

# Hospital-based Patient-specific Templates for Total Knee Arthroplasty: A Proof of Concept Clinical Study

Mahmoud A. Hafez, MD, FRCSEd, Hosamuddin Hamza, MFDS FRCSEd,  
and Ahmed Nabeel, MSc Ortho & Tr

**Introduction:** All available patient-specific instruments or patient-specific templates (PSTs) are controlled by implant companies. Most of these companies outsource some of the steps of the PST such as imaging, preoperative planning, manufacturing of PST, and packing/sterilization. This is a proof of concept clinical study on the hospital-based PST system for total knee arthroplasty (TKA).

**Methods:** A total number of 257 TKA procedures were performed on the basis of a new concept of hospital-based PSTs. All 5 steps of the PST [ie, imaging (computed tomographic scanning), planning, PST production, packing/sterilization, and surgery] were performed by the hospital. All cases included in this work are documented in the Egyptian Community Arthroplasty Register.

**Results:** All cases had their surgeries performed without resorting to conventional intramedullary guides. Computed tomography-based imaging was easy and affordable. Planning was controlled by the surgeon. Polyamide nylon was the best available material and it was autoclavable. Desktop 3-dimensional printers were able to produce PSTs made of nylon, but it was difficult and time consuming. Industrial printers were superior in quality to desktop printers but more expensive. The whole process could be performed in as short a duration as 3 working days.

**Conclusions:** Hospital-based PST was feasible and it was facilitated by the introduction of desktop 3-dimensional printers. This technique was less expensive and more time saving than commercially available PSTs as well as the conventional TKA.

**Key Words:** total knee arthroplasty—patient-specific templates—CAOS—hospital-based—custom-made cutting guides—3D printers.

(*Tech Orthop* 2018;33: 258–263)

Patient-specific instrument/template (PSI/PST) is a computer-assisted surgical technique for total knee arthroplasty (TKA), which was introduced for orthopedic surgery to be a less-invasive alternative to the conventional technique. It eliminates the use of intramedullary guides with their concerns of potential fat embolism, blood loss, and infection.<sup>1</sup> Both techniques have comparable success rates in terms of limb alignment and patient satisfaction.<sup>2–4</sup>

The concept of PST is applied by all major implant manufacturers but with some variation, such as using magnetic resonance imaging (MRI) instead of computed tomography (CT) and using the template as a guide to locate conventional cutting blocks (ie, pin locator).

From the Orthopaedic Department, October 6 University, Cairo, Egypt. The authors declare that they have nothing to disclose.

**For reprint requests, or additional information and guidance on the techniques described in the article, please contact Mahmoud A. Hafez, MD, FRCSEd, at mhafez@msn.com or by mail at The Orthopaedic Department, October 6 University, Central Axis, October 6 City, Giza, Cairo 11412, Egypt. You may inquire whether the author(s) will agree to phone conferences and/or visits regarding these techniques.**

Copyright © 2017 Wolters Kluwer Health, Inc. All rights reserved.

The commercially available PST is controlled by the company, and it takes an average working time of 3 to 6 weeks. The preparation is neither performed nor supervised by the surgeon, and it takes long duration for confirming the preoperative plan. Most of the implant manufacturers outsource some steps of PST production such as planning and template fabrication. Thereafter, the templates return to the implant company for packing/sterilization and finally delivering the PST to the surgeon at the date of surgery.<sup>5</sup>

This prolonged procedure limits the availability of PST, especially in countries where implant companies are not widely distributed. The surgeons usually need longer time for communication with implant manufacturers to obtain the PST along with the implant, with additional cost compared with conventional technique.<sup>6,7</sup>

The aim of this study was to demonstrate hospital-based PST, in terms of practicality, as a new concept in arthroplasty surgery. Using this technique, all 5 steps of PST (ie, imaging, planning, PST production, packing/sterilization, and surgery) are performed under the control of the hospital.

## METHODS

Institutional review board approval as well as written consents from all patients was obtained before establishing this work. In total, 257 cases underwent TKA at our department using hospital-based PST from 2012. The male to female ratio was 1:5, and the mean age was 58 years. Patients included in this work had knee osteoarthritis with severe varus, valgus, or fixed flexion deformity, which is beyond nonsurgical treatment. In all, 158 cases were bilateral simultaneous TKAs, whereas the rest of the cases were unilateral TKAs. All cases included in this work are documented in the Egyptian Community Arthroplasty Register.

