--- Today's Date ---

06/29/2023

--- Name of 501(c)(3) Organization ---

University of Pennsylvania School of Veterinary Medicine

--- Federal Tax-Exempt ID# ---

23-1352685

--- Year Established ---

1740

--- Amount Requested ---

$34,232

--- Name of Executive Director ---

Elizabeth Peloso

--- Mailing Address ---

3541 Walnut St., Franklin Bldg. 5th Floor Philadelphia, PA
19104

--- Email address ---

pennaors@lists.upenn.edu

--- Work Phone # ---

+12158987293

--- Organization's website ---

https://researchservices.upenn.edu/

--- Link to Organization's most recent filed IRS Financial Statements (#990): ---

https://apps.irs.gov/pub/epostcard/cor/231352685_202106_990_2022071120200882.pdf

--- Upload Organization's most recent filed IRS Financial Statements (#990) ---

https://www.terfusa.org/wp-content/uploads/wpforms/809-8fba8c278fa5e5fb5fb2cbe55842a214/Trustees-2020-Form-990-FY21-PD-5fefa85eae35380379005f1c746e5638-2.pdf

--- Farm/Facility Name ---

New Bolton Center

--- Farm/Facility Physical Location (City, State, Zip) ---

Kennett Square, PA 19348

--- Farm/Facility Mailing Address ---

382 West Street Rd
Kennett Square, PA
19348

--- Contact Name and Title ---

Holly L. Stewart, Assistant Professor of Large Animal Surgery

--- Contact Work Phone ---

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--- 1. Brief mission statement and describe the distinguishing features of your organization that supports the mission of TERF and the relevance to this proposal. ---

The University of Pennsylvania's New Bolton Center is a longstanding partner of the Thoroughbred racehorse and is committed to improving the quality of available veterinary care. With the help of this grant, we intend to develop a 3D-printed fracture repair model that will provide future equine surgeons with the necessary surgical practice to improve the outcomes of horses undergoing fracture repair.

--- 2. Briefly outline 3-5 goals for the requested funds and how these goals support your mission. ---

1. Phase I: Develop a 3D-printed model of a common Thoroughbred racehorse fracture that can be easily reproduced and provided to surgical trainees at teaching institutions for hands-on practice. The model will mimic a sagittal plane lateral metacarpal condylar fracture commonly sustained by Thoroughbred racehorses. The development of the model will be guided by similar products available in human medicine that have been shown to significantly increase the learner's comfort and surgical technique in performing the procedure.

2. Phase II: Distribute the models to both experienced veterinary surgeons and surgical trainees to incorporate into the training curriculum for testing. The models will allow learners low risk and anatomically correct surgical practice that would be otherwise difficult to obtain and provide feedback as to the efficacy of the models as a teaching tool.

3. Publication: Publish a manuscript detailing the development and efficacy of the product in a clinical teaching setting. The objective evaluation of the product will aid in further advancement and potentially the application into other equine fracture models.

--- 3. Provide a detailed description of the proposed project, how it is related to the mission of TERF and how it will impact the health and welfare of the horse. (Note: research applications should be understandable to a non-scientific audience and include sufficient detail and rigor for the scientific reviewers.) ---

The funds provided by TERF will be used to develop a fracture repair model that can provide hands-on experience to surgical trainees to improve clinical expertise and patient outcomes. Due to the regional distribution of Thoroughbred racing, many surgical training facilities face difficulties in providing their trainees with adequate fracture repair experience. Trainees are restricted to few clinical opportunities to perform fracture repair techniques and often must share the experience amongst many clinicians. Additionally, real-time training in the operating room can be time-consuming and infrequently results in medical errors that may endanger the patient's condition. Equine cadavers are often used in place of live horses in training situations, but the cost of acquiring and storing the tissue can be prohibitive for repeated practice and cadavers often lack true pathology and its accompanying distortion of anatomy. The subsequent lack of technical training results in unfamiliarity with the surgical technique and fewer veterinarians adequately prepared to perform the necessary surgeries, especially in emergency situations. The availability of a 3D-printed fracture model could provide the individual minimal-risk practice required to improve surgical ability and subsequent patient outcomes, while reducing the need for live horses or harvested materials.

