A STUDY OF SKIN PADDLE PERFORATORS OF FREE FIBULA OSTEOSEPTOCUTANEOUS FLAP IN HOSPITAL UNIVERSITI SAINS MALAYSIA

BY

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I. ACKNOWLEDGEMENT

In the name of Allah, the Beneficent, the Merciful.

First of all, I am grateful to The Almighty God for establishing me to complete this dissertation.

I would like to express my utmost gratitude appreciation to the thoughtful comments and support from my supervisor, Professor Dr Ahmad Sukari Halim for his guidance and patience throughout the completion of this dissertation.

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I also take this opportunity to thank all, who directly or indirectly, who have lent their helping hand in this venture.

Last but not least, my biggest appreciation to my parents, Omar Othman and Azizon Abdullah for their support, patience, sacrifices and encouragement throughout my life

II. ABSTRAK

Latar Belakang : Merekabentuk tisu kulit pada flap fibula osteoseptokutaneous bebas adalah kritikal kerana flap ini bukan sahaja terkenal dengan jumlah tulang yang panjang, malah ia juga mampu membekalkan tisu kulit yang banyak, terutamanya di dalam kes melibatkan trauma tulang panjang atau pun ketumbuhan tulang rahang. Oleh itu, adalah amat penting untuk mengenalpasti perforator dan laluannya untuk memastikan perfusi pada tisu kulit. Objektif kajian ini adalah untuk menganalisa pengalaman kami berkenaan perforator tisu flap fibula osteoseptokutaneous bebas selama 17 tahun.

Metodologi : Data dikumpul secara retrospektif pada semua pesakit yang menjalani pembedahan flap fibula osteoseptokutaneous bebas di Hospital Universiti Sains Malaysia, Kelantan sejak tahun 1998 hingga 2014. Kes-kes dengan data yang tidak mencukupi akan dikecualikan dari kajian ini. Jenis perforator flap fibula osteoseptokutaneous bebas dan laluannya dicatat berdasarkan kedudukan anatomi dan dicatat di dalam proforma bergambar.

Keputusan : Terdapat 156 kes flap fibula osteoseptokutaneous bebas dalam jangka masa 17 tahun akan tetapi hanya 109 kes yang dimasukkan ke dalam kajian. Sejumlah 305 perforator dari 109 kes flap fibula bebas. Kes malignan adalah indikasi tertinggi iaitu 33.9%, diikuti dengan benign, 27.5%, trauma, 22%, jangkitan kuman 7.3% dan lain-lain 9.2%. Tibia dan mandible adalah tulang yang paling kerap direkonstruksi iaitu 32.1% setiapnya.

Berdasarkan kedudukan kaki, bahagian kaki tengah mempunyai distribusi perforator yang tertinggi (72.8%), diikuti dengan sepertiga atas kaki (18.0%) and yang terakhir adalah sepertiga bawah kaki (9.2%). Terdapat 4 jenis perforator iaitu jenis 1 osteoseptokutaneous,

jenis 2 muskulokutaneous, jenis 3 septomuskulokutaneous dan jenis 4 muskuloseptokutaneous. Kumpulan osteoseptokutaneous adalah yang tertinggi di dalam tisu kulit flap fibula bebas, 40%, diikuti dengan kumpulan muskulokutaneous (34.4%), septomuskulokutaneous (15.4%) dan terakhir sekali muskuloseptokutaneous (10.2%). Di kalangan kaki atas, perforator muskulokutaneous adalah yang terbanyak. Manakala, kumpulan osteoseptokutaneous adalah yang terbanyak di tengah dan sepertiga bawah kaki, iaitu 42.3% dan 53.5% di kumpulan masing-masing.

