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RESEARCH ARTICLE

DESIGN & DEVELOPMENT OF IMMEDIATE POST SURGICAL FITTINGS FOR THE AMPUTEE

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ABSTRACT

Patients undergo amputation on their legs (either transfemoral or transtibial) for the reasons of accidents, diabetics, vascular disease and cancer. Following amputation, amputees (handicapped) are fitted with artificial limbs (prosthetics) to provide mobility. But, during utilization of the prosthetics, it is identified to provide discomfort and pain to the handicapped. This is certainly for the mismatch between the amputee's body part and prosthesis. Reason for mismatch is for the lack of products in shaping the femur during healing period. Currently, cotton gauze is wrapped over the handicapped wound. Thereby, leading to a poor shape of the healed body part, creating discomfort during the application of artificial limbs. In spite of the potential for application of products to provide shape of the amputee body part, for current manufacturing constraints products are not manufactured. This project is focused in overcoming the current intricacy, aimed to undergo a detailed research in identifying, designing and developing early / immediate post-surgical products required for the amputee.

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INTRODUCTION

Amputation is the intentional surgical removal of a limb or body part. It is performed to remove diseased tissue or relieve pain. This is probably the largest cut the amputee has ever had. The amputee feels considerable pain in their stump/residual limb. Among the vast majority of amputees, pain gradually decreases after the operation until it eventually goes away. Unfortunately, this is not always the case. If the stump is not formed well or is not properly wrapped and shrunken, it will hurt when pressure is put on it. Occasionally the end of the bone in the stump develops tiny spurs which may cause irritation of adjacent muscles and severe pain with movement. This can happen years after the amputation and they may have to be removed surgically.

Fig 1 Amputation Surgery

Fig 2 Amputed Body Part-Stump

All of these changes affect the way your prosthetic fits and how much physical stress your residual limb can take. Prevention is the best approach. Keeping the limb in good physical shape will avoid most of the pain problems and discomforts while using the prosthetic product.

For the purpose of shaping the residual limb Early Post-Surgical Fitting (EPSF) are used. Early Post-Surgical Fitting is realized to provide a general improvement for the physical condition of the. Currently, the EPSF was a disposable soft elastic band, where prior supports were provided in order to give a rigid support. But, it is found to be painful and/or difficult to use as a prosthetic device. Further, during the period of amputation, regular inspection is undertaken which leave the amputee with severe pain. To overcome the pain experienced by the wrapping of the elastic band on the stump, the patient was supplied with rigid EPSF products that were made when the patient was on the operating table. Though these rigid dressings are custom made, when they are cast and cured, a certain amount of heat is liberated that could be experienced by the amputee and these casts cannot be reused as the healing continues. However, during early stages, up to 160 days of amputation, the volume of the residual limb changes and custom manufacture of EPSF is limited because of the contact involved in manufacturing and the frequent changes of limb volume. Therefore, the need is to have a unique way of product design and manufacture of custom EPSF.

Back ground

Kraker D *et al* (1986), discussing about the early post-surgical fitting claimed the need for shaping the stump / limb.The traditional post-operative stump dressing consisted of gauze and wool dressing, held in place with creep bandages. These standard soft dressings (SSDs) are adequate but allow the

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stump to develop considerable postoperative edema, making the fitting of prosthesis more difficult. Prosthetic fitting may be delayed, and there are often several prosthetic sockets made as the edema reduces. These dressings also fail to protect the new stump from accidental bumps or trauma. An alternative to the SSD for trans-tibial amputees is the Rigid Dressing (RD),these rigid dressings produced shorter rehabilitation hospital stays (Baker et al. 1977). Due to cases of infection and re-amputation, non-removable rigid dressings fell out of favorstheir use appears to be hampered by the concern of surgeons and rehabilitation teams about the difficulty of wound inspection, which could delay early detection of wound breakdown or infection (Hughes et al. 1998).

