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Customised Jigs in Primary Total Knee Replacement

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Abstract

Patient-specific surgery employing customising jigs for bone resections is becoming increasingly popular for total knee replacement surgery. Theoretical advantages of this technology include, but are not limited to, more accurate limb alignment and reduced surgical time, blood loss and in-patient hospital stay. In turn, these may result in more cost savings when compared with standard techniques of performing knee replacement surgery. The literature published so far has primarily examined alignment data but has failed to consistently confirm the previously proposed benefits. It appears that longer-term data, focusing on patient function and implant survival, will be required before the clinical and cost utility of these guides can be determined. This article briefly outlines the manufacturing process and surgical technique of patient-specific jigs and presents the clinical evidence pertaining to key elements of this new technology.

Keywords: Knee; Replacement; Arthroplasty; Patient-specific; Custom; Instruments; Jigs

Introduction

The demand for total knee replacement (TKR) is constantly rising and is expected to continue to do so until at least 2030 [1]. It is an operation performed by general orthopaedic surgeons and subspecialists alike and, although generally successful, the levels of patient satisfaction after TKR have not paralleled those of patients undergoing total hip replacement surgery [2,3]. A plethora of reasons, acting alone or in concert, have been cited as leading to inferior outcomes, or even frank early failure, after TKR surgery [4]. The importance of restoration of the mechanical axis to neutral has been recognised long ago [5]. With a narrow window of tolerance of no more than ± 3° in the mechanical tibiofemoral angle being accepted. Recently, similar acceptable limits regarding the anatomical alignment were set between 2.4° – 7.2° of tibiofemoral valgus [6]. Deviation from these figures has been shown to affect rehabilitation, range of motion, stability and, in the long-term, wear.

Recently, patient-specific instrumentation (PSI) has been introduced in TKR surgery. These instruments are jigs manufactured on a case-by-case basis and designed to fit precisely on the tibia and femur in preparation of the bone cuts during surgery. The principal purported advantages of this new technology are an increased accuracy of bone cuts, and consequently positioning of the implants, coupled with decreased operative time. Despite their increased cost, customised cutting jigs are currently "in vogue" in many parts of the world [7]. The purpose of this review is to familiarise the reader with this emerging technology and overview the clinical results, based on the published literature.

How it Works

The manufacturing of patient-specific cutting guides became possible with the application of rapid prototyping (RP) technology. This is a technique whereby liquid, powder and sheet materials are fused, usually layer by layer, to make physical objects for three-dimensional (3D) data (additive manufacturing). In orthopaedics, the first use of a less sophisticated version of RP technology, termed Computer Numerical Control (CNC), to produce bone models, was reported by Radermacher et al. [8] Hafez et al. were the first to report on an experimental study on the use of modern RP techniques in knee surgery [7].

Contemporary techniques start by scanning the patient's knee with either computed tomography (CT) or magnetic resonance (MR) imaging, depending on the implant manufacturer. Selected slices of the ipsilateral hip and ankle are also included for the purposes of defining the mechanical and anatomical axes of the femur, tibia and the lower extremity as a whole. The scan is then processed with specialised software and the extremity is modelled in the coronal and sagittal planes. Using the individual surgeon's default preferences (thickness, orientation) of performing the bone cuts, a surgical plan is performed which includes the thicknesses of the bone cuts and the sizes of the The plan is then sent to the surgeon for review. At this stage, the surgeon can opt to either approve or modify it. Once the plan is finalized, the manufacturer is authorized to start the production of the patient-specific cutting guides that will replicate what has been templated. Typically, two guides, made of medical grade nylon (polyamide), to be used for the tibial and the distal femoral cut each, are manufactured. Nylon has excellent material properties that allow it to be sterilized and can withstand loading when applied to bone [9]. The guides are either designed with a slit to accommodate the saw blade (cutting guides) or act as blocks to determine the location of pins of a standard saw guide (pinning guides). Once ready, they are shipped to the hospital for sterilization. The entire procedure, as outlined, may take anything between three to six weeks before surgery can be performed [10,11]. If a scan is of inadequate quality, waiting times become longer [12] corresponding implants (Figure 1).