Konklusi : Tisu kulit yang efektif boleh dibedah dengan mudah pada bahagian tengah dan sepertiga bawah kerana kebarangkalian kehadiran perforator osteoseptokutaneous yang tinggi. Dalam situasi yang jarang, tisu kulit flap fibula tidak dibekali oleh perforator yang berasal dari arteri peroneal akan tetapi berasal dari arteri tibia posterior disebabkan variasi anatomi yang berbeza.

III. ABSTRACT

Background : Designing a reliable skin paddle in free fibula osteoseptocutaneous flap is critical since the flap is not only recognized for its robust amount of bone, but also provide skin paddle for soft tissue cover in long bone trauma or mandibular neoplasm. Therefore, it is important to identify the perforators and the courses to ensure the skin paddle perfusion. This study was to analyse our 17 years experiences of skin paddle perforator of free fibula osteoseptocutaneous flap in Hospital Universiti Sains Malaysia.

Methodology : Retrospective data collected in all patients that underwent free fibula flap in Hospital Universiti Sains Malaysia, Kelantan from 1998 to 2014. The cases with incomplete data were excluded. The skin paddle perforators of free fibula flap type and courses documented based on anatomic location and recorded into an image guided proforma.

Result : There was 156 free fibula cases were done within 17 years period, but only 109 cases were included in this study. There were 305 perforators out of 109 fibula flap. Malignant cases (33.9%) was the highest indication for free fibula flap, followed by benign (27.5%), trauma (22.0%), infection (7.3%) and others (9.2%). Tibia and mandible were the highest bone to be reconstructed, which were 32.1% each.

According to leg location, middle third leg has the highest number of perforator distribution (72.8%), followed by upper third of leg (18.0%) and lastly lower third of the leg (9.2%). There were 4 types of perforators that were osteoseptocutaneous, musculocutaneous, septomusculocutaneous and musculoseptocutaneous. Osteoseptocutaneous group was the highest perforator supplying the free fibula skin paddle (40%), followed by musculocutaneous

(34.4%), septomusculocutaneous (15.4%) and musculoseptocutaneous (10.2%). Among the upper leg, musulocutaneous perforator group was the highest, (49%). Meanwhile, osteoseptocutaneous perforator group was the highest in both middle (42.3%) and distal (53.5%) leg.

Conclusion : A reliable skin paddle would be easily raised over middle and distal zone due to the likelihood of the presence of osteoseptocutaneous perforator. Rarely, there would be anatomical variant that the skin paddle of fibula flap will be supplied by perforator from the posterior tibial artery instead of peroneal artery.

Key Words: free fibula flap, peroneal perforator, musculocutaneous, septocutaneous, septomusculocutaneous, musculoseptocutaneous.

IV. ABBREVIATIONS

CTA	Computed Tomography Angiogram
Hospital USM	Hospital Universiti Sains Malaysia
FHL	Flexor Hallucis Longus
PTA	Posterior Tibial Artery

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1.0 INTRODUCTION

1.1 INTRODUCTION AND LITERATURE REVIEW

Free fibula flap has become a workhorse flap due to its proven versatility and reliability to provide long robust solid bone for bone reconstruction.It was first described by Taylor et al to reconstruct long tibial defect [1]. Other majoradvantage of this flap is its ability to providereliable skin paddle as an osteocutaneous flap in case requiring soft tissue closure thatcan prevent double free flap.This was introduced initially by Chen and Yan [2] with inclusion of muscle cuff to the fibula and later improvised by Wei et al. by taking the flap with the attached skin paddle [3] as opposed to the free fibula flap that was introduced by Taylor at al as a free vascularized bone graft [1].

The skin paddle of fibula flap is connected to the fibula by the posterior intermuscular septum at the lateral leg, which made the flapan osteoseptocutaneous fibula flap. The skin paddle attachment through the intermuscular septum made the skin paddle more versatile and easier to manipulate as compared to the skin paddle attachment in iliac crest and scapular osteocutaneous flap. This is particularly important in cases of intraoral neoplasm which requiring reconstruction of both mandible and soft tissue such as lip, cheek or floor of mouth defect making the skin paddle as important as the fibula bone flap itself.

