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EVALUATION OF THE SURGERY WOUND HEALING PROCESS USING SELF-ADAPTIVE SKIN SUTURE OR MECHANICAL STAPLER

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Wound healing is a complex and time-phased process. The occurrence of numerous negative conditions as well as external factors have a significant influence on the risk of potential complications. Preparing the patient for surgery, attention should be paid to a number of factors determining the proper healing process.

The aim of the study was to compare the results of the early period of surgical wound healing process with access via laparotomy using techniques, which are self-adaptive sutures and mechanical staplers used for skin closure.

Material and methods. The study included 120 patients divided into three groups, according to the degree of wound continence, in accordance with the CDC (Center for Disease Control and Prevention). Exclusion criteria based on objective analysis were applied for patients with a higher risk of complications. In all cases the skin layer was closed with monofilament suture or single-patient use stapler. A ten-day observation of the wound healing process was implemented. The study was randomized.

Results. In the case of patients groups identified as a "Clean Wound " and " Clean / Infected Wound" no significant differences were discovered. In the group "Contaminated/Infected Wound "significantly higher percentage of wound-healing complications were reported ($p < 0.05$) for which monofilament sutures was used.

Conclusions. The study showed, that mechanical stapler is recommended for contaminated/infected surgical wounds due to significantly lower risk of complications. In the case of wounds divided as a "Clean" and "Clean/Infected" type of suturing material has no significant effect on wound healing.

Key words: surgical wound, healing process, sutures, stapler

Wound healing is a complex and time-phased process. Therefore, while preparing the patient for surgery, attention should be paid to a number of factors determining the proper healing process. Factors inhibiting the wound healing process include conditions associated with protein and energy loss: diabetes mellitus, renal insufficiency, malignancies, Crohn's disease, ulcerative colitis, exudative gastroenteropathy, iatrogenic intestinal fistulae, glucocorticosteroid use, extensive surgical wounds and their infections as well as perioperative injury itself. Burdens analysed in numerous reports form a heterogeneous group. Before every surgical procedure, one should identify burdens of marked severity and take action to achieve a possibly optimum compensation of the patient's general condition (1, 2). One undoubted cause of problems in the wound healing process is malnutrition, manifesting as a syndrome of symptoms resulting from deficiency of basic nutrients, such as carbohydrates, fats, proteins, vitamins and trace elements (3). Even though malnutrition is present in 35–55% of patients admitted to hospitals, this condition is rarely diagnosed and even less frequently treated. Another important element in the process of preparing the patient for a surgical procedure is ensuring a proper state of the skin around the surgical field (4).

In the recent years, there has been a considerable shift in approach to preparing the gastrointestinal tract in colon surgery (5, 6, 7). It is believed that both adults and children should be encouraged to oral intake of clear fluids up to 2 hours before the procedure, while food should be withheld only 6 hours before the surgery (8). Undoubtedly, the hygiene of the operated patient's environment and healing of the surgical site is affected by intraoperative factors, such as the hygiene of the operating room and adherence to the rules of aseptic and antiseptic surgery by the surgical team members. Immediately before the surgery, in order to reduce the number of microorganisms colonising the patient's skin, it is critical that the surgical field be cleaned and disinfected, with a disinfection time of approx. 3 minutes. In line with the applicable EU directives, surgical drapes and gowns must be made of barrier materials (9, 10). In order to ensure the highest possible level of skin cleanliness in the surgical field, the cleaned and disinfected skin it is then taped with sterile, iodised surgical foil. It is recommended that the procedures be performed only in air-conditioned rooms with a laminar flow and high level of microbiological purity of the air (11).

An important risk factor for surgical site infection, affecting the outcome of surgical wound treatment, is the "microbiological status" of the surgical field before the intervention. According to the CDC (Centers for Disease Control and Prevention), surgical wounds are classified into four categories: clean wounds, which usually do not become infected; clean/infected wounds (with the percentage of infections ranging from 5 to 15%); and infected and contaminated wounds (50%-risk of infection) (12-15). Such a classification facilitates identification of patients at risk and makes it possible to introduce appropriate prevention of infections. Routine antibiotic prophylaxis markedly reduces the incidence of surgical site infections (16). The most important aspect of its use is the choice of an optimum antibiotic and maximum reduction of its time of action. These recommendations were prepared based on prospective clinical trials, whose results indicate a decrease in the number of surgical wound infectious complications (16, 17). An equally important element affecting the wound healing process is the use of anticoagulant prevention (18). It is also believed that another factor significantly affecting uncomplicated course of wound treatment is the method of closure of the surgical incision. However, there is no objective wound suturing regimen. This state of affairs makes it desirable to establish a uniform and optimum method for closure of the individual layers of the wound (19-22).