Most manufacturers offer this technology in the form of the so-called mechanical axis-aligned PSI. As the term implies, the goal in these cases is to restore the mechanical axis to neutral. By comparison, kinematically-based PSI aims to place the TKR components in a way

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so that the anatomy of the knee, the three kinematic axes in particular, remain identical to those in the non-arthritic state. While a CT or MR scan is still required, the hip and ankle joints are not scanned. The 3D model of the arthritic knee is converted to its pre-arthritic state and the best-fitting components are shape-matched to it. With this technique, the collateral ligaments are not released but are restored back to length through removal of osteophytes [13].

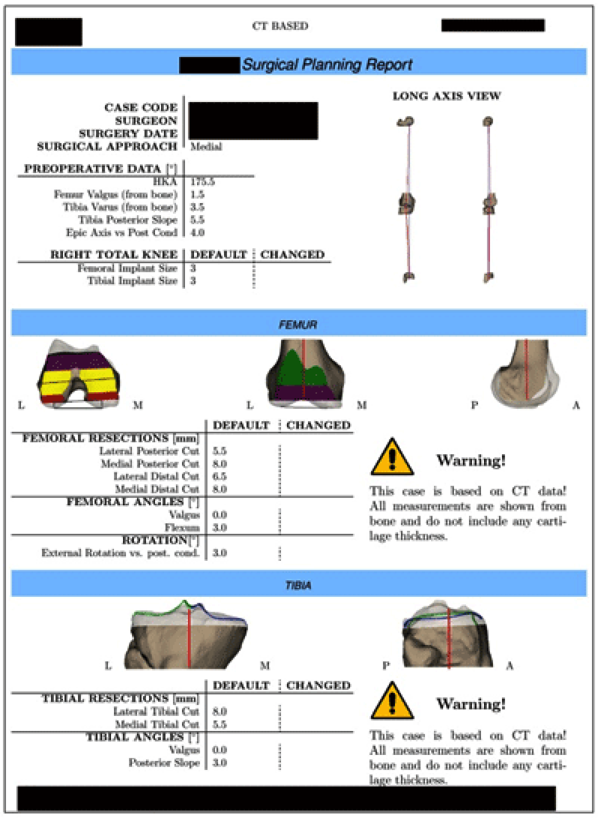

Figure 1: Surgical plan report, based on data from a pre-operative CT scan, for a patient scheduled for total knee replacement using patient-specific cutting guides (L: lateral; M: medial; P: posterior; A: anterior).

Regardless of the technique chosen, the advantages PSI in theory offers from surgical and logistical points of view are numerous: the sizes of the components likely to be used are known in advance; therefore, components of those sizes only (and, perhaps, one size smaller and larger) need be available on the shelf. Fewer instruments (trial components, alignment guides) are necessary; this results in fewer trays to be opened in the operating theatre. The surgeon can check the accuracy a particular bone cut before he performs it (by comparing the thickness of the proposed cut with the one planned) or even after the bone cut is completed (by comparing the morphology of the bone once it has been cut) (Figure 2). Because the medullary canals of the femur and tibia are not violated, there is a potential for reduced blood loss, post-operative pain and risk for fat embolism [9,14]. In all, fewer surgical steps are required [9], potentially reducing surgical time.

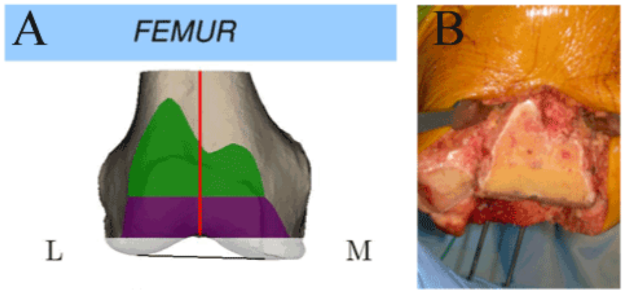

Figure 2 A: Detail of the surgical plan shown in Figure 1. B. Intra-operative photograph of the same patient showing the femur with completed bone cuts. The appearance of the anterior femur in the form of a "grand piano" sign very similar to the templated one confers confidence that surgery proceeds as planned (L: lateral; M: medial).

