REQUEST FOR PILOT GRANT PROPOSALS IN 16 POTENTIAL AREAS OF ORTHOTIC AND PROSTHETIC (O&P) RESEARCH

(This form should be used as the first page of your application.)

The Center has identified 16 areas for potential submission of proposals.

Areas for submission are:

a. Demonstration of multi-site coordination of P&O clinical outcomes data collection with emphasis on data consistency and quality
b. Quality of Life, Wellness, Patient Satisfaction and/or Outcomes Studies of Patients Who Have Received O&P Care vs. Those Who Have Not
c. L0631 bracing—Performance and Outcomes Data That Differentiate Patient Results from What Could be Achieved with an OTS Orthosis that is Provided without any Fitting, Trimming or Clinical Care?
d. TLSO/LSO: Utilization and comparative effectiveness of TLSO/LSO. Pre and postoperative use. AFO/KAFO: Utilization and comparative effectiveness of custom vs. OTS AFOs and KAFOs. Investigation and analyses of patients who receive custom orthosis subsequent to OTS AFO fitting.
e. Microprocessor Controlled Knee and Ankle Joints – Safety Benefits for Non-Variable Cadence (K-1, K-2) Ambulators
f. Does Restricted Access for K-1 and K-2 to Hydraulic Controls Adversely Impact Patient Safety?
g. Efficacy of custom vs. OTS relating to clinical outcome, analyses of providers credential Functional Impacts of Vacuum-Assisted Socket Suspension Systems
h. Outcomes Measures, Evaluation of Clinical Benefit, and Quality of Life Metrics Related to Orthotic Management (Note: Submissions Should be Pathology and/or Condition Appropriate, e.g. Stroke, Cerebral Palsy, Multiple Sclerosis, Polio, OA)
i. Orthotic management of Osteoarthritis
j. Alignment (tuning) of Ankle Foot Orthoses in the Cerebral Palsy population, measured outcome.
k. Stance Control Knee Ankle Foot Orthoses, Clinical Application and Measured Outcomes
l. Socket Interface: Methods for Measuring Quality of Socket Fit and Alignment
m. Sockets: Methods for Measuring Proper Socket Fit and Alignment
n. Open Topics – Beyond the Above Priorities, Top Quality Clinical O&P Research Topics Considered

AOPA reserves the right not to select for funding any of the proposals received. While funding is available, decisions will be made on the merits of the proposals.

TITLE OF PROJECT: Using 3D Technologies to Establish a Method of Creating a Better Fitting AK Socket Using Less Monetary and Time Energy

INVESTIGATORS:

Name(s): (list Principal investigator on line 1)
1. Diana Anthony
2. David Krupa
3. Patrick Mathay
4. Luis Aragon

FUNDS REQUESTED: $ 4200 - $6300

NAME OF RESPONSIBLE INVESTIGATOR: David Krupa

IRB STATUS:

Approved	Pending	Approval Not Required
		x

CONFLICT OF INTEREST:

None	Potential	Yes
x		

As the principal (or responsible investigator, if applicable), I agree that if this grant proposal is funded, I will acknowledge the AOPA's support in all publications that arise from the research. I also will submit to AOPA a final report within 12 months after the date of the award.

Signature of Principal Investigator: Diana Anthony

Signature of Responsible Investigator (required if Principal Investigator is a trainee):

Institution: Range of Motion Project, NFP

Address: 2425 S. Colorado Blvd

City: Denver State: Colorado Zip: 80222 Country: USA

Phone: +1-303-818-0217 Fax: n/a

E-mail: diana@rompglobal.org

A. Title Page

1. Principal Investigator: Diana Anthony

2. Co-Investigators: David Krupa (Responsible Investigator), Patrick Mathay, Luis Aragon

3. IRB Approval
   Status: Plans to apply for approval in July

4. Conflict of Interest:
   - There is no conflict of interest among the 4 investigators, as they are all employed by the Range of Motion Project, Not for Profit with a 501.c3 status in the United States.
   - There is only one for-profit company that is involved in the study, by allowing us to use their software. Because of their potential for having a conflict of interest, all patient information and results will be kept confidential within the Range of Motion Project until publication.

