

# Sodium Hyaluronate Improves Outcomes After Arthroscopic Lysis and Lavage in Patients With Wilkes Stage III and IV Disease

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**Purpose:** Among patients with Wilkes stage III and IV disease undergoing arthroscopic lysis and lavage, does the use of an intra-articular injection of sodium hyaluronate (SH), when compared with Ringer lavage, result in better postoperative pain control and temporomandibular joint (TMJ) function?

**Patients and Methods:** We designed and implemented a randomized, double-blind, pilot controlled clinical trial. The study sample was composed of patients with middle Wilkes stage (late stage III and early stage IV) disease. Subjects were randomized to 1 of 2 treatment limbs. The treatment group received Ringer lactate plus an injection of 1 mL of SH after arthroscopy, whereas the control group was given Ringer lactate during arthroscopy. The primary outcome variables were pain and TMJ function measured by use of visual analog scales. Appropriate descriptive and bivariate statistics were computed. A *P* value less than .05 was considered statistically significant.

**Results:** The study sample was composed of 40 patients with 20 subjects enrolled in both treatment groups. There were no statistically significant differences between the 2 groups in terms of demographics and preoperative variables. Postoperative analgesia was statistically significant in the treatment group with respect to the control group on the visits on days 14 and 84. No statistically significant differences were observed between the 2 groups in the maximum interincisal opening and tolerance.

**Conclusions:** An intra-articular injection of SH after arthroscopic lysis and lavage is effective in reducing pain in patients with TMJ dysfunction, enhancing postsurgical recovery. The analgesic effect of treatment with SH is maintained in the long term.

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Several lines of treatment have been described in the literature for temporomandibular joint (TMJ) dysfunction including surgery,<sup>1,2</sup> physiotherapy,<sup>3</sup> occlusal splint therapy,<sup>4</sup> arthrocentesis,<sup>5</sup> and arthroscopy.<sup>6</sup> Lysis and lavage with arthroscopy have shown efficacy as methods for diagnosis and treatment. They improve the

symptoms and restore jaw function in patients with TMJ dysfunction by removing the catabolites of the inflammatory processes and loosening the adhesions as a result of the pressure of the lavage fluid.<sup>7-9</sup>

Some studies have shown the efficacy of intra-articular (IA) injection with sodium hyaluronate (SH) in

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treating meniscus displacement with or without reduction,<sup>10</sup> administered either once only<sup>11</sup> or repeatedly,<sup>12,13</sup> either alone<sup>14</sup> or after arthrocentesis.<sup>15</sup> These series generally compare the efficacy of IA infiltration of SH with corticosteroids,<sup>16</sup> placebo,<sup>10</sup> placement of a splint,<sup>17</sup> or an orally administered drug.<sup>11</sup> Although different authors referred indirectly to the use of SH in their arthroscopic surgery procedures,<sup>18,19</sup> no study has specifically analyzed the use of this product as a complement to arthroscopy.

The aim of our study was to evaluate the postoperative benefit in terms of pain control and TMJ function of a single IA injection of SH (1 mL at 1%) as a complement to arthroscopic lysis and lavage in patients with Wilkes stage III and IV disease. The use of an IA injection of SH when compared with Ringer solution may help in arthroscopic recovery because of the restoration of the protective action of the endogenous hyaluronic acid eliminated during the arthroscopic procedure. For these reasons, we have evaluated analgesic activity, maximum interincisal opening, deviation, protrusion, lateral movements, and click and crepitus in the TMJ. We also evaluated disc position, tolerance, and safety of viscoelastic supplementation after arthroscopy.

