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Original Article

Virtual surgical planning is a useful tool in the surgical management of mandibular condylar fractures

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A B S T R A C T

Purpose: The aim of this study is to evaluate the application value of virtual surgical planning in the management of mandibular condylar fractures and to provide a reliable reference.

Methods: This was a prospective randomized controlled study and recruited 50 patients requiring surgical treatment for their mandibular condylar fractures. The inclusion criteria were patients (1) diagnosed with a condylar fracture by two clinically experienced doctors and required surgical treatment; (2) have given consent for the surgical treatment; and (3) had no contraindications to the surgery. Patients were excluded from this study if: (1) they were diagnosed with a non-dislocated or only slightly dislocated condylar fracture; (2) the comminuted condylar fracture was too severe to be treated with internal reduction and fixation; or (3) patients could not complete follow-up for 3 months. There were 33 male and 17 female patients with 33 unilateral condylar fractures and 17 bilateral condylar fractures included. The 50 patients were randomly (random number) divided into control group (25 patients with 35 sides of condylar fractures) and experimental group (25 patients with 32 sides of condylar fractures). Virtual surgical planning was used in the experimental group, but only clinical experience was used in the control group. The patients were followed up for 1, 3, 6 and 12 months after operation. Variables including the rate of perfect reduction by radiological analysis, the average distance of deviation between preoperative and postoperative CT measurements using Geomagic software and postoperative clinical examinations (e.g., mouth opening, occlusion) were investigated for outcome measurement. SPSS 19 was adopted for data analysis.

Results: The average operation time was 180.60 min in the experimental group and 223.2 min in the control group. One week postoperatively, CT images showed that the anatomic reduction rate was 90.63% (29/32) in the experimental group and 68.57% (24/35) in the control group, revealing significant difference ($X^2 = 4.919$, $p = 0.027$). Geomagic comparative analysis revealed that the average distance of deviation was also much smaller in the experimental group than that in the control group (0.639 mm *vs.* 0.995 mm; $t = 3.824$, $p < 0.001$).

Conclusion: These findings suggest that virtual surgical planning can assist surgeons in surgical procedures, reduce operative time, and improve the anatomic reduction rate & accuracy, and thus of value in the diagnosis and treatment of condylar fractures.

Introduction

The mandible occupies a prominent position on the face, and the condyle, with its slender structure, is one of the most common sites of facial fractures. Condylar fracture, compared with fractures of other parts of the mandible, is more difficult to handle with. Although currently surgical treatment is the preferred choice among surgeons for the management of condylar base and neck fractures,[1,2] the technique-demanding is much higher than that for other mandibular fractures. To improve the surgical treatment of condylar fractures, many studies targeting at the surgical approach, accurate diagnosis, accurate reduction, stable fixation, functional rehabilitation training and other aspects have been conducted.[3,4] However, despite these research, many surgeons, especially those

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with insufficient surgical experience, still struggle to establish a definite diagnosis and treatment plan during the management of mandibular condylar fractures.

In recent years, the development of digital surgery has provided a new way to solve these problems. Surgical procedures are no longer only dependent on the subjective judgment of the surgeon whereas digital technology in the surgical field is used to establish a precise medical treatment.[5,6] Virtual surgical planning (VSP) is one such digital technology innovation. The clinical use of VSP in plastic surgery, thoracic surgery, and oral and maxillofacial procedures has been discussed and published in the literature.[7–10] Yang et al.[11] used a three-dimensional (3D) simulation system to assist in the surgical treatment of condylar fractures. The results show that VSP can assist in making an accurate diagnosis and shorten the operation time. Likewise, Iwai[12] indicated that preoperative simulation can assist in selecting the method of fixation and the length of screw to fix the fractured condylar fragments. Additionally, Boffano et al.[13] reported that VSP helps surgeons to increase the intraoperative efficiency of procedures. However, there is still little literature in this field and all the previous studies we retrieved are case reports or summaries of clinical experience.[14] To date, there have been no reliable randomized controlled clinical studies. Some scholars think that VSP is of little value for condylar fractures, and VSP is still not used in most cases.

Therefore, we designed a randomized controlled study to evaluate the application value of VSP in mandibular condylar fractures, with the aim of providing a reliable reference for its clinical use in the diagnosis and treatment of condylar fractures.

Methods

This study was a prospective, randomized non-blinded controlled clinical trial and has been approved by the Institutional Review Board of West China Hospital of Stomatology at Sichuan University (2020YJ0278). The guidelines of the Helsinki Declaration were followed. Consent was obtained from the patient for the inclusion of their photographs in this article.

All patients met the following inclusion criteria: (1) they were diagnosed with a condylar fracture by two clinically experienced doctors and required surgical treatment; (2) they gave consent for the surgical treatment; and (3) they had no contraindications to the surgery. Patients were excluded from this study if: (1) they were diagnosed with a non-dislocated or only slightly dislocated condylar fracture; (2) the comminuted condylar fractures were too severe to be treated with internal reduction and fixation; or (3) the follow-up period was shorter than 3 months.

