Patient Activated Controlled Expansion (PACE) for Breast Reconstruction Utilizing Controlled CO$_2$ Inflation

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Abstract

Background: The AeroForm System (a patient-controlled tissue expansion system utilizing CO$_2$ inflation) was evaluated in patients undergoing immediate or delayed breast reconstruction following mastectomy. The primary endpoint was expansion to and maintenance of clinically desired breast volume until permanent implant placement or 6 months unless prohibited by a nondevice-related failure.

Methods: Female patients who signed informed consent were 18-70 years old, not current smokers, had BMIs < 30 and were enrolled in this prospective, open-label, single-arm, feasibility trial of the investigational device (the AeroForm System). Subjects underwent latissimus dorsi pedicled flap procedures (per standard practice of the investigator) for additional muscle coverage. Post-implant, subjects were followed until adequate wound healing. They were then instructed to use the remote dosage controller to administer 10-cc doses of CO$_2$ up to three times daily based on their comfort level. After 6–8 weeks post full expansion, subjects underwent explantation of the tissue expander and placement of a permanent implant. Descriptive statistics were used.

Results: Forty women (mean age: 45 ± 8.4 years; mean BMI: 24 ± 3.7) enrolled in the study: 26 had a breast cancer history and 14 sought prophylactic treatment. Nine subjects had unilateral placement (22%) and 31 subjects had bilateral placement (78%) for a total of 71 tissue expanders. All 71 expanders were expanded to and maintained clinically desired breast volume until permanent implant placement. Mean time to desired expansion was 17 ± 5 days; mean time from implant of expander to permanent implant exchange was 92 ± 22 days. No device-related adverse events were reported. Thirty-three of the subjects did not complain of pain post-procedure. Of the seven subjects reporting pain (7/40, 17.5%), six described their pain as mild-to-moderate and one subject (1/40, 2.5%) described her pain as severe. Thirty-one subjects found the device very easy to use and all 32 respondents were satisfied with the results (Figures 1 and 2). The surgeon was satisfied with the use of the device and with the ease of the explant procedure.

Figure 1. Expansion (400 cc; 22 days) right breast pre-explant.
Figure 2. Bilateral expansion (400 cc; 17 days) pre-explant.

Conclusions: The patient-activated and controlled expansion system provided gentle dosing for study subjects and provided the foundation for successful and timely placement of permanent implants.

Reference: