October 12, 2022

Jason Stroud, MD
Lisa Banker, MD, CPE, FACP, CCS, CCDS
Miguel Brito, MD, FCAP, FASCP
Judy Volkar, MD, FACOG, MBA
Attn: Medical Affairs, AG -275
Part A Policy
PO Box 100238 (JM) or PO Box 100305 (JJ)
AG-275
Columbia, SC 29202
Submitted via email to A.Policy@PalmettoGBA.com

RE: Proposed LCD DL39402 Sacroiliac Joint Injections and Procedures

Dear Mr. Stroud, Ms. Banker, Mr. Brito, and Ms. Volkar:

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) DL39402 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. 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. 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 quadrupolar RF ablation.

The highest quality evidence regarding the efficacy of SI joint RFA comes from six Level I manuscripts, including five sham-controlled RCTs. 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. The most recent sham-controlled trials showed relief of pain in both groups in one trial. Statistically, significant relief of pain for
the group treated with a strip-lesioning device as compared to sham. 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. Five of the six Level I trials showed statistically significantly better outcomes than either NSM or sham. 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. 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.

It should be clarified that both cooled and heated RF use 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°C. The literature supports both types of RFA, with the initial techniques focusing on traditional RFA and more recent techniques expanding the literature information on cooled and large-volume RFA. 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. 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. 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. 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. A twelve-month follow-up of these patients showed sustained results for those initially treated with lateral branch RFA. 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 pain may have resulted in the selection of some patients without SI
joint pain. 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 and the other being an RCT comparing long segment RFA with celecoxib that showed statistically significant benefit in pain reduction for the RFA as compared with celecoxib in patients treated for six months.

An additional sizeable multicenter RCT with 15 sited 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 to one year. 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. 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. Regarding safety, this large RCT showed nothing unexpected in regard to adverse events, no persistent significant adverse events, and no differences in AE’s regardless of whether the patient was treated unilaterally or bilaterally. 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. 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. 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. 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. 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. Only one Level II study compared thermal and cooled RFA. 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. 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.
The innervation was described by Solonen\textsuperscript{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.\textsuperscript{28} These nerves are not accessed by traditional dorsal nerve treatments. Szadek et al. showed the anterior SI 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\textsuperscript{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.\textsuperscript{30} In summary, most but not all nerves transmitting noxious stimuli can be reached by the traditional dorsal treatment methods.\textsuperscript{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.\textsuperscript{8-12} When comparing 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.\textsuperscript{31} The QALY for SI joint RFA following physical therapy and steroid injections is 2.52.\textsuperscript{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.\textsuperscript{32} The median duration assumption to calculate the cost-effectiveness of RFA is 7.9 months based on the current RFA evidence.\textsuperscript{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.

SIR appreciates the opportunity to provide feedback on this proposed policy. If additional information is required, don't hesitate to contact Miata Koroma Ekanem, MBA, MS, RN, SIR Senior Director, Health Policy, Clinical and Practice Affairs Division, at mkoroma@sirweb.org.

Sincerely,

Matthew Hawkins, MD
Councilor, Health Policy, and Economics

Cc: Miata Koroma Ekanem MBA, MS, RN
Senior Director, Health Policy, Clinical and Practice Affairs Division
References