B. Abstract

With the advancement of 3D printers, scanners, and software, the field of prosthetics is posed for a technological revolution. Specifically, 3D printers allow for the rapid and economical production of multiple sockets, where previous methods relied on time-consuming plaster modifications and expensive sheets of plastic. Current applications of this technology are lacking and haven't been developed for this field. I hypothesize that a procedure that uses digital casting, modifications and 3D printing can be developed to guarantee a great AK socket fit for every patient that is cheaper and faster than using plaster to cast and modify test sockets. The efficacy of using socket rings to test brim fit on a residual limb hasn't yet been tried or tested. Using this method of socket production is estimated to increase comfort while maintaining functionality of the socket for less time and money. Both qualitative feedback in the form of surveys will be administrated as well as quantitative measures, including force withstood and circumference measurements. A statistical test will be run between patients' feedback on their conventional socket and their 3D printed socket to determine whether or not the hypothesis is realized.

C. Research Grant Proposal

Specific Aims:

- To use 3D scanning and printing to rapid prototype the best fitting AK socket for each patient.
- To prove the cost and time savings in producing a great-fitting socket using the 3D technologies procedure vs plaster casting procedure.
- To demonstrate a process in which this technology can be used to close the delivery gap in prosthetic care in the developing world.

Background/Significance:

Prior work has been done on generating a trans-tibial socket and a trans-radial socket using 3D printing and scanning technologies, but no study or clinic has ever used 3D printing as a part of their toolset to test socket fit before fabricating a final socket. Since the majority of the patients that we see in Central and South America are above knee (AK) patients, and this type of amputation most often requires multiple test sockets to get the fit just right, it will be one of the most valuable starting points for the proof of the efficacy of this 3D technology socket creation process. If 3D printing can aid prosthetists and technicians in delivering a better fitting socket with drastic cuts in cost and time energy, then more amputees will be able to be treated. Overall, the end goal of this research is to develop a process that makes getting a high quality prosthesis more accessible to the thousands of people around the world living in resource poor communities.

The field of 3D printing and scanning has been around for enough time that companies and developers have been adjusting settings and manipulating the technology to the point where it is more robust than ever before. We will use a structured light scanner in this study, which allows the clinician to directly scan the patient's limb, without even having to take a plaster mold. It projects hundreds of dots onto the surface and reads their placement respective to each other to determine the shape of the surface. We will use an Ultimaker 2 Extended 3D printer and PET plastic for all prints of this study. This thermoplastic is easily heat formable, which increases the chances of being successful with a test socket fitting more quickly than with plastic that is more difficult to heat form.

With a procedure in place like the one proposed in this study, current boundaries of O&P knowledge will be expanded upon because trained professionals will have more time and resources to dedicate to getting to know their patient, gait training their patient in more difficult terrain, acquiring higher impact level components, and so forth. Not only will patients in the developing world finally get access to adequate O&P care, but patients in the developed world can expect easier fittings and more time with their prosthetist to learn the things that really matter about wearing a prosthesis.

Research Plan:

Recruitment: Recruitment of 10-15 AK amputee patients will take place in Quito and surrounding cities in Ecuador. The primary point of testing will be PROTEUS, a privately owned prosthetics clinic in the city. The investigators will work with AK patients: Ecuadorian Military patients, patients from the national social security hospital, and others. Inclusion criteria is just to have an above knee amputation and have recovered with enough time from the surgery to be suitable for wearing a prosthesis, judged by a certified prosthetist. Ideally, all of the patients will already be prosthesis users, but new users will be welcomed upon finding too few repeat users who are candidates for the study.

Compensation/Provision of care: As compensation for being a part of the study, each patient will receive $40 USD (3 visits totaling 4 hours of time). The patients will be able to keep any and all sockets from the study for future provision of new sockets and a personal record of what fits best for future prosthetists, should a change in provider occur.

Control group: Each patient will test a control socket, made for them in the traditional procedure by a US board certified prosthetist. This entails a "wet" plaster or fiberglass casting, modifying the cast by hand, and oven-heating. With this group, the study subjects will all take part in experimental socket design and the control socket design.

Independent Variable: Socket modifications. For each patient, modifications for 3 brim rings of the socket will be done over a range of 2-15mm. The brim is the most difficult part of an AK socket to fit well, due to it's need of weight bearing around sensitive tissue and bone. For this reason, it was chosen as the independent parameter to be tested in this study.

