Clinical Outcomes of a Foot and Ankle-Specific Plating System

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INTRODUCTION: The Paragon 28® Gorilla®, Baby Gorilla®, and Silverback™ Plating Systems offer a wide variety of options for bone reconstruction, arthrodesis, and fracture fixation of the foot and ankle. Together, these systems include over 400 plate configurations that can be utilized for the treatment of a range of foot and ankle procedures, including but not limited to, medial column stabilization, calcaneal fracture repair, and tibiotalocalcaneal arthrodesis. Current EU regulations require clinical evidence proving safety and effectiveness in order to market certain medical devices in the EU. While other studies have discussed the clinical efficacy of individual devices of the aforementioned systems, there have been no studies assessing the system as a whole[1-6]. The purpose of this research was to evaluate the safety, performance, and clinical benefit of the Paragon 28® Gorilla®, Baby Gorilla®, and Silverback™ Plating Systems.

METHODS: After gaining institutional review board approval, retrospective data was analyzed from consecutive patients who were under the care of one of five participating investigators and were implanted with at least one device from the Gorilla®, Baby Gorilla®, or Silverback™ Plating System. Any patient who had undergone a foot and/or ankle procedure involving bone reconstruction/osteotomy, arthrodesis/joint fusion, and/or fracture repair/fixation using an implant from at least one of the three plating systems and had a minimum of 3 months of clinical and radiographic follow-up was included.

RESULTS SECTION: A total of 62 patients with an average age of 55 years old and Body Mass Index (BMI) of 30.8 were retrospectively reviewed, with an average follow-up of 6.5 months. Silverback™ was used only for arthrodesis/joint fusion and the other systems were used for all three indications (Table 1). Primary and/or revision procedures performed across all systems throughout the foot and ankle include but are not limited to: metatarsal fracture fixation, talonavicular arthrodesis, fibular fracture fixation, malleolar fracture fixation, and ankle arthrodesis. Thirty patients (48.4%) had structural allograft used and 43 (69.4%) underwent concurrent procedures. Forty-five patients (72.5%) were implanted with at least one plate from the Gorilla® system, 15 (24.2%) were implanted with at least one plate from Baby Gorilla®, 6 (9.7%) were implanted with a plate from the Silverback™ System, and 4 (6.5%) received implants from multiple systems. At the final follow-up, 57 of the 62 eligible patients successfully (91.9%) met the primary end point of successful fusion. Overall, 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, and bone erosion. The nonunion and the delayed wound healing events were resolved surgically, while the treatment of the bone erosion was still being discussed with the patient at time of study closeout at the site. There were no intraoperative complications.

DISCUSSION: Patients who were implanted with a device from the Gorilla® Plating System experienced low rates of adverse events and high union rates over a broad set of indications. All five patients that did not have successful union had at least one reported comorbidity (current/former smoker, diabetes, osteoporosis, and/or inflammatory arthropathy) (Table 2). 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. However, there are inherent shortcomings associated with retrospective data collection and though our study population attempts to represent the demographics of a realistic patient population, all patients came from the same geographic region, thus the population in this study may not adequately reflect the overall population as a whole.

SIGNIFICANCE/CLINICAL RELEVANCE: The study results support that the Gorilla® Plating System is safe and effective for bone reconstruction, joint fusion, and fracture repair in the foot and ankle in a real-world patient population.

REFERENCES: [1] Deheer 2020, [2] Haggerty 2020, [3] Heifner 2022, [4] Mehtar 2021, [5] Stenquist 2020, [6] Wagner 2018

Table 1: Index Device Indications and Location.

System	Bone Reconstruction/ Osteotomy	Arthrodesis/ Joint Fusion	Fracture Repair/Fixation	Foot	Ankle
Baby Gorilla®	6	5	12	23	0
Gorilla®	9	23	25	37	20
Silverback™	0	6	0	0	6
Total	**15**	**34**	**37**	**60**	**26**

Table 2: Characteristics of Patients with Delayed or Nonunion

Patient Number	Union Status	Gender	BMI	Age	Smoking Status	Indication(s)
06	Nonunion	Male	36	43	Former	Arthrodesis/Joint Fusion
08	Delayed	Female	31	62	Former	Fracture Repair/Fixation
31	Nonunion	Female	36	63	Non-smoker	Arthrodesis/Joint Fusion
34	Nonunion	Female	31	57	Non-smoker	Arthrodesis/Joint Fusion
62	Nonunion	Male	37	47	Former	Arthrodesis/Joint Fusion

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