The aim of the study was to compare the surgical wound healing process in laparotomy incisions in consecutive patients, whose wounds were treated with self-adaptive sutures or a stapler. The comparison of the early period of the surgical wound healing process was aimed at determining which of the skin closure techniques used is better for the patient in terms of a lower risk of healing process complications.

MATERIAL AND METHODS

The study included 120 consecutive patients undergoing elective and emergency surgeries in the Department of General, Gastroenterological and Oncological Surgery of the Provincial Hospital Complex in Toruń, Collegium Medicum in Bydgoszcz, Nicolaus Copernicus University in Toruń, from September 2009 to December 2011. The study was approved by the Ethics Committee of the L. Rydgier Collegium Medicum, Nicolaus Copernicus University in Toruń (approval No BK/341/2009). Exclusion criteria: diabetic patients and patients hospitalised at the ICU for more than one day following the surgery as well those with a colostomy created in the proximity of the surgical wound. Patients were qualified into three groups, based on the degree of surgical wound cleanliness according to the CDC. The study was randomised. A ten-day observation of the wound healing process was implemented, based on a case report form for monitoring of the patient in the early postoperative period, created by the authors (fig. 1).

Every operated patient was adequately prepared in line with the hospital's procedure. Based on the current NRS (Nutritional Risk Screening) score, nutritional status analysis was performed, accompanied by essential laboratory tests: blood group, blood count with lymphocyte count, bleeding and clotting times as well as electrolyte, urea, creatinine, transaminase, bilirubin and protein levels. If

The patient's observation card in the early postoperative period

1. The patent's initials, the number of the medical history:
2. Age:
3. BMI:
4. Medical diagnosis:
5. Comorbidities:
6. Type of the surgical incision:
7. Suturing of the tissue:
   - peritoneum (braided suture) ☐, size ☐ ; fascia (braided suture) ☐,size ☐
   - peritoneum (braided suture) ☐, size ☐ ; fascia (absorbable monofilament suture ☐) ☐,size
   - peritoneum (braided suture) ☐, size ☐ ; fascia (non - absorbable monofilament suture ☐),size ☐
   - peritoneum and fascia (PDS LOOP) ☐, size
   - skin suture ETHILON: YES ☐, NO ☐, size ☐, quantity of sutures used ☐
   - skin suture MONOSOF : YES ☐, NO ☐, size ☐, quantity of sutures used ☐
   - skin stapler : YES ☐, NO ☐, quantity of cartridges used
   - Redon drain: YES ☐, NO ☐
8. Time of the skin suturing in minutes:
   - skin suture (ETHILON, MONOSOF) ☐
   - skin stapler ☐
9. Intraoperative antibiotic prevention: YES ☐, NO ☐
10. Medicines used:

11. Wound aspects:

II Day	III Day	IV Day	V Day	VI Day	VII Day	VIII Day	IX Day	X Day

Fig. 1. The patient's observation card in the early postoperative period, self authorship

deficiencies were observed, every patient underwent appropriate compensative treatment. In the procedure of preoperative preparation of the patient to the surgical procedure, the mandatory steps of a bath with soap and chlorhexidine, shaving of the surgical field and dressing of the patient in a surgical gown were always observed. After the patient was placed on the operating table, a sample of skin material was taken from the area of the planned surgical incision for a general microbiological test to exclude colonisation of the patient's skin with an alert micro-organism. Upon completion of the surgical procedure, the wound, irrespective of the incision type, was always closed using a layered closure technique, with a size 0 monofilament, dyed, continuous, absorbable 150-cm loop PDS II suture (polydioxanone) on a reinforced round needle used for the peritoneal layer. The same material was used to suture the fascial layer. Following the closure of the peritoneum and fascia, the sutured tissues were rinsed with the antiseptic Octenisept (Octenidinum Dihydrochloridum + Phenoxyethanolum). After the wound was dried, absorbable, dyed, multifilament, braided Polysorb 2/0 subcutaneous sutures were placed, composed of glycolide copolymer on a round needle. The skin layer, depending on the randomisation result, was treated using a monofilament, non-absorbable, blue-dyed suture Ethilon* Blue 2/0 manufactured by Ethicon, 75 cm long and with a sharp needle, or with a single-use skin stapler. The stapler, loaded with 35 metal staples produced by Sartorius Stedim Plastics GmbH, was used only after obtaining a negative nickel allergy history. Following the closure of the surgical wound, the abdominal wall was thoroughly cleaned with Octenisept, followed by disinfecting the incision with Kodan and covering the surgical access site with a hypoallergenic 3M™ Medipore™ + Pad dressing.

