Original Research

Gluteal and Posterior Thigh Pain From a Suture Compared With an Anchor-Based Device in Patients Undergoing Sacrospinous Ligament Fixation

A Randomized Controlled Trial

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OBJECTIVE: To compare postoperative gluteal and posterior thigh pain, device performance, and perioperative complications in women undergoing sacrospinous ligament fixation with an anchor-based compared with a suture-capturing device.

METHODS: This was a single-center, patient-blinded, parallel, superiority trial of patients undergoing native-tissue pelvic organ prolapse repair through sacrospinous ligament fixation with an anchor-based compared with suture-capturing device using randomized-block randomization. The primary outcome was the increase in gluteal and posterior thigh pain from baseline to 1-week postoperation using the numerical rating scale. Pain was also assessed at postoperative day 1, week 6, and a summarized assessment for the first postoperative week. Intraoperative device performance, home opioid pain medication use, and changes in prolapse symptom scores were also analyzed. To provide 80% power to detect a pain difference of 2.5 points between the groups with an SD of 2.8 and a 15% dropout estimate using a two-sided 5% significance level, 24 patients were required per group. Analysis with Student's *t* test, Wilcoxon rank-sum tests, and Fisher exact tests were performed as well as an analysis of covariance for the primary outcome.

RESULTS: Between September 2018 and June 2020, 47 patients (24 anchor-based and 23 suture-capturing) were included in the study. There was no significant difference between the anchor-based and suture-capture groups in mean change in gluteal and posterior thigh pain from baseline to 1-week postoperation (−0.4, 95% CI −1.6 to 2.3). The highest pain increase from baseline during the first postoperative week was also similar between the two groups (up 4.00 and up 4.74, respectively) with no significant difference between the anchor-based and suture-capture groups (−0.7, 95% CI −1.4 to 2.8). There were no differences in changes in pain at any of the other timepoints, in opioid pain medication utilization, device performance, or in prolapse symptom scores.

CONCLUSION: An anchor-based device did not reduce postoperative gluteal and posterior thigh pain compared with a suture-based device after sacrospinous ligament fixation.

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pal investigator-initiated study. Funding went to providing small value gift cards to patients for study completion, office supplies for the study, and funding the data analysis collaboration with the Wake Forest Baptist Health CTSI Biostatistics Department. Neomedic did not have any direct role in study design, patient recruitment, study execution, data analysis, or manuscript writing or editing.

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A common approach to repair of apical vaginal prolapse is suspension of the vaginal apex or cervix to the sacrospinous ligament.[1,2] Suture-capturing devices such as the widely used Capio Slim device work by projecting a suture in a half-circle motion into the sacrospinous ligament. These devices have been found to cause pain in the gluteal and posterior thigh postoperatively.[2–5] This pain has been attributed to suture entrapment of the levator ani nerve that runs along the surface of the coccygeus muscle[2] although entrapment of other nerves such as branches of the S3 and S4 nerves is also possible.[6] Initial postoperative gluteal and posterior thigh pain with the device has been reported in 55–84% of patients with persistent pain at 6 weeks postoperatively in 15–16% of patients.[2,3]

Anchorsure has been introduced as a U.S. Food and Drug Administration–approved, anchor-based device that is being used domestically and internationally for native-tissue repairs. This device deploys a small anchor in a linear backwards to forwards motion which could change the risk of nerve entrapment during sacrospinous ligament fixation. There are currently few data on postoperative pain from anchor-based native-tissue sacrospinous ligament fixation. (Pizarro-Berdichevsky J, Arrelano M, Goldman H. Sacrospinous ligament fixation using tissue anchoring systems may reduce the procedure length with similar outcomes compare with classical techniques. Neurourology and Urodynamics 2017;36:S7–155).

This study is a randomized comparative trial whose primary aim was to compare postoperative gluteal and posterior thigh pain after sacrospinous ligament fixation between a suture-capture and an anchor-based device at 1-week postoperation. The hypothesis was that there would be less postoperative pain with use of the anchor-based device. Secondary aims included assessments of perioperative complications, short-term surgical efficacy, posthospitalization opioid use, and surgical device performance. This study design was needed as there is a lack of detailed, prospective comparative studies specifically assessing gluteal and posterior thigh pain from sacrospinous ligament fixation.

METHODS

This was an investigator-initiated, patient-blinded, parallel, superiority, randomized trial performed at a tertiary care center. Institutional Review Board approval was obtained for the study from the Wake Forest Baptist Health Institutional Review Board (IRB00051211) and the study was registered with ClinicalTrials.gov (NCT03565640) before enrollment of the first patient. Patients with symptomatic pelvic organ prolapse were recruited from two urogynecology clinics at our institution. The decision to pursue sacrospinous ligament fixation for prolapse treatment was determined before consideration for inclusion into this study. When offering study enrollment, patients were informed that the anchor-based device is a newer device with limited data regarding efficacy and only abstract-level data regarding pain. Patients were specifically counseled on the permanent anchor that is involved in the application of the anchor-based device, that this material (polyetheretherketone) has safely been used in orthopedic and dental surgeries,[7–9] and that it may show up in imaging tests in the future. Inclusion criteria were age at least 21 years, English speaking, surgical plan for native-tissue sacrospinous ligament fixation of either the cervix or vaginal vault, and ability to understand and complete the study. Exclusion criteria included: wheelchair dependency, prior sacrospinous ligament fixation, prior mesh-based prolapse repair, history of pelvic radiation, preoperative daily opioid medication use, debilitating preoperative gluteal or posterior thigh pain or neuropathy (impeding ambulation or requiring daily pain medication use as determined by the patient), history of sacral decubitus ulcers, active auto-immune muscle conditions, and surgical plan to include a concomitant levatorplasty, anal sphincteroplasty, anal fissurectomy, rectopexy, or hemorrhoidectomy.

Patients were randomized to have their sacrospinous ligament fixation performed with either the anchor-based device or the suture-capture device. Randomization was done with 1:1 randomized-block assignments (blocks of two, four, or six) by nonclinical personnel within our department using a computerized random number generator. One patient was excluded after randomization due to her inability to fill out study questionnaires. The assignments were placed in sealed envelopes that were opened by the surgical team intraoperatively immediately before start of the surgery after all preoperative study forms were filled out. The randomization sequence was then deleted from the computer records to ensure blinding of patient recruiters from the randomization sequence.

Patients were blinded from the randomization decision until after completion of the study. Medical personnel providing clinical care to study patients had access to the device allocation information but were instructed to not search this information out.

Demographic data, medical and surgical history, and preoperative pelvic organ prolapse quantification (POP-Q) examinations were obtained from the urogynecology consultation visit. Patients determined their race during their initial patient data entry encounter with our hospital system. Race was included to determine whether our study population was representative of our general urogynecology population. The presence of chronic body pain was determined by the presence of a diagnosis of arthritis of any kind, gout, auto-immune pain conditions, chronic back pain, or other chronic pain conditions as noted by the patient in their medical history. Patients were introduced to the study during their preoperative clinic visits. Preoperative study questionnaires were given to patients at their clinic visit, by mail service, or by email. Patients receiving study documentation by mail service or email were given a thorough discussion of the study over the phone at least 24 hours before surgery. Consent forms were filled out at a point between the study discussion and the time of their surgery. Preoperative questionnaires consisted of the numerical rating scale for pain assessment and the validated PFDI-20 (Pelvic Floor Disability Index-20) and PFIQ-7 (Pelvic Floor Impact Questionnaire-7) questionnaires for prolapse symptoms.[10]

Intraoperative time from the beginning of sacrospinous ligament fixation device use to completion of sacrospinous ligament attachment was recorded. Physician satisfaction with device use was recorded on a 5-point Likert scale assessing: ease of use, safety, efficiency, sturdiness of repair, and overall satisfaction. The number of punctures into the sacrospinous ligament and the number of sutures left in the sacrospinous ligaments were recorded.

Short-term objective surgical failure was defined as descent of the C-point beyond one half of the vaginal length at the 6-week postoperative POP-Q examination. Oral opioid use after hospitalization until postoperative week 1 was recorded using opioid use questions on the week 1 postoperation questionnaire. Calculations of home opioid use were calculated in morphine equivalents.

