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RESEARCH ARTICLE

Clinical outcomes for minimally invasive sacroiliac joint fusion with allograft using a posterior approach

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Abstract

Background: Sacroiliac joint (SIJ) dysfunction can occur as a result of injury, degeneration, or inflammation. This dysfunction presents symptoms of pain at various locations, including the low back, hips, buttocks, and legs. The diagnosis of SIJ dysfunction is challenging and cannot be achieved solely with imaging studies such as X-rays, MRI, or CT. The current gold standard diagnostic modality is intra-articular SIJ blocks using two differing local anesthetics. Current treatments for SIJ dysfunction may be beneficial for short-term relief but lack long-term efficacy. The purpose of our study was to examine the outcomes of patients who underwent minimally invasive, posterior SIJ fusion using allograft at a single center.

Methods: This was a retrospective study which received exemption from the WCG IRB. Data regarding preoperative and postoperative pain levels, surgical time, complications, and medication usage were obtained retrospectively from patient electronic medical records and prescription drug monitoring program reports. No mapping was completed prior to the procedure. Pain was assessed with the 11-point (0–10) Visual Analogue Scale (VAS) and medication usage was assessed using Morphine Milligram Equivalents (MME). Patients were included if they had been diagnosed with SIJ dysfunction using two intra-articular diagnostic blocks that resulted in at least an 80% decrease in pain and had failed conservative management. Patients with sacral insufficiency fractures were excluded.

Results: VAS scores reduced from 8.26 (SD = 1.09) at baseline to 2.59 (SD = 2.57), 2.55 (SD = 2.56), 2.71 (SD = 2.88), and 2.71 (SD = 2.88) at 3, 6, 9, and 12 months, respectively. MME reduced from 78.21 mg (SD = 51.33) to 58.95 mg (SD = 48.64), 57.61 mg (SD = 47.92), 61.71 mg (SD = 45.64), and 66.29 mg (SD = 51.65) at 3, 6, 9, and 12 months, respectively. All reductions in VAS scores and MME were statistically significant. No adverse events occurred, and the average operating room time was 40.16 min (SD = 6.27).

Conclusion: Minimally invasive, posterior SIJ fusion using allograft is a safe and efficacious method for managing SIJ dysfunction.

KEYWORDS
arthrodesis, chronic pain, posterior sacroiliac joint fusion, sacroiliac joint dysfunction

INTRODUCTION

The sacroiliac joint (SIJ) is located at the intersection of the sacrum and the ilium bones of the pelvis.[1] It is characterized as a synovial joint that allows for a small amount of movement and helps to transfer load between the upper body and the lower extremities.[2] The dysfunction of the SIJ can cause low back pain, a common and debilitating condition that affects a significant proportion of the population.[3,4] Other areas of pain that may be symptomatic of SIJ dysfunction include hip pain and pain in the buttocks or legs.[5] The pain can be described as a dull ache or a sharp stabbing sensation without numbness or tingling and may be worse with certain activities, such as standing or walking.[6] Stiffness and limited mobility may also be present with SIJ dysfunction.[7]

There are several causes of SIJ dysfunction, including injury, degeneration, and inflammation.[6,8] Trauma to the joint, such as from a fall or car accident, can cause damage to the joint and lead to dysfunction. Degenerative changes, such as those seen with aging, osteoarthritis, or previous lumbar fusion surgery, can also cause the joint to become stiff and painful. Inflammation of the joint, such as from an infection or autoimmune disorder, is another etiology of dysfunction. Additional risk factors for SIJ dysfunction include pregnancy, leg length discrepancy, high body mass index, and scoliosis.

