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ORIGINAL ARTICLE

Defining the Learning Period of a Novel Imageless Navigation System for Posterior Approach Total Hip Arthroplasty: Analysis of Surgical Time and Accuracy

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Abstract

Introduction The use of imageless navigation in total hip arthroplasty (THA) is frequently associated with prolonged surgical times, predominantly during the learning period. The purpose of the present study was to characterize the learning period of a novel imageless navigation system, specifically as it related to surgical time and acetabular navigation accuracy.

Materials and Methods This was a retrospective observational study of a consecutive group of 158 patients who underwent primary unilateral THA for osteoarthritis by a team headed by a single surgeon. All procedures used an imageless navigation system to measure acetabular cup inclination and anteversion angles, referencing a generic sagittal and frontal plane. Navigation accuracy was determined by assessing differences between intraoperative inclination and anteversion values and those obtained from standardized 6-week follow-up radiographs. Operative time and navigation accuracy were assessed by plotting moving averages of 7 consecutive cases. The learning period was defined using Mann–Kendall trend analyses, student *t*-tests and nonlinear regression modeling based on surgical time and navigation accuracy. Alpha error was 0.05.

Results The average surgical time was 67.3 min (SD:9.2) (range 45–95). The average navigation accuracy for inclination was 0.01° (SD:4.2) (range − 10 to 10), and that for anteversion was − 4.9° (SD:3.8) (range − 14 to 5). Average surgical time and navigation accuracy were similar between the first and final cases in the series with no learning period detected.

Conclusions There was no discernible learning period effect on surgical time or system measurement accuracy during the early phases of adoption for this imageless navigation system.

Keywords Total hip arthroplasty · Computer assisted surgery · Learning curve · Imageless navigation · Accuracy

Introduction

The use of imageless computer navigation systems (CAS) for total hip arthroplasty (THA) has increased over the past decade. The implementation of CAS for THA has been shown to improve both the accuracy and precision of acetabular cup positioning relative to manual techniques [1], reducing rates of postoperative complications including dislocation [2].

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Apart from increased institutional costs, a potential deterrent for the use of CAS is increased surgical time, particularly during the learning period. In addition, inconsistent implant positioning and inferior postoperative outcomes have been reported during the learning period [3, 4]. The learning periods for different navigation platforms, including the HipAlign (Orthalign Inc, Aliso Viejo, CA), OrthoPilot (Aesculap Implant Systems LLC, Center Valley, PA) and Stryker Imageless Navigation (Stryker, Kalamazoo, MI) systems, have ranged from 5 to 49 cases for experienced surgeons [3, 5–7]. For patient safety, it is important for surgeons to understand the duration of the learning period for CAS.

On June 10th of 2020, the United States Food and Drug Administration (FDA) approved the use of a novel, miniature, imageless navigation for posterior approach THA. To date, there have been no investigations which have assessed the duration of the learning period associated with this navigation system. The purpose of the present study was to characterize the learning period of this CAS in terms of surgical time and acetabular navigation accuracy. We hypothesized that a learning period of ≤ 15 cases would be observed based on workflow similarities to other navigation platforms reported in the literature [5, 6].

Materials and Methods

Study Design

A retrospective review of a consecutive series of 158 patients who underwent primary, unilateral THA using a posterior approach between September of 2020 and December of 2021 was conducted. All cases were performed for a preoperative diagnosis of primary osteoarthritis, on patients ≥ 18 years of age, with the assistance of the Naviswiss Hip® CAS (Naviswiss AG, Brugg, Switzerland). The senior author began using the Naviswiss Hip® CAS in September of 2020. Patients who underwent THA through an anterior approach (93 patients) or revision THA (12 patients), who had unmeasurable 6-week radiographs due to pelvic mispositioning (31 patients), or who had cases assisted by a resident or fellow (146 patients) were excluded. This study received both Institutional Review Board (IRB) and Ethical Committee approval prior to initiation (06/03/21; IRB# 2021-0625). A waiver of informed consent was obtained to collect patient health information.

