Journal of Clinical Orthopaedics and Trauma 9 (2018) 254–259

Contents lists available at ScienceDirect

Journal of Clinical Orthopaedics and Trauma

journal homepage: www.elsevier.com/locate/jcot

Computed tomography based 3D printed patient specific blocks for total knee replacement

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ARTICLE INFO

Article history:
Received 17 May 2018
Accepted 17 July 2018
Available online 18 July 2018

Keywords:
Total knee replacement
Arthroplasty
Patient-specific blocks
Customized instruments
3D printing

ABSTRACT

Objectives: 3D printing is an emerging technology and its use in orthopaedics is being explored. We discuss the role of computed tomography based 3D printed patient specific jigs in total knee replacement. We also discuss the various advantages of 3D printed patient specific jigs and the future scope of their use in total knee replacement.
Methods: A search of English literature was done and articles discussing the role of CT scan based 3D printed patient specific jigs in total knee replacement were included in the study.
Results: The role of 3D printed jigs in total knee replacement have been found in the prediction of femoral valgus angle, component sizing and in retained hardware. They have shown promise with studies suggesting they might improve the overall mechanical alignment of the knee. There are studies which have also studied the combined role of patient specific instruments with navigation.
Conclusion: 3D printed jigs hold promise in total knee replacement. Their use in total knee replacement in the presence of retained hardware is useful for the surgeon. They have also showed promise in improving prediction of component sizing and improving mechanical alignment of the knee. Further studies with longer follow up and larger sample size will help in establishing their role in total knee replacement.

1. Introduction

Patient-specific blocks (PSB) have been in use as customized instruments option for patients undergoing Total Knee Replacement (TKR). These can be manufactured based on the images obtained by dedicated sequencing of the lower limb using either Magnetic Resonance Imaging (MRI) or by Computed Tomography (CT) scanning. The manufacturing of these customized blocks is done using 3D printing. In this review article, we shall be discussing the manufacturing process and various clinical implications of using these blocks in TKR.

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https://doi.org/10.1016/j.jcot.2018.07.013
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1.1. *Manufacturing of patient-specific blocks using 3D printing*

The manufacturing of the 3D printed patient-specific jigs for TKR uses “additive manufacturing.” Additive manufacturing is a technique in which the model is created by deposition of a powder in a layer by layer manner based on computer-aided design. The material which are used for the manufacturing of the models can be varied, ranging from nylon, polymers, and metals, based on the need. There are various techniques used for additive manufacturing, but the basic technique of manufacturing remains the same (Table 1). The additive manufacturing technique is used in orthopaedics where it can help manufacture complex anatomical models for better understanding pathology. It can also help in manufacturing patient-specific jigs and implants in unique scenarios.[1] Another advantage of AM technique is in improving bone ingrowths in implants (like Tritanium™ implants from Stryker™). Due to the use of AM, these implants have special 3D structures which have shown excellent implant incorporation into parent bone and improving implant survival and longevity.[2]

Apart from surgical planning, use for manufacturing of patient-

Table 1
Table detailing the various methods to do 3D printing along with the advantages and salient features of each technique.

Technology	Material	Raw material form	Support structure	Layer thickness	Heat deflection	Genral usage
SLA (Stereolithography)	curable resins like ABS, PC, etc	liquid	- auto generated - need to be removed after completion of build - post curing required for parts	0.004"/ 50 microns	low	Used for prototyping, fit/form Vat of resin and UV laser beam. Beam traces a pattern on surface of liquid, UV light cures and solidifies. Support is same material.
SLS (Selective Laser Sintering)	nylon PA, GF, FR: Carbon filled, aluminum filled	polymer powder	unsintered powder acts as support	0.004″	high	used for functional prototyping, snaps/live hinges, autoclavable
FDM	ABS, PLA, PC, ULTEM, NYLON PA-12	filament	usually auto generated and removed with solvent	0.007 −0.013″	high	- used for functional prototyping/production, functinal testing: high heat applications. - material properties similar to actual material
POLYJET/OBJECT	UV curable resin (rigid and elastomeric)	liquid	- auto generated, jetted from separate nozzle. - need to be removed after completion of build.	16 microns	low	Used for high resolution, smooth surface, prinintg multiple materials. Printer jets droplets of photopolymer that solidifies with UV light exposure. Support is separate material.
DMLS (Direct Metal Laser Sintering)	Stainless Steel, Aluminum, Maraging Steel, Titanium, Cobalt, Chrome, Inconel, MS1	powder metal	- auto generated. - need to be removed after completion of build.	20 - 70 microns	high	Functional production level parts. Post machining/processing applicable
LMD (Laser Metal Deposition)	Titanium, Stainless Steel, Inconel, Aluminum	powder	no support structure		high	Used for component repair, hybrid manufacturing Metal powder is injected into a focussed beam of high power laser under tightl controlled atmospheric conditions. The focussed laser beam melts the surface of the target material and generates a small molten pool of base material. Powder delivered into this same spot is absorberd into the melt pool.

