Research Article

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Selection of a workpiece clamping system for computer-aided subtractive manufacturing of geometrically complex medical models

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Abstract: Physical models of anatomical structures can be made using Additive Manufacturing (AM) or Subtractive Manufacturing (SM). The advantage of subtractive techniques over additive ones is the possibility of maintaining the homogeneity and consistency of the processed material, which is extremely important in the case of medical devices. Currently, a geometrically complex medical model can be made even on a simple, 3-axis CNC machine tool. However, often the semi-finished product must be machined in at least two clamping configurations. The aim of the work is to present the method of fixing a workpiece in the process of subtractive production of geometrically complex medical objects on the example of skull bone prostheses. The paper discusses the use of two clamping systems for machining such models. It presents the process of subtractive production of bone prostheses models fitted to the defect of the skull bone with the use of the proposed methods of fixing the workpiece. The result of the work are two models of the skull bone prosthesis. A more complex model was analysed in terms of the accuracy of geometry reproduction. The research confirmed the usefulness of the proposed clamping systems for the preparation of medical models of geometrically complex anatomical structures.

Keywords: CNC, cranioplasty, implant, machining, prosthesis

1 Introduction

The contemporary approach to product design and manufacturing is mainly based on integrated CAD/CAM systems supporting the engineering process. The designer's concept is translated by means of CAD software into a digital form (a solid or surface data file), and the process of manufacturing the actual product is then prepared in CAM software. Nevertheless, anatomical structures are not designed, and there are not many models of such structures available in electronic form. In the case of such components, it is possible to obtain virtual models with the help of reverse engineering, also called 'back engineering' [1].

Arriving at a model that accurately reflects the real object requires the correct geometrical data of the structure concerned. Reverse engineering offers various data acquisition techniques. The choice of a suitable technique is particularly important in the case of objects of complex geometry such as anatomical structures. Techniques which prove most effective for such purposes include X-ray computed tomography and magnetic resonance imaging. A key benefit of both imaging methods is their ability to reproduce the internal and external geometry of the object concerned. Data acquired from tomography and processed by specialist software are used to generate files of standard typical for CAD/CAM/CAE systems [2].

Such technologies are successfully applied with respect to custom-manufactured cranial implants. The skull is a unique bone which, unlike other bones, does not transmit weight or bear loads. Cranial bones provide natural cover for the brain's delicate tissues. Their function is to shield the brain from both trauma and infection. The skull with implants is more prone to fatal head trauma and infection. However, the removal of the skull fragment is necessary in a number of clinical procedures that aim to save lives, such as the treatment of increased intracranial pressure (ICP) or abnormal cerebrospinal fluid (CSF) flow dynamics, which are caused by head injury [3, 4].

CSF flow dynamics dysfunctions are the most dangerous complications of the basis cranii fracture, but also oc-

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cure in brain cancer. Most skull fractures will heal by themselves, particularly if they are simple linear fractures. The surgery is necessary in the case of a severe skull bone fracture. The course of the operation is dependent on the type of fracture, its location within the facial skeleton and other factors. If access to the brain is necessary, a craniotomy or a craniectomy is performed. During a craniotomy, a small piece of skull is removed so that a surgeon can access the brain, and after performing the necessary procedures, the bone fragment is put back in place. On the other hand, there is a craniectomy that is very similar to a craniotomy, but after performing it the removed bone fragment is not immediately put back into place. The bone fragment can be kept to be put back into place during a future surgery. After the craniectomy, it is usually necessary to perform a cranioplasty that aims to restoring, the natural shape of the head and providing an adequate protection against mechanical trauma. In this procedure a cranial bone defect or deformity is repaired by means of a removed bone fragment or artificial implant. However, immediate cranioplasty has a rare indications and may be performed for craniectomy for neoplastic invasion of cranium. More often the intervals between these two treatments are between 6 weeks and 1 year. The timing of cranioplasty depends on the healing of tissues after the craniectomy. The previous incision must be well healed and surrounding tissues must be vascularized [5]. The success of the cranioplasty relies heavily on the selection of the shape and the material from which the implant covering the removed cranial fragment is made [6, 7].