The assumed criteria of surgical wound healing process

The early healing process of the surgical wound was assessed in the patients since the second day following the surgery, up to the 10th day of hospital stay. Persons discharged from the hospital before 10 days were observed at follow-up visits at the hospital's surgical outpatient clinic. The course of the healing process was assessed based on the assumed criteria:

1. Normal healing. Lack of any complications. Healing per primam intentionem.
2. Non-infectious postoperative complications. We identified wounds in which the following abnormalities were seen during the observation: a) postoperative bleeding; b) tenderness; c) pain; d) scar complications (presence of skin necrosis, hypertrophic scar, deformation of the scar area – depression or elevation); e) wound dehiscence – spontaneous or opening of the wound to evacuate accumulated secretion.
3. Surgical site infections (SSIs) according to the CDC NNISS (Centers for Disease Control National Nosocomial Infections Surveillance System). Such infections develop within 30 days of a surgical procedure unless implants were used, or within a year, if an implant was placed during the surgery and is still left in place. The SSIs were divided into superficial, deep and systemic infections (23, 24). Since the first day following the procedure, the surgical wound appearance was controlled, combined with monitoring of general laboratory tests. In justified cases, nutritional treatment was initiated. Anticoagulant and antibiotic prophylaxis was routinely used. If needed, empirical and then targeted antibiotic therapy was started.

Statistical calculations

The analysis of the obtained data involved the use of the Statystyka software from StatSoft as well as the Microsoft Excel spreadsheet. Parametric and nonparametric significance tests were used to verify formulated hypotheses:

1. A parametric test for two structure indexes, also called the two-fraction test. This test was used to verify a hypothesis that the rates (percentages) of selected cases in the compared groups are not significantly different.

2. The nonparametric Shapiro-Wilk test was used to verify hypotheses of normality of distribution of the studied characteristics. In cases where the calculated values of the W statistic were higher than the critical value, W_{cr}, as taken from a relevant distribution table at a significance level of $p = 0.05$, it was necessary to determine whether the distributions of the studied characteristics deviated significantly from the normal range.

3. The Snedecor's F test to verify a hypothesis of variance homogeneity in the two compared groups.

4. Parametric tests to compare mean values. If normality of distributions and variance homogeneity was determined in the compared groups, a verification of the hypothesis of mean equality was performed using the Student's t-test. If this conditions were not met (variations turned out to be different), a modified Cochran-Cox test was used.

5. The Z-test based on the normal distribution to compare mean values in two samples of sufficiently high (> 50) sizes.

6. The nonparametric Mann-Whitney test to verify the null hypothesis that two samples come from the same population (comparison of distribution functions for distributions of the studied characteristics in the two groups). A significance level of $p = 0.05$ was assumed as a reliable one in verification of the hypotheses made, and this was the level for which critical values were provided The p-values were also given, describing the probability of making an error through rejecting the tested hypothesis and deciding that differences in the compared populations are significant. At $p < 0.05$, the difference was considered statistically significant. Otherwise, it was considered *ns* (not significant).

The 120 patients were divided into three groups of different wound cleanliness levels. Qualification to a given 40-person patient group was made by the operator. The "Clean Wound" group comprised 34 (85%) patients operated via a median incision. Half of them were treated with a stapler and the remaining ones with nylon – a surgical suture called Ethilon* Blue. The type and number of procedures performed are presented in tab. 1.

The second group also comprised 40 patients, who had a "Clean/Infected Wound". Half of the people were treated with a stapler and the other half with self-adaptive skin sutures; 50.0% of the subjects were operated via the median approach and 50% using a transverse incision. The type and number of procedures are presented in tab. 2.

