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RESEARCH ARTICLE

DESIGN IMPROVEMENT OF JAIPUR FOOT FOR A LIGHTER LOW – COST PROSTHESIS

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ABSTRACT

Jaipur foot, labeled as a culture specific innovation, evolved as a modification of the SACH foot to allow the amputees to squat, sit, cross legged, walk barefoot, negotiate uneven terrains, and work in fields while keeping the cost low to maintain affordability. Extensive use for the last 45 years and consistent growth in demand speaks volume about its acceptance. However, heavy weight, lack of standardization of materials, and a labor intensive fabrication process makes its quality control very difficult.Reducing the weight of the artificial Jaipur foot will increase the users comfort whileperforming daily activities, potentially increasing the usage of the foot while decreasing fatigue and injury, whereby improving overall quality of life. The goal of this study was to reduce the weight of the foot without compromising the mechanical integrity of the foot. Ethylene-vinyl acetate (EVA) and Nylon 6 were investigated as potential new materials. While EVA decreased the weight of the foot, it came at an expense of structural integrity. Nylon 6however, decreased the weight by 25% without any structural issues.Hence, we recommend to update the manufacturing of the Jaipur foot to utilize Nylon 6. A unique team of Mechanical Engineers, Material Scientist, physical medicine and rehabilitation expert came together to create a new, improved and modified Jaipur Foot.

INTRODUCTION

Most of the current research in recent years has focus on the development of prosthetic devices utilizing modern material and technologies at the cost of high prices even for amputees in developed countries. This type of prosthesis is out of reach for 80% of the world'samputees (Sharpa, 1994). Prosthesis should allow the users to restore their functional capacity in their cultural environment at an affordable price (Meanley, 1995), justifying the research and development of low-cost and easy to produce prosthesis such as the Jaipur foot.

The Jaipur foot wasdeveloped by Dr. P.K. Sethi(Sethi, 1978)to be used by barefoot amputees. The foot design uses locally available materials and has been used extensively in India, South East Asia and Africa with local variations in each region (Arya and Klenerman, 2008). The Jaipur foot prosthesishas helped more than 400,000 amputees (Jaipur Foot 2013). This type of foot is widely used in third world countries because of its particular features of mobility in different planes, water proof exterior, simplicity of the materials used and the fabrication process, durability, and very low cost. The Jaipur foot allows an adequate magnitude of inversion, eversion, transverse rotation and dorsiflexion and is shown to be robust (Kabra and Narayanan, 1991) with a failure rate of 27% after a period of 16 months and withgood user satisfaction (Jensen and Raab, 2007). Other advantages include a durable outer layer and anatomically-accurate appearance that allow the userto forgo wearing shoes (Seth, 1978). Finally, it is cost-effective, all the necessary materials are easily obtained, and the process to make

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the foot can be completed with minimal tools in a short time. Skilled craftsmen create a foot using wood (teak, chead, and ardu), rubbers, foam, and adhesives (Bass, 2012). The entire manufacturing process takes roughly two hours using a die, autoclave, and basic hand tools (Sethi, 1978).

The goal of this research is to improve the Jaipur footquality by lowering its weightwhile preventing structural instability in the new design. This will give amputees an improved prosthesisthat will cause less fatigue and injury. Lack of a patent and its growing demand has led to increased production in different parts of India for commercial gains without maintaining quality control. By sharing this information with the academic community, the authors hope to make this knowledge accessible for further development of the Jaipur foot.

Background of Previous Prosthetic Feet

Along with the Jaipur foot, other similar prosthetic feet have been developed over the years. The Nader foot, developed in the 1970's, is primarily a two-material foot that is very easy to make. The main structure of the Nader foot is foam polyurethane that is shaped into the ankle and tapered down into what would be the end of the tarsal bones in the foot. This is then placed in a die and a rubber is modeled to surround the solid insert in the shape of an anatomical foot (Benton, 1976). However, that the Nader foot is too flexible and thus susceptible to breakage(Wagner, 1973). This extreme flexibility is likely due to the soft materials used in the foot and their inability to recover from deformation over time. This has led to the use of a design known as the SACH foot.

SACH stands for a solid ankle, cushioned heel design and is an umbrella term for a multitude of different foot shaped devices (Wagner, 1973). The typical SACH foot is much like the Nader foot, with a single piece keel covered in rubber. While the SACH foot solved the major problems of the Nader foot by being more durable and longer lasting, other problems and challenges exist. As mentioned previously, it is extremely common for Indians to sit cross legged and squat. With the SACH foot, these positions create a twisting and adducting force that is felt in the limb and can cause immense pain. Consequently, the need for a prosthetic that has more flexion in the forefoot and the ability to move laterally at the ankle became evident(Sethi, 1978).

