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Breast

Reduction in Seroma and Other Complications with a Novel Internal Negative Pressure System in Breast Reconstruction

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Background: Seroma, along with other complications, occurs as a result of poor wound healing following breast reconstructive surgery. The Interi System was developed to address the need for more effective approaches to close internal dead space and evacuate postsurgical fluid. Interi is an internal negative pressure delivery system with a unique branching manifold for broad coverage of internal tissue planes. Initial experience in a small cohort undergoing prepectoral breast reconstruction showed a clinical and statistically significant reduction in seroma and any complication versus standard drains. The purpose of this study is to report on the safety and effectiveness of Interi, compared with standard drains, in a larger patient population followed up over a longer period than our initial study.

Methods: Data on demographics, mastectomy and reconstructive variables, postoperative complications, and manifold/drain duration were retrieved from patient records and compared between the two groups.

Results: Interi was used in 100 patients (170 breasts) and standard drains in 100 patients (166 breasts). Groups were well matched in demographic, reconstructive, and mastectomy variables. Interi was removed significantly earlier than drains (16.5 versus 19.6 days; $P < 0.0001$) and was associated with a significantly lower incidence of seroma (4.1% versus 22.9%, $P < 0.00001$), flap revision (10.6% versus 21.7%, $P = 0.006$), and any complication (23.5% versus 44.0%, $P = 0.0001$).

Conclusions: Interi effectively reduced dead space and evacuated fluid from internal tissue planes, thereby decreasing seroma and other complications after prepectoral breast reconstruction. As a viable alternative to standard drains, it could significantly improve patient outcomes. *(Plast Reconstr Surg Glob Open 2023; 11:e5261; doi: 10.1097/GOX.0000000000005261; Published online 8 September 2023.)*

INTRODUCTION

Poor internal healing following breast reconstructive surgery contributes to a number of postsurgical complications, with seroma being the most frequent complication. Reported incidences of seroma vary widely from 3% to 90%.[1] Seroma formation is somewhat expected in the reconstructive setting from the dead space created by mastectomy and axillary dissection. Elevation of chest wall muscles (in subpectoral reconstruction), prosthesis (foreign body) insertion, acellular dermal matrix use, and generalized inflammation from the surgical procedures may further contribute to seroma formation.[1–3] Additionally, patient-related factors, such as obesity, diabetes, smoking, and prior breast irradiation may increase its risk.[2,3]

Fortunately, seroma is not a life-threatening complication, but it can lead to additional complications of infection and prosthesis loss; additional surgical procedures; repeated aspirations; prolonged hospital stays; delayed wound healing; delayed adjuvant therapy commencement; and patient discomfort, pain, and morbidity.[2,3] Thus, its prevention and management are of considerable importance in breast reconstructive surgery.

Undoubtedly, prevention, by eliminating or reducing dead space, is the best strategy to managing seroma and other wound healing complications. To this end, closed-suction drainage, quilting of mastectomy flaps, flap

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fixation, and application of tissue glue are standard measures during reconstructive surgery.[4] Despite the routine use of these measures, the incidence of seroma remains elevated in the 15%–25% range.[1,5,6] There is, thus, an ongoing quest for novel approaches to mitigate seroma formation.

The Interi System (IC Surgical, Grand Rapids, Mich., registered with the US Food and Drug Administration and commercially available), an internal negative pressure delivery system, was developed to address this clinical need.[7] Although the process of delivering constant negative pressure to wounds has been well established in the treatment of surface wounds and closed incisions,[8–11] delivering negative pressure internally to the tissue planes created in mastectomy and breast reconstruction represents a novel approach to eliminating or reducing dead space.

We recently reported on our initial experience with the use of Interi to reduce seroma formation in patients undergoing prepectoral breast reconstruction.[6] In this study, Interi use was associated with a 0% seroma incidence compared with 20.5% with standard surgical drains (Table 1). The patient population was, however, small (23 patients) and patient follow-up was short (<6 mo). In addition to our early experience, there have been two other studies reporting on clinical use of the Interi System. Both studies, one prospective and one retrospective, described the use of the Interi System in full abdominoplasty (Table 1).[12,13] These reports demonstrated a seroma rate of 0% and 4%, respectively, which are well below the 10%–20% seroma rate historically published in abdominoplasty.[13,14] The Interi patient population was small in these studies, including our 2022 study. Since our initial study, we have expanded our data set and gained more experience with the use of Interi.

