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AWARD NUMBER: W81XWH-16-1-0791

TITLE: Integration of the Residual Limb with Prosthesis via Direct Skin-Bone-Peripheral Nerve Interface

PRINCIPAL INVESTIGATOR: Mark Pitkin

RECIPIENT: Poly-Orth International
Sharon MA 02067-1518

REPORT DATE: Oct 2020

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Unlimited Distribution

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REPORT DOCUMENTATION PAGE

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1. REPORT DATE Oct 2020			2. REPORT TYPE Annual		3. DATES COVERED 09/30/2019 - 09/29/2020	
4. TITLE AND SUBTITLE Integration of the Residual Limb with Protheses via Direct Skin-Bone-Peripheral Nerve Interface					5a. CONTRACT NUMBER	
					5b. GRANT NUMBER W81XWH-16-1-0791	
					5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Mark Pitkin email: mpitkin@tuftsmedicalcenter.org					5d. PROJECT NUMBER	
					5e. TASK NUMBER	
					5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Poly-Orth International Sharon MA 02067-1518					8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012					10. SPONSOR/MONITOR'S ACRONYM(S)	
					11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited						
13. SUPPLEMENTARY NOTES						
14. ABSTRACT The investigators wish the American Veterans and civilians with amputations can use powered protheses with direct skeletal attachment and direct bidirectional neural control. Since 2004, their work has been devoted improving a skin-device and bone-device interface. Current research is designed as a translational study to develop Skin and Bone Integrated Pylon with Peripheral Neural Interface (SBIP-PNI) directly attached to the residuum and the powered prosthetic hand with bidirectional control.						
15. SUBJECT TERMS- NONE LISTED						
16. SECURITY CLASSIFICATION OF:				17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U	19b. TELEPHONE NUMBER (include area code)			
				UU	24	

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1. **INTRODUCTION:** Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

The investigators wish the American Veterans and civilians with amputations can use powered prostheses with direct skeletal attachment and direct bidirectional neural control. Since 2004, their work has been devoted improving a skin-device and bone-device interface. Current research is designed as a translational study to develop Skin and Bone Integrated Pylon with Peripheral Neural Interface (SBIP-PNI) directly attached to the residuum and the powered prosthetic hand with bidirectional control.

2. **KEYWORDS:** Provide a brief list of keywords (limit to 20 words).

Direct skeletal attachment; powered prosthesis; neural interface; bidirectional control system.

3. **ACCOMPLISHMENTS:**
What were the major goals of the project?

List the major goals of the project as stated in the approved SOW.

Goals/Milestones

Year 1

Manufacture the integrated pylons with peripheral neural interface (SBIP-PNI) for animal studies and fabricate the powered prostheses with sensory feedback

Milestones #1: Meeting the Poly-Orth specification and passing the QC tests – planned in Q2; current completion 100%

Milestone #2: Ship the implants to the Pine Acre Rabbitry/Farm (PARF) and to Georgia Institute of Technology (GIT) – planned in Q2; current completion 100%.

Comment: the site #2 for animal studies with pigs has been changed from PARF to DaVinci Biomedical Research, Lancaster, MA, with corresponding approval.

Implant SBIP-PNI into cats - planned in Q4; current completion 75%

Supply cats with powered prostheses with sensory feedback and initiate gait study- planned in Q4: will be completed in Q1 of Year 3

Year 2

Conclude cat gait study with and without sensory feedback. Will be completed in Q1 of Year 3.

Implant SBIP-PNI into Yorkshire Swine and conduct gait study with and without sensory feedback: Gait study without sensory feedback completed.

Year 3

Perform mechanical testing of device skin and device-bone attachment Perform histological analysis of the samples

Conclude pig gait study with and without sensory feedback

Demonstrate infection free sustainable device-body interface with the SBIP-PNI

Demonstrate that adverse events rate (AER) in animal study is lower than the established threshold

Submit application for IDE to the FDA Comments/Challenges/Issues/Concerns

Year 4

A no-cost one-year extension has been approved to pursue the new approach being developed for amputation/implantation in the porcine sub-study at the DaVinci Biomedical, which has more translational value and for additional trials at GeorgiaTech with more functional powered prostheses.

