Hybrid Manufacturing of Upper-Limb Prosthesis Sockets with Improved Material Properties

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Abstract. This paper describes the design and manufacturing process of an advanced socket for upper limb prostheses. This device uses synergies between smart materials such as phase change materials (PCM), reduced graphene oxide (rGO) and a 3D printed metastructure to improve ergonomics and thermal comfort. Virtual prototyping was combined with traditional fabrication techniques to obtain a biocompatible, user-centered device, whose main advantage is an improved thermal behavior. Besides feasibility and biocompatibility tests, the paper describes the results of a preliminary trial involving a volunteer with upper limb amputation. It was observed that the use of an inner metastructure provides basic mechanical stability and improves resin flowability. The combination of PCM and rGO delay the increase in inner socket temperature during physical exercise on a treadmill, which induced a feeling of freshness and dryness and improved the comfort for the user. These findings, despite their preliminary nature, suggest that advanced modifications of the materials and technologies involved in the production of prosthetic sockets are able to generate appreciable benefits in terms of usability.

Keywords: 3D printing, prosthesis comfort, graphene

1 Introduction

Prostheses play a substantial role in supporting the social and work reintegration of people who have undergone an upper-limb amputation, however excessive weight or an unnatural feel of those devices may often limit their comfort and acceptability [1] therefore there is a basic interest in improving their characteristics and function. The socket is a critical interface between the user's (natural) stump and the prosthetic (artificial) device, so it ought to possess appropriate load transmission ability, stability and control, alongside efficient fitting characteristics [3]. Several patents tackled the improvement of comfort, and temperature control (cooling) [4].

The present paper is principally focussed on the re-design of the inner socket, an important element of the system directly involved in the interfacial transfer of external loads to the limb stump, and in regulating the heat exchanges between the skin surface and the environment.

To aid in the re-design of the inner socket, additive manufacturing techniques were integrated in the traditional fabrication process, in order to allow a more versatile design approach and favour multi-material integration. The function of these materials should not just be to provide structural stability and load bearing, but also to address the thermoregulation of the stump. Phase-change materials (PCMs), which consist of alkane waxes often embedded in polymeric shells, absorb large amount of heat from the environment as the solid-to-liquid phase transition takes place [5–7]. In the present context, PCMs can be incorporated into innovative prostheses and may contribute to optimise the heat transfer from the limb to the outside environment [8]. Recent studies also demonstrate that the use of graphene can improve electrical conductivity, thermal stability and mechanical properties in the production of multi-functional textiles [9–11]. Graphene is an excellent thermal conductor with a large specific surface area, especially when it is in form of reduced graphene oxide (rGO) [12].

The objective of this study is to propose a combined solution for reducing weight and improving the thermal behaviour of the socket, with expected improvements in overall users' comfort. The principal approach adopted for the study relies on the selection and application of innovative materials. In addition to the modification of the acrylic resin with PCMs and rGO, the creation of a 3D-printed metastructure to reinforce and lighten the socket structure is included. The present solution, with some modifications can be integrated with a smart-textile liner with EMG sensing capability [7].

2 Design concept

Aiming to reconcile rather binding requirements on socket shape with the desire to improve lightness and comfort, the concept design includes:

- strict geometrical reference to a professionally-stylised stump replica;
- re-definition of the composite materials, using an additively-manufactured metastructure to reinforce the resin and facilitate its lamination;
- improvement of the thermal properties of the resin by addition of phase change materials (PCM);
- improvement of the thermal properties of the knit sleeves (reinforcing fabrics) by adsorption of reduced graphene oxide (rGO);

The co-lamination of the metastructure, modified reinforcing fabrics and modified resin is expected to provide a socket with adequate mechanical properties, longer heating times and lower weight.

