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ORIGINAL ARTICLE

A novel mouthpiece prevents bite injuries caused by intraoperative transcranial electric motor-evoked potential monitoring

Kyoko Oshita[1] · Noboru Saeki[1] · Takayasu Kubo[2] · Hitoshi Abekura[2] · Nobuhiro Tanaka[3] · Masashi Kawamoto[1]

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Abstract
Purpose Intraoperative transcranial motor-evoked potential monitoring causes contraction of the masseter muscles, which may cause injuries to the oral cavity and damage to the orotracheal tube. We developed a mouthpiece made from vinyl-silicone impression material to prevent these injuries. The purpose of this study was to examine its efficacy and safety.
Methods Twenty-two patients undergoing spinal surgery under transcranial motor-evoked potential monitoring were fitted with bespoke vinyl-silicone mouthpieces by dentists before surgery. On induction of general anesthesia and orotracheal intubation, the mouthpiece was attached to the upper and lower dental arches. A lateral cervical X-ray was taken at the end of surgery to examine the condition of the orotracheal tube. The incidence of endotracheal tube deformation was compared with an historic control group of 20 patients in whom a conventional gauze bite block had been previously used before induction of the mouthpiece. The oral cavity was examined by a dentist the day before surgery and 3 days postoperatively, and intraoral injuries were recorded.
Results No endotracheal tube deformation was found in 22 patients fitted with the new mouthpiece. The incidence of tube deformation (none of 22 patients, 0 %) was significantly lower than in those who had been fitted with the gauze bite block (9 of 20 patients, 45.0 %; $p < 0.001$). Application of the mouthpiece resulted in no tongue or tooth injuries.
Conclusion A novel mouthpiece reduced the incidence of damage to the endotracheal tube caused by intraoperative transcranial motor-evoked potential monitoring.

Keywords Mouthpiece · Bite injuries · Tc-MEP monitoring

✉ Kyoko Oshita
oshitak@hiroshima-u.ac.jp

[1] Department of Anesthesiology and Critical Care, Graduate School of Biomedical and Health Sciences, Hiroshima University, 1-2-3 Kasumi Minami-ku, Hiroshima, Japan

[2] Department of Advanced Prosthodontics, Graduate School of Biomedical and Health Sciences, Hiroshima University, Hiroshima, Japan

[3] Department of Orthopedic Surgery, Graduate School of Biomedical and Health Sciences, Hiroshima University, Hiroshima, Japan

Introduction

Transcranial motor-evoked potential (Tc-MEP) monitoring is a useful means of evaluating corticospinal tract function during surgery, and may be undertaken during spinal surgery to prevent iatrogenic nerve injury [1–3]. The monitoring of Tc-MEPs involves recording neuroelectric responses elicited in the peripheral muscles by repetitive pulse stimulation of the brain, but may result in bite injuries to the teeth, tongue, and endotracheal tube due to enforced masseter contraction [2, 4–6]. Bite injuries are rare, but may cause a potentially life-threatening airway emergency if tongue swelling and/or rupture of the orotracheal tube occurs [4, 7, 8]. Conventionally, a bite block is used to prevent such injuries, but most reported bite injuries sustained during Tc-MEP monitoring occurred when a bite block was in situ. Harder bite blocks increase the risk of tooth dislocation and tongue ulceration; consequently a gauze bite block is used for patients undergoing intraoperative Tc-MEP monitoring in our institution. It has been

