Failure Analysis of Retrieved Polyethylene Insert in Total Knee Replacement

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The paper presents the study on the retrieved polyethylene components from total knee prosthesis. For the longevity of total knee arthroplasty it is very important to predict the polyethylene wear and optimize the prosthetic design. The functionality of the total knee prosthesis is affected by contact stress, sliding motion and kinematics of the prosthesis components. The most important factors which cause long-term failure of a prosthetic joint are: macroscopic fracture of the metallic components, polyethylene component wear, corrosion process, and osteolysis. Even the prosthesis development over the past decade has included improvements in implant designs and use of advanced biomaterials, is still difficult to replace some classic biomaterials. Ultra-high molecular-weight polyethylene (UHMWPE) has been the primary material for the articulating surface in prostheses for nearly 40 years. Even now there are a number of problems with the UHMWPE, which cause troubles for the patients. On retrieved polyethylene components, 7 different defects were observed (burnishing, scratching, pitting, surface deformation, delamination, abrasion, bone-cement debris) using stereomicroscopy and scanning electron microscopy. It was found that the cement debris on the surface of the polyethylene explants reduce dramatically the total knee prosthesis lifetime and using FTIR analysis was clearly identified the presence of the cement debris on the surface of polyethylene component. Delamination and abrasion contributed the most to the total amount of damage; according the Hood model, the most damage area of the polyethylene components was seen at the medial (1, 4 sections) and lateral sides (5, 8 sections), followed by the anterior and posterior sides.

Keywords: polyethylene, knee prosthesis, failure, microscopy, defects

Implant failures cause new complications for patients, lengthen the healing process and increase cost. A second surgery may be required for removal of the implant, which exposes the patient to further surgical risks. Due to biomechanical stresses inside the human body, their design is still under amelioration, a lot of information being from implants retrieved due to mechanical failure or related to other complications. Also, an implant failure often leads to a re-fracture, thus complicating the healing process. On occasion there is the need for additional, often more complicated repeated surgeries. These complications show the importance of exploring the causes of this problem [1, 2]. Also, implant failures can result from an intrinsic device fault or external factors such as the surgical process, patient non-compliance with implant instructions and the degree of union. Total Knee Arthroplasty (TKA) has become a well-established treatment modality for surgical correction of knee disorders and pain generated by arthritis and other disorders such as trauma. For the longevity of total knee arthroplasty it is very important to predict the polyethylene wear and optimize the prosthetic design. The functionality of the total knee prosthesis is affected by contact stress, sliding motion and kinematics of the prosthesis components [3, 4]. The most important factors which cause long-term failure of a prosthetic joint are: macroscopic fracture of the metallic components, polyethylene component wear, corrosion process, and osteolysis.

Even the prosthesis development over the past decade has included improvements in implant designs and use of adveanced biomaterials, is still difficult to replace some classic biomaterials. Ultra-high molecular-weight polyethylene (UHMWPE) has been the primary material for the articulating surface in prostheses for nearly 40 years. Even now there are a number of problems with the UHMWPE, which cause troubles for the patients. Oxidation of the UHMWPE component during sterilisation with high energy radiation has been recognised as one of the main problems affecting the durability of orthopaedic implants [3, 5]. Oxidation is always present in radiation-sterilised polymeric components due to the oxygen diffused into UHMWPE. Polyethylene failure is known to occur through different causes: delamination, crack formation, wear, pitting and the generation of particulate debris with a local resorptive osteoclastic response [6, 7]. Regarding wear mechanism, it's important to mention that many wear mechanism are involved: adhesion wear, abrasion wear; the third body wear.

Total knee replacement (TKR) wear is a major limitation contributing to decreased survival of these impalnts. Aseptic loosening secondary to polyethylene failure remains the single commonest indication for late revision. The ultra-high molecular weight polyethylene (UHMWPE) insert is known to ultimately fail with published 90% survivorship at 15 years [4].