An ideal implant must fit the cranial defect and achieve complete closure. On the other hand, there is a material, which should be radiolucent, infection-resistant, strong to

biomechanical processes, easy to shape and cheap [8]. Materials that are currently used for making such implants include synthetics such as polymethyl methacrylate (PMMA), carbon fiber reinforced plastic (CFRP), or polypropylene-polyester knitted fabrics. In Poland, the most popular material of this type is a rigid polypropylene-polyester knitted fabric called under brand name Codubix [9] manufactured by Tricomed. It is characterised by high biocompatibility and low price. However, at present, it is supplied only in a limited range of sizes and a fixed curvature [10, 11]. In many cases the bone defect has a complex shape and various curvatures in multiple planes (see Figure 1). The implant thickness usually depends on the defect size and location which can dictate the necessary functional rigidity [12].

The general-purpose nature of the implant in many cases limits the possibility of its proper fit to the complex shape of the defect. For this reason, in order to obtain a proper aesthetic effect, it is necessary to manually modify the cranial bone implants during the operation. This increases the duration of the procedure, and thus the risk of infection and blood loss [13]. The use of prefabricated implants matching a specific patient may reduce the need to adapt their shape during the surgical procedure, and consequently eliminate such issues [14–16]. It should also be mentioned that reverse engineering can be helpful in many other surgical reconstruction procedures [10].

Individual implants may be built using various techniques. One of such techniques is subtractive manufacturing. Implants located in the human body must be characterised by accurate reproduction of surfaces and unaltered internal structure of the material. 5-axis machine tools prove highly suitable for machining components of this level of geometric complexity. The implants can also be made using a 3-axis milling machine [17, 18]. Concave surfaces are considered to be more precise on a 5-axis machine. However, some works indicate that 3-axis and 5-axis milling show almost the same surface shape deviations [19].

Although the production of implants and prostheses using 3-axis machines is more complex than with 5-axis machines, it is more cost-effective for unit production. First of all, 5-axis machines are more expensive than 3-axis machines. The more complex the technological process, the more expensive it is, and it is more difficult to find suitable specialists who would be able to make such a model.

Furthermore, skull bone prostheses have quite a specific geometry. They are usually thin shell plates, and that makes them difficult to fix in the machine. For this reason, both 3-axis and 5-axis machine tools require a clamping device because it is not possible to clamp such a model in a holder like a tool post. It would be reasonable to make such prostheses on a 5-axis machine tool in case of serial produc-

Figure 1: Complexity of the shape of a cranial bone defect

tion. However, in this case, we are dealing with a patient-specific prosthesis. Moreover, 5-axis machining requires a longer preparation time. In the case of unit production, the preparation stage represents a significant part of the entire production time. Both 5-axis and 3-axis machining have their benefits and drawbacks. In order to produce a patient-specific prosthesis, a 3-axis machine will be sufficiently suitable.

Recently, 3D printing has started to be used to make implants and prostheses. However, it is usually not used to make such elements directly, because implantation of 3D-printed parts into the human body requires compliance with the guidelines and approval of the Food and Drug Administration (FDA) [16, 20, 21]. Apart from that, 3D printing in the context of making implants and prostheses brings several other problems. Printed parts are characterized by heterogeneity of material (anisotropy), and in the case of Fused Deposition Modelling (FDM) 3D printing, the formation of material discontinuities such as holes, which can cause tissue inflammation [22, 23]. As mentioned, 3D printing is used for the indirect manufacture of implants and prostheses. For example, it serves as a model for vacuum casting molds. Such a model is placed in a container with resin in order to obtain its imprints. These imprints are filled with the casting material and the final prosthesis is obtained [16]. Such indirect techniques require a number of technological processes and are not economically viable for the execution of a single object. These intermediate techniques also include injection moulding and thermoforming.

For these reasons, a 3-axis device will be sufficient to make a patient-specific prosthesis. However, models of cranial bone prostheses contain free surfaces, which poses serious challenges in 3-axis machining. A significant difficulty in the design of the machining process is the absence of basic reference points. One such point is the origin of the coordinate system. The semi-finished product must be machined while secured by means of at least two fixtures. Machining must be divided across two separate programs: one handling the convex surface, and the other handling the concave surface of the prosthesis. Such split is natural due to limitations related to the machine tool's kinematics but also the need to support the surfaces which have been machined during the first stage before proceeding with machining the semi-finished product in the second position. The semi-finished product must be correctly secured in order for the entire machining process to run smoothly [17, 18].

