NEAR INFRARED NAVIGATION SYSTEM (NAVI) FOR REAL TIME VISUALIZATION OF BLOOD FLOW

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INTRODUCTION

OBJECTIVE: To fabricate an economical and portable real-time imaging system to visualize real-time blood flow in graft procedures.

- Vascular grafting failures are often attributed to inadequate anastomotic perfusion assessment. Thus, graft failures can be minimized if visualization of blood flow is made feasible.
- This visualization is currently achieved via various techniques whose efficiencies are limited by cumbersome equipment, exposure to radiation, etc.
- Fluorescence image guided surgery using Near Infra-Red (NIR) dyes is one of the methods that can be utilized to monitor grafting success.
- To address current logistic challenges and costs of the existing fluorescence systems, a portable Near Infrared Navigation (NAVI) detectable camera system was fabricated for intraoperative fluorescence real-time NIR imaging.

NAVI IMAGING SYSTEM

- Our technology is based on integrated image collection electronic light amplification system coupled with optical filters for deep penetration of light (see flow chart below). Light output amplified using credit-card sized computer.
- Detect and map mobility of dye deep inside tissues (up to 50 mm). Arterial walls: 3 mm; vessels: 2 mm.
- Cost for production: ~$800.

FIGURE 1

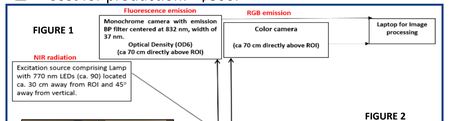
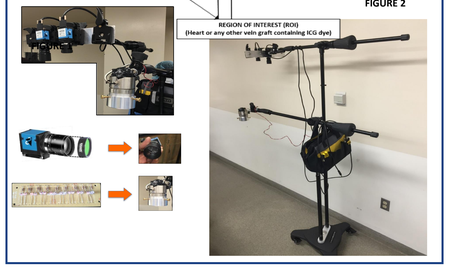


FIGURE 2



NAVI IMAGING SYSTEM

- A schematic of the integral components and assembly of NAVI are shown in Figure 1. NAVI is able to capture and record florescence emitted from ICG. The system components are listed and briefly described below. A photo of the system is shown in Figure 2. Figure 2 Shows the NAVI imaging system in an OR setting.

Components of NAVI

- **Camera**: The optical fluorescence imaging system (NAVI) employed in these studies comprises of a monochrome imaging camera with CMOS sensor with 30% quantum efficiency (QE) in the wavelength region around 837 nm (i.e., in the fluorescent emission band captured).
- **Stand**: The portability is provided by a stand having two mechanical arms for suspending the source and NIR camera, and a foot control that aids movement of the NIR camera.
- **Laptop:** Each of the cameras will be attached to a laptop via USB 3.0 cables. Images will be recorded and viewed via a program downloaded from The Imaging Source. The laptop monitor is sufficient to display images.
- **Technician:** Under the supervision of a surgeon(s), an individual who is familiar with the NAVI system and who has been trained for the use of the NAVI system, and who will have previously been an observer in the surgical operating room, will operate the NAVI system to obtain NIR and color images.

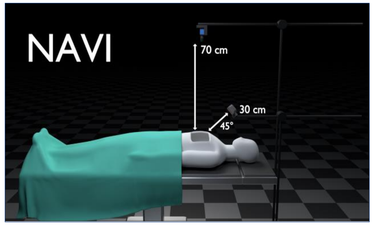


Figure 3: NAVI Imaging System in OR setting

NAVI : PRECLINICAL STUDIES

Pre-Clinical Study: A detailed preclinical study was conducted in swine model. Animal studies were performed following approval from the University of Missouri Animal Care and Use Committee. Utilizing a swine model, jugular vein to carotid artery grafting modeling human arteriovenous grafting was completed bilaterally.

- Grafting studies and real-time visualization of blood flow was visualized in carotid artery grafts by fluorescent imaging using the NAVI system.
- Bilateral carotid artery grafting was successfully demonstrated in pig and the flow was monitored by NAVI fluorescence imaging system.
- Carotid flow measurement and carotid angiography were performed to substantiate the results obtained from the fluorescence imaging.

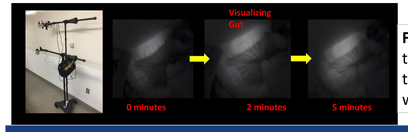


FIGURE 4: Images of gut of a swine. Real-time blood flow can be visualized using the NAVI imaging system. The images were recorded different time points.

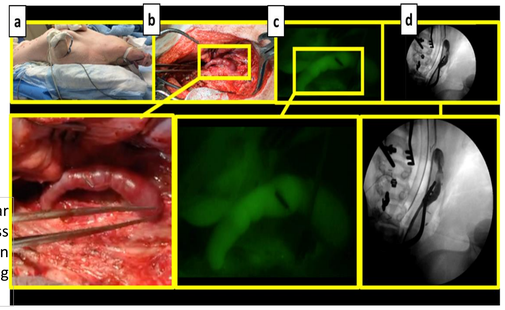


FIGURE 5: Images showing the jugular vein to carotid artery grafting process in a swine. Real-time blood flow can be visualized using the NAVI imaging system.

NAVI : CLINICAL STUDIES

Clinical Study: A detailed clinical study was conducted in India at Jubilee Mission Medical College and Research Institute, Cochin with institutional approval to determine the effectiveness of plastic surgery and burn wounds. A total of seven patients were recruited for this study. In this study, ICG dye was injected IV. After 5 minutes of injection, blood flow could be monitored. Figure 6 shows the blood flow within the grafted area.

Summary: A portable and economical NAVI camera system that can be utilized for intraoperative fluorescence imaging has been fabricated.

- The NAVI system has been validated by conducting preclinical grafting studies in swine model.
- Finally, the clinical translational capability of the NAVI imaging system has been established using suitable clinical studies.

Future study:

- The NAVI imaging system is being explored for lymph node imaging and other applications.

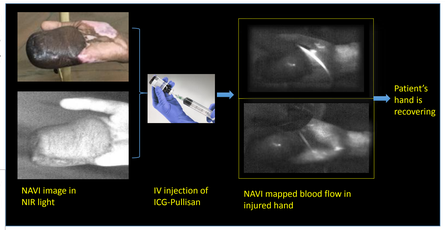


FIGURE 6: Images showing blood flow within grafted area that can be visualized using the NAVI imaging system.