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Randomized Clinical Trial

Long-term cost-effectiveness of insertion of a biological mesh during stoma-site closure: 5–8-year follow-up of the ROCSS randomized controlled trial

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Abstract

Background: The original ROCSS trial demonstrated a significant reduction in clinically detectable incisional hernias at 2 years in patients receiving prophylactic biological mesh during stoma closure. ROCSS-Ex was designed to investigate the 5–8-year cost-effectiveness of mesh in the surviving cohort using an abdominal wall–specific quality of life score.

Methods: Eligible participants from original UK centres were identified. The primary outcome (abdominal wall–specific quality of life) was measured using the HerQLes score and EQ-5D-5L. Assessors remained blind to patients' original allocation, even if the patient was aware of their treatment.

Results: Of the original 790 patients, 598 were available for long-term follow-up. HerQLes scores were available for 396 patients (no mesh: 191, mesh: 205). There was no difference in primary outcome between the two groups (mean difference of 1.48, 95% c.i. (−2.35, 5.32), $P = 0.45$) and no cost benefit of routine insertion of prophylactic biological mesh across the entire cohort in the long term. However, patients who received mesh experienced significantly fewer stoma site complications within the first 3 years after reversal and needed fewer surgical reinterventions (32 *versus* 54 for the no mesh group; incidence rate ratio of 0.55, 95% c.i. (0.31, 0.97), $P = 0.04$).

Conclusions: ROCSS-Ex has shown equivocal outcomes for prophylactic mesh insertion *versus* standard repair on abdominal wall–specific quality of life 5–8 years after surgery. As most reinterventions occurred within the first 3 years post-surgery, there may be a role for prophylactic mesh in a subset of patients who would be most adversely affected by repeated surgery early on.

Trial Registration: ISRCTN25584182 (http://www.clinicaltrials.gov).

Introduction

Stoma reversal, or closure, is a common procedure with 6295 stoma closures recorded in England during 2017–18[1]. It is associated with a high risk of complications for patients, including wound infection and breakdown, incisional hernias, reoperation and prolonged wound healing[2]. Cohort studies show that at least 30% of patients have a clinically detectable hernia in the first 2 years following stoma closure surgery[3] with nearly half of patients with incisional hernia at a closed stoma site requiring subsequent surgical repair[4]. Recent guidelines for midline laparotomy closure did not provide evidence or recommendations for management of the closure of stoma sites[5].

Using a biological (commonly denatured collagen) mesh to support stoma closure site reduces hernia formation and wound dehiscence, increasing the rate of successful wound closure by up to 50%. The risk of infection is also reduced when compared with cheaper, synthetic mesh[6]. The original ROCSS trial evaluated the benefit of biological mesh reinforcement at stoma site closure with a significant reduction in the rate of clinically detectable hernias seen in the mesh group (12% *versus* 20% respectively)[7].

The ROCSS-Ex study was designed to evaluate the long-term cost-effectiveness of incorporating a biological mesh into stoma site closures in patients from the original ROCSS study. The aim was to investigate clinical benefit to patients beyond 2 years. A comparison with the cost-effectiveness data from the original trial was performed, to determine if routine mesh use was still supported.

Methods

Study design and participants

The original ROCSS trial was a double-blind, prospective, multicentre, two-arm parallel group RCT (1:1) comparing a non-resorbable, non-crosslinked porcine collagen tissue matrix reinforcement of closure against standard closure techniques (no mesh) in patients undergoing elective stoma closure[8]. Each

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UK site identified surviving patients eligible for follow up. The extended study was registered and received ethical approval (IRAS 077075; ISRCTN25584182). Of 790 patients, 88 (46 in mesh arm and 42 in no mesh arm) randomized in the original ROCSS trial had died, did not have the stoma reversed, had already withdrawn from the trial, or were recruited from international sites. Accounting for these, 702 patients (348 in the Mesh arm, 354 in the No Mesh arm) were potentially available for inclusion. Allowing for approx. 15% dropout, we anticipated data could be obtained for approximately 598 patients. To detect a difference of 0.3 standard deviations (2-sided 5% significance level) using the primary outcome measure (the HerQLes quality of life (QOL) score) a sample size of 598 patients from the original cohort was required to give >95% power.

Ongoing blinding and consent

Patients and clinical assessors remained blinded throughout the ROCSS-Ex trial. Any patients already aware of their allocation were asked not to reveal it to assessors. Consent for the primary outcome (HerQLes) was obtained.

