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DOCTORAL SCHOOL MATERIALS  
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DEPARTMENT OF METAL MATERIALS SCIENCE, PHYSICAL  
METALLURGY



# Summary of the doctoral thesis

**Contribuții privind evaluarea biofuncționalității endoprotezelor de șoldmetal-metal tip BHR**

**Contributions on the evaluation of the biofunctionality of metal-metal hip endoprotheses type BHR**

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**Doctoral Student: NICULAE VĂLEANU**

**Scientific Coordinator: Prof.Univ. Habil.Dr. Ing. VASILE IULIAN ANTONIAC**

**Bucharest 2024**

# DOCTORAL THESIS

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**Bucharest 2024**

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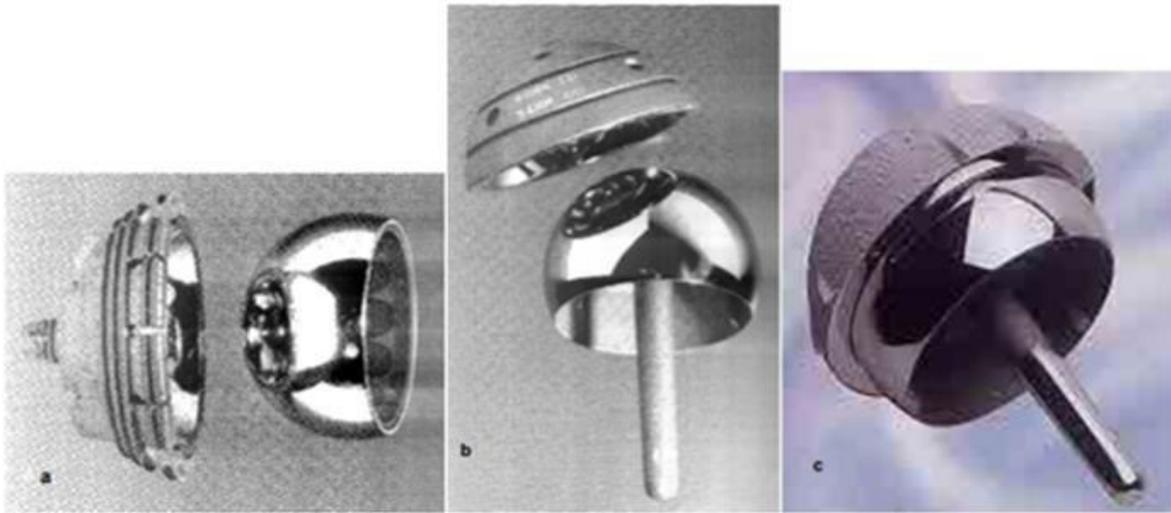
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## ABSTRACT

In the history of hip arthroplasty, innovations and technological developments have been marked by the significant contributions of several pioneers in the field. In the 1920s, Marius Smith-Petersen introduced the concept of femoral head arthroplasty, initially using a piece of glass molded into a bell shape to replace the surface of the hip joint. This method, although innovative for its time, did not withstand the biomechanical stresses of walking and led to the further development of metal prostheses. In 1938, Jean and Robert Judet created the first femoral implant using polymethylmethacrylate, but the initial clinical results were disappointing due to the formation of wear particles and inflammatory reactions [1]. During the same period, Frederick R. Thompson and Austin T. Moore contributed to the development of long-rod prostheses, which allowed biological fixation in the bone through fenestrations, which represented a significant improvement in the surgical treatment of hip dysplasias. In the 1960s, Sir John Charnley revolutionized total hip arthroplasty with the introduction of the concept of "low-friction arthroplasty", recognizing the importance of reducing friction through the use of appropriate contact surfaces. He has made several iterations of his design, including small femoral head and high-density polyethylene cup prosthetics, which have demonstrated success in the elderly and inactive population. In parallel, Peter Ring proposed a cementless approach, using metal-to-metal prostheses to avoid problems associated with cement.

This paper investigates the results and causes of failure in Birmingham Hip Resurfacing (BHR) arthroplasty of the hip, with a focus on the analysis of surgical techniques and cementation methods used in different medical facilities. In its introduction, the paper explores the history and evolution of total hip arthroplasty, starting with the first concepts and structures of endoprostheses.



*Figure 1. Models of metal-to-metal stents for the hip joint (a) Wagner prosthesis; b) McMinn prosthesis; c) The BHR prosthesis, inspired by the McMinn model.*

## Chapter 4. Protocol for analysis and experimental investigations on prosthetic explants in the category of total hip endoprostheses

The experimental research program for the characterization of hip endoprosthesis explants was structured in three distinct stages:

1. *Intraoperative aspects and experimental sampling:*

- + Participation in surgeries
- + Biological tissue sampling
- + Recovery and preservation of explanted endoprosthesis components
- + Completion of clinical investigation forms

2. *Histopathological investigations of tissues:*

- + Tissue preparation and examination by light microscopy

1. *Analysis of explanted components:*

- + Macroscopic examination using stereomicroscopy and macrophotography
- + Determination of the chemical composition of metallic biomaterials by energy dispersive spectroscopy (EDS)
- + Analysis of the surfaces of explanted components using scanning electron microscopy (SEM)

We started the research by presenting the materials and methods used in detail, and the experimental results will be presented separately for each clinical case.

### *Materials, Methods and Equipment Used*



Figure 17. Intraoperative procedural aspects during experimental sampling

In the first stage of the experimental research, surgeries were performed by the orthopedic team from the Colentina Hospital in Bucharest. During these interventions, tissues adjacent to the prosthetic explants were taken and the components of the hip endoprostheses were extracted. A specific study was carried out at Colentina Hospital, following which the necessary samples were taken to carry out detailed experimental analyses on a series of cases, each representing different types of prostheses. Figure 16 shows synthetic images of these interventions.

With the support of the medical staff from these hospital units, the clinical records for the four investigated cases were filled in as shown in Table 5.

*Table 5. Individual characteristics of each case analysed.*

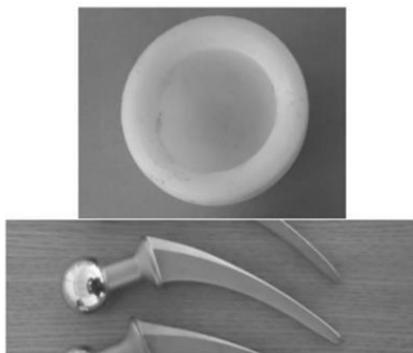
<b>Nr.</b>	<b>Hospital</b>	<b>Patient – duration</b>	<b>Endoprosthesis</b>	<b>Material</b>
Case1	Colentina	C.M. 84 years -1 year	Metal – Type Moore	Stainless steel type 316L
Case2	Colentina	M.F. 32years - 10years	Ceramic-Metal Endoplus Zweymuller	Alloy Ti-Al-Nb Alumina Polyethylene UHMWPE
Case3	Colentina	B.V. 61years -7 years	Metal-plastic Tip Charnley	Stainless steel 316L Polyethylene UHMWPE
Case4	Colentina	G.S. 45yeras - 4 months	Metal-metal Tip BHR	Alloy Co-Cr Alloy Co-Cr coated with porous Ti



**caz 1**



**caz 2**



**caz 3**



**caz 4**

3

*Figure 18. Experimental samples used in the study of hip endoprosthesis explants*

### 4.3. Study II – Metal-ceramic hip endoprosthesis

This prosthesis was brought following a revision intervention performed at Colentina Clinical Hospital. It is a state-of-the-art implant, characterized by the ceramic-polyethylene interface, but which has suffered wear, being used in a young and active patient. This case underlines the importance of studies of this kind for improving the durability of implants in real conditions of use.



Figure 32. Preoperative X-rays

Wear areas are visible in the places with maximum load, located on the aluminium head and in the head-to-tail interface area. The deposition of porous titanium was affected in certain regions, especially in the neck area and partially in the tail. The prosthesis showed adequate stability, and no significant defects were identified.

