



Patient-specific instrumentation for total shoulder arthroplasty

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- Shoulder arthroplasty is a demanding procedure with a known complication rate. Most complications are associated with the glenoid component, a fact that has stimulated investigation into that specific component of the implant. Avoiding glenoid component malposition is very important and is a key reason for recent developments in pre-operative planning and instrumentation to minimise risk.
- Patient-specific instrumentation (PSI) was developed as an alternative to navigation systems, originally for total knee arthroplasty, and is a valid option for shoulder replacements today. It offers increased accuracy in the placement of the glenoid component, which improves the likelihood of an optimal outcome.
- A description of the method of pre-operative planning and surgical technique is presented, based on the author's experience and a review of the current literature.

Keywords: patient-specific instrumentation; PSI; shoulder; arthroplasty; arthritis; glenoid; prosthesis

Cite this article: Gomes N. Patient-specific instrumentation for total shoulder arthroplasty. *EFORT Open Rev* 2016;1:177-182. DOI: 10.1302/2058-5241.1.000033.

Introduction

Accurate glenoid component placement is of major importance in shoulder arthroplasty. Improperly-placed implants are at risk of dislocation, increased component wear and loosening, and the need for revision surgery.¹⁻³

Avoiding glenoid component malposition in terms of version and inclination is therefore an important technical goal, which may be very demanding due to a variety of issues related to patient anatomy and surgical technique. Altered anatomy in revision cases, joint contractures and complex patterns of glenoid bone loss with unreliable landmarks are commonly encountered in this patient population. In such cases, directing the glenoid baseplate along an appropriate axis with sufficient bone stock for fixation may be a challenging intra-operative task.³ Surgical planning for these patients can be improved using

three-dimensional (3D) reconstructions of CT scans, but recreating that same plan at surgery can be difficult.^{4,5}

Computer navigation has been employed for this purpose, with promising results.⁶⁻⁸ However, computer-assisted glenoid implantation techniques use an intra-operative setup using a tracking system,⁶⁻⁹ with some disadvantages: instrumentation is cumbersome to use in the shoulder; pins used for array fixation may cause iatrogenic lesions such as fracture or neurovascular injury; registration of anatomical landmarks may be inaccurate; and the need for resetting may result in an increase in operative time of more than 20%.^{5,7} Finally, tracking devices may loosen, giving unreliable information.⁶

Patient-specific instrumentation has the potential to provide a similar level of accuracy as computer-assisted navigation, but without such problems or additional surgical steps. This type of pre-operative planning has grown in popularity across a wide range of orthopaedic subspecialties including total hip and knee arthroplasty, pelvic and acetabular procedures and spinal deformities, with varying degrees of success.¹ It is the most recent development in this field, and its effectiveness in both the version and inclination planes of glenoid component placement has been demonstrated for both total anatomical and reverse shoulder arthroplasties.^{1,5,10,11}

Method

Patients undergo a pre-operative thin-cut CT scan of the entire scapula and adjacent humerus following a predefined protocol. Original two-dimensional (2D) images are uploaded to a 3D image processing software system and reformatted into accurate 3D models of the scapula, in order to avoid errors in measuring actual version or inclination — the plane of image acquisition (gantry angle) can deviate from a perpendicular angle to the plane of the scapula.^{10,12} This plane of the scapula is defined by three landmark anatomical points: the inferior scapular angle point, the glenoid centre point and the trigonum spinae point (intersection of scapular spine and medial border). A neutral inclination axis, or glenoid centre line,¹⁰ is defined between the last two (Fig. 1). The version is therefore measured with respect to the scapular plane, and inclination with respect to the neutral axis, as the angle between a line perpendicular to it and a line from the superior to inferior rim of the glenoid.⁵

