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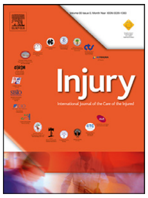

# 3D-printed patient specific instruments for corrective osteotomies of the lower extremity[☆]

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## ABSTRACT

3D-printing has become a promising adjunct in orthopedic surgery over the past years. A significant drop in costs and increased availability of the required hardware and software needed for using the technique, have resulted in a relatively fast adaptation of 3D-printing techniques for various indications. In this review, the role of 3D-printing for deformity corrections of the lower extremity is described.

## Introduction

3D-printing (also referred to as additive manufacturing) has become a promising technique in orthopedic surgery during the past decade. 3D-printing refers to the process of creating a physical 3D objects from a digital model by means of additive manufacturing. These physical objects can be anatomical models of injured or deformed bones that can be used to study a specific fracture pattern, pre-contour orthopedic implants, or educate co-workers and patients about specific conditions. Also, 3D-printing is used to produce patient specific instruments to guide a specific procedure, patient-specific implants such as anatomical plates for fracture fixation, acetabular cups for complex pelvic reconstructions, or scaffolds for the treatment of segmental bone defects. These techniques have proven to be especially helpful in reconstructive orthopedic surgery, but are also extremely instrumental in fracture care and surgical education.

Preoperative planning for correction osteotomies for congenital and posttraumatic deformities of the lower extremity has traditionally been performed using a conventional X-rays, a goniometer, pen and paper. However, difficulties with determining the exact spatial individual deformities, optimal osteotomy planes and the correct amount of reposition make the results of this procedure highly dependent on the experience and skills of the operating surgeon.

These difficulties have been the driving force behind the swift acceptation of 3D-printed patient-specific instruments in orthopedic surgery: Nowadays, correction osteotomies can be almost completely planned and performed using digital 3D modeling of the affected limb and 3D-printed patient specific implants. By using a mirrored CT scan of the contralateral (healthy) limb as a mold for the affected limb, the desired place and direction for the osteotomy as well as the desired correction can be planned to a submillimeter level such that the postoperative result exactly mirrors the contralateral side with regard to length, axis and rotation. In addition, the design and production of patient-specific instruments for sawing and drilling by 3D-printing offers the reassurance that the actual correction performed matches the preoperatively planned correction exactly. After image acquisition, and with some practice, segmentation of relevant structures from CT-scans, planning of the procedure and instrument design can be done by the surgeon using commercially available software packages (some of which are available online for free, see next paragraph). However, this can be a time-consuming process (several hours of planning per case), so commercial parties have been offering their services for long and provide clinicians with a complete package from CT to surgery; Diagnostic CT scans can be uploaded online after which a trained engineer plans the osteotomy location and plane, designs saw- and drilling guides during an online video-consultation and makes sure the patient specific instruments (PSIs) are printed and shipped to the surgeon in a matter of days (Fig. 1). Along with the matura-

