intellijoint HIP® Anterior

Disrupting Traditional Navigation: Quantifiable, Intraoperative Cup Position Accuracy without Fluoroscopy

ANTEVERSION
ACCURATE TO WITHIN **0.65°**

ACCURATE
INTRA-OP CUP POSITION
WITHOUT FLUORO

INCLINATION
ACCURATE TO WITHIN **0.47°**

INTRODUCTION

The direct anterior approach (DAA) for total hip arthroplasty (THA) is the preferred surgical method for a growing number of surgeons worldwide and is increasing in popularity (1). The proposed benefits of this approach include its potential for muscle-sparing and the potential to improve post-operative patient outcomes. Indeed, studies have associated DAA with decreased hospital time (2,3), decreased patient-perceived pain (4), and improved functional rehabilitation (2,3) when compared to other approaches. However, there is risk for component malposition. Patient-related factors including body mass index (BMI) (5) and anatomical features such as a wide or horizontal iliac wing (6), as well as surgical factors such as incision size and location (7), may interfere with and limit the access available to place components accurately.

The correct placement of the acetabular component in THA is essential to the success of the surgery and long-term stability of the hip joint prosthesis (8–10). Increased component wear (11–14), risk for impingement (15), probability of revision surgery (9,10,16), and metallosis (17,18) have all been described as a result of malposition. One advantage of DAA is that patients are typically placed in the supine position during surgery, making this approach amenable to the utilization of C-arm fluoroscopy throughout the procedure. This visual aid may assist surgeons with correctly selecting and positioning the acetabular component intraoperatively (19). However, the process disrupts the surgical workflow and requires that surgeons and some surgical team members wear heavy lead aprons throughout the procedure. The imaging equipment itself must also be transported into the operating room (OR) during surgery, adding a further delay and potentially exposing the patient to sources of infection. These factors, in addition to a substantial learning curve associated with utilization of C-arm fluoroscopy in DAA THA (19,20), suggest that this approach may not be suitable for surgeons and institutions. Despite the qualitative advantage of C-arm fluoroscopy, a demand for accurate and quantitative intraoperative measurements remains.

Figure 1: **intelli**joint **HIP** Anterior Application

> Despite the qualitative advantage of C-arm fluoroscopy, a demand for accurate and quantitative intraoperative measurements remains.

An emerging method in computer-assisted navigation for THA is utilization of **intelli**joint **HIP**® Anterior, a 3D mini-optical navigation device that provides imageless, intraoperative measurements for cup placement (CP), leg length (LL), offset (OS), and hip center of rotation (COR) in real time. First described in THA cases performed using the lateral approach, **intelli**joint **HIP** was found to provide accurate intraoperative measurements for LL, OS, and CP in both cadaver and clinical studies (21–23). However, the use of **intelli**joint **HIP** Anterior in DAA THA is uncharacterized. The objective of the present study was to evaluate the ability of **intelli**joint **HIP** Anterior to accurately quantify measurements for CP (anteversion and inclination) in benchtop validation simulations of DAA THA.

METHODS

STUDY DESIGN

This study utilized DAA THA benchtop validation, performed between 22-April-2016 and 27-April-2016. Precision phantoms were used for benchtop simulations, in which anteversion and inclination measurements obtained by **intelli**joint **HIP** Anterior were compared against known angular values.

INTELLIJOINT HIP ANTERIOR WORKFLOW

A detailed explanation of the mini-optical navigation device has been previously described (24). In brief, **intelli**joint **HIP** (Intellijoint Surgical, Inc., Waterloo, ON, Canada) is a 3D mini-optical navigation system for use in THA that integrates into standard surgical workflow with minimal disruption. The system contains a camera, probe, and tracker located within the sterile field. Using optical technology, infrared light, and integrated microelectronics, the system captures real-time data regarding cup position and relays it to a workstation, located outside of the sterile field but in view of the surgeon (Figure 1). The data is displayed on the workstation monitor and is available to the surgeon to reference at any time throughout the surgery (Figure 2 & Figure 3).

intellijoint **HIP** Anterior integrates into standard surgical work flow with minimal disruption.

