The most important advantage of resorbable osteosynthesis material is to avoid a second operation to remove the plates and screws. Additional surgery has inherent risks and further social, health political and economic burden can be avoided. There have been frequent discussions about leaving metallic osteosynthesis material in situ and this option is seen in the various regional and national differences. Despite the body’s tolerance of titanium, removal is recommended by many authors due to various reasons (metallosis, corrosion, thermal paraesthesia, risk of exposure of the osteosynthesis material on progressive resorption in the edentulous patients, artefacts on radiological investigations, malposition and loosening, migration of osteosynthesis material, especially in paediatric craniofacial surgery).

Treatment of mandibular condylar process fractures is an especially interesting field of application for resorbable osteosynthesis systems. Screw and plate loosening is not uncommon in this area. Material removal necessary after such complications leads to new scar formation as well as to a risk of facial nerve paresis. Rasse introduced the first animal study regarding the treatment of condylar process fractures with resorbable osteosynthesis plates and screws.

The lower stability of resorbable osteosynthesis materials compared to metal osteosynthesis demands a technologic rethinking. For example: the longer the screw, the larger the torque force at insertion. Long resorbable screws are difficult to connect with the screwdriver. It is not uncommon that the “normal” short resorbable screw heads break during insertion. Thread cutting requires additional time and significantly reduces stability in comparison with the mostly self-cutting metal screw osteosynthesis.

Therefore new techniques must be considered for the treatment of condylar fractures with resorbable osteosynthesis. The bone welding technology – adopted from the wood-processing industry – describes such an innovation. Bone-welding means that a resorbable pin instead of a screw is inserted with the aid of ultrasound activation during the insertion, the pin is marginally heated by ultrasound energy, enters the pre-drilled hole and fuses in the cancellous bone directly beneath the cortex of bone. This type of osteosynthesis has already proved its value in the treatment of midfacial fractures and in the craniofacial surgery, initially in animal studies and later in clinical treatment. The following work describes two new osteosynthesis methods of fractures of the condylar neck base and diacapitular fractures which have already been implemented clinically.

**Treatment of condylar head fractures by resorbable pins**

The delicate fragments and the limited visibility in treatment of condylar head fractures often lead to the malposition of fragments and osteosynthesis screws. If a screw perforates out of the articular surface, removal will be urgently required (Fig. 1).

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**Fig. 1:** Perforation of the articular surface by a malpositioned long titanium screw, due to the limited lateral visibility, which should be urgently removed

**Fig. 2:** Ultrasound-activated pins with 17, 11 and 7 x 2.1 mm
were each treated by 2 resorbable ultrasound-aided SonicWeld Rx® pins with 17 x 2.1 mm and 11 x 2.1 mm. Pin insertion was performed after a step drilling from the lateral gauge of the condyle. A previous study showed that the ideal drilling hole for the highest stability is a stepped hole with diameters of 2.1/1.6 mm (Fig. 6). A further 10 pig cadaver jaws were fixed with titanium mini screws 17 x 2.0 mm and 11 x 2.0 mm which are commonly used clinically. In this group, each drill hole diameter was 1.5 mm. After the preparation of the test jaws, stability of the osteosynthesis was determined by a shear test. This test was performed by applying the universal strength testing machine TIRAtest 2720. During the shear test, a continuously increasing force with a constant test speed (5 mm/min) was vertically applied on the condylar process. The test set-up is described in Fig. 5.

In order to determine the maximum force causing failure of the fixation, a total of 10 pin-fixed and 10 screw-fixed pig cadaver jaws were tested.

A maximum mean stability of 310 N (min 117, max 487, sd 44 N) was achieved for resorbable pin-fixed condylar head fractures. The condylar heads, which were fixed by 2 mini titanium screws each resisted a maximum mean shear force of 918 N (min 247, max 1347, sd 104 N) (Fig. 6).

While the fixation in the titanium group failed due to screw pull-out, pin fracture within the osteosynthesis gap occurred for fractures being fixed by two resorbable pins. Pull-out of pins which were fused with the bone was minimal (Fig. 7). Stability of the resorbable pin-fixed osteosynthesis in this study achieved about one third of the fracture stability of screw fixation.

