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# The effectiveness of injectable ossotide in treating condylar fractures

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**Abstract:**
The purpose of this study was to evaluate the effects of osteopeptide injections as an additional treatment for condylar fractures on pain management and changes in levels of interleukin-1$\alpha$ (IL-1ʙ) and bone glycoprotein (BGP). Eighty-two patients who had a condylar neck fracture were divided into two groups at random. While the control group underwent standard surgical procedures, the experimental group also got injections of osteopeptide. The levels of pain, IL-1, and BGP were assessed at 1, 2, and 4 weeks after surgery.

TWO WEEKS AFTER SURGERY: The experimental group outperformed the control group on the Numeric Rating Scale. The control group had greater BGP levels and lower IL-1β levels at all three assessment points (1, 2, and 4 weeks postsurgery), whereas patients who received osteopeptide injections had higher BGP levels and statistically significant differences ($P < 0.05$) in both.

CONCLUSIONS: Patients with condylar fractures may have a reduction in pain and a speedier start to muscular function training after receiving osteopeptide injections as an adjuvant treatment. Faster wound healing is another benefit of reducing inflammatory factors and increasing active osteogenesis.

**Keywords:** Ossotide for injection, numerical rating scale score, condylar fracture, interleukin-1$\alpha$, and bone G-gla protein

## Introduction

One portion of the maxillofacial region that is susceptible to fracture is the condyle. Condylar fracture diagnostic and treatment strategies need to evolve with new medicines, materials, imaging technologies, and treatment modalities. To avoid or address any complications after surgery, it is essential to manage the patient's pain and improve tissue healing. The clinical effectiveness of administering osteopeptide injections as an adjuvant therapy for condylar fractures was evaluated in this research.

## Materials and Methods

In 2020 and 2022, we used a random number table to split 82 patients admitted to our hospital with condylar fractures into two groups. The patients' numbers were determined using the website http://powerandsamplesize.com. The experimental group included a total of 41 people, with ages ranging from 20 to 61 years old, and an average age of 33.54 ± 5.12 years. The group included 20 males and 21 females. The age range of the 41 patients that made up the control group was from 23 to 62 years old, and there were 22 males and 19 females. The average age was 34.11 ± 4.45 years. Patients gave their informed permission after receiving detailed information about the trial's treatment plans, objectives, risks, and outcomes. As a component

Below are the requirements: Surgical reduction and fixation may be necessary to treat a condylar neck fracture. In cases when surgery is not done, intracondylar fractures, subcondylar fractures, comminuted condylar fractures, and high fractures (defined as lines on the surface of the condyle) are not considered. The patients in the control group had standard surgical procedures, including middle and low condyle fractures.[1] The condylar neck fractures that were chosen for this research are all in the middle or low range of the fracture spectrum. For improved fixation stability, a titanium plate and bicortical screw can be inserted through an intraoral incision, a posterior mandibular incision, or a submandibular incision (with endoscope assistance). Following this, intermaxillary traction or ligation can be applied, and the patient can be observed for 1-2 weeks. Injectable bone peptide (Jiangxi Judu Pharmaceutical Co., Ltd., approval number: Guoyao Zhunzi H36022454, 2 mL/piece) was administered to the experimental group after standard surgical procedures including reduction and fixation. Give the patient an intravenous infusion once daily for four weeks after mixing 30 milliliters of osteopeptide with 250 milliliters of 0.9% sodium chloride.

One, two, and four weeks after surgery, patients were assessed. Notable indications include: (1) The patients' pain levels may be measured using the Numeric Rating Scale (NRS) score; (2) The levels of Interleukin-1 (IL-1) in the venous blood can be measured; and (3) The levels of Bone G-Glutamate (BGP) in the venous blood can be measured. The patient's reported degree of pain was used to calculate their NRS score; a score of 1-4 indicated mild pain, 5-6 indicated moderate pain, and 7-10 indicated severe pain. The rabbit anti-human IL-1 Polyclonal Antibody (WL00891) from Shenyang Wanlei Biotechnology Co., Ltd and the BGP test kit from ESYJXZZ 2401955 were used to evaluate the levels of IL-1 and BGP, respectively, in the blood samples that were taken after fasting. Aprotinin was used to preserve the blood after it was separated at 4°C.

Statistical analysis was performed on the data collected for this investigation using SPSS (Version 23.0; IBM, Armonk, NY, USA). The data were analyzed using a paired t-test and a Chi-squared test, and the NRS score, IL-1, and BGP were shown as mean ± standard error (x ± s). To illustrate statistical significance, a P-value less than 0.05 was used.

