STAR and STIR Effectively Treat Abdominal Compartment Syndrome and Reduce Mortality of Traumatic and Infectious Abdominal Catastrophes

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Introduction

Staged abdominal repair (STAR) and staged injury repair (STIR) are two new operative strategies that have evolved since 1978 to manage conditions with abdominal hypertension seen in severe intra-abdominal infection, severe abdominal trauma, acute pancreatitis, and the difficult abdomen. The abdomen is temporarily closed with an artificial bur (STAR closure device).

We were never able to make a formal prospective, randomized comparison with the standard one-stage operation because for the IRB, the anecdotal evidence in favor of STAR was too over-whelming, with over 50% improvement in mortality.

Before starting to use the bur, there was no clinical data to base an investigational device exemption on, and the FDA requested that the bur be used on a compassionate basis and data be collected for approval of the device. The FDA has granted permission to distribute the device for investigational purposes.

In this poster, we present our experience with STAR and STIR using the artificial bur as a device for temporary abdominal closure. Most of the data has been collected prospectively, and most cases are photo documented. The current information, how-ever, must be considered as anecdotal.

Abstract

We treated 118 patients from 1988 to 1998, 63% with STAR and 37% with STIR. The artificial bur was used in all patients to bridge the fascial gap and to allow for ease of an average of 6.3±2.9 abdominal reentries, and final fascia-to-fascia closure. The mean APACHE II score was 18.5±6.8 and the mean ISS of trauma patients was 30.8±13.4. We performed STAR because we were unable to close the abdomen without undo tension in 83% of our patients. 43% were excessively bleeding and required packing. Most of the trauma patients had a coagulopathy as a result of hemorrhagic shock and hypothermia. The viability of the bowel was a concern in 17% of the cases. The first abdominal exploration (index STIR) was considered the damage control procedure, deferring definitive repair, including formation of anastomoses, to subsequent abdominal re-entries. After final closure, we saw fascial dehiscence in 9% and fistula in 5%. Patients required a median of 20 days (range 3-115) of care in the intensive care unit and they were hospitalized for a median of 32 days after the STAR index entry (range 0-131). 23.5% of patients died after STAR and 16% after STIR. The observed 60-day mortality was 17% for all patients and compares favorably to the predicted mortality of patients with the same risk factors.

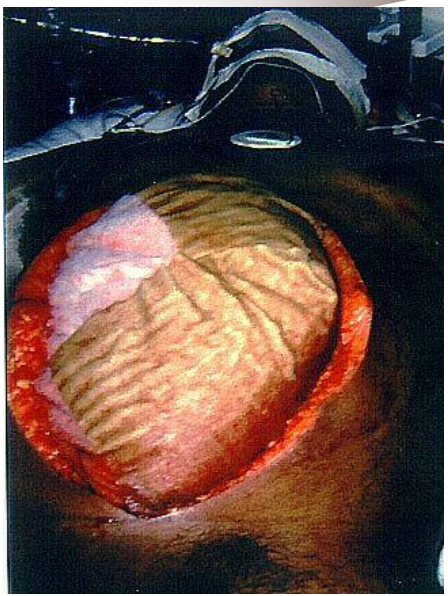
Definition of STAR and STIR

One operation with serial abdominal entries planned either before or during the first STAR index entry, and performed every 24 to 36 hours with temporary abdominal closure using an adjustable mesh such as the artificial bur

- To obviate the physiological derangement of **increased intra-abdominal pressure** from peritoneal edema and ileus
- To allow for delayed definitive repair after initial **damage control** in non-stable patients, and
- To permit **final fascia-to-fascia closure** of the abdomen.

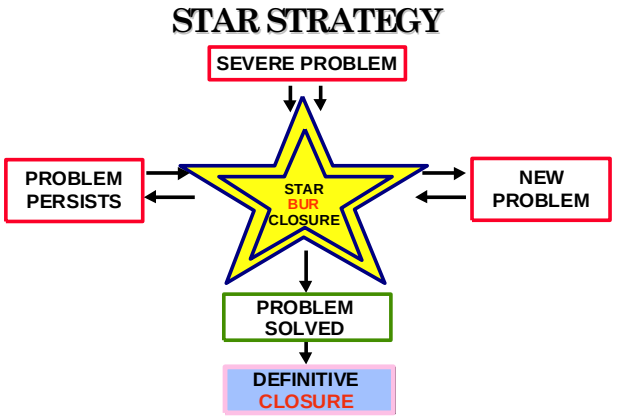
STIR (Staged Injury Repair)

STIR (Staged Injury Repair) is a STAR procedure for the injured abdomen. It combines damage control procedures with definitive fascial closure.



Fascial closure of the abdomen was not possible following resuscitation of hemorrhagic shock and repair of abdominal injuries

Methods

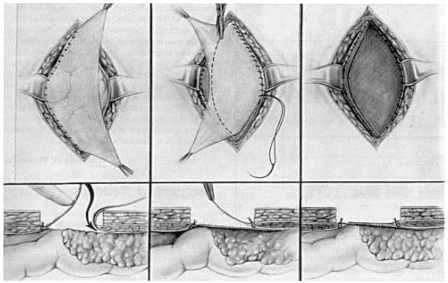


Indications:

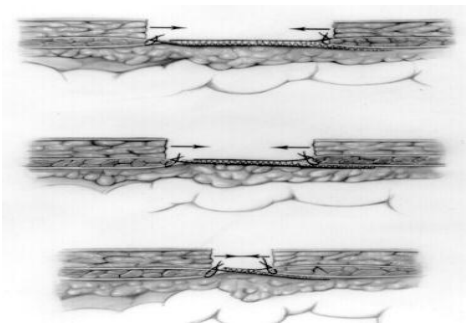
- Could not close the fascia (abdominal compartment syndrome)
- Damage control procedures in trauma
- Conditions (sepsis) precluding definitive repair
- Severe intra-abdominal infections
- Deteriorating acute pancreatitis
- Bowel ischemia
- The “difficult” abdomen

From 1988 to 1998, all patients with severe traumatic and infectious abdominal catastrophes were operatively managed with STAR or STIR when they met the criteria listed: The artificial bur was used on a compassionate basis to collect data for FDA approval. Written informed consent was obtained prior to the STAR index entry. Data were entered into a database concurrently and later supplemented with additional information from the charts. The data were statistically analyzed using the SPSS statistical package for logistic regression and simple parametric and non-parametric comparison.

