

**THE STUDY OF TRANSTIBIAL PROSTHESIS
AT
ALC, CHENNAI, WITH SPECIAL REFERENCE
TO MODULAR PROSTHESIS**

**THESIS
FOR THE DEGREE OF MD
(PHYSICAL MEDICINE REHABILITATION)**



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AIM OF THE STUDY

This study was conducted at The Artificial Limb Fitting Center of the Government Institute of Rehabilitation Medicine, Chennai. The Aim of the study was to analyse the two commonly used prosthesis namely the Laminated Exoskeletal Transtibial Prosthesis and the Modular Transtibial Prosthesis in terms of cost, efficacy, utility and also to identify the demographics profile in the study group.

INTRODUCTION

WHO estimates that there are 800 million persons with disability in the world and 100 million of them are in India alone. National sample survey organization (The Survey in the 58th Round) in 2002 has shown that 1.85 crore disabled person i.e. 1.8% of the total estimated population present in our country. Of them, 10.66 million (58% of all the disabled) are having Locomotor Disability. There are 8.3 lakh (78/1000 disabled) are with limb loss (NSSO, 2002). Amongst them, most are Transtibial amputee and they need a prosthetic device of appropriate design and at a reasonable cost to perform as effective as the lost limb.

Whether as a result of trauma or disease, amputation has always been a part of human experience. There has always been the desire to replace the lost part for functional, cosmetic reasons or for a combination of both. In our national policy and as a result of implementation of Persons with Disability Act'95, an all round effort in this regard was made.

Now there is an increased demand for prosthetic fitment services and efforts are made by our government to fit artificial limb by camp approach in order to cover a majority of the amputees.

In India there is a recent trend to provide lightweight prosthesis for Transtibial amputee. The introduction of endoskeletal prosthesis has dramatically improved the prosthetic design, especially considering the weight and material selection for the prosthesis. In the past, wood, aluminum, steel and leather were used.

Today fabrication with plastic laminate/composite fiber over a plaster cast mold of the stump is considered standard. Newer materials in use include polypropylene, polyurethane and polycarbonate. The increasing use of vacuum-forming technique with these thermoplastics has led to much lighter weight prostheses. The weight of the prosthesis depends on many factors like weight of the patient, height, muscle power, sex, age, activity level, etc .Hence optimum weight prosthesis should be given instead of light weight one to get the best possible performance. Also emphasis should be on functional restoration of amputee activities rather than on the energy consumption in prosthetic gait.

The word Prosthesis, the proper name for an artificial limb derives from the Greek words meaning

“TO PLACE AN ADDITION”

The distinct but inter dependant fields of amputation surgery & Prosthesis have historical roots extending back to about 1800 BC where, according to Rig Veda, the Indian warrior queen Vishpla had her leg amputated following a battle, was fitted with a Prosthesis made of iron and subsequent returned to lead her troops.

Despite the awaking of intellectual curiosity in the renaissance (14th to 16th centuries) the development of Prosthesis design its first 200 years did not keep pace with that of amputation surgery. The poor continued to use crude crutches, peg legs as they had for centuries before.

Prosthesis innovation finally began in 16th century. The most significant Prosthetic design was however the Transtibial Prosthesis introduced by the Dutch surgeon Verduyn. It consisted of a copper socket lined with leather, a solid ankle wooden foot and a leather thigh corset attached to the socket with jointed metal bars. This became the prototype for functional Transtibial Prosthesis until the introduction of the PTB Prosthesis in 1961 by Charles Radcliffe and James Forte at the University of California at Berkeley.

In 1912, Charleen designed an Exoskeletal Prosthesis weighing approximately 3.5 pounds with the newly available aluminum alloy named duralumin for his Amputee brother, who declined the use of heavy Prosthesis.

Since long most of the limb fitting centers in India including Artificial Limb Center, Chennai are providing Laminated Prosthesis (Conventional) with SACH foot.

The fabrication of this Prosthesis is cumbersome and takes longtime. The patient has to stay long time in hospital for complete fabrication and final finishing.

Gradually understanding the problem an Endoskeleton variety of Prosthesis namely Modular Prosthesis was developed.

It is on this basic idea that this present study was done to compare the cost efficacy and utility between Laminated Below Knee Prosthesis in our set-up.

It has been claimed that the Modular Below Knee Prosthesis is ideal for fitment, where it requires large scale production of Prosthesis and quick fitment of Prosthesis. If that claim is justified and Modular Prosthesis is found equal or better than that of Laminated Below Knee Prosthesis in terms of cost, efficacy, utility & quality, then the Laminated Prosthesis can be replaced by Modular Prosthesis.

This will make the amputee a useful productive member of the society, making them contribute to the economy of the country.

REVIEW OF LITERATURE

The oldest surviving Prosthesis (roughly 1000BC) is an artistically carved wooden hallux found on a female mummy in the west Theban necropole.

A roman Transtibial Prosthesis circa 300BCE had a wooden socket reinforced with bronze sheets

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The generation of heat by metabolic reactions in the enclosed socket is not easily taken away by natural convection and radiation. This would cause medical

problems like eczema, dermatitis etc. In order to prefabricate a comfortable prosthesis for patients, research is to done to determine the adequate air velocity in the socket by general heat balance equation. In addition an experiment was conducted to prove the value of air velocity. It was found that the experimental result is similar with result of computation. Fang-C-H, Huang-M-J, Chou-Y-L, Huang-G-F, "The study of thermal comfort for below knee Prosthesis" BIOMED-ENG-APPL-BASIS-COMMUN, 2004; Feb 25, 16/1:7-14.

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BASIC SCIENCE OF B.K. PROSTHESIS

Prosthesis is an artificial substitute to replace the lost part of the body both in appearance and in function. To achieve optional fit and alignment, a sequence of careful fittings and follow-up are necessary. In order to maintain a good condition of the Prosthesis, repairs and adjustments should be done as warranted by the individual's activity level and lifestyle. It is essential to understand the Mechanical and Biomechanical principles of Trans-Tibial Prostheses for effective Rehabilitation outcomes especially for patients who come for their first prosthesis.

COMPONENTS OF TRANSTIBIAL PROSTHESIS

Trans Tibial prosthesis has the following key components:

1. The Socket and Its Interface
2. Suspension Mechanism
3. Shank or Pylon
4. Prosthetic Foot.

Principle of making of socket design:

The PTB design distributes the loading pressures over six surfaces of the transtibial residual limb.

These include: - Patellar Tendon

- Pretibial muscle.
- Gastrocnemius-soleus muscle
- Popliteal fossa
- Lateral flat aspect of Fibula
- Medial Tibial Flare
- Around The Medial and Lateral Femoral Condyles.

Pressure intolerant areas are

- Tibial crest Tubercle and condyles
- Fibular Head
- The Distal Tibia and Fibula
- The Hamstring Tendons

The most commonly used socket varieties are the hard socket and soft socket. Plastic socket without an insert is a hard socket and when fitted with an insert it is a soft socket. Other varieties are the flexible socket in a rigid frame.

