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# Comparative evaluation of the breaking strength of a simple mobile mandibular advancement splint

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SUMMARY Mandibular advancement splints (MASs) are used to advance the mandible forward in patients with sleep-disordered breathing. The conventional rigid MAS restricts the movement of the mandible, and this immobility sometimes produces discomfort, including temporomandibular disorders. A simple method for fabricating a mobile MAS was devised, using a connector made from a polyethylene toothed belt, with the intention of making the MAS more comfortable.

The experimental connector is easily constructed, inexpensive, and small enough for use as an intraoral MAS. To evaluate durability, the axial and diagonal tensile breaking strengths of the MAS, using high- or low-density polyethylene (HDPE or LDPE) lateral toothed belts, were compared with those of a conventional mobile MAS (Silensor). The values were compared by factorial analysis of variances and *post hoc* Scheffe's *S* multiple comparison intervals, with the value of statistical significance set at alpha = 0.05. In addition, the experimental LDPE connectors were clinically tested in 30 patients (23 males and 7 females aged 19–71 years) and evaluated.

Compared with the Silensor, the experimental MAS exhibited sufficient breaking strength, especially when a diagonal tensile load was applied to mimic mandibular lateral translation. When examining the clinical evaluation between 3 and 4 months after insertion, no damage or failure was observed.

The experimental connecting system may have clinical applications. To make the connector stronger for clinical use, HDPE should be used.

## Introduction

Snoring and obstructive sleep apnoea (OSA) result from collapse of the upper airway during sleep due to loss of muscle tone and anatomical factors. Bringing the mandible forward advances the tongue and thereby enlarges the retroglossal airway, reducing the tendency to collapse. The mandibular advancement splint (MAS) is now increasingly used for snoring and mild OSA as a possible alternative treatment to nasal continuous positive airway pressure (Johal and Battagel, 1999; Robertson, 2000; Skinner *et al.*, 2002; Tan *et al.*, 2002; Ng *et al.*, 2003; Gagnon *et al.*, 2004; Rose *et al.*, 2004; Izci *et al.*, 2005; Johal *et al.*, 2005a,b; Bates and McDonald, 2006). The efficacy of the MAS is thought to be related to its design (Lamont *et al.*, 1998).

The MAS generally takes the form of a monobloc, which is simple to fabricate and holds the mandible forward. However, the single, rigid MAS restricts mandibular movement and this immobility sometimes produces discomfort, including temporomandibular disorders (Bondemark, 1999; Robertson *et al.*, 2003). The MAS is constructed as a two-unit assembly joined by a movable connection that holds the mandible and the maxilla separately (Tan *et al.*, 2002). Commercial connectors that allow the mandible some freedom of movement are, however, often bulky, expensive, and difficult to fabricate.

In the current study, a simple method for the construction of the mobile MAS was investigated. The mobility of the MAS was achieved using a connector made of a polyethylene toothed belt, which is easily obtainable, inexpensive, and sufficiently small for internal use. The resistances to tensile strength of the experimental system and of a conventional mobile MAS system were compared.

## Materials and methods

### *Mobile MAS system*

The mobile MAS system comprised two lateral connectors and individual customized oral appliances for both the maxilla and the mandible. The experimental connector comprised a polyethylene toothed belt and two acrylic caps (Figure 1). Figure 2 shows the completed mobile MAS with the experimental connectors.

High-density polyethylene (HDPE; Hi-Zex 5100E, Prime Polymer, Tokyo, Japan) and low-density polyethylene (LDPE; Petrothene, Tosoh Corp., Tokyo, Japan) toothed belts, 4.5 mm wide and 1.5 mm high, were assessed. For the cap, an acrylic disk with a diameter of 125 mm was prepared from an extruded 1.00 mm thick acrylic sheet (Comoglas, Kuraray Co. Ltd, Okayama, Japan) and acrylic resin moulds were formed using an HDPE belt with a length of 10.0 mm in a pressure-moulding machine

(Mini-Star, Scheu-Dental GmbH, Iserlohm, Germany), trimmed, and halved to achieve a cap with a length of 4.5 mm. For the individual customized oral appliances, thermoplastic polycarbonate (Imprelon 'S', Scheu-Dental GmbH) and heat-polymerizing acrylic resin (Palapress Vario, Heraeus Kulzer GmbH, Wehrheim, Germany) were used.

