Ankle fracture fixation with additive manufactured titanium shell polyetheretherketone filled (TI-PEEK) plates[1]

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Overview

GLW Foot & Ankle (Carbon22), a GLW Medical Innovation company (GLW) has developed TI-PEEK plates which have major advantages over conventional plates, including radio-transparency, superior contouring to accommodate complex anatomy and stress shielding protection.

Keywords: Fracture fixation · Ortholucent plates · Titanium / Polyetheretherketone · Stress shielding · Thin profile plates.

Introduction

Orthopedic bone plates are a standard of care for multiple types of fractures. Current market offerings consist of stainless steel or titanium alloy plates and less common and more recent carbon fiber polymer plates.

GLW developed Apollo Ankle Fracture (AFX) Plating System, a novel portfolio of see-through, "ortholucent" bone plates and screws used for orthopedic ankle fracture surgery with a new patented[1] TI-PEEK hybrid technology, which combines both materials using titanium additive manufacturing[1,2] and PEEK injection molding. The technology delivers plate performance expected of metal and carbon fiber polymer plates, along with a series of additional unique features discussed in this paper.

TI-PEEK hybrid technology has the capacity to provide the following clinical advantages currently not available in thin and malleable plates:

Ortholucency – the radio-translucent properties of these ankle fracture plates greatly improve visualization of bony structures and allow for easier assessment of implant placement and progress of healing process as well as potential for shorter time to weight bearing.

Stress Shielding Protection – allowing more weight bearing by the bones[3], potentially leading to reduced short and long-term bone loss, faster healing, non-union prevention and less refractures upon plate removal.

More Anatomical Profile – with additive manufacturing, the plate mimics anatomy and helps reduce contouring in the Operating Room (OR) during surgery.

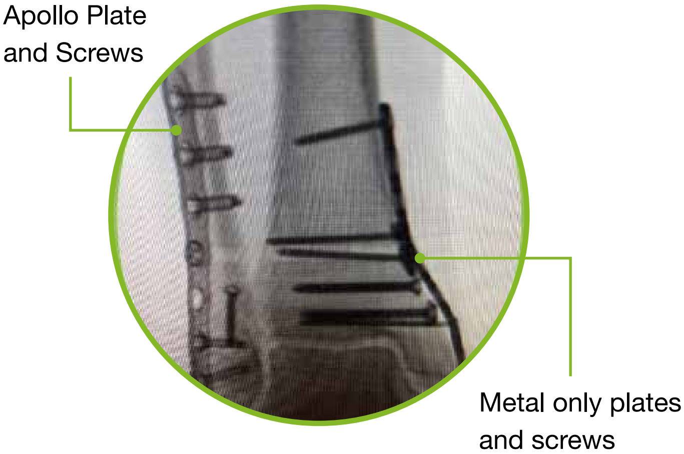

Figure 1: X-Ray image with Apollo AFX TI-PEEK vs. metal non-radiolucent implants.

[1] U.S. Pat. No. 11,628,000. Other patents pending.
[2] Additive manufacturing, often referred to as 3D printing
[3] Claim supported by existing literature and FEA analysis

Orthlucent, Malleable and Strong

Figure 2: Apollo Plates Hybrid Construction – Fibular Plate section shown.

Apollo AFX plates consist of Titanium shell and PEEK fill, as shown in Figure 2. Complex shell geometry is made possible by additive manufacturing (titanium 3D printing)[1,2] and has been created to minimize wall thickness to allow for ortholucency while maximizing plate strength as shown in Figure 3[10].

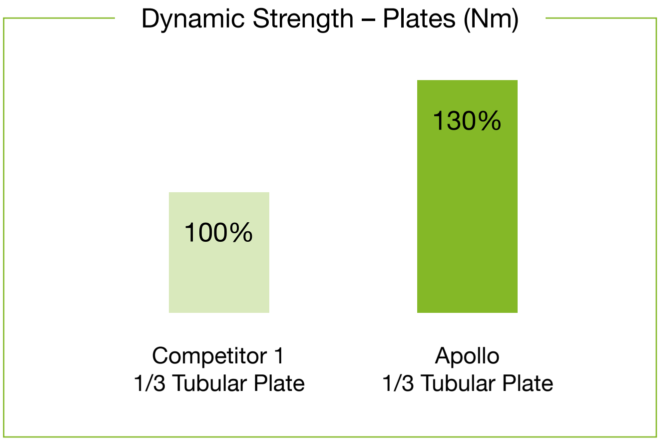

Figure 3. Dynamic Fatigue Strength of Apollo AFX plates vs. competitive plates after 1 million cycles.

