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In vivo evaluation of a 3D-printed personalized temporomandibular joint condylar prosthesis with an elastic layer for hemiarthroplasty in a goat model

Running title: Elastic TMJ condylar prosthesis evaluation

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Abstract

This study evaluated the in vivo performance of a novel, 3D-printed personalized temporomandibular joint (TMJ) condylar prosthesis featuring an integrated elastic functional layer (EFL) in a goat model. Conventional rigid metal and ultra-high-molecular-weight polyethylene prostheses often trigger stress shielding and contralateral joint degeneration due to a mechanical mismatch with the native articular disc. To address these limitations, unilateral hemi-TMJ reconstructions were performed on four adult male goats using a custom prosthesis combining a porous Ti6Al4V stem and a 3D-printed UHMWPE/HDPE composite elastic layer. Over a 6-month follow-up, clinical, radiographic, and histological parameters were evaluated. All animals survived without serious complications. Maximum passive mouth opening and lateral excursion ranges successfully returned to levels comparable to preoperative baselines, while masticatory efficiency stabilized after an initial postoperative decline. Hepatic and renal function metrics confirmed the material's systemic biosafety. CT and micro-CT imaging verified stable prosthetic positioning, robust osseointegration, and bone matrix ingrowth into the porous metallic scaffold. Histological analysis revealed the formation of a beneficial "synovial-like" membrane on the elastic substrate surface, which was supported by significantly elevated local expression of the regenerative cytokine TGF- β via ELISA. These findings suggest that the elastic design promotes favorable initial stability, good biocompatibility, and vital functional recovery. The observed synovial metaplasia provides a promising protective mechanism to minimize wear and prevent heterotopic ossification, offering strong preclinical evidence for elastic configurations in advanced TMJ arthroplasty.

Keywords: Temporomandibular joint prosthesis; 3D printing; Elastic functional layer; Synovial metaplasia; In vivo evaluation

1. Introduction

The temporomandibular joint (TMJ) is a unique and complex articulation critical for mastication, speech, and facial expression. For patients suffering from severe end-stage TMJ disorders resulting from trauma, ankylosis, or extensive tumor resection, total TMJ replacement (TMJR) has become a viable and reliable reconstructive option^[1,2]. Currently, clinical practice predominantly relies on two major commercially available TMJ prostheses: the stock or custom-made Zimmer Biomet systems (Biomet Microfixation, Jacksonville, FL, USA) and the custom-made TMJ Concepts systems (TMJ Concepts Inc., Camarillo, CA, USA)^[3]. Although traditional alloplastic TMJ prostheses offer immediate and vital structural support, they are predominantly fabricated from rigid materials, such as titanium alloys and standard ultra-high-molecular-weight polyethylene (UHMWPE). These materials possess an elastic modulus significantly greater than that of the native mandible, invariably inducing stress-shielding effects^[4]. Consequently, this biomechanical mismatch can lead to periprosthetic bone resorption and severe complications, including screw loosening and implant failure^[5]. Furthermore, this rigidity partially explains the current clinical contraindication for hemiarthroplasty, as high-modulus prostheses can inflict severe wear and structural damage on the opposing natural glenoid fossa and articular disc^[6]. Although total TMJR is technically more demanding than hemiarthroplasty, total joint replacement remains the clinical standard regardless of whether the glenoid fossa is compromised^[7,8]. To overcome the anatomical mismatch frequently encountered with off-the-shelf standard sizes, patient-specific total joint reconstruction utilizing computer-aided design and manufacturing (CAD/CAM) or 3D printing has expanded significantly, allowing for complex geometries that precisely mirror individual bony contours to improve initial fixation and safeguard vital neurovascular structures^[9,10]. However, existing prosthetic designs primarily focus on replacing the rigid bony structures. They critically overlook the distinct biomechanical roles played by the native articular disc and cartilage. The natural articular disc is integral to the complex movements of the TMJ, providing essential shock absorption, lubrication, and stress distribution^[11]. While recent polyurethane or acellular disc prostheses match certain dynamic behaviors, they still lack validation in large animal model^[12,13]. Ultimately, Xu et al. suggest that prostheses lacking physiological elasticity can adversely alter the biomechanical behavior and long-term health of the contralateral joint^[14].

Recent advancements in 3D printing and biomaterials offer unprecedented opportunities to address these biomechanical limitations through biomimetic design. Although a 3D-printed customized polyetheretherketone TMJ condylar prosthesis developed by Guo et al. showed promising in vitro validation, its wear resistance falls short compared to UHMWPE^[15]. Additionally, patient-specific musculoskeletal modeling has been successfully applied to design personalized 3D-printed titanium condylar prostheses, which actively reduce screw and bone stresses during physiological clenching^[16]. Our group has previously developed a novel elastic TMJ condylar prosthesis. This innovative design integrates a porous Ti6Al4V stem with an elastic functional layer (EFL) composed of a 3D-printed UHMWPE/HDPE composite. This EFL is specifically engineered to mimic the cushioning and load-distributing functions of the natural articular disc. In vitro studies have confirmed its optimized elastic modulus, excellent mechanical compatibility, and potential to mitigate stress concentrations^[17]. Building directly upon our prior in vitro design and fabrication framework, the current study represents a critical incremental advancement by providing the first-in-large-animal in vivo validation of this elastic functional layer configuration.

To bridge the gap between in vitro promise and clinical translation, rigorous in vivo evaluation is imperative^[18]. Large animal models, particularly goats, are considered the gold standard for TMJ research due to the distinct anatomical and biomechanical similarities of their TMJ structures to those of humans^[19]. Mommaerts et al. verified a novel TMJ prosthesis that permits the reinsertion and integration of the lateral pterygoid muscle into the prosthesis in a goat model^[20]. Therefore, the present study aims to conduct a comprehensive in vivo assessment of this novel elastic prosthesis using a goat hemi-TMJ replacement model. We evaluated its surgical feasibility, short-to medium-term biosafety, mechanical stability, and efficacy in restoring mandibular function. We hypothesized that this design would not only provide sufficient mechanical support and physiological elasticity, but also preserve joint function by preventing adverse wear on native tissues and promoting favorable osseointegration.

2. Materials and methods

2.1. Ethical Statement

All procedures were approved by the Institutional Animal Care and Use Committee of Peking University School of Stomatology (Approval No. LA2020286) and were conducted in strict accordance with national guidelines for the care and use of laboratory animals.