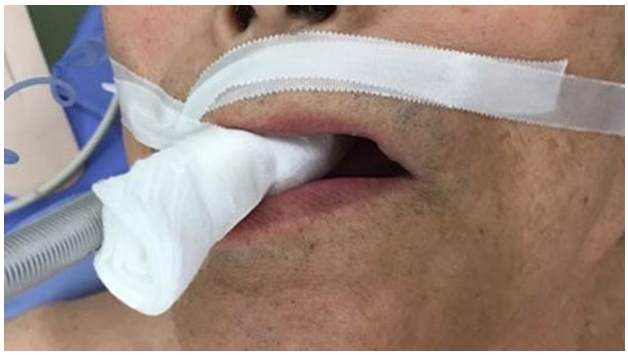

Fig. 1 A gauze bite block in situ after orotracheal intubation

reported that endotracheal tube deformation occurs in 50 % of patients when a gauze bite block is used [9]. We consider that neither hard nor soft gauze bite blocks are suitable when intraoperative Tc-MEP monitoring is undertaken, for a number of reasons. First, conventional bite blocks attach to the tip of the teeth, where Tc-MEP stimulation-induced muscle contractions converge to exert substantial force, which might be sufficient to provoke tooth dislocation (with a hard bite block) or deformation of the endotracheal tube (with a soft bite block). Second, bite blocks cannot prevent the tongue from protruding between the teeth when the patient is prone, making the tongue susceptible to a bite injury. Third, conventional or bar-shaped bite blocks may cause tongue ulceration due to direct compression. Therefore, we developed a novel mouthpiece designed to address these problems. In this study we compared its safety and ability to prevent bite injuries during Tc-MEP monitoring with those of a conventional gauze bite block.

Methods

The study was approved by Hiroshima University Hospital IRB, and written informed consent was obtained from all patients enrolled. The study was registered at UMIN-CTR (under the identifier NC: UMIN000007977; initial release date: May 17, 2012; principal investigator: Dr. Saeki).

As our previous study had found that the endotracheal tube was damaged in half of 20 patients when a gauze bite block was used [9], we judged that it was unethical to randomize patients to a prospective control group in which a gauze bite block was used. Instead, we chose to use these 20 patients as historic controls. The gauze bite block was made by rolling 2 sheets of 25 × 25 cm cellulose polyester gauze (RP cross gauze™, Osaki Medical Corporation, Nagoya, Japan) to the same size as the tube, inserting it between the lower anterior teeth, and fixing it along the endotracheal tube (Fig. 1).

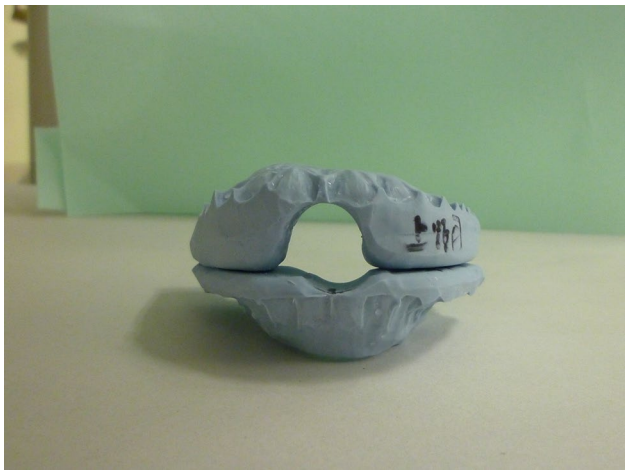

Fig. 2 A mouthpiece that was tailored to the dentition of a participant. The space for the endotracheal tube can be seen in the center

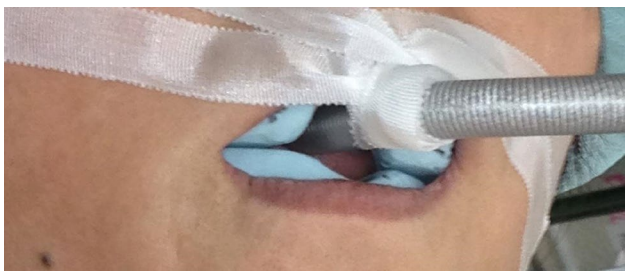

Fig. 3 A mouthpiece in situ after orotracheal intubation

With an effect size of 0.5, an alpha error of 0.05, and a power (1 − beta) of 0.80, we calculated that at least 32 subjects were needed for the study. Consequently, we enrolled 22 consecutive patients scheduled for spinal surgery with Tc-MEP monitoring using the new mouthpiece to match the number of historic controls, so as to achieve the necessary statistical power and account for any patients who do not complete the study.

On the day before surgery, a mouthpiece of vinyl-silicone impression material (Exzaine Putty Type™, GC Corp., Tokyo, Japan) was made for each patient by a dentist. Vinyl-silicone impression material is generally used in odontotherapy; it can record the dentition safely in a short time. To secure the space of an endotracheal tube, the anterior site of the mouthpiece was designed to be thick. First, the malleable vinyl-silicone impression material was attached to the upper dental arcade using a tray that was designed to allow room for an endotracheal tube to pass through the center of the mouthpiece. After the vinyl-silicone had set, it was removed from the mouth and trimmed so that it did not compress or scratch the gums or oral mucosa. The lower part was then constructed in the

