Material Science
Material Analysis of the Artificial Heart

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Introduction

Artificial hearts are useful, life-saving products, but how do the materials allow it to function as it can? This paper will analyse some of the materials used in total artificial hearts, more specifically the AbioCor. Total artificial hearts are life-support devices for short-term replacement of a failed human heart. It is most often used in the duration of waiting for a heart transplant. The AbioCor total artificial heart is completely fitted inside the human thoracic chamber (chest) and is powered by a battery that is also implanted inside the body (What Is a Total Artificial Heart?, 2012). For the analysis within this paper, the core part of the AbioCor total artificial heart - excluding the battery compartment - was divided into three different parts: atrium compartment, valves, and artery connection. The atrium, composed of AngioFlex^{TM}(trademark polymer) and Titanium, is the chamber part in which the blood flows through and is pumped to and from. The valves, also made out of AngioFlex^{TM}, also replaces the actual valves of the human hearts and control blood flow into and out of the atrium compartment. The artery connection component, made out of Dacron and polyester cuffs, connects the artificial heart to the actual human artery, allowing the artificial heart to perform its functions. Altogether, the materials that make up the different compartments are what makes this technology interesting. The most important function that these materials have to be able to achieve is biocompatibility, because it will be completely inside a human body. Other than that, it will have to altogether make up a lightweight artificial heart that is small enough to fit inside a human body. Although the technology has not reached the most efficient size yet and can only fit large-framed adults, it is still fully biocompatible (Tucson, 2014). How the materials allow the technology to be biocompatible will be analysed in the sections below.

1 Thoracic Unit Casing & Artery Connection Parts: Titanium

The AbioCor artificial heart consists of different components. Some of these components are made of titanium for various, mainly mechanical, reasons. The thoracic unit, consisting of the atriums, the hydraulic blood pump and valves is encased in a titanium shell (Gray & Selzman, 2006). This should give more stability to the artificial heart. Titanium rings are also used at the far ends of the end of the arteries where the heart is connected to the human body. Here, titanium is also used to stabilize the heart and keep it in place. If the artificial heart would only be made out of flexible plastics such as Angioflex^{TM}, the whole would be very flexible and with all the mechanical pressures it has to undergo, it would probably not stay in place.

Purpose of components

The shell that encases the thoracic unit, which is located in the middle of the heart, has several functions. First of all it encases the pump system which exerts high pressures on the different compartments of the heart as it has to pump blood through the body, and to do so, it needs to exert high pressures. The titanium casing enables the heart to withstand these pressures and to stay in place. The internal parts of the heart, where blood touches the thoracic unit, are made of Angioflex^{TM}(Abiomed, Inc. Patent, 1989).

The small titanium rings at the outer ends of the artificial arteries are used to make stable connections with biological arteries of the human body. At the same time it ensures the artificial heart to stay in the same form and place.

Material Science Analysis

Composition

For the artificial heart to function properly, it is very important that all materials used for the circulatory system are biocompatible. Titanium is considered to be the most biocompatible metal due to its high resistance to corrosion by body fluids and high fatigue limit (Otha Inc., Akiyoshi Osaka Patent, 1996). Therefore, titanium alloys are very attractive metal materials for medical applications (Elias et al., 2008).

Medical applications know various types of use of titanium. Some discuss commercially pure titanium. However, different types of titanium alloys are used. For medical applications, metals such as niobium, tantalum and zirconium are favourable, as they are non-toxic and allergy-free alloying elements suitable for titanium alloys (M. Niinomi, 2007). The two most common titanium based biomaterials are commercially pure titanium (Ti CP) and the alloy Ti-6AL-4V (ELI) (Fokter, Oldani, & Dominguez, 2012). Initially, ELI alloys were used for medical applications. However, due to a discussion around the toxicity of vanadium, a range of other alloys came to the market. For these alloys vanadium can be replaced by various different metallic alloying elements, such as iron, molybdenum and the earlier mentioned niobium and tantalum (Leyens and Peters, 2003).

Many different alloys can be used for medical applications, and even commercially pure titanium is considered. However, no specific information can be found on what type of titanium (alloy) is used for the AbioCor artificial heart. As titanium in itself is already a very interesting and particular element, it has been chosen to further investigate pure titanium, and it is assumed that commercially pure titanium is used for the AbioCor.

Structure

Titanium, being a metal, has a crystalline microstructure. Titanium can crystallise in various crystal structures, each modification being stable only within a particular temperature range. Pure titanium, as well as the majority of titanium alloys, crystallises at low temperatures in a modified ideally hexagonal close packed structure (see figure 1), called titanium (Leyens & Peters, 2003).

