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Improving Optical Damage Analysis of Knee Implants from an Engineering Perspective

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Abstract

In our studies we analyzed the wear and damages of 15 explanted total knee implants. For this purpose, we first reviewed the relevant literature, which showed that most of the available articles are rather medical and do not contain relevant information from an engineering point of view, and those that are relevant from an engineering point of view are rather outdated from today's point of view. Therefore, we have developed an optical damage analysis that can be used to filter out results that are relevant and comparable from an engineering point of view. Our damage analysis was based on an existing and well-established method, which is now outdated and therefore, its further development was highly justified. The developed optical damage analysis was then used to test our samples. We drew conclusions, and based on these conclusions, we suggested how to improve further the systems we investigated.

Keywords

total knee implant, UHMWPE, failure analysis, 3-dimensional scanning

1 Introduction

Nowadays, artificial joint replacement is becoming more and more common as the life expectancy of the population is increasing due to improving living conditions. The increasing average age and the harsh, fast-paced world we live in mean that our joints have the potential to become damaged. In such cases, to maintain proper function and living conditions, an artificial joint is inserted at the end of a multi-stage treatment process. It is clear that of all the surgical treatments, joint implants are the most successful, as they can preserve and, in some cases, improve the function of the treated joint and, thus the patient's quality of life. Currently, the second most common prosthesis joint after the hip is the knee, followed by the shoulder. Prostheses, like all engineering systems, have a life expectancy and need to be replaced at some point, which is done through revision surgery. Although hip implants are the gold standard in prosthetics, even in all but the best cases, they need to be replaced every 20–25 years. For knee implants, this time is considerably shorter, rather 10–15 years, as it can be stated that there is no truly mature design, a golden standard, among knee prostheses [1, 2].

Today, countless types of knee joint replacements have been developed. There are total knee replacements that involve only one condyle – unicondylar – and total knee replacements that replace the entire joint. There are even prostheses that replace only the knee cap - patella [2]. The first is a so-called stabilization type, where the patient's posterior cruciate ligament is removed. In the second, the patient's posterior cruciate ligament is retained. And a partial knee implant, as only one condyle is removed from the patient, these systems are called sled or unicondylar prostheses.

The main difference between stabilization and total knee replacements based on the retention of the posterior cruciate ligament lies in the aperture of the systems. This can be observed in Fig. 1. It can be seen that in the stabilization type, there is a protrusion in the center, around the fixation screw hole, which is intended to provide stability to the system, as the patient's posterior cruciate ligament is no longer present to hold the system in position. In the case of total hip implants based on posterior cruciate ligament retention, this region is flat, as stability is provided by the patient's ligamentous apparatus [2–4].

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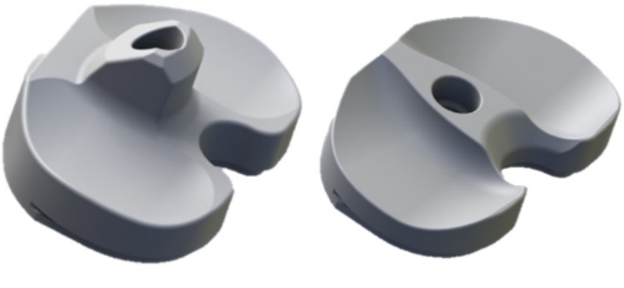
(a) (b)

Fig. 1 Inserts of posteriorly stabilized (a) and posterior cruciate ligament-retaining (b) total knee implants

From an engineering point of view, the knee joint presents many difficulties, challenging both the designers and the surgeons who install it. Resting at the end of our longest bones, it is subjected to enormous forces, which are also significant as we carry our entire body weight on our knees. Based on measurements taken on sensitized knee implants, a load of up to 7.6× times body weight can be applied to the prosthesis. FE simulations of this load on the prostheses show that the stresses are significantly higher than the yield stress of UHMWPE, an artificial joint insert. Another major challenge is that the structure has a 5 mm clearance, and in addition, polycentric rotation occurs during its movement, i.e., its center of rotation changes during bending [2–6]. The changing center of rotation during wear can be observed in Fig. 2.

As stated earlier, revision surgery tends to be needed more often than hip implant surgery, with the complicating factors detailed above contributing greatly to this. From a medical point of view, there are basically two possible reasons for revision surgery, namely septic and aseptic complications. From an engineering point of view, there are three main possible causes of revision surgery, namely loosening, wear, and possible fracture. In the present article, we will focus on wear and tear, and thus we will look at the most sensitive component of artificial knee joint implants, namely the UHMWPE insert [2].

