Surgical Endoscopy (2019) 33:2670–2679
https://doi.org/10.1007/s00464-018-6555-8

2018 SAGES ORAL

An analysis of results in a single-blinded, prospective randomized controlled trial comparing non-fixating versus self-fixating mesh for laparoscopic inguinal hernia repair

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Received: 8 May 2018 / Accepted: 17 October 2018 / Published online: 9 January 2019

Abstract

Background It remains unclear whether use of self-fixating mesh during laparoscopic inguinal hernia repair (LIHR) impacts postoperative quality of life (QoL). We hypothesize patients receiving self-fixating mesh during totally extraperitoneal (TEP) LIHR will report less pain and improved QoL compared to those receiving non-fixating mesh.

Methods An IRB-approved, single-blinded randomized controlled trial was conducted. Patients with primary, unilateral inguinal hernias were randomized to receive either non-fixating (control) or self-fixating mesh. Clinical visits were conducted 3 weeks and 1 year after LIHR. A validated Surgical Outcomes Measurement System (SOMS) instrument was used to assess patients' QoL preoperatively and postoperatively along with Carolinas Comfort Scale (CCS) at 3 weeks and 1 year after surgery. Comparisons between self-fixating and non-fixating mesh groups were made using Chi-square, Wilcoxon rank-sum or independent samples *t* tests.

Results Two hundred and seventy patients were enrolled (137 non-fixating vs 133 self-fixating). Preoperatively, there was no difference in mean age, BMI, or median hernia duration between groups (57.9 vs 56.6 years, $p=0.550$; 26.1 vs 26.8, $p=0.534$; 3.0 vs 3.0 months, $p=0.846$). Median operative times (34 vs 34 min, $p=0.545$) and LOS were similar. More patients in the non-fixating group received tacks (43 vs 19, $p=0.001$). Patients receiving non-fixating mesh recorded better mean SOMS scores for the first 3 days following surgery (Day 1: $p=0.005$; Day 2: $p=0.002$; Day 3: $p=0.024$, Table 1) indicating less pain. No differences in pain were seen 3 weeks or 1 year postoperatively. There were zero recurrences found during clinical follow-up in either of the groups.

Conclusions Patients receiving self-fixating mesh report worse postoperative pain in the first 2–3 days than those receiving non-fixating mesh. The groups showed no differences across QoL metrics (SOMS and CCS) at 3 weeks or 1 year postoperatively. Self-fixating mesh does not appear to positively impact QoL after TEP LIHR.

Keywords Self-fixating mesh · Inguinal hernia · Quality of life · Laparoscopy · Chronic pain

Treatment of inguinal hernia has significantly improved in the past two decades. Laparoscopic inguinal hernia repair (LIHR) offers better patient-centered outcomes, such as lower recurrence and reduced pain compared to open repair [1]. However, rates of chronic pain following laparoscopic hernia ranging from 3.3 to 20% have been reported [2–4]. As a result, quality of life (QoL), specifically the rate of chronic pain, is the primary improvement focus for inguinal hernia repair.

Chronic pain that interferes with activities of daily living 1 year after repair may result from mesh fixation [3]. Other implicating mechanisms include tissue ingrowth, nerve entrapment, and other poorly understood mechanisms. Self-fixating mesh is a recent development that can eliminate the need for fixation and therefore remove one main cause of chronic pain.

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Additionally, self-fixating mesh could prevent mesh migration as it allows for fixation inferior to the level of the iliopubic track. Mesh migration is a known mechanism of hernia recurrence, occurring when the peritoneum slides around the inferior edge of the mesh and re-exposes the defect. Theoretically, self-fixating mesh could reduce migration and therefore prevent recurrences.

Previous randomized trials have examined the efficacy of self-fixating mesh in open inguinal hernia repair with mixed results [5–10]. Regarding LIHR, only prospective feasibility studies have been conducted, with results indicating repair using self-gripping mesh is a promising technique [11, 12].

In our current study, we conducted a prospective, single-blinded, randomized trial between self-fixating and non-fixating mesh in LIHR, with a focus on QoL outcomes. The purpose of this study was to compare pain and QoL outcomes following laparoscopic repair between patients receiving self-fixating and non-fixating mesh. We expect patients receiving self-fixating mesh to report less pain and improved QoL outcomes. As a secondary endpoint, we also sought to determine whether patients with self-fixating mesh have a reduced incidence of recurrence compared to non-fixating mesh.

Materials and methods

Study design

This trial was approved by the institutional review board, and informed consent was given to all potential participants. All patients scheduled for elective totally extraperitoneal (TEP) LIHR from 2014 to 2017 were eligible to participate. All procedures were performed by four board-certified general surgeons at NorthShore University HealthSystem.

Only patients undergoing a primary, unilateral repair were considered. We chose unilateral procedures only to ensure a uniform patient population for the resulting pain scores, as we assumed bilateral repairs would record in a higher pain score compared to unilateral repairs.

