Sacrospinous Ligament Fixation Using an Anchor Versus Suture-Capturing Device: A Prospective Cohort Study

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Objective: The aim of the study was to compare rates of persistent gluteal and posterior thigh pain, procedural efficacy, and postoperative complications at 1 year after sacrospinous ligament fixation using either an anchor-based or suture-capturing device.

Methods: This prospective cohort study evaluated outcomes 1 year after operation in patients previously enrolled in a randomized controlled trial comparing an anchor-based versus suture-capturing device for sacrospinous fixation. Symptom scores were evaluated via Pelvic Floor Distress Inventory 20 and Pelvic Floor Impact Questionnaire 7. Pain was evaluated using the Numerical Rating Scale. Composite surgical failure was defined as prolapse beyond the hymen or C-point greater than one half down the vagina, vaginal bulge symptoms, or a need for prolapse retreatment via surgery or pessary management. Descriptive and bivariate statistics were performed.

Results: Forty three (21 anchors, 22 sutures) of the original 47 patients (91%) returned for follow-up. The mean follow-up time was 15.4 months, age was 69 years old, body mass index was 30, and preoperative Pelvic Organ Prolapse Quantification stage was 2.7. No patients reported significant increase in pain at sacrospinous fixation site above baseline, and there was no significant difference in posterior thigh or gluteal pain on the side of fixation compared with baseline in the anchor-based or suture-capture groups (-0.2 ± 0.9 and -0.5 ± 1.6, respectively, $P = 0.719$). Two patients demonstrated surgical failure (anchor group) due to bulge symptoms ($P = 0.233$). The devices similarly improved Pelvic Floor Distress Inventory 20 (-71.0 ± 45.5 vs -66.3 ± 64.4, $P = 0.652$) and Pelvic Floor Impact Questionnaire 7 (-40.6 ± 62.4 vs -26.4 ± 65.7, $P = 0.768$) scores.

Conclusions: Persistent gluteal or posterior thigh pain and surgical failure is uncommon 12 months after sacrospinous fixation and was not associated with the type of fixation device.

Key Words: nerve pain (or injury), pelvic organ prolapse, postoperative/surgical pain, surgical devices, uterine/vaginal prolapse

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Numerous vaginal surgical procedures have been described for treatment of apical prolapse, with one of the most widely practiced being the sacrospinous ligament fixation.[1,2] An unfortunate complication of this extraperitoneal procedure, however, is the high prevalence of postoperative gluteal and posterior thigh pain that can be associated with delayed recovery.[2–6]

Performance of sacrospinous fixation has been facilitated over the past decade by the introduction of suture-capturing devices that require significantly less surgical dissection. Despite a smaller profile needle as compared with devices such as the Miya hook, devices such as the Capio (Boston Scientific, Marlborough, Mass) have still been associated with significant postoperative gluteal pain in 55.4–84.1%.[3–5] Persistent pain at 6 weeks after the procedure has been reported in 15.3–26.9%.[3–5] The etiology of this pain is postulated to be caused by entrapment of the levator ani nerve that runs along the surface of the coccygeus muscle. More serious neuropathic injuries to the sciatic or pudendal nerves can also occur if fixation sutures are placed all the way through the ligament or too close to the ischial spine because these nerves travel in close proximity to the sacrospinous ligament.[2,7–9]

A more recent method of sacrospinous ligament fixation uses an anchor-based device that projects an anchor implant perpendicularly into the ligament, theoretically avoiding levator ani nerve entrapment. The Anchorsure (Neomedic International, Barcelona, Spain) device is one such U.S. Food and Drug Administration–approved tool for sacrospinous fixation. There is currently a paucity of data on postoperative gluteal and posterior thigh pain from these anchor-based tools, with only 1 prior pilot study that reported pain in 15.4%.[10] As such, from October 2018 to August 2020, we conducted a single-center randomized trial comparing short-term pain when using the Anchorsure versus Capio-Slim. Overall, 65% reported pain at day 1, 90% during the first week, and 19% at 6 weeks after the procedure with no difference between groups. Only 1 patient, however, reported a clinically significant increase in gluteal pain at 6 weeks, and none required medical or surgical therapy for refractory pain.[11]

