From the Department of Surgery, Medical College of Wisconsin, Florida, USA

Staged Abdominal Repair: Development and Current Practice of an Advanced Operative Technique for Diffuse Suppurative Peritonitis

D. H. Wittmann

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Schlüsselwörter: Infizierte Pankreasnekrose – künstlicher Klettverschluß – abdominelles Kompartmentsyndrom – offenes Abdomen – geplante Relaparotomie.

Summary: Background: To improve mortality of intra-abdominal infections, since 1975, many surgeons worldwide have been extending the classical single-stage operative approach for the sickest 10 % of patients. A variety of names have been introduced for similar operative strategies. All procedures contributed to the development of Staged Abdominal Repair (STAR).
Methods: STAR is defined as one operation performed in multiple steps at 24 hours intervals to 1) reverse or prevent the physiological derangement of increased intra-abdominal pressure from peritoneal edema and ileus and to 2) combine damage control in non-stable patients with delayed definitive repair including formation of anastomoses, and ultimate formal fascial closure. The abdomen is temporarily closed using the artificial burr that has been approved for clinical use by the European and US health authorities (www.starsurgical.com). The wound above the artificial burr is sealed with a Hypobaric Wound Shield (HBS) that acts as a barrier against exogenous contamination in the ICU and allows for collection of toxic peritoneal fluid for diagnostic purposes to provide a basis for meaningful protein substitution.
Results: Our recent series from 1988 to 1999 includes 128 patients with an Apache II score of 19 ± 7. We entered the abdominal cavity 5.9 ± 3.5 times during 6.8 ± 4.1 days per patient and performed STAR because we were unable to close the abdomen without undo tension in 83 % of our patients. The viability of the bowel was a concern in 17% of the cases. Patients required an average of 22 ± 19 (median 18) days of care in the intensive care unit and they were discharged a median of 30 (2–252) days after the Index STAR. We were able to close the fascia in 93 % of the cases. The 30 day, 60 day and hospital mortality was 11 %, 15 %, and 19 % respectively. Post STAR we saw 3 intestinal fistulae that closed spontaneously and 12 % of the patients developed abdominal wall hernias.
Conclusions: The observed mortality compares favorably to the expected mortality of 47 % for patients with similar risk factors, and there are fewer complications when compared with other open techniques.

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Schrittweise transabdominelle Rekonstruktion: Entwicklung und gegenwärtige Praxis einer fortgeschrittenen operativen Technik zur Behandlung der diffusen eitrigen Peritonitis

Zusammenfassung: Grundlagen: Um die Letalität intraabdomineller Infektionen zu verringern, haben seit 1975 viele Chirurgen weltweit die klassische einzeitige Operation für die am schwersten betroffenen 10 % der Patienten erweitert. Eine Reihe von unterschiedlichen Namen wurde geprägt, die alle sehr ähnliche operative Strategien bezeichnen. Alle diese Verfahren haben zur Entwicklung der „schrittweisen trans-abdominellen Rekonstruktion" Staged Abdominal Repair (STAR) beigetragen.
Methodik: STAR ist eine in mehreren Schritten von 24 h Abstand ausgeführte Operation, um 1) die durch peritoneales Ödem und Ileus induzierte abdominale Hypertension mit ihren Funktionsverschlechterungen zu verhindern oder rückzubilden, 2) eine notfallmässige Schadensbehebung mit der definitive Therapie wie z. B. Anastomosennaht und ultimativem Faszienverschluß zu kombinieren.
Das Abdomen wird dabei vorübergehend mit einem künstlichen Klettverschluß (artificial burr) geschlossen. Sein klinischer Gebrauch ist von europäischen und US Gesundheitsbehörden genehmigt (www.starsurgical.com). Die Wunde über dem Klettverschluß wird mit einer Wund Abdeckung (Hypobaric Wound Shield (HBS)) versiegelt, die als Barriere gegen exogene Kontamination auf der Intensivstation dient, und außerdem erlaubt, toxische Peritonealexsudat für diagnostische und therapeutische Zwecke zu sammeln.
Ergebnisse: Unsere rezente Serie von 1988–1999 umfaßt 128 Patienten mit einem APACHE-II score von19 ± 7. Die Bauchhöhle wurde pro Patient 5,9 ± 3,5mal während 6,8 ± 4,1 Tagen eröffnet. STAR wurde in 83 % der Patienten wegen der Unmöglichkeit das Abdomen spannungsfrei zu verschließen angewendet. Bei 17 % der Patienten bestanden Bedenken wegen der Vitalität des Darms. Der mittlere Intensivstationsaufenthalt betrug 22 ± 19 (Median 18) Tage, die Spitalsentlassung erfolgte nach einem Median von 30 (2–252) Tagen nach dem ersten Eingriff. In 93 % der Fälle konnten wir die Faszie verschließen. Die 30-Tage-, 60-Tage- und Krankenhaus-Letalität betrug 11 %, 15 %, und 19 %. Nach STAR beobachteten wir 3 Darmfisteln, die sich spontan verschlossen; 12 % der Patienten entwickelten Narbenhernien.
Schlußfolgerungen: Die beobachtete Letalität erscheint gering im Vergleich zu einer zu erwartenden Letalität von 47 % bei Patienten mit ähnlichen Risikofaktoren; zudem finden sich weniger Komplikationen als bei anderen offenen Behandlungstechniken.