Phase I: Model Production
To develop the fracture models, computer-aided design (CAD) software will convert computed tomography (CT) data provided from clinical cases treated at New Bolton Center to stereolithography (STL) format to create a 3D blueprint of the bone.5 The sagittal plane, complete, non-displaced, lateral metacarpal condylar fracture was chosen because it is a commonly observed injury with relatively simple anatomy. The blueprint will then be used to produce 3D-printed models in various printing materials to assess their likeness to bone, especially with regard to haptic feedback during repair. Ideally, a fracture repair model would feel and react similarly to live bone during the surgical procedure, allow for application of routine imaging and surgical instrumentation (fluoroscopy, mechanical drilling, manual tapping etc.) while maintaining an affordable cost of production. The advancement of 3D-printing technologies has produced many printing methods such as fused deposition molding (FDM), stereolithography apparatus (SLA), selective laser sintering (SLS), and three-dimensional printing (3DP). A large variety of printing materials are available with various physical properties including acrylonitrile butadiene styrene (ABS), polylactic acid (PLA), gypsum powder, resin, etc. Comparative studies performed in human medicine have identified gypsum as the material most representative of normal bone, but it requires specialized printing procedures and associated increased costs.1, 3 PLA or ABS are more affordable options and have been reported to be an adequate media for human models, but their likeness to equine bone, which is harder and stiffer than human bone, is unknown.7 The current project will trial several available combinations to ascertain the best material for an equine fracture repair

model. Most printing methods and materials will be available at low or no cost from the University of Pennsylvania Bollinger Digital Fabrication Lab, but others, specifically printing with gypsum or other materials requiring sintering, will necessitate ordering from commercially available printing services (Shapeways).

Replication of the soft tissues associated with the fracture site, most notably skin and subcutaneous tissue around the bone, will be achieved with silicon molding. The silicon will react and can be incised like skin to mimic the procedure used for surgical planning and placement of cortical screws.1 Plastic 3D printed molds will be created for no cost by the Bollinger Digital Fabrication Lab and used to embed the "bones" in a rubberized silicone to allow for realistic practice. This procedure requires manual reconstitution of the silicone and curing in a vacuum chamber to reduce imperfections in the surface.

The process of selecting the most applicable materials for the fracture model will be standardized using previously reported evaluation techniques.6 Samples of several types of media will be printed and provided to three experienced surgeons and three surgical trainees to determine the materials that best simulate live surgical practice. Subjective rating scores on a scale of 1 (least like) to 5 (most like) will be used to evaluate the substance's overall likeness to equine bone, the haptic response of the drill, and the tactile distinction between cortical and medullary bone. Statistical analyses for Phase I will focus on a descriptive report of materials for each type of 3D model material, and provide the median score +/- interquartile range (IQR) for each evaluated criterion to choose the appropriate combination of materials, while also weighing affordability and accessibility. The estimated cost of printing the models in a commercially available gypsum material has been included in the budget, but if after evaluation, a different material is elected for printing that can be provided by the Bollinger Digital Fabrication Lab at no cost, the funds for the gypsum printing will be returned to the Foundation unused.

Phase II: Model Testing

Once the appropriate combination of materials has been determined, a total of 30 lateral condylar fracture models will be produced using the necessary printing and molding applications. Six large animal surgical residents of varying expertise will be allowed to perform a repair using routine instruments (4.5 cortical screws and instrument set, hand drill, fluoroscopy, etc.). The proposed sample size of 6 residents for comparison was calculated using GPower (Version 3.1.9.6). Specifically, an a priori power analysis was conducted using the expected mean +/- STD operative times for surgeons with access to 3D models for repair of long bone fractures compared to those without, as reported by Chen et al.2 This power analysis resulted in an effect size of 1.57 and a power of 0.8, using a 95% confidence interval. No instruction or guidance will be provided during the operation. The repairs will be timed and evaluated on parameters including accuracy of screw placement, number of fluoroscopic maneuvers, and self-scored surgeon comfort. The accuracy of screw placement will be specifically measured using post-operative computed tomography to measure the angle of placed screws in relation to the sagittal and dorsal cortical bone planes, as well as, the distance between them. The residents will then be allowed three opportunities to practice the same repair on a fracture model in the subsequent 6 months. The practice opportunities will include instruction from trained surgeons that mimics the guidance normally provided in residency training. This timeline was chosen to mimic the frequency of fractures seen in clinical practice. After that period, a fifth repair will be performed without instruction, and the same parameters will be measured as the initial test.

