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Accuracy of cup placement in total hip arthroplasty by means of a mechanical positioning device: a comprehensive cadaveric 3d analysis of 16 specimens

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Abstract

Introduction: We tested whether a mechanical device (such as Hipsecure) to pinpoint the anterior pelvic plane (APP) as a guide can improve acetabular cup placement. To assess accuracy we asked: (1) is the APP an effective guide to position acetabular cup placement within acceptable ° of divergence from the optimal 40° inclination and 15° anteversion; (2) could a mechanical device increase the number of acetabular cup placements within Lewinnek's safe zone (i.e. inclination 30° to 50°; anteversion 5° to 25°)?
Methods: 16 cadaveric specimens were used to assess the 3D surgical success of using a mechanical device APP to guide acetabular cup placement along the APP. We used the Hipsecure mechanical device to implant acetabular cups at 40° inclination and 15° anteversion. Subequently, all cadaveric specimens with implants were scanned with a CT and 3D models were created of the pelvis and acetabular cups to assess the outcome in terms of Lewinnek's safe zones.
Results: The mean inclination of the 16 implants was 40.6° (95% CI, 37.7–43.4) and the mean anteversion angle was 13.4° (95% CI, 10.7–16.1). All 16 cup placements were within Lewinnek's safe zone for inclination (between 30° and 50°) and all but 2 were within Lewinnek's safe zone for anteversion (between 5° and 25°).
Conclusion: In cadaveric specimens, the use of a mechanical device and the APP as a guide for acetabular cup placement resulted in good positioning with respect to both of Lewinnek's safe zones.

Keywords
3D analysis, accuracy study, anterior pelvic plane, anteversion, inclination, Lewinnek's safe zone, total hip arthroplasty

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Introduction

Across all the countries of The Organisation for Economic Co-operation and Development (OECD) about 1.6 million total hip replacements (THR) implants are performed each year (164 per 100,000 of the population). This number is rapidly increasing due to ageing populations. Currently most acetabular cups are positioned using free-hand techniques.[1] Correct placement of the acetabular cup is crucial to achieve a good outcome, as inaccurate positioning can be a component in a multifactorial issue that can induce early loosening, postoperative dislocation[2–4] and implant wear, which has been related to metallosis in metal-on-metal prostheses. Accurate positioning can be measured in terms of the safe ranges for inclination (30–50°) and for anteversion (5–25°) as described by Lewinnek et al.[5] However, accurate cup positioning is more difficult when using only free-hand techniques.[6–8] Various studies

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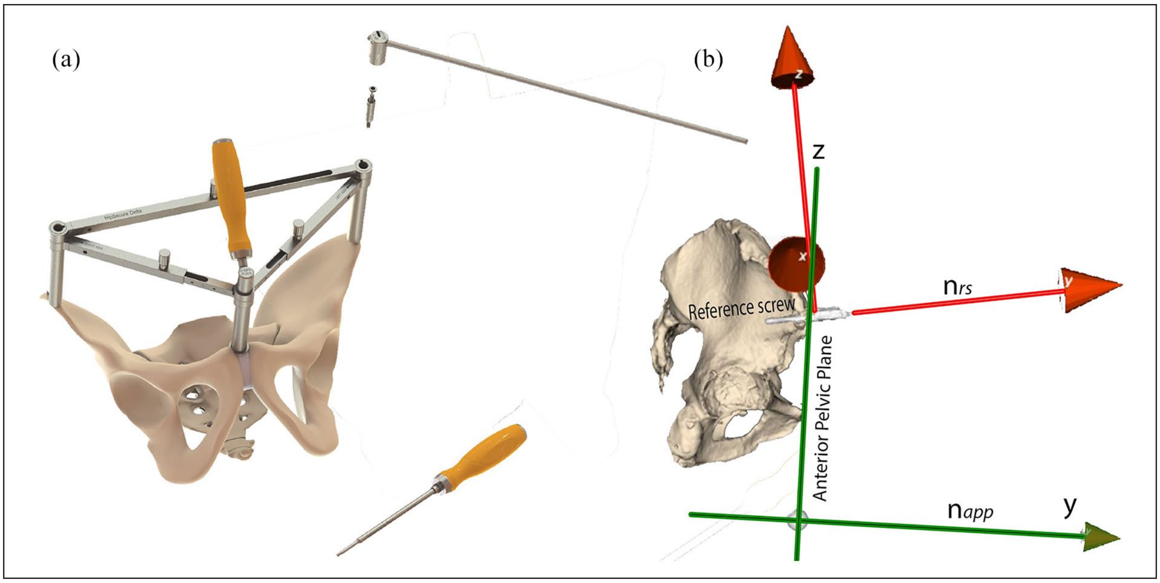

Figure 1. (a) The HipSecure system showing the frame that guides the pin placement to which is attached the guiding rod. (b) 3D model of a pelvis with a plane fitted to the anterior pelvic plane. Example of difference between the pelvic pin normal vector ($\mathbf{n}_{rs}$) and the normal vector of the anterior pelvic plane ($\mathbf{n}_{app}$) on a lateral view in the ZY plane, in this case the pin is tipped backwards which in theory would result in more anteversion.

have demonstrated that conventional free-hand positioning results in a high percentage (>50%) of acetabular cup placements outside Lewinnek's safe zones.[7–10]

In the 1990s, attempts were made to improve acetabular cup positioning by means of computer navigation and studies demonstrated that cup positioning was significantly improved.[8,11–16] However, the use of computer navigation has decreased because of its complexity and the subsequent increase in operation time. So, currently, free-hand acetabular cup positioning is the method of choice in more than 90% of hip replacements.[7]

As described earlier, results with free-hand placement are unacceptably variable so it is vital to identify a usable method to improve the accuracy of acetabular cup positioning and so reduce complications and improve patient outcome. A viable option is to implement a mechanical device, such as the new HipSecure system (Figure 1) and use the anterior pelvic plane (APP) as a reference point to guide acetabular cup positioning. This device is simple in terms of design and much easier to apply than computer navigation, which means it does not have the disadvantage of increased operation time. However, the system has not been evaluated for clinical use.

The aim of this study is a preclinical evaluation in which we investigate the applicability of the HipSecure system and the accuracy of cup placement when using the system on cadaveric specimens. The research questions of this study are: (1) how accurate is the anterior pelvic plane (APP) in guiding acetabular cup placement when using the Hipsecure system as reported in degrees (°) of error away from the aimed for 40° of inclination and 15° of anteversion; (2) in how many cases will cup placement be in Lewinnek's safe zone?

Methods

The studies were carried out by first performing surgery on the cadaveric specimens followed by a CT scan to evaluate the APP and to assess cup orientation with respect to the APP in a 3D analysis.

First step, implantation of the reference pin

For this study the step by step HipSecure surgical technique was followed according to the manufacturer.[17] The anterior os pubis and right and left spinae iliaca anterior superior (SIAS) are palpated by hand. These structures may be identified by x-ray or ultrasound if the bony structures are difficult to palpate, although in these cases it was not necessary. The HipSecure frame consists of a 3-armed metal frame that has 3 contact points that can be manually aligned with the anterior os pubis and the right and left *SIAS*. The plane between these 3 points is the APP (Figure 1). Subsequently a pin is slid through the tubular hole in the frame in supine position on the affected side and surgically fixed into the bone of either the left or right SIAS (Figure 2). The frame is removed, leaving the pin, allowing for one guiding rod to slide into place. Multiple alignment rods rods are available; in this study the 40° of inclination and 15° of anteversion rod was used for all specimens. This guide rod now delineates the APP and reflects the inclination and anteversion angle for correct

Figure 2. A cadaveric specimen in supine position following pin placement on the right side.

acetabular cup placement. Following rod placement, the next step is to implant the the acetabular cup along the alignment rod.

Second step, surgical implantation of the acetabular cup as normal, visually guided by the alignment rod

Sixteen uncemented acetabular cups were surgically placed in pelvic cadaveric specimens by our hip and knee arthroplasty surgeon who has extensive experience in primary and revision hip arthroplasty procedures. To ensure the surgical area was visually as close to a live patient as possible, the cadaveric specimens were all full torso with proximal femurs. 2 extra specimens were used for training purposes and to test the measurement and analysis procedure. Smith & Nephew (Andover, MA) supplied us with a cadaveric instrumentation set for the REFLECTION acetabular cup implant. Procedures were performed in a supine position using a straight lateral approach, which is standard care in our hospital. Other approaches are also possible. If surgery is performed in a lateral decubitus position, the pin will have to be placed in a supine position prior to turning the patient.

