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Original Article

The efficacy of pulsed radiofrequency stimulation of the glenohumeral joint and suprascapular nerve for chronic shoulder pain and function compared to physiotherapy and exercise program without pain management

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Abstract

Background: Degenerative tendon diseases are primarily treated conservatively in primary health care and the most important treatment modality is physiotherapy-guided therapeutic rehabilitation.

Method: In this prospective observational study, we investigated the effect of two different treatment approaches in patients with chronic shoulder pain. Physiotherapy-guided treatment was compared to interventional pain treatment with radiofrequency nerve stimulation (pRF) before exercise therapy. The primary outcomes were active shoulder mobility and shoulder function assessed by SPADI questionnaire at two and 6-month controls.

Results: The results of this study show that pRF treatment combined to physiotherapy seem to effect shoulder function more than physiotherapy alone. With regard to patients with chronic pain and decreased shoulder mobility (65%), pRF treatment showed a significant greater effect in relieving pain and increasing functional outcome assessed by SPADI. Also short-term pain and impairment reduction for 8-12 weeks occurred in patients with chronic rotator cuff lesions. A direct comparison between the rehabilitation programs strengthened the assumption that effective pain management could be necessary to obtain optimal effect of physiotherapy and physical training in patients with chronic (> 3 months) shoulder pain.

Conclusion: PRF can be performed in an outpatient department and provides the clinician with an alternative or additional approach to oral drug treatment and intra-articular injection. Further, it may prove to be a useful treatment for patients who are unfit or unwilling to consider surgical intervention

Level of evidence: IV.

Introduction

After spinal and knee pain, shoulder pain is estimated to be the third most common type of musculoskeletal pain, causing considerable psychosocial impact if progressing to the chronic phase [1]. While majority of patients with shoulder pain recover within few months, over 40% of patients have persisting symptoms after 12 months [1]. Non-surgical strategies are preferred in the first-line management [2.3], with physiotherapy being of the treatment of choice in the majority of cases [4]. Physiotherapy, pain medication and corticosteroid injections (CSI) are frequently used, but in cases with longstanding shoulder pain the effectiveness of these interventions may be insufficient [1-6]. Corticosteroid injections are often used in treatment of shoulder pain, though there is no clear evidence of long-term benefit. Still, in the short term, they might offer greater pain reduction compared to placebo or local anesthetic alone [7,8]. It has been reported that CSI might lead to adverse events such as tendon degeneration, cutaneous atrophy or infection [9-11]. In addition, CSI can cause systemic side effects including changes in the hypothalamic-pituitary-adrenal (HPA) axis function and elevated blood glucose levels [12]. Therefore, safer pain management options with more long-lasting pain relief are sought.

Suprascapular nerve blocks (SSNB) have been performed to manage acute and chronic shoulder pain [13-15]. In addition, the short duration of action of local anesthetics raises the question of their efficacy in the management of chronic shoulder conditions. In addition to SSNB, pulsed radiofrequency (pRF) has also been researched for its potentially greater and longer-lasting outcomes when comparing to local anesthetics. The suprascapular nerve contributes approximately 70% of the sensory innervation to the shoulder joint [16].

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Numerous mechanoreceptors and nerve endings have been found in the glenohumeral ligaments and joint capsule, some of which are thought to be nociceptive [17]. It has been proposed that the afferent fibers of the suprascapular nerve could become entrapped by injured tissues or become sensitized after long-term pain in chronic shoulder conditions [18]. There has been limited numbers of reviews specifically investigating the usefulness of SSNB for the treatment of chronic shoulder pain. Liu et al. concluded in their review [19] pRF treatment to result in good efficiency in shoulder patients with no significant complications reported. The pain relief could last several months [19]. Only few case reports have been made on pRF treatment of the glenohumeral joint [20]. Considering the adverse effects of corticosteroids, SSNB with local anesthetics could be regarded as a potential alternative for pain relief in patients who have adhesive capsulitis [21].

Controlled observational studies are used to determine whether a particular intervention is useful in real-life clinical practice [22]. Great care should be taken to ensure high quality design when observational study is being carried out [23,24]. Several studies show that the effect sizes do not differ significantly between well conducted randomized studies and well-designed observational studies [23,25].

