A Prospective Evaluation for a Possible Safe Skin Bridge in Elective Foot Surgery

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, in partial fulfilment of the requirements for the degree of Master of Medicine

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Declaration

I, Graeme John Moore, declare that this research report in the format of a "submissible" paper is my own, unaided work. It is being submitted for the Degree of Master of Medicine in the branch of Orthopaedic Surgery at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.

(Signature of candidate)

……14th …..day of …October….2024……….in……Johannesburg……………………

Dedication

To my partner, Gwyn

Acknowledgements

I wish to thank Dr Paulo Ferrao, Dr Aftab Younus and Dr Brenda Milner for their inexhaustible guidance and expertise.

I would like to thank and acknowledge Dr Gwyneth Davies for providing original hand drawn sketches (Figures 2,3,4 and 5).

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Nomenclature

AO	Arbeitsgemeinschaft für Osteosynthesefragen
BMI	Body Mass Index
cm	Centimetre
g/dL	Grams per decilitre
g/L	Grams per litre
HBA1c	Haemoglobin A1C
mm	Millimetre
MP	Metatarsophalangeal
MT	Metatarsal
PVNS	Pigmented villonodular synovitis
TMT	Tarsometatarsal
WITS	University of the Witwatersrand

“Submissible” format of a paper

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ABSTRACT

Background: In foot and ankle surgery adequate surgical exposure often requires multiple incisions to be used near one another thus creating a skin bridge. As the skin bridge becomes narrower, the wound edge vitality is potentially compromised and therefore the wound's ability to heal. The impact of local, host and surgical factors on wound healing are well documented in the literature, however little is known about the role of the skin bridge. The aim of this study is to determine if there is a recommendable safe skin bridge in elective foot and ankle surgery.

Methods: A prospective study was performed on 56 patients with 60 feet who had elective foot surgery. The length of each incision and distance between the incisions were recorded. The wounds were assessed for complications at 2, 4 and 6 weeks after surgery. Patient demographics and host risk factors were documented.

Results: The average incision length was 5.5 (range: 3 to 8.5) cm. The average skin bridge was 3.9 (range: 2 to 6.8) cm. Five (8.3%) of the 60 feet developed a wound complication. Four (80%) of these patients had a known comorbidity. Two patients had diabetes and two were smokers. The incidence of relevant comorbidities was 5.5% (n = 3) for patients without a wound complication ($p<0.001$). Age did not differ significantly between patients with and without a wound complication. Patients with a wound complication had significantly longer incision lengths ($p=0.047$). There was no significant independent association between skin bridge width and risk of wound complications ($p>0.05$) with skin bridge widths of 2cm or larger.

Conclusion: No trend towards increased wound complications was identified in skin bridges 2cm or larger, when meticulous surgical technique is practiced and host risk factors optimised, in elective foot surgery.

INTRODUCTION

Attinger et al. described four principles which need to be adhered to when performing surgical incisions in and around the foot and ankle. These principles are that the incision should: (1) provide adequate exposure, (2) maintain soft tissue perfusion on either side of the wound, (3) spare sensory and motor nerves and (4) be placed parallel to tension lines.[1] Additionally surgical procedures around the foot and ankle require meticulous soft tissue handling, with avoidance of soft tissue stripping and excessive retraction, and often necessitates more than one incision for adequate exposure.[2] The distance between two incisions is termed the skin bridge. The skin bridge is of great importance as a skin bridge that is too narrow poses a threat to the perfusion of that skin area and thus may compromise the wound's ability to heal.[1,3,4] Devitalised wound edges put the surgical site at risk of a host of complications including: wound dehiscence, skin necrosis, superficial and deep sepsis.

The acceptable skin bridge width to avoid such complications in foot and ankle surgery has been a controversial topic, with current guidelines being derived from evidence reported in surgical trauma management around the ankle.[3,5] This data is largely irrelevant in elective foot and ankle surgery as traumatic injuries around the foot and ankle require specific management of the traumatised soft tissue first, by staging the management to allow the soft tissue to recover.[6] In non-traumatised elective cases, the skin and underlying tissue has not been subjected to a primary injury and therefore should be able to tolerate and heal with a relatively narrower skin bridge.[2]

There are well documented local, host and surgical factors that influence wound healing. Although many of these have been extensively researched and invaluable in understanding the capacity for surgical wounds to heal, there is no literature to date regarding the impact of the distance between two or more incisions in elective foot and ankle surgery.

The commonly used ‘safe’ skin bridge in foot and ankle surgery is 7cm or more. This was first mentioned in 1979 in the second edition of the AO trauma manual[7] and has been echoed in numerous subsequent publications since then as an arbitrary safe distance without substantial scientific backing.[6] This traditional practice has come under recent scrutiny in the literature with a prospective cohort concluding that skin bridges used in pilon fractures can be as narrow as 5cm without significant risk of wound complications.[3] Due to the paucity of relevant literature on the topic, this measurement was adopted in elective foot and ankle surgery.

The aim of this study is to determine if a safe skin bridge in elective foot surgery can be determined.

MATERIALS AND METHODS

A prospective record review study of patients who underwent elective foot surgery at a single institution from August 2016 to October 2017 was performed. Approval was obtained from the local ethics committee.

All the patients older than 18 years of age who had elective foot surgery requiring more than one incision were included. Patients who had previous surgery or trauma to the foot were excluded. Demographic data included age, gender, medical co-morbidities, and smoking history (Table 1). Procedure related data included procedure performed, number of incisions, skin bridge width, incision length and tourniquet time. The study included 56 patients, 40 female and 16 male, with a total of 60 feet. The mean age of the patients was 52 (range: 26-78) years.

All surgeries were performed by two senior foot and ankle surgeons. Skin preparation and draping techniques and wound closure in layers were generally uniform for all the cases. All forefoot procedures were dressed using a wool and crepe bandage while mid- and hind-foot procedures were immobilised in a below knee plaster backslab. Patients were instructed to elevate the foot above heart level for the first two weeks to minimize swelling. Patients who had forefoot surgery were allowed to weightbear as tolerated in a forefoot offloading wedge shoe at day one after surgery. Patients who had midfoot and hindfoot surgery were non weightbearing for a period according to the specific procedure they had.

Incisions used for common procedures:

Below we describe the incisions made for common procedures in the foot. Depending on the presenting pathology various combinations of these incisions are used. Table 2 presents the procedures performed with associated incision parameters.

1. Forefoot

a) Hallux MP (metatarsophalangeal) fusion: Dorsomedial incision over MP joint. This incision is commonly made just dorsal to the junction between dorsalis pedis and medial plantar angiosomes.

b) Hallux valgus correction:

i: Long Chevron and Scarf osteotomy: First MT (metatarsal) medial border incision (commonly placed at the junction between dorsalis pedis and medial plantar angiosomes) and a first web incision (within the dorsalis pedis angiosome).

ii: Lapidus: First MT medial border incision (commonly made at the junction between dorsalis pedis and medial plantar angiosomes), a first web incision (within the dorsalis pedis angiosome) and a dorsal incision across the first TMT (tarsometatarsal) joint (placed within the dorsalis pedis angiosome).

c) Lesser toes and neuromas: Second and third toes approached through a second web incision. Fourth and fifth toes approached through a fourth web incision. All these incisions are made within the dorsalis pedis angiosome.

