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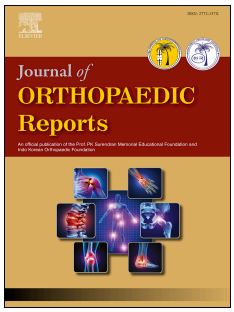

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Treatment of mild and advanced cases of Elbow OA with Arthroscopic Debridement and Intra-Articular Hyaluronic Acid injections

Running Title: Hyaluronic Acid Injections in Elbow Osteoarthritis

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Abstract

Background: Intra-articular hyaluronic acid (HA) injections have demonstrated efficacy for osteoarthritis in joints such as the hip, knee, and ankle. As few published studies exist on the subject, HA injections for elbow OA have not been proven to be effective. This study investigates the efficacy of arthroscopic debridement with/without intra-articular hyaluronic acid (HA) injections with respect to pain relief, arc of movement, and functional improvement in 24 elbows with osteoarthritis.

Material & Methods: 24 elbows were treated for posttraumatic (n=11) or primary degenerative (n=13) osteoarthritis of the elbow by arthroscopic debridement. HA (Synvisc) injection protocol was either preoperative (n=5), postoperative (n=5), combined pre- and post-operative (n=5), or without HA injections (n=9). A clinical examination and Mayo elbow performance score was conducted at an average of 15 months (range 12-18 months) post-operation. The results were statistically analysed with the Mann-Whitney, Wilcoxon, and ANOVA tests.

Results: Intra-articular cartilage changes were observed to be mild fraying (n=5), significant fraying/fibrilliation (n=6), and significant fibrillation with areas of bare bone (n=13). HA injections were associated with worse outcomes in patients with severe cartilage changes and exposed bone. A non-statistically significant trend toward improved outcomes in patients without exposed bone was seen when treated with HA injection.

Discussion & Conclusions: These results support the use of HA in combination with elbow debridement in earlier stages of osteoarthritis with intact / frayed cartilage layer, but not in advanced cases with bone in communication with the synovial cavity. There is a symptomatic benefit in earlier stages (0-2) and a symptomatic detriment associated with HA in osteoarthritic

joints with later stages (3-4), in the short term. Longer term studies are required to better understand the longevity of these results.

Level of Evidence: II

Key word: Arthroscopic Debridement; Hyaluronic Acid; Osteoarthritis-Elbow.

Introduction

Primary osteoarthritis (OA) of the elbow is rare, accounting for only 1-2 % of elbow arthritis, due to the well matched articular surfaces and the strong stabilizing ligaments of this joint.[5, 18] Primary osteoarthritis of the elbow, when sufficiently symptomatic to require treatment, has been commonly associated with heavy manual work and repetitive forceful use of the elbow, as seen in manual laborers, weight lifters, or throwing athletes.[7, 9, 11, 18] This group of patients consists mainly of middle aged men, but with a variation from the 3rd to the 7th decade.[9, 13, 14, 19]

Other known causes of elbow arthritis include rheumatoid arthritis, sequelae of joint infection, crystalline arthropathy, hemophilia, and most commonly trauma to the elbow.[11] Posttraumatic elbow arthritis can result from a myriad of insults that directly damage the cartilage , and/or distort the anatomy of the joint that leads to a progressive degeneration of articular surfaces. Regardless of the etiology of elbow arthritis, patients experience pain, decreased range of motion (ROM), and functional impairments.

As with OA in any joint, conservative management, including oral analgesia, physical therapy, and corticosteroid injections, is the initial intervention. More recently, another conservative measure, consisting of intra-articular hyaluronic acid (HA) injections, has been introduced.

When conservative management proves insufficient, operative intervention can be offered to alleviate symptoms such as pain and decreased range of motion. In a comparison of the open Outerbridge-Kashiwagi (O-K) procedure with the arthroscopic modification[8], the arthroscopic procedure was reported to have provided better pain relief, which would make it the more favorable procedure in the treatment of advanced elbow arthritis where pain is the predominant feature and the osteoarthritic change is confined primarily to the anterior compartment. However,

the open O-K procedure proved better in improving range of flexion[8], making it a more ideal procedure when range of motion is the primary complaint.

