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Open Retromuscular Sugarbaker vs Keyhole Mesh Placement for Parastomal Hernia Repair
A Randomized Clinical Trial

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IMPORTANCE Durable parastomal hernia repair remains elusive. There is limited evidence comparing the durability of the open retromuscular Sugarbaker and keyhole mesh configurations.

OBJECTIVE To determine if the open retromuscular Sugarbaker mesh placement technique would lower parastomal hernia recurrence rates.

DESIGN, SETTING, AND PARTICIPANTS In this single-center, randomized clinical trial, 150 patients with a permanent stoma and associated parastomal hernia who were candidates for open retromuscular parastomal hernia repair were enrolled and randomized from April 2019 to April 2022 and followed up for 2 years.

INTERVENTIONS Following intraoperative assessment to determine the feasibility of either technique, enrolled patients were randomized to receive either retromuscular Sugarbaker or keyhole synthetic mesh placement.

MAIN OUTCOMES AND MEASURES The primary outcome was parastomal hernia recurrence at 2 years. Secondary outcomes included mesh-related complications, wound complications, reoperations, as well as patient-reported pain, abdominal wall–specific quality of life, stoma-specific quality of life, and decision regret at 1 year and 2 years.

RESULTS A total of 150 patients were randomized, and with 91% follow-up at 2 years, there were 13 (17%) parastomal hernia recurrences in the retromuscular Sugarbaker arm and 18 (24%) in the keyhole arm (adjusted risk difference, −0.029; 95% CI, −0.17 to 0.153, and adjusted risk ratio, 0.87; 95% CI, 0.42 to 1.69). There were no statistically significant differences between the Sugarbaker and keyhole groups regarding reoperations for recurrence (2 vs 7, respectively), nonhernia intra-abdominal pathology (4 vs 10, respectively), stoma necrosis (1 vs 0, respectively), mesh-related complications (4 vs 1, respectively), patient-reported pain, abdominal wall–specific quality of life, stoma-specific quality of life, and decision regret at any time point.

CONCLUSIONS AND RELEVANCE In the setting of open parastomal hernia repair, a retromuscular Sugarbaker mesh placement technique was not superior to a keyhole configuration 2 years after repair. Further innovation is necessary to improve parastomal hernia repair outcomes.

TRIAL REGISTRATION ClinicalTrials.gov Identifier: NCT03972553

Visual Abstract

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Supplemental content

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Parastomal hernias present a major source of morbidity for the estimated 725 000 individuals in the US living with an ostomy and a unique technical challenge for surgeons.[1] Often, an open retromuscular mesh repair is preferred in order to address parastomal hernias due to the frequent presence of concomitant ventral hernias or need to resite the stoma, which can be simultaneously addressed through an open retromuscular approach. Due to the unavoidable abdominal wall defect of the stoma trephine, durable repair remains elusive, with contemporary recurrence rates up to 45%.[2,3] The retromuscular Sugarbaker mesh placement technique, which offsets stoma apertures in the anterior and posterior rectus sheaths, has been touted for its recurrence advantage compared with the keyhole technique, which aligns anterior and posterior sheath and mesh apertures. However, existing prospective data comparing the durability of surgical approaches are lacking or limited by the duration of follow-up.[4,5] Therefore, we designed this randomized clinical trial to assess whether the retromuscular Sugarbaker mesh placement technique is superior to the keyhole repair regarding parastomal hernia recurrence.

We previously reported the trial protocol and 90-day safety outcomes of this randomized study comparing the aforementioned mesh configurations. Within 90 days postoperatively, there were no differences with regards to wound morbidity and reoperations.[6] The impending assessment on recurrence, however, limited the full interpretation of these results. Here we report the primary outcome, parastomal hernia recurrence. We hypothesized that the retromuscular Sugarbaker technique would be superior, associated with a lower parastomal hernia recurrence at 2 years postoperatively.

Key Points

Question During open retromuscular parastomal hernia repair, is the retromuscular Sugarbaker mesh placement technique superior to the keyhole technique?

Findings In this randomized clinical trial, the open retromuscular Sugarbaker mesh placement technique was not superior to the keyhole technique in regard to 2-year parastomal hernia recurrence.

