OPEN ACCESS

Cooled radiofrequency ablation provides extended clinical utility in the management of chronic sacroiliac joint pain: 12-month follow-up results from the observational phase of a randomized, multicenter, comparative-effectiveness crossover study

Steven Paul Cohen ,[1,2] Leonardo Kapural,[3] Lynn Kohan,[4] Sean Li,[5] Robert Hurley,[6] Richard Vallejo,[7] Yashar Eshraghi,[8] Pradeep Dinakar,[9] Shravani Durbhakula,[10] Douglas P Beall,[11] Mehul J Desai ,[12] David Reece,[13] Sandy Christiansen ,[14] Min Ho Chang,[13] Adam J Carinci,[15] Michael DePalma[16]

For numbered affiliations see end of article.

Correspondence to
Professor Steven Paul Cohen; steven.cohen@northwestern.edu

Received 13 December 2024
Accepted 10 February 2025

To cite: Cohen SP, Kapural L, Kohan L, *et al*. *Reg Anesth Pain Med* Epub ahead of print: [*please include* Day Month Year]. doi:10.1136/rapm-2024-106315

ABSTRACT

Introduction Sacroiliac joint (SIJ) pain comprises up to 30% of cases of mechanical low back pain (LBP), the leading cause of disability worldwide. Despite sacral lateral branch cooled radiofrequency ablation (CRFA) showing efficacy in clinical trials, there is a lack of comparative-effectiveness long-term follow-up.

Methods In this randomized, multicenter, comparative-effectiveness study, 210 patients with injection-confirmed SIJ pain who responded to prognostic lateral branch blocks were randomly assigned to receive CRFA of the L5 dorsal ramus and S1–S3/4 lateral branches or standard medical management (SMM) consisting of pharmacotherapy, physical therapy, injections, and integrative therapies. Patients were followed up at 1, 3, 6, 9, and 12 months, with participants reporting unsatisfactory SMM outcomes being allowed to crossover (XO) and receive CRFA at 3 months. The primary outcome measure was the mean change in average LBP score on a 0–10 Numeric Rating Scale (NRS), with secondary outcomes including measures of quality of life (QoL) and function. A responder was defined as a participant who experienced a ≥30% or ≥2-point decrease in average daily NRS pain score coupled with a score ≥5 out of 7 (moderately better) on the Patient Global Impression of Change scale.

Results At 12 months, the mean NRS pain score declined from a baseline of 6.4±1.4 to 3.5±2.6, with 57.4% (35/61) of participants in the randomized CRFA cohort experiencing a ≥2-point or 30% decrease in average LBP from baseline. In the crossover cohort, 35/63 (55.6%) subjects had the same experience 12 months following the XO procedure; in the XO group, the mean LBP decreased from 6.1±1.5 to 3.4±2.5. Patients also experienced clinically meaningful improvements in QoL via EuroQoL-5D-5L at 12 months (mean change of +0.22±0.27 in the originally-treated CRFA group and +0.21±0.33 in the XO group). Oswestry Disability Index (ODI) scores also improved by 12.4%±14.7 (CRFA) and 13.7%±17.1 (XO) from baseline at study-end. No serious adverse events related to the CRFA procedure were reported.

Conclusion CRFA in patients with SIJ pain provided clinically significant and sustained improvements for 12 months following a single CRFA treatment, regardless of previous SMM treatment.

Trial registration number NCT03601949.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Cooled radiofrequency ablation is more effective at intermediate-term follow-up than sham radiofrequency and standard medical management, but the long-term effectiveness has not been studied in large-scale randomized trials.

WHAT THIS STUDY ADDS

⇒ Cooled radiofrequency ablation provides sustained benefit to a majority of patients who respond to diagnostic injections and prognostic sacral lateral branch blocks, with comparable proportions of patients in the randomized cooled radiofrequency and crossover radiofrequency groups experiencing clinically meaningful improvement lasting over 1 year.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study shows the superiority of cooled radiofrequency ablation over non-radiofrequency management in a recalcitrant population with long-standing sacroiliac joint pain. It suggests that improved access to care for a refractory condition has the potential to provide long-lasting, improved quality of life.

INTRODUCTION

Low back pain (LBP) has multiple etiologies, a lifetime prevalence rate ranging between 51% and 84%, and is among the leading causes of disability worldwide. There is a disturbing 28% chance of an acute mechanical pain situation turning chronic.[1] It is estimated that 15%–30% of chronic mechanical LBP originates from the sacroiliac joint(s) (SIJ).[2]

The SIJ is technically a diarthrodial synovial joint, but pain can originate from both intra- and extra-articular structures, with one randomized study finding comparable prevalence rates.[3–5]

The complexity of the structural components involved in SIJ LBP leads to challenges in identification and treatment.[4 6 7] Conventional SIJ pain treatment options are limited to pharmacotherapy, injections, integrative therapies, and, in severe refractory cases, fusion.[6 7] However, several studies have shown that cooled radiofrequency ablation (CRFA) of the sacral lateral branches and conventional radiofrequency ablation (RFA) techniques that increase nerve capture rate are effective in patients with SIJ pain who experience meaningful but temporary relief from SIJ injections.[8–13]

RFA delivers thermal energy via current delivered through electrodes, causing thermal degradation (lesions) of nerve tissue through ionic heating.[14] However, the lesion size produced by conventional RFA is limited by charring at the tissue-probe tip interface, which increases the risk of failed nerve capture, reducing efficacy.[15] In CRFA, the temperature at the tissue-tip interface is regulated by water circulating inside the probe.[16] This allows for the targeted delivery of more energy, resulting in larger thermal lesions and a higher likelihood of neural disruption, while simultaneously mitigating tissue charring.[16 17] Cooling also enables distal projection of energy, permitting more direct probe introduction and creates larger, longer-lasting, spherically-shaped lesions than those affected by conventional RFA, at tissue temperatures exceeding 80°C.[17 18] SIJ innervation is variable compared with other targets of RF, making CRFA ideal for this condition.

CRFA has emerged as a promising treatment for patients with refractory SIJ pain, with multiple studies demonstrating efficacy across the spectrum of outcomes including pain, function, analgesic reduction, and quality of life (QoL).[8–10 13 19] CRFA has demonstrated durable pain relief lasting over 1 year for multiple indications including SIJ, knee osteoarthritis, and facet joint pain.[20–23] CRFA is safe, with no major adverse events reported and a low incidence of transient postprocedure neuropathic pain similar to conventional RFA.[24 25] Guidelines recommend sacral lateral branch RFA (and specifically CRFA) for the treatment of SIJ pain following positive prognostic blocks.[26] Despite several sham-controlled studies demonstrating the efficacy of CRFA for SIJ pain, there have been few long-term comparative-effectiveness studies.[11]

The objectives of this multicenter study are to evaluate the long-term (12 months) effectiveness of sacral lateral branch CRFA in patients with chronic SIJ pain and identify variables associated with treatment response. The outcomes of the 3month- comparative-effectiveness trial comparing CRFA to standard medical management (SMM) have previously been published.[27]

PATIENTS

This randomized, controlled, multicenter clinical study was registered in ClinicalTrials.gov (NCT03601949) on 26 July 2018. All participants were enrolled, treated, and followed between 29 June 2018 and 3 November 2021. The protocol and written consent forms were approved by the institutional review boards (IRB) or ethics committees of each participating institution prior to enrollment.

Selection criteria, study sites, randomization, and trial design

Full descriptions of selection criteria, study sites, randomization, and trial design have previously been published.[27] 210 participants from 15 US centers with injection-confirmed SIJ pain who experienced at least 50% pain relief from prognostic blocks of the L5 dorsal ramus and S1-3(4) lateral branches were randomized in a 1:1 ratio to receive either CRFA (treatment group) or physician-prescribed SMM (control group). SMM consisted of self-care, pharmacotherapy, exercise recommendations, integrative therapies (ie, combining complementary treatments such as acupuncture, yoga, or psychotherapy with conventional therapies), and therapeutic injections. Blinded outcome assessors conducted all follow-ups. Follow-up visits were primarily performed in person at 3-month intervals for up to 12 months, though the COVID-19 pandemic drove some data collection to be done remotely.