Achieved infection-free dorsum implantation in pig study

Developed a strategy for addressing the issue of skin mobility in the stump of pig during first weeks after implantation with Botulinum injections.

Concluded cat gait study with and without sensory feedback with protection against infection

If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state “Nothing to Report.”

Nothing to Report

How were the results disseminated to communities of interest?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Abstracts and Publications

- Park H, Islam MS, Grover MA, Klishko AN, Prilutsky BI, DeWeerth SP. A prototype of a neural, powered transtibial prosthesis for the cat: Benchtop characterization. *Frontiers in Human Neuroscience*. *Frontiers in Neuroscience* **12**: 471, 2018.
- Jarrell J, Farrell BJ, Kistenberg RS, Dalton JF, Pitkin M, Prilutsky BI. Kinetics of individual limbs during level and slope walking with a *unilateral transtibial bone-anchored prosthesis in the cat*. *Journal of Biomechanics*, **76**: 74-83, 2018.
- Park H, Klishko AN, Oh K, Dalton JF, DeWeerth SP, Pitkin M, Prilutsky BI. *Cat locomotion with a powered prosthesis integrated with residual bone, skin, sensory nerves and muscles*. In: Minisymposium of Society for Neuroscience Annual Meeting, San Diego, CA, 2018.
- Pitkin, M., C. Cassidy, M. Shevtsov, J. Jarrell, H. Park, B. Farrell, J. Dalton, W. L. Childers, J. Temenoff, K. Oh, A. Klishko and B. Prilutsky (2019). Animal studies of the Skin and Bone Integrated Pylon with deep porosity for bone-anchored limb prosthetics with and without neural interface. Military Health System Research Symposium MHSRS-19-00758, Kissimee, FL (presented).
- M. Shevtsov, N. Yudincheva, M. Blinova, I. Voronkina, D. Suslov, O. Galibin, D. Gavrillov, M. Akkaoui, G. Raykhtsaum, A. Albul, E. Pitkin, M. Pitkin, Evaluation of the temporary effect of physical vapor deposition silver coating on resistance to infection in transdermal skin and bone integrated pylon with deep porosity, *J Biomed Mater Res B Appl Biomater* 107(1) (2019) 169-177 (attached to this report).
- Prilutsky, B., H. Park, K. Oh, J. P. Dalton IV, S. P. DeWeerth, M. Pitkin and A. Klishko (2019). Bidirectional Control of a Sensing Powered Transtibial Prosthesis during Walking in the Cat. Society for Neuroscience (presented at the October 17-23 Meeting).
- Childers LW, Jarrell JR, Klishko AN, Oh K, Grant CN, Jeffers MK, Herrin KR, Dalton JF IV, Pitkin M, Prilutsky BI. Ankle Power of Transtibial Bone-Anchored Prosthesis with Carbon Fiber and Fiberglass Passive Foot in Walking Cats. Congress of International Society of Biomechanics, Calgary, Canada, 2019.
- H. Park, E. Latash, Y. Morkov, A.N. Klishko, S.P. DeWeerth, A. Frigon, B. Prilutsky, Cutaneous Sensory Feedback from Paw Pads Affects Balance Control during Split-belt Treadmill Locomotion in the Cat, *Journal of Experimental Biology* 222(14, jeb198648) (2019).
- Klishko AN, Park H, Grenga G, Zhang C, Oh K, Herrin K, Dalton JF IV, Pitkin M, Prilutsky BI. Stimulation of residual sensory nerve modulates walking mechanics in the cat with bone-anchored transtibial prosthesis. *American Society of Biomechanics Annual Symposium*. Atlanta, August 07, 2020.
- Pitkin M, Jarrell JR, Park H, Farrell BJ, Dalton JF IV, Childers LW, Temenoff JS, Oh K, Klishko AN, Prilutsky BI. Animal Studies of The Skin and Bone Integrated Pylon With Deep Porosity For Bone-anchored Limb Prosthetics With And Without Neural Interface. *Military Medicine* (resubmitted after review).
- M. Shevtsov, D. Gavrillov, N. Yudincheva, E. Zemtsova, A. Arbenin, V. Smirnov, I. Voronkina, P. Adamova, M. Blinova, N. Mikhailova, O. Galibin, M. Pitkin, Protecting the skin-implant interface with transcutaneous silver-coated skin-and-bone-integrated-ylon (SBIP) in pig and rabbit dorsum models, *J Biomed Mater Res B Appl Biomater*. DOI: 10.1002/jbm.b.34725 (2020).

