



Novel mandibular advancement bite block with supplemental oxygen to both nasal and oral cavity improves oxygenation during esophagogastroduodenoscopy: a bench comparison

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Abstract

Drug-induced respiratory depression is a major cause of serious adverse events. Adequate oxygenation is very important during sedated esophagogastroduodenoscopy (EGD). Nasal breathing often shifts to oral breathing during open mouth EGD. A mandibular advancement bite block was developed for EGD using computer-assisted design and three-dimensional printing techniques. The mandible is advanced when using this bite block to facilitate airway opening. The device is composed of an oxygen inlet with one opening directed towards the nostril and another opening directed towards the oral cavity. The aim of this bench study was to compare the inspired oxygen concentration (FiO_2) provided by the different nasal cannulas, masks, and bite blocks commonly used in sedated EGD. A manikin head was connected to one side of a two-compartment lung model by a 7.0 mm endotracheal tube with its opening in the nasopharyngeal position. The other compartment was driven by a ventilator to mimic “patient” inspiratory effort. Using this spontaneously breathing lung model, we evaluated five nasal cannulas, two face masks, and four new oral bite blocks at different oxygen flow rates and different mouth opening sizes. The respiratory rate was set at 12/min with a tidal volume of 500 mL and 8/min with a tidal volume of 300 mL. Several Pneufflo resistors of different sizes were used in the mouth of the manikin head to generate different degrees of mouth opening. FiO_2 was evaluated continuously via the endotracheal tube. All parameters were evaluated using a Datex anesthesia monitoring system. The mandibular advancement bite block provided the highest FiO_2 under the same supplemental oxygen flow. The FiO_2 was higher for devices with oxygen flow provided via an oral bite block than that provided via the nasal route. Under the same supplemental oxygen flow, the tidal volume and respiratory rate also played an important role in the FiO_2 . A low respiratory rate with a smaller tidal volume has a relative high FiO_2 . The ratio of nasal to oral breathing played an important role in the FiO_2 under hypoventilation but less role under normal ventilation. Bite blocks deliver a higher FiO_2 during EGD. The ratio of nasal to oral breathing, supplemental oxygen flow, tidal volume, and respiratory rate influenced the FiO_2 in most of the supplemental oxygen devices tested, which are often used for conscious sedation in patients undergoing EGD and colonoscopy.

Keywords Computer assisted design · Esophagogastroduodenoscopy · Mandibular advancement bite block · Oxygen delivery · Three-dimensional printing

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1 Introduction

Supplemental oxygen is frequently administered during esophagogastroduodenoscopy (EGD) to protect the patient from hypoxia caused by drug-induced respiratory depression [1–5]. The higher the alveolar oxygen concentration before a period of hypoventilation, the longer the patient's arterial blood remains saturated. Newer generations of nasal cannulas and oral bite blocks have been designed to deliver oxygen more efficiently. Ninety percent of the flow from normal physiologic breathing via the nasal route shifts to the oral route during sedated EGD [6], so nasal and oral supply of oxygen need both to be considered. Some bite blocks divert oxygen to both the nasal and oral routes. However, devices that maintain airway patency while also delivering an adequate amount of oxygen have not been developed. The efficacy of devices designed for EGD has also not been tested or compared. We describe a novel mandibular advancement (MA) bite block designed and manufactured using a computer-assisted design system and 3D printing [7], respectively, to facilitate opening of the airway and provide oxygenation via both the nasal and oral routes. We also compared the fractional inspired oxygen concentration (FiO_2) delivered by nasal cannulas, face masks, and bite blocks as a function of the oxygen

flow to the device, the patient's minute ventilation, and the percentage of oral vs. nasal breathing.

