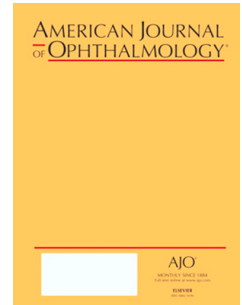


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Intraocular pressure measurement accuracy and repeatability of a modified Goldmann prism: Multi-center randomized clinical trial

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Purpose: Clinically evaluate a modified surface Goldmann (GAT) tonometer prism for IOP accuracy, repeatability, and safety.

Design: Prospective, open-label, randomized, controlled, multicenter reference device reliability and validity analysis

Methods: A GAT and a modified surface GAT prism measured IOP on 173 unique eyes. The study design and analysis complied with FDA 510(k) and ANSI Z80.10-2014 guidelines. All eyes were randomized to IOP measurement by one of 5 standard prisms or 5 modified prisms, each from different manufacturing lot. Pressures were measured by 6-investigators, 2-times with each prism for a total of 1384 IOP measurements. Analysis included Bland-Altman difference accuracy, intra-operator and inter-operator IOP measurement and manufactured lot repeatability.

Results: Bland-Altman indicated no IOP measurements pairs outside the ± 5 mmHg guidelines. Operator and manufactured lot repeatability F-tests and one way ANOVAs indicated no statistical difference between the standard and modified prisms (all $p > 0.10$). The difference in IOP measurements of the standard and modified prisms correlated well to Dresdner CCT correction ($p = 0.01$).

Conclusion: A modified surface replacement prism is statistically equivalent to a flat-surfaced prism. The modified surface prism indicated statistically significant correction for CCT requiring further testing outside the ANSI standard limits ($0.500\text{mm} < \text{CCT} < 0.600\text{mm}$) to examine its full potential.

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