In situ acoustomagnetic interrogation of a glaucoma valve with integrated wireless microactuator

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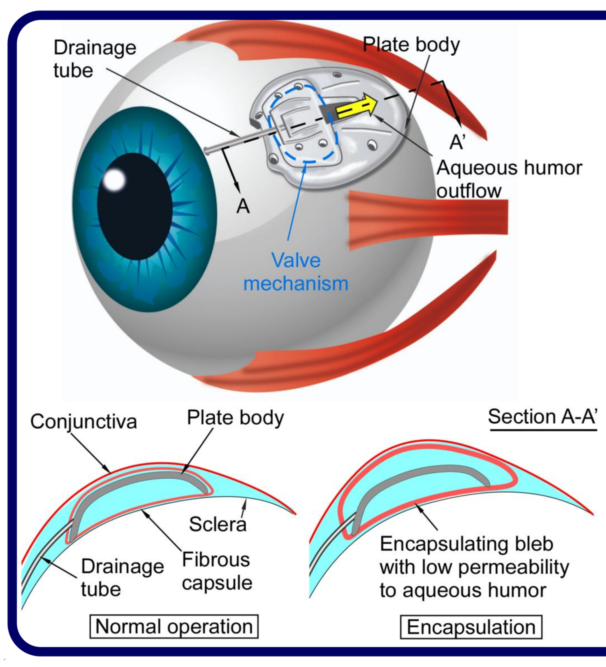
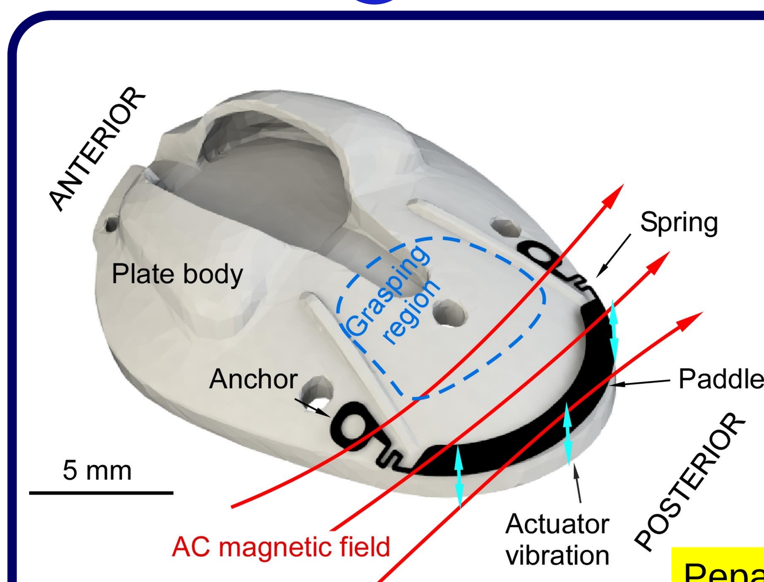
Summary: This work describes the design, fabrication and *in situ* evaluation of a system developed for interrogation of an actuator-integrated glaucoma valve. An implanted glaucoma valve facilitates drainage of aqueous humor (AH) from the eye to help lower intraocular pressure in patients with glaucoma. Here, a customized magnetoelastic actuator is integrated on the valve to limit the fibrosis and encapsulation of the valve that can otherwise lead to implant failure. The system described here excites the actuator magnetically and verifies the actuation by sensing the acoustic signals generated by the vibrating actuator. This work focuses on increasing the wireless range, reducing signal feedthrough, and establishing the clinical utility of the system. *In vitro* experiments performed with the system demonstrate a signal-to-noise ratio of ≈140. *In situ* experiments, performed with the actuator-integrated valves implanted in porcine eyes, achieve a signal to noise ratio of 3-6. These are the first recorded acoustic signatures through tissue from a magnetoelastic device in an implanted environment.

