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Development of a miniature ultrasonic device for conformal cyclocoagulation : From transducer design to early clinical trials

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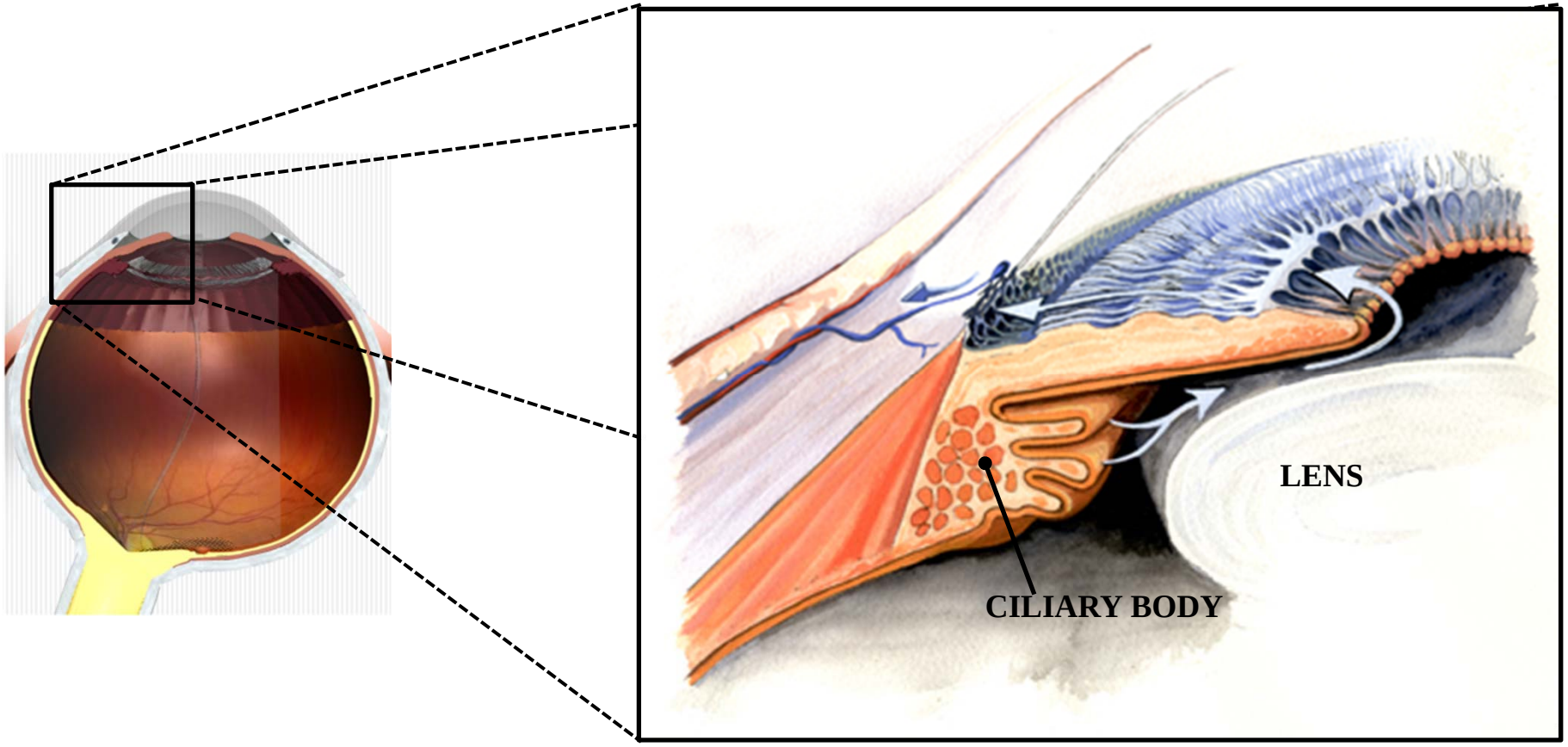
EyeTechCare
High Tech for Eye Care