Meaning The use of either retromuscular mesh placement technique based on patient anatomy and surgeon expertise is reasonable.

Methods

Study Design and Oversight

After obtaining institutional review board approval we performed a single-center, registry-based, patient- and assessor-blinded randomized clinical trial comparing Sugarbaker and keyhole technique for mesh placement in open retromuscular parastomal hernia repair. The study was conducted and analyzed in accordance with the Consolidated Standards of Reporting Trials (CONSORT) reporting guidelines.[7] The trial was registered on ClinicalTrials.gov (NCT03972553). We previously published the trial protocol and 90-day safety outcomes.[6,8] To facilitate long-term follow-up, the protocol was amended after trial initiation but prior to data analysis, to include post hoc application of patient-reported bulge on the Colostomy Impact score to screen for long-term hernia recurrence.[9,10] All participants provided written informed consent. The full protocol is available in Supplement 1.

Patients and Study Setting

Adult patients with a parastomal hernia in the setting of a permanent stoma who were candidates for an open retromuscular repair were screened. Inclusion criteria were amended after trial commencement to include patients undergoing permanent stoma creation at the time of open retromuscular ventral hernia repair as this was considered equivalent to stoma resiting. Patients were excluded if they had 2 or more stomas preoperatively, if there was insufficient bowel length for either repair technique based on intraoperative assessment, or if mesh-based reconstruction was deferred by the surgeon. Patient recruitment and surgical procedures were performed at a tertiary academic institution. Data about patient race and ethnicity were collected via patient self-report from the electronic health record and categorized as American Indian or Alaskan Native, Asian or Pacific Islander, Hispanic, Middle Eastern, non-Hispanic Black, or non-Hispanic White.

Intervention

All procedures were performed by 1 of 6 qualified surgeons (A.S.P., D.M.K, L.R.A.B., S.R., M.J.R., C.C.P.) with training in advanced abdominal wall reconstruction. Retromuscular hernia repair was performed in all patients, and medium-weight polypropylene mesh was placed using a Sugarbaker or keyhole configuration as previously described (eFigures 1 and 2 in Supplement 2).[8]

Study Outcomes

The primary outcome was the superiority of the Sugarbaker technique compared with the keyhole technique with regards to parastomal hernia recurrence at 2 years. Parastomal hernia recurrence was defined as a pragmatic measure based on blinded consensus review of radiographic imaging, clinical examination, or patient-reported bulge. Cross-sectional imaging was reviewed by 3 surgeons with training in abdominal wall reconstruction, who were blinded to operative technique and surgeon. The reviewers were instructed to consider a parastomal hernia, in accordance with Moreno-Matias classifications II and III, if it involved the protrusion of a separate and distinct segment of bowel or other intra-abdominal content within the musculofascial aperture of the stoma.[11] At least 2 of the 3 assessors needed to agree to reach a consensus assessment. Notably, midline or hernias remote from the stoma were considered separate and distinct from the primary outcome of a recurrence at the stoma site. Clinical assessment of parastomal hernia recurrence by the operating surgeon was allowed in the absence of imaging. In the absence of either radiographic or clinical examination, patient-reported bulge could be used to define parastomal recurrence.

Secondary outcomes included mesh-related complications and wound complications (defined as surgical site

infection, surgical site occurrence, and surgical site occurrence requiring procedural intervention),[12] reoperations, as well as patient-reported pain using the short-form Patient-Reported Outcomes Measure Information System (PROMIS) Pain Intensity Scale,[13] abdominal wall–specific quality of life using the Hernia-Related Quality-of-Life Survey (HerQLes),[14] stoma-specific quality of life using the Colostomy Impact score,[10] and decision regret regarding the choice to undergo parastomal hernia repair using the Decision Regret Scale[15] at 1 year (±4 months) and 2 years (±6 months). The PROMIS 3a Pain Intensity Survey is a 3-question numeric survey regarding pain in the past week, reported as T scores of 30.7 to 71.8, with higher scores indicating more pain.[13,16] The HerQLes comprises 12 Likert-scale questions regarding abdominal wall quality of life scored from 0 to 100, with higher scores indicating better quality of life and a minimum clinically important difference of 15.6 points.[14,17] The Colostomy Impact score was validated in patients with permanent colostomies and scored from 0 to 38 points, with higher scores indicating worse stoma-related quality of life.[10] The Decision Regret Scale is scored from 0 to 100, with higher scores indicating greater regret.[15]

Data Collection

Follow-up was obtained at 1 year (±4 months) and 2 years (±6 months) after surgery or more often if complications occurred. Follow-up consisted of radiographic examination, clinical examination, and patient-reported surveys.