The aim of this observational study was to compare whether pRF treatment of both glenohumeral joint and suprascapular nerve provided additional clinical benefits compared to for physiotherapy only. The rehabilitation included individual functional training and treatment as recommended by the national task group.

Methods

Design

An observational registry study of patients participating in physiotherapy-guided therapeutic rehabilitation (PT) or a interventional rehabilitation program. (pRF). All participants were referred consecutively to the programs, and were followed prospectively for a period up to 6 months.

Subjects

Register study group (PT) : Individuals referred to the unit of orthopedic surgery at Satakunta Central Hospital (n=95) during the period 3/2016- 8/2016, and who met the inclusion criteria, were included to the register-study and served as the control group. Inclusion criteria were shoulder pain with following diagnoses: rotator cuff syndrome, subacromial pain syndrome, shoulder joint instability, arthrosis and adhesive capsulitis. Patients were referred to specialist evaluation from public health general practitioners (42%), and other general practitioners (36%), vocational health care units (10%) and other specialist units within the hospital (11%). Fifty-four patients (56%) had received physical therapy before and six patients had never met physical therapist for shoulder problems (6%). For 36 patients (38%) the history of earlier therapies was not registered. Thirty-one patients (33%) were offered surgical treatment directly and 61 (67%) patients were selected to physiotherapy management. Of physiotherapy group 34 (56%) received physical therapy at the unit of physical medicine and rehabilitation. This group was the control group for physiotherapy (PT) in this study. The rehabilitation included individual functional training and treatment as recommended by the national task group (TAU). The register study was conducted by a physiotherapist, who was not involved in treatment of patients, to evaluate effects of new national recommendations to treat shoulder pain at the Satakunta Central Hospital. The aim of the first quality study 2016 was to evaluate effects of patient treatment processes at the Central Hospital as well as patient satisfaction for treatments offered.

Interventional therapy group (pRF) : The intervention group consisted of individuals with shoulder pain referred to the unit of physical medicine and rehabilitation at Satakunta Central Hospital for conservative treatment 4/2018 - 8/2018. They were first evaluated by specialist in physical medicine and rehabilitation who used ultrasound and clinical examination to estimate shoulder function. Physician made as well the assessment of pain medication used at the time. Patients who had shoulder dysfunction based on subjective symptoms and clinical evaluation were asked to participate in this intervention study. Patients with radiculopathy were excluded. Initially 90 patients were treated with pulsed radiofrequency stimulation (pRF) once before starting the training period (treatment as usual). Twenty-five persons (28%) did not want to participate in the follow up study or had not filled the questionnaire used at the clinic. Of this study group consisting of 65 individuals 59 person participated at clinical follow-up by a physician and filled the follow up questionnaire (92%). With remaining 6 persons who did not attend the 2 months follow up 2 individuals claimed worsening of pain as a reason (1 person had an acute subscapular tendon tear and both persons preferred orthopedic surgeon consultation). One person has had accidental scapula fracture and one individual was treated for arthrosis at 2-months follow up by intra-articular sodium hyaluronate injection (Hyalgan®, Takeda Pharmaceutical Company). One person had worsening of psychiatric comorbidity as a reason and one person did not attend for technical reason. Follow up questionnaire was mailed 6 months after the treatment. Seventeen people (26%) declined to participate in 6 months follow up. Six people dropped out from pRF group.

Interventions

PT : Program based on manual therapy intervention focused on increasing function and pain control. Physical training was largely based on specific movements supervised by qualified physiotherapists. The emphasis was on individual training program, and on learning a functional use of the arm. Average rehabilitation time was calculated to be three months and on average patients had four consultations (1-12) in 3 months. Physiotherapist had under rehabilitation time possibility to consult a specialist in physical medicine and rehabilitation for injections and medical advice. Thirty patients voluntarily attended this follow-up quality study and 20 (67%) patients completed the questionnaire and follow up.

pRF : All patients were at first evaluated by specialist in physical medicine and rehabilitation who used ultrasound and clinical examination to estimate shoulder function. Physician made as well assessment of pain medicine used at the time. Patients who had more specific shoulder dysfunction based on subjective symptoms and clinical evaluation were asked to participate in this intervention study. Of totally 90 consecutive persons who received PRF on the suprascapular nerve and shoulder joint, 65 consecutive patients voluntarily participated in the study. The study was performed in accordance with the Helsinki declaration and patient confidentiality was ensured. All patients had sub-acute or chronic shoulder pain unresponsive to conservative treatment for a period of at least 12 weeks. The etiology of shoulder pain was classified according

