Orthopedic Fixation of Skeletally Immature Ankle Fractures in Pediatric Populations Using Bio-Integrative Implants

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INTRODUCTION: Fracture rates are higher in children due to their skeletal immaturity. Most fractures can be treated conservatively; however, some fractures require internal fixation, often performed with metal-alloy fixation devices. In children, it is generally recommended to remove metal fixation devices to prevent future device-related complications. This, in turn, requires a second surgery that increases immediate risks and burdens for patients. However, new bio-integrative fixation devices may present an alternative to metal alloy fixation devices through minimizing device-related complications and eliminating the need for a second surgery. We hypothesized that utilizing bio-integrative fixation devices for skeletally immature ankle fractures will offer comparable rates of fusion and fixation to metal-alloy devices, while potentially demonstrating fewer complications, reduced re-operation rates, decreased costs, and improved quality of life.

METHODS: The study is a retrospective, descriptive, single-center, IRB approved study, which enrolled 35 participants who underwent internal fixation for skeletally immature ankle fractures. 12 patients received bio-integrative devices, while 23 received metal-alloy devices. Patients were followed up for up to 52 weeks post-procedure, and data analysis included visit details, radiographic studies, and treatment courses. The study measured radiographic fracture healing, using a survey-based cross-examination method among 3 attending physicians within the clinic. Device-related complications were analyzed using the Clavien-Dindo classification system. Device removal rates, surgical interventions, cost-efficiency, and quality of life outcomes were measured using statistical medical record and billing analysis techniques.

RESULTS SECTION: Radiographic assessment of fracture healing, post-procedure, demonstrates statistically insignificant differences in healing rates between the two patient populations ($t = 0.65$, $p = 0.05$, $\sigma_M = 2.4$, $V=33$). Device complications only occurred in patients with metal screws. In addition, device removal only occurred in patients with metal fixation devices. Metal screws exhibited significantly higher complications rates ($t = 0.024$, $p = 0.05$, $\sigma_M = 0.18$, $V=33$) as well as significantly increased surgical intervention rates ($t = 0.022$, $p = 0.05$, $\sigma_M = 0.060$, $V=33$). Out-of-pocket costs for patients undergoing internal fixation with bio-integrative screws and metal screws had insignificant differences procedure costs, with bio-integrative screw procedure costs averaging $4000.67 dollars and metal screw procedure costs averaging $4,228.13($t = 0.69$, $p = 0.05$, $\sigma_M = 315.77$, $V=33$). This is related to the relatively low incidence of complications in pediatric ankle fracture fixation, which produces a low re-operation rate. However, in the 5 instances in which patients required a removal of hardware, out-of-pocket procedure costs averaged approximately $3,030 higher. In terms of general measures of patient quality of life, patients had statistically insignificant differences in quality of life for the initial operations and improved quality of life after complication rates and hardware removal re-operations are factored in (refer to table 1).

DISCUSSION: In line with previous research, our study demonstrated that bio-integrative fixation devices exhibited similar rates of fracture healing and fusion compared to metal-alloy devices. Furthermore, the absence of significant differences in the quality-of-life measures for patients treated with bio-integrative devices indicates their potential as a viable alternative to metal screws. Notably, our study revealed a noteworthy disparity in the occurrence of device-related complications, with metal-alloy screws accounting for all the device-related complications. This finding echoes prior reports, highlighting the increased risk of complications and the subsequent need for surgical intervention associated with metal implants in pediatric patients. On the other hand, and in line with existing literature, bio-integrative implants showed promise in minimizing these complications and reducing the rate of device removal. Preliminary results suggest that bio-integrative fixation devices are comparable to metal-alloy devices in treating skeletally immature ankle fractures, while offering advantages in terms of complication rates, re-operation rates, cost-efficiency, and quality of life. Despite these promising results, it is essential to acknowledge certain limitations of our study. Firstly, the sample size was relatively small, and being a single-center retrospective study, potential biases and confounding factors might have influenced the outcomes. A larger, multi-center, prospective study would be necessary to further validate our findings and establish stronger evidence. Additionally, the follow-up period of 52 weeks might not have fully captured long-term complications or differences between the two implant types. Therefore, further research is warranted to address the study's limitations and establish a more comprehensive understanding of the long-term efficacy and safety of bio-integrative devices in this specific population. Nonetheless, this investigation contributes to the existing medical literature and provides valuable insights that can influence clinical practice and decision-making in the field of pediatric orthopedics, specifically in the treatment of skeletally immature ankle fractures.

SIGNIFICANCE/CLINICAL RELEVANCE: Pediatric patients with ankle fractures more often require a second surgery to remove metal-alloy fixation devices versus bio-integrative devices, which increases the risk of complications and burdens on patients. Therefore, bio-integrative implants may present a valuable solution to these issues by potentially eliminating the need for a second surgery, improving patient outcomes, reducing healthcare costs, and enhancing the overall quality of life for these young patients and their families.

Table 1: Clinical Quality of Life Outcome Measures

	Time in Cast/Splint (days)	Time in Controlled Ankle Motion Boot (days)	Time Non-Weightbearing (days)	Time until physical therapy is started (days)	Time until full activities are resumed (days)
Bio-integrative Screw Average	26.3	32.3	39.8	38.7	84.8
Metal Screw Average	22.8	34.1	36.1	37.6	90.9
t-value	0.42	0.71	0.26	0.70	0.54
Standard Error	2.08	2.27	1.49	1.65	0.54
Interpretation	All measures presented fail to reject the null hypothesis ($p = 0.05$, $V=33$)				

* All data featured is measured from days after initial operation except for time in CAM boot, which is measured from days after cast/splint is discontinued.