Power Calculation

Post hoc analysis of another randomized clinical trial at our institution found 10.7% and 30.4% recurrence rates for retromuscular Sugarbaker and keyhole mesh configurations, respectively, at the 2-year follow-up.[5] With a power of 80%, holding α at .05, we calculated a sample size of 118 to demonstrate a 20% absolute reduction in 2-year parastomal recurrence. Assuming a 20% rate of loss to follow-up, an enrollment goal of 142 was defined. The enrollment goal was increased to 150 after trial commencement because of the rate of patients who were unable to complete trial end points, given that 8 patients died from causes unrelated to randomization before completing follow-up.

Randomization and Blinding

Randomization was generated by a statistician (C.T.) using a random number of blocks and the concealed randomization scheme, which was housed in a REDCap database. Allocation occurred intraoperatively by a study coordinator once the surgeon completed adhesiolysis and confirmed that bowel length was adequate to safely perform either repair. Patients remained blinded until conclusion of the study period. Hernia recurrence was assessed using blinded consensus review of radiographic images by 3 surgeons. Study coordinators collecting patient-reported outcomes were blinded.

Statistical Analysis

Analyses were performed under the normality assumption, and tests were considered significant at the 5% level. The primary outcome of 2-year hernia recurrence was analyzed as a binary outcome (yes or no). Unadjusted and adjusted logistic regression compared recurrence rates between the 2 repair techniques at 2 years. The adjusted model included prespecified covariates related to baseline disease severity: patient body mass index, recurrent parastomal hernia, stoma disposition (stoma rematured at a new site vs not), and type of stoma. Results, obtained using g computation, are presented as relative and absolute risk differences with a 95% CI. Unbalanced follow-up times are accounted for using rate ratio and rate difference. As a sensitivity analysis, we assessed the treatment effect on time to hernia recurrence using a Cox proportional hazard model. Results are presented by hazard ratio and 95% CI, adjusting for the prespecified covariates.

The secondary end points were not dependent on the primary end point. Comparisons of categorical endpoints were performed using χ^2 or Fisher exact test as appropriate. Comparisons of continuous end points were performed using 2-sample *t* tests or Wilcoxon rank-sum tests as appropriate.