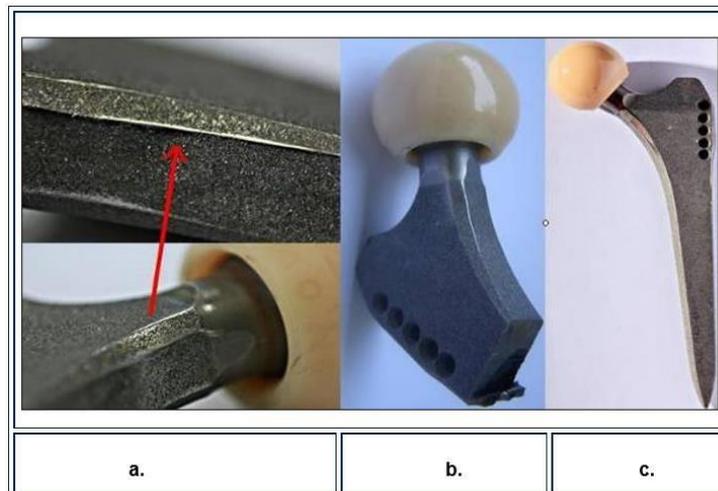
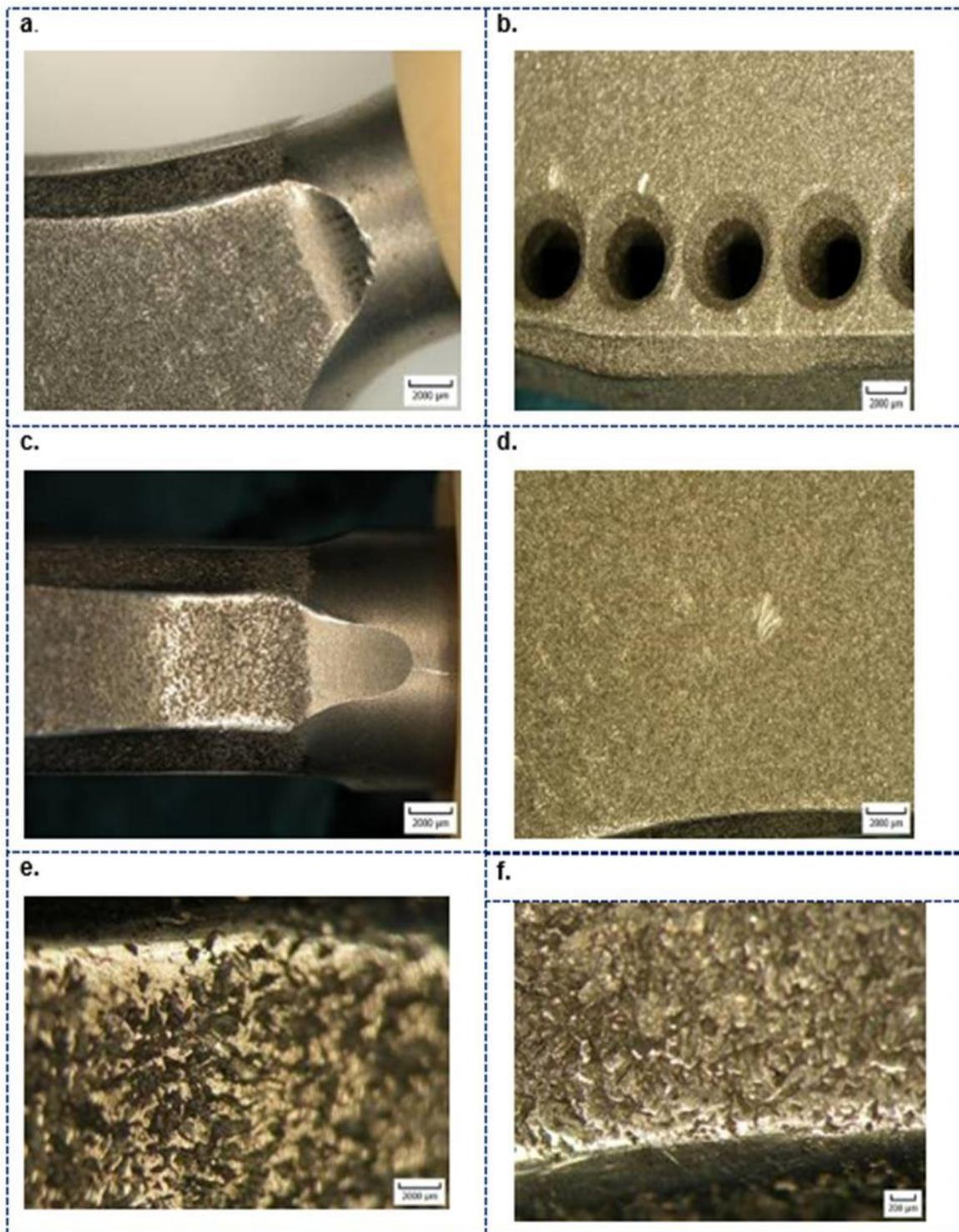


Figure 33. Macroscopic aspects of the explant: a. Obvious wear on the neck and tail of the prosthesis b. The appearance of the prosthesis after the cutting process c. Condition of the prosthesis after explantation

Relevant stereomicroscopic images of the areas of interest are illustrated in Figure 34:



6

Figure 34. Stereomicroscopic images: a. Wear at the head-tail interface, increased by 8 times; b. Areas of porous titanium affected by wear, enlarged by 8 times; c. Areas more severely affected by wear, enlarged 8 times; d. Detail of the prosthesis tail surface, magnified by 8 times; e. Detail in the neck area of the prosthesis, enlarged by 50 times; f. Detail of the tail of the prosthesis, with porous titanium deposits affected by wear, magnified by 50 times.

For histological analysis, tissue was taken from the bone-implant interface (Figure 35a). Their results are illustrated in Figure 35 b.

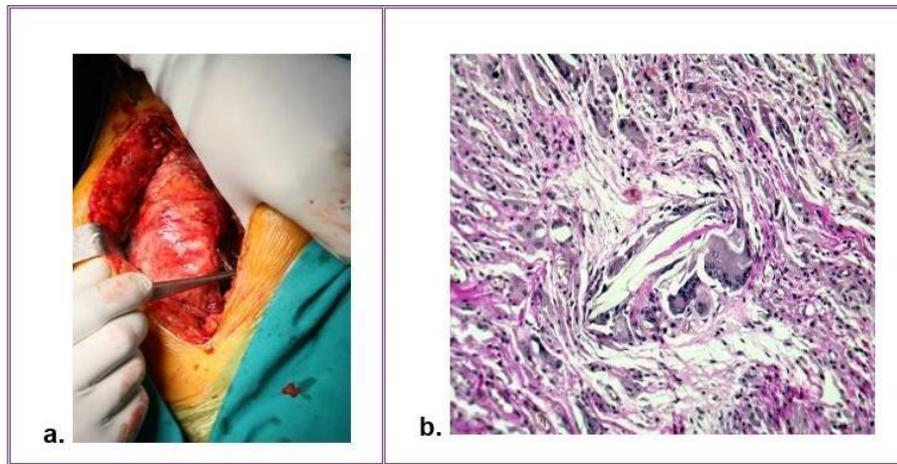


Figure 35. a. Tissue sampling for histopathological investigations during surgery. b. Optical microscopy of the tissue investigated in case II (foreign body reaction with crystalline inclusion, HE is staining, 20x magnification)

The results of the analysis details using the scanning electron microscope (SEM) combined with energy dispersion spectrometry (EDS) are illustrated in Figures 36-37.