Ortholucency enables clear visualization of fracture fixation and bone alignment and leads to easier assessment of bone healing process. In addition, screw trajectories and lengths are easily identifiable. This is especially advantageous in ankle fracture where often multiple plates are used as seen in clinical examples in Figure 4.

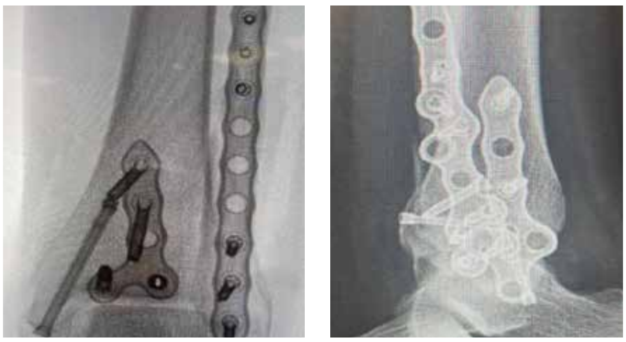

Figure 4: Examples of ortholucency of Apollo implants.

Malleability allows the plates to be contoured to patient's anatomy during the surgery, as illustrated in Figure 5, allowing the surgeon to minimize the prominence of the plate under patient's skin.

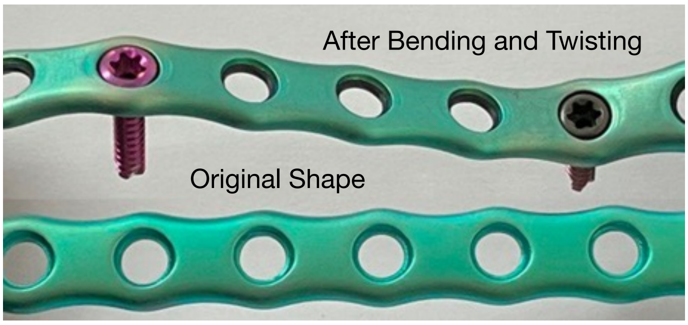

Figure 5: Apollo One-Third Tubular Plate before and after bending and twisting.

Apollo AFX plates mate with Apollo AFX hollow core screws, which are available in locking and non-locking options. Due to the hollowed nature of the screws, they offer ortholucency to complement the plates while maximizing strength as shown in Figure 6[10].

Figure 6: Torsional Strength of Apollo AFX screws vs. competitive screws.

Stress Shielding and Orthopedic Plates – Background

Traditional orthopedic bone plates have disparity in modulus of elasticity between its metals and natural bone that leads to challenges, especially stress shielding, which can hinder optimal healing and cause issues such as bone resorption.

Metal bone plates used to treat fractures have a much higher stiffness than bone and as a result carry considerably more load and shield the bone from stresses necessary for healing (Wolff's Law).This statement has been repeated in scientific research literature, along with the following potential long-term effects: delayed union, cortical bone loss underneath the plate and refracture upon removal [3,4]. These claims have been supported by scientific evidence, including results of clinical studies and X-rays[4].

Considerable amount of the research has been focused on bending stiffness as a main cause of stress shielding[5,6]. However, based on finite element analysis (FEA) and bench experiments, axial stiffness has been identified as the dominant factor in altering bone stresses[7].

Subsequently, experimental plate designs with different materials[7], elastomeric inserts[8,9] or bioresorbable inserts[4] – all aimed at reducing axial stiffness – have been developed, tested and/or analyzed, with results confirming decrease in stress shielding.