Operative Technique



Bur Insertion, A, B and C



Steps toward final fascia closure

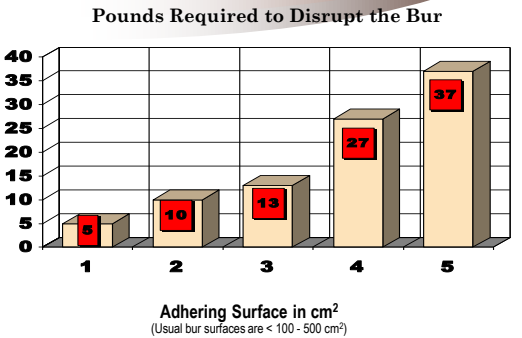
- Suture loop sheet to the right abdominal fascia, best with a running O-loop nylon, the loops facing outward
- Trim length of loop sheet to length of wound
- Insert free edge of loop sheet under opposite fascia between omentum and bowel and abdominal wall
- Suture hook sheet (harder sheet) to the left fascia, best with a running O-loop nylon
- Press hook sheet into loop sheet and cut overlapping edges
- Apply hypobaric wound shield dressing to the wound

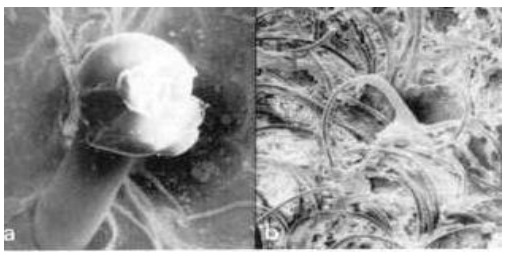
What is the Artificial Bur?

The artificial bur is a Velcro-like device consisting of two sheets of 20x40 cm that may be trimmed to adjust for the incisional aperture. The bur sheets include:

- A polypropylene hook sheet with micro-mushrooms
- A polyamide loop sheet with a sling mesh work

The tensile strength for shearing forces is above the tensile strength for the abdominal fascia. --Europ J Surg 159:75-79,1993





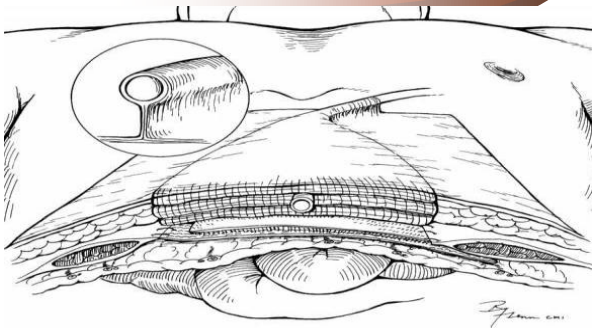
Hook Sheet Micromushroom

Loop Sheet Nylon Slings

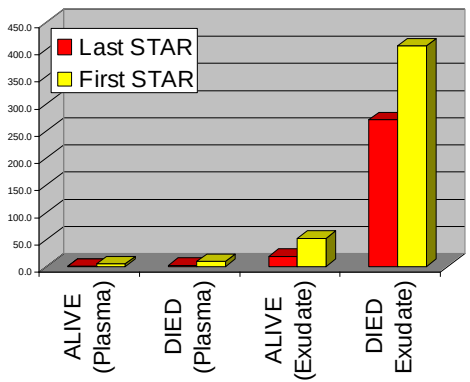
The bur is available at Osteogenics, Inc., at www.STARMED.net
or tel: 414-539-3564, fax: 414-539-2096

Hypobaric Wound Shield

The tube wrapped into the Kerlex placed on top of the bur underneath a self-adhesive Steri-drape is hooked to a suction pump to produce a slight negative pressure. With this setup, peritoneal fluid is collected and measured losses can be replaced.



TNFa Levels in Plasma and Exudate



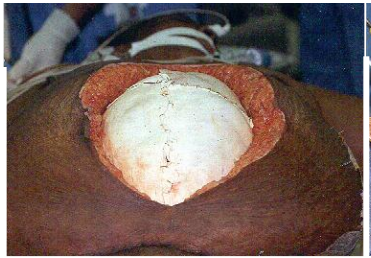
Evacuating and collecting peritoneal fluid will remove compartmentalized mediators from the peritoneal cavity. For example, in a recent study we were able to show that high TNF levels correlate with mortality.

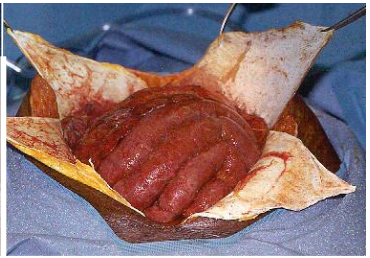
Also, digestive pancreatic juice can be removed effectively before final repair or controlled drainage is possible.

Hypobaric Wound Shield II

This patient was transferred with abdominal compartment syndrome. The abdomen had been closed with 3 Gortex sheets and one Epigard sheet (see left).

STAR was initiated using the bur (see below). The abdomen was closed fascia-to-fascia. On follow-up there was no hernia.

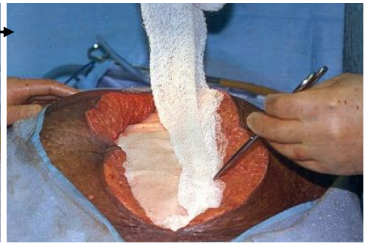




This abdomen was closed at an outside hospital with non-bur devices worth over $5000

A suction tube is inserted into a Kerlex roll and both are covered tight with a self-adhesive plastic drape.

An Ioban sheet has been used in this particular closing. It is important to start suction immediately and not to interrupt it.



CASE: A 14 Year-old Boy With Diffuse Peritonitis From Perforated Appendicitis

What has happened?

4/17/97 Diagnosis of influenza by GP, antibiotics

4/26/97 General surgeon consult: appendectomy

4/30/97 Sepsis: re-opening of the wound and midline laparotomy for multiple intra-abdominal abscesses

5/2/97 Continued sepsis: re-exploration; more abscesses found. Could not close the abdomen. Vicryl mesh closure

5/5/95 Persistence of Sepsis: transfer to MCW with the diagnosis of abdominal compartment syndrome

Abdominal Compartment Syndrome

IAP = 28 mm Hg

CASE: A 14 Year-old Boy With Diffuse Peritonitis From Perforated Appendicitis

- **STAR Index Entry** :
- Removal of Vicryl
- Extending midline incision
- Opening of a lesser sack
- Irrigation with 12 L of R/L
  - of all quadrants
  - of all interloop spaces

STAR # 2: Closing of the appendectomy wound: Note the newly formed peritoneal lining under the Vicryl mesh

- **STAR Entry # 2**
- Opening of bur
- Irrigation
- Debridement
- Removal of appendectomy wound Vicryl and fascia-to-fascia closure
- Bur closure - hypobaric wound shield dressing

CASE: A 14 Year-old Boy With Diffuse Peritonitis From Perforated Appendicitis

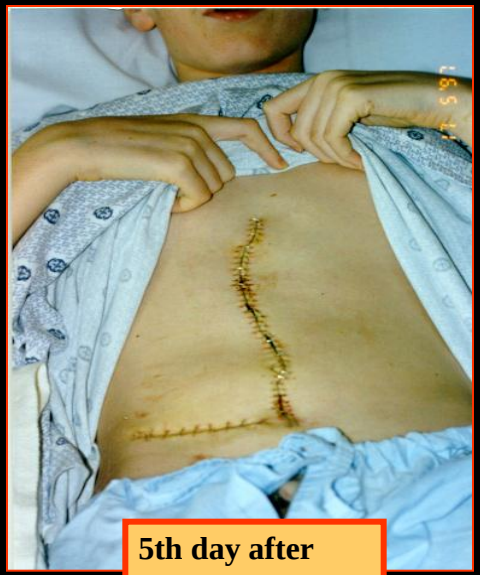
STAR Entries: May 7, 8, 9, & 11, 1997
Inspection, purge, decompression, irrigation, re-approximation of fasciae. Removal of bur, final closure: suturing fascia-to-fascia and of the skin

Post STAR
No complications, primary wound healing

Post-STAR day # 1: Antibiotic discontinued

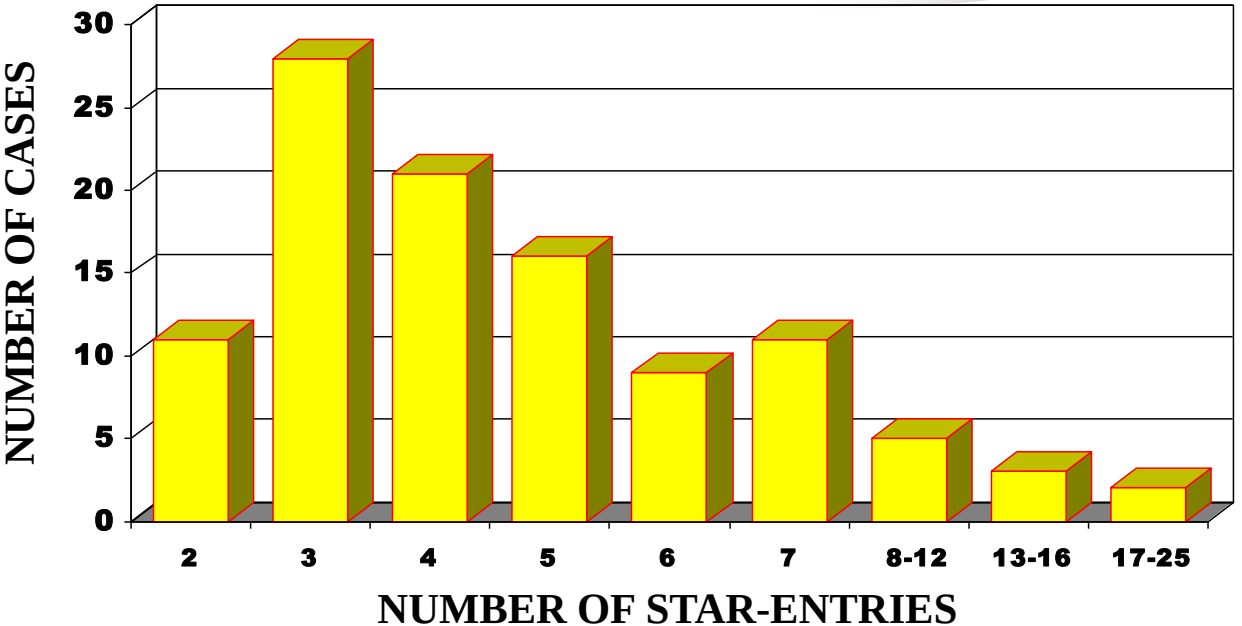
Post-STAR day # 5: Bowel movement

Post-STAR day # 6: Discharged



5th day after the final closure of the abdomen

Number of Abdominal Entries During STAR



CASE: 62 Year-Old Man With Leaking Colon Anastomosis, Small Bowel Perforations, Macronodular Cirrhosis

☺Feb. 26 (KM Hospital)
DX: Diverticulitis and Colon Polyp
OP: Resection of Sigmoid Colon
(Pararectal Incision)

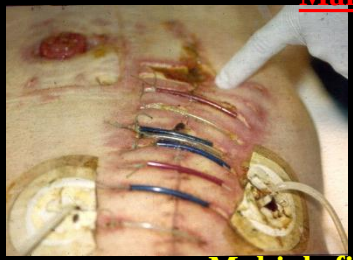
☹March 5: (KM Hospital)
Dx: Anastomotic Leak, Peritonitis
OP: Suture of Leak, Harmann's Operation

☹March 17, to 31: (MCW)
DX: Multiple SB Perforations, Anastomotic Leak, Diffuse Peritonitis
Physiology: APACHE-II = 18
MOF (Goris) Score = 50%

OP: STAR (11 Entries): Resection of Small Bowel + Anastomosis, Suture Large Bowel-Leak (STAR Entry #1), Debridement, Irrigation, Take-Down of Transverse Colostomy (STAR Entry # 3) STAR Entry 11: Final Vircyl Under Skin Closure

☺Sept. 93: (MCW)
OP: Repair of Incisional Hernia

March 17



Multiple fistulas

Bur inserted

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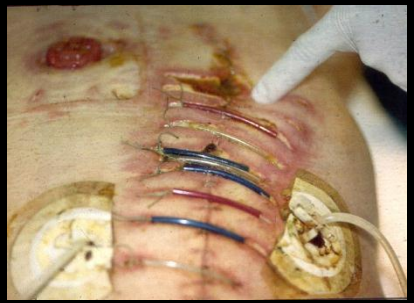