The acetabulum was under-reamed by 1–2 mm. A straight impactor was used after reaming the acetabulum according to the implantation technique of the REFLECTION cup. The cup was placed manually, visually aligned along the above-mentioned 40° of inclination and 15° of anteversion rod. The cup was then manually tested for primary stability with the impacter before the specimen was the subsequently sent to the CT-scanner.

Third step, 3D analysis of cup orientation as referenced to the actual bony APP

All pelvic cadaveric specimens were scanned using a Brilliance 64-channel CT scanner (Philips Healthcare, Best, The Netherlands) and a clinical scanning protocol (normal dosage for pelvic CT scan) following surgery.

The first step of 3D evaluation was to create a virtual model of the pelvis by means of image segmentation so that it was possible to assess cup positioning achieved by a surgeon using the HipSecure system in comparison with optimal positioning.[18] This virtual pelvis model was used to define the APP reference plane. This was defined by setting a plane so that it “rests” on both the superior anterior iliac spines and on the anterior os pubis, thus giving virtual 3-point support to the plane. The plane normal, $\mathbf{n}_{app}$, served as a reference against which we could measure any discrepancies between the virtual APP plane and that was achieved with the Hipsecure system and the eventual cup orientation. Because acetabular-cup positioning and orientation with Hipsecure is achieved by means of the guiding rod fixed to the reference pin, the orientation of this pin is defined as well as the orientation of the acetabular cup. (Figure 1)

The direction vector of the reference pin, ($\mathbf{n}_{rs}$), is found by calculating the gravitational axis, a line straight through the centre of mass of the object, of the segmented pin. The difference between $\mathbf{n}_{rs}$ and $\mathbf{n}_{app}$ is defined as the pin angulation error but also represents the error in the rod that guides the surgeon during cup placement, subsequently reported as the guiding rod angulation error. Perfect positioning would be achieved if this error were 0°.

The direction vector of the acetabular cup, $\mathbf{n}_{cup}$, is calculated by segmenting the cup, finding the 3 inertial axes of the points in its polygon object (the projection of a line straight through the centre of mass in all 3 projections i.e. sagital, coronal, and axial) and taking $\mathbf{n}_{cup}$ as the axis representing the cup orientation.

An anatomical coordinate system was defined in the following way for the pelvis so that we could measure cup orientation in terms of inclination and anteversion. (Figure 3). By computing the gravitational axes of the pelvis a coordinate system is defined with the z-axis parallel to the craniodistal mechanical axis, the x-axis perpendicular to this and in a medio-lateral direction and the y-axis which points from posterior to anterior. Because the pelvis has more bone cranially than distally, after calculation the y-axis points slightly downward instead of in the true AP direction. The y-axis is therefore re-aligned to the