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of

these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Describe the Regulatory Protocol and Activity Status (if applicable).

Describe the Protocol and Activity Status for sections a-c, as applicable, using the format described for each section. If there is nothing significant to report during this reporting period, state “Nothing to Report.”

1. The Protocol MR150051.03 entitled, "Integration of the Residual Limb with Prostheses via Direct Skin-Bone-Peripheral Nerve Interface," IACUC protocol number GT27F, Protocol Principal Investigator Evan Goldberg, is approved by the USAMRMC Animal Care and Use Review Office (ACURO) as of 13-JUN-2019 for the use of cats and will remain so until its modification, expiration or cancellation. This protocol was approved by the T3 Labs IACUC on 25-MAR-2019.
2. The Protocol MR150051.02 entitled, "Integration of the Residual Limb with Prostheses via Direct Skin-Bone-Peripheral Nerve Interface," IACUC protocol number A16063, Protocol Principal Investigator Boris Prilutsky, is approved by the USAMRMC Animal Care and Use Review Office (ACURO) as of 29-AUG-2019 for the use of cats and will remain so until its modification, expiration or cancellation. This protocol was approved by the Georgia Institute of Technology IACUC on 28-MAY-2019.
3. ACURO has completed the review of DaVinci Biomedical Research Products, Inc. protocol # DB-633, entitled, " Effect of botulinum neurotoxin serotypes A or B injections into thigh musculature of a swine," supporting CDMRP proposal MR150051.05, award # W81XWH-16-1-0791, and this protocol is approved for the use of pigs as of 16 July 2020.

What do you plan to do during the next reporting period to accomplish the goals?

If this is the final report, state “Nothing to Report.”

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

In Year 5, we plan

- To complete the Botulinum study initiated on 09-23-20 to identify an interval of 4 weeks when the immobilization of the skin underlying muscles in the implantation zone reaches its maximal level. This level will be quantified with the Index of Asymmetry in loading in gait between the involved and uninvolved legs.
- To complete the study in pigs with the silver coated pylons (SBIP-S) to demonstrate safe and sustainable bone-device and skin-device interface using modified pylons with oval, not-centered cross-sections.

4. **IMPACT:** Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

What was the impact on the development of the principal discipline(s) of the project?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

1. Cat study

The mean bone and skin tissue ingrowth showed correlation with the duration of implant use. The animals that walked for over five months had bone and dermal tissues occupying $75.7\pm 7.8\%$ and $74.4\pm 8.7\%$ of implant porous space, respectively.

The animals with powered prostheses demonstrated the better performance – peaks of vertical ground reaction forces, ankle moment and power were closer to the intact values compared to passive prosthesis [1].

The duty factor of the prosthetic hindlimb was longer for Mode 2 than for Mode 1 or Mode 3 ($p=0.004-0.050$). The relative duration of the double hindlimb support phase when the contralateral hindlimb was the trailing limb was shorter in Modes 1 and 3 than in Mode 2 ($p=0.016-0.041$). We found no difference in peak of vertical ground reaction force of the prosthetic limb between the modes.

Deep ingrowth of skin to the porous structure of the implant was the best in the cat tested with the powered ankle prosthesis. It was achieved with better elimination of skin movements around the implant during first four weeks after implantation. Healing characteristics appeared overall optimal as indicated by extensive bone ingrowth and apposition into the porous titanium implant, within the shaft and up to the amputation line (Rousselle S: Integration of the Residual Limb with Prostheses via Direct Skin-Bone-Peripheral Nerve Interface. Histology Report AGG20-018, Alizée Pathology, LLC, Thurmont, MD; available upon request) At the amputation line, the implant-skin-bone-interface was characterized by an anisotropic ingrowth of the native dermis. Deep ingrowth into the porous titanium overlying the bone was confirmed in fibrous connective tissue with small caliber blood vessels, or granulation tissue, with complete apposition between the bone, dermis, and implant shaft. There were no evidence of pocket formation, inflammation, or infection. The epithelium completely bridged the lateral aspects of the fibrous stump to meet the porous titanium. Granulation tissue extending perpendicularly and without downgrowth from the dermis over the fibrous stump and overlying the bone.

