ApolloAnkle™
Fracture Plating System

GLW medical innovation

Osteosynthesis plating with multi-directional PEEKLOC™ locking screw technology[1]

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Overview

GLW Foot & Ankle (Carbon22), a GLW Medical Innovation company (GLW) has developed PEEKLOC™ variable-angle locking screw technology which has major advantages over conventional locking, including flush screw head, cold welding protection and minimized screw backing out.

Keywords: Fracture fixation · Osteosynthesis plating · Variable-angle locking · Polyaxial screw placement.

Introduction

Locking plates are often used in a variety of bone fractures to achieve stable osteosynthesis at the fracture site. These plates have screws that are locked into the holes of the osteosynthesis plate. Current market offering consists of fixed and variable insertion angle options, the majority of which achieve locking by inserting a threaded screw head into a threaded hole in the plate – either metal screw to metal locking plate or metal screw to carbon fiber polymer (CFP) locking plate.

GLW developed a new patented PEEKLOC™ locking screw technology, which delivers stable fixation at $\pm 15^0$ variable insertion angle expected in current state of the art locking plates, along with a series of additional unique features described in this paper.

Figure 1: PEEKLOC™ Components.

Compact and Secure Design

Screw head prominence and shallow driver engagement are two of the challenges facing current thin metal plate design. These challenges are addressed by either using thicker plates or improving on only one of these two challenges at the cost of the other.

PEEKLOC™ incorporates a patent-pending self-countersinking screw head which provides room for deeper driver recess in a thin plate while keeping the top of the screw head essentially flush to mostly below the top of the plate – orientation dependent, as shown in Figure 2. Additionally, the locking interface utilizes patented TI-PEEK hybrid technology, which allows the internal locking features and PEEK fill to be incorporated into the design. This leads to a number of performance characteristics superior to metal-to-metal and metal-to-CFP interfaces as described in this paper.

PEEKLOC™ locking Interface has been designed with the user needs in mind, as shown in Figure 2.

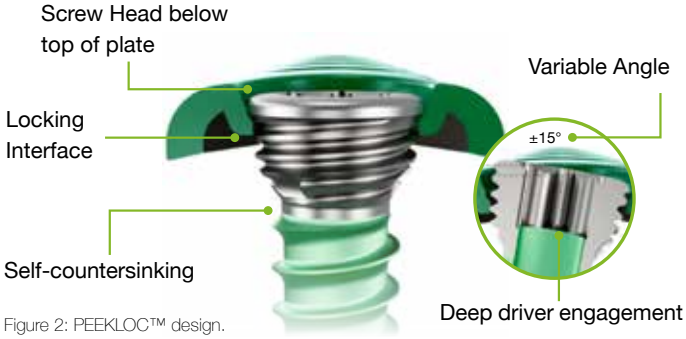

Figure 2: PEEKLOC™ design.

[1] U.S. Pat. No. 11,628,000. Other patents pending.

Minimized Risk of Stripping Screw Head

PEEKLOC™ effectively locks the screw within the full range of user insertion forces typically encountered in the OR – in the same clinical applications and screw sizes as Apollo Ankle Fracture Plating System – as shown in Figure 3[4,6,8].

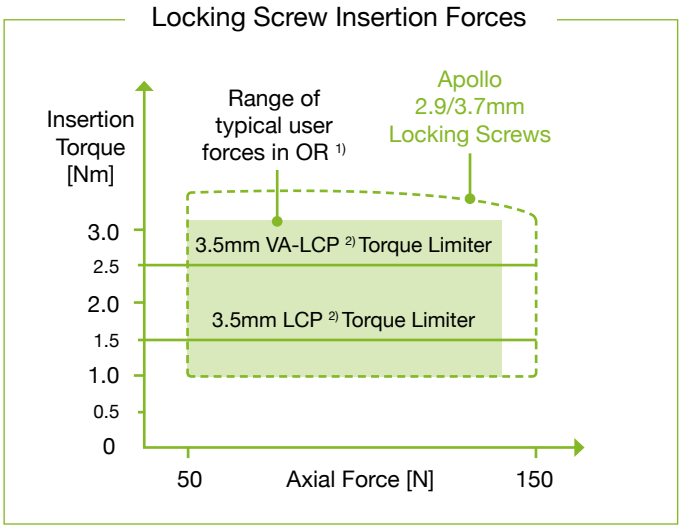

Figure 3: Range of performance parameters of 3.5mm Locking Screws 1) Range of user forces in OR assessed internally with an Apollo size handle[8]. 2) LCP and VA-LCP are plating technologies by DePuy Synthes.

Successful insertion in metal-to-metal locking interfaces relies on using torque limiters to prevent head thread stripping during insertion or on tactile feedback of the surgeon to not overtighten the screws[1].

The PEEKLOC™ ability to perform within a larger range of typical user forces in the OR minimizes the risk of head thread stripping during insertion.

Cold Welding and Screw Loosening Prevention

The locking interface between metal screws and plates is known to be susceptible to cold welding and subsequent difficulties in screw removal[2,3], as assessed during testing of Synthes 3.5mm LCP Screw[5].

GLW conducted an independent test[8] of 3.7mm Apollo Locking Screw under the same test conditions as[5] – visual graph of results shown in Figure 4.

