

Original scientific paper

APPLICABILITY ANALYSIS OF ADDITIVE MANUFACTURING PROCESSES IN THE FABRICATION OF ANATOMICALLY SHAPED LATTICE SCAFFOLDS

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Abstract. *Manufacturing of anatomically shaped scaffolds for bone tissue recovery as well as other similar anatomically shaped implants represents a major challenge for modern manufacturing technologies. The complexity of anatomically shaped lattice scaffolds for bone tissue recovery requires involvement of so-called additive manufacturing processes.*

This paper brings out the criterial matrix for the assessment of additive manufacturing processes applicability in the case of bone tissue scaffold manufacturing. Moreover, this criterial matrix serves as the basis for developing Calculator for the generic assessment of additive manufacturing processes applicability. In this very particular case the subject of consideration is an anatomically shaped lattice scaffold intended for the recovery of large trauma located in the upper part of proximal diaphyseal of rabbit tibia. The criterial matrix and the Calculator defined for this case prove themselves as generic tools for comparative analyses of applicability of different additive manufacturing processes. Furthermore, these tools can help identifying the most demanded features of some future additive manufacturing process that has to be developed for the specific case.

Key Words: *Additive Technologies, Additive Manufacturing Process, Scaffolds, Anatomically Shaped Lattice Scaffold, Applicability, Criterial Matrix, Calculator*

1. INTRODUCTION

Tissue engineering usually involves the use of so-called scaffolds, which are expected to provide for the necessary mechanical support to the cells seeding in the process of tissue reconstruction. The scaffolds perform the role of an artificial (highly porous)

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extracellular matrix which ensures a proper and sufficiently rapid cell growth as well as an efficient reconstruction of the tissue that has been damaged by injury or disease. In terms of structure, the scaffolds are usually artificial lattice-like support structures of biocompatible materials. To perform their function, they should possess:

- biocompatibility with native tissue,
- a smooth reinnervation and revascularization of new tissue inside the volume of the graft which includes suitable communication (connection, ingrowth) related to the surrounding tissue (ensuring undisturbed transport of nutrients to cells and removal of waste products from them),
- attachment of cells and grow factors to the surface of the scaffold struts (surface of scaffold struts "must be pre-processed") - a process called Surface Functionalization [1],
- appropriate mechanical properties (e.g. structural strength and elasticity or stiffness) to ensure required deformations,
- high level of geometrical, i.e. anatomical consistency (congruency) of custom shaped graft during tissue recovery,
- easy sterilization, and,
- simplicity of fixation and implantation.

Another very important feature which should be added to the above list is that the scaffold design should be relatively easy to manufacture, that is, should be characterized by a high level of manufacturability. Considering the complexity and uniqueness of the shape of the Anatomically Shaped Lattice Scaffolds – ASLS (*see Fig. 1*).[2] and the current state of manufacturing technology [3, 4], it is clear that it is necessary to employ *Additive Manufacturing Processes – AMP*.

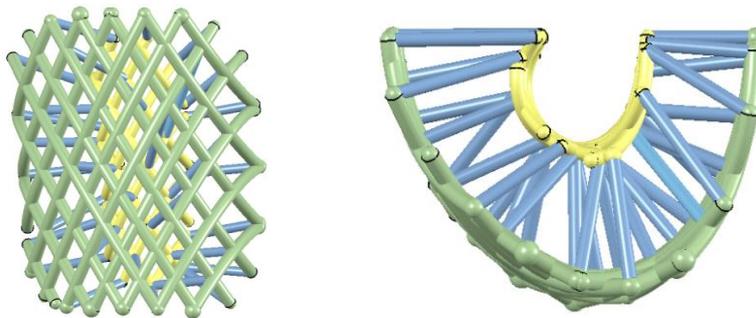


Fig. 1 ASLS design

Compatibility of the AMP with medical imaging techniques (CT, MRI ...) has opened up opportunities for the emergence of new approaches in the design of the internal architecture of the scaffolds for bone tissue reconstruction. The AMP allows the creation of anatomically shaped scaffolds in addition to the control of the size and distribution of pores as well as of the entire inner architecture. However, the scaffold's geometry complexity imposes the need to analyze applicability of different AMPs and to choose the most applicable one.