Hôpitaux de Lyon

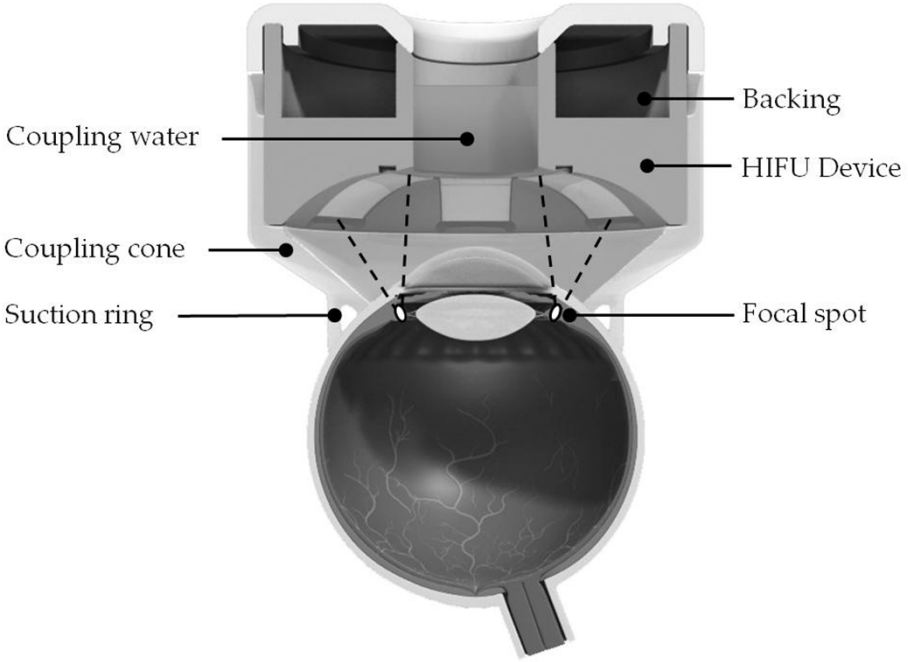
lab

Glaucoma



Aim of our study

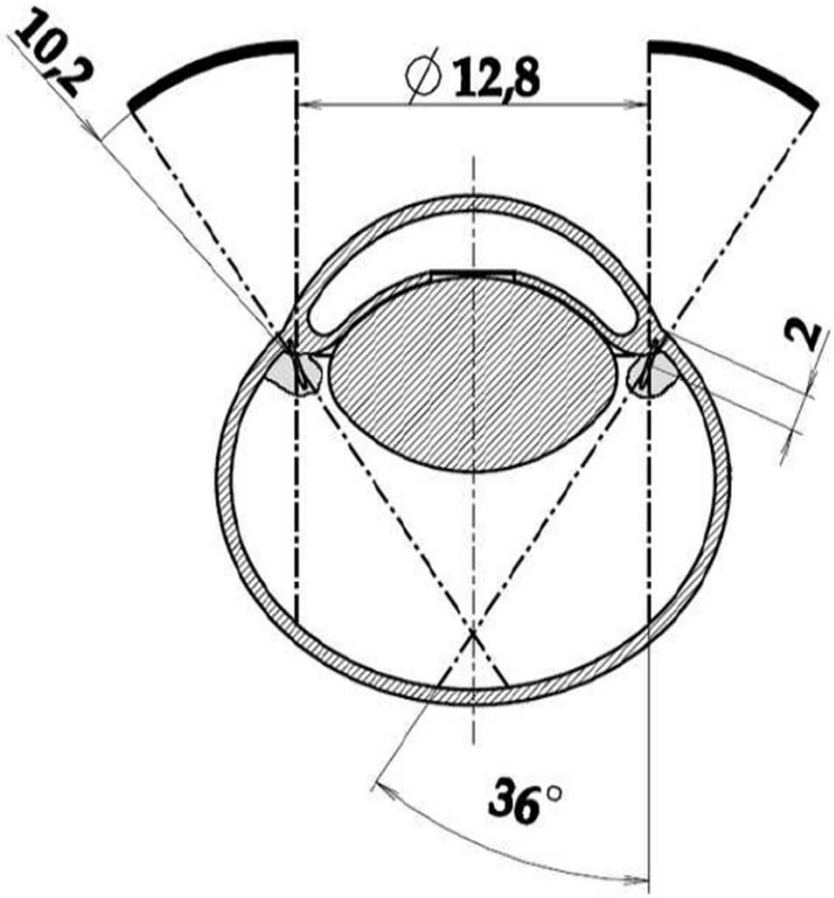
Achieve precise, fast cyclodestruction with a disposable ultrasonic device and without image guidance



1. Transducer design and characterization
2. In vivo experimentation in rabbits
3. First clinical trials

Design of the device - Methods

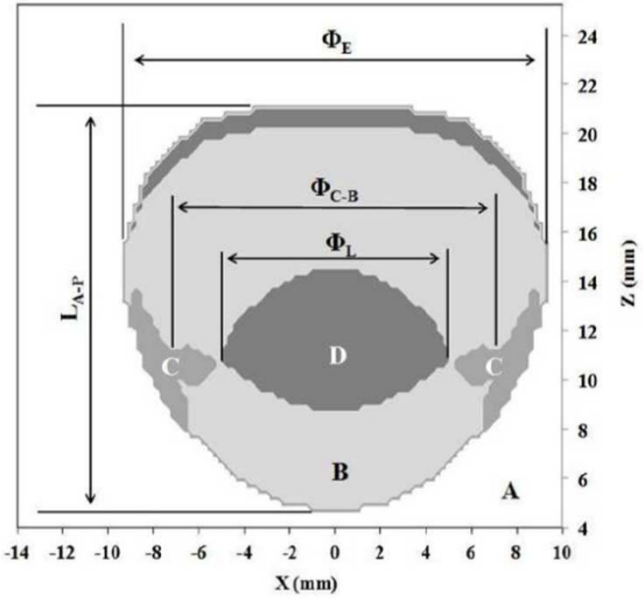
- Anatomical constraints (ciliary body, lens, cornea, retina)

