A Remote-Controlled Airbag Device Can Improve Upper Airway Collapsibility by Producing Head Elevation With Jaw Closure in Normal Subjects Under Propofol Anesthesia

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ABSTRACT Continuous maintenance of an appropriate position of the mandible and head purely by manual manipulation is difficult, although the maneuver can restore airway patency during sleep and anesthesia. The aim of this paper was to examine the effect of head elevation with jaw closure using a remote-controlled airbag device, such as the airbag system, on passive upper airway collapsibility during propofol anesthesia. Seven male subjects were studied. Propofol infusion was used for anesthesia induction and maintenance, with a target blood propofol concentration of 1.5–2 μg/ml. Nasal mask pressure (P_N) was intermittently reduced to evaluate upper airway collapsibility (passive P_{CRIT}) and upstream resistance (R_{US}) at three different head and jaw positions, jaw opening position in the supine position, jaw opening position in the sniffing position with 6-cm head elevation, and jaw closure at a 6-cm height sniffing position. The 6-cm height sniffing position with jaw closure was achieved by an airbag device that was attached to the subject's head-like headgear. Patient demographics, P_{CRIT} and R_{US} in each condition were compared using one-way ANOVA with a post hoc Tukey test. $P < 0.05$ was considered significant. We also confirmed the effects of our airbag device on improvement of upper airway collapsibility in three obstructive sleep apnea patients in a clinical study. The combination of 6-cm head elevation with jaw closure using the air-inflatable robotic airbag system decreased upper airway collapsibility ($P_{CRIT} \sim -3.4$-cm H_2O) compared with the baseline position ($P_{CRIT} \sim -0.8$-cm H_2O, $P = 0.0001$). In the clinical study, there was improvement of upper airway obstruction in sleep apnea patients, including decreased apnea and hypopnea duration and increased the lowest level of oxygen saturation. We demonstrated that establishment of head elevation with jaw closure achieved by a remote-controlled airbag device using an inflatable airbag system can produce substantial decreases in upper airway collapsibility and maintain upper airway patency during propofol anesthesia and sleep.

INDEX TERMS Upper airway collapsibility, anesthesia, sniffing position, critical closing pressure.

I. INTRODUCTION

Maintenance of upper airway patency during anesthesia with spontaneous breathing is critical, since upper airway dilator muscle activity becomes significantly compromised during the reduction of arousal responses [1], [2] resulting from anesthesia. During anesthesia, disturbances in upper airway neural control (i.e., compensatory neuromuscular responses) may compromise pharyngeal

patency [3], [4]. Under these circumstances, the overall collapsibility of the upper airway is predominantly governed by mechanical properties of the upper airway.

Anesthesiologists and nurses play a very important role in continuous maintenance of the position of the mandible and head to ensure upper airway patency during anesthesia and the postoperative period, specifically by maintenance of the sniffing position [5]–[7] with jaw closure [8]–[10] and head elevation [11], [12]. We recently demonstrated that head elevation to a height of approximately 6 cm might be effective for maintaining upper airway patency in normal healthy subjects during propofol anesthesia. Furthermore, we indicated that the combination of head elevation and jaw closure may enable establishment of the optimal position, i.e., ''sniffing position'' for maintaining upper airway patency during sleep and anesthesia. However, there are several clinical situations where the anesthesiologist or nurse cannot always be present beside the patient to maintain the optimal position and to keep the upper airway open, such as during anesthesia for diagnostic imaging, i.e., magnetic resonance image (MRI) and computed tomography (CT) [11], [13]. Although previous studies have suggested that supportive devices, such as surgical tape or a neck collar, can improve airway patency during anesthesia with spontaneous breathing [14], [15], these are not desirable tools. Therefore, it would be useful to have a supportive remote-controlled robotic device that enables maintenance of upper airway patency by ensuring effective head and mandible positions.

We hypothesized that use of an air-inflatable robotic device, such as an airbag system, might be effective in achieving the optimal airway position, i.e., head elevation with jaw closure, thus maintaining upper airway mechanical properties and minimizing upper airway collapsibility during propofol anesthesia. Nevertheless, the effect of the optimal combination of head elevation and jaw closure, i.e., the sniffing position, without use of the anesthesiologist or bed partner's hands, on passive upper airway collapsibility in anesthetized, spontaneously breathing subjects has not been quantified.

To address this hypothesis, we examined the effect of head elevation with jaw closure, obtained by using a semi-automatic air-inflatable robotic device, on passive upper airway collapsibility during propofol anesthesia. Methods for quantifying the contribution of anatomic alterations to airway collapsibility using analysis of pressure-flow relationships in both sleeping and anesthetized subjects have been established [16], [17]. We sought to establish the optimal material and shape of the device required for preventing upper airway obstruction, by evaluating the effect of the degree of jaw closure and head flexion on upper airway pressure-flow relationships.

II. MATERIAL & METHODS
A. EXPERIMENTAL STUDY
1) SUBJECTS
Seven healthy male subjects were recruited, and a detailed clinical history was obtained from them. Subjects were

excluded if they were overweight or obese (Body Mass Index (BMI) > 25 kg/m^2) had a history of frequent or excessive snoring according to the bed partner (greater than 3 times/week) had abnormal sleep patterns or reported excessive daytime sleepiness (Epworth Sleepiness Score > 10), had a significant medical disease (cardiopulmonary pathology) or other clinical history (allergy to anesthesia), or reported tobacco use or chronic alcohol or drug use. Subjects were also excluded if they had an anatomical deformation of the upper airway, such as retrognathia or maxillary hypoplasia assessed under conditions of jaw occlusion (normal overbite and overjet). The vertical occlusion condition was assessed by overbite, which indicates the degree of overlap between the upper and lower incisors (normal: 3 mm). The horizontal occlusion condition was assessed by overjet, which indicates the horizontal distance between the upper and lower incisors (normal: 3 mm). All subjects had to have a Mallampati score of I or II and a thyromental distance longer than 60 mm. The experimental protocol was approved by the Human Investigation Committee of the Nagasaki University Graduate School of Biomedical Sciences and written informed consent was obtained from all subjects.