Apart from few analyses [5, 6, 7, 8] there are not many procedures and methods for analyzing the applicability of the manufacturing processes for a specific case. For example, the results of the research related to manufacturing complexity evaluation for

additive and subtractive processes in the case of hybrid modular tooling [8] have shown that the geometric parameters do not have the same influence in the cases of subtractive or additive processes, indicating the importance of generating a method (procedure) for assessing the applicability of the technological processes which could be easily adapted for a particular case.

From that aspect, this paper analyzes the applicability of different AMPs for the manufacturing of one type of ASLS. At the same time, the paper discusses and proposes a method for assessing the applicability of different AMPs.

The crucial criteria that is used for the selection of candidates between different AMPs is the ability of using commercial biocompatible or biodegradable materials that are applied regularly. This feature allows for the implantation of ASLS samples in experiments *in vivo*. Following that criteria, the selection of the AMP that can be used for the ASLS manufacturing is reduced to three potential AMPs:

1. 3D bioplotter,
2. Direct Metal Laser Sintering (DMLS), and,
3. Electron Beam Melting (EBM).

3D bioplotter is chosen as the only commercially available AT developed to plot biodegradable materials and biological cells, for making temporary (biodegradable) ASLS of hydroxyapatite (HA) while DMLS and EBM are used to make permanent ASLS of Ti-alloys (Ti6Al4V and Ti64).

2. MANUFACTURABILITY OF DESIGN VS. APPLICABILITY OF MANUFACTURING PROCESS

In a *manufacturability* analysis different scaffold design variants are taken into consideration in order to identify the one which is possible to manufacture by using (given) particular manufacturing process while achieving the maximum level of required quality at minimum investment. On the other hand, the *applicability* analysis considers whether an AMP can be applied to fabricate a reference scaffold design variant of required quality, and if so, to give further consideration to determining investment parameters (time, material, post-processing etc.) The most applicable AMP among several potential candidates is the one which is featured by minimal investment. Therefore, when we consider *manufacturability* we bring into focus design characteristics and when we consider *applicability* we are focused on the process' characteristics. On the basis of the above, manufacturability and applicability can be presented using the following functions [10]:

Scaffold design manufacturability (M):

$$M_i = M(\{D_i\}, MP_N) \quad (1)$$

where $i = 1, 2, 3 \dots$, D_i – different design solutions of the part and MP_N – manufacturing process.

Applicability of manufacturing processes (A):

$$A_j = A(\{MP_j\}, D_n) \quad (2)$$

where $j = 1, 2, 3 \dots$, MP_j – different manufacturing processes and D_n – one (reference) design solution of the part.

Methods of assessment which are used in the determination of manufacturability can be applied for determining applicability of certain manufacturing processes. Determining the applicability of certain MP is reflected in finding answers to the following [11]:

- Determine whether or not certain manufacturing process is applicable for the manufacture of part,
- If a MP is found to be applicable, determine an applicability rating, and,
- If a MP is not applicable then identify the MP attributes that cause applicability issues.

3. THE CRITERIAL MATRIX FOR THE ASSESSMENT OF AMP APPLICABILITY

Comparative analysis of the applicability of the selected AMP in the case of ASLS manufacturing is carried out using so called abstract-quantitative evaluation [12]. This analysis begins by choosing appropriate *variables for determining the applicability of the AMP*. These variables are chosen for a specific process of manufacturing ASLS and similar forms.

Each of these variables is assigned *significance (S)* which reflects the *significance of variables for determining the applicability of the AMP* in the range of $S = (0-1)$ (Fig. 2).