specific implants and jigs and improving longevity of implants, they have an additional role in education. These models can be used for the education of the students and help in better understanding of the anatomy. Moreover, they are used for education and counseling of the patient and family, for better understanding the pathology and surgery which has been planned.[3]

The manufacturing process entails capturing the images and converting them to an appropriate format and feeding it to the computer. By using this, a CAD (computer-aided design) is created. This CAD is further converted to an appropriate file which can be read by the printer and finally the model is manufactured. In the case of CT based patient-specific jigs manufactured by Stryker (Preplan ™), the images were obtained in the form of CT scan, which is further converted to DICOM (Digital Imaging and Communications in Medicine) and component was designed on CAD. The design was converted to. stl file and finally delivered to the 3D printer, which manufactured the jigs using additive manufacturing. The jigs were manufactured using biocompatible materials which have specific characteristics. These jigs do not abrade when in contact with bone saws (Fig. 1). Moreover, the material used is compatible with autoclaving, so that it can be used during the surgery. These jigs manufactured are "negatives" of the anterior distal femoral and anterior proximal tibial anatomy and comfortably sit on the surface at a pre-defined distance from the articular surface as defined by the surgeon (Figs. 2 and 3). These are then used to pin the conventional distal femoral and proximal tibial jigs which are used for taking the final cuts.

The patient-specific blocks used in TKR have been studied for various clinical parameters. We shall discuss herewith the pros and cons of these blocks for these indications:

1.1.1. Femoral valgus angle prediction

The mechanical axis restoration is one of the significant predictors of long-term survival of a total knee replacement (TKR). On the femoral side, the mechanical and anatomical axes do not match each other, and hence the distal femoral cut has to be taken concerning the femoral valgus angle (FVA) which may vary among patients. Traditionally, the cuts have been made by keeping the femoral valgus angle fixed for all. However, there may be differences in femoral anatomy like variations in the neck-shaft angle, femoral bowing, etc.

Deakin et al. based on the pre-operative radiographs, concluded that the FVA should be individualized as there was a statistically significant difference between males and females.[4] Similar differences based on gender was reported by Barkados as well[5] Theoretically, there is a direct positive correlation between the femoral offset and the femoral valgus angle. Since there is a higher hip offset in males; they tend to have higher femoral valgus angles. The changes in the femoral valgus angles would affect the overall mechanical axis as well.

The CT based 3D printing of the femoral and tibial jigs can help in the prediction of the overall mechanical and anatomical axis of the limb (Fig. 4). It has also become possible for the surgeon to predict the postoperative alignment of the lower limb and hence help improve implant longevity.

1.1.2. Component size prediction in TKR

Preoperative templating in TKR has been used in the past to decrease the operating room (OR) instruments and trial trays[6,7] Preoperative templating can minimize the movement of personnel in the OR, by predicting the size of the components of the femur and tibia.

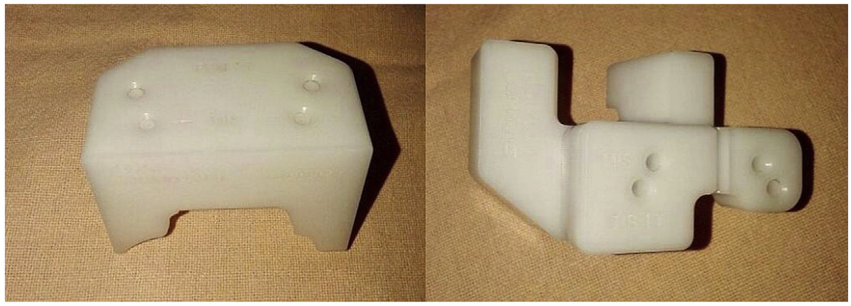

Fig. 1. The computed tomography based 3D printed jigs used for total knee arthroplasty. The left is the femoral jig matching the anterior distal femoral anatomy and the tibial jigs on the right side matches the proximal anterior tibial anatomy.

