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Overcoming Challenges With Metal Cerclage Cables

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In the US, the number of hip and upper extremity fixation procedures are expected to reach approximately 240,000 in 2022 and increase at a CAGR of approximately 7.4% in the coming years [1]. The techniques typically used in these procedures combine rigid plates, cables, and tooling. For decades, metal cables and fixations have been used in spine and trauma corrective surgeries to hold together bone.

Although in many instances metal cerclage cables work well, there are some inherent difficulties with them that need to be tolerated. For example, metal can wear over time and generate small particles that can lead to irritation. Metal cables can also be sharp, especially at the cut ends if they need to be removed, and they are also fairly bulky which can lead to irritation.

Recently, polymer cerclage cables have begun to take market share due to an accumulation of smaller benefits relative to traditional metallic cables. Primary requirements for such cables are typically size, strength, stiffness, and of course biocompatibility, but there are also important secondary considerations. These include but are not limited to cable flexibility, fatigue performance, creep, ease of handling, abrasion resistance, the ability to fix ends of the cable, ease of visualization, operator and patient comfort, and finally ease of surgical procedure.

The Benefits of Dyneema Purity® Fibers

Dyneema Purity® medical-grade ultra-high molecular weight polyethylene (UHMWPE) fiber is very well suited to such cerclage cable applications [2]. Relative to metals, one can expect the following benefits:

- A high tensile strength and modulus relative to commonly used metals. Dyneema Purity® yarn has approximately 4 GPa strength compared with 0.5 to 0.8 GPa of metallic options [9]. This provides the enticing prospect of utilizing a cable of the same size with an increased safety factor [2], or the possibility of a size reduction after considering secondary criteria.
- High tensile stiffness of approximately 120 GPa for the yarn [9], equivalent to stainless steel, providing tactile feedback during tightening and passing.
- Although strong and stiff in tension, UHMWPE is also extremely flexible [3]. This leads to easy passing and conformity to the bone and plate surface.
- No risk metallosis, the build up of metal-metal wear debris [4].
- The absence of sharps when handling during surgery.
- Excellent abrasion performance [5].
- Passing of ISO 10993 requirements for biocompatibility. [9]
- Ability to leverage use of fibers in existing 510(k)s and ongoing clinical trial for decreasing development timelines [6].
- Multiple colors are available for aiding visualization through contrast, allowing observation of relative motion through patterning and identification during surgery.
- Dyneema Purity® Radio-paque fiber provides a choice if visualization in x-ray or under fluoroscopy is desirable. (Example in Figure 1 vs traditional 2 mm Stainless Steel multifilament cerclage).

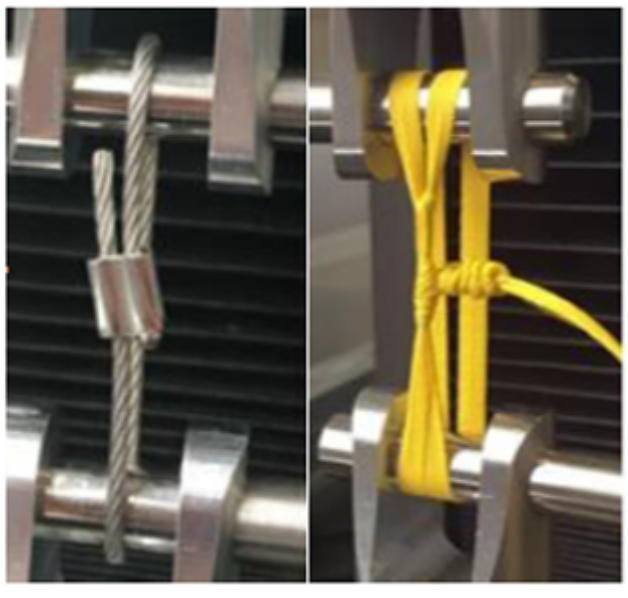

Figure 1: Biomechanical testing of a traditional metallic crimped cable compared with a flat construction of Dyneema Purity® radiopaque fiber.

Design Considerations

With any change in material, this can have additional consequences for the design of such cables, the production method, and use during surgical procedures. Because Dyneema Purity® fibers are supplied as a yarn, they need to be converted into a cable, typically by braiding, but depending on application requirements, this can also be done through other methods. One method of production that is of interest is the use of round-flat-round braiding in medical sutures.

The ends are typically round for initial easy passing, threading, or attachment to other components (such as crimps), whilst the flat section has a lower profile cable for potential improved patient comfort yet still maintains strength and can distribute pressure uniformly over a larger area. A change in cable also allows one to consider a different method of fixation. Traditionally metal cables are fixated by crimping which requires a relatively large fixation or through twisting, where the technique applied is important in determining the long-term stability of the fixation [7]. If considering a round-flat-round polymer cable, there is also potential for a smaller knot profile relative round cables, and depending on design, could be pre-knotted during manufacture to ease surgical procedure.

A change in cable size and material would also mean an update in associated tooling, such as tensioners and passers to tighten and aid in surgical procedures. A known property of Dyneema Purity® fiber is the low coefficient of friction, which is advantageous when passing or sliding knots into position for tightening. However the tensioning system must be designed to accommodate and grip the cable adequately. Another property common in all polymers is relaxation due to their visco-elastic nature. This means that polymeric cables, irrespective of the fixation, once tensioned and fixed, will lose tension with time. For a case of fracture reduction, this is important as the cable must maintain pressure between healing surfaces above a required threshold. An effective design solution to increase pressure between healing surfaces, for example, has been looping the same cable an additional time [8]. To approximate relaxation behavior, which is specific to the type of polymer utilized, DSM Biomedical has developed a visco-elastic model to estimate such behavior of Dyneema Purity® fiber to aid in design.

In conclusion, Dyneema Purity® fiber is a suitable material to consider for cerclage options and has potential for an accumulation of smaller benefits relative to older, metallic cables. It can provide the mechanical performance required with better flexibility and conformity, an option on radio-opacity, mitigates risks such as the generation of metal wear debris and exposure to sharps during surgery, and provides the possibility for using a round-flat-round construction to minimize suture profile. For more information on the benefits of Dyneema Purity® fibers, please contact Albert or Mark directly at the address below.

About the authors

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