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Clinical Paper

TMJ

Temporomandibular joint arthrocentesis with viscosupplementation in patients with osteoarthritis: a retrospective analysis of the effect of the number of sessions

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Abstract. Temporomandibular joint (TMJ) osteoarthritis (OA) is a degenerative joint disease characterized by pain, functional limitation, and reduced mouth opening. Arthrocentesis with hyaluronic acid (HA) viscosupplementation is a widely used minimally invasive treatment, often delivered according to a five-session protocol, although the optimal number of sessions remains unclear. This retrospective longitudinal observational study aimed to analyze session-specific clinical changes to identify the number of sessions required to achieve clinically relevant improvement. A total of 101 adult patients with TMJ OA unresponsive to at least 6 months of conservative therapy were included. All participants underwent five weekly arthrocentesis sessions including intra-articular HA injections. Pain at rest and during chewing, chewing efficacy, perceived functional limitation, assisted and non-assisted maximum mouth opening were assessed at baseline, before each session, and at 3-month follow-up. All clinical variables significantly improved from baseline to follow-up (all $P < 0.001$). Significant gains in mouth opening occurred only after the first session, with no further significant improvement thereafter (all $P > 0.05$). Pain at rest improved after sessions 1, 2, 3, and 5, and equally pain during chewing improved after sessions 1, 2, 3, and 5. Chewing efficacy improved after sessions 2, 3, and 5; likewise perceived functional limitation improved after the same sessions (all $P < 0.001$). The fourth session did not produce significant changes in any outcome (all $P > 0.05$). These findings support more individualized protocols with fewer interventions.

Keywords: Arthrocentesis; Temporomandibular joint; Osteoarthritis; Viscosupplementation; Hyaluronic acid.

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Osteoarthritis (OA) is a pathology involving a progressive deterioration of the joint structures, affecting the articular cartilage and subchondral bone as well as the ligaments, joint capsule, synovial membrane, and surrounding musculature[1,2]. It can affect any articulation in the body, from larger joints such as the knee and hip to smaller ones like the temporomandibular joint (TMJ), and it is part of the broader group of degenerative joint diseases (DJDs)[3]. Clinical signs and symptoms of TMJ OA potentially include joint noises, pain, and limitation in the mandibular range of motion[4].

Although cone-beam computed tomography (CBCT) remains the gold standard for assessing the hard tissues, OA diagnosis in clinical practice often relies primarily on patients' history, examination, and magnetic resonance imaging (MRI) to minimize patient exposure to ionizing radiation[5,6]. Joint crepitus is a clinical finding that is commonly indicative of DJDs, and pain is traditionally considered the key feature distinguishing active OA from silent osteoarthrosis[7]. When imaging is performed, TMJ OA is typically characterized by three hallmark features: osteophyte formation, surface erosion, and subcortical pseudocysts (i.e. geodes), while other radiographic changes, such as flattening of the articular surfaces and subcortical sclerosis, are often interpreted as adaptive remodeling responses of the joint rather than markers of active degeneration[7].

The treatment for TMJ OA includes conservative strategies such as physical therapy, anti-inflammatory medications, cognitive–behavioral interventions, but also the use of oral appliances and joint lavage through arthrocentesis plus viscosupplementation[8,9]. The latter type of intervention has gained attention for its potential to restore the viscoelastic properties of synovial fluid[10]. In osteoarthritic joints, the viscosity of the fluid is often diminished because the concentration and molecular weight of hyaluronic acid tend to decline, with a consequent alteration of the normal smoothness of function and range of motion due to the increased attrition[11]. The viscosupplementation protocol that has been proposed in the TMJ literature involves intra-articular injection of hyaluronic acid (HA), typically following arthrocentesis, which is performed to distend the capsule and potentially improve the intra-articular environment by removing the effusion to facilitate the therapeutic effect of HA[12]. The use of a multiple-session protocol has been inspired by the positive outcomes observed in the orthopedic literature on larger joints, such as the knee and hip[13,14].