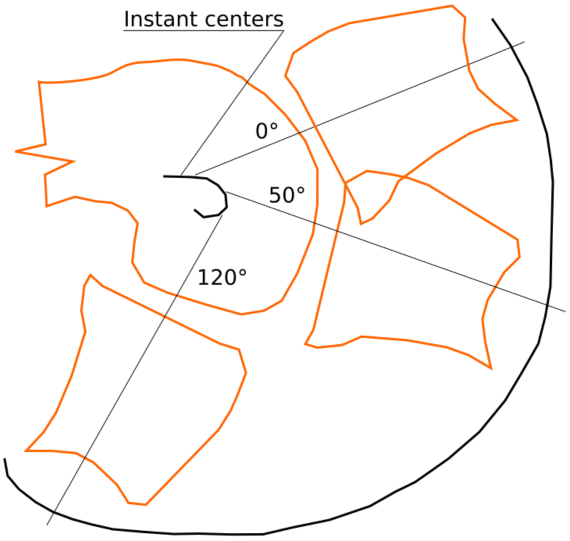

Fig. 2 When the knee is flexed, the center of rotation changes

In the 1980s, Hood et al. [7] developed a method to compare different types of damage. They classified the 7 types of damage into classes and thus determined their degree of risk. The 7 types of damage:

- Pitting: pits 2–3 mm in diameter and 1–2 mm deep on the tread. Minimal material loss.
- Embedded debris: debris embedded in the working surface of the UHMWPE insert, which may be metal or polymer. During movement, they can damage both the resin head and the diaphragm.
- Scratching: in-line – 2 dimensional – damage. This includes various scratches. Minimal loss of material.
- Delamination: the material separates into plates. Continuous cyclical stresses cause the structure to fatigue and break down into plates. There is a very serious loss of material.
- Surface deformation: a process of damage due to deformation of the surface. No loss of material.
- Burnishing: a process of damage due to surface bleaching. No loss of material.
- Abrasion: a form of damage where abrasive wear occurs. Significant loss of material.

They used an optical microscope at 10× magnification. They divided the surface of the vacuoles into zones in order to localize the lesions. Each lesion shape and region has a score number, so that their hazard can be classified and compared [2, 7]. The zones they defined can be seen in Fig. 3.

Hood et al. [7] found that the most common form of damage is scratching with a probability of 90%, followed by pitting with a probability of 81%, then burnishing with

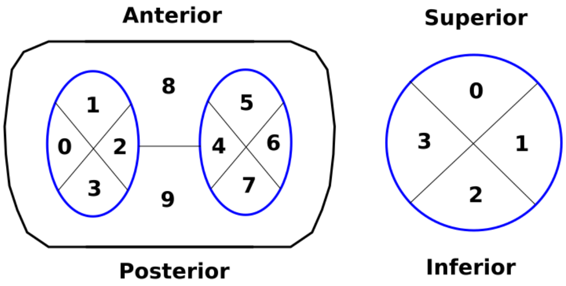

Fig. 3 The zones defined on the surface of the UHMWPE inserts in Hood's method [7] (Redrawn by Nemes-Károly and Szebényi)

a probability of 75%, surface deformation with a probability of 62%, embedded debris with a probability of 48%, and abrasion with a probability of 41%. One of the most dangerous forms of damage, delamination, has a probability of 4% [7].

Hood et al.'s article [7] was clearly a pioneering one on the subject, as it certainly provided an engineering perspective on the UHMWPE wafers removed by revision. However, we think it is important to note that we believe that the regions defined in the working surfaces should be further subdivided and their delineation should be precisely defined. Furthermore, we believe that the method defined by Hood needs to be further developed, as technology has evolved considerably in the past 40 years, and it is no longer only possible to examine different types of damage using optical microscopes.

Crowninshield et al. [8] have also carried out studies similar to Hood's. In their measurements, they found that the manufacturer's figure for wear of 4.1 µm/year did not correlate with any of their samples. None of the inserts delaminated, cracked, or significantly deformed on the top or back side. The most significant damage was embedded debris and scratching caused by bone cement [8]. Crowninshield et al. [8] divided the implant into regions, as shown in Fig. 4.

Crowninshield et al.'s article [8] is based on a substantial patient data set, but it is rather medical in its approach, so it has relatively little relevance from an engineering point of view. The zones defined on the working surfaces of the implant are, in our opinion, rather provocative and would need refinement. Furthermore, the extent of wear and deformation is determined by the distortion of the manufacturer's label, which is ingenious, but we believe there are more accurate solutions.

Muratoglu et al. [9] also conducted similar research to Hood's studies, except that they compared cross-linked and conventional UHMWPE inserts. They found that machining marks disappeared much less from the surface of the cross-linked structures. Furthermore, the two most important damage factors were abrasion and deformation and their combination. The persistence of machining marks in cross-linked systems suggests that deformation, rather than wear, was the main cause of their shape change [9]. In their study, Muratoglu et al. [9] also identified zones on the implant surface, which are shown in Fig. 5.

