can lead to long-term complications as stiffness and infection and in the worst case scenario they may lead to death following pulmonary or fat embolism. Compared with conventional techniques, MIS has the theoretical advantages of providing better short-term outcome with earlier recovery and shorter hospital stay, but it had the disadvantages of longer operative time and potential technical errors.

Deep venous thrombosis: Deep venous thrombosis (DVT) is very common after TKA, with an incidence as high as 80% without prophylaxis. Unlike THA, DVT following TKA is more common and more refractory to treatment and it may drop to only 35–50% even with DVT prophylaxis.[67] DVT *per se* is not serious, but the migration of the clot to the lung and the development of pulmonary embolism (PE) can be fatal. DVT prophylaxis is a routine practice and it reduces the incidence of DVT but not that of fatal PE. The true cause of DVT in TKA is not very clear. Sharrock et al. proved that the activation of clotting cascade occurs during IM instrumentation of THA.[69] Sculco et al. used this finding to logically suggest that the same could happen in TKA following instrumentation of the femoral IM canal.[67] The blood stasis following the longer operative time with the use of the tourniquet and with the knee subluxed or dislocated (non-anatomical position) could be a contributing factor. Studies showed that the prevalence of DVT in the operated leg is 80–85% compared with the contralateral leg.[60] Sculco also suggested that the use of tourniquets in TKA might explain this high prevalence due to the aggravation of the clotting cascade by venous stasis. It is a logical step to attribute the high incidence of DVT in TKA (compared with THA) to the use of tourniquet, which is only confined to TKA. Other complications are bleeding, chest infection and urinary tract problems; all are more common in procedures that have longer anesthetic and operative time with delayed recovery.

The Complex Primary and Revision Total Knee Arthroplasty

Young age at the time of surgery has been shown to be a risk factor for revision.[39,62,64] Rand et al. reviewed 11, 606 TKA procedures and found that the 10-year survival rate for patients younger than 55 was only 83% compared to 94% for patients older than 70 years.[62] Moreover, the level of their activity will be limited by the performance of TKA and high activity levels may result in a shorter survival time. In a review of 2003, 32,019 total knee replacements (TKRs) for primary or secondary osteoarthritis (OA) were reported to the Finnish Arthroplasty Register, Julin et al. found that "Young age impairs the prognosis of TKR and is associated with increased revision rates for non-infectious reasons.[39] Diagnosis, sex, type of TKR, use of patellar component and fixation method partly explain the differences". Bone preservation is very desirable for young patients, as they will most likely require more than one revision procedure in their lifetime. With every revision surgery surgeons have to resect more bone. The conventional technique of primary TKA involves removal of significant amount of healthy bone. This is required to allow enough space for the measured thickness of the metal implant and to balance for the thickness of PE. A minimum of 8 mm of polyethylene is recommended to avoid previous problems of failure due to polyethylene wear.[36] Downsizing of the prosthesis will lead to unnecessary bone removal. Bone loss may result from infection and failure due to bone resorption. Moreover, excessive bone loss may accidentally occur during removal of the old prosthesis.[65] Over 35,000 TKA revision TKA are performed worldwide annually, the cost and morbidity is substantial. Sharkey et al. reviewed 212 revision TKAs, more than 50% were performed to correct instability, malalignment and failure of fixation. He recommended that improvements in surgical techniques might diminish the incidence of knee revision significantly. The risk factors for revision are age (less than 55), obesity, OA, male gender and associated medical conditions.[56] Revision surgery is more difficult and results are unpredictable. The overall complication rate for revision TKA is as high as 26%. Scuderi et al[65] stated that revision TKA is a series of compromises, because reconstruction is often done with deficient bone and supporting soft tissues. Surgeons may resort to the use of bone graft, cement, metal or custom-made prosthesis to compensate for the amount of bone loss. With every subsequent revision surgery more bone will be removed and the infection and failure rate will also be increased. This renders arthrodesis more difficult due to a large dead space. If excision arthroplasty is considered, the joint becomes unstable with profound shortening of the limb. Unlike failed revision hip arthroplasty, which can be salvaged with a Girdlestone procedure, failed revision TKA may become unsalvageable and amputation can be the last resort. Accuracy of sizing and bone cutting is more critical in order to restore alignment and joint line. In one study, 79% of patients who had revision had an elevated joint line of about 24 mm.[59]

Training: There has been an increasing emphasis on teaching and evaluation of technical skills during surgical training. Current methods of training cannot cope with speed of technology and the increasing introduction of new more demanding techniques. It is difficult for trainees and nurses to learn the relatively complex TKA instrumentation systems, which vary as they move to another surgeon or another hospital. Low volume surgeons (occasional operators) may have a long learning curve that will be disturbed every time they change to a different TKA system. In one report, 50% of TKA procedures (in USA) were done by surgeons who perform about six procedures per year.[46] Operative training with hands-on patients under supervision does not allow trainees to identify the errors, correct them and evaluate the outcome.

