Műszaki Tudományos Közlemények vol. 15. (2021) 80–86.
DOI: Hungarian: https://doi.org/10.33895/mtk-2021.15.16
Engliah: https://doi.org/10.33894/mtk-2021.15.16

The Developement of a New Shoulder Joint Prothesis System

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Abstract

In our work, we designed a new metal-polymer shoulder implant system that fully meets today's requirements - minimal invasive technology, a high degree of modularity - and can be personalized as needed. At the same time, its production does not exceed the currently available production technologies. Also, the data and parameters which are needed to design the tailor-made construction are easily accessible, as we have chosen a device that is widespread and commonplace in medical diagnostics and available in any hospital. Furthermore, we have tried to make our system as easy and fast to authorize as possible because it is challenging to place medical devices on the market, especially implants. We have tried to create the cheapest, most economical system and in addition, we wanted to gain the trust of implant specialists, as we incorporated their insights and experiences into our construction through continuous consultation.

Keywords*: shoulder implant, minimal invasive technology, modularity, tailor made construction, UHMWPE.*

1. Introduction

The human upper limb, the arm, may have been extremely important in the prominence of man from the animal kingdom, as it enabled the purposeful and efficient use of tools. The arm is also perfect for performing fine movements and precise work processes, but at the same time, we are also able to produce large amounts of force.

The upper limb is connected to the torso by the shoulder girdle joints – we can talk about three shoulder girdle joints – these ensure the wide range of movement of the shoulder. The full function requires a high degree of agility but also stability, coupled with very high compactness and complexity in the shoulder joint.

The shoulder joint is extremely vulnerable and complex. Severe shoulder joint lesions may require shoulder arthroplasty surgery, which is the third most commonly used type of artificial joint in implant surgery. The two most common forms of joint surgery procedures are knee and hip replacement surgery. The success rate of shoulder surgery remains behind that of knee and hip replacements, complaints occur much more often, the incredible freedom of movement of the original structure is less resettable, and pain regularly appears for patients. Contractures often develop – narrowing the freedom of movement of the joint (often painful) – and repeated surgery and revision surgery are much more often justified after the operation.

2. Literature review

Considering the structure and operation of the shoulder joint (articulatio humeri), it is a spherical or so-called free joint between the articular cup (scapula) and the arm bone (humerus) head. In terms of its range of motion, it is our largest and most complex joint [4]. From an engineering point of view, it can be modeled as a joint with three degrees of freedom - which can move in the direction of two axes and rotate along one axis [1]. A circular fibrous ring (labrum glenoidale) at the edge of the scapula enlarges and deepens the articular surface, which has a disproportionately small surface area (1:6) relative to the humerus head, which significantly contributes to joint freedom of movement and causes a serious challenge to both surgeons and engineers [4]. After all, the small workspace and the small load-bearing surface also cause serious problems [1]. The capsule of the joint is quite loose but very strong - this is necessary because the structure does not have a particular, cohesive ligament device, such as a hip or knee joint. So the joint is held together not by these articulating parts, but by the cone-like muscle sheath (called rotator cuff) enveloping the shoulder joint. This is because in this system, a stable ligament device and a stable joint capsule would impede the freedom of our shoulder joint, which has the largest range of motion, in addition to the disproportionately small articular surface, mentioned earlier [4]. It is from these two factors that the incredible vulnerability – coupled with the amazing compactness of the system – stem from. All of the above can be seen in detail in Figure 1.

In terms of the most common diseases of the joints, coxarthrosis of various abrasive origins has now become almost a common disease, leading to painful contractures - narrowing of the range of motion - and eventually complete loss of structure. We must not forget about the various traumas - especially common on the shoulder - and cancerous lesions, as these can also lead to the need for surgical treatment [5].

