

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.

(Fax-no.: 0049 351 458 5348/Email: matthias.schneider@uniklinikum-dresden.de)

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

First announcement (immediately after operation)

Date of randomization: ___/___/___ **Fax no:** 0049 351 458 5348

Initials: **Number:** **Institution:**

3. Findings

3.1. Date of birth: _____

Age: _____ years Sex: male female

3.2. Result of Randomization: open closed

3.3. Preinterventional diagnosis:

3.3.1. Time intervall (fracture – treatment): _____ days

3.3.2. Type of the fracture

- 3.3.2.1. Judgement by:
- OPG
 - Towne/Clementschilds
 - CT (compulsory)



Fig. 1: Typ B

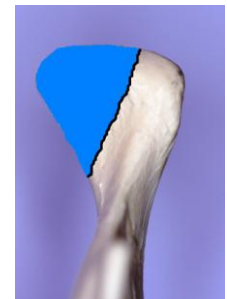


Fig. 2: Typ A

Fig. 1 and 2: Subclassification of condylar head fractures: Classification is determined by the course of the fracture line through the head of condyle. Fig. 1 shows type B demonstrating the course of the fracture through the lateral end of the condylar head with luxation of the medial fragment and loss of the vertical dimension. Fig. 2 shows type A with the course of the fracture through the condylar head that way that the lateral end and the vertical dimension of the joint are maintained on luxation of the small fragment.

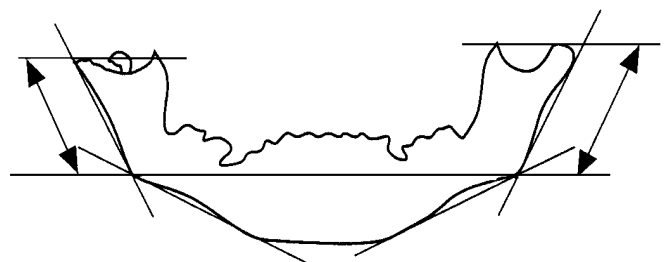
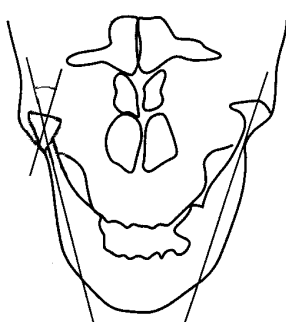
- 3.3.2.2. Level of condylar head fracture: left right
- Type A Type A
 - Type B Type B
 - Condylar neck Condylar neck
 - Condylar base Condylar base

3.3.2.3. Changing length of the ramus: left (+/-) right (+/-)

_____ mm _____ mm

3.3.2.4. Angulation of the fragment: left (+/-) right (+/-)

_____ ° _____ °

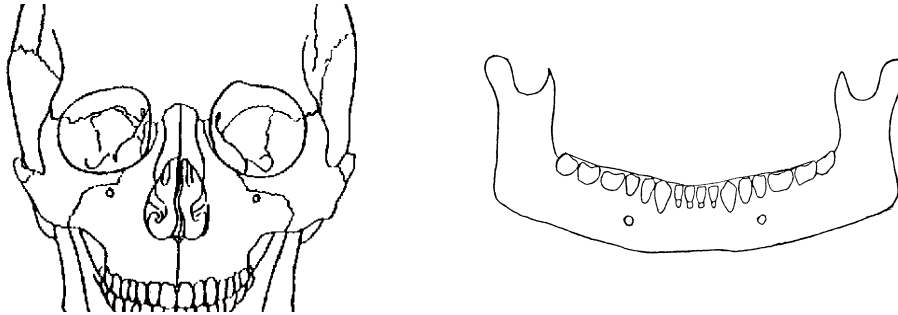


First announcement (immediately after operation)

Date of randomization: ___/___/___ Fax no: 0049 351 458 5348

Initials: Number: Institution:

3.3.3. Localisation of other mandibular and maxillar fractures and therapy



1. Mini Plate 2. Micro Plate 3. Others

3.3.4. Missing teeth (x):

8	7	6	5	4	3	2	1	1	2	3	4	5	6	7	8

3.3.5. Any lesions of the facial nerve: left right

branch (1-4):	1) 2) 3) 4)	1) 2) 3) 4)
yes	<input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/>	<input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/>
no	<input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/>	<input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/>

① temporal ② zygomatic ③ buccal ④ marginal

3.3.6. Lesion of the auriculotemporal nerve:

	left		right	
hypoesthesia/reduced sensation	yes <input type="radio"/> no <input type="radio"/>		yes <input type="radio"/> no <input type="radio"/>	
numbness	yes <input type="radio"/> no <input type="radio"/>		yes <input type="radio"/> no <input type="radio"/>	
hyperalgesia	yes <input type="radio"/> no <input type="radio"/>		yes <input type="radio"/> no <input type="radio"/>	

3.3.7. Lesion of the occipitalis minor respectively auricularis magnus nerve:

	left		right	
hypoesthesia/reduced sensation	yes <input type="radio"/> no <input type="radio"/>		yes <input type="radio"/> no <input type="radio"/>	
numbness	yes <input type="radio"/> no <input type="radio"/>		yes <input type="radio"/> no <input type="radio"/>	
hyperalgesia	yes <input type="radio"/> no <input type="radio"/>		yes <input type="radio"/> no <input type="radio"/>	

First announcement (immediately after operation)

Date of randomization: ___/___/___ **Fax no:** 0049 351 458 5348

Initials: **Number:** **Institution:**

3.3.8. Traumatic perforation of acoustic meatus

left

right

yes no

yes no

3.4. Treatment modality

3.4.1. Closed treatment

Intermaxillary Fixation no yes

Only with elastics !

First announcement (immediately after operation)

Date of randomization: ___/___/___ Fax no: 0049 351 458 5348

Initials: Number: Institution:

3.4.2. Open reduction

Date of operation: _____

Operative approach:

preauricular retroauricular

Type of fixation

Left:

Plates: Screws: Pin (resorb.): Screws (resorb.)

Number of Plates: _____

Type of plate (2,0/1,5/1,0): _____

Number of screws in proximal fragment: _____

Number of screws in distal fragment: _____

Number of screws/pin: _____

Diameter of screws/pin: _____

Length of screw/pins: _____

Right:

Plates: Screws: Pin (resorb.): Screws (resorb.)

Number of Plates: _____

Type of plate (2,0/1,5/1,0): _____

Number of screws in proximal fragment: _____

Number of screws in distal fragment: _____

Number of screws/pin: _____

Diameter of screws/pin: _____

Length of screw/pins: _____

Intermaxillary Fixation no yes

First announcement (immediately after operation)

Date of randomization: ___/___/___ **Fax no:** 0049 351 458 5348

Initials: **Number:** **Institution:**

3.5. Postinterventional period

3.5.1. Intermaxillary fixation

elastics _____ days

3.5.2. Orthodontic appliance _____ days

3.5.3. Physical therapy:

instruction by surgeon physiotherapist treatment

3.5.4. Complications

3.5.4.1. Infection no yes

3.5.4.2. Other complications: _____

3.5.5. Postinterventional radiograph (within 1 week)
(OPG, Towne/Clementsich, CT-Scan)

	<u>left</u>	<u>right</u>
1. Correct position:	no <input type="radio"/> yes <input type="radio"/>	no <input type="radio"/> yes <input type="radio"/>
2. Shortening of the ramus:	_____ mm	_____ mm
3. Angulation of the fragment:	_____ °	_____ °
4. Failure of osteosynthesis	no <input type="radio"/> yes <input type="radio"/>	no <input type="radio"/> yes <input type="radio"/>

Second announcement (after 6 weeks)

Date of randomization: ___/___/___ Fax no: 0049 351 458 5348

Initials: Number: Institution:

3.6. Postinterventional examination

3.6.1. Outcome measures after **6 weeks** Examination date: _____

3.6.1.1. Lesions of the facial nerve:	left	right
branch (1-4):	1) 2) 3) 4)	1) 2) 3) 4)
yes	<input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/>	<input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/>
no	<input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/>	<input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/>

① temporal ② zygomatic ③ buccal ④ marginal

3.6.1.2. Lesion of the auriculotemporal nerve:

	left	right
hypoesthesia/reduced sensation	yes <input type="radio"/> no <input type="radio"/>	yes <input type="radio"/> no <input type="radio"/>
numbness	yes <input type="radio"/> no <input type="radio"/>	yes <input type="radio"/> no <input type="radio"/>
hyperalgesia	yes <input type="radio"/> no <input type="radio"/>	yes <input type="radio"/> no <input type="radio"/>

3.6.1.3. Lesion of the occipitalis minor respectively auricularis magnus nerve:

	left	right
hypoesthesia/reduced sensation	yes <input type="radio"/> no <input type="radio"/>	yes <input type="radio"/> no <input type="radio"/>
numbness	yes <input type="radio"/> no <input type="radio"/>	yes <input type="radio"/> no <input type="radio"/>
hyperalgesia	yes <input type="radio"/> no <input type="radio"/>	yes <input type="radio"/> no <input type="radio"/>

3.6.1.4. Stenosis of acoustic meatus

left	right
<input type="radio"/> yesmm	<input type="radio"/> yesmm
<input type="radio"/> no	<input type="radio"/> no

3.6.1.5. TMJ mobility

1. Maximal distance between the incisors: _____ mm

2. Lateral mandibular movement: left _____ mm right _____ mm

3. Protrusion: left _____ mm right _____ mm

4. Deviation on protrusion: _____ mm

Second announcement (after 6 weeks)**Date of randomization:** ___/___/___ **Fax no: 0049 351 458 5348****Initials:** **Number:** **Institution:**

3.6.1.6. Pain assessment:

No pain

Unbearable pain

3.6.1.7. Occlusal disturbances:

- subjective - change of occlusion caused by the fracture: yes no
- objective - visible open bite: yes no

3.6.1.8. Mandibular function impairment by MFIQ (Mandibular Impairment Questionnaire)

Outcome measures after 6 weeks

Answer the following questions as explained on page 3.

How much difficulty do you have, owing to your jaw complaints, with:

- | | | | | | |
|---|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| 1. social activities (with family, friends etc.)? | 1 <input type="radio"/> | 2 <input type="radio"/> | 3 <input type="radio"/> | 4 <input type="radio"/> | 5 <input type="radio"/> |
| 2. speaking? | 1 <input type="radio"/> | 2 <input type="radio"/> | 3 <input type="radio"/> | 4 <input type="radio"/> | 5 <input type="radio"/> |
| 3. taking a large bite (e.g. from an apple) | 1 <input type="radio"/> | 2 <input type="radio"/> | 3 <input type="radio"/> | 4 <input type="radio"/> | 5 <input type="radio"/> |
| 4. chewing hard food? | 1 <input type="radio"/> | 2 <input type="radio"/> | 3 <input type="radio"/> | 4 <input type="radio"/> | 5 <input type="radio"/> |
| 5. chewing soft food? | 1 <input type="radio"/> | 2 <input type="radio"/> | 3 <input type="radio"/> | 4 <input type="radio"/> | 5 <input type="radio"/> |
| 6. work and/or daily activities? | 1 <input type="radio"/> | 2 <input type="radio"/> | 3 <input type="radio"/> | 4 <input type="radio"/> | 5 <input type="radio"/> |
| 7. drinking? | 1 <input type="radio"/> | 2 <input type="radio"/> | 3 <input type="radio"/> | 4 <input type="radio"/> | 5 <input type="radio"/> |
| 8. laughing? | 1 <input type="radio"/> | 2 <input type="radio"/> | 3 <input type="radio"/> | 4 <input type="radio"/> | 5 <input type="radio"/> |
| 9. chewing resistant food? | 1 <input type="radio"/> | 2 <input type="radio"/> | 3 <input type="radio"/> | 4 <input type="radio"/> | 5 <input type="radio"/> |
| 10. yawning? | 1 <input type="radio"/> | 2 <input type="radio"/> | 3 <input type="radio"/> | 4 <input type="radio"/> | 5 <input type="radio"/> |
| 11. kissing? | 1 <input type="radio"/> | 2 <input type="radio"/> | 3 <input type="radio"/> | 4 <input type="radio"/> | 5 <input type="radio"/> |