SUSPENSION MECHANISMS

Safe and effective Prosthetic use requires that the Prosthesis should be suspended comfortably and consistently on the limb during the activities in which the user chooses to be involved. All Suspension Mechanism must

1. Hold the Prosthesis firmly to the residual limb during the Gaitcycle
2. Allow the Patient to sit comfortably

Types

1. Sleeve Suspension
2. Supra Condylar Suspension
3. Cuff Suspension
4. Suction Suspension
5. Thigh corset with Side Joints.

SHANK OR PYLON

The definitive Prosthesis can be fabricated as either an Endoskeletal (having a central Pylon with a foam cosmetic cover) or Exoskeletal (having a hard outer shell between the Socket and Prosthetic foot) system

PROSTHETIC FOOT

The Prosthetic Foot is designed to replace many of the functions of the anatomic human foot. It must have the Biomechanical characteristics of the human foot as much as possible. The Prosthetic foot must substitute for the function of the bony anatomy as well as the loss of muscle action.

The Prosthetic Feet are classified into the following types

1. Non articulating foot (Eg. SACH feet)

2. Articulating Designs (Eg-Single Axis and Multiaxial Feet)
3. Solid ankle flexible keel foot (Eg. SAFE feet)
4. Dynamic response or Energy storing designs (Eg. The Seattle Foot and The Flex-Foot)

SACH foot continues to be one of the most widely prescribed foot because of its simplicity, low cost and durability.

PROSTHETIC ALIGNMENT

Prosthetic Alignment is defined as the relationship between the socket and the prosthetic foot. Alignment has an impact on comfort and on energy expenditure during the gait.

Three steps are necessary to achieve the accurate Prosthetic Alignment

1. Bench Alignment in Prosthetic Laboratory
2. Static Alignment while the patient is standing in the Prosthesis
3. Dynamic Alignment based on gait analysis.

TRANSTIBIAL MODULAR PROSTHETIC SYSTEM

The Term Modular always refers to an all-time relevant technology or pre-designed pre-made components aligned to complete Module. In Prosthetic Technology Modular term is always related to Endo Skeletal system.

CONCEPT

The prime aim of this versatile design is to transform the body weight through end component in accordance of normal skeletal mechanism. The system always preserves the facility of provision for flexion & adduction of 5 degree in respect to Anterior and Lateral tilting Method.

AVAILABILITY OF DIFFERENT DESIGN

Keeping the Biomechanical concept intact with relates to alignment system therefore Two types of Modular System are available in the market.

1. Translatory Swifiting Coupling System
2. Pyramidal Swifiting Coupling System

Pyramidal Swifiting System:-

This particular design incorporates a pyramid head and its counter part female structure coupled with four neck projected “**Allen Screw**” to maintain both linear and angulatory adjustment.

Translatory Swifiting System: -

This is a carriage type of device being capable of linear adjustment by a single turn screw component in relation to angular adjustment of $\pm 10^\circ$ with another oval component

The components of Modular prosthesis is illustrated as follows.

1. Ankle Adaptor-25.8mm-1no. (required for connecting socket linear extension with foot module)

incorporated with- M-10 in 6mm bolt

M-10(spring washer)

M-10(washer)

M-6 in 25 mm cap screw

2. Socket Adaptor (as same with no.1) - required for connecting alignment coupling and tubular extension.

3. Alignment Coupling System-

incorporated with

- ✓ Rotator unit
- ✓ Middle plate (concave top)
- ✓ Top plate (convex button)
- ✓ Low head height hexagonal bolt M-10 in 25 mm
- ✓ Low head height hexagonal bolt M-10 in 40
- ✓ Concave washer –M -10
- ✓ Rectangular long washer with convex bottom

RAW MATERIAL ESSENTIALS

The following raw materials are essentially required for the purpose.

NAME	SPECIFICATION	USE
1. polypropylene sheet (40% chalk filled)	330 in 12 mm Size	socket
2. Ethaflex (type- B)	5mm thick	soft insert
3. Ethaflex (type-R) or puf –cone	25 mm thick	cosmetic cover
4. Color Nylon Stockings	Adult size	Cosmetic outer lining
5. Thread locking fluid	270ml	locking of threads
6. Adhesive dendrite		Ethaflex bonding
7. Liquid soap		parting agent between POP cast & Mould
8. Glass marking / pencil		
9. Talcum powder		Socket trial
10. Petroleum jelly		parting agent between mandrill & mould
11. K.Y lubricating jelly (water soluble)		used in cast taking

MOULD PREPARATION-

The mould is prepared by specific Biomechanical process manually.

TOOLS, EQUIPMENT AND ACCESSORIES.

1. Torque wrench – 0-200 lb-f-in - 1no.
2. Allen wrench 5mm, 8mm - each 1 no.
3. Combination wrench size-17 - 1 no.
4. Halksaw - 1 no.
5. Fixture for maintaining tube paralleled & cutting – 1 no.
6. Twist drill - 1 no.
7. Actuated twist drill 10 mm - 1 no.
8. Top convex plate stud (M-10) – 1 no.
9. Drill machine 50 mm - 1 no.
10. Heat gun with variable temperature 400 °C – 1no.
11. Vacuum machine heavy duty - 1 no.
12. Electric hot air oven with thermostat control 0-400 °C – 1 no.

POSITIVE MOULD PREPARATION

After due modification on the basis of Biomechanics & finding out the geometrical attachment point by providing 5 degree flexion & 5 degree adduction angle with respect to central axial line, attach the convex cap (top plate) and make ready for Drape moulding.

SOCKET PREPARATION ON BASIS OF BIOMECHANICAL PRINCIPLE/ MOULDING/ATTACHMENT

12 mm polypropylene sheet is put in the hot oven at temperature of 230-280°C. The polypropylene sheet then becomes a transparent, this sheet is now called balloon or parison. After formation of appropriate parison, it is draped over the mould with proper vacuum application.

ALIGNMENT

Alignment of Prosthesis is defined as the position and orientation of socket over the Prosthetic Foot with optimum geometrical coherence to normal Skeletal Mechanism.

In built alignment facility has always an integral part of the Endoskeletal Prosthetic System – with a desirable flexible adjustment. In B.K. Modular system the manipulation of geo parameters can be made quicker and is also accurate. Correction can be achieved during dynamic phase also .

RANGE OF ALIGNMENT

Socket shift In (mm)	Socket tilt in(degree)	Toe out/in in (degree)
AP-20	AP-10	out-in
ML-20	M-10	up to desired angle

GAIT and GAIT OPTIMIZATION

With a series of observation from different aspect of study like In-set, Out –Set, Medial weight & Lateral weight & Vaulting the gait is optimized through dynamic process the prosthesis gets ready for final cosmetic covering.

FINISHING PROCESS

Cosmetic cover can be prepared from 12mm cross link poly Urethane foam by heating at a temperature of 140 °C. It is available in different trade names like-plastazote, ethaflex etc. The contour of the cosmetic cover this thus intricately designed.

- Its surface feel can be decided by the density
- It is durable and water resistant but not heat resistant
- Weight is very light

LAST SUPER FINISHING BY COSMETIC SOCKS

Finally the total system is covered with body color long socks to get the best natural cosmetic appearance.

