The Development of a Wireless Implantable Blood Flow Monitor

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Running head: Wireless Doppler vascular monitoring

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SUMMARY

Microvascular anastomotic failure remains an uncommon but devastating problem. Although the implantable Doppler probe is helpful in flap monitoring, the devices are cumbersome, easily dislodged and are plagued by false positives. We have developed an implantable wireless Doppler monitor prototype from off-the-shelf components and tested it in a swine model. The wireless probe successfully distinguished between femoral vein flow, occlusion and reflow and wirelessly reported the different signals reliably. This is the first description of a wireless implantable blood flow sensor for flap monitoring. Future iterations will incorporate an integrated microchip-based Doppler system that will decrease the size to 1 mm^2, small enough to fit on an anastomotic coupler.

Free tissue transfer represents an important modality for reconstructing complex anatomic defects. With refined technical and technological advancement, success rates >95% can be achieved [1, 2]. Free flap failure represents an uncommon but devastating problem leading to increased patient morbidity and mortality. Microvascular compromise threatening free flap survival has been reported in as high as 10% - 20% [2, 3]. Early detection of compromise and timely corrective action leads to improved salvage rates[4-6]. High salvage rates require an effective post-operative monitoring system. Clinical bedside monitoring is used ubiquitously for monitoring free flaps postoperatively, but is less useful in skin-grafted muscle and buried flaps[7-9]. Although good accuracy has been reported with the implantable Doppler probe[10, 11], the tethering wire that connects the Doppler probe to the external monitor is cumbersome. The readily detachable probe leads to up to 30% false positive and 8% false negative rates[12]. Hence, it is predicted that eliminating the system's transcutaneous wire will lessen the false positive rate and eliminate the risk of vessel compromise upon probe withdrawal. We present our development and testing of a prototype implantable wireless Doppler device to monitor vascular blood flow.

Prototype development

A continuous-wave Doppler device was made from commercial off-the-shelf components (Fig 1). All electronics fit on a 32mm diameter circular electronic board. Two 20-MHz piezoelectric transducers were mounted in a 5mm diameter silicone cuff. A 400mAh lithium-ion battery was outfitted to the device allowing 3 hours of continuous and 3.5 weeks of intermittent blood flow detection. The device was encased in a waterproof silicon capsule. The device was wirelessly activated using a transceiver that also received wirelessly transmitted blood flow data. The wireless link operates at 915-MHz (Industrial, Scientific, and Medical (ISM) standard radio band), with an approximately 20 feet range, using frequency modulation (FM) digital signal transmission. Wirelessly received signals were converted to audio-visual signal for computer display. To address potential electrical interference, we used our previously developed algorithm to mitigate lost data[13], an inevitability with wireless channels in the hospital setting.

In vitro testing

The silicon cuff of the Doppler device was affixed to distensible plastic tubing connected to a syringe. A blood mimicking fluid (Blue Phantom, Sarasota, FL) was pumped manually to simulate pulsatile blood flow. The device successfully detected the Doppler shifted signals and wirelessly transmitted to the receiver (see video, supplemental digital content).

In vivo testing in swine femoral vein model

Four 6-month-old female Hanford mini-swine (Sinclair Bioresources, Missouri) underwent bilateral groin dissection (Fig 2). The silicon cuff of the Doppler probe was placed around the femoral vein. A vessel loop was looped loosely around the vein proximally such that traction on it would occlude the vein. The entire Doppler device was placed subcutaneously and skin closed. The ends of the vessel loop were passed percutaneously for external control. Following Doppler probe activation, femoral vein flow was monitored for 1 minute of flow, followed by 1 minute of venous occlusion by tensioning the vessel loop ends, followed by 1 minute of restored flow. Four iterations of this cycle were performed on each femoral vein of each animal for a total of thirty-two cycles. Wirelessly received signals were amplified and conditioned to facilitate digitization. Figure 3 demonstrates a single reading from one data transmission cycle demonstrating the wide amplitude of received signals during normal flow followed by narrow amplitude during occlusion with return to pre-occlusion levels with release. The recorded mean signal strength during flow, occlusion, and release were 150μV (+/-200), 10μV (+/-10), and 160μV (+/-340), respectively ($p<0.001$) (Figure 4). The response time for the signal change between flow, occlusion and release phases was less than 1 second.

