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Validation of lumbar fusion device TILIF (Ti-6Al-4 V) manufactured by EBM additive manufacturing through fem modeling high cycle fatigue tests

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A B S T R A C T

This study aims to validate the computational fatigue analysis of a Transforaminal Lumbar Intervertebral Fusion (TLIF) prosthesis using high cycle fatigue (HCF) test data through the Finite Element Analysis Method (FEM). The Additive Manufacturing by Electron Beam Fusion process enables the construction of complex geometries for lumbar fusion prostheses, making it the preference of manufacturers for high-scale production. However, ensuring the structural validation of such products through static and dynamic tests can be time-consuming and expensive. Computational simulations using FEM can provide preventive and predictive analyses to anticipate structural problems arising from loads specified in projects, allowing for the development of geometric models that meet the mechanical tests requested by the ASTM F2077-18 standard. The HCF specimens were tested for fatigue life assessment between 10^7 cycles, improving test duration compared to traditional methods. The mechanical properties of the material, such as modulus of elasticity, yield strength, ultimate tensile strength, and density, were taken into account during testing. The results obtained through FEM were effective, demonstrating the predictive capability of this method in the development of new products manufactured by additive manufacturing technology using Titanium Grade 5. This research also compares the use of virgin powder and recycled powder in the manufacturing process, showing the differences in fatigue between the two materials. The study indicates that the mechanical properties of recycled powder are inferior to those of virgin powder, and as a result, the fatigue life of parts manufactured using recycled powder is lower than those manufactured with virgin powder. In conclusion, this study demonstrates the effectiveness of using computational fatigue analysis through FEM to predict the mechanical behavior of lumbar prostheses. The research provides valuable insights for manufacturers, indicating that the use of virgin powder in the manufacturing process can lead to longer fatigue life of the parts compared to the use of recycled powder.

1. Introduction

All the support of the human body depends on the vertebral column, whose function is to transmit the loads generated by the trunk and head to the lower limbs, it also has a connection with the neck muscles and rib bones in its curved and flexible structure. Evaluating the total measure of the human body we have [1]:

- 22% represented by the cervical spine
- 36% represented by the thoracic spine
- 15% represented by the lumbar spine
- 27% through the sacrococcygeal column

According to AMIM et al (2017) and MANSFIELD et al (2019), all vertebrae have several common features, many of which are evident after examining different views of a thoracic vertebral column. The body of a vertebra is the large cylindrical mass of bone that serves as the main weight-bearing structure in the entire spine. The intervertebral disc is the thick, fluid-filled ring of fibro-

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cartilage that serves as a shock absorber throughout the spine. The intersomatic joint is formed by the junction of two vertebral bodies and the intervening intervertebral disc. There are several types of Lumbar Fusion Device (Cage) considering different surgical techniques. The different techniques employed differ by the type of surgical access, which consequently uses different Cages for each technique [2–4]:

- ALIF (Anterior Lumbar Interbody Fusion)
- LLIF (Lateral Lumbar Interbody Fusion)
- TLIF (Transforaminal Lumbar Interbody Fusion)
- PLIF (Posterior Lumbar Interbody Fusion)

Transforaminal lumbar interbody fusion (TLIF) is a popular technique for treatment of degenerative lumbar diseases. The safety and efficacy of this technique have been demonstrated in many clinical studies. TLIF results in less destruction of the posterior elements and less gross destabilization of the spine, which maximize fusion stability. Furthermore, it allows better access to the neuroforamen and reduces the need to manipulate spinal nerve roots. Due to the simplified procedure and the unilateral technique, operative time, potential blood loss and the risk to neural structures is reduced [5].

The choice of the most appropriate type of lumbar fusion prosthesis for each patient depends on various factors, such as age, sex, height, weight, spinal condition, medical history, and lifestyle. Among the most common types of lumbar fusion prostheses are cylindrical, ring-shaped, and box-shaped prostheses. The box-shaped prosthesis is the most commonly used among these types, mainly due to its larger contact surface with the adjacent vertebral bodies. This additional surface allows for greater load distribution, reducing pressure and stress around the contact points. This results in better structural support and stability for the spinal column, as well as helping to prevent excessive movement between adjacent vertebrae [3].