The diagnosis of SIJ dysfunction can be challenging, as the symptoms are similar to those of lumbar spine-related conditions including radiculopathy, herniated disc, and spondylodiscitis.[9,10] The similarities in symptoms have resulted in SIJ dysfunction to be underdiagnosed and undertreated.[5] Imaging studies, such as X-rays, MRI, or CT, may be helpful in identifying joint abnormalities or degeneration, but they are mostly considered a poor predictor of SIJ pain generation.[11–13] In addition, bone scans are not recommended as a diagnostic tool due to the modality's low sensitivity.[14,15] Injections with local anesthetics, including intra-articular SIJ blocks using two differing local anesthetics, have become the gold standard diagnostic modality in identifying pain generation and SIJ dysfunction.[5] As an illustration, a solitary diagnostic injection into the SIJ exhibits a high Positive Predictive Value and high Negative Predictive Value when applying a 2nd diagnostic block, meeting the criteria for insurance company approvals.[16]

Current treatment options for SIJ dysfunction include physical therapy, SI belts, oral medications, injections, radiofrequency ablation, and surgery. Physical therapy can help to improve the strength and flexibility of the muscles that support the joint, and may be effective in reducing pain and improving function.[17] SI belts can reduce the load transferred by the joint, thus minimizing pain, but is only a temporary solution. Oral over-the-counter medications, such as non-steroidal anti-inflammatory drugs and painkillers, can help to alleviate pain, but they may not address the underlying problem. As with other chronic pain conditions, opioids are also not recommended due to the risks of long-term use.[18] Injections, including prolotherapy and intra-articular administration of local anesthetics or corticosteroids, also aim to mitigate pain in the short-term.[17] Another non-surgical modality is radiofrequency ablation, which has been evidenced to provide analgesia.[2] However, the evidence supporting it is still limited in literature.[19] Surgery, such as SIJ fusion, may be considered in cases where other less invasive treatments have been ineffective or if there is severe degeneration or instability of the joint.[9] Previous studies have demonstrated that SIJ fusion is effective in reducing pain resistant to other therapies.[20–22]

The purpose of this retrospective clinical study was to evaluate the results of posterior SIJ fusion using allograft at a single center. The study aimed to assess changes in pain levels, medication usage, complications, and surgical time in patients who underwent the procedure.

METHODS

This study received an IRB exemption (WCG IRB, #1-1737148-1) and included a total of 43 cases of posterior SIJ fusion using allograft (LinQ®, PainTEQ, Tampa, FL, USA) at a single center between November 2021 and November 2022. All cases were performed by an experienced interventional pain physician. All patients included in the study had a diagnosis of SIJ dysfunction and had failed conservative management. Preemptive imaging was used to rule out sacral insufficiency fractures prior to proceeding. In addition, two successful intra-articular diagnostic blocks with 80% decrease in pain were necessary before proceeding. Confirmation of accurate needle placement in the SIJ during diagnostic blocks was guaranteed through a lateral fluoroscopic image in all instances. There was no preoperative image mapping to identify exact trajectory or target approach for the posterior implant in this study.

The patients' electronic medical records and prescription drug monitoring program reports were reviewed to collect data on preoperative and postoperative pain levels, surgical time, complications, and medication usage. Pain levels were evaluated using the 10-cm Visual Analogue Scale (VAS). Medication usage was measured using Morphine Milligram Equivalents (MME). Statistical analysis was conducted using IBM SPSS Statistics 26 software, and a p-value less than 0.05 was considered significant.

Procedure

Posterior approach SIJ fusion using allograft is a surgical procedure that involves the fusion of the sacrum and the iliac bones (the two large bones in the pelvis) using an allograft (tissue taken from a donor) and demineralized bone matrix to stabilize the bones and alleviate pain. Landmark guidance under fluoroscopy views is used. The graft placement is targeted between S1 and S2 with avoidance of lower placements based on the positive studies from the biomechanics study findings.

The patient is positioned prone on a radiolucent operating table. The anesthesia team initiates MAC, ensuring the patient is comfortable but responsive to commands and questions. The lumbosacral area is prepped with antiseptic solution and covered with sterile drapes. An oblique fluoroscopic view is used to visualize the target joint, and the skin is marked accordingly. A curved-tip #22-gauge spinal needle is inserted percutaneously into the SIJ under fluoroscopic guidance, with confirmation in the lateral view. After confirming negative aspiration and no contrast uptake, 3 mL of a Lidocaine 1% and

0.25% Marcaine mixture is injected. The needle is then withdrawn to the middle cluneal nerve, where another 4 mL of the Lidocaine/Marcaine mixture is injected for acute pain management.

