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Patient-specific instrumentation improves the accuracy of acetabular component placement in total hip arthroplasty

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Aims

Accurate placement of the acetabular component during total hip arthroplasty (THA) is an important factor in the success of the procedure. However, the reported accuracy varies greatly and is dependent upon whether free hand or navigated techniques are used. The aim of this study was to assess the accuracy of an instrument system that incorporates 3D printed, patient-specific guides designed to optimise the placement of the acetabular component.

Patients and Methods

A total of 100 consecutive patients were prospectively enrolled and the accuracy of placement of the acetabular component was measured using post-operative CT scans.

Results

The mean absolute deviation from the planned inclination and anteversion was 3.9° (0.0° to 13.6°) and 3.6° (0.0° to 12.9°), respectively. In 91% of cases the planned target of +/-10° was achieved for both inclination and anteversion.

Conclusion

Accurate placement of the acetabular component can be achieved using patient-specific guides and is superior to free hand techniques and comparable to navigated and robotic techniques.

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Accurate placement of the acetabular component during total hip arthroplasty (THA) is important to minimise edge loading and its consequences such as accelerated wear, and to reduce the incidence of instability.[1-5] Previous authors have provided a framework for the safe placement of acetabular components within a target range for both inclination and anteversion.[6,7] Recently the concept of a "one safe zone fits all" approach to the placement of the acetabular component has been challenged as there are patients who experience adverse events related to acetabular orientation in spite of the component being placed within the zone.[8-10] Given this discrepancy, some thought has been given to identifying a patient-specific safe zone for placement of the acetabular component.[11]

Whether aiming for a generic or patient-specific target, the challenge remains for surgeons to introduce the component in the desired position intra-operatively. Historically, values > 10° outside of the planned orientation for inclination and anteversion have been considered outliers. Traditional free hand techniques are inaccurate, with reported rates of successfully achieving target ranges for both inclination and anteversion as low as 20%, and at, or near, 50%, in two separate large studies.[1,7,12,13] There is evidence of improved accuracy and fewer outliers when computer navigation or robotic assisted surgery are used, but with the introduction of added time and cost.[14-16] The development of 3D printing technology and image based patient-specific guides in total joint arthroplasty offers the surgeon improved accuracy without the burden of time associated with navigated or robotic surgery. Our aim was to assess the accuracy of an instrument system that incorporates 3D printed patient-specific guides designed to optimise the placement of the acetabular component during THA.

Patients and Methods

Between June and September 2015, a total of 100 consecutive patients under the care of three surgeons (AS, JB, SM) were enrolled in this prospective study. Patients aged > 50 years with a diagnosis of osteoarthritis suitable for a

Table I. Demographic data

Feature	
Age	65 yrs (50 to 82)
Gender	Male 55/100 female 45/100
Side	Right 55/100 left 45/100
Surgeon	AJS 29/100 SM 38/100 JB 33/100

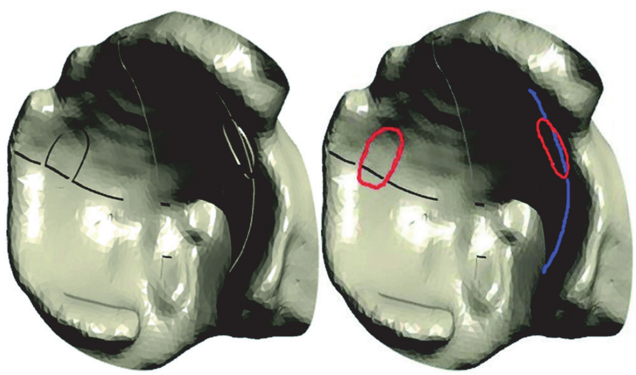

Fig. 1a

Fig. 1b

a) 3D acetabular models with etched outlines for location of the footprint of the patient-specific instrumentation (PSI) guide (red outline) and the planned position of the rim of the acetabular component after reaming (blue line). b) 3D acetabular model with PSI guide in place.

