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Evaluating the Interi System: A Novel Negative Pressure Device in Post-Mastectomy Breast Reconstruction

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Introduction: Effective post-operative fluid management is crucial for successful healing in post-mastectomy breast reconstruction. Despite the use of conventional Jackson-Pratt (JP) drains by a majority of surgeons, seromas continue to be a common post-operative complication. The Interi System is a novel internal negative pressure fluid removal device that is powered by an external therapy unit applying 125 mm Hg via four peel-apart channeled silicone branches. This prospective study aims to evaluate the Interi System device on its effectiveness in post-operative fluid management, complication rates, patient satisfaction rates and usability.

Methods From 2022-2023, 20 patients undergoing post-mastectomy breast reconstruction were enrolled in this prospective IRB-approved study, with the Interi System device used in 32 breasts. The device fluid output was followed at clinic visits and the device was removed once output was less than 30 mL in 24 hours. Patients were monitored for complications at clinic visits (on post-operative days 7, 14, and 21) and via a telephone call on post-operative day 60. At the time of device removal, all patients completed a survey assessing their post-operative pain level (on a 0-10 scale), the usability of the device and their satisfaction with the device. Ultrasound was performed one week after device removal to evaluate for interim fluid accumulation.

Results: The 20 female study patients had a mean age of 47 years (range 31-68 years). At the time of the mastectomies and Interi System device placement, 13 patients underwent tissue expander placement (10 bilateral, 3 unilateral) and 7 patients underwent bilateral direct-to-implant reconstruction. The mean total fluid output was 853 ± 333 mL (mean ± SD). Recorded output was less than 30 mL in 24 hours at an average of 13 ± 7 days post-operatively, and the Interi System device was removed at an average of 16 ± 6 days post-operatively. The ultrasound estimate of remaining fluid at one week after device removal was 8 ± 11 mL (n=15 patients).

4/20 (20%) patients experienced a post-operative complication, with the complication leading to loss of the implant or expander in three breasts (3/32 breasts, 9.4%). Of the patients with complications, one patient had bilateral flap necrosis (2/32 breasts, 6.3%) requiring operative debridement and implant exchange. One patient had wound dehiscence (1/32 breasts, 3.1%) managed with wound care. Two patients had unilateral surgical site infections (2/32 breasts, 6.3%); one patient's unilateral cellulitis resolved with IV antibiotics, while the other had unilateral cellulitis with concomitant seroma (1/32 breasts, 3.1%) requiring operative implant removal. That was the only study participant to develop a post-operative seroma.

At time of Interi System device removal, nine patients reported no pain, six reported mild (1-3/10) pain, five reported moderate (4-7/10) pain, and no patients reported severe (8-10/10) pain. 90% of patients (18/20) would recommend the Interi System device to another person having the same surgery. Of the five patients with prior experience using a post-operative JP drain, three preferred the Interi System device, one found them equivalent, and one preferred the JP drain. Most patients agreed or strongly agreed that the Interi System device was easy to use, functioned acceptably, and wasn't overly restrictive.

Conclusion: The Interi System device is effective in post-operative fluid management in post-mastectomy breast reconstruction patients, with only one reported post-operative seroma. All other complications were not directly attributable to the device and were detected at rates that were consistent with those reported in literature. Most patients reported favorable experiences with the device and recommended it to other patients. The Interi System device is a promising drainage alternative in breast reconstruction patients, warranting further investigation in larger patient cohorts with direct comparison to conventional JP drains.