## Results

The results showed that at 1 and 2 weeks after operation, the NRS score of the experimental group was significantly lower than that of the control group ($P < 0.05$), indicating that the experimental group had less pain than the control group. However, 4 weeks after operation, there

was no statistical difference in NRS score between the two groups ($P > 0.05$), indicating that the difference in pain levels between the two groups was not significant.

Table 1 shows the comparison of NRS score between the experimental group and the control group at 1, 2, and 4 weeks after operation. The results indicate that the experimental group had a lower NRS score compared to the control group at 1 and 2 weeks postoperation ($P < 0.05$), while there was no statistical difference in NRS score between the two groups at 4 weeks postoperation ($P > 0.05$). The mean NRS score in the experimental group was 4.29 ± 0.53 at 1 week,
2.21 ± 0.52 at 2 weeks, and 0.42 ± 0.20 at 4 weeks. In the control group, the mean NRS score was 7.56 ± 1.13 at 1 week, 3.77 ± 0.86 at 2 weeks, and 0.38 ± 0.24 at 4 weeks.
The *t*-value for 1 week was 23.65, for 2 weeks was 14.00, and for 4 weeks was 1.15. The corresponding $P = 0.00$, $P = 0.00$, and $P = 0.07$ [Supplementary Table 1].

Comparison of IL-1β and BGP conditions after surgery 1, 2, and 4 weeks after surgery, the IL-1β levels in the experimental group were higher than those in the control group, with statistically significant differences ($P < 0.05$). The BGP levels in the experimental group were lower than those in the control group, with statistically significant differences ($P < 0.05$), as shown in Table 2 and Supplementary Table 2.

## Discussion

Osteopeptide is a light yellow, transparent injection extracted from fresh or lyophilized pig limb bones. It is made into a sterile, lyophilized product and can be mixed with normal saline or other solvents for intravenous injection. The drug is used in clinics to repair bone injuries and promote fracture healing, as well as to regulate the balance of calcium and phosphorus in bones.[2,3] Research has shown that osteopeptide is effective in treating various conditions, such as osteoporosis, hyperosteogeny, osteoarthritis, rheumatoid arthritis, and postoperative fractures.[4,5] It has been found to relieve pain, improve bone metabolism, reduce inflammation, and promote the recovery of spinal function.[6] Although osteopeptide has proven to be effective in treating fractures of the limbs, spine, and lumbar spine, there are few reports on its use for condylar fractures.[7-9]

**Table 1: Comparison of Numeric Rating Scale score between experimental and control groups at different time points**

| Group | 1 week | 2 weeks | 4 weeks |
|---|---|---|---|
| Experimental (*n*=82) | 4.29±0.53 | 2.21±0.52 | 0.42±0.20 |
| Control (*n*=82) | 7.56±1.13 | 3.77±0.86 | 0.38±0.24 |
| *t* | 23.65 | 14.00 | 1.15 |
| *P* | 0.00 | 0.00 | 0.07 |



**Table 2: Interleukin-1β compared with bone G-Gla protein level (x±s, μg/L)**

| Group | 1 week | | 2 weeks | | 4 weeks | |
|---|---|---|---|---|---|---|
| | IL-1β | BGP | IL-1β | BGP | IL-1β | BGP |
| Experimental (*n*=82) | 319.42±26.04 | 2.86±0.62 | 234.90±51.14 | 3.36±0.69 | 177.28±42.92 | 6.31±1.35 |
| Control (*n*=82) | 386.24±43.08 | 2.09±0.44 | 327.49±59.59 | 2.55±0.52 | 219.16±69.21 | 4.32±0.50 |
| *t* | 12.02 | 9.17 | 10.68 | 8.49 | 4.66 | 12.50 |
| *P* | 0.02 | 0.00 | 0.01 | 0.01 | 0.00 | 0.00 |

