#### **Research Article**



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# Injectable ossotide's efficacy in treating condylar fractures

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#### **Abstract:**

This research aimed to assess the impact of osteopeptide injections as a supplemental therapy for condylar fractures on bone glycoprotein (BGP) and interleukin- $1\alpha$  (IL-1B) levels as well as pain management.

Two groups of eighty-two condylar neck fracture patients were randomly assigned. The experimental group received osteopeptide injections in addition to routine surgical treatments for the control group. At 1, 2, and 4 weeks after surgery, the levels of pain, IL-1, and BGP were measured. TWO WEEKS POST-SURGERY: On the Numerical Rating Scale, the experimental group fared better than the control group. At all three evaluation periods (1, 2, and 4 weeks postsurgery), the control group had higher BGP levels and lower IL-1 $\boxtimes$  levels, whereas patients who received osteopeptide injections had higher BGP levels and statistically significant differences (P < 0.05) in both.

CONCLUSIONS: After getting osteopeptide injections as an adjuvant therapy for condylar fractures, patients may have less discomfort and begin exercising their muscles more quickly. Another advantage of lowering inflammatory markers and boosting active osteogenesis is faster wound healing.

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

# Introduction

The condyle is one area of the craniofacial region that is prone to fracture. With the development of new medications, materials, imaging techniques, and therapeutic approaches, condylar fracture diagnostic and treatment approaches must change. It is crucial to control the patient's discomfort and promote tissue healing in order to prevent or treat any postoperative problems. This study assessed the clinical efficacy of using osteopeptide injections as an adjuvant treatment for condylar fractures.

### Materials and Methods

We divided 82 patients with condylar fractures who were admitted to our hospital between 2020 and 2022 into two groups using a random number system. http://powerandsamplesize.com was used to calculate the patient numbers. The average age of the 41 individuals in the experimental group was 33.54 ± 5.12 years, with ages ranging from 20 to 61. There were twenty men and twentyone women in the group. The control group consisted of 41 patients, 22 of whom were male and 19 of whom were female, ranging in age from 23 to 62. It was 34.11 ± 4.45 years old on average. After being fully informed about the treatment plans, goals, risks, and results of the study, patients granted their informed consent. As an element The prerequisites are as follows: A condylar neck fracture may need surgical reduction and stabilisation. Intracondylar fractures, subcondylar fractures, comminuted condylar fractures, and high fractures (characterised by lines on the condyle's surface) consideration in instances when surgery is taken into Middle and low condyle fractures were among the common surgical procedures performed on the patients in the control group.[1] In terms of fracture spectrum, all of the condylar neck fractures selected for this study fall into the medium or low range. An intraoral incision, a posterior mandibular incision, or a submandibular incision (with endoscopic aid) may be used to implant a titanium plate and bicortical screw for better fixation stability. After that, the patient may be monitored for one to two weeks while intermaxillary traction or ligation is used. The experimental group received injectable bone peptide (Jiangxi Judu Pharmaceutical Co., Ltd., approval number: GuoyaoZhunzi H36022454, 2 mL/piece) after routine surgical techniques, such as reduction and fixation. After combining 250 millilitres of 0.9% sodium chloride with 30 millilitres of osteopeptide, administer an intravenous infusion once daily for four weeks.

Patients were evaluated one week, two weeks, and four weeks after surgery. The following are noteworthy indications: (1) the Numeric Rating Scale (NRS) score may be used to gauge the patients' degree of discomfort; (2) the venous blood's levels of interleukin-1 (IL-1); and (3) the venous blood's levels of bone G-glutamate (BGP). The NRS score was determined by the patient's stated level of pain; a score of 1-4 denoted mild pain, a score of 5-6 moderate pain, and a score of 7-10 severe pain. The levels of IL-1 and BGP in the blood samples obtained after fasting were assessed using the rabbit anti-human IL-1 Polyclonal Antibody (WL00891) from Shenyang Wanlei Biotechnology Co., Ltd. and the BGP test kit from ESYJXZZ 2401955, respectively. The blood was separated at 4°C and preserved with

The data gathered for this study was subjected to statistical analysis using SPSS (Version 23.0; IBM, Armonk, NY, USA). The NRS score, IL-1, and BGP were shown as mean  $\pm$  standard error (x  $\pm$  s) after the data were examined using a paired t-test and a Chi-squared test. Statistical significance was shown using a P-value of less than 0.05.

