Real-Time Fluoroscopic Navigation Improves Acetabular Component Positioning During Direct Anterior Approach Total Hip Arthroplasty

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Abstract

We investigated whether a novel, real-time fluoroscopy-based navigation system optimized component positioning and leg length in fluoroscopically aided direct anterior approach total hip arthroplasty (DAA-THA). We retrospectively reviewed 75 fluoroscopically assisted DAA-THA performed by a single surgeon: 37 procedures used the software intraoperatively to overlay anteversion, inclination, and leg length information over the existing fluoroscopic radiograph with the aim of enhancing component positioning. The control group consisted of 38 procedures from the single surgeon's patient pool who had undergone non-navigated fluoroscopic assisted DAA-THA 1 month prior to the system's trial. Our results demonstrate that the navigation group measurements were significantly closer to the target numbers with less variation. The mean difference from target value were as follows: for anteversion (control: -4.68°, navigated: -01.0°), inclination (control: -1.87°, navigated: 0.8°), and leg length discrepancy (control: -2.59°, navigated: -0.98°). In addition, surgical time was shorter in the navigation group (75.7 vs. 74 minutes; p = 0.001). The real-time feedback and calculations provided by the navigation software provided a reproducible precision for component positioning and leg length measurement during DAA-THA.

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Total hip arthroplasty (THA) is one of the most commonly performed surgeries in the USA and the demand is estimated to grow by 174% to 572,000 per year by 2030.[1] As more surgeons perform these procedures, it should be the collective goal to prevent the rise in revision surgeries from matching the increase in primary THAs. This project is particularly relevant as the leading cause of revision surgery is acetabular component malpositioning, which could lead to instability and accelerated component wear.[2] One proposed method of improving THA outcomes is by enhancing intraoperative technique in a manner that enhances component positioning. Traditionally, this has been achieved through learning curves consisting of high surgery volumes. Numerous types of intraoperative navigation systems have been devised for THA surgery with the proposed benefit of minimizing human error while reducing the learning curve of component positioning.

Our goal was to evaluate whether a novel, real-time fluoroscopy-based navigation software (Radlink Inc., El Segundo, California, USA) would improve component positioning and leg length in direct anterior approach THA (DAA-THA).[3] This software system overlays anteversion, inclination, and leg length data over the existing fluoroscopic image in the operating room in real time. This system wirelessly links to the fluoroscopic image and does not require any preoperative set up time or check point registration. The aim of this study was to comparatively evaluate the efficacy of navigated fluoroscopically assisted DAA-THA as it relates to acetabular component positioning (version and inclination) and radiographic leg length assessment.

Materials and Methods

Study Design

An observational retrospective cohort study was performed at a tertiary academic center. Prior to chart review and data analysis, Institutional Review Board (IRB) approval was

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obtained. All participants included in this study underwent DAA-THA by the senior author (RD). The navigation-assisted cohort consisted of a continuous series of patients undergoing primary DAA-THA in June 2016. No patients operated on within this window were excluded. The control cohort consisted of a continuous series of non-fluoroscopically assisted DAA-THA in May 2016. Patient demographic information and intraoperative data was abstracted from all patients included in this study. Variables including patient age, sex, body mass index (BMI), laterality, surgical time in minutes, and American Society of Anesthesiologists (ASA) score were collected.[4] The ASA score is a validated method of risk stratifying surgical candidates based on their comorbidity profile.

In order to compare the effectiveness of the navigation software, three clinically relevant perioperative outcomes including were assessed: 1. acetabular component anteversion (degrees), 2. inclination (degrees), and 3. leg length discrepancy (LLD; mm). In addition, 90-day complication rates were compared between the navigation-assisted and control DAA-THA cohorts. Historically, acetabular component positioning was targeted at 15° ± 10° anteversion and 40° ± 10° inclination.[5] To further reduce poor positioning and subsequent complications, many groups have fine-tuned their target safe zones. Biedermann et al.[6] concluded in their cohort that 15° of anteversion and 45° of abduction (inclination) were optimal. For the purpose of our study we narrowed the safe zone to 15° to 20° anteversion and 40° of inclination. Unlike previous studies, we included a LLD assessment for all patients. In our study, our threshold was a difference of less than 2 mm, however less than 10 mm per differences established in previous literature was considered acceptable.[7] The difference between the target values among the cohorts was comparatively evaluated to assess whether clinical outcomes varied with the use of real-time navigation software. All three radiographic data points for the experimental group were measured by the senior surgeon (RD) using intraoperative anterior-posterior fluoroscopic images. The three radiograph data points for the control group were measured on immediate postoperative anteroposterior (AP) radiographs (within 24 hours of surgery) by one orthopedic surgery resident using the Radlink software. We uploaded the AP radiograph to the software and used the same steps and landmarks as we would intraoperatively to measure version, inclination, and leg length discrepancy. Using the software, we first measured leg length discrepancy by using the inter-teardrop line and then measured the perpendicular distance from this line to the most medial tip of the lesser