Introduction: lessons from the past

Therapeutic success in the management of intra-abdominal infections directly translates into mortality figures. Most patients die from the infection if not operated upon in a timely fashion. Kirschner presented in 1926 impressive statistics supporting the fundamental role of operative therapy (27). From 1890 to 1924 the mortality of 5,468 patients from seven major Medical Centers decreased from over 90 % to less than 40 %. Operative management was the only effective therapeutic modality that was introduced during the same period. Fluid management and nutri-

Corresponding address: D. H Wittmann, M. D., 1055 Laurel Avernue, Venice, Florida 35292, USA.
Fax: ++1/941/4121823
E-mail: DHWittmann@ATT.net

tional support was in its infant state. Effective antimicrobial therapy had not been discovered, and today's critical care therapy to support organ system function was not yet available. Nevertheless, the importance of Kirschner's contribution lies in the recognition of the pivotal role of operative management and the definition of two operative principles essential for therapeutic success: 1) the source of infections must be closed (Source Control) and 2) bacteria, toxins and adjuvants to bacterial growth must be evacuated (purged) from the abdominal cavity.

Kirschner also recognized the importance of treating bacteria with antimicrobials and the need for support of functional impairments. Surgeons at the time had a comprehensive understanding of the basic bacteriology of intra-abdominal infections including bacterial synergism between facultative and obligate anaerobic bacteria (16). The intelligence could not translate into therapeutic success, because effective antibiotics were not available. Similarly, the systemic inflammatory response to a local infection was already appreciated at the time. As early as 1914 *Schottmüller* defined sepsis as a systemic reaction to a local infection (36). It took, however, almost seven decades before physicians would begin to therapeutically address the systemic inflammatory response seen with intra-abdominal infections (3, 10, 19, 52).

After the introduction of operative management principles had brought about a dramatic 50 % mortality reduction during the first two decades of this century, mortality rates did not improve visibly during the five subsequent decades (41, 44). Therapeutic improvements resulting from better non-operative therapy were masked in mortality figures because surgeons operated older patients with more risk factors. Alarmed by ever replicating high mortality rates the time matured for new operative methods.

Development of the advanced operative procedures

The era of new operative concepts started in 1975 with the dissertation of Pujol, a young physician from Paris University (34). He concluded that intra-abdominal infections should be treated as any surgical infection following Celsus' classical rule: „ibi pus, ubi evacua" and „.... tota cutis super pus excidenda est" (7) and, thus, the abdomen should be left open. Subsequently, a series of authors published studies in which the abdomen was left open and treated as an open wound, but data are inconclusive (1, 4, 5, 6, 8, 9, 11, 12, 14, 15, 20, 22, 24, 31, 32). These studies were generally uncontrolled and did not stratify severity of disease, thus making comparison to other methods impossible (26, 55). Additionally a potpourri of names for basically the same concept led to confusion of terms. All studies, however, claimed to use the newer approaches for patients who would otherwise have been abandoned for standard treatment. This might lead one to conclude that the mortality rates reported represent a selection of the sickest patients and that the advanced open techniques outperformed the standard single operation. Huge incisional hernias, however, complicated the simple open abdomen technique. Intestinal fistulae formed in up to 40 % of the cases representing another severe complication. Fistulae probably form because the distended and inflamed and friable intestines, when exposed to atmospheric pressure, are likely to release the increased intraluminal pressure by perforation.

The pathophysiological impact of the abdominal compartment syndrome was not appreciated in any of the open abdomen studies, although one of the first papers dealing with abdominal hypertension resulting in decreased renal function was published as early as 1872 (42). Subsequently many excellent reviews were offered to the medical community (43), but the abdominal compartment syndrome remained largely unknown in clinical practice. The various new open abdomen techniques dealt effectively with abdominal hypertension, the authors, however, did not mention the intra-abdominal pressure at all. Leaving the abdomen open perfectly reverses impaired renal, hepatic, cardiovascular, and pulmonary functions, as well as intestinal and abdominal wall hypoperfusion that are the pitfalls of the abdominal compartment syndrome (43). Unknowingly the authors of this new operative technique introduced and added a new principle for operative management: abdominal decompression.

Refining *Kirschner's* criteria of operative therapy, four principles of operative management can be defined today:

(1) Repair: Close or eliminate the source of infection.
(2) Purge: Eliminate bacteria and adjuvants from the peritoneal cavity.
(3) Decompress: Reverse the negative impact of increased intra-abdominal pressure.
(4) Control: Security checks for principles (1) and (2): repair and purge by a series of abdominal reentries to ensure proper healing and diagnose and treat complications early on.

The 4th principle of therapy was introduced later by advocates of the planned re-operation conception. In this paper review I shall analyze the advanced operative procedures and their contribution to the development of STAR and present data to outline the current practice of STAR.

Methods

Analysis of advanced procedures

All publications dealing with advanced operations for peritonitis (1, 4, 5, 6, 8, 9, 11, 12, 14, 15 20, 22, 24, 26, 31, 32) have been analyzed, and a synopsis of the results published in (54) is presented here for discussion purposes.

Patients treated with STAR

The patients presented in this review include 128 with an intra-abdominal infection. They represent a subset of all patients treated between 1988 and 1999 at the Medical College of Wisconsin affiliated hospitals with STAR excluding pure trauma cases without infection. The data with focus on the closure device were submitted to the FDA to obtain approval for the clinical use of the Artificial Burr (AF).

