Two-Stage Implant-Based Breast Reconstruction is safer than Immediate One-Stage Implant-Based Breast Reconstruction augmented with an Acellular Dermal Matrix: A Multicentre Randomized Controlled Trial

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INTRODUCTION*:* The evidence justifying the use of acellular dermal matrices (ADMs) in implant-based breast reconstruction (IBBR) is limited. The aim of this prospective randomized trial was to compare the outcomes of direct IBBR augmented with an ADM (Strattice™, LifeCell Cooperation) with those of two-stage IBBR. We report on the first results on the safety outcomes of the two procedures.

MATERIALS & METHODS*:* A non-blinded randomized controlled trial was conducted at eight hospitals in the Netherlands. Patients who intended to undergo skin-sparing mastectomy and immediate IBBR were randomized to one of two procedures for IBBR: one-stage ADM-assisted IBBR or two-stage IBBR. The primary endpoint was quality of life. In the present article, we assessed the effect of the procedure on the occurrence of adverse outcomes. Analyses were performed with logistic regression and the general linear model. The trial is registered in the Dutch National Trial Register (NTR TC 5446) and the public CCMO register in the Netherlands (NL41125.029.12). The inclusion of patients is completed.

RESULTS*:* Between April 14, 2013, and May 29, 2015, 142 patients were enrolled in the study. Eventually, 59 patients (91 breasts) in the one-stage IBBR group and 62 (92 breasts) in the two-stage IBBR group were included for analysis. The overall surgical complication rates per patient (45,8% vs 17,7%, OR=4.5, p=0.008), the medical re-operation rates (37,3% vs 14,5%, OR=3.7, p=0.014) and the implant explantation rates (28,8% vs 4,8%, OR=16.8, p=0.004) were significantly higher in the one-stage group. This was also true after controlling for multiple confounding factors.

CONCLUSION*:* Immediate one-stage ADM-assisted IBBR was associated with a significantly higher rate of post-operative complications compared with two-stage IBBR. There was no evidence of adverse tissue reactions to the ADM itself. These results indicate that immediate one-stage ADM-assisted IBBR should be considered very carefully.