Additionally, box-shaped prostheses also offer a larger surface area for bone grafting, which is used to promote fusion between adjacent vertebrae. The prosthesis box can be filled with bone graft, which increases the likelihood of a solid and stable fusion between vertebrae, reducing the need for future surgery.

The most common are illustrated in Fig. 1. According to those three main types of lumbar devices, this research was guided by the box type, as shown in Fig. 1 (d).

The sizes of lumbar fusion devices may vary depending on the manufacturer and specific model, but in general, they follow the following measurements:

- Cylindrical lumbar fusion devices: have a diameter ranging from 8 to 16 mm and a length ranging from 20 to 60 mm.
- Ring-shaped lumbar fusion devices: have an inner diameter ranging from 8 to 16 mm and an outer diameter ranging from 10 to 18 mm. The length can vary from 15 to 50 mm.
- Box-shaped lumbar fusion devices: have a length ranging from 15 to 50 mm, width ranging from 10 to 20 mm, and height ranging from 10 to 18 mm.

It is important to note that the measurements of lumbar fusion devices can be customized according to the specific needs of each patient and the surgical technique adopted by the doctor.

1.1. PBF-EBM additive manufacturing process

In PBF-EBM additive manufacturing process, the electron beam is used as a heat source to melt the powder. Typically, the electron beam works nominally at 60 kV accelerating voltage to provide an energy density in the focused beam more than 106 kW/m^2 (100 kW/cm^{-2}). In Fig. 2 (a) it is illustrated a schematic diagram of the PBF-EBM process [12].

The objective of this study is to analyze the powder characteristics of virgin and recycled powders used in powder bed fusion (PBF) additive manufacturing processes. Micrographs of the powders are presented in Fig. 2 (b) and (c), showing similarities and differences between the two types of powders. At lower magnification, both powders exhibit common features such as satellites, elongations, irregularly shaped particles, agglomerates, and particles with open pores, as indicated by yellow arrows. However, at high magnification, a distinct difference in surface morphology can be seen between the two powders. The virgin powder contains a significant number of fine particles bonded to coarser particles, indicated by blue arrows, while the recycled powder shows craters and concave sites on the powder surface, indicated by red arrows in Fig. 2 (c) [8].

The study also examines the interactions between the electron beam and the virgin and recycled powder feedstock, as shown in Fig. 2 (d). The literature review demonstrates the importance of powder characteristics on the quality of the final product in PBF additive manufacturing processes. The use of recycled powders has become an attractive solution due to its cost-effectiveness and environmental benefits. However, the recycling process can affect the powder properties, which can influence the final product's quality. Therefore, understanding the characteristics of recycled powders is essential to ensure high-quality parts are produced consistently. This study provides valuable insights into the powder properties of virgin and recycled powders, contributing to the advancement of PBF additive manufacturing processes.

2. Materials and experimental methodology

The research carried out by Mohammadhosseini (2015) constitutes the database of the computational method used in this study. The method involves a high cycle rotational bending fatigue test performed on cylindrical specimens using a collet chuck and floating bearing, with a concentrated load applied by a spring counterweight and floating bearing, nine cylindrical specimens were used as per shown in Fig. 3(a). A concentrated load is applied at one end of the specimen by means of a spring counterweight and floating bearing, as shown in Fig. 3 (b). The specimens were manufactured using the EBM ARCAM Q10 additive manufacturing technology and then machined [7].

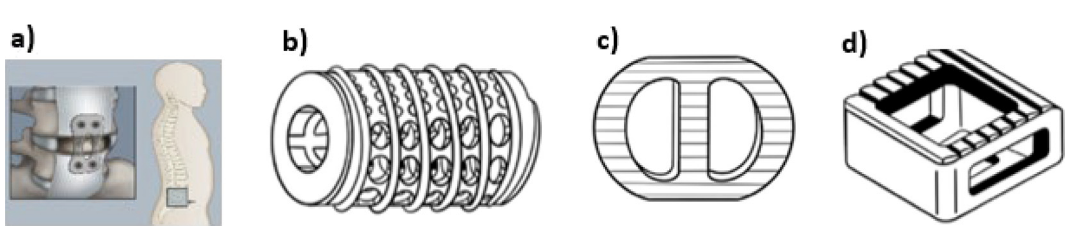

Fig. 1. (a) Spinel cages - types of Lumbar Fusion cage (b) Cylindrical; (c) Ring and; (d) Box. after [6].

