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DEVELOPMENT OF AN ULTRASONIC TOURNIQUET SYSTEM FOR SURGICAL APPLICATIONS

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ABSTRACT

An ultrasonic tourniquet system for surgical applications is being developed to dynamically adjust tourniquet cuff pressure for the duration of a surgical procedure to maintain a bloodless surgical field. User intervention is not required during operation, allowing the surgeon to focus on the surgery. Although significant progress has be made in the measurement of pre-operative limb occlusion pressure, these methods are not ideal due to their inability to respond to fluctuations in blood pressure and other physiological parameters during surgery, which may result in loss of limb occlusion or more tourniquet pressure than necessary being used. The ultrasound tourniquet system relies on ultrasound measurements to automatically determine the lowest tourniquet pressure required to maintain occlusion of the limb's main artery. A control algorithm determines if there is blood flow underneath the transducers, and increases or decreases the tourniquet pressure so that the depth of penetration of blood in the limb artery is proximal to a predetermined location underneath the cuff. The control algorithm continuously monitors the depth of penetration of the limb artery during surgery in order to account for blood pressure variations and keeps the surgical field clear of blood for the duration of the procedure.

INTRODUCTION

A surgical tourniquet is a medical device designed to be used in orthopedic surgeries to maintain a bloodless surgical field. A bloodless surgical field provides surgeons with an improved field of vision, which leads to greater surgical precision and reduced blood loss from the patient. Modern surgical tourniquets consist of a pneumatic cuff that can be inflated to a specific pressure. Microcomputer-based tourniquet systems can inflate the cuff to a specified pressure and maintain that pressure for the duration of surgery with a variance of 1%.[1] These tourniquet systems also come equipped with a timer to monitor how long the cuff has been inflated and include alarms for dangerously high or low pressures.[1]

A primary shortcoming of modern surgical tourniquets is that the cuff pressure is fixed throughout the procedure. Tourniquet pressures are often arbitrarily determined based on the surgeon's experience, or derived from the patient's vitals prior to the surgery. During surgery, a patient's physiological parameters can fluctuate due to various factors such as anesthetic effects and incisions being made on the body.[1] Current limb occlusion methods are unable to anticipate the loss of limb occlusion due to changes in patient's blood pressure and other physiological parameters.[1] As a precaution, the operating staff may set the tourniquet cuff pressure to be higher than the required occlusion pressure as a safety margin. However, studies have shown that increased tourniquet pressures are associated with higher probabilities of patient injury.[1,2,3] Another study[4] has found that the safest applied pressure is the limb occlusion pressure (LOP), defined as "the minimum pressure required, at a specific time in a specific tourniquet cuff applied to a specific patient's limb at a specific location, to stop the flow of arterial blood into the limb distal to the cuff."[5]

The ultrasonic tourniquet system discussed here aims to improve on modern tourniquet systems by having the capability to dynamically

adjust tourniquet pressure to maintain LOP in response to intraoperative changes in the patient's physiology.

DESIGN

Preliminary tests for proving the feasibility of the system were performed on the upper arm. In order to maintain a pressure slightly above LOP, ultrasonic sensors capable of detecting blood flow are used at a point proximal to the point of occlusion on the limb. Data from the sensors can be read in order to determine if the limb is occluded at that location. By integrating ultrasound transducers at multiple points proximal to the point of occlusion on the tourniquet cuff, the depth of penetration of the artery under the cuff can be determined. The depth of penetration is the distance along the limb from the proximal edge of the tourniquet cuff to the point where the vessel lumen is closed. A control algorithm increases or decreases the tourniquet pressure so that the point of occlusion is proximal to a predetermined location underneath the cuff. The control algorithm continuously monitors the depth of penetration of the limb artery during surgery in order to account for blood pressure variations and other physiological variations that affect LOP to keep the surgical field clear of blood for the duration of the procedure.

The ultrasound tourniquet system consists of an automated tourniquet, ultrasound transducers with transmit and receive hardware, and algorithms to control the tourniquet pressure and to process the Radio Frequency (RF) data from the ultrasound transducers. Ultrasound pulses are sent to the transducers from a Supertex HV7351DB1 transmit board and reflected signals are collected by a Supertex MD3872DB1 receive board. Received signals are analyzed in order to determine artery wall motion beneath the transducer. A tourniquet pressure control algorithm adjusts the pressure based on the data received from the transducers to maintain the depth of penetration of blood in the brachial artery is at the midpoint of the tourniquet cuff. See Figure 1 for a block diagram of the system.

