Level 3 Industrial Case Study

Suture Anchor Implant

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Summary

Granta EduPack provides a rational and systematic approach to materials selection which is invaluable to engineering and design. It also clearly shows the steps in this process for the purposes of teaching and training. The available databases enable informed material choices in many specialized areas. Here, we focus on selecting materials for a *biomedical implant*, to show how the methodology can be used in the field of bioengineering.

Biomedical materials have to adhere to a strict set of criteria due to their interaction with biological systems. They have to exhibit biocompatibility, either chemical inertness or biodegradability, and mechanical properties that suit the biological host. Due to the immensely complex biological environment to which biomedical materials are subjected, particularly implantable devices, it is costly, time consuming and difficult to test a large range of potential candidates. This makes accurate data and reliable selection methodology very useful.

In this advanced case study, we have investigated candidate materials for a suture anchor implant, to be fixed in bone tissue and to hold soft tissue in place, via sutures, during healing. The objective is to minimize cost under a set of constraints typical for biomedical implants. The selection procedure is described in detail and the result is related to an industry-approved suture anchor made from Polyetheretherketone, PEEK.

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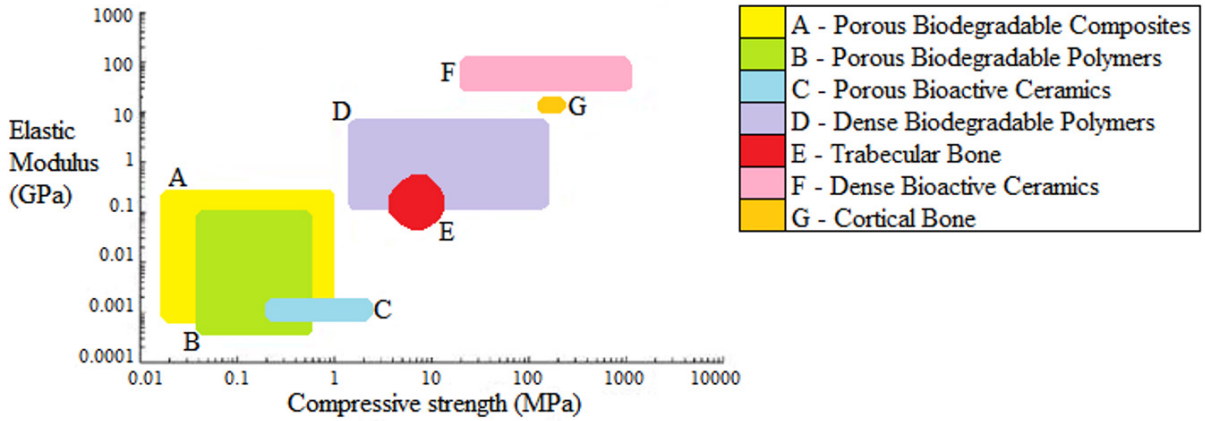
1. What is the scope?

Bioengineering relates to a range of cross-disciplinary fields, such as biomechanics, tissue engineering and biomaterials. One important application is implantable devices for use in humans, which have to work reliably in the body in order to avoid complications and unnecessary operations. They should either last as long as possible, or degrade internally at a reliable controlled rate. In addition to the mechanical performance, cost is usually important, and the implants should be biocompatible, as well as either bio-inert or bioresorbable, and they should be approved for use in the human body.

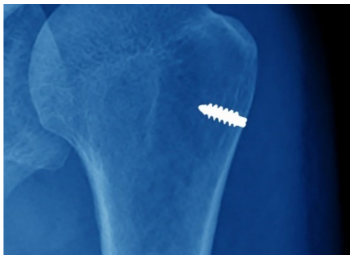
A widely used material for hip replacements and dental implants is Titanium. This and some other established metal alloys have a number of desirable properties, such as biocompatibility, and are now routinely used in surgery. There are, however, drawbacks in using metals in bone tissue engineering. Metals are significantly stiffer and harder than bone, which may cause problems and damage to the surrounding bone tissue. The underlying biomechanical properties of bone are critical to implant function *in vivo*. This is one of the reasons that high performance polymers have been developed as implant materials. Polymers, such as PEEK, have shown better mechanical compatibility with bone for applications that don't require metallic strength.