To address problems caused by the non-removal of early rigid dressings, Wu and Krick (1987) described a Removable Rigid Dressing (RRD) made from plaster bandage, which could be easily removed for wound inspection. The benefits of the RRD included: soft tissue immobilization and prevention of edema, which facilitate wound healing; elimination of skin breakdown commonly seen in poorly applied elastic bandaging; protection of the stump from trauma in the event of a fall; provision of early training in stump sock and socket donning which may facilitate independent prosthesis use.

Identified through current literature review, internationally numerous works have been undergone and still in progression, in identifying newer ways of early and immediate post-surgical fitting. Nationally, the area of immediate and post-surgical fitting of products suitable to the handicapped is not explored to a greater extent. This is particularly because, the area of prosthesis within India haven't gained much importance. Alternatively, discussing with various orthopaedicians this area of exploration was identified to have an enormous potential in serving the needs of the handicapped.

Post–operative Management

The Early/Immediate Post–operative period is then period between the time of surgery and time of fitting the prosthesis. It is also termed as the Post-Surgical period. The goal of postoperative management in patients with amputations is to ensure primary wound healing and pain control, prevent edema, shape the residual limb for prosthetic fit, and, to the extent possible, prepare the patient for restoration of function and quality of life. This is a vital period in the rehabilitation process if a good functional stump, and thus the most efficient use of prosthesis could be obtained. Delaying prosthetic fitting because of inadequate shrinkage of the residual limb is detrimental to and discouraging for the amputee. The delay is especially frustrating when the patient displays the ability to wrap the limb well and is conscientious about following the treatment program In order to begin prosthetic rehabilitation; the residual limb must be well healed and non-edematous during the postoperative period. Adequate supportive bandages during the postoperative period is required, which should

1) Act as a dressing,
2) remain securely positioned despite movement of the limb,
3) Hold tissue to control edema, and
4) Mold tissues to facilitate prosthetic fitting.

Aims of postoperative management

- To provide proper shape to the body part.
- To prevent deformities.
- To control stump edema.
- To maintain strength of whole body and increase strength of muscles controlling the stump.

Post-Operative Prostheses or Immediate Post-Surgical Prosthetics (IPOP)

Postoperative prosthetics can help speed recovery time, protect the wound from trauma, and reduce pain and swelling after amputation surgery. These types of prostheses are known as Immediate Post-Op Prostheses (IPOPs). They are applied in the operating room or in the early days following surgery. Without an IPOP, patients usually wait until the surgical wound heals before getting their first prosthesis. The longer the waiting period, the greater the risk that patients may experience limb weakness, body reconditioning, joint stiffness, or injury to the residual limb from falling while trying to move about on one leg. By getting an IPOP, many patients can begin their rehabilitation sooner, more safely, and have less uncertainty about their future.

Existing Products and Problem In Existing Products

Soft dressing - Elastic Bandages

At present elastic bandages (or cotton gauze) are widely used because they inexpensive and readily available. It has traditionally been used despite its inability to maintain continuous snugness and the difficulty encountered in applying the wrap. The usefulness of this type of dressing in amputation management is controversial. The patient's application of such Stump wrapping is a fine motor skill that is difficult for many amputees, particularly patients with multiple problems, or care givers to do. Elastic bandages do not usually remain secure, particularly when the amputee is in bed. The elastic bandage can allow the limb to form "dog-ears" and bulbous limb shaping. The elastic bandage can cause skin breakdown. Wound and stump are also not protected from an elastic bandage. The bandages provide poor control of stump edema and often cause distal edema.

Several studies have concluded that the greatest delay in prosthetic fitting occurred among amputees who used elastic bandages rather any other method. The use of a compressive elastic bandage is not only a challenging task for the patient but frequently causes skin breakdown and distal edema. The method of wrapping is also varying for each and every time it is been wrapped in terms of pressure and exact positioning of the earlier wrap of primary importance when considering a compressive bandage is the amount of externally applied pressure. Elastic bandages provide relatively low constant pressures for short periods of time. The elastic wrap exhibited the greatest range of pressures as well as the majority of highest readings.