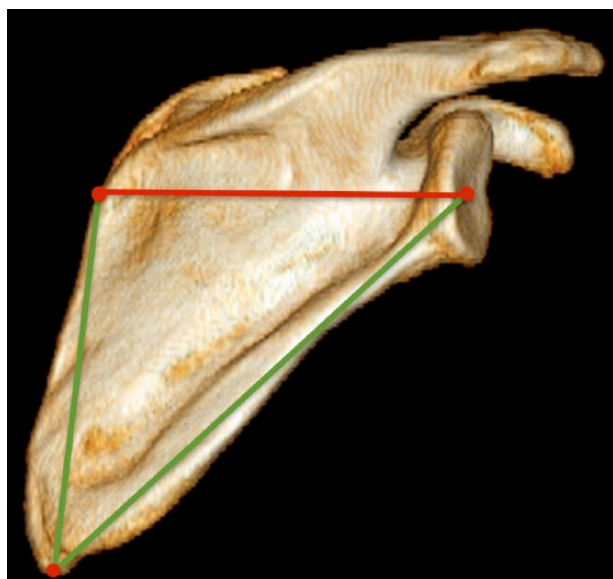


Fig. 1 Three anatomical points (red dots) used as landmarks for the definition of the scapular plane and the neutral inclination axis (red line): the inferior scapular angle point, the glenoid centre point and the trigonum spinae point.

The pre-operative planning is performed by the surgeon using adequate software, in a process that may vary according to each provider (Fig. 2). Virtual surgical planning requires the definition of the axis for the glenoid baseplate component, by creating patient-specific surgical guides. The guide is designed to fit onto the surface and border of the glenoid in each specific case, requiring minimal additional exposure, and is manufactured following a 3D stereolithography model. This guide, constructed from a sterilisable material (usually polyamide resin) has one or two drill cylinders positioned to orientate the drilling of the central glenoid guide pin. In addition to this glenoid guide, a patient-specific glenoid vault replica is also created to aid the surgeon in having the best perception of the placement of the guide on the glenoid during surgery (Fig. 3).

The technique for exposure and the use of instruments for bone preparation over a guidewire is identical whether or not the patient-specific instrumentation is used. The only additional requirements are care not to resect bony prominences such as osteophytes that were contemplated in the development of the guide and are necessary for the proper seating of the guide, and a slightly more extensive exposure of the anterosuperior aspect of the glenoid and base of the coracoid. This fact, however, may make the use of the deltopectoral approach more favourable as it may facilitate glenoid exposure, which is in fact the only restriction the surgeon may find in using a superior transdeltoid approach. The guide is then fitted to a stable position on the native glenoid and the central Kirschner wire (K-wire) is drilled into the glenoid until the far cortex is perceived (Fig. 4). This K-wire then guides further cannulated glenoid reaming and subsequent steps for both total and reverse shoulder

arthroplasties according to standard guidelines of the manufacturers (Fig. 5).

Reusable patient-specific instrumentation

In addition to single-use patient-specific instrumentation (PSI), it should be noted that reusable and adjustable PSIs are also available from some manufacturers. In the longer term, this technology may prove to be of lower cost than single-use PSIs and should result in a reduction of the time from planning to use of the instrument.¹

Results

No long-term clinical studies comparing patient-specific to standard instrumentations have been published to date, and the few reports on this subject that have been published are mostly laboratory studies on cadaver specimens, evaluating the accuracy of the baseplate positioning. The purpose of those studies was to examine the effectiveness of patient-specific planning and a patient-specific drill guide for glenoid component placement in shoulder arthroplasty. The conclusions drawn are similar in all. In 2011, Suero et al⁶ evaluated the safety and accuracy of a custom glenoid jig created using pre-operative CT imaging, with 3D modeling for glenoid component implantation. Comparison between the pre-operative plan and the result on post-operative CT scans of seven patients showed that a CT-based custom alignment can reliably guide the placement of the glenoid component during conventional and reverse shoulder arthroplasty, without technical difficulties or complications. In their Level I randomised prospective clinical trial, Hendel et al¹⁰ concluded that there was a significant improvement in the accuracy of glenoid component placement with the use of patient-specific guides in patients with bone deformity and glenoid retroversion in excess of 16°, and no difference in those with glenoid retroversion below 7°. Levy et al¹⁵ later concluded that the use of patient-specific guides in 14 reverse arthroplasties was highly accurate in reproducing a virtual 3D pre-operative plan, delivering the accuracy observed using computerised navigation without any additional surgical steps or technical difficulties. Likewise, Walch et al¹³ demonstrated in an *in vitro* study that using 3D planning software and custom guides is a reliable and precise option in total shoulder arthroplasty. The most recent papers from 2015 further support those conclusions. In 36 prostheses, Heylen et al¹⁴ found that patient-specific guidance reduced variability in glenoid component inclination, as well as the risk of extreme inclination errors for total and reverse shoulder arthroplasty when compared with standard pre-operative planning and instrumentation. In a multi-surgeon study in 70 arthritic cadaver specimens, Throckmorton et al¹⁵ found that these patient-specific targeting guides were significantly more accurate ($P = 0.01$) for the combined vectors of version and inclination, and also had fewer