Study outcomes

Abdominal wall–related health resource use was collected using electronic health data and patient telephone follow-up, including data on primary care visits, medication use, prescribed or bought truss/support and relevant emergency department visits. Data were corroborated using clinical records. If there was a discrepancy, the lower value was used (as per the original trial). Electronic records were searched for in-hospital stays, elective and emergency presentations, higher-level care admission (ICU/HDU), clinical diagnosis of incisional hernia, radiological confirmation, and additional scans, interventions or appointments related to the stoma site.

The primary outcome measure was the difference in QOL using the specific HerQLes score[9]. Each of 12 questions related to the patient's abdominal wall function are graded from 1 to 6 points, and are suitable for patients with and without a hernia. To demonstrate a significant impact in abdominal wall–related QOL, a difference of at least 15.6 points between groups is likely required[10]. The EQ-5D-5L instrument was also included to permit comparison with the initial ROCSS cohort, previously performed at 30 days post-operation, 1 and 2 years post-randomization.

For the health economic analysis, resource use was valued using unit costs from the NHS reference costs[11] and the unit costs of health and social care[12]. Costs were inflated to 2020/21 costs where applicable using the NHS cost inflation index. Costs and quality adjusted life years (QALYs) were discounted at the recommended 3.5% annual rate[13].

Initial hospitalization costs were calculated based on the following: cost of the surgery, cost of mesh and length of inpatient stay. Post-hospitalization costs included primary care costs (for example, GP and nurse visits) and readmissions due to serious adverse events such as surgical site infections. Surgical site–related surgeries such as incisional hernia repairs were classed as 'reintervention' and calculated separately.

The calculated cost of surgery used in the analysis was dependent on the incision type (circumstomal or midline), procedure (small or large bowel) and treatment allocation (mesh or not mesh), and did not differ between the two arms. Proxy costs were found in the NHS schedule of reference costs and weighted averages were assigned to both the midline and circumstomal incisions. An assumption was made that the cost of medication or antibiotic use was considered in the length of inpatient stay costs alongside staff costs and additional overheads.

In the original trial, the EQ-5D-3L index scores from each respondent at each time point were derived using the UK value set[14]. In the extended follow-up study, EQ-5D-5L data were collected and converted using the EQ-5D-3L crosswalk algorithm[15].

UK tariff values were applied to generate QALYs using the under-the-area curve method, incorporating both the patients' survival and QOL to determine potential health-related (HR)-QOL gains (if any) from biological mesh reinforcement. As patients entered the original trial at different time points and the data collection for the extended follow-up study took place at a fixed time point, for consistency the EQ-5D-5L value for the comparison was assumed to be the same value at 8 years for patients who had the telephone follow-up before then. To account for the differences in baseline EQ-5D-3L values across the two arms, adjusted mean QALY differences were calculated alongside their 95% confidence intervals.

Two main analyses were carried out to evaluate the relative cost-effectiveness of biological mesh reinforcement compared to standard closure: a cost-effectiveness analysis based on the cost per improvement from the HerQLes tool and a cost–utility analysis in terms of the cost per additional QALY gained using the EQ-5D-5L.

Multiple imputation was used for missing resource use, HerQLes and EQ-5D-5L values. Additionally, a complete case analysis was undertaken as a sensitivity analysis. Incremental costs and outcomes were calculated for each trial arm. The total costs and consequences of the interventions were compared using an incremental cost-effectiveness ratio (ICER). For the cost–utility analysis, a threshold of £30 000 per additional QALY gained was used to assess cost-effectiveness[16].

Deterministic and probabilistic sensitivity analyses were undertaken to explore the robustness of the findings to plausible variations in key assumptions and analytical methods used[17]. Non-parametric bootstrapping was undertaken using 5000 replications of the mean differential outcomes and costs for each strategy. These replications were then presented on a four-quadrant diagram, the cost-effectiveness plane, illustrating four possible conclusions in relation to the differences in costs and outcomes between the intervention and comparator[18]. A cost-effectiveness acceptability curve (CEAC) was constructed to determine the likelihood of biological mesh reinforcement being cost-effective compared to standard closure techniques, across an array of monetary thresholds. These threshold values represent decision makers' willingness to pay per additional unit of outcome[19] (there is no available benchmark on the decision maker's willingness to pay for an improvement in the HerQLes score).

