

ORIGINAL RESEARCH ORJİNAL ARAŞTIRMA

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Intraoral Device Innovation for Temporomandibular Joint Hypermobility: *in vitro* Validation of Controlled Mouth Opening

Temporomandibular Eklem Hipermobilitesi için İnovatif İntraoral Cihaz: Kontrollü Ağız Açıklığının *in vitro* Validasyonu

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ABSTRACT Objective: Temporomandibular joint (TMJ) hypermobility is characterized by excessive anterior translation of the mandibular condyle, often leading to recurrent subluxation or dislocation. Traditional immobilization methods, such as bandages or maxillo-mandibular fixation, can impair function and patient compliance. This study introduces an innovative intraoral device that limits mouth opening within a therapeutic range (35-50 mm) while allowing full mandibular function. **Material and Methods:** The device includes custom 3 dimensional (3D)-printed bands (via Selective Laser Melting) cemented to specific teeth and a detachable mechanical system using a passive Herbst arm and a nickel-titanium closed-coil spring. It enables emergency removal by the patient and has been tested *in vitro* using 3D-printed models. The apparatus is protected under national patent TR 2023 005375 B and is under international evaluation (EPO Application No: 20770/44). Ethical approval was obtained from Üsküdar University Non-Interventional Research Ethics Committee (date: October 30, 2024; no: 61351342/020-502). **Results:** *in vitro* simulations showed effective limitations of mouth opening, enhanced aesthetics, oral hygiene access, and user comfort over conventional methods. **Conclusion:** This device offers a novel, patient-friendly option for managing TMJ hypermobility. Clinical validation is needed to assess the long-term outcomes.

Keywords: Temporomandibular joint; temporomandibular joint dysfunction syndrome; temporomandibular ankylosis

ÖZET Amaç: Temporomandibular eklem (TME) hipermobilitesi, mandibular kondilin aşırı anterior translasyonu ile karakterize olup sıklıkla tekrarlayan subluksasyon veya dislokasyona yol açar. Geleneksel immobilizasyon yöntemleri olan bandajlar veya maksillomandibular fiksasyon, fonksiyonel sınırlamalara ve hasta uyumsuzluğuna neden olabilir. Bu çalışmada, ağız açıklığı terapötik aralıkta (35-50 mm) sınırlandırılırken mandibular fonksiyonu tamamen koruyan yenilikçi bir intraoral cihaz tanıtılmaktadır. **Gereç ve Yöntemler:** Cihaz, seçilen dişlere simante edilen özel tasarım 3 boyutlu [3 dimensional (3D)] yazıcıyla (Selective Laser Melting) üretilmiş bantlar ve pasif kullanılan Herbst kolu ile nikel-titanyum kapalı yay sisteminden oluşan mekanik bir üniteden oluşmaktadır. Hasta tarafından acil durumda çıkarılabilir şekilde tasarlanmış olup, 3D baskı dental modeller üzerinde *in vitro* olarak test edilmiştir. Cihaz, TR 2023 005375 B numaralı ulusal patentle korunmakta ve uluslararası başvurusu sürmektedir (EPO Başvuru No: 20770/44). Etik onay Üsküdar Üniversitesi Girişimsel Olmayan Araştırmalar Etik Kurulu'ndan alınmıştır (tarih: 30 Ekim 2024; no: 61351342/020-502). **Bulgular:** Simülasyonlar, cihazın ağız açıklığını etkili biçimde sınırladığını, estetik, hijyen ve hasta konforunu artırdığını göstermiştir. **Sonuç:** Bu cihaz, TME hipermobilitesi sonrası immobilizasyon için fonksiyonel ve hasta dostu yeni bir seçenektir. Klinik çalışmalarla uzun dönem etkinliği değerlendirilmelidir.

Anahtar Kelimeler: Temporomandibular eklem; temporomandibular eklem disfonksiyon sendromu; temporomandibular ankilozis

The temporomandibular joint (TMJ) is a complex synovial articulation responsible for critical mandibular functions such as mastication and speech. TMJ hypermobility involves excessive anterior

condyle translation beyond the articular eminence, and is often associated with recurrent subluxation or dislocation. It affects up to 5-8% of the population.¹⁻³

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TMJ subluxation is characterized by abnormal anterior movement of the condylar head during mouth opening and spontaneous return to the glenoid fossa.³⁻⁵ In contrast, TMJ dislocation refers to the condition where the condyle is locked anterior to the eminence and cannot self-reduce.^{4,6,7} Generalized joint hypermobility has been shown to be associated with TMJ hypertranslation and related dysfunctions, increasing the risk of recurrence in hypermobile cases.⁵ Patients often present with preauricular pain, restricted mandibular movements, and difficulties in closing the mouth.^{6,8} Scientific studies have indicated that the maximum mouth opening of healthy individuals should be <50 mm.^{9,10}

The current management includes both conservative and surgical approaches. Conservative methods, such as autologous blood injection, dextrose prolotherapy, and maxillomandibular fixation, often require postprocedural immobilization for 7-14 days to prevent recurrence.^{11,12} Several surgical procedures for creating an obstacle at the eminence have been suggested to limit the anterior movement of the condylar head to prevent recurrent TMJ luxation. Surgical options include condylectomy, reduction of the articular eminence (eminectomy), mini-plating, bone grafting, alloplastic materials attached to the articular eminence, and soft tissue surgery to restrict condyle movement, such as myotomy of the lateral pterygoids, lateral pterygoid muscle tendon scarification, scarification of the temporalis tendon, and capsule plication.^{8,12} However, traditional methods such as Barrel Bandages, Barton bandages, chin cup, or mandibula-maxillary fixation systems are uncomfortable, aesthetically undesirable, and risk complications such as osseous ankylosis.¹³

A novel intraoral device-the Temporomandibular Hypermobility Apparatus-has been developed and patented (TR 2023 005375 B; EPO Application No: 20770/44). It restricts mouth opening to a functional range of 35-50 mm while allowing complete mandibular movements such as protrusion, retrusion, and lateral excursions. This system consists of custom-made cementable bands and an externally screwed mechanism integrated with a passive Herbst arm and memorized closed-coil spring. The device can be removed by patients during emergencies, and is currently in the prototype stage.

MATERIAL AND METHODS

Ethical approval was obtained from Üsküdar University (date: October 30, 2024; no: 61351342/020-502). This study describes a novel intraoral mechanical apparatus, the Temporomandibular Hypermobility Apparatus, which has been invented and patented (National Patent: TR 2023 005375 B; EPO Application No: 20770/44). It was designed explicitly for patients with TMJ hypermobility. The apparatus is currently in the prototype development stage and has not yet been applied to patients. It was developed as a post-reduction immobilization alternative to the traditional bandaging and maxillomandibular fixation (MMF) systems.

APPARATUS DESIGN

The apparatus consisted of 2 modular units (Figure 1).

A) Custom-fabricated cementable bands were digitally designed and manufactured to fit the patient's dentition using 3 dimensional (3D) intraoral scans and computer-aided design (CAD)/computer-aided manufacturing technology (Figure 2).

B) The detachable mechanical component comprises the following elements (Figure 3).

- A passive Herbst arm allows a full mandibular range of motion (protrusion, retrusion, and lateral excursions) while mechanically restricting excessive mouth opening.

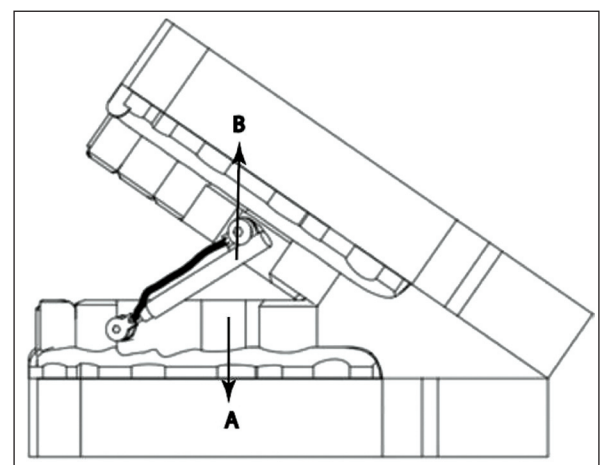


FIGURE 1: Apparatus design

A) Cementable custom band; B) The detachable mechanical component

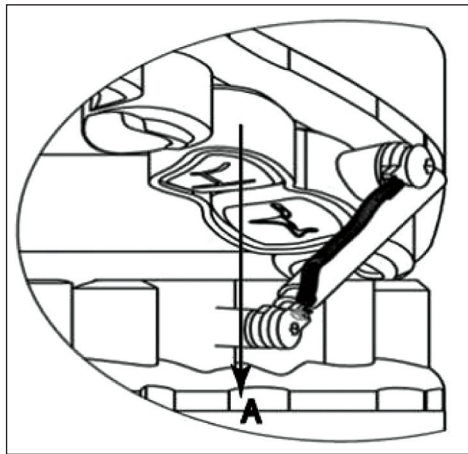


FIGURE 2: Custom band placed on the model
A) Cementable custom bands

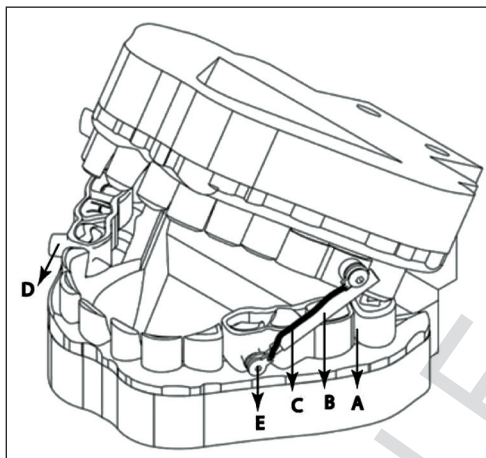


FIGURE 3: Detachable mechanical component of the TMJ hypermobility apparatus
A) Cementable custom band; B) Herbst appliance; C) Memorized closed coil spring; D) Herbst appliance flat nut part; E) Hex head screw

■ A memorized closed-coil spring was positioned to generate passive resistance beyond the targeted mouth opening range (35-50 mm).

■ A hex-head screw and flat nut assembly secured the Herbst arm and spring to the custom bands.

■ The flat nut, integrated into the design, serves as a low-profile biocompatible anchorage point for the screw. This configuration minimizes mucosal irritation, ensures stable fixation within a limited intraoral space, and supports a modular device design. Notably, the flat nut allows the mechanical unit to be detached during emergencies by using a specially designed intraoral key provided to the patient. This design feature enhances safety and clinical manageability, enabling disassembly of the mechanical unit without compromising the cemented bands.

FABRICATION PROCESS

Impressions were made from the maxillary and mandibular dental arches using conventional or digital methods. If traditional impressions were used, they were digitized using intraoral scanning. On the basis of these impressions, custom bands were designed using dental CAD software to fit the following:

Maxilla: Right and left 2nd premolars (15 and 25) and 1st molars (16 and 26) (Figure 4a).

Mandible: Right and left 1st and 2nd premolars 34, 35, 44, 45, and first molars (36 and 46) (Figure 4b).

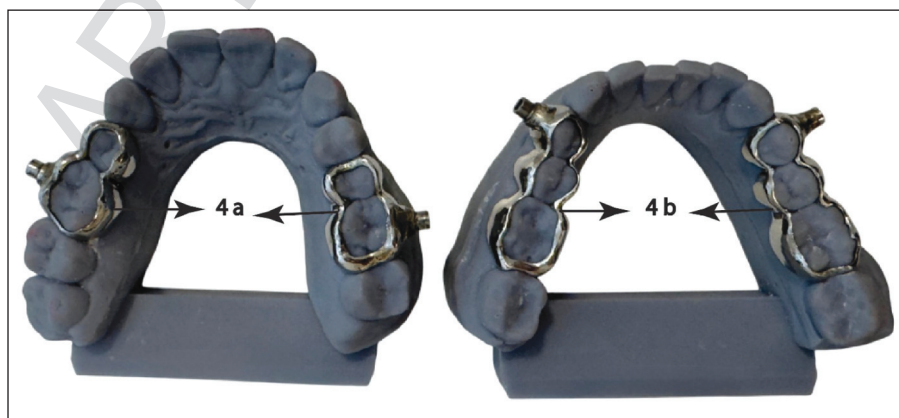


FIGURE 4: Detachable custom band
4a) Detachable custom band fixed to the maxilla; 4b) Detachable custom band fixed to the mandibula

These teeth were selected because of their anatomical stability, accessibility to cementation, and favorable distribution for anchoring the mechanical assembly without interfering with occlusion or soft tissue. Bands were manufactured from biocompatible dental metal powders using Selective Laser Melting (SLM) 3D printing and polished to fit intraorally.

