

# Thigh



# tourniquet safety

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SURGICAL TOURNIQUETS ARE ROUTINELY USED TO ESTABLISH A DRY SURGICAL FIELD, ALLOWING THE SURGEON TO WORK WITH GREATER TECHNICAL PRECISION IN A SAFE, CLEAR ENVIRONMENT. TOURNIQUET USE MAY ALSO DECREASE BLOOD LOSS, AND IN SOME INSTANCES TOURNIQUETS ARE USED FOR LIMB ANESTHESIA. DESPITE THE WELL-DOCUMENTED BENEFITS OF SURGICAL TOURNIQUETS, AND DESPITE MANY ADVANCES IN TOURNIQUET TECHNOLOGY, THEIR USE IS NOT WITHOUT RISK AND COMPLICATIONS STILL OCCUR.<sup>1</sup> HIGH PRESSURES ON THE LIMB

UNDER A TOURNIQUET CUFF CAN CAUSE NERVE, MUSCLE, AND SKIN INJURY.<sup>2,3</sup> MINIMIZING CUFF PRESSURE SHOULD MINIMIZE THESE RISKS.<sup>4,5</sup> THE QUESTION OF HOW TO MINIMIZE CUFF PRESSURE, AND THEREBY REDUCE THE RISK OF INJURY, IS OF INTEREST TO ALL MEDICAL PERSONNEL INVOLVED IN TOURNIQUET USE. RESEARCH OF EQUIPMENT AND TECHNIQUES THAT MINIMIZE CUFF PRESSURES IS OF PARTICULAR INTEREST TO SURGICAL TECHNOLOGISTS WHO ARE RESPONSIBLE FOR THE TOURNIQUET OR WHO MAY BE ASKED TO APPLY A TOURNIQUET.

Limb Occlusion Pressure (LOP, the minimum cuff pressure that stops arterial blood flow distal to the cuff) is a measure of the cuff pressure required to maintain a bloodless surgical field and has been shown in previous studies to be useful in optimizing cuff pressures.<sup>4,6,7,8,9</sup> Increasing the inflatable bladder width and contouring the shape of the tourniquet cuff to fit the taper of the limb have both been shown to reduce the cuff pressure required to occlude blood flow<sup>5,10,11,12,13</sup> and using a wide cuff when possible is recommended in nursing guidelines.<sup>14</sup> However, the current gold-standard LOP measurement method (Doppler stethoscope) is awkward, time consuming, and requires considerable operator skill to be accurate and precise and is therefore seldom used in current practice, and 4" wide cylindrical tourniquets are most commonly used.<sup>15</sup>

In the current study, we compare LOP using a wide, contoured cuff designed specifically for the thigh to LOP using a conventional cylindrical cuff (Figure 1) applied to the thigh. We also compare the Doppler stethoscope LOP measurement method to a new automatic measurement technique currently under development. In the automatic technique, a modified tourniquet controller is used that finds LOP by adjusting cuff pressure while detecting a distal pulse using a sensor (similar to a pulse oximetry sensor) temporarily clipped onto the second toe of the involved limb (Figure 2). The measurement routine takes about 30 seconds, and the toe sensor may be removed immediately after LOP is displayed.

Our hypotheses are that:

(a) the wide, contoured thigh cuff will occlude blood flow at a lower cuff pressure than the standard cylindrical cuff,

