EVALUATION OF SURFACE PROPERTIES IN 316L STAINLESS STEEL ORTHOPEDIC IMPLANTS

Hassan Nasri NASRABADI[1], Alina ROBU*[2], Robert CIOCOIU[3], Iulian ANTONIAC[4], Ruxandra DUMITRESCU[5], Daniela Alina NECSULESCU[6], Sorin CIUCA[7], Anca Maria FRATILA[8]

Orthopedic implants, such as femoral stem hip prostheses and plates for long bone fractures, are important in restoring patient mobility and overall functionality. The long-term success of these implants depends not only on the choice of biomaterial but also on their surface characteristics, which influence biocompatibility, adhesion, and cellular response. This study presents a comparative analysis of two medical devices made of 316L stainless steel: an osteosynthesis implant (S1) manufactured by cold deformation and a femoral stem hip prosthesis (S2) produced by casting. The surface morphology, elemental distribution, wettability, surface free energy (SFE), and surface roughness were evaluated. The results reveal significant differences in surface characteristics attributable to the distinct manufacturing processes. These findings emphasize the role of manufacturing processes in determining the surface properties of medical implants, with implications for their biocompatibility, mechanical performance, and overall clinical success. The study underscores the need for tailored manufacturing approaches to optimize implant design for specific applications in medical device engineering.

Keywords: 316L alloy; stainless steel; femoral stem hip prosthesis; plate for long bone fractures; surface; contact angle; roughness

[1] PhD student, Faculty of Materials Science and Engineering, National University of Science & Technology POLITEHNICA Bucharest, e-mail: hassannasri65@gmail.com
[2] Lect., Faculty of Materials Science and Engineering, National University of Science & Technology POLITEHNICA Bucharest, e-mail: alina.ivanov@upb.ro, alinarobu2021@gmail.com
[3] Lect., Faculty of Materials Science and Engineering, National University of Science & Technology POLITEHNICA Bucharest, e-mail: ciocoiurobert@gmail.com
[4] Prof., Faculty of Materials Science and Engineering, National University of Science & Technology POLITEHNICA Bucharest, e-mail antoniac.iulian@gmail.com
[5] Lect., Faculty of Materials Science and Engineering, National University of Science & Technology POLITEHNICA Bucharest, e-mail: ruxandraelenadumitrescu@gmail.com
[6] Lect., Faculty of Materials Science and Engineering, National University of Science & Technology POLITEHNICA Bucharest, e-mail: alina.necsulescu@upb.ro
[7] Conf., Faculty of Materials Science and Engineering, National University of Science & Technology POLITEHNICA Bucharest, e-mail: sorin.ciuca@upb.ro
[8] Lect., Faculty of Medicine, Lucian Blaga University of Sibiu, e-mail: anca.fratila@ulbsibiu.ro

1. Introduction

316L stainless steel is a low-carbon variant of the more common 316 stainless steel. With its enhanced corrosion resistance, high mechanical strength, and excellent biocompatibility, 316L has become a material of choice for medical implant applications. It is also known for its unique combination of properties that stem from its carefully controlled chemical composition and processing. The "L" in 316L refers to its low carbon content (≤ 0.03%), which reduces the risk of carbide precipitation during welding and high-temperature processing. The high corrosion resistance, the good mechanical properties, and the biocompatibility with the human body make it an excellent choice for implants [1,2]. Some of the properties that make this material suited for medical implant applications are presented in Fig. 1.