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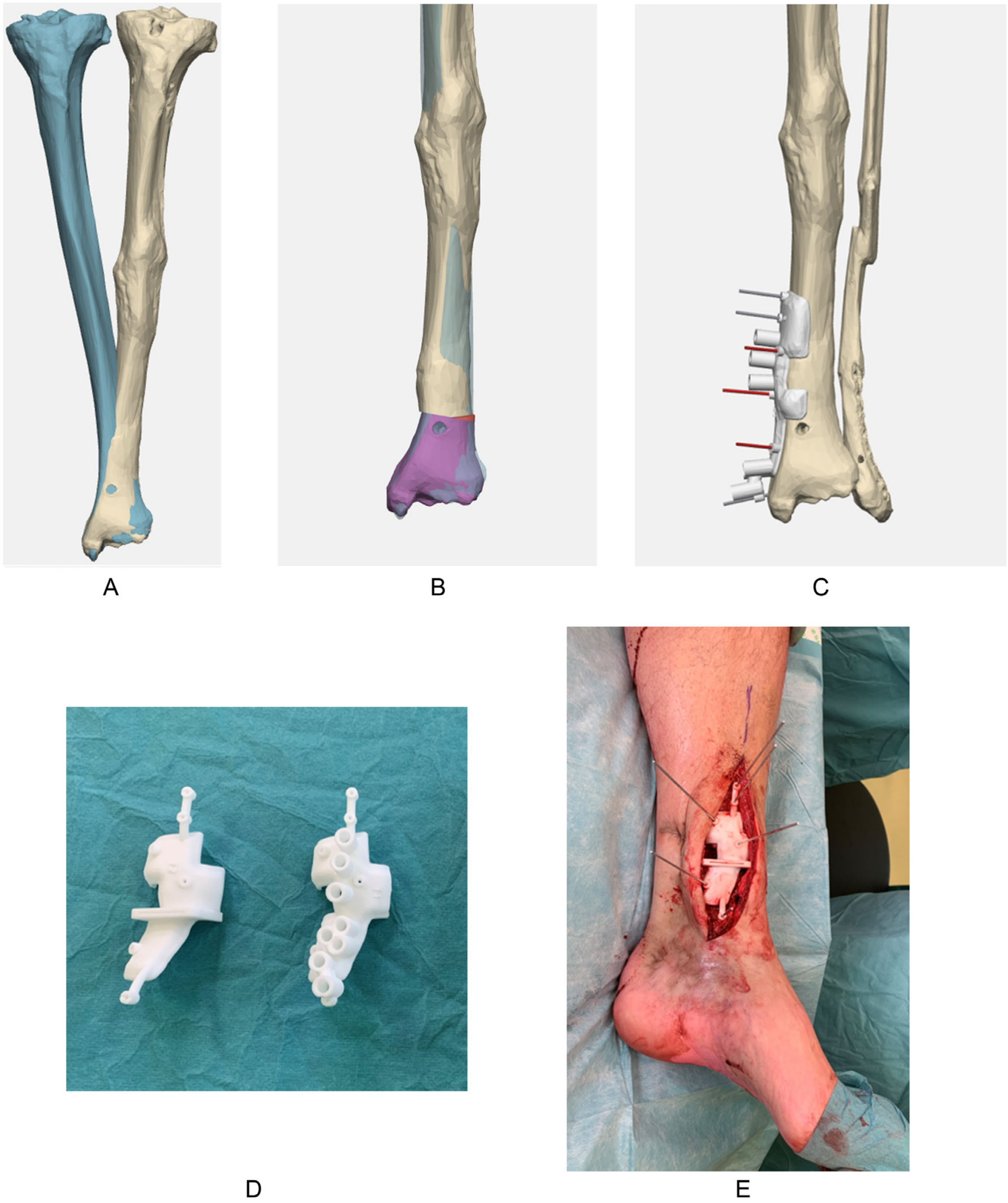

**Fig. 1.** Planning and execution of correction osteotomy for a malunited distal tibia fracture.
1A: CT-images of both legs are uploaded in an online environment and (A) the healthy, mirrored leg (blue) is showed as an overlay on the affected leg (white).
1B: After planning of the osteotomy there is a near perfect match between both legs.
1C: PSIs for drilling and sawing are designed by an engineer.
1D: 3D-printed PSIs.
1E: PSI during surgery. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

tion of these techniques, the body of literature supporting the use of 3D-printing in orthopedic surgery as a whole has been steadily increasing over recent years. Indeed, a 2016 systematic review by Tack et al. found that 73% of all papers on the use of 3D-printed PSIs reported improved patient outcomes. However, grossly two thirds of studies included in this review described PSIs for (knee) arthroplasty and craniofaciomaxillo-surgery and very few studies described the use of 3D-printed PSIs for corrective osteotomies of the lower extremities.

In this review, we provide an overview of state of the art techniques available for 3D printing and offer a comprehensive review of the application 3D printing for the treatment of deformities of the lower extremity.

## Technical details

The process that allows surgeons to eventually have 3D printed anatomical models, patient-specific instruments or implants available to use in the OR has five fundamental steps (Fig. 2).

