Aeroform Vs Saline Tissue Expansion in Breast Reconstruction: A Prospective Multi-Center Randomized Controlled Clinical Study

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Introduction: The goal of reconstructive breast surgery is to recreate symmetrical natural shaped breasts after mastectomy. Due to various factors, only approximately 40% of women undergoing mastectomy, complete breast reconstruction. Many women are overwhelmed at the time of their diagnosis and fearful of reconstruction, having heard stories of pain, multiple procedures and a lengthy process.

US statistics (ASPS 2013) note that of the women who proceed (95,589), the majority of choose implant based reconstruction (76,278), typically performed as a two stage procedure using tissue expanders followed by permanent implants (68,607). A novel remote-control breast tissue expander (AeroForm) has been developed, potentially making the process easier, more comfortable and shorter while enabling women to control their rate of expansion. A prospective, multicenter, randomized, controlled clinical trial to evaluate the safety and effectiveness of the AeroForm expander compared to traditional saline expanders was conducted.

Methods: 150 **women**, ages 18-70 with BMIs ≤ 33, were randomized to the investigational or saline control group and underwent immediate or delayed reconstruction. Expansion was performed with gradual incremental dosing up to 30-cc/day in the investigational arm and per percutaneous injections in the saline arm. Primary effectiveness was based on successful exchange to permanent implant. Secondary outcomes included time to complete desired expansion and exchange, pain and satisfaction.

Results: Sixteen US sites treated 98 women in the investigational group and 52 women in the saline control group. Successful exchange was achieved in 77 of 88 completed women in the investigational arm and 43 of 46 completed women in the control arm. The remaining women are due to complete their second stage procedure in the next few months. Reasons for failure to exchange were cellulitis/infection, delayed wound healing, extrusion, erosion expansion failure and subject choice. Median days to complete expansion was 20 [6-169] (AeroForm) versus 48 [5-280] (saline); p value 0.0001. Median

days to exchange was 98 [39-237] (AeroForm) versus 133 [69-433] (saline); p value <0.0001.

Conclusions: The XPAND study demonstrates safety and efficacy of the AeroForm expander, with second stage surgery completed significantly earlier than with the control. The device was reported to be convenient and easy to use, providing a gradual and more comfortable method of tissue expansion. With this option, women who may otherwise decline breast reconstruction may reconsider.