Tourniquet Safety in Lower Leg Applications

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Purpose: To reduce the chance of injury due to pneumatic tourniquet use, the minimum cuff pressure required to maintain a bloodless field should be used. The purpose of this study was to find out if Limb Occlusion Pressure (LOP—the cuff pressure required to occlude arterial flow) is lower with a wide contoured cuff than with a standard width cylindrical cuff at the calf, if cuff pressures based on measured LOP will be lower than the typical 250 mmHg used in lower leg cuffs, and if a new automatic LOP measurement method gives the same results as the standard Doppler stethoscope method.

Sample: 16 adult volunteers were tested in a controlled laboratory setting, and 53 clinical cases were reviewed at two centers.

Design: Repeated measures comparison of LOP on volunteers with the two different cuffs and measurement methods, and review of clinical cases.

Results: LOP was lower with the wide cuff on all volunteers (mean reduction 20 mmHg, SD 8.6, range 5–35, p < 0.001). The average difference of 1.2 mmHg between Doppler and automatic LOP readings was not significant (p = 0.43). Based on the volunteer results, using LOP plus a safety margin of 40, 60, or 80 mmHg (for LOP < 130, 131–190, or 190+ respectively) with a standard width cylindrical cuff will lead to an average cuff pressure of 223 mmHg (range 170–299, SD 36), 11% lower than typical practice and up to 80 mmHg (32%) lower on some patients. Using a wide, contoured cuff should further reduce cuff pressures to an average of 195 mmHg (range 160–280, SD 33), 22% lower than typical practice and a reduction of up to 90 mmHg (36%). At two clinics, the wide cuff maintained a bloodless field in 48 out of 53 cases (91%) when used at 200 mmHg.

Conclusions: Using a wide, contoured cuff at the calf should reduce required cuff pressures compared to a standard cuff. Setting cuff pressure based on LOP should further reduce cuff pressures for most patients compared to typically used pressures. With continued development, the new automatic method may become a viable alternative to the Doppler method and may make LOP measurement more practical in the clinical setting.

Surgical tourniquets are routinely applied to selected patients to establish a dry surgical field, to decrease blood loss, and in some instances, for limb anesthesia. The majority of surgical tourniquets used today consist of an inflatable cuff wrapped around the limb proximal to the surgical site, a source of compressed gas, and a pressure regulator. During surgery the cuff is inflated to a pressure sufficient to occlude arterial blood flow. For foot and ankle procedures in which the tourniquet can be placed below the knee, a tightly wrapped Esmarch bandage is sometimes used instead of a pneumatic cuff.

Despite the well-documented benefits of surgical tourniquets, and despite many advances in tourniquet technology, their use is not without risk (McEwen 1982). High pressures on the limb under a tourniquet cuff can cause nerve, muscle, and skin injury (Mohler, 1999; Pedowitz, 1991). Minimizing tourniquet pressure and using a pneumatic tourniquet which allows this pressure to be accurately controlled and monitored should minimize these risks (Massey, 1999; Pedowitz, 1993).

Preventing complications from use of surgical tourniquets has been of special concern with foot and ankle surgery. When a tourniquet is placed at the ankle, the lack of soft tissues over the nerves and vessels in this area may lead to an increased risk of injury (AORN, 1999; AORN, 2000a).

Nursing guidelines and many pneumatic tourniquet manufacturer's instructions currently recommend that the cuff be placed at the point of greatest circumference on the limb (i.e., the thigh) (AORN, 2000b; Smith & Neph-
ew Richards, Memphis, TN; Zimmer Patient Care, Dover, OH; DePuy Orthopaedics, Warsaw, IN), but ultimately defer to the surgeon in charge or the accepted standards at the user’s practice setting.

Many surgeons prefer to place the pneumatic tourniquet cuff at the ankle or calf (rather than the thigh) to reduce the bulk of ischemic tissue and to improve patient tolerance of the cuff. Many studies suggest that this practice is safe and effective (Chu, 1981; Dermer, 1995; Finsen, 1997; Lichtenfeld, 1992; Michelson, 1996; Mullick, 1977).

