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Hernia

Long-term assessment of surgical and quality-of-life outcomes between lightweight and standard (heavyweight) three-dimensional contoured mesh in laparoscopic inguinal hernia repair ☆

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ABSTRACT

Background: Mesh weight is a possible contributor to quality-of-life outcomes after inguinal hernia repair. This study compares lightweight mesh versus heavyweight mesh in laparoscopic inguinal hernia repair.
Methods: A prospective, single-center, hernia-specific database was queried for all adult laparoscopic inguinal hernia repair with three-dimensional contoured mesh (3-D Max, Bard, Inc, New Providence, NJ) from 1999 to June 2016. Demographics and outcomes were analyzed. Quality of life was evaluated preoperatively and after 2 weeks, 4 weeks, 6 months, 12 months, and 24 months, using the Carolinas Comfort Scale. Univariate analysis and multivariate logistic regression were performed.
Results: A total of 1,424 laparoscopic inguinal hernia repair were performed with three-dimensional contoured mesh, with 804 patients receiving lightweight mesh and 620 receiving heavyweight mesh. Patients receiving lightweight mesh were somewhat younger (52.6 ± 14.8 years vs 56.3 ± 13.7 years, $P < .0001$), with slightly lower body mass indices (26.4 ± 9.9 vs 27.1 ± 4.3, $P < .0001$). Lightweight mesh was used less often in incarcerated hernias (12.5% vs 16.8%, $P = .02$). There were a total of 3 surgical site infections. There were no differences in complications between groups except for seroma. Although on univariate analysis, seromas appeared to occur more frequently with heavyweight mesh (21.5% vs 7.9%). On multivariate analysis, heavyweight mesh was not independently associated with seroma formation. Average follow-up was 20 months. Recurrence rates were similar between lightweight mesh and heavyweight mesh (0.7 vs 0.6% $P > .05$). At all points of follow-up (4 week to 3 years), quality-of-life outcomes of discomfort, mesh sensation, and movement limitation scores were similar between lightweight mesh and heavyweight mesh.
Conclusion: Contoured lightweight mesh and heavyweight mesh in laparoscopic inguinal hernia repair yield excellent recurrence rates and no difference in postoperative complications or quality of life. Considering the lack of outcome difference with long-term follow-up, heavyweight mesh may be considered for use in laparoscopic inguinal hernia repair patients.

Introduction

Inguinal hernia repair (IHR) is one of the most common elective operations performed in general surgery, with 700,000 IHRs performed annually in the United States.[1] Whether patients receive open or laparoscopic IHR, the type of mesh the surgeon uses has been shown to decrease the recurrence rates by 50% or greater.[2] Despite IHR being the most common operation performed in the world, the choice of mesh, based on individual mesh characteristics, remains controversial. The need for long-term outcomes regarding hernia recurrence and mesh-specific complications are needed, including seroma, infection, migration, visceral erosions, adhesions, chronic groin pain, and activity limitations.[2–8]

Polypropylene is one of the most commonly used types of synthetic permanent mesh in IHR. The characterization of polypropylene can be based on weight (lightweight [LWM],

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midweight, or heavyweight [HWM]), porosity (large pores [>1 mm]), weave (multifilament versus monofilament), and flat or contoured.[6,7,9] Although conceptual advantages of LWM over HWM—such as improved quality of life (QOL), decreased rates of infection, and limited mesh contraction—have been proposed,[2,9] most clinical studies supporting these differences have been small and with short follow-up and have demonstrated mixed clinical results.[7,8,10–14] Thus, the aim of this study was to evaluate postoperative outcomes in LWM versus HWM contoured mesh in laparoscopic inguinal hernia repair (LIHR). Outcomes include traditional measures of success, including rates of recurrence and complications, but also prolonged and detailed QOL data. The authors hypothesized that in a large cohort undergoing similar operative techniques, LWM would demonstrate improved QOL outcomes.