1. Image acquisition
2. Image segmentation and 3D reconstruction of a virtual anatomical model

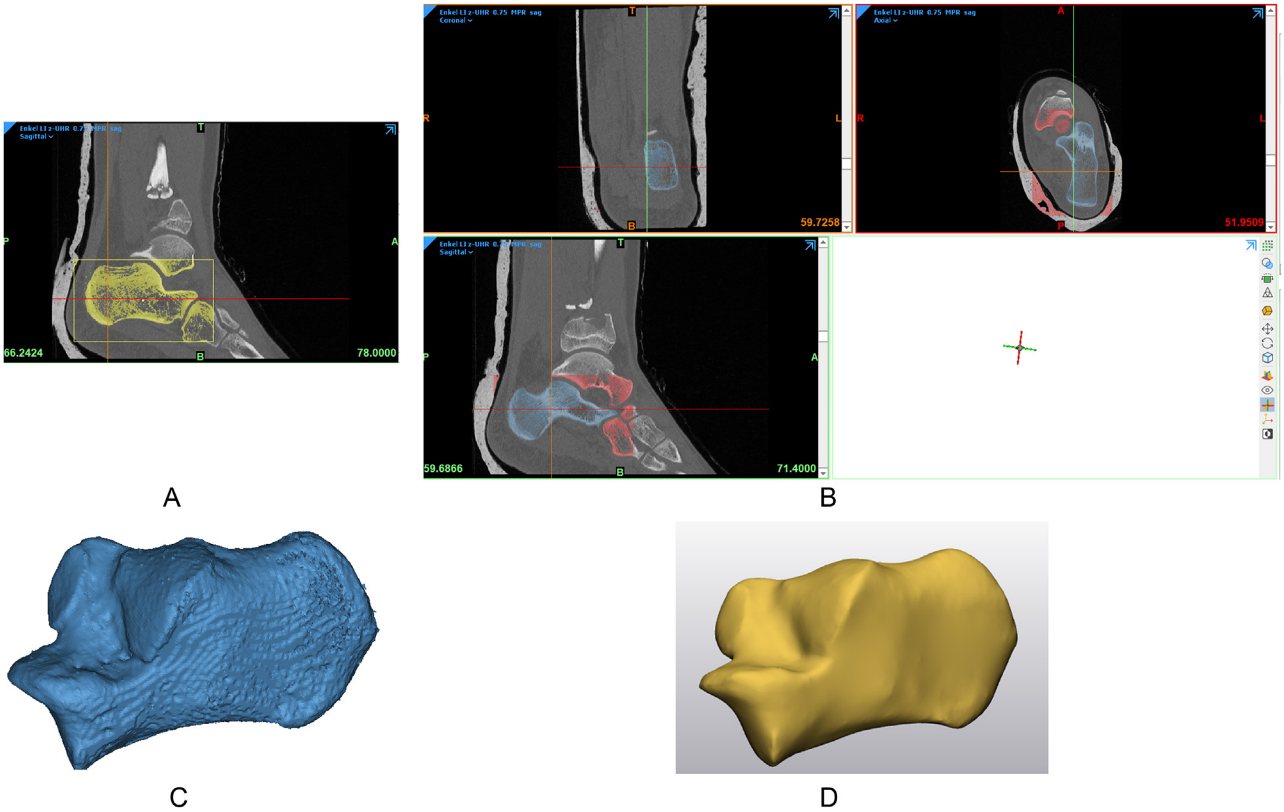

**Fig. 2.** Process of image segmentation.
2A: Region of interest and threshold for Hounsfield Units are selected.
2B: After removal of irrelevant structures (talus, cast).
2C: Reconstruction of virtual model.
2D: After cleaning up the image, wrapping for smoother surface and conversion to .stl file format for 3D-printing.

3. Procedure planning based on the 3D virtual model and design of patient specific instruments or implants
4. Conversion of virtual anatomical models or PSI into .stl files
5. 3D printing of the physical model

First, high quality diagnostic images of the affected area have to be obtained. In case of deformity correction, both the affected and healthy limb are scanned to serve as an anatomical mold. In orthopedic surgery, the main method of acquiring images that can later be used to 3D-print relevant structures of PSIs is computed tomography (CT). After image acquisition, relevant bony structures are subsequently isolated from DICOM files and converted into a virtual 3D model through a process of image segmentation. Most hospital PACS systems nowadays offer functionalities for automated image segmentation and reconstruction of virtual 3D models based on Hounsfield Units (HU), although other image processing software packages may offer better image segmentation capabilities; segmentation of posttraumatic deformities can be especially challenging and may need more sophisticated segmentation methods, as offered by software packages such as OsiriX (OsiriX, Tustin, CA, USA), materialize Mimics (materialize, Leuven, Belgium) and 3DSlicer$^{TM}$ (open-source, www.slicer.org), the latter of which can be downloaded for free.