The "Infected/Contaminated Wound" group comprised 40 subjects. In line with the assumed methodology, half of the subjects in this group were treated with a stapler and the other half

Table 1. Type and number of surgical procedures performed in the "Clean" group

Type of surgery	Arterial bypass creation	Surgical repair of paraesophageal hernia	Plastic surgery of extensive abdominal hernia j	Laparotomy: non-resectable pancreatic tumour	Resection of mesentery tumour	Resection of retroperitoneal tumour through laparotomy
n	34	1	2	1	1	1
%	85%	2,5%	5%	2,5%	2,5%	2,5%

Table 2. Type and number of individual surgical procedures performed in the "Clean/Infected Wound" group

Type of surgery	Gastrec-tomy	Colon resection	Gastroenterosto-my and choledo-choduodenostomy	Pancre-atic resection	Nutritional jejunosto-my	Internal drainage of pancreatic cyst	Restoration of gastro- intesti-nal continuity	Cholecy-stectomy
n	17	7	6	3	2	2	2	1
%	42,5%	17,5%	15%	7,5%	5%	5%	5%	2,5%

with a surgical suture; 3 (7.5%) patients were operated through the right Kocher subcostal incision, while 37 (92.5%) via the median approach. The number and distribution of procedures performed are presented in tab. 3.

Each group was further divided into two equal subgroups with different suture types used to treat the skin incision of the surgical wounds (a stapler or monofilament, non-absorbable surgical suture Ethilon* Blue – polyamide 6). In the first and second groups, complete records were obtained regarding observation of the early postoperative period in the operated patients. Two cases of death in the "Infected/Contaminated Wound" population were excluded from the analyses of hospital stay length and postoperative scar appearance. In the 120-person study population, the surgery was performed in 47 (39.2%) women and 73 (60.8%). The mean age of the study population is 60.7 ± 12.6 years.

Using the Student's *t*-test, it was determined that mean age and BMI values do not differ significantly in the "Clean Wound", "Clean/Infected Wound", "Infected/Contaminated Wound" groups or in the subgroups of subjects treated with a stapler or monofilament, non-absorbable surgical sutures. Ruling out of this statistically significant difference in the study population confirmed the possibility of performing further comparative analysis (tab. 4).

RESULTS

A comparison of the incidence of complications in the subgroups of patients treated with

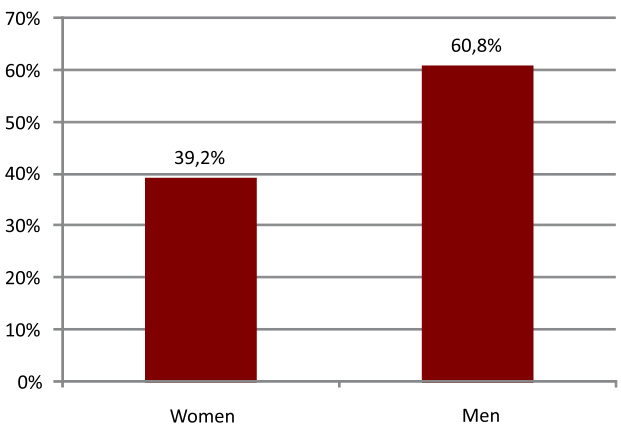

Fig. 2. Percentage distribution of sexes in the studied surgical patient population

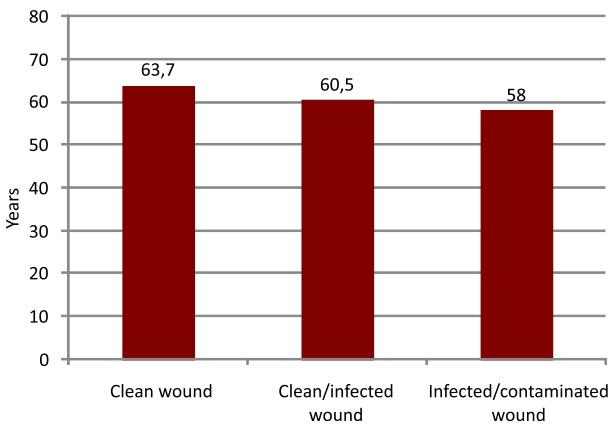

Fig. 3. Mean age in the groups: "Clean", "Clean/Infected", "Infected/Contaminated"

