DEVELOPMENT OF SINTERED ALL-UHMWPE COMPOSITES FOR JOINT IMPLANT SOCKETS

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Abstract
Improving living conditions and health achievements have led to a significant increase in our average life expectancy. One solution for destroyed joints is the implantation of joint implants, which is one of the most successful surgical procedures [1]. The most commonly used design is the metal-polymer artificial joint. This usually means that one of the surfaces that move on top of the other is a metal alloy of some kind, while the other is a plastic - usually ultra-high molecular weight polyethylene (UHMWPE). The most common cause of failure is wear of the UHMWPE, and a very significant proportion of revision surgery [2]. In our study, we developed a sintered homocomposite substitute for the UHMWPE insert, where the matrix material was a UHMWPE powder, well-established and popular in the implant industry, and the reinforcing material was UHMWPE fiber used as a suture and fixation material. Very importantly, both the matrix and the reinforcing material are medically certified and made of the same material, so that no compatibility problems arise during composite manufacturing. After a long series of iterations, it was possible to adjust the manufacturing technology to produce test specimens that are more wear-resistant and harder than traditionally used inserts.

1. Introduction
Each fast-growing industry often boosts other industries. This has been no different in medicine, where the implantation of implants has been one of the most successful procedures [2]. However, the rapid advance of implants is actually due to technological advances. This is due to the development of materials science, manufacturing technology, computer technology and many other technological industries. Over the decades, implants have changed and refined a lot thanks to the technological advances mentioned above. In the beginning, different natural materials were used, as in the case of the first implant, made by Themistocles Glück in 1853. This construction was made of ivory, but unfortunately it was poorly integrated into the human body and developed infectious complications. Similar problems occurred with the platinum and rubber prosthesis made by Jules-Émile Péan. It then took another 150 years or so to develop the design still used today. In the 1950s, metal-on-metal implants appeared, as well as systems that used a polymeric insert for the metallic counterpart [3]. A significant number of systems that used polymeric insert quickly broke down, broke or had compatibility problems, while metal-on-metal constructions had serious problems with wear products due to abrasion. The tiny

metal fragment reached the furthest reaches of the body and generated an immune response, and was responsible for many inflammations [2].
It was precisely because of these problems that, in the 1960s, British surgeon Sir John Charnley developed a system of wear-resistant polymer sockets with a metallic counterbore [2]. This metal-polymer implant system has become the gold standard to this day. The following figure (Figure 1) shows the most commonly used implant structure today.

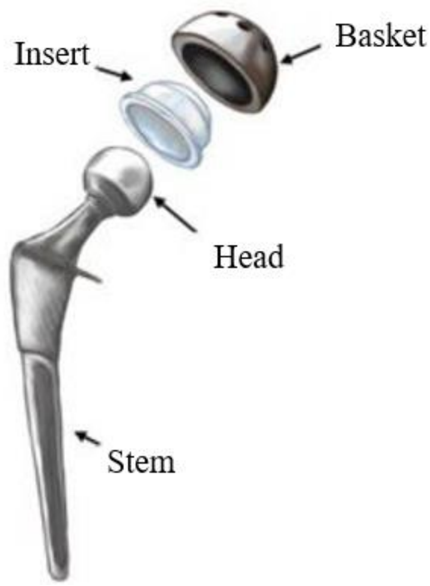

Figure 1. The most commonly used implant design today [4]

Charnley was the first to use UHMWE polymer as an insert material, which is still the most widely used today. UHMWPE is a material with outstanding properties, offering amazing wear and tribological properties. It is very tough and well resistant to fatigue and biological environments, a good part of these properties being due to its extremely long molecular chains. It is relatively inert - hence biocompatible - and is therefore very well accepted by the body [2]. But both the long molecular chain and the extreme inertness have drawbacks. The extreme length of the molecular chains makes UHMWPE unprocessable by conventional plastic processing technologies used for thermoplastics, because it makes it impossible to melt it. If melted, its molecular chains start to break, thus losing its extraordinary advantageous properties. For this reason, UHMWPE is processed by sintering, a process well-known in metals, and the desired part geometries are formed from the resulting blocks by machining [2]. The following figure (Figure 2) shows a RAM extruder for sintering UHMWPE.