2 Methods

2.1 Design and development of MA bite block

A prototype MA bite block was designed by scanning a standard dental model (D1000, 3Shape A/S, Copenhagen, Denmark) and drawing a dental arch line (Dental System™ Premium, 3Shape A/S). Mandibular advancement (or prognathism) was defined as advancement of the lower central incisor beyond an imaginary line in the coronal plane of the upper central incisor. A model was built with the aid of computer-assisted design (Creo Parametric 2.0, PTC, Needham, MA, USA) and 3D printing (Dimension 1200es, Stratasys, Eden Prairie, MN, USA) with acrylonitrile butadiene styrene. The material was tested for in vitro cytotoxicity via MTT method (Ultra Trace & Industrial Safety Hygiene, SGS Taiwan Ltd., New Taipei City, Taiwan) and thus non-toxic. The design flow chart is shown in Fig. 1.

The MA bite block (Fig. 2) was specially designed for use in endoscopic procedures performed via the oral route, such as EGD, bronchoscopy and transesophageal echocardiograms. It comprises an opening for endoscopic entry, and the lower incisor mount is advanced relative to that of the

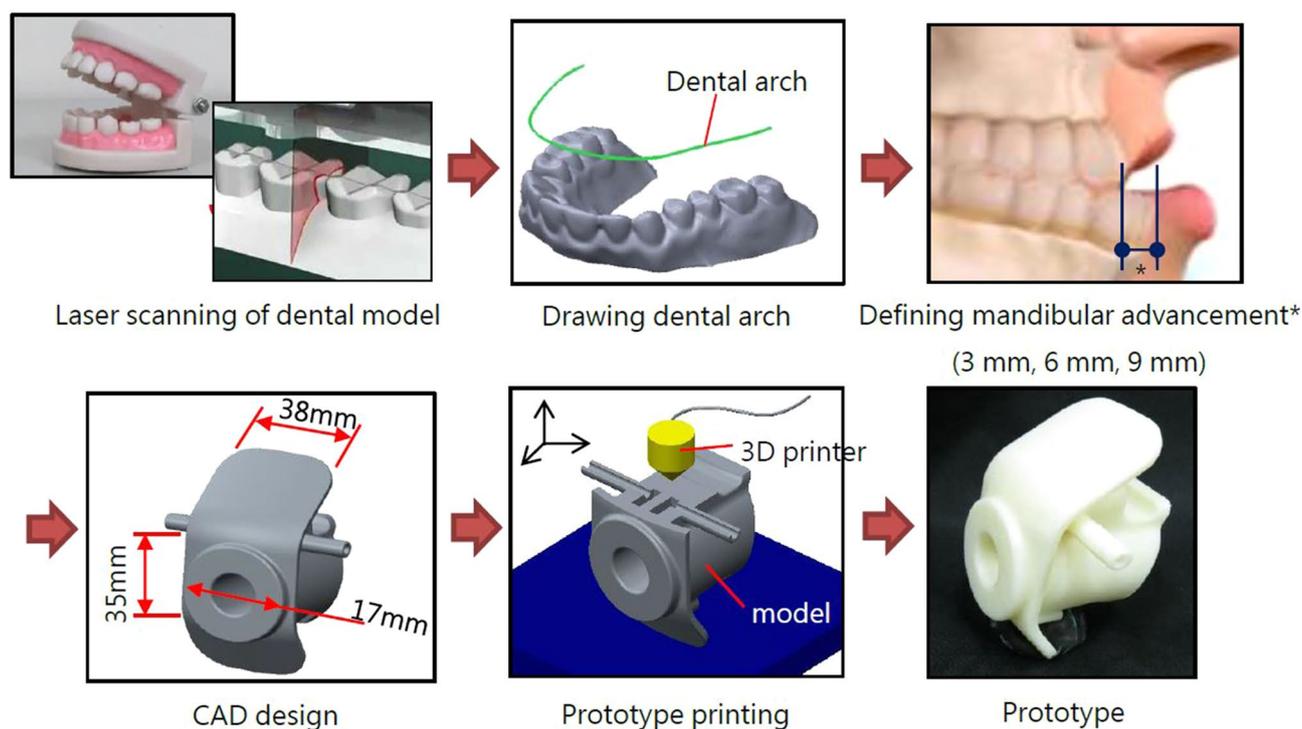


Fig. 1 Flow chart showing the design steps of the mandibular advancement bite block

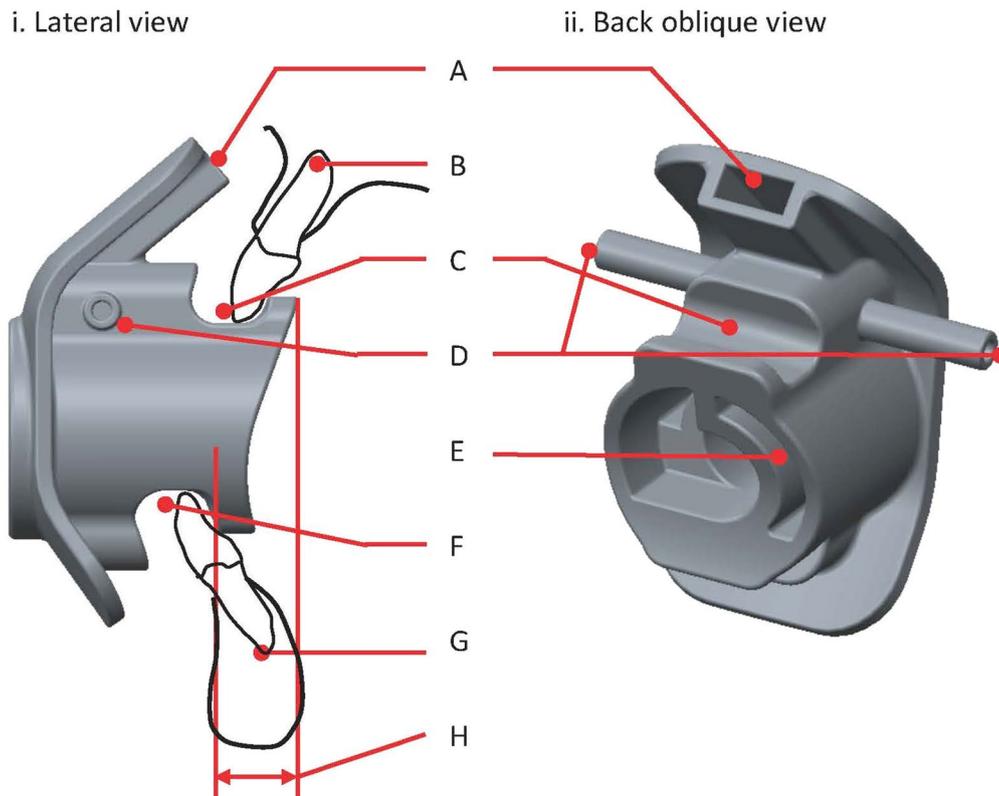


Fig. 2 Diagram of the mandibular advancement bite block. (i) Left, lateral view; (ii) right, back oblique view. (A) Gas channel opening to nostril, (B) upper incisor, (C) groove for upper incisor, (D), connector for oxygen cannula or end tidal carbon dioxide monitor catheter, (E)

gas channel opening to oral cavity, (F) groove for lower incisor, (G) lower incisor, (H) mandibular advancement from coronal plane of the upper incisor (three different degrees, 3, 6, and 9 mm) of mandibular advancement

upper incisor to provide MA for facilitation of maintained upper airway opening during endoscopic examinations. Three different degrees of MA were designed, providing 3, 6, or 9 mm advancement of the mandible from the neutral position. Separate gas supply connectors with double outlets were installed on both sides of the bite block, one directing air flow to and from the nostril and the other to and from the oral cavity. These connectors can act as oxygen supply connectors or end-tidal carbon dioxide sampling connectors, and can supply and receive air flow to and from both the oral and nasal cavity simultaneously.

2.2 Bench study to compare nasal cannulas, masks, and bite blocks for EGD

Five nasal cannulas, two face masks, and four new oral bite blocks purchased from the manufacturers were evaluated (Table 1). The 6 mm MA bite block design was used in this study. Each test device was placed individually on a manikin head (Male Styro Manikin #0831, Hairess Corporation, Crown Point, IN, USA) following the manufacturer's recommendations. An oxygen rotometer (Airgas, Tampa, FL, USA) was used to adjust oxygen flow to the

device at rates of 1, 2, 3, 4, 5, 6, and 10 L/min and was calibrated using a NM3 flowmeter (Respironics NM3, Philips, Guilford, UK). Additional details of study set-up are described in our previous study [8].

