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Effect of Hernia Mesh Weights on Postoperative Patient-Related and Clinical Outcomes After Open Ventral Hernia Repair
A Randomized Clinical Trial

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IMPORTANCE Although multiple versions of polypropylene mesh devices are currently available on the market for hernia repair, few comparisons exist to guide surgeons as to which device may be preferable for certain indications. Mesh density is believed to impact patient outcomes, including rates of chronic pain and perception of mesh in the abdominal wall.

OBJECTIVE To examine whether medium-weight polypropylene is associated with less pain at 1 year compared with heavy-weight mesh.

DESIGN, SETTING, AND PARTICIPANTS This multicenter randomized clinical trial was performed from March 14, 2017, to April 17, 2019, with 1-year follow-up. Patients undergoing clean, open ventral hernia repairs with a width 20 cm or less were studied. Patients were blinded to the intervention.

INTERVENTIONS Patients were randomized to receive medium-weight or heavy-weight polypropylene mesh during open ventral hernia repair.

MAIN OUTCOMES AND MEASURES The primary outcome was pain measured with the National Institutes of Health (NIH) Patient-Reported Outcomes Measurement Information System (PROMIS) Pain Intensity Short Form 3a. Secondary outcomes included quality of life and pain measured at 30 days, quality of life measured at 1 year, 30-day postoperative morbidity, and 1-year hernia recurrence.

RESULTS A total of 350 patients participated in the study, with 173 randomized to receive heavy-weight polypropylene mesh (84 [48.6%] female; mean [SD] age, 59.2 [11.4] years) and 177 randomized to receive medium-weight polypropylene mesh (91 [51.4%] female; mean [SD] age, 59.3 [11.4] years). No significant differences were found in demographic characteristics (mean [SD] body mass index of 32.0 [5.4] in both groups [calculated as weight in kilograms divided by height in meters squared] and American Society of Anesthesiologists classes of 2-4 in both groups), comorbidities (122 [70.5%] vs 93 [52.5%] with hypertension, 44 [25.4%] vs 43 [24.3%] with diabetes, 17 [9.8%] vs 12 [6.8%] with chronic obstructive pulmonary disease), or operative characteristics (modified hernia grade of 2 in 130 [75.1] vs 140 [79.1] in the heavy-weight vs medium-weight mesh groups). Pain scores for patients in the heavy-weight vs medium-weight mesh groups at 30 days (46.3 vs 46.3, $P = .89$) and 1 year (30.7 vs 30.7, $P = .59$) were identical. No significant differences in quality of life (median [interquartile range] hernia-specific quality of life score at 1 year of 90.0 [67.9-96.7] vs 86.7 [65.0-93.3]; median [interquartile range] hernia-specific quality of life score at 30 days, 45.0 [24.6-73.8] vs 43.3 [28.3-65.0]) were found for the heavy-weight mesh vs medium-weight mesh groups. Composite 1-year recurrence rates for patients in the heavy-weight vs medium-weight polypropylene groups were similar (8% vs 7%, $P = .79$).

CONCLUSIONS AND RELEVANCE Medium-weight polypropylene did not demonstrate any patient-perceived or clinical benefit over heavy-weight polypropylene after open retromuscular ventral hernia repair. Long-term follow-up of these comparable groups will elucidate any potential differences in durability that have yet to be identified.

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Chronic pain is a dreaded yet common complication after ventral hernia repair with mesh.[1,2] Although the cost associated with specific postherniorrhaphy chronic pain is not well quantified, a 2008 estimate of the annual cost to society of common chronic pain conditions in the US, including postoperative pain, was conservatively estimated to be in the range of $560 billion to $635 billion.[3] Furthermore, chronic postherniorrhaphy pain may contribute to new, persistent opioid use,[4] decreased patient satisfaction,[2] and a substantial health care resource use burden in terms of telephone calls to surgeons, unscheduled clinic visits, and emergency department visits.[5]