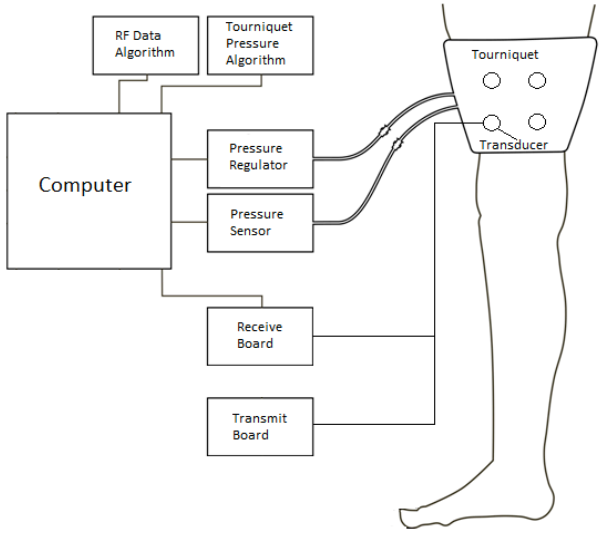

Figure 1: Block diagram of a complete ultrasonic tourniquet system

Single element transducers were selected for this proof-of-concept device as well as component evaluation boards from Supertex. The transducers chosen have a center frequency of 3.5MHz and an active diameter of 3mm. A 3.5MHz transducer frequency has a penetration depth of 17cm in soft tissue and will be sufficient for complete imaging of soft tissues on both upper and lower limbs.[6]

Signal processing of the RF data from the receive board was performed using MATLAB®. The in-phase and quadrature components of the RF data are analyzed through autocorrelation in order to determine the velocity of peak movement in the data.[7] This is similar to the colour flow imaging (CFI) technique used in ultrasound machines, which analyzes phase changes or peak movement in order to determine the velocity of the blood.[8] In order to detect the greatest phase changes, the transducers must be angled into the artery of interest.[8] The main difference is that the technique used in this design is searching for artery wall movement and therefore the transducers sit directly above the artery. The resultant velocity from autocorrelation is then bandpass filtered in order to remove DC offset and noise. Empirically, the velocity of the vessel wall was found to reduce to 45% of the unoccluded value near LOP. Therefore, the algorithm reports that there is blood flow if the

vessel wall velocity is greater than 50% of the unoccluded value, and there is no blood flow otherwise. The accuracy of this method is discussed in the next section.

The results from the algorithm are then passed to a control algorithm for adjustments of a Delfi PTSii tourniquet system. This system was custom modified to permit adjustment of tourniquet pressure through a Universal Serial Bus (USB) interface. The pressure in the tourniquet cuff is increased or decreased in increments of 5mmHg until the depth of penetration is at the predetermined location. The tourniquet cuff's maximum applied pressure is 300mmHg and can be completely inflated or deflated with a single command.

TESTING

Initial algorithm testing was performed with data collected from four subjects using a Ultrasonix Sonix RP ultrasound machine with a 10MHz linear transducer. A cuff was applied to the arm of each subject and the transducer was aligned along the sagittal plane and positioned in the center of a tourniquet cuff modified to permit imaging through the cuff. The LOP of each subject was then determined using a prototype tourniquet system equipped with a commercially available photoplethysmographic-based LOP measurement sensor. RF data were collected at various pressures from 0mmHg to a point above LOP. Using MATLAB®, the individual datasets collected at each pressure were passed through the algorithm described above in the Design section, incrementing in pressure until pulsation was no longer detected. In order to mimic the performance of the final design, three individual lines of RF data were analyzed using the algorithm, at the proximal, mid-point, and distal end of the transducer. The pressures at which the algorithm detected occlusion are outlined in Table 1. Because pulsation at the midpoint of the cuff can still be visible when the limb is occluded, a point at the distal end of the cuff reaches occlusion before the proximal end. The distal end of the artery does not have visible pulsation at lower cuff pressures, and the proximal end requires pressure in excess of the LOP in order to no longer show pulsation. From this data, it is possible to determine the depth of penetration of blood in the brachial artery, which should ideally be as close to the cuff midpoint as possible in order to minimize the pressure placed on a patient's limb. A result of "N/A" means that the algorithm never detected a loss of pulsation with the available data.

