

Research Article

Patellofemoral Pain Syndrome and Chondromalacia: The Effect of Ozone on Pain, Function and Quality of Life. A Non-Randomized Control-Trial

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- Patellofemoral pain syndrome
- Chondromalacia
- Pain
- Ozone therapy
- Quality of life

Abstract

Objectives: 1) To demonstrate the effectiveness of a treatment protocol with Ozone therapy on pain, function and quality of life in patients with Patellofemoral Pain Syndrome (PFPS) and Chondromalacia; and 2) to apply Ozone as a conservative treatment option with a demonstrable level of scientific evidence.

Material and Methods: Prospective quasi-experimental before-after study (non-randomized control-trial) on 41 patients with PFPS and Chondromalacia grade 2 or more, who attended to Santa Cristina's University Hospital, from January 2012 to November 2016

The protocol consisted of an intra articular infiltration of a medical mixture of Oxygen-Ozone (95% -5%) 20ml, at a 20ug / ml concentration, and a total number of 4 sessions (1 per week).

Pain and quality of life were measured by Visual Analogical Scale (VAS) and Western Ontario and Mc Master Universities Index for Osteoarthritis (WOMAC) at the beginning / end of treatment.

Results: Average age 46.63 years. Women 56.09% (n =23), men 43.91% (n=18).The most frequent Chondromalacia grade was 2nd degree (n = 27, 65.9%), followed by 3rd (n = 10, 24.3%) and 4th (n = 4, 9.8%). Post-puncture erythema 9.7% (n = 4).

Pain measured by VAS significantly decreased ($p < 0.0001$) from 6.87 to 1.46. The WOMAC-pain, WOMAC-stiffness and WOMAC-function subscales decreased significantly ($p < 0.0001$) from 13.9 to 3 points, 2.34 to 0.41 and 41.14 to 14.09, respectively.

Conclusion: Ozone is safe and improves significantly pain, stiffness and function in patients with Patellofemoral Pain Syndrome and Chondromalacia.

The study shows a good level of evidence and grade of recommendation that allows us to consider Ozone as a conservative therapeutic option in the treatment of PFPS and chondromalacia.

INTRODUCTION

Patellofemoral pain syndrome (PFPS) is a frequent overuse disorder that affects the patellofemoral region and is present as anterior knee pain. PFPS is the most common cause of knee pain seen by primary care physicians, traumatology, rehabilitation and sports medicine specialists [1,2]. PFPS involves pain on the patella and retinaculum once intraarticular and peripatellar pathology is excluded [3]. In that scenario, the diagnosis is difficult, because there is no consensus about the pathophysiology and the treatment remains a challenge. Sometimes chondromalacia is a term used to describe PFPS. Chondromalacia patella describes the pathologic changes in the articular cartilage of the patella, such as softening, erosion and fragmentation [4]. Indeed, some authors consider chondromalacia patella as a precursor of Osteoarthritis (OA) [5]. PFPS describes complex symptoms and is a diagnosis of exclusion, while chondromalacia patella is a pathologic diagnosis [4].

PFPS is the most common diagnosis in sports medicine, is present in active individuals in up to 25-40% with knee pain; even though, the true incidence is unknown [6]. PFPS is multifactorial, resulting from an interaction of intrinsic and extrinsic factors. To cite, overuse, malalignment and trauma are some causative factors [7]. Abnormal tissue homeostasis that include inflamed synovial lining and fat pad tissues, retinacular neuromas, increased intraosseous pressure and increased osseous metabolic activity of the patella are believed to cause pain and dysfunction [8]. In a recent study, Fernández-Cuadros et al have stated that Ozone is capable to act over inflammation; pain relief and dysfunction in knee OA [9,10]. Since chondromalacia and PFPS share these common features, we believe Ozone could be an effective treatment option for both entities.

PFPS diagnosis is based on clinical history, examination and the exclusion of alternative diagnosis [11]. PFPS has no

pathognomonic sign or symptom; however, the combination of pain with resisted quadriceps contraction and pain with squatting are the maneuvers with more diagnostic validity [12]. Plain radiographies are not necessary for initial management. They are helpful to rule out any other sources of anterior knee pain (bipartite patella, OA, loose bodies and occult fractures) [13].