2. Midfoot

a) First TMT fusion: Dorsomedial incision across the first TMT joint. This incision is made just dorsal to the junction between the dorsalis pedis and medial plantar angiosomes.

b) Second and third TMT fusion: Dorsal incision between second and third TMT joints. The incision is made within the dorsalis pedis angiosome.

c) Fourth and fifth TMT excision arthroplasty: Dorsolateral incision between fourth and fifth TMT joints. The incision is made within the dorsalis pedis angiosome.

d) Navicular-cuneiform fusion: Medial incision across medial navicular cuneiform joint (at the junction between dorsalis pedis and medial plantar angiosomes) and a dorsal incision across the middle navicular cuneiform joint (made within the dorsalis pedis angiosome).

3. Hindfoot

a) Triple fusion: Dorsal incision across the talonavicular joint in line with the lateral border of the second MT (made within the dorsalis pedis angiosome) and lateral sinus tarsi incision across the subtalar and calcaneocuboid joints (made at the junction between lateral calcaneal and anterior communicant angiosomes extending distally to the junction between the lateral planar and dorsalis pedis angiosomes).

b) Calcaneal osteotomy and lateral column lengthening osteotomy: Oblique incision directly posterior to the peroneal tendons (made at the junction between lateral calcaneal and anterior communicant angiosomes) and longitudinal incision centered over the angle of Gissane (at the junction between the lateral calcaneal angiosome and both medial calcaneal and lateral plantar angiosomes).

Patients were followed up at week 2, 4 and 6 after surgery to assess for wound complications. Wound exposure was performed at each visit and the wound assessed for any signs of complications which were then classified according to the Gililland et al.[8] classification. Grade 1: Suture line erythema or exposed suture material, grade 2: Delayed wound healing due to a seroma, haematoma, skin necrosis or exposed suture, grade 3: Wounds requiring more than 12 weeks of wound care, vacuum dressings or return to theatre.

Table 1: Patient demographics and co-morbidities

Male	16
Female	40
Bilateral	4
Smoking	2
Diabetes	2
Rheumatoid arthritis	3

STATISTICAL ANALYSIS

Power analysis was assessed using sample size estimation for descriptive studies from a 95% confidence interval formula. A proportion of 15% was estimated from a review of cases over the proposed time period with a precision of 5%. Thus, the sample size was calculated to be 49. Descriptive data are reported as medians and interquartile ranges for continuous data (due to the small sample size, non-parametric tests were performed) and proportions for categorical data. Mann-Whitney U tests compared incision length, bridge distance and between patients with and without a wound complication. Chi square tests assessed the association between wound complication and sex and comorbidities. A logistic regression model was fitted to determine the association between skin bridge width and risk of wound complications, incision length and wound complications, and type of procedure and wound complications.

RESULTS

The average incision length was 5.5cm (SD = 1.4), ranging from 3cm to 8.5cm. The average skin bridge was 3.9cm (SD = 1), ranging from 2 to 6.8cm (Table 2).

Five (8.3%) of the 60 feet developed a wound complication. Two patients had forefoot surgery and three patients had midfoot surgery. Three developed a grade 1 complication at week two (2 had mild erythema and 1 had small blisters), one developed a grade 2 wound at week two (superficial infection managed with local dressings), and one developed a grade 2 complication at week four (superficial infection requiring oral antibiotics). Four (80%) of these patients had a known comorbidity. Two patients had diabetes and two were smokers. The incidence of relevant comorbidities was only 5.5% (n = 3) for patients without a wound complication ($\chi^2 = 24.72$, $p < 0.001$; Figure 1). Age did not differ significantly between patients with and without a wound complication (Table 3). There was no association between wound complication and gender ($\chi^2 = 1.98$, $p = 0.159$). The mean surgical time for all patients was

113 minutes (SD = 20.39). The mean surgical time for patients who developed a wound complication was 115 minutes (SD = 7.07) versus 113 minutes (SD = 20.90) for patients who did not develop a wound complication. There was no statistically significant difference in mean surgical times between the two groups (p=0.900).

Table 2: Procedures performed with number of incisions, skin bridge width, incision length and tourniquet time per procedure

Region of foot	Procedure performed	Number of feet (N:60)	Number of incisions for procedure: Mean (range)	Skin bridge width: Mean (range)	Length of incision: Mean (range)	Tourniquet time
Forefoot	Hallux MP fusion and lesser toe correction(s)	14	2.7 (2-3)	3.8cm (2-6cm)	4.6cm (3-8cm)	93 minutes (67-120 minutes)
	Hallux MP fusion and neuroma excision(s)	2	2 (2)	4.5cm (4-5cm)	4.6cm (3-6cm)	85 minutes (80-90 minutes)
	Hallux MP fusion, lesser toe correction and neuroma excision	1	3	4.5cm & 6cm	5.3cm (5-6cm)	120 minutes
	Hallux valgus correction and lesser toe correction(s)	6	2.2 (2-3)	4.1cm (3-5cm)	6.1cm (3-9cm)	80 minutes (60-95 minutes)
	Hallux valgus correction and neuroma excision(s)	1	2	5cm	5 & 5.5cm	60 minutes
	Lesser toe deformity correction(s)	4	2.7 (2-4)	3.2cm (2-4cm)	4cm (3-5cm)	72 minutes (60-85 minutes)

	Lesser toe deformity correction(s) and neuroma excision(s)	3	2 (2)	2.2cm (2-2.5cm)	3.9cm (3-5cm)	55 minutes (47-60 minutes)
	Lesser toe correction(s) and bunionette correction	2	4 (4)	2.7cm (2-4cm)	4.1cm (3-5cm)	72 minutes (70-75 minutes)
	Hallux varus correction	3	2 (2)	4.5cm (4-5.5cm)	7.6cm (7-9cm)	65 minutes (6-70 minutes)
	Rheumatoid forefoot reconstruction (hallux MP fusion, MT head resections and lesser toe deformity correction)	3	3 (3)	3.4cm (2-4.5cm)	4.8cm (3-8cm)	117 minutes (110-120 minutes)
Midfoot	Hallux valgus correction with TMT fusion	1	3	3cm & 3cm	4.7cm (3-6cm)	118 minutes
	Hallux valgus correction with TMT fusion and lesser toe correction(s)	4	3 (2-4)	3.3cm (2-4.5cm)	5.1cm (3.5-8cm)	100 minutes (78-120 minutes)
	Multiple TMT fusions	4	2.25 (2-3)	3.9cm (3-5cm)	6.8cm (5-8cm)	110 minutes (90-120 minutes)
	Navicular-cuneiform and TMT fusion(s)	3	2 (2)	4cm (4cm)	7.9cm (6-12cm)	100 minutes (90-120 minutes)
	Navicular-cuneiform and calcaneo-cuboid fusion	1	2	4cm	6 & 7cm	115 minutes
Hindfoot	Triple fusion	3	2 (2)	4.5cm (4-5.5cm)	7.6cm (7-9cm)	120 minutes (120 minutes)

	Triple fusion with 1st and 2nd TMT fusion	1	3	6cm & 6cm	7cm (5-10cm)	135 minutes
	Triple fusion and tibialis anterior transfer	1	3	4.5cm & 5cm	6.8cm (4.5-9cm)	135 minutes
	Cavovarus foot deformity correction with bone and soft tissue procedures	2	3 (3)	4.6cm (3-6cm)	5.2cm (3-8cm)	130 minutes (120-140 minutes)
	PVNS* tumour excision form ankle and subtalar joint	1	2	5cm	5 & 8cm	90 minutes