After segmentation of relevant structures and digital reconstruction of a virtual 3D-model, software packages like materialize 3-matic (materialize, Leuven, Belgium), Windows 3D Builder (Microsoft, Redmond, WA, USA), Rhino$^{TM}$ (Robert McNeel &Associates, Seattle, WA, USA), ThinkerCAD$^{TM}$ (Autodesk, San Rafael, CA, USA), or Meshmixer$^{TM}$ (Autodesk, SanRafael, CA) can be utilized to plan a specific surgical procedure, determine osteotomy location or planes or simulate resections. Moreover, it is then possible to create patient specific instruments such as osteotomy saw guides, to make sure the planned procedure can be performed with high accuracy. Also, customized implants can be digitally designed at this point.

When the operative plan is ready, files containing virtual anatomical models, patient-specific instruments and customized implants are converted into .stl file-format and can then be printed by a suitable 3D printer. STL stands for stereolithography and an .stl file consists of a collection of interconnected triangles that describe the surface geometry of a given object. The .stl file is subsequently opened in the printer using a slicer software, such as Slic3r$^{TM}$ (open-source, www.slicer.org), or Cura$^{TM}$ (Ultimaker, Utrecht, Netherlands), which allows to select different options, like resolution and infill [1]. The object, i.e. the physical model, is then built of sub-millimetric thickness layers of a substrate material, such as liquid base (i.e., stereolithography, SLA), solid base (i.e., FDM – fused deposition modeling, or LOM – laminated object manufacturing), or powder base (EBM – electron beam melting, 3DP – inkjet head 3D printing, or SLS/SLM – selective laser sintering/melting) [2]. The most utilized process for metal objects are EBM and SLM, while for resin 3D-printed models FDM, SLS, an 3DP are more suitable. The latter is less accurate than SLS, but it is the most common used as it is faster and less expensive [1,3]. The final step consists of physical post processing of the model, including the removal of support structures for the printing process and sterilization of the model.

## Different applications of 3D-printing in orthopedic surgery

The availability and increasing user friendliness of the aforementioned software packages, decreasing costs of commercially

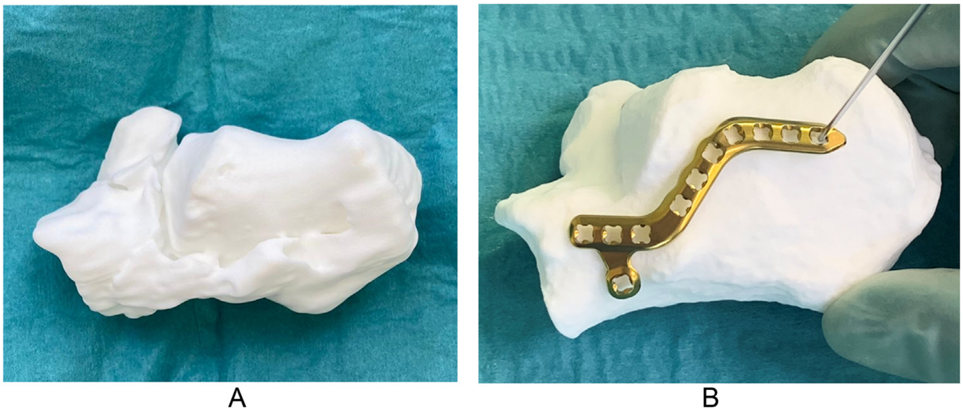

**Fig. 3.** An example of a 3D-printed anatomical model of a fractured calcaneus (3A) and a mirrored healthy calcaneus used for fitting of a minimally invasive plate (3B).