BIOMECHANICS OF B.K. ENDOSKELETAL PROSTHESIS A COMPEDIUM

The Bio Mechanics of the B.K. Endoskeletal Prosthesis always relates the influence of socket Mechanism & the alignment factor. The socket is not a simple duplication of the stump shape into which stump fits. It is rather a significantly designed receptacle to provide comfortable & functional connection between the stump and the Prosthesis under the conditions of dynamic loading. In fact the socket interface not only maximize the uniform distribution of forces also creates an augmented momentum to walk better and faster.

Stump Socket Pressure – The interface pressure between the Stump and the Socket of Transtibial amputee are influenced by –

1. Fit of the socket
2. Alignment of the socket
3. Relationship of socket to foot
4. Modifying effects of the suspension
5. Relation between suspension system and point of suspension.

At equilibrium state: The lateral forces l times the distance b equal to weight(w) times the distance (a) $\Rightarrow lb=wa$ or $l= wa/b$

But the effect of horizontal correction of center of gravity cannot be ignored and it is in accordance with the following

- a) Reduced inertia force
- b) Increased tendency to gap
- c) Increased medial pressure
- d) Increased lateral pressure
- e) Optimum position

BIOMECHANICAL SYNOPSIS FOR TRANSTIBIAL AMPUTEE.

KINETIC PARAMETERS

Prosthetic loading from the pylon transducer showed that in all cases there were significant step to step variations. The Medio-Lateral bending moment showed largest differences in the repeatability envelopes due to alignment variations in majority of subjects. In fact difference in magnitude and pattern of the force and moment traces are attributable to various alignments and it is always necessary to employ a means of averaging signals. More over Fourier analysis technique is very much helpful for optimization the alignment analysis.

Amputee walking differs with different types of prosthesis and a step to step variation in the gait parameters exists. The variation can be quantified and described by signal pattern. In other words the alignment of prosthesis has a direct effect on amputees gait pattern. In fact for complete understanding of amputee locomotion both kinetic and kinematics data are necessary.

SUBJECTS AND METHODS

Thirty unilateral Transtibial amputees of which fifteen using Laminated B.K. Prosthesis with SACH foot and fifteen using Modular B.K Prosthesis with SACH foot for more than 6 months attending ALC, Chennai were selected for the study. The study was conducted between Jan 2011 to May 2011. The patients were explained about the study. A case history format, questionnaires as per published PEQ (Prosthesis evaluation questionnaires) and consent form was filled for each of the selected cases. All the subjects had a general health check up and counseling.

INCUSION CRITERIA:

1. Unilateral Below Knee Amputees
2. Age between 10- 65 years
3. Amputee using Laminated or Modular Transtibial Prosthesis for more than 6 months
4. Willingness to cooperate in the study
5. No residual limb swelling or wound

EXCLUSION CRITERIA:

1. Amputees with other associated limb loss
2. Amputees with the problems in the sound leg such as fracture and deformities.
3. Amputees without prosthesis
4. Unmotivated persons

Baseline Assessment:

A detailed clinical history and clinical examination was done to rule out any significant associated disease such as cardiopulmonary disease, musculoskeletal disease previous history of injury and treatment history if any. Detailed examination of the stump was done and cases selected with no residual limb pain, swelling or wound. Clinical examination of the sound limb was also done.

Baseline investigations were done prior to the study for every patient to rule out any sub clinical illness. Tests included Hb%, TLC, DLC, ESR, Blood sugar, urine routine and microscopic examination and X-ray stump. When the inclusion and exclusion criteria were satisfied the case was selected and clinical and laboratory details were recorded in a case sheet.

Anthropometric measurements

All anthropometric measurements were performed with the use of standard techniques.

Height and weight:

The subjects were requested to wear their original Transtibial prosthesis before having their height in cm measured (if required, the subjects were supported against a wall with adequate precautions to guard against bending of the trunk and knees).

The patient was made to sit on an electronic weighing scale and body weight in kg was measured without the prosthesis. The weight of the prosthesis was also determined.

Stump measurements:

The length of the stump in cm was measured from the knee axis to the tip of the stump.

Length of Normal leg measurement:

The length of the normal leg in cm was measured from the knee axis to the foot with the foot resting on the ground.

Explanation and Reassurance

- All patients were explained of the procedures to dispel fear and to correct misconceptions.
- They were also explained about the harmlessness and non-invasiveness of the study
- Informed consent was taken from all patients undergoing examination.

After the data was collected, it was analyzed by entering the data into a computer & statistically analyzed which include both descriptive & international statistics.

OBSERVATION AND RESULT

1. AGE: (n = 30)

63.3% of amputee (19) belongs to age group of 16 -45 years followed by 30% (9 patients) in the age group > 46 years.

TABLE – 1

AGE DISTRIBUTION (n = 30)

Age group in years	No. of patients
<15	02
16-30	07
31-45	12
46-60	07
> 60	02

2: SEX: (n =30)

23 Amputees were Male and 7 were Female

TABLE -2

SEX DISTRIBUTION (n = 30)

Sex	No. of patients
Male	23
Female	07

M: F= 3.28:1

3. OCCUPATION: (n = 30)

40% (12 patients) were Daily Laborer; followed by 16.7% (05 patients) were in Business

TABLE – 3

OCCUPATION DISTRIBUTION (n =30)

Occupation	No. of patients
Agriculture	02
Business	05
Daily Laborer	12
Housewife	04
Student	03
Jobless	04

4. CAUSE OF AMPUTATION (n = 30)

Train and Road Traffic Accident was the commonest cause of amputation. 70% (21 patients) followed by peripheral vascular disease 13.3% (4 patients)

TABLE – 4

CAUSE OF AMPUTATION (n =30)

Cause	No. of patient
Road traffic accident	16
Train accident	07
Peripheral vascular disease (including DM)	04
Congenital	01
Osteomyelitis / Sepsis	01
Machine injury	01

5. LENGTH OF STUMPS: (n=30)

Mean length of stumps was 20.72 cm, Maximum being 32.5 cm & Minimum 9.5 cm.

TABLE- 5
LENGTH OF STUMPS (n=30)

		Length in cm
Length of stumps	Minimum	9.5
	Maximum	32.5
	Mean	20.72
	SD	± 6.76

6. STUMP LENGTH PERCENTAGE: (n=30)

Mean Stump length percentage was 43.31 %, Maximum being 67.41 % and Minimum 20.43 %.

TABLE- 6
STUMP LENGTH PERCENTAGE (n=30)

		%
Stump length percentage	Minimum	20.43
	Maximum	67.41
	Mean	43.31 %
	SD	± 12.93

7. ARCHITECTURAL BARRIER: (n= 30)

Threshold in door way were the commonest barrier in 46% (14 patients) followed by uneven road in 16% (5 patients). Difference in Architectural Barrier disturbing ADL was found statistically insignificant for both type of Prosthesis

TABLE-7
DISTURBANCE DUE TO ARCTITECTURAL BARRIER (n=30)

Architectural Barrier	No. of patients
Threshold in doorway	14
Uneven road	05
Steep slopes	01
Steps	01
Staircase	01

8. COST OF PROSTHESIS

The actual cost of both the types of Prosthesis were calculated.

