

Intraoperative Sterile Molding of Patient Specific Templates for Minimally Invasive Cochlear Implant Surgery

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Introduction

Cochlear Implant (CI) surgery is an established treatment to restore severe hearing loss and deafness caused by inner ear dysfunction. To gain access to the cochlea for insertion of the implants electrode carrier mastoidectomy (partial removal of the cranial bone) is performed. This process is sophisticated and time consuming. Minimally invasive CI surgery has the potential to reduce operating time, trauma, hospitalization time, amount of needed anesthetics and costs and additionally improve ergonomics for the surgeon. The concept of this approach is to replace the mastoidectomy by a single drill hole from the surface of the skull to the cochlea. The complexity of this lies in the accuracy requirements resulting from the vicinity of the drill trajectory to the facial nerve. The drill (typical diameter 1.8 mm) has to pass through the approximately 2.5 mm wide facial recess in a depth of about 3 cm. Marker based navigation can not be effectively applied for this intervention. One method to achieve the required accuracy is by using a patient specific template to hold a linear guide for a drill.

The first clinical results of this approach are presented with the microtable system [1]. Beside the risk of physical damaging the facial nerve or thermal necrosis from heat induced by the drilling process [2] (both not further discussed in this paper) manufacturing of the template is still an issue. Operation planning is done in reference to the frame mounted on the patients skull at the beginning of the surgery. Since this reference can only be determined after fixation, the manufacturing of the template has to be done intraoperative. Manufacturing of the microtable is done none sterile by CNC machining a ULTEM (polyetherimide, PEI) block. In a shortened autoclaving process the finished template is sterilized and then cooled down. The shortened autoclaving of the microtable is neither certified in Europe nor in Russia. The RoboJig system (Figure 1), relying on the same working principle, was developed with a sterile manufacturing system to solve this problem. This paper is centered around the manufacturing unit of the RoboJig.

For sterile manufacturing of the jig different approaches have been developed. The technical requirements include, that the process can be done fast enough to avoid surgical downtime during anesthesia of the patient. This is the reason why 3D printing is currently not an option. Further it has to be guaranteed, that the chain of errors does not lead

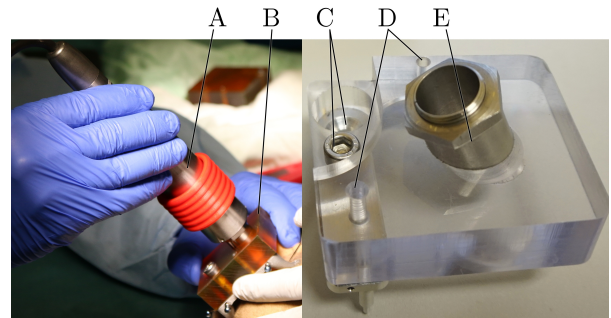


Figure 1: Left: linear guided surgical drill (A) connected to an intraoperativ milled jig (B) during initial cadaver experiment. Right: CNC milled jig prototype with connector holes (C-E).

to deviations larger than 0.5 mm in 30 mm depth during the drilling process. The jig should not hide the view of the situs for the surgeon.

template milling

In the current research setup the template is pre-formed and sterilized ahead of the surgery. The customization is done with a passive hexapod (Schick X1 med 3D, Schick-Dental GmbH, Germany) which positions the template relative to the axis of a drill unit on a linear guide. The struts of the hexapod are based on micrometer screws and adjusted manually. Their length is calculated based on the planned trajectory, which is transformed into the frame coordinates. The adapter on the hexapod platform uses a dowel pin connection dimensional similar to the one on the frame in Figure 1. Based on the planning data a stepped hole is drilled as interface for the surgical drill guide (Figure 1 part A and E). The forces generated during this customization process, as well as the angle of impact of the drill, raise the need for a stiff and highly accurate linear guide. Also a preformed and sterile template is needed for every surgery. Setup of the system and milling took 15 min in an initial cadaver trial. No deviation between drillhole and plan was visible in a postoperative CBCT scan (resolution 0.3 mm). The milling system of the RoboJig was described recently [3].

