An Approach in Manufacturing of Medical Implants

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ABSTRACT: Scanning techniques and computer aided design and manufacturing of the products, widely applied in industry, are feasible to take a place in medicine also to improve medical surgery results. Approach which is described in this paper in implant manufacturing is based on scanning, computer modelling and machining process. Proposed procedure contains rendering of 3D-models created from CT-data to design and to machine a customized implant on machine tool. As a result, implants geometry is unique and raises the precision of implantation surgery and consequently, customized implants can serve for as twice the time for standard implants. This paper will show the procedure of obtaining customized hip bone implant.

Key words: implant, machining, CT, RE

1 INTRODUCTION

Human body is exposed to injuries and aging what results with loss of functionality of certain parts. In order to achieve the earlier functionality with standardized parts, reconstruction of parts of human skeleton could result in some percentages; with decrease of the surgery success, since each bone and skeleton has unique shape. Usual procedure of implants manufacturing has been settled in production of standardized sizes and shapes of implants. These parts can be in situ combined during implantation process. Possible consequences of implantation of nonperfect implants could be shortening of service time or even loose of implant.
It seems to be reasonably to consider the other manufacturing procedure that is more flexible and custom oriented. Nowadays, it is possible to reconstruct loosen parts of bones and to produce customized implants. As a result, implant geometry is unique and raises the precision of implantation surgery and consequently, customized implants can serve for twice the time for standard implants. It should be also mentioned that this procedure can't be performed in real time and took some period of time.

2 ON THE WAY FROM VISUALIZATION TO MATERIALIZATION

Croatian Hospitals are faced with needs of substantial reduction of duration of hospital treatment per patient. In recent years has been also shortened the lead surgery time demanded by customers. This environment is of great importance and especially significant for shops that offer logistics in special medical devices and implants.
Contributing to step over, several research institutions from Croatia and abroad in recent years, leaded by medical companies and commercial organizations, have integrated Computer Aided Design (CAD) and Rapid Prototyping (RP) to produce 3D physical medical models.
This approach provides the visualization of very delicate anatomical structures within the anatomy as well as pathology in unconventional (non-standard) sections and angles of viewing, which cannot be obtained by standard endoscopy or 2D-CT scanning. Three-dimensional reconstruction of anatomic units becomes a routine preoperative procedure, providing

a high useful and informative visualization of the regions of interest, thus bringing advancement in defining the geometric information on anatomical contours of 3D model by the transfer of so-called "image pixel to contour pixel".
The most practical way of implant materialisation is early implant machining (on milling machine) and fixing it on the certain tolerances (using the user-friendly interface and visualization techniques) based on the CT data (enhanced with additionally SSD technique for 3D object obtaining). This platform containing digital model data provides that implant materials produced in blocks can be machined or even tested on the model of the origin bone material before the surgery act starts in practice. This procedure doesn't suffer from sterilization problem as one can expect if the implant is made during the surgery (that means reshaping of the implants produced in the sheet (folia) forms. Finally, the product created in this way i.e. modelled from one massive piece of biomaterial, will match exactly (3D shape) patient's anatomical region to be cured (changed or replaced). For each patient the customized 3D models of anatomical regions to be surgically treated and replaced after the tumour process has been removed, will be manufactured. This approach exhibits a large benefit for surgery practice, because it ensures properly postoperative functioning of patient's anatomical/organic system. It means that these parts becomes in fact almost the same to its original natural model.

3 VOLUME RENDERING

Standard software for volume rendering which was used, provides: a) multimodality image review; b) image comparison and c) image processing with simplicity and power. In addition, a large portfolio of clinical applications offer advanced image analysis. The system design focuses on modularity, offers leading-edge performance with a variety of product configuration.
It supports DICOM 3.0 standard in order to provide easier integration into the radiology department and to enable connection to DICOM – compliant devices from multiple vendors.
Its great advantage is that many clinical applications are compatible with our system which allows us to use some already made tools to enhance our results. It provides number of benefits that helps in reduction of operating costs, improve departments productivity and increase diagnostic confidences.