## Summary of Evidence for RFA of Sacroiliac Joint

<table>
<thead>
<tr>
<th>Author(s)</th>
<th>Year</th>
<th>Title</th>
<th>Study Design</th>
<th>Journal</th>
<th>Sample</th>
<th>Evidence Level</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mehta</td>
<td>2016</td>
<td>The Effects of Radiofrequency Neurotomy Using a Tipped-Angle Device on Patients With Sacroiliac Joint Pain: Results From a Single-Center, Randomized, Sham-Controlled Trial</td>
<td>RCT</td>
<td>Pain Physician</td>
<td>47</td>
<td>Level II</td>
<td>Double-blind, randomized, sham-controlled trial assessing the efficacy of radiofrequency neurotomy using a 21-g stainless steel needle in patients with chronic SI pain. Seventeen of 24 enrolled patients were randomized to active (n=12) or sham (n=11) treatment. Recruitment was terminated after an interim analysis indicated a statistically significant difference in pain outcome between groups. After a 9-month study period, patients receiving sham treatment did not achieve a response. There was a greater reduction in pain score at 12 months with radiofrequency neurotomy results in lower VAS scores at 12 months compared to sham.</td>
</tr>
<tr>
<td>Van Tilburg</td>
<td>2016</td>
<td>Randomized Sham-controlled Double-blinded Multicenter Clinical Trial to Assess the Effect of Percutaneous Radiofrequency Treatment for Sacroiliac Joint Pain: Three-month results</td>
<td>RCT</td>
<td>Clin J Pain</td>
<td>60</td>
<td>Level II</td>
<td>Sham-controlled, randomized trial of percutaneous RFA in 60 patients with SI pain. Patients received clinically suspected SI pain and a decrease of a 4.0% 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 by period interaction, p=0.8. Both groups improved over time (4.0% points out of 25 points for time, placebo). In their discussion, trialists mentioned the criteria and methods used for diagnosing SI pain might have resulted in the selection of some patients without SI pain.</td>
</tr>
<tr>
<td>Zheng</td>
<td>2016</td>
<td>Transperineal guided percutaneous sacroiliac joint radiofrequency neurotomy versus local anesthetic for relieving symptoms: an open-label, randomized, and controlled trial</td>
<td>RCT</td>
<td>Rheumatol Int Rheumatol</td>
<td>155</td>
<td>Level I</td>
<td>RCT of percutaneous SI RFA in 155 patients with arthritic symptomatology. Patients with SI joint pain received either radiofrequency neurotomy or local anesthetic. Patients with SI joint pain and a decrease of ≥40% on a 0-100 mm visual analog scale (VAS) at 12 months. Patients with SI joint pain who received radiofrequency neurotomy had a greater decrease in VAS score and a greater improvement in SI joint pain compared to local anesthetic.</td>
</tr>
<tr>
<td>Patel</td>
<td>2012</td>
<td>A randomized, placebo-controlled study to assess the efficacy of lateral branch neurotomy for chronic sacroiliac joint pain</td>
<td>RCT</td>
<td>Pain Med</td>
<td>51</td>
<td>Level II</td>
<td>Randomized, double-blind, placebo-controlled, 2-arm, parallel-group, multicenter, randomized, double-blind, placebo-controlled trial of the efficacy of lateral branch neurotomy with a radiofrequency probe. Twelve-month follow-up was reported in 57% of patients who had a positive response to lateral branch block. Patients were randomized to receive radiofrequency neurotomy or placebo. At 12 months, significant improvements were observed in pain levels (n=4 vs. n=5), physical function (n=4 vs. n=5), and quality of life (n=4 vs. n=5). Copeland et al. 2016.</td>
</tr>
<tr>
<td>Nishat Patel</td>
<td>2015</td>
<td>Twelve-month follow-up of a randomized trial assessing cooled radiofrequency denervation as a treatment for sacroiliac joint pain</td>
<td>Randomized</td>
<td>Pain Pract Res</td>
<td>57</td>
<td>Level II</td>
<td>Twelve-month follow-up of a randomized trial assessing cooled radiofrequency denervation as a treatment for sacroiliac joint pain. Twelve-month follow-up was reported in 57% of patients who had a positive response to lateral branch block. Patients were randomized to receive radiofrequency neurotomy or placebo. At 12 months, significant improvements were observed in pain levels (n=4 vs. n=5), physical function (n=4 vs. n=5), and quality of life (n=4 vs. n=5). Copeland et al. 2016.</td>
</tr>
<tr>
<td>Author, Year</td>
<td>Title</td>
<td>Study Design</td>
<td>Journal</td>
<td>Sample</td>
<td>Evidence Level</td>
<td>Outcomes</td>
<td></td>
</tr>
<tr>
<td>--------------</td>
<td>-------</td>
<td>--------------</td>
<td>---------</td>
<td>--------</td>
<td>----------------</td>
<td>----------</td>
<td></td>
</tr>
<tr>
<td>Cohen 2009</td>
<td>Randomized placebo-controlled study evaluating lateral branch radiofrequency denervation for sacroiliac joint pain</td>
<td>RCT</td>
<td>Anesthesiology 2005;102:279-288</td>
<td>28</td>
<td>Level II</td>
<td>A randomized, placebo-controlled study was conducted in 28 patients with injection-diagnosed sacroiliac joint pain. Seventeen patients received 4 primary lateral and 3 bilateral lateral branch radiofrequency denervation using cooled-probe technology following a local anesthetic block, and 11 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, 2, and 6-months post-procedure, 21 (79%), 19 (68%), and 15 (56%) of radiofrequency-treated patients experienced a 50% pain relief and significant functional improvement. In contrast, only 2 (19%) patients in the placebo group experienced significant improvement at their three-month follow-up, and none experienced benefit by months post-procedure. In the crossover group 21 (79%), 19 (68%), 6 (25%) and 3 (11%) patients experienced improvement 1, 2, and 6 months post-procedure.</td>
<td></td>
</tr>
<tr>
<td>Chia-Lung Shih 2019</td>
<td>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</td>
<td>Systematic Review</td>
<td>Clinical Neurology and Neurosurgery 109 (2019) 99-105</td>
<td>21 RCT (n=119)</td>
<td>Level II</td>
<td>Systematic Review</td>
<td>BMJ Open. Apr 24, 2020;10(3):e000565</td>
</tr>
<tr>
<td>Chien 2019</td>
<td>Radiofrequency neurotomy in chronic lumbar and sacroiliac joint pain: A meta-analysis</td>
<td>Systematic PRISMA Meta-Analysis</td>
<td>Medicine 2019; 98:96</td>
<td>15 Studies (n=313)</td>
<td>Level III</td>
<td>This systematic review and PRISMA meta-analysis compared the clinical effectiveness of various RF (percutaneous, cooled and pulsed) procedures to conservative non-surgical approaches for the management of chronic lumbar and SI pain. Patients treated with RF neurotomy (n=119) had significantly greater improvement in ODI scores, pain score, and QOL as measured by EQ-5D compared to controls (n=49). 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.</td>
<td></td>
</tr>
<tr>
<td>Hui-Hui Sun 2018</td>
<td>The efficacy and safety of using cooled radiofrequency in treating chronic sacroiliac joint pain</td>
<td>A PRISMA-compliant meta-analysis</td>
<td>Medicine 2015; 97:1069</td>
<td>7 Studies (n=142)</td>
<td>Level II</td>
<td>7 studies with 254 eligible patients demonstrated that pain intensity decreased significantly after cooled radiofrequency procedure compared with that measured before treatment. The mean difference (MD) was -10.86 (95% confidence interval [CI]: -15.3 to -6.4, P&lt;0.001) and 9.98 (95% CI: -4.15 to 24.05, P=0.17) as measured by the Numerical Rating Scale (NRS). In the Visual Analog Scale (VAS), respectively. Disability also relieved significantly after treatment compared with that measured before treatment. The MD was 11.82 (95% CI: -2.22 to 24.77, P=0.004) 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% CI: 0.00 to 0.79, P=0.03).</td>
<td></td>
</tr>
</tbody>
</table>
### Author, Year | Title | Study Design | Journal | Sample | Evidence Level | Outcomes
--- | --- | --- | --- | --- | --- | ---
Joch (2007) | Effects of Radiofrequency Denervation on Pain Intensity Among Patients With Chronic Low Back Pain: The MOST Randomized Clinical Trials. | Non-Biased RCT | AMA J. Am. | 228 | Level II | Nonblinded multivariate RCT of radiofrequency denervation in 228 of 249 patients with suspected sacroiliac pain who were randomized to participate in the test.
Patient selection criteria included body mass index (BMI) ≥ 35 kg/m², age ≥ 50 years old, and pain reduction of at least 50% within up to 50 minutes of receiving a diagnostic sacral nerve block (SNB). Among the 228 patients who had a negative diagnostic sacral nerve block, 168 patients declined to participate in the trial. Patients meeting criteria were randomized to receive plus radiofrequency denervation (SNB+R) or an exercise program alone (SNB-). The same was followed for a year. The RFA group had a modest improvement for the primary outcome at 3 months (31.2 vs. 16.9; P = .004), but the control group improved over time, and there were no statically significant differences between the groups for pain intensity score (SNR vs. SNR+R) in the number of patients who had more than a 30% reduction in pain intensity (SNR vs. SNR+R) in 24 months. Limitations included the use of several techniques to address radiofrequency denervation, self-selection, lack of blinding, and a high-dropout rate (45% in the control group).