All patients were treated in the intensive care unit and most remained intubated on artificial ventilation during the entire length of the STAR procedure. Informed consent was obtained initially for every single abdominal entry, later we tried to obtain one single consent only for STAR that was defined as one operation done in multiple steps. This approach became necessary to include all subsequent abdominal reentries because relatives of

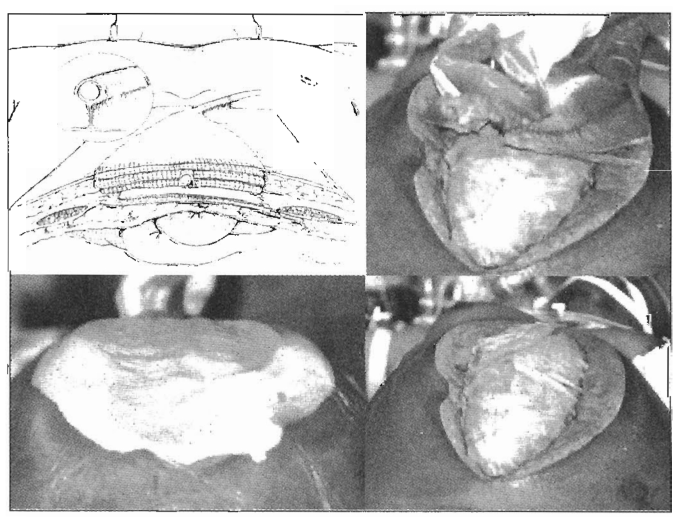

Fig. 1. Transsection through the open abdomen with the artificial burr covering the space between the incised fasciae. The Hypobaric Wound Shield (HBS) covers the burr to avoid exogenous contamination of the abdominal and to allow for removal of peritoneal fluid via a suction drain. The entire system needs to be under negative pressure between two subsequent star entries. Negative pressure must be initiated immediately upon closure of the wound to prevent leakage of peritoneal. There is gauze between the self-adhering plastic drape and the burr. On the left there is a patient with the HBS, its removal and the burr are visible (artificial burr in a patient and visible [top] and covered with the Hypobaric wound shield [bottom]).

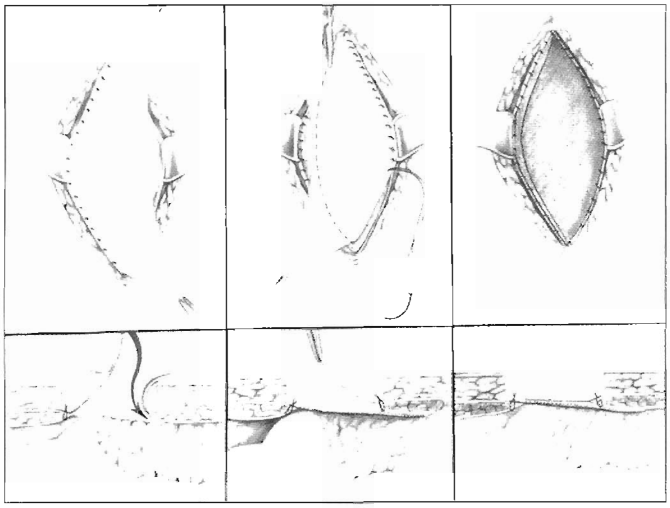

Fig. 2. Technique of suturing the burr to the fascia and to close the abdomen.

two patients declined permission to continue to operate before STAR was completed. Antibiotic therapy was done with 2 grams cefotaxime-generation cephalosporin in combination metronidazole in spontaneous and posttraumatic peritonitis or with 1 g imipenem/cilastatin in postoperative cases. Dosage and dosage interval were chosen to assure peritoneal fluid antibiotic levels in excess to the minimal inhibitory concentrations for most of the dosage interval (51). We performed hemodialysis or hemofiltration in elderly early before renal failure would become a major problem. To avoid exogenous contamination of the abdominal cavity we used the Hypobaric Wound Shield (HBS) (Fig. 1), which became a mandatory part of STAR. HBS allows for collection of peritoneal fluid and cytokines as well as drug concentrations and protein losses (23; 51). Measured protein losses were replaced with fresh frozen plasma in most instances. ICU nurses were pleased because no fluid was leaking out of the abdominal wound into the ICU beds. All operations were done in the operating room except for two cases where we confirmed preterminal excessive bowel ischemia by opening the burr in the intensive care unit.

The same surgeon treated his patient throughout the entire STAR period to provide for continuity of care because we felt that the information about the complexity of the cases could not be easily reported to another surgeon. Patient demographics and treatment parameters were documented on an ongoing basis and the intra-abdominal pathology was photo documented in the majority of cases. All case histories were submitted to the FDA and the most informational cases are accessible at www.starsurgical.com and www.colonna.net/star.html.

Intra-abdominal pressure was measured by transvesical technique (43). Statistical analysis was aided by the SPSS statistical application for PCs.

Operative technique

A large midline incision from the xyphoid process to the mons pubis is required to optimally decompress the abdominal cavity and allow for thorough inspection of all peritoneal pockets. Particular care must be taken in the presence of abdominal hypertension not to cause injuries to the distended large bowel and small bowel.

Subsequent steps are dictated by the underlying pathology and follow general rules of abdominal surgery. Particular care must be taken to handle tissue gently, avoid mass ligatures, and perform meticulous hemostasis. In any case an additional dose of the used antibiotic should be administered 30 minutes before opening the abdomen to guarantee sufficient antibacterial tissue levels during operative manipulations. Following operative management of pathology, the abdomen may then be temporarily closed utilizing the burr (Fig. 1, 2, 3). The first operation of a series is called index STAR, subsequent abdominal entries are numbered consecutively: STAR #2, STAR#3 etc.

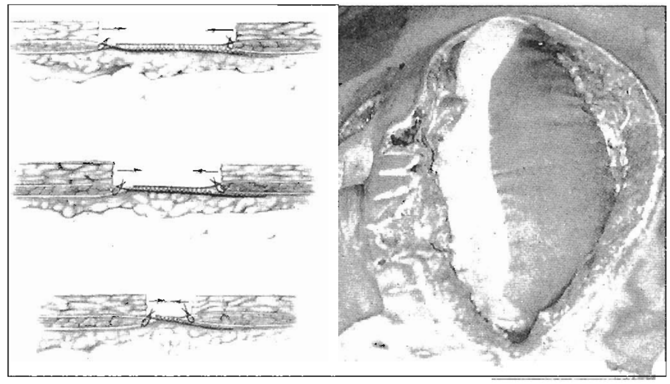

Fig. 3. Reapproximation of the abdominal wall to prepare for final fascia-to-fascia closure similar to the closure after the standard single abdominal operations.