Many versions of permanent synthetic mesh are currently available, and the potential correlation of mesh properties with chronic pain indicates a need for a better understanding of that relationship. Although standard heavy-weight polypropylene mesh significantly decreases the risk of hernia recurrence,[6] its usual configuration has rendered it capable of withstanding a force of 6 to 10 times the calculated tensile strength of the average abdominal wall, suggesting that it is overengineered to a supratherapeutic strength.[7,8] Its use is also associated with a significant risk of long-term complications,[9] notably an 8-fold increased risk for developing chronic pain after repair.[5]

The decrease of hernia recurrence rates related to the use of mesh has given way to a more contemporary but nonetheless impactful measure of success after incisional herniorrhaphy in terms of postoperative quality of life and pain.[10,11] By decreasing the overall amount of foreign-body material and presumably therefore the amount of associated unorganized or reactive scar formation, reduced-weight meshes have been developed as a means to leverage the excessive strength of standard heavy-weight polypropylene, while improving adherence and therefore theoretically improving the risk of chronic postoperative pain. Although some preliminary reports[12,13] have suggested that the decrease in overall mesh material in reduced-weight meshes may confer some unknown risk of mesh fracture, a strong argument for their use can still be made from the aforementioned data concerning maximum burst strength, abdominal wall adherence, degree of foreign-body response, amount of shrinkage, and advantages of larger pore sizes in the mesh.[8]

Given the high volume of ventral hernia repair performed annually in the US and the potential that technical specifications of mesh devices may contribute to the estimated 28% of chronic pain postoperatively,[2] there is an urgent need to produce high-level evidence delineating the relationship between specific mesh devices and chronic postoperative pain. This randomized clinical trial aimed to investigate the effect of polypropylene mesh weight on clinical outcomes and patient-reported outcomes (PROs). We hypothesized that medium-weight mesh would improve postoperative pain and quality-of-life scores, with no difference in early clinical outcomes or recurrence rates.

Key Points

Question Does hernia mesh weight impact postoperative patient-reported and clinical outcomes after open ventral hernia repair?

Findings In this randomized clinical trial of 350 patients, medium-weight and heavy-weight polypropylene mesh had similar patient-reported postoperative pain 1 year after open ventral hernia repair.

Meaning Medium-weight polypropylene mesh did not have any patient-perceived or clinical benefit over heavy-weight polypropylene mesh after open ventral hernia repair.

Methods

We designed a multi-institutional randomized clinical trial to examine whether medium-weight mesh leads to less pain 1 year after open retromuscular ventral hernia repair. The primary outcome was pain 1 year after open ventral hernia repair as defined by the National Institutes of Health (NIH) Patient-Reported Outcomes Measurement Information System (PROMIS) Pain Intensity Short Form 3a.[14,15] Secondary outcomes included 30-day postoperative morbidity, 1-year hernia recurrence, and 1-year patient-reported quality of life as defined by the abdominal wall-specific hernia-specific quality of life (HerQLes) survey.[16] The study was embedded in the Abdominal Core Health Quality Collaborative (ACHQC; formerly the Americas Hernia Society Quality Collaborative).[17] Institutional review board approval was obtained before initiating study enrollment at each institution. All patients who met inclusion and exclusion criteria and agreed to participate provided written informed consent. Study participation was voluntary, and no compensation was provided. All data were deidentified. The study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guideline. The Trial Protocol and Statistical Analysis Plan are available in Supplement 1.

Eligible patients were recruited from March 14, 2017, to April 17, 2019. Ten surgeons at 4 institutions (Cleveland Clinic, Vanderbilt University, Greenville Health System, and Medical College of Wisconsin) enrolled patients in the trial. Patients undergoing elective, open, clean, retromuscular ventral hernia repair with planned mesh reinforcement were considered for the study. Patients were excluded if they were younger than 18 years, had a nonmidline ventral hernia (ie, flank hernia), had a hernia width greater than 20 cm measured intraoperatively, primary fascial closure could not be achieved, the Centers for Disease Control and Prevention wound class was II to IV, or the patient declined participation in the trial. The study concluded in April of 2020 after the final 1-year follow-up was complete. There were 6 patients in the heavy-weight mesh group and 5 in the medium-weight mesh group who did not follow up within the 30-day outcome window and were not included in the 30-day analysis. Sixteen patients in each group were lost to follow-up, comprising 10% of the heavy-weight mesh group and 9% of the medium-weight mesh group and were not included in the final 1-year analysis regarding our primary outcome.

