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Original Article

Mini suture anchor: An effective device for reduction and fixation of displaced temporomandibular joint disc with intracapsular condylar fracture

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ABSTRACT

Purpose: The main aim is to provide clinical reference for the application of mini suture anchor in the reduction and fixation of displaced temporomandibular joint (TMJ) disc with intracapsular condylar fracture.

Methods: From October 2018 to October 2019, 21 patients (31 sides) with intracapsular condylar fractures and articular disc displacement from West China Hospital of Stomatology, Sichuan University were included. The selection criteria were: (1) mandibular condylar fractures accompanied by displacement of the TMJ disc, confirmed by clinical examination, CT scan and other auxiliary examinations; (2) indication for surgical treatment; (3) no surgical contraindications; (4) no previous history of surgery in the operative area; (5) no facial nerve injury before the surgery; (6) informed consent to participate in the research program and (7) complete data. Patients without surgical treatment were excluded. The employed patients were followed up at 1, 3, 6 and 12 months after operation. Outcomes were assessed by success rate of operation, TMJ function and radiological examination results at 3 months after operation. Data were expressed as number and percent and analyzed using SPSS 19.0.

Results: All the surgical procedures were completed successfully and all the articular discs were firmly attached to the condyles. The articular disc sufficiently covered the condylar head after the fixation. The fixation remained stable when the mandible was moved in each direction by the surgeons. No complications occurred. The functions of the TMJ were well-recovered postoperatively in most cases. CT scan revealed that the screws were completely embedded in the bone without loosening or displacement. *Conclusion:* Mini suture anchor can provide satisfactory stabilization for the reduced articular disc and also promote the recovery of TMJ functions.

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Introduction

Mandibular condylar fractures, one of the most common but technique-demanding facial fractures, usually result in malocclusion, limited mouth opening, and dysmasesia, which cause serious problems in patients' daily and social lives.^{1–3} Mandibular condylar fractures can be divided into intracapsular fracture, neck fracture and sub-condylar fracture. Among the three patterns, intracapsular condylar head fracture, also known as condylar head fracture, is a hot topic and has been largely discussed.^{3–5} In the past, surgeons believe that the condyle is capable of self-reconstruction, and thus

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conservative treatment was commonly chosen for this fracture. With a better understanding of the intracapsular condylar fracture (ICF) and accumulated clinical practices in its management, many literatures have reported that patients with ICF after conservative treatment tends to suffer from temporomandibular joint (TMJ) disorders, joint pain, limited range of mouth opening, masticatory difficulty and mandibular movement dysfunctions.^{4–7} Therefore, surgical treatment is gradually becoming the preferred choice for addressing ICFs.

In 1988, Chuong and Piper⁸ reported that usually the TMJ disc is closely connected to the condylar head, and thus in the case of fracture the TMJ disc can easily shift following the displaced condylar head. Zheng et al.⁹ stated in 2016 that ICF combines a higher incidence of disc displacement than condylar neck or sub-condylar fracture, which ranges from 75% to 100%.^{10–12} Dislocation of the TMJ disc is a common concomitant injury in ICFs. If

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displacement of the disc has not been restored simultaneously, temporomandibular disorders may occur, even ankylosis in the long-term. Therefore, reduction of the articular disc is an important key factor to achieve satisfactory results after surgical management of ICFs.¹³

After reduction of the articular disc, a stable fixation of the disc to the condyle is of vital significance. In the past, methods commonly used include drilling a hole or inserting a screw into the condyle or zygomatic arch, and then using silk or steel wire to fix the disc to the hole or screw.^{14–17} These methods are complex procedures. Sometimes screw loosening or suture breakage occurs during the surgical process or postoperatively. In recent years, mini suture anchor has been successfully designed and applied in orthopedic clinical practices, e.g. rotator cuff repair, medial and lateral ligament repair, with a high success rate.^{18,19}

In this article, the authors introduced the use of mini suture anchor in oral and maxillofacial surgery to fix the displaced TMJ discs. We aimed to evaluate the clinical effect and application value of mini suture anchor in the reduction and fixation of TMJ disc displacement following ICFs. We hypothesized that utilizing the mini suture anchor is a simple procedure during surgery, which can provide a good reliable fixation of the TMJ disc.