MECHANICAL COMPONENTS

A passive Herbst arm (commercially available in 18, 21, and 25-mm sizes) was used not for mandibular advancement as in orthodontics, but to restrict the vertical opening (Figure 5B). Herbst's arm was mounted onto the cemented bands via a flat nut, allowing secure screw fixation (Figure 5D).

The system includes a memorized closed-coil spring that is selected based on the desired range of mouth opening (Figure 5C). A spring is a vertical limiter that resists excessive opening while allowing complete lateral, anteroposterior, and rotational jaw movements. The closed-coil springs tested had lengths of 10, 12, and 14 mm, enabling an interincisal opening adjustment between 35 and 50 mm, depending on clinical needs.

A flat-nut screw mechanism was used to connect the mechanical assembly to the cemented bands (Figure 5D, Figure 5E). The flat nut embedded within the band structure provided a low-profile biocompatible anchoring site for the screw. This configuration ensured intraoral stability and allowed the patient to de-

tach the apparatus in an emergency using a custom-designed key without compromising the cemented components.

CLINICAL ADAPTATION

The clinical adaptation of the intraoral mobility-limiting device requires secure and symmetrical anchorage on premolar and molar teeth. In cases where partial edentulism exists at the planned band placement sites, adjacent teeth can be used for banding, with necessary modifications to the Herbst arm length or spring tension to preserve symmetrical force transmission across the TMJs.

In more complex clinical scenarios, the following alternative approaches are considered:

- Unilateral application of the device in patients whose symptoms are confined to one TMJ.
- Use of orthodontic retention loops: Orthodontic wires bonded with composite resin may be applied to neighboring teeth to create retention areas when standard banding is not feasible.
- Temporary anchorage devices may be employed to provide skeletal anchorage, especially in cases where sufficient dental support is unavailable.
- Integration with temporary prostheses may be planned in patients undergoing long-term rehabilitation or awaiting implant placement.

Contraindications for this device include fully edentulous patients, individuals with severe periodontal disease at anchor sites, or those with an inability to tolerate intraoral devices due to mucosal sensitivity or neuromuscular disorders. In such patients, alternative conservative or surgical interventions should be considered.

FUNCTIONAL TESTING AND SIMULATION

The prototype was tested on 3D-printed dental models to simulate patient-specific conditions (Figure 6, Figure 7).

Different combinations of the Herbst arm lengths and coil spring sizes were tested.

Determine the optimal restriction of mouth opening in the 35-50 mm range (Figure 7).

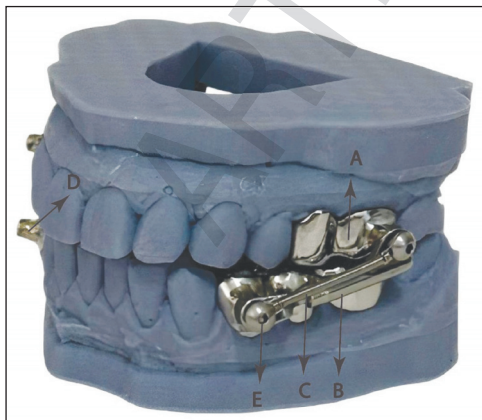


FIGURE 5: Mechanical components of the hypermobility apparatus mounted on a jaw model

A) Cementable custom band; **B)** Herbst appliance; **C)** Memorized closed coil spring; **D)** Herbst appliance flat nut part; **E)** Hex head screw

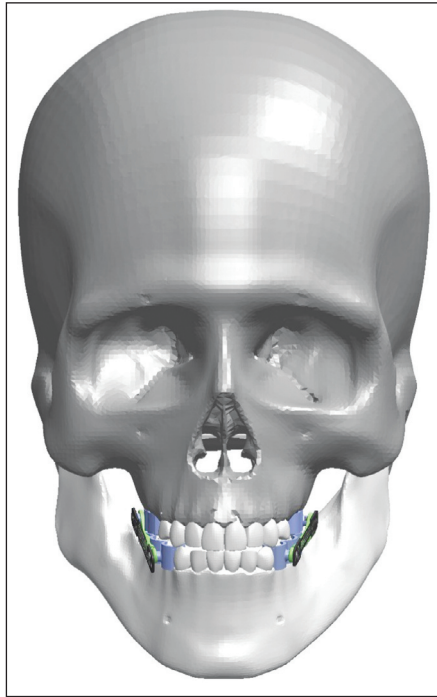


FIGURE 6: 3D simulation showing the intraoral hypermobility apparatus mounted bilaterally on the jaw

