Evaluation of a Passive Resonator-Based Force Sensor for Orthopaedic Smart Implants: Simulated *In Vivo* Testing

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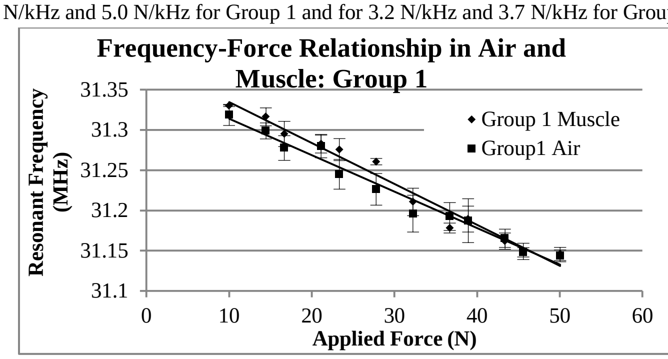
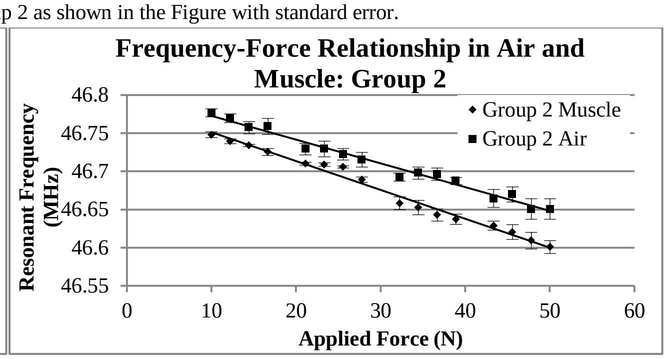
INTRODUCTION: Orthopedic "smart" implants facilitate collection of *in vivo* data that cannot be measured any other. Passive resonator-based sensors are an attractive enabling technology for smart implants relative to traditional strain gauges and telemetry.[1] Passive resonator sensors are robust, small, and have a low per unit cost.[2] We have recently developed a sub-centimeter-sized passive resonator sensor that transduces force. The sensor consists of two electrically isolated, conductive Archimedean spirals separated by an intervening solid dielectric layer. As the sensors are loaded, resonant frequency shifts which is detected using an antenna. Signal transmission is negligibly affected by presence of soft tissue and bone. However, read range (distance between sensor and antenna) has been a limiting factor of previous attempts to develop passive resonator-based smart implants. The purpose of this study was to test a novel passive resonator-based force sensor (a) to verify its ability to achieve a physiologically relevant read range (>4 cm) and (b) to measure the effects of a simulated *in vivo* environment on signal integrity.

METHODS: Individual spirals were batch fabricated on glass wafers using a combination of photolithography and electrodeposition. Sensors were assembled by aligning and bonding a pair of wafers and then dicing the bonded wafers into individual sensors. Twenty-five sensors with two different intervening layers were assembled: the first with a 10 µm intervening layer of ChronosilA (Group 1), the second with a 500 µm layer of silicone (Group 2). Sensors were interrogated using a custom fabricated eight turn, planar spiral antenna of 7 cm diameter connected to a network analyzer (Agilent, Santa Clara, CA). Sensors were immersed in 0.9% saline and interrogated to ensure that sensor function was maintained in a simulated *in vivo* environment. The maximum interrogation distance for each sensor was established by moving the sensor away from the antenna at increments of 5 mm out to a maximum distance of 5 cm. The signal was measured twice at each distance; once with an applied axial force and once without any applied force. The shift in the resonant frequency of the sensor between loaded and unloaded state was found at each distance. Sensors were then loaded from 0 to 50 N five consecutive times with and without bovine muscle tissue placed in between the antenna and sensor. The frequency spectra was captured at each loading point for analysis. For both experiments, a linear regression was performed to find a best fit linear model to represent the force-frequency relationship.

RESULTS: All sensors from both groups were functional in 0.9% saline. The sensors used for mechanical testing with the thinner intervening layer exhibited significantly less frequency shift (4%) when exposed to saline relative to the sensor with the thicker layer (21%). Sensors were functional out to a read range of greater than 4 cm. The frequency shift was extremely consistent from 0.5 cm to 4 cm for the same applied load, indicating that the sensor distance from the antenna did not affect the signal once beyond 5 mm. The mechanical testing of each sensor resulted in sensitivities in air and muscle of 4.5 N/kHz and 5.0 N/kHz for Group 1 and for 3.2 N/kHz and 3.7 N/kHz for Group 2 as shown in the Figure with standard error.





Group 1 had a correlation coefficient of 0.73 and 0.84 and Group 2 exhibited a correlation coefficient of 0.81 and 0.91 in air and muscle respectively.

DISCUSSION: The novel passive resonator-based sensor has the potential to enable force sensing smart orthopaedic implants. The sensor can transduce force changes in a simulated physiologic environment (saline and muscle) and is capable of detecting changes in load at physiologically relevant distances (>4 cm). This is sufficient for communicating with implants at anatomic locations such as the foot, tibia, knee, upper extremity, and cervical spine. The sensors have sufficient sensitivity to measure changes in force and the signal is maintained in a simulated *in vivo* environment indicating the potential translation of this technology.

SIGNIFICANCE: This passive force sensor is an excellent candidate for *in vivo* testing due to its small size, simplicity, cost, signal strength in simulated *in vivo* conditions, and greater than 4 cm read range. It exhibited sufficient force-frequency sensitivities for clinical applications while reading at physiologically relevant distances. Because the sensors are batch fabricated using photolithographic techniques, the sensors can be made in a broad range of sizes, shapes, configurations, and sensitivities. This sensing technology has the potential to measure other clinically relevant parameters such as pressure.

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