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October 18, 2022

Noridian Healthcare Solutions, LLC JE Part B Contractor Medical Director
Eileen Moynihan, MD, FACP, FACRh
Attention: Draft LCD Comments
PO Box 6781
Fargo, ND 58108-6781
Submitted via email to policydraft@noridian.com

RE: Proposed LCD DL39462 Sacroiliac Joint Injections and Procedures

Dear Ms. Moynihan:

The Society of Interventional Radiology (SIR) is a nonprofit, professional medical society representing approximately 8,000 practicing interventional radiology physicians, trainees, students, scientists, and clinical associates, dedicated to improving patient care through the limitless potential of image-guided therapies.

On behalf of our physician members of the Society of Interventional Radiology (SIR), we would like to respectfully comment on the Proposed Local Coverage Determination (LCD) DL39462 for Sacroiliac Joint Injections and Procedures. This proposed policy states, "D. SIJ Denervation (also called Radiofrequency Ablation or RFA) is considered investigational and therefore not reasonable and necessary." SIR respectfully disagrees and believes this will prevent patient access to this opiate alternative procedure.

There is ample clinical literature regarding the role of RFA in managing SIJ dysfunction. Ferrante et al. reported the first bipolar RF technique in 2001 that created a strip lesion along the posterior portion medial to the SI joint with RF needles inserted at <1-cm intervals. It gave rise to 36% of the patients experiencing at least 50% pain relief for six months.[1] Following this, conventional monopolar RFA techniques were used to target the lateral branches of the primary dorsal rami in several studies, which reported sustained relief of pain for six months in over 60% of subjects.[2-4] In addition to unipolar and bipolar RFA, other techniques have been successfully used to target the lateral branches of the primary dorsal rami, including cooled RF ablation, Simplicity III RF ablation, and quadrapolar RF ablation.[5-7]

The highest quality evidence regarding the efficacy of SI joint RFA comes from six Level I manuscripts, including five sham-controlled RCTs.[8-11] The first two sham-control trials published showed that in pooled, between-group comparisons that those treated with RFA were approximately four times more likely to achieve ≥50% pain reduction at three months compared with sham.[8, 9] In reviewing the most recent sham-controlled trials conducted in 2016 and 2018, both experiments showed that all participants reported relief of pain.. [10, 11] However, when comparing both trials, Mehta's sham showed statistical significance in relief of pain for the group treated with a strip-lesioning device. [11] A twelve-month follow-up of a previously reported sham-controlled RCT showed favorable results for patients initially treated with RFA and those initially treated with sham but were allowed to cross over.[12] Five of

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the six Level I trials showed statistically significantly better outcomes than either NSM or sham.[8-12] Recent meta-analyses have also supported RFA of the SI joints with findings that patients treated with RFA neurotomy had significantly greater improvement in ODI scores, pain scores, and QoL as compared with controls.[13] Additionally, in subgroup analyses, patients who received RF neurotomy greatly improved ODI scores compared with those with sham treatment. Patients treated with RF significantly improved pain scores compared with controls who received sham or medical treatment. Given the above findings in many different studies, RCTs, and meta-analyses, the clinical literature supports the use of RFA of the SI joints in managing pain, disability, and dysfunction originating from the SI Joint.

An interventional pain medicine evidence-based chapter by Vanelderen et al. recommended that the treatment of SI joint pain should start with conservative treatment followed by intra-articular SI joint injection and, if the latter fails to produce only short-term effects, then RFA of the lateral branches from L1 to L3 was recommended.[14]