The fibula osteoseptocutaneous flap is supplied by the peroneal artery, while the venous drainage is by the vena comitantes of peroneal artery. The skin paddle of the flap is nourished by the perforators from the peroneal artery and the sensory innervation is by sural nerve.

In the Taylor description, the peroneal vessel was not dissected out and 1 cm muscle sleeve was retained surrounding fibula and pedicle. Chen and Yan et al in their description of osteocutaneous flap also included muscle cuff surrounding the fibula to preserve the blood supply to the bone and skin paddle[2]. Later in 1986, Wei and Chen et al reported the septocutaneous perforators alone which run in the posterior crural intermuscucular septum were adequate to nourish the skin paddle and suggested to find muscular branch in the absence of the septocutaneous perforator[3]. Similar to Wei and Chen study, Winters et al. found the skin paddle to be ischaemic when based only on a septum without perforator[4].

Schusterman et al classify the lateral leg perforator types into 3, the septocutaneous, musculocutaneous and septomuscular course, and recommended to include a cuff of soleus and flexor hallucis longus [5]. Cho et al also classify the perforators similarly and found the average number of perforators per leg was 3[6]. The septocutaneous branches were found more distal than the musculocutaneous and septomusculocutaneous perforators [6, 7]. The skin paddles were designed at proximal and middle third of the fibula were noted to originate from high peroneal artery or popliteal artery [4].

An anomaly has been reported which there was no perforator from the peroneal artery and the skin paddle was supplied by soleus musculocutaneous perforators from posterior tibial artery or tibioperoneal trunk instead[8]. This was also observed and reported by Yadav et al in his case report on anomalous musculocutaneous perforator to the skin paddle that originated from proximal part of the posterior tibial artery and passed through the soleus muscle before supplying the cutaneous component [9]. Another variant is where the septocutaneous perforator was originated from the posterior tibial artery and not from the peroneal artery [10]. In this situation, skin paddle of lateral leg that is supplied by perforators

from posterior tibial artery can be anastomosed to the distal end of peroneal artery that nourished the fibula flap, making the fibula flap as a flow through flap [11].

A cadaveric study of lateral leg perforators by Lykoudis et al showed the predominant cutaneous vessel is the peroneal artery [12]. However the proximal zone was dominated by tibial-peroneal trunk and the distal region was by posterior tibial artery [12].

Peroneal arteries in a cadaveric and clinical study by Wong et al were noted to be consistently giving out branch to lateral soleus muscle, therefore making the fibula osteoseptocutaneous flap feasible to be raised as a chimeric flap together with lateral hemisoleus muscle flap in condition requiring additional soft tissue bulk [13]. This technique gives more freedom and mobility during hemisoleus inset as compared to earlier description by Baudet et al. in which the soleus muscle still remained attached to the fibula bone [14].

Yadav et al. analysed a 5 year data of 386 free fibula flaps and came out with a classification of free fibula skin paddle based on its blood supply [15]. Type A skin paddles (95.8%) received the blood supply from peroneal system only, while type B (3.6%) received the blood supply from both peroneal and posterior tibial systems and dependant on the musculocutaneous perforators from posterior tibial artery for survival. Type C skin paddles only received blood supply from posterior tibial system which was 0.5% from their review and type D skin paddles from popliteal artery.

Routine preoperative angiogram is unnecessary in planning a free fibula osteoseptocutaneous flap as it only warrant thorough clinical pulses assessment [16]. However, computed tomographic angiography does help in localizing the cutaneous perforators of the leg in 3 dimensional [17]. Martin et al. located an average 10 peroneal artery perforators which

divided into distal and proximal group. The proximal group always branched out directly through the soleus muscle.

