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Ex-vivo and in vitro validation of an innovative mandibular condyle implant concept



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ABSTRACT

Purpose: The purpose of this study is to pre-validate an innovative implant concept, and to compare the behavior of the mandibular condyle against a commercial Biomet implant in an ex vivo model and present results of the first cadaveric studies.

Materials and methods: Three experimental cadaveric condyles were tested under three conditions: one intact, another with the Biomet model, and one with the innovative concept. The condyle was tested with a reaction of 300 N in all situations and the principal strains were measured. Before the geometry of the cadaveric condyle was reconstructed from a microCT scan, and a finite element model was created. Finally, a procedure was carried out with the new implant by two expert surgeons on a two cadaveric head model.

Results: In vitro the mandible condyle presents a linear behavior until maximum load. The strain measured with Biomet implant indicates a strain shielding effect in the proximal region, inducing bone loss in the long term. The lingual side of the Biomet implanted condyle presents an increase of +44% in strain.

Conclusion: The new concept was evaluated and showed a similar behavior to the intact model, and better behavior than the Biomet. The innovative concept proves that it is possible to avoid screws for a TMJ fixation and improve the TMJ alloplastic behavior.

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1. Introduction

The temporomandibular joint (TMJ) is one of the most active and complex joint in the human body, and is formed by the bilateral articulation of the mandible and the temporal bone of the skull. The incidence of TMJ disorders varies according to different studies but is reported to affect between 5% and 25% of the world population, resulting in TMJ diseases being a common problem (Poveda Roda et al., 2007; Thomas and Matthews, 2012). The resection and replacement of the diseased TMJ is, however, usually reserved for patients with irreversible end-stage disorders. Therefore, the TMJ prosthesis is an option of last resort for replacement of an irreversibly damaged TMJ, mainly after several surgeries, failed

autogenous graft and ankylosis (Wolford et al., 2015). The market has only a few available solutions, mainly custom-made or personalized models (Ackland et al., 2017) and only one standard model on the market, the Biomet Microfixation system (De Meurechy and Mommaerts, 2018).

The evaluation of performance in TMJ prostheses is a critical point, and some studies have evaluated the clinical performance of different TMJ solutions (Aagaard and Thygesen, 2014; Alakailly et al., 2017; Gonzalez-Perez et al., 2016a,b; Gruber et al., 2015) in a different average follow-up studies in the long term of 20 years (Selbong et al., 2016). A review and comparison of 20 years of published studies since 1995 with different models (Zou et al., 2018) indicates no clinical differences between brands, presumably because same concept is used in all models.

The results point out that the benefit for the patient is significant, consisting mainly of reduced pain, increase in mandibular movements and improved quality of life (Wojczyńska et al., 2016;

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De Meurechy and Mommaerts, 2018; Gerbino et al., 2017; Zou et al., 2018). Gollow-up shows success in 87.5% of cases, with the main source of failure being mechanical (Schoorhuis et al., 2012).

The actual concepts of TMJ available use screws only to fix and stabilize TMJ devices, and this has been studied using numerical models and experimental techniques. These studies show critical regions around the screws with high strain and screw loosening in the long term. Some new concepts have been introduced for TMJ, for example condylar support (Abel et al., 2015), but the implant fixation is still done with screws.

One of the best-known commercial solutions for TMJ is the standard concept of Biomet Microfixation (Biomet Microfixation, Jacksonville, FL), approved by the U.S. Food and Drug Administration and the solution most widely applied throughout the world. Several studies were carried out before evaluating the concept, including clinical follow-up (Ackland et al., 2015; Kanatas et al., 2012; Sanovich et al., 2014.), and they referenced the critical aspect of screw fixation and the surgical procedure, adapting the bone surface, and the difficulty in determining the position of the implant (Dimitroulis, 2014). In 40 patients the accurate positioning of condyle component was analyzed, and a maximum of 5.04-mm incorrect position was observed (Sawatari et al., 2018), which did not correlate with the accurate position of condyle TMJ solution in regard to future complications. Another problem is abnormal jaw movement and click (Leandro et al., 2013), problems related to the fossa component (Aagaard and Thygesen, 2014).

The aim of this study is to validate the innovative TMJ concept with a comparative study of a new TMJ condyle implant and a commercial implant in a stock model. The study compares the in vitro condyle with a numerical model in intact conditions and also implements the new concept in cadaveric heads by surgeons. The main aim is to validate the hypothesis regarding the possibility of reducing bone loss in the alloplastic device, avoiding screws and improving load transfer.