2) EXPERIMENTAL TECHNIQUES
Physiological Measurements: All subjects underwent routine hemodynamic monitoring (systolic and diastolic blood pressure and pulse rate) and electrocardiogram, bilateral electro-oculograms, electroencephalograms (C3-A2) and submental electromyograms, to confirm the anesthetic level. Electroencephalographic signals were processed by the Bispectral Index monitor (BIS, Aspect Medical Systems Inc., Natick, MA, USA), in order to determine the depth of propofol anesthesia. Oxygen saturation (SpO$_2$) was measured by pulse oximetry. Airflow (V) was measured by a pneumotachometer (#3830, Hans Rudolph, Inc., Kansas City, MO, USA), and nasal pressure (P$_N$) was measured by a differential pressure transducer (#1100, Hans Rudolph, Inc.), both of which were connected to the nasal mask. In order to detect respiratory movement, both chest and abdominal movements were monitored with piezoelectric strain gauges (Piezo Respiratory Effort Kit for Thorax and abdomen, Embla, Medcare, Broomfield, CO, USA).

A variable pressure device (ResMed, Bella Vista, Australia) was used to deliver constant pressure in the nasal mask (P$_N$), ranging from −15 to +15 cm H$_2$O. The measurements were displayed and stored simultaneously on a computer using a data acquisition device (Embla S7000 with Somnologica, Medcare, Broomfield, CO, USA). (Fig. 1)

Propofol Anesthesia: No premedication was given. Propofol anesthesia was induced with intravenous propofol (Diprivan; AstraZeneca, Alderley Park, Cheshire, United Kingdom), administered via a Diprifusor (AstraZeneca) target-controlled infusion system (TCI pump TE371, Terumo, Tokyo, Japan), which calculated the effect site concentration on the basis of a three-compartment pharmacokinetic algorithm. The target blood concentration of propofol was
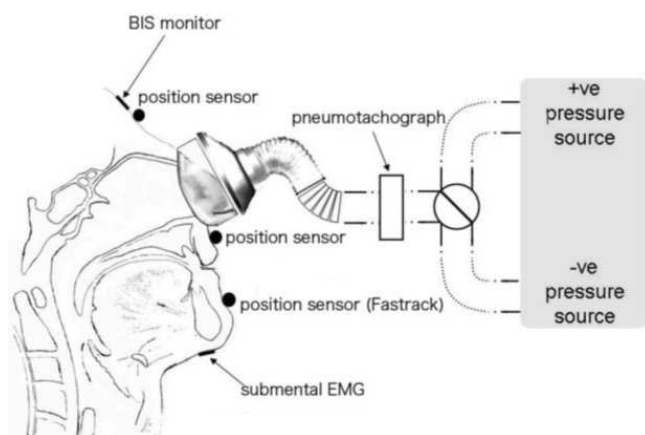
FIGURE 1. Experimental diagram. Apparatus used to apply subatomospheric nasal pressure is shown. A variable pressure device was used to deliver constant pressure in the nasal mask (P_N), ranging from −15 to +15 cm H_2O. All subjects underwent bilateral electro-oculograms, electrocephalograms (C3-A2) and submental electromyograms, to confirm the anesthetic level. Electroencephalographic signals were processed by the Bispectual Index monitor. The horizontal and vertical positional changes were directly measured by a 6 degree-of-freedom motion tracking system (FASTRAK®). Two sensors were separately attached on the forehead and chin.

FIGURE 2. Example of pressure flow relationships at four level of head elevation 6 cm with chin lift of one subject. $V_{I}max$ = maximum inspiratory flow (between dashed line). P_N = *nasal* mask pressure. P_N is abruptly reduced from an elevated holding pressure to a level that induced inspiratory airflow limitation (flattened or non-sinusoidal shape in inflow). It is noted that there is mild, moderate and severe flow limitation before reached to zero flow. Subsequently, P_N was lowered in a stepwise fashion by 2 cm H_2O every 5 breaths until zero flow was obtained or Sp_{O2} reached a lower limit of 88 to 90%. Maximal inspiratory airflow ($V_{I}max$) was measured in the last three flow-limited inspirations at each level of nasal pressure. Note that P_N to obtain zero inspiratory airflow was lower in 6 cm head elevation condition that baseline condition (0 cm head elevation). (B) The fit line for pressure-flow relationships was generated using linear regression analysis.

increased and kept constant between 1.5 and 2.0 μg/ml, to obtain an adequate level of anesthesia (BIS value between 40 and 60, no response to spoken commands). At the conclusion of the measurements, all the subjects were kept in the supine position until they showed spontaneous emergence from anesthesia.

Evaluation of Passive Upper Airway Collapsibility (Passive P_{CRIT}): Following establishment of an adequate level of stable propofol anesthesia, the subjects initially breathed via the nasal mask at atmospheric pressure. P_N was then gradually increased to a holding pressure where inspiratory airflow limitation was abolished ("*passive state*"), as previously described [18], [19]. In brief, airflow limitation was defined as a plateau in the inspiratory airflow with continued respiratory effort. To establish the passive P_{CRIT}, P_N was rapidly lowered from the holding pressure to specific levels for five successive breaths (15 $\sim$ 20 sec), before returning to the holding pressure (Fig. 2). A series of approximately six to ten pressure drops (including P_N at lowest inflow or at zero flow, i.e., airway occlusion) was obtained to generate the passive pressure-flow relationship for each level of head elevation. If any of the P_N drops were associated with transient arousal (BIS > 70) or an oxygen saturation below 90%, P_N was returned to the holding pressure without reaching zero inflow, while subjects re-established stable breathing, following which the series of pressure drops was continued.

