Dissertation

A Randomized control trial to compare the efficacy of long posterior myocutaneous flap versus skew flap in transtibial amputation in a tertiary care hospital

Dissertation submitted to

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CERTIFICATE

This is to certify that, the dissertation entitled **"A Randomized Control trial to compare the efficacy of long posterior myocutaneous flap and skew flap in Transtibial Amputation in a Tertiary Care Hospital "** is the bonafide work done by **Dr.S.Aashmi Chandrikaa** , with Registration Number: **221911001** during her **M.S. (General Surgery) course 2019-2022**, done under my supervision and is submitted in partial fulfilment of the requirement for the M.S.(BRANCH-I)- General Surgery of The Tamil Nadu Dr.M.G.R. Medical University, May 2022 examination.

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DECLARATION

I, certainly declare that this dissertation titled "**A Randomized Control trial to compare the efficacy of long posterior myocutaneous flap and skew flap in Transtibial Amputation in a Tertiary Care Hospital**" represents a genuine work of mine. The contributions of any supervisors to the research are consistent with normal supervisory practice, and are acknowledged.

I also affirm that this bonafide work or part of this work was not submitted by me or any others for any award, degree or diploma to any other University board, either in India or abroad. This is submitted to The Tamil Nadu Dr. M.G.R. Medical University, Chennai in partial fulfilment of the rules and regulations for the award of Master of Surgery Degree Branch I (General Surgery).

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The practice of surgery can be learned from teachers, by years of training, and regular honing of skills obtained. However, research is essential for the betterment of the art of surgery. Without research any new knowledge is just that- it cannot become an actualization. Through this study, I'd like to contribute my little to the research world, with the help of those who have been a good help throughout my quest of surgical education.

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LIST OF ABBREVIATION

MP	:	Metatarsophalangeal joint	$\bar{x}$	:	Arithmetic mean
M	:	Male	n	:	number of values in data set
F	:	Female	X	:	ordered list of values in data set
S	:	Skew flap	L	:	Lower limit of the modal class
L	:	Long posterior myocutaneous flap	h	:	size of the class interval
TC	:	Total count	f_m	:	frequency of the modal class
NA	:	Not Applicable	f_1	:	frequency of the class preceding the modal class
A.K.A.	:	Above knee amputation	f_2-	:	frequency of the class succeeding the modal class
COMP	:	Compression	X^2	:	Chi Squared
WDSS	:	Wound Debridement and Secondary suturing	O_i	:	Observed value
READM	:	Readmission	E_i	:	Expected value
NAMBU	:	Non-Ambulant	$\hat{p}$	:	Sample proportion
AMBU	:	Ambulant	x_i	:	Each value from the population
ADL	:	Activities of Daily Living	p_0	:	Assumed population proportion in the null hypothesis
H	:	Healthy	PIP	:	Proximal Interphalangeal joint
SSI	:	Surgical site infection	DIP	:	Distal Interphalangeal joint
SER	:	Seroma	σ	:	Population standard deviation
ASC	:	Ascending sepsis	D	:	Death
ED	:	Early death			

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ABSTRACT

Objectives: To compare the efficacy of long posterior myocutaneous flap and skew flap techniques in patients undergoing transtibial amputations for diabetic foot sepsis in terms of healthy suture line defined as painless wound, healed by primary intention. The secondary objectives included in the study are the length of the hospital stay, need for re- amputation at same or higher level and thirty-day mortality among the two groups.

Methods: 60 patients who had to undergo transtibial amputation for Ascending foot sepsis were included in this trial and were randomized into two groups-Group L and Group S-based on whether the admission numbers were odd or even.

Group A – Long Posterior flap technique closed with 1/0 ethilon using simple/mattress sutures.

Group B – Skew Flap -technique closed with 1/0 ethilon using simple/mattress sutures.

Suture line on Day 7, need for re-amputation, length of hospital stays and thirty-day mortality rate were recorded in an Excel Sheet and statistical analysis done.

Results: The percentage of primary wound healing in Long posterior myocutaneous flap is around 65.63% and 42.86% with a p value of 0.78 that is statistically not significant. The rate of re-amputation rates was 14.29 %. The mortality rate in the study population was 5.97%.

Conclusion: There is no significant advantage in terms of primary wound healing in patients undergoing transtibial amputation via Skew flap technique or long posterior myocutaneous flap technique. However, since both the flaps confer almost a similar percentage of primary wound healing, skew flap technique can be used as an alternate technique of transtibial amputation in people where a posterior flap cannot be constructed.

Keywords: Transtibial amputation, Skew flap, long posterior flap, Burgess technique

AIMS AND OBJECTIVES

Primary objective

To compare the efficacy of the skew flap and long posterior myocutaneous flap in patients undergoing transtibial amputation in terms of primary wound healing.

Primary wound healing is defined as painless, without any inflammation, non-adherent and that healed by primary intention.

Secondary objectives

The secondary objectives include

- To compare the rate of revision amputation at the same or higher level.
- To compare the thirty-day mortality.
- To compare the length of hospital, stay in the two groups.

INTRODUCTION

Lower extremity amputations are one of the oldest known surgical procedures and are dated back to the prehistoric times [1,2]. Cave wall handprints have demonstrated loss of digits. The earliest record of lower limb amputation is the Babylonian code of Hammurabi,1700 BCE found in Louvre.

The other early literatures that have described therapeutic amputations are Plato's Symposium, 385 BCE and Articulations by Hippocrates where he describes therapeutic amputation for vascular gangrene. Hippocrates had performed amputation at the edge of the ischemic tissue and had left the wound to heal with secondary intention. The surgical principles described then by Hippocrates still holds true and only small refinements of technique have been made since then.

The main risks following amputation in early days were sepsis, hemorrhage and shock and before the discovery of anesthesia performing the procedure itself was very difficult. The incidence of lower limb amputation had not been accurate due to high international variability and poor reporting systems.

Amputations are to be viewed as reconstructive procedures and not as treatment failure. Patients and their family members should be informed of all treatment options available to give informed consent regarding amputation and they should be educated regrading realistic expectation of the surgical outcome [3,4]. Removing of the diseased limb is comparatively easy when compared to the long rehabilitative process. However, the surgery must be performed with adequate standards to ensure wound healing with primary intention and early prosthesis fitting and ambulation [5].

Various methods for Transtibial amputations are Long posterior myocutaneous flap, Skew flap, Sagittal flap and Lateral flaps. The skin incision is constructed in such a way to ensure adequate

blood supply to the suture to ensure faster healing. Long Posterior Myocutaneous flaps described by Burgess is considered the gold standard method for Transtibial amputation, However the technique suffers from the disadvantage of bulbous stump, and the suture line over the anterior part of the tibia that can breakdown while using a prosthesis [(6)]. This disadvantage was overcome by Skew flap technique described by K.P. Robinson in 1991 and was said to be superior to long posterior myocutaneous flap technique and aids in better wound healing [(6)]. However comparative trials are lacking.

Hence this randomized controlled study was conducted among patients undergoing transtibial amputation at our Tertiary Care Hospital for Ascending foot sepsis due to varied reasons like Diabetic foot sepsis, Gas Gangrene and Necrotizing fasciitis with non-salvageable limb by two different techniques namely the skew flap technique and long posterior myocutaneous flap technique. Comparison was done between the two in terms of primary wound healing, need for secondary procedures, thirty-day mortality rate and length of hospital stay.

REVIEW OF LITERATURE

ANATOMY OF THE LEG

The leg is the part of the limb that is between the knee and the ankle. Reviewing the anatomy of the leg is important to proceed with the surgical procedure of below knee amputation.

Surface Landmarks [7]

- **Medial and Lateral condyles of the tibia,** visible and palpable landmarks on either side of the ligamentum patellae.

  Felt when thigh if flexed and laterally rotated and knee is flexed.
- **Tibial Tuberosity,** prominent bony part on the upper surface of tibia in the anterior part 2.5 cm below the knee joint.
- **Anterior border of the tibia,** it is felt subcutaneously throughout except the lower part. It extends from the Tibial tuberosity up to the anterior border of the medial malleolus.

Superficial venous system [7]

The superficial veins of the leg are:

- The long saphenous vein and
- The short saphenous vein

The long saphenous vein runs in front of the medial malleolus and crosses the medial surface of the lower 1/3 $^{rd.}$ of the tibia to reach the lower border of the medial surface of the tibia. Here it ascends to reach the back of the knee. The saphenous nerve runs in front of the Great Saphenous vein.

The short saphenous vein runs behind the lateral malleolus and reaches the posterior aspect of the knee where it joins the popliteal vein.

Cutaneous Nerve Supply of the leg [7]

- **Infrapatellar branch of the saphenous Nerve**, supplies the skin over the ligamentum patellae.
- **Saphenous Nerve (L3, L4):** cutaneous supply to the medial side of the leg and foot up to the ball of the big toe.
- **Lateral Cutaneous Nerve of Calf (L5, S1, S2):** Branch of common peroneal nerve. Cutaneous supply to the lateral half of the leg in the upper 2/3 rd.
- **Superficial Peroneal Nerve (L4, L5, S1):** Branch of the common peroneal nerve. Supplies the skin of the lateral part of lower 1/3 rd. of leg and dorsum of the foot except the lateral and the medial border supplied by the sural and saphenous nerve respectively.

Fascia of the leg [7]

The deep fascia of the leg is very tight and encloses the leg like a sleeve. It doesn't cover the subcutaneous bone but are attached to the edges of these bones. It appears to be fused with the periosteum of the Tibia.

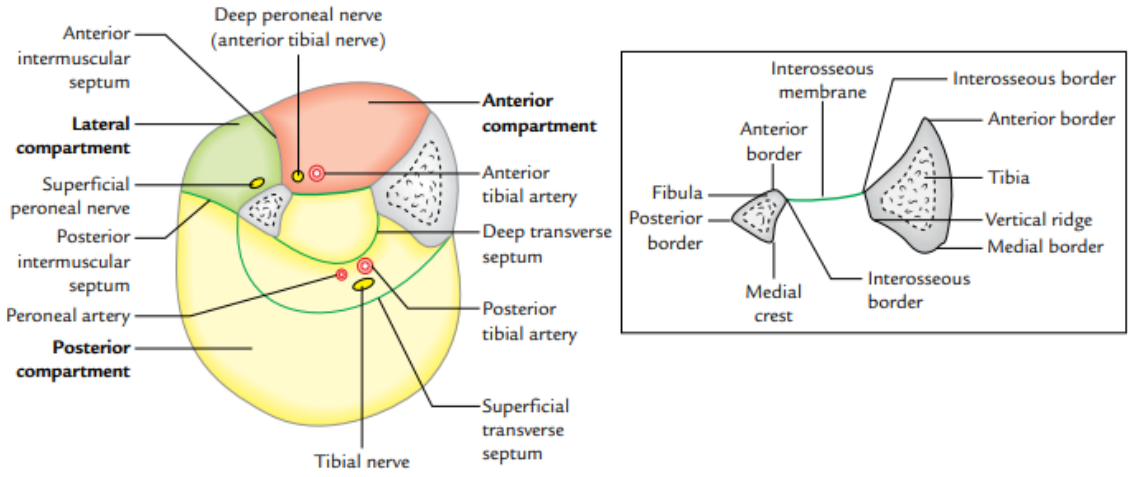


Fig 1 shows the Osseo-fascial compartments and inlet shows the various points of fixation (7)

There are two intermuscular septa – Anterior and Posterior Intermuscular septa. The fascia extends inwards and get attached to the anterior and posterior border of fibula and along with the interosseus membrane divide into three fascial compartments. Each of these fascial compartments have a separate artery, muscle and nerves. The three fascial compartments are anterior, posterior and lateral. The posterior compartment is further divided into three compartments by the superficial and deep transverse septa.

Anterior (Extensor) compartment of the Leg (7)

Boundaries	**:**	Lateral surface of shaft of Tibia
Anterior	**:**	Deep fascia of the leg
Medial	**:**	Lateral surface of shaft of Tibia
Lateral	**:**	Anterior Intermuscular septum

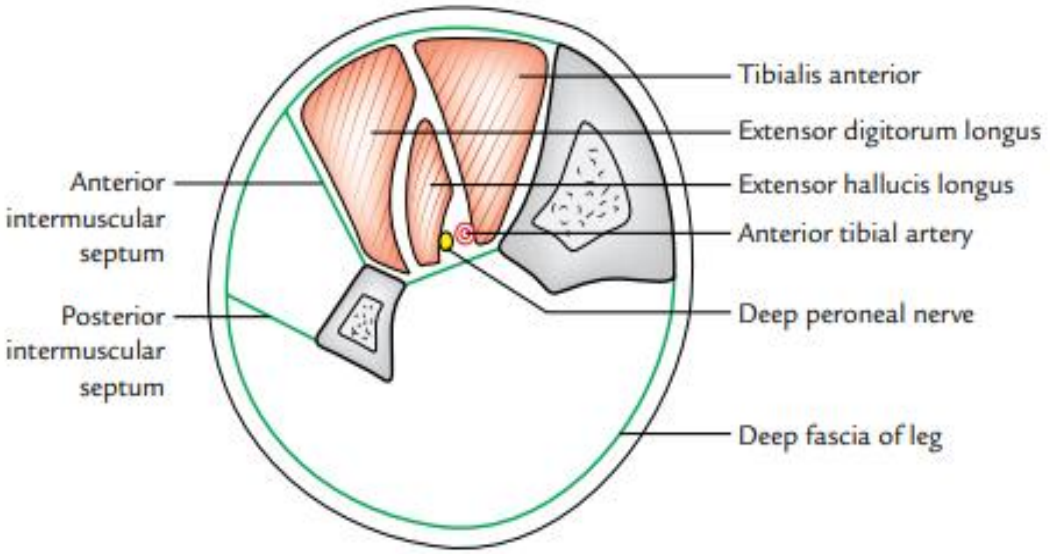


Fig 2 shows the boundaries and the compartments of the anterior compartment of the leg [7]

Contents

Muscles	Artery	Nerve
Tibialis Anterior	Anterior Tibial Artery	Deep Peroneal Nerve
Extensor Hallucis longus		
Extensor Digitorum Longus		
Peroneus Tertius		

Table 1: Contents of Anterior compartment of leg

Muscles of the Anterior Compartment of the leg

- All of the muscles of the anterior compartment have their origin from the fibula except Tibialis anterior that arises from the Tibia.
- Tibialis Major is the chief muscle of this compartment.
- All these muscles are supplied by the Anterior Tibial Artery and deep peroneal Nerve.
- The actions of these muscles are the dorsiflexion of the foot.

Tibialis anterior will be discussed in detail and the details of the other muscles are mentioned in the table.

Tibialis Anterior

It's a multipennate muscle.

Origin

- from the lateral surface of the upper 2/3 rd. of the tibia.

- Interosseous membrane.

- Distal part of lateral condyle of Tibia.

Insertion

- Medial Cuneiform.
- Adjacent part of the first metatarsal bone.

Nerve supply

- Deep peroneal Nerve.

Actions

- Chief dorsiflexor of the foot.
- Maintains the medial longitudinal arch of the foot.
- Inverts the foot at the midtalar or subtalar joint.

Muscle	Origin	Insertion	Actions
Extensor Hallucis Longus	Middle 2/4th of medial surface of shaft of fibula	Dorsal surface of distal phalanx of big toe	• Extension of Great toe • Dorsiflexion of foot
Extensor digitorum longus	Upper and middle part of anterior surface of fibula	Middle and distal phalanx of lateral 4 toes	• Dorsiflexion of foot • Extension of MP, PIP and DIP joints of lateral four toes
Peroneus tertius	Lower part of anterior fibula	Dorsal surface of base of 5th metatarsal	• Dorsiflexion of foot • Eversion of foot

Table 2 shows the origin and insertion of the muscles of the anterior compartment of the leg [7]

(a) (b)

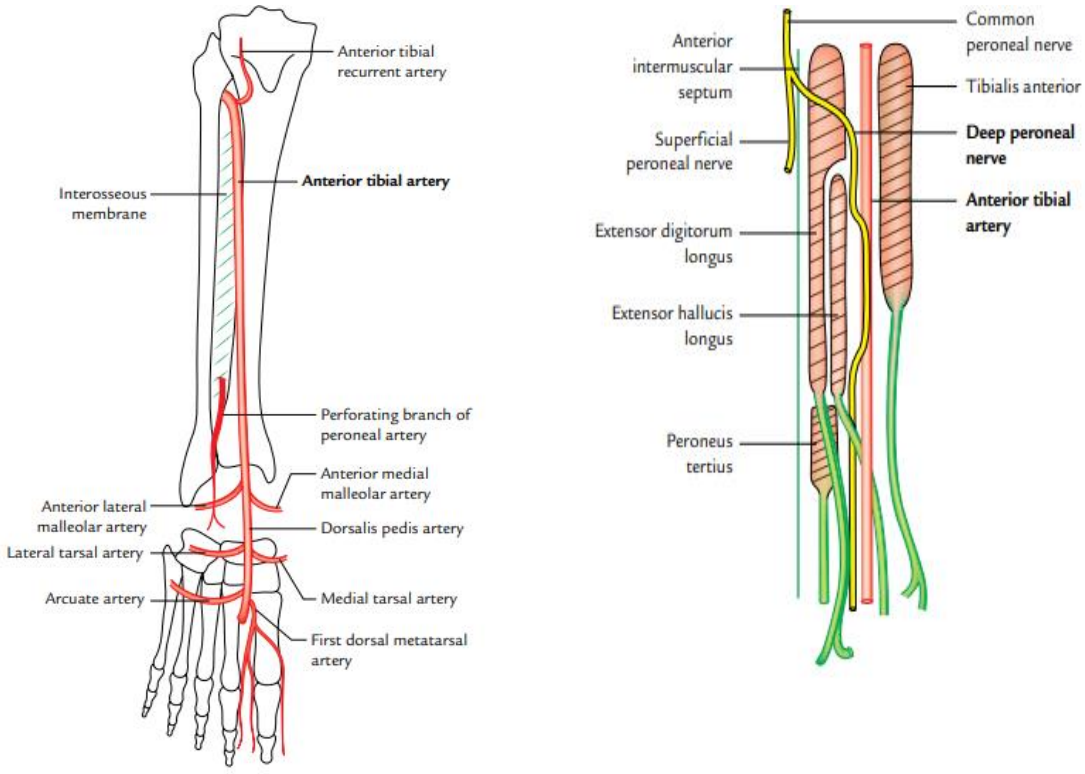


Fig 3 (a)& (b): Anterior Tibial artery and the relation of the deep peroneal nerve and the anterior tibial artery [7]

Anterior Tibial Artery

The blood supply of the anterior compartment of the leg is by anterior tibial artery and perforating peroneal artery. However, the anterior Tibial artery is the chief artery of the anterior compartment of the leg and the size of the perforating peroneal artery is inversely proportional to the size of the anterior tibial artery.

The anterior tibial artery is a branch of the Popliteal artery and starts at the lower border of the popliteus muscle. It later continues as the Dorsalis Pedis Artery.

Deep Peroneal Nerve

It is the nerve of the anterior compartment of the leg and the dorsum of the foot and it branches from the common peroneal nerve. It branches near the neck of the fibula. It accompanies the anterior tibial artery and it lies lateral to it along the middle and lateral 1/3 $^{rd.}$ of its course. The deep peroneal nerve lies anterior to the anterior tibial artery along the middle 1/3 $^{rd.}$ of the artery. The nerve divides into the medial and lateral terminal branches in front of the ankle.