For Phase II, the Shapiro-Wilk test and quantile-quantile plots will first be used to determine the normality of this data distribution. A linear mixed model for repeated measures (or Friedman's test if the distribution is non-parametric) will be used for analysis. Potential interactions will be evaluated, including evaluation of year in residency and self-reported level of competence with the surgical procedure. Model factors will be further evaluated by Tukey-Kramer (or Wilcoxon) pairwise comparisons. A level of $P < 0.05$ will be used for significance. The statistical results will be used to evaluate the efficacy of the models in training, and ideally support their application. It is our intention to publish the material selection process, associated scoring guidelines and results, and efficacy of the product as a training model in a relevant scientific publication.

The desired outcome of this project is to provide an accessible, applicable training model for new equine surgeons to better prepare them to treat Thoroughbred racehorse fractures in the future. The final files and instructions for production will be made public for other training facilities to utilize. Increased technical experience and subsequent surgical abilities will likely decrease morbidity and mortality associated with Thoroughbred fractures and make fracture repair more routine and accessible. Long-term horse health will be positively affected if the barrier to fracture repair is smaller and the outcomes more favorable.

--- 4. Provide a timeline detailing the expected progress of the project and specific milestones. ---

Month 1: CAD software selection and training, selection and conversion of CT data to necessary STL formatting, and printing of initial models (likely using PLA) Month 2-3: Subsequent printing and testing of different materials to identify most appropriate model media, timing may be dependent on commercial product turnaround Month 4-5: Production of finalized fracture repair models, applying silicon molds Month 6-10: Implementation of experimental training laboratories and objective evaluation of model efficacy Month 10-12: Data analysis; preparation of abstract for national presentation and associated manuscript for publication in peer-reviewed journal

--- 5. Provide a detailed budget for the projected use of the funds. (Note: no funds will be provided for administrative overhead or capital spending; TERF reserves the right to modify funding based on Foundation requirements). Attach budget to submitted proposal as needed. ---

Phase I: Model Production
- Opensource software to convert CT to STL: A publicly available, open-source software will be used to edit and translate the computed tomography (CT) fracture data to a printable STL file; $0
- Bollinger Digital Fabrication Lab 3D printed material samples: Small samples of six material products (ABS, PLA, Rigid 10K Resin, Tough resin, Durable resin and “High Temp” resin) will be obtained for no cost from the University of Pennsylvania Bollinger Digital Fabrication Lab to evaluate their fit for the intended fracture model; 36 total samples, $0
- Shapeways 3D printed "Sandstone" samples: Small samples of “sandstone” gypsum material will be obtained to evaluate its fit for the intended fracture model; 6 total samples, $250/sample, subtotal: $1500
- Bollinger Digital Fabrication Lab 3D printed full-scale models: *Dependent on material type chosen.* If a material provided by the Bollinger Digital Fabrication Lab is deemed the most appropriate for the fracture repair model, the full-scale models will be subsequently printed in that chosen material; 30 total samples; $0/sample
- Shapeways 3D printed "Sandstone" full-scale models: *Dependent on material type chosen.* If the “Sandstone” material provided by Safeways is deemed the most appropriate for the fracture repair model, the full-scale models will be subsequently ordered and produced. If the Sandstone material is not chosen, this allotment will be returned to the granting foundation unused; 30 total samples, $900/sample, subtotal: $27,000
- Bollinger Digital Fabrication Lab 3D printed silicone mold: The mold for submerging the 3D bone models in a rubberized skin mimic will be produced by the Bollinger Digital Fabrication Lab at no cost; 2 total samples, $0/sample

- Ecoflex 00-20 platinum-catalyzed silicones 5 gallon container: Ecoflex 00-20 silicone is the skin-safe, rubberized plastic recommended for replication of skin. It will be injected into the 3D printed molds and cured to produce the desired effect; 6 total units, $216.52/unit, subtotal: $1299.12
- Ecoflex EaseRelease 200: EaseRelease is a lubricating spray necessary for removing the cured silicon skin models from the 3D printed molds; 2 total units, $18.52/unit, subtotal: $37.04
- Bacoeng 5 Gallon Vacuum Chamber Kit with Vacuum Pump: A vacuum chamber kit with pump will be used to perfect the curing of the silicon skin molds to prevent imperfections and ensure regular consistency within the silicon. Two chambers are requested to expedite production of the models; 2 total kits, $205/kit, subtotal: $410
- Rubbermaid BRUTE 14-gallon storage container: Plastic storage totes will be used to store the manufactured models in a dry, temperature safe area; 2 total containers, $29.49/container, subtotal: $59.98
- Misc. shipping costs: This amount is requested to cover any unintended costs that may arise due to shipping. Any unused funds will be returned to the granting foundation; subtotal: $500

