Matching of Mechanical Properties of Biological Tissues and Technical Materials for the Fabrication of Anatomical Models by Material Jetting

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Abstract: Realistic, high-fidelity anatomical models with material properties corresponding to those of human tissue can be used for surgical planning and training, medical education and medical device testing and validation. Conventional manufacturing of anatomical models is a time consuming, and expensive process, which nevertheless is not able to fully mimic the complex nature of the human body regarding geometry and mechanical properties. To create models closer to reality in a fast and cost-effective way, additive manufacturing, especially the process of material jetting, can be a solution. Utilizing this process, it is possible to fabricate multi-color, multi-material objects with complex geometries, high resolution, and even gradients in material properties. To replicate the mechanical properties of biological tissues, they must be matched with the technical materials or material combinations available for the utilized manufacturing process. Therefore the authors propose to conduct measurements according to standardized testing procedures like ISO 37 for tensile and ISO 48-4 for indentation tests, which allows matching to the manufacturing materials and thus will result in the possibility to create more accurate replicas of the human body that provide realistic haptic feedback.

1 INTRODUCTION

Anatomical models provide benefits in a multitude of different fields. In preoperative planning, they support the familiarization with the patient's specific anatomy and provide a hands-on approach of testing different surgical strategies. Especially in physicians specialties which require very delicate surgical procedures, the annual likeliness of a malpractice claim can be up to 19 % (Anupam et al., 2011), which shows that accurate planning and preparation is critical to avoid mistakes during surgery. Here the field of reconstructive surgery is a good example, where, for optimal results in the recreation of appearance and healing of functional losses, a deep knowledge of the pathology is needed, which can be aided by a realistic and tangible representation of the situation (Chae et al., 2015). Detailed models can be used to show the planned procedure to the patient, explain the difficulties and thus support patient education and informed consent. They even can support the physician during surgery by providing information regarding orientation. (Malik et al., 2015) All of this leads to a reduced duration of the surgery, less trauma to the patient and overall better results (Chae et al., 2015). The use of anatomical models can also aid the understanding of the human body in general by conducting research activities on additive manufactured anatomical structures (Birkholz et al., 2020).

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Studies have shown that additively manufactured anatomical models are able to represent the human anatomy and pathologies realistic enough to be used in medical education (Riedle et al., 2019). Training by using high fidelity anatomical models providing haptic feedback was shown to result in a better performance and more profound understanding than conventional methods like educational texts, 2D images, or virtual 3D models (AlAli et al., 2018) (Ström et al., 2006). Since the use of cadaveric materials or animal tissue for the teaching of anatomics has been a controversy regarding ethics and health since its introduction, issues can be avoided by using artificial, but realistic representations of the human body (McMenamin et al., 2014).

Another important use of anatomical models is the testing and validation of medical devices. Such a mock-up does not always have to replicate the complete anatomy or all the physiological properties of the intended usage environment (Yoo et al., 2020). However, often good representation of the anatomy as well as the mechanical properties is needed to conduct meaningful research (Sulaiman et al., 2008).

Conventional manufacturing of individual, high-fidelity anatomical models is a time consuming, and expensive process, which nevertheless is not able to fully mimic the complex nature of the human body regarding geometry and diversity of mechanical properties. This problem can be solved by additive manufacturing, which allows the creation of highly complex geometries utilizing multiple materials. (Maragiannis et al., 2015)

2 POSSIBLE PROCESSES FOR ADDITIVE MANUFACTURING

The process of additive manufacturing was first presented by Chuck Hull in a 1984 patent. The presented process of stereolithography is a form of vat photopolymerization, where the resin is selectively cured by using a laser scanner (Hull, 1984). Generally speaking, additive manufacturing is a process where material is, in contrast to subtractive manufacturing, automatically added, mostly as layers, to create a physical object based on 3D-data (DIN EN ISO/ASTM 52900). Important key facts of the process are:

- The geometry is based on 3D-CAD data.
- No product specific tools are needed.
- No need for fixation of the product.
- Complex geometries, like undercuts, can be manufactured effortlessly. (Gebhardt, 2016)

DIN EN ISO 17296-2 defines the seven different additive manufacturing processes binder jetting, directed energy deposition, material extrusion, material jetting, powder bed fusion, sheet lamination, and vat photopolymerization, which are described more closely in table 1. Additionally, the processes can be differentiated according to the aggregate state of the raw material into generation from the solid, liquid or gas phase (Gebhardt, 2016).

Table 1: Additive manufacturing processes according to DIN EN ISO 17296-2 and Gebhardt et al. 2016.