4 CNC MACHINING

In CNC production, final geometry of product is machined directly from computational geometry of model. It means that whatever geometry the customer sends to the shop, the shop sends to the machine tool.
Bone implants, devices and attachments are machined from biocompatible hard metals, Co-Cr steels, stainless steel or titanium. They're mostly characterized by high length to diameter ratios, and by wide differences between cross section areas. This combination of part length to diameter ratio prolongs machining times. Material hardness and depth of cut mandates numerous machining passes or increase the cutting forces. High cutting forces increase the risk of tool/part bowing or deflection.
Some would say that complex shape surface can be divided into close to plane, mainly concave and mainly convex feature and can be arranged in related simple sculptured surfaces, but these demands on implants surface complexity does not allows fully standardized chaining of the designing procedure with machining process.
The importance of CAD/CAM integrating activities, since cutting with machine tools is a very expensive activity, in which even little progress, achieved in technology, can provide higher implant machining efficiency. E.g. efficiency to obtain acceptable tool paths is dependent on implant surface form involve big importance of feature technology development that is very optimistic in complex form machining.
This integration provides a consistent surface finish and make results predictable.
Furthermore, the basic task of applied software is to generate fast the NC code for the tool paths but these paths must be safe and free of collision. Therefore collision check algorithms have to be used and be integrated into CAM system itself. It is important that not only the tool is included into the collision check but also the spindle and machine heads.
Based on user-defined tolerances, the CAM system automatically detects and corrects gaps and also duplicates geometry during CAD import. Steadiness of the tool movements during its path as a result of acceptable tool path determination can reduce the vibration, machining time and costs as well. As a

result of such paths, rounded and smooth machined surfaces of the implants can be produced. Therefore grove profiles and large tool path spacing are not convenient. Machine tool structure has to be build up with positioning abilities in several degrees of freedom for obtaining orientation and positioning of tools and workpieces determined by measuring systems.

4.1 Tool selection and path determination

An important step in manufacture of a part by CNC machining is selection of cutting tools. Selecting an optimal combination of tools for roughing and finishing is known to be a difficult task. Previous work reported by the authors (Lim, et al. (2000)) describes a method for calculating the exact area a given size of tool can access in any given bounding volume/profile. Although, it has been known for long time that the choice of cutter sizes (diameter) can have even a dramatic effect on the overall machining time, few algorithms for optimisation have been available to the production engineer. One could say that the total outcome of machining is fully dependent on level of know-how being used in the application of the machining strategies in the means of tool trajectories.
The need for software to support the selection of tools is of increasing importance, as flexible machining systems proliferate. In such environments, where production is opportunistically scheduled, the intelligent use of available tooling will be essential. Hard work on tool selection is concerned with the effect on different production criteria (prolonged tool life or low operating costs). It is difficult for human planners to select the optimal or near optimal machining strategies due to complex interactions among tool size, part shapes, and tool trajectories.
The programming solution has to reduce the time necessary for the development of the technology necessary information enabling unification and accuracy. According to implemented knowledgebase of the CAM-system, the user will be assisted at the choice of suitable tools, best cutting speeds and best strategies. Unsteady tool path can be caused by inaccurate algorithms for path generation or by inacurate calculations within given machining tolerances, that are needed to generate linear interpolated paths on sculptured surfaces. With tolerance decreasing, a large number of points on the tool path have to be generated what decrease the points distance and slowdown machine tool.
It is very important to obtain rounded and smooth machined surface of the implants. Therefore grove profiles and large tool path spacing are not convenient.
Currently, a lot of machining shops employ the traditional method of constant feedrate cutting for sculptured surface parts. This can result in significant tolerance deviations. By varying the feedrate based on the cutter chip load predicted by machining models, a more constant tool deflection can be attained, resulting in much better tolerances in the same machining time or similar tolerances in less time.
In order to minimise number of tool changes either automatic or interactive, cutting parameters are dynamically optimised and a single tool is selected for each feature. Tool selection depends on the geometry of the feature to be machined. Issues governing the effects of residual material left behind by oversized cutters are also not adequately addressed.

4.2 Machining of the hip bone implant

To visualize hip bone we have used Computerized Tomography System Sytec 2000+ (GE).
To materialize a part of hip bone we have used cylindrical block (diameter 70 mm and 130 mm length). Milling was performed on Mori Seiki Frontier M CNC machining center with three tool (smallest diameter was 2 mm).
Some details during the milling of implant are shown in figs.1-3.

Fig. 1. Hip bone after rough machining

Fig. 2. Machining of hip bone

Fig. 3. Hip bone after machining

5 CONCLUSION

In accordance with solid model obtained after CT it is possible to manufacture hip bone implants from block material on milling machine. Approach in bone surgery treatment that was presented in this paper offers great potentials in time saving and eventually possible postoperative treatments. This procedure is revolutionized since it could be planed and starts at the moment when the preventive CT is performed. All the phases are based only on CT data and procedure of implant production is automatically linked with CT report. That means that the human errors and its leakage are reduced to minimum and the surgery results because of that become more successful. Machining time has to be improved and we pointed out a tool selection (number and paths) as very important and critical in that manner. Also, there is consideration regarding tool path overlapping to achieve better surface quality. In following work we will try to apply our theoretical considerations addressed on machining process.

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