Participants in the SMM group were permitted to crossover (XO) and receive CRFA following the 3-month time point, provided they requalified per inclusion criteria (ie, had at least one provocative test, experienced ≥50% pain relief from both an SIJ injection and L5 dorsal ramus and S1-3/4 sacral lateral branch blocks, had an average pain score ≥4/10 over the past week prior to screening), had a negative outcome from SMM, and desired to undergo CRFA.[27] Participants who originally received CRFA were not eligible to crossover to SMM. Crossover participants, those who continued receiving SMM, and the original CRFA cohort were followed for up to 12 months, with no intervening procedural interventions permitted.

CRFA procedures

CRFA procedures were performed according to standard protocol using fluoroscopic guidance in multiple views.[12 28] Small-gauge finder needles were inserted into the targeted foramina at the discretion of the provider. Nine lesions were created at locations specified in relation to the S1–S3 sacral foramina and L5 dorsal ramus, with S4 targeted at the discretion of the provider in patients with the foraminal opening situated at or above the inferior aspect of the SIJ. Details of the CRFA and SMM procedures are published in the previous report on 3-month outcomes.[27]

Outcome measures and follow-up

In addition to demographic and relevant medical history, data collected at baseline included 0–10 Numerical Rating Scale (NRS) average pain scores and questionnaires measuring non-pain outcomes that included Oswestry Disability Index 2.1 (ODI), 36-item short form survey physical function domain (SF-36), and EuroQoL-5D-5L (EQ-5D-5L), which measures QoL. These metrics were collected at all follow-ups, with the Patient Global Impression of Change (PGIC) scale added at each visit. The Patient Global Impression of Change measures how a patient feels a treatment changed their overall status. The primary outcome measure was mean change in average back pain score.

Responder analyses

Consistent with interpreting the clinical importance of treatment outcomes in chronic pain clinical trials recommendations, treatment responders were predefined as participants who reported either a ≥30% or 2-point decrease in average daily NRS pain score over the past week coupled with a score ≥5 out of 7 (moderately better) on the PGIC scale. QoL and functional outcomes were compared with baseline and between CRFA- and XO-treated groups at each follow-up.

Statistical analysis

This study represents the observational cohort from the 3-month crossover period (data previously reported) for a multicenter, randomized, assessor-blind study comparing sacral lateral branch cooled radiofrequency denervation to conservative therapy in the treatment of SIJ pain in military and civilian populations. Assessment determinations were made from aggregate data collection on all available patients at each study time point.

Baseline data, including patient demographics and medical history, are summarized using descriptive statistics for continuous variables and frequency counts and percentages for categorical variables. The primary outcome measure was a change in the 11-point (0–10) Numeric Rating Scale (NRS). Subjects were asked to rate their average daily pain (primary outcome), worst pain, and least pain over the previous week, and current pain at the time of the visit. As the primary and secondary effectiveness endpoints for the study were assessed at 3 months, additional endpoints were collected primarily to assess long-term effectiveness.[27]

Due to the very low number of subjects randomized to the SMM group who chose not to cross over to CRFA at 3 months (n=2), comparisons between CRFA and SMM groups at 12 months were not practical. Instead, a secondary focus was to compare subjects originally treated with CRFA to subjects who were randomized to the SMM group and crossed over to CRFA after the 3-month primary endpoint to receive CRFA (Avanos Medical, Alpharetta, Georgia, USA). Since between-group analyses between the original and XO-CRFA group are not the main objective and aggregated data are separately reported, no type I error adjustment for multiple comparisons was made.

The main analyses are based on available data only, although the last observation carried forward and multiple imputation sensitivity analyses were performed on change in NRS pain score at 12 months that included all treated subjects. Multiple imputation was based on preset variables and used full conditional specification with 100 imputed data sets. The variables included in the model were baseline age, sex, investigational site, response (percent pain relief) to blocks, duration of pain, baseline ODI score, baseline EQ-5D-5L index score, and all available follow-up pain scores. Two-sample t-tests were performed based on each of the 100 imputed datasets. Parameter estimates were pooled across imputations to obtain overall estimates.

Statistical comparisons between groups for normally-distributed continuous variables were conducted using t-tests for independent means and the Mann-Whitney test for non-normally-distributed data. For categorical variables, the χ^2 test was used to compare independent groups (or Fisher's exact test if the expected cell counts were too small). Paired t-tests were used to compare continuous variables across visits.

RESULTS

Baseline characteristics and previously reported primary endpoint

210 participants were randomized, with half (n=105) receiving CRFA and the other half (n=105) receiving SMM treatment. Baseline demographics across groups were comparable, with no significant differences.[27] At the 3-month primary endpoint, CRFA was superior to SMM for the primary and most secondary outcomes. At 3 months, the mean NRS pain score for the CRFA group (n=105) declined from 6.4 (±1.4) to 3.8±2.4 compared with 5.9±1.7 in the SMM group (p<0.0001).[27]

For this analysis, the mean baseline NRS average pain score for the CRFA group, 6.4±1.4, was based on the time of randomization (n=96). The mean baseline average pain score, 6.1±1.5, for those in the XO group (n=89) reflected the contemporaneous state of subjects prior to XO treatment. The difference between groups was not significant for average pain (p=0.15), but was for worst pain (8.6+1.2 vs 8.1+1.4; p=0.01), suggesting a possible modest benefit from SMM. Non-pain baseline variables were statistically similar between groups (table 1). At the 3-month primary endpoint, there were 88 CRFA patients, of which 63 completed 12-month follow-up (60.0% follow-up rate from randomization). 89 SMM patients crossed over at or after 3 months (baseline time 0), among which 63 were available for 12-month follow-up (70.1% follow-up rate from crossover; figure 1).

Primary outcome measure

With 67% (124/185) of treated subjects reporting data through 12 months, CRFA treatment, regardless of timing (ie, initially randomized procedure or following failed SMM), was equally effective in long-term chronic SIJ management (p<0.0001 from baseline and p=0.76 between groups). The mean NRS pain score for the CRFA group declined to 3.5±2.6 versus 3.4±2.5 in the XO group at 12 months, indicating a substantial treatment effect (table 1). This corresponds to similar mean NRS 'average pain score' decreases of 2.7±2.5 (43.8% improvement from baseline) and 2.6±2.8 (41.1%) in the CRFA and XO cohorts, respectively (p=0.79). 59.0% of subjects who initially received CRFA maintained ≥30% improvement in pain scores 12 months after treatment versus 61.9% of those who received CRFA at XO. At 12 months, 41.0% of the CRFA group reported substantial improvement, defined as ≥50% pain reduction, as did 46.0% of the XO cohort (p=0.57). Collectively, 60.5% (n=75) of subjects experienced ≥30% improvement in their average pain, 67.7% (n=84) had at least a 2-point improvement, and 43.5% (54/124) reported at least 50% improvement from baseline (figure 2).

Sensitivity analyses

As noted above, different methods were used to account for missing primary outcome measures, and no significant differences were identified between 12-month post-treatment average pain scores with complete case analysis (0.1 (CI = - 0.8, 1.0)), using multiple imputation (−0.1 (CI=−1.0,0.8)), with baseline observed case carried forward (−0.1 (CI=−0.9, 0.6)), and using last observed case carried forward (−0.2, (CI=−0.9,0.6)); p=0.67). As such, complete/observed case analyses are presented.

Pain responder rates

The pain responder analysis required at least a 2-point reduction or 30% drop in average NRS pain, combined with a rating of at least 5 on PGIC. At 12 months, 57.4% of the CRFA group were deemed responders, as were 55.6% of the XO group (p=0.83) (table 1).

