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Laser Additive Manufacturing of Modified Implant Surfaces with Osseointegrative Characteristics

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Abstract

Additive Manufacturing technology, such as Selective Laser Melting, allows fabrication of complex metal parts with freeform surfaces. Using biocompatible metal alloys, e.g. $TiAl_6V_4$, medical implants can be produced. To increase osseointegrative behavior the ability to fabricate filigree lattice structures can be utilized to achieve a modified implant surface. In order to increase dimensional accuracy when applying a lattice structure on a curved surface, process constraints for single lattice bars are studied. The investigated lattice structure was thereupon applied on the surface of a medical implant.

Keywords: Laser Additive Manufacturing, LAM, Selective Laser Melting, SLM, surface modification, cell structure, implant, $TiAl_6V_4$

1. Introduction

Osseous defects which exceed a critical size cannot be replaced completely by the human body. Often bone substitute materials are used to fill existing defects. By this means bone anatomy can be restored to its former condition and the mechanical functionality of the bone can be regained. In the long term bone substitute materials which are inserted in the human body have to be decomposed and replaced by autologous bone. Failing this it has to be ensured that surrounding tissue can be incorporated into the substitute material during the healing process [1].

Frequently-used bone substitutes in the human body are medical implants such as hip joint endoprosthesis. This joint replacing implant is typically made of titanium and its alloys. The disadvantage of using metallic materials is the stiffness of the implant which is significantly higher than the stiffness of cancellous bone. Hence, mechanical shielding of the bone tissue can be observed when mechanical load is applied on the implant. Along with that, degeneration of the bone occurs because of the lack of load-induced stimulation of bone growth. Eventually, stress shielding can result in implant loosening and lead to revision operations to replace the endoprosthesis [2].

In order to overcome the mismatch of the Young´s modulus between metallic implant and cancellous bone, the use of porous materials or structures is a promising approach. Additionally, such bone-like materials or structures promote bone in-growth and give rise to faster primary and higher secondary stability [2].

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There are several production techniques for the manufacture of bone replacement structures, such as casting, metal cutting, coating processes, metal foaming and sintering. Also Laser Additive Manufacturing (LAM) shows great potential to satisfy the requirements, particularly as regards the geometric complexity of the products. This technology enables the manufacture of freeform surfaces as well as periodic lattice and network structures, which are appropriate for the fabrication of bone-like structures [3].

2. State-of-the-art and current research

In orthopedic surgery titanium and its alloys, e.g. $TiAl_6V_4$, are well-accepted and often applied for the manufacture of medical implants. Titanium and titanium alloys are biocompatible and feature bioconductive properties. Implants made of this material can be characterized by faster osseointegration and a greater extent of tissue in-growth into the artificial bone structure. Further properties of the material are that titanium is not resorbable and has a high specific strength [4].

2.1. Laser Additive Manufacturing (LAM)

Medical implants manufactured by Laser Additive Manufacturing (LAM), e.g. by Selective Laser Melting (SLM), of $TiAl_6V_4$-material meet the requirements stated above. During the cyclic SLM-process a thin layer of metal powder (20 to 50 microns) is selectively molten by a laser beam. After cooling below melting temperature, the exposed area solidifies and the geometry is generated. Subsequently, a new layer of powder material is applied, molten by a laser beam and solidified due to cooling. Hence, parts are built additively layer by layer. Using this technology filigree structures, lattices and scaffolds can be manufactured which are impossible to fabricate by conventional production methods.

2.2. Approaches for the manufacture of bone replacement structures by SLM

Recently, several studies focused on the SLM-process for the production of artificial endoprostheses with porous surfaces and scaffolds to increase bone in-growth. As these modified surfaces and lattice structures have distinct characteristics, miscellaneous approaches, such as the development of special scanning strategies [5], material combinations [6] and various design and unit cell approaches [7-11] are worked on to achieve porous, bone-like structures and properties.

The so-called beam overlap technique which was introduced by Stamp et al. in order to generate porous structures is based on a modified scanning strategy [5]. The exposure of a powder layer is carried out with a 90° rotation in relation to the layer before. The distance between two exposed tracks is modified in such a manner that there is no overlap between them. The height of the tracks is defined as well. The result is a porous network structure with a regular, rectangular and inter-connecting pore distribution which can be adjusted by the choice of geometric dimensions.

