Force causing one-millimeter displacement of bone fragments of condylar basal fracture of mandible after fixation by all available designs of plates

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Abstract: Background: There has been no direct comparison of all existing plates dedicated for fracture osteosynthesis of mandibular condyle base until now. The aim of the study was to test mechanically all available designs of titanium plates on the market on polyurethane mandibles using individually designed clamping system. Methods: Forces required for 1 mm displacement of fixed fracture and incidents of screw loosening were recorded. Results indicated the best mechanical dedicated plates among all existing designs available. Results: It has occurred that some of osseofixation plates should not be used any more whereas some of the single plates shape are similar to two single plates regarded as the best osseofixation method for condyle base fracture. Conclusion: General observation is the bigger plate and more screws, the better rigid stable osteosynthesis of mandibular condyle base. 4 plates of current designs of total 30 tested series can be recommended for open rigid internal fixation of base of mandibular condyle fractures. The rest of 26 existing plates should not be used in condylar base fractures.

Keywords: mandible; condyle base fracture; plate rigid fixation

1. Introduction

1.1. Epidemiological information

The mandible is the most vulnerable bone to fractures in the maxillofacial complex. In Europe mandibular fractures amounted to 42% of all maxillofacial fractures in a recent prevalence study. Condyle extra-capsular fractures Consisted of 26% of mandibular fractures in the same previously mentioned European study, ranking first among all types of mandibular fractures [Boffano et al., 2015]. The mandibular condyle or subcondylar region is one of the most common sites of mandibular fracture encountered, occurring between 25% and 35% of all mandibular fractures [Ellis et Throckmorton, 2005; De Riu et al., 2001].

1.2. Surgical procedures

Surgical treatment is performed under general anaesthesia. Generally maxillofacial surgeons use three different surgical approaches to reach the fracture in the region of the condylar process of the mandible. For cases where submandibular approach is necessary for load bearing osteosynthesis of associated mandibular body fractures such as in cases of atrophic mandibles the already necessitated submandibular approach was used for open reduction and internal fixation of
the condylar process fracture. In cases of mild and moderately displaced condylar base fractures a transoral endoscopically assisted approach is chosen. Condylar process fractures are reached by retromandibular transparotid approaches.

1.3. Ossoefixation plates

Plenty of plates dedicated for mandibular condyle fracture fixation is available. A little help in selection of the most proper plate for clinical situation is literature. There are only fragmentary studies concerning one or few plates (Aquilina et al., 2013, 2015, Choi et al., 1999, Pilling et al., 2010, Wagner et al., 2002, Seemann et al., 2009, Parascandolo et al., 2010, Asprino et al., 2006, Kozakiewicz & Świniarski 2014, 2017, Zieliński et al., 2019). On one hand, status quo is some inconvenient knowing that the fracture of processus condylaris of mandible is the most frequent fracture of mandible. On another hand, the open rigid internal fixation is the standard surgical procedure as fracture is dislocated or significantly displaced.

In the literature bicortical screws (Luo et al. 2011), microplates, (Jones et al., 2011) a single titanium screw or pins, (Schneider et al., 2012) two resorbable screws (Wang et al., 2013) and resorbable pins (Müller-Richter et al., 2011) have been used for rigid osseofixation.

Elimination of cut micromovements from fracture line is the most important for uneventful fracture healing after plate fixation (Zieliński et al., 2019). It required proper plate fixed by screws stably. Then fracture line movement can be limited to the value significantly less than 1mm (Aquilina et al. 2013, Kozakiewicz & Świniarski 2014). The main question is which of many available on the market plates is the best for rigid fixation of basal fracture of mandibular condyle?

Aim of this study was the mechanical comparison of 30 plate designs dedicated for fracture osteosynthesis of mandibular condyle base.