3) DATA ANALYSIS

Upper airway pressure-flow relationship: At each level of P_N, breaths were evaluated for the presence of inspiratory airflow limitation, as previously described [8], [18], [19]. Inspiratory flow limitation was defined as the presence of a flattened or non-sinusoidal appearance on the inspiratory inflow signal [20] that ended abruptly with a return to
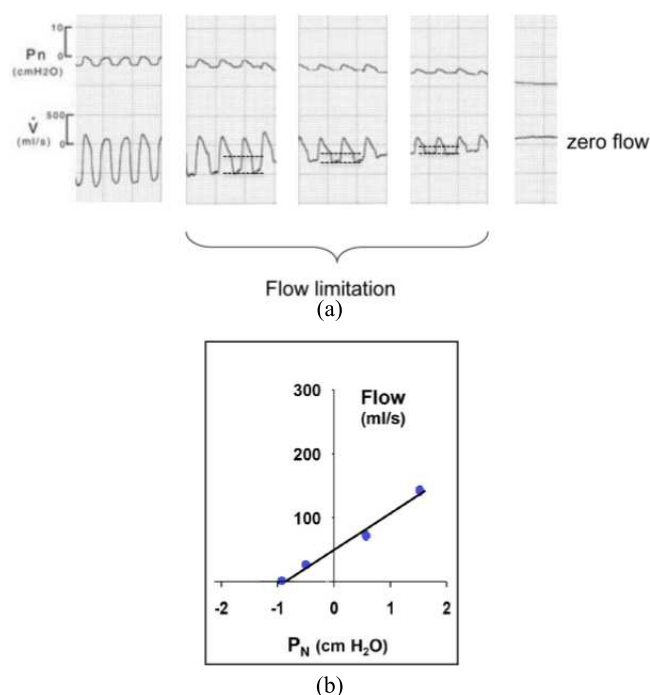
non-flow limited breaths of a sinusoidal shape when the P_N was increased to holding pressure. Breaths that were associated with arousal were excluded from analysis. Maximal inspiratory airflow ($V_I max$) was measured in the last three flow-limited inspirations at each level of nasal pressure, as previously described [18], and used to define the corresponding nasal pressure (P_N) vs. $V_I max$ relationship. Least-squares linear regression was used to generate the pressure-flow relationship [21] and fit with the following equation: $V_I max = (P_N - P_{CRIT})/R_{US}$, where P_{CRIT} was the critical closing pressure (P_N at zero flow) and R_{US} was the resistance in the portion of the airway upstream of the site of collapse.

The sniffing position with jaw closure was achieved by an airbag device. Each subject was positioned supine on a surgical bed after attaching an air-inflatable device, which is a part of the airbag device, to the head. An overview of the airbag device used in this experiment is shown in Fig. 3.

The major components of this airbag device are an air-inflatable device (headgear), a controller to control inflation/deflation of the headgear, and a PC to input command signals to the system. The headgear has two airbags. One is located at the occipital area and functions to elevate
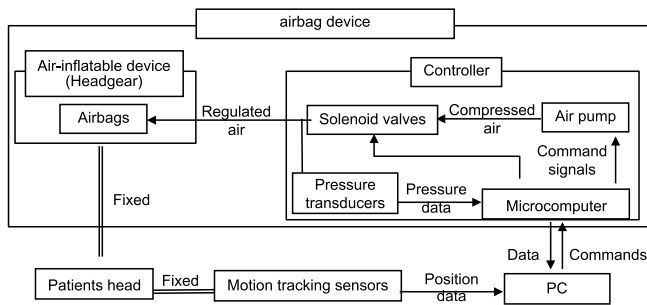
FIGURE 3. Overview of the airbag system. The major components of this airbag system are an air-inflatable device (headgear), a controller to control inflation/deflation of the headgear, and a PC to input command signals to the system.
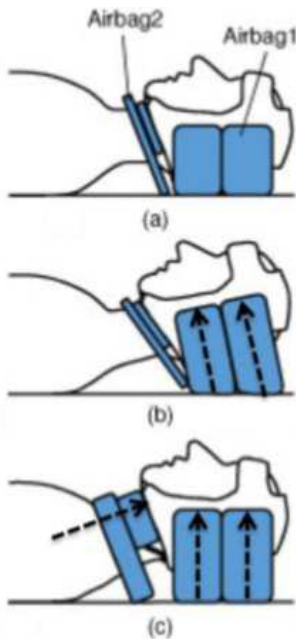

FIGURE 4. Diagram of head movements achieved by inflation of two airbags. (a) Initial position. (b) Head elevation by using airbag1. (c) Sniffing position by using airbag1 and airbag2.

the subject's head. The other is located beneath the chin and brings about head extension (backward rotation) and jaw closure. Two motiontracking sensors (FASTRAK®) are also installed on the headgear. One is located at the forehead area and measures the head position (height and head flexion angle) and the other is located at the tip of the chin and measures the position of the lower jaw. The controller includes a microcomputer, an air pump, air valves, and pressure transducers.

Fig. 4 illustrates the head movements resulting from inflation of one or both of the headgear airbags. Subjects are initially in the normal supine position as shown in Fig. 4(a). When the operator clicks the start button for "6 cm height sniffing position with mouth closure" on the PC screen, the controller starts inflating the airbag for head elevation (Airbag 1) first. However since the head automatically flexes forward during inflation of Airbag 1 because of its connection with the cervical spine as shown in Fig. 4(b) the airbag for head extension (Airbag 2) is inflated at the same time to

FIGURE 5. The photograph in one sample of sniffing position given by airbag device.

keep the head in a horizontal position and obtain the sniffing position as shown in Fig. 4(c). Inflation of the airbags automatically stops at the target height (6 cm) and level. The height of the head can be adjusted at any time through operation of buttons on the PC screen during the experiment. Airbag 2 also works for closing the mouth because its inflation leads to chin elevation. When the operator clicks the stop button, the airbags are deflated and the subject's body slowly goes back to the neutral spine position with neutral occlusion. Through these procedures, the 6 cm height sniffing position with mouth closure is remotely maintained by using this robotic device.