Methods

Study design

This was a prospective, non-controlled clinical trial approved by the research ethics committee of West China Hospital of Stomatology, Sichuan University (WCHSIRB-D-2017-216).

Patients with the following criteria were included: (1) clinical examination, CT and other auxiliary examinations suggested fracture of the mandibular condylar accompanied by displacement of the TMJ disc; (2) indication for surgical treatment; (3) no surgical contraindications; (4) no previous history of surgery in the operative area; (5) no facial nerve injury before the surgery; (6) informed

Table 1

consent to participate in the research program and (7) complete data. Patients were excluded if: (1) they denied surgical treatment, or (2) the follow-up time was less than 3 months.

For the study purpose, 21 patients with 31 sides of mandibular condylar head fractures and displaced TMJ disc were enrolled from October 2018 to October 2019. There were 5 females and 16 males with 11 unilateral and 10 bilateral condylar fractures. The average age of patients was 39.33 years. The mechanism of injury consisted of road accident and fall. Only 9.52% of cases did not have any other concomitant fractures. The demographic data of patients are shown in Table 1.

Equipments

All the preoperative and postoperative imaging data were collected using Brilliance CT apparatus. The mini suture anchor used was DePuy Mitek Mini Quickanchor plus (Johnson & Johnson, USA) (Fig. 1).

As shown in Fig. 1, mini suture anchor consists of an anchor and 2 preloaded sutures with needles. The main body of the mini suture anchor in this study is cylindrical in shape, 1.8 mm in diameter and 5.4 mm in length. Mini suture anchor has the wings of nickel titanium alloy, which utilizes the super-elastic memory properties. An eyelet in the posterior aspect of the anchor has the pre-loaded orthocord dual sutures with the needle attached to the inserter device and suture retaining cap. The orthodcord suture is synthetic, sterile, braided and composite of absorbable polydiaxanone and unabsorbable polyethylene. It is presterilized by ethylene oxide and comes with disposable inserter handle and suture retaining cap, along with disposable drill bits in each packet.

Surgical procedures

All the operations were performed under general anesthesia through nasal intubation. Supratemporalis approach with preauricular incision²⁰ was chosen to expose the capsule of the TMJ. A

Demographic data of the 21 patients with mandibular condylar head fractures and articular disc displacement.

Characteristics	Frequency (n)	Percent (%)
Gender		
Male	16	76.19
Female	5	23.81
Etiology		
Road accident	9	42.86
Fall	12	57.14
Type of intracapsular fractures		
Unilateral	11	52.38
Bilateral	10	47.62
Concomitant fractures		
Fracture in other parts of the mandible	19	90.48
Facial fractures other than mandible	7	33.33
Fractures in other body parts (limb, rib, cervical verterbra, etc.)	4	19.05



Fig. 1. Mini suture anchor. (A) The appearance of mini suture anchor; (B) The composition of mini suture anchor (a: the wings, b: the orthocord suture; c: the mini anchor screw; d: the handle).



Fig. 2. The procedure and schematic of implanting suture anchor. (A) The suture anchor was pushed into the posterior outer edge of the condyle. (B) The anchor screw was placed in the hole and two sutures with needle were led out from the hole. (C) TMJ disc was repositioned and fixed on the condyle. (D) Schematic illustration (a: The articular disc; b: The screw osteosynthesis; c: TMJ capsule; d: Mini suture anchor).