Only at high temperatures, the structure of the molecule changes to titanium, of which the body-centred cubic structure is stable. The -transus temperature, the temperature in which a molecule completely transforms from one into another crystal structure, for titanium is 8822C (Leyens & Peters, 2003). I will not discuss titanium as the application of the titanium in the thoracic unit does not require this high temperatures. At room temperature, and the temperature within the body, pure titanium is in a solid state. It only starts melting at about 1660C and boiling (thus vaporizing) at 3287C (Bentor, n.d.; Pappas, 2014).

The density of a material (for pure titanium at room temperature 4.54 g/cm3) is mainly determined by the atomic weight, not atom size, and is influenced by a lesser degree by the way in which atoms are packed. Metals are dense because they are made of heavy atoms, packed densely together. Titanium, however, is classified as a light metal, which means that the density of titanium is relatively low compared to other metals. The reason for titanium to be a light metal, but still keeping the property of being a strong material, is that the electron shells of titanium atoms are moderately wide. This means that fewer atoms can be packed into a fixed volume ("Mr titanium - Why titanium is lightweight," n.d.; Leyens & Peters, 2003).

Properties
Titanium alloys primarily stand out due to two properties: high specific strength and excellent corrosion resistance. This explains their preferential use in the aerospace sector, the chemical industry, medical engineering and the leisure sector (Leyens & Peters, 2003).

If body implants have to carry mechanical loads, often titanium alloys are used. Their outstanding strength to weight ratio and excellent fatigue behaviour are decisive for the choice of material for orthopaedic devices. Favourable to other high-strength metallic materials, titanium has a relatively low modulus of elasticity, which reduces the differences in stiffness between the human bone and the implant (Fokter, Oldani, & Dominguez, 2012; Leyens & Peters, 2003; Pappas, 2014).

Performance
Performance always describes an optimization of a combination of different important properties a material should have to fulfil a function as good as possible. Properties required for a high performance of the components of the artificial heart will now be discussed.

It is desirable that metals used for medical applications have a low elastic modulus (compared to other metals), which is comparable to that of organic tissue like that of bones. In addition, the material should have a relative low density. As can be seen in figure 3, titanium has a relatively low elastic modulus and a lower density than the for medical applications comparable metals stainless steel and Co-Cr based alloys, and is therefore often preferred for medical applications (Geetha et al., 2009; Kulkarni et al., 2015). In addition, the material should be biocompatible. A material is considered biocompatible if it can perform well in medical applications, without eliciting undesirable effects, but providing the most appropriate natural response, optimizing the performance of a medical therapy (Kulkarni et al., 2015; Williams, 2008).

Titanium and titanium alloys are widespread considered successful for biomedical applications, mainly because of the combination of properties of high corrosion resistance and appropriate mechanical performance, making it biocompatible. Titanium materials have such a great corrosion resistance due to their ability to form chemically stable, adherent and protective oxide layers on their surface (Adya et al., 2005; Donachie, 2000; Kulkarni et al., 2015).

Material Selection Analysis
When a material gets selected for a certain component, one should look at the performance of the material, thus to what extend it fulfils the requirements regarding different material properties. Other aspects that could be taken into account are costs, availability of resources and complexity of processing.

The material selected for the rings at the end of the arteries and for the casing of the thoracic unit requires the following properties: the material should be stiff and strong but comparable to bone tissue (when a metal is chosen, it should have a relatively low elastic modulus), it should be light weighted and thus have a relatively low density. Next to that it should be biocompatible, thus not biodegradable nor toxic.

From figure 2 can be concluded that ceramics and metals would be desirable when looking for a material with a relatively high Youngs modulus. However, this also often means a higher density. When looking to literature, designers often prefer the use of metals for medical applications. Figure 3 shows a comparison of various metals and their density and modulus properties with those of bone and shell tissue. From this figure can be concluded that the metals that show most properties most similar to bone and shell tissue are calcium, magnesium, aluminium, tin, selenium, europium and titanium and its alloys.

Tin is not desirable as it has the highest density of all named metals. From figure 4 can be concluded that europium and selenium, but also the metals often used in titanium alloys, tantalum, niobium and vanadium are relatively expensive. This might be the main reason why these metals are not used as a base in medical applications. The figure also shows that calcium is not desirable as it has a relatively low durability in organic solvents (even lower than that of bone and shell tissue itself).

One might say, that magnesium or aluminium are preferred over titanium for medical applications, based on figures 2, 3 and 4. They show properties comparable to that of bone and shell tissue, show an excellent durability in organic solvents, are cheap and like titanium, non-toxic and not biodegradable. However, magnesium is highly reactive in water, it oxidises rapidly. Aluminium is only stable in air as it has an oxide layer on the surface. This makes both materials less suitable to form the base material in medical applications. However, due to its properties, aluminium is often used in alloys with titanium. From this analysis, it can be concluded that titanium is the most desirable and suitable material to form a base for materials used in medical applications, both commercially pure titanium as well as its alloys.