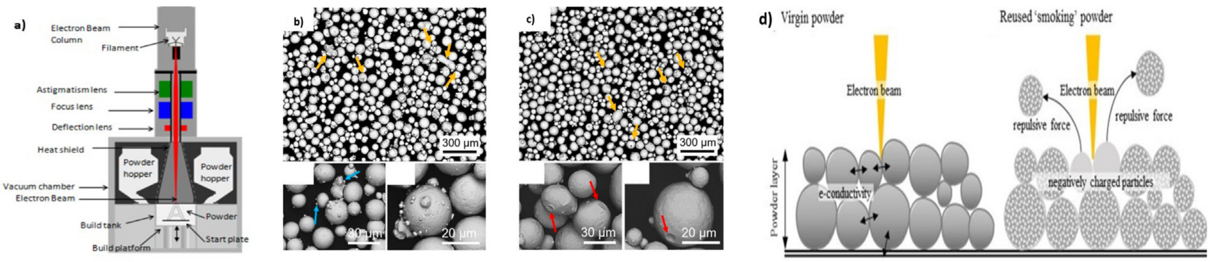

Fig. 2. (a) PBF-EBM Printer [7]; (b) Virgin powder [8]; (c) Recycled powder; (d) Different interactions between the electron beam and the virgin and recycled powder feedstock [9].

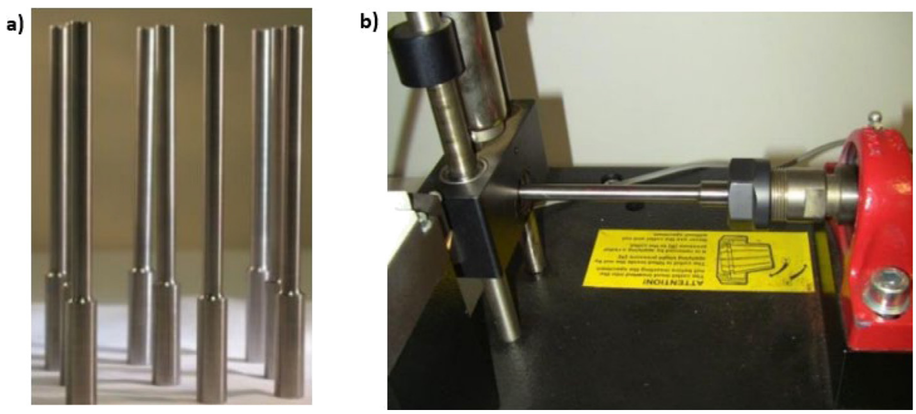

Fig. 3. (a) Rotating bending fatigue specimens [7]; (b) The rotating bending fatigue adjustment [7].

The PBF-EB additive fabrication of the spinal fusion cage was carried out in an ARCAM Q10, following the workflow process according to Table 1.

In this work, a TLIF (Transforaminal Lumbar Interbody Fusion spinal cage was tested and analyzed using an FEM model for High Cycle Fatigue (HCF) loading. In the Fig. 4, it represents the work pieces geometric dimensions (a) as well as the images of the printed components (Fig. 4b and 4c).

There is a process to be followed for introducing a TLIF lumbar prosthesis. An appropriate-sized cage filled with excised local bone was inserted into the disc space and positioned in the transverse orientation, assisted by an inserter guide rail. The step-by-step surgical procedure is illustrated in Fig. 5 [5].

The study conducted by PECK et al. (2018) highlights the importance of fatigue load measurement for acceptance criteria of Cage (TLIF) using the ASTM F2077-18 (2015) and ASTM F2267-04 (2018) standards. However, to better understand the behavior of the material in this context, MOHAMMAD HOSSEINI's research (2015) on the fatigue behavior of cylindrical specimens made with EBM additive manufacturing using Ti-6Al-4 V in two powder conditions (recycled and virgin) was analyzed. The obtained results were compared and plotted in Fig. 6 using a computational method. The S-N curve for the Ti-6Al-4 V alloy was constructed using Ansys 2021/R22 software. The results show that for a stress of 600 MPa, the TLIF (recycled) component would have a functional failure between 13,000 to 19,000 cycles and for a stress of 400 MPa (recycled), it would fail between 29,000 to 79,000 cycles, and so on. The analysis was also performed on the virgin powder of Ti-6Al-4 V. These findings provide important insights into the comparison between recycled and virgin powders in terms of fatigue behavior in TLIF components.

