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ORIGINAL ARTICLE

# Quality of life and hernia development 5 years after open abdomen treatment with vacuum-assisted wound closure and mesh-mediated fascial traction

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**Abstract**
*Purpose* To report incisional hernia (IH) incidence, abdominal wall (AW) discomfort and quality of life (QoL) 5 years after open abdomen treatment with vacuum-assisted wound closure and mesh-mediated fascial traction (VAWCM).
*Methods* Five-year follow-up of patients included in a prospective study 2006–2009. The protocol included physical examination, patient interview, chart review, questionnaires on abdominal wall and stoma complaints and the SF-36 questionnaire.
*Results* Fifty-five (12 women, 43 men; median age 70 years) of 111 included patients were alive. Follow-up rate was 91 %. Cumulative IH incidence during the whole study was 62 %. One-third of the IHs was repaired. At 5-year follow-up 59 % of IHs were clinically detectable. AW symptoms were equivalent in patients with (15/23) and without (11/21) IH ($p = 0.541$). SF-36 scores were lower than population mean for component scores and all subscales except bodily pain. Patients with major co-morbidity had lower physical component score [31.6 (95 %, CI 25.6–37.4)] compared to those without [48.9 (95 %, CI 46.2–51.4)]. Major co-morbidity was not associated with IH ($p = 0.56$), AW symptoms ($p = 0.54$) or stoma ($p = 0.10$). Patients with IH or other AW symptoms had similar SF-36 results compared to those without, whereas patients with a stoma had >5 point lower mean scores for general health, social function and physical component score compared to those without.
*Conclusions* VAWCM treatment results in high incidence of IH. However, at five years, there was no detectable difference in abdominal wall complaints and QoL in patients with IH compared to those without. Lower QoL appeared mainly to be associated with the presence of major co-morbidity.

**Keywords** Vacuum-assisted wound closure · Mesh-mediated fascial traction · Open abdomen · Incisional hernia · Quality of life · SF-36

## Introduction

Open abdomen (OA) therapy is today to be considered as standard treatment for abdominal compartment syndrome (ACS) and for several other abdominal emergencies. During the time needed for resolution of the underlying pathology necessitating OA treatment and the overall distorted physiology of the patient, a temporary abdominal closure technique (TAC) is needed before definitive abdominal closure can be performed. Vacuum as part of the TAC has demonstrated overall good results and high fascial closure rates, initially reported for trauma patients [1]. In older patients with a septic abdomen or a vascular emergency necessitating long-term OA treatment, we found vacuum-assisted wound closure (VAWC) alone to be

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insufficient for achieving high fascial closure rates. Based on our experience in incisional hernia (IH) mesh repair, the idea of combining VAWC and mesh-mediated fascial traction (VAWCM) arouse. It was tried out in a few patients at the Department of Surgery in Malmö, where after a description of the technique and excellent outcomes in seven patients was reported as the result of a collaboration with the Department of Vascular Surgery in Malmö and Uppsala [2]. The technique was thereafter prospectively evaluated in a multicentre study [3] with high fascial closure rates and few technique-specific complications. VAWCM is technically easy to perform, and several reports from other centres using the technique have later been published showing similar results [4–7]. Other techniques combining VAWC and fascial traction have been described and evaluated [8–11]. According to recent reviews [12, 13], the combination of VAWC and fascial traction seems to result in the highest fascial closure rates, without an increase in complications, when compared to other TAC techniques.

With increasing survival and fascial closure rates, the long-term incidence of IH after fascial closure as well as patient reported outcome and quality of life (QoL) have become increasingly important issues to investigate. IH rates, 1 year or more after OA therapy with successful fascial closure, are only reported in a few papers [11, 14, 15] and so is quality of life [16–18].

The aim of this paper is to report the 5-year results on IH incidence, patient reported abdominal wall (AW) symptoms and QoL from the prospective VAWCM study.

## Material and method

### Patients

Short-term outcome for 111 VAWCM-treated patients, needing OA longer than 5 days, enrolled in a prospective multicentre study at four Swedish hospitals (Malmö, Uppsala, Falun and Gävle) 2006–2009, have been reported earlier [3]. We have previously also reported the 1-year results from the study [14] concerning IH development. This is the 5-year follow-up (5yFU) for patients alive at 1 year. The 5yFU comprises a patient chart review, a physical examination at an outpatient visit, an abdominal wall complaints questionnaire, the SF-36 and, if applicable, a stoma complaints questionnaire.

### Definitions

*Incisional and parastomal hernia*

IH was defined as a fascial defect at the site of the incision with or without protrusion of intra-abdominal contents, detected at physical examination or imaging procedure [19]. Bulging without a palpable fascial defect was registered, but not defined as a hernia. Hernia width and length was determined according to European Hernia Society Classification [20]. A parastomal hernia (PH) was clinically defined as a protrusion in the vicinity of the stoma with the patient straining in a supine and an erect position [21] or as proposed by Moreno–Matias [22] (type I; the hernia sac contains only the bowel forming the stoma, Ia with a sac diameter <5 cm and Ib >5 cm; type II, the hernia sac contains omentum; type III, the sac contains other bowel loops), if discovered on a CT scan. Any available CT scan was evaluated by a senior radiologist.

