creed™ Orthulucent Implants

GLW medical innovation

Cannulated compression screws with ortholucent technology for intraoperative and postoperative visualization of bones and joint spaces

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Figure 1. X-Ray image with CREED Screws vs. conventional non-radiolucent implants.

Introduction

For end stage ankle arthritis, ankle arthrodesis remains the gold standard treatment. The arthroscopic approach, despite its greater technical difficulty, has the advantage of less wound complications, diminished post-operative pain, earlier patient mobilization, and equivalent or earlier fusion rates when compared to open arthrodesis[1,2]. Because arthrodeses have historically been evaluated by bone bridging on plain radiographs, poor visibility of the fusion site due to the radiopaque properties of metallic implants remains a challenge.

State-of-the-art for internal fixation

The advent of implantable metallic fixation devices provided many advantages for direct internal stabilization and rigid fixation for ankle arthrodesis. To achieve early stability through direct immobilization of the anatomic site, the use of multiple screws, intramedullary nails, and bone plates have been the preferred solution for multiple decades.[3] However, as with any implantable orthopedic device, there are inherent challenges with present fixation systems that require further innovation to be overcome.

Metallic implants impede visualization of the fusion site due to their radiopaque nature. These visual obstructions make it more difficult for surgeons to assess fracture reduction and can negatively impact patient outcome.

By contrast, implants that allow significant visualization of bone structures by offering less resistance to the passage of X-rays (i.e. radiolucency) are often composed of non-metallic materials that lack the strength of metallic implants. This lower implant strength can increase the risk of breakage and result in suboptimal biomechanical stabilization of the injured site.

The Ortholucent Screw

Figure 2. CREED 4.3mm, 5.6mm and 7.4mm Cannulated Headless Compression Screws.

The need to balance radiolucency with screw strength has led to the next generation of innovation. The ortholucent Creed Cannulated Screw is a novel implant designed to overcome the difficulty of poor visualization while maintaining comparable strength to conventional metallic implants. The radiolucent properties of the Creed Screws are the result of an innovative design that combines a thin walled titanium core with an overlay of implant grade Polyether Ether Ketone (PEEK). This composite approach provides a significant clinical advantage over traditional metal implants by radically improving intraoperative and postoperative visualization of bones and joint spaces.

Implant strength and bonding integrity

The strength of the Creed Screws is derived from two essential features: A grade 23 titanium core and a cross-sectional design that maximizes the resistance to torsional and bending loads. The titanium core provides the strength to withstand the biomechanical loads during fracture fixation, while the large and thin-walled shaft diameter allows the Creed Screws to retain the geometric properties of similarly sized metal screws. When tested against commercially available metallic screws, **the Creed Screws show equivalent or better dynamic fatigue strength (bending) and torsional strength (shear).**

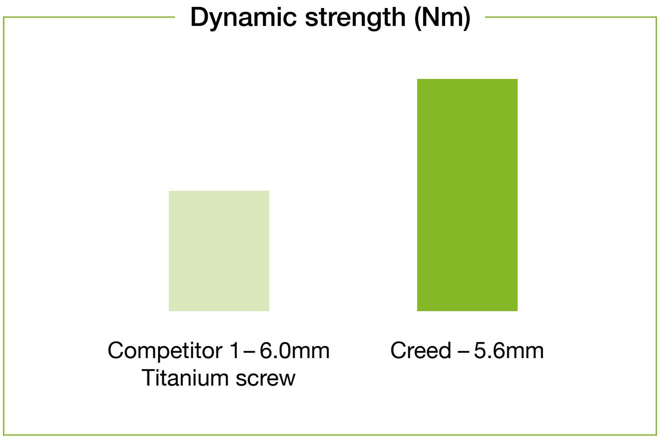


Figure 3. Dynamic fatigue strength in bending. Comparison between 6.0mm Titanium screw and Creed 5.6mm Screw.