2. Material and Methods

2.1. Mandibles

Solid polyurethane foam mandibles were utilized in this study (Image 1). The high variability in the density and the elastic modulus of bone affects biomechanical testing results (Goldstein 1987). Synthetic foam materials have been shown to produce less intra and interspecimen variability than cadaver bone (Chapman et al. 1996). A foam block has consistent material properties, similar to the human cancellous bone. Solid polyurethane foam is widely used as an ideal medium to mimic human cancellous bone and has been confirmed by the American Society for Testing and Materials (ASTM 2012, Kozakiewicz 2019) as a standard material for testing orthopedic devices and instruments. In this study, polyurethane foam (Sawbones, Vashon, WA, USA: density 0.16 g/cc, compression modulus 58MPa) was used as a substitute for bone (Assari et al. 2012, Baran et al. 2009, Ramaswamy et al. 2011, Bailey et al. 2006).
There was collected information of all available dedicated plates for rigid fixation of condylar process of mandible (tabl. 1). Next, similar plates were laser cut from medical certified titanium sheet (grade 23, 1-millimeter thickness).

The condylar base were cut in level of typical basal condylar fracture in each model. Subsequently, proximal (i.e. condylar) and distal (i.e. ramus, mandibular) fracture segment were fixed by plate and the same 6-mm length self-tapping screws of 2.0 system. Predrilling was made by 1.5 mm drill. Each hole in the plates were filled by screws. 7 models were tested for each plate design.

### Table 1. Tested designs of plates dedicated for osteosynthesis of basal condylar fracture of mandible.

<table>
<thead>
<tr>
<th>Design code</th>
<th>Manufacturer of similar plate</th>
<th>Design</th>
<th>Plate surface area (mm²)</th>
<th>Plate Design Factor</th>
<th>Fmax/dL (N/mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plate20</td>
<td>any</td>
<td></td>
<td>227</td>
<td>236</td>
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<tr>
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<td>Global D</td>
<td></td>
<td>199</td>
<td>213</td>
<td>7.14±0.89</td>
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Image 1. 5 samples of post mechanical tests polyurethane mandibles with broken plates number 20.
<table>
<thead>
<tr>
<th>Plate</th>
<th>Manufacturer</th>
<th></th>
<th></th>
<th></th>
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<tbody>
<tr>
<td>29</td>
<td>ChM</td>
<td>224</td>
<td>242</td>
<td>8.32±2.26</td>
</tr>
<tr>
<td>11</td>
<td>Synthes</td>
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<td>151</td>
<td>3.27±0.36</td>
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<tr>
<td>06</td>
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<td>211</td>
<td>195</td>
<td>6.08±1.00</td>
</tr>
<tr>
<td>14</td>
<td>Medartis</td>
<td>179</td>
<td>191</td>
<td>3.20±1.39</td>
</tr>
<tr>
<td>08</td>
<td>ChM</td>
<td>165</td>
<td>179</td>
<td>3.60±1.29</td>
</tr>
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<td>24</td>
<td>KLS Martin</td>
<td>160</td>
<td>172</td>
<td>5.53±1.35</td>
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<td>07</td>
<td>Medartis</td>
<td>143</td>
<td>163</td>
<td>4.98±1.42</td>
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<tr>
<td>09</td>
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<td>151</td>
<td>156</td>
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<tr>
<td>27</td>
<td>Synthes</td>
<td>176</td>
<td>189</td>
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<tr>
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<tr>
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<tr>
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<tr>
<td>Plate</td>
<td>Manufacturer</td>
<td>Force 1</td>
<td>Force 2</td>
<td>Force (±)</td>
</tr>
<tr>
<td>---------</td>
<td>--------------</td>
<td>---------</td>
<td>---------</td>
<td>-----------</td>
</tr>
<tr>
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<td>Medicon</td>
<td>203</td>
<td>225</td>
<td>3.46±0.51</td>
</tr>
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<td>390</td>
<td>311</td>
<td>7.03±0.56</td>
</tr>
<tr>
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<td>KLS Martin</td>
<td>405</td>
<td>415</td>
<td>5.34±0.80</td>
</tr>
<tr>
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<td>547</td>
<td>8.80±1.14</td>
</tr>
<tr>
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<td>ChM</td>
<td>410</td>
<td>428</td>
<td>14.58±2.59</td>
</tr>
<tr>
<td>30</td>
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<td>382</td>
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<tr>
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<td>392</td>
<td>408</td>
<td>11.32±1.41</td>
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<td>UMed Lodz</td>
<td>390</td>
<td>408</td>
<td>14.26±0.99</td>
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<tr>
<td>18</td>
<td>UMed Lodz</td>
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<tr>
<td>19</td>
<td>UMed Lodz</td>
<td>407</td>
<td>423</td>
<td>9.14±3.93</td>
</tr>
</tbody>
</table>