CT scanning was performed for the knee joint, proximal tibia, and distal femur, with 1-mm thick slices and 1 mm spacing, which is the minimum requirement for accurate reconstruction of the joint, along with anteroposterior and lateral scanograms (topograms) of the lower limb from the hip to the ankle. The femoral and tibial shafts were scanned with 5-mm thick slices and a scan space of 5 mm. This protocol optimized the image quality of the bone for areas of interest around the knee joint, as well as the distal femur and proximal tibia. CT scans were imported to OrthoNovi software (SurgiNovi, Sidcup, UK), which is our proprietary software and not an open-source software, and displayed in coronal, sagittal, and transverse planes. During preoperative planning, the software provides information about the implant to be used in the form of 3-dimensional (3D) CAD files of different sizes of tibial and femoral components. The anatomy of the knee could be displayed, rotated, and tilted to view all its aspects (front, back, and sides) at any angle. The reconstructed images were displayed on the computer screen as a 3D model (Fig. 1).

PSTs were designed to fit on to bones on the basis of surface matching; especially at cartilage-free areas in the distal femur and

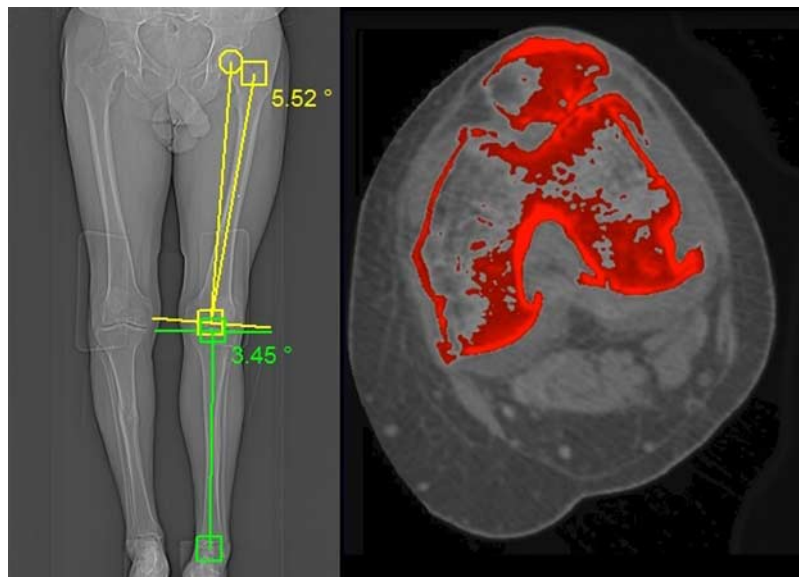


FIGURE 1. A scanogram and 3-dimensional views of the computed tomographic scan. [full color online](#)

the proximal tibia. This is based on the CT scan of the knee, which displays the specific shape of the bone of a particular patient. The template should take a single/stable position on the bone and then be fixed by pins. Default planning was based on the standard parameters, such as 3 degrees of external rotation for the posterior femoral cut and 0 degrees for coronal tibial cut. The surgeon's preference could be added to the default, such as 5 degrees of posterior slope in the tibial cut.<sup>1</sup> The default settings could be changed according to the specific nature of the case or the surgeon's preference. Sizing of the femoral and tibial components was carried out automatically by the system and verified to avoid undue anteroposterior and mediolateral mismatching or any implant overhang in any plane. The planning could reveal information that would not be available to the surgeon during actual surgery, such as posterior tibial overhang or posterior femoral offset.

Alignment (angles and rotation) and bone resection were planned according to the set default for 8 standard parameters: femoral coronal alignment, femoral sagittal alignment, femoral rotation, level of distal femoral cutting, tibial coronal alignment, tibial sagittal alignment, tibial rotation, and level of tibial cutting.<sup>8</sup> The ideal bone cuts were measured on software with definite

length, direction, and inclination.<sup>9</sup> According to the surgeon's needs, some femoral PSTs were designed with reference cuts only (distal and anterior) using the open-platform method.<sup>10</sup>

Surgeons have a major role in preoperative planning, either by performing the planning on the software or by supervising the technician, which increases the surgeon's confidence toward planning and shortens the time of the whole process (Fig. 2). In our hospital, we have a specialized technical team for more efficient preoperative planning, and direct communication with the surgeon, being also responsible for the fabrication of PSTs inside the hospital.

