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Clinical Outcome of Sodium Hyaluronate Injection into the Superior and Inferior Joint Space for Osteoarthritis of the Temporomandibular Joint Evaluated by Cone-Beam Computed Tomography: A Retrospective Study of 51 Patients and 56 Joints

Authors' Contribution:
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Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
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Background: The aim of this study was to determine the clinical effects of sodium hyaluronate injection into the superior and inferior joint space for osteoarthritis of the temporomandibular joint (TMJ) and to evaluate the joint changes using cone-beam computed tomography (CBCT).

Material/Methods: A retrospective observational clinical study included 51 patients and 56 TMJs, with a diagnosis of osteoarthritis. All patients received sodium hyaluronate injections into the superior and inferior TMJ joint spaces (articular cavities). At baseline and post-treatment the condylar bony changes were evaluated by CBCT. To evaluate TMJ function, maximum mouth opening (MMO), and Helkimo's index was used, which included an anamnestic index (Ai) and a clinical dysfunction index (Di). Patients were divided into short-term (<one year) and long-term (>one year) follow-up groups.

Results: In both patient follow-up groups, sodium hyaluronate injection of the superior and inferior TMJ space significantly improved MMO, the Ai, and the Di ($P<0.05$). There were no significant differences between the two groups in condylar bony changes of the TMJ seen by CBCT (sclerosis, erosion, hyperplasia, and flattening) ($P>0.05$). CBCT showed a good predictive ability on post-treatment symptom relief following sodium hyaluronate injection into the superior and inferior TMJ space in patients with osteoarthritis of the TMJ ($P=0.024$).

Conclusions: The findings of this clinical and CBCT imaging study showed that sodium hyaluronate injection into the superior and inferior TMJ space in patients with osteoarthritis improved clinical symptoms, but did not control the progression of osteoarthritic joint destruction.

MeSH Keywords: Cone-Beam Computed Tomography • Hyaluronic Acid • Osteoarthritis • Prognosis • Temporomandibular Joint

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Background

Temporomandibular joint (TMJ) disorders include conditions that result in clinical symptoms that may affect the masticatory musculature, the TMJ surface and joint space, and the associated regional structures [1]. Many TMJ disorders are caused by poor masticatory habits or malocclusion [2,3], which further induce functional or pathological changes of the TMJ and related structures [4]. TMJ disorders are the most common cause of pain of non-dental origin in the orofacial region [5], and occur in between 21.5–51.8% of people [6]. A recently published systematic review showed that TMJ disorders, especially osteoarthritis of the TMJ, have a negative effect on the quality of life [7], which supports the need for more research on the prevention, diagnosis, and treatment of TMJ disorders, including osteoarthritis.

Osteoarthritis of the TMJ is a slowly progressing degenerative joint disease characterized by the destruction of the mandibular condyle and glenoid fossa and is often brought about by increased load on the joint [8]. Osteoarthritis of the TMJ can result in different clinical symptoms that can vary in degree, including joint pain, crepitus, restricted motion and mouth opening, and eventually loss of joint function [9]. Currently, the treatment for osteoarthritis of the TMJ can be divided into conservative treatment and surgical treatment, which have the same primary goal of reducing pain and improving the function of the TMJ.

Conservative treatments for TMJ disorders include isometric exercises, analgesic treatment, the use of oral anti-inflammatory drugs, physical therapy, intra-articular drug injections, and correction of occlusal abnormalities [10–12]. While these conservative treatments are often encouraged for osteoarthritis of the TMJ, few have been proven to be effective [13–15].

Among the compounds used for intra-articular injection in the treatment of osteoarthritis of the TMJ, sodium hyaluronate has been used widely in the TMJ and other large joints, such as the knee, ankle, and hip. Sodium hyaluronate plays an important role in maintaining intra-articular homeostasis by improving the physiological function of the synovial fluid and protects the articular cartilage by an anti-inflammatory mechanism [16,17]. We have recently reported that sodium hyaluronate injection into the superior and inferior TMJ space (double chamber) is a treatment that is acceptable to patients and clinicians [11,18,19]. The clinical effectiveness and safety of sodium hyaluronate have been supported by a previously published systematic review and by clinical studies, most of the previously published reports focused on the changes in the clinical signs and symptoms following intra-articular injection of sodium hyaluronate [20–24]. Few studies have examined the radiological changes in bone and cartilage following intra-articular injection of sodium hyaluronate [25,26].

