Entirely Implanted Wireless Doppler Sensor for Monitoring Venous Flow

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Background: Microvascular anastomotic failure remains an uncommon but potentially devastating problem in free tissue transfer. Implantable vascular Doppler monitoring results in increased flap salvage rates. However, these devices are cumbersome, have easily dislodged wire, possible pedicle compromise upon probe removal, and false positives due to gapping between probe head and vessel. In an effort to circumvent these shortcomings, we have developed an entirely implantable wireless Doppler sensor and tested this prototype in a pig femoral vein model.

Methods: Phase 1 involved development and in-vitro testing of an implantable continuous wave Doppler device using discrete (commercially available) components for wirelessly transmitting received Doppler-shifted signals. Two opposing 5 MHz transducers were mounted in a custom silicone cuff. A 400mAh lithium-ion polymer battery with magnetic on/off switch was outfitted to device. The wireless link operates in Industrial, Scientific, and Medical radio bands at 915 MHz. In Phase 2, four 6-month-old Hanford swine underwent femoral vein dissection bilaterally. Doppler probes were mounted onto femoral veins and blood flow monitored for 1 minute, followed by 1 minute of venous occlusion, followed by 1 minute of release (restored flow). Paired t-test analyses performed comparing wirelessly transmitted signals in flow vs. occlusion vs. release periods.

Results: In Phase 1, five implantable devices have been developed and tested in vitro. The external receiver reliably detected wirelessly transmitted signals. In phase 2, wireless venous flow monitoring was achieved for all femoral veins. Mean signal strength during flow, occlusion, and release were 876.36 Hz (SD857), 72.73 Hz (SD62), and 891.74 Hz (SD758), respectively. Signal frequencies were significantly greater in flow vs. occlusion ($p < 0.001$) and during release vs. occlusion ($p < 0.001$). The response time for signal change between flow, occlusion and release phases was <1 second.

Conclusion: This proof-of-concept study is the first description of an entirely implanted blood flow monitor with wireless data transmission capability. Our device successfully distinguished between venous flow and occlusion, and between occlusion and release. More importantly, these differences in flow waveforms are obvious to the untrained eye

(Figure). Future iterations will incorporate standard integrated circuitry and an integrated microelectromechanical system (MEMS) Doppler sensor that would decrease the size of the device to 1 x 1 mm, small enough to fit entirely on an anastomotic coupler ring.

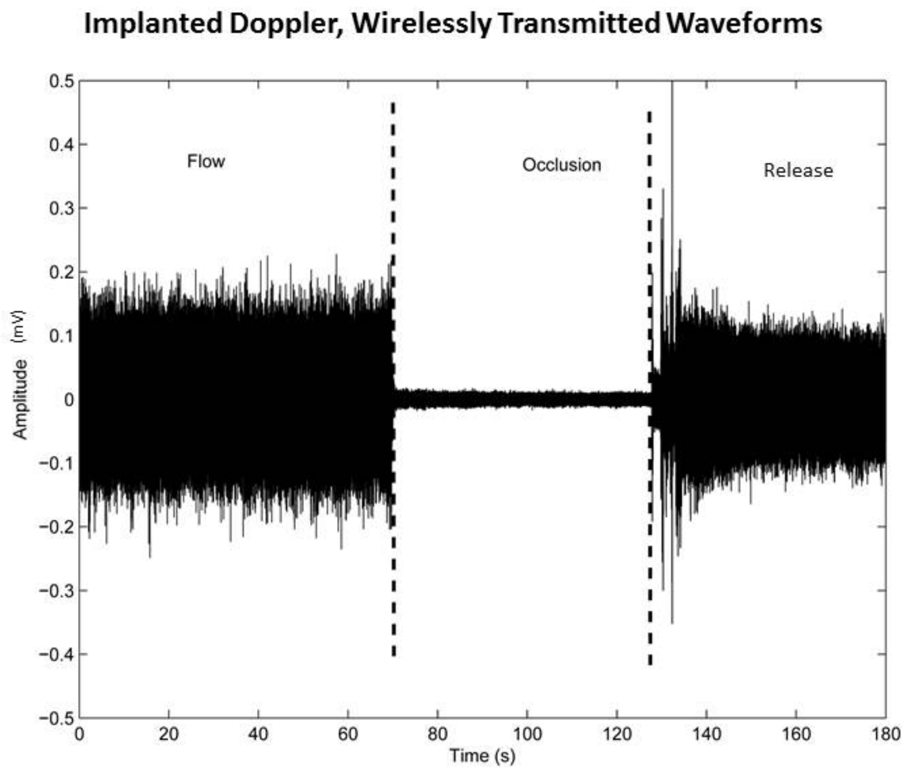

Figure. Representative waveforms from implanted Doppler device with wireless transmission of flow data during periods of venous Flow, Occlusion, and Release (restoration of flow).