Table 3. Type and number of individual surgical procedures performed in the "Infected/Contaminated Wound" group

Type of surgery	Replacement of infected vascular prosthesis	Perforation of gastrodu-odenal ulcer	Perforation of small intestine	Perforation of large intestine	Liver abscess	Diffuse appendici-tis	Acute necrotising pancreatitis	Interloop abscesses
n	3	12	7	8	4	3	2	1
%	7,5%	30%	17,5%	20%	10%	7,5%	5%	2,5%

Table 4. Mean age and BMI values in the studied "Stapler" and "Suture" subgroups of the groups: "Clean", "Clean/Infected" and "Infected/Contaminated"

		Clean wound		Clean/infected wound		Infected/contaminated wound	
		stapler (20)	suture (20)	stapler (20)	suture (20)	stapler (20)	suture (20)
Age		64,4±7,2	63,0±11,2	63,4±9,8	57,6±14,0	58,3±12,7	57,8±17,9
Student's t-test (t_{kr}=2,02)	t	0,46		1,48		0,10	
	p	0,65 (ns)		0,15 (ns)		0,92 (ns)	
BMI		26,3±2,5	25,1±3,7	24,6±5,1	22,6±3,8	24,2±4,4	24,4±3,3
Student's t-test (t_{kr}=2,02)	t	1,17		1,37		0,16	
	p	0,25 (ns)		0,18 (ns)		0,87 (ns)	

a "stapler" or "surgical suture" in the groups of different surgical wound cleanliness level. In the case of clean wounds, in the "stapler" (5%) and "suture" (5%) groups, the incidence and type of complications (subcutaneous haematoma) are identical. After evacuation of the haematomas, a normal further course of treatment was observed. In the "Clean/Infected Wound" patient group, stronger tendencies to an abnormal course of treatment were observed. In 3 patients in each of the 20-person subgroups, "stapler" and "suture", non-infectious complications were observed – subcutaneous haematomas, which became infected in spite of evacuation, delaying further healing. Among the persons in the "Infected/Contaminated Wound" group, the complication rate is much higher if the skin is treated with a monofilament surgical suture rather than with a stapler. In this population, as many as 11 out of 20 (55%) subjects had complications during the healing process. In the "stapler" patient subgroup, 5 of 20 (25%) cases of complications were observed. All problems in the wound treatment were eventually diagnosed as surgical site infection. During regular follow-ups, serosanguineous or purulent effusion was observed in the subcutaneous tissue. This statistically significant difference in the healing process ($p < 0.05$) was observed when using a two-fraction test and it was demonstrated that the Ethilon* Blue monofilament suture, in spite of its effective haemostatic action, increases the risk of complications during the healing process of infected/contaminated wounds due to the much greater tightness of its application. The table below presents the numbers and percentages of

Table 5. Percentage and numerical distributions of complications in the "Stapler" and "Suture" subgroups of the groups: "Clean", "Clean/Infected" and "Infected/Contaminated"

		Clean wound		Clean/infected wound		Infected/contaminated wound	
		Stapler	Suture	Stapler	Suture	Stapler	Suture
Number		20	20	20	20	20	20
Number of complications		1	1	3	3	5	11
% of complications		5%	5%	15%	15%	25%	55%
Two-fraction test	u	0		0		1,97	
	p	1 (ns)		1 (ns)		<0,05	

complications in the "stapler" and "suture" groups for the three levels of wound cleanliness as well as comparative results of the incidence of complications in the compared groups (tab. 5).

DISCUSSION

The study attempted to compare and assess the early stage of the healing process of surgical wounds treated with a monofilament skin suture or a stapler for 10 days following the procedure. The literature indicates that during this period the inflammatory and proliferative phases of the tissue repair process come to an end and the incised wound maintains continuity. This state makes it possible to remove the sutures and make an early assessment of the wound appearance (25, 26). The obtained results confirmed that in surgical wounds in an infected/contaminated field the staple suture used results in a significantly lower level of complications in the wound healing process.

CONCLUSIONS

In summary of the acquired data it needs to be assumed that the use of a stapler, although showing lower haemostatic properties, is preferential in the case of contaminated/infected surgical wounds due to a significantly lower risk of complications. In clean and clean/infected wounds, the type of suture used is not important.

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