Surgical Procedure, Randomization, and Masking

All operations were performed through a midline approach, and defect size was measured according to European Hernia Society guidelines.[18] After retromuscular plane development

(eMethods in Supplement 2) and closure of the posterior rectus sheath, patients were randomized to receive medium-weight (40-60 g/m^2) or heavy-weight (>75 g/m^2) polypropylene mesh. Randomization was performed by a research coordinator who was not directly involved with the operation and occurred through a central concealed randomization scheme housed in REDCap (Research Electronic Data Capture) by using a random number of blocks with a 1:1 ratio of assigning patients to each arm. Because of the multi-institutional nature of the study, specific mesh products were not standardized. Patients were blinded to mesh weight after surgery until completion of the trial.

Data Collection and Outcomes

Data on baseline patient demographic characteristics were obtained at initial patient recruitment, information on operative details was collected at the point of care, and all were maintained in the ACHQC.[10] Patient follow-up visits occurred in person or via a virtual visit at a mean (SD) of 30 (15) days and 12 (2) months postoperatively. When patients could not attend their 1-year follow-up visit in person or through a virtual visit, information was collected by telephone. The PRO forms were completed at each visit (eMethods in Supplement 2). Surgical site infection, surgical site occurrence, surgical site occurrence requiring a procedural intervention, ventral hernia recurrence, and hospital length of stay were recorded.[19] Hernia recurrence was assessed by physical examination, the Hernia Recurrence Inventory (HRI), and/or computed tomography (CT) whenever possible[20] (detailed description of hernia assessment is given in the eMethods in Supplement 2).

A data safety monitoring committee was established before initiation of the study and met after the enrollment of every 100 patients. No safety concerns were raised.

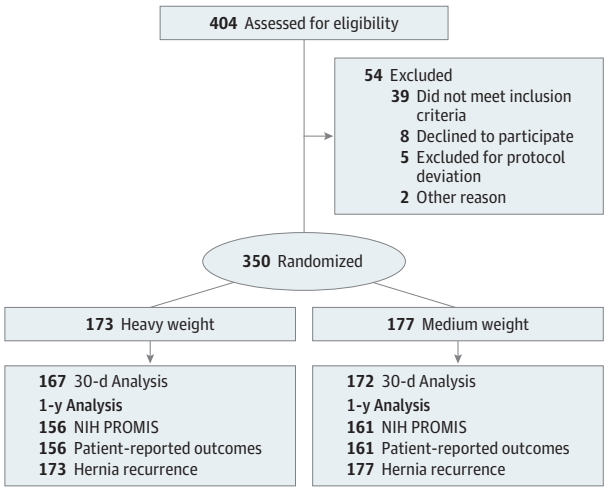
Statistical Analysis

On the basis of preliminary data from the ACHQC regarding the NIH PROMIS Pain Intensity Short Form 3a pain scores, medium-weight mesh demonstrated a 2.8-point benefit over heavy-weight mesh when comparing the degree of improvement from patients' baseline pain score to 1-year outcomes. Although there is no established minimally important clinical difference in hernia surgery, a range of 2 to 3 points has been suggested as the minimally important clinical difference for the pain domain in PROMIS.[21] Assuming an α of .05 and a β of 80% a total sample size of 320 patients was required to demonstrate difference in the NIH PROMIS Pain Intensity Short Form 3a pain scores of 2.8 between groups. Assuming a 10% long-term loss to follow-up, a patient enrollment goal of 356 was established.

All patients were analyzed on an intent-to-treat basis after randomization and included in the final analysis. Categorical variables were examined using the Pearson χ^2, and all continuous variables were examined using the nonparametric Wilcoxon rank sum test. The categorical variables are reported using proportions, and continuous variables are reported using the median and interquartile range (IQR). An adjusted analysis was performed for quality-of-life outcomes at 30 days and 1 year using a cumulative probability regression model with logit link. Baseline score and treatment assignment were included in the regression model. Odds ratios (ORs) and CIs for the treatment effect of medium-weight vs heavy-weight mesh were calculated from the regression models. Moreover, CIs were calculated for differences in means using bootstrap resampling. Logistic regression models for surgical site infection, surgical site occurrence, surgical site occurrence requiring a procedural intervention, recurrence, and mesh sensation outcomes were constructed with treatment assignment as the primary predictor and a baseline risk score (Outcomes Reporting App for Clinical and Patient Engagement predicted probability[22]) to adjust for baseline disease severity. The primary tool of inference for each model/outcome was the treatment assignment ORs and 95% CIs.

