Test of Selected Physical Characteristics of OCTO Medical POLY-LOK® Ligating Clips in comparison to Teleflex Hem-o-lok® clips

Purpose

This study was commissioned with the University of Petra Pharmaceutical Centre to independently compare physical and morphological characteristics of OCTO Medical POLY-LOK® Ligating Clips with another commercially available brand, namely Teleflex Hem-o-lok®.

References

Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process (ISO-10993-1:2018); Biological evaluation of medical devices Part 19: Physico-chemical, morphological, and topographical characterisation of materials (10993-19:2020).

Study Classification

Study Category:	Physical characterisation
Study Type:	Descriptive / Comparative
Class of Medical Device:	Class IIb

Tested February 2025

Test Facility
University of Petra Pharmaceutical Center (UPPC)
Amman, Jordan
P.O. Box. 961343 Amman 11196 Jordan

ML Medium Large
PLTX230

L Large
PLTX240

XL Extra Large
PLTX250

OCTO Medical POLY-LOK® Polymer Ligating Clips vs Teleflex Hem-o-lok® clips: Dimensions

Ligating Clip Dimensions were measured using a Digital Micrometer (Pittsburgh, China). These measurements were taken under controlled conditions, with a temperature of 22°C (± 3°C) and 65% (± 5%) relative humidity.

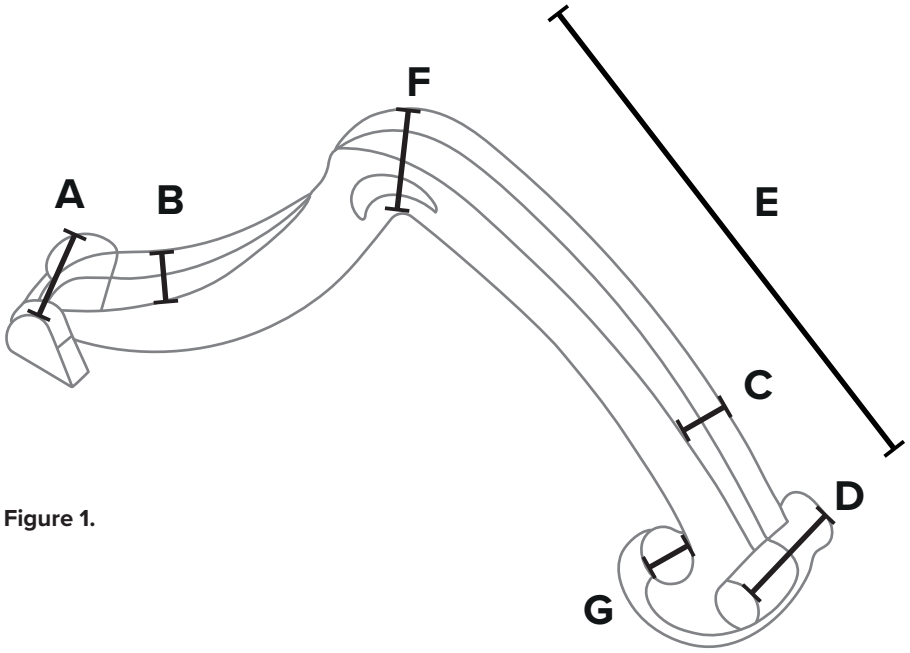

Figure 1.

