Clinical Research Bibliography (June - 2020)

OVITEX® REINFORCED TISSUE MATRIX

BRAVO Clinical Study

BRAVO Ventral Hernia Study Overview

- Study Design: prospective, single arm, multi-center study evaluating the clinical outcomes of ventral hernias treated with OviTex 1S Permanent
- Study Size and Duration: 100 patients with 2-year follow-up
- Primary Endpoints: incidence of early post-operative surgical site occurrences or wound related events occurring at the hernia repair site, including deep or superficial wound infection, seroma, hematoma, wound dehiscence, skin necrosis, and fistulas
- Secondary Endpoints: hernia recurrence, patient reported outcomes, incidence of late post-operative surgical site occurrences or wound-related events

Reinforced Biologics in MIS Ventral Hernia Repair (MIVHR)

(2020 Minimally Invasive Surgery Virtual Symposium)

- Data from the BRAVO Clinical Study were analyzed to assess the utility of OviTex 1S in laparoscopic and robotic ventral hernia repair
    - Thirty-one (31) of 92 subjects underwent MIVHR, 20 (65%) robotic and 11 (35%) laparoscopic
    - Average follow-up: ~12 months
- One SSO in the laparoscopic group – infection of superficial incision used for hernia sac removal
- One recurrence in a patient with an umbilical hernia and diastasis recti
    - Recurrence was a new herniation adjacent to original repair
    - Original OviTex construct was intact with 'OviTex completely vascularized and remodeled'
- All investigators found OviTex 'very easy' or 'easy' to use in terms of placement and fixation
- Observed incidence of SSOs and recurrence is equal or lower than those reported in the literature

Reinforced Biologic Reduces Risk of Recurrence in Ventral Hernia (VH) Patients: One-Year Data from the BRAVO Ventral Hernia Study

(2019 Abdominal Wall Reconstruction Conference)

- Positive results for the first 32 patients completing one-year follow-up
    - Average BMI: 31.0, 84% VHWG Grade 2 & 3, 44% with prior VH procedure
- No patient has experienced a ventral hernia recurrence or required an explantation
- Nine patients (28%) experienced SSOs, none of which required further surgery or removal of the implant
- At one-year, patient satisfaction was 9.3 out of 10 (n=27) and surgeon satisfaction was 9.8 out of 10 (n=32)
- OviTex was considered easy or very easy to use in all cases
- Early results are promising compared to rates reported in published literature

Initial Experience with Reinforced Biologics in Minimally Invasive Ventral Hernia Repair (MIVHR)

(2019 Abdominal Wall Reconstruction Conference)

- Data from the BRAVO Clinical Study were analyzed to compare OviTex 1S in MIVHR and Open VHR
    - Seventy-six subjects underwent surgery and completed 30-day follow-up, 50 (66%) open and 26 (33%) minimally invasive (MIS), of which 8 were laparoscopic and 18 robotic
- Open repairs were performed on more complex patients compared to MIVHRs (50% vs. 12% had prior VH repairs; 22% vs. 4% were VHWG grade 3)
- SSO rate in open repair patients was 32% compared to 0% in MIVHR patients
- Surgeon satisfaction at 30-days and 90-days was 9.7 out of 10 for both open VH repairs and MIVHRs
- The results demonstrate that OviTex 1S was equally easy to use in both open and MIS procedures, and thus opens the possibility for routine use of biologic-based implants in MIS procedures

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Journal Articles

In-vivo evaluation of a reinforced ovine biologic: a comparative study to available hernia mesh repair materials

(Hernia, December 2020)

- Pre-clinical study comparing two innovative reinforced biologic materials to seven clinically used biologic and synthetic meshes in a non-human primate hernia repair model
- **Synthetics** developed a layer of reactive tissue above and separate from the contracted mesh structure
    - Foreign body response persisted at 24 weeks with the synthetics
    - Developed less organized collagen, separate in space from the actual mesh
- **Biologics** resorbed and remodeled into naturally appearing tissue
- **Reinforced biologics** appeared similar to biologics but remodeled earlier and were less prone to stretch
    - As early as 12 weeks, the collagen networks associated with the reinforced biologics remodeled into organized host collagen
- By 24 weeks, both reinforced biologics and biologics had low levels of inflammation
- Study shows a favorable response to reinforced biologics, which were associated with an initial inflammatory response, resolving by later time points, followed by active remodeling, and the formation of new morphologically functional collagen

New Ovine Polymer-Reinforced BioScaffold in Hiatal Hernia Repair

(Journal of the Society of Laparoendoscopic Surgeons, September 2018)

- OviTex used in repair of Types I, II, III and IV hiatal hernias, both primary and recurrent, in 25 patients
    - Average follow-up: 14.2 months (range: 1-20 months)
- OviTex features included excellent strength, ease of handling and suturing, and conformation to the hiatal space
- Good to excellent symptom control reported for all preoperative symptoms
- No clinical recurrences reported

Early Experience Outcome of a Reinforced BioScaffold in Inguinal Hernia Repair: A Case Series

(International Journal of Surgery Open, June 2018)

- Data collected from 31 consecutive patients who had an inguinal hernia repair using OviTex Permanent (4x8 cm)
    - All hernia repaired using open Lichtenstein technique
    - Average follow up of 12.6 months (range: 3 – 18 months)
- No reported surgical site infections during initial 30 days postoperatively
- No reported recurrences or explantations
- No postoperative complications (seromas or hematomas) requiring surgical intervention
- No reported incidence of Chronic Postoperative Inguinal Pain
- No requests for pain medication refills (all patients prescribed standard postoperative narcotics)

White Papers

Mesh Performance in Hernia Repair in 2017: A Surgical Review of Progress to Improve Outcomes