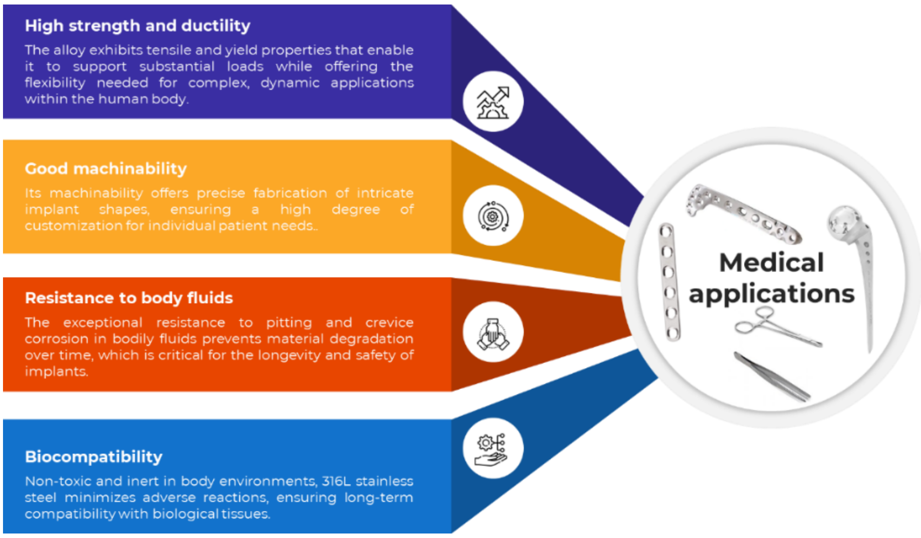

Fig. 1. Key characteristics of 316L stainless steel used in medical devices

The alloy's mechanical performance is characterized by a tensile strength approximately 480-670 MPa, ensuring adequate load-bearing capability, the yield strength about 170-360 MPa, indicative of the stress required to produce permanent deformation, the elongation around 50% that demonstrates its capacity for deformation before breaking and hardness ranging between 150-200 HV contributes to its wear resistance and longevity. 316L stainless steel exhibits good resistance to pitting and crevice corrosion, which is essential for environments exposed to body fluids, thus preventing compromise of implant integrity, and a good biocompatibility, making it safe for contact with human tissues. Thanks to its unique blend of properties, 316L stainless steel is extensively used in many medical implants such as orthopedic devices, dental implants, and cardiovascular devices.

Its robustness, coupled with ease of manufacturing complex geometries, ensures that implants can be designed to meet the specific anatomical and functional needs of the patients. These attributes contribute to longer implant life and a lower risk of complications, promoting better patient outcomes. It is a key material in the biomedical field, offering a compelling combination of corrosion resistance, mechanical strength, and biocompatibility. Its low carbon content and tailored chemical composition make it an ideal candidate for the creation of long-lasting, reliable medical implants.

Bone plates are essential in the orthopedic field because they keep the bone fragments in proper alignment, transfer mechanical loads, and provide necessary fixation while natural bone repair occurs. 316L stainless steel is used for bone plates because is suitable for load-bearing applications, it allows contouring to match the natural shape of the bone, and it is important to prevent in vivo degradation and ion release [3–5]. It is **also used** in certain hip prosthetic components because it offers high fatigue strength, good corrosion resistance, and provides a budget-friendly alternative compared to titanium alloys. Despite its advantages, 316L stainless steel faces several challenges like lower wear resistance (particularly when compared with cobalt-chromium alloys), potential for metal ion release (nickel and chromium ions may be released over time), not as lightweight (titanium may be preferred for long-term applications) and risk of long-term fretting corrosion (especially in areas subject to repetitive joint movement) [6–12].

The fabrication of 316L implants typically involves forging, machining, and heat treatment, which are used for stress relief and to optimize mechanical properties. To further enhance corrosion resistance and biocompatibility, several surface treatments are applied, like electro-polishing (used to smooth the surface and reduce the risk of corrosion), coating with hydroxyapatite (to promote better osseointegration), or passivation (to remove free iron to further enhance corrosion resistance and biocompatibility) [13–16]. 316L stainless steel continues to be a choice for orthopedic implants, particularly in bone plates and certain hip prosthesis components. Its balance of strength, malleability, and corrosion resistance makes it highly suitable for load-bearing applications. However, its limitations—especially in terms of wear resistance and potential for metal ion release—necessitate ongoing research and development. Advances in manufacturing processes and surface treatments are critical to further enhance the performance and longevity of 316L-based implants.

This article compares two commercial medical devices used in orthopedic surgery: one femoral stem hip prosthesis and one plate for long bone fractures. The focus is on their surface morphology and properties.

2. Materials and Methods

Two medical devices, both made of 316L stainless steel, were comparatively analysed: an osteosynthesis implant for traumatology (plate for long bone) obtained by cold deformation (Fig. 1a) – coded S1 and a femoral stem hip prosthesis obtained by casting the material (Fig. 1b) – coded S2. The morphology and surface properties were evaluated and compared.