A 1.5 cm posterior midline incision is made over the sacroiliac joint, and a 2 mm Steinmann pin (blunt tip) is inserted into the joint along the same path as the previously inserted spinal needle, just beneath the posterior superior iliac spine. The pin is inserted with light pressure, without the need for force or hammering. Using the Steinmann pin as a guide, two tissue dilators are placed into the joint with very light pressure. The inner dilator is removed, leaving the outer dilator as a working channel. A joint decorticator is advanced down the working channel by tapping with a mallet to prepare a cavity in the joint for the structural bone allograft implant. The 8 mm wide allograft implant is prepped and placed, and the working channel is removed, leaving only the allograft implant in the patient. This is confirmed with fluoroscopy in multiple views. The steps for this procedure are summarized with imaging in Figure 1A–I.

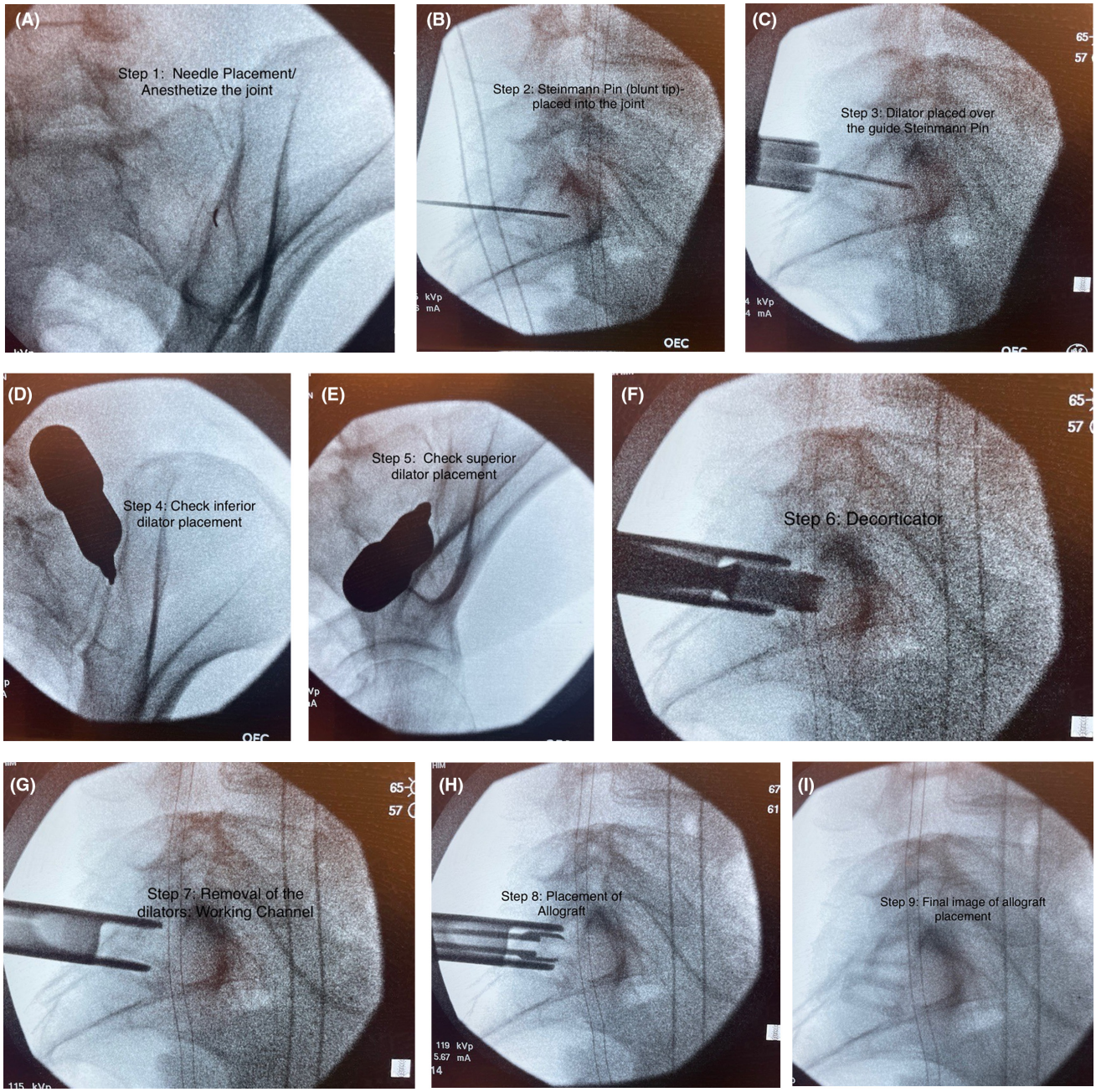

FIGURE 1 (A) Step 1—Needle placement/anesthetize the joint. (B) Step 2—Steinmann Pin (blunt tip) placed into the joint. (C) Step 3—Dilator placed over the guide Steinmann Pin. (D) Step 4—Check inferior dilator placement. (E) Step 5—Check superior dilator placement. (F) Step 6—Decorticator. (G) Step 7—Removal of the dilators: Working Channel. (H) Step 8—Placement of Allograft. (I) Step 9—Final image of Allograft placement.

The surgery concludes with wound closure in layers: intermittent 2.0 Vicryl sutures for the deep layer, intermittent 2.0 Vicryl for the superficial layers, and monocryl subcuticular sutures for the dermis. A sterile dressing is applied, and the patient is transferred to the recovery room. The patient is discharged home the same day. Physical therapy may be required following the surgery to help the patient regain strength and mobility. Patients are restricted from bending, twisting, and lifting more than 10 lbs for 6 weeks.