The aim of this work is to present two clamping systems for a 3-axis machine and to check if it is possible for

the manufacturing of the skull implants with idiosyncratic geometry with their help

2 The concept of machining a skull prosthesis using 3-axis milling

The realisation of the analysed cranial implant model requires machining the semi-finished product in two positions. As a different surface is to be milled in each of the clamping set-ups, the tool must be provided with reference

Figure 2: The concept of machining a complex model with a change in the clamping set-up: (a) the semi-finished product is placed on the work table, (b) the first surface of the semi-finished product is machined, (c) the second surface of the semi-finished product secured using a fixture is machined

in the form of a point in the machine tool's workspace: a point which can be universally referred to during both machining cycles. The semi-finished product which constitutes the base for the product must be firmly fixed on the machine tool's table, therefore its surfaces should be flat (see Figure 2a). This condition is no longer met after the first surface has been machined (see Figure 2b). Consequently, the subsequent stage of machining is possible only if the semi-finished product is secured in a fixture that ensures flatness of its bottom surface (see Figure 2c).

A considerable problem is fixing the semi-finished product in the second position, as every bone defect, and therefore the shape of the prosthesis is unique. As a result, the fixture holding down the workpiece in the second position must be dedicated to a specific model. Unfortunately, it is not possible to make a universal clamping to secure the workpiece.

3 Methodology

Two clamping systems for securing the workpiece in the milling machine's work area were developed as part of the present research. Both systems are presented in this study. Both of these clamping systems have been used to make skull implants of different geometries. The research was carried out for several models of different anatomical structures made of different materials such as polyamide PA6, PMMA, and Teflon. In order to make the article clear, only two selected models were presented: one for each clamping system.

To make the model with a clamping system featuring wax support, a PMMA semi-finished product was used, while in the case of the clamping system featuring a suction clamp it was polyamide. The models were visually inspected and, in the case of the second system, the accuracy of the model was analysed.

3.1 A clamping system featuring a wax support

The simplest and cheapest solution would be to find a material that would adapt to the machined surface and be easily removable after machining (like the process support system in additive manufacturing techniques). For this purpose, casting wax was used. In addition, a fixture securing the workpiece to the work table had to be designed.

The machining process was planned for the machine tool Roland MDX-40 (property of the Rzeszów University

of Technology) (see Figure 3). MDX-40 is a milling and engraving machine which enables high-precision milling – its software resolution is 0.01 mm, whereas mechanical resolution is 0.002 mm. The machine has a work area of 305x305x105 mm.

Figure 3: Roland MDX-40 milling machine

A purpose-built instrument was designed to firmly secure the workpiece in both fixtures on the work table. Modela Player software was used to prepare the machining program for a cranial bone implant [24]. For models machined on both sides, virtual fixtures are created. They are removed when the manufacturing process is completed. In the present case, fixtures are aimed at reducing the load on the casting wax support (see Figure 4). The surface of the cranial prosthesis model is geometrically complex, making it difficult to design such fixtures. Subsequent manual cutting off of such fixtures would negatively affect the correct reproduction of the model geometry. Therefore, in this case, it was decided that the fixtures would be removed at the last stage of CNC machining.

Figure 4: Image of the concave surface of the model

Figure 5: Processing stages of the bone prosthesis model

After machining programmes were designed and simulations were carried out, the next stage involved the construction of the bone model prosthesis. A PMMA panel was used as a semi-finished product. Prior to starting the milling process, the zero (XY) point of the machine tool was set (see Figure 5a). Subsequently, the Z axis was set, and rough milling by means of a 4 mm end mill cutter was performed. Next, finish machining was carried out with the use of a 3 mm ball nose mill cutter. In this way, the concave side of the prosthesis model was obtained (see Figure 5b). Afterwards, the milled space was filled with pre-heated casting wax as a support for the model during the subsequent convex surface machining stage (see Figure 5c). After the wax support hardened, the semi-finished product was turned over and fixed on the machine tool's work table (see Figure 5d). Next, the convex surface was machined in a way similar to the first set-up. Finish machining was performed and support fixtures were subsequently removed (see Figure 5e). During the last stage (post-processing), the finished model was separated from the wax (see Figure 5f).