*Abdominal wall symptoms*

Symptoms regarded as clinically relevant were defined as: pain not easily ignored the last week, the incision/scar site being perceived as cosmetically disturbing or socially limiting, the presence of bowel dysfunction, stiffness or other abdominal wall symptoms that the patient related to the site of the incision.

*Stoma-related symptoms*

Symptoms regarded as clinically relevant were defined as: pain not easily ignored the last week, the stoma being perceived as cosmetically disturbing or socially limiting, the presence of stoma dysfunction, stoma dressing problems or other symptoms that the patient related to the site of the stoma.

*Major co-morbidity*

Major co-morbidity was defined as the presence of disease(s) or condition(s) with obvious and serious influence on the patient's health, demanding active treatment at the time of follow-up. A solitary stable chronic disease, the presence of an IH, AW symptoms, a stoma or stoma-related symptoms, was not defined as major co-morbidity.

### Chart review

A patient chart review focusing on operative records and CT scans performed outside the study protocol after the 1-year follow-up (1yFU) was conducted. A CT scan of the abdomen was a part of the 1yFU but was not performed at 5 years.

### Physical examination

Patients were invited to an outpatient visit 5 years after their OA treatment. A physical examination for an IH or a

parastomal hernia (PH) was performed by a senior surgeon involved in the study. The examination was performed during relaxation, as well as straining and coughing in both upright and supine position.

### Abdominal wall complaints questionnaire

The AW-specific questionnaire used was the validated ventral hernia pain questionnaire (VHPQ) [23], with a slight modification approved by the inventors. It consists of 19 questions reflecting the patient's perception of the incisional site regarding pain, cosmetic issues and social limitations. Questions were included on the presence of bowel function disturbance; AW stiffness or related symptoms; and for characterizing and evaluating existing pain in terms of frequency, duration, use of pain medication and possible influence on patient's physical function.

### Stoma questionnaire

Patients with an enterostomy answered a questionnaire on stoma-related discomfort and complaints. The questionnaire specifically focused on the stoma site and resembles the AW-specific questionnaire concerning pain, cosmetic issues and social limitations. Existing pain was further characterized the same way as in the AW questionnaire. In addition, questions specific for stoma-related problems, e.g. obstructed emptying or difficulties in stoma dressing, were included. The questionnaire was created specifically for this study and is not validated.

### SF-36

The SF-36, version 2, was used for assessing general health-related QoL at the 5yFU. The SF-36 comprises eight subscales of which three correlate mainly with physical and three mainly with mental aspects. The remaining two (vitality and general health) are equally corresponding to both aspects. From the subscales, physical and mental component scores are derived.

### Ethical and license approvals

The study was approved by the ethics committee of Lund University and registered at http://www.clinicaltrials.gov (registration number: NCT00494793). License for the use of SF-36 was approved by Quality Metric/OptumInsight Life Sciences Inc. RI, USA (license number QM016519).

### Statistics

Data were analysed using *IBM SPSS Statistics version 22*. Pearson's Chi-square test, or Fisher's exact test was used for analysis of categorical data. $p$ values were not calculated for variables with less than six recorded events. Continuous data are presented as median and interquartile range (IQR). Comparison between groups were analysed using the Mann–Whitney $U$ test. In all tests, $p < 0.05$ (two-sided) was regarded as significant.

Swedish norm-based scores (standardized for age and gender) are reported for the SF-36 analyses as mean and 95 % confidence interval (CI). The subscales are transformed to have a mean of 50 and a standard deviation (SD) of 10. A score below 50 represents a health status lower than the norm, i.e. population average. In psychometric science, a change or difference of less than 0.2 SD, corresponding to two points, is empirically considered clinically unimportant, and 0.5 SD (5 points) and more than 0.8 SD (8 points) are considered a medium-sized and large effect, respectively [24].

## Results

Short-term outcome, showing 89 % fascial closure rates for patients surviving the OA period and limited technique-specific complications, has been reported earlier [3]. Outcome for the same patients 1 year after OA therapy has also been reported [14]. In the patients who had received complete closure of the OA with fascial suturing, 66 % had an IH at 1 year detected with a CT scan, whereas physical examination only revealed 36 %. One-third of patients with IH had clinical symptoms related to the hernia.

Mortality, IH development, IH repair and patients lost to follow-up for the different time periods during the study are presented in the flow chart in Fig. 1.