2 Artery Connection: Dacron

This component functions as a connection between the artificial heart and the human arteries, a crucial part in allowing the artificial organ to perform its job as a temporary life support. Since this is the component that has the most direct contact with the human body, other than the whole outer wall of the artificial heart, it is interesting to look at the material that makes up this component. This component is composed of two parts: Dacron graft and velour polyester cuffs. Since the cuffs are not the part that is in direct contact with the arteries, the focus of the material analysis in this section will be on the Dacron graft. Dacron is a patent name, but it is also known by a chemical name of polyethylene terephthalate (PET).
Before analysing the material, it is good to understand better what the component should be able to do in order for the product to function properly. Other than serving its purpose as a connection between the artificial heart and the human artery, the component should not leak and should allow the blood to flow smoothly as well. How then should the material selected contribute to the performance? It should be durable enough to withstand the force of blood flow; it should be biocompatible (does not react to human blood nor disrupt blood flow); it should not absorb the liquid; it should have low permeability; and it should have a shape that molds to fit the human artery. The sections below will analyse, in material science terms, the material Dacron or PET.

Material Science and Selection Analysis

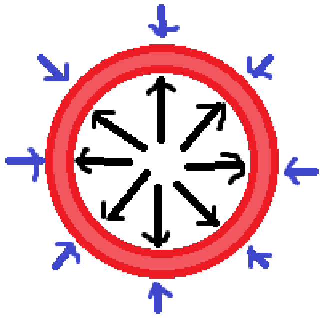
Composition and Structure

PET is composed of 100 % polyester. Therefore, it has only one base material of PET. The type of PET used in an artificial heart is amorphous and it is a thermoplastic. Because the PET that is used is amorphous, it allows for better clarity and barrier properties than if it was crystalline (see figure 5 and 6).

PET has a chemical formula of $(CO\text{-}(C_6H_4)\text{-}CO\text{-}O\text{-}(CH_2)_2\text{-}O)_n$ or $(C_{10}H_8O_4)_n$ (see figure 7). Within the structure, there are covalent bonds, more specifically ester bonds, which are considered to be very strong. This explains PETs high melting point.

Properties and Performance

Unfilled PET has a Youngs Modulus between 2.8e9 Pa and 3e9 Pa. Its yield strength or elastic limit is between 5e7 to 5.5e7 Pa. This results in the artificial artery being stiff but not too stiff. It also results in the component being able to withstand the strain from the force of the blood flow, because the normal adult diastolic blood pressure range (when blood flows into blood) is between 60-80mmHg (around 7,999-10,666 Pa). Systolic blood pressure range (when blood is pumped out of blood) is between 90-120mmHg (around 11,999-15,999 Pa) (Mayo Clinic Staff, 2015). The loading that the artificial artery has to withstand is a lot less than its limit, therefore a patient will not have to worry about a hole in his or her artificial artery. Below is a free-body force diagram of the mechanical loading on the artificial artery.



The blue arrows are the forces outside the artificial artery, while the black arrows are the forces due to the blood pressure of the blood running through the artery. The forces against the inner wall is larger than that against the outer wall, because of the blood pressure of the blood flowing on the inside. Dacron has a density of around 1.3e3 kg/m3, making it a material that is light in weight.

Even though PET is highly flammable, medical grade PET is fire retardant grade as well, making it safer for use in the human body. PET also has a thermal conductivity of 0.138 to 0.151 W/m, which makes it a good insulator, maintaining regular temperature of blood flowing through the human body. PET has a water absorption at 24 hours of only 0.14 to 0.18 percent, which is very low. The rate of water vapor transmission is 5.37e-12 to 8.18e-12 kg.m/m2s and oxygen permeability that is between 1.37e-19 to 3.17e-19 m2/s.Pa, resulting in an artificial vessel that does not absorb the blood and keeps it where it is supposed to be. This property also results in Dacron having excellent durability to both fresh and saltwater.

PET is also a material with good melt flow, allowing for ease of blood flow, and has low friction. This results in the material having a very good surface finish, allowing for smooth blood flow from the human artery to the artificial heart. This material is also resistant to gamma radiation, therefore it can be sterilized, making it a fit for medical use. This property also contributes to the biocompatibility function.

As stated earlier, PET has a fairly high melting point of 260 degrees Celsius and a boiling/decomposition point of 350 degrees Celsius. Its glass transition temperature is between 67 and 81 degrees Celsius. These temperatures are far from the average temperature of the human body of 37 degrees Celsius, making this material a safe choice (CES Edupack 2015).