Comparison of CT- with MR-based patient-specific instrumentation

An MR scan is more expensive and time-consuming than a CT scan but patients are not exposed to radiation. CT scans for the production of patient-specific TKR jigs are performed following specific protocols, though, and the radiation dose involved is considered comparable to that of a long-leg plain radiograph [9]. That said, there is at least one MR-based PSI system that requires a long-leg radiograph of the patient, in addition to the MR scan [15]. Owing to their limited ability to define articular cartilage, CT-based guides are referenced off the bone, with implications in the surgical technique, as explained later. On the other hand, measurements from CT scans have been shown to be more predictable and bone models more accurate in an experimental study of ovine knees [16]. In a report of 60 consecutive patients scheduled to undergo TKR with MR-based patient-specific technology, unacceptably high rates of implant malalignment outside the ±3° range in the coronal (20.7%), sagittal (45.5%) and axial (22.8%) planes were confirmed using computer navigation [17].

Contraindications to the use of MR-based PSI include claustrophobic patients [11] and those with pacemakers or other implanted devices prohibiting exposure to the magnetic field of an MR scanner [18]. Patients with retained hardware in or around (within 10 – 15 cm) the involved knee, often comprising challenging cases most likely to benefit from this technology, are also unable to undergo an MR scan [18-20]. CT-based PSI is not precluded in these cases [19,21].

Surgical technique

The description of surgical technique applies to mechanical axis-based PSI systems, which the authors have personal experience with. The type of anaesthesia, patient positioning and leg preparation and draping are left to the surgeon's discretion and do not differ from any conventional TKR technique. The same holds true for the surgical approach. Of utmost importance is to achieve intimate contact of the cutting jigs with the bone. This requires removal of all soft tissue from the bony surfaces intended to make contact with the jigs, so that the bone assumes a skeletonised appearance. Typically, these areas include the cortex of the anteromedial proximal tibia and the distal femur and also the area between the articular surface of the lateral tibial plateau and the tibial spine [22]. In arthritic knees, this area of the anterior distal femur is commonly covered by thick, inflamed synovium. We recommend the use of diathermy, which facilitates haemostasis during synovectomy in that area (Figure 3).

When MR-based jigs are to be used, meticulous removal of soft tissue will suffice. With CT-based PSI, one has to additionally remove all remaining cartilage from the areas where the jig will make contact with the articular surfaces [21]. Cartilage is best removed with diathermy or curettes. Again, we prefer to use the former, as curettage, if overly aggressive, may scrape the bone, too, especially in non-sclerotic areas of older patients. In addition, with CT-based guides all marginal osteophytes are to be left in place because these guides are manufactured on the basis of the pre-operative bony anatomy as a whole. For example, one should resist the temptation or habit to remove medial-sided osteophytes early in the procedure, in order facilitate exposure in varus knees. When CT-based guides are to be used, osteophytes may only be removed after completion of the bone cuts.

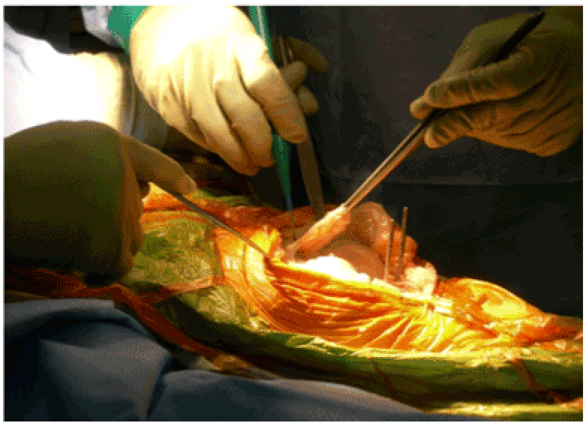

Figure 3: Excision of synovial tissue (held under tension with forceps) from anterior cortex of distal femur using diathermy.

