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COMPARISON OF RAW MATERIALS USED IN CUSTOMIZED IMPLANT SYSTEMS THROUGH FINITE ELEMENT ANALYSIS AND DYNAMIC FATIGUE TESTING

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Abstract: Customized implants offer many advantages in medical implant applications. Material selection from the limited biocompatible material choices plays a crucial role in the success of the treatment. In this study, we compare the results obtained from dynamic fatigue testing and finite element analysis of raw materials planned for use in personalized implant systems which were made possible by the advancements in production technologies and their widespread adoption in the medical sector. The study first discusses the concept of customized implants and the materials necessary for these implants. Multiple test samples were then produced using subtractive and additive manufacturing methods according to specified dimensions using the selected materials. Static and dynamic tests were applied to the produced samples. The cobalt-chromium alloy demonstrated the highest rupture value (5.9 kN) in static tests; furthermore, it exhibited the highest value (562,189 cycles) when the rupture cycle was analyzed in dynamic tests. The results from these tests were evaluated in terms of materials and manufacturing methods. Based on the evaluations, CoCr was identified as a more durable material, and in terms of manufacturing methods, parts produced by subtractive manufacturing were found to be more durable.

Keywords: Customized Implant, Material, Finite element Analysis, Fatigue testing

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1. Introduction

Implants are medical devices or materials that are surgically placed inside or on the surface of the body. They are utilized to replace missing body parts, provide support, deliver medication, or enhance bodily functions. Depending on their purpose, implants can be either permanent or temporary. Since the size and shape of the body part where the implant will be used can vary from patient to patient, adjustments to the implants are often necessary during surgery to meet the specific needs of each individual. The need for such adjustments can be avoided by using custom-made implants that are tailored to the unique requirements of each patient.

Although there is no universally accepted definition, a patient-specific implant, also referred to as a custom-made implant, can generally be defined as a medical device designed and manufactured specifically for an individual patient to meet their unique needs, in accordance with a prescription prepared by a specialist physician (de Jong et al., 2024). Patient-specific medical devices are designed to provide solutions in cases where commercially available products or alternative treatments are inadequate for the individual. Essentially, these devices are exclusively intended for use by a specific individual, custom-designed based on the request of an authorized healthcare professional, and must be tailored to the specific anatomical, physiological, and pathological characteristics of the intended patient. Any implant used for patients other than the designated individual, or that is adaptable or mass-produced, cannot be classified as a patient-specific implant.

There are several advantages to using custom-made implants. In traditional implant surgery procedures, the surgeon assesses the patient during the operation, plans the placement of the implant, and makes adjustments to the implant or the surrounding tissue in order to fit the implant to the intended position. However, surgeons often spend additional time during the operation modifying implants to fit the patient, prolonging the surgery. More adjustments mean longer surgery times. On the other hand, with patient-specific implants, which are precisely manufactured to fit the patient, the issue of intraoperative adjustments are eliminated, leading to shorter surgical durations (Wong, 2016). This reduction in surgery time also lowers the risk of complications for patients and improves medical outcomes.

One of the most significant advantages observed in studies is the ability to produce implants tailored to each patient's unique anatomy, allowing them to perform their vital functions effectively. This customization not only shortens the surgical duration but also facilitates the patient's post-operative recovery and extends the implant's lifespan (Ventola, 2014). In fields such as neurosurgery and maxillofacial surgery, there is no one-size-fits-all procedure for all patients. Designs must be tailored to accommodate the unique anatomical structures that vary from person to person. This is achievable with patient-specific implants, providing the best possible anatomical fit for each patient.

The better the compatibility of the implant with tissues and organs, the sooner it begins to function. The perfect fit mentioned earlier is the most critical factor enabling rapid recovery. Standard implants often require adjustments to fit the patient, leading to significant bone deformations, extended surgery times, and increased risks of intraoperative infection. These factors lower efficiency and recovery rates. With patient-specific applications, these risks can be minimized.