In terms of fixation, we distinguish two types of prostheses, cemented and non-cemented. In the cemented option, the bone cement (two-component polymethyl methacrylate - PMMA) provides fixation for a prosthesis after polymerization. Bone cement can be mixed with antibiotics so that local, targeted high drug concentrations can be achieved, with which inflammations and infections can be prevented or treated. Without cement, the structure is fixed with a wedge effect during implantation - this is called primary stability - and then secondary or biological stability is created by bone growth. To promote the best possible osteointegration, surfaces are often structured, for example, by metal spraying or cellular structures. Another method to support bone growth is to use various coatings such as hydroxyapatite [6, 7]. In general, cemented fixation is more commonly used in older patients, whereas in juvenile implants, cementless fixation is primarily used. However, deciding on this in each case requires an individual decision! [1] This can be explained by the fact that cement fixation becomes usable almost immediately after the operation - because no ossification is required - while without cement, full use can only be available after - 4-6 weeks - ossification. Of course, at younger age the body's bone-building capacity and bone quality is better, in the long term these implants are more successful than their cemented peers, and in case of revision surgery to remove the cemented prostheses it is more associated with higher bone loss, which further complicates subsequent operations. It is important to note that there is additional bone loss in both types of fixation, which is inevitable in the case of resection.

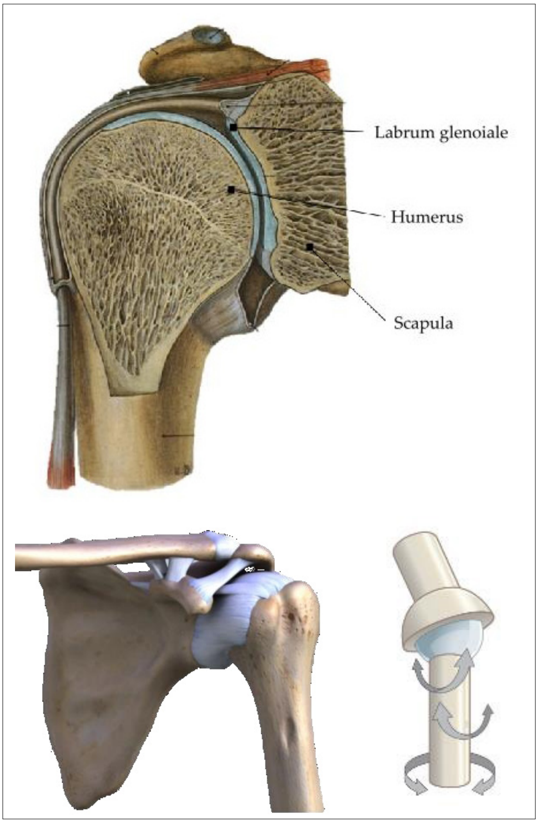

Figure 1. *Shoulder joint (articulatio humeri) – top* [1];
Sheath surrounding the shoulder joint – bottom left [2];
Engineering model – bottom right [3].

Anatomical and reverse versions are distinguished from shoulder joint implants. The difference between the two solutions is that the anatomical, as its name suggests, follows the structure of the natural shoulder in layout, while the reverse is an inverted system. So in the case of the reverse, the artificial joint head is not on the humerus, but on the scapula. An anatomical system is usually used when the muscles surrounding the shoulder are intact and reverse is implanted in the event of muscle injury. Deciding this is also an individual issue, as in the case of fixation **[1, 8]**. However, revision surgery is often performed only because the patient's condition no longer allows the use of the anatomical system - although the structure has not loosened or been destroyed - it is necessary to switch to reverse. In this case, it is a common protocol, with the exception of a few very complicated and expensive implant sets, to resect all implanted components.

In his work, Kurtz summarized the main complications of the anatomical design, which shows that the most common cause is the so-called glenoid loss - injury on the scapula joint - followed by loosening, then the rotator cuff rupture and bone fractures around the implants **[7].** It can be said that, in general, complete systems are removed in these cases during revision surgeries, although in the case of a sufficiently modular implant, it would be possible to retain certain components. It is also true if the treads of the implant are worn out. Unfortunately, these systems today are quite expensive and complicated, and difficult to authorize. Furthermore, we have to calculate with the fact that the medical community is extremely conservative - almost using just well-proven and mature implants - which makes it practically impossible to try and accept a completely new system - radically different from the previous ones. No one wishes to take responsibility and risk for a structure designed as a "greenfield investment".