### Mortality and causes of death

Of the initial 111 patients (9 trauma; 57 visceral disease; 45 vascular disease), 70 were alive and evaluated at the 1yFU (8 trauma; 40 visceral disease; 22 vascular disease) [3, 14]. Fifteen died between the 1- and 5-year follow-up at a median age of 75 (IQR 69–79) years and with a median survival time of 33 (IQR 27–47) months. The causes of death were: advanced malignancy ($n = 6$); septic infections ($n = 4$); chronic obstructive pulmonary disease ($n = 2$); myocardial infarction ($n = 1$), cerebral haemorrhage ($n = 1$) and late re-rupture of a thoracic aortic aneurysm ($n = 1$). Fifty-five patients, 12 women and 43 men, with a median age of 70 (IQR 63–76) years were alive and eligible for 5yFU (8 trauma; 30 visceral disease; 17 vascular disease).

The overall mortality during the whole study was 50 % (56/111), with 11 % (1/9) for trauma patients, 47 % (27/57) for patients with visceral and 62 % (28/45) for patients with vascular disease. The mortality was higher during the

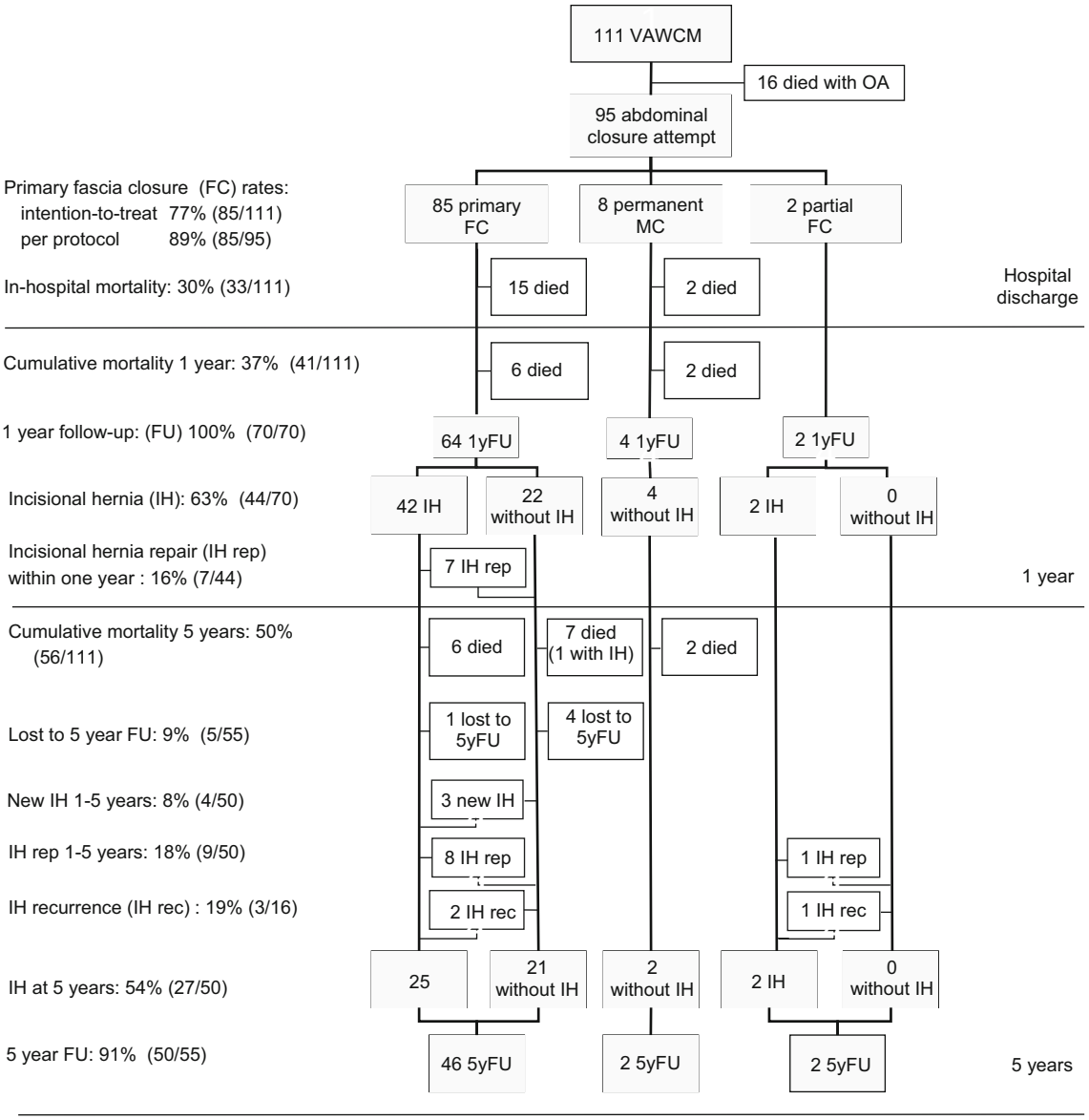


**Fig. 1** Study flow chart. *VAWCM* vacuum-assisted wound closure and mesh-mediated fascial traction, *OA* open abdomen, *FC* fascial closure, *MC* mesh closure, *FU* follow-up, *1yFU* 1-year follow-up, *5yFU* 5-year follow-up, *IH* incisional hernia, *IH rep* incisional hernia repair, *IH rec* incisional hernia recurrence

initial admission for patients with vascular compared to visceral disease ($p = 0.010$). This difference disappeared at 5 years ($p = 0.164$).