The aim of this study was to determine the clinical effects of sodium hyaluronate injection into the superior and inferior joint space of the TMJ in patients diagnosed with osteoarthritis and to evaluate the joint changes using cone-beam computed tomography (CBCT). A further aim was to determine whether there were any possible correlations between the clinical manifestations of osteoarthritis of the TMJ and the radiological bony changes, using baseline CBCT evaluation, to attempt to predict the clinical outcome following treatment.

Material and Methods

Study design

In the clinical setting of the Oral and Maxillofacial Surgery Clinic, West China Hospital of Stomatology, Sichuan University, a retrospective study was conducted that involved patient clinical chart and record review, between December 2009 and December 2013. The study inclusion criteria were as follows: a diagnosis of osteoarthritis of the temporomandibular joint (TMJ) based on the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) and confirmed by cone-beam computed tomography (CBCT) [27,28]; at least six months of patient follow-up data were required; patients underwent injection of sodium hyaluronate into the superior and inferior TMJ space; and CBCT was conducted before the first injection and during the follow-up period. The exclusion criteria were: patients who had received treatment for any other type of TMJ disorder, including drug treatment, during the previous four weeks; patients who had hypersensitivity diseases or were allergic to multiple drugs; patients with severe systemic diseases or infection in the region of the TMJ; patients who were unable to attend follow-up visits when required.

This study was approved by the Institutional Review Board (IRB) of the West China School of Stomatology (Ref: 2009022). Informed consent was obtained from the study participants.

Patients were divided into short-term (<one year) and long-term (>one year) follow-up groups.

Treatment modalities

During four consecutive weeks, all patients in the study received four injections of 20 mg in 2 ml of sodium hyaluronate (Sofast) (Bloomage Freda Biopharm Co Ltd., Shandong, China) into the superior and inferior TMJ joint spaces. The details of the injection preparations and procedures have been detailed in a previous publication from our group [18]. Other treatment modalities were provided, if required, including oral non-steroidal anti-inflammatory drugs (NSAIDs), or glucosamine chloride, for a maximum duration of three months.

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Table 1. Clinical dysfunction index (Di).

Score	Clinical symptoms							
	Range of mandibular motion				TMJ function impairment	Muscle tenderness during palpation	TMJ pain during palpation	Pain during mandibular movement
	Maximum mouth opening	Maximum protrusion	Maximum right movement	Maximum left movement				
0	≥40 mm	≥7 mm	≥7 mm	≥7 mm	No TMJ sounds and deviation on opening or closing movements ≤2 mm	No pain on palpation of masticatory musculature	No tenderness to palpation	No pain on movement
1	30–39 mm	4–6 mm	4–6 mm	4–6 mm	TMJ sounds in one or both joints and/or deviation ≥2 mm	Tenderness in 1-3 palpation sites	Tenderness to palpation laterally	Pain in 1 movement of the mandible
5	<30 mm	0–3 mm	0–3 mm	0–3 mm	Locking and/ or luxation of the TMJ	Tenderness in 4 or more palpation sites	Tenderness to palpation posteriorly	Pain in 2 or more movements

* First, sum the scores of the four items in "range of mandibular motion" (maximum mouth opening, maximum protrusion, maximum right and left movement), we obtain three score levels: 0 point, 1–4 points, 5–20 points which was standardized to the score of 0 point, 1 point and 5 points, respectively. Then add the standardized score above with the scores of the other four clinical symptoms (TMJ function impairment, muscle tenderness during palpation, TMJ pain during palpation and pain during mandibular movement) to get the Di. TMJ – temporomandibular joint; Di – clinical dysfunction index.

Evaluation of clinical symptoms

The clinical signs and symptoms were scored for each study participant based on the Helkimo Index, including the clinical dysfunctional index (Di) (Table 1) and the anamnestic index (Ai) [29]. Also, maximal mouth opening (MMO) was recorded using Vernier calipers.

Evaluation of cone-beam computed tomography (CBCT)

All patients were scored based on CBCT imaging of the changes found in the TMJ. Two trained clinicians, with experience in TMJ disorders, conducted the imaging scoring in duplicate, and any discrepancies were resolved by discussion with or without another trained clinicians, with experience in TMJ disorders. The CBCT scoring system for osteoarthritis of the TMJ included extent and severity of the joint changes.