Fig 3 Cotton Gauze

Therefore, this method is unreliable and potentially dangerous in terms of pressure and pressure distribution. Due to the

uneven compressive pressure the stump portion is poorly shaped hence leading to pain and discomfort while wearing a permanent prosthesis.

It was identified elastic bandage was the most widely used because it was less expensive, even though it had serious drawbacks like primarily not shaping the stump because of the uneven pressure (wraps).The directions of wrapping the elastic bandages in both Above Knee(AK) and Below Knee(BK) are given below

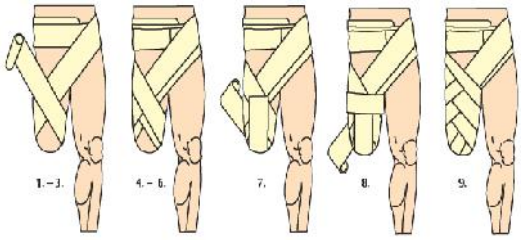


Fig .4 Wrapping with an Elastic Bandage (Above-Knee Amputations)
Figure adopted from Paddy Rossbach, RN

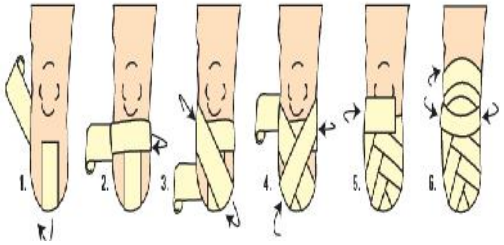


Fig .5 Wrapping with an Elastic Bandage (Below-Knee Amputations)
Figure adopted from Paddy Rossbach, RN

Rigid dressing – Plaster of Paris

In some cases plaster cast is also used as IPOP, which is a rigid dressing. This process is better in providing uniform pressure than in the case of Elastic bandage. When the limb volume changes the old dressing has to be replaced by a new dressing corresponding to the altered limb volume. This process continues until the final limb volume is achieved. This makes the process inefficient.

Fig .6 Rigid Dressing
Figure adopted from R Kyte; R Wolfson; J Engelbrecht, 2010

Project Work Approach

The project work is approached in such a way to replace the existing post surgical fitting to favour the amputees in their successful rehabilitation after the amputation surgery. The use of soft dressing as the post-surgical period causes problem for the amputee after the rehabilitation process, when the artificial limbs are fitted due to the mismatch prevailing between the artificial limb and the amputed body part. This mismatches leads to pain and discomfort for the amputee. Replacing the soft dressing with a rigid dressing could shape the amputed body part such a way the mismatch could be eliminated. As the mismatch is eliminated the amputee could be relieved from the pain when utilizing the artificial limb. The project work a

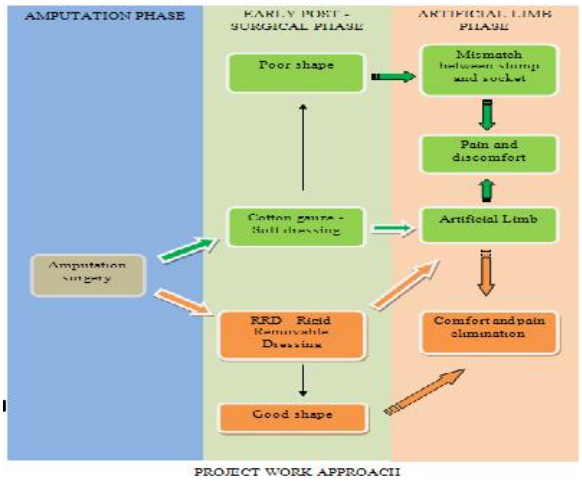


Fig .7 Project approach

Data Collection

The data collection of this project comprised of a detailed study on the current post surgical method, wound management strategies, the advantages and disadvantages of the current process through consultations with doctors and prosthetics in and around Coimbatore. This gave a clear idea of the existing problem and also guiding towards the identification of a suitable solution for the problem.

Consultation with Experts

The consultation with the experts was done on the topics amputation, immediate post-operative wound management and also about the various prosthetic solutions during the post-operative period. Though the literature survey covered the advantages of removable rigid dressing utilization over soft dressing or a rigid dressing, it was still vital to restore the real time data. Hence a ranking table was prepared with ranking ranged from 1-5. This ranking was done between the various types of dressing namely soft dressing, rigid dressing, removable rigid dressing and semi rigid dressing. The ranking covered was based on Stump shaping, Edema control, Wound healing. This ranking table with the suggestions from consulted doctors and prosthetist is as follows

Tab 1 Ranking Table – Stump Shape

	Stump Shaping			
Doctors	Soft dressing	Rigid dressing	Removable Rigid dressing	Semi Rigid dressing
Dr. S. Elangovan, M.S (ortho)	2	4	4	2
Dr. Major. K. Kamalnath M.S, D. ortho,	2	3	3	2
Dr S. Noorul Amin Shahul Dighys Med, D	1	2	3	2
Mr.Balakannan, Prosthetist & Orthotist	2	2	3	3
Mr.Mohanci, Prosthetist & Orthotist	1	3	4	2
Mr.Saravanan, Prosthetic & Orthotic Engineer	2	2	4	3
Mr.Moorthy, Prosthetist & Orthotist	1	4	4	2

From the table stump shaping at an average, removable rigid dressing top ranked 3.5 following Rigid dressing which was ranked 2.8.The reason is in some cases the rigid dressing causes complications while healing which result in adverse

shapes. But still rigid dressing could accomplish better shape than soft dressing.

Tab 2 Ranking Table – Edema Control

	Edema Control			
Doctors	Soft dressing	Rigid dressing	Removable Rigid dressing	Semi Rigid dressing
Dr. S. Elangovan M.S (ortho)	4	2	4	3
Dr. Major. K. Kamalnath M.S, D. ortho,	3	1	3	2
Dr.S. Noorul Amin Shahid D.phys Med, D	4	2	3	4
Mr.Balakannan, Prosthetist & Orthotist	3	1	4	3
Mr.Mohanti, Prosthetist & Orthotist	3	2	3	4
Mr.Saravanan, Prosthetic & Orthotic Engineer	4	1	3	3
Mr.Moorthy, Prosthetist & Orthotist	2	2	4	2

From the table edema control at an average, removable rigid dressing top ranked 3.4 following soft dressing which was ranked 3.28. The reason is soft dressing reduces edema successfully but it takes longer time, similar is the case of Semi rigid dressing. Rigid dressings are not reusable once the limb volume changes.

Tab 3 Ranking Table – Wound Healing

	Wound Healing			
Doctors	Soft dressing	Rigid dressing	Removable Rigid dressing	Semi Rigid dressing
Dr. S. Elangovan M.S (ortho)	2	3	4	3
Dr. Major. K. Kamalnath M.S, D. ortho,	2	3	3	3
Dr.S. Noorul Amin Shahid D.phys Med, D	1	3	4	3
Mr.Balakannan, Prosthetist & Orthotist	2	2	3	3
Mr.Mohanti, Prosthetist & Orthotist	1	3	4	3
Mr.Saravanan, Prosthetic & Orthotic Engineer	2	2	4	3
Mr.Moorthy, Prosthetist & Orthotist	1	2	4	3

From the table wound healing at an average, removable rigid dressing top ranked 3.7 following Semi rigid dressing which was ranked 3. The reason is soft dressing and Semi rigid dressing reduces edema successfully but it takes longer time, hence takes a longer healing period. Rigid dressings cause complications while healing in some cases which prolongs the healing period. Hence the ranking table gave a clear idea about a better wound management strategy to be followed, replacing the currently available strategy.

Design and Development

The design and development phase involves the entire design process performed, the other operations related with initial design considerations and the fabrication of the product. It also comprises the existing products and the problem in a brief description. The design of the product was performed with SolidWorks 2010.

Design Considerations

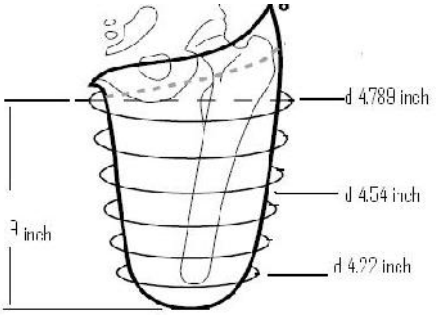
- Clinical Investigation ,Volume Changes of the residual limb, Compressive pressure
- Ambulation, Ease of application, Side effects

The list of experts consulted are given below

- Dr.S. Noorul Amin ShahidD.phys Med, D. Acu, D. sports &Exs. Med (UK) Coimbatore Govt. Hospital-Rehabilitation Centre.Dr. S. Elangovan M.S (ortho) D. ortho, chief orthopedic surgeon, GH Coimbatore &Chief Doctor at Gowtham ortho Hospital,Dr. Major. K. Kamalnath M.S, D. ortho, D.N.B (ortho) MNAMS.GH Coimbatore,Mr.Balakannan, Prosthetist& Orthotist, Ramakrishna Mission Vidyalaya – Orthotics & Prosthetics Unit, Coimbatore,
- Mr.Mohanti, Centre Manager, Prosthetist&Orthotist,Otto bock Prosthetics Centre, Coimbatore
- Mr.Saravanan, Prosthetic & Orthotic Engineer, KMCH - Artificial Limb Centre, Mr.Moorthy, Prosthetist& Orthotist, Endolite India Private Ltd, Coimbatore.

Design Outcome (Design of Immediate Post-Operative Prosthesis /Removable Rigid Dressing)

Based on the deign considerations four design assemblies were done using SolidWorks® 2010.Amongst which one of the design will be selected with the suggestion from the experts and doctors. The selected model will then be fabricated at a prosthetic center. The measurements for the design were taken as shown below, considering AK amputation. All the measurements are in inches.



Design 1Design 2

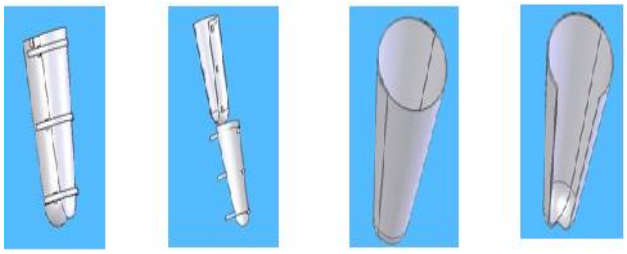


Fig 8 Model 1Fig 7: Model 2

It is an assembly consisting of two parts, where one layer covers up the other as a sliced arc in a conical cylinder. The supports are given by the Velcro arrangements on the sliced part. The sliced part is flexible than the other part so as to adjust to the volume changes in the stump region. It can be used for both above Knee and below knee amputations. The weight bearing can be given AK- hip articular weight bearing; BK-Patellar tendon weight bearing. Since the body part is exposed to the inner surface silicone liners can be used to prevent skin and wound complications it can also be provided with arrangements for pylon inserts for ambulation. It is easily removable for the purpose of clinical investigation

It is an assembly comprising of two semi-circular conical cylinder, where one of the cylinder is fixed and the other one movable over the fixed cylinder. The fixed one has a lesser radius than the one which surrounds it. In this case the design can only be useful with an air bag or a bladder cushioning the surface of the limb so that the inner surface could be made uniform. It can be used for both above Knee and below knee amputations. The weight bearing can be given AK- hip auricular weight bearing; BK-Patellar tendon weight bearing. Since the body part is not exposed to the inner surface due to

the air bladder silicone liners can be neglected. It can also be provided with arrangements for pylon inserts for ambulation.