Fig. 2

Illustration of the patient-specific guide *in situ*, connected to the handle-mounted laser beam defining the target acetabular orientation. The pelvic reference laser has been mounted in the ischium. Inset – demonstration of patient-specific guide and pelvic reference laser projections focused on a single point on the wall of the operating theatre.

cementless THA, with no prior history of reconstructive surgery of the hip which was to be treated, were invited to participate. The demographic data are presented in Table I. Each patient underwent low dose computed tomography (CT) as part of the OPS Dynamic Hip Analysis Protocol (Optimized Ortho, Corin, Sydney). This protocol is based on the work of Huppertz et al[17,18] and involves a mean dose of 2.8 to 4.0 mSv per scan. Each CT was segmented by a qualified engineer in ScanIP v5.1 (Simpleware, Exeter, United Kingdom) to produce a 3D reconstruction of the pelvis. The anterior superior iliac spines and pubic prominences were identified virtually on the 3D reconstruction to define the Anterior Pelvic Plane (APP). Using Murray's radiographic definition,[19] a range of nine options of the acetabular orientation for each patient was provided by the OPS system.[20] The optimal acetabular inclination and anteversion was selected by the surgeon several weeks prior to surgery. Using equations similar to those described by Lembeck et al,[21] the planned supine orientation of the component was transformed into the APP reference frame. The 3D pelvic geometry, APP coordinates and planned orientation with reference to the APP, were imported into Solidworks 2013 (Dassault Systems, Vélizy-Villacoublay, France) and a patient-specific guide was designed to give the planned orientation. Each guide and acetabular model was 3D printed from Nylon PA 2200 using Selective Laser Sintering.

Each procedure was performed through a posterolateral approach. After exposure and excision of the soft tissue in the acetabular fossa, the guide was placed rigidly into the acetabulum ensuring that each of its arms was seated according to the pre-operative plan. This position was cross-checked against a printed model of the acetabulum (Fig. 1). A handle was then connected to the guide that projected a laser beam on to the operating room ceiling or wall. This laser axis defined the planned orientation of the acetabular component. A second laser mounted on a screw placed in the pelvis was adjusted so that its projection was coincident with the projection of the guide laser on the ceiling or wall of the operating theatre. This fixed pelvic laser was then locked in place, controlling for intra-operative changes in pelvic position (Fig. 2), and the guide was removed from the acetabulum. Reaming was conducted to

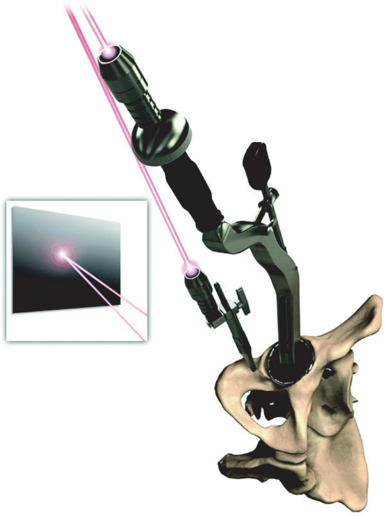

Fig. 3

Illustration of placement of the acetabular component, guided by the removable laser adapter on the introducer. Inset – demonstration of the introducer and pelvic reference laser projections focused on a single point on the wall of the operating theatre.

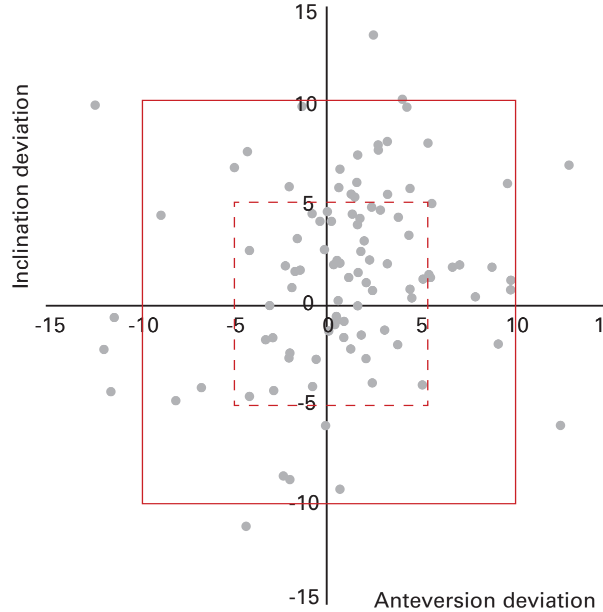

Fig. 5

Scatter plot showing the position of the acetabular component within 5° (hashed line box) and 10° (solid line box) of deviation from the planned inclination and anteversion.

