

THE STOMA-CONST TRIAL: *A STOMA CONSTRUCTION STUDY*

**CIRCULAR INCISION VS CRUCIATE INCISION VS
PROPHYLACTIC MESH REINFORCEMENT IN THE ABDOMINAL
WALL FASCIA FOR COLOSTOMY CONSTRUCTION.
A RANDOMISED TRIAL**

A TRIAL WITHIN THE SCANDINAVIAN SURGICAL NETWORK FOR
CLINICAL TRIALS

Project plan

CONTENTS

1.1 Protocol committee	3
1.2 Steering committee	3
1.3 Writing committee	3
1.4 Coordinating centre	3
1.4.1 <i>Principal investigator</i>	3
1.4.2 <i>Deputy Principal Investigator</i>	3
1.4.3 <i>Pb.D.-student</i>	4
1.5 Protocol summary	4
2. Protocol	4
2.1 Background	4
2.2 Study design	5
2.3 The hypothesis	6
2.4 endpoints	6
2.4.1. <i>Primary end-point</i>	6
2.4.2. <i>Secondary end-points:</i>	6
2.5 Ethics	6
2.6 Eligibility	7
2.6.1 <i>Inclusion criteria</i>	7
2.6.2 <i>Exclusion criteria</i>	7
2.6.3 <i>External validity</i>	7
2.7 Randomization	7
2.8 Pre and per-operative care & examinations	7
2.9 Surgical procedure	8
2.10 Histopathology	9
2.11 Post-operative treatment	10
2.12 Follow-up	10
2.13 Health related Quality of Life	10
2.14 Recurrent disease	10
2.15 Data collection	11
2.16 Study organization	11
2.17 Safety committee	11
2.18 Work plan	11
2.19 Statistical Methods	12
3.0 Financing	12
4.0 Bibliography	13

1.0 STUDY ORGANISATION

1.1 PROTOCOL COMMITTEE

Eva Haglind, MD, PhD, professor, Department of Surgery, Sahlgrenska University Hospital/Östra and Sahlgrenska Academy.

Eva Angenete, MD, PhD, Department of Surgery, Sahlgrenska University Hospital/Östra and Sahlgrenska Academy.

Ulf Angerås, MD, PhD, associate professor, Department of Surgery, Sahlgrenska University Hospital/Östra and Sahlgrenska Academy.

Adiela Correa Marinez, M.D., Department of Surgery, Sahlgrenska University Hospital/Östra.

Martin Gellerstedt, PhD, statistician, SSORG

Jacob Rosenberg, M.D., Professor of Surgery, Herlev University Hospital.

Frederik Helgstrand, MD., Dept. of surgical gastroenterology, Rigshospitalet

The Scandinavian Surgical Outcomes Research Group

1.2 STEERING COMMITTEE

Protocol committee plus the local investigator for each participating center.

1.3 WRITING COMMITTEE

In agreement with internationally accepted guidelines (“the Vancouver criteria”) for authorship the members in the planning group who are active in planning, running, analysis and writing will be part of the writing committee. Doctoral/post.doc students actively working with the trial will also be included in the writing committee.

Publication of results is planned to be in international ”peer review” scientific journal.

1.4 COORDINATING CENTRE

SSORG/Göteborg, Department of Surgery, Sahlgrenska Academy at University of Gothenburg, Sahlgrenska University Hospital/Östra

1.4.1 Principal investigator

Eva Angenete, M.D., Ph.D., Department of Surgery, Sahlgrenska Academy at University of Gothenburg, Sahlgrenska University Hospital/Östra

1.4.2 Deputy Principal Investigator

Jacob Rosenberg, M.D., Professor of Surgery, Herlev University Hospital

Frederik Helgestrand, M.D., Dept. of surgical gastroenterology, Rigshospitalet

Ulf Angerås, M.D., Ass. Professor of Surgery, Department of Surgery, Sahlgrenska University Hospital/Östra and Sahlgrenska Academy.

1.4.3 Ph.D.-student

Adiela Adriana Correa-Marinez M.D.

1.5 PROTOCOL SUMMARY

All patients planned for elective colostomy formation. Patients undergoing rectal resection with a TME and a colostomy (Hartmann's procedure) for rectal cancer, abdominoperineal resection for rectal cancer or diverting colostomy for any reason are all included.