The trachea of the manikin head was connected to one side of a two-compartment test lung (Vent Aid TTL; Michigan Instruments, Grand Rapids, MI, USA) using a 7.0 mm endotracheal tube (Mallinckrodt, Covidien, Mansfield, MA, USA) [9–11]. Lung compliance was set to 50 mL/cm H₂O and airway resistance to 8.2 cm H₂O/(L × s). The second chamber of the test lung was connected to a 900C ventilator (Siemens-Elema, Solna, Sweden), and the tidal volume and respiratory rate were set at 500 mL and 12 breaths/min (i.e., normal ventilation) or at 300 mL and 8 breaths/min (hypoventilation). The inspiratory to expiratory ratio was set to 1:2. The two separate chambers of the test lung were physically linked together with a rigid metal strap. When the ventilator delivered a tidal volume to the first chamber, the second chamber rose, drawing in a tidal volume through the trachea of the manikin head, thus simulating a spontaneously breathing patient. Pneu-flo resistors (Vent Aid TTL, 3.3, 5.6, and 7.7 mm sized

Table 1 Main characteristics and manufacturing details for the masks, nasal cannulas, and mouth bite blocks tested in this study

Devices	Type	Manufactures	Country
YX nasal mask II	Nasal mask	Yong-Xu Medical Instrument Co.	Taiwan
Flexicare dual mask	Face mask	Flexicare Medical Limited	Mountain Ash, UK
Hauge airway bite block	Bite block	Penlon	Abingdon, UK
CO25 bite block	Bite block	Encompas Unlimited Inc	FL, USA
Smart CapnoLine Guardian O ₂	Bite block (hybrid)	Oridion	Jerusalem, Israel
Mandibular advancement bite block (6 mm)	Bite block (hybrid)	National Yang-Ming University Biomedical Engineering Laboratory	Taiwan
Adult nasal cannula	Nasal cannula	Flexicare Medical Limited	Mountain Ash, UK
Dual nare nasal cannula	Nasal cannula	Flexicare Medical Limited	Mountain Ash, UK
Smart CapnoLine Plus	Nasal cannula	Oridion	Jerusalem, Israel
Adult divided cannula 4707	Nasal cannula	Salter Labs	Arvin, CA, USA
Oral Trac nasal cannula 4797	Nasal cannula	Salter Labs	Arvin, CA, USA

openings) placed in the mouth of the manikin head were used to simulate three levels of nasal/mouth breathing.

The sampling gas port of a paramagnetic oxygen analyzer (Capnomac, Datex, Helsinki, Finland) was connected to the sampling lumen of the nasal cannula or bite block being tested and recorded the average FiO₂ over a 3-min period. For the five nasal cannulas, oxygen was delivered at the typical rate of 2 L/min. Higher flow rates without proper humidification cause mucosal dryness and are not recommended for long-term oxygen delivery [12]. As such, oxygen was delivered through the two masks and four bite blocks at the recommended rate of 6 L/min. FiO₂ samples were collected for each device during steady state after changing the ventilator, airway resistance, and oxygen flow settings. Each setting and measurements were repeated five times.

3 Results

Figure 3 shows the mean value for each individual device over a range of oxygen flows. The FiO₂ measured at the trachea increased as the supplemental oxygen inflow increased in the nasal cannulas (blue), face masks (green), and bite blocks (red; Fig. 3a, b). The FiO₂ increased more during hypoventilation than during normal ventilation. The oral bite blocks, especially the MA bite block, provided the highest FiO₂, while the nasal cannulas provided the lowest FiO₂ in both normal ventilation and hypoventilation states.

