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An new and efficient method to produce presurgical and patient specific cranial calottes

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Standard Method

The gold standard in the cranio plasty to close a skull defect is the manual and careful kneading of high viscose bone cement (Polymethylmethacrylat, PMMA) directly and intraoperative onto the dura mater. That fact causes different problems:

- The contact with the sensitive dura mater hinders the possibility to knead and bring the bone cement into the right and patient specific shape.
- The standard bone cement is a two component bio plastic which begins to cure after 7 minutes after the mixing process under an exothermic reaction (up to over 100 C).
- Because of the exothermic reaction the careful shaped bone cement has to be removed from the defect before the material is fully cured and hardened out! This causes the risk to lose the right shape of the calotte.

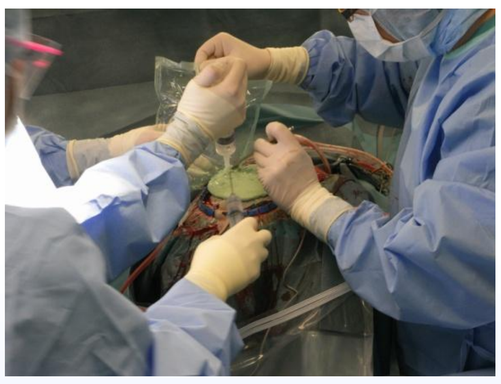

Figure 1: carful kneading of PMMA directly onto the Dura Mater permanently cooling required, at least two surgeons

Figure 2: Waiting time during preparation of PMMA calotte, time for the conventional preparation around 20 minutes

New Method

In the feasibility study should be proofed the new method fundamentally. On the basis of the presurgical taken CT data a thermoforming die will be designed (Mimics, Materialise Ltd.) and produced with the Selective Laser Sintering process (SLS, EOS GmbH). On this die a plastic foil will be thermoformed. This blister like plastic foil has the shape of the inner side of the new designed patient specific calotte and is the product which is used by the surgeon to knead the bone cement in the right shape. The surgeon shall get it sterilized and packed.

The advantages of the new method are:

- Presurgical preparation of implant
- No waiting time, less OR time
- Lower risk of infection
- Optimized and better fit of the implant
- first time right
- Cost savings for the healthcare because of better quality

Figure 3: Kneading of PMMA into CranioTool

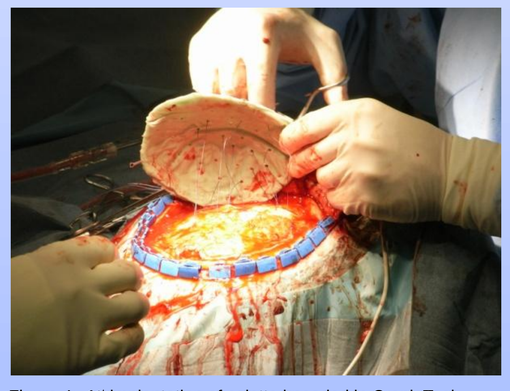

Figure 4: 1st implantation of calotte kneaded in CranioTool

Milestones of the project

The following questions has to be answered in that project:

- Give the CT-data enough information for the engineering and design of the patient specific thermoforming die?
- Definition of optimal shape of the SLS - thermoforming die.
- Is the plastic foil rigid enough to stand the pressure during kneading and to stand the heat of the exothermic reaction?
- Can the CranioTool be declared as biocompatible? Migrate any substances from the plastic foil into the bone cement during the exothermic reaction?
- Can the above mentioned advantages be confirmed by the surgeon after two clinical tests?

First results

- An expert analysis of the CranioTool has confirmed that the product CranioTool is not categorized as an medical product according the guidelines 93/42/EWG or 812.21. Heilmittelgesetz CH
- The problem of the migration of substances is secondary because of two reasons: a) the used plastic foil is FDA approved for a temperature up to 140 C (<1h) and b) the temperature of exothermic reaction reaches < 106 C
- The process chain was optimized and made more reliable. With a boolean step in the CT-data treating software (Mimics) we get the shape of the implant directly and could safe the step of designing in CAD
- Two Quality Control steps were defined: a) comparison of the designed thermoforming die with CT-data and b) comparison of the 3D scanned CranioTool with the CT-data (general approval)
- Surgeon could confirm the above mentioned advantages after the first surgery

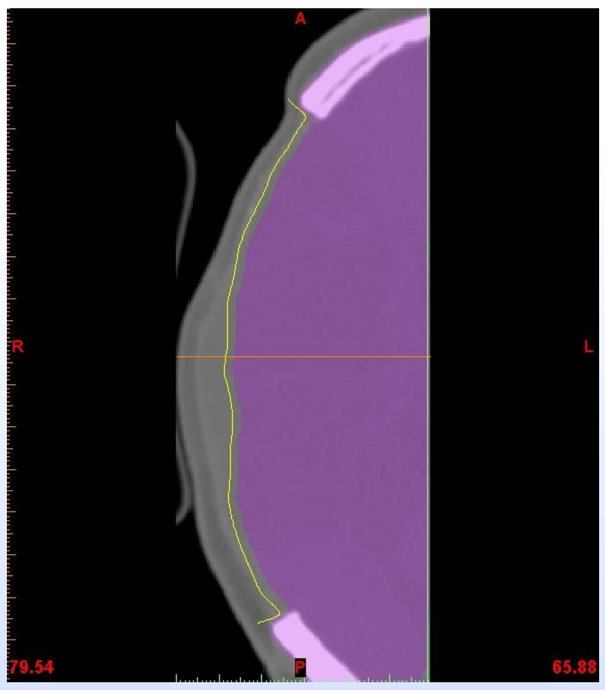

Figure 5: comparison of 3D scann of end produced sterilized CranioTool with CT-data as general approval (pink: bone and brain/dura tissue, yellow: 3D scanned inner surface of the presurgical in CranioTool kneaded PMMA calotte)

Conclusions and Outlook

During the development of a new method it is essential to proof the process chain more times. This led to a simplified and safer method.
The temperature during the exothermal reaction remains under the FDA approved temperature of the used foil material.

In the next step of project the results of the first clinical test has to be confirmed by a second and last surgery . Further a chemical test of the in CranioTool cured PMMA bone cement shall confirm the biocompatibility.

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