Alternatives for Conventional Instrumentation

Computer-assisted orthopedic surgery (CAOS) is an enabling technology that has the potential to overcome some of the drawbacks of conventional techniques of TKA such as IM guides. CAOS has the ability to improve accuracy and reproducibly of surgical techniques, provide objective means to measure surgical performance and outcomes, and supply powerful training tools. TKA, like many other orthopedic procedures, is well suited for the application of CAOS. There are different modalities of CAOS, but navigation techniques are by far the most commonly used in clinical settings. There are some old classification systems for CAS techniques that focused on robotics and navigation and did not include other techniques that are either in use or under development. The author proposed a classification system for CAOS techniques[22,23] based on their functionality and clinical use. They included six main categories, which are then sub-grouped on technical basis (Table 12.1). Using this classification, surgeons can understand the mechanism and function of other common CAOS techniques that

Table 12.1 Classification of different CAOS systems

	Categories	*Subcategories (based on mechanism of action)*
1	Robotics	Industrial, hand-held, bone-mounted
2	Navigation	Image-free, image-based (preoperative) fluoroscopy-based (intraoperative)
3	Hybrid techniques	Image-free and image-based
4	Templating	Guide (pin positioning) instrument (cutting block), tool (implant)
5	Simulation	Planning simulators (templating software) Virtual reality and augmented reality
6	Telesurgery	Telepresence and telementoring

were not included in older classifications systems, but are currently in use such as PSI (cutting guides) and preoperative planning software, arthroscopy simulator, etc.

Navigation and Robotics

Navigation techniques for TKA are now the most common clinically applied CAOS procedure. Several reports showed superior accuracy over conventional instrumentation.[1,2,4,9,18,34,49,76] Navigation techniques reduced the inaccuracies and the outliers in alignment and rotation. Navigation techniques provide intraoperative measurement and can gauge the surgical performance. It can also provide a complete documentation of the surgical procedure and can be used as a training tool. The broad application of CAS is limited by cost, complexity, set-up time and a long learning curve. Navigation requires intraoperative collection of kinematic or morphological data. The data collection depends on the surgeons' experience. Inaccurate collection of data leads to inaccurate measurements by the navigation as the system cannot recognize the inaccuracy of the inputted data. This phenomenon can be described as "error in, error out". Navigation and robotic systems require intraoperative registration and tracking, this increases operative time. Ergonomics are more difficult to achieve with these bulky navigation and robotic devices that require continuous tracking and line of sight. It may take up to 10 procedures for a surgeon to develop a reliable registration technique in TKA.[73] The errors from registration can occur as a result of pin movement (in case of navigation) or movement of the limb (in case of robotics) and both may occur at any time during the procedure. Registration is also very sensitive to some hardware used by CAS systems.[73] Navigation techniques still rely on conventional instruments for making the various bone cuts and they require even additional instruments and insertion of tracking pins. This double instrumentation system may overload hospital inventory, sterilization services and OR time.

The overwhelming intraoperative information from navigation systems may result in conflicting decisions and the rate of complications may increase during the early stages of the learning curve. There are safety issues and contraindications, such as extreme obesity, fragile bones and metallic implants that may cause artifacts. Moreover, there are pitfalls and errors that may occur with navigation and robotics.[27] The cost of double instrumentation systems is also very high. The cost of navigation is around £ 100,000 with a life span of roughly 5 years, so if one assumes that the average number of TKA procedures per year for a medium volume hospital is 30, which would be a total of 150 procedures over a 5-year period. The cost per one TKA procedure would be more than £ 650. The volume of TKA procedures is variable and there are two known extremes. The high volume surgeons or group of surgeons may perform more than 500 TKA procedures per year. The low volume surgeons perform less than 10 procedures per year.

PATIENT SPECIFIC INSTRUMENTS

Background

The ideal technique for TKA should provide technical success (reflected on better function and survival), fast recovery, less complications and be cost effective. As mentioned above, the alternative solutions of robotics and navigation could not overcome the limitations and drawbacks of the conventional techniques. The technique of PSI for TKA is an emerging technology that involves image-based preoperative planning followed by the production of templates that match the surface geometry of the individual bony structures. It has some capabilities of navigation and robotics, but it confines computer-assisted work to the preoperative stage and provides the surgeon with simple, user-friendly instruments. It does not have the drawbacks of navigation and robotics, such as high cost, complexity and problems of using bulky devices, in the OR that need an intraoperative set-up with an extra space and time. It also saves OR time by shifting some intraoperative steps into the preoperative stage. It is more likely to be accepted by surgeons, nurses, patients and the public, as it is a simple modality that is midway between CAOS and conventional surgery. The templating technique has been made possible by the advent of rapid prototyping (RP) technology.[6] RP is the technology that allows automatic production of physical objects using additive manufacturing. RP machines act as 3D printers joining liquid, powder or sheet materials and forming complex models. The clinical applications of RP are still in their infancy[50] and the majority of clinical reports come from dentistry and maxillofacial surgery.[31] Orthopedic applications are limited in number and confined to the production of customized models. Brown et al. reported their clinical results using this technique in the surgical treatment of fractures in 117 patients, where RP is used to print CT images and produce physical anatomical models, including the fractures, this allowed preoperative planning including reduction and fixation. Although the emergency nature of trauma surgery may not allow enough time for preoperative preparation of this technique, they reported that they were able to do the preparation overnight, in as little as 3 hours. They found RP to be successful and cost effective and they depicted it as the future of trauma surgery. There is another technology called computer numerical control (CNC) that appeared several years before RP. The CNC can be used to produce simple models, but not able to produce complex shapes such as PSI. The older technology of CNC was used by Radermacher et al. to produce models and templates based on CT scans in spinal, hip and knee surgery and they described the technique as individual templating.[61] The potential clinical benefits of these templates (guides) could not outweigh the drawbacks of using CT (cost and radiation), which was a major obstacle toward the clinical application of such techniques.