As demonstrated in Fig. 6 (b), the maximum applied stress was 800 MPa, which resulted in almost 30.000 cycles. By decreasing the load, more cycles to failure was 145 achieved until to get the fatigue endurance. The XY manufactured test specimen showed higher cycles to failure. The endurance limit for the as-built XY direction was 450 MPa, while for the Z direction it was slightly lower, which was 390 MPa. For the as-built specimens, our results were lower than those reported by Arcam. Due to the fact that the process parameters of their build were not reported and also we did not have access to the SEM and microstructure of the test specimens, the reason for difference in results cannot be explained.

The Ti-6Al-4 V alloy printed by PBF-EBM process has specific properties and in order to optimize the reliability of the numerical simulation, mechanical tests were conducted using the additive manufactured samples. The obtained stress–strain curve details were imputed in the software Ansys 2021/R2, according to Table 2.

Table 1
Workflow used for the development of customized additive manufactured spinel cage [13].

DESIGN	PREPARE	MANUFACTURE
• Raw design from CT/MRI data. Analyse & refinement of design according to the need of specific case. FEA study to determine its stability and estimated fatigue life.	• Support generation for printing Simulation of printing process to check the printability and avoid material wastage. Assigning PBF-EBM printing parameters & generating scan path.	• Printing in neutral environment. Post processing like heat treatment & shot peening etc. Inspection - certification

3. Results and discussions

After creating the new material variables in the FEM software Ansys 2021/R22 called Ti-6Al-4 V (virgin) and Ti-6Al-4 V (recycled), the main boundary conditions for performing the computa-

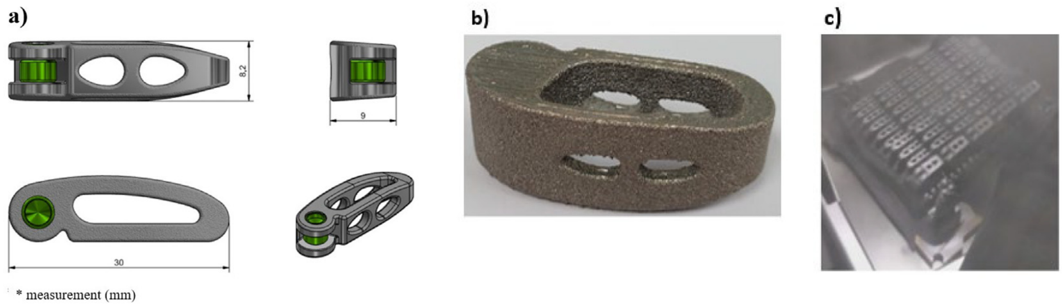

Fig. 4. (a) Cage TLIF Geometry; (b) Cage TLIF Ti-6Al-4 V; (c) Additive Manufacturing Cage TLIF ARCAM Q10.

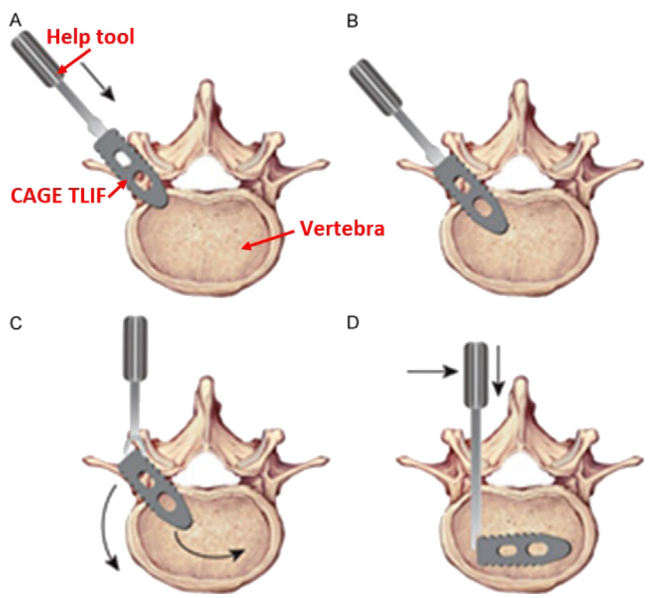

Fig. 5. (a -d) sequence performed for introduction of the Transforaminal Lumbar Interbody Fusion spinal cage between two vertebrae after removal of the degenerated disc [5].