2.2. Research Subjects and CT Acquisition

Four healthy adult male goats (aged 1.5–2 years, weighing 60–70 kg) were selected for this study. Inclusion criteria included good nutritional status, absence of systemic diseases, and normal dentition without missing teeth or malocclusion. Following a two-week acclimatization period in the animal facility, preoperative computed tomography (CT) scans were performed. Anesthesia was induced via intramuscular injection of Zoletil (tiletamine/zolazepam) and xylazine (0.14 mL/kg). A 16-slice CT scan (uCT510, United Imaging, Shanghai, China) was conducted with a slice thickness of 0.6 mm, and data were exported in DICOM format. Scans were acquired in four mandibular positions: closed mouth, passive maximum mouth opening, passive maximum left lateral excursion, and passive maximum right lateral excursion. During anesthesia recovery, respiration was carefully monitored to prevent airway obstruction.

2.3. Prosthesis Design and Fabrication

The specific TMJ condylar prosthesis was designed using the preoperative CT data of each subject. The personalized TMJ prosthesis was designed using a digital workflow involving Geomagic Wrap 17.0 (3D Systems, Rock Hill, SC, USA), SolidWorks (Dassault Systemes, Velizy-Villacoublay, France), and Element (nTopology Inc., New York, NY, USA). The prosthesis comprised two primary components:

- The Ti6Al4V mandibular ramus stem, manufactured via selective laser melting (SLM), utilized a topologically optimized porous scaffold to mitigate the stress-shielding effect, thereby preventing periprosthetic bone resorption. Concurrently, an inlay rod and an onlay plate were designed to provide immediate mechanical stability against the remaining mandible [21].
- The EFL composed of a UHMWPE/HDPE composite (4:6 mass ratio, selected based on our prior optimization study demonstrating its superior balanced elasticity and wear resistance [17]), fabricated using a proprietary fused deposition modeling (FDM) 3D printing system. Crucially, the composite material has excellent biocompatibility reported in Shokrgozar et al.'s research [22]. The key FDM printing parameters were set as follows: nozzle temperature

of 240°C, layer thickness of 0.2 mm and a printing speed of 350 mm/min. The internal porous scaffold of this layer was designed with eight staggered layers and a 0°/90° infill pattern to achieve an optimized elastic modulus ^[17].

The two components were mechanically integrated using a custom "mortise-tenon" joint and subsequently welded. The articular surface was polished to a final roughness of $S_a < 2 \mu\text{m}$, which was verified by white light interferometry (Figure 1).

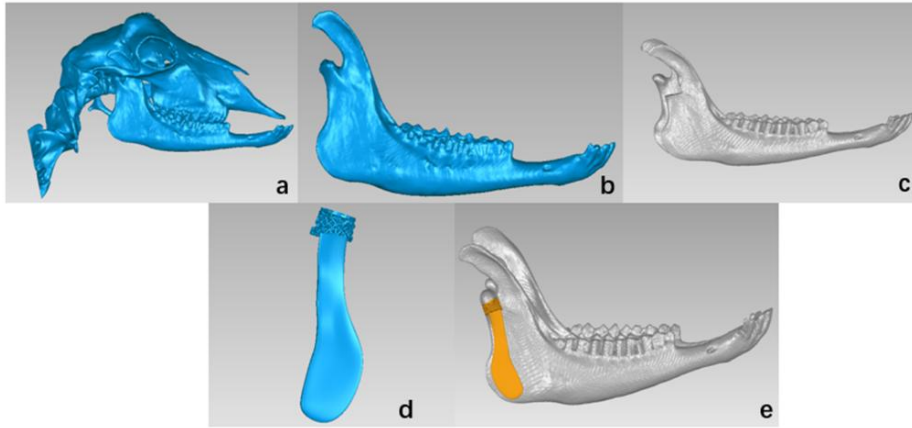


Figure 1. Digital design workflow of the elastic temporomandibular joint (TMJ) condylar prosthesis for goats. a. Goat craniomandibular model. b. Mandibular model. c. Right TMJ defect model. d. Mandibular ramus stem component (Ti6Al4V) model. e. Final assembly model showing the integrated elastic TMJ condylar prosthesis in situ.

2.4. Animal Model and Surgical Procedure

Following a six-hour preoperative fasting period, anesthesia was induced identically to the CT acquisition protocol. The surgical site over the right TMJ was shaved, prepared, and draped under standard aseptic conditions.

An incision was made along the posterior border of the mandible. The anterior attachment of the parotid gland was carefully dissected and retracted posteriorly to protect the facial nerve. The mandibular ramus and condyle were exposed, and the condyle was meticulously dissected from the articular disc to allow full mobilization. According to the preoperative plan, a condylectomy

was performed 15 mm from the condylar apex using a powered surgical saw. Sharp bony edges were smoothed to finalize the hemi-TMJ defect model.

For prosthesis implantation, a fixation hole was drilled perpendicular to the cross-section of the mandibular ramus to accommodate the inlay stem. The custom 3D-printed prosthesis was inserted into the defect, ensuring the onlay plate adapted seamlessly to the lateral contour of the mandible. Rigid fixation was achieved using titanium screws at the pre-planned sites. The surgical site was irrigated with sterile saline. The periosteum was left unsutured, while the subcutaneous tissue and skin were closed in layers. A surgical drain was placed and subsequently removed 24 hours postoperatively (Figure 2).

Postoperative care included intramuscular administration of penicillin sodium (1.6×10^6 U/day) for one week as infection prophylaxis, and lidocaine for analgesia. The goats were maintained on a soft/liquid diet for the first week. Feeding behavior and general health were monitored daily.