TABLE -8
COST OF PROSTHESIS

Type of prosthesis	Cost (rupees)
Laminated	6360.00
Modular	3905.00

COST OF PROSTHESIS

The actual cost of both the Prosthesis were calculated as follows

A. Laminated Prosthesis (PTB):

I- Cost of Prosthesis raw materials like

- ✓ SACH foot-1
- ✓ Ankle block-1
- ✓ Socket block(puf)-1
- ✓ Stockinette (roll)-1
- ✓ Thermoset resin- 800gm
- ✓ Additives-20gm
- ✓ Pigments- 15gm
- ✓ PVC film -1mt
- ✓ Ethaflex (6mm)- ½ sheet
- ✓ Shoe - 1 pair
- ✓ Prosthetic button -2 nos.
- ✓ Copperrivet – 2nos.
- ✓ Chrome leather-1.5 spt
- ✓ Lever- 1.5 sft
- ✓ POP bandage(10cm) -3 roll
- ✓ Pop powder -8 kg
- ✓ Vaseline -5 gm

All are calculated & fixed rate as Rs.2910.00

II. Cost of Fabrication:

The time spend by in fabricating the Prosthesis, hrs/day/Prosthesis Average time to complete a PTB prosthesis is 6 working day

(i.e. 8 multiply 6 = 48 hrs)

Monthly Pay of Senior Qualified Prosthetist (govt.) = Rs 8250.00

(i.e. Rs 275.00/day or Rs. 34.37 /hr)

Therefore, cost of Fabrication of PTB Prosthesis

=275 Multiply 6=Rs. 1650.00

III. Expenditure met by the patient to procure a Prosthesis

Patients stays in the hospital for about 15 days

Average wages loss /day =Rs.70 /day (apx. 70 x 15= Rs. 1050

Average daily expenses including transportation, boarding and lodging etc.
=Rs.50.00/day

The average duration for consultation, measurement, fitting, trials & gait training was taken as 15 days

There fore 50 x 15 days = Rs. 750.00

The overall cost for fabrication of Transtibial Laminated Prosthesis was worked out to be Rs 6360.00 approximately.

(Administrative & Manufacturing over head not included details in discussion)

B. ACTUAL COST OF MODULAR T.T. PROSTHESIS:

I Cost of Prosthesis raw materials like

- ✓ TT rod kit
- ✓ Polypropylene sheet(12mm)- 15sqinch
- ✓ Ethflex/puf covering
- ✓ Out covering shocks
- ✓ Shoes
- ✓ SACH foot
- ✓ Prosthetic button
- ✓ Copper rivet
- ✓ Leather chrome
- ✓ Leather liner

- ✓ Pop bandage
- ✓ Pop powder
- ✓ Vaseline

All are calculated & fixed Rate as Rs 2910.00

II. Cost of Fabrication:

Average time to complete a PTB Prosthesis=1 days

Therefore cost of Fabrication of a modular PTB Prosthesis is Rs.275.00 (Monthly pay of senior qualified Prosthetics (govt.) = Rs 8250.00(i.e. Rs 275.00/day or Rs. 34.37 /hr)

III. Patient Expenditure to procure a Prosthesis:

The average duration for Consultation, Measurement, Fitting , Trials , and gait training was taken as 6 days

Average wages loss/day =Rs.70.00 x 6=Rs.420.00

Average daily expenses= Rs.50.00 x 6= Rs300.00

The over all cost for fabrication of a B.K. modular Prosthesis was worked out as Rs. 3905.00 apx.

9. NEED FOR REPAIR-

There was no patient who required their prosthesis to be repaired in both the groups for repair within 6 months of getting their new prosthesis.

10. WEIGHT OF PROSTHESIS :

Mean weight of laminated prosthesis was 1.8 ± 0.3 kg & modular prosthesis was 1.5 ± 0.2 kg. weight difference was statistical in significant. The modular prosthesis was more acceptable to the patients in subjective feelings.

TABLE-10
WEIGHT OF PROSTHESIS

Type of prosthesis	Weight (Kg)
Laminated	1.8 ± 0.3
Modular	1.5 ± 0.2

11.COSMESIS OF PROSTHESIS :

Modular Prosthesis was cosmetically acceptable by 80% (12 patients) of Amputees & only 60% (9 patients) in the Laminated Prosthetic groups. The differences of cosmetics acceptability between two prosthesis groups were found to be statistically significant.

TABLE-11

COSMESIS OF PROSTHESIS (n=30)

Cosmesis	No of patients	
	Laminated	Modular
Acceptable	09	12
Unacceptable	06	03

12. COMFORT:

Problem like Heaviness, Cumbersome, Ill-fitting, Pain, Skin reaction, Excessive sweating, need of more stockinet due to loosening of socket are depicted in the table. However discomfort due to below mentioned problems was found statistical significant, for the laminated prosthesis. Few patients had more than one problem.

TABLE-12

COSMESIS OF PROSTHESIS (n=30)

Problems	No. of patients	
	Laminated	Modular
Heaviness	5	3
Cumbersome	3	1
Ill-fitting	2	0
Pain	1	0
Skin reaction	1	0
Excessive sweating	1	1
Need for more stockinet	2	0
None	0	10

13. EASE OF ADL & OTHER COMMON ACTIVITIES:

Differences of the two Prosthesis while performing activities like Sitting, Walking, Toilets, Dressing, Cycling, House Hold, Field & Recreational activities was found to be statistically insignificant.

TABLE-13

EASE OF ADL & OTHER COMMON ACTIVITIES

Ease of ADL & other common activities	No. of patients					
	Laminated			Modular		
	A	B	C	A	B	C
Sitting	10	3	2	10	4	1
Walking	2	13	0	1	14	0
Toileting	10	5	0	3	12	0
Dressing	0	15	0	0	15	0
Cycling	2	12	1	2	13	0
Household activities	7	8	0	3	12	0
Field activities	5	2	8	5	7	3
Activities at work place	5	7	3	4	10	1
Religious activities	0	0	15	0	0	15
Recreational activities	6	7	2	6	8	1

A = ABLE TO DO WITH DIFFICULTY

B= ABLE TO DO WITHOUT DIFFICULTY

C= NOT POSSIBLE

DISCUSSION

In the present study 63.3% of amputee belongs to age group of 16 -45 years followed by 30% in the age group > 46 years. The mean (\pm SD) age of the subjects was 37.86 ± 14.43 years.

Biswas observed in his study, that most patients were in age group of 21-40 years (55.29%) which is comparable with our study which shows that 63.3% patients belong to the age group 16-45 years

Sharma observed that 50 % of cases were in age group of 21-30 years, Agrawal et al (1978,1980) observed in their study commonest age group is in the third decade and male slightly older than female. This can be explained by the fact that, the age group of 26-45 years is the active members of the society and with family and social responsibility are more exposed to accident and injury.

In our study most of the patients (23) ie 76.67% were males and 23.33% (7 patients) were females. Biswas (1996) reported 146 cases of male (85.95) & 24 cases of female (14.1%) a male female ratio of 6.1:1, Agarwal et al (1978) observed a male female ratio of 4: 1. HLA PE (1988) reported a ratio of 4.2:1

Gafoor Abdul K (1991) reported a male female ratio of 3.4:1 which is comparable with our study in which the Male: Female ratio is 3.18:1. The high male incidence could be due to the reason that they are mostly involved in outdoor activities and hence, more exposed to injury & accidents.