Statistics

Parametric data were analyzed using one-way ANOVA with Bonferroni's post-hoc analysis. $P \leq 0.05$ was considered significant.

DISCUSSION

Clinical evaluation of free flaps by an experienced clinician has stood the test of time and proved to be the irreplaceable gold standard. However, an experienced examiner may not be always available. Furthermore, it is difficult to clinically monitor completely buried free flaps, skin grafted muscle flaps and flaps with small skin paddles.

To overcome these shortcomings numerous devices have been developed. The implantable Doppler probe[11] enables continuous monitoring of blood flow. This probe is connected to an external monitor via a wire that is simply pulled at the conclusion of the monitoring period, leaving the silicon cuff attached to the vessel. Several studies have demonstrated its efficacy in monitoring free flaps[14-16] and improved salvage rates following microvascular compromise[17, 18]. The wired implantable Doppler, purposefully designed to allow wire/sensor removal with a gentle tug, has an inherently high risk of false positive alerts due to due to inadvertent probe disengagement. . Additionally, the sensor may occasionally be too adherent to the silicon cuff, such that wire withdrawal creates a kink or injury to the vessel. These design weaknesses are the impetus behind the development of a wireless system.

To our knowledge, the current prototype is the first implantable wireless Doppler flow monitor of its kind, designed to monitor free flap perfusion. The device promptly and unambiguously distinguished between flow and occlusion. With the current prototype, Doppler shifted signals were successfully transmitted via Federal Communications Commission (FCC) approved ISM 915Mhz wireless radio band without significant interference or ambiguity.

The current prototype, designed from off-the-shelf, commercially available components, is too large to be used clinically as an implanted device. The future generation of this device will use ultra-small integrated circuit microchip technology, allowing miniaturization to 1x1 x0.5mm. While our prototype uses a 400mAh lithium battery that provides 3.5 weeks of intermittent blood flow detection, miniaturization will significantly reduce power requirements. This reduction facilitates batteryless, wireless transcorporeal inductive powering with no practical limits on lifetime of use.

CONCLUSION

We have created the first entirely implantable wireless Doppler device that distinguishes clearly between venous blood flow and occlusion. The future generation of this device will be miniaturized, batteryless, and incorporated into an anastomotic coupler. Miniaturization will also enable implementation of the technology into a new generation of vascular stents and other novel implantable devices that have the potential to improve care and lower health care costs.

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FIGURE LEGENDS

Figure 1: A. Wireless Doppler Prototype.

B. Wirelessly transmitted signals were received by a remote receiver connected to a laptop via USB.

Figure 2: Animal surgery

A: Close up of silicon cuff affixed to the femoral vein with vessel loop wrapped around the vein proximally.

B: A subcutaneous pocket is dissected and the Doppler device is placed in it.

C: Skin is closed leaving the vessel loop ends externalized.

Figure 3: Representative waveforms from implanted Doppler device with wireless transmission of flow data during periods of venous Flow, Occlusion and Release (restoration of flow).

Figure 4: Mean Signal Strength during flow, occlusion and release

Video, Supplemental Content:

The silicon cuff of the Doppler device was affixed to plastic tubing through which a blood-mimicking fluid was injected. The Doppler device detected the flow and wirelessly transmitted the signals to a remote receiver attached to a laptop. The video demonstrates the fluid being pushed through the tubing. In the inset is the laptop screen view demonstrating the visual signals relayed by the receiver. The audio signals heard correspond to the flow of the fluid. Note the intermittent audio in the first half of the video corresponding to intermittent flow and continuous audio corresponding to constant flow as seen in the plastic tubing.