More common for the design of porous structures is an approach based on unit cells. The basis of the unit cell approach is a regular cell. A three-dimensional structure can be designed by a geometrically defined sequence of unit cells. The cells can be strung together in desired alignments which reflect specific physical and mechanical properties of the resulting structure [7, 12].

Imagining the load on a knee or hip joint endoprosthesis during everyday situations, it becomes obvious that there is a balancing act to avoid stress shielding on the one hand and to meet the mechanical requirements placed upon the implant on the other hand.

3. Research approach

This study focuses on the feasibility of producing an endoprosthesis surface modification at the joint interface by unit cells by SLM. Simultaneously, a solid base geometry of the implant is maintained for stability purposes. Usually, the interface between natural bone and implant surface is a freeform geometry and complex to describe. Surface approximation with regular unit cells results in errors when fitting a desired structure to it. Figure 1 shows induced errors on a curved surface and presents different approximation possibilities.

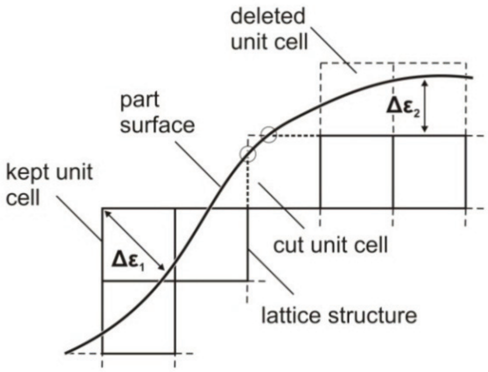

Figure 1: Errors in fitting regular unit cell lattice structure to curved surface

When fitting unit cells to a surface without changing the cell structure, the cell can either be kept, removed or the intersecting bars can be cut at the surface, cp. Figure 1. This, however, does either lead to an error with regards to the required position ($\Delta\varepsilon_1$, $\Delta\varepsilon_2$) or leaves exposed and unstable single bars. A solution approach is to adapt the structure to the surface by deforming cells. This leads to a contradiction to general design rules for the SLM process, though, because bars would have to be built lying in x-y-plane parallel to the powder bed in order to optimally describe a complex surface. General design rules for solid geometries state that parts with overhanging structures of angles below 30° with respect to the building platform are not built up [13]. Another challenge that has to be faced is to mathematically describe the application and alignment of unit cells on a three-dimensional freeform surface.

Once these challenges have been addressed a software-based description can be derived to calculate all necessary information. This includes the generation and positioning of a cell structure as well as the subsequent computation of manufacturing data in form of exposure vectors for each layer.

This paper covers on the one hand the fundamentals which are necessary in order to theoretically describe a freeform surface consisting of unit cells. On the other hand it concentrates on the investigation of manufacturing lattice bars contradicting conventional design rules to allow the build-up of tilted unit cells and whole structures. Results of the study are implemented in the development and manufacture of an innovative implant featuring a modified surface with osseointegrative characteristics.

4. Fundamentals

For the modification of the implant´s surface a unit cell approach was used. In order to avoid the errors discussed above when approximating a complex surface by cells, the unit cell has to be transformed. This transformation can be described by a set of mathematical operations. Figure 2 shows the combination of the operations scaling (*S*), distortion (*D*), rotation (*R*) and transformation (*T*) which are necessary to describe the surface by a combination of several cells. The order of these operations is dependent on the choice of the coordinate system and the routine chosen for software-related realization. To simplify matters, the possibility to describe any surface by an alignment of unit cells is only exemplified in two dimensions and on the basis of a circle.

The starting point is a quadratic unit cell, or its bounding box, with the edge length *a*. This cell has to be scaled to fit into the space between an inner radius (r_i) and an outer radius (r_o) of a curved surface. The inner radius r_i reflects the outer contour of the solid part geometry. The outer radius r_o determines the final shape combining the solid body and the applied network structure. The centre of the unit cell is supposed to be in the middle of the inner and outer radius at

$$r_m = \frac{r_o + r_i}{2}. \tag{1}$$

Moreover, the position of the unit cell is described by the angle φ which is determined by splitting the circle in n parts and is calculated according to

