

Biosynthetic meshes in hernia repair « Newer class of materials »

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COCHRANE DATA BASE 2008

“There is good evidence from three trials that open mesh repair is superior to suture repair in terms of **recurrences**, but inferior when considering **wound infection**. Six trials yielded insufficient evidence as to which type of mesh or which mesh position (on- or sublay) should be used. There was also insufficient evidence to advocate the use of the components separation technique.”

- **Open surgical procedures for incisional hernias**
- Dennis den Hartog², Alphons HM Dur³, Wim E Tuinebreijer¹, Robert W Kreis³
- ¹Wijk aan Zee, Netherlands. ²Surgery, Erasmus MC, University Medical Center Rotterdam, Rotterdam, Netherlands. ³Surgery, Red
- *Cochrane Database of Systematic Reviews*, Issue 3, **2008** (Status in this issue: *New*)
- Copyright © 2008 The Cochrane Collaboration. Published by JohnWiley & Sons,

International Endohernia Society 2014

R. BITTNER SURG ENDOSC (2014) 28:2–29

Recommendations

Grade A

For repair of primary defects larger than 2 cm or recurrent hernias of any size, **mesh repair should be considered as the first choice.**

GradeC

Suture repair should be used only for very small primary defects of the abdominal wall in the absence of any possible recurrence risk factors.

GradeD

In terms of recurrence, the available evidence is sufficiently strong to recommend that all defects of the abdominal wall, whether inguinal, **incisional**, or umbilical hernias, and of whatever size should be repaired with **the use of prosthetic mesh**

« The dream mesh »

- RECURRENCE = 0
- CHRONIC PAIN = 0
- INFECTION = 0
- VISCERAL ADHESIONS = 0

BUT « DREAM MESH » MUST GIVE ALSO :