(b) 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, and

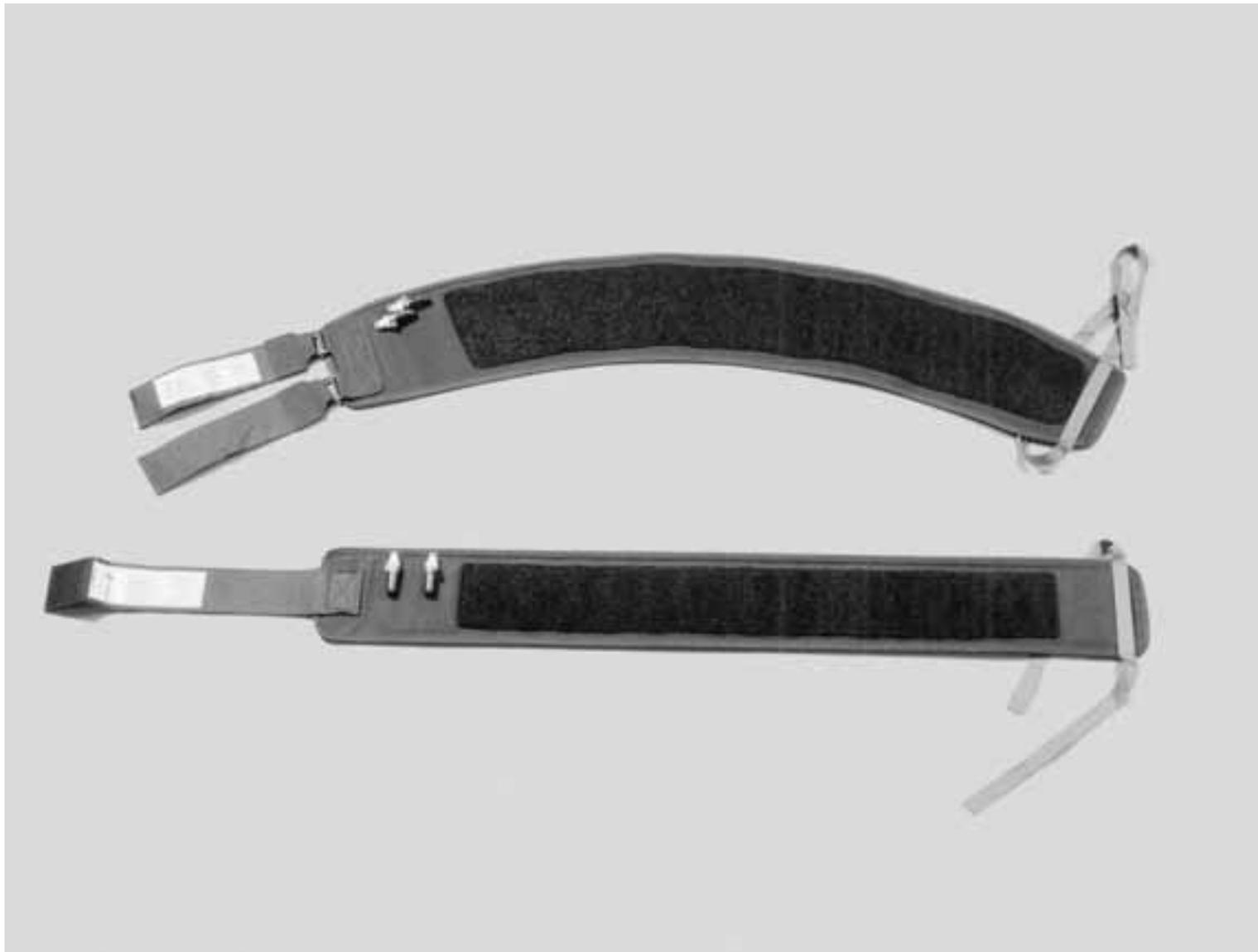
(c) the automatic LOP measurement method is no different from the current standard (Doppler), and therefore is potentially a clinically practical alternative to the Doppler method.

## Method

Ethical approval for this study was granted by the University of British Columbia. Twenty healthy adult volunteers with no history of vascular disease were recruited by poster among medical research center staff members (13 male/7 female, ages 24-57 [median 32], 48-91 kg [median 74]).