On the other hand, carbon fiber polymer plates have a much lower modulus of elasticity than metal plates. It is similar to that of cortical bone, resulting in less stress shielding – as reiterated in numerous research papers. Fatigue testing, infrared thermography and FEA confirm that bone stress under carbon fiber polymer plate is substantially higher than under metal plate, while axial stiffness is similar[3].

However, in order to maintain adequate bending stiffness for bone fracture alignment, carbon fiber polymer plates need to be substantially thicker than metal plates[11].

Stress Shielding Protection

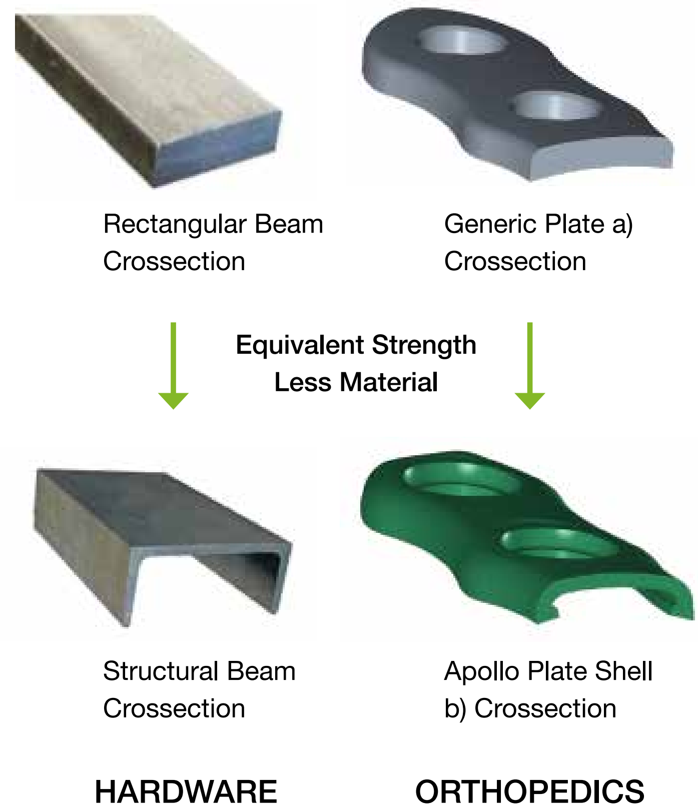

Figure 7: Illustration of the principle used in structural beams and applied to Apollo plates (not to scale). a) machined titanium plate b) additively manufactured titanium plate shell.

Two factors of the Apollo AFX plate design contribute to decreased axial stiffness which benefits the patient from stress shielding. One factor is the thin profile which can only be produced by additive manufacturing. The second factor is the PEEKLOC™ holes that act similarly to the elastomeric inserts.

Thin Profile: Apollo AFX plate strength and stiffness properties are parallel to those in structural beams used in buildings and bridges – see Figure 7. Structural beam shapes are created by removing internal material to reduce weight and cost while maintaining bending strength. Similarly, Apollo AFX plates are created by printing the shells with a hollow middle to enable ortholucency while maintaining bending strength.

PEEKLOC™ Holes: Elastomeric inserts[8,9] or bioresorbable inserts[4] can be used to decrease axial stiffness. Apollo AFX PEEKLOC™ technology – as shown in Figure 8 – acts similarly to both of those types of inserts.

Figure 8: A cross section of the PEEKLOC™ Technology screw interface that serves as an elastomeric insert.

A combination of material removal and PEEK inserts (PEEKLOC™) in the holes, decreases axial stiffness of the Apollo AFX plates and leads to lower stress shielding and higher cortical bone stress – by 16% in comparison to a generic titanium plate of equivalent strength, as shown in Figure 9[11].

