

# A Prospective, Randomized Study of Surgical Positioning Software Shows Improved Cup Placement in Total Hip Arthroplasty

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# abstract

Several technologies are available to assist surgeons with acetabular component positioning in total hip arthroplasty. The purpose of this study was to determine whether surgical positioning software would improve cup position compared with fluoroscopy. This prospective, randomized study compared 200 primary total hip arthroplasty cups placed with and without surgical positioning software. All cases were performed by a single surgeon using the direct anterior approach with fluoroscopy. The target abduction and anteversion angles were set at 40° and 20°, respectively, and measured postoperatively. Cup placement time, total fluoroscopy time, and cup position were compared between groups. Mean abduction was 40.4° (range, 32.7°-49.0°) in the software group compared with 42.3° (range, 33.7°-51.1°) in the control group. The cups placed using software were significantly closer to the target abduction angle (P<.001) with fewer outliers. Mean anteversion was 20.8° (range, 11.2°-31.7°) in the software group compared with 21.8° (range,  $11.3^{\circ}-34.3^{\circ}$ ) in the control group (P=.063). Eighty-seven percent of cups in the software group fell within 5° of the abduction target, compared with only 68% in the control group (P<.01). Cup placement took longer in the software group (7:04 minutes vs 4:58 minutes, P<.001), and 2 seconds more total fluoroscopy time was used in that group as well (12.9 seconds vs 11.1 seconds, P<.001). The software improved both the accuracy and the precision of cup placement, with only modest increases in surgical time and fluoroscopy time. [Orthopedics. 2019; 42(1):42-47.]

It is well established that proper acetabular component positioning is important to reduce failures after total hip arthroplasty (THA). Although exact target ranges are debated, cup malpositioning has been implicated in problems such as dislocation,<sup>1-4</sup> accelerated wear of both polyethylene<sup>2,5-7</sup> and metal articulations,<sup>8,9</sup> implant breakage,<sup>10-12</sup> limited range of motion,<sup>13</sup> and pain.<sup>14</sup> Achieving accurate component positioning has been the subject of several recent studies, often implementing new technologies.

In a 2011 award-winning study, Callanan et al<sup>15</sup> showed that even experienced surgeons have difficulty positioning the acetabular cup using their eyes alone. When abduction and anteversion angles of 1823 total hip cups were measured, only half of the implants were found to be within the surgeon's target zone for both measurements (30° to 45° of abduction and 5° to 25° of anteversion). More recently, studies have shown improved accuracy when using one of several available technologies, including intraoperative radiograph or fluoroscopy, robotics, computer-assisted surgery, and patient-specific guides. 16-21 Each tech-

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nology has pros and cons such as ease of use, availability, cost, and interruption of workflow.

The early results of hip arthroplasty with the anterior approach and fluoroscopy have been compared with those of hip arthroplasty with the posterior approach,<sup>22</sup> with the former showing improved cup placement. However, a small percentage of malpositioned implants remain, even in the hands of experienced surgeons using fluoroscopy. Surgeon's Checklist positioning software (Radlink Inc, El Segundo, California) is designed to be used in concert with an intraoperative fluoroscopic image, with tools to measure angles and attain a specific target cup position. To the authors' knowledge, little data have been published documenting the effectiveness of this product in THA. This prospective, randomized study was designed to compare the accuracy of acetabular component positioning using the software vs fluoroscopy alone. The authors posed the following questions: Will the software lead to accurate and precise acetabular component positioning? Will it reduce the number of outliers when compared with fluoroscopy alone? How much surgical and fluoroscopy time will be added?

#### **MATERIALS AND METHODS**

This prospective, randomized study compared the hip cup component abduction and anteversion angles placed using 2 surgical techniques. The protocol, materials, and consent form received institutional review board approval. To power the study adequately, the authors compared historical data based on standard surgical methods (average abduction of 43.2° and standard deviation of 4.5°) with a predicted mean of 41.6° of abduction (ie, half the distance to the goal of 40°) and a standard deviation of 2.25° (50% of the historical standard deviation). A total of 99 cases in each group would be required to achieve 80% power at P=.01.