# **Results**

The experimental group's NRS score was considerably lower than the control group's at 1 and 2 weeks following surgery (P<0.05), suggesting that the experimental group had less pain than the control group. Nevertheless, four weeks after surgery, there was no statistically significant difference in the two groups' NRS scores (P > 0.05), suggesting that the two groups' pain levels differed insignificantly.

The NRS scores for the experimental and control groups at 1, 2, and 4 weeks after surgery are compared in Table 1. The findings show that at 1 and 2 weeks after surgery, the experimental group's NRS score was lower than the control group's (P < 0.05), but after 4 weeks, there was no statistically significant difference in the two groups' NRS scores (P > 0.05). At one week, the experimental group's mean NRS score was  $4.29\pm0.53$ .

At two weeks,  $2.21\pm0.52$ , and at four weeks,  $0.42\pm0.20$ . The mean NRS score for the control group was  $7.56\pm1.13$  at one week,  $3.77\pm0.86$  at two weeks, and  $0.38\pm0.24$  at four weeks. The t-value was 23.65 for one week, 14.00 for two weeks, and 1.15 for four weeks. P = 0.00, P = 0.00, and P = 0.07 are the matching values [Supplementary Table 1]. When IL-1 levels and BGP conditions were compared 1, 2, and 4 weeks after surgery, the experimental group's levels were greater than the control group's, with statistically significant differences (P<0.05). Table 2 and Supplementary Table 2 demonstrate that the experimental group's BGP levels were lower than those of the control group, with statistically significant differences (P<0.05).

# **Discussion**

Osteopeptide is a translucent, pale yellow injectable that is taken from freshly or lyophilised pig limb bones. It may be combined with regular saline or other solvents for intravenous injection and is converted into a lyophilised, aseptic product. In clinics, the medication is used to treat bone damage, encourage fracture healing, and control the ratio of calcium to phosphorus in bones. [2, 3] Numerous disorders, including osteoporosis, hyperosteogeny, osteoarthritis, rheumatoid arthritis, and postoperative fractures, have been shown to respond well to osteopeptide treatment. [4,5] It has been shown to lessen inflammation, enhance bone metabolism, ease pain, and aid in the rehabilitation of spinal function. [6] Few studies have examined the use of osteopeptide for condylar fractures, despite the fact that it has shown promise in treating fractures of the soft limbs, spine, and lumbar spine. [7–9]

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

<u>Group</u>	1week	2weeks	4weeks
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
<u>P</u>	0.00	0.00	0.07

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Table 2: Interleukin-1βcompared with bone G-Glaprotein level (x±s, μg/L)

1week		2weeks		4weeks	
	BGP		BGP	IL-1β	BGP
319.42±26.04	2.86±0.62	234.90±51.14	3.36±0.69	177.28±42.92	6.31±1.35
386.24±43.08	2.09±0.44	327.49±59.59	2.55±0.52	219.16±69.21	4.32±0.50
12.02	9.17	10.68	8.49	4.66	12.50
0.02	0.00	0.01	0.01	0.00	0.00
	IL-1β 319.42±26.04 386.24±43.08 12.02	IL-1β BGP  319.42±26.04 2.86±0.62  386.24±43.08 2.09±0.44  12.02 9.17	IL-1β     BGP     IL-1β       319.42±26.04 $2.86\pm0.62$ $234.90\pm51.14$ 386.24±43.08 $2.09\pm0.44$ $327.49\pm59.59$ 12.02 $9.17$ $10.68$	IL-1β     BGP     IL-1β     BGP       319.42±26.04 $2.86\pm0.62$ $234.90\pm51.14$ $3.36\pm0.69$ 386.24±43.08 $2.09\pm0.44$ $327.49\pm59.59$ $2.55\pm0.52$ 12.02 $9.17$ $10.68$ $8.49$	IL-1β     BGP     IL-1β     BGP     IL-1β       319.42±26.04 $2.86\pm0.62$ $234.90\pm51.14$ $3.36\pm0.69$ $177.28\pm42.92$ 386.24±43.08 $2.09\pm0.44$ $327.49\pm59.59$ $2.55\pm0.52$ $219.16\pm69.21$ 12.02 $9.17$ $10.68$ $8.49$ $4.66$

