

Fabrication of Total Contact Socket Made up of High-Density Polyethylene using Vacuum Forming Technique with Below-Knee Exoskeletal Jaipur Prosthesis

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Introduction

Prior to the development of total contact socket for below knee prosthesis, the majority of below knee sockets did not provide contact between the end of the stump and socket. From a biomechanical standpoint, the total contact socket is generally preferable because it offers the following advantages:

1. As total contact socket is in contact with lower surface area of the stump it provides better sensory feedback.
2. In immediate post-operative period, it prevents edema and aids in venous return.
3. Although the major weight is borne by patellar tendon & medial tibial flare, the total contact socket provides larger area over which load is distributed.
4. It increases the proprioception.

Several materials have been used from time to time to fabricate total contact socket, which includes leather, wood, thermosetting composites, thermoplastic etc.

A long-term appraisal has revealed some of the constraints, which are related to thermosetting composites. Once the resin is cured, no major alternation is possible. If the socket is ill fitting then whole of the socket will have to be re-made which will add to the cost of manufacturer and ultimately to the patient. Resins may also cause skin allergic reaction to the amputees.

High-density polyethylene (HDPE) is a thermoplastic polymer consisting of literally hundreds of composition, based on polymers of different molecular weight, branching co-polymers cross linking polymers with additives. High-density polyethylene of 95% crystallinity and 0.95 density exhibits a high melting point, higher tensile strength and greater hardness. It is lighter in weight, has higher mechanical strength than other thermoplastics. It is corrosion and chemical resistant, does not absorb moisture.

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Melting point of high-density polyethylene thermoplastic is 125°-133°C. It can be thermoformed easily and corrections can be made (easing out of pressure points) by simply heating it with a heat gun. It is free from allergic reaction, has a desirable degree of flexibility, abrasion resistance, easy availability of the material in local market and is manufactured indigenously.

There are some disadvantages with this material however. High-density polyethylene in pure form is very brittle and very vulnerable to heavy impact and liable to crack in heavy individuals. To overcome this problem, during manufacturing of high-density polyethylene, co-polymers or some other thermoplastic material is added to reduce its brittleness. Poor ventilation and excessive perspiration in hot climate is a frequent complaint made by most of the users of high-density polyethylene total contact socket. Biggest disadvantage with high-density polyethylene is its inability to bond or to adhere to any other substance.

Since this technique is relatively new for Jaipur prosthesis, it is presented here in detail so that fabricators are facilitated to use it.

Technique

Total contact sockets were made up of 15"x15" square 10mm thick high-density polyethylene sheet for each amputee and this socket was fitted to HDPE / aluminium shank and Jaipur foot.

Material

- Cotton stockinette 6"x 1.5 metres.
- Two pre-formed POP bandages of 6".
- Indelible pencil.
- POP paste.
- Inch tape.
- Measuring caliper.
- Mandrel.
- Wire mesh and wire screen.
- 15" x 15" high-density polyethylene sheet (10 mm thick).

- 2 Metal frames of 15”x15” (square).
- 4 Metal clamps.
- Soap stone powder: to avoid adherence between high-density polyethylene sheet and cotton stockinette.
- Pre-heated over with maximum temperature of 180°C to heat the HDPE sheet.
- Suction machine
- Vacuum forming apparatus.
- Asbestos gloves.
- Scalpel with surgical blade attached to it to cut the excessive HDPE sheet.
- Metal file to trim off the HDPE socket.
- Hammer and iron nail: to break the positive mould inside HDPE socket.
- Cutting machine.
- Deburring knife: for finishing of the HDPE socket.
- Wall Frame to check alignment.
- LASER liner to confirm alignment.

Fabrication of total contact socket and PTB prosthesis

A. Evaluation of the stump

The stump was evaluated for joint function, muscle strength, skin condition, scarring and pain.

B. Measurements:

1. Stump Measurements

- Stump length: (a) From head of fibula to distal end of the stump and (b) From inferior edge of patella to the distal end of the stump.
- Circumferences of the stump: At mid patellar level, then after every 2” below till distal end of the stump.
- Antero-posterior dimension: Using A-P caliper, it was recorded from just below the inferior edge of patella to popliteal area.
- Medio-lateral dimension: Using M-L caliper, it was recorded from the widest area medio-laterally of the amputated knee joint.

