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Development and initial evaluation of novel tourniquet apparatus for improved safety through optimization of tourniquet inflation time

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Abstract— **Current clinical practice for reducing tourniquet inflation time by applying a cuff and only inflating it when necessary, can introduce a hazard of venous congestion if the cuff is applied tightly. Venous congestion is associated with risks such as limb swelling, excess blood loss, thrombosis, and hemorrhagic infiltration of nerves. Clinical feedback and results of a conducted survey indicate that venous congestion due to improper cuff application is common, and likely related to variations in training or experience of the applicator, cuff design, and the inaccurate and subjective methods for assessing proper cuff snugness. Therefore, a novel self-loosening tourniquet cuff was developed to reduce the risk of venous congestion by ensuring proper and consistent application snugness, facilitating the optimization of tourniquet time by enabling a cuff to be applied safely and remain uninflated until necessary. After development, a pilot clinical study was conducted to evaluate the cuff's efficacy in reducing venous congestion caused by tight application when compared to a standard cuff and a no-cuff control. A published air plethysmography method was adapted to characterize changes in limb volume indicative of venous congestion in ten healthy subjects (5 male, 5 female; 36.4 ± 10.7 years). The no-cuff control showed no increase in plethysmography pressure above the baseline. The greatest pressures above the baseline were reduced by 20.98 ± 3.55mmHg (83.7%), when comparing the standard cuff (25.07 ± 3.41mmHg) to the self-loosening cuff (4.09 ± 1.00mmHg). Regardless of the cuff application tightness, the novel cuff significantly reduced the change in pressure (4.09mmHg) indicative of venous congestion, while achieving a consistent snugness (±1.00mmHg). These results indicate that the self-loosening tourniquet cuff can reduce the risk of venous congestion and improve cuff application consistency, enabling the optimization of tourniquet time by enabling a cuff to be applied and safely remain uninflated until needed.**

Keywords— **safety, tourniquet, venous congestion, optimization, time**

I. Introduction

Basic research and many clinical studies in the field of orthopedic and arthroscopic surgery have clearly indicated both the benefits and risks associated with the use of surgical tourniquets. Benefits of surgical tourniquet use include reduced blood loss, improved visualization of the surgical field, and shorter procedure times [1]. Conversely, tourniquet-related risks have been categorized as pressure and time-related, and are generally associated with nerve, skin, and subcutaneous tissue injury [2].

Modern surgical tourniquet systems reduce pressure-related risks through accurate and automatic pressure control of personalized minimum pressures for effective occlusion, which are based on the patient's limb occlusion pressure (LOP) [2, 3]. Wide contour cuffs designed to lower pressure gradients also help to reduce pressure-related risks.

One method of reducing time-related risks, while retaining the benefits of tourniquet use is to apply the cuff at the beginning of the procedure, but only inflate it when necessary, such as during cementation in total knee replacements or when improved visualization is especially important such as during arthroscopy [4]. While this method can reduce risks by reducing tourniquet time, it may also result in an increased risk of venous congestion. An over-tightened tourniquet cuff, when left uninflated, may apply pressure to the limb sufficient to cause venous congestion, whereby venous drainage is restricted without stopping arterial inflow [5-7]. In surgery, this can cause limb swelling, excess blood loss, thrombosis, and hemorrhagic infiltration of nerves [1, 8, 9].

Current methods of ensuring proper cuff application snugness can be subjective and inaccurate, such as the 'finger test' recommended by the Association of Surgical Technologists (AST) [10] and many tourniquet manufacturers. Due to a lack of published research on tourniquet application-induced venous congestion, we consulted with local orthopedic surgeons and examined clinical feedback regarding tourniquet usage from a survey of members of the Arthroscopy Association of North America (AANA). This information indicates that venous congestion caused by tight cuff application is common, and likely related to variations in applicator experience and training, generic cuff designs, and the lack of reliable methods for assessing proper cuff application snugness.

