AUTOMATIC ADAPTATION OF TOURNIQUET PRESSURE DURING SURGERY TO IMPROVE PATIENT SAFETY

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ABSTRACT

Our objective is to determine the feasibility of improving surgical patient safety by automatically adapting the pressure of a pneumatic tourniquet system to the minimum effective pressure needed to reliably stop arterial blood-flow into a patient's limb while facilitating surgery. That minimum quantity, called 'limb occlusion pressure' (LOP), is 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.[1] LOP is affected by variables including: limb size, shape and tissue characteristics; physiologic parameters such as blood pressure, heart rate and temperature; and tourniquet cuff shape, width, design, position and application technique.[1][2]

Some commercial tourniquet systems allow LOP to be automatically estimated preoperatively. However, LOP is known to vary intraoperatively, especially in response to changes in blood pressure and other physiologic variables.[1][2] Existing systems do not adapt automatically to intraoperative changes in LOP. Adapting pressure to remain at a minimum above LOP is important for patient safety because many studies have shown that higher tourniquet pressures are associated with higher probabilities of patient injuries.[1]

This study investigates the feasibility of an adaptive tourniquet by using a commercial tourniquet instrument to estimate LOP preoperatively, periodically measuring changes in blood pressure and heart rate intraoperatively, incorporating that blood pressure and heart rate data into an algorithm for estimating intraoperative LOP, and finally comparing the algorithmically estimated LOP to actual LOP measured at the end of each surgical procedure.

A total of 45 surgical procedures have been completed following the above protocol. Results indicate that an algorithm can be devised to enable a surgical tourniquet system to adapt automatically to LOP changes related to intraoperative changes in blood pressure.

BACKGROUND

Modern pneumatic tourniquets are microprocessor-controlled instruments capable of safely stopping blood flow into a patient's limb during orthopaedic surgery.[1] An electronic instrument controls the pressure within a pneumatic cuff that surrounds the operative limb proximal to the surgical site. The tourniquet could be used to create a bloodless surgical field or to administer regional anaesthesia.[3] Though current tourniquet devices maintain a high level of safety, the risk of tourniquet-related nerve injury remains relevant.[1]

Mechanism of Injury

Studies showed that tourniquet-related nerve injuries occur primarily due to large pressure gradients – or spatial changes in applied pressure across the width of the cuff – underneath the tourniquet cuff. The large

pressure gradient displaces soft tissues in the limb toward uncompressed regions at the cuff edges, which causes stretching and damage in nervous tissue.[4][5] Figure 1 illustrates the pressure distribution underneath a tourniquet cuff and the directions of tissue displacement.[1]

Limb Occlusion Pressure

Many modern tourniquet instruments and cuff designs significantly reduce pressure gradients by either lowering the maximum pressure or increasing the width of pressure distribution. For example, automatic approximation of limb occlusion pressure (LOP) can effectively lower the tourniquet pressure being used, which in turn reduces the pressure gradient applied to the patient. LOP is 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.[1][2] This study investigates how LOP changes during an orthopaedic procedure, and whether the tourniquet pressure can be adapted intraoperatively to further improve patient safety.

METHODS

Investigators enrolled patients scheduled for elective total or partial knee arthroplasty at the University of BC Hospital. The LOP was measured before, during and immediately after the procedure along with the patient's systolic blood pressure and heart rate. Preoperative and postoperative LOP were measured using a commercial tourniquet instrument and a photo-plethysmographic probe on the patient's lower digit. Since the probe is not for sterile use, LOP during the procedure was estimated by gradually deflating the tourniquet cuff until bleeding was observed in the surgical field. Additional information such as quality of cuff application, limb characteristics and anaesthetic technique were noted to supplement the data set.