QoL, functional capacity, and PGIC

As noted in table 2, most participants receiving CRFA reported statistically and clinically significant improvements in QoL and function from baseline (p<0.0001), with no differences at 12 months between the initial CRFA treatment and XO groups for ODI (p=0.80), EQ-5D-5L (p=0.33), and SF-36 Physical Domain (p=0.85) (table 2). The ODI score improved from a baseline of 41.0%±13.6 to 27.7%±16.6 in the CRFA group and from 41.7%±13.3 to 28.4%±16.6 in the XO group at 12 months (p<0.0001). These changes represent clinically relevant functional improvements of 12.4 points (31.2% improvement) and

Table 1 Pain outcomes stratified by treatment group

Study time point	Baseline			1-month follow-up			3-month follow-up			6-month follow-up			9-month follow-up			12-month follow-up		
	CRFA (n=96)	Crossover (n=89)	P-value	CRFA (n=95)	Crossover (n=86)	P-value	CRFA (n=87)	Crossover (n=82)	P-value	CRFA (n=75)	Crossover (n=72)	P-value	CRFA (n=62)	Crossover (n=64)	P-value	CRFA (n=61)	Crossover (n=63)	P-value
Average Pain Score (mean, SD)	6.4 (1.4)	6.1 (1.5)	0.15	4.1 (2.4)	3.3 (2.2)	0.03	3.9 (2.4)	3.3 (2.6)	0.17	3.6 (2.4)	3.6 (2.5)	0.96	4.0 (2.6)	3.1 (2.2)	0.06	3.5 (2.6)	3.4 (2.5)	0.76
Change from baseline in average pain (mean, SD)*	-	-	–	2.3 (2.1)	2.8 (2.6)	0.28 <0.0001	2.5 (2.2)	2.8 (2.9)	0.42 <0.0001	2.7 (2.2)	2.5 (3.0)	0.51 <0.0001	2.3 (2.4)	2.9 (2.6)	0.19 <0.0001	2.7 (2.5)	2.6 (2.8)	0.79 <0.0001
Worst Pain Score (mean, SD)	8.6 (1.2)	8.1 (1.4)	0.01	6.1 (3.0)	5 (2.9)	0.01	6 (2.9)	5.2 (3.3)	0.10	5.5 (3.1)	5.5 (3.2)	0.95	5.7 (3.3)	5.2 (2.8)	0.23	5.5 (3.2)	5.3 (3.0)	0.69
Change from baseline in worst pain (mean, SD)*	-	–	–	2.3 (2.9)	3.0 (3.0)	0.06 <0.0001	2.3 (2.8)	2.9 (3.2)	0.04 <0.0001	2.8 (3.0)	2.5 (3.3)	0.41 <0.0001	2.6 (3.2)	2.7 (3.0)	0.53 <0.0001	2.7 (3.1)	2.7 (3.1)	0.78 <0.0001
Responder analyses †																		
≥30% Improvement in average pain (N, %)	–	–	–	48 (50.5)	50 (58.1)	0.30	45 (51.7)	49 (59.8)	0.29	49 (65.3)	36 (50.0)	0.06	31 (50.0)	39 (60.9)	0.22	36 (59.0)	39 (61.9)	0.74
≥50% Improvement in average pain (N, %)	–	–	–	38 (40.0)	41 (47.7)	0.30	35 (40.2)	45 (54.9)	0.06	34 (45.3)	30 (41.7)	0.65	21 (33.9)	34 (53.1)	0.03	25 (41.0)	29 (46.0)	0.57
At least a 2-point decrease in average pain (N, %)	–	–	–	51 (53.7)	54 (62.8)	0.22	54 (62.1)	52 (63.4)	0.86	52 (69.3)	45 (62.5)	0.38	38 (61.3)	43 (67.2)	0.49	43 (70.5)	41 (65.1)	0.52
Positive responder (N, %)†	–	–	–	39 (41.1)	45 (52.3)	0.13	45 (51.7)	49 (59.8)	0.29	41 (54.7)	37 (51.4)	0.69	32 (51.6)	37 (58.7)	0.42	35 (57.4)	35 (55.6)	0.84

*Top p-value represents the difference between CRFA group as initial treatment and crossover CRFA group, while the bottom p-value represents the change from baseline for the entire cohort. When only a single p-value is listed, *it represents the difference between the CRFA group as an initial treatment and the crossover CRFA group.*
†Positive responder is defined as (1) at least a 2-point or 30% reduction in average NRS pain from baseline and (2) a rating of at least 5 on the Patient Global Impression of Change.
CRFA, cooled radiofrequency ablation.

13.7 (30.7%), respectively (p=0.82). The proportion of patients with minimal disability increased from 5.2% at baseline to 34.4%, and the proportion with severe or crippling disability decreased from 46.8% to 22.9% at 12 months in the CRFA group. Similar trends were observed in the XO cohort (figure 3).

Mean PGIC scores following CRFA and XO treatment were 4.9±1.8 and 4.9±1.9 at 12 months (p=0.78), with 67.2% and 65.1% reporting at least moderate improvement (PGIC ≥5) at 12 months, respectively. Similarly, clinically meaningful improvements in QoL were noted on the EQ-5D-5L index, where the CRFA group reported a 0.22-point (+0.27) improvement from baseline and the XO group experienced a 0.21-point (±0.33) improvement (p=0.87). The SF-36 physical function subscale score improved from 33.3±7.9 to 40.7±9.9 in the CRFA group and from 33.0±7.9 to 41.0±8.6 in the XO group at 12 months, respectively (p=0.82 between groups, p<0.0001 from baseline).

Factors associated with positive outcome

When combining data from all CRFA-treated subjects (n=185), linear regression models indicated that predictors of NRS pain score reduction at 3 months included duration of pain (longer duration was associated with smaller reduction in pain; estimate=−0.003, SE=0.002, 95% CI −0.007 to −0.000, p=0.04) and pain relief in response to prognostic sacral lateral branch blocks (greater response to blocks was associated with greater reduction in pain; estimate=0.030, SE=0.012, 95% CI 0.007 to 0.053, p=0.01). At 6 months, response to blocks remained the only positive outcome predictor of NRS pain score reduction (estimate=0.030, SE=0.013, 95% CI 0.004 to 0.055, p=0.02). At 12 months, linear regression indicated that females responded more favorably than males (estimate for female=1.355, SE=0.570, 95% CI 0.239 to 2.472, p=0.02) and subjects with no baseline opioid use responded better than opioid users (estimate for baseline opioid users=−1.275, SE=0.517, 95% CI −2.288 to −0.262, p=0.02).

Adverse events

Adverse event profiles were similar for the CRFA and XO cohorts with no related serious events reported. In the original CRFA group, a total of 129 adverse events were reported through 12 months with 16 deemed related to the procedure as previously reported (ie, no treatment-related events emerged >3 months after treatment).[27] In the XO group, a total of 96 adverse events were reported, with nine deemed possibly treatment-related. Among these were six reports of severe postprocedure pain, one case of neuritis, one case of worsening pain 117 days post-treatment (deemed possibly related), and one case of new-onset lumbar radiculopathy 15 days post-CRFA treatment, which was deemed unlikely related to treatment and led to removal from the trial. With the exception of the lumbar radiculopathy case, all adverse events resolved, and most were transient (median 15 days (range 0–101).

DISCUSSION

The principal finding in this large, multicenter, randomized study is that CRFA treatment resulted in clinically significant and sustained improvements for 12 months following a single CRFA treatment regardless of previous SMM treatment (ie, timing). The clinically relevant improvements in primary and secondary outcomes were statistically comparable in both groups.[29 30] Combined analysis of the 124 treated participants indicates that at 12 months, 43.5% reported substantial improvement in pain (≥50% reduction in pain) and 56.5% were responders.