*PVNS: *Pigmented villonodular synovitis*

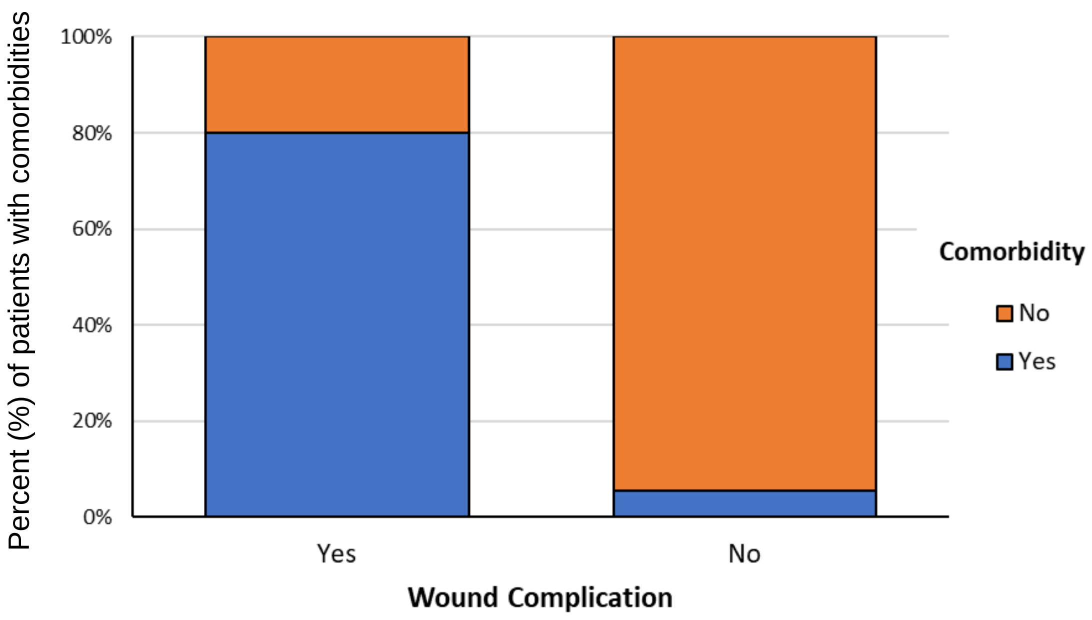

Figure 1: Association between wound complications and comorbidities

Table 3: Comparison between variables and impact on wound complication

	Wound Complication		**Test Statistics**	
	Yes (n = 5)	**No (n = 55)**	***z***	***p***
Incision length	7.25 (5.13 – 8)	5.17 (4.5 – 6.5)	1.77	0.077
Bridge size	4.2 (3.5 – 4.63)	4 (3 – 4.75)	0.63	0.550
Age	63 (63 – 66)	62 (56 – 68)	0.71	0.498

Table 4 shows the results of the univariable and multivariable logistic regression showing the association between, skin bridge, incision length and risk of wound complications. The models show that there was no significant independent association between skin bridge width and risk of wound complications (p>0.05). However, there was a significant adjusted association between incision length and risk of wound complications (p=0.047) – patients with a wound complication had a longer wound incision. No trend towards increased wound complications was identified in skin bridges 2cm or larger in size.

Table 4: Association between bridge size, incision length and risk of complication.

	Unadjusted		**Adjusted**	
	OR (95%CI)	p-value	OR (95%CI)	p-value
Bridge size	1.22 (0.5-2.94)	0.664	0.58 (0.14-2.40)	0.452
Incision length	2.11 (0.99-4.51)	0.055	2.57 (1.01-6.55)	**0.047**

DISCUSSION

The 'safe' skin bridge to avoid wound complications in elective foot and ankle surgery has been a controversial topic, with current guidelines being derived from evidence found in surgical trauma management around the ankle.[3,7,9] While the relevance of this data in elective foot and ankle surgery is marginal, the understanding of safe skin bridges in a trauma setting does elicit some relevant considerations for this study. What has become evident in the literature is that a sufficiently wide skin bridge is important to prevent wound complications, along with numerous other factors (local, host and surgical) that contribute to a wound's ability to heal.[1,10] (Table 5)

Identifying these potential risk factors begins with risk stratifying a patient preoperatively by identifying systemic host factors that may compromise the wound's ability to heal. Non-modifiable systemic conditions such as age, renal disease, liver disease, micro-vasculopathy and peripheral neuropathy, have been established as risk factors.[10] More importantly, modifiable conditions such as diabetes mellitus, smoking, malnutrition, obesity and concurrent steroid use need to be corrected or optimised prior to surgery.

Table 5: Factors affecting wound healing in foot and ankle surgery

Local Factors	**Modifiable Host factors**	**Non-modifiable host factors**	**Surgical factors**
Infection	Smoking history	Peripheral vascular disease	Duration of procedure
Venous insufficiency	Obesity	Liver disease	Duration of tourniquet inflation
Foreign body	Nutrition	Peripheral neuropathy	Prophylactic antibiotics
	Diabetes	Renal disease	Skin preparation solution
	Steroid use	Age	
	Alcoholism		

A relative risk increase of 1.59 fold for postoperative infection has been described for every 1% increase in HBA1c above 7.0% in foot and ankle surgery.[11] An elevated BMI greater than 30kg/m^2 has also been shown to be a significant risk factor for wound complications and postoperative infections.[12] The proposed mechanisms for this being diminished tissue perfusion and oxygen delivery, and impaired immune function.[12] Impaired wound healing due to malnutrition is also well described and is qualified and quantified with laboratory tests including a serum albumin of <3.5g/dL (35g/L), transferrin of <200mg/dL and a total lymphocyte count of <1500mm^3.[13] Tobacco smoking has been associated with massively increased rates of wound complications with one retrospective cohort reporting a wound complication rate of 36.4% in smokers undergoing forefoot surgery compared to a rate of 8.5% for non-smokers.[14] While smokers and even former smokers show significantly higher rates of wound complications when compared to people who have never smoked, cessation of smoking six weeks prior to surgery and for at least three months after surgery diminishes a patient's risk for postoperative wound complications.[14] These modifiable and non-modifiable host risk factors were evident in the current study as 4 of the 5 patients who had wound complications had comorbidities (2 smokers and 2 diabetics).

Intraoperative factors that have been shown to have an impact on wound healing include duration of the procedure, tourniquet inflation time, prophylactic antibiotic use, skin preparation solution and soft tissue handling.[15,16,17] Rates of wound complications increase with surgical duration and tourniquet time over 90 minutes.[15] The current study found no correlation between surgical duration and risk of wound complications. With regards to skin preparation, a meta-analysis concluded that alcohol-based chlorhexidine was significantly superior to alcohol-based povidone-iodine solution in decreasing hallux nail fold and toe web space bacterial load.[16] Interestingly, the method of wound closure with either staples, interrupted nonabsorbable or subcutaneous absorbable sutures in orthopaedic surgery showed no significant difference in rates of wound dehiscence, inflammation, discharge, necrosis, allergic reaction or superficial infection.[18,19,20] However, a prospective case series looked at 11 feet that had surgical incisions closed using the self-locking barbed V-Loc 180® (Covidien, Mansfield, MA) and reported a wound complication in all but 1 patient. The authors concluded that closure with barbed sutures was not recommendable in foot surgery. A similar prospective study reported on 123 surgical incisions in foot surgery closed using Quill® (Angiotech, Vancouver, BC) self-locking barbed sutures and found a wound complication rate of only 6.5%. The authors concluded that the Quill® barbed sutures are a safe and effective option for wound closure in foot surgery.[21]

With regards to the actual placement of incisions, angiosomes of the foot and ankle are frequently taken into consideration for planning purposes. An angiosome is a block of tissue (skin, subcutaneous tissue, fascia, muscle and bone) that is fed by the same source artery. There are six distinct angiosomes in the foot and ankle arising from the three main arteries (Figures 2 and 3).[1]