The first prosthetic foot to take the natural movements of the patient into consideration was the Seattle foot. While previous prosthetics allowed patients to walk fairly well, they made running or jumping an awkward gait. During the 1980s, Ernest M. Burgess developed and patented the Seattle foot, a prosthetic designed for ease of motion while walking, running, and jumping (Illman, 1985). The foot uses energy-restoring technology that helps to contribute to the patient's range of motion.A biomechanical comparison of the Jaipur, SACH, and Seattle feet (Arya, et al., 1995) using a force plate revealed that the SACH had better shock absorption, however the Jaipur foot showed a more natural gait that was closer to the gait of unimpaired subjects. While other prostheses have their own unique advantages, an improved Jaipur foot is preferred because of its simplicity and ease of assembly.While the Jaipur foot fits into the SACH category, it is very different from the standard SACH design. The main difference in the Jaipur foot compared to the SACH foot is the addition of a softer rubber in the heel and a stiffer material used in the keel.

Current Fabrication Process

The Jaipur foot is currently manufactured using microcellular rubber (MCR) inserts. Sheets of MCR are adhered together using vulcanizing agent and cushion compound. Twoblocks are then shaped into the forefoot and heel blocks and a third block is carved from wood with a hole drilled through it for abolt to attach to the residual limb. All three blocks are coated in vulcanizing agent and wrapped in a cushioning compound. They are then attached together with tire cord to simulate the tendons in the foot. The entire assembly is covered in natural rubber to mimic the skin tone of the patient and provide a durable waterproof layer(Sethi, 1978).The resultant foot shows a range of motion up to 35° of dorsiflexion, 29° of inversion, 22° of eversion, 12° of internal rotation, and 8° of external rotation. It also has a heel compression of up to 2.8mm (Mukul).

Need for Improvement

Many patients with a prosthetic limb complain of fatigue associated with their prosthesis. With the Jaipur foot, patient fatigue results from the weight of the prosthetic and loss of energy during stride.Thus, the goal of this work was to investigate new materials, namely ethylene-vinyl acetate (EVA) and Nylon 6, for reducing the weight of the Jaipur foot without compromising structural integrity.

Lack of a patent and its growing demand has led to increased production in different parts of India for commercial gains without maintaining quality control. By sharing this information with theacademic community, the authors hope to make this knowledge accessible for even further development of the Jaipur foot.

MATERIALS AND METHODS

Prototype Fabrication

Prototypes were made to test the compatibility of the inserts with the heating process. Eleven feet were made with EVA inserts, and the three prototypes were made using Nylon 6 foam. New feet were fabricated by replacing the microcellular rubber (MCR) used for the heel and forefoot blocks with both EVA and Nylon 6. Based on results of these fabrications, it was noted that a major problem of the new design using EVA was incompatibility of materials with the rubber vulcanization process used in manufacturing. Heating of the entire foot to temperatures near 125°C during this manufacturing step is necessary, but lead to shrinkage of the EVA blocks due to poor heat resistance properties (Figure 1). The decrease in insert volume caused the natural rubber outer layer to separate from the EVA. Excessive flexibility and bending were exhibited, as well as folding at the ankle joint. This applied additional stress on the outer layer, leading to eventual failure. Thus additional testing was completed to eliminate insert shrinkage within the feet made with EVA, thus improving the mechanical properties of the foot,while maintaining weight reduction and cost-effectiveness. Three potential solutions included utilizing additional adhesives between layers, preheating inserts to induce shrinkage, or selecting a new material (Nylon 6).

Tests were performed to investigate the actual cause of the gaps in the feet with the EVA. It was proposed that two factors were the main cause, the first being that the adhesion between the inserts and cushion compound was not strong enough and the second that the inserts themselves were simply shrinking. Additionally, a tensile test was done to study the effects of heat on the EVA insert strength.

Adhesive Test

Samplesmade of MCR, EVA with different Shore hardness (A35, A45, A65), andthe same EVA with a jute and Chemlok adhesive interfacewere prepared in 1″×3″. The MCR samples were tested to measure the property of material used in the original Jaipur foot. Each of the samples was overlapped by a 1″×3″ piece of cushion compound backed by a same sized piece of tire cord. Between the cushion compound and MCR as well as the plain EVA, vulcanization agent was applied. The overlap was a 1″×1″ area. Between the cushion compound and EVA for the new interface was a 1″×1″ square of jute fabric that had been submergedinto Chemlok. All samples were placed at the room temperature in open air to dry. Once dry the samples were baked in an oven at 150°C for 30 minutes then cooled in a freezer at -20°C for 30 minutes. Each sample was then tested in a tension puller and a peak force was recorded.