1.2 RATIONALE OF THE STUDY

Designing a reliable skin paddle in this flap has become a challenge due to the need to include the perforators that run along the posterolateral intermuscular septum of the leg. There has been various courses of perforators supplying the skin paddle of fibula flap. This retrospectively study documented the various type of perforators and its distribution along the lateral leg in relation to the fibula which will help planning, locating and dissecting the skin paddle perforators of free fibula flap. It also helps in raising perforator based flap which requiring the same knowledge of perforators distribution in lateral leg.

1.3 GENERAL ANDSPECIFIC OBJECTIVE

1.3.1 General Objectives

1.3.1.1 To study the skin paddle perforator offree fibula osteoseptocutaneous flap cases in Hospital Universiti Sains Malaysia.

1.3.2 Specific Objectives

1.3.2.1 To study the distribution of skin paddle perforators of free fibula osteoseptocutaneous flap.

1.3.2.2 To determine the skin paddle perforators according to type and location of leg.

1.3.2.3 To determine anatomic variant supplying the skin paddle of free fibula osteoseptocutaneous flap.

2.0 STUDY PROTOCOL

2.1 DOCUMENTS SUBMITTED FOR ETHICAL APPROVAL

2.1.1 Study Proposal

TITLE PAGE (PROPOSAL)

A STUDY OF SKIN PADDLE PERFORATORS

OF FREE FIBULA OSTEOSEPTOCUTANEOUS FLAP IN

HOSPITAL UNIVERSITI SAINS MALAYSIA

STUDENT	: FARAH HANY BINTI OMAR
MATRIC NUMBER	: P-UM 0022/12
PROGRAMME	: MASTER OF SURGERY (PLASTIC SURGERY)
SUPERVISOR	: PROF DR AHMAD SUKARI HALIM

INTRODUCTION

Free fibula flap has become a workhorse flap due to its proven versatility and reliability. It was first described by Taylor et al to reconstruct long tibial defect [1]. Fibula flap can provide long and robust solid bone, therefore making it suitable for long bone reconstruction such as tibia, femur, humerus and radius.

The advantage of this flap is not only on the bone length available, but also it can provide reliable soft tissue when is taken along with the overlying skin paddle and the nearby muscle such as soleus. This can therefore avoid the need of double free flap. The skin paddle of this flap is connected to the fibula by the posterior crura of lateral septum of the leg, which made the flap an osteoseptocutaneous fibula flap. Therefore, the overlying skin paddle in osteoseptocutaneous flap is more versatile and easier to manipulate as compared to the skin paddle in iliac crest and scapular osteocutaneous flap. This gives huge advantages for the defects that require both bone and soft tissue reconstruction such as post traumatic long bone defect, limb sparing procedure or post oncological resection at tibia, femur, radius and mandible.

The fibula osteocutaneous flap was introduced by Chen and Yan [2] with inclusion of muscle cuff and later improvised by Wei et al. by taking the flap with the attached skin paddle by posterior crura of lateral intermuscular septum [3].

The flap is mainly supplied by the peroneal artery, while the venous drainage is by the vena comitantes of peroneal artery. The skin paddle of the flap is nourished by the perforators from the peroneal artery and the sensory innervation is by sural nerve.

Designing a reliable skin paddle in this flap has become a challenge due to the need to include the perforators that run along the posterolateral intermuscular septum of the leg. There has been various courses of perforators supplying the skin paddle of fibula flap. The purpose of this study is to retrospectively study the various type of perforators and its distribution along the lateral leg in relation to the fibula. This study will assist the surgeon in planning, locating and dissecting the skin paddle perforators of free fibula flap. This information also can be used in raising peroneal perforator flap which requiring the same knowledge of perforators distribution in lateral leg.

LITERATURE REVIEW

Free Fibula Osteoseptocutaneous Flap

The free fibula flap was introduced by Taylor at al as a free vascularized bone graft in 1975 to reconstruct long tibial defect [1]. Later, the flap harvest technique has evolved by taking skin paddle along as an osteocutaneous flap which was introduced by Chen and Yan [2]. This is particularly important in cases of intraoral neoplasm which requiring reconstruction of both mandible and soft tissue such as lip, cheek or floor of mouth defect making the skin paddle as important as the fibula bone flap itself.