It was concluded that initial immobilization of skin at the implantation site is a key for further deep ingrowth and integration with the implants either SBIP for passive, or SBIP-PNI for powered prostheses.

2. Pig study

Symmetry of loading the intact and passive prosthetic limbs during gait was $80\pm 5.5\%$. Skin-implant interface was infection-free, but developed as a stoma type, not with deep ingrowth as anticipated, due to the high mobility of the skin and soft tissues in the pig's thigh.

A mechanical testing was performed post-mortem with the Instron testframe. In pull-out tests, the implant broke at 5,450 N pull-out force, keeping its in-bone portion non-detached. In two animals, non-treatable infection occurred within first week after implantation.

In the pig with silver coated SBIP, compared to non-coated control, there was no evidence of adverse tissue responses (e.g., infection, hemorrhage, necrosis, exuberant fibrosis/scarification).

Histology evaluation showed creation of a viable skin seal within the porous structure of the SBIP (Stanley JRL: Non-GLP Evaluation of Subcutaneous Titanium-Based Devices in Pig and Rabbit model. Report FEE18-604, Alizée Pathology, LLC, Thurmont, MD; available upon request). This antimicrobial feature of the silver-coated implant will be used in the next animals in anticipation of its positive effect during initial post-implantation period [1].

3. Development of a modified protocol for osseointegration

The current studies with cats and pigs showed that even the casting of the leg residuum did not **limit** the skin movement around the implant. That movement did not disrupt the skin seal once it has been developed inside of the deeply porous cladding of the SBIP implant. However, at the initial period after implantation the skin movement compromised the skin ingrowth.

Since our overall intention is the establishment of the sustainable and safe skin seal providing natural barriers against infection, we began to test a modified protocol of the implantation. Photos **A-F** in **Figure 1** illustrate the first stage of the Botulinum study being approved by the ACURO on July 16, 2020. **A** – Xeomin®, an incobotulinum toxin A product, equivalent to Botox® and Dysport®. **B** – GE Ultrasound laptop machine for guidance to injections. **C, E** –