Dependent Variable: Socket fit and comfort.

Methods: There are four (4) Phases to this study. Phases I, III, and IV involve both the patient and practitioner. Phase II involves only the practitioner and technician.

Phase I: Casting
Each patient will first be cast in the conventional method of fabricating a prosthesis. The practitioner will take measurements of the residual limb before wrapping it in plaster bandages or fiberglass. Once the cast hardens, it can be removed and the patient is ready for their digital casting. The practitioner will then use the Structure Sensor Scanner from Occipital to digitally cast the patient's limb. Estimated time for total visit of both casts: 1 hr.

Phase II: Fabrication
The certified practitioner will fill the physical cast with plaster to make the mold. Then he/she will modify the mold according to the measurements taken during the casting appointment and based on the patient's anatomy. Then, a sheet of vivac plastic will be heated up in an oven and pulled around the mold. After cooling, being cut from the mold, and ground smooth, the conventional test socket is finished. Estimated time for modifications and fabrication: 5 hrs.

The technician will take the digital cast of the patient's limb and modify it online using Standard Cyborg's Design Studio. The technician will modify 3 sections of the socket according to 3 different measurements, within a range of 2-15mm. Socket rings will be created for each modification for each section, for a total of 9 ring files. These files will then be 3D printed using PET plastic. Estimated time for fabrication: 1hr to modify and 24 hrs passive printing.

Phase III: Fitting
The patient will return to the clinic for the fitting of their sockets. He/she will be fit first with the conventional vivac test socket, and heat-formed modifications will be performed if necessary. All additional modifications will be recorded. Once the patient feels comfortable, the evaluation phase will begin for the conventional method.

Then, the patient will try on each section of the 3D printed brim of their socket and determine which modifications feel most comfortable. This completes the fitting phase. The technician will return to the digital file and assemble a full 3D printed socket according to the specifications laid out by the patient. Estimated time of fitting: 1-2 hrs.

Phase IV: Evaluation

The patient will return to the clinic for their third and final visit. During this visit, they will complete the evaluation phase of the 3D printed socket.

Evaluation methods for both types of final socket (conventional vivac and 3D printed) are as follows: Each patient will assess the comfort and functionality of their socket fits both quantitatively and qualitatively. Quantitative analysis will take place by using a portable hand scale to determine the amount of pounds of force that can be exerted on the limb while wearing the socket from 6 directions (up, down, left, right, forward, backward). Qualitative analysis will take place in two methods: surveys and skin irritation scaling (using a color scale to determine points of discomfort). The survey will use number scaling to determine various aspects of the fit of their socket: skin irritation, weight, pressure points, and overall extension of your own limb will be measured in this survey. After wearing the socket for 20 minutes and completing the quantitative evaluation, the practitioner will examine the residual limb for redness and compare it to an existing color scale to quantify internal pressure points.

<u>Results</u>: A T-test will be used to determine the statistical significance between the fits of the sockets fabricated in conventional vs new 3D technology driven methods. The test will be administered on all data from Phase IV. FEM analysis of the digital sockets will also be performed to demonstrate the yield strength of the material. T-tests will also be used between data sets of time and cost for each patient's case regarding time to modify, fabricate, and fit each type of socket, and regarding the cost in raw materials to fabricate conventional test sockets vs 3D printed test sockets.

References:

Due to the fact that this is relatively new technology, and that this application of the technology to the field of prosthetics to develop AK sockets is especially new, there are no scientific studies upon which this study can build. Apart from seeing major success ourselves when fitting transradial amputees with 3D printed test sockets, the only references to extrapolate from are news articles explaining what actually has been done. Some of these are shown here:

- RESEARCHERS CREATE PERFECT FITTING 3D PRINTED TRANSTIBIAL LEG SOCKET FOR PROSTHETIC LEGS, Feb 2015, Eddie Krassenstein: https://3dprint.com/41606/3d-printed-prosthetic-leg/

- MIT lab's FitSocket measures human limb tissue to 3D print better-fitting prosthetics, September 2015, Kira Charron : http://www.3ders.org/articles/20150909-mit-labs-fitsocket-measures-human-limb-tissue-to-3d-print-better-fitting-prosthetics.html