In the Taylor description, the peroneal vessel was not dissected out and retained 1 cm muscle sleeve surrounding fibula and pedicle. Chen and Yan et al in their description of osteocutaneous flap also included muscle cuff surrounding the fibula to preserve the blood supply to the bone and skin paddle [2].

In 1986 Wei and Chen et al reported of osteoseptocutaneous fibula flap harvest, which the skin paddle attached to the fibula via posterior crural septum. He demonstrated that septocutaneous perforators alone were adequate to nourish the skin paddle and suggested to find muscular branch in the absence of the septocutaneous perforator [3].

Meanwhile, Jones observed in his series that harvesting the skin paddle solely on the septum was adequate without additional muscular branch [18]. He also found that distally designed skin paddle noted to be more reliable than proximally located skin paddle [18]. In contrast to Jones, Winters et al. found the skin paddle to be ischaemic when based only on a septum without perforator [4].

Limiting the inclusion of muscle as in osteoseptocutaneous fibula flap gives several advantages such as less hematoma in the recipient site, reduce the dead space at donor site, facilitate the skin paddle folding surrounding the fibula, relatively increasing the length of lateral crural septum and preserve the donor limb strength [19].

Skin Paddle Perforators and The Variant Anatomy

Schusterman et al divided the lateral leg perforator types into 3, the septocutaneous, musculocutaneous and septomuscular course, and recommended to include a cuff of soleus and flexor hallucis longus [5]. Cho et al also divided the perforators similarly and found the average number of perforators per leg was 3 [6]. The septocutaneous branches were found more distal than the musculocutaneous and septomusculocutaneous perforators [6, 7].

Meanwhile, the skin paddles that was designed at proximal and middle third of the fibula noted to be originate from high peroneal artery or popliteal artery [4].

There are variations when there is absent of perforators from peroneal artery and the skin at lateral leg which was supplied by soleus musculocutaneous perforators from posterior tibial artery or tibioperoneal trunk [8]. This was also observed and reported by Yadav et al in his case report on anomalous musculocutaneous perforator to the skin paddle that originated from proximal part of the posterior tibial artery and passed through the soleus muscle before supplying the cutaneous component [9].

There is also another variant anatomy where the septocutaneous perforator originated from the posterior tibial artery and not from the peroneal artery [10]. In this situation, skin paddle of lateral leg that was supplied by perforators from posterior tibial artery can be anastomosed to the distal end of peroneal artery that nourished the fibula flap, making the fibula flap as a flow through flap [11].

A cadaveric study of lateral leg perforators by Lykoudis et al showed the predominant cutaneous vessel is the peroneal artery [12]. However at the proximal zone was dominate by tibial-peroneal trunk and the distal region was by posterior tibial artery [12].

Peroneal arteries in a cadaveric and clinical study by Wong et al were noted to be consistently giving out branch to lateral soleus muscle, therefore making the fibula osteoseptocutaneous flap feasible to be raised as a chimeric flap together with lateral hemisoleus muscle flap in condition requiring additional soft tissue bulk [13]. This technique

gives more freedom and mobility during hemisoleus inset as compared to earlier description by Baudet et al. in which the soleus muscle still remained attached to the fibula bone [14].

Yadav et al. analysed a 5 year data of 386 free fibula flaps and came out with a classification of free fibula skin paddle based on its blood supply [15]. Type A skin paddles (95.8%) received the blood supply from peroneal system only, while type B (3.6%) received the blood supply from both peroneal and posterior tibial systems and dependant on the musculocutaneous perforators from posterior tibial artery for survival. Type C skin paddles only received blood supply from posterior tibial system which was 0.5% from their review and type D skin paddles from popliteal artery.