Eating food involves **taking a bite, chewing and swallowing**. The following addresses some types of food. We want to know how much difficulty you have with eating these types of food. It may be possible that you have not eaten this food lately. In that case you should answer the question with a comparable type of food in mind or indicate how much difficulty you would have in case you were forced to eat this type of food.

How much difficulty do you have, owing to your jaw complaints, with eating:

- | | | | | | |
|------------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| 12. a hard cooky | 1 <input type="radio"/> | 2 <input type="radio"/> | 3 <input type="radio"/> | 4 <input type="radio"/> | 5 <input type="radio"/> |
| 13. meat (e.g. porc or beef) | 1 <input type="radio"/> | 2 <input type="radio"/> | 3 <input type="radio"/> | 4 <input type="radio"/> | 5 <input type="radio"/> |
| 14. a raw carrot | 1 <input type="radio"/> | 2 <input type="radio"/> | 3 <input type="radio"/> | 4 <input type="radio"/> | 5 <input type="radio"/> |
| 15. french bread/white bread | 1 <input type="radio"/> | 2 <input type="radio"/> | 3 <input type="radio"/> | 4 <input type="radio"/> | 5 <input type="radio"/> |

Second announcement (after 6 weeks)

Date of randomization: ___/___/___ Fax no: 0049 351 458 5348

Initials: Number: Institution:

16. peanuts or almonds 1 2 3 4 5
17. an apple (not cut to pieces) 1 2 3 4 5

Third announcement (after 6 months)**Date of randomization:** ___/___/___ **Fax no: 0049 351 458 5348****Initials:** **Number:** **Institution:****3.7 Outcome measures after 6 months** Examination date: _____

3.7.1. Duration of physiotherapy: _____ months _____ days

 Still going on

3.7.2. Lesions of the facial nerve: left right

branch (1-4):	1) 2) 3) 4)	1) 2) 3) 4)
yes	<input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/>	<input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/>
no	<input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/>	<input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/>

① temporal ② zygomatic ③ buccal ④ marginal

4.7.3 Lesion of the auriculotemporal nerve

	left		right	
hypoesthesia/reduced sensation	yes <input type="radio"/>	no <input type="radio"/>	yes <input type="radio"/>	no <input type="radio"/>
numbness	yes <input type="radio"/>	no <input type="radio"/>	yes <input type="radio"/>	no <input type="radio"/>
hyperalgesia	yes <input type="radio"/>	no <input type="radio"/>	yes <input type="radio"/>	no <input type="radio"/>

3.7.4 Lesion of the occipitalis minor respectively auricularis magnus nerve:

	left		right	
hypoesthesia/reduced sensation	yes <input type="radio"/>	no <input type="radio"/>	yes <input type="radio"/>	no <input type="radio"/>
numbness	yes <input type="radio"/>	no <input type="radio"/>	yes <input type="radio"/>	no <input type="radio"/>
hyperalgesia	yes <input type="radio"/>	no <input type="radio"/>	yes <input type="radio"/>	no <input type="radio"/>

3.7.5 Stenosis of acoustic meatus

left	right
<input type="radio"/> yesmm	<input type="radio"/> yesmm
<input type="radio"/> no	<input type="radio"/> no

3.7.6. TMJ mobility

1. Maximal distance between the incisors: _____ mm

2. Lateral mandibular movement: left _____ mm right _____ mm

3. Protrusion: left _____ mm right _____ mm

4. Deviation on protrusion: _____ mm

Second announcement (after 6 weeks)**Date of randomization:** ___/___/___ **Fax no: 0049 351 458 5348****Initials:** **Number:** **Institution:**

