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Opinion

Is 3D-Printing Viable to Make Artificial Lower Limb Sockets with Improved Comfort and Fit for Amputees?

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Introduction

The number of major lower limb amputations in the National Health Service (NHS) England has been increasing with over 8000 amputations performed in year 2019/2020 [1]. Following an amputation, the patient requires a prosthesis attached to the residual limb using a socket which can be uncomfortable due to misfit. Replacing a labour intensive, handcrafted process with a data-driven engineered 3D printing process capable of individual customisation could transform patient outcomes without runaway cost to the service provider.

How is a lower limb amputee socket manufactured in the majority of NHS Trusts?

A custom-made amputee socket in the NHS takes about 2 weeks from the first visit to patient fitting [2-4]. It involves the stump shape capture by creating a plaster cast. A prosthetist guides the mould design that is created from the plaster cast. The socket is hand made using a fibre reinforced resin on the mould. Once fully cured, the excess material is trimmed, and the socket and artificial limb are assembled to create the prosthesis. This process is adopted worldwide [5]. New amputee patients may need up to 6 different sockets in 1 year to achieve the right fit due to rapid stump shape changes. Immediately following amputation, a trial socket is made to help the patient adapt to the new artificial limb whilst still recovering in the hospital. More generally amputees suffer seasonal related stump shape changes that affects the socket fit which can cause increased pain and discomfort. Often a thicker sock is used and can cause discomfort when worn over extended periods and during warmer weather. Each patient is provided with at least two prosthetic limbs which are replaced every 2 years [6]. More actively mobile patients may require an additional limb with socket, such as a swim leg [3]. Actively mobile patients generally prefer a suction socket, but this gradually damages the skin over the years resulting in less use of the artificial limb [4]. A composite socket made using resin is toxic to manufacture, requiring the use of personal protective equipment, and produces harmful waste and dust that requires breathing and extraction equipment. Additional strengthening may be required with fibre reinforcement added after the socket is made. Presently there is no stringent standard for the design and manufacture of sockets [7]. The design and fabrication of a socket is extensively hand-crafted, resulting in significant hidden manufacturing cost within NHS settings.

How does a poorly fitted socket affect an amputee's comfort?

A socket is a load bearing rehabilitation device. A well-designed socket ensures an evenly distributed pressure is transferred between the patient's stump and the artificial limb. Although the approach to fabricating a socket using fibre and resin provides the strength needed together with personal customisation, it does not easily accommodate functionality that could improve the fit and comfort to patient, allowing the patient to wear the socket for longer periods. A poorly fitted socket can cause pain and discomfort, through localised peak pressures, malalignment of the natural biomechanics of the lower limbs, change in the gait pattern and loading on other joints and the patient expends higher metabolic energy in community ambulation.

Can 3D-Printing be used to produce better fitting and more comfortable prosthetic sockets?

3D-Printing (3DP) enables many design freedoms to improve the functionality of the device at no extra cost which is not practically possible with conventional methods. 3DP uses digital design data, and this could be obtained from laser scanning the patient's stump [8]. 3DP would enable a digitalised workflow that could retain patient records in a digital format and enable a more efficient design and fabrication process, which is additional to the socket functional design enhancements. In today's current best practice, when an amputee's stump shape changes, a new cast and mould is made followed by hand layup on the mould [6]. The process is inefficient with unquantified precision and lacks important engineering control elements such as design, automated manufacture, and measurement to achieve a consistent quality for the device which can result in misfit. There are 34 3DP polymer materials that are safe to use for skin contact that use 5 different 3DP process technologies. Two of these were only commercialised within the past 5 years. These 3DP processes differ significantly in the method of printing with feedstocks using either a filament, liquid or powder. Furthermore, an increasing trend among 3DP machine suppliers is to supply their own polymer materials and printing process parameters that cannot be adjusted by the machine user. There is a need to understand the viability of 3DP polymers to make prosthetic sockets. Polyamide-12, PA12 is a nylon based thermoplastic material and polyamide-11, PA11, is a 100 % biobased nylon. Both are known to have the mechanical properties required for rehabilitation devices [9] and are biocompatible (ISO10993). PA12 and PA11 test samples were 3DP using SLS and MJF and their tensile properties were determined (ASTM D638-14) [10]. PA11 was found to have higher modulus (39%) and strength (15%) than PA12 and MJF-PA11 had higher strength than SLS-PA11. They are both suitable candidates for prosthetic sockets.

Can 3D-Printed sockets perform similarly as composite sockets under static loading?

When a sample stump cast, obtained from the NHS, was 3D-scanned a prosthetic socket was digitally designed and 3DP using PA11 [powder-based 3DP]. The 3DP socket was stress tested under static loading [ISO10328:2016]. The tensile properties of the PA11 input to the simulation were obtained from the 3DP tensile coupons. A simulation of the traditionally made socket using a composite material Ramie Stockinette fibre reinforced resin [11] was also performed. The simulation represented a person weighing 100 Kg. The maximum stress in the simulated PA11 socket (1.3 MPa) was well below the allowable design stress (25.5 MPa) for this material. The distortion of the PA11 socket was slightly more pronounced than the composite socket which was stiffer. This was anticipated because the design of the socket made from PA11 was not optimised for use with this material. Nonetheless, 3D-printed PA11 displayed similar characteristics to the composite socket.

Conclusion

We have shown technically that 3DP is a potential solution to make custom-fit prosthetic sockets for lower limb amputees. To exploit the advantages of 3DP, further work is needed to study the different 3DP polymer materials and methods, to select the candidates on which to develop a functional socket with improved comfort and fit.

Acknowledgments

None.

Declaration of Interest

None.

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