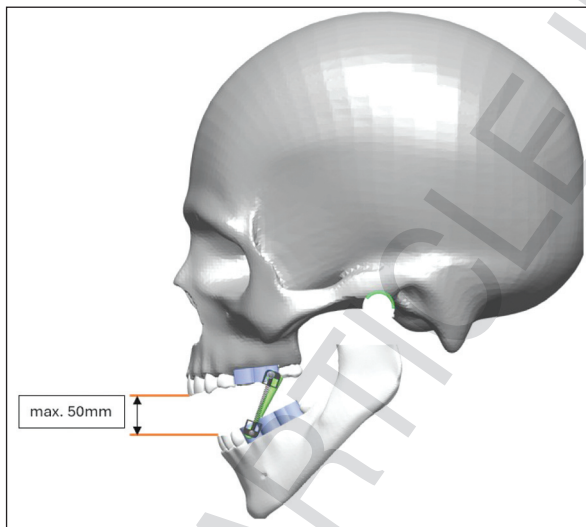


FIGURE 10: Intraoral hypermobility apparatus mounted on the mandible, limiting maximum mouth opening to 50 mm

Ensure uninhibited functional jaw movements (retrusion, protrusion, and lateral excursion).

Confirm removability in emergency situations via a custom-designed hex screw system that allows patients to detach the apparatus independently if necessary.

This prototype eliminates complications associated with traditional immobilization methods, such as osseous or fibrous ankylosis and degenerative cartilage damage. The apparatus combines clinical efficiency, aesthetic intraoral application, and patient-controlled removability, providing a conservative and patient-friendly alternative to rigid fixation techniques.

STATE OF THE ART

Post-reduction immobilization is critical for preventing recurrence and managing TMJ hypermobility and recurrent dislocation. Whether a surgical or conservative approach is used, the jaw is routinely immobilized for a minimum of seven days to facilitate soft tissue healing and promote joint stabilization.^{4,12,14}

Currently, several immobilization techniques have been employed, including;

- Barrel bandage (Figure 8a),
- Barton bandage (Figure 8b),
- Chin cup appliances (Figure 9),
- MMF with arch bars or intermaxillary fixation screws (Figure 10).^{13,15}

However, each of these methods has significant limitations. Barrel and Barton bandages provide limited stability, often require external support, and may cause patient discomfort owing to facial pressure. While more acceptable in terms of aesthetics, chin cup appliances can exert undesired retrusive forces on the mandible, potentially interfering with the discodyle complex positioning and retrodiscal tissue health.¹⁶

MMF, while effective in limiting mouth opening, is invasive and traumatic; significantly impairs nutrition, oral hygiene, and speech; and increases the risk of fibrous or osseous ankylosis, especially with prolonged use.^{17,18}

These methods often fail to offer controlled, quantifiable restrictions on mouth opening, and do not allow independent jaw movements, which are crucial for patient function and comfort. Moreover, none of these techniques are intraorally placed, removable by the patient, or designed with a custom-fit architecture based on dental anatomy.