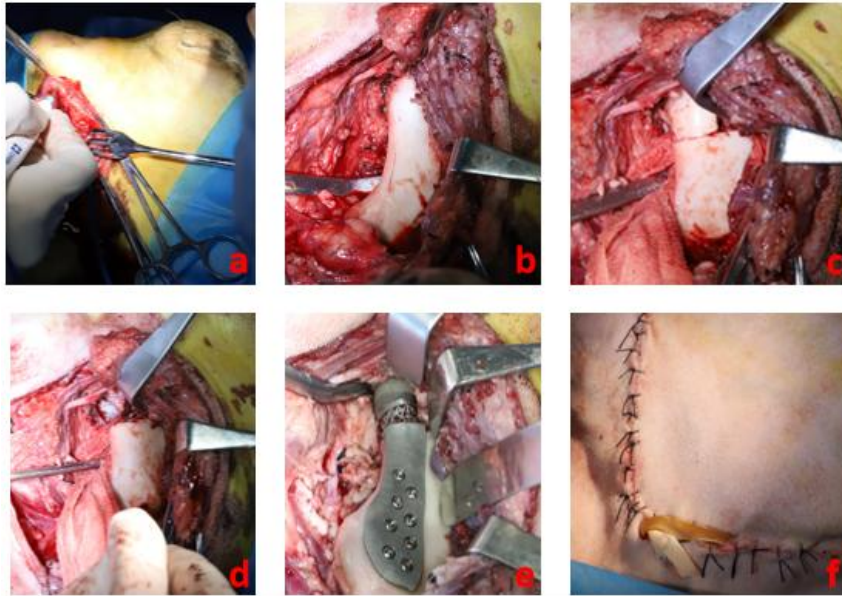


Figure 2. Surgical procedures for the implantation of the TMJ condylar prosthesis in a goat model. (a. Skin and subcutaneous tissue incision. b. Surgical exposure of the mandibular ramus. c. Osteotomy performed along the pre-planned line using a power tool system. d. Resection of the native condyle. e. implantation and fixation of the personalized prosthesis. f. Layered wound closure and placement of a surgical drain.)

2.5. Postoperative Observation and Tissue Sampling

At the designated end of the 6-month observation period, prior to euthanasia, the body weight of each goat was recorded. Under induction anesthesia (0.14 mL/kg Zoletil/xylazine), postoperative CT imaging was conducted in the aforementioned four mandibular positions. The surgical sites were then prepared, and the animals were humanely euthanized.

Soft tissues surrounding the right TMJ were dissected to expose the prosthesis. Tissue samples closely adhering to the anterior, posterior, medial, and lateral aspects of the prosthetic condyle were harvested in duplicate, labeled, and snap-frozen at -80°C for molecular biological analysis. Subsequently, the TMJ prosthesis in situ, along with adjacent bone tissue within a 1 cm radius, was excised en bloc and fixed in formalin for histological evaluation. Contralateral native TMJs (left side) were similarly dissected, and corresponding soft tissue samples were collected as self controls.

2.6. Evaluation Protocol

Comprehensive evaluations were conducted preoperatively, and at 2 weeks and 6 months postoperatively:

- Clinical Observation: General health, wound healing, and signs of complications (e.g., infection, wound dehiscence, or prosthesis exposure) were routinely monitored.
- Maximum Passive Mouth Opening (MPMO): The maximum distance between the incisal edges of the upper and lower central incisors during passive opening was measured using a steel caliper.
- Maximum lateral range of movement (MLRM): The maximum horizontal displacement of the mandible to the left and right was recorded.
- Masticatory Efficiency: The time required for each goat to completely consume 100 g of standardized feed (dry pelletized forage, 5 mm diameter, 12% moisture content) was documented.
- Serum Biochemistry: Blood samples were collected to evaluate liver and kidney function using an automatic biochemical analyzer (Catalyst One, IDEXX, USA). Metrics included

alanine aminotransferase (ALT), alkaline phosphatase (ALP), total protein (TP), albumin (ALB), creatinine (CR), and blood urea nitrogen (BUN) [23].

- **Macroscopic CT Analysis:** Symmetrical comparisons between the prosthetic and healthy joints were performed. Measurements included ramus height (RH; condylar apex to mandibular angle), mandibular body length (ML; mandibular angle to mental protuberance), condyle-incisor distance (CI; condylar apex to mandibular central incisor), and submental-condyle distance (BC) [24].
- **Micro-CT Analysis:** Explanted bone-prosthesis blocks were scanned using a Micro-CT system (Inveon, Siemens, USA) at 60 kV and 220 μ A, with an exposure time of 500 ms and a voxel size of 8.82 μ m. Images were reconstructed via the Inveon Research Workplace to evaluate prosthetic fit, bone ingrowth, and structural integrity compared to the healthy joint.
- **Histological Staining and Cytokine Analysis:** Hard tissue specimens were processed and sectioned, followed by staining with Hematoxylin-Eosin (H&E), Masson's Trichrome, and Toluidine Blue to assess osseointegration and tissue response. Additionally, enzyme-linked immunosorbent assay (ELISA) was employed to quantify local inflammatory and remodeling cytokines (IL-1 α , IL-1 β , IL-8, IL-10, TNF- α , IFN- γ , TGF- β) in the peri-prosthetic soft tissues. All tissue specimens were standardized to a wet weight of 50 mg, and final cytokine concentrations were strictly normalized against the total protein content of the respective supernatant.

To eliminate observer bias, all postoperative functional assessments (MPMO, MLRM, masticatory efficiency), radiographic measurements, and histological evaluation were performed by two independent investigators who were completely blinded to the surgical protocol and animal identity. Inter-observer discrepancies were resolved by consensus.

3. Results

3.1. General observations

All four experimental animals survived the entire experimental period and successfully completed the study protocol, including clinical observations, specimen collection, and radiographic imaging. No postoperative complications, such as infections, trismus, or prosthesis exposure, were observed.

3.2. Masticatory efficiency

Masticatory efficiency exhibited a significant postoperative decline across all subjects compared to the preoperative baseline. At the 6-month postoperative mark, the average chewing time required to consume 100 g of standardized feed increased by 8.25 ± 2.99 minutes relative to preoperative levels, representing a statistically significant reduction in efficiency ($P < 0.05$). Notably, masticatory efficiency stabilized after the initial healing phase, showing no statistically significant differences among the 2-week, 1-month, and 6-month postoperative time points ($P > 0.05$) (Figure 3).

