High Intensity Focused Ultrasound treatment in Refractory Glaucoma patients. Results at 1 year.

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PURPOSE
To evaluate the safety and the Efficacy of High Intensity Focused Ultrasound (HIFU) – EyeOP1-1, allowing to perform a UC3 procedure (Ultrasonic Circular Cyclo Coagulation) in patients with Refractory Glaucoma.

METHODS
Our study is a prospective study of 20 eyes of 20 patients with Refractory Glaucoma (POAG (n=13) and secondary (n=7)) and with an IOP before treatment > 30 mmHg. The study started in June 2012 and the last patient was enrolled in September 2012. HIFU is a new technology now available for cyclocoagulation, utilizing the medical device EyeOP1 (EyeTechCare – France) and a novel ring-shaped miniature probe with 6 piezoceramic transducers emitting ultrasound energy focused on the ciliary body and processes.

All patients had an IOP of at least 30 mmHg with maximally tolerated medical treatment and at least one previous invasive glaucoma surgery which failed. All eyes were treated with HIFU delivered through 6 high-frequency transducers operating at 21 MHz and firing for 6 seconds each. Complete ophthalmic examination was performed before treatment and at 1 day, 1 week, 1 month, 3 months, 6 months, 12 months follow up.

The procedure was performed as shown below. Primary outcomes were surgical success (defined as IOP reduction from baseline ≥ 20% and IOP > 5 mmHg) at the last follow-up visit. Secondary outcomes were mean IOP at each follow-up visit compared to baseline, medication use, complications and re-interventions.

Procedures: we performed a UBM exam on all the patients before treatment to determine the size of the probe to be used (3 sizes were available: 11, 12 and 13 mm). The size of the probe was then determined according to the simulation as shown on the picture below (Figure 2). All patients were treated in an ambulatory procedure. All treatments were performed after retrobulbar or peribulbar anesthesia.

Patients: Twenty eyes of 20 patients (12 males and 8 females) with a mean age of 70 years (Range=31-85) were treated in the study. Six eyes were phakic and fourteen Pseudophakic.

Efficacy Results

Table 1 : Baseline and postoperative mean IOP (mmHg) and mean IOP reduction (%).<br>Mean ± SD.

<table>
<thead>
<tr>
<th>Baseline</th>
<th>All patients (n=20)</th>
<th>Responding patients at last follow-up (n=13)</th>
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<tbody>
<tr>
<td>IOP (mmHg)</td>
<td>36.5 ± 6.5 (n=20)</td>
<td>26.5 ± 6.5 (n=13)</td>
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<tr>
<td>1 day</td>
<td>27.5 ± 6.5 (n=20)</td>
<td>17.5 ± 6.5 (n=13)</td>
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<tr>
<td>1 week</td>
<td>18.5 ± 6.5 (n=20)</td>
<td>11.5 ± 6.5 (n=13)</td>
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<tr>
<td>1 month</td>
<td>20.3 ± 6.5 (n=20)</td>
<td>11.5 ± 6.5 (n=13)</td>
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<tr>
<td>3 months</td>
<td>21.1 ± 6.5 (n=20)</td>
<td>18.3 ± 6.5 (n=13)</td>
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<tr>
<td>6 months</td>
<td>23.2 ± 6.5 (n=20)</td>
<td>18.3 ± 6.5 (n=13)</td>
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<tr>
<td>12 months</td>
<td>19.2 ± 6.5 (n=13)</td>
<td>18.3 ± 6.5 (n=13)</td>
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<tr>
<td>Last follow-up</td>
<td>18.4 ± 6.5 (n=13)</td>
<td>18.4 ± 6.5 (n=13)</td>
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</table>

SAFETY RESULTS
No complications occurred during any of the procedures. Four patients felt pain during the treatment, each time during the activation of one transducer, and pain completely disappeared immediately at the end of the session.

No major postoperative complications such as phthisis, hypotony, cataract formation or retinal detachment occurred.

None of the patients encountered IOP spikes in the early follow-up. Minor postoperative complications were encountered such as hyperemia or superficial punctal keratitis.

DISCUSSION
High Intensity Focused Ultrasound (HIFU) was found to be safe and effective in 65% of our Refractory Glaucoma cases. Most patients tolerated the procedure very well, with minimal temporary side-effects such as conjunctival irritation, flare and cells in the anterior chamber.

It is apparent that the accurate delivery of Ultrasound Energy to the ciliary body and processes due to the pre-measurements and design of the instrumentation, may provide an added value, affecting larger regions of tissue compared to other cycloablative techniques, with subsequent sharp reduction in IOP.

CONCLUSION
Ultrasonic Circular Cyclo-coagulation using HIFU is a promising new technology for lowering IOP in refractory glaucoma cases. The good per- and post-operative tolerance and the encouraging results of IOP reduction over time in such difficult cases make this new method a useful tool in glaucoma treatment.

References

Commercial Relationships: Shlomo Melamed, Edo, Aptel F, Chappelat F, Darie P, Latinyo C. No other conflicts of interest.

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Figure 1: HIFU Device (A) and UC3 procedure (B). The ultrasound beam (A) focused and the device held 30-40 mm from the globe. Creating a cone (B) is placed directly in contact with the eye. The piezoelectric device is used to couple energy to the eye through saline solution before starting the treatment.

Figure 2: UBM exam prior to treatment, which is used to determine the size of the probe to be used in this case.