As a control, a conventional mobile MAS system (Silensor, Erkodent, Pfalzgrafenweiler, Germany) was selected. In this system, an exclusive cellulose acetobutyrate foil (Erkodur, Erkodent) was used for individual customized oral appliances. Information on the connector and oral appliances is shown in Table 1.

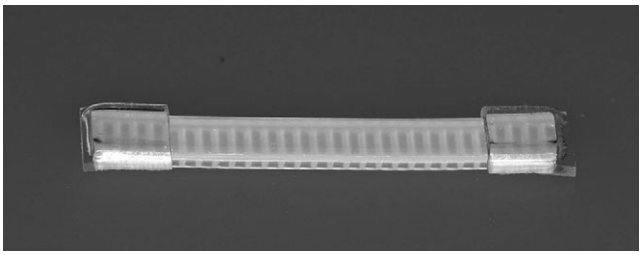

**Figure 1** The experimental connector comprising a polyethylene toothed belt and acrylic caps.

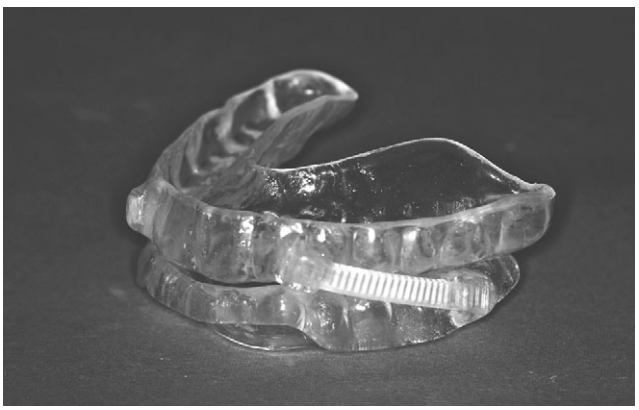

**Figure 2** An example of a complete experimental mandibular advancement splint.

*Breaking test*

A total of 56 plates with dimensions of 15.0 × 30.0 × 2.0 mm were prepared from thermoplastic polycarbonate and heat-polymerizing acrylic resin. Before bonding, dichloromethane (PC Adhesive, Dentsply-Sankin K.K, Tokyo, Japan) and ethyl acetate (Tokuyama Rebase II Adhesive, Tokuyama Dental Corp., Tokyo, Japan) were applied to the polycarbonate and acrylic resin corresponding to a 4.5 × 4.5 mm bonding area, 5.0 mm from the edge of the plate.

The plates were then divided into two equal groups: the first to be used with HDPE toothed belt connectors and the second with LDPE. Both ends of belts were fixed on the primed bonding areas of two plates using auto-polymerizing acrylic resin (Unifast II, G-C Corp., Tokyo, Japan) and the acrylic caps were treated with ethyl acetate (Tokuyama Rebase II Adhesive).

Each Silensor connector was fixed to two cellulose acetobutyrate plates according to the manufacturer's instruction. A total of 14 specimens comprising a connector and two copolyester plates were prepared as the controls.

To evaluate breaking strength, a tensile breaking test was performed. The specimens ($n$ = 14) were divided into two groups of seven; the first underwent axial tensile loading representing retractive movement of the mandible from the protrusive position, while in the second a diagonal tensile loading representing lateral movement of the mandible was carried out. Figure 3 shows a schematic representation of the breaking test for each system.

A universal testing machine (AGS-10kNG, Shimadzu, Kyoto, Japan) was used to determine the maximum breaking load of each specimen. The tensile stress was loaded at a crosshead speed of 25 mm/minute and the load at fracture was recorded as the breaking strength. After testing, the fracture mode was evaluated.