Lateral Compartment of the Leg [8]

Boundaries

Anterior: Anterior Intermuscular septum.

Posterior: Posterior Intermuscular septum.

Medial: Lateral surface of the fibula.

Lateral: Deep fascia of the leg.

Contents

Muscles: Peroneus longus and Peroneus brevis.

Nerves: Superficial Peroneal Nerve.

Artery: No specific artery for the lateral compartment of the leg.

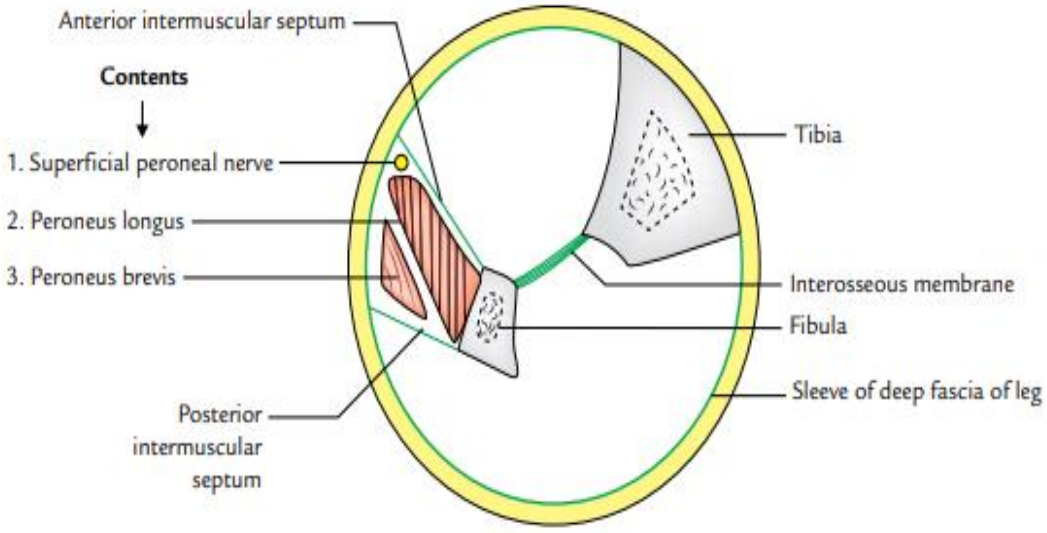


Fig 4 shows the Lateral Compartment of the leg [8]

Peroneal Muscles

Peroneus Longus

It is a longer and larger muscles. It is bipennate at the upper half and unipennate at the lower half.

It arises from the upper part of the lateral surface of fibula and the adjoining surfaces of head of tibia. From the point of origin, it fuses with the tendon of Peroneus brevis and it lodges itself into a groove behind the lateral malleolus and goes underneath the superior retinacula and downward and forward over the inferior retinacula and then go below the peroneal trochlea of the calcaneum. Then it changes the direction and goes in the Osseo fibrous tunnel of the cuboid and crosses from the lateral to the medial side and gets inserted into the inferolateral surface of the base of the first metacarpal and the adjoining medial cuneiform. The muscle is supplied by the Superficial Peroneal Nerve.

The actions of the muscle are

1. Chief evertor of the foot.

2. Maintains the Lateral Longitudinal arch of the foot.
3. Maintains the transverse arches of foot.

Peroneus Brevis

It is a fusiform bipennate muscle that lies deep to the peroneus longus muscle and originates from the lower 2/3 $^{rd.}$ of the lateral surface of the fibula. It then lies in the groove behind the lateral malleolus and underneath the superior peroneal retinacula and then the inferior peroneal retinacula and gets inserted on the tubercle on the lateral side of the base of the 5th metatarsal.

It is supplied by the superficial peroneal nerve.

Its action is eversion of foot and it maintains the lateral longitudinal arch of the foot.

Superficial Peroneal Nerve

It is also known as the Musculocutaneous Nerve of the leg.

It is the chief nerve of the Lateral compartment of the leg.

It is one of the branches of the common peroneal nerve and it arises at the neck of the fibula in the substance of the peroneus longus muscle.

At the terminal portion it divides into the medial and lateral terminal branches that supply the dorsum of the foot and it branches in front of the ankle.

Medial side of the leg

Medial side of the leg consists of the medial surface of the tibia and the upper portion gives attachment to the Tibial collateral ligament and the tendons of Gracilis, Sartorius and Semitendinosus. All of these structures are covered with deep fascia. The Long Saphenous vein and the Saphenous nerve lie in the superficial fascia. The medial surface of the tibia lies subcutaneous along most of the part except for lower 1/3 rd.

Posterior part of the leg [9]

The back of the leg is also called as the calf. It is the bulkiest of all three compartments of the leg and it contains bulky antigravity muscles.

The posterior compartment of the leg continues superiorly to the popliteal fossa and inferiorly to the sole of the foot.

Bony framework of the posterior compartment of the leg

The bony framework of the posterior compartment of the leg is made by the Tibia and Fibula joined by the Interosseous membrane and the posterior part of the Talus and the calcaneum. The posterior one-third of the calcaneum projects outward and is called the heel and this ends in a large medial process and this parts rests on the ground.

Superficial fascia of the posterior aspect of the leg

The superficial fascia of the posterior compartment of the leg contains the long saphenous vein, short saphenous vein and the cutaneous nerves.

Short Saphenous vein

The short saphenous vein is formed by the joining of lateral end of the dorsal venous arch and the lateral dorsal digital vein of the little toe. It ascends the posterior part of the leg behind the lateral malleolus and pierces the deep fascia and joins the popliteal vein.

It drains the lateral side of the ankle, foot and back of the leg. It is accompanied by the sural nerve along its lateral side.

Long Saphenous vein

It starts in the medial aspect of the foot and ascends above in front of the medial malleolus and lies postero-medially in the back of the leg.

Cutaneous Nerve of the Posterior part of the leg

The Superficial cutaneous nerves of the leg are

- Saphenous Nerve
- Posterior Division of the Medial Cutaneous Nerve of thigh
- Posterior Cutaneous Nerve of thigh
- Sural Nerve
- Sural Communicating nerve
- Lateral Cutaneous nerve of the calf
- Medial Calcaneal nerve

The saphenous nerve has a root value of L3, L4 and it accompanies the Great Saphenous vein. It supplies the skin of the medial surface of the leg, knee and the medial aspect of the foot.

Posterior Division of Medial Cutaneous Nerve of thigh has a root value of L2, L3 and supplies the uppermost part of the medial one-third of the calf.

Posterior Cutaneous Nerve of the calf. Its root value is S1, S2, S3. It supplies the uppermost part of the intermediate area of the calf.

Sural nerve, has the root value of L5, S1, S2 and it accompanies the short saphenous system laterally and it supplies the skin of the lateral part of the leg, lateral part of the dorsum of the foot and the lateral side of the little toe.

Lateral cutaneous nerve of the calf, has a nerve supply of L4, L5, S1 and is a branch of the common peroneal nerve. It pierces the deep fascia near the lateral head of the Gastrocnemius and it supplies the skin on the upper 2/3rd of the lateral area of the leg.

Sural Communicating nerve, has a root value of L5, S1, S2 and is a branch of the common peroneal nerve. It supplies the posteromedial part of the lateral area of the calf.

Medial Calcaneal Branch, has a root value of S1, S2, a branch of the Tibial Nerve and it supplies the skin of the heel and the medial aspect of the sole of the foot.

Posterior compartment of the leg

Boundaries and Subdivisions

Anterior: Posterior surface of the Tibia, fibula, interosseous membrane and posterior intermuscular septum.

Posterior: It is bounded by the deep facia of the leg.

It is divided into three compartments namely superficial, middle and deep by the superficial transverse septum and the deep transverse septum.

The superficial transverse septum is attached medially to the medial border of the tibia and laterally it is attached to the posterior border of the fibula.

The deep transverse septum is attached medially just below the Soleal line and is attached to the posterior surface of the tibia and laterally it is attached to the medial crest of the fibula.

Superficial part- contains Gastrocnemius, Soleus and Plantaris.

Middle part-It consists of the Flexor Digitorum Longus, Flexor Digitorum Hallucis and the Posterior Tibial Vessels and Posterior Tibial Nerve.

Deep Part – It contains the Tibialis Posterior Muscle.

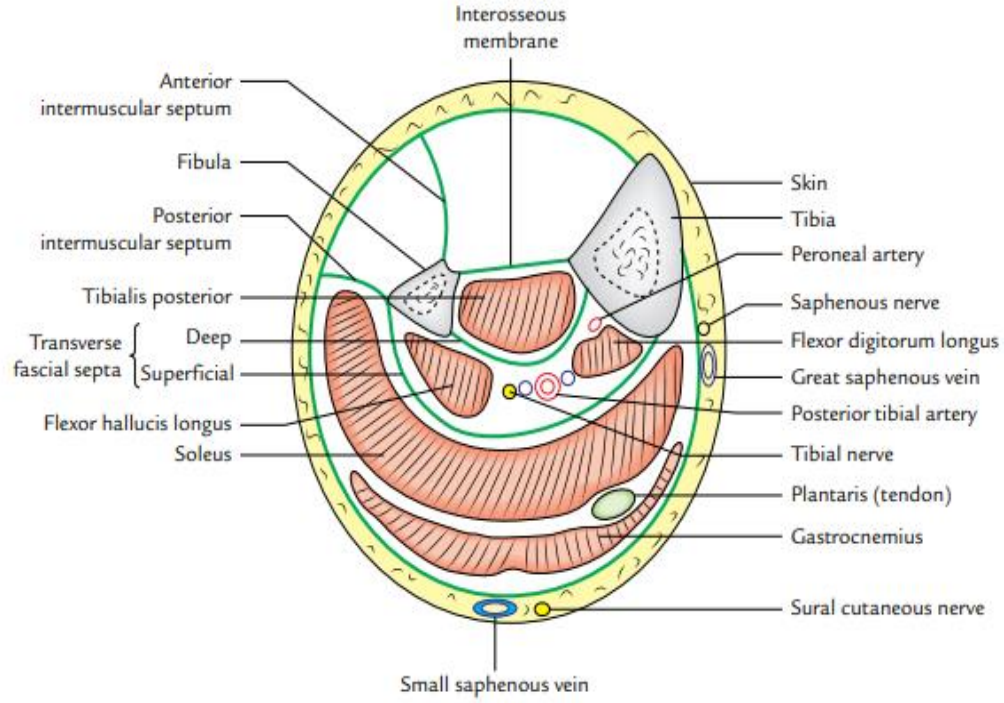


Fig 5 shows the posterior compartment of the leg [9]

Superficial Muscles of the back of the leg

Gastrocnemius

It is the largest muscle and has two head of origin – the medial head and the lateral head. The medial head arises from the medial condyle of the femur and the posterior surface of the shaft of femur. The lateral head is small and arises from the lateral surface of the lateral condyle of the femur and the adjoining part of the lateral supracondylar line. After its origin it forms a thin aponeurotic tendon and it joins with the tendon of soleus and forms the Tendoachiles which gets inserted in the middle of the posterior surface of the calcaneum. It is supplied by the Tibial Nerve. It provides fast movement while jumping and running. The chief action of the muscle is the plantar flexor of the foot when the knee is extended and it also helps in the flexion of the knee.

Soleus

Soleus is a multipennate muscle and it has a U shaped or horse shoe shaped origin. It originates from the posterior surface of the upper one-fourth of the shaft of fibula, soleal line, middle 1/3rd of medial border of tibia and the tendinous arch between Tibia and Fibula. It joins with the Gastrocnemius and forms the Tendoachiles and gets inserted into the middle part of the posterior surface of the calcaneum. It is supplied by two nerves of Tibial Nerve and the two nerves supply the superficial and the deep part separately. The soleus is the plantar flexor of the foot at the ankle and is called the workhorse of plantar flexion.

Plantaris

It is a muscle that has a short belly and long slender tendon and lies between the gastrocnemius and soleus muscle. It arises from the lateral supracondylar line and the adjoining part of the popliteal ligament. It gets fused with the Tendoachiles and gets inserted into the calcaneum. The plantaris muscle is vestigial in humans and can be absent in 5-10% of the population. Hence the plantaris tendon can be grafted. It is a weak plantar flexor of the foot.

Deep muscles of the foot

The deep muscles of the foot include

- Popliteus
- Flexor Digitorum Longus
- Flexor Hallucis longus
- Tibialis posterior

The Origin, Insertion, Nerve supply and the actions of the muscle are tabulated below:

Muscle	Origin	Insertion	Nerve Supply	Action
Popliteus	Popliteal groove on the lateral condyle of femur	Medial 2/3rd above soleal line and posterior surface of tibia	Tibial Nerve	• Unlocks the knee joint
Flexor digitorum longus	Medial part of the posterior surface of Tibia below soleal line	Plantar surface of distal phalanx of lateral 4 toes	Tibial Nerve	• Plantar flex lateral 4 toes • Plantar flex the ankle
Flexor hallucis longus	Lower part of posterior surface of shaft of fibula	Plantar surface of the base of great toe	Tibial Nerve	• Plantar flexes the great toe • Weak plantar flexor of ankle
Tibialis Posterior	Upper 2/3rd of lateral part of Tibia Posterior Surface of fibula	Tuberosity of the Navicular bone	Tibial nerve	• Invertor of the foot

Table 3 shows the origin, insertion, nerve supply and actions of the deep muscle of the posterior part of the leg [9]

Posterior Tibial Artery

The popliteal artery branches of into a larger posterior tibial artery and supplies the posterior and lateral compartment of the leg and the sole of the foot. It begins at the lower border of the popliteus muscle, deep to the gastrocnemius and deep to the tendinous arch of the soleus. In leg it runs downwards and medially to reach the posteromedial surface of the ankle, midway between the medial malleolus and the medial tubercle of the calcaneum. It terminates deep to the flexor retinaculum into a large lateral plantar artery and a small medial plantar artery. It is accompanied by the Tibial Nerve and it crosses from the medial to lateral side. The main branch of the posterior tibial artery is Peroneal Artery.

Peroneal Artery

It is the largest and the most important branch of the Posterior Tibial Artery and it arises 2.5 cm from the lower border of the popliteus muscle. It descends along the medial crest of the

fibula and between the Tibialis posterior and flexor hallucis longus. It ends on the lateral surface of the calcaneum and terminates as the lateral calcaneal arteries. It supplies the posterior and lateral compartment of the leg.

Tibial Nerve

It is one of the largest branches of the Sciatic Nerve. It arises on the back of the thigh at the junction of the upper 2/3rd and lower 1/3rd and enters the popliteal fossa. It has the same course as the posterior tibial artery. In the leg the nerve initially lies lateral to the artery and then it crosses posterior to the artery from the medial to the lateral side and lies lateral to the artery.

Lower Limb Amputation – Epidemiology, Principles and Techniques

Disability can be defined in Various ways and one among them is loss of health which includes mobility, cognition, hearing and vision [(10)]. An estimate of 10% of the world's population suffer from disability [(11)]. Amputation contributes to this and is one of the ancient forms of surgical treatment. Amputations are indicated in a lot of conditions like Peripheral vascular disease, Gas Gangrene, Diabetic Foot Syndrome with Ascending sepsis, Tumors and Trauma [(1,2)]. Currently there is a rise of peripheral vascular disease-causing major limb amputations in developing countries [(12)].

Ascending sepsis and major limb amputation

One of the most common causes of Ascending sepsis leading to amputation is Diabetic malperforans ulcers with normal circulation without proper treatment harbor florid infection. This in turn leads to major limb amputation.

India had become the diabetic capital of the world and almost 35 million people are affected by diabetes and is expected to raise to 80 million by 2030 [(13)]. Amputation among Diabetics is more common than the non-diabetics and the amputation is almost always preceded by a foot

ulcer. Diabetics are 15 times more at risk for major lower limb amputation than non-diabetics. [14]

The development of a foot ulcer is multifactorial and the commonest causes are infection, neuropathy, microangiopathy, altered biomechanics of the foot and poor foot hygiene. In a Multicentric trial conducted in India, the most common cause of amputations was found to be infections [15]. In those Amputations, trans-tibial was the commonest, accounting for 50% of the major lower amputations, followed by trans-femoral in 11.9% cases. Up to 30 percent of the amputee population undergo contralateral lower limb amputation within 3 years of the initial amputation [16].

General Surgical Principles of Amputation

- Arterial perfusion and bone architecture to be assessed.
- All tissue to be handled with atraumatic technique.
- All nonviable and infected tissue to be excised.
- Minimize blood loss by applying torniquet.
- All sharp bone edges and fragments to be eliminated.
- Minimal number of cuts across muscle.
- Nerves sharply transected and is allowed to retract.
- Electrocautery use to be minimized.
- Wounds closed under no tension.
- Myodesis or myoplasty is to be performed to stabilize antagonistic muscle groups.
- Dead space is reduced with the use of drains.
- Prophylaxis for deep venous thrombosis to be given [17].
- Prophylactic antibiotics administered [18].

- Weight bearing to be avoided until adequate wound healing has occurred.
- Protective soft and rigid dressings to be used.
- Excessive cosmetic tailoring of wounds should not be attempted [19].
- Barrier and adhesive drapes are used to isolate infected or gangrenous tissue [20].

Technical aspects of Transtibial amputation

The ideal stump length is between 12cm to 18cm. As it may vary according to height, the rule of thumb is to give a 2.5cm bone length for every 30cm of height. An acceptable length is at least 15cm distal to the medial tibial articular surface. It is important to preserve the limb length as much as possible because the energy expenditure associated with reduced limb length following major limb amputation is very high compared to minor amputations. This is supported by the study of Waters et al which compared the energy costs of walking with major and minor limb amputation [5].

On comparing with controls, the energy expenditure associated with minor amputations resulted in better performance and lower energy expenditure. Hence it is confirmed that the lowest level of amputation is required when importance is given to providing a functional limb [5]. The skin incision is to be made such a way that the skin flaps have adequate vascularity to undergo primary healing, and that the healed scar doesn't lie exactly over the tibia so that it doesn't breakdown when a prosthesis is used.

Techniques of Transtibial Amputations

Various techniques of transtibial amputations have been described to provide a strong and a functional limb post amputation and healing of the suture line must also be taken into consideration. The higher the level of Amputation provides a better healing but it is associated with more morbidity and mortality and is associated with difficulties in rehabilitation [22]. The following techniques have been described in literature for transtibial amputation.

- Burgess Long posterior Flap technique
- Skew flap technique
- Sagittal flap techniques
- Medial flap techniques
- Fish Mouth flap

Long posterior flap is the standard technique used for transtibial amputation.

