

Accuracy of Navigated Hip Replacement: In-Vivo Analysis (Lateral 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 2D and 3D radiography/CT. The accuracy of the following variables were validated: acetabular inclination, anteversion, femoral offset, and leg length.

Methods

Study Design and Participants

A retrospective cohort study was conducted within a single-centre, single-surgeon private practice, for patients who underwent total hip replacement surgery via a lateral approach between September 2019 - February 2020.

Data Collection and Measurements

Surgical logs and imaging data were retrospectively retrieved and reviewed. Intraoperative measurement of acetabular inclination, anteversion, femoral offset and leg length were recorded from the Naviswiss device log; the corresponding variables were measured from pelvic radiographs using digital planning software (Imatri Medical, South Africa).

Data Analysis

Differences between the Naviswiss log and post-op measurements of 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 total of N=38 primary THR cases were reviewed. Cases with pre/postoperative imaging matched to surgical logs were included in the accuracy analysis (N = 16).

Differences in median cup acetabular inclination (-1° , 95%CI -3 to 2 , $P = 0.04$), anteversion (3° , 95%CI 0 to 5 , $P = 0.01$), and femoral offset (2° , 95%CI 1 to 3 , $P = 0.00$) were observed between the intraoperative and postoperative measurements. There was no difference in intraoperative and postoperative median leg length (0mm, 95%CI -1 to 1 , $P = 0.61$).

Bland-Altman 95% limits of agreement for matched pairs were within 7.8° for cup inclination and 10.6° for version (N = 16), and 5.5mm for offset and 2.2mm for leg length difference (N = 15) (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	-1.82	2.88	1.80	0.20
SD	3.15	3.79	1.90	1.01
Upper 95% limit	4.5	10.6	5.5	2.2
Lower 95% limit	-7.8	-4.7	-1.9	-1.8

Bland Altman - Limits of Agreement: Inclination

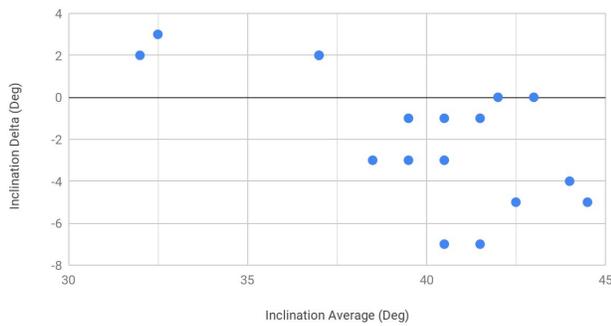


Fig 1: Limits of agreement for cup inclination accuracy. $r(14) = -0.67$

Bland Altman - Limits of Agreement: Version

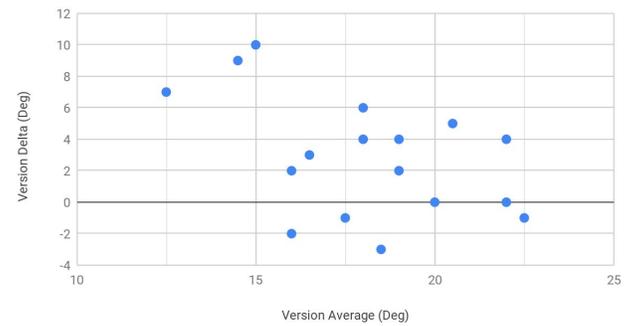


Fig 2: Limits of agreement for cup version accuracy. $r(14) = -0.47$

Bland Altman - Limits of Agreement: Leg length

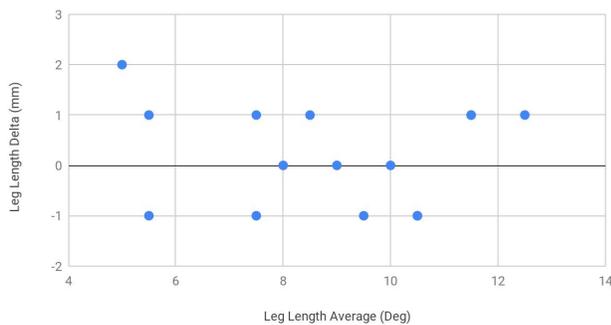


Fig 3: Limits of agreement for leg length accuracy. $r(13) = 0.40$

Bland Altman - Limits of Agreement: Offset

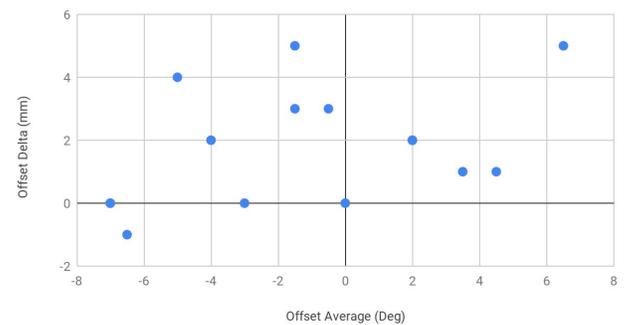


Fig 4: Limits of agreement for femoral offset accuracy. $r(13) = -0.09$

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 a lateral surgical approach was validated to be within the following specifications:

- a) 1.8° (SD 3.2°) for cup inclination and 2.9° (SD 3.8°) for cup version, and
- b) 1.8 mm (SD 1.9 mm) for femoral offset and 0.2mm (SD 1.0 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. The patterns of data observed, with moderate correlations observed between the average and delta for inclination, version and leg length, are likely due to the pelvic obliquity and lateral approach during surgery.

Limitations of the study include missing data rates which were reflective of patients returning for postoperative imaging and intraoperative technicalities. Further clinical investigations to monitor the in-vivo accuracy of the device are warranted.