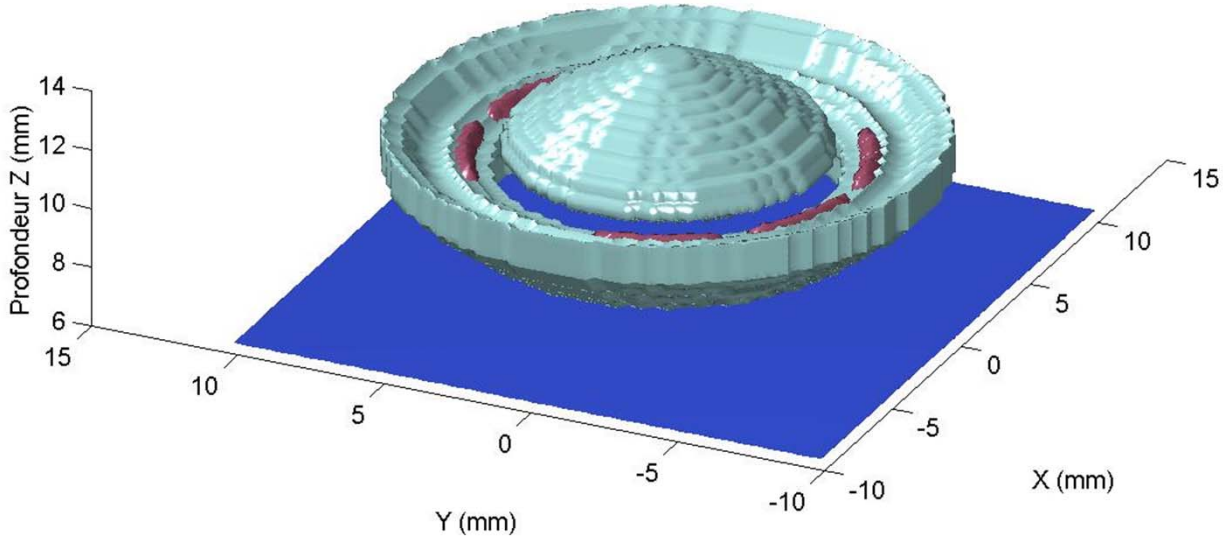


Design of the device - Methods

- Numerical modeling (→ exposure conditions)
  - Rayleigh integral
  - Bio Heat Transfer Equation
  - Thermal Dose

