Automated Cuff Occlusion Pressure Effect on Quality of Operative Fields in Foot and Ankle Surgery: A Randomized Prospective Study

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Automated Cuff Occlusion Pressure Effect on Quality of Operative Fields in Foot and Ankle Surgery: A Randomized Prospective Study

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ABSTRACT

Background: **Limb occlusion pressure, which is present when blood flow ceases, has not had a practical method described for attainment. An automated tourniquet system was modified to set tourniquet pressure based on measurement of limb occlusion pressure (LOP). In this single surgeon randomized prospective study, the effectiveness of this system was assessed on patients undergoing foot and ankle surgery.** ***Materials and Methods:*** **Two hundred forty-four patients were randomized to the study group of automated pressure ($n = 112$) or to the control group ($n = 132$). The primary outcome measure was tourniquet pressure used for either group. Secondary measures included the time to set the pressure and number of patients failing LOP measurement. The tourniquet field was assessed intraoperatively and postoperatively in a blinded manner.** ***Results:*** **The tourniquet pressure was significantly lower in the study group at 198.5 ± 20.2 mmHg compared to 259.6 ± 4.4 in the control group ($p < 0.001$). The time to measure the LOP was 20 ± 6 seconds. Six patients failed to be measured. The quality of the surgical field was judged to be better in the study group based on all three methods of assessment.** ***Conclusion:*** **LOP measurement was a practical way of setting tourniquet pressures for limb surgery. The automated pressure averages were lower than those routinely used by most surgeons for thigh tourniquets.**

Level of Evidence: I, Prospective Randomized Study

Key Words: Tourniquet; Plesthmography; Surgical Field

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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INTRODUCTION

Thigh tourniquet pressures of 300 mmHg or higher are still routinely used by the many surgeons.[6,9,12] The use of tourniquets in lower extremity surgery is desirable but is not without risk. Tourniquet complications are still reported by foot and ankle surgeons.[3,12] Tourniquet use may increase pain and swelling after ankle fracture surgery.[4] Tourniquet pain remains a challenge in extremity surgery and is probably pressure related.[2,10,11] Tourniquet pain increases with prolonged tourniquet time.[7] Wound hypoxia is increased with high versus low tourniquet pressures.[1] Higher tourniquet pressures caused greater muscle impairment in a rabbit study.[5]

Long tourniquet times may also result in complications. Two hours is the accepted standard for length of tourniquet time, but the combination of both pressure and time are important in avoiding complications.[12]

Wide contoured cuffs can reduce the pressure required to achieve limb occlusion.[13] The pressure required to achieve occlusion of blood flow in a limb is dependent on several factors including the circumference of the limb, the width of the tourniquet, the fit or firmness of application of the tourniquet, the compressibility of the underlying vessels and the patient's systolic pressure. Using a single rule for inflation pressure of the tourniquet therefore can potentially lead to unnecessarily high pressure in some patients and ineffectively low pressures resulting in a venous tourniquet in others.

This study was designed to determine the extent of reduction of tourniquet pressure that could be obtained using limb occlusion pressure measurement in each patient. Furthermore, the study was to determine if the use of the ATS 3000 prototype to measure limb occlusion pressure and calculate tourniquet pressures based on preset increments was practical in the clinical setting. A third aim of the study was to compare the quality of the surgical fields in the study group with those of the control group.

We hypothesized that without compromise to the quality of the operative field, the tourniquet pressure determined by

the use of the prototype would be lower than what is usually chosen by surgeons.

MATERIALS AND METHODS

After obtaining IRB approval, patients undergoing elective foot and ankle surgery were randomized to one of two groups: surgeon chosen cuff pressure, or cuff pressure calculated after measurement of limb occlusion pressure using a prototype ATS 3000 tourniquet. Patients included in the study were undergoing open foot and ankle surgery.

Exclusion criteria included patients with vascular disease preventing tourniquet use, refusal to consent to the study, arthroscopic procedures and fracture surgery. Patients unable to communicate for consent were also excluded. Patients were randomized using a coin toss after the initiation of general anesthesia. Two hundred forty-two patients were included in the study. One hundred thirty-two patients were in the control group and 112 in the study group. All underwent a foot and ankle procedure under the care of one surgeon. The average tourniquet time for all patients was 68 minutes.