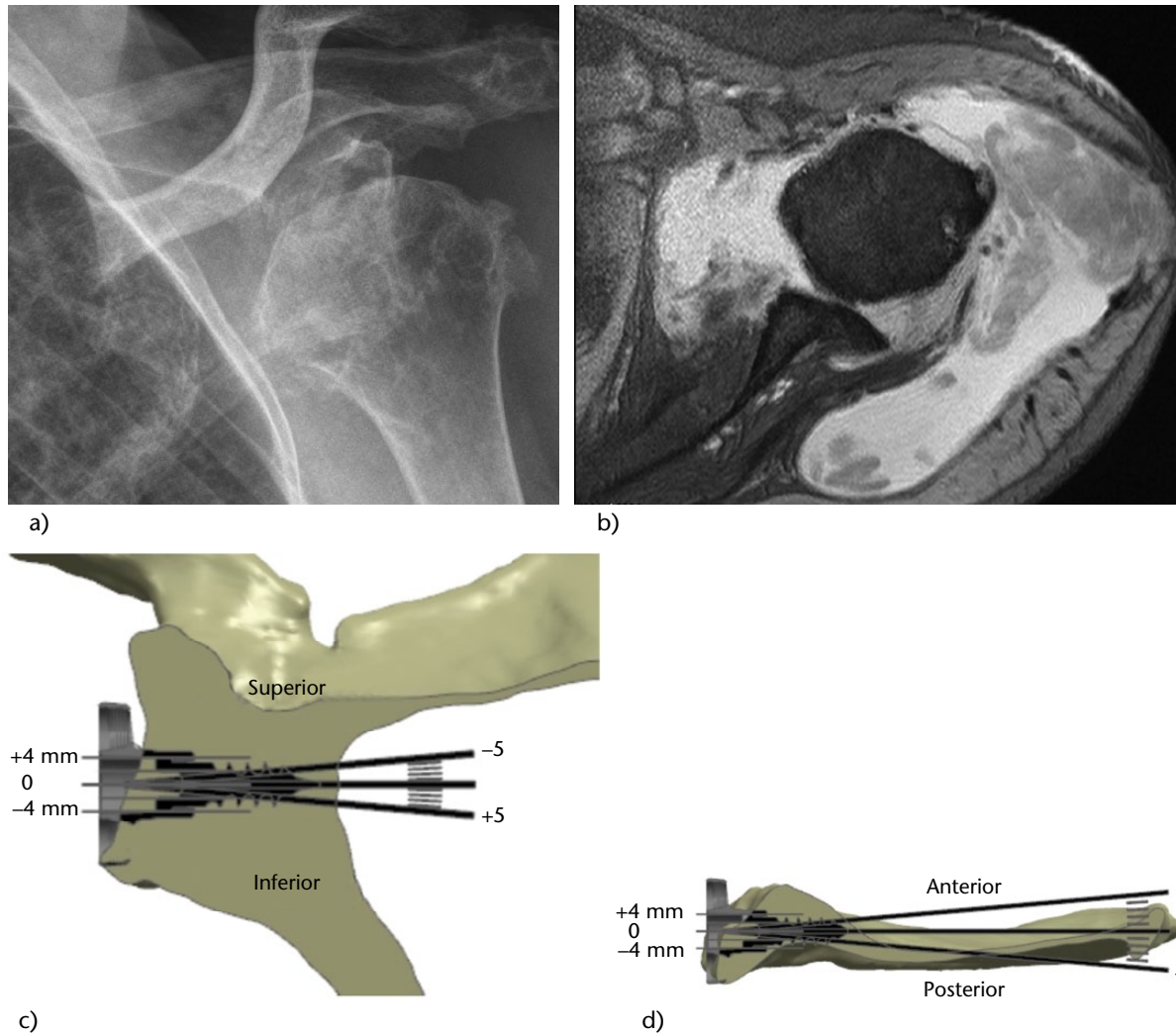


Fig. 2 a) Radiograph and b) MRI of a shoulder with extensive glenoid destruction for a reverse prosthesis; c) coronal, and d) transverse view of the pre-operative planning.