The final design of the PST was transferred electronically to the rapid prototyping machine. Desktop 3D printers are used in our hospital for this purpose. However, in case there was overload on these printers, industrial 3D printers outside the hospital were used. The desktop printer used was Creatr HS (Leapfrog, the Netherlands) (Fig. 3).

The guides are made of 3 biocompatible materials (ie, polyamide nylon, acrylonitrile butadiene styrene (ABS), and polycarbonate). Nylon was the most commonly used material, as it was durable enough to withstand the heat of sterilization

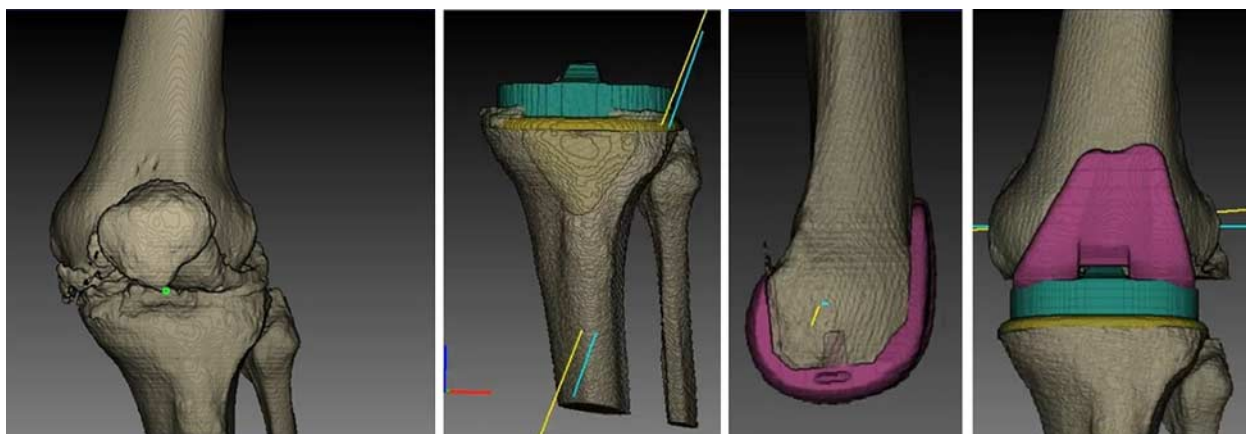


FIGURE 2. Planning for patient-specific template. [full color online](#)

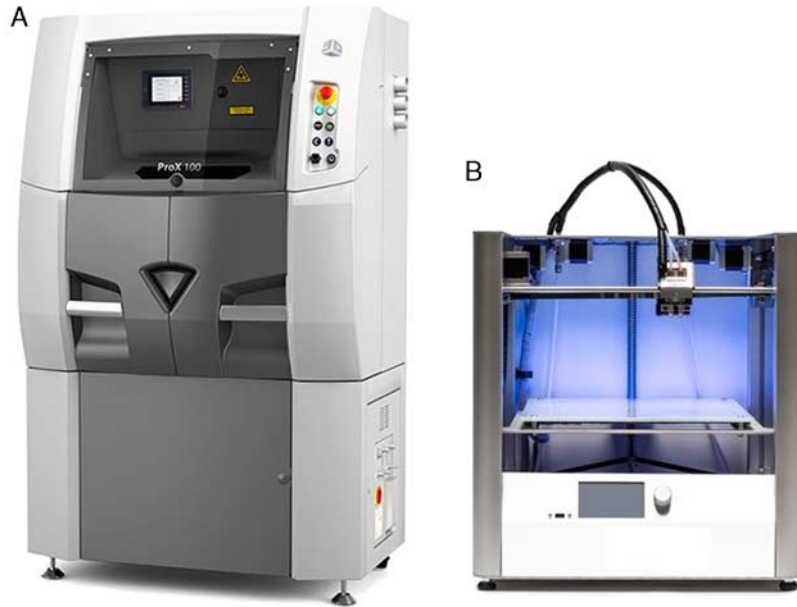


FIGURE 3. (A) Industrial and (B) desktop 3D printers used for the production of PST. full color online