Table 1. *Base-line descriptive data of the participants in the rehabilitation programs. Physiotherapy-guided treatment approach (PT) and treatment with radiofrequency nerve stimulation before the exercise starts under physiotherapist supervision (pRF)*

	PT (n=33)	pRF (n=65)	F or χ2	p-Values:
Age, mean (SD)	52(13)	54 (13)	F=0.25	p=0.62
Pain duration (months), m(SD)	16(7)	21(19)	F=0.39	p=0,54
Women, n. (%)	62%	57%	χ2 0.26	p=0.61
Adhesive capsulit	9%	8%	χ2 0.03	p=0,89
Rotator cuff syndrome	84%	86%	χ2 0.04	p=0,88
Arthrosis of the shoulder joint	6%	5%	χ2 0.02	p=0,90
Shoulder surgery before, n (%)	8%	18%	χ2 0.22	p=0,64
Decreased active mobility: Active flexion or active adduction	65%	64%	χ2 0.02	p=0,91
Trauma	4%	18%	χ2 0.02	p=0,90
Smokers, n (%)	10%	20%	χ2 0.40	p=0.52
Diabetes, n (%)	4%	18%	χ2 0.72	p=0.39
Depression, n (%)	8%	22%	χ2 3.78	p=0.05
Pain VAS	62(24)	67(17)	F=1.96	p=0.16
(AROM) Adduction	134 (49)	128 (47)	F=0.16	p=0.69
(AROM) Flexion	136 (46)	143 (41)	F=0.11	p=0.37
SPADI (total)	49 (17)	55 (18)	F=1.86	p=0.18
HRQoL 15 D index	0,84 (0,09)	0,81 (0,1)	F=2.49	p=0.12

to de Winter (Table 1). Conservative treatment included pharmacotherapy (Opioid analgesics, NSAIDs, paracetamol, adjuvant medication) and physiotherapy. Those patients with a pain of visceral origin or cervicobrachial syndrome were excluded from the study. PRF treatment was performed under ultrasound guidance. The suprascapular notch was identified using ultrasound with the patient in the sitting position, shoulders relaxed and forearms placed on the thighs. Following the puncture, an isolated radiofrequency 23-G 60 mm needle with a 5 mm active tip (Top Neuropole needle XE 60mm 23G) was introduced perpendicularly to the skin in all planes. Selective stimulation of motor fibers (50 Hz) commenced after the needle tip had penetrated into the suprascapular notch. Motoric response or paresthesia at a voltage between 0.3 and 0.5 V was sought. After positive stimulation, a 4-minute cycle of PRF with STP (Sluijter Teixeira Pulsed Poisson) program (TOP Lesion Generator TLG10, Equip Medikey BV, The Netherlands) were performed. One ml Lidocaine (10%) was injected at the end of therapy since irritation of nerve fibers by the electrical field (without thermolesion) has been described in earlier studies with PRF [26]. Shoulder joint RF stimulation procedure used posterior approach. The patient sits with their arm resting at their side with the shoulder in neutral rotation resting on their lap. The sulcus between the head of the humerus and acromion is identified by ultrasound. The needle is inserted 2-3cm inferior, medial to the posterolateral corner of the acromion and directed anteriorly towards the coracoid process. An isolated radiofrequency 23-G 60 mm needle with a 5 mm active tip (Top Neuropole needle XE 60mm 23G) was introduced perpendicularly to the skin in all planes completely into the joint. First, 0.1-0.2 ml Lidocaine (10%) was injected after puncture of skin and after pRF stimulation 0,8 ml in the shoulder joint. Joint capsule stimulation, a 4 minute cycle of PRF with STP (Sluijter Teixeira Pulsed Poisson) program (TOP Lesion Generator TLG-10, Equip Medikey BV, The Netherlands) were performed. Pain VAS, glenohumeral joint active range of motion and any complications were recorded before discharge. The patients were given contact details of an available nurse prior to discharge. Next week after the RF-stimulation we recommended restart of physiotherapy intervention focused on increasing function and pain control. Physical training was largely based on specific movements supervised by qualified physiotherapists. The emphasis was on individual training program, and on learning a functional use of the body.