Fig. 2. Experimental orthopedic implants used in the study: a) plate for long bone fractures – sample S1, b) femoral stem hip prosthesis – sample S2

2.1. Materials Characterization

Surface Morphology and Composition were investigated using an FEI QUANTA INSPECT F microscope with an EDAX detector. The contact angle measurements were performed on a KRÜSS DSA30 Drop Shape Analysis System using water (W), diiodomethane (DM), and ethylene glycol (EG). The surface free energy was computed via the OWRK method. The profilometry measurements were made with a Taylor Hobson Form Talysurf I-Series PRO (using Metrology 4.0 Software). Before the measurement, 70% ethanol was used to clean the specimen. The parameters determined were Ra (arithmetic average deviation) and Rz (average maximum height of the roughness profile) over five observations.

3. Results and discussion

3.1. Scanning Electron Microscopy and Energy Dispersive X-Ray Analysis

In this comparative analysis, we can observe key differences and similarities through their respective electronic microscopy (SEM) images and energy-dispersive X-ray spectroscopy (EDS) results. The SEM images show a relatively smooth surface with some minor irregularities.

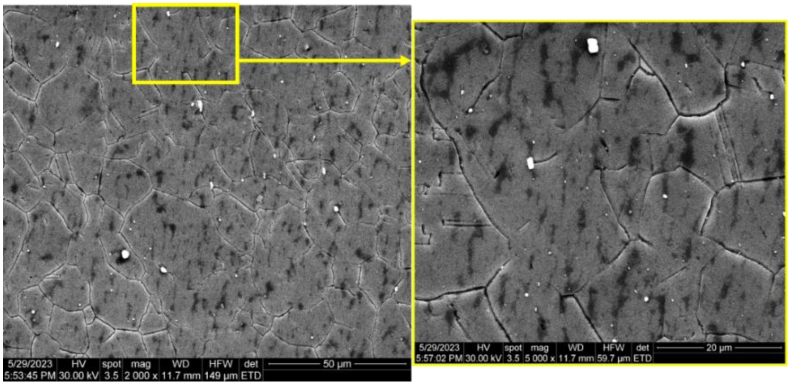

Fig. 3. SEM images of sample S1 at 2000x and 5000x magnification

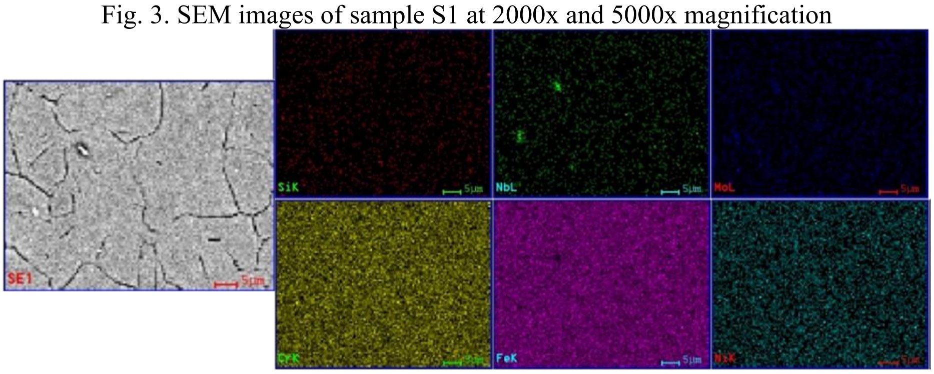

Fig. 4. SEM micrographs and EDAX diagrams of compositions sample S1

There are visible features indicating the cold deformation process, which may affect the mechanical properties. The EDS analysis revealed peaks for elements such as Silicon (Si), Nickel (Ni), Molybdenum (Mo), and Iron (Fe). The distribution of these elements indicates a uniform composition typical of cold-worked materials.