Four common wear modes affecting joint prostheses have been described [2, 4]. Unlike the highly congruent ball-and-socket articulation in the hip, the geometry and articulation of the knee is more complex - one consequence is the large number of designs with different features as condyle anatomy, anatomical left-right implants for better patellar groove angles, single or multiple radius for different flexion performances, cruciate retaining or sparing etc. This is why polyethylene wear occurs from a combination of

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rolling, sliding, and rotational motions, which may lead to delamination, pitting, and fatigue failure of the polyethylene surface in contact with the metallic bearings [4].

Many total knee replacements are designed with more conforming articular geometry to increase the femoral contact area and decrease surface stresses. These designs are supported by studies suggesting that implants with coronally flat articular surfaces are vulnerable to medial-lateral lift-off and edge-loading on the polyethylene insert with consequent delamination of that area. Interesting enough, concerns of high contact stresses associated with edge-loading (proposed by in vitro studies) were unsupported by retrieval studies of several implants, mainly cruciate sparing. Condylar lift-off, if it occurs, does not appear to substantially impact polyethylene damage in coronally flat-on-flat articulations.

Osteolysis caused by wear debris from UHMWPE inserts is still a serious problem associated with TKR. Several strategies were proposed to reduce wear and osteolysis: from femoral design and component materials to insert sterilization and composition [8, 9]. In several published studies of retrieved alumina ceramic TKRs, were found with smooth and burnished surfaces without any scratches or defects, constantly found on the surface of metallic CoCr components [5, 9, 10]. This surface observation is explained by third-body wear. In the case of the Co-Cr implants, burnishing was frequently observed in areas corresponding to the disappeared machine marks, along with numerous intersecting scratches. Damage in the form of scratches on the surface of the insert can also be produced because of the microscopic asperities on the opposite surface of the femoral component. The Co-Cr femoral component surface (hardness Hv = 285-340), which is not harder than a ceramic surface (alumina ceramic Hv = 1900 and TZP ceramic Hv = 1400), is sensitive to third-body wear [8, 10].

Retrieval analysis of the failed knee prosthesis is important because it brings information about how the prosthesis is worn and the area that failed. With the results obtained from the explant analysis we could identify the type of defect and the most affected area on the polyethylene component of total knee prosthesis [6-9, 11].

The most used model for analysis the affected area on the polyethylene components of total knee prosthesis was proposed by Hood [6]. These results help improve the area's most commonly affected and to develop new implants that have in the composition different active substances. Retrieval studies of components of knee prosthesis should help to answer some of these questions. This paper aims to study the wear characteristics of retrieved total knee implants.

Experimental part
Material and methods

We examined 36 tibial components of knee prosthesis retrieved at revision between 3 and 5 years after implantation. After a carefully analysis of the clinical data, we select six representatives explants from all this series of polyethylene components because the main objective of our study was to identify and analyze the types of wear defects and also the areas where the wear defects appears on the polyethylene component. The macroscopic view of the selected polyethylene components from the failed total knee prosthesis that will be investigated are shown in figure 1.

In table 1 are shown the clinical data and the details about the explanted polyethylene components of total knee prosthesis.
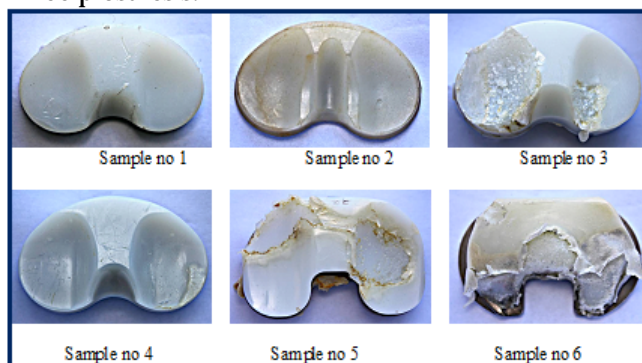

Fig. 1. Macroscopic images of the failed polyethylene components from total knee prosthesis selected for the study

The damage of the polyethylene was analyzed by stereomicroscopy, using 10x light stereomicroscopy, and scanning electron microscopy, using a Philips XL-30 microscope. Microscopically techniques are used with good results for the analysis of retrieved implants or biomaterials surfaces [6, 7, 12-15].

