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Ultrasound-guided radiofrequency Ablation for SI joint pain:An observational study

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ABSTRACT

Objective: An ultrasound (US) guided RFA technique for the SIJ, utilizing bipolar RF cannula placements along the lateral sacral crest (LSC), has been proposed in anatomical studies. This study evaluated changes in pain intensity, function and quality of life following this technique.

Methods: Patients achieving ≥50% pain relief on two blocks (one FL- and one US-guided) were included. US-guided SIJ RFA was performed with sequential bipolar lesions using two multitined RF cannulae placed along the LSC. The Pain, Disability, Quality of Life Questionnaire-Spine (PDQQ-S), which includes an 11-point (0–10) numeric rating scale (NRS) for pain intensity, was completed pre-RFA, and 2, 6, 9, 12 and 16 months post-RFA. Outcomes at 2 months post-RFA were compared between US-guided and FL-guided SIJ RFA in participants with previous FL-guided SIJ RFA.

Results: 31 patients were included. Statistically significant decreases in pain intensity were observed up to 9 months after US-guided SIJ RFA (Baseline NRS: mean = 6.8 SD = 1.6, 95%CI [6.169, 7.347]; 9 month: mean = 4.8, SD = 2.6, 95%CI [3.891, 5.786]; p = 0.0005), and up to 12 months for PDQQ-S. A clinically significant ≥2 point reduction in pain intensity on the NRS was seen in 48.4% of participants at 9 months. 11 participants had previous FL-guided SIJ RFA; no statistically significant differences were found in pain intensity or PDQQ-S scores between US- and FL-guided SIJ RFA 2-months post-RFA.

Conclusions: Preliminary results suggest that SIJ RFA could be performed using US guidance. Further study is required to establish effectiveness.

1. Introduction

The sacroiliac joint (SIJ) is estimated to be the cause of mechanical low back pain in 10–27% of patients [1]; the prevalence of SIJ origin pain increases with age [2,3]. Radiofrequency ablation (RFA) is a minimally invasive treatment option for SIJ pain that is refractory to other treatments. RFA involves the application of thermal energy to denervate the peripheral innervation of the SIJ, which could lead to pain relief. The success of SIJ RFA has been variable in the literature, with 32–89% of patients achieving at least 50% pain relief for 6 months, and 11–44% of patients achieving 100% pain relief for 6 months [1]. Recent meta-analyses of SIJ RFA, however, have demonstrated significant improvements in pain and disability for up to 12 months utilizing a variety of RFA techniques (cooled, thermal, and pulsed RFA) and RFA needle placements [4–6]. A prospective observational study that examined a bipolar strip lesion technique encompassing the L5 dorsal ramus to the lateral branches of S3 demonstrated >50% pain relief in 50% of patients at 12 months [7]. Therefore, SIJ RFA could provide significant and durable relief for SIJ origin pain.

While a variety of SIJ RFA techniques have been described [8], all current SIJ RFA techniques utilize fluoroscopic (FL) guidance [1]. A technique combining fluoroscopy and ultrasound was recently described [9]. To the best of our knowledge, there are no clinical studies evaluating ultrasound (US) only guided SIJ RFA techniques. US guidance has been

Abbreviations: SIJ, Sacroiliac joint; RFA, Radiofrequency Ablation; US, Ultrasound; FL, Fluoroscopy.

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increasingly explored for a variety of interventional spine procedures [10]. There are a number of advantages to US over FL, including the lack of ionizing radiation, portability and accessibility of US equipment, and the reduced cost of US equipment. Our research group has proposed an US-guided technique for SIJ RFA based on two cadaveric studies we recently conducted [11,12]. These studies identified the posterior sacral network (PSN), a plexus of nerves originating primarily from the S1 to S3 lateral branches, as supplying the SIJ. Our research group demonstrated that US-guided needle placement along the lateral sacral crest (LSC) for SIJ RFA was consistent, safe, and could capture the majority of the PSN within an anatomical model [13].

The purpose of this study was to evaluate preliminary clinical outcomes of our proposed US-guided SIJ RFA technique. The primary outcomes of this study were changes in pain intensity, function and quality of life following US-guided SIJ RFA at 2, 6, 9, 12 and 16 months post-RFA. A secondary outcome of this study was to compare 2-month results from US-guided SIJ RFA to FL-guided SIJ RFA in participants who had previously received FL-guided SIJ RFA. We hypothesized that US-guided SIJ RFA would lead to a clinically significant reduction in pain and improvement in function and quality of life.

2. Methods

A pre-post study design was used to examine clinical outcomes following US-guided SIJ RFA. Ethics approval for this study was obtained from the University of Alberta Research Ethics Board, the University of Western Ontario Research Ethics Board, and the University of Toronto Health Sciences Research Ethics Board. This study was registered at clinicaltrials.gov on Jan. 5, 2015, ID number: NCT02335190. All subjects provided written informed consent to participate in the study.

Subjects were recruited from patients referred to the interventional pain practices of two right-hand dominant study authors, RB (Central Alberta Pain and Rehabilitation Institute, Lacombe, Alberta, Canada) and EL (St. Joseph's Pain Clinic, London, Ontario, Canada), for potential SIJ RFA. RB and EL are Physical Medicine and Rehabilitation specialists with 27 and 10 years of experience, respectively, in interventional musculoskeletal pain management procedures.

Potential participants were initially screened with a FL-guided lateral branch block. Block techniques under FL varied depending on the practices of the physician performing the procedure (not all FL-guided blocks were performed by the study authors). Lateral branch block techniques included 3–4 needle placements at each individual posterior sacral foramen (PSF) from S1 to S3, with 0.2 mL of local anesthetic injected at each needle placement, and multiple needle placements (1 cm apart) along a strip that was lateral to the PSF from S1 to S3. Needles were placed at the level of the periosteum, no more than 1 cm lateral from the lateral border of the PSF. Contrast was not used. Although these techniques are not validated, they were used pragmatically to identify patients who may benefit from SIJ RFA. Intra-articular injections and single site/single-depth blocks were not accepted as diagnostic lateral branch blocks. If patients achieved $\geq$50% relief for at least the duration of the local anesthetic on lateral branch blocks done under FL, an US-guided diagnostic block was performed by RB or EL to confirm response. This involved injecting 0.2–0.5 mL of 2% lidocaine along the LSC from the first transverse sacral tubercle (TST1) to the third transverse sacral tubercle (TST3) at approximately 1 cm intervals as measured and marked along the skin surface. Patients needed to demonstrate $\geq$50% index pain relief for at least the duration of the local anesthetic with US-guided diagnostic block to be included. US identification of landmarks was done using the same methodology that was used for SIJ RFA, described in the next section. The block technique used in this study is similar to an US-guided lateral branch block technique evaluated by Finalyson et al. [14], which demonstrated comparable anesthetization of pain-generating SIJ structures as Dreyfuss' multi-site, multi-depth fluoroscopic technique [15].

In addition to receiving 2 diagnostic blocks (one under FL and a subsequent one under US), inclusion criteria were age 18 years or older, and a clinical presentation compatible with SIJ origin pain (back pain below L5; >2 out of 5 positive SIJ provocative tests [16]).