The aim of this extension cohort study is to report the outcomes of these patients at least 1-year postprocedure to determine whether there were any longer-term differences in pain or apical failure between devices. Our primary objective, therefore, was to compare rates of persistent gluteal and posterior thigh pain. Our secondary objectives were to compare composite success, defined as absence of vaginal bulge symptoms, no prolapse beyond the hymen or vaginal apex greater than one half of vaginal length, and no retreatment and postoperative complications between the two devices. The results may further inform surgeons regarding specific device efficacy.

MATERIALS AND METHODS

This study was a prospective cohort study that used patients previously enrolled in an investigator-initiated, single-blinded, head-to-head comparative randomized controlled trial performed at a tertiary care center. Institutional review board approval was obtained for the study.

Inclusion criteria for the initial randomized trial were age at least 21 years, English speaking, surgical plan for native tissue sacrospinous fixation, and the ability to understand and complete the study. Non-English speakers were excluded from this study because we did not have access to personalized language services appropriate for written translation for all of the patient documents that are needed in a randomized controlled trial. Patients with wheelchair dependency, prior sacrospinous fixation, prior mesh-based prolapse repair, history of pelvic irradiation, preoperative daily opioid medication use, significant preoperative gluteal and posterior thigh pain, history of sacral decubitus ulcers, active autoimmune muscle conditions, history of motor or sensory dysfunction of the lower extremity, surgical plan to include a concomitant

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levatorplasty, anal sphincteroplasty, anal fissurectomy, rectopexy, or hemorrhoidectomy were all excluded from participation.

After completion of the 6-week postoperative visit for the initial pain study, women were all invited to return at 1-year postprocedure for repeat assessment. Those who declined an in-person visit were invited to repeat the validated Pelvic Floor Distress Inventory 20 (PFDI-20) questionnaire, Pelvic Floor Impact Questionnaire 7 (PFIQ-7), and a Numerical Rating Scale (NRS) to assess current pain in the posterior thigh and gluteal area by telephone.[12,13] Women who agreed to an in-person visit also underwent a Pelvic Organ Prolapse Quantification (POP-Q) examination by a blinded examiner.[14] Repeat informed consent was obtained either in person or via telephone.

Data Collection

Baseline demographic data, preoperative and 6-week postoperative questionnaire results, and POP-Q examination results were carried forward from the initial study. Interval changes in medical and surgical history, as well as assessment for interval adverse events, were assessed by direct inquiry and chart review of the electronic medical record. Responses to repeat questionnaires and physical examination findings were recorded on study data collection forms and then transcribed into a secure RedCap Database.

Composite surgical failure was defined as recurrent apical prolapse greater than one half vaginal length (C-point), any prolapse beyond the hymen, reoperation or pessary management for recurrent prolapse, or answering "Yes" to the question "Do you usually have a bulge or something falling out that you can see or feel in your vaginal area?" on the PFDI-20.

Postoperative pain was assessed via an NRS questionnaire at 1-year or greater postoperation. Patients rated their pain in the pelvis, posterior right thigh and gluteal region, and posterior left thigh and gluteal region on a 1–10 scale. Consistent with prior publications, we considered a change in NRS score from baseline to postoperative of 2.5 as clinically significant.[5,15,16]

Surgical Technique

Sacrospinous fixation was performed by an anterior, posterior, or apical approach depending on patient-specific anatomic defects and concomitant procedures. Additional procedures, such as hysterectomy, McCall's culdoplasty, anterior and posterior colporrhaphy, perineoplasty, cystoscopy, adnexal procedures, and incontinence procedures were performed as indicated. Fixation of the vaginal cuff to the sacrospinous ligament used two delayed absorbable sutures into the middle of 1 (right side) or both sacrospinous ligaments depending on surgeon's preference. Sacrospinous hysteropexy was performed with the placement of 1 delayed absorbable suture and 1 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.