### Author, Year | Title | Study Design | Journal | Sample | Evidence Level | Outcomes
--- | --- | --- | --- | --- | --- | ---
Srivastava (2013) | Systematic review of the diagnostic accuracy and therapeutic effectiveness of sacroiliac joint interventions. | Systematic Review | Pain Physician | 15 Studies | Level II | A total of 14 diagnostic accuracy studies and 14 therapeutic studies were included. The evidence for diagnostic accuracy is Level I for single diagnostic blocks with at least 70% pain relief using the criterion standard and Level III evidence for single diagnostic blocks with at least 70% pain relief using the criterion standard. The evidence for cooled radiofrequency neurotomy in managing sacroiliac joint pain is Level III. The evidence for conventional radiofrequency neurotomy, epidural steroid injections, and percutaneous injections with steroids or total innominate block is Level IV.

### Author, Year | Title | Study Design | Journal | Sample | Evidence Level | Outcomes
--- | --- | --- | --- | --- | --- | ---
Tovalato (2011) | Conventional (Similitude B) and Cooled (Gyn Radios) radiofrequency for Sacroiliac Joint Denervation: One-year retrospective study comparing two devices | Retrospective observational | Pain Medicine | 43 | Level III | Average pain group NPS and GDI scores were consistently less than those in the Similitude B cohort at each post-RF denervation follow-up, with the differences being statistically significant at six and 24 months. The Similitude B procedure was completed approximately 2.5 times faster.