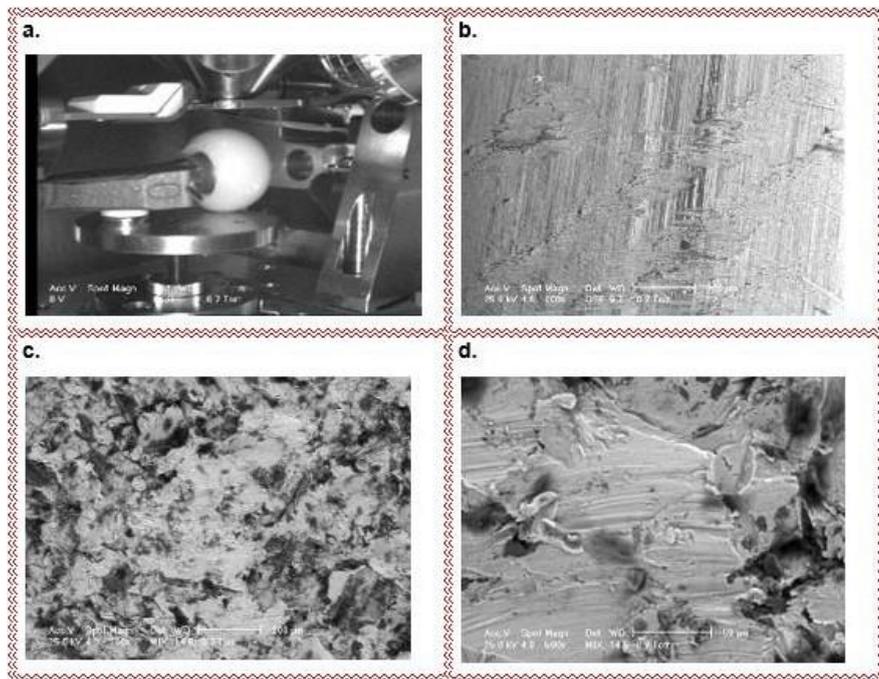
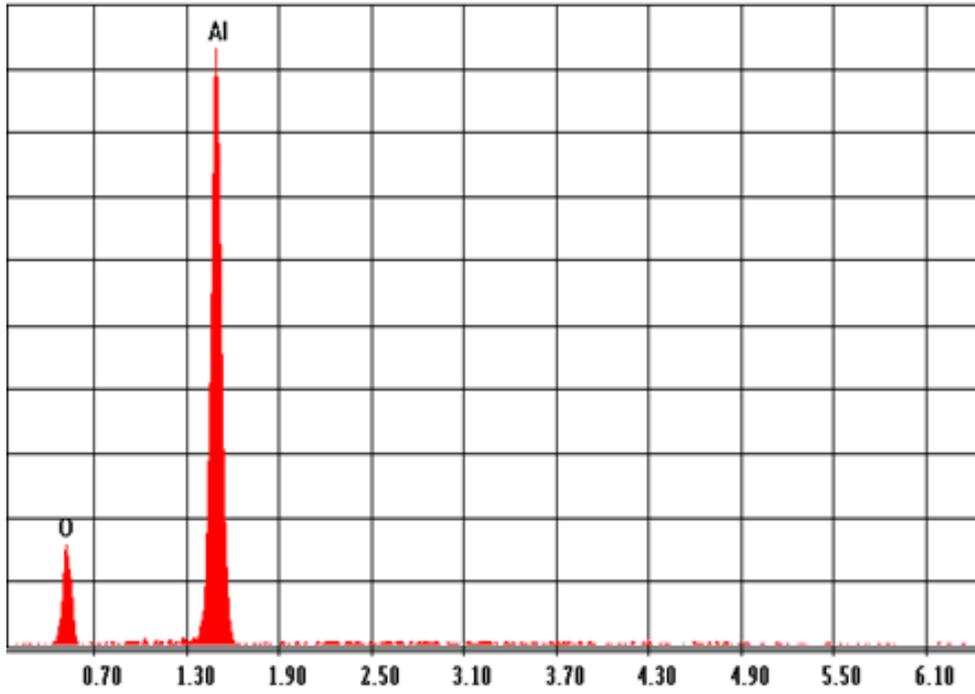
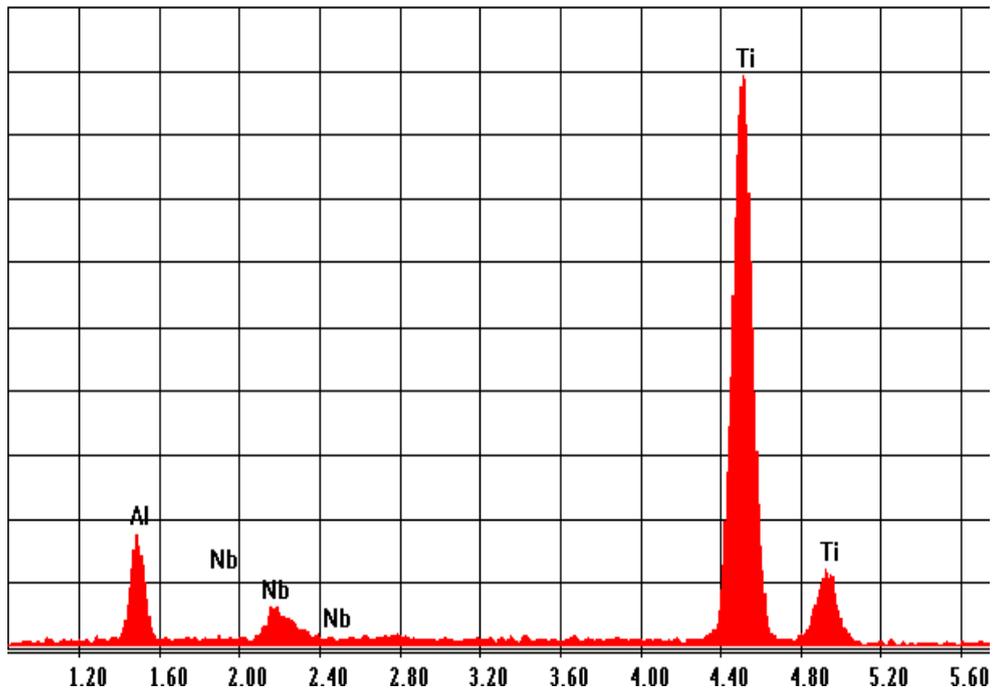


Figure 36. Image of the explanted prosthesis on the working table in the sample room of the scanning electron microscope: a,b,c,d. Scanning electron microscopy images of surfaces of interest

Label A: Bila ceramica



Label A: Cooda



b.

9

Figure 37. EDS analysis of the components of the hip prosthesis

## Chapter 5. Analysis of Causes of Failure for Birmingham Hip Resurfacing (BHR) Hip Endoprostheses Based on Investigation of Prosthetic Explants

### 5.1. Statistical analysis of clinical cases regarding the use of BHR hip endoprostheses

A retrospective study was conducted based on data collected from patients admitted to the Colentina Clinical Hospital in Bucharest. In this study, various specific aspects were analyzed, including the average age of the patients, the distribution by sex, and the evolution of the methods of fixation of the prostheses in hip arthroplasty interventions, as well as the cementation of the acetabular and femoral components.

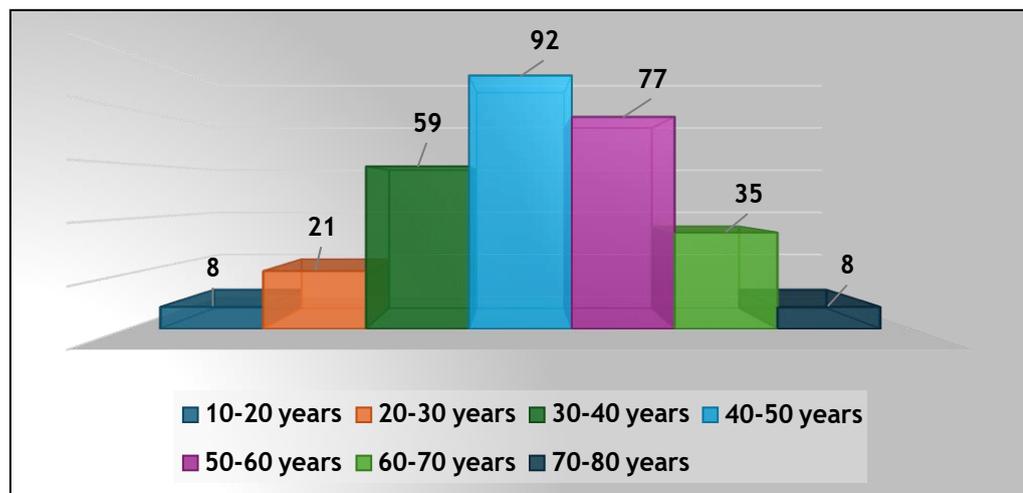


Figure 44. Breakdown of BHR hip endoprosthesis cases by age groups <sup>10</sup>

Analysing the distribution by age groups of cases of hip surface endoprosthesis, the following results are observed: Most procedures are performed on people aged between 40 and 60 years, suggesting a prevalence of joint diseases in this age range. In the 40-50 age group, a significant number of 92 cases stand out, indicating an increased need for surgery during this period of life. However, the number of cases decreases considerably in younger and older age groups, which may reflect the level of physical activity and exposure to age-specific risk factors.

People under 30 and over 70 are less represented in the data analysed, suggesting either a lower incidence of joint conditions at younger ages or a more rigorous selection of candidates for surgery in the older age group. Thus, the distribution by age categories within this surgical procedure provides a detailed perspective on the profile of patients and their medical needs.

During the analysis of the distribution of patients undergoing hip surface endoprosthesis surgery by gender categories, it was observed that the number of cases in men was 202, while in women there were 98 cases.

From this comparison, it can be concluded that male patients are more likely to develop orthopaedic conditions that require interventions such as hip surface endoprosthesis, compared to female patients.

Totuși, este esențial de menționat că această concluzie necesită o analiză mai detaliată și cuprinzătoare pentru a confirma corelațiile specifice între sex și predispoziția la afecțiuni ortopedice.

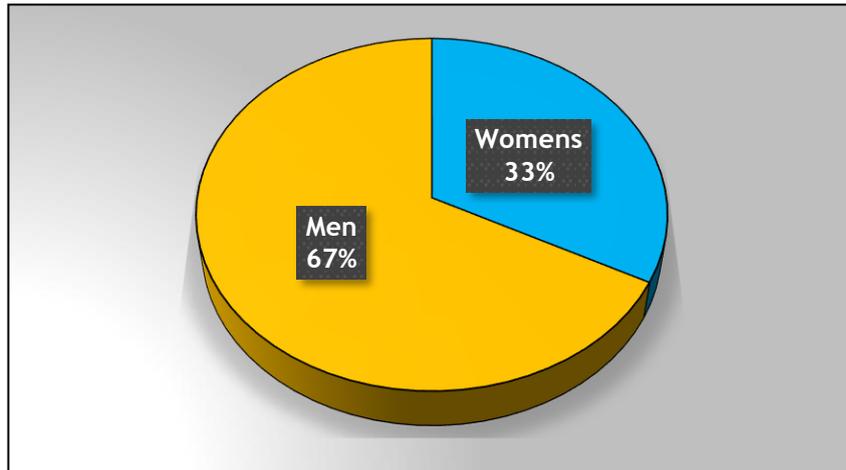


Figure 45. Gender distribution of cases of hip surface endoprosthesis <sup>11</sup>

Based on the clinical data provided and analysing the distribution of cases according to the different types of surgical indications and the sex of the patients, a series of specific observations are outlined.