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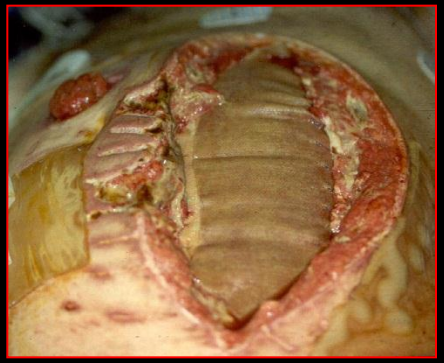
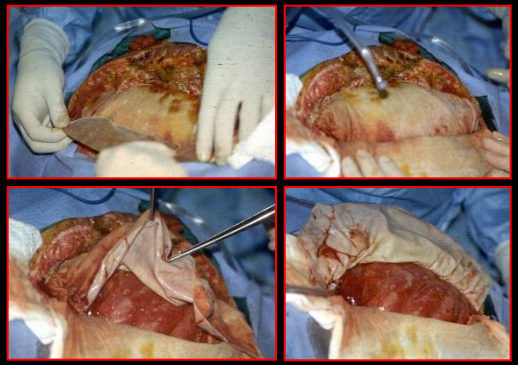
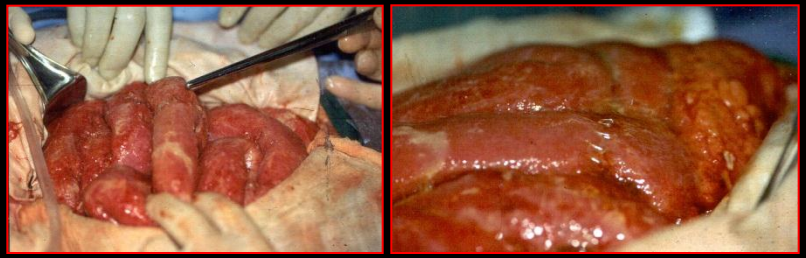


STAR
ENTRY # 2

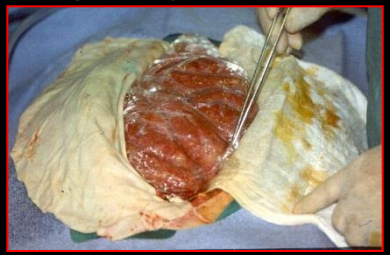
Re-opening of Bur



Inspection of Anastomosis



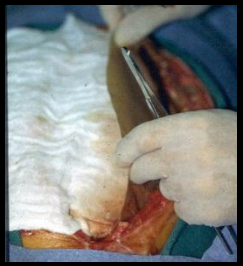
Preparing Re-closure



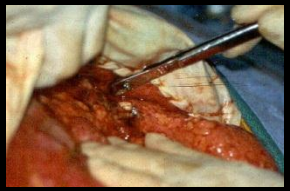
CASE: 62 Year-Old Man With Leaking Colon Anastomosis, Small Bowel Perforations, Macronodular Cirrhosis

Note Increased edema while reopening the bur





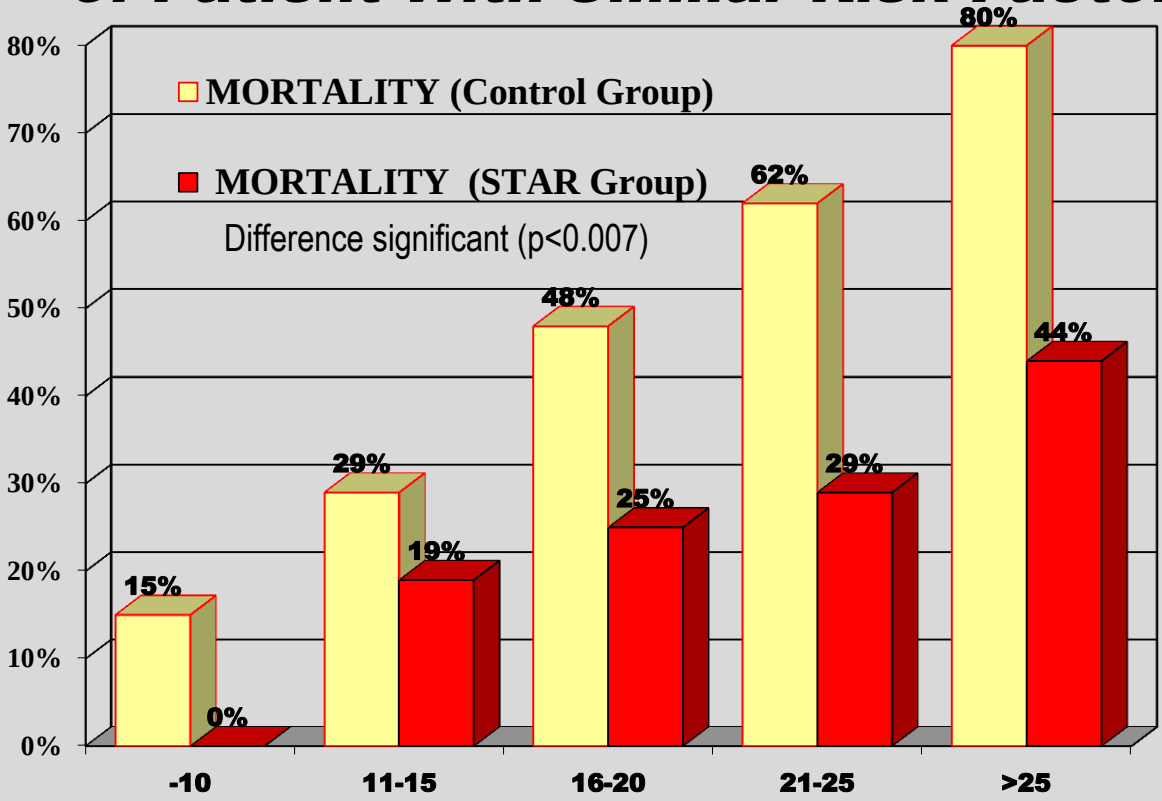


STAR-Entry # 3

Inspection of Anastomoses, Takedown of Colostomy and Abdomen after Discharge from Hospital

