Level 3 Industrial Case Study

Biomaterials Selection for a Joint Replacement

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Summary

The Bioengineering database of Granta EduPack offers the possibility to compare and select materials for various medical implants. We can draw on our experience in applying tools, both for teaching bioengineering students and for making materials decisions in the biomedical field.

In this advanced industrial case study, we explore how Granta EduPack can be used to identify and assess the optimum materials for a total hip replacement – with a specific look at the roles of the main material classes in the implant. Metal alloys for structural integrity, ceramics for minimizing wear in the articulating surfaces or polymers as a lightweight alternative. All under the constraints of biocompatibility. To add realism, we explore the ASM Medical Materials Database™ which contains over 60,000 approved medical devices.

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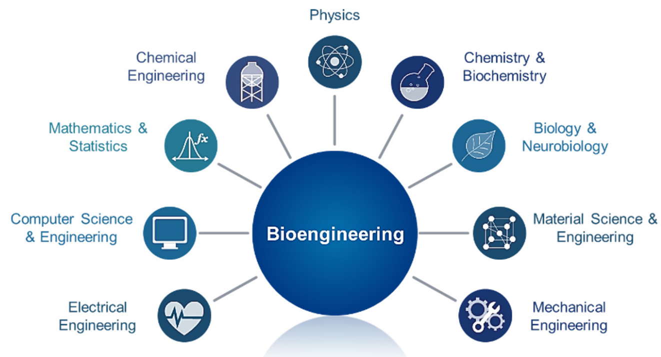
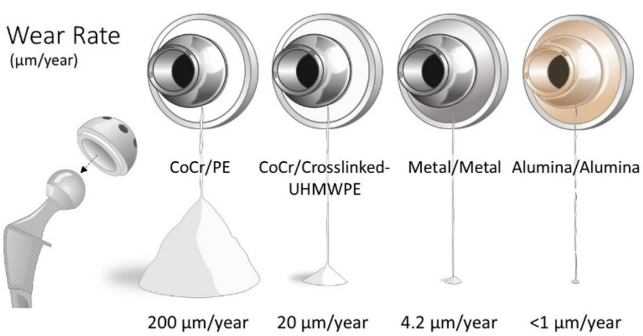
1. What is the scope?

Bioengineering, also known as biomedical engineering, refers to the field of study that merges biology and engineering. This unique, interdisciplinary field allows you to cover a wide range of subjects, where you use an in-depth understanding of engineering to solve medical and biological problems. Bioengineering overlaps with many other academic disciplines, for example:

- **Physics, Chemistry & Biology:** Nanotechnology, Biophysics, Materials chemistry, Surface science
- **Mechanical Engineering:** Biomechanics and Prosthetics
- **Materials Science & Engineering:** Biomimetics, Biomaterials, Materials characterisation, Hybrids & Composites



Biomaterials, synthetic as well as natural ones, are designed to be in contact with and interact with a biological system, such as the human body. The study of such materials can be called *biomaterials science* or *biomaterials engineering*, depending on focus. The area has grown considerably over the past 50 years, both in research and in higher education. In this advanced industrial case study, we have chosen to focus on biomaterial properties relating to implants—in particular joint replacements—and aspects of material selection.



Implants constitute an important application of bioengineering and offer engaging examples of biomaterials. They are designed to either replace, support or enhance an existing biological part. In an aging population, where more people have an active lifestyle, there is an increasing need to develop implants, such as hip replacements, that have greater longevity. On average, a Total Hip Replacement (THR) has a service life of 15 years [1]. For patients receiving the treatment aged 55-60, for example, there is a high chance that a secondary procedure will be required.

THR surgery is one of the most common medical procedures and it is estimated that approximately one million hip replacements are carried out per year [2]. There is a rich history of materials that have been used, with the earliest record said to date back to the late 1800s [3]. Examples include ivory femoral heads, glass articulating surfaces and more recently, metals and polymers. Sir John Charnley, sometimes called the *father of modern THR,* designed a low friction arthroplasty in the early 1960s, which principles still remain today. It consists of three main parts: 1) femoral stem, 2) femoral head, and 3) acetabular component. Parts 2-3 constitute the mutually mobile parts of the joint.