Measurements

Data was collected from March 2016 to August 2016 for the PTR group and April 2018 to August 2018 for the pRF intervention group. Data for prognostic factors were collected from each participant and their physiotherapist. These were identified from our literature review of previous studies of prognostic factors for the physiotherapy management of shoulder pain [7] and prognostic factors documented for other management approaches [28]. Summary baseline characteristics are presented in table 1. There was no convincing evidence from previous studies that psychological measures were associated with outcome for our specific population. Prior to the first physiotherapy or physician appointment, participants completed questionnaire. At the first appointment, using standardized clinical data forms; physiotherapists or physician recorded the history of the participant's shoulder problem and clinical examination findings. At discharge, physiotherapists or physician recorded details of treatment and attendance on a standardized clinical data form. In addition to active and passive ranges of motion, Visual Analogue Scale (VAS) and Shoulder Pain and Disability

Index (SPADI), were used to assess shoulder function [29]. The SPADI is a patient administered questionnaire consisting of 13 items divided into two subscales: pain (5 questions) and disability (8 questions). The pain and disability subscales are scored separately and then calculated into a total SPADI score. Higher scores demonstrate increased pain and disability [26]. SPADI has been shown to have good reliability and responsiveness in validation studies [30].

The delivery and content of treatment were unaffected by participation in the study. Participants were sent a postal follow-up questionnaire, 8-10 weeks and 6 months after starting their course of therapy. This included one validated patient-reported outcome measure also collected at baseline: the Shoulder Pain and Disability Index (SPADI) [29]. We also included 15D [31] self-administered measure of health-related quality of life (HRQoL). 15D is a generic, comprehensive, 15-dimensional, standardized, self-administered measure of health-related quality of life (HRQoL) and it can be used as a profile and single index score measure. The single index score (15D score) on a 0–1 scale, representing the overall HRQoL, is calculated from the health state descriptive system by using a set of population-based preference or utility weights. Depression was derived from 15D depression scale (50% or more impairment).

All background variables presented in Table 1 are included in the study.

Statistical analyses

All statistical analyses were carried out in the Statistical Package for Social Sciences (SPSS.21). The Wilcoxon signed-rank test was applied to compare differences in treatment groups at baseline and follow-up. The alpha level for significance was set at P<0.05. Between groups, data were examined using analysis of variances (ANOVAs). Demographic variables were compared using a t-test or chi-squared test for continuous and categorical variables, respectively. Independent sample test (Levene´s test) was utilized for the primary outcome of AROM and SPADI and the secondary outcomes of the Pain NRS and HRQoL.

Ethics and informed consent

The study was approved by the Research Ethics Committee at the Satakunta Central Hospital (SS/1184/13.01/2018) and written informed consent was obtained from all participants in intervention study.