These patients were > 18 years old, with an American Society of Anesthesiologists (ASA) classification of I, II, or III. Patients < 18 years old, or with an ASA class of IV or greater, or those needing emergency repair were excluded. We also excluded patients undergoing a concomitant umbilical hernia repair, those undergoing bilateral or recurrent inguinal hernia repairs, and patients with a known history of narcotic dependence.

Patients who enrolled ($n = 283$) were randomized to one of two study arms using a randomization program. The sample size of this study was determined through a power analysis based on accepted rates of short- and long-term postoperative pain.

After enrollment, patients completed a preoperative, objective QoL assessment using the Surgical Outcomes Measurement System (SOMS), a validated extension of the Patient-Reported Outcomes Measurement Information System [13, 14]. The SOMS consists of four domains, pain impact, pain quality, fatigue, and physical functioning. Lower scores on the first three domains indicated better scores, while higher scores on the physical functioning domain indicate better physical functioning. The study coordinator then informed the surgeon of each patient's randomization prior to surgery. Several patients were found to have a bilateral inguinal hernia in the operating room, while a few others withdrew from the study. The final enrollment was 270 patients. Patients were blinded to their group. The control group ($n = 137$) received the non-fixating mesh, while the study group ($n = 133$) received self-fixating mesh. A flowchart outlining the study randomization is shown in Fig. 1. All statistical analysis was performed using SAS 9.3 (SAS Institute, Cary, NC) at a significance level of $p = 0.05$.

Mesh prosthesis

The non-fixating group received a hydrophilic, monofilament polyester mesh. The self-fixating mesh group received hydrophilic, monofilament polyester mesh with absorbable, polylactic acid microhooks that result in in vivo tissue fixation.

Surgical tack use

As standard protocol at our institution, surgeons do not use fixation, such as tacks, for direct hernias < 2 cm or indirect hernias < 4 cm. This is in accordance with guidelines from the European Hernia Society and established outcomes for patients undergoing LIHR [15, 16].

An additional, subgroup randomization was conducted on the self-fixating mesh group to determine whether mesh fixation was required for direct hernias. Only those with direct hernias > 2 cm ($n = 38$) were included. Half of this group ($n = 19$) was randomized to receive surgical tacks while the other half ($n = 19$) did not (Fig. 1).

Postoperative follow-up

In the immediate postoperative period, 1–7 days following surgery, patients completed a daily pain journal and a pain medication diary. Patients returned to clinic for a follow-up visit at 3 weeks postoperatively for a standard assessment for pain, complications, and recurrence. Additionally, both groups completed the SOMS preoperatively and at 3 weeks and 1 year postoperatively.

Additionally, patients completed the Carolinas Comfort Scale (CCS) at 3 weeks and 1 year postoperatively, a

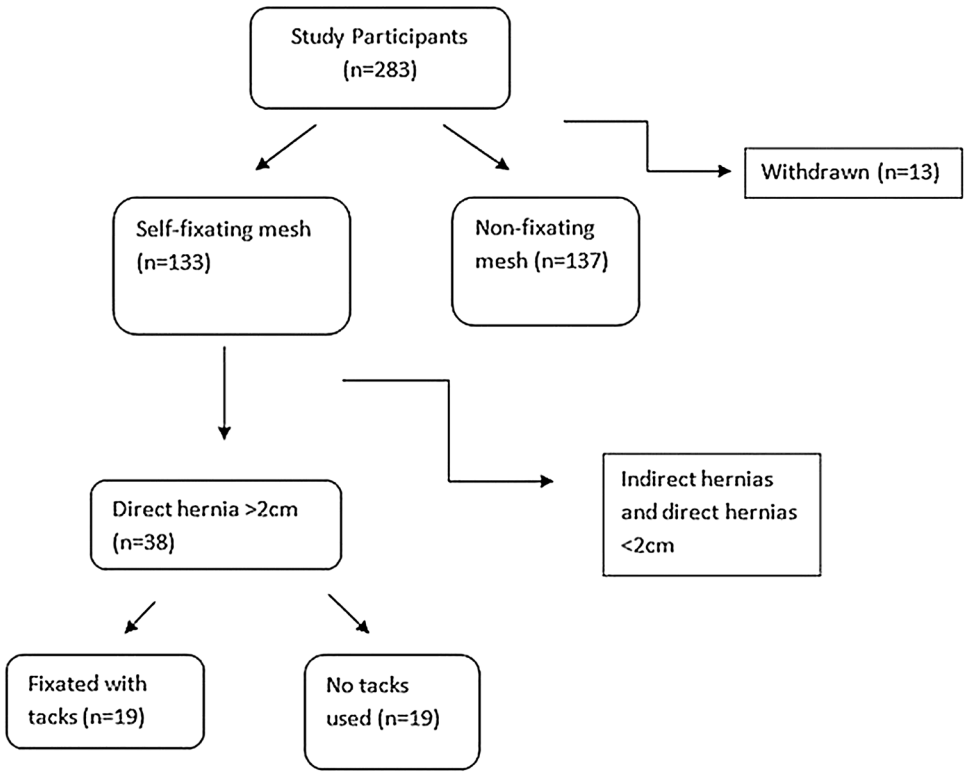

Fig. 1 Study schematic depicting the randomization to self-fixating or non-fixating mesh. The subgroup randomization, only for direct hernias > 2 cm in the self-fixating group, is also shown