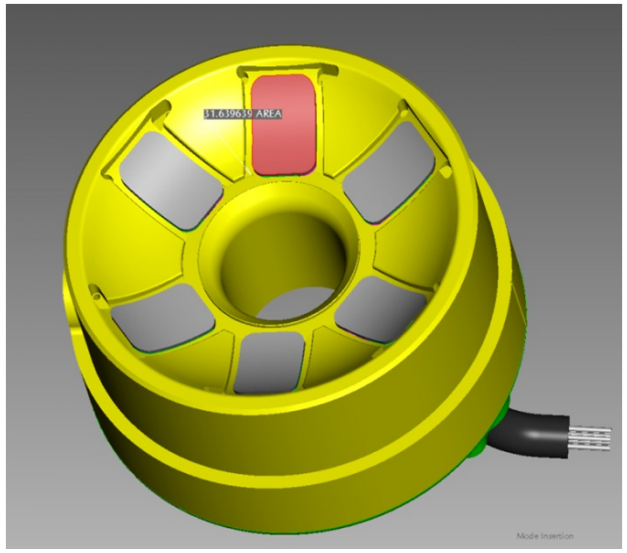
2 W
3s ON
20s OFF

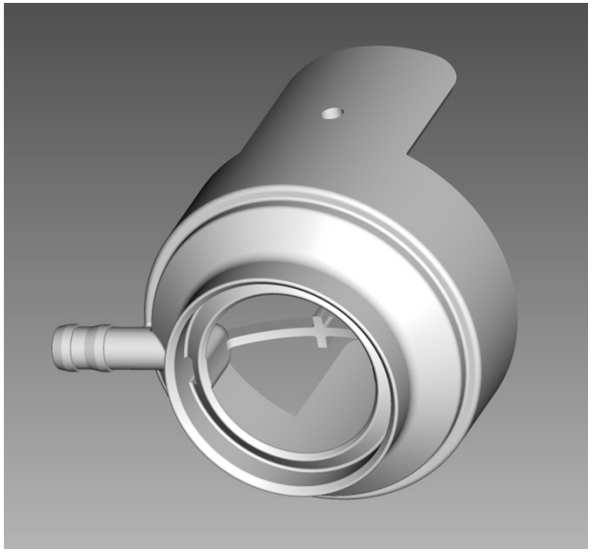




Design of the device - Results

Feature	Value
Piezo ceramic elements	6 (~70% of CB)
Operating frequency	21 MHz
Focal distance	10.2 mm
Diameter of circular lesion	11.7, 12.2 or 12.7 mm
Diameter of central hole	12.8 mm





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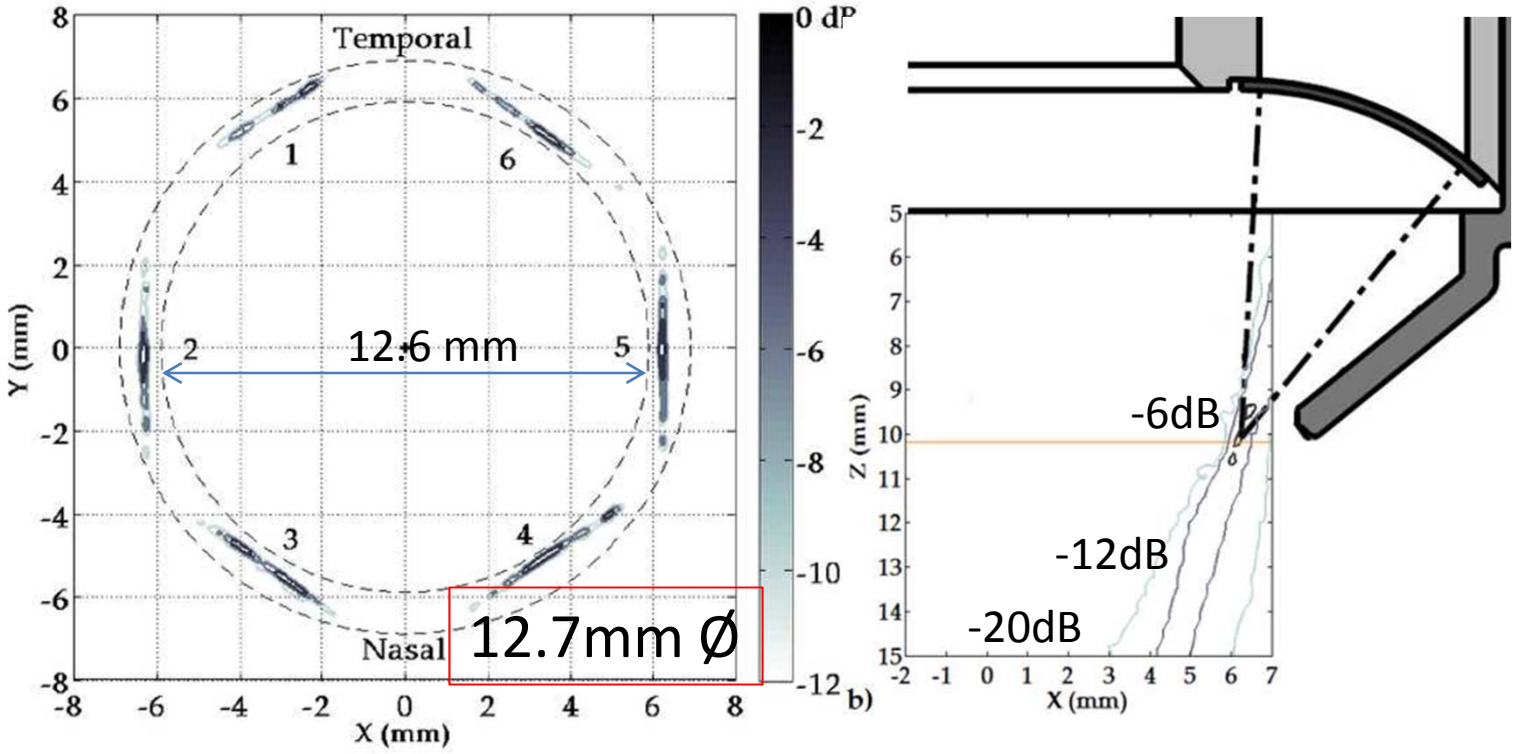
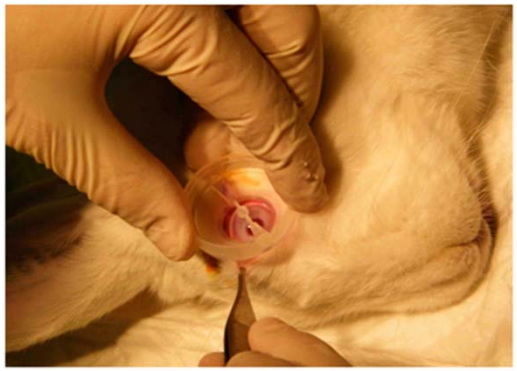
Characterization of the device