In the literature, we observe applications of patient-specific implants primarily in the fields of orthopedics and oral and maxillofacial surgery. One example is an implant prepared in 2020 for a craniomaxillofacial reconstruction surgery in China (Du et al., 2020). Craniomaxillofacial reconstruction, a common procedure following tumor removal or trauma surgery, often involves bending standard implants during surgery to fit the bone structure. This makes the procedure highly prone to errors, especially for inexperienced surgeons. Since standard implants require bending, the study is on creating a model suitable for the patient's jaw structure using a 3D printer. The model was designed based on computed tomography data from the patient, validated through simulation software, and optimized as necessary. Subsequently, the data files required for the 3D printer were generated, and the production was carried out. Pre-surgery, surface quality was enhanced, and sterilization procedures were performed to prepare the implant for operation.

In the demanding domain of craniomaxillofacial surgery, the primary objective is the restoration of function, while preserving anatomical characteristics such as symmetry and harmony constitutes a secondary goal. A study undertaken in 2016 in Portugal exemplifies this commitment. Utilizing CT imaging technology, Matias et al. designed a model aimed at addressing anatomical and pathological deficiencies. The fabrication of the model involved a combination of block material processing and additive manufacturing techniques, ensuring precision and fidelity to the original design (Matias et al., 2017).

Orthopedics is another field where patient-specific implants are widely used. An example of the use of patient-specific implants in orthopedics is a personalized plate design created in 2021 in China for tibia-calcaneal arthrodesis (Yao et al., 2021). Tibia-calcaneal treatment, which involves the fusion of the foot and ankle, is a frequently used procedure that restores the foot's functionality and stabilizes the ankle. Foot drop, a common orthopedic condition, is characterized by difficulty in lifting the forefoot. A common approach to enhance gait and stability is tibia-calcaneal arthrodesis, a procedure that fuses the foot and ankle joints. This study includes the same stages described in the previous maxillofacial reconstruction study. After data collection, design, simulation, and production, the operation was performed.

Another noteworthy orthopedic study in the literature pertains to hip implants, which are frequently utilized in trauma surgery. Conditions such as hip joint damage due to cancer, fracture, poor or unhealthy diet, and other factors may necessitate surgical intervention. Also, postoperative joint wear may necessitate revision surgery. To expedite postoperative recovery and minimize the need for revision surgeries, it has become a prevailing practice to design and manufacture hip joint prostheses on an individualized basis. In their study, Brăileanu et al. propose a methodology for the fabrication of a customized model, utilizing patient-specific imaging data from CT and MRI scans (Brăileanu et al., 2018). The model's performance under various conditions and loads is assessed through simulation tests, aiming to optimize patient outcomes and minimize the need for revision surgeries.

In addition to the examples from oral and maxillofacial surgery and orthopedics, patient-specific implant studies are also found in dental applications. An example of such work is the subperiosteal implant in (Nemtoi et al., 2022), where the prostheses and dental abutments used are manufactured and made available following the same procedure.

The patient-specific implant applications are performed in three major phases. In the initial phase, namely the design phase, the surgeon and the engineers work together to design an implant with the best fit for the body. This phase consists of multiple iterations on the design and simulations in order to find the optimum geometry for the implant. In the second phase, namely the fabrication phase, engineers use various prototyping and production methods to achieve the best results on both implant geometry and material properties. In this phase, the selection of raw material to be used and the production method to be employed play a major role in the result. After the production of the implant, post-processing methods are applied to achieve better mechanical properties and to improve surface quality. In the last phase, namely the clinical application phase, the surgeon performs surgery for implant application, and the surgery is followed by a rehabilitation process (Du et al., 2020).

The advancements in manufacturing technologies and the use of these technologies in the medical sector have enabled the widespread use of patient-specific implants. Advancements in medical imaging, computational programs, and surgical techniques have also increased the rate at which patient-specific procedures and virtual models representing patient anatomy are developed. These capabilities encourage both patients and physicians to opt for patient-specific implant applications (Wong, 2016).

Additionally, due to factors such as the usability of biomaterials in 3D metal printers and CNC machines, the ability to perform both micro- and macro-scale processing, and the revolutionary impact of production methods across various industrial sectors beyond medicine, both 3D printers and CNC machines have emerged as viable production methods.

