Open versus closed treatment of fractures of the mandibular condylar process—a prospective randomized multi-centre study

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SUMMARY. Aim: The aim of this international prospective randomized multi-centre study was to compare operative and conservative treatment of displaced condylar fractures of the mandible. Methods and patients: Out of a total of 88 randomized patients from 7 centres, 66 patients with 79 fractures of the mandibular condylar process completed the study and were evaluated. All fractures were displaced, being either angulated between 10° and 45° or the ascending ramus was shortened by more than 2 mm. The follow-up examinations 6 weeks and 6 months following treatment included evaluation of radiographic measurements, clinical, functional and subjective parameters including visual analogue scale for pain and the Mandibular Function Impairment Questionnaire index for dysfunction. Results: Correct anatomical position of the fragments was achieved significantly more often in the operative group in contrast to the closed treatment group. Regarding mouth opening/lateral excursion/protrusion, significant (p = 0.01) differences were observed between both groups (open 47/16/7 mm versus closed 41/13/5 mm). The visual analogue scoring revealed significant (p = 0.03) differences with less pain in the operative treatment group (2.9 open versus 13.5 closed). The Mandibular Function Impairment Questionnaire index recorded a significant (p = 0.001) difference with less pain and discomfort in the open treatment group (10.5 versus 2.4 points). Conclusion: Both treatment options for condylar fractures of the mandible yielded acceptable results. However, operative treatment, irrespective of the method of internal fixation used, was superior in all objective and subjective functional parameters. © 2006 European Association for Cranio-Maxillofacial Surgery

Keywords: mandible fractures; condylar fractures; open reduction; closed reduction multi-centre study; open rigid fixation; maxillomandibular immobilization; temporomandibular joint

INTRODUCTION

The condylar process is frequently involved in fractures of the mandible (Ellis et al., 1985; Silvennoinen et al., 1992; Thoren et al., 1997; Rasse, 2000; Maladiere et al., 2001; Iida et al., 2003). However, the treatment of fractures of the condylar process is controversial. In line with the basic principles of trauma surgery regarding open reduction and internal fixation of displaced fractures, open surgical management has been recognized to be best for fractures of the body of the mandible and of the midface for more than three decades. However, for moderately displaced condylar fractures, closed reduction with rigid or elastic maxillomandibular fixation is still frequently selected. The reasons for this may be the difficult surgical access to the condylar area and the frequently difficult repositioning of the proximal fragment. Even for the experienced maxillofacial surgeon the delicate bony structures involved and the risk of damage to the surrounding tissues are challenging, regardless of the method of internal fixation used. Consequently, several publications have emphasized the acceptable functional results of conservative treatment in contrast to the risks of surgery (Bornemann, 1956; Steinhardt, 1966; MacLennan and Glas, 1969). However, after a critical review, those studies did not
differentiate between the degrees of fracture displacement or dislocation of the condyle, nor shortening of the height of the ascending ramus. In addition, due to the lack of fracture classification, most non-randomized studies comparing open versus closed treatment might have the methodological shortcoming that heavily displaced and bilateral condylar fractures with a worse prognosis tended to be treated surgically, whereas the groups of patients treated conservatively consisted of unilateral and/or less complicated fractures. A meta-analysis of these studies was attempted but failed due to lack of comparable conditions and prerequisites in the study populations (Eckelt and Hlawitschka, 1999).

Evidence-based comparison of open and closed treatment of fractures of the condylar process of the mandible is possible in a prospective randomized study. There is consensus that the correct anatomical reconstruction of the condylar process is an important prerequisite for re-establishing function (Baker et al., 1998). The aim of the present study was to compare open and closed treatment of moderately displaced condylar fractures (10–45°) and/or fractures with shortening of the ascending ramus (≥2 mm) under the conditions of an international prospective and randomized multi-centre study.

PATIENTS AND METHODS

Eight contributing centres initially took part in the preparation of the international multi-centre study. All contributing centres (see title page) had to be able to treat condylar fractures surgically with open reduction and internal fixation. Members of the group from contributing centres developed the study design and a data collection form. The recruitment phase of the patients started in May 2001 and was terminated after 28 months in September 2003.

