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Early Experience With The Use Of The Interi System To Facilitate Internal Wound Control After Abdominoplasty

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Purpose:

The Interi System is a new internal wound control system specifically designed to deliver continuous, consistent negative pressure (125 mmHg) to closed internal wound spaces in order to approximate surgically-created tissue planes. Seroma formation and subsequent poor wound healing are the most common complications following surgery and are costly to the healthcare system. Currently used single-channel drains for fluid evacuation provide limited and inconsistent levels of negative pressure, and by design are not able to achieve broad access to internal wound sites. As effective tissue approximation and fluid evacuation is critical to wound healing, there is thus a need for alternate strategies.

Negative pressure delivery to deep tissue planes is accomplished through the Interi System's multi-branched Manifold that can be peeled, as needed, to create a total of 4 branches. The Manifold, placed intraoperatively, is arranged within the surgical site for maximum coverage. The Manifold exits through a single exit site and is attached to a Therapy Unit via a one-way connector. The Therapy Unit is a single-use, portable device that simultaneously delivers continuous, consistent negative pressure and evacuates fluid. The system was designed for patient ease and to minimize hassle when removing and replacing the Therapy Unit when full. The system delivers negative pressure therapy internally, with the branching Manifold providing broad coverage of the internal site. Therapy Units are available in three sizes, 150mL, 300mL and 500mL, and patients are trained to remove and replace the unit when full. The Therapy Units are disposable.

In advance of broad commercialization of the Interi System, this survey-based study was undertaken to assess surgeons' early experience with the use of the Interi System in patients undergoing abdominoplasty.

Methods:

This survey-based study was conducted with surgeons who had performed abdominoplasty and used the Interi System between July and October 2020. Surgeons were surveyed on the day of surgery and at the end of therapy for each patient. The survey included questions on ease of use of Interi intraoperatively, ease of training the patient in using the Therapy Unit at home, acceptable functioning of the Interi System as perceived by the patient and the surgeon, and ease of removal of the Manifold by the surgeon. Surgeons were asked to rate their responses on a 5 points agree/disagree scale (where 5 = Strongly Agree and 1 = Strongly Disagree). The duration of therapy and volume of fluid collected were also captured in the survey.

This study follows a prospective pilot study completed in 2017, reported in an abstract submitted by Marc Walker, MD and accepted for presentation at the Aesthetic Meeting 2020 and 2021. In this recent report, the commercially available Interi System was utilized by surgeons in their own practices and integrated into their own standard of care for abdominoplasty.

Results:

A total of 13 surgeons participated in the survey reporting initial use of Interi in 33 patients. Results from 12 surgeons and 29 patients who completed therapy with Interi and submitted the final survey are reported here. 72% of the patients (n=21) underwent concurrent abdominoplasty and liposuction. Surgeons trimmed Manifold branches in 21% of patients (n=6). All, but 3 patients, were discharged on the same day following surgery. The surgeons reported that the Manifold was easy to place intraoperatively with average score of 4.9 on 5-point scale where 5 = Strongly Agree. All surgeons strongly agreed that the connector was easy to attach with 100% scoring 5.0; training the patient to use the therapy unit at home was simple and straightforward, with an average score of 4.8.

The Manifold was left in place for an average of 8.4 days (range: 6-14 days). An average of 643 mL (range: 260-1605 mL) of fluid were collected during the therapy period. High-resolution ultrasound was performed in 12 patients during the therapy period, with no fluid detected in the subcutaneous spaces in any patients. Surgeons reported that the Interi System functioned acceptably during the duration of therapy with an average score of 4.8 and that the Manifold was "easy to remove, considering force required and patient tolerance compared to standard surgical drains" with an average score of 4.8. Similarly, surgeons reported that the majority of patients strongly agreed that the Interi System functioned acceptably during the therapy period, average score of 4.6.

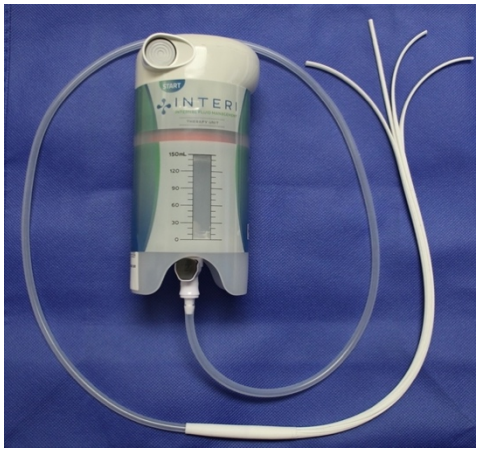
Open-ended survey responses commented on patient and operating room staff ease of use, ease of manifold removal as well as no negative comments on the size or weight of the Therapy Unit. There were also general comments regarding observations of little edema and soft overlying tissue. Two surgeons noted a slightly larger exit site hole after Manifold removal compared with standard drains.

Conclusion:

Early experience with the use of the Interi System in abdominoplasty suggests that the system is easy to use, is well tolerated, and functions acceptably as conceived. Future controlled studies to evaluate the safety and efficiency of the Interi System are planned.

Limitations of this study are the small number of patients and no control comparing to standard drains or other methods of tissue closure. The objective here was simply to report on surgeons and patients intial use of this novel technology for internal wound control. Further studies in aesthetic and reconstructive plastic surgery are planned to demonstrate reduction in seroma and others complications, along with patient satisfaction.

Interi System



Manifold – with four trimmable branches

Therapy Unit – 150mL size