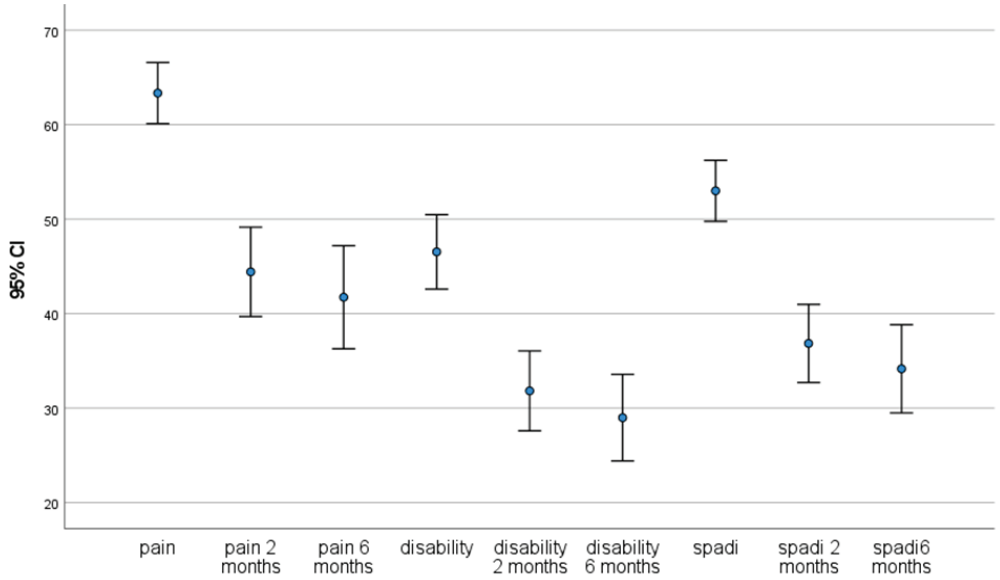
Results

While comparing results between groups with individuals with impaired active flexion (<170 gr) or adduction (<170 gr) at the beginning, pRF group had significant increased shoulder function measured with SPADI and active adduction at follow-up. Difference at follow up AROM for flexion was 0,8 dg (SD=26) for PT group and pRF group +15 (SD=40), (F=4.6 p=0.005 95% CI:-40.0 to -7.8). Difference for impairment and pain measured by SPADI was – 1.7 (SD=22) for PT and -14.6 (SD=19) for pRF (F=0.07 p= 0.04 95% CI:-25.2 to -0.48). AROM adduction was at follow-up for PT + 15.1 (SD=38) and +30.0 (SD=49) for pRF, (F=6.5 p=0.18 CI:-37.2 to 7.3). As indicated in Table 1, participants of the physiotherapy group (PT) and the pRF differed in some respects. Treatment outcomes for both of two treatment groups are shown in Table 2. The results suggest additional therapeutic benefit at 2-months follow-up obtained when pRF was performed in addition to physiotherapy. Difference at follow up AROM for flexion was -2,2 dg (SD=26) for physiotherapy group and pRF group +14 (SD=36), (F=6.2 p=0.01 95% CI:-29.6 to -3.5). AROM adduction was at follow-up for PT + 5.0 (SD=38) and +15.8 (SD=42) for pRF, (F=1.4 p=0.22 CI:-28.4 to 6.7). Difference for impairment measured by SPADI was – 5,7 (SD=22) for PT and -13,6 (SD=18) for pRF (F=1.3 p=0.12 95% CI:-19.7 to 3.8).

An improvement of 10 on the SPADI has been shown to represent significant clinical improvement [11]. In this study nearly two thirds (57%) of the patients who received the pRF stimulation had at least this level of improvement at 8-12 weeks compared to 33% for the physiotherapy group (Pearson Chi-Square 3,67, p=0,05). While both pain and disability subscales improved significantly for pRF group, the pain subscale improved more than the disability scale (17 vs. 11, p = 0,02). (Figure 1).

Table 2. *Treatment outcomes for patients participating in physiotherapy-guided therapeutic rehabilitation (PT) or an interventional pain rehabilitation program (pRF).*

	PHYSIOTHERAPY PT (N=27)			**PULSED RADIOFREQUENCY (N=65)**		
	Baseline	**3-months**	**Wilcoxon p (Z)**	**Baseline**	**3-months**	**Wilcoxon p (Z)**
AROM (degree, mean SD) Flexion Adduction	 142 (47) 141 (49)	 142 (48) 140 (49)	 p=0.82 (-0.23) p=0.21 (-1.25)	 143 (41) 129 (46)	 158 (35) 145 (47)	 p=0.003 (-2.88) p=0.005 (-2.82)
SPADI (mean, SD)	49 (17)	42 (27)	p=0.57 (-0.57)	55 (20)	41 (24)	p=0.000 (-4.99)
Pain VAS (mean, SD)	58 (23)	48 (31)	p=0.01 (-2.59)	67 (17)	49 (23)	p=0.000 (-4.87)
HRQoL 6-months follow-up (mean, SD)						
	Baseline	**6-months**	**Wilcoxon p (Z)**	**Baseline**	**6-months**	**Wilcoxon p (Z)**
15D total score	0.84 (0.08)	0.84 (0.1)	p=0.64 (-0.47)	0.80 (0.1)	0.84 (0.03)	p=0.02 (-2.32)
Usual activities (ICF)	0.68 (0.20)	0.77 (0.13)	p=0.03 (-2.12)	0.65 (0.23)	0.70 (0.23)	p=0.17 (-1.78)
Vitality (ICF)	0.70 (0.12)	0.78 (0.18)	p=0.11 (-1.62)	0.66 (0.20)	0.75 (0.16)	p=0.005(-2.84)
Sleeping (ICF)	0.69 (0.22)	0.69 (0.17)	p=1	0.58 (0.23)	0.64 (0.25)	p=0.11 (-1.16)
Discomfort andsymptoms (ICF)	0.53 (0.19)	0.63 (0.21)	p=0.01 (-2.43)	0.48 (0.22)	0.58 (0.25)	p=0.02 (-2.31)