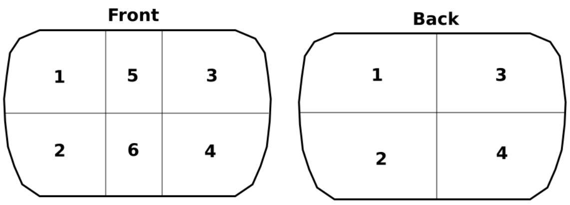

Fig. 4 Zones defined on the surface of UHMWPE inserts in Crowninshield et al.'s study [8] (Redrawn by Nemes-Károly and Szebényi)

This article is similar to the previous one in that it contains valuable and encouraging results, but its tone is rather medical in nature and, therefore, often irrelevant from an engineering perspective. They consider it unfortunate to divide the working surface in such a way that its longitudinal axis coincides with the longitudinal axis of movement of the structure, as this does not allow specific failure zones and weak points to be identified. There is a good chance that they will overlap into several zones that we have defined, making it difficult to localize the damage. Also, in this article, the use of machining marks and manufacturer's markings to determine wear and deformation is ingenious, but we believe there are more accurate solutions.

Miller et al. [10] investigated the extent to which the electrocautery used during surgery damages the artificial heads and the effect of this damage on the UHMWPE inserts. Their measurements used a scanning electron microscope to detect pitting and minor surface damage and a profilometer to detect surface irregularities. They concluded that damage to the artificial head, as well as head-induced abnormalities in the vault, can be well detected using this method. However, it is questionable whether these abnormalities can cause clinical complications [10].

It is clearly positive that wear and substrate changes are no longer inferred from machining marks, but the article does not contain much relevant information from an engineering point of view, its tone is rather medical.

Kahlenberg et al. [11] compared four different rotational knee implants using damage analysis. The UHMWPE components were divided into zones, and then the damage was evaluated based on subjective criteria [11]. The zones

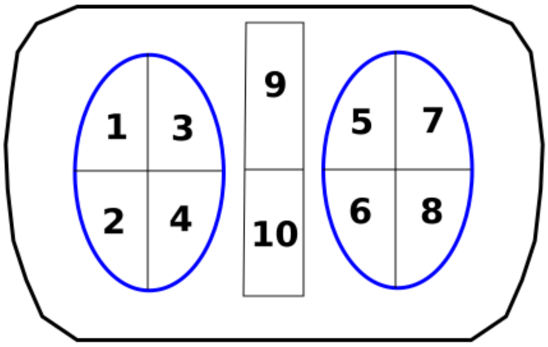

Fig. 5 Zones defined on the surface of UHMWPE inserts in Muratoglu et al.'s study [9] (Redrawn by Nemes-Károly and Szebényi)

defined by the authors are shown in Fig. 6. It was observed that there was significantly more rear wear. Finally, virtually all implants received similar scores [11].

While the article is an excellent application of Hood's damage analysis and contains many encouraging and engineering-relevant values, our assertion here, as in Hood et al.'s article [7], is that the method needs to be revised and modernized. We consider it important to emphasize that the subdivision of implant zones needs refinement.

Eckert et al. [12] examined the thickness of the inserts in terms of their survival. For their measurements, they used a light microscope and Hood's damage analysis. They concluded that there is no difference between thick and thin inserts. Burnishing, followed by scratching and pitting damage forms, were the load is the most prominent on the surface of the implants. In their measurements, they divided the working surfaces of the implants into regions [12], which can be seen in detail in Fig. 7.

Again, the division of the working surface of the implant could have been more refined.

Manson et al. [13] studied unicondylar knee prostheses and found that designs that performed worse in survival also scored worse in damage analysis. From this finding, it can be concluded that, basically, Hood's damage analysis works well. In their investigations, they concluded that scratching and pitting damage forms are most frequently encountered, followed by surface deformation [13].

Bourdon et al. [14] investigated the wear of currently popular knee implants that have already been removed by revision. They used radio-stereometric analysis (RSA), with images taken from multiple angles, to determine a 3-dimensional representation of the implant and the position of the systems relative to each other. It was possible to tell that the medial condyle always showed more wear. It is concluded that implants with posterior overdenture have a more favorable wear behavior [14]. We believe that this is possible because these systems have a larger contact area.

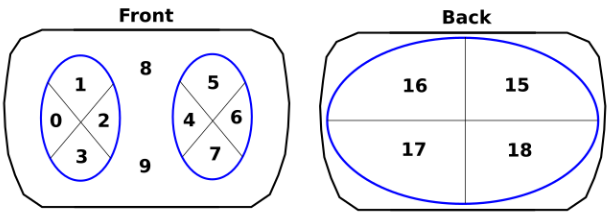

Fig. 6 Zones defined on the surface of the UHMWPE inserts in Kahlenberg et al.'s study [11] (Redrawn by Nemes-Károly and Szebényi)

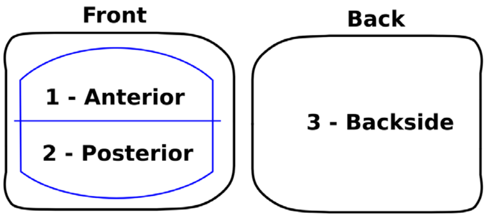

Fig. 7 Eckert et al. [12] have investigated the zones defined on the surface of UHMWPE inserts (Redrawn by Nemes-Károly and Szebényi)

The article is clearly new compared to the others and contains interesting information from a metrological point of view, as well as engineering. However, the authors only studied wear, so their damage analysis is not complete.

