

# Manual In-line Stabilization Increases Pressures Applied by the Laryngoscope Blade during Direct Laryngoscopy and Orotracheal Intubation

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**Background:** Manual in-line stabilization (MILS) is recommended during direct laryngoscopy and intubation in patients with known or suspected cervical spine instability. Because MILS impairs glottic visualization, the authors hypothesized that anesthesiologists would apply greater pressure during intubations with MILS than without.

**Methods:** Nine anesthetized and pharmacologically paralyzed patients underwent two sequential laryngoscopies and intubations, one with MILS and one without, in random order. A transducer array along a Macintosh 3 laryngoscope blade continuously measured applied pressures, and glottic view was characterized.

**Results:** With MILS, glottic visualization was worse in six patients, and intubation failure occurred in two of these six patients. Maximum laryngoscope pressure at best glottic view was greater with MILS than without ( $717 \pm 339$  mmHg vs.  $363 \pm 121$  mmHg, respectively;  $n = 8$ ;  $P = 0.023$ ). Other measures of pressure application also indicated comparable increases with MILS.

**Conclusion:** Pressures applied to airway tissues by the laryngoscope blade are secondarily transmitted to the cervical spine and result in cranio-cervical motion. In the presence of cervical instability, impaired glottic visualization and secondary increases in pressure application with MILS have the potential to increase pathologic cranio-cervical motion.

bation are urgently needed in patients with known or suspected cervical spine instability.<sup>1</sup> By externally limiting head and neck movement, MILS is presumed to minimize pathologic cervical spine motion that might otherwise occur at unstable segments during conventional DL and intubation. This potential benefit of MILS is counterbalanced by the fact that MILS significantly worsens glottic visualization.<sup>2-6</sup> Impaired glottic visualization increases time required for intubation<sup>2,5</sup> and the likelihood of failed intubation.<sup>2</sup>

Impaired glottic visualization with MILS may result in another potential hazard in patients with unstable cervical spines. Hastings *et al.* reported anesthesiologists apply greater lifting force with the laryngoscope when glottic visualization is impaired.<sup>7</sup> Because MILS impairs glottic visualization, we hypothesized that anesthesiologists would apply greater pressures during DL and intubation with MILS than they would without it. To test our hypothesis, we constructed a prototype pressure-sensing laryngoscope blade.

CURRENT Advanced Trauma Life Support standards indicate that manual in-line stabilization (MILS) should be used when direct laryngoscopy (DL) and tracheal intu-

## Materials and Methods

### Subjects

This study was conducted in accordance with guidelines set forth by the University of Iowa Institutional Review Board for Human Subjects (Iowa City, Iowa). All patients and all anesthesiologists gave written informed consent before participation.

This study's predefined primary outcome measure was maximum pressure applied by the laryngoscope blade (any transducer) at the point of best glottic visualization immediately before endotracheal tube insertion. To estimate patient enrollment, we performed simulations with an intubation manikin (Airway Management Trainer [25000033]; Laerdal Medical Corporation, Wappingers Falls, NY). In these simulations, mean individual difference in maximal pressure between intubations with and without MILS was  $465 \pm 1086$  mmHg (mean  $\pm$  SD). Twenty patients were required to detect a 750-mmHg pressure difference between MILS and non-MILS techniques (SD = 1000 mmHg, two-sided *t* test,  $\alpha = 0.05$ ,  $1 - \beta = 0.80$ ). Accordingly, we planned to enroll up to 20 patients. However, because we were uncertain how well manikin data predicted human responses, we planned *a priori* to conduct an interim analysis after randomizing 10 patients. On the basis of the interim

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analysis (see Results, paragraph 3), this study was stopped after 10 patients.