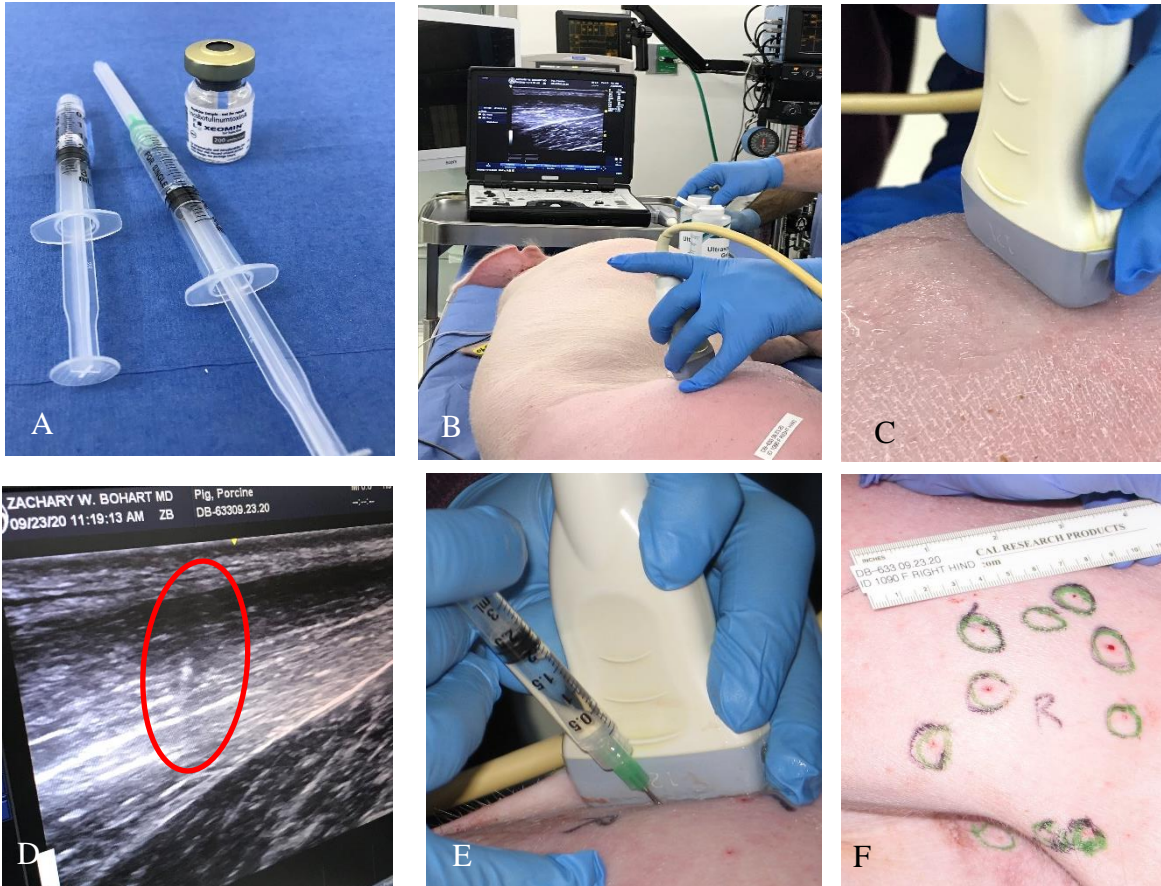


Figure 1. A study on immobilizing skin and muscles before the osseointegration procedure for better integration of tissues at the skin-implant (SBIP) interface. **A** – Xeomin®, an incobotulinum toxin A product equivalent to Botox® and Dysport®. **B** – GE Ultrasound laptop machine for guidance to injections. **C, E** – finding a spot for injection with visual confirmation (**D**). **F** – Schematics of the injection spots in the study, 9-23-20.

finding a spot for injection by moving the transducer with visual confirmation on the screen of the GE Ultrasound machine (D). F – Schematics of the injection spots in the study, 9-23-20.

Following the protocol, we conducted a baseline gait analysis with the Strideway System, Tekscan Technology, Inc. South Boston, MA (Figure 2).

