

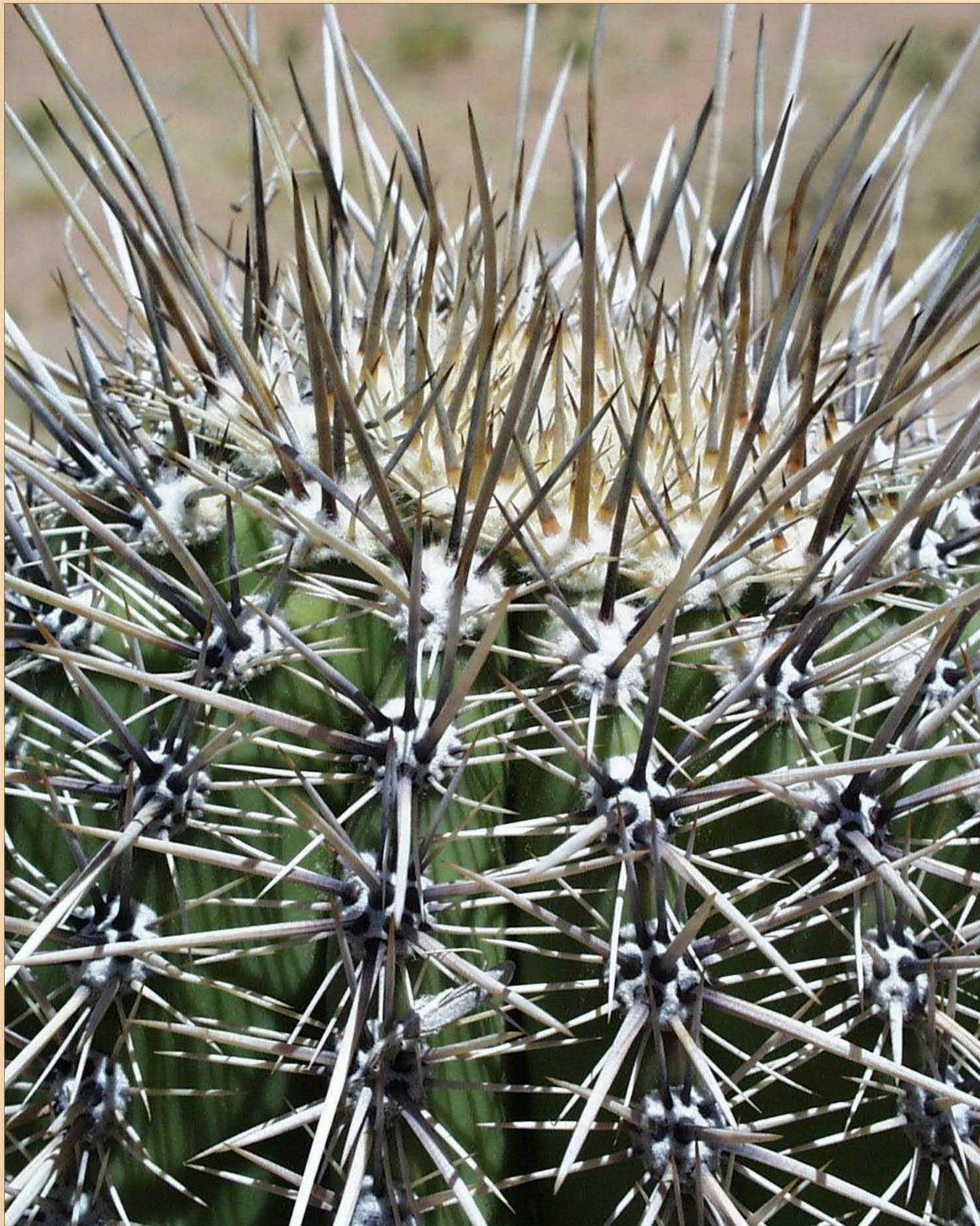
AMNIOTIC TISSUE IN COMPLEX HERNIA REPAIR & ENTEROCUTANEOUS FISTULAS

RECONSTRUCTIVE SURGERY & WOUND CARE PRINCIPLES, APPLIED TO A NOTORIOUSLY MORBID & DIFFICULT TO TREAT PROBLEM

—◆ **AND** ◆—

Insights Into Effective Management & Cure Utilizing Classic Principles of Plastic Surgery
Combined With Modern Technology Based Biological Materials.





AMNIOTIC TISSUE IN
COMPLEX HERNIA REPAIR &
ENTEROCUTANEOUS FISTULAS

A THORNY PROBLEM THAT HAS
NO
SIMPLE CONVENIENT FIX
OR EASY PATHWAY
TO A CURE

Good Results Based on Diligent Application
of Surgical Principles, Persistent Care
of Difficult Wounds, Stoma Care,
Nutritional Support, - and -
Patient Hand Holding.

Uncertain or Unobservable Response to Wound
Regulatory & Stimulatory Products

ELEMENTS

OF

SURGERY:

FOR THE USE OF STUDENTS;

WITH PLATES.

BY

JOHN SYNG DORSEY, M. D.

ADJUNCT PROFESSOR OF SURGERY IN THE UNIVERSITY OF PENNSYLVANIA,
ONE OF THE SURGEONS OF THE PENNSYLVANIA HOSPITAL, &c.

IN TWO VOLUMES.

VOL. II.

..... for want of timely care
Millions have died of medicable wounds.
ARMSTRONG.

PHILADELPHIA:

PUBLISHED BY EDWARD PARKER, NO. 178, & KIMBER & CONRAD,
NO. 93, MARKET STREET.

W. Brown, Printer, Church Alley.

1813.

Enterocutaneous fistulas are not necessarily ipso facto bad.

We make them deliberately to treat more morbid conditions.

For drainage & diversion.

Colostomy

Ileostomy

Cholecystostomy

Urostomy

For intake & irrigation.

Gastrostomy

Jejunostomy

Appendicostomy

Vesicostomy

History of therapeutic and surgical stomas.

“Artificial Anus”, a natural entero-cutaneous fistula following trauma or inflammatory disorders, has long been recognized. If high, death results, but colonic artificial anus is a survivable condition, with deplorable quality of life.

Deliberate colocutaneous fistula formation for therapeutic reasons was first tried in 18th century Europe. Typically done for desperate conditions to try and save a life, failures and deaths were accepted, but successes established validity of the concept.

ELEMENTS OF SURGERY. 65

CHAPTER IX.

Artificial Anus.

When in consequence of mortification the intestinal tube is partially or completely destroyed, and unites to the wound in the parietes of the abdomen, an unnatural or artificial anus is produced through which the feces are evacuated. If this aperture be high up in the intestine death is said to result from inanition, in consequence of the deficiency of absorbents to take up nourishment for the body. The intestine contracts considerably below the aperture, and no feces are voided by the anus, although some mucous evacuations are occasionally discharged.

Such a condition is truly deplorable, and every effort should be made to avoid the evil by effecting the restoration of the parts, previously to mortification, but where the intestine is found mortified, surgical aid is very often unavailing, and the artificial anus is the only event by which life can be preserved.

The involuntary discharge of wind and feces from the artificial anus, is a great inconvenience, and compresses have been applied with a view to prevent it, but the most common apparatus is a receptacle of leather or horn fastened over the part by means of a band passed round the body. Various machines have been constructed for the purpose, but the more simple are to be preferred for a very obvious reason—they are the most cleanly. Whatever apparatus may be used however, should be so constructed as to make pressure upon the part, in order to

VOL. II. K

Therapeutic enterostomy was sporadic until mid 19th century, when anesthesia & asepsis set foundations for modern surgical techniques.

By 20th century, colostomy was legitimate but infrequent. Use increased after WWI which spurred advances in surgery and long term patient support. After WWII, colostomy became normative surgical practice.

66 ELEMENTS OF SURGERY

prevent a prolapsus or eversion of the intestine, which is otherwise apt to occur.

When this prolapsus takes place, a tumour of considerable size forms, and sometimes the prolapsed intestine inflames and swells, obstructing the evacuation of the feces. In general it can be readily replaced and occasions no permanent inconvenience, but it is best to guard against a return of it, by means of a compress of lint bound firmly upon the part, a plan which Desault recommends in preference to all others; when, however, the reduction cannot be effected by the hand, it must be attempted by gradual and long continued pressure upon the prolapsed parts.

In order to prevent the inconveniences attending such cases, Mr. Cooper recommends a square cushion covered with oil silk which is to be placed over the artificial anus, and a steel truss which exerts but a slight degree of pressure being placed upon it confines the feces so as to lessen the offensive smell, and allows the patient to seek a convenient situation for an evacuation. This plan answers extremely well if the feculent matter has some consistence, but if the aperture is in the ileum, the contents of this intestine are with difficulty confined. These remedies only palliate the disease, in order to effect a radical cure, other measures become necessary.

DESAULT accomplished the radical cure of artificial anus in several instances. The means which succeeded in his hands were the application of compresses or plugs of lint, introduced into both portions of the intestine, which by pressing down the angle formed by their junction, make a direct passage for the feces and dilate the canal at the injured part. When this is done air and feces are found to pass sometimes through the natural passage, after which the external aperture gradually closes. Laxative medicines are to be occasionally administered during the treatment. Unhappily, however, the plan

Ileostomy lagged behind colostomy in usage, infrequent until mid 20th cent.

Everted mucosal “spigot”, innovation by Bryan Brooke 1952, solved most ileostomy issues, making it accepted.

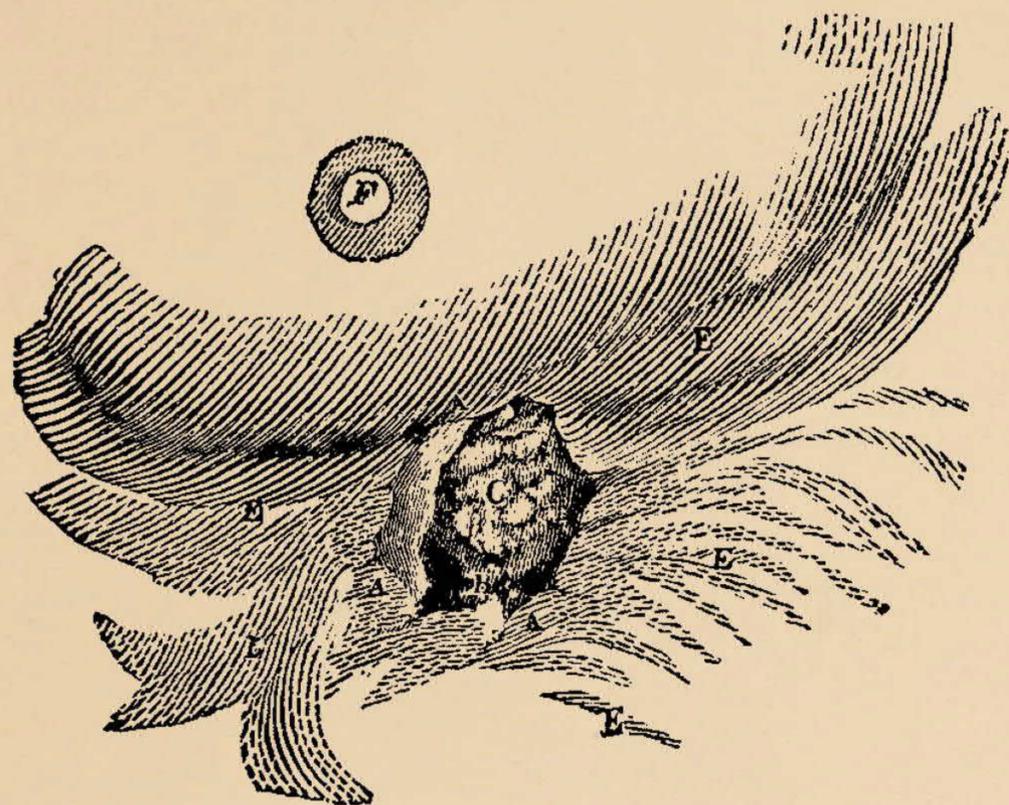
ELEMENTS OF SURGERY. 67

found successful in a few cases by Desault, has not succeeded equally with other surgeons, and it evidently cannot be employed where the angle of junction between the two ends of intestine is very acute.

In a patient with artificial anus at the Pennsylvania Hospital Dr. Physick performed an operation, which will probably be found to afford complete relief in many similar cases. The sides of the intestine in this instance, were consolidated laterally, or in Mr. Cooper’s language, like a double-barrelled gun. In order to ensure this union a ligature was passed through the intestine and suffered to remain a week, keeping its sides in close contact, after which Dr. Physick cut a hole in the side of the intestine where the two portions had thus united, and by stopping the external orifice, the feces regained their natural route, the external aperture was afterwards healed, and the patient relieved from his most loathsome complaint; he has for several years enjoyed perfect health.

From America’s first textbook of surgery.

1813



This engraving represents the appearance of the aperture with the valve depressed.

A A A Edges of the aperture through the integuments and intercostals, on the inside and around which is the union of the lacerated edges of the perforated coats of the stomach with the intercostals and skin.

B The cavity of the stomach, when the valve is depressed.

C Valve, depressed within the cavity of the stomach.

E E E E Cicatrice of the original wound.

F The nipple.

ENTEROCUTANEOUS FISTULAS - METRICS

Causes - Trauma, Surgery, Rx

75 - 85% of fistulas
 accidental enterotomy at surgery
 persistence after catheters
 perforation from mesh
 anastomotic leak
 radiation

Causes - Natural Disease

15 - 25% from natural pathology
 inflammatory - infection (*typhus, tb, amebiasis*)
 inflammatory - gi (*diverticular, appendicitis*)
 inflammatory - ibd (*Crohn's*)
 cancer

Morbidity

morbidity = 40-85%
 mortality = 44% (c1960)
 mortality = 5-30% (current)

Disabilities, Costs

crippling effects on lifestyle
 wounds & dermatitis
 nutritional deficits

Outcomes

non-op closure = 5-30%
 successful surgery = 75-90%
 persistence or recurrence after rx = 15-25%

ENTEROCUTANEOUS FISTULAS - CAUSES AND CLINICAL SCENARIOS



37 f

Crohn's

The intestine contracts considerably below the aperture, and no faeces are voided by the anus.
John Syng Dorsey, 1813



74 f

Surgical mesh

shown after removal and reconstruction



52 m

Diverticular

Hyper-coagulable

Critical Considerations

location, proximal or distal
distal obstruction, or not
surrounding skin, or not
active disease, or not
output volume

**Favoring Good Outcome
or Spontaneous Closure**

**Favoring Poor Outcome
or Persistent Fistula**

ETIOLOGY

surgery or trauma
bowel disease quiet
crohn's
no comorbidities, or controlled

active natural disease
active bowel disease
other bowel disease
active collateral disease

ANATOMY

no obstruction
colon
distal small bowel
small defect < 1 cm
long fistula > 3 cm
sub-surface bowel

distal obstruction
duodenum
proximal small bowel
large defect > 1 cm
short fistula < 3 cm
extrophied bowel

WOUND

no abscess or inflammation
no foreign materials
no skin wound or dermatitis
soft tissue cover, sinus, valve
(no epithelium)
no radiation

active inflammation
alloplastic materials present
persistent wounds & dermatitis
open bowel surface
(epithelium in sinus)
radiated field

FUNCTION

output volume < 500 cc/day
nutrition maintained

output volume > 500 cc/day
malnourished

ENTEROCUTANEOUS FISTULAS - CAUSES AND CLINICAL SCENARIOS

Critical Considerations

location, proximal or distal
 distal obstruction, or not
 surrounding skin, or not
 active disease, or not
 output volume

Favoring Good Outcome or Spontaneous Closure

Favoring Poor Outcome or Persistent Fistula

ETIOLOGY

surgery or trauma
 bowel disease quiet
 crohn's
 no comorbidities, or controlled

active natural disease
 active bowel disease
 other bowel disease
 active collateral disease

ANATOMY

no obstruction
 colon
 distal small bowel
 small defect < 1 cm
 long fistula > 3 cm
 sub-surface bowel

distal obstruction
 duodenum
 proximal small bowel
 large defect > 1 cm
 short fistula < 3 cm
 exstrophied bowel

WOUND

no abscess or inflammation
 no foreign materials
 no skin wound or dermatitis
 soft tissue cover, sinus, valve
 (no epithelium)
 no radiation

active inflammation
 alloplastic materials present
 persistent wounds & dermatitis
 open bowel surface
 (epithelium in sinus)
 radiated field

FUNCTION

output volume < 500 cc/day
 nutrition maintained

output volume > 500 cc/day
 malnourished

Critical Considerations

*More proximal = more liquid and caustic, more dermatitis, worse nutrition.
 If obstructed, the fistula is the vent for the obstruction, and it can never close.
 Lack of surrounding skin = stoma bags leak, inflammation persists, scar gets worse.
 "It" caused the fistula, and if active is certain to lyse the repair and recreate the leak.
 Output volume reflects location, affects nutrition-electrolytes-hydration, lifestyle.*

Favoring Good Outcome or Spontaneous Closure

Favoring Poor Outcome or Persistent Fistula

ETIOLOGY

*Traumatic fistulas are usually through healthy bowel which will heal.
 Inflammation risks wound-anastomosis failure, so primary disease must be quiet.
 Autoimmune Crohn's amplifies the above risk, hard to win when it is active.
 Non-causative disorders can have collateral effects, anything that affects wounds.*

ANATOMY

*Distal obstruction is the prime discriminator between who gets better or not.
 Colon fistulas are errant colostomies and can be fixed or lived with.
 The more proximal fistulas make all worse; duodenal fistulas can be disastrous.
 Small diameters which minimize drainage and allow distal transport are favorable.
 Long sinuses create a valve effect, favoring spontaneous healing. ** Matrices, etc.
 Below-surface bowel via a sinus has less drainage, etc.; exstrophied is the opposite.*

WOUND

*Abscess makes bowels fragile and adherent, unsafe or impossible to operate on.
 Alloplastic materials will perpetuate inflammation, but once eliminated, bowel heals.
 Open wound around the stoma makes leak, inflammation, persistent wound and scar.
 Scar contraction of open bowel serosa favors persistence; tissue cover makes a valve.
 (Epithelialization equals healed, so sinus persists, but it means healing is normal.)
 Radiation damages intrinsic wound repair, and must be corrected or circumvented.*

FUNCTION

*Higher fistulas draining more make management more difficult and dangerous.
 Regardless of any wound healing or surgical effects, patient must remain nourished.*

ENTEROCUTANEOUS FISTULAS - FOCUS ON SPECIAL CAUSES

Ibd & Cvd-Ctd

Never miss the diagnosis of Crohn's & IBD.

Clinical: History and physical exam.

Problematic scars and obstruction.

Recurrent refractory problems with surgery.

Contrary or unexpected responses or results.

Persistent or recurring leaks or fistulas.

General auto-immunity, inflammation, CVD-CTD.

Do not assume UC by history, look for Crohn's.

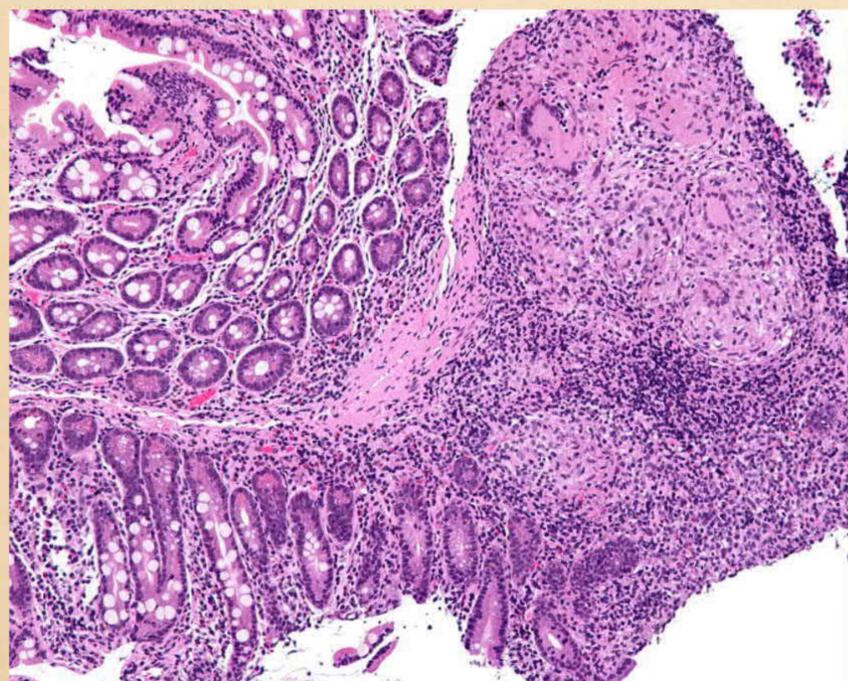
Endoscopy: Above, below, through. Imaging.

Serologies: ANCA's, ASCA's.

Histology: Granulomas, trans-mural, others.

Comprehensive Rx: Pharma, diet, general care.

Surgery: Wait until disease is treated & settled.



Hypercoagulable Disorders

Prevalent & morbid, but often overlooked.

Hypercoagulable disorders and patients are prone to wound pathergy and infarction.

In face of odd, unexpected, repetitive wound complications, suspect hypercoagulability.

Abdominal and bowel surgery are at risk for infarction, perforation, leak, fistula.

Make diagnosis on specific criteria:

Clinical: History and exam, pathergy events.
Thrombo-infarctive pattern of injury.

Lab: Hypercoag studies, flow & O₂ studies, histo.

Hypercoagulable Syndrome

Thrombotic or embolic event

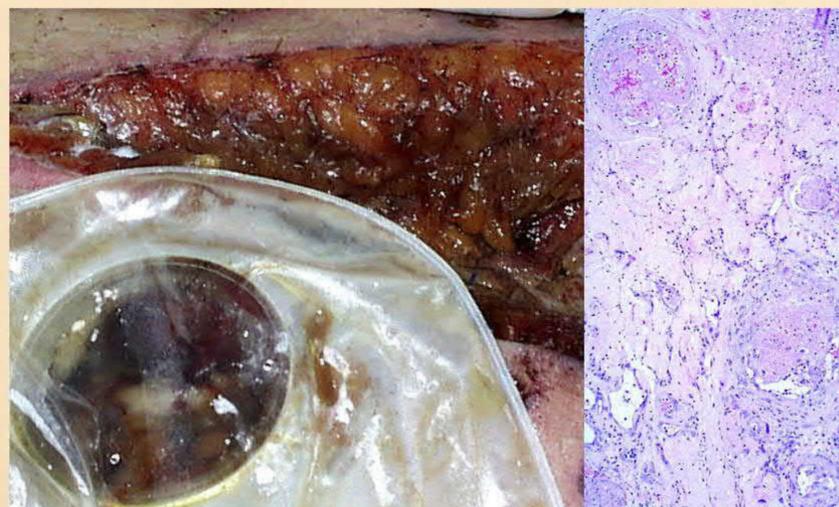
Autoimmune cvd-ctd

Wound pathergy

Miscarriage

Family history of same

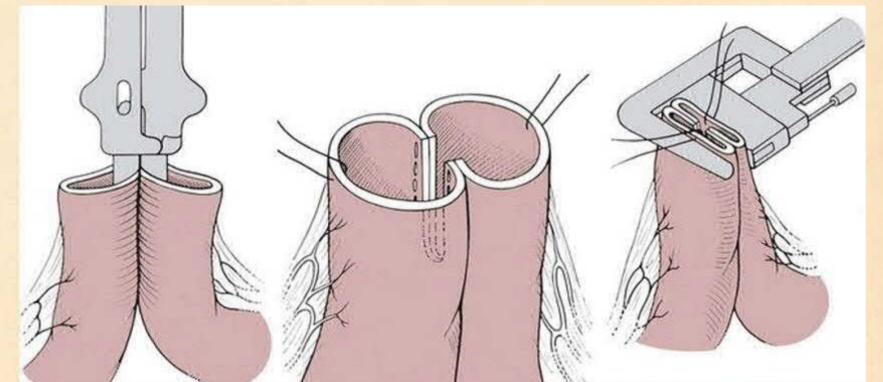
Anticoagulation before, during, & after surgery.



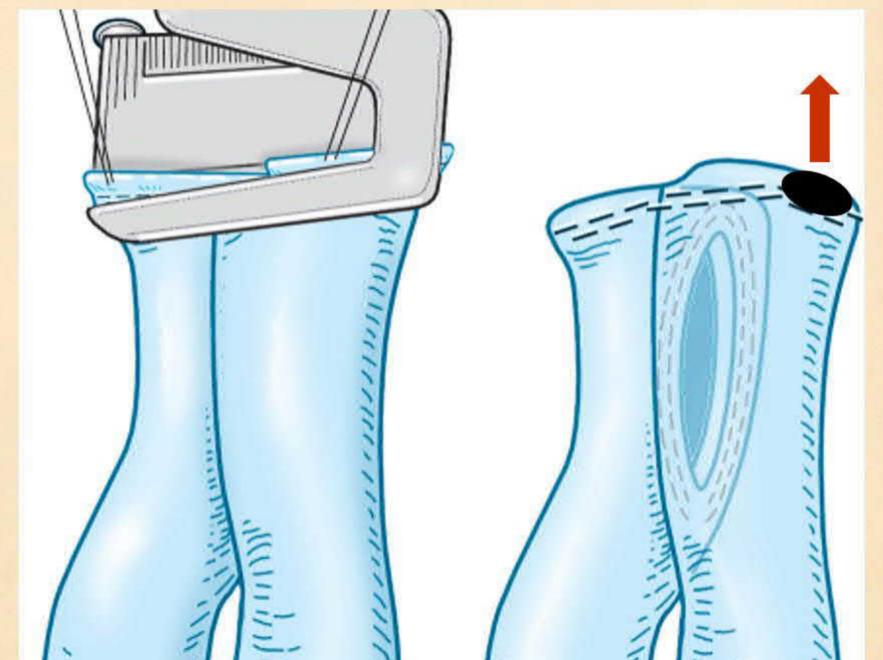
The Stapler

An inordinate number of fistulas these days emanate from a stapled bowel anastomosis, most commonly the butt end transverse staple line.

The longitudinal side-to-side staple line is a proper coaptation, serosa-to-serosa. It rarely fails.



Transverse staple line coapts mucosa-to-mucosa. It has inherent risk for leak, especially when it is done sloppily. **Oversew or patch the staple line.**



ENTEROCUTANEOUS FISTULAS - A PRELUDE TO MANAGEMENT

CRITICAL CONSIDERATIONS: IMPORTANT THINGS THAT GUIDE THERAPY & MANAGEMENT

CORRECT DIAGNOSIS Understand the cause, pathogenesis, and true nature of the problem.

PATHOLOGICAL -vs- Non-PATHOLOGICAL Pathological lesions must have primary disease and inflammation under control.

NON-PATHOLOGICAL These lesions need anatomy restored while respecting tissue mechanics & wound healing. **Proper timing.** Have a plan.

OBSTRUCTED -vs- Non-OBSTRUCTED If the fistula is the “end of the road” vent for a distal obstruction, it cannot be closed. **Proper timing.**



ENTEROCUTANEOUS FISTULAS - MANAGEMENT STRATEGIES & PLANNING

GENERAL MANAGEMENT

Bowel rest & reducing chyme, bile, succus, stool.
npo versus diet ◊ *bulking agents* ◊ *bowel pharma*

Nutrition support.
oral-enteral diet ◊ *modified & elemental diets* ◊ *parenteral nutrition*

Managing drainage.
skin protection ◊ *absorbing or catching fluids* ◊ *suction*

Stoma care.
bags & products ◊ *avoiding leak* ◊ *dry skin vs wet wound*

Skin and wound care.
barrier products ◊ *drying agents* ◊ *topical steroids*

Nursing support – at home if possible.
home health services ◊ *family & patient* ◊ *technical & financial support*

General lifestyle.
maintain mobility ◊ *maintain home life* ◊ *patient & family psychology*

Treat the primary disease or disorder.



PLANNING FOR CLOSURE

Managing for spontaneous closure.

Those that close themselves vs those that do not.
cf. tube ostomies after tube removal – trach, gastro, jejunal, etc.

Maintain all general management without lapse.
dietary-nutrition, effluent, skin & wound care

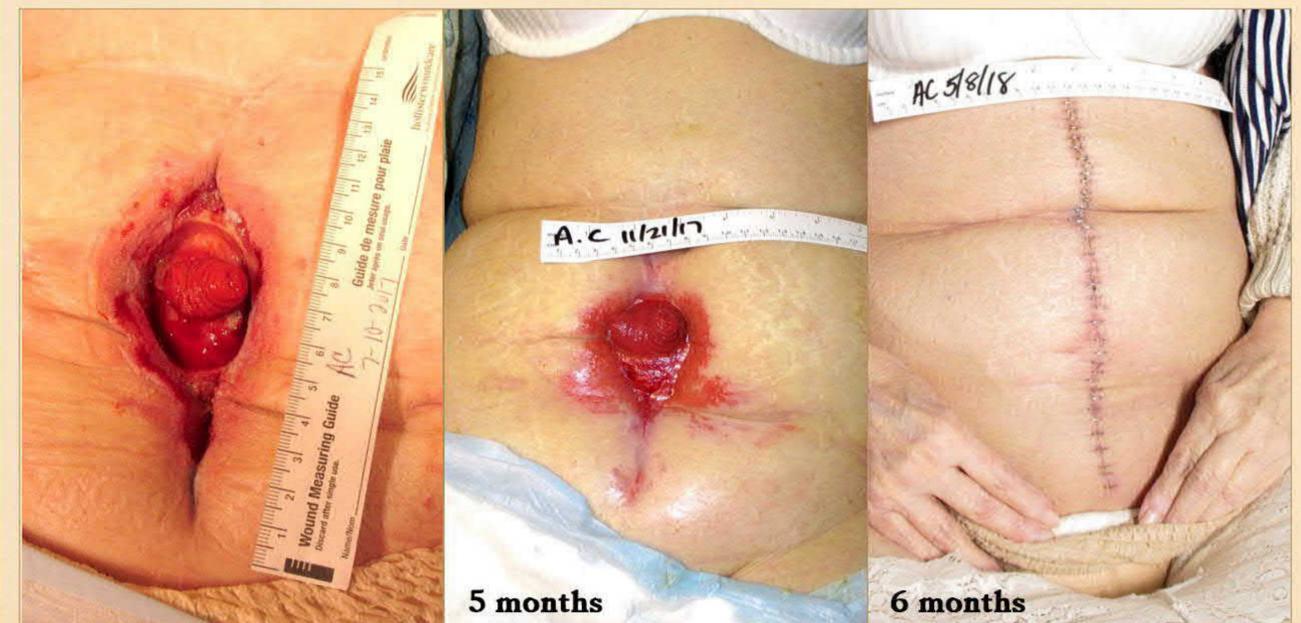
Role for regenerative & stimulatory products.
matrices & biologics – unproven but sound concept

Planning for surgery.

The importance of Nature's timeline.
subsiding disease ◊ *subsiding inflammation* ◊ *wound & scar maturation*
9-12 months from last surgery if possible

Maximum control of primary disease & inflammation.
control enteritis and any pathergy prone disorder

Imaging, and understanding anatomy best as possible.
because intra-operative findings are sometimes confusing





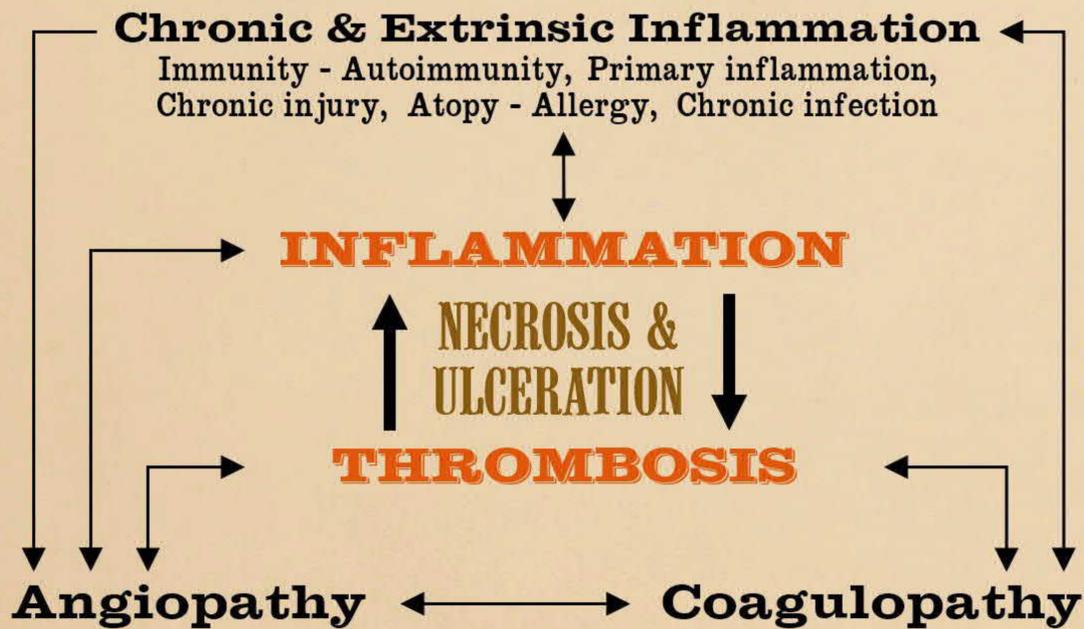
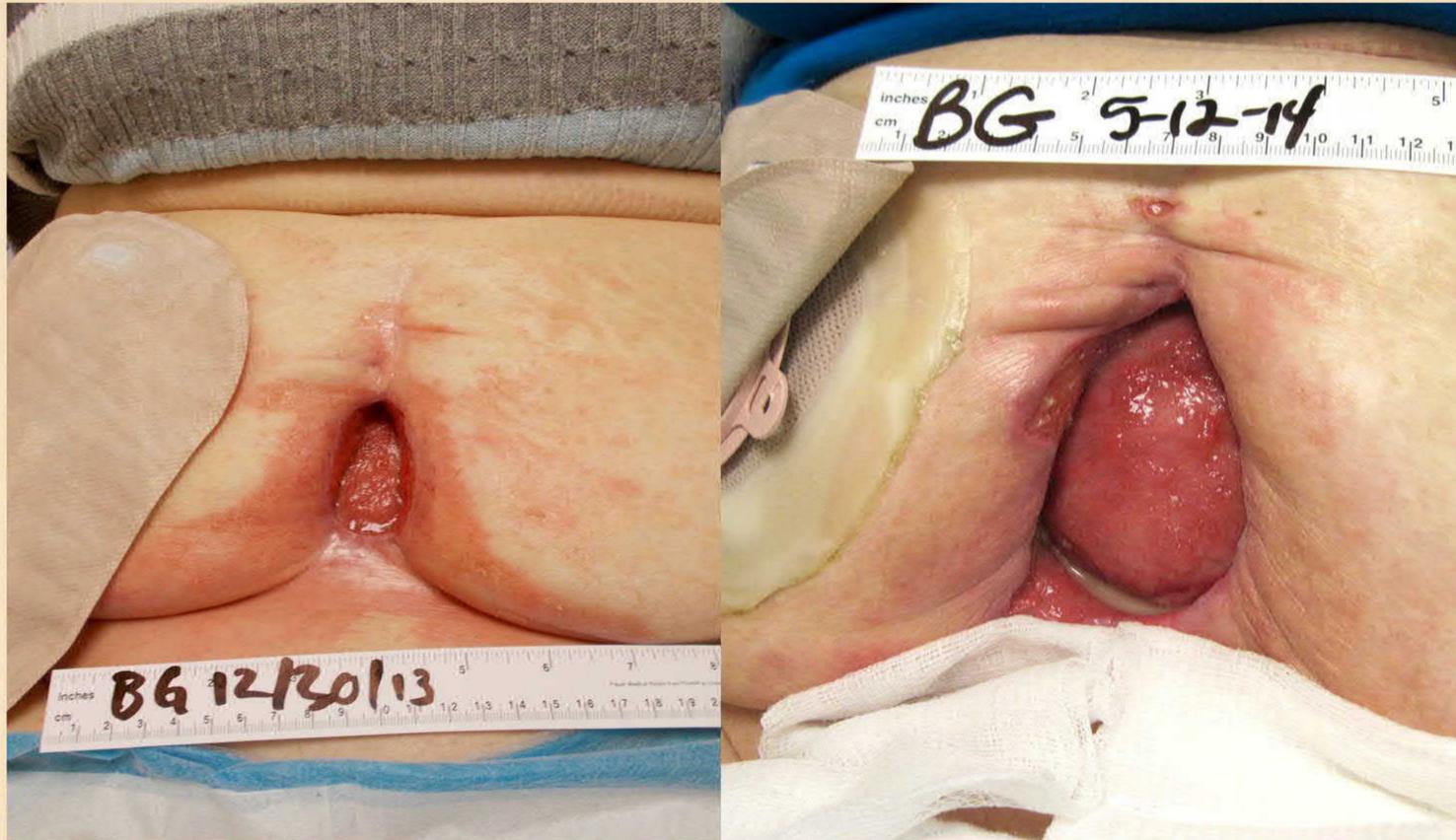
DO NOT DO
 too much
 too soon
 too often.

