Method to analyse the failure process of metal-polymer implants by 3D scanning

István Nemes-Károly[1], Gábor Szebényi[1,2]

[1] Department of Polymer Engineering, Faculty of Mechanical Engineering, Budapest University of Technology and Economics

[2] Biomechanical Research Centre, Faculty of Mechanical Engineering, Budapest University of Technology and Economics

szebenyi@pt.bme.hu

DOI: 10.17489/biohun/2022/1/296

Abstract

In our study, we have demonstrated that 3D scanning provides a powerful tool for the examination of explanted worn implants. The 3D models of 6 worn hip and 6 worn knee implants were created by 3D scanning and compared to the original geometries. The root causes of the failure of the implants could be assumed even without information about the service of the implant. This can help in the design of more durable and robust implants and to select the most critical operation parameters, and to avoid premature loosening.

Keywords: hip implant, knee implant, wear process, 3D scanning, failure process analysis

Introduction

The goal of our research is to examine and evaluate the wear process of hip and knee prostheses and to create a model that adequately represents the wear and failure process of the chosen implants based on 3D scanning of explanted parts. Based on our findings, we refined and generalized the created theses to the different types of prosthesis groups studied, thus pointing out the strengths and possible shortcomings, weaknesses, or defects of the implants currently in use and analysed by us. The examined prostheses were divided into groups by type and implantation procedure. Based on the literature and the results, we tried to conclude comparable and relevant consequences.

To understand the very complex and complicated process of wear, we considered it essential to analyse the summary of the most common diseases of the examined joints, which leads to prosthesis implantation and to try to briefly describe the possible treatments. In excerpts, we covered the entire life cycle of the implant – its effect on the biological and physiological processes of the body – highlighting revision surgeries and their leading causes. One of the fundamental pillars of our work is to determine the cause of the processes leading to the removal of the implant and to compare the degree of wear with the original part, possibly with its model. Removed prostheses were examined by a 3-dimensional imaging procedure – 3D scanning and visual inspection to determine the regions most exposed to wear.

These zones were then examined more closely for characteristic lesions. Furthermore, the length of operation of the prosthesis, the manufacturing and material quality of the part itself and, of course, what kind of professional surgical procedure of the implantation, as well as the lifestyle and discipline of the patient can be deduced from the extent of the wear areas.

Finally, we compared the obtained results with the information obtained from the literature and drew our conclusions based on this.

From an engineering point of view, it is essential to say a few words about the structure and properties of bones. In terms of bone architecture, it is found in two types of arrangement, on the one hand in a solid-hard (*substantia compacta*) and on the other hand in a porous-spongy (*substantia spongiosa*) form.[1] Solid bone tissue mostly forms a relatively thin cortex (cortical) on the surface of the bones.[2] The modulus of elasticity of the bone cortex ranges from 7 to 30 GPa.[3] The spongy bone stock forms the bones' inner part instead of the cortical - solid cortex.[2] Due to its highly sophisticated – strict trajectory – structure, Young's modulus is 0.5-1.5 GPa – significantly lower than the mechanical properties of solid bone tissue –, yet it provides adequate strength with low self-weight.[3] This is because the spongy bone is a complex web of beams made of bone tissue, the gaps of which are interwoven by a network of medullary cavities. The beams of the spongy bone stock do not occur irregularly but in orderly into strictly lawful architectures,

Figure 1. Structure of human bone in the cross-sectional view of a hip joint[2]

in accordance with the static lines of force passing through them.

The structure of the bones is continuously adapted to the mechanical stresses effected on them - since the human body also aspires for the principle of minimum - so it is „economical" in the biological sense, i.e. it reaches the necessary strength with minimal use of materials. At the same time, the bone-losing and building processes rebuild the trajectory structure according to changes in stress conditions. The phenomenon is most clearly observed in the femur neck (*Figure 1*). In terms of structure, the femoral neck and upper femur can be compared to a crane boom, as the top of the femoral neck is a tensile – blue – highlighted lamellar bone tissue – while the bottom is pressurized – a red – highlighted tubular bone beam.[4]