An appropriate size standard cylindrical cuff (24" or 30" Zimmer ATS Cylindrical Cuff, 100 mm [4"] wide, Zimmer Patient Care, Dover, Ohio, USA) and a wide, contoured cuff (Delfi Low Pressure Thigh Cuff, 140 mm [5.5"] wide, Delfi Medical Innovations, Vancouver, 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 technologist and left undisturbed throughout its two LOP measurements. To protect the volunteer's skin a limb protection sleeve (two layers of 6" lay-flat tubular stockinette, as supplied with the wide cuff) was used under both cuffs on all volunteers.<sup>16</sup>

Each volunteer 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 thigh. If the volunteer 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 volunteer was then asked to relax and after approximately five minutes systolic blood pressure (SBP) was measured using a Doppler stethoscope (Versatone D9, MedSonics, Mountain View, California) at the radial artery. BP cuff pressure was increased slowly using a hand-operated regulator (Zimmer Inflatomatic 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 mea-



surements taken. A randomized sequence of both cuff type and measurement method was used (Table 1). All Doppler LOPs were measured at the posterior tibial artery<sup>4</sup> using the Zimmer pressure regulator, Doppler unit, pressure gauge, and technician as described above for the SBP. After the last measurement in the sequence for the volunteer, the SBP measurement was repeated. One experienced technologist performed all measurements. Pilot testing has shown that the standard deviation (SD) of a single experienced technologist taking repeated Doppler LOP measurements on the same limb and cuff (without removal and reapplication of the cuff) is 2 mmHg (within 4 mmHg at 95% confidence).

The study is a repeated measures design in which a pair of treatments are applied to the same volunteer 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 (paired t-test, 1 sided). To detect a difference between the Doppler and the automatic measurement methods, the two LOPs from each cuff on each volunteer are compared (paired t-test, 2 sided). To determine if there was a significant mean SBP change during the test among the volunteers (which would possibly make the sequence of the measurements affect the results), SBP before and after the test

## FIGURE 1

Wide, contoured thigh cuff (top) and standard width 30" cylindrical cuff (bottom).

## Recommendations for tourniquet use on the thigh 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 thigh region on adults is presented:

1. Select the widest cuff suitable for the selected limb location<sup>5,10,11,12,13,14</sup> and if possible use a contoured cuff able to match the taper of the thigh.<sup>5</sup> Ensure that the cuff is clean and in good working condition<sup>14</sup> (for example 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).
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 tubular 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.<sup>16</sup>
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.<sup>14</sup>
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 for a normotensive patient having a normal limb.<sup>5,6,7,8,9</sup>
5. Exsanguinate by elastic bandage or elevation, as appropriate for the patient and procedure.<sup>14</sup>
6. Inflate the tourniquet cuff and monitor the tourniquet during use, as recommended by the manufacturer.<sup>14</sup>
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.<sup>5</sup>
8. Minimize tourniquet time.<sup>14</sup>
9. Immediately upon deflation of the tourniquet, remove the cuff and sleeve from the limb.

are compared (paired t-test, 2 sided). Normal distribution of the data for each treatment was confirmed using normal scores plots.

After completion of the volunteer series, the wide cuff and the automated LOP measurement unit were put into use for orthopaedic foot and ankle surgery as part of an ongoing study. SBP and LOP are measured prior to cuff inflation, after the patient had stabilized under the general anesthetic. Cuff pressure is set at LOP + 40, 60, or 80 mmHg for LOP less than 130, 131-190, and greater than 190 respectively. The first 15 cases are presented, and mean LOP and cuff pressure are compared to the volunteer results for the wide cuff (non-paired t-test assuming unequal variances, two sided). The third author was surgeon-in-charge in all 15 clinical cases and rated the quality of the bloodless field as excellent, good, fair, or poor.

