

# Intraocular Pressure Measurement during Application of the Oraya I-Guide™ in Yucatan Mini-swine

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## Purpose

The purpose of this study was to measure the intraocular pressure (IOP) during application of the Oraya I-Guide in Yucatan mini-swine.

The I-Guide is a vacuum-coupled scleral lens designed for stabilization and precise manipulation of the eye and is used during radiotherapy treatment for wet age-related macular degeneration on the Oraya IRay™ system. While no radiation was delivered in this study, clinical parameters were simulated to evaluate IOP across a range of testing conditions.



I-Guide



IRay System

During IRay treatment, vacuum is supplied by the disposable syringe in the I-Guide kit while applanation (small bias force applied to stabilize the eye) is supplied by a spring-loaded mechanism on the IRay system.

## Methods

Four eyes from mini-swine were subject to tests lasting approximately five minutes. For each eye, a pressure sensor catheter (Data Sciences International PA-C40) was inserted into the vitreous (Figure 1) and monitored remotely by a receiver (DSI RMC-1).

Application of the I-Guide was repeated using different levels of vacuum and applanation, both below and above the clinical standard. A spring attached to a force gauge was used to simulate applanation bias on the eye. A vacuum gauge (Supco DPG25V) placed inline with the I-Guide tubing was used to verify the suction levels (Figure 2).

## Financial Disclosures

MEA: E; EMS: E; GG: C; SS: C; SH: E

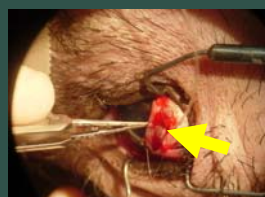


Figure 1: Insetion of the pressure sensor catheter.

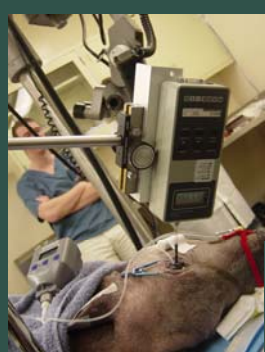


Figure 2: Testing setup, including a spring-biased applanator with force gauge and an inline vacuum verification.

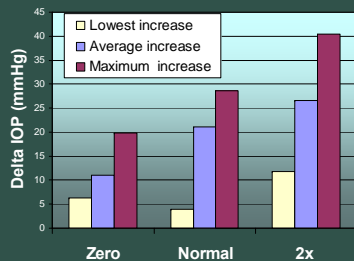


Figure 4: The minimum, average, and maximum peak increases in IOP during I-Guide application, separated by level of applanation force.

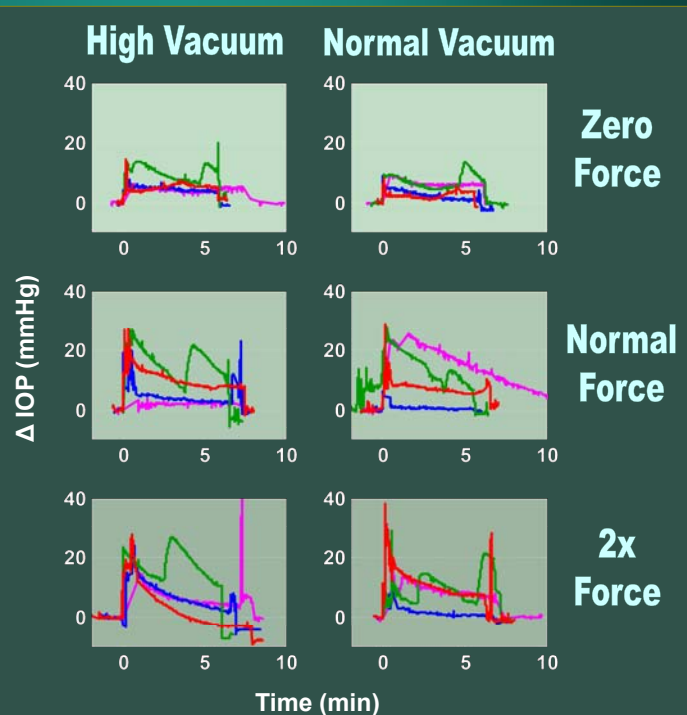


Figure 3: IOP increase for varying levels of vacuum and applanation force, with each color representing an individual test on an eye (six tests per eye).

## Less than 30 mmHg

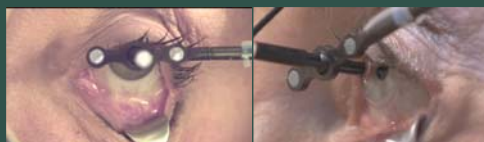


Figure 5: The I-Guide has been used on over 80 subjects in pre-clinical testing, in over 60 patients in pilot clinical studies, and in over 50 patients in clinical trials underway in Europe.

## Results

The increase in IOP during application of the I-Guide results from the cornea conforming to the lens under an applied vacuum as well as the applanation force holding the eye stable. All tests showed a slight decrease in vacuum pressure over time, but were absolutely stable in terms of the I-Guide remaining coupled to the eye. Figure 3 shows a comparison of IOP at two levels of applied vacuum and three differing applanation levels. There is no significant difference between elevated IOP at normal vacuum versus the higher vacuum level while there is a slight upward trend as a function of applied force. The maximum IOP levels generally occurred at the beginning or end of each procedure when the I-Guide was placed or removed. Direct physical manipulation of the eye is already known to cause transient changes in IOP.

## Conclusion

The maximum IOP increase due to application of the I-Guide was recorded at 40.5 mmHg using a sensor inserted into the posterior chamber of pig eyes. Under normal conditions, the increase in IOP was well below 30 mmHg (Figure 4). Once the eye is captivated by the lens, the level of vacuum does not appear to have an impact on IOP. Additional forces applied to the eye, whether by the user placing the I-Guide or from the spring-loaded holder, cause a transient increase in IOP. In addition to information gathered from human clinical studies (Figure 5), these results show that the I-Guide is a safe patient interface for performing treatments on the IRay system.