Based on clinical feedback and the risks associated with current clinical use, the need for an improved tourniquet cuff was identified. We developed a novel self-loosening tourniquet cuff to reduce the risk of venous congestion by ensuring consistent cuff snugness, thus enabling the optimization of surgical tourniquet time by enabling a tourniquet cuff to be

applied safely and remain uninflated until needed. Upon development of the novel tourniquet cuff, a pilot clinical study was conducted to evaluate its efficacy in reducing venous congestion when applied tightly, compared to an equally tight application of a standard cuff. An air plethysmography method was adapted to characterize limb volume changes indicative of venous congestion.

II. Development

The novel tourniquet cuff is cylindrical in shape and has an elastic fastening element at one end that stretches to self-loosen the cuff to a predetermined ideal snugness if it is applied too tightly (Fig. 1). The amount of stretch required to achieve ideal snugness is related to the magnitude of the initial application force. To apply the cuff, the elastic fastening element must first be fastened and allowed to stretch (Fig. 1), before the non-elastic retaining strap can be applied to prevent further loosening during use or inflation. Three novel tourniquet cuffs were developed in different sizes (24", 30", and 34"), to cover a range of limb circumferences from 15" to 30.5". The specification of the elastic element was kept identical for each cuff size. Limb protection sleeves matched to each cuff size were used to protect the skin underlying the cuff. Equivalent standard tourniquet cuffs employed for comparison do not have the novel self-loosening characteristic, but are otherwise identical in materials and sizes.

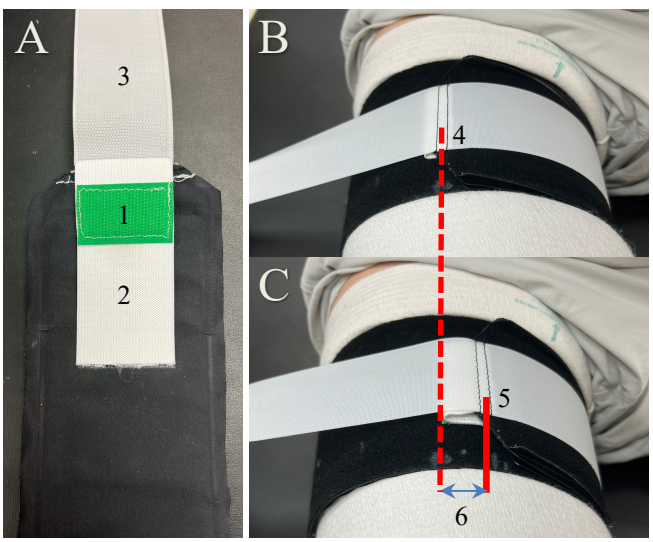

Fig. 1 The novel self-loosening tourniquet cuff.
A) View of the elastic fastening element consisting of the hook-style fastener (1), and elastic element (2). The retaining strap is also shown (3).
B) Tight cuff application, showing the initial position of the cuff end (4).
C) Final position of the cuff end after self-loosening (5) resulting in a self-loosened distance (6) and an ideal application snugness.

III. Methods

A. Participants

Ten healthy participants (5 male and 5 female; 36.4 ± 10.7 years) were recruited for the study, conducted at the Medical Device Development Centre (MDDC) in Vancouver, Canada. No participants met any standard contraindications to the use of tourniquet apparatus. The purpose, procedure, risks, and benefits of participation in the study were clearly communicated, and a written consent form was voluntarily signed by all participants. All procedures carried out in the study were in accordance with the Helsinki Declaration of 1964 and its amendments or comparable ethical standards.

B. Air Plethysmography

An air plethysmography method established in existing clinical literature was adapted to measure the relative change in limb volume indicative of venous congestion [11,12]. This non-invasive technique monitors the pressure inside a pneumatic measuring cuff applied around the distal portion of the limb. When a tourniquet cuff is applied proximally and with sufficient tightness to cause venous congestion, distal limb volume and circumference increase (swelling), and thus increase pressure in the measuring cuff above the initial pressure [12].

In this study, a tourniquet cuff (Lower Limb Vari-Fit, Delfi Medical Innovations, Vancouver, Canada) was used as the distal measuring cuff. It was connected to an external pressure transducer to record changes in cuff pressure at a rate of 100 samples per second.

C. Experimental Procedure

Each subject laid in a supine position on an examination table, with their right ankle in a holder, elevated slightly above the table surface to the level of the heart [7]. Circumference of the right upper thigh was measured and recorded to determine the appropriate size of cuff and sleeve. Subjects were instructed to relax over a period of 5 minutes to allow for adjustment to the environment [13]. During this time, the distal measuring cuff was applied, encircling the largest portion of the subject's right calf. The distal cuff was briefly inflated to form the cuff around the limb, then pressure was adjusted to a stable baseline pressure, as close to 15mmHg as possible.

Three different tourniquet cuff application interventions were then applied and left uninflated on the right upper thigh of the subject in a randomized order, each for a period of 4 minutes:

1. Tight application of the self-loosening tourniquet cuff

2. Tight application of a standard tourniquet cuff
3. No cuff applied

All cuffs for each subject were applied consistently by the same researcher, knowledgeable and experienced in cuff application. A tight application was defined as an application of the cuff with a force greater than what would be considered proper by current clinical standards of practice [10].

Each trial was recorded over 5 minutes, with 30 seconds being captured before and after the 4-minute cuff application trial. After the 5-minute recording period, the distal measuring cuff was deflated. The subject was asked to relax for 3 minutes to allow for circulation to normalize. The measuring cuff was then inflated and re-adjusted to the baseline pressure to begin recording of the next trial. This process was repeated until all three trials were completed.

D. Data Analysis

Raw data was smoothed over 3-second intervals, then normalized to the intended baseline pressure of 15mmHg at the beginning of the recording period. The relative effectiveness of the self-loosening tourniquet cuff in reducing the risk of venous congestion was evaluated by determining:

1. The greatest change from the baseline pressure (15mmHg) for each subject.
2. The average change in distal cuff pressure over time for each cuff application intervention.

IV. Results

The mean and standard deviation of subjects' greatest change in distal cuff pressure from the baseline is summarized in Table 1. The difference in pressures between the standard and self-loosening tourniquet cuff trials are also summarized. Distal cuff pressures in Table 1 are relative to the baseline pressure (15mmHg). Negative pressures indicate a drop in pressure below the baseline.

Table 1: Average greatest change in distal cuff pressure from the baseline for experimental and control trials. The pressure difference between standard and self-loosening cuff trials are included with the percent decrease.

	Standard Cuff	Self-Loosening Cuff	No-Cuff Control
Average greatest change from baseline pressure	25.07 ± 3.41mmHg	4.09 ± 1.00mmHg	-0.56 ± 2.00mmHg
Difference between cuff trials	20.98 ± 3.55mmHg (83.7%)		

The average distal cuff pressures for all three cuff interventions over the 5-minute recording period are shown in Fig. 2. The standard deviations of the averages are indicated by the shaded regions surrounding each plot.