$$\varphi = \frac{360°}{n}. \tag{2}$$

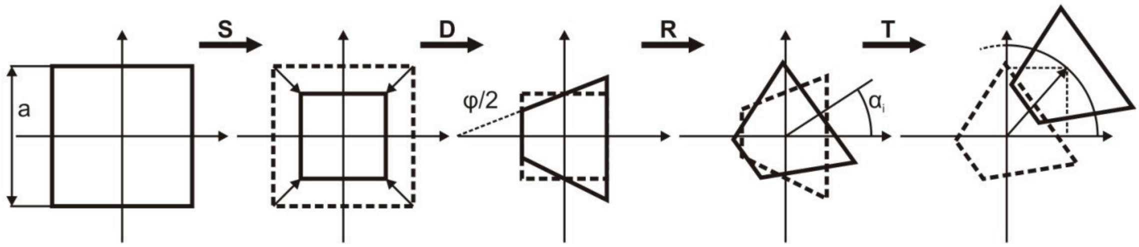

Figure 2: Schematic representation of the two dimensional transformation of a unit cell

The scaling operation is expressed by

$$S = \frac{1}{a}\begin{pmatrix} 2 \cdot r_m \cdot sin\left(\frac{\varphi}{2}\right) & 0 \\ 0 & r_o - r_i \end{pmatrix}. \tag{3}$$

Once the unit cell has the adequate size it has to be distorted. This distortion is necessary to allow for an optimal fit when aligning cells. By this means a surface without cut or kept unit cells can be realized. The distortion is based on a shear operation which describes the shear parallel to a specific axis by linear mapping. Depending on the coordinates x and y, the distortion can be accomplished using the following shear matrix

$$D = \begin{pmatrix} 1 & 0 \\ tan\left(\frac{\varphi}{2}\right) & 1 \end{pmatrix}. \tag{4}$$

In the operations performed above the position of the unit cell is dependent on the choice of the coordinates x and y. These coordinates show a position-dependency when aligned on the radius r_m which can be indicated by an angle α_i. This angle is calculated for each cell i to be

$$\alpha_i = \frac{360°}{n} \cdot i. \tag{5}$$

When rotating the unit cell, this angle α_i has to be taken into account in order to achieve the desired orientation of the cell on the surface. The rotation can be expressed by

$$R = \begin{pmatrix} cos\ (\alpha_i) & -sin\ (\alpha_i) \\ sin\ (\alpha_i) & cos\ (\alpha_i) \end{pmatrix}. \tag{6}$$

The final step is a translation of the cell in order to move it to the desired position on the surface. The cell is translated in x and y direction according to

$$T = \begin{pmatrix} r_m \cdot cos\ (\alpha_i) \\ r_m \cdot sin\ (\alpha_i) \end{pmatrix}. \tag{7}$$

As the cells chosen for the modification of the surface are very small any chord deviation caused by approximation of the circle by a line segment can be neglected. Accordingly a description of the relations by trigonometric functions is absolutely acceptable.

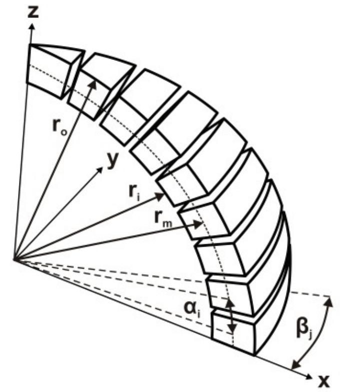

Figure 3: Three dimensional alignment of unit cells on a curved surface

In order to achieve a mapping in the three-dimensional domain the cells have to be distorted and projected into z direction as it can be seen in Figure 3. The effect is that cells differ in size dependent on their position on the sphere.

5. Experimental procedure

Experiments were conducted using an EOSINT M270 Xtended SLM machine by EOS GmbH with a 200 W Ytterbium doted fiber laser beam source. Solid part geometry was produced with default parameters from $TiAl_6V_4$-powder material applied in layers of 30 microns. The required inert atmosphere within the process chamber was achieved by argon gas supply.

5.1. Manufacture of single lattice bars

Direct layer information for exposure of single lattice bars was derived using an in-house developed C++-program [8]. This development resolves shortcomings of general STL data representation in regard to describing filigree lattice structures.

Stable SLM-process parameters for point-wise exposure were determined by experimental studies of defined combinations of scanning speed (50 mm/s up to 1000 mm/s) and laser beam power (20 W up to 195 W). For this purpose a simple cell structure appropriate for fabrication by SLM was chosen.

Process capabilities for production of freely suspended structures were examined by fabricating single lattice bars inclined in angles from 0° to 80° with respect to the base plate. To study additional interrelations length of the bars was also taken into account and varied from 0,5 mm up to 5 mm. All investigated specimens were produced using an energy input per unit length of 0,4 J/mm, which describes a stable region for lattice bar production.

5.2. Development of lattice structure and determination of mechanical behavior

On the basis of these principal studies, a lattice structure based on a hexagonal unit cell was developed that incorporates horizontal x-y-bars, cp. Figure 4. Theoretical calculations on the resulting porosity with respect to previously determined lattice bar diameter and geometrical restrictions, such as unit cell height or maximal aspect ratio for cell structures [9], were chosen as development criteria.

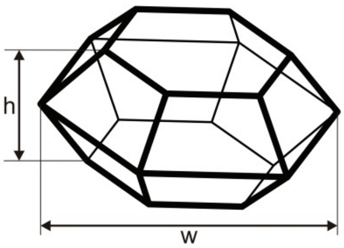

Figure 4: Hexagonal unit cell

Figure 5: Uniaxial compressive testing of specimen

Cellular structures are typically described by their specific values with respect to the theoretical solid geometry. The specific Young's modulus is thus defined as $E^*= \sigma^*/\varepsilon$. The specific stress σ^* can be similarly derived from the orthogonal load F on the theoretical cross sectional area A^*, $\sigma^*=F/A^*$ [8]. Additionally to the actual unit cell layout and lattice structure, the choice of process parameters such as scanning speed or laser power directly influence the lattice structure's mechanical behavior due to a change of beam diameter [14].

The cell structure was created by arranging a layer of unit cells and vertically stacking the layers. Cylindrical test specimens of height 22 mm and diameter of 28 mm were produced from $TiAl_6V_4$-powder material using energy inputs per unit length from 0,3 to 1,0 J/mm, which result in a change in beam diameter and hence a change in porosity. The aim of this investigation is to generate a porous structure with a porosity of about 70% up to 90% similar to the conditions of bone tissue [15-17]. Uniaxial compressive testing was conducted in order to study resulting mechanical behavior, cp. Figure 5. The determined parameter combinations were used in subsequent investigations.

5.3. Surface modification by application of the structure

After the definition of process parameters and the examination of the feasibility of producing lattice bars independent of the direction, the developed unit cell structure is placed on a solid plate. In a first step inclination levels of 0°, 30° and 60° of the plate and lattice structure are studied. In a second step, the analysis was extended to investigate the application of transformed unit cells on a curved surface, such as a thin walled hemisphere.

6. Results and discussion

6.1. Results of the manufacture of single lattice bars

The influence of process parameter combination of scanning speed and laser power on the production of single lattice bars is shown in Figure 6. Below a threshold laser power of about 60 W no $TiAl_6V_4$ lattice structures are built up successfully. The dependency of the energy input per unit length on the lattice bar diameter is displayed in Figure 7.