3 Materials and Methods

3.1 Virtual prototyping of the socket and topological considerations

The surface of the stylised stump replica was digitalised using a structured-light 3D scanner (Artec EVA, Artec3D). A triangulated mesh was reconstructed (Artec Studio 13, Artec3D), simplified, and then imported into Rhinoceros 5 (McNeel) with Grasshopper, by which the socket design process was implemented. A semi-automated routine was developed, able to create a trabecular metastructure (named '*Hypermat*') for the socket. The topological features in the metastructure are imparted using a Voronoi tessellation, which originates from a distribution of points on the anatomical surface, and can be controlled at user-interface level in the Grasshopper routine. In particular, the operator can modify: the number and density of the cells, resulting in trabeculae of variable thickness in different regions of the socket; the principal orientation paths, along which the cells are distributed in the axial and circumferential directions of the forearm; the insertion of regions with a pre-established shape (such as apertures for the EMG sensors), which determine an organic adaptation of the tessellation pattern, so that they can be coherently included within the metastructure; other global parameters such as the overall thickness of the structure.

Preliminary FEM simulations under Comsol Multiphysics 5.5 (COMSOL Inc.) were run to optimise topological features (Fig 1 - Left). In particular, utilising a constant thickness for the trabeculae may cause plastic strain concentration due to a lack of material in regions with large cells. This problem appears to be minimised if the thickness of the trabeculae is made proportional to the cell size. Early transition to plastic behaviour was also observed around triangular cells, which were therefore avoided in the following tests.

By modifying the cell orientation paths, it is possible to obtain different metastructures with varying degrees of anisotropy and provide distinctive structural/functional contexts for regions of the stump with specific characteristics (Fig. 1 – Right).

3.2 Additive manufacturing

The *Hypermat* metastructure was produced in two half-shells using fused-filament deposition of ABSplus (Dimension Elite, Stratasys). The shells were built with a printing layer thickness of 0.15mm and 100% filling. The building direction was perpendicular to the stump axis, close to the radio-ulnar direction. After printing, the support material was removed from the shells; the metastructure was then exposed for 45 minutes to a controlled atmosphere with high saturation of acetone vapours, to obtain a smooth finish.

3.3 Modification of the lamination resin and reinforcing fabrics

The thermal properties of a common resin (acrylic resin: Laminhartz, Acrylhartz and catalist, purchased by Otto Bock, Germany) were modified by using a selected

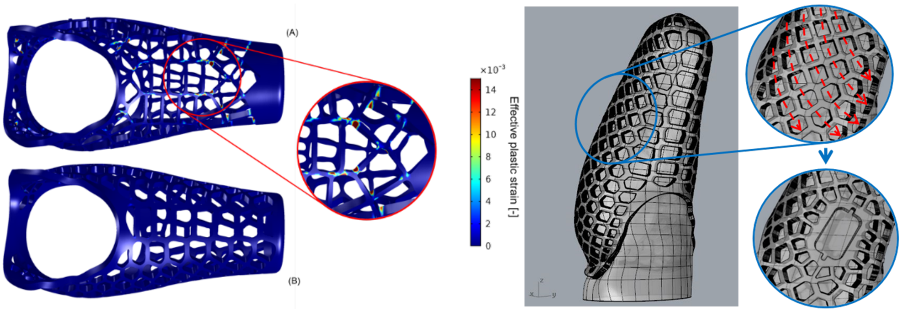

Fig. 1. *Left*. Results of preliminary FEM simulations. Plastic strain field for a velar-dorsal load of 25N on the distal end. The models were implemented as Voronoi-tassellated metastructures with trabeculae of constant thickness (A) and with thicknesses proportional to the cell size (B). Notice that in (A) strain concentration occurred particularly around cells with triangular morphology (detail), which were avoided in (B). *Right*. Example of *Hypermat* metastructure with anisotropic cell distribution. It is possible to observe principal orientation paths in the axial and circumferential directions, as well as the metastructure adapted for the insertion of fixed-shaped EMG sensors.

mixture of phase change microcapsules (purchased from Microtek Lab) characterized by phase transition temperatures compatible with the management of heat released by human body. Acrylic resin was added with 40wt% of PCMs and mixed by hand up to get a homogeneous dispersion.