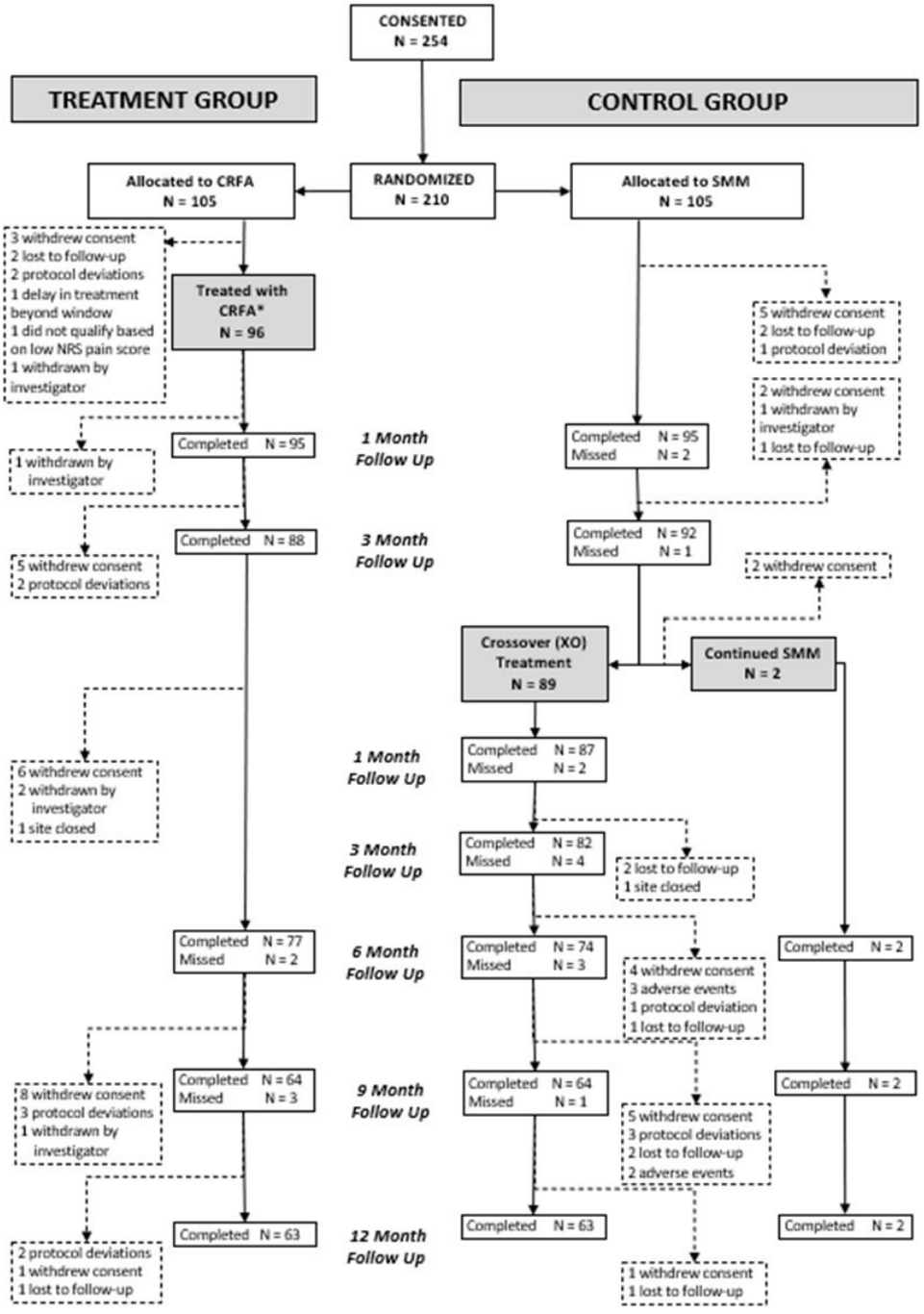

Figure 1 Consort diagram: study flow chart showing the randomization of subjects between CRFA and a crossover group receiving CRFA following SMM and study progress. CRFA, cooled radiofrequency ablation; SMM, standard medical management, XO, crossover. *One subject randomized to SMM but inadvertently received CRFA treatment. The subject is summarized in the CRFA group. "Missed" suggests the subject returned for at least one subsequent visit. The lost-to-follow-up designation indicates a subject who never returned. AEs or deviations reflect the primary reason that subjects were removed from the trial by the investigators.

Comparison to other studies

These findings corroborate previously published literature demonstrating that CRFA can provide sustained benefit to patients with refractory SIJ pain. Two previous clinical studies evaluating efficacy for cooled versus sham RFA in SIJ pain reported near-identical 59% success rates at 6-[8] and 9-month follow-ups,[9] while categorical success rates in controlled and uncontrolled studies found success rates ranging between 40% and 75% of patients at 12-month follow-up periods.[10 13 19 20] These, along with support from other non-sponsored studies, demonstrate that CRFA can provide durable improvements in pain, QoL, and opioid consumption in patients who experience temporary pain relief after diagnostic and prognostic (lateral branch) blocks.[9 12 13 19 20 31]

CRFA versus SMM

Compared with the neuroanatomy of lumbar facet joints, the innervation of the SIJ is more complex, with significant differences in the number and location of nerves that vary from

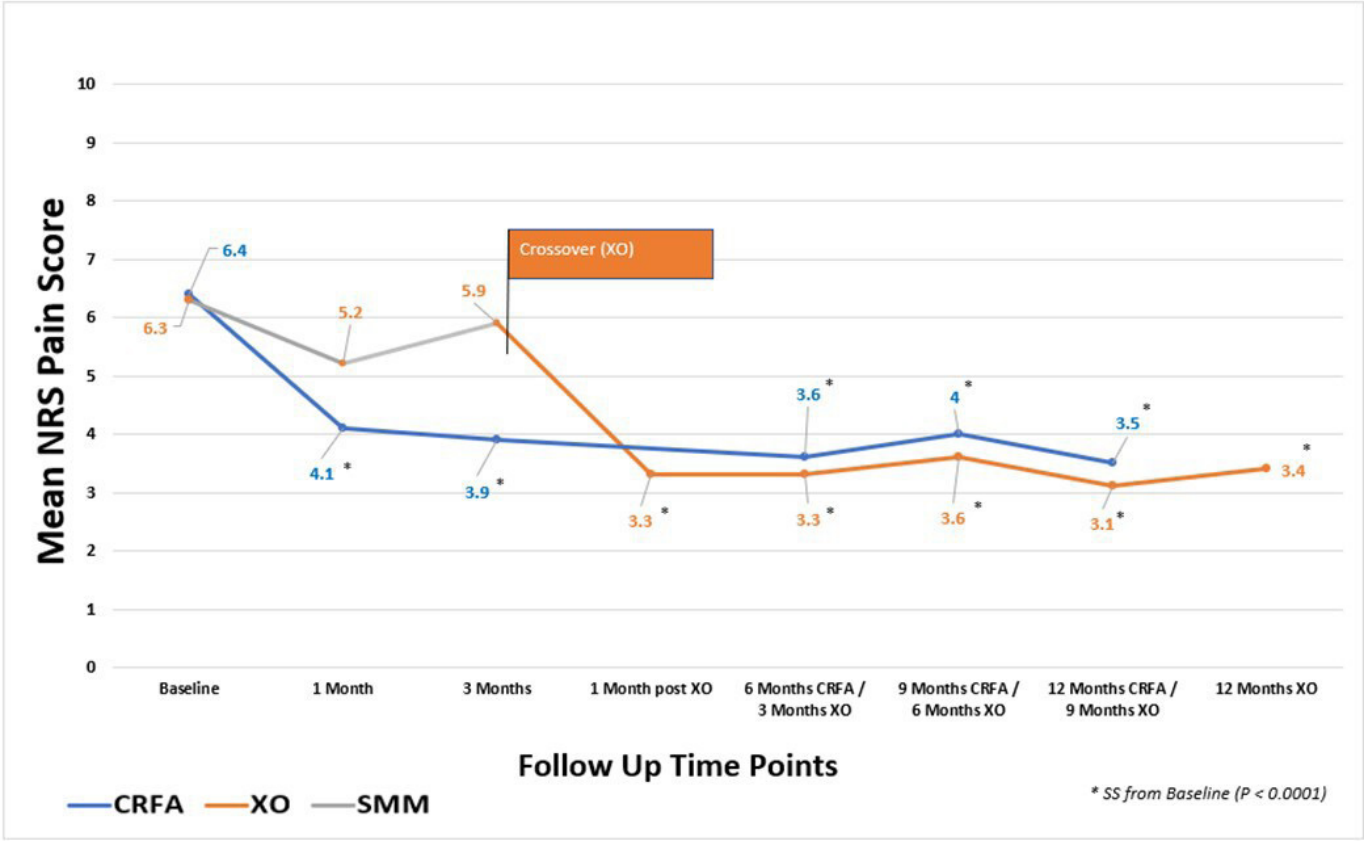

Figure 2 Numeric Rating Scale Pain Scores stratified by treatment group throughout the study. CRFA, cooled radiofrequency ablation; NRS, Numeric Rating Scale; SMM, standard medical management; XO, crossover; SS, statistically significant.