Expanding the abdominal wound with the artificial burr is relatively simple and shown in Fig. 2 and 3. The artificial burr consists of a larger loop sheet and a smaller hook sheet, which is pressed with the hooks facing inwards into the loops of the loop sheet once both sheets have been sutured to the opposing fasciae. Fig. 1 shows the abdominal wound with the HBS in place. For that purpose gauze covers the hook sheet and subcutaneous tissue up to the level of the skin. A suction drain is imbedded into the gauze, and a self-adhering plastic drape is applied to the skin to cover the entire abdominal wall and the wound, and leaving a tunnel with a mesentery for the drain. This seals the abdominal cavity and keeps it sterile. While the patient still lies on the operating table it is important to immediately apply suction (10 to 20 cm H_2O subpressure) to the suction drain to produce negative pressure above the wound and collect abdominal fluid before it leaks into the bed.

Intensive care unit

Between operations the patient remains in the intensive care unit for the staff to monitor vital signs and cardio-pulmonary, renal and hepatic function, and to permit sufficient nutrition, oxygen supply and replacement of losses. The patient is usually sedated and requires mechanical ventilation for sufficient oxygenation of tissues for optimal healing. Intra-abdominal pressure is measured via urinary catheter.

Interval between two STARs

The interval between two abdominal entries should not exceed 36 hours. After 24 hours bacteria have regrown to their original

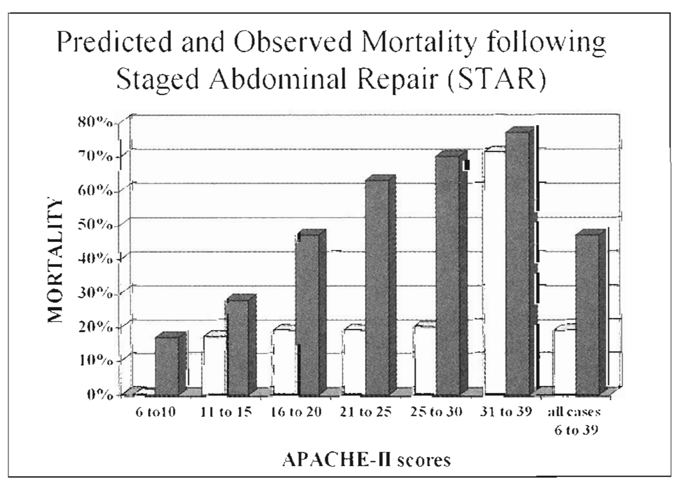

Fig. 4. Comparison of the observed and predicted mortality using the Apache II system. The difference is significant at $p < 0.05$ except for the very high scores over 25 (7 cases of which 5 died). STAR cuts the mortality in half.

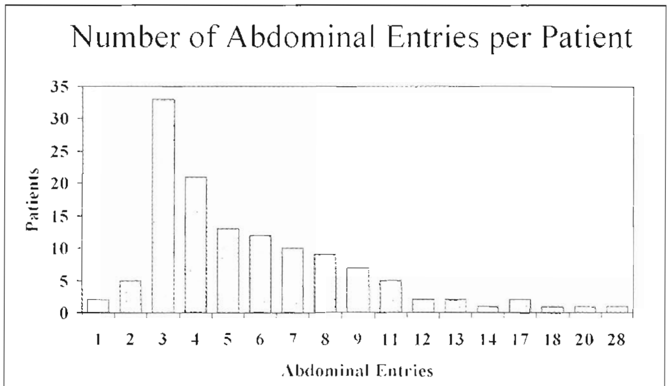

Fig. 5. Number of abdominal entries during STAR per patient. The largest group of patients required only 3 abdominal entries.

inoculum size (13) and tissue handling becomes increasingly traumatic because wound-healing processes impair tissue plane separation, and hemorrhage from neovascular buds is easily induced. For further details about the operative technique see my Chapter in Mastery of Surgery (45) and www.starsurgical.com

Results

Non-STAR advanced operations

Results of an analysis of all advanced operative techniques that have contributed to the development of STAR are presented in Tab. 1.

STAR

The median age of 128 cases with intra-abdominal infections was 44 years ranging from 13 to 85. Risk factors and physiologic impairment with increased acute physiology scores are reflected in a mean Apache II score of 19 ± 6.9 with a median of 18 ranging from 6 to 39 (Fig. 4). Organ dysfunction is echoed in a mean Goris multi-organ dysfunction score of 2 ± 2.3. 83 % of the patients had excessive peritoneal edema and the mean intra-abdominal pressure before the index STAR (first abdominal entry of STAR) was 24 ± 20. Spontaneous peritonitis due to bowel perforation was present in 28 %, postoperative peritonitis in 43 % of which 15 % happened after trauma. 29 % of the patients had infected pancreatic necrosis. Bowel ischemia was seen in 13% of all cases and was associated with spontaneous and postoperative peritonitis. We opened the abdominal cavity 756 times every 24 to 36 hours (mean 27) and the abdomen was closed after an average of 6.8 ± 4.1 days (Fig. 5). The artificial burr was replaced in 2 patients after 8 abdominal re-entries. The fascia had dehisced in 6 cases. 12 % of all patients developed a hernia, and 3 bowel fistulae healed spontaneously post STAR. The patients stayed a median of 18 days (0–115) in the critical care unit

Tab. 1. Mortality reported with various forms of laparostomy and control groups respectively.