In terms of the most common diseases of the joints, coxarthrosis of various abrasive origins, which has now become almost a common disease, leads to painful contractures – narrowing of the range of motion – and finally to complete loss of function. We must also not forget about the various traumas and cancerous lesions, which can also lead to surgical treatment. In the field of surgical interventions, arthroplasty has significantly reduced the number of other such therapies. Arthroplasties include surgeries in which joint movements are improved by re-forming, possibly replacing, or removing joint ends. Implantation of joint prostheses is one of the most successful surgical procedures.[5] In terms of fixation, we distinguish two types of prostheses, cemented and non-cemented. In the case of cement, the bone cement (two-component polymethyl methacrylate) ensures the fixation of the prosthesis in the bone bed after polymerization. In the case without cement, the structure is fixed with a wedge effect during implantation – this is called primary stability, which could easily fall victim to "economic" osteoporotic processes. The surface of the prosthesis is often coated with a hydroxyapatite surface layer, so it can interweave with bone tissue by bone-building, thus creating secondary or biological stability (*Figure 2*).[1,6]

Today, the most commonly used implant sliding surface material pairings are UHMWPE – cap – and cobalt-chromium (230 GPa), or TiAl6V4 (110 GPa) – head. These promise the most favourable results, and also the greatest experience has been gained in these fields. UHMWPE, like cartilage tissue, distributes the load and reduces the modulus of elasticity for the entire prosthesis – as the modulus of the metals is two orders of magnitude higher than that of bone tissue – thus improving the integration of the artificial joint. The serious problem is that the mechanical properties of implants differ significantly from that of the body, as stress creates micromovements between the bone tissue and the implant, causing the prosthesis to irritate bone tissue in its environment, causing osteolysis – bone loss – and eventually complete dislocation.

Its mechanical properties similar to those of the human body, and its special tribological properties and excellent biocompatibility also contribute to achieving excellent results with UHMWPE systems.[6]

Although UHMWPE systems have numerous advantages, they need to be replaced after a period of time, as septic loosening can occur. Some infection usually occurs often due to abrasion products. The excretion of these products from the joint occurs through the lymphatic circulation, through complex mechanisms, some of which are still unknown even today. This is limited by the ability of the "assigned" cells to absorb and absorb, and after a while, the tired mechanism is unable to process foreign abrasion products. Reactive tissue is formed, which, penetrating between the bone bed and the layers of prosthesis or adhesive cement, initiates implant loosening.[7]

Furthermore, another major cause of revision surgeries is aseptic dislocation, in which case no infection is present. These include various traumas – often caused by the implant itself – allergic reactions, granulomatous inflammation, metallosis (metal allergy), or Willert disease. Also, the implant can simply wear out and break down.[3,7,8]

For these reasons, it can be seen that a severe proportion of revision surgeries can be traced back to artificial joint wear and its negative consequences. Therefore, it is in our fundamental interest to better understand these processes and reduce them to the minimum possible level concerning our possibilities.

a)

b)

Figure 2. Different shapes for hip prosthesis implants.
a) polished surface for cement fixation; *b)* structured surface for integration without bone cement[6]

Biomechanica Hungarica 2022;15(1):17-27

UHMWPE abrasion testing in the 1980s attempted to classify various surface abrasions – defects – and identified different numbered regions on each prosthesis. After examining implants at 10x magnification under a light microscope, Hood[9] identified seven forms of surface damage:

1. "Pitting" (point corrosion): 2-3 mm wide, 1-2 mm deep craters, depressions on the surface.
2. "Embedded debris" (fragile debris): Bone chips or a metal component may cause this phenomenon. In addition to osteolysis, it damages the metal surface and causes further abrasive wear on the UHMWPE.
3. "Scratching": Linear defects on the surface, which are a form of abrasive wear, are likely caused by microscopic unevenness on metal surfaces.
4. "Delamination": Severe forms of damage, which can lead to catastrophic wear and tear, the disintegration of the implant, require immediate revision.
5. Surface Deformation: Unlike other forms of damage, it does not lead to material loss and strictly speaking, is not considered wear.
6. "Burnishing" (grinding): Abrasive wear so that it can be considered as adhesive, abrasive wear, but it also produces a wear product, debris, which can cause an osteolytic reaction.
7. "Abrasion": Bruising of the surface, typical abrasive wear.