tional calculation by the finite element method (FEM) were selected, according to Fig. 7:

- FEM mesh: Tetrahedral using a mesh size of 0,5 mm and a scale factor of 1.
- Simulation: Type zero-based.
- Cages undergo compressive loading after spinal disc replacement as per standard ASTM F2077-18 (2015) [16].
- Mean Stress Theory: Goodman.
- Stress component: Equivalent Stress (Von-Misses).

The S-N curves imported in the Ansys 2021/R22 FEM software are shown in Fig. 8(a) and 8(b).

The fatigue curve shows the relationship between the applied stress amplitude and the number of cycles that the material can withstand, which is different for virgin and recycled titanium powder, as evidenced by the presented data that the recycled powder exhibits lower stresses for the same number of cycles. This could be caused by differences in material properties or the production process.

Regarding the stress–strain curve, for the static analysis by finite elements: it was performed considering a load of 10.799 N [10], as shown in Fig. 9, with a schematic loading representation.

The static analysis shows a satisfactory result since the maximum stress found was 740 MPa and the yield stress of Ti-6Al-4 V MA EBM is 852 MPa. When applying the fatigue analysis by elements it was selected three analysis variables on the high cycle S-N curve:

- Fatigue life.
- Fatigue damage.
- Fatigue safety factor.

The fatigue life results for the Ti-6Al-4 V using virgin and recycled powders show for the Cage TLIF the result of 10^7 cycles, high cycle fatigue which represents the infinite life over the load of 3.000 N in compression, and predictively validating the conditions set by ASTM F2077-18, as shown in Fig. 10.

Fatigue damage is defined as the available design life and values greater than 100 indicate failure before the design life is reached. The results shown in Fig. 11 demonstrate a satisfactory result for this geometry.

a) Fatigue testing Ti6Al4V PBF-EBM- Z direction

Maximal stress (S_a) [MPa]	Number of cycles to failure N: Virgin	Recycled
600	30,988	13,016
600	30,650	15,780
600	32,255	19,400
400	166,510	29,167
400	310,735	79,539
350	492,143	62,133
350	1226,124	82,850
300	10^7	188,607
275	-	10^7

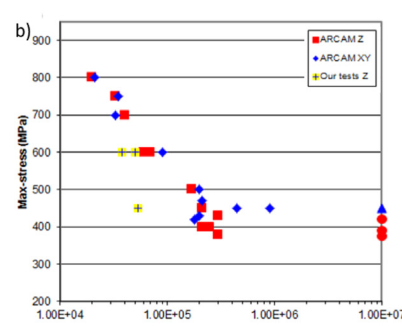

Fig. 6. Experimental results of a bending fatigue test on PBFEB samples: (a) table with maximal alternating stress (Samax) versus cycles to failure (Nf) and (b) graph of fatigue resistance for PBF-EB samples [8].

Table 2
Mechanical properties of the Ti-6Al-4 V PBF-EBM additive manufactured samples.

Density	Young's Module	Yield strength	Rupture Strength	Elongation at rupture	Hardness - Rockwell B
4,4 Kg/m^3	118 GPa	851 MPa	982 MPa	10–15%	30–35 HRB

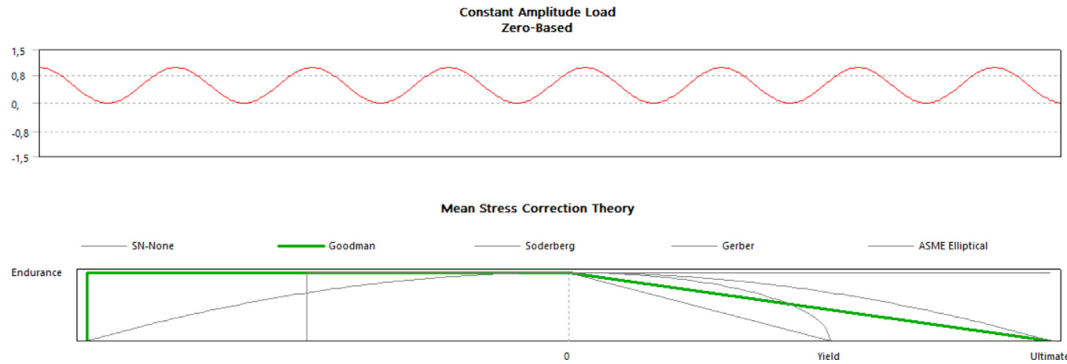

Fig. 7. Experimental results of the bending fatigue test on samples MA EBM. (Source: Authors).