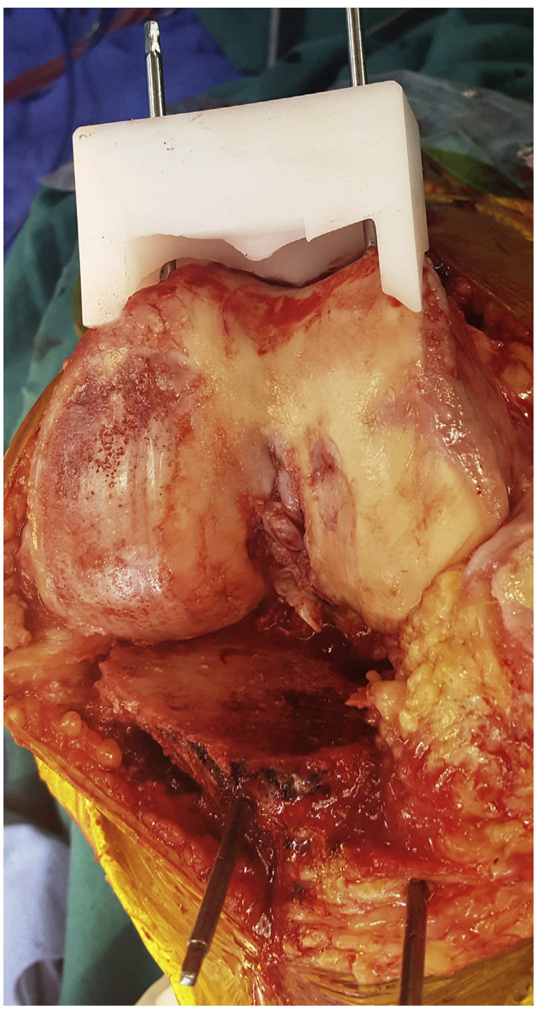

Fig. 2. The femoral patient specific jig depicted intra-operatively matching the distal anterior femoral anatomy and sitting snug on the anterior femoral cortex.

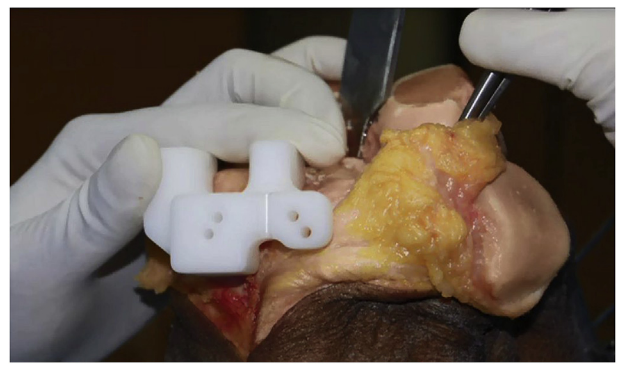

Fig. 3. The tibial patient specific jig anatomically matching the proximal tibial anatomy and is used to pin the conventional proximal tibial cutting jigs for the cuts.

In a low volume replacement set up, preoperative templating can help the surgeon know if there are unusual femoral or tibial component sizes which may be needed. An idea about the predicted sizes can help in decreasing the costs associated with transportation and storage of sizes widely away from the predicted sizes. The insertion of the ideal size is also crucial for the restoration of the correct biomechanics in the knee. The changes in the flexion gap in the knee are affected by a change in the femoral component. There are deleterious effects of an oversized and undersized component. An oversized component may lead to soft tissue impingement whereas a smaller component may sit on purely cancellous bone and also lead to higher stress over a small bone cement interface.[8]

A high correlation was noted in the planned and implanted sizes by Kotela et al.[9] In a study by Koch et al., which examined 301 TKRs using CT based PSI, only 10.8% change in the preplanned size was noted out of a total of 602 components.[10]

Using the MRI based technique, Stronach et al. reported that the MRI based component sizing was correct in 47% tibia and 23% femur.[11] Lustig et al. reported femoral component matching in 52% and 50% tibial component matching using MRI based PSI.[12] This difference between the CT and MRI based technology may be due to the bone based 3D printing in CT and cartilage based 3D printing in MRI based PSI. In a recently published series assessing the component size prediction using CT based 3D printed technology, 72% accuracy was there as far as the tibial component sizes were concerned. This accuracy decreased to 66% in the femoral component size prediction. This difference in the predicted and implanted sizes was not statistically significant in the tibial side whereas the difference was statistically significant on the femoral side.[13]

The tibial component size depends on the proximal cut of the tibia. Since the variables involved in the prediction of the tibial component size is single, there are higher chances of a correct prediction. In the femur, the component size depends on anteroposterior as well as medio-lateral diameters. On the femoral side, care also needs to be given for avoiding notching (Fig. 5). These multiple variations may lead to lesser accurate size prediction on the femoral side. Future research may help in further refining the use of CT scan-based patient-specific jigs for the prediction of the component sizes in TKR.