Wear is classified by region and severity. The Hood-type methodology, which we used in our studies, is semi-quantitative and allows comparison between different types of prostheses.[6,9]

Nowadays, there are several methods to evaluate UHMWPE wear and tear gravimetric, radiographic, optical, fluid-displacement, and micro-computed tomography (microCT). All of these techniques have unique peculiarities and advantages. Fluid-displacement and gravimetric methods provide relatively accurate results, but these techniques were sometimes time-consuming because from the results, they do not find the damaged region from where implants have lost material. The optical method is included in this group, but in recent years – due to reverse engineering and image processing – computer science and software engineering has been so dynamically developed. Using the optical method, we can also get a point cloud – like from the end of the microCT technique – but it is sometimes faster, easier, cheaper, requires smaller and mobile equipment and contains fewer hazards.[6]

Because of the advantages of the optical method, it is widely used in anatomical studies, implant modelling, and pre-surgical planning. Sindhu and colleagues modelled knee load-bearing joints for developing the surgery process of total knee replacement. They compared different scanning techniques like coordinate measuring machine, 3D laser scanner, X-ray computed tomography and FARO arm edge. And then they examined the point clouds with CAD systems. At the end of the study they found, that X-ray computed tomography had given the most accurate data from scanning techniques, but the laser scanner was the second, not far behind from CT.[10]

Kocsis and his colleagues measured the wear rate of 24 total shoulder replacements with a 3D scanner. They found that the volumetric wear rate is more than twice as fast as in the case of total hip replacement.[11] Sometimes implants have a coating, and a group of researchers proposed an intelligent automatic control system for plasma processing of medical products with complex shapes utilizing 3D scanning. This system uses the data of a 3D scanner to control a robot manipulator.[12]

3D scanning is the most widely used in the dental industry today because tailor-made implants are a common way in dentistry.[13,14] Below a tailor-made implant model is presented (*Figure 3*) in scanned anatomical position.

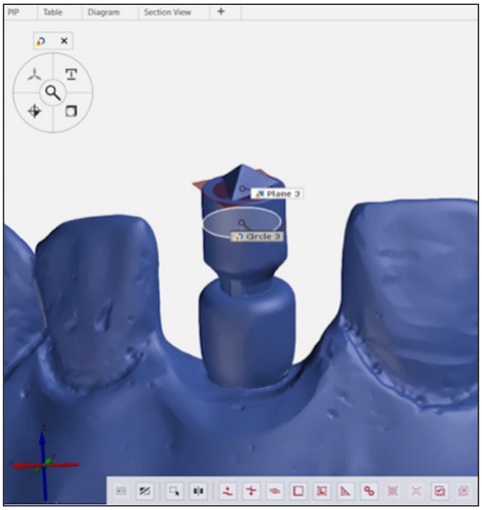


Figure 3. Tailor-made implant model in an anatomical position[13]

Materials and methods

In our study, we investigated 3 cementless and 3 cemented hip prostheses, 3 unicondylar and 3 total knee implants, removed by revision. Our measurements were performed with a GOM ATOS Core 5M 3D scanner (Carl Zeiss GOH Metrology GmbH, Braunschweig, Germany). We created a point cloud of each implant, which was compared with the CAD model of the parts. Where the CAD model was not available, we tried to assume a geometry that best represented the original, as the working surfaces of the implants are usually standardized. Either we compared our workpiece with a CAD model from another manufacturer's system, assuming identical standardized working surfaces, or we created a geometry that best represents the original system using a CAD program (*Figure 4*).

The warm colours displayed by the software in the figures show deviations from the reference surface in a positive direction, which means that the surface element under examination exceeds the reference. Cold colours have just the opposite meaning, so the deviation is in a negative direction, which means that the surface under study is under the reference surface. The green colour indicates the perfect fit. The method of the description given by us can only be interpreted on the surface of bodies and this is also given for the sake of illustration, not as an exact definition. The more intense the colour, the greater the deviance. The scale can be adjusted appropriately to the differences in the examined implant in the program.

