A POST-MARKET CLINICAL FOLLOW-UP STUDY OF THE GORILLA® PLATING SYSTEM

Paragon 28® Research & Development

Exclusively foot & ankle
Paragon 28®

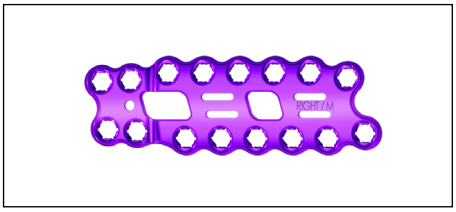
Abstract

An ambispective, single-site, multi-surgeon, consecutive-case clinical study was performed to assess the Paragon 28® Gorilla® Plating System. Retrospective data from 62 patients was collected and 60 of these patients provided retrospective and prospective patient reported outcomes measures (PROMs). Overall, 57/62 (91.9%) patients implanted with a device from the Paragon 28® Gorilla® Plating System successfully met the primary endpoint of successful union at final follow-up, a minimum of three months after their procedure.

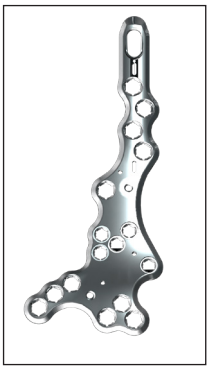
Purpose

The Paragon 28® Gorilla® Plating System, initially released in U.S. markets in 2014, includes an array of instrumentation and implants to accommodate a variety of procedures with designs specific for use in the foot and ankle.* Additional plating systems, Baby Gorilla® and Silverback™, were later released in U.S. markets in 2017 and 2019 (Figure 1). The purpose of this study was to assess safety, performance, and clinical benefit of the Paragon 28® Gorilla® Plating 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 Gorilla® Plating System as a whole[1-6].

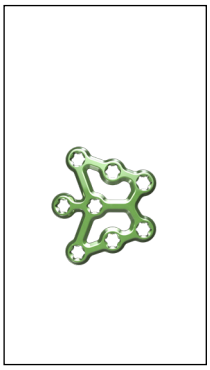
Figure 1: Examples from Gorilla Plating System



Gorilla® Medial Column Straddle Plate



Silverback™
Lateral TTC Plate



Baby Gorilla®
Cuboid Plate

Methods

An ambispective, single-site, multi-surgeon, consecutive-case clinical study of patients implanted with at least one device from the Gorilla® Plating System was performed to assess safety, performance, and clinical benefit.

The systems under review include:

- Gorilla® Plating System
- Baby Gorilla® Plating System
- Silverback™ Ankle Fusion Plating System

The study, led by Dr. Clifford Jeng, MD, was conducted at the Mercy Institute for Foot & Ankle Reconstruction (Baltimore, Maryland). Patients under the care of Dr. Jeng or one of the other four sub-investigators were included. The inclusion criteria for this study were patients who had undergone a foot and/or ankle procedure involving bone reconstruction/osteotomy, arthrodesis/joint fusions, and/or fracture repair/fracture fixation using the Gorilla® Plating System with a minimum of 3 months of clinical and radiographic follow-up. There were no exclusion criteria, so any patient that met the aforementioned criteria were included until the enrollment criteria were satisfied. After IRB approval, retrospective data of 62 consecutive patients' charts was analyzed. Sixty of these patients completed a variety of PROMs, either retrospectively and/or prospectively at various time points. Informed consent was obtained for all subjects who participated in prospective PROM portion of the study.

Rate of union reported at final follow-up, defined as >50% osseous bridging at the location of fixation, was the primary outcome of the study. Additional secondary endpoints focused on clinical benefit, such as rate of secondary procedures or adverse events related to the device were also recorded. The revised Foot Function Index Short Form (rFFI), a 10-point pain scale, the PROMIS Physical Function 12a Short Form, and PROMIS Pain Interference 8a Short Form were assessed preoperatively and at multiple varying timepoints postoperatively for each patient participating in the prospective portion of the study. Each patient enrolled in the prospective section also completed a prospective patient satisfaction survey postoperatively.

A power analysis based on published success rates of similar devices was conducted to determine the minimum sample size required for the study[7-12]. Based on 80% power, the minimum sample size was determined to be 60 patients.

Results

A total of 62 patients with an average age of 55 years old and Body Mass Index (BMI) of 30.8 were retrospectively reviewed (Table 1). Primary procedures performed across all systems, included but is not limited to: metatarsal fracture fixation, lateral column lengthening, lisfranc fracture fixation, talonavicular arthrodesis, fibular fracture fixation, malleolar fracture fixation, and ankle arthrodesis. Average length of clinical follow-up was 6.5 months, with the PROMs collected at multiple varying time-points post-operatively. Thirty patients (48.4%) had structural allograft used and 43 (69.4%) underwent concurrent procedures. At the final follow-up, 57 of the 62 eligible patients (91.9%) successfully met the primary endpoint of successful fusion (Table 2). There were five instances of delayed or non-union (8.1%), four adverse events related to the device (6.5%), and three instances of loss of correction at final follow-up (4.8%). Adverse events related to the device included non-union, delayed wound healing, or bone erosion. These adverse events were resolved surgically or treated conservatively and there were no intraoperative complications.

