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CREATION OF PERSONALIZED 3D MODEL OF BONE SCAFFOLD BY USING CURVE AND PATTERN BASED METHODOLOGIES

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Abstract: *Tissue engineering is an important domain that is related to the creating of biocompatible solutions that are necessary to replace injured or diseased tissues. These solutions usually involve cells, a stabilizing structure referred to as a scaffold, and essential growth factors. The scaffold provides an essential support matrix for the cells, aiding their growth and promoting tissue repair. The design or blueprint of the scaffold is vital for maintaining its mechanical robustness and ensuring efficient nutrient delivery to the tissue replacement. This research introduces an innovative technique for designing individualized 3D scaffold blueprints by employing the Method of Anatomical Features (MAF) along with two distinct methodologies. The first technique is anchored on curves, and the second draws inspiration from patterns. MAF has already shown its prowess in crafting individualized geometrical models of bones. Scaffolds crafted through this method stand out due to their streamlined design approach, enabling almost automatic customization, and the resulting detailed 3D representation of the scaffold.*
Keywords: *scaffold, 3D model, design, human tibia, CBM, PBM.*

1. INTRODUCTION

Additive Manufacturing has become increasingly popular in the medical area, particularly for forming diverse implants using materials ranging from plastics to metals [1,2]. In the domain of orthopedic surgery, forming implants or fixators demands an in-depth understanding of the human bone's geometry. Hence, generating models that are both geometrically precise and anatomically accurate are highly important [3,4]. Earlier research had focused into the classification and evaluation of methodologies for 3D modeling in the context of designing human bone geometric models [5-8]. Broadly, these bone models can either be constructed using predictive models or from geometrical information derived from medical scans like CT in Reverse Engineering (RE) processes [8-10]. These individualized bone models become indispensable when there's a need to tailor-make bone implants in line with unique bone shapes and structures. This necessity arises particularly when bones experience different traumas such as fractures, diseases, or infections. To recover the bone tissue at the affected region, scaffold bone grafts or implants can be employed. Essentially, bone grafts are implants fostering bone recovery, utilizing growth factors and the patient's native cells [11-13]. At their core, scaffolds serve as the critical foundation for bone grafts, promoting cellular adherence, nutrient circulation, and tissue proliferation. A scaffold ought to be biocompatible, adhere well to biology, degrade over time, and possess mechanical resilience [14,15]. The design structure of scaffolds is broad, encompassing designs rooted in unit cells, image-centric blueprints, and more [16-19].

This paper introduces a novel design methodology for scaffold structure creation, based on the use of core geometric elements and Method of Anatomical Features (MAF). This methodology has been previously used to develop varied geometric representations of human bones and their components. The applied strategy is focused on developing a parametric scaffold design which is suited for

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long bone tissue restoration [7]. A scaffold model defined parametrically allows adjustments of its geometry, based on the patient specific bone parameters. These parameters values can be acquired from medical images and applied to the 3D parametric scaffold model, and as a result patient-unique scaffold model is formed.

2. MATERIAL

In order to demonstrate the main advantages of the design methodology, five human tibia specimens were used. These samples were scanned using a 64-slice CT (MSCT) scanner (the Aquillion 64 variant of scanner produced by Toshiba company in Japan, and used in Clinical Center Nis, Serbia). The scan settings were set at a resolution of 512x512 pixels and a slice depth of 0.5mm. It is important to mention that these specimens, previously employed in an earlier study [8], were repurposed for this research. One tibia specimen formed the foundation for the primary scaffold design, and the other four served as experimental models in this case.

3. ANATOMY OF THE HUMAN TIBIA

For a comprehensive understanding of the methodology showcased in this paper, it is imperative to understand the significant anatomical segments of the human tibia. As illustrated in Fig. 1, the tibia is segmented into three main sections: the proximal epiphysis, diaphysis (or shaft), and the distal epiphysis. The upper segment of the tibia is marked by an articular facade that joins with the femur bone. The diaphysis, recognized for its elongated prismatic form, encompasses most of the tibia's volume. Embedded within the diaphysis is a central space which comprises the medullary cavity. This is forming the bone marrow, also known as the primary nutritional source for the bone. Encasing the medullary cavity is a dense layer of bone that provides foundational support. At the exterior of this compact bone is a slender membrane, known as “the periosteum”. This layer is instrumental in supplying blood to the bone and plays a pivotal role in bone recovery mechanisms, such as post-fracture. The tibia's lower section, combined with the fibula and talus is constituting the ankle joint [10].