- TELA Bio convened a panel of 7 expert surgeons to review the current landscape of mesh-based hernia repair
- The surgeons had experience in over 200 cases using OviTex
- Early outcomes in demanding cases have been very promising, and to date, no adverse events were possibly or definitely related to the implant

TELA BIO® INC SURGICAL RECONSTRUCTION COMPANY

- Surgeons commented that OviTex RBSs handle well compared to biologic implants and are suited for use in open and minimally invasive surgeries
- Surgeons agreed that their usage reflected the versatility of the OviTex RBS product portfolio for a wide range of ventral hernias

Conference Poster Presentations

Using a Reinforced Biologic Mesh in a Minimally Invasive Technique for Ventral Hernia Repair

(2020 Minimally Invasive Surgery Virtual Symposium)

- Retrospective review of 27 patients from a single surgeon using single incision retrorectus (SIRR) or single incision preperitoneal (SIPP) technique for repair of ventral hernia between 2018-2019
  - 25 cases completed with SIRR technique, 2 with SIPP
  - Average follow-up: ~ nine months (36 to 459 days)
  - OviTex 1S Permanent – 19 patients
  - OviTex LPR – 4 patients
  - OviTex Core Permanent – 4 patients
- No reported cases of recurrence
- One reported surgical site occurrence (3.7%).
  - Post-operative hematoma identified in a patient on chronic anticoagulation
- The use of a reinforced biologic mesh during the minimally invasive SIRR or SIPP procedure for ventral hernia appears to be an effective and safe option

Reinforced BioScaffold Mesh Lowers Recurrent Hernia Rate in High-Risk Ventral Hernia Repair with Surgical Site Occurrences

(2019 Americas Hernia Society Annual Meeting)

- Retrospective review of two cohorts of 50 patients at Indiana University who underwent open VHR with either OviTex or synthetic mesh in 2017
  - OviTex group had significantly more high-risk patients (VHWG grade 3: 68% vs. 6%)
  - OviTex group had a significantly higher % of concomitant surgeries (70% vs. 10%)
- Endpoints including SSO, readmission rate, and hernia recurrence were evaluated 6 months postoperatively
- Lower hernia recurrence rate in OviTex group vs. synthetic mesh group (8% vs. 12%*, p-value > 0.05), “suggesting that OviTex may be better suited for definitive hernia repair in higher risk patients in place of synthetic and biologic meshes”

Ovine Polymer-Reinforced BioScaffold in Abdominal Wall Reconstruction

(2019 Americas Hernia Society Annual Meeting and 2018 Americas Hernia Society International Hernia Congress)

- OviTex used in 23 consecutive patients undergoing abdominal wall reconstruction with myofascial advancement flap creation
  - Less than half the patients were VHWG Grade 1 or Grade 2
  - Patients generally had multiple comorbidities, with an average of 3.4 per patient
  - Nearly two-thirds of patients had recurrent hernias, with 15 synthetic/biologic mesh explantations
- “Acceptably low” rates of recurrence (9%) and complications and excellent patient satisfaction at an average of 18.7 months of follow up (range of 9 to 33 months)

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Resilience and Healing of a Novel Reinforced BioScaffold (RBS) Matrix in the Setting of High-Risk Incisional Hernia Repair After Enterocutaneous Fistula (ECF) Takedown

(2019 Americas Hernia Society Annual Meeting)

- OviTex used in 66-year-old male with COPD and severe malnutrition presenting for enterocutaneous fistula takedown and incisional hernia repair
    - One week postop, a deep SSI with dehiscence of skin and anterior rectus sheath closures developed, exposing the OviTex, which was left in place with wound care initiated
- OviTex "seamlessly and effectively incorporated within the wound with rapid granulation"
    - Patient is 12 months postop with a completely healed incision and no recurrence
- OviTex allowed robust wound healing without recurrence of the hernia

A Study of Mesh Compliance: Implications for Proper Splinting for Fascial Repair in Abdominal Wall Reconstruction

(2019 Americas Hernia Society Annual Meeting)

- The ideal mesh for abdominal wall repair should provide ongoing support without altering the native compliance of the abdominal wall, which ranges between 11% and 32%
- OviTex (4 layers), OviTex 1S (6 layers), OviTex 2S (8 layers) were tested for uniaxial compliance
- OviTex meshes exhibited a compliance ranging from 10.9% to 14.2%, within the native range of the abdominal wall, showing that they may be well suited to offload or splint a primary fascial repair

Surgeon Feedback on Initial Clinical Experience with OviTex Reinforced BioScaffolds in a Wide Range of Hernia Patients

(2017 Abdominal Wall Reconstruction Conference)

- Reported initial observations on hernia repair with OviTex in 134 patients, with surgeon feedback for 128 patients and an average follow-up of 108 days
- OviTex successfully used in a wide range of hernia patients, including ventral, hiatal, parastomal, and inguinal
- Surgeons noted that OviTex was easy to handle, trim, suture, and tack in all surgical approaches (including minimally invasive) and conformed well to the contours of surgical site
- Reported complication rates lower than those typically observed within the reported follow-up period
- No device failures, explants, or hernia recurrences reported

Case Studies

Open Abdomen Incisional Herniorrhaphy in a High Risk, Complex Patient

- OviTex performed well in a hostile field of a complex recurrent abdominal wall hernia in a patient with numerous significant comorbidities

Repair of Incisional Hernias in 2 Patients with More Than 1 Year of Follow-up

- OviTex used in two patients with multiple comorbidities undergoing abdominal wall reconstruction
- Both patients satisfied with their repairs and exhibited no signs of surgery-related recurrence or other complications after 15 months and 17 months of follow-up

* 4 of 50 recurrences in OviTex group; 6 of 50 recurrences in synthetic mesh group

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