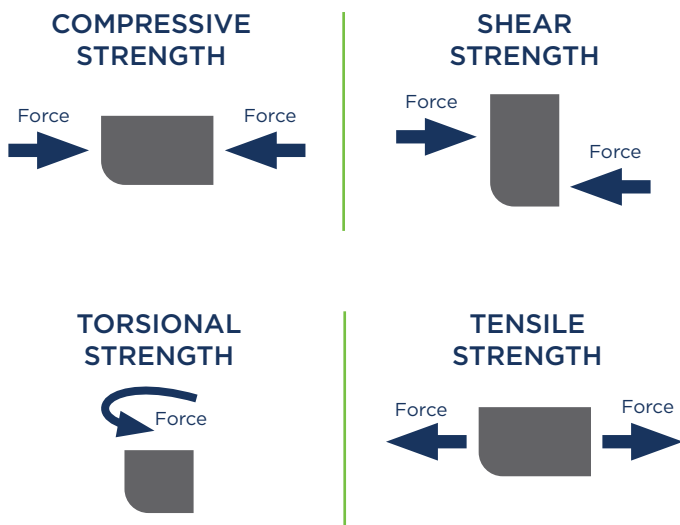


A CONVERSATION ABOUT THE “STRENGTH” OF VALKYRIE™ PEEK PLATES

Strength will certainly be a question you face as you present Valkyrie to customers. It is a legitimate question and makes perfect sense to ask! The fact of the matter is, PEEK may be the ideal material to use for a plate on the sternum. Let's talk about why.

First, when talking about strength, we need to establish what type of forces the plates, screws and sternum are subjected to. Here are some examples of the types of forces or loads that a material may experience (Figure 1). Materials are strong in different ways.

FIGURE 1



These illustrations show the types of forces exerted on the sternum and plating systems.

When comparing the different types of forces as they apply to the sternum, we can conclude that the compressive and torsional strength of a material are both irrelevant in this application. Shear? Maybe a little bit but it is definitely not the primary load.

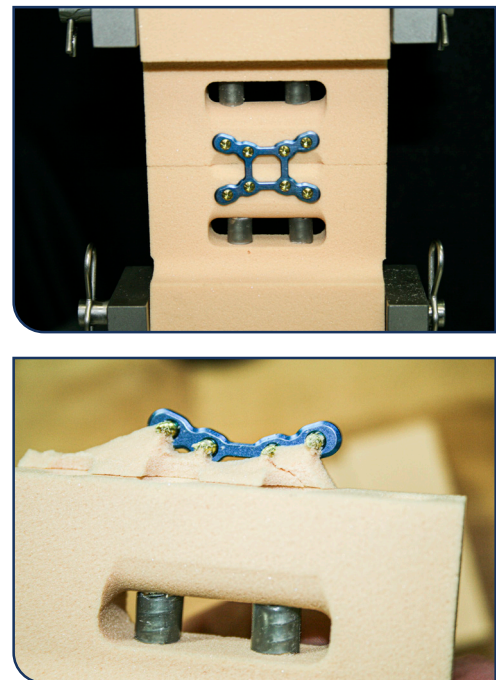
Tensile strength is a pulling or separating load and is the type of force we need to be most concerned with. Tensile strength is measured by the maximum amount of force that can be applied to a material before experiencing cross sectional failure (in our example the plate breaks). This can be measured in a couple different ways... static load (ultimate yield strength), or dynamic load (fatigue strength).

How do we test tensile strength? In static form, this is a very simple test. We create a fixture on the test machine that isolates the plate material and set the machine to increase the force until failure is achieved. We isolate the plate by driving the screws into a material that is much stronger than the plate so that we are measuring the strength of the material rather than the strength of the substrate.

Is this type of test relevant in a clinical setting? Not really and here is why:

We know that a sternal closure can only be as strong as its weakest link so what happens when we pull to failure using a simulated bone substrate like sawbone foam (Figure 2)?