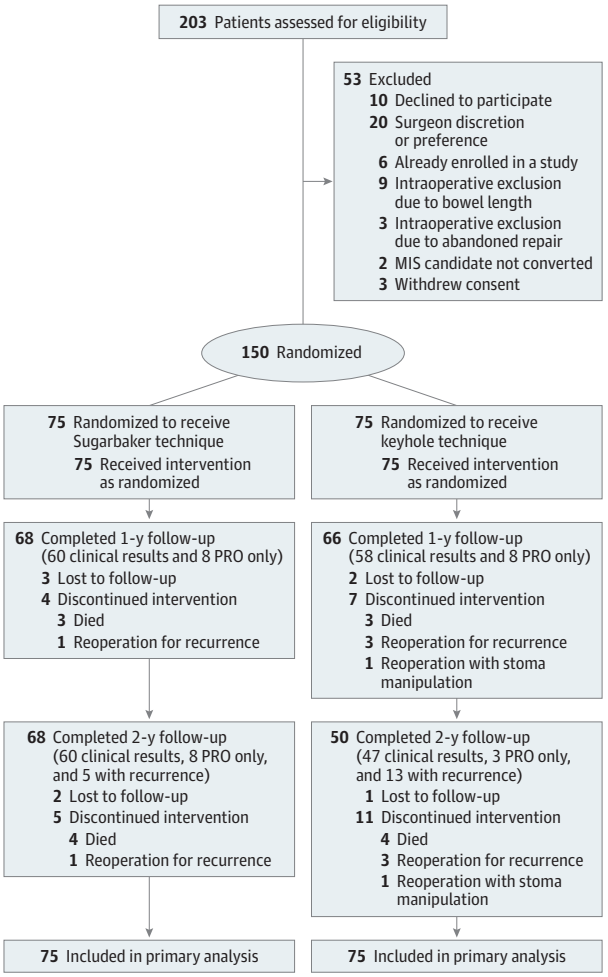
Results

A total of 203 patients were assessed for eligibility from April 2019 to April 2022, of which 150 were randomized (75 to receive Sugarbaker and 75 to keyhole) (**Figure 1**). Baseline characteristics were similar between patients who did not provide consent and enrolled patients (eTable 1 in Supplement 2). The trial ended when follow-up was completed in November 2023. Baseline medical and hernia characteristics were similar between arms. Ileostomy was the most common stoma type, and most were end stomas (**Table 1**). There was 1 case in which the surgeon placed heavyweight polypropylene mesh; this patient was included in analyses as a protocol deviation.

During long-term follow-up, 8 patients died of unrelated causes (4 in each group). Median (IQR) follow-up was 1.7 (1.6-1.9) years postoperatively. A total of 136 patients (90.7%) had follow-up at 2 years postoperatively: 69 patients in the Sugarbaker group and 67 in the keyhole group. Twenty-three patients had a radiographic parastomal hernia recurrence within 1 year postoperatively, 9 of whom underwent reoperation for the recurrence (eTable 2 in Supplement 2). Four patients underwent reoperations unrelated to the parastomal hernia involving manipulation of the stoma or removal of mesh, so they were excluded from additional data collection. Two patients in the Sugarbaker arm and 1 patient in the keyhole arm were lost to follow-up. A total of 102 patients had a radiographic follow-up at 2 years postoperatively. There were 11 patients (8 Sugarbaker, 3 keyhole) with patient-reported outcomes at 2 years postoperatively without clinical or radiographic follow-up. Two of those patients in the Sugarbaker arm with patient-reported outcomes only at the 2-year follow-up reported a parastomal bulge and were considered to have parastomal hernia recurrences by pragmatic definition; the other 6 patients in the retromuscular Sugarbaker group and 3 in the keyhole group denied parastomal bulge and were considered as nonrecurrence per pragmatic definition.

The parastomal hernia recurrence rate at 1 year was 6 patients (8%) in the Sugarbaker arm and 16 patients (21.3%) in

Figure 1. CONSORT Diagram



MIS indicates minimally invasive surgery; PRO, patient-reported outcomes.

the keyhole arm (P = .04). The parastomal hernia recurrence rate at 2 years was 21% overall (31/150 patients), 13 patients (17%) in the Sugarbaker arm and 18 patients (24%) in the keyhole arm with an unadjusted risk difference of −0.067 (95% CI, −0.21 to 0.044; risk ratio, 0.72; 95% CI, 0.35 to 1.24) and adjusted risk difference of −0.029 (95% CI, −0.17 to 0.153; risk ratio, 0.87; 95% CI, 0.42 to 1.69). The hernia recurrence risk Kaplan-Meier time-to-event log-rank test revealed no significant difference in parastomal hernia recurrence risk (**Figure 2**). On multivariate Cox hazard regression model, there was also no difference in parastomal hernia recurrence (hazard ratio, 0.98; 95% CI, 0.44 to 2.20; P = .97) (**Table 2**).

There was no difference in rates of surgical site infection, surgical site occurrence, or surgical site occurrence requiring procedural intervention at the 1- and 2-year follow-ups (eTable 2 in Supplement 2). There were no statistically significant differences in reoperations for hernia recurrence (2 vs 7), unrelated abdominal pathology (4 vs 10), mesh-related complications (4 vs 1), or stoma necrosis (1 vs 0) in the Sugarbaker arm compared with the keyhole arm, respectively. Patients had similar baseline quality-of-life measurements and overall