Although HA injections have proven both safe and effective in the treatment of OA pain of the knee[4, 7, 22], ankle[7, 16] and hip [7, 12], further evidence of its usefulness in the elbow has yet to be reported. This study is the first to our knowledge to compare patient outcomes for treatment of elbow OA with arthroscopic debridement alone or arthroscopic debridement plus pre- and/or postoperative intra-articular HA injections into the elbow.

Material & Methods

Study site and patients

This prospective, randomized study reports the outcome of twenty-four elbows, which were treated over a two-year period for posttraumatic (11 elbows) or primary degenerative (13 elbows) osteoarthritis of the elbow. All these patients had a minimum of six months of conservative management including oral analgesics, braces, physical therapy, and intra-articular corticosteroid injections. When these conservative measures were ineffective, or a corticosteroid injection resulted in less than one month of symptom relief, patients with recalcitrant symptoms, with which they were unable to cope on a daily basis, had a discussion about surgical options. Patients with no clear joint line lucency across the width of the whole elbow joint, inflammatory arthritis, and previous surgeries were excluded from this study, whereas those with a radiologically visible lucent (cartilage space) line across the whole joint were included.

The surgical option discussed with this cohort of patients was an arthroscopic debridement, with adjunctive use of an intra-articular hyaluronic acid (HA) supplement (Synvisc™). The course of HA was either 6 weeks preoperative (Group 1: n = 6 cases), 6 weeks postoperative (Group 2: n = 4 cases), both 6 weeks pre-operative and 6 weeks postoperative (Group 3: n = 5 cases), or no adjuvant HA injections (Group 4: n = 9 cases). All patients were followed up at 2, 6, 12, 24, and 48 weeks post operatively, with additional follow up performed as needed.

Data were collected prospectively when patients with pre-requisite elbow pain, recalcitrant to conservative management, were assessed for their suitability for an arthroscopic debridement, at which point they were randomly allocated into one of 4 groups: group 1 – pre-arthroscopic HA injection, group 2 – post-arthroscopic HA injection, Group 3 – pre- and post-arthroscopic HA injection, and Group 4 – no HA injection (only arthroscopic debridement). In addition to a

91 standard examination and radiographs, a Mayo elbow performance score was performed, both
92 immediately pre-operatively and at post-operative visits.

93

94 ***Statistical methods***

95 The Wilcoxon signed rank test, a non-parametric test of paired comparisons, was used to
96 compare the difference between Mayo scores before and after treatment in the same patients.
97 The Mann Whitney Test of Medians was used to compare patients with and without cartilage
98 change down to bone, i.e. a non-parametric test of paired comparisons. Non-parametric tests
99 were used because the data was likely to be normally distributed. One Way Analysis of
100 Variance (ANOVA) was used to compare data between the 4 injection groups. In all cases a two
101 tailed test of significance was used so that there was no pre-assumption that the difference being
102 sought was in one particular direction. A p-value of $p<0.05$ was taken to be significant.

103

104

Results

Outerbridge Cartilage Degradation Scale was used to grade the cartilage during the arthroscopies:

- Grade 0 - Normal cartilage.
- Grade 1 (I) - Articular cartilage has softening and swelling.
- Grade 2 (II) - Articular cartilage has a partial-thickness defect with fissures on the surface that do not reach subchondral bone or exceed 1.5 cm in diameter.
- Grade 3 (III) - Articular cartilage has fissuring to the level of subchondral bone in an area with a diameter more than 1.5 cm.
- Grade 4 (IV) - Articular cartilage is worn to the extent that there is exposed subchondral bone.

The notes were consulted for the preoperative data and we were able to identify the state of the articular cartilage in 19 cases by means of arthroscopy video clips. The cartilage was graded according to the Outerbridge classification. For the remaining 5 cases these data were extracted from the operation notes. In 13 cases cartilage changes down to bare bone (bone could be probed with a hook probe or exposed bone) were seen on the video clips. Six patients had cartilage changes, but not to the depth of the bone. In the remaining 5 cases the cartilage changes were reduced to mild surface fraying only.