The three groups for randomization are:

- A. circular incision in the abdominal wall fascia
- B. cruciate incision in the abdominal wall fascia
- C. Mesh reinforcement in the abdominal wall fascia with cruciate incision according to Sublay Technique.

Primary endpoint is the parastomal hernia rate within 12 months from index surgery. Secondary end-points include clinical variables, re-admission and/or re-operation due to any stoma complication, quality of life and health economy analyses, at 12 months.

2.0 PROTOCOL

2.1 BACKGROUND

Colostomy formation has been a standard surgical procedure for more than 100 years. Initially the quality of life for stoma patients was all but good, as the appliances to collect the feces were cumbersome, smelly and did not ensure non-leakage. As late as in the 60-ies bandages were still primitive(1). Gradually these problems have decreased as techniques for bandages have improved. A well functioning colostomy may in itself not negatively affect the patient's Quality of Life (QoL)(2), although thorough information and support from stoma care nurses is of utmost importance (3). However, this can only be said if the stoma is well functioning and if the complications are kept to a minimum. The complication rate after stoma formation is still considerable, with figures of 21-70% (4, 5) and studies have shown that adequate height; type of stoma, BMI, emergency surgery and gender may be of importance in reducing the risk of complications both in the short and long-term (6-8).

The surgical technique of stoma formation is only partly evidence based. There are few studies directed at technical details about stoma construction and their future impact on stoma function, apart from the importance of the stoma height (6). One study has tested to standardize the skin incision to 2/3rds of the width of the bowel (9), although the actual impact of this on the functional outcome of the stoma was not presented.. In the surgical literature a cruciate incision in the fascia and extraction of the bowel through a hole sufficient in size is a short description of the surgical technique (10). In clinical practice sufficient size of the hole has often been equal to "two fingers-width", is commonly used, which refers to the width of the surgeon's fingers, a fairly inexact measurement. A pilot study from Sahlgrenska University Hospital has found that this

clinical practice for the most part results in a fascia incision diameter of 50% of the bowel width.

There have been discussions regarding the placement of the stoma and effects on hernia incidence, whether in the obliquous muscle or the rectus abdominis (11) or if the bowel should take an extraperitoneal route (ad modum Goligher) or not (12). No studies have been sufficient in design or size to thoroughly answer the question.

Parastomal hernia is a long-term complication that is common, in the literature figures up to almost 50% have been reported (13, 14). Attempts to reduce the rates of parastomal hernias have been made in the last few years with a placement of a mesh, at the construction of the stoma, (15-20). This practice has not been universally accepted, in part due to a hesitance in the surgical society because of the risk of infections with foreign body material, and partly due to that most studies are underpowered for their main outcome variable (21). Another suggestion for the basic construction of the stoma has been to make a circular incision in the fascia instead of a cruciate, but this has not been documented in any studies. It has been described in conjunction with use of circular stapling devices, no hernias were found, however the patient numbers were small (22, 23). It is apparent that further studies are most welcome (19, 24-26).

The evaluation of parastomal hernias has been discussed. Janes et al. used clinical examination in their studies (16, 17), and confirmed in a later study that the concurrence with a CT-verified parastomal hernia was (27) sufficient if performed in a prone position. Another recent study found that results from a CT-scan was not correlated with patient symptoms (28). Other studies have evaluated the use of ultrasound and found it feasible (29). The conclusion must be that evaluation of parastomal hernias may be difficult and must be standardized in a study.

The hypothesis to be tested in this study is that it is possible to obtain a lower parastomal hernia incidence with a circular incision in the abdominal fascia or reinforcement of a mesh instead of a cruciate incision in the abdominal fascia.

The aim of this trial is to compare the parastomal hernia formation within 12 months after stoma surgery between circular incision, cruciate incision and reinforcement with a mesh.

2.2 *STUDY DESIGN*

The design is:

- randomized
- international
- multi-center

The study will compare circular, cruciate incision and cruciate incision with reinforcement with prophylactic mesh in sublay position at the fascia during stoma formation surgery. The design involves all consecutive patients with an elective/planned operation including a colostomy construction. Patients will be recruited from the hospitals represented in the SSORG network, any surgical department with interest in

the treatment of stoma surgery is welcome to join the trial.
The trial will be stratified according to hospital.