Figure 4 shows the change in delivered FiO₂ as the ratio of oral to nasal breathing changed from mouth closed to mouth open. During normal ventilation, the delivered FiO₂ did not change with the switch from nasal to oral breathing. During hypoventilation, the FiO₂ delivered by the nasal cannulas decreased with the change from nasal to oral breathing except for the Hauge airway (red circles).

4 Discussion

Our results show that FiO₂ delivery during EGD simulation model is generally higher when using a mask or bite block than when using a nasal cannula. Masks and bite blocks were more effective during hypoventilation, thereby providing greater oxygenation and patient safety when respiratory drive is depressed in sedated patients.

Masks and bite blocks deliver a higher FiO₂ because of the greater device volume. During the expiratory pause that precedes inspiration, the mask or bite block cavity is filled with oxygen, similar to a reservoir effect [13]. The larger the volume, the greater the amount of oxygen inspired and the higher the FiO₂.

During hypoventilation, the volume in the mask, bite block, and nasal and oral cavity form a larger fraction of the inspired tidal volume than they do during normal breathing. When the volume is filled with oxygen, this oxygen forms a larger portion of the inspired tidal volume and FiO₂ increases. With high supplemental oxygen flow, the oxygen fraction in the volume increases and FiO₂ increases. In addition, at high oxygen flows, the size of the oxygen cloud over the nose and mouth increases, further increasing the amount of oxygen inspired and further increasing FiO₂.

A nasal cannula is more effective during nasal only breathing than during oral breathing by design because oxygen is only directed to the nasal cavity. As patients undergo EGD and a scope passes through the mask or bite block, the open cross section area of the oral airway decreases and the percentage of air entering via the oral route decreases. An increase in nasal breathing caused most nasal cannulas to become more effective as seen by an increase of FiO₂. A mask may become more effective during nasal breathing because entry point of the supplemental oxygen flow is near the nose. For oral bites, the effect is less distinct. Table 2 summarizes the relative