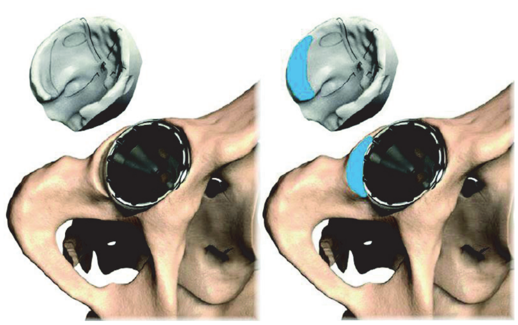

Fig. 4

Final verification of the orientation of the acetabular component by comparison of the amount of overhanging native bone (shaded blue) compared with the planned position of the component on the printed 3D model.

a pre-operatively planned depth, using a laser to assist in the angle of reaming if desired. The placement of the acetabular component was guided by a laser attached to the end of the introducer, which when aligned with the fixed pelvic reference laser, delivers the planned inclination and anteversion (Fig. 3). Final orientation was confirmed by verifying that similar amounts of native bone could be seen above or below the rim of the component when compared with the etched markings on the printed 3D model (Fig. 4).

A low-dose CT scan was repeated within the first week post-operatively and a 3D model of the implanted acetabular shell was virtually registered to the CT scan in +CAD v5.1 (Simpleware, Exeter, United Kingdom), and the APP coordinates were re-defined in ScanIP v5.1. The registered virtual shell and APP coordinates were then imported into Solidworks and the orientation in reference to the APP was measured. Values for the actual inclination and anteversion were compared with the planned pre-operative values. Two observers performed the post-operative measurements (JP, MT) and both were blinded to the other's results.

Statistical analysis. Mean and ranges are reported for continuous data, categorical data are presented as counts and percentages. Absolute error was calculated to account for values above and below the planned acetabular inclination and anteversion. Thresholds of 5° and 10° were used for measurements of accuracy of post-operative acetabular inclination and anteversion.

The study had ethical approval and each patient gave informed consent.

Results

No patient was lost to follow-up. The measurements of the position of the acetabular component differed between observers by a mean of 1.1° (0° to 3.0°) for inclination and 1.0° (0° to 2.9°) for anteversion. The measurements reflecting the accuracy of the placement of the acetabular component are shown in Table II and Figure 5. The mean planned supine target for inclination and anteversion was 40.2° (32.3° to 45.4°) and 24.1° (13.0° to 29.6°), respectively. The mean post-operative supine inclination and anteversion was 41.8° (29.6° to 58.1°) and 25.1° (9.6° to 36.3°). The mean absolute deviation from the planned patient-specific inclination and anteversion was 3.9° (0.0° to 13.6°) and 3.6° (0.0° to 12.9°) respectively (Table II). In

Table II. Accuracy of placement of the acetabular component

	Inclination	Anteversion
Mean deviation (SD) range	1.6° (4.6°) -11.1° to 13.6°	1.0° (4.7°) -12.4° to 12.9°
Mean absolute deviation (SD) range	3.9° (2.9°) 0.0° to 13.6°	3.6° (3.2°) 0.0° to 12.9°
% within +/- 5°	*71* (71/100)	*77* (77/100)
% within +/- 10°	*96* (96/100)	*94* (94/100)
% within +/- 5° (both)	*54* (54/100)	
% within +/- 10° (both)	*91* (91/100)	

SD, standard deviation

54% (54/100) of cases, the patient-specific target for both inclination and anteversion was achieved to within +/- 5°. In 91% of cases (91/100) the patient-specific target of +/- 10° was achieved for both inclination and anteversion (Fig. 5). There were no instances where the patient-specific system had to be aborted. There was one complication of a fractured ceramic liner due to incomplete seating at the time of the initial procedure; this required revision surgery with exchange of the liner. There were no dislocations during the study period.

Discussion

We found that the accuracy of placement of the acetabular component to within 10° of a patient-specific target using specific instrumentation was 91%. There were a total of nine outliers in this series. Outliers were malpositioned greater than 10° from pre-planned orientation in one plane, with just one exception. There were three cases of increased anteversion and retroversion respectively. There were two cases of increased inclination and one case of combined increased inclination and retroversion. This accuracy of placement is comparable with previous reports of both robotic and navigated techniques and is vastly better than free hand techniques. Using previously reported data, a historical control group of the authors experience with the free hand technique provided comparative data to show the superiority of the patient-specific technique.[22] In this historical control group, a total of 188 THAs were available for radiographic measurement of acetabular inclination and anteversion using Ein-Bild-Roentgen-Analyse (EBRA).[23] When aiming for inclination of 40° and anteversion of 20°, the accuracy in this series was 61% within 10° and 21% within 5°. One retrospective study of 1823 patients reported the accuracy of a free hand technique aiming at a modification of Lewinnek's safe zone and found that only 47% were within target ranges for both inclination (30° to 45°) and anteversion (5° to 25°).[7] Smaller studies reported even lower rates with just 22% and 25% within both these target safe zones.[12,13] The free hand technique relies on landmarks which can be altered by variations in the anatomy of the patient. Fujita et al[24] for example noted patient-specific variability in the orientation of the transverse acetabular ligament (TAL) with 5% being excessively anteverted beyond Lewinnek's safe zone. Changes in patient and pelvic positioning during THA have also been found to influence the placement of the acetabular component using the free hand technique.[25]