Sagittal flap

In case a long posterior flap is not possible then a sagittal or a skew flap is fashioned. It was described by Persson [23]. In this an equal length of medial and lateral myocutaneous. Myoplasty is performed to cover the tibia by suturing the anterior and lateral compartment to the medial component of the gastrocnemius and soleus. The scar lies directly on the anterior crest of the tibia and is prone to breakdown. It shows no difference over a posterior flap [24]

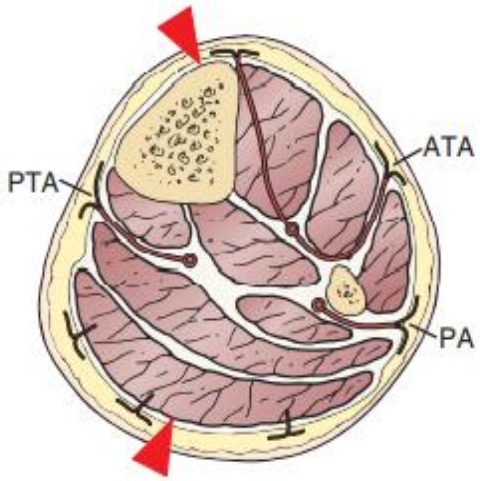


Fig 6 shows the plane of incision for sagittal flap technique [21]

Fish mouth flap

It was the technique that was followed before long posterior flap technique. It contains the creation of an anterior and posterior technique and was the most common technique of transtibial amputation before long posterior flap technique. The disadvantage of this technique is the vulnerability of the anterior flap to ischemia. [21].

Medial Flap technique

(a) (b)

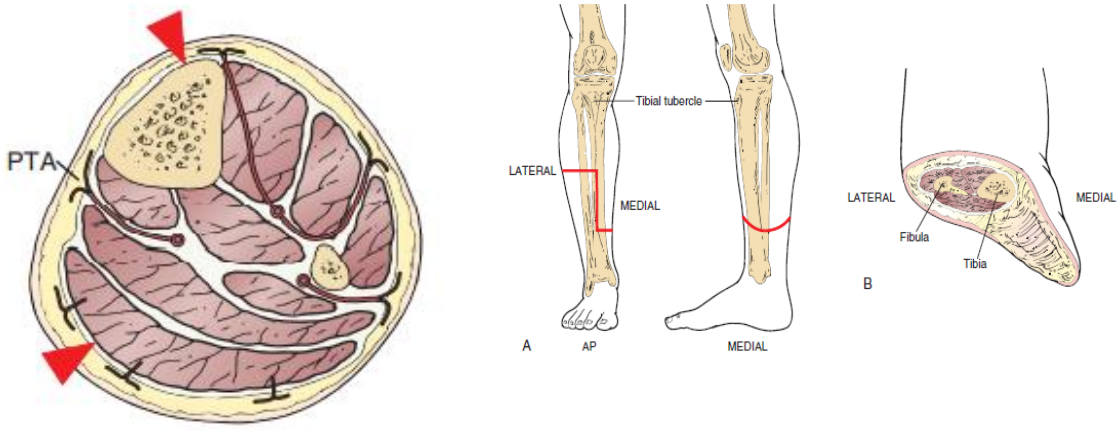


Fig 7 (a) & (b) shows the incision for medial flap technique [21]

This technique was described by Jain and colleagues [25]. Based on Thermographic findings, a long medial flap and a short lateral flap are designed.

Since we will be comparing the long posterior flap and the skew flap in this trial, we will be looking at the in a detailed manner.

Long Posterior Flap Technique

The posterior flap technique is being done since 1956[31], but was popularized by Burgess et al and is the most commonly used technique [26-28]. The posterior skin flap is based on the

gastrocnemius muscle surface by perforating arteries [6]. The tibia should be cut minimum at a distance of 12-15cm from the tibial tuberosity to create a stump that has favorable biomechanics so that the amputee can ambulate well with the prosthetics. However, the level of amputation is decided by the presence /absence of infection, the vascular supply to that region, and scarring of the tissue.

- The anterior part of the incision should be 2/3rd of the leg circumference.
- The length of the posterior flap is 1/3rd of the circumference (Fig8a).
- The skin, subcutaneous and fascia are incised along the transverse incision anteriorly before extending it to the posterior part.
- The anterior compartment muscles are divided first and then the lateral compartment muscles are divided.
- The anterior tibial vessels and the deep peroneal nerve are ligated in continuity and cut. The deep peroneal nerve is transected at the highest level possible and is allowed to retract proximally away from the wound.
- The periosteum of the tibia is elevated and the tibia is cut 3-5 cm from the edge of the skin flap. The periosteum is once again elevated for a length of about 1 cm from the cut edge of the tibia.
- Rounding of the cut edge of the tibia should be done with careful consideration to prevent high unit pressure on any left-over sharp edge.
- The fibula is transected at 2-3 cm higher than the tibia. The fibula should not be cut at much higher level than this as it can lead to the formation of a conical stump that will not be an ideal fit for the prosthesis.

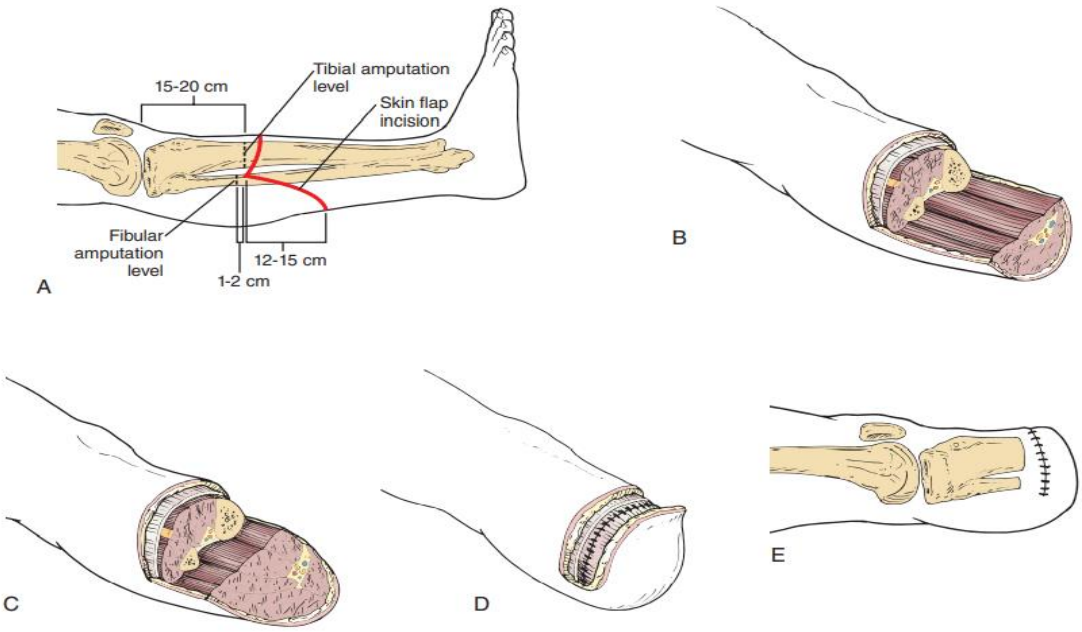


Fig8 (a), (b), (c), (d)& (e) shows the various steps in Burgess technique of transtibial amputation [21]

- A large amputation knife is used to create the posterior flap deep to the posterior surface of the Tibia and Fibula. The posterior compartment muscles are preserved as much as possible so that the gastrocnemius soleus muscle flap can be fashioned according to the required length at a later point of the procedure.
- The posterior tibial pedicle is identified and ligated. The tibial nerve is transected at the highest level possible and is allowed to retract.
- The posterior myocutaneous flap containing the soleus and the gastrocnemius muscle is cut in a beveled manner (Fig 8c) and is sutured to the anterior tibial periosteum and anterior deep fascia of the leg (Fig 8d).
- Before closure the wound is washes to remove of the debris and dust that had formed after the sawing of the bone.

- The moderately bulbous stump will slowly contour into an ideal cylindrical stump following postoperative rigid dressings [26].
- The skin incision is then closed using simple or mattress sutures using 1/0 ethilon.
- Drainage of the stump can be optional and it can be done using a through and through Penrose drain, or suction drain and in some cases no drainage is required [26].
- The entire procedure is to be done to produce an ideal cylindrical stump and a scar that is non adherent, non-tender and withstand properly and comfortably to wear a total contact socket prosthesis (Fig8e).

The advantage of this flap is that the myoplasty of the gastrocnemius and soleus muscle aids in venous return and helps in flexion of the knee. The other advantage of the procedure is that it provides an ideal stump for many of the prosthesis. However, in certain conditions there is a disadvantage that the stump becomes more bulbous and there is an increase in the transverse diameter of the amputated stump. Another potential disadvantage is ischemia to the anterior flap [21].

These disadvantages were overcome by the skew flap technique described by Robinson in the year 1991 based on thermographic studies.

The Skew flap Technique

The skew flap technique was described by Robinson in the year 1991. It was made to overcome the disadvantage of long posterior flap technique in terms of a bulbous postamputation stump that requires time to be shaped into a cylindrical stump needed for the effective fitting of the prosthesis [26]. At the same time, the skew flap can be used when a long posterior myocutaneous flap cannot be fashioned [21].

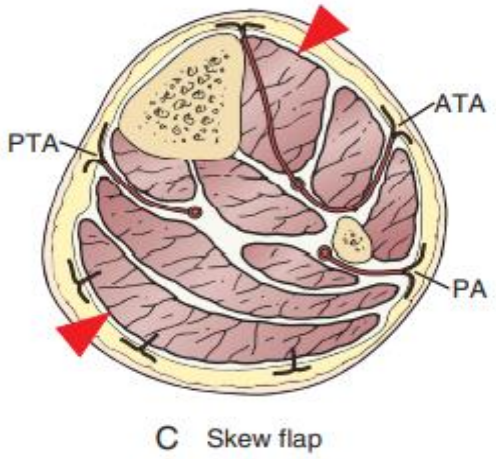


Fig 9 shows the skew flap incision in cross sectional view [21]

The skew flap can also avoid the breakdown of the wound by displacing the scar from the anterior crest of the tibia, where the scar of the Sagittal flap technique usually lies [6].

However, the displacement of the scar makes it difficult to construct a myocutaneous flap. Hence the skew flap is a myoplastic flap and the skin flaps are constructed based on the Saphenous artery and the sural artery respectively [29,30]. This leads the construction of an equal length posteromedial and anterolateral flaps are obtained.

Method of the skew flap technique

The perineum is isolated and under general/ regional anesthesia, parts are painted and draped. The patient is in supine position.

The skin incision is marked as follows [6]

- The site of transection of the bone is selected 10-15 cm from the tibial plateau. The minimum stump length for amputation is such that the stump extends 3 cm below the flexor tendons of the knee when the knee is in 90-degree flexion.

- A scar is marked 2 cm lateral to the tibial crest and this marks the anterior point of the incision. The tape is now folded in half and marked to find the posterior point of the incision.
- The measuring tape is now quartered to find the midpoint of each flap and used to mark the limit of the semicircular flap.
- A 2 cm proximal extension of the scar is made to give a better access to the anterior tibial compartment.

After marking the skin incision, the incision is deepened in layers, the skin and subcutaneous tissue is cut up to the deep fascia.

The long saphenous vein and the short saphenous vein are identified, ligated and cut. The related arteries are preserved and the sural and saphenous nerve are transected at the highest level.

The anterior scar is retracted to expose the anterior tibial compartment. The muscles of the anterior tibial compartment are cut until the anterior tibial pedicle. The anterior tibial pedicle is dissected and the anterior tibial vessels are ligated and cut. The deep peroneal nerve is cut at the highest level under traction and is allowed to retract. Next the lateral compartment muscles are dissected and The Peroneus Longus and the peroneus brevis muscles are divided. The Superficial Peroneal Nerve or the Musculocutaneous nerve of the leg is transected with sharp cut. Fibula is transected about 2 cm at a higher level than the tibia. The tibia is transected at the previously marked level.

The posterior flap with gastrocnemius and soleus is fashioned by holding the amputation knife deep to the plane of the posterior surface of tibia and fibula and soleus and gastrocnemius are cut at the lowest level possible. This can be refashioned in terms of length depending on the length of the flap that is required for the myoplasty. The lateral ends of the gastrocnemius flap

are shaved on either side and mad to taper towards the end to avoid the bulbous nature of the stump at a later date.

The bleeding from the soleal venous sinuses is controlled with underrunning stitches. The posterior tibial vessels are ligated and cut and the Tibial nerve is transected at a higher level under traction and is allowed to retract.

The cut ends of the Tibia and Fibula are smoothened to avoid any sharp bony edges. The bony debris post smoothening is washed of before closure.

The myoplasty is done by folding the gastrocnemius soleal flap over the tibia and it is trimmed so that it meets the anterior tibial fascia and the anterior tibial periosteum. The Gastrocnemius and soleus are then sutured to the anterior deep fascia and the anterior periosteum with or without drain placement neat the cut ends of the bone. The skin flaps are then sutured with minimal redundancy using 1/0 ethilon in simple or mattress sutures.

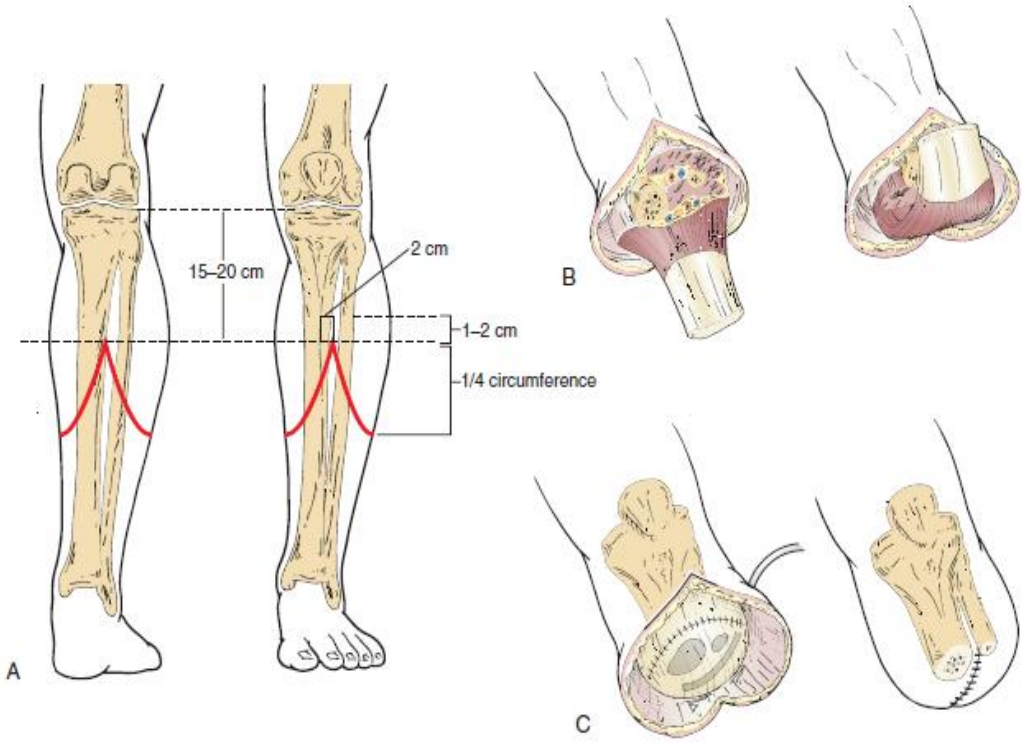


Fig 10 (a), (b) & (c): Technique of Skew flap in Transtibial Amputation

Postsurgical care [6]

- Mild opiates and sedatives are required for the relief of the pain.
- The weight bearing can start as early as the 2nd postoperative day.
- Activity to be increased daily as much as the condition of the patient permits.
- Patient should never be allowed to ambulate independently.
- 48 hours after the procedure the drain is removed.
- The sutures are removed 10-14 days after surgery.
- The antibiotics were continued for 5 postoperative days and depending on whether the patient has surgical site infection, if so, the antibiotics are continued based on culture and sensitivity.

Postoperative complications

Postoperative complication in Transtibial amputation include

- Complications due to transtibial amputation.
- Complications due to the coexistent comorbidities.

Below knee amputations are associated with a lesser mortality rate when compared to above knee amputation [32]. The percentage of mortality in below knee amputation is around 5-10% and the mortality associated with above knee amputation is around twice that value around 10-17%. [33].

The complications that can arise include cardiac and pulmonary complication, pressure sores due to immobilization, sepsis, wound infection, revision surgery and Deep vein Thrombosis. The risk of deep vein thrombosis after lower extremity amputation increases by 50% and hence chemoprophylaxis needs to be given [34-37]. The below knee amputation is associated with a higher percentage of improper wound healing due to the impaired microvascular circulation

and it is highly imperative to determine the amputation level appropriately [38]. The stump infection is usually managed conservatively and is managed surgically with amputation when there is a stump infection along with compromised vascularity. Previous records in literature show that below knee to above knee amputation conversion rates is around 14.3% [32].

Ulcers are other common complication following transtibial amputation. They usually occur at the site of bony prominences and are seen in the anterior part of the tibia in transtibial amputation [39]. This occurs more frequently when the skin overlying the stump is not taken care of properly. Hence maintaining stump hygiene is highly essential. There is no significant difference in the wound sepsis rate between diabetics and non-diabetics [40].

Contractures, after transtibial amputation 3 to 5 % of the patients develop flexion contractures of the knee and hip joint [21]. To prevent these rigid dressings, need to be applied postoperatively.

Chronic Pain, is experienced by 95% of the amputees who had undergone transtibial amputation [41]. It cannot be detected by physical examination, but can be detected by Transcutaneous Oxygen levels when below 20mm Hg. It can be due to neuroma or pressure points formed on the bone ends. Inadequate control of pre and postoperative pain is associated with increased risk of chronic pain post amputation [37].

Phantom Limb pain, has been described as a burning, aching and electrical type of pain at the site of amputation and it occurs in around 49-88% of the amputees [42]. It was first described by Ambroise Pare.

There are three distinct elements to the Phantom Limb pain

- Pain sensation that are being referred to the amputated limb
- Sensation other than pain being referred to the amputated limb

- Pain localized at the stump site.

The pathogenesis that are described for the generation of the Phantom limb pain are

- Formation of a neuroma.
- Spontaneous activity on mechanical or chemical stimulation due to upregulation of sodium channels.

Neuromas can be prevented by avoiding crushing of the nerves before transection. Gabapentin given for the treatment of phantom pain is inconsistent in reducing postoperative pain.

Characteristics of Residual Lower Limb

Once the amputation is done and reconstruction of the limb is done, the next and final stump of the treatment includes the Rehabilitative measures that mainly include mobilization with prosthetics.

Adequate fitting of the soft tissue stump to the socket occurs when the amputation stump achieves the adequate stump shape, volume, scarring from the surgical wounds, sensitivity and tissue composition. This is in turn dependent on Temperature, tissue hydration, activity, muscle atrophy, postoperative edema and tissue remodeling. All these factors contribute to the ideal fitting of prosthesis and the stump.

An ill-fitting prosthesis can lead to injury of the stump site and other degenerative musculoskeletal changes like osteoarthritis, osteoporosis and low back ache [(43)]. In a transtibial amputation stump, the tibial plateau, the anterior surface of the tibial shaft, and the patellar tendon becomes the primary load bearing surfaces. Hence it is imperative to maintain an adequate residual limb length to maintain an adequate load transfer.

The Anatomical factors that are considered in maintain adequate load transfer in an amputation stump are

- Length of the residual limb.
- Range of motion of the proximal joint.
- Presence of deformities or contracture.
- Skin Condition at the stump site.
- Volume of the amputation stump.
- Position of the scar and its status.

