For Scientific study or technical/P&O contribution

Summary*:
This study provides quantitative data demonstrating the benefits of partial hand prostheses. These data can be used to improve insurance authorization requests and regulatory submissions. Additionally, this study identified a possible need for a task-based outcome measure more tailored to the partial hand population.

Introduction/Basics*:
There are more than 25,000 partial hand amputations each year in the U.S1. There are now many more devices available to treat partial hand amputations, but there is still not an adequate amount of quantitative clinical data to support the application of these devices. This presents regulatory and reimbursement challenges for both manufacturers and practitioners which ultimately limits access to partial hand prostheses. A robust interventional clinical study on partial hand prostheses was thus conducted to address this need.

Patient outcomes before and after being fit with ratcheting mechanical prosthetic fingers were assessed using two task-based and two patient reported outcome measures.

Material/methods*:
The Western Institutional Review Board approved this study (protocol #20182022), and informed consent was obtained from all subjects.

Participants: Eleven (11) subjects with partial hand amputation were recruited. Eight (8) participants were male, and three (3) were female; with an age range of 22 – 61 years. Inclusion criteria was loss of at least index and/or middle fingers, but an intact thumb.

Prosthesis: Each subject was fit with a partial hand prosthesis made of a HTV silicone liner, carbon fiber frame, and ratcheting mechanical prosthetic fingers.

Procedures: Subjects participated in four data collection sessions: prior to prosthesis fitting (Pre), immediately after definitive prosthesis fitting (Post), 30 days after prosthesis fitting (30-day post), and 60 days after prosthesis fitting (60-day post). Outcome measures were collected each session using the EQ-5D-5L, DASH, SHAP, and CAPPFUL.

Analysis: A linear mixed effects model was used. The model determined how significant age, gender, hand dominance, days since amputation, the number of fingers involved, and prosthesis use were in determining the total scores for all outcome measures.

Results:
All post-fitting visits were coded as the “Prosthesis” condition and the pre-fitting visit was coded at the “No Prosthesis” condition. Significant differences between these two conditions were found for the DASH, EQ-5D-5L, and CAPPFUL. The SHAP did not show a significant difference.

No significant effects were found for age, gender, hand dominance, or days since amputation. There was a significant difference in the SHAP and CAPPFUL scores with and without a prosthesis for the 4-finger but not for the 2 or 3-finger presentations.

Discussion/Conclusion for clinical practice*:
There was a significant improvement in both patient reported and task-based outcome measures from the no prosthesis condition to the prosthesis condition. Additionally, a larger benefit was found

for patients missing 4 fingers. This demonstrates that partial hand prostheses are state-of-the-art and clinically sound treatments for partial hand amputation.

This study provides quantitative data demonstrating the benefits of partial hand prostheses. These data can be used to improve insurance authorization requests and regulatory submissions. Additionally, this study identified a possible need for a task-based outcome measure more tailored to the partial hand population.

Literature references:

Conn, J. M, et. al. (2005). Annals of emergency medicine, 45(6), 630-635.

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Table 1: Effect of partial hand prostheses on outcomes

Fixed Effects	Outcome Measure	Coefficient	p. Value	Low. CI	High. CI
No Prosthesis vs. Prosthesis	DASH	-12.2	1.92E-05**	-17.1	-7.4
	EQ-5D-5L	4.8	0.002**	2.0	7.7
	CAPPFUL	12.7	0.018*	2.5	22.9
	SHAP	2.5	0.408	-3.4	8.3

*p<0.05, ** p<0.001