

Extended Tourniquet Times and the Impact on Wound Healing in Foot Surgery

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Abstract

Objective: The aim of this study was to compare the effect of tourniquet time less than or in excess of 120 minutes on foot surgery wound healing. Null hypothesis: A tourniquet time of over 120 minutes will not affect wound healing in foot surgery.

Design, Setting, Participants and Method: A retrospective comparative cohort analysis was performed on 96 patients undergoing complex hindfoot surgery in a large central teaching hospital. Fifty-five patients receiving tourniquet pressure for >120 minutes and 41 receiving <120 minutes of tourniquet pressure were identified from electronic case records. The primary outcome was surgical wound healing. Secondary outcomes were discharge date and complication rate.

Results: There was no significant difference in reported time for wounds to heal in the <120-minute or >120-minute cohort. There were no other significant differences in secondary clinical outcomes and no significant variations in patient demographics.

Conclusion: This study suggests that tourniquet times from 2 to 3 hours in foot and ankle surgery with pressures up to 300 mmHg are not associated with a significant effect on wound healing.

Keywords: Extended tourniquet time; Newman's recommendations; Complex hindfoot surgery;

Orthopaedic surgery; Foot and ankle

While arterial tourniquets in Orthopaedics can offer a clear visual field their use is often controversial.¹⁻¹² Risks associated with tourniquets include nerve injury, muscle damage, compartment syndrome, tourniquet pain and if used incorrectly even death^{1,3}. Despite this they are often used for peripheral limb surgery and believed to reduce overall surgical time under anaesthesia.^{1,3}

Animal trials and experience surveys suggest that 2 hours of continued tourniquet is the limit of safe use.^{3,5,8,12} Trials show that at 2-hours intracellular cyclic phosphatase levels are depleted and myofibillar degeneration occurs in muscles, with complete adenosine triphosphate (ATP) exhaustion after 3 hours^{8,12}. The current standard based on Newman's recommendations is no more than 90 minutes of continued tourniquet time followed by 10 minutes of rest before reapplying if necessary⁸. Newman's method has been shown to reduce the ischaemic changes to muscle tissue, in particular to the area directly below the tourniquet.^{3,5,8}

In addition to the length of tourniquet time, the pressure in which it is inflated is a contributory factor for ischaemic damage.^{7,9-12} While animal studies suggest 300 mmHg is an effective upper limit for reducing blood in the surgical field, even in prolonged operations greater than 3 hours⁴, using the lowest effective pressure for the shortest time is thought to correlate with better outcomes.^{7,11,12} In the initial few hours of tourniquet usage, damage is primarily to the underlying muscles and vasculature with damage only evident distally after 4 hours.^{4,11,12} This can be seen even at low pressures.^{11,12}

In our trust, a large central teaching hospital, we regularly exceed 2-hour tourniquet times in our elective foot and ankle surgeries and do not use the recommended 10-minute deflation after 90 minutes. The primary aim of this study was to test the hypothesis that there is no significant difference in ankle surgery wound healing with thigh tourniquet times greater than or less than 120 minutes. Secondary objectives were to look at discharge date and post-operative complication rates.

Patients and Methods

Retrospectively, we gathered data of all patients operated on by a single surgeon in a large central teaching hospital utilizing an electronic database and electronic patient records. Data was gathered from September 2015 to February 2018 based on power calculations to include an adequate sample size. Inclusion criteria was any patient receiving (1) a single limb complex hindfoot operation, defined as subtalar or triple fusion, (2) revision procedures, or (3) hindfoot arthroplasty. Exclusion criteria was (1) subsequent revision during the time frame, where only the first operation would be included to minimise bias of a recurrent difficult operation, and (2) patients identified as significantly non-compliant with post-operative instructions.