Over 15 years ago, a protocol of five weekly arthrocentesis sessions followed by HA injections was introduced into the temporomandibular disorders (TMD) clinical practice[15]. However, in recent years, the orthopedic literature has shifted toward optimized injection protocols, proposing less than five injections, based on updated insights into HA pharmacokinetics and formulations[16]. In the case of patients with TMJ OA, a reduction in the number of injections could diminish invasiveness, and improve patients' satisfaction and compliance with the treatment. In this regard, the number of arthrocentesis interventions could also be influenced by the molecular weight, concentration and structural characteristics of each HA preparation[17,18]. For instance, randomized controlled trials suggested that high molecular weight HA may exhibit excessive viscosity and too large steric interaction for the narrow intra-articular space of the TMJ[19,20]. Conversely, other studies have reported potential clinical benefits using just one session of high molecular weight HA viscosupplementation[21–25].

Within these premises, there is currently no consensus on the ideal number of injections that is needed to achieve therapeutic outcomes in TMJ OA. Depending on the research group and type of investigation, treatment protocols existing in the literature may range from a single session up to five[20,26–30], whereas clinical experience seems to suggest that completing the entire five cycles of arthrocentesis may not be necessary for all patients. This impression is supported by two multiple-session studies, whose data supported the effectiveness of a five-session protocol and also showed that most clinical improvements seem to occur within the first two sessions[15,31].

The general objective of this study was to evaluate the effectiveness of a five-session protocol of arthrocentesis combined with hyaluronic acid (HA) injections, investigating whether the clinical benefits progress uniformly across sessions or whether some sessions contribute less or are not relevant in terms of clinical improvement. The null hypothesis was that all five treatment sessions are necessary to obtain significant clinical benefits.

Patients and methods

Participants recruitment

This preliminary investigation is a retrospective, observational, longitudinal study performed on a single cohort of patients with TMJ OA. The study population was composed of patients recruited at the Unit of Oral and Maxillofacial Surgery, Ca' Foncello Hospital (Treviso, Italy) between 2023 and 2024. Data were extracted from both electronic and paper medical records.

All included subjects were adults aged between 18 and 80 years and had a diagnosis of TMJ OA, established according to the patient's history and clinical examination of the diagnostic criteria (DC) for TMD, with radiographic confirmation provided by MRI[32], and had persistent pain for 6 months after failure of the first-line conservative management adopted. The first-line intervention included a combination of conservative therapies: cognitive–behavioral therapy, oral appliances, physical therapy, and anti-inflammatory drugs[9]. In particular, the first-line treatment consisted of ten sessions of physiotherapy coupled with cognitive–behavioral therapy over an 8-week period, and the use of an oral appliance during sleep-time for 3–6 months. Additionally, the patients received the administration of non-steroidal anti-inflammatory drugs for 2 weeks, twice a day. To be eligible for inclusion, patients were required to complete the standard treatment protocol for TMJ OA, which consists of five weekly arthrocentesis sessions followed by HA injections[15]. Patients who had previously undergone surgical interventions on the TMJ and those with a history of head and/or neck trauma were excluded from the study. To collect the data necessary for the study, the patient's electronic hospital records were reviewed, and the required information was entered into Excel software (Los Angeles, CA, USA) for analysis.

The outcome variable was the therapeutic effectiveness, as evidenced by the following parameters: maximum pain at chewing and at rest, which were assessed by visual analog scale (VAS)

from 0 to 10, with 0 representing no pain and 10 representing the worst pain experienced; chewing efficacy, evaluated by VAS from 0 to 10, with 0 representing the capability to eat only soft food and 10 representing the possibility to eat also the hardest food without any problem; subjective functional limitation, evaluated by a Likert-type scale with 0 as the worst outcome and 4 as the best; range of motion (ROM) measurements taken in millimeters, recorded as maximum non-assisted mouth opening and maximum assisted mouth opening.

For each patient, baseline measurements were taken immediately before the first arthrocentesis, and then before every subsequent session. A final set of measurements was also collected at a 3-month follow-up after treatment. To determine the impact of each intervention, a comparison between the clinical measurements taken between two consecutive measurements was performed. The use of these outcome variables had been previously discussed and applied in several other studies on TMJ arthrocentesis[15,31,33–37]. All the aforementioned measurements were performed by two calibrated examiners (A.R. and O.I.S.) through a brief interview and clinical examination conducted just before each intervention.