Patients enrolled in the study had to be at least 18 years old and undergoing pri-

mary unilateral THA. Once patients were identified, were screened, and gave consent in the clinic, they were randomized to one of the parallel study arms preoperatively: the control group or the software study group. A 1:1 block randomization created by a computer-generated randomization program with 2 blocks of 100 was developed by the project director (N.L.P.). Sequential numbers with stickers over the group allocation were revealed at the time of surgery.

All cases were performed by a single, fellowship-trained surgeon (W.G.H.) who was experienced with the direct anterior approach using fluoroscopy. Using the appearance of the obturator foramen on the preoperative supine pelvic radiograph as a baseline, the fluoroscope is manipulated to make the intraoperative fluoroscopic image match the preoperative pelvis. In the control group, the acetabular cup was placed using the fluoroscopic image and adjustments were made to the cup position until it appeared to be in approximately 40° of abduction and 20° of anteversion, based on the surgeon's visual estimation of the angles.

In the software group, Surgeon's Checklist positioning software was used to assist with cup position. The intraoperative fluoroscopic image was uploaded, and the same goal parameters of 40° of abduction and 20° of anteversion were set. The program displays a target cup ellipse based on bony landmarks, and the surgeon matches the acetabular component to the ellipse (Figure 1). This is done with the final component with adjustments to cup position made until the position is correct. Secondary outcomes included the length of fluoroscopy in seconds and the amount of time required to place the acetabular cup. The timer was started when the surgeon was handed the final cup on the insertion handle and was stopped once the liner was impacted. All hip arthroplasties were performed through a direct anterior approach and received identical acetabular implants (Pinnacle; DePuy Synthes, Warsaw, Indiana).



**Figure 1:** Hip positioning software sets an elliptical target for the surgeon to match.

A total of 265 primary total hips in 262 patients were screened for this study. Twenty-seven patients declined to participate. Twelve patients were not included for the following reasons: long distance/no plan to return for followup (n=2); spine or pelvis anatomy/prior fracture or hardware that made a primary cup inappropriate (n=5); and inadequate time/too nervous to thoroughly discuss consent (n=5). The remaining 223 patients (226 hips) consented to participate in the study. Eight of those never scheduled surgery, and 9 scheduled but later canceled surgery. Six additional patients changed their mind and withdrew their consent to participate. The remaining 203 hips in 200 patients were randomized and had surgery between December 2015 and October 2016. In 2 cases, there were technical difficulties with the computer during surgery; those 2 cases could not be performed with the software and were excluded from the study. One additional case was found to have a pelvic deformity secondary to a spinal fusion and was withdrawn from the study to place the cup in a target position that was more appropriate for the patient's unique anatomy. The software group had 100 cases that had their cup placed according to the



Table 1						
Patient Demographics						
Characteristic	Control Group	Software Group	P			
Patients, No.	100	100				
Age, mean, y	66.2	64.8	.34			
Height, mean, in	67.4	66.6	.17			
Weight, mean, kg	82.1	82.6	.83			
Body mass index, mean, kg/m <sup>2</sup>	28.0	28.8	.33			
Sex, male	36%	33%				

target of the software positioning system. The control group had 100 cases that had their cup placed with the standard technique.

The 2 groups were not different regarding age, body mass index, or sex (**Table 1**). Patients had a supine anteroposterior pelvic radiograph obtained 4 weeks postoperatively. These images were measured by a single, blinded examiner (J.F.M.) using the Martell Hip Analysis Software Suite (University of Chicago, Chicago, Illinois).<sup>23</sup> Images of all prosthetic measurements and angles were saved for comparison. Anatomical and prosthetic landmarks, such as the superior and inferior aspects of the cup rim, were defined on each image, which the Martell software then uses to identify the cup and its inclination (abduction) and anteversion angles. Data were entered into SPSS software (IBM, Armonk, New York) for descriptive analysis, including mean, maximum, minimum, and standard deviation, as well as to determine the homogeneity of variance to assess the spread of the data in each group. Differences in means of cup angles and timed measurements were examined using t tests.

