Laparoscopic umbilical hernia repair with Su2ura® Approximation Device

Introduction:

This study was performed to assess the safety and efficacy of the Su2ura® Approximation Device, a newly developed instrument for the approximation of soft tissue defects, investigated here for laparoscopic closure of primary umbilical hernia defect with intraperitoneal mesh placement (IPOM).

IPOM for primary umbilical hernia repair is a well-established laparoscopic method for the treatment of this pathology. Suturing of the defect during a laparoscopic procedure is challenging and requires skills to be earned over many repetitive procedures before making such surgery short and effective.

The Su2ura® Approximation Device was used in this first-in-human trial to simplify the closing of the umbilical hernia defect. The safety and efficacy of this device during umbilical hernia repair were assessed.

Methods and Procedures:

A prospective, multi-center, single-arm study was conducted. Patients aged 18 and more, with BMI comprised between 20 and 40 and with hernia defects of up to 5 cm were enrolled. The first ten patients who completed a six-month postoperative follow-up underwent standard laparoscopic umbilical hernia repair, during which the Su2ura Approximation Device was used for closing the defect after which a mesh was fixated. The safety endpoints were the overall rate of serious adverse events and serious adverse device effects up to hospital discharge and up to the 60th post-operative day. The efficacy endpoints were assessed up to 6 months follow-up by measuring the hernia recurrence rate, the patient satisfaction, the clinical bulging, and the evidence of seroma.

Our Company:

Anchora Medical, founded in 2014, is introducing a new approximation device – Anchor based continuous suturing. Anchora specializes in simplifying of suturing in both Laparoscopic and Endoscopic applications.

Our Device:

a single use approximation device, incorporates tiny stainless still anchors threaded on a surgical thread, creating either running or interrupted sutures

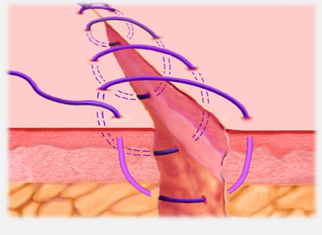




Larger surface area

Our solution:
Open “U” shape loop
Avoids entrapment –
by design

Open “U” loop



Existing solution:
Closed “O” shape loop
Over tightening can cause entrapment of blood vessels resulting in ischemia and necrosis

Results:

Patients presented with a defect size ranging in diameter between 0.5 cm and 5 cm; 2 patients also presented with diastasis. All 10 umbilical hernia repairs were successfully completed with the Su2ura® Approximation Device, and surgeries were performed as per protocol. No patients suffered hernia recurrence, clinical bulge, or seroma. All patients reported good Quality of Life, significant improvement in pain-related parameters, and daily and sports-related activities. By six months post-surgery, none of the patients felt restricted in their daily activities. Most patients reported improvements in the shape of their abdomen.

Conclusions:

These preliminary results indicate the safety of the Su2ura® Approximation Device when used in standard laparoscopic hernia repair surgery, and its efficacy when approximating primary defect prior to mesh fixation.

Links:

CLICK: procedure animation

CLICK: human clinical case

CLICK: pre-clinical case