Comparison of mechanical properties for a variety of biomaterials including polymers and bone [1]

Despite high material cost, PEEK is being widely used in commercial implants, such as suture anchors to be fixed in cortical bone for surgeries including rotator cuff and anterior cruciate ligaments repair. In this case study, we set out to investigate alternative materials for this application with considerably lower cost, as this is an increasing concern [2] in medical implant technologies. Our objective is to minimize cost under mechanical and typical biomedical constraints. Also, it is of interest to find suitable biodegradable polymers, but only if the mechanical performance in terms of the design requirements is not compromised.

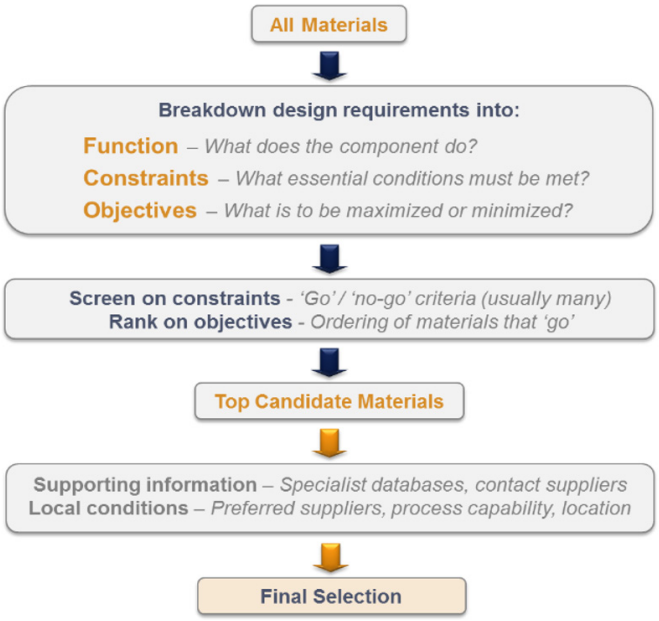
The choice of PEEK as a reference material, was inspired by a commercially available suture anchor implant.



RoG Sports Medicine Suture Anchor Implant developed using ZenivaTM PEEK material manufactured by Solvay [3-4]

2. How to tackle the problem

Granta EduPack provides a systematic approach based on the work of Professor Mike Ashby [5]. This can easily be applied to biomedical materials, since this is one of several provided subsets within the bioengineering database. You can identify materials that meet your bioengineering design requirements and study top-ranking alternatives against an objective or the trade-off between two objectives. This enables an informed material choice based on the widest range of available information, while maintaining traceability to facilitate critical discussions about decisions. Below is a schematic description of a typical selection process.



In this case study, the PEEK implant constitutes a fixed volume situation. A typical derivation of a performance index based on mechanical properties uses a limiting constraint to eliminate a *free design parameter*. This is necessary in order to enable a free choice of material. Since there is no such free design parameter in this case (due to fixed geometry), we cannot derive a conventional mechanical performance index. The choice of objective in our case will therefore be simply to *minimize the cost per volume*. This will be combined with constraints regarding mechanical performance, such as the stiffness and yield strength.

3. Using Granta EduPack to perform materials selection

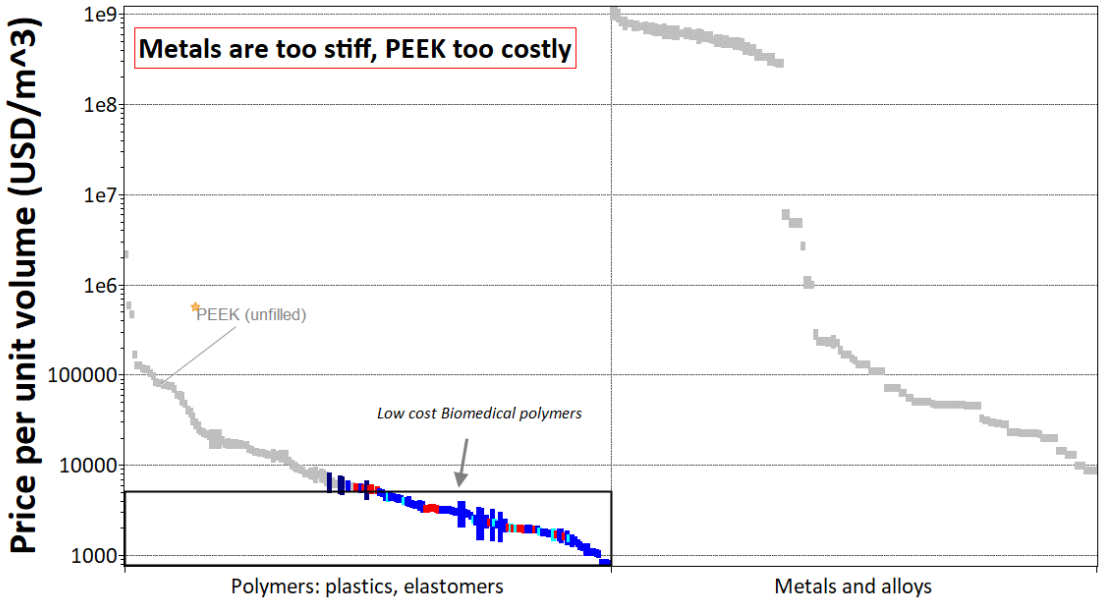
The basis for the selection is the Bioengineering Level 3 database of the Granta EduPack, containing data records for over 4000 engineering materials. We can immediately limit the number of candidates by using the subset of biomedical materials, and by considering only unfilled thermoplastic grades. This results in around 100 eligible material records in the selection. Fillers and reinforcements or biocomposites can be considered at a later stage and is touched upon in the discussion.