diluted saline solution of epinephrine was injected in the joint space, then an inverted "T" was made to expose the joint. The fractured portion of the condylar head was firstly located, reduced and fixed. Following the reduction of the condylar head, sometimes the disc came back to its original position. If it has not come back to its original position, the disc can be located by inferiorly retracting the mandible. Once the disc has been located, the ligament that adhesions between the disc and the surrounding tissue was loosened. Then the disc could be pulled back and out to its original position or overcorrected position. After the disc has been confirmed to be completely reduced, a hole was drilled on the condylar neck, usually on the posterolateral side of the condylar neck, approximately 8-10 mm below the top of condyle and 4-5 mm inferior to the fractured line. Then, the anchor was inserted into the hole (Fig. 2A). The wings of the mini suture anchor will be stuck on the wall of the hole. After inserting the mini anchor. the slide cover was retracted to be fully open so as to release the sutures and needles from the inserter handle and suture retaining cap (Fig. 2B). Each suture was inserted in the posterior outer aspect of the disc, needles were cut, sutures were pulled outward, downward and tightened to make the disc firmly attached to the condylar head and a knot was made in the end (Fig. 2C and D). If necessary, a second mini suture anchor was placed either medially or laterally to the first one for better stabilization of the TMJ disc. Occlusion and disc-condyle mobility were checked. The surgical site was profusely irrigated and the lateral capsule was sutured using 3-0 antibacterial Vicryl suture. A layered closure of the incision was complete using 4-0 antibacterial Vicryl suture subdermally followed by 5-0 prolene on skin. Patients were followed up at 1, 3, 6 and 12 months after operation.

Data collections

Postoperatively, CT and clinical examination of all the patients were conducted and recorded. Postoperative follow-up visits were done in 1, 3, 6 and 12 months. Clinical follow-up was done by 2 surgeons who were in the surgical team. Radiological analysis was done by 2 doctors not in the surgical team. The outcome variables included the success rate of operation, TMJ function and radiological examination results at follow-up of 3 months after operation. Data were expressed as number and percent and analyzed using SPSS 19.0 (IBM Corp., Armonk, New York, USA).

Results

All the surgical procedures were completed successfully. Intraoperatively, among the 31 sides of fractures, 14 were fixed with one mini suture anchor and 17 fixed with two mini suture anchors. After fixation, the TMJ disc and condyle mobility was checked. All

Table 2

Temporomandibular joint function of the 21 cases of mandibular condylar head fractures and articular disc displacement at 3 months after reduction and fixation with mini suture anchor, n (%).

Temporomandibular joint function	Normal	Abnormal
Mouth opening	19 (90.48)	2 (9.52)
Laterotrusive movement	20 (95.24)	1 (4.76)
Protrusive movement	21 (100.00)	0(0)
Occlusal evaluation	20 (95.24)	1 (4.76)
Lateral deviation while mouth opening	18 (85.71)	3 (14.29)
Joint noises	21 (100)	0(0)
TMJ discomforts (pain, heaviness)	20 (95.24)	1 (4.76)

Note: Normal mouth opening >3.5 cm.

the articular discs sufficiently covered the condylar heads after fixation. The fixations remain stable when the mandible was moved in each direction by the surgeon. No intraoperative complications occurred.

One week postoperatively, all the incisions healed without bleeding, facial nerve injury, salivary fistula, wound infections or other complications. The average follow-up time was 6.6 months. Table 2 shows the postoperative follow-up clinical examination result after 3 months. Most of the patients were well recovered in aspect of mouth opening and mandibular movements, indicating a well-recovered TMJ function following surgery.

Also, postoperative CT examination at 3 months postoperatively showed that all the mini suture anchors were firmly placed within the bone without any loosening or displacement (Fig. 3). Among the 31 sides of ICFs, 26 were anatomically reduced and 5 had acceptable reduction.

Discussion

Failure to reduce the displaced disc with ICFs often causes continued anterior displacement resulting in deformation of the disc, including folding, enlargement of the posterior band, and even thickening and increased convexity. So, some scholars tried to solve this problem with surgery. It has been proved that reduction and fixation of TMJ disc with complete closure of the articular capsule can effectively reduce the incidence of both TMJ disorder and joint ankylosis.²¹ Therefore, many surgeons also agree that reduction and fixation of the TMJ disc is one of the key factors for successful surgical treatment of ICF.^{22,23} For patients with displacement or tear of the TMJ disc, surgical management should be the first choice of treatment.