Surgical and Navigation Technique

All surgeries were performed by the same surgical team, led by a single devoted arthroplasty surgeon at the same urban high-volume orthopedic specialty hospital. A navigated acetabular cup placement of 40 ± 5° and 20 ± 5° for inclination and anteversion, respectively, was targeted for all procedures.

The CAS consisted of a handheld unit containing an infrared stereo camera and inertial measuring unit, which tracked the camera's positioning in space, along with the placement of optic tags. The pelvic tag was fixed using two pins inserted into the iliac crest, whereas the femoral tag was affixed to the greater trochanter. A caliper was used to establish a generic sagittal and frontal plane, to quantify acetabular cup inclination and anteversion. The purpose of the femoral tag was to assess changes in center of rotation, leg length and offset [8].

Outcome Variables

The primary and secondary outcome variables used to evaluate the learning period were surgical time, measured in minutes, from initial skin incision to final wound closure, and acetabular navigation accuracy, respectively. Using a previously published methodology [1, 5, 9], navigation accuracy was defined as the difference between CAS-generated values for intraoperative inclination and anteversion, and those derived from postoperative X-rays (6-week follow-up). Postoperative values for both inclination and anteversion were subtracted from system values (Raw accuracy), and thus a negative difference indicated that postoperative values exceeded system values. The absolute value (ABS accuracy) was computed for these differences to evaluate the overall magnitude of discrepancies in measurement.

Postoperative values for acetabular inclination and anteversion were obtained from 6-week follow-up supine pelvic X-rays. The imaging protocol was standardized by capturing a strict anteroposterior view centered on the pubic symphysis. The methodologies originally proposed by Lewinnek et al. [10] and Bachhal et al. [11] were used to measure acetabular inclination and anteversion, respectively. All radiographic measurements were validated by dual review from the first author-who did not participate in patient care-and the senior author.

Statistical Analysis

Descriptive statistics were used to report patient demographics. Continuous variables were reported as means, SDs and ranges. Categorical variables were presented as percentages. Using the methodology previously utilized by Maccario [12] and Wei [13] et al., the learning period was analyzed using the Simple Moving Average (SMA) method with subgroups of 7 cases. Changes in learning variables over case progression were visualized by plotting all SMA values on a Cartesian plane. A Mann–Kendall test was performed for surgical time to determine if a significant trend could be characterized from the plotted curve [12–15]. The presence of a learning period was also tested using nonlinear regression models for surgical time and ABS accuracy [12]. In addition to these analyses, we compared average surgical time and navigation accuracy between the first and final 20 cases in the series, using student *t*-tests. All tests were two-tailed. Alpha error was defined as 0.05. Statistical analyses were performed using Rstudio version 1.4.1717 (RStudio, PBC, Boston, MA) and SAS 9.4 (SAS Institute Inc., Cary, NC).

Results

Our cohort had an average age of 64.2 years [Standard Deviation (SD):11.1] (range 32–96), was 55.3% female, 84.3% White, 8.2% ethnically Latino and/or Hispanic, and had an average body mass index (BMI) of 29.7 kg/m^2 (SD:5.4) (range 19.6–46.8).

Table 1 A comparison between average surgical times and system accuracy between the first and final 20 cases in the series

Variable	20 case average		
	First	Final	p
Surgical time (min)	70.1	67.6	0.47
Raw inclination accuracy (°)	– 1.1	0.9	0.90
ABS inclination accuracy (°)	3.0	3.4	0.48
Raw anteversion accuracy (°)	– 4.8	– 4.1	0.57
ABS anteversion accuracy (°)	5.0	4.7	0.80

ABS absolute value

The average surgical time was 67.3 min (SD:9.2) (range 45–95). The Mann–Kendall analysis demonstrated that average surgical time did not change throughout the case series (Kendall's tau (T) = – 0.03; $p = 0.65$). Average surgical times were similar between the first and final 20 (70.1 vs. 67.6 min; $p = 0.47$) cases.