validated QoL tool for pain following inguinal hernia repair. This instrument has three subscales: sensation of mesh, pain, and movement limitations, in addition to a total scale. Patients are asked whether they experience symptoms in either of these three domains during eight activities ranging from laying down to walking up stairs and exercising.

Statistical analysis

Comparisons between the non-fixating and self-fixating mesh groups were made using Fisher's exact or Wilcoxon rank-sum tests.

Results

A total of 270 patients were enrolled in the trial and randomized; 133 in the self-fixating group and 137 in the control group. Thirteen patients were consented but withdrew during the study period or were found to have a bilateral hernia during surgery and excluded. Of the 270 patients, 22 were lost to follow up before the 3-week postoperative visit, a rate of 8.1%.

Patient demographics and surgical characteristics

Patient characteristics are shown in Table 1. There was no difference in age (57.9 vs 56.6, $p = 0.55$), BMI (26.1 vs 26.8, $p = 0.534$), or gender (males 128 vs 126, $p = 0.65$) between the control and self-fixating mesh group, respectively. Both groups had similar preoperative hernia pain scores on a scale of 1–10, with 10 indicating severe pain (2 vs 2, $p = 0.158$). Duration of hernia prior to the first office visit was also similar between groups (3 vs 3 months, $p = 0.846$). Both groups had similar operative times (33.9 vs 33.9 min, $p = 0.55$). Hernia types, such as indirect and direct, and sizes were similar between the two groups (Table 1).

Postoperative outcomes between the groups were also similar (Table 1). There was no difference in the number of emergency department visits (5 vs 6, $p = 0.73$), hospital readmissions (0 vs 1, $p = 0.468$), seroma (9 vs 8, $p = 0.910$), hematoma (1 vs 3, $p = 0.356$), or incidence of urinary retention (3 vs 8, $p = 0.098$) within 30 days between groups. The control group did have a longer length of stay compared to the self-fixating mesh group (7.5 vs 7.1 h, $p = 0.041$). Additionally, the control group had more patients with surgical tack use compared to the self-fixating group (43 vs 19, $p < 0.001$). However, among patients receiving tacks, the number of tacks each patient received was the same between groups (5.4 vs 5.1, $p = 0.468$). To date, there have been no recurrences in either group.

The subgroup randomization of direct hernias in the self-fixating mesh group ($n = 38$) was too small to conduct statistical analysis between the tacks ($n = 19$) and no tacks ($n = 19$) groups.

Table 1 Patient characteristics

Characteristic	Control *N* (%)	Self-fixating *N* (%)	*p* value
Total patients	137 (50.7)	133 (49.3)	
Age, years (Mean ± SD)	57.9 ± 15.0	56.6 ± 15.5	0.5498
Preop BMI	26.1 ± 3.5	26.8 ± 4.4	0.5340
Gender			
Female	9 (6.6)	7 (5.3)	0.6495
Male	128 (93.4)	126 (94.7)	
Preop Hernia Pain Score (median, Q1–Q3)	2 (1–4)	2 (1–4)	0.1577
Hernia duration, months (median, Q1–Q3)	3 (1–8)	3 (1–7)	0.8458
Hernia type			
Indirect	43 (31.4)	49 (36.8)	0.3444
Direct	104 (75.9)	98 (73.7)	0.6733
Femoral	5 (3.7)	5 (3.8)	0.6437
Pantaloon	14 (10.2)	16 (12.0)	0.6359
Hernia size	2.3 ± 1.1	2.2 ± 0.9	0.6793
OR time (min)	33.9 ± 11.4	33.9 ± 9.8	0.5449
LOS (h)	7.5 ± 2.2	7.1 ± 2.5	0.0408
Tacks used	43 (31.6)	19 (14.3)	0.0007
Number of tacks	5.4 ± 1.5	5.1 ± 1.3	0.4682
ED visit w/in 30 days	5 (3.7)	6 (4.5)	0.7296
Hospital readmission	0 (0.0)	1 (0.7)	0.4944
Seroma[a]	9 (7.0)	8 (6.7)	0.9096
Hematoma[a]	1 (0.8)	3 (2.5)	0.3564
Urinary retention[a]	3 (2.3)	8 (6.7)	0.0984
Post-op complications[a]	2 (1.6)	4 (3.3)	0.4341
Narcotic use[b]	53 (50.5)	57 (59.4)	0.2055

[a]Control $N = 128$ self-fixating $N = 120$

[b]Control $N = 105$ self-fixating $N = 96$

Pain journal

Responses to the 7-day pain journal are shown in Table 2. Patients in the control group report less total mean pain during postoperative day 1 (8.7 vs 8.1, $p = 0.001$), day 2 (8.5 vs 9.2, $p = 0.003$), and day 3 (9.4 vs 9.8, $p = 0.036$) compared to the self-fixating mesh group, where less pain is indicated by a higher score. There was no difference in reported pain between the control and self-fixating mesh group during the remainder of the postoperative dates.