For devices integrated within the human body, *biocompatibility* is of course a design essential. This can be defined as the ability of a material to cause an appropriate biological response for a given application in the body [4]. Whereas earlier definitions of the term focused simply on the non-toxic response of the material, revised biocompatibility definitions also acknowledge that a material must be able to perform the correct function. Therefore, orthopedic implants must have sufficient structural integrity but should, ideally, also have similar mechanical and physical properties to that of bone to avoid complications, such as *stress shielding*.

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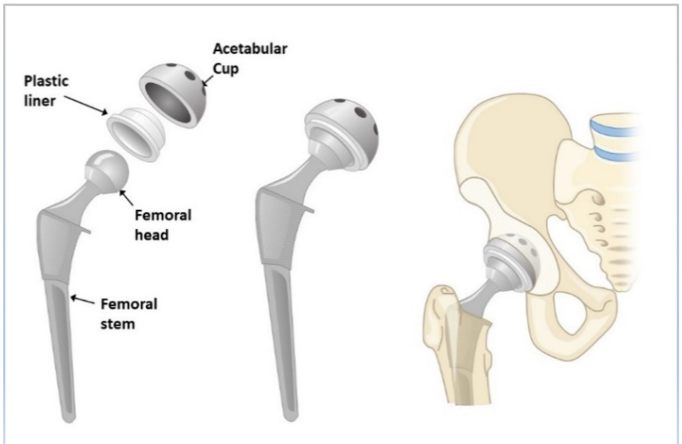


The most common type of THR currently used is metal-on-polyethylene. With an elastic modulus almost half that of steel, titanium-alloys (Ti-6Al-4V) have become the material of choice for most femoral implants. Ceramics are good for increased wear resistance in mobile parts while polymers are cheaper, lighter and easier to manufacture.

This case study makes use of the advanced Bioengineering database of Granta EduPack and its capability to simultaneously give information on both biological materials (tissue) and engineering materials, such as biomaterials for implants.

2. What can Granta EduPack do?

Granta EduPack has relevant data for biomaterials, both at Level 2 and Level 3. Whereas the former is less overwhelming to students and suitable for learning about material properties and selection, the latter contains a full range of alloys and grades to provide data for realistic projects in bioengineering. The Bioengineering Level 2 database is, however, extended with bio-related materials. This more than doubles the number of the basic Level 2 MaterialUniverse, resulting in 260 datasheets. One important detour from conventional terminology is that the subset of biomaterials (around 160 of them) are defined as *all bio-related subsets* in this database, as described in the *Science Note* to the right.

Biomaterial

Biomaterials - All:

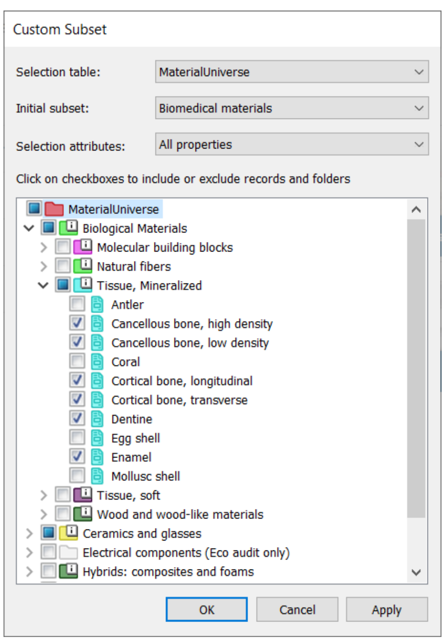
Indicates that the material is a biomaterial - a blanket term used in MaterialUniverse to mean biological, natural, bio-derived, bio-inspired and bio-medical materials.

Biological & natural materials:
Indicates that the material is produced by biological systems, including both plants and animals. Thus skin, bone, wood, shell, hair are biological materials.

Bio-derived materials:
Indicates that the material uses natural biological sources as the raw materials for its production. Thus bio-polymers, paper, plywood, twine and rope are bio-derived materials.

Bio-derived polymers:
Indicates that the polymer uses renewable sources as the raw materials for its production, rather than the more typical petroleum-based polymers.
Common sources for bio-polymers include plant starch from corn, wheat, sugar beets or sugar cane.

Biomedical materials:
Indicates that the material is used in medical applications, such as implants to replace or support body parts, medical devices, and also materials synthesised for tissue engineering.
They must be compatible with the human body and be manufactured under clean conditions.
Thus bio-glass, alumina bio-ceramics, titanium grade F67(B652), silver amalgam, and ultra-high molecular weight polyethylene (UHMWPE) are bio-medical materials.



