GRAPPLER®

INTERFERENCE SCREW SYSTEM

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

Paragon 28® Research & Development

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Abstract

An ambispective, single-site, multi-surgeon, consecutive-case clinical study was performed to assess the Paragon 28® Grappler® Interference Screw System. Retrospective data from 69 patients was collected, 68 of which were used in the primary endpoint analysis. Additionally, 37 of these patients provided prospective patient reported outcomes measurements (PROMs). Overall, 98.5% of patients implanted with a Paragon 28® Grappler® Interference Screw successfully met the primary outcome with only one instance of implant failure (1.5%).

Purpose

Interference screws have been widely used the past several decades throughout the body for the reattachment of ligaments and tendons to bone[1]. The Paragon 28® Grappler® Interference Screw System, initially released in 2019 in U.S. Markets, was designed for soft tissue reattachment specifically in the foot and ankle.* The purpose of this study was to assess safety, performance, and clinical benefit of the Paragon 28® Grappler® Interference Screw System. To the best of our knowledge, this is the first clinical study to evaluate the Grappler® Interference Screw System.

Methods

An ambispective, single-site, multi-surgeon, consecutive-case clinical study of patients implanted with the Grappler® Interference Screw System was performed to assess the device. The study was conducted at the Orthopedic Foot and Ankle Center (Worthington, Ohio). Patients under the care of Drs. Mark Prissel, DPM and Patrick Bull, DO were included in the study. Patients who had undergone a foot and/or ankle procedure involving soft tissue attachment to bone using the Grappler® Interference Screw System and had a minimum of 6 months of clinical and radiographic follow-up were eligible for this study. Patients that did not meet these criteria were excluded from the study. After IRB approval, 69 consecutive patients' charts were retrospectively reviewed, and 37 of these patients provided prospective PROMs, after providing informed consent.

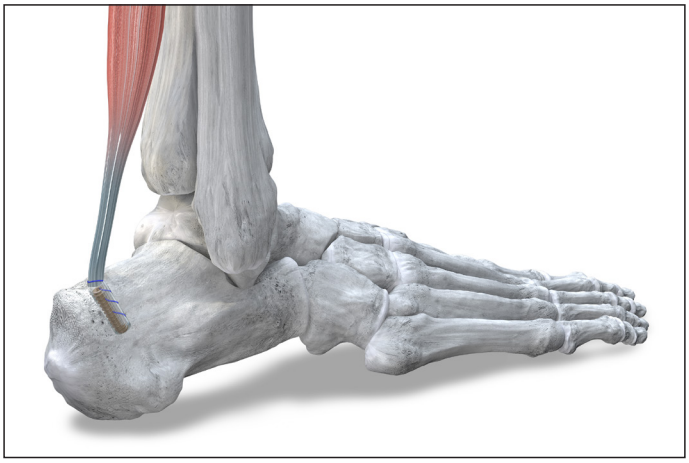

Figure 1 Paragon28's Grappler Interference Screw used for Flexor Hallucis Longus Tendon Transfer

Patients who were free from any device related complication which required surgical intervention and free from any instances of re-tear/re-rupture of the reattached tissue met the definition of success for the primary outcome. Noted radiographic abnormalities and adverse events 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[2-9]. Based on 90% power, the minimum sample size was determined to be 38 patients.

Results

In total, 69 patients with average age of 52.4 years old and Body Mass Index (BMI) of 35.4 were retrospectively reviewed (Table 1). Average length of clinical follow-up was 6.5 months, with the PROMs collected, on average, at 16.1 months post-operatively. A majority of patients, 67 out of 69 (97.1%), underwent concomitant procedures. Diagnoses included: lateral ankle instability, Achilles tendinopathy, and pes planovalgus, among others. Common treatments included: FDL transfer, lateral ankle stabilization, and deltoid reconstruction. One patient was

removed from the primary analysis set due to inadequate follow-up time. A total of 67 of the 68 eligible patients (98.5%) successfully met the primary endpoint with one patient undergoing screw removal due to implant failure at 6-months post-operative (Table 2). Two intraoperative complications were noted: one related to instrumentation failure and the other related to device fracture. Both complications were addressed intra-operatively and went on to successful screw implantation without sequelae. There were no instances of radiographic abnormalities.

Table 1: Patient Demographic and Comorbidity Data.

Variable	n (%) or Mean (SD)
Male	21 (30.4%)
Female	48 (69.6%)
Age at pre-op visit (years)	52.4 (14.8)
BMI	35.4 (8.7)
Average post-operative clinical follow-up (days)	197.6 (74.2)
Current/former smoker	14 (20.3%)
Diabetes	16 (23.2%)
Vascular disease	7 (10.1%)
Osteoporosis	2 (2.9%)
Osteoarthritis	20 (29.0%)
Collagen vascular disease	2 (2.9%)
Inflammatory arthropathy	2 (2.9%)
Neuropathy	3 (4.3%)
Iron deficiency anemia	1 (1.4%)
Average post-operative prospective PROM follow-up (days)	489.5 (178.9)

Table 2: Post-Operative outcome data for primary endpoint analysis.

Primary Endpoint Components (n = 68)	n (%)	95% Confidence Interval
No device related complications which required surgical intervention	68 (100%)	(94.72%, 100%)
No re-tear/re-rupture of fixated soft tissue	68 (100%)	(94.72%, 100%)
No revision and/or screw removal	67 (98.50%)	(92.08%, 99.96%)
No implant failure	67 (98.50%)	(92.08%, 99.96%)
Primary Endpoint: Free from any device related complication which required surgical intervention and free from re-tear/re-rupture	67 (98.50%)	(92.08%, 99.96%)

All PROMs were collected post-operatively at a single time point. The FAAM Activities of Daily living subscale and Current Level of Function scores were reported as a percentage of total possible score. The average scores for the ADL subscale and Current Level of Function were 76.6 (SD=19.3) and 78.6 (SD=21.2), respectively. The mean score for VAS pain was 20.2 (SD=22.0) based on a 100-point scale. 26 out 37 (70.3%) patients reported "excellent" or "good" satisfaction. At final follow-up, 1 (1.4%) patient reported abnormal sensations, 2 (2.9%) reported pain, and 1 (1.4%) reported swelling.

Conclusion

Overall, 67 out of 68 patients (98.5%) who were implanted with the Paragon 28® Grappler® Interference Screw successfully met the primary endpoint in this ambispective, single-site, multi-surgeon, consecutive-case clinical study. There was one instance of device failure and there were two intraoperative complications that were resolved intra-operatively. No post-operative radiographic abnormalities were found. There were few post-operative complications at final follow-up, occurring in approximately 6% of the study population.

This study is not without its limitations. There are inherent shortcomings associated with retrospective

data collection. Additionally, while this was a multi-surgeon study, both surgeons treat patients from the same geographic region, thus the population in this study may not adequately reflect the overall population on the whole. PROMs were only collected at one prospective time point, thus a comparison to the pre-operative state was not possible.

Strengths of this study include a relatively large sample size, patient reported outcomes captured outside of the traditional standard of care timeframe, and broad inclusion/exclusion criteria which led to inclusion of smokers, diabetics, and obese patients who underwent a variety of different procedures.

The findings from this study help support the safety, performance, and clinical benefit of the Grappler® Interference Screw System.

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*https://paragon28.com/ifus/P41-IFU-0001

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