To conclude, Dacron is not only a suitable material for food processing, but it is also a suitable material for an artificial artery of an artificial heart. Because of its properties combined, it can be considered biocompatible. Biocompatibility can be defined as the following the ability of a biomaterial to perform its desired function with respect to a medical therapy, without eliciting any undesirable local or systemic effects in the recipient or beneficiary of that therapy, but generating the most appropriate beneficial cellular or tissue response to that specific situation, and optimizing the clinically relevant performance of that therapy (Williams, 2008).

According to the definition above, Dacron mainly can be considered biocompatible because of its properties such as how it does not ruin the blood flow (due to surface finish) nor potentially cause infection (due to the possibility to be sterilized) (Pinto, Saito, & Glerean, 1993). Dacron is also most suitable for the component of this product, because of its good tensile strength and lightweight. The artificial heart needs to be made as small and light as possible, while still being able to take on the mechanical loading.

But why then can this artificial heart not last forever? This is because although Dacron has low water absorption rate, it cannot withstand too much acidity or alkaline, because it can hydrolyse the ester bonds. (Clark, n.d.) This in combination with long-term heat exposure, leads to the biodegradation of PET.

3 Valves: Angioflex^{TM}

The AbioCor valve is the only moving part of the artificial hearth. It is a trialeaflet, which means that it has three flaps that open and close, valve of a diameter of 24 mm (see figure 8) (Dowling, Etoch, Stevens, Johnson, & Gray, 2001). The artificial valve performs the task of a normal valve, therefore it opens and closes to allow blood through from the different heart compartments, atriums and ventricles. The company Abiomed developed a product that seems to have the best combination of properties for the performance required, Angioflex^{TM}. Because it is a trademark polymer only for use within Abiomed, specific information about the material were fairly difficult to find. ^{TM}is a particular type of polymer, more specifically a thermoplastic polyether polyurethane. Specifically, the two monomers used in combination to create Angioflex^{TM}are tetrahydrofuran and 1,4-dioxane. The combination of these monomers is the result of a polyether based polyurethane, rather than a polyester. Angioflex^{TM}is an elastomer, and it has a segmented structure (Szycher, 1991).

These were all the labels that are publicly available about Angioflex^{TM}, but what these properties mean for the function of the material within its intended use are not mentioned. The following sections aims at giving an explanation about how these affect the performance. Some specific values of a comparable material will also be mentioned to provide a better understanding.

Material Science Analysis

Properties and Performance

The material under study is Angioflex^{TM}, that, as it has been said, was defined as a thermoplastic polyether based polyurethane and a segmented elastomer. What does this mean for the performance of the material?

A material with thermoplastic properties, as opposed to thermosetting, will soften when heated and harden when cooled, and the process is reversible so this can happen multiple times without damaging the material. Upon implantation, the material will soften after experiencing a humid environment with a high temperature. Being thermoplastic, the degradation of the material is prevented. Furthermore, as body temperature may change over time multiple times, it is important that the material is able to sustain this change (Szycher, & Sharma, 1990).

The hardness of the material is also a very interesting topic to look at. Angioflex^{TM}was defined as having a segmented structure. Roughly, this means that the material is composed by blocks of hard and soft (flexible) segments together. The soft and hard segments have different phases, resulting in the characteristics that make polyurethane very suitable for valve applications. The hard segments are responsible for good tensile strain and tear strength, by means of breaking hydrogen bonds between them and forming more favourable ones wherever a mechanical force is applied. The soft segments are responsible for the specific chemical properties of the plastic as well as the elasticity of the material. Overall their interplay contributes to polyurethanes typical elastomeric, hardness and stiffness properties, which changes depending on the percentage of hard and soft segments (Szycher & Sharma, 1990; Alves, Ferreira, & Gil, 2012).

Specific information about ratio of hard and soft segments in Angioflex^{TM}could not be found. A comparable segmented material (Elasthane, DSM) has a tensile strength of 6354 psi (43.8 MPa), showing really high resistance to tensile stress for a polymer, much higher than any stress the valve would actually experience. The hardness of Elasthane is defined as 82A, which means it shows medium hard characteristics. Furthermore, the flexural modulus is 5220 psi (36 MPa), again showing high stress resistance, and the Youngs modulus at 37C is humid condition is 4.7MPa. The blood pressure can range from 0.008 to 0.18 MPa, which is way lower overall than what the material is able to sustain.

Because of the function the material should perform, it is very important that it shows elastic characteristic. Indeed the material is defined as an elastomer, which means the material will return to its original position after bending or stretching. This is extremely important as the valve should be able to move but to also return to its original position without being damaged. Looking at the values of Elasthane^{TM}the ultimate elongation is 603%, which is comparable to the average ultimate elongation of rubber, the ultimate elastomer.