One great feature of the Bioengineering databases is that they allow for property charts which simultaneously include both engineering materials and bio-related materials, such as human tissue and biomaterials (in the conventional sense, meaning materials designed to interact with biological systems). For the purpose of this case study, dealing with implants, the subset of *Biomedical materials* can be used to represent suitable candidates. An overview chart can easily be created which covers most relevant biomaterials, without applying constraints such as durability in water, etc. In Level 2, this also includes the most relevant human mineralized tissues, as shown to the left.

The *Bioengineering Level 3* database of Granta EduPack contains data records for over 4000 materials. Using this as the advanced selection platform for a hip replacement—both the femoral stem, head and the liner—a custom subset of biomedical materials can be created. In this case, it is necessary to manually add *Human bones* to the subset in order to have a comparative overview of both the implant material and the tissue it will replace and attach to.

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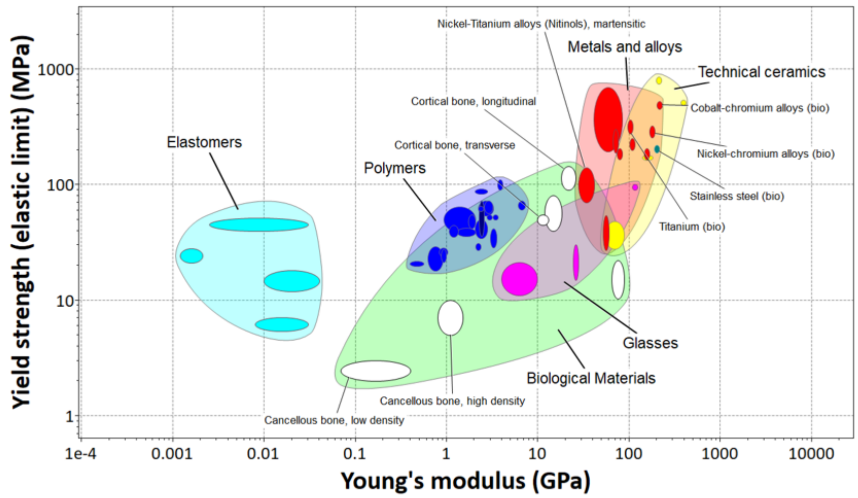
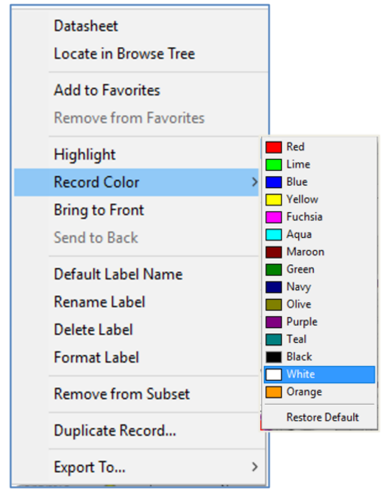
The biomedical materials at Level 2, with bone records highlighted in white, shows that bone tissues span a wide range of mechanical properties. The metal alloys are generally both stiffer and stronger than the Femur. The same applies to ceramics, that might be used for the top parts of the joint, primarily loaded in compression. The polymers tend to match cortical bones in strength but are closer to cancellous bones in stiffness.

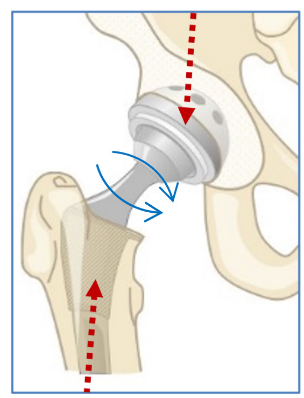




3. Using Granta EduPack Level 3 to select biomaterials

In order to follow the Ashby systematic selection methodology, we start with all *Biomedical materials*, then filter out unsuitable materials with additional screening, and finally consider one or more performance indices for ranking. The *Function* of the implant is to replace the original hip joint in sustaining load and wear arising from the weight and movements of the body. This can be divided into two parts:

Function 1 (stem) – sustain compressive load from external forces (red dashed arrows) resulting also in shear and bending (illustrated schematically by blue arrows) of the femoral stem. Strength-limited design was assumed.



Constraints for the stem:

- Biomedical material
- Stiffness and strength not less than those of cortical bone
- Fracture toughness so to avoid fast fracture (>11 MPa*m^0.5)
- Unfilled grade + Non-magnetic + Bulk material

Objectives for the stem:

- Maximize specific strength
- Minimize cost

Function 2 (head) – sustain compressive load and wear at the femoral head and liner/acetabular cup.

Constraints for the head:

- Consider only the *Joint replacement* materials of the *Healthcare applications*

Objectives for the head:

- Maximize compressive strength
- Minimize wear (blunt abrasion)

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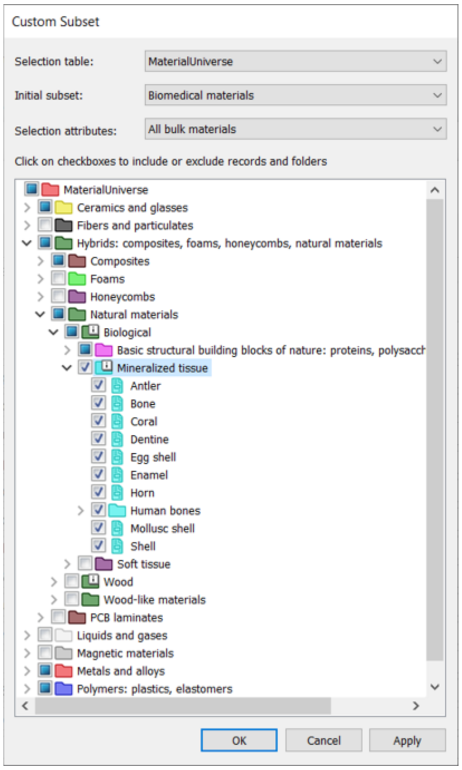
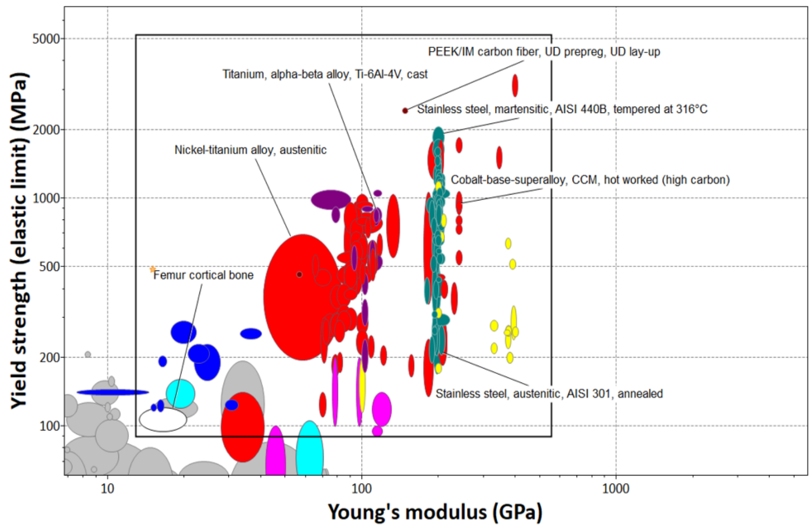
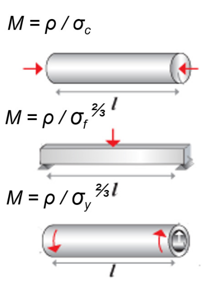
The femoral stem



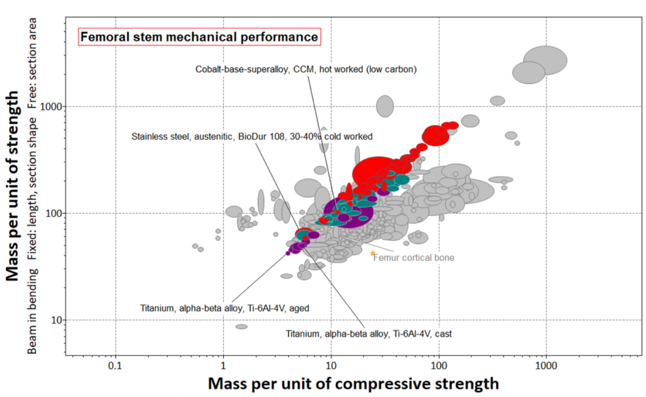
The Custom subset of *Biomedical materials* at Level 3 is modified by adding all *Mineralized tissue*. The *Human bones* records are changed to white and added to favourites by right-clicking. Since the stem cannot have a yield strength or elastic modulus lower than cortical bone, these constraints are added by a box selection, positioned so that materials with values above the *Femur cortical bone* properties are included. Fracture toughness and other constraints can be added in a Limit stage.





