

Alignment of the lower limb following extra-osseous talotarsal stabilization - clinical study.

University: Toledo	
PI and Co-PI name(s): Michael E Graham, DPM Vijay Goel, Phd	Proposed Budget: (includes 10% indirects): \$39,600
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<p>Need and Industrial Relevance: Chronic over-use musculoskeletal diseases of the lower extremity represent a significant expenditure of healthcare funds. The majority of “treatments” are aimed at ameliorating the symptoms, rather than the underlying etiology. Furthermore, lower extremity misalignment has a negative impact to pelvic and spine alignment. This study will investigate the role of hindfoot misalignment (talotarsal joint subluxation) on lower extremity alignment and evaluate the effect of a titanium stent that can internally realign and stabilize the TTJ while still allowing a normal range of motion.</p>	
<p>Project Aims (including Hypotheses): Talotarsal joint (TTJ) instability leads to chronic "wear-and-tear" and misalignment of proximal musculoskeletal structures. Extra-osseous talotarsal stabilization (EOTTS), the insertion of a titanium stent in to the sinus tarsi, has been proven to realign and stabilize the TTJ, yet there is little evidence published on the positive effects to proximal musculoskeletal structures. This research will show the negative effects, if any, to the lower extremity alignment from TTJ instability and if a positive correlation can be made by realigning the TTJ with an EOTTS stent.</p>	
<p>Methods: Thirty-six skeletally mature adults, over the age of 21 will be selected for this outcome based study. Candidates for this study must show clinical and radiologic signs consistent to diagnose a candidate with TTJ instability who also relates to lower extremity symptomatology. Only candidates who meet</p>	

established criteria for the EOTTS procedure will be included. Exclusions criteria are patients less than 21 years of age, severe or less-than-ideal candidates for the EOTTS procedure.

Candidates will answer a pre- and post-EOTTS intervention survey. An independent team will also analyze radiographic angles such as "Q" angle for the knee and pelvic tilt angle to show improved alignment following the EOTTS procedure.

Milestones:

- Obtain IRB Approval – Nov 30, 2017
- Gather comparison weightbearing radiographs, pre-operative questionnaires, and perform EOTTS procedure – March 31st, 2018.
- Collect 2nd post-op EOTTS data (weightbearing radiographs and post-operative questionnaires) – July 31, 2018
- Finish data analysis – August 31, 2018

Deliverables (must include):

Quarterly presentation updates:

- *December 2017 – conference call*
- *Spring 2018 – Spring Symposium @ UT (conference call option for non-UT teams)*
- *June 2018 – conference call*
- *September 2018 – Fall Symposium @ UCSF (conference call option for non-UCSF teams)*

Final written report including results – November 2, 2018

Specific work product (e.g. protocols, material, device, database)

General Budget Outline:

Personnel	\$	28,500
Imaging	\$	7,5000
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Total Direct	\$	36,000
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Indirects (10%)	\$	3,600
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Total	\$	39,600

Start Date: October 15, 2017

End Date: September 30, 2018

Please limit this document to 2-3 pages and email it to kimberley.mcintosh@utoledo.edu by September 8th.