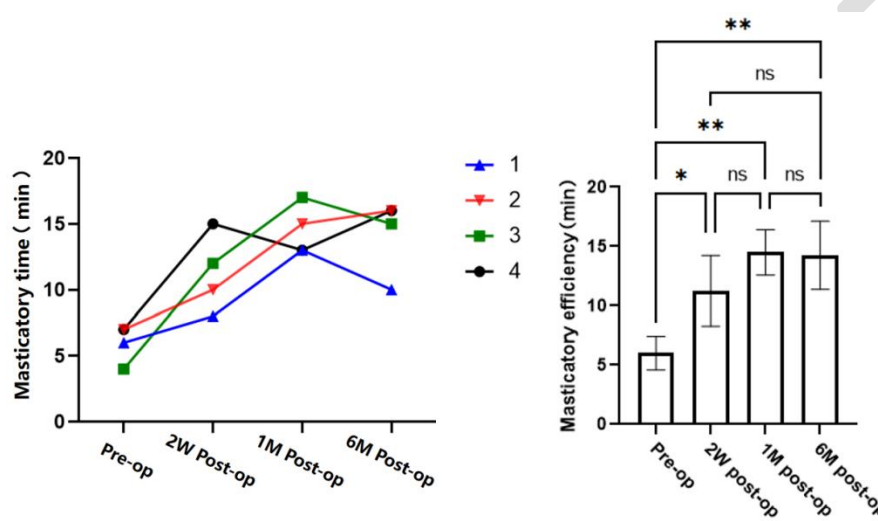


Figure 3. Changes in masticatory efficiency in four goats following TMJ replacement: Mean values and inter-group comparisons at different time points. The graph displays the time required for mastication (min) for the four experimental goats (1–4) at preoperative (Pre-op), 2-week postoperative (2W Post-op), 1-month postoperative (1M Post-op), and 6-month postoperative (6M Post-op) intervals. Statistical analysis was performed using paired t-tests for pairwise comparisons. (ns: $P > 0.05$; *: $P < 0.05$; **: $P < 0.01$).

3.3. Maximum passive mouth opening

At 6 months post-operation, the MPMO in two goats returned to preoperative levels, while the remaining two goats exhibited a slight decrease compared to baseline. There were no statistically significant differences in MPMO between the 2-week and 6-month postoperative intervals

compared to the preoperative baseline, indicating excellent preservation of vertical mandibular mobility ($P > 0.05$) (Figure 4).

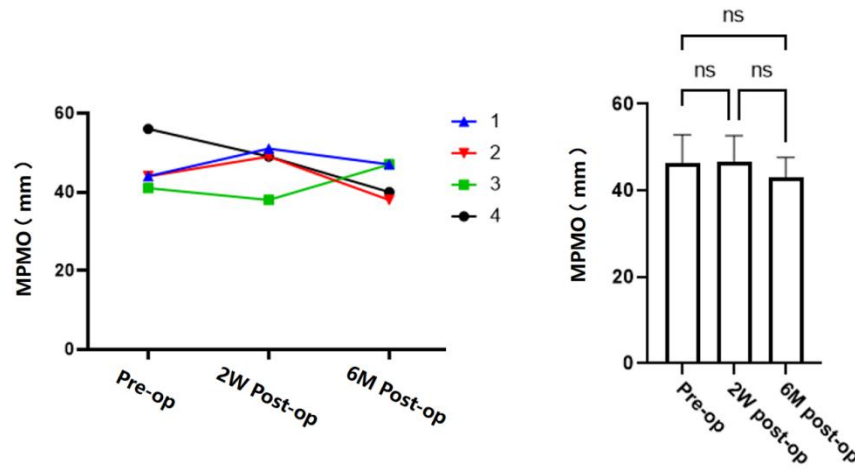


Figure 4. Changes in maximum passive mouth opening (MPMO) in the goat model: Mean values and inter-group comparisons at different time points. The graph displays the individual trends of MPMO (mm) for the four experimental goats (1–4) at preoperative (Pre-op), 2-week postoperative (2W Post-op), and 6-month postoperative (6M Post-op) intervals. Statistical analysis was performed using paired t-tests for pairwise comparisons. (ns: $P > 0.05$).

3.4. Maximum lateral range of movement

All animals effectively retained lateral mandibular mobility postoperatively. At 2 weeks post-operation, the right lateral excursion range was significantly reduced compared to preoperative levels ($P < 0.05$). However, by the 6-month follow-up, both left and right lateral excursions had progressively recovered, demonstrating no statistically significant differences compared to their baseline states ($P > 0.05$), thereby confirming the functional restoration of lateral excursion (Figure 5).

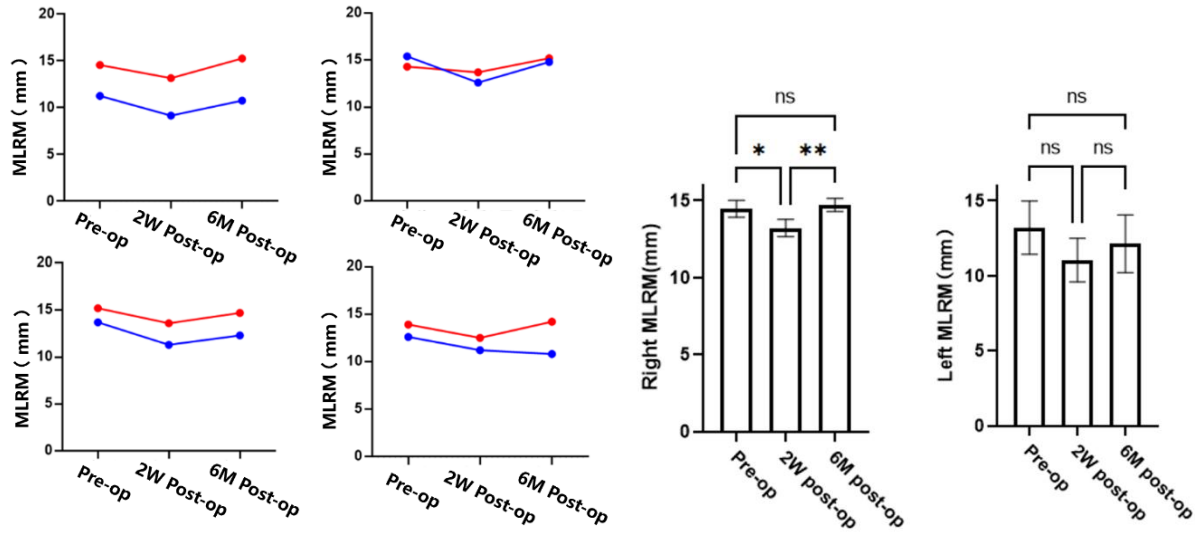


Figure 5. Changes in the maximum lateral excursion range in four experimental goats: Mean values and inter-group comparisons at different time points. The red lines represent the range of left lateral excursion, and the blue lines represent the range of right lateral excursion. Data were recorded at preoperative, 2-week postoperative, and 6-month postoperative intervals. Statistical analysis was performed using paired t-tests for pairwise comparisons. (ns: $P > 0.05$; *: $P < 0.05$; **: $P < 0.01$).