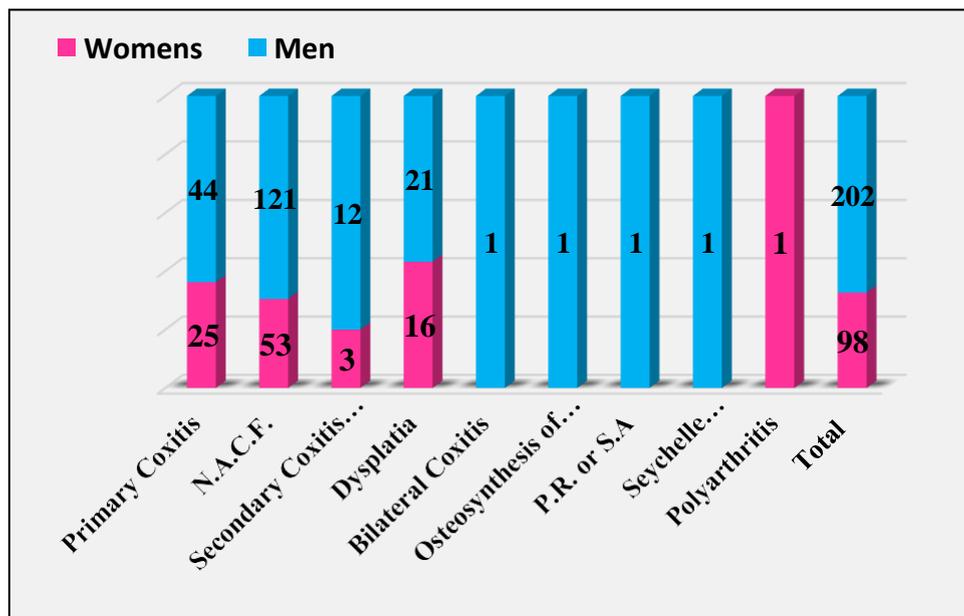


Figure 46. Graphical representation of the number of surgical cases for each type of indication, classified by the sex of the patients. <sup>12</sup>

In this study, we accumulated a total of 30 implant failures, of which we analysed 9 explants.

We performed analyses based on intraoperative radiographs and images for two samples of explanted endoprostheses from a 72-year-old patient and a 63-year-old patient. Also, another sample was taken from a 50-year-old patient, who presented a case of metalloids and in addition to intraoperative radiographs and images, tissue was taken from the area near the explant to make a clear diagnosis with the help of histological analysis.

Am acordat o atenție deosebită procesului de cimentare, realizând un studiu extins asupra endoprotezelor afectate de această problemă. Am început prin analizarea a trei explante

with cementation defects from two male patients (45 years and 53 years) and one female patient (47 years), initially using stereomicroscopic analysis and later SEM analysis for these three samples.

Subsequently, we analysed a series of three explants from two female patients (41 years and 64 years old) and one male patient (69 years old), performing a detailed SEM analysis for each explant.

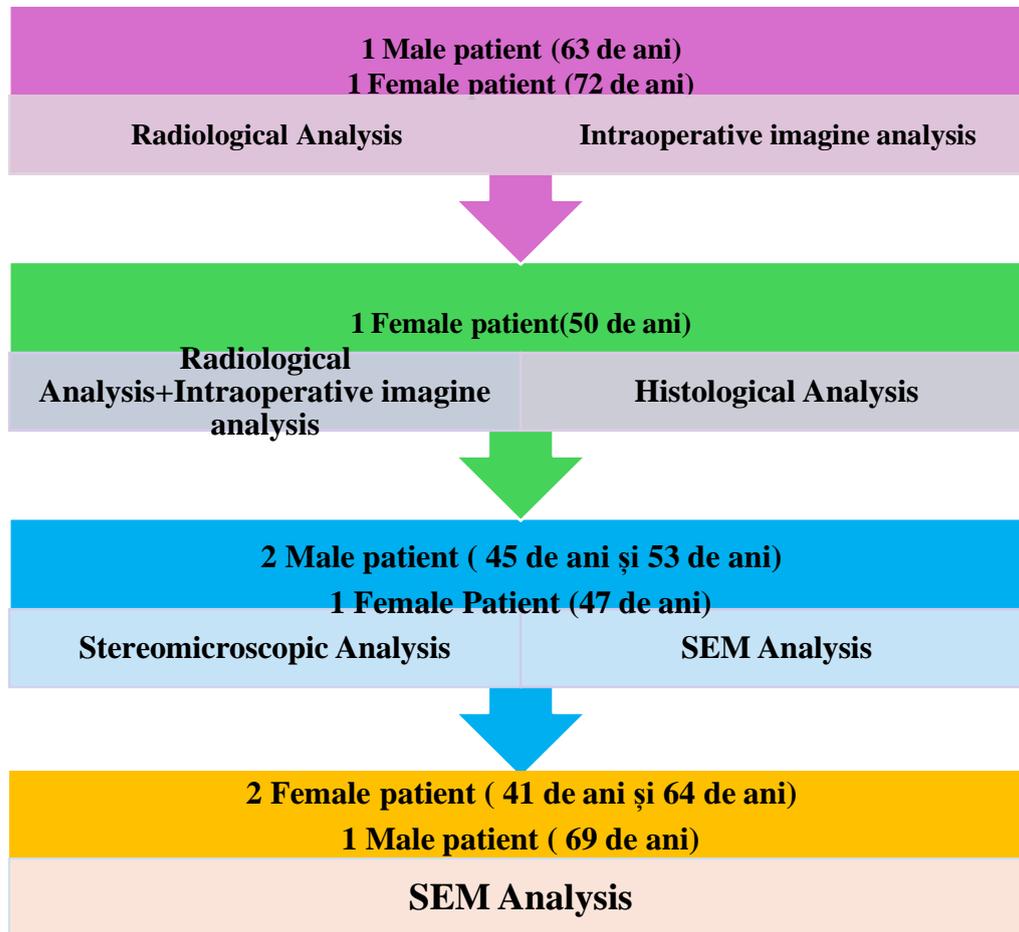


Figure 48. BHR 48 explant analysis protocol <sup>13</sup>

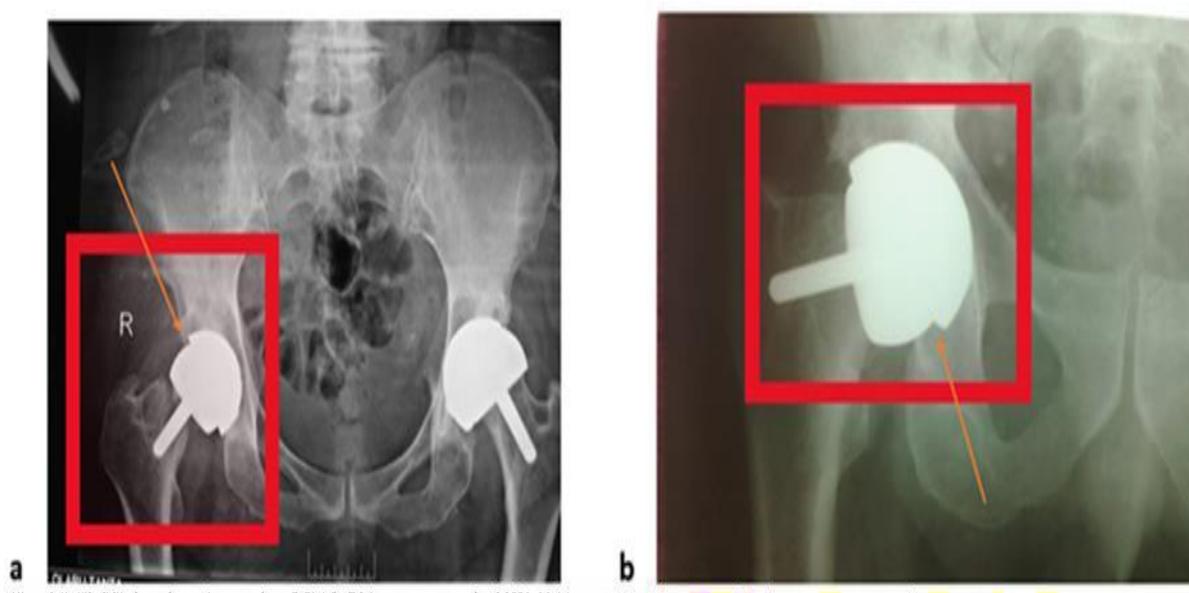
## 5.2. Intraoperative aspects and histological analysis of clinical cases regarding the use of BHR hip endoprotheses

Relevant concerns were identified, including complex issues related to the biomechanics of implant implantation, such as precision in implantation angle selection and impact on bone quality. The relevance of the analysis is further emphasized by the focus on BHR implants in patients over 50 years of age and the associated cementation methods, highlighting the need for a comprehensive and detailed approach to orthopedic biomechanics.

