

## **Multi-Center Study:**

### **“Diacapitular Fracture of the mandible – Open reduction versus closed treatment: a randomized clinical trial”**

- 1. Purpose**  
To study the outcome of open reduction and fixation versus closed treatment of diacapitular fracture of the mandible
- 2. Study design**  
**Randomized prospective clinical study for patients with primary dislocation of the fragments of diacapitular fractures**
  - 2.1. Inclusion criteria**
    - 2.1.1. Patients age > 18 years
    - 2.1.2. Unilateral condylar head with loss of vertical height Fractures Typ B +/- contralateral condylar process fracture of any type.
  - 2.2. Exclusion criteria**
    - 2.2.1. Patients with preexistent symptomatic TMJ disorders that had been treated
    - 2.2.2. Patients affected by generalized synovial joint pathology
    - 2.2.3. Patients unable to make decisions
    - 2.2.4. Delay of treatment more than 2 weeks
    - 2.2.5. Comminuted fractures with sub-fragmentation of the major proximal fragment.
  - 2.3. Randomization Procedure**  
Patient wants to participate in the study after adequate information and explanation about both treatment modalities: open reduction versus closed treatment.
  - 2.4. Outcome measures (after 6 weeks and 6 months)**
    - 2.4.1. Primary outcome measures**
      - 2.4.1.1. TMJ mobility measured by:
        - incisal distance (clinically relevant difference 5 mm)
        - lateral mandibular movement (clinically relevant difference 3 mm)
      - 2.4.1.2. Pain assessment by VAS (Visual Analogue Scale) (clinically relevant difference 20 %)
    - 2.4.2. Secondary outcome measures**
      - 2.4.2.1. TMJ mobility measured by:
        - protrusion (measured on both sides in canine region) (clinically relevant difference 3 mm)
        - deviation on protrusion
      - 2.4.2.2. Occlusal disturbances

subjective - change of occlusion caused by the fracture

objective - visible open bite

- 2.4.2.3. Lesions of the facial nerve (4 branches)
- 2.4.2.4. Lesion of the auriculotemporal nerve
- 2.4.2.5. Lesion of the occipitalis minor respectively auricularis magnus nerve
- 2.4.2.6. Lesion/Stenosis of acoustic meatus
- 2.4.2.7. X-ray examination
  - displacement
  - shortening
  - resorption of condyle
- 2.4.2.8. Mandibular function impairment by MFIQ (Mandibular Function Impairment Questionnaire)

**2.5. The following centres participate in the study,**  
the responsible persons are in brackets:

University Hospital Dresden, Oral and Maxillofacial Surgery (Eckelt) Germany  
 University Hospital Vienna, Oral and Maxillofacial Surgery (Ewers/Undt) Austria  
 Department of Maxillofacial Surgery, Leeds Dental Institute (Loukota) GB  
 University Hospital Innsbruck Oral and Maxillofacial Surgery (Rasse) Austria  
 University Hospital of Marburg, Department of Oral and Maxillofacial Surgery  
 (Neff) Germany

The centres report the randomization of a new patient to the Dresden clinic within a week and the Multi-Center Study Forms (6 weeks and 6 months) will be sent to Dresden within 2 weeks. The demand is made by the above mentioned clinic if the results are not sent in on schedule. The data input into an Excel file is carried out in Dresden.

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**2.6. Sample size calculation**

Since the distribution of the three primary outcome measures incisal distance, lateral mandibular movement and pain assessment by VAS after 6 months is not known at time of study planning, it will be estimated after 6 months follow-up of a preliminary sample of 20 per group (half-sampling method). Sample size calculation will then be based on unpaired tests using the observed within-group standard deviation, a significance level of 5% and a statistical power of 85%, and clinically relevant differences of 5 mm for incisal distance, 3 mm for lateral mandibular movement, and 20% of pain assessment by VAS. The final sample size will be based on the outcome measure yielding the largest calculated sample size.

**2.7. Statistical analysis**

The three primary outcome measures incisal distance, lateral mandibular movement and pain assessment by VAS, after 6 weeks and after 6 months, possibly after transformation to normal distributions, will be analysed using linear regression, stratifying by study centre and taking into account potential risk factors such as age and delay of surgery. All other outcomes will be analysed using adequate statistical methods. P-values < 0.05 will be considered as indicating statistical significance. The

SAS System V8.1 (SASA Institute Inc., Cary, NC, 2000) will be used for statistical analysis.

## 2.8. Mandibular Function Impairment Questionnaire (M.F.I.Q.)

This questionnaire addresses functional jaw activities. With this questionnaire we want to learn to what extent your symptoms affect your ability to use your jaw. To this end it is important that you answer **all** questions honestly.

With all activities mentioned in the questions, you have to use your jaw. You can indicate how much difficulty you have to use your jaw **due to your present complaints** by selecting one of possible answers:

- 1 no difficulty
- 2 a little difficulty
- 3 quite a bit difficulty
- 4 much difficulty
- 5 very much difficulty or impossible without help

Explanation:

- 1 You can carry out the jaw-activity without any problem or extra effort.
- 2 You experience some disturbance with carrying out the jaw-activity, but you can accomplish the task without difficulty.
- 3 You can carry out the jaw-activity, but at the expense of extra effort or difficulty.
- 4 You cannot carry out (part of) the jaw-activity properly and for this reason you avoid the activity occasionally.
- 5 You cannot carry out (part of) the jaw-activity at all, and for this reason you have to avoid the activity or need help from others.

Scoring key of the MFIQ

Score per item:

$s = i - 1$  (range: 0-4)

( $i=1,2,3,4$  of 5)

sum score =  $S = s_1 + \dots + s_{17}$

maximal score =  $17 \times 4 = 68$

Rough score =  $C = S/68$  (range: 0-1)

Function impairment ("rating")

0 all  $i < 2$  and  $C \leq 0.3$

1 at least one  $i \geq 2$  and  $C \leq 0.3$

2 all  $i < 3$  and  $0.3 < C \leq 0.6$

3 at least one  $i \geq 3$  and  $0.3 < C \leq 0.6$

4 all  $i < 4$  and  $C > 0.6$

5 at least one  $i=4$  en  $C > 0.6$

Qualitative measure for  
function impairment:

I = low: rating = 0 or 1

II = moderate: rating = 2 or 3

III = severe: rating = 4 or 5