Phase II: Model Testing
- Dewalt Atomic 20V Max cordless hammer drill: A cordless, hammer drill will be used in the product testing portion of the project. This drill exactly replicates that regularly used in surgery; 1 total drill, $96.83/drill, subtotal: $96.83
- Synthes 4.5 cortical screws (50 and 52 mm length): Routine repair of equine condylar fractures typically requires two 4.5 mm cortical screws, so the testing of the fracture repair models will require two screws each; 90 total screws, $32/screw, subtotal: $2880
- Disposable #10 scalpels: Scalpels required to make the incisions for screw placement in the model; 30 total units, $3/unit, subtotal: $90
- Flurofil 2-0 nylon suture: Routine nylon suture used to close the incisions following screw placement; 30 total units, $12/unit, subtotal: $360
- Fluoroscopy use fee: Used for imaging; $0
- Operating room use fee: Physical space used for surgery; $0
- 4.5 mm Screw Instrument Set Use Fee: Associated supplies for surgical procedure; $0

Total requested budget: $34,232

--- 6. Provide a list of all other sources of funding and the amount(s) received. ---

None

--- 7. Briefly summarize your charity's past public education and research efforts. ---

New Bolton Center is a premiere veterinary facility committed to performing relevant and applicable research that will result in improved care of the horse. The research interests of the specific authors of this proposal are varied and include such recent publications as “Identification of a previously unreported site of subchondral bone injury in the dorsodistolateral calcaneus in Thoroughbred racehorses” (2023) and “Computed tomographic assessment of fracture characteristics and subchondral bone injury in Thoroughbred racehorses with lateral condylar fractures and their relationship to outcome” (2022). New Bolton Center is practiced at producing thorough research projects and disseminating that knowledge to the public. The existing infrastructure will ensure this project is well supported and carried to completion.

--- 8. If you received funding from TERF previously, describe how these funds were used and outcomes achieved. Include any relevant publicity your charity received relating to the funding. (i.e.: media coverage, such as news articles, scientific publications, provide links to copies, as appropriate). ---

None

--- 9. List other organizations or major contributors that have provided funding to your organization in the last calendar/fiscal year. For research grant applications, provide a list of all current funding relating to your current proposal. ---

None

--- 10. Name a responsible person with whom TERF may communicate regarding specific questions and who will be responsible for follow-up information regarding the project. ---

Holly Stewart

--- 11. Provide appropriate references to support the proposed research. ---

1. Bento, Ricardo Ferreira, et al. "Otobone®: three-dimensional printed temporal bone biomodel for simulation of surgical procedures." International archives of otorhinolaryngology 23 (2019): 451-454.
2. Chen, C., et al. "The efficacy of using 3D printing models in the treatment of fractures: a randomised clinical trial." BMC Musculoskelet Disord 20, 65 (2019).
3. Hao, John, et al. "Material characterization and selection for 3D-printed spine models." 3D printing in medicine 4.1 (2018): 1-17.
4. Jacobo, Oscar Mario, et al. "Three-dimensional printing modeling: application in maxillofacial and hand fractures and resident training." European Journal of Plastic Surgery 41 (2018): 137-146.
5. Sander, Ian M., et al. "Three-dimensional printing of X-ray computed tomography datasets with multiple materials using open-source data processing." Anatomical sciences education 10.4 (2017): 383-391.
6. Shujaat, Sohaib, et al. "Visual and haptic perceptibility of 3D printed skeletal models in orthognathic surgery." Journal of dentistry 109 (2021): 103660.
7. Yuan, Zhi-Ming, et al. "A simple and convenient 3D printed temporal bone model for drilling simulating surgery." Acta Oto-Laryngologica 142.1 (2022): 19-22.

--- 12. How many Executive Staff and Board of Directors does your organization have? ---

1

--- Director Name (1) ---

https://secretary.upenn.edu/trustees-governance/trust

--- 1. Name - Job Title ---

Not applicable