BIORESONATOR ART

The BioResonator ART® is based on advanced resonance technology and has been developed through well documented research.

Development of the Applanation Resonance Tonomerty, ART®, for IOP measurement

The novel ART® was developed as a new method for IOP measurement. The tonometer is based on resonance technology where the sensor is sustained at its resonance frequency. When applied against the cornea there will be a frequency shift which is proportional to the contact area. By continuous measurement of the contact force and the frequency shift (Figure 1), the IOP can be calculated according to the applanation principle, which states that the IOP equals the ratio between force and contact area.

The tonometer was first evaluated in an in vitro model. An optimization algorithm determined the optimal analysis and time interval for measurement of IOP. The tonometer proved to have high precision. [1]

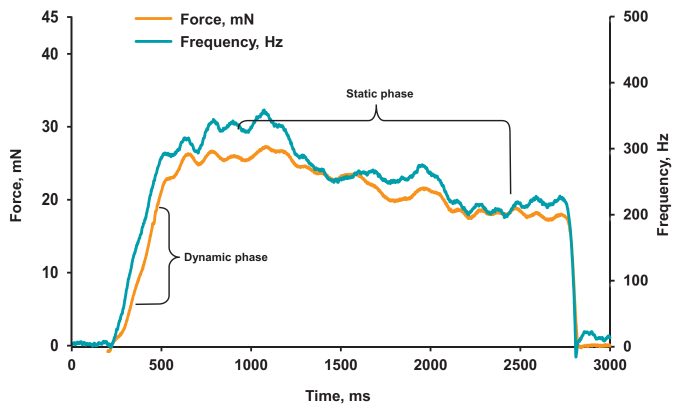

Figure 1. During ART® measurements there is a continuous registration of force and frequency. IOP can be measured during the static as well as the dynamic phase.

Adjustments to minimize the effects of off-centre placements

In a clinical setting, off-center placements of the sensor against cornea are unavoidable. The ART® design was optimized to minimize the risk of reduced precision under these circumstances. The new design included a modified sensor with a symmetric probe which decreased the placement dependence significantly. The precision of the new design fulfilled the ISO standards for eye tonometers. [2]

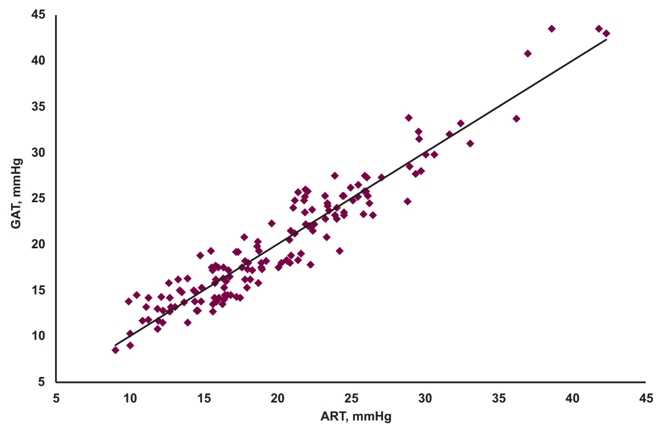

Figure 2. IOP was measured on 153 eyes using ART® and Goldmann. The correlation between the methods was 0.95 and the standard deviation 2.1 mm Hg.

Clinical evaluation verifying ART® precision within ISO requirements

The ART® instrument was evaluated in a clinical study, both as a handheld device and in a biomicroscope setup, with the Goldmann technique as a reference method. Again, the results showed that the precision of ART® was within the ISO standards (Figure 2). [3]

Further refinement of the technique and introduction of ART® Servo

The ART® instrument was further developed with two analysis methods. The dynamic method measures IOP during the indentation phase and the static resemble the Goldmann technique (Figure 1). The instrument was also complemented with a servo-controlled version.

A clinical study was performed to find whether ART® Manual still fulfilled the ISO standards after the refinements and if the new ART® Servo would meet the demands. The results showed that the precision of ART® Manual was within the ISO requirements for both dynamic and static readings. The ART® Servo was close to meet the standard with static analysis and only failed in the highest IOP range, due to technical issues with the prototype. These effects are not present in the commercial ART® Servo. [4]

Underestimation of IOP after LASEK

For eyes treated with laser surgery there is a risk of underestimation of IOP. The impact of keratectomy on ART® results was analyzed in an in vitro study, where it was compared against the Goldmann technique. The underestimation by ART® was significantly lower than with the Goldmann method. [5]

Underestimation of IOP was further investigated in a clinical study on LASEK treated subjects. The study compared ART® with both another commercially available method and Goldmann. The mean underestimation was smallest with ART® . However, there was no significant difference between the three methods (Figure 3). [6]

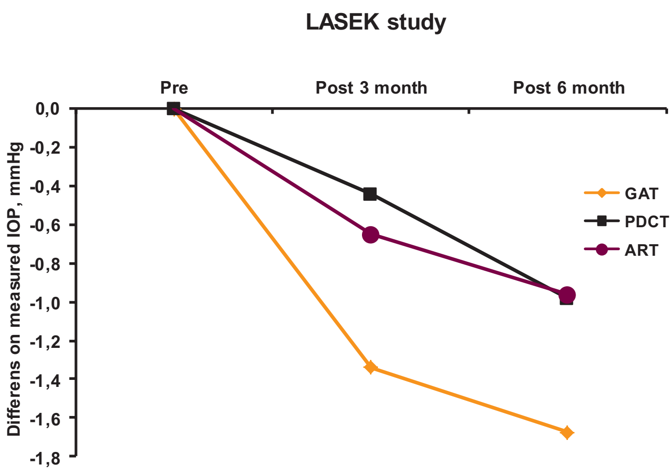

Figure 3. IOP was measured on 53 eyes before and after LASEK using ART® and two other methods. A significant reduction in the IOP reading was observed with all three methods.

References

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3. Hallberg, P., et al., *Clinical evaluation of applanation resonance tonometry: a comparison with Goldmann applanation tonometry.* J Glaucoma, 2007. 16(1): p. 88-93.

4. Johannesson, G., et al., *Introduction and clinical evaluation of servo-controlled applanation resonance tonometry.* Acta Ophthalmol, 2011.

5. Hallberg, P., et al., *Underestimation of intraocular pressure after photorefractive keratectomy: a biomechanical analysis.* Med Biol Eng Comput, 2006. 44(8): p. 609-18.

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