2.3 *THE HYPOTHESIS*

It is possible to obtain a lower parastomal hernia incidence with a circular incision in the abdominal fascia or reinforcement of a mesh instead of a cruciate incision in the abdominal fascia.

2.4 *ENDPOINTS*

2.4.1. **Primary end-point**

- Parastomal hernia 12 months postoperatively, for all patients in each group
- Sub-group analysis planned for patients with BMI>30 and for patients with immunosuppression

2.4.2. **Secondary end-points:**

- Re-admission
- Postoperative infections, wound or deep infection (abscess formation)
- Postoperative thrombosis
- Stoma related complications
- Other complications
- Bowel obstruction, requiring hospitalisation or operation
- Total length of hospital stay during 12 months
- Quality of life
- Health economy analysis
- Re-operation 30 days
- Mortality within 30 days of primary operation
- Mortality within 12 months
- Re-admissions and re-operations registered in including hospital database at 24 months.

2.5 *ETHICS*

The trial must be approved by the appropriate ethics committee for each participating institution prior to entry into the study. In Sweden the coordinating centre (Sahlgrenska University Hospital) will apply for all Swedish participating centres.

In Denmark professor Jacob Rosenberg will apply for all Danish participating centres.

Eligible patients will be informed personally by a surgeon or a research-nurse and given written information about the trial. Informed consent should be obtained from each patient according to the guidelines of the ethical committee, prior to randomization into the study. Patients remain free to withdraw their consent to participate in the study at will and at any time without giving their reasons.

2.6 ELIGIBILITY

2.6.1 Inclusion criteria

Patients are eligible if the following conditions are met:

- presenting with a cancer or another condition for which an elective surgical procedure is planned that includes formation of a colostomy
- possible to operate in regard to concomitant disease
- giving informed consent to participate

2.6.2 Exclusion criteria

- Participation in other randomized trials in conflict with the protocol and endpoints of the Stoma-Const trial.

2.6.3 External validity

All patients with cancer or other conditions for which an elective surgical procedure is planned and includes a colostomy formation, and who not included and randomised, will be registered in the “screening log” at each participating centre. Thus patients who do not meet the inclusion criteria, as well as patients excluded after randomization, will be registered concerning date, hospital patient identification number, gender, age, ASA class, type of operations. The reason for non-inclusion or exclusion should always be noted.

2.7 RANDOMIZATION

Once eligibility has been established and patient details have been logged, the patient will be randomised to either circular incision or cruciate incision or prophylactic mesh of the fascia during surgery. Randomization will be performed by blocks of closed envelope systems in each participating hospital. Randomization will be balanced and stratified by hospital. Laparoscopic as well as open procedures will be included and although not stratified by open or laparoscopic procedures it will be noted in the protocol.

Including hospitals may choose to randomise between all three techniques or two of them. This decision is made before the hospital enters the study. The blocks will be according to this, and the total number of 80 patients in each group will be managed through this block system.

When patients are not subjected to the treatment modality as randomized, data will be analyzed on an “intention to treat basis” (once randomized, patients will not be excluded or change groups because of conversion or type of surgery).

Patients who do not consent to participation or are excluded should be treated by cross incision surgery as the usual routine.

2.8 PRE AND PER-OPERATIVE CARE & EXAMINATIONS

The following will be registered:

- Diagnosis
- Haemoglobin

- Leucocytes
- CRP
- ASA classification
- S-albumin
- BMI
- Nutritional status (by questions)
- Pre-operative marking of the stoma site

The preoperative and perioperative treatment must follow local guidelines and must be applied equally in all groups, without any systematic differences, apart from those that are with regard to randomisation (circular or cruciate incision with/without mesh).

All patients should be given pre-operative prophylactic antibiotics before the start of the operation, the same regimen regardless of randomization, and according to the routine in each participating hospital. Patients included in this trial cannot be included in other randomised trials in conflict with the protocol and end-points of the Stoma-Const trial.