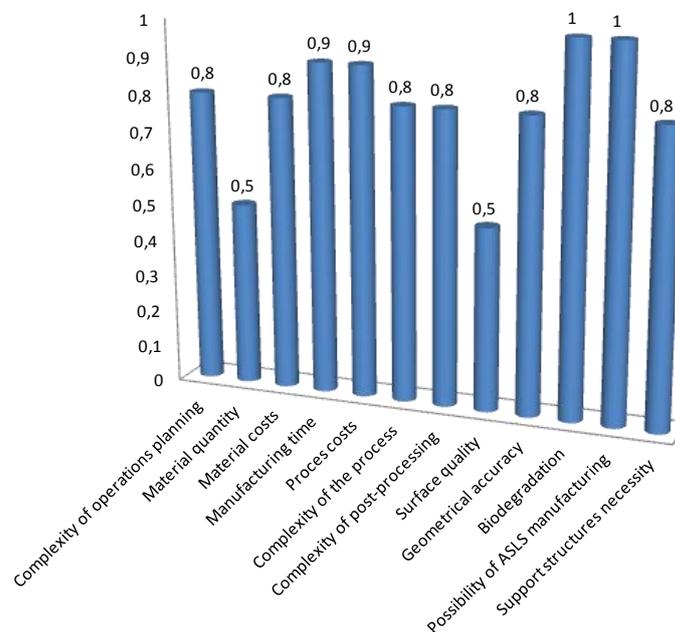


Fig. 2 Significance (S) of variables for determining the applicability of the AMP

Values of these variables are obtained as statistical averages of summary assessments provided by multidisciplinary experts from different laboratories.

It should be kept in mind that the value of the *significance* (*S*) of some *variables* can be changed toward a certain (reference) scaffold design. Based on the specifics of each of the AMPs, which is applicable to manufacture specific classes of bone scaffold (ASLS), a *criteria matrix for the assessment of the AMP applicability* is defined [10].

To fill up this matrix, in addition to already defined *significance* value (*S*) for corresponding *variables*, each variable *value* (*V*) has to be determined (see Figs. 3, 4 and 5, and Table 1). It is done through abstract-quantitative and experts assessments.

Definitions of variables that are chosen as relevant for AMP applicability assessment in the case of ASLS design are listed below:

- *Complexity of operations planning* takes into account the number of required operation iterations and the complexity of the same.
- *Material quantity* implies total material consumption - the overall quantity of material which is necessary for manufacturing a sample (including support structures) - The higher consumption of material the lower the absolute value of the variable.
- *Material costs* are determined on the basis of proportionality: BP: EBM: DMLS. For this case this value is the highest for bioplotter (150 € / g) and this value is taken as maximum value of the variable: -1. Consequently for the other two AMPs the value of this variable (considering that the price of a material is known) is determined: BP: EBM: DMLS = 1: 0.0013: 0.003.
- *Manufacturing time* is also determined on the basis of proportionality: BP: EBM: DMLS. The longest manufacturing process for the scaffold sample is for bioplotter (4,72h) and this value is taken as maximum value of the variable -1. For the other two AMPs, the value of this variable is determined: BP: EBM: DMLS 1: 0.42: 0.39.
- The assessment of *Process costs* is performed according to the standard price of the machine with the amortization period of 5 years and an average interest rate of 5%. Since the value for the EBM process is the highest (€ 105) in relation to the bioplotter (€ 47) and DMLS (€ 89.95), the adopted value of the variable for the EBM is -1 and for the other two AMP value of this variable is determined on the basis of proportionality.
- *Complexity of the process* includes: the number of process iterations (interruption of the machine to reposition, changing tool during operation, etc.) special conditions (protective atmosphere), the need for additional devices and equipment and like.
- Complexity of post-processing is determined in the same way as *Complexity of the process*.
- Values for *Surface quality* depend on particular case. It should be kept in mind that for the scaffold struts lower surface quality (rougher surface) is better because it increases bioadhesiveness.
- *Geometrical accuracy* takes into account the deviation of the manufactured ASLS sample compared to the digital model. The higher deviation of the manufactured ASLS sample, the lower the absolute value of the variable.

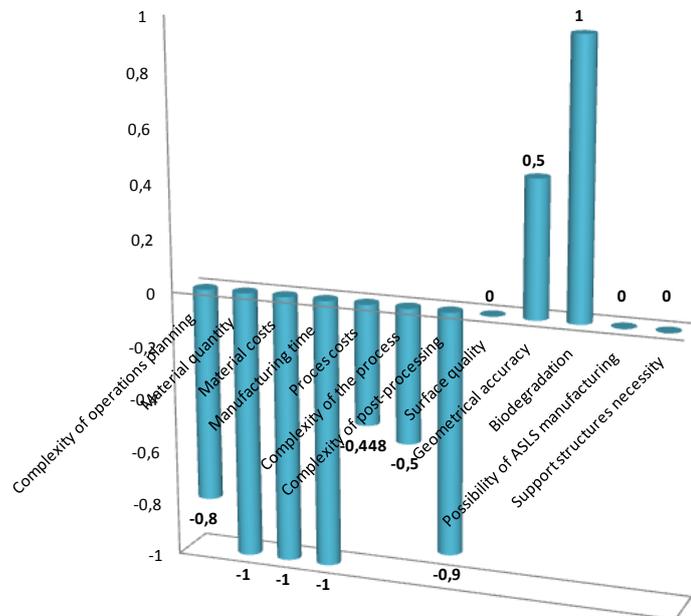


Fig. 3 Values (V) of variables for determining the applicability of 3D bioplotter in ASLS manufacturing

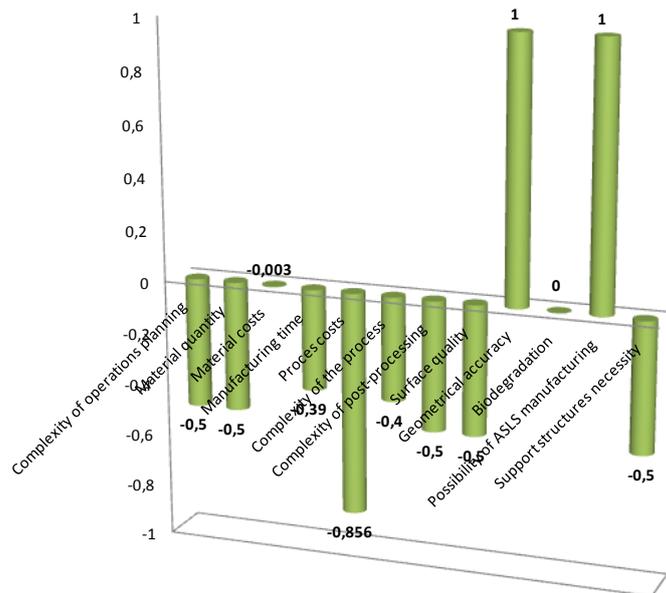


Fig. 4 Values (V) of variables for determining the applicability of DMLS in ASLS manufacturing