2. Materials and methods

The success of each alloplastic TMJ concept is listed and associated with the device registers (Sidebottom and UK TMJ Replacement Surg, 2008). It is important to understand the fixation procedure and the implications of using experimental and numerical models before implantation or clinical trials. The ex vivo trials were developed in four steps. First, we tried the novel concept and procedure in two cadaveric condyles, and second, three cadaveric condyles were instrumented. After that, we mounted the system and tested intact condyles. The third step was testing the new concept, and in fourth step the commercial model was implemented and tested in the same condyles.

2.1. In vitro experimental models

Experimental models are used because it is possible to test the real bone ex vivo and measure bone behavior locally, for example with a strain gauge or fiberoptic techniques. In a second phase, numerical models are validated, such as (FEM) (Ramos et al., 2011), but the ex vivo models present patient variability as to the type of bone and bone geometry. The experiments in this study were based on a cadaveric condyle, and two implants were introduced in the same condyle for comparison with the intact situation.

Three cadaveric mandibles from 45- to 50-year-old men were provided by the Laboratoire d'Anatomie Fonctionnelle (University of Bordeaux, France). Mandibles were cleaned and fresh frozen then cut into two symmetrical parts. The innovative concept presents the concept of press fitting fixation, but the contact in the TMJ with the fossa component is like the condyle and the plate. The

condyle component is made of titanium Ti–6Al–4V and the fossa component is in ultra-high-molecular-weight polyethylene (UHMWPE) fixated by three screws. The innovative concept is easy to implant, and it allows more bone preservation with high-level condyle dissection, and does not need screws in the condyle to fix it in place (Fig. 1).

An instrument, a kind of reamer, was developed to open a hole and introduce the implant into the right position (Fig. 1). The implantation procedure begins with the cutting of the top of the condyle. Opening a hole in the condyle is necessary before introducing a preformed implant using a specific tool. Less cutting of the bone is required (Fig. 1). The process was validated in two ex vivo cadaveric condyles and is presented in Fig. 1.

The cadaveric right ramus was then fixed in an apparatus using polymeric bone cement to maintain the position at a 5-mm mouth opening. Four rosettes were glued on the ramus surface (Fig. 2a), one in the posterior side of condyle, two positioned on the labial surface, the fourth one on the buccal surface, following the same procedure (Mesnard and Ramos, 2016). The rosette model (KFG-1-120-D17-11 L3M2S, by Kywoa Electronic Instruments Co., Japan) measured strains. The intact condyle was maintained in the same position for all experiments, intact, with a Biomet and with a new condyle. First the intact condyle was tested, followed by the new intramedullary condyle concept using a press-fit fixation, which was introduced because it allows bone preservation for the next implant the commercial model (Fig. 1b).

The second implant was the Biomet Microfixation system (Biomet Microfixation, Jacksonville, FL). This was implanted after the previous new concept implantation (Fig. 1c) and the first rosette was removed with bone dissection. The mandibular ramus surface was prepared to best fit the surface of the implant. The mandibular implant was positioned according to the surgical protocol, respecting the mandibular ramus head center position. The implant was 50 mm in length and fixed with five 6AL/4V titanium screws in the positions shown in Fig. 2c. These self-tapping 2.7 mm diameter screws were long enough to establish a bi-cortical support. They were screwed into the bone with a torque-screwdriver (Stahlwille no.76/3, range 0–0.3 Nm, Wuppertal, Germany) with a constant torque of 0.2 Nm, which corresponds to the minimal torque surgeons use to test TMJ prostheses (van Loon et al., 2000).

After the implantation and instrumentation, the intact condyle was fixed on a compression testing machine, and the experiment was conducted at a constant velocity of 1 mm/min in three continuum phases and with three stops at 100 N, 200 N and 300 N in the condyle reaction. The 300 N load was the maximum, defined as the maximum reaction with a TMJ prosthesis (de Zee et al., 2007), and the system was stopped for 10 s at each level (100, 200 and 300 N). Ten trials were carried out on each model and the average of principal maximum and minimum strains and STD were recorded.