## 5-year follow-up

Ninety-one per cent (50/55) of the patients were possible to evaluate. Clinical examination was performed in 75 % (41/55). A telephone interview and an extended chart review were undertaken for 7 % (4/55) of patients living far from the participating study centres. For 9 % (5/55) of the patients, an interview was not possible (one patient living abroad and could not be located; one severely ill and immobilized patient could not be interviewed; two patients declined examination or interview but authorized chart review; and one patient died shortly after 5 years but before follow-up). For these patients, an extended chart review revealed applicable information. Nine per cent (5/55) were lost to follow-up since the charts of these patients did not include applicable information. Median follow-up was 63 (IQR 61–68) months.

## Incisional hernias

The cumulative incidence of IH among all patients surviving the initial hospitalization was 62 % (48/78). Ninety-two per cent (44/48) were diagnosed at the 1yFU [3]

and 8 % (4/48) at the 5yFU (three by clinical examination and one by CT scan performed for other reasons). One was a de novo IH after primary fascial closure of the OA, and three were IH occurring after an additional laparotomy.

Among the patients available for 5yFU, 54 % (27/50) had an IH diagnosed during the course of the study by any modality, i.e. clinical examination and chart review, reported by the patient or previously radiologically diagnosed and not repaired. The clinical examination revealed IH in 39 % (16/41) of the patients.

Twelve patients with an IH only detectable with a CT scan at 1yFU were available for clinical 5yFU. Five of these had become clinically detectable with a median area of 18 (IQR 6–33) $cm^2$.

During the study period, IH repair was performed in 33 % (16/48) of the patients, of which seven during the first year. The nine hernias being operated year one to five were larger (median 140, IQR 33–320 $cm^2$) than those not being treated (median 38, IQR 6–78 $cm^2$), $p = 0.033$. Bulging of the abdominal wall without clinical IH diagnosis was found in one patient.

### Parastomal hernias

Forty-four patients had a stoma created at the OA admission [3]. At 1yFU, 56 % (18/32) of the stoma patients had a PH [14]. One new PH was diagnosed at 5yFU. At 5yFU, 53 % (8/15) of the remaining stoma patients had a PH. Seventy-five per cent (6/8) of the patients with a PH and 57 % (4/7) of those without had a concomitant IH at 5 years ($p = 0.282$). A total of nine patients had their stoma taken down, and two had a PH repair performed over the 5 years.

### Abdominal wall complaints questionnaire

The AW complaints questionnaire was answered by 80 % (44/55) of eligible patients. Any symptom from the AW was reported by 59 % (26/44) and was as frequent in patients with (15/23) and without (11/21) IH ($p = 0.541$). The prevalence and distribution of different symptoms between patients with and without IH are illustrated in Fig. 2 and Table 1. Fourteen per cent (6/44) of the patients reported pain that was not easily ignored during the last week. Of these, three experienced pain once and three more than once that week. Pain duration was less than 1 h in four and longer in two. One had taken analgesics during the last week and four reported decreased physical function of some kind due to the pain.

### Stoma questionnaire

The stoma questionnaire was answered by 93 % (14/15) of patients with a stoma at 5 years. All 14 patients reported some symptoms from the stoma. Three or more symptoms from the stoma was reported by 71 % (10/14) without difference between patients with (6/7) and without (4/7) PH, $p = 0.559$. The prevalence and distribution of different symptoms between patients with and without PH are shown in Table 2. Twenty-nine per cent (4/14) of the patients reported pain related to the stoma that was not easily ignored during the last week. Of these, two experienced pain once and two more than once that week. Pain duration was less than 1 h in three and longer in one. One

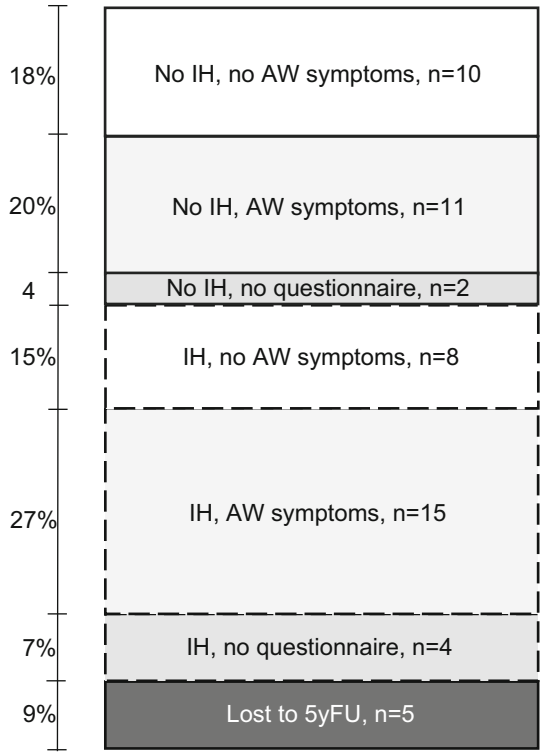


**Fig. 2** 55 patients eligible for 5-year follow-up. Patients lost to overall follow-up, patients lost to questionnaire follow-up and abdominal wall (AW) symptoms in patients with and without incisional hernia (IH) are shown