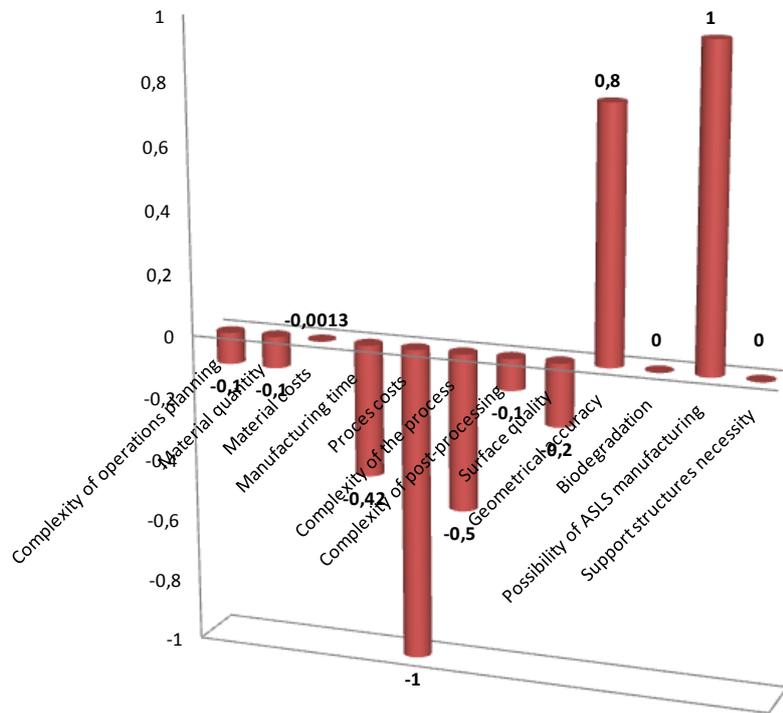


Fig. 5 Values (*V*) of variables for determining the applicability of EBM in ASLS manufacturing

Value of the expression: $S \times V$ is a parameter that affects the assessment of the AMP applicability and $\sum_1^n S \times V$ is a summary assessment of the applicability of particular ASLS manufacturing process.

Bearing in mind that the value of the eliminatory coefficient - *Possibility of manufacturing ASLS* - is equal to 0 for 3D bioplotter process because it appears as unable to manufacture such a free-form geometry, the bioplotter is not used for further comparisons. However, the values of the above mentioned variables obtained for bioplotter are shown in the criterial matrix for assessing the AMP applicability (Table 1, shaded columns), in order to obtain a realistic insight about advantages and disadvantages of the actual 3D bioplotter process.

Table 1 Criterial matrix for the assessment of AMP applicability

Variables for determining the applicability of the AMP	S(0,1-1)	DMLS		EBM		3D bioplotter	
		V	S×V	V	S×V	V	S×V
Complexity of operations planning	0,8	-0.5	-0.4	-0.1	-0.08	-0.8	-0.64
Material quantity	0,5	-0.5	-0.25	-0.1	-0.05	-1	-0.5
Material costs	0,8	-0.003	-0.0024	-0.0013	-0.00104	-1	-0.8
Manufacturing time	0,9	-0.39	-0.351	-0.42	-0.378	-1	-0.9
Process costs	0,9	-0.856	-0.7704	-1	-0.9	-0.448	-0.4032
Complexity of the process	0,8	-0.4	-0.32	-0.2	-0.16	-0.5	-0.40
Complexity of post-processing (if there is a need for)	0,8	-0.5	-0.40	-0.1	-0.08	-0.9	-0.72
Surface quality	0,5	-0.5	-0.25	-0.2	-0.10	0	0
Geometrical accuracy	0,8	1	0.8	0.8	0.64	0.5	0.40
Biodegradation	1	0	0	0	0	1	1
Possibility of ASLS manufacturing	1	1	0.9	1	1	0	0
Support structures necessity	0,8	-0.5	-0.40	0	0	0	0
Σ	-	-	-1.3438	-	-0.1184	-	-

S – Significance of variables for determining the AMP applicability

V – Values (*V*) of variables for determining the AMP applicability

Comparative analysis of the value of expression $S \times V$ using DMLS and EBM additive manufacturing processes for ASLS manufacturing is given in the diagram (Fig. 6).