*Statistical analysis*

The breaking strength for each condition ($n$ = 7) was primarily analysed using the Levene test for evaluation of equality of variance. Two-way analysis of variance (ANOVA) and Scheffe's *post hoc* test were then performed with the value of significance set at alpha = 0.05. All analyses were

**Table 1** Information on the connector and oral appliance.

| Material | Abbreviation | Lot no. | Manufacturer | Composition |
|---|---|---|---|---|
| Connector | | | | |
| Hi-Zex 5100E | HDPE | 180228 | Prime Polymer | High-density polyethylene |
| Petrothene | LDPE | 180228 | Tosoh Corp. | Low-density polyethylene |
| Silensor | SLSR | 20705 | Erkodent | Polyoxymethylene copolymer |
| Individual oral appliance | | | | |
| Imprelon 'S' | PC | 0806A | Scheu-Dental GmbH | Polycarbonate |
| Palapress Vario | AR | 10872 | Heraeus Kulzer GmbH | Heat-polymerizing acrylic resin |
| Erkodur | CA | 10465 | Erkodent | Cellulose acetobutyrate |

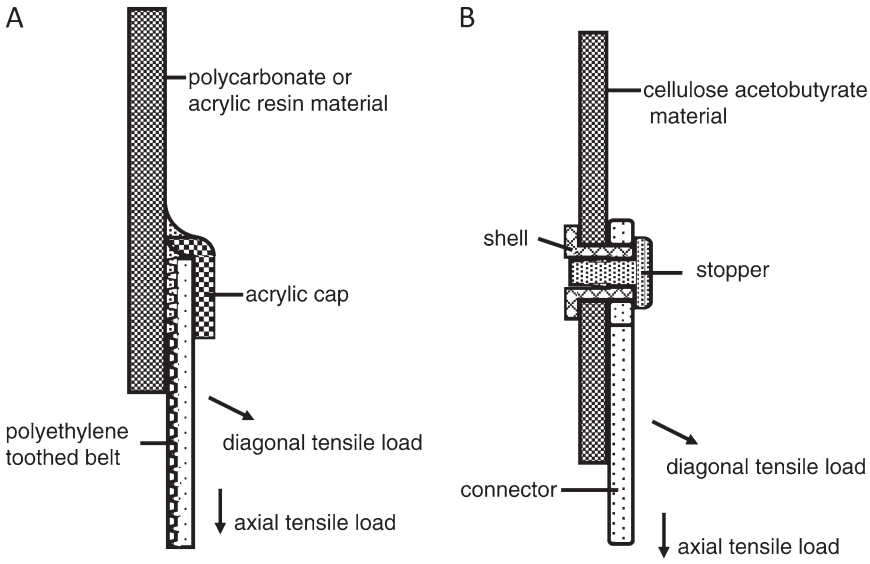


**Figure 3** Schematic representation of the breaking test. (A) Experimental mandibular advancement splint. (B) Silensor.

carried out using the Statistical Package for Social Sciences 12.0J for Windows (SPSS Japan Inc., Tokyo, Japan).

*Clinical trial*

Thirty patients (23 males and 7 females), aged 19–71 years (mean age 51.9 years), who underwent only mandibular advancement with the experimental connectors at the Department of Oral and Maxillofacial Surgery, Nagasaki University Hospital of Medicine and Dentistry, in the years 2003–2008 were studied prospectively. All patients gave written consent for participation. The clinical protocol was approved by the Ethical Committee for Clinical Practice of the Nagasaki University Hospital of Medicine and Dentistry (Approval Nos 0516 and 0843).

The individual customized oral maxillary appliance was fabricated with polycarbonate and that for mandible with acrylic resin. After trial fitting of the device, the patient was instructed to protrude the mandible to an edge-to-edge position. The occlusal surface of the device was adjusted so that the interincisal opening was from 12 to 15 mm (Knudson *et al.*, 1992), and the occlusal relationship was registered using impression material. The LDPE connectors were then fixed between the maxillary canines and mandibular molar regions.

