



## Treace Announces Peer-Reviewed Publication of ALIGN3D™ Multicenter Prospective Clinical Data

May 5, 2022

PONTE VEDRA, Fla., May 05, 2022 (GLOBE NEWSWIRE) -- Treace Medical Concepts, Inc. ("Treace") (Nasdaq: TMCI), a medical technology company driving a fundamental shift in the surgical treatment of hallux valgus (commonly known as bunions) through its Lapiplasty® 3D Bunion Correction™ procedure, today announced the publication of a peer-reviewed manuscript that details an interim dataset of its ALIGN3D™ multicenter prospective clinical study in the *Journal of Foot & Ankle Surgery*.

Published interim results of "One- and Two-Year Analysis of a Five-Year Prospective Multicenter Study Assessing Radiographic and Patient-Reported Outcomes Following Triplanar First Tarsometatarsal Arthrodesis with Early Weightbearing for Symptomatic Hallux Valgus" include data on 117 patients with at least 12 month and 40 patients with at least 24 month follow-up (of 173 total study patients) following the Lapiplasty® Procedure, showed:

- Early return to weight bearing in a walking boot at an average 7.8 days;
- Significant improvement in radiographic measures of 3-dimensional bunion correction from pre-surgery to 6 weeks and maintained at 12 months (n=108) and 24 months (n=38) post-surgery, with 1 recurrence reported at 12 months post-surgery (0.9% recurrence rate); and
- Return to work within 4 weeks (25.2 days) and to full, unrestricted activity within 4 months post-surgery on average.

Additionally, the study reported statistically significant improvement in Patient-Reported Outcomes (PRO) across three validated scoring systems, including the Visual Analog Pain Score (VAS), the Manchester-Oxford Foot Questionnaire (MOxFAQ), and the Patient Reported Outcomes Measurement Information Systems (PROMIS-29). At 24 months post-surgery (n=40), patients reported greater than 80% reduction in pain versus pre-surgery levels per both VAS and MOxFAQ scoring systems, while 87% improvement was observed in walking/standing as well as social interaction using the MOxFAQ scoring system. Additionally, statistically significant improvement in physical, mental, and social health scores were reported using the PROMIS-29 scoring system.

John T. Treace, CEO, Founder and Board Member of Treace said, "We are pleased to announce our first ALIGN3D™ peer-reviewed publication in the *Journal of Foot & Ankle Surgery* reporting on the study's one- and two-year results. This type of multicenter, prospective study is unique in the field of bunion surgery, and this positive interim data documents successful patient outcomes utilizing our proprietary Lapiplasty® Procedure. Aligned with our corporate mission to improve surgical outcomes of bunion patients, we continue building upon our unique and differentiated body of clinical data and advancing the Lapiplasty® Procedure as the standard of care for bunion surgery."

The publication, which includes additional details such as patient demographics, inclusion/exclusion criteria, and complications reported in the study, can be accessed on the *Journal of Foot & Ankle Surgery* [website](#) and is also available on the Treace Medical [website](#).

### About the ALIGN3D™ Clinical Study

The ALIGN3D™ clinical study is a prospective, multicenter, post-market study designed to evaluate outcomes of Lapiplasty® 3D Bunion Correction™ in the surgical management of symptomatic hallux valgus. The study will evaluate for consistent and reliable correction of all three dimensions of the bunion deformity with the Lapiplasty® Procedure, as well as maintenance of such correction following accelerated return to weight-bearing, initially in a walking boot. The primary effectiveness endpoint is radiographic recurrence of the hallux valgus deformity at 24 months follow-up. Key secondary endpoints include change in three-dimensional radiographic alignment; clinical radiographic healing; time to start of weight-bearing in a boot and in shoes; pain; quality of life; and range of motion of the big toe joint. The study enrolled 173 patients, aged 14 to 58 years, at 7 clinical sites in the United States with 13 participating surgeons. Final patient follow-up for the primary endpoint is anticipated in the first half of 2023.

### About Treace Medical Concepts

Treace Medical Concepts, Inc. is a medical technology company with the goal of advancing the standard of care for the surgical management of bunion deformities and related midfoot correction. Bunions are complex 3-dimensional deformities that originate from an unstable joint in the middle of the foot. Treace has pioneered and patented the Lapiplasty® 3D Bunion Correction™ system – a combination of instruments, implants, and surgical methods designed to correct all 3 planes of the bunion deformity and secure the unstable joint, addressing the root cause of the bunion and helping patients get back to their active lifestyles. Treace recently expanded its offering with the Adductoplasty™ Midfoot Correction System, designed for reproducible correction of the midfoot to provide further support to hallux valgus patients. For more information, please visit [www.treace.com](http://www.treace.com).

### About the *Journal of Foot & Ankle Surgery*

The *Journal of Foot & Ankle Surgery* is the leading source for original, clinically-focused articles on the surgical and medical management of the foot and ankle.

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