ULTRASONIC TOURNIQUETS FOR SURGICAL APPLICATIONS: INITIAL DEVELOPMENT AND FEASIBILITY

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ABSTRACT

A proof-of-concept ultrasonic tourniquet system for surgical applications has been successfully developed and initially evaluated. By adapting conventional ultrasound techniques to monitor the distance of arterial blood penetration beneath a tourniquet cuff, arterial occlusion can be maintained safely and effectively for the duration of an operation at the minimum pressure required, thereby achieving optimal patient safety for individual surgical patients.

INTRODUCTION

Typical surgical tourniquet include a tourniquet cuff which encircles the limb of a surgical patient and a tourniquet instrument which is connected to an inflatable portion within the tourniquet cuff through a length of tubing, thereby establishing a gas-tight passageway between the cuff and the tourniquet instrument. The tourniquet instrument supplies pressurized gas to inflate and regulate the pressure in the tourniquet cuff above a minimum pressure required to stop arterial blood flow distal to the cuff, for a duration suitably long for the performance of a surgical procedure.

Studies published in the surgical literature have shown that the safest tourniquet pressure is the lowest pressure that will stop the flow of arterial blood past a specific cuff applied to a specific patient for the duration of that patient's surgery[1,2,3,4,5]. Such studies have shown that higher tourniquet pressures are associated with higher risks of tourniquet-related injuries to the patient. Therefore, when a tourniquet is used in surgery, surgical staff generally try to use the lowest tourniquet pressure that in their judgment is safely possible.

The inward compressive force applied to a limb by a pressurized tourniquet cuff to close underlying arteries is not equal across the width of the cuff, from proximal to distal edges. Consequently when inflated to a minimum pressure required to stop arterial blood flow past the distal edge of the tourniquet cuff, arterial blood still penetrates beneath the proximal edge of the cuff for some distance to a location where the arteries become closed. In addition to the pneumatic pressure to which a selected tourniquet cuff is inflated, several variables affect the distance to which arterial blood penetrates beneath the cuff. These variables include: the patient's limb characteristics (for example, limb shape, circumference and soft tissue characteristics at the cuff location); characteristics of the selected tourniquet cuff (for example, cuff design, cuff shape and cuff width); the technique of application of the cuff to the limb (for example, the degree of snugness or looseness of application and the absence, presence and type of underlying limb protection sleeve); physiologic characteristics of the patient including blood pressure and limb temperature; the anesthetic technique employed during surgery (for example, whether a general or regional anesthetic is given, the types and dosages of anesthetic agents employed and the degree of attention paid to anesthetic management); the length of time the tourniquet remains inflated on the limb; changes in limb position during surgery; and any shift in the location of the cuff relative to the limb during surgery.

Current tourniquets in the market today do not monitor the depth of arterial blood penetration underneath the tourniquet cuff. An adaptive tourniquet has been described by McEwen in 1984[6], but the adaptive element relies solely on changes in blood pressure which is just one of the items that affect the level of arterial blood penetration under the tourniquet cuff. There is a commercial product in the market[7] that measures the minimum pressure required to stop arterial blood flow; however the measurement is only done once at the beginning of the case and does not account for the intra-operative changes during the surgical procedure.

There is a need for tourniquet apparatus that can monitor and control the distance of penetration of blood past the proximal edge of a tourniquet cuff when blood flow past the cuff is stopped, thereby facilitating improvements in tourniquet safety during surgery and in other settings.

WHY ULTRASOUND?

Of the imaging techniques that are available, ultrasonic imaging provides fast, clear imaging to identify vessel walls and even blood flow to assist identifying vessel walls.

SYSTEM DESCRIPTION

The ultrasonic tourniquet system consists of an ultrasound imaging device, pneumatic tourniquet, and a computer system to analyze ultrasound output and to provide pneumatic tourniquet input. The tourniquet cuff has been modified such that there is an ultrasonic window on the cuff so that acoustic energy may be transmitted through the cuff. The system is capable of identifying vessel walls and the distance of penetration. Figure 1 shows the concept of distance of penetration.