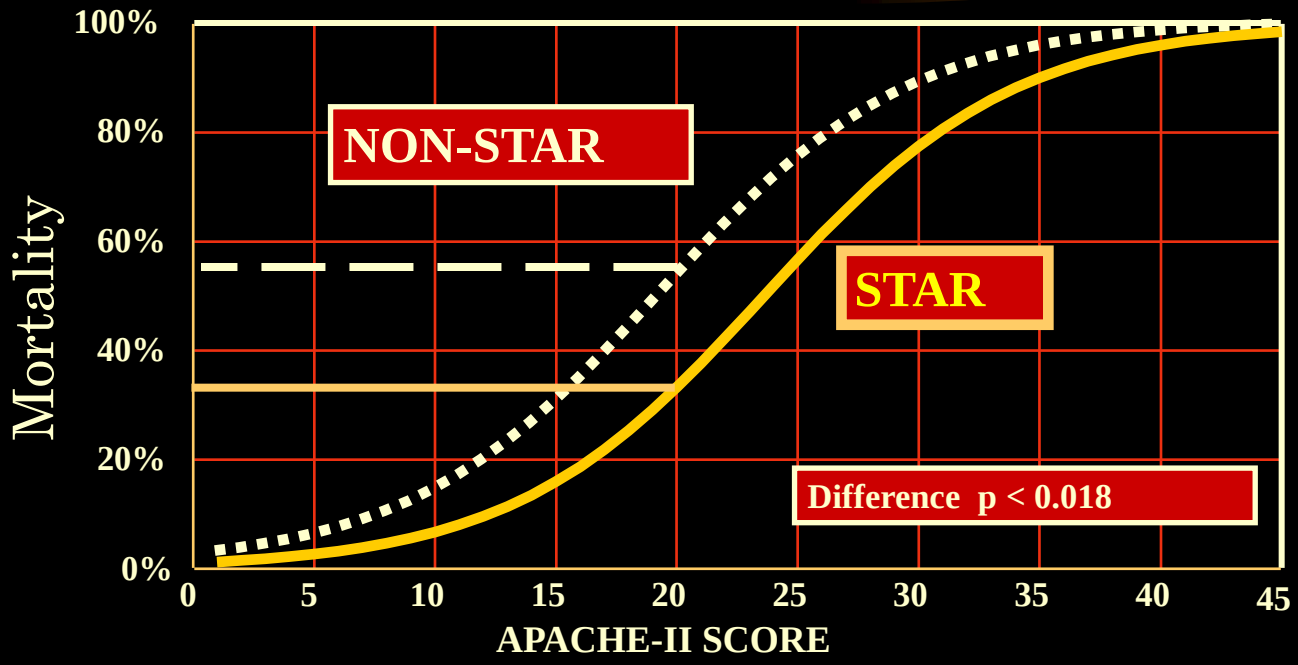
Mortality of STAR Versus Mortality of Patient With Similar Risk Factors

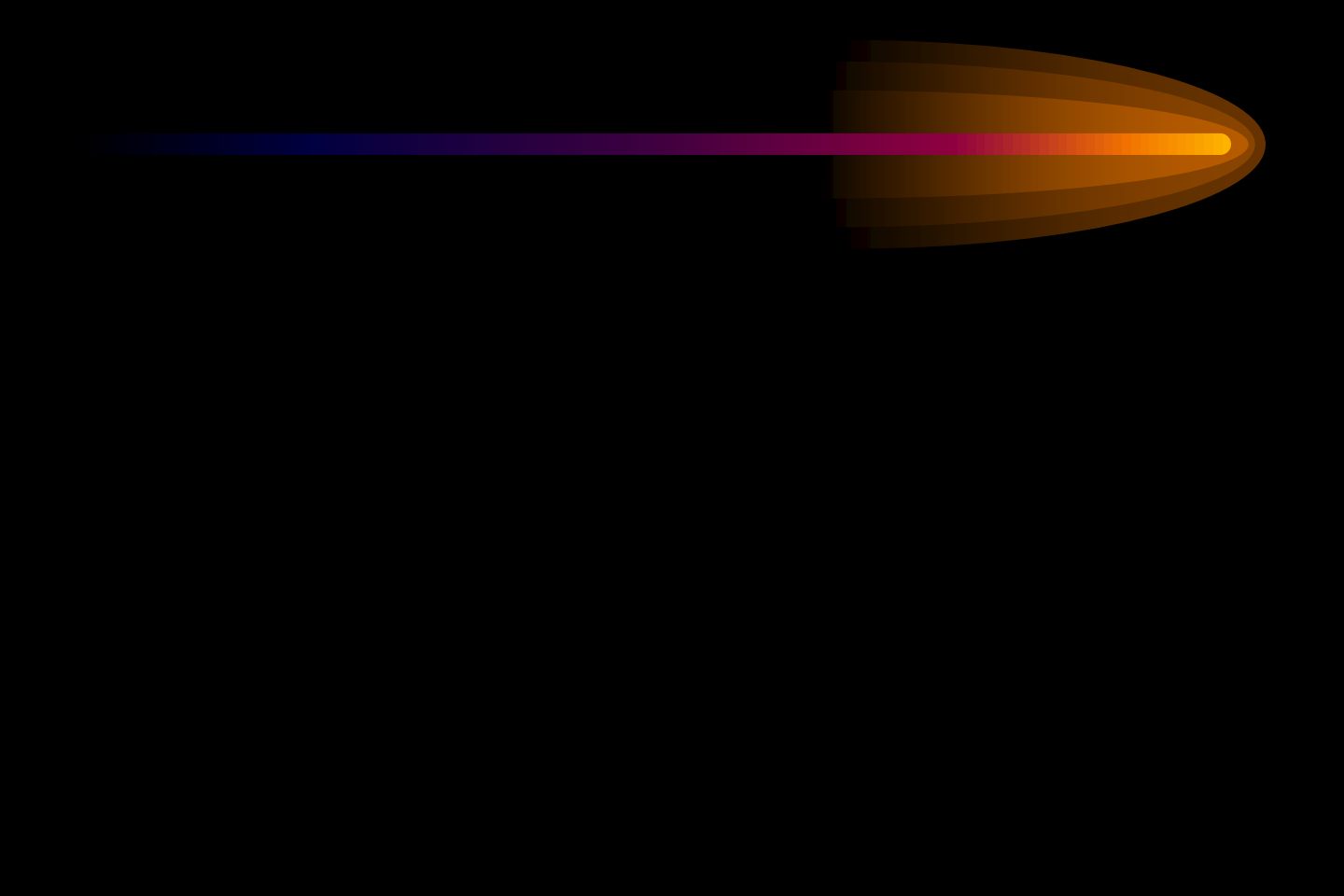


Series I: STAR (n=95) vs. NON-STAR (n = 261)
Same Risk Factors During the Same Period

Ln (R/1-R)= 4.14426 + (APACHE-II * 0.193) + (OPERATION * 0.4121); (STANDARD OPERATION = + 1; STAR = -1)

Theoretical Surg (Now European J Surg) 25:273-284, 1994.