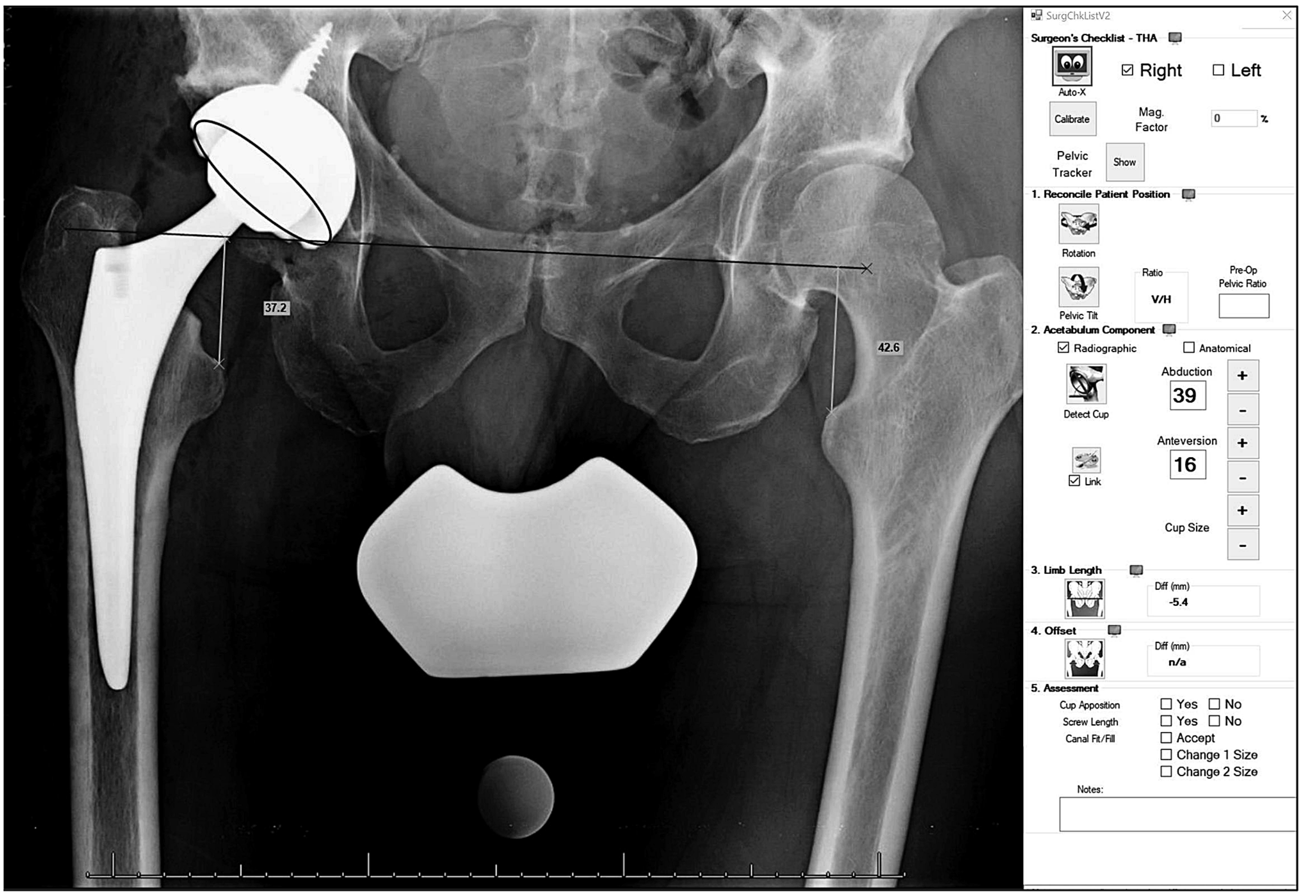

Figure 1 Leg length discrepancy, anteversion, and inclination on a control radiograph.

trochanter.[8] For anteversion, the software generated an elliptical template and measured the acetabular cup version.[9,10] Finally, it measured inclination by assessing the angle between the greater diameter of the cup face and a parallel line to the ischial tuberosities.[11] Figure 1 demonstrates these three measurements on a control radiograph.