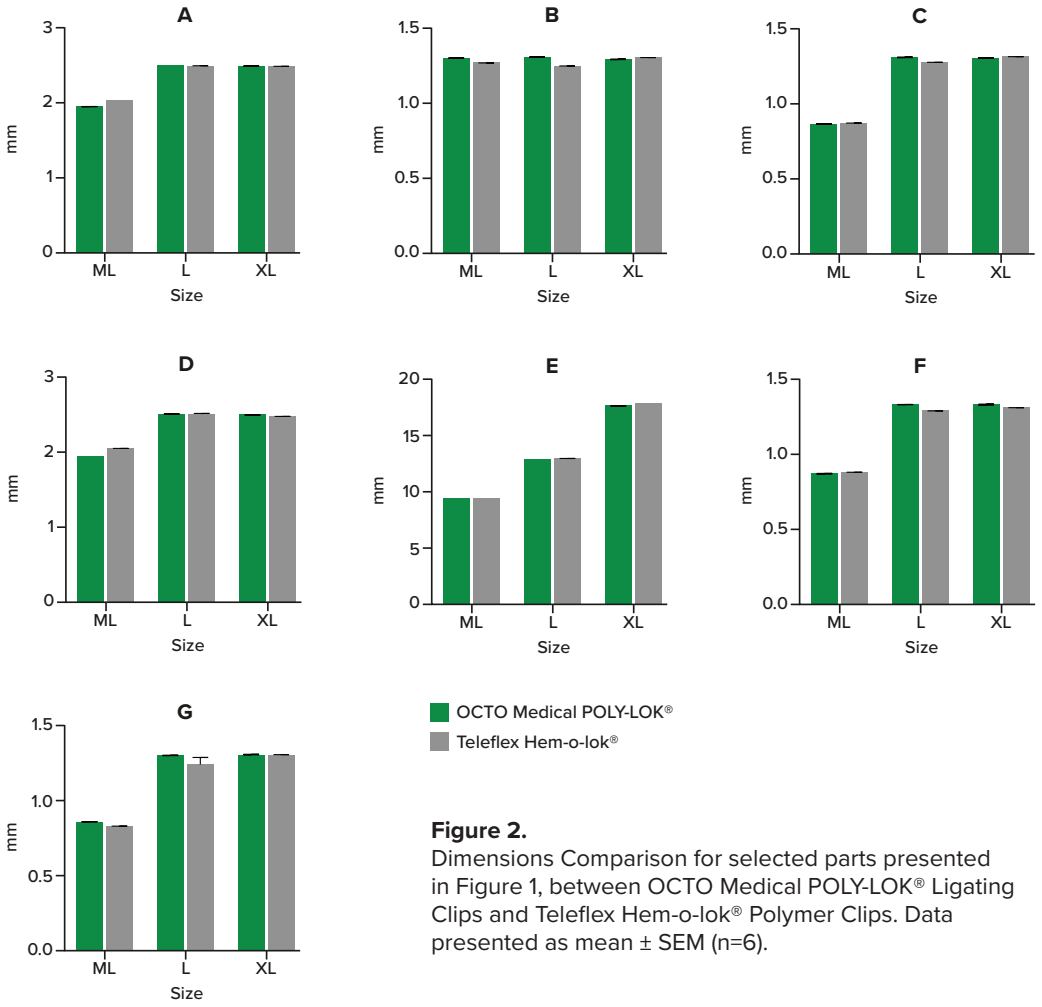

Figure 2.
Dimensions Comparison for selected parts presented in Figure 1, between OCTO Medical POLY-LOK® Ligating Clips and Teleflex Hem-o-lok® Polymer Clips. Data presented as mean ± SEM (n=6).

“Our studies identify a 99.54% correlation between the two brands in their physical form, across seven key dimensions.”

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OCTO Medical POLY-LOK® Polymer Ligating Clips vs Teleflex Hem-o-lok® clips: Mass Identification

	Weight (g)		
	 **ML** Medium Large	 **L** Large	 **XL** Extra Large
OCTO Medical	0.0238±0.0001	0.0637±0.0001	0.1220±0.0006
Teleflex	0.0227±0.0002	0.0626±0.0002	0.1223±0.0003

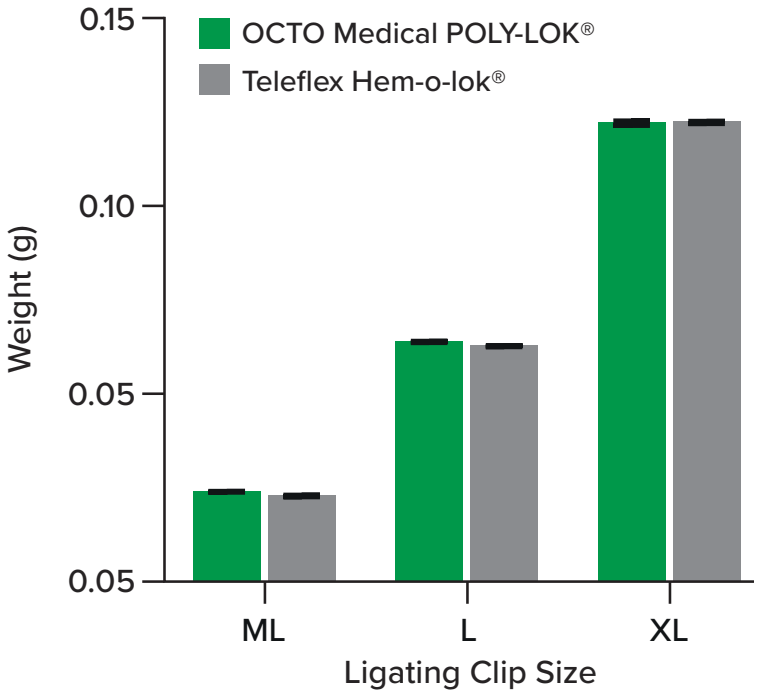

Figure 3. Mass Identification of OCTO Medical POLY-LOK® Ligating Clips and Teleflex Hem-o-lok® polymer clips. Data presented as mean ± SEM (n=3).

“Statistical analysis revealed no significant differences in dimensions or weights between OCTO Medical POLY-LOK® Polymer Ligating Clips and Teleflex Hem-o-lok® clips with p-values ≥ 0.05. Furthermore, the visual inspection of the clips, including three-dimensional detailing, showed no differences in design, texture, or colour.”

“In conclusion, the OCTO Medical POLY-LOK® Polymer Ligating Clips and Teleflex Hem-o-lok® clips are similar in terms of physical dimensions, shape, and mass.”