## Results

### *Wide, contoured cuff vs standard cuff*

Using the standard width cylindrical cuff, the average cuff pressure required to occlude arterial flow was 192 mmHg (range 145-250, SD 27, Doppler measurement). Using the wide, contoured cuff, the average cuff pressure required to occlude arterial flow was 143 mmHg (range 110-182, SD 17, Doppler measurement). The wide, contoured cuff occluded flow at a lower pressure than the standard width cylindrical cuff on all volunteers, with an average reduction of 49 mmHg (range 25-77, SD 16, Doppler measurement, P is less than 0.001, paired t-test, 1 sided). A hypothesized mean difference of 42 mmHg is significant at the 95% confidence level, meaning that we can conclude (with a 5% chance of being wrong) that the average volunteer would experience an LOP reduction of at least 42 mmHg with the wide cuff. If the true difference between the two cuffs is as little as 13 mmHg, the test can detect the difference 19 times out of 20 (95% power to detect a 13 mmHg difference in means). See Table 1 for the data and the sequence of measurements used on each volunteer. See Figure 3 for comparison of mean LOP. On average there

was no significant change in SBP of the volunteers between the beginning and the end of the test sequence (Table 1: Mean drop in SBP during test of 1.3, ranging from a rise of 5 to a drop of 9, SD 4.0,  $P = 0.16$ , paired t-test, 2 sided).

#### **Automatic LOP measurement vs Doppler**

There is no significant difference in LOP reported between the Doppler method and the automated method (mean difference 1.7 mmHg, SD 8.9,  $P = 0.24$ , paired t-test 2 sided,  $n = 39$  pair). An automatic reading was not made on volunteer T with the wide cuff due to an equipment malfunction. In the remaining 39 pair of measurements, the automatic LOP was between 22 mmHg higher and 14

mmHg lower than the Doppler result. The power of this test to detect a true mean difference of 5 mmHg between the two methods is 95%.

#### **Wide cuff and automatic LOP clinical application**

In the first 15 surgical cases in which the wide cuff, automatic LOP measurement, and cuff pressure set at LOP + 40, 60, or 80 mmHg (for LOP less than 130, 131-190, and greater than 190 respectively) was used, LOP ranged from 97-183 mmHg (mean 144, SD 26). The resulting cuff pressures ranged from 137-243 mmHg (mean 200, SD 32; Figure 4). An adequate bloodless field was maintained in 14/15 cases (93%). Mean clinical LOP ( $P = 0.93$ ) and cuff pressures ( $P = 0.87$ ) were not

**FIGURE 2**

Volunteer thigh LOP test setup showing **a** sensor, **b** prototype hand-held LOP measurement module, **c** modified tourniquet instrument, and **d** cuff with limb protection sleeve.



**Table 1 Volunteer SBP and LOP data (with sequence in parentheses) for thigh cuffs**

Volunteer	SBP start (mmHg)	SBP finish (mmHg)	Doppler LOP standard cuff (mmHg)	Automatic LOP standard cuff (mmHg)	Doppler LOP wide cuff (mmHg)	Automatic LOP wide cuff (mmHg)
A	120	116	176 (1)	174 (2)	130 (3)	118 (4)
B	137	142	212 (2)	213 (1)	160 (3)	159 (4)
C	115	118	200 (2)	199 (1)	140 (4)	137 (3)
D	120	125	194 (1)	189 (2)	148 (4)	165 (3)
E	114	114	217 (3)	205 (4)	140 (1)	138 (2)
F	110	108	145 (3)	151 (4)	110 (2)	120 (1)
G	121	112	189 (4)	185 (3)	137 (2)	146 (1)
H	135	139	193 (4)	215 (3)	168 (1)	154 (2)
I	165	165	250 (1)	246 (2)	182 (3)	186 (4)
J	130	128	234 (2)	227 (1)	165 (3)	172 (4)
K	123	121	216 (2)	223 (1)	140 (4)	153 (3)
L	121	116	178 (1)	183 (2)	141 (4)	142 (3)
M	118	119	191 (3)	190 (4)	146 (1)	150 (2)
N	130	125	185 (3)	180 (4)	150 (2)	150 (1)
O	126	125	198 (4)	190 (3)	147 (2)	140 (1)
P	103	98	148 (4)	150 (3)	123 (1)	120 (2)
Q	110	113	178 (1)	170 (2)	130 (3)	130 (4)
R	122	118	203 (2)	210 (1)	138 (3)	160 (4)
S	130	129	180 (2)	200 (1)	148 (4)	150 (3)
T	120	113	153 (1)	160 (2)	123 (4)	N/a (3)
Median age/weight (ranges): 32 yr (24-57); 74 kg (48-91); 13 m, 7 f	Mean SBP drop: 1.3 SD = 4.0 Range: -5-9	Mean LOP: 192 SD = 27 Range: 145-250	Mean LOP: 193 SD = 25 Range: 150-246	Mean LOP: 143 SD = 17 Range: 110-182	Mean LOP: 147 SD = 18 Range: 118-186	

