RAPID MATERIALIZATION OF A SMALL SERIES OF BONE STRUCTURE REPLICATIONS FROM A DIGITALIZED MODEL, CREATED BY COMPUTER TOMOGRAPHY

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Abstract: The recreation of bone structures from the human body has very complex geometry and a lack of symmetry. A small series of vertebrae replications, digitized by computed tomography, could serve in exercises for medical students to help them perform operational planning for inserting implant structures, cage type implants, or screws and rods implants. Additionally, these replications could be used in the planning of extraordinary clinical cases, for example complex vertebrae deformities. The replicated structure could be fulfilled in a 1:1 ratio or scaled. For the selection of an appropriate production technology a block diagram is followed which considers suitable technologies for the production of polymer parts, compared to the series size and the complexity of the geometry. Both criteria must be taken into account when considering which technology should be used in the production of polymer parts. Comparing the advantages and disadvantages of additive technologies and replication in silicone mold, the best choice for technology is set to be replication in silicone mold. The initial preparation for the manufacture of the silicone mold includes a detailed analysis of the geometry of the model for replication. The first step includes defining the runner place as well as mounting the runner to the model. To ensure the mold is completely filled while casting, positive-shaped vents in the mold are defined. Because of the complex shapes of the spinal vertebrae and the need to take out elements in many directions, the mold is divided into multiple parts. A block-diagram that summarizes the entire manufacturing cycle for replication in a silicone mold is developed.

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Introduction

Producing a part with complex geometry is always a challenging task, especially when it has to be achieved with high accuracy. The recreation of bone structures from the human body has very complex geometry and a lack of symmetry. The main rapid prototyping technologies are subtractive and additive which have applications in Implantology (Todorov, 2019) (Kamberov, 2020). In order to recreate an element of the human body, the element should first be digitalized by making a computed tomography scan and then the data processed with specialized software. The initial step is a CT (computer tomography) scan of the patient. The accuracy of the 3D model depends directly on the accuracy of the CT scan. This process is described in detail in a paper by Todorov (2018). The manufacture of a small series (50 pieces) of spinal replications, previously digitalized by computed tomography, is shown in the current research. Such sets of polymer replications can be used in exercises for medical students, to help them perform surgical planning for implant replacement of damaged lumbar intervertebral disc or to produce physical models of complex deformities. Using such models as a template, the appropriate shape of the plate-rod construct could be created in advance and inserted into the injured area. Full-scale three-dimensional (3D) models could be used as a useful tool for preoperative planning (Izatt MT, 2007).

Figure 1: Example of cage implant	Figure 2: Meshed model of vertebrae

Source: Med Tech, n.d.	Source: Author

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The replicated structure could be made at a 1:1 ratio or scaled. The cage implants are intended to replace the damaged lumbar disc and reduce pressure on nerves by providing space between two vertebrae. Example of a cage type implant is shown in Figure 1 (MedTech, n.d.).

Spine surgeons engage in complex and innovative surgical procedures to stabilize and improve injury-related spinal deformities (Zhang, 2019). The advantages of having a 3D model is that it allows for a detailed perception of human anatomy and it can be used as a tool for planning surgical procedures with computer-assisted navigation systems (Matsubara, 2008). The cage implants could be standard or patient-specific. Patient-specific implants are manufactured for each individual clinical case and have higher precision. The standard implants are manufactured in large quantities with few variants and the most suitable implant is chosen for the current patient (Gavrilov, 2019). The process of implementation includes intraoperative treatment for adjusting the cage to the bone structure. It is important to have operational planning where replications of bone structure are used. The current paper explains step by step the technology of replication in a silicone mold. The first step is shown in Figure 2, a meshed model in a STL file format after digitalizing the vertebrae from the initial CT file model.

Methods and Materials

The use of 3D modeling and rapid prototyping (RP) or additive manufacturing has been increasingly used in complex surgical pre-operative planning, as these techniques can accurately reproduce the anatomic details of highly complex deformities that could be missed or misinterpreted with standard imaging modalities (Zhang, 2019). There is also another type of technique which could beneficially be used in some clinical cases considering the manufacturing cost, material cost and complexity of the model – replication of silicon mold.

In small batches, the manufacturing product should have lowest possible cost price, which assumes the use of methods, which do not require expensive equipment (Ostev, 2017). Most conventional technologies are not applicable because of high production costs or taking too much time. For the selection of an appropriate production technology, the block diagram shown in Figure 3 is followed, which considers suitable technologies for the production of polymer parts, compared to the series size and the complexity of the geometry. The diagram in Figure 3 shows that the production of batches with complex geometry could be reduced to two technologies:

- 3D printing applying FDM technology
- Replication in a silicone mold

For both technologies, the pros and cons for making the adequate technology choice are considered. The comparison between both technologies is shown in Figure 4.