In total this revealed 96 patients who had a complex hindfoot operation on a single limb in this single site operated by the same surgeon. We had removed one patient in the over 2-hour cohort due to significant non-compliance. Fifty-five patients had tourniquet times greater than 2 hours and 41 patients had a tourniquet time of less than 2 hours. All patients were followed until they were discharged from the orthopaedic clinic. If the patient required re-admission for inpatient wound management including intravenous antibiotic therapy or surgical intervention they were

treated as operative failure and subsequently excluded from the wound healing calculation. The rationale for this exclusion was that subsequent surgical interventions including washout or skin grafting precluded wound closure, so inclusion in the wound healing calculation could be both misleading and skew our dataset. In addition, the heterogeneity of managing patients with a deep infection was an uncontrolled element that contributed potentially misleading astronomical points in our data set. In total, this correlated to 11 patients, six patients in the less than 2-hour tourniquet time cohort (15%) and five in the greater than 2-hour cohort (9%). Nevertheless, the rate of operative failure due to infection would be directly compared between the two cohorts using descriptive and inferential statistics as discussed below. In addition, delayed wound healing described as blistering, necrotic tissue, infection or wound breakdown by the primary assessor at clinic review was recorded and analysed for the two cohorts.

Data Collection

Operation notes and clinic reviews were analysed using electronic records. Tourniquet time was cross checked with the operation note, anaesthetic chart and nursing records to minimise any operator bias. Typically, patients were reviewed after 2 weeks from operation in clinic to assess their wound or in the first week if there were initial concerns on wound healing such as infection. In addition to the above we also collected demographical data, complication rates, use of regional anaesthetic blocks and discharge date from operation. Of note, all operations took place on a Friday elective list and all patients had a tourniquet inflation pressure of 300 mmHg for the duration of tourniquet use. Tourniquets were documented as inflated after draping of a patient and deflated after wound closure.

Patient Data/Demographics

Patient demographics are shown in Table 1. The age range was 24-83 years, with no significant difference in age, weight, diabetic or smoking status. To assess patient frailty/comorbidity influence we utilized American Society of Anesthesiologists (ASA) scores as determined by our anaesthetic team. There were no significant demographical differences between either cohort. Patients were assessed by the consultant prior to operation. As part of the assessment, a vascular examination was completed to assess suitability for the operation and likelihood of successful healing. The results were not routinely documented on electronic records.

Power Calculation and Statistical Analysis

To calculate our study power to assess our primary goal, wound healing, we completed an initial power calculation using a 3-month dataset with a 1:1 recruitment ratio and standard values for alpha and 1-beta (5% and 0.8, respectively). As a marker of clinical significance, we used a minimal clinical difference of 2 weeks based on our clinic review times as a smaller difference would be difficult to detect clinically for the purposes of this trial. Our initial power calculation suggested we would need 29 patients for each cohort as part of a one tailed hypothesis. At a midpoint in data gathering we completed a priori statistical analysis to ensure our data would remain adequately powered, which suggested we would need 34 patients to achieve adequate power, achieved by February 2018.

Statistical analysis of wound healing and discharge date was calculated using unpaired 2-tailed student *t*-test analysis with an alpha value of 0.05. If the *t*-test revealed a *P* value <0.05 this was

regarded as significant. Infection rate and patients with delayed wound healing were analysed using the Mann Whitney U test with a P value of <0.05 correlating to significance.

Results

The mean tourniquet time for the <120 -minute cohort was 95 minutes and 142 minutes for the >120 -minute cohort. There was no significant difference in average wound healing time between the two cohorts as demonstrated in Table 2 (P value >0.05 , $n=85$).

We excluded 11 patients from our dataset of 96 patients from the calculation due to operative failure as described in the methods section. This included six patients in the <120 -minutes of tourniquet time cohort with three patients admitted for a prolonged stay with intravenous antibiotics, 2 requiring re-operation due to failed alignment and one requiring a skin graft due to wound breakdown. In the >120 -minutes of tourniquet time cohort, five patients were excluded with three managed for deep infection requiring intravenous antibiotics, 1 requiring re-operation for realignment and one requiring a skin graft due to skin breakdown. The numbers of patients excluded due to deep infection were 3/40 (7.5%) in the <120 -minutes of tourniquet time cohort and 3/56 (5.4%) in the >120 -minutes of tourniquet time cohort which was found to be non-significant (P value=0.84).