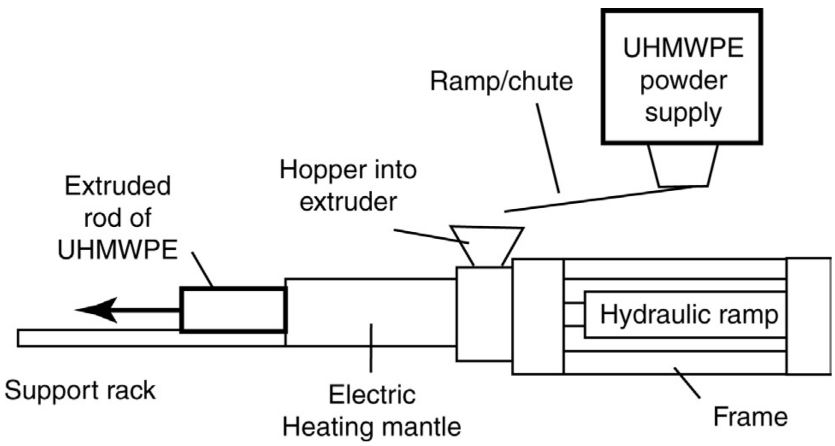

Figure 2. RAM extruder [2]

The other major drawback of UHMWPE is that its extreme inertness makes it difficult to combine with other materials, making it very difficult to adhere to anything.
Like all engineering structures, implants have a certain service life, after which they need to be replaced. In the case of prostheses, this replacement involves revision surgery. In the majority of cases, this operation is associated with wear of the UHMWPE insert. Either because the inserts are practically completely worn out and no longer perform their function. Or because the wear products from the UHMWPE trigger an immune response, resulting in inflammation, which leads to loosening of the implant and subsequent revision surgery [2]. It can be seen that the wear and tribological properties of UHMWPE should definitely be improved. At present, the tribological properties of UHMWPE inlays are improved by irradiation, which results in the formation of cross-links in the structure, in effect a post-crosslinking. This technology improves the wear resistance but also makes the structure more brittle. The glass transition temperature of the materials is also increased. It should also be borne in mind that irradiation is a complex and costly process which complicates the manufacturing process [5,6].
Therefore, the aim of our research is to create a self-reinforced homocomposite structure. Previous attempts to use inserts made of UHMWPE matrix were quickly abandoned because they were not compatible due to the low surface energy of UHMWPE, often failing faster than conventional UHMWPE inserts. In addition, the reinforcing materials used were often found to be biocompatible, in many cases generating a violent immune response and requiring revision surgery [2].
In the early 1990s, attempts were made to produce UHMWPE homocomposites, but these attempts were abandoned. The main problem was the lack of medical-grade UHMWPE fibre. However, in 2006, DSM launched a medical grade UHMWPE fiber under the brand name Dyneema Purity. This is currently used as a suture and fixation material with very good results. The importance of this fiber is that not only the matrix material, but also the reinforcing material is now certified as medical grade, thus eliminating biocompatibility problems. There is already considerable clinical experience with UHMWPE, both in terms of its effects on the human body and in terms of the very conservative medical society, which is very reluctant to change what is well established because of the serious responsibility involved. It also avoids the compatibility problems encountered with previous UHMWPE composites, which make it virtually impossible to produce any kind of composite from UHMWPE, since the matrix and the reinforcing material are practically the same material, but produced by different technologies.
The aim is to create an insert where the matrix material melts and fuses with the outer part of the reinforcing material, while the reinforcing material retains its incredible orientation, as the outer part of the matrix melts while the inner part remains intact. This also allows the matrix material to perform its role of protecting and enclosing the reinforcing material and distributing the load between the fibers of the reinforcing material. The reinforcing material is also able to reinforce due to its orientation. This is possible because the melting point of the reinforcing material is slightly higher than that of the matrix material due to its orientation [2].

2. Experimental part

The first step in the production of the test specimens was to prepare the raw materials for manufacture. The matrix material used was GUR 1020 UHMWPE powder, a commonly used implant material. However, the reinforcing material was in the form of endless fibers, as it is currently mostly used as a fixation and suture material. However, for our studies we wanted to use 1-2 mm chopped fiber. It turned out that cutting UHMWPE fiber is a very difficult task. After several attempts, the cryogenic grinder was chosen as other equipment was not capable of cutting the fiber. Liquid nitrogen is fed into the grinder, which cools the material to below the glass transition temperature, where a sieve knife rotating device cuts the fibers into the desired 1-2 mm lengths. The following figure (Figure 3) shows the cryogenic grinding equipment.