Routine preoperative angiogram is unnecessary in planning a free fibula osteoseptocutaneous flap as it only warrant thorough clinical pulses assessment [16]. However, computed tomographic angiography does help in localizing the cutaneous perforators of the leg in 3 dimensional [17]. Martin et al. located an average 10 peroneal artery perforators which divided into distal and proximal group. The proximal group always branched out directly through the soleus muscle.

OBJECTIVES

General Objectives

1. To study the skin paddle perforator of free fibula osteoseptocutaneous flap cases in Hospital Universiti Sains Malaysia.

Specific Objectives

1. To study the distribution of skin paddle perforators of free fibula osteoseptocutaneous flap.
2. To determine the skin paddle perforators according to type and location of leg.
3. To determine anatomic variant supplying the skin paddle of free fibula osteoseptocutaneous flap

METHODOLOGY

Study Design

This is a retrospective study involving all the patients who underwent reconstruction with free fibula osteoseptocutaneous flap under the Plastic and Reconstructive Surgery Department, Hospital Universiti Sains Malaysia from January 1998 to December 2014. The surgeries were done by 3 plastic surgeons in Hospital USM.

The data collection will be obtained by using the operative record book, patient case notes, flap proformas and the intraoperative photos. All data will be fill in an image guided proformas.

Sample Size

Using Single Proportion Formula.

i. Sample size calculation

$$n = (Z/\Delta)^2 \, p \, (1-p)$$

$$= (1.96/0.05)^2 \, (0.38) \, (0.62)$$

= 362 samples (Cho et al, 2001) [6]

Assuming 10% dropped out rate, n = 373 samples

Statistical Analysis

All data will be entered, managed and analysed using Statistical Package for Social Science (SPSS PC version 22). Descriptive statistics (frequency, mean, median and standard deviation) for the selected variables will be estimated.

Exclusion Criteria

Patient with incomplete record and data.

Proforma

Proforma is attached at the end of proposal. The proforma consist of several images showing various courses of perforators supplying the skin paddle of free fibula flap. The proforma also showed the level of perforators in relation to the lateral malleolus.

Operational Definitions

a) **Fibula Osteoseptocutaneous Flap**

Composite fibula flap that is consists of bone, posterior crura septum and cutaneous component.

b) **Septocutaneous Perforator**

Perforator from the main pedicle comes out through the muscular septum to supply the cutaneous component.

c) **Musculocutaneous Perforator**

Perforator from the main pedicle goes through the muscle to supply the cutaneous component.

d) **Septomusculocutaneous Perforator**

Perforator from the main pedicle comes out through the muscular septum and later go through muscle to supply the cutaneous component.

e) **Musculoseptocutaneous Perforator**

Perforator from the main pedicle go through muscle before comes out and run through the muscular septum to supply the cutaneous component.

Flow Chart

Patients Underwent Free Fibula Flap from January 1998 to December 2014

↓

Case Notes, flap performa & photos → **Inadequate data**

↓ ↓

Fill up performa **Excluded**

↓

Data entry, analysis & write up

Gantt Chart

Year	**2016**			
Month	**May**	**June**	**July**	**August**
Data Collection				
Data Analysis				
Writing Up and Publication				

RESULTS

Table 5.1 : Patients demographic data

Patient Demographic Data		No (%)
Age	0 – 10 year old	
	11 – 20 year old	
	21 – 30 year old	
	31 – 40 year old	
	41 – 50 year old	
	51 – 60 year old	
	61 – 70 year old	
	More than 70 year old	
Gender	Male	
	Female	

Table 5.2 : Number of Free Fibula Flap According to Year

Year	Number
1998	
1999	
2000	
2001	
2002	
2003	
2004	
2005	
2006	
2007	
2008	
2009	
2010	
2011	
2012	
2013	
2014	