4. THE NOVEL APPROACH

In order to realize the designing of a 3D parametric scaffold model, a new design methodology approach that is based on the MAF has been introduced [20,21].

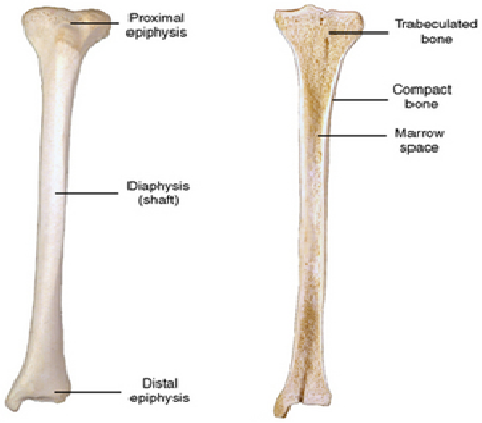


Fig. 1. Anatomy and inner structure of the human tibia [20]

The MAF is based on the developing of tailor-made geometric forms of human bones, using Referential Geometrical Entities (RGEs) as its base. RGEs comprise geometric constructs (such as lines, planes, axes, and points) that were referenced to distinctive anatomical markers (like crests and specific anatomical locations) on each bone [10]. The tailored nature of the bone's geometric design was realized through the parametric model shaped by MAF. This model is defined as a point cloud, specifically design for each individual bone in the human skeleton, like the Tibia, Femur, Mandible, among others [13,22]. Model points' coordinates are enumerated as parametric functions. The parameters where morphometric dimensions which can be extracted from medical images such as CT scans or X-rays [5,6,21]. By using the MAF principles in designing the 3D scaffold models, two important advantages are introduced:

- There is no need to manually design a CAD model. This procedure is executed by integrating the specific bone parametric

model. The scaffold's structure is semi-automatically derived by leveraging MAF for the specific bone.
- This method allows for the distinct definition of specific segments within the scaffold's design, such as those influenced by the bone's internal configuration.

The methodology opens the way for a scaffold structure that is highly controlled and defined through parameters. In this context, seven crucial parameters have been highlighted, as following [22]:

- Compact Bone Width (CBW): This reflects the width of the dense bone, individually outlined for distinct anatomical sections of the bone (Proximal epiphysis, Diaphysis, Distal Epiphysis). It is characterized as a steady metric for a given bone segment, aligning with information find in the medical literature [22].
- Missing Part of the bone Angle (MPA): This angle defined the extent of bone injury and is positioned in a plane perpendicular to the Anterior Posterior (AP) plane and the Lateral Medial plane (LM) of the tibia, corresponding to the shaft's axial plane, as one may notice in Fig. 2.
- Missing Part of the bone Height (MPH): This parameter denotes the magnitude of bone damage, measured in the AP plane, as illustrated in Fig. 2.
- Number of Layers of Scaffold (NLS): It specifies the amount scaffold layers across the trauma's height.
- Scale Factor input Set (SFS): This governs the scale ratio for the nucleus (central) elements in the axial plane.
- Number of Straight Nucleuses (NSN): It defines the linear nucleuses in the axial plane.
- Nucleus Definition Parameter (NDP): Recognized as the foundational element of the 3D scaffold model, the nucleus encapsulates multiple individual parameters.

All these parameters can be personalized and can be controlled for a scaffold structure that is aimed to be designed in close correlation with the individual bone in the human skeleton that is being considered and customized needs.