The purpose of this study is to report on the safety and effectiveness of Interi, compared with standard drains, in a larger patient population undergoing prepectoral breast reconstruction followed up over a longer period than our initial study.

Takeaways

Question: Poor internal healing following breast reconstruction contributes to seroma and other postsurgical complications, despite current standard interventions.

Findings: The Interi System was developed to provide a more efficient and reliable approach to postsurgical internal wound control and fluid evacuation. This study reports on the safety and effectiveness of Interi, compared with standard drains, in well-matched groups of prepectoral breast reconstruction patients. Interi use was associated with a significantly lower incidence of seroma, flap revision, and any complication, and it was removed significantly earlier.

Meaning: Interi effectively reduced dead space and evacuated fluid from internal tissue planes resulting in reduced complications compared to standard drains.

PATIENTS AND METHODS

Study Design

Consecutive patients who underwent immediate direct-to-implant or two-staged tissue expander/implant prepectoral breast reconstruction from December 2018 to December 2022 in the author's practice were included in this retrospective study. Patients who underwent delayed reconstruction, hybrid procedures (implant and latissimus flap), or revision reconstruction were excluded. Two cohorts of patients were identified: those who received Interi and those who received standard drains for fluid management. Patients were not selected for the two cohorts. The study was approved by Ascension St. Vincent Health institutional review board (Indianapolis, Ind.).

Breast Reconstruction

All breast surgical procedures were performed by a single breast surgeon, and all breast reconstructive procedures were performed by the author. Prepectoral breast reconstruction was performed according to the author's routine protocol, ensuring best practices for dead space management, excess mastectomy flap management, appropriate implant/expander selection, acellular dermal matrix usage for implant coverage and support, and fluid management. The same types of acellular dermal matrix, expander, and implant, obtained from the same respective manufacturers, were used in all reconstructions. All procedures were standardized across all reconstructions, except for postoperative fluid management, with patients receiving Interi or standard drains. Interi is an internal negative pressure delivery system that consists of an internal manifold, with three "peel-apart" channel branches (four branches total) and an external therapy unit, which simultaneously delivers continuous negative pressure of 125 mm Hg to tissue planes and removes excess fluid from subcutaneous spaces, producing immediate and sustained apposition of tissues in this interface (Fig. 1).[6] Standard drains utilized were 19F round Blake drains.

In patients who received Interi, the manifold was placed in the subcutaneous plane, with one branch

Table 1. Published Series Reporting Experience with Interi System

Study	Type	Procedure	No. Patients	Seroma Rate, %	Mean Follow-up
Shestak[12]	Prospective	Abdominoplasty	24	0	30 d
Paul[6]	Retrospective, 2-arm	Prepectoral BR	Interi: 23	0%	156 d
			Drain: 23	20.5%	337 d
Alfonso et al[13]	Retrospective	Abdominoplasty	71	4%	6.3 mo

BR, breast reconstruction.

Fig. 1. The Interi System. Reprinted with permission from *Plast Reconstr Surg Glob Open.* 2022;10:e4030.[6] This article is available under the Creative Commons CC-BY-NC-ND license and permits non-commercial use of the work as published, without adaptation or alteration provided the work is fully attributed.