We considered it essential to analyse the wear of implants that had already been artificially removed, so we used the so-called Hood method, which was initially used for the prostheses of knee implants. UHMWPE abrasion testing attempted to classify various surface abrasions - defects and discrepancies - in the 1980s, so different numbered regions were identified on each prosthesis, and then implants were examined at 10× magnification under a light microscope – Hood – **[9]**.

Seven forms of surface damage have been identified:

1. Pitting: on the running surfaces 2-3 mm diameter and 1-2 mm deep craters. The abrasion products released due to the loss of material can cause osteolysis (bone loss);
2. Embedded debris: May be caused by bone shavings, metal components, or any other debris, abrasion product. It causes serious osteolysis, furthermore damaging both work surfaces;
3. Scratching: One-dimensional surface damage - abrasive errors - likely at the metal surfaces and microscopic unevenness, or has debris among the treads caused;
4. Delamination: One of the most severe forms of damage, usually requiring immediate revision surgery, can lead to a rapid catastrophic system failure;
5. Surface deformation: Does not lead to material loss, thus significantly different from other forms of damage;
6. Burnishing: In case of the polished contact surface brighter, but also wear products are generated which lead to osteolytic reactions;
7. Abrasion: Goudging of the contact surface is a very common phenomenon.

Wear is classified by region and severity. The Hood-type methodology is semi quantitative and makes it possible to compare different types of prostheses **[7, 9]**.

3. Experimental part

In our studies, we examined three shoulder implants in detail using a GOM Atos Core 5 M 3-dimensional optical measurement system, and for evaluation, employed a program that displays the differences between the scanner-generated point cloud and the CAD model of the components. This representation is similar to the contour lines of a map. Thus clearly illustrating wear and various deviations. In the figures, the warm colours show deviations in the positive direction from the reference surface, which means that the examined surface element exceeds the reference. Cold colours have just the opposite meaning, so the deviation is in a negative direction, which means that the studied surface is below the reference surface. The more intense a colour type, the greater the deviance. Green indicates a perfect fit.

From **Figure 2** it can be seen that the edge of each sample and the lowest point of the treads were damaged, as discoloration was observed in these areas. Interestingly, all of them are intact along a ring ribbon covered with green colour, which indicates a perfect fit. In the case of the first implant, we can see a material loss on the edge of the spherical surface, but rather positive deviation from the reference surface on the middle of the implant due to the damaged – yellow area – and warm colour of the bottom, which results from the up crease due to the remaining deformation. There is also some difference on the edges – material loss – but it is not significant, however for the other two specimens it is just the opposite. Their outer edges were more damaged, in some places almost so deformed that they exceeded the range of the given scaling - grey regions - and the material was consumed from their inner areas, in contrast to the reverse artificial joint. However, there are more irregularities at the bottom of the treads of the second and third anatomical implants than in the first. At the same time, it can be said that the material loss and deformations of the anatomical prosthesis were smaller overall than that of the reverse.