Patients were thoroughly informed, explaining the possible advantages and disadvantages of the open and closed options. The patients had to give informed consent or refusal regarding participation in the study. The patient information was documented in a consent form. If the patient consented to either treatment option, the randomization process continued. The type of treatment was chosen by opening a sealed envelope which had been prepared by the study coordination centre (Dresden). The study design and the method of randomization had been approved by the ethics committee of the University of Dresden and was then confirmed by the local ethics committees at each of the local contributing centres. The inclusion criteria were:

1. Age of the patient: ≥ 18 years and
2. Unilateral or bilateral condylar fracture and
3. Location of the fracture in the condylar base, in the condylar neck region, or in the condyle itself and
4. Degree of displacement of the condylar fragment in the frontal or sagittal plane: 10–45°
5. and/or shortening of the height of the ascending ramus of the mandible: ≥2 mm.

Additional fractures of the mandible were treated with open or closed reduction independently of the result of the randomization.

The exclusion criteria were:

1. Pre-existing skeletal discrepancies with malocclusion.
2. Pre-existing pathological conditions of the temporomandibular joints.
3. The study protocol required an informed and active decision by the patient.

Patients who were not able to follow the information given or to make a decision themselves due to mental or other reasons were excluded from the study (e.g. multiply injured patients in intensive care units).

The following parameters were used to assess the treatment result.

1. Range of motion of the injured joint together with the contralateral joint as given by the mouth opening (maximum interincisal distance) and by the extent of lateral excursion and of protrusion.
2. Deviation or deflection during mouth opening when assessing the function of the TMJ with the Mandibular Function Impairment Questionnaire (MFIQ) according to Stegenga et al. (1993) and Kropmans et al. (1999).
3. Assessment of pain and discomfort with a visual analogue scale (VAS) with values from 0 (no pain) to 10 (strongest pain or discomfort). 10 questions per patient.
4. Malocclusion as assessed by an examiner and described by the patient.

A classification of the location of the fractures (Fig. 1) was performed according to the criteria of Loukota et al. (2005) and the criteria described below on the basis of the radiographs (panoramic view and posterior–anterior cranial radiograph (10° off) according to Clementschitsch (1955)). As an alternative to plain radiographs a computed tomogram was permitted by the study.

The following method was used to measure the degree of displacement of the fracture: The angle between the vertical axis of the displaced condylar fragment and the axis of the original position of the condylar fragment as mirrored from the contralateral side in the frontal plane was measured (Fig. 2). Furthermore the vertical height of the ascending ramus from the condylar surface to the level of the lower border of the horizontal ramus was measured on both sides. The amount of shortening of the fractured side was recorded. In bilateral condylar fractures this measurement was replaced by measuring the radiologically detectable overlap of the fragments.
In this study, follow-up data of up to 6 months are reported. The clinical units reported to the study coordination centre at the time of randomization, after the first (6 weeks) and second follow-up examination (6 months). The results of the clinical examinations were recorded on a specific form. The time tolerance was ±2 weeks for the first recall and ±2 months for the second. Follow-up examinations outside these limits were not evaluated.

The data was collected in the study coordination centre with a custom-programmed version of Microsoft Access (Microsoft, Redmond, USA). The database could easily be searched and exported into statistical software SPSS 12.0 (Fa. SPSS Inc., USA). The data was further processed with SPSS 12.0 and Microsoft Excel 2003 (Microsoft, Redmond, USA).

From the initial eight contributing units 7 departments (University Hospital Dresden, Hospital Flam-wood, University Hospital Halle, University Hospital Kiel, Leeds Dental Institute, University Hospital Magdeburg, AKH Wels) contributed data from 88 patients until March 2004. One department failed to recruit patients and did not further take part in the evaluations. At this time 66 patients (75%) had
completed the 6 months follow-up and were fully documented (Dresden 22, Flamwood 5, Halle 3, Kiel 8, Leeds 2, Magdeburg 4, Wels 22). In 22 patients (25%) either treatment had not been completed, they had missed the follow-up examinations or data files were incomplete.