2 Materials and methods

It can be seen that many people have done damage analysis on knee implants, often not with the proper accuracy and often lacking an engineering approach. Thus, it is often not possible to draw appropriate, relevant, long-term conclusions from their results or to compare them with results measured by others.

Our aim is to develop an optically based test method that can be used to screen for engineering-relevant results that can be compared with each other and applied uniformly to the different knee implant systems on the market. As a starting point, the Hood's theme is perfect, as the seven damage types defined are still perfectly valid today. However, using only an optical microscope to determine the different deformations and abrasions is no longer viable.

For this reason, we used a scanning electron microscope (SEM), an optical microscope, and a 3-dimensional scanner.

Before the scans, we prepared the implants in two steps, the first step was to clean the surface of the implants, and then to place the reference points. Based on these points, the software can match the different views. Secondly, we applied developer spray to the surface. Before the SEM examinations, we made the surface of the polymer inserts electrically conductive by gold sputter coating with a Jeol FC-1200 device.

As the first step in our tests, we divided the implant surface. The two intersecting lines were adjusted so that they were level with the top of the upper mantle of the fixation hole at the top and the bottom of the lower edge of the midspine at the bottom. This is so that the point of intersection of the two lines is approximately where the artificial head touches the tendon at rest. For other knee implant constructions – unicondylar or posteriorly stabilized – the point of contact can also be determined so that the intersection of the two dividing lines can be placed there. We have refined Hood's division by dividing the middle and outer parts of the treads by a circle. This is necessary because the middle areas are subject to almost continuous loading and are, therefore, more likely to be damaged. It also provides more accurate information about where the artificial head is located during operation and where it is subjected to the greatest stress and is also useful for color plots, as the color scale can be precisely tuned to the area of interest. The radius of the circle is defined so that the prosthetic head is always in the resting position, even with the anatomically defined 5 mm of play. And the center of the circle is naturally aligned with the intersection of the two straight lines drawn earlier. The division can also be placed on a microscope image, photograph, or 3-dimensional scanned model. See Fig. 8 for a more detailed view of the division we have in mind. (The colors used are also shown later in the diagrams to help.)

We have also numbered the regions we have defined, for better identification, which can be seen in Fig. 9. The inner parts start with 1 and increase counterclockwise, while the outer parts start with 2 and are numbered in a similar logic.

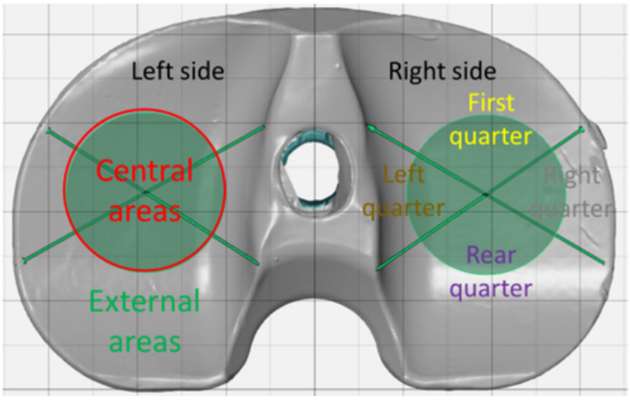

Fig. 8 The proposed division (colors will appear later in the diagrams for better understanding)

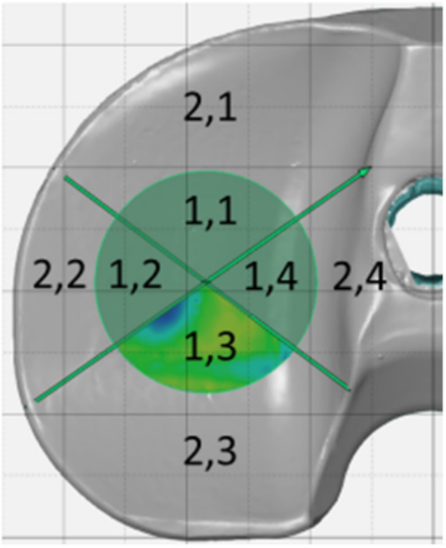

Fig. 9 Numbering of the regions we have defined

After dividing the implant's running surface, we examined the lesions using optical microscopy and SEM and classified them into seven categories of Hood's method, taking into account the area of the implant where they are located.

In turn, a 3-dimensional scanner was used to determine the wear and deformations. To do this, we first prepared the specimens and then used a GOM ATOS Core 5M 3-dimensional scanner to create a point cloud of the worn inserts. Then, using GOM Inspect 2018, the point cloud was repaired and compared with the CAD model of the original part and the point cloud of the worn insert.