**2.3. Simulation set**

The condyles were set at a 15° inferior tilt in the sagittal plane and at a 10° lateral in the coronal plane to simulate actual masticatory force loading on the temporomandibular joint. This model results in the condyle exerting a force upwards and somewhat forwards and medially [Byung-Ho Choi 1999]. For testing purposes Zwick Roell Z020 universal strength machine (Zwick-Roell, Ulm, German) with individually-made clamping system was used. Clamping system comprises flat 1 mm thick stainless steel based on 70 cm x 60 cm angulated aluminium block with milled 4 x M6 threaded holes for screwing flat base plate (Image 2). On the plate for stabilization of mandible stainless steel try square was used. Pre-load force was 1 N and test speed was 1 mm/min. The action point of the compressive forces was located at the condyle. The load vs displacement relationship, load for permanent deformation and maximum load at fracture were recorded using the Instron chart recorder. Permanent deformation was defined as the initial point that the load-displacement relationship was no longer linear. Maximum load was defined as the greatest load recorded just before any sudden decrease in load level (Fig. 1).
Figure 1. General comparison of the amount of required force for one-millimeter displacement in fracture line after plate fixation. Data in Newtons.

2.4. Statistical analysis

Number of holes in the plate, plate height, plate width, surface area of the plate which is faced to the bone were noted for interpretation of the experimental data.
Statistical analysis was performed in Statgraphics Centurion 18 (Statgraphics Technologies Inc. the Plains,. Virginia, US). Kruskal-Wallis test was applied for between design comparison. Categorical variables were tested for independence by Chi-Square test. Objective description of plate design was attempted basing on factor analysis due to the need of the best plates indicating. The mathematical purpose of the analysis was to obtain a small number of factors which account for most of the variability in the 4 basing variables describing plate features: height (mm), width (mm), plate surface area (mm²), total fixing screws. Neural Network Bayesian Classifier i.e. a probabilistic neural network (PNN) was used to classify designs into different condyle screw pullout, based on 4 input variables of the 210 mechanical tests: Plate Design Factor, F max/dL (N/mm), number of screws in condyle, number of screws in ramus. PNN had 2 hidden layers, and two outputs: pulled out screw from condyle fragment or no pulled out condylar screw.

2.5. Surface treatment

Surface treatments of metals are intended to produce a biologically active surface. Already from a macrosurface, design, retention increases in the tissues being formed. In order to obtain an ideal, efficient roughness as already demonstrated, different techniques have been proposed. The implant surfaces are subdivided into two large groups, the smooth and the rough ones.

Rough surfaces can be obtained with two types of treatments, additive and subtractive techniques.