significantly different than the volunteer results (non-paired t-test assuming unequal variances, two sided). However the clinical LOPs were more variable than the volunteer results ( $P = 0.046$ , F test for variances). See Table 2 for the clinical data.

## Discussion

### *Wide, contoured cuff vs standard cuff*

Previous studies have shown that wide, contoured tourniquet cuffs occlude flow at lower pressures.<sup>5,10,11,12,13</sup> For tapered limbs, contouring the cuff so that it matches the conical shape of the limb when applied has also been shown to reduce LOP.<sup>5</sup> In a review of an earlier version of the wide

cuff used in the current study, a bloodless field was maintained in 58/58 cases at a standardized 250 mmHg cuff pressure at the thigh (approximately 25% higher than the mean cuff pressure predicted by our volunteer results and used in our clinical series).<sup>17</sup> In a clinical series, Pedowitz obtained a “fair” or better bloodless field in 10/10 patients using a slightly narrower (120 mm) contoured cuff at LOP plus 50-75 mmHg (mean cuff pressure 197, range 160-275, SD 37).<sup>5</sup> Our current results support these findings.

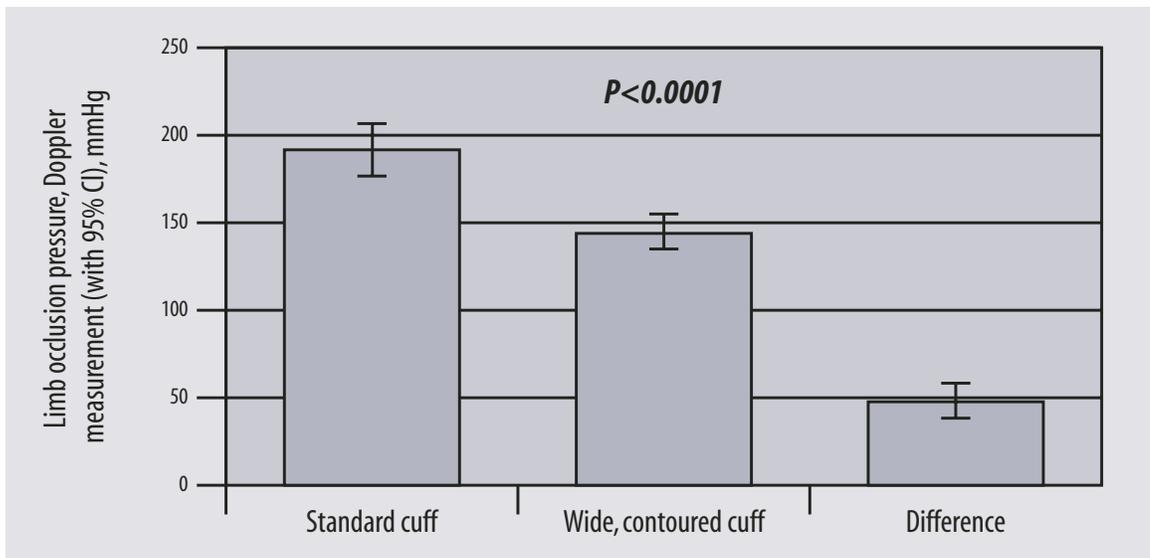
### *Automatic LOP measurement vs Doppler*

Measurement of 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 technologists 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.<sup>18</sup>

