Current Status of Clinical Research of Ultrasound Ciliary Plasty and Implications for Clinical Practice

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- Ultrasound ciliary plasty (UCP) is a new procedure that has been developed to gently and precisely modify the structure of the ciliary body to reduce intra-ocular pressure (IOP) in open-angle glaucoma, while sparing the adjacent ocular structures.
- UCP is particularly useful for patients with an elevated risk of surgical failure and for refractory glaucoma following failed filtering surgery.
  - The procedure uses a positioning cone and a sterile, single-use therapy probe, which contains six ultrasound transducers.
  - A second-generation probe has been developed that has a broader active transducer area compared with the original as well as a more precise temperature calibration of the individual transducers.
- A meta-analysis was performed from 7 clinical trials (n=251) that involved a follow-up of up to 12 months.
  - 53% (133 patients) had refractory glaucoma
  - 47% (118 patients) were naïve of filtering surgery
  - 84% (211 patients) had primary open angle glaucoma
  - 16% (40 patients) with secondary glaucoma
- Devices with either the first- and second-generation probe were effective in reducing the mean IOP across all indications (see figure below).
- Safety and tolerability were good; persistent hypotony, phthisis bulbi or induced cataract were not observed.
- The most common side effect was conjunctival hyperemia, which occurred in 69% of patients (n=173).
- Serious complications were rare. These included:
  - Loss of visual acuity (>2 Snellen lines) in 6 patients;
  - Corneal abrasions/epithelial defects (4 patients); and
  - Induced astigmatism (3 patients).
- Superior reproducibility of IOP reduction was observed with procedures using the second-generation therapy probe over the original probe.
- The CE mark of the treatment has been extended from refractory glaucoma after a failed filtering surgery to include non-refractory patients.
- Recommended patient profile is:
  - Between 18 and 90 years old, male or female, able and willing to be followed up at 7 days, 1 month, 3 months, 6 months, 12 months, and every 6 months thereafter.
  - Primary open angle glaucoma including pigmentary glaucoma and pseudoxfoliative glaucoma.
  - Any patient having previously failed filtration surgery or patients having an elevated risk for surgical failure.
  - Patients having an IOP which is not adequately controlled with maximally tolerated glaucoma medication, with IOP ≥21 mmHg and IOP <35 mmHg.
- UCP is not to be performed earlier than 90 days after previous intraocular surgery or laser treatment.
- One re-treatment procedure is possible, provided the IOP is not sufficiently controlled after one procedure and the patient is complication free. Re-treatment is not recommended until month 3 postoperatively.

UCP with high-intensity focused ultrasound delivered by miniaturised high-frequency transducers appears to be a promising, effective treatment for reducing IOP in patients with refractory and non-refractory open-angle glaucoma.

Mean intra-ocular pressure reductions for first- and second-generation probes – all indications

<table>
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<th>Follow-up (days)</th>
<th>Base</th>
<th>D1</th>
<th>D7</th>
<th>M1</th>
<th>M2</th>
<th>M3</th>
<th>M6</th>
<th>M12</th>
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<td>1st generation</td>
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<td>135</td>
<td>138</td>
<td>93</td>
<td>126</td>
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<td>101</td>
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IOP = intra-ocular pressure