Additive techniques:
- Titanium Plasma Spray
- Coating with hydroxyapatite
- Anodic oxidation

Subtractive techniques:
- Sandblasting with alumina oxide
- Sandblasting with titanium particles
- Sandblasting with soluble or reabsorbable materials
- Etching with strong acids
- Double acid etching

It is also possible to find new combined techniques that involve sanding and acid etching or sandblasting and thermal etching. The smooth implants can be electropolished or machined, the former having a surface that is subjected to an electrochemical treatment by immersion in electrolytic solution. The implants with a machined surface have a surface that appears shiny and smooth but in any case show streaks. Other surfaces are those (TPS) with the treatment of Plasma surface, therefore titanium powders. The problem with this technique is the bad control of contamination and the possibility of the detachment of particles from the metal surface. There are also surfaces covered with hydroxyapatite, the latter binds to the patient’s bone and does not induce toxic or inflammatory phenomena. The sandblasted and etched surfaces defined as SLA are surfaces with coarse-grained and acid-etched sand. SLA surfaces have a larger contact surface than the roughest Plasma-Spray. There are also surfaces coated with biologically active glass, experimentation on these surfaces has shown positive characteristics. The glass material is against resorption and degradation with complete replacement by the bone tissue. These surfaces are characterized by a high wettability. In any case, all the surfaces before marketing are sterilized with treatments that do not affect the characteristics of the metal. The purity of the surfaces and the absence of contaminants is a much
debated element that influences the quality and the cost of the material itself. (Cicciù et al., 2019, Smeets et al., 2016)

3. Results

The most available osteosynthesis material for basal condylar fractures made possible an application of plates of height 19±6mm, width 13±4mm, fixed by 4±1 screw in ramus and 3±1 screw in condyle. Performed tests revealed that such fixations produce 1-millimeter displacement in fracture line as 8±5 N force was loaded. As far as the force required for 1-millimeter displacement in fracture line after osteosynthesis was considered (fig. 1) then the six best designs were 20, 23, 10, 13, 18 and 22 and the six worst designs were 14, 11, 28, 8, 21 and 2 (Kruskal-Wallis statistics = 179.77; p<0.05).

Observed incidents of pull the screw out from condyle fragment (Kruskal-Wallis statistics =1.81; p=0.178) or ramus fragment (Kruskal-Wallis statistics=0.001; p=0.976) were not related to loaded force, but the number of pull out condyle screws (Chi-Square statistic = 142.4; p<0.05) and ramus screws was related to the design (Chi-Square statistic = 121.7; p<0.05). The least condyle screws was lost in plate designs: 1, 2, 5, 6, 7, 8, 9, 10, 11, 13, 21, 22, 23, 24 and 28, the ramus screws least lost was observed in designs: 1, 5, 12, 21, 22, 23 and 25. The loss of condyle screws was related to ramus screws pull out (Chi-Square statistic = 15.4; p<0.05). Number of all applied fixing screws was directly proportional to force required for 1-millimeter displacement of osteosynthesized bone fragments (Kruskal-Wallis statistics = 65.7; p<0.05). The best results was observed as 7, 8 or 9 screws fixed the plate, contrary to plates fixed by only complete of 4 or 5 screws (fig. 2). The highest forces could be bear by osteosynthesis as 4 (11±5N), 5 (8±3N) or 6 screws (10±4N) were applied in ramus/distal fragment (Kruskal-Wallis statistics = 62.3; p<0.05). Fixation was significantly weak as 2 screws were used there (5±2N). As far as number of screws in condyle portion was considered then 4- or 3-screw fixations in that proximal fragment (10±4N and 9±4N, respectively is required for 1-millimeter displacement in fracture line) were significantly better than 2-screw fixation (5±2N).

Figure 2. Register results of the amount of required force for one-millimeter displacement in fracture line after plate fixation in view of total number of holes designed in tested plate. The best results for plates with 7-9 holes (p<0.05).
The force causing 1-millimetre displacement in fracture line after fixation depended on dimensions of used plate directly proportional: on height (correlation coefficient=0.35, R-squared=13%, p<0.05), on width (correlation coefficient=0.52, R-squared=27%, p<0.05) and plate surface area (correlation coefficient=0.58, R-squared=35%, p<0.05).