Statistical Analysis

Baseline characteristics and outcomes were comparatively assessed between patient cohorts using the navigation platform and control. In order to be classified as a confounding factor, the variable must meet the following three criteria. It must be associated with the exposure (navigation-assisted or traditional DAA-THA), associated with the outcome (e.g., anteversion, inclination, LLD, and postoperative complications), and must not be on the causal pathway between the two.[12] All covariates were assessed to determine their statistical significance and potential presence as a confounding factor. Unadjusted analysis was then conducted if no variance was identified between the covariates. Chi-squared tests for categorical covariates (i.e., sex, laterality, and ASA) and t-tests for continuous covariates (i.e., age, BMI, and surgical time) were used to test for an association with exposure (i.e., surgical method: navigation software versus control). All statistical analyses were performed using SAS v9.4 (SAS Institute; Cary, North Carolina, USA). A p-value of < 0.05 was considered statistically significant.

Results

Baseline Demographics

A total of 75 patients were included in this study. Thirty-seven patients operated on in June 2016 were included in the navigation DAA-THA cohort. A comparative control cohort of 38 patients were selected from May 2016, prior to the implementation of the navigation software, and designated as the conventional DAA-THA cohort. There was no significant variance among the study arms in regard to demographic variables including age, sex, laterality, BMI, and ASA score (Table 1).

Perioperative Outcomes

In regard to perioperative outcomes, surgical time was shorter in the navigation cohort (75.7 versus 74 minutes; p = 0.001). When examining the difference from target values, navigation-assisted DAA-THA was associated with significantly less variation in anteversion, inclination, and LLD (Figs. 2, 3, and 4). In comparing the control and navigation cohorts, mean acetabular cup anteversion was measured at 15.32º ± 2.82º and 19.0º ± 3.16º, inclination of 38.13º ± 4.11º and 40.8º ± 3.59º, and LDD of 4.59 mm ± 3.26 mm and 1.02 mm ± 1.24 mm, respectively (Table 2; Figs. 2, 3, and 4). As the study had less than 100 observations, we felt it would be telling to include the median and range in addition to the mean and standard deviation. These values are also included in Table 2 as outliers and are helpful in understanding this software's effect on LLD. Additionally, only one complication was documented in each cohort. In the control group, there was one intraoperative femur fracture (a proximal cortical perforation treated with a longer stem through the same approach), while in the experimental group there was one periprosthetic femur fracture 42 days after the primary surgery (revised to a longer stem). No periprosthetic infections or dislocations were identified in either group.

Discussion

Total joint replacements comprise two of the most common elective surgical procedures covered by Medicare, and as such a significant amount of effort has been allocated to improving postoperative outcomes in a value-based manner.[13] Maximizing outcomes and streamlining treatment pathways are essential if high quality and reliable care is to be delivered. The majority of patients receiving THA report excellent outcomes, however, a substantial cohort of patients report poor postoperative outcomes often due to prevent-

Table 1 Characteristics of Navigation and Control Patients

Characteristics	Control (N = 38)	Navigation (N = 37)	P-value
Age (years), N (SD)	64.4 (± 8.3)	67 (± 9.9)	0.221
Body Mass Index (kg/m^2), N (SD)	27.5 (± 5.3)	27 (± 5.2)	0.681
Sex, N (%)			
Male	14 (36.8)	15 (40.5)	0.815
Female	24 (63.2)	22 (59.5)	
Laterality, N (%)			
Right	23 (60.5)	18 (48.6)	0.357
Left	15 (39.5)	19 (51.4)	
ASA Score, N (%)			
1	4 (10.5)	2 (5.4)	0.515
2	28 (73.7)	26 (70.3)	
3	6 (15.7)	9 (24.3)	
4	0	0	

Table 2 Perioperative and Radiographic Outcomes

Intraoperative Variables	Target	Control	Navigation	Control	Navigation	Control	Navigation	P-value
		Mean (SD)		Mean Difference (SD)		Median (range)		
Anteversion	20°	15.32° (± 2.82°)	19.0° (± 3.16°)	-4.68° (± 2.82°)	-1.0° (± 3.16°)	16° (9°-22°)	19° (13°-25°)	< 0.0001
Inclination	40°	38.13° (± 4.11°)	40.8° (± 3.59°)	-1.87° (± 4.11°)	0.8° (± 3.59°)	37° (29°-47°)	41° (34°-48°)	0.0007
Leg length discrepancy (mm)	2 mm	4.59 mm (± 3.26)	1.02 mm (± 1.24)	2.59 mm (± 3.26)	-0.98 mm (± 1.24)	4.1 mm (0.2-13.7)	0.7 mm (0-5.7)	< 0.0001
Surgical time (minutes)	-	75.7 (± 15.4)	74 (± 13.4)	—	—	—	—	0.0001

*P-values for anteversion and inclination are from unadjusted analyses; p-values for leg length discrepancy and radiation are from adjusted analyses due to the presence of confounding variables.