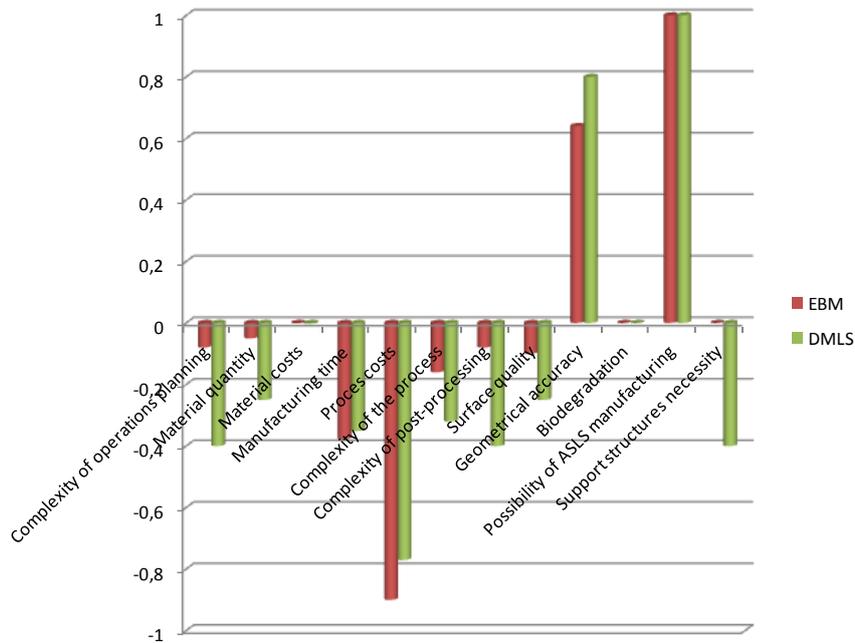


Fig. 6 Comparison of values: $S \times V$ in DMLS and EBM

The highest value of expression $\sum_1^n S \times V$ in the criterial matrix for assessing the applicability of AMP indicates that EBM technology has the fewest features that adversely affect the applicability of the manufacturing process, i.e. EBM appears as the most suitable for manufacturing of ASLS and similar type of scaffolds.

4. PROCESS APPLICABILITY CALCULATOR

Criterial matrix for the assessment of the AMP applicability defined in this way serves as the basis for creating so-called *Calculator for generic assessment of additive manufacturing processes applicability* [10].

The appropriate *case* (in this case manufacturing of ASLS), is initially entered in the calculator which is followed by the input of the appropriate processes (AMP) that are used for ASLS manufacturing and for each of them: **variables for determining the applicability of the AMP**, their **significance** -S and **values** -V. All these input parameters are variable and depend on the particular design and its functionality.

Calculator automatically calculates $\sum_1^n S \times V$ which is a summary assessment of the AMP applicability for ASLS manufacturing and, according to the results, it gives the recommendation for the most appropriate technology for manufacturing of ASLS or similar bioforms. Relational database schema that supports this calculator is given in Fig. 7. Database for the Calculator is made in Microsoft Access 2007 .

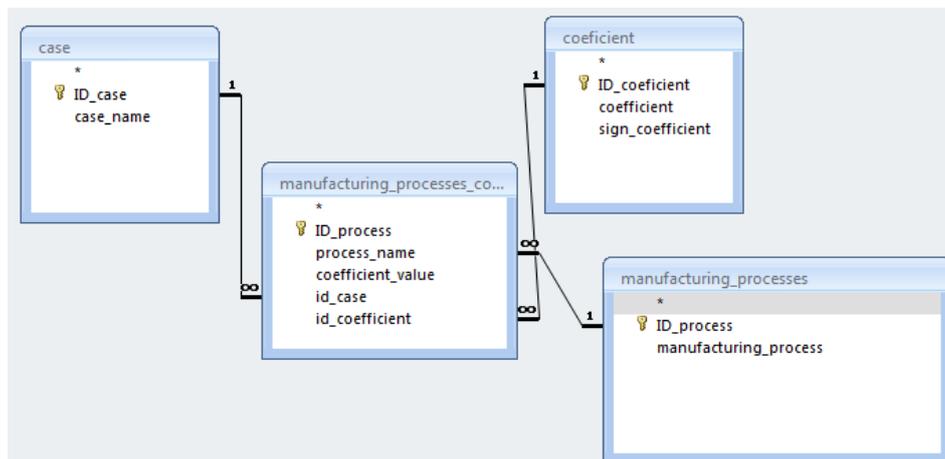


Fig.7 Relational database schema of *Calculator*

The Calculator can be used to add a new AMP and to change or add new *variables for determining the applicability of the AMP*, their *significance* -S and *values* -V depending on the part being manufactured, i.e. requirements of the case. The Calculator also may include a variety of cases. In this way, the Calculator encompasses the ability to configure an applicability analysis to a particular case; thus, it makes it very flexible and efficient.