Clinical procedure

All patients underwent arthrocentesis using the single-needle technique[38]. Initially, the preauricular area was disinfected, and two local anesthetic injections were administered: 1 mL of 2% mepivacaine with vasoconstrictor was injected into the surrounding tissues, followed by 2 mL of 2% mepivacaine without vasoconstrictor within the TMJ capsule, to ensure adequate pain control. With the anesthesia in effect, the Holmlund line served as a reference to locate the glenoid fossa, and an 18 G needle was inserted ~10 mm anterior to the tragus and 2 mm inferior to the line with the patient in an open-mouth position. This needle was then used first to irrigate the joint with about 10–50 mL of saline solution and subsequently to deliver 1 mL of medium molecular weight (800–1200 kDa) HA (Synovial 16 mg/2 mL, IBSA Farmaceutici, Lodi, Italy). All the arthrocentesis procedures based on the single-needle technique were performed by two expert operators (M.V. and L.G.N.).

Statistical analysis

Regarding the statistical analysis, *t*-tests for unpaired groups and the Mann–Whitney *U*-test were adopted to compare the clinical outcomes analyzed before each intervention and the corresponding values before the previous session. The same tests were used to compare the outcomes between the baseline and the 3-month follow-up.

Pain at chewing, pain at rest, masticatory efficacy, and perceived functional limitation were expressed as continuous variables, while the assisted and non-assisted mouth opening were expressed as continuous variables. Statistical significance was set at $P < 0.05$, with 95% confidence intervals (CIs). Based on literature data (mean baseline value 6/10 ± 3/10)[15], a sample size of groups with 70 individuals would warrant a statistical power of 5% for type I errors (false-positive results) and 20% for type II errors (false-negative results). Based on power analysis on actual data of the primary outcome variable (mean baseline value 8.1 ± 2.2), the study had 80% power to detect a 25% difference between the baseline and the 3-month follow-up.

Results

The sample comprised 101 patients who met the inclusion criteria. Demographic variables of the study population are presented in Table 1. Figs. 1–3 illustrate a steady, progressive improvement in all clinical variables throughout the treatment sessions, while Table 2 shows changes in the outcome variables from baseline to the 3-month follow-up. All of them showed a statistically significant difference (Table 2).

A session-by-session analysis was then performed to evaluate the effects of each arthrocentesis procedure. The results of these comparisons are reported in Table 3.

Regarding non-assisted and assisted ROM parameters, the first session was associated with a statistically significant increase in both assisted ($P = 0.03$) and non-assisted mouth ($P = 0.02$) opening compared to baseline. However, no statistically significant differences were observed between subsequent sessions (all $P > 0.05$).

For functional limitation and chewing efficacy, statistically significant improvements were observed after the second ($P < 0.001$ and $P = 0.02$,

Table 1. Demographic variables of patients diagnosed with temporomandibular joint degenerative joint disease.

Variable	Value
No. of patients	101
Male/female	15/86
Age (years)	
Mean ± SD	57.47 ± 18.10
Median	58

SD, standard deviation.