Fiure 1. *SPADI results for pulsed radiofrequency treatment group at 2- and 6-month follow-up. SPADI pain, SPADI disability and SPADI total scores presented.*

At 6-months follow up quality of life increase (HRQoL) measured by 15D was +0.4% for physiotherapy group and +2.9% for pRF group (F=1.93 p= 0.27 95% CI: -0.07 to 0.02).

Discussion

Our results suggest additional therapeutic benefit obtained when pRF was performed in addition to physiotherapy (TAU). Significant better outcome was observed for both SPADI an active shoulder joint mobility for pRF- treatment group for patients with reduced active movement of shoulder joint. Adhesive capsulitis contributed to a considerable portion of study population, and this condition is known to be responsive to intra-articular administration of corticosteroid with local anesthetics. Corticosteroid injection is frequently used because of its anti-inflammatory actions and expansion of constrictive joint capsules. However, one should take into account the adverse effects of corticosteroid injections, as discussed before [21]. With regard to adhesive capsulitis, pRF treatment showed a greater effect in relieving pain and on functional outcome. PRF can be performed in an outpatient department and provides the clinician with an alternative or additional approach to oral drug treatment and intra-articular injection. Further, it may prove to be a useful treatment for patients who are unfit or unwilling to consider surgical intervention.

Chan et al. [13] investigated the role of SSNB for shoulder pain management in patients with various shoulder conditions e.g. tendinopathy or adhesive capsulitis. In their review, it was concluded that SSNB treatment could be more effective in treating pain in patients with longstanding rheumatoid arthritis when compared to intra-articular injection of corticosteroid. Also short-term pain reduction was noted in patients with chronic rotator cuff lesions. With regard to adhesive capsulitis, SSNB treatment showed a greater effect in relieving pain but on functional outcome, the results were inconclusive. In their quantitative meta-analysis, Chang et al. [14] examined the effectiveness of SSNB for treating chronic shoulder pain. Their results suggested that the use of SSNB could be more effective than physiotherapy, with the effect lasting for at least 12 weeks. The findings could reflect the role of neuropathic pain in longstanding shoulder conditions. Another reason for the diminished effectiveness of physiotherapy could be pain from multiple origins and central sensitization, which can be difficult to treat with a single physical modality or therapeutic exercise.

Pulsed radiofrequency is thought to be a non-neurolytic neuromodulation method, showing some effectiveness in relieving of both experimental and clinical neuropathic pain. Despite the fact that the precise mechanism of PRF for pain relief is still unclear, several studies [32,33] have pointed that a neuromodulatory effect was created through altering gene expression such as c-fos in neurons, which might contribute to the long-lasting duration of pain relief of pRF treatment. In review by Liu et al. [19], the included studies showed long lasting effect during their follow-up periods of both comparative interventions in relieving pain and improving function. They found the similar results, showing pRF treatment could function effectively for 12 weeks [34,35]. It is known that pRF applied to SSN is an invasive treatment approach. Potential complications could be bleeding, infection, nerve injury, neuroma formation and pneumothorax. In line with previous studies [36,37] about pRF treatment, no complications or side effects were reported in our study.

A small sample size and significant dropout made not possible to provide strong conclusive results. Kukkonen's et al. 2013 [38] estimated the clinically important minimal difference in patients with rotator cuff rupture surgical treatment for CM score in 10.4 points. The sample size of 45 patients per group would be needed to reach 90% power to detect a 10.4 difference between the groups in the CM in follow-up score. The placebo response is usually estimated as high as 30%.

In summary, this study provides evidence that pRF is effective and well-tolerated treatment for patients with chronic shoulder pain from arthritis, frozen shoulder and/or degenerative shoulder disease. PRF can be performed in an outpatient department and provides the clinician with an alternative or additional approach to oral drug treatment and intra-articular injection. Further, it may prove to be a useful treatment for patients who are unfit or unwilling to consider surgical intervention.

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