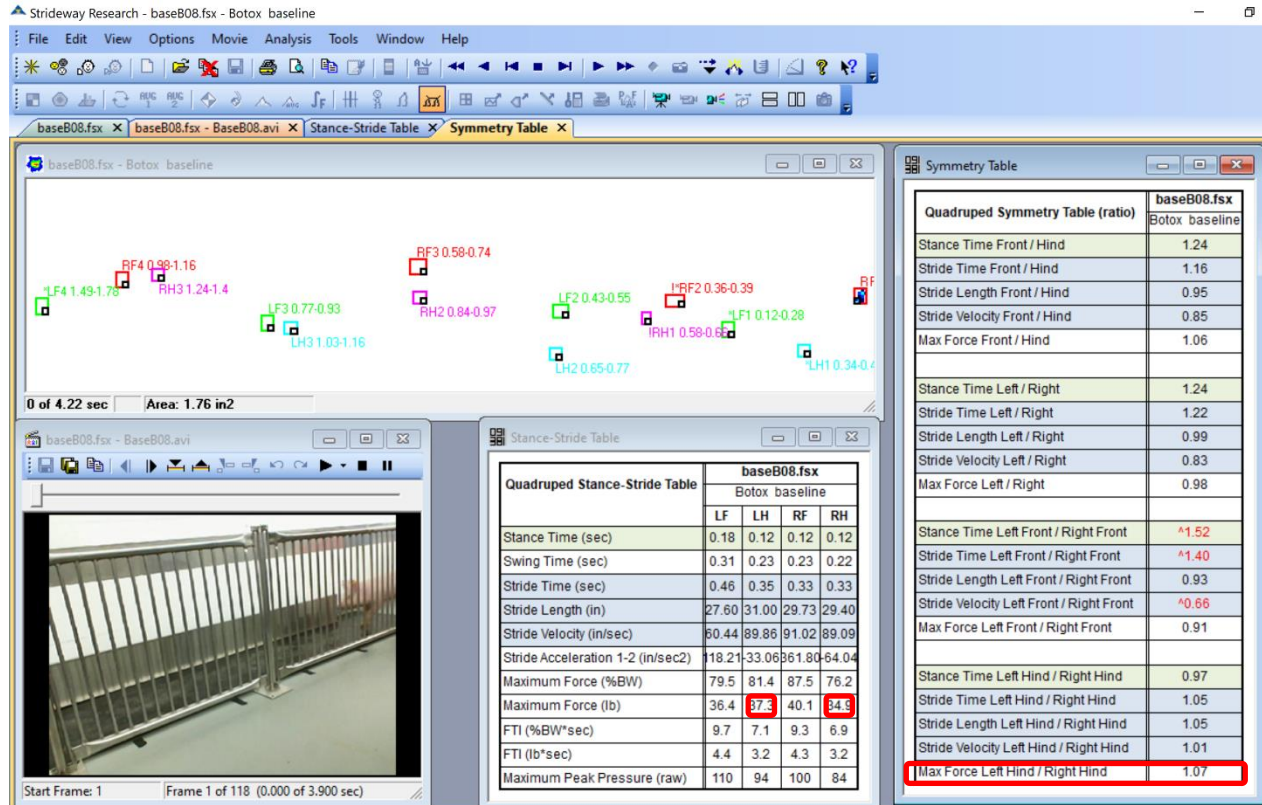


Figure 2. Baseline 09-21-20 recording of sound gait parameters in the pig #1090 before injections of Botox on 09-23-20. IACUC DB-633 approved by ACURO 07-16- 2020.

Sound gait parameters were recorded two days before Botulinum injections. Lower left photo shows the pig #1090 waling along the instrumented walkway. Normal ground reaction for all four legs were recorded and analyzed.

Symmetry of loading between left hind leg and the right hind leg with injected Botulinum

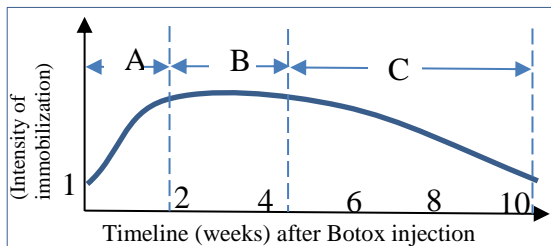


Figure 3. Anticipated intensity of the Botox in: A – pre-implantation; B - deep ingrowth of skin to the pores of the SBIP; C - recovery of gait.

will be used to select best timing for the implantation, when the injection effect reaches its maximum as presented in Figure 3. Intensity of immobilization will be quantified with the Index of Asymmetry (IA) calculated by the Strideway software. Ideal IA for sound gait, when the load on the right and left legs are equal, is 1.00.

Immobilization is developing to its maximum within 2-3 weeks after injections. Consequently, the loading of the injected leg is decreasing and it

will be seen in a growth of the IA. The purpose of this Botulinum study is to determine a period

of 3-4 weeks (interval **B** in **Fig. 3**) with the greatest values of the IA in anticipation that with implantation at the beginning of **B**, skin-implant interface will not be disrupted by the activities of the underlying muscles in the stump.

A red square at the lower right corner of the **Fig.2**, points to the Index of Aymmetry (1.07) obtained for the baseline sound gait in the pig #1090. It is a ratio of the maximal normal ground reactions on of the left and right hind legs shown in the red squares.

We plan to continue investigation of the effect of Botulinum injections to temporarily limit muscle contraction and the mobility of the skin with gait resumed after 2-3 months.