Table 1. Patient Characteristics

Characteristic	No. (%)	
	Sugarbaker arm (n = 75)	Keyhole arm (n = 75)
Age, median (IQR), y	67.0 (54.0-74.0)	64.0 (54.0-73.5)
BMI, median (IQR)[a]	31.1 (27.9-35.0)	30.1 (27.3-36.0)
Sex		
Male	38 (50.7)	38 (50.7)
Female	37 (49.3)	37 (49.3)
Race and ethnicity		
Black, non-Hispanic	2 (2.7)	1 (1.3)
Hispanic	0	1 (1.3)
Middle Eastern	2 (2.7)	0
White, non-Hispanic	71 (94.7)	73 (97.3)
ASA class		
2	3 (4.0)	5 (6.7)
3	68 (90.7)	68 (90.7)
4	4 (5.3)	2 (2.7)
Diabetes	14 (18.7)	19 (25.3)
Hypertension	49 (65.3)	48 (64.0)
Smoking history		
Current	5 (6.7)	6 (8.0)
Former (<1 y)	2 (2.7)	4 (5.3)
Former (>1 y)	6 (8.0)	10 (13.3)
Never	62 (82.7)	55 (73.3)
History of AAA	2 (2.7)	0
Anticoagulation use	12 (16.0)	5 (6.7)
Antiplatelet use	5 (6.7)	4 (5.3)
Current steroid use	6 (8.0)	11 (14.7)
Heart failure	2 (2.7)	6 (8.0)
COPD	10 (13.3)	7 (9.3)
Dialysis	0	1 (1.3)
Liver failure	0	1 (1.3)
Functional status		
Independent	75 (100)	73 (97.3)
Partially dependent	0	2 (2.6)
Stoma type		
Colostomy	22 (29.3)	26 (34.7)
Ileostomy	39 (52.0)	38 (50.7)
Urinary diversion	14 (18.7)	11 (14.7)
Ileostomy type		
End	38 (97.4)	38 (100)
Loop	1 (2.6)	
Colostomy type		
End	22 (100)	26 (100)
Colostomy location		
Descending	18 (81.8)	22 (84.6)
Transverse	4 (18.2)	4 (15.4)
Urinary diversion type		
Ileal conduit	14 (100)	11 (100)
Ostomy disposition		
Left in situ	38 (50.7)	11 (14.7)
Rematured at the same location	13 (17.3)	17 (22.7)
Moved to a new site	24 (32)	47 (62.7)

Abbreviations: AAA, abdominal aortic aneurysm; ASA, American Society of Anesthesiologists; BMI, body mass index; COPD, chronic obstructive pulmonary disease.

[a] Calculated as weight in kilograms divided by height in meters squared.

Figure 2. Kaplan-Meier Plot for Parastomal Hernia Recurrence

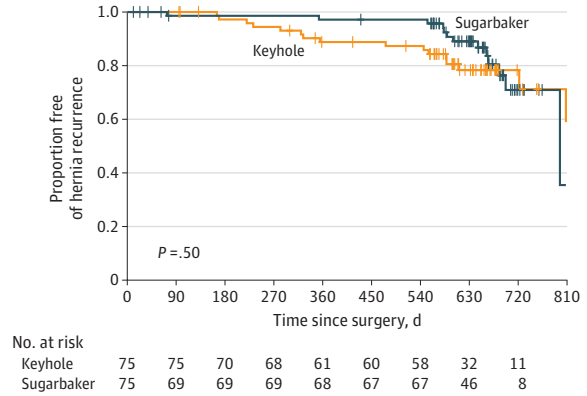


Table 2. Cox Proportional Hazard Regression With Outcome Hernia Recurrence

Characteristic	Hazard ratio (95% CI)	*P* value
Randomization		
Keyhole	1 [Reference]	
Sugarbaker	0.98 (0.44-2.20)	.97
Body mass index	0.94 (0.88-1.01)	.10
Recurrent hernia		
No	1 [Reference]	
Yes	0.67 (0.31-1.45)	.31
Ostomy disposition		
Left in situ	1 [Reference]	
Moved to new site	1.98 (0.76-5.17)	.16
Rematured at same location	0.96 (0.29-3.21)	.95
Stoma type		
Colostomy	1 [Reference]	
Ileostomy	0.95 (0.42-2.17)	.91
Urinary diversion	0.77 (0.29-2.94)	.70

improvements in both groups as well as similar postoperative decision regret (**Table 3**).