For the analysis of areas where the wear defects appear on the polyethylene component we use Hood's scoring [6].

Results and discussions

According the literature there are 7 modes of damage [2, 6, 7, 9, 11]:
- scratching: superficial trail left on the surface of the polyethylene
- burnishing: the material has a shiny surface after excessive rubbing
- pitting: points in the material surface
- surface deformation: areas with permanent deformation occurring on or around the articulating surfaces

Table 1

CLINICAL DETAILS ABOUT THE RETRIEVED POLYETHYLENE COMPONENTS FROM FAILED TOTAL KNEE PROSTHESIS

No.	Hospital who perform the surgery	Period in use [years]	Manufacturer	Patient data		
				Gender	Age [year]	Weight [Kg]
1	Colentina Hospital	6	Biomet	Female	59	70
2	Colentina Hospital	10	Biomet	Male	67	87
3	Colentina Hospital	4	Biomet	Male	81	110
4	Colentina Hospital	12	Biomet	Male	69	96
5	Colentina Hospital	16	Biomet	Female	71	100
6	Colentina Hospital	18	Biomet	Male	76	120

- abrasion: a shredded or tufted appearance of the polyethylene (caused by direct contact with bone or PMMA)
- bone-cement debris: embedded PMMA or bone debris, recognized by the color and/or texture difference between PMMA, bone and polyethylene.
- exfoliating: cracking and break of thin layers on the polyethylene surface

All of these modes were observed on our experimental retrieved samples, using stereomicroscopy analysis. The results are presented in figure 2.

In the authors experimental retrieved specimens, both longitudinal and transverse wear patterns r*ipples* were observed consistent with the *natural* sliding and rolling movement of the knee.
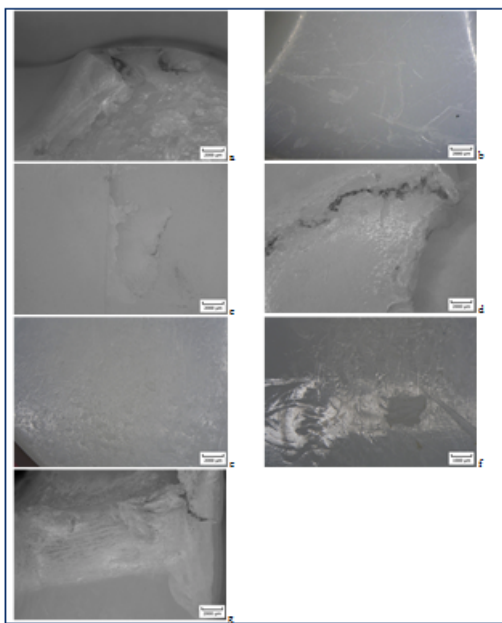

Fig. 2. Stereomicroscopy images made on experimental samples highlighting the types of defects (a-surface deformation, b-scratches, c-debris, d-abrasion marks, e- pitting, f- burnishing, g- exfoliating)

In order to define the location of wear on the retrieved polyethylene components where the damage occurred and make a quantitative analysis of the severity of wear, we use the scoring system described by Hood [6]. According this, each retrieved polyethylene component will be divided into 10 different sections (fig. 3). We calculated the surface defects score as follows: for each type of wear we give between 0 points (to wear 0%) and 3 (to wear over 50%) for each zone. For only one area the maximum
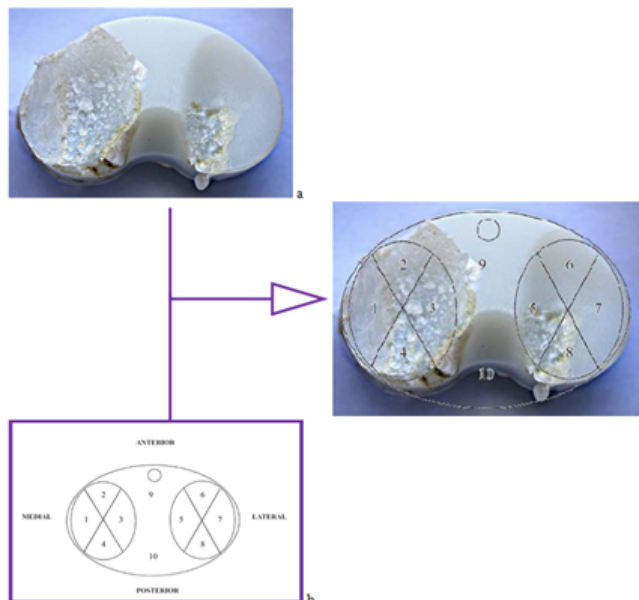