The anterior application of **intelli**joint **HIP** utilizes the same hardware as the lateral application, with slight modifications resulting from a difference in patient positioning (lateral decubitus vs. supine). In lieu of attachment of the pelvic platform to the lateral aspect of the ipsilateral iliac crest as in the lateral application, in the anterior application, the screws supporting the pelvic platform are inserted into the anterior aspect of the iliac crest. This installment can be done on either the ipsilateral or contralateral side at the preference of the surgeon. As in the lateral application, a small femoral platform is subsequently attached to the greater trochanter. The registration method of the anterior application is unique and is accomplished using the tracker and probe to register the patient in either the anterior pelvic plane (APP), or the coronal plane. When registering the APP, surgeons use the probe to mark the left and right anterior superior iliac spine (ASIS) and the symphysis pubis, with each location captured by the system camera. When registering the coronal plane, only the bilateral ASIS are probed and recorded. Following dislocation and acetabular reaming, the tracker can be positioned onto the impactor to provide real-time measurements of anteversion and inclination to assist with cup implantation. Once seated, trial reductions and final cup and leg length measurements can be measured and saved, accordingly.

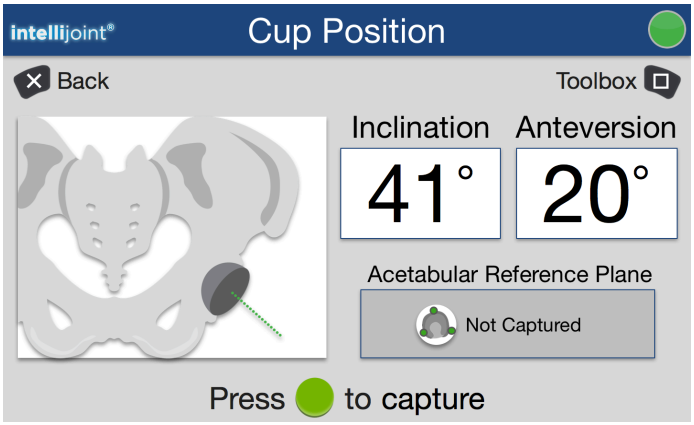

Figure 2: **intelli**joint **HIP** Anterior - Cup Position

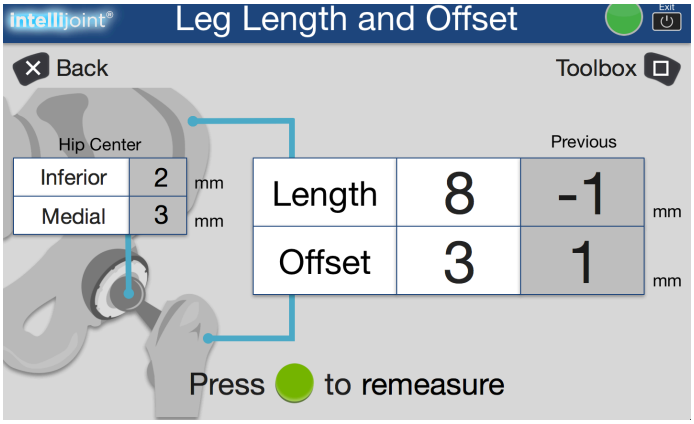

Figure 3: **intelli**joint **HIP** Anterior - LL, OS, COR

BENCHTOP VALIDATION TESTING

Two precision benchtop phantoms (Thorlabs, Newton, New Jersey) were developed to provide accurate reference values for positional measurements. Cup position (anteversion and inclination) was evaluated and all measurements were completed by a single observer. To test acetabular cup position, the phantom used angular positioning stages and precision fixtures to mimic precise cup angles. Vertical and horizontal rotation stages were set at discrete angles that corresponded to impactor inclination and anteversion angles commonly observed during surgery. A calibrated electronic level confirmed angles prior to device testing. During device testing, a precision flat plate and v-channel, mounted on the rotation stages, established the precise acetabular/implant and impactor planes, respectively. The probe function of the **intelli**joint **HIP** Anterior was used to determine the acetabular reference plane and implant face. The cup impactor with the device tracker attached was then inserted into the v-channel to determine cup angle. Measurements were performed bilaterally to simulate both left and right hips and a variety of inclination and anteversion angles were used to simulate likely cup positions encountered in surgery. Measurements obtained by the **intelli**joint **HIP** Anterior were compared with the target values.