The program visualizes the differences between the original CAD model and the point cloud of the worn implant, as well as the topological level lines, by displaying negative deviations from the reference surface – in this case, the CAD model – in cold colors and positive deviations in warm colors. The stronger the intensity of a color, the greater the distance between the two surfaces under consideration. Green areas indicate an exact fit between the two surfaces.

The above method can be used to produce very informative color plots, but in order to obtain accurate numerical data, it is possible to export the differences between the two surfaces under investigation. With these, it is now easy to produce diagrams.

3 Measurements

During our measurements, we had 15 anatomically designed knee implants with cemented fixation, of which seven were right-leg, and eight were left-leg implants.

In the first step, optical microscopy and electron microscopy investigations were performed. Some typical differences can be observed in Fig. 10 and Fig. 11.

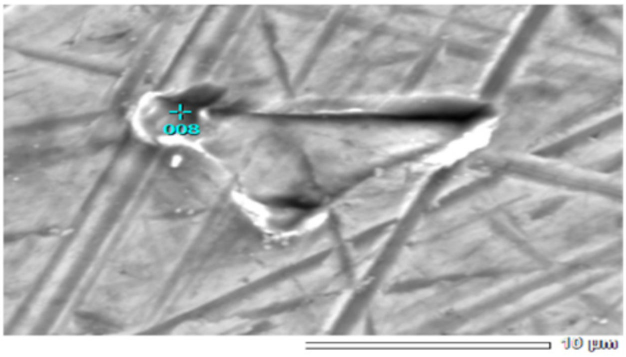

Fig. 10 An incipient pitting crater in the SEM image

Fig. 11 Significant surface deformation, pitting, scratching, burnishing and abrasion on the tread surface

Overall, most of the lesions were found in the inner regions, but there were also cases where the defects extended to the outer regions. It was also observed that the right side of the left implants contained more lesions, while the left side of the right implants contained more lesions.

Pitting was the most common type of damage, followed by scratching and burnishing, and surface deformation. In some cases, embedded debris and abrasion were also present, and in one case, extremely severe delamination was present, which extended not only to the middle but also to the lower regions.

Point clouds were then produced using the 3-dimensional scanner to produce informative color plots corresponding to the map contours, some of which are shown in Fig. 12.

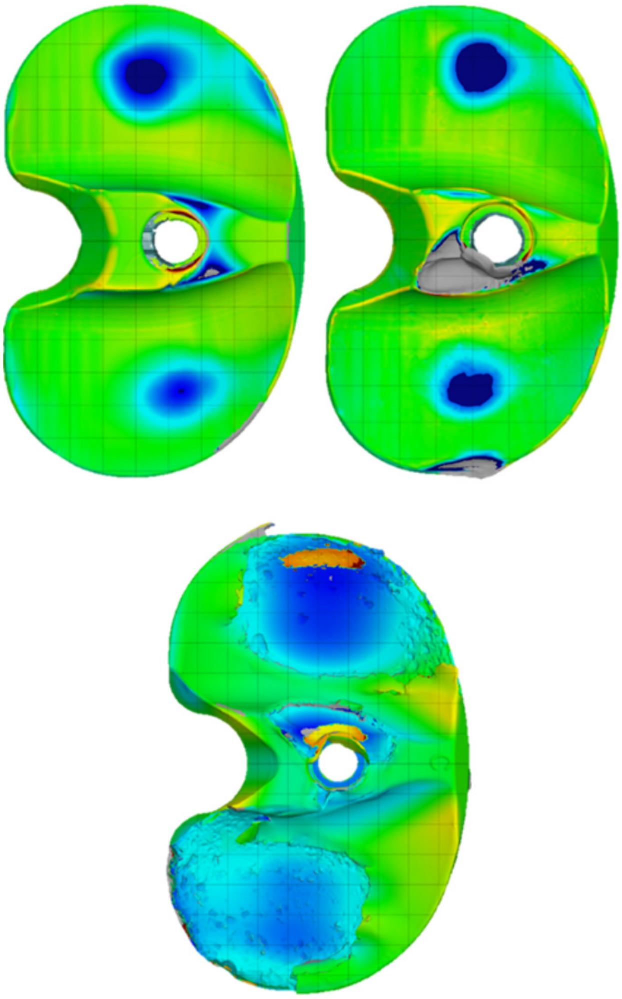

Fig. 12 3D scanner measurement results compared to the original CAD models

The first two images in Fig. 12 show a typical damage pattern with negative deformation in the central regions, these are the cold colors (different shades of blue). In addition to the negative deformation, there is always a curling effect, which is due to the specific behavior of polymers, as the residual deformation and stresses cause protrusions from the reference surface (different shades of red and yellow). The curling usually surrounds the parts that have undergone negative deformation. It was also observed that not only the central part of the treads but also the corners of the implants were significantly damaged, as well as the central ridge part of the implants. The damage to the central ridge part was already evident during disassembly, as it was often quite difficult to unscrew the fixation screws due to the deformation of the bore. Fig. 12 also shows how damaged the central ridges were, this is particularly evident in the case of the second sample, where the deformation was so great that it did not fit on the scale, and the program marked this part of the ridge in grey. On the lower edge of the second implant, the so-called bow tie sign is observed, which occurs when the damage to the edge is such that the UHMWPE insert edge suffers a large degree of residual deformation and an ear is formed. The same phenomenon can be observed on the upper edge of the last sample, but here it is more obvious how much material loss has occurred due to delamination. This insert required immediate revision.