1 Challenges with Glaucoma Treatment



- 11.1 million people will be bilaterally blind due to glaucoma by the year 2020
- The Ahmed Glaucoma Valve (AGV) uses a drainage tube that drains AH into the space created by the plate body, located in a subconjunctival space over the sclera
- Over time, a fibrous capsule of tissue, or "bleb," is formed around the AGV, reducing permeability to AH, which, in turn, increases the resistance to AH outflow
- ~ 70% failure rate reported in AGVs due to this issue

2 Wireless Fibrosis Mitigation Concept

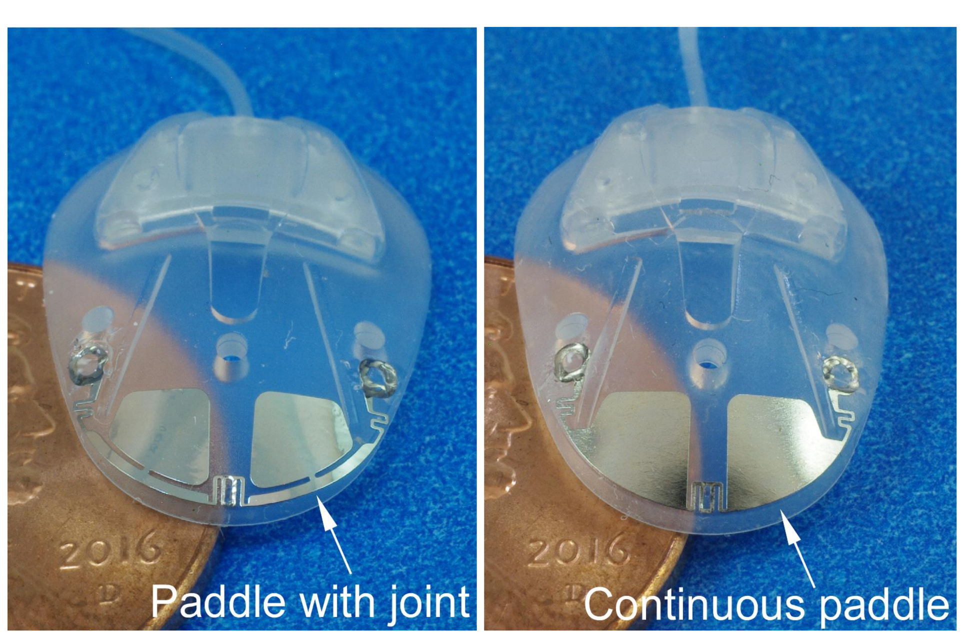


- The formation of the fibrous bleb is mediated by the adhesion and proliferation endothelial cells on the implant surface
- Magnetoelastic actuators can be Integrated with AGV to limit this cellular adhesion
- The actuation would impede complete encapsulation by preventing cells from adhering to large portions of the implant

Pepakayala, *Nature: Microsystems & nanoengineering* 1, Featured Article, December 2015.