In any case, suboptimal seating of a patient-specific jig should never be accepted, as the resultant bone resection will be malaligned and/or of incorrect thickness. With correct preparation of the bone, the jig should sit securely against it with minimal manual force (Figure 4). If this is not the case, there will usually be residual soft tissue or cartilage that should be removed. Usually, manufacturers provide nylon models of the distal femur and the proximal tibia, too, which can be sterilised and are very useful, enabling the surgeon to confirm how and where the jigs are intended to fit on bone (Figure 5). Should it prove impossible to obtain a secure fit of a custom jig intra-operatively, the PSI technique should be abandoned in favour of the standard intra- or extra-medullary alignment guides [10] or computer navigation [23].

As a general rule, it should be emphasised that PSI is not foolproof. Surgeons should always use their clinical acumen and experience to confirm that bone resection levels, component sizes and alignment are appropriate [10,15,24].

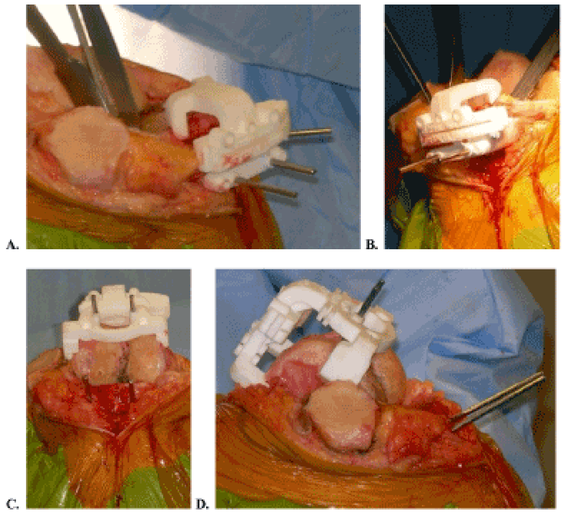

Figure 4: Intra-operative photographs of tibial (A, lateral-sided view; B, medial-sided view) and femoral (C, end-on view; D, lateral-sided view) CT-based, mechanical axis-aligned customised cutting jigs pinned in place. Intimate contact and a perfect fit with the patient's bone are sine qua non for accurate bone resections.

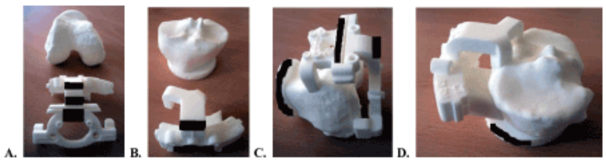

Figure 5 A: Photograph of a CT-based, mechanical axis-aligned customised cutting jig of the femur. The model of the patient's distal femur is also shown. B. Corresponding jig and bone model for the tibia (same patient). The jigs are made to fit perfectly on the models of the femur (C) and tibia (D). Performing this manoeuvre intra-operatively allows the surgeon to locate which bony excrescences the jigs are designed to rest on. These are the areas where soft tissue or cartilage needs be removed (patient details have been deleted).

Results

Accuracy of pre-operative planning

Three retrospective reviews of prospectively collected data [10,24,25] have addressed the need to change intra-operatively the predicted bone resections and implant sizes of the surgical plans of PSI. In a group of 66 TKRs (60 patients) performed by a single surgeon, 161 changes to the pre-operative plan were made (2.4 changes / knee). Of the 95 changes that were measurable radiographically, 82 (86%) were judged to be an improvement to the predicted plan. Incorrectly predicted implant sizes were usually too large for the femoral and too small for the tibial component [10]. In a multi-surgeon study of 89 knees (84 patients), only 29 changes to the plan had to be made (0.3 changes / knee). Of those, 16 (18%) were defined as minor, affecting only the selection of the appropriate thickness of the polyethylene insert [24]. In a series of 50 consecutive patients (50 knees) [25], the size of the tibial component was different to that planned in 8 (16%), although that of the femoral component was correctly predicted in all cases. Alterations to the predicted level of the tibial and distal femoral cuts were frequent (62% and 34%, respectively) but no changes of alignment were necessary. Other investigators have reported variable rates of changes to the predicted component sizes [12] or levels of bone resections,[26] at times causing the surgeon to abandon the PSI technique at significant rates [27,28].