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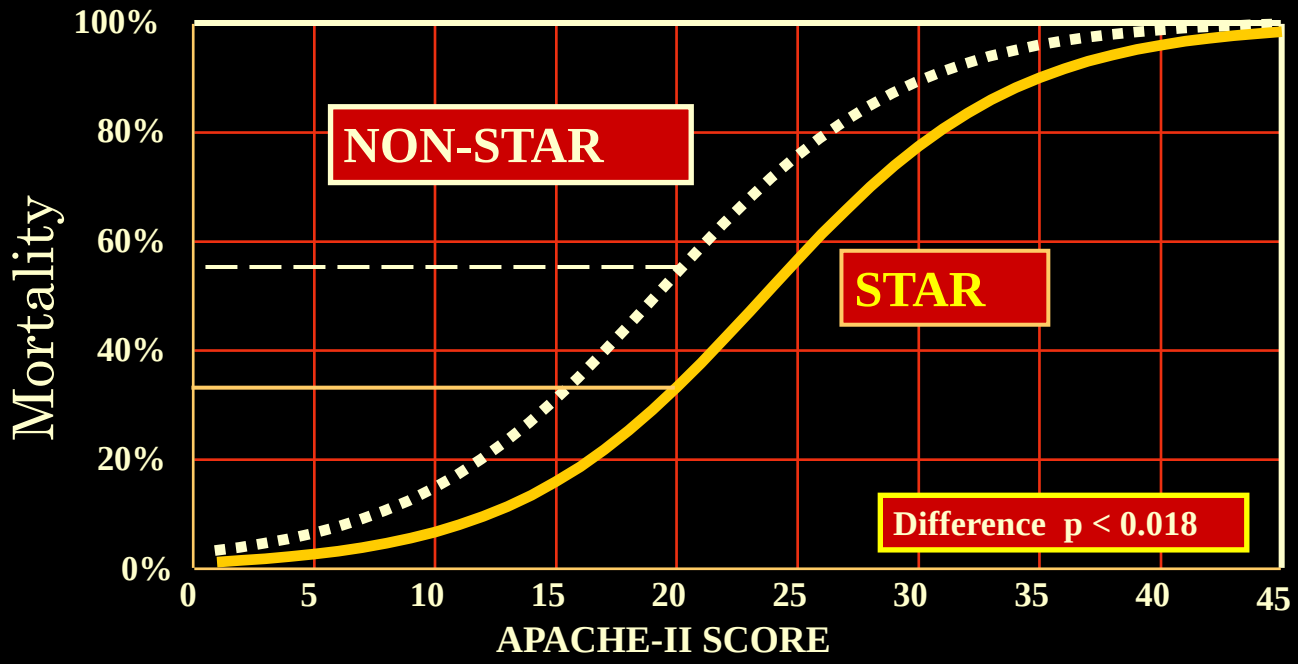

CASE: 69-Year Old Man with Diffuse Peritonitis, Ischemic Colostomy, Perforated Duodenal Ulcer, & Multiple Bleeding Gastric Stress Ulcers

☹Hx: Sigmoid colon resection for diverticulitis and postoperative leak repaired with colostomy and subsequent colostomy necrosis repaired with second more proximal colostomy

☺**July**

Dx: Hypertension, ischemic heart disease R R Colostomy, L mucous fistula,107Kg

OP: Takedown of both colostomies and formation of 2 colon anastomoses

☹**Aug 5**

Dx: Peritonitis leak of proximal and distal anastomosis

OP: Suture of leak, Hartmann's operation

☹**Aug 12**

DX: Septic shock, stress ulcer bleeding, duodenal perforation, ischemic colostomy, DIC, ATN, hepatorenal failure, pulmonary failure, Diffuse Peritonitis

Physiology: APACHE-II = 29 (survival probability of 10%)

OP: STAR (12 Entries): gastrostomy & oversewing of multiple bleeding ulcers, vagotomy, closure of duodenal perforation (#1,4,10,12), closure of colostomy (#4), colorectostomy (#5), extirpation of left & transverse Colon (#7), final closure

☺Sept. 29: (MCW)

Discharged home, no hernia, no colostomy

STAR-Entry # 2

Opening of the bur. Note the black spots on the bowel. These are bowel wall necroses from poor perfusion, due to increased abdominal pressure

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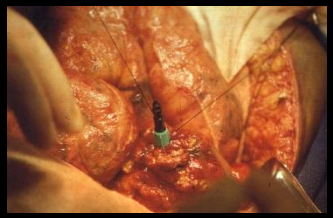
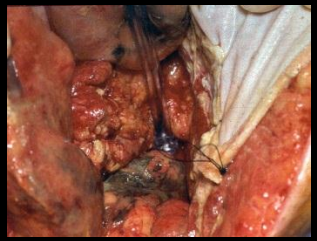
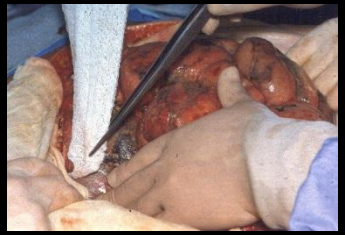
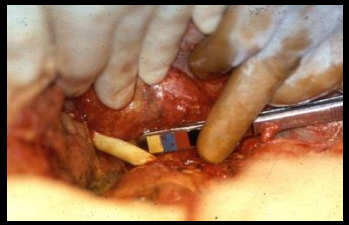


Preparation of the Hartmann's stump and formation of a colorectal anastomosis with 32 mm stapler in the presence of peritonitis





Tissue necrosis observed and technique of packing with Kerlex



The duodenal leak was originally drained with a T-tube. The T-tube was removed and the duodenum closed and healing controlled during subsequent STAR entries

CASE: 69-Year Old Man with Diffuse Peritonitis, Ischemic Colostomy, Perforated Duodenal Ulcer, & Multiple Bleeding Gastric Stress Ulcers



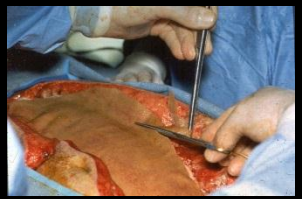


Opening of bur, removal of packs at subsequent STAR entries

Abdomen after final closure: note the colostomy sites. The transverse incision extension was done prior to STAR to gain access to the duodenal perforation

Same patient 3 months after discharge


Trimming of the bur as edema decreases to prepare for final fascia-to-fascia closure