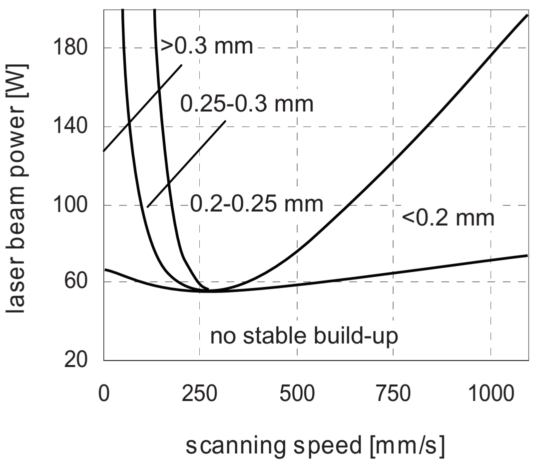

Figure 6: Influence of scanning speed and laser beam power on bar diameter

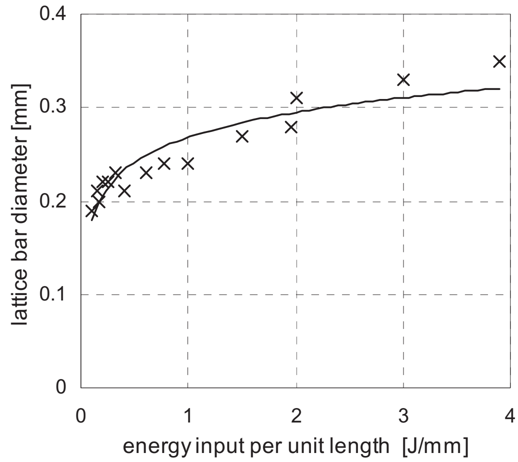

Figure 7: Influence of energy input per unit length on bar diameter

Figure 8 illustrates manufactured specimens from different perspectives. The study of producing freely suspended lattice bars with a length of up to 5 mm showed a stable and robust build-up of all bars for all studied angles, which was not expected. Thus, general SLM design rules do not apply for lattice structures of bars with up to 5 mm length. However, different characteristics of the lattice bars with respect to their build angle could be investigated. With a decrease of the building angle the diameter of the lattice bar increases, as can be seen in Figure 8 (right). An explanation can be found by considering the heat dissipation. In the SLM process introduced heat is mainly dissipated by conduction over the solid material. The lower the angle, however, the smaller is the connected area to solid material. Thus, for low angles partially molten powder particles are attached due to heat dissipated by convection.

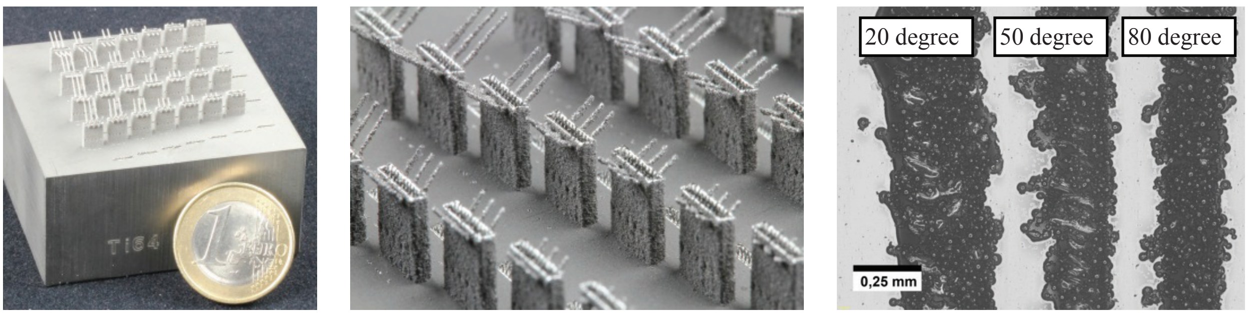

Figure 8: Single lattice bars with different angels, left: production batch, middle: magnification of production batch, right: microscopic investigation of single lattice bars with building angles of 20°, 50° and 80°

6.2. Results on mechanical properties of the developed lattice structure

Porosity of all cylindrical test specimens made up from hexagonal unit cells was determined by gravimetric analysis. Porosity between 68% and 87% was measured, cp. Figure 9. As expected, compressive testing of these cylindrical lattice structures yields a specific Young's modulus with dependency on the energy input and resulted in values in the range of 0,4 GPa to 1,2 GPa, cp. Figure 10. Thus, considering the determined results for porosity and stiffness, a bone-like behavior of the developed structure can be observed.