Then, to obtain the numerical data, the program was used to export the differences between the original CAD model and the scanned point cloud at the given positions. For comparability, the distances of the surfaces were standardized by the total average deviation for the given implant.

In Fig. 13, we observe the speciation in the previously defined regions, separating the left and right sides of the inserts. It can be observed that the right condyles are mostly abraded. Also, regions 1,1 and 1,4 showed the highest deformation, which means that the plane of motion showed the highest deformation. It is also apparent that in one case, there was a relatively significant upswelling. It can be seen that in the case of the left condyles, zones

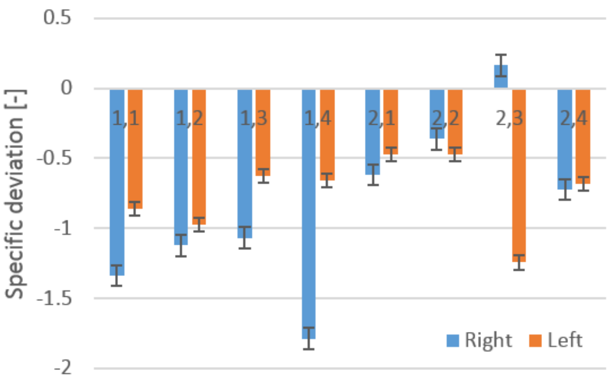

Fig. 13 Specific wear values taken in the given regions, separating the left and right condyle

1,1, 1,2 and 2,3 were most affected. This can be explained by the fact that there were more left foot implants, with the right condyle receiving more stress and the left condyle receiving less, but more uncertain, stress.

Fig. 14 shows that, on average, the right condyles are more damaged, which supports our previous statements and the literature that the inner side of the implants is more stressed. So, because we had more left foot implants, the left condyles were more damaged.

In Fig. 15, we examined whether the outer or inner regions of the implants were more damaged. It can be seen that if we take the right condyles, the inner regions are clearly more damaged. However, if we look at the right condyles, there is only a minimal amount of damage to the inner regions. It can be said that what we mentioned earlier applies here as well, that the right side of the system receives a greater and more pronounced directional load in the case of left-leg implants.

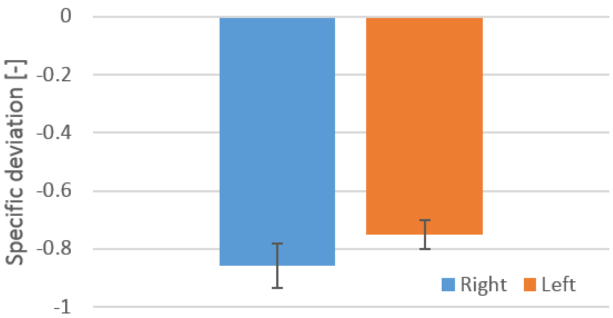

Fig. 14 Comparison of average wear of right and left condyles

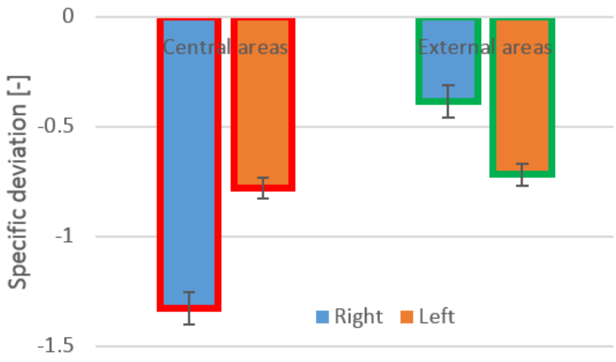

Fig. 15 Comparison of the outer and inner regions of the inserts (columns frame according to the colors in Fig. 8)

In Fig. 16, we have determined which quarter of the inserts receive the highest load. It can be seen that the front and right quarter are prominent, which is also not surprising, since we have mainly examined left-leg implants. Fig. 16 explains why it was essential to refine Hood's distribution, as looking at this diagram alone would suggest that the right-hand side was the most affected. However, from Fig. 13, we can see that the most damaged regions are the inner front and rear regions.

However, in Fig. 16, the resolution is not as fine, so after averaging, it is the right and front regions that are most damaged.

