Manufacturing technology of prosthetic parts: 3-axis CNC milling of master model

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Abstract— Medical prostheses are intended to replace human body parts lost by injury or missing from birth or to supplement defective body parts. The current trend of prostheses production is directed to the application of computer systems processing digitized information and to a marked increase in the use of computer numerical machine tools (CNC). The objective of this study is to extend the application of reverse engineering technology and knowledge to fabricate the master model of missing limb. The optically digitized right upper limb was transformed into the computer master model. Further computer aided (CA) systems were implemented to automate manufacturing process and to improve the flexibility of production. The resulting master model is a crucial for the fabrication of unique prosthetics, cosmetic covers, or cavities for injection and casting. In the case study, emphasis is placed on computer aided manufacturing (CAM) and 3 axis milling on regular CNC machine tool.

Keywords— CAD/CAM, CNC Milling, Master model, Prosthetics.

I. INTRODUCTION

Prosthesis is derived from the original missing human body part. In medical practice is prosthesis an artificial device, mostly in the field of biomechatronics that helps the human body, its muscles, skeleton, and nervous system to assist with motor control lost in traumatic shock, illness or disability. Its shape is dependent on the type and extent of amputation. Prosthesis is a complex element that is requested by a series of often conflicting requirements [1]. Prosthesis material must be resistant to wear, high-strength but lightweight, harmless, and their appearance should be realistic [2], [3]. Each prosthesis is customized to disabled person, which excludes many industrial production technologies. Production of prostheses is associated with a request for special medical supplies, short fabrication time and last but not least the price as the deciding factor. These requirements are demanding for the use of new technologies. In case of replacement of the paired organ for artificial replacement is successfully used technology of acquisition and conversion into 3D digitized model. Having these data can be independent of the presence of the patient further. The subsequent step is the processing using Computer

Aided Design (CAD) systems that govern data for conventional production technologies. CAD systems work with 2D and 3D structural shapes often interconnected. The advent of CAD system was accompanied by a significant efficiency increase of the design, creation and modification of geometric entities. In today's modern manufacturing plant life cannot be imagined working without them [4]. It replaces the original drawings to electronic agenda management with all data management capabilities [5], [6]. CAD systems are available free of charge (DesignSpark) for general use. On the other hand for professional use the licensed CAD systems are required and small and medium-sized enterprises deploy CAD software that allows designing and editing 2D and 3D engineering components (e.g., Solid Edge, Inventor, PTC Creo and others). Mass production deploys CAD systems with coherent production modules (such as in NX, Catia or SolidWorks software, etc.). One of the most common synergistic modules of CAD systems, that can be a stand-alone application, is Computer Aided Manufacturing (CAM) systems. Likewise CAD, the CAM systems are tied to the emergence and development of computer technology. CAM systems are used for comfortable tool path planning of Computer Numerical Control (CNC) machine tools [7]. The complexity of engineering elements and functional requirements is necessary for the use of CAM systems. The output is a CNC program in the instructions for the machine tool, still the most commonly interpreted as a G-code according to standard ISO 6983 [8], [9]. The instructions for the machine are post processed from Cutter Location Data (CL data) as the output of CAM system. Firstly, CL data is used to verify the cutting tool movements of the machining operation and to detect collision among tool, workpiece and clamping devices of the machine. On the other hand, the CL data is input information to the postprocessor that translate instruction for a particular type of CNC machine with certain type of control system.

Small and medium volume production is necessarily performed by CNC machine tools. This category of machines the motions of tool and workpiece, process and auxiliary inputs are controlled from one control unit based on the given NC program [10]. Due to the complexity of workpieces nowadays is the NC program as an output of CAM systems [11]. Feedback among the machining part and the control unit of CNC machine allow to regulate the speed and position. This ensures tight tolerances and high accuracy of

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manufacturing process moreover support of high speed machining. CNC machine appeared during 1960s as a successor to copy and NC machine. In mechanical engineering are widely used for machining most engineering materials with considerably complicated shape surfaces [12]. In the field of medicine are serve on micromachining of biomedical materials, fabrication of implants and replacements, dental prostheses, bone machining [13], and recently for surgical procedures [14].

CNC machines are distinguished by the arrangement of the kinematic structure, the number of simultaneously controlled axes or by the machining operation. While CNC lathes are used for production of rotary parts, CNC milling machines are designed to produce flat or shape surfaces. CNC production area in the last-years has experienced considerable growth and in the scientific field is deeply explored. As for main limit of CNC manufacturing technology is highlighted a geometric shape complexity that can be achieved. Thus, for example, deep cavities, undercuts or sharp inner corners need an assistance of special technologies such as Electro-discharge machining (EDM) or Ultrasonic Machining (USM) [15].

There is no doubt that any disability significantly reduces the quality of human life. Disability from birth or accidents that lead to loss of organ, limb or other part of the human body, can be for handicapped the cause that prevents being self-reliant. In addition to associated health problems may disability be accompanied by inability to perform basic movements and thus its applicability in human society, moreover in the labor market becomes less likely. Amputation of limbs may be in addition to accidents also as a result of other health problems. Amputate is in many cases the only way of saving human life even at the expense of the organ loss. At present, orthopedics has sophisticated methodology to replace missing limbs [16]. Their purpose is to help the patient return to the greatest extent possible to wide-ranging independence. In addition to basic orthopedic compensation to control basic movements and grip ability, goes further development of prostheses to construction of the bionic prostheses, the prostheses for disabled athletes for above average physical activities and prostheses allowing a sense of touch [17-21].

Prostheses replace in part or in full the missing limb. The necessary requirement is to replace the defect, although the functionality of the prosthesis may not be completely perfect. A secondary requirement is the function of health and cosmetic compensation of anatomic loss [22]. Replacement of the function of the prosthesis is tied to the overall condition of the organism, the size of the residual stump and varies with age of the patient.

In recent years have been significant advances in artificial limbs and their production. New materials and technologies enable faster production of reliable prostheses [23]. This is achieved by using modern CAD/CAM systems that can semiautomatically create functional prosthesis with a realistic appearance [24], [25]. This paper focuses on the use of CAD/CAM systems for modeling of transradial prosthetic limbs from optically digitized existing and healthy limb. The implementation was carried out in Tomas Bata University in Zlín. Figure 1 shows the flowchart of the integrated systems of 3D scanning, CAD/CAM and CNC machining as used in article.

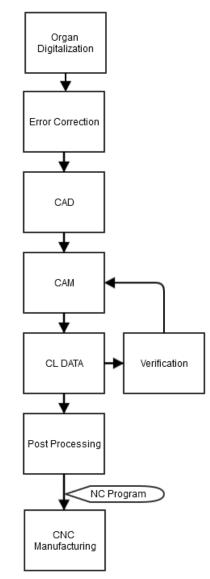


Fig. 1 General process of artificial limb production using CAD/CAM systems

II. 3D DATA ACQUISITION METHODOLOGY

The aim is to propose an appropriate procedure and fast method for fabrication a model of the human left upper limb amputated before the elbow. Procedure begins with examination of patient condition. The right upper limb is scanned since has no surgical intervention. When follows the implementation of the experiment is used 3D scanning device Atos II Triple Scan from GOM mbH. A characteristic of the device and setting parameters are shown in Table I. During the testing process was unsuitable direct scanning of the patient's arm. To obtain quality data was needed to make multiple scanning from different angles. The requirement is the absolute limb fixation in the same position throughout the entire scan. Although the scanning process is long and in this case in about minutes, any patient movement during scanning is the cause of the error rate of the spatial data. Has proven to be included an operation of casting arm preproduction. It is the fast process of obtaining limb imprint, into non-toxic alginate [26] casting die. This solution is advantageous in many ways: for scanning is obtained a solid limb model that can be fixed on a rotating table, thereby ensures a faster process of scanning and patient may not be present during the scanning. The material for making imprinted limb is a gypsum plaster, the material commonly used in medical application, in addition having excellent reflective properties for scanning by 3D scanner. Above mentioned arrangement on the basis of experience is shown in figure 2 as an intermediate step of plaster casting.

