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

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Standard Method
The gold standard in cranioplasty 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.

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 production 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

First results
- An expert analysis of the CranioTool has confirmed that the product CranioTool is not categorized as a medical product according the guidelines 93/42/EGW or 812.21. Heimittelgesetz 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

Milestones of the project
The following questions has to be answered in this project:
- Give the CT-data enough information for the engineering and design of the patient specific thermofoming die?
- Definition of optimal shape of the SLS - thermofoming die.
- Is the plastic foil rigid enough to stand the pressure during kneading and to withstand 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?

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 exothermic 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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References: