Evaluation of Operator Variability in Point Registration with an Image-based Software Navigation System Used in Total Hip Arthroplasty

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INTRODUCTION: The VELYS[TM] Hip Navigation (VHN) software uses fluoroscopic images obtained intraoperatively during total hip arthroplasty (THA) to evaluate acetabular cup position, leg length, and offset. The system uses standardized anatomic landmarks of the pelvis and femur in the supine view. Mathematical analysis of the acetabular component ellipse face can then determine cup anteversion and inclination (abduction), which can help minimize variability of intraoperative parameters and improve accuracy of acetabular implant positioning and restoration leg length and offset. The anatomic landmarks must be registered by users of the software, and therefore, the aim of our study was to find out how consistently users can register points within the VHN software.

METHODS: A set of ten image sets (cases) representing both normal and complex THA cases was selected, and 10 sales representatives with experience of minimum five cases were selected to serve as VHN operators to register points on each case. Each of the 10 operators registered points on each of the 10 cases twice, resulting in a standard 10, 10, 2 gage R&R (repeatability and reproducibility) study design. The first and second reviews of the cases by an operator were separated in time by one week or more, and the order of cases was changed. The gage R&R analysis was conducted with a 2-way ANOVA random effects model with interaction term. The study was reviewed and approved by an institutional review board (IRB) and written informed consent was obtained from all operators before starting the study.

RESULTS: A statistical summary of all 20 evaluations for each case (two evaluations for each case from 10 operators) is provided in Table 1, along with the standard deviation for the operator component and the percent of total variation due to operator from the gage R&R analysis.

DISCUSSION: As expected there was operator variability associated with each of the outcome measurements. These estimates of variability might be considered as the extremes of what will be exhibited with the VHN system in practice, given the variety of normal and difficult cases that were included in this study. Studies have shown that use of the software helps increase cup positioning and leg length and offset accuracy[1,2,3].

SIGNIFICANCE/CLINICAL RELEVANCE: The use of VHN offers an analysis of implant selection and positioning through easy-to-use non-invasive navigation, pre-operative digital templating, and case planning. The system provides actionable, real-time data designed to help with increased accuracy and surgical reproducibility. Surgeons should consider verification of landmark identification and acquisition in complex primaries or difficult cases.

REFERENCES: 1) O'Leary R, Saxena A, Arguelles W, Hernandez Y, Osondu CU, Suarez JC. Digital Fluoroscopic Navigation for Limb Length Restoration During Anterior Total Hip Arthroplasty. Arthroplasty Today; 18 (2022). 2) Fawley D, Bernard T, Morrison JC, Redmond J. Cup Positioning Accuracy of Direct Anterior Approach Using a Non-Invasive, Image-Based Software Navigation System in Primary Total Hip Arthroplasty. *Accepted for presentation at ISTA; Sept 2023, NY, New York*. 3) Brady, A.W.; Tatka, J.; Fagotti, L.; Kemler, B.R.; Fossum, B.W. Accuracy and Reliability of Software Navigation for Acetabular Component Placement in THA: An In Vitro Validation Study. Medicina 2022, 58, 663.

Table 1. Summary of Case Evaluations

Table entries: Mean (SD); Min, Max

Case	Total Evaluations (twice per each of 10 operators)	Leg Length (mm)	Total Offset (mm)	Femoral Offset (mm)	Cup Inclination (degrees)	Cup Version (degrees)
1	20	2.45 (1.10); 1,5	-0.20 (1.20); -3,2	-0.05 (0.89); -2,1	36.45 (1.32); 34,39	22.70 (1.49); 19,25
2	20	3.50 (1.36); 0,5	-2.05 (1.28); -4,0	2.10 (1.21); 0,4	38.75 (2.45); 30,41	29.60 (1.60); 26,32
3	20	4.85 (2.48); -4,8	-3.75 (2.99); -9,3	3.25 (2.29); -3,7	43.10 (1.77); 41,47	20.95 (1.54); 18,23
4	20	4.95 (1.00); 3,7	4.25 (1.07); 3,6	3.85 (1.39); 1,7	42.45 (1.54); 38,45	23.55 (1.05); 21,25
5	20	2.85 (0.93); 2,5	5.15 (1.81); 2,8	6.90 (1.94); 3,10	42.90 (1.12); 41,45	21.15 (1.53); 18,23
6	20	-0.40 (0.82); -2,1	-4.20 (1.51); -7,-2	1.60 (1.35); -2,4	48.25 (1.29); 45,50	26.10 (1.45); 23,28
7	20	0.50 (1.15); -2,3	0.65 (1.46); -1,4	0.70 (1.26); -1,3	39.20 (1.67); 37,43	24.90 (1.52); 22,28
8	20	5.05 (1.28); 2,7	-0.55 (1.57); -3,2	2.05 (1.15); 0,4	39.00 (1.41); 38,43	16.85 (1.23); 14,19
9	20	1.85 (1.31); -2,4	5.25 (1.74); 3,9	9.40 (1.23); 7,12	49.25 (1.16); 47,51	22.50 (1.36); 19,25
10	20	3.45 (1.36); 1,6	8.50 (2.19) 5,14	9.60 (1.31); 8,12	46.00 (1.08); 43,48	18.00 (1.03); 16,20

Entries below are gage R&R results: SD for Operator component, % of Total Variation due to Operator

	SD=1.36, 35.1%	SD=1.78, 14.9%	SD=1.47, 15.2%	SD=1.52, 11.6%	SD=1.41, 12.5%