**OVERVIEW**

**Clinical Problem**
- There are approximately 150,000 non-traumatic lower extremity amputations performed in the US each year, with diabetic patients accounting for over fifty percent of these.
- The annual cost of lower extremity amputations due to diabetes alone is more than $1.5 billion.
- Diabetic patients are also more likely to require re-amputation to a higher level, costing an additional $1 billion per year.
- With incidence of diabetes estimated at 6% in the U.S. and growing, the number of amputations is also expected to grow.
- The proper selection of amputation level, to avoid tissue ischemia and assure healing while maximizing mobility, is critically important for assuring quality of life for each patient.
- Experience of the surgeons performing the amputations has been shown to be a factor in revision rate. An imaging tool that can provide information regarding optimum amputation level selection could be of particular use to those surgeons who do not perform large numbers of amputations.

**Amputation Levels**

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**Approach**
- Our goal is to quantitatively assess and display tissue perfusion throughout the leg to guide surgeons in selecting ischemic tissues for excision and perfused tissues for salvage.
- The proposed modality, Video Imaging Oximetry, will characterize the perfusion of the limb and differentiate between tissues that will survive and those that will fail to heal.
- The end product will consist of an easy-to-use, low-cost portable device appropriate for the clinical and/or surgical setting.
- In the long term, the same tool can be used to assess surgical response both during and at the completion of the procedure, during the immediate post-operative period, and during the use of a prosthesis.

**Impact**
- The broad goal of this project is to develop and commercialize a low-cost, non-contact 2D optical imaging device for measuring local tissue perfusion and oxygenation.
- For amputation level selection, this instrument will provide the following benefits:
  - Fewer surgical revisions
  - Reduced stress on patients
  - Lower health care costs
  - Improved healing of residual limb
  - Greater success in rehabilitation using a prosthesis
- Additional applications of the device include monitoring of diabetic foot ulcers, burns, and surgically-created skin flaps.

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**METHODS**

**Plethysmography**
- Plethysmography is the measurement of volume changes in tissue due to the inflow and outflow of blood.
- The waveform, shape, and timing of the plethysmographic signal can be used to characterize tissue perfusion and diagnose various conditions.
  - (a) Standard strain gauge plethysmograph placed on the thumb.
  - (b) Typical arteriolar pulse amplitudes are 0.1% by volume.
- Examples of arterial plethysmographic waveforms for different vascular conditions. The arterial plethysmographic waveform shape is determined by vasodilatation; its amplitude is determined by arterial pulsations and anatomic tone. Comparable waveforms can be measured optically.

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**Signal Processing and Analysis**
- Independent Component Analysis: Left: Strain gauge plethysmographic waveform from the leg with mixed arterial and venous tissue volume signals. Right: Extracted components from an ultrasonic strain waveform include the arterial waveform (top) and the respiratory waveform (bottom).
- Fourier decomposition of a normal (upper) and ischemic (lower) waveform. The red, green, and blue curves indicate the H1, H2, and H3 sinusoids, respectively. The amplitudes of the harmonic components are shown on the right.

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**PRELIMINARY STUDIES**
- Arterial oxygenation synchronized with the cardiac cycle represents lung function rather than local perfusion. Venous oximetry, based on venous pressure changes synchronized with the respiratory cycle, represents local tissue oxygenation by displaying the remaining equilibrium oxygen saturation in the blood after the tissue is supplied.
- Standard pulse oximetry is limited to arteriolar oxygenation measurements; it is also spatially limited to a single point on the skin. We propose to extend the standard pulse oximetry method to a 2D imaging method that can measure both arterial pulse waveform and venular oxygenation. Examples of waveform and oxygenation measurements are shown below.

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**Video Oximetry**
- Video imaging results for a cuff occlusion experiment. Top row: Video frame and waveforms for a normal control finger (red region) and a finger occluded with a pressure cuff (blue region). Average reflectance waveforms over one cardiac cycle are shown at rest, during the cuff occlusion, and 30 seconds after release of the cuff for each finger (red ≠ control, blue ≠ cuff). Bottom row: The amplitudes of the first harmonic component of the waveform is mapped as color (blue = low, red = high) to the two fingers.

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**Exercise study with ultrasound**
- The upper plot shows the mean and standard deviation of the harmonic mean pulsatility within the gastrocnemius and soleus muscles before and after exercise. A higher harmonic mean indicates improved vasodilation and less perfusion.
- The lower images show a B-Mode ultrasound image along with 4 Tissue Pulsatility images. The 4 waveforms on the right show the mean pulsatility waveforms from the 4 images.