Reliability and Correlation of the Force-PRO Device and Computer-Assisted Navigation System for Measurement of Acetabular Cup Position in Total Hip Arthroplasty

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ABSTRACT

Introduction: Acetabular cup malposition is very common in total hip arthroplasty (THA) and is significantly associated with many serious postoperative complications, such as dislocation, wear and loosening, and decreased range of motion. To improve the accuracy of intraoperative assessment, we recently developed an innovative sensor-based navigation system (Force-PRO device) using an inertial measurement unit and a 3D-printed liner for acetabular cup measurement, and aimed to evaluate its reliability and correlate its accuracy with that of a computer-assisted navigation system (CANS).

Design: Method-comparison study between the Force-PRO device and a standard CANS in a 1:1 pelvic bone model.

Methods: The test-retest reliability of both the Force-PRO device and CANS, and agreement between the Force-PRO device and CANS, for the measurement of acetabular inclination and anteversion angles, were examined using 40 random acetabular cup positions. Statistical analysis was performed by using limits of agreement and intraclass correlation coefficient (ICC).

Results: The mean differences in the inclination angle and anteversion angle in test-retest of the Force-PRO device were -0.43°±1.03° and -0.40°±0.78°, respectively. The mean differences in the inclination angle and anteversion

angle between the Force-PRO device and CANS were 0.70°±0.94° and -0.10°±0.44°, respectively. Excellent reliability in the inclination and anteversion angles of the Force-PRO device and excellent agreement between the Force-PRO device and CANS were demonstrated, with ICC values of 0.994 and 0.997, and 0.993 and 0.999, respectively.

Conclusion: The Force-PRO device showed excellent reliability equivalent to CANS with excellent agreement in acetabular cup position measurement comparable to that with CANS. Future clinical studies will be needed to evaluate the efficacy of this device.

INTRODUCTION

Total hip arthroplasty (THA) is one of the most effective and common procedures in orthopedic surgery for the treatment of hip joint osteoarthritis.[1] Regarding the surgical technique, implant positioning is the most critical factor for achieving successful postoperative outcomes. Malpositioning of the implant, especially of the acetabular cup, increases the risk of postoperative dislocation, to as high as 3% in primary cases.[2] Previous studies showed that the error of acetabular cup positioning could be as high as 26%–78%,[3-5] especially when performed with the conventional freehand technique, which could make postoperative dislocation four times more likely.[6] Moreover, acetabular cup malposition in THA also increases polyethylene wear and loosening, and restricts postoperative range of motion.[7] Therefore, accurate and consistent placement of the prosthesis is vital to preventing postoperative complications and achieving implant longevity in THA.

Among the surgical techniques available for acetabular cup placement, a computer-assisted navigation system (CANS) has been demonstrated to significantly improve the precision of acetabular cup placement compared to the conventional freehand technique.[8,9] However, CANS has some drawbacks, such as the high cost of the navigation system, a significant learning curve, an increase in operative time, and the need for additional pin placement resulting in a risk of iliac crest fracture due to pin insertion.[10] Recently, the application of an inertial navigation system with sensor technology, such as the highly sensitive accelerometer in smartphones, was introduced in THA, and was shown to improve the precision of cup positioning.[11-13] Therefore, we developed a simple navigation system (the "Force-PRO device") by using an inertial navigation sensor with a 3D-printed acetabular liner for assessment of the acetabular cup position.[14]

This study aimed to evaluate the reliability of the Force-PRO device and agreement of the acetabular cup orientation measurement between the Force-PRO device and a standard CANS.