Sufficient ingrowth

Small or no shrinkage

Conserve or restaure functionality abdominal wall

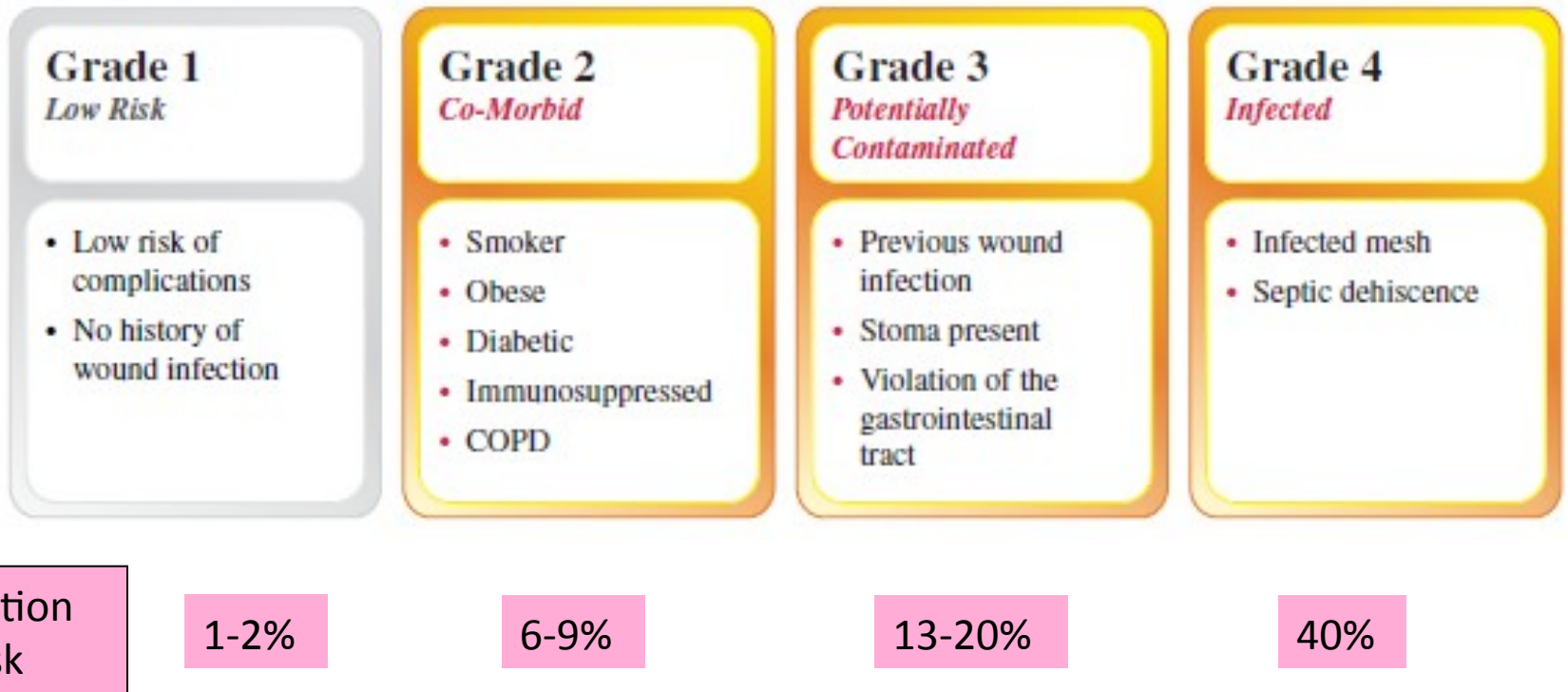
No seroma

Easy handling

Low cost

Classification

- Ventral Hernia Working Group (VHWG)



A 5-Year Clinical Experience With Single-Stage Repairs of Infected and Contaminated Abdominal Wall Defects Utilizing Biologic Mesh

Michael J. Rosen, MD, David M. Krpata, MD, Bridget Ermlich, RN, and Jeffrey A. Blatnik, MD

Objective: Our objective was to evaluate the safety and durability of biologic mesh for single-staged reconstruction of contaminated fields.

Introduction: The presence of contamination during ventral hernia repair (VHR) poses a significant challenge. Some advocate for a multistaged reconstructive approach with delayed definitive repair, whereas others perform definitive repair at the initial operation.

Methods: Patients undergoing single-staged VHR in a contaminated field with biologic mesh over a 5-year period were retrospectively reviewed from a prospectively maintained database. Outcome measures included wound complication and hernia recurrence.

Results: A total of 128 patients (76 F, 52 M) were identified, with a mean age of 58.2 years, mean American Society of Anesthesiologist (ASA) score 3.1, and mean body mass index (BMI) $34.1 \pm 9.7 \text{ kg/m}^2$. Comorbidities included COPD ($n = 29$), diabetes ($n = 65$), smoking ($n = 29$), and immunosuppression ($n = 8$). Mean hernia defect size was 431 cm^2 (range 40–2450 cm^2). Reasons for contamination included the presence of infected mesh ($n = 45$), stoma ($n = 24$), concomitant gastrointestinal (GI) surgery ($n = 17$), enterocutaneous fistula ($n = 25$), open nonhealing wound(s) ($n = 6$), enterotomy/colotomy ($n = 5$), and chronic draining sinus ($n = 6$). Postoperative wound complications were identified in 61 (47.7%) patients. Predictors of wound complications included ASA score, diabetes, smoking, number of previous abdominal surgeries or hernia repairs, hernia defect size, and operative time. With a mean follow-up time of 21.7 months, hernia recurrence was identified in 40 (31.3%) patients. The majority of recurrent hernias were asymptomatic and 7 patients underwent repair.

Conclusions: Despite the high rate of wound morbidity associated with single-staged reconstruction of contaminated fields, it can safely be performed with biologic mesh reinforcement. Although biologic mesh in these situations is safe, the long-term durability seems to be less favorable.

Keywords: abdominal wall reconstruction, biologic mesh, infection, single-staged repair, ventral hernia

(*Ann Surg* 2013;257: 991–996)