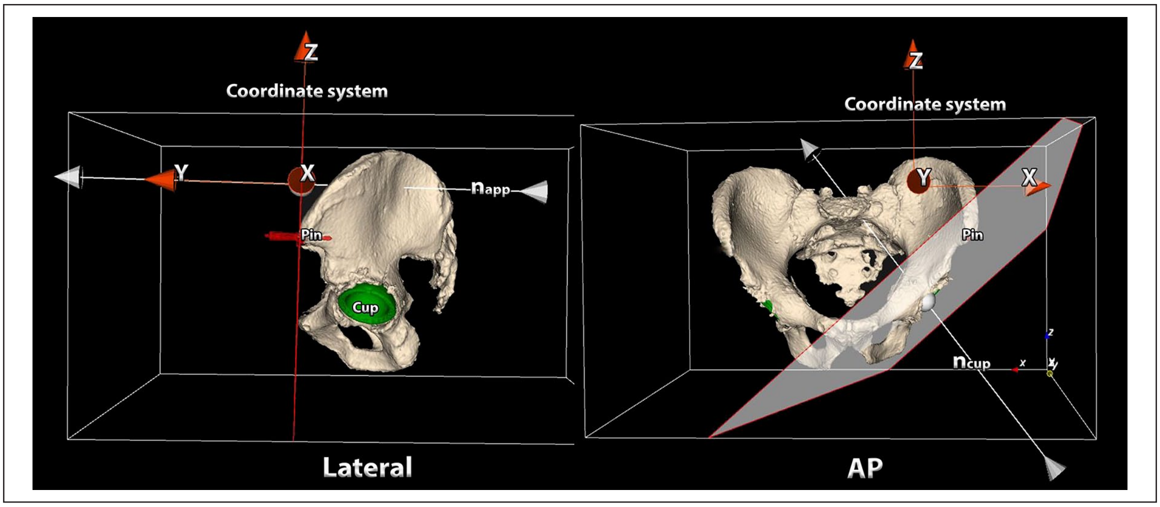

Figure 3. The coordinate system (XYZ) in which the normal vectors of both the cup ($\mathbf{n}_{cup}$) and the pin are projected is shown in red. The z-axis is parallel to the craniodistal mechanical axis, the x-axis perpendicular to this and in medio-lateral direction and the y-axis points from posterior to anterior.
The white arrow driving through the cup represents the normal vector ($\mathbf{n}_{cup}$).

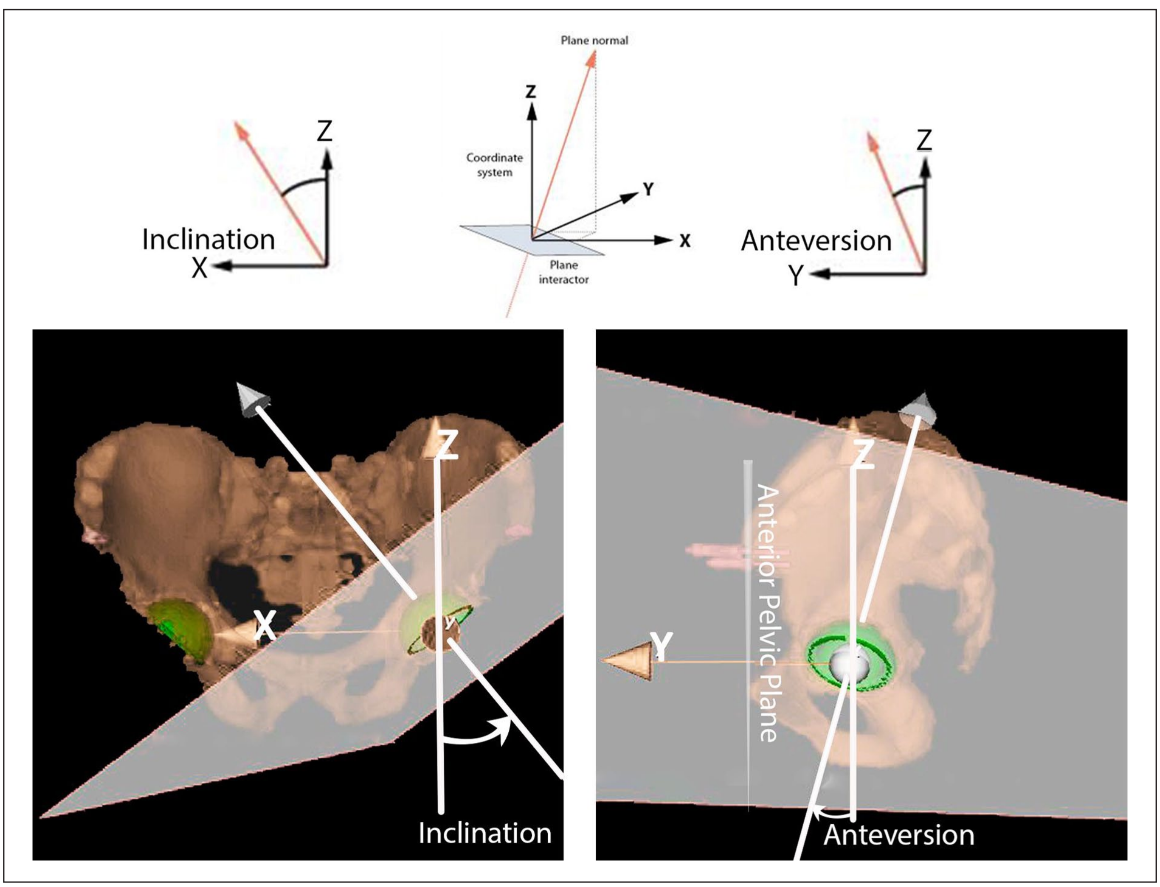

Figure 4. The white arrow driving through the cup represents the normal vector ($\mathbf{n}_{cup}$). On the left, AP view of the acetabular cup plane and normal vector projected in the XZ plane provides the inclination angle. On the right, a lateral view of the acetabular cup plane and normal vector projected in the ZY plane provides the anteversion angle.

previously defined normal of the APP ($\mathbf{n}_{app}$) rotating around the x-axis. This realignment also repositions the z-axis in the exact cranial direction in line with the APP. To evaluate the inclination-*error* of the cup $\mathbf{n}_{cup}$ was projected in the AP plane (XZ, Figure 4 left). To evaluate the anteversion-*error* of the cup $\mathbf{n}_{cup}$ was projected in the sagittal plane (YZ, Figure 4 right). Inclination and anteversion are reported in °. Inclination-error and anteversion-error are also reported in degrees ° as the deviation from the target (40° of inclination and 15° of anteversion).

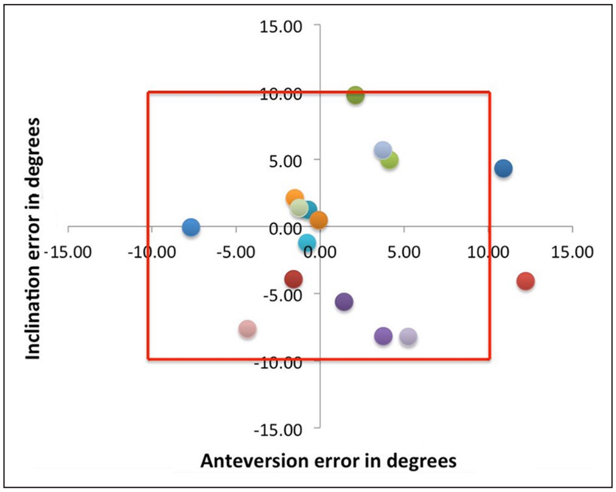

Figure 5. Angulation errors for all 16 specimens in anteversion (– too much, + too little) and inclination (– too much, + too little). Target angles (with an error of zero °s) are 40° of inclination and 15° of anteversion.
The box represents Lewinnek's safe zone. Each dot represents the error in placing each individual acetabular cup.

The Shapiro-Wilks test was used to test for normality. If the results were non-normally distributed medians and min-max should be reported, for normally distributed values means and 95% confidence interval (CI) were reported.

Results

The guiding rod error was distributed non-normally. The median guiding rod angulation error, the difference between $\mathbf{n}_{rs}$ and $\mathbf{n}_{app}$, was 3.1° (min–max 0.7–10.5). Inclination, inclination-error, anteversion and anteversion-error of the acetabular cup were normally distributed in this study. The mean inclination was 40.6° (95% CI, 37.7–43.4) and the mean anteversion angle was 13.4 (95% CI, 10.7–16.1). All inclinations were within Lewinnek's safe zone of between 30 and 50°. 2 acetabular cups were outside Lewinnek's safe zone of between 5° and 25° anteversion. They had an anteversion respectively of 4.1° and 2.8° (Figure 5) (Table 1).

Discussion

The most import finding of this study is that delineating the APP plane as a reference plane, by means of the HipSecure system, results in accurate acetabular cup placement. Inclination was within Lewinnek's safe zone in all sixteen specimens (100%). Anteversion was within

Table 1. Result following placements as shown in inclination and anteversion in ° (– too much, + too little).