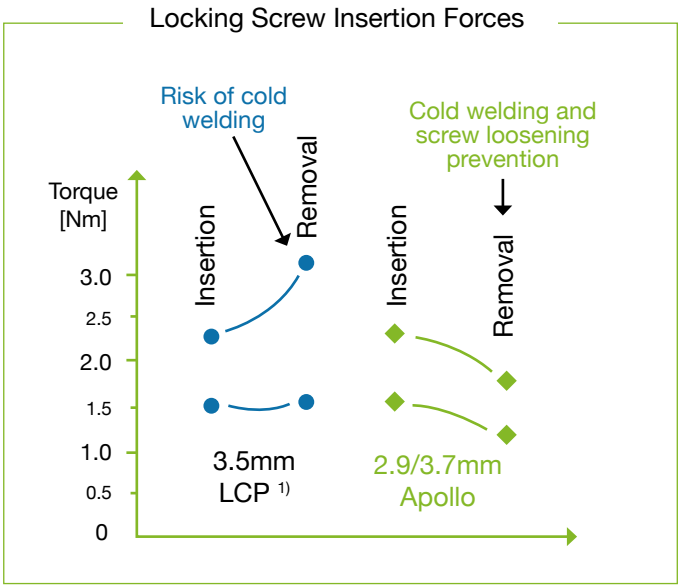

Figure 4: Locking Screw Insertion and Removal – results of independent testing [5,8].1) LCP is a plating technology by DePuy Synthes.

Comparison of test results indicate that the removal torque of the locking screw from the metal plate rises with increased insertion torque, placing the screw at risk of cold welding, while the removal torque of the locking screw from PEEKLOC™ TI-PEEK interface remains within 60-75% of the insertion torque over the entire range of the insertion torque. This offers cold welding protection.

Another known failure mode of screws is their tendency to loosen and back out of the plate in the patient. This failure mode is well known in the fastener hardware industry and overcome by using locking patches (commonly made from Nylon) on fastener threads – see Figure 5[7]. PEEK in PEEKLOC™ interface plays a similar role, acting as a wedge between the locking thread on the screw and the metal features in the plate and creating a positive resistance to micromotion and loosening.

This unique characteristic of PEEKLOC™ has the potential to lower the risk of the screw backing out of the plate, even in the case of non-union.

Figure 5: Illustration of the elastic locking principle used in common fastener hardware and applied to PEEKLOC™ interface.

Reliable and Resilient Locking

PEEKLOC™ design allows for multiple insertions and removal of the locking screw with little impact on the locking strength, as verified during internal testing[8] and illustrated in Figure 6.

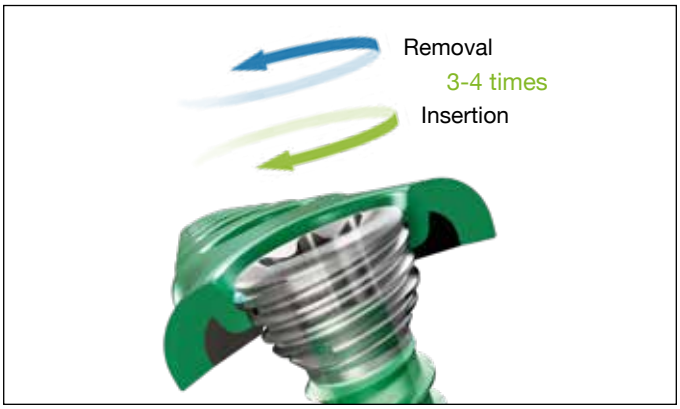

Figure 6: PEEKLOC™ Locking Interface. The screw can be inserted and removed 3-4 times with little degradation.

Effective Locking Ability

The forgiving nature of the locking interface enables the locking screws insertion after plate bending, as illustrated in Figure 7. This unique ability provides surgeons with more options to secure the plate to bone, in particular in challenging situations with small bone fragments or site inaccessibility.

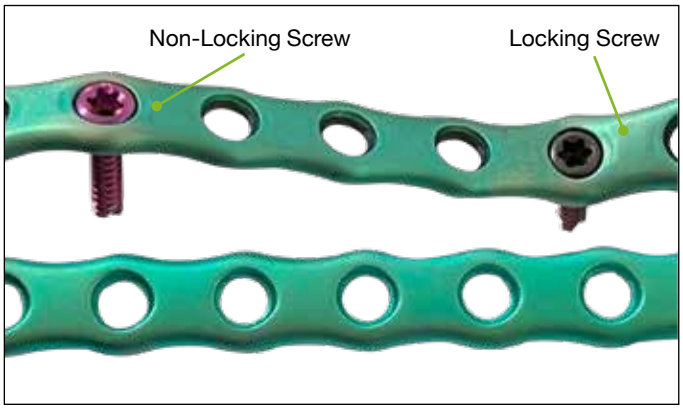

Figure 7: Apollo Tubular Plate before and after bending and twisting, with Locking and Non-Locking Screws inserted afterwards

Conclusion

GLW developed a patented PEEKLOC™ technology with a set of unique design features offering the following clinical advantages:

- Screw head essentially flush or mostly below the top of the slim profile plate, which minimizes soft tissue irritation and prominence under the patient skin
- Deep driver engagement, which leads to a more secure driver connection with less risk of disengagement and screw head socket stripping during screw insertion and removal
- Increased range of screw insertion torque, which covers a full range of typical user forces in the OR and minimizes the risk of head thread stripping during screw insertion
- Elastic locking interface, which offers cold welding protection, minimizes the risk of cold welding and screw backing out in the patient as well as allows multiple screw insertions and locking engagement even after moderate plate contouring during surgery

Ultimately, PEEKLOC™ performance is less technique sensitive while assuring a more reliable outcome than the majority of the metal and carbon fiber polymer locking plates currently on the market.

References

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