Use of the resorbable ultrasound-activated pin system (Fig. 2), which requires no thread cutting, is an innovative alternative solution and allows an osteosynthesis without the necessity of future material removal.

Prior to clinical introduction, biomechanical stability of the osteosynthesis of diacapitular condylar process fractures of the mandible with ultrasound-activated pins (PLA) had to be compared to the previously used titanium screws. A cadaver model was used (Fig. 3). After applying burr hole orientations, using a Lindemann’s burr, a diacapitular fracture was created with an osteotome on fresh, denuded, 4 to 6 months old pig cadaver jaws. The fracture line typically ran from the lateral condylar pole to caudal beyond the capsule and corresponds to fracture type B according to Rasse and Neff et al. 13 14. 10 fractured pig cadaver jaws were each treated by 2 resorbable ultrasound-aided SonicWeld Rx® pins with 17 x 2.1 mm and 11 x 2.1 mm.

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In a mandibular model bone analysis under realistic loading conditions, Neff et al. detected a stability of 200 N for the 1.7-mm small fragment screw, 150 N for the 1.2 mm screw, 100 N for the resorbable screw and 50 N for the Ethisorb® pin, which was already being used by Rasse. However, this study evaluated the extension of the fracture gap under loading and did not analyse maximum power at failure of osteosynthesis. Even though the nominal results are only partially comparable due to the different test conditions, figures show an acceptable level of clinical stability. Differences can also be caused by different fracture geometry. In the present study, realistic fractures were created by superficial preformation, the application of an osteotome and good fracture interdigitation. In cases where the entire surface of the fracture is produced by sawing, less friction and lower stability of the fragments occurs. A further possibility of increasing stability would be the procedure of divergent insertion of multiple pins as proposed by Rasse.

Perforation of the condyle medially or into the joint is less problematic when using a resorbable material. Pins also facilitate the treatment of comminuted fractures. Compared to the application of resorbable screws, the time-consuming process of thread cutting, which may cause secondary fragment displacement, is avoided. Due to the fusion of pin and bone, primary stability of the condylar head is comparable to titanium screws. As pin fractures regularly occurred, stability of the fixation could be increased by increasing the number of pins.

The aim of the following animal study was to compare the stability of condylar head fractures treated by resorbable pins and by the well-established titanium mini screws in vivo. Long-term stability of the osteosynthesis, dynamics of fracture healing within the fracture gap area and the performance of the resorbable pins were evaluated by a macroscopic, radiological and histological analysis at the end of the test period. Furthermore, information about the resorption of the PLA pins in vivo and the impact on the bone tissue should be examined. After the intravitral polychrome sequence bone labeling, the animals were sacrificed 3 months after surgery and examined.

10 animals were treated with resorbable pins and further 10 animals with titanium mini screws according to the well-established method. All animals were always housed and fed species-appropriately in a barn and free-range.

The surgical approach to the temporomandibular joint was performed via a preauricular skin incision being extended to the zygomatic arch of the animal. Thus, the joint could be better demonstrated and the condylar head could be osteotomised dorsally. Each test animal received a unilateral fracture through the condyle. Osteotomy and fracture creation respectively were performed after initial preformation with a drill and completion with an osteotome. In order to still enable mastication dynamics and to minimise the animal’s functional reduction, the temporomandibular joint at the opposite side remained intact. Osteosynthesis was performed at 10 test animals each with either 2 or 3 resorbable pins (Ø 2.1 x 17 and Ø 2.1 x 11 mm) from the SonicWeld® pin system (Fig. 8). 10 further animals acted as a control group and were operated the same way but with 2 to 3 conventional titanium mini screws (Ø 2.0 x 17 and Ø 2.0 x 11 mm). The number of used pins or screws used depended on the anatomical proportions of the fracture.

For optimal evaluation, the animals achieved intramuscular applications of different fluorochromes during the first 8
weeks of healing. After 12 weeks, all animals were sacrificed. The mandibles were exarticulated, removed and after thorough decortications they were retained in Schaffer’s solution. In order to obtain a radiological and macroscopic comparison, preparations of the intact opposite side were similarly preserved. A total of 40 preparations were available for macroscopic analysis and the following radiological three-dimensional evaluation.