To gain insight into current practice patterns, we performed a survey of pediatric surgeons. We mailed 1665 surgeons a practice survey. Of the 317 completed responses (19% response rate), only 11 (3.4%) indicated that they “never or rarely” use a tourniquet. Another 8 (2.5%) reported use of an Esmarch bandage as a lower leg tourniquet. The majority (94%) indicated that they use a pneumatic cuff as a surgical tourniquet.

Regarding placement, over 92% indicated that they place the tourniquet at the lower leg (calf or ankle). Eighty-three respondents specifically noted that they do not use a thigh cuff when using local anesthetic due to thigh cuff intolerance. Ninety-three percent use local anesthetic (63% indicated “most often”) and only 4% of calf cuff users and 10% of ankle cuff users experienced patient intolerance of the cuff “often.” Many noted that the lower leg cuff is usually well tolerated when IV sedation is used along with local anesthetic (Kalla, 2002, in review).

As pneumatic tourniquets are being used at the lower leg in practice, the question of how to minimize pressure, and thereby reduce the risk of injury, is of interest to clinicians. Research of equipment and techniques that minimize cuff pressures is of particular interest to orthopaedic operating room nurses who may be asked to apply a tourniquet at locations and pressures they think are unsafe (AORN, 1999; AORN, 2000a).

**Purpose**
This study compared Limb Occlusions Pressures (LOP – the minimum cuff pressure that stops arterial blood flow distal to the cuff) using a wide, contoured cuff designed specifically for the calf to a conventional cylindrical cuff applied at the calf (see Figure 1).

We also compared the current “gold standard” LOP measurement method (Doppler stethoscope) to a new automatic measurement technique currently under development for research use at the first author’s center.

In the automatic technique, a modified tourniquet controller finds LOP at the beginning of a case by adjusting cuff pressure while detecting a distal pulse using a sensor (similar to a pulse oximetry sensor) temporarily clipped onto a toe of the involved limb (see Figure 2). The measurement routine takes about 30 seconds, and the toe sensor may be removed immediately after LOP is displayed.

**Hypotheses**
Three hypotheses proposed the following:

1. Wide, contoured lower leg cuffs will occlude blood flow at a lower cuff pressure than standard width cylindrical cuffs when the cuffs are applied to the calf.
2. Basing cuff pressure on LOP measured on each patient immediately before cuff inflation will lead to lower cuff pressure settings than those normally used in current clinical practice.
3. The average difference between automatic LOP measurements and Doppler stethoscope LOP measurements is zero, and therefore the new automatic method is potentially a clinically practical alternative to the Doppler method.

**Method**

**Sample**
Ethical approval for this study was granted by the University of British Columbia. Healthy adult volunteers with no history of vascular disease were recruited by poster among medical research center staff members. Volunteers were selected to obtain a balance of males and females of a wide age range. The sample of 16 adults included 9 males/7 females between ages 19 and 52 (median 33), weighing between 48 kg and 91 kg (median 72). Three volunteers were normally hypertensive and had a systolic blood pressure (SBP) greater than 140 mmHg before and/or after their participation in this study.

**Procedure**
A standard cylindrical cuff (18” Zimmer ATS Cylindrical Cuff, 100 mm [4"] wide, Zimmer Patient Care, Dover, OH) and a wide, contoured cuff (Delfi Low Pressure Lower Leg Cuff, 140 mm [5.5"] wide, Delfi Medical Innovations, Vancouver, BC, Canada) were tested on each volunteer.

Both cuffs are reusable and are supplied nonsterile. For each cuff, a Doppler LOP measurement and an automatic LOP measurement was made. Each cuff was applied by an experienced technician and left undisturbed throughout its two LOP measurements. A limb protection sleeve (two layers of 4” layflat tubular elastic bandage, as supplied with the wide cuff) was used under both cuffs on all patients (Tredwell, 2001).

Each subject lay supine and a
blood pressure (BP) cuff was applied to the left arm. The first tourniquet cuff in the sequence was applied snugly to the calf. If the subject was not familiar with tourniquet testing, the cuff was inflated to 200 mmHg for several seconds and deflated to ensure that the subject was comfortable with continuing the test. The subject was then asked to relax. After approximately 5 minutes, systolic blood pressure (SBP) was measured using a Doppler stethoscope (Versatone D9, MedSonics, Mountain View, CA) at the radial artery. BP cuff pressure was increased slowly using a hand operated regulator (Zimmer Inflomatic 3000) until the pulse was no longer detected.

The BP cuff pressure indicated by a digital pressure gauge with resolution of 1 mmHg (Cecomp Electronics Inc.) was recorded as the SBP before testing. The tourniquet cuff was then “seated” by inflation to 200 mmHg and immediate deflation. Doppler and automatic LOP measurements were then made on the first cuff. The first cuff was removed and the second cuff applied at the same location, and Doppler and automatic LOP measurements taken.

A randomized sequence of both cuff type and measurement method was used (see Table 1). All Doppler LOPs were measured at the posterior tibial artery (Massey, 1999) using the Zimmer pressure regulator, Doppler unit, pressure gauge, and technique as described above for the SBP. After the last measurement in the sequence for the subject, the SBP measurement was repeated and recorded.

One experienced technician performed all measurements on 15 volunteers, and a second experienced technician performed measurements on one volunteer. Pilot testing has shown that the standard deviation (SD) of a single experienced technician taking repeated Doppler LOP measurements on the same subject and cuff (without removal and reaplication of the cuff) is 2 mmHg (within 4 mmHg at 95% confidence), and mean interobserver differences are within 3 mmHg. The automatic routine takes steps of 10 mmHg to find the LOP; therefore the automatic LOP results are rounded up to the nearest multiple of 10.

**Analysis**

The study is a repeated measures design in which a pair of treatments is applied to the same subject and the mean difference between the two treatments is detected using a paired t-test. To find out if the wide cuff provides a significant LOP reduction, the Doppler results of the two cuffs are compared (n = 16, one-tailed test).

To detect a difference between the Doppler and the automatic measurement methods, the differences between Doppler and an automatic measurement made in succession on each volunteer with the same cuff type are analyzed (n = 32, two-tailed test). Normality of the data for each treatment was confirmed using normal scores plots.

**Clinical Evaluation**

The wide, contoured cuffs and matching limb protection sleeves were used in independent clinical evaluations at two clinics. Cuff pressure, quality of bloodless field, and notes on cuff fit and skin condition were recorded by operating room nursing staff. Note that LOP measurement is not part of the current clinical protocol at the two clinics and was not used. Cuff pressure was initially set at the manufacturer's recommended pressure of 200 mmHg on all patients.

**Results**

**Cuff Type**

Our current results show that the wide, contoured cuff occluded flow at a lower pressure than the standard width cylindrical cuff on all volunteers (see Table 1), with the reduction ranging from 5 to 35 mmHg based on the Doppler measurements. The mean reduction was 20 mmHg (SD 8.6), which was significant at the p < 0.001 level (see Figure 3).

A hypothesized mean difference of 16 mmHg is significant (p = 0.05) thus concluding (with a 5% chance of being wrong) that the average volunteer would experience an LOP reduction of at least 16 mmHg with the wide cuff.

Using the standard width cylindrical cuff, the average cuff pressure required to occlude arterial flow ranged from 130 to 219 mmHg based on the Doppler measurements (see Table 1: mean 162, SD 25). Using the wide, contoured cuff, the average cuff pressure required to occlude arterial flow ranged from 120 to 200 mmHg based on the Doppler measurements (see Table 1: mean 142, SD 21).

**Measurement Approach to Limb Occlusion Pressure**

The average difference between a Doppler and an automatic measurement made in succession on the same volunteer with the same cuff is 1.2 mmHg (SD 8.2). This average difference is not statistically significant (p = 0.43), and the hypothesis that the mean difference is zero is accepted. The power of this test to detect a mean difference of 10 mmHg between the two methods is greater than 99% (alpha = 0.05, beta < 0.01). However in four pairs of measure-
ments, the automatic result was more than 10 mmHg different than the Doppler result (range 24 mmHg lower to 13 mmHg higher), suggesting that the automatic method may not be as precise as the Doppler method.

Clinical Evaluation
At the second author’s clinic, the wide contoured cuff used in the current study has recently been introduced. At a cuff pressure of 200 mmHg, no instances of breakthrough bleeding requiring a cuff pressure increase have occurred in the 45 cases observed to date. Two of these cases showed slight oozing but did not require a cuff pressure increase.

At the third author’s clinic, using the wide cuff at 200 mmHg was adequate in 5 out of 8 cases while some bleeding was noted in 2 out of 8 cases but did not require a pressure increase. Cuff pressure was raised to 250 mmHg in 1 case. At both clinics, no problems in fit and stability of the wide cuff were noted, and with use of the limb protection sleeve (supplied with the wide cuff), wrinkling and indentation of the skin under the cuff were eliminated.

Discussion
Wide, Contoured Cuffs
Previous studies have shown that wide tourniquet cuffs occlude flow at lower pressures (AORN 2000b; Crenshaw, 1988; Esteb, 2000; Graham, 1993; Moore, 1987). For tapered limbs, contouring the cuff such that it matches the conical shape of the limb when applied has also been shown to reduce LOP (Pedowitz, 1993). In a review by Pauers (1994) of an earlier version of the wide cuff used in the current study, a bloodless field was maintained in 30 out of 33 cases (91%) at 200 mmHg cuff pressure at the lower leg. Our current volunteer and clinical results support these findings.
Measurement Approach to Limb Occlusion Pressure

Limb occlusion pressure (LOP) can be used to minimize the cuff pressure required to maintain a bloodless surgical field. Measuring LOP directly at the time of cuff application takes into account variables such as the type of cuff, the tightness of cuff application, the fit of the cuff to the limb, and the properties of the patient's soft tissues and vessels under the cuff.

However, setting cuff pressure based on LOP is not often done in practice because the current gold standard LOP measurement (Doppler stethoscope) is time consuming and requires skill and consistency among technicians to be precise and error free.

The automatic LOP measurement system is being developed to make LOP measurement at the beginning of each surgical procedure clinically practical and to allow clinical studies involving LOP measurement to proceed (Warriner, 1993). At this stage, the prototype system is generally within 10 mmHg of a Doppler LOP reading but may be less precise than the Doppler method.

Cuff pressures of LOP plus a safety margin of 50 to 100 mmHg (to allow for changes in BP during surgery) have been suggested for various cuff locations (Davies, 1983; Diamond, 1985; Lieberman, 1997; Reid, 1983). In particular, Diamond used LOP + 50 mmHg with standard cuffs located at the ankle and obtained a bloodless field in 49 out of 54 cases (91%).

Based on the range of safety margins and the better occlusion afforded by wide, contoured cuffs shown in the literature, we propose a 40, 60, or 80 mmHg safety margin (for LOP of less than 130, 131–190, and greater than 190 mmHg respectively).

Cuff pressure should not exceed 300 mmHg (Diamond, 1985), and pressures approaching this level should rarely be required, particularly when a wide, contoured cuff is used. We are currently proceeding with clinical trials using this guideline.

Many clinicians use a standard pressure for a given cuff and limb based on experience, but this pressure may be higher than that required for many patients. At the second author's center, preliminary results from an ongoing study of pneumatic tourniquet usage in pediatric surgery include 605 cases in which tourniquets were used over a 6-month period.

At the time of the study, only standard cylindrical cuffs were available for use. Ankle cuffs were used for 93.4% of the cases (565), with the remainder placed at the calf (1) and the thigh (39). Postoperative complications were noted in only 3 of the 565 ankle cuff cases (0.5%).

Doppler LOP measurement is never used at this center to establish the minimum pressure required for a bloodless field, since it is considered to be too time-consuming. As a result, doctors tended to use a "default" standard pressure, starting the cuff at 250 mmHg in 526 of the 565 ankle cases (93.1%).

None of these cases required any increased pressure to maintain a bloodless field, thus suggesting that the "default" pressure of 250 mmHg was likely to be excessive in a significant number of cases. In 20 cases, a starting pressure of 225 mmHg was sufficient 90% of the time. Only 2 cases required any increase, and those cases were successfully contained at 250 mmHg.

Effective control of bleeding was maintained at pressures as low as 200 mmHg, the lowest attempted during this period. No attempt was made to determine the lowest pressure required, so it is likely that the true minimum requirement for a given case could have been even lower. Since the average tourniquet duration was nearly 52 minutes, the impact could be substantial.

It is interesting to note that with
Background and Clinical Relevance

In the surgical setting, a tourniquet is often used to provide a bloodless operating field, improving the surgeon's ability to clearly see tissue structures and to perform delicate dissections. Foot and ankle surgery, total knee replacement, and hand surgery are typically performed under tourniquet control with the tourniquet placed at the ankle, calf, thigh, or upper arm as required. Pneumatic tourniquets are also commonly used to Intra-Venous Regional Anesthesia (IVRA, also known as Bier block) technique to contain anesthetic within the involved limb.

The majority of tourniquets used today are pneumatic (inflatable) and consist of a source of pressurized gas connected to an inflatable cuff that is wrapped and secured around the limb. Upon inflation, the cuff applies an even compression around the circumference of the limb sufficient to occlude the arteries and prevent blood flow into the limb distal to the cuff.

Modern tourniquet systems use microprocessor technology to regulate cuff pressure throughout the procedure, monitoring the time that the tourniquet has been inflated, and alert OR staff of various hazardous conditions (such as excessive tourniquet time, accidental disconnection of the cuff, or accidental deflation when dual cuffs are in use).

In typical tourniquet application, an appropriate cuff is selected for the limb, a matching stockinet sleeve or other padding material is applied to the limb, the cuff is snugly wrapped around the limb over the sleeve ensuring that the proximal and distal cuff edges are a safe distance from superficial nerves and vessels at the joints, the hook-and-loop type fasteners on the cuff are secured, and the pneumatic hoses from the tourniquet instrument are connected to the cuff.

Immediately before incision, the limb is exsanguinated (drained of blood using an elastic bandage wrap, elevation, or both), and the cuff is rapidly inflated to the predetermined pressure. When the bloodless field is no longer required, the cuff is deflated and removed, and the extremities are observed to ensure that circulation has been restored.

Although tourniquet use greatly improves the surgeon's ability to perform many procedures and has become standard practice, it is not without risk. Excessive tourniquet pressure can damage the skin, muscle, nerves, and vessels beneath the cuff.

Conversely, a tourniquet pressure that is too low may allow some arterial blood flow to enter the limb yet may occlude venous return, leading to venous congestion. Maintaining tourniquet occlusion for excessive periods of time can also damage the tissues distal to the cuff due to prolonged lack of circulation.

Intraoperatively, some tourniquet complications are bleed-through (leading to loss of bloodless field) and in local anesthetic cases, patient intolerance due to pain at the site of the cuff.

Postoperative complications are usually transient, such as pain in the area where the cuff was applied, or numbness in the limb. However, serious complications, such as compartment syndrome and permanent nerve damage, do occasionally occur and good tourniquet practice is an essential part of operating room staff's responsibility to patient safety.