**Table 1** Selected questions from the abdominal wall complaints questionnaire

| | IH | No IH | $p$* |
|---|---|---|---|
| Pain right now—not easily ignored | 2/23 | 1/21 | – |
| Pain last week—not easily ignored | 4/23 | 2/21 | 0.666 |
| Disturbed bowel function | 8/23 | 4/21 | 0.318 |
| Scar cosmetically disturbing | 11/23 | 6/21 | 0.228 |
| Scar socially limiting | 8/23 | 4/21 | 0.318 |
| Abdominal wall stiffness | 7/23 | 4/17 | 0.730 |

Affirmative answers shown

*IH* incisional hernia

* Pearson Chi-square

**Table 2** Selected questions from the stoma questionnaire

| | PH | No PH | *p** |
|---|---|---|---|
| Pain right now—not easily ignored | 1/7 | 2/7 | – |
| Pain last week—not easily ignored | 2/7 | 2/7 | – |
| Disturbed stoma function | 1/6 | 1/7 | – |
| Stoma cosmetically disturbing | 5/7 | 7/7 | 0.462 |
| Stoma socially limiting | 5/7 | 5/7 | 1.000 |
| Difficulties with stoma bandaging | 6/7 | 2/7 | 0.103 |

Affirmative answers shown

*PH* parastomal hernia

* Pearson Chi-square

had taken analgesics during the last week. Out of eight patients having difficulties with stoma dressing, six experienced this less than once a week. Seven reported decreased physical function due to the stoma.

## SF-36

SF-36 was answered by 80 % (44/55) of the patients alive at 5 years. OA-treated patients scored worse than the population mean. The subscales physical function (PF), vitality (VT) and mental health (MH) had the lowest scores, but also role physical (RF), general health (GH) and social function (SF) had mean scores lower than 45, corresponding to a medium-sized effect (>5 points mean score difference) compared to the population mean. Bodily pain (BP) and role emotional (RE) scores did not reach a mean score difference of five points between OA-treated patients and the population mean. The low physical component score (PCS) and mental component score (MCS) reflect the subscales. The 95 % confidence intervals for the component scores and all subscales, except for BP, were below 50 (Fig. 3).

Subgroup analyses were performed in order to evaluate the impact of IH, AW symptoms, the presence of a stoma and major co-morbidity, respectively, on the SF-36 outcome. Nineteen patients answering the questionnaire were considered having major co-morbidity due to: on-going therapy for malignancy ($n = 4$), Crohn's disease with frequent hospitalization ($n = 2$); stroke with sequelae and diabetes mellitus ($n = 2$); chronic cardiac insufficiency, diabetes mellitus and renal insufficiency ($n = 1$); chronic cardiac insufficiency, nephrostomy and renal insufficiency ($n = 1$); sequelae of multitrauma (suprapubic catheter, pelvic pain, walking difficulties, $n = 1$); advanced multiple sclerosis ($n = 1$); chronic cardiac insufficiency, chronic obstructive pulmonary disease (COPD), aortic aneurysm and ischemic colitis ($n = 1$); angina pectoris, COPD, Mb Parkinson, and sleep apnoea ($n = 1$); chronic pain (spinal stenosis), COPD and diabetes mellitus ($n = 1$); renal failure (dialysis), diabetes, obesity and sleep apnoea ($n = 1$); obesity, sleep apnoea, lymphedema and chronic erysipelas ($n = 1$); rheumatoid arthritis, alcohol dependency and obesity ($n = 1$); and alcohol dependency, chronic pancreatitis and COPD ($n = 1$). The results from these subgroup analyses are presented in Table 3. There were no differences (mean score difference <5) in SF-36 results for any subscale or component score between patients with or without IH or AW symptoms. In the presence of a stoma, GH, SF and PCS scores were lower (mean score difference >5) compared to patients without a stoma. The presence of major comorbidities leads to lower scores (mean score difference >5) in all subscales except RE and MH, and as a result of this, PCS, but not MCS, was lower compared to patients without major comorbidities. There were no significant differences in the distribution of IHs, AW symptoms or stomas between patients with or without major co-morbidities (Table 4).