Figure 2: Angiosomes of the foot and ankle

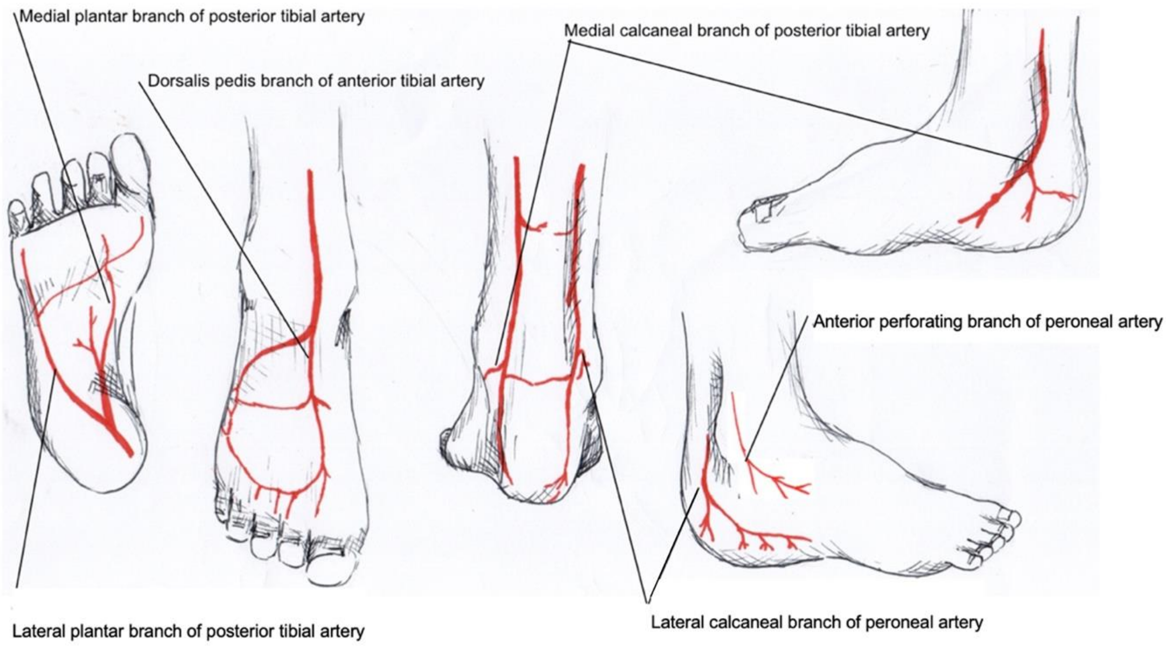

Figure 3: Arterial supply of the foot and ankle

Based on this model, the safest incisions in patients with a normal blood supply are those made between the watershed areas of two adjacent angiosomes. This leaves the tissues on either side of the incision with intact blood supplies. Incisions outside of these junctions create devascularised islands with compromised blood supply, which may result in compromised wound healing. Therefore, incisions along the central raphe of the Achilles tendon, glabrous junction on the lateral aspect of the foot and along the midline of the sole of the foot are ideal incisions when utilising this principle.[1,4] An example of this is the L-shaped extensile approach to the lateral calcaneus that is utilised to address calcaneal fractures (Figure 4).[22] The incision is made along the glabrous junction which divides the lateral calcaneal angiosome supplied by the lateral calcaneal branch of the peroneal artery and the medial calcaneal angiosome supplied by the medial calcaneal branch of the posterior tibial artery. [1,4]

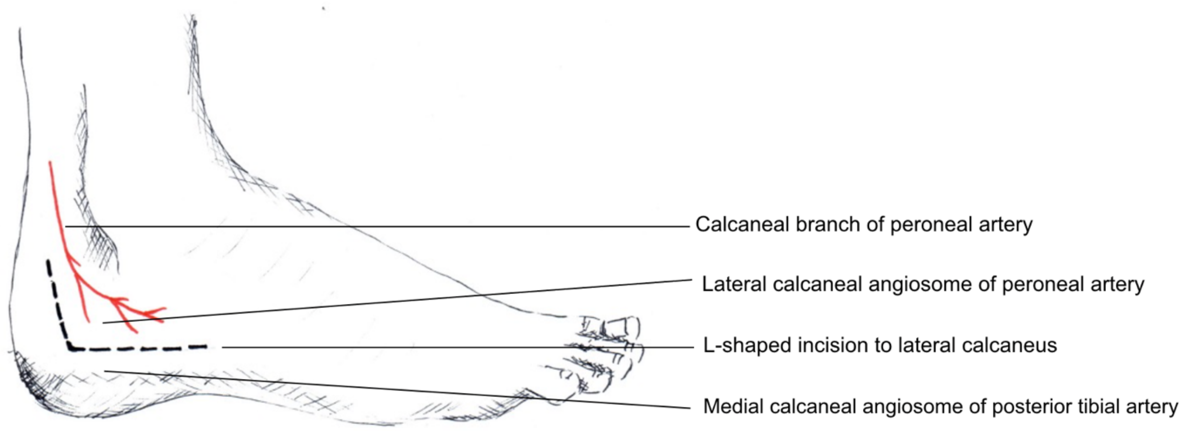

Figure 4: L-shaped lateral calcaneus incision

An exception to this rule was proposed by Attinger et al. in the forefoot where there are numerous and extensive anastomosis between the dorsal and plantar arteries. This arterial network, they suggested, should provide adequate perfusion to surgical wounds in the forefoot with relatively narrow skin bridges even if made outside of the angiosome junctions. This study was based on cadaveric dissections and anatomical mapping using a doppler.[1,4] Findings in the current study support this hypothesis as the incisions at the forefoot were frequently made outside of the angiosome junctions with skin bridges as narrow as 2cm with no association increased risk of wound complications.

Angiosome based incisions are not always possible as they may not allow for adequate exposure to perform certain procedures. Hammit et al. reported on a prospective case series of 17 patients who underwent a Dwyer calcaneal osteotomy and peroneal tendon repair and/or lateral ankle ligament reconstruction using dual incisions instead of the traditional single incision. The average skin bridge was 2.3cm with one of the 17 patients developing wound dehiscence that resolved after 10 days with oral antibiotics. These authors proposed that vascular anatomy should be taken into consideration when planning skin incisions but not dictate skin incision placement.[2] Our results echoed these findings suggesting that skin incisions with relatively narrow skin bridges that are placed away from angiosome junctions still maintain the ability to maintain vascularity and vitality allowing adequate wound healing.

The probable reason for incisions made outside of the junction between two angiosomes being able to remain vascularised and heal is due to choke vessels becoming patent. Choke vessels are arterial-arterial connections at watershed areas that offer a neighbouring angiosome a safety conduit should its primary source artery become compromised. Choke vessels take between 3 and 10 days to become patent once adjacent blood flow ceases, during which time the incision is at the highest risk of ischaemic related wound complications. Should one source artery's flow be compromised (and therefore the perfusion to its angiosome) and the adjacent angiosome is well perfused, then it is advisable to place the incision away from the angiosome with a patent source artery. This is done to avoid damage to the crucial choke vessels that will subsequently be depended on for perfusion to the compromised angiosome (Figure 5). [1,4,23]