Exclusion criteria were clinical and/or investigative evidence of inflammatory spondyloarthropathy, fibromyalgia, radiculopathy, symptomatic spinal stenosis, facetogenic or discogenic low back pain, contraindication to the procedure (generalized infection, localized infection to the low back/SIJ, coagulopathy or anticoagulation use, and allergy to local anesthetic), and pain intensity <3/10 on the numeric rating scale (NRS). Patients were not excluded if they had previously received FL-guided SIJ RFA and were returning for a repeat RFA after their pain relief had subsided. Those who had suspected bilateral SIJ involvement were also not excluded. Participants were able to continue their usual adjunctive treatments (e.g. physiotherapy, massage, pharmacotherapy) but could not receive other interventional procedures for sacroiliac joint pain (e.g. sacroiliac joint corticosteroid injections, prolotherapy). Medication dosage and the intensity/frequency of other therapies were not controlled for in this study. If participants chose to pursue other interventional SIJ treatment options during the follow-up period, they were withdrawn from the study, with the assumption that their pain had returned to a baseline level.

2.1. US-guided SIJ RFA

All subjects received US-guided SIJ RFA after enrollment in the study. A Sonosite M-Turbo US machine (Sonosite, Bothell, Washington, USA) was used. Screening US examination around the targeted SIJ was performed using a curvilinear (5-2 MHz) or straight (13-6 MHz) transducer, depending on the depth of the overlying soft tissue. On screening examination, the sacral hiatus and the adjacent S4 posterior sacral foramen on the targeted side were identified in the transverse plane. The S3 through S1 PSF were then identified proximally in the transverse plane, along with the adjacent TSTs on the LSC [11]. TST1, TST2, TST3, and the course of the LSC from TST1 to TST3 were identified and marked on the skin. 1.5 cm intervals (based on manufacturer recommendations for optimal bipolar spacing and studies on RF lesion morphology) [17–19] were then marked on the skin from TST1 to TST3 along the LSC. The skin was prepped and draped in a sterile fashion, and anesthetized with 2% lidocaine at each of the 1.5 cm interval markings.

Using an out-of-plane approach, a 10 cm multitined RF cannula (Nimbus Concepts LLC, Greenwood Village, CO, USA) was inserted at the most distal skin marking (TST3), and advanced under US guidance until the needle was in contact with the LSC. A second multitined RF cannula was inserted at the next 1.5 cm interval skin marking using the same technique.

A small amount of 1% lidocaine was injected through each of the cannulae to ensure comfort as they were advanced. The tines were deployed and RF probes were inserted through each of the cannulae (Diros Technologies Inc., Markham, ON, Canada). The probes were connected to an RF generator (Diros OWL URF-3AP, Diros Technologies Inc., Markham, ON, Canada) and a grounding pad applied. A motor stimulus (1.5V) was applied through each probe. If twitching was felt perianally or into the lower extremities, the position of the cannula was adjusted until twitching stopped. An 80 °C bipolar lesion was then generated for 120 s, after a 30 s ramp time.

The most distal needle was then moved to the next 1.5 cm interval skin marking and advanced to the LSC under US, and the lesioning procedure was repeated. Bipolar lesions were generated in an identical leapfrogging manner until the skin mark identifying TST1 was reached.

Occasionally, the most proximal RF cannula (at TST1) had to be inserted between an in-plane and an out-of-plane approach if the iliac crest interfered with needle advancement. Throughout the procedure, the cannulae were placed as close to parallel as possible to ensure a consistent distance between cannulae at the level of the periosteum.

Table 1 summarizes the protocol used by the authors for performing US-guided SIJ RFA in this study. Fig. 1 demonstrates the ultrasound images for TST1 to TST3, and the projected RFA lesion generated using the described technique.

Table 1
Technique for US-guided SIJ RFA.

Curvilinear (5-2 MHz) or straight (13-6 MHz) transducer, depending on overlying tissue depth
Screening examination and landmark identification:
1) Transverse Plane:
a Identify the sacral hiatus, and the adjacent S4 posterior sacral foramen (PSF)
b Identify the S3 through S1 PSF and the adjacent transverse sacral tubercles TSTs on the lateral sacral crest LSC.[3]
c Mark TST1, TST3, and the course of the LSC on the skin.
d Mark 1.5 cm intervals on the skin from TST1 to TST3 along the LSC.
Needle insertion and Radiofrequency ablation:
1)Prep and drape skin in a sterile fashion.
2)Anesthetize skin with 2% lidocaine at each of the 1.5 cm interval markings.
3)Using an out-of-plane approach
aInsert a 10 cm multitined RF cannula at the most distal skin marking (TST3), and advance cannula under US guidance until contact with the LSC
bInsert a second multitined RF cannula at the next 1.5 cm interval skin marking using the same technique.
4)Inject a small amount of 1% lidocaine through each of the cannulae, insert RF probes and perform an 80 °C bipolar lesion for 120 s, with a 30 s ramp time.
5)Move the most distal needle to the next 1.5 cm interval skin marking and advance to the LSC under US as before. Repeat the lesioning procedure
6)Bipolar lesions were generated in an identical leapfrogging manner until the skin mark identifying TST1 was reached.

Note: The most proximal RF cannula (at TST1) may need to be inserted between an in-plane and an out-of-plane approach if the iliac crest obscures access to TST1.
Ensure that the cannulae are placed as close to parallel to each other as possible to ensure a consistent distance between cannulae at the level of the periosteum.

2.2. Outcome measures

Participants completed a Pain, Disability and Quality of Life Questionnaire – Spine (PDQQ-S) [20] before US-guided SIJ RFA. The PDQQ-S was developed by RB and demonstrated adequate reliability and validity, and superior responsiveness, when compared to the McGill Pain Questionnaire, the Oswestry Disability Index and the Assessment of Quality of Life Scales [20]. The PDQQ-S contains 6 questions that evaluate the domains of pain (1 question on pain intensity, 1 question on pain frequency), disability (respondents are asked to list 2 activities that are limited by pain and to rate their difficulty performing each task), satisfaction (1 question), and quality of life (1 question). The PDQQ-S was validated using a visual analogue scale (VAS) to collect responses for each question. Because follow-up was conducted via telephone in this study, an 11-point (0–10) numeric rating scale (NRS) was used to capture participant responses for each item on the PDQQ-S. Psychometric evaluation of the NRS version of the PDQQ-S has also demonstrated favourable characteristics [21] An overall PDQQ-S score was generated by adding the scores of each domain; the maximum possible score was 60.

At 2 and 6 months post-RFA, subjects were contacted via telephone and the PDQQ-S was completed again. If there was ongoing, clinically significant relief at 6 months (at least a 2-point improvement in pain intensity on the PDQQ-S compared to baseline), subjects were contacted by phone to complete the PDQQ-S at 9, 12 and 16 months post-RFA. If the pain intensity score of the PDQQ-S demonstrated less than a 2-point improvement compared to baseline for 2 consecutive follow-ups, then follow-ups were discontinued.

2.3. Participants with previous FL-guided RFA

A subset of participants in the study (n = 11) had previous FL-guided SIJ RFA performed by RB as part of routine clinical care, and had achieved sufficient pain relief to warrant a repeat RFA. FL-guided SIJ RFA was accomplished by creating a strip lesion lateral to the PSF from S1 to S3. In all but one of these subjects, four conventional 18 gauge monopolar RF cannulae were placed in series lateral to the PSF under FL. Quadripolar RFA was performed at 80 °C for 120 s, after a ramp time of 25 s. For each thermal lesion, cannulae were placed parallel to each other 0.8 cm apart. Two or 3 adjacent quadripolar strip lesions were used to achieve a sagittally aligned strip lesion extending from lateral to the first PSF to the third PSF. The remaining subject had two Nimbus multitined cannulae placed in series, 1.5 cm apart, lateral to the PSF under FL. In this subject, four sequential bipolar lesions were used to generate a strip lesion from the first to third PSF. 8 of 11 patients also had the L5 dorsal ramus ablated as part of the procedure.

