Research protocol

Research leader: assistant professor **Ieva Bagante**, researcher in Riga Stradins University Institute of Stomatology, Baltic Biomaterials Centre of Excellence (BBCE) project.

Research title: **3D printing and planning for orbital floor fractures**

Place of research:
Riga Stradins University (RSU) Institute of Stomatology, Baltic Biomaterials Centre of Excellence (BBCE), P. Stradins Clinical University Hospital. (CUS)

Objective of the study:
To analyse and compare treatment outcomes in patients with orbital floor fractures without and with three-dimensional (3D) planning and cranial prototyping. To improve and optimize the treatment of orbital floor fractures in Latvia.

Study design:
A comparative cross-sectional study.
It will consist of a retrospective analysis of patient data and a prospective study with 3D planning before surgery.

Study population:
All consecutive adult patients from January 2022 who are treated at P. Stradins CUS due to orbital floor fractures and who have indications for orbital floor reconstruction surgery with titanium mesh participate in the study. Patients with orbital floor fracture suffer from double vision, enophthalmos/exophthalmos, n. Infraorbitalis paresthesias. Orbital floor reconstruction is a challenging surgical manipulation, due to complex orbital anatomy and it is difficult to see the exact position of the mesh in the orbital floor (it is impossible to remove the eyeball from the orbit and then put it back), always performing a postoperative computed tomography (CT) examination (usually next day after the surgery) to detect position of the titanium mesh.
The control group consists of all patients who were treated at P. Stradin's CUS in the period between January 1, 2018 and December 31, 2021 with orbital floor fracture.

Control group:

Inclusion criteria:

- All consecutive adult patients who have been treated at P. Stradins CUS from January 1, 2018 to December 31, 2021 with an orbital floor fracture.
- All adult patients with orbital floor fracture who had surgical treatment with titanium mesh.
- Patients who have access to pre- and post-operative CT examinations of appropriate quality (0.625mm section).

Exclusion criteria:

- Minor patients who have been treated at P. Stradins CUS from January 1, 2018 to December 31, 2021 with an orbital floor fracture.
- Patients with orbital floor fracture who had surgical treatment without titanium mesh insertion (eg, revision, various absorbable membranes).
- Patients with orbital floor fracture who underwent re-surgical treatment due to inadequate titanium mesh position or other complications.
- Patients who don't have or have inadequate quality of pre- and post-operative CT scans and orbital volume measurements are not possible.

Research group:

Inclusion criteria:

- All consecutive adult patients who will be treated at P. Stradins CUS or RSU Institute of Stomatology from January 1, 2022 - December 31, 2026 (?) with an orbital floor fracture.
- All adult patients with orbital floor fracture who will have surgical treatment with titanium mesh.
- Patients who will have access to pre- and post-surgery CT examinations in appropriate quality (0.625mm section).
- Patients with 3D planning and printing of orbital prototypes and pre-bended titanium mesh before surgery.

Exclusion criteria:

- Minor patients who will be treated at P. Stradins CUS from January 1, 2022 – 2026 (?). on December 31 with an orbital floor fracture.
- Patients with orbital floor fracture who will have surgical treatment without titanium mesh insertion (eg, revision, various absorbable membranes).
- Patients with an orbital floor fracture who won't have 3D printing and planning with pre-bended titanium mesh due to unexpected circumstances.
- Patients who don't have or have inadequate quality of pre- and post-operative CT scans and orbital volume measurements are not possible.

Methods of obtaining primary data:

- Patient data will be obtained from P. Stradins CUS, the data of the patients included in the study will be anonymous, coded in a combination of letters and numbers and will be stored electronically by the study leader in accordance with Cabinet of Ministers regulations no. 265 on the storage of medical documentation.
- Before and after the surgery, a CT of the orbits with coronary and sagittal reconstruction will be performed (provided by P. Stradins CUS or any other medical institution, where the patient will seek first help after the injury and where a CT of the orbits with sufficient resolution has been performed).
- After CT data processing with Mimics and 3-Matic software (Materialise, Leuven, Belgium) a virtual 3D orbit model will be created in native and mirror image, which will then be printed with a 3D printer (Asiga 4K Max UV printer machine, Australia) from Polymer light cure resin (Asiga, Dental Model, Australia), after printing, the part is carefully cleaned with isopropanol from the print material and performed removal of auxiliary fasteners with abrasive cutters. Illumination (hardening) of the material "Otoflash post curing light pulsing unit" 600 flashes or 10 flashes per second for 60 seconds, then final treatment of the material with polishing tools (provided by the BBCE project, RSU Stomatology Institute).
- A titanium orbital reconstruction mesh (KLS Martin, USA) will be folded over the mirrored image of healthy orbit prototype, then sterilized in a standard metal instrument sterilization as prepared, and both printed skull prototypes will be sterilized at 55 degrees in a gas autoclave.
- Standard surgical approaches will be used to treat the orbital floor fracture using both transconjunctival and subciliary approaches at the discretion of the surgeon and patient.
- During surgery, before placing the pre-bended mesh into the orbit, it will be checked again on both printed skulls to avoid deformation of the pre-bended mesh. The mesh will be inserted into the floor of the orbit and fixed with 5mm titanium screws.
- After the surgery, patient will have a control CT of the orbits according to the already existing standard protocol.
- Post-operative care according to an existing standard protocol. Control after 1 - 2 weeks, after 2 months, after 6 months (if diplopia persists).
- CT data will be analysed with free of charge program 3D Slicer 5.0.3 r30893 / 7ea0f43 Supported by: NA-MIC, NAC, BIRN, NCIGT and the Slicer Community. Orbital volume will be measured before surgery in the affected orbit and in the healthy orbit and after surgery in the affected orbit and in the healthy orbit.
- Objective measurements will be performed in the study, volume will be compared before and after surgery both between the healthy and affected side in the control and study group, as well as subjective measurements such as double vision and enophthalmos/exophthalmos before and after the surgery clinically.

- It is not possible to identify printed 3D orbit prototypes by the patient's affiliation. Prototypes will be stored in the Baltic Biomaterials Center of Excellence in accordance with Cabinet of Ministers Regulation No. 265 on the storage of medical documentation.
- Late results will be documented at least 6 months after surgery with questionnaire using visual analogue scale to understand patients well-being and quality of life.

List of statistical data analysis methods:
1) Descriptive statistical methods for determining the arithmetic mean, standard deviation.
2) t test for statistical reliability between two groups.
3) chi square test for data analysis (whether variances in two groups differ)
4) Wilcoxon (Mann Whitney U) test for quantitative data analysis between two groups.

The study will be conducted in accordance with the provisions of the World Health Organization and the Declaration of Helsinki, with patients' informed consent and a signed consent document for the study.