Table I Technical parameters of Atos II Triple Scan

Camera Pixels	2x 5 000 000
Measuring Area	2000 x 1500 mm ²
Point Spacing	0.02 - 0.79 mm
Measuring principle	Optical
Processing software	ATOS 7.5 Professional, GOM
	Inspect

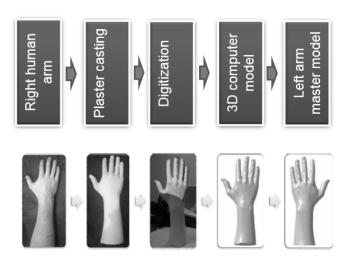


Fig. 2 Manufacturing process of left missing arm

The process of 3D data acquisition technology uses blue light spectrum in high resolution 2x5MPix with the lowest resolution 0.02 mm. The output is 3D point of cloud. While the control software to scan is the Atos Professional, for processing scan data was used GOM Inspect software SR1. Notwithstanding Atos 7.5 Professional allows working with the lowest resolution, during the scanning and processing of data was appropriate to work with a less level of detail. This results in faster processing without loss of details of the limb. Point of cloud carry information about the spatial coordinates in X, Y, Z. The data are difficult to process with engineering systems and therefore in GOM Inspect 7.5 is converted into a polygon mesh (Fig. 3). Such solution allows identifying

defects in the scanned model and repairs them. After the reconstruction a polygon mesh is stored in the Standard Tessellation Language (STL), supported by many applications as for modeling, machining, as well as for rapid prototyping [27-29].

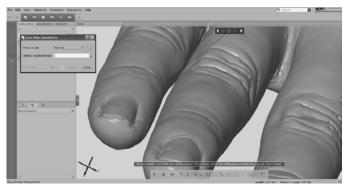


Fig. 3 Limb shape as a polygon mesh created by Atos system

Parameters	Input	Resulting surface
Mean surface deviation	0.75 mm	
Surface detail	500	
Target ratio	50	
Mean surface deviation	0.75 mm	
Surface detail	1692200	
Target ratio	50	
Mean surface deviation	0.5 mm	
Surface detail	500	
Target ratio	90	
Mean surface deviation	0.5 mm	
Surface detail	1692200	
Target ratio	90	
Mean surface deviation	0.25 mm	
Surface detail	500	
Target ratio	100	
Mean surface deviation	0.25 mm	
Surface detail	1692200	
Target ratio	100	

Fig. 4 Surface reconstruction

III. CAD/CAM PROCESSING

The physical model of the limb is directly generated from

collected spatial data. CAD/CAM systems work with a model in a graphical environment. To address adjustments is used CAD system Catia v5r18 from Dassault Systèmes. Catia allows retrieving data from STL and enables conversion into surface or volume objects. The level of details in the conversion influence not only the amount of data describing the object, but also can filter out the areas below the resolution of production technology. The effect of parameter changes can be seen in figure 4. From combinations of parameter values implies that the optimal result is given at the mean surface deviation of 0.25 mm, surface detail 1 692 200 and target ratio 100. This phase is an important pre- machining step, because the model of the limb must comply with all medical requirements. Design modifications are made depending on the initial state of the patient's limb, to adjust the dimensions of the individual part, to subtract or union entities, or to improve appearance of the limb. Further, mirror transformation of the 3D model obtains the copy of the missing limb (Fig. 5).

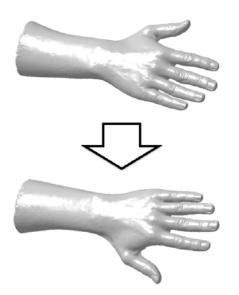


Fig. 5 Mirror transformation of the limb in CAD system

Socket is reconstructed on the resulting solid model of the limb according to amputation by subtraction of the scanned model. The most important aspect of the leg prosthesis is the socket design - the socket is the interface between the human limb and a mechanical support system. Note that the average amputee requires three to five prostheses during five years, because of changes in the residual limb.

Preferably, the volumetric model of the limb is used for prosthesis reconstruction, but also for making cosmetic prostheses (Fig. 6) or molds for fabrication (Fig. 7). Computer CAD systems allow storing 3D models and promptly remodel to the current requirements and inexpensively create a new prosthesis custom made and particularly comfortable.