References

1. Pitkin M, Jarrell JR, Park H, Farrell BJ, Dalton JF IV, Childers LW, Temenoff JS, Oh K, Klishko AN, Prilutsky BI. Animal Studies of The Skin and Bone Integrated Pylon with Deep Porosity For Bone-anchored Limb Prosthetics With And Without Neural Interface. Military Medicine (2020) (resubmitted after review).

What was the impact on other disciplines?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Nothing to report for Year 4.

What was the impact on technology transfer?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- transfer of results to entities in government or industry;
- instances where the research has led to the initiation of a start-up company; or
- adoption of new practices.

Recommendations for implantation of the pylons with peripheral neural interface and on bidirectional control of powered prostheses are anticipated at the completion of the project. A modified protocol for implantation with Botulinum immobilization will be proposed for clinical trials.

What was the impact on society beyond science and technology?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- improving public knowledge, attitudes, skills, and abilities;
- changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or

- improving social, economic, civic, or environmental conditions.

The investigators wish the American Veterans and civilians with amputations can use powered prostheses with direct skeletal attachment and direct bidirectional neural control, which could improve the quality of life and social integration of the patients.

5. **CHANGES/PROBLEMS:** The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, “Nothing to Report,” if applicable:

Nothing to report

Changes in approach and reasons for change

Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

Nothing to report

Actual or anticipated problems or delays and actions or plans to resolve them

Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

Nothing to report

Changes that had a significant impact on expenditures

Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

Nothing to Report

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

N/A

Significant changes in use or care of vertebrate animals.

All modifications in studies have been approved by ACURO.

6. PRODUCTS: List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state “Nothing to Report.”

• Publications, conference papers, and presentations

Abstracts and Publications

- Park H, Islam MS, Grover MA, Klishko AN, Prilutsky BI, DeWeerth SP. A prototype of a neural, powered transtibial prosthesis for the cat: Benchtop characterization. *Frontiers in Human Neuroscience*. *Frontiers in Neuroscience* **12**: 471, 2018.
- Jarrell J, Farrell BJ, Kistenberg RS, Dalton JF, Pitkin M, Prilutsky BI. Kinetics of individual limbs during level and slope walking with a *unilateral transtibial bone-anchored prosthesis in the cat*. *Journal of Biomechanics*, **76**: 74-83, 2018.
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- M. Shevtsov, N. Yuditceva, M. Blinova, I. Voronkina, D. Suslov, O. Galibin, D. Gavrilov, M. Akkaoui, G. Raykhtsaum, A. Albul, E. Pitkin, M. Pitkin, Evaluation of the temporary effect of physical vapor deposition silver coating on resistance to infection in transdermal skin and bone integrated pylon with deep porosity, *J Biomed Mater Res B Appl Biomater* 107(1) (2019) 169-177 (attached to this report).
- Prilutsky, B., H. Park, K. Oh, J. P. Dalton IV, S. P. DeWeerth, M. Pitkin and A. Klishko (2019). Bidirectional Control of a Sensing Powered Transtibial Prosthesis during Walking in the Cat. Society for Neuroscience (presented at the October 17-23 Meeting).
- Childers LW, Jarrell JR, Klishko AN, Oh K, Grant CN, Jeffers MK, Herrin KR, Dalton JF IV, Pitkin M, Prilutsky BI. Ankle Power of Transtibial Bone-Anchored Prosthesis with Carbon Fiber and Fiberglass Passive Foot in Walking Cats. Congress of International Society of Biomechanics, Calgary, Canada, 2019.
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- Klishko AN, Park H, Grenga G, Zhang C, Oh K, Herrin K, Dalton JF IV, Pitkin M, Prilutsky BI. Stimulation of residual sensory nerve modulates walking mechanics in the cat with bone-anchored transtibial prosthesis. *American Society of Biomechanics Annual Symposium*. Atlanta, August 07, 2020.
- Pitkin M, Jarrell JR, Park H, Farrell BJ, Dalton JF IV, Childers LW, Temenoff JS, Oh K, Klishko AN, Prilutsky BI. Animal Studies of The Skin and Bone Integrated Pylon With Deep Porosity For Bone-anchored Limb Prosthetics With And Without Neural Interface. *Military Medicine* (resubmitted after review).
- M. Shevtsov, D. Gavrilov, N. Yuditceva, E. Zemtsova, A. Arbenin, V. Smirnov, I. Voronkina, P. Adamova, M. Blinova, N. Mikhailova, O. Galibin, M. Pitkin, Protecting the skin-implant interface with transcutaneous silver-coated skin-and-bone-integrated-ylon (SBIP) in pig and rabbit dorsum models, *J Biomed Mater Res B Appl Biomater*. DOI: 10.1002/jbm.b.34725 (2020).