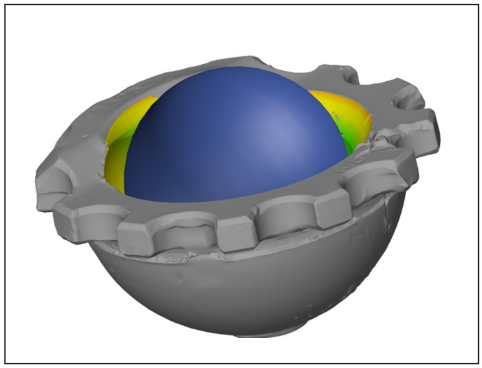


Figure 4. Definition of a sphere into the 3D scanned socket

Results and discussion

In the case of implants without cement fixation – *Figure 5* top line – it can be noted that the first and third samples are of an older type, but the middle one is a modern prosthesis.

The first implant can be said to have worn along a band during wear, so a stripe can be seen in the images. The spherical part of the cup, which came into contact with the head, became ellipsoidal, the major axis of which is the previously mentioned band. Point corrosion, scratches, and abrasions can be observed on the surface. The edges of the right-hand cup were wrinkled – also along a band – due to deformations. Abrasions and scratches could also be observed on its surface. However, these changes are perhaps not as conspicuous as the change in the middle workpiece, which is strange since it seemed the youngest of the three prostheses based on its design.

The middle (upper) sample shows that the head began to deepen the ravine around a point, and this process was already very advanced (*Figure 6*). On the opposite side, however, the material was practically not consumed, so there was no stress on the part at that location. At this certain critical point the material thinned so much that, if the implant was kept in intense light, it was almost transparent. The shadows on the other side were already visible, so this clearly had to be replaced during revision surgery.
This wear process appears to be more dangerous than that of the other two implants, as here the loads and abrasive effects are concentrated at and around the critical point, but the only abrasion was observed on the work surface.

The approximate original wall thickness is shown at the below part of the cross-sectional figure in *Figure 6*, where the point cloud and the geometry of the CAD model are presented together in overlay. On the other hand, as we look upwards, these two surfaces become more and more distant from each other. The change can also be traced in the colouring, the almost perfect fit is green, while in the upper section, it is getting darker blue with a marked dark blue spot between the blue and green gradients, probably representing damage created during resection.

In the case of cement-fixed implants – *Figure 5* lower line – the difficult-to-remove bone cement caused some problems during the meas-

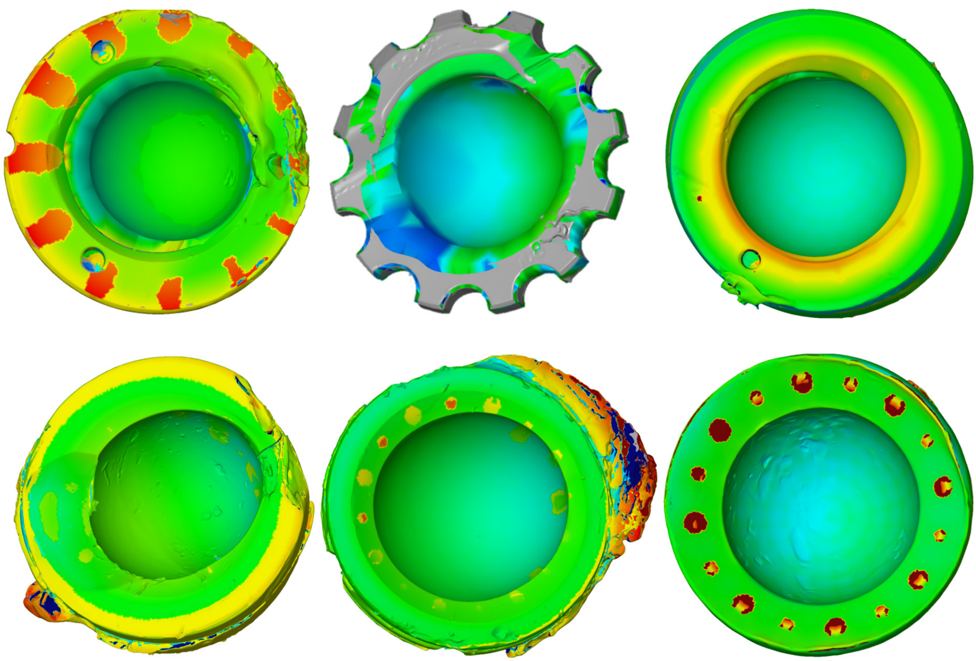


Figure 5. Scanned hip joint implant sockets (upper row – cementless, lower row – cemented sockets)

urements but here we had a CAD model of the original parts for each of them.