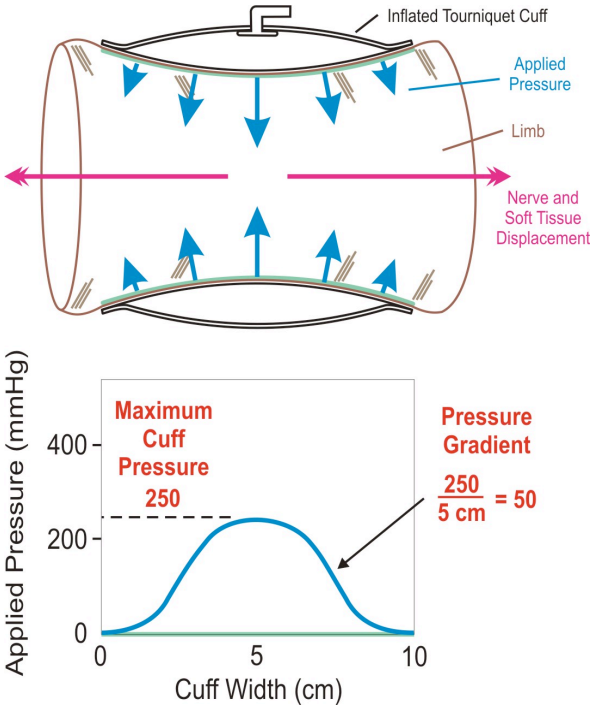

Figure 1: Pressure distribution and pressure gradient applied by a tourniquet cuff on underlying tissue (adapted from Noordin et al, 2009) [1]

RESULTS

A total of 45 knee procedures were assessed. A third and final LOP measurement was recorded for the last 25 cases in order to add additional data to improve the data set.

For each procedure, all LOP values were normalized with respect to patient blood pressure at time of measurement. If blood pressure is indeed a good predictor of LOP, then subsequent LOP measurements should not deviate significantly from the initial, preoperative value. Currently available data indicates that, for most cases, subsequent LOP measurements were within +50/-60 mmHg of expected values. Figure 2 is a graphical summary of the results to date.

Though intraoperative and postoperative LOP measured in this study only correspond loosely with the predicted values, an algorithm could still adapt the tourniquet pressure to intraoperative changes to LOP given an

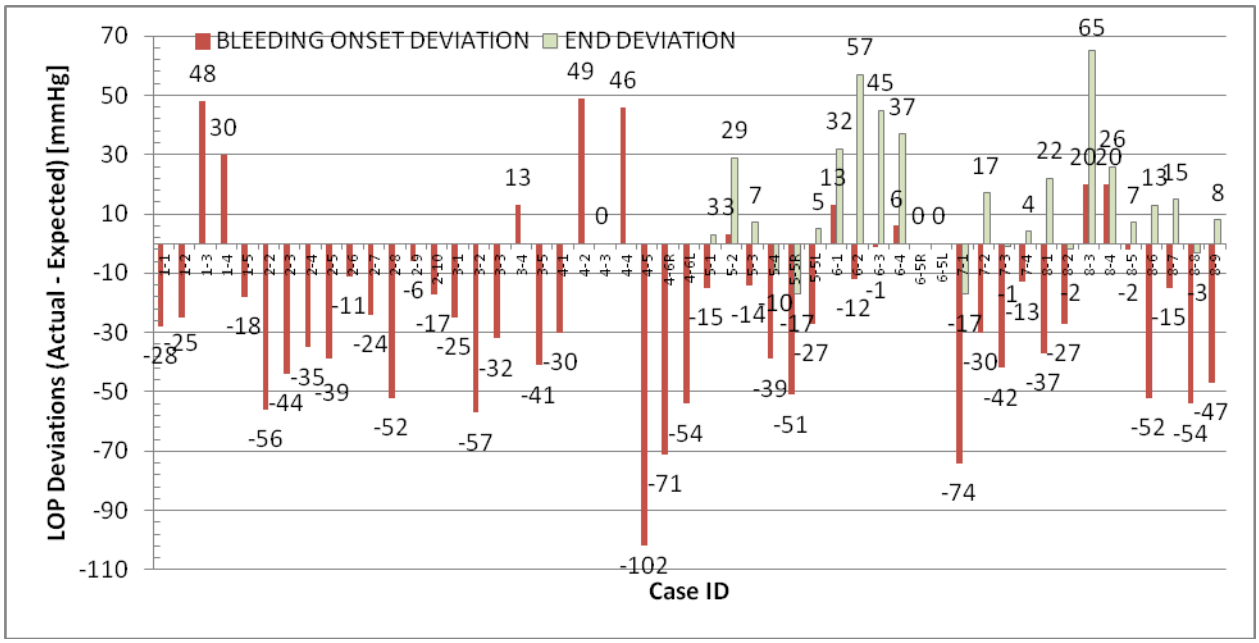

Figure 2: Deviation of bleeding onset pressure and end LOP from expected values based on start LOP. 'Bleeding onset deviation' is the difference between intraoperative LOP, estimated as tourniquet pressure at the first sign of arterial bleeding, and the expected value. 'End deviation' is a similar comparison between end LOP measurements and expected values.

adequate safety margin. Figure 3 shows one such algorithm. Since personalized tourniquet pressures based on LOP are generally much lower than standard tourniquet pressures, patient safety is increased despite the additional safety margin. An adaptive system incorporating LOP would ensure that the limb continues to be occluded with only the lowest pressure necessary.

