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Micro-machining of bovine bone for otologic applications

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Abstract
Prosthetics in otology plays a significant role in restoring the structures damaged by traumas or pathologies. The aim of this work is to propose a new approach to manufacture and to control the finishing of bone mini-devices for otologic applications through a combined use of CAD/CAM and CNC.Indeed, micromanufacturing can improve the fabrication process of bone components with respect to the traditional hand-sculpting approaches. After a description of the preliminary studies carried out to define the best cutting parameters for bovine bone, this study focused on the manufacturing process and quality, by an *ex-post* analysis, of two bone structures useful for reconstructive surgery: the external auditory canal wall and the modified incus to be repositioned during ossiculoplasty. In the first case, a microCT analysis showed a flaw that led to a decrease of the thickness, which was compensated and controlled on a second prototype. As for the incus, due to its tiny dimensions few detachments of the material were noticed on the surface which needed a further step of refining to accomplish the surgeons' specifications. This new approach, based on innovative manufacturing technologies, may represent a significant advancement towards industrially reliable approaches to produce new biocompatible devices in the otologic field.

Micro-machining, bone, micro-prostheses, biomaterials, bioengineering

1. Introduction

The auditory system is a complex apparatus in which the acoustic vibrations are collected, amplified and ultimately transmitted as electric impulses to the nervous system. Traumas or pathologies can affect both the bone and the membranous structures, which are particularly involed in sound conduction and mechanical transmission, thus leading to conductive hearing loss. Therefore, to restore the auditory sense it is important to replace the damaged parts with prostheses [1, 2]. The currently implanted replacements are made of syntethic materials, such as titanium and hydroxylapatite, or graft tissues, such as autologous, homologous and heterologous bone and cartilage. While synthetic prostheses are industrially produced to achieve the requested precision, biologic materials are still hand-sculpted in the operatory theater. The rate of extrusion of synthetic material-based devices is still relevant (up to 20% in midterm). On the other hand, biologic materials like bone are rarely available in pre-formed sizes with good finishing. Recently, micro-machined devices made of biologic materials have been proposed in otology. Homologous bone was used to produce micro-prostheses able to replace partially or totally the ossicular chain [3]. Bovine bone shows biomechanical features similar to those of the human counterpart, and represents a convenient choice for availability, since it has been proven that the risk of infection is significatively low [4]. This work focuses on the manufacturing of two bone structures useful during reconstructive surgery: the external auditory canal (EAC) wall and the modified incus to be used in ossiculoplasty. The EAC wall is an osseocartilagineous structure that is demolised during tympanoplasty; differently, the modified incus serves to restore the mechanic connection in the damaged ossicular chain during ossiculoplasty. In this study, computer numerically controlled (CNC) manufacturing was applied to obtain these two structures in bovine bone with suitable precision.

2. Preliminary studies on the cutting parameters

Bone is a anisotropic nano-fibrous composite with a complex hierarchical structure: it is special connective tissue consisting of bone cells (osteocytes) and an intercellular substance (primarily, collagen type I) impregnated with hydroxyapatite. The presence of this latter, gives bone the hardness that distinguishes it as a rigid connective tissue, whereas collagen imparts resistance. Bone is more resistant and more rigid, hence more fragile, along the longitudinal direction with respect to the circumferential and radial directions [6]. In order to define the best cutting parameters, two preliminary studies on bovine bone manufacturing were performed. In both cases, a pre-processing of the raw material was performed to obtain a complete decellularization: the extremities were cut into cubes and washed in an ultrasonic bath at 37 °C in a solution of hydrogen peroxide (3%) and propylene glycol (17%) and rinsed in sterile physiological solution for 10 minutes. The samples were then clamped on the locking plate of a CNC micro-milling machine (CnC 4 Axis, Esanastri, Calcinaia, Pisa, Italy) equipped with a micro-end mill (0.0310'' Stub, T-Tech, Norcross) to be suitably processed [3, 4]. Table 1 reports the cutting parameters to perform single grooves within the first studies: the parameters adopted for Case #2 revealed a better surface finishing, with a reduced number of burrs and detachments, making them preferable for the specific applications here presented.