Results

	Intra-Abdominal Infections	Trauma/ Hemoperitoneum	Pancreatic Necrosis	Difficult Abdomen	All Patients
Number of Patients	60	31	23	4	118
Mean Age (years)	49	47	37	46	46
Men	77%	65%	94%	50%	77%
Median APACHE II Score	17	18	19	18	18
Mean APACHE II Score	18.7 ± 7.3	18.0 ± 5.5	19.0 ±6.6	16.5 ±8.7	18.5 ±6.8
Mean Injury Severity Score		30.8 ±13.4			
Number of Surgeons Operating	17	8	7	2	21
Median (range) Days from Admission to STAR	7(0-53)	0(0-4)	5(0-30)	5(0-27)	3(0-53)
Median (range) Days from STAR to Discharge	27(2-131)	19(4-122)	63(5-108)	49(10-51)	29(2-131)
Days in Critical Care Units	20(0-115)	12(4-51)	21(9-97)	15(8-75)	20(3-115)
ICU Mortality	15%	22%	10%	0%	14%
60-Day Mortality	20%	16%	13%	0%	17%
Hospital Mortality	28%	22%	19%	0%	24%
Number of STAR Entries	5.7	71	3.6	4.0	5.4
Number of Days with Bur	6.7	8.1	4.1	3.8	6.2
Mean Time Between 2 entries (days)	1.5±0.5	1.3 ±0.4	1.6 ±0.5	1.2 ±0.3	1.5 ± 0.5

Lessons Learned

Indications for STAR

- Severe Abdominal Trauma
  - Major Hemorrhage Requiring Packing
  - Excessive Intra-abdominal Edema
- Diffuse Suppurative Peritonitis
  - Increased intra-abdominal pressure
  - Conditions with progressive deterioration
  - Inability to perform definitive repair
  - Inability to to eliminate the source of infection
  - Inability to debride dead tissue sufficiently
  - Multiple previous operations
- Infected Pancreatic Necrosis
- Bowel Ischemia
- Ruptured Aortic Aneurysm

Critical Details

★ Technical
- ★ Handle tissue and fascia gently, replace packs often
- ★ Exert some tension to the fascia via bur
- ★ Do deferred anastomoses early, avoid colostomies
- ★ Stick to 24 hrs interval. Avoid transmural feeding tubes
- ★ Final fascial closure at the end of STAR tolerates more tension than closure after a single laparotomy
- ★ Do abdominal x-ray at last STAR to account for packs

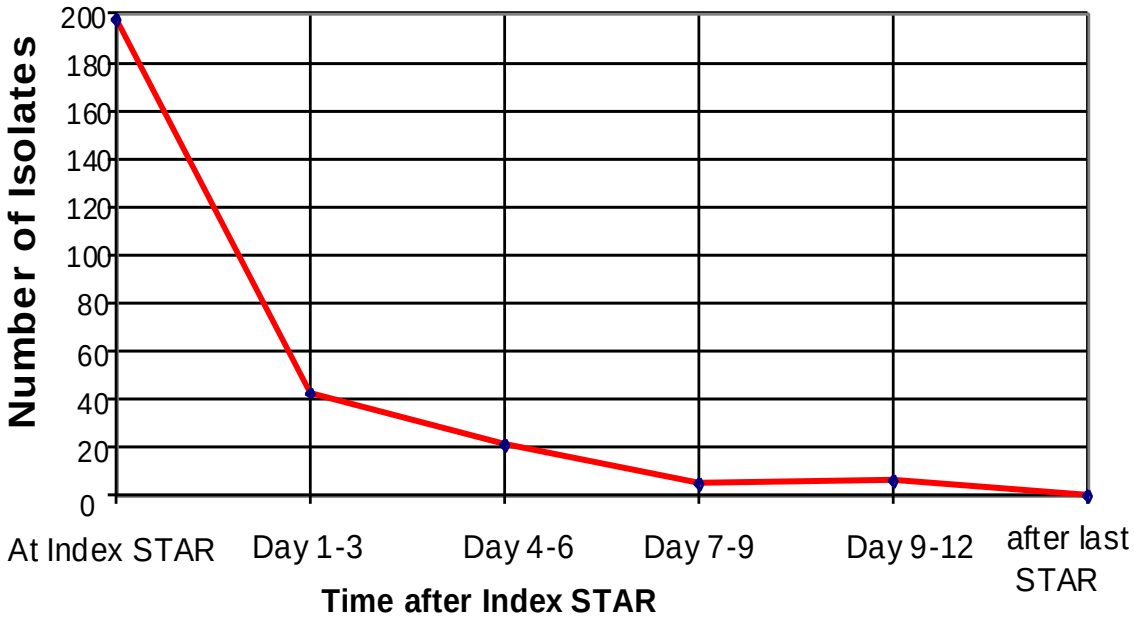
★ Infectious
- ★ Prevent contamination of wound in the ICU
- ★ Time antibiotic, like prophylaxis 1h prior to STAR entry
- ★ Know antibiotic tissue concentration in peritoneal fluid

★ Abdominal Hypertension & Mediators
- ★ Measurement of intra-abdominal pressure
- ★ Purging of “bad” cytokines (TNF)
- ★ Replacing lost proteins with FFP

STAR: Antibiotic Choice is Important

Bacterial elimination during 74 STAR patients is shown in the graph below.
Most bacteria were Gram-negative rods.

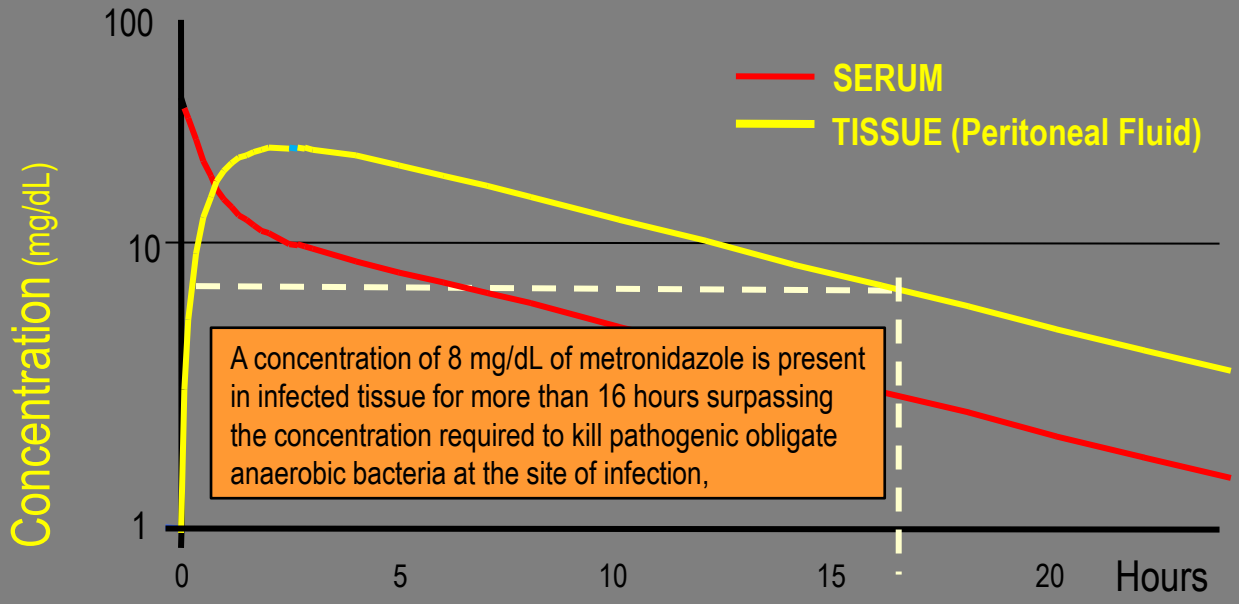
Bacterial Elimination from Abdominal Cavity During STAR