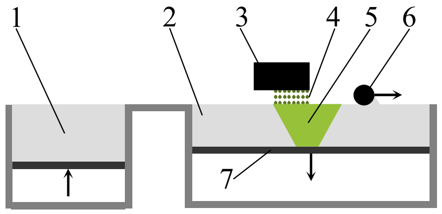
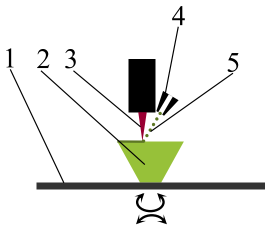
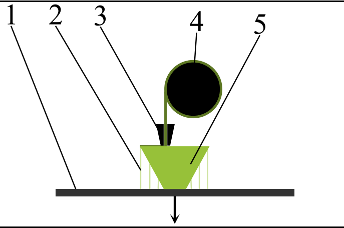
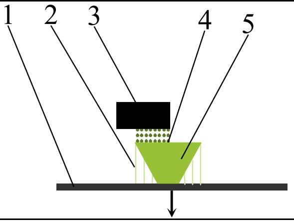
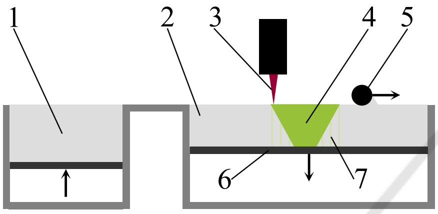
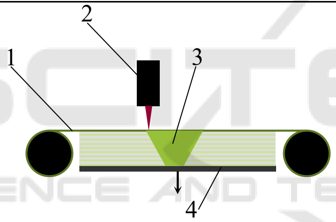
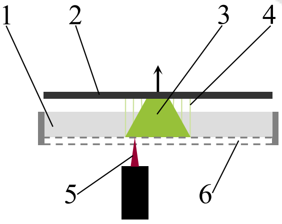
	**Binder Jetting** Binder jetting is a process, where a liquid (4) binder is applied by a print head (3) to selectively bond powdered raw material (2). New layers of material are added by a roller (6) out of the material reservoir (1), which is made possible by lowering the build platform (7). The process often consists two steps, where the additive manufacturing is creating a green body (5) which afterwards is infiltrated or cured. By using different binder colors, a multi-color, single-material part can be fabricated.
	**Directed Energy Deposition** Directed energy deposition uses a directed energy beam (3) to bond the raw material (5), often jetted through a nozzle (4), via melting to the product (2). The process is mostly used for the creation of metal parts and often does not depend on support structures due to the possibility of 5-axis movement of the build platform (1). By using different raw materials, multi-material or gradient parts can be fabricated.

Table 1: Additive manufacturing processes according to DIN EN ISO 17296-2 and Gebhardt et al. 2016 (cont.).

	**Material Extrusion** One of the most known processes is material extrusion, where the raw material (4) is extruded through a nozzle (3). Layers are created by lowering the build platform (1) or raising the nozzle. Products (5) with complex geometries depend on support structures (2). By using different raw materials, multi-material and multi-color parts can be fabricated.
	**Material Jetting** In material jetting the print head (3) deposits the raw material (4) in form of droplets. The layers mostly are created by lowering the build platform (1). For the fabrication of the product (5), support structures (2) are required most of the time. Due to the voxel-based approach, multi-material, multi-color, and gradient parts can be fabricated.
	**Powder Bed Fusion** Powder bed fusion uses thermal energy (3) to selectively bond powdered raw material (2) by melting or sintering. New layers of material are added by a roller (5) out of the material reservoir (1), which is made possible by lowering the build platform (6). Depending on the material used, support structures (7) can be necessary for heat dissipation to prevent the product (4) from deforming. Only single material parts can be fabricated.
	**Sheet Lamination** Using sheet lamination, the three-dimensional part (3) is created by bonding sheets of material (1). Here a thermal energy source (2) can be used, but also a separated system consisting of a cutter and a lamination tool are common. The layers are created by lowering of the build platform (4). By coloring the sheets, multi-color parts can be fabricated.
	**Vat Photopolymerization** In the process of vat photopolymerization, a liquid photopolymer (1) is selectively cured inside a vat by a light source (5), often through a transparent bottom (6) of the vat. Layers can be created by raising the build platform (2) out of the photopolymer. Single material parts (3) can be fabricated, depending on support structures (4) for complex geometries.

3 ADDITIVE MANUFACTURING OF ANATOMICAL MODELS

For the creation of anatomical models, a wide variety of direct or indirect additive manufacturing processes has been used so far with varying degrees of success (AlAli et al., 2015). To generate high fidelity replicas of the human anatomy with a realistic haptic behavior that can possibly be used to replace human or animal tissue for medical education, surgical training, and medical device testing, a suitable manufacturing process is needed. Based on the specifics of the structure of biological tissues (Fung, 1993), certain requirements can be derived:

- High resolution
- Ability to create complex geometries
- Ability to replicate different tissues
- Ability to manufacture gradients and create anisotropic material properties

To achieve these, material jetting is the best-suited process. Because of the voxel-based approach and multi-material capabilities of typical machines utilizing this approach (stratasys, 2020), gradients and anisotropic materials can be manufactured. Additionally, the process has a high resolution and can create complex geometries using water-soluble support materials, which allows the removal from areas inaccessible to conventional tools. The selection of the proper materials or material mixtures to accurately resemble the mechanical properties of the corresponding human tissue is one of the most important points in the creation of realistic high-fidelity anatomical models.