4) STUDY PROTOCOL

Each subject was asked to restrict food intake for 6 hr prior to participating in the experimental measurements. Initially the monitoring sensors and air-inflatable airbag system were attached to the subject who was then laid on a flat, firm bed with no pillow. The subject's head was positioned in a neutral position with the face straight up and with the individual's Frankfort plane angled at $70° \sim 80°$ to the horizontal plane of the bed (i.e., without head extension or flexion). The Frankfort plane could be calculated on the basis of at least three coordinates including the orbitale ORB of the first or second choroidal fissures and the first or second tragion. The nasal mask was fitted over the subject's nose and checked for leaks by asking the subject to try to expire through the mask while occluding the airflow pathway. If air leaks were detected, the mask was repositioned and re-tested for leaks. To prevent air leaks, the subject's lips were sealed with flexible surgical tape without interfering with jaw opening.

Once steady state anesthesia was attained, pressure-flow measurements were conducted at each of three different head and mandible conditions, neutral occlusion (rest position of jaw) in the supine position, neutral occlusion at 6 cm head elevation, and jaw closure at 6 cm head elevation. The second condition, i.e., neutral occlusion at 6 cm head elevation, was achieved by manipulation by an assistant, while the third condition, i.e., jaw closure at 6 cm head elevation, was achieved using the robotic device.

Fig. 5 shows a photograph of the sniffing position attained using the airbag device in the experiment. On completion of

the measurements, anesthesia was withdrawn and all subjects continued to be monitored for spontaneous emergence from anesthesia and for a 2 hr post study period.

Measurement of jaw closure and head position: The horizontal and vertical positional changes were directly measured by a 6 degree-of-freedom motion tracking system (FASTRAK®). Two sensors were separately attached on the forehead and chin. The Frankfort plane was defined as a plane passing through the inferior margin of either orbit (orbitale) and the upper margin of each ear canal (porion). The degree of head flexion was assessed by measuring the angle between the Frankfort plane and the horizontal plane. The Frankfort plane angle was used to indicate head position, a decrease indicating head flexion and an increase signifying head extension. The degree of jaw opening was defined by the difference between rotation angles of the forehead and the chin relative to the one obtained under jaw occlusion conditions.

Sample Size Analysis: Prior to the experiment, we calculated sample size estimation using a statistical tool (Stat-Mate2, GraphPad Software, Inc. CA, USA), to determine how much of a difference in passive P_{CRIT} is of clinical significance. Estimates of mean and SD values for passive P_{CRIT} by head elevation during propofol anesthesia were 4.4 ± 0.7 cm H_2O from data obtained in a previous study in our laboratory [10]. Based on the performance characteristics of repeated measurements of P_{CRIT} [22] we estimated that a sample size of seven subjects would have 90% power to detect a difference in means of passive P_{CRIT} of 3 to 5 cm H_2O using a non-paired t-test with a two-sided significance level of 0.05.

Statistical Analysis: All statistical analyses were performed using Prism5 (GraphPad Software, Inc., La Jolla, CA, USA) to test a two-tailed hypothesis. We used one-way ANOVA with a post hoc Tukey test to examine the effect of jaw closure on the primary outcome variables (passive P_{CRIT}). Secondary outcome analysis was performed on R_{US} using the Mann-Whitney test (data not normally distributed). Statistical significance was assumed for $P < 0.05$. The data are presented as mean ± standard deviation (SD), unless otherwise noted.

5) CLINICAL STUDY

In this study, we confirmed the effects of our airbag device on improvement of upper airway collapsibility.

6) SUBJECTS

Three healthy male obstructive sleep apnea and hypopnea patients were recruited after obtaining written informed consent.

7) CLINICAL STUDY PROTOCOL

All three obstructive sleep apnea patients had completed a portable PSG test prior to the day of the clinical study. All three were males (age 32, 35, 62 years old, BMI 22, 26, 35 kg/m^2) who had been diagnosed with mild, moderate and moderate-to-severe OSA with obesity ($AHI = 5, 25, 28$). The clinical study tested whether the airbag device could improve

TABLE 1.

subject	height(m)	weight(kg)	BMI(kg/m2)	age(years)
No.1	1.63	58	21.8	23
No.2	1.65	65	23.9	23
No.3	1.74	63	20.8	27
No.4	1.72	73	24.7	29
No.5	1.68	56	19.8	24
No.6	1.67	56	20.1	24
No.7	1.63	56	21.1	25
MEAN	1.67	61.0	21.7	25
SD	0.04	6.43	1.86	2.24

TABLE 2. Experimental variables.

	0cm head-elevation	6cm head-elevation	6cm head-elevation + chin lift
Propofol (μ g/ml)	1.9±0.1	1.8±0.1	1.7±0.1
BIS value (a.u.)	51.1±3.5	48.7±4.7	47.6±5.4
Baseline SpO₂ (%)	97.4±0.5	97.7±0.5	97.6±0.5
Lowest SpO₂ (%)	95.0±1.6	94.3±2.8	95.6±1.7

Data are mean±SD; a.u.=arbitrary units.

Bispectral Index = BIS

upper airway obstruction in one patient during propofol anesthesia and in two patients during "day sleep" and "night sleep." All three patients were tested using the short period (120min) of the PSG screening test (EEG, oxygen saturation and nasal airflow).