Discussion

In a randomized clinical trial of patients undergoing open parastomal hernia repair with retromuscular synthetic mesh, the Sugarbaker technique did not reduce 2-year parastomal hernia recurrence compared with a keyhole repair as hypothesized. Moreover, recurrence rates were relatively high (17% and 24%) regardless of technique. Additional secondary end points regarding mesh-related complications, wound morbidity, reoperation, as well as patient-reported pain, abdominal wall-specific quality of life, stoma-specific quality of life, and decision regret revealed no notable benefit of either technique. The theoretical advantage of the retromuscular Sugarbaker mesh placement technique should be tempered, particularly as it is more technically challenging with a potential for increased early stoma complications.[6]

For a surgical problem with no great solution, the retromuscular Sugarbaker technique has been met with enthusiasm and speculation for surgeons treating patients with parastomal hernia. Originally described in a cadaver model in 2016,[18] the technique allows the stoma bowel to drape over the edge of the prosthetic reinforcement akin to a Sugarbaker parastomal hernia repair with an intraperitoneal prosthetic.[19] Uniquely, the Sugarbaker technique used here places the mesh in the retromuscular position rather than intraperitoneal. Holes in the anterior and posterior layers are intentionally offset to create a "valve effect" that can theoretically overcome chronic intra-abdominal pressure and aperture widening that can lead to recurrence. Our group first reported clinical outcomes of this approach in 38 patients repaired from 2014 to 2016, finding an 11% 1-year recurrence rate and 8% rate (3/38 patients) of mesh-related stoma complications requiring reoperation for associated stoma necrosis, obstruction, and/or erosion.[20]

These stoma complications transiently tempered our use of the technique until we decided to minimize (and in most cases, abandon) the use of transfascial mesh fixation that was thought to contribute to complications at the mesh/stoma interface. This anecdotally reduced perioperative stoma complications. Additional reports of the technique have mostly consisted of case reports and small series with limited follow-up.[21,22] Meanwhile, a post hoc analysis of 108 patients undergoing parastomal hernia repair in a randomized clinical trial of biologic vs medium-weight polypropylene mesh found that retromuscular Sugarbaker repairs had a 10.7% 2-year parastomal hernia recurrence rate compared with 30.4% for keyhole repairs.[5] Pursuing a superiority trial powered to detect a 20% difference in 2-year recurrence seemed both timely and feasible.

The importance of long-term follow-up was evident in our results. First, our 90-day assessment highlighted that our modification to transfascial mesh fixation did not eliminate complications at the stoma/mesh interface that remained more common in retromuscular Sugarbaker repairs, despite not achieving statistical significance. Next, surgeons' anecdotal impression that retromuscular Sugarbaker repairs are more durable is explained by the early recurrences in the keyhole arm that were erased by the second year. As Figure 2 highlights, had our primary outcome ended at 1 year, we would likely have touted the superiority of the retromuscular Sugarbaker technique. Additional follow-up offers interpretations that keyhole operations fail earlier or that the retromuscular Sugarbaker repairs delay recurrence. Finally, an overall 21% recurrence rate at 2 years for an operation often characterized as an exercise in futility may be interpreted as the best case scenario offered by a high-volume center, though this recurrence rate was still coupled with humbling episodes of stoma complications.[2,23]

Regarding our pragmatic recurrence definition, it is important to note that most recurrence assessments were based on blinded computed tomography assessments with agreement from at least 2 of 3 surgeons regarding parastomal hernia recurrence, defined as a "the protrusion of a separate and distinct segment of bowel or other intra-abdominal content within the musculofascial aperture" (ie, Moreno-Matias II/III).[11]