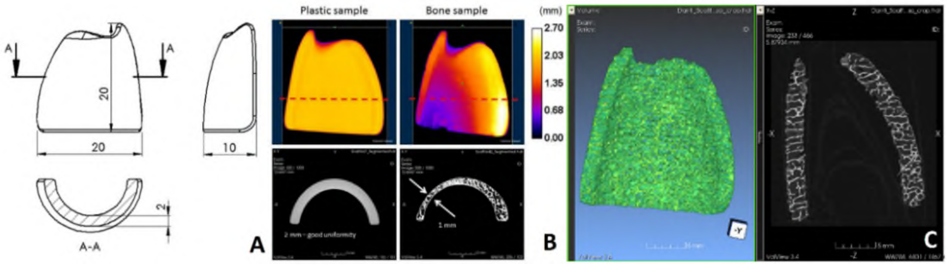

Figure 1. (A) Technical drawing of the posterior canal wall. (B) Color-coded map of sample thickness of the plastic and bone samples. (C) MicroCT of the final prototype in bone without eccentricity problems.

Cutting parameter	Case #1	Case #2
Spindle speed [rpm]	15,000	10,000
Cutting depth [µm]	400	100
Feed rate [mm·min^{-1}]	30	120

Table 1 Cutting parameters to process cortical bone during two preliminary studies.

3. Manufacturing of two bone ear structures

3.1. The EAC wall

It was decided to manufacture the EAC wall replacement using spongy bone due to its large dimensions (Figure 1A). Indeed, it is not possible to acquire a bovine cortical bone block also from a femur. However, since the part do not support any significant load, it is possible to use the exploit the porous structure to allow the growth of new bone cells. A first prototype was manufactured with the CNC machine equipped with a 0.2 and 0.1 mm end-mill with the cutting parameters reported in Table 1, Case #2. The outcome was then controlled via micro computed tomography (microCT, available at CNR Institute of Clinical Physiology, Pisa) to evaluate the discrepancies in terms of dimensions with respect to a plastic sample made via 3D printing (Zortrax M200). The analysis highlighted an eccentricity problem thar led to a not constant thickness of the bone shell (Figure 1B). A refining of the path program was then carried out to fix the problem and to deliver a second prototype (Figure 1C) able to respect the nominal dimensions.

3.2. The incus

The shape of the incus was acquired by a 3D scanner and filtered by the ImageJ software. Data were then elaborated through the 3D Software SolidWorks in order to get the morphology and the main dimensions, depicted in Figure 2A. The incus was than made from a bovine bone cortical block through the abovementioned CNC machine equipped with a 0.1 mm end mill using the cutting parameters reported in Table 1 for Case #2. The main dimensions of the part were analyzed with a digital equipment (CNC Measuring Machine Video-Check-EA, Werth Messtechnik GmbH, Gießen, Germany) and it was observed a good matching between the nominal and the actual dimensions with an average error less than 5%.

However, as shown in Figure 2B and 2C through red circles, some detachments of the material were noticed in correspondence of the extremities. A further analysis conducted together with surgeons, highlighted that these defects do not compromise the application of the part during surgery since a preliminary adaptation of device is necessary to make the replacement patient specific.

5. Conclusions

The study of this two applications for otology shows significant advancements in manufacturing biologic materials, such as bone, for applications in which small size and concave shape may represent a challenge. Specifically, the microfreshing cutting parameters for both cortical and spongy bone showed the complexity of the mechanical properties of this material. The anisotropy and the inhomogeneity of the material may induce damages on the surface with detachment and deposit of micro-shafts in case of incorrect use of the different cutting parameters in roughing operations. The parameters reported in Table 1 are the best trade-off between quality and production time. The outcomes of the manufacturing for the EAC wall and the modified incus revealed how slight variations from a precise micro-machining may lead to defects. Future steps in this direction will include the manufacturing of these replacements at industrial level including the use of banked bone.

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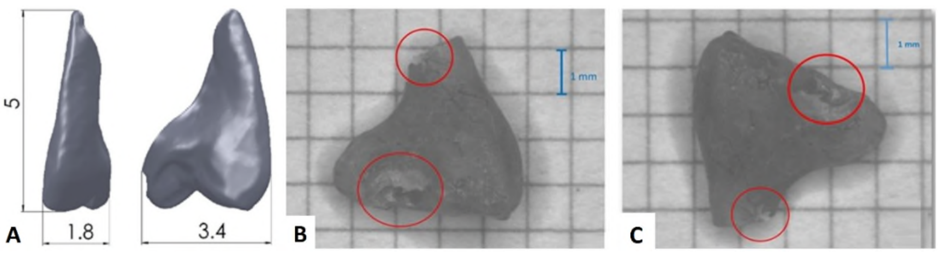

Figure 2. (A) Technical drawing of the incus. (B-C) Analysis of the structure after the micro-milling. Red circles notes the detachment of the material.