Figure 3. Cryogenic grinding equipment

The next task was to define the technological window in which we would work. So, what is the difference between the melting point of the matrix material and the reinforcing material. To do this, we performed DSC on the base materials using a TA Instruments DSC Q2000. The results are shown in the following figure (Figure 4).

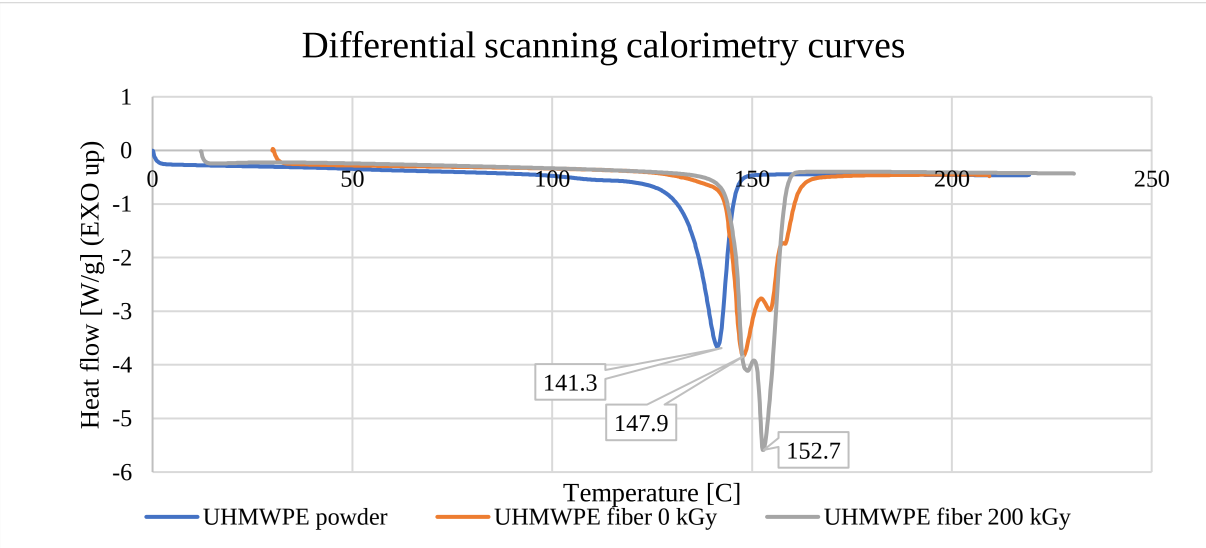

Figure 4. Melting point marked on differential scanning calorimetry curves

It can be seen from the previous figure (Figure 4) that the melting point of the fiber material is only slightly above the melting point of the powder matrix, the resulting technology window is only 6 °C. Therefore, we chose a 200 kGy electron beam irradiated UHMWPE fiber with a slightly higher melting point, which allows us to extend the resulting technology window up to 11 °C.
Then we had to set up the technology, exactly what temperature program to heat the specimens to in order to fit the technology window. We did not change the sintering pressure, we left it as per the manufacturer's directive. After several iterations, it was possible to achieve the retention of reinforcing fibers in the specimens, which was examined by optical microscopy and electron microscopy.
A serious problem was the distribution of the chopped fiber and powder material, which, as the literature showed, was not easy for others. We finally succeeded in distributing the two materials properly in a

grinder.
After the exact technological parameters were determined, the test specimens were manufactured, containing 0, 25 and 50 m/m% reinforcing material. In addition, we used plain and irradiated fibers. We then tested our specimens using a pin-on-disk tribometer for tribology and wear. We also measured the hardness of the samples. The following figure (Figure 5) shows the construction of the pin-on-disk tribometer.