RESULTS

Patients

Forty-three patients were included in our study with 17 males and 26 females (Table 1). The average age of patients was 65.51 (SD = 12.31) years and average BMI was 32.43 (6.29) kg/m^2. In all, 24 patients underwent left SIJ fusion and 19 underwent right SIJ fusion. All 43 patients completed the preoperative, 3-, and 6-month post-surgery assessments, whereas 21 reported outcomes at the 9- and 12-month follow-ups.

Changes in pain levels

Our study yielded data demonstrating a statistically significant decrease in pain levels among patients at 3-, 6-, 9-, and 12-month post-surgery (Table 2). The mean preoperative VAS score for the 43 patients included in the study was 8.26 (SD = 1.09), whereas the mean postoperative pain score at 3 months was 2.59 (SD = 2.57, $p < 0.001$), indicating a 69% reduction in pain levels. At six months, the mean VAS score was 2.55 (SD = 2.56, $p < 0.001$) for the same 43 patients. Lastly, the mean VAS scores at both nine and 12 months was 2.71 (SD = 2.88, $p < 0.001$) for the 21 patients available at follow-up. These results are consistent with the outcomes of an ongoing randomized controlled trial (SECURE study).[23]

TABLE 1 Patient demographics.

Sex	Male—17 Female—26
Mean age (SD) [range]	65.51 (12.31) years [27–83 years]
Mean BMI (SD)[a] [range]	32.43 (6.29) kg/m^2 [21.40–46.10 kg/m^2]
Laterality of fusion	Left—24 Right—19

[a]BMI available for 41/43 cases.

TABLE 2 Mean VAS scores.