Statistical Analysis

Based on a prior study of pain at 6 weeks, with anticipated mean pain scores at 1 year to be similar, a standard deviation of 2.8 was expected in NRS pain scores.[5] Our initial randomized trial projected that 23 patients were required in each arm to provide a power of at least 80% to reject a null hypothesis of device equivalence using a two-sided 5% significance level and assuming 15% data loss. Because this study was a longitudinal follow-up of the patients originally enrolled in the randomized trial, we did not perform a second power calculation. Analysis of the data included descriptive statistics. Bivariate analysis with Mann-Whitney U and χ^2/Fisher exact tests using IBM SPSS Statistics software was performed. A P value less than 0.05 was considered significant.

RESULTS

Between October 2018 and August 2020, a total of 47 women underwent surgery (23 in the suture group vs 24 in the anchor group). Of these, 43 (91%, 22 in the suture group vs 21 in the anchor group) agreed to inclusion in this extension trial: 37 of 43 (86%) returned for in-person assessment and 6 of 43 (14%) responded via telephone questionnaire only (Fig. 1). The mean follow-up time was 15.4 months with a median of 13.7 months (range, 11.2–26.3 months). The mean age of the study cohort was 69 years, body mass index was 30, and preoperative POP-Q stage was 2.7. There were no statistically significant differences in demographics, medical history, surgical history, prolapse stage, preoperative PFIQ-7 or PFDI-20 scores, pain history, preoperative pain ratings, or concomitant procedures between groups (Table 1).

For our primary outcome, when compared with baseline, women reported a mean level of pain in the gluteal or posterior thigh area on the side of sacrospinous fixation of −0.3 ± 1.3 with no significant differences between groups (mean: anchor group −0.2 ± 0.9, suture group −0.5 ± 1.6, $P = 0.719$) (Table 2). At 1 year, 3 patients (2 in the anchor group and 1 in the suture group) reported any pain at the site of sacrospinous fixation but no patient met our

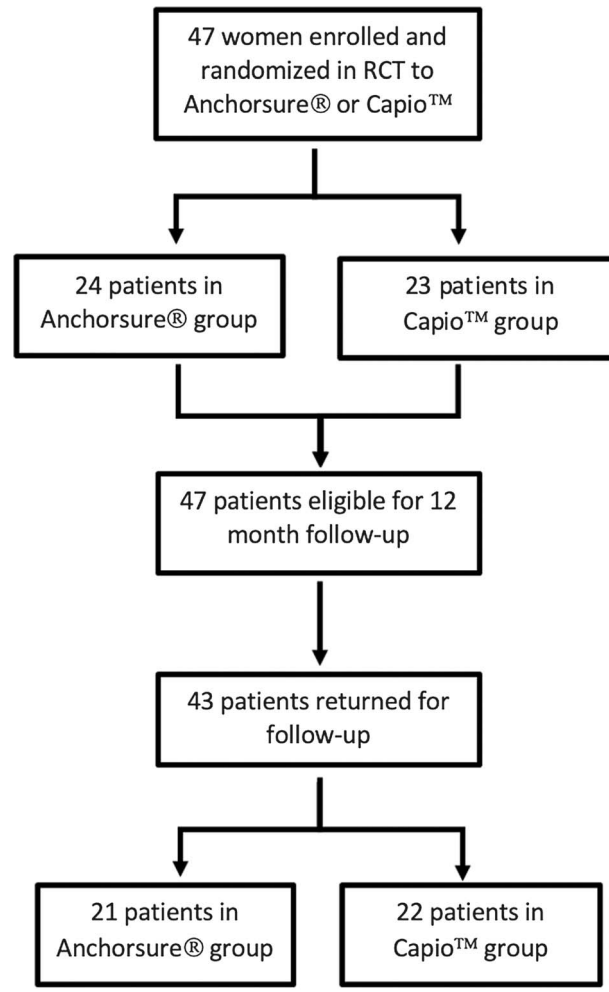

FIGURE 1. Patient flow chart.

