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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 ANSIZ80.10-2014 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 +/-5mmHg 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 ($0.500mm<CCT<0.600mm$) to examine its full potential.