Another method to assess the accuracy of the surgical plan is to validate it intra-operatively, usually using computer navigation. Assessment of two different systems by the same surgical team reported significant disagreements between the plan of PSI and that of navigation, with outliers (> ±3°) in overall coronal alignment found in up to 27% of knees [17,20]. In another cohort of 12 knees assessed for accuracy of the tibial jig only, navigation showed this to be less accurate than the standard extra-medullary guide [29]. In these three studies, the PSI systems were MR-based. Nevertheless, in a comparative study of a CT- vs. an MR-based system, the number of outliers in coronal alignment with the former was more than double (37% vs. 18%) [30]. In all studies, reported discrepancies in alignment were even more pronounced in the sagittal and axial planes.

Alignment

Results on post-operative alignment following TKR with patient-specific jigs are anything but consistent. Rates of outliers (± 3° from neutral) around 10% have been reported in small case-series of surgeons with no prior experience with the technique [31-32]. In studies using standard instrumentation as a control, outliers have been found to be reduced by more than half [19], marginally reduced [33] unchanged [18] or even increased [34] with PSI. Similarly conflicting findings have been reported in comparison with navigation, with equivalent [12] or substantially inferior [35] results for PSI.

The first prospective randomised trial to be published on the topic showed a significant difference in coronal alignment in favour of an MR-based customised jig system over traditional instrumentation (mean, 1.7° vs. 2.8°, $p = 0.03$) [36]. Rates of outliers were not reported. No power analysis was conducted for this single-surgeon study, which is regarded as a preliminary report on a small sample size ($n = 29$) [37]. Subsequent adequately powered randomised controlled trials have failed to detect any significant differences in the overall coronal alignment or the numbers of outliers thereof between customised jigs and traditional techniques [12,26-28,37,38]. While differences in the individual alignment of the femoral or tibial components have been reported [27,37,38], the clinical significance of some [37] and the methodology used for others[38] are, in the view of the authors of the present paper, questionable. Rotational alignment has specifically been investigated with post-operative CT scans in fewer studies. Parratte et al. [26] found similar mean rotation (direction not specified) of the femoral components in the two groups (0.4° vs. 0.2°). The tibial tray was more internally rotated in the traditional group (15° vs. 8°), although the difference was not statistically significant. Roh et al. [28] reported slight mean internal rotation of the femoral component with both techniques, PSI being slightly better (0.5° vs. 1.2°, $p = 0.213$).

Importantly, the study by Victor et al. [27] is the only one having used four different PSI systems (three MR-, one CT-based) in a total of 61 patients. A subgroup comparison of these revealed significantly ($p = 0.04$) more outliers of overall coronal alignment for one, confirming previously published concerns for the same system.[15, 17] The same system produced superior outcomes ($p = 0.001$) of the alignment of the femoral component in the sagittal plane.

Blood loss, surgical time, duration of hospital stay

Intra-operative or total blood loss of TKR performed with customised jigs or standard techniques has been similar in most studies [10,15,28,36,37]. While a significant difference of intra-operative blood loss, in favour of TKR using customised jigs, was found in a prospective, randomised controlled trial (mean, 193.2 ml vs. 297.9 ml; $p < 0.001$), the reported mean values of pre- and post-operative haemoglobin levels on days 1 and 3 did not differ between groups [38].

Using customised jigs, some investigators have reported reductions of surgical time approaching [12] or reaching [36-38] statistical significance. The mean actual differences from standard TKR, however, have consistently been between 5 – 7 minutes [12,36-38]. Others have found no differences in surgical time [11,15,34] and longer times by 13 minutes with PSI have been reported, too [28]. Additional time savings because of sterilisation and opening of fewer trays may impact the cost-effectiveness of PSI, although this remains controversial [11,39,40]. This is discussed later in the current review.

Two studies have recorded shorter durations of stay in hospital after TKR with patient-specific jigs. In one, the difference from the standard technique was small (59.2 hours vs. 66.9 hours, $p = 0.043$) [36]. In the case-control study by Barke et al. [15] there was a mean difference of one day (5.74 days vs. 6.72 days, $p = 0.254$) but, as the authors of that study acknowledged, the older mean age of the patients in the standard group (64.0 years vs. 72.7 years, $p = 0.0001$) might have influenced the results. Other investigators have failed to replicate these findings in prospective randomised controlled studies [37,38].