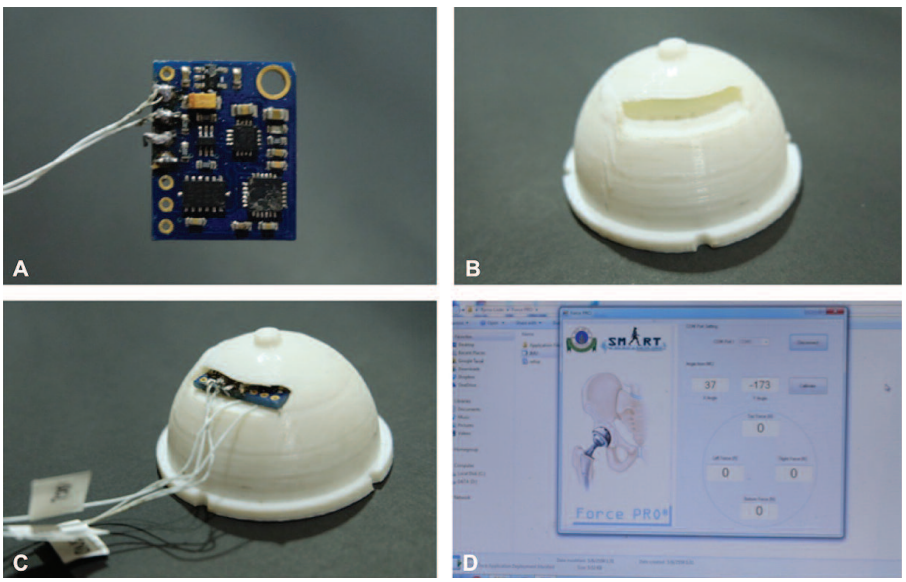

Figure 1. Force-PRO device components and software related to acetabular cup measurement. Gyro sensor (GY-85, Shenzhen Jubaolai Electronics Co., Ltd, Huaqiangbei, China) (A), 3D-printed acetabular liner (B), Force-PRO device (C), and software (D).

MATERIALS AND METHODS

Study design and pelvic model setup

This study employed a method-comparison design, between the Force-PRO device and a standard CANS, in a 1:1 synthetic pelvic bone model (Sawbones, Vashon, WA, USA). The study protocol was approved by the ethics committee of our hospital (COA. MURA2020/92). The pelvic bone model was fixed in the lateral decubitus position with a pelvic model-holder. The model was then calibrated with a standard calibration box, resulting in the APP plane being perfectly perpendicular to the floor before every acetabular cup measurement. The acetabular cup component used in this study was an uncemented cup with a 56-mm diameter (Plasmafitâ Acetabular Cup System, B. Braun-Aesculap, Tuttlingen, Germany) that fit the pelvic-model acetabular socket.

Force-PRO device setup

The Force-PRO device in this study was developed by the Faculty of Engineering, Mahidol University, based on the engineering process published in a previous study.[14] The acetabular cup measuring system is a combination of an inertial measurement unit (IMU) sensor (9-axis sensor, GY-85, Shenzhen Jubaolai Electronics Co., Ltd, Huaqiangbei, China), a 3D-printed liner based on the design from the corresponding uncemented cup, and innovative software from the previous study (Fig. 1). The Force-PRO device was calibrated using a

Figure 2. Experimental model setup. (A) Force-PRO device setup with software (A), computer-assisted navigation system (Orthopilot THA version 2.0,B. Braun-Aesculap, Tuttlingen, Germany) setup (B), and referencing information obtained from the alignment guide (C).

Table I
Agreement between the measurements obtained by the Force-PRO device and a computer-assisted navigation system

	Force-PRO 1st vs 2nd			Force-PRO vs CAN			CAN 1st vs 2nd		
	Mean difference (°)	95%LOA (°)	ICC	Mean difference (°)	95%LOA (°)	ICC	Mean difference (°)	95%LOA (°)	ICC
Inclination	-0.10	-1.56 to 1.36	0.997	0.70	-1.14 to 2.54	0.993	-0.43	-2.45 to 1.60	0.994
Anteversion	-0.03	-1.16 to 1.11	0.999	-0.10	-0.97 to 0.77	0.999	0.40	-1.13 to 1.93	0.997

CAN: computer-assisted navigation, LOA: limits of agreement, ICC: intraclass correlation coefficient

calibration box to ensure that the device was synced in the zero position with the APP plane to align with the pelvic model. The inclination and anteversion angles of the acetabular cup were reported by the software, as shown in Fig. 2A.