*debride & control
 - then -
 repair & reconstruct*

*paramount is:
 patience, prudence,
 staged surgery*

*respect biology of
 injury, inflammation,
 and wound healing.*

66m, ankle fracture, 15 operations in 18 days



ENTEROCUTANEOUS FISTULAS - SURGICAL MANAGEMENT - PRINCIPLES

Two Types of Patients, Two Approaches to Surgery

Abdomen Can be Opened and Bowels Operated

long interval since last surgery
fewer surgical episodes
mesh & hernia complications
trauma & incidental injury
non-inflammatory disorders
no intra-abdominal abscess
no open wounds or dermatitis
functional bowel and diet

Bowels can be directly exposed, manipulated, resected, repaired, with little risk of additional injury or failure.

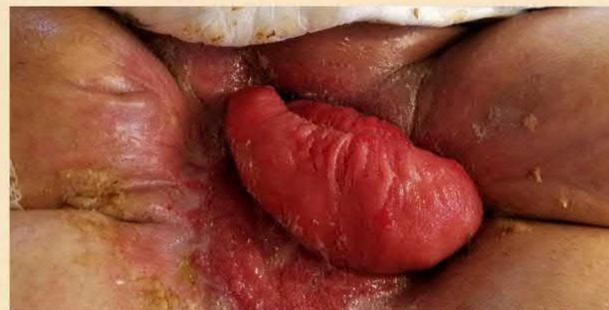
Abdomen is Frozen, Surface Approach Only

short interval since last surgery
greater no. surgical episodes
inflammatory disorders, prior or active
active intra-abdominal abscess
prior extensive peritonitis
inflammatory bowel disease
crohn's especially
open wounds with dermatitis-panniculitis
dysfunctional bowel without diet

*Fistula is through wound and scar on surface.
Entry to abdomen is risky or impossible.
The perforation can be patched only.*



	Repair bowel	Create stoma
Open abd.	resect-repair	proper stoma
Surface only	flap patch	restore skin



Two Restorative Strategies, Two Techniques at Surgery

Repair Bowel to Close Fistula & Restore Continuity

IF ABDOMEN CAN BE OPENED:

direct repair of perforation
or, bowel resection & repair

IF ABDOMEN CANNOT BE ENTERED:

patch perforation with flaps

Flap delays required or preferable.

These are opportunities to stimulate or augment wound healing by use of wound regulatory biologics.

Convert the Fistula to a Functional Stoma

IF ABDOMEN CAN BE OPENED:

exteriorize perforation through skin

*Suited to ileum and colon, like any deliberate enterostome.
Only if bowel can be mobilized and if there is adequate skin.*

IF ABDOMEN CANNOT BE ENTERED:

restore skin around the fistula with flaps

*This allows a stoma bag to be applied without leak
Flap delays required or preferable.*

These options are for the more desperate conditions in which bowel is missing and short, frozen in scar, or wet surface wound prevents a bag.

ENTEROCUTANEOUS FISTULAS - SURFACE REPAIR & PRINCIPLES OF DELAY



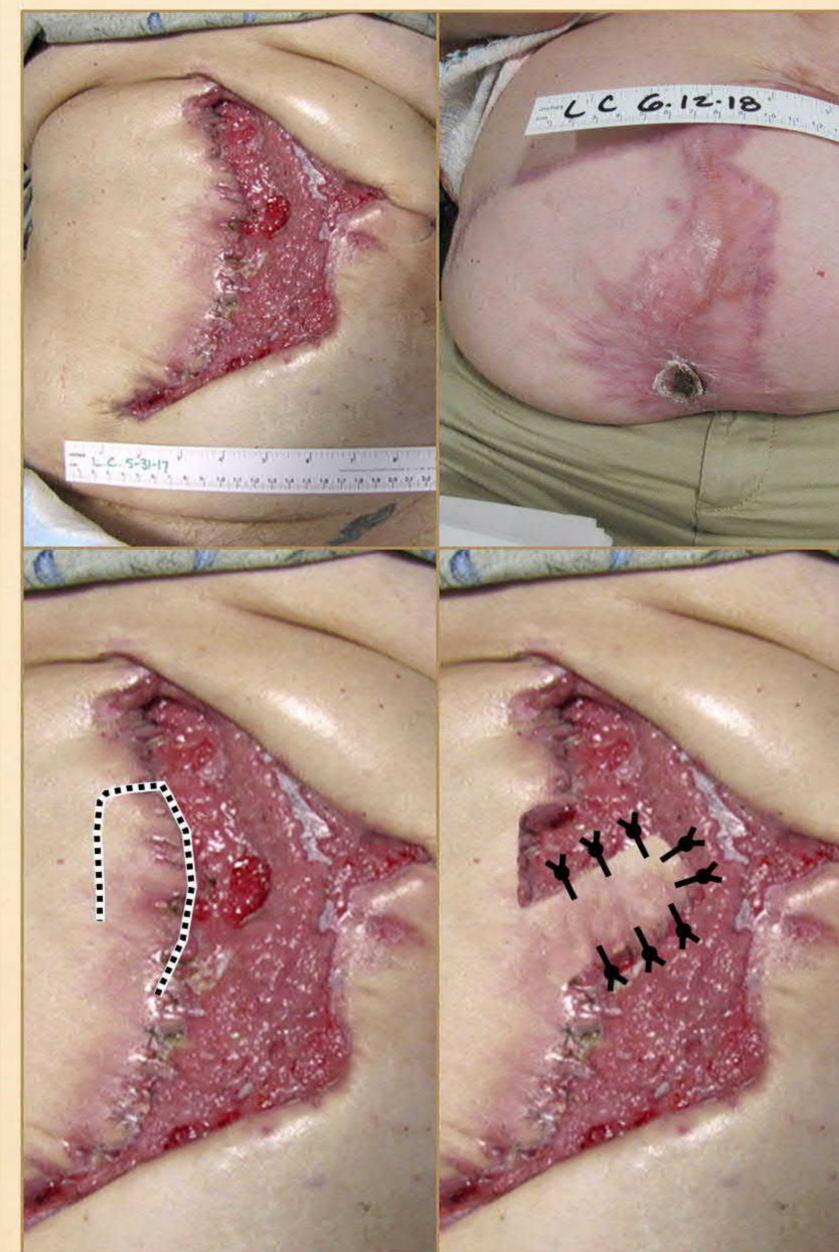
Reasons to Delay Flaps

VASCULAR DELAY, to develop circulation.

SURETY DELAY, declares good vs bad.

HEALING DELAY, activates wound.

Delaying flaps to cover fistulas ensures that the flap adheres to the bowel repair more quickly than the bowel closure is slipping apart.



ENTEROCUTANEOUS FISTULAS - SURGICAL MANAGEMENT - MISCELLANY

Abdominal Wall Restoration

There has been an exponential and epidemic rise in ventral hernia rate, and rate of hernia repair complications since 1990.

Many fistulas and enteric perforations today are a consequence of alloplastic hernia mesh.

Conflating abdominal wall reconstruction with mesh excision, enteric fistula control and bowel repair is dangerous.

Do separate staged procedures when required.

Avoid alloplastic mesh.



Miscellaneous Management

Successful management of enterocutaneous fistulas is contingent on many activities, not just the surgery. You must be able to manage:

Inflammatory Bowel Disease

Acute flareups

Dietary adjustments

Pre-operative suppression

Steroids & anti-inflammatory drugs

My favorite "go to" cocktail:

prednisone, sulfasalazine-mesalamine, metronidazole

Total Parenteral Nutrition

Periodic catheter complications.

Metabolically, TPN is mostly self-tending.

Fluid & electrolyte issues are from the fistula.

Wound, Skin, and Stoma Care

Proper daily wound hygiene.

Protection of the surrounding skin.

"Wound managers" and custom appliances.

Nursing support, in you own practice or facility.

Home Health Services

Getting patients home while planning for definitive surgery is a meritorious goal.

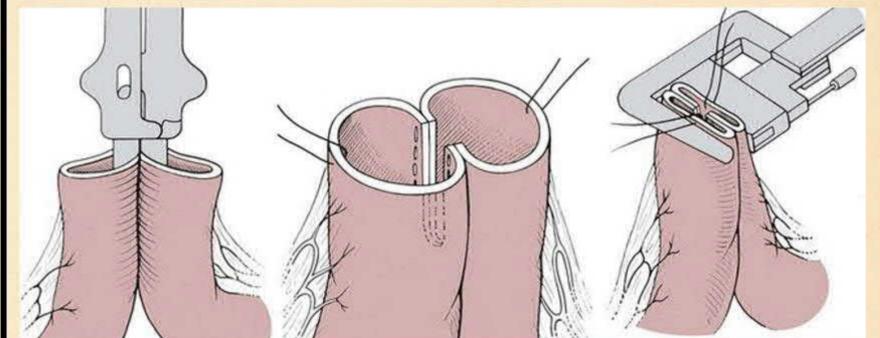
Sometimes impossible, but successful with an engaged family and quality home health services.

Wound, skin, & stoma care, and TPN.