available 3D-printers, increasing prominence of commercial partners offering their 3D-printing services combined with the apparent advantages in education and surgical care have led to the adaptation of this technique over the past years on a large scale. Many orthopedic surgeons have experimented with 3D-printed anatomical models or PSIs and a substantial number of hospitals and orthopedic departments across the globe have invested in their own 3D-printing capacities. As such, computer assisted surgery and 3D printing have been utilized in orthopedic surgery in many different ways. First, patient specific anatomic physical models can be generated from patient's CT images using 3D technology and allow surgeons a tactile and direct visualization of relevant anatomy. 3D printed models are an important tool to assist with complex surgical cases prior to the actual surgery, for instance to precontour implants or to plan or practice osteotomies (Fig. 3). Another important application of 3D printed models is in education. Anatomical models allow for preoperative discussion among different specialists, but also facilitate communication with other caregivers and patients by facilitating comprehension of musculoskeletal pathology. This could increase patients and their family satisfaction due to better understanding their conditions on real models [4]. Certain potential benefits of 3D-printed models concern their application in surgical orthopedics training, improving patients' safety. Solid models give the opportunity to senior surgeons to easily convey their surgical experience to residents. In addition, complex or rare cases reproduced in 3D-printed models can provide residents or junior surgeons unique opportunities for authentic simulation-based surgical training [5].

Second, customized implants created using 3D-printing technology are widely used nowadays. Examples include plates for fracture fixation, acetabular molds for revision of complex acetabular revision surgeries or scaffolds for the treatment of large segmental bone defects. These patient specific implants are characterized by a perfect match for the unique patients' anatomy and are indicated when anatomical conformation does not allow the use of standard implants and better surgical outcomes are expected due to better fitting between implants and patients' anatomical needs [4,5]. Another interesting application of 3D printing is the design and production of upper limb prosthesis based on the contralateral side for amputees. This may be especially helpful in low-resource environments [6].

At last and perhaps currently the most frequently used, patient-specific instruments (PSIs) are customized tools created on 3D-models of bony anatomy which allow to execute surgical plans including guiding a saw and/or a drill in a specific planned direction. The theoretical advantage of PSIs results from an improved surgical accuracy and efficiency by using customized tools which are developed to execute a digitally planned procedure and serve to guide surgical instruments. PSIs are used in different procedures, such as guiding prosthetic implant placement [7–9], improving bone resection accuracy for oncological clearance [10], inserting pedicle screws in spinal surgery [11] and for performing difficult osteotomy in deformity correction of fracture malunion [12–14]. For the latter, it is assumed that the mirrored contralateral side is identical to the affected side.

## 3D-printing of patient specific instruments for deformity correction

As stated above, PSIs can be especially helpful to guide correction osteotomies. While far from new (commercial parties have been offering CT to surgery service for over two decades), evidence supporting the use of PSIs is certainly not abundant. One of the few randomized controlled trials on the subject investigated the use of 3D-procedure planning and 3D-printed PSIs for corrective osteotomies of extra-articular distal radius malunion versus conventional 2D-planning without the use of PSIs. In the intervention arm, there was significantly less residual deformity after correction without an increase in complications [15]. However, patient-reported outcomes (PROMs) did not differ between groups. A potential explanation for the lack of any significant difference in PROMS, is that the wrist is a relatively forging joint when it comes to minor deformities. This may be different for deformity corrections of the lower limb.

## 3D-printing and correction osteotomy of the femur

3D-printing of anatomical models and patient-specific instruments has been used to perform corrective osteotomies of the femur for varying indications. Oraa et al. described successful preoperative planning of a derotational osteotomy of the femur in six patients [16]. All patients had developed a malunion of the femur after previous treatment for a unilateral femoral shaft fracture. After scanning of both legs, a correction osteotomy was planned using the unaffected mirrored side as a template and patient-specific instruments were developed. Postoperative measurements showed a normalized anteversion angle of the femur (average −10.3°). In addition, several case reports have described the successful application of computer assisted planning and 3D-printed PSI's in (proximal) femur correction osteotomies for varying indications, including corrective osteotomies for hip-dysplasia 12 and two in children [17,18] and correction of deformities in a patient with Blount disease [19].

## 3D-printing for correction osteotomies of the tibia

3D-printed patient specific implants for tibia osteotomies have predominantly been described for proximal opening wedge osteotomies for the treatment of knee osteoarthritis [20]. A comparative study from 2020 showed that the use of 3D-printed patient specific instruments for medial opening wedge high tibia osteotomy resulted in more accurate and faster surgical procedures with faster patient recovery [21]. Yang et al. described the use of 3D printed anatomical models to plan intra-articular correction osteotomies for posttraumatic deformities of the tibiaplateau [22]. Wang et al. went a little further and described the use of tailor-made 3D-printed PSIs for the treatment of complex intra-articular proximal tibia malunions. Surgeon satisfaction with the technique was high and radiographic assessment showed a significant decrease in articular step-off. At last, in a study by Corona et al., 3D-printed anatomical models were used to plan surgery for malunions of the tibia using circular frames. Compared with procedures in which no 3D printed models were used, surgery time was 48% shorter and significantly fewer modifications to the preassembled frame were needed during surgery.