In order to ensure rapid production of prosthesis with the required quality offers the CAM systems necessary solution. The technology uses automated operations for creating tool paths for machining on a CNC machine tool. This study uses CAM system NX 8.5 by Siemens. NX is not limited to one

machining technology: allows milling and turning in two or automation of drilling more axes. the machining. unconventional machining methods and other engineering technologies. In the case of mono block workpiece machining, first are arranged roughing operations that using large diameter tool withdraw as much material as possible in the shortest time. The surface after machining contains more or less residual material depending on the previous set of cutting conditions. It must be therefore followed by the finishing operations. Finishing operation in comparison to roughing, cuts minimum amount of material, for machining of common surfaces are used cutting tools with the radius and diameter gradually decreasing. In this case, three-axis milling technology has been used with double workpiece clamping. Cavity Mill was used as roughing algorithm, where machining takes place in the gap between the workpiece material and the model of the limb. Since the vector of the fingers of the limb is parallel to the Y axis, moreover model contains a minimum surface area of steep and therefore is applied Contour Area algorithm. Tool paths in the Contour Area are projected off the reference plane on the surface of the limb (Fig. 8), and individual cuts take place incrementally in the parallel ZY planes.



Fig. 6 Prosthesis and cosmetic covers

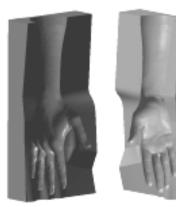


Fig. 7 Example of casting mould

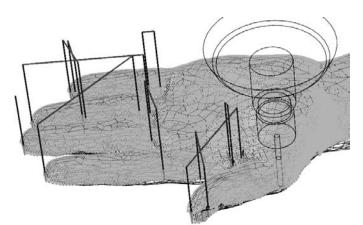


Fig. 8 Tool paths of finishing operation programmed by NX CAM system

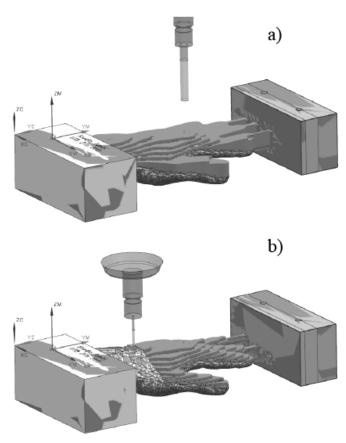


Fig. 9 Rough milling (a) and finish milling programming (b)

CAM system ensures that the limb is machined to the required quality, without collisions and in the shortest possible time. To this end, the vast majority as well as NX includes a module for tool path verification and collision detection. In the event that the proposed machining strategy by CAM system is acceptable, follows a conversion of CL data into instructions for the CNC machine tool, transfer to the CNC machine and manufacturing. Although instructions contain information about the movement of the tool in space and process changes, cannot be used for manufacturing since they do not distinguish the type of specific machine tool. Before post-processing CL data for finishing are as follows: TOOL PATH/CONTOUR_AREA, TOOL, BALLMILL_D3 TLDATA/MILL,3.0000,1.5000,41.0000,0.0000,0.0000 MSYS/-70.0000,25.0000,-198.9586,0.0000000,1.0000000,0.0000000,0.0000000,0.00 00000,1.0000000 \$\$ centerline data PAINT/PATH PAINT/SPEED,10 PAINT/COLOR,186 RAPID GOTO/301.2516,59.8328,25.0000,0.0000000,0.0000000,1. 0000000 PAINT/COLOR,211 RAPID GOTO/301.2516,59.8328,-15.2000 PAINT/COLOR,42 FEDRAT/MMPM,2500.0000 GOTO/301.2516,59.8328,-23.9235 GOTO/301.3015,59.2560,-24.0092

PAINT/COLOR,37 GOTO/-1.4995,2.8406,17.8000 PAINT/COLOR,211 RAPID GOTO/-1.4995,2.8406,25.0000 PAINT/SPEED,10 PAINT/TOOL,NOMORE END-OF-PATH

Below is a part of the CNC program for finishing the top of the limb model translated from CL data:

% N0010 G40 G17 G90 ;operation: Finish2 N0020 T00 M06 N0030 G00 X301.252 Y59.833 S10000 M03 N0040 G43 Z25. H00 N0050 Z-15.2 N0060 G01 Z-23.923 F2500. M08 N0070 X301.302 Y59.256 Z-24.009 N0080 X301.35 Y58.69 Z-23.867 N0090 X301.391 Y58.222 Z-23.518 N0100 X301.417 Y57.923 Z-23.016 N0110 X301.426 Y57.814 Z-22.712 N0120 X301.436 Y57.706 Z-22.673 N0130 X301.454 Y57.49 Z-22.737 N0140 X301.466 Y57.359 Z-22.794