Early Development of Patient Specific Instrument

The first report in the literature on the concept and laboratory application of PSI was by Hafez et al. in 2004 using PSI (two-piece cutting blocks) to successfully perform 17 experimental cases of TKA (14 cadaveric and 3 plastic knee specimens) without resorting to conventional instrumentation systems. The technique was made possible by the advanced technology of RP allowing the production of complex 3D virtual models that have curves, slits and holes such as PSI or cutting blocks. The RP machines also allowed the production of suitable materials, such as polyamide (PA) that is biocompatible, durable and heat stable to withstand the heat of the autoclave (Fig. 12.2). The suitable material and the complex shape of PSI could not be done previously using the older technology of CNC. The PSI technique involved preoperative planning of the entire surgery based on CT images. The planning included sizing, alignment measurements, bone cutting and placement of the implants using the 3D data [computer aided design (CAD) files of TKA implants]. This allowed the simulation of TKR and review of the results on the computer screen before performing the surgery on real patients. The work started in 2001 and presented in 2002 at the Annual Meeting of the International Society of Technology in Arthroplasty (ISTA), Oxford, UK. Then a complete description of the technique, including the principles and the experimental use of 45 TKAs, was reported by Hafez et al. in 2006,[20,25] naming the technique patient specific templating.[20,24,25,27] Although the term "Custom Made Cutting Guides" is very popular now and easily taken by surgeons, the term "Templating" is more scientific and descriptive from technical and engineering aspects. This is because the technique involves preoperative planning with sizing, alignment, cutting and verification of implant positioning and surgical simulation, then the production of patient specific templates. These templates can be used as guides, cutting blocks, instruments or tools and the concept is applicable to other procedures in orthopedics (THA, osteotomy, spine surgery) or other specialties like dental and maxillofacial, where the term template would be more relevant than the term cutting guides.

Figure 12.2 Example of a rapid-prototyping machine that was used to produce PSI made of polyamide

Validation of Patient Specific Instrument

During the development of the technique of PSI, it was realized that the most critical step was intraoperative positioning of the PSI. The risk of incorrect positioning is high and may lead to errors in bone cutting and subsequently malalignment of the implants. Unlike navigation systems, PSI does not have intraoperative information systems that can reveal errors and allow surgeons to correct them. In spite of all drawbacks of conventional instruments, they still have the advantage of intraoperative measurements and re-adjustments of some steps of TKA. With this in mind, two laboratory studies were done to test the accuracy and then the reliability of the new concept and technique of PSI.[24,25,28] In the first study,[25] PSI were used to perform 45 TKAs on 16 cadaveric and 29 plastic knees including a comparative trial against conventional instrumentations (PFC, DePuy, Johnson and Johnson). All operations were performed PSI with no conventional instrumentations or IM perforation. Using CAD software, computer-assisted analysis of six random CT scans showed mean errors for alignment and bone resection within 1.7° and 0.8 mm (maximum, 2.3° and 1.2 mm, respectively). The level of accuracy and reliability of this technique was better than what was reported for conventional techniques[63,72] that had errors more than 3°. This level of accuracy also compares favorably with the results of navigation (within 3°).[2,4,72] Although this study was reassuring, it was not representative as the experimental surgery was performed by the developer of the technique. The concern was how accurate this technique is for new users? And how this level of accuracy is reproducible? Therefore, the second study was performed by five observers, the author and four independent observers who were not familiar with the PSI technique (new users).[24,28] The experiment was conducted using plastic knee specimen (Foam Cortical Shell, Model # 1151). The planning for TKA was based on the PFC prosthesis (DePuy/Johnson and Johnson, Warsaw, USA). The typical steps for the PSI technique include CT scanning, reconstruction of 3D images, sizing and alignment of prosthetic components, template designing, surgical simulation and finally production of PSI using selective laser sintering (SLS) RP machines (3D Systems, Valencia, CA, USA). The primary outcome measure was alignment and level of bone cutting, as determined by the position of the PSI. A navigation system (Vector Vision, BrainLab, Heimstetten, Germany) was used only as a measurement tool for the positioning of PSI by the observers without playing any role in guiding them. An independent assessor recorded the measurements that were displayed on the navigation monitor. The level of accuracy for new users was satisfactory with a mean alignment error of 0.67° (maximum 2.5°). The mean error for bone cutting was 0.32 mm (maximum 1 mm). All measured values were within 3° indicating complete interobserver and intraobserver agreement. For quantitative analysis using Friedman test and Kendall concordance coefficient, there was an overall significant agreement between the observers ($p < 0.05$). The concordance coefficient was high, indicating a considerable interobserver agreement for all measured parameters except femoral cutting level that had a relatively low concordance coefficient. Comparison between different recorded measurements for the same observer (intraobserver variation test) showed significant agreement (p value < 0.003) and the concordance coefficient was very high. This means that there was no difference after repeating the same test by the same observer and there was a considerable intraobserver agreement. This laboratory study showed that the positioning of the PSI was reliable, as there was no significant intraobserver and interobserver variation for alignment, or levels of bone cutting, in both the femur and the tibia.

Clinical Development

Until 2008, there were no published studies on PSI techniques apart from what was reported by the author.[8,24,26] However, there was a parallel development to produce custom made implants for unicompartmental and bicompartmental knee arthroplasty using computer aided design–computer aided manufacturing (CAD-CAM) technology that started as early as 1980s to produce custom made implants especially for tumors. In 2008, Howell et al. reported the first clinical application of PSI named Otis knee.[33] They used MRI rather than CT scan and they based the position of the implants on kinematic rather than mechanical alignment. The concept of PSI was developed by all major industrial companies, but with some modifications, such as using the PSI as a guide, to locate conventional cutting blocks i.e. pin locator.

THE PRESENT

The technique of PSI is currently used in North America, Europe, Middle East, Asia and Australia and the rate is on the rise. There are no published statistics on the number of procedures, but on a rough estimate, it should be about 5,000 TKA procedures using PSI per month in early 2011. One of the major implant companies claims that one quarter of their TKA procedures are done using PSI technique. All patients selected for TKA who can have CT or MRI are indicated for this technique. Some patients are not suitable for MRI such as obese, medically unfit, claustrophobic and patients having a pacemaker. Those patients could go for CT-based techniques. There are no known contraindications apart from the theoretical risk of allergy to the material of the cutting guides. However, the technique is limited by some logistics that may lead to a delay of several weeks until the cutting guides are produced and delivered to the surgeon, unlike conventional TKA instrumentation that can be used any time. This current limitation will restrict the use of the technique to certain cases rather than being extended for routine use.

Author's Technique

The PSI technique, the author is using, is not restricted to a single implant company, but is rather an open platform. It can be used with any TKA prosthesis, provided that implant manufacturers are willing to provide the CAD files of their prostheses for preoperative planning. Patients should have a CT scan of the knee and a scanogram (topogram) extending into the hip and the ankle in both AP and lateral projections following a specific protocol. An appointment for surgery can be scheduled 2–3 weeks later. Figure 12.1 shows the steps for this technique including CT scanning, reconstruction of 3D images, sizing and alignment of prosthetic components, template designing and surgical simulation. The virtually designed cutting guides are transferred to production machine using electronic mail. The femoral and tibial cutting guides were produced using SLS RP machine (3D Systems, Valencia, CA, USA), the material used is PA (nylon). The production service is done outside the hospital (outsourcing to a private firm) without the need to buy an expensive machine. The patient initials, the side of the knee to be operated on and the surgeons name ± a code number are engraved on the body of the PSI. The cutting guides are autoclaved in the hospital and the OR staff is informed about the size of the tibial and femoral implant to be used and that conventional instruments are not required.

The knee is exposed through a medial parapatellar approach, with the use of a tourniquet without using a drain at the end. The femoral cutting guide is positioned first, making sure that all locating probes in the under surface of the guide are touching the distal femur centrally, medially and laterally at the same time. Once this unique single position is achieved, the guide is fixed by fixation pins passing through drill guides in the femoral cutting guide. An angle wing can be used to verify the amount of bone to be removed distally and anteriorly. Saw blades with appropriate thickness are inserted first into the slit for distal cut, the cut bone is removed through the gap between the cutting block and the distal femur. The same is applied for the anterior, posterior and chamfer cuts. Lug holes can also be done through the cutting guide. The tibial cutting guide is positioned over the tibial plateau and the antero-medial surface of the proximal tibia just close to patellar tendon insertion after clearance of soft tissues in this area. The position is verified based on surface matching and making sure that there is no other chance of having more than one matching position. The cutting guide is then fixed by fixation pins from the front and optionally from the top. An angle wing is used to verify the amount of bone to be cut. Then the cut is performed through the slit and the cut bone is removed from the medial and lateral side. The stem and keel are prepared through the corresponding hole and slit at the top of the tibial cutting guide, thus determining the rotation of the tibial implant. The cutting guides are removed and trial implants are used to verify the accuracy of the cuts and adjust the soft tissue balance for the mediolateral and flexion extension plane. Trial implants are made of plastic (Polyamide) and produced by the same production machine as the cutting guides.

Although the technique can be used for routine TKA procedures, the preference is usually given to complex cases that are difficult to be done by conventional techniques or even contraindicated. Such conditions are, extra-articular deformities or retained hardware (nails, plates and screws) when IM instrumentation is problematic; bleeding tendencies such as hemophilia; medically unfit patients with anesthetic risk, severe OA with bone loss and articular deformities, abnormal anatomy, or augmented risk of infection. In some of these cases (e.g. extraarticular deformities), the conventional TKA techniques are both difficult and risky to use or cannot be used at all.

Clinical Application

The author[21,28] reported the clinical application of PSI based on CT scan. What is different from other PSI techniques is the complexity and difficulty of cases performed by this technique. These cases were divided into five different unusual categories of patients: (1) extra-articular deformities, (2) bleeding tendencies, (3) bilateral DVT and/or pulmonary embolism, (4) bilateral TKA in patients seeking short recovery and (5) medically unfit patients (usually cardiorespiratory compromise). Patients with these problems were either refused conventional TKA or denied the procedure by anesthetists or other arthroplasty surgeons. In all cases, the PSI was successfully applied as were preplanned and without using conventional instruments. Neither IM guides nor alignment rods were used in these cases. Preoperative sizing was accurate in all cases. Tourniquet was used routinely, but no drains were used. No reported intraoperative or postoperative complications with any case. No report of postoperative confusion or respiratory symptoms to indicate fat embolism. Postoperative recovery was uneventful and all patients had full extension and more than 100 of flexion. Figure 12.3 shows examples of category-1 and category-4 patients. In category-1 patient, a preoperative AP radiograph and a lateral view of the planned surgery with superimposed implants are showing no possibility for the insertion of femoral IM guides of conventional jigs. In category-4 patients, there are severe deformities with bone loss. Figure 12.4 shows part of the preoperative planning and positioning of the guides based on mechanical rather than anatomical axes. Figure 12.5 shows the final planning ready to be approved by the surgeon verifying sizing, alignment, implant positioning and bone cutting. It also reveals a very important piece of information about the shape of the femoral and tibial cutting guides and the way they should be positioned during surgery. This should guide the surgeon while positioning the cutting guides on real patients. A printed copy of the final plan should accompany the surgeon in the OR. Figure 12.6 shows the final and an important step of the PSI

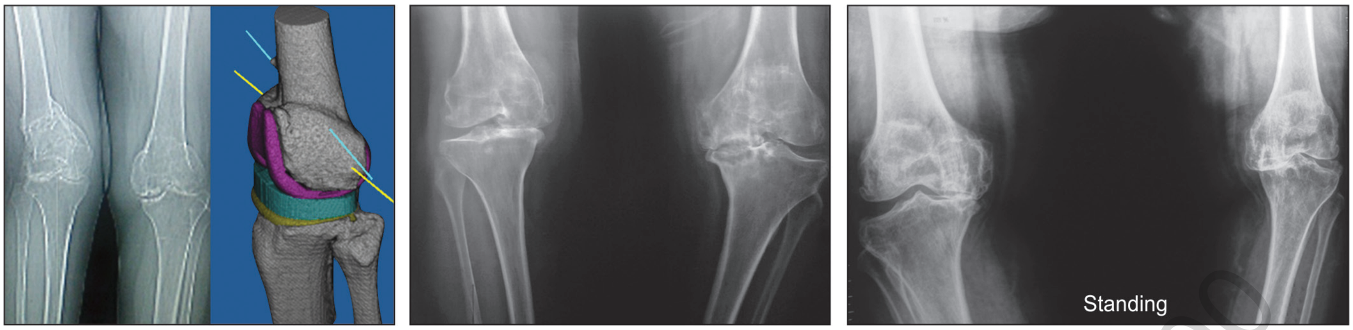

Figure 12.3 Examples of bilateral TKA using PSI in patients with severe articular and extra-articular deformities

technique, which is the positioning and fixation of the cutting guides over the bone and then the bone cutting. This step could be guided by the printed copy of the final planning (Fig. 12.5). This final step required accurate implementation with a double check to avoid inaccurate positioning of PSI and subsequently inaccurate bone cutting and implant malalignment. The Longest time of positioning was 5 minutes for each guide. The matching of to the respective bone was satisfactory. In patients who had severe flexion deformity more than 30°, two femoral cutting guides had to be designed to provide a second option for excessive distal cutting. The optional guide was used intraoperatively and proved to be the optimal one for such cases. CT scan had to be repeated for patients who do not follow the protocol (e.g. moving during scanning) and also in some patients who had TKA on the other side due to the interference caused by the knee prosthesis in the contralateral knee, which was supposed to be bent and not kept straight during scanning.

Different Techniques of Patient Specific Instruments

In addition to the author's technique, currently, there are at least eight competitive PSI techniques in use. Now, all major implant companies are using PSI although, FDA is considering these instruments to be Class 2

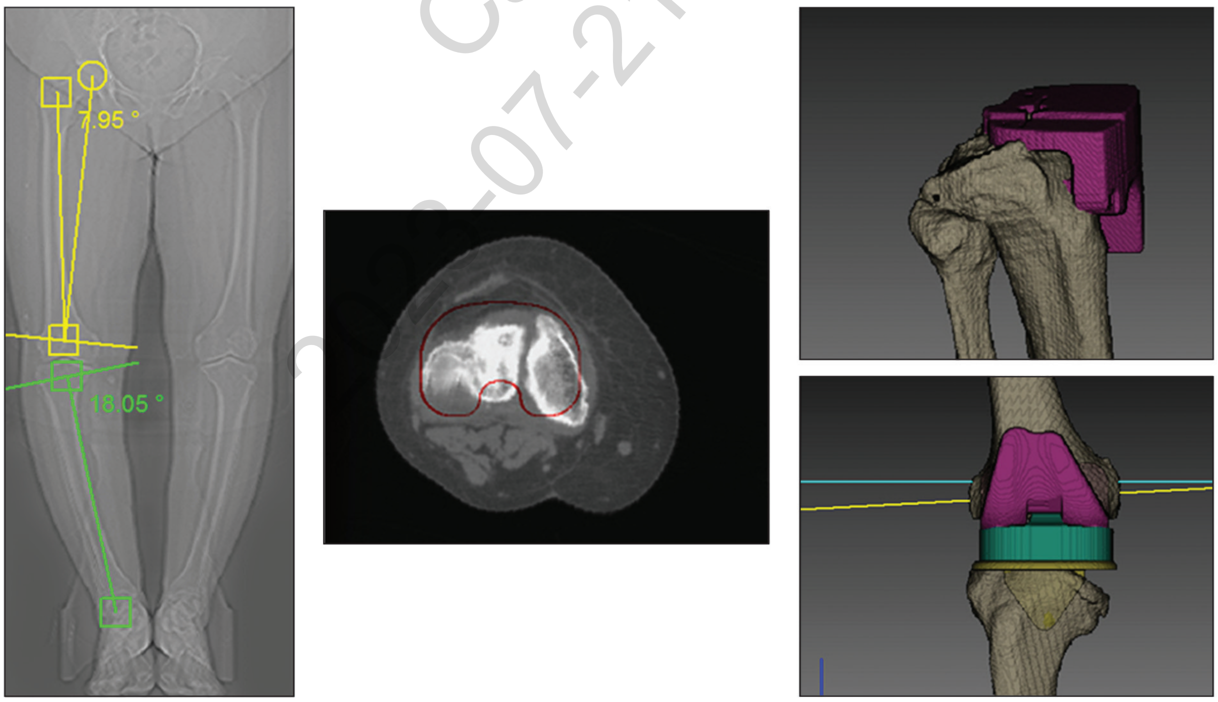

Figure 12.4 CT-based planning for a bilateral TKA showing bone loss and severe varus