3.5. Hepatic and Renal Function Metrics

The levels of alanine aminotransferase (ALT), alkaline phosphatase (ALP), total protein (TP), albumin (ALB), creatinine (CR), and blood urea nitrogen (BUN) were measured preoperatively, at 2 weeks, and at 6 months post-operation. The normal reference ranges for these parameters are as follows: ALT (23-44U/L), ALP (26.9-283.3U/L), TP (57-81g/L), ALB (21-37g/L), CR (53-159 μ mol/L), BUN (1.8-7.1mmol/L). All parameters remained within physiological ranges throughout the study period, indicating no systemic toxicity and the safety of the implanted materials (Figure 6).

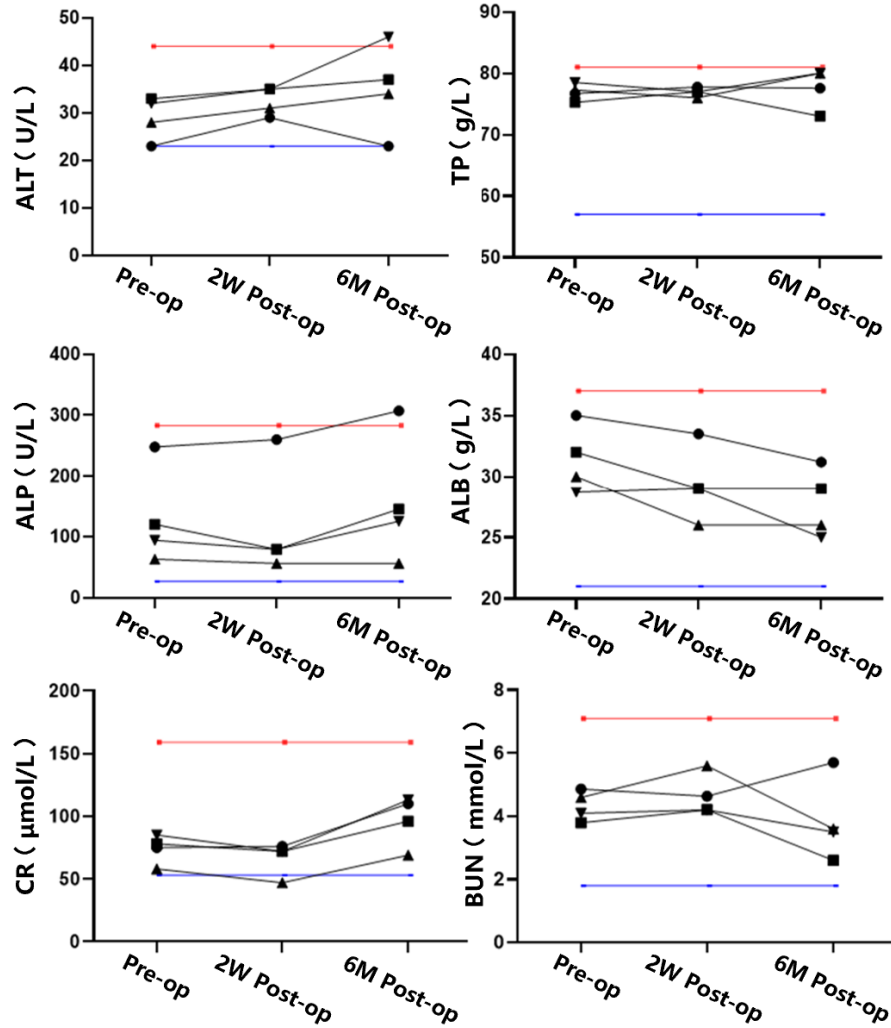


Figure 6. Longitudinal assessment of hepatic and renal function indicators in goats. The graphs show the levels of ALT, TP, ALP, ALB, CR, and BUN at preoperative (Pre-op), 2-week postoperative (2W Post-op), and 6-month postoperative (6M Post-op) stages. The red horizontal lines indicate the upper limit of the physiological reference range, while the blue horizontal lines indicate the lower limit. All parameters for the four experimental goats remained within normal physiological limits throughout the study period.

3.6. Three-dimensional (3D) morphometric and Micro-CT analysis

No significant differences were observed in RH, ML, CI, and BC between the 2-week and 6-month postoperative intervals ($P > 0.05$). All deviations in these parameters were within a margin of 2 mm, suggesting structural stability of the prosthesis (Figure 7). CT imaging showed the TMJ

prosthesis was in a stable position (Figure 8). Micro-CT imaging of the four specimens at the 6-month mark demonstrated a tightly apposed interface between the prosthesis and the mandible, with no signs of loosening or gaps. Notably, increased radiopaque signals (indicating higher density) were observed within the internal porous metal scaffold, suggesting potential bone ingrowth and integration into the structure. The bone architecture and mineral density of the contralateral healthy joints remained within physiological limits (Figure 9).

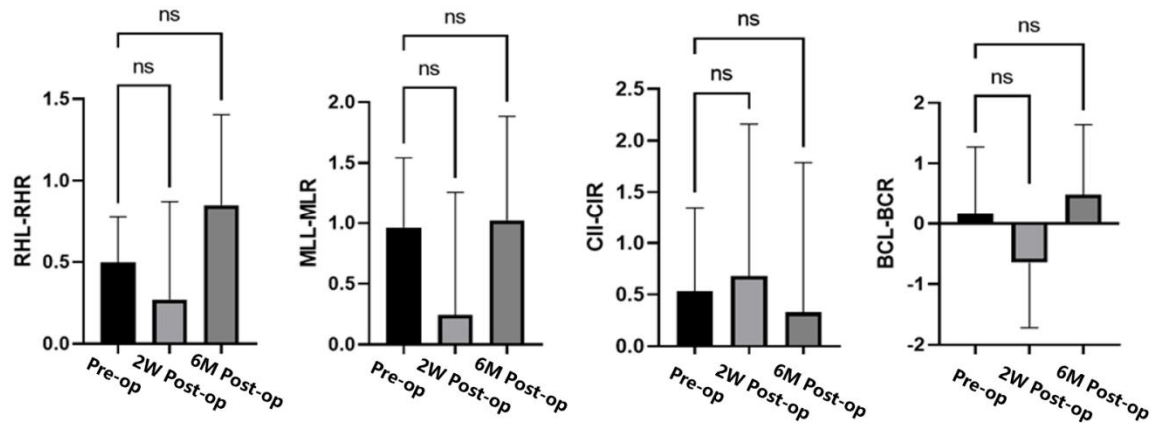


Figure 7. Comparison of bilateral symmetry in RH, ML, CI, and BC at different time points. The bar graphs represent the differences between the left and right sides for each parameter (RH, ML, CI, and BC) at preoperative, 2-week postoperative, and 6-month postoperative intervals. Statistical analysis was performed using paired t-tests for pairwise comparisons. (ns: $P > 0.05$).