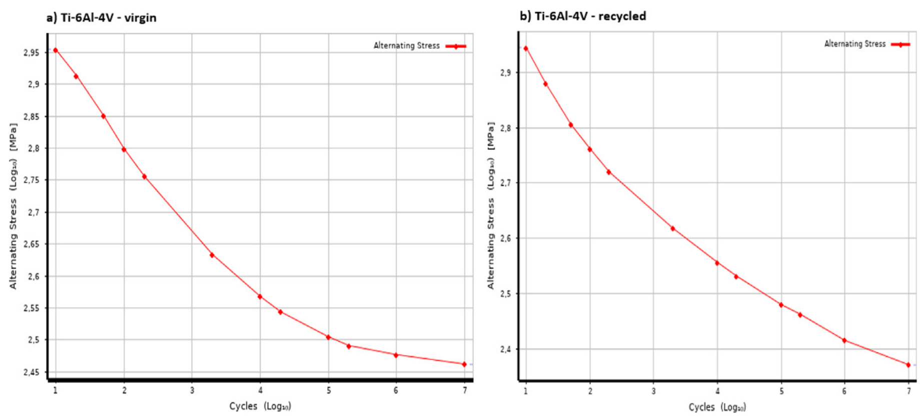

Fig. 8. Ti-6Al-4 V imputed S-N fatigue curves in FEM - Ansys 2021/R22 (a) virgin (b) recycled. (Source: Authors).

The safety factor analysis represents the relationship of a fatigue failure over a given design life. The maximum safety factor is 15. Here, values less than 1 indicate failure before the design life is reached. As shown in Fig. 12, the fusion device shows values greater than 1.

4. Conclusions

The results obtained in this work made it possible to correlate experimental results for the construction of the computational S-N curve in the ANSYS 2021/R2 FEM software, measuring the results through the high cycle fatigue analysis by FEM, achieving great cost and time reduction in the development of geometric proposals for TLIF cages manufactured with EBM additive manufacturing technology with Ti-6Al-4 V grade 5.

The cages (TLIF) were tested according to ASTM F2077-18, resisting the fatigue test satisfactorily, but for reasons of confidentiality of the company that supported the research, the results could not be shared in this research, but confirm the effectiveness of the computational method performed. in this study.

With this process, it was possible to establish a predictive method for the development of new products that meet the ASTM F2077-18 standard, which regulates fatigue tests for cages, comprising computational possibilities for other high-cycle fatigue analysis solutions based on the measurement of computational data by correlating them with experimental data.

The results showed that recycled Titanium has losses in its fatigue properties, and the recycling of the powder for use in the manufacturing processes can be studied in greater detail, as it is possible to reuse the Titanium powder in the EBM Additive Manufacturing Process for more than ten times, which suggests a progressive loss of mechanical properties.

This method can be applied in the future in other products of this commercial segment, as well as in other products that use additive manufacturing in their conception, allowing to extend the studies on products manufactured through traditional manufacturing (extractive)

Data availability

Data will be made available on request.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

