Self-adapting washer system for lag screw fixation of mandibular fractures. Part II: in vitro mechanical characterization of 2.3 and 2.7 mm lag screw prototypes and in vivo removal torque after healing

Hendrik Terheyden,¹ Christian Mühlendyck,¹ Martin Sprengel,¹ Klaus Ludwig,² Franz Härle¹

¹Department of Oral and Maxillofacial Surgery, University of Kiel, Arnold Heller Str. 16, D-24105 Kiel, Germany (Head: Prof. Dr Dr F. Härle); ²Department of Maxillofacial Prosthodontics, Propaedeutic and Dental Material Science, University of Kiel, Arnold Heller Str. 16, D-24105 Kiel, Germany (Head: Prof. Dr M. Kern)

SUMMARY. The aim of this study was to mechanically characterize self-tapping 2.3 and 2.7 mm titanium lag screw prototypes which are part of the newly developed 'self-adapting washer' maxillofacial lag screw osteosynthesis system. In vitro in a screw testing machine the insertion torque, maximum locking torque and axial force and the ultimate torsional strength were assessed. In vivo in six miniature pigs using a mandibular symphyseal fracture model, the removal torques after 3 and 6 months of healing were measured. Additionally the bone-metal contact (BMC) of the screws was assessed histometrically. The maximum insertion torque (0.185 Nm) was far below the mechanical limits of the screws (2.3 mm = 0.96 Nm, 2.7 mm = 1.6 Nm). A tightening of the 2.7 mm screw with an axial force of 1000 N and of the 2.3 mm screw with 500–550 N leaves a safety margin of approximately one-third on the ultimate torsional strength. Clinically these values permit the use of two 2.3 mm lag screws or one 2.7 mm lag screw in mandibular symphysis fractures since 1000 N tensile axial force are required in this indication. During screw removal after 6 months healing, torque levels close to the mechanical limits of the screws were observed. This failure rate may have been due to the BMC of 49.8% which was in the range of titanium dental implants. Accordingly the screw heads were reinforced to prevent fractures. \bigcirc 1999 European Association for Cranio-Maxillofacial Surgery

INTRODUCTION

A new self-adapting washer for lag screw fixation of mandibular fractures has recently been introduced (*Terheyden* et al., 1999). That previous work and the present study are part of the development of a new maxillofacial lag screw osteosynthesis system.

Open reduction and internal fixation of mandibular fractures using plates has become an accepted method during the past three decades (Luhr, 1968; Champy and Lodde, 1976; Cawood, 1985; Iizuka and Lindqvist, 1992; Tuovinen et al., 1994). In contrast to orthopaedic surgery lag screws play a minor role in maxillofacial osteosynthesis (Krenkel, 1994; Kallela et al., 1996). However, besides rigid fixation, lag screws have distinct advantages when compared with plates in appropriate indications in mandibular fractures (Shetty et al., 1995). Forces are applied inside the cross-section of the fractured bone (Shetty and Caputo, 1992). Thus, in the mandible there is no tendency to develop lingual or alveolar gaps which are often encountered with plates (Ellis and Ghali, 1991a; Iizuka and Lindqvist, 1992; Hayter and Cawood, 1993). Owing to compression of the fragments the gaps in the fracture line vanishes almost completely (Ellis and Ghali, 1991a; Kallela et al., 1996). Lag screw fixation requires minimal equipment and is quicker than plating (Niederdellmann and Shetty, 1987; Ellis and Ghali, 1991a; Shetty et al., 1995). Finally, lag screws require minimal surgical

approaches for insertion and removal (Niederdellmann and Shetty, 1987).

Currently available lag screw systems have external diameters of 2.0 mm (*Krenkel*, 1994), 2.3 mm (*Chotkowski*, 1997) or 2.7 mm (*Niederdellmann* and *Shetty*, 1987; *Ellis* and *Ghali*, 1991a; b). The use of two lag screws has been advocated in mandibular symphysis fractures (*Ellis* and *Ghali*, 1991a). A resistance against minimum of 1000 N of tensile force has been postulated for osteosynthesis devices in the mandibular symphysis, which is mechanically the most demanding region of the mandible (*Champy* et al., 1986).