Methods

Study design

After obtaining approval by our institutional review board, a prospective, single-center, hernia-specific database maintained at the Carolinas Hernia Center (Carolinas Medical Center, Charlotte, NC) was queried for all adult LIHRs performed with three-dimensional (3-D) contoured mesh from January 2006 to June 2016. Data are collected by trained abstractors and entered into the Carolinas Hernia Center Database on a rolling prospective basis. The trained abstractors enter such data without surgeon review to prevent surgeon bias from influencing outcomes. Most of the data come from surgeons involved in the Hernia Center, data also include outcomes from other faculty surgeons as part of the Carolinas Medical Center in Charlotte, NC. All patients were consented preoperatively by research personnel for study participation. Once enrolled, patients completed QOL surveys, using the Carolinas Comfort Scale (CCS), both preoperatively and postoperatively. All repairs were categorized into either Lightweight 3DMax (LWM) or Standard 3DMax (HWM; Bard, Inc). Demographics, operative details, patient outcomes and recurrence rates, and QOL were recorded.

QOL assessment: Carolinas comfort scale

The primary outcome of this study was postoperative QOL as measured by the CCS. CCS was developed specifically for patients undergoing hernia repair with mesh. The CCS is a self-reported survey developed as a hernia-specific QOL assessment tool that has been validated utilizing an international cohort and is currently in use in more than 40 countries.[15,16] Patients are independently surveyed preoperatively and postoperatively at 2 weeks, 1 month, 6 months, and yearly. The CCS quantifies 3 specific indicators of QOL after hernia repair: pain, limitation of movement, and hernia sensation, which can be totaled into an overall QOL score for comparison. Patients are surveyed regarding 7 activities and at rest. The CCS scores are reported by patients on a 6-point Likert scale (0 equals no pain, 5 equals disabling pain) for each indicator. An average score of 2.0 (“mild but bothersome”) or greater is considered symptomatic. QOL questionnaires are returned to nonmedical personnel by mail to prevent observer or expectation bias, which could occur if the form were filled out in the presence of the physician or office staff. The CCS has been utilized in a multitude of studies on inguinal hernia repair.[17,18]

Statistical analysis

Standard statistical analysis was performed using the Pearson χ^2 and the Fisher exact test for categorical variables and the unpaired t test or the Kruskal-Wallis test for nonparametric continuous data and ordinal variables as appropriate to obtain a 2-tailed P value. Univariate analysis was first performed to compare 3DMax LWM or Standard 3DMax HWM. Logistic regression with forward stepwise selection methodology was used to identify independent risk factors for primary outcomes, including both minor and major complications. Odds ratios with corresponding 95% confidence intervals are used to report the results of the logistic regression models. Statistical significance was set at $P < .05$, and all reported P values are 2-tailed. All data were analyzed using Statistical Analysis Software v 9.4 (SAS Institute, Inc, Cary, NC).

Table 1
Patient demographics and comorbidities.

	LW $n = 804$ (56.5%)	HW $n = 620$ (43.5%)	P value
Age (years)	52.6 ± 14.8	56.3 ± 13.7	< .001
Sex (% male)	91.5	94.8	.017
BMI (kg/m^2)	26.4 ± 9.9	27.1 ± 4.2	.001
Race (% Caucasian)	88.8	83.9	.133
Preoperative steroids (%)	0.8	1.8	.121
Previous IHR (%)	18.9	17.2	.400
ASA score ≥3 (%)	11.4	20.5	< .001
Comorbidities	1.9	2.2	.031
Tobacco use (%)	5.6	7.33	.187

LW, lightweight; *HW*, heavyweight; *ASA*, American Society of Anesthesiologists.

Results

Patient characteristics of LIHR, comparing LWM and HWM 3-D contoured mesh

A total of 1,424 LIHRs were performed with 804 (56.5%) using LWM and 620 (43.5%) using HWM. Table 1 presents full details of patient demographics and comorbidities. Patients who underwent repair with LWM were somewhat younger (52.6 ± 14.8 years vs 56.3 ± 13.7 years; $P < .001$) and had a similar body mass index (BMI) (26.4 ± 9.9 kg/m^2 vs 27.1 ± 4.2 kg/m^2; $P < .001$). LWM patients had fewer comorbidities, with an average of 1.9 comorbidities compared with 2.2 in the HWM cohort ($P = .031$). There were no differences between the groups in the prevalence of tobacco use. The incidence of a previous inguinal hernia repair was similar between the 2 groups.