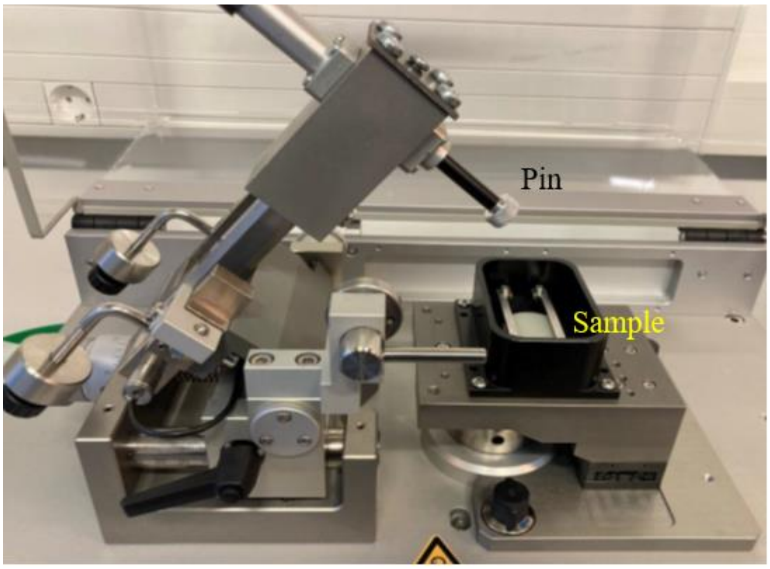

Figure 5. Pin-on-disk tribometer

In contrast to the disc-shaped UHMWPE homocomposite sample, a titanium pin is located in the pin-on-disk tribometer, just like the working surfaces of real implants. The mass of the samples was recorded before the measurements and the same was done after the tribometer test. Alternatively, we used a confocal microscope to examine the resulting wear marks. The following figure (Figure 6) shows a confocal microscope image of one of the wear marks. Unfortunately, the examination of UHMWPE was rather difficult with the confocal microscope.

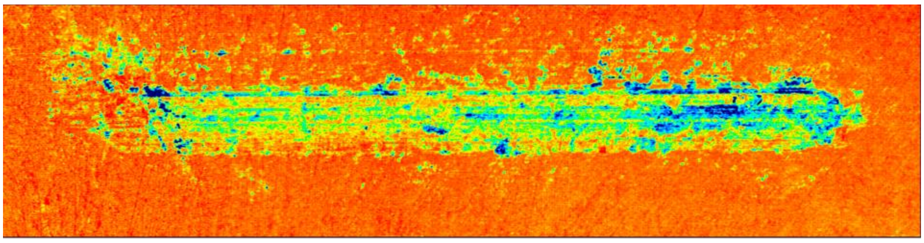

Figure 6. Confocal microscope image

The volume loss was combined from the results of the mass measurement and the confocal microscope measurement. The following diagram (Figure 7) shows the volume loss for each sample.