The length of the residual limb is an important factor and depending it, they are categorized into three types [44]

Long – 80% of length is preserved.

Medium- 50% of the length is preserved.

Short – 30% of the length is preserved.

Hence an ideal stump must have the following characteristics

- The limb length should be ideal.
- Effective skin and muscle cover should be given to cover the bony prominences.
- The suture line should have no evidence of seroma, oedema, surgical site infections or wound gaping.
- There should be no neuromas on the suture line.
- The joint proximal to the amputation should be free of contracture or deformity and should have full range of movements.

Based on this the length of the residual stump and the healed scar site are few of the many factors that are involved in the ideal socket and stump fitting and give a good alignment for adequate weight bearing.

The latest review of literature on the type of incision and its outcome on the below knee amputation stump was published in 2014[45]. The main focus of this review was to assess the efficacy for skew flap techniques and long posterior myocutaneous flap. The study included randomized controlled trial studies conducted between 1977-1991 and it includes 309 participants. The skew flap technique or the sagittal flap technique of the below knee amputation has no benefit in terms of primary wound healing over the long posterior myocutaneous flap and the percentage of wound healing reached up to 60%. Postoperative infection rate, Reamputation rates, rate of wound necrosis and mobility with a prosthetic limb, the secondary objectives of the review showed almost similar rates among different comparisons. The latest review i.e., the 2014 update of the Cochrane review also showed that the there was no difference between skew flap and long posterior flap technique on factors like primary wound healing, revision rates and prosthetic fitting rates [45]. However, this was based on the single multicenter joint trial by Joint Vascular Research Group study by Ruckley in the year 1991. Recent studies are lacking and hence a Randomized Controlled trial comparing the efficacy between long posterior myocutaneous flap and skew flap technique was conducted in out tertiary care hospital at RGGGH, Chennai.

MATERIALS AND METHODS

Study design: Randomized Controlled Trial with single blinding.

Study duration: February 2021- February 2022.

Study center: Institute of General Surgery, Rajiv Gandhi Government General Hospital, Chennai-3.

Ethical Clearance: Applied.

Selection of Subjects: All patients indicated to undergo Transtibial amputation for Ascending foot sepsis.

Study population: 60 patients- 30 in each group.

Inclusion criteria:

All patients undergoing Transtibial amputation for Ascending foot sepsis without any age restriction.

Exclusion criteria:

- Patients who do not give consent.
- Patients undergoing amputation for vascular insufficiency.
- Patients undergoing Traumatic amputations.
- Patients undergoing Amputations for bone / soft tissue tumors.
- Patients who require amputations at higher level.

Ethics clearance: Approved.

Methodology:

60 consecutive patients presenting to Rajiv Gandhi Government General Hospital

- Patients who fit the inclusion criteria
- Consented to participate in the study

were included in the trial

All the participants who were included in the trial were Randomized based on the last digit of their hospital admission number assigned in the counter. It the last digit of the admission number was odd they would be assigned to undergo Skew flap technique and if the last digit of the admission number was even, they would undergo Long Posterior Myocutaneous flap technique.

Informed consent was obtained from the patients after they have read the patient information sheet.

The patients undergoing skew flap technique was categorized into Group S and the participants undergoing Long Posterior Myocutaneous flap technique was classified into Group L

Basic Biochemical Parameters of the participants undergoing the study was recorded.

The choice of anesthesia- Regional/General Anesthesia- was decided by the anesthetist based on the general condition of the patient.

With the patient in supine position, parts painted and draped. Based on the Randomization technique, people who were allocated to Group S underwent Transtibial amputation by Skew flap technique.

(a) (b)

Fig 11(a) &(b): Incision marked for Skew flap amputation

Fig 12: Completed Skew flap Amputation

The people who got allocated to Group L underwent transtibial amputation via Long posterior myocutaneous flap technique

Fig 13: Transtibial Amputation by Long Posterior Myocutaneous

In both the technique the skin flaps are closed with 1/0 ethilon in simple or mattress suture. The stump is covered with Gamgee pad and wrapped in a roller gauze. The soft dressing was kept in an above knee plaster of Paris slab. They were put on Antibiotics Injection cefotaxime 1g iv bd and Injection metronidazole 500mh iv tds for 5 days. If the patient developed sepsis the antibiotics were stepped up based on culture and Sensitivity reports. The wounds were opened on post operative day 2. Drains if placed are removed on the 2nd postoperative day.

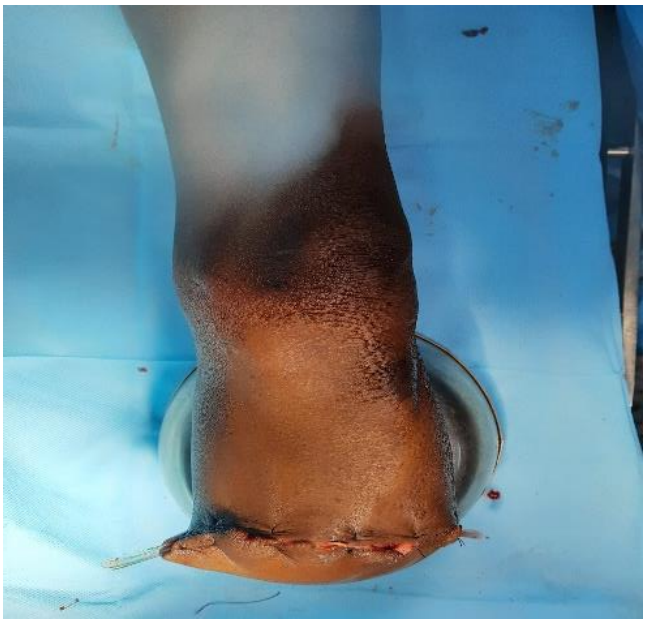


Fig 14: Postamputation stump after Long Posterior Myocutaneous flap

Cleaning and Compressive Dressing of the wound is done daily. Plaster of Paris slab is maintained till the 7th postoperative day. Ambulation is started as early as the 2nd day depending on the general condition of the patient using assistive support under supervision. Physiotherapy is started on the 2nd postoperative day. The suture line is assessed on postoperative day 7.

If the patient had healthy suture line and the comorbid conditions are under control patient was discharged subsequently. If the wound showed seroma formation, then compressive dressing with elastocrepe bandage was advised. If the flap showed signs of flap necrosis or ascending infection depending on the degree of necrosis and wound infection the patient was treated with wound debridement and secondary suturing and in certain cases to extreme measures like revision amputation at the same or higher level. Once the wound is healthy patient and the general condition improves the patient was discharged. After discharge the patient was reviewed every week for the 1st month and reviewed after that if any complaints arose. In case of Surgical site infection, the patient was readmitted and treated for the same.

(a)

(b)

(c)

(d)

Fig 15 (a), (b), (c)& (d): Suture line on Day 7

(a): Healthy Long Posterior Myocutaneous flap on Day 7.

(b): Seroma of the wound.

(c): Secondary wound infection treated with wound debridement and planned for secondary suturing.

(d): Healthy skew flap.

The death during the first 30-day period of Amputation and the length of the hospital stay was recorded.

The findings were recorded in an excel sheet and statistical analysis was done.

The results and discussion of which are as follows:

RESULTS & DISCUSSION

Demographic characteristics

Age Distribution

Age Distribution		
Age group (years)	**Frequency**	**Percentage (%)**
Less Than 36	4	5.97
36-40	3	4.48
41-45	10	14.93
46-50	12	17.91
51-55	9	13.43
56-60	13	19.40
61-65	5	7.46
66-70	7	10.45
Above 70	4	5.97
Total	67	100

Table 4: Age distribution in the study sample

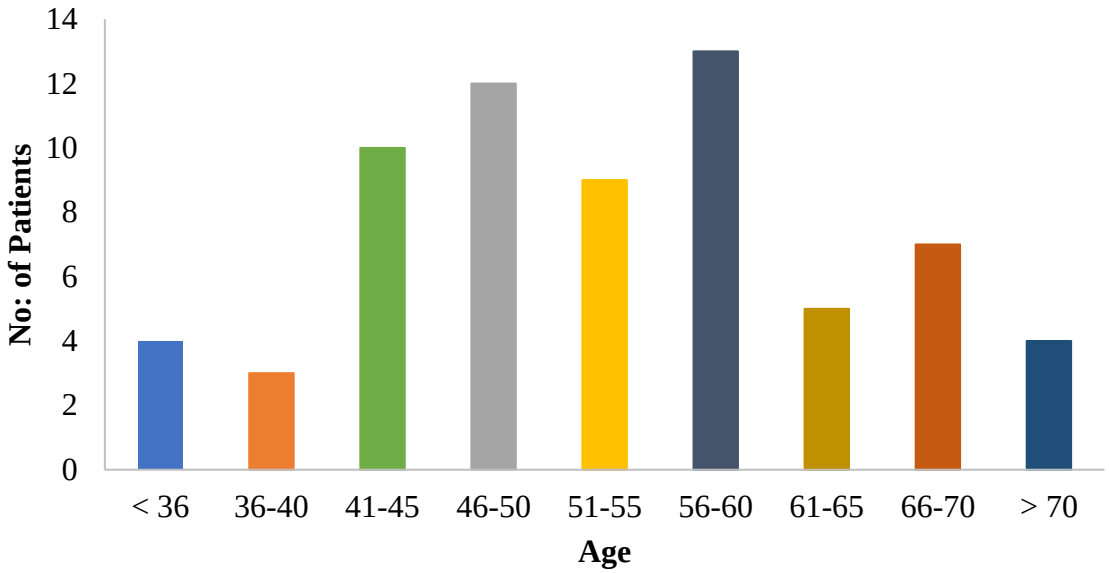


Fig 16: Age Distribution of patients selected for study

The study population includes people from the age of 25 to the age of 80. Majority of the population belong to the age group of 56-60 years and second and the third common

subgroup where 46-50 years and 41-45 years. These two subgroups account for almost 23% of the study population and they belong to the population who have productive years of their life left. Hence undergoing amputation during these productive years not only affects the person physically but also affects the person mentally and the family economically. Hence it is important to provide an adequate functional stump that heals primarily that is comfortable for early prosthetic fitting and rehabilitation, so that the individual can return to his normal life as early as possible.

Comparison between age and group

Age (Years)	Category		Total	Chi Squared	P Value
	L	S		$X^2 = \sum \frac{(O_i - E_i)^2}{E_i}$	$Z = \frac{\hat{p} - p_0}{\sqrt{\frac{p_0(1-p_0)}{n}}}$
Less Than 36	2	2	4		
36-40	1	2	3		
41-45	5	5	10		
46-50	2	10	12		
51-55	5	4	9	0.333	0.925
56-60	8	5	13		
61-65	4	1	5		
66-70	4	3	7		
Above 70	1	3	4		
Total	32	35	67		

Table 5: Distribution of age across the two comparison groups

X^2 – Chi Squared, O_i – observed value, E_i – expected value

$\hat{p}$ – Sample proportion, p_0 - assumed population proportion in the null hypothesis

In the analysis of distribution of age among the two groups. In the long posterior myocutaneous flap the largest subgroup of age was 56-60 years and the skew flap technique the largest subgroup of age was 46-50 years. The total number of patients in group L was 32 and the total number of patients in Group S was 35. The study included a total of 67 participants.

	Category	
	L	**S**
No: of patients	32	35
Mean age (years)	54.97	53.31
Standard Deviation	10.96	10.70
Unpaired T Test	0.62437	
P value	0.53	
P > 0.05, Hence not significant		

Table 6: Statistical Analysis of Age in the two study groups

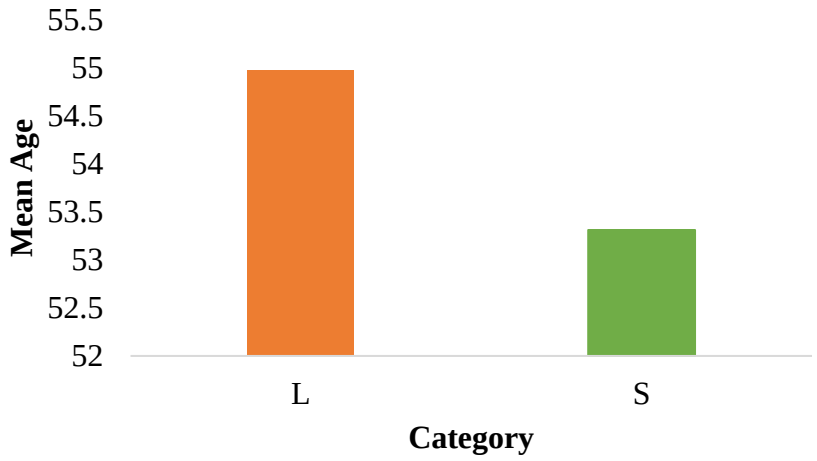


Fig 17: Mean of Age in the two categories of the trial

The mean age in the study Group L and Group S were 54.97 and 53.31 respectively and the standard deviation was 10.96 and 10.70 respectively. The P value for age in the two different groups were 0.53 which is statistically not significant.

Gender Distribution

	Frequency	Percent
Female	20	29.85
Male	47	70.15
Total	67	100.00

Table 7: Gender distribution in the study population

The study comprised 70.5 % male and 29.85 % females. Male: Female ratio for the study was 7:3.

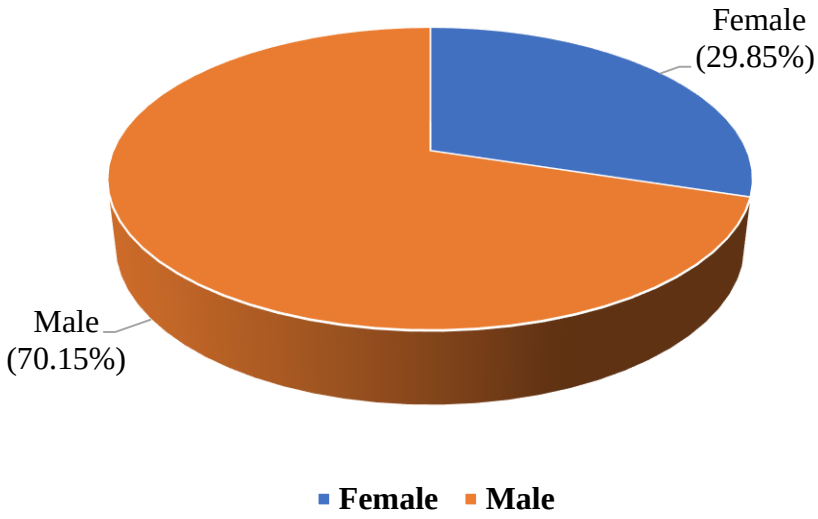


Fig 18: Gender distribution among the two groups

Gender	Category		Total	Chi Squared	P Value
	L (N=32)	S (N=35)	(N=67)	$X^2 = \sum \frac{(O_i - E_i)^2}{E_i}$	$Z = \frac{\hat{p} - p_0}{\sqrt{\frac{p_0(1-p_0)}{n}}}$
Female	11	9	20	0.44	0.74
Male	21	26	47		
Total	32	35	67		

Table 8: Distribution of Sex among the two groups

The p value for study of Sex distribution among two groups is 0.74(p value more than 0.05) is not statistically significant.

Analysis of Total count on admission

Sl.No.	Total Count			
	L		S	
	Age	Total count value	Age	Total count value
1	25	22600	38	30100
2	35	27700	38	22400
3	40	28500	40	24500
4	42	16700	40	20190
5	45	16500	41	26900
6	45	26400	44	38870
7	45	18800	45	24000
8	45	27100	45	16700
9	47	22250	45	22400
10	50	14500	47	15800
11	52	38000	48	23700
12	53	18400	48	16300
13	53	18700	49	29000
14	54	18700	49	32000
15	54	21800	49	17800
16	57	27000	50	13000
17	57	17500	50	19800
18	57	29000	50	34400
19	60	25000	50	32500
20	60	18900	52	3500
21	60	37600	52	26900
22	60	18000	55	18600
23	60	19700	55	18900
24	61	24700	57	28600
25	65	14700	58	19200
26	65	19600	58	22300
27	65	16400	59	21800
28	68	39900	60	23900

29	68	19800	62	23500
30	69	37100	68	18900
31	70	30000	68	2000
32	72	18400	70	24200
33	-	-	71	21500
34	-	-	75	34500
35	-	-	80	16600
Mean $\bar{x} = \frac{1}{n}\left(\sum_{i=1}^{n} x_i\right)$		7129.20		22436
Standard Deviation $\sigma = \sqrt{\frac{\sum(x_i - \mu)^2}{N}}$		23435.94		7754.96
Median $(X) = \begin{cases} X\left[\frac{n}{2}\right], \\ if\ n\ is\ even \\ \frac{\left(X\left[\frac{n-1}{2}\right] + X\left[\frac{n+1}{2}\right]\right)}{2}, \\ n\ is\ odd \end{cases}$		20800		22400
Mode $M = L + h\frac{(f_m - f_1)}{(f_m - f_1) + (f_m - f_2)}$		18400		18900
Minimum		14500		2000
Maximum		39900		38870

Table 9: Value of the Total count on admissions tabulated across the two groups. σ - population standard deviation, μ- the population mean, x_i- each value from the population, N- the size of the population, $\bar{x}$ – arithmetic mean, n - number of values in data set, X-

ordered list of values in data set, L- lower limit of the modal class, h- size of the class interval, f_m- frequency of the modal class, f_1- frequency of the class preceding the modal class, f_2- frequency of the class succeeding the modal class

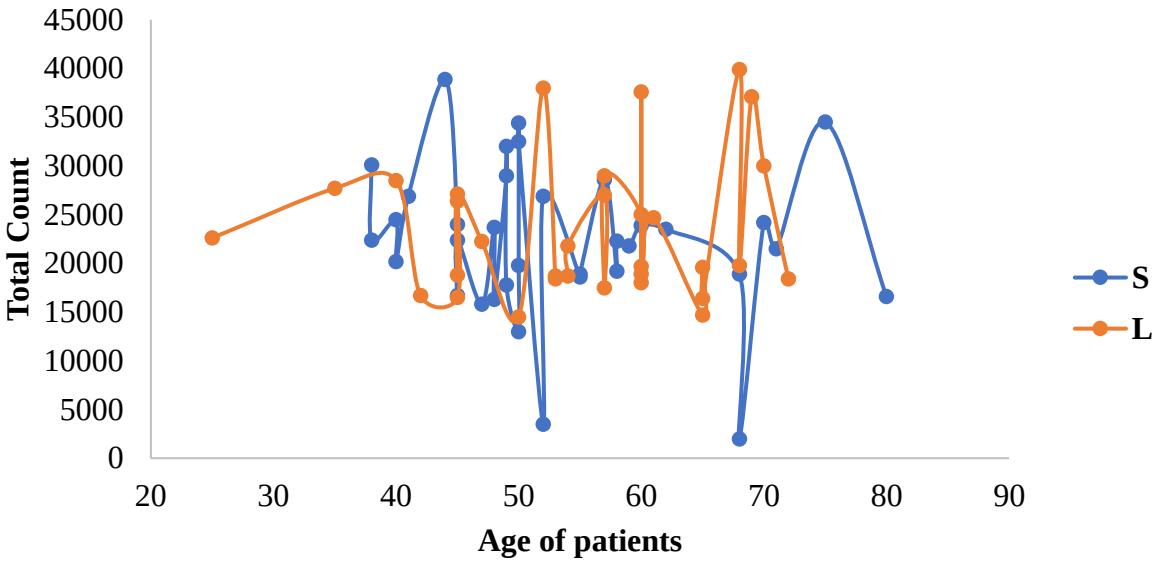


Fig 19: Distribution of Total count on admission of Group L and Group S through various age groups.