Technique	Studies	Patients	Died	
	(n)	(n)	(n)	Ratio
Open Laparostomy	37	869	362	41.7 %
Control group: Standard OP.		195	76	39.1 %
Mesh laparostomy	12	439	171	38.9 %
No control group	0	–	–	–
STAR laparostomy or (Mesh laparostomy combined with Planned relaparotomy)	11	385	108	28.1 %
Control group: Standard OP.		95	43	44.2 %
				38.2 %

Tab. 2. Comparison of the advanced operations.

	Repair	Purge	Decompress	Control
Standard operations	yes	yes	no	no
Open laparostomy	yes	yes	yes	no
Mesh laparostomy	yes	yes	yes	no
Planned relaparotomy	yes	yes	no	yes
STAR (stage abdominal repair)	yes	yes	yes	yes

and were discharged after a median of 30 (2 – 252) days after the Index STAR. 24 of the patients died after a median of 20.5 (5–103) days from the index STAR which translates in a 30-day mortality of 11 %, a 60-day mortality of 15 % and a total hospital mortality of 19 %. In Fig. 4 the observed total mortality is compared to the mortality of patients with similar risk factors using the Apache-II risk factor stratification system. The difference is significant for all groups with score of less than 25.

Discussion

Advanced Operations with Abdominal Decompression

There is plenty of information available dealing with the open abdomen technique. It is difficult, however, to assess the benefits of the new procedures because most of the information is anecdotal. In only a few studies have risk factors been assessed reproducibly to allow for comparison. Prospective randomized trials are difficult to perform because the number of patients that may benefit from the new advanced procedures is small, approximately 10 to 15 % of all cases of intra-abdominal infection in an institution. Consequently, we have to analyze less convincing information to assess the benefit of the open abdomen procedures, such as data from 1983 patients of 60 studies dealing with the new procedure (Tab. 1).

The profuse terminology published in the literature could be confusing. Names such as Open Abdomen, Laparostomy, Semi-Open Technique, Planned Relaparotomy, Relaparotomy On Demand, Programmed Laparotomy, Programmed Relaparotomy, Four-Quadrant Lavage, Scheduled Reoperations, Scheduled Repeated Laparotomy, Etappenlavage, Second-Look Strategy, Laparostomy, Semi-Open Laparostomy, Staged Operative Repair have been used. In essence, there are three different procedures that cover the strategy of all the various open abdomen approaches: (1) open laparostomy; (2) mesh laparostomy; and (3) STAR laparostomy. The advanced procedures address not only the first and second principles of operative management, to repair and purge, but also effectively deal with two new principles: 3) to decompress and 4) to control. While all three new procedures decompress the abdominal compartment from increased pressure, only the STAR laparostomy allows for the control and security check of the intra-abdominal healing process (Tab. 2).

Addressing the concept of increased intra-abdominal pressure as a new therapeutic principle seems to be of primary importance because almost all organ system functions are heavily impaired in the presence of abdominal hypertension (43). There is abundant literature about the decrease of renal function, pulmonary function, and cardiovascular performance in the presence of increased abdominal pressure. Abdominal hypertension also decreases venous return and hepatic perfusion as well as perfusion to the intestines and other abdominal organs and the abdominal wall. Reestablishing blood flow to all these organs may be paramount in the healing process from diffuse intra-abdominal infection and prevent necrcotizing abdominal wall infections.

Open Laparostomy: Open laparostomy is defined as laparotomy without the re-approximation and suture closure of the abdominal fascia (Fig. 6). It may be combined with a relaparotomy on demand. It has been performed on 869 patients in 37 studies (54). In 3 studies there were 195 patients entered into control

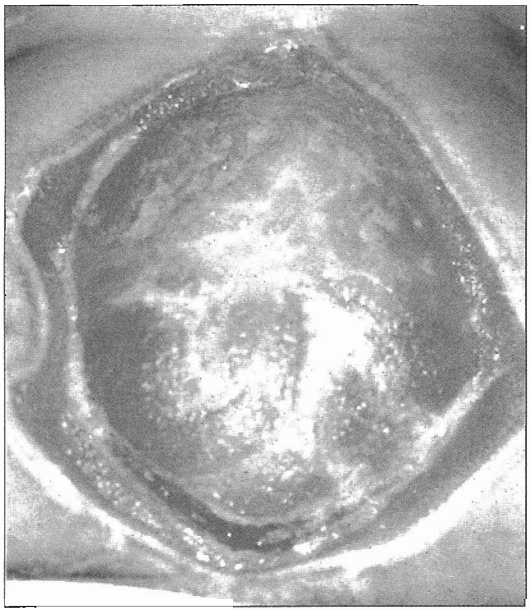

Fig. 6. Open abdomen with granulation tissue covering the bowel. These patients develop difficult-to-treat herniae.