### Author, Year | Title | Study Design | Journal | Sample | Evidence Level | Outcomes
--- | --- | --- | --- | --- | --- | ---
Wolfgang Steffen (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 | 116 | Level IV | In 105 patient records were reviewed. The results of CRFA for LBP was reported 4.6 months post-treatment. A significant decrease in mean LBP pain scores from baseline was observed in all groups as follows: 8.3 ± 3.9 to 2.3 ± 3.2 in 4.6 months group, 8.2 ± 4.2 to 4.3 ± 2.3 in 8 months group, 8.2 ± 4.2 to 2.5 ± 3.0 in 12 months group, and 8.2 ± 4.2 to 2.4 ± 3.0 in 12 months group. LBP scores were significantly lower in the cooled group compared to the uncooled group (P ≤ 0.001). For the 12 months follow-up group (P ≤ 0.001), the results of cooled RF LBP on quality of life were improved. At 12 months post-CRFA, 26 of 27 patients (96%) rated LBP and quality of life significantly improved. At 12 months post-CRFA, 26 of 27 patients (96%) rated LBP and quality of life significantly improved. At 12 months post-CRFA, 26 of 27 patients (96%) rated LBP and quality of life significantly improved. At 12 months post-CRFA, 26 of 27 patients (96%) rated LBP and quality of life significantly improved.

### Author, Year | Title | Study Design | Journal | Sample | Evidence Level | Outcomes
--- | --- | --- | --- | --- | --- | ---
Wolfgang Steffen (2013) | Influence of BMI, gender, and sports on pain decrement and medication usage after facet-median lateral branch neurotomy in 90 patients with sacroiliac joint-mediated low back pain: original research in the Austrian population | Retrospective Study | Journal of Pain Research | 160 | Level III | Both cooled and uncooled RF provided 50% pain reduction at 6 months in 60% of the patients.

### Author, Year | Title | Study Design | Journal | Sample | Evidence Level | Outcomes
--- | --- | --- | --- | --- | --- | ---
Kok-Yuen Hng (2011) | Cooled radiofrequency denervation for treatment of sacroiliac joint pain: two-year results from 200 cases | Retrospective Review | Journal of Pain Research | 20 | Level III | Both cooled and uncooled RF provided 50% pain reduction at 6 months in 60% of the patients.

### Author, Year | Title | Study Design | Journal | Sample | Evidence Level | Outcomes
--- | --- | --- | --- | --- | --- | ---
Cohen (2009) | Outcome predictors for sacroiliac joint pain lateral branch radiofrequency denervation. | Retrospective Study | Reg. Anesth. Pain Med. | 77 | Level IV | Seventy-seven patients with refractory, injection-confined SI joint pain underwent SI joint denervation at a academic institution. A composite binary variable "successful" outcome was predicted as greater than 50% reduction in pain lasting at least 6 months coupled with a patient's global perceptual effect. Secondary outcome measures included Oswestry Disability Index. Forty patients (51%) obtained a positive outcome. The use of cooled, rather than conventional RF, was associated with a higher percentage of positive outcomes.

### Technology Papers

### Author, Year | Title | Study Design | Journal | Sample | Evidence Level | Outcomes
--- | --- | --- | --- | --- | --- | ---
Kapural & Deering (2020) | A technological overview of cooled radiofrequency ablation and its effectiveness in the management of chronic low back pain. | Device Evaluation | Pain Management | - | - | While the clinical protocol for CRFA sets the tip temperature at 76°C, studies have shown that the measured temperature beyond the tissue tip interface reaches 80°C.

### Author, Year | Title | Study Design | Journal | Sample | Evidence Level | Outcomes
--- | --- | --- | --- | --- | --- | ---
Cedeño (2017) | Comparison of fusion volumes and shapes produced by a radiofrequency system with a cooled, a producing or a monopolar probe | Technical | Pain Physician | - | - | While the clinical protocol for water-cooled RF sets the electrode temperature to 65°C (optimum) studies have demonstrated that the electrode tissue interface reached 80°C and that the volumes created were larger than those of standard RF.

### Author, Year | Title | Study Design | Journal | Sample | Evidence Level | Outcomes
--- | --- | --- | --- | --- | --- | ---
Bell (2014) | The science of conventional and water-cooled monopolar and bipolar radiofrequency ablation: an electro-anatomically post-view. | Technical | Pain Physician | - | - | A RF generator target temperature of 60°C and ablation time of 60°C (60°C) studies have demonstrated that the electrode tissue interface reaches 85°C. That these values provide some approximate information on the tissue temperatures around the distal electrode, but the target temperature of water-cooled RF provides information only about the temperature of the electrode thermocouple.