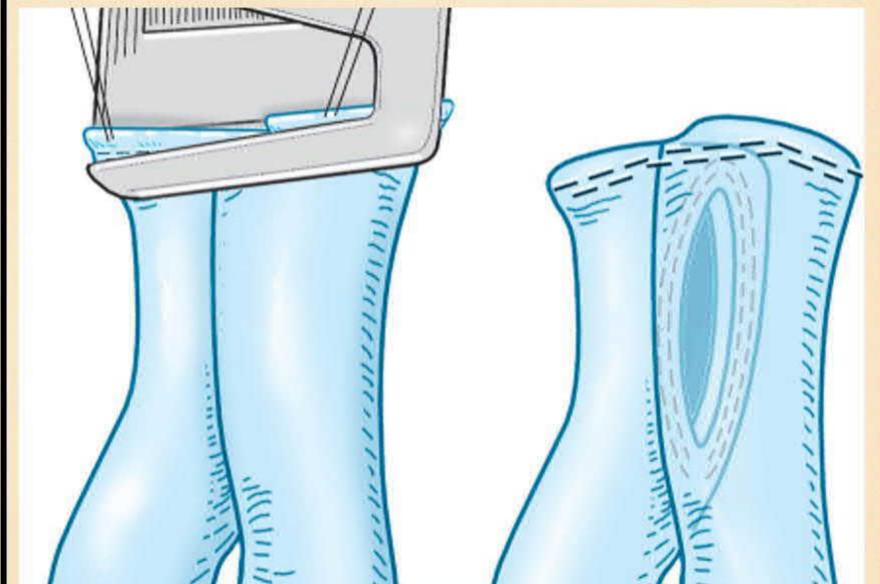
Staples versus Sutures

An inordinate number of fistulas these days emanate from a stapled bowel anastomosis, most commonly the butt end transverse staple line.

The longitudinal side-to-side staple line is a proper coaptation, serosa-to-serosa. It rarely fails.



Transverse staple line coapts mucosa-to-mucosa. It has inherent risk for leak, especially when it is done sloppily. **Oversew or patch the staple line.**



For some enteric fistula repairs, whether on surface or intra-abdominal, it will not be physically possible to apply the stapler, so do not be overly dependent on it.

(top) 85 m, multiple hernia repair, mesh eroding small bowel and skin

(bottom) 66 m, colon tumor resection, multiple hernias, mesh eroding small bowel

Incidence, Ventral and Incisional Hernias

(ESTIMATES FROM MULTIPLE SOURCES)

Laparotomies / year, USA	2,000,000 – 3,000,000 – 4,000,000
Ventral hernia operations / year, USA	150,000 – 300,000 – 500,000 <i>Includes natural & incisional hernias.</i>
Hernia incidence % of laparotomies, 1°	5 % – 10-20 % – 35 % <i>Estimates have increased with time.</i>
Recurrence % after primary repair, 2°	5 % – 10-20 % – 35 % <i>Variable, depending on technique.</i>
Recurrence % after secondary repair, 3°	20 % – 35 % – 65 %

Hernia incidence rates reported from other countries are generally comparable.

Progressive Poor Results for Incisional Hernias

2011: "794 patients: 61% primary VHR, 26% IHR-1 [1st incisional hernia repair], 9% IHR-2, 4% IHR-3. Patients with multiple repairs were more likely to undergo reoperation, have longer operative duration, develop infection, and recur. At 140 months, 37% of primary ventral hernias and 64% of incisional hernias have recurred. Highest recurrence rates 73% are in IHR3. **Previous VHR creates a vicious cycle of repair, complications, reoperation, re-repair.**"

2015: "250,000 ventral hernia repairs each year in the U.S., recurrence rates high: 54% after primary repair, 25% after synthetic mesh repair, and 22% after components separation."

2000-2011: "Recurrent hernia following incisional hernia ranges from 18 to 50 percent."

Various studies estimate, and decry, economic and social impact.

The problem is confused and compounded by inconsistent techniques, and variety of manufactured "meshes" and other products, many of questionable nature.

Alloplastic meshes can provide structural stability, but many reports document increased complications rates that offset any anatomical gains.

Changing Incidence & Mix of Hernia Types

(ESTIMATES FROM MULTIPLE SOURCES)

2011 (USA)

"RESULTS: The number of inpatient VHRs [ventral hernia repairs] increased from 126,548 in 2001 to 154,278 in 2006. Including 193,543 outpatient operations, an estimated 348,000 VHRs were performed for 2006. Inpatient costs consistently rose.

"CONCLUSIONS: VHRs continue to rise in incidence and cost. By reducing recurrence rate alone, a cost saving of US \$32 million dollars for each 1% reduction in operations would result."

2011 (England)

"2389 patients, 2510 hernia repairs during three periods: 1985-1988; 1995-1998; 2005-2008.

Inguinal hernia repair was universally commonest. Femoral hernia repair was second commonest in the 1980s, the fifth most common by 2005-2008. Proportion of groin hernia repairs has decreased over time; proportion of midline abdominal wall hernias has increased.

... The relative frequency of groin hernia repair has decreased over time, frequency of midline abdominal wall hernia repair has increased. Relative frequency is: inguinal, midline, femoral. This contrasts with figures quoted in common reference books over the last 30 years."

2013 (India)

"Inguinal hernias, 77.81% of cases. Ventral hernias were 18% of cases. Femoral hernias were rare ... which obviously differs from literature mentioning frequency as: inguinal, femoral, umbilical and others. Incidence of femoral hernia is very low as compared to literature where it comes as third commonest type of hernia. Incisional hernia was approximately 3% which is significantly lower than USA and UK where it is 6% - 10%, but in accordance with African literature (underreporting as our population is less disease conscious?)."

Analysis & Summary

Hernia incidence and mix is traditional surgical knowledge

found in surgical journals, textbooks, and curricula of the 20th century.

Historically, most hernias are natural, inguinal hernias about 75%,

femoral hernias the traditional second.

Experienced surgeons perceive, and recent papers confirm, beginning c 1990,

an increase in ventral hernias, mostly post-operative incisional hernias.

Modern hernia rates exceed historical controls by as much as 6-8 fold,

a morbid and expensive problem that rises to status of epidemic.

The zeal to address the problem may be making it worse,

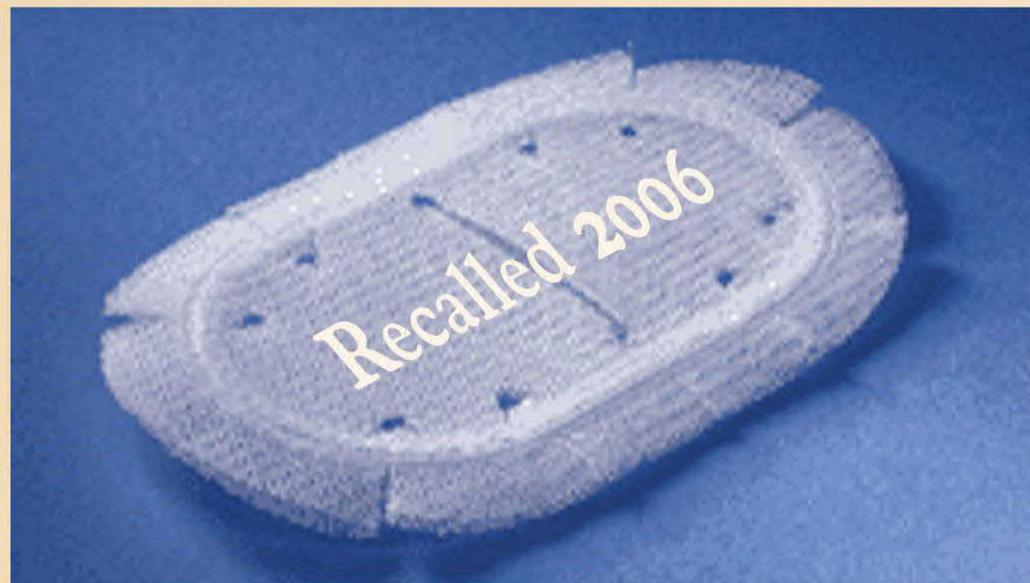
many patients crippled by repetitive failed repairs and complications.

The zeal to fix the problem has resulted in products that make more trouble,

typically alloplastic materials made of non-biological materials.

Bad Engineering & Misguided Surgery

"Kugel Hernia Repair is gaining momentum around the world as the next step in hernia repair when comparing laparoscopic versus open procedures. The benefits to the patient, surgeon, and hospital make this procedure a winning combination." **Bard Promotion**



"Kugel Mesh Patch: "A Terrible Ordeal" In 2003, when Janine Ryan's (not her real name pending a lawsuit) mother, Sophia, had a Kugel Mesh hernia patch implanted, neither knew that there were any possible risks associated with the patch. But Sophia's patch broke, causing her to experience severe pain and other serious problems." **Lawyer Site**

HERNIA & THE MODERN SURGEON

VENTRAL AND INCISIONAL HERNIAS, including the perverse subtype of the iatrogenic multiply recurrent hernia, and those complicated by morbid, disabling, & lethal complications, complicated yet more by poor products, have reached epidemic proportions during the past **25** years.

Hernia Repair & Reconstruction done effectively and safely, must acknowledge the nature of the problem as a musculoskeletal procedure and apply relevant techniques. This can, often must, include manufactured products, but the choice of proper materials is essential and is the responsibility of the surgeon.

The Pathway to Safe and Effective Repair is revealed in the biology of hernia, and the principles of classical hernia surgery, and the newer principles of care, the good and the bad, revealed over the past 25 years: Proper handling of the native autogenous tissues, the choice and use of reinforcing materials, and the avoidance of non-biological materials lead to proper results.

Parietex™ Composite Ventral Patch

Symbotex™ Composite Mesh
For Ventral Hernia Repair

3DMax™ Mesh

COMPOSIX™ L/P Mesh

KUGEL™ Hernia Patch

PERFIX™ Plug

VENTRALEX™ ST Hernia Patch
Featuring Sepra™ Technology

C·qur | MESH
O3FA FILM COATED MESH

GORE DUALMESH®
BIOMATERIAL

PROCEED™ PVPM 2 Pieces
VENTRAL PATCH 6.4 cm x 6.4 cm (2.5 in x 2.5 in)

ETHICON PHYSIOMESH™

PROLENE* Mesh
Polypropylene
Nonabsorbable Synthetic Surgical Mesh

Complicated devices I have removed:

COMPOSIX	BARD
C-QUR	ATRIUM
GORETEX	GORE
KUGEL	BARD
PROCEED	ETHICON
SYMBOTEX	MEDTRONIC
OTHERS UNKNOWN	

Products withdrawn, recalled, or in class action and extensive personal injury litigation:

PARIETEX	COVIDIEN
C-QUR	ATRIUM
PHYSIOMESH	ETHICON
PROCEED	ETHICON
PROLENE HS	ETHICON
KUGEL	BARD
3DMax	BARD
PERFIX	BARD
VENTRALEX	BARD