The machining parameters used for this clamping was shown in Table 1.

Table 1: Machining parameters used for clamping system featuring a wax support

Rough machining	
XY feed	1000mm/min
Z feed	800 mm/min
Tool rotation	1000 rpm
Fine machining	
XY feed	1200 mm/min
Z feed	800 mm/min
Tool rotation	2000 rpm

3.2 The concept of a clamping system featuring a suction clamp

In this type of clamp system, the workpiece is held in position by vacuum. The clamp holding down the workpiece was designed in SOLIDWORKS software.

The first stage of the clamp design was the creation of a suitable work plane, perpendicular to the Z axis of the milling machine. On the plane, an outline corresponding to the contour of the prosthesis was generated (see Figure 6a). Subsequently, the base of the clamp to be secured in the machine tool's fixture was designed (see Figure 6b). Vacuum openings for the clamp were also designed (see

Figure 6: Design stages of vacuum clamp

Figure 7: Stages of machining the vacuum clamp

Figure 8: Stages of manufacturing cranial bone model

Figure 6c). The base of the clamp contained two pockets: a vacuum pocket and the space for the sealing cover (see Figure 6d). Lateral surfaces of the clamp featured connections for vacuum pump lines. Figure 6e the design of the clamp complete with the sealing cover (see Figure 6e).

The machining program was prepared in SolidCAM software, which is an add-on to SOLIDWORKS. The clamp holding down the cranial bone prosthesis was made on a Lagun FTV-5 3-axis CNC machine featuring Heidenhain 355 control system (see Figure 7).

The next stage after constructing the clamp was the machining of the intended part. First, the semi-finished product was pre-processed. In the first clamping set-up, the convex part of the prosthesis was machined (see Figure 9a). For the second configuration, the vacuum clamp build at a previous stage was used. A silicon sealant was applied to the edge of the clamp and the prosthesis model (see Figure 8b). Afterwards, the concave surface of the cranial bone implant was machined (see Figure 8c).

The machining parameters used for this clamping was shown in Table 2.

Table 2: Machining parameters used for clamping system featuring a suction clamp

Rough machining	
XY feed	62,5 mm/min
Z feed	25 mm/min
Tool rotation	4000 rpm
Fine machining	
XY feed	50 mm/min
Z feed	25 mm/min
Tool rotation	4000 rpm

3.3 Analysis of the accuracy of manufactured prototypes

The prosthesis for the second case, manufactured with the use of a suction clamping system, was measured by means of NIKON MCA II, a coordinate measuring arm. The measurement system is equipped with an MMDx100 laser head, which provides a measurement accuracy of ± 0.02 mm [25].

The complex shape of the implant made it impossible to precisely measure the edge of the model. Therefore, the measurement was made separately for the internal and external part of the surface of the prosthesis model. Point clouds were obtained in the measurement, allowing us to create virtual surfaces of the prosthesis. They were subsequently used to analyse the manufacturing accuracy of the prosthesis prototype model. The analysis was carried out by means of GOM Inspect software [26].

4 Results and Discussion

The clamping system designed in this study allowed us to manufacture an object of complex geometry on a 3-axis machine tool. In the clamping system featuring wax support, the wax of the increased melting temperature was used. Due to that there has not been observed the wax melting during the machining. However, considering the possibility of melting the wax, the parameters were lowered to avoid this phenomenon. The use of cooling was not necessary.

By using a wax support cushion, the contact surface of the model to be machined also supports the material, taking on the function of the material restraint. This way, it was possible to minimize the overlap area to a minimum, and the forces required to remove the object were negligible. In the final processing phase, the only clamping (model support) was a wax cushion, which at the same time, was protecting the model against edge damage during tear-out operations. The finished cranial prosthesis model made

using a clamping system featuring a wax support correctly reproduced the geometry of the virtual model (see Figure 9a and 9b).

