Retrospective Study

Long-term Outcomes of Pulsed Radiofrequency for Supraorbital Neuralgia: A Retrospective Multicentric Study

Xiong Xiao, MD[1], Guoliang Chai, MD[2], Longjun Liu, MD[3], Lei Jiang, MD[4], and Fang Luo, MD[1]

From: [1]Department of Neurosurgery, Beijing Tiantan Hospital, Capital Medical University, Beijing, China; [2]Imaging Department, Beijing Puhua International Hospital, Beijing, China; [3]Department of Pain Management, Beijing Red Cross Peace Orthopedic Hospital, Beijing, China; [4]Department of Anesthesia, Beijing Fengtai Hospital, Beijing, China; [5]Department of Pain Management, Beijing Tiantan Hospital, Capital Medical University, Beijing, China

Address Correspondence:
Fang Luo, MD
Department of Pain Management
Beijing Tiantan Hospital
Capital Medical University
Beijing 100070, P.R.China
E-mail: 13611326978@163.com

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Background: Pulsed radiofrequency (PRF) is a percutaneous, micro-invasive, and micro-destructive neuromodulation technology. It has been reported to be useful in the treatment of supraorbital neuralgia (SN). However, the long-term effectiveness and safety of this technique in SN has not been reported yet.

Objectives: To investigate the outcomes of PRF on supraorbital neuralgia (SN) in multi-centers and a long-term perspective.

Study Design: Retrospective case series.

Methods: Patients who underwent PRF for SN at 4 hospitals in Beijing between Jan 2007 and Jan 2021 were identified and reviewed for inclusion. Their demographic data and baseline conditions were statistically described, and their conditions of pain control were analyzed using Kaplan-Meier survival analyses. A survival curve was plotted, the cumulative proportion of pain-free at specific time points was determined, and the median pain-free time was estimated. Complications related to PRF treatment were summarized. The risk factors for initial pain control and pain-free survival were analyzed using logistic regression and Cox regression.

Results: A total of 116 patients were included; 91 (78.4%) patients got initial pain control with just one attempt of PRF. The maximum length of follow-up was 127 months, with a median of 18 months. During follow-up, 29 (31.9%) patients suffered from pain recurrence, and 11 (12.1%) were lost. The cumulative pain-free survival at 6 months, 1 year, 2 years, 3 years, 5 years, 8 years, and 10 years were estimated as 70%, 64%, 59%, 55%, 44%, 37%, and 37%, respectively. The median pain-free time was 52 months. No severe complications were observed or reported. Duration of disease could significantly influence initial pain control, while no risk factors for pain-free survival were recognized.

Limitations: A retrospective study setting without a control group.

Conclusion: The performance of PRF for the treatment of SN was confirmed to be favorable in a multicentric, relatively large scale, and long-term perspective.

Key words: Supraorbital neuralgia, pulsed radiofrequency, facial pain, survival analysis, long-term outcome, complications, micro-invasive, multicentric study

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The supraorbital nerve is a purely sensory nerve and a terminal branch of the ophthalmic division of the trigeminal nerve. Supraorbital neuralgia (SN) is an uncommon form of severe neuropathic pain in the supraorbital nerve distribution area that severely influences the quality of life of patients (1,2). The prevalence of SN was reported to be 0.65% (2). The diagnostic criteria for SN, as published in the 2nd edition of the International Classification of Headache Disorders (ICHD-2), are as follows: 1) paroxysmal or constant

pain in the region of the supraorbital notch and the medial aspect of the forehead in the area supplied by the supraorbital nerve, 2) tenderness over the nerve in the supraorbital notch, and 3) pain eradicated by local anesthetic blockade or ablation of the supraorbital nerve (3-5). However, because of its rarity, this painful disorder is still inadequately reported, and no standard for the treatment of SN has been established yet.