DISCUSSION

An adaptive tourniquet system can automatically adapt the pre-operative estimate of LOP, and the pneumatic tourniquet cuff pressure itself, based on physiologic changes intraoperatively. By doing so, it can improve safety and performance. Results to date from this study indicate that an adaptive algorithm is feasible, but that an algorithm using only intraoperative and intermittent measurement of changing blood pressure will not provide sufficient accuracy and reliability for a surgically useful system. To remedy this, improvements in the surgical study method and equipment

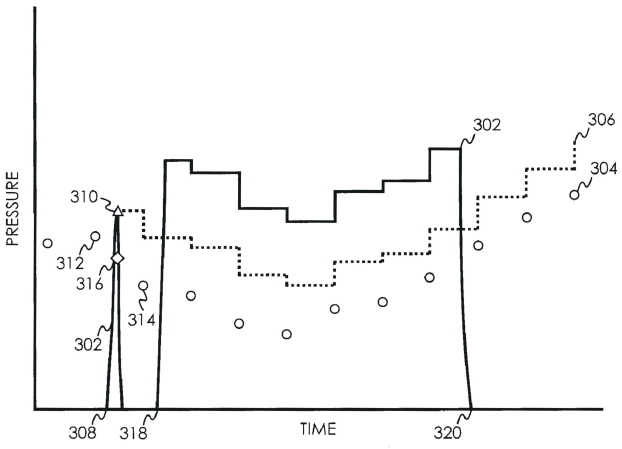

Figure 3: Initial algorithm for adaptive LOP.[6] *Circular points represent BP measurements at set intervals. The estimated LOP (dotted line) changes by the same amount as changes in BP. The tourniquet pressure is adapted to the latest LOP estimate to maintain a constant safety margin.*

have been identified, and are being used in ongoing data collection.

- *LOP measurement improvements*. Temperature measurement at the LOP sensor

location are being introduced to screen out inaccurate initial LOP measurements, to assist in comparisons with the quality of end LOP measurements in the study, and to allow regulation of sensor temperature to improve LOP accuracy for a future implementation of an adaptive system.

- *BP measurement improvements*. To reduce error in the ongoing study, more frequent non-invasive measurements of BP are being attempted: triggering BP measurements in sync with initial and end LOP measurements, and reducing the intraoperative measurement interval from 5 min to 3 min.

- *Inclusion of other physiologic parameters*. Inclusion of EKG and HR should help to improve accuracy of an adaptive system, eg by allowing the incorporation of dynamic pulse wave transit time (PWTT) estimations in an adaptive algorithm tracking BP changes. Inherent PWTT limitations related to drift and error can be effectively offset in an adaptive implementation.

- *Equipment*. Incorporation of a motion artifact detector into the LOP sensor would help to reduce erroneous initial LOPs. Future incorporation of an arterial bloodflow sensor and an arterial blood penetration sensor into a smart tourniquet cuff could aid the development and practical implementation of an adaptive system. Such sensors could use oscillometric, ultrasonic or optical principles for monitoring this additional physiologic parameter.

FUTURE WORK

The above improvements will assist in the development and practical implementation of an adaptive tourniquet algorithm based on adapting initial LOP. An alternate approach to an adaptive tourniquet system is being investigated for comparison: in this system, the depth of penetration of arterial blood beneath a tourniquet cuff can be monitored and controlled directly. This would eliminate the need to measure LOP initially, and would make possible a possible 'set and forget' tourniquet system requiring less operator attention and skill, while providing more safety and reduced risk of breakthrough bleeding intraoperatively.

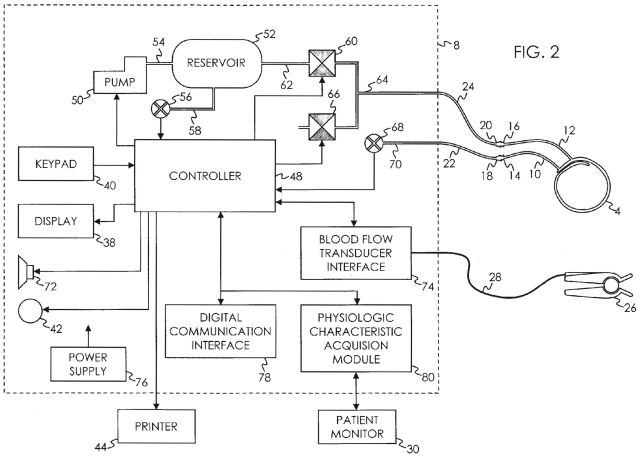

Figure 4: Block diagram of adaptive implementation [6]

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