A prerequisite for a valid result was that the finally evaluated patient sample adequately represented the whole study population to prevent a selection bias. Therefore as a first step the evaluated group of patients was compared with the entire study population to uncover any discrepancies. These structural data were treatment type (open/closed treatment), fracture location (condylar base, neck or head), gender and side of fracture. There were no relevant differences.

After this check, 66 patients from 7 centres with a total of 79 fractures were evaluated. Fifty-three (80%) patients had unilateral—sides matched—(27 left and 26 right sided fractures) and 13 patients (20%) had bilateral fractures. Twenty-three fractures were located in the condylar head, 14 in the neck and 42 fractures were found in the condylar base (Fig. 3). The age distribution was similar to other studies on condylar fractures (Kniggendorf, 1979; Günther et al., 1966; Silvennoinen et al., 1992; Joos and Kleinheinz, 1998). The average age of the study population was 32 years (Fig. 4). The representation of the genders resembles the usual distribution in maxillofacial trauma with 52 (78%) male and 14 (22%) female patients (Fig. 5).

The two treatment groups (operative versus conservative) were then compared for structural homogeneity. For the parameters, fracture location (condylar base, neck, or head), gender, and side location no significant differences were observed, using the Breslow test. The only significant difference ($p = 0.0006$) detected was in the time lag between diagnosis and treatment in the open versus closed treatment groups.

In the closed treatment group, therapy usually consisted of short-term elastic maxillomandibular immobilization applied to arch bars for 10 days. This was occasionally prolonged in cases with complications (e.g. occlusal problems). In the subsequent phase of functional treatment the patients were assessed by the maxillofacial surgeon. In more complex cases physiotherapy and orthodontic appliances were used in this phase.
The decision about the type of operation chosen in the operative treatment group (42 condylar neck fractures) was made by the surgeon. Depending on the position of the fracture (Fig. 1) and the degree of displacement (Fig. 2) the submandibular (Perthes, 1924), periangular (Eckelt, 2000) for 12 condylar neck fractures, retromandibular (Ellis and Dean, 1993) for 5 fractures, preauricular (Rasse, 2000) for 12 fractures, or the transoral approach (Silvermann, 1925; Steinhäuser, 1964; Undt et al., 1999) for 13 fractures were used. The type of osteosynthesis used depended on the surgical approach and fracture location, i.e., miniplates (Champy et al., 1978; Gerlach and Pape, 1980) for 33 condylar neck fractures, miniscrews (Rasse, 1993; Kermer et al., 1998; Neff et al., 1999) for 4 fractures, or lag screws (Eckelt and Gerber, 1981; Eckelt, 1984; Eckelt and Hlawitschka, 1999) for 5 fractures.

RESULTS

Clinical results

There were no severe clinical complications in either treatment group. In particular, there was no permanent damage to the facial nerve branches in the surgically treated group.

Radiographic results

The accuracy of fracture reduction and the stability of fixation were assessed on the basis of radiographs obtained preoperatively, 6 weeks and 6 months postoperatively. In the operatively treated group, the average preoperative shortening of the ascending ramus was 6.3 mm (range 0–13 mm, SD 3.8 mm—Fig. 6). The average degree of preoperative fracture angulation was 18.5° (range 0–45°, SD 15.3°—Fig. 7). Six months after the operative treatment the average shortening of the ascending ramus height was 0.31 mm (range 0–6 mm, SD 1.2 mm—Fig. 6) and the average residual angulation was 2.13° (range 0–35°, SD 6.7°—Fig. 7).

In the closed treatment group the average pre-treatment shortening was 6.1 mm (range 0–17 mm, SD 4.3 mm) and the angulation was 23° (range 0–45°, SD 14.7°). Thus, both treatment groups were comparable preoperatively, with no significant differences in these parameters (shortening $p = 0.751$, degree of angulation $p = 0.376$). At 6 months follow-up in the closed treatment group shortening was still 5.75 mm (range 0–15 mm, SD 4.4 mm) and had not substantially improved when compared with the preoperative values (Fig. 6). A similar situation occurred in the degree of angulation which had only slightly improved with 16.8° (range 0–45°, SD 14.6°) when compared with the preoperative situation (Fig. 7).