In accordance with the above-defined approach the eliminatory coefficient in the matrix and the Calculator the *Possibility for Manufacturing* of ASLS is calculated. For

this specific case of design, *Possibility for Manufacturing of 3D Bioplotter is 0* (it cannot be manufactured on 3D Bioplotter), i.e., this AMP is shown as incapable to employ and 3D Bioplotter is excluded from further comparisons.

The outputs from this application are assessments of AMP applicability used for manufacturing of ASLS and recommendation for the most applicable (quality) manufacturing process among them (Fig. 8).

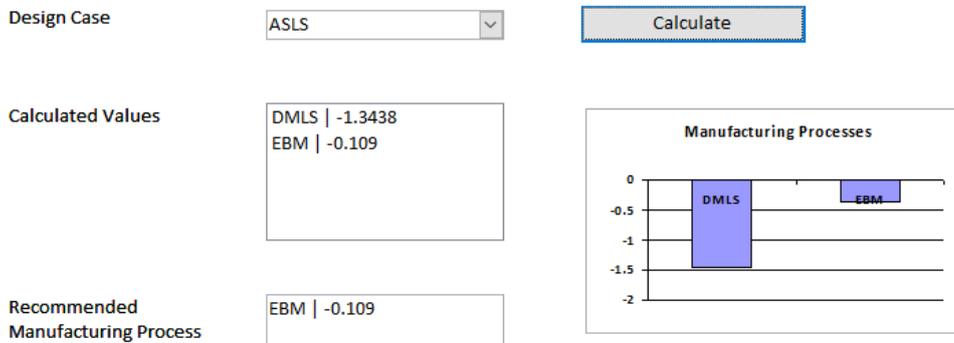


Fig. 8 Result of the Calculator for the assessment of selected AMP applicability for ASLS manufacturing

The criterial matrix indicates that an indisputable advantage of 3D bioplotter, compared to other technologies, is its ability to plot biodegradable materials, and even cells. However, the matrix shows that the main drawback of this technology is that it cannot be used (at the actual state of development) to make complex forms like ASLS. On the other hand, Calculator shows that EBM is currently the optimal choice for manufacturing of ASLS in metal. According to comparative analysis of applicability, DMLS is just behind EBM, but with slightly lower performance. However, at this point of development, EBM and DMLS cannot be used to manufacture temporary ASLS, that is, they cannot utilize biodegradable materials. Moreover, it should be noticed that the analysis of variables involved in the matrix and Calculator can bring out what AMP features are or could be appropriate for manufacturing of a particular design case like ASLS. In this way, the criterial matrix and Calculator may help either improving the existing or defining new AMP for a particular product design.

5. CONCLUSIONS

The modern society clearly shows its increasing demands for further improvements in health care. This, among other things, involves the development and manufacturing of biological implants, which, in its turn, urges a more rapid development of additive technologies, which seem to be optimal for this application. In this regard, the selection of the most applicable AMP represents an essential step for determining the optimal manufacturing process for a certain biological implant. In addition, the definition of an efficient and traceable method for the assessment of applicability of certain AMP to

fabricate biological implants such as, for example a bone tissue scaffold, is of great importance. However, it seems that, at present, there is no a suitable method for the purpose of an AMP applicability analysis. The criterial matrix and the Calculator that are described in this paper propose a kind of method and corresponding software solution for the assessment of the AMP applicability for the case of anatomically shaped lattice scaffold fabrication. The proposed method appears as a very flexible one that can be changed, expanded and/or adapted according to the needs of a particular case. Moreover, the application of Calculator implies the ability to configure an analysis of applicability of different AMP to fabricate similar bio-structures, by changing the existing and adding new variables, their values and significance as well as defining and including new assessment and elimination criteria. Ultimately, this whole methodology may indicate requirements for an ideal *additive manufacturing* machine for bone tissue scaffold manufacturing.

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