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Defining Internal Tissue Closure: High Resolution Ultrasound Evaluation of Interi - A Novel Internal Tissue Closure System

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Goals/Purpose: High Resolution Ultrasound (HRUS) has been utilized by plastic surgeons since the 1980's to diagnose, locate, and treat active post-surgical fluid collections and seromas. Most recently, HRUS is gaining momentum in plastic surgery for the diagnosis of breast implant shell failure, fat transfer, and diagnosis of fluid collections postoperatively. Conventional drains have been used by surgeons for the past 75 years, but persistently high reported rates of seroma and poor wound healing continue and are indicative of their ineffectiveness in closing down and healing of surgical spaces. Current drains access only limited areas of the surgical space, and the generated negative pressure delivered is too inconsistent and low to actively facilitate closure of post-surgical tissues planes.

A novel system, Interi™ (IC Surgical, Grand Rapids MI), includes a branching 4-channel internal manifold connected to a therapy unit to deliver -125 mmHg continuous negative pressure to internal tissue planes while simultaneously removing all fluid from the surgical spaces. By effectively removing blood and fluid, and drawing together and approximating internal tissue planes, primary tissue healing may occur unhindered without detrimental fluid collection or seroma formation.

The objectives of this consecutive patient retrospective review are to: 1) Evaluate the ability of Interi to fully evacuate postoperative effluent and blood from within the surgical space, 2) Evaluate the ability of Interi to approximate and hold together surgical tissue planes in a series of abdominoplasty patients, 3) Document adverse events and complications in the series including fluid collection and seroma and compare to historical outcome studies, and 4) Document, demonstrate and define what internal tissue closure looks like radiographically.

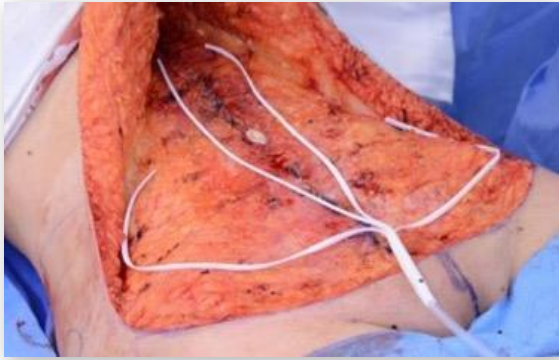
Methods/Technique: IRB approval was obtained for a retrospective review of the first 71 consecutive full abdominoplasty patients utilizing the Interi System from July 2020 through March 2021, by 3 board certified plastic surgeons at 2 surgical sites. High Resolution Ultrasound (Plastic Surgery Imaging - 12 MHz Transducer) was used to visualize whether any fluid collections were present in the surgical site at the time of manifold removal and HRUS performed postoperatively with any signs of swelling or clinical suspicion of seroma. Images

were reviewed by both the surgeons and an independent radiologist. Any visible fluid collections were documented. All adverse events were recorded.

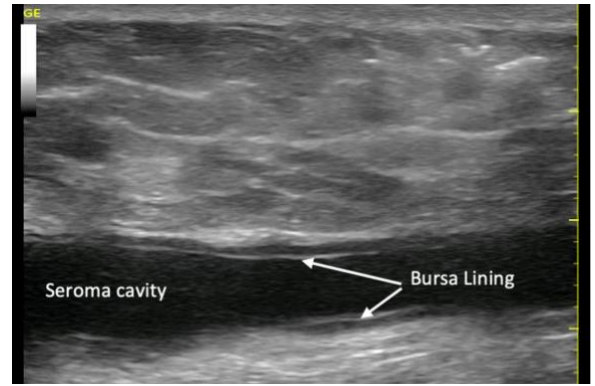
Results/Complications: A total of 71 consecutive full abdominoplasty patients receiving the Interi system from three plastic surgeons were evaluated. There were 68 females and 3 males. The patient age range was from 21-74 years, with an average age of 43 years. The Body Mass Index (BMI) ranged from 19-44 with a mean of 28. Fifty-nine of 71 patients (83%) had concurrent liposuction of the flanks and 44 of 71 (62%) had liposuction of their anterior abdomen. The length of therapy on Interi, calculated as the number of days from surgery until manifold removal, ranged from 5-18 days with an average of 9 days. Total fluid output averaged 570 cc's with a range of 90-1550 cc's.