Figure 1A

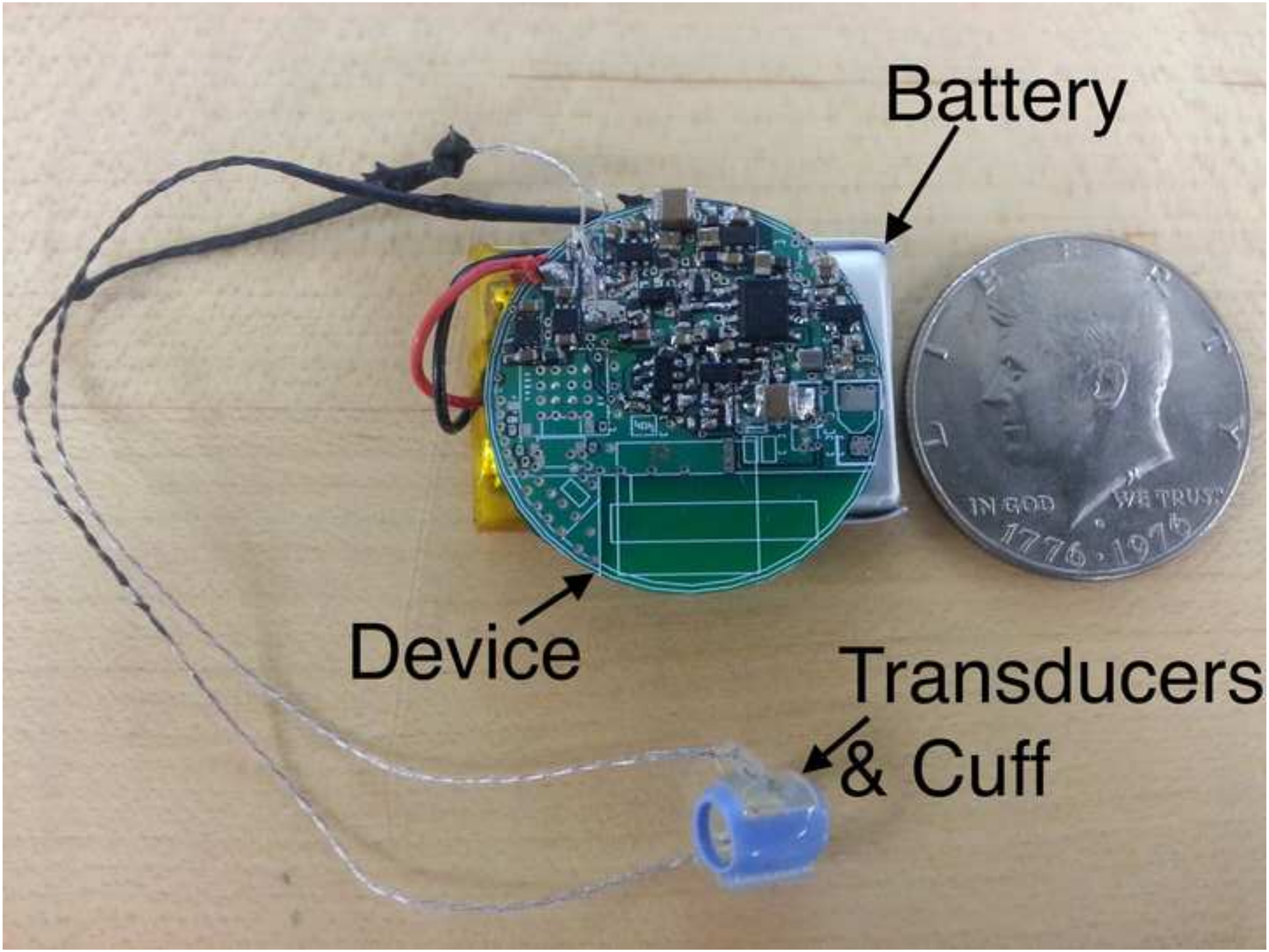


Figure 1 B

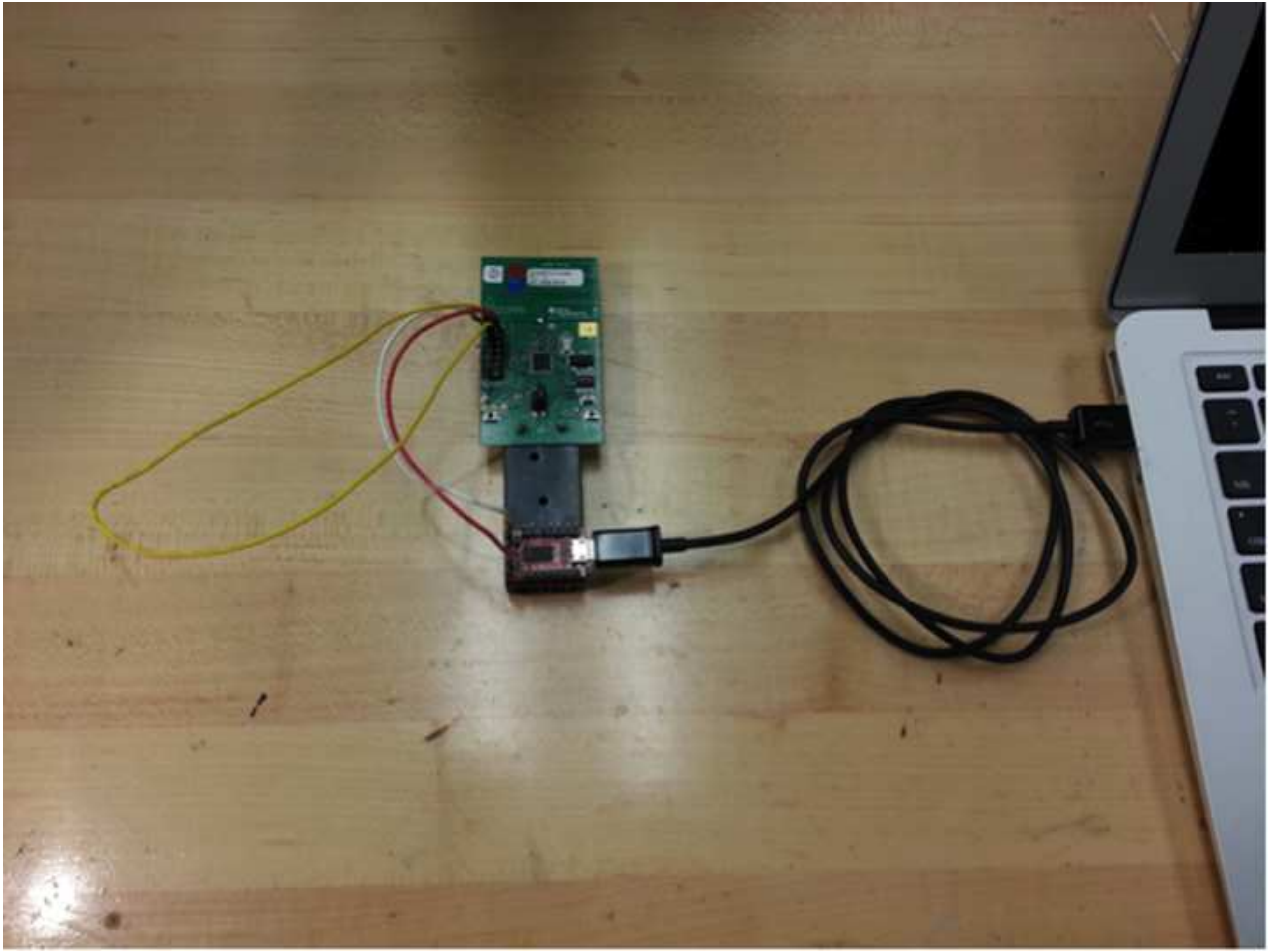