On Analysis of the Total count on admission, the mean total count on admission is 7129 in the Long Posterior myocutaneous flap group and the mean of the total leucocyte count on admission 22,436. However total leucocyte count on admission has not known to affect the status of the suture line.

The next parameter that was analysed was the haemoglobin levels on admission. Haemoglobin levels usually reflect on the nutritional status of the patient, however most of the patients included in our trial, have anaemia that is usually due to chronic disease and undergo serial debridement due to chronic ulcer.

Analysis of Haemoglobin on Admission

Sl.No.	Haemoglobin			
	L		S	
	Age	Haemoglobin count	Age	Haemoglobin count
1	25	11.2	38	9.8
2	35	12.8	38	6.8
3	40	7.2	40	10.2
4	42	8.6	40	8.6
5	45	9.2	41	10
6	45	9.2	44	9.5
7	45	10.1	45	11.8
8	45	9.5	45	8.8
9	47	9.5	45	8.6
10	50	13.4	47	7.1
11	52	11.2	48	9.8
12	53	7.8	48	8.5
13	53	6.4	49	9.8
14	54	8.8	49	10.2
15	54	8.6	49	11
16	57	7.8	50	7.3
17	57	8.8	50	11.3
18	57	8.9	50	11.1
19	60	9	50	7.5
20	60	8.9	52	9.8
21	60	5.8	52	9.7
22	60	8.7	55	7.9
23	60	9.2	55	10.4
24	61	9.6	57	10.2
25	65	9	58	8
26	65	10	58	9.2
27	65	10.1	59	13
28	68	11	60	6.2

29	68	9.6	62	9.8
30	69	7.8	68	9.2
31	70	9.9	68	8.9
32	72	10.3	70	8.1
33	-	-	71	10.8
34	-	-	75	7.8
35	-	-	80	11.7
	Mean $\bar{x} = \frac{1}{n}\left(\sum_{i=1}^{n} x_i\right)$	9.31		9.37
	Standard Deviation $\sigma = \sqrt{\frac{\sum(x_i - \mu)^2}{N}}$	1.57		1.56
	Median $(X) = \begin{cases} X\left[\frac{n}{2}\right], \\ if\ n\ is\ even \\ \frac{\left(X\left[\frac{n-1}{2}\right] + X\left[\frac{n+1}{2}\right]\right)}{2}, \\ if\ n\ is\ odd \end{cases}$	9.2		9.6
	Mode $M = L + h\frac{(f_m - f_1)}{(f_m - f_1) + (f_m - f_2)}$	9.2		9.8
	Minimum	5.8		6.2
	Maximum	13.4		13

Table 10: Value of Haemoglobin on admissions tabulated across the two groups.

σ - population standard deviation, μ- the population mean, x_i- each value from the population, N- the size of the population, $\bar{x}$ – arithmetic mean, n - number of values in data

set, X- ordered list of values in data set, L- lower limit of the modal class, h- size of the class interval, f_m- frequency of the modal class, f_1- frequency of the class preceding the modal class, f_2- frequency of the class succeeding the modal class

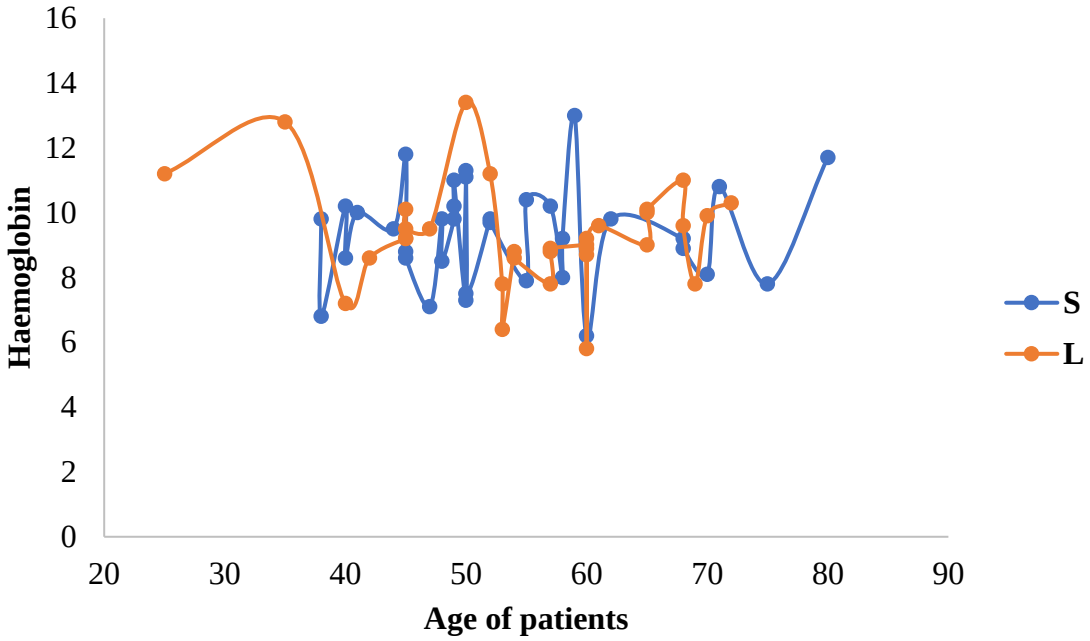


Fig 20: Distribution of the Haemoglobin levels across the two groups.

On analysis the mean value of Haemoglobin in the two groups was 9.31 and 9.37 respectively with a standard deviation of 1.57 and 1.56 respectively. The minimum and maximum values in the patients who underwent skew flap amputation are 5.8 and 13.4 respectively, while the minimum and the maximum values of the long posterior myocutaneous flap was 6.2 and 13 respectively. A schematic representation for the same is shown above.

The haemoglobin levels of these patients needed to be optimised using blood transfusion as they are in need of emergency surgery.

Since the patients included in the study are in sepsis their blood clotting parameters are usually deranged and the cell that is chiefly important for coagulation function are the platelets and they were analysed.

In sepsis there is both thrombocytopenia and reactive thrombocytosis. Even if the platelet counts are normal the function of the platelet is deranged and can led to excessive bleeding during surgery and which can give rise to postoperative complication.

Decreased platelet count usually occurs when the patient is in severe sepsis.

Here we have analysed the platelet count on admission and its distribution across the two groups.

Analysis of Platelets

Sl.No.	Platelets			
	L		S	
	Age	Platelet count	Age	Platelet count
1	25	1,95,000	38	1,20,000
2	35	3,82,000	38	1,85,000
3	40	3,80,000	40	3,50,000
4	42	3,40,000	40	1,40,000
5	45	2,20,000	41	2,70,000
6	45	2,80,000	44	78000
7	45	3,20,000	45	1,90,000
8	45	2,34,000	45	3,20,000
9	47	3,20,000	45	2,45,000
10	50	2,86,000	47	2,10,000
11	52	86,000	48	3,20,000
12	53	4,50,000	48	2,20,000
13	53	3,20,000	49	2,80,000
14	54	4,32,000	49	5,80,000
15	54	2,42,000	49	1,86,000
16	57	1,85,000	50	1,72,000
17	57	3,40,000	50	3,10,000
18	57	1,70,000	50	8,00,000
19	60	3,00,000	50	86,000

20	60	1,28,000	52	80,000
21	60	50,000	52	3,20,000
22	60	3,74,000	55	2,50,000
23	60	2,78,000	55	2,40,000
24	61	3,80,000	57	3,10,000
25	65	2,50,000	58	1,85,000
26	65	2,00,000	58	2,72,000
27	65	2,70,000	59	2,80,000
28	68	6,20,000	60	1,00,000
29	68	3,00,000	62	2,54,000
30	69	96,000	68	2,60,000
31	70	4,20,000	68	56,000
32	72	2,80,000	70	2,60,000
33	-	-	71	2,50,000
34	-	-	75	1,20,000
35	-	-	80	2,50,000
Mean $\bar{x} = \frac{1}{n}\left(\sum_{i=1}^{n} x_i\right)$		2,44,257		2,85,250
Standard Deviation $\sigma = \sqrt{\frac{\sum(x_i - \mu)^2}{N}}$		139465		117611.7
Median $(X) = \begin{cases} X\left[\frac{n}{2}\right], & if\ n\ is\ even \\ \frac{\left(X\left[\frac{n-1}{2}\right] + X\left[\frac{n+1}{2}\right]\right)}{2}, & n\ is\ odd \end{cases}$		2,50,000		2,83,000
Mode		320000		320000

$M = L + h\frac{(f_m - f_1)}{(f_m - f_1) + (f_m - f_2)}$			
Minimum	56,000		50,000
Maximum	8,00,000		6,20,000

Table 11: Value of Platelet on admissions tabulated across the two groups.

σ - population standard deviation, μ- the population mean, x_i- each value from the population, N- the size of the population, $\bar{x}$ – arithmetic mean, n - number of values in data set, X- ordered list of values in data set, L- lower limit of the modal class, h- size of the class interval, f_m- frequency of the modal class, f_1- frequency of the class preceding the modal class, f_2- frequency of the class succeeding the modal class

On analysis, the mean platelets in Group L and Group S were 2,44,257 and 2,85,250 respectively. The standard deviation of the population was 139465 and 117611.7 respectively.

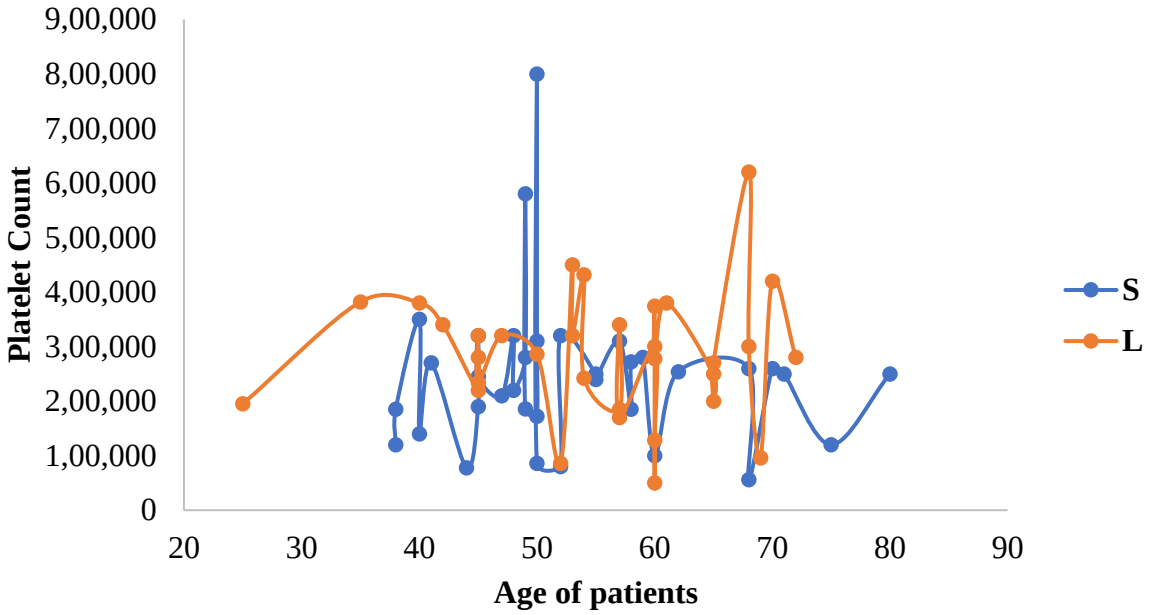


Fig 21: Distribution of platelets over the age in the two groups

Urea

Sl.No.	Urea			
	L		S	
	Age	Urea	Age	Urea
1	25	32	38	87
2	35	60	38	57
3	40	54	40	86
4	42	32	40	42
5	45	38	41	56
6	45	58	44	143
7	45	40	45	58
8	45	58	45	40
9	47	36	45	56
10	50	38	47	60
11	52	160	48	58
12	53	42	48	60
13	53	45	49	86
14	54	36	49	120
15	54	68	49	42
16	57	34	50	43
17	57	38	50	40
18	57	58	50	88
19	60	64	50	167
20	60	48	52	160
21	60	138	52	62
22	60	40	55	38
23	60	38	55	32
24	61	96	57	60
25	65	36	58	54
26	65	38	58	50
27	65	43	59	35
28	68	108	60	58
29	68	68	62	68

30	69	142	68	42
31	70	72	68	178
32	72	38	70	42
33	-	-	71	56
34	-	-	75	102
35	-	-	80	40
Mean $\bar{x} = \frac{1}{n}\left(\sum_{i=1}^{n} x_i\right)$		70.46		59.25
Standard Deviation $\sigma = \sqrt{\frac{\sum(x_i - \mu)^2}{N}}$		38.96		33.78
Median $(X) = \begin{cases} X\left[\frac{n}{2}\right], \\ if\ n\ is\ even \\ \frac{\left(X\left[\frac{n-1}{2}\right] + X\left[\frac{n+1}{2}\right]\right)}{2}, \\ n\ is\ odd \end{cases}$		58		44
Mode $M = L + h\frac{(f_m - f_1)}{(f_m - f_1) + (f_m - f_2)}$		42		38
Minimum		32		32
Maximum		178		160

Table 12: Value of Urea on admissions tabulated across the two groups.

σ - population standard deviation, μ- the population mean, x_i- each value from the population, N- the size of the population, $\bar{x}$ – arithmetic mean, n - number of values in data set, X- ordered list of values in data set, L- lower limit of the modal class, h- size of the class

interval, f_m- frequency of the modal class, f_1- frequency of the class preceding the modal class, f_2- frequency of the class succeeding the modal class

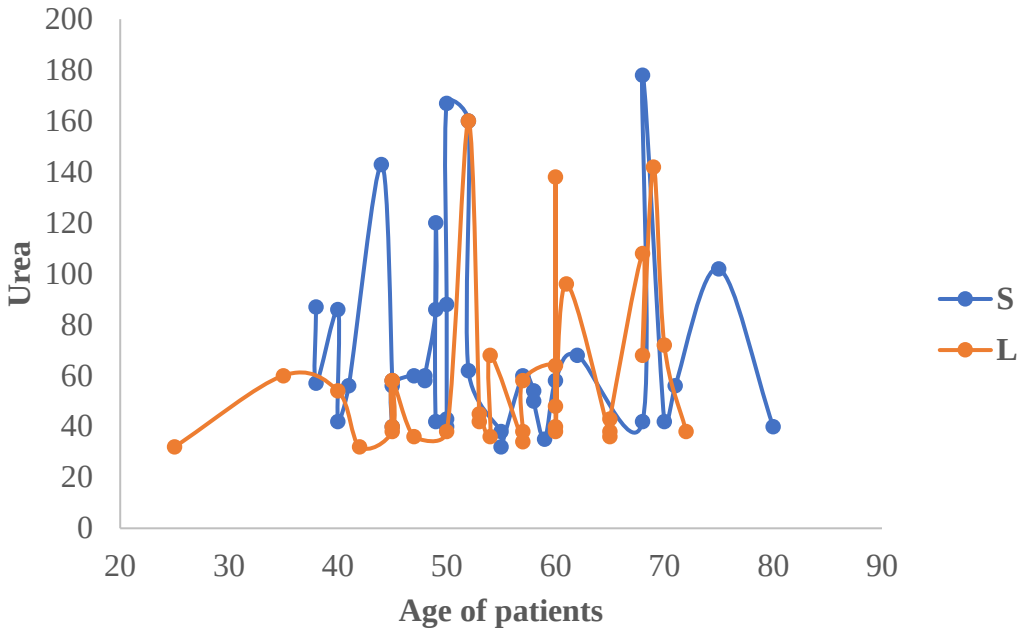


Fig 22: Distribution of Urea in the two groups across age

Creatinine

Sl.No.	Creatinine			
	L		S	
	Age	Creatinine	Age	Creatinine
1	25	1.8	38	0.7
2	35	1.6	38	1.1
3	40	1.7	40	1.3
4	42	0.6	40	0.6
5	45	1.3	41	0.6
6	45	2.6	44	1.2
7	45	1.3	45	0.6
8	45	1	45	1.2
9	47	1.4	45	0.6
10	50	1.2	47	0.5
11	52	0.9	48	3.8
12	53	1.8	48	0.6
13	53	1.6	49	0.5
14	54	2	49	0.6

15	54	0.7	49	1.3
16	57	0.7	50	0.7
17	57	0.5	50	0.7
18	57	1.4	50	1.2
19	60	3.4	50	1.2
20	60	4.8	52	0.6
21	60	1.2	52	0.6
22	60	0.6	55	3.2
23	60	0.4	55	0.6
24	61	1.4	57	2.2
25	65	1.3	58	0.4
26	65	1.3	58	1
27	65	0.7	59	0.7
28	68	1.8	60	2.5
29	68	1.1	62	1.6
30	69	0.6	68	3.8
31	70	5.8	68	1.7
32	72	0.8	70	0.7
33	-	-	71	0.7
34	-	-	75	1.1
35	-	-	80	1.3
Mean $\bar{x} = \frac{1}{n}\left(\sum_{i=1}^{n} x_i\right)$		1.52		1.21
Standard Deviation $\sigma = \sqrt{\frac{\sum(x_i - \mu)^2}{N}}$		1.13		0.93
Median		1.3		0.7

(X) $= \begin{cases} X\left[\frac{n}{2}\right], \\ if\ n\ is\ even \\ \frac{\left(X\left[\frac{n-1}{2}\right] + X\left[\frac{n+1}{2}\right]\right)}{2}, \\ n\ is\ odd \end{cases}$		
Mode $M = L + h\frac{(f_m - f_1)}{(f_m - f_1) + (f_m - f_2)}$	1.52	0.6
Minimum	1.13	0.4
Maximum	1.3	3.8

Table 13: Value of Creatinine on admissions tabulated across the two groups

σ - population standard deviation, μ- the population mean, x_i- each value from the population, N- the size of the population, $\bar{x}$ – arithmetic mean, n - number of values in data set, X- ordered list of values in data set, L- lower limit of the modal class, h- size of the class interval, f_m- frequency of the modal class, f_1- frequency of the class preceding the modal class, f_2- frequency of the class succeeding the modal class

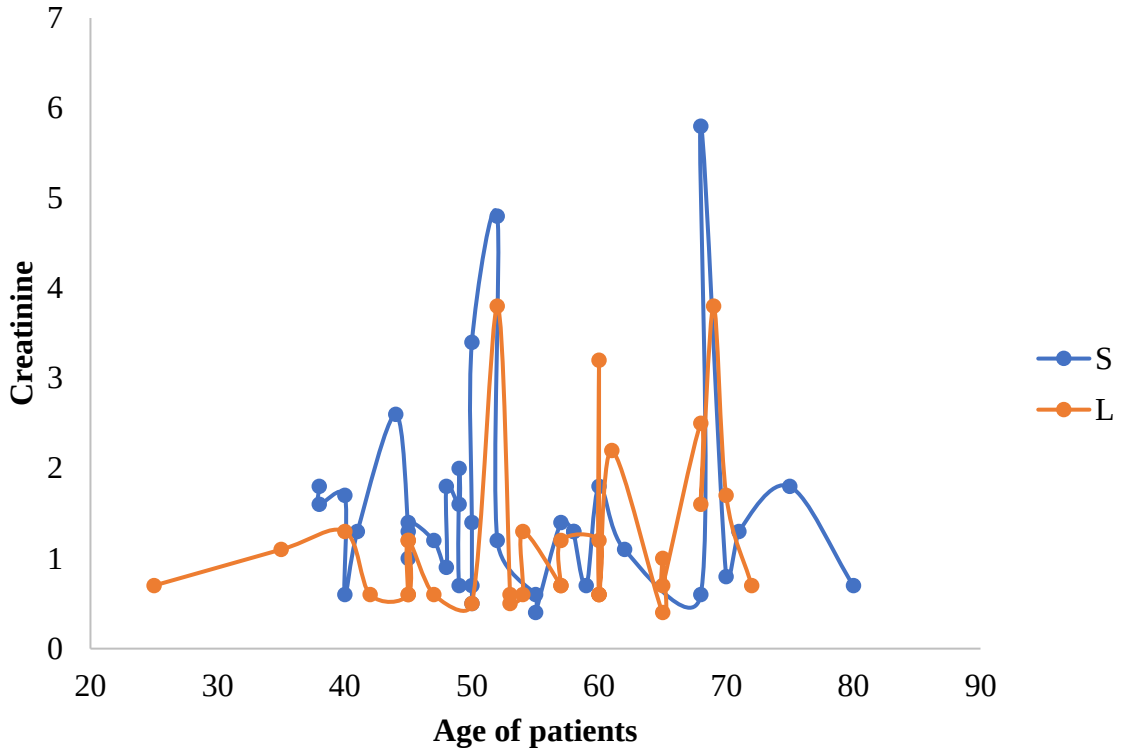


Fig 23: Distribution of Serum Creatinine in the two group across various ages

On analysis the distribution of Serum Urea and Creatinine was studies and the resultant values were plotted in a graph. The mean value of Urea in Group L and Group S were 70.46 and 59.25 respectively. The standard deviation for the two groups is 38.96 and 33.78 respectively. The mean value of serum Creatinine in Group L and Group S are 1.52 and 1.21 respectively with a standard deviation of 1.13 and 0.93. The raised Urea value in the two groups is usually due to dehydration by poor intake that leads to haemoconcentration and can lead to the formation of pre renal acute kidney injury. Adequate fluid resuscitation should be given before taking the patient for surgery.