There are a few options for the treatment of SN. Oral medications such as carbamazepine, gabapentin, and pregabalin are given as the first step of treatment to all patients with SN, except those who show spontaneous relief, especially post-traumatic patients (1,6-10). If patients fail to respond to these medications, nerve block using local anesthetics could provide pain relief. However, its effect is not usually long-lasting (3,7,8). Other therapeutic options include neurologically damaging interventions on the supraorbital nerve, such as chemical neurolysis, surgical ablation, cryoneuroablation, and radiofrequency thermocoagulation (1,9,11,12). However, they inevitably cause numbness and hypoaesthesia in the innervated region that severely affect the postoperative quality of life of patients (1,8,9,11,12). Also, skin sloughing and neuritis were reported to occur in chemical neurolysis (11,13). Surgical decompression is not neurologically damaging and is a treatment option for SN (13,14). However, similar to surgical ablation, surgical decompression is also a traumatic surgical approach. In recent years, peripheral nerve stimulation has produced satisfactory efficacy in some cases, but its long-term safety and effectiveness have not been reported yet (13,14). Nonetheless, complications such as skin erosion, breakdown of the anchoring site, infection, and lead migration have been identified and are of major concern. To avoid these side effects and complications, minimally invasive non-destructive treatment techniques must be explored.

Pulsed radiofrequency (PRF) is a percutaneous micro-invasive and micro-destructive neuromodulation technology (15). Unlike radiofrequency thermocoagulation (RT), a similar approach, PRF does not show neurologically damaging effects (15-21). In recent studies, PRF on the Gasserian ganglion was reported to be effective in the treatment of trigeminal neuralgia and was proven to be a minimally invasive, safe, and effective treatment option (22-25). Reports also show the potential of PRF in the treatment of extracranial neuralgia of trigeminal nerve, including infraorbital nerve and mental nerve, by exhibiting improvements in symptoms of neuralgia (26-28). Moreover, PRF is reported to be useful in other head or facial neuralgias, such as glossopharyngeal neuralgia (29,30). In the past few years, we and other researchers have reported the usage of PRF for the treatment of idiopathic SN, which showed satisfactory potential (10,31). However, the studies included a relatively small number of patients, and the long-term effectiveness and safety of this technique in SN have not been reported yet.

Therefore, to address these concerns, we conducted this study to investigate the outcomes of PRF on SN at multiple study centers in a long-term perspective.

Method

Patient Selection

This study was performed at Beijing Tiantan Hospital, Beijing Puhua International Hospital, Beijing Fengtai Hospital, and Beijing Red Cross Peace Orthopedic Hospital. The study was approved by the IRB (Institutional Review Board) of Beijing Tiantan Hospital. Patients who underwent pulsed radiofrequency for supraorbital neuralgia between Jan 2007 and Jan 2021 were identified from hospital-based information systems and the research databases of these centers. After identification, medical and research records were reviewed to evaluate whether patients were eligible for this study according to the inclusion and exclusion criteria. Informed consent from patients were waived by the IRB due to the retrospective nature of this study.

The inclusion criteria were: (1) patient age greater than 18; (2) patients who suffered from repeated pain in the innervations of the supraorbital nerve who responded to diagnostic supraorbital nerve blocks and were diagnosed as SN; (3) patients who underwent PRF for their SN. The exclusion criteria were: (1) patients without complete medical records or surgical records; (2) patients whose SN diagnoses were challenged by a review of their medical records; (3) patients who once showed their unwillingness to be included in a scientific research or report during medical services or follow-ups.

Procedure of PRF and Postoperative Medications

All the participating centers followed the same protocol for manipulations of pulsed radiofrequency. The patients were asked to lie down in a supine position with continuous monitoring of blood pressure, heart rate, electrocardiogram, and pulse oxygen saturation. A negative electrode pad was attached to the patient's back and connected to a Pain Management Generator

(PMG-230; Baylis Medical Inc., Montreal, Canada). The intersection of the middle third and the medial third of the ipsilateral superior orbital margin was identified as the puncture site. Routine disinfection and local anesthesia were then performed according to the puncture site. Usually, the puncture was conducted with the assistance of ultrasound. A 6-13 MHz linear transducer (probe) of SonoSite M-Turbo portable ultrasound with coverage of a sterile sheath was placed above and parallel to the eyebrow after the application of aseptic ultrasound gel on and above the eyebrow. A 5 cm, 21-gauge radiofrequency trocar (PMF-21-50-2; Baylis Medical Inc.) was used to puncture the supraorbital notch under the guidance of ultrasound. After the removal of the needle core and confirmation of no bleeding, a radiofrequency electrode (PMK-21-50; Baylis Medical Inc.) was inserted into the trocar. The sensory threshold was determined through 50 Hz electrical stimulation so that the depth and direction of the puncture needle were fine-tuned until abnormal sensation could be induced by a voltage of 0.1 V. The settings of the pain management generator were set at 42°C, 2 Hz pulsed radiofrequency, 120 seconds in duration, for 2 consecutive treatments. After the treatment, 0.7 mL of solution containing 0.5 mL 1% plain lidocaine and 1mg dexamethasone was injected into the puncture site.