Biomechanics is the scientific field that studies the interaction between biological structures and the mechanical forces that act on them. In implanting prostheses such as BHR, it is crucial to consider the specific biomechanics of the joint to ensure optimal prosthesis functionality. This involves selecting a prosthesis that matches the patient's natural biomechanics and positioning it to minimize stress on the joint while maximizing the stability and durability of the prosthesis.

The study highlights the crucial role of biomechanics in the implantation process of BHR prostheses, with particular emphasis on the importance of precise selection and positioning at appropriate angles. X-rays and images from patients who required post-implantation revision were meticulously analysed, revealing that incorrect placement of prostheses can lead to complications. These include dislocation of the acetabular component, contributing to denture instability, pain, and functional limitations.

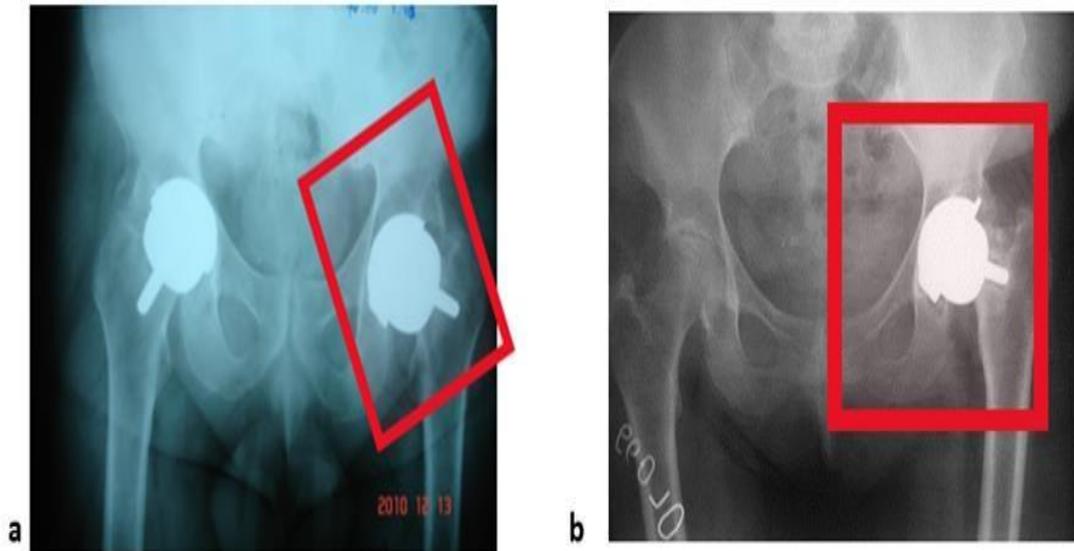
Figure 49 corresponding to the first case in the series of BHR implant failures, analysed, illustrates the wear induced by the marginal load due to the excessively vertical positioning of the acetabular cavity. In image B, the degree of inclination is even more pronounced, resulting in progressively more severe wear.



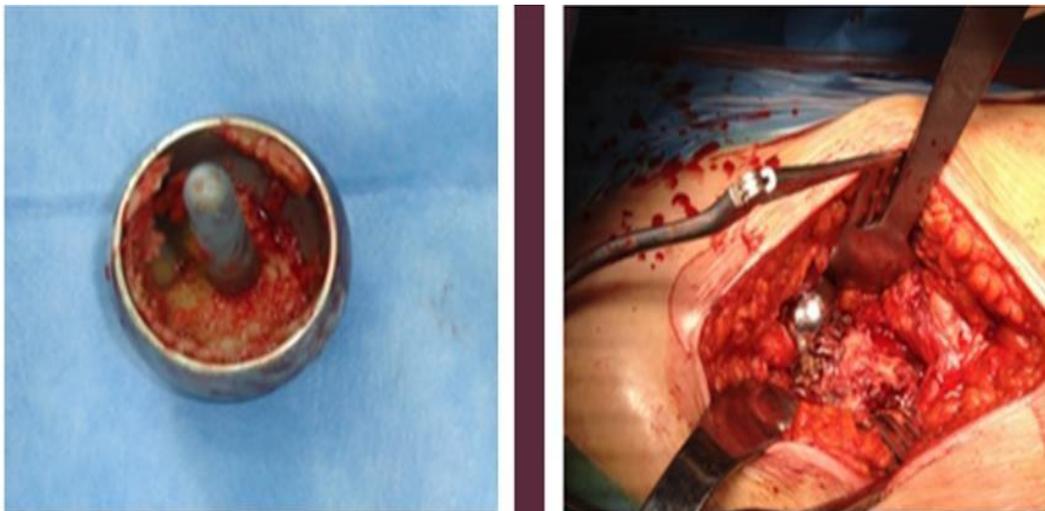
*Figure 50. X-rays of acetabular component failure: Edge loading at different degrees of loading* <sup>14</sup>

Also, improper positioning of the femoral component can lead to imbalance, asymmetrical wear and the risk of bone fracture. As can be seen in the second case of this series from the radiographs in Figure 50 (a, b), a wrong positioning angle caused the displacement of the femoral component and the dislocation of the prosthesis from the integration area.

The analysis of the intraoperative images performed for this patient reveals that, despite an apparent good integration between the prosthesis and the bone, incorrect positioning remains a recurring problem, highlighting the need for increased attention and expertise in the implantation process to minimize risks and maximize the success of orthopaedic surgeries.



*Figure 51. X-rays of femoral component failure: analysis of the consequences of inadequate positioning* <sup>15</sup>



*Figure 52. Intraoperative Images: Monitoring of Bone Integration and Adjustment of Prosthesis Position* <sup>16</sup>

In order to obtain a complete picture of the patient's condition, preoperative and postoperative radiographs, histological and bacteriological investigations were performed and analysed. During revision surgery, tissue samples were taken from the implant area for detailed histological analysis. These samples were analysed using staining techniques, including H&E (haematoxylin and eosin) staining at 100x, 200x, and 400x magnification, as well as Perl staining at 100x and 400x magnifications.

Histological analysis of the tissue taken from the BHR implant during the explanatory surgery revealed several complex tissue and cellular reactions, which can significantly contribute to the failure of these implants.

Our study revealed the presence of a foreign body-like granulomatous inflammatory reaction, characterized by multinucleated giant cells surrounding pseudo cystic spaces containing fine granular material, possibly from radiopaque prosthetic cement.

We also observed perivascular infiltrates of lymphocytes and mature cancellous bone tissue with intertrabecular fibrosis, suggesting inflammatory and fibrous reactions that may compromise implant stability.

The presence of macrophages with cytoplasm loaded with yellow-brown granular pigment and multinucleated giant cells indicates a chronic inflammatory reaction to foreign materials, which can lead to instability and degradation of the implant.

In addition, the appearance of the synovial membrane with fibrinous exudate and calcified detritus reflects an adverse tissue reaction, which can compromise the stability of the implant by inducing local inflammation and damage to the surrounding bone tissue.

The pronounced hyperaemia and capillary haemorrhages observed in the superficial areas of the tissue fragment suggest poor vascularization and increased susceptibility to inflammation and tissue degradation.

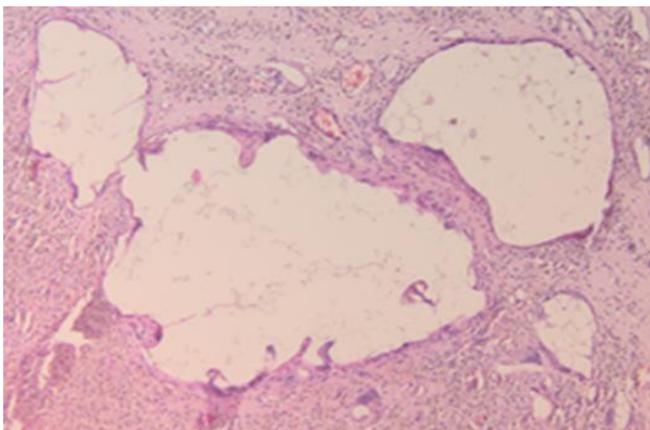
Through histological analysis, we discovered several significant features of the tissues examined. We identified macrophages with cytoplasm containing yellow-brown granular pigment, as well as giant multinucleated "foreign body" cells, one of which had an intracytoplasmic asteroid body at the top of the image (HE x400).

At Perl staining for iron compounds, several hemosiderin-containing siderophilin macrophages were identified, identified by their blue-stained cytoplasm, most of which remained reactive, possibly suggesting the presence of prosthetic cement (Perl's x400).

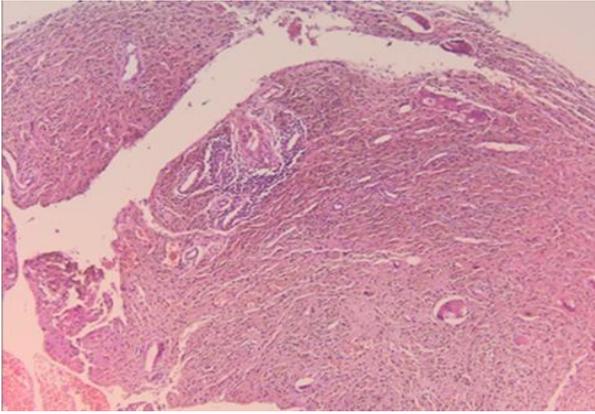
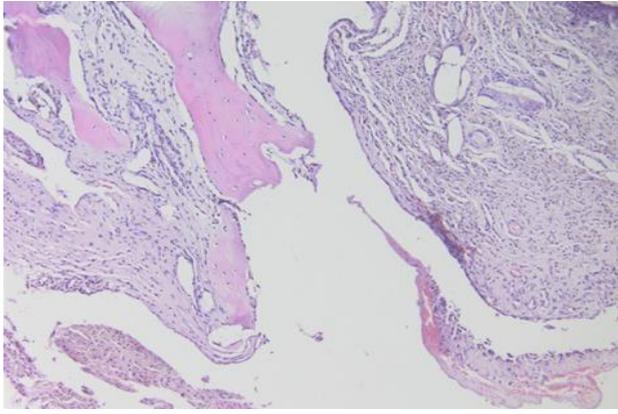
A synovial membrane-like appearance was observed in the centre of the image, with fibrinous exudate on the surface containing detritus of calcified material, possibly crushed bone, on the right side of the image (HE x400).

Significant hyperaemia was evident in the superficial areas of the tissue fragment, with dilated blood capillaries and haemorrhagic areas (HE x200).

The granulomatous inflammatory reaction of the foreign body type was characterized by multinucleated giant cells clustered around the pseudo-cystic spaces containing fine granular material, possibly radiopaque material from the prosthetic cement, and macrophages with foamy and finely granular cytoplasm (HE x100)



**a.** Granulomatous inflammatory foreign body reaction, characterized by the presence of multinucleated giant cells grouped around pseudo cystic spaces containing fine granular material (radiopaque material from prosthetic cement), accompanied by accumulations of macrophages with fine foamy and granular cytoplasm. (HE x100).

	<p><b>b.</b> Perivascular lymphocytic infiltrate located at the top of the image. (HE x100).</p>
	<p><b>c.</b> Mature spongy bone tissue showing intertrabecular fibrosis and, on the right side of the image, a granulomatous foreign body inflammatory reaction surrounding small pseudo cystic spaces. They are associated with groups of macrophages having cytoplasm containing a fine, granular pigment of yellow-brown color. (HE x100).</p>

*Figure 55. Histological analysis of the tissue taken from the explant area, using the HE x100 staining technique.<sup>17</sup>*

### **5.3. Analysis of representative explants of BHR hip endoprostheses**

Detailed explant studies were conducted to examine defects and bone-cement integration using advanced techniques such as scanning electron microscopy (SEM) and histological analysis. These analyses were crucial for understanding the causes of Birmingham Hip Resurfacing implant failures. SEM allows detailed examination of explant surfaces at a very high resolution, providing accurate images of the morphology of the bone-cement interface. The research highlighted the presence of microcracks, porosity and air bubbles in the cement mantle, confirming that these structural defects contribute significantly to the instability of the implant. SEM also identified uneven cement distributions and areas of poor adhesion between bone and cement, factors associated with an increased risk of prosthesis failure.

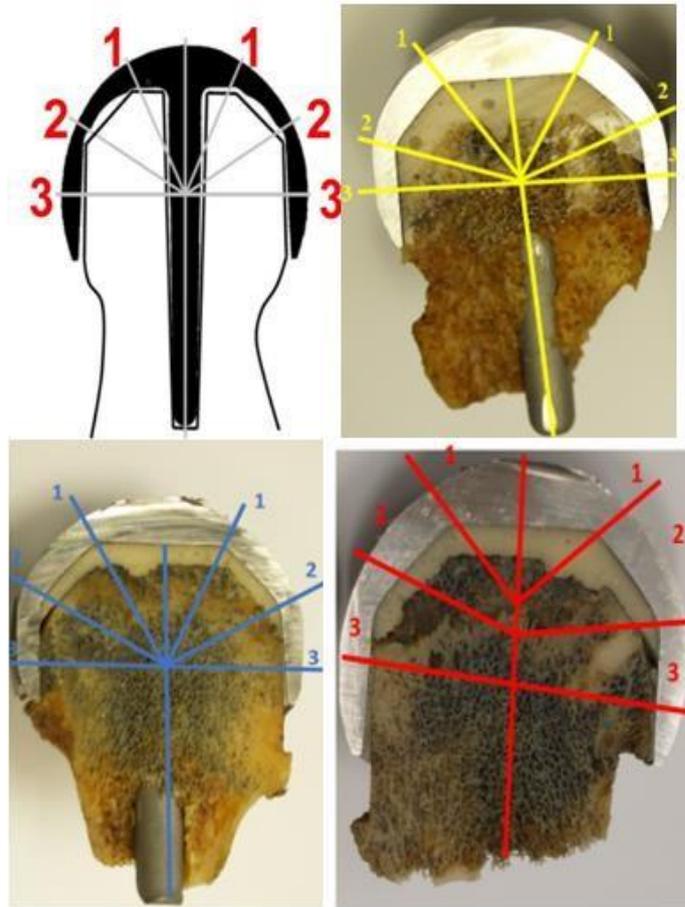


Figure 59. Contextual exemplification of the samples analyzed according to the reference model: Regions of interest for cement thickness and penetration analysis (1-3) <sup>18</sup>

In Table 8, we have calculated the parameters for this sample. The much too thick layers of cement are highlighted by the values of about 40 mm. We assume that the penetration of orthopedic cement into the bone is influenced by its low viscosity. By enlarging the image, in area three we notice gaps and metal debris that are visibly present.

Table 8. Acetabular Cup and Acrylic Cement Mantle Contact Evaluation Regions - Sample 1-3 <sub>2</sub>

	Zone	Min	Max	Perimeter	Unghi	Circumf.	Lenght Pixel	Lenght mm
1	1	54.333	127.667	153	-90	0.083	153	40.48125
2	1	62.333	128.333	79	-90	0.161	79	20.902083
3	2	73.000	124.683	59.414	-136.364	0.214	59.414	15.719954
4	2	48.331	120.079	56.586	-43.568	0.228	56.586	14.971712
5	3	42.667	130.342	143.283	-139.529	0.088	143.283	37.910294
6	3	82.500	118.193	164.201	-42.532	0.077	164.201	43.444848

In our research we observed a significant variation in cement mantle thickness in cases of failed BHR implants. In some situations, it was found that the cement sheath was completely missing in zone 3, which caused the appearance of irregularities and, ultimately, the failure of the prosthesis. These findings underscore the crucial importance of correct cement application and cement layer uniformity to ensure the long-term success of BHR implants.