2.9 SURGICAL PROCEDURE

1. The main surgical procedure
 - a. If a resection planned (TME, APE etc.) it is performed according to established methods.
 - b. At the time of the stoma formation, randomization to one of the three (or in applicable cases two) procedures is made.
2. The initial part of the stoma formation related to laparoscopic and open procedures:
 - a. Laparoscopy: The laparoscopy is initiated and the necessary number of work ports are used. No trocar may be placed in the planned incision of the stoma or the stoma appliance. If necessary a 5 mm trocar may be placed in the site of the stoma, but the trocar must be placed perpendicular to skin and muscle and not interfere with the rest of the protocol. The steps of the procedure to identify, dissect and divide the left colon are made laparoscopically. The proximal end of the divided colon is caught by an instrument. At this point the surgery is continued from the outside (see below) and at this time-point the randomisation is performed.
 - b. Open procedure: A midline incision is used, to access the abdominal cavity. The steps of the procedure to identify, dissect and divide the left colon are made. At this point the surgery is continued from the outside (see below) and at this time-point the randomisation is performed.
3. Details of the stoma formation:
 - a. The centre point of the pre-operatively marked place for the stoma is lifted and a circular skin incision is performed.
 - b. Blunt or “semi-blunt” dissection through the subcutaneous tissue, using a step-wise downwards movement with retractors assisted by sharp dissection as needed. Meticulous control of bleeding. When the ventral fascia of the rectus abdominis has been reached, dissection is stopped.

- c. Measure the subcutaneous fat and add approximately 2-3 cm to the acquired measurement to identify the part of the colon that will be in the level of the fascia. Then measure the width of the left colon together with the mesocolon, (ascertain that the colon is properly evacuated in the measured area), to calculate the fascia incision - **circular incision** in the fascia with a diameter equal 50% of the width of the patient's left colon or a **cruciate incision** where the arms measure 1/2 of the width of the patients left colon and respective mesocolon.
- d. The muscular fibres are separated bluntly (until now the same procedure is done to mesh group).
4. Stoma formation without a mesh - How the mesh is placed is described below at number 5.
 - a. The dorsal fascia opened in exactly the same way as the ventral one.
 - b. The proximal colon end is taken through the stoma incision, any plica epiploicae may be removed, if they are substantial and in the way of the fastening of the colon in the stomal incision.
 - c. Ascertain adequate circulation to the colon involved in the stoma. **If the width of the incision is not sufficient for adequate circulation a widening may be performed and noted in the CRF.**
 - d. The mucocutaneous suturing is made using 4-0 absorbable interrupted sutures 3-point sutures (mucosa-muscular layer and skin) starting with one in each quadrant and adding sutures in between those as needed.
 - e. The midline incision (open) and port-site incisions (laparoscopic) are closed by the method used in each hospital, independent of which group the patient was randomised to.
 - f. The length of the stoma after it is created should be at least 1 cm.
 - g. The diameter of the stoma will be measured immediately post-operatively.
5. Stoma formation with a mesh. The incision in the fascia is performed with a **cruciate incision** and the mesh will be inserted using sublay technique. A fine-thread, large-pore lightweight monofilament mesh such as "Ultrapro" (Ethicon, Johnson&Johnson) measuring 10x10 cm.
 - a. The mesh is placed dorsal to the rectus abdominis muscle and anterior to the posterior rectus sheath by dissection through either midline in open surgery or blunt dissection under rectus abdominis muscle in laparoscopic surgery. **A cruciate incision** is made in the anterior sheath of the fascia and in the mesh.
 - b. The bowel is brought out through a cross-cut in the center of the mesh where the arms measure 1/2 of the width of the patients left colon and respective mesocolon. **If the width of the incision is not sufficient a widening may be performed and noted in the CRF.**
 - c. An absorbable stitch fix the lateral corners of the mesh to the posterior rectus sheath. The medial corners of the mesh are grasped with a stitch of the running suture closing the midline incision.

2.10 HISTOPATHOLOGY

All resected specimens should undergo standard histological examination depending on the type of underlying disease.