2-month PDQQ-S outcome data captured using the NRS was available for those who had prior FL-guided SIJ RFA. Pain intensity and total PDQQ-S scores were compared between FL- and US-guided SIJ RFA at 2 months. Note that these participants received at least one FL-guided SIJ RFA, with success, prior to each of the procedures (either FL-guided or US-guided SIJ RFA) where outcomes were recorded and used in this study. Thus, outcomes utilized in this study for this particular subgroup of participants, whether it was for the FL-guided or US-guided SIJ RFA

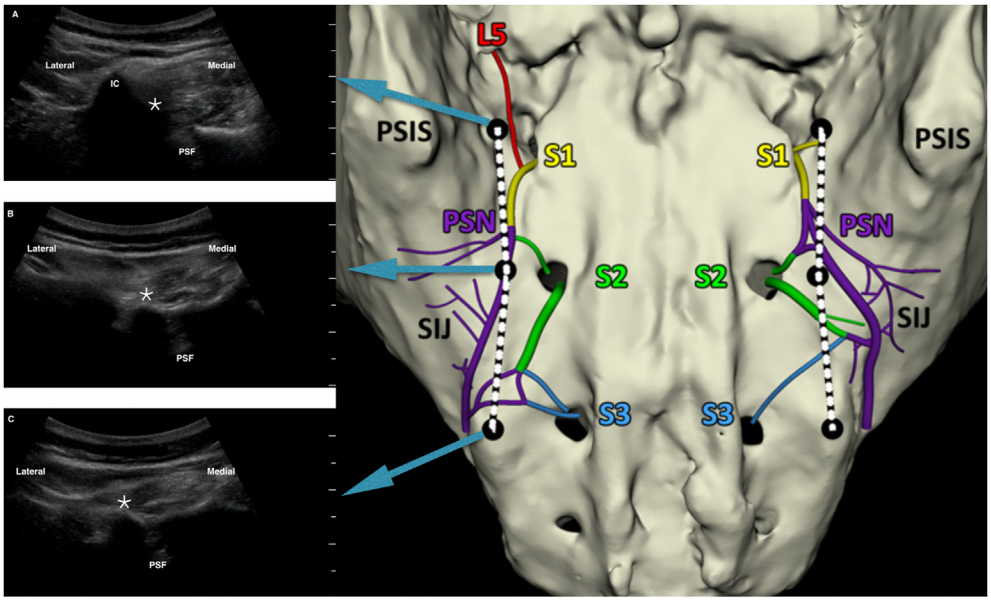

Fig. 1. Anatomical model of sacroiliac joint innervation with associated ultrasound images. On the right, a model of the sacrum is shown with the posterior innervation of the SIJ. The positions of the posterior superior iliac spine (PSIS) and the sacroiliac joint (SIJ) are labelled on the model. The L5 (red), S1 (yellow), S2 (green), and S3 (blue) lateral branches that contribute to the PSN (purple) innervating the SIJ are illustrated. The black dots on the model indicate the transverse sacral tubercles (TST). Each blue arrow indicates the corresponding ultrasound images of TST1 (A), TST2 (B) and TST3 (C), and are marked by an asterisk (*) on the ultrasound image. PSF indicates the associated posterior sacral foramen at each level, IC indicates the iliac crest at TST1. The dotted line indicates the expected extent of the strip lesion generated along the lateral sacral crest from TST1 to TST3, using the leapfrogging bipolar RFA technique outlined in Table 1. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

they received, were repeat procedures following successful FL-guided SIJ RFA.

2.4. Statistical analysis

Statistical analysis was performed using SPSS Statistics version 24.0 (IBM Corp, Armonk, New York). The data were summarized with descriptive statistics. Pain intensity score on the PDQQ-S, overall PDQQ-S scores, and scores on other domains of the PDQQ-S (pain frequency, disability, satisfaction, and quality of life) at each post-RFA time point were compared to pre-RFA scores using a one-way repeated measures ANOVA. As the disability domain includes scores for 2 separate self-identified activities that are difficult to perform because of pain (each scored out of 10), the average of a participant's 2 scores was used for analysis of the disability domain. For those participants who withdrew, no longer met requirements for follow-up (less than 2-point improvement in pain intensity compared to baseline for 2 consecutive follow-ups), or were lost to follow-up, baseline scores were used for subsequent data collection timepoints after withdrawal, and also for any timepoints with missing/incomplete data. The proportions of subjects who achieved a ≥2-point reduction on pain intensity as measured on the NRS, and a ≥50% and ≥90% reduction in pain intensity and PDQQ-S were also quantified. An analysis of pain intensity and overall PDQQ-S outcomes was also conducted with participants who had received prior FL-guided SIJ RFA excluded.

In addition, for participants who had received both US-guided and FL-guided SIJ RFA, a one-way repeated measures ANOVA was used to compare the mean pre-RFA and 2 months post-RFA NRS and PDQQ-S scores between the US-guided and FL-guided SIJ RFA techniques. Statistical significance was set at $p < 0.05$.

3. Results

A total of 32 participants were enrolled in the study. Final sample size was 31, as one participant was withdrawn from the study after developing a new, unrelated lumbar radiculopathy during the follow-up period. As this participant no longer met study criteria, data from this participant was not included in the analysis. 26/31 participants achieved ≥80% relief on US-guided diagnostic blocks as part of this study. At each post-RFA follow-up time point, the number of withdrawals was as follows: at 2 months, no withdrawals; at 6 months, 2 withdrawals (both sought alternative treatments); at 9 months, 7 withdrawals (5 sought alternative treatments, 1 had <2 point relief compared to baseline on 2 consecutive follow-ups, 1 was lost to followup); at 12 months, 6 withdrawals (2 sought alternative treatment, 3 had <2 point relief compared to baseline on consecutive follow-ups, 1 was lost to followup); and at 16 months, 4 withdrawals (2 had <2 point relief compared to baseline on 2 consecutive follow-ups, 2 were lost to followup). 13 participants had both sides treated with US SIJ RFA because of bilateral SIJ involvement. 11 participants had previously received FL-guided SIJ RFA. Participant characteristics are presented in Table 2.

Table 2
Participant characteristics.

Characteristic	US-guided SIJ RFA (n = 31)
Age (years), mean ± SD	56.5 ± 10.1
Sex, n (%)	
Male	11 (35.5)
Female	20 (64.5)
Side, n (%)	
Left	6 (19.4)
Right	12 (38.7)
Bilateral	13 (41.9)
BMI (kg/m^2), mean ± SD	28.6 ± 8.3

BMI, body mass index; RFA, radiofrequency ablation; SD, standard deviation; SIJ, sacroiliac joint; US, ultrasound.

Table 3
US-guided SIJ RFA: Mean pain intensity and overall PDQQ-S scores pre- and post-RFA (n = 31).