bone cement fixation

To reduce process forces and complexity an alternative manufacturing approach was developed. Its concept is to adjust a linear guide with the hexapod similar to the template milling approach. After orientation the guide is fixed to a mounting adapter using bone cement [4, 5]. This has

the advantage of low hardware costs and lower effort for certification.

polymer molding

In this paper a novel intraoperative manufacturing approach is presented. Our hypothesis is that a molding process results in lower process forces than in the template milling and therefor leads to a higher manufacturing accuracy and lower manufacturing time at lower costs. Injection molding is well established for processing thermoplastics. The melted material is extruded under high pressure into the mold. This typically leads to sterile parts depending on the environment [6]. For this process a mold has to be created for every new part. This is not feasible for the RoboJig since the part is different for every patient. An adjustable mold is not possible for injection molding because it has to be closed and leakproof. We experimentally investigated two low pressure process with an open mold. Pre sterilized granular material was used in combination with the inductively heated mold as well as a photopolymer cured under UV light.

Materials and Methods

The design of the jig is shown in Figure 1. It contains two holes for the dowel pin connection (Figure 1 part D) on the titanium frame of the system, two holes for the connection screws (Figure 1 part C) and one guiding hole for attaching a surgical drill unit (Figure 1 part A) through a locking ring (Figure 1 part E). Critical structures regarding accuracy, are the dowel pin connectors, the guiding hole and the lower surface of the jig attaching to the frame. The shown manufacturing concept is based on the adjustment of the guiding hole by a sterile hexapod. The endeffector of this hexapod is a 14 mm pin that is held in place in the fluid polymer during curing to create the guiding surface (not applied in initial tests). The shape of the jig is defined by the open mold shown in Figure 3.

material choice

In the current template milling approach ULTEM 1000 (PEI) is used as material. Its benefits lie in its high young's modulus and medical certification. Due to its high transition temperature it is not suitable for the molding approach. For an alternative material a low transition temperature is favorable to reduce risk and cooling time. Still the material should withstand the autoclaving process without losing form stability. A high melt flow rate (low viscosity) ensures that small structures in the mold get modeled. This is important for building the dowel pin connection. The chosen material should not inhibit medical certification of the system. Table 1 summarizes the properties of alternative materials. For an initial selection material probes were heated and cured in a miniature mold. The resulting probes are shown in Figure 2. From this initial experiment CALIBRE and TOPAS were chosen for further work because

of their material properties, melting behavior (little to no blistering) and transparency (enables view on the situs).



Figure 2: Materials after initial mold test in which the granulate was heated to its transition temperature

Table 1: comparison of material properties of suitable polymers from corresponding material data-sheets

	ULTEM 1000	CALIBRE 2081	LEXAN HP1REU
Material type	poly-etherimid	poly-carbonate	poly-carbonate
Young's modulus [MPa]	3500	2400	2400
Density [$\frac{kg}{m^3}$]	1270	1200	1200
Transition temperature [$^{\circ}C$]	195	142	126
Mold shrinkage [%]	0.5 - 0.7	-	0.7
Melt flow rate [$\frac{^{\circ}C}{kg}$]	9 [$\frac{337^{\circ}C}{6.6kg}$]	22 [$\frac{330^{\circ}C}{1.2kg}$]	35 [$\frac{300^{\circ}C}{1.2kg}$]
Melt volume flow rate [$\frac{^{\circ}C}{kg}$]	13 [$\frac{360^{\circ}C}{5kg}$]	-	33 [$\frac{300^{\circ}C}{1.2kg}$]
ISO 10993-1	yes	yes	yes

	Emerge 9500CR	VALOX HX312C	TOPAS 8007
Material type	poly-carbonate	polybutylene terephthalate	cycloolefin-copolymere
Young's modulus [MPa]	2270	2500	2600
Density [$\frac{kg}{m^3}$]	1290	1310	1020
Transition temperature [$^{\circ}C$]	109	54	75
Mold shrinkage [%]	-	1.6	0.1 - 0.5
Melt flow rate [$\frac{^{\circ}C}{kg}$]	10 [$\frac{260^{\circ}C}{5kg}$]	35 [$\frac{250^{\circ}C}{1.2kg}$]	-
Melt volume flow rate [$\frac{^{\circ}C}{kg}$]	-	31 [$\frac{250^{\circ}C}{1.2kg}$]	32 [$\frac{360^{\circ}C}{2.16kg}$]
ISO 10993-1	yes	yes	yes

mold design

Main task of the mold is providing an accurate negative volume for the jig. Figure 3 shows the design concept. The mold is build from three detachable parts for releasing the final jig. All structures relevant for the system accuracy (pins for the connection interface of the later part) are on a single part to avoid inaccuracy resulting from assembly.