2.2. Numerical models

FEMs were created based on a micro-CT scan of the intact mandibular condyle (scanner G.E. *eXplore* RS rodent CT), and the DICOM images were imported to ScanIP software. Cancellous bone was defined between 600 and 1300 HU and cortical bone between 1300 and 1600 HU (Park et al., 2008; Ramos et al., 2015a). The computer-aided design (CAD) model and the FEM with Biomet implant are shown in Fig. 3. The FEM model runs were performed with an MSc MARC solver with a nonlinear package. The mesh was built with tetrahedral and hexahedral linear elements, with 144,000 elements for the intact condyle. The mechanical properties of the models were as follows: cortical bone $E = 14.7$ GPa, $\nu = 0.3$, cancellous bone $E = 400$, $\nu = 0.35$ MPa, and the innovative concept, which was in titanium, $E = 110$ GPa, $\nu = 0.3$ (Ramos et al., 2014). The

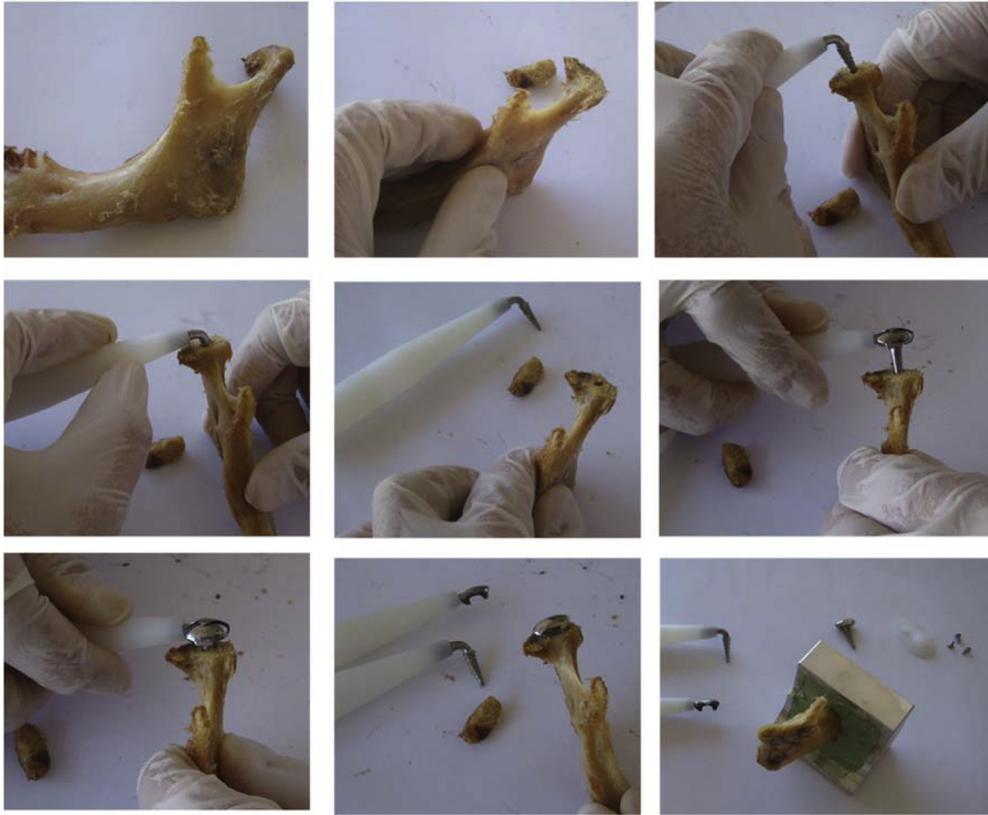


Fig. 1. Experimental procedure to implant the novel concept and the instrumental developed to introduce the novel concept in condyle.

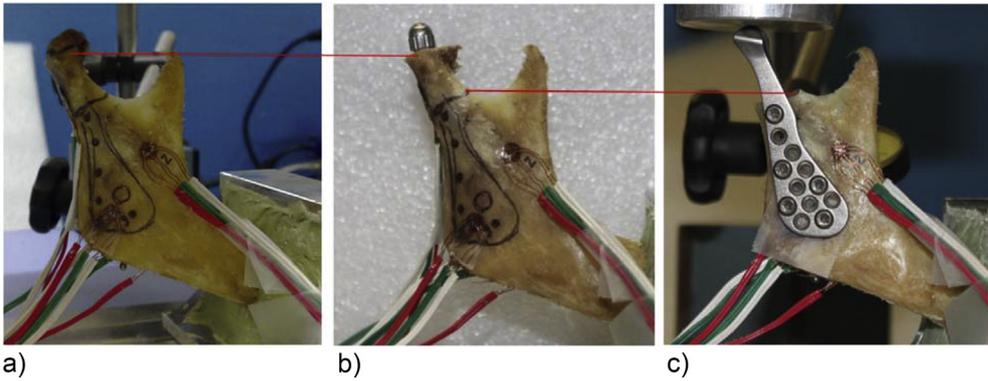


Fig. 2. Experimental models of mandible, a) intact model, b) implanted with new intramedullary concept, c) Biomet microfixation implant.