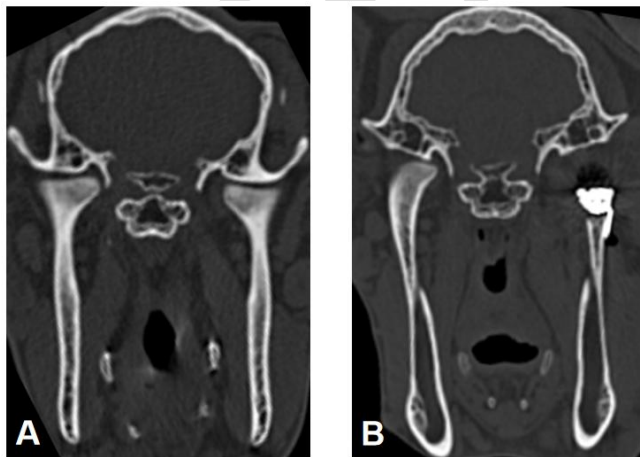


Figure 8. Coronal CT images. A. Preoperative CT scan. B. Postoperative CT scan at 6 months follow-up.

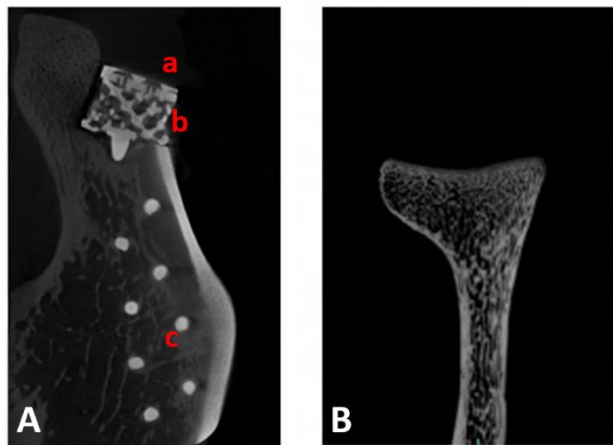


Figure 9. Micro-CT images of the operated and contralateral TMJs. A. Representative Micro-CT image of the operated side showing the prosthesis: a. the 3D-printed elastic porous layer, b. the metallic scaffold structure (Ti6Al4V), and c. the fixation screws. B. Micro-CT image of the contralateral TMJ as a baseline.

3.7. Histological evaluation

Histological analysis using HE, methylene blue, and Goldner's trichrome staining (10× magnification) revealed the formation of a synovium-like acellular structure on the surface of the condylar prosthesis 6 months post-operation (Figure 10). The joint cavity remained patent with no evidence of fibrous adhesion. Furthermore, the porous elastic scaffold maintained structural integrity, with visible intramedullary bone matrix formation.

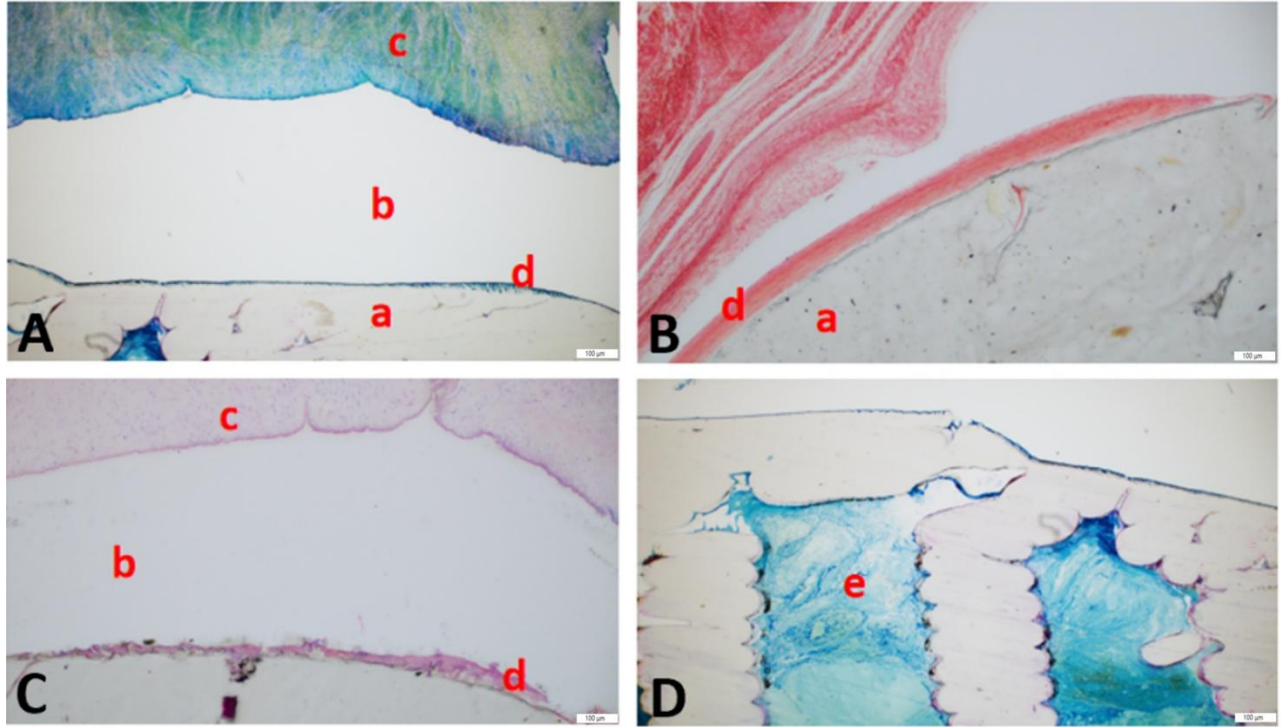


Figure 10. Histological evaluation of hard tissue sections in the prosthetic TMJ region (10× magnification). Representative images stained with Methylene Blue, Goldner's Trichrome, and Hematoxylin and Eosin (H&E) show: a. the porous elastic prosthesis layer; b. the joint cavity, c. the natural articular disc; d. the "synovial-like" membrane formation on the prosthesis surface; e. bone matrix ingrowth within the porous metallic scaffold. Scale bar: 100 µm.