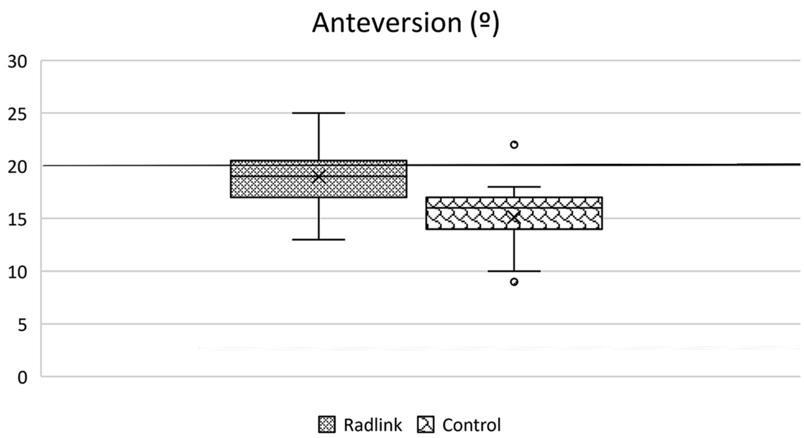

Figure 2 Anteversion of navigation versus control.

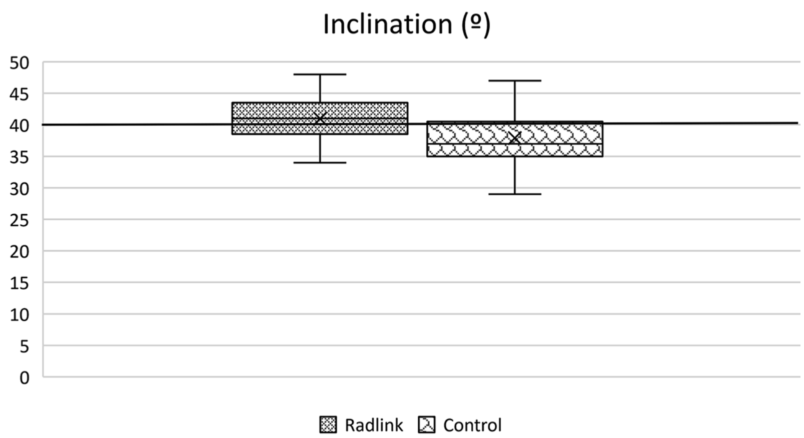

Figure 3 Inclination of navigation versus control.

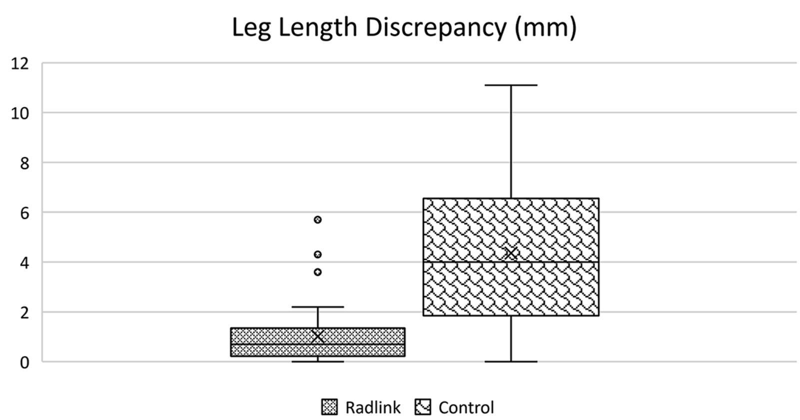

Figure 4 Leg length discrepancy of navigation versus control.

Table 3 Complication Rates

Cohort	Complication Rate	During Procedure	90-Day Postoperative Complications
Control	(1/37) 2.7%	1 intraoperative femur fracture	None
Navigation	(1/37) 2.7%	None	1 periprosthetic femur fracture

able complications related to poor component positioning. In particular, poor positioning of the acetabular cup has been identified as the leading cause for dislocations and is estimated to be responsible for 22% of all THA revisions and 33% of acetabular revisions.[14,15] A study by Kennedy et al.[16] demonstrated how improper acetabular component positioning can lead to rapid progression of polyethylene wear, pelvic osteolysis, acetabular migration, and recurrent dislocation. In response, several navigation and robotic-assisted platforms have been developed for the purpose of guiding surgeons when positioning THA components, potentially reducing the risk for component malpositioning and other related complications.