(eg, autoclave) and contact with surgical instruments, such as power drills and saws. It possessed a tensile strength of 43 MPa and withstood a temperature of up to 180°C. Figure 4 shows the complete set for TKA including A trial implant, B PST and C supporting instrumentation (impactors, fixation pins, drill bits for stem and lug holes). ABS and polycarbonate were sterilized using plasma or ethylene oxide.

The patient’s initials along with the side and size of the knee implant were printed on the templates, and packing was

done in special packs. The sterilization of nylon was performed by autoclaving, which is an easy, affordable, and available method in our hospital. The used packs do not interfere with the sterilization process, being well sealed to keep the template sterile and to avoid any moisture from reaching the material.<sup>11</sup>

The work cycle till the production of the final cutting guides could thus be used for a specific patient,<sup>4</sup> and the surgeon could finally do the operation using these templates (Fig. 5).

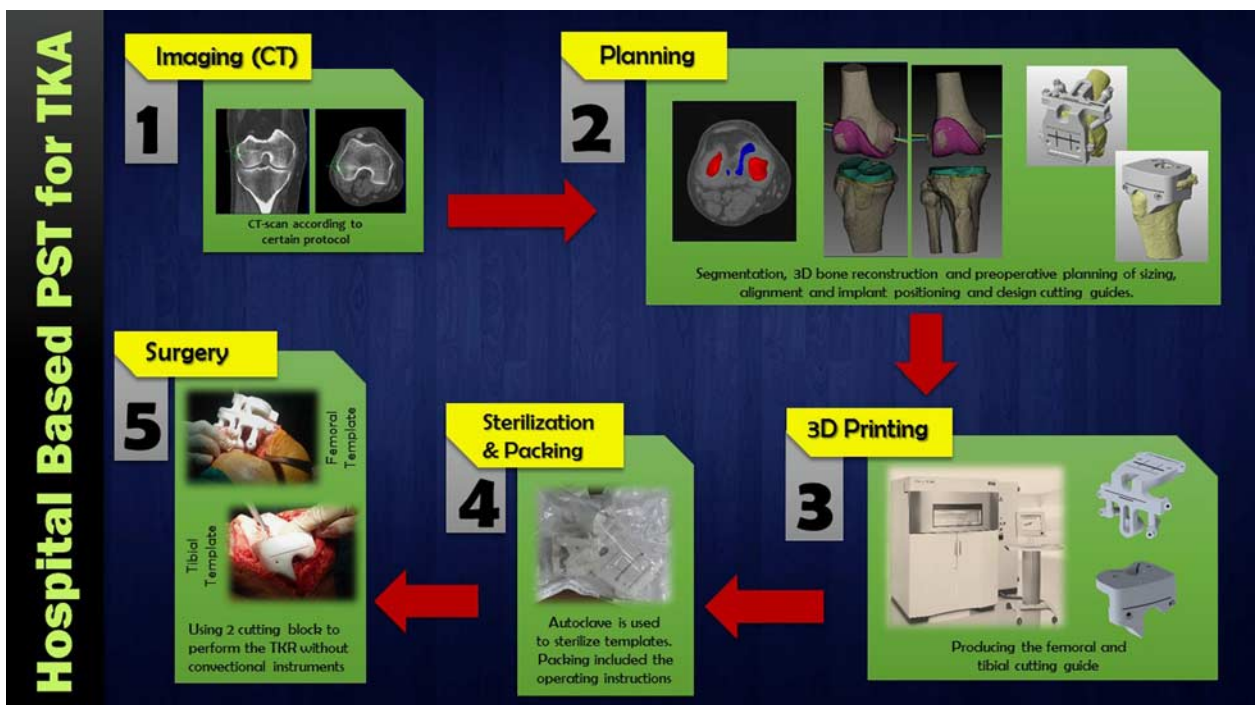
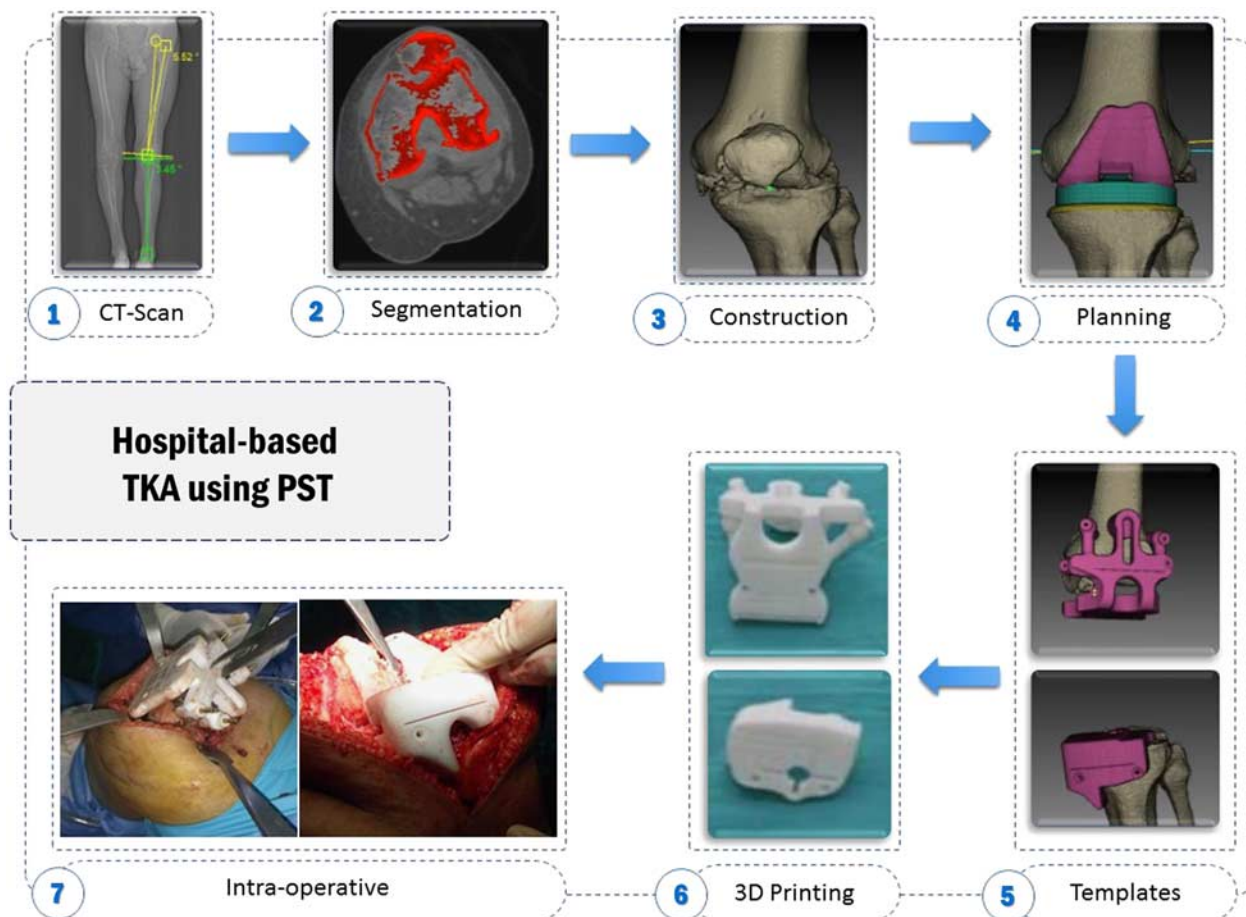


FIGURE 4. Trial implant, PST, supporting instruments for TKA. full color online



**FIGURE 5.** Work cycle of hospital-based PST. CT indicates computed tomography; PST, patient-specific template; TKA, total knee arthroplasty; 3D, 3-dimensional. full color online

## RESULTS

The process of hospital-based PST technique (Fig. 6) was used for 257 cases at our department including bilateral TKA. The whole procedure took an average of 3 to 5 days. The number of instruments used was reduced by an average of 50% to 70%, that is, from 30 to 43 instruments to an average of 15 instruments when comparing different implants' companies using available custom-made cutting guides to our hospital-based technique (Fig. 7). The CAD files of the selected sizes of prosthetic components are transferred to special, sophisticated rapid prototyping or production machine to produce physical models of the components trials (Fig. 4) on the basis of the virtual design created by the planning software. In terms of cost-effectiveness, we mainly corresponded to the pricing of the 3D printing materials and maintenance of the 3D printers. In 30% of cases, 3D printing was performed using industrial printers.