For the severity assessment for osteoarthritis of the TMJ, the mandibular condylar bony change was classified as sclerosis (including cysts), erosion, hyperplasia (or the presence of osteophytes), and condylar flattening. Flattening was scored 0 (absent), and 1 (present). Other parameters were all scored from 0–2, and included the severity of bony destruction (0, none; 1, present with a height <1 mm; 2, present with a height ≥1 mm).

For the evaluation of the extent of osteoarthritic changes in the TMJ on CBCT, the mandibular condyle of the TMJ and its corresponding glenoid fossa were evaluated in the sagittal and coronal planes. The CBCT images in the sagittal plane were divided into the anterior third, the middle third, and the posterior third. The CBCT images in the coronal plane were divided into the lateral third, the middle third, and the median third. The sum of the severity scores in each recorded area was the total score of the extent of osteoarthritic changes in the TMJ on CBCT.

Statistical analysis

Data were analyzed using SPSS version 17.0 (SPSS, IBM, Chicago, IL, USA) and GraphPad Prism. Paired sample t-tests were used to compare the baseline results with the post-treatment results. The Spearman's rank correlation test was used to evaluate the correlation between the osseous destruction and the clinical findings. The level of significance (*P*) was set at 0.05.

Results

A total of 56 temporomandibular joints (TMJs) from 51 patients were included in this study, as five of the patients had

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Table 2. Demographic characteristics of included patients.

Items	Short term group	Long term group
Number of TMJs	26	30
Number of patients (Male/Female)	22 (5/17)	29 (5/22)
Age	30.31±14.75	34.37±16.39
Disc displacement with reduction	5	3
Disc displacement without reduction	8	14
Follow-up period	7.85±2.72	19.83±6.20

TMJ – temporomandibular joint.

bilateral osteoarthritis of the TMJ, and received a bilateral sodium hyaluronate injection into the superior and inferior joint space. However, no patient or TMJs overlapped between the short-term and long-term follow-up groups. The clinical and demographic characteristics for each patient included in the study are shown in Table 2.

Injection of sodium hyaluronate into the superior and inferior TMJ space did not affect osteoarthritic bony destruction of the joint

When evaluated by cone-beam computed tomography (CBCT), injection of sodium hyaluronate into the superior and inferior TMJ space in patients with osteoarthritis showed no significant effect on reducing or preventing the progression of bony destruction in the short-term and long-term assessment