Of course, this is not a bad result either, as it is consistent with the right side being the most damaged in the case of left leg implants, but the division we chose allowed us to be much more precise and fine-grained in identifying the most significant damage sites.

In Fig. 17, we illustrate the probability that a region will produce a positive upswing or a negative deformation.

Fig. 17 shows that the most likely direction of deformation will be negative, but it is striking that the most likely direction of deformation will be positive in the outer regions. This supports our assertion that around large negative deformations there will always be a positive upswing due to residual deformations.

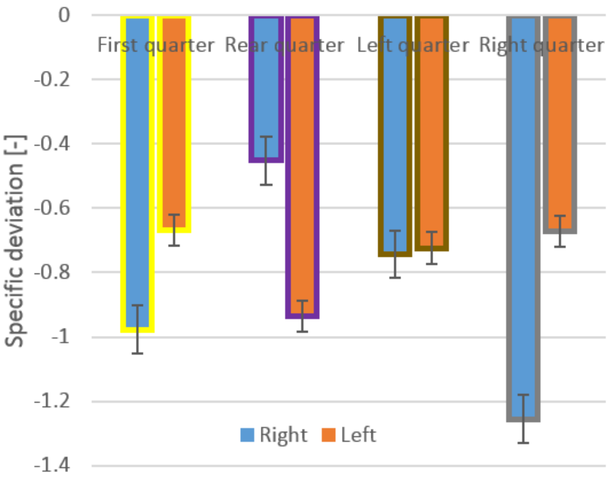

Fig. 16 Specific deformation of the investigated inserts divided into quarters according to the auxiliary lines (columns frame according to the colors in Fig. 8)

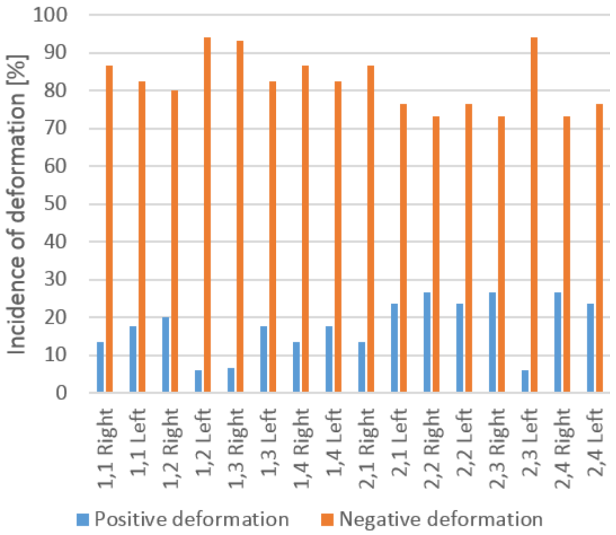

Fig. 17 Probability of positive roll-up and negative roll-over for each region

Fig. 18 shows in detail the specific numerical value of the possible negative and positive deformations in the given zones. For this purpose, we have separated the samples with negative and positive deformations and plotted them separately, of course keeping the difference between the right and left condyle of the implants.

What is striking is that the specific magnitude of the upswelling can often be larger than the negative deformation. It is important to note, however, that the extent of the possible wrinkling is comparable to the negative deformations, which result from the special properties of polymers. In fact, they suggest that deformation rather than wear and various material loss processes are predominant in the case of knee implants. This statement is based on the fact that the height of the surface remains almost constant since the extent of deformation in the negative direction is comparable to that of the upswelling. However, it should be borne in mind that the probability of negative deformations is much higher than that of upswelling (Fig. 17) so there is still a significant loss of material, but positive deformations are comparable to these processes.

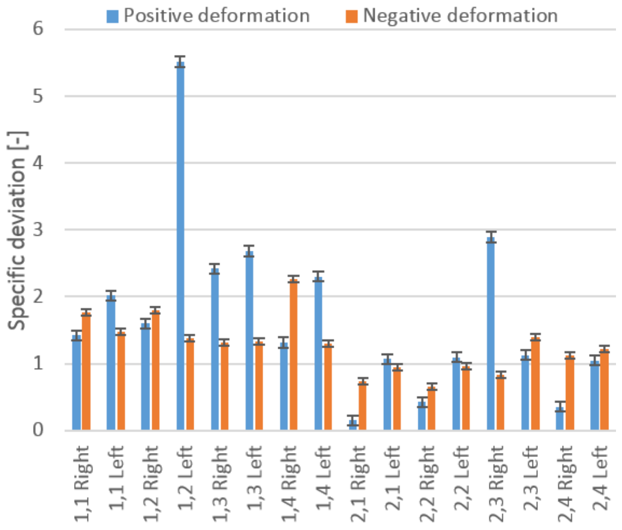

Fig. 18 The specific magnitude of the possible positive and negative deformations for the different regions

In Fig. 19, we examined the probability of a negative deformation or a positive upswing in a given region.