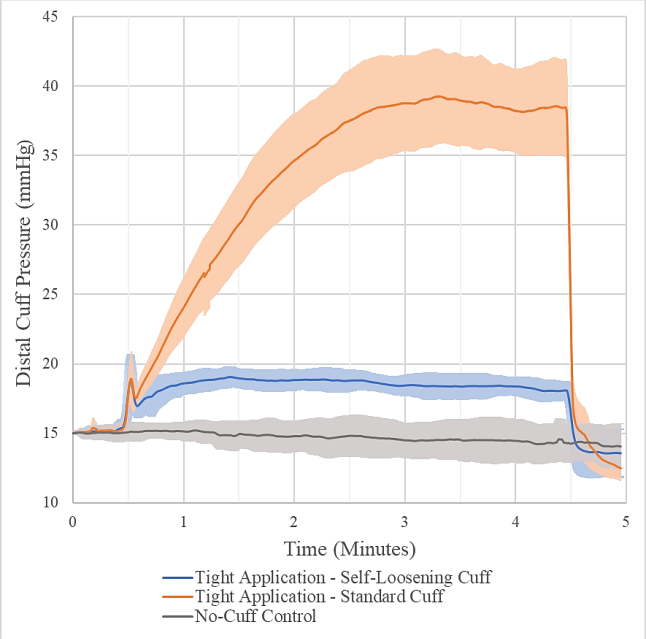

Fig. 2 Average of subject data recorded over time for experimental and control trials with data normalized to an initial baseline pressure (15mmHg). Standard deviations of the averages are indicated by the shaded regions.

V. Discussion

Overly tight tourniquet cuff application can introduce the hazard of venous congestion. The development of a novel self-loosening tourniquet cuff substantially reduced that risk, as determined in the pilot clinical study.

The results in Table 1 and Fig. 2 show that the novel self-loosening tourniquet cuff reaches a significantly lower distal cuff pressure compared to the standard cuff, when applied similarly tightly to the thigh. As the air plethysmography method is a relative measure of limb volume change, these results indicate that the self-loosening tourniquet cuff significantly minimizes, and may eliminate the hazard of venous congestion caused by tight cuff application.

The self-loosening tourniquet cuff also improved the consistency of application snugness as indicated by the lower standard deviation of the self-loosening cuff trial results in Table 1. Control trials did not deviate significantly from the

baseline pressure as indicated by the relatively consistent plot in Fig. 2 and the control results in Table 1. No significant correlation in distal cuff pressures via the air plethysmography method was found to be associated with age, sex, or limb circumference of subjects.

In Fig. 2, the plethysmography plot of the self-loosening tourniquet cuff trials reaches a slightly higher pressure than the no-cuff control. This may be expected, as an ideal cuff application, which the novel cuff was intended to achieve, is moderately snug. A slight decrease in distal cuff pressures can also be seen over time in Fig. 2. This may be due to slight tissue and skin deformations under the distal measuring cuff over time.

Although changes in air plethysmography indicate changes in limb volume, actual limb volumes were not determined in this initial evaluation due to the many associated variables and the need for an optimized and calibrated plethysmography apparatus [12].

For follow-up studies, results may be improved through the use of specialized measuring cuffs that cover a larger surface area of the limb and are calibrated with a known initial volume of air. This would allow for an estimation of limb volume change using Boyle's law. Other plethysmography transducers and methods such as mercury-in-silastic strain gauges or water displacement plethysmography should also be evaluated [12]. Further studies should also be conducted with the novel cuffs to determine their efficacy when applied to upper limbs.

Results of this pilot clinical study should be used to guide future research and bring awareness to training and clinical practices associated with tourniquet cuffs and their application.

VI. Conclusions

The results of this pilot clinical study indicate that the novel self-loosening tourniquet cuff can reduce venous congestion by ensuring proper and consistent cuff application snugness. This represents a significant advance in tourniquet safety, as it enables the reduction of tourniquet inflation time by allowing the cuff to be safely applied, and to remain uninflated until needed. Standard tourniquet cuffs however, when used with this clinical practice, may introduce harmful venous congestion if they are applied too tightly.

This pilot study highlights a novel and innovative solution to a clinical problem. However further studies with larger sample sizes should be carried out to further evaluate the efficacy of the novel self-loosening tourniquet cuff. Clinical and surgical outcomes associated with use of this cuff should also be explored through further studies, to determine the scope of its implications in practice.

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Conflict of Interest

J.A. McEwen, T. Lai, J. Egan, and M. Yee have financial interests in companies that carry out research, development, evaluation, and commercialization of surgical tourniquet systems.

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