After PRF treatments, patients were routinely prescribed the same dose of carbamazepine as they were receiving preoperatively. The dose of carbamazepine was gradually decreased and even stopped if the pain was under control. Meanwhile, non-steroidal anti-inflammatory drugs were also conventionally prescribed to patients to prevent postoperative pain caused by postoperative tissue damage and the dose was adjusted according to the degree of pain.

Data Collection

The medical records and related previous research data of eligible participants were collected, from which a list of variables was extracted. The extracted data included gender, age at PRF, age at onset, duration of pain, the score of visual analog scale (VAS) before PRF, affected side, history of trauma or compression in the periorbital area, family history of head or facial pain, type and dose of preoperative oral medication, VAS score within 1 month after PRF, and complications observed during and immediately after PRF treatment. VAS scores were defined as integer values ranging from 0 to 10, with 0 representing no pain and 10 representing the worst pain imaginable.

All the participating hospitals performed their follow-ups routinely for the purpose of improving medical quality and supporting research. For patients who underwent PRF for SN, telephone calls were made at 3 days, 7 days, 14 days, 1 month, 3 months, 6 months, then every 6 months after treatment. Self-measured VAS scores, type, and dose of medications and subsequent surgeries or interventions, if any, were asked during the follow-ups and recorded thoroughly. Postoperative outpatient services also played a role in gathering follow-up data. These variables regarding follow-up were also extracted.

Initial pain control was a VAS score of 0, or a decreased VAS score lower than 50% of the preoperative VAS score, acquired without medications or other surgical interventions, during the first postoperative month. Otherwise, the PRF was deemed ineffective. After initial pain control was obtained, a VAS score greater than 50% of the preoperative VAS score at any time throughout the follow-up period was considered to be pain recurrence (1).

Statistical Analyses

IBM SPSS Statistics version 23 (IBM Corporation, Armonk, NY) was used for statistical analyses. Each collected variable was statistically analyzed. For measurement data, if the variables followed a normal distribution, means and standard deviations were calculated; otherwise, quartiles were calculated. Kaplan-Meier analyses were used to estimate the effectiveness of pain control and the effective rates at 6 months, 1 year, 2 years, 3 years, 5 years, 8 years, and 10 years. Logistic regressions were used to find out risk factors for initial pain control. Cox regressions were used to figure out factors that could influence pain control.

Results

Demographic Features of Included Patients

A total of 131 patients underwent PRF for the treatment of SN at the departments of Pain Managements of Beijing Tiantan Hospital, Beijing Puhua International Hospital, Beijing Fengtai Hospital and Beijing Red Cross Peace Orthopedic Hospital from January 2007 to January 2021. After a thorough review of the data, 15 patients were excluded based on the exclusion criteria, and 116 patients who met the inclusion criteria were included. The procedure of filtering patients is shown in the following flow chart (Fig. 1).