In the figures, the elliptical shape of the spherical part of the tufts can be observed with a simple eye measure without taking colouring into account. It was also visible that the rate of uneven wear was also much higher than that of their cementless counterparts.

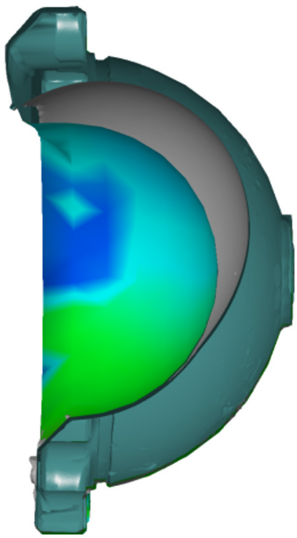


Figure 6. Cross-sectional 3D scan view of the second investigated cementless (*Figure 5* upper row, middle) hip joint socket

Also, with these implants, it can be seen that there is a privileged direction in which the head begins to wear out the cup. In the first two cases this is well visible but even in the third, it can be seen, although it presumably spent a much shorter time in regular use. This can be explained by the fact that the material loss found on it is much less than that of other cement-fixed ones. Still, on its surface, a significant amount of craters, abrasive debris, and abrasions can be observed in the pitting pattern. At the same time, relatively large pieces also detached from the cup, leading to implant loosening and premature revision.

Similar surface damage was observed on the first implant, but there the surgeon performing the primary operation fixed the prosthesis into the pelvis in the wrong position, so the femoral neck of the prosthesis touched the cup, creating a depression on the left side of the part of the implant. Damage to this prosthesis (*Figure 7*) suggests that this may have inhibited the patient's movement, as otherwise, such damage on the cup would not have occurred. This could have caused several problems and symptoms while wearing it.

Implantation of the second prosthesis was appropriate. Even so, its distortion is comparable to that of the first. The recess on the right side is also shown to be blue on the colour scale (*Figure 7*), and it can be seen with the naked

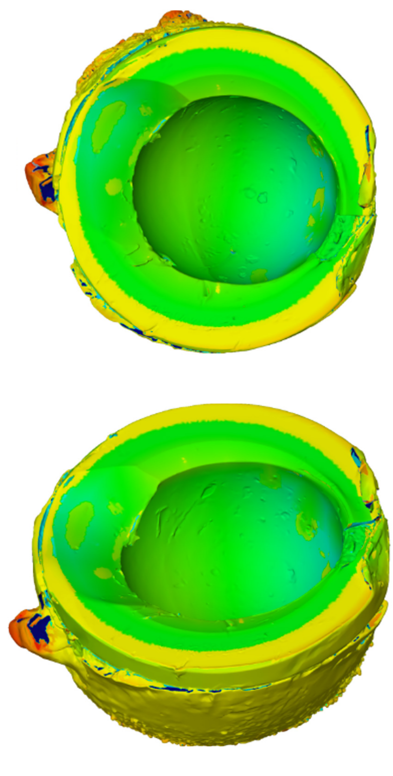


Figure 7. 3D scan of an incorrectly implanted socket

Biomechanica Hungarica 2022;15(1):17-27

eye that its shape has changed to an oval shape during use. On the other hand, the inner surface of this - in contact with the head of an artificial joint - is relatively even. There are no grooves, scratches, or other signs of damage.

In the case of knee implants, we examined 3 unicondylar knee implants – *Figure 8* upper row – the first two without cement and the last with cement fixation. With these implants, only one condyle of the knee is removed. During the measurements, we did not have a CAD model of the workpieces, and, considering the severe damage, we could not fit a structure that adequately represented the original geometry to the point clouds, but the extent of the damage is still obvious. It can be said that practically all 7 forms of damage can be found on all uni knee implants, so it does not make sense to highlight them separately. It can be seen that the artificial heads did not wear their surfaces parallel to their longitudinal axis and often not in the middle, so their positioning was not correct. It is due to this, and probably their asymmetrical design – as well as their small tread area – that they received such high forces and abrasive stresses locally that all of them required immediate revision surgery due to an accident-like, sudden failure.