# **RESULTS**

Ninety-nine percent of the software group and 97% of the control group were in the combined safe zone of  $40^{\circ}\pm10^{\circ}$  of abduction and  $20^{\circ}\pm10^{\circ}$  of anteversion. The mean cup abduction angle was significantly closer to the  $40^{\circ}$  target

for the software group than for the control group  $(40.4^{\circ}\pm3.5^{\circ} \text{ vs } 42.3^{\circ}\pm4.1^{\circ},$ P<.001; **Figure 2**). The mean anteversion angle was approaching a significant difference between the groups with a mean of 21.8° for the control group and  $20.8^{\circ}$  for the software group (P=.063). Differences in angles and errors in each group are listed in Table 2. Eighty-seven percent of the software-assisted cases were within 5° of the goal. The variation in the cup anteversion angle was significantly different between the groups (P=.042). The variation in abduction angle approached, but did not achieve, significance (P=.051).

Two patients in the software group did not have their cup placed according to the software recommendations. The surgeon chose to instead override the cup position that the computer directed and place the cups in what he thought was a better position. In the first case, the cup abduction was increased because the preoperative radiograph had low contrast, making it difficult to view the bony landmarks. This cup had a final measured abduction angle of 38.1°, close to the 40° target. In the second case, the surgeon chose to antevert the cup more than the software prescribed. That cup measured 33.3° of anteversion, the only outlier in the software group. There have been no dislocations among the 200 cases in this study.

The mean time for cup placement was 2:46 minutes longer in the software group

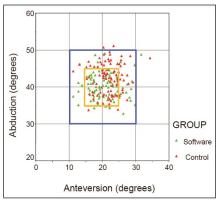


Figure 2: Scatter plot of abduction vs anteversion. Software-assisted abduction angles were centered around the 40° target and had a tighter range.

than in the control group (7:04 $\pm$ 1:52 minutes vs 4:58 $\pm$ 1:38 minutes, P<.001). The total fluoroscopy time, as measured by the time readout on the fluoroscopy machine, was 1.8 seconds longer in the software group compared with the control group (12.9 $\pm$ 3.4 seconds vs 11.1 $\pm$ 2.7 seconds, P<.001).

#### DISCUSSION

Several technologies have been proposed to aid in cup positioning, with intraoperative fluoroscopy being the preferred technique during the past several years. The addition of software for guidance during cup placement was hypothesized to improve the accuracy and precision of cup placement in THA, and this study has shown that to be true.

This study had weaknesses. Because the study surgeon had performed more than 2000 THAs with the fluoroscopy-assisted anterior approach, his experience may have influenced the outcomes of the control group. However, with little prior experience using the software technology, placing cups according to the on-screen guide should produce results similar to those of the current study group. Another weakness of the study was that the cup position was measured on a postoperative pelvic radiograph. Computed tomography scans may have provided a more accurate measurement,



but prior studies have shown that the anteroposterior radiograph closely corresponds to measurements made on computed tomography scan.<sup>24</sup> Furthermore, obtaining computed tomography scans for 200 patients would have made study enrollment and completion overly cumbersome.

Placing the cup in excessive abduction, anteversion, or retroversion reduces the distance that the femoral head must travel to dislocate. The safe zone for acetabular cup position has been defined in different studies. Lewinnek et al1 established the safe zones as 30° to 50° of abduction and 5° to 25° of anteversion, citing an increased rate of dislocation with hips positioned outside of this zone. Barrack et al<sup>25</sup> defined an acceptable range of 45°±10° of abduction and 20°±10° of anteversion. The current authors chose an abduction angle of 40° and an anteversion angle of 20°, as these were average targets in several published studies, consistent with historical cup placement,<sup>22</sup> and well within published safe zones. The results of the current study compare favorably with those of prior studies (**Table 3**). 15,22,26,27 Although both groups showed accurate and precise placement, an on-screen guide to assist with positioning may help a less-experienced surgeon even more.