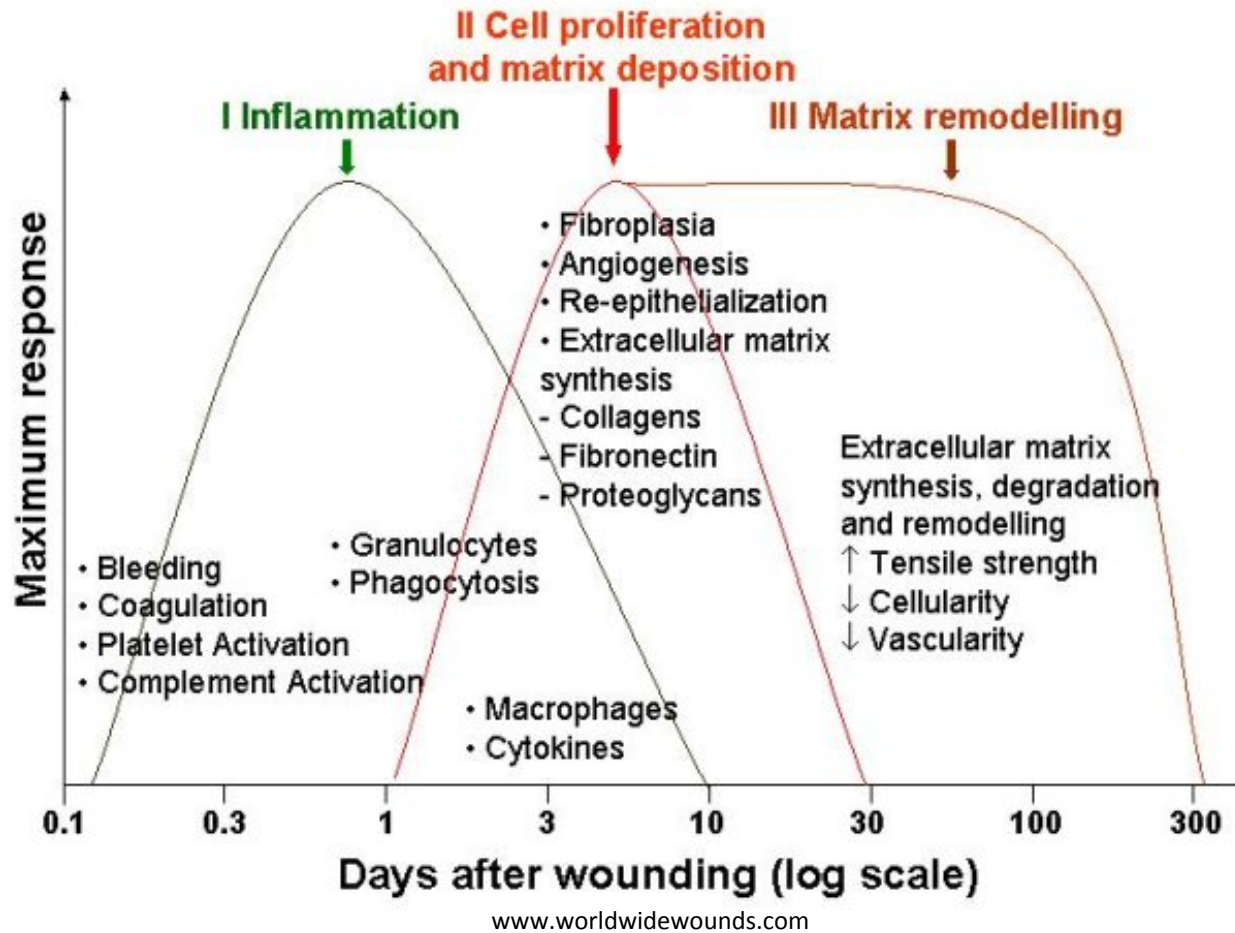
has led to a 50% reduction in hernia recurrence.¹ Mesh selection in the presence of contamination is highly controversial, but an important question to address given the impact of mesh on repair durability.

The challenge of managing contaminated ventral hernias is that synthetic mesh materials are perceived as contraindicated. As a result, some advocate for a multistaged reconstructive approach with delayed definitive repair.^{2,3} This method requires an initial operation to remove and clear the infectious source. Patients then return for definitive repair of their hernia 6–12 months later. This prolonged convalescence and the complexity of the large abdominal wall defect created has prompted surgeons to investigate options for a single-staged approach to repairing contaminated abdominal wall hernias. The development of biologic grafts has been instrumental in providing the potential for a single-staged approach. These grafts reportedly promote cellular infiltration, neovascularization, and potentially regenerate into native tissue that might provide significant advantages over synthetic materials in the setting of contamination.⁴ With the introduction of these materials into the surgical armamentarium, several small series with relatively short-term follow-up have suggested these materials are safe to use.^{5–11} However, the ultimate measure of success of these materials is to provide a durable single-staged repair with a low hernia recurrence rate and avoid long-term infectious complications for these patients. The aim of this study was to provide the first long-term data evaluating the durability of biologic grafts when utilized during the single-staged repair of contaminated and infected abdominal wall hernia repairs.

METHODS

After obtaining the Institutional Review Board approval, a retrospective analysis of a prospectively maintained database was undertaken. Patients undergoing open VHR between September 2005 and February 2012 by a single surgeon (MJR) at a single institution were reviewed. Patients included in this analysis underwent an open single-staged reconstruction procedure for an incisional hernia in the

Over time, the body completely replaces the scaffold with healthy native tissue

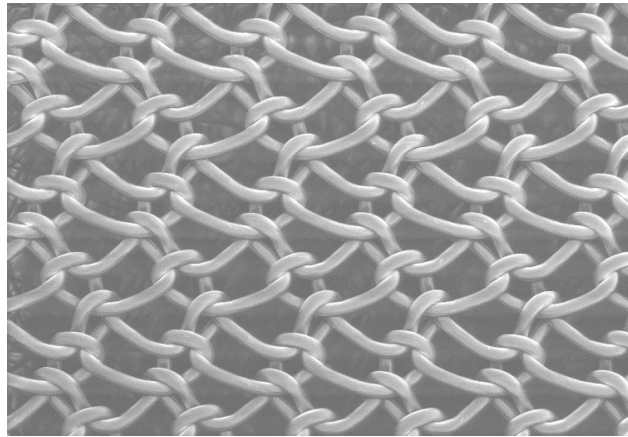


- Badylak, S. F. (2007). "The extracellular matrix as a biologic scaffold material." *Biomaterials* 28(25): 3587-3593.

End point is : a mesh with
favorable aspects of biologic
material and those of a synthetic
material?

Biosynthetic meshes

- Stable scaffold for tissue remodeling and in the same time totally dissolve into tissue



Biosynthetic meshes

- Vicryl Mesh (Ethicon Endo Surgery inc)
- Tigr Resorbable matrix (Novus Scientific)
- Phasix Mesh (Bard Davol Inc)
- Seri Surgical Scaffold (Allergan)
- Gore Bio-A tissue Reinforcement (W L Gore associate)

Biosynthetic meshes

- Vicryl Mesh (Ethicon Endo Surgery inc)
- Seri Surgical Scaffol (Allergan)

Biosynthetic meshes / TIGR

Tigr Resorbable matrix (Novus Scientific)

Knitted 2 synthetic resorbable fibers :

1° Copolymer of glycolide, lactide and trimethylene carbonate strength 2 weeks absorbed 4 months

2° Copolymer lactide and trimethylene carbonate absorbed 3 years

Special design : strength and facilitate stimulation new tissue

Biosynthetic meshes / TIGR

Inguinal hernia repair using a synthetic long –term resorbable mesh: results from a 3 year prospective safety and performance study

Ruiz-Jabson F and coll : Hernia 2014;18: 723-30

Prophylactic resorbable synthetic mesh to prevent wound dehiscence and incisional hernia in high high-risk laparotomy: a pilot study of using Tigr matrix Mesh

Soderback H and coll Front Surg 2016; 18: e_

Biosynthetic meshes

- Gore Bio-A tissue Reinforcement (W L Gore associate)
- One type of synthetic resorbable fiber
- Polyglycolic acid and trimethylene carbonate
- Absorbed over 6 to 7 months

Cobra Study

Complex Open Bioabsorbable Reconstruction of Abdominal wall

- Multicenter prospective longitudinal trial
- Contaminated or clean contaminated operative field
- An open sublay repair with fascial closure
- 104 patients
- 24 fistula and 29 infected mesh
- 18% infection, 5% seroma rates; no explantation
- Recurrence rate is 15.5% at 24 months

Biosynthetic meshes

- Phasix Mesh (Bard Davol Inc)
- Poly-4-hydroxybutyrate (P4HB) selected as Phasix **biopolymer**
- A naturally derived fully resorbable polymer
- Complete *in vivo* resorption at 1 ½ to 2 years
- Eliminated from the body via the Krebs cycle as CO₂ and water

Phasix Class I/Clean Study Interim Report

- 121 subjects implanted / 16 US Sites
 - CDC Wound Classification I (uninfected)
 - Up to 3 prior recurrences allowed
- High Risk Factors (1 or more required for entry)
 - Obese: Body Mass Index (BMI) 30 - 40 kg/m²
 - Active Smokers: within the last 2 weeks
 - Chronic Obstructive Pulmonary Disease
 - Diabetes mellitus
 - Immunosuppression
 - Coronary Artery Disease
 - Chronic corticosteroid : > 6 months use
 - Serum albumin less than 3.4 g/dL
 - Advanced Age: > 75 years old
 - Renal insufficiency (Serum Creatinine \geq 2.5 mg/dL)

Preoperative Diagnosis & Presentation

Class I / Clean

	Total	
	N	%
Preoperative diagnoses		
Primary Ventral Hernia	19	15.7
Primary Incisional Hernia	52	43.0
Recurrent Ventral Hernia	15	12.4
Recurrent Incisional Hernia	34	28.1
Other	1	0.8

	Total	
	N	%
If recurrence, prior mesh?		
Missing	3	2.5
No	23	19.0
Yes	24	19.8
NA, no recurrence	71	58.7

SAGES 2015
2% = 1 Patient

Adverse Events of Special Interest	<i>Percentage of Patients Interim Analysis</i>
Skin Dehiscence	16%
Tissue Ischemia	14%
Hematoma	12%
Seroma	12%
Drain Complications	10%
Superficial Infection	10%
Deep Infection	4%
Recurrence	2%*
Wound Cellulitis	2%

***At 12 months, onlay repair without CST**

Some questions are left ?

What we wait : long term follow up to evaluate recurrence, and using in contaminated field ?

What indications for this new biosynthetic mesh?

Between or instead of du synthetic et du biologic?



Lesson 1

ANATOMY AND PHYSIOPATHOLOGY OF THE ANTERIOR ABDOMINAL WALL

Performed by:

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UNIVERSITY PARIS-DESCARTES,
FRANCE

B

Subcostal

Flank

Iliac