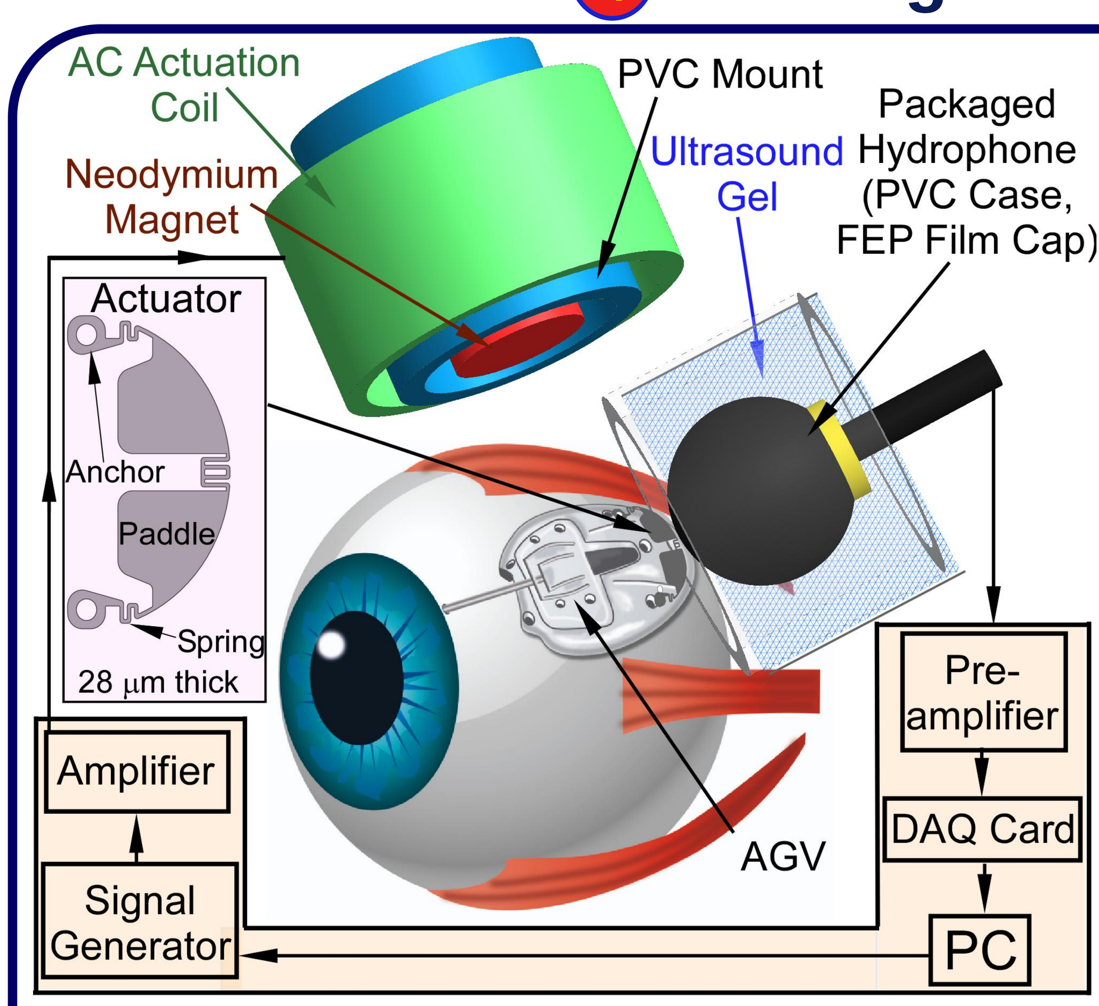
- An interrogation system is needed to facilitate *in vivo* studies to test whether there is indeed a vibratory response from the actuators after implantation
- Signal feedthrough elimination, wireless range and clinical utility are the main challenges associated with such an interrogation system

3 Fabrication



- The actuators are fabricated from 28 µm thick Ni/Fe foil using photochemical machining
- Aspheric 3D curvature is imposed by annealing in a mold
- The actuator are coated with aluminum oxide using atomic layer deposition in order to prevent corrosion and to provide biocompatibility
- The actuators are then mounted on AGVs using silicone epoxy