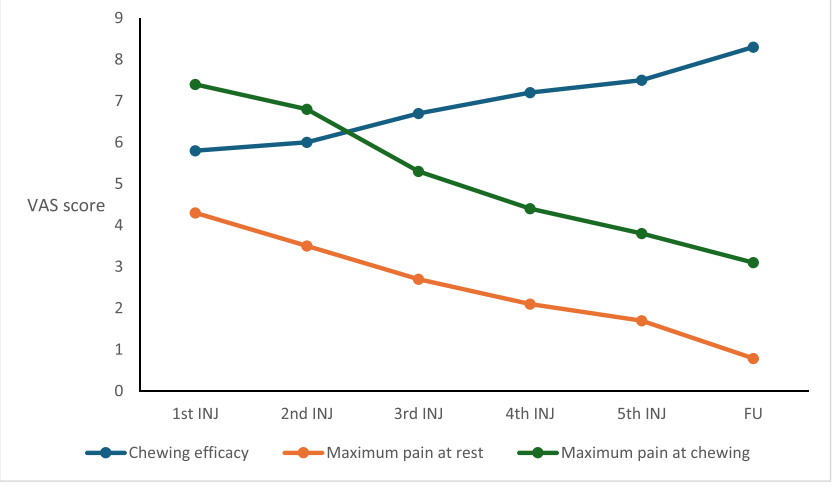


Fig. 1. Visual analog scale (VAS) score of pain-related outcome variables (chewing efficacy, maximum pain at rest, maximum pain at chewing) during treatment and follow-up. INJ, injection; FU, follow-up.

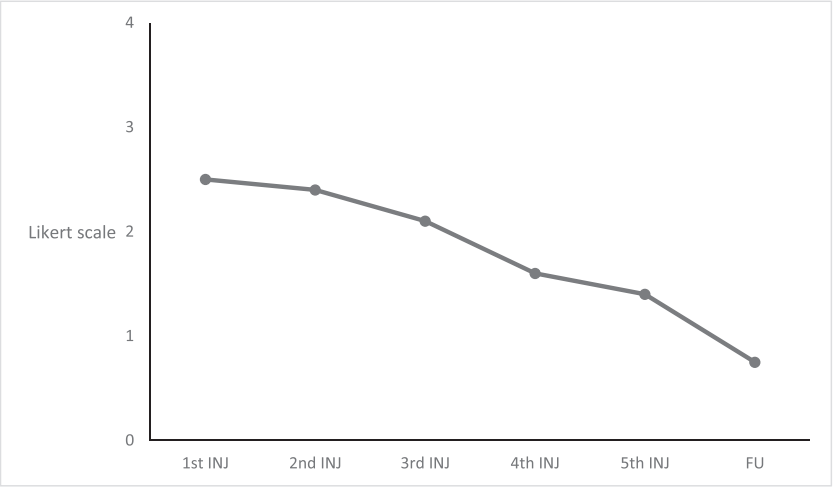


Fig. 2. Subjective functional limitation values over the course of treatment and follow-up span (Likert-type scale from 0 to 4). INJ, injection; FU, follow-up.

respectively), third ($P < 0.001$ and $P = 0.02$, respectively), and fifth (both $P < 0.001$) sessions, whereas no significant differences were found after the first ($P = 0.33$ and $P = 0.235$, respectively) and fourth ($P = 0.6$ and $P = 0.25$, respectively) sessions.

Concerning pain at rest and pain during chewing, statistically significant differences were observed after the first ($P < 0.001$ and $P = 0.03$, respectively), second (both $P < 0.001$), third ($P = 0.002$ and $P = 0.02$, respectively), and fifth sessions ($P < 0.001$ and $P = 0.003$, respectively), whereas the fourth session did not show statistically significant changes ($P = 0.3$ and $P = 0.13$, respectively).

Overall, the fourth session did not show statistically significant differences in any of the evaluated outcome variables (all $P > 0.05$).

Discussion

Since the introduction of viscosupplementation as a management strategy for TMJ OA, the literature has extensively studied this approach, demonstrating its clinical efficacy in relieving symptoms and improving joint function over the short, medium, and long-term follow-up spans[35]. Nevertheless, as previously mentioned, there is currently no consensus regarding the ideal number of sessions for TMJ viscosupplementation, which was commonly indicated as five in the orthopaedic literature.