It should be clarified that both cooled and heated RF use the heat generated by radiofrequency as an ablative mechanism, with the cooling mechanism using water to cool the tip of the needle to propagate the heat farther into the tissue. Still, both techniques generate heat in the surrounding soft tissues up to approximately 85^{o} C. The literature supports both types of RFA, with the initial techniques focusing on traditional RFA [1-3, 6-9] and more recent techniques expanding the literature information on cooled and large-volume RFA. [11,12,14-17] The advent of cool-RF has been characterized by multiple different studies of this application to treat painful SI joints. Kapural et al. showed in a retrospective review of 27 patients who had chronic low back pain (CLBP) and underwent cooled RFA of the lateral, medial branch nerves that these patients had statistically significant improvements in pain and function and a decrease in opioid use that was durable to at least four months.[15] A randomized placebo-controlled study of 28 patients by Cohen et al. compared cooled RF to placebo denervation and found statistically significant improvements in pain and function from the patient's baseline status and a much greater global perceived effect in the treated patients 73 to 93 as compared to the placebo patients.[14,3] Karman, et al. studied 15 patients suffering from chronic SI joint pain and found that it reduced the median pain score from eight to a three by month six. The ODI decreased from 36 to 14 during the same time frame.[17] These authors also reported a 50% reduction of pain in 80% of the patients and concluded that cooled RFA was influential in the short to intermediate term. Patel et al. showed in a randomized placebo-controlled study that lateral branch RFA using cooled RF was statistically better concerning improvements in pain, function, disability, and quality of life compared to sham treatment. The benefits of the treatment lasted up to and beyond nine months.[8] A twelve-month follow-up of these patients showed sustained results for those initially treated with lateral branch RFA.[12] A 2016 sham-controlled RCT by Van Tilburg et al. failed to show statistically significant superiority of SI joint RFA over sham. Still, this study was widely criticized due to the statement in the discussion of the trial stating that the criteria and method for diagnosing SI joint pay may have resulted in the selection of some patients without SI joint pain.[18] After this, there were two RCTs that evaluated long segment or strip RF lesioning using traditional RFA, one being a double-blind sham-controlled RCT that showed a statistically significant reduction in pain at three months[19] and the other being an RCT comparing long segment RFA with

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celecoxib that showed statistically significant benefit in pain reduction for the RFA as compared with celecoxib in patients treated for six months.[20]

An additional sizeable multicenter RCT with 15 sites compared cooled RFA to standard medical management with 210 patients was designed to test the superiority of cooled RFA compared to SMM at three months, with the study carried out for one year.[21] To be included, the patients had to have a response of 50% or more decrease in back pain following an SI joint injection, and the SMM patients were allowed to cross over after three months. The patients had been in pain for an average of 10 years and had never had an RFA before enrolling in the trial. The three-month results included statistically significant and clinically relevant changes in pain, function, quality of life, disability, and patient global impression of change.[21] This trial is the largest RCT trial to date, demonstrating cooled RFA is statistically significantly superior to standard medical management for the clinical treatment of SI joint-mediated pain.[21] Regarding safety, this large RCT showed nothing unexpected in regard to adverse events, no persistent, significant adverse events, and no differences in AEs, regardless of whether the patient was treated unilaterally or bilaterally.[21] At the time of the database lock, 47 patients in the cooled RFA had completed the 12-month visit with a mean pain score of 3.4, down from 6.3 at the beginning of the trial and down from 3.8 at the 3-month time point.[21] In summary, there is ample literature support for cooled RFA, including case reports, case series, two meta-analyses, three systematic reviews, four blinded sham-controlled RCTs, and a large multicenter prospective RCT.[8,9,11-26] In addition to the high-quality data, there are six Level III and Level IV manuscripts and three technological contributions to the literature. In summary, there is strong literature support for both heated and cooled RFA.

In performing RFA of the SI joints, several factors have been found to influence outcomes. These include preprocedural pain intensity, age > 65 years, and pain radiating below the knee, all significant predictors of failure.[12] Notwithstanding these factors, which have been found to influence the outcome, no single clinical variable, including the type of RFA (cool or standard), has been shown to have significantly better treatment results.[13] There are also multiple RCTs, including sham-controlled trials and large trials comparing SI joint RFA to standard medical management, all showing statistically significant between-group comparisons with SI joint RFA over either sham or SMM regardless of whether the RFA is cooled or traditionally heated.[8,9,15] Only one Level II study compared thermal and cooled RFA.[22] This report supported all three techniques as effective for treating SI joint pain for up to 12 months and concluded that standard thermal and cooled RFA were similar.[22] Also, no type of RFA is superior to the other.