The treatment goals for PFPS are to reduce pain (on the acute phase), improve patellofemoral tracking and alignment, and return the patient to as a high level of function as possible (on recovery phase). Physical therapy focused on improving the strength and flexibility of the lower extremity and core muscles, included hip adductors and quadriceps, are effective in the treatment of PFPS [14-18]. NSAIDs (non-steroidal anti-inflammatory drugs) are only valid for short term pain relief (two to three weeks) [19]. With respect to physical therapies, ice applied to the anterior knee relieves pain associated to PFPS. There is no empiric evidence to support the use of ultrasound, iontophoresis, phonophoresis or electrical stimulation in the treatment of PFPS [19-22]. Surgical intervention for PFPS is considered when all previous therapies have failed. It is a last resort treatment; then, non-operative therapy should be pursued for 6 to 12 months prior to considering operative intervention [2].

The main objective of this study is to postulate Ozone as a conservative therapeutic option for pain relief, function and quality of life on PFPS and chondromalacia, since its treatment remains a challenge. A second objective is to provide clinical-based-evidence on Ozone as a feasible treatment for such entities.

MATERIAL AND METHODS

A prospective before-and-after quasi experimental study is been performed on 41 patients with PFPS/Chondromalacia grade 2 or more (Figure 1). The follow-up period has been two years (from January 2014 to November 2016) to patients who attended the Rehabilitation Department at Santa Cristina's University Hospital. All patients performed previous medical and Rehabilitation treatment but without symptomatic improvement. The study was approved by the Hospital Ethical Committee.

Inclusion criteria: 1) patients with PFPS/Chondromalacia grade 2 or more diagnosed by MRI (magnetic Resonance Imaging); 2) with pain greater than 3 on the VAS (visual analogical scale) scale; 3) who have failed any other conservative treatments (NSAIDs, rehabilitation, physical therapy); 4) older than 18 years of age.

Exclusion criteria: 1) any formal contraindication to Ozone Therapy (favism, pregnancy, angiotensin converting enzyme inhibitors treatment, hyperthyroidism, thrombocytopenia, serious cardiovascular instability and allergy to Ozone); 2) patients who failed to complete the whole Ozone therapy treatment protocol; 3) patients who failed to fill any of the questionnaires applied (VAS/WOMAC or Western Ontario and Mc Master Index for OA).

On initial evaluation, age, comorbidities, occupation and other demographic data were obtained. An explanation of the Ozone treatment protocol and Informed Consent were

performed. Initial WOMAC Index and initial weight bearing bilateral radiographies were taken. The Ozone protocol consisted of four sessions (1 session/week) of an intra articular infiltration of a medical mixture of Oxygen-Ozone (95%-5%) at a 20 µg/ml concentration. A 27G, 4cm Quincke needle was used to deliver Ozone into the joint. The skin was previously cleaned with 1% Chlorhexidine. With the knee semi-flexed, Ozone was slowly infiltrated on the lateral aspect of the knee next to the patella, and with mild patella subluxation, to expose the articular joint space (Figure 2). After infiltration, the knee was flexed and extended several times in and attempt to distribute the Oxygen-Ozone mixture all over the articulation and the lateral recesses, and to confirm that the infiltration was delivered into the articulation, by listening a crepitus noise (Pérez-Moro Maneuver).

After four sessions are performed, a control with WOMAC Index is filled, one-two months after treatment. From that point on, evaluations every 6 months are accomplished, depending on the clinical symptoms. If treatment is necessary, a new 4-session protocol is applied afterwards.

The symptoms severity is evaluated using the WOMAC Index

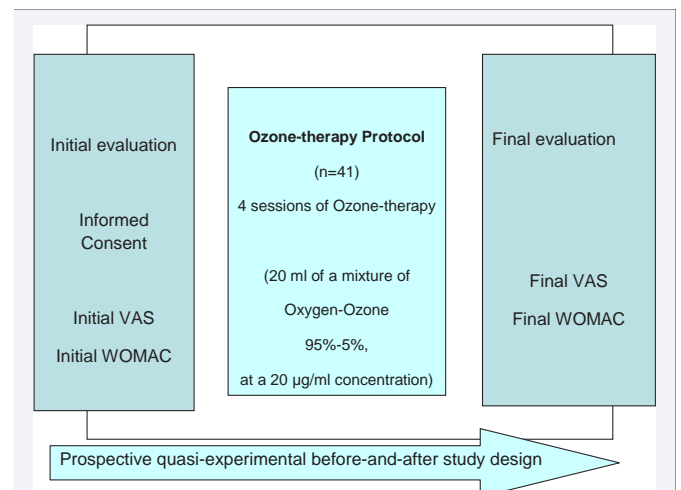


Figure 1 Study design.

Note: VAS, Visual Analogical Scale. WOMAC, Western Ontario and Mc Master Universities Index for Osteoarthritis Protocol applied at the Department of Rehabilitation at Santa Cristina's University Hospital. The study ran from January 2014 to November 2016.



Figure 2 Ozone intra-articular infiltration in a patient, with the knee semi flexed.

[23-25]. The WOMAC Index contains 24 questions in a total of three sections, namely pain, stiffness and function [24-26]. Each section has five response options (none, mild, moderate, severe and extreme), and subtotal scores for pain (five items), stiffness (two items) and function (17 items) range from 0-20, 0-8 and 0-68, respectively [23-26].

Outer bridge classified Chondromalacia in grades as follows: Grade 0, no features of Chondromalacia; Grade 1, edema and softening of cartilage; Grade 2, fibrillation and fissure lower than 1 cm; Grade 3, fibrillation and fissure between 1-2 cm; and Grade 4, fibrillation greater than 2 cm and exposure of sub chondral bone [27,28].

We consider a difference greater than 6% of the maximum scores of the WOMAC Index as being clinically important [29]. That is, for the WOMAC: pain=1.2; stiffness=0.5; function=4.1 [29]. Statistical analyses were conducted using the SPSS® version 20.0 to evaluate initially quantitative and qualitative variables, frequencies, means and percentages were used. To evaluate a significant change before-and-after the treatment, t-student test for quantitative variables was used; while for the evaluation of qualitative variables, χ^2 test was used. The level of significance was 99% ($p=0.01$). If a new treatment cycle was needed, repeated measurement for statistical analysis was applied.

RESULTS

The mean age of the patients was 46.63 ± 12.6 years. The women studied corresponded to 56.09% ($n = 23$) and men 43.91% ($n = 18$) (Table 1). As for laterality, the most affected knee was the right side ($n=30$, 73.1%), while the left knee affection was about 26.9% ($n=11$) (Table 1).

The most frequent Chondromalacia grade was 2nd degree ($n = 27$, 65.9%), followed by 3rd ($n = 10$, 24.3%) and 4th ($n = 4$, 9.8%), (Table 1).

Before treatment pain measured by VAS was 6.87 points and significantly ($p<0.0001$) decreased to 1.46 (Table 2 and Figure 3).

Prior to treatment, the WOMAC-pain subscale was 13.9, the WOMAC-stiffness subscale was 2.34 and the WOMAC-function subscale was 41.14. All these values significantly decreased post-treatment to 3 points, 0.41 points and 14.09 points respectively ($p<0.0001$), Table (2), (Figures 4-6).

A significant difference was seen in decline on pain measured by VAS and an improvement in WOMAC subscales, with $p<0.0001$ (Table 2).

As complications, mild pain accompanied by erythema in 9.7% of cases (4 patients) after the infiltration was seen; the same disappeared in a few minutes.

DISCUSSION

Patellofemoral pain syndrome and Chondromalacia are among the most common etiologies of anterior knee pain in the general population. PFPS can be defined as pain involving the patella and retinaculum that excludes other intraarticular and peripatellar pathology [3]. Chondromalacia patellae is characterized by pain, and it is exactly located on the patella; it

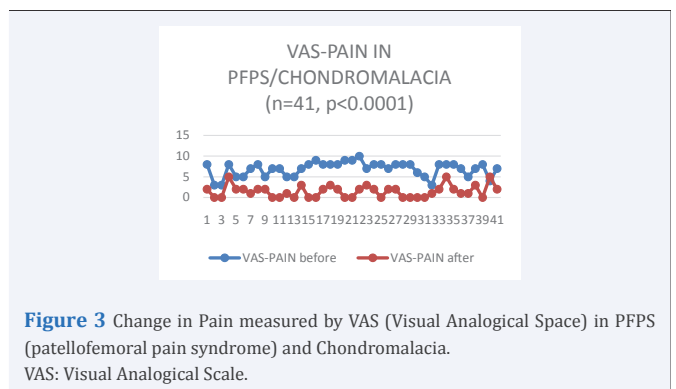
Table 1: Principal characteristics of the patients studied (n=41).