Surgical outcomes measurement system

The SOMS scores are given in Table 3. The mean preoperative scores across the four SOMS domains, pain impact (9.7 vs 9.8, $p = 0.158$), pain quality (9.5 vs 9.7, $p = 0.155$), fatigue (10.0 vs 9.5, $p = 0.658$), and physical function (32.6 vs 32.7, $p = 0.49$), were similar between the control and self-fixating mesh groups, respectively. At 3 weeks postoperatively, there was no difference in SOMS scores for pain impact (8.3 vs 8.0, $p = 0.920$), pain quality (9.1 vs 8.7, $p = 0.740$), fatigue (9.5 vs 8.6, $p = 0.266$), and physical function (31.9 vs 32.3, $p = 0.528$) between the control group and self-fixating mesh group, respectively. At 1 year postoperatively, scores across the SOMS domains pain impact (6.4 vs 6.5, $p = 0.086$), pain quality (6.0 vs 6.5, $p = 0.106$), fatigue (8.0 vs 7.8, $p = 0.522$), and physical function (35.3 vs 35.1, $p = 0.657$) were similar between the control and self-fixating mesh group, respectively. The relationship between the scores over the three time points for each domain is shown in Figs. 2 and 3.

Carolinas comfort scale

The CCS scores are reported in Table 3. A preoperative survey is not administered as this tool's utility is in assessing postoperative pain after inguinal hernia repair. There was no difference between the control group and self-fixating mesh group in all subscales at both 3 weeks and 1 year postoperatively. Additionally, scores on the total scale were similar between the two groups. Overall, at 1 year postoperatively, 16.2% of patients ($n = 24$) reported symptoms that were mild and bothersome or worse, while 83.2% of patients reported

Table 2 Pain journal scores for control versus self-fixating mesh groups, postoperative days 1–7

Time	Control		Self-fixating		*p* value
	Mean ± SD	Median (Min–Max)	Mean ± SD	Median (Min–Max)	
Total patients	*N* = 109		*N* = 98		
Day 1 AM	4.4 ± 1.0	4 (2–7)	4.0 ± 1.0	4 (2–7)	0.0154
Day 1 PM	4.3 ± 0.9	4 (2–7)	4.0 ± 0.9	4 (1–7)	0.0116
Day 1 total	8.7 ± 1.7	9 (4–14)	8.1 ± 1.7	8 (4–14)	0.0099
Day 2 AM	4.6 ± 1.0	5 (2–7)	4.2 ± 1.1	4 (2–7)	0.0009
Day 2 PM	4.6 ± 1.0	5 (2–7)	4.3 ± 1.0	4 (2–7)	0.0100
Day 2 total	9.2 ± 1.9	10 (4–14)	8.5 ± 1.9	8 (4–14)	0.0025
Day 3 AM	4.9 ± 1.0	5 (2–7)	4.6 ± 1.1	5 (3–7)	0.0081
Day 3 PM	4.9 ± 1.0	5 (2–7)	4.8 ± 1.2	5 (2–8)	0.2950
Day 3 total	9.8 ± 1.9	10 (5–14)	9.4 ± 2.1	10 (6–15)	0.0356
Day 4 AM	5.1 ± 1.2	5 (2–7)	5.0 ± 1.0	5 (3–7)	0.5773
Day 4 PM	5.0 ± 1.2	5 (2–7)	5.0 ± 1.1	5 (3–8)	0.7269
Day 4 total	10.2 ± 2.2	10 (5–14)	10.0 ± 2.0	10 (6–15)	0.6772
Day 5 AM	5.2 ± 1.2	5 (2–7)	5.2 ± 1.1	5 (3–7)	0.9502
Day 5 PM	5.2 ± 1.2	5 (3–7)	5.1 ± 1.2	5 (3–8)	0.4945
Day 5 total	10.4 ± 2.3	10 (5–14)	10.3 ± 2.2	10 (6–15)	0.8986
Day 6 AM	5.5 ± 1.2	5 (2–7)	5.3 ± 1.1	5 (3–7)	0.2643
Day 6 PM	5.5 ± 1.3	5 (2–7)	5.3 ± 1.2	5 (2–8)	0.2323
Day 6 total	10.9 ± 2.4	10 (5–14)	10.6 ± 2.3	10 (6–15)	0.1986
Day 7 AM	5.7 ± 1.3	5 (2–7)	5.6 ± 1.2	5 (3–7)	0.4906
Day 7 PM	5.7 ± 1.2	5 (3–7)	5.5 ± 1.2	5 (2–8)	0.2883
Day 7 total	11.4 ± 2.4	11 (6–14)	10.9 ± 2.5	10 (5–15)	0.2895

no or mild, but not bothersome, symptoms. Six patients, or 4.2%, reported severe pain, defined as a total mean score ≥ 4. All three subscales and the total scale for both postoperative time points are displayed in Fig. 4.