TABLE 1. Patient Demographics and Preoperative Data

	Total (N = 43)		Anchorsure (n = 21)		Capio (n = 22)		
Category	**n (%)**	**Avg (SD)**	**n (%)**	**Avg (SD)**	**n (%)**	**Avg (SD)**	***P***
Time to follow-up, mo		15.4 (4.3)		15.3 (4.1)		15.5 (4.5)	0.966
Age, y		69.4 (9.7)		68.7 (8.8)		70.1 (10.7)	0.652
BMI		30.0 (6.4)		29.9 (6.6)		30.1 (6.4)	0.898
Race							
White	38 (88%)		19 (90%)		19 (86%)		1.000
Black	5 (11%)		2 (10%)		3 (14%)		
Sexually active	18 (42%)		10 (48%)		8 (36%)		0.455
Postmenopausal	40 (93%)		19 (90%)		21 (95%)		0.607
Obstetrical hx*							
No. vaginal deliveries		2 (1)		2 (1)		2 (1)	1.000
No. cesarean deliveries		0 (0)		0 (0)		0 (0)	1.000
Charlson Comorbidity Index		3.5 (1.6)		3.4 (1.5)		3.5 (1.7)	0.991
Smoking history	16 (37%)		8 (38%)		8 (36%)		1.000
Preop pain status							
Chronic pain	24 (56%)		11 (52%)		13 (59%)		0.763
Highest preop pain score		2.3 (2.4)		2.2 (2.5)		2.3 (2.4)	0.896
Future sacrospinous ligament fixation site preop pain score		0.7 (1.5)		0.6 (0.3)		0.7 (1.7)	0.892
Surgical history							
Abdominal surgery	27 (63%)		13 (62%)		14 (64%)		1.000
Vaginal prolapse surgery	2 (5%)		1 (5%)		1 (5%)		1.000
Any hysterectomy	11 (26%)		6 (29%)		5 (23%)		0.736
Other pelvic/vaginal surgery	26 (60%)		14 (67%)		12 (55%)		0.537
Preop data							
POP-Q stage		2.7 (0.7)		2.8 (0.8)		2.7 (0.6)	0.807
POP-Q C-point		- 0.2 (3.8)		−0.2 (4.1)		−0.5 (3.5)	0.758
POP-Q TVL		9.3 (0.9)		9.3 (1.0)		9.3 (0.7)	0.795
PFIQ-7 score		59.7 (55.4)		57.8 (60.0)		61.7 (51.6)	0.655
PFDI-20 score		115.2 (50.1)		106.2 (46.4)		124.7 (53.3)	0.257
Type of fixation							
Hysteropexy	19 (44%)		8 (38%)		11 (50%)		0.543
Vaginal vault suspension	10 (24%)		6 (29%)		4 (19%)		0.719
Bilateral sacrospinous fixation	4 (9%)		2 (10%)		2 (9%)		1.000
Concomitant procedures							
Hysterectomy	14 (33%)		7 (33%)		7 (33%)		1.000
Anterior repair	34 (79%)		15 (71%)		19 (86%)		0.281
Posterior repair	38 (88%)		19 (90%)		19 (86%)		1.000
Salpingo-oophorectomy	15 (36%)		7 (33%)		8 (38%)		1.000
Midurethral sling	22 (51%)		12 (57%)		10 (45%)		0.547

Demographic information, medical/surgical history, and preoperative prolapse/pain/symptom score data.

*Median values with interquartile range given.

BMI, body mass index; (calculated as weight in kilograms divided by height in meters squared); PFDI-20, Pelvic Floor Distress Inventory 20; PFIQ-7, Pelvic Floor Impact Questionnaire 7; POP-Q, Pelvic Organ Prolapse Quantification; TVL, total vaginal length

predefined clinically significant increase of 2.5 on NRS above baseline. None of the patients required anchor or sacrospinous suture removal within the first year after implantation, and no patient had requested any pain intervention. When comparing individual patients' baseline worst pain to pain at 1 year, there was a significant decrease noted ($P = 0.001$).

