Novel Body Access for Hemodialysis

KTI Project: n 12593.1
Main industrial partner: Cendres+Métaux SA, J.M. Guenat
Project goal: Scientific and technical development of the dialysis port prototype up to the clinical trial phase.
Key findings: The port is designed to its full functionality and the surgery is successfully tested on cadavers.
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Project summary
For hemodialysis patients, a frequent venous access is required in order to filtrate the patient’s blood. The state of the art method is repeated perforation of the skin with a needle or a permanent central venous catheter that passes through the skin in the abdomen. A high rate of catheter related infection as well as cutaneous pain is reported.

Anatomical study
To support the design of the BAP an anatomical study was conducted. The average shape and size of the bone designed as the implantation site was measured on the basis of CT images. A method called statistical shape modeling, used among other in prosthetics design was adapted and applied to the temporal bone.

Results
The statistical study showed that the average bone thickness available in the retro-aural region restricts the size of the implant to 6-7 mm in depth. It also showed that the best implantation site is the frontal-caudal portion of the mastoid. The implant size was modified accordingly to target a broad population.

Fig.3: Average bone thickness of the temporal bone (n=10). Circles show isodistances to the ear canal.

Surgical Planning: the focus on patient safety
Uncovering the Dura Mater or injuring critical structures such as the Facial Nerve or the Sigmoid Sinus must be avoided. During implantation a passive surgical guide based on a surface distance map was developed and tested on cadaver models.

Fig.4 Left: impact of guided surgery on surgical safety. Right: typical surgical guide for BAP implantation.

Conclusion
At this point of the project, a fully functional prototype has been developed. State of the art image analysis methods allow a safe implantation of the BAP.

Economical impact
It is estimated that about 1.5 million people are treated with hemodialysis worldwide. An increase is expected due to the growth of health co-factors (obesity, diabetes). 25% of the overall cost of dialysis therapy is caused by venous access issues. The BAP could reduce the overall cost of hemodialysis therapy thus lowering the load on the healthcare systems.

Main advantages of the BAP
- Low complication rate
- No pain
- Improved quality of life for the patients

Fig.2 Schematic drawing of the implanted BAP and catheter. The novelty of the BAP is the interface between the catheter and the dialysis machine.

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