Tensile Test

1″×3″ samples were created from EVA with different Shore hardness (A35, A45, A65)and subjected to the sample heating process as in the shrink test. They were heated to 150°C for 30 minutes then cooled, followed by another heating to 150°C and cooled to room temperature again. A tension puller was used to find the peak force.

Shrink Test

3″×3″samples were created from MCR, EVA, and Nylon 6. Samples were first measured using calipers, placed in an oven at 150°C for 30 minutes then cooled, measured and placed back in the 150°C oven for 30 minutes. Once cooled measurements were taken and the total volume calculated from each heating and percent shrink was calculated.

To try to prevent shrinkage of the EVA, the EVA inserts samples were pre-heated before shaping them to prevent shrinkage upon the second heating that cured the outer layer of rubber. To avoid the improper curing of the outer natural layer of rubber, the temperature and time in the oven was increased. While thiscorrected the curing of the outer layer of natural rubber, it caused shrinkage of the inserts.To fix this probleman autoclave (125°C, 23 psi for 20 minutes) was utilized to cure the rubber, however the insert shrinkage was not prevented. To combat this insert shrinkage the inserts were preheated at a higher temperature which actually started to burn the EVA on the outer edges. Thus, using Nylon 6 instead of EVA was proposed.

RESULTS

EVA reduced the weight an average by 608 grams, a 18% reduction from the previous design. Nylon 6 reduced the weight by 25%.

Adhesive Test

The maximum load of the samples with EVA were greater than the original MCR samples that the adhesion between the inserts and cushion compound wasadequate (Table 1). Additionally, it shows that the average of the load capacity were increased in plain EVA 35 and 65 Shores compared to the samples with similar EVA and added jute layerbut decreased in plain EVA 45 Shore compared to EVA 45 Shore with added jute layer.

Table 1 Adhesive Test

Material	Test Number	Max Load (N)	Mean± Standard Error of Max Loads (N)
MCR	1	132.433	125.65±21.02
	2	158.194	
	3	86.335	
EVA 35 Shore	1	174.802	158.04±13.09
	2	132.244	
	3	167.074	
EVA 45 Shore	1	149.769	142.40±9.67
	2	154.206	
	3	123.223	
EVA 65 Shore	1	160.931	194.70±16.91
	2	213.171	
	3	210.01	
EVA 35 Shore with Jute	1	158.99	116.49±26.80
	2	123.494	
	3	66.974	
EVA 45 Shore with Jute	1	167.148	159.40±8.91
	2	141.622	
	3	169.428	
EVA 65 Shore with Jute	1*	141.349	136.00±10.83
	2*	151.51	
	3	115.142	

* denotes break

Tensile Test

Heating the 35 and 65 Shores do not have a significant effect on the material properties but that 45 Shore becomes slightly more resistant to tension (Table 2).

Table 2 Tensile Test. (The units are in Newton).

EVA Type	35 Shore		45 Shore		65 Shore	
Sample	Pre-heat	Post-heat	Pre-heat	Post-heat	Pre-heat	Post-heat
1	351.2	312.9	468.5	496.2	979.9	945.3
2	352.9	371.2	393.8	500.6	1005.4	983.5
3	352.1	342.0	423.6	498.4	992.6	964.4

Shrink Test

Shrink volumes after each heating cycle and the total shrink volume are shown in Table 3. The shrinkage volume after the second heating is greatly decreased from the first for both EVA and Nylon 6. The results indicate that using Nylon 6 will eliminate the need for the second heating and can lead to a faster fabrication time.

Table 3 Shrink Test

Material	Mean Shrink Volume Post-Heat 1 (%)	Mean Shrink Volume Post-Heat 2 (%)	Mean Shrink Volume Total (%)
MCR	22.21	3.23	24.95
EVA 35 Shore	22.5	2.16	24.18
EVA 45 Shore	31.85	-1.57	30.78
EVA 65 Shore	28.06	0.24	28.23
Nylon 6	-1.03	-0.04	-1.06

Prototype Fabrication

The final design with the Nylon 6 foam solved the problems that were experienced with the EVAfoot. There was no insert shrinkage and the natural rubber outer layer was completely cured (Figure 2). The new design and fabrication process decreased production time. Additionally, the average weight of the foot with Nylon 6 was 552g that compare to an original Jaipur foot weighing 739g shows a 25% weight reduction. Fabrication of Prototype is described in Appendix A.