patient to patient, side to side, and level to level. Unlike facet joint innervation, these nerves also traverse tissue surrounding the SIJ at different depths.[32 33] This variability favors the use of an ambitious ablation strategy with greater denervation depth and assessment of the distance to the posterior sacral foraminal openings to promote safety. In CRFA, the distal projection of current creates larger, deeper, more spherically shaped lesions, which can increase nerve capture rate.[16] In contrast, conventional RFA contains inherent limitations for treating SIJ pain, including tissue desiccation, which constrains lesion expansion and limited lesion depth, which collectively increase the risk of failed nerve capture. Not surprisingly, a systematic review on the diagnostic accuracy and therapeutic effectiveness of SIJ interventions found CRFA to be more effective in managing SIJ pain than conventional RFA, with both CRFA and conventional RFA being more effective than steroid injections.[34] One limitation in this review is that it did not distinguish between anatomically valid and invalid conventional RFA techniques. More research is needed to compare CRFA with other anatomically valid RFA protocols, including the use of bipolar electrodes and these alternative techniques to SMM.

Although differences in patient selection, study design, and outcome assessment limit comparisons between RFA studies, the literature does provide some basis for contrasting approaches. Two of the three retrospective studies that compared CRFA to conventional RFA for SIJ pain found CRFA to be superior, with the negative study containing a higher proportion of postlaminectomy syndrome patients in the CRFA group.[13 35 36] However, it should be noted that these studies did not use other anatomically valid and comprehensive RFA strategies that potentially increase the nerve capture rate, such as bipolar RFA and possibly tined electrodes.[37] For bipolar RFA, lesion confluence and technical optimization are highly dependent on factors such as electrode size, heating time, inter-probe distance, and tissue impedance, which is unknown to physicians.[38]

Overlapping chronic pain sources from advanced degenerative disease of the spine may bias optimal outcomes from SIJ denervation. Although there are no comparable studies on SIJ RFA, for lumbar facet RFA, postlaminectomy syndrome is associated with a higher failure rate.[39 40] These findings are consistent with both basic science and clinical studies conducted in other conditions associated with considerable variability in innervation (eg, knee osteoarthritis) that demonstrate more pronounced and longer-lasting effects with CRFA than traditional ablation.[17 41 42] Furthermore, another retrospective study found that repeat CRFA provided longer relief than the initial CRFA treatment, which is in contrast with observations from monopolar conventional RFA wherein the beneficial effects tend to diminish with repeat exposures.[31 43] Collectively, these findings suggest CRFA provides significantly greater improvements compared with SMM, sham and conventional RFA.

Durability of results

This and other clinical studies have repeatedly demonstrated long-term benefits from CRFA for patients with refractory SIJ pain, with durable pain relief frequently lasting over 1 year.[10 13 19 20] Reasons for this may be that larger and more profound nerve lesions take a longer time to regenerate, as suggested by a preclinical study performed in rodents[17] and a clinical study showing a slower success drop-off rate with cooled versus a non-cooled RF modality,[13] or that sustained pain relief

Table 2 Non-pain outcomes stratified by treatment group

Study time point	Baseline			1-month follow-up			3-month follow-up			6-month follow-up			9-month follow-up			12-month follow-up		
	CRFA n=96	Crossover n=88	P-value	CRFA n=94	Crossover n=86	P-value	CRFA n=88	Crossover n=82	P-value	CRFA n=75	Crossover n=72	P-value	CRFA n=62	Crossover n=63	P-value	CRFA n=61	Crossover n=63	P-value
Patient Global Impression of Change (%)																		
(1) No change (or the condition has gotten worse)	–	–	–	16.0	9.3	–	15.9	8.5	–	9.3	5.6	–	8.1	7.9	–	4.9	7.9	–
(2) Almost the same, hardly any change at all	–	–	–	8.5	8.1	–	6.8	14.6	–	12.0	13.9	–	14.5	9.5	–	8.2	6.3	–
(3) A little better, but no noticeable change	–	–	–	10.6	9.3	–	4.5	3.7	–	4.0	6.9	–	4.8	3.2	–	9.8	11.1	–
(4) Somewhat better, but the change has not made any real difference	–	–	–	9.6	11.6	–	8.0	7.3	–	10.7	8.3	–	11.3	11.1	–	9.8	9.5	–
(5) Moderately better, and a slight but noticeable change	–	–	–	18.1	18.6	–	20.5	15.9	–	17.3	19.4	–	19.4	22.2	–	27.9	15.9	–
(6) Better and a definite improvement that has made a real and worthwhile difference	–	–	–	22.3	29.1	–	26.1	29.3	–	25.3	25.0	–	17.7	30.2	–	16.4	25.4	–
(7) A great deal better and a considerable improvement that has made all the difference	–	–	–	14.9	14.0	–	18.2	20.7	–	21.3	20.8	–	24.2	15.9	–	23.0	23.8	–
Mean (SD)	–	–	–	4.3 (2.1)	4.7 (1.9)	0.32	4.6 (2.1)	4.8 (2.0)	0.51	4.8 (2.0)	4.8 (1.9)	0.94	4.7 (2.0)	4.8 (1.8)	0.83	4.9 (1.8)	4.9 (1.9)	0.79
Distribution of Patient Global Impression of Change (PGIC) (%)																		
Not improved/worse (PGIC ≤4)	–	–	–	44.7	38.4	–	35.2	34.1	–	36.0	34.7	–	38.7	31.7	–	32.8	34.9	–
At least a 'Moderate' improvement (PGIC ≥5)	–	–	–	55.3	61.6	0.39	64.8	65.9	0.88	64.0	68.3	0.87	61.3	68.3	0.42	67.2	65.1	0.80
SF-36 Physical Component Summary (PCS) Score																		
Mean (SD)	33.3 (7.9)	33.0 (6.7)	0.76	38.3 (9.0)	41.2 (9.5)	0.05	40.1 (9.0)	41.0 (9.7)	0.55	39.3 (9.5)	41.3 (10.0)	0.23	38.2 (9.0)	41.2 (9.4)	0.07	40.7 (9.9)	41.0 (8.6)	0.85
Change from baseline in SF-36 Physical Component Summary (PCS) Score (mean, SD)	–	–	–	5.0 (8.2)	8.0 (8.5)	0.02	6.5 (9.1)	8.4 (9.8)	0.25	5.8 (8.8)	8.3 (9.4)	0.10	4.3 (8.2)	8.1 (8.4)	0.01	7.2 (8.8)	7.5 (7.7)	0.82
P-value for change from baseline	–	–	–	<0.0001	<0.0001	–	<0.0001	<0.0001	–	<0.0001	<0.0001	–	<0.0001	<0.0001	–	<0.0001	<0.0001	–
Oswestry Disability Index (ODI)																		
Mean (SD)	41.0 (13.6)	41.7 (13.3)	0.89	32.0 (16.7)	28.2 (16.3)	0.12	29.8 (15.1)	27.3 (16.6)	0.25	29.5 (16.3)	27.5 (16.7)	0.35	30.0 (16.0)	28.7 (15.9)	0.65	27.7 (16.6)	28.4 (16.6)	0.80
Change from baseline in ODI Score (mean, SD)	–	–	–	8.8 (14.9)	13.5 (15.5)	0.03	10.7 (15.4)	15.5 (17.3)	0.07	11.7 (16.5)	15.0 (18.3)	0.17	10.1 (14.7)	14.4 (16.8)	0.14	12.4 (14.7)	13.7 (17.1)	0.83
P-value for change from baseline	–	–	–	<0.0001	<0.0001	–	<0.0001	<0.0001	–	<0.0001	<0.0001	–	<0.0001	<0.0001	–	<0.0001	<0.0001	–
EQ-5D-5L Index Score																		
Mean (SD)	0.48 (0.27)	0.74 (0.28)	0.85	0.65 (0.25)	0.72 (0.24)	0.06	0.68 (0.22)	0.70 (0.25)	0.28	0.63 (0.31)	0.69 (0.22)	0.34	0.65 (0.28)	0.70 (0.20)	0.69	0.71 (0.24)	0.67 (0.26)	0.33
Change from baseline in EQ-5D-5L Index Score (mean, SD)	–	–	–	0.17 (0.28)	0.24 (0.28)	0.23	0.19 (0.26)	0.26 (0.31)	0.16	0.15 (0.30)	0.23 (0.31)	0.06	0.18 (0.32)	0.25 (0.28)	0.17	0.22 (0.27)	0.21 (0.33)	0.88
P-value for change from baseline	–	–	–	<0.0001	<0.0001	–	<0.0001	<0.0001	–	<0.0001	<0.0001	–	<0.0001	<0.0001	–	<0.0001	<0.0001	–