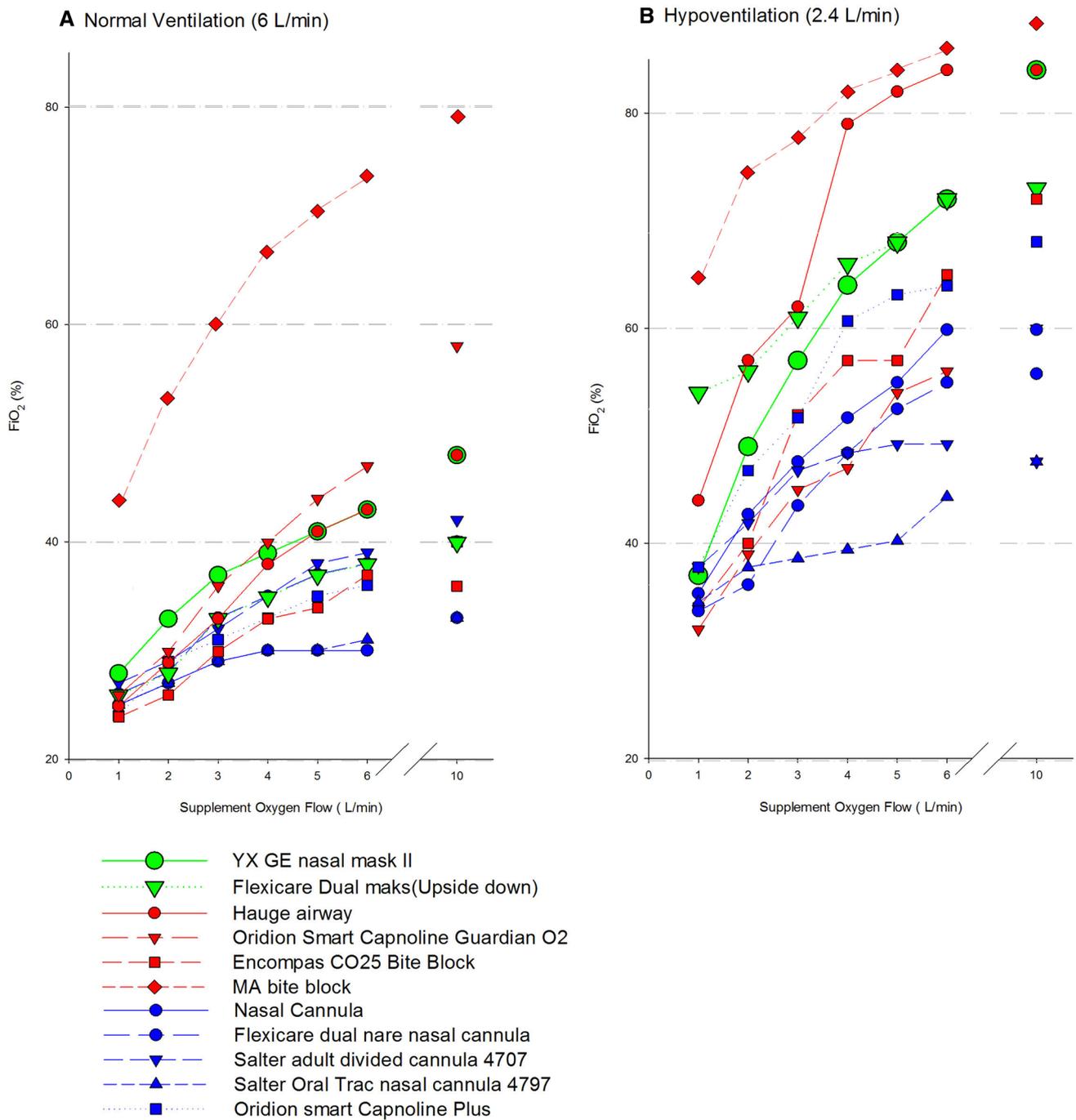


Fig. 3 Mean inspired oxygen concentration as the oxygen flow increased for five nasal cannulas (blue), two masks (green), and four oral bite blocks (red). **A** Change during normal ventilation (minute

ventilation 6 L/min). **B** Change during hypoventilation (minute ventilation 2.4 L/min). For both plots, the mouth orifice was 7.7 mm, simulating partial nasal and partial oral breathing

effectiveness of the devices used to deliver oxygen in this study. The MA bite blocks and Hauge airway bite blocks delivered the highest FiO_2 during hypoventilation. However, when the mouth was totally closed, the MA bite block maintained this advantage but the Hauge airway lost its advantage over other bite blocks.

Hybrid devices such as the MA and CapnoLine (Oridion, Jerusalem, Isreal) bite blocks provide oxygenation through both the nasal and oral routes and deliver higher FiO_2 than cannulas and masks. The oxygen is connected from an oxygen source to a connector on the bite block, and the oxygen inflow is then directed to the nasal and