Fig. 3. Practical example of using Hood protocol in order to define the location of wear on the retrieved polyethylene components where the damage occurred (a-the explanted polyethylene sample, b-the grid model to locate the severity of damage on the polyethylene insert/ Hood Model, c- the polyethylene and the grid model overlaid)

score for all defects was 21 points and for all tipes of areas the maximum score was 210 points.

A subjective grading system was used to quantify the presence and severity of each mode of surface damage in each section [6, 7, 12]:
-Grade 0: the damage mode is absent from the section.
-Grade 1: the damage mode is evident in less than 10% of the surface area of the section.
-Grade 2: the damage mode is evident in 10-50% of the surface area of the section.
-Grade 3 the damage mode is evident in more than 50% of the surface area of the section.

The difference in the different modes of surface damage and in location of damage was analyzed according to Hood protocol [6]. The mean total score for damage of all retrieved tibial inserts was 56.5 points ±48.8. The severity of each mode of damage and the number of inserts with the respective mode of damage are listed in table 2.
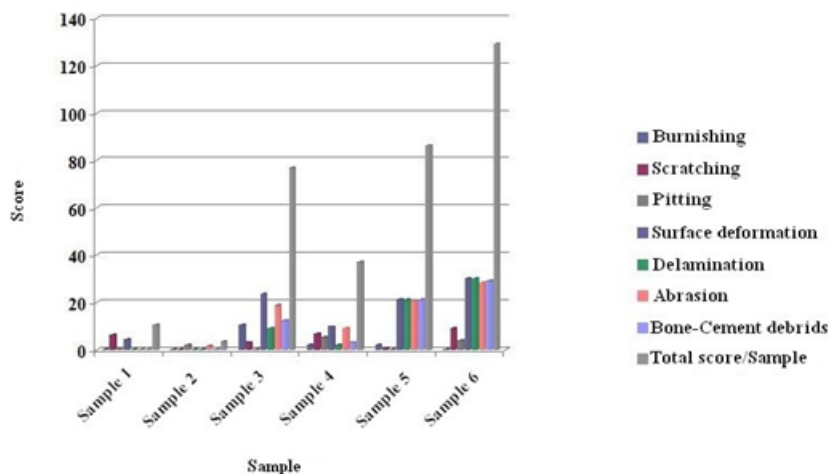
It's also important to analyze the result for each mode of damage in correlation with the location of damage on each experimental sample, according to Hood protocol [6].
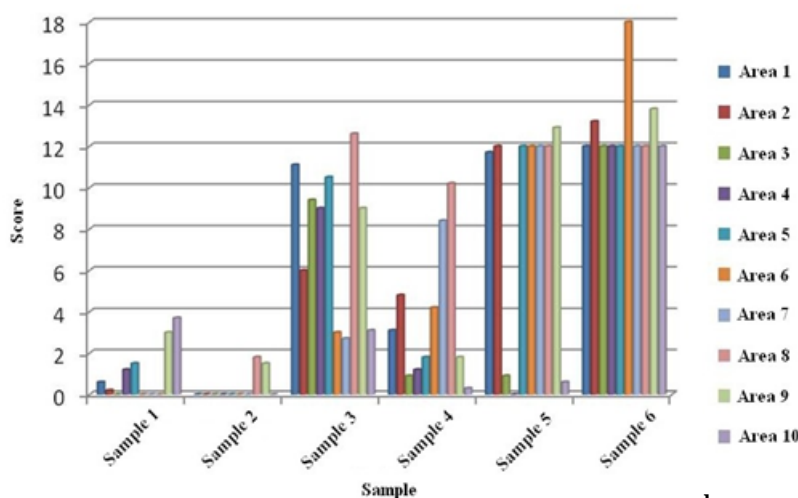
Table 2
THE RESULTS FOR ANALYSIS OF THE DIFFERENT MODES OF SURFACE DAMAGE ON SELECTED EXPERIMENTAL RETRIEVED POLYETHYLENE COMPONENTS FROM FAILED TOTAL KNEE PROSTHESIS