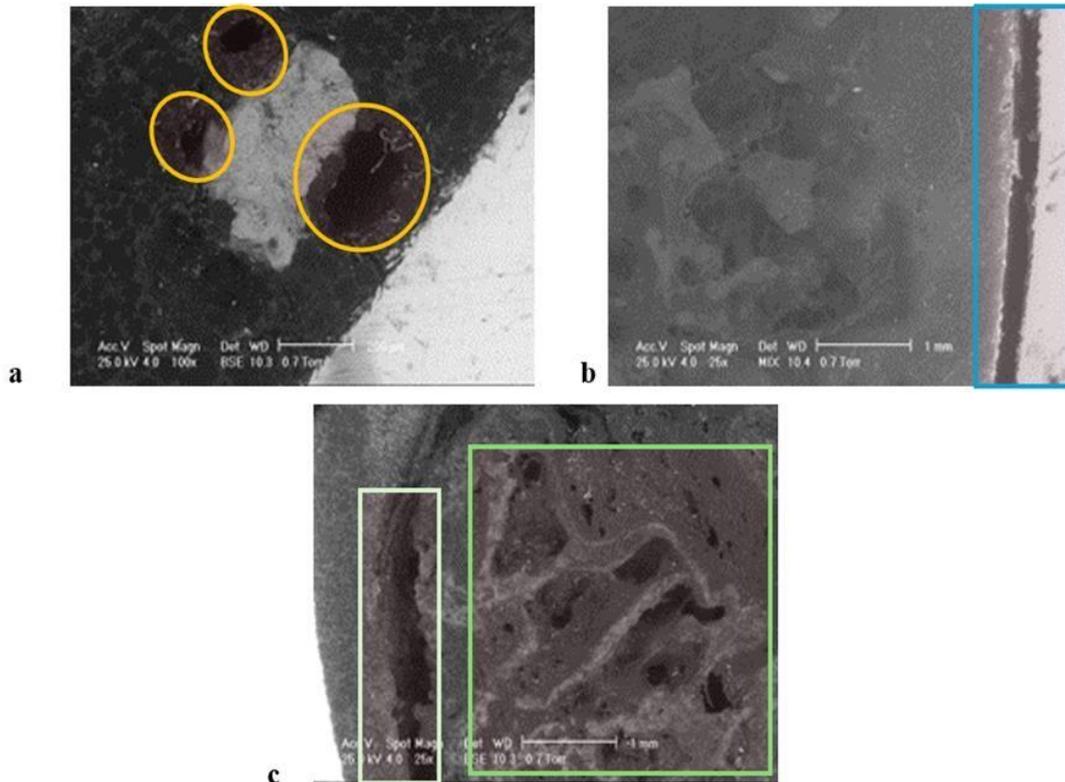
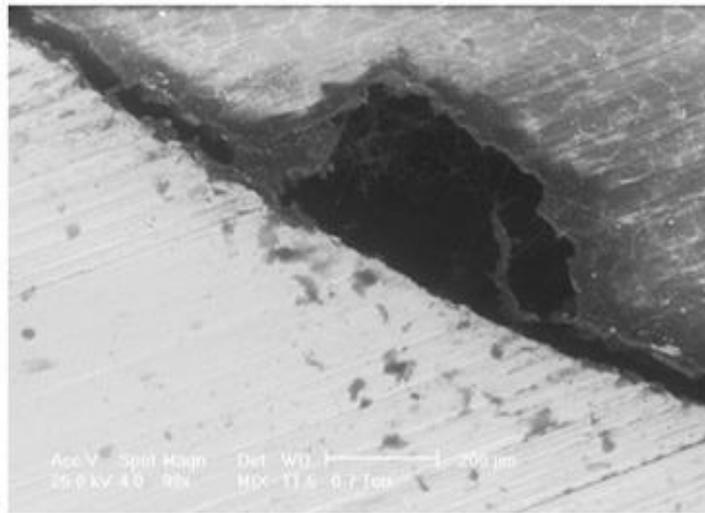
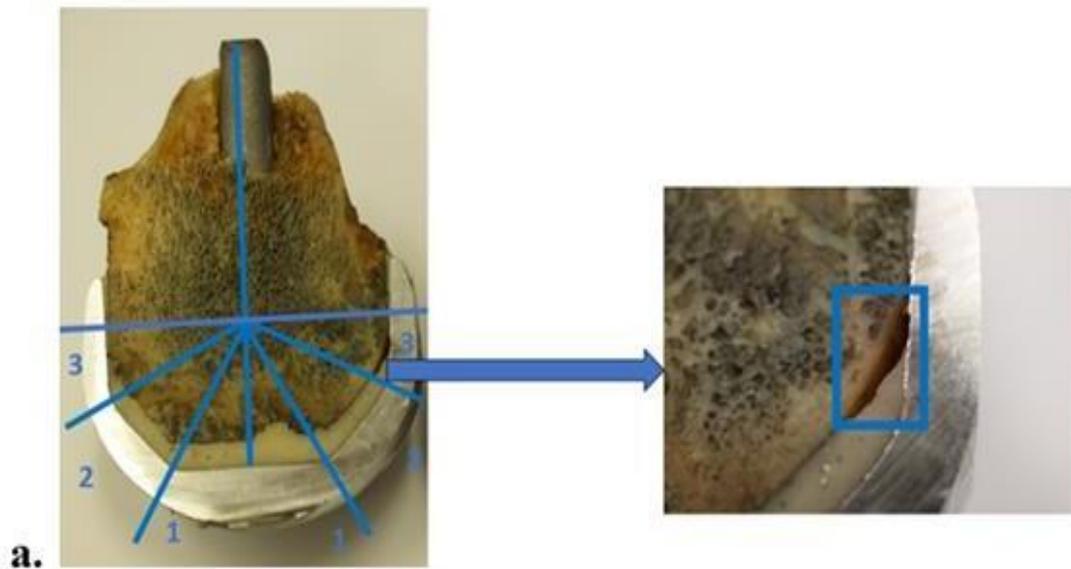


Figure 64. SEM Analysis of Structural Defects Caused by Improper Cement Application Technique

Our macroscopic analysis showed that zone 1 consistently had the highest cement layer thickness, and in some cases, the cement exceeded the reference area, interacting directly with the bone. In contrast, zone 2, although generally within normal limits, showed small and negligible deviations.

To carry out a more detailed analysis, we also used SEM analysis, which allowed us to investigate in depth the macroscopic defects observed in explantations, such as air bubbles, poor interface and irregularities, highlighting the negative impact of inadequate cementation technique on the success of the implants.

In the analyzed samples, various problems were identified that led to the failure of BHR implants. In Figure 64a, it can be seen that the mixing technique used for the preparation of acrylic cement was not efficient, with air bubbles in the final material being highlighted. Also, the viscosity obtained was not suitable for a uniform application, which resulted in an uneven distribution of the cement mantle, although the measurements indicated values close to the required standard dimensions. In Figure 64b, a large air gap between the cement mantle and the bone is visible, which prevented the formation of a proper cement-bone interface. In Figure 64c, the lack of cement-bone interface is highlighted, caused by the incorrect application of cement, and an advanced state of bone necrosis is observed compared to previous cases; The cement penetrated the bone unevenly due to inadequate viscosity.



*Figure 66. a. Weak interface indicates cementation defect, b. SEM micrograph of cement in sample 5 highlights cracks* <sup>20</sup>

Figure 66 shows poor bonding both between the cement and the denture surface and between the cement and the adjacent bone. In zone 3, the formation of an air gap between the cement sheath and the bone is noted, which prevents the formation of a proper interface between the cement and the bone. Dark, porous areas indicate the presence of necrotic bone, while lighter areas show how cement has penetrated the bone structure. The poor interface can be caused by an incorrect cement mixture or contamination with moisture or other foreign substances during application. The main problem exposed in the case of this prosthesis is the weakening of the fixation of the prosthesis, followed by displacement and degradation over time.

In Figure 66 b, the SEM analysis reveals a problem because the human bone comes into direct contact with the metal part of the acetabular cup. Also, the lack of cement-bone interface is observed due to the space formed by improper cement application. A significant deficiency is highlighted due to insufficient filling of the acetabular cup with bone cement.