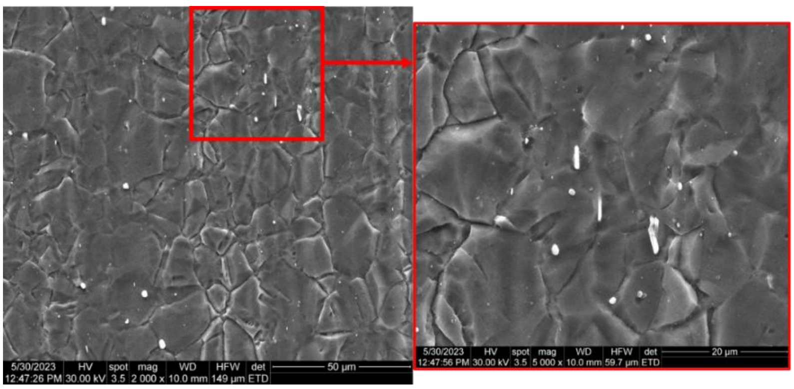

Fig. 5. SEM images of Sample 2 at 2000x and 5000x magnification

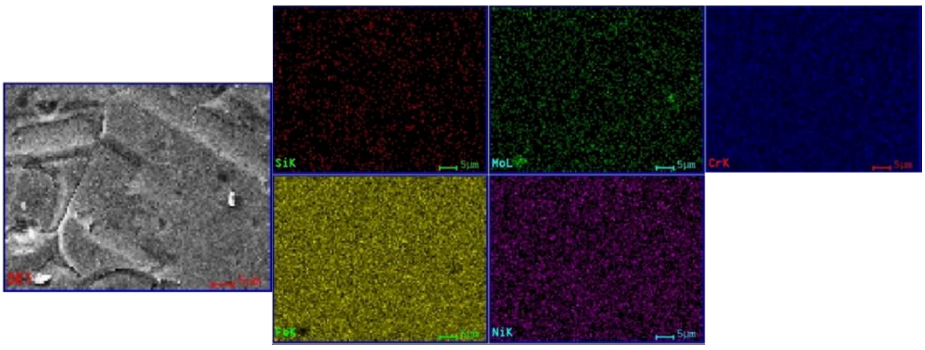

Fig. 6. SEM micrographs and EDAX diagrams of compositions sample S2

Fig. 6 reveals a more complex surface texture with significant features that could be attributed to the casting process. The irregularity in the surface may influence the biological response and mechanical interlocking in vivo. The EDS analysis reveals that similar elemental peaks for Silicon (Si), Nickel (Ni), Molybdenum (Mo), and Iron (Fe) are present. However, the distribution and intensity of these elements differ, reflecting variations in alloying or casting defects.

By comparing the two surfaces, S1 appears smoother due to cold deformation, while S2 exhibits a rougher texture typical of cast materials. Regarding the elemental distribution, both samples contain the same core elements; however, the concentration and distribution vary due to their different manufacturing processes. The differences in surface morphology and elemental distribution can impact the mechanical properties and biocompatibility of the implants, indicating that the choice of manufacturing process is important in device performance.

3.2. Contact Angle

Wettability, measured by contact angle (CA), determines how fluids interact with the implant surface. Hydrophilic surfaces (CA < 90°) enhance osteointegration and protein adhesion, and hydrophobic surfaces (CA > 90°) reduce corrosion and bacterial adhesion. It has been noted that the wettability of an implant surface affects bacterial adhesion to it. Table 1 presents the contact angle values obtained for the experimental samples.

Table. 1

Contact angle measurements of the samples

	S1			**S2**		
	Water	Diiodomethane	Ethylene glycol	Water	Diiodomethane	Ethylene glycol
Average	56.48	52.62	52.64	53.94	51.59	49.01
Standard deviation	2.17	2.92	1.88	1.94	0.94	1.93

Both samples exhibit relatively low contact angles for water, indicating hydrophilic behavior, which is beneficial for biological interactions. The contact angles evaluated for diiodomethane and ethylene glycol suggest that S2 has slightly better wettability compared to S1, which may enhance its performance in a biological environment.

The obtained data for contact angle values for the three liquids and the surface free energy was analyzed statistically via a t-Test using with α=0.05.

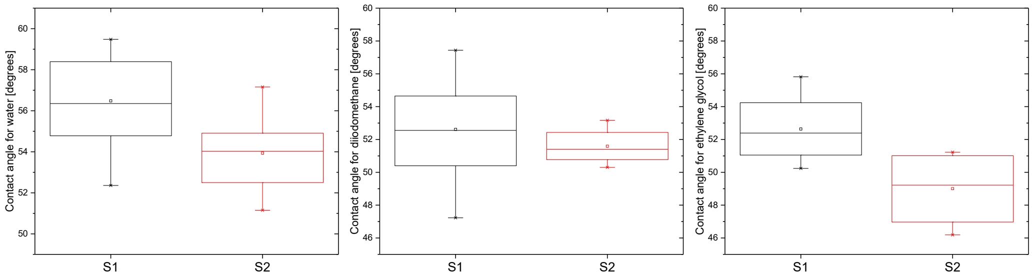

Fig. 7. Box plot showing the statistics for the measured contact angle for water (a), diiodomethane (b) and ethylene glycol (c)

The t-Test performed on the means of the contact angle for **water,** diiodomethane and ethylene glycol suggests revealed that there is a statistically significant difference between the means value of S1, 56.48° and one of S2, 53.94°. The surface is hydrophilic, given the low contact angle values for water. Diiodomethane shows good surface wetting, but the surface of sample S1 appears to be less wetted at 52.62°, given higher contact angle values. Like the other two liquids, ethylene glycol shows an enhanced surface wetting, and sample S2 shows lower contact angle values. A t-Test indicated a statistically significant difference between the contact angle means of S1 and S2, particularly for water. This underscores that the manufacturing processes (cold deformation vs. casting) have led to notable differences in surface characteristics.

In summary, the comparative analysis of contact angles and surface free energy provides essential insights into how manufacturing methods influence the surface characteristics of these medical implants, which are crucial for their functionality and acceptance in biological environments.

The choice of manufacturing process significantly influences surface characteristics. Cold deformation leads to less roughness, while casting can create more complex surface textures. Understanding these characteristics allows for better design choices tailored to the specific application and desired performance of the implant.

3.3. Surface-free energy

In this analysis, the contact angle measurements and surface free energy (SFE) values for the osteosynthesis implant (S1) and the femoral stem hip prosthesis (S2) provide valuable insights into the surface characteristics and their implications for biocompatibility and material performance.

Table 2

Surface-free energie and work of adhesion values

	S1				S2			
	Surface free energy [mN/m]	Work of adhesion for W [mN/m]	Work of adhesion for DM [mN/m]	Work of adhesion for EG [mN/m]	Surface free energy [mN/m]	Work of adhesion for W [mN/m]	Work of adhesion for DM [mN/m]	Work of adhesion for EG [mN/m]
Average	42.84	111.54	76.10	84.91	44.94	114.34	77.40	86.66
Standard deviation	1.80	2.35	1.41	0.77	1.49	1.89	0.73	86.66

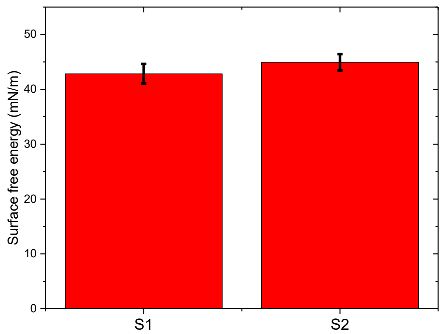

Fig. 8. Surface-free energies chart.

The surface free energies of both samples are slightly different. Even though the sample P2 is showing a slightly higher value, 44.94 mN/m±1.49 mN/m compared to 42.48±1.80 mN/m for P1. From a statistical point of view, the average values can be regarded as equal. The higher SFE of S2 suggests that its surface is more energetically favorable for interactions with biological tissues. This could enhance cell adhesion and integration. As for the SFE the t-Test result suggests that there is a statistically significant difference between the means. S1 and S2 show varying work of adhesion values, with S1 having lower values for diiodomethane and ethylene glycol, indicating that S2 may provide better surface interactions, contributing to its overall performance.

The differences in the contact angles and SFE values can be attributed to the distinct manufacturing processes. Cold deformation (S1) results in a smoother surface, while casting (S2) may create a more textured and reactive surface. The hydrophilic nature and higher SFE of S2 suggest better potential for biological integration, which is critical for long-term implant success.