Fig. 19 shows that the likelihood of positive-directional folding is higher in the outer regions, which is consistent with our earlier finding that positive-directional folding occurs around large negative deformations - inner regions. Furthermore, it is also found that positive directional upswelling is more likely to occur in the outer quadrants, a statement also consistent with our earlier finding that the quadrants in the plane of motion are more subject to loading. However, it is also observed here that the right quarter is more likely to develop negative deformation, which is also consistent with the fact that the right quarter of the left leg implants is more loaded.

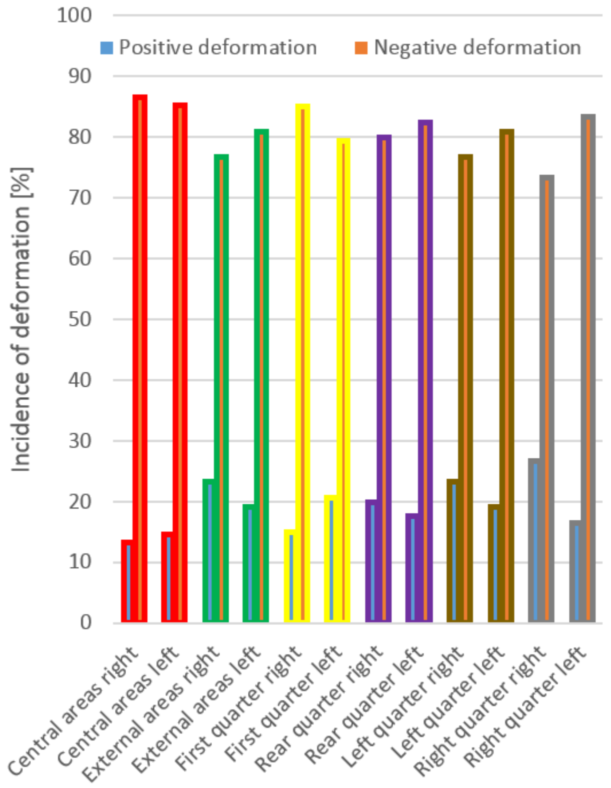

Fig. 19 The probability of occurrence of positive-directional upturns and negative-directional deformations in different regions of the inserts (columns frames according to the colors in Fig. 8)

4 Summary

After a review of the relevant literature, we concluded that there is a need to develop an optical inspection method to detect abnormalities in knee implants removed during revision surgery. Therefore, as a first step, we have developed an exact method of examination that allows us to examine the implants much more quickly and with greater accuracy. Furthermore, at the end of the study, we will obtain results that are relevant from an engineering point of view and comparable with other measurements, as this was almost completely absent in the existing literature.

The method we developed is based on Hood's damage analysis since the seven damage forms he has constructed are appropriate, but the measurement method needed to be modernized. Therefore, the steps of the method we have developed are as follows:

- The first is to divide the running surface of the implant into 8–8 regions per condyle, as described in detail in the article.
- Then, optical microscopy and SEM microscopy measurements are performed to detect and classify the abnormalities by location, distribution, and severity. The deviations are classified according to the seven categories already defined.
- Subsequently, using a 3-dimensional scanner, deformations and abrasions are investigated and also classified by location and severity. The scanned point clouds can be used to produce colorful, highly informative plots of the deviations. Numerical diagrams for different locations are also available, allowing exact, semi-quantitative comparisons.

After developing the measurement method, we performed an optical damage analysis of the 15 total knee implants available. From this, we concluded that, based on the optical microscopy and SEM images, the most common type of damage was pitting, followed by scratching and burnishing, and surface deformation. The damage was mostly on the inner parts of the inserts, and it was also striking that the right condyle of the left leg implants was more damaged, while the left condyle of the right leg implants was more damaged. The 3-dimensional scan data also confirmed that the opposite condyle of the implants always receives the greater load than the side of leg condyle side. It was also evident that the internal regions of the implants receive the highest load, with the emphasis on those regions that fall in the longitudinal axis of motion. While the outer zones tended to be more convoluted and suffered deformation in a positive direction. It was also observed that the areas with high negative sub-strain were always surrounded by positive directional curvatures, due to residual strain. The extent of positive directional upswelling is comparable to the negative directional deformations, thus it can be stated that deformation and not necessarily material loss processes are present in knee implants. This statement is in agreement with the results of FE simulations in the literature reviewed, which show that the loads in the knee implant inserts are well above the yield strength of the UHMWPE and that significant ductile deformation can occur.

In the light of our findings, we suggest that the currently used knee implants should definitely be subject to an increase in the running surface of the systems to reduce the high local loads. In addition, the central regions of the inserts should be strengthened, as this is where the greatest loads are applied. Furthermore, the right and left condyle should not be the same, as the right condyle of left leg implants receives the higher load. Therefore, the size of the bearing surface on the side receiving the higher load should be increased, thus reducing the high local stresses, and the UHMWPE insert should be strengthened on the side receiving the higher stress.

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