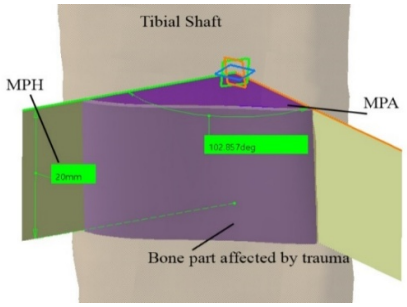


Fig. 2. 3D model of the bone trauma [20]

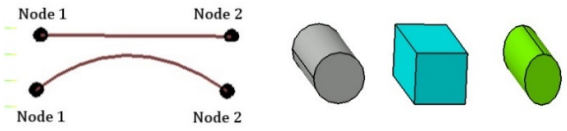
A. The methods for Scaffold Creation

The innovative methodologies that refine the unit cell creation strategy are presented in this paper. Two significant improvements are demonstrated. The foremost enhancement is the adoption of MAF in the design and articulation of the scaffold's 3D model. MAF's flexibility allows its adaptation to any human bone, leading to a unique parametric geometric representation exclusively related to that bone. This model involves a set of functions that lay out the coordinates for distinct points on the bone's contour. Each point's coordinates (X, Y, and Z) are controlled by a specialized parametric function. Linked to the type of the bone samples, these functions were determined through statistical methods and artificial intelligence techniques [20]. To tailor the model for a specific patient, morphometric geometric data, acquired from X-rays or CT scans were integrated into the parametric equations. Applying MAF to the scaffold's 3D models brings significant advantages in the design methodology, such as the following ones:

a) MAF enables the automated crafting of the CAD model for the bone's specific segment.
b) MAF assists in the semi-automatic assembly of the scaffold's internal architectural design.

Other major adaptation is the introduction of nucleus elements defined parametrically. Acting as base element units in scaffold design, these nucleus elements can be linear or contoured bars, anchored by two endpoints, as shown in Fig. 3a. Depending on their design,

these nucleuses can generate a variety of cross-sectional dimensions, shapes, and lengths, as exemplified in Fig. 3b.

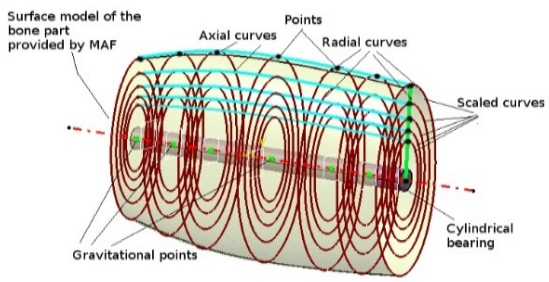


a) Straight or curved nucleus b) cross-section shapes

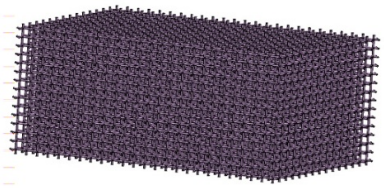
Fig. 3. The shapes and cross-sections of nucleus elements vary depending on the specific requirements of the model. [20]

In the provided examples, nucleus measurements, such as its cross-sectional size and length are variable and require tailoring for individual patients. To facilitate this customization, two strategies have been conceived for this purpose: the Curve Based Method (CBM) and the Pattern Based Method (PBM). Within the structuring of the CBM, the parametric nucleus model serves as the primary elements in shaping the scaffold's structure, as shown in Fig. 4a. On the other hand, the PBM leans on the nucleus element as a primary module to form the unit cell, mirroring a 3D intersection, as illustrated in Fig. 4b. These methods involve three phases: the preparatory phase, common operations, and procedure-specific operations.

The preparatory phase involves specifying the nucleus's length and its cross-sectional dimensions. For a precise articulation of a parametric nucleus model, three attributes are needed to be introduced and defined at this stage: the shape of the cross-section, its corresponding size, and the nucleus's elongation. Common operations are pivotal in sculpting the boundary surface of the bone's missing segment.



a) Curve Based Method – CBM



b) Pattern Base Method – PBM

Fig. 4. Two methodologies for creation of scaffolds models

Within this set of operations, pinpointing specific locations within the affected zone is an procedure that demands the involvement of surgical professionals. They possess the knowledge to mark the limits of the resection that it is necessary in this case.

B. Curve Based approach demonstration

To demonstrate the outlined approach, the tibia diaphysis was chosen as the bone segment affected by trauma. The initial phase in illustrating this method involves characterizing the type of bone injury. In this instance, the trauma was manually infused into the generated tibia designed model. It was hypothesized that a portion of the bone was missing, and the scaffold's role was: to catalyze the genesis of new bone tissue and to provide structural support. Such trauma can be categorized as a complex irregular fracture as per the AO/OTA classification [23,24] specific to the tibia, by being related to a particular bone illness, such as osteoporosis, which impacts the bone in the demonstrated manner. The subsequent phase required the definition of MPA, MPH, NLS and CBW. These metrics collectively shape the scaffold's overarching geometry, as following:

- MPA = 102.857°
- MPH = 20 mm (defined symmetrical to axial plane)
- NLS = 5
- NSN = 5
- CBW – In this case Compact Bone Width (CBW) was defined based on the extent of the medullary cavity. CBW varies along the scaffold's height. This is a crucial metric as the compact bone constitutes the bone's weight-bearing mass. Enhancing the scaffold material in this bone area is essential for supporting weight.