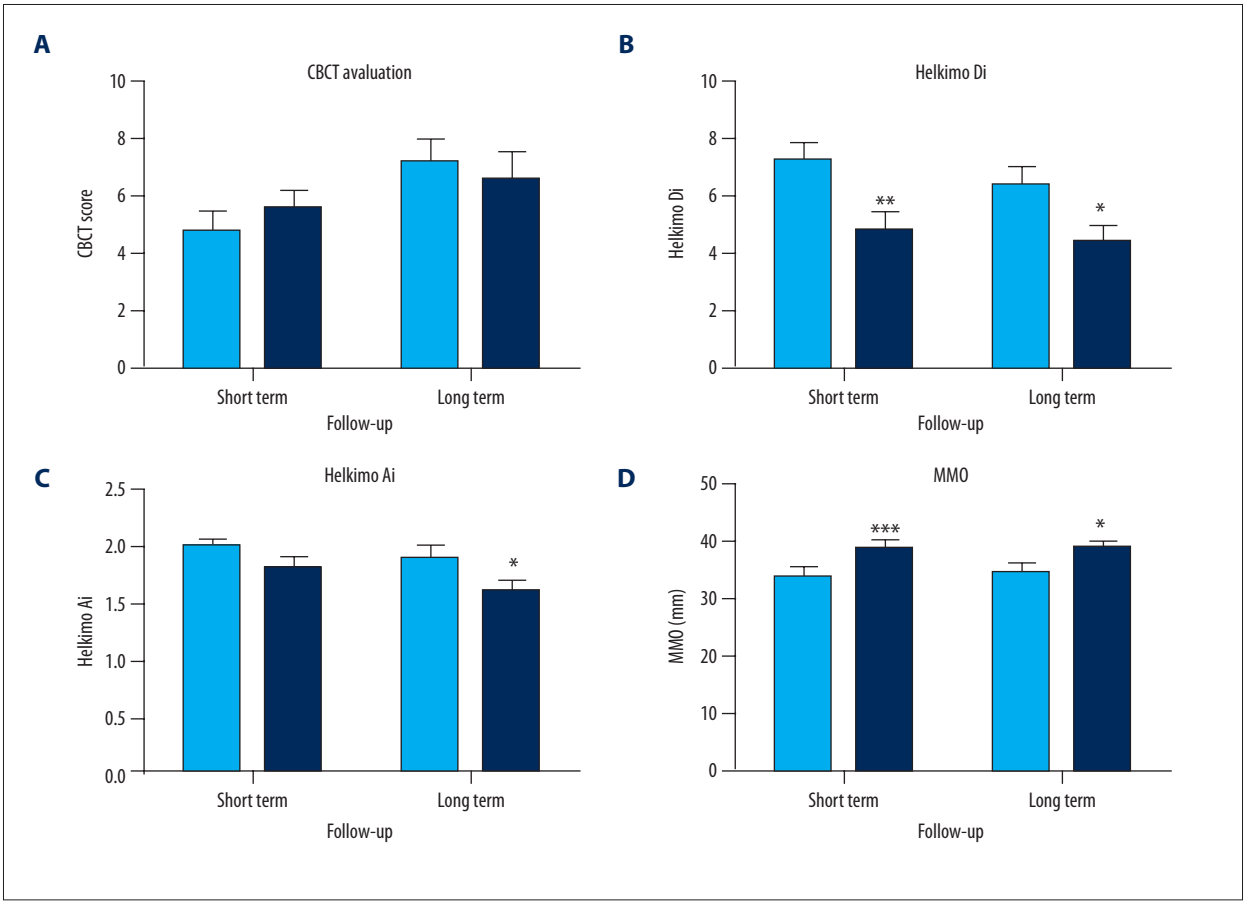

Figure 1. The effect of treatment with injection of sodium hyaluronate into the superior and inferior joint space for osteoarthritis of the temporomandibular joint (TMJ) assessed by clinical parameters and cone-beam computed tomography (CBCT). (**A**) Results of the cone-beam computed tomography (CBCT) evaluation. (**B**) In the evaluation of temporomandibular joint (TMJ) function, the use of Helkimo's index includes a clinical dysfunction (Di). Results of the Helkimo clinical dysfunction index (Di). (**C**) In the evaluation of temporomandibular joint (TMJ) function, the use of Helkimo's index includes an anamnestic index (Ai). Results of the Helkimo Ai. (**D**) Results of the maximal mouth opening (MMO) recorded using Vernier calipers. * $P<0.05$; ** $P<0.01$ compared with baseline. SH – sodium hyaluronate; TMJ – temporomandibular joint; CBCT – cone-beam computed tomography; MMO – maximal mouth opening; Di – Helkimo clinical dysfunction.

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Table 3. Effect of HS on bone destructions.

Group	Bony change	Pre-injection	Post-injection	P
Short term	Sclerosis	0.58±1.27	0.85±2.13	0.497
	Erosion	1.50±2.16	1.58±2.25	0.759
	Hyperplasia	1.92±3.39	2.35±3.24	0.584
	Flattening	1.12±1.48	1.15±1.43	0.870
	Total	4.73±3.73	5.50±3.67	0.338
Long term	Sclerosis	2.20±3.87	2.03±3.26	0.764
	Erosion	1.03±2.53	0.30±0.95	0.064
	Hyperplasia	2.87±3.38	3.03±3.54	0.721
	Flattening	0.83±1.12	0.87±1.14	0.839
	Total	7.13±4.40	6.53±4.82	0.390

groups (P>0.05) (Figure 1A). Also, when the bony destruction parameters were evaluated separately, no positive effects from treatment with sodium hyaluronate were observed (Table 3). For some patients, CBCT showed that flattening, sclerosis, hyperplasia, and erosion of the mandibular condyle of the TMJ showed an improvement after injection of sodium hyaluronate (Figure 2), but disease progression was observed for most of the patients studied (Figure 3).

Injection of sodium hyaluronate into the superior and inferior TMJ space reduced the clinical signs and symptoms of osteoarthritis of the TMJ

The effect of injection of sodium hyaluronate into the superior and inferior TMJ space in patients on the clinical signs and symptoms of osteoarthritis of the TMJ were more positive. Helkimo's index was used, which included a clinical dysfunction index (Di) which significantly decreased in both the short-term and long-term observation patient groups (P<0.01, and P<0.05, respectively). The Helkimo anamnestic index (Ai) decreased significantly in the long-term observation patient group (P<0.05). The maximum mouth opening (MMO) measurement increased significantly in both observation groups (P<0.001, and P<0.05, respectively) (Figure 1B–1D).