 $BGP = Bone G\text{-}Glap rotein, IL\text{-}1\beta = Interleukin\text{-}1\beta$ 

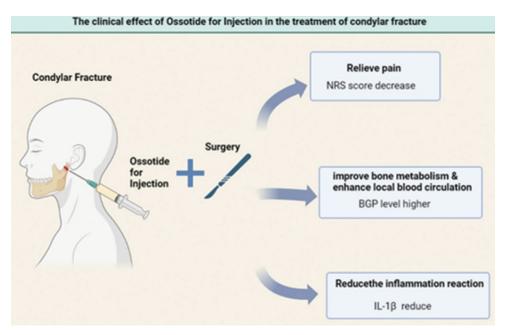


Figure1:Graphicalabstracts

Anywhere in the craniofacial area, condylar process fractures may cause patients to suffer from intense pain that becomes worse very rapidly. Symptoms may include paleness, coldness, and maybe shock due to the intense pain. Therefore, reducing surgical pain, promoting tissue repair, and preventing postoperative complications are critical. 10, 11 Exercise for functional rehabilitation is crucial after surgery to avoid the atrophy of muscles brought on by inactivity. However, because of the pain and inflammatory reaction, patients could be reluctant to continue muscular function training, which might delay the healing process. Reducing the agony that patients with condylar fractures endure is not only a vital part of postoperative recovery, but it is also a crucial component of compassionate care. According to research, giving patients osteopeptide injections in the early postoperative phase significantly reduces pain (as measured by the NRS score), which enables more effective functional recovery training and reduces the risk of muscle atrophy. By the fourth week after surgery, there was no appreciable difference in the two groups' pain levels, perhaps due to the bodv's natural capacity for healing and nain Active peptides and trace elements produced from mammalian bones are responsible for the antiinflammatory and pain-relieving effects of bone peptide injection. BGP, a protein released by osteoblasts, is a widely used clinical diagnostic of bone metabolism. BGP is a protein that is not collagen.A increase in serum BGP levels between the ages of 12 and 14 signifies the formation of healthy fractures and is essential for accelerating the healing process references 15–17 According to the study's findings, osteopeptide injection may enhance local blood circulation, promote bone metabolism, and hasten the healing of condylar fractures. BGP levels were higher in the injection group compared A condylar fracture causes an inflammatory reaction that slows down the healing process and impairs the body's normal tissue function. IL-1 is one of the primary inflammatory factors in the body. [18, 19] When triggered, it may enhance the formation of thrombus, accelerate bone resorption, reduce bone density, damage the function of vascular endothelial cells, and encourage the synthesis and differentiation of osteoclasts. During inflammation, it manifests and intensifies the inflammatory response. Its content, which rises sharply during the acute phase of inflammation, is what causes inflammatory cells to aggregate. Twenty-one (21) It may cause hypercoagulability, stimulate immunological reactions, and boost white blood cell formation in addition to controlling inflammation. Therefore, after a fracture, IL-1 may disrupt the balance between bone formation and bone resorption, making the healing process more challenging.[22] is a Following the adjunctive use of bone peptide injection, this study observed a substantial drop in IL-1 in the patient's blood, as well as an effective management of inflammatory variables, reduction of inflammation response, and stimulation of bone production. Conclusions

When used as an adjuvant therapy after normal surgery for condylar fractures, bone peptide injection may successfully reduce inflammation, improve bone metabolism, and greatly reduce pain, all of which contribute to a faster and more effective healing process [Figure 1].

