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3D printing and unicompartmental knee arthroplasty

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- In suitable patients, unicompartmental knee arthroplasty (UKA) offers a number of advantages compared with total knee arthroplasty. However, the procedure is technically demanding, with a small tolerance for error. Assistive technology has the potential to improve the accuracy of implant positioning.
- This review paper describes the concept of detailed UKA planning in 3D, and the 3D printing technology that enables a plan to be delivered intraoperatively using patient-specific instrumentation (PSI).
- The varying guide designs that enable accurate registration are discussed and described. The system accuracy is reported.
- Future studies need to ascertain whether accuracy for low-volume surgeons can be delivered in the operating theatre using PSI, and reflected in improved patient reported outcome measures, and lower revision rates.

Keywords: unicompartmental knee arthroplasty; partial knee arthroplasty; osteoarthritis; patient-specific instrumentation; patient-specific guides; 3D printing

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Introduction

Osteoarthritis (OA) is an important cause of disability in both the United Kingdom and United States, representing a significant individual and socioeconomic burden.[1–3] The knee joint is most commonly affected (termed 'gonarthrosis'), and in an ageing society, with rising levels of obesity, the number of people with gonarthrosis is predicted to double by 2035.[1,4,5] Knee arthroplasty surgery is indicated in end-stage disease, and in appropriate patients, unicompartmental knee arthroplasty (UKA) offers a number of advantages compared with total knee arthroplasty (TKA). It is associated with a shorter length of stay, a more physiological gait, higher outcome scores and significantly lower rates of venous thromboembolism, stroke, myocardial infarction and overall mortality.[6-9] However, UKA is also associated with higher revision rates, which is an important factor in explaining why it accounts for less than 10% of knee arthroplasty procedures in the United Kingdom and elsewhere.[10-12]

A number of studies have concluded that a caseload effect exists for UKA, with lower revision rates recorded in higher volume practices.[13-16] The aetiology for this observation is likely to be multifactorial, but one explanation is that UKA is a technically demanding procedure with a significant learning curve.[17] Over- or under-correction of leg alignment is associated with an increased risk of failure, and the tolerances for tibial component malpositioning are small, with changes from the native joint line of more than just 3° in the coronal plane, and 2° in the sagittal plane, associated with decreased prosthesis survival.[18,19] This has led some authors to the conclusion that UKA should only be performed in specialist, high volume centres.[15,16]

An alternative response is to try and replicate the technical skills of experts in surgeons who never, or infrequently, perform UKA. Assistive technology, in the form of 3D printed patient-specific instrumentation (PSI), represents one possible approach to achieve this goal. This review article explores the use of PSI for UKA, including our experience with this technology in the MSk Lab at Imperial College London.

Additive layer manufacturing

Unlike traditional computer numerical control machining, where the starting point is a large block of material which is then milled away to create a 3D object, additive layer manufacturing (3D printing) describes the process by which computer-designed 3D objects are manufactured by fusing material together, usually layer by layer. This represents a much more cost-effective and time-efficient method of producing low volume,

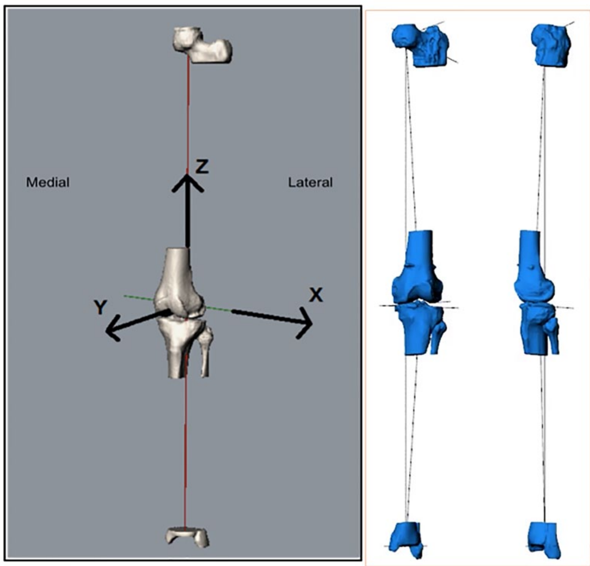

Fig. 1 CT-scan derived 3D bone model reliably orientated in space according to established frames of reference.

complex, 3D objects and has led to its widespread adoption in industry.[20] More recently the technology has been translated to orthopaedic surgery, with a number of commercially available PSI (also known as 3D printed guides) which aim to guide surgeons' saw-cuts, and *ipso facto* implant position, according to a preoperative plan. Other orthopaedic applications of this technology include the rapid production of bone models to help surgeons understand and plan their approach to operations, and 3D printed implants for patients with complex bone loss or deformity.