BGP=Bone G-Gla protein, IL-1β=Interleukin-1β

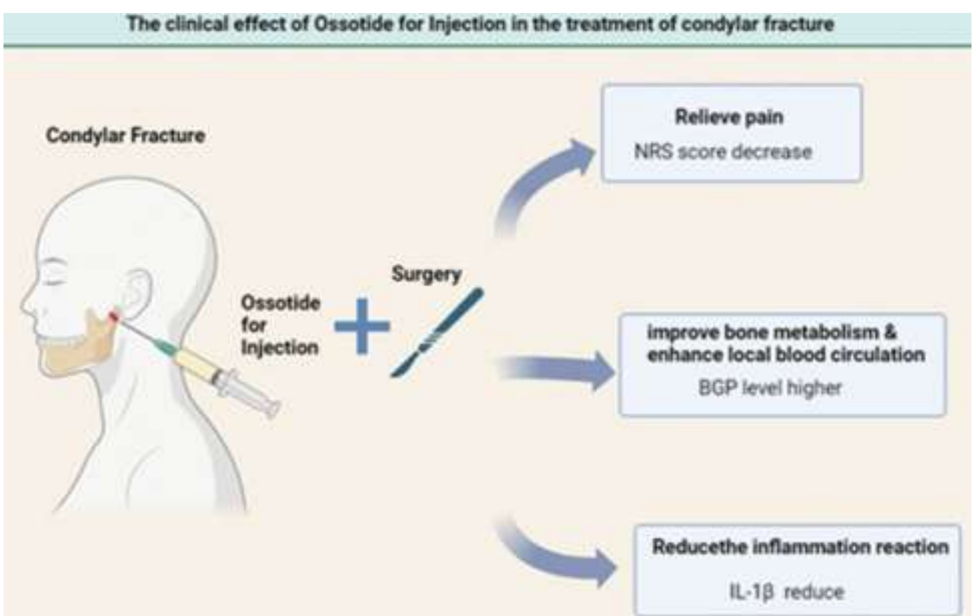


**Figure 1:** Graphical abstracts

Fractures of the condylar process, which may occur anywhere in the craniofacial region, can cause patients to experience excruciating pain that becomes worse very quickly. As a result of the severe pain, symptoms may include coldness, a pale complexion, and maybe shock. Consequently, it is crucial to lessen discomfort during surgery, facilitate tissue healing, and forestall postoperative problems.10, 11 After surgery, it is important to engage in functional recovery exercise to prevent muscular atrophy caused by inactivity. However, patients may be hesitant to continue muscular function training due to the inflammatory response and discomfort, which may impede the healing process. In addition to being a critical component of postoperative healing, reducing the discomfort experienced by patients with condylar fractures is an important aspect of compassionate care. Researchers have shown that injecting patients with osteopeptides in the early postoperative period greatly decreases pain (as indicated by the NRS score), which in turn allows for more efficient functional recovery training and lessens the likelihood of muscle atrophy. Perhaps as a result of the body's inherent ability to heal and tolerating pain, there was no discernible difference in pain levels between the two groups by the fourth week after surgery. The anti-inflammatory and pain-relieving properties of bone peptide injection are attributed to the presence of active peptides and trace elements derived from mammalian bones. Osteoblast-secreted bone growth protein (BGP) is a popular clinical biomarker of bone metabolism. BGP is a noncollagen protein.From 12 to 14, A rise in serum BGP levels indicates healthy fracture development and plays a crucial role in speeding up the healing process.references 15–17 The results of this research indicate that osteopeptide injection may help improve bone metabolism, increase local blood circulation, and speed up the healing process of condylar fractures. The injection group had greater BGP levels than the control group.

An inflammatory response is triggered by a condylar fracture, which hinders the body's normal tissue function and slows down the healing process. One of the body's main inflammatory factors is IL-1.both [18,19] When activated, it may promote the production and differentiation of osteoclasts, accelerate bone resorption, decrease bone density, harm the function of vascular endothelial cells, and increase the development of thrombus. It emerges and amplifies the inflammatory response during inflammation. The aggregation of inflammatory cells is caused by its content, which increases dramatically during the acute phase of inflammation.Twenty-one (21), In addition to regulating inflammation, it may increase the production of white blood cells, lead to hypercoagulability, and trigger immunological responses. Hence, IL-1β may interfere with the equilibrium of bone creation and bone resorption after a fracture, making the healing process more difficult.[22] is a An effective control of inflammatory variables, reduction of inflammation response, and promotion of bone formation were seen in this research after the adjunctive use of bone peptide injection, with a significant decrease in IL-1β in the patient's blood. Conclusions

The use of bone peptide injection as an adjuvant treatment following routine surgery for condylar fractures can significantly alleviate pain, enhance bone metabolism, and effectively control inflammation, promoting a quicker and more efficient healing process [Figure 1].


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## Conflicts of interest

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There are no conflicts of interest.

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