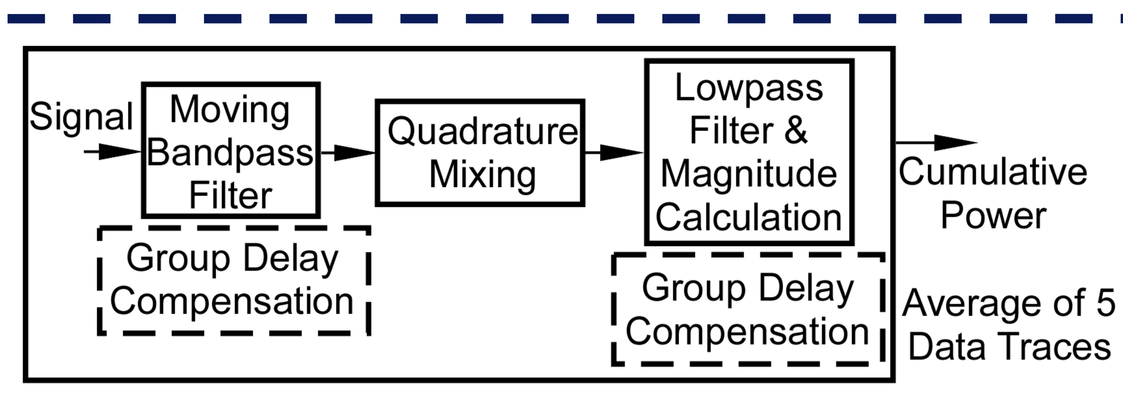
4 Interrogation System



- The interrogation system consists of inductive coils for exciting the actuator and a hydrophone for sensing the actuation
- A signal generator and power amplifier provide the actuation AC magnetic field via a coil
- A neodymium magnet is used for providing the required DC field
- A commercially available hydrophone is used for sensing acoustic signals generated by the actuator vibration

Nambisan, *Solid-State Sensors, Actuators and Microsystems (TRANSDUCERS), 2017 19th International Conference on*, pp. 383-386. IEEE, 2017.

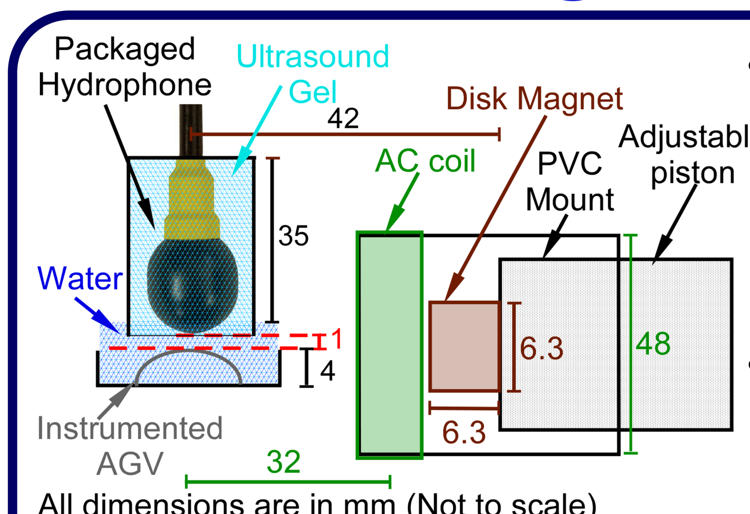
- An audio preamplifier is used to amplify acoustic signal received while sensing
- The signal is then collected by a data acquisition device and sent to a PC for digital signal processing and display of the results
- The hydrophone is custom-packaged in ultrasound gel to reduce acoustic attenuation at tissue/air interfaces



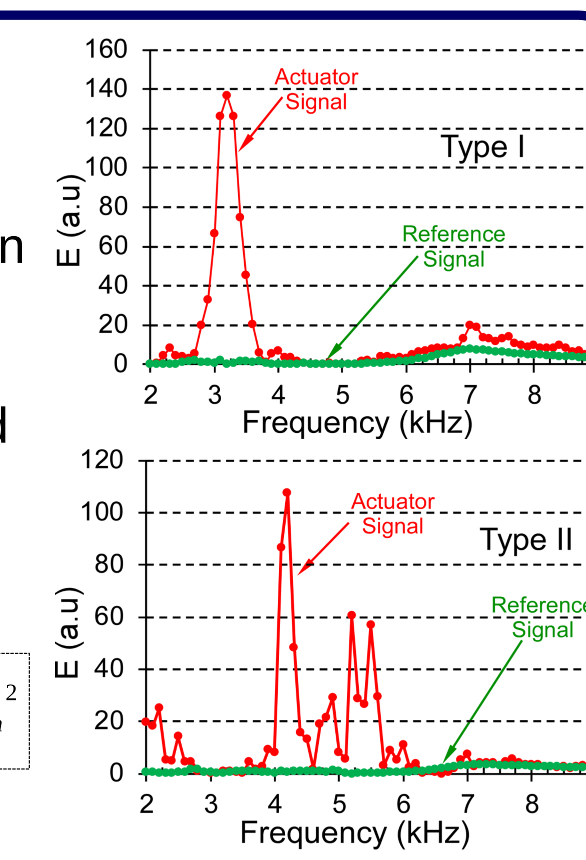
To increase the signal to noise ratio, several digital signal processing steps are implemented