The widespread adoption of patient-specific implants can undoubtedly be attributed to the numerous advantages they offer. By utilizing production methods such as 3D printing, custom implant models—regardless of their complex geometries—can be developed and manufactured in a short timeframe. The reduced production time enabled by 3D printers is a significant advantage for manufacturers, while for patients, it eliminates the long waits for surgery dates.

Material selection is a crucial factor in patient-specific implant systems, as it is essential for realizing the aforementioned advantages. The chosen material must not only be biocompatible but also possess the appropriate mechanical properties required for the intended application area within the body.

Biomaterials, which can be either natural or synthetic, are utilized to replicate the functions of living tissues within the body. They must possess the necessary biomechanical properties and biocompatibility characteristics (Güven, 2014). Selecting the right materials for implants is crucial to ensure their long-term functionality and optimal performance (Saini et al., 2015).

Today, a wide variety of biomaterials are available that satisfy the necessary biocompatibility and biomechanical properties. However, despite the availability of many suitable materials, factors such as manufacturability, formability, and cost can restrict the range of material options.

Materials commonly used in mass production often allow for the use of CNC machines when they are available in bar or plate forms, and metal printers when they are in metal powder form. Rod or plate materials are produced by melting the extracted minerals, followed by shaping and cooling, while powdered materials are created through grinding.

Another significant trend in material selection is the frequent preference for cobalt-chromium (CoCr) and titanium alloys among institutions that request patient-specific implants. After analyzing the mechanical properties of these two commonly preferred materials, the final material selection is made based on the functional characteristics of the body part to be treated and the physical forces it will encounter.

Cobalt-based alloys are widely used in various engineering applications. In its pure form, cobalt lacks sufficient corrosion resistance and is therefore not suitable for surgical applications. The two most important alloying elements added to cobalt are chromium and carbon. Carbon increases the castability of the material, while chromium provides high corrosion resistance to the alloy. The addition of chromium allows the material to protect itself in corrosive environments (Şap and Çelik, 2013). In CoCr alloys, corrosion resistance to liquid solutions is provided by cobalt, while resistance to solid solutions is achieved through the addition of chromium (Gür and Taşkın, 2004).

CoCr alloys are classified as base metal alloys and are widely used in biomedical applications in orthopedics and dentistry. The growing global interest in using CoCr alloys for dental applications is due to their low cost and adequate physico-mechanical properties (Al Jabbari, 2014).

By adding molybdenum (Mo) and nickel (Ni) to CoCr alloys, two significant cobalt-based alloys are obtained. Among these, CoCrMo is used primarily in dentistry and newly developed artificial joints due to its high fatigue resistance, while CoNiCrMo is primarily employed in high-load applications, such as hip and knee joint prostheses, due to its high strength values (Şap and Çelik, 2012).

Titanium alloys, due to their properties such as low density, high strength, good plasticity, and corrosion resistance, have been used in orthopedics and dental applications since the 1960s (Subaşı and Karataş, 2012), and currently being used not only in the medical industry but also in industries like aerospace, automotive, and energy (de Viteri and Fuentes, 2013).

Titanium provides advantages over other metal implant materials due to its biocompatibility. Notably, its low density, surface oxide layer for biocompatibility, and mechanical properties similar to bone, such as elastic modulus, have made it a preferred material among medical manufacturers and users (de Viteri and Fuentes, 2013). The ability to improve its mechanical properties by altering alloy compositions makes it suitable for many biomedical applications. Beyond mechanical properties, its minimal side effects and chemical stability have contributed to its acceptance as a safe material (Şap et al., 2019). Although there are many titanium alloys, the most popular options are pure titanium and the Ti-6Al-4V alloy. Both are commonly used in artificial bones, hard tissue applications, and dental applications.

Titanium, particularly in hard tissue applications, is known for its easy machinability, high strength, low elastic modulus, and excellent fatigue resistance. The mechanical properties of titanium alloys depend directly on their composition and phase distribution (Uzun and Bayındır, 2010). Titanium can be alloyed with many metals. This allows for the improvement of properties such as tensile strength, yield strength, and castability compared to pure titanium.