Integration of navigation technology for the purpose of optimizing component positioning can reliably and reproducibly improve alignment and may positively effect clinical outcomes. A study by Nam et al.[17] reported that computer navigation resulted in 91% of acetabular components within 40° ± 10° and 15° ± 10° for acetabular abduction (inclination) and anteversion compared to only 70% within those ranges for the freehand technique. In addition, as less invasive approaches are used, there may be greater risk of malpositioning due to inadequate exposure. Computer navigation can be one solution for these unforeseen complications, allowing surgeons to more reproducibly position components.[18] Although, mid- and long-term follow-up studies on the available navigation platforms are lacking, the short-term data suggests improved acetabular component alignment and decreased leg length discrepancy.

Our study demonstrates that navigation-assisted fluoroscopic DAA-THA can decrease the variability and human error associated with acetabular positioning, thus potentially enhancing clinical outcomes. The increased reliability and reduced range in acetabular inclination, version, and leg length discrepancy with the use of navigation—seen through the reduction in number of outliers—confirmed our hypothesis that using real-time imaging software can standardize acetabular positioning reducing intraoperative variability. Ninety-day complication rates (Table 3) among the cohorts were similar, however, we predict that the more accurate positioning of the acetabular cup may enhance long-term implant wear properties and survivorship.

The real-time feedback added a mathematical precision to THA that may be helpful even among high-volume surgeons. Surgical times were slightly decreased in the navigation group compared to the control group (74 versus 75.7 minutes, $p = 0.001$). The small decrease in operative time could become clinically significant over time, as surgeons adapt to the learning curve of using the software, further streamlining and increasing efficiency of this procedure. Furthermore, this system did not alter the surgeons workflow since no checkpoints or sensors are utilized.

In addition to decreasing surgical time, navigated instrumentation has the capacity to reliably improve component positioning potentially enhancing postoperative outcomes. This may be particularly true among surgeons with lower procedural volume, as they often have fewer opportunities to refine their procedural precision. The measured anteversion, inclination, and LLD of the navigated cohort were all closer to previously established target values. A recent meta-analysis of computer navigation in THA showed its success in reducing the number of outliers in multiple measured aspects of the surgery.[19] Computer navigated component placement also has potential in complex THAs. Perfetti et al.[20] investigated the increased dislocation and revision rate of THAs in patients with previous spinal fusion surgeries and found that these patients were 7.19 times more likely to dislocate and 4.64 times more likely to undergo revision THA. Although revision THA candidates were not included in our study, these patients undergoing revision hip arthroplasty may also benefit from navigated instrumentation. Akiyama et al.[21] reported that the use of computer-assisted fluoroscopy in revision THAs resulted in superior outcomes for removing distal femoral bone cement. In summary our study illustrates that navigation in primary THA can provide a safe and reliable method for the acetabular cup positioning.

Limitations

There were several limitations to our study. First, only one surgeon was included in this trial potentially confounding results. Incorporating additional surgeons may strengthen the study by introducing variability in surgical skill allowing us to more critically assess the impact of navigated-assisted THA. However, this lack of operative variability also illustrates that this fluoroscopy-based navigation system can, within a short period of time, improve component positioning and reduce leg length discrepancies even in experienced hands. Another limitation is the sample size. Although we had less than 100 subjects, all of our data points met statistical significance. In addition, our study and results are in line was a meta-analysis conducted by Beckmann et al.[22] that explored navigation in THA in a variety of smaller scale studies similar to our size and concluded "navigation as a reliable tool in optimizing cup placement and minimizing outliers." A third limitation of our study is the short time period over which the trial of the software took place. Total hip arthroplasty candidates within the treatment arm were operated on in a 1-month period due to the trial period provided by the software's company. As with any new technology, there is a learning curve that effects its impact and success rate. Not only could surgical time further decrease with more use of the software, but also a longer trial would allow the impact of fine tuning measurements and potentially decreasing complication rates to emerge. Despite these limitations, our study demonstrates that this real-time navigation software may effectively guide the surgeon when dialing in acetabular version and inclination during DAA-THA.

Conclusion

Our study indicated that integrating real-time fluroscopically based navigation software enhanced component positioning and leg length assessment during DAA-THA, potentially improving clinical outcomes and implant survivorship. Based on these results we are now routinely using this navigation system for DAA-THA.

Disclosure Statement

Roy I. Davidovitch, MD, receives royalties from and has stock options with Radlink. None of the other authors have a financial or proprietary interest in the subject matter or materials discussed herein, including, but not limited to, employment, consultancies, stock ownership, honoraria, and paid expert testimony.

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