Extra-articular deformities and conditions precluding use of traditional instrumentation

In a group of 25 consecutive patients undergoing TKR with CT-based jigs, the one outlier of femoral alignment was attributed to a pre-existing post-traumatic deformity of the femur, which necessitated a deviation from the surgical plan [33]. On the other hand, excellent results were reported in the single available published study on customised TKR for post-traumatic arthritis [21]. In this multi-surgeon case series of 10 knees, there were nine cases of malunited fractures; in another case, the presence of retained hardware on the femur precluded the use of intra-medullary instrumentation. MR-based and CT-based jigs were used in eight and two cases, respectively. The surgical plan was followed in all cases but one, in which rotation of the femoral component had to be changed intra-operatively. The mean tourniquet time was 62 minutes and no blood transfusions were necessary. Alignment was restored to a mean of 179.3° of varus (range, 177° - 181°). There was only one case of suboptimal patellar tracking with patellar tilt. Of note, this is the only study so far that has examined functional scores of patients undergoing PSI with mechanical axis-based customised jigs: the Knee Society pain and function scores and the Oxford knee score all improved significantly ($p < 0.05$) at a mean follow-up of 3.4 (range, 2 – 5) years.

A case report of a man with osteopetrosis treated with TKR using customised jigs (MR-based) described a favourable outcome at six months' follow-up, despite an intra-operative fracture of the medial femoral condyle [41]. However, no details on alignment or other objective results were given. The use of customised jigs obviated the need for extra-medullary femoral alignment guides described in the past for TKR in this condition [42].

Function

Functional results of TKR with use of mechanical axis-based customised jigs have not been published, with the exception of the study by Thienpont et al. [21], as discussed previously. More data are available for the kinematically aligned jigs, as explained later.

Cost-effectiveness

The utility of customised jigs in healthcare economics has been explored in three published studies [39,43,44]. None has managed to show that this technique was cost-effective. On a per-case basis, patient-specific TKR was found to be less costly than computer navigation but more so when compared to the conventional technique. However, time gains were evident with PSI, which saved the theatre 28 and 67 minutes less than conventional and navigation techniques, respectively, per intervention [39]. In another study, where instrument processing times were calculated using industrial deficiency methodology, modest time savings (11 minutes of operative time, 90 minutes for processing) could not offset the extra costs amounting to \$1775 per case. The authors concluded the value of PSI could potentially only be justified by improved clinical or radiological results, although alignment was not improved in that study [43]. A similar conclusion was reached by Slover et al. [44], who used Markov decision modelling and a two-way sensitivity analysis to demonstrate that cost-effectiveness of the customised jigs would depend on reduced revision rates. The same authors stressed that the potential fiscal benefits associated with reduced times and resource utilisation would be highly individualised for surgeons and institutions.

Kinematically-based customised jigs

This is technique is based on restoration of the kinematic axes of the knee described by Hollister et al [45], and was not used in TKR surgery before 2006. Concerns were raised after the results of a small (n = 4) case-series were published, showing the potential for unacceptable alignment with use of kinematically-based customised guides, as confirmed by computer navigation [23]. This study has been criticised by the developers of kinematic PSI as being a pilot study using a malaligned MRI protocol [46]. Early experience with kinematically-aligned PSI has been positive [46,47], with two alignment outliers in a total of 21 patients, similar blood loss at 48 hours post-operatively and slightly better flexion, compared to a conventional TKR group [47], while favourable functional outcomes, reflected by high Knee Society scores at three months post-operatively, have also been recorded [46].

A more recent retrospective comparison of TKR with conventional, mechanical axis-based and kinematically-based jigs (n = 50 per group) found no reduction in outliers when customised jigs were used. The kinematically-based group had the most outliers, typically in valgus malalignment. This finding was attributed to the mere nature of the technique, which restores the knee to its pre-arthritic, and not necessarily a neutral, condition [18]. In a double-blind, prospective, randomised controlled trial comparing kinematically-based jigs with conventional TKR, the mean overall alignment was comparable between the two (0.3° vs. 0.0°, $p = 0.693$). Significant differences in the alignment of the individual components (femur: 1.4° valgus vs. 1.0° varus, $p < 0.000$; tibia: 2.4° varus vs. 0.1° varus, $p < 0.000$) mirrored the different philosophies on which the two techniques are based. Blood loss was similar between groups but surgical time was shorter in the kinematically-based group (106 vs. 127 minutes, $p < 0.000$), which also had significant better WOMAC ($p < 0.000$), Oxford ($p = 0.001$) and Knee Society ($p = 0.001$) scores at six months post-operatively [48].