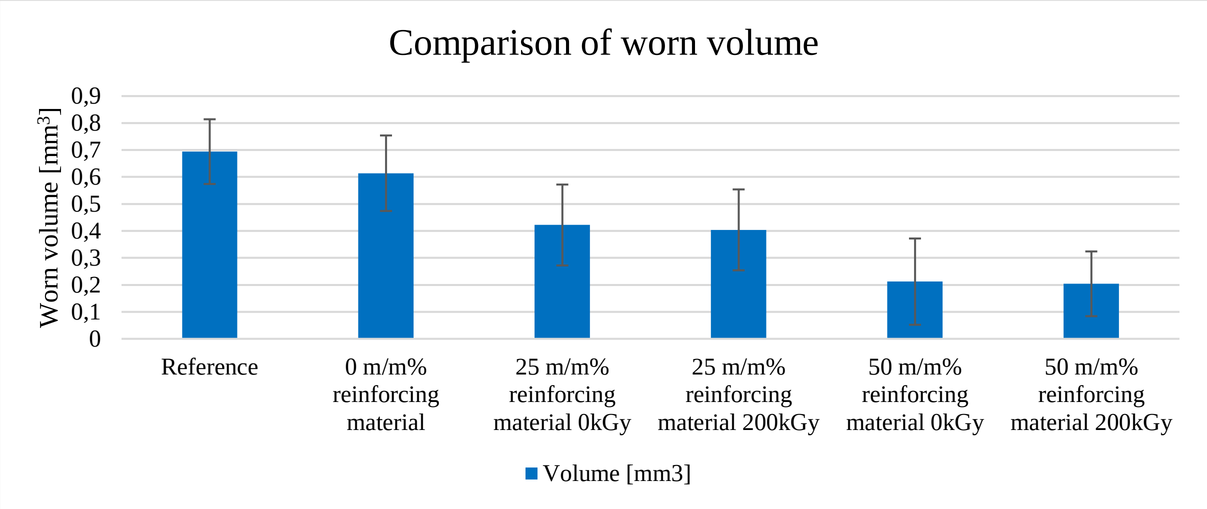

Figure 7. Comparison of wear volumes

It can be seen (Figure 7) that the wear resistance of the samples increases with increasing the proportion of reinforcing material, and it can also be seen that the irradiation of the reinforcing material also leads to a minimal increase in the resistance of the base material. It was also observed in the confocal microscope images that the higher the content of reinforcing material in the specimens, the lower the wear rate, and the larger the pieces of the resulting wear trace tended to be torn off, but with a smaller overall volume. It was also observed that the specimen we produced with 0 m/m% reinforcement had a higher wear resistance than the reference specimen.

We also measured the hardness of the samples. For this we used the KB Prüftechnik 250 BVRZ universal hardness testing machine, with a Vickers hardness tester, with a load of 10 kg. The resulting impressions were then examined with an optical microscope and hardness was calculated. The hardness values obtained are shown in the figure below (Figure 8).

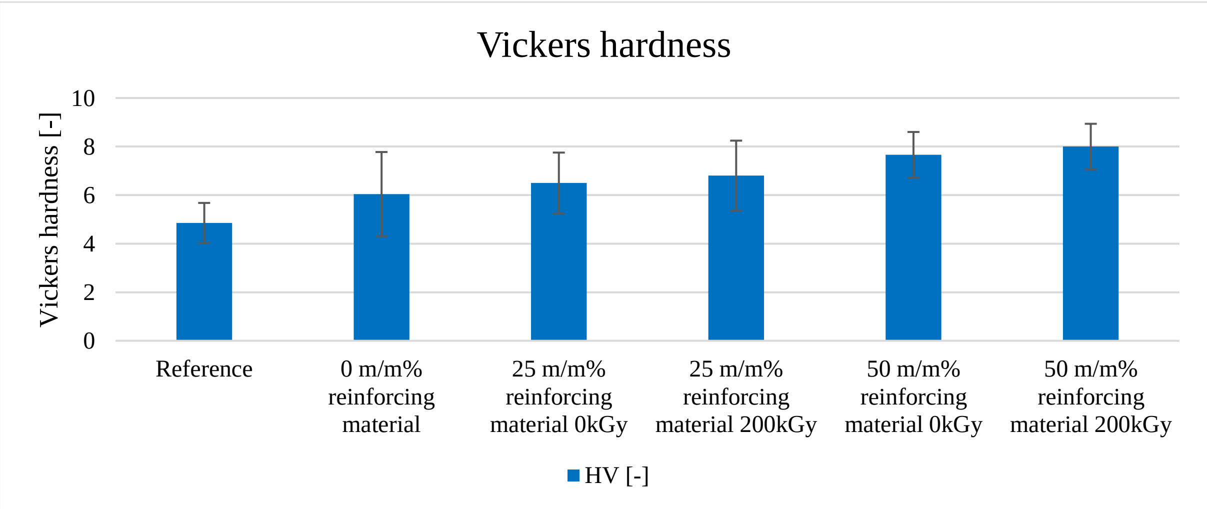

Figure 8. Comparison of Vickers hardness values

It can be seen (Figure 8) that the hardness of the specimens increases with the content of the reinforcing material, and the strength of the specimens is also slightly increased by the radiation-treated reinforcing material.

3. Conclusions

Overall, the production of the UHMWPE homocomposites was successful, after a long series of iterations the technology was adjusted. By irradiating the reinforcing material, we can increase the technological window in which we can work. Our tests have shown that the use of the reinforcing material improves the wear properties, and the use of the irradiated fiber also improves the wear properties slightly further. The same is also true for hardness, so increasing the content of reinforcing material increases the hardness of the sintered samples, and the use of irradiated reinforcing material increases the hardness even further. An explanation for the improved properties of samples containing irradiated reinforcement is that the irradiated fiber retains its properties - its orientation - better than the untreated reinforcement, and is therefore more resistant to the thermal effects of sintering.

The study shows that it makes sense to use UHMWPE homocomposites for implants, and therefore we would like to continue our studies in the future and extend the testing of sintered homocomposite samples to a multi-axis joint simulator. We would also like to carry out clinical trials.

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