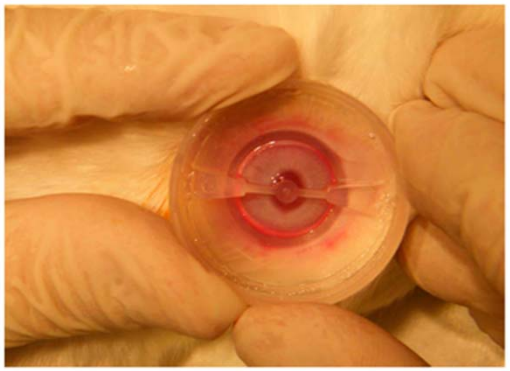
- Field maps to assess the effect of the coupling cone

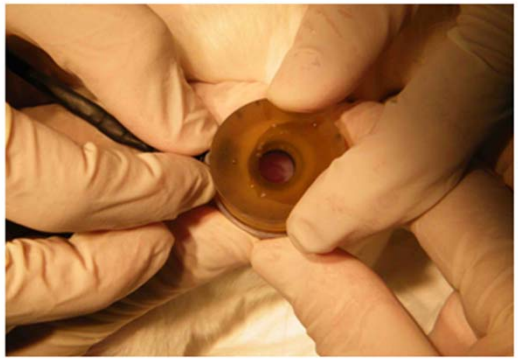


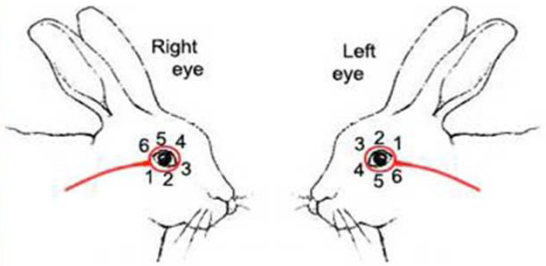
Animal experimentation - Methods

- 18 rabbits, 6 (Gr 1), 5 (Gr 2) or 4 (Gr 3) activated sectors
- IOP followed for 28 days after sonication, assessment of undesired effects
- Exposure conditions: 21 MHz, 2 W for 3 s, 20s OFF