CRFA, cooled radiofrequency ablation.

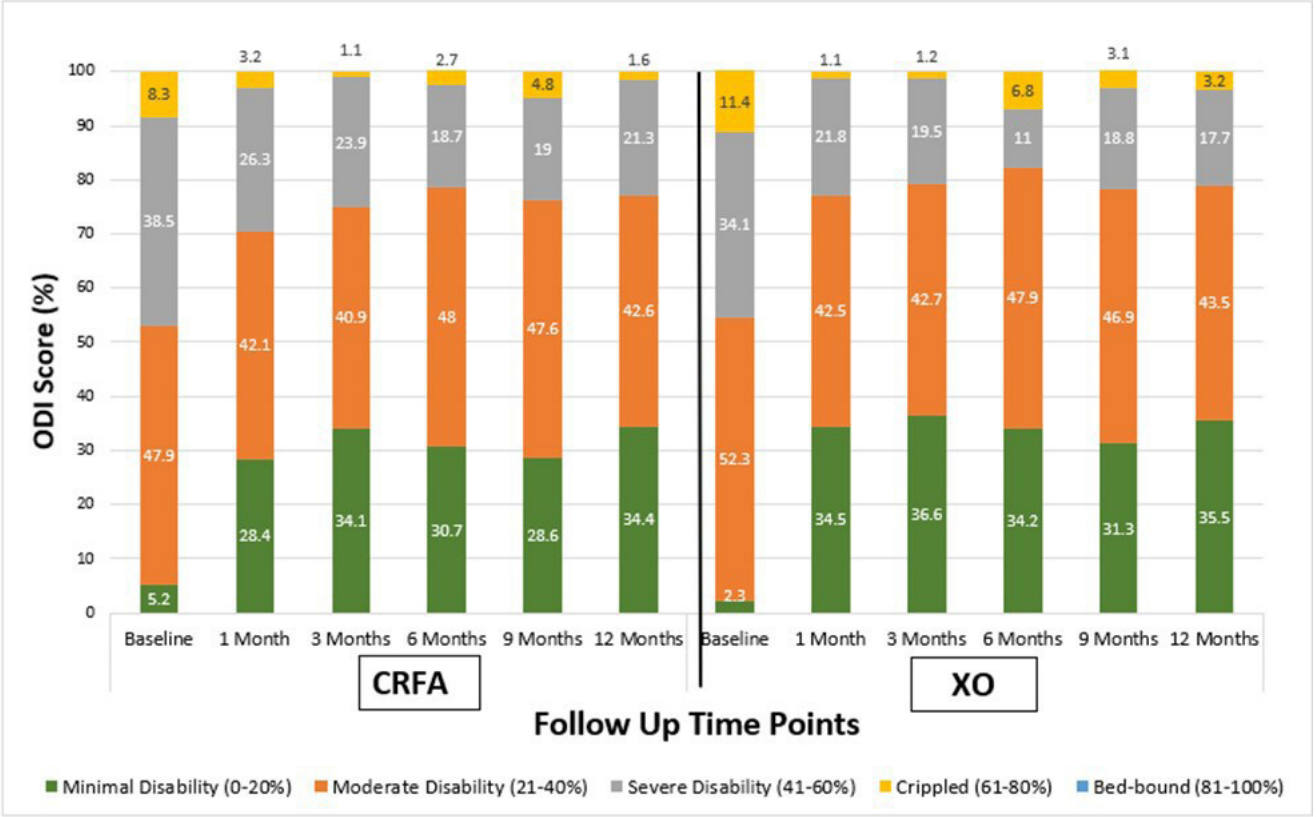

Figure 3 Proportion of subjects in different Oswestry Disability Index (ODI) categories. CRFA, cooled radiofrequency ablation; XO, crossover from standard medical management to CRFA.

results in other long-term benefits such as improved conditioning and activity levels, better mood and sleep, and the reversal of sensitization.

Limitations

Due to the nature of CRFA and SMM, this study design did not permit blinding of participants, which can magnify the effect size compared with sham-controlled trials.[44] Similar to comparably designed studies, it is likely that many patients in the SMM arm already failed conservative interventions and entered the study with high expectations for CRFA, leading to a robust placebo effect.[45 46] In light of the ethical concerns regarding an ineffective comparator, this study also did not include any control group beyond 3 months post-treatment. The lengthy observation period, which necessitated that patients avoid any procedural cointerventions that could confound interpretation, may have also left an enriched population available for long-term follow-up.

One-third of patients in both CRFA and XO cohorts were non-responsive to treatment. This may be due in part to the patient selection criterion of not requiring a higher threshold for SI joint injections or prognostic LBB. However, studies have consistently failed to find significant differences in RFA outcomes when lumbar and cervical medial branch blocks are stratified by pain relief cut-off thresholds: a systematic review found that lowering the cut-off threshold for uncontrolled blocks does not meaningfully affect the reported prevalence (ie, positive block) rate, and the two studies that examined the effect of cut-off point found no difference in RFA success rates stratified by a 50% versus 80% pain relief cut-off for SIJ injections or based on whether or not prognostic lateral branch blocks were employed.[36 43 47–49] The rationale for using higher cut-off rates is that the magnitude of pain relief from RFA is generally less than that achieved with prognostic blocks owing to the latter's lack of specificity (ie, inadvertent spread to other pain generators); permitting volumes of up to 2 mL during prognostic sacral lateral branch blocks may have contributed to this lack of specificity.[43 48]

Isolation of a single source of CLBP can be complicated. Patients with SIJ pain have high coprevalence rates of other painful conditions such as lumbar spondylosis, myofascial pain, radiculopathy, and central sensitization, none of which are likely to respond to SIJ CRFA.[50–52] They may also have had SIJ pain emanating from the joint capsule, deep (more anterior) bony structures, and the ventral ligaments, which are not targeted by CRFA, and were selected based on false-positive results from prognostic sacral lateral branch blocks.[33 53] Response to the COVID-19 pandemic also forced some visits to be completed remotely (over the phone) versus in the office, though studies have consistently found no significant differences in outcomes.[54] The long duration of symptoms may also have predisposed some participants to treatment failure, as studies have consistently shown an inverse correlation between symptom duration and treatment outcome, including for SIJ interventions.[36 55 56] Explanations for this are that symptom duration is an indicator of disease burden and that these patients may have had higher rates of psychopathology, secondary gain, and central sensitization, which are strong harbingers for poor treatment outcomes.[52 57 58] Nevertheless, the high response rate for CRFA in this refractory population suggests a possible reprieve from continued pain and suffering.

CONCLUSIONS

This large, multicenter study demonstrates that CRFA may provide long-term benefit for SIJ pain regardless of prior SMM treatment. The majority of participants receiving CRFA achieved clinically significant improvements in pain, function, and QoL, despite reporting long-standing and recalcitrant symptoms. Further research is needed to better identify likely CRFA treatment responders which can favorably alter the risk-benefit and cost-effectiveness ratios, optimize neural targets, and ultimately improve access to CRFA care.