Operative details

Nearly all (99%) of all LIHR were elective cases, with no difference in rates of elective or emergent repair between LWM and HWM. Table 2 presents data on hernia and operative characteristics. The LWM group had similar, clinically irrelevant average mesh size than HWM (196.9 ± 18.7 cm^2 vs 201.9 ± 16.8 cm^2; $P = .001$). LWM was more likely to be utilized when the hernia defect was considered “small” (25.2% vs 11.9%; $P < .0001$), and HWM was more likely to be used when the defect was considered “large” (24.8% vs 60.6%; $P < .0001$). Defect size was determined by the operating attending surgeon. LWM was less likely to be used when the hernia was incarcerated (12.5% vs 16.8%; $P = .0202$). There was no difference in operative time between the groups. A transabdominal preperitoneal (TAPP) approach was utilized less in the LWM group (66.2% vs 83.7%; $P < .001$). Tacks were much more likely to be utilized for the peritoneal closure in the LWM group (44.6% vs 29.9%; $P < .0001$), and staples were more likely to be used in the HWM group (23.9% vs 56.8%; $P < .0001$).

The overall complication rates were similar between the LWM and HWM groups (11.4% vs 11.5%; $P = .948$). Table 3 presents more details regarding postoperative outcomes and complications. The incidence of urinary retention was equal between mesh groups.

Table 2
Hernia and operative details.

	LW $n = 804$ (56.5%)	HW $n = 620$ (43.5%)	*P* value
Mesh size (cm^2)	197 ± 19	202 ± 17	.001
Elective (%)	99.6	99.5	.512
Incarcerated hernia (%)	12.5	16.8	.02
Indirect hernia (%)	51.3	44.3	.038
Femoral component (%)	5.7	7.2	.261
TAPP approach (%)	66.2	83.7	< .001
Permanent tacks (%)	81.4	73.5	.191
Fibrin glue (%)	32.5	40.2	.003
Defect size			
Large (%)	25.2	11.9	< .001
Small (%)	24.8	60.6	<. 001
Peritoneal closure			
Tacks (%)	44.6	29.9	< .001
Sutures (%)	31.6	13.3	< .001
Staples (%)	23.9	56.8	< .001
EBL (mL)	20 ± 19	20 ± 24	NS
OR time (min)	89.7 ± 34.0	89.8 ± 34.0	.988

LW, lightweight; *HW*, heavyweight; *TAPP*, transabdominal preperitoneal; *EBL*, estimated blood loss; *OR*, operating room; *NS*, not statistically significant.

Table 3
Postoperative outcomes and complications (univariate analysis).

	LW $n = 804$ (56.5%)	HW $n = 620$ (43.5%)	*P* value
Average follow-up (months)	21.8	17.2	< .001
Overall complication (%)	11.4	11.5	.948
Superficial SSI (%)	0.1	0.0	.377
UTI (%)	0.0	0.2	.432
Pneumonia (%)	0.2	0.0	1.000
Hematoma (%)	0.0	0.0	1.000
Seroma (%)	7.9	21.5	< .001
Ileus (%)	0.0	0.5	.186
SBO (%)	0.5	0.0	.186
Arrhythmias (%)	1.1	1.0	.794
Urinary retention (%)	7.5	7.1	.816
30-day readmission (%)	1.1	0.7	.739
Hernia recurrence (%)	0.6	0.7	.802

LW, lightweight; *HW*, heavyweight; *SSI*, surgical site infection; *UTI*, urinary tract infection; *SBO*, small bowel obstruction.

The LWM patients had a notably lesser rate of postoperative seroma (7.9% vs 21.5%; $P < .0001$) on univariate analysis. There were 2 episodes of ileus postoperatively in the HWM group compared with none in the LWM group (0.5% vs 0.0%; $P = .186$). There were no significant differences in superficial surgical site infections (SSIs), urinary tract infections, pneumonia, bowel obstruction, postoperative arrhythmias, hematoma formation, unplanned reoperations, or 30-day readmissions. There were no deaths at 30 days. There were 3 hernia recurrences in both the LWM group (0.6%) and the HWM group (0.7%; $P = .802$).

