Patient-specific Instrumentation for Acetabular Cup Orientation: Accuracy Analysis in a Pre-clinical Study

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Abstract

Purpose
We investigated two major factors which affect the overall accuracy of patient specific instrumentation (PSI) for cup insertion in total hip arthroplasty; 1) the fitting of PSI on the bony surface, and 2) deviation of cup impaction under a linear visual reference.

Methods
Using 12 cadaveric hips, we inserted Kirschner wire (K-wire) through PSI on the acetabulum for the linear reference to transfer planned cup alignment. Deviation of the K-wire was then measured. With bone models, deviation when aligning an impactor to the K-wire was also measured.

Results
The mean deviation of the fitting was 1.9° for inclination and 2.0° for anteversion. The mean deviation when aligning the two lines was 1.2° for inclination and 1.4° for anteversion.

Discussion
This PSI can transfer the pre-operative plan to the operating room with acceptable accuracy.

Keywords: Patient specific instrumentation; Total hip arthroplasty; Cup insertion; Computer assisted orthopaedic surgery

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1. Introduction

Proper component alignment in total hip and knee arthroplasty (THA and TKA) is one of the most important key elements in obtaining long-term functional survival of implants in satisfied patients without wear of polyethylene or the implant itself in both arthroplasties (Sharkey et al 2002, Sugano et al 2007, De Haan et al 2008, Sikorski et al 2008, and Small et al 2013) and without postoperative dislocation in THA (Lewinnek et al 1978 and Sugano et al 2008). To achieve this, patient specific instrumentation (PSI) has been initially developed as the latest computer-aided technology (Radermacher et al 1998). PSI is designed to transfer the preoperative surgical plan intraoperatively by fitting on anatomical structures available in a normal surgical window. It aims for optimal alignment or positioning of surgical instrument(s) and implants. It is manufactured by three-dimensional (3D) printing.

In THA, PSI is used to indicate a pre-operatively planned cup orientation (Hananouchi et al 2009 and 2010, Sakai et al 2014 and Small et al 2014). In one system (Hananouchi et al 2009 and 2010, and Small et al 2014), surgeons put PSI on the acetabulum and insert a metallic pin (such as a Kirschner wire, or a Hoffman pin; in this manuscript, this term is unified as “K-wire”) through PSI. The K-wire is aligned parallel to the planned orientation and allows the surgeons to place the cup under alignment with the K-wire as a visual reference. Previously published papers have stated that PSI provides more reliable cup insertion compared with conventional techniques (Hananouchi et al 2010, and Small et al 2014). Another system has been established in a pre-clinical study (Sakai et al 2014). The shape of PSI is a partial circle frame which allows surgeons to control the alignment of the cup impactor, which means that the base part of PSI fitted on the acetabulum is docked to an optional part of the cup impactor. Since 2012, several companies have commercialized a PSI system for cup insertion (Biomet Orthopedic; available at: http://www.biomet.com/orthopedics/getFile.cfm?id=3029&rt=inline accessed Oct. 14th 2014 and Medacta; available at: https://www.medacta.com/ja/japan/news/news/single?newsid=4014&t=myhip-now-available accessed Oct. 10th 2014)

On the other hand, PSI for TKA, which is used to cut both distal femur and proximal tibia, has been already commercialized since 2008 by several companies using similar systems (Lombardi et al 2008, Krishnan et al 2012, Nam et al 2012, and Thienpont et al 2013). Some authors have recommend the use of PSI in TKA to achieve a neutral mechanical axis resulting in a reduction of outliers (Danilidis and Tibesku 2013 and Ng et al 2013). Other authors, however, have reported an absence of proven value because the coronal plane alignment with PSI after TKA is not better than that achieved with conventional techniques (Nunley et al 2012, Lustig et al 2013, and Victor et al 2014). Although the reason why PSI accuracies for TKA are not consistent has not been clear, in this context, some factors regarding the accuracy of PSI for cup insertion should be investigated before disseminating its use. On the basis of previous papers about PSI which reported some errors affecting overall accuracy (Hananouchi et al 2009 and Ruppin et al 2008), we believe that the most critical points are: 1) fitting of PSI on the bony surface, and 2) deviation of cup impaction under the alignment of K-wire.

