The Use of Porous Titanium Coated Polyetheretherketone wedges in Reconstructive Foot and Ankle Surgery

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PURPOSE

The goal of this retrospective study is to demonstrate in the clinical setting that Ti-PEEK wedges can be used for Evans and Cotton osteotomies without fixation to achieve both clinical and radiographic healing.

LITERATURE REVIEW

Two of the most common procedures in flatfoot reconstructive surgery are the Evan's and Cotton osteotomies. Traditionally, bone (allograft of autograft) is utilized to attain and maintain correction. However, bone must go through creeping substitution to incorporate into the osteotomy site. This creates a period of vulnerability in which some type of fixation must be employed to avoid subsidence and loss of correction. Unfortunately, the most frequently reported complication of these osteotomies is hardware irritation. [1,2]

To overcome these shortfalls, different materials have been investigated and utilized including porous titanium and titanium coated PEEK (Ti-PEEK). Porous titanium is chemically active when implanted. It has an elastic modulus that is nearly 6-times greater than bone. [3] This results in potentially greater stress shielding and possible aseptic loosening over time. Last, it is not radiolucent making the radiographic assessment of boney healing very difficult. Conversely, Ti-PEEK is inert and has an elastic modulus very similar to bone. [3,4] This allows strain transfer to the adjacent bone resulting in bone remodeling and a more stable graft-bone interface as the bone will grow onto the graft. Therefore, the period of vulnerability is avoided and fixation may not be necessary.

Due to the ideal qualities of Ti-PEEK the authors have been utilizing Ti-PEEK wedges in Evan's and Cotton osteotomies without fixation. This consecutive case series presents our experience and outcomes to date.

Figure 5 – Cross - sectional SEM of the Ti-PEEK interface.

METHODS

Consecutive patients who underwent implantation of Ti-PEEK wedges for the surgical correction of flatfoot without fixation were assessed for time of radiographic ongrowth, complications and loss of surgical correction. Radiographic ongrowth was assessed by two practitioners independently (M.G and C.H) at post op weeks 6, 10, 16. from a private foot and ankle surgery practice who have undergone Evans' and/or Cotton osteotomies without fixation.

Implant complications:

- Any event that results in the explant of the implant.
- Lack of boney ongrowth evident on 2 orthogonal radiographs at post-op week 6.
- Lack of >66% boney ongrowth on 2 orthogonal radiographs by post-op week 16.

Figure 2 – Surface topography of different materials: PEEK, titanium and Ti-PEEK

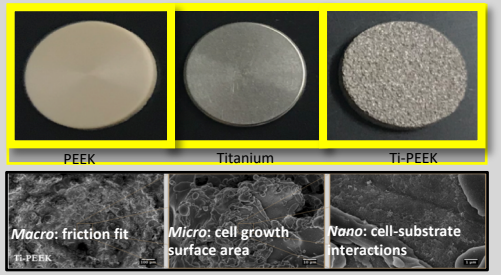


Figure 3 – Ti-Peek surface exhibiting roughness at the macro, micro and nano cellular levels.

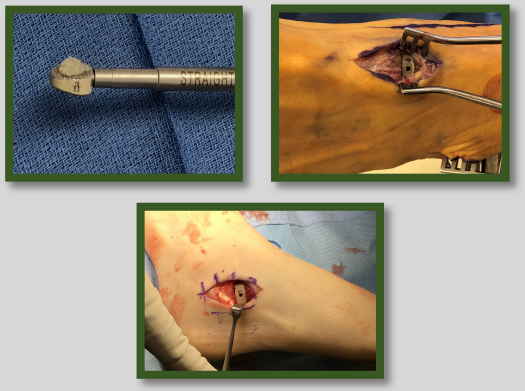
Patient	Procedure	6 weeks	10 weeks	16 weeks	Complications
TPW1	E + C	Y	Y	Y	None
TPW2	E+ C	Y	Y	Y	None
TPW3	C	Y	Y	Y	None
TPW4	E	Y	Y	Y	None
TPW5	E	Y	Y	Y	None
TPW6	E	Y	Y	Y	Anterior process collapse
TPW7	E	Y	Y	Y	None

Table 1 – data collection on patient population. Key: Ti-Peek Wedge (TPW), E-Evans, C-Cotton . Y-Radiographic bone ongrowth.