Discussion

Long-term pain following inguinal hernia repair is a significant QoL issue, with higher incidence than recurrence. Mesh fixation has been established as a cause of long-term pain. Self-fixating mesh may minimize the need for fixation as other non-randomized series of self-fixating mesh have demonstrated low recurrence without fixation. However, in our current, single-blinded, randomized controlled trial, we found no difference in long-term QoL outcomes in patients receiving self-fixating mesh compared to non-fixating mesh regardless of mesh fixation.

While some studies have shown improved chronic pain outcomes with self-fixating mesh [7, 17], others, such as Ozmen et al. [11] and Nikkolo et al. [5, 6] have found no difference in chronic pain through the use of self-fixating mesh. Similarly, our study found no difference in reported pain on either of our QoL instruments at both 3 months and 1 year postoperatively. Self-fixating mesh showed no benefit over non-fixating mesh in the immediate post-op period with regard to pain medication use and daily pain symptoms. Of note, while we lost 8.1% of patients to follow up before the first postoperative visit at 3 weeks, a sizable portion of our patients travel long distances to undergo hernia repair at our institution. In these cases, we typically convey follow-up information over the phone or through email. Some of these cases contributed to the 8.1% lost to follow up before 3 weeks.

We found an overall rate of chronic pain of 16.2%. In our study, patients who reported a total mean score > 1 on the CCS were considered to have chronic pain. Our reported rate is within the previously reported range of 5–20% [2–4], although it is on the higher end. This is likely because our definition captures patients with mild and bothersome symptoms on the CCS scale, in addition to those with severe or disabling symptoms. For severe chronic pain, defined as a CCS total mean score ≥ 4, we found a rate of 4.2%. This rate is more in line with other reported chronic pain rates from laparoscopic repairs [3, 4, 18, 19].

Nikkolo et al. [5] found a higher rate of foreign body feeling in patients receiving self-fixating mesh at 6 months, which was attributed to microhooks on the self-fixating mesh. These have a resorption time of up to 12 months. We did not find a difference in CCS sensation of mesh scores between groups in our current study. This suggests

Table 3 SOMS and CCS pain scores for control versus self-fixating mesh groups

Variable	Control		Self-fixating		*p* value
	Mean ± SD	Median (Min–Max)	Mean ± SD	Median (Min–Max)	
SOMS preoperative	*N* = 133		*N* = 130		
SOMS pain impact	9.7 ± 4.9	8 (6–30)	9.8 ± 4.1	9 (6–27)	0.1578
SOMS pain quality	9.5 ± 5.4	8 (2–28)	9.7 ± 4.1	9 (4–20)	0.1547
SOMS fatigue	10.0 ± 5.0	8 (6–29)	9.5 ± 4.3	8 (6–28)	0.6580
SOMS physical Function	32.6 ± 4.7	35 (10–36)	32.7 ± 4.0	34 (13–36)	0.4899
SOMS 3 weeks post-op	*N* = 108		*N* = 99		
SOMS pain impact	8.3 ± 3.7	7 (3–23)	8.0 ± 2.9	7 (3–18)	0.9200
SOMS pain quality	9.1 ± 4.5	8 (4–23)	8.7 ± 3.9	8 (4–22)	0.7404
SOMS fatigue	9.5 ± 4.3	8 (5–23)	8.6 ± 3.3	7 (6–21)	0.2664
SOMS physical function	31.9 ± 7.3	35 (6–36)	32.3 ± 7.4	35 (6–36)	0.5275
CCS 3 weeks post-op	*N* = 70		*N* = 78		
Mesh	1.0 ± 2.8	0 (0–18)	0.8 ± 1.8	0 (0–8)	0.8062
Pain	1.9 ± 4.8	0 (0–27)	2.0 ± 3.3	0 (0–12)	0.5722
Movement	1.6 ± 4.5	0 (0–24)	1.0 ± 2.1	0 (0–8)	0.7019
Total	5.9 ± 12.7	1.5 (0–74)	5.0 ± 6.8	2 (0–35)	0.5810
SOMS 1 year post-op	*N* = 82		*N* = 77		
SOMS pain impact	6.4 ± 1.7	6 (3–15)	6.5 ± 1.5	6 (6–14)	0.0860
SOMS pain quality	6.0 ± 3.2	4 (2–19)	6.5 ± 3.2	5 (3–18)	0.1059
SOMS fatigue	8.0 ± 3.3	6 (4–22)	7.8 ± 2.7	7 (5–18)	0.5218
SOMS physical function	35.3 ± 1.5	36 (29–36)	35.1 ± 2.3	36 (20–36)	0.6567
CCS 1 year post-op	*N* = 71		*N* = 72		
Mesh	1.1 ± 4.1	0 (0–31)	0.9 ± 3.2	0 (0–24)	0.8252
Pain	1.0 ± 2.7	0 (0–16)	1.2 ± 2.9	0 (0–16)	0.2622
Movement	0.3 ± 1.7	0 (0–13)	0.4 ± 1.8	0 (0–13)	0.9917
Total	2.5 ± 7.5	0 (0–56)	2.5 ± 7.3	0 (0–53)	0.6429