A 2-sided $P < .05$ was considered statistically significant. Statistical analysis was performed with R software (R Foundation for Statistical Computing).

Figure. Study Flow Diagram



NIH PROMIS indicates National Institutes of Health Patient-Reported Outcomes Measurement Information System.

Results

A total of 350 patients participated in the study, with 173 randomized to receive heavy-weight polypropylene mesh (84 [48.6%] female; mean [SD] age, 59.2 [11.4] years) and 177 randomized to receive medium-weight polypropylene mesh (91 [51.4%] female; mean [SD] age, 59.3 [11.4] years) (**Figure**). Baseline patient demographic characteristics are outlined in **Table 1**. No significant differences were found in demographic characteristics (mean [SD] body mass index of 32.0 [5.4] in both groups [calculated as weight in kilograms divided by height in meters squared] and American Society of Anesthesiologists classes of 2-4 in both groups), comorbidities (122 [70.5%] vs 93 [52.5%] with hypertension, 44 [25.4%] vs 43 [24.3%] with diabetes, 17 [9.8%] vs 12 [6.8%] with chronic obstructive pulmonary disease), or operative characteristics (modified hernia grade of 2 in 130 [75.1] vs 140 [79.1] in the heavy-weight vs medium-weight mesh groups). Operative and hernia-related

Table 1. Patient Demographic Characteristics and Operative Details[a]

Characteristic	Heavy-weight mesh (n = 173)	Medium-weight mesh (n = 177)
Age, mean (SD), y	59.2 (11.4)	59.3 (11.4)
Sex		
Female	84 (48.6)	91 (51.4)
Male	89 (51.4)	86 (48.6)
BMI, mean (SD)	32.0 (5.4)	32.0 (5.4)
ASA class		
1	0	0
2	27 (15.6)	39 (22.0)
3	141 (81.5)	135 (76.3)
4	5 (2.9)	3 (1.7)
5	0	0
Immunosuppressants	22 (12.7)	18 (10.2)
Smoker within 1 y	20 (11.6)	19 (10.7)
Hypertension	122 (70.5)	93 (52.5)
Diabetes	44 (25.4)	43 (24.3)
COPD	17 (9.8)	12 (6.8)
Recurrent hernia	94 (54.3)	91 (51.4)
No. of prior hernia repairs		
0	79 (45.7)	86 (48.6)
1	47 (27.2)	42 (23.7)
2	25 (14.5)	22 (12.4)
3	6 (3.5)	11 (6.2)
4	11 (6.4)	7 (4.0)
≥5	5 (2.9)	9 (5.1)
Modified hernia grade		
1	43 (24.9)	37 (20.9)
2	130 (75.1)	140 (79.1)
3	0	0
Prior mesh present	67 (38.7)	69 (39.0)
Mesh excision during hernia repair		
None	7 (10.4)	9 (13.0)
Partial	8 (11.9)	9 (13.0)
Complete	52 (77.6)	51 (73.9)
Hernia width, median (IQR), cm	14 (12-16)	15 (12-17)
Myofascial release	173 (100)	177 (100)
Posterior rectus sheath release	31 (17.9)	33 (18.6)
Transversus abdominis release	142 (82.1)	144 (81.4)
Mesh size, median (IQR), cm^2	900 (900-900)	900 (900-900)
Subcutaneous flaps raised	10 (5.8)	8 (4.5)
Operative time, min		
0-59	0	0
60-119	19 (11.0)	26 (14.7)
120-179	75 (43.4)	59 (33.3)
180-239	47 (27.2)	57 (32.2)
≥240	32 (18.5)	35 (19.8)

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); COPD, chronic obstructive pulmonary disease; IQR, interquartile range.