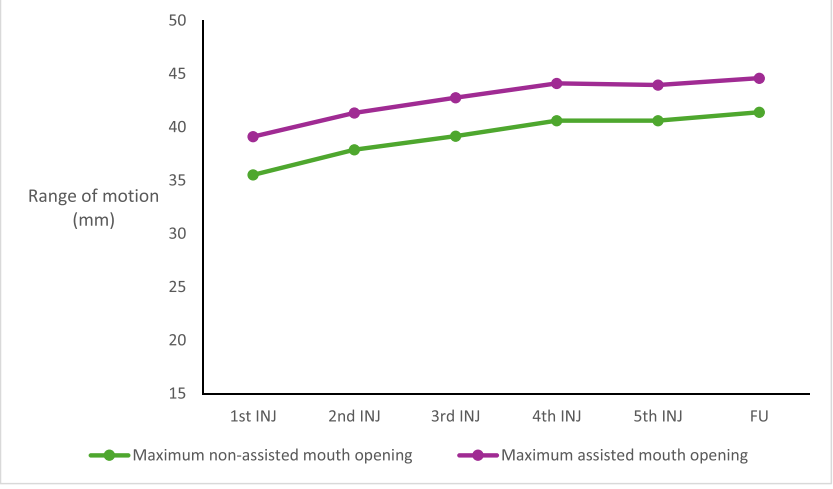


Fig. 3. Range of motion measurements in millimetres during treatment and follow-up. INJ, injection; FU, follow-up.

The purpose of this investigation was to analyze the improvement in pain and function associated with TMJ OA in patients who underwent TMJ arthrocentesis. In particular, the study aimed to analyze retrospectively the pain levels and range of motion after each session of arthrocentesis plus viscosupplementation in a cohort of patients who underwent the typical protocol of five sessions.

The results of this investigation confirmed that the protocol of five arthrocentesis sessions with HA injections leads to a relevant clinical improvement in patients with TMJ OA. All analyzed parameters showed a statistically significant improvement from baseline to the 3-month follow-up, in agreement with the existing literature[35].

Two previous studies have attempted to determine the optimal number of arthrocentesis sessions through randomized clinical trials[19,21]. The first study by Manfredini et al.[19] compared the clinical outcomes of four different protocols: an arthrocentesis session alone, a single-session arthrocentesis plus intrarticular corticosteroids positioning, a single arthrocentesis with HA viscosupplementation, and five arthrocentesis sessions with HA viscosupplementation. At the 3-month follow-up, no statistically significant differences were found among the groups, although the five-session protocol yielded better outcomes overall. The second study compared a single arthrocentesis with medium molecular weight HA viscosupplementation, a single session with high molecular weight HA, and a five-session protocol with medium molecular weight HA[21]. In this case, the five-session protocol showed superior results at the 6-month follow-up, but only in terms of pain reduction. The findings of the present study appear to be consistent with both these previous investigations, especially with respect to the results of the second study regarding the effectiveness of multiple injections in terms of pain reduction over time.

However, in addition to previous studies, the present investigation was designed to include a session-by-session analysis of clinical outcomes, based on pairwise comparisons between consecutive treatment sessions. This represents a novel aspect of the study, as it allows a more detailed evaluation of the temporal progression of each clinical parameter compared to the conventional baseline-to-follow-up

Table 2. Changes in the various outcome variables from baseline to the 3-month follow-up.

Outcome variable	Baseline	3-month follow-up	*P*-value
Chewing efficacy (VAS)	5.8 ± 1.9	8.3 ± 1.4	< 0.001
Maximum pain at rest (VAS)	4.3 ± 3.5	0.4 ± 0.8	< 0.001
Maximum pain at chewing (VAS)	7.4 ± 1.9	2.7 ± 3.1	< 0.001
Subjective functional limitation (0–4)	2.5 ± 0.76	0.7 ± 0.7	< 0.001
Maximum non-assisted mouth opening (mm)	35.5 ± 7.2	41.4 ± 6.0	< 0.001
Maximum assisted mouth opening (mm)	39.1 ± 7.1	44.6 ± 6.1	< 0.001

VAS, visual analog scale.

approach. Indeed, although the five-session protocol was shown to be helpful, the pattern of symptom course after each session showed that not all injections contribute equally to clinical improvement.

These findings support the hypothesis that the therapeutic effect does not progress in a steady, cumulative manner, but rather follows a more complex trajectory, challenging the idea that a standard protocol of five arthrocentesis sessions is always needed in all patients. One of the most interesting findings is that the measures associated with ROM improve significantly only after the first session, thus potentially suggesting that a single session may be sufficient in cases where mouth opening limitation is the chief complaint. On the contrary, the measures related to pain, masticatory efficacy, and perceived limitation require multiple injections to return to normal levels.