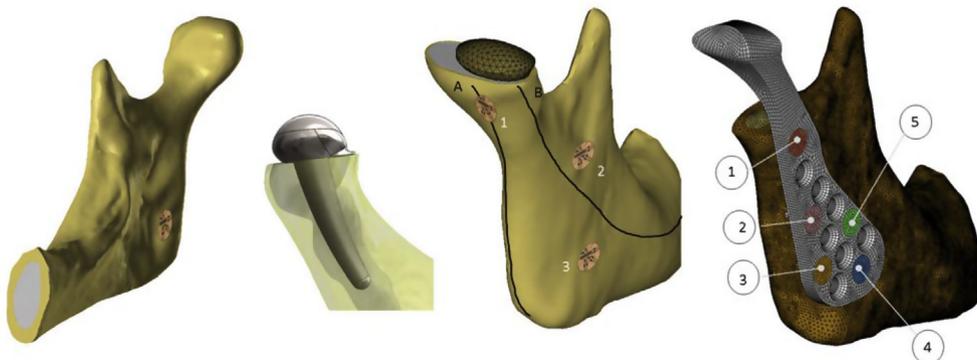


Fig. 3. Finite element models of mandible and rosette positions, a) CAD of intact model, b) implanted condyle with an intramedullary concept, c) Biomet Microfixation implant and screw positions.

materials were considered isotropic and linear elastic with respect to the load magnitudes applied experimentally.

The bone–implant contact was modeled as a touching contact with a 0.3 friction factor and contact between implant and screws with 0.1. Principal strains were analyzed on the surface of the ramus in the region of the four rosettes to validate the model. Lines A and B (Fig. 3b) were for comparison between intact and implanted condyles.

3. Results

The results are presented in two steps: first, the experimental results with the cadaveric mandible. Next, a FEM validation was carried out with experimental principal strains and numerical model results. The numerical model results were validated around the experimental cadaveric condyle rosettes, and the values were taken as an average of 10 nodes in the FEM. The strain pattern in all condyle models in the FEMs was then analyzed along lines A and B.

3.1. Ex vivo experimental results

The mandible condyle presents a linear behavior until the maximum experimental load (300 N) and corresponds to the linear behavior in FEM modes. The vertical displacement at the point of contact for the maximum load presents an increase in displacement in the implanted condyles, with a difference of around 2.8% for Biomet and 2.6% in the new condyle, representing a decrease in stiffness in the implanted condyle; maximum displacement for the intact model was 1.18 mm (SD ± 0.01).

In all load conditions, maximum strain values with the implanted condyle were observed in rosette #3, with a maximum principal strain value of 1487 µε (SD ± 25.9) for the new concept implant, 1308 µε for Biomet and 1235 µε for the intact condyle. This value does not take into account the strain generated by the screws in the Biomet alloplastic experiments.

Rosette #1 presents an increase in strain for the new concept 629 µε, but the values are smaller than the maximum observed in other rosettes. Minimum compression was in the lingual side of the mandible in rosette #4 with -1014 µε (SD ± 30.5) for the new concept, but the Biomet presents a higher value with -1120 µε. The strain results demonstrate total recovery of the mandible after the experiment in all rosettes.

The differences in the three experimental models in the rosette positions are presented in Fig. 4. The influence of the new concept,

with an increase in maximum and minimum principal strains at the surface in the proximal region, is more critical in rosette #3 (+20%). The critical region is in rosettes #3 and #4, where the maximum difference was observed in the Biomet implant with +44%. This indicates more load transfer proximally with the new concept and more distally with Biomet on the lingual side.

The experimental results presented do not take the implantation process into consideration or the strain concentration around the screws in the Biomet model, which will increase. After analyzing the experimental results in the cadaveric models, we observed the influence of the two concepts; to analyze the results in other regions, it is necessary to validate the FEM models.