3.8. ELISA results

ELISA analysis showed that TGF- β levels in the affected joint group were significantly higher than those in the healthy control group ($P < 0.05$). In contrast, no statistically significant differences were observed in the levels of IL-1 α , IL-1 β , IL-8, IL-10, TNF- α , and IFN- γ between the test and control groups ($P > 0.05$) (Figure 11). This cytokine profile indicates a localized tissue response characterized by elevated TGF- β up-regulation.

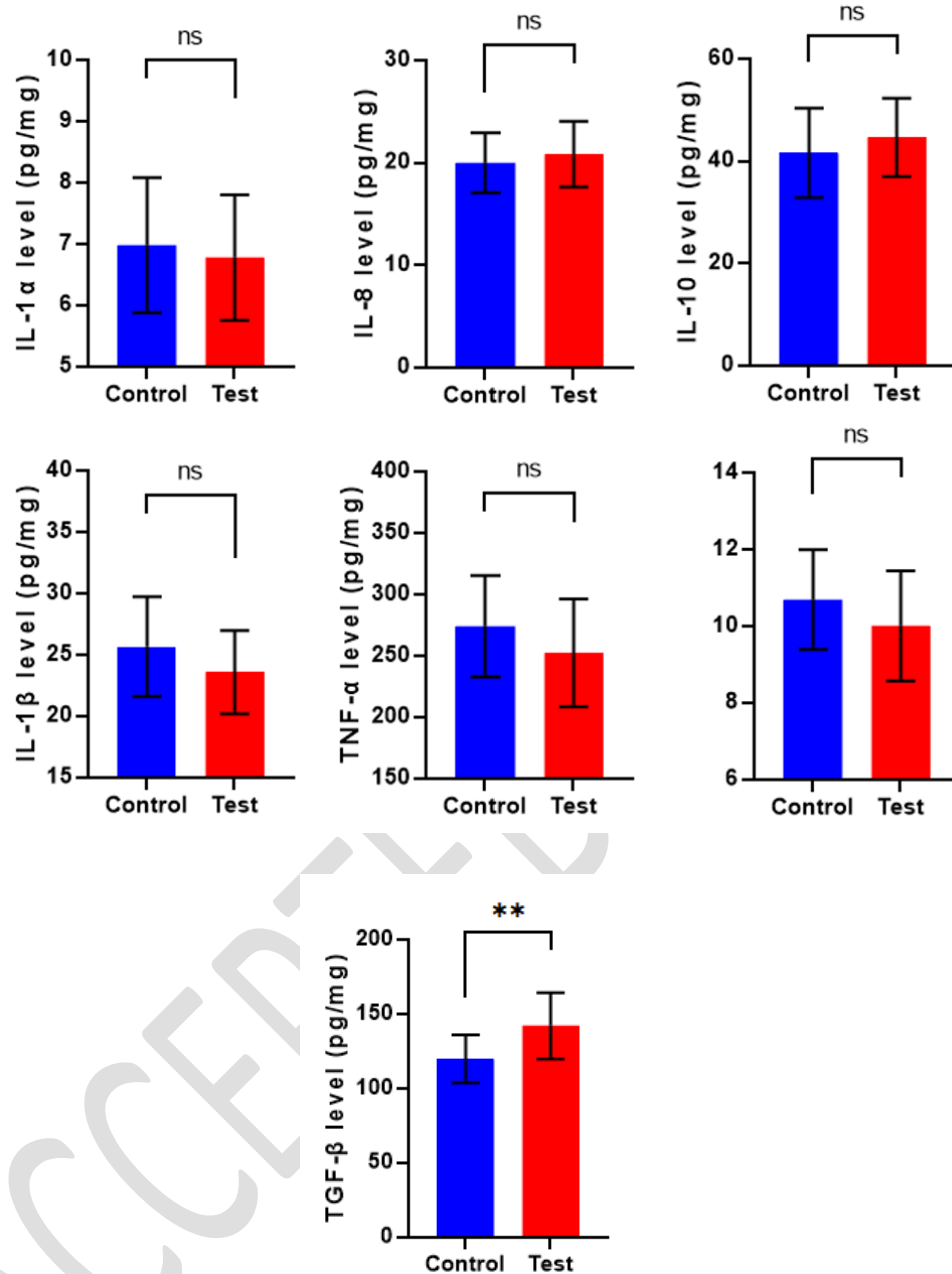


Figure 11. Local cytokine expression profiles via ELISA analysis. Concentration of inflammatory cytokines (IL-1 α , IL-1 β , IL-8, IL-10, TNF- α , and IFN- γ) and the regenerative factor TGF- β in the peri-prosthetic tissues (Test) compared to the contralateral natural joint tissues (Control). Statistical significance was determined using paired t-tests. (ns: P > 0.05; *: P < 0.05; **: P < 0.01).

4. Discussion

The clinical management of severe end-stage TMJ disorders via hemiarthroplasty remains historically constrained by the high elastic modulus of traditional rigid materials, which invariably inflicts catastrophic mechanical wear on the native glenoid fossa and alters contralateral joint kinematics^[25,26]. By evaluating our independently developed elastic functional layer (EFL) prosthesis in a goat model, this study demonstrates that introducing localized mechanical compliance can fundamentally bridge this structural mismatch. The successful recovery of mandibular mobility, stable spatial alignment, and preserved tissue architecture observed within 6 months suggest that mitigating interfacial rigidity facilitates functional joint adaptation without inducing immediate structural failure or periprosthetic gaps. This biomechanically inspired approach presents a stark contrast to traditional custom-made systems that rely strictly on rigid metals or solid UHMWPE, offering a viable preclinical strategy to preserve the natural fossa and reduce surgical invasiveness.