Postoperative pain was assessed using a numerical rating scale on paper questionnaires on the morning of postoperative day 1 as well as week 1 and week 6 postoperation. The difference in pain from baseline to 1 week postoperation was the primary outcome. Patients were asked to rate pain in the pelvis, posterior right thigh and gluteal area, and posterior left thigh and gluteal area on 1–10 numerical rating scales. The postoperative day 1 questionnaire was filled out by patients after their vaginal packing (placed in all patients) had been removed, however a few patients who were discharged home on the day of surgery filled out the questionnaires at home on the morning of postoperative day 1. The week 1 postoperation questionnaires were filled out at home or in the clinic at 1 week postoperation when patients were asked to evaluate their pain since discharge from the hospital. The week 6 questionnaires were either filled out in the clinic or at home 6 weeks after surgery. Originally, all patient questionnaires were planned to be completed in the clinic, but the coronavirus disease 2019 (COVID-19) pandemic and logistics of having patients who live more than 2 hours from the clinic led to a revised plan allowing for the filling of patient questionnaire forms at home. Postoperative POP-Q examinations were performed at the 6-week follow up visit that were performed by urogynecology attendings or Fellows under the supervision of attendings. These evaluators were not blinded to patient allocation as this was detailed within the operative note.

Sacrospinous fixation in this study was performed by two board-certified urogynecologists and four Fellows under their supervision. The surgeons all received training and simulation on use of the anchor-based device before the study, but did not have significant prior intraoperative experience with the device. All surgeons had extensive experience with the use of the suture-capture device. An anterior, posterior, or apical approach was used to achieve fixation to the vaginal cuff or cervix. Concomitant hysterectomy, McCall's culdoplasty, anterior and posterior colporrhaphy, perineoplasty, cystoscopy, adnexal procedures, and incontinence procedures were performed as indicated. Sacrospinous ligament fixation to the vaginal cuff was performed with placement of two delayed absorbable sutures into the middle of one (right-side) or both sacrospinous ligaments according to the surgeon's preference. Sacrospinous hysteropexy was performed with the placement of one delayed absorbable suture and one permanent suture into the middle of the right sacrospinous ligament. All absorbable sutures were passed through the apical vaginal epithelium and the permanent sutures were passed through the subepithelial cervical tissue.

All patients were given scheduled acetaminophen and ibuprofen during their hospitalization unless