Today osteosynthesis devices are often removed once fracture healing is complete. Titanium and its alloys are preferred materials for osteosynthesis devices owing to their high biocompatibility. Titanium dental implants develop a direct bony anchorage of high mechanical strength, called 'osseo-integration' (*Brånemark*, 1983). The force required for removal of large titanium lag screws after healing is completed has not been reported yet.

The first part of this study (*Terheyden* et al., 1999) dealt with the preclinical in vivo and in vitro evaluation of the self-adapting washer. The aim of this second part, was to evaluate in vivo and in vitro mechanical parameters of lag screws which are planned for use in combination with the self-adapting washer in a planned osteosynthesis system for mandibular fractures.

MATERIAL AND METHODS

Lag screw prototypes

The screw prototypes were fabricated from a titanium aluminium vanadium alloy (Ti6Al4V) (Figs 1 and 2). In the prospective osteosynthesis system these screws will be combined with a self-adapting washer (*Terheyden* et al., 1999) and two diameters will be available (2.3 and 2.7 mm). The screws have a self-tapping cutting flute and have a 1.65 mm quadrangular slot called 'centre drive'. A 1.6 mm quadrangular wrench was used. Pilot holes were made with 2.01 and 2.31 mm spiral drills at a size of 85% of the external diameter of the screws (*Heidemann* et al., 1988).

In vitro analysis

The measurements were performed with 2.3 and 2.7 mm lag screw prototypes. For this purpose a screw testing machine was developed. This machine consisted of an electric screw driver. Power, rotational speed and axial preload of the screw driver were all adjustable. Torque was monitored continuously using an UTA-check Star Torque Auditing System (Type UTA-444-V-0). The screw was inserted at 20 r.p.m. into samples of plain polyvinylchloride (PVC) plates of 1-6 mm thickness at an axial preload of 5 N. The pilot holes had been previously drilled with a 2.01 mm diameter for the 2.3 mm screw and a 2.31 mm diameter for the 2.7 mm screw. At the end of the insertion process the screw head became seated in a tightly fitting brass washer and at this point the maximum torque was recorded. With the maximum torque the screw also exerted its maximum axial force. The axial force was measured by a Kistler piezo-electric load cell, placed between the washer and the PVC plate (Type 9132A). For each material thickness/screw combination ten measurements were performed.

The same screw testing machine was used to determine the ultimate torsional strength of the screws. For this purpose the screw tip was fixed and the electrical screw driver started to turn. Torque was recorded until either the threaded part, the screw shaft or the centre drive slot in the screw head failed. Seven measurements were done for each screw (2.3 and 2.7 mm). The axial preload of the screw driver was adjusted to exert between 5 and 20 N in this part of the study.

In vivo analysis

Six female Göttingen miniature pigs 18 months of age and weighing approximately 40 kg (Ellegard Göttingen Minipigs ApS, Dalmose, Denmark) were used.¹



Fig. 1 – Engineering drawing of the 2.3 mm self-tapping lag screw fabricated from the titanium alloy Ti6Al4V. The spherical head together with the washer form a ball and socket joint.

The animals were fed with $2 \times 250 \text{ g/d}$ standard soft diet (Altromin 9023[®], Altromin International GmbH, Lage, Germany) and water ad libitum. Anaesthesia was induced with intramuscular 30 mg ketamine (Ketavet[®], Upjohn GmbH, Heppenheim, Germany) and 2 mg xylazalin (Rompun(R), Bayer AG, Leverkusen, Germany). Intratracheal intubation was performed and anaesthesia was maintained with gas (66% N_2O and 32% O_2 and 2% isoflurane [Forene[®], Abott GmbH, Wiesbaden, Germany]). Perioperative antibiotic levels were achieved with a preoperative i.m. injection of 1 g Clemi-zol-Penicillin (Clemizol-Penicillin i.m. forte[®], Grünenthal GmbH, Aachen, Germany). Postoperative pain control was performed with one injection of 500 mg metamizol i.m. (Novalgin®, Hoechst AG, Bad Soden, Germany) and oral tramadol $2 \times 50 \text{ mg/d}$ (Tramal[®], Grünenthal GmbH, Aachen, Germany).

Mandibular symphysis fractures were created as described previously (*Terheyden* et al., 1999). Briefly, the mandibular symphysis was exposed extraorally and a fracture line was marked by pilot holes. A chisel was used to split the mandible in a sagittal direction, preserving as much as possible of the

¹The animal study was approved by the Minister of Environment, Nature and Forestry of Schleswig-Holstein.