Report only the major publication(s) resulting from the work under this award.

Journal publications. List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume; year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).

Books or other non-periodical, one-time publications. Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: Author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).

Nothing to report

Other publications, conference papers, and presentations. Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.

Nothing to report

- **Website(s) or other Internet site(s)**
List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to report

- **Technologies or techniques**
Identify technologies or techniques that resulted from the research activities. In addition to a description of the technologies or techniques, describe how they will be shared.

Nothing to report

- **Inventions, patent applications, and/or licenses**
Identify inventions, patent applications with date, and/or licenses that have resulted from the research. State whether an application is provisional or non-provisional and indicate the application number. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to report

- **Other Products**
Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment, and/or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:
 - data or databases;
 - biospecimen collections;
 - audio or video products;
 - software;
 - models;
 - educational aids or curricula;
 - instruments or equipment;
 - research material (e.g., Germplasm; cell lines, DNA probes, animal models);
 - clinical interventions;
 - new business creation; and
 - other.

Nothing to report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate “no change.”

Name: Mark Pitkin

Project Role: PI

Researcher Identifier (e.g. ORCID ID): L-7934-2017

Nearest person month worked: 5

Contribution to Project: Dr. Pitkin has directed all aspects of the project

Name: Grigory Raykhtsaum
Project Role: Director of Engineering
Nearest person month worked: 3
Contribution to Project: Mr. Raykhtsaum was responsible for development and manufacturing of the SBIP-PNI pylons for animal studies

Name: Charles Cassidy
Project Role: Investigator
Nearest person month worked: 0.1
Contribution to Project: Dr. Cassidy is a surgeon on the project performing two procedures in Year I.

Name: Boris Prilutsky
Project Role: Director of the Georgia Tech study
Nearest person month worked: 1
Contribution to Project: Dr. Prilutsky has directed development of the powered prosthesis for animal studies and the animal trials with SBIP-PNI in Year I.

Name: Hangu Park
Project Role: Investigator/Postgraduate student of Georgia Tech
Nearest person month worked: 10
Contribution to Project: Dr. Park developed the powered prosthesis for animal studies.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

What other organizations were involved as partners?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

1. DaVinci Biomedical Research, 20 Maple St, Lancaster, MA 01523
 - Financial support: MR150015 Integration of the Residual Limb with Prostheses via Direct Skin-Bone-Peripheral Nerve Interface
 - Facilities and personnel collaborating on animal studies with pigs.
2. Advanced Manufacturing Products (ADMA), Hudson, OH
 - Financial support: MR150015 Integration of the Residual Limb with Prostheses via Direct Skin-Bone-Peripheral Nerve Interface
 - Facilities and personnel for sintering titanium SBIP-PNI pylons with selected specifications for animal studies
3. Georgia Institute of Technology, Atlanta, GA
 - Financial support: MR150015 Integration of the Residual Limb with Prostheses via Direct Skin-Bone-Peripheral Nerve Interface
 - Conducting animals study with cats wearing powered prostheses following DSA
4. T3 Labs, Atlanta, GA 30313
 - Financial support: MR150015 Integration of the Residual Limb with Prostheses via Direct Skin-Bone-Peripheral Nerve Interface
 - Facilities and personnel collaborating on animal studies with cats.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: For collaborative awards, independent reports are required from BOTH the Initiating PI and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to <https://ers.amedd.army.mil> for each unique award.

Nothing to report

QUAD CHARTS: If applicable, the Quad Chart (available on <https://www.usamraa.army.mil>) should be updated and submitted with attachments.

9. **APPENDICES:** Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

None