Several deterministic sensitivity analyses were undertaken. Initially the macro-costing of the initial hospitalization was employed in the base-case analysis. However, as a sensitivity analysis, a partial bottom-up costing (micro-costing) was carried out to estimate the costs of the initial hospitalization. Staff wages were derived from the Personal Social Services Research Unit (PSSRU) costs report[12] and were modified according to the duration of the surgery (per minute). Another sensitivity analysis included a disutility of −0.10 of a 1-month duration for any operations between the original trial and the extended follow-up to assess the impact on the results. Lastly, a

sensitivity analysis was conducted modifying the mesh price to zero.

All primary analyses (primary and secondary outcomes including safety outcomes) were based on the patients' intention-to-treat (ITT) principle (that is, patients analysed according to their randomized allocation irrespective of non-compliance). The no mesh arm was the reference category for all analyses. Primary outcome was analysed using a linear regression model to estimate an adjusted mean difference between groups at 5–8 years following closure of the stoma site. In the first instance, primary outcome was analysed using a complete-case approach. As sensitivity analysis, a per-protocol analysis and missing data imputation was carried out for the primary outcome only. Secondary outcomes that were binary (for example, participant-reported incisional hernia rate) were analysed using a log-binomial regression model to estimate an adjusted relative risk and 95% confidence interval. Any secondary outcomes that count data (for example, number of interventional procedures related to the stoma closure site or hernia) were analysed using a Poisson regression model (or negative binomial regression model if there was evidence of overdispersion) to estimate the adjusted incidence rate ratio and 95% confidence interval. An offset for the length of time the patient was in the trial was included in the model. Analyses were performed using SAS version 9.4 or Stata 17.

Subgroup analyses, predefined exploratory analyses and handling of missing data are given in the supplementary methods file.

Results

The number of patients successfully followed up is shown in *Fig. 1*. Data addressing the primary outcome were available for 210 patients in the mesh group and 196 patients in the non-mesh group. There were incomplete questionnaire data for 10 patients, but all had answered more than six questions. After discussion with the original authors and the trial management group, primary outcome data for these patients were included in the ITT analysis.

Baseline characteristics of the cohort are shown in *Table 1*. The mean age of the participants was 60 years old, with more men (64.5%) than women. Stomas originally formed for cancer treatment made up 57.7%. The majority (81.1%) had been closures of small bowel stomas. A parastomal hernia had been present at the time of the index procedure in 27.4%.

HerQLes summary score at 5–8 years

Scores for the HerQLes questionnaire range from 0 to 100 with a value of 0 indicating the worst possible response, and 100 the best possible response and a better quality of life. There were no differences in reported abdominal wall QOL between the mesh and no mesh groups on an ITT analysis (mean difference 1.48, 95% c.i. −2.35 to 5.32, $P = 0.45$; *Table 2*). This was also the case for the per-protocol analysis (mean difference 1.12, 95% c.i. −2·83 to 5.07, $P = 0{\cdot}58$). Scores were similar for all pre-planned subgroup comparisons including BMI, age, and whether the original stoma was created for cancer or non-malignant pathologies (*Fig. S1*, supplementary material). No heterogeneity in outcome according to the subgroups was observed.

The other predefined exploratory analyses did not find differences in the long-term reported QOL for the following comparisons:

1) Patients without a mesh, with or without a patient reported, clinical or radiological parastomal hernia during the follow-up period (87.20 (20.35) *versus* 89.61 (11.96) in those who did not develop a hernia).
2) Patients in both groups who did not go on to develop a parastomal hernia (90.21 (18.08) with mesh *versus* 87.20 (20.35) without mesh).
3) Patients in both groups who did go on to develop a parastomal hernia (80.43 (27.82) with mesh *versus* 89.61 (11.96) without mesh).

Cost-effectiveness

Cost-effectiveness outcomes are shown in *Table 3*. In all scenarios, no mesh proved superior for QALYs. There was a wide distribution of QALYs seen across the study population (*Fig. 2*), but the mesh intervention was always associated with increased costs. Translating the iterations on the cost-effectiveness plane to the CEAC, the intervention had approximately 12% probability of cost-effectiveness at the £30 000 willingness-to-pay threshold for an additional QALY (*Fig. S2*, supplementary material).

A sensitivity analysis incorporating a retrospective disutility from the need for additional operations in between the extended follow-up and the original trial reduced the QALY difference to −0.052. Despite this, the 'no mesh' strategy continued to dominate.

Secondary clinical outcomes and additional health utility

Patients in the control group underwent more surgical reinterventions relating to the index reversal procedure. They visited the emergency department with issues related to the stoma reversal more often than the mesh group, as well as requiring more frequent hospitalization. The most common reintervention was repair of an incisional hernia at the stoma revision site (*Table 2*). The timeline for surgical reinterventions is shown in *Fig. 3*. Most occurred within the first 3.5 years after reversal (mesh 13/303 (4.29%), no mesh 26/295 (8.81%)). By 5–8 years, there was no difference in patient-reported incisional hernia rates at the site of stoma reversal.