VARIABLE	ANALYZED VALUE
Female, n (%)	23 (56.09)
Male, n (%)	18 (43.91)
Ratio female-male	1.3-1
Age, mean \pm SD	46.63 ± 12.6
Laterality: Right knee; frequency; (percentage)	30 (73.1%)
Laterality: Left knee; frequency; (percentage)	11 (26.9%)
Chondromalacia 2 ^o grade, n (%)	27 (65.9)
Chondromalacia 3 ^o grade, n (%)	10 (24.3)
Chondromalacia 4 ^o grade, n (%)	4 (9.8)
Visual Analogical Scale (0-10) mean \pm SD	6.87 ± 1.74
WOMAC Pain-Subscale (0-20) mean \pm SD	1.9 ± 3.61
WOMAC Stiffness-Subscale (0-8) mean \pm SD	2.34 ± 2.22
WOMAC Function-Subscale (0-68) mean \pm SD	41.14 ± 16.19

WOMAC: Western Ontario and Mc Master Universities Index for Osteoarthritis. SD: Standard Deviation.

Table 2: Change in Pain, Function and Quality of Life, measured by VAS and WOMAC Scales, before and after Ozone therapy treatment (n=41).

CLINICAL VARIABLE	BEFORE (mean \pm SD)	AFTER (mean \pm SD)	Statistical Significance (p)
Visual Analogical Scale (0-10)	6.87 ± 1.74	1.46 ± 1.45	0.0000
WOMAC Pain-Subscale (0-20)	13.90 ± 3.61	3 ± 2.66	0.0000
WOMAC Stiffness-Subscale (0-8)	2.34 ± 2.22	0.41 ± 0.89	0.0000
WOMAC Function-Subscale (0-68)	41.14 ± 16.19	14.09 ± 11.68	0.0000



is associated to anomalous articular cartilage changes on inferior patellar surface. These changes are more common at the union of the medial to the odd facet union [30].

PFPS has no pathognomonic sign or symptom. PFPS is a clinical diagnosis made based upon the history, examination, and the exclusion of alternative diagnosis. Plain radiographies are not required for initial management [3,13].

Physical therapy focused upon improving the strength and flexibility of the lower extremity and core muscles, including

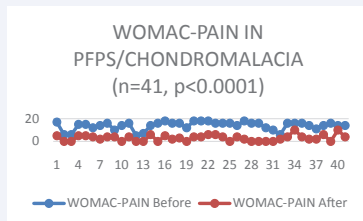


Figure 4 Change in Pain measured by WOMAC-PAIN Subscale in PFPS (patellofemoral pain syndrome) and Chondromalacia. WOMAC, Western Ontario and Mc Master Universities Index for Osteoarthritis

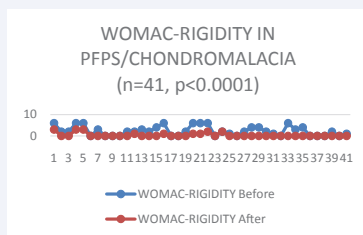


Figure 5 Change in Rigidity measured by WOMAC-RIGIDITY Subscale in PFPS (patello-femoral pain syndrome) and Chondromalacia. WOMAC: Western Ontario and Mc Master Universities Index for Osteoarthritis

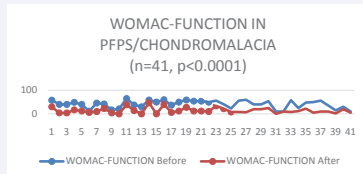


Figure 6 Change in Function measured by WOMAC-FUNCTION Subscale in PFPS (patello-femoral pain syndrome) and Chondromalacia. WOMAC: Western Ontario and Mc Master Universities Index for Osteoarthritis

the hip adductors and quadriceps, are generally effective in the treatment of PFPS¹⁴⁻¹⁸, [20-22]. Ice applied into the anterior knee alleviates pain associated to PFPS. There is no empiric evidence to support the use of ultrasound, iontophoresis, phonophoresis or electrical stimulation on the treatment of PFPS/chondromalacia.

There is no evidence to support the long-term use of NSAIDs for the treatment of PFPS/Chondromalacia; limited evidence supports their use for short-term pain relief [19].