These observations open the way to several interpretations. A first hypothesis could be that, even after a single session, joint lavage and HA viscosupplementation may help to get rid of most the inflammatory liquid accumulated within the TMJ, which can represent a mechanical obstacle as well as a stimulus for inducing a protective co-contraction of antagonist muscles that impedes proper mouth opening[8]. Additionally, the elimination of most of the effusion, along with the mechanical adhesions, helps to reduce friction between the articular surfaces and allows better mouth opening right after the first TMJ lavage. In contrast, it is plausible that pain mediators and nociceptive pathways might require more time or repeated injections to return to normal levels and allow a clinically relevant improvement in terms of pain, perceived functional limitation, and masticatory capacity. Nevertheless, among the subjective clinical outcomes reported by the patients, pain seems to be the most rapidly improving parameter, as the first arthrocentesis was already associated with significant changes in this parameter. On the other hand, perceived functional limitation and masticatory efficiency seem to require more time or sessions to achieve a significant improvement, as the first cycle of arthrocentesis did not change the parameters relevantly.

A second possible interpretation explaining the present findings is related to the types of outcomes analyzed. The parameters that were analyzed can be

Table 3. Statistical significance of changes in clinical outcomes before and after each arthrocentesis session to assess session-specific effectiveness.

	Effectiveness (mean ± SD)				
Outcome variable	1st INJ (T1 vs T2)	2nd INJ (T2 vs T3)	3rd INJ (T3 vs T4)	4th INJ (T4 vs T5)	5th INJ (T5 vs FU)
Chewing efficacy (VAS)	5.8 ± 1.9	6.0 ± 1.8	6.7 ± 1.7	7.2 ± 1.8	7.5 ± 1.7
	vs	vs	vs	vs	vs
	6.0 ± 1.8	6.7 ± 1.7	7.2 ± 1.8	7.5 ± 1.7	8.3 ± 1.4
	$P = 0.235$	$P = 0.02$*	$P = 0.02$*	$P = 0.25$	$P < 0.001$*
Maximum pain at rest (VAS)	4.3 ± 3.5	3.5 ± 3.3	2.7 ± 2.9	2.1 ± 2.5	1.7 ± 2.1
	vs	vs	vs	vs	vs
	3.5 ± 3.3	2.7 ± 2.9	2.1 ± 2.5	1.7 ± 2.1	0.39 ± 0.79
	$P < 0.001$*	$P < 0.001$*	$P = 0.002$*	$P = 0.3$	$P < 0.001$*
Maximum pain at chewing (VAS)	7.4 ± 1.9	6.8 ± 2.2	5.3 ± 2.8	4.4 ± 2.7	3.8 ± 2.9
	vs	vs	vs	vs	vs
	6.8 ± 2.1	5.3 ± 2.8	4.4 ± 2.7	3.8 ± 2.9	2.7 ± 3.1
	$P = 0.03$*	$P < 0.001$*	$P = 0.02$*	$P = 0.13$	$P = 0.003$*
Subjective functional limitation (0–4)	2.5 ± 0.76	2.4 ± 0.75	2.1 ± 0.77	1.6 ± 0.81	1.4 ± 0.81
	vs	vs	vs	vs	vs
	2.4 ± 0.75	2.1 ± 0.77	1.6 ± 0.81	1.4 ± 0.81	0.75 ± 0.75
	$P = 0.33$	$P < 0.001$*	$P < 0.001$*	$P = 0.6$	$P < 0.001$*
Maximum non-assisted mouth opening (mm)	35.52 ± 7.2	37.89 ± 6.2	39.15 ± 6.0	40.6 ± 5.7	40.6 ± 5.9
	vs	vs	vs	vs	vs
	37.89 ± 6.2	39.15 ± 6.0	40.6 ± 5.7	40.6 ± 5.9	41.4 ± 6.0
	$P = 0.02$*	$P = 0.13$	$P = 0.78$	$P = 0.7$	$P = 0.24$
Maximum assisted mouth opening (mm)	39.11 ± 7.1	41.34 ± 6.0	42.76 ± 6.1	44.1 ± 5.4	43.96 ± 4.9
	vs	vs	vs	vs	vs
	41.34 ± 6.0	42.76 ± 6.1	44.1 ± 5.4	43.96 ± 4.9	44.6 ± 6.1
	$P = 0.03$*	$P = 0.09$	$P = 0.13$	$P = 0.85$	$P = 0.5$

