

**Re: Annual call for translational design projects**

Design Title: Remote monitoring application/device after microvascular free tissue transfer

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**Clinical Problem**

Since the description of the first successful free tissue transfer in humans in 1973, microvascular transfer of tissues has become an important tool for all plastic and reconstructive surgeons. With the increase in mastectomies, anticipated increase in gender reassignment/confirmation surgery and the evolution of tissue engineering, (requiring microsurgical implantation of engineered organs and tissues), microsurgical reconstructions and constructions are likely to only increase in number in the upcoming decades.

Microsurgical reconstruction involves removing tissue from one part of the body and transplanting it to another. This removed tissue is often referred to as a “flap” or “free flap”. In order to successfully accomplish this transfer, the blood supply of the removed tissue must be connected to the blood supply at the recipient site. This connection of blood vessels is referred to as an “anastomosis.” The vessels being connected in microsurgical reconstruction are very small, often ranging in size from 1-3 mm in diameter. The most dreaded complication of microsurgery is flap failure or loss, which most often is the consequence of venous or arterial thrombosis, or formation of a blood clot. Arterial or venous thrombosis is not necessarily synonymous with tissue death, however, as flap salvage is possible with prompt return to the operating room. Current literature has identified the most controllable factor increasing flap salvage is time required to return to the operating room once thrombosis is suspected. This places a large emphasis on postoperative flap monitoring, and significant time, energy and financial investment has been applied towards developing technology that detects thrombosis as early as possible. Despite significant advancement in these technologies including Doppler probes (detecting blood flow) attached directly to the anastomoses, tissue oximetry, tissue temperature measurement, multispectral imaging, and many others, the current “gold standard” for detection of flap compromise remains clinical examination. This however does not preclude the use of adjunctive technologies, and most microsurgeons use one or multiple adjuncts in addition to clinical examination. Additionally, many flaps are “buried,” meaning there is no visible portion of the flap external to the patient’s body. In this scenario the microsurgeon must rely on adjunct technologies alone to monitor the health of the free flap.

As a result, the staff surgeon is relied upon for personal examination of the tissue transfer (typically every hour) unless there is a qualified, available resident and/or nursing staff. Qualified nursing staff exists only in a few specialized medical centers, and resident surgical staff has been limited in part due to duty hour restrictions. Therefore, the attending surgeon must rely on either his or her own examination and/or adjunctive measures and staff to promptly identify flap compromise. In the 21<sup>st</sup> century there are available technologies that should allow us to examine the patient remotely, and remote examination has been successfully employed by our colleagues in Neurology. To date, unsuccessful attempts have been made to demonstrate meaningful use of remote monitoring by our colleagues in reconstructive surgery.

**Translational Importance/Opportunity:**

Using singular or multiple adjuncts requires audiovisual monitoring at the bedside, and observation of this monitoring should theoretically be possible remotely. Tissue Oximetry is a flap monitoring technology that has successfully set up an application that allows the reconstructive surgeon to monitor oxygen concentration measurements of tissue via a cellphone. Studies have also previously examined the usefulness of remote photographic monitoring of non-buried free tissue transfer but did not demonstrate significant improvement in flap salvage. Finally, the implantable Doppler probe has become the most used adjunct to the clinical examination among reconstructive surgeons, yet remote monitoring of the implantable Doppler probe has yet to be developed. Theoretically this should be simple as the monitoring signal is audio only, and the availability of cellular networks and/or wireless internet is nearly ubiquitous among recovery and intensive care units in developed nations.

**Desired Outcome:**

We propose that an application be developed with the goal of remotely monitoring the audio signal from the implantable Doppler probe so that the reconstructive surgeon can monitor the flap Doppler signal at any time, remotely. The signals are analyzed (e.g. biphasic vs. triphasic arterial signal vs. venous hum) and transmitted to surgeon via WIFI/internet to an iphone or android Application. A secondary goal of this project would be a universal application that allows the reconstructive surgeon not only to monitor a Doppler signal, but all other commonly used flap monitoring modalities remotely.

Success in this endeavor would be of immense value to the reconstructive surgeon, not only because of flap salvage but also due to time saved by eliminating unnecessary return trips to the hospital for flap examination, significantly improving quality of life for the reconstructive surgeon. An application of such magnitude would require investigation after development, and we are prepared to launch and/or assist in the investigation of the usefulness of such an application at our and other institutions.

Thank you for your time and consideration of our proposal.