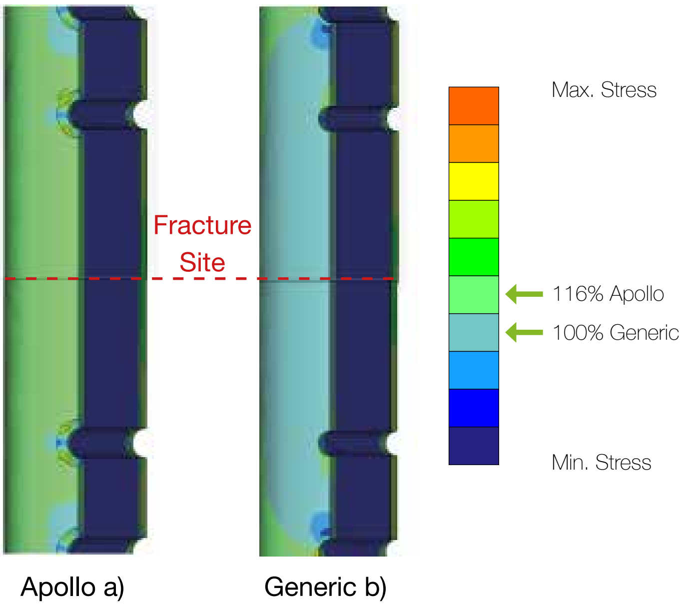

Figure 9: Stress in cortical bone under two plates of equivalent strength a) Apollo AFX TI-PEEK Plate b) Generic solid titanium Plate. Results of FEA; axial stiffness effect only.

The results of the Apollo AFX plate FEA analysis have not been confirmed by further studies, however there is ample evidence of this cause and effect in existing white papers[4,7,8].

More Accurate Anatomical Profile

Traditional or generic forms of orthopedic bone plates manufacturing methods, such as machining, forging, or milling, have limitations in producing complex and customized shapes and can only approximately fit the patient's anatomy.

The Apollo AFX additive manufacturing process enables the plate shape to closely match bone anatomy. The difference between generic and Apollo AFX plate profiles is shown in Figure 10. The matching anatomical plate means less time in the OR contouring to the bone. Also, placement and location of the screws better match the anatomy.

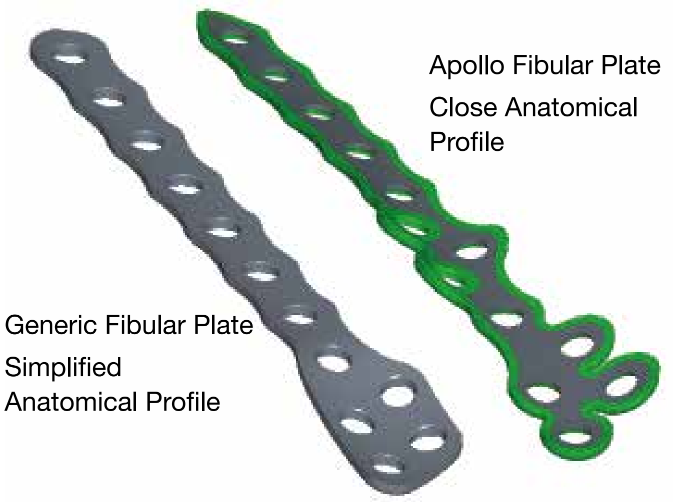

Figure 10: Comparison of anatomical fit between Apollo AFX and commercially available fibular plate.

Conclusion

GLW developed a new patented TI-PEEK hybrid technology and applied it in the creation of Apollo AFX Plates.
The benefits of this technology and clinical significance of Apollo AFX Plates lie in the fact that they combine confirmed and potential clinical advantages, only partially available in current state-of-the-art plates as seen in Table 1 and the following list:

- Ortholucency, which enables clear visualization of fracture fixation and bone alignment, leading to easier assessment of implant placement and progress of bone healing process as well as potential for shorter time to weight bearing.
- Stress shielding protection, which potentially leads to reduced short and long-term bone loss, faster healing, non-union prevention and less refractures upon plate removal.
- More accurate, thin and malleable anatomical profile, which minimizes soft tissue disruption and prominence under the skin.

Table 1: Apollo AFX vs. Competitive Plates.

Features	Metal Plate	CF Polymer Plate	Apollo AFX Plate
Ortholucency		✓	✓
Lower Stress Shielding [a)]		✓	✓ [b)]
Thin plate (≤1.8mm)	✓		✓
Malleable in OR	✓		✓
Anatomical Profile	✓	✓	✓✓

a) In comparison to metal plates.
b) Supported by existing literature and FEA analysis.

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