## DISCUSSION

In the literature, there are several reports documenting the use of PSTs and PSIs. However, the concept of hospital-based PST has not been previously reported. The data presented in this work are collected prospectively from the Egyptian Community Arthroplasty Register, which acts as a database for our patients.

The commercially available PST is still not popular, and the majority of developing countries are deprived from the privilege of using PSTs. The company-based PSTs usually use MRI rather than CT scanning, and hence rely on kinematic rather than mechanical alignment.<sup>7</sup> MRI has the theoretical advantages of detecting cartilage and being a radiation-free imaging; however, it is more expensive than CT and requires longer waiting time, reimbursement, and other logistics.<sup>8</sup>

Most commercially available MRI-based systems have ~6-week interval from the time of acquiring the MRI scans until the templates are delivered to the hospital. This may carry the risk of anatomic changes to the articular cartilage of the knee as a result of daily activities or any abnormal loading during this long delay, resulting in intraoperative malpositioning of the templates and subsequently implant malalignment.

The same errors of malpositioning of the templates can occur as a consequence of incorrect bone segmentation with MRI, which is less likely to occur with CT. The available custom-made cutting guides could be limited in late-presentation cases or for old patients, which could be explained by the fact that the technique does not depend on CT scans.<sup>12</sup>

In the available company-based PST systems, planning is routinely carried out by the technician rather than the surgeons. The technique needs >1 workplace: the hospital scanning center, preoperative planning or department, the factory where





**FIGURE 6.** Conventional instrumentation in > 10 trays as compared to PST and few pieces of supporting instruments used for bilateral total knee arthroplasty. full color online

3D printing is carried out, and the implant company responsible for packing, sterilization, and delivery of PSIs.

In addition, medicolegal experts described patient-specific cutting guides (known as PSIs) as a complex process and surgeons hold the responsibility toward its failure; furthermore, companies should not produce PSTs without achieving an acceptance from the surgeon.<sup>13</sup>

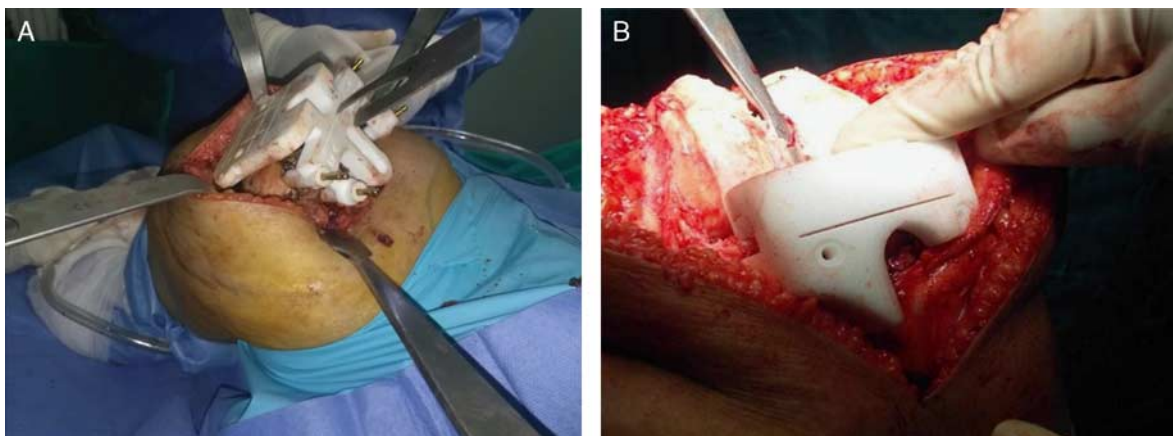
The PST used in this work refers to cutting blocks and not pin locator, which is, in our experience, more useful than the PSI reported in the literature. A modification was made by implant companies using the cutting guide template as a pin locator, which defeats the objective of using the templates, which is meant to replace conventional instrumentation; however, using the templates as a pin locator means adding extra pieces of instruments to conventional instrumentation and mixing the principles of PST and the conventional technique. Our PST technique is based on mechanical alignment and not kinematics.