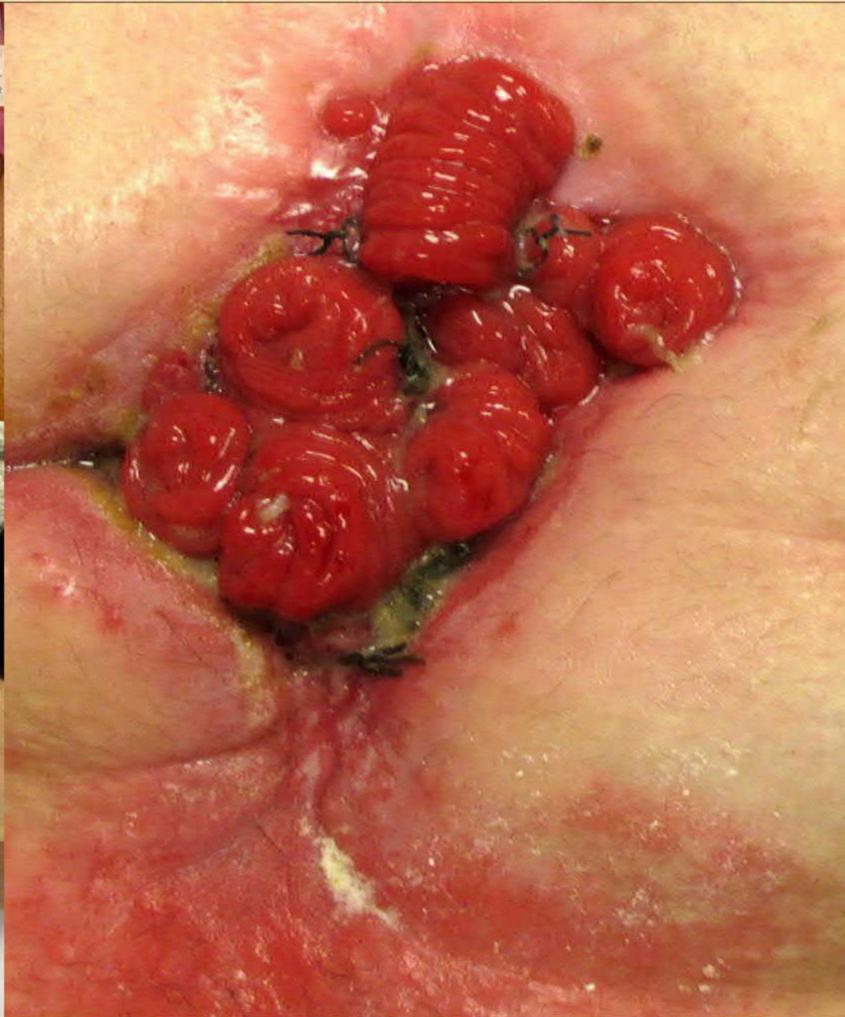
ENTEROCUTANEOUS FISTULAS - AN INTERLUDE - CASE STUDIES

**UNLIKE ARIZONA'S EVER BEAUTIFUL SONORAN DESERT,
The only inspiration caring for these patients is the good results
that come from proper & successful management based
on comprehensive care & well planned surgery.**





37 f, Crohn's, fistulas, hernias, complications of surgery.
*certolizumab (Cimzia®), peri-op steroids, TPN
multiple bowel resection & anastomosis*



69 m, multiple hernia, multiple mesh, small bowel erosion, chronic abscess.
*staged debride then reconstruct
direct bowel repair, omentum & other flaps*



85 m, multiple hernias & failures, mesh related fistula.
*staged debride then reconstruct,
direct bowel repair, abd wall recon*



66 m, colon tumor resection, hernias, mesh related fistula.
*combined resection-reconstruction
bowel resection & anastomosis*



23 f, Crohn's & complications, fistula.

Wound pathergy, wound infarcts. Hypercoagulable.

fibrinogen	521 H
d-dimer	706 H
antithromb-3	81 L
protein C	67 L
protein S	47 L
plasminogen	73 L

Distal colon fistula.

Debride only wound care.

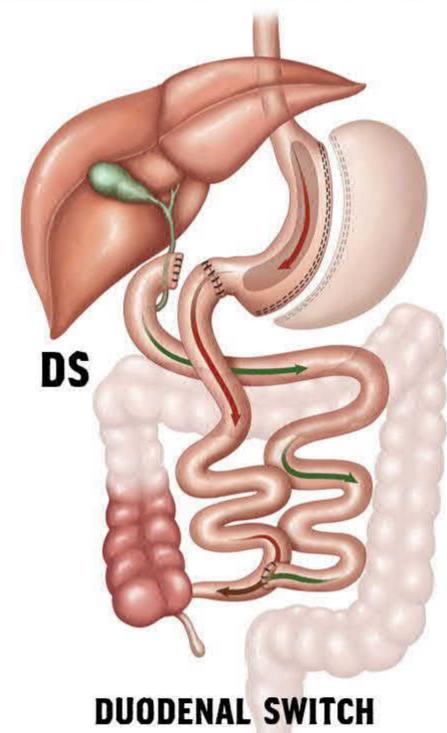
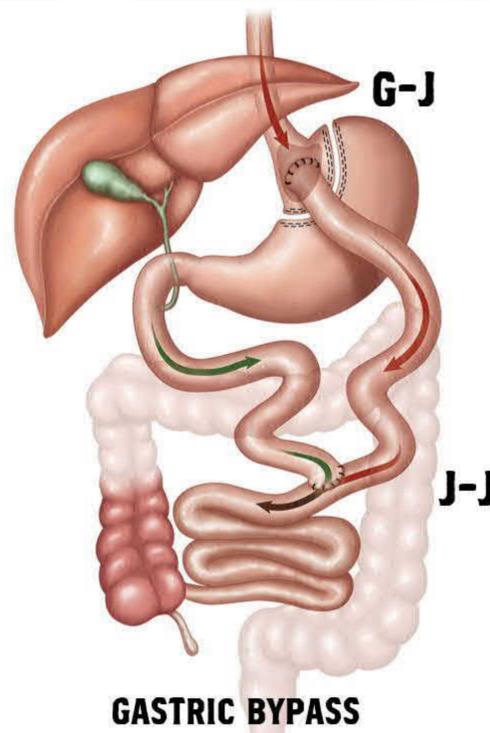
*prednisone
sulfasalazine
metronidazole*

*heparin
enoxaparin*

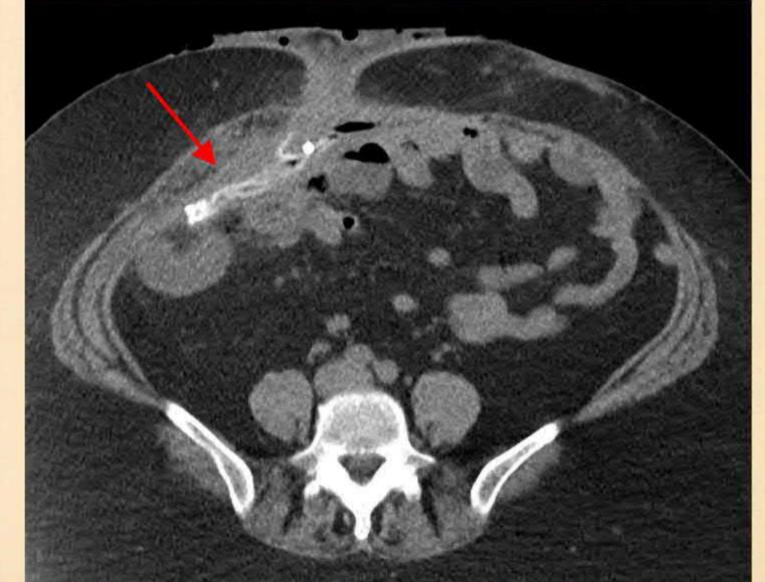
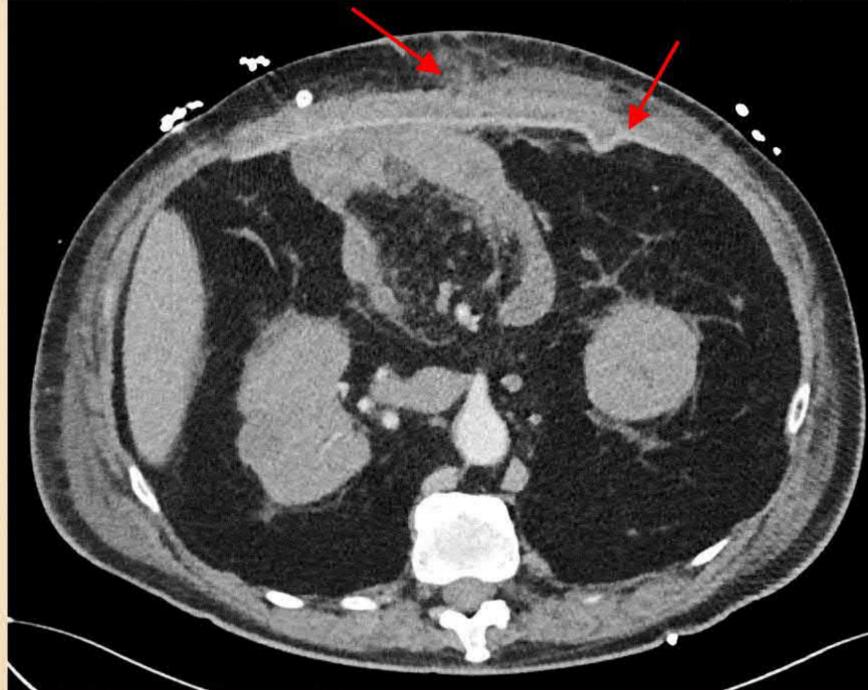
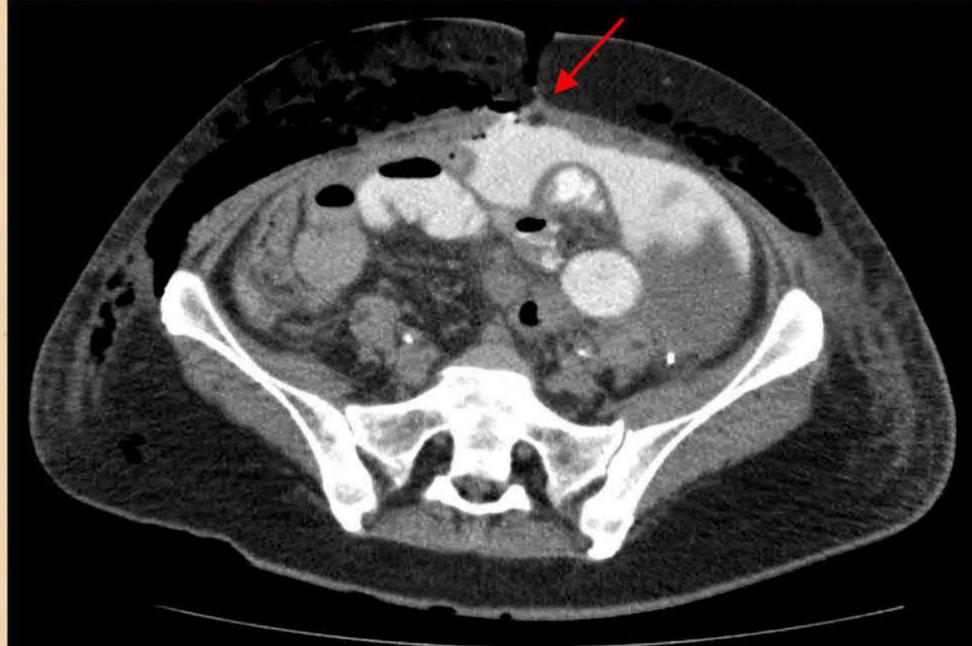
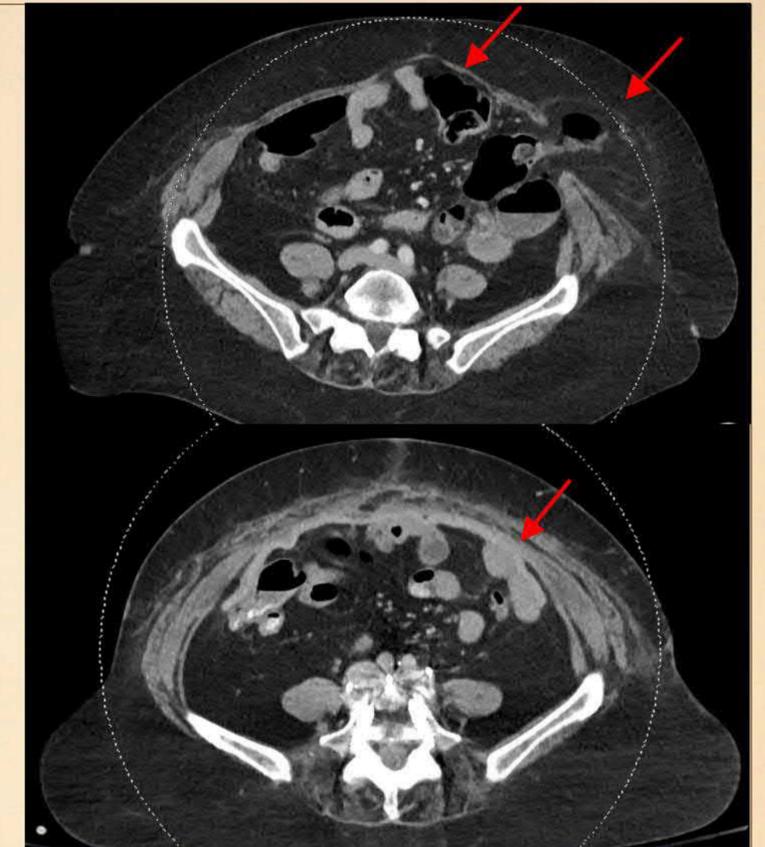


66 m, rectal cancer resection, hernias, abscessed mesh, small bowel fistula, no surrounding skin, incompetent bag & leak.