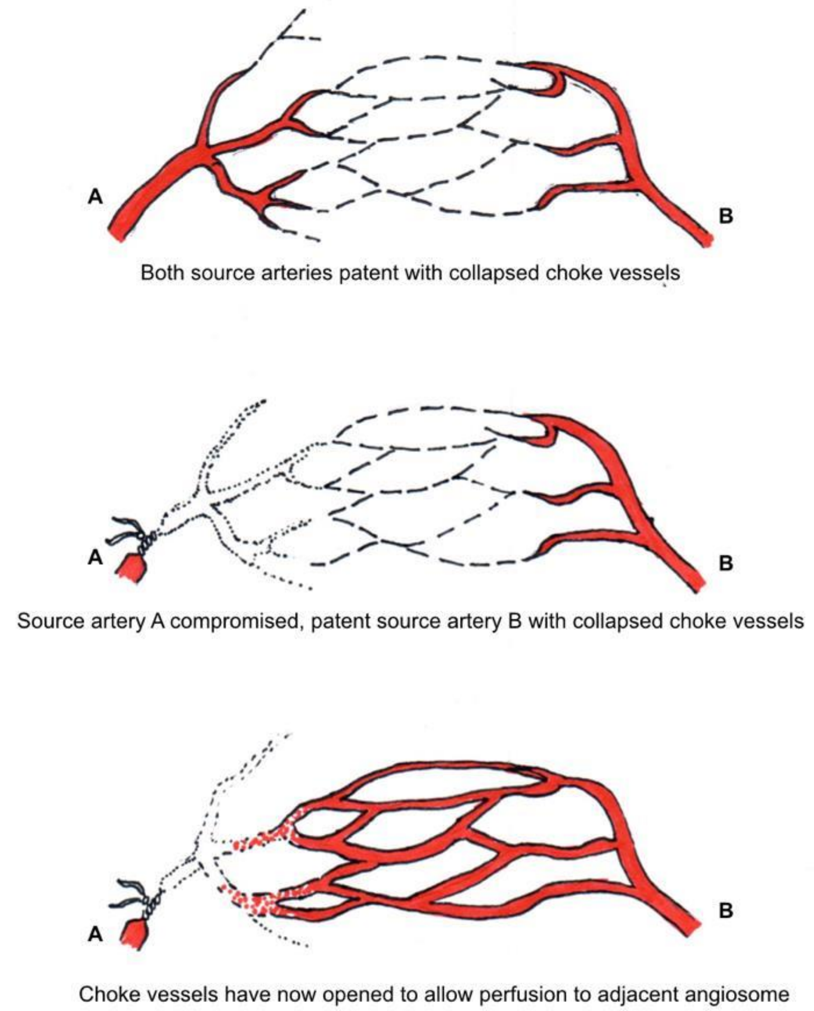

Figure 5: Choke vessels

The choke vessel mechanism along with the abundant anastomotic blood supply of the foot may explain why this study found no increased rate of wound complications with skin bridges as narrow as 2cm. We did however identify a trend in increased wound length increasing the risk of developing a wound complication irrespective of the skin bridge size. This finding may be due to the fact that longer incisions are required for more extensive pathology which in turn requires more soft tissue stripping.

The limitation of this study is the relatively small cohort size. A larger cohort may elicit a stronger correlation between skin incision length, skin bridge and wound complications.

CONCLUSION

Consideration of the vascular anatomy of the foot and ankle is vital in surgical planning, but the foot does seem to be able to compensate for and tolerate skin incisions placed in close proximity to each other. The current study found no trend towards increased wound complications with skin bridges 2cm or larger. When meticulous surgical technique is practiced and host risk factors optimised a skin bridge width of 2cm is safe in elective foot surgery.

ETHICS STATEMENT

All procedures done were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008. Ethics clearance was obtained from the Human Research Ethics Committee (Medical) of the University of the Witwatersrand: Clearance Certificate Number: M2210102. Permission has been granted by the Chief Executive Officer (CEO) of Linksfield Netcare Hospital. The author/s declare that this submission is in accordance with the principles laid down by the Responsible Research Publication Position Statements as developed at the 2nd World Conference on Research Integrity in Singapore 2010.

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APPENDICES

Appendix A: Research Protocol

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Appendix D: Wits Ethics Clearance certificate

Appendix E: Hospital CEO clearance

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Appendix A: Research Protocol

An Evaluation of a Safe Skin Bridge Distance in Foot Surgery

UNIVERSITY OF THE
WITWATERSRAND,
JOHANNESBURG

Dr Graeme John Moore

(BSc (U.C Berkeley), MBBCh (Wits))

Supervisors:

Dr Paulo Ferrao (MBChB (UP), FC Ortho(SA))

Professor Aftab Younus (MBBCh (WITS), FC Ortho(SA))

Dr Brenda Milner (PhD (WITS))

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Acknowledgements

I would like to thank and acknowledge Dr Gwyneth Davies for providing original hand drawn sketches (Figures 1.1, 1.2, 1.3 and 1.4).

Nomenclature

AO	Arbeitsgemeinschaft für Osteosynthesefragen
BMI	Body Mass Index
CM	Centimetre
g/dL	Grams per decilitre
g/L	Grams per litre
HBA1c	Haemoglobin A1C
Mm	Millimetre
WITS	University of the Witwatersrand

1. INTRODUCTION AND LITERATURE REVIEW

There are four principles, which should be adhered to when making surgical incisions in and around the foot and ankle, as described by Attinger et al. These principles are that the incision should: (1) provide adequate exposure, (2) maintain soft tissue perfusion on either side of the incision to allow optimal wound healing, (3) spare sensory and motor nerves and (4) be placed parallel to tension lines [1]. Surgical procedures in foot and ankle require meticulous soft tissue handling, by avoidance of soft tissue stripping and excessive retraction, and often necessitates more than one incision for adequate exposure [2]. The distance between two incisions is termed the 'skin bridge'. As with any other surgical procedure involving more than one surgical incision, the skin bridge is of great importance as a skin bridge that is too narrow poses a threat to the perfusion of that skin area and thus may compromise the wound's ability to heal [1,3,4]. Devitalised wound edges put the surgical site at risk of a host of complications including: wound dehiscence, skin necrosis, superficial sepsis and deep sepsis.

The acceptable skin bridge distance to avoid such complications in foot and ankle surgery has been a controversial topic, with current guidelines being derived from evidence found mostly in surgical trauma management around the ankle [3]. This data is largely irrelevant in elective foot and ankle surgery as surgery on traumatised soft tissues around the foot and ankle requires specific management of the traumatised soft tissue first, by staging the management to allow the soft tissue to recover [5]. In non-traumatised elective cases, the skin and underlying tissue has not been subjected to a primary injury and therefore should be able to tolerate and heal with relatively narrower skin bridges as compared to cases with traumatised tissue [2].

The commonly used 'safe' skin bridge in foot and ankle surgery is 7cm or more [3]. This was first mentioned in 1979 in the second edition of the AO trauma manual [6] and has been echoed in numerous subsequent publications since then as an arbitrary safe distance without substantial scientific backing [5,7]. This traditional practice has come under recent scrutiny in the literature with a prospective cohort concluding that skin bridges used in pilon fractures can be as narrow as 5cm without significant risk of wound complications [3]. Due to the paucity of relevant literature on the topic, this measurement was adopted in elective foot and ankle surgery. While the relevance of this specific skin bridge size in elective foot and ankle surgery is marginal, a further understanding of safe skin bridges in a trauma setting does illicit some relevant considerations for this study [3,5,6,7]. What has become evident in the literature is that a sufficiently wide skin bridge is important to prevent wound complications, along with numerous other factors (both local, host and surgical) that contribute to a wound's ability to heal [1,6,7].

Identifying these factors begins with risk stratifying a patient preoperatively by identifying systemic host factors that may compromise the wound's ability to heal. Non-modifiable systemic conditions such as age, renal disease, liver disease, microvasculopathy and peripheral neuropathy, have been established as risk factors [6]. More importantly modifiable conditions such as diabetes mellitus, smoking, malnutrition, obesity and concurrent steroid use need to be documented and corrected prior to surgery.