microhooks may not cause significant discomfort before they are reabsorbed, whether at 3 weeks or 1 year.

Aasvang and Kehlet [20] and Nikkolo et al. [5, 6] report severe preoperative and acute postoperative pain as individual risk factors for chronic pain development. In our study, patients in both groups reported similar preoperative pain across the SOMS domains, suggesting both groups were at similar risk for chronic pain based on the preoperative factor. While we found patients in the self-fixating mesh group had worse pain during the first 3 days postoperatively, we did not find a difference in reported pain between groups at any other time point, including 1 year postoperatively. This suggests acute postoperative pain may not be causative of chronic pain in our study, although this correlation is beyond our scope.

Previous studies have reported shorter operative times for repairs using self-fixating mesh [21] with considerations for reduced wound infection rate [22] and cost-effectiveness [5]. We found no difference in operative times between groups, indicating the potential benefits of reduced operative time in self-fixating mesh may be unfounded. Self-fixating mesh is more difficult to manipulate laparoscopically, and this may lead to longer operative times, particularly early in a surgeon's learning curve. Postoperatively, the control group in our study had a longer length of stay, by an average of around 30 min. Whether this difference has economic implications for the use of self-fixating mesh is beyond the scope of our study.

In our study, we found no recurrences for either group. However, our power analysis was based on estimated incidence of short and long-term postoperative pain, and the study was not powered to determine a difference in recurrence. A randomized trial powered to detect differences in recurrences would likely require over a thousand participants with a recurrence risk of roughly 1%. Therefore, our conclusions regarding the incidence of recurrence should be taken with caution. Future trials are necessary to determine whether self-fixating mesh prevents mesh migration