Data from navigated series have shown improved accuracy. Moskal and Capps[26] undertook a literature review including nine studies with 1479 patients and found that the combined safe zone was achieved in 81% of cases using navigation, compared with 63% when navigation was not used. In a more recent matched pair study comparing robotic to free hand acetabular positioning through a posterior approach, navigation was found to be 100% and 92% accurate for positioning within Lewinnek's[6] and Callanan's[7] safe zones, respectively, whereas free hand positioning was 80% and 64% accurate.[27] Data in other imageless navigation series have shown improved accuracy and significantly fewer outliers when compared with free hand techniques.[28,29] The mean increase in reported operating times for navigated THA have ranged from 8 minutes to 58 minutes.[14,16] In the authors' experience, total operating time using the patient-specific guides for placement of the acetabular component typically requires an additional 3 minutes to 5 minutes.

Although the additional intra-operative time is negligible, the pre-operative evaluation and fabrication of the patient-specific guides requires three weeks. However, this can be expedited if necessary. Another factor worthy of discussion is the cost associated with this technology. However, a complete cost analysis is beyond the scope of this study. The cost of the pre-operative CT scan is dependent on the health system providing the scan. Otherwise, there are no additional direct costs to the patient or physician by using the system beyond the cost of the implants.

Although navigation in its various forms may have improved the accuracy of placement, the debate continues about the ideal safe zone for placement of the acetabular component. In one retrospective review of 9784 patients, a rate of dislocation of 2% was reported. Of the 206 dislocations, 58% were found in patients whose acetabular component was placed within Lewinnek's safe zone for both inclination and anteversion.[8] These findings are similar to those of Esposito et al,[9] who noted a 2% dislocation rate and 54% were found in patients whose acetabular components were within the safe zone. While useful, the historical safe zone may not account for all the factors that determine stability.

We believe that the result of an accurately positioned component, within the ideal target range, will be improved outcomes for patients with fewer complications but acknowledge our investigation has not yet established this. One complication occurred during the study period, which required revision surgery to exchange a fractured ceramic liner. The liner was found to be displaced on review of the post-operative CT scan that was obtained in accordance with the study protocol, within the first week after surgery. The patient was asymptomatic; however, the decision was made to revise the liner. Revision surgery occurred 15 days after the initial procedure. A small portion of the rim of the liner was cracked; the remainder was intact. The liner was changed to another ceramic liner without incident and the patient has had no further complications.

There are important limitations of this study including the lack of a control group which would allow for direct comparison between techniques. Given the availability of data from prior studies using both free hand and navigated techniques it was felt that these studies provided sufficient points of reference for the accuracy of placement of the acetabular component. Another limitation is the lack of long-term follow-up which would allow the inclusion of data relating to survivorship.

In conclusion, accurate placement of the acetabular component in THA can be achieved using patient-specific instrumentation. The results are comparable with those of both robotic and navigated surgery and are superior to conventional free hand techniques. The potential benefit of this technology would be a reduction in both edge loading related wear and instability related to malorientation of the component.

Take home message:

Accurate placement of the acetabular component can be achieved using patient-specific guides and is superior to free hand techniques and comparable to navigated and robotic techniques.

Author contributions:
L. Spencer-Gardner: Manuscript preparation/editing.
J. Pierrepont: Study design, Data analysis, Manuscript preparation.
M. Topham: Data analysis, Manuscript preparation.
J. Baré: Study design, Manuscript editing.
S. McMahon: Study design, Manuscript editing.
A. Shimmin: Study design, Manuscript preparation/editing.

J. Baré, S. McMahon and A. J. Shimmin are consultants for Corin, whilst J. Pierrepont and M. Topham are employed by the same.

The author or one or more of the authors have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this article.

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