Evaluation of a New Concept in Two-Stage Breast Reconstruction: Patient Controlled Tissue Expansion using the AeroForm CO_2 Tissue Expander System

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Background: Two-stage breast reconstruction using saline tissue expanders is the standard of care utilized for greater than 50 years. Recently the status quo has been challenged by a CO_2 filled, remote controlled tissue expander. The AeroForm expander (AirXpanders, Palo Alto, CA) has CE Mark certification and has been commercially available in Australia since 2015. Data from multiple clinical studies have shown that this method can be used effectively and safely to prepare the surgical pocket for placement of a permanent implant. The purpose of this paper is to review the clinical data for the latest generation AeroForm with regard to outcomes and management of patients implanted with this new technology.

Methods: Data from a US, prospective, multi-center, randomized, controlled study were analyzed for successful second stage surgery, time to complete expansion and reconstruction, and satisfaction. Patients were enrolled and randomized (2:1) to receive either the CO_2- expander or saline expander. Inclusion was limited by age (18-70), BMI (<33) and tissue suitability for expansion.

Results: Data were reviewed for 72 (44 CO_2/28 saline) patients implanted with the current generation of the AeroForm or a saline expander within the same time period. Data are presented by breast (AeroForm = 78, saline = 50) with the primary endpoint achieved in 97.3% (CO_2) and 97.8% (saline) of patients. The treatment difference (-0.51) is within a margin of non-inferiority of -7.7. The study was a non-inferiority design and the protocol stated success range was a margin of < -10 %. The results with the CO_2 device versus earlier reported results reflect enhancements made to the design and manufacturing process during the trial. The average expansion and total reconstruction days were 17 and 111 respectively (CO_2) and 35 and 121 days respectively (saline). Overall satisfaction for the AeroForm was 84% (patient) and 89% (physician).

Conclusions: The AeroForm expander which uses CO_2 as the filling medium has been used successfully by patients for home dosing in clinical trials in the last five years. These results confirm earlier reports and demonstrate that the current generation of AeroForm is a viable alternative to saline for two-stage breast reconstruction. With the planned introduction of this novel technology in the U.S., patient management and training for home use will be required for its success.