Case	Anteversion error (target anteversion is 25°)	Inclination error (target inclination is 40°)	Guiding pin error (°)	Guiding pin sagittal plane error (°)	Guiding pin coronal plane error (°)
Case 1	10.9	4.29	6.5	6.17	–2.06
Case 2	–1.59	–3.91	3.23	–1.82	–2.68
Case 3	2.1	9.77	3.58	2.77	–1.73
Case 4	1.43	–5.61	1.39	0.07	3.4
Case 5	–0.71	1.21	1.8	–0.69	–2.12
Case 6	–0.08	0.43	3.66	–2.67	–1.74
Case 7	–7.67	–0.1	10.54	–10.3	–1.04
Case 8	12.22	–4.06	9.32	9.32	0.64
Case 9	4.13	4.94	1.97	1.63	–1.11
Case 10	3.76	–8.17	1.08	1.07	1.29
Case 11	–0.77	–1.26	1.06	–0.19	–1.39
Case 12	–1.5	2.09	4.04	–3.01	–1.28
Case 13	3.73	5.68	0.73	0.58	–0.89
Case 14	–4.32	–7.62	5.15	–4.89	–1.64
Case 15	–1.25	1.35	2.96	–2.93	0.54
Case 16	5.24	–8.24	2.04	–0.61	3.67
Mean	**1.6**	**–0.58**	**3.69**	**–0.34**	**–0.51**
Median	**0.67**	**0.16**	**3.1**	**–0.4**	**–1.19**
SD	**5.1**	**5.36**	**2.9**	**4.43**	**1.91**
95% CI	2.5	2.63	1.42	2.17	0.93
–	–1.83	–2.46	1.67	–2.57	–2.12
+	3.18	2.79	4.52	1.77	–0.26

Lewinnek's safe zone in all but 2 (12.5%) of the 16 specimens, which both had slightly more anteversion. Therefore, 87.5% met both targets.

The reason for complications, like dislocations, are very complex and many factors are responsible. Factors involved can be patient related, anatomy related, prosthesis related or surgery related. Accurate instruments and good surgical planning and technique can help reduce part of these risk factors and improve outcome. Lewinnek et al.[5] described a safe anteversion range of (5–25°) and inclination range of (30–50°) to position the cup. The chance that free-hand placement of the acetabular component is within 5° of an intended position, for both inclination and anteversion is only 21.5%.[7] It is, therefore, clinically relevant if the HipSecure system can lead to a >21.5% improvement of implant placed within 5° of the intended position.

Barrack et al.[19] reported that when previously published target ranges of inclination (in their study 30–45°) and anteversion (5–25°) angles were used, only 665 total hip replacements (43%) met the inclination target, 1325 (86%) met the anteversion target, and 584 (38%) simultaneously met both targets.[19] Bosker et al.[7] reported that, based upon the inaccuracy of estimation of 200 cup placements, the chance of cup placement within Lewinnek's safe zone (5–25° anteversion and 30–50° inclination) is 82.7% and 85.2% for anteversion and inclination separately.[7] When both parameters are combined, the chance of accurate placement is only 70.5%. This study used normal radiographs to assess cup positioning.

Saxler et al.[8] showed even poorer outcomes with free-hand positioning. They assessed free-hand results in terms of Lewinnek's safe positions and found that only 27/105 (26%) cups were implanted within the safe limits. In another study that compared freehand cup positioning to computer-assisted cup placement 16 (53%) of the 30 cups placed freehand and 5 (17%) of the 30 in the computer-assisted group were outside of the defined safe zone.[15] In a more recent study by Callanan et al.[20] the results of 1823 cups are described. In this study acceptable ranges were defined for inclination (30–45°) and anteversion (5–25°) as measured on radiographs. From these 1823 hips, 1144 (63%) acetabular cups were within the inclination range, 1441 (79%) were within the version range, and 917 (50%) were within the range for both.[20] In this study the APP plane and HipSecure system as a reference seems superior with respect to the achieved inclination and inclination angles over free-hand as well as computer-assisted placement.

Interestingly, Barrack et al.[19] report that the odds of missing the target increased by a factor of 0.2 for every 5 kg/m^2 increase in body mass index. This finding is probably due to the fact that in a patient who is overweight, free-hand placement becomes more difficult. As the HipSecure system uses a bony reference plane it could be expected that obesity is less of a problem, although additional research is required to validate this assumption.