In our study 40% amputees were Laborers and 13.3% were jobless and most of our amputee patients belong to low socioeconomic group.

In our study Train and Road Traffic Accidents were the commonest cause of amputation 70% (21 patients) followed by peripheral vascular disease 13.3% (4 patients). Our study matches with the other studies in developing countries where the major cause of amputation was trauma. Mittal et al in his study, report 96% of amputation as due to trauma, HLA PE (1988) in his study observed, trauma (55.25%) was the leading cause of amputation out of which the major specific cause of trauma causing amputation was Railway Accident (20%) followed by Road Traffic Accident (19%)

Turakhi HAS et al (1993) have reported 52.9% amputation due to trauma. Agarwal, A.K. et al (1980) in their study observed that trauma was the most common cause of amputation followed by peripheral vascular disease. Staats T.B. (1996) reported that there are 14000 amputations every year in India due to train accidents. Sharma cited 74% cases as due to train & road traffic accident, Biswas in his study found 71% of amputations are due to Train & Road Traffic Accident and 15% as due to vascular cause. Priyadarshini C.S et al (2005) in their study observed

that 67.8% cases were due to trauma of which 36.6% was due to road traffic accident alone.

The present study further strengthened our knowledge that trauma is the most common cause of amputation in developing countries, of which train & road traffic accidents is the main cause of amputation in India.. Amputation due to vascular disease is common in developed western countries. In this study 13.3% (4 patients) of amputation was due to peripheral vascular disease.

This can be explained by the fact that the age group of 26-45 years are the active members of the society. With the increase in the family and social responsibility, there is increase in their activity and hence exposing them to accident and injury.

In this study the age between 15 years and 65 years were selected because it was easier to get a precise feed back through interview. If the patient were too young or old, there may be chances where the patient may restrict his movement or may not wear the prosthesis at all or may not be able to give accurate feedback.

In this study the average stump length percentage was 43.31 %. The mean stump length was 20.07 cm, maximum stump length was 32.5 cm and minimum was 9.5 cm. When we excluded the two pediatric patient's data the average stump length percentage was 43.6 %, with a mean stump length of 21.2cm which is little more than recommended by surgeons when the amputation site is not dictated by trauma, tumour or vascular considerations. The length of a standard Trans Tibial

Residual Limb is between 12.5 and 17.5 cm (M. Lusradi, Orthotics and Prosthetics in rehabilitation Chapter 21:371). Adherent scar present in 2 patients and neuroma in 1 patient were responsible for pain, apart from pressure points due to continuous wearing of prosthesis.

Depending on the geographical and socio-economic factors, some forms of Architectural Barriers were experienced by Amputees. Commonest being Threshold in door way which was 46% followed by 16 % for Uneven Roads. Of the total 22 patients whose day to day activities were disturbed due to Architectural Barriers there were 12 Amputees with Laminated (40%) and 10 (33%) Amputees with Modular Prosthesis. However there was no statistical significance.

There was substantial difference in the cost of the Prosthesis. Laminated Prosthesis was one and half times more costly than the Modular Prosthesis. In calculating the cost of the Prosthesis, the actual cost and the subsidized cost was considered. Subsidized cost was not considered in this study, because all the above Prosthesis are given free of cost by the state government at ALC. Hence to arrive at the cost differences the actual cost of Prosthesis was worked out as follows.

- ✓ Actual cost of the prosthesis raw material
- ✓ Cost of fabrication-manual workers
- ✓ Patient's expenditure
- ✓ Administrative & workshop over head (not taken into consideration)-
explanation below

L. Sapp et al (1995) have cited that the overall gait training time for a Transtibial Amputee was 44.0 ± 26.5 days. Christensen et al (1995) have given a longer duration of 187 (86-314) days as a median period for gait training in a unilateral TransTibial Amputee. However, in calculating the cost of the Prosthesis, only 5 to 10 days was considered as time spent for gait training.

Unlike in western countries, our amputees don't spend much time for regular gait training due to lack of knowledge, economic reasons and family problems, despite its importance stressed by Rehabilitation professionals. Considering the time duration analyzed as in the above literature and doing a comparative analysis of the cost in our study would be a bias, since amputees fitted with the Prosthesis, did not spend enough time for gait training in our study.

Due to complexity and variability of calculating the cost of administrative and manufacturing overhead, it was not taken into consideration while calculating the cost of the Prosthesis.

In the present study, apart from the above factors, the low cost of Modular Prosthesis the following additional factors were noted. The time taken for fabrication of the Prosthesis was much less. The amputee comes in the morning and by afternoon the Prosthesis is ready for fitting and trials. After necessary adjustments and corrections in alignment (if needed) the Prosthesis is finalized by evening. This minimized the time required by the prosthetist for fabrication and also minimized the

days lost by the Amputee. Thus the overall expenditures of the patient are reduced. It also requires less man power.

T.B.Straats has stated that in developing countries, limited financial or personal resources are available for Amputee Rehabilitation. H.J.B. day have cited that the cost of Prosthesis have to be divided into two parts, the cost of the Prosthesis (actual cost) and the cost of Transport & accommodation at the fitting centre. He further stated that due to absence of any standardization in the method of calculating the costs, he observed that the cost of transport & accommodation may be as great as or greater than the prosthetic cost.

Poonekar(1992) identified a list of prevailing factors affecting Prosthetic & Orthotic in India. He feels that for an appliance to be appropriate in India, it should be:

- ✓ Low cost
- ✓ Easy availability
- ✓ Capable of manual fabrication
- ✓ Considerate for local climate & working conditions
- ✓ Durable
- ✓ Simple to repair
- ✓ Technically functional
- ✓ Biomechanically appropriate
- ✓ As light weight as possible

- ✓ Adequately cosmetic
- ✓ Psychosocially acceptable

In the present study there is no such statistical significant for repairing of Prosthesis to come to a conclusion

Weight of Modular Prosthesis was found to be lighter than the Laminated Prosthesis subjectively. The difference was insignificant statistical. Gailey et al (1997) in their study have observed that if the mass of prosthesis is increased by more than 907 gms, there is increased in energy expenditure & increased heart rate. In the present study the weight of the laminated Prosthesis was 1.8 ± 0.3 kg & Modular Prosthesis was 1.5 ± 0.2 Kg.

Prosthetic manufacturers and prosthetists have long been concerned with minimizing the mass of the amputee's prosthesis. During the past two decades, use of lightweight materials including titanium and carbon graphite composites has decreased overall prosthesis mass but there was no significant variance was observed in ambulation VO_2 and hence in energy expenditure.

It has been suggested that heavier prosthesis might stimulate musculoskeletal and cardiopulmonary adaptations favoring greater tolerance of the additional mass. This finding is important, especially as considerable emphasis is placed during prosthesis design and fabrication on minimizing its mass, emphasis

possibly at the exclusion of componentry or materials which might favor improved function and decreased energy expenditure.

Research by Donn (1989) and coworkers supports the notion that a lighter prosthesis may not necessarily be better. Another argument against lightweight prosthesis is supported by the work of Dillingham et al (1992) who have found that the major force of propulsion is not only produced by the push-off but rather by the deceleration of the mass of the swing leg.