Study patients were a convenience sample of adults (American Society of Anesthesiologists class I or II) undergoing elective surgery requiring general anesthesia and oral tracheal intubation using pharmacological paralysis. Inclusion criteria were aimed at enrolling patients who would be easy to intubate with a Macintosh 3 blade: (1) Mallampati airway class I or II,<sup>8</sup> (2) thyromental distance of at least 6 cm, (3) clinically unrestricted head and neck extension, (4) ability to place lower incisors anterior to upper incisors, (5) height between 1.53 and 1.83 m, and (6) body mass index of no more than 30 kg/m<sup>2</sup>. Exclusion criteria were aimed at eliminating patients who might be at increased risk of intubation-related and/or other study-related complications: (1) previously difficult DL and intubation, (2) maxillary incisors that were loose or in poor condition, (3) cervical spine instability or cervical myelopathy, (4) need for a rapid sequence intubation, (5) gastroesophageal reflux disease, regardless of symptom status, (6) symptomatic asthma or other reactive airway disease, (7) coronary artery disease, regardless of symptom status, (8) any preoperative systolic blood pressure greater than 170 mmHg or diastolic blood pressure greater than 90 mmHg, and (9) contraindication to administration of 100% oxygen. Consenting patients were assigned a study identification number to link them to a randomization sequence.

Faculty anesthesiologists (19 ± 10 [mean ± SD] years of postresidency experience) who were routinely assigned to provide consenting patients' anesthesia care were invited to participate. They were informed that they would intubate each patient twice, once with MILS and once without, and that laryngoscope pressures would be measured. To minimize potential bias, anesthesiologists were not informed of the primary study hypothesis. To prevent learning, each anesthesiologist participated in this study only once. To limit dissemination of experience, participating anesthesiologists were not informed of any results and were asked to avoid sharing their experience with others until after study completion.

#### *Intubation Protocol*

Each anesthesiologist was free to use any anesthetic agent or adjunct as long as it was consistent with the following general protocol. Each patient was supine on a flat operating table with their occiput resting on a pillow. After establishment of standard respiratory and hemodynamic monitoring and preoxygenation, intravenous premedication (0.015–0.083 mg/kg midazolam and/or 0.80–1.6 mg/kg lidocaine) was administered if desired. General anesthesia was induced with 1.7–4.0 mg/kg intravenous propofol with supplemental intravenous opioids (0.6–4.0 µg/kg fentanyl or 40 µg/kg alfentanil), and mask ventilation was established. The patient was ventilated with a volatile anesthetic (desflurane, sevoflurane, or isoflurane) at 1–2 minimal alveolar concentration inspired concentration in oxygen before intravenous administration of a nondepolarizing neuromuscular blocking agent (0.44–1.40 mg/kg rocuronium, 0.06–0.14 mg/kg vecuronium, or 0.21 mg/kg mivacurium). The patient was ventilated by mask for 4–6 min until complete pharmacological paralysis was achieved as indicated by no response to a supramaximal train-of-four stimulus of the ulnar nerve at the wrist. Thereafter, a sealed opaque envelope with a matching patient identification number was opened, revealing the randomized order of two sequential intubations, either (1) conventional intubation first and intubation with MILS second, or (2) intubation with MILS first and conventional intubation second.

Just before the first intubation, the pillow was removed so that the patient's shoulders and occiput rested on the operating room table. The patient's head and neck were placed in neutral position by a study physician. The participating anesthesiologist then performed the first DL (with MILS or without) and intubated the patient's trachea. Correct endotracheal tube position was verified after the first intubation, and the patient was ventilated with the same volatile anesthetic in oxygen at 1–2 minimal alveolar concentration inspired concentration. The patient was extubated when hemodynamically stable and adequately oxygenated and ventilated, and mask ventilation with volatile agent was resumed. Anesthetic medications were administered and/or volatile agent concentration adjusted before the second intubation, although no additional muscle relaxants were given. Approximately 3–5 min after the first intubation, the patient's head and neck were again positioned neutral, and a second intubation was performed. After the second intubation, correct endotracheal tube position was verified and the protocol was complete. Surgery then proceeded.