# References

- 1. YangSY,MaYF.Progressinthetreatmentofcondylarfractures and research. Electronic J Gen Stomatol 2017;4:57-8.
- 2. ZhuLY,XieYY,WenBT,YeML,LiuYS,K.M.S.Uetal.Porcinebone collagen peptides promoteosteoblastproliferation and differentiation by activating the PI3K/Akt signaling pathway. JFunct Foods 2020;64:10369.
- 3. ZhangK,LiB,ChenQ,ZhangZ,ZhaoX,HouH.Functionalcalciumbinding peptides from pacific cod (*Gadusmacrocephalus*) bone:Calcium bioavailability enhancing activity and anti-osteoporosiseffectsintheovariectomy-inducedosteoporosisratmodel.
  - Nutrients 2018;10:1325.
- ZhuJR.Clinicaleffectoftechnetium[99tc]methylenediphosphonateinjection on postmenopausal osteoporosis patients. China ModMed 2019;26:65-7, 74.
- 5. WangJ,XuS,LiuHY.Hiddenbloodossduringposteriorlumbarinterbody fusion in lumbar spinal stenosis patients with and without rheumatoidarthritis.Chin]TissueEngRes2020;24:5307-14.
- 6. Xiao F, Qu XC, Fang ZY, Yan J. Effect of ossotide injection onpain in patients with limb fracture and its influence on bonemetabolism and inflammatory factor. Chin Foreign Med Res2019;17:137-8.
- Yang L, Liu TS, Wu DB. The clinical effect of ossotide injectionand risedronate for the treatment of lumbar bone tissue repairafter surgery for fracture. J ClinExp Med 2017;16:675-7.
- 8. Xu T. Observation of the effect of bone peptide injection combined with risedronate sodium in the treatment of postoperative patients with lumbar fracture. Contemp Med 2017;23:114-5.
- 9. WuJF.Effectofossotideinjectiononboneformationindexandhemorheology in patients with spinal fracture. Med Innov China2022;19:58-62.
- 10. McLeodNM,KeenanM.Towardsaconsensusforclassificationof mandibular condyle fractures. J CraniomaxillofacSurg 2021;49:251-5.
- ZhouHH,LiuQ,ChengG,LiZB.Aetiology,patternandtreatmentof mandibular condylar fractures in 549 patients: A 22-yearretrospective study. J CraniomaxillofacSurg 2013;41:34-41.
- ZhaoY,YinK,ChenHD,ShangXH.Observationoftheeffectofbone peptide injection on postoperative patients with complextibial plateau fracture. J Shandong Med J 2018;58:69-71.
- 13. Atluri K, Lee J, Seabold D, Elangovan S, Salem AK. Gene-activated titanium surfaces promote in vitro osteogenesis. Int J Oral Maxillofac Implants 2017;32:e83-96.
- 14. Gossiel F, Paggiosi MA, Naylor KE, McCloskey EV, Walsh J,PeelN,etal.Theeffectofbisphosphosphonatesonboneturnoverandbonebalanceinpostmenopausalwomenwithosteoporosis:The T-score bone marker approach in the TRIO study. Bone 2020;131:115158.
- 15. Jin Y. Experimental Study of the Effect of Experience Fang HuoxueJieGu Decoction Antagonism Etoricoxib on BGP and TGF-1during Fracture Healing. D Guangxi University of ChineseMedicine; 2018.
- 16. LiX,LiuD,LiJ,YangS,XuJ,YokotaH,*etal*.Wnt3ainvolvedinthemechanicalloadingonimprovementofboneremodelingandangiogenesis in postmenopausal osteoporosis mouse model.FASEB J 2019;33:8913-24.
- 17. BeilerTF,deMelloNetoJM,AlvesJC,HamletS,IpeD,da Silva Figueredo CM. Impact of non-surgical periodontaltreatment on salivary expression of cytokines related to bonemetabolism. Odontology 2020;108:646-52.
- 18. Xia LX, Wang H, Jian LI. Effect of ossotide injection combined with tan shin one injection on postoperative levels of serum bone marker and joint function of tibia fracture. Chin J Biochem Pharm 2016; 36:151-153.
- 19. AristizabalJF,RíosH,ReyD,ÁlvarezMA,ParraPatiñoB, Ortiz M. Interleukin 1-beta (IL-12) polymorphism andorthodontics: A systematic review. Journal of the Faculty of Dentistryat Antioquia University 2019;31:147-161. [Doi:10.17533/UDEA.RFO.V31N1-2A13].
- 20. Wang L. Effect of injection of bone peptide on the treatment offracture healing and nursing observation. Drug Eval 2019;16:2.
- 21. Kresnoad U, Prabow TS. Expression of interieukin-1 and TGFdue to inducion with natural Propolisexract and bovine bonegraft combinaon in tooth extraction sockets leading to alveolarbone regeneration. J Int Dent Med Res 2020;13:938-45.
  - 22. WuX.Effectsofcelecoxibcapsulesoninflammatoryfactorsandhemorheologyinpatientswithdelayedlimbfracturehealing. J Hubei UnivSciTechnol (Med Sci) 2018;32:3.