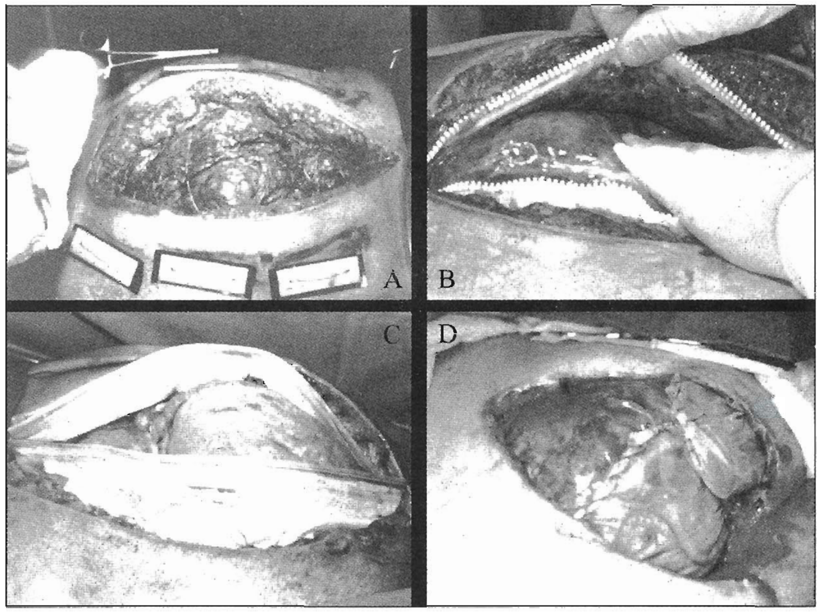

Fig. 7. Temporary abdominal closure methods.
A = Retention sutures B = a simple zipper used for planned relaparotomy without decompression C = an adjustable mesh that has the problem to open spontaneously between abdominal entries. D = Marlex meshes sutured together to cover the abdominal opening (Mesh laparostomy).

groups for comparison. While the mortality of the control group was 39.1 %, the mortality of the open abdomen group was 41.7 %. Schein published a series in which patients undergoing the open laparostomy technique were stratified for risk factors using the Apache II system (35). Comparison of the mortality rates of the various risk factor groups with those that had been managed by standard operative management showed no significant difference. In the lower Apache II-defined risk groups, the outcome was even better following the standard operation than that seen following open laparostomy. A wound infection was virtually present in all published cases; fistulae formed in 16 % of the cases; and 69 % of the surviving patients developed huge abdominal wall hernia.

Mesh laparostomy: The mesh laparostomy is a laparotomy without re-approximation and suture closure of the abdominal fascia, where the facial gap is bridged with a mesh of Marlex, Vicryl, or other material (Fig. 7). *Levy* et al. use mobilized skin flaps to close the abdominal wound (30). When a relaparotomy becomes necessary, the mesh needs to be removed and reinserted. Patients who underwent planned re-exploration with mesh in place are addressed in the STAR laparostomy group. 439 cases of mesh laparostomy have been analyzed in twelve published studies. The combined mortality of all these cases was 39 %. 82 % developed wound infections. Fistulae formed in 22 %. Incisional hernias complicated the outcome in 68 % of the patients. In none of the studies were cases compared to a control group; nor were any of the patients stratified for risk factors.

STAR laparostomy: Sometimes, following both open and mesh laparostomy, subsequent procedures have become necessary and have been performed as a relaparotomy on demand. While the advocates of planned relaparotomy closed the abdomen tight

Tab. 3. When to close the abdomen definitively.

- Abdominal pressure less than 15–20 mmHg when fasciae are approximated
- No persistent bowel leak
- Bowel continuity established
- No further healing problem expected
- Debridement sufficient

without decompression (25, 39) few authors have combined the strategy of scheduled re-exploration with the open abdomen techniques (17, 21, 46). Patients who underwent scheduled re-operations have been included in the STAR laparostomy group because, being proactive, the strategy is different from the former two groups.

STAR laparostomy was thus initially defined more broadly as a series of operations, planned either before or during the first index operation and performed every 24–36 hours with temporary closure of the abdomen using devices such as the artificial burr resulting in a final fascia-to-fascia closure. Controlled tension is exerted to the fascia to a point of avoiding an increase in intra-abdominal pressure with its harm to pulmonary, renal, cardiovascular and hepatic function, and intestinal and abdominal wall perfusion. The abdominal wound is typically closed with a device for temporary abdominal closure such as a simples mesh (18), mesh with zipper (29, 40, 38), a glider (Ethizip™) (46), or the artificial burr (48) (Fig. 1, 2, 3, 7, 9). As the disease improves

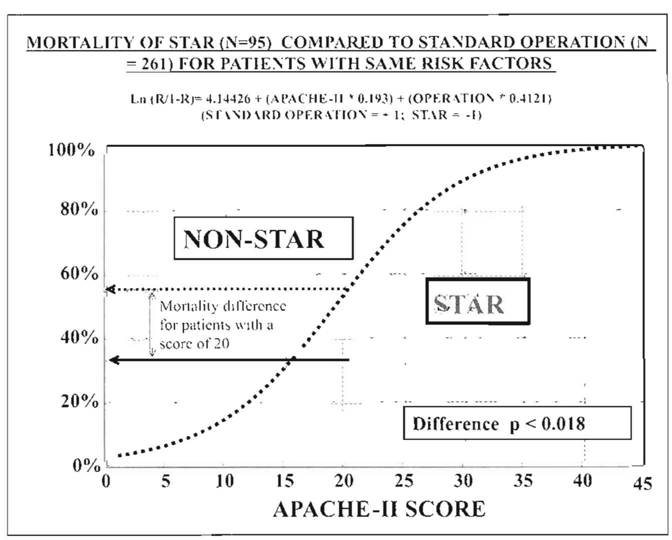

Fig. 8. Comparison of observed and expected mortality using a logistic regression model, STAR patients had a significantly better outcome (p = 0.008) than patients treated by the standard operation (50).