[a] Data are presented as number (percentage) of patients unless otherwise indicated.

characteristics were similar between groups, with median (IQR) hernia widths of 14 (12-16) vs 15 (12-17) cm, rates of prior mesh placement of 67 (38.7%) vs 69 (39.0%), operative times of 120 to 179 minutes in 75 (43.4%) vs 59 (33.3%) participants, and use of myofascial advancement flaps in 173 (100%) vs 177 (100%) participants in the heavy-weight vs medium-weight mesh groups, indicating comparable operative complexity. No significant differences were found in 30-day outcomes in the heavy-weight vs medium-weight mesh groups (median [interquartile range] NIH PROMIS pain T score at 30 days, 46.3 [43.5-54.5] vs 46.3 [43.5-52.7]; mean [interquartile range] hernia-specific quality of life score at 30 days, 45.0 [24.6-73.8] vs 43.3 [28.3-65.0]) (**Table 2**). A detailed description of the 30-day outcomes is given in the eResults in Supplement 2.

Evaluation of quality of life and pain occurred at 3 time points: baseline, 30 days after surgery, and 1 year after surgery. All patients completed the NIH PROMIS Pain Intensity Short Form 3a pain assessments and the HerQLes forms except for 6 (4 in the heavy-weight mesh group and 2 in the medium-weight group) patients at baseline, 10 (5 in the heavy-weight mesh group and 5 in the medium-weight mesh group) patients at 30 days, and 33 (17 in the heavy-weight mesh group and 16 in the medium-weight group) patients at 1 year after surgery. Patients with missing PRO forms were excluded from analysis for that time point. No significant difference was found between groups at any time point for the primary outcome measure of the study, the NIH PROMIS Pain Intensity Short Form 3a pain score (median [interquartile range] NIH PROMIS pain T score at 30 days, 46.3 [43.5-54.5] vs 46.3 [43.5-52.7] in the heavy-weight vs medium-weight mesh groups) (**Table 3**). There was a reduction in median pain by 33% from baseline scores in both groups at 1 year after surgery (from 46.3 to 30.7 in the heavy-weight mesh group and 46.3 to 30.7 in the medium-weight mesh group) as well as a baseline-adjusted difference in expected 30-day pain scores of −0.25 (95% CI, −1.8 to 1.34) and in 1-year pain scores of −0.37 (95% CI, −2.15 to 1.29). Likewise, the median (IQR) HerQLes scores were similar at baseline (35.0 [20.0-48.3] vs 36.7 [22.5-58.3]), 30 days (45.0 [24.6-73.8] vs 43.3 [28.3-65.0]), and 1 year (90.0 [67.9-96.7] vs 86.7 [65.0-93.3]) in the heavy-weight vs medium-weight mesh groups (Table 3). Patients demonstrated a significant improvement in functional quality of life in both groups because the median HerQLes scores increased from 35 to 90 in the heavy-weight mesh group and 37 to 87 in the medium-weight mesh group. Differences were seen in the expected HerQLes scores of −1.87 (95% CI, −6.86 to 3.012) at 30 days and −3.87 (95% CI, −8.22 to 1.09) at 1 year after adjusting for baseline scores.

Patients' perception of mesh within their abdominal walls was the same despite mesh weight, with 33 patients (19.1%) in the heavy-weight mesh group and 32 patients (18.1%) in the medium-weight mesh group answering yes to the question, "Do you feel your mesh?" (P = .93).

Hernia recurrence was measured at 1-year follow-up in 3 ways: (1) physical examination, (2) HRI, and (3) radiographically with CT. At 1-year follow-up, 215 patients (105 in the heavy-weight mesh group and 110 in the medium-weight mesh group) were assessed via physical examination, 317 (156 in the heavy-weight mesh group and 161 in the medium-weight mesh group) via HRI, and 178 (93 in the heavy-weight mesh group and 85 in the medium-weight mesh group) had CT evaluation. No differences were detected in hernia recurrence rates in the heavy-

Table 2. Outcomes at 30 Days of Follow-up[a]