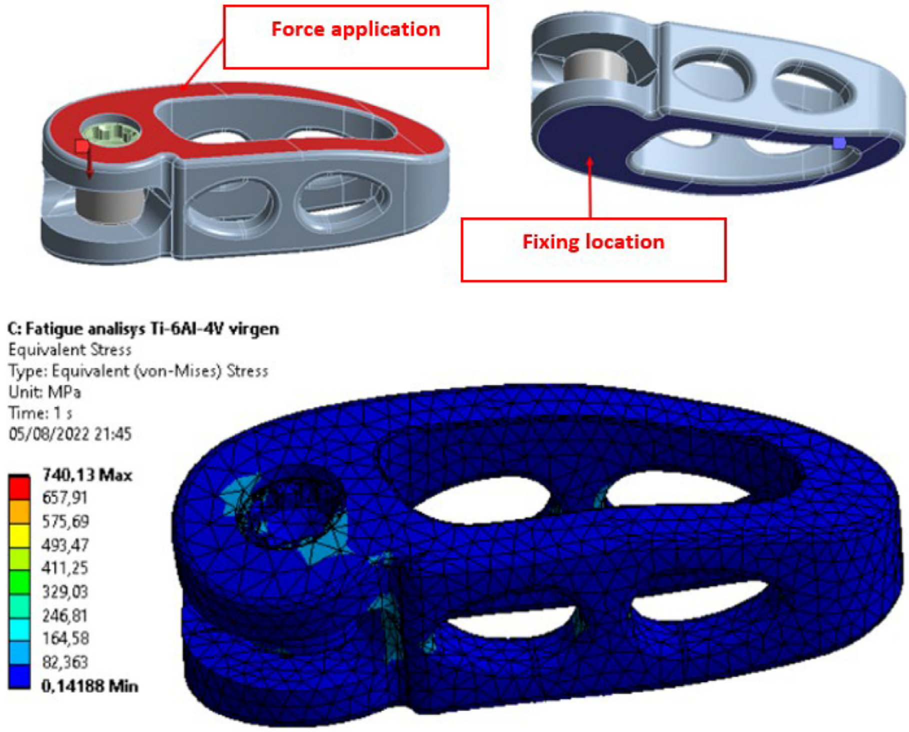

Fig. 9. Static FEA Result on Cage TLIF. (Source: Authors).

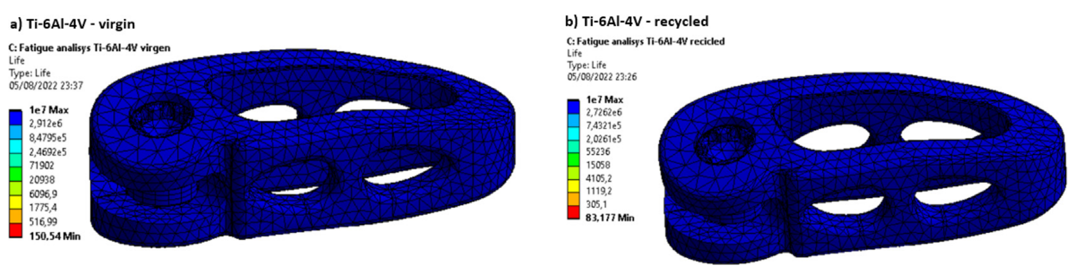

Fig. 10. Fatigue Life Result on Cage TLIF; (a) Virgin powder; (b) Recycled powder. (Source: Authors).

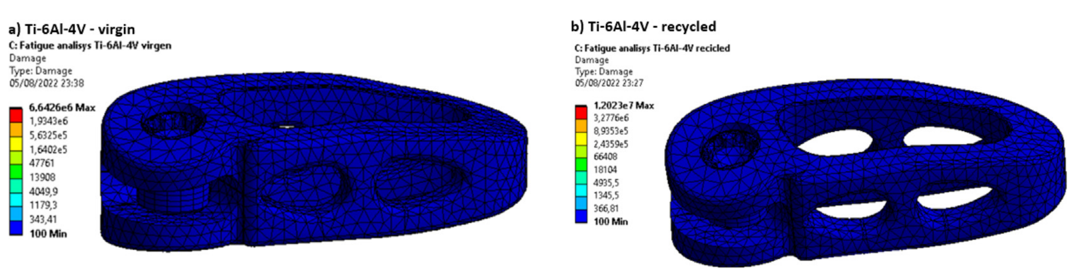

Fig. 11. Damage Result on CAge TLIF; (a) Virgin powder; (b) Recycled powder. (Source: Authors).