Annandale²⁴ was the first person to describe disc repositioning, after which McCarty employed a similar technique. After that, the most commonly used method for repositioning and fixation of TMJ disc is to place mini or micro screws at the posterolateral edge of



Fig. 3. CT image at 3 months postoperatively shows anatomical reduction and the mini suture anchors. Red arrow indicates the mini anchor screw within the bony surface.

the condyle, and then use silk thread on the lateral and posterolateral sides of the TMJ disc, then rotate the silk thread around the screws and finally knot and fix.²⁵ This method does not require extra equipment, but the procedure is tedious. Moreover it is not stable enough and has the risk of recurrent disc displacement. To improve the fixation method of articular disc, some scholars used mini traction screw to fix the articular disc.²⁶ There is a hole in the tail of the traction screw, and the disc can be fixed to the screw by stitching with silk thread or polypropylene thread through the hole and then stabilized by knotting. However mini traction screws have exposed the head outside the bone, which may lead to screw loosening due to constant frequent movement between the mandible over time, therefore there is need of observation for its long-term stability. In addition, silk suture does not have histocompatibility and may get broken apart or loosened with time going, whereas polyprolene suture used in general surgery is mostly designed to be used for soft tissues, and thus the strength is relatively weak, so there is a risk of breaking apart when used for fixation of articular disc. Then Wolford²⁷ firstly reported the disc repositioning surgery with anchor screw. After that, Albilia et al.²⁸ shared the effective use of anchor screws in disc repositioning after TMJ pathologies in a case report. However, the screws reported in the above studies did not carry any sutures. The surgeons still need to insert and fix the sutures and the screws during the procedure, therefore making the manipulation complicated and lengthened the surgical duration.

In this study, the authors introduced mini suture anchor used in their department of orthopaedics to fix the TMJ disc. The results showed that surgical procedures were carried out successfully in all the cases. Intraoperatively, fixation of the disc was examined for its stability and reliability, also the mobility of condyle was examined. All the articular discs sufficiently covered the condylar heads after

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fixation. The fixations were stable when the mandible was moved in each direction by the surgeon. Postoperative CT revealed that the anchor screws were placed firmly and the screw was completely embedded in the bone without loosening or displacement. Postoperative follow-up showed that most patients achieved significantly improved TMJ disc function (mouth opening and mandibular movement) in comparison to that before operation. The results showed that mini suture anchor can provide a good stability of the TMJ disc fixation and help for a good rehabilitation of TMJ function, thereby increasing the likelihood of a satisfactory therapeutic outcome.

Compared with the traditional disc fixation methods, mini suture anchor has the following advantages: (1) after insertion of the screw in the bone, the main body gets completely embedded with only 2 sutures coming out of the bone surface. Thus the osseointegration property provides better and long-term stability; (2) the surgical procedure is simple and quick as suture is connected to the screw, and the TMJ disc could be fixed just by inserting the suture, pulling and tying the knot; (3) the sutures attached to the mini anchor are the composite of absorbable polydiaxanone and unabsorbable polyethylene, which has strong strength and provides better stability for a long period of time. There is also disadvantage of this device. It is more expensive than conventional screw. However, taking the treatment effectiveness into account, the authors believe that the additional cost for using mini suture anchor were acceptable and appropriate.

According to the authors' experiences, this device could also be used for other purposes, such as fixation of displaced TMJ disc with TMJ disorder, inner canthal ligament and lateral canthus ligament with orbit fractures. In fact, these studies are still in progress and the results will be reported later.

This study is a preliminary study on the fixation of TMJ disc with mini suture anchor after condylar fractures. There are still several limitations in this study, such as lack of control, small sample sizes, only a single center study, etc. As a result, selection bias and confounding bias may still exist. Hence a multicenter clinical study with larger populations is still required to confirm the practical value of this technique in the treatment of the ICF.

In conclusion, mini suture anchor could provide a promising outcome in the stable reduction and fixation of TMJ disc with ICFs.

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Ethical statement

This study has been approved by the responsible committee (WCHSIRB-D-2017-216) and informed consent has been obtained from all the patients or relatives.

