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Application of Reverse Engineering and CAD/CAM in Field of Prosthetics-A Make in India Concept

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Abstract: *A prosthetic is a device that replaces any missing human body part visibly and functionally. Reverse engineering is a field of engineering wherein a model and further a prototype can be generated by extracting information from previous design or available model using the advanced tools of CAD/CAM. This paper aims at exploring the needs and advantages of connecting the prosthetic industry with reverse engineering in a developing country like India for patients with lower limb amputations under the brimming concept of "Make in India".*

Keywords*:* reverse engineering, CAD/CAM, rapid prototyping, prosthetic sockets.

INTRODUCTION

An amputation can occur due to various reasons- disease, accident, tumor or infections. Lower limb amputations today are the most common type of amputations occurring worldwide, including developing countries like India. The lower limb amputations are also of two types- Trans tibial and Trans femoral. In either of the cases, a prosthetic device is required to restore functionality of the limb. Such prosthetics basically have three parts- the socket, pylon and the foot (fig.1).

Figure 1. A Trans tibial prosthetic limb

Here pylon and foot are the compensation for the residual limb. The socket forms the connection between the residual limb and the artificial limb. The interface between the socket and the residual limb is the most crucial area in terms of comfort to the patient since it bears all the weight of the patient and forces produced during gait. The shape of every residual limb is unique. Hence a customized socket is the need of the hour for patient satisfaction. Conventionally, sockets have been manufactured by technicians by following these steps (fig.2):

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1. Negative mould preparation (fig 2.a) - This is done by wrapping POP bandages around the residual limb to capture the basic shape of the limb. Once dried, it is removed from the limb
2. Positive mould preparation (fig 2.b) - the negative mould is filled with POP and hardened. Then rectification of the positive mould is done at pressure sensitive and pressure tolerant areas. This is achieved by adding plaster at pressure sensitive areas and removing plaster at weight bearing or pressure tolerant areas.
3. Socket preparation (fig 2.c) - the positive mould is sealed in poly vinyl alcohol bags and filled with resins. Once this hardens, the positive mould is broken and the socket is obtained.

Figure 2.a. Taking negative mould of the residual limb by plaster wrapping.

Figure 2.b. positive mould by filling POP and socket rectification by adding and removing POP.

Figure 2.c. socket preparation by lamination and final trimming

After this the patient tries on the socket and gives feedback about the level of comfort and fit. If the patient feels discomfort, the above procedure has to be followed again and again until a satisfactory fit until comfort is experienced by the patient. As it is clear from above that the customizing of the socket is dependent on the technician to a large extent. So, skilled technician can reduce the number of iterations but not eradicate them. Also, this type of procedure causes mental stress to the patient who, already, goes through the trauma of loss of a limb. Even after this, perfect fit may not be obtained. Also physiologically, the shape of the residual limb changes over time and the old socket may not suffice anymore. In such a case again a new socket would be required.

Here steps in the innovative thinking of applying reverse engineering (RE) powered with the tools of latest CAD/CAM advancements (fig.3). By the application of reverse engineering, the shape of the limb can be captured most accurately. It is important, though, to remember that a good socket is not the true copy of the residual limb but rectified appropriately at the pressure sensitive and pressure bearing areas. The shape of the captured limb can be transferred to a CAD platform and rectified accordingly and number of models can be created. Once rectification is achieved, a finite element analysis can be carried out on all the prospective socket designs to analyze the pressure distribution during gait. The best design can be selected. This can be transferred to a rapid prototyping machine and socket can be obtained in way lesser time and with better quality.

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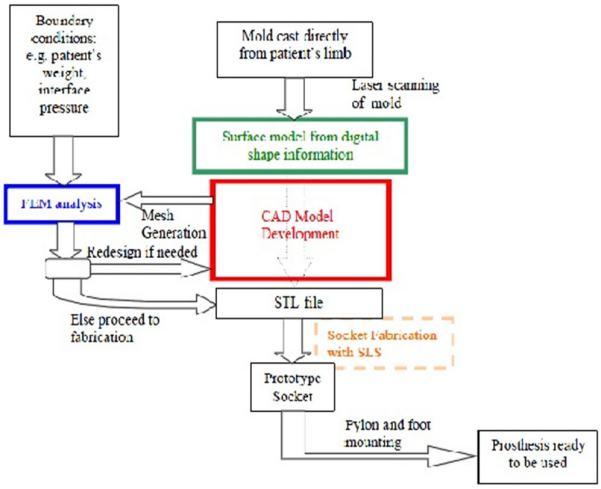