QOL after LIH comparing LWM versus HWM

QOL scores were also evaluated. Preoperative screening and follow-up QOL scores are presented in Table 4. Patients who subsequently underwent LIHR utilizing HWM had greater preoperative pain scores (58 .0% vs 49.3%; $P = .029$) and an overall worse QOL preoperatively (59.1% vs 51.1%; $P = .045$). There were no differences in any of the QOL scores for any of the t3 domains (pain, mesh sensation, and limitation of movement) at any of the postoperative time points evaluated—at 2 weeks, and 1, 6, 12, 24, and 36 months. When examining patients with a low or normal BMI (18.5–25 kg/m2), 36.5% received HWM and 63.5% had LWM placed; no difference was found in any QOL scores (Table 5).

Table 4
Preoperative and postoperative QOL outcomes.

	LW	HW	*P* value
Preoperative screen	$n = 272$	$n = 369$	
Max mesh sensation ≥ 2 (%)	25.6	25.7	.9943
Max pain ≥ 2 (%)	49.3	58.0	**.029**
Max movement limitation ≥ 2 (%)	46.3	39.5	.0955
Max overall QOL score ≥ 2 (%)	59.1	51.1	**.045**
2 wk	$n = 258$	$n = 366$	
Max mesh sensation ≥ 2 (%)	19.4	21.7	.481
Max pain ≥ 2 (%)	46.0	49.6	.371
Max movement limitation ≥ 2 (%)	39.7	46.2	.107
Max overall QOL score ≥ 2 (%)	51.5	58.1	.098
1 month	$n = 146$	$n = 263$	
Max mesh sensation ≥ 2 (%)	15.2	18.8	.357
Max pain ≥ 2 (%)	27.4	26.7	.885
Max movement limitation ≥ 2 (%)	23.9	25.3	.736
Max overall QOL score ≥ 2 (%)	32.7	34.5	.716
6 months	$n = 213$	$n = 322$	
Max mesh sensation ≥ 2 (%)	12.9	8.0	.073
Max pain ≥ 2 (%)	15.8	10.5	.084
Max movement limitation ≥ 2 (%)	8.3	5.8	.275
Max overall QOL score ≥ 2 (%)	20.5	15.0	.109
12 months	$n = 197$	$n = 311$	
Max mesh sensation ≥ 2 (%)	9.9	6.2	.149
Max pain ≥ 2 (%)	13.2	13.4	.942
Max movement limitation ≥ 2 (%)	8.3	7.4	.718
Max overall QOL score ≥ 2 (%)	17.28	16.2	.764
24 mo	$n = 205$	$n = 116$	
Max mesh sensation ≥ 2 (%)	6.11	11.5	.072
Max pain ≥ 2 (%)	12.8	9.9	.426
Max movement limitation ≥ 2 (%)	7.8	7.2	.841
Max overall QOL score ≥ 2 (%)	14.6	15.8	.767
36 months	$n = 114$	$n = 76$	
Max mesh sensation ≥ 2 (%)	7.7	5.6	.560
Max pain ≥ 2 (%)	11.9	7.4	.299
Max movement limitation ≥ 2 (%)	6.8	2.9	.243
Max overall QOL score ≥ 2 (%)	13.8	8.5	.244

LW, lightweight; *HW*, heavyweight.

Table 5
Normal BMI (18.5 to 24.9) mesh use and QOL.

Patients BMI (18.5 to 24.9)	LW$n = 324$	HW$n = 186$	*P* value
2 wk			
Max mesh sensation ≥ 2 (%)	24.2	17.7	>.05
Max pain ≥ 2 (%)	46.4	53.3	>.05
Max movement limitation ≥ 2 (%)	38.4	41.4	>.05
Max overall QOL score ≥ 2 (%)	52.2	57.8	>.05
1 month			
Max mesh sensation ≥ 2 (%)	19.1	14.9	>.05
Max pain ≥ 2 (%)	25.9	21.3	>.05
Max movement limitation ≥ 2 (%)	12.8	18.2	>.05
Max overall QOL score ≥ 2 (%)	28.6	23.4	>.05
12 mo			
Max mesh sensation ≥ 2 (%)	9.9	6.2	>.05
Max pain ≥ 2 (%)	13.2	13.4	>.05
Max movement limitation ≥ 2 (%)	9.9	11.6	>.05
Max overall QOL score ≥ 2 (%)	15.8	19.4	>.05
24 mo			
Max mesh sensation ≥ 2 (%)	5.1	4.4	>.05
Max pain ≥ 2 (%)	8.9	6.7	>.05
Max movement limitation ≥ 2 (%)	4.4	6.7	>.05
Max overall QOL score ≥ 2 (%)	11.0	8.5	>.05

LW, lightweight; *HW*, heavyweight.