In our hospital-based system, imaging, planning, sizing, designing, and production of PSTs are performed by the technical team, and the overall procedure is performed under direct supervision of the surgeons. The communication is rapid and easy, and direct feedback can be given by the surgeon to adjust the plan to an optimally desired design.

In this work, we could reach some cost savings by using CT scans, which are less expensive than MRI. Moreover, the number of instruments used was reduced from 2 PSTs and 30 to 43 instruments of different companies using available custom-made cutting guides to 2 PSTs and 15 accessory instruments in our hospital-based PST. In addition, we replaced industrial 3D printers by desktop machines for the production of trial implants and PSTs, although there was tendency to use industrial printers for complete cutting blocks and also for patients who can afford extra payment and are willing to wait for a longer time. The authors believe that there are large regional, international cost variations associated with the types of implants and instruments used; however, from the findings presented herein, time and cost saving are reproducible for any hospital. In other words, there was considerable cost in the hospital-based system presented herein, but the savings were more.

The material used for the production of PSTs in our hospital-based PST was nylon, which meets certain criteria such as being heat stable to withstand the high temperature of sterilization, durable enough not to be damaged by saw blades, and inexpensive. In addition, it is easily manufactured within a short period of time. ABS plastic is another material of use; it is not expensive, has a tensile strength of 61 MPa, and withstands temperatures of up to 96°C. It could be sterilized by  $\gamma$  radiation, ethylene oxide, or low-temperature steam. The polycarbonate could also be used, as it is not expensive and can withstand heat up to 133°C. Its tensile strength is 57 MPa and could be sterilized by autoclaving,  $\gamma$  radiation, and ethylene oxide.

Once the operation is planned and the template is fabricated, the surgery is performed at the same hospital. Thus, the overall



**FIGURE 7.** Intraoperative images of the femora and tibial PST used for TKA. full color online

procedure of hospital-based PSIs can be performed in 1 place under surgeon control, and the average time needed for imaging, planning, fabrication of templates, packing/sterilization, and surgery can be cut short to 3 days.<sup>10</sup> The objective of this proof of concept is to indicate the practicality of the procedure. This is described by the conversion rate or switching from the PST to conventional TKA. The actual conversion rate was 0% for femur and 10% for tibia, which is increased to 20% for educational purposes when the surgeon uses an extramedullary guide for verification and comparison of PST tibial cuts.

Our hospital-based PST technique does not require a company's representative for transferring the data, radiographs, or documents; thus, the technique seems suitable for countries that are out of the scope of implant companies' interests.

McWilliams and colleagues presented several benefits of hospital-based health care systems, which were consistent with our findings. As hospitals routinely have a high number of physicians in different specialties, this could be an important predictor for quality and cost of care; consolidation of such different specialties contributes further for better quality-of-care environment. Moreover, promoting health care system integration while providing risk sharing could decrease the expenses of procedures, imaging, and tests while improving the quality of care.<sup>14</sup>

Hospital-based health care services should be provided in public and academic hospitals with clinical, administration, and economic staff who are capable of undertaking clinical practice, administrative decision making, assessment of devices and procedures, examining the effectiveness, safety, and cost data, as well as organizing training workshops, seminars, learning courses, and collaborative networks. The staff also need to design a strategy that balances both academic and operational efficiency to impact health care decisions. Junior staff can thus work jointly with consultants to prioritize projects, conduct research work, do effective analyses, and potentially achieve evidence-based, resource-based, and value-based innovations in the medical field. Moreover, an organizational approach should be built up to overcome any malpractice and to implement and develop timely, valid, and actionable decisions.<sup>11,15</sup>

