Homeland Defense & Security
Information Analysis Center

Technical Inquiry 2018-5028

Developed by:
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This inquiry response is the result of four hours of research and analysis by HDIAC. This report is intended solely for informational purposes and is a cursory review and analysis of information available at the approved distribution level for each customer. This report is not to be construed as a comprehensive look at the topic in question. For more information on utilizing HDIAC for a more in-depth Core Analysis Task, visit www.hdiac.org.

Overview

A Department of Defense Information Analysis Center representative for the United States Special Operations Command (USSOCOM) requested information on behalf of the Department of Veterans Affairs (VA) regarding methodologies for releasing scar tissue and adhesions to allow patients with amputations the ability to wear a prosthesis for longer periods without skin breakdown, thus lowering pain and increasing quality of life.

Findings

HDIAC identified a limited number of FDA-approved scar tissue release technologies. Because of this, HDIAC expanded the inquiry to include systems and solutions that would enable extended use of prosthetics with limited pain. Relevant information, including primary point of contact, email, phone number, and a brief description of the solutions is provided below.

Dolphin Neurostim [1]

Performing Organization: Center For Pain and Stress Research Ltd.	Primary POC: Bruce Hocking
Email: bhocking@dolphinmps.com	Phone: 416-253-6060

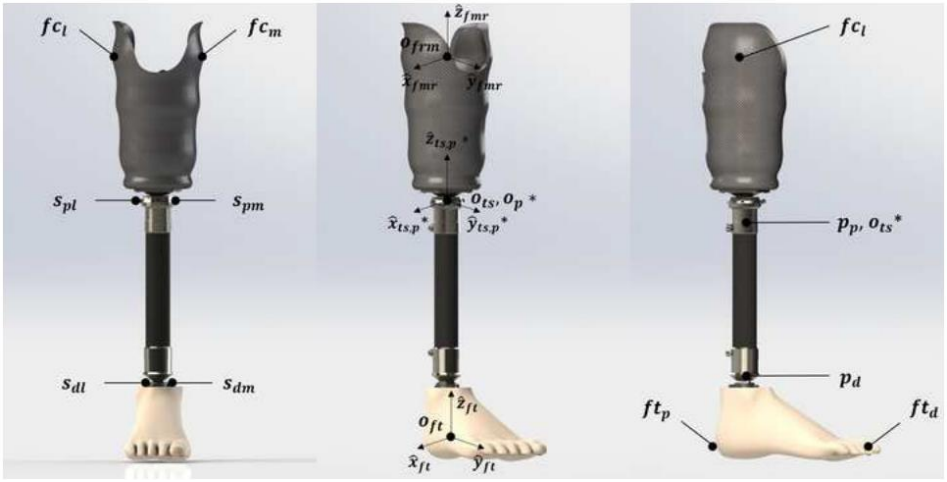
Description: The Dolphin Neurostim is an FDA-approved, hand-held, micro-current point stimulation (MPS) device used for pain relief and scar tissue release. Clinical trials have shown that a bilateral use of micro-current stimulation at a low amplitude and frequency, and a square waveform gives pronounced cellular tissue changes [1]. The goal of this new technique is to electrically repolarize positively poled scar tissue with negatively poled current to give cellular change to scar and adhesion tissue and reduce pain at the site of scar tissue [1].

The Dolphin Neurostim [1]

A Component-Based Coordinate System for Static and Dynamic Evaluation of Standard Transtibial Prosthesis Alignment [2]

Performing Organization: Auburn University	Primary POC: Michael Zabala
Email: zabalme@auburn.edu	Phone: 205-447-3130

Description: HDIAC subject matter expert (SME), Dr. Michael Zabala, created a lower limb prostheses, component-based, coordinate system for reducing pain while wearing prosthetics. According to Dr. Zabala, excess buildup of scar tissue and increased pain can be a result of poor prosthetic fit and alignment. With the pylon coordinate system, Dr. Zabala utilizes a mathematical equation to identify ideal placement of transtibial prosthesis across its three components: the tibial socket, the pylon, and the foot/foot shell. This system uses points on the prosthesis as well as anatomical benchmarks, when available [2]. Once reference frames have been created for each element, alignment is then calculated using transformation matrices that measure differences in position and orientation between components [2]. This method aims to reduce buildup of scar tissue and pain by creating an ideal fit of the prosthetic to the patient, thereby reducing the overall shifting of the limb against the skin.