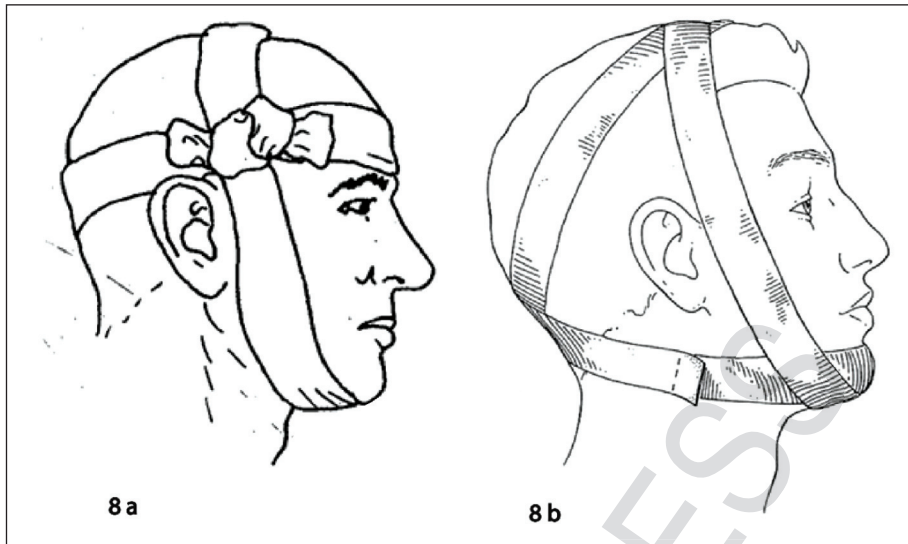


FIGURE 8: Barrel Bandage&Barton Bandage

8a) Barrel Bandage from right side

8b) Barton Bandage from right side

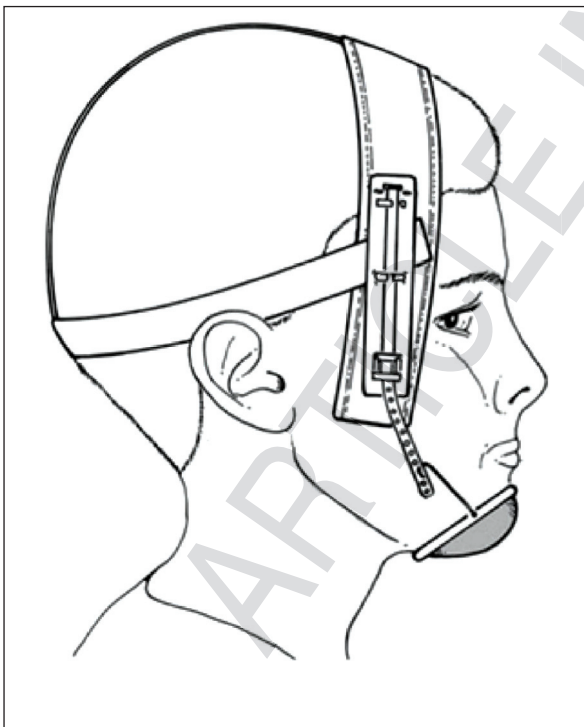


FIGURE 9: Chin cup from side view

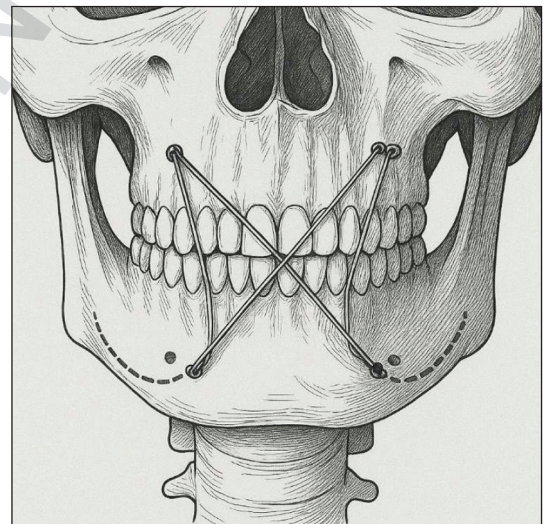


FIGURE 10: Maxillomandibular fixation

Thus, a clear clinical gap exists for these devices.

- Intraoral and aesthetic
- Non-invasive and comfortable
- Capable of restricting maximum mouth opening within a therapeutic range (35-50 mm)
- Compatible with oral hygiene and speech
- Removable in emergency situations

The temporomandibular hypermobility apparatus developed in this study was designed to address these unmet clinical needs and to eliminate the risks associated with conventional immobilization systems. This device is the first to use a passive Herbst arm in combination with a closed coil spring, not for mandibular advancement but as a controlled opening limiter, offering a novel biomechanical solution to TMJ hypermobility.

RESULTS

A prototype of the temporomandibular hypermobility apparatus (National Patent TR 2023 005375 B/EPO Application No. 20770/44) was developed to provide controlled restriction of mouth opening in patients with TMJ hypermobility. The system was engineered to allow a functional jaw-opening range of 35-50 mm while preserving essential mandibular movements including mouth closure, lateral excursions, protrusion, and retrusion.