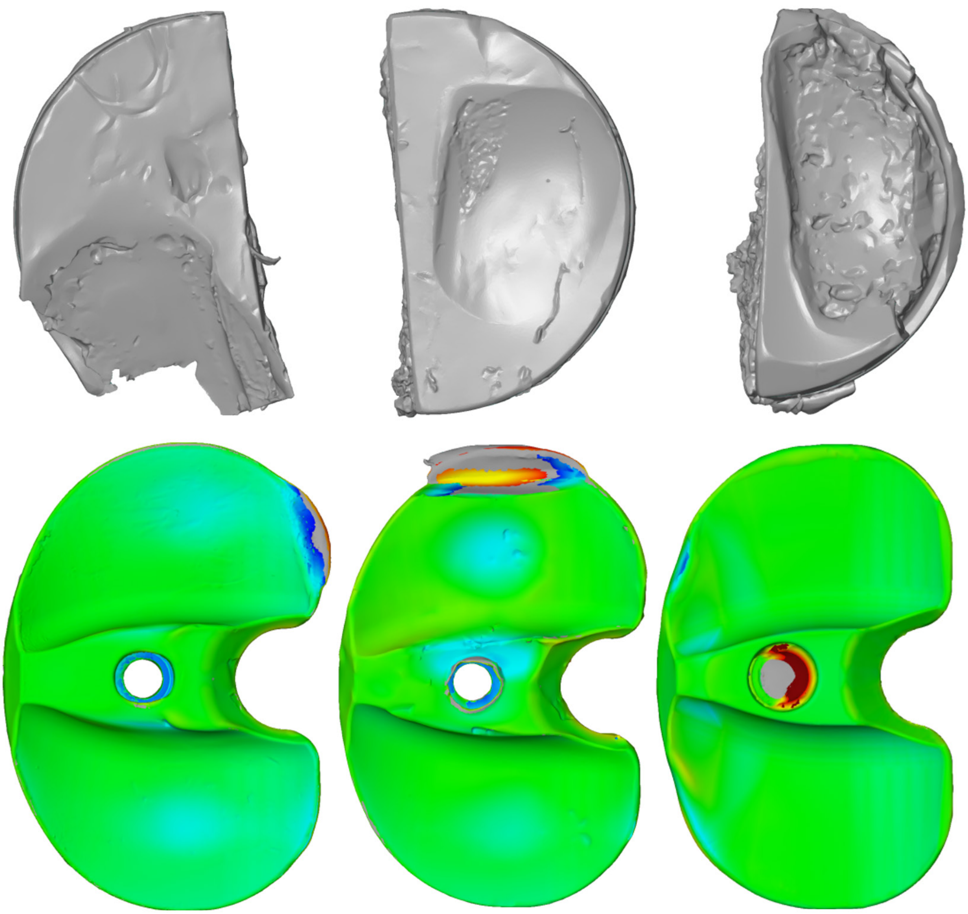


Figure 8. 3D scans of total knee replacement implants

Looking more closely at the first implant, it can be said that the lower corner was practically completely perforated, the artificial head was already working on the metal basket of the cup. This may be one of the interpretations because metal shards were practically rolled into the UHMWPE in the damaged zone. A further interpretation for this is that the metal fibre used for the marker, which can be used to tell how much the implant is worn *in vivo* on X-rays, has wholly disappeared near the cavity.