Figure 9: Finished cranial bone prosthesis model: (a) convex surface of the model, (b) concave surface of the model

Also, the use of the vacuum clamp enabled the correct manufacturing of a cranial bone implant model matching the bone defect (see Figure 10a and 10b). There weren't any additional forces needed to tear out the workpiece from the clamping system, because the element was held by the generated vacuum. After the pressure vacuum is turned off, the component can be easily removed from the clamping system. During the machining it was not use the coolant because it wasn't necessary. The usefulness of the fixing method in manufacturing complex components on a 3-axis milling machine was confirmed.

Skull implants are usually shell type objects, which have specific geometry. They are characterized by a small thickness of a few millimetres, which is connected with the difficulty of fixing such an element in the machine and the lack of possibility to fix it in the holder, *e.g.* tool post. The

Figure 10: Finished cranial bone prosthesis model: (a) convex surface, (b) concave surface

used clamping systems enabled the machining process to be carried out. Both of them ensured that the semi-finished product is properly fixed. For shell objects, which are characterized by small thickness, it is important that the tool performs precise movements. The vibrations from the tool plays a significant role in surface generation in precise machining [27]. For this reason, a clamp with a wax cushion can be a more appropriate clamping system for this type of objects, as the model is supported on a wax cushion that additionally suppresses vibrations from the tool. However, more appropriate for more-complex models is the clamping system featuring a suction clamp.

Both models were visually inspected to detect non-progressive anomalies such as marks, stains, deformations and pollutions. Marks are surface damages such as scratches, scuffs, dent, etc. while stains are a kind of heterogeneity of the surface. The types of pollution can be any undesirable elements that are added to the surface likes a hair or a dirt particle. Deformations are any changes in the shape of the surface [28]. As a result of the inspection no anomalies were found in the model made with the second clamping. However, darker lines have been noticed on the surface of the model made with the first clamping. This

is probably due to the fact that the model was made using a portable machine, which has worse parameters than industrial machines. The cranial implants can be made using both types of 3-axis machine tools. Better quality is achieved by using industrial machines, although the execution of both models is sufficient for use as an implant.

The machining time of the models is not an important parameter because the cranioplasty is usually carried out in a planned system. The operation is preceded by stabilization of the wound, reduction of ruptures and hematomas, etc., which may take several weeks [5]. Therefore, there is enough time to produce such an implant.

The part machined with the use of clamping featuring a suction clamp was measured by means of a coordinate measuring arm, and it was performed an analysis of the manufacturing accuracy. Results for the external part of the model's surface in the form of a colour-coded deviation map are shown in Figure 11a). The results for the internal surface are shown in Figure 11b).

Figure 11: Analysis of the reproduction accuracy of the surface of the cranial bone prosthesis model: (a) convex surface, (b) concave surface

The grey colour displayed in the results of the analysis indicates locations in which attempts at measurements failed. The results suggest that the model was slightly de-

formed during machining. The biggest errors are present on the edges of the prosthesis, which may suggest that the tool working in a 3-axis system was unable to reach areas with a local surface curvature radius smaller than the radius of the machine tool cutter. The edge area machining accuracy could have been improved if a ball nose milling cutter of a smaller diameter was applied in finish machining. On the basis of the results of reproduction accuracy analysis we can confirm the usefulness of the method in terms of the reproduction of complex medical models. Deviations in the area of ± 0.4 mm are negligible in that they should not negatively impact the models' suitability in most medical application.

5 Conclusions

The aim of the present study was to verify the usefulness of various workpiece clamping methods for the purpose of machining geometrically complex components on a 3-axis milling machine. On the basis of the analyses performed, it was concluded that:

- it is possible to make geometrically complex models by means of a 3-axis milling machine. However, this approach requires preparing special machining tools beforehand. Models manufactured in this way are characterised by good reproduction of geometry. Their accuracy is satisfactory.
- in conventional methods the implant manufacturing process is performed during a surgical operation, significantly extending the duration of the procedure. The methods of manufacturing cranial implants described here almost entirely eliminate the need to adjust their shape during the procedure, which radically shortens their duration.
- fixing the workpiece using a wax base clamping system may be used in simple models with larger curvature radii. For more complex-shaped models, it is necessary to use a suction clamp or a more advanced (e.g. 5-axis) machine tool.

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