INJ, injection; FU, follow-up; VAS, visual analog scale.
Measurements were taken before the first injection (T1, baseline), second injection (T2), third injection (T3), fourth injection (T4), and fifth injection (T5).
*$P < 0.05$.

divided into objective variables, which are directly assessed by the TMD clinician (i.e. ROM), and subjective variables reported by the patients. In this context, the objective variables are the only two requiring just one session to achieve a statistically significant improvement; in fact, the subsequent sessions do not show any further significant improvement. In contrast, all the variables in which the patient is required to provide a score (pain at rest, pain at chewing, masticatory efficacy and perceived functional limitation) followed a much more gradual pattern of improvement. In this context, the subjective nature of these variables can explain an irregular pattern of improvement, which can be influenced by numerous elements belonging to the biopsychosocial factors. Indeed, by the 2020 IASP definition, pain is 'an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage'[39]. In view of this, from a psychological perspective, it is also possible to speculate that the gradual improvement reported by the patients might result from a placebo effect[40]. The more the sessions the more the contact with the clinician, which is a factor that may positively influence the patient's perception of recovery.

A third aspect to consider is that the pain and discomfort reported by patients may result from an overlap between muscular and articular sources. It is possible that intra-articular pain is relieved after the first injection, while the muscular component may require time to adapt. As a result, the perceived need for additional injections to address subjective symptoms might instead reflect the natural course of muscular recovery, rather than the actual necessity for further procedures[41–43].

Within these premises, it is important to recognize that it is not possible to determine whether the improvement in variables is related to the number of injections or to the natural progression of recovery. In this context, a limitation of this study is the short time between sessions (1 week), which could make it unclear whether the improvement is due to the treatment session itself or simply to the course of time. This limitation is inherent to the study design, which aims to analyze a five-session protocol rather than compare different protocols. Longer between-session intervals may be useful to add data to this speculation.

Importantly, one of the key factors affecting the predictability of treatment outcomes is the Axis II of the DC/TMD, which was not evaluated a priori in this study. This omission may help explain the non-linear behavior of the subjective variables[44]. Additionally, systemic factors, known to significantly influence the patient's perception of pain (e.g. sleep, other undiagnosed medical conditions), were not assessed, which may have further contributed to the lack of a clearly defined pattern in the pain-related outcomes[43,45–47].

Finally, a potential further limitation of the study is that radiographic confirmation of the diagnosis of TMJ OA was obtained using MRI rather than CBCT, a choice driven by the ethical concerns related to the unnecessary radiation exposure concerning the treatment plan decision. This radiographic diagnostic approach can make the sample slightly less homogeneous, since, with regard to degenerative bone abnormalities, MRI has shown lower sensitivity, but almost identical specificity with respect to CBCT[48].

In conclusion, the overall results of the present investigation may support the idea that the treatment protocol should be flexible and personalized at the individual level, rather than rigid and standardized. This retrospective data analysis needs to be confirmed by further similar studies and by other types of research protocols (e.g. RCTs); however, it leaves the door open to the possibility that the five-session injection protocol could be reconsidered in terms of reducing the number of sessions. Future projects might focus on phenotyping patients, for example based on the severity of TMJ OA and the psychosocial profile, to assess the potential predictability of the number of arthrocentesis plus HA viscosupplementation sessions that may be required for different types of patients.

The findings of this study question the need for the application of the standard protocol of five arthrocentesis sessions with viscosupplementation in all patients affected by TMJ OA, suggesting instead that, depending on the clinical outcome considered, clinical benefits may be achieved with a reduced number of sessions.

Ethical approval

Approved by the Institutional Review Board of Ca' Foncello Hospital, Treviso ('581/CE Marca').

Patient consent

Not required due to the retrospective nature of the study.

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None.

Competing interests

None.

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