In addition to the benefits associated with these materials, their use also presents certain drawbacks. The bending hardness of titanium is lower than that of nonprecious metal alloys. Moreover, from the perspective of machinability, challenges arise in the titanium casting process due to the material's melting point of approximately 1720°C and its sensitivity to oxygen. In addition to its mechanical disadvantages, the metallic color of the implant is also visible, which is especially problematic in the field of dentistry (Yılmaz, 1998).

The disadvantage of CoCr alloy, especially when utilized in load-bearing applications such as hip and joint implants, is its lower bioactivity in comparison to titanium (Çetiner et al., 2014).

In this study, we compare two of the most common materials used in implants in terms of tensile strength and fatigue resistance, depending on the fabrication methods used, namely additive manufacturing and machining. The selected materials to compare are Ti6A14V and CoCrMo alloys. A review of the extant literature on the materials used in personalized implants revealed that the majority of studies compared the production method on only one material or compared different materials with the same production method. In this study, two different commonly used materials and two different production methods were compared in terms of mechanical properties. In Section 2, we present the details of the design and preparation of test specimens and the methods we use for analyzing the mechanical properties of these materials in terms of production methods. In Section 3, we present the tests we performed on the test specimens and the results we obtained from these tests. Our conclusions on this study are presented in Section 4.

2. Materials and Methods

In this section, we first present the design of the test samples and the fabrication methods employed for test sample preparation. The materials we use are titanium and CoCr, and we prepared the test samples utilizing both additive manufacturing and machining techniques. Following this, we present a finite element method (FEM) analysis of the designed test samples, along with the details of the tests conducted on them.

2.1. Preparation of the Test Samples

The samples used in this study were designed in a bow-tie shape. This design choice focuses on material identification, production method, and the determination of material properties, rather than the advantages or disadvantages associated with the geometric structure of the design. Test samples are typically produced according to the dimensions specified in the ASTM E8 standard. However, the samples prepared for this study were designed with dimensions that are suitable for the production and testing equipment.

When machining methods are employed, CNC machines offer extensive working capacities, eliminating dimensional limitations in determining sample size. However, the scanning range of the 3D metal printer utilized for additive manufacturing imposes constraints on the design of the sample. Based on this criterion, the length of the sample was determined according to the scanning range of the 3D printer, and the sample was designed using the SOLIDWORKS software. The solid model and technical drawing of the designed sample are shown in Figure 1.

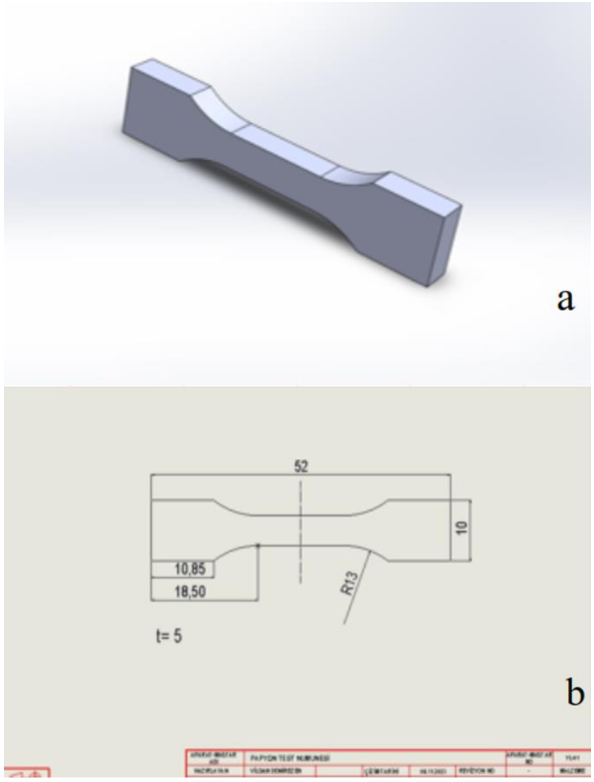

Figure 1. Initial design of the test sample. a) Solid model, b) Technical drawing.