The purpose of the study was to investigate, in a pre-clinical study, the accuracy of the above two major factors which affect the overall accuracy of PSI for cup insertion. Using cadaveric specimens,
we explored how accurate alignment for cup insertion was obtained inserting a K-wire as a 3D linear visual reference for the planned cup orientation. Then, using bone models, we also investigated the deviation of the cup impactor when aligning it to the K-wire.

2. Material and Methods

We examined the two important factors during cup insertion with PSI, which were; 1) whether PSI was placed accurately, and 2) whether alignment of the cup impaction was controlled accurately while observing the alignment of the K-wire as the 3D linear reference.

For the first research question, PSI for cup alignment was designed preoperatively on the computer using CT images of 12 hemi-pelvises of six cadaveric specimens. PSI was then manufactured with 3D printing. PSI was then fitted on the acetabulum of the cadaveric pelvis. The difference between the preoperative plan and the actual orientation was then measured. For the second research question, a laboratory setting was developed to simulate a clinical situation during cup impaction using an acetabular bone model. In the clinical setting, we measured the angle deviation of the cup impactor.

In the first analysis, six cadaveric specimens were collected from the anatomy department of the Faculty of Medicine, Lille University, France (Université de Lille, Faculté de Médecine, France). Preoperative CT images of the full pelvises were obtained with a 1.25–1.50 mm slice thickness and slice increment of 0.625–0.75 mm (Somatom “Definition” AS 64®, SIEMENS Healthcare AG, Henkestrasse 127, D-91052 Erlangen, Germany). Images were transferred to computer software (Mimics®, Materialise, Leuven, Belgium) for the creation of a 3D model (Figure 1).

Fig. 1. View of the patient’s anatomy. CT image data is segmented into a 3D model of the pelvis using Mimics® software.

The 3D model of the full pelvis was placed in a patient-specific coordinate system using another computer software program (3-matic ®, Materialise, Leuven, Belgium). The anterior pelvic plane (APP) was used as a reference (Lewinnek et al 1978). Each side of a pelvis was considered as a test setting for THA. A best-fit sphere was fitted onto the acetabulum. The center of the sphere was used as restored center of rotation (Figure 2).
A generic cup implant consisting of a hollow hemi-sphere with a given thickness and outer diameter was placed in the center of rotation. Inclination and anteversion of the cup were planned to be 40° and 15° respectively with radiographic definition (Murray 1993). This plan was then transferred to the laboratory by the means of PSI. The guide was designed to insert the K-wire on the acetabular rim of the patient. The K-wire was planned to be placed aligned parallel to the pre-operatively defined cup alignment. The zone for K-wire placement was approved by two independent experienced hip surgeons (TH and HD). This zone is usually denominated as the postero-superior or posterior region.

PSI was also designed in the computer software program 3-matic®. The guide was equipped with a break-off tag for identification purposes, a central cylinder and four arms providing stable and patient-specific positioning (Figure 3). Since the shape of the acetabular edge is not perfectly hemispherical (Vandenbussche et al 2007), the PSI can be designed to stabilize on the acetabular edge. At the end of the superior arm, two drill cylinders were provided to accommodate a K-wire with a pre-operatively planned orientation. The diameter of the K-wire is 2.0 or 3.2 mm. The PSI was produced in a medical production facility, using the 3D printing technique. Material for the PSI constituted of biocompatible polyamide. The bone model of the acetabulum of the patient was produced in the same material, which could be used by the surgeon as a reference intra-operatively.
Fig. 3. A view of PSI, designed using 3-matic® software.