Measurement of tourniquet pressure in the study group

The device used in the study was a prototype provided by Western Clinical Devices (Vancouver, British Columbia, Canada). A prototype photoplethysmograph sensor (similar to a pulse-oximetry sensor) and a handheld module containing the prototype hardware and software required for the LOP function were added to a standard Zimmer ATS 2000 tourniquet (Zimmer, Warsaw, IN). The software was modified, allowing the results of the LOP measurement to be shown on the standard ATS 2000 display panels, and the cuff pressure setting to be set to the Recommended Tourniquet Pressure (RTP). Various error messages related to the LOP measurement were also displayed (Figure 1). RTP was defined as the LOP reading plus 40 mmHg for pressures of less than 130 mmHg, LOP plus 60 mmHg for pressures between 130 to 190 mmHg, and LOP plus 80 mmHg for pressures greater than 190 mmHg as determined by the designers.

The setup procedure was initiated by placing the photoplethysmograph sensor on the second toe. A 5.5-in (13.8 cm) wide contoured cuff (Delfi Low Pressure Tourniquet Cuff, Delfi Medical Innovations Inc., Vancouver, BC, Canada) automatically inflated to 100 mmHg and then deflated while the patient's pulse signal was detected and the parameters were adjusted. If a suitable signal was detected, the pressure was raised incrementally until the pulse signal in the toe ceased for four consecutive pulse intervals. The cuff was again deflated and the LOP was displayed along with the corresponding RTP. The tourniquet set the cuff pressure to the RTP; however, the clinician could manually override this pressure setting at any time. This setup routine took approximately 30 seconds.

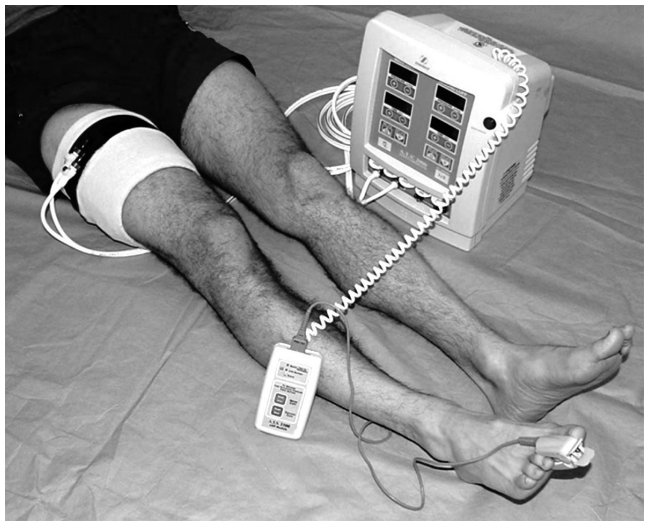

Fig. 1: Limb occlusion pressure measurement device and wide tourniquet cuff used.

Patients in the control group had the tourniquet pressure selected by the surgeon. This was usually in the 250 to 350 mmHg range. This level may have been lower than that used by other surgeons.[12] The surgeon chose higher values if the patient had a large thigh or elevated systolic pressure.

Intraoperative assessment of the operative field

The field was assessed by the surgeon as excellent, good, fair or poor. The assessment was made after the procedure. Factors that were considered when determining the quality of the field were visibility, venous congestion and bleeding. A poor field was one in which blood obscured the field, a fair field had blood present but not significantly interfering with surgery, a good field had some blood with no interference with the procedure, and an excellent field had no blood present.[13]

Blinded assessment

During the procedure a digital picture was taken. To standardize the picture, it was taken with flash and using the same camera (Figure 2). The digital picture was taken towards the end of the procedure. For procedures requiring fusion, the picture was taken at the time of hardware insertion and after debridement had been completed. For hardware removal, the picture was taken at the completion of the hardware removal. Care was taken to avoid irrigating the wound or blotting the field prior to the picture being taken.

Digital picture assessment

Two independent reviewers graded the field quality on two occasions. The pictures were read 2 weeks apart and were reshuffled before second review. The kappa statistic for inter- and intraobserver reliability was calculated using the results of these readings. Comparing these results with the intraoperative assessment assessed the validity of the postoperative assessment.