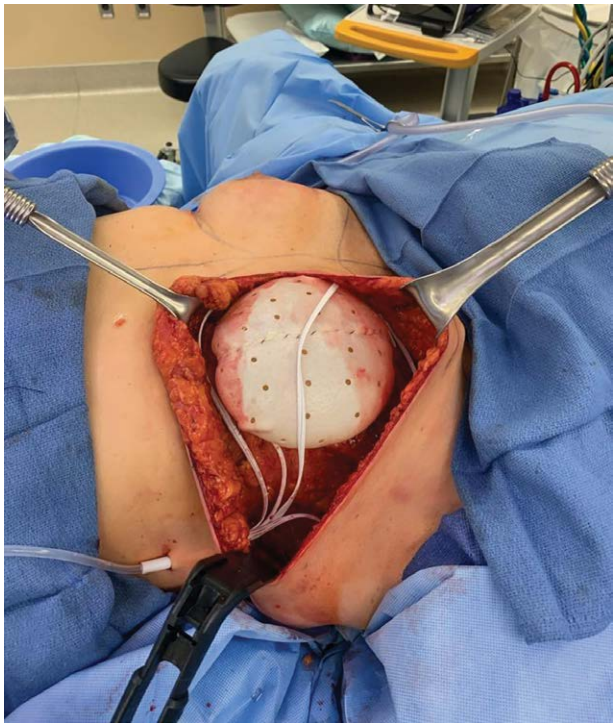

Fig. 2. Implant with manifold branches in place.

centered over the prosthesis, one at the superior border, one at the inferior border, and the fourth in the periimplant space behind the prosthesis and acellular dermal matrix[6] (Fig. 2). This arrangement of the manifold branches ensured maximal coverage of internal tissue planes for fluid evacuation. Using a trocar, the manifold tubing was tunneled down inferiorly through the chest wall and exited through a single opening at the inferior lateral portion of the breast approximately 8–10 cm below the extent of the mastectomy incision (Fig. 3). After closure, the manifold tubing was placed on surgical suction. This step is important to remove tissue debris, fluid, and air from the internal tissue planes before connecting the therapy unit. Dressings were applied over the manifold exit and incision closure sites, per standard practice. The exited manifold was attached to the external therapy unit, via a connector, and then activated. At discharge, patients

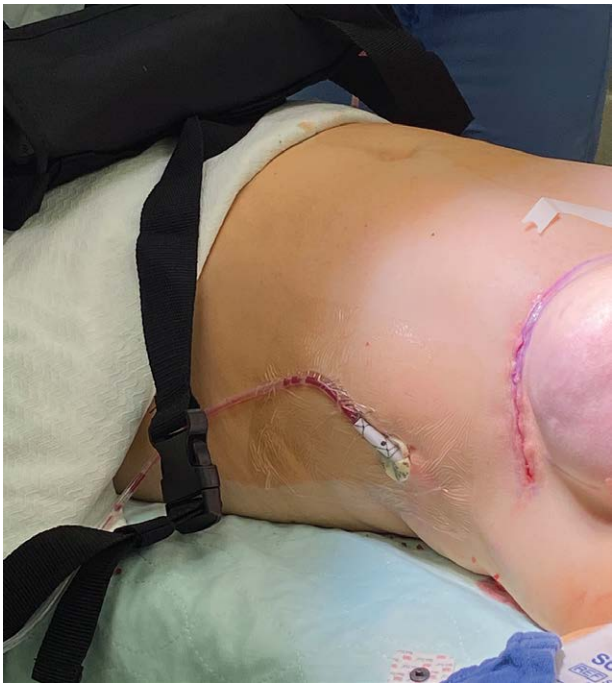

Fig. 3. Manifold exit site location. The exit site is located approximately 8–10 cm below the extent of the mastectomy incision, created by tunneling trocar inferiorly through the chest wall. Shown here after dressings applied.

were taught to read fluid levels in the therapy unit and to replace full units.

In patients who received standard drains, one drain was utilized and inserted in the most lateral and inferior position in the breast pocket and placed along the inframammary fold. The tubing was tunneled to a single lateral exit site. The incision was closed, and dressings were applied over the closed incision and drain exit sites, per standard practice. At discharge, patients were taught to measure fluid in suction bulbs, empty and dispose of fluid from the bulbs, and prime the bulbs to reinitiate suction.

Patient Follow-up

Patients were scheduled for office visits at postoperative days 7–9, at postoperative days 14–21, and 7 days after manifold/standard drain removal. At each visit, patients were assessed for any postoperative complications including seroma (after manifold/standard drain removal), skin edge/flap necrosis, and surgical-site infection. Seroma was defined as any clinically detected seroma (palpable or visible fluid), whether treated or not. Manifolds/standard drains were removed when output volumes were 30 mL or less for at least 3 days.