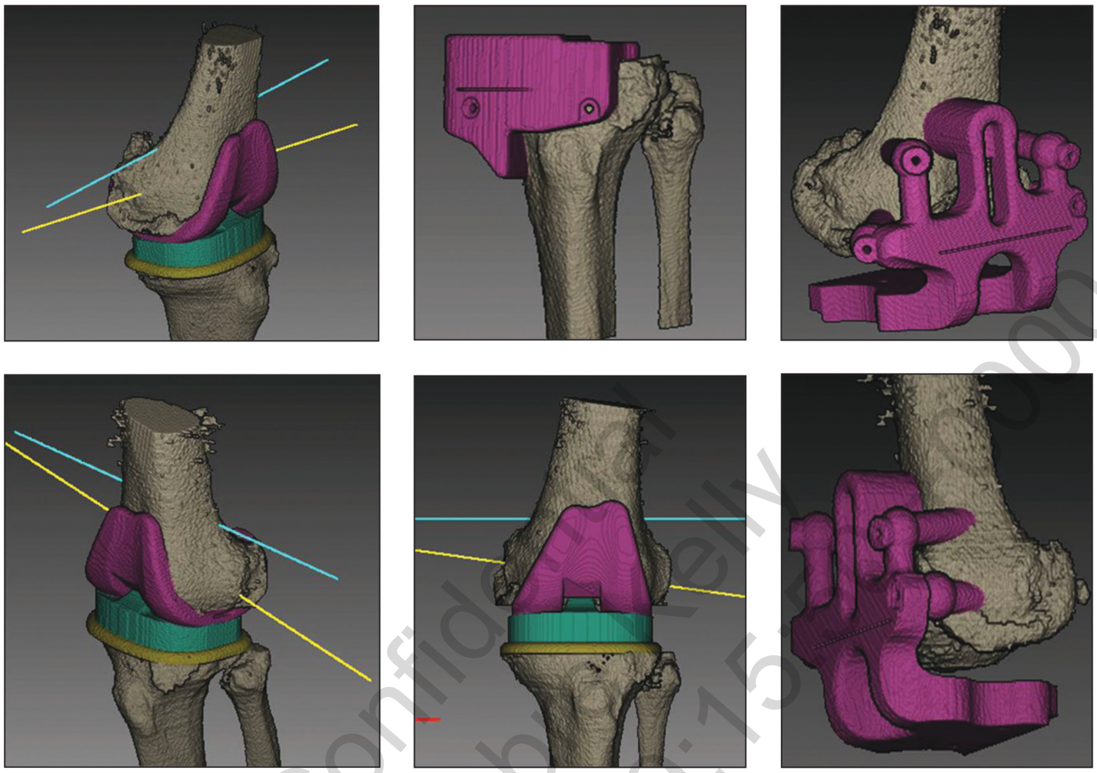

Figure 12.5 A print out of the planning showing sizing, alignment and implant positioning and the position of the PSI on bone

and requiring all companies to reclassify from Class 1–Class 2 designation. Different names are used by different manufactures such as "Custom-Made Cutting Guides", "Custom Fit Total Knee", "Patient Specific Cutting Guides", "Shape Fit" and "TruMatch".

Table 12.2 displays the similarities and differences of all nine techniques of PSI. The two main differences are the type of imaging (CT or MRI) and the function of PSI (pin locator or cutting guide). MRI has the theoretical advantages of detecting cartilage and being a radiation free imaging. However, CT scan is easier to use owing to the limitations of MRI such as difficult segmentation, contraindications with the presence of pacemaker, implants and obesity. The other limitations, which have a different magnitude according to different health care systems are, cost, long waiting list, reimbursement and other logistics. In addition, most of commercially available MRI-based systems have about 6 weeks interval from the time of acquiring the MRI until the PSI is delivered to the hospital. This may carry the risk of anatomical changes to the knee as a result of daily activities or any abnormal loading during this long waiting period. The same errors of malpositioning of the PSI can happen from errors in bone segmentation

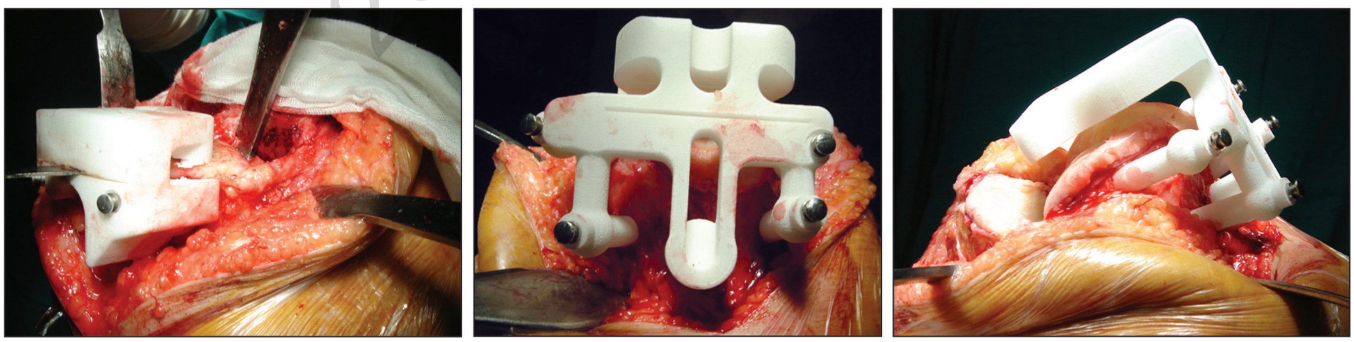

Figure 12.6 Patient specific instruments acting as cutting blocks for femur and tibia