Histological analysis revealed the formation of characteristic "synovial-like" structures on the surface of the EFL, a phenomenon known as synovial metaplasia (SM). First reported on the surfaces of silicone TMJ implants in 2012^[27], the exact mechanism of SM remains to be fully elucidated. It is hypothesized that SM arises from a combination of the material's inherent properties and the long-term biological response to implantation. Mechanical stress is considered a critical inductive factor^[28, 29]; for instance, Drachman et al. demonstrated that synovial tissue fails to develop normally during embryonic stages in the absence of mechanical stimulation^[30]. While the exact etiology of SM in TMJ reconstruction remains to be fully elucidated, mechanical stress and biomaterial surface properties are considered critical inductive factors. In this study, the formation of a "synovial-like" membrane on the EFL suggests that the material not only provides a biocompatible substrate but also effectively transmits mechanical stress to promote membrane formation. This synovial-like layer may serve a dual purpose: preventing heterotopic ossification and creating a biological "articulation-like" interface that reduces the generation of wear particles. The formation of this membrane suggests potential biological interface adaptation, though its long-term role in mitigating wear requires further validation. Our ELISA results, showing elevated TGF- β levels, align with previous findings that certain growth factors regulate SM^[31]. However, as excessive SM may lead to soft tissue hyperplasia and jeopardize long-term stability^[32], future

research should focus on the precise regulation of this metaplastic process to mitigate potential fibrosis and adhesion.

Radiographic results at 6 months post-operation confirmed that the prosthesis remained symmetrically positioned with the healthy joint, showing no signs of dislocation or screw loosening. This underscores the robust initial stability of the elastic prosthesis. While traditional hip and knee prostheses typically serve 10 to 20 years, systematic longitudinal data for TMJ prostheses are currently lacking^[33]. Given our 6-month observation period, longer-term follow-up is essential to establish a reliable theoretical basis for clinical translation.

A significant finding of this study is the restoration of lateral range of motion. Traditionally, total joint replacement (TJR) often limits patients to vertical hinge movements, largely due to simplified bulbous socket designs and the loss of the lateral pterygoid muscle attachment^[34]. Our elastic condylar prosthesis, designed with biomechanical biomimicry in mind, successfully restored lateral mandibular function, offering a critical reference for anatomical and functional reconstruction. Interestingly, while vertical and lateral mobility were effectively restored, masticatory efficiency did not fully return to preoperative levels by the 6-month mark ($P < 0.05$). This discrepancy may be attributed to the surgical disruption of the masticatory musculature, particularly the lateral pterygoid muscle, or a lingering compensatory chewing pattern following unilateral surgery. Alternatively, this may be associated with temporary dysfunction of the masticatory muscle secondary to surgical trauma or postoperative compensatory occlusion, warranting long-term follow-up^[35]. Furthermore, our metric for masticatory efficiency is inherently subject to behavioral confounding factors such as animal appetite and temperament. Future trials should implement more objective, biomechanical metrics, including chewing cycle count tracking via video analysis or direct bite-force transduction^[36]. However, the stabilization of efficiency after the initial healing phase suggests a positive adaptation to the prosthesis. This is further supported by our ELISA results, which showed significantly elevated TGF- β levels in the peri-prosthetic tissues. As an essential mediator of tissue repair and synovial homeostasis, the upregulation of TGF- β indicates an active regenerative microenvironment that supports synovial metaplasia^[37,38], and bone remodeling without triggering a systemic inflammatory response, as evidenced by the stable hepatic and renal function metrics. However, the pleiotropic nature of TGF- β mandates caution in its interpretation. While its elevated expression correlates with

protective synovial metaplasia and bone remodeling, chronically elevated TGF- β is a primary driver of tissue fibrosis and extracellular matrix deposition^[39]. As highlighted by Angelo et al. ^[32], unchecked synovial metaplasia can transition into pathological soft tissue hyperplasia and capsular fibrosis, potentially restricting joint mobility over longer durations. Therefore, the long-term homeostasis between TGF- β -mediated tissue repair and fibroproliferation requires vigilant longitudinal monitoring.

Current clinical protocols favor total joint replacement because rigid hemi-arthroplasty materials often induce "stress shielding" and subsequent bone resorption in the glenoid fossa. Our novel elastic design challenges this paradigm by introducing a buffering capacity that preserves the natural fossa and reduces surgical invasiveness. Despite these promising results, this study has limitations, including a relatively small sample size ($n=4$) and a 6-month observation period, which may not fully capture long-term wear characteristics. Specifically, the small cohort size may limit statistical power and increase susceptibility to individual biological variability. A post hoc power analysis revealed that while the statistical power for masticatory efficiency recovery reached 0.72 due to a large effect size ($d=1.76$), the power for lateral excursion metrics remained below 0.50, meaning subtle between-group differences might have been obscured. Therefore, these pilot findings must be interpreted as preliminary trends rather than definitive statistical proof. Additionally, the lack of post-explantation surface characterization (such as scanning electron microscopy for wear tracks or surface roughness re-measurement) represents a notable omission. Because the specimens were processed en bloc for hard-tissue histology to preserve the bone-implant interface, the polymeric surface could not be harvested separately for tribological analysis. Future studies must allocate dedicated specimens to explicitly quantify long-term in vivo wear kinetics and particle debris migration^[40]. Future research will focus on the development of a complete "condyle–disc–fossa" elastic bionic system. By combining the wear resistance of CoCrMo alloys with our 3D-printed elastic composites, we aim to provide a personalized, fully functional reconstruction that more closely mimics the complex physiological state of the human TMJ.

5. Conclusion

In conclusion, this study demonstrates that the novel 3D-printed personalized elastic bionic TMJ condylar prosthesis provides favorable initial stability, high biocompatibility, and facilitates partial

functional recovery in a goat model. Notably, the elastic substrate promoted the in vivo formation of a 'synovial-like' membrane. The formation of this membrane suggests potential biological interface adaptation, though its long-term role in mitigating wear and preventing heterotopic ossification requires further validation. Ultimately, our findings supply robust preclinical validation for the integration of elastic designs in the next generation of TMJ arthroplasty.

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Conflict of interest

The authors declare they have no competing interests.

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Ethics approval and consent to participate

All procedures were approved by the Institutional Animal Care and Use Committee of Peking University School of Stomatology (Approval No. LA2020286) and were conducted in strict accordance with national guidelines for the care and use of laboratory animals.

Consent for publication

Not applicable.

Availability of data

Data are available from the corresponding authors upon reasonable request.

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