This technology could be applied in hospitals that have the required facilities (imaging, sterilization apparatuses, 3D printers, 3D software, and qualified personnel). The authors encourage orthopedic surgeons to universally apply the proposed technique. The cost of 3D printers and the salaries of the technical team (or R&D unit in hospitals) would be reasonable within the context of well-established workflow.<sup>10</sup>

The limitation of this work is that it does not include enough data on postoperative outcomes; however, this is a proof of concept study that explains that our hospital-based PST technique is different from commercially available ones. It is worth mentioning that in a low percentage of cases we outsourced 3D printing in an affiliated institute; however, all steps were still under the control of the hospital and/or the surgeon rather than the implant companies. It also involved the control of the 5 steps of PST even if one of these steps was carried out outside the hospital.

## CONCLUSIONS

Hospital-based PST is a practical, user friendly, inexpensive, and time-saving technique. The procedure has proven

feasible. The outcome of the process showed that CT-based imaging was practically easier and more affordable. Planning was controlled by the surgeon. Template production with nylon was carried out by desktop 3D printers, which are less expensive than industrial printers.

## REFERENCES

- Hafez MA, Chelule K, Seedhom BB, et al. Computer-assisted total knee arthroplasty using patient-specific templating. *Clin Orthop Relat Res*. 2006;444:184–192.
- Snider MG, MacDonald SJ, Pototschnik R. Waiting times and patient perspectives for total hip and knee arthroplasty in rural and urban Ontario. *Can J Surg*. 2005;48:355–360.
- Sadoghi P. Current concepts in total knee arthroplasty: patient specific instrumentation. *World J Orthop*. 2015;6:446–448.
- Mohamed MM, El Assal MA, Adbel Aal AM, et al. Postoperative mechanical axis alignment and components position after conventional and patient-specific total knee arthroplasty. *Open J Orthop*. 2016;6:253–258.
- Zhu F, Chen KZ, Feng XA. Converting a CAD model into a manufacturing model for the component made of a multiphase perfect material. Proceedings of the Fifteenth Solid Freeform Fabrication Symposium, Austin, TX, August 2–4 2004, pp 532–43. 2004. ISSN 1053-2153.
- Gromov K, Korchi M, Thomsen MG, et al. What is the optimal alignment of the tibial and femoral components in knee arthroplasty? an overview of the literature. *Acta Orthop*. 2014;85:480–487.
- Murphy L, Schwartz TA, Helmick CG, et al. Lifetime risk of symptomatic knee osteoarthritis. *Arthritis Rheum*. 2008;59:1207–1213.
- Hafez MA. Custom made cutting guides for TKA. In: Insall JN, Scott N, eds. *Surgery of the Knee*, 5th ed. London, UK: Churchill Livingstone; 2012:1240–1254.
- Hendel MD, Bryan JA, Barsoum WK, et al. Comparison of patient-specific instruments with standard surgical instruments in determining glenoid component position: a randomized prospective clinical trial. *J Bone Joint Surg Am*. 2012;94:2167–2175.
- Hafez MA. International Patent application no. PCT/EG/2013/000014 "Device and Method for Fitting an Artificial Knee Joint Using Universal Electronic Templates Which Can be Adapted to All Artificial Joints". 2014. Available at: <https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2014198279&redirectedID=true>. Accessed June 11, 2013.
- Vaishya R, Vijay V. Comment on Conteduca et al: patient-specific instruments in total knee arthroplasty. *Int Orthop*. 2014;38:1123–1124.
- Elnemr M, Hafez M, Abelnasr K, et al. Patient-specific template shortens the operative time in total knee arthroplasty in comparison to the conventional technique. *Curr Orthop Pract*. 2016;27:187–191.
- Wilson NA, Schneller ES, Montgomery K, et al. Hip and knee implants: current trends and policy considerations. *Health Aff*. 2008;27:1587–1598.
- McWilliams JM, Chernew ME, Zaslavsky AM, et al. Delivery system integration and health care spending and quality for medicare beneficiaries. *JAMA Intern Med*. 2014;173:1447–1456.
- Umscheid CA, Williams K, Brennan PJ. Hospital-based comparative effectiveness centers: translating research into practice to improve the quality, safety and value of patient care. *J Gen Intern Med*. 2010;25:1352–1355.