Fig. 2 – Engineering drawing of the self-adapting washer (SAW). A ball and socket joint is formed together with the spherical screw head, range $0-60^{\circ}$. The SAW automatically aligns to a bone surface in a defined position guided by the slut.

natural serration of the fragment ends. Large reduction forceps were used to adapt the fragments. The fractures were treated with prototypes of three 2.3 mm self-tapping lag screws and self-adapting washers using 2.31 mm gliding holes, plus 2.01 mm pilot holes in the distant fragment. Four additional screws were placed in the anterior mandible. Their length (20–35 mm) depended on the bone thickness available.

After two weeks the intraperitoneal injection of fluorochromes started under sedation: xylenol orange (6% in 2% NaHCO₃ solution, 1.5 ml/kg body weight) after 2 and 3 weeks, calcein green (1% in 2% NaHCO₃ solution, 5 ml/kg body weight) after 4 and 5 weeks, alizarincomplexon (3% in 2% NaHCO₃ solution, 0.8 ml/kg body weight) after 6 and 7 weeks and doxycycline (1 ml/kg body weight, Doxycyclin Ratiopharm SF[®], Ratiopharm GmbH & Co, Ulm, Germany) after 8 and 9 weeks.

Two animals were sacrificed 3 months postoperatively and four animals were sacrificed after 6 months. In the three-months animals, all available screws were subjected to mechanical analysis. In the six-months animals two screwsites were used for histology and the rest subjected to mechanical analysis. The removal torque was assessed using an UTA-check Star Torque Auditing System (Type UTA-444-V-O), the screw driver being handturned. Afterwards an intracardic perfusion with 101 saline and 101 fixation solution (Glutaraldehyde 2.5% with formalin 3%) was performed at 120 mm/Hg.

Histology

After harvesting, the mandibular symphyseal block was immersed for 3 days each in 10% formalin, Sörensen's phosphate buffer and 70% isopropyl alcohol. Along the axis of the screw a vertically (dorsoventral) orientated section for each screw was cut from the tissue block. The sections were prepared according to the method described by Donath and Breuner (1982). After gradual dehydration in ethyl alcohol the block was embedded in acrylic resin (Fluka Chemie AG, Buchs, Switzerland) and sectioned in 0.5 mm slices. One section per screw (a total number of eight sections) was fixed on an acrylic carrier and ground and polished down to approximately 90 µm for fluorescence microscopy under UV light. Afterwards the sections were ground and polished to approximately 30 microns and stained with toluidine blue for further evaluation including histometric analysis. The percentage of metal-bone contact (BMC) was measured in the threaded area. This was accomplished using a computer morphometry program in a digital image analysis workstation (Q500MC, Leica[®] Cambridge Ltd, Cambridge, UK). Briefly the microscopic image was digitized by a video camera and a frame grabber card in the computer from the microscope at a magnification of $10 \times$. The digital image was read by the computer program. Bone, stained blue, was easily discernable from metal. A measuring frame $(1.5 \times$ 3.0 mm) was placed over the screw/bone interface. The metallic surface of the titanium implant was traced by hand using the computer mouse. The total length of the metal surface was measured by the computer after calibration. Then the contact areas of bone to metal were traced and the length of the line segments were added (bone-metal interface). By division of the bone-metal interface by the total length, the percentage of BMC was calculated.

Statistical methods

The in vivo and in vitro mechanical data were checked for normal distribution by visual control. Variances were checked with the Hartley *F*-test and subsequently the appropriate *t*-test was used to compare the data. The significance level α was 0.05.

RESULTS

Ultimate torsional strength

The mechanical failure of the shaft region and failure of the centre drive slot, depending on the axial preload of the screw driver, are summarized in Table 1.

Table 1 – Torsional strength of the 2.3 and 2.7 mm screws and limits of the centre drive slot in the screw head at 5 and 20 N axial preload of the screw driver (mean values and standard deviations). Differences were significant using the *t*-test ($\alpha = 0.05$)

Mechanical failure screw shaft (Nm)						
2.3 mm Ø	2.3 mm Ø	P value (t-test) $n = 7$				
0.957 ± 0.056	1.599 ± 0.052	0.0149				
Mechanical failure centre drive slot (Nm)						
500 g axial load	2000 g axial load	P value (t-test) $n = 7$				
$1.31\overline{2} \pm 0.069$	1.460 ± 0.068	< 0.001				

Insertion torque

Insertion of the 2.7 mm self-tapping screws required increasing torque with increasing material thickness. The maximum insertion torque (Fig. 3) was more than 8 times lower than the torsional strength of the screw shaft and more than 7 times lower than the limits of the centre drive slot (5 N axial screw driver preload) (see Fig. 3 and Table 1).

Maximum locking torque and axial force

Except for the 1 mm PVC plate the 2.7 mm screw exerted slightly higher compression forces. Material thickness is the most important parameter in axial force (Fig. 4). For the 1000 N axial force of the 2.7 mm screws a torque of 1.050 Nm was required (Fig. 5). This is 65% of the torque at failure



Fig. 3 – Insertion torque of the 2.7 mm self-tapping screw in PVC plates of 1–6 mm thickness (n = 10, mean values and standard deviations). The increment is due to friction of the threaded part of the screw, not caused by cutting of the threads. \Rightarrow , 2.7 mm.



Fig. 4 – Maximum torque after the screw became seated (n = 10, mean values and standard deviations). Differences were tested with a *t*-test, * significant. ($\alpha = 0.05$). \Rightarrow , 2.7 mm, \rightarrow , 2.3 mm.

(1.600 Nm) which equals approximately a 33% safety margin. In the 2.3 mm screw a 33% safety margin resulted in a torque of 0.630 Nm and an axial force of approximately 500-550 N.

Animal study

After healing the removal torque for the screws was assessed. A total of 33 screws with a diameter of 2.3 mm were retrieved for mechanical analysis (Fig. 6). Removal torque was significantly dependant on duration of healing and length of the screws (Table 2). In the 25 mm length group only 3 screws were retrieved (mean removal torque 0.647 Nm) and excluded from statistical analysis owing to the low number in this group.

Fluorescence microscopy revealed Haversian remodellig close to the screw beginning in the third week (Fig. 7). During the first 8 weeks approximately one-third of the bone adjacent to the screw was remodelled (Fig. 7). In the toluidine blue-stained sections bone was found in direct apposition to the metal surface (Fig. 8). The mean BMC in the shaft region was 49.8% and the standard deviation was 17.9%.

DISCUSSION

In investigating mechanical properties of bone screws *Ansell* and *Scales* (1968) demonstrated the need for a synthetic material owing to the great variation of the mechanical properties of natural bone. Polyvinyl-



Fig. 5 – Maximum compression of the load cell = maximum axial force of the screw after the screw became seated (n = 10, mean values and standard deviations). Material thickness is more important for axial force than screw diameter. Differences were tested with a *t*-test, * significant. ($\alpha = 0.05$). \Rightarrow , 2.7 mm, -, 2.3 mm.



Fig. 6 – Removal torque of 2.3 mm screws (20–35 mm in length) after 3 and 6 months of healing of mandibular symphysis fractures. More torque is required in longer screws and after longer healing period. Statistical analysis is given in Table 2.

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Table 2 – Removal torque of a total number of 33 2.3 mm lag screws of different lengths after 3 and 6 months of healing. A high failure rate of the screw shaft was recorded. Owing to the low number (n=3) the 25 mm group was excluded from statistical analysis (*t*-test, $\alpha = 0.05$) (compare Fig. 6). In the 35 mm group '6 months' required a significantly higher removal torque (P=0.018). The removal torques in the 20 (P<0.001) and 30 mm (P<0.025) groups were significantly lower than in the 35 mm screws. This means that increasing screw length and duration of healing results in higher removal torques

	Removal torque (Nm)					
	6 months	6 months	6 months	6 months	3 months	
Screw length (mm)	$20 \\ 0.600 + 0.192$	25 0.647	$30 \\ 0.754 \pm 0.326$	35 1.138 + 0.248	35 0.857+0.135	
п	7 -	3	7	9	7	
n (fractured)	0	0	4	7	2	



Fig. 7 – Fluorescence microscopy after polychromic sequential labelling of the threaded part of the screw after 6 months of healing. Remodelling with new formation of Haversian systems (arrows) close to the metal surface (black area at the bottom). Remodelling was enhanced in the proximity of the screws. About one-third of the pre-existing bone was remodelled during the first 8 postoperative weeks (Fluorescence, composite slides, \times 65).

chloride (PVC) has been proven to have mechanical properties comparable to cortical bone at a low variability owing to its homogeneity (*Heidemann* et al., 1998). Thus, the use of natural bone samples was unnecessary in the present study for evaluating the limits of mechanical failure among two groups of screw diameter.