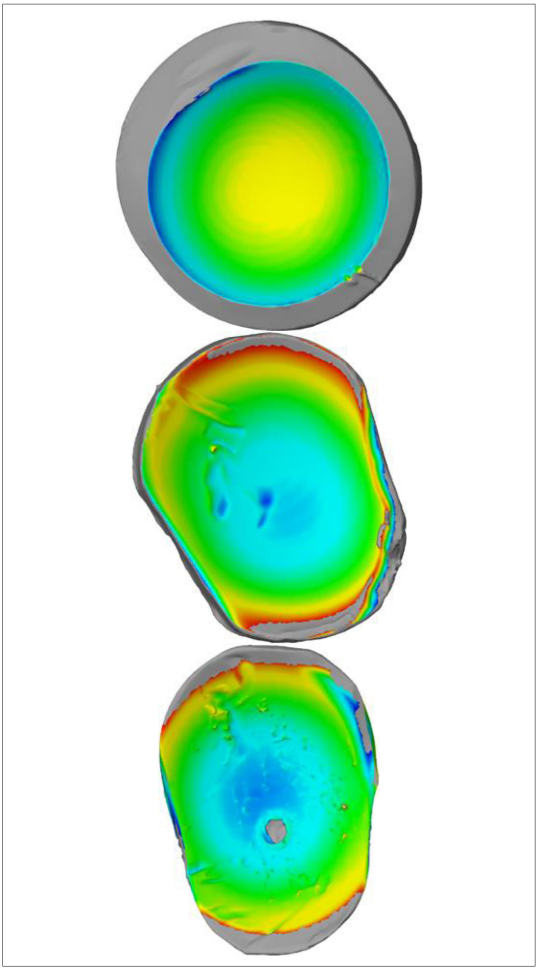

Figure 2. *Measurement results of prosthetic shoulder prostheses (Wear occurred in the blue areas, while creasing occurred in the yellow and red regions, but the fit was perfect in the green ring.)*

The loss of material with an annular structure, which is an interesting phenomenon, can be explained by the fact that the contact surface of the shoulder implants is rather small, this is necessary in order to expand the range of motion. Thus, the loads that occur are also distributed on this small surface, and in some situations, the implant may even lean on the head - perhaps this is why the edges of the second and third insert are more damaged.

Upon further examination of the implants, pitting, scratching, surface deformation, and in some cases, burnishing can be observed on the surface of each of them. The extent of pitting is most significant in the third sample, as some craters there are already so deep that they can also be detected on the scanner image. The second implant also has some of these deep pits, but significantly fewer, however, severe scratches can be observed on this. Pitting and scratches can also be observed on the first insert, but its size is so small that it is not visible in the image of the measuring system, just as abrasion can only be detected with the naked eye.

One of the implant revisions was necessary because its UHMWPE insert turned out from the basket and took place in a lateral position next to the head while the head continued to operate on the basket – metal-to-metal contact – thus generating significant wear damage.

By examining the relationship between the basket and the insert, a relatively large force is needed to break this contact. This indicates that a significant tensile force is present between surfaces in the shoulder prosthesis during operation.

The above thesis seems relatively logical since, for example, when we cling to the bus and the bus accelerates, it causes traction on our arm. Furthermore, the literature review also shows that the shoulder is held together only by the surrounding muscle cone – rotator cuff – which makes it an extremely mobile joint.

However, reviewing the literature, the producer planned and tested just for pressure, but we plan to perform examinations for pulling forces also. We also consulted implant specialists, whose statements revealed that the protrusion and the pulling force on the prosthesis is a real and unsolved problem.

4. Development part

We started with a model that is used very often today and can be considered well-proven – a construction on the top of **Figure 3**, – which is anatomically designed, non-modular, and not personalized, nor is it protected for tensile stress - so it can be seen that its further development is justified. We chose an anatomical design because, based on 3-dimensional optical measurements, this seemed to be more favourable in terms of material loss and deformation.

Modular implants do not require the removal of already fixed, ossified parts during revision surgery. This practically means that the artificial head and the insert can be replaced independently of the other components, so no resection is required. Thus there is no additional bone loss. There are currently such systems on the market, which are extremely expensive and complicated, so they are not widespread, and their effectiveness is very low. During our literature research it became apparent that for shoulder implants there are fairly modest results, so during the operation of this prosthesis, there is a relatively short period in which the system works well. This means that revision surgeries need to be performed more often.