Declaration of competing interest

The authors declare no conflicts of interest.

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Author contributions

Conception and design: Lei Liu; Development of methodology: Shubhechha Shakya; Acquisition of data: Shubhechha Shakya, Kai-De Li and Dou Huang; Analysis and interpretation of data: Shubhechha Shakya, Zuo-Qiang Liu and Zhi-Ru Liu; Writing, review, and revision of the manuscript: Shubhechha Shakya and Lei Liu; Study supervision: Lei Liu.

References

- Fama F, Cicciu M, Sindoni A, et al. Maxillofacial and concomitant serious injuries: an eight-year single center experience. *Chin J Traumatol*. 2017;20:4–8. https://doi.org/10.1016/j.cjtee.2016.11.003.
- Sambataro S, Cervino G, Bocchieri S, et al. TMJ dysfunctions systemic implications and postural assessments: a review of recent literature. *J Funct Morphol Kinesiol.* 2019;4:58. https://doi.org/10.3390/jfmk4030058.
- Valiati R, Ibrahim D, Abreu ME, et al. The treatment of condylar fractures: to open or not to open? A critical review of this controversy. *Int J Med Sci.* 2008;5: 313–318. https://doi.org/10.7150/ijms.5.313.
- He D, Yang C, Chen M, et al. Intracapsular condylar fracture of the mandible: our classification and open treatment experience. J Oral Maxillofac Surg. 2009;67:1672–1679. https://doi.org/10.1016/j.joms.2009.02.012.
- Vesnaver A. Open reduction and internal fixation of intra-articular fractures of the mandibular condyle: our first experiences. *J Oral Maxillofac Surg.* 2008;66: 2123–2129. https://doi.org/10.1016/j.joms.2008.06.010.
 Boffano P, Corre P, Righi S. The role of intra-articular surgery in the manage-
- Boffano P, Corre P, Righi S. The role of intra-articular surgery in the management of mandibular condylar head fractures. *Atlas Oral Maxillofac Surg Clin North Am.* 2017;25:25–34. https://doi.org/10.1016/j.cxom.2016.10.001.
- Hirjak D, Machon V, Beno M, et al. Surgical treatment of condylar head fractures, the way to minimize the postraumatic TMJ ankylosis. *Bratisl Lek Listy*. 2017;118:17–22. https://doi.org/10.4149/BLL_2017_004.
- Chuong R, Piper MA. Open reduction of condylar fractures of the mandible in conjunction with repair of discal injury: a preliminary report. J Oral Maxillofac Surg. 1988;46:257–263. https://doi.org/10.1016/0278-2391(88)90003-1.
- Zheng J, Zhang S, Yang C, et al. Assessment of magnetic resonance images of displacement of the disc of the temporomandibular joint in different types of condylar fracture. Br J Oral Maxillofac Surg. 2016;54:74–79. https://doi.org/ 10.1016/j.bjorns.2015.10.005.
- Yu YH, Wang MH, Zhang SY, et al. Magnetic resonance imaging assessment of temporomandibular joint soft tissue injuries of intracapsular condylar fracture. *Br J Oral Maxillofac Surg.* 2013;51:133–137. https://doi.org/10.1016/ j.bjoms.2012.03.019.
- Chen M, Yang C, He D, et al. Soft tissue reduction during open treatment of intracapsular condylar fracture of the temporomandibular joint: our institution's experience. J Oral Maxillofac Surg. 2010;68:2189–2195. https:// doi.org/10.1016/j.joms.2009.09.063.
- He D, Yang C, Chen M, et al. Effects of soft tissue injury to the temporomandibular joint: report of 8 cases. Br J Oral Maxillofac Surg. 2013;51:58–62. https://doi.org/10.1016/j.bjoms.2012.02.005.