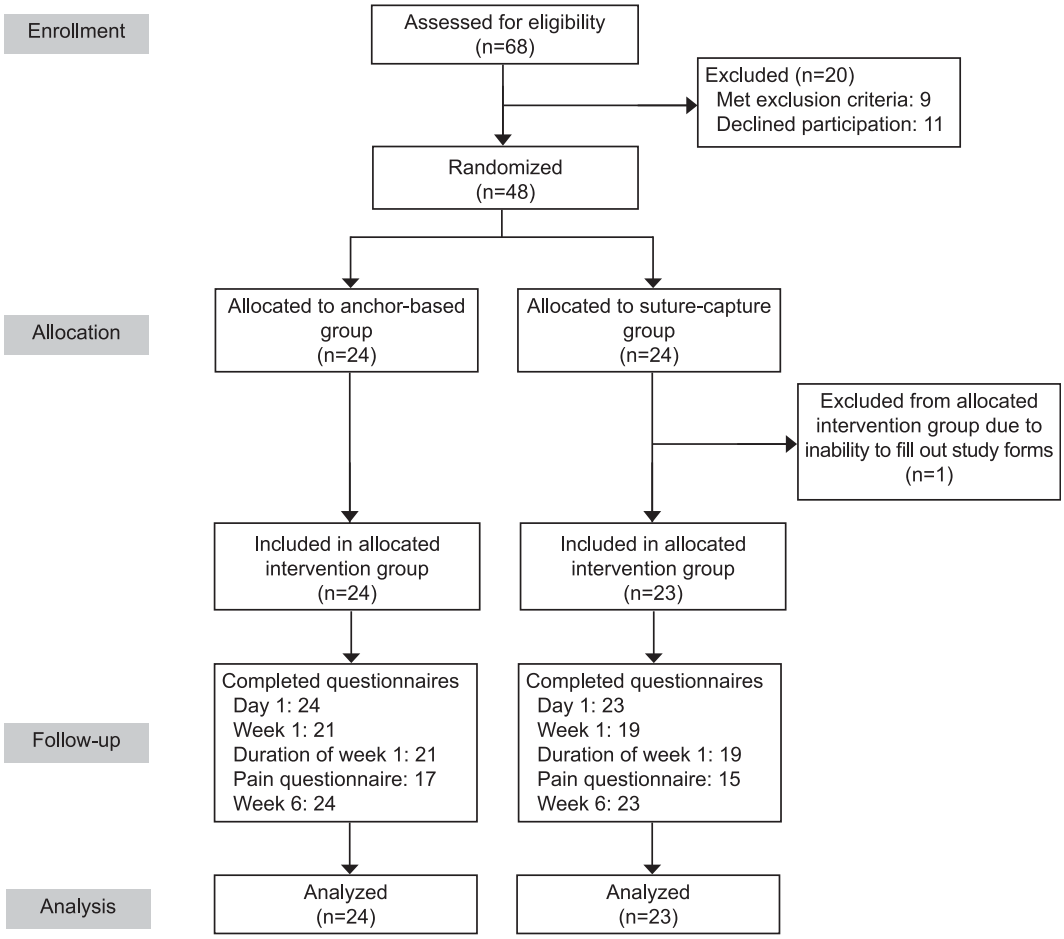

Fig. 1. CONSORT (Consolidated Standards of Reporting Trials) enrollment flowchart.
Plair. Postoperative Pain From Two Sacrospinous Fixation Devices. Obstet Gynecol 2021.

medical conditions prevented their use. As-needed oral opioid pain medication was ordered for all patients for them to use as they required for severe breakthrough pain. Nurses administering opioid pain medication to patients were blinded to patient's study group allocation. The specified administration of this available pain medication was not tracked in the study. All patients were given a script for opioid narcotics on discharge but were informed to use this medication only for pain breaking through the use of acetaminophen, ibuprofen, and ice packs which is our department's standard practice.

A difference in numerical rating scale scores of 2.5 was considered clinically significant based on prior published studies.[11–13] An expected SD of 2.8 for pain scores was based on a previous sacrospinous ligament fixation study[11] and a 15% incomplete data estimate was used. In the end, 24 patients (including dropouts and those with incomplete data) were required in each group to provide a power of at least 80% to reject the null hypothesis using a two-sided 5% significance level.

Descriptive statistics were performed on the data. Inter-group bivariate analyses consisted of Student's *t* test (scaled, interval data), Wilcoxon rank-sum tests (nonparametric data), and Fisher exact tests (categorical data) were performed. An analysis of covariance was performed on the difference in gluteal and posterior thigh pain compared with baseline while controlling for the operating surgeon as this parameter was found to be statistically different between the two groups. All data were kept in REDCap databases and statistics were performed with IBM SPSS Statistics in collaboration with our medical center's biostatistics department. CONSORT (Consolidated Standards of Reporting Trials) guidelines were followed in reporting this study. There was not a data-monitoring committee for this study due to the study size, but an institutional review of record keeping was performed without significant issues after 1 year of

Table 1. Patient Demographics, Preoperative Data, and Concomitant Procedures

	Anchor-Based (n=24)	Suture-Capture (n=23)
Age (y)	71.2±8.4	71.0±10.9
BMI (kg/m^2)	29.4±6.4	29.7±6.6
Race		
Black	2 (8)	3 (13)
White	22 (92)	20 (87)
Sexually active	11 (46)	8 (35)
Postmenopausal	22 (92)	22 (96)
Parity (median)	3	3
CCI	3.6±1.5	3.6±1.6
Pain condition status		
Chronic body pain*	12 (50)	13 (57)
Dyspareunia	4 (31)	4 (29)
Occasional opioid use	2 (8)	1 (4)
Past surgical history		
Pelvic or vaginal surgery	18 (75)	13 (57)
Hysterectomy	9 (38)	6 (26)
Lower extremity	4 (17)	6 (26)
Prolapse measurements		
Total vaginal length (cm)	9.2±1.0	9.2±0.8
Preoperative POP-Q stage (median)	3	3
Preoperative questionnaires		
PFIQ-7 total	56.0±62.2	64.9±48.4
PFDI-20 total	104.6±43.8	120.9±53.6
Preoperative pain (0–10)		
Pelvis	1.8±2.2	2.1±2.1
Left gluteal and back of the thigh area	1.0±1.9	0.8±1.9
Right gluteal and back of the thigh area	0.7±1.5	0.7±1.8
Concomitant procedures		
Hysterectomy	9 (38)	7 (30)
Hysteropexy	8 (33)	10 (45)
Vaginal vault suspension	7 (29)	6 (25)
Bilateral SSLF	2 (8)	2 (95)
Anterior colporrhaphy	17 (71)	19 (83)
Posterior colporrhaphy	22 (92)	20 (87)
Midurethral sling	14 (58)	10 (43)

BMI, body mass index; CCI, Charlson Comorbidity Index; POP-Q, pelvic organ prolapse quantification; PFIQ-7, Pelvic Floor Impact Questionnaire-7; PFDI-20, Pelvic Floor Disability Index-20; SSLF, sacrospinous ligament fixation.
Data are mean±SD or n (%) unless otherwise specified.

patient recruitment. There were not any changes to trial outcomes measured or analyzed during the study.

