PEEK-OPTIMA Enables Enhanced Safety in Fracture Treatment Applications

Orthopedic technologies are dominated by metal materials in the fabrication of implants and other devices used in this sector. However, increasingly, advanced, high-performance plastics are enabling enhancements with regard to safety and functionality. In this case history style presentation, PEEK-OPTIMA polymer was selected as the material of choice for a polymer locking device to offer these benefits.

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While osteosynthesis plate and intramedullary (IM) nail systems are proven safe and effective fixation devices, several medical device manufacturers have begun adding polymeric locking devices to these applications to increase safety and improve functionality. By using polymeric locking devices in combination with metal plates and nails, device manufacturers can improve osteosynthesis stability, increase strain absorption, and prevent early failure.While medical device manufacturers have used polyethylene and nylon in these applications, studies indicate PEEK-OPTIMA polymer has shown the most promise when used as a locking device in osteosynthesis and IM nail fracture treatment systems.

ELIX high tibial osteotomy plate with PEEK-OPTIMA inserts. (Photo: Biotech International)

In the early 1980s and ‘90s, the operative fracture treatment was dominated by biological osteosynthesis, which includes techniques such as interlocked IM nailing, distraction osteogenesis, and minimally invasive surgery.
The long practice with conventional bone plates was replaced by more complex systems adapted to the anatomical region rather than just metal parts with holes. These applications allow for a minimally invasive no-touch technique, based on the mechanical principle of a longitudinal carrier which converts axial loads across the bone to compressive forces across fracture sites, minimizing gap and strain.

The screws are stable fixed into plates and the loads are transferred via the angle stable screw to avoid tilting. This technique does not require a direct contact of the plates to the bone surface to give the stability. Conversely, conventional plates require friction on the bone to provide stabilityif they are not pressed against the bone or if the plate does not support the defected side, no stability is provided.
The new osteosynthesis plate systems allow for internal fixation using implanted anatomically preformed angle stable plates and polyaxial screw placements.
Internal fixation has several advantages compared to external fixation devices. They reduce the potential for pin tract infection, are not as difficult for surgeons to assemble, and are less cumbersome for patients.
Consequently, the new locking plate technique gives the necessary stability to the fractured region and promotes greater blood circulation in the fractured area. This leads to a better callus formation and hence, a better fracture healing to the point where a full load can be applied.

range of screw angulations.">
The PEEK-OPTIMA locking device inserts allow up to a 20° range of screw angulations. (Photo: Biotech International)

Locking Plate Technology

The introduction of locking plates triggered a major change in the rationale and approach to fracture fixation. This system allows the use of a covered surgical treatment, where the incision is made distal from the fracture and lends itself well to minimally invasive insertion. The locking plate system merges locking screw technology with conventional plating techniques. It creates a fixed-angle construct in osteopenic or multi-fragmented bone and does not rely on plate-bone compression for stability. It is similar to inserting multiple small angled blade plates and is often referred to as an internal fixator.But there are also potential disadvantages such as cold welding when the screw is over-tightened, as well as screw back-out and screw loosening. To address the problems of screw back-out and loosening, newer designs focused on systems with subsequent locking options.1
There were other challenges as well.
“With past locking devices, screws had to be inserted perpendicular to the plate, because that is how the threads were manufactured,” says Frederic Impellizzeri, vice president, products of Biotech International, talking about small size plating systems. “The screws had to be inserted exactly on the axis of the fixation plate’s thread. Surgeons couldn’t choose the angulations of the insertion. They were very limited.”

To address this scenario, Biotech International was one of the first companies to develop a small size locking device that allowed surgeons to choose the screw angulations, enabling them to determine the best angulation during implantation.

Intramedullary Nailing Systems

New nailing systems have improved design and surgery technique allowing a proximal and distal interlocking to stabilize the fracture from inside of the bone. These IM nails, also known as IM rods, are anatomically formed, which allows an easier approach and reduces the risk of vessel injury. With the introduction of angle stable nailing systems, the interlocking of the nails was improved even in situations with reduced bone quality. To secure the angle stability, specifically in the proximal part, systems like closing screws are necessary.1However there is the problem, specifically in humerus nail systems, of backing-out of the locking screws. This causes painful irritation of the muscle, which may cause patients to stop their shoulder activities in order to facilitate recovery.
To solve the problems of cold welding, screw back-out and screw loosening associated with osteosynthesis plates and intramedullary nailing systems, specific screw heads, thread types, or interlocking devices may be used.