Figure2A

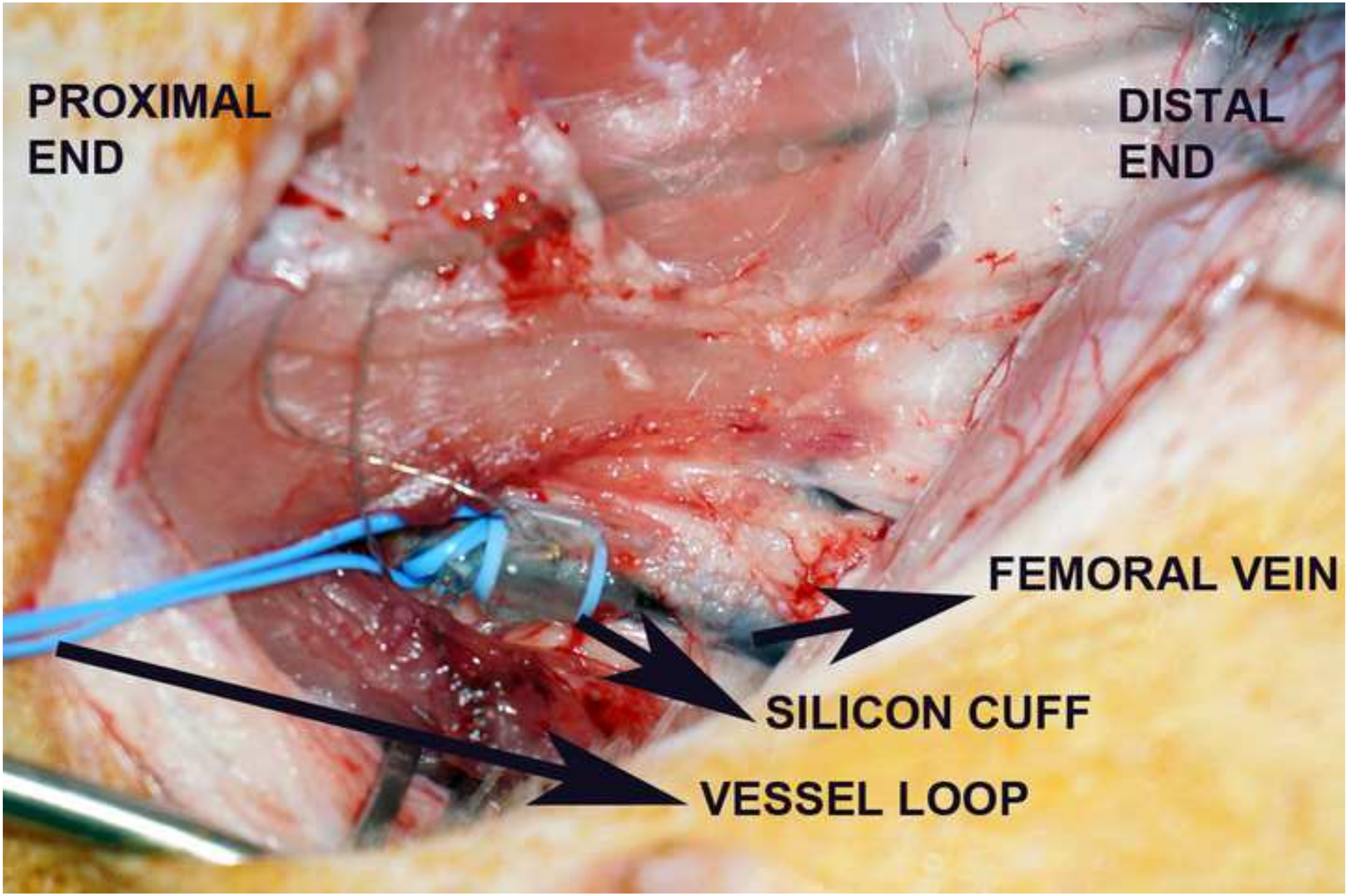

PROXIMAL
END
DISTAL
END