The decision to use *specific strength* as the primary objective can be justified by considering the performance index for minimization of a strength-limited design of a column in compressive load: $M = \rho / \sigma_c$. This can be plotted on, for example, the X-axis using the Performance Index Finder of the Chart stage. Moreover, for the flexural (bending) load: $M = \rho / \sigma_f{}^{2/3}$ or torsional load: $M = \rho / \sigma_y{}^{2/3}$, we can plot a complementary index on the other, Y-axis (bubble chart below).

It is well known that the compressive strength is significantly higher than the tensile or yield strength for most materials. The flexural strength, however, is generally very similar to the yield strength, so the plotted flexural performance index can represent both loads. As shown below, the performance ranking of relevant materials, such as Titanium or stainless steel, is consistent for all main types of loading (compression, bending, torsion). Here. Ti-6Al-4V alloys, austenitic stainless steels and cobolt chromium alloys are performing the best.



The way we screened for austenitic grades, was to filter on magnetic properties in the Limit stage. Non-magnetic grades were selected in the drop-down menu for *Magnetic type*. In implants, austenitic stainless steels are used, rather than martensitic, partly due to:

- Better corrosion resistance
- Better fraction toughness
- Hardness better matched to bone
- Non-magnetic (for MRI etc)

The austenitic stainless steels are, largely, matched in performance by cobalt chromium alloys, which are historically the most used material for hip replacement implants.

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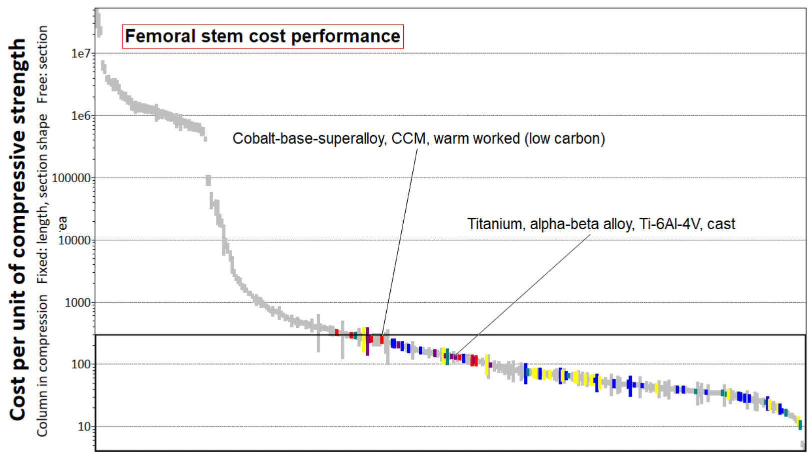
For the second objective, to minimize cost, we can plot the cost performance: $M = c_m * \rho / \sigma c$ on the Y axis (bar chart below). This gives the fairest comparison between materials of different types. Whereas Ti-6Al-4V was the best in mechanical performance, as shown previously, stainless steels appear best in cost performance. They are also easy to manufacture. Unrealistic options, such as gold can be excluded by a box selection if desired. We have used an arbitrary upper limit of around 300 in our example.