Table 5.3 : Indications for Reconstruction with Osteoseptocutaneous Fibula Flap

Indications		Number (Percentage)
Tumour Resection	Benign	
	Malignant	
Trauma		
Infection		
Others		

Table 5.4 : Bone or Region Reconstructed by Osteoseptocutaneous Fibula

Reconstructed Region / Bone	Number (Percentage)
Mandible	
Tibia	
Femur	
Radius	
Others	

Table 5.5 : Free Fibula Osteoseptocutaneous Flap

Fibula Total Length		Cm
Harvested Length		Cm
Number of Skin paddle	1	
	2	
	More than 2	

Table 5.6 : Distribution of Perforators of Free Fibula Osteoseptocutaneous Flap

Type Of Perforator	Number and Percentage According to the Location of Fibula		
	Proximal	Middle	Distal
1			
2a			
2b			
3a			
3b			
3c			
3d			
4 (Others)			

Table 5.7 : Donor Site Clossure

Method of Donor Site Clossure	Number
Primary Clossure	
Skin graft	
Others – Dermal substitute, secondary healing	

LIMITATIONS

1. Not all data and photos may be achieved accurately through retrospective data collections due to under reporting.
2. There are several surgeons with different operative and technical skills which may affect the dissection of the perforators.

REFERENCES

1. Taylor GI, Miller GD, Ham FJ. The free vascularized bone graft: a clinical extension of microvascular techniques. Plastic and Reconstructive Surgery. 1975;55(5):533-44.

2. Chen ZW, Yan W. The study and clinical application of the osteocutaneous flap of fibula. Microsurgery. 1983;4(1):11-6.

3. Wei FC, Chen HC, Chuang CC, Noordhoff MS. Fibular osteoseptocutaneous flap: anatomic study and clinical application. Plastic and reconstructive surgery. 1986;78(2):191-9.

4. Jones NF, Monstrey S, Gambier BA. Reliability of the fibular osteocutaneous flap for mandibular reconstruction: anatomical and surgical confirmation. Plastic and reconstructive surgery. 1996;97(4):707-16.

5. Winters HA, de Jongh GJ. Reliability of the proximal skin paddle of the osteocutaneous free fibula flap: a prospective clinical study. Plastic and reconstructive surgery. 1999;103(3):846-9.

6. Graham RG, Swan MC, Hudson DA, van Zyl JE. The fibula free flap: advantages of the muscle sparing technique. British journal of plastic surgery. 2003;56(4):388-94.

7. Schusterman MA, Reece GP, Miller MJ, Harris S. The Osteocutaneous Free Fibula Flap: Is the Skin Paddle Reliable? Plastic and reconstructive surgery. 1992;90(5):787-93.

8. Cho BC, Kim SY, Park JW, Baik BS. Blood supply to osteocutaneous free fibula flap and peroneus longus muscle: prospective anatomic study and clinical applications. Plastic and reconstructive surgery. 2001;108(7):1963-71.

9. Tang M, Mao Y, Almutairi K, Morris SF. Three-dimensional analysis of perforators of the posterior leg. Plastic and reconstructive surgery. 2009;123(6):1729-38.

10. Wong CH, Tan BK, Wei FC, Song C. Use of the soleus musculocutaneous perforator for skin paddle salvage of the fibula osteoseptocutaneous flap: anatomical study and clinical confirmation. Plastic and reconstructive surgery. 2007;120(6):1576-84.

11. Yadav PS, Ahmad QG, Shankhdhar VK, Nambi G. Successful management of free osteocutaneous fibula flap with anomalous vascularity of the skin paddle. Indian journal of plastic surgery: official publication of the Association of Plastic Surgeons of India. 2009;42(2):255.

12. Tan BK, Wong CH. An anomalous septocutaneous perforator to the skin paddle of the fibula osteocutaneous flap originating from the posterior tibial artery. Journal of Plastic, Reconstructive & Aesthetic Surgery. 2009;62(5):690-2.