Secondary Outcomes

Delayed wound healing, described as blistering, necrotic tissue, infection or wound breakdown by the primary assessor at follow up clinic was not significantly different between the two cohorts. In total, eight patients (8/35) had delayed wound healing in the less than 120-minutes of

tourniquet time cohort compared to 9 (9/50) in the greater than 120-minute cohort (P value=0.36)

Comparing infection rates in the full cohort ($n = 96$) showed no significant difference between the two cohorts. There were 4 (4/41) cases of infection identified in the < 120 minutes of tourniquet time cohort compared to 5 (5/55) in the >120-minutes cohort (P value=0.91).

Table 3 compares the discharge date between the two cohorts. As shown, both groups of patients are discharged on average less than 4 days from their operation. Patients with operative failure were treated as failed discharges and excluded from this calculation.

Post-operative Complications

No patients in this time frame had a significant post-operative bleed requiring transfusion, developed a deep vein thrombosis (DVT) or compartment syndrome.

Regional Anaesthesia

There was considerable variability in the choice of regional anaesthesia in these patients, with the trend that a spinal +/- regional had a superior outcome on wound healing as shown in Table 4.

Discussion

We report no significant difference in wound healing time in hindfoot operations greater than or less than 2-hours tourniquet time. Interestingly no patient had a tourniquet time greater than 3

hours with the mean tourniquet time in those in the greater than 2-hour cohort, 142 minutes. This result can perhaps be reflected back to the aforementioned animal trials demonstrating that ATP wasn't exhausted until the 3-hour mark perhaps at which point damage distal to the tourniquet may be significant.^{3,4,8} Our hypothesis is that until the distal limb musculature is affected ie, after the suggested 3-hour point, there is no discernible difference in wound healing.

Both cohorts demonstrated similar baseline demographics with no significant differences.

Selection bias may be a feature as these patients were all operated on in a large central teaching hospital where its day surgery units are peripherally located and not included in this study. Thus, those selected for the central site often are higher risk through comorbidity, anatomical complexity or severity of disease. However, since both cohorts were selected for this site, they are likely of a similar complexity and as a result comparable. The decision to use ASA grade as a marker of comorbidity rather than, for example, the Charlson index, was based on the adequacy of electronic records which often lacked details necessary for the commonly used morbidity indexes where in contrast an ASA grade was always completed by the anaesthetic team.

Interestingly, a study by Whitmore et al, suggested that the ASA grade is comparable to the Charlson index as a marker of morbidity and anticipating complications.¹³

In addition to wound healing, the discharge date did not achieve a *P* value <0.05, although this outcome was not specifically powered for in our initial calculations. One point of contention is that all operations were performed on a Friday and thus may be affected from reduced availability of out-of-hours physiotherapy and medical teams, which may have had an impact on discharge date. As there is a trend for those in the over 2-hour cohort to be discharged at a later

date, this outcome requires further analysis before conclusions can be drawn. Both cohorts did not demonstrate any incidence of compartment syndrome, major blood loss or DVT, comparable to current literature.^{3,11,17}

One weakness of this trial is the lack of a formalized wound assessment tool used in clinic and thus we have some operator dependent variability. Infection was regarded as stated in clinic or a prescription of antibiotics by the clinician or general practitioner after wound review in this timeframe, which potentially excludes some patients with milder infections or those who received antibiotics in a different health board. The lack of a formalized wound assessment tool may also impact the objective point of wound healing due to clinician variability. To overcome this challenge a future prospective trial would be of value utilizing a formalized wound assessment tool to ensure a continuous objective assessment process. Utilizing a prospective design would also allow enhanced follow up of patients and perhaps detect clinical improvement earlier.

Post-operative analgesia requirements were difficult to appreciate and thus were excluded from this trial. One previous trial used total oral morphine equivalence to assess pain requirements; however, given the varying long-acting opiate regimes prescribed by anaesthetics in this time frame, not all patients had the same access to opiates, thus limiting its value.¹⁸ Previous studies have suggested that tourniquet usage alone does not significantly affect post-operative pain control.¹⁵⁻¹⁶ In contrast there are animal trials which describe reperfusion hyperalgesia.¹⁷ Heterogeneity of post-operative analgesia regimes, including use of long-acting opiates, impaired retrospective data collection in this study. For a future prospective trial, we could utilize a single

form of regional anaesthesia and prescribe all patients a patient-controlled analgesia (PCA) device for 24 hours to allow a more objective comparison between the two cohorts and, by extension, surgeons using Newman's recommendations. However, given the prevalence of chronic pain in cohorts requiring complex hindfoot surgery, any assessment of post-operative analgesia requirement particularly using opiate analgesia could be misleading.^{19,20} In addition, assessing post-operative pain in follow up clinic is also challenging as grading severity of neuropathic pain is subjective.²¹

Regional anaesthesia use in lower limb surgery has also been controversial in recent years.¹⁴ A recent critical review suggests that regional anaesthesia alone does not delay a diagnosis of compartment syndrome, a rare complication not demonstrated in this small sample size¹⁴. Due to the heterogeneity of regional technique used, statically meaningful data on block superiority is unlikely to be produced from this data set. There was an interesting trend showing that patients receiving a spinal anaesthetic had superior wound healing times. Perhaps spinal anaesthesia achieves superior pain control in the immediate post-operative period and obtunds the stress response resulting in improved wound healing. This finding mirrors work in the British Journal of Anaesthesia recommending spinal anaesthesia in hip and knee arthroplasty.²² A prospective trial comparing spinal anaesthesia and regional neuromuscular blockade would be of value in demonstrating their safety profile and effect on surgical outcomes.

All patients had the same tourniquet inflation pressure; our principal variable was time under pressure. Although a universal tourniquet time allows us to directly compare our patients between the two cohorts there is suggestion that individualized tourniquet pressures may lead to

better outcomes.⁹ Past recommendations suggested a single tourniquet pressure (eg, 300 mmHg) or by adding a set number to systolic BP to be a safe method of deciding on pressures.^{10,11} However, recent evidence shows this is often excessive and is associated with a higher increase in nerve injuries.^{3,12} A recent trial using Doppler Ultrasound to find the optimum tourniquet pressure in knee arthroplasty reported better outcomes in comparison to control.⁹ Certainly, these new techniques may influence future practice. Optimized tourniquet inflation pressures may further reduce the risks perceived with extended tourniquet use. In addition, techniques such as ischaemic preconditioning, repeated exposure to ischaemic conditions prior to operation up regulating protective cell responses, may be of benefit.^{18,23-28} Notably this has been demonstrated and researched considerably in cardiothoracic surgery and a recent abstract suggests the potential to apply these protective benefits to skeletal muscle.^{20,26-28}

In conclusion, our study suggests that tourniquet times up to 3 hours in foot and ankle surgery with pressures up to 300 mmHg are not associated with differences in wound healing. While there are limitations of this study given its retrospective nature and the multifactorial nature of wound healing, this expands on previous work and challenges Newman's recommendations. Further work will explore the impact on analgesia, nerve injury and discharge date using a prospective controlled study design to further test our hypothesis.

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TABLES**Table 1.** Patient Demographics

	<120 minutes	>120 minutes	P value
Age (mean)	48.3	52.4	0.22
Weight (kg) mean	89.6	87.7	0.66
ASA grade mean	2.02	2.09	0.60
Smoking status: stopped before operation (%)	44%	40%	0.70
Smoking status: current smoker (%)	26%	19%	0.30
Diabetes status (%)	14%	7%	0.25
History of vascular disease	29%	38%	0.37

Table 2. Mean time for wounds to heal

	<120 minutes (n=35)	>120 minutes (n=50)	P value
Mean weeks to heal	6.66	6.44	0.78
Standard deviation	3.33	3.79	

Table 3. Discharge date from operation (n=85)

	<120 minutes	>120 minutes	P value
Discharge days from operation (mean)	3.17	3.71	0.18
Standard deviation	2.32	1.85	

Table 4. Regional anaesthesia used

Block	Number of patients			Mean time to heal (weeks)	
	Total	<120 min cohort	>120 min cohort	<120 min cohort	>120 min cohort
Local anaesthetic only	8	3	5	8.50	4.67
Popliteal block	27	27	0	7.56	n/a
Popliteal and adductor canal	10	2	8	4.33	5.86
Popliteal and saphenous	35	14	21	7.08	6.79
Spinal	7	3	4	6.00	4.00
Spinal and block	5	3	2	4.67	6.00
Sciatic	4	1	3	3.00	5.00
All popliteal regional blocks	72	43	29	6.72	6.92
All spinal (+/- regional)	12	6	6	5.20	5.00