(From Zimmer-Biomet software; with permission).

instances of significant component malposition than traditional instrumentation. Iannotti et al,¹ in a comparison among 46 patients, reached similar conclusions.

3D surgical planning and patient-specific guidance reduce variability in glenoid component inclination, which should result in fewer malpositioned glenoids in both total and reverse shoulder arthroplasty. In severe glenoid deformations, namely when bone grafting is required, PSI will aid in estimating the best alignment, in terms of version and inclination, as well as the best fixation on stable bone stock, avoiding glenoid vault perforation (Figs 6 and 7).

However, there are a few important points that need consideration when using this technology. First, manufacturing the PSI guide is based on an accurate 3D model of the patient's scapula made from CT-scan cuts, which may be conditioned by cartilage loss, severe bone deformity or calcified labrum.¹⁴ Second, seating the guide properly on

the native glenoid demands good exposure of the antero-superior glenoid rim, with removal of any soft tissues that may impair it.^{10,14} Third, reaming to the adequate depth and orientation is still dependent on the surgeon's ability, as bending or pushing the guide pin with the reamer can mislead further reaming.¹⁴ Likewise, overtightening screws on soft bone or graft may asymmetrically overcompress the glenoid component against bone and change its final position, despite adequate reaming over a well-positioned central pin. Hendel¹⁰ reported four in 15 cases with over 10° of deviation in version or inclination from the pre-operative plan, despite the use of PSI, all performed by surgeons with little experience with this technology.

By way of addressing these limitations, some manufacturers have developed multiple PSI guides to help correct off-axis reaming, control the depth of reaming and assist in the orientation of the fixation screws.

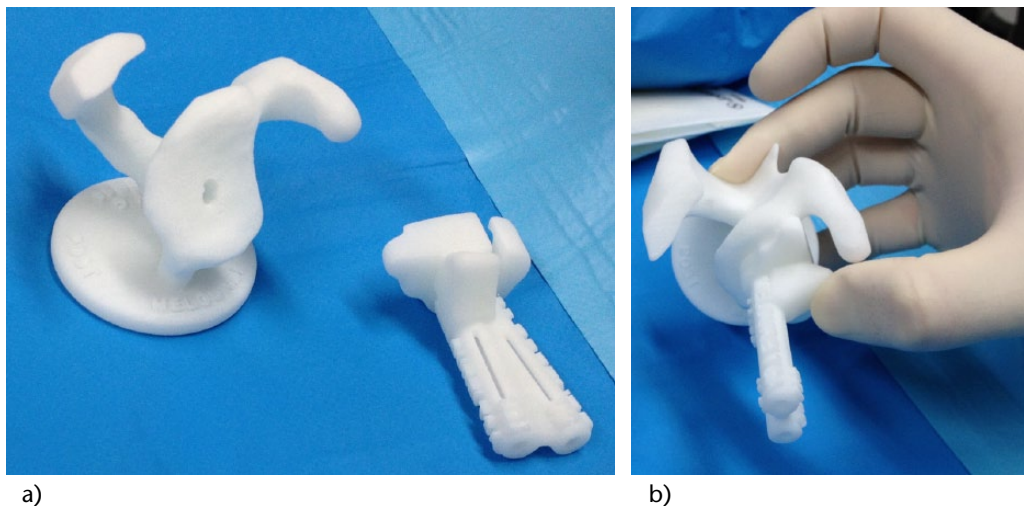


Fig. 3 a) Sterilised bone model and glenoid guide, with b) one inferior-tilted pin hole for a reverse procedure and a second superior one for an anatomical procedure.