Outcome	Heavy-weight mesh (n = 167)	Medium-weight mesh (n = 182)	*P* value
SSI	8 (4.8)	10 (5.5)	
Deep	3 (1.8)	5 (2.7)	
Organ space	0	0	.68
Superficial	5 (3.0)	5 (2.7)	
SSI requiring treatment	8 (4.8)	10 (5.5)	
Oral antibiotics	8 (4.8)	7 (3.7)	.68
Intravenous antibiotics	2 (1.2)	3 (1.6)	
SSI requiring procedural intervention	5 (3.0)	9 (4.9)	
Wound opening	3 (1.8)	9 (4.9)	
Wound debridement	1 (1.2)	5 (2.7)	
Percutaneous drainage	2 (1.2)	0	.30
Mesh removal			
Partial	0	1 (0.5)	
Complete	0	0	
SSO	20 (12.0)	18 (9.9)	.66
SSO requiring treatment	20 (12.0)	18 (9.9)	
Oral antibiotics	8 (4.8)	6 (3.3)	.66
Intravenous antibiotics	0	3 (1.6)	
SSO requiring procedural intervention	5 (3.0)	6 (3.3)	
Wound opening	4 (2.4)	6 (3.3)	.80
Wound debridement	2 (1.2)	3 (1.6)	
Length of stay, median (IQR), d	5 (4-7)	5 (4-6)	.08
Additional operation	3 (1.8)	5 (2.7)	.50
Readmission	17 (10.2)	17 (9.3)	.93

Abbreviations: IQR, interquartile range; SSI, surgical site infection; SSO, surgical site occurrence.

[a] Data are presented as number (percentage) of patients unless otherwise indicated.

Table 3. Quality-of-Life Outcomes[a]

Outcome	Heavy-weight mesh (n = 173)	Medium-weight mesh (n = 177)	*P* value
NIH PROMIS pain T score			
Baseline	46.3 (36.3-52.1)	46.3 (33.5-52.1)	.47
30 d	46.3 (43.5-54.5)	46.3 (43.5-52.7)	.89
1 y	30.7 (30.7-43.5)	30.7 (30.7-40.2)	.59
HerQLes score			
Baseline	35.0 (20.0-48.3)	36.7 (22.5-58.3)	.28
30 d	45.0 (24.6-73.8)	43.3 (28.3-65.0)	.58
1 y	90.0 (67.9-96.7)	86.7 (65.0-93.3)	.41
Do you feel your mesh? (yes), No. (%)	33 (19.1)	32 (18.1)	.93

Abbreviations: HerQLes, hernia-specific quality of life; NIH PROMIS, National Institutes of Health Patient-Reported Outcomes Measurement Information System.

[a] Data are presented as median (interquartile range) unless otherwise indicated.

weight vs medium-weight mesh groups within any of the 3 modalities (physical examination: 2 [1%] vs 4 [2%]; HRI: 52 [30%] vs 62 [35%]; CT: 3 [3%] vs 3 [3%]) (**Table 4**). There were considerably more hernia recurrences using the HRI definition (30% in the heavy-weight mesh group vs 35% in the medium-weight mesh group) compared with 3% overall for physical examination and 3% overall for CT. The consensus definition of a hernia recurrence, which was agreed on by all surgeons before analysis, had a 1-year hernia recurrence rate of 8% for the heavy-weight mesh group and 7% for the medium-weight mesh group (*P* = .79). Notably, this consensus definition accounts for circumstances in which patients were only assessed by 1 or 2 of the modalities rather than all 3 and offers the most comprehensive definition of a hernia recurrence. Hernia recurrence was also assessed for maximum sensitivity and specificity using the 3 modalities of hernia recurrence detection, and no difference was found in hernia recurrence rates in the heavy-weight vs medium-weight mesh groups (maximum sensitivity: 24% v 27%, *P* = .54; maximum specificity: 2% vs 2%, *P* = .73). The odds of recurrence adjusted for baseline risk were 1.0 (95% CI, 0.4-2.2) for consensus, 1.2 (95% CI, 0.7-1.9) for maximum sensitivity, and 2.0 (95% CI, 0.4-14.3) for maximum specificity.