The prototype consisted of the following components:

Custom-fabricated bands are digitally designed and produced using SLM from biocompatible cobalt-chromium alloys intended for cementation.

Maxilla: right and left 2nd premolars and 1st molars

Mandible: right and left 1st and 2nd premolars and 1st molars

Flat nut connection units are laser-welded onto the buccal surface of custom bands, allowing the secure fixation of auxiliary components.

Herbst arms (18, 21, or 25 mm) were used passively to anchor the restriction mechanism, depending on the patient's planned interincisal opening.

Closed-coil nickel-titanium springs, commercially available in lengths of 10-15 mm with preset force values, were attached to the Herbst arms to limit maximum jaw opening via elastic resistance.

Hex-head screws were used to attach the coil spring and Herbst arms to the flat nut connections, thereby enabling a secure and removable assembly.

The physical components of the apparatus are custom bands, Herbst arm, coil spring, and hex-screw

mechanism. The prototype design allows customization of the maximum mouth opening by selecting appropriate Herbst arm lengths and coil spring characteristics. Based on *in vitro* model simulations,

An 18 mm Herbst arm combined with a 14 mm spring allowed for approximately 45 mm of interincisal opening.

A 21 mm Herbst arm combined with a 14 mm spring allowed for an approximately 52.5 mm interincisal opening.

A 25 mm Herbst arm combined with a 14 mm spring allowed for an approximately 62.5 mm interincisal opening.

All configurations permitted unrestricted jaw closure and functional movement. The memorized closed-coil spring enables precise vertical control of the opening limit without compromising the lateral or anterior-posterior movements. This modularity allows the system to be individually adjusted to each patient's needs by simulating and selecting the appropriate components during the planning phase.

Alternative fixation strategies, such as mini-screw anchorage or resin-bonded temporary crowns, are currently being developed to broaden the applicability of this device to partially edentulous patients.

Although the prototype has not yet been clinically applied, *in vitro* simulations of dental models have demonstrated that the apparatus successfully maintains a restricted range of mouth opening while preserving full mandibular function. Importantly, unlike other external or internal fixation methods, this device does not exert unwanted force vectors on the temporomandibular joint. Future studies will further evaluate this using Finite Element Analysis (FEA) to quantify the stress distribution and ensure biomechanical safety.

DISCUSSION

TMJ hypermobility is characterized by excessive anterior translation of the mandibular condyle beyond the articular eminence during wide mouth opening.^{1,4,9} It accounts for approximately 3% of all reported hypermobile joints.¹⁸ TMJ hypermobility can be clinically classified as subluxation, where the

condyle displaces anteriorly and spontaneously returns to the glenoid fossa, and dislocation (luxation), where the condyle becomes locked anterior to the articular eminence and requires manual reduction.^{6,14,19} Patients frequently present with symptoms such as inability to close the mouth, preauricular pain, and tenderness of the masticatory muscles.^{4,9}

Currently, conservative and surgical approaches are available. Surgical interventions included capsule plication, lateral pterygoid myotomy, condylectomy, eminectomy, and augmentation of the articular eminence with miniplates or implants.^{12,13,20,21} However, the success rates of surgical treatment remain limited because of complications, such as facial nerve injury, relapse, and ankylosis.^{20,21}

Conservative treatments aim to limit mouth opening and include MMF, external devices such as Barton or Barrel bandages, chin cups, and intra-articular injections (autologous blood, prolotherapy, botulinum toxin).^{11,22,23} Clinical studies have demonstrated that immobilization for 1-4 weeks following reduction is essential for forming intra-articular fibrous tissue, stabilizing the joint, and reducing recurrence.^{14,16} Maxillomandibular fixation, although effective in limiting mandibular movement, significantly compromises oral hygiene and function.²⁴ Rigid and prolonged fixation methods have drawbacks such as poor aesthetics, impaired nutrition and oral hygiene, limited patient compliance, and most importantly, the risk of fibrosis or osseous ankylosis and degenerative changes in the joint cartilage.²⁴

Therefore, we developed a novel intraoral temporomandibular hypermobility apparatus to overcome these limitations. The prototype, currently at the experimental stage and registered under a national patent (TR 2023 005375 B) and internationally filed under EPO application number 20770/44, aims to provide controlled, non-invasive immobilization without compromising jaw function.