## **Patients and Methods**

A comparative, randomized, single-center (Hospital Son Dureta, Palma de Mallorca, Spain), double-blind pilot study was designed. Fifty-one patients were registered. Eleven patients were not randomized because they were not surgical candidates according to the clinical criteria. We randomly distributed 40 patients into 2 groups of 20. A follow-up of all the patients over a 6-month period was carried out, exempting a patient who was not assessable because of the lack of magnetic resonance imaging (MRI) after arthroscopy. The patients were men and women aged over 18 years with the following inclusion criteria: MRI-confirmed meniscus displacement with or without reduction, Wilkes stage III or IV TMJ disorder, and TMJ joint pain and/or mouth-opening limitation (TMJ pain at rest or mastication  $>20$  mm on visual analog scale and/or maximum interincisal opening  $\leq 30$  mm). It was also necessary to have an absence of response to conservative measures (surgical splint, medication, physiotherapy) for at least 6 months. Major exclusion criteria included degenerative illnesses such as rheumatoid arthritis; arthrocentesis, arthroscopy, or previous open surgery on the same joint; extra-articular pain; impossibility of the arthroscopic technique being correctly performed; and severe osteoarthritis or disc perforation (Wilkes stage V).

The treatment group was administered a 1-mL injection of SH (Ostenil mini; Masterfarm Laboratories,

Barcelona, Spain) in the superior joint space of the TMJ, after arthroscopic lysis and lavage. The control group was given IA Ringer lactate during arthroscopic lysis and lavage without final viscoelastic supplementation. To ensure that this was a double-blinded study, the surgical procedure was carried out by the main investigator, whereas the later evaluations were performed by another investigator not associated in any way with the surgical process.

TMJ arthroscopy was performed with the patient under general anesthesia and with nasotracheal intubation. The technique began by expanding the superior joint space with an injection of 4 mL of saline solution and 0.5% bupivacaine in equal proportions, by use of a 23-gauge needle. The superior joint space was then carefully punctured with straight and curved-end trocars to insert a cannula, and its position was checked with a Dyonics 1.9-mm-diameter, 30° angular arthroscope (Smith & Nephew, Melbourne, Australia). A continuous Ringer lactate irrigation system was connected. Once drainage had been established and after inspection of the superior joint space, a second cannula was inserted by the triangulation technique at an anterior-superior angle, which was manipulated to move the disc and release any adhesions. Meanwhile, lavage continued with at least 200 mL of Ringer solution. This second portal was finally used to administer 1 mL of SH in the treatment group, and its entry in the superior joint space was visually confirmed arthroscopically.

The primary efficacy parameter was analgesic activity, measured with a 100-mm visual analog scale. Further evaluation of TMJ function was performed in terms of maximum interincisal opening (in millimeters), deviation of the jaw from the midline when opening, protrusion and lateral movements, and click and crepitus in the joints. The secondary efficacy parameters were the disc position evaluated by MRI and overall evaluation by the patient and the investigator on a 5-point scale from worst (0) to optimal (4). Adverse effects were also noted. The patients were evaluated at the beginning of the study (7 days before arthroscopy), on the day of the intervention (day 0), and on days 14, 28, 56, 84, and 168 after arthroscopy. The visit before arthroscopy (7 days preoperatively) was considered the baseline for the objective and clinical measures, and the visit on day 14 was considered the baseline for the comparative analyses as the percentage of patients with pain improvement. From day 14 on, we considered the groups comparable, because 2 weeks is the mean time for postsurgical recovery (in both cases pain was due to surgery and not the joint pathology itself). MRI evaluation of the disc position was done at the baseline visit and at the last visit (day 168). The study protocol was previously approved by the Comité de Ensayos Clínicos de la

**Table 1. MRI BASELINE EVALUATION**

	Treatment Group		Control Group		Overall		P Value <sup>†</sup>
	n	%*	n	%*	n	%*	
Disc position	20	100.0	20	100.0	40	100.0	.4648
Normal	1	5.0	0	0.0	1	2.5	
Displaced with reduction	3	15.0	5	25.0	8	20.0	
Displaced without reduction	16	80.0	15	75.0	31	77.5	
Disc morphology	20	100.0	20	100.0	40	100.0	.5231
Normal	10	50.0	7	35.0	17	42.5	
Pathologic	10	50.0	13	65.0	23	57.5	
Exudate	20	100.0	20	100.0	40	100.0	.4872
Without effusion	20	100.0	18	90.0	38	95.0	
With effusion	0	0.0	2	10.0	2	5.0	
Diagnosis: Subgroups	19	100.0	19	100.0	38	100.0	.6928
Wilkes stage III (late)	3	15.8	5	26.3	8	21.1	
Wilkes stage IV (early)	16	84.2	14	73.7	30	78.9	

\*Percentage calculated with respect to all patients evaluable.