Based on these data, we hypothesized that in the period before requiring a surgical reintervention, those patients may have reduced QOL scores linked to symptoms of whatever pathology required further surgery. Supplementary post-hoc analysis of EQ-5D scores from the original study were performed. Full methods and results are included in the supplementary material.

QOL data from the original ROCSS trial were compared between patients who underwent reoperations of any type related to the original stoma reversal procedure, at any time point after 1 year ('cases'), and those patients who did not (controls). A repeated-measures model was used including EQ-5D data from baseline, 30 days and 1 year. The analysis was repeated for patients who were operated on again at any time point after 2 years, and the repeated-measures model included data from the same time points, plus data from 2 years after index surgery. Both models were case-matched for age, sex, cancer status and stoma type. For those having further surgery after 1 year, there was no QOL difference. However, in the group of patients who underwent further surgery more than 2 years post-randomization, the cases had a mean score of 9.26 (of 100) lower that those who never had to undergo a redo surgery. Confidence intervals were wide and the result not statistically significant.

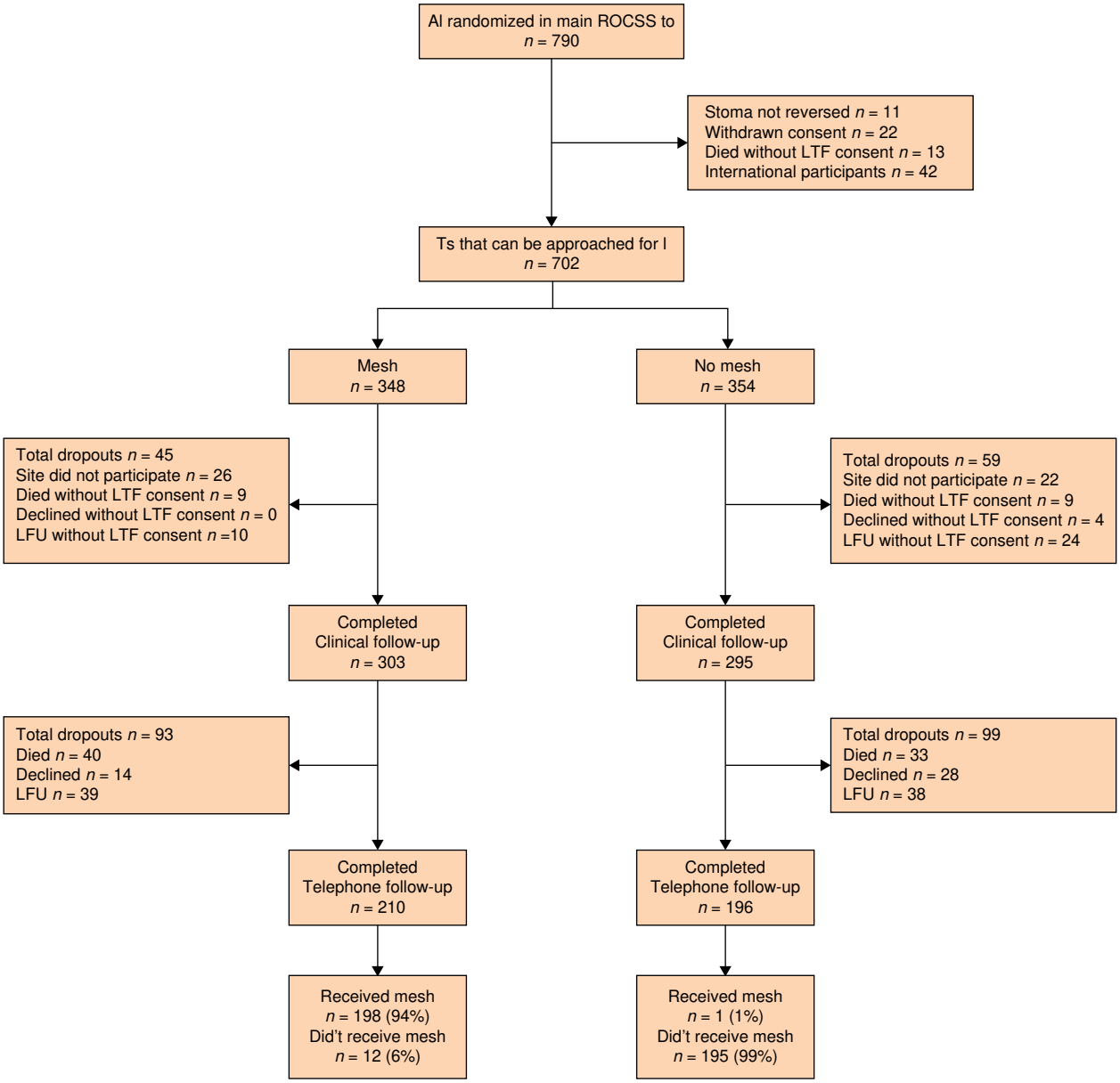

Fig. 1 Trial consort diagram. LFU = lost to follow-up; LTF = long-term follow-up

Discussion

This study assesses the primary outcomes of long-term QOL and economic evaluation of the original ROCSS cohort, capturing additional resource use and abdominal wall–related QOL information. This was the first trial-based economic evaluation to provide evidence on the cost-effectiveness of biological mesh reinforcement *versus* standard closure techniques aimed at informing decision making and policy. Ultimately, after 8 years following the index stoma reversal surgery, there were no measurable QALY gains seen.

To address the possibility that QOL differences may have been evident at earlier time points in the patient journey, that is when the patient developed complications and needed more surgery, led to our use of proxy measure of EQ-5D measured at 1 and 2 years. This did find negative trends in QOL measures at 2 years for those who needed further surgery in the subsequent year, but no more than that. This pattern was not replicated in patients who had surgery within 1 year after stoma reversal. Interpretation was limited by the post-hoc nature of the analysis and would be influenced by an assumption of the negative impact of additional and unexpected redo surgery. These assumptions could include loss of employment income, finding cover for childcare or other carer responsibilities, not being able to drive, additional pain and low mood.

