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Original research

A prospective randomised trial comparing mesh types and fixation in totally extraperitoneal inguinal hernia repairs

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HIGHLIGHTS

- Totally extraperitoneal inguinal hernia repairs are now a popular technique.
- A prospective RCT compared comfort scores using different mesh types and fixation.
- At 1, 2, 4 & 12 weeks, median global CCS scores were low for all treatment groups.
- No statistical differences in CCS scores amongst mesh type or fixation method used.

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ABSTRACT

The totally extraperitoneal (TEP) approach for surgical repair of inguinal hernias has emerged as a popular technique. We conducted a prospective randomised trial to compare patient comfort scores using different mesh types and fixation using this technique.

Over a 14 month period, 146 patients underwent 232 TEP inguinal hernia repairs. We compared the comfort scores of patients who underwent these procedures using different types of mesh and fixation. A non-absorbable 15 × 10 cm anatomical mesh fixed with absorbable tacks (Control group) was compared with either a non-absorbable 15 × 10 cm folding slit mesh with absorbable tacks (Group 2), a partially-absorbable 15 × 10 cm mesh with absorbable tacks (Group 3) or a non-absorbable 15 × 10 cm anatomical mesh fixed with 2 ml fibrin sealant (Group 4). Outcomes were compared at 1, 2, 4 and 12 weeks using the Carolina Comfort Scale (CCS) scores.

At 1, 2, 4 and 12 weeks, the median global CCS scores were low for all treatment groups. Statistically significant differences were seen only for median CCS scores and subscores with the use of partially-absorbable mesh with absorbable tacks (Group 3) at weeks 2 and 4. However, these were no longer significant at week 12.

In this study, the TEP inguinal hernia repair with minimal fixation results in low CCS scores. There were no statistical differences in CCS scores when comparing types of mesh, configuration of the mesh or fixation methods.

1. Introduction

Studies involving the totally extraperitoneal (TEP) approach for surgical repair of inguinal hernias have illustrated advantages, such as quicker recovery, earlier return to work and reduced post-operative pain [1]. The TEP approach has the potential to repair bilateral inguinal hernias using the same three access ports, the ability to diagnose and repair associated femoral and obturator hernias, and is excellent for recurrent hernia management following previous open repair [2]. Evolution from sutured to mesh repair has reduced the incidence of hernia recurrence, however groin pain continues to be an issue for some patients, and mesh type and fixation methods are often implicated [3].

In this study, we trialled three different light-weight mesh types using two different fixation methods in relation to post-operative

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groin pain measured by Carolina Comfort Scale (CCS) scores [4].

2. Methods

From 2005, over an accrual period of 14 months, patients were prospectively randomised between using the non-absorbable anatomical mesh with absorbable tacks (Control group; Parietex, 15 × 10 cm) with either non-absorbable folding slit mesh with absorbable tacks (Group 2; Parietex, 15 × 10 cm), partially-absorbable mesh with absorbable tacks (Group 3; Ultrapro, 15 × 10 cm) or non-absorbable anatomical mesh fixed with 2 ml fibrin sealant (Group 4; Parietex, 15 × 10 cm; Tisseel fibrin glue).

Patient's demographic and medical history was recorded. They were consented for the trial, which had ethics committee approval. Immediately preoperatively an opaque envelope was opened which dictated the type of mesh and fixation technique randomised for each hernia side (random allocation numbers were utilised for allocation).

Each surgeon had performed over 1000 TEP procedures previously. All were performed under general anaesthetic. A subrectus space was created using a small incision just below the umbilicus. The subrectus space was inflated under vision using a dissection balloon to create the extraperitoneal space. Two 5 mm ports were sited under vision in a vertical line below the umbilicus and at least 5 cm above the symphysis pubis. Following reduction of all hernias, the mesh was fixed medially to the lacunar ligament (two sites), medial and superior (two sites), and lateral and superior (one site) using absorbable tacks (Control group, Group 2, and Group 3) or using 2 ml of fibrin sealant (Group 4) in similar areas. Up to 20 ml of 0.25% bupivacaine was injected to the three skin incisions at the end of the procedure.

All patients were discharged home within 24 h of their admission on oral paracetamol and ibuprofen for use at their discretion. Patients were asked to refrain from heavy lifting for 2 weeks as the only limitation to activities.

