**Project title:**

Use of Diced Cartilage for Management of Internal Mammary Vessel Exposure Sites in Autologous Breast Reconstruction

Date: 10.07.2024

# 1) Studyprotocol

**Procedures for informing and obtaining consent:**

The recruited subjects will be informed about the nature, importance, risks (anonymizes data management) and scope of the intended scientific investigation in a personal conversation with one of the investigators and will receive patient information. After sufficient time for reflection, the consent will be confirmed in writing on the form prepared for this purpose - declaration of consent.

**Measures:**

This retrospective single-center cohort study included all autologous breast reconstructions performed from October 2021 to June 2023, in which diced cartilage (DC) was used to manage internal mammary vessel exposure sites (IMVES). These reconstructions will be divided into two groups: one with prior ipsilateral breast radiotherapy (DCR) and one without irradiation (DC) to evaluate the suitability of irradiated cartilage for the DC procedure. The control group consisted of an equal number of consecutive autologous breast reconstructions performed before the implementation of the DC procedure, for which rib cartilage segments were also removed but IMVES were managed conservatively. Controls will not be recruited during the period of DC use because initially, DC was not used consistently by all team members and may have been avoided in difficult reconstructions limiting the comparability of these patients. Data will be collected using electronic patient records, photographic documentation, and available postoperative MRI of reconstructed breasts.

Magnetic resonance imaging (MRI) scans performed at least 6 months postoperatively will be used to evaluate the sinking depth of epicostal soft tissue into the space of rib segment resection on axial planes (JiveX Software, VISUS Health IT GmbH, Bochum, Germany).

Postoperative photographic images will be examined by two investigators (blinded to group assignments) for IMVES-associated deformities using standardized photographic images of the reconstructed breasts at the 6-month follow-up.

## 2) Statistical Analysis Plan

Statistical analysis will be performed using IBM SPSS Version 24 (IBM, Somers, NY, USA) and R 4.3.2 (R Core Team). Metrically scaled parameters will be assessed for a normal distribution using Shapiro–Wilk tests. Results for normal data will be presented as mean ± standard deviation (SD) and will be analyzed using multi-factor variance analysis. Paired t-tests with Bonferroni correction will be used when significant differences were observed. Non-normally distributed metric parameters will be expressed as median (Q25–Q75) values and will be assessed using the Kruskal–Wallis test. Pairwise Mann–Whitney U tests with the Bonferroni correction will be used when significant differences were found. Categorical parameters will be assessed using the Chi-squared or Fisher tests, without tests for normality. Pairwise chi-square tests (or Fisher tests) with Bonferroni correction will be used when significant results were found. MRI data will be analyzed by isolating subgroups of the study population with MRI and applying pairwise case exclusions. A Chi-square test of independence will be performed to determine whether the groups differed significantly with regard to the presence of MRI. In addition, further comparison of the three groups will be carried out for the variables surveyed to clarify group differences. The significance level will be set at $\alpha = 0.05$ for all tests.