In summary, multiple RCTs, including sham-controlled trials and large trials comparing SI joint RFA to standard medical management, show statistically significant between-group comparisons with SI joint RFA over either sham or SMM regardless of whether the RFA is cooled or traditionally heated.[8,9,15]

The innervation was described by Solonen[27,] who reported the innervation is derived from the lumbosacral trunk, the superior gluteal nerve, and the dorsal rami of S1 and S2. Ideda described the anterior joint as innervated by the ventral rami of L5 and S2 nerves from the sacral plexus.[28] These nerves are not accessed by traditional dorsal nerve treatments. Szadek et al. showed the anterior SI

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ligaments are innervated by the lumbosacral trunk, which is also anterior and not reached by conventional dorsal treatments. There are some reports of the innervation carrying noxious stimuli being from the dorsal portion[29,] but the most recent study showed that although most of the innervation is from the posterior portion of the joint, there is still some ventral nerve contribution by primarily the L4, L5, and S1 nerves but also some from S2.[30] In summary, most but not all nerves transmitting noxious stimuli can be reached by the traditional dorsal treatment methods.[27-30]

The best quality data measures clinical response from six months to one year and has significantly improved the measured clinical parameters to at least six months.[8-12] When comparing the RFA of the SI joint directly to non-surgical management and SI joint fusion, this shows a response of SI joint RFA of approximately six months.[31] The QALY for SI joint RFA following physical therapy and steroid injections is 2.52.[32] It is less than fusion (3.27) and similar to initial RF treatment or no RFA (2.47) and treatment with RFA only (2.49). Therefore, the most cost-effective application of RFA of the SI joint was after failed NSM or when the patient started with RFA.[32] The median duration assumption to calculate the cost-effectiveness of RFA is 7.9 months based on the current RFA evidence.[33] In summary and based on the existing literature and what is clinically and financially sustainable, an adequate length of time for an RFA procedure of the SI joint(s) to last is six months.

The Society of Interventional Radiology believes that all of the supporting evidence above qualifies Sacroiliac Joint (SIJ) Denervation, also referred to as SIJ Radiofrequency Ablation (RFA), as a reasonable and medically necessary intervention to treat patients suffering from SIJ dysfunction and chronic pain. The indication that RFA is investigational and, thereby, not medically necessary will prevent patient access to a highly effective opiate alternative treatment option. In addition, the evidence above clearly proves that using RFA successfully treats unmanaged pain within the SIJ population. Most importantly, it minimizes the probability of said group transitioning into opioid abuse. Therefore, the Society strongly recommends that the proposed local coverage determination (LCD) DL39462 for sacroiliac joint injections and procedures properly reflect radiofrequency ablation (denervation) as a medically necessary and reasonable treatment for patients suffering from sacroiliac joint dysfunction and pain.

SIR appreciates the opportunity to provide feedback on this proposed policy. If additional information is required, don't hesitate to contact SIR's Manager of Coding and Reimbursement, Ashley Maleki, at amaleki@sirweb.org or (703) 844-0378.

Sincerely,

Parag J. Patel

Parag J. Patel, MD, FSIR
President, Society of Interventional Radiology

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Cc: Keith M. Hume
Executive Director, Society of Interventional Radiology

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Summary of Evidence for RFA of Sacroiliac Joint

Author, Year	Title	Study Design	Journal	Sample	Evidence Level	Outcomes
CLINICAL TRIALS						
Mehta (2018)	The Effects of Radiofrequency Neurotomy Using a Strip-Lesioning Device on Patients with Sacroiliac Joint Pain: Results from a Single-Center, Randomized, Sham-Controlled Trial.	RCT	Pain Physician. Nov 2018; 21(6): 607-618.	17	Level I	Double-blind, randomized, sham-controlled trial assessing the efficacy of radiofrequency neurotomy with a strip-lesioning device in patients with chronic SIJ pain. Seventeen of 30 enrolled patients were randomized to active (n=11) or sham (n=6) treatment. Recruitment was terminated after an interim analysis indicated a statistically significant difference in the pain outcome between groups. After the 3-month study endpoint, patients receiving sham treatment were allowed to crossover. While a ***statistically significant reduction in pain scores was reported at 3 months,*** there was no significant difference in functional outcome as measured by the Physical Component Score at 3 months. Due to the crossover design, it is difficult to gauge long term outcomes and durability of the treatment.
Van Tilburg (2016)	Randomized Sham-controlled Double-Blind Multicenter Clinical Trial to Ascertain the Effect of Percutaneous Radiofrequency Treatment for Sacroiliac Joint Pain: Three-month Results.	RCT	Clin J Pain. Nov 2016; 32(11): 921-926	60	Level I	Sham-controlled randomized trial of percutaneous RFA in 60 patients with SIJ pain. Patients selected had clinically suspected SIJ pain and a decrease of 2 or more points on a 10-point pain scale with a diagnostic sacroiliac block. At 3-month follow-up, there was no statistically significant difference in pain level over time between groups (group by period interaction, p=0.56). Both groups improved over time (»2 points out of 10; p-value for time, p<0.001). ***In their discussion, trialists mentioned the criteria and method used for diagnosing SIJ pain might have resulted in the selection of some patients without SIJ pain.***
Zheng (2014)	Tomography-guided palisade sacroiliac joint radiofrequency neurotomy versus celecoxib for ankylosing spondylitis: an open-label, randomized, and controlled trial.	RCT	Rheumatol Int. Sep 2014; 34(9): 1195-202	155	Level I	RCT of ***palisade*** sacroiliac RFA in 155 patients with ***ankylosing spondylitis***. Palisade RFA uses a row of radiofrequency cannulas perpendicular to the dorsal sacrum. Inclusion criteria were ages 18 to 75 years; diagnosis of ankylosing spondylitis; chronic low back pain for at least 3 months; axial pain below L5; no peripheral involvement; pain aggravation on manual pressing of the SIJ area; and at least 50% pain relief following fluoroscopically guided anesthetic injection into the joint. Patients who met the inclusion criteria were **randomized to palisade RFA or celecoxib**. Blinded evaluation to 24 weeks found that RFA (2.8) resulted in lower global VAS scores than celecoxib (5.0; p<0.001) as well as improved scores for secondary outcome measures. This study lacked a sham control.
Patel 2012	A randomized, placebo-controlled study to assess the efficacy of lateral branch neurotomy for chronic sacroiliac joint pain	RCT	Pain Med. Mar 2012; 13(3): 383-98.	51	Level I	Randomized, double-blind, placebo-controlled trial of lateral branch neurotomy with a ***cooled radiofrequency probe. Twelve-month follow-up*** was reported in Fifty-one patients who had a positive response to 2 lateral branch blocks were randomized 2:1 to lateral branch radiofrequency or to sham. At a 3-month follow-up, significant improvements were observed in pain levels (-2.4 vs -0.8), physical function (14 vs 3), disability (-11 vs 2), and QOL (0.09 vs 0.02) for radiofrequency treatment compared with controls (all respectively). With treatment success defined as a 50% or greater reduction in numeric rating scale score, ***47% of radiofrequency-treated patients and 12% of sham-treated patients achieved treatment success.*** The treatment response was durable to 12 months visits in the 25 of 34 patients who completed all follow-up. Of the 9 patients who terminated study participation, 4 (12%) of 34 were considered treatment failures.
Nilesh Patel 2015	Twelve-month follow-up of a randomized trial assessing cooled radiofrequency denervation as a treatment for sacroiliac region pain	Randomized Trial	Pain Practice 2016; 16:154-167.	51	Level I	***12-month outcomes for cooled RFA of the SIJ compared to baseline were favorable,*** with a mean 2.7-point drop in the NRS score, a 13.9 decrease in the ODI, and a 15.8 increase in SF-36BP.