† $\chi^2$  test.

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Islas Baleares-Spain (Balearic Islands Clinical Trials Committee). All patients had to give their signed informed consent to be included in the protocol.

The results were statistically analyzed with the SPSS statistical system, version 15.0 (SPSS, Chicago, IL). Suitable parametric and nonparametric tests were performed, and the level of statistical significance was set at .05.

## Results

Forty patients were recruited and randomly divided into 2 groups. Follow-up was complete in all patients, so all of them reached the visit at 6 months (day 168) but not all of the parameters were assessable in 1 patient because a second MRI scan was not available. The mean age of the patients was 35.3 years (SD, 13.3 years), and 92.5% of them were women. There were no statistically significant differences between the groups ( $P > .05$ ). Table 1 shows the initial situation of

all included patients.

In analyzing the primary endpoint (pain control), a patient was considered to have improved if each scale decreased by at least 10 mm for each visit in comparison to baseline (7 days preoperatively). Statistically significant differences ( $P < .05$ ) were seen between the treatment group and the comparator group in joint pain on day 14 and day 84 (Table 2). Statistically significant differences ( $P < .05$ ) could also be seen in both the treatment and comparator groups when we compared joint pain at the first visit and at the rest of the visits (significant reduction).

Table 2 shows the variation in the differences in TMJ pain, including within- and between-group differences, both in the group treated with SH injection after arthroscopic lysis and lavage and in the control group, which received arthroscopy and lavage with Ringer lactate without final viscoelastic supplementation.

**Table 2. DIFFERENCES IN JOINT PAIN OVER TIME (VISUAL ANALOG SCALE)**

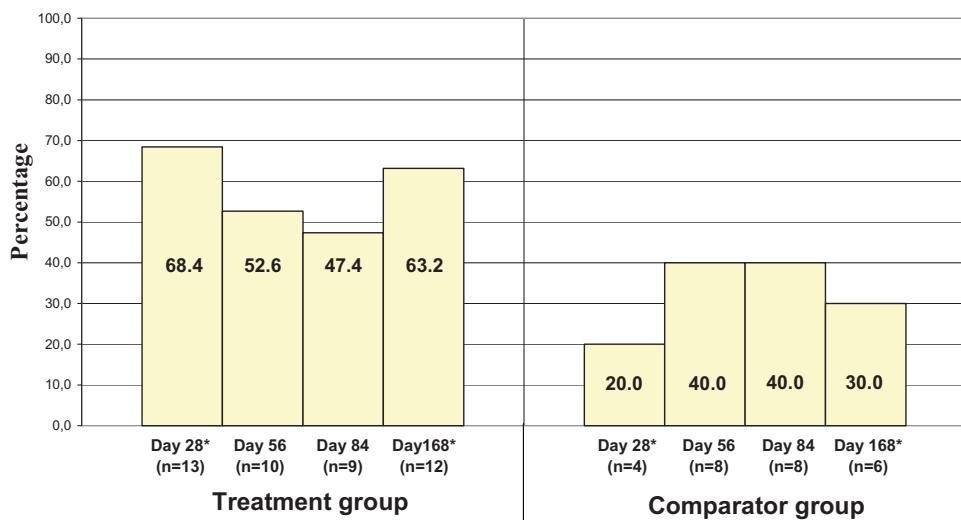
	Treatment Group			Control Group			Overall		
	Mean	Range	P Value*	Mean	Range	P Value*	Mean	Range	P Value <sup>†</sup>
Baseline visit	62.0	31.0-100.0	—	47.9 (20.2)	18.0-90.0	—	54.8 (21.0)	18.0-100.0	—
Visit day 14	32.4	0.0-80.0	.0007 <sup>‡</sup>	17.5 (16.7)	0.0-59.0	.0002 <sup>‡</sup>	24.7 (21.5)	0.0-80.0	.0360 <sup>‡</sup>
Visit day 28	20.3	0.0-69.0	.0002 <sup>‡</sup>	15.2 (18.4)	0.0-56.0	.0002 <sup>‡</sup>	17.7 (18.7)	0.0-69.0	.3058
Visit day 56	22.1	0.0-71.0	.0005 <sup>‡</sup>	14.0 (19.7)	0.0-74.0	.0001 <sup>‡</sup>	17.9 (21.7)	0.0-74.0	.2005
Visit day 84	23.0	0.0-61.0	.0002 <sup>‡</sup>	10.9 (16.1)	0.0-62.0	.0001 <sup>‡</sup>	16.8 (19.0)	0.0-62.0	.0420 <sup>‡</sup>
Visit day 168	19.0	0.0-59.0	.0001 <sup>‡</sup>	9.6 (17.0)	0.0-64.0	.0001 <sup>‡</sup>	14.2 (19.4)	0.0-64.0	.1004