Design 3

Fig. 9 Model 3

This design consists of two parts which interlocks with a help of locking and unlocking characteristic provisions in the parts. This assembly also requires air bag so as to adjust itself to changing stump volume. The air bag requires a higher inflatable range. This design provides better inner surface and hence will provide better results with fast healing and stump shape. This design also suits for both BK and AK. The weight bearing can be given AK- hip articular weight bearing; BK-Patellar tendon weight bearing. Since the body part is not exposed to the inner surface due to the air bladder silicone liners can be neglected. It can also be provided with arrangements for pylon inserts for ambulation. The usability of the product is so simple. Hence it provides greater flexibility towards clinical investigation

Design 4

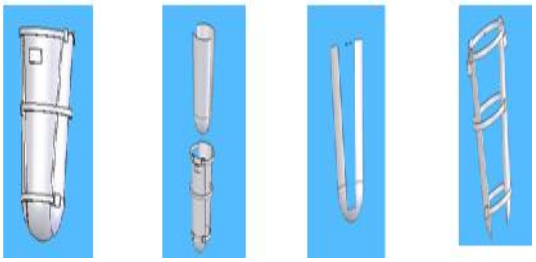


Fig 10 Model 4

This design consists of two parts where one of the part is provides with Velcro which helps in adjusting the socket to the stump volume changes. The other part is used within the surface of the first part. This part just provides the support to the stump portion. This assembly also requires air bag so as to adjust itself to changing stump volume. The air bag requires a lesser inflatable range such that the pressure applied is of the range 15 to 20 mmHg. This design provides better inner surface and hence will provide better results with fast healing and stump shape. This design also suits for both BK and AK. The weight bearing can be given AK- hip articular weight bearing; BK-Patellar tendon weight bearing. It can also be provided with arrangements for pylon inserts for ambulation.

Selection of Design

The Design 4 was selected to be the suitable design for the IPOP-RRD. The design was selected on basis of consultation with orthopedic doctors and expert prosthetist and orthotist. Reasons for selecting this design

- The shape of the IPOP is adjustable both with the Socket design and also with the air bladder provided. Hence gives more flexible size adjustments to the stump volume changes
- This design provides better inner surface(due to the air bladder)
- The air bladder also provides proper cushioning to the pressure points in the stump wounds which helps the healing of wounds
- This design can also be easily used.

Material Selection

Regarding the material selection for the IPOP; the selection was purely made on cost basis. The polypropylene material is commonly used for socket fabrication, which is economical and suitable than other plastics and polymers. Regarding the material selection for the air bladder is concerned; the selection was based on the material that would not cause any wound complications. The reason is the bladder is in direct contact with the limb. Silicone is the material used commonly as liners and air splints, hence silicone was chosen.

Fabrication of the selected design

Since IPOP is only used as a temporary socket, the consumers will not be in a position to spend too much money on it. Though advanced technologies like RP, CAT/CAM has the feasibility to manufacture much customized IPOPs with better results; in Indian conditions economically this process of fabrication will make the product unaffordable for the consumers. Hence the traditional method of fabrication, the Jaipur method was chosen for fabrication of IPOP. The manufacturing of the rigid dressing is similar to that of the manufacture of the sockets, apart from the final stage. This is because the mould preparation is the key source in the manufacture of both the socket and the rigid dressing. In the case of the rigid dressing certain modifications are done prior to the selected suitable design by the prosthetist in the final stage of the manufacture of the prosthetic device.The product was manufactured using the Jaipur method at the National Orthotic centre, Gandhipuram at a cost of 1500 rupees with polypropylene material. The fabricated model comprises of two parts namely Part A and Part B. Part A is provided with Velcro for the purpose of size adjustments to the residual stump.