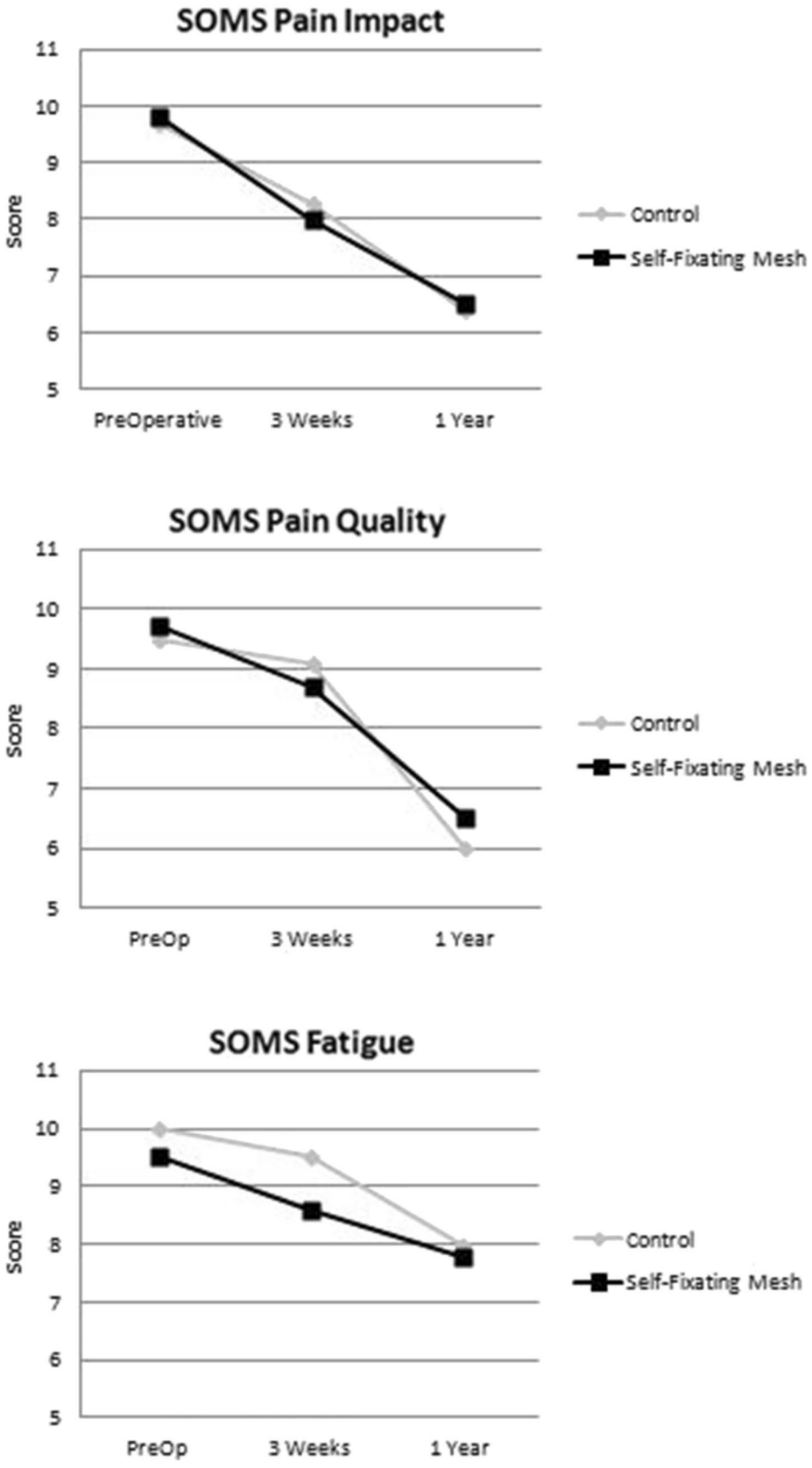

Fig. 2 SOMS pain impact, pain quality, and fatigue domains measured at three time points: preoperatively, 3 weeks and 1 year postoperatively. Lower scores indicate a better QoL outcome

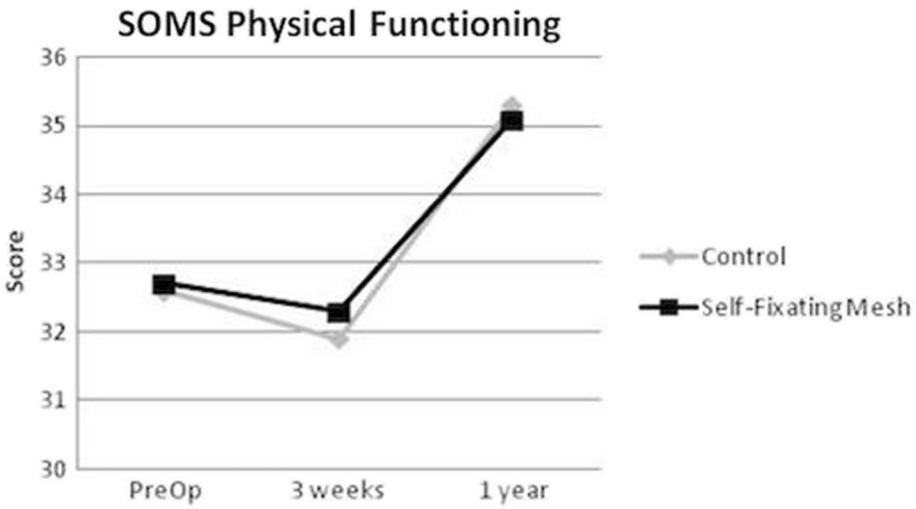

Fig. 3 SOMS physical functioning domain measured at three time points: preoperatively, 3 weeks and 1 year postoperatively. A higher score indicates a better QoL outcome

and leads to reduced recurrence rates. One might postulate that perhaps the most valuable aspect of self-fixating mesh, the ability to provide mesh fixation inferior to the level of the iliopubic tract where tacks cannot be placed due to risk of nerve and vascular injury may prove superior to non-fixating mesh. If fixation below the iliopubic tract could be achieved, this may prevent recurrences that occur independent of tack use, preventing the peritoneum from sliding around the inferior margin of the mesh. This is a known mechanism of recurrence that may be avoided with self-fixating mesh, though additional studies would be required.

Another potential limitation of this study is that both groups were subjected to the same activity restrictions postoperatively. A potential advantage of self-fixating mesh is the ability to return to activities of daily living and strenuous activities, such as lifting, more quickly following surgery than after a repair with non-fixating mesh since mesh migration should be less likely to occur. Further research, including a randomized controlled trial, would be required to determine these potential benefits.

Our study did not scientifically address the cost of these interventions, and in the era of value-based care delivery, this does require consideration. On its face, self-fixating mesh is significantly more expensive than non-fixating mesh at present day; justifying this increased cost may require a clear benefit in terms of recurrence or patient-centered QoL. This cost may be partially offset if costly mesh fixation devices such as tackers or sealants and adhesives are avoided, though most LIHRs can be safely performed with non-fixating mesh and no fixation as discussed earlier.