Angioflex^{TM}is a polyether based polyurethane, which means its base has the chemical structure of an ether. What this means for the properties its very important, as this is what it allows it be implanted in the body for long periods of time. Having an ether base prevents the material from undergoing hydrolysis processes, and allowing the material to be placed in contact with blood for long periods of time (Szycher & Sharma, 1990).

Material Selection Analysis

Why Angioflex^{TM}?

Angioflex^{TM}, or at least thermoplastic polyether polyurethanes, seem to be a good solution to the artificial valve problem. However there are of course other opportunities out there. So why this material?

An option for valve replacement could be to use tissue valves. However, they are more likely to experience calcification. Furthermore they are all slightly different and may have different properties, thus having unpredictable results (Lutchmun, 2011).

Another option that may be cheaper but very not suitable is using polyester polyurethane. Because of their chemical structure, a long term usage of polyester materials in contact with blood would not be suitable. Polyester polyurethane undergo hydrolysis which causes degradation in the material, thus not being as biologically inert as its fairly similarly structured polyether based material. Polyester however still remains an ok choice for very short term implants (one to three hours) (Szycher & Sharma, 1990).

A very good competitor for polyether based polyurethane in internal bodily implants is silicon based materials. These have very good bio-stability and flexure endurance. However, silicon is a soft material and its hardness is not enough to sustain the performance required from a material used to create artificial valves (Szycher & Sharma 1990).

Another material that could be used is the aromatic version of polyether polyurethane, compounds that take up a ring structure. However, it appeared to yellow from exposure to UV light, which in itself, however, did not affect performance. The reason why aromatic polyether materials are not a better choice than polyether materials is that exposure to high temperature causes the material to become toxic and carcinogen. The material is exposed to high temperatures during sterilisation, therefore the chance of the material becoming not suitable for human implant anymore are really high (Szycher & Sharma, 1990).

To conclude
The characteristic properties of thermoplastic polyether based polyurethane are very suitable for an internal body implant, able to sustain the contact with blood and the change in temperature. Angioflex^{TM}specifically is claimed to be highly fatigue and abrasion resistance, however specific information could not be found. A specific downside of this material in artificial valve application is that there is some structural degradation present at the closing of the valve after about 29 days. This however, does not heavily impact performance (Gourlay & Black, 2010). A more general disadvantage of ether based polyurethanes is that they are fairly expensive. It would be interesting to know about specific mechanical properties of Angioflex^{TM}, especially in terms of cyclic loading and fatigue resistance, given the application of the material which is claimed to be able to sustain a normal bpm value of 60 to 100 beats per minute for long periods of time.

