A new device that uses high-intensity ultrasound for targeted cyclodestruction of the ciliary body shows promise as a safe and effective means of lowering intraocular pressure (IOP) in refractory glaucoma, according to a study presented at the World Ophthalmology Congress.

“UC3 is a technique that stands for ultrasound circular cyclo-coagulation, which seems to be an effective and well-tolerated method to reduce IOP in patients with refractory glaucoma, although it is a technique that is still in its infancy.”

Philippe Denis MD, Hôpital de la Croix Rousse, Lyon, France.

Prof Denis noted that the conventional clinical treatment for advanced refractory glaucoma using diode laser trans-scleral cyclophotocoagulation works by partially destroying ciliary body processes and reducing production of aqueous humour and IOP. “The studies that were previously carried out used ultrasound techniques for cyclodestruction, which are effective in terms of lowering IOP, but they are also associated with a high risk of complications, including hypotony, inflammation and irreversible visual loss,” he said.

The first commercial EU-approved high-intensity focused ultrasound (HIFU) system (Sonocare) has been used since the 1980s to treat refractory glaucoma, said Dr Denis, but the device’s popularity has been hindered by its bulky design, the complexity and duration of the procedure and complications associated with its use.

To overcome these drawbacks, the EyeOP1 device (EyeTechCare) uses miniature piezoelectric transducers for non-invasive treatment that can be administered on an outpatient basis under local anaesthesia, said Prof Denis.

The EyeOP1 system contains a command module that enables the ophthalmologist to set parameters for the procedure and to control the procedure throughout the treatment period. The command module is connected to the therapy device which is a sterile disposable part placed on the patient’s eye.

The major feature of UC3 treatment is the fact that it is circular and extremely accurate, said Prof Denis. The practitioner can administer treatment to the whole periphery of the globe of the eye in a single procedure, therefore avoiding many applications that are usually needed. The system can also produce partial coagulation of the ciliary body by perfectly controlling the process, positioning the device simply, accurately and reproducibly.

“The machine features a powerful ultrasound generator with six cylindrical transducers in order to produce six lesions with accurate positioning on the target and focalised on a linear segment. The transducers deliver energy to the eye with a specifically made aspiration system. Due to the high transducer operating frequency of 21 MHz, we obtain a highly focused, reproducible coagulation which preserves tissue barriers and reduces postoperative inflammation,” he said.

Preclinical studies of the device in albino rabbits observed no issues in terms of safety, said Prof Denis. “There were no problems in terms of local tolerance, no conjunctival burns, no scleral perforation, no cataract and we obtained very nice IOP reduction of up to 55 per cent in some cases. And this effect was durable after three months.”

Positive results Results from the first pilot study evaluating the safety and efficacy of the device in patients with refractory glaucoma were similarly positive, said Prof Denis. In the prospective, non-comparative, interventional clinical study, 12 eyes of 12 patients with glaucoma and uncontrolled IOP were treated using the EyeOP1 device. Patients were divided into two groups: group one in which patients received a three second spot duration, and group two in which the spot duration was four seconds.

In group one, IOP was reduced from a mean preoperative value of 29.9 mmHg at day one, 26.9 mmHg at one week, 23.1 mmHg at one month and 20.0 mmHg at six months. In group two, IOP was reduced from a mean preoperative value of 39.1 mmHg to 26.9 mmHg at day one, 23.0 mmHg at one week, 24.2 mmHg at one month and 25.1 mmHg at six months.

“These patients had very high mean preoperative IOP and we observed that IOP reduction was up to 33 per cent from baseline IOP in group one and up to 45 per cent from baseline in group two,” he said.

No major intraoperative or postoperative complications occurred, said Dr Denis. Superficial punctate keratitis was reported in three patients and central superficial corneal ulceration in one patient, but these were all treated successfully and all of these patients presented with a preoperative pathological condition of the cornea.

Prof Denis also noted that UBM imagery demonstrated localised and reproducible cystic involution of the ciliary body in eight of the 12 eyes, with no damage to the surrounding ocular tissues and a suprachoroidal fluid space in six of the 12 eyes.

Summing up, Prof Denis said that ultrasound circular cyclo-coagulation is an effective and well tolerated method to reduce IOP in patients with refractory glaucoma. “We now want to extend these results to less advanced glaucoma cases and to that end we have just begun a multicentre clinical trial in nine centres in France, and a European multicentre study is scheduled to begin in the fourth quarter of 2012,” he concluded.