B. RESULTS

1) RESULTS OF THE EXPERIMENTAL STUDY

The demographic and anthropometric characteristics of the subjects are displayed in Table 1. The average age of subjects was 25.0 ± 2.2 years, height was 1.67 ± 0.04 cm, weight was 61.0 ± 6.4 kg, and BMI was 21.7 ± 1.9.

The experimental conditions for each of the groups were similar in terms of the mean target blood concentration of propofol, BIS value, and baseline and lowest SpO$_2$ (all $p > 0.2$; t-tests; Table 2).

The mean holding pressure required to abolish flow limitation was 6.9 ± 2.5 cm H_2O. For all subjects, the average number of pressure drops in each experimental condition was 8, ranging from 6 to 10. The range of P_N applied across all conditions was 12.0 ± 2.8 cm H_2O to -8.2 ± 3.1 cm H_2O.

2) EFFECT OF MOUTH CLOSURE ON UPPER AIRWAY COLLAPSIBILITY

Fig. 6 shows the mean passive P_{CRIT} at each mandible and head position condition.

P_{CRIT} (-2.0 ± 2.8 cm H_2O) in the head elevated condition (neutral occlusion with 6 cm head elevation) was not significantly different compared to the value of P_{CRIT} (-0.8 ± 1.9 cm H_2O) in the baseline condition (neutral occlusion with 0 cm head elevation). However, P_{CRIT} significantly decreased to -3.4 ± 3.0 cm H_2O under the combination of 6 cm head
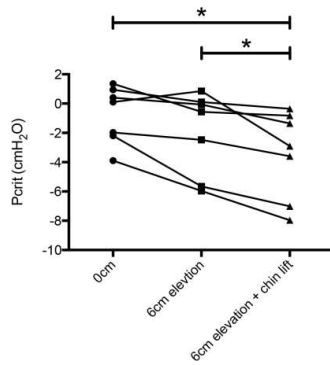
FIGURE 6. The change of mean passive P_{CRIT} at three different head and mandible positions, *$p < 0.05$ vs. neutral position (0 cm head elevation).
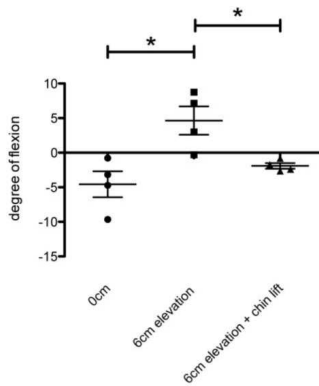

FIGURE 7. The change of mean degree of flexion at three different head and mandible positions. *$p < 0.05$ vs, neutral position (0 cm head elevation).

elevation and jaw closure achieved with the air-inflatable device. The R_{US} did not change with jaw closure (33.7 ± 17.7 cm $H_2O \cdot$ ml$^{-1} \cdot$ s) compared to the neutral condition (31.9 ± 12.4 cm $H_2O \cdot$ ml$^{-1} \cdot$ s; $p > 0.3$).

3) DEGREE OF JAW CLOSURE AND CHIN LIFT IN THE HEAD ELEVATED POSITION

The degree of head flexion was -4.6 ± 3.8 degrees under baseline conditions (neutral occlusion in the supine position), indicating slight head extension against the horizontal plane. The degree of head flexion (4.6 ± 4.1 degrees) with 6 cm simple head elevation without jaw closure and chin lift significantly increased compared to baseline values. The degree of head flexion (1.9 ± 0.8 degrees) in the 6 cm elevation sniffing position with jaw closure was significantly lower compared to the value with simple 6 cm head elevation. This value may indicate the position in which the face is straight up with the Frankfort plane angle almost parallel to the horizontal plane (Fig. 7).

The degree of jaw closure was 7.2 ± 3.1 degrees under baseline conditions (neutral occlusion in the supine position), indicating a slightly open mandible. The degree of jaw closure (11.5 ± 2.3 degrees) in the 6 cm simple head elevation without jaw closure and chin lift position significantly increased compared to baseline values. The degree of jaw closure (5.9 ± 2.1 degrees) in the 6 cm head elevation sniffing position
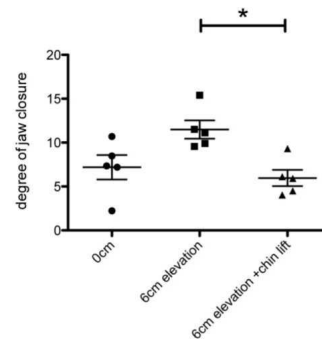

FIGURE 8. The change of mean degree of jaw closure at three different head and mandible positions. *$p < 0.05$ vs. neutral position (0 cm head elevation).

TABLE 3.

Table.3					supine position (0cm head elevation with jaw closure)		sniffing position (6cm head elevation with jaw closure)	
subjects	age	BMI	severity of OSA(AHI score)	condition (120min)	lowest SpO2	longest apnea/hypopnea duration	lowest SpO2	longest apnea/hypopnea duration
A	32	22	mild (AHI=5)	propofol sedation	90%	21 sec	95%	10 sec
B	62	26	moderate (AHI=25)	Day sleep (stage2)	87%	35 sec	93%	10 sec
C	35	35	moderate to severe (AHI=28)	Night sleep (stage3)	91%	30 sec (hypopnea)	95%	15sec (hypopnea)

was significantly lower than the value with simple 6 cm head elevation (Fig. 8).

4) RESULTS OF CLINICAL STUDY

We have confirmed in three patients that the application of the airbag device decreased apnea and hypopnea duration and increased the lowest level of oxygen saturation by preventing sustained upper airway obstruction during sleep (summary data shown in Table 3).

III. DISCUSSION

The major finding of this study was that the remote-controlled air-inflatable device can improve upper airway collapsibility by producing the sniffing position with jaw closure in normal subjects under propofol anesthesia with spontaneous breathing.