ROLE OF FUNDING SOURCE

Neomedic provided an unrestricted educational grant of $25,000 to assist with Fellow and research coordinator support for this principal investigator-initiated study. Neomedic did not have any role in study design, patient recruitment, study execution, data analysis, or manuscript writing or editing. The authors collected and controlled relevant aggregated study data and other information (such as study protocol, analytic plan and report, validated data table, and clinical study report) required to understand and report research findings. The authors take responsibility for the presentation and publication of the research findings, have been fully involved at all stages of publication and presentation development, and are willing to take public responsibility for all aspects of the work. All individuals included as authors and contributors who made substantial intellectual contributions to the research, data analysis, and publication or presentation development are listed appropriately. The role of the sponsor in the design, execution, analysis, reporting, and funding is fully disclosed. The authors' personal interests, financial or nonfinancial, relating to this research and its publication have been disclosed.

RESULTS

From September 2018 through June 2020, 60 patients met inclusion criteria and were approached for

Table 2. Postoperative Pain Scores

Pain Parameter	Anchor-Based (n=24)	Suture-Capture (n=23)	Mean Difference (95% CI)	RR (95% CI)	*P*
At day 1					
Pain at SSLF site*	3.0±2.5	3.1±3.2	−0.1 (−1.6 to 1.8)		.898
Increase in pain from baseline at SSLF site	2.3±2.7	2.3±3.0	0 (−1.6 to 1.7)		.938
% with any pain increase from baseline at SSLF site	16 (70)	14 (61)		1.2 (0.7–2.2)	.758
% with significant pain increase from baseline at SSLF site†	12 (52)	12 (52)		1.0 (0.6–1.8)	>.99
SSLF side is more painful side‡	10 (48)	5 (24)		1.8 (0.8–3.9)	.197
SSLF side is most painful site§	7 (30)	5 (22)		1.3 (0.6–2.7)	>.99
At week 1 (primary outcome)					
Pain at SSLF site*	3.5±2.8	3.4±3.2	0.1 (−2.0 to 1.8)		.911
Increase in pain from baseline at SSLF site	2.7±2.8	3.1±3.3	−0.4 (−1.6 to 2.3)		.723
% with any pain increase from baseline at SSLF site	15 (71)	12 (63)		1.2 (0.6–2.3)	.738
% with significant pain increase from baseline at SSLF site†	10 (48)	9 (47)		1.0 (0.5–1.9)	>.99
SSLF side is more painful side‡	14 (70)	9 (53)		1.5 (0.7–2.9)	.328
SSLF side is most painful site§vb	9 (43)	7 (37)		1.14 (0.6–2.3)	.755
During 1st postoperative week					
Pain at SSLF site*	4.8±3.1	5.1±2.7	−0.3 (−1.6 to 2.0)		.757
Increase in pain from baseline at SSLF site	4.0±3.4	4.7±3.1	−0.7 (−1.4 to 2.8)		.481
% with any pain increase from baseline at SSLF site	18 (86)	18 (95)		0.5 (0.1–2.8)	.607
% with significant pain increase from baseline at SSLF site†	14 (67)	13 (68)		1.0 (0.5–1.9)	>.99
SSLF side is more painful side‡	13 (65)	10 (59)		1.2 (0.6–2.3)	.745
SSLF side is most painful site§	7 (33)	7 (37)		0.9 (0.5–1.8)	>.99
At week 6					
Pain at SSLF site*	0.5±0.9	0.7±1.9	−0.2 (−0.7 to 1.0)		.727
Increase in pain from baseline at SSLF site	−0.2±1.2	−0.1±1.7	−0.1 (−0.8 to 1.0)		0.855
% with any pain increase from baseline at SSLF site	4 (17)	5 (22)		0.9 (0.4–1.7)	.724
% with significant pain increase from baseline at SSLF site†	0 (0)	1 (4)		—	>.99
SSLF side is more painful side‡	8 (36)	3 (14)		2.1 (0.8–5.7)	.162
SSLF side is most painful site§	8 (36)	5 (22)		1.4 (0.7–2.9)	.517