The average intraoperative inclination was 41.0° (SD:3.4) (range 30–54). The average radiographic inclination was 41.0° (SD:3.8) (range 32–52). The average Raw navigation accuracy for inclination was 0.01° (SD:4.2) (range – 10 to 10), and the average ABS accuracy was 3.4° (SD:2.4) (range 0–10). The average intraoperative anteversion was 17.9° (SD:3.3) (range 9–26). The average radiographic anteversion was 22.8° (SD:2.9) (range 14–31). The average Raw navigation accuracy for anteversion was – 4.9° (SD:3.8) (range – 14 to 5), and the average ABS accuracy was 5.2° (SD:3.3) (range 0–14). Average Raw/ABS navigation accuracy for inclination and anteversion were also similar between the first and final 20 cases (Table 1; Figs. 1, 2, 3).

Nonlinear regression modeling confirmed the absence of a learning period by demonstrating weak relationship

Fig. 1 Plot of 7-case simple moving averages for surgical time

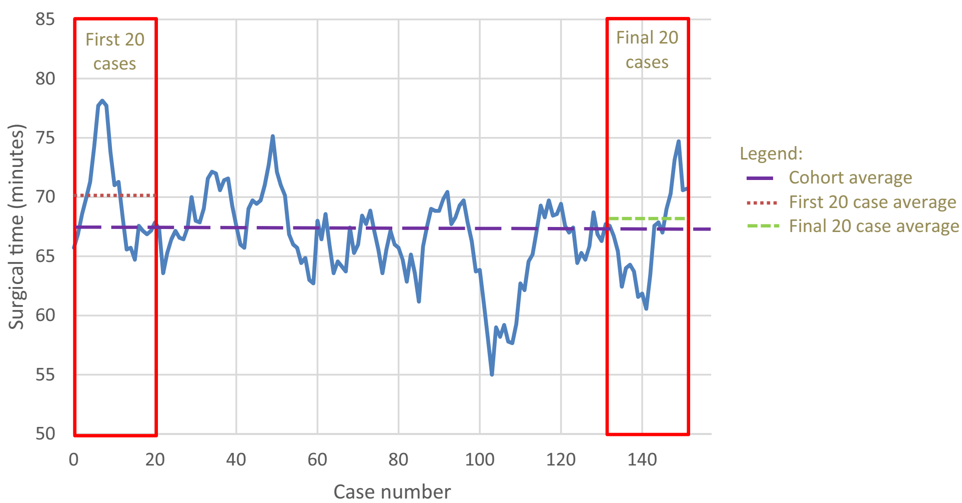
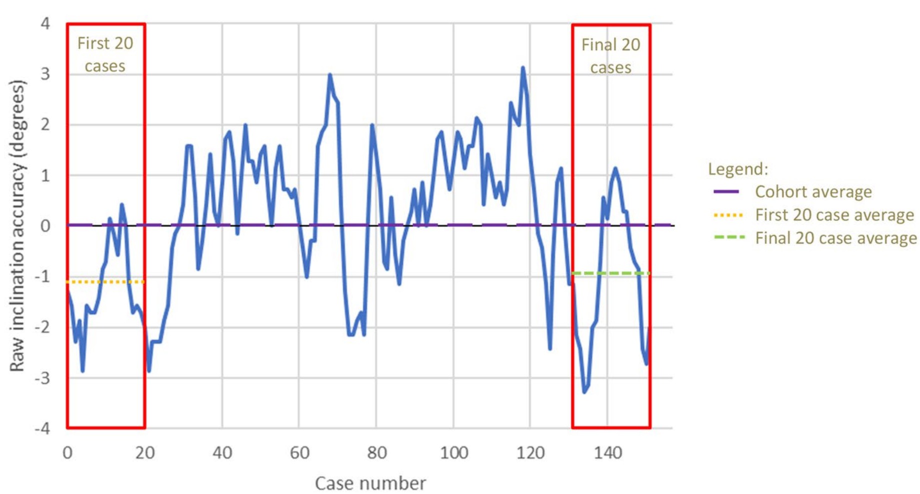
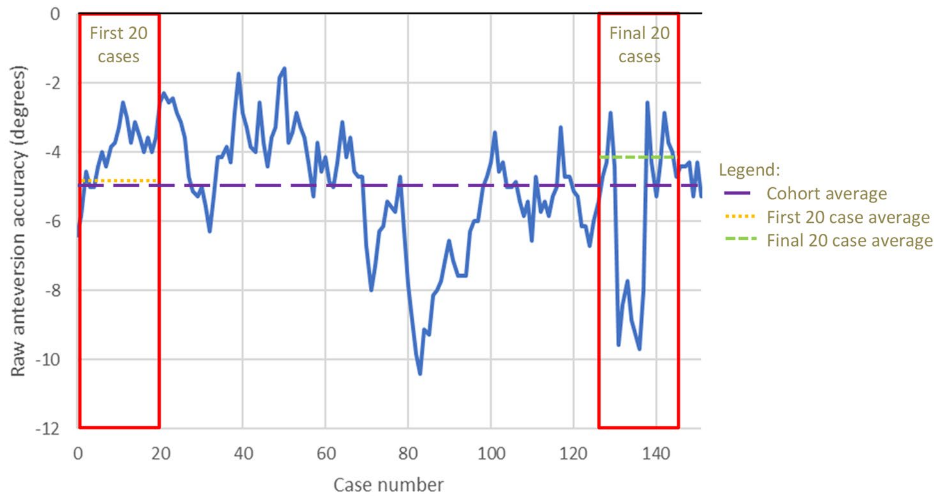