In conclusion, our study demonstrates that self-fixating mesh does not lead to better QoL outcomes in LIHR at 12-month follow-up. Further trials are needed to determine whether self-fixating mesh reduces recurrence rates or offers advantages for activity resumption for inguinal hernia repair.

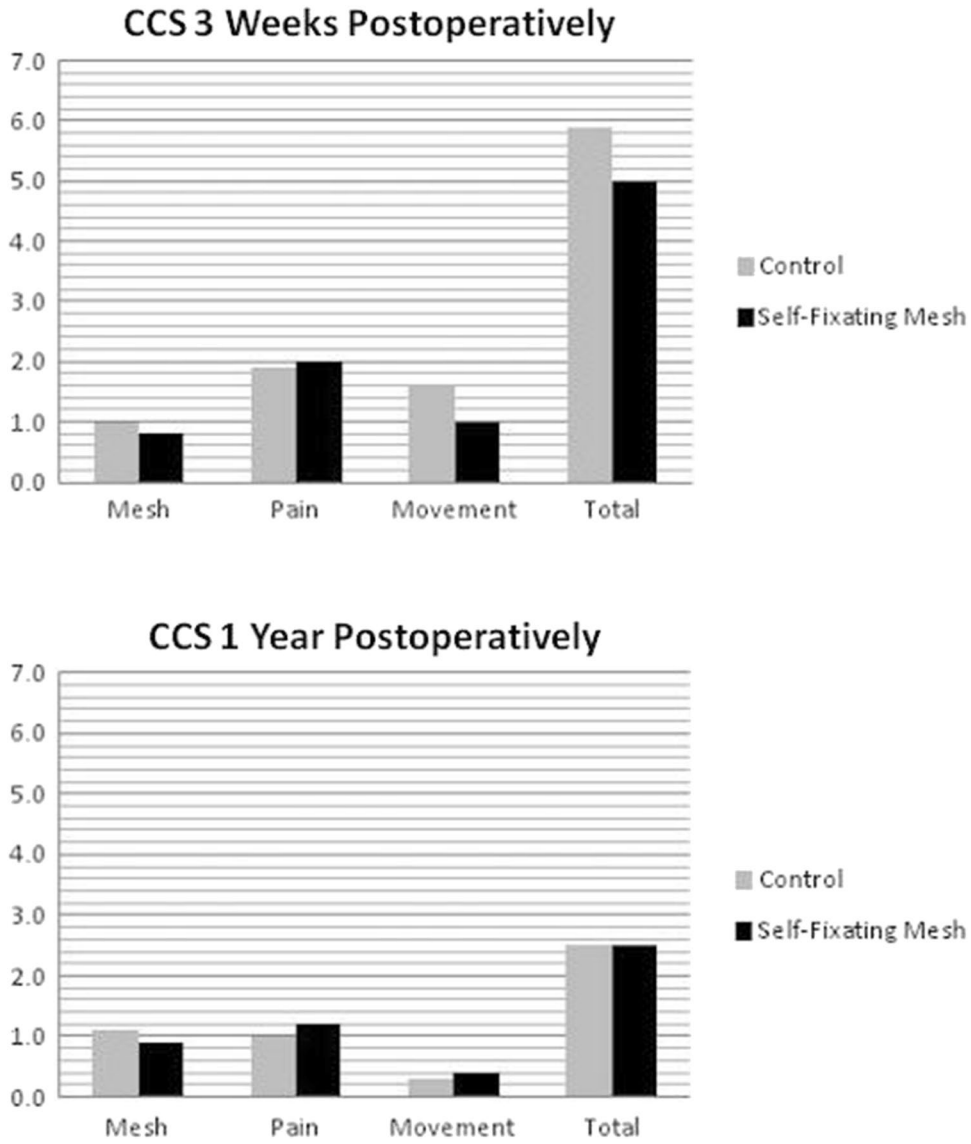

Fig. 4 CCS measured at 3 weeks and 1 year postoperatively. The subscales are sensation of mesh, pain, and movement limitations, while the total reflects the combined score of the three subscales. Lower scores indicate a better QoL outcome

Funding An industry sponsored research grant from Medtronic was received for this study.

Compliance with ethical standards

Disclosures Dr. Michael Ujiki declares honoraria received from Medtronic for speaking engagements unrelated to any commercial products or services utilized in the current study. Dr. John Linn declares industry sponsored research grants from Medtronic and CR Bard for the current study. He also declares personal fees from Medtronic for speaking and teaching unrelated to any commercial products or services utilized in the current study. Merritt Denham, Brandon Johnson, Michelle Leong, Kristine Kuchta, Eliza Conaty, Matt Gitelis, and Drs. Stephen Haggerty, Zeeshan Butt, and Woody Denham have no conflicts of interest or financial ties to disclose.

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