Mobility of the mandible

The range of movement was assessed by maximal mouth opening, protrusion and lateral excursion (Fig. 8). In the closed treatment group the average interincisal distance postoperatively was 40.9 mm (SD 6.7) and in the operatively treated group 46.5 mm (SD 5.3). There was a significant difference ($p = 0.01$). A similar situation was observed in the protrusion (Fig. 9). In the closed treatment group the average range of protrusion was significantly less ($p = 0.0005$) with 4.7 mm (SD 2.5) when compared with 7.3 mm (SD 2.0) in the operatively treated
group. The range of lateral excursion (assessed by the addition of the lateral excursion values to both sides) is depicted in Fig. 10.

Disturbances of function

Deflection and lateral shift of the mandible during mouth opening is often a sign of compensatory movements of the contralateral joint due to shortening of the ascending ramus height on the affected side. In 20 of 30 (66%) patients in the closed treatment group, terminal lateral shifts were observed. The average deflection from the midline was 3.1 mm (range 1–7 mm) in this group. In contrast, in the operatively treated patients, a deflection was observed in 7 cases (19%) with an average of 2.6 mm (range 1–7 mm). There was a significant difference between both groups ($p = 0.03$).

Occlusal disturbances

After 6 months, in the closed treatment group 7 out of 30 (23%) patients reported occlusal disturbances. In the operatively treated group, 3 out of 36 (9%) patients reported occlusal disturbances. The clinical examination by the surgeon revealed occlusal disturbances in 6 patients (20%) in the closed treatment group and in none of the operatively treated group (Fig. 11).

Subjective pain and discomfort

The results of the VAS (0–100) pain assessment were 13.5 (SD 3.1, range 0–59) in the closed treatment group with 13 of 30 patients having no pain. In the operatively treated group, the corresponding value was 2.9 (SD 1.0, range 0–25) with 28 of 36 patients reporting no pain after 6 months. Comparison of the arithmetic means ($t$-test) revealed a significant difference ($p = 0.003$; Fig. 12).

Subjective functional index (MFIQ)

The detailed analysis of the Mandibular Function Impairment Questionnaire (MFIQ) revealed similar results. If all 17 questions were answered with the most negative score $= 5$ (Score $= 1 \times 17 = 68$), then a maximum of 68 points could be achieved. The lower
the score – the lower the subjective clinical limitations. Fig. 13 shows the specific functional impairment in the closed treatment group with 10.5 points (SD 2.2, range 0–47), whereas only 2.4 points (SD 0.76, range 0–18) were scored in the operative treatment group, a significant difference ($p = 0.001$).

Table 1 contains the data and the level of significance of all clinical and subjective parameters.

**DISCUSSION**

Today, for dislocated fractures, open approaches are considered as the treatment of choice in many units. However, for moderately displaced condylar fractures, open treatment is still controversial (Silvennoinen et al., 1994; Baker et al., 1998; Banks, 1998; Joos and Kleinheinz, 1998, Smets et al., 2003). As expected, in the closed treatment group, shortening of the ascending ramus, and angulation of the fragments remained basically unchanged after 6 months. These two criteria were significantly improved in the open treatment group postoperatively. In the closed treatment group the values had to be interpreted as fracture healing in a misaligned position. For most functional parameters, a significantly better outcome was observed in the patients of the open treatment group. The patients in the open treatment group also reported better treatment results in terms of less pain and discomfort. Previously reported retrospective studies demonstrated a better anatomical position after operative treatment. However, there was no significant difference in the functional clinical results (Takenoshita et al., 1990; Hayward and Scott, 1993).

In this multi-centre study, 7 treatment units with similar treatment philosophies were brought together. However, the operative approaches differed depending on the degree of displacement and location of the fracture. The selected method of internal fixation also differed. But, in all 7 of those a functionally stable
method of fixation (miniplates or lag screws) was used with immediate postoperative mobility without maxillomandibular fixation.

After the primary evaluation of the results, further recruitment of patients ceased for ethical and legal reasons, because there was a clear trend for better results in the open treatment group. Other comparative studies are only available in limited numbers but have inconsistent results. Retrospective studies from Hidding et al. (1992) and Konstantinovic and Dimitrijevic (1992) report no functional advantages for the operative option. In contrast, the studies of Worsae and Thorn (1994) found better results from the operative option in a prospective study. In those studies, wire osteosynthesis was applied in conjunction with 4-weeks of maxillomandibular immobilisation. In general, a postoperative maxillomandibular immobilization is disadvantageous for rapid restoration of function. Therefore, these studies are difficult to compare with studies which used functionally stable methods of internal fixation. A prospective, but not randomised study by Haug and Assael (2001) with 10 patients in each treatment group found no statistical advantage for either of the two treatment options. However, there was more chronic pain in the closed treatment group. It is of importance that in all non-randomized studies there is the shortcoming that usually the more complicated displaced or dislocated fractures were more likely to receive operative treatment. Thus there is a bias due to patient selection.

The development of stable osteosynthesis modalities with miniplates (Pape et al., 1980), lag screws (Wackerbauer, 1962; Petzel, 1980; Eckelt and Gerber, 1981; Krenkel, 1992) and the further development of the surgical approaches have made the operative treatment safer and have the functional advantage of earlier mobilization of the traumatized tissues. Sugirua et al. (2001) compared lag screws, miniplates and Kirschner wires in evaluating different methods of osteosynthesis. In a series of non-randomized observations Ellis and co-workers compared open and closed treatment. Whilst there were no significant differences in bite force (Ellis and Throckmorton, 2001). In terms of occlusion, Ellis et al. (2000) observed a higher rate of occlusal disturbances after closed treatment and Throckmorton and Ellis (2000) and Palmieri et al. (1999) found more favourable outcomes after operative treatment. In terms of facial asymmetry Ellis and Throckmorton (2000) observed a shorter posterior facial height on the injured side after closed treatment. Rasae et al. (1990) demonstrated better clinical results for operative treatment in a retrospective study.

The better results for open (operative) treatment suggest that the current general trend for conservative treatment should be discontinued. Looking at the absolute values of the present study it has been demonstrated that both treatment options can yield acceptable results in some cases.

**CONCLUSION**

This randomized prospective study yielded functional results which were clearly in favour of open reduction and fixation of moderately displaced condylar fractures. The present results enable us to inform the patient preoperatively on the basis of statistically proven data, so that they may actively participate in making a decision. This is becoming more important nowadays from a legal point of view.

**References**


| Table 1 – Overview of all data assessed in 66 patients following treatment of condylar fractures |
|-------------------------------------------------|-------------------------------------------------|-------------------------------------------------|-------------------------------------------------|
| Closed reduction n = 30 (mean; min; max;±SD) | Open reduction n = 36 (mean; min; max;±SD) | Statistical significance | p value |
| Maximal interincisal dist. (mm) | 40.93; 22; 50; ±6.8 | 46.47; 37; 56; ±5.3 | Yes | 0.001 |
| Left lateral excursion (mm) | 6.33; 1; 12; ±2.7 | 8.44; 2; 16; ±3.0 | Yes | 0.004 |
| Right lateral excursion (mm) | 7; 1; 12; ±2.7 | 9.06; 2; 16; ±2.7 | Yes | 0.004 |
| Sam of both excursions (mm) | 13.33; 2; 24; ±4.97 | 17.50; 5; 32; 5.1 | Yes | 0.001 |
| Protrusion (mm) | 4.7; 8; ±2.5 | 7.33; 4; 12; ±2.0 | Yes | <0.001 |
| Terminal deviation left (mm) | 0.77; 0; 6; ±1.68 | 0.03; 0; 1; ±0.167 | Yes | 0.023 |
| Terminal deviation right (mm) | 1.30; 0; 6; ±1.75 | 0.47; 0; 7; ±1.34 | Yes | 0.037 |
| VAS (pain assessment) | 15.53; 6; 59; ±17.14 | 2.89; 0; 25; ±6.52 | Yes | 0.003 |
| MFIQ | 10.53; 0; 47; ±12.1 | 2.47; 0; 18; ±4.6 | Yes | <0.001 |

MFIQ – Mandibular function impairment questionnaire,
SD – standard deviation,
VAS – Visual analogue scale.
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**Paper received 29 March 2005**

**Accepted 1 March 2006**