By providing modularity, we want to facilitate such interventions. It is not necessary to remove the stem built into the upper arm or the tray screwed into the scapula – it is not necessary to remove the parts highlighted in red in **Figure 3** Thus, it also means less burden for the body – minimal invasive technology - because the rate of surgery is lower - there is no additional bone loss - in addition, the risk of infection and the chances of complications are reduced due to the reduced surgical time. Our development is also useful in cases where the patient's muscles are further damaged, so the prosthesis would no longer be able to perform its function because the anatomical implants are held in the correct position by the muscles, which surround the shoulder. In the case of modularity - revision surgeries performed from such an indication - it is sufficient to replace the two components since the reverse implants provide adequate stability in these cases as well.

To achieve the earlier outlined modularity, the only component of the system which needed to be changed is the tray that goes into the scapula because a socket had to be formed on it, in which - in the reverse case - the artificial head could seat. Furthermore, the UHMWPE insert alone cannot be placed on the other side - without any support - as this solution would lead to extremely fast destruction of our structure due to the increased stress during loading and the different material pairing. Thus in the case of a reverse design, a tray under the insert is required, which is highlighted in green in **Figure 3.** The tray of the insert was based and designed on the opposite side tray to make it as simple and cheap as possible to manufacture.

The tensile stress protection was solved with morse-cones – highlighted in red in **Figure 4.** Finding a solution was not easy because the disassembly required a high degree of modularity. At the same time, a fixed joint is essential to ensure adequate stability and support. Above all, the compactness and small size of the system also caused a serious problem. **Figure 4** shows the hole in the tray, which goes in the scapula - in the middle of the part - into which the head can be fixed in the reverse case.

Finally, we performed the personalization of the implant, for which we had CT images of cadaver bones, from which we made a CAD model. Based on these, we created the "Tailor made" construction, during which we collected the parameters to be modified, and finally tested the finished system within its anatomical environment and tested it within a CAD program. We examined col-

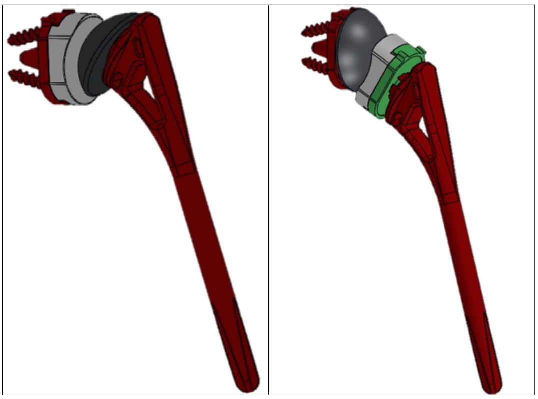

Figure 3. *The original – anatomical – prosthesis model and the modified reverse construction.*

lisions, fit, and freedom of movement (**Figure 5**). Parameters to be modified wer:

- Stem length;
- Stems (mainly thickness);
- The angle of the fixations on the tray;
- Tray bone contact surface shape;
- Head fixation angle.

We would like to note that we recommend (because of high variations and differences between people) better integration of the implant to set the artificial joint for the patient's intact joint and not for the textbooks data - which are considered normal positions - if possible.

Figure 4. *Tray, which goes in the scapula – on the top – the tray, which goes the top of the stem in case of reverse design – on middle part – UHMWPE insert – at the end*

5. Summary

In our studies, we modified an already well-proven and used implant system. We chose this because it makes marketing, testing, licensing, and dissemination easier, faster, and less expensive — because of the experience we have gained and the trust — and it can be used to make any similar system suitable for modern criteria. In this way, we want to achieve the broadest possible spread of modular systems and the most popular use of "Tailor-made" constructions. We collected together the necessary modified parameters for customization. The customization based on CT images – that is a completely standard procedure of medical diagnostic practice – can easily be done based on our developed implant and can make any other similar system possible.

Acknowledgements

The research reported in this paper was supported by the NRDI Fund (TKP2020 IES, Grant No. BME-IE-BIO) and by the National Bionics Program

Figure 5. *Our implant placed in an anatomical environment*

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