Demographic data is shown below in Table 1.

There were no differences in the 3 outcomes for groups receiving HA injections, regardless of the timing relative to surgery (i.e. pre- and/or post-op).

Pain Relief

The treatment overall resulted in very significant pain reduction at follow up examination/inquiry ($p < 0.0001$, Wilcoxon Test), with $p = 0.014$ for the posttraumatic osteoarthritis (OA) and $p=0.001$ for the primary degenerative OA group. Pain improved in 20 of 24 cases (7 cases from severe to no or mild pain / 2 cases from moderate to mild or no pain/5 cases from mild to no pain/5 cases from severe to moderate pain). Pain was not changed in 2 cases, both of which were only described as moderate preoperatively. In 2 cases the pain was slightly increased postoperatively. Pain relief was significantly better in the group where the cartilage was worn down to bone on the arthroscopy videos, compared to the group with cartilage changes, where bare bone was not visible.

($p = 0.003$, Mann-Whitney tests).

For the examined group of patients with cartilage wear down to bare bone, pain relief was significantly better without additional intraarticular HA injection ($p = 0.039$).

In the group with only mild cartilage fraying, a trend towards better pain relief in the group treated with additional HA became apparent. Due to the small numbers in this group this finding could not be confirmed statistically ($p=0.2$). When the groups with cartilage changes not down to bone and minimal fraying only were combined (1-2) versus the group with cartilage changes

down to bone (3-4), the differences were not significant, but closer to statistical significant (p = 0.095)

Mayo Score

The Mayo Score improved very significantly by an overall average of 30 points ($p < 0.0001$ Wilcoxon test), with $p = 0.002$ in the post-traumatic group and $p=0.0001$ in the primary degenerative group.

The Mayo Score gain for the elbows with cartilage wear down to bone was significantly better when no additional HA treatment was given ($p=0.036$). The subgroup with mild cartilage fraying on the other hand, showed a very clear trend towards a better Mayo Score improvement with additional HA injections (50 points compared with -5 in the control group), but the relatively small numbers prevented valid statistical tests ($p=0.2$). The group with altered cartilage not down to the bone had a slight improvement with HA injections but again statistically was insignificant ($p=0.7$).

In the group with cartilage changes there was no significant difference when the control group Mayo score change was compared to that of the other 3 injection groups ($p=0.115$; 95% confidence interval [-5 to 60]). In the no cartilage change group, there was a significant difference when the control group Mayo score change was compared to that in the other 3 injection groups combined ($p=0.04$; 95% CI for difference [-60 to 0])

Arc of Movement

Arc of movement improved overall significantly (p= 0.0008), and particularly in the post traumatic subgroup (p=0.004). The arc of movement was not significantly improved in the primary degenerative OA subgroup (p=0.065). This difference regarding the postoperative mobility between the two subgroups was not statistically significant (p= 0.33).

Arc of improvement was better in the no-injection group in bare bone/altered cartilage (Cartilage 3-4) groups and improved in the injection group in the mild-fraying cartilage group, although statistically insignificant.

In both the no cartilage change and the cartilage change group there was no significant difference in the change in arc of movement between pre and post op injection groups when the control group was compared to the other injection groups(p=0.90; CI [-40 to 40] and p=0.22; 95% CI [-20 to 80] respectively). One way ANOVA did however, show a significant difference between all 4 injection (control) groups (p=0.04).

Complications:

An allergic type of response was observed in a single group 1 patient and a single group 3 patient. Both presented with a hot swollen joint after the third pre-operative and post-operative injections respectively, and both had a thorough haematological investigation, and joint aspiration with culture, which excluded infection. In a previous pilot study one patient withdrew from the study after a similar reaction after the second injection, but was also proven to be a non-infective response.

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Discussion:

Hyaluronic acid, such as the FDA approved cross-linked version Hylan G-F 20 (Synvisc™), improves the viscoelastic quality of synovial fluid[22] and has been shown to have protective effects on cartilage in experimental models[2]. Hyaluronic acid (HA) has also significant effects on inflammatory mediators, which may translate into cartilage protection[2]. HA was found to produce smoother articular surface in animal models by inducing partial healing with growth of a hyaline like cartilage[2, 10], in addition to possessing analgesic effects by directly inhibiting nociceptors or indirectly binding Substance P[2, 17].

The treatment with arthroscopic debridement, with or without intraarticular HA injections, resulted in very significant pain relief and Mayo Score improvement in all groups. Therefore, our study confirmed the beneficial effects of arthroscopic debridement on elbow OA, consistent with previous studies performed by O'Driscroll et al[15] and Cohen et al[8]. Comparable to findings reported by Cohen et al[8], we also found that arc of movement was significantly improved overall. There were no systemic or local adverse effects of HA injection in our study, similar to Bellamy et al[4]. Overall, these results show arthroscopic debridement provides pain relief and improved range of motion in patients with elbow OA and that HA injections are safe.

While the combined results above have been previously described in other studies, sub-analysis reveals some novel findings. Although the posttraumatic OA patients demonstrated improved arc of movement with arthroscopic debridement, this finding was not seen for the primary degenerative OA subgroup, perhaps due to better preoperative arc of movement (Tables 2 and 4). However, the primary degenerative OA subgroup still experienced significant pain relief and

Mayo Score improvement. These findings allow for more informed preoperative decision-making and patient counselling on expected outcomes depending on the mechanism of OA.

We also found that arthroscopic debridement provided more effective pain relief in patients with cartilage changes down to bone compared to patients without cartilage changes down to bone ($p=0.005$). Furthermore, we found the subgroup of patients with cartilage changes down to bone actually had worse pain relief and Mayo scores when treated with adjunctive HA injections compared to no injections. This is an important consideration when contemplating adjunctive HA injections in patients undergoing arthroscopic debridement for advanced elbow OA. These findings allow for more informed preoperative decision-making and patient counselling if advanced imaging such as MRI is performed to evaluate extent of cartilage changes. If advanced imaging is not obtained preoperatively, our results suggest it may be prudent to defer HA injections until after surgery as the extent of cartilage changes cannot otherwise be reliably evaluated without arthroscopy. This suggestion is also supported by the lack of difference in outcomes between patients receiving preoperative vs postoperative HA injections.

For the group without cartilage changes down to bone, a trend towards better pain relief (1.33 vs 0, $p=0.0814$) and Mayo Score improvement (35.83 vs 5, $p=0.0502$) could be observed when additional intraarticular HA was injected. However, likely due to the small number of patients in the cohort, these trends were not statistically significant. HA injections therefore could be beneficial, if used selectively in milder forms of elbow OA. Further investigation with larger numbers will be performed to continue to evaluate this potentially significant observation, which is biologically plausible.

When considering the properties and degradation of hyaluronic acid, this finding makes sense intuitively. Hyaluronic acid is a high molecular weight molecule composed of alternating

glucosamine and glucuronic acid residues[6]. Endogenous HA naturally occurs within cartilage and synovial fluid and, although its precise mechanism of action is incompletely understood, its mechanical and viscoelastic properties are considered vital[1, 6, 20]. During the progression of OA, endogenous HA is depolymerized by hyaluronidases into a lower molecular weight form that has decreased mechanical and viscoelastic properties[1, 3, 6, 20]. As the average size decreases, HA residues aggregate less, leading to faster exponential degradation[20]. In patients with advanced OA, HA residues are smaller compared to patients with mild OA[3]. Therefore, patients with mild OA could reasonably be expected to gain more benefit from HA supplementation as the exogenous residues will be depolymerized at a slower rate compared to patients with severe OA.

Our findings of paradoxical pain relief with HA injections in patients with cartilage changes down to bone has not previously been described in the literature, which has posited that all stages of arthritis can be treated with HA injections (citation). However, this literature comes from studies on the lower extremities, which may not be applicable to the elbow.