As it is seen in the chart above, the replication in silicone mold technology has better characteristics. The time for manufacturing one item using FDM technology takes 13 hours, which is longer, because the inside structure is solid. For the aims of the research, a software for 3D printing is used which

Figure 3: Choosing the most suitable technology for the production of polymer parts by taking into account the series size and the complexity of the geometry

Source: Author

Figure 4: Manufacturing time according to the volume of the part

Source: Author

calculates the cost per printing of a part compared to its volume by using an ABS material. It comes up to 2,25 € each. For calculating the price per part using a silicone mold, the price for polyurethane resin package similar to PMMA considering technical parameters is divided by the mass of the implant. The density of the resin is $\rho = 1.67 \text{ g/cm}^3$ and volume of the implant $V = 30 \text{ cm}^3$, the price for each unit is roughly 0.53 €. By adding 30% additional material cost for the casting system, the final price is roughly 0.69 € for each unit.

The replication in silicone mold has better characteristics compared to a FDM technology when we are taking into account the manufacturing time[h] /part volume[cm³]. Another main advantage of replication in the silicone mold is the higher accuracy achieved in comparison to FDM technology where it is necessary to conduct several experiments with a reference model. (Todorov, 2018).

This technology is applicable in the field where other manufacturing technologies are inappropriate. It is hard to apply subtractive technology due to complex geometric shapes, and the alternative is additive technology with 3D printing which is not optimal in some cases. Silicone mold casting is an easy and cheap manufacturing process for small complex forms (Monroe Engineering, 2019).

For the manufacture of a silicone mold for replication it is necessary to have an initial positive-shaped part. In the current case, a preliminary manufactured 3D printed model was used. For manufacturing the mold, a transparent two-component additive silicone elastomer with polymerization at room temperature was used. This product was intended for flexible forms with complex geometry that needed a high precision for manufacturing.

Initial preparation for the manufacture of the silicone mold included a detailed analysis of the geometry of the model for replication. The first step included defining the runner place as well as mounting the runner to the model. To ensure the mold was completely filled while casting, positive-shaped vents in the mold were defined. With thermoplastic material, a pouring basin is formed. The model is shown in Figure 5.

After finishing the initial preparation, the components of the silicone are mixing together until the mix is homogeneous. For precise measuring of the components, an electronic balance was used. The main issue in the process of manufacturing the silicone mold is aerifying the mixture while stirring. This problem not only leads to appearance defects, but it reflects in the physical properties of the mold (Bozzelli, 2015). One of the ways to eliminate the problem is mixing the components in a specialized vacuum chamber shown in Figure 6. Another way is degassing of the mixture in a vacuum after stirring it. This is applicable when creating a mold for small-sized parts because the time for stirring the mixture and pouring it into the mold is less than 20 minutes. After pouring the mixture and its hardening in the right conditions and ambience, it is time to divide the mold into the parts needed. Because of the complex shapes of the spinal vertebrae and the need to take out the elements in many directions, the mold is divided into 5 parts. Taking the model of the vertebrae out of the silicone mold is gently done without

Figure 5: 3D printed sample prepared for silicone casting

Source: Author

Figure 6: Degassing of the silicone in a vacuum chamber

Source: Author

Figure 7: Methods for manufacturing the silicone mold

Manufacturing of possitive-shaped model

Possitive-shaped model + casting elements

Mixing the components of the silicone

Degassing in vacuum chamber

Casting of the possitive-shaped model

Source: Author

Figure 8: Replicated model of vertebrae manufactured by casting in a silicone mold

Source: Author

damaging the integrity of the silicone model especially the inner part of the vertebrae. The whole manufacturing cycle of the silicone mold is generalized in the block-diagram shown in Figure 7.

The manufacturing process of casting of vertebrae in the created mold, until the defined series of replications is reached, is carried out in the following way. The parts of the mold are connected ensuring

the unique surfaces match. The mold is heated and the resin is poured into the pouring basin until the mold is filled. The cast vertebrae are taken out of the mold and are cleaned of the casting elements.

Conclusion

After receiving the task for manufacturing 50 vertebrae replications of a Virtual model, created by a CT file, a detailed analysis of the geometry of the replication was held in order to choose optimal manufacturing technology after considering economical and time factors. The chosen technology was casting in a silicone mold which was created using an initial 3D printed model. For creating the mold, transparent silicone elastomer with polymerization at room temperature was used which has a high accuracy of recreation. The manufactured series is appropriate for conducting exercises with medical students for operative planning for inserting implants replacing a lumbar intervertebral disc. As the wide spreading of implants in healthcare and the development of technologies for rapid materialization of digital models, common collaborations between medical specialists and engineers could be used for increasing the practical training of future medics. Moreover, applying this technology could improve the practice process of medical students with common vertebrae structures.

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