Multivariate analysis

To control for potentially confounding variables, multivariate logistic regression was performed. Multivariate data are presented in Table 6. Response variables that were evaluated included postoperative seroma formation. Factors that were believed to be possible

Table 6
Multivariate analysis, predictors of seroma.

Covariates	OR (95% CI)
Heavyweight mesh	1.717 (0.855–3.449)
Age (years)	1.029 (1.006–1.052)
BMI (kg/m^2)	1.018 (0.944–1.097)
Tobacco use	1.082 (0.286–4.093)
COPD	0.555 (0.110–2.804)
Diabetes	0.787 (0.211–2.932)
Previous inguinal hernia	0.597 (0.249–1.434)
Mesh size	1.022 (0.995–1.049)
Indirect hernia	0.961 (0.516–1.788)

OR, odds ratio; *CI*, confidence interval.

confounding variables included mesh weight (LWM versus HWM), age, tobacco use, chronic obstructive pulmonary disease, mesh size, previous inguinal hernia, and hernia type (direct versus indirect). After controlling for age, tobacco use, mesh size, and hernia type, we found that HWM was not an independent risk factor for a postoperative seroma formation. Age, however, was independently associated with an increased risk of seroma formation (OR 1.029; 95% CI 1.006, 1.052). No other factors were independently associated with seroma formation.

Discussion

LWM was introduced to hernia surgery, with the hope that a decrease in foreign body mass and larger pore sizes between filaments would induce less inflammation and mesh contraction, improve tissue ingrowth and mesh and perimesh tissue compliance, and subsequently decrease patient discomfort, improve mobility, and decrease mesh-related complications. Although this seemed logical, the literature regarding the long-term improvements on outcomes with LWM is unclear or lacking in small, short-term studies.[10,11,14,19] This study compared more than 1,400 patients undergoing LIHR with either 3-D contoured LWM versus 3-D contoured HWM and compared long-term QOL data.

Patients who had an LWM repair were younger, less obese, and had overall fewer comorbidities. Hernias repaired with HWM were larger and had somewhat larger meshes. Postoperative complications were similar between the 2 groups when a multivariate analysis was performed. The use of tacks, staples, and sutures in the hernia repairs were different, but we demonstrated elsewhere that their use does not impact long-term QOL in LIHR.[20]

When examining QOL in the present study, HWM patients had greater rates of discomfort, limitations in movement, and an overall worse QOL preoperatively, but at no postoperative time point was there any significant difference in QOL outcomes between LWM and HWM. This lack of difference included both short-term QOL outcomes (2 weeks, 1 month and 6 months) and long-term outcomes (12, 24, and 36 months).

When performing an inguinal hernia repair in a normal weight or thin patient, some have advocated for LWM use, assuming that LWM would result in an improved QOL compared with HWM.[21] In the current study, 510 LIHs were performed in patients with decreased or normal BMI; 36.5% received LWM and 63.5% HWM. There were no differences in QOL at any follow-up point.