For secondary outcomes, there was no difference between the anchor- and suture-based groups. At 1-year follow-up, composite surgical failure was seen in 2 patients in the anchor group due to bulge symptoms compared with none in the suture group ($P = 0.233$). Of note, neither patient with composite failure based on bulge symptoms had cervical descent at least half-way down the vagina or bulge beyond the introitus on examination. There were no failures based on POP-Q results or retreatment. Mean POP-Q stage in the anchor-based and suture-capture groups were similar (0.9 ± 0.8 vs 0.8 ± 0.9, $P = 0.633$; Table 3).

Within the first year postoperatively, there were no serious adverse events in either group, including no cases of surgical hemorrhage or visceral injury due to sacrospinous fixation. There were 10 adverse events (2 in the anchor and 8 in the suture groups) noted in a total of 7 patients that occurred after the final visit of the randomized trial (6-week postoperative visit) and the 1-year

TABLE 2. Postoperative Pain Scores (All Data Presented as Mean)

	Total (N = 43)		Anchorsure (n = 21)		Capio (n = 22)		
Category	**n (%)**	**Avg (SD)**	**n (%)**	**Avg (SD)**	**n (%)**	**Avg (SD)**	***P***
Sacrospinous ligament fixation site pain rating		0.3 (1.2)		0.6 (1.7)		0.1 (0.4)	0.803
Sacrospinous ligament fixation site pain compared with preop		−0.3 (1.3)		−0.2 (0.9)		−0.5 (1.6)	0.719
Sacrospinous ligament fixation site increase in pain compared with preop	3 (7%)		2 (10%)		1 (5%)		0.607
Significant sacrospinous ligament fixation site pain compared with preop	0 (0%)		0 (0%)		0 (0%)		—
Worst pain in pelvis rating		0.6 (1.8)		0.7 (1.9)		0.5 (1.8)	0.866
Worst pain compared with preop		−1.7 (3.0)		−1.5 (2.8)		−1.8 (3.1)	0.645

assessment. These adverse events included 3 cases of urge urinary incontinence and 7 cases of urinary tract infection. There were no cases of delayed infection or anchor erosion. The devices similarly improved PFDI-20 (anchor-based −71.0 ± 45.5 vs suture-capture −66.3 ± 64.4, $P = 0.652$) and PFIQ-7 (anchor-based −40.6 ± 62.4 vs suture-capture −26.4 ± 65.7, $P = 0.768$) scores at 1 year compared with baseline levels.

DISCUSSION

In this cohort extension study, we demonstrate that the use of a permanent anchor as compared with a suture-capturing device for native tissue sacrospinous ligament fixation did not result in any significant difference in longer-term posterior thigh or gluteal pain. Notably, neither device was associated with any clinically significant, chronic neuropathic pain, or other serious adverse events, and no interventions for suture or anchor removal were required. Because 1 group had a permanent anchor implanted into the sacrospinous ligament, we considered it important to assess pain beyond the original randomized trial period of 6 weeks. Both surgical approaches performed well with a less than 5% rate of composite surgical failure, with no failures at the vaginal apex due to "pull out" of sutures or the anchor, and there were no cases of retreatment. Validated questionnaires confirmed significant improvement in subjective outcomes in both groups. Experienced pelvic floor surgeons can, therefore, choose to use either device with equal expectations for performance as long as the same level of precision of sacrospinous ligament fixation is achieved.

There are limited data regarding longer-term pain after native tissue sacrospinous fixation especially with the use of newer suture-fixation devices. In a randomized trial of sacrospinous versus uterosacral ligament suspension, persistent pain beyond the more commonly analyzed 6-week time point was noted to be 4.3% with the Capio suture-capturing device at 12 months.[6] The only other data come from a prospective multicenter study reporting a persistent pain rate at 12-month follow-up of 0%.[3] Our study similarly showed no patients with significant pain (>2.5 change on NRS) at 1 year (0%) but 3 patients did have some level of pain increase from baseline. These findings, in combination with known pain data for the first 6-week postoperative period, show that although rates of pain in the acute postoperative period can be as high as 55.4–84.1%, pain continues to decline at 6-week postoperative visit (15.3–26.9%) and beyond.[3–6] The use of a permanent anchor did not elicit a chronic pain response.