Diag Micro & Infect 22(1995)183-188

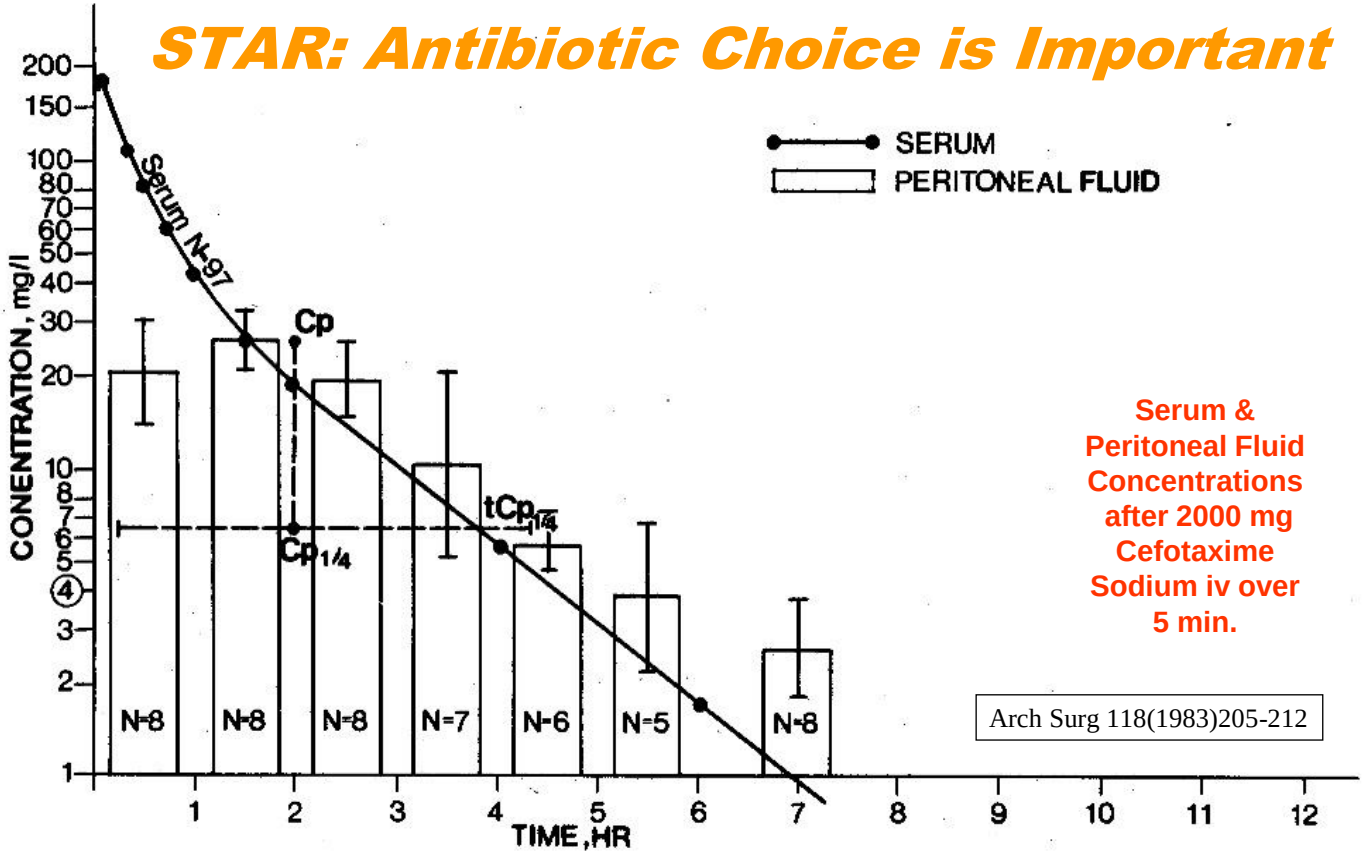
STAR: Antibiotic Choice is Important

Serum & Peritoneal Fluid Concentrations after 500 mg Metronidazole iv.



With the antibiotic combinations of 2000 mg cefotaxime q 8 hrs and 500 mg metronidazole q 12 hrs, concentrations in peritoneal fluid were above the MIC^{100} of most pathogens for most of the time between two dose administrations. (See figure above an on next page.)

STAR: Antibiotic Choice is Important



Serum & Peritoneal Fluid Concentrations after 2000 mg Cefotaxime Sodium iv over 5 min.

Arch Surg 118(1983)205-212

Fig 5.—Mean concentrations of cefoxitin sodium in serum and peritoneal fluid after intravenous injection of 2.0 g. Cp indicates peak concentration; Cp¼, one fourth of Cp; and tCp¼, duration of Cp¼.

Benefits of Staged Abdominal Repair

STAR Advantages

- ★ Effective Elimination of the Cause/Source of Infection
- ★ Effective Reduction of Bacterial Inoculum
- ★ Effective Elimination of Toxins
- ★ No Complications of Increased Intra-abdominal Pressure
- ★ Flexible Therapeutic Concept
- ★ Timely Diagnosis and Therapy of Complications

Benefits of Bur Closure

- ★ Bridges fascial gap
- ★ No evisceration, no fistula
- ★ Decreases intra-abdominal pressure
  - ★ Improves renal and hepatic function
  - ★ Improves pulmonary & cardiac function
  - ★ Improves intra-abdominal perfusion
  - ★ improves fascial perfusion
- ★ Adjusts in size to change of girth
- ★ Rapid entry and re-entry
- ★ Final fascia-to-fascia closure