A high-precision automated test set-up for evaluating optical passive tracker performance in surgical navigation

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INTRODUCTION: Optical navigation trackers or arrays are essential instruments to track anatomical regions of interest in navigation and robotic surgeries. Accurately tracking these instruments and localizing the anatomy is crucial for the robotic system to compute the precise 3D coordinates of the anatomical region requiring surgical resection. The accuracy of tracking and positioning directly affects the accuracy of surgical navigation system and endangers the safety of surgery [1]. One commonly used performance metric in navigation systems is the pivot performance or localization error, which determines the transformation between the navigation system and the tool tip using a stationary point [2]. To design an array and to evaluate its performance, it is important to build a robust test method that can be used to measure the pivot accuracy of these trackers and provide feedback to its design. This study aimed to develop and validate a novel approach to quantify pivot performance of an array while reducing variation or noise in the error measurements.

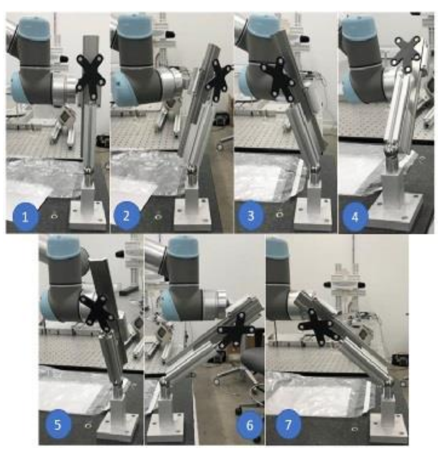
METHODS: A passive (uses retroreflective marker to reflect IR light) optical array called Scapular Array, developed as part of Stryker Mako shoulder application, was used in this study. The array was attached to a fixture with a pivot distance (distance between the bottom-most fiducial of the array to the center of the resection surface) of 151mm (**Fig.1**). The array fixture was then attached to the flange of an industrial robot (UR5e, Universal Robot). A stainless-steel ball bearing was mounted at the bottom of the array fixture, which was then secured to a magnetic base fixture featuring a concave cavity designed to facilitate smooth pivot movement of the ball within the cavity. On the other end of the test set-up, an optical navigation camera (NDI Polaris Vega® ST, CA) was used to capture the pose data with rotational and translational values as the output. This optical camera works using a near-infrared (IR) light to wirelessly detect and track these markers. The camera was attached to a fixture at 1680mm distance (acceptable range in Mako shoulder surgeries) from the tracker fixture. The array was placed in the middle of the camera field of view when visualized from the top view of the test set-up.

UR5e was programmed to move dynamically to several poses pivoting the array on the stationary point in a conical boundary for N = 30 times (**Fig.2**). The data was collected at 60Hz using the optical camera with close to 3000 data points in less than a minute. The data was then processed utilizing the translational and rotational values to determine the error in pivot length. The final error or 95% pivot error was then calculated by adding 2X standard deviation (SD) to the average error. This 95% pivot error was calculated for all 30 data points before being fed into statistical software for data analysis. The acceptance criterion for validation was set at <20% precision-to-tolerance when tested at 0.25mm as tolerance range.

RESULTS SECTION: The test data was analyzed using precision-to-tolerance ratio (Type 1 gage study) in MINITAB (Minitab, PA). The data was first analyzed for normality test (p = 0.76) and then for stability using I-MR chart. The data was then tested using Type I Gage quality tool with 5.15 as the study variation (SD factor) and 0.25mm tolerance range (**Fig.3**). The test resulted in the precision-to-tolerance value (%variability) of 5.88%.

DISCUSSION: The described test method demonstrated minimal pose-to-pose variability and successfully met the predefined validation acceptance criteria. The test method was further utilized for all the other optical navigation arrays available as part of Mako shoulder application system. Further assessment and comparison with manual methods is recommended to analyze superiority in terms of repeatability and data robustness.

SIGNIFICANCE/CLINICAL RELEVANCE: Reducing measurement noise allows for high confidence in tracker accuracy — a critical factor in surgical navigation safety and precision.



Basic Statistics		Capability	
Mean	0.372	Cg	3.4
StDev	0.003	%Var(Repeatability)	5.88%
5.15 X StDev (SV)	0.015		
Tolerance	0.25		

Fig. 1: Array attached with a pivot distance calculated from center of resection surface

Fig. 2: Array pivoting in a cone shape

Fig 3: Variability in pivot error data

REFERENCES: 1. Long Chen et al. ESA, 2023, Vol 230, 120743 2. Matt Clarkson et al. MPHY0026, Computer Assisted Surgery and Therapy at University College London (UCL)