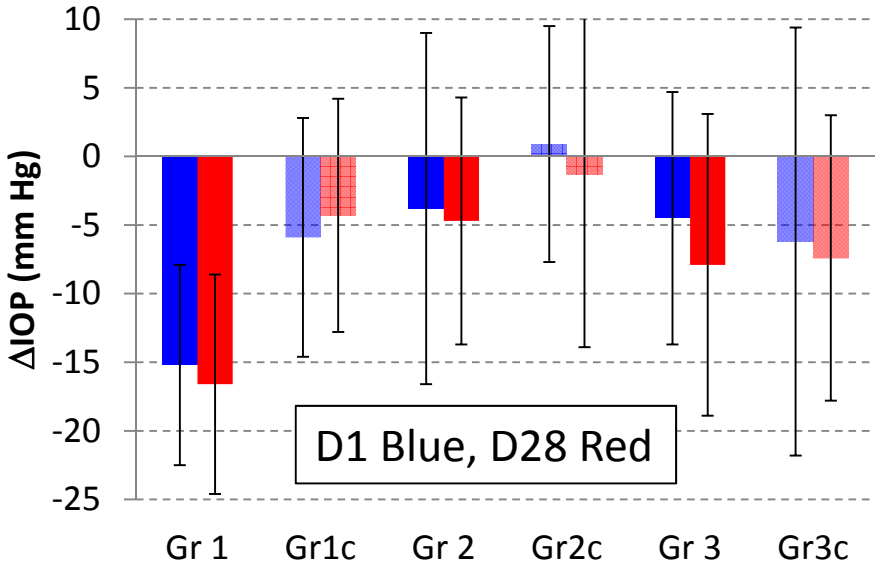


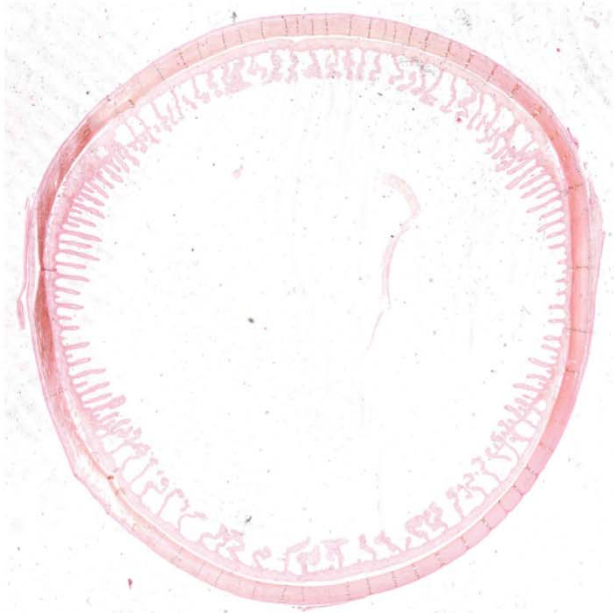


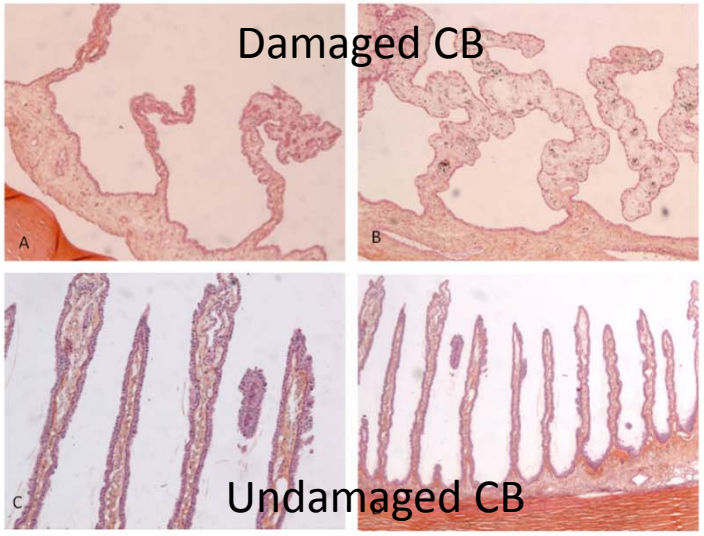


Animal experimentation - Results

- Sustained IOP reduction at D28 for Gr 1
- Damages very localized to the ciliary body (CB)

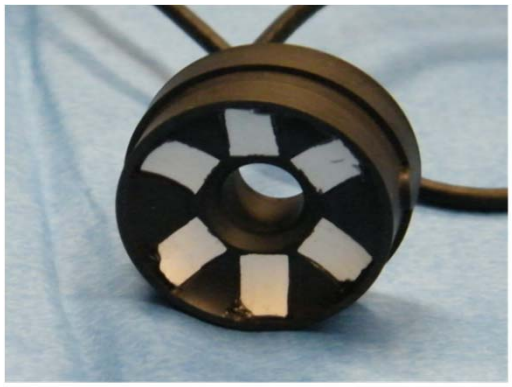


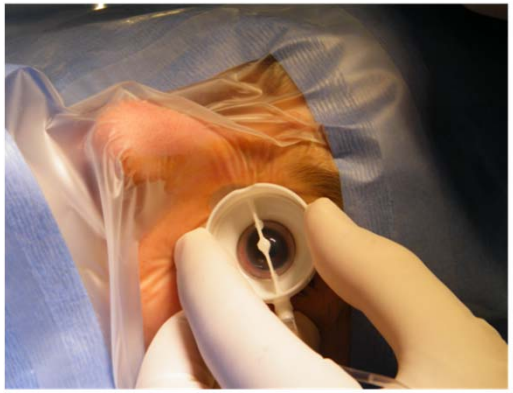




Clinical trials - Methods

- Treatment under general anesthesia
- Exposure conditions: 21 MHz, 2 W, 3 s ON (1→4) and 4 s (5→12), 20 s OFF