FEMORAL VEIN
SILICON CUFF
VESSEL LOOP

Figure2B

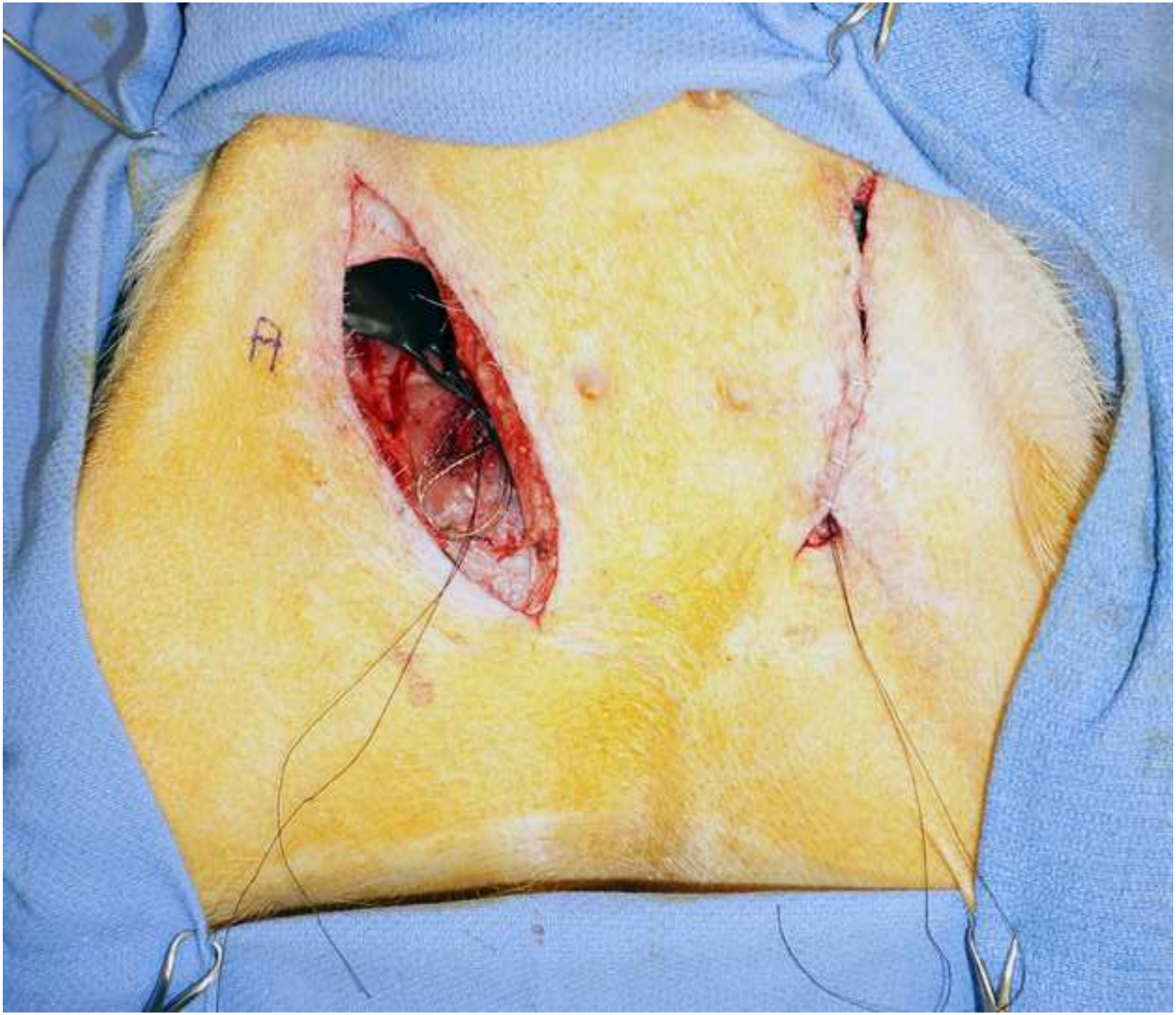