Figure 3. Steps for application of RE, CAD/ (CAM or RP) in prosthetics

Literature review

Literature review suggests that a lot of work has already been done to link lower limb prosthetic industry with RE [2, 3, 8, 15].
Linking socket designing with RE and CAD/CAM allows the results from finite element analysis on all possible socket designs. This opens a gateway to obtaining a reference to shape and material library to choose socket material and design from [2, 3, 5].
Apart from this sockets can be manufactured by using different materials in the same socket according to the strength and properties required at different parts of the residual limb. Such sockets are called variable-impedance socket and they improve comfort to the patient. These sockets can be manufactured by reverse engineering since variable materials are used in manufacture of one socket [7].
The time taken to manufacture a socket is greatly reduced by using rapid prototyping and reverse engineering technologies. 3D printed sockets have come out to be more cost effective as well as comfortable. Since all measurements are taken through scanning techniques the fit is better than obtained by manual measurement [6].
Pressure distribution patterns can be obtained during gait of the patient by carrying out finite element analysis on the model [2, 3, 6, 7, 8].
Scanning techniques, if not available, can be replaced by other techniques for obtaining the limb measurements accurately. These are MRI and CT scan of the patient's limb. These can be converted into 3D limb models by software like MIMICs [8].
Comparisons have been done between traditionally manufactured sockets and once obtained from 3D reconstruction of limb shape. It has been observed that some variations occur in obtaining the shape and measurement of the socket through manual and RE method. The RE methods are more accurate because human involvement is lesser [11, 12, 13].

Make in India concept

A thorough literature survey indicates that lot of stress is given in researches outside on application, advantages and exploitation of RE in field of prosthetics.
Developing countries like India is still following the conventional approach to socket manufacturing. The progress using advanced techniques and combining medical field with CAD/CAM/RE has been slow. This being despite the humanitarian factor being involved here. The rehabilitation industry requires a make in India concept on a robust level to meet the ongoing world standards. The number of amputation patients in India is large and the number is increasing only. Also it is true that conventional methods of socket manufacturing do not comply to the patient specific parameters on a very successful level. Hence, there is an open field to apply RE and CAD/CAM techniques here. A lot of potential is definitely held by RE in field of prosthetics in India.

Method and Materials

For the success of application of RE in lower limb socket design in India, it is important to have the following

1. Equipment and software- A machine or method to capture the residual limb shape. As seen in literature, this can be done by using a 3D laser scanner, CMM or simply by segmenting the MRI and CT scan of the residual limb on certain software platforms like MIMICS. In proper formats like .stl this data is transferred to CAD software like CATIA, CREO to convert the scanned information of the residual limb into a solid model. Form here, the rectified model of the socket is transferred in format like .IGES to Finite element software as indicated by literature like ANSYS, ABAQUS and Altair Hypermesh. A rapid prototyping machine involving any of the processes like fused deposition melting (FDM); selective laser sintering (SLS), 3D printing and steleolithography can be employed to obtain a socket.

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2. Manpower – skilled manpower is a requisite to obtain successful results from the application of RE in field of lower limb prosthetics.
    - Assistants fluent with the entire software platform.
    - Collaboration with medical experts in field of orthopedics
    - CAD/CAM engineers.
3. Industry institute collaboration- This is one of the most important factors that can be employed in a developing country like India where the level of technical education is so high. Premier engineering institutes should provide training to the students in emerging fields of RE and collaborate with prosthetic industries to help revolutionize these industries by application of the skills of the students. There is a need to create awareness about the wide application of RE in the field of prosthetics to the students, researchers and prosthetists as well as its long term benefits to the prosthetic industry and the amputees in India.

Conclusion

India is one of the fastest growing developing countries in the world. The new national motive of "make in India" opens plethora of options to innumerable industries, prosthetics being one of them. It not only promises to explore new dimensions in field of engineering but medicine as well. It will definitely add a new horizon to the make in India concept at the global platform. Also its humanitarian aspect is no less important.

The main advantage of applying RE in design and manufacture of prosthetics sockets is:

- The socket manufactured by RE will technically have better design and quality.
- The process is computerized and digitized with lesser manual work.

Hence, it will be consistent and independent of technician skill. This lessens the chances of errors and iterations required to achieve the needed fit and design of the socket.

- Record of the residual limb and socket design can be maintained. As the shape of the residual limb changes over time, the shape library can be referred for comparison and modification. Ability to modify material and design of socket easily without going through all the tedious process of creating a mould all over again.
- RE based process is faster and a socket can be manufactured in way lesser time than conventional process.
- Easier to carry out rectification on pressure sensitive and pressure tolerant areas.
- Feasibility analysis- a lot of previous research have already shown that it will save time as well as money. This is the current trend in research and studies have shown that all parts (RE+CAD+CAM) of this have not been exploited in India. Studies also show that it is feasible to manufacture socket with rapid prototyping method. Work has been done on suitable materials. Also strength analysis has been carried out. Previously, clinical evaluation of conventional versus rapid prototyping sockets have been done to calculate pressure distribution during gait and comparisons have been drawn as in favour of those manufactured by RE and CAD/CAM completely.

It is time that the modern techniques like RE replace the conventional methods of socket manufacturing in India to establish footing in global market by fully utilizing the newest methods of available with RE, CAD/CAM and RP.

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