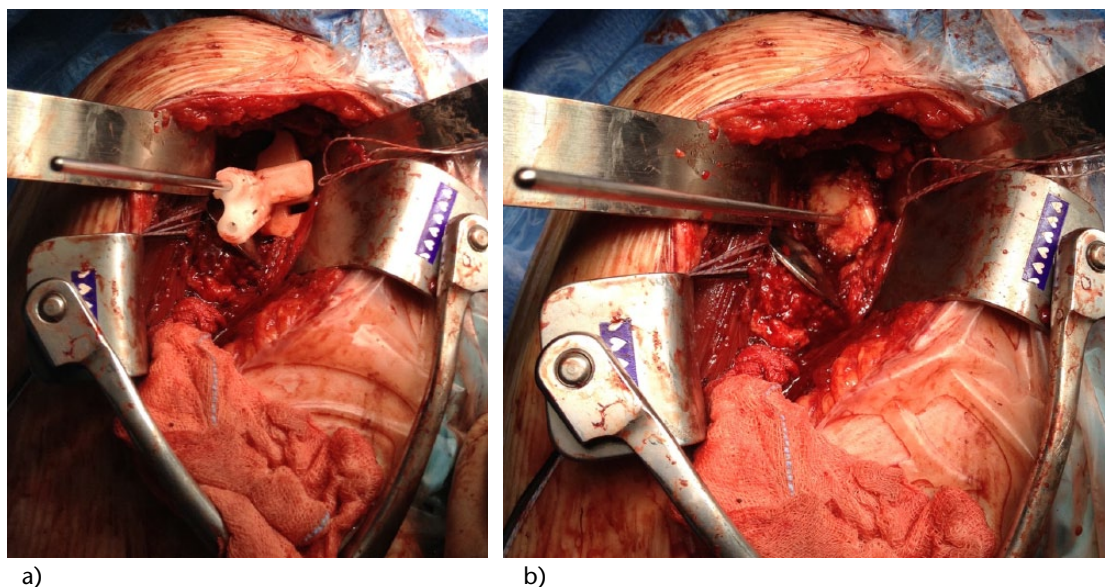


Fig. 4 a) Glenoid central pin placement for an anatomical prosthesis in a right shoulder; b) good exposure of the anterosuperior glenoid rim is required for the proper seating of the guide.

Discussion

Current evidence suggests that the use of PSI can assist in the avoidance of significant glenoid baseplate orientation errors, especially by less experienced surgeons,¹ resulting in fewer malpositioned glenoid components. Custom-made guides will play an important role in the placement of the central pin on glenoids with severe deformation, in cases where the best anatomical landmarks may have vanished and the use of bone grafting is anticipated. However, the surgeon's expertise and intuition remains invaluable, both in the pre-operative planning and in the final component implantation, especially concerning the reaming depth. However, PSI seems to offer a distinct advantage to lower-volume surgeons, by reducing the risk of guide-pin malposition, a step

that is very much dependent on the surgeon's expertise. Furthermore, pre-operative planning time is longer and may be dependent on external technical support, limiting its usage to elective surgeries and making it unsuitable for acute cases such as fractures.

PSI offers a greater chance of accurate alignment of the glenoid component, which seems to be an advantage. However, scapulae are not all the same, so when we try to align all glenoids in the same way, we may actually be changing the native alignment of some shoulders. Predicting the physiological glenoid version for a particular pathologic shoulder can be difficult, unless comparison with a normal contralateral shoulder (if present) is done. Scalise et al¹⁶ concluded that a 3D vault model, as described by

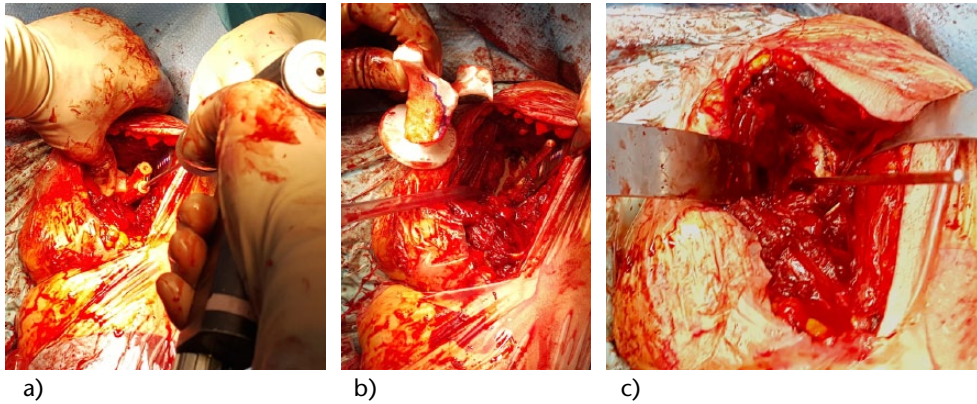


Fig. 5 a) Reverse prosthesis in a left shoulder and guided central pin drilling; b) native glenoid and patient-specific bone models are compared to check accurate placement of the guide on a very deformed scapula; c) central screw drilling completed over a guide pin that keeps its stability due to the integrity of the far cortex with no glenoid vault perforation, made possible with an accurate drilling direction.