Planning

The first step in PSI production is a 3D surgical plan. This requires the patient to have a preoperative CT or MRI scan, which needs to include the hip and ankle to ascertain the tibial and femoral mechanical axes. In order to create a virtual 3D bone model, the pixels/voxels which represent bone are identified and isolated from the surrounding structures in a process called 'segmentation'.

Using software designed for the task, the 3D bone model can then be reliably orientated in virtual space using established frames of reference – we use the tibial mechanical axis in the Z plane, and the anatomical tibial axis in the X and Y planes (Fig. 1).[21] This process permits reliable and repeatable planning and measurement, avoiding the potential inconsistencies in knee positioning associated with conventional 2D radiographs, which are known to introduce measurement errors.[21,22]

Virtual computer-aided design models of the chosen UKA implant can then be positioned on the bone model in a truly patient-specific manner according to the implant manufacturer's guidelines, and/or surgeon preference. For example, we aim to match the planned tibial component position with both the native medial proximal tibial angle and anatomic posterior proximal tibial angle of the diseased compartment, with axial orientation parallel to the anatomical tibial axis (Fig. 2).[21,23] The femoral

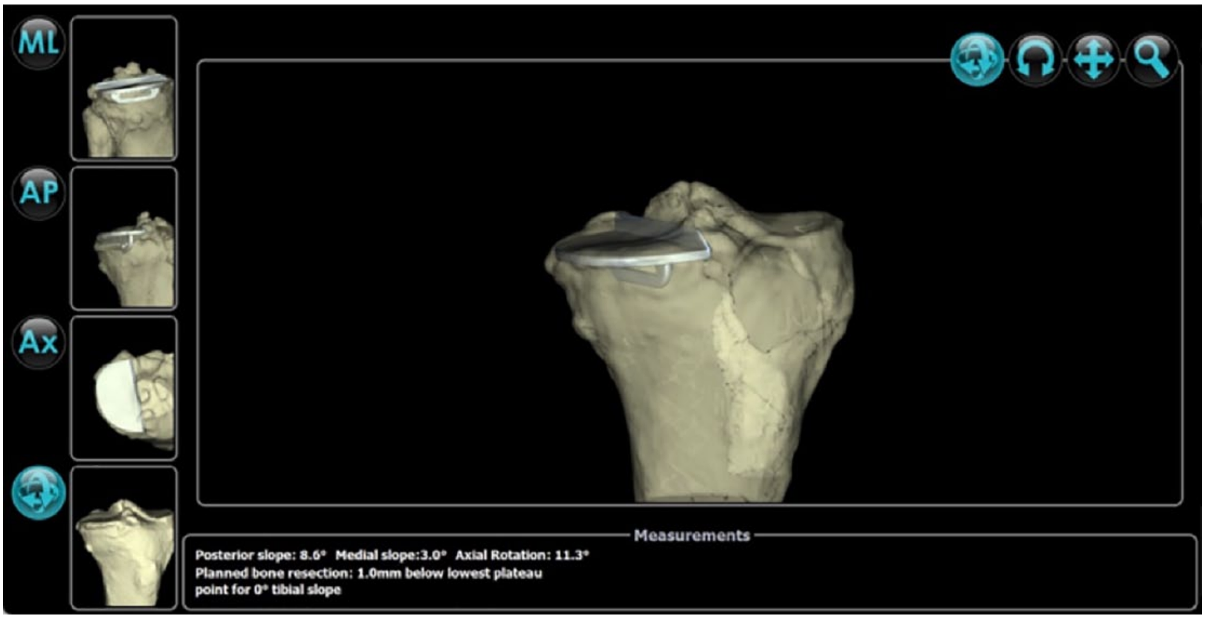

Fig. 2 Screenshot of a planned tibial component using software designed for the task.

Fig. 3 Illustration of an Embody (Embody, London, UK) patient-specific instrument guide incorporating distant patient-specific referencing for the malleoli (red) and local patient-specific referencing of the proximal tibia exposed by the surgical incision (blue).

component position is planned in a similar manner, according to preference.