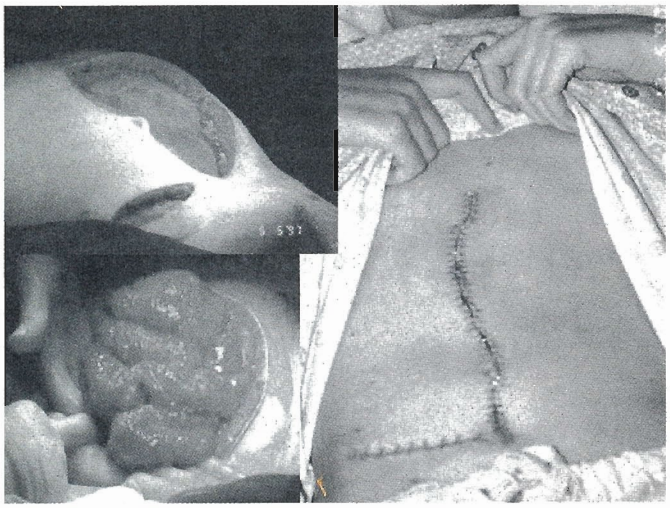

Fig. 9. Formal skin closure in a patient who came with diffuse suppurative peritonitis and multiple abscess and abdominal compartment syndrome following delayed surgery for appendicitis. He required 9 STAR entries until final closure. The wound healed without complications.

during subsequent planned, scheduled re-explorations, and intra-abdominal pressure returns to baseline, the fascia may be re-approximated, and finally the abdomen is closed, typically with a fascia-to-fascia suture. The patient appears at the end as if he had had only one operation (Fig. 9). Drains are not necessary; colostomies can be avoided because anastomotic healing may be observed and final closure is only performed when the surgeon is certain that further complications are unlikely to develop (47, 50) (Tab. 3).

The combined mortality following STAR laparostomy in 385 patients published in eleven studies is 28 %. 95 patients served as a control group and their mortality was 44 %. Fistula formed in 5 % following the last STAR. Incisional hernias complicated the outcome in 7 % of the cases. In one study, patients were stratified according to the Apache system and the mortality seen was 23 % superior to the Apache II score-predicted mortality of 60 % (47).

In summary analysis of the literature on the various open abdomen techniques shows that open laparostomy and mesh laparostomy do not improve mortality and are associated with too many complications. Furthermore STAR laparostomy seems to reduce mortality by one-half over the standard operation and patients who were operated on a 24 hours interval seem to perform better than with a longer than 48 hour interval between scheduled operations.

Our recent study seems to confirm the previous experience with STAR. Unfortunately we were not able to produce a prospective randomized study because initially our IRB (Institutional Ethical Committee) had problems submitting the control group to standard therapy because the anecdotal evidence appeared to them sufficient proof of the superiority of STAR over standard therapy. Later FDA classified the artificial burr as a risk device that required official approval to be used in a study. Therefore we could not perform an official study and had to use the burr on a compassionate basis. After its introduction surgeons and residents were quickly convinced about the benefits of the burr (Tab. 4) and its use became quickly the standard practice at our department. Of particular value was the STAR/BURR concept to the transplant surgeons who claimed dramatic survival improvements in transplant pancreatitis (37).

Our observed mortality can be further improved because the logistics and techniques require experience, which the surgeons did not have when I was recruited to the Medical College of Wisconsin. The logistics of the procedure are very complex and require a dedicated surgeon and a good infrastructure with a resident team that is available round the clock. Timing of the operation in relation to subsequent operations, and effective antibiotic tissue levels at the time of surgery are important, but easily forgotten (2, 52, 54). After 24 hours bacteria have re-grown to their original number and further delays of the abdominal reentry increases the endotoxin load (13). Capturing the protein losses and neutralizing "bad" cytokines (23) is another issue that can only be solved with the use of the Hypobaric Wound Shield applications (Fig. 10) and paying attention to details at the same time. A colostomy in STAR patients is a bad idea because it invariably will contaminate huge areas of exposed tissue. The fact is difficult for the experienced surgeon to accept because the topic has been dogmatized following dramatic improvements seen in second World War. The introduction of STAR changed the rules. Anastomotic healing can by observed at every abdominal entry and repaired if necessary – and it works. The abdomen should only be closed with established bowel continuity and colostomies must be avoided when the rectum is intact.

The burr itself is easy to handle and the fascia should be reapproximated as soon as possible. Gentle tissue handling is

Tab. 4. Benefits by STAR with artificial burr.

A) Optimizes Operative Technique & Options
- Eases closure of the difficult-to-close abdomen
- Simplifies abdominal access for relaparotomies
- Allows quick, easy abdominal entry & reclosure
- Is adjustable to changes in girth & pressure
- Ensures secure closure between abdominal entries
- Permits final fascia-to-fascia closure

B) Improves Organ Function
- Improves fascial perfusion
- Improves perfusion to abdominal organs
- Improves renal function
- Improves liver function
- Improves pulmonary function
- Improves cardiovascular performance

C) Enhances Treatment & Prophylaxis of Infection
- Prevents abdominal wall infection including necrcotizing fasceitis
- Prevents pulmonary infection
- Enhances healing of intra-abdominal infection
- Allows for secure drainage of intra-abdominal abscesses

D) Mitigates Complications
- Controls peritoneal fluid losses for analysis
- Minimizes injury to fascia
- Restores optimal venous flow
- Reverses all adverse effects of abdominal hypertension
- Prevents fascial retraction
- Averts fistula formation
- Reduces hernia formation risk

Tab. 5. Indications for STAR.

STAR is indicated:
- When the abdomen cannot be closed without undue tension
- When the intra-abdominal pathology cannot be removed completely
- When the patient is unstable and too sick for an extended operation to do simple damage control
- When the bowel viability is questionable and warrants a second look
- When an anastomosis is performed where in the past a colostomy would have been done
- When packs are required to control hemorrhage
- When organ perfusion is critical after a lengthy operation resulting in peritoneal edema from exposure (Transplant surgery, extendended bowel resections with reconstructions)
- When huge abdominal wall hernias with bowel fistulas after "leaving the abdomen open" must be closed