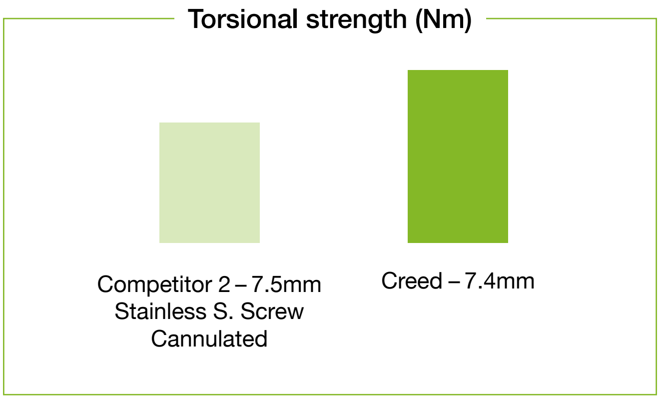
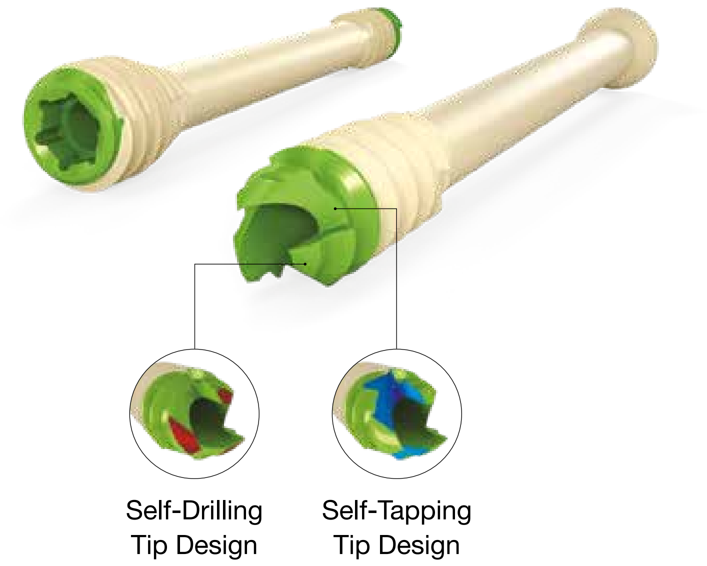


Figure 4. Torsional strength. Comparison between cannulated 7.5mm stainless steel screw and Creed 7.4mm Screw.

In addition, the composite design of the Creed Screw incorporates a proprietary bond technology that is highly resistant to delamination of the PEEK from the Titanium core. Aggressive testing of multiple Creed screw sizes in simulated dense bone under supraphysiological loads demonstrated significant resistance to delamination with no evidence of the PEEK debonding from the Titanium core under multiple test scenarios.



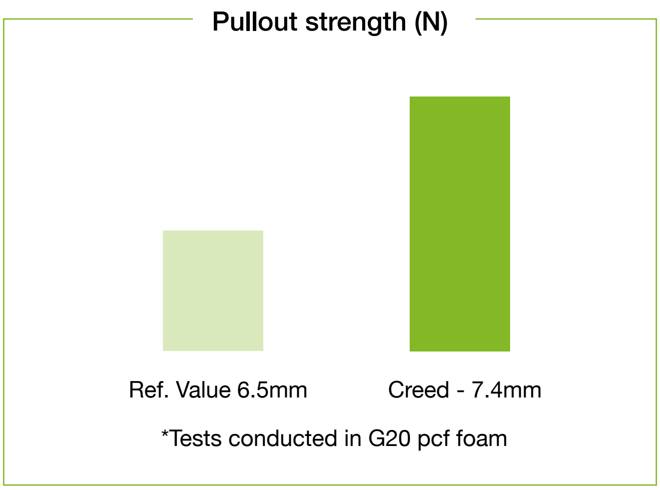


Figure 5. Pullout strength of Creed Screws. Reference value displayed taken from the FDA Guidance document for Orthopedic Non-Spinal Metallic Bone Screws.