Table 1.1: Factors affecting wound healing in foot and ankle surgery

Local Factors	**Modifiable Host factors**	**Non-modifiable host factors**	**Surgical factors**
Oxygenation	Diabetes	Renal disease	Duration of procedure
Infection	Obesity	Liver disease	Duration of tourniquet inflation
Foreign body	Nutrition	Peripheral neuropathy	Prophylactic antibiotics

Venous insufficiency	Peripheral vascular disease	Age	Skin preparation solution
	Steroid use		
	Alcoholism		
	Smoking history		

A relative risk increase of 1.59 fold for postoperative infection has been described for every 1% increase in HBA1c above 7.0% in foot and ankle surgery [8]. An elevated BMI greater than 30kg/m^2 has also been shown to be a significant risk factor for wound complications and postoperative infections in foot and ankle surgery [9]. The proposed mechanisms being diminished tissue perfusion and oxygen delivery, and impaired immune function [9]. Impaired wound healing due to malnutrition is also well established and can be qualified and quantified with laboratory tests including a serum albumin of <3.5g/dL (35g/L), transferrin of <200mg/dL and a total lymphocyte count of <1500mm^3 [10]. Tobacco smoking has been associated with massively increased rates of wound complications with one retrospective cohort reporting a wound complication rate of 36.4% in smokers undergoing forefoot surgery compared to a rate of 8.5% in patients who never smoked [11]. While smokers and even former smokers show significantly higher rates of wound complications when compared to people who have never smoked, cessation of smoking six weeks prior to surgery and for at least three months after surgery does appear to diminish a patient's risk for postoperative wound complications [11,12].

Intraoperative surgical factors that have been shown to correlate with wound healing are the duration of the procedure, tourniquet inflation time, prophylactic antibiotic use, skin preparation solution and soft tissue handling. Rates of wound complications increase with surgical duration and tourniquet time over 90 minutes [13]. The guidelines for the use of prophylactic antibiotics in foot and ankle surgery are based on literature emanating from other orthopaedic specialties such as arthroplasty and hand surgery. However, the importance of perioperative antibiotic administration and the timing of the dose (being given within sixty minutes of tourniquet inflation) is considered the standard of care [14]. With regards to skin preparation, a meta-analysis concluded that alcohol-based chlorhexidine was significantly superior to alcohol-based povidone-iodine solution in decreasing hallux nail fold and toe web space bacterial load [15]. Interestingly, the method of wound closure with either staples or sutures in orthopaedic surgery showed no significant difference in rates of wound dehiscence, inflammation, discharge, necrosis, allergic reaction or superficial sepsis [16,17,18]. With regards to wound closure using barbed sutures, a prospective case series looked at 123 surgical incisions in foot surgery closed using Quill® (Angiotech, Vancouver, BC) self-locking absorbable sutures and found a wound complication rate of 6.5% with only one of the patients developing a deep wound infection requiring a return to theatre for surgical debridement. The authors concluded that barbed sutures are a safe and effective option for wound closure in foot surgery [19].

With regards to the actual placement of incisions, angiosomes of the foot and ankle are frequently taken into consideration when making surgical incisions. An angiosome is a block of tissue (skin, subcutaneous tissue, fascia, muscle and bone) that is fed by the same source artery. There are six distinct angiosomes in the foot and ankle arising from three main arteries (Figures 1.1 and 1.2). The posterior tibial artery gives rise to the medial calcaneal, medial plantar and lateral plantar angiosomes. The peroneal artery gives rise to the anterior communicant angiosome and the lateral calcaneal angiosome. The anterior tibial artery gives rise to the dorsalis pedis angiosome [1].

Figure 1.1: Angiosomes of the foot and ankle

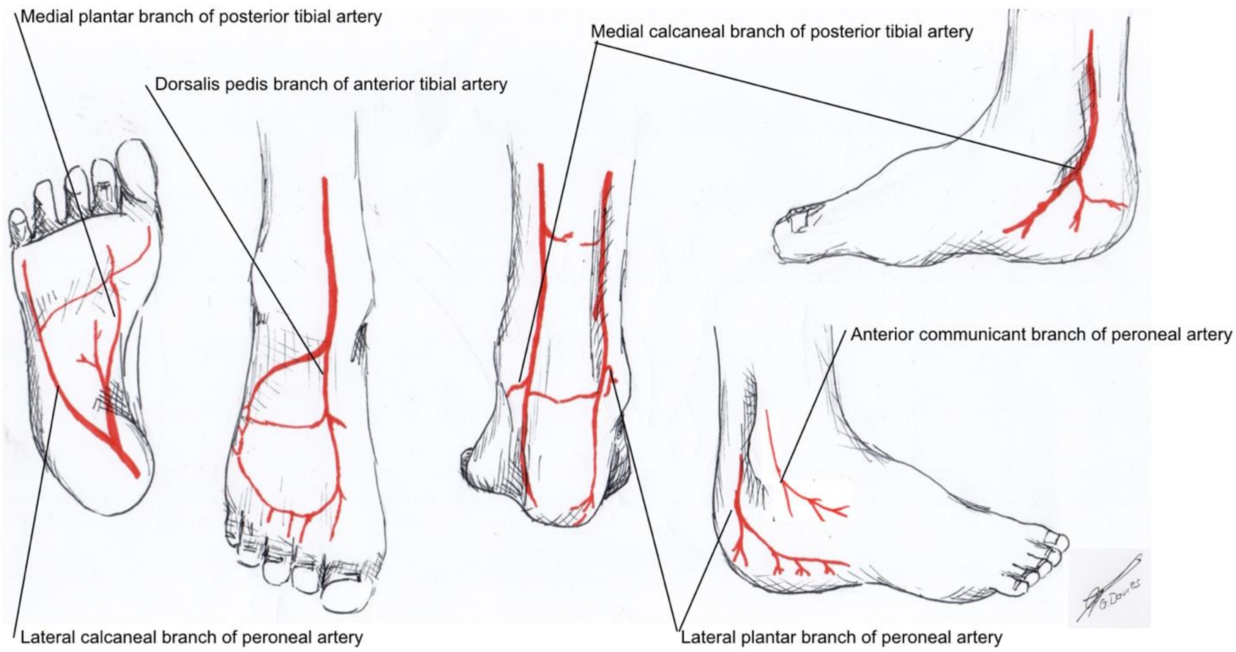

Figure 1.2: Arterial supply of the foot and ankle

As a general rule, the safest incisions in patients with a normal blood supply from each nutrient artery are those made between the watershed area of two distinct angiosomes. This leaves the tissues on either side of the incision with intact blood supplies. Incisions outside of these junctions create devascularised islands with compromised blood supply resulting in compromised healing. Therefore, incisions along the central raphe of the achilles tendon, glabrous junction on the lateral aspect of the foot and along the midline of the sole of the foot are ideal incisions when utilising this principle. An example of this is the L-shaped extensile approach to the lateral calcaneus that is utilised to address calcaneal fractures [20] (Figure1.3). The incision is made along the glabrous junction which divides the lateral calcaneal angiosome supplied by the lateral calcaneal branch of the peroneal artery and the medial calcaneal angiosome supplied by the medial calcaneal branch of the posterior tibial artery [1,4].