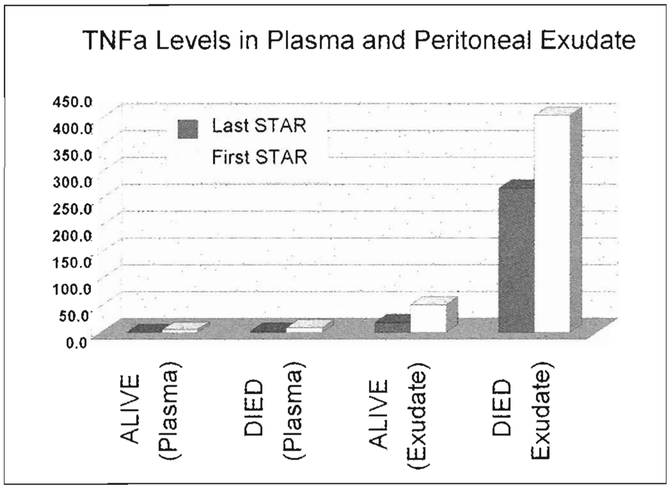

Fig. 10. TNFα (Tumor necrosis factor) concentrations in plasma compared to TNFα concentrations in peritoneal fluid during STAR in patients who survived and who did not survive. The difference exudates concentrations between survivors and non-survivors is significant.

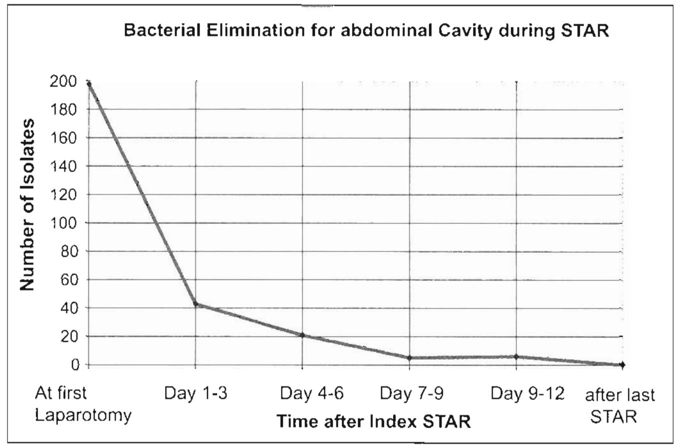

Fig. 11. Bacterial elimination during STAR using 2000 mg intravenous Cefotaxime-sodium every 12 hours and 500 mg metronidazole every 12 hours (2).

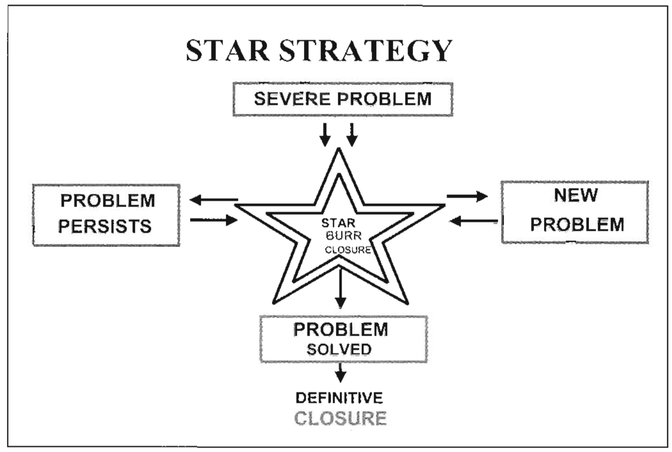

Fig. 12. STAR algorithm (49).

very important to minimize the peritoneal inflammatory response with edema, which may delay final closure. Electrolyte and fluid management should be adjusted to allow for early final closure. Overhydration can be avoided with finely tuned cardiovascular management. We were able to close the abdomen after 2 to 3 entries in most cases (Fig. 5). The longer one waits the more difficult the final closure will be and some experience is required to identify the right moment. At the time of final closure, the surgeon should be convinced that there is no further leak likely and the pathology removed (Tab. 4). As opposed to a fresh abdominal incision with no local defence established, the granulating wound of the STAR incision tolerates some more tension at final fascial closure. One does not want to lose precious time waiting for total disappearance of the edema and wait for the abdomen to be totally relaxed. If good granulation tissue is present even the skin can be closed in most cases, usually when the wound is 5 or more days old.

STAR is indicated (Tab. 5) in septic non-stable patients who do not tolerate long operative manipulations, in the presence of bowel ischemia, and most importantly when increased intra-abdominal pressure precluded tension-free fascial closure. Formation of an anastomosis can be deferred to subsequent abdominal entries when it is safe to suture a well-perfused anastomosis. Further indications for STAR are listed in Tab. 5.

Initially we thought that the indications for STAR should be linked to a severity of disease score, because early results demonstrated a significant difference for patients with Apache II scores of 10 to 25 only (46). Using a logistic regression model however, taught us that scores are not the decisive factors to do a STAR. The logistic model, compared STAR patients to 261 patients who underwent standard operative management adjusting both groups for prognostic factors and using the Apache II system (28, 33, 47, 49, 52). It showed a significant difference between STAR and Non-STAR patients for all risk groups (49). In the range of Apache scores of 10 to 20, however, the most striking 20 to 40% improvements of mortality rates are achieved, and these patients may be the best candidates for STAR (Fig. 8). The benefits of STAR in combination with the artificial burr are listed in Tab. 4.

Although the results are excellent, it must be emphasized that final proof of the superiority of the STAR technique will have to be established by a prospective, randomized, control trial. The foundation for such a trial is laid. One must acknowledge, however, that such a study may be extremely difficult to perform. Previous attempts have failed because of the complexity of the issue and inclusion criteria. Should infected pancreatic necrosis be included? Although it is formally an intra-abdominal infection, its clinical course may vary significantly. A major caveat is the small number of patients available per institution where less than 20 patients are available per year, an insufficient number to plan a single institutional study. On this background the anecdotal evidence presented up to this point may be sufficient to have more patients benefiting from the improved outcome provided by STAR (Fig. 12).

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