The condition of the MAS, including the connectors, was evaluated between 1 and 2 weeks and between 3 and 4 months after insertion. The analysis was carried out by one author (SY).

## Results

The Levene test run on the breaking strength for each condition did not show homoscedasticity. The results of the two-way factorial ANOVA are shown in Table 2. The two factors studied (the connector–oral appliance material and the direction of load) and their interactions were statistically significant ($P < 0.05$). Figure 4 shows the breaking strength (N) and the statistical groupings for each material and direction. The Silensor constructed of cellulose acetobutyrate exhibited the greatest breaking strength for axial tensile load and the lowest breaking strength for diagonal load.

Table 3 shows the mode of failure observed after the breaking test. With axial tensile stress, all the MAS systems, including the Silensor, showed extension and tearing of the connector belt. With a diagonal tensile load, most of the MAS systems with an HDPE connector showed fracture of the acrylic cap, while most of those with a LDPE connector showed extension and tearing of the belt. In all cases, the Silensor showed fracture of the stopper (Figure 2) after the diagonal breaking test.

One patient (3.3 per cent) dropped out of the clinical trials. Among the 29 MASs assessed, three were damaged within 2 weeks; one due to breakage of the belt and two due to ‘pulling out’ of the connector belts. In contrast to the breaking test results, no acrylic cap fractured and no connector belt was extended. The three MASs were not re-fabricated but immediately repaired. No damage or failure was observed between 3 and 4 months after insertion even in repaired MAS.

## Discussion

A mobile MAS system generally comprises upper and lower elements with two lateral connectors and allows mouth opening without loss of mandibular advancement. Given that a MAS that immobilizes the mandible is more likely to

**Table 2** Breaking test results of two-way analysis of variance.

| Source of variation | df | Sum of squares | Mean square | *F* value | *P* |
|---|---|---|---|---|---|
| Condition (combination of connector and oral appliance materials) | 4 | 10612.551 | 2653.128 | 143.986 | 0.0001 |
| Direction (axial or diagonal tensile load) | 1 | 7327.749 | 7327.749 | 397.679 | 0.0001 |
| Condition/direction | 4 | 21916.957 | 5479.239 | 297.360 | 0.0001 |

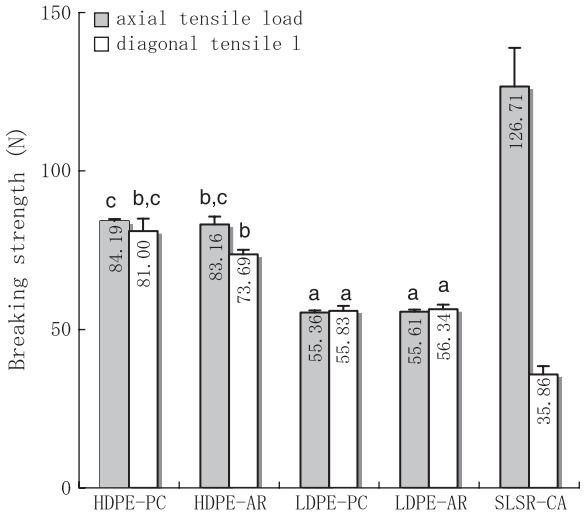


**Figure 4** Results of the breaking test. Identical letters indicate that the values are not statistically different ($P>0.05$). PC, polycarbonate; AR, acrylic resin; CA, cellulose acetobutyrate; HDPE, high-density polyethylene; LDPE, low-density polyethylene; SLSR, Silensor.

cause temporomandibular disorders/arthralgia (Bondemark, 1999; Robertson *et al.*, 2003), a mobile MAS is likely to be more comfortable for long-term clinical use.

In the current study, a polyethylene toothed belt was employed as a connector in a trial mobile MAS that permits the mandible some freedom of movement.