	Mean VAS score (SD)	*p*-value	Sample size
Pre-op	8.26 (1.09)	-	43 patients
3 months	2.59 (2.57)	<0.001	
6 months	2.55 (2.56)	<0.001	
Pre-op	8.71 (0.72)	-	21 patients
9 months	2.71 (2.88)	<0.001	
12 months	2.71 (2.88)	<0.001	

Changes in medication usage

A statistically significant decrease in the utilization of analgesics was observed at all follow-ups post-surgery (Table 3). The mean preoperative MME consumption for 43 patients was 78.21 mg (SD = 51.33), whereas the mean postoperative consumption at three and six months was 58.95 mg (SD = 48.64, $p < 0.001$) and 57.61 mg (SD = 47.92, $p < 0.001$), respectively. At nine and 12 months, the mean MME consumption was 61.71 mg (SD = 45.64, $p < 0.001$) and 66.29 mg (SD = 51.65, $p < 0.001$), respectively, for the 21 patients available at follow-up.

Other outcomes

We found no instances of adverse events or post-operative complications among the patients included. Patients required minimal post-operative prescription medication support. Notably, none of the patients reported an increase in pain or worsening harm after the intervention. This is despite no preoperative mapping. Operating room (OR) times were under an hour for every case with a mean of 40.16 min (SD = 6.27). The maximum OR time was 54 min, and the minimum was 29 min. Blood loss experienced was negligible.

DISCUSSION

Our study determined that posterior SIJ fusion using allograft significantly reduced pain and medication consumption without any adverse events. The use of an 8 mm wide allograft in posterior SIJ fusion is novel, with current evidence being reported in conference abstracts and the ongoing prospective SECURE study.

TABLE 3 Mean MME.

	Mean MME (SD)	*p*-value	Sample size
Pre-op	78.21 (51.33)	-	43 patients
3 months	58.95 (48.64)	<0.001	
6 months	57.61 (47.92)	<0.001	
Pre-op	85.95 (49.69)	-	21 patients
9 months	61.71 (45.64)	<0.001	
12 months	66.29 (51.65)	<0.001	

The limited evidence so far has been positive with regard to outcomes for pain. Our mean reductions in pain level aligns with results from five conference abstracts examining posterior SIJ fusion using an allograft which reported reductions in pain scores ranging from 5.9 to 6.29.[24] This improvement is much greater than that reported by previous reviews on minimally invasive SIJ fusion without using an allograft where improvements of pain scores ranged from 2.5 to 4.9 in one,[25] and 3.7 to 5.5 in another.[26] It has been proposed that the enhanced improvement of pain using an allograft may be due to greater stability of the fused SIJ.[27]

In general, the minimally invasive approach we took mitigates many risks attributed to traditional open surgeries. Due to the less invasive nature, less damage is caused to surrounding tissues and organs. This results in a reduced risk for patients to experience complications as well as less pain and blood loss.[28] The reduced risk for complications can be evidenced in our study where no occurrences of adverse events or post-operative complications were found. Patients in our study also experienced negligible blood loss. Recovery is also faster with minimally invasive surgery, with patients typically going home the same day and able to return to work or other activities sooner. Due to the quicker recovery and fewer complications, the need for postoperative care is also reduced.[29] Furthermore, OR times are shorter, resulting in less anesthesia required and allowing for greater numbers of patients with uncontrolled pain who require SIJ fusion to have the procedure done with a shorter wait time.[30] Overall, minimally invasive surgeries can lead to significant healthcare cost reductions for both patients and healthcare providers.[31]

It has long been recognized that the SIJ is a source of low back pain.[32,33] However, the diagnosis of SIJ pain/dysfunction is frequently overlooked.[34] The prevalence of SIJ pain in low back pain patients vary across reports but range from 15% to as high as 30%.[32–37] SIJ pain has comparatively low quality of life than other disorders including chronic renal failure and epilepsy. This may be attributed to the lack of effective long-term management strategies.