First of all, the scar development in the area of the surgery was assessed by macroscopic evaluation. The position and possible deformation of the condylar head were evaluated by assessment of the width of the fracture gap, the height of the mandibular ramus, pin remains and the callus reaction.

A computer-assisted analysis based on computer tomography data (CT) was applied for the objective evaluation of the three-dimensional stability. The condylar processes were examined in pairs and in conventional position in the computer tomography in axial view. A Multislice CT was used for this examination. The data records obtained were saved as DIOCM files and followed up at a BrainLAB® workstation using the program iPlan® cranial 2.6 (BrainLAB AG, Munich, Germany). For this purpose, the mandibular fragments were initially segmented automatically. Then the condylar heads of both sides were segmented with orientation on the semilunar incisure and, then, their volume was determined. A volume comparison between the intact and the surgically treated side could be carried out by means of this method. Callus adsorption and also the enlargement of the joint gap could be digitally recorded (Fig. 9).

A further important evaluation criterion regarding the success of open reduction of temporomandibular joint fractures is the preservation of vertical dimension of the ramus. A uniform height of the joint is highly significant for an undisturbed articulation of both temporomandibular joints. If shortening of the mandibular condylar process occurs, a disharmony of the interdependent movements will result. A further consequence of loss of height will be structural alterations also at the intact joint of the opposite side. Measurement was carried out on the computer tomograms by means of the iPlan® cranial 2.6 software as well as to the method proposed by Lindqvist and Iizuka (Fig. 10).

After removal, all fractures were healed with full stability. As far as it can be seen in macroscopy, remains of pins were present. However, the majority of the insertion holes were covered with callus, especially at the lateral exterior pole of the condylar process. A similar callus covering was seen over the titanium screws. The original shape of the condylar head was preserved. There were no obvious height reductions visible in the macroscopy. The fracture gap was barely detectable in all surgically treated joints.

Based on the CT evaluation, numerical data regarding the volume of the condylar process and a possible height reduction, a comparison with the intact side could be achieved. The difference between pin and screw group is not significant (p = 0.66) so that there is no difference between both groups regarding a volume increase. A height reduction of the mandibular ramus in comparison to the intact side was determined in both groups. The resorbable pin group showed an average reduction of -1.33 mm (min. -4.2 mm, max. +2.1 mm, sd 1.8 mm). The analysis of the screw group shows an average reduction of -1.75 mm (min. -5.6 mm, max. +3.0 mm, sd 2.5 mm). The preparations of the intact joints showed no verifiable differences, neither macroscopically nor radiologically.
In summary, no disadvantages of the resorbable pin osteosynthesis compared with the titanium screw osteosynthesis were identified. Insertion and resorption behaviour of the pin material has been already comprehensively examined in animal experiments and in other human indications. Advantages of the resorbable material (degradability, no necessity of material removal) prevail so that the use of it for treatment of condylar head fractures in humans is a possible indication.

Clinical introduction of the new ultrasound-assisted osteosynthesis technique was possible after successful in vitro test of the resorbable SonicWeld Rx® pins and the animal experimental establishment of the surgery method. The following CT images and the photographs of the intraoperative site show a condylar head fracture of the right temporomandibular joint (Fig. 11). The 48 years old female patient was roller-skating and fell on her chin. As a result she suffered a type B condylar head fracture with complete loss of the support in the mandibular fossa. Open reduction was therefore indicated. Stability of osteosynthesis was assessed by careful movement tests of the reposition pin and by mouth opening movements. Fig. 12 shows the immediate postoperative CT image. A normal position of the joint fragment and an anatomically correct reconstruction of the condylar head can be seen. To prevent postoperative malocclusion which could be caused by a joint effusion despite correct fragment position, a two-day postoperative immobilisation using Ivy ligatures was carried out. Prior to mobilisation the patient was able to eat soup. Secondary displacements during the further healing process are not expected.
Three-dimensional resorbable osteosynthesis at the condylar base

With moderately or grossly displaced condylar process fractures there are considerable intraoperative and postoperative forces after repositioning. A sufficiently stable fixation with conventional plate systems made of PLA seems to be problematic. Three-dimensional shaping of a resorbable mesh made of Resorb x® around the condylar process following reduction is proposed for these cases (Fig. 14).

