Biodegradability and waste management of Jaipur Foot

Anil Kumar Jain[1]*, Mona Kejariwal[2]
[1] Dr. P.K. Sethi Rehabilitation Centre, Santokba Durlabhji Hospital, Jaipur, Rajasthan, India
[2]Department of Botany, R.D. National and W.A. Science College, Bandra (west), Mumbai, India.
*anil.rehab64@gmail.com

ABSTRACT

Designed in and named after Jaipur, India, the prosthetic foot was designed to be inexpensive, water-resistant, and quick to fit and manufacture. Several field trials case studies were made and this artificial aid was found to be very comfortable and acceptable to the amputee population following floor sitting culture. The quality assertion and standards related to these prostheses at affordable cost assume great significance especially for India and other developing countries. Environmental issues such as biodegradability of various components like microcellular rubber, tread rubber, nylon cord, cushion compound and skin colour rubber and other. It is necessary that biodegradation issues should be widely held at various platforms beside its bioengineering and designing issues for proper handling and storage concerns. Approval standards and quality control should be a part of the development effort prior to regular production and use of these low cost prostheses.

Keywords: Jaipur foot, Biodegradation, Prostheses.

INTRODUCTION

Jaipur foot designed and developed by Late Dr. P.K. Sethi is second most widely used prosthetic foot piece in the world after SACH (Solid ankle, cushion heel) foot. SACH foot designed for use in the colder climate western countries were not acceptable for most amputees in India, with their barefoot, floor - sitting life style and walking over an unpaved irregular terrain.

Floor sitting culture required much more mobility at the ankle and subtalar joint to allow squatting and sitting cross legged on floor.

Jaipur foot looks like a normal foot. It has heel block (280 to 320 shore A) and forefoot block and toes (340 to 380 shore A) made by gluing various layers of microcellular rubber. Micro cellular rubber is the same rubber which is used here in making ordinary hawai chappal is available in open market. On the top, it has wooden ankle block with stainless steel carriage bolt held in place by two iron nails, through which the rest of the leg could be attached.

All the three structural blocks are cleaned with toluene solution and are smeared with black solution (Vulcanizing cement). This entire assembly of ankle, heel and forefoot block is assembled together with cushion compound.

A layer of tread rubber is placed on under surface which is strong and highly abrasion resistant due to its high carbon content. Nylon cord is placed in between all the blocks and other high stress areas in the foot to make it stronger.

Now this entire assembly is covered with skin color compound to make it cosmetically more acceptable and water proof. The whole assembly is packed inside a metal die and is placed in hospital autoclave for vulcanization at 125^{0}C, 25 Psi for one hour. The die is allowed to cool slowly and opened. The product we get is Jaipur foot. Excess rubber hanging from sides is removed by scissors.

This can be used with or without shoes. One can slit the rubber between great toe and second toe to use it with chappals and sandals. Women can apply nail paint and toe rings to make it look more natural. A farmer walking barefoot, working in the mud and water, moving around on uneven and hilly roads may need a replacement after 3 years.

The increase in civil wars, global use of landmines, increasing number of road traffic and train accidents, rising incidence of diabetes, cancer and growing terrorism has enormously increased the number of amputees, thus the demand of Jaipur foot.

Even the more advanced limb centres and gait labs around the world are willing to work in association with our department to incorporate controlled mobility provided by Jaipur foot in western foot pieces to provide greater comfort at the "stump-socket" interface. Jaipur foot originally labeled as a "culture specific" innovation is now looked upon as

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simple solution to a very complex problem has much greater universal relevance. Due to its considerably low cost and high durability it has potential for the use by poor population in affluent countries also.

With the idea to overcome its main draw backs of being heavy in weight and lack of standardization of materials and fabrication process, we did a research project to replace the rubber with polyurethane. Government of India funded it in collaboration with IIT Mumbai and NCL Pune, which continued for nearly 5 years. We could reduce the weight but durability and stability got severely compromised forcing us to drop the idea. Polyurethane Jaipur foot is no more used.