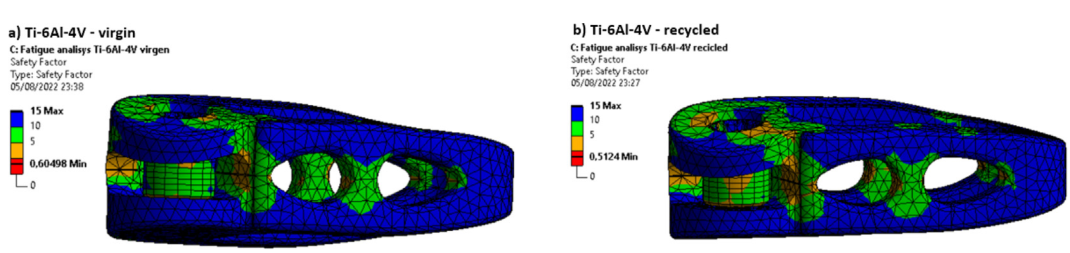

Fig. 12. Safety Factor Result on Cage TLIF; (a) Virgin powder; (b) Recycled powder. (Source: Authors).

References

[1] Marieb EN, Wilhelm PB, Mallatt J. Human Anatomy. 8th ed. Pearson Education; 2017. doi:10.1097/00001888-194811000-00033.

[2] R.J. Mobbs, K. Phan, G. Malham, K. Seex, P.J. Rao, Lumbar interbody fusion: techniques, indications and comparison of interbody fusion options including PLIF, TLIF, MI-TLIF, OLIF/ATP, LLIF and ALIF, J. Spine Surg. 1 (1) (2015) 2–18, https://doi.org/10.3978/j.issn.2414-469X.2015.10.05.

[3] A.J. Talia, M.L. Wong, H.C. Lau, A.H. Kaye, Comparison of the different surgical approaches for lumbar interbody fusion, J. Clin. Neurosci. 22 (2) (2015) 243–251, https://doi.org/10.1016/j.jocn.2014.08.008.

[4] Vaccaro AR. Fractures of the Cervical, Thoracic, and Lumbar Spine. Marcel Dekker, Inc.; 2002. doi:10.2106/00004623-200305000-00051.

[5] S.J. Wang, Y.C. Han, F.M. Pan, B. Ma, J. Tan, Single transverse-orientation cage via MIS-TLIF approach for the treatment of degenerative lumbar disease: a technical note, Int. J. Clin. Exp. Med. 8 (8) (2015) 14154–14160.

[6] H. Huang, J. Liu, L. Wang, Y. Fan, A critical review on the biomechanical study of cervical interbody fusion cage, Med. Nov. Technol. Devices 11 (2021) 38, https://doi.org/10.1016/j.medntd.2021.100070.

[7] A. Mohammadhosseini, Properties and Performance of Titanium Alloy Processed by Electron Beam Melting Additive Manufacturing, Swinburne University of Technology, 2015.

[8] Soundarapandiyan G, Hohnston C, Khan RHU, et al. The effects of powder reuse on the mechanical response of electron beam additively manufactured Ti6Al4V parts. Elsevier. Published online 2021:36

[9] Melting E beam, Cordova L, Raza A, Hryha E. Rheological Behavior of Inconel 718 Powder for Electron-Beam Melting. Metals (Basel). Published online 2022.

[10] J.H. Peck, K.D. Kavlock, B.L. Showalter, B.M. Ferrell, D.G. Peck, A.E. Dmitriev, Mechanical performance of lumbar intervertebral body fusion devices: an analysis of data submitted to the Food and Drug Administration, J. Biomech. 78 (2018) 87–93, https://doi.org/10.1016/j.jbiomech.2018.07.022.

[12] S. Palanivel, A.K. Dutt, E.J. Faierson, R.S. Mishra, Spatially dependent properties in a laser additive manufactured Ti-6Al-4V component, Mater. Sci. Eng. A 654 (2016) 39–52, https://doi.org/10.1016/j.msea.2015.12.021.

[13] C.D. Cole, T.D. McCall, M.H. Schmidt, A.T. Dailey, Comparison of low back fusion techniques: transforaminal lumbar interbody fusion (TLIF) or posterior lumbar interbody fusion (PLIF) approaches, Curr. Rev. Musculoskelet. Med. 2 (2) (2009) 118–126, https://doi.org/10.1007/s12178-009-9053-8.

[16] AMERICAN SOCIETY FOR TESTING AND MATERIALS. Intervertebral Body Fusion Devices. . ASTM Int. 2015;03:1-9. doi:10.1520/F2077-11.2