The study group included 50 patients with condylar fractures who underwent surgery between January 2018 and August 2019, respectively 33 male and 17 female patients following 24 road accidents, 23 fall injuries, 2 sport injuries, and 1 workplace accident. There were 33 unilateral condylar fractures and 17 bilateral condylar fractures. Patients were randomly divided into two groups according to a random numbers table ($n = 25$ per group). All the patients were surgically treated by one experienced surgeon who usually performs about 150 maxillofacial open reduction and internal fixation operations per year. A preoperative VSP was performed in every case. But patients in the control group were treated without the assistance of VSP (the surgeon was not informed about the planning results and did not use VSP before or during the operation), while patients in the experimental group were treated in accordance with the VSP.

Twelve patients in the experimental group and 13 patients in the control group had fractures in other areas. The baseline information of the patients is presented in Table 1. No significant difference was found regarding general data between the two groups (all $p > 0.05$).

All preoperative and postoperative imaging data were obtained using a Brilliance CT apparatus (Philips, Amsterdam, the Netherlands). Digital imaging and communications in Medicine (DICOM) data were imported into Materialise Mimics 16.0 (Materialise, Leuvin, Belgium) for VSP. Geomagic studio 11 (Geomagic, Research Triangle Park, NC, USA) was used to analyze the imaging data.

The predictor variable was defined by use or non-use of VSP. The primary outcome variables were: (1) the rate of perfect reduction by radiological analysis; (2) the average distance of deviation between preoperative and postoperative CT measurements (in mm) using Geomagic software; and (3) postoperative clinical examinations (e.g., mouth opening, occlusion). The secondary variables assessed included age, sex and complications.

All the patients underwent a preoperative clinical examination and a CT scan. The preoperative CT data in DICOM format was imported into Mimics 16.0 planning software. The mandible and each fracture block were divided into segments. The 3D model reconstruction displayed each fracture block individually, then the displacement angle and the distance of the fractured portion of the condyle were measured and the height of the ramus was noted. The fractured part was then reduced into the anatomic position by means of virtual translations and rotations. In accordance with this planning, screws or plates were selected for fixation of the condyle. For screw fixation, the length, position, drilling position, and direction of the screws were determined using the tools offered by the software. Finally, the detailed VSP was obtained.

All the patients underwent general anesthesia with nasal intubation and were operated on by one experienced surgeon. The surgical approach was determined in accordance with the classification of condylar fractures used by Neff et al.[15] in their 2014 tutorial article. For condylar head fractures, a supratemporalis approach with preauricular incision[16] was used; and for neck and subcondylar fractures, a minor parotid anterior approach,[17] which is a kind of transmasseteric anteroparotid approach, was used. Once the condyle and the fractured segment were exposed, the

Table 1
Baseline information of the included 50 patients with condylar fractures.

Study variables	Experimental group ($n = 25$)	Control group ($n = 25$)	Statistical values	p value
Mean age (years)	37.72	32.68	$t = 1.081$	0.285
Male/Female	18/7	16/9	$\chi^2 = 0.368$	0.544
Fracture side, n (%)			$\chi^2 = 0.802$	0.370
Unilateral	18 (72)	15 (60)		
Bilateral	7 (28)	10 (40)		
Accompanied injuries, n (%)				
Other fractures of the mandible	12 (48)	13 (52)	$\chi^2 = 0.08$	0.777
Fractures in other parts of the maxillofacial region	8 (32)	10 (40)	$\chi^2 = 0.347$	0.556
Other body fractures (limb fractures, rib fractures, cervical vertebra fractures, etc.)	5 (20)	7 (28)	$\chi^2 = 0.439$	0.508

fractured condylar portion was reduced to a more favorable anatomic position. In the experimental group, the fracture was reduced and fixed in accordance with the presurgical VSP, whereas in the control group the treatment was performed only on the basis of the surgeon's experience. Other facial fractures that required surgical treatment were also reduced and fixed.

All the patients were treated with intermaxillary traction for 1 week. A postoperative CT scan was taken 1 week after the surgery. Follow-up visits took place at 1, 3, 6 and 12 months after surgery. Clinical follow-up was provided by two surgeons from the surgical team. Radiological analysis was performed by two doctors who were not in the surgical team. The judgement criteria were based on the method of Ellis et al.[18] The fracture reduction results were classified as "perfect", "satisfactory" and "poor" reduction. A "perfect" was one in which the condylar process was anatomically aligned along all external osseous contours without gaps or irregularities. A "satisfactory" reduction was one in which there may have been a gap (<2 mm) between the fragments, or a slight misalignment of external osseous contour. However, the condylar process was still in good alignment with the head located in the center of the mandibular fossa. A "poor" reduction was one in which there was lack of alignment of the external contour, a large gap, or in which the head was not located in the center of the mandibular fossa. The average distance of deviation between the preoperative surgical plan and the postoperative imaging data was analyzed using Geomagic Studio software.[4] (Fig. 1).