The Perlon® fabric (Perlon Elastic Stockinette white, 6 cm of diameter, purchased by Ottobock, Germany), which is based on nylon fibres and is commonly used for the lamination of acrylic-based composites for traditional upper limb prosthesis sockets, was modified by depositing on its yarns a continuous layer of rGO. In detail, the graphene-modified fabric was prepared by chemically reducing the Graphene Oxide powder (produced by Hummers' method according to the procedure previously adopted by some of the authors [13]) with L-ascorbic acid in presence of the tubular fabric. After this process, the Perlon fabric, which is initially white, becomes completely dark grey, due to the presence of the rGO layer homogeneously deposited on the nylon fibres.

3.4 Biocompatibility studies: indirect and direct tests

The biocompatibility of standard and new laminates was tested according to ISO 10993-5 and 10993-12. The elution test (cytotoxic indirect assay) was performed by adding 1.0 mL of sterile and complete DMEM solution (extraction vehicle) to 0.2 g of material at 37 °C according to ISO 10993-5/10993-12 guidelines. After 72 hrs of elution time, the conditioned media (eluants) were removed and 500 µL were pipetted into a 48-well plate previously seeded with murine fibroblasts L929 at 80 % of confluence, and incubated for further 24 hrs (exposure time). Alamar blue assay (AbD Serotec, Milan, Italy) was used to evaluate the cell vitality according to the manufacturer's instructions. Absorbance was measured at wavelengths 540 and 600 nm by using a UV-Vis spectrophotometer (Victor X3, Perkin Elmer).

3.5 Co-lamination of the socket

The co-lamination procedure was carried out by an orthopaedic technician expert in the conventional socket lamination technique. The modified process includes layering of one Perlon fabric modified with rGO, the two half-shells of the *Hypermat* metastructure, a second Nylon/Perlon fabric without rGO, followed by perfusion under vacuum with acrylic resin with 40% PCM and suitable solvents to control the viscosity (acetone). Once curing is complete, the socket shell is dismounted from the stump replica and is finished by hand.

3.6 Preliminary performance tests with a volunteer

One individual (male, 65 years old) with a right trans-radial amputation volunteered for the current study. The volunteer was a long-time user of traditional and innovative upper-limb prosthetics. After signing informed consent for the procedures connected with the research, he made himself available for acquisition of the stump geometry by a trained orthopaedic technician, and participation in the tests to evaluate the performance of the new prosthesis socket.

Three thermocouples (TC1, TC2 and TC3) have been employed to measure temperature: TC1 on the medial aspect of the stump (wrist flexors); TC2 on the lateral aspect of the stump (wrist extensors); TC3 away from the body, to monitor the room temperature. The test protocol included three successive evaluation periods, each lasting ca. 30 min:

Rest 1: Wearing the prosthesis at rest;
Treadmill: Wearing prosthesis during fast walking on a treadmill;
Rest 2: Wearing the prosthesis at rest.

At the end of each period, the temperature of the contralateral limb was checked with the subject at rest. After the test, the volunteer was interviewed about his experience with the device.

The same protocol was repeated with the volunteer's own traditional device. In both cases, during the tests the inner socket was covered by the same outer socket (traditional material).

4 Results

4.1 Cytotoxicity: Indirect and direct tests

The quantitative results of the indirect contact assay after 24 hrs of exposure time (elution time: 72 hrs) on L929 cells are reported in Fig 2 - *Left*. The innovative materials (reported in the figure as new) produce no negative effect on L929 cell vitality, with respect to the control (cells at contact with no-conditioned medium) Light microscopy results reported in Fig 2 – *Right* support the same outcome in terms of cell viability for traditional and new materials, compared to control plate.