Table 1: Patient Demographic and Comorbidity Data

Variable	n (%) or Mean (SD)
Male	26 (41.9%)
Female	36 (58.1%)
Age at pre-op visit (years)	55 (15.6)
BMI	30.8 (7.8)
Average post-operative clinical follow-up (days)	196 (54.5)
Current/former smoker	23 (37.1%)
Diabetes	10 (16.1%)
Vascular disease	2 (3.2%)
Osteoporosis	5 (8.1%)
Osteoarthritis	2 (3.2%)
Neuropathy	7 (11.3%)
Inflammatory Arthropathy	5 (8.1%)

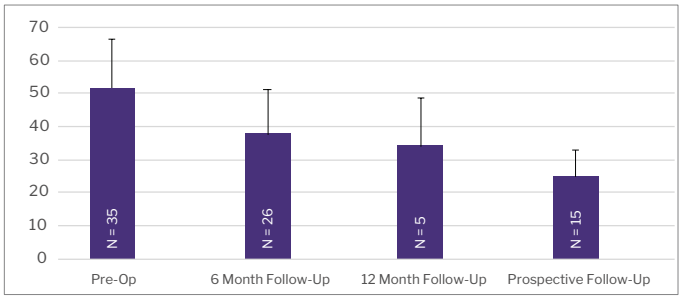
Table 2: Post-Operative Outcomes Data

Outcomes	n (%)
Primary Endpoint: Successful Union	57 (91.9%)
Delayed or Non-union	5 (8.1%)
Adverse Events Related to the Device	4 (6.5%)
Loss of Correction at Final Follow-up	3 (4.8%)
Secondary Procedures Directly Related to the Device	3 (4.8%)

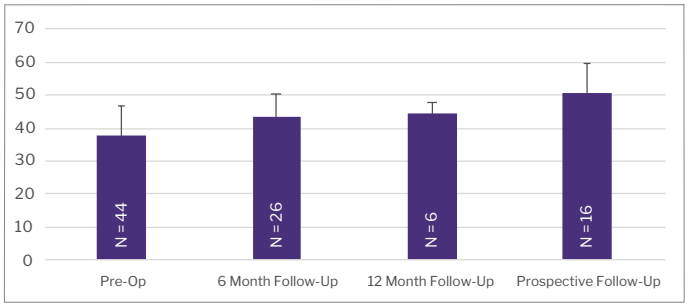
Prospective PROMs were collected post-operatively at multiple varying time points. Improvement between pre-and post-operative PROMs scores are presented in Figure 2. For the revised Foot Function Index, lower scores indicate better physical function. With respect to PROMIS physical function, higher scores indicate better physical function. Lower scores for PROMIS pain interference represents less pain interference. Finally, 15/16 (93.8%) of subjects were satisfied with the procedure.

Figure 2: Patient Reported Outcomes Measures

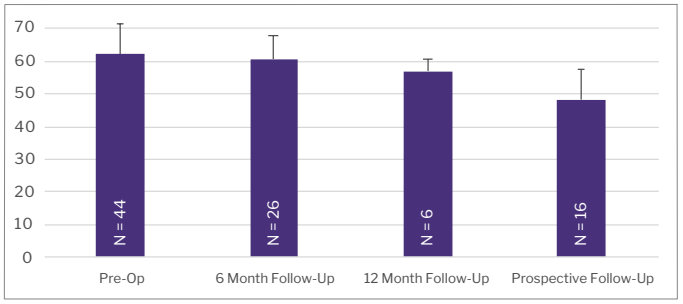
2A: Revised Foot Function Index



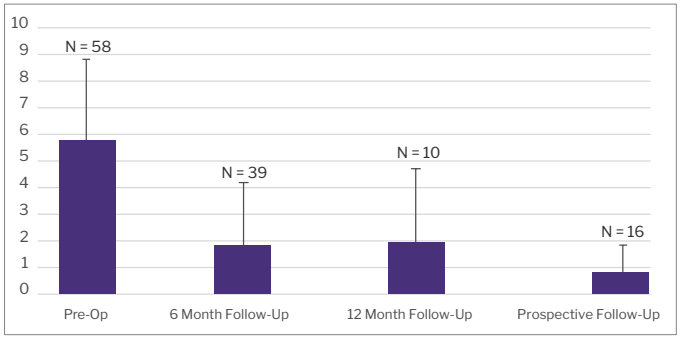
2B: PROMIS - Physical Function



2C: PROMIS - Pain Interference



2D: Pain Score



Conclusion

In summary, 57 out of 62 patients (91.9%) who were implanted with at least one device from the Paragon 28® Gorilla® Plating System successfully met the primary endpoint in this ambispective, single-site, multi-surgeon, consecutive-case clinical study. In total, there were five instances of delayed or non-union (8.1%), four adverse events related to the device (6.5%), and three instances of loss of correction at final follow-up (4.8%) There are several factors that contribute to the strength and applicability of this study to a general patient population. The intentional omission of exclusion criteria and broad inclusion criteria created a study with a variety of comorbidities and demographics. Approximately one-third of the patient population were current or former smokers, and the average BMI was 30.8. Additionally, a variety PROMs were collected preoperatively and at multiple time points prospectively, which provides more information about the clinical benefits of the device over time.

However, this study is not without its limitations. There are inherent shortcomings associated with retrospective data collection. Although PROMs were collected both pre- and post-operatively, not all patients who were enrolled in the prospective portion completed all the assessments. Additionally, while this was a multi-surgeon study and our study population attempts to represent the demographics of a realistic patient population, the surgeons treat patients from the same geographic region, thus the population in this study may not adequately reflect the overall population on the whole.

Overall, the findings from this study help support the safety, performance, and clinical benefit of the Gorilla® Plating System.

Paragon 28® would like to thank Dr. Clifford Jeng, MD and the Mercy Institute for Foot and Ankle Reconstruction for their participation in the Gorilla® Plating System Post-Market Clinical Follow-Up Study. The Mercy Institute for Foot and Ankle Reconstruction was compensated for participating in this research.

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

Exclusively foot & ankle

www.Paragon28.com