In view of the finding that the breaking test results for the acrylic resin and polycarbonate materials were not very different from each other, any combination of acrylic resin and polycarbonate could be used for individual customized devices. However, the material used for oral appliances should always be selected with consideration of its clinical applicability.

Toothed belts are easily obtainable, inexpensive, and sufficiently small for the fabrication of an intraoral MAS. Although polyethylene cannot be chemically bonded to self-polymerizing acrylic resin [poly(methyl methacrylate) in the current study], the teeth of the belt played a role as an undercut in the resin and strongly resisted a tensile load representing the force produced when the mandible fixed in the protrusive position moves to the former or a lateral position.

**Table 3** Test failure mode grouping after breaking.

| Condition | Direction of tensile load | A | B | C |
|---|---|---|---|---|
| HDPE–PC | Axial | 7 | 0 | 0 |
| | Diagonal | 1 | 6 | 0 |
| HDPE–AR | Axial | 7 | 0 | 0 |
| | Diagonal | 0 | 7 | 0 |
| LDPE–PC | Axial | 7 | 0 | 0 |
| | Diagonal | 7 | 0 | 0 |
| LDPE–AR | Axial | 7 | 0 | 0 |
| | Diagonal | 6 | 1 | 0 |
| SLSR–CA | Axial | 7 | 0 | 0 |
| | Diagonal | 0 | 0 | 7 |

A, extension and tear of the belt; B, fracture of the acrylic cap; C, fracture of the stopper; HDPE, high-density polyethylene; PC, polycarbonate; AR, acrylic resin; LDPE, low-density polyethylene; CA, cellulose acetobutyrate; SLSR, Silensor.

During axial loading the strength of trial MAS system was inferior to that of the Silensor. However, when excessive diagonal stress was applied, the trial MAS was significantly stronger than the conventional Silensor. The fragility of the Silensor system has been reported (Tan *et al.*, 2002), even though its efficacy is widely recognized. Thus, the results indicate that the Silensor may break during clinical use when excessive diagonal stress is loaded. To improve the strength of the MAS, it is necessary to increase its endurance to excessive diagonal stress. In this respect, this trial MAS system may be suitable for clinical use.

The observed fracture mode of the trial system (Table 3) shows that the connector (belt or cap) was always damaged by the breaking load irrespective of the direction of load and the density of polyethylene, meaning that an individual customized appliance would always remain intact allowing easy repair of the MAS. Even if the trial MAS was broken by excessive stress, the repair would be easily achievable by changing the two connectors. Although there are many devices that can function as a mobile MAS, the use of a toothed belt as a connector may be beneficial in terms of laboratory time as well as cost reduction.

The sturdiness and safety of any connector in an MAS is of importance. Polyethylene was used in the present study because its sturdiness and safety as a biomaterial has been reported previously (Cooksey, 2005). However, as shown in Figure 4, the breaking strength of the LDPE was inferior to that of HDPE (Manero *et al.*, 2003), regardless of the direction of the load. The HDPE, which has greater intermolecular forces, tensile strength, and hardness and can withstand somewhat higher temperatures than LDPE, is therefore recommended to increase the strength of the MAS.

The utility of the MAS system was also confirmed by the results of the clinical trial. Although three failures occurred within a short period (2 weeks), the failure modes were

different from those found experimentally. The major cause of the failures might be technical errors in the fabrication procedures of the MAS, as pulling out did not occur in the experimental breaking tests. In particular, the connector should be carefully bonded for satisfactory durability of the MAS.

The trial mobile MAS system may possibly have clinical application. Nevertheless, its performance in long-term clinical use remains to be determined.

## Conclusions

Within the limitations of this study, the following conclusions were drawn:

1. The breaking strength of the MAS was influenced by the materials of the connector and oral appliance and by the direction of the tensile load.
2. Compared with the conventional Silensor system, the experimental MAS with a toothed belt and acrylic cap exhibited sufficient breaking strength when a diagonal tensile load was applied to mimic mandibular lateral translation.
3. To make the experimental connector stronger for clinical use, a HDPE toothed belt should be selected.

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