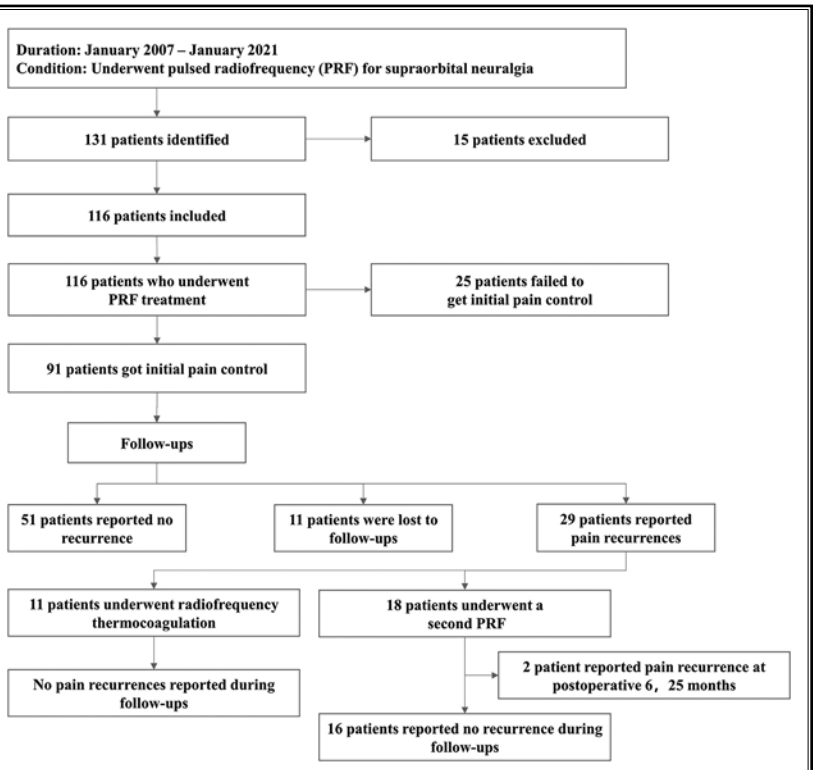

Fig. 1. *Flow diagram of the study.*

Table 1. *Preoperative conditions of included patients.*

Parameters	Value (n = 116)	Range (IQR)
Gender (Female/Male, n (%))	64 (55.2%)/52 (44.8%)	-
Age (yrs-old)	64	32-83 (56-69)
Age at onset (yrs-old)	59	27-80 (51-65)
Duration of disease (years)	4	1-14 (2-7)
Side (Left/Right, n (%))	63 (54.3%)/53 (45.7%)	
History of trauma (n, %)	32 (27.6%)	
History of compression (n, %)	26 (22.4%)	
Family history (n, %)	11 (9.5%)	
Dose of carbamazepine (mg/day)	600	0-1200 (500-800)
VAS	8	7-10 (8-9)

The demographic features and baseline clinical conditions are shown in Table 1. Among the included participants, 64 (55.2%) were women. The median age at treatment was 64 years old (range: 32-83, IQR: 56-69), and the median age at onset was 59 years old (range: 27-80, IQR: 51-65). All patients suffered from unilateral pain, and 63 (54.3%) patients suffered pain in their left sides. Thirty-two (27.6%) patients reported a previous history of trauma, and 26 (22.4%) patients reported a history of compression in the periorbital area on the affected side. No patients had a history or evidence of intracranial disease. No patients had a history of herpes zoster. Eleven (9.5%) patients had a family history of head or facial pain. The median dose of carbamazepine intake of the included patients was 600 mg. However, all patients had endured failed treatments by oral medications and had suffered from severe pain with a median VAS score of 8 (range: 7-10, IQR: 8-9) before PRF treatments.

Effectiveness of PRF

Twenty-five (21.6%) patients failed to achieve pain control after the initial PRF treatment. Other patients started to develop pain control within a median of 5 days (Range: 1- 18 days, IQR: 3-9 days) after PRF treatment. The median length of follow-up before pain recurrences was 18 months (Range: 0-127months, IQR: 9-44 months), among all included patients. Among the patients who achieved initial pain control, 11 (12.1%) patients were lost, and 29 (31.9%) reported pain recurrences during follow-up. The median pain-free time was estimated to be 52 months. The cumulative pain-free survival at 6 months, 1 year, 2 years, 3 years, 5 years, 8 years, and 10 years were 70%, 64%, 59%, 55%, 44%, 37%, and 37%, respectively. The condition of pain control is presented by a survival curve in Fig. 2.

Among the 29 (31.9%) patients who showed recurrences, repeated PRF was performed in 18 patients. All of these 18 patients showed a good response to the second intervention. Follow-up lasted for 24.4 ± 10.9 months after the second attempt. One patient reported pain recurrence at 6 months, and one reported pain at 25 months after the second PRFs. The other 16 patients reported satisfactory pain control. Eleven patients underwent RT after pain recurrence; none

of them reported a second pain recurrence during follow-up, which lasted for a median of 26 months.

Complications of PRF

No severe complications were observed or reported. Forty-nine (42.2%) patients had swelling or ecchymosis in the area of the eyelid and eyebrow arch which recovered within 14 days. Fifteen (12.9%) patients reported slight numbness in their ipsilateral forehead, and all of these patients reported recovery from numbness within one month after PRF. No other complications, such as anesthesia, paresthesia, corneal injury, keratitis, blindness, or infection were observed.