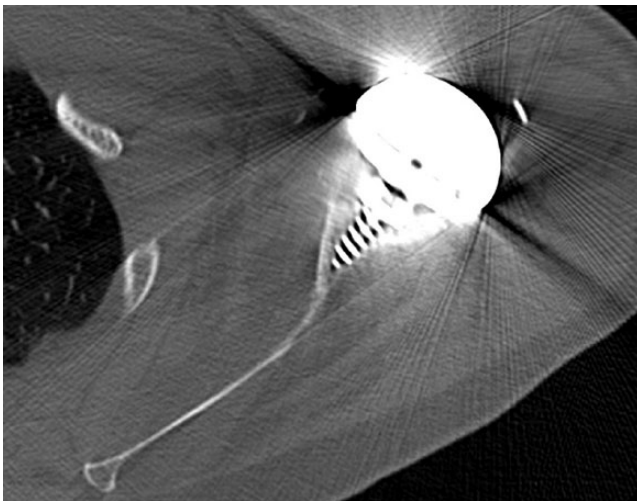


Fig. 6 Good baseplate alignment on the same patient as shown in Figs 2 and 5, with severe glenoid deformation requiring bone grafting.

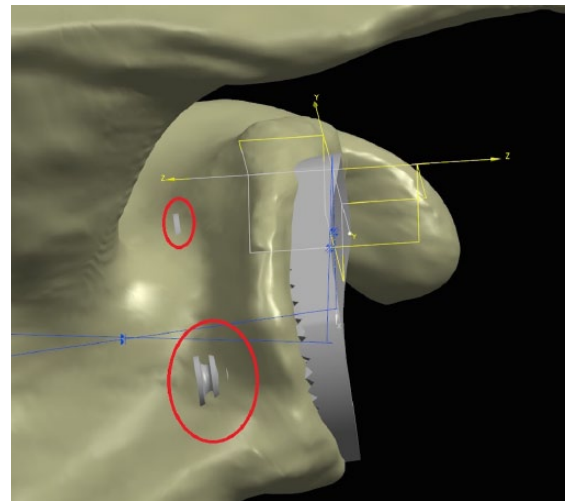


Fig. 7 Digitised image from pre-operative plan of an anatomical glenoid component, displaying peg penetration from the vault posteriorly.

(From Zimmer-Biomet software; with permission).

Codsi et al,¹⁷ could be used as a template to predict normal or baseline glenoid version for a particular patient. Youderian and Iannotti¹⁸ have concluded from surgical simulation in a 3D virtual environment that additional use of a patient-specific glenoid vault can predict pre-morbid version, inclination and amount of volumetric bone loss, which can help to generate the best possible scenario of bony structural support for the glenoid implant and can minimise the amount of bone loss, by reaming. These findings are invaluable for further development of systems which may help surgeons in estimating the right degree to which pathological version should be corrected. PSI will help in the placement of the glenoid component on the best bone stock with the desired alignment.

PSI has had wide acceptance among knee surgeons. Clear advantages in total knee arthroplasty are the fact

that it is very intuitive and effective in placing the components in the desired position, it is attractive to patients because they like a personalised patient-care approach and it increases efficiency in the operating room (OR) due to the reduced number of instruments required, which leads to reductions in OR setup time, turnover time and overall surgical time.¹⁹ While the former may also be observed in PSI for shoulder prosthesis, the latter will not necessarily be met.

The added cost of PSI manufacturing will need to be judged against the potential benefit in clinical outcomes.^{5,14} The cost-benefit analysis and long-term clinical studies remain lacking; these are necessary components in the evaluation of the potential benefits of this alternative.

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CONFLICT OF INTEREST

None declared.

FUNDING

NG has received financial support outside of the current work in the form of consultancy and lecture fees from Zimmer Biomet.

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