- The acquired signal is first filtered using a moving bandpass filter (centered at the sweeping frequency) to remove the higher and lower frequency noise
- The filtered signal is then quadrature mixed to isolate the essential frequency
- The magnitude calculation and the low pass filter are then used to extract the envelope of the amplitude of the signal
- In the final step, the signal amplitude is integrated over time to leverage the full signal response energy inorder to improve the signal to noise ratio

5 Experimental Results



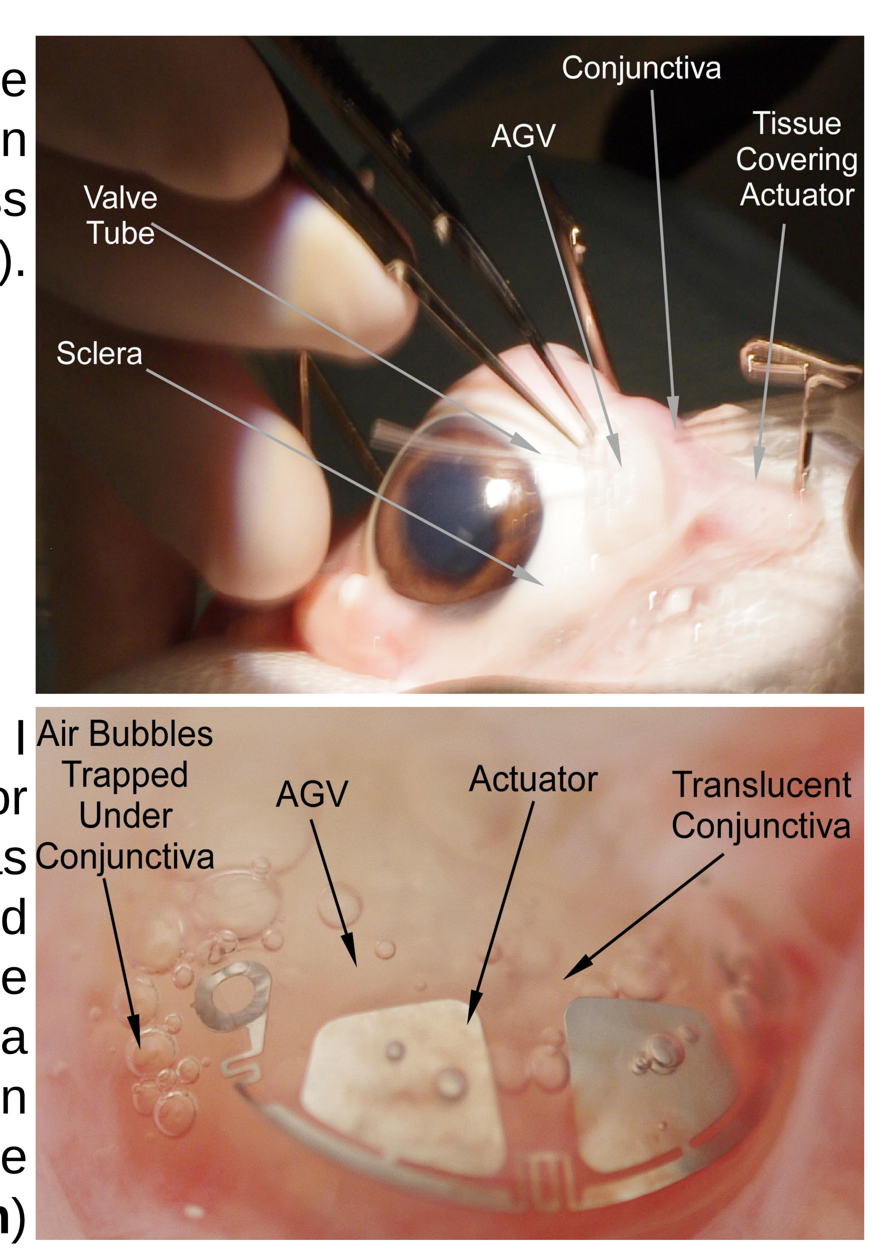
- *In vitro* tests were performed by immersing the instrumented AGVs in water **(Left)**
- The frequency responses measured using this setup are shown **(Right)**