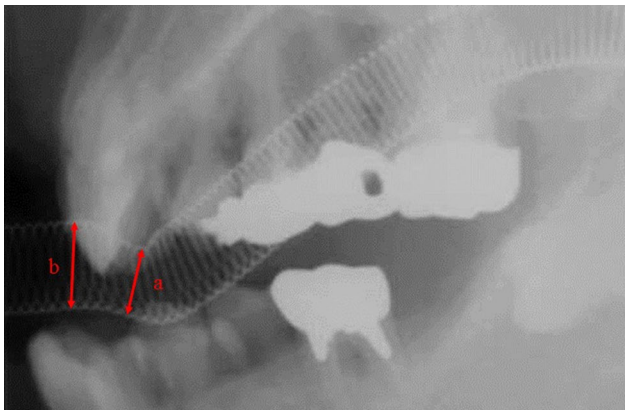

Fig. 4 Representative photo of tube deformity. The natural inner diameter (*b*) and the inner diameter of the most stenosed part (*a*) were measured, and the magnitude of tube deformation was assessed as the ratio of *a* to *b*. The classification of tube deformation was defined as: class I >90 %, class II 70–90 %, class III 50–70 %, class IV <50 %

Table 1 Participants' demographic and clinical characteristics

	Gauze bite block	Mouthpiece	*p* value
Number of patients	20	22	
Age (years)	53.7 ± 13.0	62.3 ± 14.0	0.036
Sex (male/female)	9/11	7/15	0.527
Duration of surgery (min)	159.8 ± 84.6	184.7 ± 94.6	0.375
Duration of anesthesia (min)	243.3 ± 93.4	283.2 ± 97.7	0.184
Surgical level			
Cervical	0	3	
Thoracic	10	9	
Lumbar	5	6	

Data are presented as the number or the mean (± standard deviation)

same way. When both parts were inserted into the mouth, there was sufficient space for an endotracheal tube to pass between them (Fig. 2).

Anesthesia was administered according to a standardized protocol. Anesthesia was induced with intravenous propofol and a remifentanil infusion. After administration of rocuronium, the patient's trachea was intubated with a Curved Reinforced Murphy Cuffed endotracheal tube (Teleflex Medical Japan, Tokyo, Japan). Anesthesia was maintained with a target-controlled infusion of propofol and remifentanil; no further muscle relaxants were administered. The two parts of the mouthpiece were inserted after intubation, and the endotracheal tube was secured in the central gap between the upper and lower parts (Fig. 3). Surgery was perfomed with the patient in the prone position.

Transcranial electrical stimulation was administered by a train of five pulses with an interval of 2 ms using a multipulse stimulator (D-185; Digitimer, Welwyn Garden City, UK). Stimulation electrodes were placed at C3 and C4 of the International 10–20 system for electrode placement. Myogenic motor-evoked potentials were recorded at the deltoid, biceps brachii, triceps brachii, abductor pollicis brevis, and anterior tibial muscles.

Table 2 Data on the incidence of deformation of the endotracheal tube

	Gauze bite block	Mouthpiece	*p* value
Number of patients	20	22	
Endotracheal tube deformation	9 (45 %)	0 (0 %)	<0.001
Class I	11	22	
Class II	8	0	
Class III	1	0	
Class IV	0	0	

Before extubation, a lateral cervical X-ray was taken to evaluate the extent of any deformation of the endotracheal tube in situ. The inner diameters of the most stenosed part and the natural part of the tube were measured on cervical X-ray. The magnitude of tube deformity was graded according to the stenosis, which was derived from the calculation of $(a/b)\times 100$ %, as represented in Fig. 4 (class I >90 %, class II 70–90 %, class III 50–70 %, class IV <50 %). Significant endotracheal tube deformation was defined as class II, III, or IV. To detect adverse effects caused by the mouthpiece, the teeth, tongue, oral mucosa, and lips were examined and the mouth opening was measured three times: on the day before and 3 days after surgery by dentists, and just after extubation by anesthesiologists. The incidence of deformation of the endotracheal tube was compared with that of the historic gauze bite block group, whose data were obtained from clinical and research records [9].

Data were compared using the chi-squared test and the Mann–Whitney *U* test for nonparametric data. Data are presented as the mean ± standard deviation. Data processing and statistical analysis were performed using IBM SSPS Statistics 22 (IBM Japan, Tokyo, Japan). Statistical significance was defined as a p value <0.05.