Computer-assisted navigation setup

The computer-assisted navigation system used in this study was OrthoPilot Total Hip Arthroplasty version 2.0 (B. Braun-Aesculap, Tuttlingen, Germany), and the procedure followed all of the manufacturer's instructions. The tracker pin was placed on the alar on the iliac crest, and the APP plane was registered using the bilateral anterior superior iliac spines (ASIS) and the center of the pubic symphysis. The acetabular cup position was measured using the reference alignment guide attached to the cup insertion handle (Fig. 2B). The inclination and anteversion angles of the acetabular cup were demonstrated by the computer software (Fig. 2C).

Data collection and outcome measurement

The acetabular cup position was set randomly in 40 positions, which varied from 20°–60° for inclination and 10°–30° for anteversion. Regarding each position, repeated measurements were performed alternating between the two devices (i.e., Force-PRO device 1st, OrthoPilot 1st, Force-PRO device 2nd, and OrthoPilot 2nd), with a 5-minute interval to minimize measurement bias. All measurements were performed by one of the authors (CV), an experienced surgeon, under supervision of the Force-PRO engineer (UM) and the senior hip arthroplasty surgeon (SW), who performs more than 200 hip arthroplasty procedures per annum. All of the assessors (CV, UM, and SW) were blinded to the device monitor report. The acetabular inclination and anteversion angles from each device were recorded by a research assistant who did not participate in the statistical analysis.

Statistical analysis

Stata software version 11.0 (Stata Corp, College Station, TX, USA) was used to perform the statistical analysis. The mean differences in the inclination and anteversion angles between the Force-PRO device and CANS were presented as mean and standard deviation, and presented using a scatter diagram. Limits of agreement between the two devices were examined with a Bland-Altman plot analysis. The test-retest reliability and agreement between the two devices were analyzed with an intraclass correlation coefficient (ICC) and classified as poor (ICC < 0.5), moderate (ICC between 0.5 and 0.75), good (ICC between 0.75 and 0.9), and excellent (ICC > 0.9).[15] These are the most common methods for evaluating agreement between measurements with medical instruments.[16]

RESULTS

Test and re-test reliability for each device

The test-retest reliability study for the Force-PRO device showed that the mean inclination angle difference and the mean anteversion angle difference were -0.01°±0.74° and -0.03°±0.58°, respectively. The ICC values for the inclination and anteversion angle measurements were 0.997 (95% CI 0.995 to 0.999) and 0.999 (95% CI 0.997 to 0.999), respectively (Table I). Figure 3A–D shows the scatter diagram and the Bland-Altman plot of the mean difference between the repeated measurements of the Force-PRO device.

Regarding the test-retest reliability study for CANS, the mean differences for the inclination and anteversion angles were -0.43°±1.03° and -0.40°±0.78°, respectively. The ICC values for the incli-