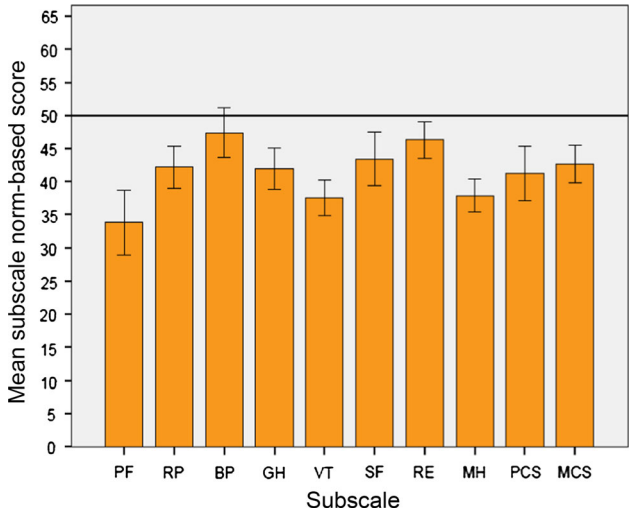


**Fig. 3** SF-36 norm-based scores for the 44 patients answering the questionnaire. *Error bars* showing the 95 % confidence interval (CI). The score 50 (SD 10) is the norm for each subscale. *PF* physical function, *RP* role physical, *BP* bodily pain, *GH* general health, *VT* vitality, *SF* social function, *RE* role emotional, *MH* mental health, *PCS* physical component score, *MCS* mental component score

## Discussion

This is a report on the long-term outcome after OA treatment with vacuum-assisted wound closure and mesh-mediated fascial traction. In addition to a detailed description of the overall outcome of the study population, the emphasis was on IH and PH development, AW and stoma-related symptoms, as well as general health-related QoL.

Half of the included patients were alive after 5 years and causes of death, between 1 and 5 years, were not associated

**Table 3** SF-36 results for subgroup analyses. Table showing mean values (95 % CI)

| Groups | *n* | PF | RP | BP | GH | VT |
|---|---|---|---|---|---|---|
| IH | 23 | 33.3 (26.1–40.5) | 42.2 (36.4–47.0) | 47.3 (42.1–52.5) | 42.6 (38.5–46.8) | 36.4 (33.0–39.7) |
| No IH | 21 | 34.4 (28.3–40.6) | 42.1 (38.2–46.1) | 47.4 (42.3–52.6) | 41.1 (37.1–45.8) | 38.8 (34.7–42.9) |
| AW symptoms | 26 | 36.0 (30.2–41.7) | 42.0 (37.9–46.2) | 47.3 (42.2–52.4) | 43.4 (39.3–47.5) | 37.2 (33.4–41.0) |
| No AW symptoms | 18 | 32.5 (24.6–40.3) | 43.2 (38.4–47.9) | 48.3 (43.0–53.7) | 41.1 (36.9–45.3) | 39.1 (36.2–42.0) |
| Stoma | 14 | 32.1 (22.8–41.4) | 39.4 (33.9–44.8) | 47.0 (40.3–53.8) | *38.8 (33.3–44.4)* | 35.2 (29.8–40.6) |
| No stoma | 30 | 34.9 (29.4–40.2) | 43.5 (39.8–47.4) | 47.6 (43.1–52.1) | *44.0 (40.5–47.5)* | 39.0 (36.5–41.6) |
| Major co-morbidity | 19 | *22.9 (15.6–30.1)* | *36.2 (31.5–40.8)* | *42.3 (36.4–48.1)* | *35.5 (30.7–40.3)* | *32.8 (28.8–36.8)* |
| No/minor co-morbidity | 25 | *42.2 (38.3–46.0)* | *46.7 (43.6–49.8)* | *51.3 (47.2–55.3)* | *47.1 (44.2–50.0)* | *41.3 (38.7–43.9)* |
| Groups | *n* | SF | RE | MH | PCS | MCS |
| IH | 23 | 43.7 (37.5–49.8) | 45.7 (41.4–50.0) | 38.1 (35.2–41.1) | 41.2 (35.0–47.4) | 42.1 (37.8–46.4) |
| No IH | 21 | 43.1 (38.1–48.2) | 47.0 (43.9–50.1) | 37.6 (33.7–41.6) | 41.4 (36.3–46.4) | 43.2 (39.7–46.8) |
| AW symptoms | 26 | 43.6 (38.8–48.4) | 46.2 (42.8–49.6) | 37.8 (34.3–41.3) | 43.2 (38.1–48.3) | 41.7 (38.3–45.2) |
| No AW symptoms | 18 | 45.0 (38.6–51.3) | 47.5 (43.2–51.8) | 38.6 (35.4–41.8) | 40.1 (33.8–46.3) | 44.9 (40.5–49.3) |
| Stoma | 14 | *39.0 (32.0–45.9)* | 48.2 (43.6–52.8) | 38.9 (34.8–42.9) | *37.5 (29.9–45.1)* | 43.2 (37.6–48.9) |
| No stoma | 30 | *46.1 (41.7–50.6)* | 45.8 (42.5–49.1) | 37.4 (34.3–40.5) | *43.6 (39.3–48.0)* | 42.7 (39.6–45.8) |
| Major co-morbidity | 19 | *35.9 (29.2–42.5)* | 43.9 (39.2–48.6) | 35.9 (32.2–39.7) | *31.6 (25.6–37.4)* | 41.1 (35.9–46.3) |
| No/minor co-morbidity | 25 | *49.2 (45.6–52.7)* | 48.2 (45.2–51.2) | 39.4 (36.4–42.5) | *48.9 (46.2–51.4)* | 43.9 (41.0–46.7) |