The pylon coordinate system [2]

High-Fidelity Interface System [3, 4]

Performing Organization: Biodesigns, Inc.	Primary POC: Randall Alley
Email: ralley@biodesigns.com	Phone: 310-291-4543

Description: HDIAC SME Randall Alley, CEO and Chief Prosthetist at Biodesigns, Inc., developed the High-Fidelity Interface System, which enables the capture, control, and connection of the underlying bone for improved movement. With the use of osseostabilization, his approach enables a non-surgical method of stabilizing and controlling the intrinsic bone within the interface, removing the risk of surgery [3-4]. Creating a dense matrix of soft tissue around the bone maximizes stabilization and range of motion for the limb and minimizes bone shifting. This movement reduction of the bone, which would normally come in contact with skin in traditional prosthetic limb fixtures, reduces scarring and pain associated with bone-to-skin friction [3-4]. With the reduction in friction/bone movement, patients are able to use prosthetics for longer periods without further scar/hard tissue build-up.

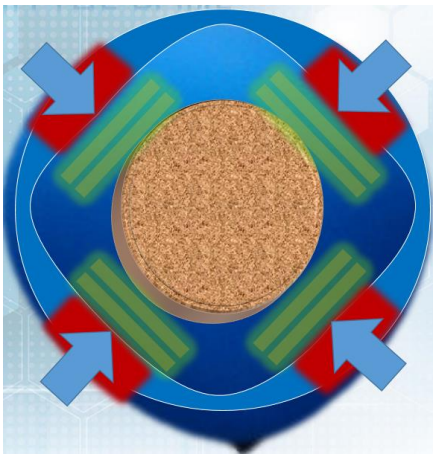
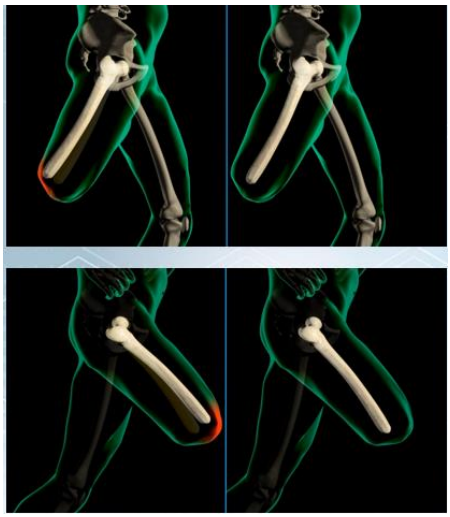


Illustration of the creation of a dense soft tissue matrix around the intrinsic bone [3]



Comparison of bone movement in traditional prosthetic (left) to High-Fidelity Interface System (right) [3]

Conclusion

HDIAC identified solutions that can address USSOCOM and VA needs for methodologies to release scar tissue and adhesions, enabling patients with amputations to wear a prosthesis for longer periods. A more comprehensive analysis of scar tissue release methodologies is available through an HDIAC Core Analysis Task (CAT). A CAT would feature in-depth SME elicitation and coordination with leading industry representatives, as well as prototype development of leading technology candidates to meet requirements in pain-reducing prosthetic alignment.

We request your feedback on this Inquiry: https://www.hdiac.org/new-inquiry-assessment-form/

References

1. Hocking, B. (2018). Method and system for rehabilitation of scar tissue *US9968773B1.* Retrieved from: https://patents.google.com/patent/US9968773B1/en
2. Zabala, M., Gupta, R., Dueitt, M., Pasquerello, N., Vazquez, M. (2018, May). *A component-based coordinate system for static and dynamic alignment evaluation of standard transtibial prosthesis alignment*. Unpublished manuscript.
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4. Alley, R. (2014). *US8656918B1.* Method, system, and tool for affixing compression stabilized prosthetic socket interface. Retrieved from: https://patents.google.com/patent/US8656918B1/en