High resolution ultrasound was performed by all three surgeons on the majority of patients on the day of manifold removal or subsequent visits. Sixty-six of 71 patients had HRUS documented. Images from 24 patients were recorded throughout the post-operative course were evaluated by the operating surgeon and independent radiologist with seroma confirmed in 3/71 patients (4.2%). Two patients developed seromas secondary to patient error failing to activate their system after a change of the therapy unit. The third patient failed to recognize the therapy unit was full with subsequent seroma development. No other fluid collections or seromas were identified on clinical exam or on High resolution ultrasound at the time of device removal or throughout follow-up. Identification of the healing tissue planes without evidence of any fluid in the 68 remaining patients were confirmed on HRUS. One patient had a suture abscess with associated cellulitis that resolved with oral antibiotics. No other major complications were noted. No skin flap necrosis was seen in any patient postoperatively.

Conclusion: This novel Interi device effectively removed all visible blood and fluid visualized on HRUS within the surgical space in 68 of 71 patients resulting in a 4.2% seroma rate. This is in direct contradistinction to a prior seroma rate of 22% at our center with standard drains. Additional complications occurred in 2 additional patients resolving with oral antibiotics. No patients required early reoperations within the first 6 months and there were no patients with skin flap necrosis. Importantly, evacuation of all blood and fluid is easily identified on HRUS, with the exception of the 3 seroma patients, and the healing tissue plane can be clearly visualized on HRUS. This healing tissue plane we describe as *Internal Tissue Closure* and is the first time it has been radiographically defined and documented. This is the first and largest consecutive series with the Interi device effectively showing its ability to draw together and hold closed tissue plans allowing for primary healing with optimal functioning. In addition, we believe HRUS will become the gold standard after body contouring procedures and may be used to document tissue healing planes while simultaneously truly ruling out any seroma collection.



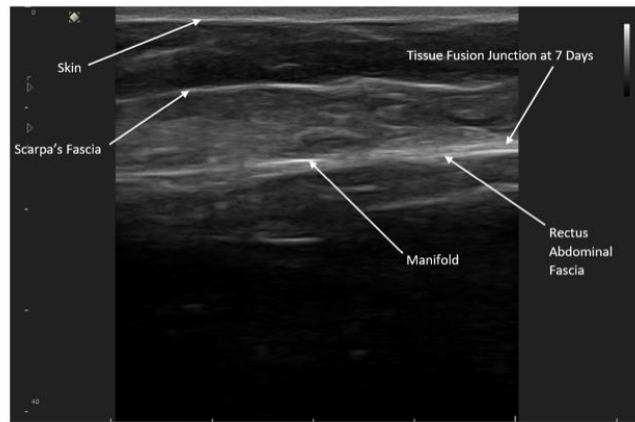
The internal manifold is in position allowing broad distribution of -125mm HG negative pressure throughout the entire surgical space.



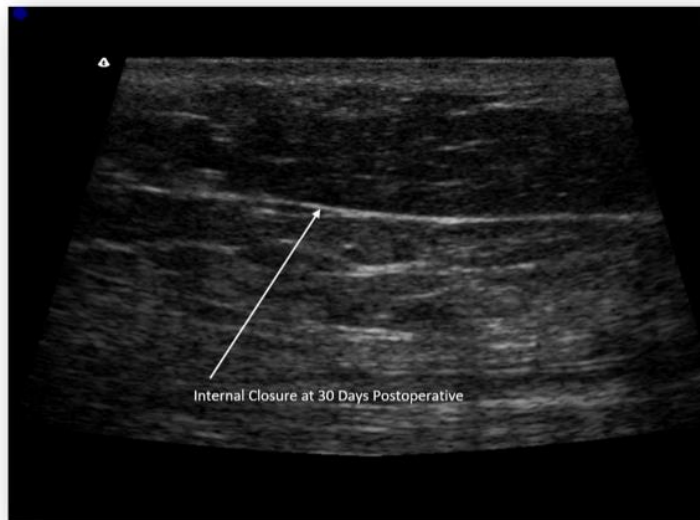
Seroma cavity following abdominoplasty with standard drain technology.



300cc Interi Therapy Unit.



Internal anatomy of High-Resolution Ultrasound.



Internal Tissue Closure Plane of healing at 30 days postoperatively.