During each DL and intubation, anesthesiologists were instructed to achieve the best possible glottic view using only the laryngoscope. Manual head and neck movement and external laryngeal manipulation were not permitted. Use of an endotracheal tube stylet was also not permitted. Anesthesiologists were instructed to verbally indicate when each event in the intubation sequence occurred: E1, starting intubation; E2, epiglottis first seen; E3, final position (best glottic view) immediately before endotracheal tube insertion; E4, intubation complete. Laryngoscope pressures were recorded throughout both DLs and intubations, and data were electronically marked at each of the four events designated by the anesthesiologist. Laryngoscope pressure data were not made available to participating anesthesiologists during or after the study. After each intubation, anesthesiologists rated glottic visualization using the four-point scale

and diagram of Cormack and Lehane: 1, most of the glottis visible; 2, only the posterior aspect of the glottis visible (at least the arytenoids); 3, no part of the glottis seen, but epiglottis seen; 4, not even the epiglottis seen.<sup>9</sup>

Preintubation head and neck positioning and MILS were performed by the same study physician in all cases. Standing or kneeling to the left of the anesthesiologist, both mastoid processes were grasped by the fingertips, and the occiput was cupped in the hands. While avoiding axial traction, forces equal and opposite to those created by the anesthesiologist were applied so as prevent or minimize head and neck movement.<sup>2,4,10-12</sup>

All patients underwent at least one follow-up interview by study personnel within 24 h after surgery. Patients were asked specifically about the presence and severity of sore throat, voice change, voice pain, swallowing difficulties, or dental damage. Positive responses resulted in additional follow-up until symptom resolution. Each anesthesiologist was asked to report any complication they considered to have been study related.

#### Data Acquisition and Processing

The pressure-sensing laryngoscope blade was a conventional Macintosh 3 blade modified to measure applied pressures. As shown in figure 1, six miniature pressure transducers (Precision Measurements, Ann Arbor, MI) were equally spaced and mounted in midline along the blade with high-strength cyanoacrylate adhesive. The transducers were encased within a thin layer of biocompatible high-strength polyurethane to maintain a smooth surface. Transducer output voltages were transformed by a standard analog-to-digital converter and interfaced with a laptop computer (Toshiba, New York, NY). Voltage and time data were sampled at 9 Hz with data collection software (InstruNet; Omega Engineering, Stamford, CT). Transducer calibration was accomplished by placing the instrumented blade in a pressure chamber and recording voltages from each transducer at air pressure levels between 500 and 5000 mmHg. Linear pressure-voltage regressions were generated, and the standard Pearson correlation coefficient was greater than 0.95 for all calibrations. Transducers were recalibrated after every two patients. Before each use, the blade was

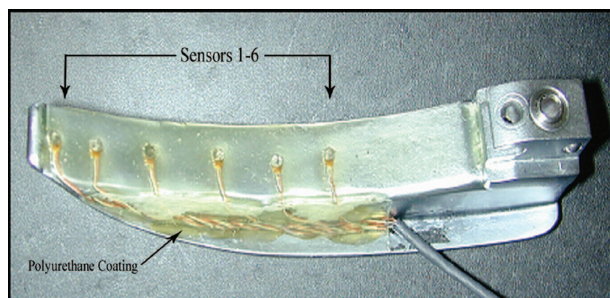


Fig. 1. Pressure-sensing Macintosh 3 laryngoscope blade. Sensor 1 is the most distal, and sensor 6 is the most proximal.

cleansed according to standard clinical procedures used at the University of Iowa.

#### Statistical Analyses

As described in Results, one patient (patient 7) was excluded from all data analyses because of intubation difficulty and abandonment of study protocols.