Data Collection and Analyses

Patient records were reviewed and data on demographics, comorbidities, neoadjuvant therapy use, mastectomy type and specimen weight, reconstruction type, postoperative complications, and manifold/standard drain duration were retrieved and tabulated for the Interi and standard drain groups. Summary statistics of

the data, including mean, SD, and range for continuous variables and frequency and percentages for categorical variables were performed. Statistical differences between groups were determined using the Fisher exact test or the chi-square test for categorical variables and Student *t* test for continuous variables, setting the significance level at below 5%.

RESULTS

Study Participants

A total of 200 patients met the inclusion criteria and formed the analytical cohort of this study. Interi was placed in 100 patients (170 reconstructions) and standard drains in 100 patients (166 reconstructions). Patients were not selected for the type of fluid management that they received. Patients who received Interi were the most recent 100 patients reconstructed in the author's practice from September 2020 through December 2022 since the author began using this fluid management system. Patients who received standard drains were the previous 100 patients reconstructed between December 2018 and November 2020 before the use of Interi.

Baseline Demographics and Mastectomy and Reconstructive Characteristics

Patients in both groups were well matched in baseline demographics, comorbidities, neoadjuvant therapy, and mastectomy and reconstructive variables (Table 1). Overall, patients had a mean age of 50 years and were overweight with a mean body mass index of 28 kg/m^2. A third of the patients had one or more comorbid conditions; notably, a third were obese (body mass index ≥ 30.0 kg/m^2). Prior radiotherapy was uncommon, but a quarter of the patients had neoadjuvant chemotherapy. About half of all mastectomies were for oncologic reasons. Skin-sparing mastectomies were more common and performed in about 60% of cases. Direct-to-implant and expander/implant reconstructions were equally represented. There was no significant difference between the groups in any of the above variables. The only variable that differed significantly between the groups was axillary dissection, the incidence of which was higher in the standard drain group (9.6% versus 3.5%). (**See table, Supplemental Digital Content 1**, which shows demographic, comorbidity, neoadjuvant/adjuvant therapy, and mastectomy and reconstructive variables for the Interi group and the standard drain group. **http://links.lww.com/PRSGO/C760**.)

Duration of Interi/Standard Drains

Interi manifolds were maintained for a significantly shorter period and were removed at a mean of 16.5 versus 19.6 days for standard drains ($P < 0.0001$) (Table 2).

Duration of Follow-up

Patients in the standard drain group were followed up for a significantly longer period than patients in the Interi group: 42.3 ± 6.7 (range: 28.6–52.6) versus 16.3 ± 7.8 (range: 3.8–30.9) months ($P < 0.0001$). Because patients in the drain group were operated on at an earlier time period before the author switching to using Interi, the longer follow-up in this group is to be expected. Follow-up in both groups included a mandatory minimum of 14 days after manifold/drain removal to capture seroma development that typically occurs within 1–2 weeks after termination of fluid evacuation therapy.

Postoperative Complications

During the follow-up period, complications occurred in 40 breasts (23.5%) in the Interi group and 73 breasts (44.0%) in the standard drain group, with the difference being statistically significant ($P = 0.0001$) (Table 3). All complications occurred within the first 90 days of follow-up, and all patients were followed up for at least that long.

Recorded complications (Interi versus standard drain) included seroma (4.1% versus 22.9%), skin/mastectomy flap revision (10.6% versus 21.7%), prosthesis replacement (10.0% versus 6.6%), failed reconstruction (1.2% versus 4.2%), infection (5.9% versus 5.4%), red breast (2.9% versus 2.4%), and edematous flap (1.2% versus 1.8%). Seroma ($P < 0.00001$) and skin/mastectomy flap revision ($P = 0.006$) were significantly lower in the Interi group. Among breasts

Table 2. Duration of Interi/Standard Drains

Variable	Interi System, N = 170	Standard Drains, N = 166	*P*
Duration, mean ± SD, days (range)	16.5 ± 3.5 (9–27)	19.6 ± 6.2 (9–44)	**<0.0001**

Values in boldface indicate statistical significance.