3.2. Validation of the finite element model

Overall, the FEM and average experimental strains for the maximum load presents a correlation in the three models, the intact and the two implanted condyles (Fig. 5). Linear regressions were performed for the maximum and minimum principal strains. The correlation value R² and slope of the regression line are 0.95 and 0.899 for all models. The intercept value in origin is small (3 µε) and the normalized root-mean-square deviation (NRMSD) value of the measured strains is 6.5%. This comparison indicates that the validation of the numerical models and the numerical results could represent condyle behavior.

3.3. Numerical results

Results in lines A and B (Fig. 3) present the behavior for the three models. The condyle implanted with the innovative concept (Fig. 6, lines A) presents behavior similar to that of the intact condyle, and major differences are observed proximally with an increase in principal strain of around 12% in the middle region of line (A), suggesting an implant tip effect, with a small decrease near the dissection plane.

The Biomet implant condyle presents a strain-shielding effect proximally with a reduction of around 10 times less strain, suggesting bone loss in the condyle in the long term. The effect of strain shielding disappears after screw #2, and the behavior is similar.

On the external lateral surface of the condyle (line B, Fig. 3), the principal strain distribution shows that the global behavior of the condyle is similar in the three models (Fig. 7), and the strain pattern

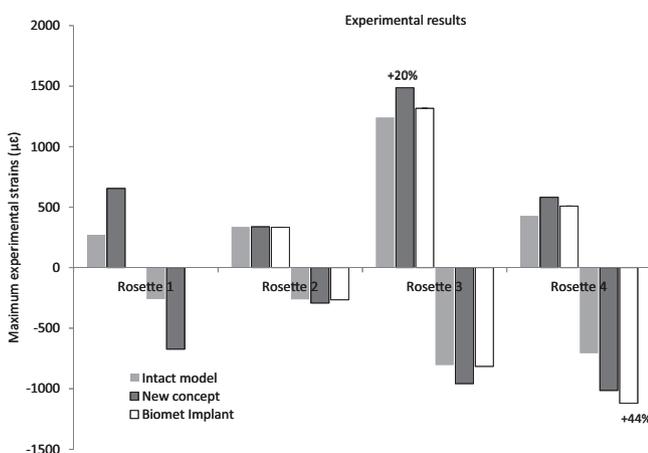


Fig. 4. Comparison of experimental principal strains in rosettes for maximum load (300 N).

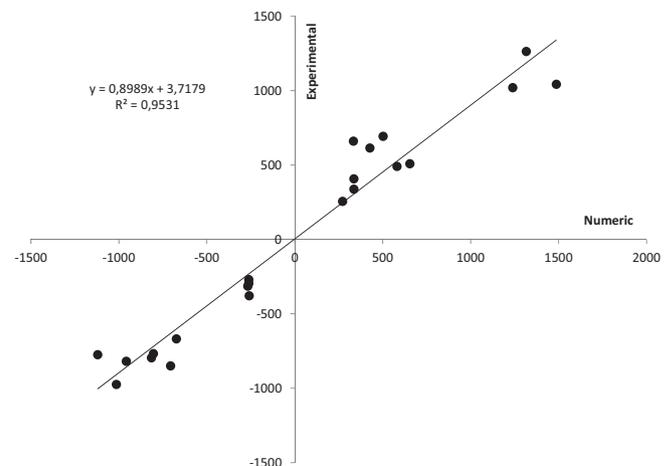


Fig. 5. Correlation between experimental and numerical principal strains for maximum load (300 N).