Function:

The function of a suture anchor is to aid in re-attachment or fixing of soft tissue to bone. The implant is threaded so it screws into pre-drilled holes in the bone, thus anchoring the suture that facilitates reuniting the soft tissue and bone.

Objective:

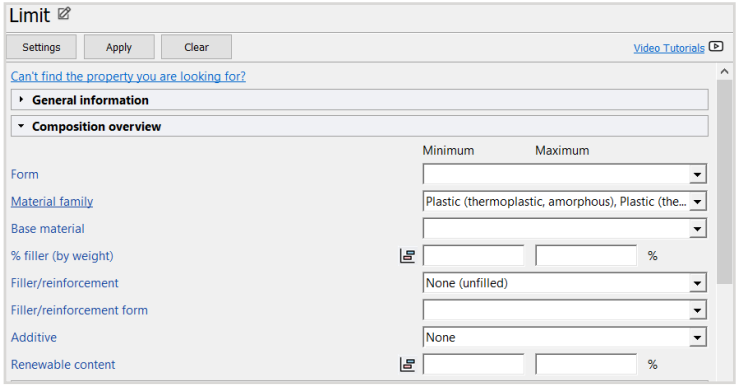
In this case, the objective can be plotted at first. Here the objective is to minimize *Price per volume*, which we can define as the y-axis of a chart (or *Price * Density* using the *Advanced + Attributes* feature). As can be seen in the figure below, PEEK (marked with a *Favorite* star by right-clicking) is at the high-cost end of the price spectrum for polymers. If lower-cost polymers are desired, these can easily be box selected, after plotting a bar chart of biomedical grade materials. Dividing them up along the x-axis into polymers and metals for comparison, using the *Advanced + Trees* function, makes it easy to find polymers that are cheaper than metals (traditional implants). A good starting point for the selection is to place around 100 of these low-cost biomedical polymers in the box selection, which in this case will result in materials cheaper than the metals per volume.



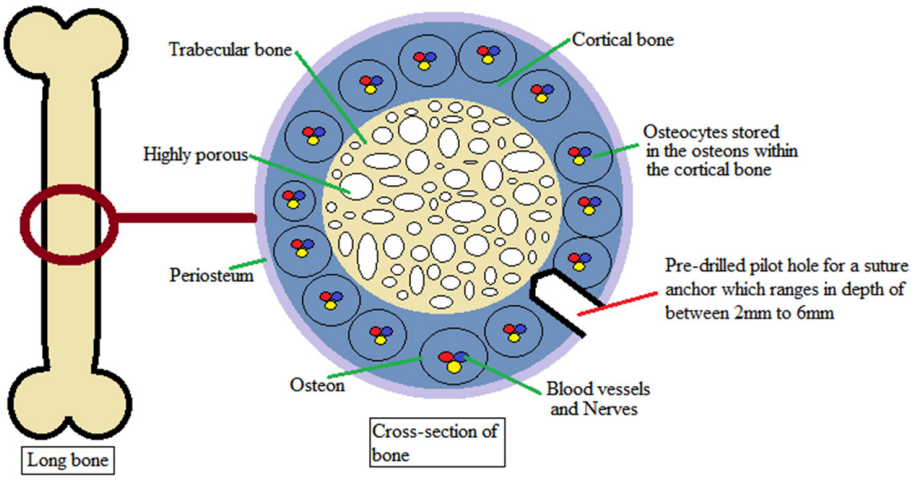
A good starting point for this selection is a group of ~100 polymers from the Biomedical subset.

Constraints:

In the Granta EduPack software, we now start the screening of biocompatible polymers using the constraints. This will constitute the main part of the selection. The bioengineering database allows screening in the limit stage based on composition and bio subsets. Here, we limit our selection to unfilled thermoplastics (both semi-crystalline and amorphous) without additives, as shown to the right.

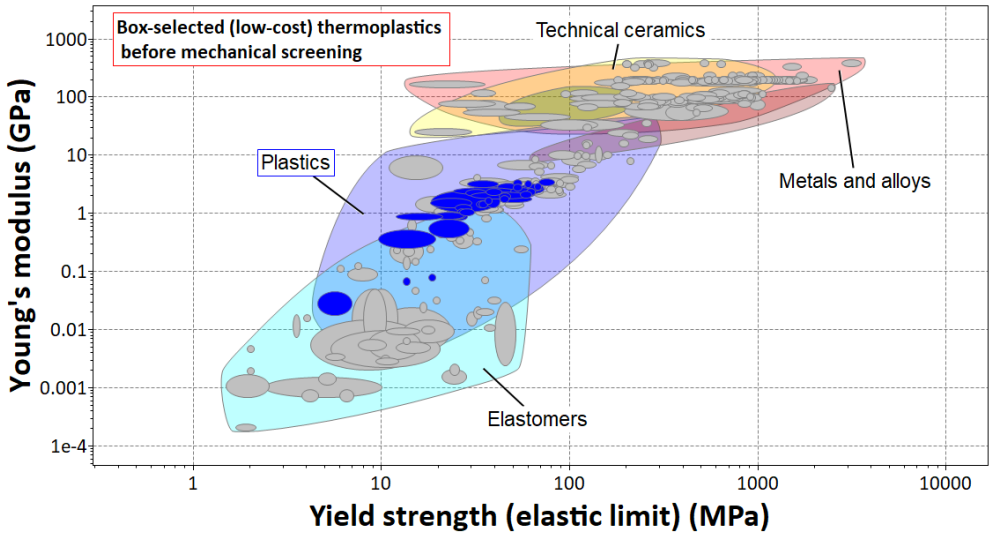


In order to avoid the problems of metal implants being too stiff (stress shielding), we limit Young's modulus to a value lower than a typical human cortical bone in the region where the implant should function, see below. Of course, the material needs to be stiff enough to allow being inserted into position via the pre-drilled hole, which can also be specified in a limit stage during screening of materials (3 < *Young's modulus* [GPa] < 10).

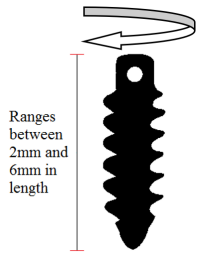


Schematic diagram of the cross section of an adult human bone showing the complex structure in detail [6-7]

The other mechanical properties that need to be considered during screening is *yield strength* (to support tensile stress from the suture as well as stress during the insertion procedure) and *fracture toughness*, to avoid brittle fracture *in vivo*. In the chart below, it can be seen that the reference material, Unfilled PEEK, performs "better" in comparison with the low-cost biomedical polymers from the previous selection.



It is possible to label the reference material, unfilled PEEK, which was screened out by the initial box-selection, using the Favorite function in EduPack. Here, it compares well mechanically with other polymers.