Discussion

To our knowledge, this is the first prospective randomized clinical trial using a hernia-specific quality-of-life tool to compare

Table 4. Hernia Recurrence

Test	No. (%) of patients		*P* value
	Heavy-weight mesh (n = 173)	Medium-weight mesh (n = 177)	
Hernia recurrence			
Physical examination	2 (1.2)	4 (2.3)	.42
HRI	52 (30.1)	62 (35.0)	.36
CT	3 (1.7)	3 (1.7)	.93
Composite hernia recurrence			
Consensus	14 (8.1)	13 (7.3)	.79
Max sensitivity	42 (24.3)	48 (27.1)	.54
Max specificity	3 (1.7)	4 (2.3)	.73

Abbreviations: CT, computed tomography; HRI, Hernia Recurrence Inventory; Max, maximum.

medium- vs heavy-weight polypropylene mesh for clean, open ventral hernia repair. The summative findings are that medium-weight mesh does not appear to demonstrate any added benefit at 30 days or 1 year regarding pain, mesh sensation, or improvement in quality of life compared with heavy-weight mesh.

The consideration that reduced-weight, macroporous materials could demonstrate a clinical benefit over traditional heavy-weight polypropylene is not novel. Animal studies[23-25] first suggested that lighter-weight materials and larger pore sizes could allow for the deposition of more mature type 1 collagen and less fibrosis, potentially increasing tensile strength without restricting abdominal wall mobility. Following these animal studies, multiple randomized clinical trials were performed comparing lightweight and heavy-weight polypropylene in open inguinal hernia repair. A meta-analysis of these 9 randomized clinical trials was performed by Sajid et al,[26] and although there was a fair amount of heterogeneity among those trials, ultimately the meta-analysis demonstrated no significant difference in chronic pain; however, there was an increase in groin stiffness and foreign-body sensation. Instead, our results found similar improvements in quality of life and identical rates of mesh sensation (21%) for ventral hernia repair regardless of mesh weight. This distinction between open inguinal hernia studies and our experience could be attributed to a less substantial difference in mesh weight (heavy weight/lightweight vs heavy weight/medium weight) and the somewhat unique problem of patients sensing mesh in the groin with sensory nerves near the prosthetic.

Perhaps more relevant is the collective experience of clinical trials that compare mesh weights for laparoscopic inguinal hernia repair because this mesh is similarly placed in the retromuscular position. Although lightweight mesh has demonstrated limitations in regard to durability for such repairs, these trials[27,28] have likewise found no difference between rates of pain and foreign-body sensation. Finally, 2 randomized clinical trials[29,30] comparing mesh weight in open ventral hernia repair likewise found no patient-perceived benefits to the lightweight material. Rickert et al[29] compared lightweight and medium-weight macroporous polypropylene in 80 open sublay repairs and found no difference in Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) results, daily activities, or pain scores at 21 days and 6 months. Conze et al[30] compared lightweight and heavy-weight mesh in 165 open sublay repairs and likewise were unable to demonstrate a difference in any SF-36 scores or daily activities between 21 days and 24 months. To our knowledge, this is the first clinical trial that compared medium- and heavy-weight mesh for ventral hernia repair, with a focus on pain, mesh sensation, and abdominal wall–specific quality of life. Although we found the absence of any patient-perceived benefits favoring medium-weight mesh surprising, we still find it reassuring that heavy-weight mesh can be used in this context without the aforementioned concerns, and we can now counsel patients appropriately while long-term data are awaited.

Framing the trial design around PROs rested on the assumption that rates of wound morbidity and mesh-related complications in clean cases would be comparable. Still, it is important to underscore that even in the rare instances of a surgical site infection (5%-6%) and/or surgical site occurrence requiring a procedural intervention (3%), there appeared to be no evidence of a relationship between mesh type and resolution of the complication. In fact, the sole partial mesh excision took place in the medium-weight mesh group that would theoretically be more resilient.[31,32] Although it is important to acknowledge that these repairs were done by high-volume abdominal wall reconstruction surgeons, it seems that any reluctance to use heavy-weight mesh because of a rare mesh-related complication in clean cases is unfounded. This finding is important because even a subtle, unanticipated benefit of medium-weight mesh from this perspective could guide surgeon decision-making if all other outcomes were equal.