The independent-samples t-test and χ^2 test (Fisher's exact probability method) were used for statistical analysis. All statistical analyses were calculated using SPSS 21.0 for Windows software (IBM Corp, USA). A value of $p < 0.05$ was considered to indicate statistical significance

Results

All the 50 patients (67 sides) completed the study, and all of the surgical procedures were finished successfully. The average surgical duration was 180.60 min in the experimental group and 223.2 min in the control group.

As shown in Table 2, the study variables of postoperative radiological analysis and Geomagic comparative analysis showed statistically significant differences. Postoperative CT examination showed that 29/32 sides in the experimental group (90.63%) achieved anatomic reduction compared with only 24/35 sides in the control group (68.57%) ($\chi^2 = 4.919$, $p = 0.027$), indicating that preoperative VSP can assist surgeons in achieving more precise reduction of the fractured segment. Comparative Geomagic analysis showed that the average distance of deviation in the experimental group was 0.639 mm, and that of the control group was 0.995 mm. The statistical analysis showed that the fractured bone was in a more desirable anatomic position in the experimental group than in the control group ($t = 3.824$, $p < 0.01$).

Postoperatively, all the patients healed uneventfully without any complications such as infections, facial nerve injuries, or salivary fistulae. As shown in Table 3, the 3-month follow-up showed that the range of mouth opening, occlusion, and temporomandibular joint function in the experimental group were slightly better than those in the control group. However, there were no significant differences between the two groups.

Discussion

With abundant evidence of successful case reports and studies supporting the advantages and better prognosis of mandibular