Table 12.2: Currently available custom-made cutting guides for total knee replacement

Supplier	*Author's Technique (classic)*	*Stryker*	*Biomet*	*Smith & Nephew*	*Zimmer*	*Medacta*	*ConforMIS*	*Wright Medical*	*J&J DuPuy*
Cutting guides	Patient specific templating	OtisKnee	Signature	Visionaire	Patient specific instruments	MyKnee	iJig	Prophecy	TruMatch
Implant name	Open platform (any implant)	Triathlon	Vangaurd	1. Journey BCS 2. Legion 3. Genesis II	1. Gender solutions 2. NexGen	1. GMK System 2. Cinétique 3. Evolis	iUni G2 iDuo G2	1. Advance 2. Evolution	Sigma
Functionality	Cutting guide	Cutting guide	Pin locator	Cutting guide	Pin locator	Dual	Dual	Both types	Cutting guide
Need for CI	No	No info	Yes	Yes	Yes	Yes	No info	Yes	No info
Guide material	Polyamide	Dupont Delrin	Polyamide	No info	No info	Polyamide PA2200	No info	Nylon	No info
Scan Type	CT	MRI	MRI	MRI or X-ray	MRI	CT or MRI	MRI or CT	CT or MRI	CT
Scan protocol	CT scan of knee + Scanogram from hip to ankle	Knee scan only	MRI of hip, knee and ankle	No info	No info	No info	Spiral scans of hip, ankle and knee	CT: Hip, femoral shaft, ankle and knee. MRI: hip, ankle and knee	Entire leg scan or separate Hip, ankle and knee scans
Software	Materialize SurgiTaix	OtisMed	Vanguard (Materialize Mimics)	No info	Materialize	No Info	ConforMIS iFit	No info	Trumatch
Startingy year	2002	2008	2008	2009	2010	2009	2008	2009	2009
Laboratory Clinical & validation	2006-2011	2008	None	None	No info	None	2009	None	None

of MRI which are less likely to occur with CT. These types of errors have already been reported.[33,43] CT-based software systems are easier to use as image segmentation can be done automatically, allowing surgeons to do the preoperative planning and the designing of their PSI. On the other hand, MRI-based systems have to be done by experienced technicians due to the need to perform manual segmentation of the images. PSI that are used as cutting guides have the advantage of eliminating the use of conventional instruments, while PSI that are used as pin locators require conventional cutting blocks. The author believes that the main objective of using PSI is to replace conventional instrumentation systems and eliminate all their drawbacks as mentioned above.

The reported clinical results of PSI systems have confirmed the clinical applicability of this technique.[33,43,70] Although one report[43] revealed suboptimal clinical results and criticized the technique, the other reports[33,70] showed good clinical results using the same technique. Klatt et al. used an image-free navigation system to evaluate the recommended custom-made cuts and alignment of the components and found that they were more than 3° of mechanical axis.[43] Spencer et al. reported the results of 21 patients with custom-fit TKA who were compared to a matching cohort of previous 30 conventional TKA.[70] In the custom-fit series, there was a mean decrease in operative time of 14% and an average deviation from the mechanical axis of 1.2° of varus. The authors concluded "the technique appeared to be a safe procedure for uncomplicated cases of OA". Howell et al. reported the results of 48 consecutive patients with the use of custom fit technique showing rapidly returned function; restored motion, stability and postoperative good mechanical axis alignment; high patient satisfaction and had an acceptable clinical outcome. They noticed that none of their cases required soft tissue (collateral ligaments or retinacular) release. In their series, there were three tibial guides and three femoral guides that were not positioned properly. Their retrospective analysis attributed the cause of poor positioning to a random error by the technician who was aligning the MRI. They also conducted a similar retrospective analysis for the cases that were reported by Klatt et al. and found a similar type of errors caused by the technician who malaligned the MRI in two of the four knees in that pilot study. Their conclusion was that the poor results reported by Klatt et al. was due to poor positioning of the guides that affected the position of the components because of an MRI alignment error, which was not a known problem at the time the surgeries were performed.

FUTURE DIRECTION

Technical Development

Rapid prototyping machines are frequently modified to add more features such as the ability to produce complex tools. There are new generations of compact RP machines that are as small as an office PC printer. These compact machines can be purchased by hospitals and stored inside the OR, radiology department or outpatient clinic. This will allow imaging, planning and the PSI production to be done at one site, saving time and resources. Other imaging modalities may be used in the future, such as 3D radiographic X-ray.

The materials in RP used for PSI should be biocompatible, heat stable to withstand high temperatures of sterilization, durable enough not to be damaged by saw blades and inexpensive. The ideal material should have these properties, and in addition, should be easily manufactured within a short period of time. There are a few materials that are currently in use for PSI, the most popular is PA.

Table 12.3 shows a list of all biocompatible materials with the highest temperature tolerance that can be used for the rapid manufacturing of PSI.