To the best of our knowledge, there is no support on the use of Ozone in the treatment of PFPS and Chondromalacia. There subsides the importance of this study. The etiology, diagnosis and treatment are still a challenge. Ficat believes there is a degradation of articular cartilage, secondary to mechanical factors, releasing proteolytic enzymes (cathepsines, to date one); they would be responsible to the fibrillation and breakdown of cartilage [30,31]. Fernández-Cuadros et al have recently stated that Ozone could act on proteolytic enzymes, included cathepsines, neutralizing its effects [10].

Surgical intervention for PFPS may be considered only when non-operative therapies have failed. Non-operative therapy

should be pursued for 6 to 12 months prior to considering operative intervention and a clearly identified structural abnormality amenable to surgery (for example, tight lateral retinaculum) should exist [2].

The majority of PFPS/Chondromalacia patients experience a resolution of symptoms following conservative treatment [3]. However, up to 40% of patients remain painful one year after onset of symptoms; this fact worsens the quality of life in such an extent that effective measures should be accomplished. Some authors consider Chondromalacia as a pre-evolutionary stage of OA. Since recent studies, like those of Fernández-Cuadros et al, state that Ozone is effective in the relief of pain, improvement on function and quality of life and reversal of cartilage damage [9,10,32]; we postulate Ozone as a feasible therapeutic weapon in PFPS/chondromalacia.

In our series, the mean age was 46 .63 years. This is in accordance with several studies, which state that PFPS/Chondromalacia is very frequent in the second and third decades of life [33]. Wiles states that the process often begins during the second decade of life, and by the age of thirty nearly everyone is affected. It is, however, in only a few individuals that the changes cause symptoms, and in fewer still that they progress to osteoarthritis [5].

PFPS/Chondromalacia affects more commonly women [3,5,29], with a female to male ratio of nearly 2:1 [33,34]. In our study the female to male ratio was similar (1.3:1).

The natural history of PFPS/Chondromalacia is controversial. Wiles consider this entity as a pre-stage of Osteoarthritis [5]. Conversely, Karlson states that the conversion of Chondromalacia to OA is very uncommon, that in 20 years' follow-up, he found no incidence in OA [30,35]. In our study, we have found the prevalence is greater in lower Chondromalacia degrees, probably because of the slow progression of this entity [5,30,35].

When a histological study is performed on chondromalacia patients, the synovial membrane shows some hyperemia and proliferation in almost all cases. In a few, usually near the near of fissuring, a synovial pannus spread over the outer rim of the articular cartilage. This pannus consists of relatively vascular connective tissue covered by flattened synovial cells, and it is so firmly adherent to the cartilage as to be inseparable [5]. This suggests that inflammation subsides under this entity. As formerly stated, Fernández-Cuadros et al., showed that Ozone acts on several targets besides inflammation [10]. This could be the reason why Ozone was effective in the treatment of pain, function and quality of life in such patients.

PFPS and Chondromalacia affect pain, function and quality of life in young populations, as OA affects pain, function and quality of life in older populations [36,37]. As pain and inflammation are common features in both entities, Ozone is an effective therapeutic weapon, as it is being demonstrated improving WOMAC and VAS pain scales on this case series.

STUDY LIMITATION

An important Limitation of the study is the lack of control group. This is mainly due to the limited number of cases (n=41). As the effectiveness of Ozone on the control of pain in knee OA

is been for decades demonstrated, and all patients accepted the proposed alternative treatment protocol, it is not ethical to deny Ozone intervention. A quasi-experimental before-after study (also referred to as a Non-Randomized Control-Trial) is applied in this specific ethical situation, in order to solve the lack of control group and to give clinical-based evidence. In such a case, a pretest-post-test is performed on the same treatment group; and, the change observed after the intervention is expected as a direct consequence of the Ozone treatment protocol.

CONCLUSION

Ozone is a safe and effective treatment able to reduce significantly pain, stiffness, and to improve function, as measured by VAS/WOMAC scales, in patients with PFPS and Chondromalacia.

The results of this study show a good level of evidence and grade of recommendation that allows us to use Ozone as a conservative therapeutic option in the treatment of PFPS and Chondromalacia

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AUTHOR'S CONTRIBUTION

ME Fernández-Cuadros participated in acquisition of patients' data, drafting and designed of the article and analysis and interpretation of results; besides, the translation of the paper. MJ Albaladejo Florin participated in acquisition of patients' data. OS Pérez-Moro participated in the conception and design of the study, designed the manuscript, supervised and interpretation of results.

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