\*Wilcoxon test.

†Mann-Whitney U test.

‡Statistically significant result ( $P < .05$ ).

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**FIGURE 1.** Percentage of patients whose joint pain improved by at least 10 mm compared with day 14. \* $\chi^2$  test;  $P < .05$ .

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In addition, the percentage of patients in whom the joint pain scale score decreased by at least 10 mm compared with day 14 was calculated. A significant increase was observed in the percentage of patients in the comparator group who improved throughout the study ( $P < .05$ , Friedman test). Moreover, for each visit, more than 45% of the patients in the treatment group and more than 20% in the control group improved. Statistically significant differences were seen between groups on days 28 and 168 in the percentage of patients with pain improvement compared with day 14 ( $P < .05$ ,  $\chi^2$  test) (Fig 1).

The maximum interincisal opening was also evaluated at each visit, from the baseline visit to the visit on day 168. No statistically significant differences were observed in maximum interincisal opening between the treatment and control groups ( $P > .05$ ). Statistically significant differences were found in the treatment group ( $P < .05$ ) in the maximum mouth opening between the baseline and day 56 visits and between the baseline and day 168 visits, as well as

both in the control group and in the overall population between the baseline visit and days 28, 56, 84, and 168.

Most of the patients evaluated in both groups presented with disc displacement without reduction. Table 3 describes the disc position at the beginning and end of treatment: at the baseline visit, 79.5% of the study population presented with a displaced disc without reduction, whereas by day 168, this parameter had decreased to 68.4%. No statistically significant differences were observed in disc position between the treatment and comparator groups ( $P > .05$ ).

Treatment tolerance was analyzed from the point of view of both the patient and the investigator. On day 14, 60.5% of the overall population considered the treatment optimal or good, and this percentage was 74.3% on day 168. At the end of the study, a larger percentage of patients in the comparator group considered the therapy optimal compared with the treatment group, although the difference was not statistically significant ( $P > .05$ ).

**Table 3. CHANGE IN DISC POSITION AT THE BEGINNING AND END OF TREATMENT**

	Treatment Group		Comparator Group		Overall		<i>P</i> Value*
	n	%	n	%	n	%	
Baseline visit	19	100.0	20	100.0	39	100.0	.4765
Normal	0	0.0	0	0.0	0	0.0	
Displaced with reduction	3	15.8	5	25.0	8	20.5	
Displaced without reduction	16	84.2	15	75.0	31	79.5	
Visit day 168	18	100.0	20	100.0	38	100.0	.8877
Normal	2	11.1	3	15.0	5	13.2	
Displaced with reduction	3	16.7	4	20.0	7	18.4	
Displaced without reduction	13	72.2	13	65.0	26	68.4	

\* $\chi^2$  test.

With regard to adverse events, these occurred in 15.0% (n = 3) of the patients in the treatment group and 10% (n = 2) in the comparator group. The most common adverse events were earache and joint noise, each present in 5.0% (n = 2) of the population. Tolerability both at the start and at the end of the study was considered better in the control group (a larger percentage of patients qualifying tolerability of treatment as good or excellent) than in the treatment group, but the differences were not statistically significant.