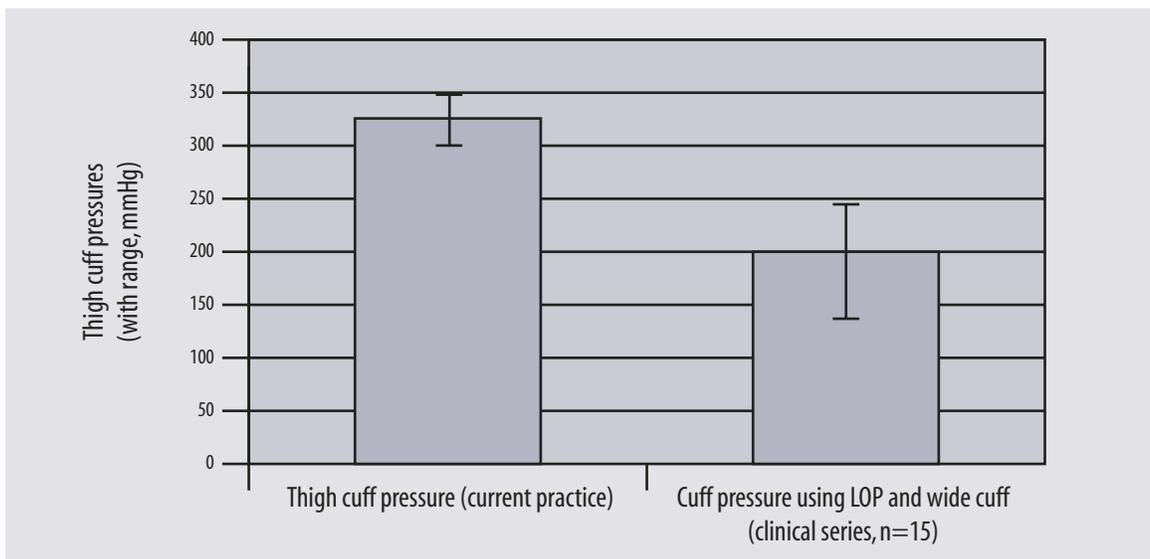
Limb occlusion pressure (LOP) can be used to minimize the cuff pressure required to maintain a bloodless surgical field. Cuff pressures of LOP plus a safety margin of 50 to 100 mmHg (to allow for changes in BP during surgery) have been suggested.<sup>6,7,8,9</sup> Based on the range of safety margins, the trend toward greater margins at higher LOP, and the better occlusion afforded by wide, contoured cuffs all 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). We use this guideline in the current and ongoing clinical trials.

Many clinicians use a standard pressure for a given cuff and limb based on experience, but this



**FIGURE 3**

Comparison of mean Doppler LOP for standard and wide cuffs (n = 20).



**FIGURE 4**

Comparison of most commonly used thigh cuff pressure to clinical results using LOP and a wide cuff.

**Table 2 Surgical patient SBP and LOP data for thigh cuffs**

Patient	SBP (mmHg)	Automatic LOP wide cuff (mmHg)	Wide cuff pressure (mmHg)	Cuff pressure– SBP difference (mmHg)	Bloodless field rating
1	106	133	193	87	Excellent
2	96	142	202	106	Good
3	131	161	221	90	Excellent
4	83	97	137	54	Excellent
5	109	149	209	100	Good
6	94	131	191	97	Excellent
7	134	145	205	71	Good
8	125	119	159	34	Fair
9	99	131	191	92	Fair
10	109	180	239	130	Excellent
11	142	159	219	77	Good
12	130	180	240	110	Good
13	120	141	201	81	Excellent
14	124	183	243	119	Good
15	143	109	149	n/a	Poor
	Mean SBP: 116 SD = 18 Range: 83-143	Mean LOP: 144 SD = 26 Range: 97-183	Mean cuff pressure: 200 SD = 32 Range: 137-243	Mean difference: 89 SD = 25 Range: 34-130	

pressure may be higher than necessary for many patients. In thigh cuffs, 300–350 mmHg is commonly used,<sup>15,19</sup> but in the current clinical results a bloodless field was successfully maintained at pressures as low as 137 mmHg using the LOP measurement and the wide cuff.