RESULTS

Independent radiographic union was evaluated and compared. There was successful bony on-growth of >66% by week 16 for all 7 patients. There were two complications that were reported. One patient had sural neuritis which was resolved with physical therapy. Second patient had an unrelated injury resulting in anterior process of calcaneus collapse secondary to Charcot neuroarthropathy. Patient TPW6's wedge was explanted. Bone biopsy was obtained to rule out osteomyelitis. Patient's bone biopsy and deep tissue cultures were negative.

Figure 4 – Intra-Operative Photos of ti-PEEK wedge before and after implantation.



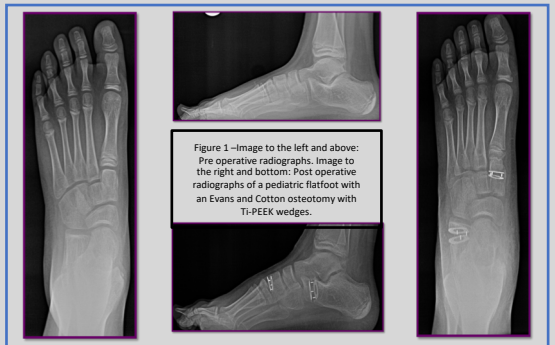


Figure 1 –Image to the left and above: Pre operative radiographs. Image to the right and bottom: Post operative radiographs of a pediatric flatfoot with an Evans and Cotton osteotomy with Ti-PEEK wedges.

ANALYSIS AND DISCUSSION

This case series presents our experience with Ti-PEEK wedges in Evan's and Cotton osteotomies without fixation. All cases showed radiographic evidence of boney on-growth by post-op week 6. Correction was maintained and >66% boney on-growth was seen by post-op week 16 and beyond.

When considering what type of wedge to use for Evan's and Cotton osteotomies, several criteria should be met. These include a similar elastic modulus to bone, predictable and efficient osseo-integration, durable deformity correction, avoidance of internal fixation, and cost-effectiveness. Ti-PEEK wedges fit all of these criteria.

Compared to bone and porous titanium, Ti-PEEK wedges are unique in that the period of vulnerability is avoided as the bone will "grown on" instead of "grow into" the implant. Compared to porous titanium, it has been shown that osteoblasts will adhere to the Ti-PEEK surface in as little as 4 hours. Within just one day, the amount of calcified tissue interlocking with the rough Ti-PEEK surface (figure 2, 3) has been measured to be more than 300% greater than on conventional titanium, and it remains significantly higher beyond 4 weeks. [5] Due to the rapid osteoblast proliferation, calcification, and bony on-growth, Ti-PEEK wedges attain superior stability sooner than porous titanium. In addition, the load-sharing ability of Ti-PEEK preserves the natural bone remodeling activity to enable long-term tissue retention. If the rationale for fixation is to prevent graft subsidence and loss of correction, the need for fixation and thus the risk for higher complications are eliminated with the use of Ti-PEEK wedges.

The limitations of our study include the small sample size. Another limitation is not obtaining CT radiographs when calculating the approximate amount boney on-growth and trabeculation seen within the implant. However, this is usually reserved for cases where there is a concern for inadequate healing. The authors have 2 patients who underwent MRI for unrelated reasons and showed T1 signal homogenous to the surrounding bone through the wedge graft window.

The Ti-PEEK implant results in less complications including painfully palpable hardware, irritation of adjacent nerves and/or tendons, and revision surgery, while achieving the goals of deformity correction and efficient return to function and productivity.

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