2. Sound Limb Measurements:

Following measurements of the sound limb were taken: Length from middle of the patellar tendon to medial malleolus.

- Length from tip of the head of the fibula to floor.
- The size of foot to ascertain the size of the Jaipur foot.

C. Positive mould by “Wrap Casting” method –

Positive mould was made as described by “Radcliffe & Foort”¹².

After the wrap cast was made, it was filled with plaster of paris paste. For this, the wrap was fixed in the cast holder, attached to wall frame. This cast was marked with central lines on anterior, lateral and medial sides. A mandrel and a sliding rod were chosen and separating agent like vaseline was applied over them. This mandrel was fixed in the wall frame in a way that anterior and lateral lines in the cast holder and mandrel were aligned perfectly. This alignment was re-confirmed by a LASER line. Now POP paste was poured in the wrap cast. When the plaster was set completely, the POP wrap cast was slit open and positive mould of the stump was obtained. After checking all measurements, it was ready for modification.

D. Modification of the mould – as described by “Radcliffe & Foort”¹².

E. Fabrication of Soft Insert:

To make soft insert, three dimensions of the positive mould of the stumps were taken:

- Proximal circumference.
- Distal circumference.
- Total length of the positive mould.

These measurements were transferred on a 6 mm piece of ethaflex sheet. This sheet was 5” longer than the length of positive mould and ½” wider at the top and bottom than the proximal and distal circumferences of the stump. The edges of the sheet were then beveled using a belt grinder, on the opposite sides and glue was applied on both ends. When it is completely dried, both ends are pasted together and pressed by gently hammering the surfaces. Thus, a cone was obtained. It was placed in a preheated oven (»110°C) for 10-15 minutes. The positive mould with mandrel was clamped in a vise. The cast was powdered thoroughly. Now the pre-heated ethaflex sleeve is pulled down snugly over the cast, making sure that it conformed closely to the distal end. A sheath was pulled over this and vacuum was applied. The distal end of the soft insert was then bevelled.

A cap was made to cover the distal end of the soft insert. It was made by cutting a round disk from a 6 mm thick sheet, 2-3 cms larger than the exposed distal end of the cast including the bevelled edge of the liner. This disk was heated at 110°C in the oven and moulded over the distal end of the model. Carefully excess of the beveled edge was trimmed off, without shifting the cap. Glue was applied to the inside of the cap. After drying of the glue, this cap was bonded to the distal end of the stump.

F. Fabrication of total contact socket made up of high-density polyethylene sheet by vacuum forming technique

- A 15"x 15" high-density polyethylene piece of sheet (10 mm thick) was cut from high-density polyethylene sheet.
- It was fixed between 2 metal frames of same dimension (15"x15") with the help of metal clamps.
- It was placed on a stockinette (unfolded) and soap stone powder was sprinkled between sheet and stockinette fabric so that sheet did not stick to fabric.
- It was placed in a pre-heated oven at 180°C for 20 minutes. At this temperature high-density polyethylene started melting (melting point of high density polyethylene thermoplastic is 125°-133°C).
- As it reached melting point it, became transparent. This property is of great help in recognizing that the sheet was ready for thermoforming.
- The mould with mandrel was placed in inverted position over the metallic platform of the vacuum forming apparatus.
- A nylon sock or stockinette was put over the stump model so that a smooth inner surface of socket could be attained later.
- The oven was switched off as the sheet becomes transparent.
- 2 persons wearing asbestos gloves, took out this heated sheet, with each person holding two ends, off the oven. This sheet was held over the mould.
- The sheet was allowed to hang in the air, forming a bubble.
- Great care was taken that the sheet fell itself on the mould rather than "pulled down" by persons. Otherwise the socket obtained could be of unequal thickness.
- The suction apparatus is needed to be handled carefully. Instead of switching it on totally at once, it was switched on and off as rapid burst. This method helps a great deal in preventing wrinkling and uneven thickness of the socket and getting perfect approximation of the sheet over the mould.
- The sheet took the shape of stump model as vacuum is created with the help of suction apparatus.

- Now the excessive area of the socket, which was to be trimmed off, was marked with the help of pencil:
 1. Anteriorly, the wall of the socket extended up to lower 1/3rd to lower 1/2 of the patella.
 2. Medio-laterally the socket walls covered the medial and lateral femoral condyles respectively.
 3. Posterior wall was of unequal height at medial and lateral ends to accommodate medial and lateral hamstring tendons in the socket. So, the medial side of the posterior wall was lesser in height as compared to the lateral side.
- The stump mould (inside the socket) was then broken off with the help of mallet and nail.
- The socket was shaped properly with the help of cutter chisel, file and deburring knife.
- After trimming off socket, amputee was made to wear this socket for trial.

G. Extension of the socket

- Next stage was fixing of the total contact socket in the exoskeletal HDPE prosthesis. First, trial of the socket on the amputee was taken, by making them wear this socket. This was to ascertain that the trim lines were correct and amputee was comfortable with the fitting of the socket.
- Amputee was asked to stand in a frame, wearing the socket keeping the pelvis level. With the help of trisquat, a line was drawn on the center of the thigh extension over the anterior surface of the socket. This line described about the varus (adduction) and valgus (abduction) in the stump and was used as a guide while extending the positive mould.
- A similar line was also drawn on lateral aspect of the socket. This line showed the amount of flexion in the stump.
- Using a wall frame, now the socket was fixed in a cast holder with its reference lines in vertical position. Any inclination can be corrected by loosening the nut in the alignment coupling and adjusting the cast holder accordingly. After adjustments, the nut was tightened.
- A mandrel was fixed at the upper end of the wall frame, conforming to the anterior and

lateral alignment line. A pre-formed shape of the limb was sleeved over it keeping this mandrel in the center of this preformed model. The POP paste was poured now into the preformed model to fill it completely.

- As soon as this hardened, the preformed model was removed, thus obtaining a positive mould of the exoskeletal B-K limb with total contact socket in complete alignment.
- It was ensured that the diameter of distal end of the mould matched with the diameter of the malleolar region of the Jaipur foot.

H. Fabrication of the HDPE shank

- A 24" long HDPE pipe having diameter of 90 mm was covered with B-K stockinette both from inside and outside. It is important to cover the pipe in this fashion in order to avoid sticking of the same. It was kept in the preheated oven at 180-200°C temperature for about 20 minutes.
- When pipe became malleable, it was pulled over the positive extended mould.
- The heated pipe was then given the shape of the mould by hand moulding. The hands continued working for a few minutes until pipe became partially cool. The extra material was cut off from both ends. When the pipe was completely cooled off, the plaster of paris inside was beaten out either by using a hammer or by using pneumatic chisel.
- The cutting and finishing was done as per trim lines of inner socket. For better smoothness of the edges, it was always suggested to use buff wheels, which can be fixed with drill machines. The HDPE shank with total contact socket inside (assembly is known as double-wall socket) was now ready for trial on the amputee and fitting of the Jaipur foot.

I. Trial & Fitting with Jaipur Foot

- The amputee was asked to wear this double-wall socket and to flex and extend the stump several times. The posterior brim of the socket was made so as not to hurt the popliteal area when it was flexed to the maximum extent.
- Amputee was then asked to stand erect with the help of supports. A pencil mark was put on the double-wall socket at the level of medial malleolus of the sound limb. This was

matched with recorded measurement of head of the fibula to medial malleolus of the sound limb. The excess of distal end of the socket is cut from this mark.

- Distal 3" area of the double-wall socket was heated to make it malleable and to hold the Jaipur foot when it was cooled down.
- The Jaipur foot is now inserted in the heated area and amputee was made to stand wearing the prosthesis. The rotation of the Jaipur foot was checked.
- After checking the length of the prosthesis, the socket-foot assembly was further secured with four screws on each side of the distal end of the socket. A small portion of the screw was hammered, one drop of feviquick glue was applied on the threaded portion and the screws then, were tightened with a screwdriver.
- Leather suspension belt was pasted and riveted on the proximal end of the socket and now the prosthesis was ready to wear by the amputee.

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