The analysis raised questions around the best time to look at QOL following abdominal surgery. New patient-reporting 'apps' evaluated in other specialties may help address this challenge. Data indicated that most stoma closure site complications appeared within the first 3 years following surgery, suggesting that if it were to be considered on a case-by-case basis, the greatest benefit of prophylactic mesh would be found during this period. The economic data indicated that initial surgery costs accounted for the greatest financial outlay in both groups, and those costs were not mitigated by the additional costs linked to reinterventions associated with no mesh at any time point.

Table 1 Baseline characteristics

Baseline data	Mesh (N = 303)	No Mesh (N = 295)	Total (N = 598)
Age			
Mean(s.d.)	59.6(14.6)	60.3(15.5)	60(15.1)
Min—Max	18–89	19–89	18–89
Gender			
Male	204 (67.3%)	182 (61.7%)	386 (64.5%)
Female	99 (32.7%)	113 (38.3%)	212 (35.5%)
Body mass index			
Mean(s.d.)	27(4.8)	26.9(5.4)	26.9(5.1)
Min—Max	16–49	15.6–48	15.6–49
Diabetic patient			
No	274 (90.4%)	266 (90.2%)	540 (90.3%)
Yes	28 (9.2%)	29 (9.8%)	57 (9.5%)
Missing	1 (0.3%)	0 (0%)	1 (0.2%)
Patient taken any steroid medication			
No	291 (96%)	285 (96.6%)	576 (96.3%)
Yes	10 (3.3%)	10 (3.4%)	20 (3.3%)
Missing	2 (0.7%)	0 (0%)	2 (0.3%)
Original indication for stoma			
Cancer	179 (59.1%)	166 (56.3%)	345 (57.7%)
Non-cancer	124 (40.9%)	129 (43.7%)	253 (42.3%)
Type of stoma opening			
Loop	233 (76.9%)	235 (79.7%)	468 (78.3%)
End	70 (23.1%)	60 (20.3%)	130 (21.7%)
Type of stoma being closed*			
Illeostomy	246 (81.2%)	239 (81%)	485 (81.1%)
Colostomy	57 (18.8%)	56 (19%)	113 (18.9%)
Side stoma being closed			
Right	235 (77.6%)	233 (79%)	468 (78.3%)
Left	68 (22.4%)	62 (21%)	130 (21.7%)
Planned skin closure			
Primary	209 (69%)	205 (69.5%)	414 (69.2%)
Secondary	94 (31%)	90 (30.5%)	184 (30.8%)
Parastomal hernia evident			
No	213 (70.3%)	221 (74.9%)	434 (72.6%)
Yes	90 (29.7%)	74 (25.1%)	164 (27.4%)
Midline laparotomy planned*			
No	261 (86.1%)	258 (87.5%)	519 (86.8%)
Yes	42 (13.9%)	37 (12.5%)	79 (13.2%)
Midline incisional hernia evident			
No	285 (94.1%)	284 (96.3%)	569 (95.2%)
Yes	18 (5.9%)	11 (3.7%)	29 (4.8%)

*Minimization variables from original ROCSS trial.