Figure 1 Gaps due to shrinkage of the EVA blocks.

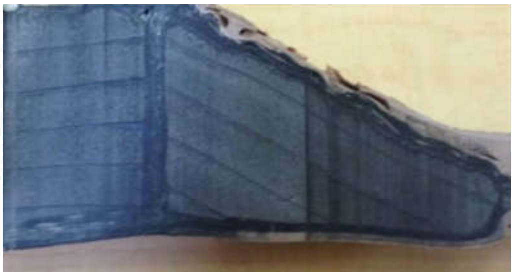

Figure 2 Gaps were eliminated by using Nylon 6 that shows no shrinkage.

Appendix A

Fabrication Procedure

The procedure for fabricating the Jaipur Foot consists of three steps; Shaping the insert, wrapping the foot, and molding. The details of each step are follows:

Shape Inserts

Forefoot insert

1. Cut 5: 14cm x 11.5cm rectangles of Nylon 6 Foam
2. Coat the rectangles on both sides with vulcanizing agent as shownin Figures 1 and 2 (except the end pieces that just one side will be replaced)
3. Stretch cushioning compound sheets and firmly press them on each 14cm x 11.5cm rectangle. Stack the foam rectangles with the cushioncompound between each layer to form a block. It should set instantly.
4. Mark off excess material on the block. Then cut the excess off with a band saw.
5. Trace the top and side outlines onto the block. Double check that the orientation is correct
6. Use the band saw to roughly cut out the angled side outline. Then cut the top outline while keeping the cut blocks stacked together
7. Trace the front outline onto the block.
8. Use a sander to roughly shape the contours of the block.
9. Use a rasp to make final touches to the contours. Check the block with the mold to make sure it fits.

Figure 1 Vulcanizing Agent

Figure 2 Cushion Compound

Figure 3 Cushion Compound application

Figure 4 Completed Block

Figure 5 Forefoot Trace

Figure 6 Completed Trace

Figure 7 Side Outline

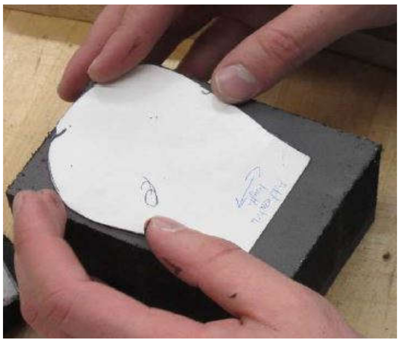

Figure 8 Top Outline

Figure 9 Front Outline

Figure 10 Sanding

Figure 11 Size check

Heel

1. Cut 6: 10 cm x 7.5cm rectangles of Nylon 6 Foam
2. Coat the rectangles on both sides with vulcanizing agent (except the end pieces, just one side) (see Figure 1 and Figure 2)
3. Stretch cushioning compound sheets and firmly press them on each 10 cm x 7.5cm rectangle. Stack the foam rectangles with the cushion compound between each layer to form a block. It should set instantly. (See Figure 3, Figure 4 and Figure 5)
4. Trace top and front outlines from patterns onto the block.
5. Use the band saw to roughly cut out the top outline.
6. Trace the side and front outlines onto the block.
7. Use the cylindrical sander to roughly shape the contours of the block. (See Figure 11)
8. Use the rasp to make final touches to the contours. Check the block with the mold to make sure it fits. (See Figure 12). Be sure to leave a few millimeters of space between the heel and forefoot inserts for the tire cord to fit.

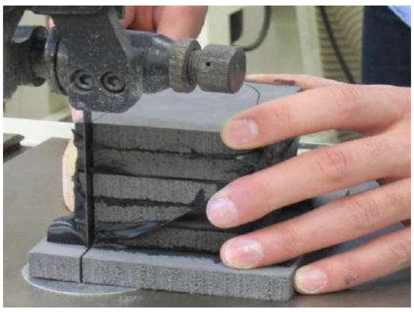

Figure 12 Cutting the Outline

Figure 13 Side Outline

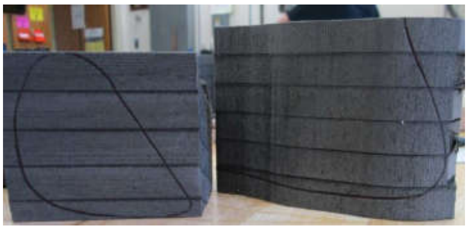

Figure 14 Side and Front Outlines

Toes

Cut nylon into toes using toe outlines and make sure they fit by measuring them in the mold.