In order to test and compare two different materials using two different fabrication techniques, four types of test samples must be prepared. These are:

- Ti6A14V with Additive Manufacturing (Ti-AM).
- Ti6A14V with Machining (Ti-Ma).
- CoCr alloy with Additive Manufacturing (CoCr-AM).
- CoCr alloy with Machining (CoCr-Ma).

For each test case, four test samples are prepared: one of which is for tensile testing, and the remaining three test samples are for fatigue testing. The Ti-Ma and CoCr-Ma samples were produced from a plate by wire erosion cutting at Estaş Medikal Tic. San. A.Ş. Meanwhile, CoCr-AM and Ti-AM samples were produced using a 3D metal printer with predefined parameters. Since the two samples produced through additive manufacturing were fabricated by different companies, the parameter specifications of their respective 3D metal printers were obtained. Because the parameters of the 3D printer used for CoCr-AM production could not be modified, the same values used for CoCr-AM were also used for Ti-AM. The printing parameters for the materials produced by the 3D metal printers are given in Table 1.

Table 1. Printing parameters for the materials produced by 3D Printers

Parameter	Value
Particle Size	40 µm
Laser Poer	150 W
Layer Thickness	30 µm
Scanning Range	70 µm
Scanning Speed	500 mm/s
Scanning Strategy	Stripes

The test samples produced using CoCr and Ti6Al4V materials through machining and additive manufacturing are shown in Figure 2.

Heat treatment was conducted using argon gas on the samples produced by additive manufacturing to enhance hardness. This process took place in the sintering furnace at Estaş Eksantrik A.Ş., following the steps outlined below.

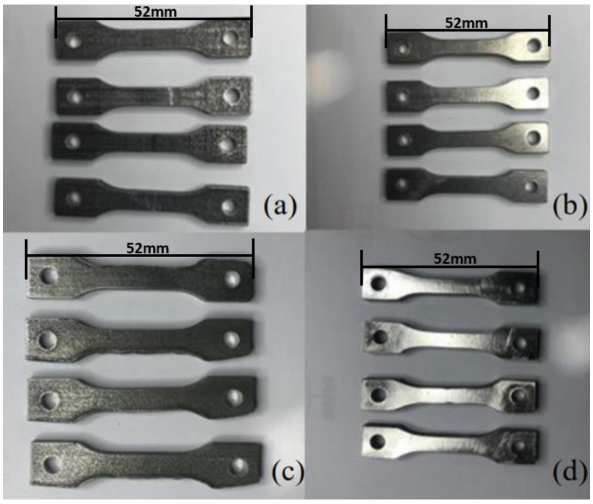

Figure 2. Test samples. a) Ti-AM, b) Ti-Ma, c) CoCr-AM, d) CoCr-Ma.

Sintering Process

1. The furnace was heated to 150°C within 10 minutes, and the samples were maintained at this temperature for 5 minutes.
2. The temperature then increased to 450°C over a period of 20 minutes, and the samples were maintained at this temperature for an additional 5 minutes.
3. Subsequently, the temperature was raised to 800°C within 30 minutes, and the samples were maintained at this temperature for 20 minutes.
4. The furnace was turned off, and the samples were allowed to cool to 300 °C.
5. After cooling, the furnace door was opened, and the samples were removed and allowed to cool to room temperature.

2.2. Challenges with Initial Samples

Some of the prepared samples were sent to the testing institution for trials. However, the samples could not be attached to the testing device due to their short length, preventing the tests from being conducted. To address this issue, a mounting fixture, as shown in Figure 3, was designed to extend the gripping length of the samples and allow for pin holding at both ends.

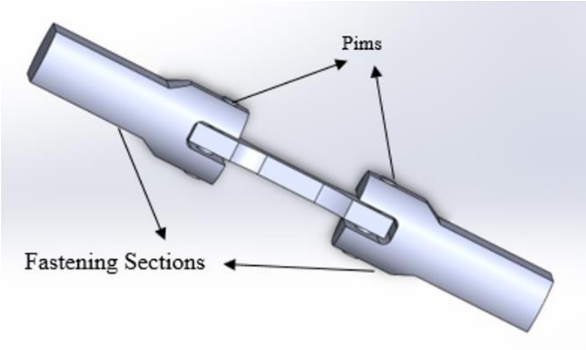

Figure 3. The mounting fixture.