During the experiment, cadavers were placed in a lateral decubitus position and stabilized to the table. A normal-sized incision was made along a postero-lateral approach in four cadavers, lateral approach in one cadaver, and anterolateral approach in remaining one cadaver. Then soft tissue was removed from the acetabular region, as in the conventional surgical procedure for THA. The joint was dislocated and the femoral head was removed using a saw blade. PSI was first fitted on the bone model of the patient’s anatomy, then subsequently fitted onto the acetabular rim (Figure 4). Using a power drill, a K-wire was inserted through one of the drill holes of the guide. Prior to placement, the K-wire was marked for maximal entry depth with a marker pen. After insertion of the K-wire, PSI was removed by a slide-off movement or a cut-through leaving the K-wire in place. Wounds were closed with extra care taken with the K-wire, and cadavers were taken for postoperative CT imaging. All experiments were carried out by the two hip surgeons (TH and HD).

Fig. 4. Intraoperative view of the guide fitted onto the acetabulum of the cadaveric specimen in question. The alignment metallic pin is placed in the drill cylinder of the guide and indicates the pre-operatively planned orientation for cup placement.
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Postoperative CT image data of each acetabulum with the placed K-wire were transferred to Mimics® and the 3D model was registered to the pre-operative one. The inclination and the anteversion of the placed K-wire was calculated and compared to the pre-operatively planned orientation. The absolute difference in degrees was calculated.

The secondary analysis was carried out to assess the error during cup impaction while observing the alignment K-wire as a linear reference. Although not directly linked with the performance of the guide, the ability to align two different lines with this visually linear reference affects the overall accuracy of the system. A printed cup impactor, a printed acetabular bone model, two k-wires with diameter of 2 mm were prepared for the second analysis. On a hollow cylindrical handle of the cup impactor, a hemispherical cup with diameter of 56 mm is attached by a screw-on mechanism (Figure 5).

![Fig. 5. Printed cup impactor consists of three parts; cup, a hollow cylindrical handle, and a holder. K-wire is fixed with the holder, and is inserted on the acetabulum through the cup by hammering the top of the holder.](image)

The cup was planned to receive an effect of “press-fitting” when performing 1mm under-reaming. Then, the first K-wire is placed on the printed acetabular bone as an alignment guide. The second K-wire is fixed by a holder, into the hollow cylindrical handle inserted on the acetabulum, by hammering the top of the cup impactor. The printed acetabular bone was derived from a commercialized plastic bone (Sawbones, Pacific Research Labs). The above reaming shape (1 mm under reaming to the cup size) was removed from the bone model in advance. The bone model was secured to the table with a ball-jointed table clamp (Figure 6). Ten test subjects were asked to place the K-wire using the cup impactor. The test was carried out in triplicate for each test subject. Afterwards, optical scans (GOM Atos II, GOM, Germany; accuracy level 0.02–0.05 mm) of specimens with impacted K-wires were registered to the bone model carrying the alignment of the first K-wire by using 3-matic® registration tool. The deviation angle between both K-wires was measured.
3. Results

The mean absolute deviation between planned and postoperative orientations of the alignment of the K-wire were $1.9^\circ$ (SD $2.0^\circ$) for inclination and $2.0^\circ$ (SD $2.0^\circ$) for anteversion. In one specimen, the K-wire lost its fixation therefore no data were recorded.

The second analysis showed the alignment validation test resulted in an average deviation of $1.2^\circ$ for inclination and $1.4^\circ$ for anteversion. The inter-user variability was $0.9^\circ$ and $0.8^\circ$ for anteversion and inclination, respectively. The intra-user variability was $1.6^\circ$ and $1.0^\circ$ for anteversion and inclination, respectively. Tests per test subject were conducted in a consecutive manner.

4. Discussion

We investigated the accuracy of the two main factors affecting overall accuracy in the cup insertion with PSI, i.e. accuracies of the errors of bony fitting and cup impaction.

The first analysis demonstrated the accuracy of the fitting of PSI on the acetabular edge. The results were acceptable (mean: $1.9^\circ$ for inclination, and mean: $2.0^\circ$ for anteversion) (Table 1). There exist two similar cadaveric studies related to this first analysis (Sakai T et al 2014, Hananouchi et al 2008). One reported results (mean $0.8^\circ$ for inclination, and $0.5^\circ$ for anteversion) (Hananouchi et al 2008) that were slightly better than our results, especially regarding the accuracy of the inclination. However, this study used dried bones, ignoring the effect of soft tissues around the acetabulum.
Another study prepared two designs for PSI for cup insertion (Sakai T et al 2014), which were the designs of an anterior rim contact type (almost whole rim contact) and a non-anterior rim contact type (partially posterior rim contact). While accuracy of the former was better than the accuracy level we achieved, the latter was worse (Table 1). From this we assume that the accuracy of PSI for cup insertion depends on the design of the PSI. In addition, the accuracy of our first analysis included an error of insertion of the K-wire after placing the PSI on the acetabular edge. We believe that it was not significant.