RR, relative risk; SSLF, sacrospinous ligament fixation.
Data are mean±SD or n (%) unless otherwise specified.
* Gluteal or posterior thigh pain on the side of sacrospinous ligament fixation.
† Increase in pain greater than 2.5 points; pain was averaged for bilateral fixation cases.
‡ Comparison of SSLF site pain with the contralateral side without fixation; bilateral fixation cases were excluded.
§ Comparison of SSLF site pain with the contralateral side without fixation (if applicable) and with general pelvic pain.

potential study enrollment. Study recruitment was ended after 48 patients were randomized. Ultimately, 47 patients were included in the study as depicted in Figure 1. One patient was excluded from the study after randomization due to an inability to fill out study questionnaires. There were no statistically significant differences in demographics, medical–surgical history, prolapse stage, preoperative PFIQ-7 or PFDI-20 scores, pain history, or preoperative pain ratings (Table 1) between groups. The mean age was 69.9 years and median prolapse stage was three. The percentages of hysterectomies (*P*=.760), hysteropexies (0.556), vaginal vault fixations without hysterectomy (*P*=1.00), bilateral sacrospinous ligament fixations (*P*=1.000), anterior colporrhaphies (*P*=.494), posterior colporrhaphies (*P*=.666), and incontinence procedures (*P*=.387) performed were similar between the anchor-based and suture-capture groups, respectively (Table 1). There was a statistically significant difference in the distribution of surgeons using the two devices (*P*=.037) due to chance variations in the makeup of the surgical team.

Table 3. Postoperative Opioid Pain Medication Use

Pain Medication Parameter	Anchor-Based (n=17)	Suture-Capture (n=15)	P
Opioid medication			.440
Tramadol	12 (71)	11 (73)	
Oxycodone	5 (29)	2 (13)	
Hydromorphone	0 (0)	2 (13)	
Total MME taken	10 (0–22.5)	35 (0–60)	.174
Total MME taken/d	1.3 (0.0–8.6)	5 (0.0–7.5)	.293

MME, morphine milligram equivalents.
Data are n (%) or median (25^{th}–75^{th} interquartile range).

There was no difference in the distribution of surgeons for the two devices according to the level of training (attending vs Fellow) (P=.245).

For the primary outcome, there were no significant differences in changes in pain from baseline across all timepoints between groups (Table 2). There was no difference in the average increase in pain on the side(s) of sacrospinous ligament fixation at day 1 (0, 95% CI −1.6 to 1.8), at week 1 (−0.4, 95% CI −1.6 to 2.3), and week 6 (−0.1, 95% CI −0.8 to 1.0) in the anchor-based group compared with the suture-capture group. The highest pain increase from baseline during the first postoperative week was also similar between the two groups (up 4.00 and up 4.74, respectively) with no significant difference between the anchor-based and suture-capture groups (−0.7, 95% CI −1.4 to 2.8). The analysis of covariance revealed no differences in pain at day 1 (P=.644), at week 1 (P=.723), during the first postoperative week (P=.770), and at week 6 (P=.103) between the two groups when controlling for the sacrospinous ligament fixation surgeon. There were no statistical differences in the percentages of patients that rated gluteal and posterior thigh pain on the side of sacrospinous ligament fixation as being more painful than the side without fixation or as being the most painful site of postoperative pain. Similar percentages of patients were found to have any increase in gluteal and posterior thigh pain on the side of sacrospinous fixation and in those found to have clinically significant increases in such pain.