However, all patients who underwent RT after pain recurrences reported numbness after the procedure. Among these 11 patients, 7 reported still reported numbness at 12 months after RT, and 4 reported numbness at 24 months after RT.

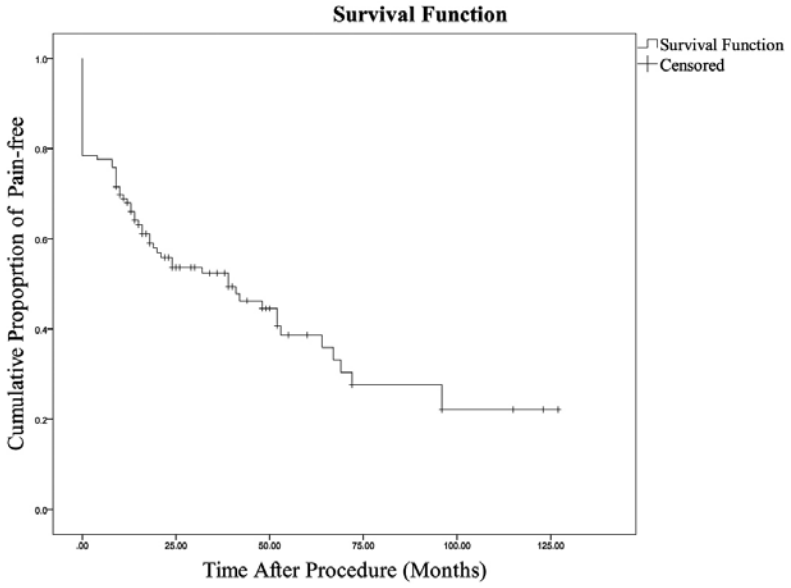

Fig. 2. *A Kaplan-Meier survival curve showing the condition of pain control.*

Other Results

For the risk factors of initial pain control of PRF treatment, we observed that only the duration of disease could significantly influence initial pain control in univariate logistic regression and multivariate logistic regression (Table 2).

For the factors of pain control, we performed Cox analyses in patients who gained initial pain control. No variables could independently influence the length of pain control (Table 3).

Table 2. *Logistic regression for initial pain control.*

Parameters	Univariate Analysis		Multivariate Analysis	
	Exp (B)	*P*	Exp (B)	*P*
Gender	1.775	0.208	1.616	0.312
Age	0.969	0.185	0.985	0.543
Age at onset	0.988	0.585		
Duration of disease	0.830	0.005	0.845	0.017
Side	0.744	0.520		
History of trauma	1.267	0.651		
History of compression	0.524	0.199		
Family history	0.707	0.629		
Dose of carbamazepine	1.000	0.691		
VAS	0.790	0.324		

Discussion

To further measure the performances of PRF on SN, we included data collected during more than 10 years of clinical practices from multiple treatment centers. To the best of our knowledge, this is the largest scale study with the longest follow-up period, regarding the study of PRF treatment for SN. Due to the relatively low incidence of SN, it had not been adequately investigated or reported before. New approaches reported to be effective in the treatment of other neuralgia were rarely systematically tested in treating SN, let alone investigations with a large patient population scale in a multicentric setting, with a long follow-up period. In this study, the observed cumulative pain-free survival at 6 months, one year, 2 years, 3 years, 5 years, 8 years, and 10 years were 70%, 64%, 59%, 55%, 44%, 37%, and 37%, respectively. The estimated median pain-free time was 52 months. PRF's effective rate within 2 years in this study is similar to that of our previous mono-centric study (10). And the long-term results on effectiveness showed the more significant potential of this micro-invasive technique. While comparing this with the effectiveness of RT on SN, which we recently reported, we found that RT provided a higher rate of