Outcome Measure	Time Point	Mean ± SD	95% CI (LL, UL)	*p*
Pain Intensity	Pre-RFA	6.8 ± 1.6	(6.169, 7.347)	–
	2 mos post	3.4 ± 2.6	(2.473, 4.365)	<0.0001*
	6 mos post	4.0 ± 2.5	(3.097, 4.934)	<0.0001*
	9 mos post	4.8 ± 2.6	(3.891, 5.786)	0.0005*
	12 mos post	5.4 ± 2.7	(4.368, 6.342)	0.0760
	16 mos post	6.0 ± 2.4	(5.058, 6.846)	0.6602
PDQQ-S	Pre-RFA	44.4 ± 7.6	(41.625, 47.182)	–
	2 mos post	22.0 ± 15.8	(16.252, 27.813)	<0.0001*
	6 mos post	26.0 ± 14.6	(20.700, 31.396)	<0.0001*
	9 mos post	31.1 ± 14.7	(25.696, 36.498)	0.0002*
	12 mos post	36.0 ± 15.8	(30.214, 41.786)	0.0317*
	16 mos post	39.1 ± 14.0	(33.976, 44.250)	0.2324

CI, confidence interval; mos, months; PDQQ-S, Pain Disability Quality of Life Questionnaire-Spine; LL, lower limit; RFA, radiofrequency ablation; SD, standard deviation; SIJ, sacroiliac joint; UL, upper limit; US, ultrasound.
*Statistically significant difference ($p < 0.05$) compared to pre-RFA score.

3.1. Pain intensity and PDQQ-S scores after US-guided SIJ RFA

There was a statistically significant reduction in mean pain intensity scores at 2, 6 and 9 months after US-guided SIJ RFA compared to pre-RFA scores (Table 3, Fig. 2). Statistically significant reductions in mean overall PDQQ-S scores were seen at 2, 6, 9 and 12 months (Table 3, Fig. 3). For specific categories on the PDQQ-S, there were statistically significant reductions in pain frequency and disability at 2, 6 and 9 months post-RFA; statistically significant improvements in satisfaction and quality of life were present up to 12 months post-RFA (Table 4). PDQQ-S subscore data was missing (even though total PDQQ-S scores were available) for 2 participants starting at 2 months, 3 participants starting at 9 months, 1 participant starting at 12 months and 1 participant at 16 months. This was in addition to missing data for participants who had withdrawn, sought other treatments, or were lost to follow-up (described above). Baseline observation carried forward analysis was used for all missing subscore data.

77.4% of subjects had a ≥2-point reduction in pain intensity at the first 2-month follow-up, with a gradual decrease in the proportion of subjects achieving that degree of pain relief over time (Table 5). 48.4% of subjects had a clinically significant ≥2-point reduction in pain intensity up to 9 months after US-guided SIJ RFA. Twelve months post-RFA, 25.8% of subjects continued to experience a clinically significant reduction in pain intensity.

Two months post-RFA, 61.3% of subjects achieved a ≥50% reduction in pain intensity, with 41.9% of subjects continuing to experience this magnitude of pain relief at 6 months post-RFA (Table 5, Fig. 4). Sixteen months post-RFA, the proportion of subjects with ≥50% pain relief declined further to 12.9%. A similar decrease in the proportion of subjects achieving ≥50% reduction on the PDQQ-S was observed in the first 16 months post-RFA (from 54.8% at 2 months post-RFA to 9.7% at 16 months post-RFA) (Table 5, Fig. 4).

9.7% of subjects achieved ≥90% relief in pain intensity for the entire follow-up period (Table 5). Similarly, 6.5% of subjects experienced ≥90% reduction on the PDQQ-S that persisted for the duration of the study (Table 5).

3.2. US-guided SIJ RFA in those without prior FL-guided SIJ RFA

20 participants had not received prior FL-guided SIJ RFA. When the 11 participants who had prior FL-guided SIJ RFA were excluded from the analysis, statistically significant reduction in pain intensity was seen up to 9 months (Table 6), as in the full sample. Statistically significant improvement in overall PDQQ-S scores was observed up to 9 months in

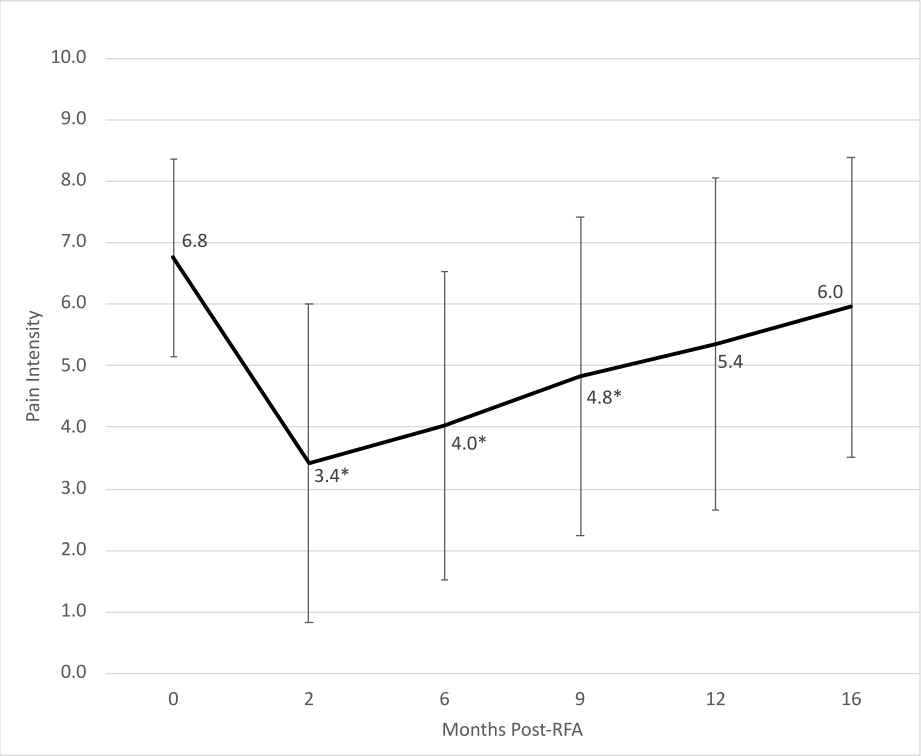

Fig. 2. Mean Pain Intensity Scores following US-guided SIJ RFA. (* = statistically significant change).

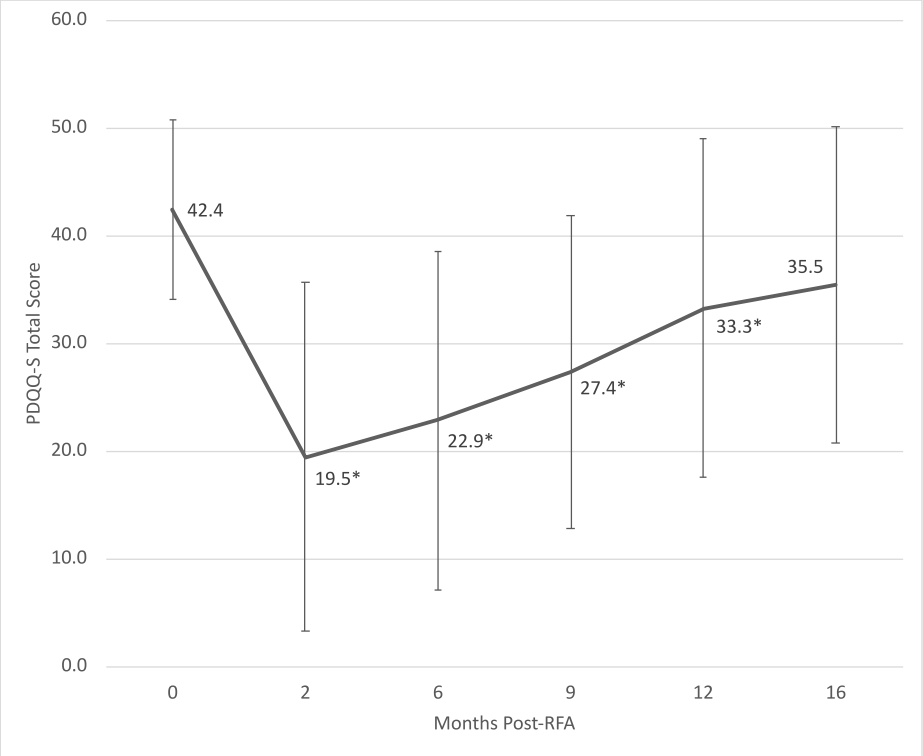

Fig. 3. Mean PDQQ-S Scores following US-guided SIJ RFA. (* = statistically significant change).

this subgroup (Table 6), whereas statistically significant improvement was present up to 12 months in the full sample.

In the subgroup that excluded those with prior FL-guided SIJ RFA, a similar proportion of participants demonstrated a ≥2-point reduction, a ≥50% reduction and a ≥90% reduction in pain intensity for each time period post-RFA as compared to the full sample (for example, 80% vs. 77.4% at 2 months and 30% vs. 25.8% at 12 months for a ≥2-point reduction; 70.0% vs. 61.3% at 2 months and 25.0% vs. 22.6% at 12 months for a ≥50% reduction; 10% vs. 9.7% at 12 months for a ≥90% reduction) (Tables 7 and 5). Similar proportions between this subgroup

Table 4
US-guided SIJ RFA: PDQQ-S domain scores pre- and post-RFA (n = 31).

PDQQ-S Domain	Time Point	Mean ± SD	*p*	95% CI (LL, UL)
Pain Frequency	Pre-RFA	8.4 ± 2.1	–	(7.577, 9.133)
	2 mos post	4.0 ± 3.3	<0.0001*	(2.840, 5.225)
	6 mos post	4.8 ± 3.3	<0.0001*	(3.611, 6.002)
	9 mos post	5.9 ± 3.2	0.0050*	(4.753, 7.118)
	12 mos post	6.9 ± 3.2	0.1537	(5.780, 8.091)
	16 mos post	7.0 ± 3.0	0.1356	(5.930, 8.135)
Disability	Pre-RFA	7.1 ± 1.7	–	(6.510, 7.683)
	2 mos post	3.7 ± 2.8	<0.0001*	(2.682, 4.640)
	6 mos post	4.5 ± 2.7	<0.0001*	(3.659, 5.405)
	9 mos post	5.4 ± 2.6	0.0043*	(4.471, 6.238)
	12 mos post	6.0 ± 2.9	0.1085	(5.048, 7.016)
	16 mos post	6.4 ± 2.7	1.0000	(5.661, 7.532)
Satisfaction	Pre-RFA	8.2 ± 2.0	–	(7.433, 8.889)
	2 mos post	3.9 ± 3.5	<0.0001*	(2.614, 5.193)
	6 mos post	4.6 ± 3.5	0.0002*	(3.359, 5.932)
	9 mos post	5.7 ± 3.4	0.0027*	(4.467, 6.953)
	12 mos post	6.5 ± 3.3	0.0341*	(5.340, 7.757)
	16 mos post	7.4 ± 2.8	0.4933	(6.373, 8.401)
Quality of Life	Pre-RFA	6.9 ± 1.7	–	(6.322, 7.549)
	2 mos post	3.3 ± 2.8	<0.0001*	(2.279, 4.366)
	6 mos post	4.0 ± 2.6	0.0002*	(3.048, 4.952)
	9 mos post	4.9 ± 2.6	0.0054*	(3.979, 5.892)
	12 mos post	5.3 ± 2.8	0.0478*	(4.305, 6.340)
	16 mos post	6.1 ± 2.5	0.8053	(5.162, 7.031)

CI, confidence interval; LL, lower limit; mos, months; PDQQ-S, Pain Disability Quality of Life Questionnaire-Spine; RFA, radiofrequency ablation; SD, standard deviation; SIJ, sacroiliac joint; UL, upper limit; US, ultrasound.
*Statistically significant difference ($p < 0.05$) compared to pre-RFA score.

and the full sample achieved a ≥50% reduction and a ≥90% reduction on overall PDQQ-S score for each time period post-RFA (Tables 7 and 5).

3.3. Changes in pain intensity and PDQQ-S between US-guided and FL-guided SIJ RFA

In the 11 subjects who had previously received FL-guided SIJ RFA, there was no statistically significant difference in NRS (Fig. 5) and PDQQ-S (Fig. 6) scores at baseline or 2 months between US- and FL-guided SIJ RFA (Table 8). There may be a trend to improved outcomes following FL-guided SIJ RFA, but this was not statistically significant.

Average number of months between FL-guided SIJ RFA and US-guided SIJ RFA was 15.9 months (±11.2 months). 4 participants had a FL-guided SIJ RFA ≥12 months before US-guided SIJ RFA (average time between procedures was 27.8 ± 10.8 months for these participants), while the remaining 7 participants had the two procedures <12 months apart (average time of 8.8 ± 1.6 months between procedures).

4. Discussion

This observational pre-post study is the first to evaluate the use of an US only-guided technique for SIJ RFA. The findings of this study suggest that the US-guided PSN lateral crest RFA technique may reduce pain intensity, improve function, and improve quality of life for a number of months post-RFA in those with SIJ pain. The proportion of patients experiencing 50% and 90% improvement in pain intensity at 6-month follow-up in this study is similar to prior studies that evaluated FL-guided SIJ RFA techniques [1,22]. Additionally, there was no statistically significant difference in pain relief and overall PDQQ-S score at 2 months after US-guided SIJ RFA compared to FL-guided SIJ RFA for those who had previously obtained benefit from FL-guided SIJ RFA (although only 11 participants were included in this particular analysis). Therefore, US-guided SIJ RFA shows promise as an alternative to FL-guided SIJ RFA.

There was a subset of participants who had protracted pain relief of ≥50% for the duration of the study. In particular, those with ≥90% pain relief post-RFA (n = 3/31 (9.7%, 95% CI: -0.7%, 20.1%)) had consistently excellent relief throughout the follow-up period. This suggests that there is an important group of patients who could benefit significantly from this procedure. Further research is required to identify factors that predict a high likelihood of excellent response to SIJ RFA, which could be used to define appropriate selection criteria.

It should be noted that in this study, US-guided SIJ RFA did not include the L5 dorsal ramus; conversely, FL-guided RFA techniques have usually targeted the L5 dorsal ramus in their protocols [8]. In a prior anatomical study conducted by our group, when the L5 dorsal ramus contributed to the PSN, the L5 lateral branch anastomosed with the S1 lateral branch at the level of TST1 [12]. Thus, the traditional approach of targeting the L5 dorsal ramus at the junction of the transverse process and sacral ala [23] may not capture any additional innervation to the SIJ and was therefore not included as part of the RFA technique in this study. A prior randomized trial of US-guided lateral branch blocks also did not target the L5 dorsal ramus, and demonstrated similar anesthetization of pain-generating SIJ complex structures compared to the multi-site multi-depth fluoroscopic technique [14]. As clinical outcomes from this study are similar to prior FL-guided SIJ RFA studies that included the L5 dorsal ramus, and a randomized trial exploring US-guided lateral branch blocks that excluded the L5 dorsal ramus demonstrated similar results to FL-guided multi-site multi-depth blocks including L5, there is emerging evidence to suggest that including the L5 dorsal ramus in SIJ block/RFA protocols may not be necessary.