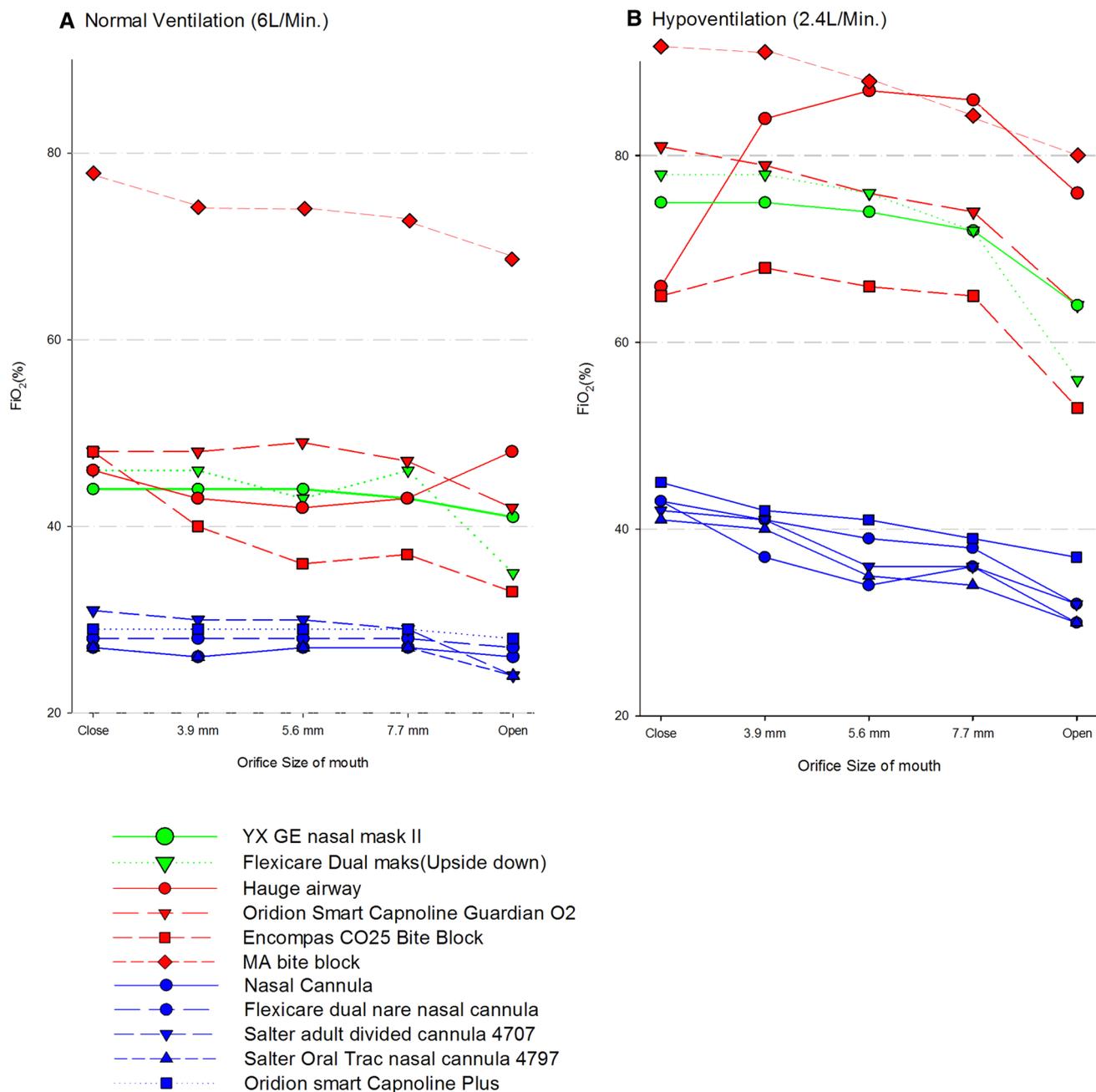


Fig. 4 The mean of inspired oxygen concentration as the ratio of oral to nasal breathing changed from mouth closed to mouth open for five nasal cannulas (blue), two masks (green) and four oral bite blocks (red). **A** Shows the change during normal ventilation. **B** Shows the

change during hypoventilation. Oxygen was delivered through the nasal cannulas at the recommended rate of 2 L/min. Oxygen was delivered through the masks and bite blocks at the recommended rate of 6 L/min

oral delivery ports simultaneously. The MA bite block's design provides MA by holding the lower jaw in a protruding position during EGD and thus delivering a high 46% FiO_2 during normal ventilation at a low supplemental oxygen flow of 2 L/min. This permits lower oxygen flow rates to be used with these devices. It has the advantage of oral bites with a large volume, which as mentioned above,

result in a larger reservoir for oxygen. Further, it directs the flow of oxygen to the nasal cavity, as does a nasal cannula, delivering oxygen whether the patient is mouth breathing or nasal breathing. The high FiO_2 delivered is similar between the open mouth and closed mouth scenarios. Devices that deliver a higher FiO_2 at lower oxygen flow rates are of significant advantages where price and