Performance in surgery

To facilitate operational steps, Creed Screws have a self-cutting and self-tapping design and do not require predrilling. The optimization of the titanium cutting geometry results in a low insertion torque, a commonly used metric to measure cutting performance. When compared to established competitor implants such as Wright Medical, the insertion torque of Creed Screws is up to 27% lower. Low insertion torque is linked to reduced risk of microfractures and fragment displacement, which favors patient outcome.

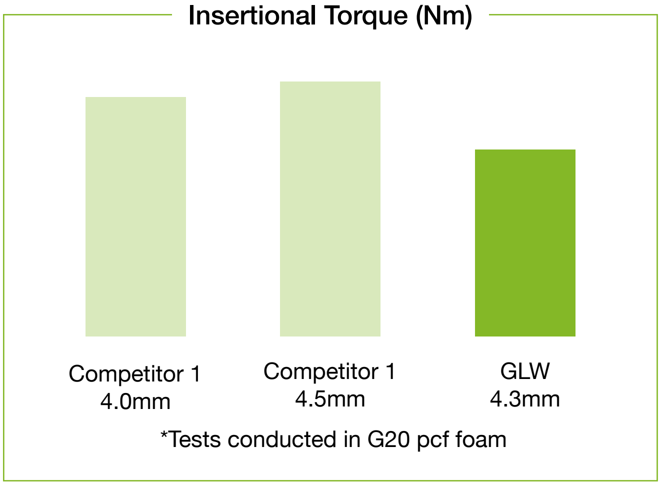


Figure 6. Insertion torque. Comparison between Wright Medical 4.0mm and 4.5mm cannulated screws vs. Creed 4.3mm screws.

Interaction with bone

Titanium and PEEK are known to have favorable biocompatible properties and have been widely used as implant materials. Nevertheless, Titanium has been observed to promote greater osteointegration when compared to PEEK[4,5]. Given that most of the outer surface of the Creed composite screws consists of PEEK, the potentially lower osteointegration could result in an easier extraction of the screw if necessary. Therefore, the ortholucency of the Creed Screws and its removal capabilities provide an innovative and novel screw design that benefits the patient population.

Surgery-ready solution

Creed Screws and instrument kits are sterile packaged, enabling a surgery-ready solution for the hospital and ambulatory surgical centers.

Figure 7. Creed Screws Single Use Instrument Kit – Small.

Case Study: Creed 7.4mm cannulated compression screw

26-year-old male, police officer, presented for a second opinion after stepping through a board in an attic suffering a left ankle bimalleolar fracture. Postoperatively he developed symptomatic posttraumatic arthritis and deformity and elected to have a left ankle arthroscopic arthrodesis with tendoachilles lengthening.

To allow visualization of the fusion site post operatively, without sacrificing compression, it was decided to use the 7.4mm Creed Screw for fixation. A three-screw fixation technique was used, with one headed and two headless screws in a divergent fashion. Appropriate compression was able to be seen on multiple fluoroscopic angles. 2 and 6 weeks post-operative x-rays below show the fusion site visualized through hardware with ankle arthrodesis in acceptable alignment (Figure 8-9).

Figure 8. Week 2 post-operative AP ankle radiograph of left ankle arthrodesis using 3 Creed 7.4mm cannulated compression screws in a divergent fashion.

Figure 9. Week 6 post-operative lateral ankle radiograph of left ankle arthrodesis using 3 Creed 7.4mm cannulated compression screws in a divergent fashion.

Conclusion

The novel implant design of the Creed Screws combines a titanium core with a full radiolucent PEEK overlay that offers the unique advantage of improved visualization of the fusion site, while providing the needed strength for successful fusion. This ortholucent design allows surgeons to better orient the joint into the correct position for fusion intraoperatively, with the benefit of post-operative visualization of the fusion status. The surgical procedure is further aided by a self-drilling and self-tapping screw design with a low insertion torque and a PEEK surface that facilitates screw removal due to low osteointegration. By combining these features, the Creed Screws represent a new innovative step in implant design that aims to address surgeons needs and promises to benefit patient outcome.

References

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