Much of the inguinal hernia research comparing mesh weight has been performed examining patients undergoing the Lichtenstein technique for open IHR. There are studies showing improved QOL with LWM over HWM, including a randomized trial by Bringman et al.[10] from 2006. Bringman's study[10] found that those patients who had LWM had less pain on examination, less pain when going from lying to sitting, and "felt the mesh" less often than those with HWM. Similarly, O'Dwyer et al.[3] found that those who underwent open inguinal hernia repair with LWM had significantly less pain at 12 months postoperatively compared with HWM. Post et al.[4] also found in their study of 122 patients that LWM was associated with significantly less pain with exercise at 6 months postoperatively and less foreign body sensation at 6 months postoperatively. Recently, these results were supported in a series of 808 open IHRs, with worse QOL at 6 months with HWM.[5] These results have an important distinction from the current laparoscopic study, because of the worse QOL with HWM was during open repair. Other studies, however, have found QOL outcomes with no difference between HWM or LWM in open repair. Koch et al.[22] reported outcomes in 317 patients, with no difference in postoperative pain or recurrence at 1 year, but LWM had a lesser convalescence than HWM (7 versus 10 days; $P = .005$). Given the conflicting results in open repair, one must recognize the necessity of a robust study, examining such outcomes in laparoscopic hernia repair as well, which was the focus of the present study. Evaluating the effect of mesh weight in laparoscopic repair, Bringman et al.[23] compared LWM with HWM in 140 bilateral LIHR (totally extraperitoneal repair [TEP] technique), using the visual analog score (VAS) and SF-36 questionnaire for QOL data. These authors found no difference in QOL outcomes with 8 weeks of follow-up.[23] Similarly, Heikkinen et al.[24] reported no difference between LWM and HWM in LIHR (TEP technique) in QOL outcomes of 140 recurrent inguinal hernia patients, including postoperative pain, during the first 8 weeks after operation, except that the LWM group did have a better SF-36 score ($P = .045$).[24] Finally, Burgmans et al.[25] performed a randomized, double-blinded, prospective trial comparing LWM and HWM in 950 TEP repairs, with no difference in postoperative pain (2.0% vs 0.9%; $P = .17$) or mesh sensation (20% vs 18%; $P = .62$) at 3 months after operation. Notably, LWM had greater rates of symptomatic pain at 1 year (2.9% vs 0.7%; $P = .01$) and 2 years (3.0% vs 0.9%; $P = .03$) follow-up.[25] Moreover, they found a greater rate of recurrence in the LWM group at 2 years (2.7% vs 0.8%; $P = .03$).[25]

The present study demonstrates results in 1,424 patients with a 20-month average follow-up. In univariate analysis, an increased rate of seroma formation existed in the HWM group. Although the rates of seroma formation were relatively high in the HWM cohort, particularly given that other studies have shown rates of 6.5%.[26] Only 4 of the patients required seroma intervention, with 3 requiring percutaneous drainage and 1 requiring a return to the operating room for drainage. Furthermore, the recurrence rate of 0.58% and 0.71% in the LWM and HWM groups, respectively, with a 20-month follow-up, is very favorable compared with other studies with recurrence rates for LIHR ranging from 2.4% to 5.9% with 3 to 5 years of follow-up.[27,28]

The present study has limitations. All the hernia repairs were performed at a single institution, and as such, there may be single-center bias, and it may be difficult to apply our data more broadly. Although most of the operations were performed by surgeons involved in the Hernia Center, other surgeons with advanced minimally invasive surgery experience also participated. The procedures were done similarly with some subtle differences. For example, use of fibrin glue, staples, and tacks vary among surgeons, with some surgeons utilizing HWM more than others. There was no randomization in our study. Thus, patient enrollment in either arm was based on surgeon preference at the time of the procedure. Thus, some data could be affected by selection bias. HWM was chosen more frequently in large and direct defects. The use of LWM in these settings was not as well evaluated because of the inherent selection bias. Although there were no differences in recurrence or QOL comparing LWM and HWM, the data do not support the use of LWM for all laparoscopic inguinal hernia repairs. It does appear that HWM can be used safely in smaller and indirect defects, potentially supporting the use of HWM in all LIHRs.

In conclusion, in LIHR, there is little difference in the various outcomes we evaluated between HWM and LWM. Overall

complication rates, including recurrence rates, were similar between the groups; even differences in seroma formation in the HWM group did not persist after multivariate analysis. There was no QOL outcome difference between LWM and HWM at any postoperative time point evaluated. LWM was used more frequently in the nonobese, healthier, and younger patients, as well as more frequently in smaller and indirect defects. Thus, the use of LWM in obese patients with large or direct defects needs further evaluation. HWM appears safe and effective for all LIHRs, regardless of the type of inguinal hernia or the size of patient.

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