Fig. 11 Part A with Velcro

Fig. 12 Part B

This portion covers the Medio-Lateral area of the stump. This forms the outermost region i.e. Part A provides space to place Part B within it, such away the stump portion is completely

covered by the product. Part B is just a supporting device, which covers up the uncovered regions of Part A.
This portion covers the Antero-Posterior area of the stump. Part B is flexible enough to accommodate within the Part A. Then flexibility also provides the adjustments to changing limb volume.

Fig .13 Assembled Model

The assembly and prosthetic usage is made such a way the Part A with Velcro is first loosened and the Part B is placed within Part B. Now holding both the parts the setup is inserted to the residual stump and is placed to the exact fit of the stump. Then the Velcro is tightened such a way the stump is not over stressed by tightening the Velcro straps.

The assembly and prosthetic usage is made such a way the Part A with Velcro is first loosened and the Part B is placed within Part B. Now holding both the parts the setup is inserted to the residual stump and is placed to the exact fit of the stump. Then the Velcro is tightened such a way the stump is not over stressed by tightening the Velcro straps.

Suggestions

The final suggestions of the design led to the inclusion of air bladder. The reason is the presence of the airbladder will enhance the even distribution of compressive pressure in the stump. This in turn also provides the necessary cushioning effect at the pressure points in the wound site than any other stump wraps. The stump portion during the post-operative period is much sensitive; the application of a rigid dressing might cause complications on either the wound site or the skin. The air bladder will also provide protection at the wound sites from the rigid dressing. Since the implication of air bladder was suggested at the final stage of the project, the fabrication of the bladder was not possible. The air bladder required much of a customization (patient specific) and also the absence of suitable fabricating facilities in and around Coimbatore was the main reasons for not fabricating the bladder.

RESULT AND DISCUSSION

The fabricated immediate post-surgical prosthetic product was verified with experts at each and every stage of the design and development process. The final product was found to be satisfactory, but it required an air bladder (as mentioned in the earlier chapters). The presence of an air bladder will help in providing the uniform pressure and the degree of elongation seems to imply that the shape fit the stump approximately. They stick to random areas of the lay-up. This can result in some sections of the bladder expanding to fit small areas of the cavity and provide pressure at those regions.

The immediate post-surgical prosthetic product manufactured was observed to be suitable for the following outcomes

- The prosthetics was rigid, such that it facilitates a better stump shaping than in case of soft dressing like elastic bandages.
- The rigidity will also add up the property to control the edema and thereby facilitate faster wound healing. The presence of the air bladder will also provide the faster healing.
- The product thereby manufactured was simpler in terms of usability. The application and removal of the prosthetic device was easier because of it unique design.
- The product is also size adjustable based on the limb volume changes.
- Since the dressing is rigid, it will provide to protect the residual limb from possible trauma to a certain extent. The trauma reduction is better than the soft dressings which are currently used.
- Since the traditional method of manufacturing process was used. The product is cheaper, which makes it affordable in Indian conditions.

CONCLUSION

Currently, the lack of products (immediate post-surgical prosthetics) and technology in India was taken as the main scope of this project. Keeping this in mind an innovative design was modeled and manufactured in this project. The final product was fabricated such a way it meets the outcome that was expected. Since the economic conditions and the affordability of consumers played a key role in development of IPSF, the implementation of advanced technologies was sacrificed. This work was initially projected towards the application of advanced technologies like RP, CAT/CAM technology, 3D reconstruction etc. but due to the cost factor these methodologies were neglected and traditional method was used in the fabrication of IPSF. The use of traditional technique was quite advantageous in reducing the cost of the product greatly.

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