N7760 X-1.5 Y2.841 Z13.538 N7770 Z-22.97 N7780 Z17.8 N7790 G00 Z25. N7800 M02 ;end of the program %

IV. CNC MACHINING

Machining is the final step in the fabrication of the artificial limb. All data prepared in the previous steps must ensure to build the prosthesis adapted to different medical requirements. Successful production is the result of synthesis of design data, processing conditions, but also an accurate machine tool, cutting tool and the workpiece material. In our case, for the model of the limb is selected plastic material based on polyurethane resin as shown in table II.

Table II Technical data and processing of polyurethane resin

Hardness (ISO 868)	62 Shore D
Coefficient of thermal	52 x 10 ⁻⁶ K ⁻¹
expansion (ISO 75)	
Density	0.70 g/cm^3
Compressive strength (ISO 604)	26 N/mm ²
Flexural strength (ISO 178)	30 N/mm ²
Application	master and copy models,
	general modeling
Cutting tools	for wood and metal cutting

Polyurethane is physiologically harmless, has excellent processing properties, together with a fine structure and smooth and paintable surface. This material supports the use of high cutting conditions and high speed machining (HSM). It is a material that is used also in the automotive industry for the production of general models. Three-axis CNC milling HWT AZK-C442 was used, intended for plastics machining, graphite and light metals. In CAM systems were designed tool paths, optimal process conditions and tools. In the table III are listed the process parameters and associated tools from SECO company. Three-axis machining requires two clamping. The operations were carried out in order first clamping, roughfinish cutting of palm, second clamping, and rough-finish cutting the back of the limb (Fig. 10).

	*	-
	Roughing	Finishing
Cutting speed	314 m/min	169 m/min
Feed per tooth	0.125 mm	0.250 mm
Revolutions	10 000 min ⁻¹	18 000 min ⁻¹
Feed rate	2500 mm/min	2500 mm/min
Axial depth of cut	4 mm	-
Radial depth of cut	$75\% \times Tool$	$8\% \times Tool$
	diameter	diameter
Tool type	End mill	Ball mill
Tool specification	SECO 93L100	SECO 971032
Tool diameter	10 mm	3 mm
Tool length	72 mm	41 mm
Flute length	52 mm	23 mm
Flutes	2	2

CAM system estimates the total cutting time based on process parameters. Roughing time was calculated to 56

minutes, while finishing operations, due to the small radial depth of cut and takes 1 hour and 32 minutes. It is necessary to consider during machining that the real processing time on CNC machines will be longer, depending on the machine type, degree of automation and tool changer and the dynamics of movements. The resulting machining time can be extended by up to 60%. The result of processing is shown in figure 11.

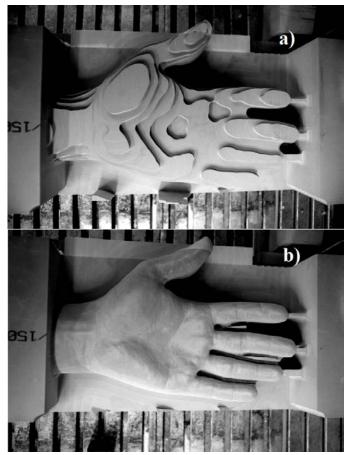


Fig. 10 After first clamping: rough milling (a) and finish milling (b)



Fig. 11 Final part of the limb machined by three-axis CNC machine tool

V. CONCLUSION

The proposed process for the fabrication of artificial limb is rapid owing to the application of Computer Aided systems. Procedure includes making a plaster casting of the limb which is better for the patient, since this step requires a few minutes on average. The resulting artificial limb can be obtained by CNC machining within 4 hours. Further acceleration can be achieved by multi-axis CNC machining.

The advantage of this solution is in making solid model of the missing limbs, moreover the electronic data can be archived, as well as adjusted to custom requirements, and besides prostheses can also be created tools such as molds for casting or injection moldings.

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