A simulation was performed to evaluate the fixture's suitability for testing. Stress distributions on the fixture, pins, and sample were observed, as shown in Figure 4.

The dimensional accuracy of the prepared samples was checked against the specifications outlined in the technical drawings using a calibrated caliper. After making the necessary revisions and validating them through simulations, the updated samples were sent to the testing institution. However, the tests could not be conducted again due to issues with the sample dimensions.

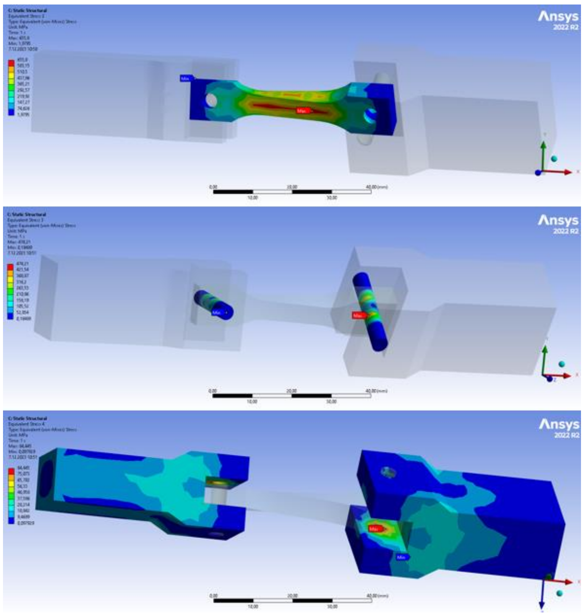

Figure 4. Stress distribution analysis of the fixture, pins, and sample.

2.3. Final Revisions

As a final revision, improvements were made to the sample dimensions. The thickness of the sample was reduced from 5 mm to 2 mm, and the cross-sectional area at the planned fracture zone was reduced from 25 mm² to 4 mm².

The final sample, obtained after implementing these improvements, is shown in Figure 5. The final tests were conducted on this sample.

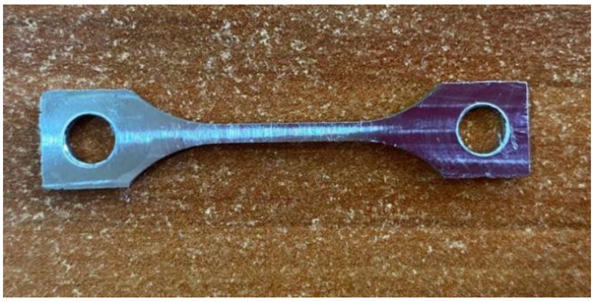

Figure 5. The final geometry of the test samples.

2.4. Simulation and Tests

2.4.1. Finite element analysis

The initial solid model was updated to match the dimensions of the final test sample. Using a simulation program, static analyses were conducted on the updated model. The primary purpose of these analyses was to assess the compatibility of the manufactured samples with the testing device and determine whether failure would occur in the intended region.

According to the literature, the CoCr alloy is the strongest material among those to be tested. To ensure that failure occurs in the sample during tensile and fatigue testing, the fixtures and pins must be made from materials that are stronger than CoCr. Therefore, structural steel was used for the fixtures, and AISI 316 stainless steel was used for the pins. Based on this, the material definition for the sample in the simulation was set to CoCr, as it is the strongest alloy among those utilized. If failure occurs in the desired region of the CoCr sample, it can be assumed that failure will also occur in samples made from softer materials.

Given that the maximum force capacity of the testing device is 120 kN, a maximum tensile force of 130 kN was applied in the simulation to ensure sufficient loading. During the tensile simulation, one side of the fixture was secured, while the defined tensile force was applied to the other side. The region experiencing the highest stress was analyzed. As shown in Figure 6, stress accumulates on the test sample, indicating that failure is expected to occur in the central region.