This study also indicates that the beneficial effect of remote-controlled maintenance of the sniffing position with jaw closure on airway collapsibility may be clinically relevant. Our findings suggest that manipulation of the jaw and head position by the air-inflatable device, resulting in maintenance of the sniffing position, produces substantial decreases in upper airway collapsibility and maintains upper airway patency during anesthesia management with spontaneous breathing for surgical procedures and diagnostic imaging.

A. VALIDATION OF P_{CRIT} ANALYSIS FOR EVALUATION OF UPPER AIRWAY COLLAPSIBILITY

The quantitative evaluation of upper airway collapsibility using an application of negative airway pressure to determine the collapsibility of the upper airway using pressure-flow relationships, as seen with flow limitation or complete obstruction, has been used during anesthesia and sleep.

The concept of critical closing pressure (P_{CRIT}) arises from modeling the upper airway as a simple collapsible tube [23] and the generation of multipoint pressure flow (P-Q) relationships, which are then used to assess upper airway patency [23]. It has been shown that P_{CRIT}, representing nasal pressure at zero flow (an index of upper airway collapsibility), and resistance (which reflects the degree of upper airway narrowing upstream of the site of collapse) are key elements governing upper airway patency [24].

For example, reductions in P_{CRIT} of 4 $\sim$ 5 cm H_2O magnitude are equivalent to the stabilizing effect of applying an equivalent level of continuous positive airway pressure ($CPAP = 4 \sim 5$ cm H_2O) to reverse upper airway obstruction. Such decreases in P_{CRIT} also approximate the magnitude of the response required to convert either obstructive events to less severe hypopneic events or hypopneic events to stable breathing during anesthesia and sleep [10], [11], suggesting head elevation as a source of variability in sleep apnea severity throughout the night.

B. INFLUENCE OF THE SNIFFING POSITION USING THE ROBOTIC DEVICE ON PASSIVE UPPER AIRWAY COLLAPSIBILITY

This study quantified the influence of the sniffing position with jaw closure using an air-inflatable robotic device on passive upper airway collapsibility in spontaneously breathing subjects during propofol anesthesia. P_{CRIT} significantly decreased in the sniffing position with 6 cm head elevation and jaw closure, achieved by application of the robotic device, compared to neutral jaw occlusion in the supine position. Nevertheless, changes in the degree of jaw closure were equal to the degree of head flexion when the airbag device was applied, suggesting that an optimal manipulating device can produce both jaw closure and chin lift (head extension) for maintenance of airway patency. Moreover, P_{CRIT} fell by 2.6 cm H_2O with positional changes using the robotic device, suggesting a substantial reduction in passive mechanical properties of the pharynx [2], [4]. Reductions in P_{CRIT} of this magnitude are equivalent to the stabilizing effect of applying nearly 3 cm H_2O of continuous positive airway pressure to reverse upper airway obstruction during anesthesia. Such decreases in P_{CRIT} also approximate the magnitude of the response required to convert either obstructive events to less severe hypopneic events or hypopneic events to stable breathing during anesthesia [11], [25], suggesting the utility of the jaw closure-head elevation robot as a means to reduce sleep apnea severity throughout the night.

C. EFFECT OF PREVENTION OF NECK FLEXION AND JAW OPENING ON UPPER AIRWAY COLLAPSIBILITY

We recently evaluated the effect of concomitant jaw opening on passive P_{CRIT}, based on the changes in the Frankfort and mandibular plane angles with head elevation, and found that there were no significant differences in the change in the Frankfort plane angle between jaw-fixed and jaw-free conditions [10]. In contrast, there was a significantly greater change in the mandibular plane angle in the jaw-free relative to the jaw-fixed positions. Our findings suggest that head elevation is associated with some degree of jaw opening, which increases in a height-dependent manner with head elevation. While head elevation with a pillow appears to improve pharyngeal patency in a height-dependent manner, prior studies suggest that concomitant neck flexion is likely to attenuate the beneficial effects of head elevation [5], [26] on pharyngeal size and passive P_{CRIT} in anesthetized patients [9], [11]. Walsh et al. [11] reported that neck flexion with 10-degree deviation from the neutral position produced a 4.9 cm H_2O increase in passive P_{CRIT} under propofol anesthesia, suggesting that the 5.6 degree change in neck flexion induced by head elevation produced an offset in P_{CRIT} of $\sim$ 2.7 cm H_2O. The mechanism underlying the change in upper airway collapsibility associated with head flexion and jaw opening might relate to the decrease in tracheal length and traction by flexion [11] and displacement of the tongue by jaw opening [8], [9]. These anatomical influences promote alterations in extraluminal tissue pressure on the upper airway segment and increase upper airway collapsibility by changing transmural pressure.

D. POSSIBLE LIMITATIONS OF THE CURRENT STUDY

There are several limitations to this study. First, we did not evaluate the effectiveness of the sniffing position with the air-inflatable robotic device in obese subjects in this study. Levitan *et al*. [12] described the use of a single standard pillow size, which did not always provide optimal cervical flexion for all subjects because of modest variations in weight, head circumference, and length of the neck. We suspect that obese individuals with a large neck circumference, or large-built subjects or those of taller stature might require greater robotic power to change the position of the head and mandible than normal weight individuals, to produce a comparable amount of jaw-closure and head-lift strength because of greater amounts of body fat on the neck and shoulders. Although not defined in this study, we predict that a safer airway management technique, such as continuous positive airway pressure (CPAP) treatment, should be selected in obese patients if anesthesia management is required during diagnostic imaging, a situation where the anesthesiologist cannot provide direct airway support. Second, we acknowledge that this airbag system is not a fully automated controlled device because in this study we adjusted height and confirmed optimal position of the airbag. Therefore, we cannot in all honestly state that this system does not require ''an anesthesiologist's or attendant's hand.'' However, we suppose that this conceptual robotic system for airway management may be clinically relevant and may open the door for future alternative airway management robotic devices. Thirdly, it should be noted that our findings cannot be generalized to the population at large even though our study design was powered to detect both clinically and statistically significant differences in a relatively homogeneous cohort study.