Unlike conventional methods, our system passively integrates a Herbst arm, which is typically used for mandibular advancement in orthodontics, in a non-active configuration. The Herbst arm was paired with a nickel-titanium closed-coil spring (available in lengths ranging from 12 to 16 mm), which defines

and limits the maximum interincisal opening to a therapeutic range of 35-50 mm. Importantly, the device does not apply intrusive forces to the TMJ region and allows unrestricted protrusive, retrusive, and lateral jaw movements.

The apparatus was anchored to teeth using custom-fabricated bands produced using SLM technology from biocompatible dental alloys. These bands were cemented to the maxillary 2nd premolars and 1st molars, mandibular 1st and 2nd premolars, and the 1st molars. Future designs should incorporate alternative retention mechanisms in edentulous areas, such as mini-screw anchorage and splinted band extensions.

In addition, the apparatus features a removable emergency mechanism using a hex-head screw system that enables patients to safely detach the appliance from the clinical setting. This enhances both patient safety and psychological comfort, while ensuring that the clinical objectives of immobilization are met.

Although the current prototype has only been tested on dental models and has not yet undergone *in vivo* trials, preliminary simulations suggest that it may overcome the many disadvantages of the traditional methods. Intraoral placement offers superior aesthetics and hygiene accessibility, and its modular structure is necessary to evaluate long-term efficacy and patient-reported outcomes. Integration of this approach ensures functional control and reversibility.

This apparatus can potentially fill an essential gap in TMJ hypermobility management, offering a user-friendly, non-invasive alternative to surgical intervention and rigid immobilization. Future clinical studies are needed to assess long-term efficacy, patient-reported outcomes, and integration in various clinical scenarios.

Recent advances in signal-based biomechanical diagnostics suggest that further validation through FEA is encouraged for structurally novel intraoral devices.³ Considering the encouraging results obtained from model-based simulations, further biomechanical validation of the apparatus was planned using FEA. This analysis assessed the device's stress distribution, material deformation, and load-bearing capacity under various mandibular motion scenarios. A

FEA study, which will be published as a separate investigation, is expected to provide valuable insights into the apparatus' safety, mechanical efficiency, and durability under physiological conditions.

CONCLUSION

TMJ hypermobility is a challenging condition that often requires post-reduction immobilization to prevent recurrence. However, conventional immobilization methods such as barrel bandages, Barton bandages, chin cups, and MMF devices are often uncomfortable and aesthetically undesirable. They may lead to serious complications such as fibrous or osseous ankylosis and degeneration of the joint cartilage.

To address these limitations, we developed a novel intraoral mechanical apparatus that passively limits mouth opening within a therapeutic range (35–50 mm), without interfering with essential jaw functions. This device has been granted a national patent (TR 2023 005375 B) and is currently under international patent evaluation (EPO application no. 20770/44). It was custom-designed using digital dental scans and 3D printing technology, and cemented to selected teeth via biocompatible custom-fabricated bands. It was assembled with a passively used Herbst arm and nickel-titanium closed-coil spring.

The apparatus allows free mandibular movement while restricting excessive mouth opening, potentially preventing recurrent dislocations. Intraoral placement ensures patient comfort and esthetic ac-

ceptability, and the emergency release mechanism provides additional safety. Although clinical trials have yet to be conducted, model-based simulations have shown promising outcomes in function, patient adaptability, and biomechanical stability.

This innovation offers a potentially effective, aesthetic, and patient-friendly alternative to existing immobilization strategies, and represents a step forward in the conservative management of TMJ hypermobility. Future studies should focus on clinical application, long-term outcomes, and device integration into broader treatment protocols.

Source of Finance

During this study, no financial or spiritual support was received neither from any pharmaceutical company that has a direct connection with the research subject, nor from a company that provides or produces medical instruments and materials which may negatively affect the evaluation process of this study.

Conflict of Interest

No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.

Authorship Contributions

Idea/Concept: Hacer Fulya Üçem; **Design:** Hacer Fulya Üçem; **Control/Supervision:** Ziver Ergün Yücel; **Data Collection and/or Processing:** Hacer Fulya Üçem; **Analysis and/or Interpretation:** Hacer Fulya Üçem; **Literature Review:** Hacer Fulya Üçem; **Writing the Article:** Hacer Fulya Üçem; **Critical Review:** Ziver Ergün Yücel; **References and Fundings:** Hacer Fulya Üçem.

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