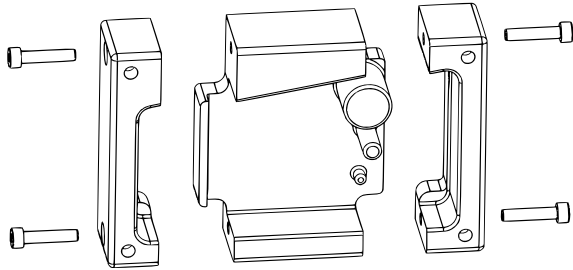


Figure 3: Design of the mold

system setup

The sterile hexapod uses magnetic ball joints to attach on a grid of base points on both connecting platforms. Since the micrometer screws allow for an adjustment in six degrees of freedom this coupling options leads to redundancy for most endeffector positions. This redundancy enables optimization regarding the systems accuracy. More information about the used hexapod can be found in [7, 8]. For a clinical implementation of either the granular melting or the photopolymer approach a lid has to be added to shield the system from its environment.

melt on and curing

To melt on the granular polymer it has to be heated to its transition temperature. The heating process should be fast and uniform while avoiding overheating and thus carbonisation of the melt. The system should be reasonably small to fit in the OR environment and pose a minimal risk to the clinicians. Inductive heating of the mold was chosen as compromise of those requirements.

experimental evaluation

To evaluate the feasibility of the manufacturing process two experiments were conducted. Aim was the production of an accurate jig comparable to a milled version. The pin for the guiding hole was not used in both initial experiments. In the first experiment the mold was filled with granular CALIBRE or TOPAS and then inductively heated until uniformly melted (Figure 5). After curing the jig was removed and measured with a coordinate measuring arm (FARO GAGE, Faro Technologies Inc., Lake Mary, FL, USA). Four specimen were produced for CALIBRE and ten from TOPAS (showed better initial results regarding accuracy). In a second experiment the medical photopolymer Med610 (Stratasys, Minnesota, USA) was used and cured

under UV light exposure. Typically this polymer is used for printing of patient specific templates for dental surgery.

Results

The described melt on process was successfully applied. Figure 4 shows two finished templates. The standard deviation of the measured distances of the dowel pin holes was 0,058 mm (n=10) for the TOPAS and 0,149 (n=4) for the CALIBRE specimen. The photopolymer approach was discarded due to blistering of the material (Figure 6C).

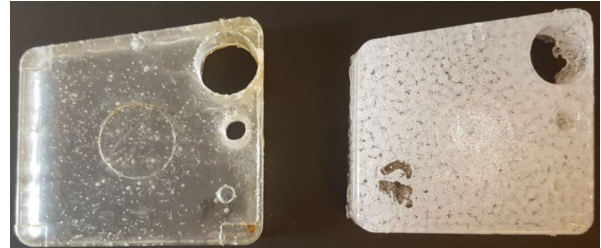


Figure 4: Cured jig made from TOPAS granulate (left) and CALIBRE granulate (right)

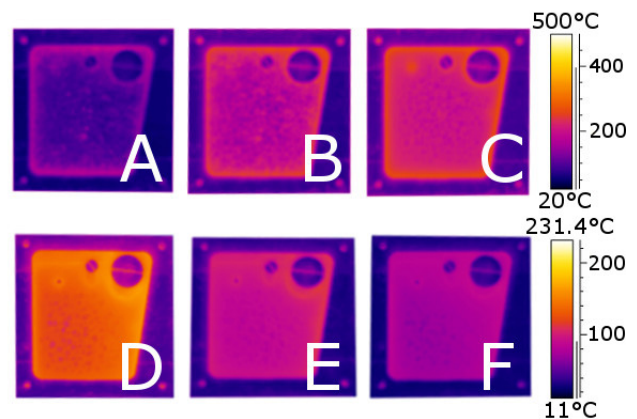


Figure 5: Exemplary heating and curing process taken from an infrared camera. A - C show the temperature distribution of the melt after 5 min, 25 min and 45 min respectively. D - F show the cooling process after 5 min, 15 min and 25 min. Please note the different color scale for A - C and D - F.