Despite the fact that L5 dorsal ramus ablation was not included in the US-guided protocol, persistent benefit from ablation of the L5 dorsal ramus (and potentially other nerves innervating the SIJ) from prior FL-guided SIJ RFA is a potential confounding factor that could account for similar outcomes between FL- and US-guided SIJ RFA. The impact of

Table 5
US-guided SIJ RFA: Proportion of subjects who achieved a ≥2 point, ≥50% or ≥90% reduction in pain intensity and overall PDQQ-S scores post-RFA.

Outcome Measure	Time Point Post-RFA	≥2 Point Reduction		≥50% Reduction		≥90% Reduction	
		n/31	% (95% CI) (LL, UL)	n/31	% (95% CI) (LL, UL)	n/31	% (95% CI) (LL, UL)
Pain Intensity	2 mos	24	77.4 (62.7, 92.1)	19	61.3 (44.1, 78.4)	3	9.7 (−0.7, 20.1)
	6 mos	21	67.7 (51.3, 84.2)	12	41.9 (21.6, 55.9)	3	9.7 (−0.7, 20.1)
	9 mos	15	48.4 (30.8, 66.0)	8	25.8 (10.4, 41.2)	3	9.7 (−0.7, 20.1)
	12 mos	8	25.8 (10.4, 41.2)	7	22.6 (7.9, 37.3)	3	9.7 (−0.7, 20.1)
	16 mos	5	16.1 (3.2, 29.1)	4	12.9 (1.1, 24.7)	3	9.7 (−0.7, 20.1)
PDQQ-S	2 mos	–	–	17	54.8 (37.3, 72.4)	4	12.9 (1.1, 24.7)
	6 mos	–	–	12	38.7 (21.6, 55.9)	2	6.5 (−2.2, 15.1)
	9 mos	–	–	8	25.8 (10.4, 41.2)	2	6.5 (−2.2, 15.1)
	12 mos	–	–	7	22.6 (7.9, 37.3)	2	6.5 (−2.2, 15.1)
	16 mos	–	–	3	9.7 (−0.7, 20.1)	2	6.5 (−2.2, 15.1)

CI, confidence interval; LL, lower limit; mos, months; PDQQ-S, Pain Disability Quality of Life Questionnaire-Spine; RFA, radiofrequency ablation; SIJ, sacroiliac joint; UL, upper limit; US, ultrasound.

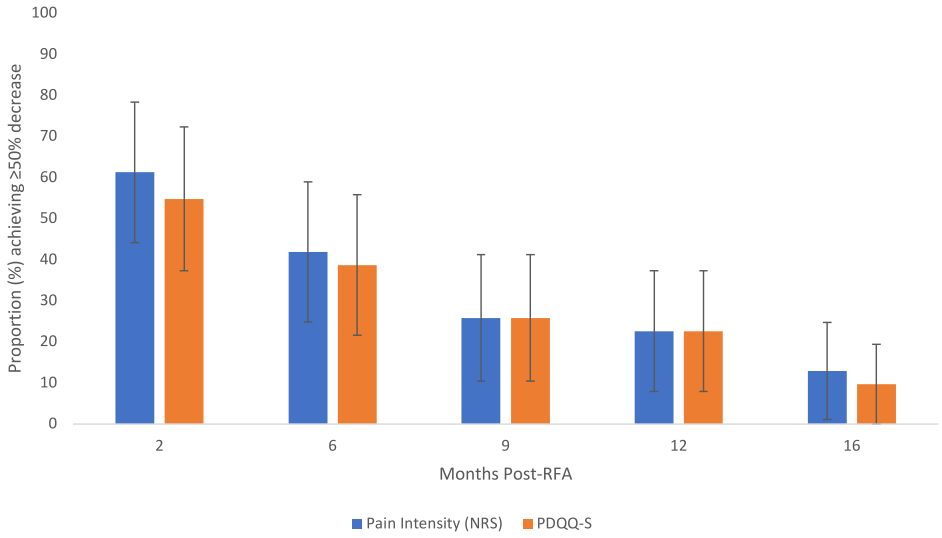

Fig. 4. Proportion of participants achieving at least 50% reduction on pain intensity and the PDQQ-S 2–16 months post-RFA. Error bars represent 95% confidence intervals.

Table 6
US-guided SIJ RFA: Mean pain intensity and PDQQ-S scores pre- and post-RFA of those without a prior history of fluoroscopic-guided RF ablation (n = 20).

Outcome Measure	Time Point	Mean ± SD	95% CI (LL, UL)	*p*
Pain Intensity	Pre-RFA	6.6 ± 1.8	(5.804, 7.446)	–
	2 mos post	3.2 ± 2.8	(1.906, 4.494)	<0.0001*
	6 mos post	3.7 ± 2.9	(2.364, 5.086)	0.0040*
	9 mos post	4.6 ± 2.6	(3.340, 5.760)	0.0109*
	12 mos post	5.2 ± 2.7	(3.868, 6.432)	0.3226
	16 mos post	5.8 ± 2.5	(4.617, 6.933)	1.0000
PDQQ-S	Pre-RFA	43.5 ± 7.4	(39.990, 46.96)	–
	2 mos post	19.5 ± 16.2	(11.922, 27.078)	<0.0001*
	6 mos post	22.9 ± 15.7	(15.516, 30.234)	0.0005*
	9 mos post	28.5 ± 15.2	(21.385, 35.615)	0.0036*
	12 mos post	34.4 ± 15.9	(26.912, 41.788)	0.1618
	16 mos post	36.6 ± 14.8	(29.659, 43.491)	0.3628

CI, confidence interval; mos, months; PDQQ-S, Pain Disability Quality of Life Questionnaire-Spine; LL, lower limit; RFA, radiofrequency ablation; SD, standard deviation; SIJ, sacroiliac joint; UL, upper limit; US, ultrasound.
*Statistically significant difference ($p < 0.05$) compared to pre-RFA score.

ongoing denervation of the L5 dorsal ramus and other nerves innerating the SIJ is less likely a factor given the length of time that elapsed between FL-guided and subsequent US-guided SIJ RFA (15.9 ± 11.2 months). 7/11 participants, however, had repeat RFA under US-guidance <12 months after FL-guided RFA (8.8 ± 1.6 months apart), so the effect of ongoing denervation cannot be excluded. One finding in this study that may support the inclusion of the L5 dorsal ramus when performing SIJ RFA was the trend (though not statistically significant) of improved outcomes after FL-guided SIJ RFA compared to US-guided SIJ RFA; 8 of 11 participants in the FL-guided SIJ RFA group had the L5 dorsal ramus included as part of the FL-guided RFA procedure. Additional study is needed to confirm the importance of the L5 dorsal ramus in SIJ RFA.

A technical consideration of the US-guided RFA technique was the use of multitined electrodes in a bipolar distribution to generate the RFA lesion. An advantage of this technique was to minimize the number of placements that were necessary to generate a strip lesion. Separating adjacent RFA cannulae by 1.5 cm also increased the ease of manipulating the US probe while placing the RFA cannula. If a conventional RFA cannula was used in a bipolar configuration, the distance between adjacent needles would have to be approximately 1 cm, which would increase the technical difficulty of the procedure as the number of cannulae placements and consequently the procedure time would increase, and it would be more difficult to manipulate the cannulae and the US probe simultaneously. In addition to improving the technical ease of the procedure, a multitined electrode was used because it generates a larger lesion volume at its distal tip than a conventional RFA electrode [24]. Since the PSN courses along the periosteum at the level of the lateral crest, a larger lesion at the periosteum would increase the chances of successful RFA of nerve branches innervating the SIJ.