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Appendix

Figure 1

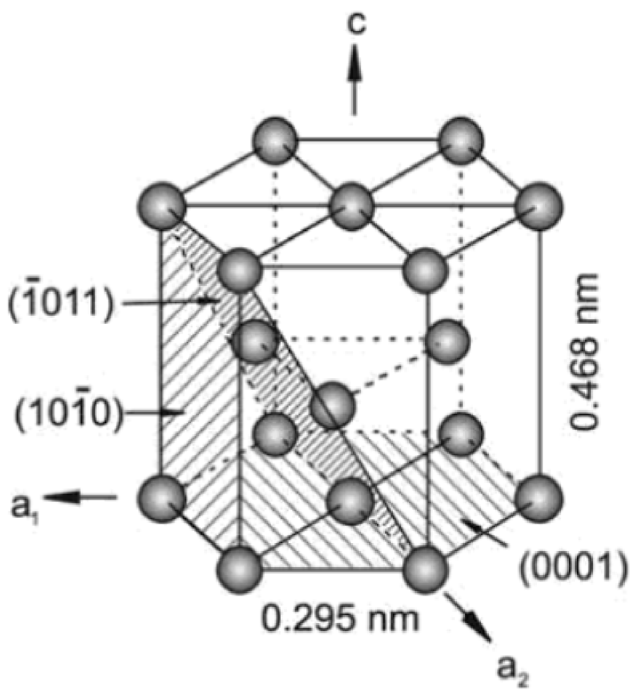

Figure 1: close packed, hexagonal titanium

Figure 2

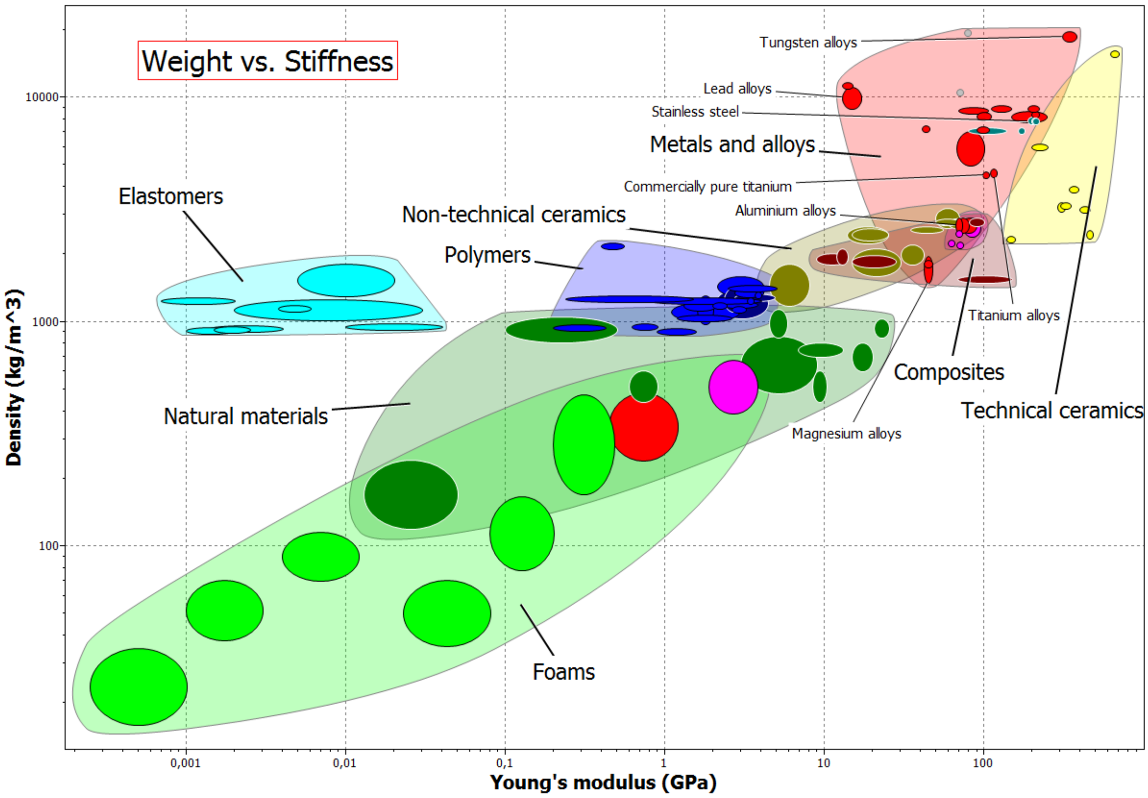

Figure 2: weight vs. stiffness of various material (families)