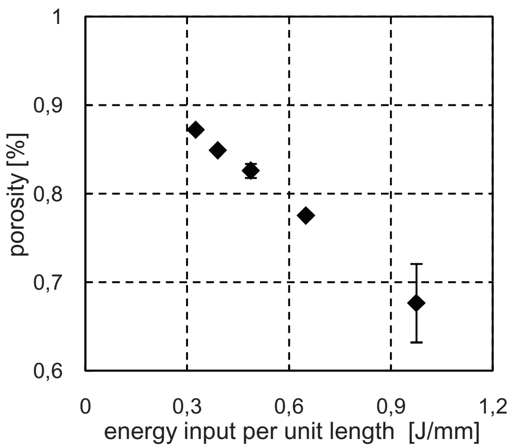

Figure 9: Influence of energy input per unit length on porosity

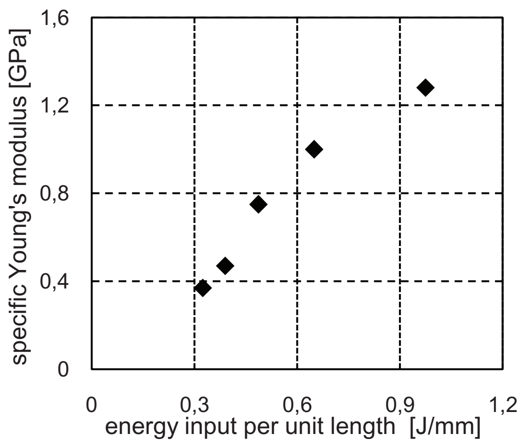

Figure 10: Influence of energy input per unit length on Young´s modulus

6.3. Application of the lattice structure

By means of a C++ based software a hexagonal unit cell was designed and cells were arranged without pyramiding to form a single lattice layer. A single layer was regarded as sufficient to satisfy required osseointegrative characteristics. A stable SLM-process was achieved for applying only one layer of the designed lattice on an even surface, on surfaces inclined by angles of 30° and 60° with respect to the base plate as well as on curved part geometries. The findings of these investigations made it possible to apply the tested lattice structure on a medical implant which features a surface in the form of a hemicycle.

In order to produce the hemispherical geometry by the chosen structure, unit cells had to be transformed and distorted in a way that the lattice at the bottom of the hemisphere appears wide-meshed whereas the top of the geometry is covered by closer cell alignment, cp. Figure 11. The fundamentals discussed above provide the basis for these operations. All cells are oriented with respect to the normal vector of the curved surface. By this means a modified surface without significant errors ($\Delta\varepsilon_1$, $\Delta\varepsilon_2$) or cut bars was generated and manufactured.

The lattice structure which consists of an alignment of hexagonal unit cells arranged in a single layer encloses the hemispherical surface of the implant as it can be seen in Figure 11. Due to the three-dimensional transformation of each unit cell according to the aforementioned operations, the modified surface of the endoprosthesis shows no irregularities. The designed structure and the determined mechanical properties of the developed lattice strongly suggest that the created surface of the implant is suitable to promote bone in-growth when introduced into the corresponding environment in the human body.

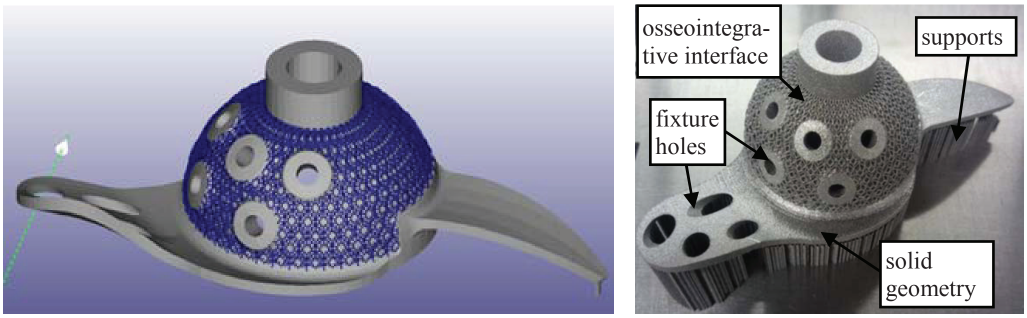

Figure 11: Left: CAD design of the implant and cell structure, right: manufactured hip endoprosthesis

7. Conclusion and Outlook

The aim of the investigations discussed in this paper was to develop and manufacture an osseointegrative surface of a metallic medical implant which avoids the phenomenon of stress shielding and simultaneously promotes bone in-growth. The main focus was on both creating a surface formed by unit cells with high dimensional accuracy and manufacturing filigree lattice bars by SLM. The examination of the manufacturing process as regards the production of single, freely suspended lattice bars demonstrated that the SLM technology enables the fabrication of bars with different length of up to 5 mm and with various angles with respect to the powder bed. By means of this study, it became apparent that desired characteristics of unit cell structures can be adjusted by the choice of positioning of lattice bars. In addition, the studies showed that it is possible to develop a lattice structure that optimally approximates a curved surface. A mathematical description of the problem could be derived and implemented into a software solution.

In summary, the experimental results satisfied the criteria put on the development and manufacture of endoprostheses with modified surface structures. To achieve marketability of the developed implant investigations on biocompatibility as well as application-oriented dynamic analysis according to specific motion profiles are necessary and still in work. Results and final evaluation will be available soon.

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