Our findings are also in contrast with Van Brakel et al[21], who did not show any difference with HA injections after 6 months. However, there are a few differences between the study designs. First, we performed arthroscopic debridement in addition to HA injections. This allowed us to reliably stratify patients into subgroups based on extent of cartilage changes. Like the Van Brakel study, no significant findings regarding HA injections were demonstrated when all patients were analysed together. However, once we created subgroups based upon cartilage damage, some interesting trends were noted.

Limitations of our study include the small cohort sizes in the treatment groups. This was amplified by further dividing treatment groups based upon extent of cartilage damage. Furthermore, as the treatment groups were assigned preoperatively, extent of cartilage damage was not distributed evenly across the treatment groups. Conducting a similar study with significantly more patients will help with both of these limitations. A final limitation was the scale used to measure pain, which consisted of none, mild, moderate, and severe pain, as there is no quantitative relationship between groups.

Conclusion

Previous literature has posited that HA is beneficial in all stages of arthritis. Our study indicates that this may not be true for elbow OA, although a definitive determination could not be made. Our results have not previously been described in the literature and can be very valuable in the selective management of various stages of elbow OA. Numerous factors may need to be considered when considering surgical approach and HA injections, as also outlined by previous studies, such as the severity of osteoarthritis with respect to cartilage erosion, pain severity and flexion limitation. Whilst arthroscopic debridement plus/minus HA injections looks promising, larger study sizes will be needed to provide statistically stronger evidence for this treatment.

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Appendix A: Figure and Table Legend

Figure 1: Intra-articular HA injection performed via posterolateral soft spot route

Table 1: Demographics

Table 2: Posttraumatic Osteoarthritis Outcomes Before and After Treatment

Table 3: Posttraumatic Osteoarthritis Outcomes Stratified By HA vs No HA

Table 4: Degenerative Osteoarthritis Outcomes Before and After Treatment

Table 5: Degenerative Osteoarthritis Outcomes Stratified by HA vs No HA

Table 6: Advanced Osteoarthritis Outcomes Before and After Treatment

Table 7: Advanced Osteoarthritis Outcomes Stratified by HA

Table 8: Early Osteoarthritis Outcomes Before and After Treatment

Table 9: Early Osteoarthritis Outcomes Stratified by HA vs no HA

Table 1: Demographics

Outcome	**Traumatic (n=11)**	**Degenerative (n=13)**	**P-value**
Mean Age	50.1±13.9	56.0±11.9	0.2734
Mean Follow-up	15.5±8.1	11.4±5.6	0.1575
Male/female ratio	5/6	11/2	0.0426

Outcome	**Mean Before Treatment**	**Mean After Treatment**	**P-value**
Pain	2.00	1.00	0.0255
Mayo Score	50.91	83.64	0.0018
Range of Motion	74.00	104.50	0.0105

Outcome	**HA**	**No HA**	**P-value**
Pain Improvement	1.5	0.4	0.1606
Mayo Score Improvement	43.33	20	0.1428
Range of Motion Improvement	25	36	0.5921

Outcome	**Mean Before Treatment**	**Mean After Treatment**	**P-value**
Pain	2.15	0.85	0.0003
Mayo Score	55.38	86.15	0.0009
Range of Motion	95.42	98.75	0.6013