- He D, Cai Y, Yang C. Analysis of temporomandibular joint ankylosis caused by condylar fracture in adults. J Oral Maxillofac Surg. 2014;72. https://doi.org/ 10.1016/j.joms.2013.12.015, 763.e1-9.
- Yan G, Zhou Q, Yang M. A new method to reposition the displaced articular disc for a patient with comminuted condylar fracture. J Craniofac Surg. 2019;30: e373–e376. https://doi.org/10.1097/SCS.00000000005384.
- Mehra P, Wolford LM. Use of the Mitek anchor in temporomandibular joint disc-repositioning surgery. SAVE Proc. 2001;14:22–26. https://doi.org/10.1080/ 08998280.2001.11927726.
- Shakya S, Zhang X, Liu L. Key points in surgical management of mandibular condylar fractures. *Chin J Traumatol.* 2020;23:63–70. https://doi.org/10.1016/ j.cjtee.2019.08.006.
- Zhang S, Liu X, Yang X, et al. Temporomandibular joint disc repositioning using bone anchors : an immediate post surgical evaluation by Magnetic Resonance Imaging. BMC Muscoskel Disord. 2010;11:262. https://doi.org/10.1186/1471-2474-11-262.
- Chaudhry S, Dehne K, Hussain F. A review of suture anchors. Orthop Traumatol. 2019:263–270. https://doi.org/10.1016/j.mporth.2016.12.001.
- Visscher LE, Jeffery C, Gilmour T, et al. The history of suture anchors in orthopaedic surgery. *Clin Biomech.* 2019;61:70–78. https://doi.org/10.1016/ j.clinbiomech.2018.11.008.
- Li H, Zhang G, Cui J, et al. A modified preauricular approach for treating intracapsular condylar fractures to prevent facial nerve injury: the supratemporalis approach. J Oral Maxillofac Surg. 2016;74:1013–1022. https:// doi.org/10.1016/j.joms.2015.12.013.
- Li ZB, Li Z, Shang ZJ, et al. Potential role of disc repositioning in preventing postsurgical recurrence of traumatogenic temporomandibular joint ankylosis: a retrospective review of 17 consecutive cases. Int J Oral Maxillofac Surg. 2006;35:219–223. https://doi.org/10.1016/j.ijom.2005.06.021.
- Kolk A, Neff A. Long-term results of ORIF of condylar head fractures of the mandible: a prospective 5-year follow-up study of small-fragment positionalscrew osteosynthesis (SFPSO). J Cranio-Maxillofacial Surg. 2015;43:452–461. https://doi.org/10.1016/j.jcms.2015.02.004.
 He D, Yang C, Zhang S, et al. Modified temporomandibular joint disc reposi-
- He D, Yang C, Zhang S, et al. Modified temporomandibular joint disc repositioning with miniscrew anchor: part i surgical technique. J Oral Maxillofac Surg. 2015;73. https://doi.org/10.1016/j.joms.2014.06.452, 47.e1-e9.
- Annandale T. On displacement of the inter-articular cartilage of the lower jaw, and its treatment by operation. *Lancet.* 1887;129:411. https://doi.org/10.1016/ S0140-6736(02)28282-3.
- 25. Cai BL, Ren R, Yu HB, et al. Do open reduction and internal fixation with articular disc anatomical reduction and rigid anchorage manifest a promising prospect in the treatment of intracapsular fractures? J Oral Maxillofac Surg. 2018;76:1026–1035. https://doi.org/10.1016/j.joms.2017.12.015.
- Pessoa PF, De Brito Silva LN, et al. Utilization of intermaxilar fixation screws as anchors in the treatment of the mandible recurrent dislocation. J Craniofac Surg. 2019;30:1272–1274. https://doi.org/10.1097/SCS.000000000005301.
- Gonçalves JR, Cassano DS, Rezende L, et al. Disc repositioning does it really work ? Oral Maxillofac. Surg.NA. 2015;27:85–107. https://doi.org/10.1016/ j.coms.2014.09.007.
- Albilia JB, Weisleder H, Wolford LM. Treatment of posterior dislocation of the mandibular condyle with the double Mitek mini anchor technique: a case report. J Oral Maxillofac Surg. 2018;76:396.e1–396.e9. https://doi.org/10.1016/ j.joms.2017.09.017.