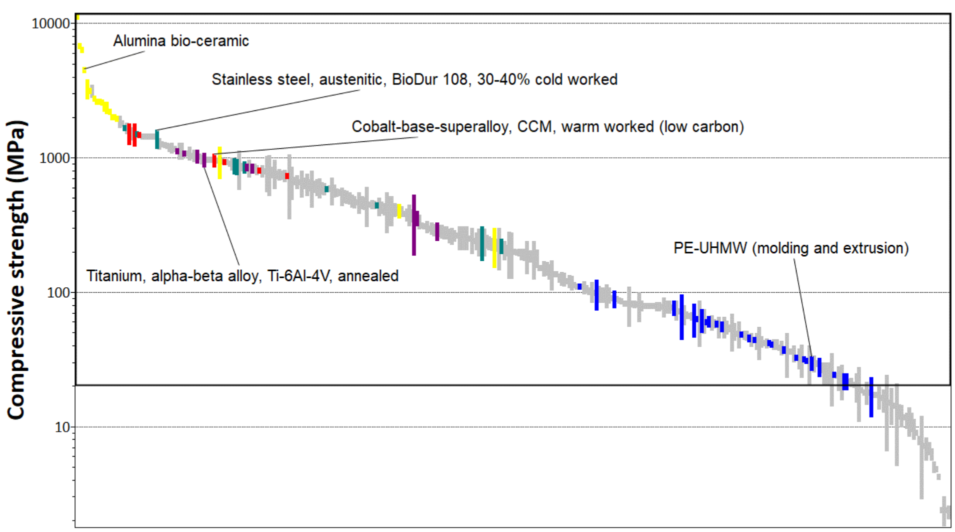


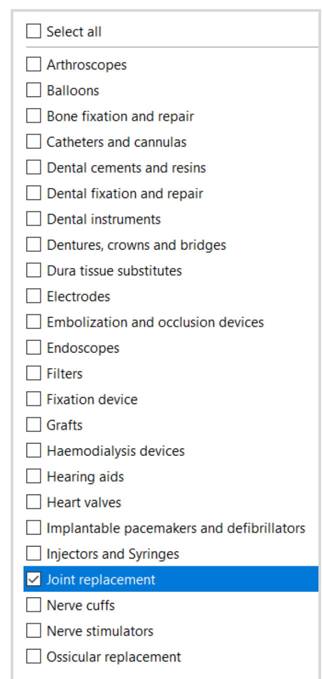
Cobalt chromium alloys are highly resistant to corrosion and have some mechanical properties that are superior to stainless steels, such as fracture and fatigue resistance. Although more expensive than these steels, cobalt chromium is still used for the ball joint of the head. It has, however, gradually been replaced by titanium for the stem part. Ti-6Al-4V osseointegrates and has:

- Stiffness better matched to bone
- Higher specific strength
- Good corrosion resistance

The femoral head/ball joint

For this part, the main load is compression of the ball joint. The index to maximize for the primary objective is *compressive strength*, which is readily available in Granta EduPack. This is the property that best represents the performance, since the dimensions are more or less fixed by the natural geometry of the hip.





In this section, we have restricted ourselves to benchmark the subset of materials available in the Limit stage under *Joint replacement*, which is found within the *Healthcare applications* of the *Healthcare & food section*. This will be our effective constraints, superseding a regular screening.

Objectives relating to wear resistance are complicated, since this is not a straightforward material property. It depends strongly on the combination of materials and environmental conditions, such as temperature and lubrication. We nevertheless used an option built in to the Performance Index Finder, *Abrasion by blunt contact.* This secondary objective deals with abrasion caused by yielding (metals/polymers) or cracking (ceramics).

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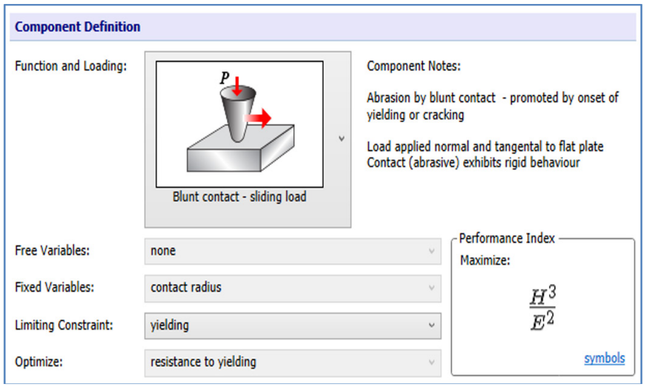
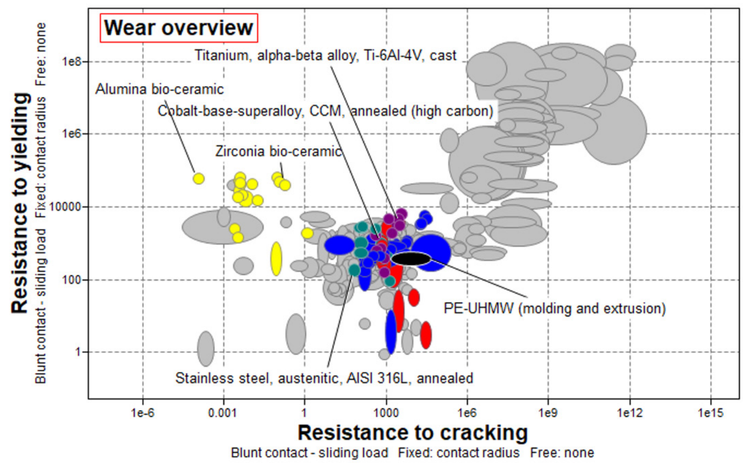