STATISTICAL ANALYSIS

Statistical comparisons were made with alpha set a *priori* at 0.05. Independent samples t-tests and/or single-factor ANOVA were used to compare means, presented as mean [95% CI] or mean (SD).

RESULTS

ANTEVERSION

Reference target anteversion angles of 0°, 15°, and 30° were used across 20 separate simulations during the benchtop validation testing. There was no statistically significant difference between the reference anteversion angle and the anteversion angles measured by **intelli**joint **HIP** for either the native anteversion angle (P=0.99) or the simulated artificial cup anteversion angle (P=0.95). The absolute mean difference between the native acetabular anteversion values and measurements obtained by the probe of **intelli**joint **HIP** was 0.66° (0.37). The absolute mean difference between artificial cup anteversion values and the values obtained by **intelli**joint **HIP** using the impactor was 0.47° (0.19). These results are summarized in Table 1.

INCLINATION

Reference target inclination angles included 0°, 15°, 30°, 45°, and 60° across 20 separate simulations. Similar to the results for anteversion, no statistically significant difference was observed between the reference inclination angle and the inclination angles measured by **intelli**joint **HIP** for either the native inclination angle (P=0.99) or the simulated artificial cup inclination angle (P=0.98). The absolute mean difference between the native acetabular inclination values and measurements obtained by the probe of **intelli**joint **HIP** was 0.54° (0.26). The mean absolute difference between artificial cup inclination values and the values obtained by **intelli**joint **HIP** using the impactor was 0.65° (0.32). These results are summarized in Table 1.

DISCUSSION

Despite the high success rate of THA, a subset of patients experience post-operative complications that result in extensive rehabilitation therapy and/or patient readmission. Correct positioning of the acetabular component is essential for patient satisfaction and long-term preservation of the prosthetic hip joint. However, surgeons generally lack accurate quantitative measurements for cup positioning intraoperatively. The present study evaluated the ability of **intelli**joint **HIP** Anterior to accurately measure inclination and anteversion values in benchtop-simulated DAA THA. The device accurately measured both parameters in comparison to the known target values to within less than 1°. This mini-navigation device may therefore represent a simple and effective solution for measuring inclination and anteversion during THA.

Surgeons have traditionally relied on experience, utilization of manual measurement tools such as calipers, or utilization of intraoperative methods like tissue tensioning, to properly select and position prosthetic components during THA. The primary drawback of these methods; however, is that they are not quantifiable. In addition, much of their success is based on surgeon experience and subjective intraoperative feedback. There is also the significant drawback of not providing data regarding cup position. This is of importance for DAA especially, as it has been described that correctly positioning components may prove difficult given certain patient- and surgical-related factors (5–7).

C-ARM RADIATION

- A steep learning curve has been described for utilization of C-arm fluoroscopy in DAA THA [20,25–27]
- C-arm usage is an additional risk for the patient and OR personnel alike.

In DAA THA, the use of C-arm fluoroscopy is common, as it provides surgeons with real-time visualization of the operative hip and can assist with selection and placement of the acetabular cup. However, a steep learning curve has been described for utilization of C-arm fluoroscopy in DAA THA (20,25–27), and the equipment itself adds the risk of introducing contamination to the surgical field, which could subsequently result in infection (28,29). Similarly, the radiation exposure associated with C-arm usage is an additional risk for the patient and OR personnel alike. This factor has been addressed in studies considering the risk of exposure to both the patient and surgeon (30,31). Surgeons practicing anterior approach THA have been shown to reach half of the recommended maximum radiation exposure of 2000 mrem/year within their first 100 cases (27,32). High volume surgeons (>189 cases/year) regularly exceed

Table 1. Summary of the difference between the reference values and the values measured by the navigation tool