In this study, only one factor has been extracted during factor analysis, since only one factor had an eigenvalue greater than or equal to 1.0 (3.04). It accounted for 76% of the variability in the original data. The factor has the equation:

Plate Design Factor = 0.850954*Height(mm) + 0.846751*Width(mm) + 0.936732*Plate surface area(mm2) + 0.848039*Total fixing screws

where the values of the variables in the equation are standardized by subtracting their means and dividing by their standard deviations. It also shows the estimated communalities which can be interpreted as estimating the proportion of the variability in each variable attributable to the extracted factor. Thus, one natural number describes the plate design. Design characterized by higher value of Plate Design Factor (PDF) required higher force for displacement the fixed bone fragments (moderately strong relationship between the F max/dL and Plate Design Factor (PDF), cc=0.58, R²=34%, p<0.05). Moreover, the factor construction causes that each plate design is significantly different from another (fig. 3, Kruskal-Wallis statistic=209, p<0.05). Less screws were lost from distal/ramus fragment as Plate Design Factor higher (Kruskal-Wallis statistics=13.4, p<0.05) contrary to proximal/condyle fragment where higher values of Plate Design Factor (PDF) were related to screws pull out (Kruskal-Wallis statistics=18.2, p<0.05)

Figure 3. Calculated feature: Plate Design Factor, numerically describes each plate design.

The correct prediction by the neural network of condyle screw pull out was noted for 83% of mechanical tests, and 90% as far as ramus pull out screws were registered (fig. 4).
Figure 4. PNN procedure revealed that the incidents of condyle fragment screw loss are seldom predicted as Plate Design Factor is over 350 (plate 10, plate 13, plate 22, plate 23) in relatively high resistance to displacing forces (especially as 4 screws is fixing the plate in proximal fragment). But also, lower values (below 300) of Plate Design Factor (PDF) can predict stable plates fixed by only 2 screws in proximal fragment. Unfortunately, resistance to displacing forces in case of those plates is low. In ramus (distal fragment), the 2-screw fixation always is predicted as failure, as far as the ramus pull out screw parameter is considered. The best designs is the plate 10 (tabl. 1) i.e. resistant to displacing force and described by Plate Design Factor (PDF) (over 450) are 4-screw fixed in the ramus fragment. Moreover, it can be noticed two designs described by Plate Design Factor approx. 250 as resistant to ramus screw pull out, but not so much resistant for displacing force unfortunately.
4. Discussion

4.1. Plates combination

Two straight plates fixing the bone along the stress lines in condylar region of mandible, lead to the very rigid internal fixations. It was confirmed in many previous studies, (Aquilina et al., 2013, Choi et al., 1999, Hammer at al., 1997, Pilling et al., 2010, Wagner et al., 2002, Seemann et al., 2009, Parascandolo et al., 2010, Asprino et al., 2006).

As one performs the fixation of fracture of condylar base, 3 screws in proximal fragment should use and minimum 4 screws in distal fragment (or 5-6 screws). It obviously depends on chosen design of plate in order to maintain the osteosynthesis balanced and rigid. Application of 2 screws in proximal fragment with 2 or 3 screws in distal fragment (i.e. 4- or 5-hole plates) resulted as the weakest fixations of basal condylar fractures. Plate dimensions are some related feature of the dedicated plate, and easily can be noticed that as the plate bigger, the force required to 1-millimeter displacement in fracture line higher (p<0.05). The correlation coefficient equals 0.58, indicating a moderately strong relationship between the plate surface area and the displacing force, points to the valuable feature of plates design which plays significant role in stable osteosynthesis (p<0.05). The highest surface area are presented by plates (390-538 mm²): short ACP (design 25), tall ACP (design 23), universal XCP (design 22), universal XCP with 3+5 hole configuration (design 19), side-dedicated XCP with 3+5 hole configuration (design 18), new endoscopic KLS Martin plate (design 16), big ACP (design 12) and side-dedicated XCP (design 10).

Some studies (Aquilina et al., 2013, Kozakiewicz & Świniarski, 2017) show that imagine of maxillofacial surgeons is unlimited. The same osteosynthesis plate has been screwed in different positions and it surprisingly biomechanical effect was not worse than positions suggested by the manufacturer.