4 MATCHING OF BIOLOGICAL AND TECHNICAL MATERIALS

To be able to match a material or material combination to the corresponding tissue, the mechanical properties of that tissue must be known and be comparable to the technical materials available. When it comes to mechanical characterization of tissue, especially soft tissue like muscle, tendons, ligaments, internal organs, and vascular tissue, researchers face special challenges. A lot of the times the desired tissue cannot be isolated for testing, the size of the specimen is too small for regular characterization procedures and it is difficult to keep the tissue in physiological condition. In addition, soft tissues show nonlinear, history dependent stress-strain relations, and large deformations, which leads to complex constitutive equations. (Fung, 1993) The tissue properties vary largely depending on sex and age, harvesting site, pathophysiological condition, environmental and physical testing conditions, temperature and time since extraction (Mattei et al., 2016).

To fully be able to predict the mechanical behavior of these materials, a multitude of different testing procedures like uniaxial tension tests, uniaxial ring tests, planar biaxial tests, inflation tests, whole-body measurements, membrane bulge tests, and many more where developed (Macrae et al., 2016). However, it has been shown, that complex testing protocols are probably not necessary for the acquisition of mechanical data with the intention to match a tissue to a technical material. The well-established process of preconditioning biological tissues before mechanical characterization might not be suitable for the creation of anatomical models as the behavior of human tissue during surgery does not correspond to a preconditioned state (Cotin et al., 2004). It also was shown that a long relaxation time between loads "resets" the materials behavior to pre-preconditioning state (Sacks, 2000). Because of this, it is recommended to characterize the mechanical properties of the tissues using industry standard testing procedures for technical materials to get matchable parameters (Riedle et al., 2018). Here especially the measurement of the stress-strain relation using tensile tests and the measurement of the tissues hardness using indentation tests will deliver meaningful results (McKee et al., 2011) and allow the comparison to technical materials usable for additive manufacturing (Riedle et al., 2019).

5 HOW TO CREATE REALISTIC ANATOMICAL MODELS

As shown in the previous sections, the demand for realistic and high-fidelity anatomical models utilizing different materials to replicate the complex tissue structures of the human body is high. Currently the most promising way to achieve this in a fast and cost-effective manner is the fabrication by additive manufacturing. Here especially the material jetting process is a good choice, since it has a high resolution and can utilize multiple materials, which allows the production of multi-color and multi-material models. Even gradients of material properties can be produced. The ability to use soluble support structures makes the creation of complex geometries, like those occurring in anatomy, possible.

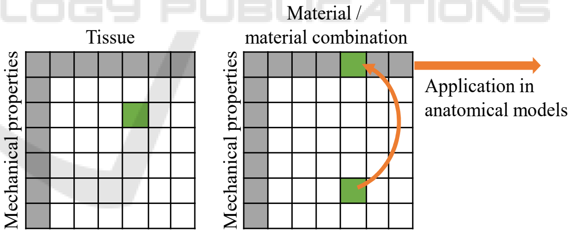


Figure 1: Matching different tissues to available materials or material combinations, the creation of highly detailed anatomical models with realistic mechanical properties will be possible.

The goal of future research is now to compare the mechanical properties of materials available for processing via material jetting with those of biological tissues. To utilize a standardized testing process increases comparability between biological and technical materials and seems to be suitable for the usage in production of anatomical models. Here especially the execution of uniaxial tension tests according to ISO 37, which mostly corresponds to DIN 53504 available for the authors, and indentation tests according to ISO 48-4 should be conducted.

While doing this, the general considerations regarding the mechanical characterization of biological tissue, like respecting its anisotropic properties, and keeping it as close to physiological condition as possible, still have to be made.

By matching the different tissues to the available technical materials for the material jetting process, as shown in Figure 1, it will be possible to create highly detailed anatomical models with realistic mechanical properties, which can be used for surgery planning and training, medical education and medical device testing without raising concerns about health or ethical issues.

6 CONCLUSIONS

This paper shows that there is a demand for realistic, high-fidelity anatomical models for surgical planning and training, medical education, and medical device testing. Since conventional manufacturing of anatomical models is a time consuming, and expensive process, which is not able to fully mimic the complex nature of the human body regarding geometry and mechanical properties, the creation of such models by additive manufacturing, especially the process of material jetting, is proposed. By utilizing this process, it is possible to fabricate multi-color, multi-material objects with complex geometries, high resolution, and even gradients in material properties. To be able to generate appropriate mechanical properties, which resemble those of biological tissues, the conduction of biomechanical measurements according to standardized testing procedures for technical materials like ISO 37 for tensile and ISO 48-4 for indentation tests is proposed, since it eases the matching to the manufacturing materials and thus will result in the possibility to create more accurate replicas of the human body, which provide realistic haptic feedback.

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