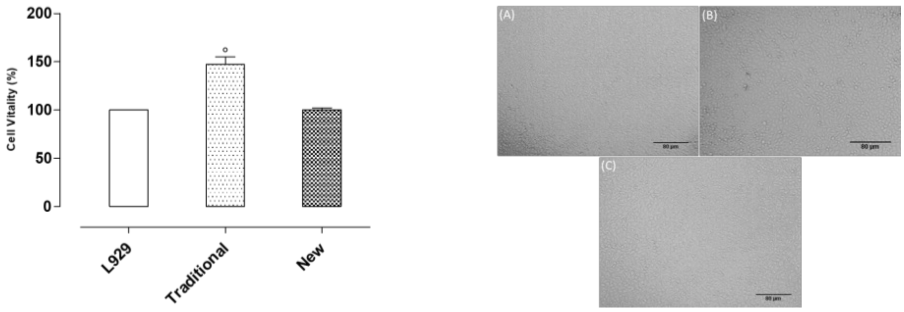

Fig. 2. *Left.* Cell vitality: Elution studies (indirect assay) performed using L929 cell line. Effect of eluants (72hrs of elution time) from traditional and new laminates on cell vitality after 24hrs of exposure time. Data are expressed as Cell vitality (%) normalized to plate control (L929). Results are mean ± standard error of the mean (SEM) of 3-4 experiments. p<0.001 vs L929. *Right*. Optical microscopy images of L929 for traditional (B) and new based-materials (C) conditioned media compared to control L929 (A) after 72 hrs of elution time and 24 hrs of exposure time. Scale bar= 80 µm.

4.2 Prosthesis socket prototypes

A first prototype of the prosthesis socket (Fig. 3) has been manufactured. The geometry was obtained from the stylised gypsum cast of a right upper-limb with trans-radial amputation. The modified resin, albeit more viscous than the basic formulation, flowed well during the lamination procedure. The presence of the *Hypermat* appeared to facilitate uniform spreading of the resin, by breaking the fluid mass and holding parts of it in the cells while the rest of it got progressively pushed forward.

Fig. 3. *Left*: *Hypermat* metastructure just before the lamination process. The black knit sleeve of Nylon/Perlon modified with rGO is visible. *Middle*: *Hypermat* metastructure embedded in the resin modified with PCM after the lamination process. Right: Volunteer wearing the prototype of the prosthesis socket. The socket weighed 165g.

The reduction in shear stress possibly also depended on the rather sparing use of knit sleeves (only 5 rather than the usual 6 or 8), whose reinforcing action was partially taken over by the solid metastructure. The final overall mass of the socket was 165g

4.3 Preliminary performance tests with a volunteer

The test was conducted in order to follow the temperature evolution at the interface between the stump and prosthesis under different physical conditions (rest and fast walking on treadmill). The temperature was recoded with a multichannel thermometer, which simultaneously acquired temperature signals from 3 thermocouples (Figure 4). It appears that during the Treadmill phase the temperature curves for the socket fabricated with the modified resin have a lower slope than those for the traditional socket. Moreover, it can be observed that the temperature crossed the 32 °C (discomfort) threshold earlier with the traditional socket. This happened although in the modified socket test the temperature of the contralateral limb rose 5°C warmer (35°C vs. 30°C) after the Treadmill phase than in the traditional socket test (likely due to an incidentally higher movement intensity/exertion). Finally, the feelings verbally expressed by the patient upon doffing the prosthesis fabricated with the modified resin, which was of dryness and freshness. An immediate and direct measure of the limb temperature at this point indicated 30 °C.

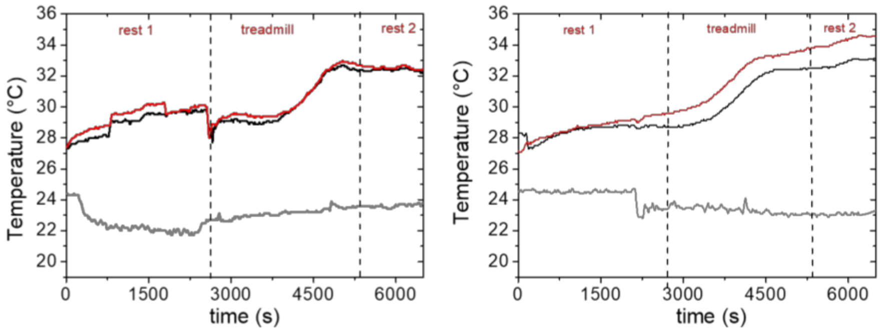

Fig. 4. Results of temperature monitoring referred to TC1 (black), TC2 (red) and TC3 (gray) of the socket produced with traditional (*left*) and modified (*right*) laminates.

