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Title

Digital transformation and 3D printing in lower extremity prosthetic solution - A new approach for low middle income countries

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Summary

The talk highlights the application of digital transformation and 3D printing method to produce socket designs for weight bearing transtibial prostheses. It also focusses on efficacy of the load bearing transtibial sockets, design philosophies involved, materials used and the forthcoming challenges.

Introduction

The census of India 2011 (2016 updated) shows, out of 1.21 billion people, 26.8 million are persons with disabilities which is 2.21% of the total population. Out of this, 20.2% have movement related disabilities. The last comprehensive survey done by the National Sample Survey organisation (NSSO) 2002, found that 8% of disabled population are with upper and lower extremities amputations. There are over 4,00,000 amputees who do not have any aids. Rehabilitation and assistive technology field has witnessed various approaches and changes in the course of evolution. Materials like wood or heavy metals are taken over by plastics. The need to deliver assistive devices on the fly has enabled, to integrate new technologies like 3D printing and digital transformation, Internet of Things etc.

Modern technologies is enabling standard design and manufacturing processes, with better precision, consistency and delivery lead times. This could help in reaching out to users in less resource settings.

Methods

There is a need for automation and digital manufacturing in healthcare and assistive devices as the demand will be increasing, as per the predicted market research².

The present paper highlights the key research work done on the development of below knee sockets prototypes with the use of Digital transformation and 3D printing, and there by producing precise product at a faster rate as well as automating the process for future iterations. This involves limited man power use, overheads and eco-friendly method.

The important stages involved are:

- Physical data capture using a 3D laser scanner with a good accuracy upto 100 Microns.
- Digital design team with prosthetists to work on the data on an open source or a proprietary software depending on the level and budget of the research.
- Additive manufacturing team to perform design for additive manufacturing procedures to validate the design for 3D Printing.
- Prosthetists and therapists to observe the gait and provide training.

Results

The project could be the first of its kind in Indian context, which aims at developing the following:

- Weight bearing transtibial socket fabrication method on digital transformation platform and produce few prototypes as a proof of concept in the first stages.
- Application of locally developed technology including 3D printers to keep it cost effective.
- Fabricating the sockets by filament deposition method using locally available materials, infrastructures after scanning the residual limb with a hand held scanner of acceptable resolution.
- Using the certified personnel (prosthetists, design engineers, AM engineers, service users) to work as a team to build every socket.
- Able to carry out scanned data collection in remote locations in less resource settings and service delivery at doorsteps of assistive devices.
- Assembly of the digitally transformed sockets with locally available quality assured components and foot pieces under the supervision of the prosthetists and conducting the trials and fittings.
- Conducting clinical validation on the effectiveness of the sockets using outcome measures and gait training protocols with the support of clinical therapists.

- Doing data collection on the piloting of the small number of users of the sockets followed by long duration clinical trials and assessing the effectiveness of the same over the existing conventional mode of developments.
- Dissemination of the technology to other developing countries through education and training.

Conclusion

Digitally transformed and 3D printed sockets could be an important technique that will be used for transtibial amputee rehabilitation. The digital transformation technology could be considered for the design and development of other assistive devices like trans femoral prostheses, orthoses and other weight bearing applications. There is a need to carry out long duration clinical trials over a large subject group and to work towards the future design philosophies to conform to the ISO 10328 specifications. To work on the strengths of the materials used in filament deposition methods and test the infill in the walls of the sockets as per the material specification to ensure appropriate quality and durability.

Prototyping phase has proved the following:

- No need for big tool room and shop floor and minimum material stock required.
- The digital model can be developed remotely and passed on to the printing point on cloud and remote production with minimum wastages.
- Reduction of monotonous tasks and productive reuse of the resources doing things digitally.
- No health hazards compared to the traditional methods.
- Data analysis, generation and tracking can be flawless, everything being monitored by a product development platform. No data loss and redundancy.

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Image: PMD-3d socket phase_2630.PNG

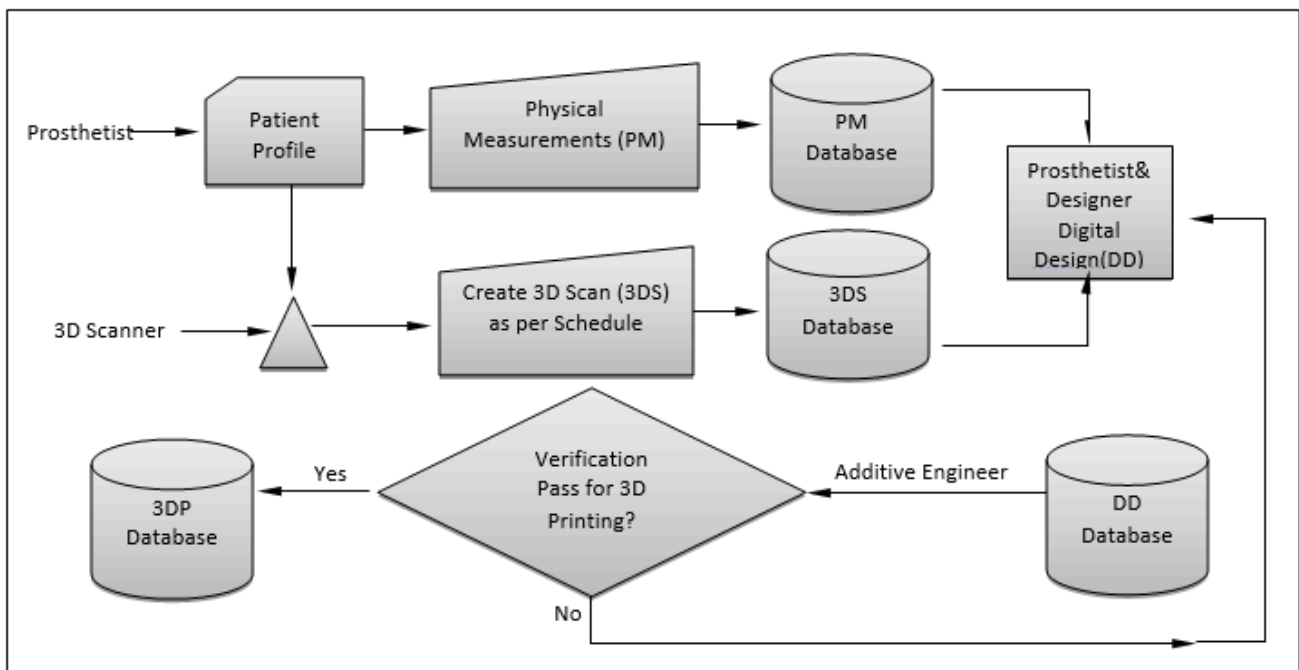


Figure 1 Schematic of Product Development for a Typical TT Prosthetic socket