Because kinematic alignment restores the pre-arthritic anatomy, the tibial and femoral components often have to be placed in slight varus and valgus, respectively. Howell et al [49] investigated whether this had any bearing on implant survivorship and patient function at a mean follow-up of 38 (range, 31 – 43) months. In all, 51 (24%) knees were categorized as outliers, most of them (21%, n = 40) being in mechanical valgus. No patient underwent a revision for loosening, wear or instability. The WOMAC and Oxford knee scores were comparable among knees with in-range, varus and valgus alignment. In fact, varus knees had slightly higher scores, although differences were not statistically significant ($p = 0.23$ for both scores). Intra-operative data showed that components of the planned sizes were used in all cases and all customised jigs, except for two femoral ones, fitted well on bone.

Discussion - Conclusions

Patient-specific customised jigs have failed to consistently confer the advantages they were designed for in TKR surgery. In particular, it is unclear whether this technology results in a mechanical alignment that is better than the one produced using standard instruments. Several reasons may account for this finding. First, the production of jigs necessitates numerous measuring stages and manufacturing processes, each of them being a potential error generator [9]. Secondly, most studies have been conducted by high-volume, subspecialty-trained surgeons who were already very adept with standard techniques but early in their learning curve with the patient-specific guides. In the hands of these physicians, there may be little room for improvement of TKR results to begin with, and their published results may not be extrapolated to less experienced surgeons [11]. Thirdly, the majority of investigators have examined this technology as applied to primary straightforward TKRs, usually excluding morbidly obese patients and those with metal hardware, previous fracture, osteotomies or other reasons for an altered anatomy [18,36]. It is our contention that PSI would be most useful in those more challenging cases, obviating the need for the more expensive and time-consuming computer navigation. The results of one study on the use of PSI in the presence of significant pre-operative extra-articular deformities are encouraging [21].

With the advent of this new technology, a debate concerning what constitutes the ideal knee alignment has emerged. Neutral mechanical alignment has been the cornerstone of TKR surgery until recently, when a long-term study showed evidence of better survivorship in outlier knees [50]. Moreover, the early functional results of aligned kinematically TKRs are promising [48-49], despite being mechanically "malaligned" in the traditional sense. These findings confirm the claims made about the survivorship of TKRs being multifactorial [44] and has caused the orthopaedic community to once again start wondering what the best axes are for optimal alignment of TKR [51].

Lastly, a word of caution is essential. Although PSI can be an excellent teaching tool for trainees [52], future surgeons intending to routinely use this technology should be fully familiar with the principles of TKR surgery and have acquired sufficient experience with

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traditional instrumentation. This will enable them to appreciate the accuracy of planned bone resections intra-operatively and make amendments as necessary. Although rare, administrative errors, such as the manufacturer shipping components of incorrect size to the hospital, have been reported [27]. These mishaps should never be reasons on their own for cancelling a patient's operation.

Despite other shortcomings of computer navigation, the primary reasons why it was not embraced widely by TKR surgeons were (a) the associated high initial capital investment and (b) its inability to eliminate outliers of alignment [11]. Prerequisites for widespread acceptance of new technology are a low level of complexity during use and demonstrable cost-effectiveness [9]. Patient-specific technology appears to overcome most of the problems of navigation. It is our notion it has the potential to supersede navigation in the near future, as a faster and cheaper alternative, in cases with deformities or metalware preventing use of standard instruments. However, it still lacks robust proof evidence on cost-effectiveness for routine use. Given the scientific data thus far, experts agree that this can most safely be demonstrated through improved functional outcomes or implant survivorship [33,43,44]. PSI can presently serve as an attractive marketing tool for surgeons and hospitals [44] but it is conceivable we will have to wait for years before definitive conclusions on the true utility of this new technology will be made.

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