Table 3. Patient-Reported Outcomes

Score	No. of patients	Sugarbaker (n = 75)	Keyhole (n = 75)	*P* value
Pain intensity, median (IQR)[a]				
Baseline	148	49.4 (40.2-57.5)	52.1 (40.2-57.5)	.62
30 d	144	52.1 (43.5-54.5)	52.1 (46.3-54.5)	.43
1 y	130	36.3 (30.7-46.3)	36.3 (30.7-49.4)	.85
2 y	122	30.7 (30.7-43.5)	30.7 (30.7-43.5)	.56
Abdominal wall quality of life, median (IQR)[b]				
Baseline	148	33.3 (18.3-56.7)	30.0 (16.7-53.5)	.67
30 d	144	45.0 (29.2-75.8)	48.3 (28.3-68.3)	.73
1 y	128	68.3 (40.0-91.7)	71.7 (41.7-86.7)	.76
2 y	123	78.3 (50.0-93.3)	78.3 (60.4-91.7)	.91
Stoma quality of life, median (IQR)[c]				
Baseline	97	18.0 (14.5-24.0)	21.0 (13.0-24.8)	.44
30 d	103	12.0 (6.0-17.2)	11.0 (7.5-17.0)	.81
1 y	127	11.5 (8.0-17.0)	12.0 (8.5-17.0)	.56
2 y	120	11.0 (7.0-16.0)	11 (7.0-15.0)	.93
Decision regret, median (IQR)[d]				
30 d	103	7.5 (0-20.0)	0 (0-17.5)	.10
1 y	129	0 (0-10.0)	0 (0-12.5)	.65
2 y	121	0 (0-10.0)	0 (0-10.0)	.96

[a] National Institutes of Health Patient-Reported Outcomes Measure Information System short form 3a (T score).

[b] Hernia-Related Quality-of-Life Survey summary score.

[c] Colostomy Impact score.

[d] Decision Regret Scale score.

Given no "gold standard" for recurrence assessment and limitations of cross-sectional imaging in supine positioning, exploratory outcomes are critical to identify patient-perceived benefits relative to either technique that are not elucidated by recurrence assessment. As Table 3 summarizes, there does not appear to be a signal benefiting either technique for pain, abdominal wall quality of life, stoma-specific quality of life, or decision regret relative to undergoing either operation. Furthermore, while a 21% overall 2-year recurrence rate could be viewed pessimistically, patient-reported outcomes offer a more optimistic interpretation, with dramatic improvement in pain, quality of life, and low decision regret regardless of technique. In the absence of obstruction or strangulation, parastomal hernia repair is generally undertaken to improve quality of life. These data suggest that patient-reported outcomes may be the paramount metric of a parastomal hernia repair's success rather than absolute recurrence rates.

Limitations

There are several legitimate criticisms to the design of this endeavor. First, the protocol was amended after commencement to include patients undergoing permanent stoma creation at the time of ventral hernia repair. This led to the enrollment and randomization of 3 patients who would otherwise have been excluded. The investigators felt that this scenario was equivalent to resiting an existing stoma but acknowledge that a surgeon's decision whether or not to relocate the stoma, and whether or not that constitutes repair vs prophylactic reinforcement, is a confounding variable in itself. The decision to relocate or remature could be confounded by the randomization, as surgeons randomized to perform the keyhole technique may prefer to take down the stoma to bring it through a cruciate incision rather than a true "keyhole" slit, and patients randomized to receive retromuscular Sugarbaker could conversely avoid stoma mobilization more often if there was no other reason to move the stoma. Ultimately, we considered this decision inherent to the operation and part of intraoperative decision-making and opted for a prespecified logistic regression to account for this in addition to stoma type, stoma disposition (ie, left in situ, rematured, etc), recurrent nature, and body mass index. Following such analysis, none was identified as an independent predictor of recurrence or protective factor.

Second, the definition of parastomal hernia recurrence was amended after trial commencement to include patient-reported bulge to maximize follow-up in the case that radiographic follow-up was lacking. Ultimately this proved unnecessary as 23 patients had known recurrences and 102 additional patients had radiographic follow-up at 2 years, and the addition of the 11 patient-reported bulge responses did not affect the recurrence. Notably, any protocol changes occurred before any review of the data, and there were no interim analyses.

Third, the data used to power this trial were based on an exploratory post hoc analysis of another randomized clinical trial that included biologic and synthetic mesh, which may have been a confounding variable in the parastomal recurrence assessment that was an exploratory outcome. Fourth, there were unmeasured technical factors for both configurations that could not be standardized or measured. Examples include the "tightness" of a keyhole/cruciate mesh incision or fascial aperture or the amount of offset between anterior and posterior apertures for retromuscular Sugarbaker repairs. Finally, it is unknowable whether these results for either technique generated by a high-volume center are reproducible elsewhere.