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OCTO Medical POLY-LOK® Polymer Ligating Clips vs Teleflex Hem-o-lok® clips: Topography

The topography of OCTO Medical POLY-LOK® polymer ligating clips was evaluated using an Optika® light microscope (Italy) and compared to Teleflex Hem-o-lok® clips. The Teleflex Hem-o-lok® clips exhibited curved teeth, whereas the OCTO Medical POLY-LOK® polymer clips had slightly angled teeth.

However, within both brands, no significant morphological or topographical differences were observed in other regions, including the hinge, lock, and key, between the tested OCTO Medical POLY-LOK® and Teleflex Hem-o-lok® polymer clips (see below).

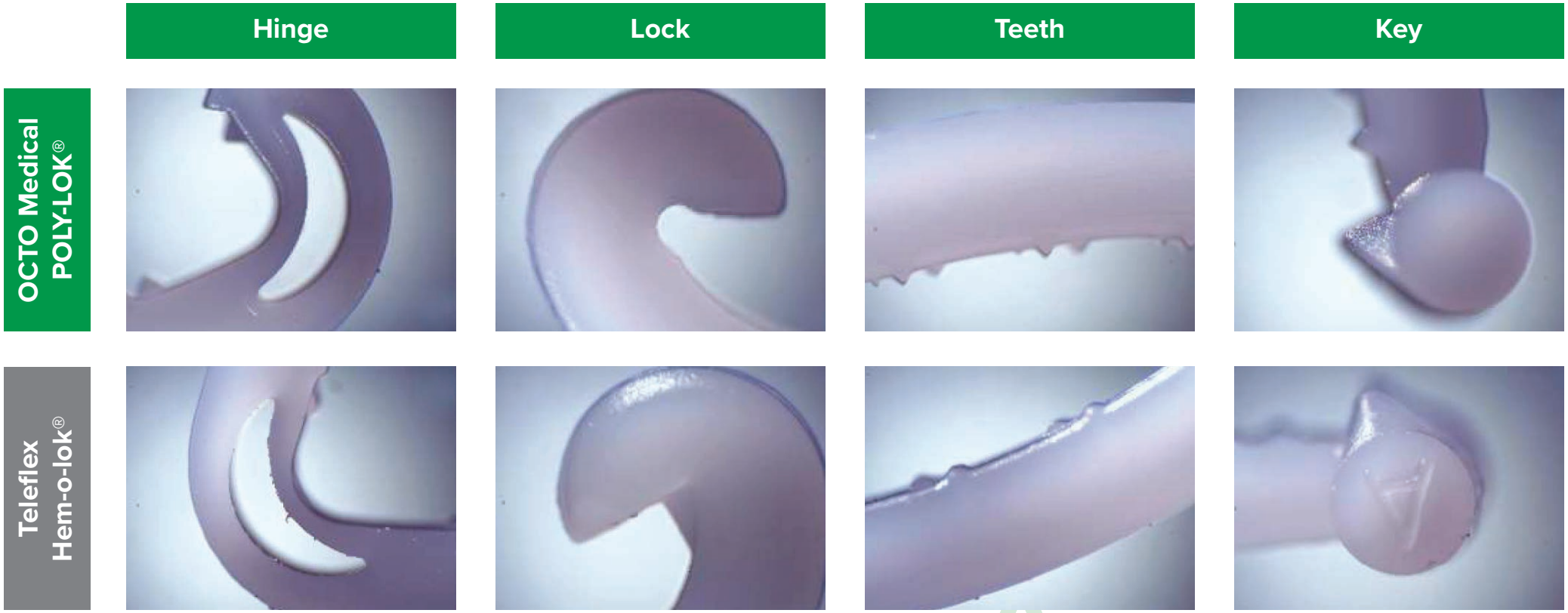

Figure 4. Representative images of medium-sized polymer ligating clip internal surface.

OCTO Medical POLY-LOK® Polymer Ligating Clips vs Teleflex Hem-o-lok® clips: Conclusion

This report highlights the strong similarity between OCTO Medical POLY-LOK® and Teleflex Hem-o-lok® polymer ligating clips, confirming that both share nearly identical material properties and chemical composition as reported by the manufacturers. Furthermore, our studies identify a 99.54% correlation between the two brands in their physical form, across seven key dimensions. A detailed examination of the clip topography, a key functional aspect, revealed a close resemblance in design and surface characteristics.

Finally, it can be concluded that OCTO Medical POLY-LOK® and Teleflex Hem-o-lok® are effectively equivalent in their application. Based on the reported similarity, OCTO Medical POLY-LOK® polymer ligating clips seem to be compatible with Da Vinci robotic arms since the manufacturer Teleflex has already validated the compatibility of their product with Da Vinci robotic arms. Due to similarity in durability, design, functionality, and performance, both products seem compatible with Da Vinci robotic arms, following both manufacturers' recommendations and validations.

All data held on file with OCTO Medical Ltd.
For further information please contact us at email: info@octomedical.org

OCTO MEDICAL®

OCTO Medical Limited
7 Bell Yard, London, WC2A 2JR, UK
Tel: +44 (0) 203 633 0198
email: info@octomedical.org
www.octomedical.org

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