We can plot both these indices simultaneously in one bubble chart using the Performance Index Finder, as shown below for yielding onset. The performance index to maximize for cracking is: $M = K_{1c}^{\ 3} / E^2(1\text{-}2v)^3$.

As expected, ceramics have the lowest resistance to cracking however, this has been addressed more recently by developing finer-grain medical grades with higher purity. The trend for metals, is that stainless steels are lower than cobalt chrome superalloys in performance and that Ti-6Al-4V is amongst the best.

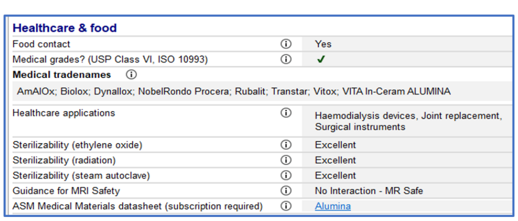
Yielding is generally preferred as a failure mechanism than cracking (catastrophic) and polymers, such as ultra-high molecular weight polyethylene (UHMWPE, PE-UHMW), perform very well in this respect. The 1:st generation of *highly cross-linked* UHMWPE has improved wear resistance while the 2:nd generation of highly cross-linked UHMWPE has improved mechanical performance resulting from an additional heat treatment. However, to find data on this, the ASM medical materials database needs to be consulted.



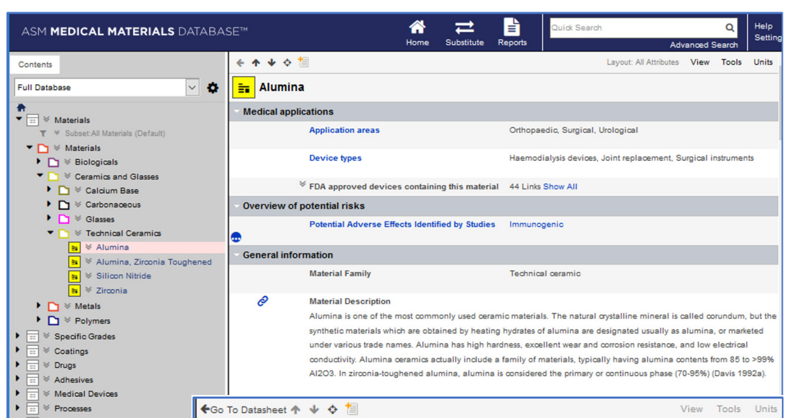
4. Analysis and reality check

Total hip replacements are interesting from a biomaterial perspective, since they encompass metal alloys, bioceramics and ultra-high molecular weight polyethylene in standardized and widespread medical procedures. The femoral stem needs to be a biocompatible metal alloy in order to provide combined strength, stiffness and fracture toughness. Whereas stainless steel has the best cost performance and compressive strength, cobalt chrome (molybdenum) alloys have better resistance to abrasion promoted by onset of cracking. Ti-6Al-4V has good overall performance and excels at mechanical properties in relation to weight (specific strength etc).

More information about a range of biomaterials and biomedical devices on the market can be found in the ASM Medical Materials Database, accessible via the Bioengineering Edition of Granta EduPack with the appropriate subscription. This contains information on relevant commercial biomaterials and tens of thousands of medical devices.



Healthcare & food	
Food contact	Yes
Medical grades? (USP Class VI, ISO 10993)	✓
Medical tradenames	
AmAlOx; Biolox; Dynallox; NobelRondo Procera; Rubalit; Transtar; Vitox; VITA In-Ceram ALUMINA	
Healthcare applications	Haemodialysis devices, Joint replacement, Surgical instruments
Sterilizability (ethylene oxide)	Excellent
Sterilizability (radiation)	Excellent
Sterilizability (steam autoclave)	Excellent
Guidance for MRI Safety	No Interaction - MR Safe
ASM Medical Materials datasheet (subscription required)	Alumina



Therein is more information on standards etc.