Figure 3

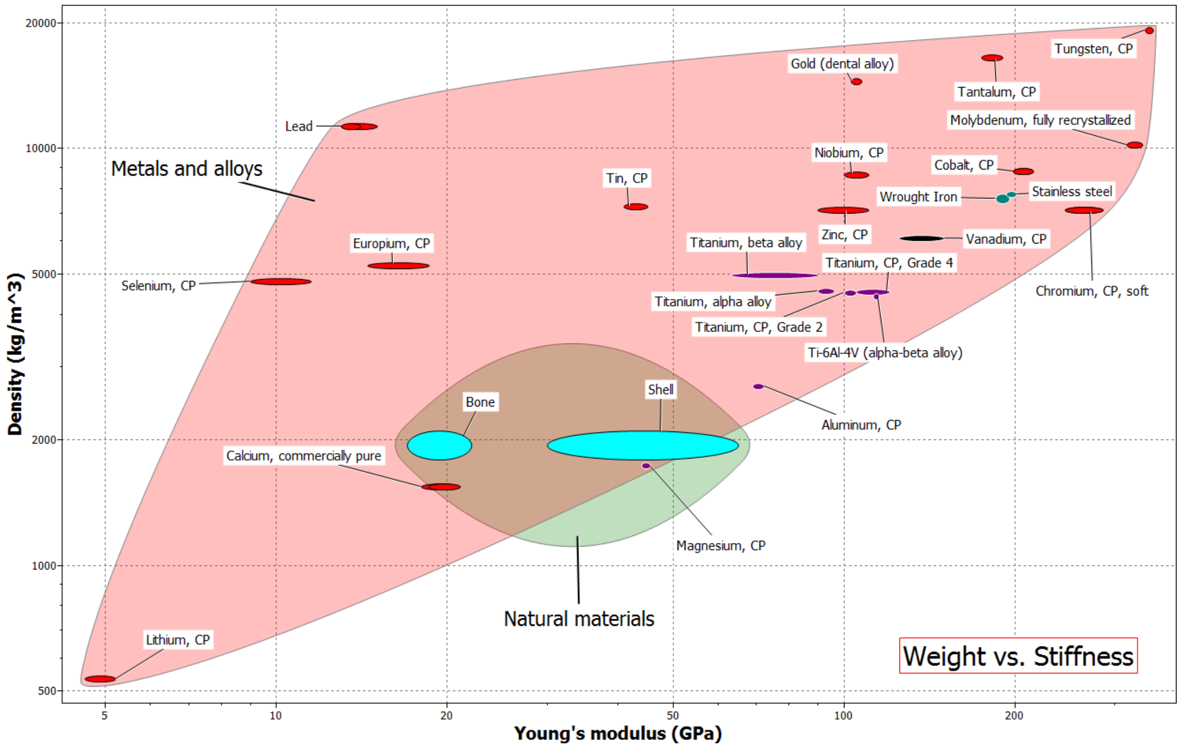

Figure 3: weight vs. stiffness; various metallic materials compared to bone and shell tissue

Figure 4

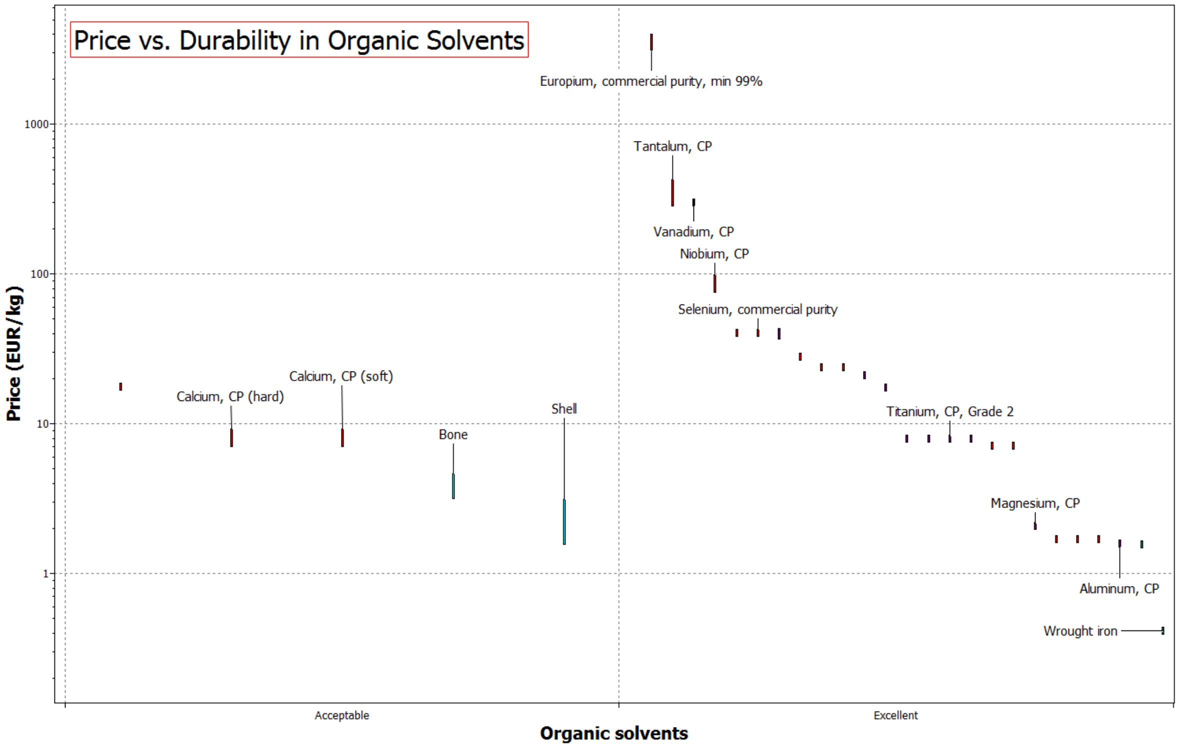

Figure 4: price vs. durability in organic solvents; comparing various metallic materials with a potentially high performance rate for medical applications.