In general, the process of segmentation, orientation of the virtual bone model according to common frames of reference and implant position planning are performed by engineers. The provisional plan is then sent to the operating surgeon for approval.

Guide design and production

With the desired implant position confirmed, the next step is to design a PSI capable of accurately translating the planned saw-cuts *in vivo*. A number of commercially available PSIs exist, and common to all is the concept that the under-surface of the guide is designed to match the contour of the tibia and femur exposed by the surgical incision. This surface matching is used to position the guide intraoperatively – it should only fit in one position, with confirmation aided by comparison with a sterile 3D printed bone model. It is then secured in place with pins, and depending on design, the planned saw cuts are either performed through slots integral to the PSI (which is our approach), through metal guides, which fit into the PSI, or through traditional metal guides which are slid over pins positioned by the PSI. Despite adding cost, the advantage of metal guides is increased rigidity and avoidance of debris from the guide itself.

Where the guides differ significantly between manufacturers is in the location and area of tibia used for matching. MRI-based guides, such as the Signature System (Zimmer Biomet, Warsaw, Indiana) are designed to reference primarily off the articular surface and surrounding osteophytes. This allows for a relatively large area of surface matching through a routine mini-arthrotomy. The disadvantage to this approach is that the 3D bone models produced after MRI segmentation are dimensionally less accurate than CT-based models and may introduce errors in guide, and hence saw cut, positioning.[24]

For CT-based PSI, because cartilage is not included in the 3D bone model, the tibial surface available for matching is potentially reduced. One solution, used for example in the UKA guides from ConforMIS (Burlington, Massachusetts), is to ask the surgeon to remove any remaining cartilage at the time of operation, allowing the guide to sit on the underlying bone. Another solution, pursued by a spin-off company in our laboratory (Embody, London, United Kingdom) is to use patient-specific distant bony landmarks, in the form of the medial and lateral malleoli, to help with global positioning of the guide. The result is that the footprint of the cutting guide resting on the bony contour of the proximal tibia can be relatively small, and suitable for use via a standard minimally invasive UKA approach (Fig. 3).

The finalized virtual 3D PSI design is then sent to a 3D printer for production. Medical grade CE approved printers are used, which are accurate to within 100 microns. The majority of guides are manufactured using nylon, which is biochemically inert and can be safely sterilized in a standard fashion using a steam autoclave, in accordance with ISO 17665 guidelines. Nylon is also attractive because both the raw material, and medical grade nylon 3D printers, are relatively cheap.

Results

Currently, Ollivier et al[25] have conducted the only randomized controlled trial of medial UKA with PSI or conventional instruments, using a fixed bearing prosthesis (ZUK; Zimmer Biomet) and an MRI-based PSI manufactured by Materialise NV (Leuven, Belgium). They reported no difference in implant position between the techniques at three months postoperatively, no difference in gait parameters (double limb support, single limb support, cadence, stride length and walking speed) at one year postoperatively, and no difference in functional scores at three months and one year (KSS [Knee Society Score], KOOS [Knee injury and Osteoarthritis Outcome Score] and SF-12 [12-Item Short-Form Health Survey]). The authors concluded that claiming PSI improves alignment, pain or function cannot be used 'to justify the extra cost and uncertainty related to this technique'.[25] A similar conclusion was reached by Kerens et al,[26] who found no difference in postoperative implant positioning between their first 30 PSI medial UKA cases and their last 30 cases performed using conventional instrumentation.

However, some limitations in Ollivier et al's[25] methodology should be noted. They did not compare planned implant position with achieved position, but rather reported and compared overall mean implant position for the two groups. Additionally, the power calculation was based on walking speed, rather than accuracy of implant positioning, with the result that only 30 patients were included in each group. Both of the aforementioned studies also relied on 2D radiographs to measure postoperative UKA implant position, which is recognized as unreliable given the impact leg position has on 2D radiographic measurements.[27] Above all, the surgeons involved in these studies were experienced UKA surgeons. Indeed, the two surgeons in Ollivier et al's[25] study perform more than 200 UKAs per year, so the results could equally be interpreted as demonstrating that PSI reliably replicates the radiological and functional results of expert surgeons.[28] The real question raised by these studies is whether PSI might allow inexperienced and low-volume surgeons to achieve similar results.