Setting cuff pressure based on SBP plus a margin of 100 mmHg has also been suggested and found to reduce cuff pressures and early postoperative thigh pain.<sup>19</sup> However, in both our volunteer and our clinical results, LOP varied widely relative to SBP. In the clinical series, the resulting successful cuff pressures ranged from 34–130 mmHg above SBP (mean 89, SD 25; Table 2) in the 14 cases with an acceptable bloodless field. This variability suggests that cuff pressure based on SBP alone will not be optimal for many patients. SBP is only one variable affecting LOP and correlation between SBP and LOP is not always strong, particularly in normotensive

patients.<sup>4,10,13</sup> In our volunteer results, LOP showed some linear relation dependent on SBP with the wide cuff (r-square = 0.79), but the resulting 95% confidence interval (CI) of an LOP predicted from SBP on the average volunteer in this series is 127–160 mmHg; too wide for SBP alone to be a reliable predictor of LOP. With the standard cuff the relation is weaker (r-square = 0.50, 95% CI of LOP 151–233 mmHg), while in the clinical series, there was almost no linear relation (r-square = 0.11, 95% CI of LOP 90–198 mmHg).

**Wide cuff and automatic LOP clinical application**

Initial experience with the wide cuff and the automated LOP measurement technique in foot and ankle surgery confirms the volunteer test results for the wide cuff and shows that substantially lower pressures are possible with these techniques. Average cuff pressure was 200 mmHg, a

20% reduction over published results using a similar wide cuff without LOP measurement<sup>17</sup> and a 33% reduction over the surgeon's normal practice of using 300 mmHg in standard width, cylindrical thigh cuffs. No problems in fit and stability of the wide cuff were noted. Substantial bleed through was experienced in one case (patient 15). In this case, the LOP was significantly lower than the SBP and a sensing malfunction leading to a low, inaccurate LOP reading is suspected. LOP was lower than SBP in only one other case (patient 8), and the bloodless field was rated "fair." At this stage of development, the automatic LOP system gives an error message if the pulse signal in the toes is too weak. For example, two attempts were required to get an LOP reading on patients 10 and 15. For some patients no measurement can be made, and in this initial clinical series, LOP could not be measured on three patients (after five attempts). There were five additional cases in which cuff pressure was set to higher pressure than defined by the safety margins listed above, including one poor field in which a sensing malfunction (similar to that on patient 15) is suspected. Development of an automatic LOP system is ongoing in an effort to make the system more robust to weak pulse signals.

## Conclusions

Based on results from 20 healthy adult volunteers in a controlled laboratory setting and 15 surgical cases, all three hypotheses are supported:

1. Use of a wide contoured cuff should reduce Limb Occlusion Pressure (LOP, the cuff pressure required to occlude arterial flow) by an average of 49 mmHg compared to a standard width cylindrical cuff when the cuffs are applied at the thigh.
2. Use of an LOP measurement on each patient prior to cuff inflation and setting cuff pressure 40-80 mmHg higher than the LOP will significantly reduce cuff pressures compared to the typical 300-350 mmHg pressures currently used in tourniquet cuffs applied to the thigh. With the standard width cylindrical cuff the average cuff pressure setting would

be 263 mmHg, a 12-25% reduction. With the wide, contoured cuff the average cuff pressure setting would be 198 mmHg, a 34-43% reduction compared to current practice. In clinical use the average cuff pressure used was 200 mmHg, and a bloodless field was maintained in 14/15 cases (93%).

3. In the volunteer series there is no significant difference between the automatic and Doppler LOP measurements, indicating that with continued development the automatic method may become a viable alternative to the Doppler method and may make LOP measurement more practical and reliable in the clinical setting.

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