Table 2 Relative effectiveness of the devices used to deliver oxygen

	Normal ventilation		Hypoventilation	
	Nasal breathing	Oral breathing	Nasal breathing	Oral breathing
Nasal cannulas				
Nasal cannula	+	+	++	+
Flexicare dual nare nasal cannula	+	+	++	+
Salter adult divided cannula 4707	+	+	++	+
Salter Oral-Trac nasal cannula 4797	+	+	++	+
Oridion Smart CapnoLine Plus	+	+	++	+
Masks				
YX GE nasal mask II	++	++	+++	+++
Flexicare dual mask	++	++	+++	++
Bite blocks				
Hauge airway	+++	+++	+++	+++
Oridion smart capnoline guardian O2	++	++	++++	+++
Emcompas CO25 bite block	++	+	+++	++
Mandibular advancement bite block	+++	+++	++++	++++

The oxygen flow through the nasal cannulas was 2 L/min, while the flow through the masks and mouth bites was 6 L/min (clinical recommended rates). + delivered FiO_2 21–39%, ++ delivered FiO_2 40–59%, +++ delivered FiO_2 60–79%, ++++ delivered $\text{FiO}_2 > 80\%$

availability are of concern. Our results may help clinicians decide which device is best for their practice.

Our results suggest that it would be best to continue using the bite block or mask and continue high oxygen flows when EGD is followed by colonoscopy. The bite block orifice does not alter FiO_2 significantly, so may be open or closed. However, it is important to keep the patient's mouth closed when a nasal cannula is used. When a nasal cannula is used during colonoscopy, closing the patient's mouth will increase the FiO_2 .

Nasal cannulas are not recommended for use at oxygen flow rates above 3 L/min, as high flow rates dry the nasal mucosa and cause discomfort to the patient (e.g., epistaxis or rhinorrhea) [14]. However, should high flows become necessary to increase FiO_2 rapidly during a rescue maneuver, a nasal cannula is nearly as effective as a mask or bite block at high oxygen flow rates. A simple mask over a nasal cannula will increase the FiO_2 further, as would be the case with the YX GE nasal mask.

Given the clinical adaptations of an existing mask, the Flexicare dual mask was tested in an upside-down position, i.e., with the nose piece over the mouth and the mouth piece over the nose. Many clinicians use this mask upside down so they can pass the scope more easily into the patient's mouth. Its performance in this unusual position was found to be equivalent to the performance of specially designed nasal masks and bite blocks. This reflects the ingenuity of practicing clinicians, who will find a way to solve a problem while waiting for new devices to become available.

The Encompas CO25 bite block provided a relatively low FiO_2 when compared with the other masks and bite blocks in

both the normal ventilation and hypoventilation states and in different mouth opening size conditions, except for a closed mouth with normal ventilation, which may be because of its relative shallow design in comparison with the other two bite blocks (Fig. 4).

The most important limitation in this study is the fact that a manikin head with a lung model was used instead of actual patients. It is possible that the performance of the devices compared in this study may be different in patients. However, the manikin model used in our study had an advantage in that the mechanical characteristics of the devices used to deliver oxygen could be standardized and reproduced. In addition, the test lung was modified to simulate spontaneous breathing. Hence, the different devices were tested under similar conditions during dynamic experiments. However, it is clear that these laboratory conditions are not representative of real life, so the findings of such bench studies should be extrapolated to patients with caution. Clinical studies are needed to further evaluate these characteristics and other aspects of the performance of nasal cannulas and oral mouth bites, e.g., on delivery of oxygen (FiO_2) and comfort during EGD and colonoscopy examination. In addition, and perhaps more importantly, the volume of the oral cavity in a manikin head may need to be estimated and whether this volume may play a role in the FiO_2 in sedated patients investigated. We cannot explain why some devices deliver higher FiO_2 than others, further exploration of this issue is clearly warranted.

In conclusion, an increase in supplemental oxygen flow, a decrease in minute ventilation, and an increase in FiO_2 was found with all devices used in this study. Decreases in the ratio of nasal to oral breathing cause FiO_2 to decrease in all

devices tested except for the Hauge airway, and hypoventilation augments this decrease. Hybrid devices, such as the MA bite block, that provide oxygenation to both the oral and nasal cavities provide the highest FiO_2 for a given oxygen flow rate. Further clinical studies are needed to assess the efficacy of the MA bite block.

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