Defect \ Sample	Burnishing	Scratching	Pitting	Surface deformation	Delamination	Abrasion	Bone-cement debris	Mean score
1	0	6	0.2	4	0	0	0	10.2
2	0	0	1.8	0	0	1.5	0	3.3
3	10.2	3	0	23.5	9	18.6	12.1	76.4
4	1.8	6.4	5.1	9.6	1,8	9	3	36.7
5	1.8	0.6	0	21	21	20.7	21	86.1
6	0	8.7	3.6	29.7	30	28.2	28.8	129

(a) Histogram score defect/sample

(b) histogram score defects/area

Fig. 4. Graphical representation of the distribution of defects according Hood model: (a) distribution of defects per each sample and (b) the distribution of defects per each area.

The results was:

-Burnishing: Appears in the medial (1,3) and lateral (5,7) areas and less in the posterior zone and affects only a few samples.

-Scratching: Scratching was seen in all sections, most on the medial(1,4), anterior (9)and posterior (10) zones and less in the lateral zone.

-Pitting: Pitting was seen the most in medial(1,4) and anterior(9) zones and less pronounced in the other zones. Pitting affects only a few samples.

-Surface deformation: Surface deformation was seen in medial, lateral and anterior zones and it's quite pronunced in (1,2,4-9) sections.

-Delamination: Delamination was seen the most on the medial, anterior and posterior sides in sections (1, 4) and on the lateral side in sections (7,8).

-Abrasion: Abrasion was seen the most on the lateral side in sections (7,8).

-Bone-cement debris: Bone and cement debris was seen the most on the medial and lateral sides in sections (1, 4) and least at the posterior side in section (10).

Two graphical representation were realized regarding the repartition of defects per each sample and about the repartition of defects per each area (fig. 4). We could mention that the most damaged area was seen on the medial and inside of the lateral sides in sections 1, 5 and 8, and the lowest amount of damage was see on the posterior zone on section 10. According the analysis of defects per each samples, we could conclude that the results are in concordance with the clinical data related to the period in use. One exception was observed, in the case of sample number 3. The authors considered that this component show an accentuated rate of damage and failed much faster because the degradation was emphasized by the presence of bone cements particle on the polyethylene component surface.

Conclusions

The main conclusions of the present study on the retrieved polyethylene components from total knee prosthesis was that the damage mechanisms on polyethylene are varied and we cannot say that we have just a single mechanism or a single type of defect. On retrieved polyethylene components, 7 different defects were observed (burnishing, scratching, pitting, surface deformation, delamination, abrasion, bone-cement debris) using stereomicroscopy and scanning electron microscopy. The cement debris on the surface of the polyethylene explants reduce dramatically the total knee prosthesis lifetime. Delamination and abrasion contributed the most to the total amount of damage; according the Hood model, the most damage area of the polyethylene components was seen at the medial (1, 4 sections) and lateral sides (5, 8 sections), followed by the anterior and posterior sides. The results suggest that the medial side of the TKA prosthesis carries most of the load. In this case, the explant analysis is very useful because we can find the type of defects who damage the most and the zone where the defect is present, these analysis can support the research and help to improve the new designs of implants.

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