An anatomical study that quantified the percentage of lateral branches that would be captured with different SIJ RFA techniques estimated that 93.4%–99.7% of lateral branches, on average, would be captured by the majority of bipolar RFA techniques [8]. Conversely, in clinical studies that utilized a bipolar SIJ RFA technique, only 33–69% of patients achieved at least 50% relief at 6 months [8]. Results of the current study fit this trend; only 41.9% of participants had at least 50% relief at 6 months. Capturing >90% of the posterior innervation of the SIJ would be expected to lead to better clinical results than have been achieved. Possible reasons for the lower than expected benefit of SIJ RFA in clinical studies, despite a sound anatomical rationale, include [1] incorrect attribution of pain to the posterior SIJ innervation (as would be the case with false positive diagnostic blocks), and [2] inadequate capture of the posterior SIJ innervation using the selected RFA technique *in vivo*. This study utilized a lateral branch block technique similar to the US technique evaluated by Finlayson et al., which was shown to have similar outcomes to a FL-guided multi-site multi-depth block approach [14]; we would expect this to partially mitigate the number of false positives after diagnostic block. Finlayson's technique involved the infusion of local anesthetic at TST1, TST2 and TST3, while the block technique in this study utilized sequential infusion of local anesthetic along the lateral crest from TST1 to TST3 at 1 cm intervals. Although patients were only included if they had demonstrated ≥50% relief on fluoroscopic lateral branch blocks, different techniques under FL were performed prior to enrollment in the study, and this block was not standardized. It is possible that the false positive rate during the diagnostic testing phase, and thus the clinical success of RFA, may have been improved if the US block was performed on 2 occasions, rather than utilizing one FL-based and one US-based diagnostic block.

Inadequate capture of the posterior SIJ innervation as a possible reason for the reduced clinical success of US-guided SIJ RFA, compared to the expected outcomes from anatomical studies, may relate to the morphology of the lesions that were generated. Given the undulating posterior surface of the sacrum [8], various local tissue properties [19],

Table 7
US-guided SIJ RFA: Proportion of participants who achieved a ≥2 point, ≥50% or ≥90% reduction in pain intensity and PDQQ-S scores post-RFA, excluding those participants who previously received FL-guided SIJ RFA.

Outcome Measure	Time Point (Post-RFA)	≥2 Point Reduction		≥50% Reduction		≥90% Reduction	
		n/20	% (95% CI) (LL, UL)	n/20	% (95% CI) (LL, UL)	n/20	% (95% CI) (LL, UL)
Pain Intensity	2 mos	16	80.0 (65.9, 94.1)	14	70.0 (53.9, 86.1)	3	15.0 (2.4, 27.6)
	6 mos	13	60.0 (48.2, 81.8)	10	50.0 (32.4, 67.6)	3	15.0 (2.4, 27.6)
	9 mos	10	50.0 (32.4, 67.6)	6	30.0 (13.9, 46.1)	2	10.0 (−0.6, 20.6)
	12 mos	6	30.0 (13.9, 46.1)	5	25.0 (9.8, 40.2)	2	10.0 (−0.6, 20.6)
	16 mos	4	16.1 (5.9, 34.1)	3	15.0 (2.4, 27.6)	2	10.0 (−0.6, 20.6)
PDQQ-S	2 mos	–	–	12	60.0 (42.8, 77.2)	4	20.0 (5.9, 34.1)
	6 mos	–	–	9	45.0 (27.5, 62.5)	2	10.0 (−0.6, 20.6)
	9 mos	–	–	5	25.0 (9.8, 40.2)	2	10.0 (−0.6, 20.6)
	12 mos	–	–	5	25.0 (9.8, 40.2)	2	10.0 (−0.6, 20.6)
	16 mos	–	–	2	10.0 (−0.6, 20.6)	2	10.0 (−0.6, 20.6)

CI, confidence interval; LL, lower limit; mos, months; PDQQ-S, Pain Disability Quality of Life Questionnaire-Spine; RFA, radiofrequency ablation; SIJ, sacroiliac joint; UL, upper limit; US, ultrasound.

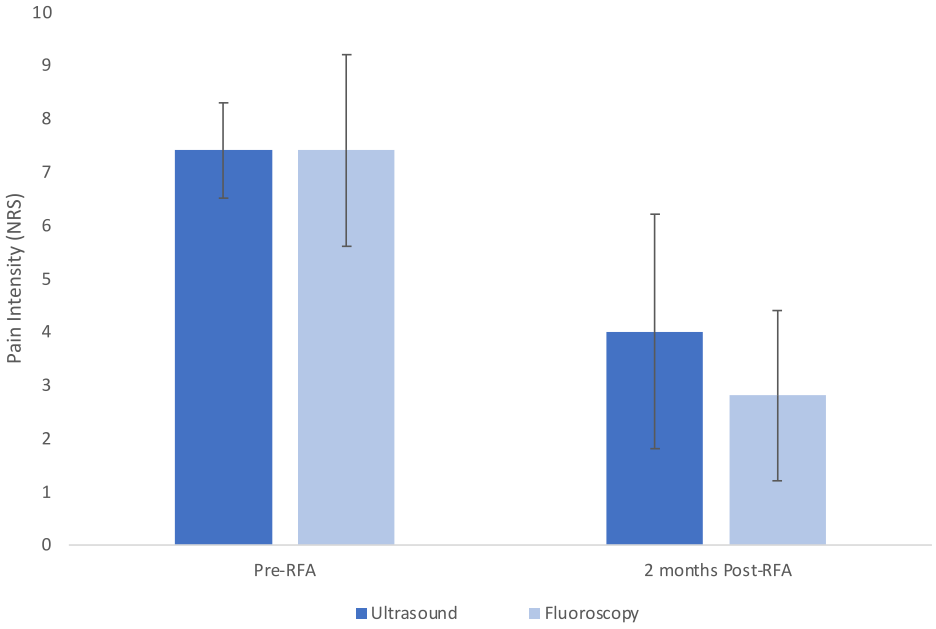

Fig. 5. Mean Pain Intensity Scores before and 2 months after US-guided SIJ RFA (dark blue) or FL-guided SIJ RFA (light blue). Error bars represent standard deviation. No statistically significant difference was found between US and FL. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

and other local factors (initial temperature, bloodflow, electrothermal properties, injected fluids) [19], a bipolar strip lesion along the surface of the periosteum may not have been consistently generated despite sound placement technique. In addition, although care was taken by the interventionalists to ensure that the RFA cannulae were placed parallel to each other, parallel placement was challenging to achieve at TST1. The prominence of the PSIS made a purely sagittal, out-of-plane approach to TST1 difficult, therefore, an approach that was between an out-of-plane and in-plane approach was necessary to reach TST1. If the distance between electrodes at the periosteal level was too far apart, an adequate bipolar lesion may not have been generated [18]. Difficulties generating a strip lesion at the surface of the sacrum may account for the trend towards improved outcomes for FL-guided SIJ RFA in the group that had received both FL-guided and US-guided procedures. The FL-guided SIJ RFA technique using conventional RFA cannulae in a quadripolar arrangement (which necessitated a closer interelectrode spacing of 0.8 cm) was used in 10/11 participants – this closer interelectrode spacing may have mitigated the impact of undulations on the sacral surface, allowing the generation of a more consistent lesion at the periosteum. Closer interelectrode spacing may therefore need to be considered for SIJ RFA given the need to generate a lesion at the periosteum on an undulating surface, even if 15 mm (or more) distance between electrodes is sufficient to generate an adequate bipolar lesion in an *ex vivo* model. A pre-RFA ultrasound scan of the dorsal surface of the SI joint, to determine if the path of the thermal lesion is on a smooth or undulating surface, may be useful in choosing the optimal SIJ RFA technique.