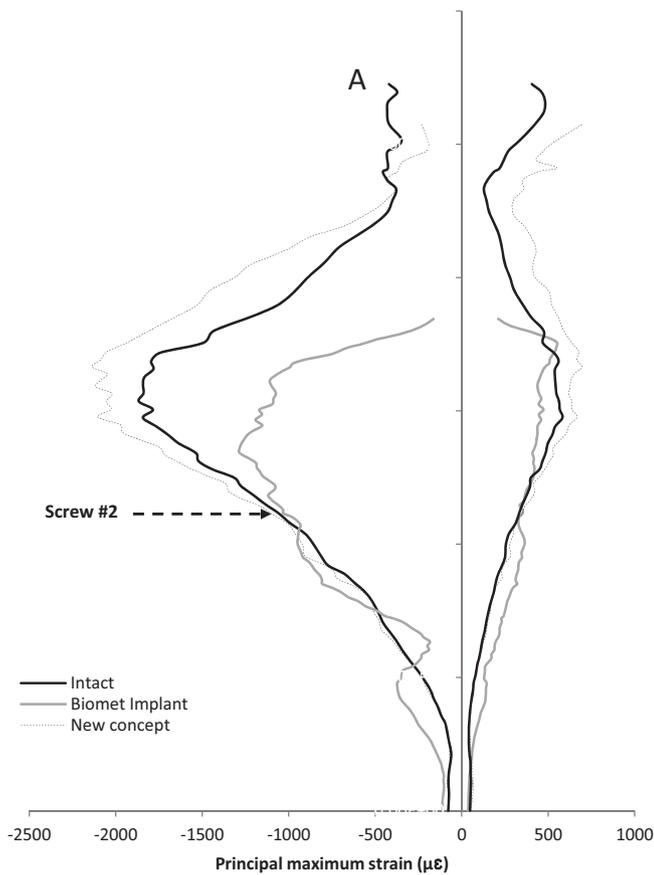


Fig. 6. Maximum and minimum principal strains in posterior side of condyle (line A).

changes in the proximal region when the Biomet implant is implanted.

The maximum value observed in the implanted condyle is not critical, $-2130 \mu\epsilon$, and is around 14% less than the maximum observed in the intact model. The condyle with the Biomet implant presents an increase in strain before screw #1, decreasing as far as the region of screw #5, and then with lower strains than the intact condyle. In both implants, results far from the fixation show a small decrease in principal strains, suggesting a greater transfer from the lingual side of the bone.

When analyzing the minimum principal strain pattern of the condyle (Fig. 8) a great difference in distribution was observed between intact and implanted, and between the two implanted models. A dashed line in the figure was added to show the principal line of load transfer, and to present the same orientation in the intact condyle and the new concept implant. The Biomet implanted condyle presents a different behavior, with a concentration in the region around screws #1, #3 and #5.

4. Discussion

The alloplastic TMJ prosthesis is a complex form of surgery and is the last solution for a severely damaged TMJ with extensive destruction when no joint components are salvageable. Only a few systems are available and very well known: the TMJ Concepts System (Ventura, CA, USA), the Biomet System (Biomet/Lorenz Microfixation, Jacksonville, FL, USA) and the Christensen System (Nexus, CMF, USA) is no longer available (Idle et al., 2014; De Meurechy and Mommaerts, 2018). However, a new model from OMX custom made and with new technologies with 3D print has

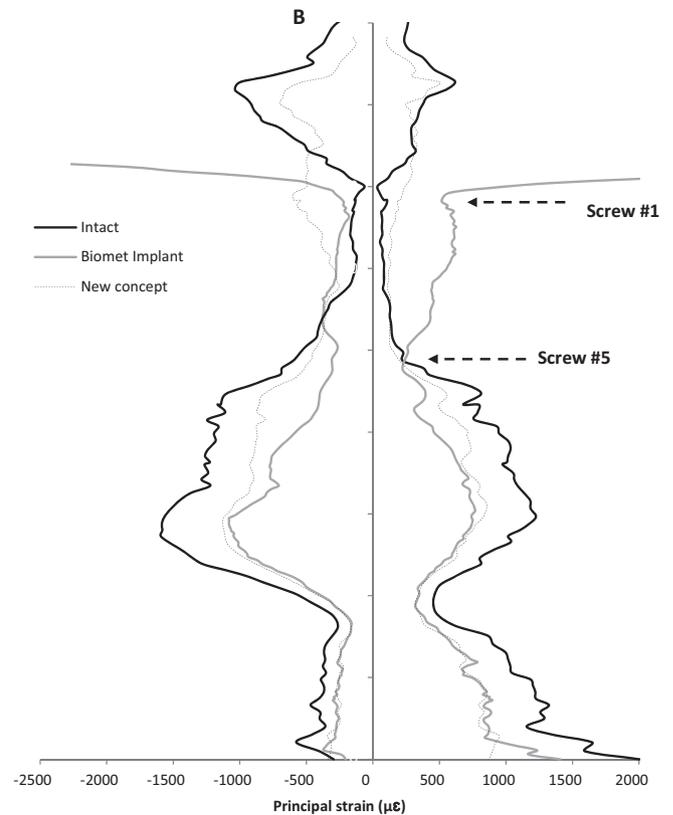


Fig. 7. Maximum and minimum principal strains in external lateral side of condyle (line B).

appeared in the recent years, but with same concept of screw fixation (Dimitroulis et al., 2018).