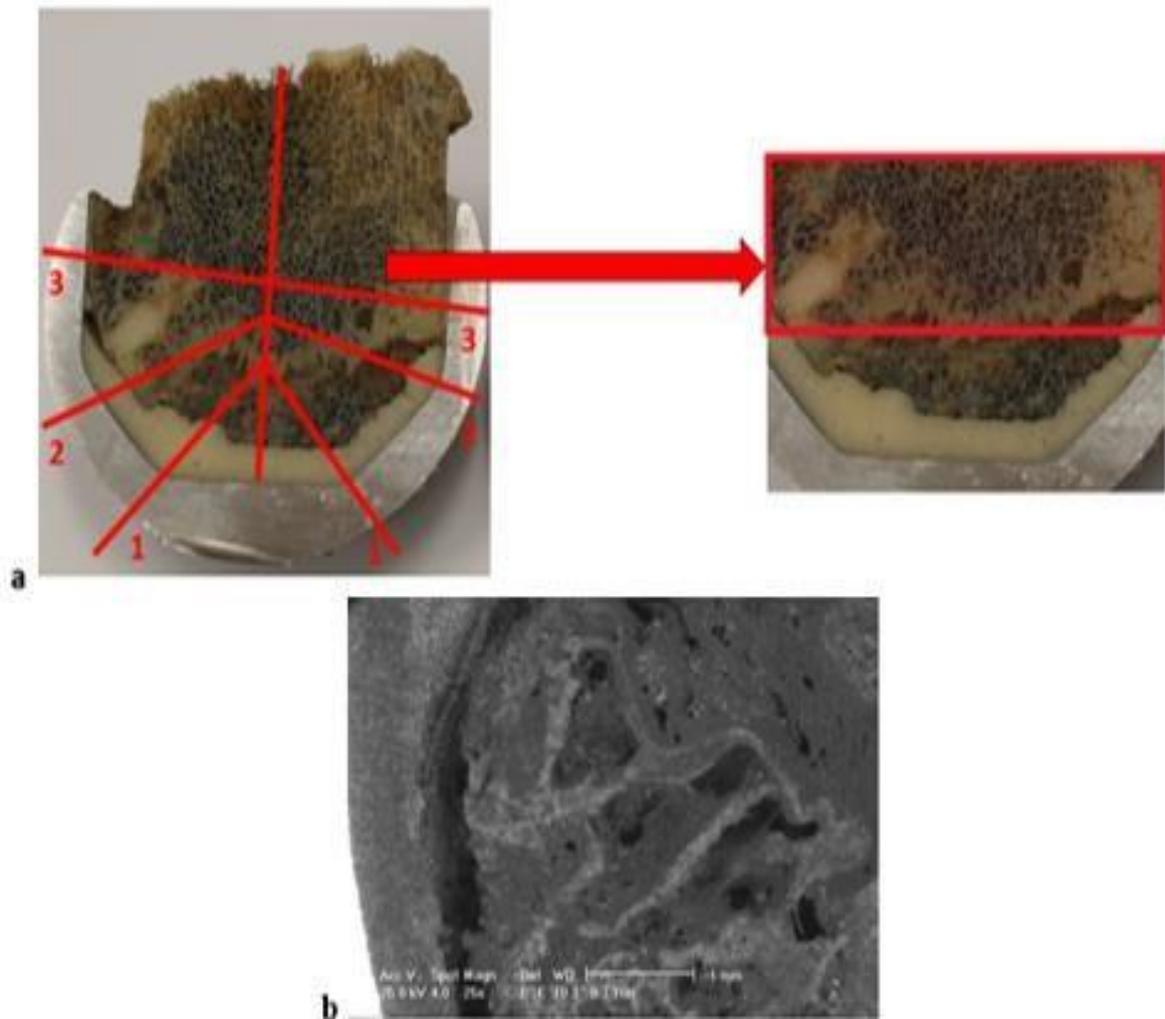


Figure 67. BHR prosthesis explanation: Cementation deficiency evidenced by uneven texture (a. Macroscopic analyses and b. SEM analyses)

Sample 3, shown in Figure 67, shows a much more advanced state of bone necrosis compared to previous cases, both at the macroscopic level and following the SEM analysis. The dimensions of the cement mantle do not comply with the necessary standards and its application is not uniform. The cement penetrates the bone without following clear rules, resulting in a distance between the cement mantle and the bone. Detailing the image, a crack was observed that had started from the space formed in the cement mantle and extended to the edges of the acetabular capsule.

We identified a few significant issues during the analyzes performed. One of these was the presence of air bubbles in the cement mantle, resulting from the inadequate mixing of cement, affecting its integrity. We have also noticed an uneven thickness of the cement mantle, caused by incorrect cement application or uneven pressure exerted during the cementing procedure. Another major problem was the poor interface between cement and bone, caused by incomplete cleaning of the femoral canal prior to cement application, allowing tissue materials to interfere with the proper adhesion of cement to the bone. To highlight these shortcomings – air bubbles, unevenness and poor interface – we performed further analyses using scanning electron microscopy (SEM).

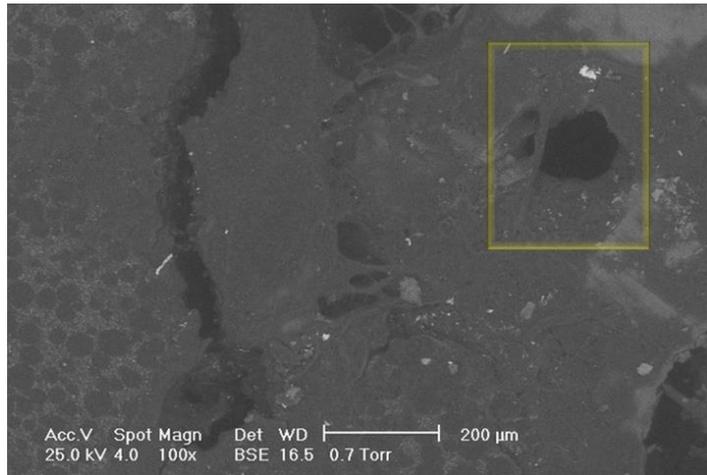


Figure 68. SEM analysis of air bubbles of varying sizes that have arisen in the cement mantle because of a defective procedure. <sup>22</sup>

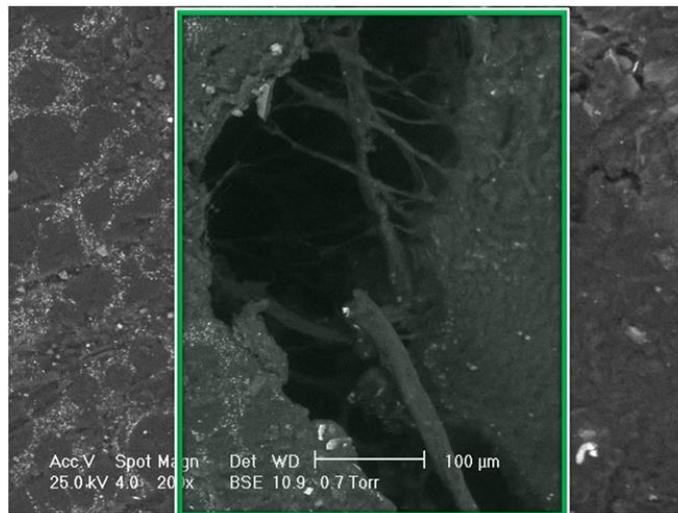


Figure 69. BHR prosthesis explanation: The cementation problem illustrated by the poor interface between bone cement and metal component. <sup>23</sup>

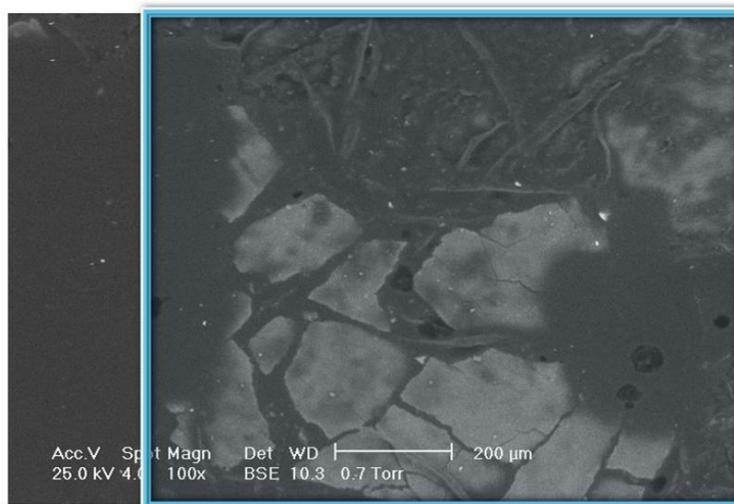


Figure 70. BHR Denture Removal: Cementation Defect Evidenced by Uneven Texture

## Conclusions

As a result of sustained research, the fundamental importance of the cementation technique in hip implants is confirmed, with a special focus on Birmingham Hip Resurfacing (BHR) implants. The detailed analysis of the factors associated with the failure of these implants emphasizes the need for a precise and systematic approach in the application and management of the cementation process.

The combined study of the results obtained by electronic and histological analyses provides a comprehensive picture of the factors contributing to the failure of BHR implants. These techniques allowed for the precise identification of structural defects and biological responses, emphasizing the importance of proper cementation technique and detailed attention to ensure the long-term success of hip implants. Thus, the research highlights the need for optimized surgical practices and strict cementation protocols to minimize the associated risks and improve clinical outcomes for patients.

Histological analysis revealed that the use of an appropriate cementation technique, together with the choice of a suitable cement, can help minimize the inflammatory response and improve the integration of the implant into adjacent tissues. These findings underscore the importance of a precise approach in implant management and support the need for further research to optimize clinical outcomes in implant surgery.

The data obtained by combining investigative methods, including electron microscopy and histological analyses, bring to the fore the conclusions that the application of an appropriate cementation technique can significantly reduce the incidence of complications and positively influence the clinical course of treated patients. Thus, the increased attention paid to details such as mixing and uniform application of cement, rigorous cleaning of the femoral canal and monitoring the thickness of the cement mantle proves to be of crucial importance in preventing the failure of BHR implants.

The main causes of failure of BHR implants included fracture of the femoral neck, detachment of the acetabular component, and collapse of the femoral head. It is obvious that certain problems are more common or more serious depending on gender and other individual risk factors.

Risk factors such as osteoarthritis, acetabular dysplasia, and history of previous interventions for acetabular dysplasia have been identified as having a significant impact on the stability of the acetabular component and the risk of implant failure. These findings underscore the importance of a rigorous and personalized assessment of each patient prior to surgery.

Clinical and imaging analyses revealed wear induced by incorrect positioning of the acetabular cup, which led to progressive wear and implant failure. Also, analyzing the explants, problems related to cementation were observed, including the presence of air bubbles and uneven cement application, which compromised the adhesion and stability of the prosthesis.

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