All patients underwent clinical examination between four to eight weeks postoperatively and were contacted per phone by an independent scientific researcher at 1, 2, 4 and 12 weeks to complete the CCS questionnaire, hence a 100% response rate. For bilateral repairs, patients were interviewed to complete two CCS scores, one for each side.

The CCS questionnaire was used to collect responses to a total of 23 questions relating to eight domains. Totals were calculated for each of the eight domains and a global CCS score was calculated as the sum of all 23 values. Analgesic consumption post-operatively was not quantified.

Statistical analysis was performed using the R Development Core Team [5]. The global CCS scores and subscores for each review week were summarised as median. The control group (non-absorbable anatomical mesh with absorbable tacks) was then compared to each of the other treatment groups using the Mann–Whitney U test. Statistical significance was defined at the conventional level of 0.05.

3. Results

One-hundred and forty-six patients underwent 232 TEP inguinal hernia procedures. Using five absorbable tacks only for fixation, 58 inguinal hernias were repaired with non-absorbable anatomical mesh (Control group), 27 with non-absorbable folding slit mesh (Group 2), and 66 with partially-absorbable mesh (Group 3). A further 81 hernial defects were repaired with non-absorbable anatomical mesh and fibrin sealant (Group 4) (Table 1).

Significantly lower global CCS scores and subscores were seen at weeks 2 and 4 with the use of partially-absorbable mesh (Group 3).

Table 1
Patient characteristics by treatment combination.

	# Patients	# Females	Mean age (SD)
Single hernia	60	2	
Control group	13	0	49.2 (16.8)
Group 2	14	2	55.8 (15.8)
Group 3	16	0	52.2 (17.1)
Group 4	17	0	51.2 (15.6)
Bilateral hernia	86	3	
2 × Control group	15	0	48.5 (18.2)
2 × Group 2	5	0	59.0 (10.0)
2 × Group 3	23	0	56.6 (15.1)
2 × Group 4	28	3	56.2 (15.0)
1 × Control group, 1 × Group 2	3	0	35.7 (6.4)
1 × Control group, 1 × Group 3	4	0	40.0 (4.5)
1 × Control group, 1 × Group 4	8	0	49.8 (7.5)

However, there were no statistically significant differences in regards to global CCS scores or subscores in any of the treatment groups by week 12 post-operatively (Table 2).

Over the course of the study, fortunately no significant intra-operative complications were encountered, and there was no conversion to open surgery. Two patients required a course of oral antibiotics for minor superficial infections at the umbilical port site. One hernia recurred two weeks postoperatively following placement of a non-absorbable anatomical mesh using fibrin sealant (Group 4) for a 5 cm direct inguinal hernia. This was subsequently repaired using an open approach with on-lay mesh reinforcement.

Clinical follow-up was performed between four to eight weeks post-operatively without further adverse findings.

4. Discussion

The first TEP inguinal hernia repair was described by Dulucq JL in 1992 [6]. Whilst relatively safe, higher recurrence and complications rates seen in earlier studies may have been due to evolvement of technique and the inherent learning curve of a new procedure [7,10,13,19]. Prospective studies and meta-analyses have suggested significant reduction in chronic pain and numbness [3,11,17–19], improvement in quality of life [9], reduced wound infection, seroma and hematoma rates when compared to the open procedure [8,12,16,17,19]. Despite this, post-operative groin pain remains a significant issue which is often attributed to the type of mesh used or fixation technique employed [3].

Evidence suggests that the ideal mesh for use in inguinal hernia repair should be monofilamentous, non-absorbable, light weight (<50 gm/m^2), macroporous (>1 mm pore size), stable (16 N/cm) and elastic (>20%) [20]. Although there are approximately 130 mesh types available, marketing ploys related to the above physical properties lack any comparative scientific substance in randomised human clinical trials. Light weight macroporous non-absorbable and partially-absorbable meshes were used in our study, in line with the European Hernia Society guidelines [14]. Whilst associated with less pain and foreign body sensation, several meta-analyses

Table 2
Summary statistics for the Carolina Comfort Scale scores.

	Review week			
	1	2	4	12
Control group	24.6	14.7	8.2	5.1
Group 2	27.2	14.4	3.9*	3.2
Group 3	26.4	11.3	3.7*	3.9
Group 4	30.4	13.4	7.4	2.3

* denotes statistical significance ($p < 0.05$).