The purpose of this study is to validate a novel concept of an intramedullary condyle TMJ implant, comparing it with intact and commercial standard models. The goal of this new concept is to preserve bone and to improve load transfer.

The solutions currently on the market require complex surgery, great care with screw positions, and condyle position. They need a well-prepared condyle surface and the correct screw sizes, and in addition a very high strain concentration is observed experimentally in the screws and some critical aspects related to the nerve and screw positions (Ackland et al., 2017). The best solution is therefore to avoid using screws altogether. The critical aspect with the market solutions is bone loss; the dissection plane is in a very low position, and the stability of the articulation is lost. The new concept has the advantage of preserving bone and removing just 20% compared to the Biomet implant procedure; revision surgery could be possible with commercial concept. The novel concept of TMJ is not a solution for everything, but only in the case of good bone condition and mainly in cases of ankyloses.

The intramedullary concept condyle uses a press-fit stem, which changes the fixation status compared with solutions on the market (Gonzalez-Perez et al., 2016a,b). With the current fixation system, which requires screws in the condyle component, screw fixation is critical in order to guarantee implant stability. Some studies have suggested using more screws, which may reduce screw stress (Ackland et al., 2015), or they have positioned the screws in a zigzag formation (Chowdhury et al., 2011). However, screw fixation causes higher strain concentrations than the normal load, as previously observed (Mesnard and Ramos, 2016) and depending of geometry some screws are critical (Ackland et al., 2017). Screw #1 presents

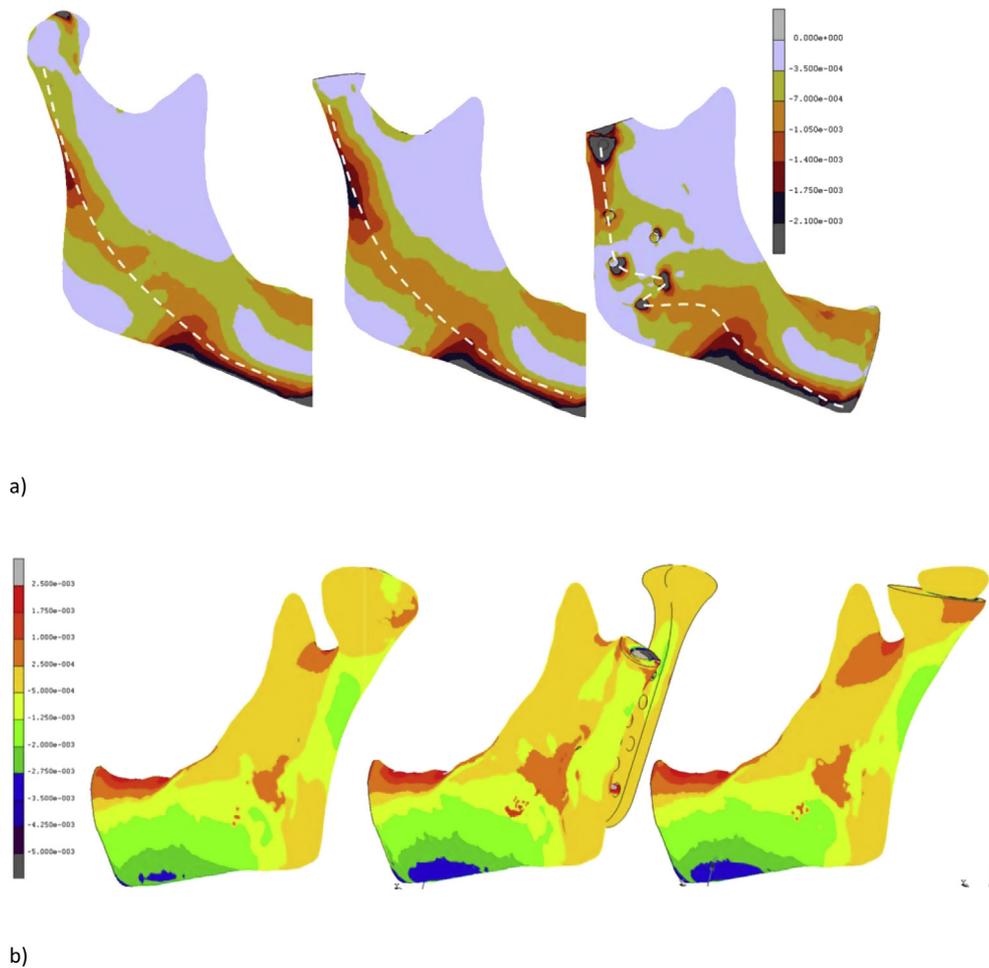


Fig. 8. a) Minimum principal strain pattern in lateral side of condyle, b) major principal strains in lingual and posterior region.

