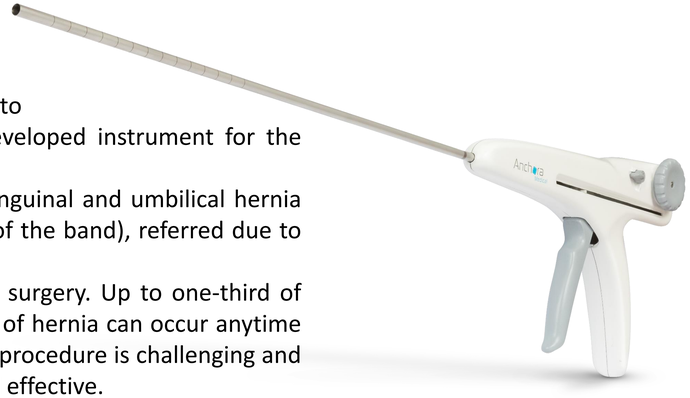
Su2ura Approximation Device - Case Study

Introduction:



This report describes a case presenting with 4 hernia defects, two of which are located close to the ribs, which were sutured with the Su2ura® Approximation Device (AD), a newly developed instrument for the approximation of soft tissue.

The patient is a 61-yo male (BMI: 29.1), with a history of laparoscopic bilateral repair of inguinal and umbilical hernia repair, and 3 laparoscopic gastric band procedures (placement, removal, and replacement of the band), referred due to swelling in the surgical scars area (left upper abdominal wall).

Incisional hernia or post-operative ventral hernia (POVH) develops at the site of previous surgery. Up to one-third of patients who had abdominal surgery develop an incisional hernia at the scar site. This type of hernia can occur anytime from months to years after abdominal surgery. Suturing of the defect during a laparoscopic procedure is challenging and requires skills earned over many repetitive procedures before making such surgery short and effective.

The Su2ura® AD was used in this first-in-human trial to simplify the closing of the POVH. The safety and efficacy of this device during this procedure were assessed.

Methods and Procedures:

Two subcostal incisional hernias (size 1.5 cm each) were located 2cm apart on the left abdomen. Two additional defects were observed left of the Linea Alba (Figure 1).

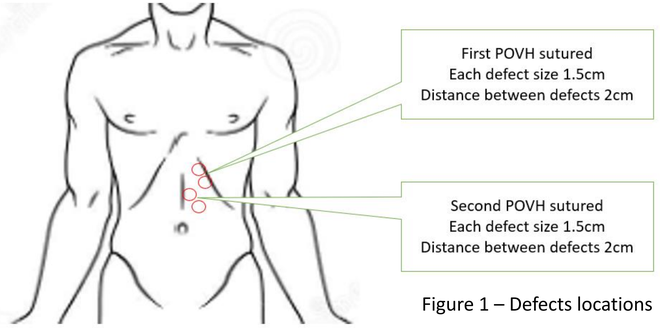
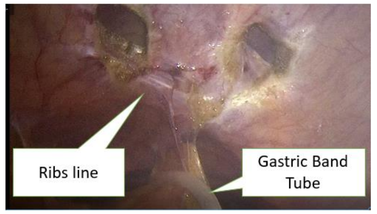


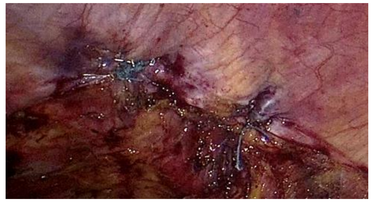
Figure 1 – Defects locations

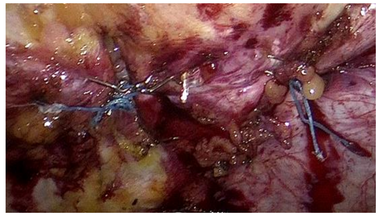




All defects contained omentum and preperitoneal fat. Multiple adhesions were observed around the defects and the gastric tube. Using diathermia, the peritoneum was incised and adhesions and preperitoneal fat were removed to expose the fascia surrounding the defects. (Figure 2).

Figure 2 – Defects before suturing





All four defects were independently sutured and approximated using the Su2ura® AD, with 4 anchors for each defect (Figure 3).

Following approximation, meshes were used to cover the defects of the abdominal wall, fixated using tackers. Tackers could not be used to fixate the meshes over the ribs area, surgical glue was used instead.

Figure 3 – Defects after suturing

Results:

Suturing and approximation were effective using the Su2ura Approximation Device, as shown below in Figure 3.

After a 6-week follow-up, the patient does not show any device-related adverse events, nor any hernia recurrence, clinical bulge, or seroma.

Conclusions:

Suturing defects located on the ribs area is particularly challenging, given the anatomical limitations. The Su2ura® AD, a new automated suturing device, facilitated the approximation of these defects in this particular anatomical area quickly and effectively.