- A Step Forward in Below Knee Prosthesis Socket Design, April 2014, Victor Devadass, Julaiha Adnan, Nor Azura Mohamed, Mohd Fadly Razikin, Azeze Aziz, Mohd Nazrol Hisham from SIRIM BERHAD, Bukit Jalil, Malaysia: http://biomedical.materialise.com/cases/step-forward-below-knee-prosthesis-socket-design

- 3D Printing: Opportunity for Technicians? July 2014, Judith Philipps Otto: http://www.oandp.com/articles/2014-07_01.asp

- Standard Cyborg Design Studio: http://www.standardcyborg.com/designstudio/

Budget:

Line Item	Cost ($)
Value technician time for conventional socket/fitting	200
Value technician time for 3D technology driven socket/fitting	50
Raw materials conventional socket	100
Raw materials 3D tech socket	30
Patient compensation	40
Total Budget per patient	420
Total (10-15 patients):	4200-6300

D. Other Support:

Diana Anthony, Primary Investigator, Manager of Operations

- Funding agency: Range of Motion Project, NFP
- No active awards or pending funding

David Krupa, Responsible Investigator, Co-Founder, Volunteer CPO

- Funding agency: Range of Motion Project, NFP
- No active awards or pending funding

Patrick Mathay, Executive Director

- Funding agency: Range of Motion Project, NFP
- Active funding for Range of Motion Project
    - Project title: Emerging Technologies
    - Funding Agency: Trip Advisor Foundation
    - Aims: This fund is to invest in new technologies or machines that ROMP will experiment with in order to develop new process flows in the fabrication of prosthetics and/or orthotics for the developing world.
    - Relevance to this application: All of the printers, scanners, and software costs, or "start-up" costs to complete a project like this have already been allocated to ROMP for operational purposes, outside of this study. Therefore, this dictates the budget for this study in review since the only costs to cover are the operating costs of each phase for each patient, and no start-up costs for the lab to complete the study.

Luis Aragon, Director of ROMP Guatemala

- Funding agency: Range of Motion Project, NFP
- No active awards or pending funding

E. IRB Approval Letter
Status: not yet applied.

F. Conflict of Interest Statement
N/A

G. Biographical Sketch

OMB No. 0925-0001 and 0925-0002 (Rev. 10/15 Approved Through 10/31/2018)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Diana Anthony

eRA COMMONS USER NAME (credential, e.g., agency login): n/a

POSITION TITLE: Operations Manager, Range of Motion Project NFP

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Duke University, Durham NC	BSc Eng	05/2015	Biomedical Engineering

Personal Statement

Having studied biomedical engineering and very recently been involved with various studies across my discipline, I am familiar with the kind of integrity and methodology that is necessary to complete a valid research study for publication. Areas of my studies have involved genetic manipulation of cell lines, cancer drug development, literature reviews, and most recently, using statistics to draw physiological conclusions about a person's adaptation and reaction to different gas blends at hyperbaric conditions. I am familiar with statistics and am confident that I will be able to prove my assertions undoubtedly.

Regarding the currently proposed study, I am the most qualified candidate to complete this research. Using 3D technologies in the field of O&P is so new that there are not many who are integrating the two fields. Where the integration does occur in developed countries, this integration is often split by various technicians and clinicians, often separated from each other and their patients by large geographical barriers. However, having been uniquely positioned to use 3D technologies from start to finish in the entire process of delivering a prosthetic device, I am confident that I will provide the most valuable insight to anyone reading the study results. I can provide insight from a clinician's point of view, a technician's point of view, and a patient's point of view, as I interact with all of them on a daily basis. As the Operations Manager for the Range of Motion Project, I have played a crucial role in delivering O&P care to underserved populations in Latin America, and because of this, have gained crucial experience in using new technologies to bridge the delivery gap. I have experience casting, modifying and fabricating a traditional prosthesis, in addition to 3D scanning, modifying, and printing transradial sockets. I have printed the first 3D printed leg in South America, and successfully manage two 3D printing labs in Ecuador and Guatemala. For as long as I have worked with ROMP (1 year to date), I have developed, strategized, and executed various projects involving the integration of 3D scanning and printing into O&P care.