Mechanical engineers from Michigan Technological University worked with us for nearly two and a half years and replaced microcellular rubber with EVA and nylon 6 to reduce excess weight and standardize the fabrication process. Specimen foot piece was fabricated in Michigan Technological University. Its performance was not up to the mark on testing machine and on clinical trials but it enriched us about behavior of certain materials when used in combination with others. It helped us in simplifying the fabrication process.

National Science Foundation, USA in association with Ohio State University is funding a three years research project for up gradation of Jaipur foot to be carried out at Dr. P.K. Sethi Rehabilitation Centre, Santokba Durlabhji Memorial Hospital Jaipur in association with Malviya National Institute of Technology, Jaipur. First year has completed. This will continue up to August 2017.

BIODEGRADABILITY OF MATERIALS USED IN JAIPUR FOOT

Microcellular rubber:

Microcellular rubber which is used in Jaipur foot is polyurethane plastic. Most commercial polyurethane products are composed of soft segments derived from the polymer-diol, e.g., PCL-diol, polyethylene glycol, poly-tetramethylene glycol, and hard segments from the diisocyanate, e.g., 1,6-hexa methylene-diisocyanate (HDI), diphenylmethane -4,4’-diisocyanate (MDI), tolylene-2,4-diisocyanate (TDI), and diols such as ethylene glycol and butanediol. Studies have been carried out regarding biodegradability of such compounds.

Polyurethane polymers a versatile polymer system and its advanced derivatives are extensively used in ISRO Space program for various uses viz., elastomers, adhesives, foams for cryogenic insulation, light weight structural applications, acoustic damping, coatings and so on. Polyurethane foams are produced using an external blowing agent like freon (now replaced by environment friendly materials)[1].

Darby and Kaplan[2] (1968) reported that polyester-type polyurethanes (ES-PU) were more susceptible to fungal attack than polyether-type polyurethanes (ET-PU). Two species of the Ecuadorian fungus *Pestalotiopsis* are capable of biodegrading Polyurethane in aerobic and anaerobic conditions such as found at the bottom of landfills. One hundred laboratory-synthesized polyurethanes were tested by a mixed-culture petri dish method for susceptibility to fungus attack. Polyether polyurethanes were moderately to highly resistant to fungal attack, whereas all polyester polyurethanes tested were highly susceptible. The susceptibility of the polyethers was related to the number of adjacent methylene groups in the polymer chain. At least two such groups were required for appreciable attack to occur. The presence of side chains on the diol moiety of the polyurethane reduced susceptibility [3].

Polyester type polyurethanes are more easily biodegraded by fungus than polyether type. Tokiwa *et al*. (1990)[4], found that R. delemar lipase and hog pancreatic lipase can hydrolyze the PU composed of MDI, PCL-diol (Mn 2,000) and 1,4-tetramethylenediol (molar ratio 2:1:1).

Crabbe et al. (1994)[5], reported on the degradation of an ES-PU and the secretion of an enzyme-like factor with esterase properties, by Curvularia senegalensis, a fungus isolated from soil. Subsequently, Nakajima-Kambe et al. showed that Comamonas acidovorans strain TB-35 was able to degrade ES-PU made from poly(diethylene adipate) (Mn 2,500 and 2,690) and TDI. A purified ES-PU-degrading enzyme from C. acidovorans TB-35, a type of esterase, hydrolyzed the ES-PU and released diethylene glycol and adipic acid.

Santerre et al. (1994)[6] and Wang *et al*. (1997)[7], reported that cholesterol esterase from bovine pancreas degraded ES-PU synthesized from TDI, PCL-diol (Mn 1,250) and ethylenediamine, and released the hard-segment components.

However, it seems that no microbe can degrade polyurethane completely, and therefore, it is difficult to clarify the fate of residues after degradation of ES-PU by both microorganisms and enzymes. Furthermore, it is difficult to determine whether ET-PU itself was degraded by microbes to any significant extent [8].

Tread and Cushion compound

Tread rubber is strong, abrasion resistance, not slippery on wet surface and has a good bonding property to cushion compound after vulcanization, hence used for sole of Jaipur foot. Cushion compound is used to assemble or wind up all the structural blocks made up of micro cellular rubber.