CBCT imaging showed that osteoarthritic bony destruction of the TMJ did not correlate with clinical parameters

To evaluate whether CBCT imaging of the TMJ might be used to evaluate treatment effects, the following correlation tests were performed: baseline CBCT score versus baseline clinical parameters; post-treatment CBCT score versus clinical results; and changed CBCT scores (post-treatment score minus baseline) versus changed clinical results. These tests indicated no significant associations between bony destruction of the TMJ and clinical signs and (P>0.05) (Table 4).

CBCT imaging showed baseline TMJ bony destruction of the TMJ was negatively correlated with relief of clinical symptoms

To further evaluate the effect of baseline CBCT on predicting the progression of osteoarthritis of the TMJ and patient outcome following sodium hyaluronate injection into the superior and inferior joint space, a correlation between the baseline CBCT scores versus the change in clinical results showed that baseline CBCT scores were negatively predictive of the Helkimo Ai (P<0.05), but were not associated with the other changes in clinical parameter scores (P>0.05) (Table 5).

Discussion

The findings of this study showed that injection of sodium hyaluronate into the superior and inferior temporomandibular joint (TMJ) space in patients with osteoarthritis of the TMJ significantly improved clinical symptoms, including maximum mouth opening (MMO), and the components of Helkimo's index, the anamnestic index (Ai) and the clinical dysfunction index (Di). However, using cone-beam computed tomography (CBCT) to evaluate the osteoarthritic joint changes at baseline and following treatment, no significant differences were found in the mandibular condylar bony changes of the TMJ (including sclerosis, erosion, hyperplasia, and flattening) (P>0.05). Also, there were no significant correlations between any clinical parameters and the TMJ joint changes seen on CBCT. Despite these findings, the CBCT showed that the osteoarthritic TMJ joint changes at baseline were significantly associated with patient symptom relief following injection of sodium hyaluronate into the superior and inferior TMJ space (P=0.024). Therefore, evaluation of the TMJ using CBCT in patients with osteoarthritis of the TMJ might be useful for predicting improvement in clinical symptoms.

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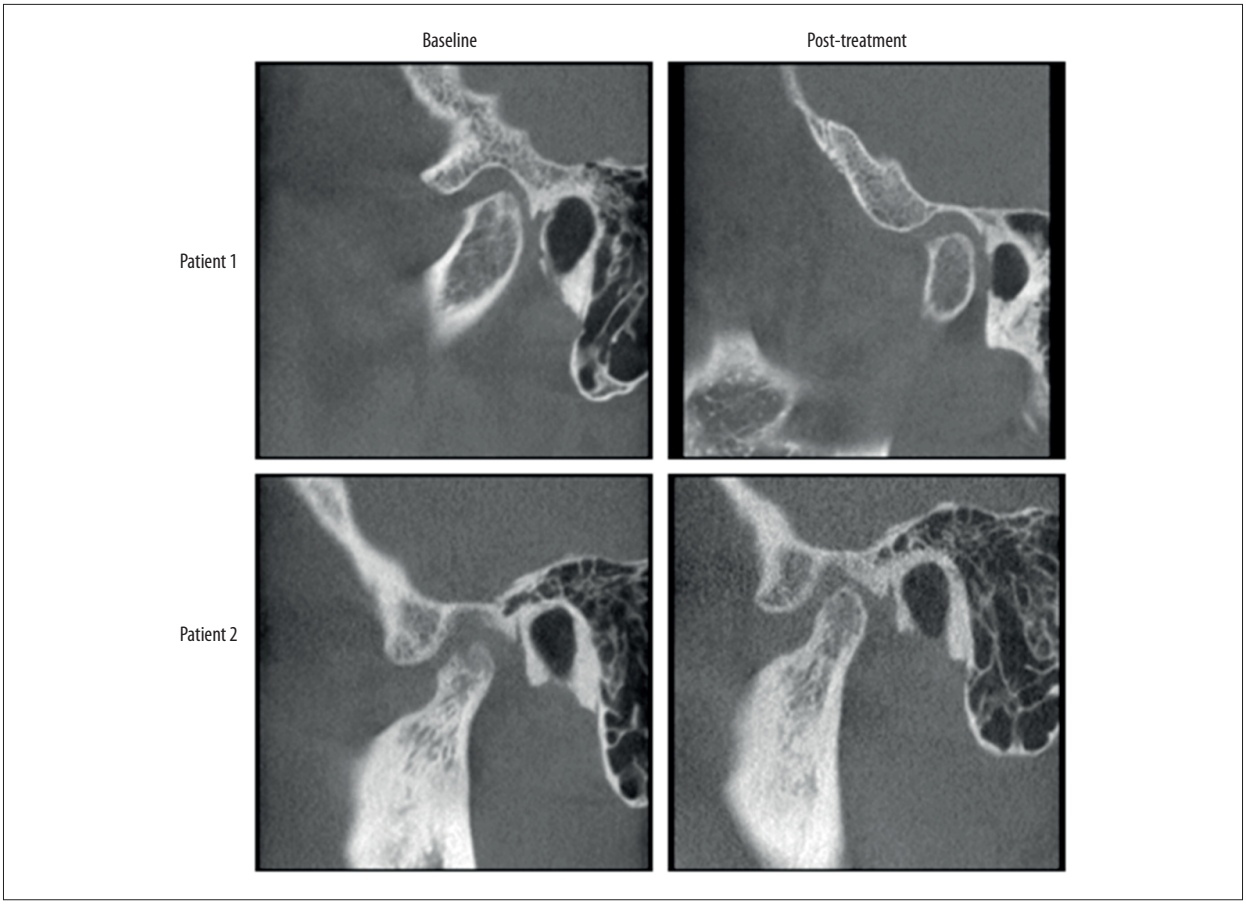