Table 3. *Univariate Cox Regression for length of pain control.*

Parameters	Exp (B)	*P*
Gender	0.740	0.421
Age	1.008	0.690
Age at onset	1.008	0.687
Duration of disease	1.006	0.925
Side	1.134	0.741
History of trauma	1.875	0.097
History of compression	0.955	0.920
Family history	0.897	0.883
Dose of carbamazepine	1.001	0.300
VAS	0.835	0.359

pain control in a series of postoperative time points, where cumulative pain-free survival was reported to be 96.2%, 88.4%, 82.7%, 66.3%, and 49.7% at postoperative one year, 2 years, 3 years, 5 years, and 8 years, respectively (1). However, PRF is a micro-destructive approach which does not induce neurodestructive side effects showing advantage over RT. In this study, 62.1% of patients who suffered relapses chose to receive the same PRF treatment for a second time. It was observed that these patients who underwent PRF treatment after pain recurrences showed satisfactory responses. Although the effectiveness of repeated PRF had not been reported before, and the sample size of repeated PRF in this study was relatively small, the satisfactory results indicate that PRF might be a rather useful technique in the treatment of SN.

As reported in previous studies, treatment of supraorbital neuralgia using PRF did not immediately achieve satisfactory efficacy. And it was consistent with previous reports on the treatment of trigeminal neuralgia or extracranial neuralgia of the trigeminal nerve using PRF (10,26,32,33). This condition was once considered to be caused by the time course for the effect of PRF (10); however, pathological or physiological mechanisms were not clarified, and more reasonable explanations were not available. In this study, a combination of oral drugs was prescribed for a short postoperative period, generally 7 days to 14 days, and the pain was well controlled during this period in all patients who confirmed their initial pain control. However, due to an overlap of drugs it was not possible to further investigate the time course and plot a time-to-effect curve which was proposed in our previous report. Considering the results of this study, we suggest that the doses of oral medications should not be reduced within a short period of time after PRF.

There were no severe complications observed in our study. The most common complications were swelling or ecchymosis in the area of the eyelid and eyebrow arch, induced by percutaneous punctures, which would gradually improve. Numbness, which might be due to injury of supraorbital nerves caused by punctures and PRF, only occurred in a small proportion of patients. During follow-ups, we observed a similar trend that had been reported in previous reports that the numbness reported by a minority of patients would recover within a short period of time. It was obvious that PRF treatment on SN showed considerable safety. In addition, due to the micro-destructive nature of this approach, we recommend this method be considered a priority for patients with a history of failed medication treatments.

We did notice that a portion of patients did not successfully achieve initial pain control after the first attempt of PRF. Univariate and multivariate logistic regressions were performed to figure out the risk factors. We found that patients with a longer disease duration were less likely to get immediate responses. Although more detailed investigations are needed to confirm this finding, as PRF is micro-invasive, early attempts of this treatment may be appropriate for patients with drug-refractory SN.

The settings of PRF were fixed at 42°C, 2 Hz pulsed radiofrequency, 120 seconds in duration for 2 consecutive treatments. However, the safety and effectiveness may vary according to the settings. Moreover, similar analyses were reported in other neuralgia study reports (24,34,35). Unfortunately, we did not compare the influences of different settings on their performances. Meanwhile, in recent years, other neuromodulation approaches have been reported to have significant pain control of SN and showed their potential (13,14,16,36). However, comparisons of performance among these approaches have rarely been reported, and no comparisons were made in this study. These factors will be addressed in our future research.

This study had several limitations. Firstly, this study was conducted retrospectively without setting of control groups or comparisons. Before this study, long-term outcomes of PRF treatments for SN had not been reported. Similar to previous studies in which PRF showed potential in the treatment of other neuropathic pain such as trigeminal neuralgia (37-39), the performance of PRF for the treatment of SN was favorable in this study. However, due to the lack of a control group, patients may have experienced reduced pain as the natural course of disease rather than the result of PRF treatment. The evidence and conclusions of this study

cannot be considered strong, and the results should be interpreted with caution. A better-designed prospective study with a comparison group is needed to further confirm the discovery in this study. Secondly, due to the low incidence of SN, despite a large duration of the study, the sample size was still not large enough. Thirdly, the VAS score we used in this study as a tool to determine effectiveness as a subjective variable, which might have induced bias. Lastly, as discussed above, the best setting for PRF and long-term advancements or shortages compared to other approaches were not addressed. These concerns will be focused on in future studies. However, in this study, PRF has been shown to have satisfactory effectiveness and safety in long-term observation.

Conclusion

This study reports the results of long-term follow-up on the effectiveness and safety of PRF for the treatment of SN. The performance of PRF is confirmed to be favorable in a multicentric, relatively large scale, and long-term perspective.

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