Wrap Foot

Cushion Compound

1. Before wrapping with cushioning compound dry fit the heel, forefoot and ankle blocks in the mold. The bolt of the ankle block should be lined up and remember where the ankle lays on the heel block so later it can be correctly lined up. Otherwise a crooked bolt will made.
2. Each insert and the ankle block must be painted in vulcanizing agent then wrapped in cushion compound. Allow the blocks to dry before covering with cushion compound (about 1-2 minutes)
3. Carefully stretch the cushion compound around the block to attach.
4. The toes must also be coated in vulcanizing agent. This works best bydipping the toes in a cup of vulcanizing agent. Then allow them to dry.

Tire Cord

Cut 12 pieces of tire cord at the following lengths:

1. 8 pieces: 15cm x 2.5cm
2. 1 piece: 18cm x 4cm
3. 1 piece: 33 cm x 4cm
4. 1 piece: 50cm x 4cm
5. 1 piece: 71cm x 4cm

Tire cord wrapping

1. Place the ankle block and heel insert together pressing firmly.
2. Place the 33cm piece about half way on the bottom of the heel insert. Wrap it up the flat face (junction of heel and forefoot) of the heel then up the front of the ankle. Cut the excess off the top of the ankle leaving just enough to be able to fold over the top edge of the ankle block.
3. Also place the 18 cm piece at the same starting point or a little shorter on the heel. Wrap up the flat face of the heel (junction of heel and forefoot) then over the top of the forefoot insert. Be sure to press firmly together the heel/ankle assembly and forefoot insert before folding over the tire cord.
4. Fill in the gaps between the forefoot, heal and ankle blocks with a piece of cushion compound that has been stretched and folded into a cord.
5. Lay the 71cm piece along the bottom part of the mold length wise, this is to make sure your toes will line up correctly. Leave more tire cord on the heel side so you have enough to wrap up the heel. Cut the toe side of the tire cord into 5 segments and pull each down to the arch of the foot in the mold. Lay each of segments where the toes will lay in the mold.
6. Take the forefoot/heel/ankle assembly and press firmly down on the bottom part of the mold with the 71cm piece.
7. Lift the inserts and now bottom tire cord up and place the 50cm strip perpendicular to the 71cm strip, crossing them at the heel centered on the ankle bolt.
8. Place the toes in their spots within the mold and hold them tightly against the forefoot insert as you fold over th3e segments of tire cord over each toe. Let the segments run up to the junction of the heel and forefoot before cutting.
9. Fold the 50cm strip upward on both sides to the top of the ankle block. Cut off the excess leaving enough to just wrap over the top of the ankle.
10. Take the back of the 71cm strip and fold it over the ankle block, splitting the tire cord in half once it reaches the top of the ankle. Fold the now two pieces over the top of the ankle and down the front of the ankle. Cut off the excess.
11. Use the 8 15 cm pieces to form X patterns centered at the ankle/forefoot joint. There should be one X on each side of the3 foot. Cut the tire cord to fit.
12. Wrap the toes in a sheet of cushion compound.

Tread Compound

1. Use the paper pattern with toes to trace out the outline for the bottom of the foot. Cut it out.
2. Place this outline on the bottom of the foot.

Natural Rubber

1. Use the paper pattern without toes to trace the outline for the bottom of the foot. Cut it out.
2. Place this on the bottom of the foot and stretch it around the toes and as far up the foot as it will go without breaking.
3. Cover the rest of the foot with natural rubber. Stretch the rubber before applying to make it more flexible.

Figure 15 Heal block with cushion compound, ankle and forefoot coated in vulcanizing agent.

Figure 16 Tire Cord

Figure 17 33cm piece and 18 cm piece

Figure 18 Bottom View

Figure 19 Top View

Figure 20 Cushion compound between Forefoot, heal and ankle blocks.

Figure 21 71 cm piece aligned in mold.