Figure 2. The recession of osteoarthritic bony destruction of the temporomandibular joint (TMJ) following injection of sodium hyaluronate into the superior and inferior joint space, assessed by cone-beam computed tomography (CBCT) Patient 1. Fourteen months after sodium hyaluronate treatment, A relatively normal right temporomandibular joint (TMJ) contour, and bone surface compared with a flattened shape, osteophytes at the anterior surface, and sclerosis, before treatment. Patient 2. Before treatment. Erosion and sclerosis of the mandibular condyle of the temporomandibular joint (TMJ), and hyperplasia in the glenoid fossa. Eight months after treatment, a normal mandibular condyle and a relatively smooth reconstructed glenoid fossa are shown. SH – sodium hyaluronate; CBCT – cone-beam computed tomography; TMJ – temporomandibular joint.

Several previously published studies have shown that intra-articular injection of sodium hyaluronate can relieve the clinical signs and symptoms of TMJ disorders, including osteoarthritis of the TMJ [16,17,30–32]. The results of the present study support these previous findings. However, the effect of intra-articular injection with sodium hyaluronate on the destruction of the joint in patients with osteoarthritis of the TMJ has rarely been previously reported.

The first study to investigate bony destruction in osteoarthritis of the TMJ was reported in 2008 by Møystad et al., who evaluated the osseous change in 36 patients with osteoarthritis of the TMJ who were randomly allocated into the sodium hyaluronate or corticosteroid upper joint space injection groups [26]. In this previous study, at six-month follow-up, neither sodium hyaluronate nor corticosteroid injection had a significant effect on the TMJ on CBCT evaluation [26]. Similarly, Li et al. investigated 141 patients with osteoarthritis of the TMJ who were randomly allocated to upper or lower TMJ space injection with sodium hyaluronate, and found no change in the joint damage score evaluated by CBCT after three months and nine months follow-up [33]. However, when these authors investigated the remodeling scores, the lower TMJ space injection of sodium hyaluronate showed improved clinical follow-up results [33]. These two previously published studies used relatively short-term follow-up periods of less than nine months [26,33]. Therefore, until the present study, no previous study had evaluated the osseous changes of patients with osteoarthritis of the TMJ treated with sodium hyaluronate using long-term follow-up.

In the present study, data were collected to evaluate the short-term and long-term bony changes following TMJ injection with