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Author, Year	Title	Study Design	Journal	Sample	Evidence Level	Outcomes
Cohen 2008	Randomized placebo-controlled study evaluating lateral branch radiofrequency denervation for sacroiliac joint pain	RCT	Anesthesiology. 2008 August; 109(2): 279–288	28	Level I	A randomized, placebo-controlled study was conducted in 28 patients with injection diagnosed sacroiliac joint pain. Fourteen patients received L4-5 primary dorsal rami and S1-3 ***lateral branch radiofrequency denervation using cooling-probe*** technology following a local anesthetic block, and 14 patients received the local anesthetic block followed by placebo denervation. Patients who failed to respond to placebo injections crossed over and were treated with radiofrequency denervation using conventional technology. ***One, 3 and 6-months post-procedure, 11 (79%), 9 (64%) and 8 (57%) of radiofrequency treated patients experienced ≥ 50% pain relief and significant functional improvement***. In contrast, only 2 (14%) patients in the placebo group experienced significant improvement at their 1-month follow-up, and none experienced benefit 3-months post-procedure. In the crossover group (n=11), 7 (64%), 6 (55%) and 4 (36%) patients experienced improvement 1, 3 and 6-months post-procedure.
Systematic Reviews & Meta Analyses						
Chia-Lung Shih (2020)	A comparison of efficacy among different radiofrequency ablation techniques for the treatment of lumbar facet and sacroiliac joint pain: A systematic review and meta-analysis	Systematic Review	Clinical Neurology and Neurosurgery 195 (2020) 105854	21 RCT (n=1129)	Level II	***Thermal, pulsed, and cooled radiofrequency*** techniques in the treatment of LFJ or SIJ with follow-up at 1,3, 6 and 12 months were compared with meta-analysis. ***Results support that the three RFA techniques were effective for treating LFJ or SIJ for up to 12 months***. Efficacy of the three techniques did not reach statistical significance but possibly revealed a trend for variance in efficacy. ***At 12 months the efficacy of standard thermal and cooled RFA was similar (p=0.82)***. For LFJ pain the trend for efficacy of cooled RFA was the most effective, standard thermal radiofrequency was second and pulsed was the least effective only at follow-up visit at 6 months.
Chappel (2020)	Radiofrequency denervation for chronic back pain: a systematic review and meta-analysis	Systematic Review	BMJ Open. Jul 21, 2020; 10(7): e035540	5 studies (n=384)	Level II	Review included 5 RCTs comparing RFA to sham or medical treatment in patients with chronic SIJ pain with follow-up from 1 to 3 months, and 1 study that had follow-up to 12 months. This meta-analysis did not include pulsed RFA. Low quality evidence indicated that RFA led to a modest reduction in pain at 1-to-3-month follow-up, but there was no significant reduction in pain in the single RCT (n=228) that had 6- and 12-month follow-up.
CH Chen, 2019	Radiofrequency neurotomy in chronic lumbar and sacroiliac joint pain. A meta-analysis	Systematic PRISMA Meta-Analysis	Medicine 2019; 98:26	15 Studies	Level II	This systematic review and PRISMA meta-analysis compared the clinical effectiveness of various RF ***(percutaneous, cooled and palisade)*** procedures to conservative non-surgical approaches for the management of chronic lumbar and SIJ pain. Patients treated with RF neurotomy (n=528) had significantly greater improvement in ODI scores, pain scores and QoL as measured by EQ-5D compared to controls (n=457); however significant heterogeneity was observed when data were pooled from eligible studies. In subgroup analysis, patients who received RF had a significantly greater improvement in ODI compared to those with sham treatment. Patients treated with RF also had significantly greater improvement in pain scores compared to controls who received sham or medical treatment. The authors conclude that ***use of RF neurotomy as an intervention for chronic lumbar and sacroiliac joint pain led to improved function***.
Hui-Hui Sun, 2018	The efficacy and safety of using cooled radiofrequency in treating chronic sacroiliac joint pain	A PRISMA-compliant meta-analysis	Medicine 2018; 97:6 (E9809)	7 Studies (n=240)	Level II	7 studies with 240 eligible patients demonstrated that pain intensity decreased significantly after cooled radiofrequency procedure compared with that measured before treatment. The mean difference (MD) was 3.81 [95% confidence intervals (95% CIs): 3.29–4.33, P<.001] and 3.78 (95% CIs: 3.31–4.25, P<.001) as measured by the Numerical Rating Scale (NRS) and Visual Analog Scale (VAS), respectively. Disability also relieved significantly after treatment compared with that measured before treatment. The MD was 18.2 (95% CIs: 12.22–24.17, P<.001) as measured by the Oswestry Disability Index (ODI). Seventy-two percent of the patients presented positive results as measured by the Global Perceived Effect (GPE). The OR was 0.01 (95% CIs: 0.00– 0.05, P<.001).

3975 Fair Ridge Drive, Suite 400 North | Fairfax, Virginia 22033
(703) 691-1805 | Fax (703) 691-1855

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Author, Year	Title	Study Design	Journal	Sample	Evidence Level	Outcomes
Juch (2017)	Effect of Radiofrequency Denervation on Pain Intensity Among Patients With Chronic Low Back Pain: The Mint Randomized Clinical Trials.	Non-Blinded RCT	JAMA. Jul 04 2017; 318(1): 68-81.	228	Level II	Nonblinded multicenter RCT of radiofrequency denervation in 228 of 2498 patients with suspected sacroiliac pain who were asked to participate in the trial Patient selection criteria included body mass index (<35 kg/m²) age (<70 years old), and pain reduction of at least 50% within 30 to 90 minutes of receiving a diagnostic sacroiliac block (n=228). An additional 202 patients had a negative diagnostic sacroiliac block; 1666 patients declined to participate in the trial. Patients meeting criteria were randomized to exercise plus radiofrequency denervation (n=116) or an exercise program alone (n=112) and were followed for a year. The RFA group had a modest improvement for the primary outcome at 3 months (-0.72; 95% CI, -1.35 to -0.06), but the control group improved over time and there were no statistically significant differences between the groups for pain intensity score (p=0.09) or in the number of patients who had more than a 30% reduction in pain intensity (p=0.48) at 12 months. **Limitations included the use of several techniques to achieve radiofrequency denervation, self-selection, lack of blinding, and a high dropout rate (31%) in the control group.**
Simopoulos 2015	Systematic review of the diagnostic accuracy and therapeutic effectiveness of sacroiliac joint interventions	Systematic Review	Pain Physician 2015; 18: E713-E756	25 Studies	Level II	A total of 11 diagnostic accuracy studies and 14 therapeutic studies were included. The evidence for diagnostic accuracy is Level II for dual diagnostic blocks with at least 70% pain relief as the criterion standard and Level III evidence for single diagnostic blocks with at least 75% pain relief as the criterion standard. ***The evidence for cooled radiofrequency neurotomy in managing sacroiliac joint pain is Level II to III.*** The evidence for conventional radiofrequency neurotomy, intraarticular steroid injections, and periarticular injections with steroids or botulinum toxin is limited: Level III or IV.
Level III-IV Studies						
Tnnirello A 2020	Conventional (Simplicity III) and Cooled (SInergy) Radiofrequency for Sacroiliac Joint Denervation: One-year retrospective study comparing two devices	Retrospective observational	Pain Medicine 2017; 18: 1731–1744	43	Level III	Average SInergy group NRS and ODI scores were consistently less than those in the Simplicity III cohort at each post-RF denervation follow-up, and such differences were statistically significant at six and 12 months. The Simplicity III procedure was completed approximately 2.5 times faster
Jianguo Cheng, MD, PhD, 2013	Comparative outcomes of cooled versus traditional radiofrequency ablation of the lateral branches for sacroiliac joint pain	Retrospective Review	Clinical J Pain 2013; 29:132–137	88	Level III	***Both cooled and traditional*** RFAs provided >50% pain reduction for 3 to 6 months in majority of the patients.
Wolfgang Stelzer, 2013	Use of cooled radiofrequency lateral branch neurotomy for the treatment of sacroiliac joint-mediated low back pain: a large case series	Case Series	Pain Medicine 2013; 14: 29-35	126	Level IV	105 patient records were reviewed. The results of CRFA for LBN was reported 4-20 months post treatment. A significant decrease in mean VAS pain scores from baseline was observed in all groups as follows: 8.52 ± 1.07 to 2.34 ± 2.27 in the 4–6 months group; 8.07 ±1.11 to 2.64 ± 2.67 in the 6–12 months group; and 7.99 ± 1.44 to 4.10 ± 2.93 in the >12 months follow-up group ($P < 0.001$, for all). ***The results of cooled RF LBN on quality of life: 69-79% rated quality of life much improved. At 12 months post CRFA, 20% of baseline opioid users stopped opioid use and 47% reported using less.***
Wolfgang Stelzer,2017	Influence of BMI, gender, and sports on pain decrease and medication usage after facet–medial branch neurotomy or SI joint lateral branch cooled RF-neurotomy in case of low back pain: original research in the Austrian population	Retrospective Study	Journal of Pain Research 2017:10 183-190	160	Level III	***Cooled RFA demonstrated a VAS decrease of 4 points on a 10-point scale (from 8 to 4) was seen after 6 months and of 4.5 after 12 months.*** Lower medication usage was reported with opioids decreased by 40% and nonsteroidal anti-inflammatory drugs (NSAIDs) by 60%. Decreased pain lasted for 12 months. Significantly better outcomes were reported by patients with BMIs <30.
Kok-Yuen Ho, 2013	Cooled radiofrequency denervation for treatment of sacroiliac joint pain: two-year results from 20 cases	Retrospective Review	Journal of Pain Research 2013:6 505–511	20	Level III	In 15 of 20 patients ***cooled RFA showed a significant reduction in pain*** (a decrease of at least 3 points on the NPS). Mean Numeric Pain Scale decreased from 7.4±1.4 to 3.1±2.5. Mean Patient Global Impression of Change was "improved" (1.4±1.5) and Global Perceived Effect was reported to be positive in 16 patients at two years post CRFA.