E. CLINICAL IMPLICATIONS

In this study, we also tested the effects of our airbag device on improvement of upper airway collapsibility in three obstructive sleep apnea patients in a preliminary clinical study. The study confirmed in three patients that the application of the airbag device decreased apnea and hypopnea duration and increased the lowest level of oxygen saturation by preventing sustained upper airway obstruction during sleep and propofol anesthesia. Therefore we speculate that it may be worthwhile to investigate the clinical relevance of this device in further clinical trials using a full night PSG test in a large number of OSA patients.

Adnet et al. indicated in a magnetic resonance imaging study that the sniffing position might hypothetically be obtained by flexing the neck on the chest and by elevating the head approximately 7–10 cm with a pad under the occiput [6]. They concluded that cervical extension by head elevation with jaw closure increases the distance between the mentum and cervical column. The findings of this study have substantial clinical implications. First, our data suggests that the efficacy of the airbag device is mainly associated with jaw closure, head elevation and chin lift (head extension), which leads to establishing the optimal "sniffing position." It is known that maintaining the sniffing position with jaw closure and chin lift (head extension) by a handling maneuver by an anesthesiologist or nurse is one of the best options for maintenance of upper airway patency. However, we suggest that maintenance of the sniffing position with jaw closure using a remote controlled airbag device may be a suitable alternative to direct handling by the clinician in medical situations or the bed partner in daily life situations. These considerations also have implications for optimizing head and jaw posture in the management of sedated patients during MRI or CT examinations, aiding in determination of the best use of pillows to obtain optimal head and jaw position.

Second, these findings may have implications in positional therapy for obstructive sleep apnea (OSA) patients during anesthesia and in the postoperative period, as well as during sleep. We previously reported that passive structural properties of the pharynx during non-REM sleep were similar to those in anesthetized subjects [8], [10], [25], [27]. Therefore, improving the mechanical characteristics of the upper airway during both REM sleep and anesthesia is of prime importance in the maintenance of airway patency. Since passive collapsibility of the upper airway during propofol anesthesia is similar to passive airway collapsibility during REM sleep [2], [28], our passive P_{CRIT} data simulates the mechanical influences of jaw closure in the sniffing position during sleep. Head and jaw position during sleep is mainly determined by appropriate height and placement of the pillow under the head, which cannot be controlled by the bed partner. Our data clearly show that remote controlled changes in the head and jaw position by a airbag device can promote improvement in upper airway collapsibility. Such changes during sleep could lead to improvement in upper airway obstruction during the postoperative period in OSA patients. It has been suggested that producing the sniffing position with head extension using a cervical pillow or support collar may improve mild but not severe OSA [29], [30]. However, it is impossible for us to speculate that jaw closure with head elevation and extension (sniffing position) using an air-inflatable device might also be effective for OSA patients, because we tested a limited number of OSA patients in the preliminary clinical study. We speculate that the combination of jaw closure, head elevation and head extension can decrease upper airway collapsibility during sleep in OSA patients. Further study will be needed to develop and test more sophisticated, fully automated robot device systems to produce "the desired sniffing position" with jaw closure, head elevation and head extension during sleep in OSA patients.

IV. CONCLUSION

This study indicates that the remote-controlled air-inflatable robot device can improve upper airway collapsibility by producing the sniffing position with jaw closure in normal subjects under propofol anesthesia with spontaneous breathing. This information is directly relevant to maintaining upper airway patency during anesthesia with spontaneous breathing in special medical situations, when the anesthesiologist and nurse cannot be present right by the patient's bedside.

REFERENCES

[1] D. R. Hillman *et al.*, "Evolution of changes in upper airway collapsibility during slow induction of anesthesia with propofol," *Anesthesiology*, vol. 111, no. 1, pp. 63–71, Jul. 2009.

[2] Y. Hoshino *et al.*, "The compensatory responses to upper airway obstruction in normal subjects under propofol anesthesia," *Respirat. Physiol. Neurobiol.*, vol. 166, no. 1, pp. 24–31, Mar. 2009.

[3] S. Isono, "Obstructive sleep apnea of obese adults: Pathophysiology and perioperative airway management," *Anesthesiology*, vol. 110, no. 4, pp. 908–921, Apr. 2009.

[4] T. Ayuse *et al.*, "The effect of gender on compensatory neuromuscular response to upper airway obstruction in normal subjects under midazolam general anesthesia," *Anesthesia Analgesia*, vol. 109, no. 4, pp. 1209–1218, Oct. 2009.

[5] S. Isono *et al.*, "Sniffing position improves pharyngeal airway patency in anesthetized patients with obstructive sleep apnea," *Anesthesiology*, vol. 103, no. 3, pp. 489–494, Sep. 2005.

[6] F. Adnet *et al.*, "Randomized study comparing the 'sniffing position' with simple head extension for laryngoscopic view in elective surgery patients," *Anesthesiology*, vol. 95, no. 4, pp. 836–841, Oct. 2001.

[7] I. Takenaka, K. Aoyama, T. Iwagaki, H. Ishimura, and T. Kadoya, "The sniffing position provides greater occipito-atlanto-axial angulation than simple head extension: A radiological study," *Can. J. Anesthesia*, vol. 54, no. 2, pp. 129–133, Feb. 2007.

[8] T. Ayuse *et al.*, "Mouth-opening increases upper-airway collapsibility without changing resistance during midazolam sedation," *J. Dental Res.*, vol. 83, no. 9, pp. 718–722, Sep. 2004.