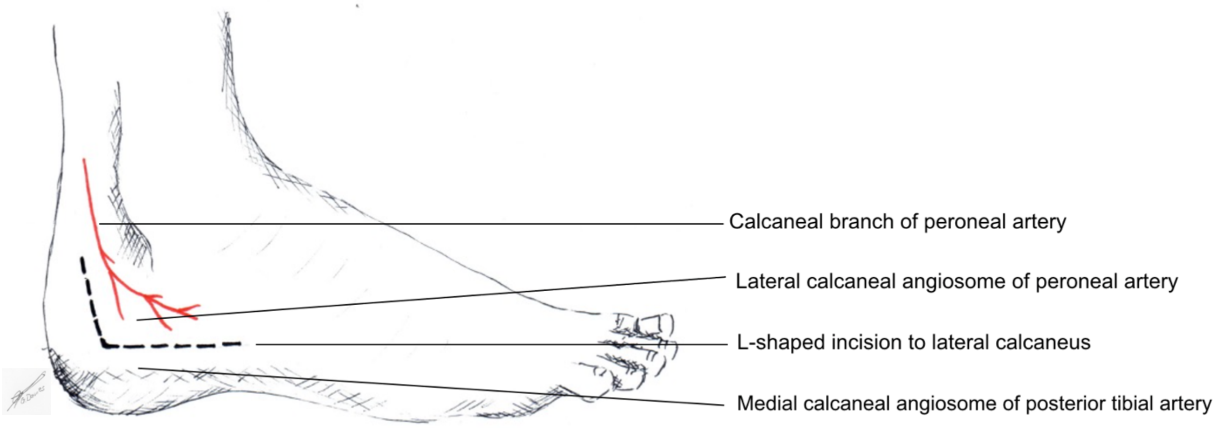

Figure 1.3: L-shaped lateral calcaneus incision

An exception to this rule was proposed by Attinger et al. in the forefoot where there are numerous and extensive anastomosis between the dorsal and plantar arteries. This arterial network, they maintain, should provide adequate perfusion to surgical wounds in the forefoot with relatively narrow skin bridges even if made outside of angiosome junctions [1,4].

However, angiosome based incisions are not always possible as they do not fulfil the four principles as described by Attinger et al. An example of a scenario resulting in inadequate exposure with one incision is the large lateral calcaneal incision made when performing a

Dwyer calcaneal osteotomy together with lateral ankle ligament repair or reconstruction. Hammit et al. performed a prospective case series with twenty patients who underwent both a Dwyer calcaneal osteotomy and peroneal tendon repair and/or lateral ankle ligament repair or reconstruction with dual incisions instead of the traditional single incision. The average skin bridge distance was 2.3cm with one of the twenty patients developing wound dehiscence that resolved after ten days with oral antibiotics. These authors proposed that vascular anatomy should be taken into consideration with skin incisions rather than standardised skin bridges [2].

When incisions are made away from junctions between two angiosomes, choke vessels become patent. Choke vessels are arterial-arterial connections at these watershed areas that offer a neighbouring angiosome a safety conduit should its primary source artery become compromised. Choke vessels take between three and ten days to become patent once adjacent blood flow ceases, during which time the incision is at the highest risk of ischaemic related wound complications. Should one source artery's flow be compromised (and therefore the perfusion to its angiosome) and the adjacent angiosome is well perfused, then it is advisable to place the incision away from the angiosome with a patent source artery. This is done to avoid damage to the crucial choke vessels that will subsequently be depended on for perfusion to the compromised angiosome [1,4,21].

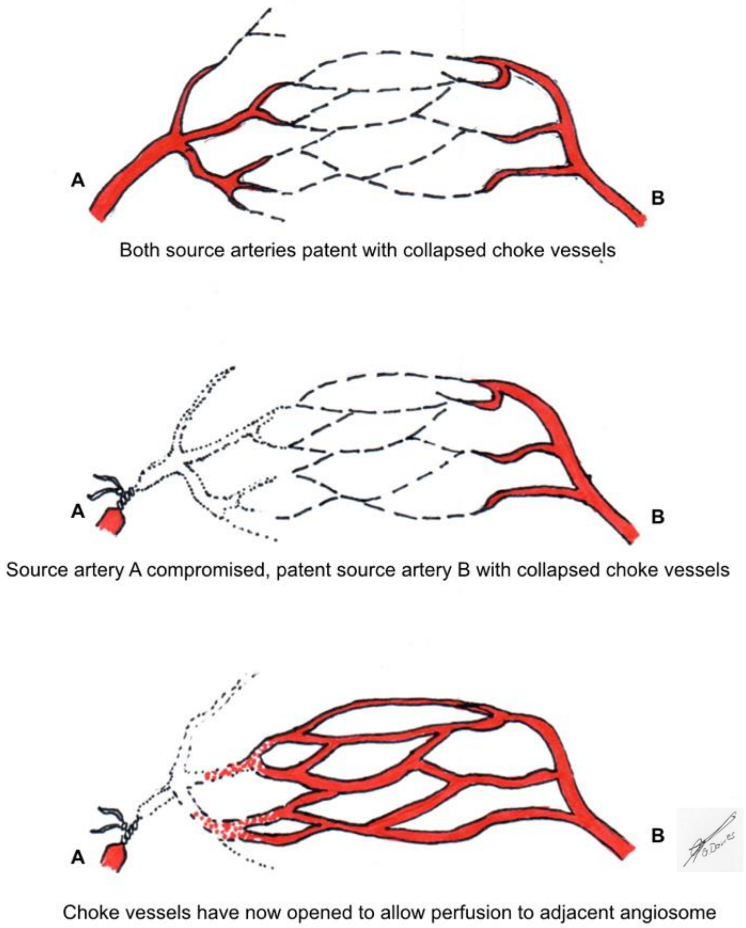

Figure 1.4: Choke vessels

As is evident in the literature, there are well documented local, host and surgical factors that influence wound healing. Although many of these have been extensively researched and invaluable in understanding the capacity of surgical wounds around the foot and ankle to heal, there is no literature to date regarding the impact of the distance between two or more incisions at different locations of the foot and ankle.

Therefore, the aim of this study is to determine if a safe skin bridge in elective foot and ankle surgery can be established, and if so, what that distance is.

2. AIM AND OBJECTIVES

2.1 Aim:

The aim of this study is to determine if there is a recommendable minimum safe skin bridge in elective foot surgery and what that distance is.

2.2 Objectives:

- To estimate a mean safe skin bridge distance in foot surgery that is associated with low rates of wound complications.

- To correlate the rate of wound complications with the length of incisions

- To assess if surgical or tourniquet time influences the rate of surgical site wound complications

3. METHODS

3.1 Research design: Prospective record review study.

3.2 Research site: The Foot and Ankle Unit at Netcare Linksfield Hospital.

3.3 Patient sample size: The calculated sample size is 49.

Sample size for descriptive studies from 95% confidence interval formula calculation

$N=1.96^2 \times [p(1-p)] / d^2$

P= Proportion (15%)

Precision of 5%

D= 0.1

Therefore: $N=1.96^2 \times [0.15(1-0.15)] / 0.1^2 = 48.98$

3.4 Selection criteria:

Inclusion criteria:

- Patients 18 years of age and older.
- Patients undergoing elective foot surgery.
- Surgical procedure with two or more incisions on the foot.

Exclusion criteria:

- Patients having undergone a previous surgical procedure of the foot.
- Patients with previous fractures of the foot or ankle managed operatively.

4. DATA COLLECTION AND ANALYSIS

The data that will be collected and analysed was recorded prospectively at the Orthopaedic Foot and Ankle Unit, Netcare Linksfield Hospital. Consent was sought and obtained.

Only data from patients who fit the inclusion criteria will be collected. All participants will be assigned a unique participant number to ensure anonymity and confidentiality.