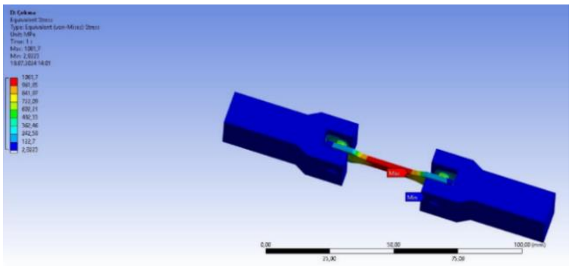

Figure 6. Stress distribution on the test sample.

2.4.2. Testing

The manufactured samples underwent both static and dynamic tests at the Scientific and Technical Application and Research Center of Hitit University. To establish the force value to be applied periodically during the dynamic tests, a static tensile test was first conducted on one of the samples. The testing institution determined the parameters suitable for the tensile tests on our samples.

The force value at which failure occurred during this test was used to establish the load value for the fatigue tests. The load applied during dynamic testing was determined to be 25% of the failure value obtained from the tensile test.

In the fatigue tests, maximum and minimum stress loads were applied over a specified number of cycles. Cracks began to form on the surface of the sample, progressively growing until failure occurred. The number of cycles at which failure occurred was recorded by the testing device.

A critical factor in fatigue testing is the R-value, which represents the ratio of minimum stress to maximum stress. This value is essential for determining the fatigue life or stress range of a material. Considering factors such as real-world applications, durability, lifespan assessment, standard testing procedures, industrial guidelines, and recommendations from the testing institution, the selected R-value for the tests was 0.1. An R-value of 0.1 indicates that the minimum stress is 10% of the maximum stress, subjecting the material to both positive and negative loads at 10% of the maximum value.

3. Results

After revising the design of the test samples, four specimens were prepared for each test case. Initially, tensile tests were conducted on the samples from each material and production method. Figure 7 shows the results of the tensile tests, presenting the average tensile force at which rupture occurs for each material. The findings indicate that the CoCr alloy demonstrates a higher rupture force compared to titanium. Additionally, the graph includes the calculated force values for the fatigue tests.

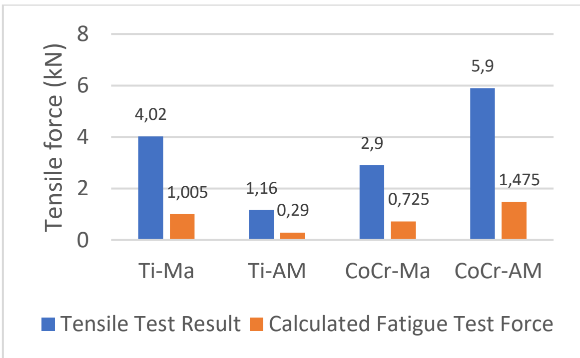

Figure 7. Tensile test results and calculated fatigue test force.

The fatigue test force values presented in Figure 7 are derived by calculating 25% of the tensile test results. Using these force values, fatigue tests were conducted on the remaining three test samples from each case. Figure 8 displays images of the test samples from each case following the fatigue tests.

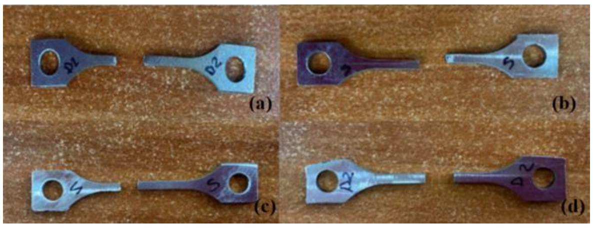

Figure 8. Images of test samples after fatigue testing. a) Ti-Ma b) Ti-AM c) CoCr-Ma d) CoCr-AM.

Figure 9 shows the average values of the cycle amounts obtained from three fatigue tests for each test case. The mean cycle values presented in the graph have been calculated based on the moment of rupture in the sample. Subsequent analysis of the data reveals that the CoCr material exhibits a higher cycle value.

