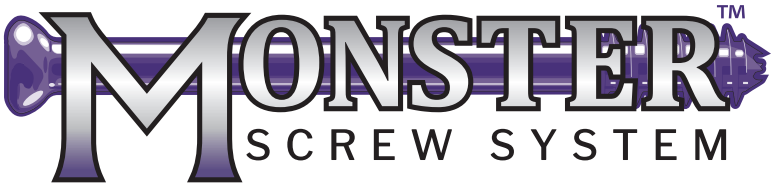

A POST-MARKET CLINICAL FOLLOW-UP STUDY OF THE MONSTER® SCREW SYSTEM

Paragon 28® Research & Development

Exclusively foot & ankle Paragon 28®

Abstract

An ambispective, single-site, multi-surgeon, consecutive-case clinical study was performed to assess the Paragon 28® Monster® Screw System. Retrospective data from 81 patients was analyzed, with 16 of these patients providing prospective patient reported outcomes measures (PROMs). Overall, 98.8% of patients implanted with a device from the Paragon 28® Monster® Screw System successfully met the primary endpoint of being free from device related serious events. The union rate for the Monster® Screw System was 95.1%.

Purpose

The Paragon 28® Monster® Screw System, initially released in U.S. Markets in 2013, includes an array of instrumentation and implants to accommodate a variety of procedures and was specifically designed for use in the foot and ankle.* The purpose of this study was to assess safety, performance, and clinical benefit of the Paragon 28® Monster® Screw System. While other studies have evaluated individual devices of the system, to the best of our knowledge, this is the first clinical study to evaluate the Monster® Screw System as a whole[1-3].

Figure 1: Monster Screw Systems

Monster® BITE Screw

Mini-Monster® Solid Screw

PRECISION® Jones Screw

Mini-Monster® Screw

Monster® Screw

Joust™ Beaming Screw

Methods

An ambispective, single-site, multi-surgeon, consecutive-case clinical study of patients implanted with at least one device from Monster® Screw System was performed to assess the system.

Monster® Screws under review in this study include: (Figure 1)

- Mini-Monster® Screw System
- Monster® Hindfoot Screw System
- PRECISION® Jones Fracture Screw System
- Joust™ Beaming Screw System
- Mini-Monster® Solid Screw System
- Monster® BITE Snap-Off Screw System

The study was conducted at the Henry Ford Health System (Jackson, Michigan), led by Dr. Tudor Tien, MD. Patients under the care of Dr. Tien or one of the other three study surgeons were eligible for the study. Inclusion criteria for this study were patients who had undergone a foot and/or ankle procedure involving bone reconstruction/osteotomy, arthrodesis/joint fusions, ligament fixation, or fracture repair/fracture fixation using the Monster® Screw System with a minimum of 3 months of clinical and radiographic follow-up. No exclusion criteria were present for the study. Subjects who met the aforementioned criteria were included in the study until enrollment was satisfied. After IRB approval, retrospective data from 81 consecutive patients' charts was analyzed, and 16 of these patients completed prospective PROMs, after providing informed consent.

Patients who were free from any device related serious events met the definition of success for the primary outcomes. Device related serious events include: the device causing or contributing to death, life threatening illness/injury, permanent impairment, or the patient requiring surgical intervention. Additional secondary endpoints assessing safety and performance were also recorded. The Activities of Daily Living (ADL) subscale and the Current Level of Activity from the Foot and Ankle Ability Measure (FAAM), along with the Visual Analog Scale (VAS), and a patient satisfaction survey were assessed prospectively at one varying timepoint for each patient participating in the prospective portion of the study.

A power analysis based on published success rates of similar devices was conducted to determine the minimum sample size required for the study[4-7]. Based on 80% power, the minimum sample size was determined to be 76 patients. A larger target minimum of 80 patients was set for this study.

Results

A total of 81 patients with average age of 54.2 years old and Body Mass Index (BMI) of 32.2 were retrospectively reviewed (Table 1). Average length of clinical follow-up was 5.4 months. Most patients, 59 out of 81 (72.0%), underwent concurrent procedures as well. The procedures performed in this study include, but are not limited to: 5th metatarsal fracture fixation, Lisfranc repair, metatarsal osteotomy, Weil osteotomy, subtalar arthrodesis, triple arthrodesis, and pilon fracture fixation. A total of 80 out of the 81 eligible patients (98.8%) successfully met the primary endpoint (Table 2). There were four instances of delayed or non-union (4.9%), one instance of loss of correction by final follow-up (1.2%), and one adverse event related to the device (1.2%). The related adverse event was loosening of a proximal screw and was resolved with surgical removal of the screw.

Table 1: Patient Demographic and Comorbidity Data

Variable	n (%) or Mean (SD)
Male	26 (32.1%)
Female	55 (67.9%)
Age at pre-op visit (years)	54.2 (14.6)
BMI	32.2 (7.1)
Average post-operative clinical follow-up (days)	163.5 (55.7)
Current/former smoker	49 (60.5%)
Diabetes	9 (11.1%)
Vascular disease	3 (3.7%)
Osteoporosis	6 (7.4%)
Osteoarthritis	23 (28.4%)
Neuropathy	6 (7.4%)

All PROMs were collected post-operatively at a single, varying time point (Table 3). The FAAM Activities of Daily Living subscale and Current Level of Function scores were reported as a percentage of total possible score and VAS pain was based on a 100-point scale.

Table 2: Post-Operative Outcomes Data

Outcomes	n (%)
Primary Endpoint: Free from device related serious events	80 (98.8%)
Union Rate	77 (95.1%)
Delayed or Non-union	4 (4.9%)
Loss of Correction	1 (1.2%)
Adverse Events related to Device	1 (1.2%)

Table 3: Patient Report Outcome Measures

Patient Reported Outcome Measure	n (%) or Mean (SD)
FAAM Activities of Daily Living	77.4 (17.1)
FAAM Current Level of Function	74.3 (26.3)
VAS Pain	24.1 (23.2)
Patient Satisfaction (Excellent, good, or fair)	15 (93.8%)

Conclusion

Overall, 80 out of 81 patients (98.8%) who were implanted with at least one device from the Paragon 28® Monster® Screw System successfully met the primary endpoint in this ambispective, single-site, multi-surgeon, consecutive-case clinical study. There were four instances of delayed or non-union at final follow-up (4.9%), one instance of loss of correction (1.2%), and one adverse event related to the device (1.2%).

Strengths of this study include a relatively large sample size attributed to broad inclusion criteria and lack of exclusion criteria, across a variety of primary procedures. This allowed for a patient population with many comorbidities, which can be more representative of a realistic patient population. Over half of the patient population in this study were current/former smokers (60.5%), the average BMI was 32.2, and the average age was 54.2. This study also captured patient reported

outcomes completed outside of the traditional standard of care timeframe, providing more information about the performance of the variety of implants.

Although, the inclusion and exclusion criteria allowed for a diverse patient population, the patients were from the same relative geographic region and may not best represent the general population. Additionally, PROMs were only collected at one prospective time point, thus a comparison to the pre-operative state was not possible.

In summary, the findings from this study help support the safety, performance, and clinical benefit of the Monster® Screw System.

Paragon 28® would like to thank Dr. Tudor Tien, MD and the Henry Ford Health System for their participation in the Monster® Screw System Post-Market Clinical Follow-Up Study. The Henry Ford Health System was compensated for participating in this research.

References

1. Heifner, J. J., Materón, S. R., Zhang, L., & Giovanni, T. (2022). Union Rates With the Use of Structural Allograft in Lapidus Arthrodesis: A Comparison Between Two Fixation Constructs. J Foot Ankle Surg., S1067-2516(22)00153-3. https://doi.org/10.1053/j.jfas.2022.05.004
2. Wagner, P., & Wagner, E. (2018). Proximal Rotational Metatarsal Osteotomy for Hallux Valgus (PROMO) Short-term Prospective Case Series With a Novel Technique and Topic Review. Foot & Ankle Orthopaedics, 3(3), 2473011418790071.
3. So, E., Mandas, V. H., & Hlad, L. (2018). Large Osseous Defect Reconstruction Using a Custom Three-Dimensional Printed Titanium Truss Implant. J Foot Ankle Surg. 57(1), 196–204. https://doi.org/10.1053/j.jfas.2017.07.019
4. Devos Bevernage, B., Deleu, P. A., & Leemrijse, T. (2010). The translating Weil osteotomy in the treatment of an overriding second toe: A report of 25 cases. Foot and Ankle Surgery, 16(4), 153–158. https://doi.org/10.1016/j.fas.2009.08.003
5. Gougoulias, N. E., Agathangelidis, F. G., & Parsons, S. W. (2007). Arthroscopic ankle arthrodesis. Foot and Ankle International, 28(6), 695–706. https://doi.org/10.3113/FAI.2007.0695
6. Walter, R. P., Walker, R. W., Butler, M., & Parsons, S. (2018). Arthroscopic subtalar arthrodesis through the sinus tarsi portal approach: A series of 77 cases. Foot and Ankle Surgery, 24(5), 417–422. https://doi.org/10.1016/j.fas.2017.04.006
7. Wang CS, Tzeng YH, Lin CC, Chang MC, Chiang CC. Comparison of screw fixation versus non-fixation in dorsal opening wedge medial cuneiform osteotomy of adult acquired flatfoot. Foot Ankle Surg. 2020 Feb;26(2):193-197. doi: 10.1016/j.fas.2019.01.011. Epub 2019 Feb 11. PMID: 30796000.

* https://paragon28.com/ifus/P20-IFU-0001

P20-WP-0001 Rev A [2022-12-14]

Paragon 28, Inc.
14445 Grasslands Dr.
Englewood, CO 80112 USA
(855) 786-2828

Exclusively foot & ankle

www.Paragon28.com