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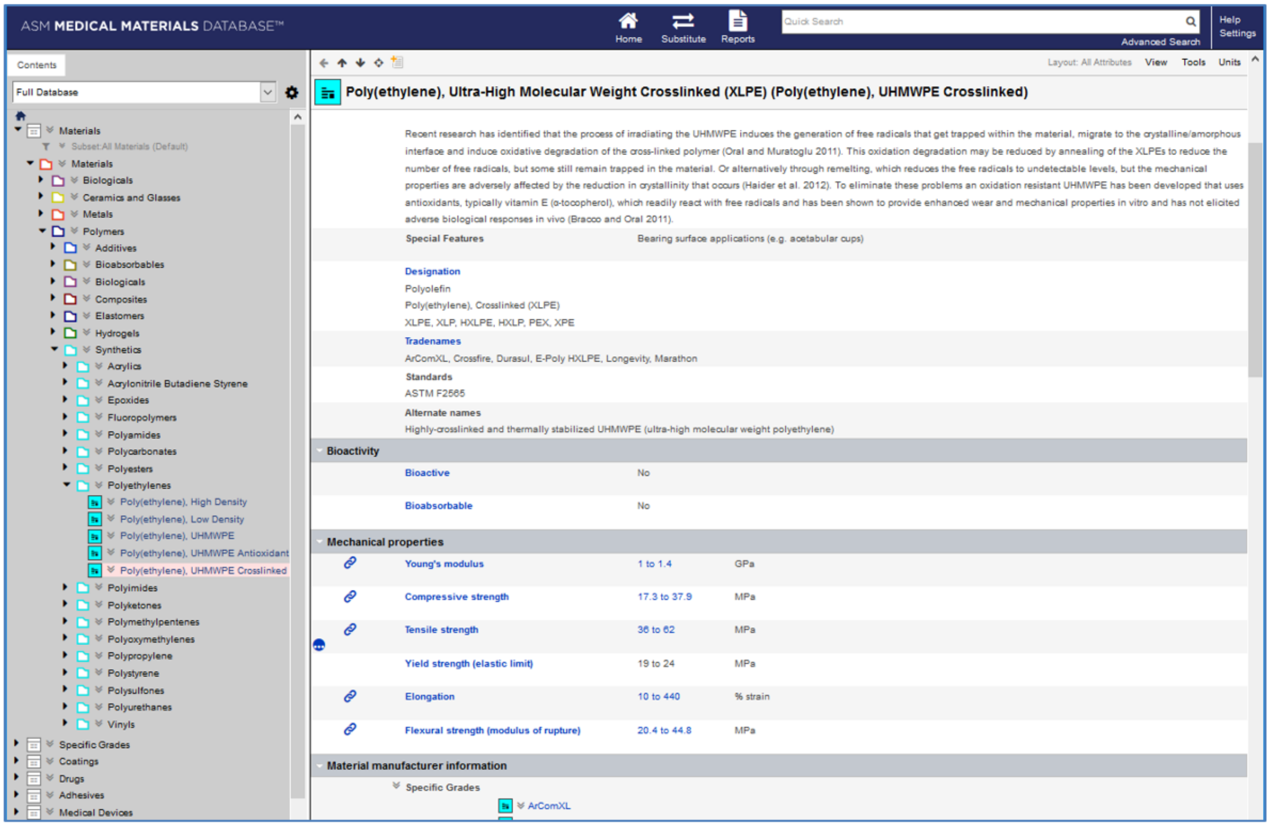
There is also extensive information 1:st and 2:nd generation highly crosslinked UHMWPE as shown below.



5. What does Granta EduPack bring to the understanding?

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

- Granta EduPack Bioengineering Level 3 database is useful to select and understand the biomaterials used for the femoral stem and also benchmark the femoral head of a total hip replacement.
- Both properties of cortical bone and biocompatible metal alloys can be used in a selection process. The identified candidates match real-world implant materials and adds to the understanding of their development in recent history
- Bio-ceramics and biocompatible metal alloys can be compared and contrasted to the UHMWPE used as lining. To follow the development for highly crosslinked UHMWPE of generation 1 and generation 2 (heat treated), with enhanced mechanical properties for use in the joint, the ASM medical materials database can be invoked from within the software, provided a subscription with ASM.

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