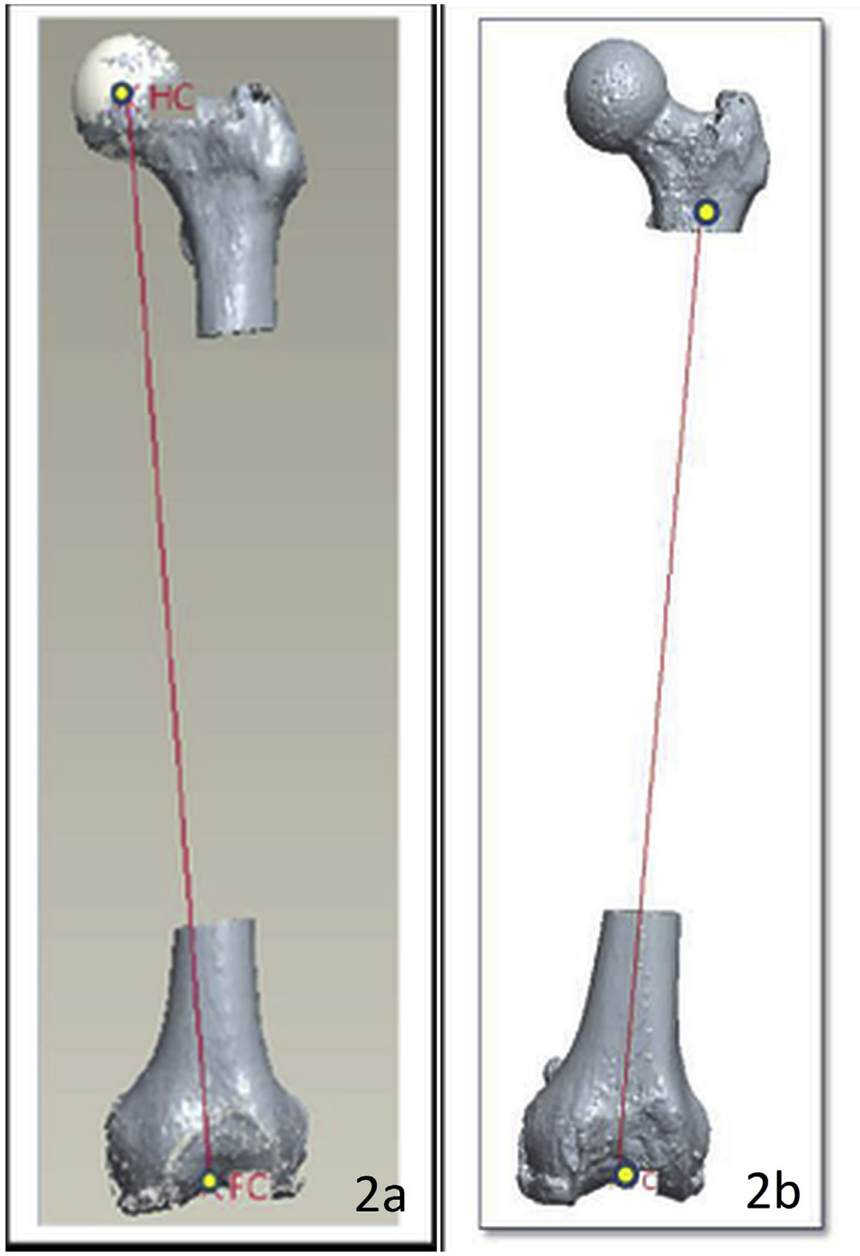

Fig. 4. Image depicting the calculation of the mechanical axis, anatomical axis and femoral valgus angle in a virtual 3D model of the patient femur.