Ultimately, these findings allow for several important clinical takeaways that we have applied to our practice. Neither

technique emerged as a clear winner. While it seems that the retromuscular Sugarbaker technique may at least delay recurrence, the increased complexity of the operation, potential for more upfront stoma complications, and similar patient-reported outcomes provide reassurance that using the keyhole mesh placement technique is still reasonable, particularly if the patient anatomy or surgeon experience does not favor pursuing a retromuscular Sugarbaker approach. Parastomal hernia repairs are complex operations, and regardless of surgical approach, recurrence rates are high. Additional innovation is needed to improve outcomes, but elective repairs should be reserved for specialized centers dedicated to abdominal wall reconstruction.

Conclusions

In open parastomal hernia repair with retromuscular mesh, Sugarbaker mesh placement was not superior to a keyhole configuration at 2 years postoperatively. Further innovation is necessary to improve outcomes in parastomal hernia repairs.

ARTICLE INFORMATION

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Concept and design: Fafaj, Thomas, Krpata, Rosen, Petro.
Acquisition, analysis, or interpretation of data: Maskal, Ellis, Costanzo, Thomas, Prabhu, Krpata, Beffa, Tu, Zheng, Miller, Rosen, Petro.
Drafting of the manuscript: Maskal, Thomas, Beffa, Rosen.
Critical review of the manuscript for important intellectual content: Maskal, Ellis, Fafaj, Costanzo, Prabhu, Krpata, Beffa, Tu, Zheng, Miller, Rosen, Petro.
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Supervision: Fafaj, Prabhu, Krpata, Beffa, Rosen, Petro.

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Data Sharing Statement: See Supplement 3.

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Invited Commentary

Parastomal Hernias—A Recurring Problem for Surgeons and Patients

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Parastomal hernias present a difficult (and recurring) problem for surgeons. Despite advances in surgical techniques and prosthetic reinforcements, there has not been a dramatic reduction in recurrence rates for this patient population.

In an effort to bring an evidence-based algorithm to decision-making around the surgical technique used for parastomal hernia repair, the recent study in *JAMA Surgery* by Maskal et al[1] assessed 2-year recurrence rates in the retromuscular Sugarbaker vs keyhole mesh repair in a randomized clinical trial. This article[1] addresses an important gap in the literature. In prior studies, surgical techniques for repair were only evaluated in a retrospective or post hoc fashion. Meta-analysis and systematic reviews concluded that the Sugarbaker technique was associated with a lower rate of hernia recurrence.[2,3] Subgroup analysis, however, did not identify a difference when only "modern studies" (ie, those from 2015-2021) were included.[3]

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The current study[1] provides randomized clinical trial data that no difference exists in recurrence rates between the 2 techniques at 2-year follow-up. These conclusions were based on a relatively large sample size with excellent follow-up, which would usually indicate wide applicability. However, there is a subtle bias inherent to the study. The authors only compared the 2 techniques in the open approach. In the era of minimally invasive techniques (which are widely used at the study site), the choice to perform an open repair already influences the patient cohort that is being studied. Further explanation about the algorithm by which this decision was made (ie, comorbidities, anatomy, etc) would be useful to understand whether the conclusions would be applicable to the same techniques performed with a minimally invasive approach.

Another technical aspect to consider is that some stomas were resited during the operation, which the authors acknowledge as a confounding variable. Interestingly, this occurred in 63% of individuals in the keyhole group vs only 31% in the Sugarbaker group, although stoma relocation was not identified as a significant factor in logistic regression analysis. Nonetheless, a portion of the results from this study straddle the line between hernia repair and hernia prevention.

The study also posits that these hernia repairs should be done at specialized abdominal wall centers to provide the best patient outcomes. This strategy has been tried in Denmark, without any demonstrable difference in recurrence rates.[4]

As we continue to search for the most durable technique for parastomal hernia repair, the patient-related outcomes are certainly favorable for both strategies studied. It may be reasonable to conclude that in the complex patient population requiring an open parastomal hernia repair with possible relocation of the stoma, a retromuscular Sugarbaker technique with some of the significant complications noted may not confer an advantage over the keyhole technique, which is often technically easier to perform.

ARTICLE INFORMATION

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