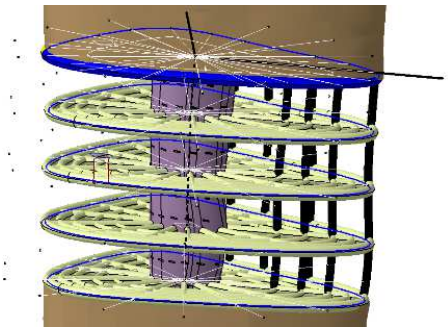
A pivotal step in the designing stage consisted in the definition of nucleus elements in the tibia shaft's axial plane. Nucleuses have been

designed as sweep elements with circular cross-sections guided by spline curves. Two primary nucleus categories emerged in this variant: curved and straight. The axial plane showcases five curved nucleus elements. Nucleus radius value was set at 0.5mm. The radius of a nucleus's circular cross-section has been correlated with its distance from the bone's exterior that was governed by the Scale Factor Set (SFS). Predefined scale factors were set at: 0.9, 0.8, 0.65, and 0.5. This yielded a minimal radius of 0.25mm and a maximum of 0.5mm. In certain configurations, nucleuses might overlap. While this aspect significantly influence scaffold model creation and can provide enhanced support, it was preferable to minimize such overlaps due to potential impacts on cellular nutrition.

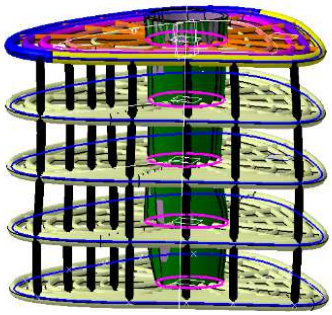
Fig. 5 visually presents the scaffold's axial plane. Observably, nucleuses were arranged as spline sweep elements, exhibiting a decreased spacing in the compact bone area. As the scaffold structure approaches the medullary canal, the inter-nucleus distance has been increased, with smaller nucleus radius. Central to the scaffold, there is a shell element replicating the medullary canal. Designed with multiple perforations, this shell fosters proper nutrition and it also facilitates scaffold anchoring to the bone fixating areas via screws and plates. Straight nucleuses, presented as linear sweep elements with a consistent circular section, act as supplementary support and connectors for curved nucleuses.

Their radius was set uniformly to a value of 0.5mm. The count of these nucleuses was proportionated to the Missing Part of the bone Angle (MPA). The applied formula was considered MPA/NSN, with NSN being five (5). However, one can easily determine the number of nucleuses by adjusting NSN accordingly.

In order to fulfill the bone's absent segment along its height, five scaffold layers were design, considering NLS set as five. These supplementary nucleuses have been important in order to link the nucleuses across axial planes with the structure of the bone. Constructed as sweep elements, spline guiding curves and circular cross-sections were utilized. The guiding splines derived from intersection points (or nodes) of curved and straight nucleuses in axial planes have also considered to personalize the scaffold. In case if more stabilization nucleuses are necessary, one may consider adding extra nodes on the axial planes curved and straight elements in this case. Fig 5a presents the construction support of the scaffold, while Fig 5b illustrates the CBM scaffold model.



a) Construction support for scaffold



b) Scaffold model with axial and transversal curves

Fig. 5. CBM scaffold model for the tibia bone

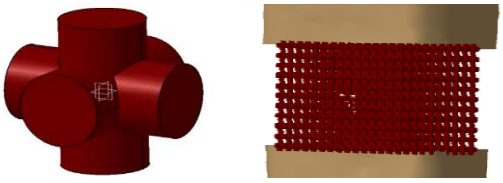
To validate the proposed methodology, the same scaffold model generation procedure was implemented on four sample models. The input parameters mirrored those of the development model. The primary test parameters were the Number of Straight Nucleuses (NSN) and the Scale Factor Set (SFS) since they have a direct impact on the scaffold's architecture. Consistency across all models with regard to NSN and SFS values were considered for the developed model, indicating the efficiency of the chosen parameters for this sample set. However, it is crucial to note that this setting pertains solely to geometrical precision of the designed structure. Further studies are required to evaluate the scaffold's robustness and its capacity for cell nutrition.