Next, it is worth briefly discussing our definition of recurrence at 1 year, which proved to be more challenging than anticipated. Patients were assessed using the validated HRI as well as physical examination and CT. The presence, absence, or contradiction of these findings created an impressive number of permutations outlined in the eTable in Supplement 2. We had difficulty agreeing on which assessment tool was most reliable, particularly when variables were absent. Even when CTs were available (regarded among most authors as the definitive test), the interpretation of the CT images sometimes generated disagreement among blinded assessors. Ultimately, we created an algorithm and composite scoring system summarized in our Methods section, and our presentation of the maximum sensitivity and maximum specificity analysis represents our

sincere effort to present a fair and balanced worst-case/best-case scenario of our results. Although any representation of the 1-year recurrence rates was ultimately comparable between our 2 arms, we hope that our methods for reporting recurrence can serve as an example for future works.

In the absence of any discernable clinical or patient-reported difference, long-term durability would seem to be the next most important consideration. Certainly, reports of lightweight mesh fracture are mounting for both polypropylene and monofilament polyester.[30,33,34] Specifically, Cobb et al[33] identified a recurrence rate of 23% for lightweight mesh repairs, more than half of which were attributed to mesh fracture, with a mean follow-up of only 17 months. This finding compared to a recurrence rate of 11% in medium-weight mesh repairs (P = .045). The aforementioned randomized clinical trial by Conze et al[30] that compared lightweight and heavy-weight mesh also identified a 10% difference in 2-year recurrence (17% vs 7%, P = .052) that favored heavy-weight mesh. Although this finding was not statistically significant, the design was likely prone to a type II error because the SF-36 functional assessment was their primary end point. Although evidence condemning the durability of lightweight mesh mounts, use of medium-weight mesh would appear to be a reasonable compromise. Still, its superiority over traditional heavy-weight mesh has yet to be established. Anecdotally, our group has seen instances of medium-weight polypropylene mesh fracture. Long-term follow-up of these well-matched patients will be an important contribution to our understanding of these materials. In the meantime, if surgeons have concerns regarding the durability of medium-weight mesh, there is no clinically apparent contraindication to using heavy-weight polypropylene mesh in open clean retromuscular repairs for midline hernias with a width of 20 cm or less. On the basis of our group's interpretation of these data, we prefer heavy-weight mesh in clean cases. Given the lack of heavy-weight mesh greater than 30 × 30 cm, we use medium-weight mesh when a mesh larger than 30 × 30 cm is desired. There is a lack of level I evidence to guide mesh choice for contaminated cases, and these data should similarly not be used to guide mesh choices for contaminated cases.

Limitations

Our study has limitations. The most notable is that we only address mesh weight as it pertains to flat sheet polypropylene placed in a retromuscular position, and these results are therefore not generalizable to intraperitoneal mesh placement. Because of the multicenter nature of this trial there was some variability in mesh weight within each category given the products available to each surgeon. This variability in mesh weight could potentially add variability to the results. In addition, our focus on patient perception of their hernia repair through PROs is nearsighted and temporarily ignores what some surgeons may argue is the most important hernia repair outcome, hernia recurrence. Admittedly, our anecdotal experience of noticing an increasing rate of medium-weight mesh fractures (from prior hernia repairs) during the study has heightened our sense of the importance of durability between heavy-weight and medium-weight mesh. Thus, we are committed to following up these patients long term to address this question. Finally, we did not evaluate chronic pain syndromes in our patients and thus cannot comment on the effect on our outcomes. However, the fact that our patients had similar rates of baseline NIH PROMIS Pain Intensity Short Form 3a scores suggests that there were not major differences between the 2 groups with regard to preoperative pain.

Conclusions

Medium-weight polypropylene mesh failed to demonstrate a patient-perceived or clinical benefit compared with its heavy-weight counterpart in the first year after open retromuscular ventral hernia repair. Long-term follow-up will provide valuable insight into the durability of these materials—a characteristic that has accrued significance given the resemblance of all other findings.

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