Author, Year	Title	Study Design	Journal	Sample	Evidence Level	Outcomes
Cohen 2009	Outcome predictors for sacroiliac joint (lateral branch) radiofrequency denervation.	Retrospective Study	Reg Anesth Pain Med. 2009 May-Jun; 34(3):206-214	77	Level IV	Seventy-seven patients with refractory, injection-confirmed SI joint pain underwent SI joint denervation at 2 academic institutions. A composite binary variable "successful" outcome was predefined as greater than 50% reduction in pain lasting at least 6 months coupled with a positive global perceived effect. Secondary outcome measures included Oswestry Disability Index. Forty patients (52%) obtained a positive outcome. ***The use of cooled, rather than conventional RF, was associated with a higher percentage of positive outcomes.***
Technology Papers						
Kapural & Deering 2020	A technological overview of cooled radiofrequency ablation and its effectiveness in the management of chronic knee pain	Device Evaluation	Pain Management 2020; 10(3):133-140	-	-	While the clinical protocol for CRFA sets the tip temperature at 60˚C, studies have shown that the ***measured temperature beyond the tissue-tip interface reaches 80˚C.***
Cedeno 2017	Comparison of lesion volumes and shapes produced by a radiofrequency system with a cooled, a protruding or a monopolar probe	Technical	Pain Physician 2017; E915-E922	-	-	While the clinical protocol for water-cooled RFA sets the electrode temperature to 60˚ C (165 seconds), studies have demonstrated temperature beyond the electrode tissue interface reach 80˚ C and that ***the lesions created are larger than those of standard RF***
Ball 2014	The science of conventional and water-cooled monopolar lumbar radiofrequency rhizotomy; an electrical engineering point of view.	Technical	Pain Physician. 2014; 17: E175-211	-	-	***An RF generator target temperature of 60 degrees C using water-cooled RF electrodes creates tissue temperatures of 80 deg C or higher.*** The generator target temperature of 80°C using standard conventional RF electrodes provides some approximate information on the tissue temperatures around the distal electrode, but the target temperature of water-cooled RFA provides information only about the temperature of the electrode thermocouple.