



Treace Announces Peer-Reviewed Publication of Four-Year Results of the ALIGN3D™ Lapiplasty® Multicenter Prospective Clinical Study

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PONTE VEDRA, Fla., Aug. 05, 2025 (GLOBE NEWSWIRE) -- Treace Medical Concepts, Inc. ("Treace" or the "Company") (NasdaqGS: TMCI), a medical technology company driving a fundamental shift in the surgical treatment of bunions and related midfoot deformities, today announced the [peer-reviewed publication](#) of the four-year interim results from its ALIGN3D™ multicenter prospective study demonstrating positive clinical and radiographic outcomes of the Lapiplasty® Procedure in the *Journal of Foot & Ankle Surgery*.

The published results entitled, "Four-Year Outcomes Following Triplanar Tarsometatarsal Arthrodesis with Early Weightbearing for Hallux Valgus: A Multicenter Prospective Study" include interim data on 139 of 173 study patients treated with at least four years of follow-up from Lapiplasty® in the prospective, five-year, multicenter ALIGN3D™ clinical study. The data showed:

- Early return to protected weight bearing at an average of 7.7 days and return to athletic shoes at 6.5 weeks;
- Low radiographic recurrence rates of 0.8% using HVA>20° and 8.4% using HVA>15° at 48 months; and
- Continued significant improvement in pain and patient-reported outcome scores (VAS, MOxFAQ and PROMIS), including an 81% improvement in pain and 89% improvement in walking/standing on the MOxFAQ scoring system through 48 months.

John T. Treace, CEO, Founder and Chairman of Treace said, "We are pleased to announce this new peer-reviewed publication from our flagship ALIGN3D™ study demonstrating sustained, successful patient outcomes from our proprietary Lapiplasty® Procedure out to four years. This long-term, multicenter, prospective study sets a high standard for a commercial bunion technology and further differentiates Lapiplasty® in the marketplace with surgeons and patients. We look forward to expanding our market-leading body of clinical evidence as we continue to focus on advancing the standard of care for bunion surgery."

"These interim results from the ALIGN3D™ study showed consistent, positive radiographic and patient-reported outcomes maintained at four years," stated Daniel Hatch, DPM, of the Foot and Ankle Center of the Rockies in Greeley, Colorado and publication author.¹ "Importantly, by consistently performing a comprehensive 3D correction of the bunion deformity, the recurrence rates with the Lapiplasty® Procedure are very low and compare favorably to long-term studies of traditional osteotomy with high rates of recurrence."²

The full publication, which includes additional details such as patient demographics, inclusion/exclusion criteria, and complications reported in the studies, is available on the *Journal of Foot & Ankle Surgery* website [https://www.jfas.org/article/S1067-2516\(25\)00210-8/fulltext](https://www.jfas.org/article/S1067-2516(25)00210-8/fulltext).

About the ALIGN3D™ Clinical Study

The ALIGN3D™ clinical study is a prospective, multicenter, post-market clinical study designed to evaluate outcomes of the Lapiplasty® 3D Bunion Correction® procedure in the surgical management of symptomatic hallux valgus. The study evaluates consistency and reliability of 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. 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 was completed in the first half of 2023, and study completion with 5-year data is expected in 2026.

Internet Posting of Information

Treace routinely posts information that may be important to investors in the "Investor Relations" section of its website at www.treace.com. The Company encourages investors and potential investors to consult the Treace website regularly for important information about Treace.

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 and related midfoot deformities. Bunions are complex 3-dimensional deformities that originate from an unstable joint in the middle of the foot and affect approximately 65 million Americans, of which Treace estimates 1.1 million are annual surgical candidates. Treace has pioneered and patented the Lapiplasty® 3D Bunion Correction® System – a combination of instruments, implants, and surgical methods designed to surgically correct all three 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. To further support the needs of surgeons and bunion patients, Treace offers its Adductoplasty® Midfoot Correction System, designed for reproducible surgical correction of midfoot deformities, two systems for minimally invasive osteotomy procedures, namely the Nanoplasty® 3D Minimally Invasive Bunion Correction System and the Percuplasty™ Percutaneous 3D Bunion Correction System, as well as the SpeedMTP® MTP Fusion System. Treace continues to expand its footprint in the marketplace by extending its SpeedPlate® rapid compression implant platform to new applications, as well as providing surgeons with advanced digital solutions with its IntelliGuide® patient specific, pre-op planning and cut guide technology. For more information, please visit www.treace.com.

To learn more about Treace, connect with us on [LinkedIn](#), [X](#), [Facebook](#) and [Instagram](#).

¹ Daniel Hatch, DPM is a member of Treace's Surgeon Advisory Board and a paid consultant for Treace.

² Lalevee M, et al. Recurrence Rates With Longer-Term Follow-up After Hallux Valgus Surgical Treatment With Distal Metatarsal Osteotomies: A Systematic Review and Meta-analysis. *Foot & Ankle International*. 2023;44:210-222.

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