*1st surgery – skin flaps to make effective stoma
2nd surgery – patch & close fistula with flaps
3rd surgery – abdominal wall recon. (later)*



ABDOMINAL WALL - HERNIAS & RECONSTRUCTION



74 f, colon cancer & radiation, colectomy

66 m, colon tumor, hernias, mesh related fistula

60 f, hernia, abscess, mesh related fistula

AMNIOTIC TISSUE IN COMPLEX HERNIA REPAIR & ENTEROCUTANEOUS FISTULAS

RECONSTRUCTIVE SURGERY & WOUND CARE PRINCIPLES, APPLIED TO A
NOTORIOUSLY MORBID & DIFFICULT TO TREAT PROBLEM

—♦ AND ♦—

Insights Into Effective Management & Cure Utilizing Classic Principles of Plastic Surgery
Combined With Modern Technology Based Biological Materials.



ENTEROCUTANEOUS FISTULAS - WOUND HEALING CONSIDERATIONS

GENERAL CATEGORIES OF WOUND CARE AND WOUND HEALING PRODUCTS AND DEVICES

Wound & Skin Management

GENERAL WOUND HYGIENE

dressings
non-specific topicals

PURPOSE-SPECIFIC TOPICALS

pharmaceuticals
semi-stimulatory
semi-regenerative

SKIN CARE

general skin care
stoma & peri care

DEVICES

npwt
debridement
catheters & drains

Wound Healing

STIMULATORY THERAPIES

platelets & releasates
living cell biologics
acellular biologics
growth factors
amnion
physical agents (e.g. rf, us, em)
research pipeline

REGENERATIVE THERAPIES

regenerative skin substitutes
cadaveric skin matrices
bio-matrices, other parts
miscellaneous biologicals
auto-cell culture technologies

Patient Support & Rehab

orthotics
support surfaces
home health services

Diagnostics

pressure mapping
O₂ & blood flow measures
histopathology & micro lab
immune & coag chemistries
research pipeline

Ancillary Therapies

hbo
vascular technologies
surgical instruments & devices

Colored items are those most useful in ordinary clinical care of enterocutaneous and other fistulas.



WOUND STIMULATORY PRODUCTS & REGENERATIVE MATRICES

TECHNOLOGY-BASED BIOLOGICALLY-DERIVED PRODUCTS TO PROMOTE WOUND HEALING

Wound Stimulatory & Wound Regulatory Products

Influence local wound cells to promote healing of extant tissues.

circa 1995 - 2010

platelets & releasates

e.g., Procuren, Platelet Rich Plasma's

growth factors

e.g., Regranex PDGF

circa 2000 - 2010

living cell biologics

e.g., Apligraf, Dermagraft, Transcyte

circa 2000 - 2010

acellular biologics (skin, submucosa, etc.)

e.g., Oasis, Primatrix, misc collagen products

circa 2000 - 2010

physical agents (e.g., rf, us, em)

e.g., Mist US, Provant RF

circa 2010 - ongoing

amnion & placenta (topical & injectable, living & sterile)

e.g., Amniomatrix, AmnioExcel, Biovance, EpiFix, Grafix, PalinGen

Wound stimulatory therapies - Indications

Wounds under control with basic care but not healing.

Accelerate wound rate or strength in at-risk wounds.

CAP wounds. Impaired, dysregulated wounds.

C A P = "Chronic And Pathological"

Regenerative Biomatrices

Provide a scaffold on which stromal cells can create new tissue.

1994

Alloderm® (Lifecell)

ADM - Acellular Dermal Matrix

1996

Integra Dermal Regen. Template® (Integra Life Sciences)

DRM - Dermal Regeneration Matrix

circa 2000 - 2010

cadaveric ADM's (human, porcine, bovine)

e.g., FlexHD, Strattice, Surgimend

circa 2010 - ongoing

diversified sources

e.g., Cytal porcine urinary bladder, Tutomesh bovine pericardium

micronized and flowable forms

e.g., Flowable Integra, Acell MicroMatrix

current status

proven method for quality skin restoration, essential coverage, prevent contracture, abdominal wall, breast recon.

Regenerative Biomatrices - Indications

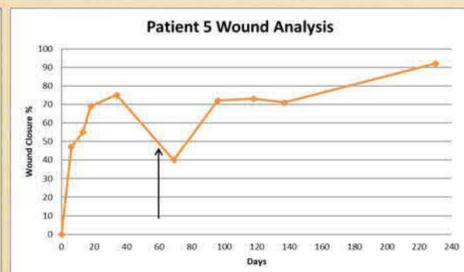
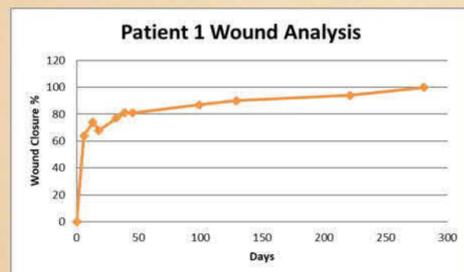
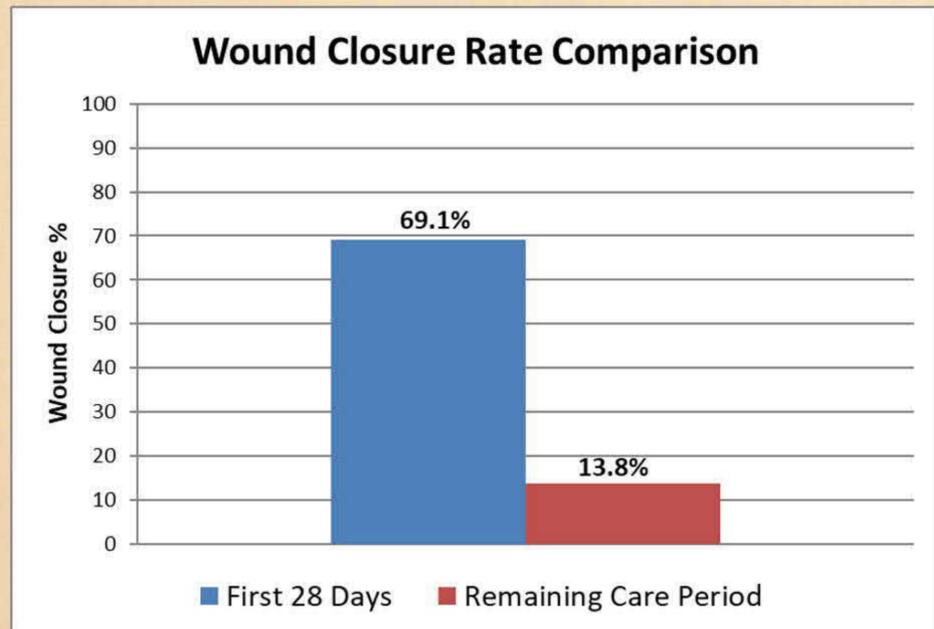
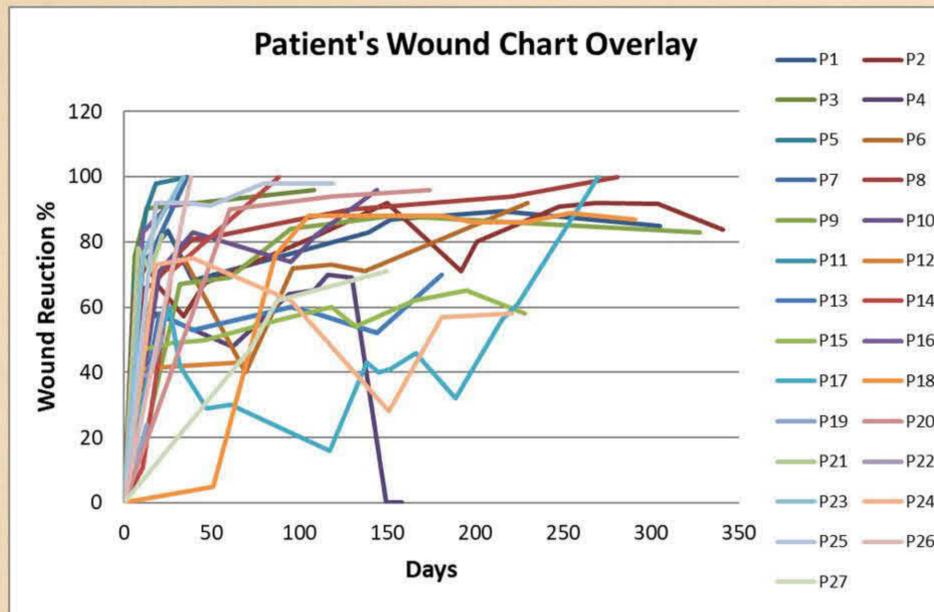
Quality skin substitution or regeneration.

Reconstruction to avoid scars & contractures.

Reconstruction & reinforcement for tensile strength.

Number & Percent of Patients

Wound Reduction >	0 %	26/27	96 %
Wound Reduction >	50 %	24/27	89 %
Wound Reduction >	80 %	19/27	70 %
Wound Reduction =	100 %	7/27	26 %



Study

27 wounds in
17 patients
injectable amnion
(cryo-preserved living)

Indications

Wounds controlled
with basic care but
not healing.

CAP wounds,
impaired -
dysregulated.

Diagnoses

scleroderma-crst
lupus
hypercoagulable
aso-pvod w/wo dm
cancer - radiation
thrombocytosis
sickle
trauma
pressure

Analysis

1 no-response wound
(pt's 2nd wound did),
eventual amputate,
dx: scleroderma, AS.

Nearly 100% response.

70% reduction 1 month.

Response drops at 1 mo.

84% avg total decrease.

26% total heal rate.

Re-dosing appropriate
at 3-4 weeks, or when
response curve drops.

THE EFFECTS OF AMNION PRODUCTS

Single center small study.

Amniotic membrane can be a valid source for wound healing

ElHeneidy H, Omran E, et al. *Int J Womens Health*. 2016 v8.

Chronic leg ulcers, random two groups.

Group I control, 11 patients, dressings.

Group II study, 14 patients, amnion.