5 Discussion and Conclusions

The present prototype of socket with modified materials is proposed as a new concept in upper-limb prosthesis design. The study suggests that the introduction of new materials and fabrication technologies like additive, could improve aspects such as comfort and tolerability. The use of composite and hybrid structures, including modifications of the conventional resins and reinforcing fabric sleeves, besides the introduction of additively-manufactured metastructures with structural and process-easing capabilities, could improve thermal control in the socket. The combined use of PCMs and rGO in the socket material synergistically produces an enhancement of the heat storage effects. The mechanism can be explained by an improved heat conductivity of the resin in the intimate thickness of the shell (rGO near the skin), and a subsequent heat storage by the PCMs. Overall, the new socket delayed temperature increase during rest and gym exercise. The presence of the *Hypermat* metastructure improves the overall flowability during lamination, allowing the use of PCMs concentrations as high as at least 40wt%, which are essential to favour heat absorption.

The preliminary test with a volunteer, although insufficient to draw final conclusions, showed that this patient's subjective impression was of an improved dryness and freshness, which paired with the quantitative observation that, with the modified socket, the temperature increase during exercise was delayed with respect to the traditional socket. More subjects will be enrolled in future to confirm the current evidence.
Although the adoption of new and hybrid manufacturing techniques could pose questions in practical terms, it is expected that appropriate guidelines and well thought-out virtual design systems could smooth transition towards a more integrated approach to the production of advanced prostheses.

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References

1. K. Ghoseiri and M. R. Safari, J. Rehabil. Res. Dev. 51, 855 (2014).
2. Y. Sang, X. Li, and Y. Luo, Proc. Inst. Mech. Eng. Part H J. Eng. Med. 230, 239 (2016).
3. L. Paternò, M. Ibrahimi, E. Gruppioni, A. Menciassi, and L. Ricotti, IEEE Trans. Biomed. Eng. 65, 1996 (2018).
4. D. S. GL Walters, JP Montez, 15/652,695 (2018).
5. A. Sharma, V. V. Tyagi, C. R. Chen, and D. Buddhi, Renew. Sustain. Energy Rev. 13, 318 (2009).
6. M. Fatih Demirbas, Energy Sources, Part B Econ. Plan. Policy 1, 85 (2006).
7. X. Huang, G. Alva, Y. Jia, and G. Fang, Renew. Sustain. Energy Rev. 72, 128 (2017).
8. M. M. Wernke, R. M. Schroeder, C. T. Kelley, J. A. Denune, and J. M. Colvin, J. Prosthetics Orthot. 27, 134 (2015).
9. M. S. Ersoy, U. Dönmez, K. Yildiz, T. Salan, M. Yazici, İ. Tiyek, and M. H. Alma, 5th Int. Istanbul Text. Congr. 82 (2015).
10. G. Cai, Z. Xu, M. Yang, B. Tang, and X. Wang, Appl. Surf. Sci. 393, 441 (2017).
11. L. Gan, S. Shang, C. W. M. Yuen, and S. xiang Jiang, Compos. Sci. Technol. 117, 208 (2015).

12. N. M. S. Hidayah, W. W. Liu, C. W. Lai, N. Z. Noriman, C. S. Khe, U. Hashim, and H. C. Lee, AIP Conf. Proc. 1892, (2017).
13. W. S. Hummers and R. E. Offeman, J. Am. Chem. Soc. 80, 1339 (1958).