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

In the 80s, HIFU were successfully tested for treating refractory glaucoma (Lizzi et al.). However, more clinically feasible laser-based approaches are now considered to be the gold standard. The new proposed ultrasonic device aims to perform a conformal, partial and fast thermal ablation of the ciliary body for reducing the production of aqueous humor and intraocular pressure (IOP).

Numerical simulations and anatomical constraints were considered for designing the device. It is made of six cylindrical transducers operating at 21MHz for modulating and producing sharp zones of ablation. In vitro tests and animal experimentation on rabbits were performed for characterization purpose. Each transducer generated sequentially an ultrasonic beam at an acoustical power of 2W for 3s. Significant decreases of IOP were obtained in vivo and no adverse effects were evidenced on histology. The feasibility, the tolerance and the efficacy of the treatment of refractory glaucoma were assessed during a clinical pilot study on eight patients. The absence of side-effects and the significant decrease of IOP, up 45% six months after treatment, proved the clinical relevance of this new device for treating refractory glaucoma.

Glaucoma is a very frequent ophthalmologic disease. An increase of the intraocular pressure (IOP) results in mechanical damage over the retina and the optical nerve.