Table 1 Accuracy of bony fitting of patient specific instrument for cup insertion

<table>
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<tr>
<th></th>
<th>Inclination (°)</th>
<th>Anteversion (°)</th>
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<tbody>
<tr>
<td>Hananouchi et al</td>
<td>0.8 ± 0.8</td>
<td>0.5 ± 0.6</td>
</tr>
<tr>
<td>Sakai et al ( anterior rim contact)</td>
<td>1.0 ± 0.9</td>
<td>1.7 ± 1.1</td>
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<tr>
<td>(non-anterior rim contact)</td>
<td>3.4 ± 2.4</td>
<td>3.6 ± 2.8</td>
</tr>
<tr>
<td>Our study</td>
<td>1.9 ± 2.0</td>
<td>2.0 ± 2.0</td>
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Values are mean±standard deviation

A second analysis of our study considered the error of parallel impacting under linear visual alignment. This error was small, but not to be ignored. Although humans have some ability to control two lines in a parallel manner, perfect control might be impossible when considering the factor of impaction. The current study recruited only engineers for the second analysis (not surgeons) for practical reasons. However, we found two previous reports (DiGioia et al 1998 and Hananouchi et al 2009), which investigated an adverse effect of the press-fit technique during cup impaction. One report showed that the mean cup alignment deviation during cup impaction was 1.1° to 1.8° and the maximum value was 10° (Hananouchi et al 2009). Furthermore, another report showed the mean value was 3.7° to 5.1° and the maximum value was also 10° although the data was from an initial ten cases (DiGioia et al 1998). Therefore, this adverse effect of cup impaction on the overall accuracy of cup placement should be taken into consideration when reading papers about PSI for cup placement.

Currently, there are three clinical studies and one cadaveric study (Table 2) available describing overall accuracy of PSI for cup insertion. The overall accuracy in the first two reports, from one institution, demonstrated an average deviation of approximate three degrees. In the remaining one clinical report, the concept of PSI was comparable to ours because the K-wire was inserted through the PSI, which then was used as linear visual reference. However, the design of this PSI differed from our design since the native acetabular notch was used to stabilize the guide. Although the absolute value between the preoperative and postoperative angle was not described, the standard deviation in this study was quite large. Since osteophytes often arise around the acetabular notch (Varich et al 1993). One should be cautious about applying this part for stabilizing. In the cadaver study (Sakai et al 2014), the concept of PSI differed from the above studies. PSI in the study was designed as a round shape which is contacted on the acetabular rim. Then, an optional part of the cup impactor was docked to PSI. Thus, PSI in the study did not provide the linear visual reference as did our PSI. Unfortunately, the accuracy was the worst in the above four studies.
Table 2 Overall accuracy of patient specific instrument for cup insertion

<table>
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<tr>
<th>Study</th>
<th>Inclination (°)</th>
<th>Anteversion (°)</th>
</tr>
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<tbody>
<tr>
<td>Hananouchi et al</td>
<td>2.8 ± 2.1</td>
<td>3.7 ± 2.7</td>
</tr>
<tr>
<td>Hananouchi et al</td>
<td>3.2 ± 2.3</td>
<td>3.7 ± 2.7</td>
</tr>
<tr>
<td>Small et al</td>
<td>-2.0 ± 7.3*</td>
<td>-0.2 ± 6.9*</td>
</tr>
<tr>
<td>Sakai et al</td>
<td>(anterior rim contact)</td>
<td>3.4 ± 2.1</td>
</tr>
<tr>
<td></td>
<td>(non-anterior rim contact)</td>
<td>6.7 ± 4.2</td>
</tr>
</tbody>
</table>