Discussion around the cost of the mesh itself is not within the scope of the study. However, the way the costs of additional surgical time associated with the mesh are calculated heavily impacted the economic analysis. Mesh insertion added 20 minutes to the median recorded duration of surgery. The study costed it as if those 20 min could have been used for other operation whereas in fact, an all-day list contains a set number of planned surgeries, during which an additional (planned) 20 min would not have required any additional time or staffing cost compared to the expected list time.

We found repair of incisional hernia was the most recorded surgical reintervention. Patients at higher risk for stoma site hernias after reversal include those with an existing parastomal hernia. Other reported risk factors include obesity, hypertension, the presence of malignant disease, diabetes mellitus and stoma prolapse[20]. Therefore, when deciding on whether to use a mesh, targeted insertion will likely provide greatest benefit.

The original ROCSS trial reported fewer incisional hernias than expected from previously published data (the predicted control event rate from the original study was 25% at 2 years, with an actual overall reported rate of 20%), which meant that the potential for reducing healthcare costs from managing this complication, including hospital admissions/attendances and any interventions/operations, was lower than anticipated. Our results suggest that the original 2-year follow-up probably missed many of the late complications, as the extended follow-up found that the majority of complications and reinterventions occurred a year after the original ROCSS study's period had ended.

A strength of ROCSS-EX is that it is the only study of long-term follow-up for QOL and cost-effectiveness of prophylactic mesh insertion at the time of stoma closure. The original study's focus was on reduction in incisional hernia. This long-term analysis has identified similar long-term QOL measures despite earlier differences and reintervention rates. It also confirms the safety and acceptability of the mesh for patients.

Limitations

The original trial suspected that patients stratified as high risk for incisional hernia by the surgeon did not meet equipoise for randomization and therefore were not recruited. Therefore, the true benefit of the mesh in terms of reducing additional surgery costs, especially in high-risk patients, may not have been fully realized during extended follow-up.

Table 2 Results of the intention to treat analysis and per-protocol analysis for the primary outcome (HerQles summary score at 5-8 years post index stoma site closure)

Outcomes	Mesh	No Mesh	Treatment effect (95% c.i.)†	P
Primary outcome (HerQLes summary score at 5–8 years following closure of stoma site) - Intention to treat analysis*	N = 205 89.11(19.57)	N = 191 87.63(19.13)	1.48 (−2.35, 5.32)	0.45
Sensitivity analyses for primary outcome				
Per-protocol analysis	N = 193 88.87(20.07)	N = 190 87.75(19.10)	1.12 (−2.83, 5.07)	0.58
Missing data imputation	N = 210 88.39(20.11)	N = 196 87.19(19.46)	1.11 (−2.77, 5.00)	0.57
Secondary outcomes				
N of interventional procedures related to stoma site	32	54	0.55 (0.31, 0.97)‡	0.04
Type of procedure				
Repair of stoma site incisional hernia	14	30		
Superficial wound complications requiring intervention	10	6		
Division of adhesions	4	7		
Drainage of surgical site infection	2	3		
Bowel resection ± division of adhesions	1	3		
Reformation of stoma	0	2		
Other	1	3		
Patient-reported incisional hernia—no./total no. (%)	33/210(16)	38/196(19)	0.82 (0.53, 1.24)§	0.34
Visited emergency department with issues related to stoma site—no./total no. (%)	51/303(17)	73/295(25)	0.69 (0.51, 0.95)§	0.02
Hospitalized because of their stoma—no./total no. (%)	46/303(15)	61/295(21)	0.76 (0.54, 1.07)§	0.12

Values are mean(s.d.) unless specified otherwise. All analyses were adjusted for minimization variables. *Score ranges from 0 to 100 with a value of 0 indicating worst possible response and 100 the best possible response; therefore, higher scores represent a better quality of life. †All treatment effects are shown as the mean between-group difference except as marked. ‡This treatment effect is reported as incidence rate ratio (IRR). §This treatment effect is reported as a relative risk.