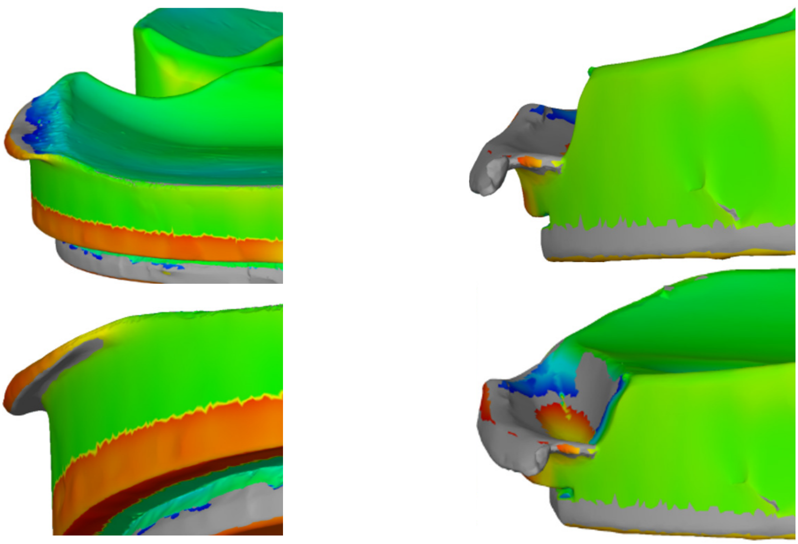
Examining the second prosthesis, it can be declared that it suffered the least damage and the operation was the best performed, but at the same time, extensive damage and severe locally concentrated lesions can be observed.

Taking the third implant under examination, it can be said that the material detachment was already extremely increased here – huge craters on the tread surface – and grandiose pieces were torn off the corner of the cup. This can be observed between 1 and 5 o'clock since the lower side of the groove containing the marker thread has already become free – the upper side has disappeared – fortunately, the metal thread has not been damaged. Here too, it can be said that the damage was already in the phase of sudden destruction and due to the large detached pieces, this was probably the greatest danger to the patient.

Examining total knee implants, it can be said that they suffered significantly less damage than the sledge prostheses. In terms of their fixation, all were cement-free.

The most seamless was the third cup, with some abrasions and polishes on the back, running all the way to the middle tract, where scratches can be observed. Deformation is still visible in the posterior and central areas, but the extent of this is not significant either. The almost novel condition of the examined sample suggests that it was most likely removed due to infection or loosening.

Examining the first prosthesis, the middle and back sections were damaged and, not signifi-



a) *b)*

Figure 9. Investigated right back edge of the first investigated sample
a) left edge of the second investigated sample; *b)* tie-shaped deformation

Biomechanica Hungarica 2022;15(1):17-27

cantly, obliquely, with scratches and abrasions, and a phenomenon known in the literature as a bow tie, a bow-tie sign (*Figure 9*).

This can also be observed on the right side of the middle sample. However, two recesses can be seen in the central area of the implant – with pitting, abrasion, and scratches around them – it does not appear so markedly here that the wear in the posterior regions is almost the same as in the middle. It can be said that the structure operated at least one-sided, as the deformation on the right side is more extensive, but this is not as significant as in the case of uni knee implants.

Conclusions

In our study, we have demonstrated that 3D scanning provides a powerful tool for the examination of explanted worn implants. The root causes of the failure of the implant can be assumed even without information about the service of the implant. This can help in the design of more durable and robust implants and to select the most critical operation parameters, and to avoid premature loosening.

Overall, it can be concluded from the hip implants that cementless fixation is more favourable not only for loosening but also for the lifetime of the artificial cup. With the establishment of biological stability, the structure behaves like an adjustable bearing and adapts to loads to a certain extent, making wear processes more even. While for cemented prostheses, a lot depends on the precision of the implant surgeon. Finally, it is no coincidence that the literature calls hip implants a "golden standard" among prostheses, as they do not show sudden breakage, are more balanced, have stable wear, and have a significantly longer lifetime.

The conclusion of our examinations about knee implants is that small bearing surfaces, and asymmetrical designs should be avoided. It was also observed in the case of hip prostheses that point contact is not desirable. This is much more pronounced here. Uni knee implants probably performed poorly because their mechanical properties were significantly different from human tissues, so it would be essential for the body and the artificial systems to be implanted to have the same mechanical properties. This can be explained by the fact that bone and cartilage tissues absorb the load much softer than the implant, resulting in asymmetric stress and increased wear if only one of the condyles is replaced. However, due to the micro-displacements between the bone and the implant, it is also vital to achieve equivalent mechanical properties. It can also be observed that – according to the literature – the middle and posterior sections of most of the knee prostheses are worn, to eliminate which it would be essential to copy the original – polycentric – geometry of the knee joint as accurately as possible as well as designing an implant that has a play of about 5 centimetres, similar to the original joint. This would prevent entrapment, extreme loads and protrusions in the system – and thus the formation of a bow tie signal – asymmetrical failures – as the structure could work like an adjustable bearing.