There is a huge controversy as to whether light or heavy weight prosthesis is required for the patient. Meanley S in 1995 had stated that the major objective of lower limb prosthesis is to the restore the amputee to his original functional capacity as possible. Nielsen CC et al in 1989 found in their study that 47.6% of their patient fitted with lower limb prosthesis was concerned about comfort.

The weight of the Laminated Prosthesis was mostly due to the Lamination of the socket & shin-piece by polyester resin & SACH foot piece contribute only about 1/6th the weight of the Laminated Prosthesis. The weight of the Transtibial Modular Prosthesis was mostly due to SACH foot piece and coupling agent.

Weight of the Prosthesis is an important consideration while selecting prosthesis because energy consumption is directly proportional to the weight of the Prosthesis and in term of minimal gait disturbance.

Stability with Prosthesis was comparable for both the Prosthesis and there was no statistical significant difference.

Cosmesis of the Prosthesis has been an important factor for its acceptability. In the present study Laminated Prosthesis was cosmetically unacceptable in 40% & Modular in 20% of patients. This difference is statistical significant. Due to last supper finishing by cosmetic socks Modular Prosthesis is cosmetically more acceptable .

Meanley S. in 1995 had stated that the major objective of Prosthetics is to restore as much as functional capacity as possible while maintaining a good cosmetic result. Red chiffe C.W. in 1974 fabricated cosmetic cover for lower limb prosthesis which is well acceptable to the amputees.

Problems such as heaviness, cumbersome, ill-fitting, pain, skin reaction, perspiration and need for more stockinet was noted among laminated prosthesis. Caloline C.Nelson etal in 1989 found in their study that 47.6% of their patients fitted with lower limb prosthesis were concerned about comfort.

Meanley has stated that the use of plastics or other materials which will neither rust nor rot is important in communities where much walking is done through mud is a daily occurrence.

In this study while comparing the comfort of the prosthesis, no statistical significance was observed. While comparing the ease of performing ADL and other activities there were no statistical significant finding in terms of Sitting, Walking, Toileting, Dressing, Cycling, House Hold Activities, Field Activities & Recreational Activities.

Astrom & A. stenstrom (2004) state that polyurethane concept was better in physical capacity in 56% and socket comfort was better in 82% compared with the Conventional Suspension.

Although there was patient satisfaction of 85% and compliance of 94% for the HDPE Jaipur Trans Tibial system it was not considered acceptable as 49% reported walking distances less than 1 km and 36% discomfort-J.S.Jensen, J.G.Craig, L.B.Mtalo & C.M. Zelaya “clinical field follow up of high density polyethylene (HDPE)-Jaipur Prosthetic Technology for Trans-Tibial Amputees.” *Prosthes.-Orthos.Int.* 2004; 28(3):230-244

Therefore, in this comparative study between Laminated B.K. Prosthesis & Modular Prosthesis, following advantages are seen in modular system.

- ✓ It permits use of both thermosetting & thermoplastic socket
- ✓ It facilitates Instant Alignment permutable for any Anterior-Posterior, Medial-Lateral Tilting change during the Dynamic Gait Cycle.

- ✓ Modular concept always helps to reduce the fabrication time considerably and eliminate various raw materials.
- ✓ It enhances cosmetic appearance
- ✓ Without sacrificing the quality it reduces cost factors.

Thus modular Transtibial. Prosthesis always promotes an economical simplified technology to combat the Transtibial disability.

The limitations in this study are

Sample size was 30 in number, this was because of the limited time duration available for this study. Due to the small size of the sample actual statistical significance could not be judged accurately.

Hence the interpretation of the results should be done keeping in mind this limitation.

SUMMARY

The study was conducted on 30 unilateral below knee amputees at ALC, Chennai, to compare the cost, efficacy and utility of Transtibial prosthesis. To summarise

- 63.3% of amputee belongs to age group of 16 -45 years
- Majority of amputees were males 76.67% were males.
- 40% of the patients were Daily Laborers
- Train and Road Traffic Accident were the commonest cause of amputation 70%
- The average stump length percentage was 43.31 %. The mean stump length was 20.07 cm.
- Laminated Prosthesis was costlier than Modular Prosthesis
- Laminated Prosthesis was cosmetically unacceptable in 40% & Modular in 20% of patients
- Threshold in doorway was the commonest (70%) Architectural Barrier.
- Heaviness of Prosthesis was complained by 33% of patients with Laminated Prosthesis and 20 % Patients using Modular Prosthesis.

- There was no statistical significant findings in terms of ease of performing daily activities such as Sitting, Walking, Toileting, Dressing, Cycling, House Hold , Field Work Place and Recreational Activities.

Salient features of Modular Prosthesis system For Amputee

- Very light in weight
- Less energy required for Ambulation
- Superior cosmetic appearance
- Fabrication time is less
- Low cost
- Better comfort with self suspension provision
- Less maintenance
- Easy change in socket if required
- It increases prosthesis wearing time
- It increases patient's activity sphere.

For Prosthetist

- Easy to manufacture
- Fabrication time is less

- Adjustments can be done even after final finishing
- All component are available in prefabricated form except socket
- Any manipulation in alignment factor, i.e.(prosthetic factor & amputee factor) can be established with little effort
- Improve quality of prosthetic management for transtibial amputee.

For Rehabilitation Centre

- Accelerate prosthetic management and simplify the process of rehabilitation with quality concerned
- Reduces infrastructure's value by requiring less number of machinery, tool & equipment
- Procuring & handling of the component management services is very simple.
- Even a small limb fitting centre having minimum infrastructure facilities will be able to manufacture modular Transtibial prosthesis.

CONCLUSION

This study was aimed to find out the cost, efficacy and utility of the two types of Transtibial Prosthesis i.e. Modular Transtibial Prosthesis and Laminated Transtibial. Prosthesis (Conventional) with SACH foot. It was found that Modular Prosthesis was superior in terms of low cost, high cosmesis and more comfort with a comparable efficacy and utility as compared to the Laminated Prosthesis.

In smaller institutions where there is limited financial and manpower availability relative to the patient load Modular Prosthesis is definitely going to be a better choice for Transtibial Amputees. The lesser cost of fabrication of modular prosthesis is an added advantage.

Disadvantages of fabricating modular prosthesis are it requires expertise and prefabricated Modular kits must be available. This would mean that it requires a well equipped institutional set up such as ALC, Chennai with adequately trained Prosthetist and facilities for gait analysis and training.

The combination of skills, concepts, and techniques of the amputation surgeon, prosthetist, and has enabled amputees to successfully compete in sports and other recreational activities because of their prostheses, rather than inspite of them.

Hence due consideration has to be given while designing lower limb prosthesis and it should to cater to the amputee's need.

So as Meanly S. has stated in 1995 the major objective of Prosthetics the world over is to restore the amputee as functional a capacity as possible in his cultural environmental , at the same time achieving a good cosmetic result.

Therefore we conclude from the study that comparing Modular Transtibial Prosthesis with conventional laminated Transtibial prosthesis, modular prosthesis is by far superior in terms of technology, cost effectiveness, comfort and cosmesis.