Author affiliations
[1]Depts. of Anesthesiology, Physical Medicine & Rehabilitation, Neurology, Psychiatry and Neurological Surgery, Northwestern University Feinberg School of Medicine, Chicago, Illinois, USA
[2]Physical Medicine & Rehabilitation and Anesthesiology, Uniformed Services University, Bethesda, Maryland, USA
[3]Carolinas Pain Institute, Winston-Salem, North Carolina, USA
[4]Department of Anesthesiology, University of Virginia, Charlottesville, Virginia, USA
[5]Premier Pain Centers, Shrewsbury, New Jersey, USA
[6]Atrium Health Wake Forest Baptist, Winston-Salem, North Carolina, USA
[7]Millennium Pain Center, Bloomington, Illinois, USA
[8]Ochsner Clinic Foundation, New Orleans, Louisiana, USA
[9]Mass General Brigham Inc, Boston, Massachusetts, USA
[10]Johns Hopkins Medicine, Baltimore, Maryland, USA
[11]Clin Invest C LLC, Edmond, Oklahoma, USA
[12]International Spine, Pain, and Performance Center, Washington, District of Columbia, USA
[13]Womack Army Medical Center, Fort Bragg, North Carolina, USA
[14]Anesthesiology and Perioperative Medicine, Oregon Health & Science University, Portland, Oregon, USA
[15]Department of Anesthesiology & Perioperative Medicine, University of Rochester Medical Center Department of Medicine, Rochester, New York, USA
[16]MEDRVA Healthcare, Richmond, Virginia, USA

Contributors All authors contributed to the design and implementation of the research, to the analysis of the results, and to the writing of the manuscript. Dr SPC is the guarantor of this manuscript.

Funding Financial support was provided to each of the investigator's institutions by Avanos Medical to cover the budgeted costs necessary to conduct this study protocol. Data management, study site monitoring, and statistics services were performed by a third party, independent of Avanos Medical.

Competing interests SPC, LKap, LKoh, and SL are members of the steering committee for this project for Avanos Medical. SL and DPB are consultants for Avanos Medical (which makes radiofrequency equipment). The other authors declare no conflict of interest.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants. This randomized, controlled, multicenter clinical study was registered in ClinicalTrials.gov (NCT03601949) on 26 July 2018. All participants were enrolled, treated, and followed between 29 June 2018 and 3 November 2021. The protocol and written consent forms were approved by the institutional review boards (IRB) or ethics committees of each participating institution prior to enrollment. Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer-reviewed.

Data availability statement Data are available upon reasonable request.

ORCID iDs
Steven Paul Cohen http://orcid.org/0000-0001-5928-2127
Mehul J Desai http://orcid.org/0000-0001-6870-9436
Sandy Christiansen http://orcid.org/0000-0002-0531-0708

REFERENCES

1 Hooten WM, Cohen SP. Evaluation and Treatment of Low Back Pain: A Clinically Focused Review for Primary Care Specialists. *Mayo Clin Proc* 2015;90:1699–718.
2 Kiapour A, Joukar A, Elgafy H, *et al*. Biomechanics of the Sacroiliac Joint: Anatomy, Function, Biomechanics, Sexual Dimorphism, and Causes of Pain. *Int J Spine Surg* 2020;14:3–13.
3 Cohen SP, Bicket MC, Kurihara C, *et al*. Fluoroscopically Guided vs Landmark-Guided Sacroiliac Joint Injections: A Randomized Controlled Study. *Mayo Clin Proc* 2019;94:628–42.
4 Luukkainen R, Nissilä M, Asikainen E, *et al*. Periarticular corticosteroid treatment of the sacroiliac joint in patients with seronegative spondylarthropathy. *Clin Exp Rheumatol* 1999;17:88–90.
5 Luukkainen RK, Wennerstrand PV, Kautiainen HH, *et al*. Efficacy of periarticular corticosteroid treatment of the sacroiliac joint in non-spondylarthropathic patients with chronic low back pain in the region of the sacroiliac joint. *Clin Exp Rheumatol* 2002;20:52–4.
6 Rashbaum RF, Ohnmeiss DD, Lindley EM, *et al*. Sacroiliac Joint Pain and Its Treatment. *Clin Spine Surg* 2016;29:42–8.
7 Cohen SP, Chen Y, Neufeld NJ. Sacroiliac joint pain: a comprehensive review of epidemiology, diagnosis and treatment. *Expert Rev Neurother* 2013;13:99–116.
8 Cohen SP, Hurley RW, Buckenmaier CC, *et al*. Randomized Placebo-controlled Study Evaluating Lateral Branch Radiofrequency Denervation for Sacroiliac Joint Pain. *Anesthesiology* 2008;109:279–88.
9 Patel N, Gross A, Brown L, *et al*. A randomized, placebo-controlled study to assess the efficacy of lateral branch neurotomy for chronic sacroiliac joint pain. *Pain Med* 2012;13:383–98.
10 Patel N. Twelve-Month Follow-Up of a Randomized Trial Assessing Cooled Radiofrequency Denervation as a Treatment for Sacroiliac Region Pain. *Pain Pract* 2016;16:154–67.
11 Yang AJ, Wagner G, Burnham T, *et al*. Radiofrequency Ablation for Chronic Posterior Sacroiliac Joint Complex Pain: A Comprehensive Review. *Pain Med* 2021;22:S9–13.
12 Stelzer W, Aiglesberger M, Stelzer D, *et al*. Use of cooled radiofrequency lateral branch neurotomy for the treatment of sacroiliac joint-mediated low back pain: a large case series. *Pain Med* 2013;14:29–35.
13 Tinnirello A, Barbieri S, Todeschini M, *et al*. Conventional (Simplicity III) and Cooled (SInergy) Radiofrequency for Sacroiliac Joint Denervation: One-Year Retrospective Study Comparing Two Devices. *Pain Med* 2017;18:1731–44.
14 Ball RD. The science of conventional and water-cooled monopolar lumbar radiofrequency rhizotomy: an electrical engineering point of view. *Pain Physician* 2014;17:E175–211.
15 Kapural L, Deering JP. A technological overview of cooled radiofrequency ablation and its effectiveness in the management of chronic knee pain. *Pain Manag* 2020;10:133–40.
16 Cedeno DL, Vallejo A, Kelley CA, *et al*. Comparisons of Lesion Volumes and Shapes Produced by a Radiofrequency System with a Cooled, a Protruding, or a Monopolar Probe. *Pain Physician* 2017;20:E915–22.
17 Zachariah C, Mayeux J, Alas G, *et al*. Physiological and functional responses of water-cooled versus traditional radiofrequency ablation of peripheral nerves in rats. *Reg Anesth Pain Med* 2020;45:792–8.
18 Cobbs A, Alas G, Yadav R, *et al*. Water-circulating probes significantly modify lesion length and axon damage in cooled radiofrequency ablations when compared with similar-sized standard radiofrequency probes in rats. *Reg Anesth Pain Med* 2024;49:448–54.
19 Tinnirello A. Reduction of opioid intake after cooled radiofrequency denervation for sacroiliac joint pain: a retrospective evaluation up to 1 year. *Korean J Pain* 2020;33:183–91.
20 Ho K-Y, Hadi MA, Pasutharnchat K, *et al*. Cooled radiofrequency denervation for treatment of sacroiliac joint pain: two-year results from 20 cases. *J Pain Res* 2013;6:505–11.
21 Burnham T, Conger A, Salazar F, *et al*. The Effectiveness of Cervical Medial Branch Radiofrequency Ablation for Chronic Facet Joint Syndrome in Patients Selected by a Practical Medial Branch Block Paradigm. *Pain Med* 2020;21:2071–6.
22 Hunter C, Davis T, Loudermilk E, *et al*. Cooled Radiofrequency Ablation Treatment of the Genicular Nerves in the Treatment of Osteoarthritic Knee Pain: 18- and 24-Month Results. *Pain Pract* 2020;20:238–46.
23 Lyman J, Khalouf F, Zora K, *et al*. Cooled radiofrequency ablation of genicular nerves provides 24-Month durability in the management of osteoarthritic knee pain: Outcomes from a prospective, multicenter, randomized trial. *Pain Pract* 2022;22:571–81.
24 Stolzenberg D, Gordin V, Vorobeychik Y. Incidence of neuropathic pain after cooled radiofrequency ablation of sacral lateral branch nerves. *Pain Med* 2014;15:1857–60.
25 Sun HH, Zhuang SY, Hong X, *et al*. The efficacy and safety of using cooled radiofrequency in treating chronic sacroiliac joint pain: A PRISMA-compliant meta-analysis. *Medicine (Baltimore)* 2018;97:e9809.
26 Lee DW, Pritzlaff S, Jung MJ, *et al*. Latest Evidence-Based Application for Radiofrequency Neurotomy (LEARN): Best Practice Guidelines from the American Society of Pain and Neuroscience (ASPN). *J Pain Res* 2021;14:2807–31.
27 Cohen SP, Kapural L, Kohan L, *et al*. Cooled radiofrequency ablation versus standard medical management for chronic sacroiliac joint pain: a multicenter, randomized comparative effectiveness study. *Reg Anesth Pain Med* 2024;49:184–91.