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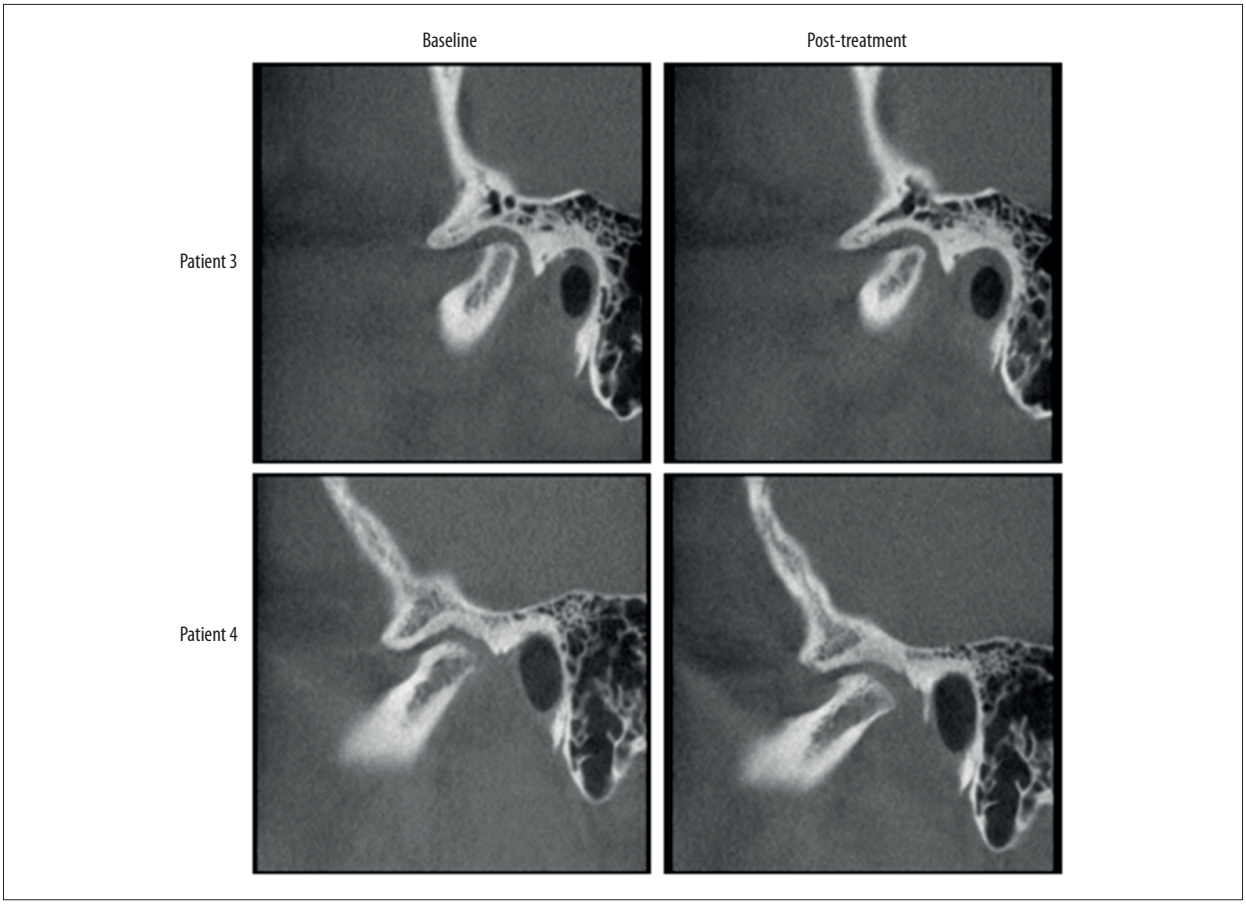

Figure 3. Progression of bony destruction of the temporomandibular joint (TMJ) following injection of sodium hyaluronate into the superior and inferior joint space, assessed by cone-beam computed tomography (CBCT). Patient 3. Before treatment, slight sclerosis on the anterior surface. Six months after treatment: flattening, sclerosis, and osteophyte formation are seen on the anterior surface. Patient 4. Before treatment, sclerosis and slight flattening on the anterior surface of the mandibular condyle of the TMJ, with hyperplasia in the glenoid fossa. Nine months after treatment: increased sclerosis, osteophytes, and slight flattening on the anterior surface of the mandibular condyle are shown, but glenoid fossa hyperplasia remains unchanged. SH – sodium hyaluronate; CBCT – cone-beam computed tomography; TMJ – temporomandibular joint.

sodium hyaluronate. For the short-term results, the findings were supported by previous publications and showed that superior and inferior joint space (double chamber) injection with sodium hyaluronate did not alter the osseous destruction in the TMJ [26,33]. As the recession of the osseous destruction may require more follow-up time, in the present study, data were collected for 30 TMJs where the follow-up information was available for a period longer than one year. During the long-term follow-up, injection of the TMJ with sodium hyaluronate still had no significant impact on avoiding destruction of the TMJ osseous structures.