[9] S. Isono, A. Tanaka, Y. Tagaito, T. Ishikawa, and T. Nishino, "Influences of head positions and bite opening on collapsibility of the passive pharynx," *J. Appl. Physiol.*, vol. 97, no. 1, pp. 339–346, Mar. 2004.

[10] M. Kobayashi *et al.*, "Effect of head elevation on passive upper airway collapsibility in normal subjects during propofol anesthesia," *Anesthesiology*, vol. 115, no. 2, pp. 273–281, Aug. 2011.

[11] J. H. Walsh, K. J. Maddison, P. R. Platt, D. R. Hillman, and P. R. Eastwood, "Influence of head extension, flexion, and rotation on collapsibility of the passive upper airway," *Sleep*, vol. 31, no. 10, pp. 1440–1447, Oct. 2008.

[12] R. M. Levitan, C. C. Mechem, E. A. Ochroch, F. S. Shofer, and J. E. Hollander, "Head-elevated laryngoscopy position: Improving laryngeal exposure during laryngoscopy by increasing head elevation," *Ann. Emergency Med.*, vol. 41, no. 3, pp. 322–330, Mar. 2003.

[13] D. C. Thut, A. R. Schwartz, D. Roach, R. A. Wise, S. Permutt, and P. L. Smith, "Tracheal and neck position influence upper airway airflow dynamics by altering airway length," *J. Appl. Physiol.*, vol. 75, no. 5, pp. 2084–2090, Nov. 1993.

[14] A. Reber, S. G. Wetzel, K. Schnabel, G. Bongartz, and F. J. Frei, "Effect of combined mouth closure and chin lift on upper airway dimensions during routine magnetic resonance imaging in pediatric patients sedated with propofol," *Anesthesiology*, vol. 90, no. 6, pp. 1617–1623, Jun. 1999.

[15] P. M. Kleffner, P. C. Collins, and C. P. Collins, "Cervical support collar: A substitute to the jaw thrust/chin lift methods of airway management during oral maxillofacial surgeries," *J. Oral Maxillofacial Surgery, Official J. Amer. Assoc. Oral Maxillofacial Surgeons*, vol. 68, no. 3, pp. 684–685, Mar. 2010.

[16] P. R. Eastwood, I. Szollosi, P. R. Platt, and D. R. Hillman, "Collapsibility of the upper airway during anesthesia with isoflurane," *Anesthesiology*, vol. 97, no. 4, pp. 786–793, Oct. 2002.

[17] S. P. Patil, H. Schneider, J. J. Marx, E. Gladmon, A. R. Schwartz, and P. L. Smith, "Neuromechanical control of upper airway patency during sleep," *J. Appl. Physiol.*, vol. 102, no. 2, pp. 547–556, Feb. 2007.

[18] A. R. Schwartz *et al.*, "The hypotonic upper airway in obstructive sleep apnea: Role of structures and neuromuscular activity," *Amer. J. Respirat. Critical Care Med.*, vol. 157, no. 4, pp. 1051–1057, Apr. 1998.

[19] A. Boudewyns *et al.*, "Abbreviated method for assessing upper airway function in obstructive sleep apnea," *Chest*, vol. 118, no. 4, pp. 1031–1041, Oct. 2000.

[20] J. Hosselet, I. Ayappa, R. G. Norman, A. C. Krieger, and D. M. Rapoport, "Classification of sleep-disordered breathing," *Amer. J. Respirat. Critical Care Med.*, vol. 163, no. 2, pp. 398–405, Feb. 2001.

[21] A. R. Gold and A. R. Schwartz, "The pharyngeal critical pressure: The whys and hows of using nasal continuous positive airway pressure diagnostically," *Chest*, vol. 110, no. 4, pp. 1077–1088, Oct. 1996.

[22] J. P. Kirkness *et al.*, "Performance characteristics of upper airway critical collapsing pressure measurements during sleep," *Sleep*, vol. 34, no. 4, pp. 459–467, 2011.

[23] A. R. Gold, P. L. Smith, and A. R. Schwartz, "The study of maximal nasal inspiratory flow in humans," *J. Appl. Physiol.*, vol. 81, no. 2, pp. 627–635, Aug. 1996.

[24] A. R. Schwartz, P. L. Smith, R. A. Wise, and S. Permutt, "Induction of upper airway occlusion in sleeping individuals with subatmospheric nasal pressure," *J. Appl. Physiol.*, vol. 64, no. 2, pp. 535–542, Feb. 1988.

[25] H. Ikeda, T. Ayuse, and K. Oi, "The effects of head and body positioning on upper airway collapsibility in normal subjects who received midazolam sedation," *J. Clin. Anesthesia*, vol. 18, no. 3, pp. 185–193, May 2006.

[26] M. P. Boidin, "Airway patency in the unconscious patient," *Brit. J. Anaesthesia*, vol. 57, no. 3, pp. 306–310, 1985.

[27] T. Inazawa *et al.*, "Effect of mandibular position on upper airway collapsibility and resistance," *J. Dental Res.*, vol. 84, no. 6, pp. 554–558, Jun. 2005.

[28] P. R. Eastwood, I. Szollosi, P. R. Platt, and D. R. Hillman, "Comparison of upper airway collapse during general anaesthesia and sleep," *Lancet*, vol. 359, no. 6, pp. 1207–1209, Apr. 2002.

[29] C. A. Kushida, C. M. Sherrill, S. C. Hong, L. Palombini, P. Hyde, and W. C. Dement, "Cervical positioning for reduction of sleep-disordered breathing in mild-to-moderate OSAS," *Sleep Breathing*, vol. 5, no. 2, pp. 71–78, Jun. 2001.

[30] M. A. Skinner, R. N. Kingshott, D. R. Jones, and D. R. Taylor, "Lack of efficacy for a cervicomandibular support collar in the management of obstructive sleep apnea," *Chest*, vol. 125, no. 1, pp. 118–126, Jan. 2004.

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