5. PATTERN BASED METHOD

PBM uses nucleus elements to define a unit cell. A nucleus element is essentially a cylinder with a parameterized geometry and form. For this particular example, a circular cross-section with a radius r=0.5mm and a cylinder length L=1mm extending in both directions was considered. However, depending on specific medical scenarios, the generated structures might differ. The base unit cell can be seen as a 3D cross with nucleus elements arranged in four different orientations, as presented in Fig. 6a. The corresponding pattern model for the bone shaft is shown in Fig. 6b. Through the creation and application of unique unit cells, varied porosity values (P) and surface-area-to-volume ratios (R) can be obtained. These metrics are defined according to reference [16] and equation (1).

$$P = 1 - \frac{V_s}{V_t};\ R = \frac{S}{V_s} \tag{1}$$

where: V_s is the volume of scaffold material,
V_t is the total volume contained by scaffold,
S is the surface area defined by scaffold volume.
The 3D pattern structure was made up of unit cells and was formed by duplicating this unit cell across the volume model of the bone's missing segment, as illustrated in Fig. 6b. This patterned structure functions as the cut out element in the intersection Boolean operation, where the boundary volume has been considered the primary object in this case.



a) Nucleus element b) Created Scaffold Pattern

Fig. 6. Pattern scaffold model based on the simple cross nucleus element

6. CONCLUSION

The paper presented unique personalized design strategy that was based on two methodologies for creating parametric scaffold models. This strategy allowed the generating of individualized scaffold models for patients, using either a Curve-based or Pattern-based approach. Both methods can be used to produce effective models, with the PBM being more computationally demanding. The decision on which model to be selected is up to the medical specialist, based on the specifics of the clinical situation. The introduced parameters facilitate customizing of diverse scaffold architectures, allowing for variations in the geometry of nucleuses and the sizes of pores and cells for the scaffold. Using these parametrically designed scaffolds, surgeons can design the ideal scaffold model for individual patients. Patient-specific scaffolds can be produced by using additive manufacturing processes. The current approach was focused on geometric aspects, implying the primary concern in designing of structures. Future research are needed to explore materials that are ideal to be used for producing the scaffolds, mechanical resilience, cell nutrition and other scaffold prerequisites to validate the potential application of the showcased scaffold model effectively in practice.

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Crearea modelului 3D personalizat al structurilor osoase prin utilizarea metodologiilor bazate pe modelare cu suprafeţe curbe şi modele parametrizate personalizate

Rezumat: Ingineria țesuturilor este un domeniu științific care se concentrează pe dezvoltarea de alternative biocompatibile pentru țesuturile deteriorate sau bolnave. Aceste structuri înlocuitoare constau de obicei din celule, o structură de susținere şi factori ce favorizează osteointegrarea. Structura de susţinere acționează ca un sistem de sprijin pentru celule, facilitând creșterea acestora și regenerarea țesutului. Designul sau arhitectura structurii de susţinere a celulelor joacă un rol crucial în asigurarea stabilității mecanice a structurii și a transportului eficient al nutrienților către înlocuitorul de țesut. În această lucrare este prezentată o abordare nouă pentru crearea modelelor de structuri de susţinere a celulelor 3D personalizate, utilizând Metoda caracteristicilor anatomice împreună cu două metodologii originale personalizate dezvoltate de către autori. Prima metodologie este bazată pe generarea unor structuri de susţinere curbe, în timp ce a doua este bazată pe modele de structuri personalizate parametrizate ce au fost dezvoltate de autori. Metoda caracteristicilor anatomice este o metodă de succes care a fost deja implementată pentru generarea de modele geometrice personalizate ale oaselor. Principalele avantaje ale structurilor de susţinere a celulelor personalizate create folosind această abordare includ un proces de proiectare simplificat, care permite personalizarea semi-automată și crearea unui model tridimensional al unei astfel de structuri de susţinere în final.

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