28 Kapural L, Nageeb F, Kapural M, *et al*. Cooled radiofrequency system for the treatment of chronic pain from sacroiliitis: the first case-series. *Pain Pract* 2008;8:348–54.
29 Schwind J, Learman K, O'Halloran B, *et al*. Different minimally important clinical difference (MCID) scores lead to different clinical prediction rules for the Oswestry disability index for the same sample of patients. *J Man Manip Ther* 2013;21:71–8.
30 Coretti S, Ruggeri M, McNamee P. The minimum clinically important difference for EQ-5D index: a critical review. *Expert Rev Pharmacoecon Outcomes Res* 2014;14:221–33.
31 Kurklinsky S, Boone MK, Candler SA, *et al*. Repeat Cooled Radiofrequency Ablation Is Beneficial for Chronic Posterior Sacroiliac Joint Pain. *Pain Med* 2020;21:1532–7.
32 Roberts SL. Sacroiliac Joint Anatomy. *Phys Med Rehabil Clin N Am* 2021;32:703–24.
33 Dreyfuss P, Henning T, Malladi N, *et al*. The ability of multi-site, multi-depth sacral lateral branch blocks to anesthetize the sacroiliac joint complex. *Pain Med* 2009;10:679–88.
34 Simopoulos TT, Manchikanti L, Gupta S, *et al*. Systematic Review of the Diagnostic Accuracy and Therapeutic Effectiveness of Sacroiliac Joint Interventions. *Pain Physician* 2015;18:E713–56.
35 Cheng J, Pope JE, Dalton JE, *et al*. Comparative outcomes of cooled versus traditional radiofrequency ablation of the lateral branches for sacroiliac joint pain. *Clin J Pain* 2013;29:132–7.
36 Cohen SP, Strassels SA, Kurihara C, *et al*. Outcome predictors for sacroiliac joint (lateral branch) radiofrequency denervation. *Reg Anesth Pain Med* 2009;34:206–14.
37 Roberts SL, Stout A, Loh EY, *et al*. Anatomical Comparison of Radiofrequency Ablation Techniques for Sacroiliac Joint Pain. *Pain Med* 2018;19:1924–43.
38 Wondra A, Gulhar S, Brestle MD, *et al*. Bipolar radiofrequency ablation lesion areas and confluence: An ex vivo study and technical report. *Pain Pract* 2024;24:489–501.
39 Cohen SP, Larkin TM, Chang AS, *et al*. The causes of false-positive medial branch (facet joint) blocks in soldiers and retirees. *Mil Med* 2004;169:781–6.
40 Cohen SP, Hurley RW, Christo PJ, *et al*. Clinical predictors of success and failure for lumbar facet radiofrequency denervation. *Clin J Pain* 2007;23:45–52.
41 Kapural L, Minerali A, Sanders M, *et al*. Cooled Radiofrequency Ablation Provides Prolonged Pain Relief Compared to Traditional Radiofrequency Ablation: A Real-World, Large Retrospective Clinical Comparison from a Single Practice. *J Pain Res* 2022;15:2577–86.
42 Vanneste T, Belba A, van Kuijk S, *et al*. Comparison of conventional and cooled radiofrequency treatment of the genicular nerves versus sham procedure for patients with chronic knee pain: protocol for a multicentre, double-blind, randomised controlled trial (COGENIUS). *BMJ Open* 2023;13:e073949.
43 Hurley RW, Adams MCB, Barad M, *et al*. Consensus practice guidelines on interventions for cervical spine (facet) joint pain from a multispecialty international working group. *Reg Anesth Pain Med* 2022;47:3–59.
44 Hróbjartsson A, Thomsen ASS, Emanuelsson F, *et al*. Observer bias in randomised clinical trials with binary outcomes: systematic review of trials with both blinded and non-blinded outcome assessors. *BMJ* 2012;344:bmj.e1119.
45 Thomas M, Eriksson SV, Lundeberg T. A comparative study of diazepam and acupuncture in patients with osteoarthritis pain: a placebo controlled study. *Am J Chin Med* 1991;19:95–100.
46 Kaptchuk TJ, Stason WB, Davis RB, *et al*. Sham device v inert pill: randomised controlled trial of two placebo treatments. *BMJ* 2006;332:391–7.
47 Amatto A, Burnham T, Teramoto M, *et al*. The effectiveness and predictive factors of Sacroiliac Joint Radiofrequency Neurotomy success - A retrospective cohort study. *Interv Pain Med* 2023;2:100271.
48 Cohen SP, Bhaskar A, Bhatia A, *et al*. Consensus practice guidelines on interventions for lumbar facet joint pain from a multispecialty, international working group. *Reg Anesth Pain Med* 2020;45:424–67.
49 Kennedy DJ, Engel A, Kreiner DS, *et al*. Fluoroscopically Guided Diagnostic and Therapeutic Intra-Articular Sacroiliac Joint Injections: A Systematic Review. *Pain Med* 2015;16:1500–18.
50 Oliver JD, Lessing NL, Mushlin HM, *et al*. Radiculopathy with concomitant sacroiliac dysfunction and lumbosacral degenerative disease: illustrative case. *J Neurosurg* 2021;2:CASE21102.
51 Telli H, Hüner B, Kuru Ö. Determination of the Prevalence From Clinical Diagnosis of Sacroiliac Joint Dysfunction in Patients With Lumbar Disc Hernia and an Evaluation of the Effect of This Combination on Pain and Quality of Life. *Spine (Phila Pa 1976)* 2020;45:549–54.
52 Fitzcharles MA, Cohen SP, Clauw DJ, *et al*. Chronic primary musculoskeletal pain: a new concept of nonstructural regional pain. *Pain Rep* 2022;7:e1024.
53 King W, Ahmed SU, Baisden J, *et al*. Diagnosis and treatment of posterior sacroiliac complex pain: a systematic review with comprehensive analysis of the published data. *Pain Med* 2015;16:257–65.
54 Hatef E, Wilson RF, Zhang A, *et al*. Effectiveness of telehealth versus in-person care during the COVID-19 pandemic: a systematic review. *NPJ Digit Med* 2024;7:157.
55 Dunn KM, Croft PR. The importance of symptom duration in determining prognosis. *Pain* 2006;121:126–32.
56 Cohen SP, Doshi TL, Kurihara C, *et al*. Multicenter study evaluating factors associated with treatment outcome for low back pain injections. *Reg Anesth Pain Med* 2022;47:89–99.
57 Fitzcharles M-A, Cohen SP, Clauw DJ, *et al*. Nociplastic pain: towards an understanding of prevalent pain conditions. *Lancet* 2021;397:2098–110.
58 Edwards RR, Dworkin RH, Sullivan MD, *et al*. The Role of Psychosocial Processes in the Development and Maintenance of Chronic Pain. *J Pain* 2016;17:T70–92.