Fig. 2 Plot of 7-case simple moving averages for Raw inclination accuracy



Note: Values <0 indicate that radiographic values were larger than intraoperative values, and vice versa.

Fig. 3 Plot of 7-case simple moving averages for Raw anteversion accuracy



Note: Values <0 indicate that radiographic values were larger than intraoperative values.

between case number in the series and surgical time [Correlation coefficient (R) = − 0.11], ABS accuracy for inclination (R = 0.07), and ABS accuracy for anteversion (R = 0.03).

Discussion

Patients who undergo primary THA during the learning period for a new technology may experience prolonged surgical times and inferior outcomes compared to patients who undergo surgery after proficiency has been achieved [3, 4]. The early learning period for CAS in THA is estimated to range from 5 to 49 cases [3, 5–7, 16, 17]. The results of our investigation demonstrated that the adoption of this novel CAS for primary, posterior approach THA did not result in prolonged surgical times, or decreased acetabular cup placement accuracy. These findings, in conjunction with regression modeling, suggest an absence of a learning period for this system with regards to surgical time and navigation accuracy.

The first significant finding of our study was that use of the CAS did not result in longer surgical duration for earlier cases in the series. Our results support those of two previous studies [7, 18]. In an analysis of 100 patients who underwent minimally invasive posterolateral approach THA using the Stryker Imageless Navigation System, Najarian et al. found equivalent surgical times between the first and final 50 cases in their series (128 min vs. 124 min; $p = 0.51$) [7]. Notably, the average surgical time reported by Najarian et al. for the proficiency phase (124 min) was nearly two times longer than that of our study (67.3 min; Table 1). The authors surmise that this discrepancy may have been caused by differences in surgical approach, as well as differing intraoperative workflows between navigation platforms [7]. In contrast to our findings, a learning period with a longer surgical time was detected by other investigators who assessed the OrthoPilot and HipAlign navigation platforms used in anterolateral, posterior and transgluteal approach procedures [5, 6, 9]. The learning period of CAS may be modified by a number of factors including surgeon experience, surgical approach and system workflow [19]. The results of our investigation suggest that experienced surgeons seeking to utilize this novel CAS for posterior approach THA should experience minimal prolongation of operative time.

The second significant finding of this study was that there was no difference in accuracy for acetabular navigation between the first and final 20 cases in the series (Table 1). Previous investigation has demonstrated that the use of CAS for posterior approach THA presents several benefits compared to non-navigated procedures, including more accurate acetabular cup placement [2]. Our data align with those of Kamenaga et al., who conducted a review of 75 primary anterolateral approach THA procedures performed with the HipAlign CAS, finding no difference in Raw navigation accuracy for inclination and anteversion between the first and final 25 cases [5]. However, in another review of 60 primary transgluteal approach THA cases performed with the OrthoPilot CAS, Thorey et al. noted a significant difference in the mean Raw accuracy for cups placed during and after the learning period [9]. The authors interpret this data similarly to that of surgical time, in that the learning curve for cup placement accuracy may also be influenced by differences in surgical technique and workflow between navigation platforms. Regardless of the workflow used, surgeons should take special consideration to optimize precision and accuracy during the early phases of adoption for a new technology, in order to facilitate consistently favorable clinical outcomes irrespective of the learning period [2–4].

This study had a number of design strengths, including the large number of consecutive cases incorporated into the analysis, as well as the stringent selection criteria which reduced confounding by different surgical approaches, surgeon experience levels, institutional practices and patients demographic or surgical factors. Despite these strengths, there were still several limitations to these findings. First, the retrospective design introduced potential for documentation biases in that not all patient data was possible to obtain. Second, despite the primary physician being new to the CAS at the start of our study, he is a devoted arthroplasty surgeon beyond the learning period for posterior approach THA. Surgeon experience has been found to modify the duration of the learning curve for navigated THA [20]. Third, this investigation involved the learning experience of a single surgeon, and so our findings may not be generalizable to other practitioners. Differences in surgical technique, including approach and patient table positioning have also been demonstrated to impact the duration of the learning period [19]. Fourth, while only primary cases were selected, it is possible that case complexity fluctuated between patients based on individual anatomical factors, which may have impacted calculations for the learning period. Fifth, the learning period may have extended beyond the 159 cases included in our analysis. While possible, this is unlikely given that the learning periods of related systems are confined to less than 50 cases [3, 5–7]. Sixth, the findings of our study describe the learning period of a single navigation platform and are not applicable to those of other manufacturers due to differences in workflow [5–7]. Lastly, acetabular inclination and anteversion were measured using radiographs, as opposed to computerized tomography (CT) images. To ensure high-quality measurements, all radiographs received dual review from the first and senior author to mitigate measurement inaccuracy. Overall, the authors do not believe that these limitations have significantly biased the results of our investigation.

Conclusion

The results of this investigation suggest that a specialized arthroplasty surgeon should not experience a learning period characterized by prolonged surgical times or decreased navigation accuracy during the early phases of using this novel imageless navigation system. These findings can be used by surgeons who seek to begin using this system, in order to establish learning period expectations.

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Author Contributions CBO: Study conceptualization; data curation; investigation; methodology; project administration; resources; validation; visualization; writing—original draft/review and editing. JMO: Data curation; investigation; writing—original draft/review and editing. Y-FC: Conceptualization; data curation; formal analysis; methodology; software; validation; visualization. JG: Data curation; project administration; resources; writing—review and editing. AP: Data curation; project administration; resources; writing—review and editing. G-CL: Conceptualization; investigation; methodology; project administration; supervision; writing—review and editing. AGDV: Conceptualization; funding acquisition; investigation; methodology; project administration; supervision; writing—review and editing.

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Data availability The data that support the findings of this study are available upon reasonable request from the corresponding author. The data are not publicly available due to privacy orethical restrictions.

Declarations

Conflict of interest Author A.G.D.V. is a paid consultant for, and owns stock or stock options in Naviswiss.

Informed Consent A waiver of informed consent was obtained to collect patient health information.

Institutional Ethical Committee Approval (For All Human Studies) This study received both Institutional Review Board and Ethical Committee approval.

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