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Chart 1: AGE DISTRIBUTION (IN YEARS)

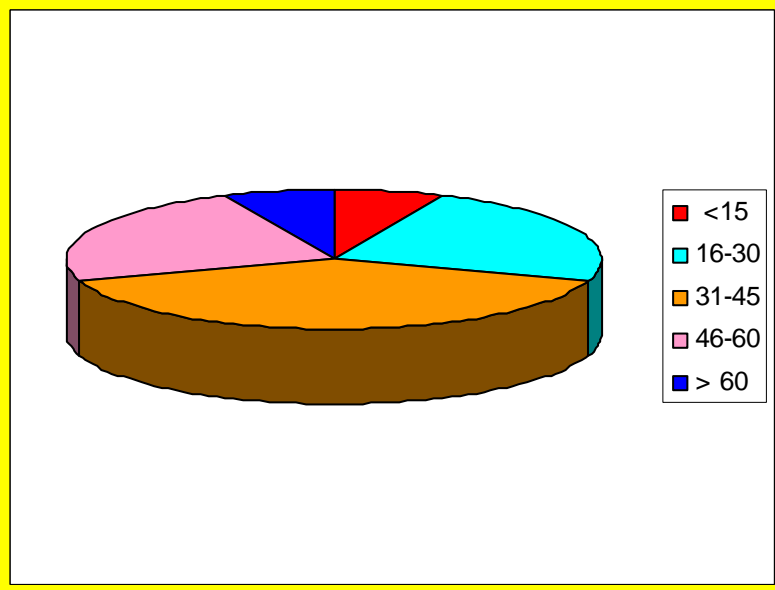


Chart 2: SEX DISTRIBUTION

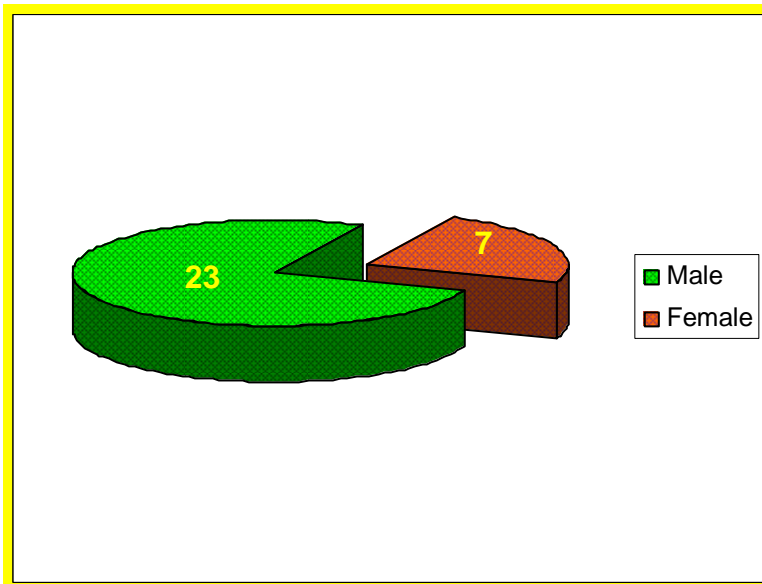


Chart 3:

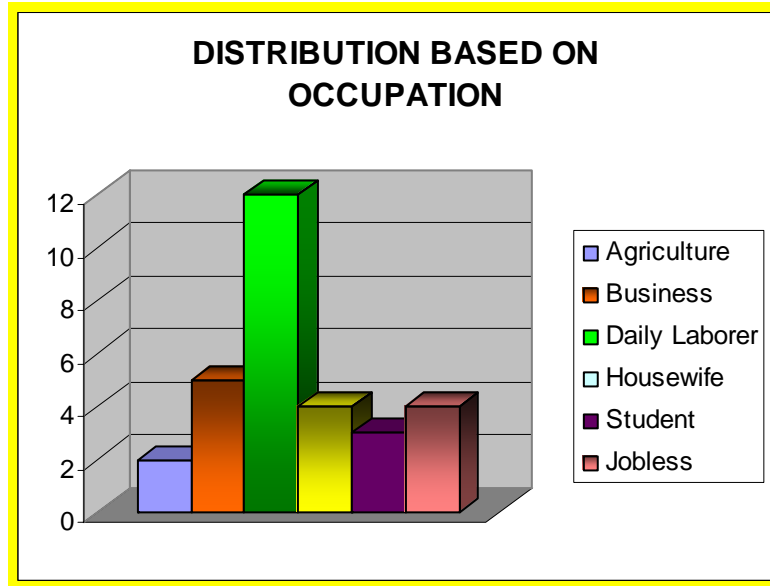


Chart 4:

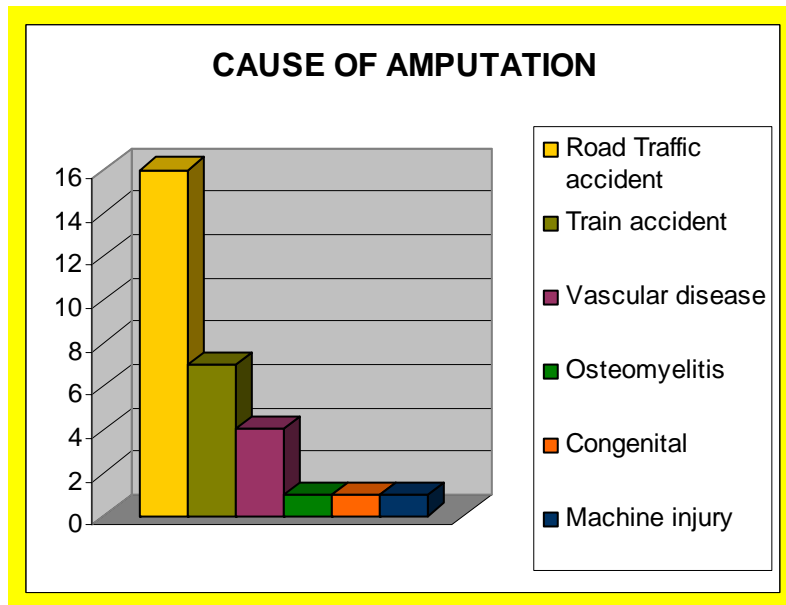


Chart 5:

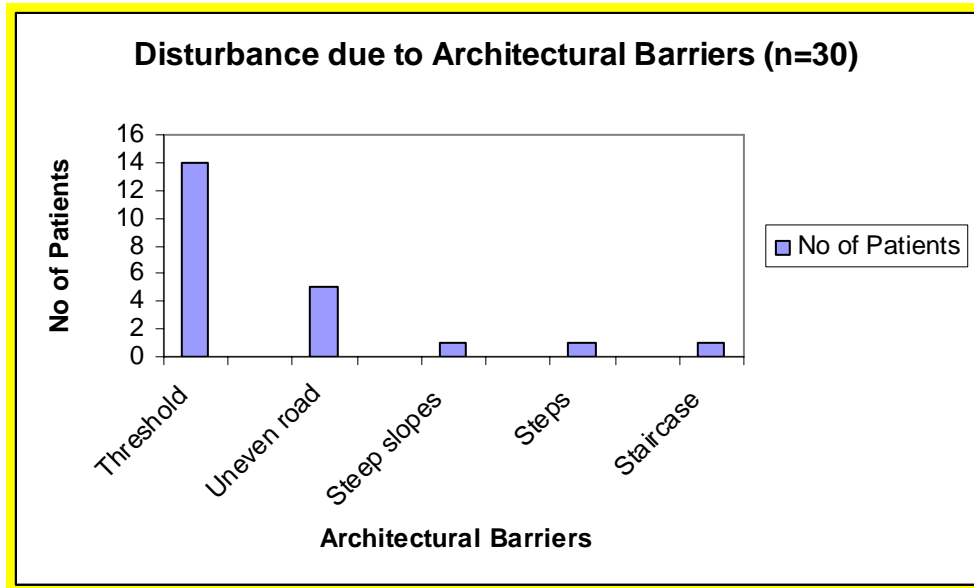
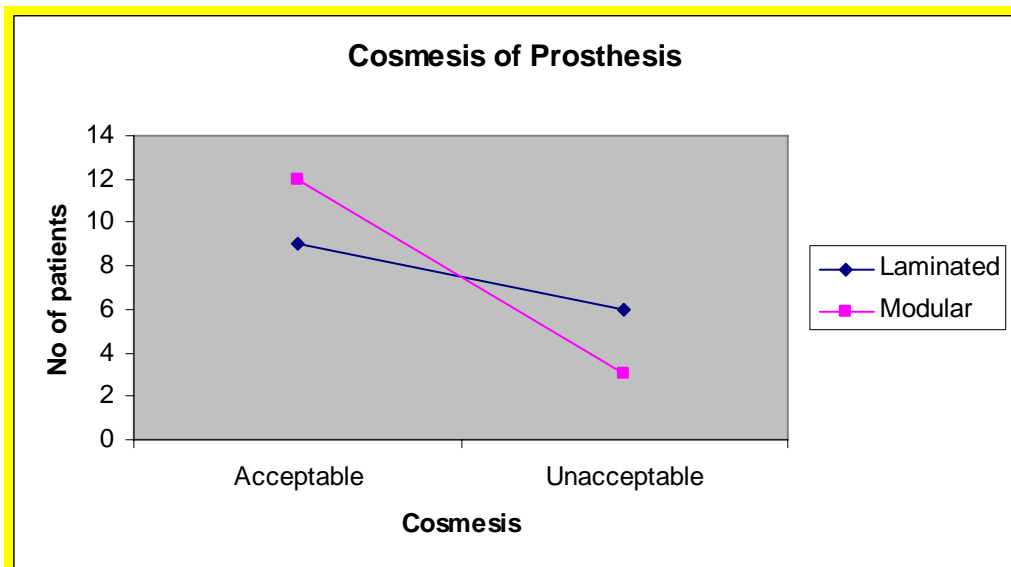


Chart 6:





NEGATIVE MOULD



POSITIVE MOULD



SOCKET WITH LINER



PYLON



EXOSKELETAL TT PROSTHESIS



HOT AIR OVEN



GAIT TRAINING

ANNEXURE

PROFORMA FOR TRANSTIBIAL AMPUTEE PATIENTS

PATIENT DETAILS:

NAME:

ACC NO:

DIAGNOSIS

AGE:

SEX

HEIGHT:

WEIGHT:

ADDRESS:

PH NO:

HABITAT (RURAL/SEMI URBAN/URBAN):

OCCUPATION:

ANNUAL INCOME:

SOCIOECONOMIC STATUS:

MEDICAL HISTORY:

AMPUTATION HISTORY:

CAUSE OF AMPUTATION:

SIDE OF AMPUTATION:

SOUND LIMB CONDITION:

SPINE CONDITION:

A. STUMP:

1. LEVEL OF AMPUTATION:

2. LENGTH OF STUMP

3. INSPECTION- SCAR

4. PALPATION- TENDERNESS

ADHERENT OF SKIN
 BONY PROJECTION
 EDEMA
 NEUROMA

5. ROM OF KNEE JOINT
6. STRENGTH OF STUMP
7. ANY OTHER ABNORMALITIES

NORMAL LEG DETAILS:

LENGTH (cm)	DEFORMITY/FRACTURE/SKIN CONDITION

B. PROSTHESIS DETAILS:

No of PROSTHESIS	TYPE OF PROSTHESIS (ENDO/EXOSKELETAL)	SOCKET TYPE	SOCKET ALIGNMENT	FOOT TYPE	FOOT ALIGNMENT

C.Architectural Barrier:

1. THRESHOLD IN DOORWAY
2. UNEVEN ROAD
3. STEEP SLOPES
4. STAIRCASE
- 5..STEPS

DOES PATIENT HAVE PROBLEMS IN AMBULATION/ DAY TO DAY ACTIVITIES – YES/NO

D.COST:

1. ACTUAL COST OF PROSTHESIS
2. PROVIDED – STATE GOVERNMENT SCHEME
- FULL COST
3. NO. OF DAYS REQUIRED FOR TRAINING
4. EXPENDITURE OF TRANSPORTATION FOR TRAINING WITH/WITHOUT ACCOMPANYING PERSON
5. NO OF DAYS STAY IN HOSPITAL

E. NEED OF REPAIR- IN THE LAST SIX MONTHS: YES/NO

1. BREAKAGE SITE:
2. LOOSE SOCKET
3. CUFF SUSPENSION

F. WEIGHT:

1. ACTUAL WEIGHT WITH SHOE
2. PATIENT FEELS – LIGHT / HEAVY / VERY HEAVY

G. STABILITY

1. ABLE TO BEAR WEIGHT ON AMPUTATION SIDE
-PARTIALLY
-FULLY
-NOT POSSIBLE
2. ABLE TO AMBULATE WITH / WITHOUT ASSISTIVE DEVICE
3. ABLE TO WALK INDEPENDENTLY

H.COMFORT

- | | |
|----------------|--------|
| 1. HEAVINESS | YES/NO |
| 2. CUMBERSOME | YES/NO |
| 3. ILL FITTING | YES/NO |
| 4. PAIN | YES/NO |

5. EXCESSIVE SWEATING YES/NO

I. COSMESIS

1. ACCEPTABLE / NOT ACCEPTABLE

J. EASE WITH ADL

1. SITTING YES/NO

SQUATTING YES/NO

CROSS LEGGED SITTING YES/NO

2. MOBILITY

- WALKING YES/NO

- CYCLING YES/NO

-OTHER TRANSPORT PROBLEMS YES/NO

3. TOILET ACTIVITIES A/B/C

4. DRESSING ACTIVITIES A/B/C

5. EATING ACTIVITIES A/B/C

6. ACTIVITIES AT WORK PLACE A/B/C

7. HOUSEHOLD ACTIVITIES (COOKING, CLEANING, WASHING) A/B/C

8. FIELD ACTIVITIES A/B/C

9. RELIGIOUS ACTIVITIES A/B/C

10. RECREATIONAL ACTIVITIES A/B/C

A – ABLE TO DO WITH DIFFICULTIES

B – ABLE TO DO WITHOUT DIFFICULTIES

C – NOT POSSIBLE

K. PATIENT'S SATISFACTION-

REMARKS:

DATE:
TIME:

PLACE:
.....

SIGNATURE OF PATIENT