While both devices facilitate minimal dissection to the sacrospinous ligament from either an apical, anterior, or posterior approach, haptic feedback is required for accurate placement through the middle portion of the ligament. Anecdotally, we note that the anchor is difficult to remove once deployed and, thus, confidence with correct placement of the protective sheath is necessary before deployment. Although we did not have to navigate trying to remove an anchor remote from surgery, it likely would be

TABLE 3. Subjective and Objective Success Data

	Total (N = 43)		Anchorsure (n = 21)		Capio (n = 22)		
Category	**n (%)**	**Avg (SD)**	**n (%)**	**Avg (SD)**	**n (%)**	**Avg (SD)**	***P***
PFIQ-7 score		23.6 (47.2)		11.8 (23.7)		34.8 (60.4)	0.084
PFIQ-7 difference from preop		−33.3 (63.7)		−40.6 (62.4)		−26.4 (65.7)	0.768
PFIQ-7 improvement		0.7 (0.5)		0.7 (0.5)		0.8 (0.4)	0.510
PFDI-20 score		41.3 (37.9)		30.2 (22.2)		51.8 (46.5)	0.229
PFDI-20 difference from preop		−68.6 (55.4)		−71.0 (45.5)		−66.3 (64.4)	0.652
PFDI-20 improvement		0.9 (0.3)		1.0 (0.3)		0.9 (0.4)	0.607
Bulge symptoms	2 (5%)		2 (10%)		0 (0%)		0.233
	Total (n = 37)		**Anchorsure (n = 19)**		**Capio (n = 18)**		
Category	**n (%)**	**Avg (SD)**	**n (%)**	**Avg (SD)**	**n (%)**	**Avg (SD)**	***P***
Anatomical failure	0 (0%)		0 (0%)		0 (0%)		—
C-point		−7.7 (1.3)		−7.6 (1.3)		−7.8 (1.3)	0.730
TVL		8.7 (0.9)		8.6 (0.9)		8.8 (1.0)	0.641
POP-Q stage		0.9 (0.8)		0.9 (0.8)		0.8 (0.9)	0.663

PFDI-20, Pelvic Floor Distress Inventory 20; PFIQ-7, Pelvic Floor Impact Questionnaire 7; POP-Q, Pelvic Organ Prolapse Quantification; TVL, total vaginal length.

challenging if the anchor is well applied. If the anchor is not felt to be causing injury to nerves or vessels, it could be left in place and a new anchor placed into a more ideal location. Sciatic and pudendal nerve entrapment due to surgeon error in placement is likely not as easily reversed with the anchor as the suture device.

Although adequately powered for the primary outcome of short-term pain in the original randomized trial,[11] this study was not powered to evaluate any differences in chronic pain or surgical success and is limited by the relatively small size and length of follow-up. However, we had an 86% rate of in-person follow-up and successfully queried symptoms in 91% of the initial cohort with a low rate of loss to follow-up. Although postoperative pain related to sacrospinous fixation decreases over time, failure increases over time as well and, thus, comparative assessment over several years would be necessary to determine whether equivalent long-term surgical outcomes exist between these 2 devices. In addition, long-term follow-up is necessary for any permanent implant, regardless of how small, to ensure no adverse events. Another limitation is that the study may not be generalizable to a broader population of surgeons, or non-English–speaking patients because it was performed at a single medical center. Fellows did, however, participate in all procedures, which improves external validity.

In conclusion, this extension study reveals no significant cases of persistent gluteal or posterior thigh pain in women undergoing sacrospinous fixation at 1-year postprocedure with no differences when using an anchor versus suture-based fixation device. Overall, patients had excellent results with no serious adverse events. Levator ani nerve entrapment did not seem to factor as a major issue in either group. Future research, in the form of longer prospective studies or larger randomized controlled trials, can confirm the surgical efficacy findings outlined here.

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