Quantitative Diagnostic Tool for Determining Physiological Best Fit of Prosthetic Liners

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There are nearly 2 million amputees worldwide due in large part to vascular diseases and trauma. Last year in the US, there were over 180,000 amputations performed and the numbers continue to grow due to advances in emergency medicine and the increasing incidence of vascular disease among the US population. As the market grows, companies continue producing new prosthetic technology, such as liners and sockets, without advice on how to choose the best option for individual patients. The current gold standard of care involves patients and physicians choosing the appropriate liner on the basis of comfort after long trial periods, costing the patient thousands of dollars and months of pain. Physicians need a quantitative diagnostic tool by which to give an educated recommendation on the type of liner the patient should use without an extensive trial and error period. This is particularly important for patients with peripheral vascular disease because prostheses exacerbate their condition and place them at risk for additional amputation.

The current study was designed in an attempt to provide such a quantitative diagnostic tool for choosing the most appropriate liners for amputees. The hypothesis of the current study was that a liner that best promotes microvascular health will be the optimal liner for a patient and will correlate positively with patient-reported comfort. Assessment of microvascular health can be made using a TcOM machine which measures local pO2 based on passive diffusion from the skin to a chemical sensor using a contact solution medium. By strategically placing TcOM sensors in liners, it is then possible to measure pO2 in the tissue within the liner in real time. Then by using a baseline measurement of pO2 from the chest, the relative pO2 can determined for the tissue within the liner as well as in tissue from the healthy or unaffected leg.

Relative pO2 has been determined at several time points in 4 subjects using silicone, urethane, or thermoplastic elastomer gel liners. Results thus far have demonstrated that the relative pO2 measured from the tissue within the liner differs based on the particular liner being tested. The optimal liner based on relative pO2 alone cannot be determined due to the small sample size. Furthermore, in the subjects investigated, the best relative pO2 measures were produced using different liner materials suggesting that there is not a universal optimal liner material. As expected, the relative pO2 in the unaffected leg remains unchanged with the use of different liners on the affected leg. Subjects were also divided into two cohorts, those without peripheral vascular disease, and those with peripheral vascular disease. Our results demonstrate a difference in the optimal liner for patients with versus without peripheral vascular disease, however with the small sample size (n=2 vs n=2), the significance of this variation requires further investigation. Patient-reported comfort has correlated with the measurements of pO2 in the tissue within the liner. Patients report the highest level of comfort with liners that produce the highest relative pO2 values.

The current study has demonstrated a potential quantitative diagnostic tool for determining the optimal liner for a patient. By integrating TcOM sensors into liners, the current study demonstrated the ability to measure local pO2 which can be used as a surrogate measure of microvascular health. Further investigation is required to evaluate the clinical effectiveness of using pO2 measurements to choose an optimal liner however the results thus far suggest this will be a useful and effective diagnostic tool.