In 2 cases, the surgeon chose to override the on-screen ellipse and place the cup in the appropriate position based on his experience. This scenario was anticipated by the institutional review board, the members of which agreed at the time of study approval that in such a case, to minimize patient risk, the surgeon's experience and judgment should be called on to make the final decision for cup placement. Of note, these 2 manual overrides occurred in the first quartile of the study, when the surgeon was less comfortable with the software. Indeed, in the case of a poor-quality radiograph, his judgment proved correct, indicating the importance of good-quality images for the software

	Table 2					
Variation and Range of Cup Position						
Outcome Parameter	Control Group	Software Group	P			
Abduction						
Mean	42.3°	40.4°	<.001			
Range	33.7°-51.1°	32.7°-49.0°				
Standard deviation	4.1°	3.5°				
Interquartile range	38.5°-45.6°	37.7°-42.6°				
Mean error (degrees away from 40)	4.0°	2.8°	<.001			
Within 10°	98%	100%				
Within 5°	68%	87%	.002			
Anteversion						
Mean	21.8°	20.8°	.063			
Range	11.3°-34.3°	11.2°-31.7°				
Standard deviation	3.6°	3.0°				
Interquartile range	19.8°-24.5°	17.5°-23.7°				
Mean error (degrees away from 20)	3.2°	3.5°	.384			
Within 10°	99%	99%				
Within 5°	81%	78%	.724			
Both angles within 10%	97%	99%				
Both angles within 5%	57%	71%	.053			

Table 3						
Accuracy of Various Techniques Reported in the Literature						
Technique	Abduction Target ±10°	Anteversion Target ±10°	Both Angles Within 10°			
Callanan et al <sup>15</sup>	63%	79%	50%			
Posterior approach <sup>22</sup>	80%	91%	76%			
Anterior, no fluoroscopy <sup>26</sup>	75%	79%	59%			
Three-dimensional planning assisted <sup>25</sup>	86%	93%	79%			
First 100 direct anterior approach with fluoroscopy <sup>22</sup>	94%	93%	87%			
Experienced direct anterior approach with fluoroscopy <sup>26</sup>	98%	99%	97%			
Surgical positioning software	100%	99%	99%			

to function properly and correctly identify all necessary bony landmarks. In the case of the second cup, which was overly anteverted, following the software would have put the cup closer to the target angle.

The exact target angle for an acetabular component is debatable, with more recent data suggesting that there may be different targets between individuals. It is now recognized that there is a dynamic relationship between the spine and the



pelvis, with the pelvic position change between sitting and standing varying between individuals.<sup>28</sup> The ideal cup position to prevent impingement and dislocation for any one patient likely depends on this relationship. If a preoperative target can be determined, technology such as cup positioning software may improve the ability to reach that specific patient goal.

Each technology or approach aimed at improving cup positioning has pros and cons. Use of internal anatomic landmarks or commonly available alignment guides adds little time and cost, yet fails to achieve high levels of accuracy and precision.<sup>29,30</sup> Although computer-assisted surgery and/or robotic surgery offer high accuracy and precision,<sup>31</sup> they have substantial expense and add time intraoperatively. These often require preoperative computed tomography scans, which expose patients to additional radiation, cost, and time. Intraoperative fluoroscopy is a well-established, commonly taught technique that is growing in popularity. Use of the software with the standard fluoroscopy routine adds little time (more than 2 minutes to the surgery and less than 2 seconds for fluoroscopy, on average) and cost.

### CONCLUSION

This study has documented the results of surgical positioning software in conjunction with intraoperative fluoroscopy for anterior approach THA. Although the results were good in both arms of the study, the accuracy and the precision of the software-placed cups were superior. The authors continue to use this software to aid in component placement.

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