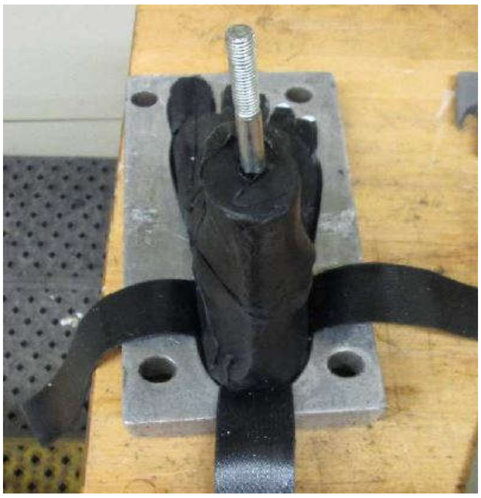

Figure 22 50 cm strip and 71cm strip on the mold.

Figure 23 Toes

Figure 24 Top of Ankle

Figure 25 X pattern on foot

Figure 26 Cushion compound on toes.

Figure 27 Cut out on Tread Compound

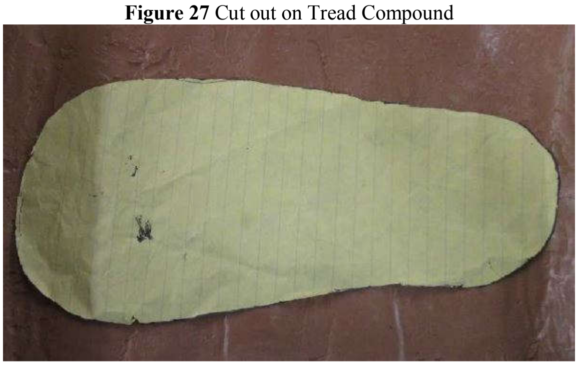

Figure 28 Cut out on Natural Rubber Sole

Figure 29 Foot with sole

Mold

a. Put the assembled foot into the mold and tighten all of the bolts.
b. Leave it to compress for 4-6 hours at a minimum.
c. Open the mold and fill in any gaps that might have formed with natural rubber.
d. Re-tighten the mold.

Heat in Autoclave

125° and 23 psi for 20 minutes.

Air-cool foot for 6-8 hours then remove it from the mold.

DISCUSSION AND CONCLUSIONS

This paper presents the efforts and analysis for improving the original Jaipur foot and reducing itsweight that has been the focus of the recent international and interdisciplinary collaborations between Colorado State University, Michigan Technological University and Dr. P.K. Sethi Rehabilitation & Jaipur Limb Training Centre.

The difference between the current Jaipur foot fabrication processand the method proposed here is that the inserts used for improved Jaipur foot are made of Nylon6 foam. This foam is readily available and compatible with the manufacturing process used tocreate the Jaipur foot. Due to the inconsistency of the EVA inserts they were deemed non-compatible with the current foot process. Nylon 6 foam is highly heat resistant foam with a low density. The fabrication process is the same as the process that is being used currentlyin India with few minor adjustments for creating the Nylon 6 foam blocks that are shaped into the inserts.

Using EVA decreased the weight of the Jaipur foot by 18% but the resulting foot had structural issues. It was hypothesized that two factors could contribute to poor insert integrity: shrinking of EVA during the use of an oven or autoclave, and separation of EVA from the natural rubber layer. The use of additional adhesives was eliminated from the final design, because during tension tests, the interface materials failed before the adhesive bond. The shrink test proved that over 80% of EVA shrinkage occurs during the first heating cycle, with negligible amounts resulting from a second cycle. This suggestedthat blocks of EVA exposed to 150°C for 30 minutes will preshrink enough to prevent significant shrinkage within the foot, rendering them useable in fabricating the Jaipur foot. The tensile test demonstrated that preheating EVA blocks will not compromise the tensile properties of the insert material. Therefore the preheating cycle was incorporated into the final design.

Despite material testing results, preheating EVA did not prevent additional shrinkage from occurring during the vulcanization cycle. It was determined that EVA cannot withstand the temperatures required to obtain sufficient vulcanization of the outer rubber. A material with greater heat resistance should be considered.

For the final design, Nylon 6 foam was selected and evaluated. Lack of insert shrinkage during prototype fabrication established this as a suitable material. Furthermore, the material is compatible with current production processes. The 25% weight reduction and improved insert integrity accomplished with the use of Nylon 6 has increased the usability of the Jaipur foot. It is anticipated that the patients will experience less fatigue when controlling a foot with the lighter foot. Future work will include evaluation of the improved design with both transtibial and transfemoral amputees at Dr. P.K. Sethi Rehabilitation & Jaipur Limb Training Centre in Jaipur, India through the ongoing research collaborations.

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