To address this question, a soon to be published sawbone study from our laboratory compared the ability of expert and inexperienced surgeons to achieve a planned medial UKA implant position using conventional (Oxford Phase III, Zimmer Biomet) and PSI instruments (Embody, London, United Kingdom). The results confirmed that inexperienced surgeons are significantly less accurate than expert surgeons with conventional instruments, but also demonstrated that PSI immediately allowed the same inexperienced surgeons, who had not previously performed a UKA, to achieve the same level of overall tibial component accuracy as expert UKA surgeons.

Discussion

In addition to the benefits associated with a 3D preoperative plan, and a potential improvement in surgical accuracy, PSI is also economically attractive. Each guide costs approximately a few hundred Euros, but equipment and sterilization costs can be reduced by replacing traditional large trays of instruments with a single personalized pack.[29] By predicting implant size based on the 3D plan, the need for large, costly, inventories of implants can be avoided, freeing up valuable theatre space.[30] The attendant reduction in operative set-up time, quick availability of definitive implants, and improved surgical workflow, also translates to improved operating theatre efficiency.[31] This explains why PSI has been estimated as cost neutral irrespective of its ability to deliver improvements in long-term revision rates.[30]

There are some disadvantages associated with PSI. For 3D planning, an additional preoperative scan is required, which introduces extra cost, and in the case of a CT scan, extra radiation for the patient (accepting that novel low-dose radiation CT protocols, which include the hip and ankle, have been shown to be comparable in radiation dose to long leg radiographs).[32] Once performed, these scans require segmentation, which together with guide design, requires input from an engineer and forms a significant part of the cost associated with PSI. Currently, this process is also time consuming, which means that PSI might not be appropriate for a surgical practice with short waiting times, although with an on-site 3D printer, our experience is that the process from scan to guide can be completed in less than 24 hours if required. It is also reasonable to expect that these processes will become progressively quicker and cheaper with inevitable advances in automation.

It is important to remember that the 3D bone models are non-weight-bearing, which makes planning of alignment correction uncertain. Arguably this should justifiably be an intraoperative decision, based on ligament tension, but it highlights the need for PSI to allow surgeons intraoperative flexibility with regards to resection depth. For inexperienced and low volume surgeons it might be necessary to develop a reliable method of informing soft-tissue tensioning alongside PSI, perhaps using technology such as digital load sensors.[33]

There is also the question of who should be responsible for planning the implant position. Ultimately the surgeon is responsible for their patient, which is why all commercially available PSI systems require the surgeon's approval before production. However, there is a risk with this approach that the very learning curve which assistive technology seeks to circumnavigate might simply be transferred from the operating theatre to the computer planning stage. Algorithmic automated planning based on expert surgeons might be the answer, but there is also a need to guard against surgeons becoming technicians who are unable to independently identify and address unexpected errors in the process.

Conclusion

In the context of an increasing disease burden, and a challenging economic outlook, it is clear that more cost-effective operative interventions are required to treat end-stage knee OA. In suitable patients UKA has been found to be more cost-effective than TKA across all age groups, but concerns regarding revision rates when performed by low volume and inexperienced surgeons are a barrier to its increased use, and may in part be related to accuracy of component positioning.[34]

In an era of increasingly personalized medical care, PSI has been shown to deliver promising levels of accuracy for UKA in the hands of expert surgeons. The true test will be whether accuracy for inexperienced surgeons can be delivered in the operating theatre, and reflected in improved patient reported outcome measures, and lower revision rates. Such improvements are not always immediately apparent, so in the interim, technology such as PSI will need to demonstrate other benefits too, such as improved theatre efficiency and lower procedure costs, if it is to be widely adopted.

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G. Jones reports a grant from The Michael Uren Foundation, activity relating to the submitted work. S. Clarke declares provision of equipment from Embody Orthopaedic, activity relating to the submitted work; board membership, royalties and stocks/stock options from Embody Orthopaedic, activity outside the submitted work. M. Jaere declares consultancy for Embody Orthopaedic, activity outside the submitted work. J. Cobb declares consultancy for Microport; patents for Imperial Innovations; royalties from MatOrtho; stock/stock options from Embody Orthopaedic; travel/accommodation/meeting expenses from Zimmer Biomet, activities outside the submitted work.

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