Total Bilirubin & Albumin

Sl.No.	Total Bilirubin & Albumin					
	L			S		
	Age	Total Bilirubin	Albumin	Age	Total Bilirubin	Albumin
1	25	1.2	2.2	38	2.6	2.9
2	35	1.2	2.5	38	1.8	1.7
3	40	1.2	2.5	40	2.5	2.6
4	42	1.8	2.5	40	1	2.8
5	45	0.8	2.9	41	1	2.9
6	45	3.4	3	44	3.6	2.3
7	45	0.5	2	45	0.8	2.4
8	45	0.9	2.6	45	1.2	3.5
9	47	0.8	2.4	45	2	2.4
10	50	0.3	3.2	47	1.5	1.8
11	52	4.2	1.8	48	1.4	2.7
12	53	0.8	1.9	48	1.2	2.4
13	53	0.6	2.6	49	2.9	2.4
14	54	0.5	3.2	49	4	2.8
15	54	0.6	2.4	49	0.4	3.4
16	57	2.6	2.9	50	0.9	2.6
17	57	1	2	50	2.8	3.2
18	57	2.5	2.4	50	2	2.3
19	60	1.5	2.8	50	2.8	1.8
20	60	0.9	2.2	52	3.2	2
21	60	2.8	1.8	52	1.5	3.1
22	60	0.4	2.7	55	1.8	2.3
23	60	0.9	2.8	55	0.8	2.9
24	61	2.5	3.1	57	1.8	2.7
25	65	1.8	2.2	58	1	2.1
26	65	0.8	2.8	58	0.6	3.5
27	65	1.8	2.3	59	1.2	2.9
28	68	3.6	2.8	60	2	1.9

29	68	2	2.5	62	1.6	2.5
30	69	3.2	2.1	68	2	2.6
31	70	3.9	2.9	68	3.8	2.2
32	72	0.6	2.9	70	2	2.5
33	-	-	-	71	2.8	2.8
34	-	-	-	75	3.8	1.9
35	-	-	-	80	1.2	3.2
Mean		1.61	2.53		1.93	2.57
Standard Deviation		1.13	0.40		0.98	0.48
Median		1.61	2.53		1.93	2.57
Mode		1.13	0.40		0.98	0.48
Minimum		1.2	2.5		1.8	2.6
Maximum		2	2.5		2	2.9

Table 14: Value of Total Bilirubin and Albumin levels on admissions tabulated across the two groups. σ - population standard deviation, μ- the population mean, x_i- each value from the population, N- the size of the population, $\bar{x}$ – arithmetic mean, n - number of values in data set, X- ordered list of values in data set, L- lower limit of the modal class, h- size of the class interval, f_m- frequency of the modal class, f_1- frequency of the class preceding the modal class, f_2- frequency of the class succeeding the modal class

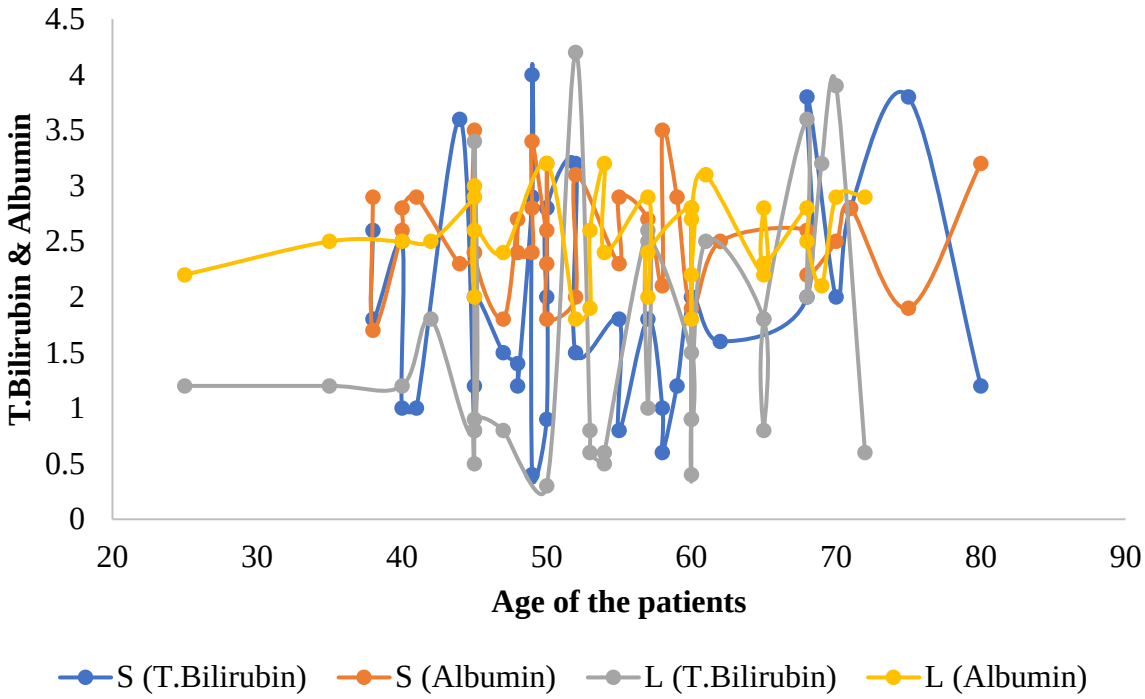


Figure 24: Distribution of Total Bilirubin and Serum Albumin in the two groups among various age groups.

The mean value of Total Bilirubin levels in Group L and group S are 1.61 and 1.93 respectively. Liver dysfunction in sepsis is due to the defect in a conjugation in the initial phase that leads to an elevated indirect bilirubinaemia and elevated alkaline phosphatase level. The incidence of liver dysfunction and liver failure range from 34 to 46% respectively [46-53]. However, the incidence of liver dysfunction is reduced when compared to other systems and this is due to the regenerative capacity of the liver [54]. The incidence of mortality in patients of sepsis that are associated with hepatic dysfunction is more when compared to those with respiratory failure and ranges from 54-68% [48,49,52]. In early dysfunction there are no histological changes, however in late stages it is associated with histologic changes like periportal inflammation, centrilobular necrosis, lobular inflammation, cholangitis, hepatocellular apoptosis and steatosis [55].

The level of Serum Albumin reflects the nutritional status of the individual. However, most of the patients undergoing transtibial amputation for Ascending foot sepsis have Hypoalbuminemia. It is postulated that the rate of wound healing is affected when Serum Albumin levels are less than 3.5g/dl [56]. However, based on our studies the level of Albumin seemed to have no statistically significant effect on healing.

Effect of albumin on wound healing

Wound status on Day 7	Albumin Range					
	</=2		2.1 to 3		>3	
	L	S	L	S	L	S
Healthy	2	2	18	10	1	3
Ascending sepsis	0	0	0	4	0	1
Surgical Site Infection	2	2	4	6	2	1
Seroma	0	2	1	2	0	1
Death	1	0	1	1	0	0
Total	5	6	24	23	3	6

Table 15: Effect of Albumin on wound healing

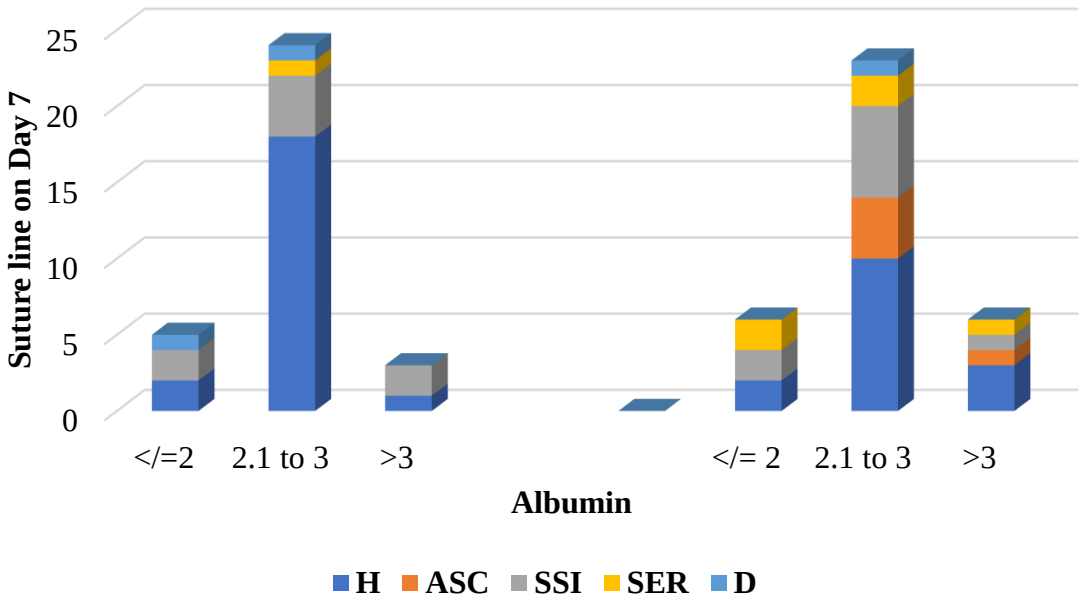


Fig 25: Comparison of the wound status on Day 7 and the level of Serum Albumin among the two groups

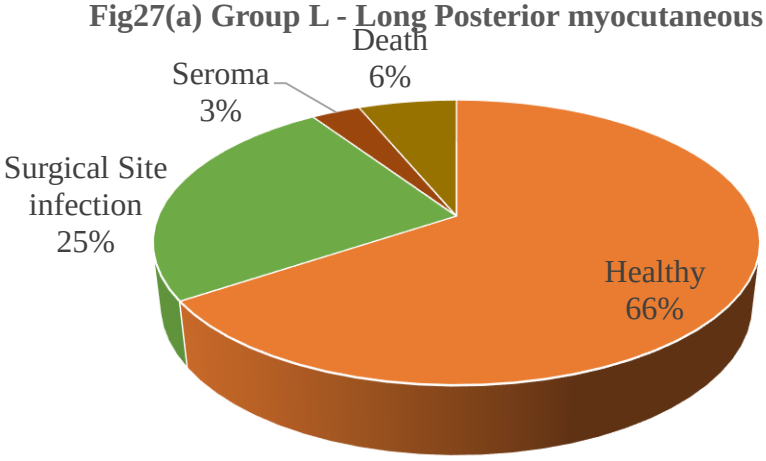
Analysis of the wound status on Day 7

	L	Percent for L	S	Percent for S
Healthy	21	65.63	15	42.86
Ascending sepsis	0	0.00	5	14.29
Surgical Site Infection	8	25.00	9	25.71
Seroma	1	3.13	5	14.29
Death	2	6.25	1	2.86
Total	32	100	35	100

Table 16: Wound status on Day 7

On analysis if the wound status on wound 7. The percentage of stump undergoing primary wound healing in Group L and Group S were 65.63% and 42.86% respectively. This is similar to the study done by Ruckley 1991 and is also similar to the metanalytical review conducted by Cochrane in 2014[45,57]. The decreased rates of primary wound healing achieved in the skew flap amputation technique when compared to Ruckley 1991 and Termansen 1977 [58] can be due to decreased surgical experience in Skew flap amputation. The percentage of Surgical Site Infection in people who undergo Long Posterior Myocutaneous flap technique and Skew flap technique were 25% and 25.71% respectively. This is similar to 21% and 24% of Skew flap and Burgess flap respectively [57]. The percentage of Ascending sepsis was nil in long posterior myocutaneous flap and it was around 14% in skew flap technique. Death within 1 week after

Fig27(a) Group L - Long Posterior myocutaneous flap



the procedure was taken as early death. The percentage of death was 6.25% and 2.86% respectively this is similar to the rates published by Ruckley in 1991[57]

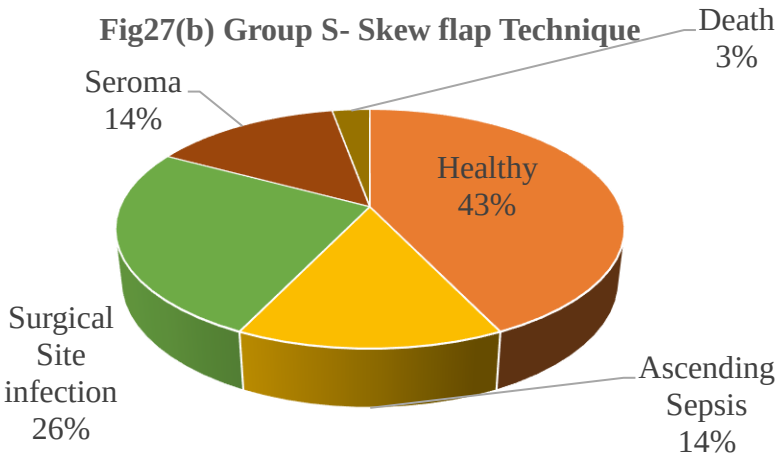


Fig 26(a) & (b): The status of the wound on Day 7 in Group S and Group L

Wound problems develop in 20% to 30% of patients following transtibial amputation [60,61,62]. The likelihood of wound infection following major lower extremity amputation ranges from 13% to 40% [20,59,63]. The infection rates were around 16 % observed in the study conducted by Jain [64]. The percentage of Surgical Site infection in our study was 25%. The slightly increased percentage of wound infection in our study can be due fact that the flap techniques are being studied in patients who are undergoing transtibial amputation for Ascending foot sepsis.

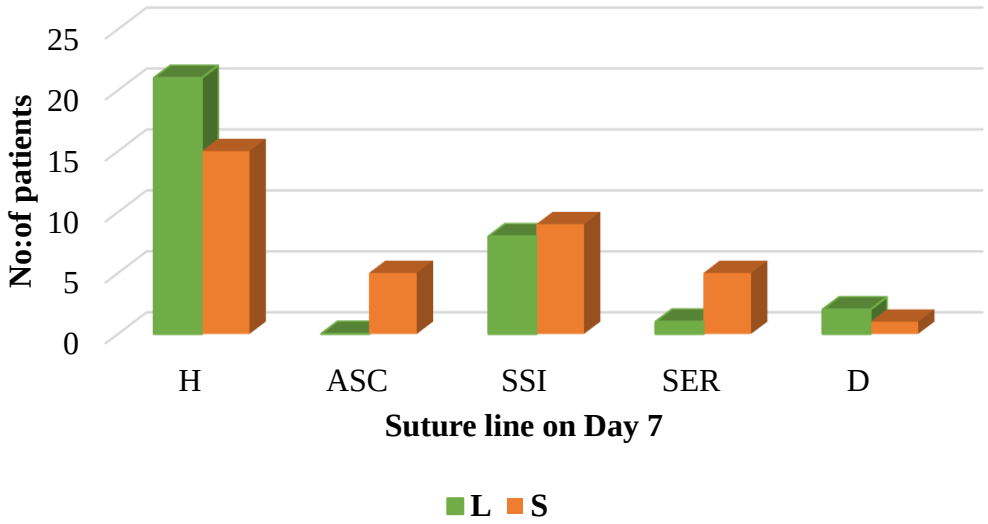


Fig 27: Distribution of the various wound status in both the Groups compared Simultaneously

Wound Status on Day 7	Category L	Category S	Total	Chi Squared $X^2 = \sum \frac{(O_i - E_i)^2}{E_i}$	P Value $Z = \frac{\hat{p} - p_0}{\sqrt{\frac{p_0(1-p_0)}{n}}}$
Healthy	21	15	36		
Ascending infection	0	5	5		
Surgical site infection	8	9	17	0.063	0.78
Seroma	1	5	6		
Death	2	1	3		
Total	32	35	67		