Italics indicate a difference in mean scores of >5 points between compared groups

*IH* incisional hernia, *AW* abdominal wall, *PF* physical function, *RP* role physical, *BP* bodily pain, *GH* general health, *VT* vitality, *SF* social function, *RE* role emotional, *MH* mental health, *PCS* physical component score and *MCS* mental component score

**Table 4** Prevalence of incisional hernias (IH), abdominal wall (AW) symptoms and stomas in patients with and without major co-morbidity

| Groups | Major co-morbidity | No/minor co-morbidity | *p** |
|---|---|---|---|
| IH | 11 | 12 | 0.557 |
| No IH | 8 | 13 | |
| AW symptoms | 10 | 16 | 0.542 |
| No AW symptoms | 9 | 9 | |
| Stoma | 9 | 5 | 0.101 |
| No stoma | 10 | 20 | |

* Pearson Chi square

with complications to or late effects of the OA treatment, but rather due to the underlying disease and comorbidities. Fortelny et al. [11] reported similar mortality rate in a prospective study on OA treatment for secondary peritonitis, with 45 % survival after a mean follow-up of 40 months. In another study on OA treatment of secondary peritonitis, Brandl et al. [15] reported 65 % survival after a median follow-up of 26 months. Patients with vascular causes for OA treatment had higher mortality at the initial admission but not in the long term, compared to patients with visceral causes. In view of the previously reported survival rates, the 5-year 50 % survival rate in the present cohort of old patients with predominantly visceral and vascular cause of OA therapy is better than expected.

When all available diagnostic modalities were used during the total study period, a cumulative IH incidence of 62 % was found. At five years, 60 % of the IHs could be diagnosed by clinical examination. At the present time, the knowledge on IH development after OA treatment is limited. A prerequisite for comparison of IH rates across OA studies is in the first place, the use of a recommended and standardized fascial closure technique [25]. According to the protocol for this study, fascial closure was performed with a running 0 polydioxanone suture achieving a suture to wound length ratio of at least 4:1, and diagnosis of IH was included as an endpoint for the long-term follow-up study. All but one of the de novo IHs in our study was diagnosed at the 1yFU. In the retrospective study by Brandl et al. [15], patients were treated with vacuum-assisted delayed primary fascial closure aided by elastic vessel loop traction, where after varying techniques for fascial suturing were used. After a median follow-up of 26 months, 90 % of the patients were examined with CT, ultrasound or at operation showing an IH rate of 35 %. A Kaplan–Meier analysis estimated the IH rate to be 66 % at 5 years. The mean time to IH diagnosis was 11 months, indicating a somewhat later occurrence of the hernias compared to our study. Suturing of the mesh to the fascial edges as in the

VAWCM method may lead to earlier IH development, due to greater injury caused by traction on the fascial edges, compared to traction applied on the fascia at a distance from the edges as in the Brandl study. Regardless of the time for appearance, the IH rate at 5 years seems similar between the studies. In the prospective study by Fortelny et al. [11], however, a very low IH rate of 5.9 % (4/68 patients) was reported after 40 months using the same TAC technique as in the Brandl study. This incidence is lower than what can be expected after primary closure of midline incisions, according to a recent systematic review and meta-analysis by Bosanquet et al. [26]. In their review of 56 papers, the mean IH rate was 12.8 % after a mean follow-up of almost 2 years. In the report by Fortelny et al. [11], the follow-up protocol and the modality for IH diagnosis were not described and it is therefore not possible to compare the results. In this study, six of ten IHs were detected by clinical examination and two-thirds of these patients experienced AW symptoms. This indicates that if only clinical examination is used for diagnosis, a considerable proportion of hernias in patients with as well as in patients without AW symptoms will be missed. These findings underline the importance of being aware of the diagnostic modality used when comparing different TAC techniques regarding IH development. Nonetheless, it is not unlikely that technique-related differences may affect the risk of future IH development, and this is certainly an area for further research.

Fifty-nine per cent of patients answering the AW complaints questionnaire reported symptoms 5 years after OA treatment. Even if complaints numerically were almost twice as common in patients with an IH compared to those without, no statistically significant difference was found. Unfortunately, due to high mortality in an elderly cohort, the number of patients decreased over time, making subgroup analyses prone to type II statistical error. In the systematic review by Bosanquet et al. [26], half of the IHs was described as symptomatic compared to two-thirds in the present study. Pain was not the dominating symptom since a low frequency and short duration of pain and minor need for analgesics were reported by 14 % of our patients. During the study, one-third of IHs were repaired which is similar to the hernia repair rates in the studies reviewed by Bosanquet et al. Whether an increased rate of hernia repairs would improve the results and lower the AW symptoms was outside the scope of this study, but AW symptoms reported by half of the patients without IH may indicate that only marginal positive effects on QoL could be accomplished. It seems that OA treatment as such might leave some sequelae to the AW, even if the symptoms are mild.