Results

The demographic and clinical characteristics of the patients are shown in Table 1. There were no significant differences between the two groups in terms of male/female ratio or duration of surgery or anesthesia. The average age of the mouthpiece group was significantly higher than that of the gauze group. Tube deformation was found in 9 patients in the gauze bite block group (8 class II, 1 class III), whereas significant tube deformation was not observed in the

mouthpiece group. The incidence of deformation of the endotracheal tube was significantly lower in the mouthpiece group (Table 2). Nine patients were found to have a loose tooth preoperatively. There were two patients with class I tooth mobility, five with class II tooth mobility and two with class III tooth mobility [10]. Postoperative dental and oral examinations identified two patients in the mouthpiece group with slight postoperative oral mucosal erosion (lip abrasion and aphthae) that resolved without treatment. No tongue or tooth injuries were found. Exacerbation of the movement of loose teeth was not assessed postoperatively. There was no significant difference between the mean unassisted maximum mouth opening before surgery and that after surgery (47.0 ± 4.4 mm compared with 42.0 ± 7.0 mm, respectively; $p = 0.206$). None of the patients had postoperative temporomandibular joint pain or dysfunction.

Discussion

The monitoring of Tc-MEPs is a sensitive means of detecting corticospinal tract injury during surgery compared with other clinical brain stimulation techniques [2, 3, 11]. There have been no reports of seizure, cardiac arrythmia, scalp burn, intraoperative awareness or postoperative headache caused by Tc-MEP monitoring. Indeed, the most common major adverse event caused by Tc-MEP monitoring is bite injury. The manufacturer, Digitimer Ltd., provides warnings of the potential for bite injuries to its customers. The incidence of bite injuries caused by Tc-MEP monitoring has been reported to be between 0.14 and 0.63 % in studies of more than 10,000 patients who had undergone spine surgery [2, 4, 11]. In our clinical practice, we have experienced patients with two severe bite injuries causing tongue lacerations and tooth dislocation requiring surgical repair [9]. Most bite injuries are not severe and resolve without the need for treatment, but some have resulted in distressing complications such as tongue lacerations requiring suturing and extensive tongue swelling that delayed tracheal extubation [3, 6, 12]. A potentially catastrophic airway emergency caused by rupture of the orotracheal tube requiring emergency re-intubation has been reported in two patients [7, 13]. Promptly re-intubating the trachea in a patient undergoing surgery in the prone position is likely to be very challenging.

Soft or hard bite blocks and plastic airways have been recommended as a means of preventing bite injuries during Tc-MEP monitoring [2]; however, Tamkus and colleagues [4] reported an incidence of severe oral injury of 0.14 % despite the presence of some form of bite block in situ in most patients. Inadvertent displacement of a bite block may also occur in the prone position, or during electrical stimulation. Moreover, even if a bite block is positioned correctly, the tongue may still protrude between the teeth in the prone position. A means of retaining the tongue behind the teeth is needed throughout surgery. Access to the mouth and airway is particularly difficult for the anesthesiologist during cervical spine surgery, so a device to prevent the tongue protruding between the teeth is desirable.

There have previously been reports that devices used during dental treatment can be used to prevent bite injuries during Tc-MEP monitoring. Mahmoud and colleagues [8] placed dental guards on the maxillary and mandibular dental lines to cover sharp teeth, and placed a soft bite block between the dental guards after experiencing a patient with postoperative tongue necrosis. However, these investigators have not established the efficacy and safety of their recommended strategy in a formal study. Deiner and colleagues [6] reported several patients with lingual hematoma when rolled gauze bite blocks were used, and proposed using a commercially available soft square bite block used in dental care to afford additional protection from compression of the posterior portion of the tongue between the molars. They also reported that no lingual hematomas occurred after they began to use what they described as a "soft bite block." The incidence of endotracheal tube deformation was not examined in either study.

Our custom-made vinyl-silicone mouthpiece substantially reduced the incidence of endotracheal tube deformation caused by masseter contraction. Comprehensive examination by dentists detected only very few minor oral complications. A bespoke vinyl-silicone mouthpiece has two main advantages over a bite block. First, it completely covers both dental arches, receiving all the masticatory pressure exerted by the masseters and so preventing injury to the teeth. Second, leaving room for the endotracheal tube means that external forces upon it are minimized. In our opinion, these advantages make our mouthpiece superior to other devices, including ready-made dental protectors.