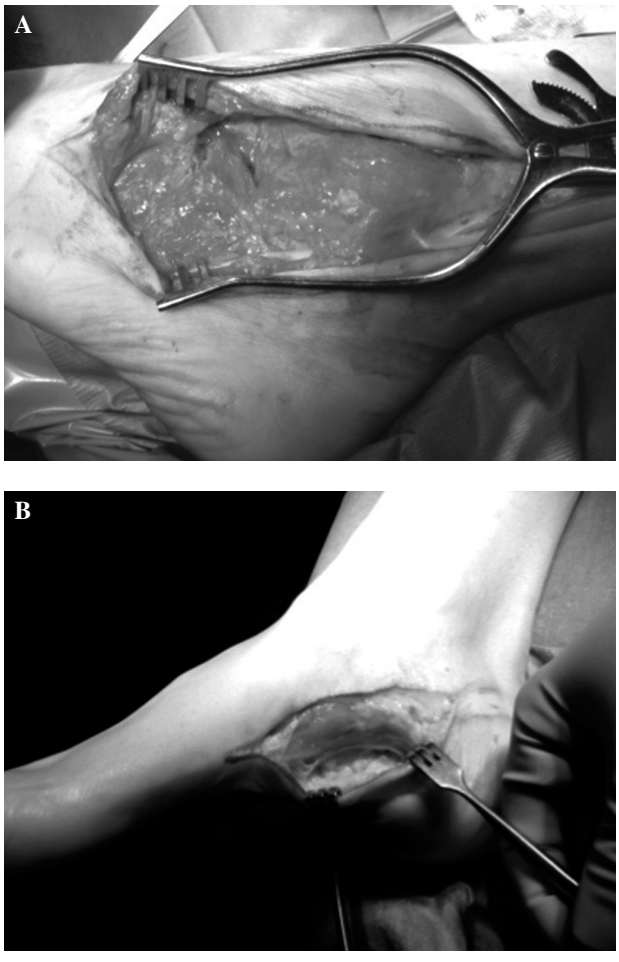

Fig. 2: Examples of a poor field (A) and an excellent field (B) from the digital pictures taken intraoperatively.

Color assessment of the operative field

The digital photographs were also assessed using the degree of color change within the operative field. Using Adobe Photoshop (San Jose, CA) the central portion of the operative field was outlined (Figure 2). The pixel rating was averaged for the area. Adobe Photoshop averaged the three color spectrums over the highlighted area. A score for the degree of red, blue, and green within the highlighted area was obtained. The score of red was divided by the score of green and blue to assess the "redness" of the operative field. This allowed a blinded score to be used for the operative field that was objective. The score was compared between the control group and the study group.

Statistical analysis

The primary outcome measure was the tourniquet pressure in each group. Secondary outcome measures included the quality of operative field assessed by blinded assessment of intraoperative digital radiographs, surgeon assessment and postoperative assessment. Other secondary assessments included comparison of operative fields based on color analysis and the number of failed measurements for limb occlusion pressure measurement.

Chi-squared test was used for categorical data. Analysis of variance was used for numeric data. A weighted Kappa statistic was used to analyze the reliability of the wound grading. The weighting was linear which means a miss by 3 is worth 0, a miss by 2 is worth 0.33 and a miss by 1 is worth 0.67. Agreement was considered fair at 0.21 to 0.4, moderate at 0.41 to 0.6, substantial at 0.61 to 0.80, and almost perfect at 0.81 to 1.

RESULTS

Tourniquet pressure

The average time to measure the limb occlusion pressure and set the cuff was 20 ± 6 seconds. Six patients (5%) failed to obtain a tourniquet pressure reading and were therefore converted to a surgeon chosen pressure. In these patients the pressure sensor failed to pick up a signal despite the patient having adequate pulses.

The mean tourniquet pressure in the study group was 198.5 ± 20.2 mmHg compared to 259.6 ± 4.4 in the control group ($p < 0.001$). The difference averaged 60 mmHg.

The limb occlusion pressure did not correlate well with systolic blood pressure recorded at the start of the procedure. The r^2 value was 0.32 (Figure 3).

Reliability and validity of the new assessments

Figure 4 demonstrates the validity of the digital assessment of the operative field. The intraoperative assessment compared with the blinded digital radiograph assessment resulted in a near perfect agreement with a weighted Kappa of 0.94 (unweighted Kappa = 0.91). Comparison within observers on two occasions (intra observer agreement) of the postoperative digital pictures resulted in near perfect agreement and a linear weighted Kappa of 0.94 (unweighted Kappa = 0.91) (Figure 5). The interobserver agreement of postoperative digital pictures resulted in moderate agreement with a linear weighted Kappa of 0.45 (Unweighted Kappa = 0.35) (Figure 6).

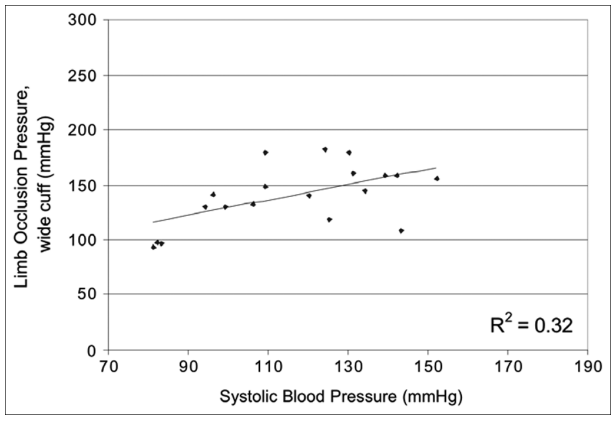

Fig. 3: Limb occlusion pressure versus systolic pressure.

	Excellent	Good	Fair	Poor	Total
Excellent	32	38	6	0	76
Good	6	34	7	1	48
Fair	4	15	5	1	25
Poor	2	6	4	2	14
Total	44	93	22	4	163

Fig. 4: Validity: Comparison of intraoperative field versus postop blinded assessment. Linear Weighted Kappa = 0.94 (unweighted Kappa = 0.91).

	Excellent	Good	Fair	Poor	Total
Excellent	75	6	0	0	81
Good	1	51	0	0	52
Fair	0	0	25	2	27
Poor	0	0	2	14	160
Total	76	57	27	16	176

Fig. 5: Intra observer agreement of postoperative digital pictures. Linear Weighted Kappa = 0.94 (unweighted Kappa = 0.91).

	Excellent	Good	Fair	Poor	Total
Excellent	26	2	1	1	30
Good	20	19	6	3	48
Fair	2	2	5	3	12
Poor	0	3	2	4	9
Total	48	26	14	11	99

Fig. 6: Interobserver agreement of postoperative digital pictures. Linear Weighted Kappa = 0.45 (unweighted Kappa = 0.35).

Operative field assessment

The intraoperative assessment demonstrated 87.5% good and excellent fields in the study group compared to 80% in the control group ($p > 0.05$) (Figure 7). There was a trend for the study group to be better although the difference was not significant. The postoperative blinded assessment of the operative field included the assessment of 167 pictures. 85 subjects did not have an intraoperative digital picture for assessment for a variety of reasons including failure to obtain the picture or an inadequate picture.

	Automatic	Surgeon	Total
Excellent	36(45.0%)	40(46.0%)	76
Good	23(28.8%)	26(29.9%)	49
Fair	11(13.8%)	15(17.2%)	26
Poor	10(12.5%)	6(6.9%)	16
Total	80	87	157

Fig. 7: Quality of the operative fields as assessed by the surgeon.

Of the 80 blinded digital pictures assessed in the study group, 59 were good or excellent (74%), and of the 87 in the control group 66 were good or excellent (76%) showing no difference between the groups.

There was no significant difference in the score of the digital photographs assessed by digital score. However there was a trend for the digital score to be worse in the control group. The digital color score for the study group was 65.6 ± 48 units (a higher score is more red) compared to 75.7 ± 43 units for the control group ($p > 0.05$).

When the scores were compared between groups (excellent to poor) within the intraoperative classification there was a highly significant difference ($p < 0.001$). This blinded and quantitative assessment based was therefore validated by the surgeon's intraoperative assessment.

DISCUSSION

This study shows that limb occlusion pressure can be practically used to set the tourniquet pressure for extremity surgery. The tourniquet pressure for the study group was 60 mmHg lower than the control group. The surgeon in the study already was choosing a lower pressure than the 300 mmHg used by many surgeons so the gains may be more striking for other surgeons.[6,9,12] The reduction of tourniquet pressure may assist in reducing the rate and

severity of tourniquet complications. Postoperative pain may also be reduced. From a surgeon's perspective a reduction of tourniquet pressure cannot result in a greater degree of failed operative fields. However, we found the number of failed fields may be reduced by the use of the automatic setting.

Some patients failed to obtain a pressure measurement. The toe sensor failed to pick up a signal despite the patients having an adequate pulse. In some cases the toes were clawed or were larger preventing the sensor from seating appropriately. As this was a prototype device future developments may avoid this.

The standard assessment of the operative field lacks validation. Bias may also exist as the surgeon knows which arm of the study the patient belongs to. We therefore designed a blinded method of assessing the operative field. Concern exists as the picture taken may not represent the quality of the operative field and the picture may not represent the bleeding present in a poor or failed field. However, there was a reasonable correlation with the intraoperative assessment.

There was no statistical difference between the study group and control group on any method of assessment. There may be a significant difference but the study may not have been powered to show it. However it would appear even if this was the case that the fields are at least equivalent. Obtaining equivalent fields at a lower pressure is encouraging and may lead to fewer tourniquet related complications. Further study, perhaps by EMG, would be of value to determine if the use of automated cuff pressures reduces EMG identified nerve injury. While a clinical study may be of benefit, nerve injury, partial or complete, single or multiple, temporary or permanent are hard to define and may have other causes than the tourniquet.