It must be said that there is also still controversy over what is actually good cup placement.[21] 1 previous study reported no difference in dislocation rate between cups placed within or outside of the safe zone.[22] Furthermore, Biedermann has suggested that there is no specific range for cup placement.[23] However, this study is more about the accuracy of placing cups close to the planned orientation. It might be that some patients walk with a more anteriorly tilted and others with a more posteriorly tilted pelvis. In a previous study by DiGioia et al.[24] it has been reported that the mean anterior pelvic plane angle is 1° (range –22° to +27°) when standing upright. It tilts posteriorly by a mean angle of –36° (range –64° to +4°) degrees when sitting down. There was a wide variation in the arc of pelvic flexion extension as patients moved from standing to sitting, with are of pelvic motion in some patients as mobile as 70° and in others as stiff as 5°.[24]

In other studies it was also shown that the APP is dynamic and changes between supine, standing and sitting positions.[25,26] For these patients different anteversions might be suitable. If a surgeon would prefer to position the cup more patient-specifically, the frame could be used with different alignment rods. In some situations, cup positioning can also be adjusted to a specific lifestyle. For instance, if a patient has a hobby or work that involves deep hip flexion, more anteversion can be chosen to reduce the chance of dislocation while performing these activities. Or, if on a lateral standing x-ray the APP is tilted posteriorly at a 5-degree angle, a rod with 5 degrees less anteversion can be chosen. Postoperatievly the cup will have been placed at 40° inclination and 10° anteversion to the APP, but at 15° anteversion in that patient's natural vertical plane. What is perfect cup placement individually is still to be determined; the APP could, however, be used as a reference as it shows an accurate translation from the mechanical APP reference to cup placement in this study.

There are, however, also multiple studies that report limitations of the APP.[27] Parrate et al.[28] reported variability on manual cutaneous acquisition of mainly the pubic symphysis, possibly resulting in rotation of the acquired APP compared to the true bony APP. Another group found the APP to be less reliable than expected in navigation use when assessed with the EOS system.[29] To overcome the problem of having to change the patient from supine to lateral decubitus in navigational surgery 1 group found that they preferred the transverse pelvic plane over the APP.[30] A computed tomography (CT) scan based method to extract the APP from CT volume has previously proven robust.[31]

There are certain limitations to this mechanical system. In cases in which the pelvis has been traumatically damaged resulting in a change of the APP as assessed on CT, the frame cannot not be used. The placement of the reference pin creates a second wound, which in itself can increase postoperative pain. The pin is placed in a supine position; for surgery in the lateral approach the patient should be subsequently turned. Furthermore, there is an extra chance of infection. In obese patients, if there is an unequal distribution of body fat, especially differences of soft tissue covering the pubic bone, this might affect pin placement and increase anteversion. The surgical placement itself can lead to lateral femoral cutaneous nerve damage with nerve palsy over that specific skin area. Pin placement needs to be done in a supine position, for surgeons used to performing total hip prostheses, with the patient lying on his or her side to create an extra positioning step. During repositioning there is a risk of pin displacement. As this is a pre-clinical study there are no figures on these additional complications.

Another limitation is that this system has not been compared with control free-hand placement in the same experimental setting. Due to financial reasons the number of cadaveric specimens was limited. The choice was made to relate the outcome to previously reported accuracy data on freehand cup positioning. By doing this we could implant twice as many cups with the current reported system. A benefit is that the combined freehand reference values for accurate cup placement are based on much higher numbers, different surgeons and different centres, making these numbers more externally valid. As this is an observational study and not a comparative one it is uncertain what the results will be in real patients. This is due to financial reasons as cadaveric specimens are costly, and our primary goal was to evaluate the effectiveness of the system to guide correct placement within the safe zone.

Conclusion

The use of the anterior pelvic plane as bony reference for acetabular cup placement as used by the HipSecure system achieved accurate acetabular cup placement with a mean inclination of 40.6° (aim 40°) and mean anteversion angle of 13.4° (aim 15°). 88% showed an anteversion within Lewinnek's safe zone. All cups had a correct inclination angle with 100% within Lewinnek's safe zone. Therefore, both Lewinnek's safe zone targets were met in 88% of cases.

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Declaration of conflicting interests

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