Values are mean±standard deviation  
* This data is not absolute value (simple deviation)

Until now, the overall accuracy of PSI for TKA has not been described by matching between preoperative and postoperative images. However some papers have attempted to investigate this problem by performing postoperative analysis with long-standing radiographs (Ng et al 2012) or scout CT images in coronal plane (Nunley et al 2012), with plain radiographs in sagittal plane (Delport and Chandrashekar 2012, Victor et al 2014), with axial CT images for post-evaluation of axial rotation (Delport and Chandrashekar 2012, Victor et al 2014), and with Multi-planar views (coronal, sagittal, and axial) and digitally reconstructed plain radiographs (Hananouchi 2014). In the follow-up analysis of TKA, patients with a varus/valgus deviation in the coronal plane of 3° or more are branded as outliers (Bäthis et al 2004, Victor et al 2012). If this required value (3°) is applied to the investigation of cup insertion with PSI, all the above reports about PSI for cup insertion might not reach the required value. However, we believe that the mean overall accuracy of PSI of cup insertion within 3° to 4° (or 5°) is acceptable. This is because the conventional technique of cup placement cannot even reach a safe zone within 10° in approximate 20–80% of the cases in several previous reports (Sugano et al 2008, Bosker et al 2007, DiGioia et al 2002, Kalteis et al 2006, Bosker et al 2007, Parratte et al 2007, and Sugano et al 2008). Large angle deviations (e.g. over 10°) immediately affect the outcome for patients who have undergone THA, as they may result in postoperative dislocation due to mal-alignment (Lewinnek et al 1978, Sugano et al 2008). We believe that computer-aided technology is required for controlling the alignment of cup insertion. In the current study, each analysis provides acceptable accuracy (1° to 2°), with the combined value of the two accuracies being close to the best overall accuracy of all previous studies regarding PSI for cup insertion. Therefore, we believe the design of our PSI offers good control of cup insertion.

We note some limitations of our study. First, we used a small number of cadaver specimens, and this may have influenced our results. In addition, cadaver specimens usually show less degenerative changes in the acetabulum. This might affect segmentation from CT images being more accurate than of classical osteoarthritic hips. However, the PSI in the current study was basically designed to fit on the acetabular edge. Even if the acetabulum had degenerative changes, there are few cases in which all area of the acetabular edge had degenerative change. Then, if degeneratively changed area is not selected for the fitting area of PSI, this effect can be zero or small. As so far one author in the current study has confirmed that this PSI can be used to severe dysplasia cases with moderate high hip center (Crowe’s classification 2 or 3) (Crowe et al 1979) (Figure 7). Although the PSI provides only preoperatively planned alignment of the cup, the bone model of the patient's anatomy might be used for controlling height and/or position of the cup. Second is surgical approach. Although we
used three different surgical approaches and we consider these three surgical approaches can be used in this PSI, we did not perform any sufficient investigation of the surgical approach in terms of the accuracy of this PSI. According to one previous report about accuracy for cup insertion with PSI (Small et al 2014), the accuracies with one postero-lateral and one lateral approaches were comparable. Furthermore, there are some drawbacks to the clinical use of PSI. Radiation exposure due to the CT scans might be a concern. However, that might be justified by the benefits of the imaging information. If using CT image data, Pre-operative planning can be improved because we can know thickness and coverage of the acetabulum as well as femoral anteversion. As an alternative modality, magnetic resonance imaging might be substituted.

In conclusion, since the accuracy of the two major contributing factors (i.e. fitting on bony surfaces, and cup impaction) to the overall accuracy of PSI for cup insertion with linear visual reference of K-wire was within the acceptable range of 1 to 2 degrees, we state that the PSI we have designed assists in achieving the preoperatively planned orientation of the cup and as such leads to the reduction of outliers in cup orientation.
Conflict of interest

The two surgeons (TH and HD) of the authors have been financially compensated for their participation to the cadaveric test and that the two other authors (EG and JE) are employees of Materialise. One author (HD) is also a consulting surgeon for Materialise.

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