



Treace Medical Announces Publication of Additional Positive Clinical Data Supporting Lapiplasty® 3D Bunion Correction™

March 28, 2019

195 patient study published in *The Journal of Foot & Ankle Surgery* demonstrates high bone fusion rates under a rapid weightbearing protocol in patients treated with biplanar plating fixation

PONTE VEDRA, Fla.--(BUSINESS WIRE)--Treace Medical Concepts, Inc., a medical device company focused on advancing the standard of care for hallux valgus (bunion) surgery, announces publication of additional positive clinical data supporting Lapiplasty® 3D Bunion Correction™ in *The Journal of Foot & Ankle Surgery*. The objective of the study was to evaluate bone healing with an accelerated weightbearing protocol in patients undergoing fusions of the tarsometatarsal joint ("3-plane Lapidus fusion") or fusions of the great toe ("MTP joint fusion") with biplanar plating fixation, the implant fixation construct used in the Lapiplasty® Procedure. Highlights of the study:

- 195 patients were included in the study with a mean follow up of 9.5 months (19.5% of the patients had comorbidities known to compromise bone healing including tobacco use and controlled diabetes).
- Patients were allowed to begin weightbearing on their operative foot at approximately 5 days following surgery.
- 97.4% of the patients demonstrated a successful bony fusion of the joint and 98.9% of the patients maintained a stable joint position over the course of the study.

Paul Dayton, DPM of the Midwest Bunion Center (Des Moines, IA) and lead author on the publication stated, "This study demonstrated positive bone healing rates over progressive timepoints when utilizing biplanar plating without a cross-joint compression screw in procedures used to treat bunions or arthritis of the big toe joint. The bone healing rates were quite encouraging given this unique fixation approach allowed patients to undergo an accelerated recovery protocol and to initiate weightbearing in a post-operative boot within their first week of surgery. Additionally, there were 29 smokers and 9 controlled diabetics in the cohort; comorbidities known to negatively impact bone healing. Further, implant removal rate was a very low 3.1% compared with conventional plate implants where published removal rates can be upwards of 17% for tarsometatarsal¹ and 20% for MTP joint fusion procedures². Overall, I'm very pleased with these results as they reinforce that I can offer this fixation option to my patients with a high level of confidence that they will experience reliable bone healing under an accelerated weightbearing protocol."

"The outcomes of this new study are noteworthy in that they closely mirror those reported in our 13-month multicenter dataset presented at the 2018 American Orthopaedic Foot & Ankle Society's (AOFAS) annual meeting in Boston," said Robert Santrock, MD of West Virginia University and co-author on this new publication. "In the AOFAS dataset, the 61 feet treated with Lapiplasty® 3D Bunion Correction™ showed low 1.6% symptomatic non-union rate and 3% radiographic recurrence rate³. Patients in the AOFAS study initiated weightbearing in a post-operative boot at an average of 10.5 days, which is consistent with this new study."

"The rapid time to weightbearing, high rate of bone healing, and low implant removal rate reported in this study further highlight the patient benefits of biplanar plating - the fixation method used in the Lapiplasty® Procedure," says John T. Treace, CEO of Treace Medical. "The study represents the 9th peer review publication supporting the Lapiplasty® Procedure, another important milestone for our company which was recently recognized as *the industry leader in advancing the science of bunion surgery*. With a pipeline of studies underway, we continue to build upon the robust clinical dossier supporting the Lapiplasty® Procedure so that patients, practitioners, and payors can make treatment decisions based on clinical evidence."

The patented Lapiplasty® 3D Bunion Correction™ Procedure represents a new paradigm in the assessment and surgical management of hallux valgus, a deformity of the foot which affects about 60 million Americans and results in approximately 400,000 surgeries in the United States annually.

About Treace Medical Concepts, Inc.

Based in Ponte Vedra, FL, Treace Medical Concepts, Inc. is a privately-held medical device company focused on advancing the standard of care for the surgical management of bunion deformities. The company's patented Lapiplasty® 3D Bunion Correction™ procedure is designed to reproducibly correct all 3 planes of the bunion deformity and address the root cause of the bunion, while allowing patients to get back to their active lives quickly.

To learn more about Lapiplasty® 3D Bunion Correction™, or find a Lapiplasty® surgeon in your area, please visit: www.alignmytoe.com or www.treace.com/patients.

1. Cottom JM, Vora AM. *J Foot Ankle Surg* 52:465-469, 2013.
2. Wanivenhaus F, et al. *J Foot Ankle Surg* 56:50-53, 2017.
3. Santrock R, et al. AOFAS Annual Meeting, Boston, MA, 2018.

Robert Jordheim
rjordheim@treace.net