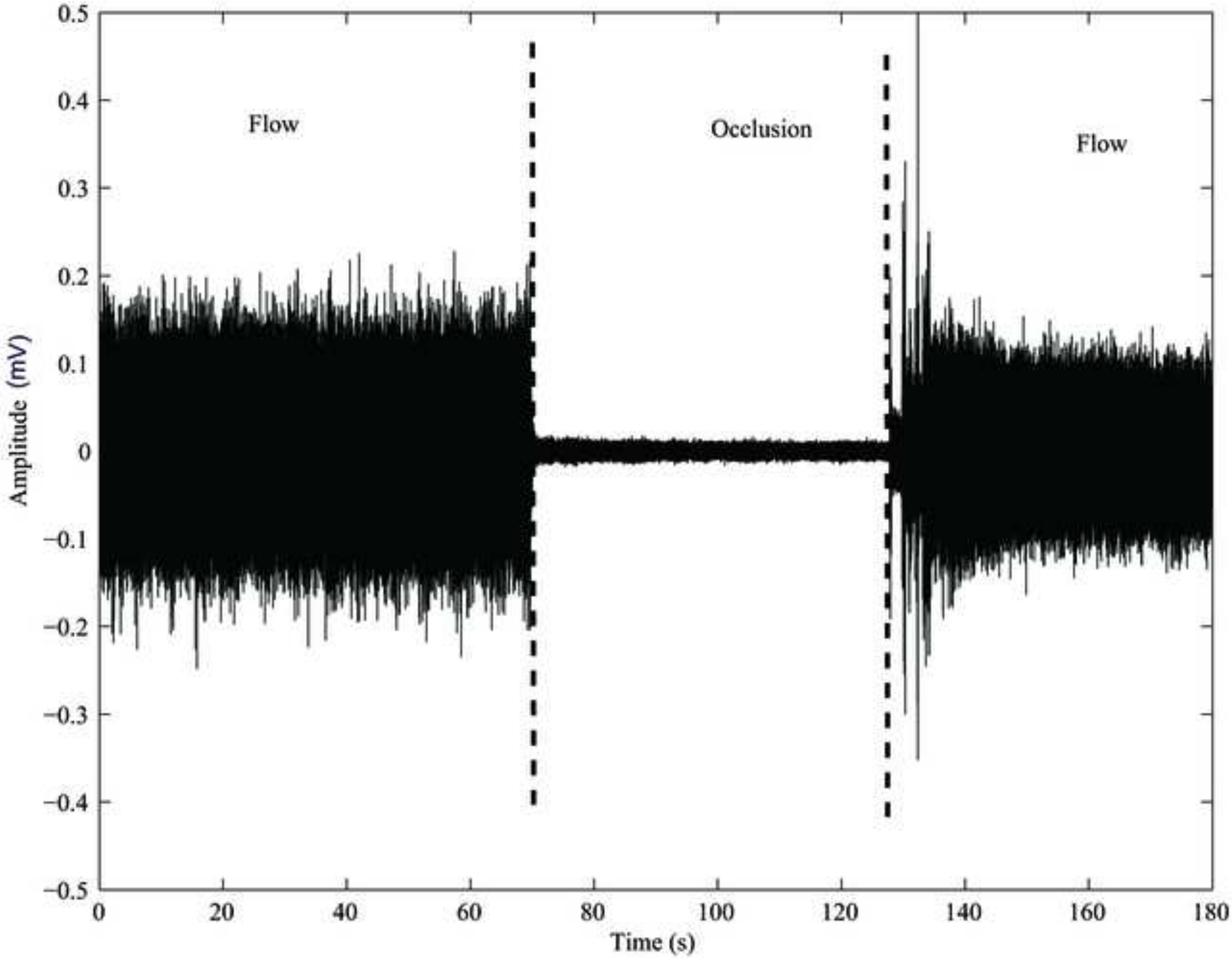


Figure2C

Figure 3



Flow
Occlusion
Flow
Amplitude (mV)
Time (s)
0.5
0.4
0.3
0.2
0.1
0
−0.1
−0.2
−0.3
−0.4
−0.5
0
20
40
60
80
100
120
140
160
180

Figure 4