Table 17: Statistical Significance of wound status in comparison with two groups

X^2 – Chi Squared, O_i – observed value, E_i – expected value

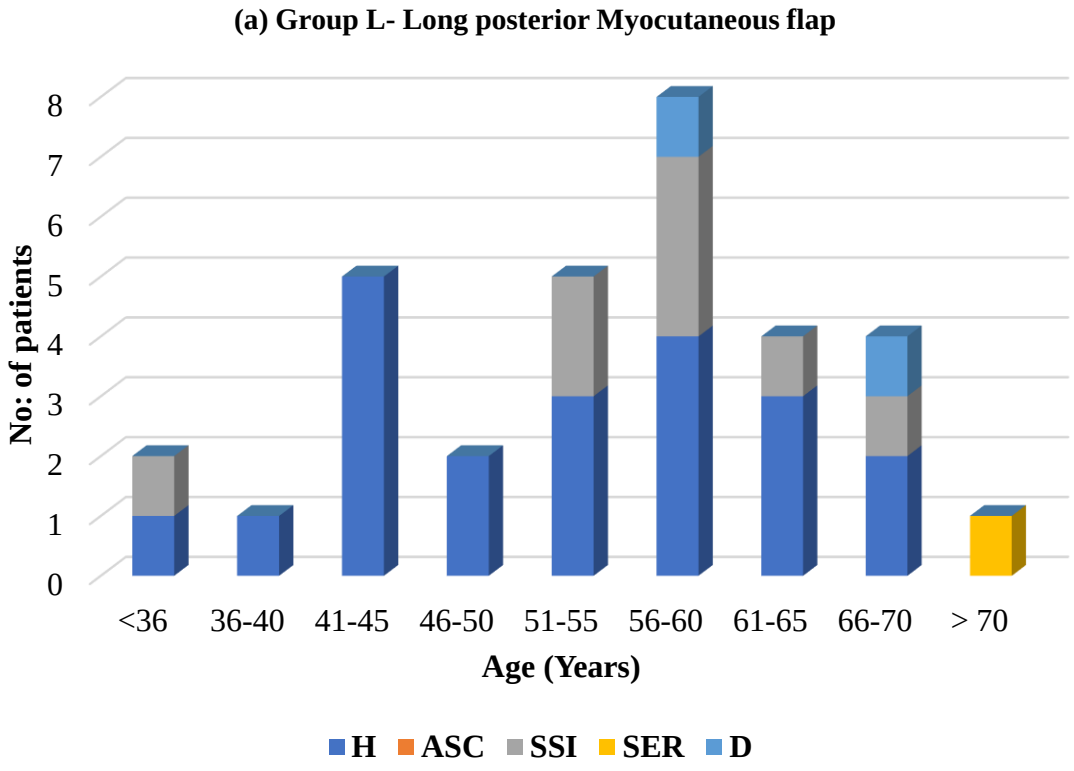
$\hat{p}$ – Sample proportion, p_0 - assumed population proportion in the null hypothesis

The p value for the comparison of the two flap techniques in terms of wound status on day 7 was 0.78 which is more than 0.05. This is statistically insignificant and that primary wound healing doesn't improve based on the technique used. This is similar to all the studies published till date and is similar to the study published by Ruckley in 1991 and the meta-analysis review published Cochrane in 2004. [45,57]

Age	Group L					Group S				
	Healthy	Ascending sepsis	Surgical site Infection	Seroma	Death	Healthy	Ascending Sepsis	Surgical Site Infection	Seroma	Death
<36	1	0	1	0	0	0	0	0	0	0
36-40	1	0	0	0	0	2	1	0	1	0
41-45	5	0	0	0	0	3	2	0	0	0

46-50	2	0	0	0	0	5	0	2	3	0
51-55	3	0	2	0	0	0	0	4	0	0
56-60	4	0	3	0	1	2	0	2	1	0
61-65	3	0	1	0	0	1	0	0	0	0
66-70	2	0	1	0	1	1	1	0	0	1
> 70	0	0	0	1	0	1	1	1	0	0
Total	21	0	8	1	2	15	5	9	5	1

Table 18: Distribution of wound status in both the groups across various ages



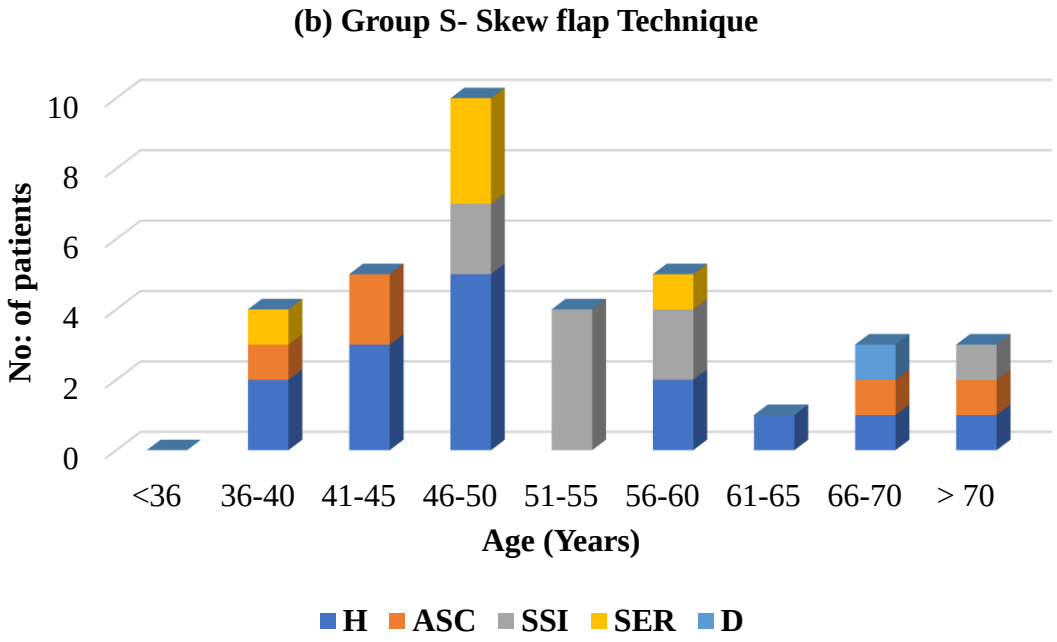


Fig 28 (a)&(b): Distribution of wound status in the two groups across various age

The age of the patient doesn't seem to have effect on the healing of the wound in both the patient group as per Fig 29(a)&(b).

Wound status on day 7	**Category**				**Total**	**Chi Squared**	**P Value**	
	L		**S**					
	(N=32)		**(N=35)**		**(N=67)**	$X^2 = \sum \frac{(O_i - E_i)^2}{E_i}$	$Z = \frac{\hat{p} - p_0}{\sqrt{\frac{p_0(1-p_0)}{n}}}$	
	Female	**Male**	**Female**	**Male**			**Female**	**Male**
Healthy	7	14	3	12	36			
Ascending Sepsis	0	0	2	3	5	0.341	0.5	0.26
SSI	1	7	2	7	17			
Seroma	0	1	2	3	6			
Death	1	1	0	1	3			
Total	9	23	9	26	67			

Table 19: The wound status on Day 7 in both groups distributed across sex of the patient

The Wound status on Day 7 is not affected by the sex of the patient as the p value for the analysis is 0.5 and 0.26 for male and female respectively. This is more than 0.05 and is not statistically significant

The next parameter that was studied is the duration of hospital stay that is directly proportional to wound healing status on day 7

Statistical Analysis on Duration of hospital Stay

Sl.No.	Duration of Hospital Stay			
	Group L		Group S	
	Age	Duration of Hospital Stay	Age	Duration of Hospital Stay
1	25	16	38	12
2	35	7	38	10
3	40	8	40	21
4	42	8	40	7
5	45	8	41	23
6	45	8	44	20
7	45	10	45	9
8	45	10	45	7
9	47	5	45	9
10	50	7	47	13
11	52	15	48	8
12	53	18	48	18
13	53	7	49	8
14	54	16	49	12
15	54	8	49	8
16	57	16	50	18
17	57	14	50	10
18	57	7	50	14
19	60	0	50	14
20	60	8	52	16
21	60	3	52	14

22	60	14	55	15
23	60	8	55	12
24	61	20	57	10
25	65	7	58	16
26	65	7	58	12
27	65	8	59	10
28	68	8	60	16
29	68	10	62	8
30	69	4	68	16
31	70	14	68	1
32	72	12	70	8
33	-	-	71	18
34	-	-	75	10
35	-	-	80	16
Mean		12.54		9.72
Standard Deviation		4.71		4.57
Median		12		8
Mode		10		8
Minimum		1		0
Maximum		23		20

Table 20: Distribution of Duration of Hospital Stay in both the groups

On analysing the duration of hospital stay, the mean duration of Hospital stay in the long posterior myocutaneous flap technique was 12.54 with a standard deviation of 4.71. The mean duration of Hospital stays in the skew flap technique ass 9.72 days with a mean standard deviation of 4.57. However, this cannot be compared with the existing studies as the standard deviation had not been quoted in Fischer 1988 and hence it provides an incomplete data

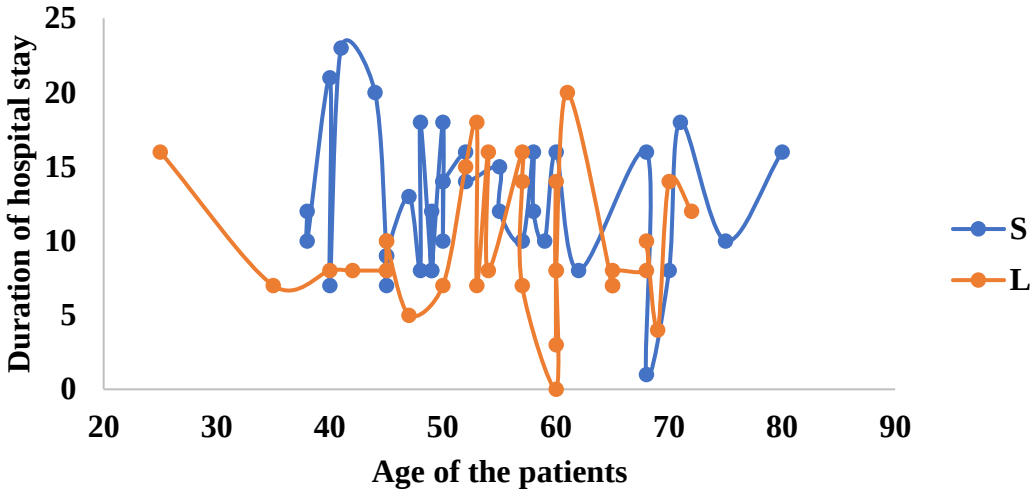


Fig 29: Distribution of Duration of Hospital stay in both the groups

Another study published by Ruckley in 1991 the average duration of Hospital stay was 36 days after a skew flap and 42 days after long posterior myocutaneous flap technique. This time includes the time taken for rehabilitation of the patient using prosthesis.

Analysis done on secondary procedures done for wound complications

Secondary procedure for wound complication				
	Group L		Group S	
AKA	0	0	5	14.29
WDSS	8	25%	9	25.71
COMP	1	3.12%	5	14.29
Total	9		19	

Table 21: Distribution of secondary procedures for wound complication

The percentage of amputees who undergo revision amputation for Ascending sepsis or major flap necrosis was 14.29%. This similar to conversion rates as mentioned in Ruckley,

1991[57]. The incidence of Postoperative complication was increased in the amputees undergoing skew flap amputation; however, the difference is not statistically significant. This is in a part may be due to the lack of expertise in performing the new skew flap technique.

Analysis on Outcome after 30 days

	L	Percent for L	S	Percent for S
Ambulating	8	25	14	40
ADL	15	46.88	12	34.29
Non ambulating	4	12.5	7	20
Readmission	2	6.25	1	2.86
Death	1	3.13	0	0
Early death	2	6.25	1	2.86
Total	32	100	35	100

Table 22: Outcome of the patient after 30 days of amputation

ADL*- activity of daily living,

On following the patients after 30 days, 46.88% of the amputees of the long posterior myocutaneous flap technique return to doing activities of daily living and 34.29% of the amputees who had undergone skew flap technique returned to doing activities of daily living. 40% of the Skew flap Group had returned to ambulation while only 25% of the population had returned to full ambulation. The total percentage of the death in the study was 5.97%. which is reduced when compared to the operative mortality rate of 11% and 17 % and a follow up mortality rate of 9% and 12 % respectively. This can be attributed to the advancements in anaesthesia and the availability of antibiotics and better health care facilities. The 1-year survival following below knee amputation is 65-80% [61,65-68], The median survival was around 2.4 years in patients undergoing transtibial amputation [69]

Outcome after 30 days	Category		Total	Chi Squared	P Value
	L	S		$X^2 = \sum \frac{(O_i - E_i)^2}{E_i}$	$Z = \frac{\hat{p} - p_0}{\sqrt{\frac{p_0(1-p_0)}{n}}}$
Ambulant	8	14	22		
ADL	15	12	27		
Non-Ambulant	4	7	11	0.50	0.73
Readmission	2	1	3		
Death	1	0	1		
Early death	2	1	3		
Total	32	35	67		

Table 23: Testing the statistical significance between Outcome at 30 days and the two flap techniques

Two recent reports states that approximately 25% of major lower extremity amputees ambulate with a prosthesis outside their home [60,70]. These patients were not able to use a prosthesis for varied number of reasons, including mental illness, cardiopulmonary insufficiency, inadequate balance, and stump problems. [60,71] The following perioperative risk factors were independently associated with failure of the amputees to maintain an independent status. They are age more than 70 years, level of amputation, homebound ambulatory status and dementia.

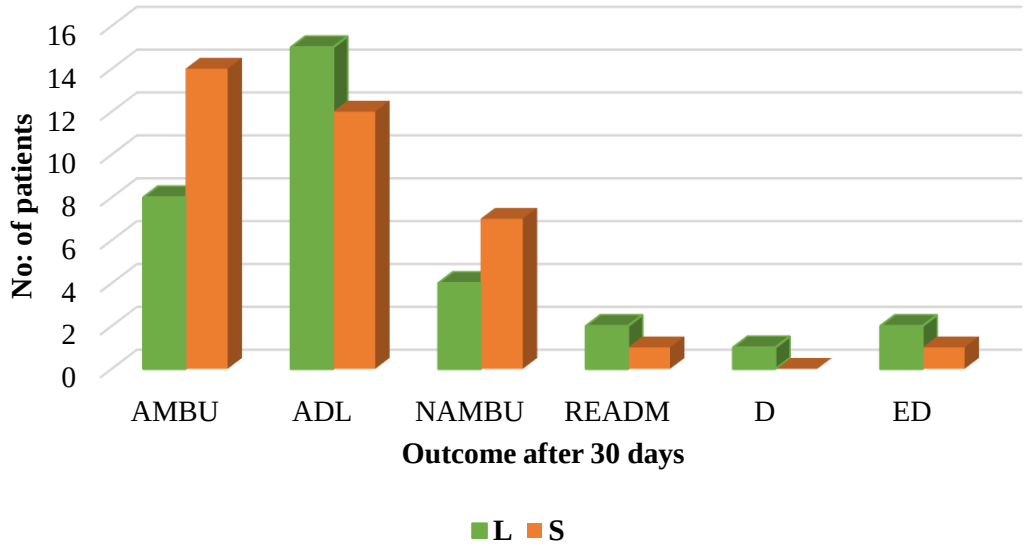


Fig 30: Graphical representation of the comparison of outcome at 30 days between the two groups

The non-ambulant population of the amputees usually belonged to the elderly more than 55 years of age group. The P value for the outcome at 30 days in the two comparison groups was 0.73 which is more than 0.05 and is not statistically significant

Outcome at 30 days distribute across various ages in the two comparison groups

Age	**Group S**						**Group L**					
range	**AMBU**	**ADL**	**NAMBU**	**READM**	**D**	**ED**	**AMBU**	**ADL**	**NAMBU**	**READM**	**D**	**ED**
<36	0	0	0	0	0	0	1	1	0	0	0	0
36-40	2	2	1	0	0	0	0	1	0	0	0	0
41-45	2	2	0	0	0	0	4	0	1	0	0	0
46-50	6	4	0	0	0	0	0	2	0	0	0	1
51-55	0	1	2	1	0	0	0	2	1	1	1	0
56-60	2	2	1	0	0	0	2	4	0	1	0	0
61-65	1	0	0	0	0	0	1	2	1	0	0	0
66-70	1	1	0	0	0	1	0	2	0	0	0	1
> 70	0	0	3	0	0	0	0	1	1	0	0	0
Total	14	12	7	1	0	1	8	15	4	2	1	2

Table 24: Outcome at 30 days distributed across age in the two comparison groups

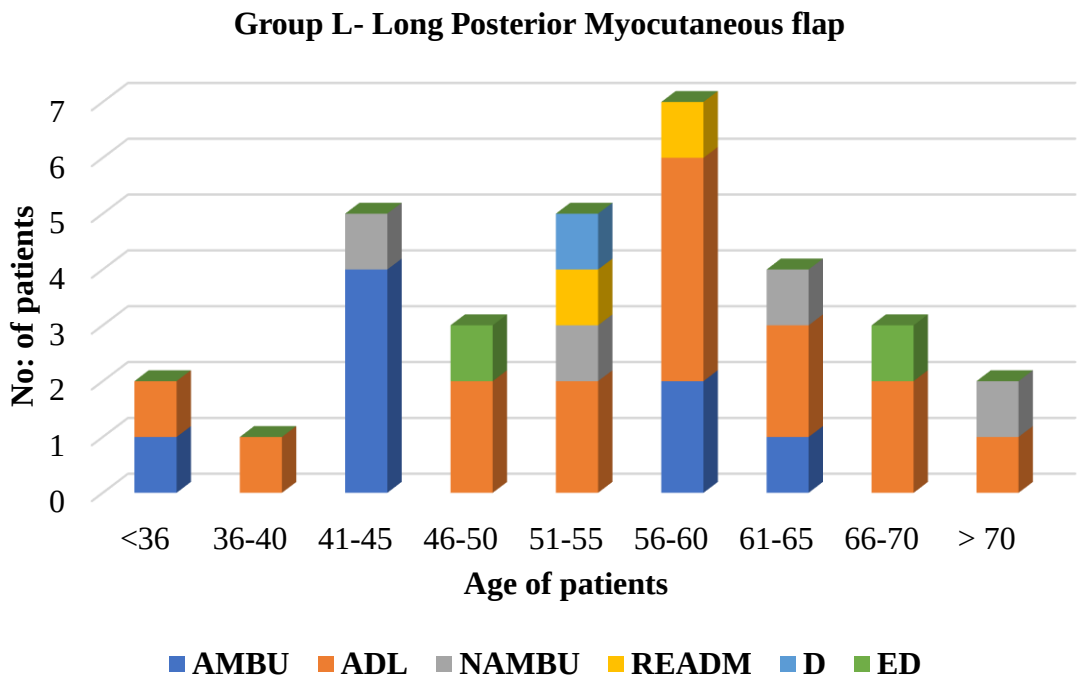


Fig 31: Outcome at 30 days in the long posterior flap across various age

AMBU- Ambulating, ADL- Activities of Daily Living, NAMBU- Not Ambulating, READM- Readmission, Death, ED- Early death

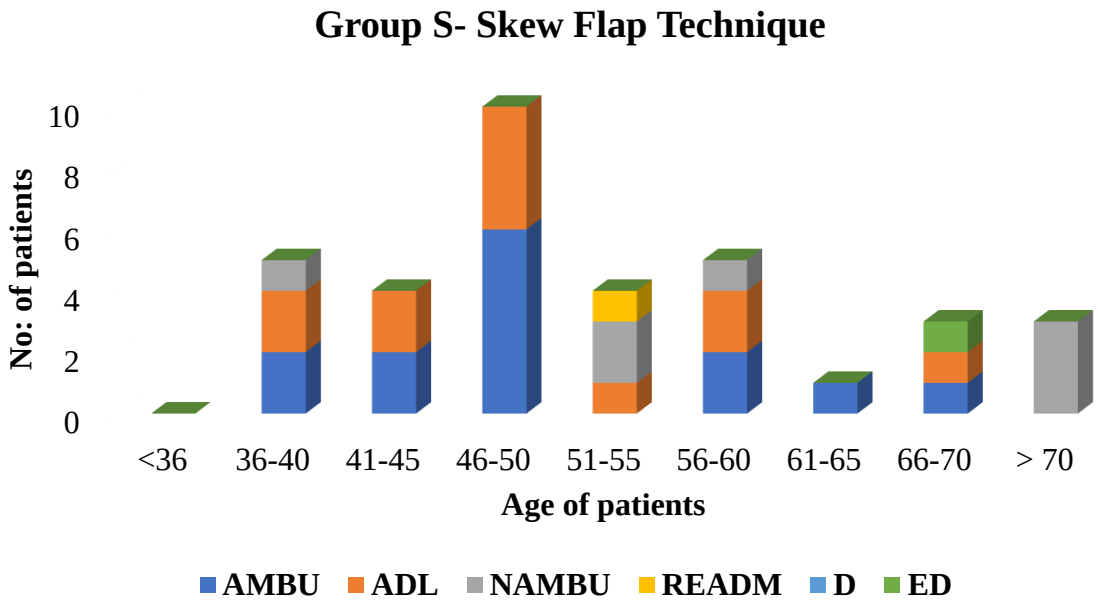


Fig 32: Outcome at 30 days in the skew flap distributed across various age

AMBU- Ambulating, ADL- Activities of Daily Living, NAMBU- Not Ambulating, READM- Readmission, Death, ED- Early death

	Category			Total	Chi Squared	P Value	
	L		S				
	(N=32)		(N=35)	(N=67)	$X^2 = \sum \frac{(O_i - E_i)^2}{E_i}$	$Z = \frac{\hat{p} - p_0}{\sqrt{\frac{p_0(1-p_0)}{n}}}$	
	Female	**Male**	**Female**	**Male**		Female	Male
Ambulant	3	11	1	7	22		
ADL	4	8	5	10	27		
Non-Ambulant	2	5	1	3	11	0.91	1	0.60
Readmission	0	1	1	1	3		
Death	0	0	0	1	1		
Early death	0	1	1	1	3		
Total	9	26	9	23	67		

Table 25: Sex distribution of the outcome at 30 days across the two comparison groups

ADL- Activities of Daily Living**.**

The p value of the Outcome at 30 days in the two comparison groups across the male and the female population is 1 and 0.60 and hence is not statistically significant

CONCLUSION

On demographic analysis the mean age of the population in both groups were 55 years of age. The male to female ratio is 7:3 and there is a male preponderance.