The reduced clinical symptoms and signs observed in the present study, and in those of other studies, might be due to a decrease in inflammatory factors caused by the sodium hyaluronate injection rather than any effect on bone regeneration [34].

Although recent research has indicated that intra-articular sodium hyaluronate injection might increase the secretion of cartilage surface protective factors [35], there is little evidence sodium hyaluronate can accelerate bone regeneration. Some clinical reports have indicated that intra-articular injection might increase the risk of articular adhesion, which would further accelerate osseous destruction [36]. This effect might explain why bone regeneration was not found in patients with osteoarthritis of the TMJ patients after sodium hyaluronate injection. Another possible explanation is that the patients were not followed-up for long enough. In this study, the mean follow-up time was 19.32 months in the long-term group. In the future, longer follow-up times may be necessary to observe an effect of sodium hyaluronate treatment on TMJ bone regeneration.

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Table 4. Correlations between clinical parameters and CBCT scores.

Group	Comparison object	Baseline		Post-treatment		Change value	
		r	P	r	P	r	P
Short term	Helkimo Di	–0.200	0.923	–0.41	0.843	–1.77	0.386
	Helkimo Ai	0.054	0.794	–0.483	0.012	–0.312	0.121
	MMO	0.242	0.233	–0.180	0.372	0.300	0.137
Long term	Helkimo Di	–0.250	0.895	–0.50	0.792	–0.45	0.811
	Helkimo Ai	0.342	0.064	–0.201	0.287	–0.256	0.172
	MMO	–0.290	0.879	–0.030	0.986	0.200	0.289
All TMJs	Helkimo Di	–0.057	0.675	–0.051	0.708	–0.101	0.460
	Helkimo Ai	0.103	0.448	–0.018	0.898	0.227	0.092
	MMO	0.181	0.182	–0.334	0.012	–0.249	0.064

CBCT – cone-beam computed tomography.

Table 5. Predictive ability of baseline CBCT values on the prognosis.

Comparison object	Short term		Long term		All TMJs	
	r	P value	r	P value	r	P value
Helkimo Di	–0.079	0.702	0.051	0.787	0.028	0.840
Helkimo Ai	–0.185	0.366	–0.390	0.033	–0.302	0.024
MMO	–0.144	0.482	–0.076	0.691	–0.101	0.461

CBCT – cone-beam computed tomography; TMJ – temporomandibular joint; MMO – maximal mouth opening; Helkimo Di – Helkimo clinical dysfunction index; Helkimo Ai – helkimo anamnestic dysfunction index.

In the present study, in addition to analyzing the treatment effect of intra-articular sodium hyaluronate, there was no association between TMJ changes seen on CBCT evaluation and the clinical symptoms and signs. These findings were in accordance with most of the previously published studies, which used CBCT or X-ray scans to assess the clinical and imaging correlations [13,37,38]. However, Su et al. did find an association between the baseline CBCT scores and the baseline clinical parameters in 240 patients with osteoarthritis of the TMJ [39]. The differences between the findings of the present study and previous studies such as that of Su et al., are difficult to explain, as the method of CBCT evaluation were similar [39]. A limitation of the present study was that it did include a small number of patients (51 patients) from a single center. However, even with a larger study population, and based on the data from the present study, it is unclear whether a larger study population would show any difference in the results.

The latter part of the present study focused on the predictive ability of the baseline CBCT evaluation on the prognosis of patients with osteoarthritis of the TMJ, which has not been undertaken before. The results showed that baseline CBCT score was negatively correlated with the Helkimo anamnestic index (Ai). Therefore, the higher the CBCT score, the more symptom relief the patient will have in the long term. However, a larger, multi-center, controlled study is recommended in future to explore the predictive value of CBCT in the evaluation of patient outcome following treatment for osteoarthritis of the TMJ.

Conclusions

The findings of this study showed that the injection of sodium hyaluronate into the superior and inferior temporomandibular joint (TMJ) space could relieve the clinical signs and symptoms of osteoarthritis of the TMJ, but did not reverse or prevent the progression of bony destruction during short-term and long-term follow-up. Also, this study showed the value of using cone-beam computed tomography (CBCT) to evaluate osteoarthritic changes in the TMJ and that the changes imaged at baseline could predict the likelihood of symptom relief following treatment. Sodium hyaluronate injection into the superior and inferior TMJ space can be an effective treatment to relieve the clinical symptoms for patients with osteoarthritis of the TMJ.

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