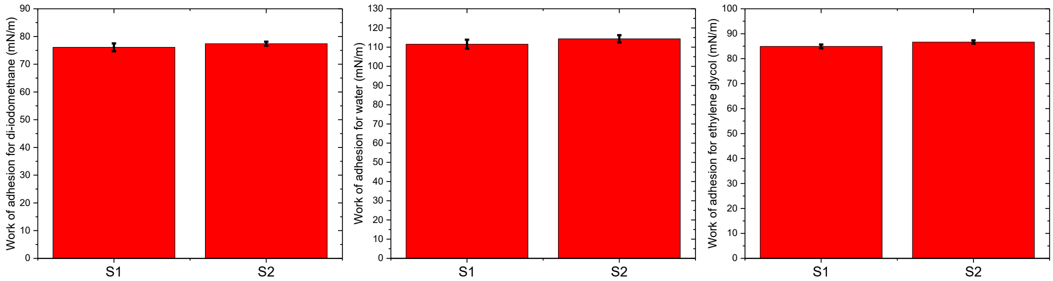

Fig. 9. Work of adhesion chart for both samples.

The ability of S2 to facilitate wetting with common biological liquids may enhance its performance within the body. These findings highlight the importance of selecting appropriate manufacturing processes to optimize surface properties for specific applications in medical devices.

3.4. Roughness

Surface roughness and wettability are essential for implants and prostheses used in medicine [8,17–19]. A rough and hydrophilic surface will favour protein adsorption and promote osseointegration, which will subsequently lead to the formation of a strong and stable bond between the implant and the bone tissue [20]. To improve the prosthesis's ability to adhere to cement, a variety of surface polishing, proximal porous coatings, and grist-blasting techniques have been used to roughen the metal prosthetic stem's surface [21,22]. Surface roughness and wettability are essential factors that may be used to assess the trauma plate's mechanical characteristics and biocompatibility [23]. The ideal surface roughness of hip prosthesis stems is still debatable. The surface condition of a cemented femoral component can influence implant function by modifying the cement adhesion properties. Crowninshield & al. [24] characterized the surface roughness of over 20 types of commercial hip prostheses used over time and obtained a significant variety of the roughness parameter Ra - between 0.05 µm and 14.5 µm. Surface roughness influences the fixation of the implant-cement interface, thus, smoother surfaces provide a weaker fixation, while a rougher surface provides a higher fixation strength[25].

Also, rougher implant surfaces have a lower probability of interface movement, while smoother surfaces have a higher probability of interface movement [26]. In the initial prosthesis made by Charnley, a polished stem with an average roughness of 0.1 mm was used.

Later, its roughness was modified, and an average surface roughness of 0.75 mm was applied to influence the fixation of the prosthesis in cement. Through mathematical modelling, it was proven that at a roughness of Ra = 15 µm, the grip between the bone cement and the femoral prosthesis stem is improved [27]. Various companies have modified the surface roughness (Exeter increased the surface roughness to approximately 1 µm, while the polished stem was less than 0.1 µm) [28].

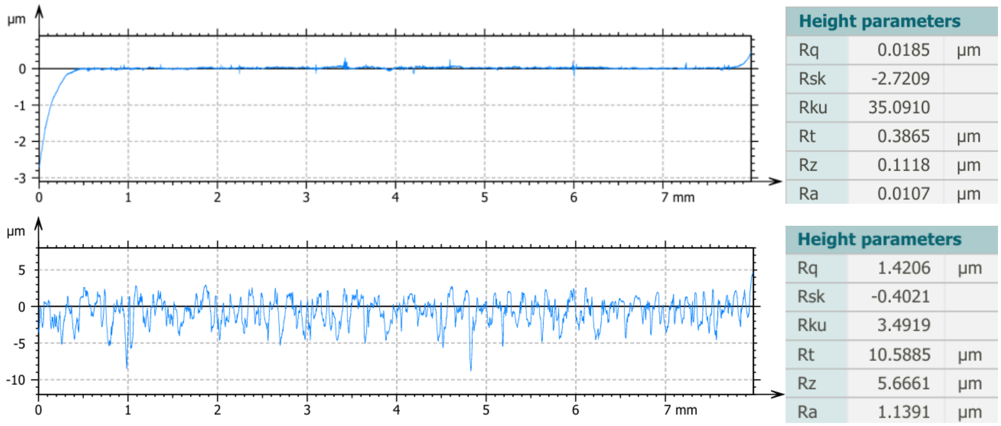

Fig. 10. Roughness profile of the samples S1 and S2 investigated.

There is a difference between matte stems (which have a roughness Ra of 2.2 µm) and smooth Harvard-type stems (Ra 2.2 µm). Over time, it has been proven that the smooth surface stem has a higher efficiency. There are also stems with a rough surface, such as the Lubinus SPII, which have reported very good results, both clinically and in the literature, which demonstrates that the efficiency of a hip prosthesis cannot be determined solely based on its roughness, but several factors must be considered [29].