3.7.7. Pain assessment:

No pain

Unbearable
pain

3.7.8. Appearance of scar:

Completely satisfied

Completely
dissatisfied

3.7.9. Removal of osteosynthesis material

 Yes, after months No

3.7.10. Occlusal disturbances

- subjective - change of occlusion caused by the fracture: yes no - objective - visible open bite: yes no - major correction by dentist yes no

3.7.11. Mandibular function impairment by MFIQ (Mandibular Function Impairment Questionnaire)

Outcome measures after 6 months

Answer the following questions as explained on page 3.

How much difficulty do you have , owing to your jaw complaints, with:

- | | | | | | |
|---|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| 1. social activities (with family, friends etc.)? | 1 <input type="radio"/> | 2 <input type="radio"/> | 3 <input type="radio"/> | 4 <input type="radio"/> | 5 <input type="radio"/> |
| 2. speaking? | 1 <input type="radio"/> | 2 <input type="radio"/> | 3 <input type="radio"/> | 4 <input type="radio"/> | 5 <input type="radio"/> |
| 3. taking a large bite (e.g.from an apple) | 1 <input type="radio"/> | 2 <input type="radio"/> | 3 <input type="radio"/> | 4 <input type="radio"/> | 5 <input type="radio"/> |
| 4. chewing hard food? | 1 <input type="radio"/> | 2 <input type="radio"/> | 3 <input type="radio"/> | 4 <input type="radio"/> | 5 <input type="radio"/> |
| 5. chewing soft food? | 1 <input type="radio"/> | 2 <input type="radio"/> | 3 <input type="radio"/> | 4 <input type="radio"/> | 5 <input type="radio"/> |
| 6. work and/or daily activities? | 1 <input type="radio"/> | 2 <input type="radio"/> | 3 <input type="radio"/> | 4 <input type="radio"/> | 5 <input type="radio"/> |
| 7. drinking? | 1 <input type="radio"/> | 2 <input type="radio"/> | 3 <input type="radio"/> | 4 <input type="radio"/> | 5 <input type="radio"/> |
| 8. laughing? | 1 <input type="radio"/> | 2 <input type="radio"/> | 3 <input type="radio"/> | 4 <input type="radio"/> | 5 <input type="radio"/> |

Third announcement (after 6 months)**Date of randomization: ___/___/___ Fax no: 0049 351 458 5348****Initials: Number: Institution:**

9. chewing resistant food? 1 2 3 4 5
10. yawning? 1 2 3 4 5
11. kissing? 1 2 3 4 5

Eating food involves **taking a bite, chewing and swallowing**. The following addresses some types of food. We want to know how much difficulty you have with eating these types of food. It may be possible that you have not eaten this food lately. In that case you should answer the question with a comparable type of food in mind or indicate how much difficulty you would have in case you were forced to eat this type of food.

How much difficulty do you have, owing to your jaw complaints, with eating:

12. a hard cooky 1 2 3 4 5
13. meat (e.g. porc or beef) 1 2 3 4 5
14. a raw carrot 1 2 3 4 5
15. french bread/white bread 1 2 3 4 5
16. peanuts or almonds 1 2 3 4 5
17. an apple (not cut to pieces) 1 2 3 4 5

3.8. Results of X-ray examination 6 months postinterventional (OPG, Towne/Clementsich, CT-Scan)

- | | <u>left</u> | <u>right</u> |
|--------------------------------|--|--|
| 1. Correct position: | no <input type="radio"/> yes <input type="radio"/> | no <input type="radio"/> yes <input type="radio"/> |
| 2. Shortening of the ramus: | ____mm | ____mm |
| 3. Angulation of the fragment: | ____° | ____° |
| 4. Resorption of condyle | no <input type="radio"/> yes <input type="radio"/> | no <input type="radio"/> yes <input type="radio"/> |
| 5. Failure of osteosynthesis | no <input type="radio"/> yes <input type="radio"/> | no <input type="radio"/> yes <input type="radio"/> |