Clinical Development

New Users and Clinical Trials

Future clinical trials should adopt a graduated approach. During the early learning curve, the surgeon(s) can perform this technique on patient-specific plastic knee models that can be produced by a RP machine based on patients' own CT scans. Thus, the surgeon can see the results of surgery before using the PSI technique on real patients. The surgeon can position the PSI over the bone to test the ease and accuracy of positioning and mark the level and inclination of bone cutting on the bone. And then, use conventional instruments for comparison and evaluation of the proposed cuts. Navigation techniques (if available) can be used in a similar manner to what was performed by the author.[24,25,28] Once the surgeon develops confidence with this technique, the latter can be used for bone cutting, without resorting to conventional instrumentation. Simple instruments, such as angel wings, can be used to mark the level of bone cutting for visual inspection and confirmation by the surgeon before real cuts. With improved learning curve, possibly after five cases, the surgeon(s) may proceed to a comparative trial.

Table 12.3: Popular medically-approved rapid-prototyping materials

Material	*Technology*	*Manufacturer*	*Tensile strength*	*Flexural strength*	*Heat Deflection*	*Sterilization*	*Medical Compliance*
Duraform Polyamide	SLS	3D Systems	43 MPa	48 MPa	180°C	Autoclavable	USP Class 6 certified
Primepart	SLS	EOS	47 MPa	58 MPa	172°C		USP class 6 and EU 2002/72/EC
Polyphenylsulfone (PPSF)	FDM	Stratasys	55 MPa	110 MPa	189°C	1. Steam autoclave 2. EtO Sterilization 3. Plasma 4. Chemical 5. Radiation	USP Class 6 compliant
PolyCarbonate ISO (PC-ISO)	FDM	Stratasys	57 MPa	90 MPa	133°C	1. Gamma radiation 2. Ethylene oxide 3. Autoclave	certified ISO 10993 and USP class 6
ABS-M30i	FDM	Stratasys	36 MPa	61 MPa	96°C	1. Gamma radiation 2. Ethylene oxide 3. Low temp. steam	ISO 10993 certified
Renshape SL 7800	SLA	Huntsman	44 MPa	75 MPa	62°C (postcured)	- 75°C steam - 80°C Formaldehyde - gamma radiation - 55°C ethylene oxide	FDA approved
Somos Nanotool	SLA	DSM	61-78 MPa	100 MPa	225°C		FDA approved
Perfactory E-Shell 200/300	DLP	Envisiontec	57/51 MPa	103/88 MPa	109/ (86-160)°C		ISO 10993 certified

Applications of Patient Specific Instrument for Challenging Cases of Total Knee Arthroplasty

The PSI technique would be useful for patients with complex extra-articular deformities[29] and for young active patients with additional benefits of preserving bone stock by quantifying the volume of removed bone during planning and before actual surgery. The advantages of the PSI technique with its accurate preoperative planning become more important for revision surgery and the costs become less significant.

Applications of Patient Specific Instrument to Other Surgical Procedures

The PSI technique has the potential to be used for other procedures, such as unicompartmental, bicondylar [a new procedure to replace the medial and lateral compartments only while preserving anterior and posterior cruciate ligaments (PCL)] and patellofemoral arthroplasty that require a higher level of accuracy and less invasive approaches. The same can be applied to hip resurfacing and the PSI technique for these procedures might be easier to learn and perform and can provide a better environment for training in TKA.

The Use of Patient Specific Instrument in Training

The technique can serve as a powerful and inexpensive training tool. The preoperative planning software can be installed on desktop and laptop computers with modest cost. The software may provide the opportunity for surgeons in training to practice on the preoperative planning of TKA, including sizing, measuring alignment and rotation, and performing virtual bone cutting. The surgical simulation allows the identification and analysis of errors in 3D planes and in real time. It also provides training for both cognitive and motor skills, allowing repetitive practice and committing errors and correcting them. For workshops on plastic bones, RP machines can produce reusable PSI guides specific to the plastic knee model. The PSI technique itself requires less training as compared with conventional instrumentation, since it is easier to use and it involves only a very few intraoperative steps. With further modification and refining of the PSI technique and the combination with MIS approaches, it may prove possible to achieve the ideal TKA procedure.

CONCLUSION

There are several limitations of the current techniques for TKA, especially the limited accuracy of 2D planning using short leg radiographs and limited accuracy with several drawbacks of conventional instruments. The conventional instrumentation systems consist of numerous pieces of jigs and fixtures. These are cumbersome, as they require set-up, assembly, dismantling and cleaning, all of which are time consuming. Alignment guides perforate medullary canals, leading to a higher risk of bleeding, infection, fat embolism and fractures. Reusable instruments carry a theoretical risk of contamination and may overload hospital sterilization services. The available solutions (navigation and robotics) are not popular due to the high costs and complexity. An alternative that can be user-friendly, inexpensive, MIS and accurate would be more attractive to patients, surgeons and health care systems. Such an alternative must allow surgeons to improve the outcome of TKA, provide a better training environment and help surgeons to cope with the increasing challenges of new surgical techniques as MIS and difficult cases of complex primary and revision surgery.

The PSI technique has several advantages over conventional instrumentation and can be used for complex cases of extra-articular deformities and medically unfit patients. It eliminates medullary guides, reduces operative time and provides more accurate planning. Due to its simplicity and reduced costs, it is considered an attractive alternative to conventional and navigation TKA. The adoption of the PSI technique by all surgeons should be delayed until level I clinical studies are published.

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