An additional technical factor that may have impacted success of the RFA procedure was the lesioning time used as part of the study (120 s after a 30 s ramp time). A lesion beyond 2 min has been suggested to ensure adequate temperatures to induce cell death [25]; improved results from a more consistent lesion may have been achieved in this study with a longer duration lesion at 80 °C. The lesion time in this study was chosen to be consistent with the lesioning time used in those who had received prior FL-guided RF ablation.

The main limitation of this study was its observational nature. Thus, the causal effect of US-guided SIJ RFA on pain intensity, function, and

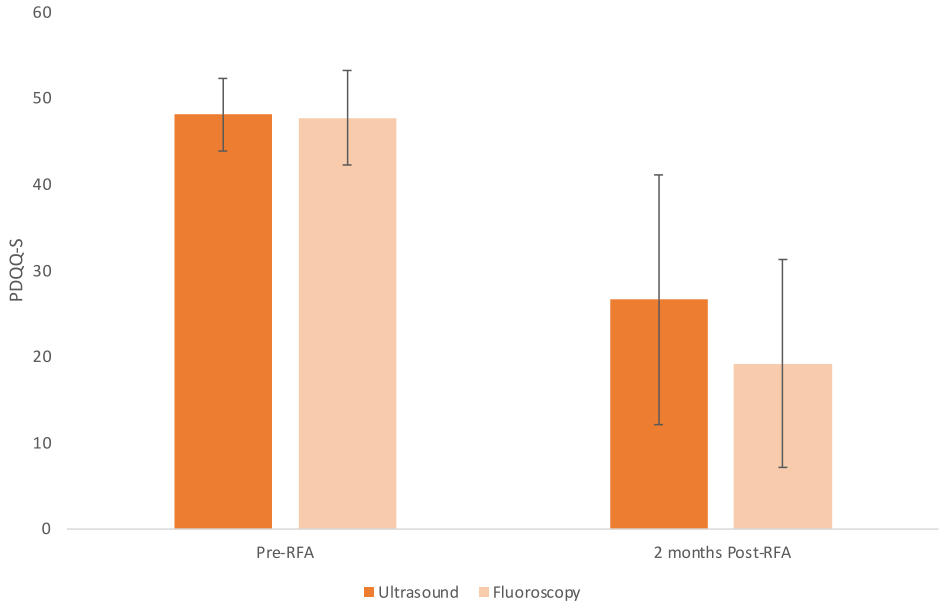

Fig. 6. Mean PDQQ-S scores before and 2 months after US-guided SIJ RFA (dark orange) or FL-guided SIJ RFA (light orange). Error bars represent standard deviation. No statistically significant difference was found between US and FL. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

quality of life could not be definitively established. Numerous confounding factors may have impacted the results of the trial, including lack of randomization, persistence of benefit from SIJ RFA in those who had the procedure previously done under FL, and the effect of other treatments [26]. Concurrent treatments, such as pharmacotherapy (including opioid use), physical therapy, and other therapy modalities, were not controlled in this study, although participants were restricted from receiving other SIJ interventional procedures. The effect of concurrent treatments may account for some of the improvement in the post-RFA period; however, the patients referred to the study authors' practices have often maximized and failed other medical treatments, including pharmacological management and other therapies.

As success with prior RFA is a strong predictor of success with subsequent RFA [27], the inclusion of pateints who previously had successful SIJ RFA under FL may introduce bias into the results. The impact of this on the current study was likely minimal for two reasons. First, an analysis of pain intensity and overall PDQQ-S scores that excluded those who received prior FL-guided SIJ RFA demonstrated similar results to the entire sample. Secondly, order effects bias was not expected to be a factor as 10/11 participants with prior FL-guided SIJ RFA had received at least one FL-guided SIJ RFA before the FL-guided procedure that was used to compare outcomes with US-guided SIJ RFA. Thus, participants with a prior FL-guided SIJ RFA had a FL-guided SIJ RFA preceding each of their procedures (either FL-guided or US-guided SIJ RFA) where outcomes were captured for analysis.

Table 8
US-guided vs. FL-guided SIJ RFA: Mean pain intensity and PDQQ-S scores pre- and 2 months post-RFA for patients who have had both procedures (n = 11).

Outcome Measure	Time Point (Pre/Post-RFA)	US-guided RFA (n = 11)	FL-guided RFA (n = 11)	*p*
		Mean ± SD	Mean ± SD	
Pain Intensity	Pre-RFA	7.4 ± 0.9	7.4 ± 1.8	1.000
	2 mos post-RFA	4.0 ± 2.2	2.8 ± 1.6	0.144
PDQQ-S	Pre-RFA	48.1 ± 4.2	47.7 ± 5.5	0.810
	2 mos post-RFA	26.6 ± 14.5	19.2 ± 12.1	0.126

FL, fluoroscopy; mos, months; PDQQ-S, Pain Disability Quality of Life Questionnaire-Spine; RFA, radiofrequency ablation; SD, standard deviation; SIJ, sacroiliac joint; US, ultrasound.

While no differences were observed in mean pain intensity scores at 2 months post-procedure for those who received both FL- and US-guided SIJ RFA, only 11 participants were included in this analysis. It is possible that persistent benefit from previous FL-guided SIJ RFA may have had a positive effect on outcomes associated with US-guided SIJ RFA. Although outcomes in previous FL-guided SIJ RFA studies demonstrate similar results to US-guided SIJ RFA in this study [1,22], direct comparisons to previously published data are challenging given methodological differences. As this study was neither powered nor designed to compare the results of FL-to US-guided SIJ RFA, further study is necessary to determine if FL- and US-guided SIJ RFA yield similar outcomes.

In future, a randomized trial comparing active and placebo US-guided SIJ RFA techniques would confirm the preliminary findings of this study. Use of a standardized dual US-guided block protocol within the randomized trial would be necessary to minimize false positive diagnostic blocks. To improve clinical outcomes, future studies should also evaluate the characteristics of patients who have a high likelihood of achieving significant pain relief; and *in vivo* lesion morphology following SIJ RFA to evaluate the adequacy of the lesions generated. The consistency and size of the lesion along the surface of the periosteum *in vivo* is important to ensure appropriate capture of the SIJ posterior innervation; factors that can optimize lesion generation for SIJ RFA, such as tip spacing, lesion duration, and cannula type, should also be evaluated. Additionally, a study directly comparing FL-guided and US-guided SIJ RFA techniques would help to determine if one is preferable to the other for SIJ RFA.

In conclusion, clinical outcomes following US-guided SIJ RFA are promising. These findings suggest that US could be used to guide SIJ RFA. Further randomized controlled studies are necessary to establish the effectiveness of this technique.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Eldon Loh reports equipment, drugs, or supplies was provided by Nimbus Concepts LLC. Robert S. Burnham reports equipment, drugs, or supplies was provided by Nimbus Concepts LLC.

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