The cumulative PH incidence was 43 % with all but one PH diagnosed at the 1yFU. As with IH, the PH development was detected early in this cohort. The PH rate does not differ from other reports [27], where no mesh reinforcement of the stoma site is used, and the PH development does not seem to be associated with the OA treatment.

All patients with an enterostomy reported one or more symptoms related to the stoma. The presence of a PH did not significantly add to the symptoms. Neither pain, stoma function, perception of impaired cosmetic appearance and social limitation due to the stoma, nor problems with application of the stoma dressing were related to the presence of a PH. As for patients reporting AW symptoms, pain was not a dominating symptom associated with the stoma, since a low frequency and short duration of pain and minor need for analgesics were reported by 29 % of the stoma patients. Half of the stoma patients reported problems with stoma dressing as well as a decreased physical function due to the stoma. However, it is noteworthy that a PH did not inflict negatively on the outcome. In a recent review, Vonk–Klaassen et al. [28] evaluated the effect of a stoma on QoL after colorectal cancer surgery, using validated questionnaires for QoL assessment in stoma patients. A colostomy was shown to have a negative influence on QoL in all of the 14 included studies, affecting several different aspects of the lives of the patients. It is likely that the negative influence of a stoma is of such a magnitude that the addition of a PH without severe symptoms has little extra negative impact on the patients' perception of stoma-related problems.

The study patients reported lower SF-36 scores than the population mean for the component scores and all of the subscales, except Bodily Pain. Patients with an IH or AW symptoms did not score worse compared to patients without. The dominating reason for the lower QoL was the presence of major co-morbidity. Impaired QoL was reported by Codner et al. [16] on 27, mostly trauma patients, where half of the patients had the fascia primarily closed. In that study, physical and mental component scores were lower than the population mean after more than 4 years when assessed with SF-12. Zarzaur et al. [17] assessed QoL by the use of SF-36 in a cohort of 41 trauma patients initially left with a planned ventral hernia with a later AW reconstruction. They found significantly lower scores compared to the population mean, especially for the physical subscales, despite the hernia repair. On the other hand, Cheatham et al. [18] reported on normal SF-36 scores 6 months after discharge from hospital in patients whose fascia was closed, whereas in patients whose fascia could not be closed at the initial admission, QoL was lower at 6 months but normalized at 18 months. It is notable that half of the IHs had been repaired at 18 months, possibly contributing to the improved QoL for this group.

In the current study, the SF-36 questionnaire was only answered at the 5yFU, and a possible positive effect of the

performed hernia repairs can thereby not be evaluated in this study. Subgroup analyses of the SF-36 results were done to investigate any factor with negative impact on the QoL. Unexpectedly, the SF-36 results did not differ between patients with or without IH or AW symptoms. In stoma patients, general health, social function and physical component score were worse than in patients without a stoma which underlines the negative impact of a stoma on QoL. The presence of major comorbidities resulted in the lowest scores, especially for the physical subscales and physical component score. In lack of a difference in the number of stomas between patients with and without major comorbidities, it appears that the presence of major co-morbidity, in this cohort of elderly patients, is the main but not sole reason for the lower QoL scores.

Previous studies on long-term follow-up of these challenging cases are virtually non-existing. The 91 % follow-up rate at 5 years concerning IH development is a strength of this study, and so are the use of validated general health and ventral hernia-specific questionnaires and reporting of patient-related outcome measures. The main limitation is the reduced number of patients available for 5-year follow-up due to the relatively high mortality over time caused by associated conditions. Another limitation is that only 80 % of the patients answered the questionnaires. This must be kept in mind when interpreting the statistical findings, especially on a subgroup level.

In conclusion, this 5-year follow-up study showed that approximately half the patients were alive. QoL was lower than the population mean and was mainly a result of the presence of major co-morbidity and not of the frequently developing and predominantly mild symptomatic IHs. With refinement of TAC techniques, where fascia reinforcement at closure might be one option, a major decrease in IH rates and repairs should be within reach.

#### Compliance with ethical standards

**Funding** This study was not funded by grants or other contributions.

**Conflict of interest** Author UP has received speaker honorarium from KCI. Author TB has received speaker honorarium from Smith and Nephew. Author SA has received speaker honorarium from Acelity. Author MB, AM, PR, MS and KS declare that they have no conflict of interest.

**Ethical approval** The study was approved by the ethics committee of Lund University (Dnr 564/2005) and registered at www.clinicaltrials.gov (registration number: NCT00494793). All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

**Informed consent** Informed consent was obtained from all individual participants included in the study.

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