Accuracy of Navigated Hip Replacement: In-Vivo Analysis (Anterior Approach)

Introduction

Optimal patient outcomes in total hip replacement are dependent on appropriate placement of components during surgery. Improvements in surgical technologies have provided a platform for guiding component placement during surgery to reduce the risk of malpositioning.

Objectives

The objectives of this study were to validate intraoperative data captured using a handheld imageless THA navigation system developed by Naviswiss, against postoperative measurements using computerised tomography (CT). The accuracy of the following variables were validated:

A. Acetabular inclination,
B. Anteversion,
C. Femoral offset, and
D. Leg length.

Methods

Study Design and Participants

An observational cohort study was conducted within a single-centre, single-surgeon private practice.

Data Collection

Surgical and imaging data were retrospectively collated for patients who underwent total hip replacement surgery via an anterior approach from the research registry established at the surgeon's practice. Ethics approval for the registry was provided through a certified ethics committee (Bellberry HREC approval number 2017-07-499).

Data Analysis

Differences between the Naviswiss system and post-op CT measurements for the variables of interest were determined using a 95% bootstrap confidence interval around the median. Wilcoxon sign rank tests were used to assess the probability of deviation from zero as large as those observed assuming the null hypotheses (median difference =0) were true. The Bland-Altman method was used to determine the accuracy of the Naviswiss variables using 95% limits of agreement.

Results

A sample of primary cases were retrieved (N = 38, 21 males, median BMI 28.7, IQR 26.6 - 33.2). No difference in median cup inclination was observed between methods (-0.35°, 95%CI -2.0 to 3.45, P = 0.83). The median cup version measured on CT was 1.80° greater than Naviswiss (95%CI -3.90 to -0.95, P = 0.06). Median femoral offset differed by 0.0mm between methods (95%CI -1.00 to 2.00, P = 1.00) and 2.0mm for leg length differences (95%CI 0.00 to 4.50, P = 0.07), but were not statistically significant. Bland-Altman limits of agreement for matched pairs were within 9.0° for cup inclination and version (N = 18) and 7.1mm for offset and leg length difference (N = 11) (Table 1, Fig 1-4).

Table 1: Summary of average differences between the Naviswiss system and post-op CT measurements

	Cup Inclination	Cup Version	Femoral Offset	Leg Length
Average difference	0.2	-1.8	-0.1	1.7
SD	4.4	3.7	3.4	2.7
Upper 95% limit	8.9	5.4	6.7	7.1
Lower 95% limit	-8.4	-9.0	-6.8	-3.6

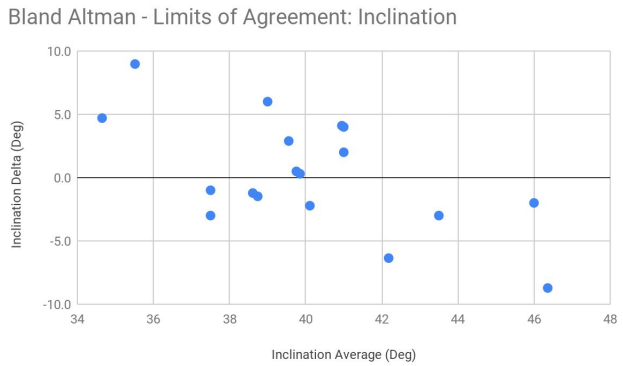

Fig 1: Limits of agreement for cup inclination accuracy.

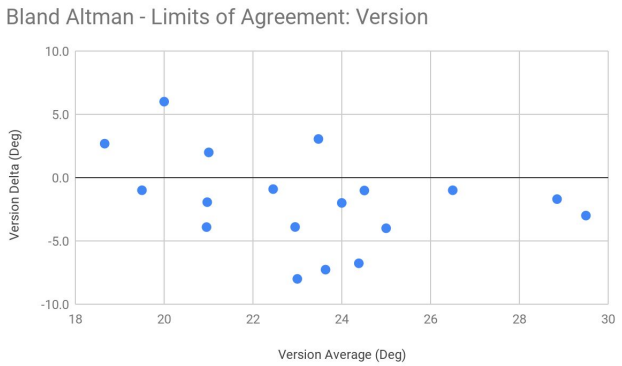

Fig 2: Limits of agreement for cup version accuracy.

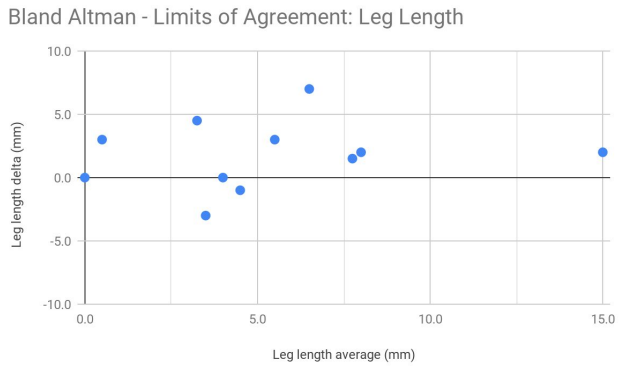

Fig 3: Limits of agreement for leg length accuracy.

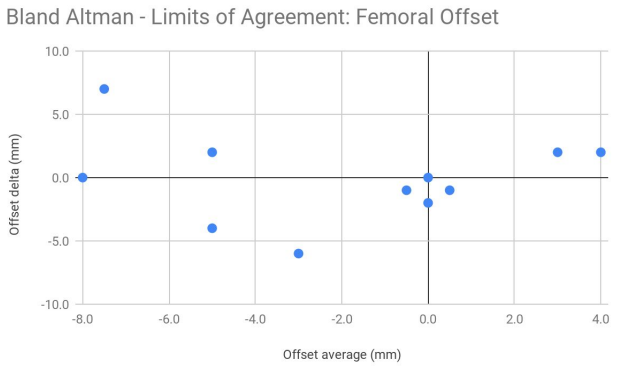

Fig 4: Limits of agreement for femoral offset accuracy.

Conclusion and Discussion

This in-vivo study demonstrated the accuracy of the Naviswiss handheld surgical navigation system within a clinical setting. The accuracy of the Naviswiss system for guidance during total hip replacement surgery using an anterior approach was validated to be within the following specifications:

a) 0.2° (SD 4.4°) for cup inclination and 1.8° (SD 3.7°) for cup version, and
b) 0.1 mm (SD 3.4 mm) for femoral offset and 1.7mm (SD 2.7 mm) for leg length.

The accuracy of the system was within clinically acceptable margins determined from contemporary literature of clinical investigations of other navigation devices.

This study was not without limitation. Missing data were reflective of patient compliance and technicalities experienced intraoperatively, and will likely improve with surgeon experience and familiarisation with the device. A more comprehensive and complete dataset may provide more robust information regarding the validity of accuracy measurements, and clinical investigations should continue to monitor the in-vivo accuracy of the navigation device.