## Ankle and foot

There are very few reports on the use of 3D printed PSIs for corrections in the ankle and foot. Duan et al. used 3D printed PSIs for arthroscopic ankle arthrodesis in 14 patients. Surgery time was shorter than in conventional artroscopic arthrodesis without PSIs. Time to fusion and complication rates were similar [23]. Kadakia et al. used 3D printed PSI and navicular prosthesis for the treatment of a ballistic midfoot injury with significant bone loss [24].

As can be seen above, scientific backup for the use of 3D-printed PSIs for deformity correction is somewhat scattered and certainly not as robust as desirable. This is problematic for several reasons. First, the use of 3D-printed PSIs is associated with additional costs per patient. At this moment, commercial parties offering CT to surgery services charge somewhere in between €1000 and €E3000 per case. If the whole process is done by surgeons or technicians employed by the hospital themselves, costs of software licenses, buying and maintaining a 3D-printer and materials and time invested in preparing the models need to be considered. Also, 3D-files of the intended implants (e.g. plates) need to be provided by the manufacturer to plan plate and screw position and direction, which can be quite difficult in our experience. And while the hypothetical shortening of operative times as well as the increased quality of the operation may offer a later return of investments, there is only very little data to support this notice for deformity corrections of the lower limb, thus hampering the opportunities to charge additional costs to patients or insurance companies. Interestingly, a comprehensive study by Ballard et al. elegantly showed that the use of 3D printed PSIs for total knee arthroplasty resulted in an estimated annual gain of 8–32 h of OR time, corresponding to approximately $1500 per case (approximately €1350) saved from reduced time. Based on this, the authors calculated that in order to break even and see a return on investments, 3D-printed PSIs should be used in 63 TKA cases per year on average [25]. This study can be easily repeated for deformity corrections of the lower extremity, if sufficient comparative data is published in the upcoming years.

## Disadvantages of 3D-printed PSIs for deformity correction

While computer assisted procedure planning and subsequent use of tailor-made 3D-printed PSIs holds great promise, there are some disadvantages of the technique that should be taken into account. First, as opposed to other means of navigation (such as optical navigation based techniques), there is no direct feedback on the accuracy of the procedure once started. Correct placement of the PSI is therefore paramount to achieve the result as planned in the preoperative phase, but can be impacted by soft tissue or lack of distinctive bony landmarks (especially in diaphyseal areas). Moreover, flexibility of K-wires often used to position PSI's or flexibility of the material PSI's are printed from can result in undercorrection of a deformity as soft-tissues may deliver significant counter force. Also, PSIs should be designed in such a way that they require minimal soft-tissue and periostal stripping and removal, as this may impact on osteotomy healing. At last, extended radiation exposure due to CT-scanning of the contralateral limb, time requirements for planning and production and finalization of PSIs as well as regulatory burdens that come with the production and post-processing (sterilization) of implants and instruments should be considered.

## Conclusion

In conclusion, 3D-printing has proven to be a useful adjunct in many areas of orthopedic surgery, including deformity corrections. A variety of software packages for image segmentation, procedure planning, and PSI design as well as 3D-printers are commercially available and surgeons can learn how to operate these systems their selves or can delegate the whole process from CT to surgery to a myriad of commercial partners, making this technique available for many. However, substantial evidence for the use of PSIs for deformity correction of the lower limb is lacking. Therefore, to justify the additional costs associated with 3D-printing of PSIs, future comparative studies to investigate the additional value of this technique compared to conventional deformity corrections should focus on quality of care, safety, but also cost-effectiveness.

## Declaration of Competing Interest

This is to confirm that none of the authors of the review: "3D-printed Patient Specific Instruments for Corrective Osteotomies of the Lower Extremity" have any conflicts of interest to report.

## Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.injury.2022.08.069.

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