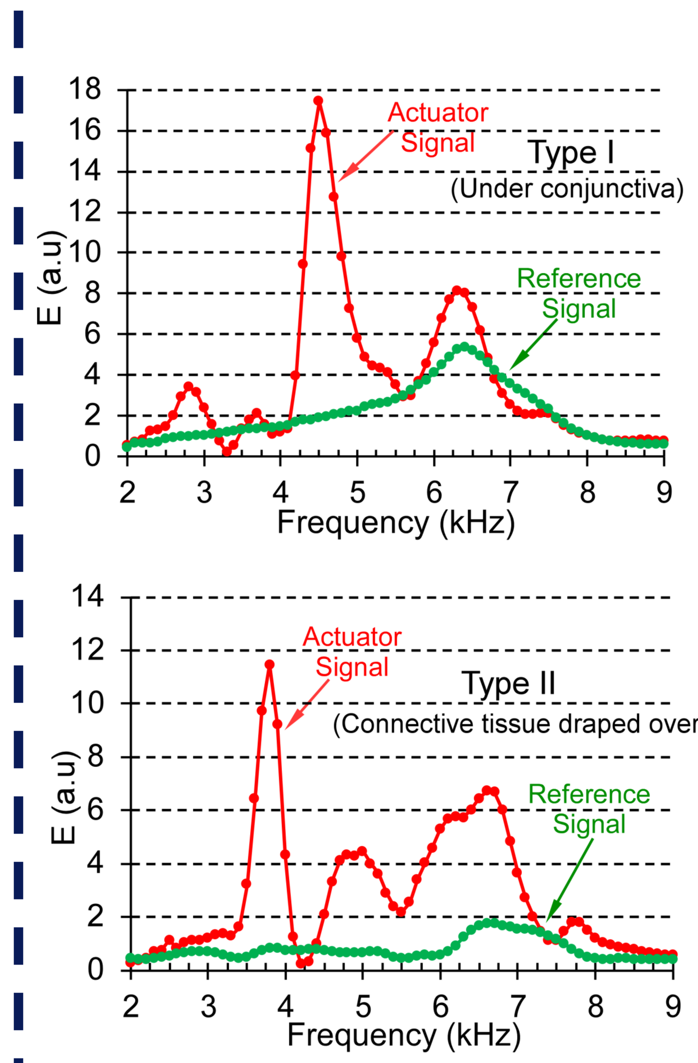


- The measured E is the summed squared signal amplitude and defined by the formula; $E = \sum_{n=0}^{1000} x_n^2$
- In the formula, x_n = amplitude of the signal at sample *n* after digital signal processing
- The reference signal is the signal measured when the actuator was absent

The implantation in progress **(Top)**.

The Type I actuator was measured with the conjunctiva layer in place **(Bottom)**





Figures showing typical measurements from the implanted actuators

- The reference signal in these plots is the signal measured on an eye which is not implanted with the instrumented AGV

The results demonstrate that acoustic interrogation can be effectively used to assess vibrating actuators that are integrated with glaucoma drainage valves. In particular, it permits the detection of weak and dampened resonant signals by eliminating feedthrough from the transmitting coil. The in situ measurements represent the first recorded acoustic signals from an implanted magnetoelastic device through tissue. Future work will include performing in vivo tests as well as adaptation to other types of glaucoma drainage devices