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

Cyril Lafon, Florent Aptel, Thomas Charrel, Alain Birer, Françoise Chavrier, Jean-Yves Chapelon, Fabrice Romano, Philippe Denis
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

<table>
<thead>
<tr>
<th>Feature</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Piezo ceramic elements</td>
<td>6 (~70% of CB)</td>
</tr>
<tr>
<td>Operating frequency</td>
<td>21 MHz</td>
</tr>
<tr>
<td>Focal distance</td>
<td>10.2 mm</td>
</tr>
<tr>
<td>Diameter of circular lesion</td>
<td>11.7, 12.2 or 12.7 mm</td>
</tr>
<tr>
<td>Diameter of central hole</td>
<td>12.8 mm</td>
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</tbody>
</table>

![Diagram of the device](image-url)
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
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