1.1.3. *Use of patient-specific blocks in TKR with retained hardware*

Retained hardware in an osteoarthritic knee poses unique issues to the replacement surgeon. The medullary canal may be obstructed by the presence of retained hardware along with canal sclerosis due to callus. There may be associated extra-articular deformity.[14] It may preclude the use of intra-medullary rods for alignment in these cases.[15] The option is to do hardware removal, but if done in the same sitting, there is a risk of intra-operative fracture.[16]

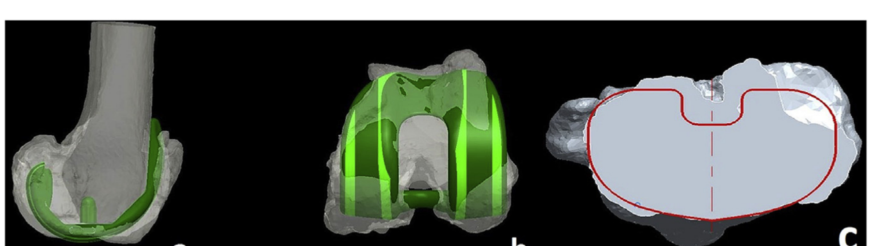

Fig. 5. An illustrative case depicting the sizing of the femoral and tibial components on the 3D reconstructed model of the bones.

Implant removal is also associated with increased duration of surgery, increased blood loss, increased risk of infection along with the increased risk of intra-operative fracture due to stress risers.[17] The surgery for implant removal involves increased exposure to anesthesia, blood loss, and delayed final surgery of TKA. Moreover, routine removal of the retained hardware may lead to further bone damage and soft tissue dissection and hence lead to delayed recovery and more extended rehabilitation periods.[18] CT based 3D printed model of the femur and tibia can help in circumventing this issue of hardware removal. This technology can assist in identifying the hardware which may hinder the insertion of the pins and final implant. It can also help in obviating the need for insertion of the intramedullary rod for the femur. In a recently published series, patients had suffered an extra-articular ipsilateral femoral fracture in the past and underwent open/closed reduction and internal fixation either by nail or plate and had retained hardware. The average distance from the distal side of the implant to the intercondylar notch was 5.43 cm.[18] None of the patients needed the use of special implants like wedges or stems in the present series (Fig. 6, illustrative case). Only one patient required the removal of a screw which was hindering the insertion of the pin for the distal femoral block.

None of the patients needed an invasion of the medullary canal, and none required complete hardware removal and hence prevented the need for second surgery and delayed rehabilitation.

1.1.4. The accuracy of alignment using patient-specific blocks

The postoperative alignment achieved in total knee replacement has been shown to have a significant bearing on the long-term outcomes of total knee. The overall alignment of the lower limb depends on predicting or supposition of the femoral valgus angle of the patient while using the IM femoral jig. On the tibial side as well, the alignment in the tibia depends on the relationship of the EM jig to the shaft, tibial tuberosity and the ankle joint. These all factors may vary from surgeon to surgeon and may result in the presence of “outliers.”

3D printed patient specific jigs, which match the anterior femoral and the proximal tibial anatomy, can help in improving the overall alignment of the lower limb. The surgeon can predict the postoperative limb alignment using the virtual cuts made on the 3D reconstruction of the lower limb anatomy. It can help the surgeon to plan the distal femoral and the proximal tibial cuts.

The jury is still out on the improved alignment using 3D printed patient specific jigs. A decreased number of outliers have been reported using PSI as compared to conventional technique TKRs.[19] On the contrary, Chen et al. reported increased outliers with the use of PSI in a series of 60 patients.[20] Vaishya et al. in their comparison of conventional instruments with patient-specific instruments, reported significantly improved limb alignment in the PSI group.[21] A recent systematic review of patient-specific instrumentation in total knee replacement concluded that PSI does decrease the number of surgical trays needed in surgery, but there was no significant improvement in postoperative component alignment.[20]

While the discussion overall implant survival using PSI in TKA is awaiting mid-term and long-term results, the other advantages of the PSI like with retained hardware, component size prediction, and femoral valgus prediction are potential uses which may help improve outcomes of replacement surgeons.

1.1.5. Comparison to other technologies

Total knee replacement volumes have risen over the years. It has led to debates and discussions over finding the ideal solution which can help in providing the best outcomes. Apart from achieving the ideal postoperative alignment, there are other issues like component size prediction, component positioning and retained hardware which needs to be addressed.