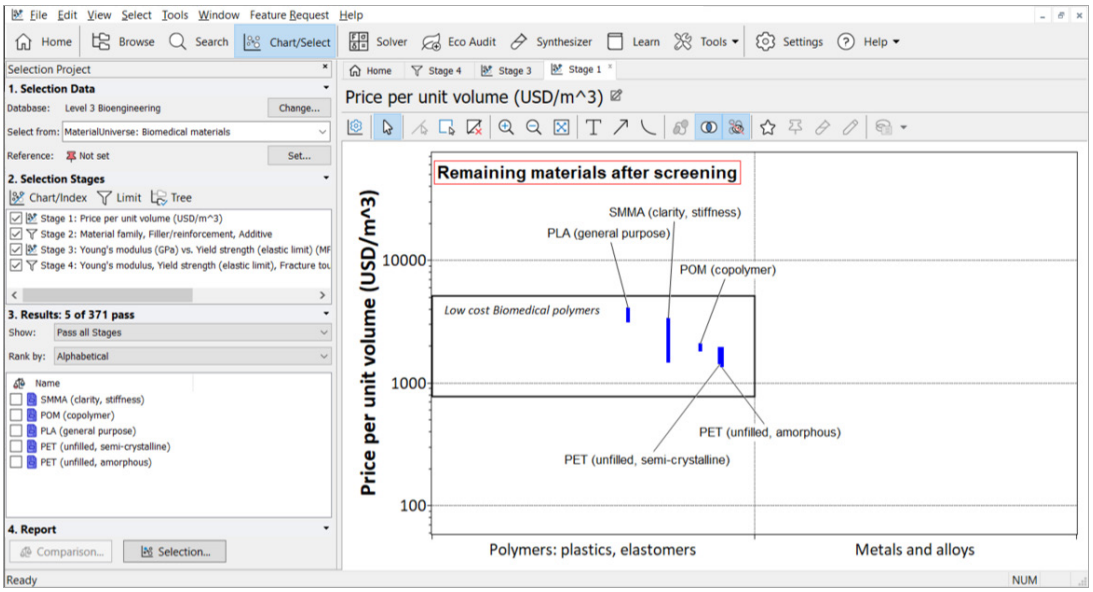


Summary of applied constraints:

- Unfilled Thermoplastics, no additive
- Young's modulus: Min 3 GPa and Max 10 GPa (Cortical bone)
- Adequate yield strength: Min 50 MPa (for application)
- Fracture toughness Min 4 MPam^0.5
- Max Service temperature: Min 40°C
- Excellent/Acceptable resistant to: water

Result:

The resulting chart after completing screening is shown below. The screenshot also shows the values of the objective function for the five best candidates in the ranked list. If this objective (see also first chart) is considered, the two forms of Polyethylene terephtalate, PET, are the cheapest alternatives. They suffer from poor sterilizability in dry heat/steam though, which is a disadvantage. Even the most costly of these five materials, Styrene methyl methacrylate, SMMA, is around 30 times cheaper per volume than PEEK in this comparison. Both PET and SMMA (*e.g.*, under the trade name NAS® 30) are indeed materials used for implants [8-9] and would be plausible candidates to replace PEEK. Two very interesting alternatives would be Polyoxymethylene, POM (copolymer), for a permanent option and Polylactide, PLA, for a degradable option. In addition to being cost effective and its current use in suture anchors, PLA is a biodegradable polymer, which is a desirable property for short term treatments.



Screenshot of the final stage of the selection, when 5 candidates remain after screening

POM was dismissed as an option for bone contact applications due to its bio-inertness and the lack of interaction with bone, back in 1993 [10]. Since then it has been used for a range of medical devices, such as replacement heart valves and catheters [11]. Due to its lack of interaction with bone, the concern is that the suture anchor could slip in its pre-drilled hole, leading to complications where the suture anchor has to be replaced or re-inserted [10, 12]. This is something that also has to be considered for PET and SMMA. If POM was chosen as a new suture anchor material, it would need to be formed into a bio-composite or coated with a material that would encourage bone bonding, such as Hydroxyapatite (HA) or Bioglass® [7]. This would promote bone formation and fix the suture anchor. Composites of bio-inert polymers and materials that encourage bone interaction are currently being explored for future [13].

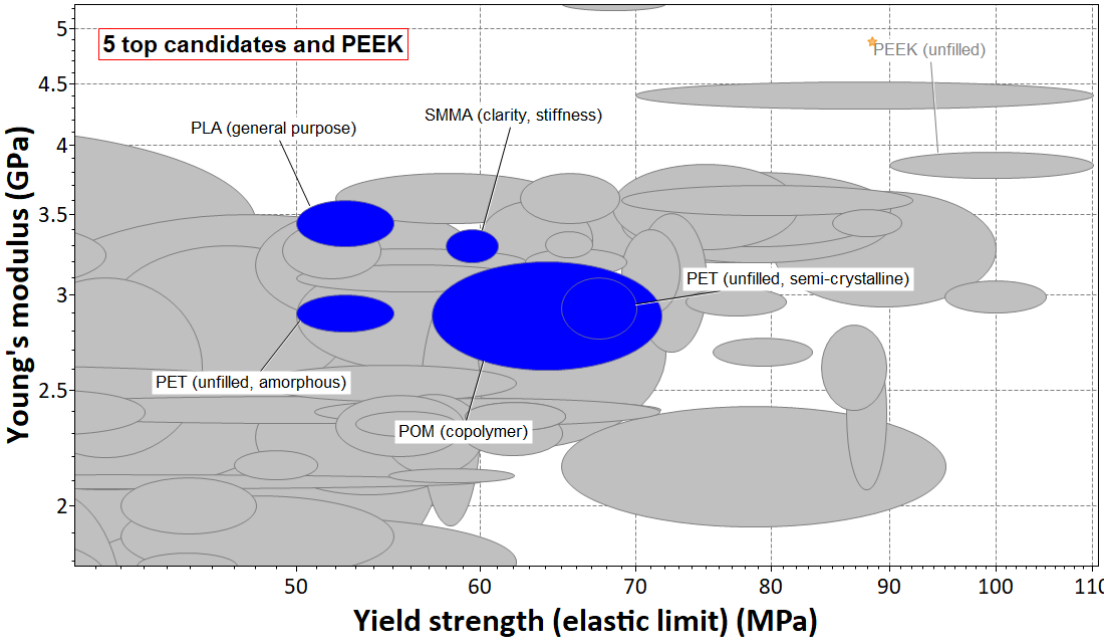
PLA has a long degradation time, in the region of 12 to 24 months, which means it can be used for short-term treatments where the anchor is not permanent [14]. In this situation, the degradation rate should match the bone formation rate in order for the hole that is left behind to be filled [15]. For an adult human, this process takes three to six months [1]. One option would be to increase the degradation rate of the polymer but this would reduce the mechanical stability leading to a greater probability of failure. Another option would be to encourage bone bonding with the implant so that, as the implant degrades, the space left behind is filled with new bone. This can be done by introducing