Table 1: Results from simulation of limb occlusion for each subject. Numbers in bold show LOP measurements obtained using the standard photoplethysmographic-based LOP measurement sensor. Numbers in regular font show LOP measurements determined using the algorithm at three different locations on the transducer

Data Position on Cuff	**Subject 1 - LOP of 165mm Hg**	**Subject 2 - LOP of 165mm Hg**	**Subject 3 - LOP of 150mm Hg**	**Subject 4 - LOP of 138mm Hg**
Proximal	N/A	N/A	230mm Hg	140mm Hg
Mid-point	165mm Hg	185mm Hg	180mm Hg	130mm Hg
Distal	165mm Hg	150mm Hg	180mm Hg	130mm Hg

There is some variation in the performance of the algorithm in a simulated environment. For subjects 2 and 3, the LOP found through the algorithm was 25-30mmHg greater than the measured LOP. This could potentially be due to a higher blood pressure causing the algorithm to register blood vessel movement despite the vessel being occluded. In the case of subject 2, moving the observation point to the distal end of the cuff shows clearly that blood is occluded near the LOP. For subject 3, however, this was not the case. It is important to perform more trials with more subjects in order to determine a better trend of the data.

Alternative methods of tracking artery wall movement were also tested. The amplitude of the in-phase and quadrature signals was tracked over time for oscillations that corresponded to movement in the b-mode image. Additionally, tracking changes in the phase of the signal were examined over time for relevant trends. However, both of these methods had inconsistent results and were not successful in determining LOP.

DISCUSSION

The accuracy of the algorithm used to determine LOP needs to be improved for the adoption of the system into a commercial product. Presently, the algorithm based LOP has a variance of 10-20mmHg compared to the measured LOP. More data must be collected from a wider range of subjects. Tests must also be performed in order to determine if the system is robust enough to respond to fluctuations in blood pressure. This can be accomplished by immersing the patient's arm in cold water in order to induce an increase in higher blood pressure.

Tracking artery wall movement with ultrasound RF data comes with many challenges. Despite bandpass filtering, noise and fluctuations from non-artery movement are still present in the signal. Although it is possible to estimate the location of the brachial artery, the artery was found to shift considerably as the pressure of the cuff is adjusted. This made it difficult to ensure that the ultrasound transducer was consistently placed above the brachial artery. Additionally, integrating larger and less precise ultrasound transducers into the system may create more noise, making artery motion detection more difficult.

CONCLUSION

A proof-of-concept of an ultrasonic surgical tourniquet system has been designed and constructed, and preliminary results of testing show that the system is viable. Using ultrasound data, it has been shown that it is possible to determine the LOP of an individual. However, the accuracy, reliability and robustness of the system must still be determined. The overall accuracy of the system has to be tested by increasing the number of test cases over a wider range of age, gender, weight and medical conditions. This will facilitate improvement of the blood detection algorithm. This method could be adapted to continually monitor the LOP of the limb in order to adapt to changes during surgery. Further testing of the transducers with the cuff and signal processing algorithm is required for determining the depth of penetration of an artery.

The next step requires more thorough testing with custom transducers to ensure accurate detection of arterial activity. The performance of the transducers has to be tested through complete integration of eight transducers with eight channels on the evaluation boards tested with our current signal processing algorithm. The algorithm must also be tested using ultrasonic transducers placed directly under the tourniquet cuff, which may decrease the accuracy. The appropriateness of the transmit frequency, transmit voltage, sequencing and pulse repetition frequency (PRF) along with the transducer specifications has to be assessed. These specifications include the number of transducers used, size, depth of focus, center frequency, arrangement and orientation.

Upon successful implementation of the ultrasound tourniquet system on the upper arm, the scope of testing can be broadened to the thigh where the femoral artery lies. System modifications may be required to accommodate for differences such as increased limb circumference and increased depth of penetration required of the ultrasound transducers.

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