Table 3. Postoperative Complications

Complication	Interi System, N = 170, n (%)	Standard Drains, N = 166, n (%)	*P*
Seroma*	7 (4.1)	38 (22.9)	**<0.00001**
Skin/mastectomy flap revision	18 (10.6)	36 (21.7)	**0.006**
Prosthesis loss	19 (11.2)	18 (10.8)	0.922
With replacement	17 (10.0)	11 (6.6)	0.263
Without replacement (RF)	2 (1.2)	7 (4.2)	0.101
Red breast	5 (2.9)	4 (2.4)	1.000
Edematous flap	2 (1.2)	3 (1.8)	0.682
Infection	10 (5.9)	9 (5.4)	0.855
Any complication	40 (23.5)	73 (44.0)	**0.0001**

*After Interi/standard drain removal; any clinically detected seroma, whether treated or not.
RF, reconstructive failure.
Values in boldface indicate statistical significance.

Table 4. Postoperative Complications: Subgroup Analyses

Complication	Interi System, n/N (%)	Standard Drains, n/N (%)	*P*
Previously irradiated breasts	7/170 (4.1)	8/166 (4.8)	0.797
Seroma	2/7 (28.6)	3/8 (37.5)	1.000
Any complication	4/7 (57.1)	5/8 (62.5)	1.000
BMI ≥ 30.0 kg/m²	57/170 (33.5)	63/166 (38.0)	0.398
Seroma	4/57 (7.0)	21/63 (33.3)	**0.001**
Any complication	16/57 (28.1)	32/63 (50.8)	**0.011**
Smokers	8/170 (4.7)	13/166 (7.8)	0.237
Seroma	0/8 (0)	0/13 (0)	1.000
Any complication	5/8 (62.5)	9/13 (69.2)	1.000
Axillary dissection	6/170 (3.5)	16/166 (9.6)	**0.028**
Seroma	0/6 (0)	4/16 (25.0)	0.541
Any complication	3/6 (50.0)	9/16 (56.3)	1.000

BMI, body mass index.
Values in boldface indicate statistical significance.

that had prosthesis loss, with or without replacement, one (5.3%) started with seroma in the Interi group, and four (22.2%) started with seroma in the drain group. The difference in seroma as an initiator of prosthesis loss was, however, not significantly different between the groups.

Subgroup analyses were performed to assess the impact of the type of fluid management system on the incidence of seroma and any complication in patients with risk factors such as obesity, prior breast irradiation, smoking, and axillary dissection (Table 4). In breasts of obese patients from the Interi group, 7% developed seroma compared with 33.3% from the drain group, with the difference being statistically significant ($P = 0.001$). Any complication was also significantly lower in breasts from obese patients in the Interi group versus the drain group (28.1% versus 50.8%; $P = 0.011$). A quarter of the breasts of patients who had axillary dissection in the drain group had seroma, whereas none of the breasts of patients who had axillary dissection in the Interi group had seroma; however, the difference was not statistically significant. Any complication in these patients was similar between the groups. In previously irradiated breasts or in breasts of smokers, the incidence of seroma or any complication did not differ between the two groups.

DISCUSSION

Prevention of fluid collection in the internal tissue planes following mastectomy and the resulting seroma formation post breast reconstruction remains a challenge for breast surgeons despite current standard interventions.[1,5] The Interi System was developed to provide a more efficient and reliable approach to postsurgical internal wound control and fluid evacuation. Our initial experience with Interi in a small cohort of 23 patients showed a significant reduction in the incidence of seroma after prepectoral breast reconstruction compared with standard drains.[6] In the present study, we confirm this finding in a larger population of 100 patients with 170 reconstructions followed up for a longer period, a mean of 16.3 months, where Interi use resulted in a significant five-fold reduction in the incidence of seroma compared with the use of drains.

Seroma has been correlated with the development of subsequent complications, including infection, prosthesis loss, and delayed wound healing.[3] A reduction in seroma incidence is, thus, likely to lead to a reduction in seroma-related complications as well as any complication. Some of these correlations were observed in this study, particularly, a significant two-fold reduction in the incidence of flap revision and any complication in the Interi group. Interestingly, a significant reduction in seroma with Interi did not appear to have an impact on prosthesis loss or infection, the rates of which were similar to those in the drain group. However, among breasts that had prosthesis loss, seroma as an initiator of the loss was numerically lower in the Interi group.

