

Clinical Efficacy and Safety of Titanium-Sprayed PEEK Implants for PIPJ Fusion Procedures

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INTRODUCTION: The HammerTube™ Hammertoe System consists of a titanium-sprayed polyetheretherketone (PEEK) implant intended for use in proximal-interphalangeal joint (PIPJ) fusions i.e. hammertoe, claw toe, and mallet toe deformity corrections. PEEK is a non-reactive biomaterial with similar mechanical properties to bone¹. The addition of a porous titanium spray on each end improves fixation by increasing friction between the implant and bone, resisting rotational and pullout forces². This system has been FDA cleared, but to fulfill the new EU medical device regulations, this clinical study was conducted to evaluate the performance and safety of these implants.

METHODS: This IRB-approved study was a post-market, ambispective, single-arm, non-randomized, multi-surgeon, consecutive case series study of patients who had undergone reconstruction or fusion of their toe(s). The surgery was performed by a designated investigator during which they received one or more HammerTube™ implants as indicated and had a minimum follow-up of three months. Patients were evaluated for clinical outcomes including implant retention, retrospective radiographic and clinical exam data, device-related secondary procedures, and adverse event incidence.

RESULTS SECTION: A total of 41 patients (49 toes) were included in this study. The mean age of the study cohort was 63.9 years and the majority were female (32/41, 78%). All patients received PIPJ fusion surgery, with the main indication being hammertoe deformity correction (46/49 toes, 93.9%) and remaining cases indicated for phalangeal shortening (3/49 toes, 6.1%). All cases utilized a straight PEEK implant with temporary K-wire retention. K-wires were later removed at a predetermined time. All devices were implanted successfully (49/49 toes, 100%) and no issues or problems were reported with the associated instrumentation (41/41 cases, 100%).

Of the 41 patients, 40 (97.6%) retained their PEEK implant(s) at the 3-month timepoint. Only one patient required revision surgery with a new implant within three months of the initial procedure due to an index device-related adverse event. None of the patients experienced loosening, migration, deformation, or breakage of the implant during the study.

DISCUSSION: This study confirms the safety and performance outcomes of a PEEK implant for PIPJ fusion procedures, as evidenced by the high rate of implant retention (97.6%) three months post-operation. This retention rate is favorable when compared to previously reported findings on similarly indicated implants^{3,4}. The implant seemed to avoid complications commonly associated with hammertoe correction procedures, such as joint dislocation, implant breakage, and infection⁵. While nearly all patients had successful PIPJ fusion and implant retention at the 3-month timepoint, one patient required revision surgery within three months of the initial procedure due to implant failure. In this case, the previous 2.75mm diameter implant was removed and the procedure repeated with a larger 3.50mm diameter implant. The clinical reasons behind this implant failure are difficult to determine due to many confounding variables, however the revision surgery was able to be performed without complication.

The use of broad inclusion and no exclusion criteria in patient enrollment allowed for a study population with a variety of demographics and comorbidities. Just over half of the patients enrolled were current or former smokers (51.3%), several had diabetes (15.6%), and the mean Body Mass Index (BMI, kg/m²) was 30.1, all reflective of common health traits encountered by health care providers when performing these kinds of procedures. Nearly all patients (39/41, 95.1%) underwent concomitant procedures during the implant placement as well, capturing performance in a wide range of likely surgical scenarios.

As with all similar clinical studies, there are limitations to the results that are worth mentioning. This study was conducted at a single medical site with only two participating surgeons, ensuring procedural consistency but limiting the ability to assess device effectiveness across a range of surgeons with varying experience levels. The use of a single site may have limited the ability to collect data on a diverse patient population, as the patients enrolled all came from the same geographic region and do not reflect nationwide or worldwide demographic diversity. Despite these limitations, the findings demonstrated that the PEEK implant is both safe and effective for use in PIPJ fusion procedures.

SIGNIFICANCE/CLINICAL RELEVANCE: This study was the first to assess safety and performance outcomes of the HammerTube™ Hammertoe System for use in PIPJ fusion procedures such as hammertoe deformity correction. The study results showed that the system is safe and effective for this indication, evidenced by high implant retention rates at three months and low adverse event rates.

Table 1: Patient Demographic and Comorbidity Data

Variable	n (%) or Mean (SD)
Males:Females	9:32
Age at Pre-op Visit (Years)	63.9 (14.62)
BMI	30.1 (6.81)
Mean Post-op Clinical Follow-up (months)	6.38 (3.24)
Current/Former Smoker	21 (51.3%)
Diabetes	6 (15.6%)

Table 2: Post-Operative Outcomes Data

Outcomes	n (%)
Implant Retention at 3 Months Post-op	40 (97.6%)
Adverse Events Related to the Device	1 (2.4%)
Tenderness over Implant	1 (2.4%)
Implant Loosening	0 (0%)
Implant Migration	0 (0%)
Implant Deformation	0 (0%)
Implant Breakage	0 (0%)

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