Table 3 Cost-effectiveness outcomes, showing the mean costs per patient between the mesh and no mesh cohorts. Dominated indicates that for each scenario, no mesh was superior in terms of QALYs

Cost utility analysis

	Costs (£)	Incremental Cost (£)	QALYs	Incremental QALYs	ICER
Base case					
No mesh	9505		6.1231		
Mesh	10 066	557	6.0711	−0.0655	Dominated
Complete case					
No Mesh	9579		6.2904		
Mesh	9833	254	6.2288	−0.0616	Dominated
Deterministic sensitivity analysis: Surgery micro-costing					
No Mesh	4779		6.1231		
Mesh	5046	270	6.0711	−0.0655	Dominated
Deterministic sensitivity analysis: Mesh cost of zero					
Mesh	9093		6.0711		
No Mesh	9496	406	6.1231	0.0655	6207
Deterministic sensitivity analysis: Disutility of −0·1					
No Mesh	9505		6.1221		
Mesh	10 066	557	6.0704	−0.0517	Dominated

Cost-effectiveness analysis

	Costs (£)	Incremental cost (£)	HerQLes	Incremental HerQLes	ICER
Base case					
No Mesh	9505		87.64		
Mesh	10 066	557	89.05	1.41	394
Complete case					
No Mesh	9841		89.23		
Mesh	9641		90.95	1.72	116
Deterministic sensitivity analysis: Surgery micro-costing					
No Mesh	4779		87.64		
Mesh	5046	270	89.05	1.41	191
Deterministic sensitivity analysis: Mesh cost of zero					
Mesh	9093		89.05		
No Mesh	9496	406	87.64	−1.41	Dominated

ICER = incremental cost-effectiveness ratio, QALYs = quality-adjusted life years.

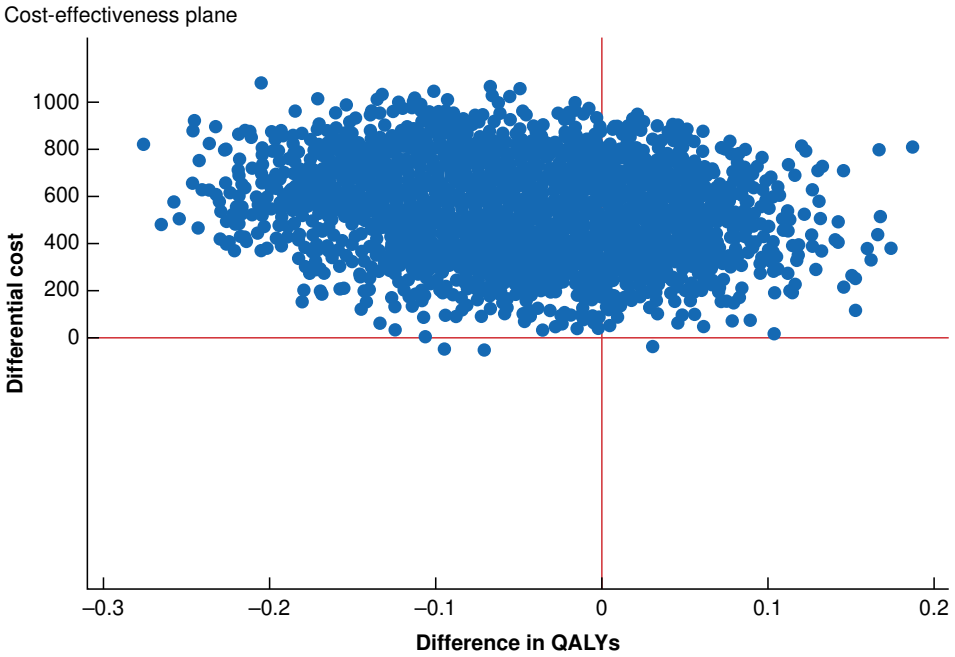

Fig. 2 Cost-effectiveness plane with macro costing surgery results comparing costs per QALY gained at 5–8 years follow-up. Most of the iterations show that the intervention was costlier (above the zero differential cost mark) with many of them showing a reduced QALY compared with iterations in the standard care group (positions in the north-west quadrant). The greater representation in the upper-left quadrant supported the lack of treatment effect on quality of life in the long term