the highest strain, at around $-7600 \mu\epsilon$, suggesting fracture and screw loss, as observed in some clinical cases (Gonzalez-Perez et al. 2016a,b).

The experimental results point out the influence of the implants on condyle behavior. Condyle stiffness decreased experimentally less than 3% in both cases, and the implant was introduced in the same contact point position. Experimental results show different behavior between the new concept and Biomet, where the new concept presents an increase in strain proximally and the Biomet model presents a decrease in the posterior region of the condyle. The novel concept increases strains in the proximal region by around 140%, but this value is lower compared with the maximum in rosettes #3 and #4 and will be important to guarantee bone stimulation in this region. Meanwhile, the Biomet implant induces bone loss and bone atrophy.

The critical region for the Biomet implant is the distal region in the lingual side with a +44% increase in strain, but this effect can be explained by the proximity of the screw. However, in this case, the defect of self-tapping screws was not considered, and if both effects are combined this could create bone microfractures. The Biomet implant induces strain concentration in the lateral surface from screws #1 to #5, indicating a change in load transfer and resulting in some condyle bending. The strain pattern in the lateral surface of the condyle results in different behavior between models, and the intramedullary concept presents a similar line of load transfer.

Some recent clinical studies compare the custom-made and standard TMJ models, which have the same concept (Gerbino et al.,

2017), and conclude that these solutions present good results but indicate the application of custom-made implants with CAD/CAM technology (Ackland et al., 2018). This custom made presents the major disadvantage the cost, surgical skills needed and potential wear, but no significant difference in terms of results. In our opinion, a custom-made or a patient-specific implant is the best solution for a complex case (Chaurand and Pacheco-Ruiz, 2018), because of the specificity.

Overall, the innovative concept presents a similar distribution pattern on the external face of the mandible. This is important for maintaining the same load effect and ensuring that bone structure is maintained in the long term. The new concept presents some positive points, such as the possibility of maintaining the same contact point position in the condyle, and maintaining kinematics is also an important factor in the success of the alloplastic TMJ, unlike the Groningen implant solution (van Loon et al., 1999), where rotation of the mandible is possible.

To validate the implantation protocol and the procedure, four cadaveric in vitro surgeries were carried out in two head models in the Department of Oral and Maxillofacial Surgery, Virgen Del Rocio University Hospital. The first and the second experiments (Fig. 9) proved that the implantation was possible and the protocol has been improved. The instruments developed have made it possible to implement the implant but need more improvements. However, the first trial points out a less invasive surgery, and some aspects as bone quality and thickness need to be checked beforehand with a CT scan. If the patient presents a degenerative condyle or disease in



Fig. 9. Cadaveric experiments on the new concept implantation.

condyle bone, this innovative concept will be not a solution. Two trials pointed out a difficulty to center the implant into the condyle and to open the hole if the patient presents a limited cancellous bone volume.

The fossa component is in the UHMWPE and fixed by a maximum of three screws.

There are some limitations to this study, mainly related to bone condyle geometry, and the fact that there is no muscular action in the in vitro models; however, the results are in agreement with previous studies. In future work, we will analyze the custom-made implant behavior in comparison with the novel concept.

5. Conclusion

The results from the in vitro experiments suggest that the behavior of the novel intramedullary concept is more similar to the intact condyle than to the Biomet concept. The Biomet presents a strain shielding effect near the condyle region and bone loss in the long term and, as a result, also loosening of screws.

This innovative concept requires less complex surgery and ensures more accuracy in the implant position, which can improve the kinematics of the mandible.

This first ex vivo trial has successfully demonstrated the concept potential and validated the implantation procedure; now the concept validation leads to clinical trials to analyze the long-term stability.

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Conflict of interest

None to declare. There was no funding for this work.

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