Table 4. Surgical Device Performance Data

Performance Parameter	Anchor-Based (n=24)	Suture-Capture (n=23)	Median Difference	RR (95% CI)	P
% successful deployments	56/62 (90)	49/55 (89)		1.12 (0.39–3.29)	>.99
Time to apply device (min)	6.3±5.4	6.9±6.8	−0.6		.894
No. of device deployments/side applied	2.4±0.6	2.2±0.5	0.2		.247
No. of sutures left in SSLF/side applied	2.0±0.2	1.9±0.2	0.1		.305
Surgeon applying device					.037
1	6	6			
2	5	3			
3	0	2			
4	11	5			
5	1	7			
6	1	0			
Applications performed by Fellows	18/24 (75)	20/23 (87)			.245
Device evaluation (1–5)*					
Ease of use	3.7±1.6	4.1±1.3	−0.4		.442
Design	3.7±1.7	4.3±1.4	−0.6		.157
Surgical efficiency	3.6±1.7	4.2±1.3	−0.6		.585
Impression of sturdiness of repair	4.0±1.8	4.4±1.4	−0.4		.566
Overall satisfaction	3.8±1.7	4.3±1.4	−0.5		.189

RR, relative risk.
Data are n/N (%), mean±SD, or n unless otherwise specified.
* The evaluating Likert scale ranged from 1 to 5, with higher values indicating higher performance perceived by the surgeon.

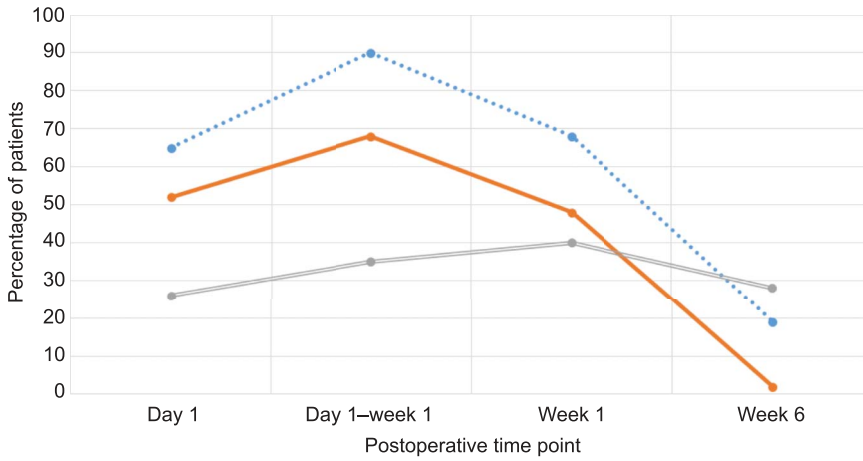

Fig. 2. Sacrospinous ligament fixation pain profile. The *dashed line* shows the percentage of patients with any increase in gluteal and posterior thigh pain on the side of sacrospinous ligament fixation from baseline levels, the *solid line* shows the percentage of patients who had a clinically significant (greater than 2.5 points) increase in pain in this area, and the *double line* shows the percentage of patients who identified this pain as the greatest pain in the pelvis.

Plair. Postoperative Pain From Two Sacrospinous Fixation Devices. Obstet Gynecol 2021.

Postoperative pain management requirements were similar between the two groups with no differences in opioid medication use in the first week after hospital discharge (Table 3). None of the patients required sacrospinous ligament fixation suture removal due to pain.

The anchor-based device performed similarly to the suture-capture device according to the tested parameters (Table 4). The two devices were similarly efficient at achieving sacrospinous fixation with average application times of 6.3 and 6.9 minutes, respectively (P=.894). Surgeon ratings of the ease of use, design, surgical efficiency, sturdiness of repair, and overall satisfaction were similar between the two devices. There were no surgical complications related to sacrospinous ligament fixation in the study. There was one sacrospinous ligament fixation site infection postoperation in the suture-capture group diagnosed by unilateral pelvic pain and purulent discharge from the sacrospinous ligament fixation site which was effectively treated with antibiotics and did not require surgical intervention.

Other secondary measures of success were similar between the two groups. Changes in PFDI-20 (-82.57 ± 32.75 vs -75.06 ± 50.52, P=.587) and PFIQ-7 (-26.82 ± 52.53 vs $+3.97\pm70.80$, P=.837) scores at 6 weeks postoperation compared with baseline levels were similar between the anchor-based and suture-capture groups, respectively. There were no cases of apical surgical failure in the study at 6 weeks postsurgery.