A Viable Material in Locking Devices

Based on the long and successful industrial experience of using polymers to lock screws, it is not a surprise that over the past several years, OEMs have begun using implant-grade polymers in the production of several locking systems for intramedullary nails or osteosynthesis plates. These subsequent polymer locking systems:

- Improve hold strength
- Help avoid screw back-out
- Prevent bone screw disengagement
- Help to prevent screw migration
- Provide angular stable fixation
- Improve axial stability
- Avoid cold welding, which causes revision problems

Several leading orthopedic medical device manufacturers have developed locking devices based on polyethylene, nylon, and PEEK-OPTIMA polymers for their humerus nail systems or osteosynthesis plates.
The ability to be repeatedly sterilized is an important property for locking devices since the correct size is often not known until the procedure is underway and multiple sizes have been exposed to the operating room. Unlike polyethylene or nylon, PEEK-OPTIMA based devices can be repeatedly sterilized, using steam and other conventional methods, without significant degradation of its mechanical, physical, or biocompatible properties.
Biotech International selected PEEK-OPTIMA for the development of three internal fixation devices for use in the hand, knee, and ankle.
“We selected PEEK-OPTIMA polymer for its biocompatibility, strength, and fatigue resistance,” says Impellizzeri. “There are few polymeric materials available with

these characteristics.”
Due to its ability to be repeatedly sterilized as well as its exceptional mechanical properties and biocompatibility, PEEK-OPTIMA has emerged as the material of choice for this application with leading manufacturers.

Advantages of PEEK-OPTIMA Locking Device System

PEEK-OPTIMA polymer, from Invibio Biomaterial Solutions, has gained acceptance across a wide range of implantable applications as a safe biomaterial which offers the combination of excellent strength, stiffness, toughness, chemical and hydrolysis resistance, radiation stability, biocompatibility, and biostability.The advantages of PEEK-OPTIMA polymer include:

- Gamma, steam and EtO sterilization compatibility and resistance to hydrolysis
- Low creep
- Good fatigue strength
- Radiolucentexcellent compatibility with imaging techniques
- Can be tailored to meet radio opaque requirements
- Good buffer function to distribute load
- Proven biocompatibility for long-term implantation

Several in-vitro and in-vivo studies support the use of angular stable locking systems and suggest PEEK-OPTIMA polymer is an advantageous material for designing screw locking devices.
Hntzsch et al reported that in a human cadaveric tibia study using the distal tibial fracture model, they found that an angular stable locking of the bolts with an additional locking option being a sleeve, improved osteosynthesis stability compared to the non-locked version. Specifically when the bone is poor quality, the enhanced stability coming from the additional locking is favorable.2,3
Stedtfeldt et al reported there were no further backing-out issues when PEEK-OPTIMA polymer locking devices in IM nail systems were used.4
Furthermore, Stedtfeldt also reports that PEEK-OPTIMA polymer locking devices provide good strain absorption between the contact lines of the humeral head and the locking screws. Specifically when the bone is weakened by osteoporosis, the need for a buffer to distribute the loads becomes more urgent. While the PEEK-OPTIMA device can reduce stress shielding between the interlocking screws and bone, the loosing of the screws and failure of the fixation can be avoided. Therefore, locking devices made form PEEK-OPTIMA polymer work well as a buffer to strain peaks.4
In addition to the scientific evidence, Impellizzeri offers an additional benefit. “Our PEEK-OPTIMA based fixation devices are in high demand,” he explains. “We’ve seen a 30% increase in sales annually.”

Conclusion

The current osteosynthesis plate and intramedullary nail systems are proven to be safe products but, nevertheless, a subsequent locking option provides further safety, especially in cases of poor bone quality. PEEK-OPTIMA polymer has shown to

be an excellent biomaterial meeting the requirements of such locking systems to prevent early failure of osteosynthesis plate and nail systems. Generally in all systems where screws have to be fixed to prevent loosening of the screw, PEEK-OPTIMA polymer offers a suitable solution to the medical device industry and enables engineers to develop safer systems.

References

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For additional information on the technologies and products discussed in this article, see *MDT* online at www.mdtmag.com [2] and the following websites:
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