Clinical trials – Inclusion criteria

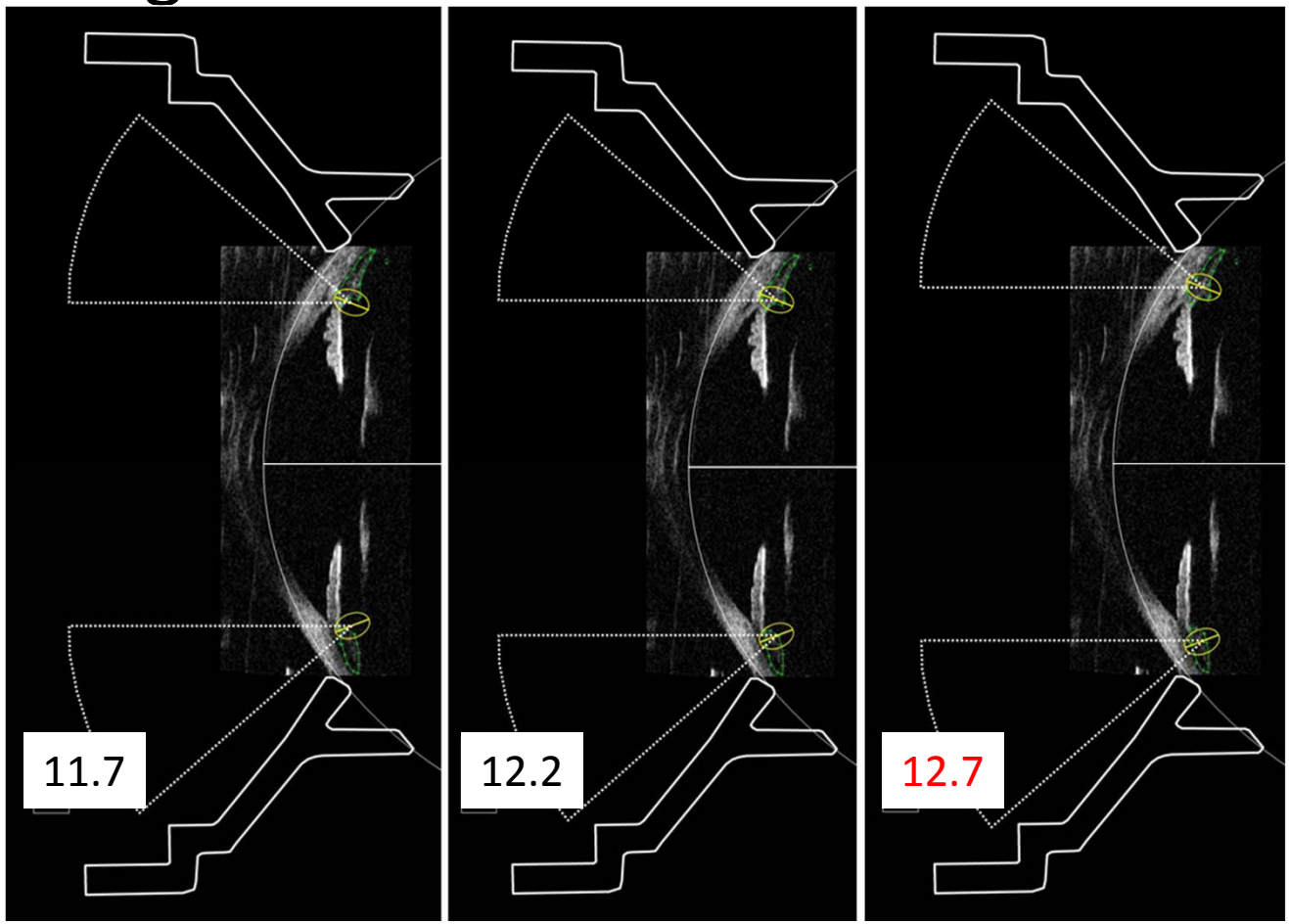
- Men or women aged of 18 years or older
- Ability and willingness to return for scheduled visits
- Diagnosis of refractory primary or secondary glaucoma with at least one previous incisional glaucoma surgery
- Average baseline IOP of 21 mm Hg or more
- Best corrected visual acuity less than 20/60
- Visual field defect with a minimum of one location in the paracentral region exhibiting repeatable abnormality at the $p < 0.5\%$ level in the study eye.

Clinical trials – Exclusion criteria

- Mental impairment conflicting with informed consent or follow-up
- Current use of any investigational drug or device
- Pregnancy
- Concomitant systemic medications that can affect the IOP
- Diagnosis of normal tension glaucoma
- History of refractive surgery, retinal detachment or ocular tumor
- Intraocular surgery or laser within the last month
- Ocular infection in the past 2 weeks.