2.11 POST-OPERATIVE TREATMENT

Postoperative treatment should follow local guidelines and must be applied equally in all three (in applicable cases, two) groups, without systematic differences. Any treatment with antibiotics post-operatively should be noted in the CRF, including reasons and total treatment time. This applies to both systemic as well as oral antibiotics. Any post-operative information regarding stoma and stoma function will be given according to local guidelines.

2.12 FOLLOW-UP

The follow up should include:

- Time for full oral feeding resumed
- Time for stoma function, days to first gas and stool
- clinical control,
- re-admittance/s, re-operation/s, date, type of procedure will be registered in 12 month follow-up CRF.
- Radiologic follow up as needed, date and type should be noted.

Patients will be clinically examined at 6 months, at 12 (11-13) months postoperative and as needed (suspected parastomal herniation), by a surgeon (not one of the colorectal team) preferably specialised in hernia surgery, to diagnose parastomal hernia. At 12 months all patients undergo a CT examination of the abdomen (wall) in prone position, which can be part of a routine 12 months follow-up by CT abdomen for colorectal cancer patients. A study specific standardized background and question is used on the referral to CR abdomen, and type of incision should not be included in this.

Stoma variables measured by nurse specialised in stoma care during hospitalisation and at 4-6 weeks, 6 months and 12 months will be registered in a CRF. Height, diameter, colour, skin irritation and bandaging problems will be documented.

Patient reported Quality of Life (QoL) by questionnaires pre-operatively and 6 months and at 12 months after discharge from hospital.

All operations for stoma revision are noted during 5 years, and reasons for revisions are noted.

2.13 HEALTH RELATED QUALITY OF LIFE

Face validated questionnaires regarding bowel symptoms, bowel related episodes requiring re-admittance and re-operation, socio-economic status, stoma care and ADL will be included in the QoL questionnaire.

2.14 RECURRENT DISEASE

Reported in the follow-up CRFs.

2.15 DATA COLLECTION

An operative CRF including reasons for operation, planned operation and patient data; it should be filled in for the operation (by the surgeon), for the hospitalisation period (nurse) and for each follow-up visit (surgeon and nurse).

The postoperative questionnaires will be given to the patients by the stoma therapist. All data will be kept within the University of Gothenburg and the Sahlgrenska University Hospital IT systems using inherent security systems. A logistic database with complete patient ID will be used, kept within a separate IT system from the result database with all study information. Security measures will include one to maximum two users of this database, with unique usernames and personal login, as well as automatic throw-out. The questionnaires filled out by the patients are returned to the trial coordinating centre, SSORG, at Sahlgrenska University Hospital. The result database, based on trial number and without patient ID, will be kept within another IT system than the logistic database. The database will be kept on a server with automatic backup and will be registered with “personuppgiftsombudet” for Sahlgrenska University Hospital.

2.16 STUDY ORGANIZATION

The secretariat will be in the Scandinavian Surgical Outcomes Research Group unit in the Department of Surgery, Område 2, Sahlgrenska University Hospital, Göteborg. In each participating hospital a local investigator will be responsible for the inclusion, the control of the internal validity, the data collection and participate in the steering committee.

Data can only be analysed or copied from the database by decision of the principal investigator and the deputy principal investigator together. All such decisions should be discussed by the steering committee, before data retrieval or at latest at the next steering committee. The results of data analysis should be presented to the steering committee before publication (even as abstracts).

The trial will be registered at the website ClinicalTrials.gov for clinical trials.

2.17 SAFETY COMMITTEE

When half the intended accrual has been reached a group of three independent scientists, who are not directly involved in the trial, will be asked to form a committee and discuss re-operations to compare the findings in the two groups with the safety view.

The committee will be asked to suggest to the steering committee whether the trial should continue or stop. The results as such will not be made apparent to or discussed by the trial steering committee at this point.

2.18 WORK PLAN

The questionnaires and the CRFs were made during the beginning of 2013. An application to the Ethical Committee in Göteborg and the Radiation Safety Committee at Sahlgrenska University Hospital will be submitted in February 2013, and after approval the study is planned to begin at including hospitals in the summer of 2013.