Discussion

The complete process currently takes 70 min plus the time for the system setup (5 - 10 min). Increasing the power output of the induction heater is not an option because it leads to carbonization of the edges of the jig while the inner parts are still granular (Figure 6A). The heating process can be started before surgery to avoid a bottleneck during the intervention. Curing can be speed up by emerging the mold in sterile water, however this has not been tested yet. An overview over the planned workflow is shown in Figure 7. The top surface of the jig might become uneven due to

shrinkage in the curing process (Figure 6B). This is not relevant for the system accuracy. Only the guiding holes (Figure 1 parts D and E) and the bottom surface (Figure 4) are relevant reference structures. UV curing did not meet the requirements. During the process gas development leads to hollow volumes. Blistering is avoidable by successively adding layers of < 1 mm thickness but this increases the process time and therefore eliminates its advantages over conventional 3D printing.

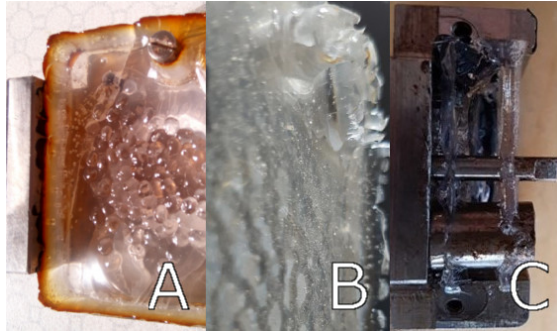


Figure 6: Three failure modes during molding. Uneven and fast heating (A), uneven surface from uneven heating and melt shrinkage during curing (B) and gas formation when UV curing thick layers of Med610 (C).

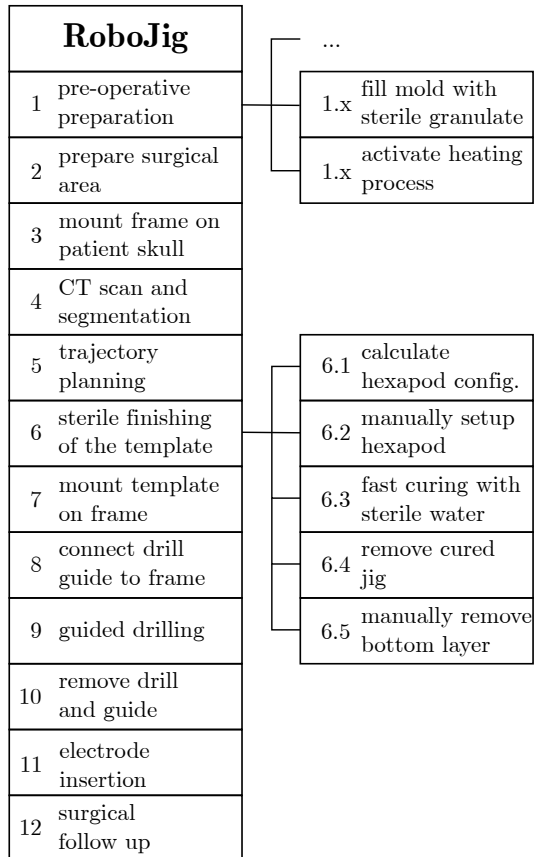


Figure 7: Proposed surgical workflow for the RoboJig system.

Conclusions

The concept of low pressure molding granular thermoplastics was successfully proven. Relevant structures were reproduced sufficiently accurate in the initial experiments. Still the surface quality can be improved by parameter optimization. For a clinical implementation further work is needed. Accuracy has to be evaluated in a next step by using multiple molded jigs to drill into artificial bone. Also the system needs to be optimized regarding usability, safety and process time. Currently the milling approach is beneficial due to shorter processing time. Implementing the workflow shown in Figure 7 could change this.

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Acknowledgments

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