Thickness of fixed material is probably one of the most important factors determining the axial force of screws, more important than screw diameter (*Phillips* and *Rahn*, 1989; *Boyle* et al., 1993). The data observed in the present study using PVC are consistent with previous studies using mandibular bone (*Phillips* and *Rahn*, 1989). A maximum torque of 1.43 Nm for 2.7 mm screws and an axial force of between 300 and 1200 N were observed in mandibular bone of 1 to 4 mm thickness (*Phillips* and *Rahn*, 1989). As observed in the present study the larger 2.7 mm screws in thin bone (1 and 2 mm) had no significant advantage when compared with smaller 2.0 mm

screws (*Phillips* and *Rahn*, 1989). If the 2.7 mm screws are tightened to a 1000 N compression force, the torque would be 1.050 Nm. This is 65% of the torque at failure (1.600 Nm) which equals an approximately safety margin of 33%. In the 2.3 mm screw a 33% safety margin would result in a torque of 0.630 Nm and a compression force of approximately 500–550 N. These recommendations could be implemented by the use of a torque limiting screw driver, which has been advocated frequently (*Ansell* and *Scales*, 1968; *Ellis* and *Laskin*, 1994).

The question of pretapped versus self-tapping screws has caused controversy (*Nunamaker* and *Perren*, 1976; *Phillips* and *Rahn*, 1989). In selftapping screws an increased incidence of microfractures may lead to decreased retention (*Phillips* and *Rahn*, 1989). In contrast, a more intimate contact of the screw flanks may improve retention (*Bähr*, 1990). In mandibular bone, locking torque was greater for self-tapping screws (*Ellis* and *Laskin*, 1994). Histolo-



Fig. 8 – Bone (arrows) in close apposition to the metal surface (black area at the bottom). Bone-metal contact (BMC) was assessed histometrically (Toluidine blue, non-decalcified, $\times 60$).

gically pretapped screws cause more remodelling and presumably earlier loss of retention (Bähr and Lessing, 1992). The process of pretapping decreases the insertion torque by 35-40% by virtue of the fact that torque is not expended in cutting the threads (Hughes and Jordan, 1972). In the present study, by comparison of the insertion torque in different material thicknesses, it was obvious that friction of the threads and not the cutting flute accounted for the progressive increment of insertion torque associated with material thickness. Moreover, in the present study the maximum insertion torque in the thickest samples was 0.183 Nm. This is within the mechanical failure limits of the center drive slot and well within the fracture torque of the investigated screw prototypes. Thus, measuring the 2.3 mm insertion torque was unnecessary in the present study regarding mechanical overload. Pretapping has been claimed to allow removal of debris prior to screw insertion (Phillips and Rahn, 1989). However, using a drill bit slightly larger than the core diameter of the screw will create enough extra room for the deposition of bone debris (Ansell and Scales, 1968; Robinson et al., 1992). The drill hole can be enlarged up to 85% of the external diameter of the screw without loss of retention (Heidemann et al., 1998). This relationship has been applied in the present study. The lag screw should be carefully anchored bicortically, providing that the cutting flute (which is a region of decreased retention) protrudes through the far cortex (Phillips and Rahn, 1989). This should also help to prevent problems in screw removal owing to bone growth into the cutting flute (Ansell and Scales, 1968).

It is recommended that there should be sufficient internal fixation to resist the maximum forces of mastication (Champy et al., 1986; Tate et al., 1994; Loukota and Shelton, 1995). The maximum masticatory forces in healthy dentate young men have been measured at 660 N in the molar and 290 N in the incisor regions (Champy et al., 1986). Owing to additional torsion forces Champy and co-workers (1986) determined that an osteosynthesis device should be able to resist a tensile force of 1000 N in the anterior mandible. These forces are probably higher than the forces generated shortly after trauma which have been measured with a maximum of 215 N after 4 weeks (Gerlach et al., 1984) and 138 N within the first 6 weeks after trauma (Tate et al., 1994). However, these forces can serve as a safety limit for screw design. Static compression should always exceed the dynamic forces (Perren, 1979). Thus, in the clinical situation two 2.3 mm screws have to be placed in the anterior mandible in accordance to previous recommendations (Ellis and Ghali, 1991a). Based on the present data each screw contributes 500-550 N compressive force. However, if 2.7 mm screws are applied, the present data suggest the use of only one lag screw. It has yet to be investigated whether interlocking of the natural serrations of the fragment ends counteract rotational forces sufficiently in anterior mandibular fractures.

Owing to bone healing the resistance to removal of a bone screw usually exceeds the initial forces at insertion (*Bechtol*, 1959). Using stainless steel screws, a layer of connective tissue was found at the bonemetal interface (*Uhthoff*, 1973). For titanium a direct

bone to metal bond of high mechanical strength was described, the basis for the concept of osseointegration of dental implants (Brånemark, 1983). This intimate contact has also been demonstrated in osteosynthesis screws in facial bones (Bähr and Lessing, 1992). In the present study the mean BMC was 49.8% for machined screws made of Ti6A14V. The value is comparable with the BMC observed in dental implants. In a number of those studies attempts have been made to increase bone contact with implant surfaces by modifying the surface structure of the implants (Gotfredsen et al., 1995). In canine maxillae after 4 months, BMC ranged between 42.9% for a machined and 65.1% for a TiO₂-blasted surface (Ericsson et al., 1994). In a miniature pig study different types of titanium implants were inserted into cancellous bone around the knee joint. Among the titanium surfaces after 6 weeks, the highest BMC was observed in rough sandblasted titanium (57.7%) significantly superior to plasma sprayed titanium (37.8%) and electropolished titanium (25.1%). An acid pretreatment (33.6% vs. 57.7%) and surface roughness (medium grit sandblasting 21.6% vs. large grit 57.7%) significantly increased BMC (Buser et al., 1991). In the latter study (in the minipig) BMC did not significantly increase after 3 weeks when compared to 6 weeks (Buser et al., 1991). Seven out of 9 of the 2.3 mm screws fractured at the 35 mm length group after six months of healing caused by removal of torques exceeding their mechanical limits. However, after only 3 months bone healing, the mean removal torque and the rate of screw failure were significantly reduced. This suggests that lag screw removal can be problematic after longer periods of healing. However, the application of such data to humans may be limited since the minipig is known for its rapid and high bone forming capacity (Buser et al., 1991). Based on present data, a reinforced version of the screw head was developed (Fig. 1) and for screws longer than 30 mm it would be advisable to select the larger 2.7 mm diameter screws.

The use of resorbable self reinforced poly-L-lactide screws (SR-PLLA) has been proposed for fixation of symphyseal fractures (Kallela et al., 1999). As with most bone screw systems currently in clinical use (Altobelli, 1992) the present lag screw is made of titanium alloy (Ti6A14V). This material has better mechanical properties (yield strength 838–1036 MPa) than commercially pure titanium (yield strength 170-485 Mpa) at a comparable biocompatibility (Altobelli, 1992). The mechanical properties of the alloy are comparable to stainless steel (yield strength 689–1160 Mpa). Since yield strength of cortical bone is 130 Mpa (Altobelli, 1992), this means that overtightening of the present screw type would probably lead to bone failure rather than to screw failure. In contrast, for bioresorbable SR-PLLA screws (maximum tensile strength of PLLA is 15.94-17.4 Mpa, (Giordano et al., 1996) failure would occur in the screw. That means that a resorbable screw cannot be tightened as much as a metal screw and that larger

screw diameters are required to obtain a certain force. In a study using resorbable SR-PLLA lag screws for mandibular symphysis fractures this problem was addressed (Kallela et al., 1999). Although two 3.5 mm screws and a precompression with pliers was recommended, clinically only moderate interfragmentary compression was reported (Kallela et al., 1999). This observation may be explained by an in vitro study (Shetty et al., 1997). A maximum of only 100 N axial force was achieved with the 3.5 mm SR-PLLA screw and, before screw failure, a non-linear behaviour was observed. In contrast, in the present study a linear mechanical behaviour and a ten-fold higher axial force of more than 1000 N was measured for a single even smaller 2.7 mm metal screw. Thus, if a minimum of 1000 N axial force was accepted as the requirement for an osteosynthesis device at the mandibular symphysis (Champy et al., 1986), 3.5 mm SR-PLLA screws would not reach the required force. Bioresorbable osteosynthesis certainly has advantages to metal. However, biomechanically the compression force would not even reach the estimated dynamic bite forces (Perren, 1979). Thus, for the use of resorbable screws in the anterior mandibular body fractures, additional means of fixation need to be considered. Furthermore, resorbable screws cannot be used in a self tapping fashion.

In conclusion, the maximum insertion torque of the self-tapping lag screw occurred far below the ultimate torsional strength. Tightening of the 2.7 mm screw with an axial force of 1000 N and the 2.3 mm screw with 500–550 N left a safety margin of approximately one-third of the ultimate torsional strength. Clinically these figures would suggest the use of two 2.3 mm lag screws or one 2.7 mm lag screw to fix mandibular symphysis fractures.

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References

- Altobelli DE: Implant materials in rigid fixation: physical, mechanical, corrosion and biocompatibility considerations. In: Yaremchuk MJ, Gruss JS, Manson PN (eds.): Rigid fixation of the craniomaxillofacial skeleton. Butterworth-Heinemann, Stoneham 28, 1992
- Ansell H, Scales JT: A study of some factors which affect the strength of screws and their insertion and holding power in bone. J Biomech 1: 279, 1968
- Bähr W: Pretapped and self-tapping screws in the human midface. Torque measurements and bone screw interface. Int J Oral Maxillofac Surg 19: 51, 1990
- Bähr W, Lessing R: The response of midfacial bone in sheep to loaded osteosynthesis screws in pretapped and nontapped implant sites. J Oral Maxillofac Surg 50: 1289, 1992
- Bechtol CO: Internal fixation with plates and screws. In: Bechtol CO, Ferguson AB, Laing PG (eds.): Metals and engineering in bone and joint surgery. Baltimore: Williams and Wilkins, 152, 1959
- Boyle JM, Frost DE, Foley WL, Grady JJ: Comparison between uniaxial pull-out tests and torque measurement of 2.0-mm selftapping screws. Int J Adult Orthodon Orthognath Surg 8: 129, 1993

- Brånemark PI: Osseointegration and its experimental background. J Prosth Dent 50: 399, 1983
- Buser D, Schenk RK, Steinemann S, Fiorellini JP, Fox CH, Stich H: Influence of surface characteristics on bone integration of titanium implants. A histomorphometric study in miniature pigs. J Biomed Mater Res 25: 889, 1991
- Cawood JI: Small plate osteosynthesis of mandibular fractures. Br J Oral Maxillofac Surg 23: 77, 1985
- Champy M, Lodde JP: Synthesis mandibulaires. Location des synthesis en fonction des contraintes mandibulaires. Rev Stomatol 77: 971, 1976
- Champy M, Pape HD, Gerlach KL, Lodde JP: The Strasbourg miniplate osteosynthesis. In: Krüger D, Schilli W (eds.): Oral and maxillofacial traumatology, Vol. 2. Chicago: Quintessence, 19, 1986
- Chotkowski G: Symphysis and parasymphysis fractures. Atlas Oral Maxillofac Clin North Am 5: 27, 1997
- Donath K, Breuner G: A method for the study of undecalcified bones and teeth with attached soft tissues. J Oral Pathol 11: 318, 1982
- Ellis E, Ghali G: Lag screw fixation of anterior mandibular fractures. J Oral Maxillofac Surg 49: 13, 1991a
- Ellis E, Ghali G: Lag screw fixation of mandibular angle fractures. J Oral Maxillofac Surg 49: 234, 1991b
- Ellis JA, Laskin DM: Analysis of seating and fracturing torque of bicortical screws. J Oral Maxillofac Surg 52: 483, 1994
- Ericsson I, Johansson CB, Bystedt H, Norton MR: A histomorphometric evaluation of bone-to-implant contact on machine-prepared and roughened titanium dental implants. A pilot study in the dog. Clin Oral Impl Res 5: 202, 1994
- Gerlach KL, Pape HD, Naßbaum: Untersuchungen zur Belastbarkeit nach der Miniplattenosteosynthese von Unterkieferfrakturen. Dtsch Z Mund Kiefer Ges Chir 8: 363, 1984
- Giordano RA, Wu BM, Borland SW, Cima LG, Sachs EM, Cima MJ: Mechanical properties of dense polylactic acid structures fabricated by three dimensional printing. J Biomater Sci Polym Ed 8: 63, 1996
- Gotfredsen K, Wennerberg A, Johansson C, Skovgaard LT, Hjørting-Hansen E: Anchorage of TiO₂-blasted, HA-coated, and machined implants: an experimental study with rabbits. J Biomed Mater Res 29: 1223, 1995
- Hayter JP, Cawood JI: The functional case for miniplate osteosynthesis. Int J Oral Maxillofac Surg 22: 91, 1993
- Heidemann W, Gerlach KL, Grobel KH, Kollner HG: Influence of different pilot hole sizes on torque measurements and pullout analysis of osteosynthesis screws. J Craniomaxillofac Surg 26: 50, 1998
- Hughes AN, Jordan BA: The mechanical properties of surgical bone screws and some aspects of insertion practice. Injury 4: 25, 1972
- Iizuka T, Lindqvist C: Rigid internal fixation of mandibular fractures. An analysis of 270 fractures treated using the AO/ ASIF method. Int J Oral Maxillofac Surg 21: 65, 1992
- Kallela I, Iizuka T, Laine P, Lindqvist C: Lag-screw fixation of mandibular parasymphyseal and angle fractures. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 81: 510, 1996
- Kallela I, Iizuka T, Salo A, Lindqvist C: Lag-screw fixation of anterior mandibular fractures using biodegradable polylactide

screws: a preliminary report: J Oral Maxillofac Surg 57: 113, 1999

- Krenkel C: Biomechanics and osteosynthesis of condylar neck fractures of the mandible. Carol Stream: Quintessence, 47, 1994
- Loukota RA, Shelton JC: Mechanical analysis of maxillofacial miniplates. Br J Oral Maxillofac Surg 33: 174, 1995
- Luhr HG: Zur stabilen Osteosynthese bei Unterkieferfrakturen Dtsch Zahnärztl Z 23: 754, 1968
- Niederdellmann H, Shetty V: Solitary lag screw osteosynthesis in the treatment of mandibular angle fractures. Plast Reconstr Surg 80: 68, 1987
- Nunamaker DM, Perren SM: Force measurements in screw fixation. J Biomech 9: 669, 1976
- Perren SM: Physical and biological aspects of fracture healing with special reference to internal fixation. Clin Orthop 138: 175, 1979
- Phillips JH, Rahn BA: Comparison of compression and torque measurements of self-tapping and pretapped screws. Plast Reconstr Surg 83: 447, 1989
- Robinson RC, Mosby EL, Eick JD: Bone hole diameter as a function of drill guide length and drilling method in rigid internal fixation. J Oral Maxillofac Surg 50: 613, 1992
- Shetty V, Caputo A: Biomechanical validation of the solitary lag screw technique for reducing mandibular angle fractures. J Oral Maxillofac Surg 50: 603, 1992
- Shetty V, McBrearty D, Fourney M, Caputo A: Fracture line stability as a function of the internal fixation system. J Oral Maxillofac Surg 53: 791, 1995
- Shetty V, Caputo A, Kelso I: Torsion-axial force characteristics of SR-PILLA screws. J Cranio Maxillofac Surg 25: 19, 1997
- Tate GS, Ellis E, Throckmorton G: Bite forces in patients treated for mandibular angle fractures: implications for fixation recommendations. J Oral Maxillofac Surg 52: 734, 1994
- Terheyden H, Mühlendyck C, Feldmann H, Ludwig K, Härle F: The self-adapting washer for lag screw fixation of mandibular fractures – finite element analysis and preclinical evaluation. J Craniomaxillofac Surg 27: 58, 1999
- Tuovinen V, Norholt SE, Sindet-Pedersen S, Jensen J: Retrospective analysis of 279 patients with isolated mandibular fractures treated with titanium miniplates. J Oral Maxillofac Surg 52: 931, 1994
- Uhthoff HK: Mechanical factors influencing the holding power of screws in compact bone. J Bone Joint Surg 55B: 633, 1973

Dr Dr H. Terheyden

Dept. of Oral and Maxillofacial Surgery Arnold Heller Str. 16 D-24105 Kiel Germany

Tel.: +49 431 597 2820 Fax: +49 431 597 2950 E-mail: terheyden@mkg.uni-kiel.de

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