Abbreviations

- UHMWPE: Ultra High Molecular Weight Polyethylene
- CAD: Computer Aided Design

Irodalom

1. *Szentágothai J.* Functionalis Anatomia – Az ember anatómiája, fejlődéstana, szövettana és tájanatómiája I. kötet. Budapest: Medicina Kiadó; 1975.
2. *Vízkelety T.* Az ortopédia tankönyve. Budapest: Semmelweis Kiadó; 1999.
3. *Poprády H.* Újszerű vállprotézis fejlesztése orvosi és mérnöki követelményrendszer alapján [Diplomadolgozat]. Budapest: Budapesti Műszaki és Gazdaságtudományi Egyetem, Gépészmérnöki Kar; 2019.
4. *Szendrői M.* Ortopédia. Budapest: Semmelweis Kiadó; 2006.
5. *Jones CA, Voaklander DC, Johnston DW, Svarey-Almazor ME.* Health related quality of life outcomes after hip and knee arthroplasties in a community based population. The Journal of Reumathology 2000;27(7):1745-52.
6. *Kurtz SM, editor.* UHMWPE Biomaterials Handbook. 3rd ed. Amsterdam: Elseiver Inc.; 2016.
7. *Sarungi M.* Arthroplastica regiszter [PhD értekezés]. Pécs: Pécsi Orvostudományi Egyetem; 2003.
8. *Holnapy G, Szalay K, Szendrői M.* A csípő arthroplasztika tribológiai vonatkozásai. Magyar Traumatológia, Ortopédia, Kézsebészet, Plasztikai Sebészet 2012;55(3):185-94.
9. *Hood RW, Wright TM, Burstein AH.* Retrieval analysis of total knee prostheses: A method and its application to 48 total condylar prostheses. J Biomed Mater Res 1983;17(5):829-42.
10. *Sindhu V, Soundarapandian S.* Three-dimensional modelling of femur bone using various scanning systems for modelling of knee implant and virtual aid of surgical planning, Elsevier Measurement 2019;141:190-208.
11. *Kocsis G, Payne CJ, Wallace A, McNally D.* Wear analysis of explanted conventional metal back polyethylene glenoid liners. Medical Engineering and Physics 2018;59:1-7.
12. *Alontseva DL, Ghassemieh E, Krasavin AL, Kadyroldina AT.* Development of 3D scanning system for robotic plasma processing of medical products with complex geometries, J Electronic Science and Technology 2020;18(3):212-22.
13. *Atalay S, Çakmak G, Donmez MB, Yilmaz H, Kökat AM, Yilmaz B.* Effect of implant location and operator on the accuracy of implant scans using a combined healing abutment-scan body system. Journal of Dentistry 2021;115:103855.
14. *Sami T, Goldstein G, Vafiadis D, Absher T.* An in vitro 3D evaluation of the accuracy of 4 intraoral optical scanners on a 6-implant model. J Prosthet Dent 2020 Dec;124(6):748-54.

Hereby we would like to thank Dr. Zoltán Kiss, who supported the preparation of this paper. The research reported in this paper and carried out at BME was supported by the NRDI Fund (TKP2020 IES, Grant No. BME-IE-BIO) based on the charter of bolster issued by the NRDI Office under the auspices of the Ministry for Innovation and Technology. The research has been supported by the NRDI Office (OTKA K 138472). The project is funded by the National Research, Development and Innovation (NKFIH) Fund, Project title: „Developing a new generation of customized medical implants and medical aids for additive technologies"; the application ID number: NVKP_16-1-2016-0022.

Gábor Szebényi
Budapest University of Technology and Economics, Faculty of Mechanical Engineering, Department of Polymer Engineering
H-1111 Budapest, Műegyetem rkp. 3.
Tel.: (+36) 1 463-1466