The goal of care, therefore, is to minimize the risk of a poor outcome for the patient by ensuring that a tourniquet is not contraindicated, a safe location on the limb is chosen for the cuff, the skin is protected, the limb is properly exsanguinated, optimum tourniquet pressure is used, and tourniquet duration is minimized.

Although it is impossible to define an absolutely safe tourniquet pressure and duration, it is generally accepted that using the lowest cuff pressure and shortest tourniquet time possible minimizes the risk of complications.

Many factors determine the tourniquet pressure required to safely maintain arterial occlusion throughout the procedure, such as tissue and vessel properties, limb size, cuff design and width, and systolic blood pressure. Of these, no single factor can be used to reliably determine the ideal tourniquet pressure and, in practice, many clinicians use a standard value that they have found through experience to give a bloodless field. In many cases, this pressure is substantially higher than necessary for the individual patient, and this condition of excess pressure is never detected.

In the accompanying study, the investigators combine two techniques that have been shown in previous studies to reduce the cuff pressures required in surgery but are not commonly used in current practice: (1) use of a commercially available, wide, contoured cuff which fits the taper of the limb, and (2) the measurement of the Limb Occlusion Pressure (LOP, the cuff pressure actually required to stop arterial flow in the limb) on each patient to determine the cuff pressure setting.

LOP measurements are made by auscultation of arterial flow past the cuff by Doppler stethoscope, the current standard method that can be used in most practice settings. In the study, the investigators also test a prototype automatic LOP measurement device (currently under development), which is more convenient than the Doppler stethoscope method. For the lower leg cuff locations tested, substantially lower cuff pressures than those commonly used are predicted for many patients if the wide cuff and LOP measurement techniques are used. Also, the particular patients likely to require high pressures were identified using the LOP technique.

These results are relevant to foot and ankle surgical practice where the tourniquet cuff is placed at the lower leg. In these settings, wide, contoured cuffs and LOP measurement technique should be considered in an effort to reduce patients’ risk of tourniquet pressure-related complications and associated poor outcomes.
Summary of Recommendations for Tourniquet Use on the Lower Leg for Adult Patients

In view of the results of this study and prior recommendations in the relevant clinical literature as described above, the following summary for applying and using tourniquet cuffs in the lower leg region on adults is presented.

1. Select the widest cuff suitable for the selected limb location (AORN, 2000b; Crenshaw, 1988; Estebe, 2000; Graham, 1993; Moore, 1987; Pedowitz, 1993) and if possible, use a contoured cuff able to match the taper of the calf (Pedowitz, 1993). Ensure that the cuff is clean and in good working condition (e.g., check for excessive lint fouling of the hook and loop fasteners and that the cuff does not have permanent kinks or ridges on its inner surface). Place the proximal edge of the cuff near the point of largest calf circumference, at least 50 mm (2") distal to the head of the fibula. The distal edge of the cuff should be at least 50 mm (2") proximal to the ankle malleoli.

2. If possible, select a limb protection sleeve specifically designed for the selected cuff. If such a sleeve is not available, apply two layers of tubular stockinette or elastic bandage, sized such that it is stretched when applied to the limb at the cuff location and such that the compression applied by the stockinette or elastic bandage is less than venous pressure (~20 mmHg) and less than the pressure of a snugly applied cuff (Tredwell, 2001).

3. Apply the tourniquet cuff snugly over the limb protection sleeve, and prevent fluids (such as limb preparation solutions) from collecting between the cuff/sleeve and the patient’s skin (AORN, 2000b).

4. Using the applied cuff, measure the patient’s Limb Occlusion Pressure (LOP), and set the tourniquet pressure at LOP plus a safety margin, normally 40, 60, or 80 mmHg (for LOP of less than 130, 131-190, and greater than 190 respectively), not exceeding a cuff pressure of 300 mmHg (Davies, 1983; Diamond, 1985; Lieberman, 1997; Reid, 1983).