Referring to Figure 1, section (A) shows a non-occluded limb with the tourniquet cuff depicted on the top and bottom of the limb. Under the cuff is an ultrasonic transducer with a sensing region nearby the artery. Section (B) depicts the tourniquet cuff inflated to a pressure high enough to have an initial occlusion. The depth of penetration is measured from the proximal edge of the cuff horizontally to the point at which the vessel lumen is closed. Section (C) depicts the tourniquet cuff inflated to a pressure substantially higher than the initial pressure. This value is typically based on the initial pressure itself. The adaptive tourniquet would then measure this current depth of penetration and manipulate the cuff pressure to maintain it.

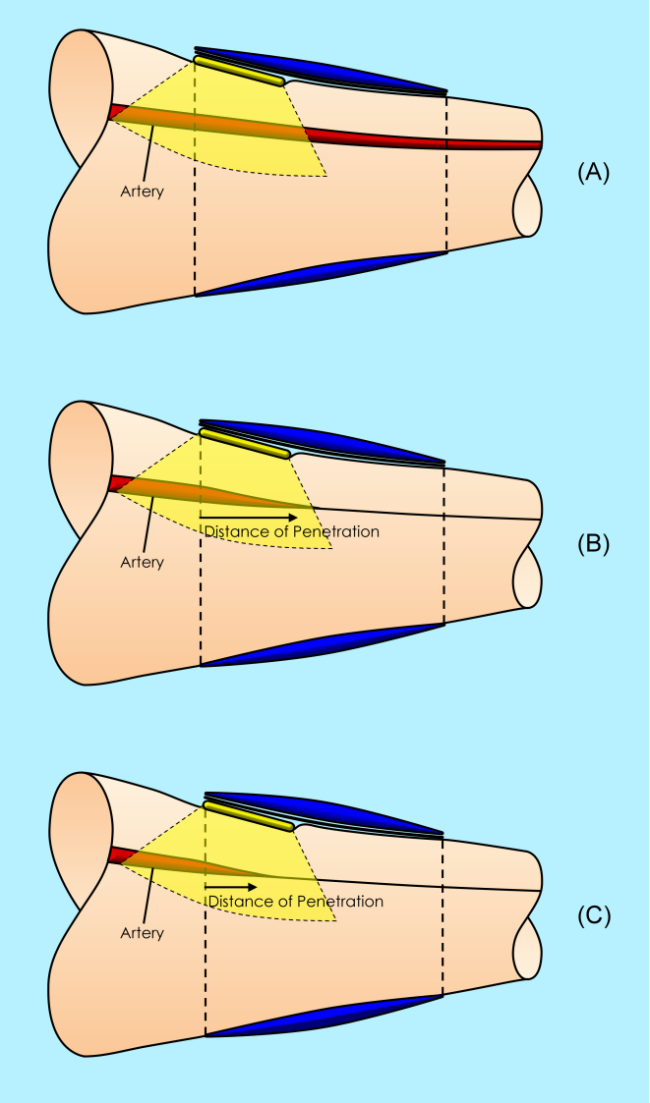

Figure 1 – Distance of penetration concept: (A) shows an non-occluded limb, (B) shows initial distance of penetration with an inflating cuff, and (C) shows a reduced distance of penetration when the tourniquet cuff is inflated further

The conceptual system can be described in Figure 2. The transducer interface output is used to estimate the distance of penetration underneath the tourniquet cuff. The microcontroller would take this distance estimate and regulate the cuff through the pressure regulator. The conceptual system would also have all of the components that a modern tourniquet would have such as a user interface, alarm indicators, and an operating room information network interface.

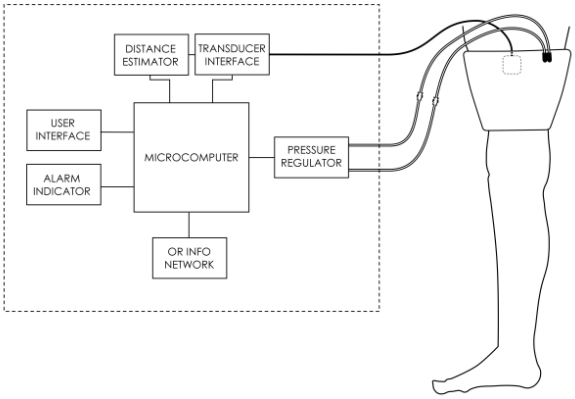

Figure 2 – Block diagram of a complete ultrasonic system.