Demographic data include age, gender, medical co-morbidities, alcohol and smoking history. Procedure related details include procedure performed, location and length of the incisions, skin bridge size, and tourniquet and surgical time. Data will be collected from patients records and follow up visits at week 1, 2, 4 and 6 after the index surgery. The collected data will be captured on a data collection sheet (Appendix A) and then summarised on a Microsoft Excel spreadsheet for comparison and statistical analysis (Appendix B).

The Excel spreadsheet with the summarised data will then be transferred to the Stata version 17.0 statistics and software package (StataCorp, College Station, Texas). The data will be analysed with assistance of a biostatistician.All data will be stored securely in a password protected computer.

Data analysis plan

Descriptive statistics will be used to firstly summarise the patient data, operative data, and grade of complication of the sample as a whole. Graphic representation will be utilised to display this data.

Inferential statistics will then be used to determine, by univariate analysis, if any of the patient variables namely (1) Age, (2) Gender, (3) Medical co-morbidities, (4) Smoking and (5) Alcohol use, are significantly associated with Grade 1, Grade 2, and Grade 3 complications in elective foot surgery at the 1, 2, 4 and 6 week post-operative study end points.

Inferential statistics will then be used to determine, by univariate analysis, if any of the surgical variables namely (1) Incision length, (2) Incision location, (3) Skin bridge distance, (4) Duration of surgery, and (5) Tourniquet time, are significantly associated with Grade 1, Grade 2, and Grade 3 complications in elective foot surgery at 2 weeks and 6 weeks post-operative study end points.

5. ETHICS

Ethics approval to conduct the study was obtained from the Human Research Ethics Committee (HREC) (Medical) of the University of the Witwatersrand (Appendix C). Permission was also obtained from the Chief Executive Officer (CEO) of Netcare Linksfield Hospital to conduct research at this facility (Appendix D).

6. TIMING

Table 6.1: Gantt Chart

Stage	April-May 2022	June-July 2022	August-September 2022	October-November 2022	December-January 2023	February-March 2023	April-May 2023
Literature search							
Preparing protocol							
Protocol assessment							
Ethics application							
Collecting data							
Data Analysis							
Writing up research report							
Publishing paper							

7. FUNDING

All costs will be incurred by the principal researcher and will include the following:

Item	Cost (ZA Rand)
Transport	R 4000
Phone calls	R 2000
Total	**R 6000**

8. ANTICIPATED PROBLEMS

Prospective data collected is reliant on surgeons’ measurements accuracy and detailed documentation in the medical notes.

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18. Daiwei Yao 1 , Julian Nachtsheim 2 , Sarah Ettinger 2 , Anna Altemeier 2 , Leif Claassen 2 , Christian Plaass 2 , Michael Schwarze 3 , Kiriakos Daniilidis 4 , Bernd Brüggenjürgen 2 , Christina Stukenborg-Colsman 2 ML 2. Foot and Ankle Surgical Incision Closure With Three Different Materials. J Foot Ankle Surg. 2022;61(4):760-765.

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Appendix B: Data Collection Sheet 1

Data Collection Sheet

Age :
Gender :

Date of surgery : Follow up date :
Follow up period : 1 week 2weeks 4weeks 6weeks
Surgery Description :

Incision length :
Incision location : Anterior midline ankle
Lateral ankle/hindfoot
Medial ankle/hindfoot
Posterior ankle
Dorsal foot
Lateral border foot
Medial border foot
Other (describe)

Skin bridge distance:
Surgical time:
Tourniquet time:
Co-morbidities :
(exclusion of diabetes, Rheumatoid arthritis)
Smoking : yes no
Alcohol:
Medications :

Comments :

Wound complications:

Grading : (if there are wound complications)
Grade 1 temporary suture line erythema, or exposed suture needing removal
Grade 2 <12 weeks of delayed wound healing due to seroma, haematoma, skin necrosis or exposed suture. Closure outside theatre
Grade 3 wound care over 3 months, required VAC or return to theatre, or affected quality of life.

Appendix C: Data Collection sheet 2

Study Number	Age	Gender	Date of surgery	Procedure done	Incision location	Incision lengths	Skin bridge distance	Wound complications details

Appendix D: Wits Ethics Clearance certificate

UNIVERSITY OF THE
WITWATERSRAND,
JOHANNESBURG

R49 Dr GJ Moore

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M2210102

NAME: (Principal Investigator)	Dr GJ Moore
DEPARTMENT:	School of Clinical Medicine Department of Orthopaedic Surgery Medical School University
PROJECT TITLE:	*An evaluation of a safe skin bridge distance in foot surgery*
DATE CONSIDERED:	Ad hoc
DECISION:	Approved unconditionally
CONDITIONS:	Formerly M18/02/18
NOTE:	If contact information regarding student study participants is required, please contact the Registrar's office - <Nicoleen.Potgieter@wits.ac.za>
SUPERVISOR:	Drs P Ferrao, B Milner and A Younis
APPROVED BY:	Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	2022/11/16

This Clearance Certificate is valid for 5 years from the date of approval. An extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office secretariat on the 3rd floor, Phillip Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated from the research protocol as approved, I/we undertake to submit details to the Committee. **I agree to submit a yearly progress report**. When a funder requires annual re-certification, the application date will be one year after the date when the study was initially reviewed. In this case, the study was initially reviewed in **2022/10/01** and therefore reports and re-certification will be due in the month of **2022/10/01** each year. Unreported changes to the study may invalidate the clearance given by the HREC (Medical).

Signature of Principal Investigator	18/11/2022 Date

Appendix E: Hospital CEO clearance

Netcare Linksfield Hospital

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Fax: +27 (0) 11 640 3576
24 12th Avenue, Linksfield West, Johannesburg, South Africa
PO Box 46337, Orange Grove, 2119, South Africa
www.netcare.co.za

28 October 2022

LETTER CONFIRMING KNOWLEDGE OF NON-TRIAL RESEARCH TO BE CONDUCTED IN THIS NETCARE FACILITY

Dear Dr Moore

Re: What is a Safe Skin Bridge in Foot Surgery

We hereby confirm knowledge of the above named research application to be made to the Netcare Research Operations Committee and in principle agree to the research application for Netcare Linksfield Hospital, subject to the following:

1. That the data collection may not commence prior to receipt of FINAL APPROVAL from the Netcare Research Operations Committee.
2. A copy of the research report will be provided to the Netcare Research Operations Committee once it is finally approved by the tertiary institution, or once complete.
3. Netcare has the right to implement any recommendations from the research.
4. That the Hospital / Management reserves the right to withdraw the approval for research at any time during the process, should the research prove to be detrimental to the subjects / Netcare or should the researcher not comply with the conditions of approval.

We wish you success in your research.

Yours faithfully

28.10.2022

Lisete Vieira **Date**

Hospital General Manager

Netcare Hospitals (Pty) Ltd T/A Netcare Linksfield Hospital
Directors: J du Plessis, R H Friedland, K N Gibson, C Grindell
Company Secretary: C Vikisi
Reg. No. 1996/006591/07

Appendix F: Student's contribution to the research and writing of the paper

Division of Orthopaedic Surgery

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22 April 2024

Faculty of Health Sciences, University of the Witwatersrand

RE: GRAEME JOHN MOORE'S CONTRIBUTION TO THE RESEARCH AND WRITING OF THE "SUBMISSIBLE" PAPER

To whom it may concern,

This letter serves to confirm that the co-authors of the "submissible" research paper have agreed to its use by Graeme John Moore student number 705721, as part of his MMed research report. Graeme John Moore made a substantial contribution to conducting the research study and writing the manuscript.

Yours sincerely,

Dr Paulo Ferrao
Primary Supervisor

Dr Aftab Younus
Co-supervisor

Dr Brenda Milner
Co-supervisor

Dr Graeme John Moore
MMed Candidate