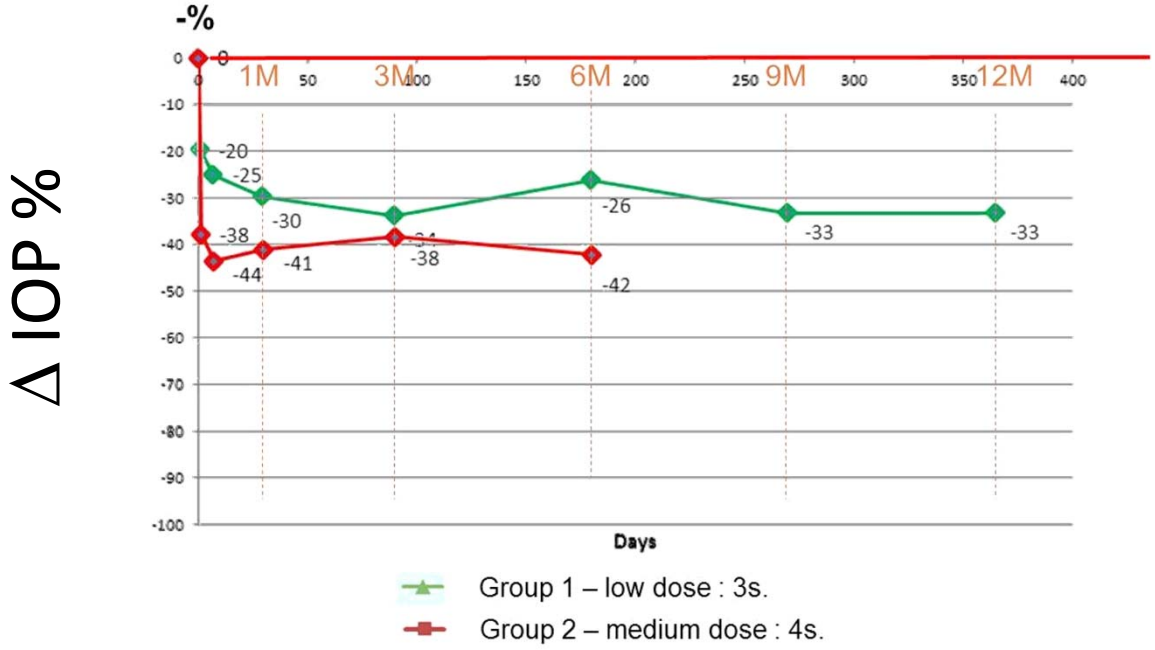
Clinical trials – Choice of device

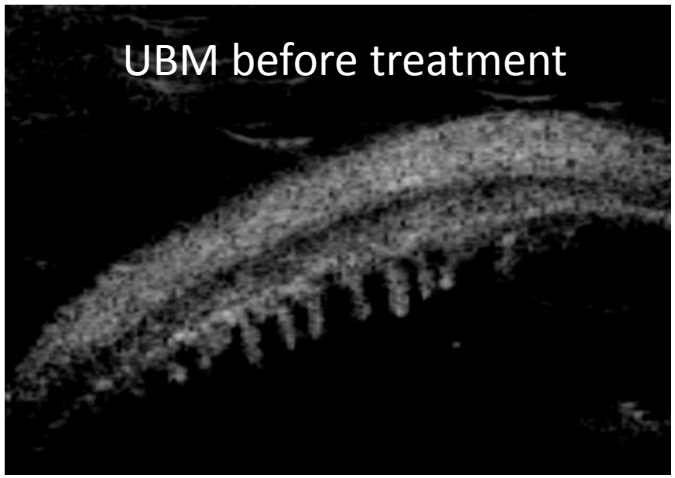
- Fit device and expected treatment zone over UBM images

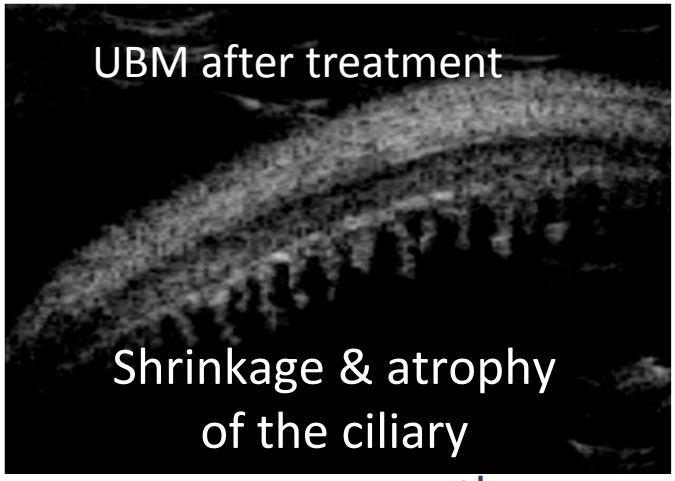


Clinical trials - Results

- 12 patients (3 et 4 s)
- No major side effects (Corneal ulcerations)
- One failure → trabeculectomy
- IOP↘ up to 45% - stable







processes, no other damages

Conclusions

- Design and test in vivo an ultrasonic device for easy, fast and conformal destruction of the CB
- Perform very promising clinical trials with excellent tolerance and significant drop of IOP on patients with refractory glaucoma