materials, as mentioned above, that encourage this bone formation [7]. Bio-composites such as PLA/HA [16-17] are already being used as alternatives to a permanent suture anchor. It has mechanical properties that make it suitable whilst having the ability to degrade away.

4. Analysis and reality check

Suture anchors come in a range of sizes and variable diameters to help the surgeon to accommodate a patient's natural anatomy and the type of surgery being performed. The implants are widely used in many parts of the body where soft tissue and bone have been separated, resulting in pain and loss of mobility. With an aging population and more active lifestyles, there is a growing demand for these procedures and for lower cost. Biomedical polymers offer advantages over metals such as titanium for these implantable devices. In addition to biocompatibility and chemical inertness, they have a modulus of elasticity that is closer to that of bone. PEEK and other polymers are also totally radiolucent enabling the surgeon to clearly see the bone/soft tissue interface on x-rays without the shadows and opacity of titanium.

RôG (pronounced Rogue) Sports Medicine Inc., based in Illinois, USA has received 510(k) clearance from the U.S. Food & Drug Administration (FDA) for its RôG Suture Anchor [2-3] made of Zeniva® polyetheretherketone (PEEK) resin from Solvay Advanced Polymers [18]. This biomaterial, used as a reference in this case study, has a modulus very close to that of bone plus excellent toughness and fatigue resistance. These suture anchors are made from 6-mm diameter PEEK rod stock and are threaded to screw into bone, thus securing the soft tissue to the prepared bone surface so that the soft tissue and bone re-unite. In this case study, five polymers meet the constraints that were used and perform well in the objective of minimizing cost. They do, however, in comparison to PEEK have slightly lower values for the mechanical parameters used in this study, shown below.



The values are some 30% less than those of PEEK, and it must be confirmed that this will not impede the performance in the application. These values are still higher than, for example ABS that is used for LEGO and other robust toy products, as a comparison. The values used in the constraints in this case study are chosen to be realistic but do not reflect actual test data requirements.

5. What does Granta EduPack bring to the understanding?

Granta EduPack produces quantitative and highly visual results interactively which, combined with the materials expertise of an educator, can help to teach the design process and how to make good materials decisions.

In this case study, Granta EduPack suggests the following conclusions:

- The Bioengineering database has a large number of specialized materials and data organized into useful subsets, as demonstrated for biomedical materials.
- The systematic selection methodology allows design requirements typical of bioengineering to be used for screening. The Bioengineering database also allows screening in the limit stage based on composition and bio subsets, for example unfilled biomedical thermoplastics.
- An actual PEEK implant can be used as a reference material, using the *Favorite* function, and then easily be compared with candidate materials and used as benchmark for improvements
- When fillers, reinforcements and modifiers are considered, these records in the database can be used to refine the properties towards final selection

The MaterialUniverse Bioengineering database used so far provides generic material property data, enabling identification of the best materials options from the full range of possibilities. The next step may be to use a specialized database, such as Global Polymers database available in Granta Selector, or the ASM Medical Materials database, available via Granta EduPack for those that have a subscription with ASM. These give more detailed information about specific polymer grades and niche bio-composites which can be explored as a more advanced extension to this case study.

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