The tread and cushion compound sheets is made of butyl rubber (Poly(Butylene Succinate) (PBS)) that often includes additives such as carbon black, which gives it its characteristic colour, and silicon. These additives improve wear resistance usually at the expense of traction. [9]

PBS degrading microorganisms are widely distributed in the environment, but their ratio to the total microorganisms is lower than other synthetic rubber degraders. The degradation of butyl rubber by Amycolatopsis sp. HT-6 was investigated and results showed that this strain can degrade not only poly (butylene succinate) (PBS) but also poly (hydroxybutyrate) (PHB) and Polycaprolactone (PCL). Several thermophilic actinomycetes from Japan Culture of Microorganisms (JCM) were screened for their capability of degrading PBS. Microbispora rosea, Excellospora japonica and E.viridilutea formed clear zone on agar plates containing emulsified PBS. M. rosea was able to degrade 50% (w/v) of PBS film after eight days cultivation in liquid medium.[10]

Nylon cord and skin colour cord

These are essential parts of foot assembly and aesthetic value. Polyamide (nylon) has excellent mechanical and thermal properties, good chemical resistance and low permeability to gases, but it is known to be resistant to degradation in the natural environment. The poor biodegradability of nylon in comparison with aliphatic polyesters is probably due to its strong inter chain interactions caused by the hydro bonds between molecular chains of nylon. Some microorganisms such as Flavobacterium sp. [11] and Pseudomonas sp. (NK87) [12] have been reported to degrade oligomers of nylon 6, but they cannot degrade nylon 6 polymers. Moreover, some white rot fungal strains were reported to degrade nylon 66 through oxidation processes.[13]

It has been reported that nylon 4 was degraded in the soil and in the activated sludge. The results confirmed that Nylon 4 is readily degradable in the environment. Furthermore, the biodegradability of nylon 4 and nylon 6 blends was investigated in compost and activated sludge. [14] The nylon 4 in the blend was completely degraded in 4 months while nylon 6 was not degraded.[15] Recently, Yamano et al. was able to isolate polyamide 4 degrading microorganisms (ND-10 and ND-11) from activated sludge. The strains were identified as *Pseudomonas* sp. The supernatant from the culture broth of strain ND-11 degraded completely the emulsified nylon 4 in 24 h and produced γ-aminobutyric acid (GABA) as degradation product. [16]

Generally speaking, degradation of polyamides is still unclear. Thus further investigations on the pathways of degradation are necessary. When the biodegradability of solid polymers is assessed, aside from their chemical properties, we should also note their physical properties as polymer aggregates. In other words, we should consider not only the first order structures but also the high-order structures of polymers that play an important role in the biodegradation process. Furthermore, it is worth mention that surface conditions (surface area, hydrophilic, hydrophobic properties) of plastics also generally influence the biodegradation mechanism of plastics. In this review, we will be discuss the biodegradation of plastics by both microbial and enzymatic processes and several factors that govern their biodegradability. Polycaprolactone (PCL), and poly(butylene succinate) (PBS) are petroleum based, but they can be degraded by microorganisms. On the other hand, poly(hydroxybutyrate) (PHB), poly(lactide) (PLA) and starch blends are produced from biomass or renewable resources, and are thus biodegradable. [17]

Jaipur foot is a purely indigenous cheap product affordable by poor section of society in India and other third world countries. The blending of biodegradable polymers is one approach of reducing the overall cost of the material and modifying the desired properties and degradation rates. Compared to copolymerization method, blending may be a much easier and faster way to achieve the desired properties. More importantly, through blending, other less expensive polymers could be incorporated with one another. However formation of miscible blends especially with non-biodegradable polymers can slow down or even inhibit the degradation of the biodegradable components. [18]

Iwamoto et al., 1994[19] developed blend plastics by combining PCL with conventional plastics such as low density polyethylene (LDPE), polypropylene (PP), polystyrene (PS), nylon 6 (NY), poly(ethylene terephthalate) (PET) and PHB, and evaluated their enzymatic degradability. The blends of PCL and LDPE, PCL and PP retained the high biodegradability of PCL. In contrast, the degradability of the PCL part in the blends of PCL and PS, PCL and PET, PCL and PHB dropped off remarkably. In case of blends of PCL and NY or PS, the biodegradability of PCL did not change so much. In general, it seems that the higher the miscibility of PCL and conventional plastics, the harder the degradation of PCL on their blends by R. arrhizus lipase. Furthermore it was found that degradability of PCL/LDPE and PCL/PP blends by the lipase could be controlled, depending on their phase structure[20].

OTHER COMPONENTS OF JAIPUR FOOT:

1. Vaseline or any vegetable oil: petroleum based products are easily degradable by various microorganis like *Pseudomaonas* species [21]

2. Aluminum sheet or cardboard and Wooden plank: waste generated by these die and sheets are managed by work shops.

Toluene or any other cleaning, rubber adhesive solution and vulcanizing cement: rubber cement is an adhesive made from elastic polymers (typically latex) mixed in a solvent such as acetone, hexane, heptane or toluene to keep them fluid enough to be used. Water-based formulas, often stabilized by ammonia, are also available. This makes it part of the class of drying adhesives: as the solvents quickly evaporate, the "rubber" portion remains behind, forming a strong, yet flexible bond. Often a small percentage of alcohol is added to the mix. Alcohol does not pose a problem, but acetone—a solvent widely used in nail polish removers—does irreparable damage on polished surfaces and many plastics. The solvents which used for the preparation also require proper discharge. Benzene, toluene and xylene isomers (BTX) are the major components of in the adhesive. Because of their low water solubility and their acute toxicity and genotoxicity, BTX components are classified as priority pollutants by the U.S. Environmental Protection Agency. Due to the sequences of accidental gasoline spills and leakage from service station tanks, they are prime sources of aquifer contamination. BTX degradation by microorganisms possesses several advantages over traditional methods. Enriched cultures obtained from soil exposed to BTX mineralized benzene and Toluene and co-metabolized Xylene isomers, producing polymeric residues. [22]

Most synthetic polymers are not biodegradable; however, there are a few that are when dissolved in water. The major families are lactic acid-based polymers, poly-caprolactone, certain polyesters, and polyvinyl alcohol.

Esterases (ester-hydrolyzing enzymes) and some microorganisms are known to biodegrade polyesters at a reaction rate depending upon the polyester structure. While many aliphatic polyesters are suited for biodegradation, the aromatic polyesters (e.g., polyethylene terephthalate) do not possess this property. [23]

Polyvinyl alcohol is the most readily biodegraded polymer, compared to other vinyl polymers such as polystyrene, polyethylene, and polypropylene. Enzymes isolated from pseudomonas have proved to be particularly degradative to polyvinyl alcohol. The polymer is degraded as the sole carbon source by these organisms. [24] [25]

3. Waste Management: The waste pieces of rubber are sent to automobile tyre retreading shop. Trimmed wooden pieces from wooden ankle block are used as fuel in kitchen.

CONCLUSION

With the increasing number of persons with locomotor disability, a number of materials and designs are used in making rehabilitation aids to make them able to stand and walk on their own. After every 2 to 3 years the article has to be replaced as they undergo wear and tear, or the patients outgrow them. This generates considerable amount of prosthetic and orthotic waste (p-waste and o-waste) which if not biodegradable, can create serious environmental problems, same as created by the e-waste.

Present article focuses on the biodegradation and waste management practices of Jaipur foot which can be combined while foot designing and fabrication processes. The materials which are used for Jaipur foot should be durable enough to make it last for 3 to 5 years. Selecting the natural polymers and other components is essential because synthetic polymers often pose environmental hazards due to low biodegradation rates and resulting accumulation. Keeping in mind the increasing demand of eco-friendly polymers and their biodegradation mechanism, recent article open channels for more use of eco-friendly polymers, though they may not be cost effective.

Note– Jaipur foot has not been patented. Information provided for Jaipur foot is based on the original article titled "Vulcanized rubber foot for lower limb amputees" published by Dr. P.K. Sethi in prosthetics and orthotics International, 1978 (125-136) and the personal discussion with him. [26]

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