DISCUSSION

In this randomized trial, the use of an anchor-based device for sacrospinous ligament fixation did not decrease posterior thigh and gluteal pain compared with a suture-capture device at 1 week postoperation or at any timepoint analyzed. Our results challenge the assertion that postoperative gluteal and posterior thigh pain is largely attributable to nerve entrapment at the sacrospinous ligament as the anchor-based device cannot physically encircle nerves with its linear application motion. We postulate, alternatively, that direct pressure to surrounding soft tissues near adjacent nerves is causative of short-term pain. In native tissue sacrospinous fixation, direct tissue apposition to the ligament is the surgical goal. It is plausible that with time, this pressure dissipates and the pain resolves, as was demonstrated in this study. Alternatively, pressure from wound healing processes, such as inflammation after dissection and fixation to the sacrospinous ligament, are other possible causes of this pain.

Our results corroborate and build from those of other cohort studies. The percentage of patients with an increase in gluteal and posterior thigh pain was 65% at day 1, 90% at some point within the first postoperative week, and 19% at week 6. These compare with 55%,[4] 84%,[3] and 15%[2,3] from other studies. As we assessed pain at a multitude of timepoints postoperation and with a distinction for clinically significant pain, we are able to describe postoperative pain profiles with a novel level of detail which can assist with patient and physician expectations for recovery (Fig. 2). Specifically, gluteal and posterior thigh pain is likely to significantly increase on the side(s) of sacrospinous ligament fixation during the first postoperative week, but this pain will not likely be higher than the general postoperative pelvic pain, and it is expected to be resolved or improved from baseline by 6 weeks postoperation. There was only one patient in our study who reported a clinically

significant gluteal and posterior thigh pain increase from baseline at the site of sacrospinous ligament fixation at week 6.

Comparative assessment of new surgical device performance is critical for patient safety.[14–16] Importantly, we did not observe any cases of intraoperative hemorrhage and no anchors or sutures had to be removed due to pain. There were no apical failures within the first 6 weeks postsurgery which suggests an absence of postoperative suture or anchor "pull-out" from the ligament. In terms of device performance, we demonstrated equivalent time to achieve sacrospinous fixation as Mowat et al[3] and there were no major differences in surgeon satisfaction with the devices according to a Likert scale. The similarity in intraoperative and immediate postoperative surgical performance between the two devices in this study suggests further equivalence between the devices. It is important to note that a complete comparison of the devices requires long-term surgical efficacy data and study size to power the secondary analyses in this study.

There are several limitations to the current study and its findings. This was a randomized trial performed at one medical center and thus may not be generalizable to the broader community of pelvic surgeons. This study was not designed to evaluate the surgical efficacy of the devices in terms of durable pelvic organ prolapse repair; larger studies with longer follow up would be needed for such analysis. The numerical rating scale is less precise than the visual analog scale[17] but it allowed for easier and perhaps more reliable interpretation of patients' pain ratings as it did not require the measurement and patient adherence to striking a precise line through the visual analog scale, especially as many of the pain questionnaires were filled out at home. Difficulties in use of the visual analog scale compared with the numerical rating scale have been previously cited.[18,19] The rating of pain for the duration of the first postoperative week was recorded on a questionnaire filled out at 1 week and therefore relied on patients' recall of their pain. A daily pain diary would have eliminated this potential recall bias and detailed pain each day of the first postoperative week. Clinical staff performing postoperative examinations had access to the patient surgical records and this could have introduced detection bias. There was no significant pain regimen standardization in this study, however the pain regimen parameters reflect common practice and therefore decrease internal validity but may increase external validity. Despite the lack of involvement of Neomedic in the design, execution, or analysis of the study, their funding of the study adds a potential source of bias for the study. Lastly, the power to detect a 2.5-point pain difference at the week 1 and the duration of the first postoperative week timepoints reduced to 73.7% and 68% with their larger SDs, whereas the day 1 and week 6 timepoints preserved high power levels of 86% and 100%, respectively.

Study strengths include the use of block-randomization that allowed for statistically similar study groups. The intraoperative parameters tested for the two devices confirm and enhance general knowledge on sacrospinous ligament fixation with contemporary surgical devices. Unlike prior studies, this study assessed postoperative pain relative to baseline levels of pain at multiple timepoints, a strategy that helps better isolate and compare novel gluteal and posterior thigh pain during postoperative recovery and assess for clinically significant changes in pain.

In conclusion, this study demonstrated no differences in postoperative gluteal and posterior thigh pain between the two devices. This study helps inform surgeons on the efficiency, performance, and efficacy of two surgical tools that many surgeons rely on to perform native tissue prolapse surgery.

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