5. Exsanguinate by elastic bandage or elevation, as appropriate for the patient and procedure (AORN, 2000b).

6. Inflate the tourniquet cuff and monitor the tourniquet during use, as recommended by the manufacturer (AORN, 2000b).

7. In the event that arterial blood flow is observed past the tourniquet cuff, increase tourniquet pressure in 25 mmHg increments until blood flow stops (Pedowitz, 1993).


9. Immediately upon deflation of the tourniquet, remove the cuff and sleeve from the limb.

the exception of hypertensive volunteers K and L, this clinical experience seems consistent with the range of standard cuff LOP values found in the current volunteer results (plus the 40-80 mmHg safety margin). It even allowed for differences due to cuff placement at the calf rather than the ankle and possible volunteer and laboratory setting effects.

Clinical literature also shows that 250 mmHg is common for ankle cuffs (Chu, 1981; Mullick 1977) and in one series of 454 standard cylindrical cuff applications at the calf, 250 mmHg or less was used for 81% and 251-300 mmHg for 16% (Michelson, 1996).

In a recent e-mail survey of pediatric surgeons, only 7% indicated that they consider Limb Occlusion Pressure when setting cuff pressure. The most commonly used lower leg pressures were 201-250 mmHg (by 72% of ankle cuff users and 57% of calf cuff users); 251-300 mmHg was most commonly used by 23% of ankle cuff users and 42% of calf cuff users (Kalla, 2002, in review).

Setting cuff pressure based on SBP plus a margin of 100-150 mmHg has also been suggested, leading to average pressures of about 250 mmHg and giving successful occlusion in most cases with the cuff applied at either the ankle or the calf in two clinical studies (Finsen, 1997; Lichtenfeld, 1992). However, SBP is only one variable affecting LOP and correlation between SBP and LOP is not always strong, particularly in normotensive patients (Crenshaw, 1988; Massey, 1999; Moore, 1987). The LOP technique optimizes cuff pressure, leading to generally lower pressures than those currently used for most patients and identifying the need for higher pressures specifically on limbs that may be difficult to occlude.

Testing healthy adult volunteers in a controlled laboratory setting allows a repeated measures study design (in which each subject receives all of the treatments being compared, in this case different cuffs and measurement methods), which is the most powerful way of measuring differences between treatments. A repeated measures study would not be practical in the clinical setting and, as a result, a substantially greater number of subjects would be required. To date, results from a long-term clinical study currently underway at the first author’s center follow the trend of the laboratory results presented above.

Conclusions

Based on testing of 16 healthy adult volunteers in the a controlled laboratory setting, all three hypotheses are supported with the limitation that the differences between treatments and average LOP values are assumed to be similar for patients in the surgical setting:

1. Use of a wide contoured cuff should reduce Limb Occlusion Pressure by an average of 20 mmHg compared to a standard width cylindrical cuff when the cuffs are applied at the calf.

2. Setting cuff pressure based on an LOP measurement of the limb before cuff inflation should significantly reduce pressures compared to the typical 250 mmHg currently used in lower leg tourniquet cuffs, particularly for normotensive patients. The current results suggest that using measured LOP plus a safety margin of 40, 60, or 80 mmHg (for LOP < 130,
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131-190, or 190+ respectively) with a standard width cylindrical cuff will lead to an average cuff pressure of 223 mmHg (range 170-299, SD 36), 11% lower than typical current practice and a reduction of up to 80 mmHg (32%) on some patients.

Using a wide, contoured cuff should further reduce cuff pressures to an average of 195 mmHg (range 160-280, SD 33), 22% lower than current practice and a reduction of up to 90 mmHg (36%) on some patients.

3. The average difference between the automatic and Doppler LOP measurement methods is not significantly different from zero (p = 0.43), and the hypothesis that the average difference between the methods is zero is supported. However the results suggest that at its current stage of development, the new automatic method may be less precise than the Doppler method. With continued development, the automatic method may become a viable alternative to the Doppler method and may make LOP measurement more practical in the clinical setting.

References

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