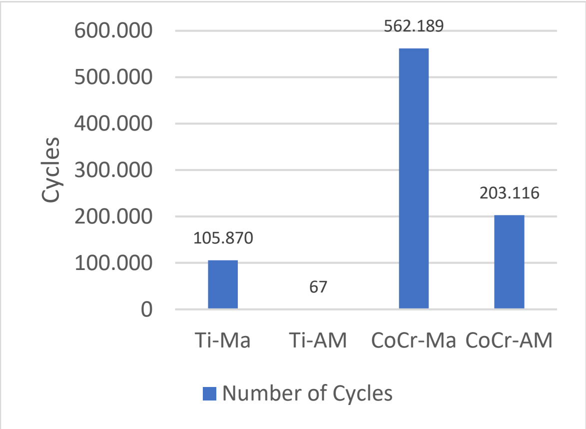

Figure 9. Average of the number of cycles obtained from fatigue tests.

A comparison of the results from samples produced using the same manufacturing method but different materials reveals that the CoCr alloy is more durable than the titanium alloy. This conclusion is based on the greater number of cycles to failure and the higher tensile strength at failure observed for CoCr. When comparing the manufacturing methods applied to the same material, machining stands out as a superior choice compared to additive manufacturing.

4. Discussion

In the literature, it is observed that comparisons between additive manufacturing and subtractive manufacturing are not frequently encountered. However, when comparing samples made from different materials but produced using the same manufacturing method, it has been found that forged CoCr alloy exhibits superior mechanical properties compared to titanium alloy. For this reason, in the literature, CoCr is often preferred for prostheses used in body regions subjected to motion and heavy loads, while titanium and its alloys are more commonly utilized for orthopedic implants designed to remain stationary (Aherwar et al., 2016; Joshi et al., 2022).

When the results of the tests conducted on the prepared samples are compared with the results of the simulations, it is clear that the findings are consistent with one another. The predicted failure regions in the simulations align with the actual failure regions observed during the tests.

From the perspective of manufacturing methods, it was observed that samples produced through subtractive manufacturing exhibited failure after a higher number of cycles for both materials. This indicates that fatigue resistance is greater in samples produced by subtractive manufacturing.

When all this information is evaluated collectively, it can be concluded that CoCr alloy samples produced using the subtractive manufacturing method exhibit greater durability in fatigue tests. This indicates that utilizing CoCr alloy manufactured through subtractive methods for weight-bearing body regions, such as the hip, shoulder, and knee, would be more suitable for health and durability.

On the other hand, titanium, when evaluated for its biocompatibility and biomechanical properties, is anticipated to be more suitable for use in bone plates and screw systems that are subjected to static forces.

To obtain more conclusive results concerning materials and manufacturing methods, further studies should be conducted using samples of various designs made from the CoCr alloy and Ti6Al4V material utilized in this research. Additionally, more mechanical tests should be performed.

5. Conclusion

Implants are commonly used in medical applications to repair, replace, or reinforce the structural parts of the human or animal body. In this paper, we compare two of the most common materials used in implant applications, namely titanium and CoCr. Based on our FEM analysis results, we designed and prepared multiple test samples of these materials using both subtractive and additive manufacturing techniques. We initially conducted static testing in order to determine the appropriate force values for dynamic fatigue testing. In the static tests, CoCr exhibited the highest rupture force, measuring 5.9 kN. The fatigue test result of 562,189 cycles indicates that CoCr is the superior candidate among these two materials for applications requiring high fatigue resistance. Furthermore, in terms of manufacturing methods, subtractive manufacturing yielded better results in fatigue testing.

Author Contributions

The percentages of the authors' contributions are presented below. All authors reviewed and approved the final version of the manuscript.

	V.F.D.	K.I.
C	60	40
D	40	60
S	40	60
DCP	75	25
DAI	50	50
L	60	40
W	30	70
CR	25	75
SR	50	50
PM	60	40
FA	50	50

C=Concept, D= design, S= supervision, DCP= data collection and/or processing, DAI= data analysis and/or interpretation, L= literature search, W= writing, CR= critical review, SR= submission and revision, PM= project management, FA= funding acquisition.

Conflict of Interest

The authors declared that there is no conflict of interest.

Ethical Consideration

Ethics committee approval was not required for this study because there was no study on animals or humans.

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