109
Venous Flow Monitoring Using an Entirely Implanted, Wireless Doppler Sensor

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PURPOSE: Successful salvage of the threatened free flap is dependent upon prompt diagnosis of vascular occlusion and timely restoration of blood flow. Many monitoring systems can be used to augment clinical exam, but all suffer from drawbacks. The implantable venous Doppler offers rapid diagnosis of vascular compromise, but has a cumbersome transcutaneous wire and is reported to have high false positive rates largely due to inadvertent internal probe dislodgement. A wireless device would avoid these problems. This study describes the implementation of an entirely implanted Doppler sensor with wireless transmission of flow data in a pig femoral vein model.

METHODS: An encapsulated implantable Doppler sensor with self-contained power source and wireless data transmission capability was developed. Four 6 month old 30kg Hanford swine underwent femoral vein dissection bilaterally. Femoral veins were skeletonized and affixed with wireless Doppler probes and skin was closed, with no transcutaneous wires. After equilibration, femoral vein flow was monitored (via wireless transmission to a receiver connected to a computer running custom software) for 1 minute of uninterrupted **Flow**, followed by 1 minute of venous Occlusion, followed by 1 minute of Release (restored flow). Four iterations of this cycle were performed on each femoral vein of each animal, a total of 32 cycles. Transmitted digital flow data was recorded in millivolts (mV) and filtered for noise reduction. Paired t-test analyses were performed comparing signal strength in Flow vs Occlusion periods and Occlusion vs Release periods.

RESULTS: Successful implanted, wireless venous flow monitoring was achieved for all femoral veins in this study. Mean signal strength during Flow, Occlusion, and Release were 0.103 mV (SD 0.139), 0.018 mV (SD 0.029), and 0.105 mV (SD 0.185), respectively. Signal strengths were significantly greater in the Flow period vs the Occlusion period ($p < 0.001$) and during the Release period vs the Occlusion period ($p = 0.006$).

CONCLUSION: While clinical exam remains the gold standard for free flap monitoring, many microsurgeons find added value using flap monitoring sensors for their reconstructions. The currently available implantable Doppler devices suffer from problems largely related their cumbersome transcutaneous wires, including inadvertent wire probe removal, false positive signals from unrecognized internal probe dislodgement, and the necessity of potentially harmful probe withdrawal. 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 with statistical significance. Importantly, these differences in flow waveforms are obvious to the untrained eye. Future work will include device miniaturization through integrated circuit technology.