## Discussion

Our purpose was to evaluate the analgesic efficacy and TMJ function after a single IA injection of SH into the TMJ as a complement to arthroscopic lysis and lavage in Wilkes stage III and IV disease. The results show that SH is effective in pain improvement and in the maximum interincisal opening. In addition, SH maintains its analgesic effect in the long term.

A number of studies describe the results of arthroscopic lysis and lavage of the TMJ in the medium and long term, and high success rates are achieved in reducing pain and improving joint mobility, even in advanced states of dysfunction.<sup>20-26</sup> The patients with Wilkes stages III and IV were treated with lysis and lavage, whereas those in stage V were submitted to more advanced arthroscopic techniques. Most of the patients evaluated in our study in both groups presented with disc displacement without reduction, which is to be expected because they were patients who had not responded to the previous conservative measures, corresponding to middle Wilkes stage<sup>27</sup> (late stage III and early stage IV). With respect to Wilkes stage V, some studies question the efficacy of lysis and lavage (including Murakami et al,<sup>26</sup> in addition to Indresano<sup>23</sup> and McCain et al,<sup>18</sup> who recommend more complete arthroscopic operating techniques and arthrotomies). In our study we therefore decided to consider Wilkes stage V as a reason for exclusion. Other studies support the efficacy of IA injection of SH in TMJ dysfunction treatment in different stages, used as a single treatment or with other drugs (glucocorticoids, analgesics, and so on) and other treatments (arthrocentesis, splint, and so on).<sup>10-17</sup> However, there is controversy over the use of SH as a complement to arthroscopic treatment of TMJ, and few articles in the literature specifically analyze this question.<sup>18,19,23</sup> Our study therefore differs from those of Guarda-Nardini et al<sup>17</sup> and Alpaslan and Alpaslan,<sup>15</sup> in which arthrocentesis was performed. It is necessary to separate the mechanisms of action of the 2 treatments (lysis/lavage and SH injection) and to attribute the therapeutic effect corresponding to each one. In joints with dysfunction,

arthroscopy is responsible for the removal by lavage of catabolites of inflammation from the synovial fluid, as well as for the lysis of adhesions.<sup>28,29</sup> SH has a lubricating, protective, and repairing effect on the joint surfaces, as well as analgesic and anti-inflammatory action.<sup>30,31</sup> The analgesic effect is attributed to the blocking of nociceptive terminals and is directly proportional to the molecular weight of the SH<sup>32</sup> and the elastoviscosity of the solution.<sup>33</sup> Furthermore, the SH prevents the formation of adhesions,<sup>34</sup> which explains its long-term beneficial effect. Our results match those of other studies in observing better pain control after 6 months, a time in which the exogenous SH has disappeared from the joint space, as described in many articles in the orthopedic literature.<sup>35,36</sup> In the processes of TMJ dysfunction, the concentration and molecular weight of the hyaluronic acid in the synovial fluid decrease as a result of the dilution and fragmentation in metabolites with a lower weight than normal, which compromises homeostasis.<sup>34</sup> Therefore, for improvement of TMJ symptoms and function, it is necessary to remove the catabolites from the inflammation by lavage and to maintain the effect with exogenous SH and physiotherapy exercises. This could be more effectively done if the pain was suitably controlled in the early periods, as occurred in our study, with significant pain improvement by day 14 in the viscoelastic-supplemented group.

In conclusion, an IA injection of SH after arthroscopic lysis and lavage is effective in reducing the pain in patients with TMJ dysfunction, this being statistically significant by day 14 after surgery, and so it could be used to aid normal postsurgical physiotherapy. Furthermore, treatment with SH maintains its analgesic effect in the long term (6 months), justifying its post-arthroscopic use. In addition, unlike in other previous studies, it has been shown that the results of SH viscoelastic supplementation enhance arthroscopy, because arthroscopic lysis and lavage already comprise a technique with a great therapeutic effect in treating TMJ dysfunction.

These results encourage us to continue to perform prospective follow-up of patients at our hospital over the next few years. Thus we will be able to have information relative to a larger population than in this pilot study. In addition, these new data will allow us to subclassify the patients depending on their Wilkes stage and to analyze possible differences.

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