Positions and Honors

Operations Manager, Range of Motion Project, June 2014-Present

- *ICRC Enable Makeathon Finalist, 2015*

Contribution to Science

N/A

Research Support

1. *Feasibility of operating a 3D print center in Quito, Ecuador – The overall goal of this study was to determine whether or not a 3D print center could operate itself and be self-sustaining. My responsibilities were to develop a business model for the lab to generate profit and serve the community, and determine the feasibility of running the lab long term. I sold printing and scanning services, hosted public, educational, and business classes regarding 3D printing and 3D modelling, and operated the finances of the lab. While it was asserted that it is in fact not only feasible but possible, this team decided to move away from the business model to devote more time to new technological O&P projects.*

2. *Influence of heightened partial pressures of nitrogen on the effect of hypercapnia in divers – The overall goal of this study was to determine if the effect of "nitrogen narcosis" from elevated pressures of inhaled nitrogen lessened the effect of hypercapnia, physically and cognitively. As the primary investigator, my role was not only to aid physiological and cognitive data collection, but mostly analysis using statistical tests to prove the effect of the different gas blends. This was conducted under the Duke Center for Hyperbaric Medicine under Dr. John Freiberger.*

H. Supporting Letters

To whom it may concern,

Diana is the Operations Manager for the Range of Motion Project (ROMP), and has also been an assistant technician for O&P patients in the clinic at Proteus in Quito, Ecuador. She interns in the lab every week, learning how to evaluate patients, take casts, modify, and fabricate entire prosthesis. She has experience with both upper and lower limb prosthesis, and often has projects regarding new 3D printed parts or tools for us to experiment with in the lab. Her O&P experiences with ROMP in addition to her scientific and engineering background at university make her eligible to complete this study on behalf of ROMP.

I will be the primary physician to see patients here in Quito, and the other technicians who work in the lab will aid in these processes. Diana will be the primary engineer to modify the molds and run the statistics on our findings. Patrick will help with 3D printing logistics on the ground, and our Director of ROMP Guatemala, time allowing, will provide additional AK patients to test this hypothesis on, providing data from two different clinic locations.

I am happy to act as Responsible Investigator in this research, since I believe it will contribute to the way prosthetics are created in the future. With the projected time and cost savings, this technology will allow more prosthetists, like myself, time for meaningful interactions and evaluations with our patients, as well as increase my ability to see more patients. If Diana gets hung up with some aspect of the study, I will provide whatever logistical, clinical, or personal experience I have to move this study forward.

Thank you for your review,

David Krupa, CP

I. Appendices

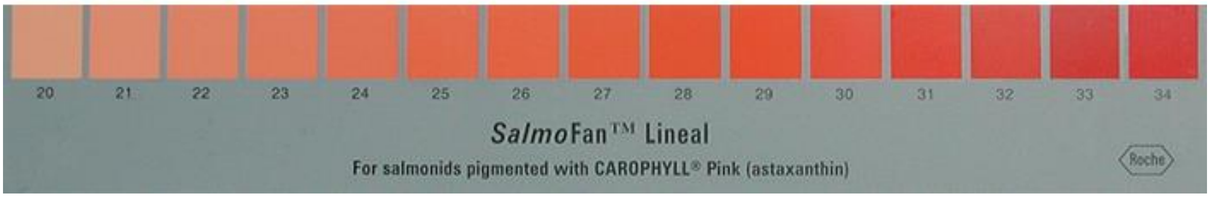
Appendix A - Qualitative Survey, to be taken with each socket

a. On a scale from 1-10 (hardest), how hard was it to put the socket on?
    i. What was the hardest part of putting the socket on?
b. On a scale from 1-10 (tightest), how much is this prosthesis squeezing your leg?
    i. Where does it feel tightest?
c. How would you rate your mobility level wearing this socket?
    i. 1 – no mobility, I can hardly move
    ii. 10 – full flexion and extension
    iii. When you flex/extend, do you feel any sinching or pulling on your skin?
d. How would you rate your control over this socket?
    i. 1 – no control, it's sliding off
    ii. 10 – perfect control, it feels like it's my own limb
e. On a scale from 1-10 (most comfortable), how would you rate your overall comfort level in this socket?

Appendix B: Redness Scale, to be assessed with each socket, after 20 minutes of wear

In order to get a more accurate scale of redness than just the raw colors, I decided to use this test, used for determining color of skin/muscle in the field of salmon, another living being with similar tissues.

The numbers will read from 1-15 per upscale of color.



Source: SalmoFan