13. Parr JM, Adams BM, Wagels M. Flow-Through Flap for Salvage of Fibula Osseocutaneous Vascular Variations: A Surgical Approach and Proposed Modification of Its Classification. Journal of Oral and Maxillofacial Surgery. 2014;72(6):1197-202.

14. Lykoudis EG, Koutsouris M, Lykissas MG. Vascular anatomy of the integument of the lateral lower leg: an anatomical study focused on cutaneous perforators and their clinical importance. Plastic and reconstructive surgery. 2011;128(1):188-98.

15. Wong CH, Ong YS, Chew KY, Tan BK, Song C. The fibula osteoseptocutaneous flap incorporating the hemisoleus muscle for complex head and neck defects: anatomical study and clinical applications. Plastic and reconstructive surgery. 2009;124(6):1956-64.

16. Baudet J, Panconi B, Caix P, Schoofs M, Amarante J, Kaddoura R. The composite fibula and soleus free transfer. Int J Microsurg. 1982;4(10).

17. Yadav PS, Ahmad QG, Shankhdhar VK, Nambi G. Skin paddle vascularity of free fibula flap–A study of 386 cases and a classification based on contribution from axial vessels of the leg. Indian journal of plastic surgery: official publication of the Association of Plastic Surgeons of India. 2012;45(1):58.

18. Lutz BS, Wei FC, Ng SH, Chen IH, Chen SH. Routine donor leg angiography before vascularized free fibula transplantation is not necessary: a prospective study in 120 clinical cases. Plastic and reconstructive surgery. 1999;103(1):121-7.

19. Martin AL, Bissell MB, Al-Dhamin A, Morris SF. Computed Tomographic Angiography for Localization of the Cutaneous Perforators of the Leg. Plastic and reconstructive surgery. 2013;131(4):792-800.

2.1.2 Profoma Of Free Fibula Osteoseptocutaneous Flap – Appendix 2.

2.2 ETHICAL APPROVAL LETTER

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Universiti Sains Malaysia
16150 Kubang Kerian, Kelantan.

JEPeM Code : USM/JEPeM/16030093
Protocol Title : A Study of Skin Paddle Perforator of Free Fibula Osteoseptocutaneous Flap in Hospital USM.

Dear Dr.,

We wish to inform you that your study protocol has been reviewed and is hereby granted approval for implementation by the Jawatankuasa Etika Penyelidikan Manusia Universiti Sains Malaysia (JEPeM-USM). Your study has been assigned study protocol code **USM/JEPeM/16030093**, which should be used for all communication to the JEPeM-USM related to this study. This ethical clearance is valid from **29th June 2016** until **28th June 2017.**

Study Site: Hospital Universiti Sains Malaysia.

The following researchers also involve in this study:

1. Prof. Dr. Ahmad Sukari Halim

The following documents have been approved for use in the study.

1. Research Proposal

In addition to the abovementioned documents, the following technical document was included in the review on which this approval was based:

1. Data Collection Form (Performa)

Attached document is the list of members of JEPeM-USM present during the full board meeting reviewing your protocol.

While the study is in progress, we request you to submit to us the following documents:

1. Application for renewal of ethical approval 60 days before the expiration date of this approval through submission of **JEPeM-USM FORM 3(B) 2015: Continuing Review Application Form.** Subsequently this need to be done yearly as long as the research goes on.
2. Any changes in the protocol, especially those that may adversely affect the safety of the participants during the conduct of the trial including changes in personnel, must be submitted or reported using **JEPeM-USM FORM 3(A) 2015: Study Protocol Amendment Submission Form.**
3. Revisions in the informed consent form using the **JEPeM-USM FORM 3(A) 2015: Study Protocol Amendment Submission Form.**
4. Reports of adverse events including from other study sites (national, international) using the **JEPeM-USM FORM 3(G) 2014: Adverse Events Report**