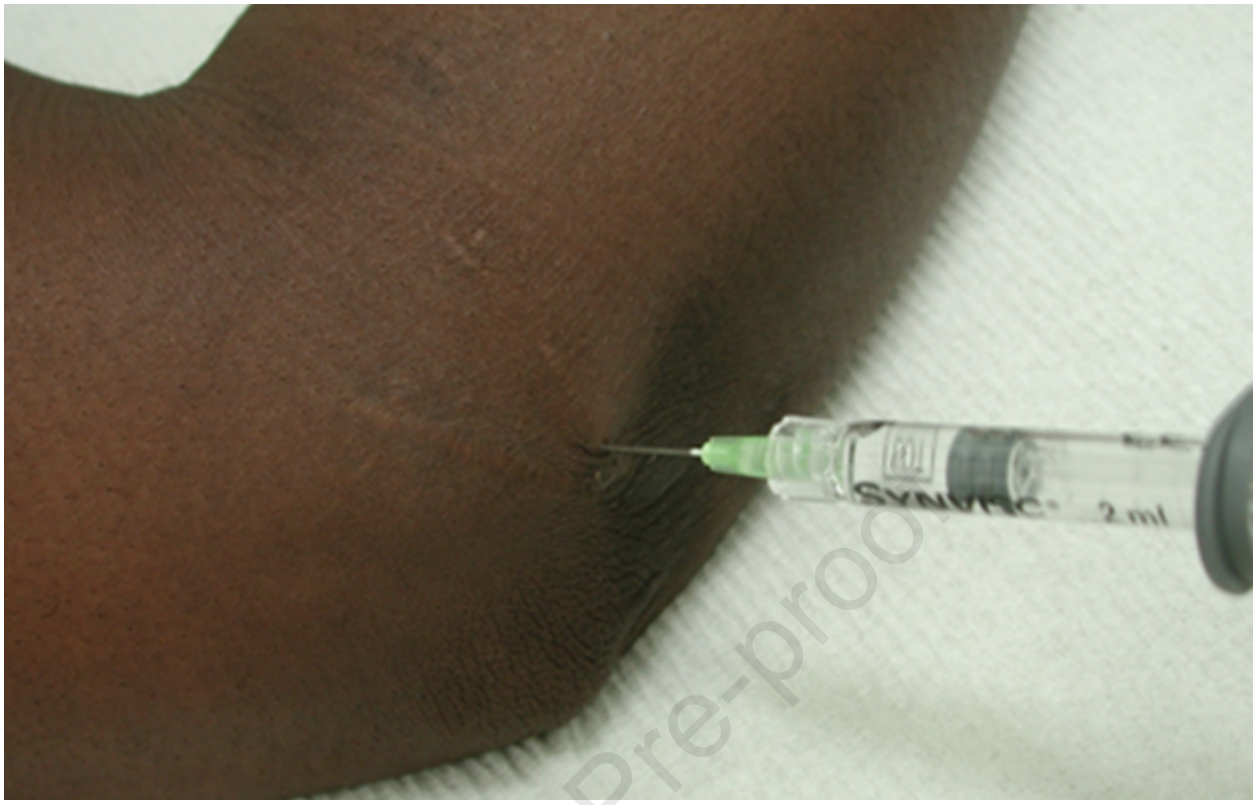
Outcome	**HA**	**No HA**	**P-value**
Pain Improvement	1.22	1.75	0.3837
Mayo Score Improvement	27.22	38.75	0.4757
Range of Motion Improvement	2.78	5	0.8851

Outcome	**Mean Before Treatment**	**Mean After Treatment**	**P-value**
Pain	2.46	0.92	0.0001
Mayo Score	45	85	0.0001
Range of Motion	88.18	95	0.4734

Outcome	**HA**	**No HA**	**P-value**
Pain Improvement	1.33	2.25	0.0405
Mayo Score Improvement	32.22	57.50	0.0398
Range of Motion Improvement	1.25	21.67	0.3467

Outcome	**Mean Before Treatment**	**Mean After Treatment**	**P-value**
Pain	1.64	0.91	0.0872
Mayo Score	63.18	85	0.0222
Range of Motion	83.18	107.73	0.0085

Outcome	**HA**	**No HA**	**P-value**
Pain Improvement	1.33	0	0.0814
Mayo Score Improvement	35.83	5	0.0502
Range of Motion Improvement	26.67	26	0.9672



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Conflict of Interests

Anika Yadav BS: This author, their immediate family, and any research foundation with which they are affiliated did not receive any financial payments or other benefits from any commercial entity related to the subject of this article.

Srinath Kamineni MD: This author, their immediate family, and any research foundation with which they are affiliated did not receive any financial payments or other benefits from any commercial entity related to the subject of this article.

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