XPAND Patient-Activated Controlled Tissue Expander System for Breast Reconstruction: A Multi-Center Randomized Controlled Clinical Trial

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Abstract

Purpose: Implant-based breast reconstruction is the most common method of breast reconstruction in the United States and frequently involves a two-stage approach with tissue expanders. A novel patient-activated controlled expander, the AeroForm tissue expander, has been developed which obviates the need for saline injections associated with traditional expansion. Our objective was evaluation of the safety and effectiveness of the patient-controlled tissue expander compared to traditional saline expanders in a prospective, multicenter, randomized, controlled clinical trial.

Methods: Subjects, ages 18-70 with BMIs ≤33, were enrolled and randomized using a 2:1 permuted block design to either the investigational patient-controlled tissue expander or the saline expander control group and underwent immediate or delayed breast reconstruction. Patient-controlled expansion was performed using a 10-cc dose volume up to 30-cc/day. Saline expansion was performed according to current standard of care using percutaneous saline injections. Primary effectiveness was measured based on successful exchange to permanent implants. Failures to exchange due to device related events were considered study failures. Secondary outcome measures included time to desired expansion/exchange, pain scores and ease of use.

Results: The trial, conducted at seventeen clinical sites in the US, has enrolled 115/138 planned subjects with 107 (69 AeroForm/38 saline) treated. Successful exchange has been achieved in 61 of 69 subjects in the investigational arm and 36 of 38 subjects in the control arm. The reasons for failure to exchange were cellulitis, delayed wound healing, erosion, under-expansion or over-expansion. Mean time to desired expansion is 18.2 ± 9.2 days (AeroForm) and 57.4 ± 33.6 days (saline). Mean time to exchange is 106.3 ± 42.9 days (AeroForm) and 151.7 ± 62.6 (saline).

Conclusions: The investigational expander provides, relative to saline expanders, a needle free, time conserving and more convenient method of tissue expansion for breast reconstruction and is associated with high patient and physician satisfaction.

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