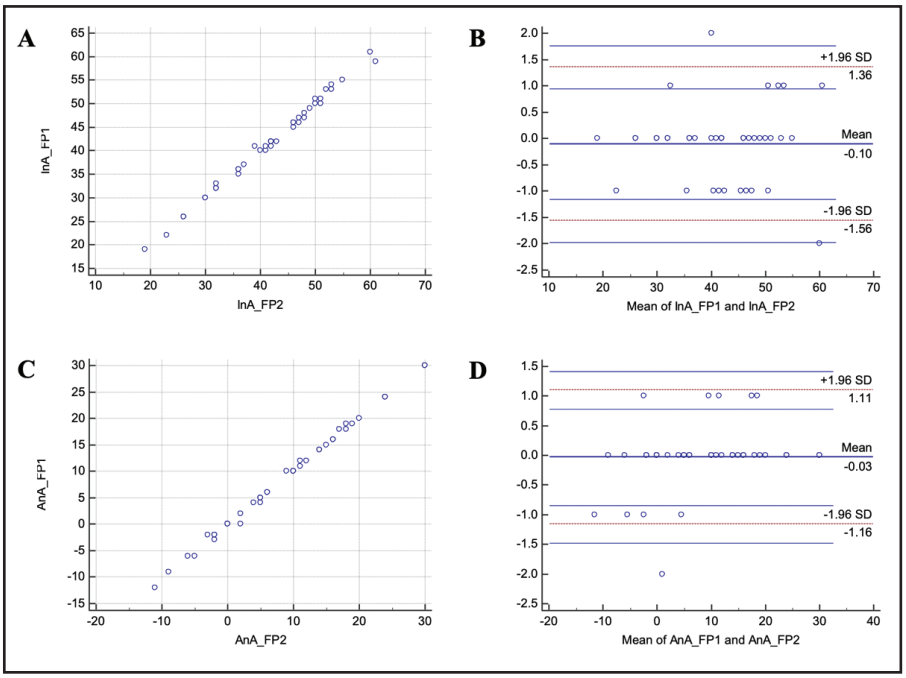

Figure 3. Test-retest reliability of the Force-PRO device. Scatter diagram (A) and Bland-Altman plot (B) of the mean difference in inclination angle measurement between the first (InA_FP1) and second tests (InA_FP2). Scatter diagram (C) and Bland-Altman plot (D) of the mean difference in anteversion angle measurement between the first (AnA_FP1) and second tests (AnA_FP2).

nation and anteversion angle measurements were both excellent: 0.994 (95% CI 0.989 to 0.996) and 0.997 (95% CI 0.993 to 0.998), respectively (Table I).

Comparison of the Force-PRO device and CANS

In the comparison of the Force-PRO device and CANS, the mean inclination angle difference and the mean anteversion angle difference were 0.70°±0.94° and -0.10°±0.44°, respectively. The ICC values for the inclination and anteversion angle measurements were 0.993 (95% CI 0.988 to 0.997) and 0.999 (95% CI 0.998 to 1.000), respectively (Table I). Figure 4A–D shows the scatter diagram and the Bland-Altman plot of the mean differences between the Force-PRO device and CANS.

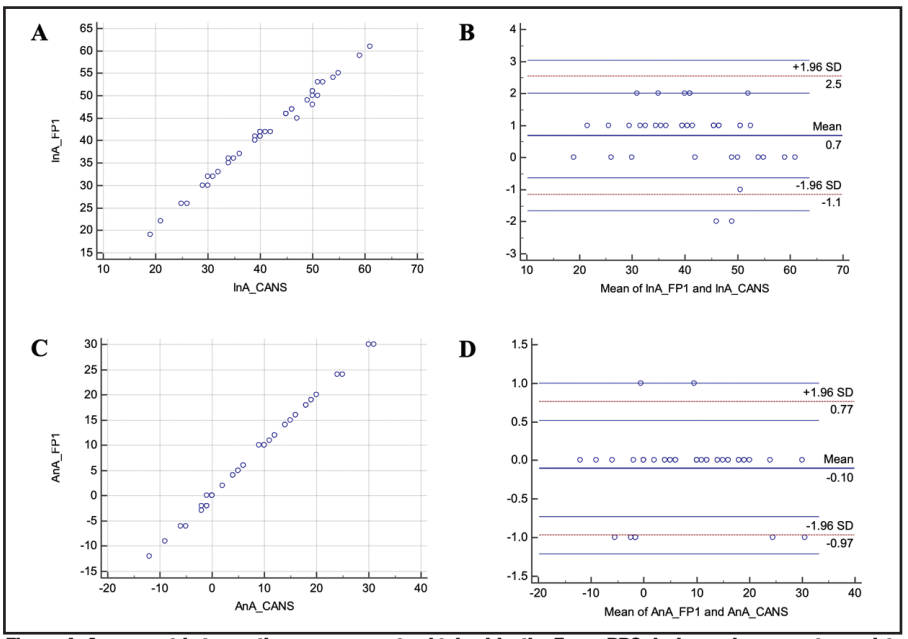

Figure 4. Agreement between the measurements obtained by the Force-PRO device and a computer-assisted navigation system (CANS). Scatter diagram (A) and Bland-Altman plot (B) of the mean difference in inclination angle measurement between the Force-PRO device (InA_FP1) and CANS (InA_CANS). Scatter diagram (C) and Bland-Altman plot (D) of the mean difference in anteversion angle measurement between the first (AnA_FP1) and second tests (AnA_CANS).

DISCUSSION

Acetabular cup positioning significantly impacts the postoperative outcome after total hip arthroplasty with respect to dislocation, range of motion (ROM), impingement, wear and osteolysis, loosening, and early acetabular cup failure.[15] Among the existing techniques for acetabular cup placement, an imageless navigation system, such as CANS, has been shown to have potential for significantly improving cup placement as reflected by a higher incidence of cup position in the safe zone and a lower dislocation rate.[8,9,16] Recently, we successfully developed a new navigation device (Force-PRO) for hip arthroplasty using a force and IMU sensor.[14] The aim of this study was to measure the test-retest reliability of the force-PRO device and the imageless CANS, as well as the agreement between these two devices for measuring the acetabular cup position in a pelvic bone model.

The results of this study showed that the Force-PRO device exhibits excellent reliability, with mean differences of -0.10° and -0.03° and ICC values of 0.997 and 0.999 in cup inclination and anteversion measurements, respectively (Table I, Fig. 3A–B). CANS also showed excellent test-retest reliability, as illustrated by mean differences of -0.43° and 0.40° and ICC values of 0.994 and 0.997 in cup inclination and anteversion measurements, respectively (Table I). Therefore, these results imply that the Force-PRO device has excellent reliability and precision comparable to those of CANS, with a mean difference of less than 0.5°.

The present study also revealed an excellent agreement of the Force-PRO device compared to the CANS, with mean differences of -0.70° and -0.1.0° and ICC values of 0.993 and 0.999 in cup inclination and anteversion measurements, respectively (Table I, Fig. 3C-D). These findings are comparable to those in a previous study by Kamenaga et al.,[17] who demonstrated a non-significant difference in the accuracy of acetabular inclination and anteversion angles between an accelerometer-based portable navigation system and postoperative CT evaluation. Our results also support the usefulness of accelerometer application in THA, as shown in previous

studies which demonstrated that the cup position could be improved by attaching a smartphone device to the cup impactor, as a navigated sensor.[11,12] Additionally, in terms of a device design comparison, we believe that the Force-PRO device should be more reliable than the smartphone method due to the sensor's closer proximity to the cup and the risk of the connector loosening during impaction. This implies that the Force-PRO device, as an imageless navigation system, has an accuracy comparable to that of CANS.

This study has a few limitations. First, this was a cross-sectional study using a pelvic bone model, since we wanted to have a benchmark test for the device prototype. Therefore, our results may not be directly applicable to real-world clinical situations and further clinical studies will be required to demonstrate the efficacy of the Force-PRO device in clinical practice. Second, like most navigated systems, the Force-PRO device requires a local pelvic reference (APP).[15] However, recent studies have shown that the reliability of APP is still limited, especially for guiding anteversion alignment in patients with thick soft tissue in the anterior pelvic area.[18,19] For example, a total error of 4 mm in identifying these landmarks could result in errors of 2° inclination and 7° anteversion.[20] Therefore, anatomical landmarks (pubis and iliac spine) must be accurately identified to reduce technical errors with this device.

CONCLUSION

Accurate acetabular cup position is essential for achieving good postoperative outcomes and preventing cup malposition-related complications. Our study showed that the Force-PRO device has excellent reliability with excellent agreement for acetabular cup position measurements, compared to the standard CANS. The Force-PRO device should be considered an alternative option for imageless navigated total hip arthroplasty. However, further studies will be required to demonstrate its effectiveness in clinical practice. **STI**

AUTHORS' DISCLOSURES

The authors declare that there are no conflicts of interest.

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