On analyzing the biochemical parameters of the study, anemia and hypoalbuminemia was prevalent among the study population. The mean value of Hemoglobin was 9g/dl in both the groups with a standard deviation of 1.5g/dl. The mean value of Serum Albumin in the study was 2.5 g/dl in the both the categories with a standard deviation of 0.5g/dl. However, anemia and hypoalbuminemia had no statistically significant effect of the primary wound healing.

Most of the patients who underwent Transtibial amputation for Ascending sepsis also had deranged renal and liver parameters. The renal derangement can be due to pre renal azotemia because of poor oral intake and derangement of liver parameters can be due to bacterial toxins and inflammatory mediators. The hypoalbuminemia can also be due to the derangement of the liver.

On analysis of primary wound healing, the skew flap technique does not offer any advantage in terms of primary wound healing and no statistical significance was observed in the amputees of the two groups. This is similar to the studies published previously and the rates of primary wound healing are 65.63 % and 42.86% in the patients who had undergone transtibial amputation via Long posterior myocutaneous flap technique and the skew flap technique respectively. This is similar to the primary wound healing rates observed in the previous studies.

The secondary objectives that were study during the analysis are Duration of Hospital stay, outcome at 30 days and rates of Reamputation at the same or higher level. The two groups did

not have any statistical difference on the length of duration of hospital stay, outcome at 30 days or the rates of revision surgery.

The percentage of the amputees having surgical site infection after amputation is around 25% in both the groups and is similar to the rates previously observed in our study

However, the mortality that is associated with Transtibial amputation is reduced when compared to the previous studies. This can be attributed to improvements in the health care system and to the availability of antibiotics.

Finally, to conclude, both long posterior myocutaneous flap technique and skew flap technique doesn't confer any added advantage on Primary wound healing and the technique of amputation always depends on the surgeon's preference. The only added advantage in a skew flap technique is that it can be used when a long posterior flap cannot be constructed due to deficiency of tissue for a posterior flap and that it overcomes the disadvantage of a sagittal flap by moving the scar line away from the anterior tibial crest. Hence the skew flap technique is an ideal alternative to long posterior myocutaneous flap technique for patients undergoing transtibial amputation.

SCOPE FOR FURTHER STUDY

All the surgeons who had performed the skew flap technique had very little of expertise in the technique. Hence having adequate expertise in the technique may yield superior results. The study had been done only in patients undergoing transtibial amputation for ascending foot sepsis, but further study can be done to include patients undergoing transtibial amputation for other causes. The percentage of prosthetic fitting should also be included in this study. The functional outcome of the study could have been more objectively measured using K-Levels, A Classification System Created by the US Centers for Medicare and Medicaid Services Are Used to Stratify Potential Functional Ability in Amputees.

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ANNEXURE I: LIST OF FIGURES

ANNEXURE: LIST OF TABLES

ANNEXURE III: INFORMATION SHEET

We are conducting a randomized control trial to compare the efficacy of skew flap and long posterior flap technique in transtibial amputation in a tertiary care hospital in the Institute of General surgery at Rajiv Gandhi Government General Hospital, Chennai

Transtibial amputations (removal of the limb below the knee) can be lifesaving procedure in ascending foot sepsis. Following transtibial amputations, once the incision site heals patients can be fitted with appropriate prosthesis to allow for ambulation, Early primary wound healing is essential for proper prosthetic fitting and rehabilitation Long posterior flap and skew flap are both approved methods of transtibial amputations (removal of the limb below the knee) for ascending foot sepsis

This study is conducted to compare the efficacy of the two flaps - long posterior and skew flap - in transtibial amputations. Post operatively wound healing was assessed on day 7 in terms of painless, healed suture line - with no discharge, necrosis or wound dehiscence. Early healing of the skin incision is essential for fitting of prosthetics and aids in rehabilitation. If there is any of the above complications occur or the infection keeps on ascending patient will be treated accordingly with wound debridement or revision amputation at the same or higher level.

Results of the study will help in understanding whether performing one of the two procedures helps in primary healing of the incision in transtibial amputation and prosthetic fitting, in turn helping in earlier rehabilitation to work and ambulation

The participation for the study is voluntary and participants are free to exit the study at any point of time even after consenting initially. The identity of the participant shall remain confidential throughout out the study period and while publishing the study. The decision to

withdraw from the study will not result in loss of the required medical care or benefits of the participant.

The results of the study will be informed to the study after analysis

The participants are free to ask questions and clarify their doubts during any point of the study time

ANNEXURE IV: PATIENT CONSENT FORM

TITLE: **"A Randomised control trial to compare the efficacy of long posterior myocutaneous flap versus skew flap in transtibial amputation in a tertiary care hospital"**

Study centre: **INSTITUTE OF GENERAL SURGERY,**
RAJIV GANDHI GOVT. GENERAL HOSPITAL,
MADRAS MEDICAL COLLEGE,
CHENNAI-03.

Participant name: Age: Sex: I.P.No:

I confirm that I have understood the purpose of procedure for the above study. I have the opportunity to ask the question and all my questions and doubts have been answered to my satisfaction.

I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving any reason.

I understand that investigator, regulatory authorities and the ethical committee will not need my permission to look at my health records both in respect to current study and any further research that may be conducted in relation to it, even if I withdraw from the study. I understand that my identity will not be revealed in any information released to third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from the study.

Time:

Date:

Place:

Signature / thumb impression of patient

Signature of the investigator:

Name of the investigator: Dr.S. Aashmi Chandrikaa

ANNEXURE V: QUESTIONAIRRE

DATE:

NAME:

AGE: SEX: IP NO: Ward:

D.O.A. D.O.D. D.O.S

CHIEF COMPLAINTS:

Comorbidity

Procedures undergone before transtibial amputation

VITALS:

- Temp :
- PR :
- BP :
- RR :
- Spo2 :

GENERAL EXAMINATION:

SYSTEMIC EXAMINATION

Local Examination

Investigation

- Total count
- Haemoglobin
- Platelets
- Urea
- Creatinine
- T. Bilirubin
- D. bilirubin
- Na
- K
- Albumin
- Protein

Wound swab for culture sensitivity

X ray local part

DIAGNOSIS:

Procedure done – Transtibial amputation (long posterior flap / skew flap)

Suture line status on Day 7 –

Reamputation if needed – Procedure done

Duration of HOSPITAL STAY :

Outcome at 30 days - Recovered / Expired

ANNEXURE VI: ETHICAL COMMITTEE APPROVAL

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI 600 003

EC Reg.No.ECR/270/Inst./TN/2013/RR-16
Telephone No.044 25305301
Fax: 011 25363970

CERTIFICATE OF APPROVAL

To
Dr.S.AASHMI CHANDRIKAA,
Post Graduate in General Surgery,
Institute of General Surgery,
Rajiv Gandhi Govt. General Hospital,
Madras Medical College,
Chennai-600003.

Dear Dr. S.AASHMI CHANDRIKAA,

The Institutional Ethics Committee has considered your request and approved your study titled **"A RANDOMISED CONTROLLED TRIAL TO COMPARE THE EFFICACY OF LONG POSTERIOR MYOCUTANEOUS FLAP VERSUS SKEW FLAP IN TRANSTIBIAL AMPUTATION IN A TERTIARY CARE HOSPITAL"- NO.09022021.** The following members of Ethics Committee were present in the meeting held on **17.02.2021** conducted at Madras Medical College, Chennai 3.

1. Prof.P.V.Jayashankar :Chairperson
2. Prof.N.Gopalakrishnan,MD.,DM., FRCP, Director, Inst. of Nephrology, MMC, Ch : Member Secretary
3. Prof. K.M.Sudha, Prof. Inst. of Pharmacology,MMC,Ch-3 : Member
4. Prof. Alagarsamy Jamila ,MD, Vice Principal, Stanley Medical College, Chennai : Member
5. Prof.Rema Chandramohan,Prof.of Paediatrics,ICH,Chennai : Member
6. Prof.S.Lakshmi, Prof. of Paediatrics ICH Chennai : Member
7. Tmt.Arnold Saulina, MA.,MSW., :Social Scientist
8. Thiru S.Govindasamy, BA.,BL,High Court,Chennai : Lawyer
9. Thiru K.Ranjith, Ch- 91 : Lay Person

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

Member Secretary – Ethics Committee

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE
CHENNAI-600 003.

ANNEXURE VII: PLAGIARISM CERTIFICATE

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CERTIFICATE II

This is to certify that this dissertation work titled **"A Randomised control trial to compare the efficacy of long posterior myocutaneous flap versus skew flap in transtibial amputation in a tertiary care hospital**" of the candidate Dr.S. Aashmi Chandrikaa with Registration Number 221911001for the award of M.S degree in the BRANCH -1 of General Surgery. I personally verified the urkund.com website for the purpose of plagiarism Check. I found that the uploaded thesis file contains from introduction to conclusion pages and result shows 7% percentage of plagiarism in the dissertation.

Guide & Supervisor sign with Seal.

ANNEXURE VIII: MASTER CHART

S.No	Age	Sex	Flap type	TC	Haemoglobin	Platelet	Urea	Creatinine	T.Bilirubin	Albumin	Suture line on Day 7	Secondary Procedures	Duration of Hospital Stay	Outcome at 30 days
1	75	M	S	34500	7.8	1,20,000	102	1.8	3.8	1.9	H	NA	10	NAMBU
2	49	M	S	29000	9.8	2,80,000	86	1.6	2.9	2.4	H	NA	8	AMBU
3	49	F	S	32000	10.2	5,80,000	120	2	4	2.8	H	NA	12	AMBU
4	44	F	S	38870	9.5	78000	143	2.6	3.6	2.3	ASC	A.K.A.	20	ADL
5	60	F	L	25000	11.2	3,00,000	64	1.2	1.5	2.8	H	NA	7	ADL
6	80	F	S	16600	11.7	2,50,000	40	0.7	1.2	3.2	ASC	A.K.A.	16	NAMBU
7	58	M	S	19200	8	1,85,000	54	1.3	1	2.1	SSI	WDSS	16	AMBU
8	50	M	S	13000	7.3	1,72,000	43	0.7	0.9	2.6	SSI	WDSS	18	AMBU
9	45	M	L	16500	9.2	2,20,000	38	0.6	0.8	2.9	H	NA	8	AMBU
10	52	M	L	38000	7.8	86,000	160	3.8	4.2	1.8	H	NA	15	D
11	68	F	L	39900	11	6,20,000	108	2.5	3.6	2.8	H	NA	8	ADL
12	40	M	S	24500	10.2	3,50,000	86	1.7	2.5	2.6	ASC	A.K.A.	21	ADL
13	71	M	S	21500	10.8	2,50,000	56	1.3	2.8	2.8	SSI	WDSS	18	NAMBU
14	70	M	L	30000	9.9	4,20,000	72	1.7	3.9	2.9	SSI	WDSS	14	NAMBU
15	45	M	L	26400	10.1	2,80,000	58	1.2	3.4	3	H	NA	8	AMBU
16	50	M	S	19800	11.3	3,10,000	40	0.5	2.8	3.2	H	NA	10	AMBU
17	55	M	S	18600	7.9	2,50,000	38	0.6	1.8	2.3	SSI	WDSS	15	ADL
18	57	M	L	27000	8.8	1,85,000	34	0.7	2.6	2.9	SSI	WDSS	16	ADL
19	68	M	S	18900	9.2	2,60,000	42	0.6	2	2.6	ASC	A.K.A.	16	AMBU
20	65	F	L	14700	9	2,50,000	36	0.4	1.8	2.2	H	NA	7	AMBU
21	42	F	L	16700	9.2	3,40,000	32	0.6	1.8	2.5	H	NA	8	NAMBU
22	59	M	S	21800	13	2,80,000	35	0.7	1.2	2.9	H	NA	10	NAMBU
23	45	M	S	24000	11.8	1,90,000	58	1.3	0.8	2.4	H	NA	9	AMBU
24	41	M	S	26900	10	2,70,000	56	1.3	1	2.9	ASC	A.K.A.	23	ADL

25	50	M	S	34400	11.1	8,00,000	88	1.4	2	2.3	SER	COMP	14	ADL
26	47	F	S	15800	7.1	2,10,000	60	1.2	1.5	1.8	SER	COMP	13	AMBU
27	48	M	S	23700	9.8	3,20,000	58	0.9	1.4	2.7	H	NA	8	AMBU
28	65	M	L	19600	10	2,00,000	38	1	0.8	2.8	H	NA	7	ADL
29	47	M	L	22250	13.4	3,20,000	36	0.6	0.8	2.4	H	NA	5	ADL
30	25	M	L	22600	12.8	1,95,000	32	0.7	1.2	2.2	SSI	WDSS	16	AMBU
31	57	M	L	17500	8.9	3,40,000	38	0.7	1	2	SSI	WDSS	14	ADL
32	53	M	L	18400	6.4	4,50,000	42	0.6	0.8	1.9	SSI	WDSS	18	ADL
33	40	F	L	28500	8.6	3,80,000	54	1.3	1.2	2.5	H	NA	8	ADL
34	69	F	L	37100	7.8	96000	142	3.8	3.2	2.1	D	NA	4	NAMBU
35	57	F	L	29000	9	1,70,000	58	1.2	2.5	2.4	H	NA	7	ADL
36	65	M	L	16400	10.1	2,70,000	43	0.7	1.8	2.3	H	NA	8	NAMBU
37	35	M	L	27700	7.2	3,82,000	60	1.1	1.2	2.5	H	NA	7	ADL
38	61	M	L	24700	9.6	3,80,000	96	2.2	2.5	3.1	SSI	WDSS	20	ADL
39	38	M	S	30100	9.8	1,20,000	87	1.8	2.6	2.9	SER	COMP	12	AMBU
40	60	M	L	18900	8.9	1,28,000	48	0.6	0.9	2.2	H	NA	8	AMBU
41	50	M	S	32500	7.5	86,000	167	3.4	2.8	1.8	SER	COMP	14	ADL
42	70	F	S	24200	8.1	2,60,000	42	0.8	2	2.5	H	NA	8	ADL
43	45	M	S	16700	8.8	3,20,000	40	1	1.2	3.5	H	NA	7	ADL
44	54	M	L	18700	8.6	4,32,000	36	0.6	0.5	3.2	SSI	WDSS	16	READM
45	58	F	S	22300	9.2	2,72,000	50	1.3	0.6	3.5	SER	COMP	12	ADL
46	68	F	L	19800	9.6	3,00,000	68	1.6	2	2.5	H	NA	10	ADL
47	72	M	L	18400	10.3	2,80,000	38	0.7	0.6	2.9	SER	COMP	12	ADL
48	38	F	S	22400	6.8	1,85,000	57	1.6	1.8	1.7	H	NA	10	AMBU
49	60	M	S	23900	6.2	1,00,000	58	1.8	2	1.9	SSI	WDSS	16	AMBU
50	48	F	S	16300	8.5	2,20,000	60	1.8	1.2	2.4	SSI	WDSS	18	ADL
51	54	M	L	21800	7.8	2,42,000	68	1.3	0.6	2.4	H	NA	8	ADL
52	45	M	L	18800	9.5	3,20,000	40	0.6	0.5	2	H	NA	10	AMBU
53	60	M	L	37600	5.8	50,000	138	3.2	2.8	1.8	D	NA	3	NA
54	40	M	S	20190	8.6	1,40,000	42	0.6	1	2.8	H	NA	7	NAMBU
55	45	M	L	27100	9.5	2,34,000	58	1.2	0.9	2.6	H	NA	10	AMBU
56	52	M	S	3500	9.8	80,000	160	4.8	3.2	2	SSI	WDSS	16	READM
57	60	F	L	18000	8.7	3,74,000	40	0.6	0.4	2.7	SSI	WDSS	14	READM
58	50	M	L	14500	11.2	2,86,000	38	0.5	0.3	3.2	H	NA	7	ADL

59	49	M	S	17800	11	1,86,000	42	0.7	0.4	3.4	H	NA	8	ADL
60	55	M	S	18900	10.4	2,40,000	32	0.4	0.8	2.9	SSI	WDSS	12	NAMBU
61	52	F	S	26900	9.7	3,20,000	62	1.2	1.5	3.1	SSI	WDSS	14	NAMBU
62	62	M	S	23500	9.8	2,54,000	68	1.1	1.6	2.5	H	NA	8	AMBU
63	68	M	S	2000	8.9	56,000	178	5.8	3.8	2.2	D	NA	1	NAMBU
64	53	M	L	18700	8.8	3,20,000	45	0.5	0.6	2.6	H	NA	7	NAMBU
65	60	M	L	19700	9.2	2,78,000	38	0.6	0.9	2.8	H	NA	8	AMBU
66	45	M	S	22400	8.6	2,45,000	56	1.4	2	2.4	H	NA	9	AMBU
67	57	M	S	28600	10.2	3,10,000	60	1.4	1.8	2.7	H	NA	10	ADL