Measure	Inclination		Anteversion	
	Native acetabulum	Acetabular cup component	Native acetabulum	Acetabular cup component
Mean difference (°)	0.54	0.65	0.66	0.47
Standard Deviation	0.26	0.32	0.37	0.19

the maximum exposure, thus exposing themselves to potential long-term effects on their overall health (27,32). Given the jurisdictional differences in radiation exposure limitations, which see more stringent limitations internationally versus in the United States (33), and the recently adopted ALARA (As-Low-As-Reasonably-Achievable) philosophy to establish safe radiological practices, any means by which C-arm fluoroscopy use during THA can be minimized should be pursued. The use of a mini-optical navigation system such as **intelli**joint **HIP** may prove to be such an alternative solution.

C-arm fluoroscopy, in addition to disrupting the surgical workflow, also necessitates the use of heavy lead aprons, worn by the surgeon and some surgical team members as THA is performed. A study by Ross et al (34) identified statistically significant differences between surgeons who wear heavy lead aprons versus those who do not for a variety of quality of life parameters. Specifically, prolonged use of heavy lead aprons was associated with increased axial skeletal complaints, frequency of missed days from work secondary to neck or back pain, cervical disc herniations, and multiple level disc herniations. The authors propose these results confirm the existence of "interventionalist's disc disease", a distinct occupational hazard influenced by the ergonomic impact of wearing heavy lead aprons in surgery.

The recent introduction of traditional computer-assisted navigation to orthopaedic surgery has provided surgeons and hospitals with the opportunity to obtain quantifiable, intraoperative measurements for THA. Utilization of computer-assisted navigation could mitigate the surgical shortcomings of C-arm fluoroscopy and potentially facilitate its removal from use in the OR, however, adoption of traditional computer-assisted navigation into orthopaedic surgery is sparse (35). Notably, many traditional computer-assisted navigation systems are expensive and cumbersome to use (36,37), and add significantly to surgical time (38). These drawbacks have thus limited the use of traditional computer-assisted navigation to less than 3% of THAs (35). An advantage of **intelli**joint **HIP** Anterior, however, is its ability to integrate into standard surgical workflow with minimal disruption. Requiring only 2 stab incisions on the iliac crest and a small platform fixed to the greater trochanter with a single screw, the mini-optical navigation device easily integrates without lengthening surgical time. This benefit, paired with the device's considerable accuracy, may allow for a decrease in the reliance on C-arm imaging and its associated shortcomings during anterior THA.

Importantly, the present study addressed the ability of **intelli**joint **HIP** Anterior to accurately measure anteversion and inclination values within a controlled, DAA THA-simulated benchtop validation test. This device has been clinically investigated with the lateral approach, showing leg length measurements accurate to within 0.6 mm of standard postoperative radiographic measurements in patients undergoing primary THA (21). Additionally, cadaver studies compared the accuracy of the **intelli**joint **HIP** platform with CT results for measurements of anteversion and inclination. In one study, **intelli**joint **HIP** was shown to accurately measure anteversion and inclination values to within less than 1° of CT images (22). In a second study, patient registration error was taken into consideration, and the device was able to accurately measure anteversion and inclination values within statistical and clinical limits of acceptability when compared to standard postoperative radiographic images (23). The data in the present study is the first available for the **intelli**joint **HIP** platform in DAA THA. Clinical studies to further evaluate the accuracy of this application are currently underway.

CONCLUSION

This study demonstrated the features of **intelli**joint **HIP** Anterior to measure artificial cup anteversion and inclination angles to within 0.47° and 0.65° of target benchtop values, respectively. This mini-optical navigation device may not only provide a practical alternative to traditional navigation to improve accuracy in component placement during THA, but could potentially offer surgeons intraoperative advantages over C-arm fluoroscopy in DAA THA, specifically. Clinical studies evaluating intraoperative accuracy of the device are required moving forward.

intellijoint **HIP** Anterior may not only provide a practical alternative to traditional navigation to improve accuracy in component placement during THA, but could potentially offer surgeons intraoperative advantages over C-arm fluoroscopy in DAA THA, specifically.

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