2.19 STATISTICAL METHODS

The Swedish trial on the effect of prophylactic net placement has reported 50% incidence of parastomal hernia without mesh. Our own data on abdominoperineal excision from Sahlgrenska University Hospital indicate an incidence of 24%-30%. The power calculation based on available information has used the hypothesis that the cruciate incisional stoma formation, performed as described here, should result in parastomal hernia incidence of 30% and the circular incision or prophylactic mesh reinforcement could lead to a risk of 10% each. An 80% power and a 5% level of significance would require 62 patients per group. The calculation is based on a two-sided test, using normal approximation of binomial distribution. Expecting 20% drop-outs, 80 patients will be recruited in each group.

3.0 FINANCING

The study is supported by ALF-grants at Sahlgrenska University Hospital (Eva Haglind, ALFGBG-138751 and Eva Angenete, ALFGBG-136151).

4.0 BIBLIOGRAPHY

1. Hardy KJ. Surgical history. Evolution of the stoma. *Aust N Z J Surg.* 1989 Jan;59(1):71-7. PubMed PMID: 2643941. Epub 1989/01/01. eng.
2. Pachler J, Wille-Jorgensen P. Quality of life after rectal resection for cancer, with or without permanent colostomy. *Cochrane Database Syst Rev.* 2005 (2):CD004323. PubMed PMID: 15846707. Epub 2005/04/23. eng.
3. Nugent KP, Daniels P, Stewart B, Patankar R, Johnson CD. Quality of life in stoma patients. *Dis Colon Rectum.* 1999 Dec;42(12):1569-74. PubMed PMID: 10613475. Epub 1999/12/29. eng.
4. Shabbir J, Britton DC. Stoma complications: a literature overview. *Colorectal Dis.* 2010 Oct;12(10):958-64. PubMed PMID: 19604288. Epub 2009/07/17. eng.
5. Porter JA, Salvati EP, Rubin RJ, Eisenstat TE. Complications of colostomies. *Dis Colon Rectum.* 1989 Apr;32(4):299-303. PubMed PMID: 2924670. Epub 1989/04/01. eng.
6. Cottam J, Richards K, Hasted A, Blackman A. Results of a nationwide prospective audit of stoma complications within 3 weeks of surgery. *Colorectal Dis.* 2007 Nov;9(9):834-8. PubMed PMID: 17672873. Epub 2007/08/04. eng.
7. Persson E, Berndtsson I, Carlsson E, Hallen AM, Lindholm E. Stoma-related complications and stoma size - a 2-year follow up. *Colorectal Dis.* 2010 Oct;12(10):971-6. PubMed PMID: 19519689. Epub 2009/06/13. eng.
8. Parmar K, Zammit M, Smith A, Kenyon D, Lees N. A Prospective Audit of Early Stoma Complications in Colorectal Cancer Treatment throughout the Greater Manchester and Cheshire Colorectal Cancer Network. *Colorectal Dis.* 2010 May 17. PubMed PMID: 20478001. Epub 2010/05/19. Eng.
9. Nguyen MH, Pittas F. How large should a skin trephine be for an end stoma? *Aust N Z J Surg.* 1999 Sep;69(9):675-6. PubMed PMID: 10515344. Epub 1999/10/09. eng.
10. Keighley MR, Williams NS. *Surgery of The Anus, Rectum & Colon: Saunders, Elsevier;* 2008.
11. Sjudahl R, Anderberg B, Bolin T. Parastomal hernia in relation to site of the abdominal stoma. *Br J Surg.* 1988 Apr;75(4):339-41. PubMed PMID: 2965951. Epub 1988/04/01. eng.
12. Lian L, Wu XR, He XS, Zou YF, Wu XJ, Lan P, et al. Extraperitoneal vs. intraperitoneal route for permanent colostomy: a meta-analysis of 1,071 patients. *Int J Colorectal Dis.* 2011 Sep 3. PubMed PMID: 21892608. Epub 2011/09/06. Eng.
13. Carne PW, Robertson GM, Frizelle FA. Parastomal hernia. *Br J Surg.* 2003 Jul;90(7):784-93. PubMed PMID: 12854101. Epub 2003/07/11. eng.
14. Pilgrim CH, McIntyre R, Bailey M. Prospective audit of parastomal hernia: prevalence and associated comorbidities. *Dis Colon Rectum.* 2010 Jan;53(1):71-6. PubMed PMID: 20010354. Epub 2009/12/17. eng.
15. Serra-Aracil X, Bombardo-Junca J, Moreno-Matias J, Darnell A, Mora-Lopez L, Alcantara-Moral M, et al. Randomized, controlled, prospective trial of the use of a mesh to prevent parastomal hernia. *Ann Surg.* 2009 Apr;249(4):583-7. PubMed PMID: 19300232. Epub 2009/03/21. eng.

