



A NOVEL SOCKET DESIGN WITH VOLUME ADAPTATION PROPERTIES

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INTRODUCTION

The performance of the traditional Patellar Tendon Bearing (PTB) socket and its most recent rival, the Total Surface Bearing (TSB) socket, depends greatly on the natural process of limb volume change. An alternative approach to this problem is the technology of Elevated Vacuum (EV) that works by reducing the air pressure between the patient's skin and socket counteracts to the limb shrinkage. EV sockets however, cannot respond to large stump volumetric changes that may occur seasonally. In the present study a novel prosthetic device is presented designed to adapt to geometry changes of the patient's extremity in order to deal with the short and long term changes of the limb volume. Although the current research prototype must be improved from packaging and manufacturing point of view, it is expected to improve the comfort of the patient and give a more natural feel as it could adapt in almost real time to the shape changes (instantaneous, daily, weekly, monthly, seasonal) of the residual limb.

METHOD

The operation of the socket is based on the inflation and deflation of three bladders located along the body of the socket (Fig.1). The pressure in each one of these bladders is constantly monitored, for safety so that increases past a predefined threshold are prevented. The feasibility studies are designed to warrantee that the prototype is capable of adapting initially to overall volume changes, and can gradually (within 5 minutes maximum) fix the socket internal volume profile using adaptable pressure actuators while continuously apply elevated vacuum conditions in the cavity. A specialized Materials testing machine (customized MTS-BIONIX II) with axial and torsional loading capabilities was designed to fit inside the dynamic Radiography (DRSA) machine of SSD LLC (Fig. 2a) so that a full 3D kinematics analysis of the new socket's moving internal parts will be possible (Papaioannou 2009).



Figure 1: iSocket design with three bladder rings.

To avoid interfacing directly with the force cell we constructed a phantom of the stump using plastics that included Delrin, urethane, polyurethane foam, and vinyl, materials used often in the construction of crash test dummies. Tekscan Pressure sensor (Tekscan, Boston MA) assessed the socket-phantom stump interface.

RESULTS. Safety testing for actuator-bladder-conduit internal pressure indicated safe ranges those between 27.94 to 278 cm of Hg in the following loading scenarios: combinations of different displacement-load-rate curves: 0.5-28kN (force)(sample loading/displacement pattern in Fig.2d) and 0.5-12kNm(moment) at 0.02-3m/s. The flow rates in fig.2e indicate the functional ranges for appropriate bladder pressure at the desired flow of ~4-6lpm.

DISCUSSION. We benchmarked a novel bladder based socket for 1) Electric pump and circuitry voltage stability tests; 2) air pump and bladder flow, leakage and pressure loss assessment; 3) endurance and structural integrity tests of tube, sensor and pump power using the DRSA set-up;

CONCLUSION. The laboratory tests performed with phantom stumps demonstrate through safety, sensitivity, operability, durability and efficiency tests that the socket can sustain structural and operational integrity within predefined specifications and operational boundaries.

CLINICAL APPLICATIONS. These laboratory tests were a necessary preamble to actual patient tests with the next generation of prototypes. This definition of fail-safe boundaries is important before the sockets can be worn by patients.

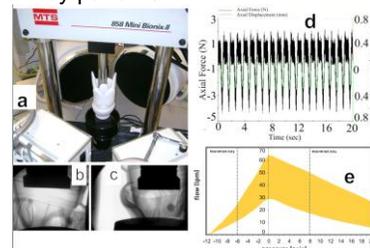


Figure 2. a) MTS and DRSA configuration with socket under test; b,c) DRSA images of the response of the bladders during the safety and durability testing; d) sample loading profile for the socket;(e) The electric pump flow-pressure relationships assessed in functional prototypes during different pressure inputs is shown.

REFERENCES

Papaioannou, G. J P&O, 392, 931-936, 2009.