Further, we used a digital image assessment of the color of the operative field. This also appears to be valid as there was a significant difference between the score between the intraoperative groups. This technique allows a value to be applied to the quality of the field as well as being blinded and objective. We would recommend this technique for the assessment of the field for future tourniquet studies.

A limitation of the study was that an assessment of pain and function was not performed postoperatively. A lower tourniquet pressure may reduce perioperative pain as well as reducing complications. Neither were formally recorded in this study. The color measurement did not have a color control card. This may increase the error created by photographic technique. If this technique is used in the future a sterilized color control card may be beneficial.

CONCLUSION

We conclude that the tourniquet system allowed lowering of the tourniquet pressure without compromising the operative field based on three methods of assessment. We would therefore recommend its use to potentially reduce pressure related tourniquet complications.

REFERENCES

1. **Clarke, MT; Longstaff, L; Edwards, D; Rushton, N:** Tourniquet-induced wound hypoxia after total knee replacement. J Bone Joint Surg Br. **83**(1):40–4, 2001. http://dx.doi.org/10.1302/0301-620X.83B1.10795
2. **Fuzier, R; Hoffreumont, P; Bringuier-Branchereau, S; Capdevila, X; Singelyn, F:** Does the sciatic nerve approach influence thigh tourniquet tolerance during below-knee surgery? Anesth Analg. **100**(5):1511–4, table of contents, 2005.
3. **Kalla, TP; Younger, A; McEwen, JA; Inkpen, K:** Survey of tourniquet use in podiatric surgery. J Foot Ankle Surg. **42**(2):68–76, 2003. http://dx.doi.org/10.1016/S1067-2516(03)70004-0
4. **Konrad, G; Markmiller, M; Lenich, A; Mayr, E; Ruter, A:** Tourniquets may increase postoperative swelling and pain after internal fixation of ankle fractures. Clin Orthop Relat Res. **433**:189–94, 2005. http://dx.doi.org/10.1097/01.blo.0000151849.37260.0a
5. **Mohler, LR; Pedowitz, RA; Lopez, MA; Gershuni, DH:** Effects of tourniquet compression on neuromuscular function. Clin Orthop Relat Res. **359**:213–20, 1999. http://dx.doi.org/10.1097/00003086-199902000-00024
6. **Nicholas, SJ; Tyler, TF; McHugh, MP; Gleim, GW:** The effect on leg strength of tourniquet use during anterior cruciate ligament reconstruction: A prospective randomized study. Arthroscopy. **17**(6):603–7, 2001. http://dx.doi.org/10.1053/jars.2001.24854
7. **Rudkin, AK; Rudkin, GE; Dracopoulos, GC:** Acceptability of ankle tourniquet use in midfoot and forefoot surgery: audit of 1000 cases. Foot Ankle Int. **25**(11):788–94, 2004.
8. **Tamvakopoulos, GS; Toms, AP; Glasgow, M:** Subcutaneous thigh fat necrosis as a result of tourniquet control during total knee arthroplasty. Ann R Coll Surg Engl. **87**(5):W11–3, 2005. http://dx.doi.org/10.1308/147870805X60761
9. **Tejwani, NC; Immerman, I; Achan, P; Egol, KA; McLaurin, T:** Tourniquet cuff pressure: The gulf between science and practice. J Trauma. **61**(6):1415–8, 2006. http://dx.doi.org/10.1097/01.ta.0000226159.84194.34
10. **Vas, L:** Continuous sciatic block for leg and foot surgery in 160 children. Paediatr Anaesth. **15**(11):971–8, 2005. http://dx.doi.org/10.1111/j.1460-9592.2005.01620.x
11. **Worland, RL; Arredondo, J; Angles, F; Lopez-Jimenez, F; Jessup, DE:** Thigh pain following tourniquet application in simultaneous bilateral total knee replacement arthroplasty. J Arthroplasty. **12**(8):848–52, 1997. http://dx.doi.org/10.1016/S0883-5403(97)90153-4
12. **Younger, AS; Kalla, TP; McEwen, JA; Inkpen, K:** Survey of tourniquet use in orthopaedic foot and ankle surgery. Foot Ankle Int. **26**(3):208–17, 2005.
13. **Younger, AS; McEwen, JA; Inkpen, K:** Wide contoured thigh cuffs and automated limb occlusion measurement allow lower tourniquet pressures. Clin Orthop Relat Res. **428**:286–93, 2004. http://dx.doi.org/10.1097/01.blo.0000142625.82654.b3