Conservative management strategies for SIJ dysfunction have been largely ineffective for many patients. Dengler et al. (iMIA study) and Polly et al. (INSITE study) in separate randomized controlled trials reported that patients undergoing SIJ fusion using triangular titanium implants experienced greater levels of pain and functional improvement than those in the conservative management group.[4,38] Specifically, the iMIA study found that improvements in the 100-point VAS and Oswestry Disability Index (ODI) were more substantial by 34 and 18 points, respectively, in the SIJ fusion group at 24 months.[4] The INSITE study reported the reductions in the 100-point VAS and ODI were 38.2 and 22.8 points, respectively, more for SIJ fusion patients at 6 months.[38] Furthermore, opioid consumption decreased more substantially in the SIJ fusion groups. A comparative study conducted by Vanaclocha et al using the same SIJ fusion implant found similar results, with SIJ fusion patients reporting greater pain improvement (6-point reduction in 11-point VAS vs. no change in conservative management) and functional recovery (25-point reduction in ODI vs. no change in conservative management), along with reduced opioid consumption at the 6-year follow-up.[39]

Strengths of our study includes having data from a large cohort of 43 patients up to 6 months after surgery, and long-term outcomes up to 12 months for 21 of the patients. Additionally, one interventional pain physician completed all of the cases at the same site, reducing the risk of variations in surgical technique or environment. Despite the strengths, there are also limitations to acknowledge. The retrospective nature of our study limited our ability to assess additional dependent variables. Outcomes commonly reported by previous studies such as function, quality of life, or patient satisfaction were unable to be assessed by our study.[40–42] Additionally, our study design lacked a control or comparative arm. However, due to the surgical nature of SIJ fusion, it would be unethical to subject control patients to sham surgery. Furthermore, patients in our study have already exhausted other less invasive therapeutics prior to undergoing SIJ fusion. Another limitation was that no post-operative imaging was completed to confirm fusion, which can take up to 3 months for evidence to appear. Lastly, we were limited by the follow-up period that did not extend past 12 months, so placebo effects cannot be completely ruled out.

Future studies should utilize a prospective study design so that additional outcomes can be assessed and include a larger cohort. Patients should also be followed up for >2 years so that the long-term safety and efficacy of SIJ fusion can be verified. New studies should also examine the differences in outcomes for bilateral SIJ fusion, unilateral SIJ fusion, and history of previous lumbar fusion, an area which still lacks sufficient literature.[17,43] Differences in outcomes for the lateral, lateral oblique, versus posterior SIJ fusion procedures should also be examined. Possible comparison groups for future studies include injections and radiofrequency ablation, two treatment modalities which aren't required by the International Society for the Advancement of Spine Surgery to be attempted prior to SIJ fusion.[44] Finally, considering the significant variability of the SIJ, a study comparing preoperative mapping to no preoperative mapping could provide valuable insights. This comparison aims to enhance the precision and effectiveness by ensuring that the implant makes proper contact with both the ileum and sacrum within the joint space which could not be verified in this study.

CONCLUSION

The present retrospective clinical study has provided evidence that the utilization of allograft in posterior SIJ

fusion is a safe and efficacious method for managing SIJ dysfunction. The procedure resulted in a substantial decrease in pain levels and medication consumption, and no complications were reported, including worsening pain. Additionally, the duration of surgery was minimal, which limited postoperative complications. These findings contribute to the increasing body of literature supporting the use of allograft in SIJ fusion surgery.

AUTHOR CONTRIBUTIONS

Robert Moghim and Alaa Abd-Elsayed: conceptualization; Robert Moghim and Katie Edwards: data acquisition; Robert Moghim, Chris Bovinet, Max Y. Jin, Katie Edwards, and Alaa Abd-Elsayed: data analysis and interpretation; Robert Moghim and Max Y. Jin: writing—original draft preparation; Robert Moghim, Chris Bovinet, Max Y. Jin, Katie Edwards, and Alaa Abd-Elsayed: writing—review and editing; All authors have read and agreed to the published version of the manuscript.

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None.

CONFLICT OF INTEREST STATEMENT

Dr. Robert Moghim and Dr. Chris Bovinet are consultants for Painteq. Dr. Abd-Elsayed is an editorial board member of Pain Practice. All other authors have no conflicts of interest to disclose.

DATA AVAILABILITY STATEMENT

Data is available upon request to the corresponding author. The data that support the findings of this study are available from the corresponding author upon reasonable request.

CONSENT

Patient consent was not required as this was exclusively a retrospective chart review with no contact with the patients.

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