When comparing 3D printed patient specific jigs to navigation, there does not seem to be a significant difference in the postoperative alignment and outcomes.[22] Yan et al. in their RCT compared patient-specific instruments with conventional and navigation and found out that there was no clear radiological or clinical difference.[23] Studies like Kawaguchi et al. have even reported better femoral alignment with computer navigation as compared to both conventional and patient-specific jigs.[24] Rahm et al. concluded that the real use of PSI over conventional jigs and navigation lies in avoiding the severe outliers and achieving the ideal posterior tibial slope,[25] The significant deterrent for PSI is the additional cost and delay in surgery which prevents the routine use

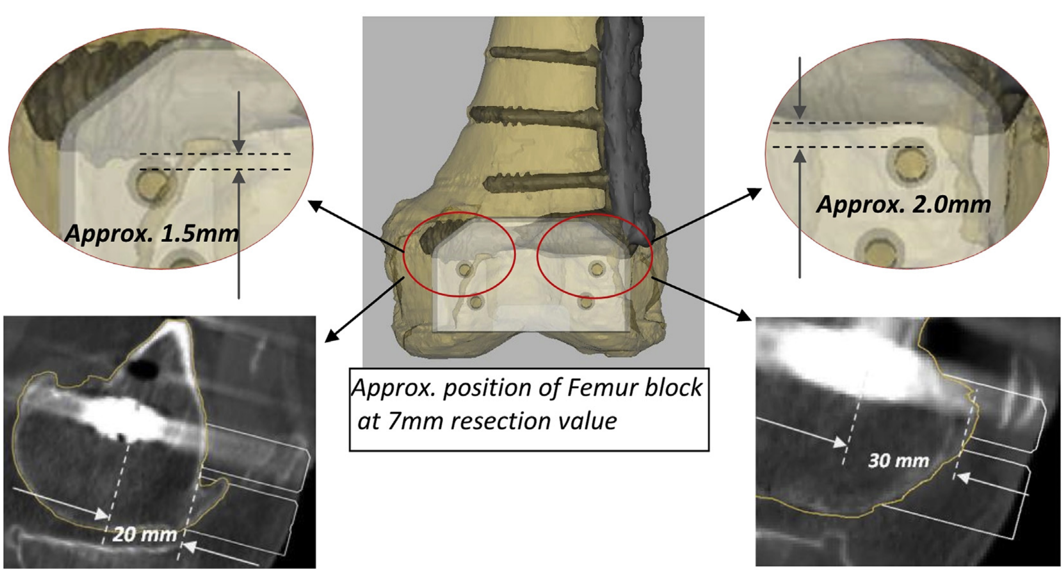

Fig. 6. A case of retained hardware with the presence of a dynamic condylar screw in the distal femur needing total knee arthroplasty. The preoperative planning depicted that the screw was approximately 2 mm away from the position of the pins for the distal femoral jig after preoperative planning. Since, the use of intramedullary rod was not needed and there was no interference with the implants, implant removal was averted and routine total knee arthroplasty was performed.

of PSI. With the use of local manufacturing process, we have been able to decrease the cost of manufacturing of the jigs to under $400 and the waiting period has come down to less than a week.[26]

While the debate about the advantage in limb alignment is on, there are several other advantages of PSI over conventional and navigation. Both conventional and navigation assisted techniques fail to predict the component sizes. Studies have shown the good accuracy of the component size prediction with 3D printed jigs.[13] Similarly, Briffa et al. found that the femoral component alignment along with size prediction is an additional advantage of PSI.[27] The prediction of femoral valgus and the additional use in the presence of retained hardware and extra-articular deformity, are clear advantages of PSI over conventional techniques and has shown similar results to navigation. Some studies have even recommended the PSI with CAS for achieving best results.[27]

3D printed patient specific jigs hold promise for complex primary total knee replacement. Their role in routine TKR is still undergoing refining and mid-term as well long-term results are awaited. As the knowledge and follow-ups grow, this technology holds promise for the future. Moreover, the recent interest in 3D printing technology and its use in orthopaedics has pushed this technique. As mentioned, the cost and waiting period of the jigs has come down significantly, and with the broader availability of 3D printing technology, this will further come down.

2. Conclusion

3D printing technology is an exciting opportunity, and its role in total knee replacement is multifold. 3D printing in orthopaedics is done using additive manufacturing and can be used for planning and educational purposes. 3D printed patient specific jigs can be used for prediction of component sizes in total knee replacement which can help in improving OR efficiency and decreased armamentarium. Its role has also been studied in the prediction of patient-specific distal femoral valgus angles, and the results are encouraging. Their role in retained hardware is unequivocal with significant advantages. 3D printed patient specific jigs have been shown to improve post operative mechanical alignment in total knee replacement. Their usage is still in its early stage and more studies with larger number of patients and longer follows up will help in establishing their role in total knee replacement.

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