A89 Miniaturized High-Intensity Focused Ultrasound device for the treatment of Glaucoma: a Clinical Pilot Study

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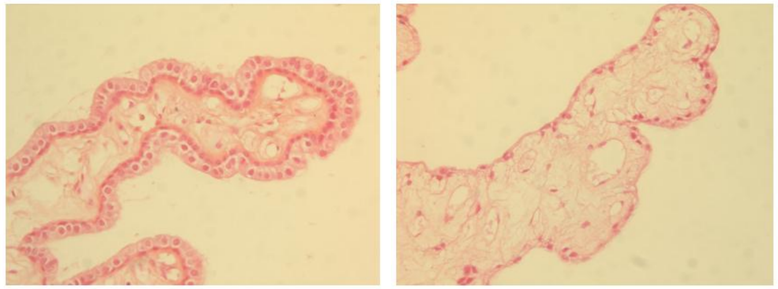
PURPOSE

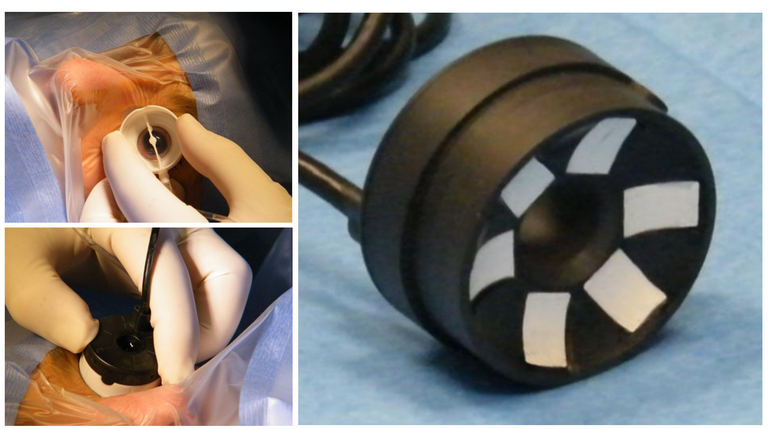
To evaluate the safety and efficacy of HIFU (high-intensity focused ultrasound) delivered by a miniaturized annular therapy probe in patients with refractory glaucoma.



High-magnification photomicrograph (120x) showing details of necrotic ciliary processes with loss of the ciliary epithelium, vascular congestion, and distension of the stromal collagen fibers (right) and an untreated ciliary processes (left) in rabbits (**Aptel *et al*, IOVS 2010**).

METHODS

HIFU device: A ring shaped therapy probe containing six active piezoelectric elements was inserted in a coupling cone made of polymer. Each of the six transducers was a segment of a 10.2 mm radius cylinder with a 4,5 mm width and a 7 mm length (surface area of about 35 mm²). The focal volume of each transducer has approximately an elliptic cylinder geometric shape (axial length 1,4mm, transverse width 0.7 mm and the lateral width 3,5 mm).



METHODS

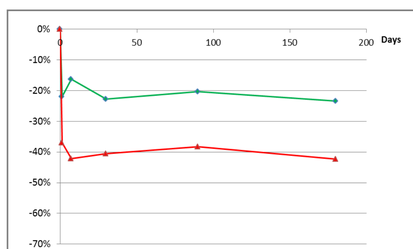
The six transducers were placed at regular intervals on the circumference of the ring and oriented in order to create a focal zone consisting of 6 elliptic cylinders regularly disposed in a 11.7, 12.2 or 12.7 mm diameter circle superimposed on the ciliary body. The resonant frequency of the transducers was 7 MHz; and we operated it at its third harmonic, i.e. 21 MHz.

Procedures: Prospective non comparative interventional clinical study in 12 eyes of 12 patients with refractory glaucoma and uncontrolled intraocular pressure (IOP). UBM and a complete ophthalmic examination were performed before the procedure, and at 1 day, 1 week, 1, 3 and 6 months after the procedure. The following parameters were used: acoustic power 2 W, duration of each shot 3 s (group 1: patients 1 to 4), 4s (group 2: patients 5 to 12), time between each shot 20 s.

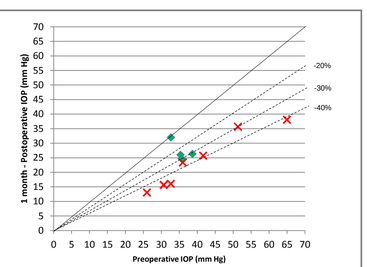
RESULTS

IOP reduction

IOP was reduced from a mean **preoperative** value of 35.6 ± 2.5 mmHg (n=2.5 glaucoma medications) to a mean **postoperative** value of 27.9 ± 5.7 (n=1.8), 29.6 ± 4.9 (n=2.3), 27.3 ± 3.2 (n=3.0), 27.8 ± 9.0 (n=2.8) and 27.0 ± 4.9 (n=2.3) at 1 day, 1 week, 1, 3 and 6 months respectively in the **group 1** and from a mean preoperative value of 40.5 ± 13.6 (n=3.3) to a mean postoperative value of 27.1 ± 16.3 (n=2.9), 24.6 ± 13.4 (n=2.9), 23.9 ± 9.9 (n=3.3), 29.1 ± 9.5 (n=3.5), 23.4 ± 7.0 (n=3.5) in the **group 2**. IOP reduction appears to be more important in the group 2 than in the group 1.



Relative IOP reduction from baseline in groups 1 (**green**) and 2 (**red**).



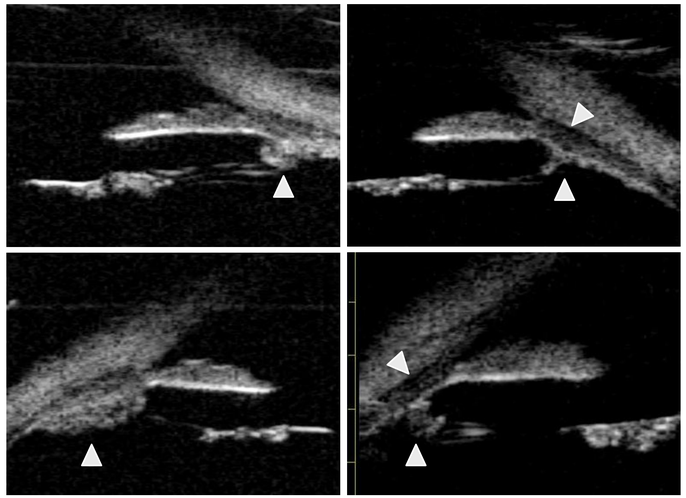
Scattergram at 1 month : groups 1 (**green**) and group 2 (**red**).

Safety and tolerability

No major intra- or post-operative complications occurred. Trabeculectomy was performed in one patient due to lack of efficacy at one month. Superficial punctuate keratitis occurred in 3 patients and central superficial corneal ulceration in 1 patient. All of them presented a pre-operative pathologic condition of the cornea. All were successfully treated with artificial tears and vitamin A. Visual acuity remained statistically unchanged.

Ultrasound Biomicroscopy

UBM showed cystic involution of the ciliary body in 9 of the 12 eyes, and a suprachoroidal fluid space in 6 of the 12 eyes.



Ultrasound biomicroscopy showing the ciliary body and ciliary processes before (left) and 30 days after (right) ultrasonic circular cyclocoagulation (Aviso 50 MHz probe, Quantel Medical, Clermont-Ferrand, France).

CONCLUSIONS

Circular coagulation of the ciliary body using HIFU (high-intensity focused ultrasound) delivered by a ring shaped miniaturized therapy probe seems to be an effective and well-tolerated method to reduce intraocular pressure in patients with refractory glaucoma.

The single step procedure was short (less than 2 minutes), easy and accurate.

UBM showed localized and reproducible cystic involution of the ciliary body and no damages of the adjacent ocular structures.

References :

Aptel F, Charrel T, Palazzi X, Chapelon JY, Denis P, Lafon C. Histologic effects of a new device for high-intensity focused ultrasound cyclocoagulation. Invest Ophthalmol Vis Sci. 2010 Oct;51(10):5092-8.

Charrel T, Aptel F, Birer A, Chavrier F, Romano F, Chapelon JY, Denis P, Lafon C. Development of a miniaturized HIFU device for glaucoma treatment with conformal coagulation of the ciliary bodies. Ultrasound Med Biol. 2011 May;37(5):742-54. Epub 2011 Mar 25

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