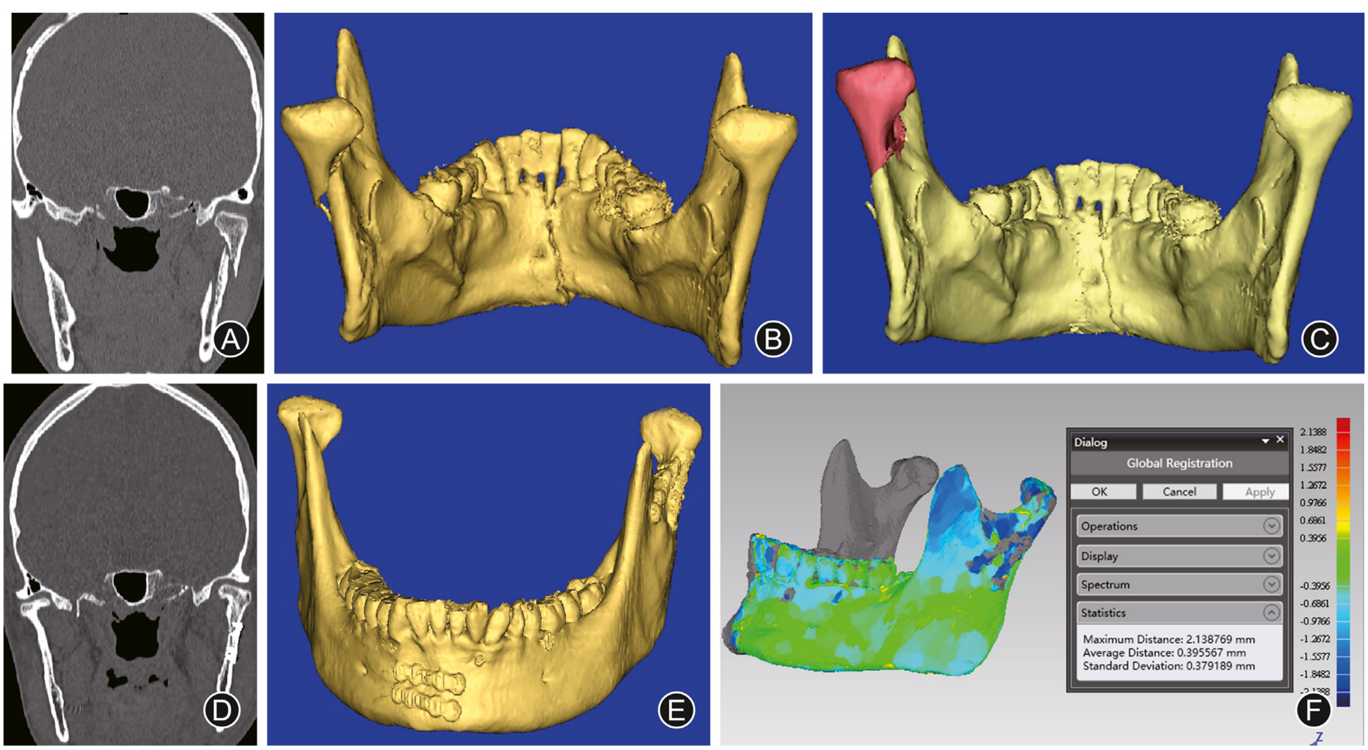

Fig. 1. The protocol for the experimental group. (A) Preoperative CT coronal view; (B) Preoperative digital model constructed with Mimics software; (C) Virtual surgical planning showing repositioning of the fractured portion and preoperative design of the location and direction of screw insertion; (D) Postoperative CT coronal view; (E) Postoperative digital model constructed with Mimics software; (F) Measurement of the average distance of deviation using Geomagic software.

Table 2
Comparison of the primary outcome variables, *n* (%).

Study variables	Experimental group (25 patient with 32 sides)	Control group (25 patient with 35 sides)	Statistical value	*p* value
Average distance of deviation (mm)	0.639	0.995	$t = 3.824$	<0.001
Radiological analysis (No. of sides of condylar fracture)			$\chi^2 = 4.919$	0.027
Anatomic reduction	29 (90.6)	24 (68.6)		
Basic anatomic	3 (9.4)	11 (31.4)		
Non-anatomic	0 (0)	0 (0)		

Table 3
Clinical examination results at the 3-month follow-up after surgery, *n* (%).

Study variables	Experimental group ($n = 25$)	Control group ($n = 25$)	χ^2 value	*p* value
Postoperative normal occlusion	24 (96)	23 (92)	0.000	1.00
Postoperative normal mouth opening	22 (88)	20 (80)	0.149	0.70
Postoperative normal lateral movement	22 (88)	21 (84)	0.000	1.00
Postoperative normal forward movement	25 (100)	25 (100)	/	/
Lateral deviation while mouth opening postoperatively	1 (4)	1 (4)	/	/
Temporomandibular joint discomforts (pain, heaviness)	0 (0)	2 (8)	0.521	0.47

Note: Normal mouth opening >3.5 cm.

condylar fractures by surgical management, it has become one common choice among many surgeons.[2,19] However, due to the location of the condyle, the difficulty of stabilizing a weak fractured portion of the condyle, and intraoperative and postoperative complications, surgical management still presents technical-demanding.[20] Therefore, many surgeons, especially those with limited surgical experience, regard surgical treatment of condylar fractures as challenging.

VSP, a recent adjunct to the surgical treatment of maxillofacial fractures, has been reported to intraoperatively assist to achieve superior results for reduction and fixation.[21–25] To date, however, there have been no randomized controlled clinical studies of its application in the surgical management of mandibular condylar fractures. We therefore undertook this study to provide a clinical reference and further understanding of the application value of VSP.

The results of this study showed that perfect reduction was superior in the experimental group than in the control group. Additionally, the average distance of deviation from the preoperative VSP was shorter in the experimental group than in the control group according to Geomagic analysis. These results indicate that the probability of obtaining a more precise perfect reduction was higher in the experimental group than in the control group. Perfect reduction promotes early healing, reduces bone remodeling, and thus significantly enhances the early recovery of temporomandibular joint function. The above results are consistent with the research conclusion by Dr. Pavlychuk et al.[26] They treated 14 patients with 16 condylar head fractures (CHFs) by open reduction and internal fixation with the use of CAD/CAM technology. The results showed that the application of the CAD/CAM technologies for condylar head fractures helps to improve the accuracy and quality of fragments reduction with minimal risks of intraoperative complications.

The findings of this study have demonstrated the following application values of VSP: (1) allows prediction of the postoperative outcome, mainly for condylar head fractures; (2) assists in the perfect reduction of the fractured portion, and predetermination of the screw length in cases of condylar head fractures; (3) provides accurate digital evaluation after the successful surgical treatment. These attributes are of great significance not only in improving the surgical outcomes of condylar fractures, but also in reducing the likelihood of medical disputes.

In conclusion, VSP has major application value in the diagnosis and treatment of condylar fractures, especially for condylar head fractures. It's well worth using in clinical practice.

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Ethical statement

This study was approved by the Institutional Review Board of West China Hospital of Stomatology at Sichuan University (Approval No. WCHSIRB-D-2017-216).

Declaration of competing interest

The authors declared no conflicts of interest.

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Author contributions

Lei Liu and Shubhechha Shakya designed experiments. Shubhechha Shakya, Kai-De Li and Dou Huang conducted the experiments. Shubhechha Shakya, Zuo-Qiang Liu and Xiao Zhang analyzed data. Shubhechha Shakya wrote original draft. Lei Liu conducted writing revisions and editing. Lei Liu supervised the work. All authors approved the final version of the paper.

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