In addition to the overall population, the subgroup of obese patients was found to benefit from the use of Interi. In these patients, Interi significantly reduced the incidence of seroma by approximately five-fold and the incidence of any complication by approximately two-fold, as in the overall population. It is well established that obesity increases the risk of seroma and any complication. Each unit increase in obesity has been associated with a 7%–14% increased risk of seroma.[3,15] Obesity is also an independent predictor of any complication.[16] Obese patients often have large breasts that leave a large volume of dead space following mastectomy. In addition, large breasts have longer mastectomy skin flaps that are often stretched and thinned. This can compromise incisional wound healing, which, in turn, may prolong inflammation and serous exudate.[3] Thus, dead space and mastectomy flap management, together with an effective fluid evacuation system, are critical in obese patients undergoing breast reconstruction. Here, we have shown that Interi can serve as an effective internal wound control and fluid evacuation therapy in these high-risk patients.

We also evaluated the impact of Interi in other high-risk subgroups, such as smokers, those with preoperative breast irradiation, and axillary dissection. Interi use in the smoker and prior irradiation subgroups did not appear to have a significant impact on the incidence of seroma or any complication, but this could be likely due to the small patient numbers in these subgroups. There were significantly fewer axillary dissections performed in the Interi group compared to the drain group; however,

these patients did not experience seroma rates that were different from the overall rate reported using the respective device. Our results suggest that Interi is an efficient fluid evacuation system across all patient groups.

As in our initial experience study, Interi use in this study was again found to be associated with a significantly shorter duration of fluid management therapy compared with standard drain usage. On average, Interi was removed 3 days earlier than drains. This earlier discontinuation may be attributed to Interi's ability to approximate internal tissue planes and evacuate fluid more efficiently from internal wounds. Interi works by delivering negative pressure internally, between tissue planes where fluid collection occurs, via a unique internal branching manifold, with up to four branches that ensure broad coverage of internal tissue planes.

Since introducing Interi in his practice, the author has observed a reduction in the number of in-office seroma aspirations and flap revision cases than historically. These observations corroborate the study findings of a reduced incidence of seroma, flap revisions, and any complication with the use of Interi. External negative pressure systems are known to improve the vascularity of tissues in the postoperative period[17] and lead to reduced flap necrosis and overall complications.[18] The same phenomenon is also likely to occur with an internal negative pressure system and may partly explain the reduction in flap revisions in this study. Reduction in complications in general would lead to a reduction in total cost of care of patients. Thus, Interi use could potentially result in cost savings, although the cost of Interi exceeds the cost of standard drains.

The author also found that Interi was easy to deploy, and there were no device-related issues or complications or identified contraindications for its use. Since the initial trial period, there have been no implant-based breast reconstruction patients who were excluded from using Interi in the author's practice. Another observation is that the Interi System did not clog throughout the tubing to the extent traditional drains did, potentially as a result of the continuous and consistent suction pressure delivered by the mechanical therapy unit. Patients have reported minimal to no discomfort with the use and removal of the device.

The study is limited by the retrospective design. However, the fact that baseline patient characteristics were well matched between the Interi and standard drain groups and that the same breast surgeon and reconstructive surgeon performed all mastectomies and breast reconstructions, respectively, lend credence to the study and its findings. Further studies, including prospective studies, are needed to support and increase clinical experience with the use of Interi for wound healing and fluid evacuation from internal tissue planes in breast reconstruction and other types of surgery.

CONCLUSIONS

Interi, an internal negative pressure fluid management system, more effectively closed dead space and evacuated fluid from internal tissue planes and mitigated seroma formation and associated complications than standard drains in patients undergoing prepectoral breast reconstruction. The observed reductions in mastectomy skin flap revisions and seroma are indicative of improved internal wound healing. Interi is effective across a broad spectrum of patients, including those who are at high risk of developing seroma. It is easy to handle and deploy intraoperatively and has no device-related safety concerns. As an effective and safe fluid management system, Interi represents a viable alternative to standard drains with the potential to significantly improve patient outcomes.

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DISCLOSURE

Dr. Paul serves on the Medical Advisory Board of IC Surgical, Inc.

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