4.2. Biodegradable materials

Despite the biocompatibility of titanium, many authors recommend removal for different reasons, such as metallosis, corrosion, thermal dyseaesthesia, difficulties with future radiological diagnosis, malpositioning, and the migration of osteosynthesis material, particularly in craniofacial surgery (Schneider et al., 2012; Singh et al., 2013). On the other hand, biodegradable osteosynthesis devices offer numerous advantages over metallic implants and recently systems using biodegradable devices have been accepted as suitable tools for osteosynthesis. (Oki et al., 2006) Biodegradable materials disappear gradually and therefore, obviate the need for removal. (Suuronen et al., 1991) The bending moduli of biodegradable materials are close to that of bone and will enhance stress protection when bone support is no longer required. (Singh et al., 2013; Suuronen et al. 1991) The most commonly used biodegradable material, PLLA, is slowly degraded in the human body and physical stress is gradually transferred to the healing bone. It is believed that this property of PLLA screws prevents osteoporosis which is one of the main disadvantages of titanium fixation systems. (Singh et al., 2013) Although, some in vitro studies have reported the biomechanical stability of resorbable pins and osteosynthesis with resorbable screws, (Wang et al., 2013; Schneider et al., 2011, 2012; Pilling et al., 2007). Some authors mentioned that resorbable screws exert lower retention forces than titanium ones, which result in a less stable fixation. In addition, besides their poor mechanical stability, biodegradable screws also have the number of limiting factors, such as difficult handling properties and time-consuming fixation. (Pilling et al., 2007)

4.3. FEM analysis

The rehabilitative dentistry has always paid particular attention to the detailed analysis and the application of the occlusal forces, the distribution of tensional forces, and stress dissipation, as
biomechanical factors influence the prosthetic success substantially. In time, several methods have been used to study the action of the functional forces on the prosthesis and on hard and soft tissues of the oral cavity. The finite element analysis, however, is a tool that allows analytically evaluating the distribution of tensional forces at every point of the surface taken as a reference, by creating a mathematical virtual model. (Bramanti et al., 2017)

4.4. Plate Design Factor (PDF)

The proposed Plate Design Factor (PDF) can be simple measure for future plates design comparisons as far as the rigidity of osteosynthesis (force causing 1-millimeter displacement in fracture line) will be considered. The discrimination power of that factor is such high as even very similar plates in this study can reach significant difference from another (and can be individually considered). PNN procedure points that plates of construction described by Plate Design Factor over 300 (fig. 9) are the most resistant to as the screw pull out as well displacing force. There are the plates: 10, 13, 22 and 23, which were investigated in this study.

This study cannot reject the usefulness of the plates which were poorly sited in this comparison (low 1-millimeter displacement force, screw pull out, low Plate Design Factor). It can only be said that those plates should not be used (or used with great attention during reduction and occlusal control) for osteosynthesis of fractures of mandibular condyle base. It is possible that in higher level fractures those plate could be significantly better fitted. Next issue are this study limitations. Although the mechanical properties of the synthetic bones were similar to those of human bone, some differences were present in the structure of the materials. Specifically, synthetic bones have an almost uniform pore size, whereas human cancellous bone has a complex anatomical texture. This can affect the compression efficacy and fastening torque of the screws. The results of this study were based on a single-density synthetic bone; however, the biomechanical performance of the screws changes with the bone density environment (Ramaswamy et al; 2011). The tests were conducted on synthetic bones with a perfect fracture gap simulated by parallel planes. Only specific types of fractures, types A and B, of the condyle head were simulated. These simulations were required to perform replicable and reliable testing. Finally, most screw loosening cases can be attributed to physiological cyclic loading during biting. Further evaluation of interfragmentary compression that simulates the cyclic loading of screws under physiological situations is necessary.

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Conflicts of Interest: “The sponsors had no role in the design, execution, interpretation, or writing of the study”

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