FIGURE 2

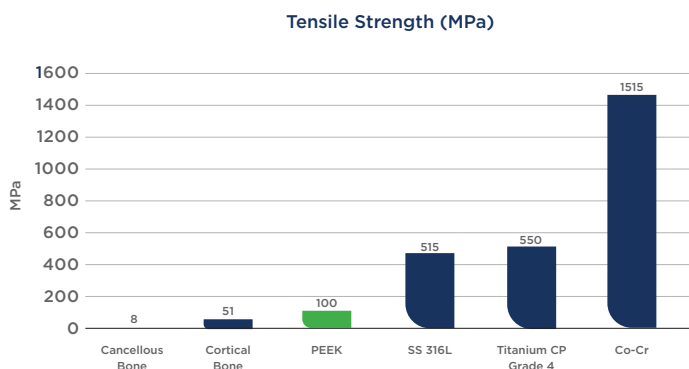


As you can see, the foam fails. Theoretically, bone would break before a plate would. Has there ever been an issue with a sternal plate NOT being strong enough for use on a sternum? Plate breakage would be a very rare (if not unheard of) mode of failure in a clinical setting. The sternum is a very low density, fairly flexible bone with a low percentage of cortical bone in comparison to cancellous bone. A PEEK plate and screw construct does not need to be stronger than metal.... It needs to be stronger than the adjacent bone.

Stronger is better, right? Not necessarily. If a material is too stiff for a specific application that extra strength can start to become a negative. An important material characteristic to take into consideration is the modulus of elasticity which quantifies a material's resistance to non-permanent (elastic) deformation (flex). Examples of permanent deformation would be ductile deformation (a permanent bend) or fracture (breakage). As mentioned, the sternum is actually somewhat flexible, and when one attaches an extremely rigid stiff plate. It creates what is called a "stress riser"; which is a location where stress is significantly greater than the surrounding area. A stress riser can transfer force to the weaker component (bone) and can actually be the CAUSE of bone failure. PEEK has a modulus of elasticity very similar to bone and translates less stress to the surrounding bone (load-SHARING rather than load-BEARING).

FIGURE 3

AVERAGE ANISOTROPIC VALUES FOR TRANSVERSE LOADING OF BONES



This graph illustrates that PEEK's average tensile strength is greater than the surrounding bone. Illustrating bone will fail before the PEEK plate does.

Is the tensile strength of a material even important then? To a certain degree, yes. The material should be stronger than the bone, but whether it is twice as strong, 10 times as strong, or 50 times as strong, it makes no difference. All are strong enough (as illustrated in Figure 3). Luckily, there is a much more applicable test to predict resistance to failure: fatigue.

Material fatigue is a phenomenon where structures fail when subjected to a cyclic load over time. After a sternal closure, the sternum will be subjected to continuous fatigue forces during the 6-to-8-week healing period before the osteotomy fuses completely. Every movement and every breath will contribute to material fatigue, and that material can be the bone, the screws, or the plate. All three are affected.

Most comparison testing is performed on a V-Plate since it is the minimum size plate used for sternal closure. Any other plate option would be stronger, so the V-Plate is considered "worst case." When performing fatigue tests using various materials and closure methods, we found regardless of whether a single V-Plate is made of metal or PEEK, it is between 2-3 times stronger than two single loops of wire.

When testing plates for fatigue, rather than increasing force to obtain breakage, the force remains constant and is continuously cycled for a set number of "pulls." The current standard is 2.2 million cycles. If the plate/screw construct survives the number of cycles without failure, it is said to have "cycled out" under that particular amount of force. The test would then be repeated at a higher value. When breakage occurs, we drop back down to the highest force that passed, and that value becomes the minimum acceptance criteria and is often submitted in FDA filings. Literature shows that a metal V-Plate will cycle out at a force of 200 newtons (N). When performing our equivalence testing on Valkyrie, we were able to establish our minimal acceptance criteria at 270N; about a 35% increase in fatigue than a similar metal plate.

CONCLUSION

Here are the key takeaways you should remember:

- PEEK is strong enough to resist the separation forces the sternum will experience. Bone will fail before the PEEK plate does.
- PEEK has an ideal modulus of elasticity to match that of bone. This makes the surrounding bone load-sharing and not load-bearing.
- PEEK performs extremely well in fatigue. A 35% increase in overall minimal acceptance criteria.

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- FIGURE 3:
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