All 11 - ulcers no reduction in their size

All 14 - **complete healing 14-60 days**, mean 33±15;
healing rate 0.064-2.22 cm²/day, mean 0.90±0.65.

Informal literature survey.

Amniotic Membrane Adjuncts and Clinical Applications in Wound Healing: A Review of the Literature

Kogan S, Sood A, Granick M. *Wounds Jun* 2018.

Literature review of amniotic membrane (human subjects only), publication dates 2013-2017.

Results: treatment of burns, diabetic foot ulcers, fistulas, ocular defects, venous leg ulcers, others.

Amnion/chorion allografts **beneficial in difficult-to-heal fistulas, diabetic and venous ulcers.**

Amnion membrane products have **increased wound healing rates** compared with standard of care.

Formal meta analysis.

Amnion Membrane in Diabetic Foot Wounds: A Meta-analysis

Haugh A, Witt J, et al. *Plast Reconstr Surg Glob Open*. Apr 2017.

DFU's, 596 potentially relevant articles, 5 randomized controlled trials, with total 311 patients.

Pooled **relative risk of healing** with amniotic products cf. control **was 2.75** (2.06-3.67, P < 0.001).

Amniotic products increase diabetic foot ulcer **DFU healing rates** (RR = 2.75).

Amnion patients **less likely for infection or hospitalization** from DFU adverse events.

Average **cost is smaller** than average cost burden per DFU patient per year.

Data strongly favor use of amnion to improve wound healing with potential cost savings.

"Amniotic products should be revisited for their regenerative properties, not only for DFUs, but **for other high-risk surgical procedures** including cardiac surgery, abdominal surgery, and implant-based procedures."

The nearly universal experience with amnion products is that they:

increase time-wise rate of healing, for a variety of wounds

increase incidence of healing, for a variety of wounds

are effective for more refractory wounds

reduce complications or morbidity

are cost effective

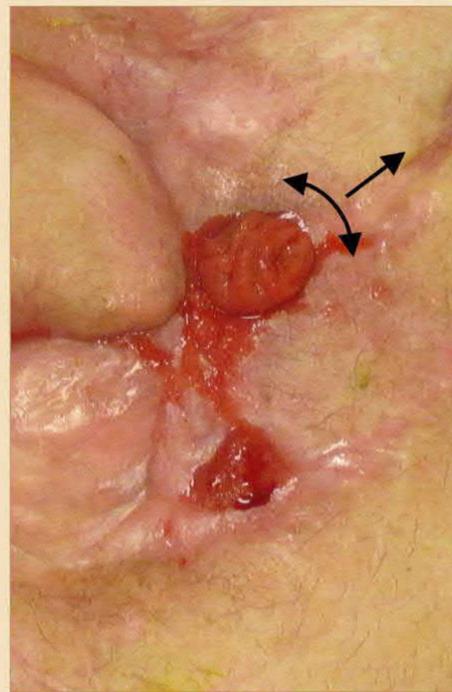
ENTERIC FISTULAS & ABDOMINAL WALL - ROLE OF AMNION PRODUCTS

Amnion & Abdominal Surgery

Use of amnion for fistulas, enteric and elsewhere, is limited. Reports are favorable, but they tend to be incidental case reports.



amnion or matrix eligible



amnion eligible



tried & failed - digested, Crohn's



amnion only X, with surgery +



not eligible - obstructed



not eligible - foreign body

Amnion & Fistulas

Pro

Would stimulate the surrounding tissues to contract and hopefully heal.

Protected by injection into the periwound tissues, not the fistula per se.

Con

Will not overcome active disease, foreign objects, distal obstruction.

Sheet or surface applied materials not eligible.

Matrices & Fistulas

Pro

Would pack a non-epithelialized sinus and permit new tissue to form and fill it.

Proven good results for non-enteric sinuses, e.g., open joints, tendon & wound bursas.

Con

Will not overcome active disease, foreign objects, distal obstruction.

Will not work if there is no mesenchymal sinus, just epithelium of the bowel.

Risk of digestion and loss of the material.

Amnion & Abdominal Wall

Pro

Hypothetically would encourage strength and resistance to future rupture.

Might give an advantage to marginal closures that might avoid a future procedure.

Cooperates well with biomatrices, and might give a cumulative better result.

Con

Economics & logistics good for small defects, (small umbilical, inguinal), not for large ones.

Will not protect against fundamentally flawed technique or inept repair.

Matrices & Abdominal Wall

Pro

Validated, verified value to reinforce autogenous repair. Mandatory for some cases.

Protected by injection into the periwound tissues, not the fistula per se.

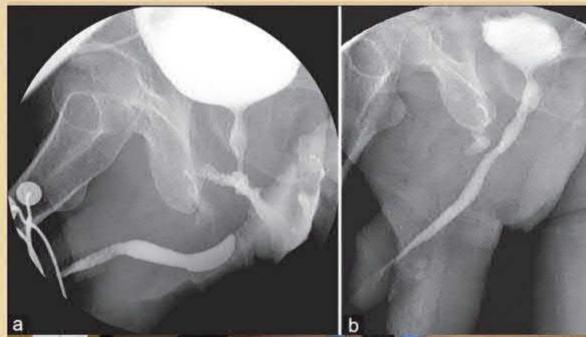
Cooperates well with amnion, and might give a cumulative better result.

Con

As abdominal wall substitute only, suitable as interim fix, but not a permanent reconstruction.

Variety of materials, not all equal.

OTHER FISTULAS, CLOSURE & RECONSTRUCTION - ROLE OF AMNION



58 m, **rectourethral** fistula after prostate cancer & radiation.
Healed with flaps.



40 f, **vaginal-cutaneous** fistula after proctectomy for Crohn's.
Healed with flaps.



38 f, Crohn's, resect, **bowel** fistula.
Healed with non-operative care.
Recurring non-bowel wounds.
Persistence after small flaps.
Endo- & exo-salpingosis
with **peritoneal** fistula.
Healed with large resection & flaps.



56 m, pharyngeal cancer, radiation, neck necrosis & **pharyngeal** fistula.
Healed with flaps & autologous fat.



Fistulas to skin or any other surface or bursa can affect any organ or structure with a hollow or cavitory anatomy or architecture.

Fistulas and perforations from the author's practice in the past 4 years:

- | | | |
|------------|-------------|------------|
| nose | duodenum | prostate |
| mouth | jejunum | urethra |
| pharynx | ileum | salpinx |
| esophagus | anastomoses | vagina |
| bronchi | appendix | tendon |
| pleura | colon | joint |
| peritoneum | rectum | lymphatic |
| pelvis | anus | skull-dura |
| stomach | bladder | spine-dura |

Options for closure include :

- | Strict non-op | Technical | Surgical |
|----------------|-------------------------|-------------|
| wound care | stimulus rx | diversion |
| fistula care | <i>amnion</i> | fistulotomy |
| drainage | <i>platelets</i> | repair |
| tube diversion | matrix - regen. | resection |
| site specific | <i>acellular dermis</i> | flaps |
| peritoneum | <i>other tissues</i> | fat grafts |
| stomach | <i>re-engineered</i> | |

There is a proliferation of published papers using amnion products to stimulate healing in fistulas of many varieties.

Likewise for regenerative biomatrices.

As adjuncts to conventional care and surgery, or as primary therapy in select circumstances, these biotech products are achieving more certain results with less cost & less morbidity.

AMNIOTIC TISSUE IN COMPLEX HERNIA REPAIR & ENTEROCUTANEOUS FISTULAS

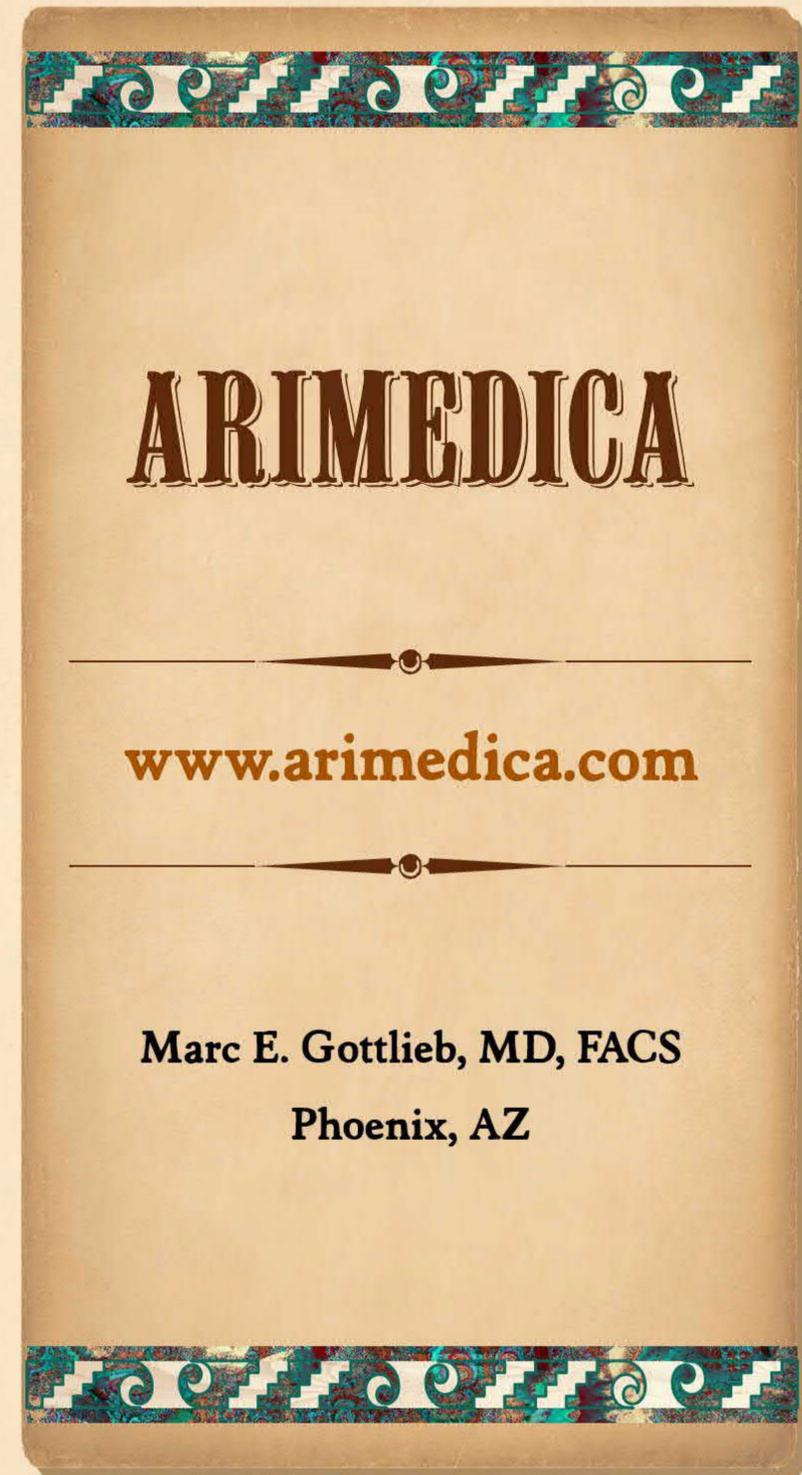
Amniotic membrane products may be considered proven in their ability to stimulate or regulate wound healing dynamics. They have a verified role in the management of impaired wounds.

They have a hypothetical role to improve management of enteric fistulas and complex abdominal wounds for select situations.
Use as part of a coordinated program of fistula closure.

Enterocutaneous fistulas present a spectrum of severity, but at their worst they are a devastating disruption of normal life, with a non-trivial mortality rate.

Those with distal obstruction may be impossible to treat, but mostly all others can have effective preliminary management leading to successful closure.





ARIMEDICA