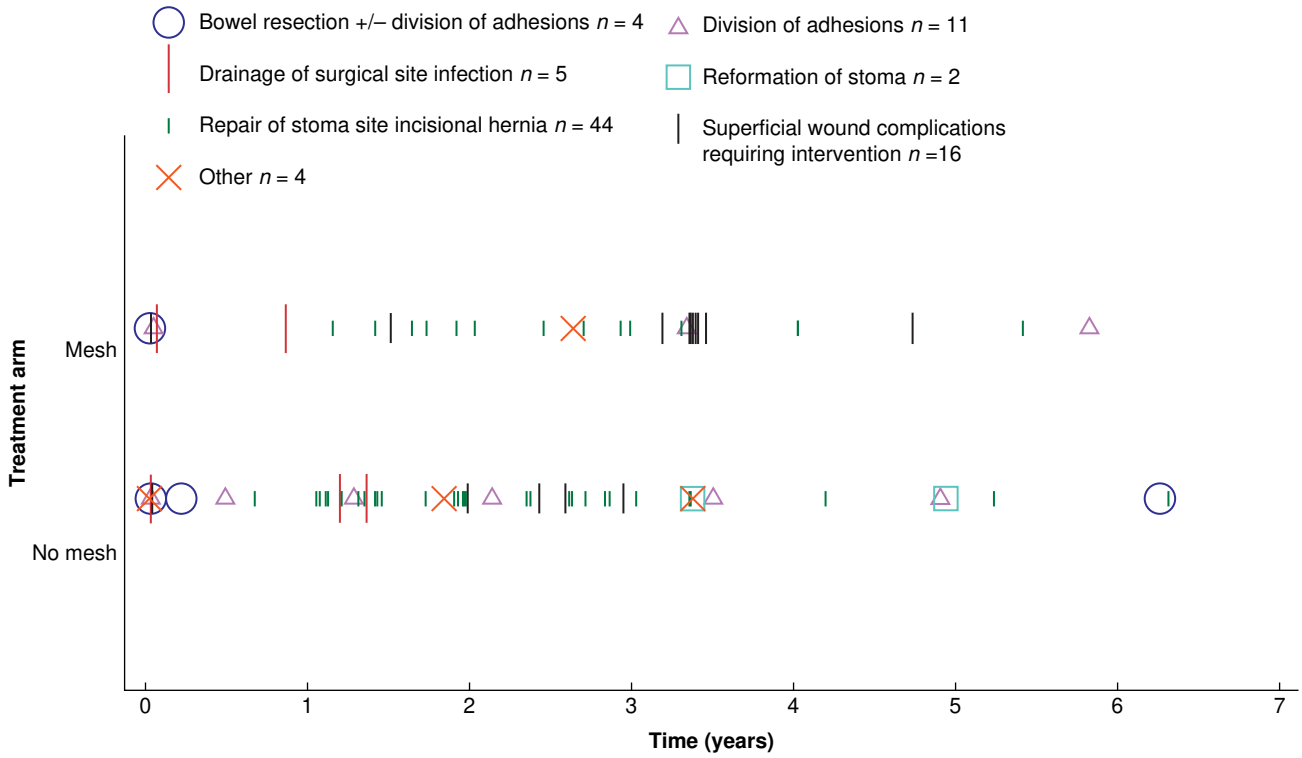

Fig. 3 Surgical reintervention following the original stoma reversal procedure

Another limitation was the method for calculation of the surgery costs per patient. It consisted of resources that were known to be different between the two arms and did not include fundamental costs such as overheads. To calculate the surgery costs for each arm, only theatre staff costs were included. It was assumed that the cost of medication or antibiotic use was considered in the length of inpatient stay costs for additional hospital visits and reinterventions alongside staff costs and additional overheads. Different length of stay was not accounted for, as the macro costs used provide a mean cost of the procedure (including length of stay).

The original trial attempted to ensure similar closure techniques were used across the centres, but the type of fascial closure technique was left up to the surgeon. Patients were not stratified by closure technique, but it has been established that it can impact incisional hernia rates[21]. Finally, we had not formally validated the use of the HerQLes tool over telephone interviews before the study. We tried to mitigate this as much as possible using detailed scripts for investigators to use, and decision trees based on patients' answers. This helped us prevent unintentional interviewer unblinding.

Conclusion

ROCSS-Ex has shown equivocal outcomes for routine prophylactic mesh insertion *versus* standard repair on abdominal wall–specific QOL 5–8 years after surgery. As most reinterventions occurred within the first 3 years post-surgery, there may be a role for prophylactic mesh in a subset of patients who would be most adversely affected by repeated surgery early on. The question of optimal timing of QOL measures following an intervention and how best to cost theatre time in a randomized study are worth careful consideration in future interventional trial designs.

Collaborators

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Supplementary material

Supplementary material is available at *BJS* online.

Data availability

Data-sharing requests will be considered by the trial management group on written request to rocss@trials.bham.ac.uk. De-identified participant data or other prespecified data will be available, subject to a written proposal and an agreed data-sharing agreement.

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