16. Janes A, Cengiz Y, Israelsson LA. Preventing parastomal hernia with a prosthetic mesh. *Arch Surg.* 2004 Dec;139(12):1356-8. PubMed PMID: 15613293. Epub 2004/12/23. eng.
17. Janes A, Cengiz Y, Israelsson LA. Preventing parastomal hernia with a prosthetic mesh: a 5-year follow-up of a randomized study. *World J Surg.* 2009 Jan;33(1):118-21; discussion 22-3. PubMed PMID: 19011935. Epub 2008/11/18. eng.
18. Tam KW, Wei PL, Kuo LJ, Wu CH. Systematic review of the use of a mesh to prevent parastomal hernia. *World J Surg.* 2010 Nov;34(11):2723-9. PubMed PMID: 20661562. Epub 2010/07/28. eng.
19. Shabbir J, Chaudhary BN, Dawson R. A systematic review on the use of prophylactic mesh during primary stoma formation to prevent parastomal hernia formation. *Colorectal Dis.* 2011 Sep 20. PubMed PMID: 21929523. Epub 2011/09/21. Eng.
20. Janes A, Cengiz Y, Israelsson LA. Experiences with a prophylactic mesh in 93 consecutive ostomies. *World J Surg.* 2010 Jul;34(7):1637-40. PubMed PMID: 20182719. Epub 2010/02/26. eng.
21. Evans MD, Williams GL, Stephenson BM. Preventing parastomal herniation: is prophylactic prosthetic mesh absolutely necessary? *World J Surg.* 2009 Jul;33(7):1538-9; author reply 40-1. PubMed PMID: 19288283. Epub 2009/03/17. eng.
22. Wang J, Dou Z, Wang T, Liu D, Wang L. Circular stapler-assisted extraperitoneal colostomy. *Dig Surg.* 2010;27(6):521-4. PubMed PMID: 21196736. Epub 2011/01/05. eng.
23. Resnick S. New method of bowel stoma formation. *The American Journal of Surgery.* 1986;152(5):545-8.
24. Wijeyekoon SP, Gurusamy K, El-Gendy K, Chan CL. Prevention of parastomal herniation with biologic/composite prosthetic mesh: a systematic review and meta-analysis of randomized controlled trials. *J Am Coll Surg.* 2010 Nov;211(5):637-45. PubMed PMID: 20829077.
25. Sajid MS, Kalra L, Hutson K, Sains P. Parastomal hernia as a consequence of colorectal cancer resections can prophylactically be controlled by mesh insertion at the time of primary surgery: a literature based systematic review of published trials. *Minerva Chir.* 2012 Aug;67(4):289-96. PubMed PMID: 23022753.
26. Helgstrand F, Gogenur I, Rosenberg J. Prevention of parastomal hernia by the placement of a mesh at the primary operation. *Hernia.* 2008 Dec;12(6):577-82. PubMed PMID: 18523836. Epub 2008/06/05. eng.
27. Janes A, Weisby L, Israelsson LA. Parastomal hernia: clinical and radiological definitions. *Hernia.* 2011 Apr;15(2):189-92. PubMed PMID: 21188441. Epub 2010/12/29. eng.
28. Gurm A, Matthiessen P, Nilsson S, Pahlman L, Rutegard J, Gunnarsson U. The inter-observer reliability is very low at clinical examination of parastomal hernia. *Int J Colorectal Dis.* 2011 Jan;26(1):89-95. PubMed PMID: 20821218. Epub 2010/09/08. eng.
29. Gurm A, Gunnarsson U, Strigard K. Imaging of parastomal hernia using three-dimensional intrastomal ultrasonography. *Br J Surg.* 2011 Jul;98(7):1026-9. PubMed PMID: 21509751. Epub 2011/04/22. eng.