Ultrasonic Imaging Device

The ultrasonic imaging device used is an Ultrasonix Sonix CEP with the research software package installed. The transducer used is a linear transducer array that is manually controlled to ensure alignment with the artery cross section.

Pneumatic Tourniquet

The pneumatic tourniquet used is a Delfimedical PTS ii. It has a modified firmware that responds to the computer system's input to either increase, decrease, or maintain the current tourniquet cuff pressure.

Computer System

The computer system is a standard desktop computer with a serial port and a network interface. A program written in Visual Studio C++ captures image data from the ultrasonic imaging device and displays it on the screen. The depth of penetration is calculated based on the received image stream. If the depth of penetration is above a certain threshold a signal is given to the tourniquet through the serial interface to increase the cuff pressure by 5 mmHg. If the depth of penetration is below a certain threshold a signal is given to increase the cuff pressure by 5 mmHg.

TESTING

A preliminary proof-of-concept test has been carried out in the lab and the results are promising. The zone of penetration can be monitored and changed based on tourniquet cuff pressure.

Figure 3 shows the depth of penetration on a limb. Section (A) shows the arterial vessel under a non-occlusive tourniquet cuff pressure. Section (B) shows the initial point of arterial occlusion with a measureable depth of penetration. In this experiment the edge of the cuff is not visible but can be calculated knowing where the transducer is in relation to the cuff. Section (C) shows the arterial vessel under a pressure higher than the initial pressure required to occlude the arterial vessel.

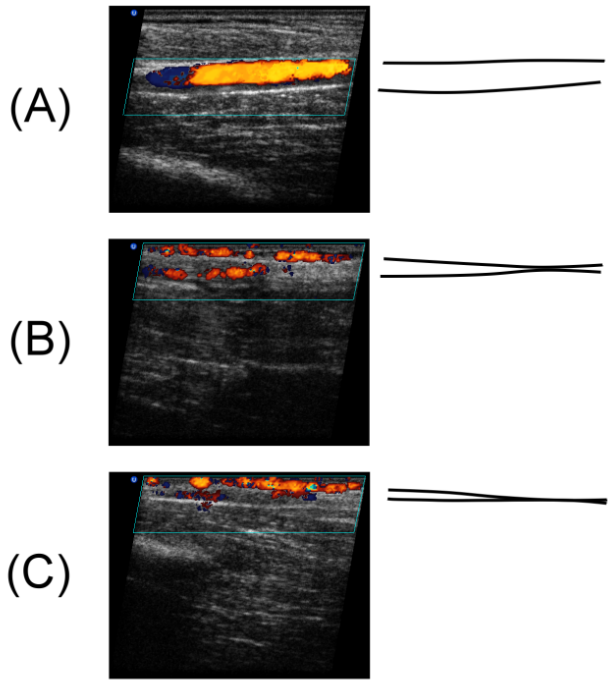

Figure 3 – Measuring the distance of penetration (with vessel walls clarified on the right): (A) shows an non-occluded limb, (B) shows initial distance of penetration with an inflating cuff, and (C) shows a reduced distance of penetration when the tourniquet cuff is inflated further

SUMMARY

A proof-of-concept ultrasonic tourniquet system for surgical applications has been successfully developed and initially evaluated. The preliminary tests have shown that by adapting ultrasound techniques to monitor the distance of arterial blood penetration beneath a tourniquet cuff, arterial occlusion can be maintained safely and effectively for the duration of an operation at the lowest pressure required. The safest tourniquet pressure is the lowest pressure that will stop the flow of arterial blood past a specific cuff applied to a specific patient for the duration of that patient's surgery. Further experiments will be carried out to demonstrate the usefulness of the device and its potential application in the field of medical devices.

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