To interpret the surface roughness data for the osteosynthesis implant (S1) and the femoral stem hip prosthesis (S2), we can consider several key aspects related to the manufacturing processes and their implications for performance. The surface roughness values are typically quantified using parameters such as Ra (average roughness), Rz (average maximum height of the roughness profile), or others depending on the specific analysis used. Each parameter provides insights into the texture of the surface.

According to the literature, S1 (manufactured by cold deformation) is likely to show a smoother surface due to the cold working process, which typically results in less pronounced surface features. The S2 (femoral stem hip prosthesis manufactured by casting) may exhibit greater surface roughness due to the nature of the casting process, which often introduces irregularities and textures.

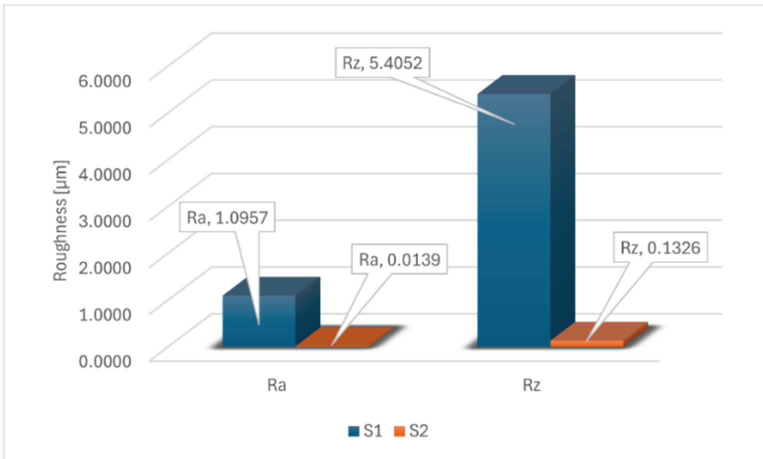

Fig. 11. Ra and Rz parameters for surface roughness of the investigated samples

Surface roughness (Ra) affects mechanical stability, corrosion resistance, and biological response. Our results revealed that the S1 sample (the bone plate) had the highest values of the Ra and Rz parameters (e.g., Ra = 1.0957 µm, Rz = 5.40518µm). In the case of femoral stem hip prosthesis manufactured by casting (S2) generated a lower roughness parameter (Rz = 0.13258 µm and Ra = 0.0139 µm). A smoother surface (as in S2) may be beneficial in reducing the risk of bacterial adhesion, potentially lowering infection rates. Conversely, a rougher surface (as in S1) can promote better cell attachment and proliferation, which is particularly important for implants in terms of osseointegration. The surface roughness can affect mechanical interlocking with bone tissue, impacting the stability and longevity of the implant. A balance between sufficient roughness for biological integration and smoothness for reducing wear and tear is important.

Overall, the surface roughness data complements the findings from the contact angle measurements and surface free energy analysis. It reinforces the understanding that the manufacturing process significantly affects the surface characteristics of medical implants, which in turn influences their biological performance, mechanical stability, and overall effectiveness in application. This holistic view is essential for optimizing implant design and material selection in medical applications.

4. Conclusion

The comparative analysis of the osteosynthesis implant (S1) and the femoral stem hip prosthesis (S2), both made of 316L stainless steel, reveals significant differences in surface morphology, elemental distribution, wettability, surface free energy, and surface roughness. These differences are primarily attributed to the distinct manufacturing processes—cold deformation for S1 and casting for S2. The hydrophilic nature and higher SFE of S2 suggest better potential for biological integration, which is critical for long-term implant success. The enhanced wettability and surface roughness of S2 can promote better cell adhesion and proliferation, improving osseointegration. The smoother surface of S2 may reduce wear and tear, while the rougher surface of S1 can improve mechanical interlocking with bone tissue, enhancing implant stability. The manufacturing process plays a pivotal role in determining the surface properties of medical implants, which in turn affects their biological and mechanical performance.

These findings underscore the importance of selecting appropriate manufacturing techniques to optimize the surface characteristics of medical devices for specific applications, ensuring better performance and patient

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