Figure 5

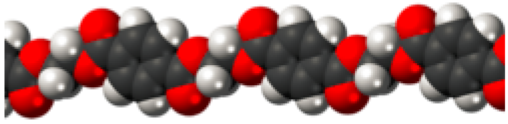

Figure 5: structure of PET

Figure 6

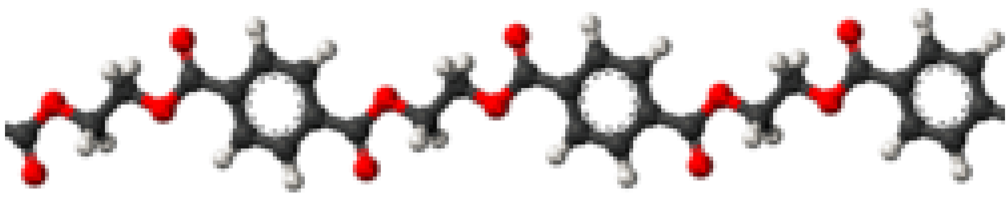

Figure 6: structure of PET

Figure 7

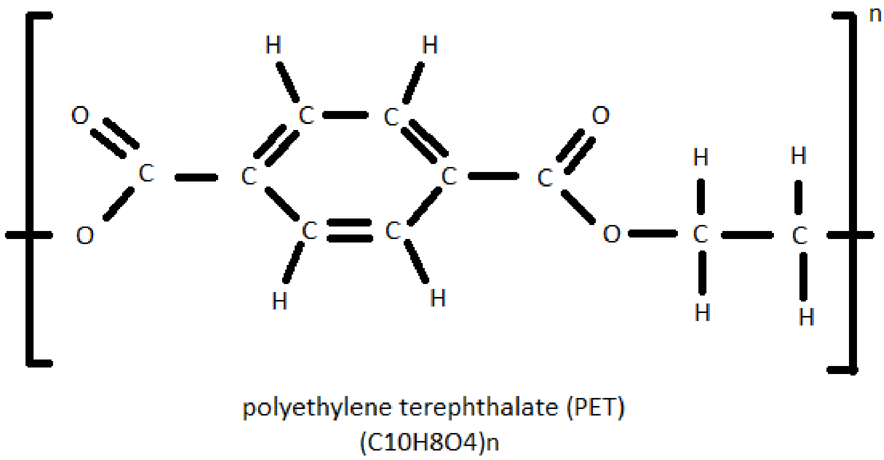

Figure 7: chemical structure of PET

Figure 8

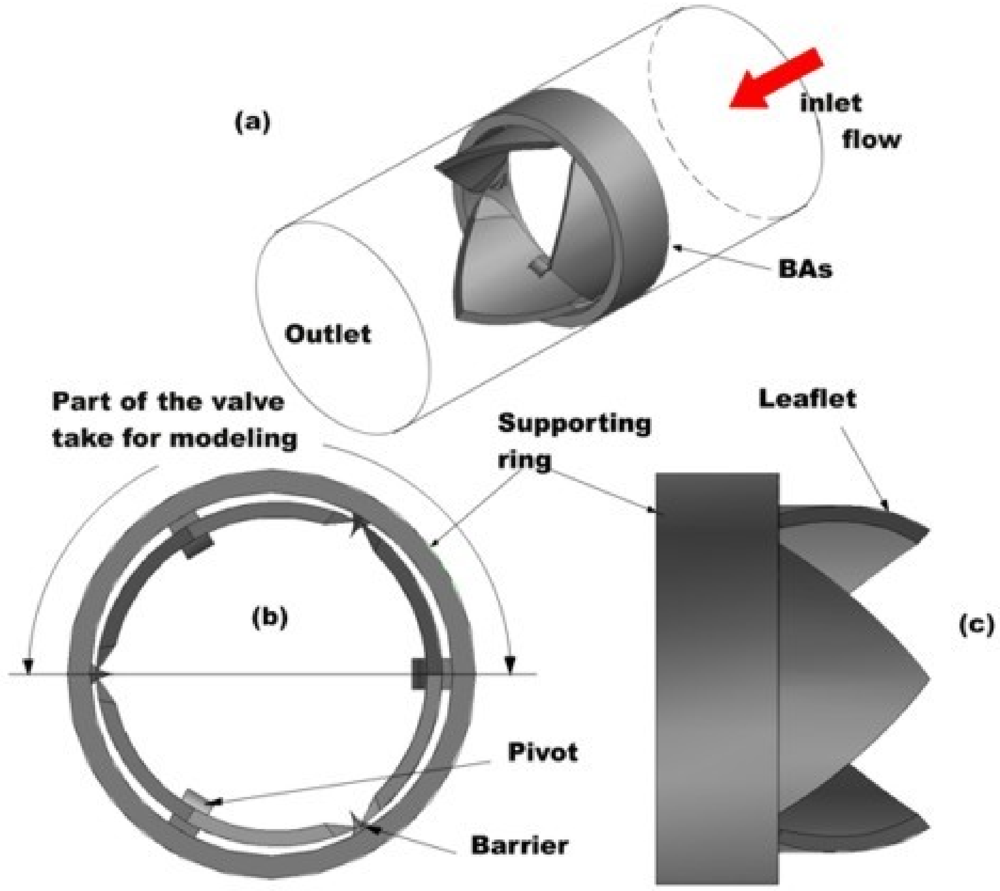

Figure 8: structure of a triafleatet valve