We chose the incidence of endotracheal tube deformation as the primary outcome measure of this study. Our previous study found that the endotracheal tube had been deformed in 50 % of patients in which Tc-MEP monitoring was used. The high incidence of tube deformation confers our study with substantial statistical power. A stainless-steel-reinforced endotracheal tube is generally used for airway management when the patient is anesthetized in the prone position. It is resistant to torsion and kinking, but does not return to its original shape if it becomes occluded, and therefore may cause airway stenosis or obstruction. Our novel vinyl-silicone mouthpiece reduced the incidence of endotracheal tube damage from 50.0 % to 4.5 % during Tc-MEP monitoring, which we judge to be a statistically and clinically significant difference.

Our novel mouthpiece showed some disadvantages. It requires the cooperation of dentist colleagues; a bespoke

fitting requires their time and assistance, and consequently increases cost. All the mouthpieces used in this study were made by two dentists (T.K. and H.A.); the lack of complications with the mouthpieces used in this study may reflect their expertise—it might be more difficult to maintain the quality of the bespoke mouthpieces if they were in more widespread use and made by a larger number of dental practitioners. Our study also had some limitations. We used historic patients in which a gauze bite block had been used as a control group. Although this means that our study was not randomized, we believe it would have been unethical to undertake such a study prospectively, a decision justified by our findings. Nonetheless, as the protocol of our previous study did not include a detailed examination by a dentist, we cannot comment on the incidence of intraoral injuries in the historic controls, and thus cannot make a comparison with our novel mouthpiece. Nevertheless, we encountered no serious adverse events with the vinyl-silicone mouthpiece design.

Conclusions

A bespoke vinyl-silicone mouthpiece substantially reduced the incidence of damage to the orotracheal tube caused by intraoperative Tc-MEP monitoring during spine surgery.

References

1. Wang AC, Than KD, Etame AB, La Marca F, Park P. Impact of anesthesia on transcranial electric motor evoked potential monitoring during spine surgery: a review of the literature. Neurosurg Focus. 2009;27:E7.
2. MacDonald DB. Safety of intraoperative transcranial electrical stimulation motor evoked potential monitoring. J Clin Neurophysiol. 2002;19:416–29.
3. Lieberman JA, Lyon R, Feiner J, Hu SS, Berven SH. The efficacy of motor evoked potentials in fixed sagittal imbalance deformity correction surgery. Spine. 2008;33:E414–24.
4. Tamkus A, Rice K. The incidence of bite injuries associated with transcranial motor-evoked potential monitoring. Anesth Analg. 2012;115:663–7.
5. Davis SF, Kalarickal P, Strickland T. A report of two cases of lip and tongue bite injury associated with transcranial motor evoked potentials. Am J Electroneurodiagnostic Technol. 2010;50:313–20.
6. Deiner SG, Osborn IP. Prevention of airway injury during spine surgery: rethinking bite blocks. J Neurosurg Anesthesiol. 2009;21:68–9.
7. Duma A, Novak K, Schramm W. Tube-in-tube emergency airway management after a bitten endotracheal tube caused by repetitive transcranial electrical stimulation during spinal cord surgery. Anesthesiology. 2009;111:1155–7.
8. Mahmoud M, Spaeth J, Sadhasivam S. Protection of tongue from injuries during transcranial motor-evoked potential monitoring. Paediatr Anaesth. 2008;18:902–3.
9. Kuwahara Y, Taguchi S, Kuroda M, Kawamoto M. Adverse events during transcranial muscle evoked potential monitoring. Masui. 2011;60:692–6.
10. Miller PD Jr, McEntire ML, Marlow NM, Gellin RG. An evidenced-based scoring index to determine the periodontal prognosis on molars. J Periodontol. 2014;85:214–25.
11. Schwartz DM, Sestokas AK, Dormans JP, Vaccaro AR, Hilibrand AS, Flynn JM, Li PM, Shah SA, Welch W, Drummond DS, Albert TJ. Transcranial electric motor evoked potential monitoring during spine surgery: is it safe? Spine. 2011;36:1046–9.
12. Davis SF, Altstadt T, Flores R, Kaye A, Oremus G. Report of seizure following intraoperative monitoring of transcranial motor evoked potentials. Ochsner J. 2013;13:558–60.
13. Macdonald DB. Intraoperative motor evoked potential monitoring: overview and update. J Clin Monit Comput. 2006;20:347–77.