The mesh plate is softened in a water bath and can be primarily moulded on a sterile phantom model. Final adjustment can be made on fixing to the bone. After hardening of the mesh plate in situ, the fracture is stable and fixed in the correct position. Finally, the osteosynthesis is fixed by the application of pins from the SonicWeld® system which has only to resist further movement of the fragments (Fig. 15). The suggested system has been successfully used several times so far. Deep and medium high, medially and laterally displaced fractures of the condylar process were treated. No secondary displacements were seen on the routine postoperative x-rays (Fig. 16). There were no problems with wound healing nor swellings associated with resorbable materials.

In different experimental in vivo studies, uncomplicated osseointegration of large mesh plates made of poly-D/DL-lactide fixed with pins from the SonicWeld Rx® has been verified. Clinical use in craniofacial surgery and with midface fractures is well-established. The three-dimensional fixation of condylar fractures could be indicated for stable resorbable osteosynthesis.

Fig. 14: Mesh plate with pin outlined at a model.

Fig. 15: Fracture of the condylar process base – left: fracture reduced, middle: fixation of the molded resorbable mesh with another pin, right: complete osteosynthesis.

Fig. 16: Left: displaced condylar fracture on orthopantomography detail, right: treated with resorbable mesh (Resorb x®) and pins from the SonicWeld Rx® system.
References

1) Obwegeser J.A.
Resorbier- und umbaubare Osteosynthesematerialien in der Mund-, Kiefer- und Gesichtschirurgie.

2) Fischer-Brandies E., Zeintl W., Schramel P., Brenner K.
Zum Nachweis von Titan im Organismus bei temporärer Alloplastik.

3) Iizuka T., Lindqvist C.
Rigid internal fixation of mandibular fractures. An analysis of 270 fractures treated using the AO/ASIF method.

4) Kim Y.K., Yeo H.H., Lim S.C.
Tissue response to titanium plates: a transmitted electron microscopic study.

5) Obwegeser J.A.
Osteosynthesis using biodegradable Poly-p-dioxanon (PDS II) in Le Fort I-osteotomy without postoperative intermaxillary fixation.

6) Schneider M., Lauer G., Eckelt U.
Surgical treatment of fractures of the mandibularcondyle: a comparison of long-term results following different approaches - functional, axiographical, and radiological findings.

Resorbable poly(D,L)lactide plates and screws for osteosynthesis of condylar neck fractures in sheep.

An experimental in vivo analysis of the resorption to ultrasound activated pins (SonicWeld®) and standard biodegradable screws (Resorb X®) in sheep.

9) Eckelt U., Nitsche M., Müller A., Pilling E., Pinzer T., Roensner D.
Ultrasound aided pin fixation of biodegradable osteosynthetic materials in cranioplasty for infants with craniosynostosis.

10) Meissner H., Pilling E., Richter G., Koch R., Eckelt U., Reitemeier B.
Experimental investigations for mechanical joint strength following ultrasonically welded pin osteosynthesis.

Bone welding - a histological evaluation in the jaw.

An experimental study of the biomechanical stability of ultrasound-activated pinned (SonicWeld Rx®, Resorb X®) and screwed fixed (Resorb X®) resorbable materials for osteosynthesis in the treatment of simulated craniosynostosis in sheep.

13) Rasse M.
Diakapituläre Frakturen der Mandibula. Die operative Versorgung - Tierexperiment und Klinik.

Neue Aspekte zur Indikation der operativen Versorgung intraartikulärer und hoher Kiefergelenkfraktur.

Stabilität der Osteosynthese bei Gelenkwalzfrakturen in Klinik und biomechanischer Simulation.
16) Rasse M.  
Diakapituläre Frakturen der Mandibula. Eine neue Operationsmethode und erste Ergebnisse.  

17) Schneider M., Loukota R., Eckelt U.  
Reduction of diacapitular fractures of the mandibular condyle using a special repositioning pin.  

18) Lindqvist C., Iizuka T.  
In: Härle F, Champy M, Terry B, editors.  
Atlas of Craniomaxillofacial Osteosynthesis.  

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

Open reduction and internal fixation versus closed treatment and mandibulomaxillary fixation of fractures of the mandibular condylar process: a randomized, prospective, multicenter study with special evaluation of fracture level.  

21) Spiessl B., Schroll K.  