Our predefined primary outcome measure was maximum pressure (any transducer) at final position (best glottic view) just before endotracheal tube insertion. However, in one patient (patient 6), the anesthesiologist was not able to visualize the glottis with MILS and did not attempt intubation. As a consequence, the anesthesiologist did not designate a final position (E3, best glottic view) time point. Therefore, for our primary outcome measure, statistical analyses were limited to the 8 patients in whom final position (best glottic view) was designated by the anesthesiologist during both intubation attempts. Likewise, measurements of time for intubation and laryngoscope center of pressure (see next paragraph) were limited to these 8 patients.

To characterize the distribution of pressure along the laryngoscope blade, the location of the center of pressure (COP) along the blade was calculated using the following formula:

$$\text{COP} = \frac{\sum_{i=1}^n p_i s_i}{\sum_{i=1}^n p_i}$$

where  $p_i$  is the pressure of the  $i$ th sensor and  $s_i$  is the distance from the reference point to the  $i$ th sensor. The reference point was taken to be the distal tip of the laryngoscope blade, with the distance (in cm) being measured linearly along the blade towards the handle (distal to proximal measurement).

*Post hoc* inspection of the data showed the designated time of final position (E3, best glottic view) usually did not correspond well to either maximum pressure during intubation or to the proximate insertion of the endotracheal tube (Results, paragraph 4). Therefore, as an alternate (secondary) measure of maximum pressure during intubation, maximum pressure at any time after visualization of the epiglottis (any transducer) was compared between DLs with and without MILS, irrespective of whether or not intubation was attempted. Thus, all 9 patients were included in this measure. *Post hoc* inspection of the data also showed that laryngoscope pressures varied widely among transducers; in some cases, pressures markedly oscillated during DL and intubation. For these reasons, a single pressure measurement from a single transducer seemed potentially inadequate to characterize pressures applied over the length of laryngo-

scope blade throughout the entire intubation sequence. Accordingly, as another secondary measure of pressure application, each transducer's continuous pressure-time curve was numerically integrated (representing the area under the curve) over the entire laryngoscopy sequence, and the values from all transducers were summed. The summed value is a quantitative measure of the total work (pressure  $\times$  time) applied by the anesthesiologist during intubation. In patient 6, the anesthesiologist abandoned the intubation attempt; therefore, this comparison of total work during intubation (with MILS and without) was limited to the eight patients in whom intubation was attempted under both conditions. Finally, for all patients, the summed pressure-time integration was divided by the total time of laryngoscopy. This secondary analysis produced a cumulative pressure average that was independent of both pressure oscillations and the time of each DL; data from all nine patients was used for this comparison. The duration of laryngoscopy was the time difference between event E4 (intubation complete) and event E1 (starting intubation).

The Wilcoxon signed rank test was used to compare pressure values between conventional DL (no MILS) and MILS. The Spearman rank correlation coefficient was used to assess the relationship between change in glottic view and change in maximum applied pressure. All *P* values are two-sided and exact. Because interim analysis carries an increased risk of a type 1 error, the threshold *P* value for significance for the primary outcome measure was adjusted to a more conservative value (*P* = 0.025) according to the method of DeMets and Lan<sup>15</sup>. All statistical analyses were performed using SigmaStat (Systat Software, Inc., San Jose, CA).

## Results

This study was stopped after randomizing ten patients. One male patient (patient 7) who was randomized to MILS first had a grade 4 glottic view and was considered by the faculty anesthesiologist to require a Macintosh 4 blade. Accordingly, study protocols were abandoned. All data from patient 7 were excluded from analysis.

Demographic characteristics of the nine patients who completed the study are summarized in table 1. Intubation characteristics are summarized in table 2. Compared

**Table 1. Patient Demographics**

Age, yr	39 $\pm$ 11 (36, 27–63)
Sex, n	
Male	1
Female	8
Height, m	1.68 $\pm$ 0.08 (1.69, 1.55–1.78)
Weight, kg	67 $\pm$ 9 (67, 50–77)
Body mass index (kg/m <sup>2</sup> )	23.6 $\pm$ 2.0 (23.7, 20.3–25.4)

Data are presented as mean  $\pm$  SD (median, range) unless otherwise indicated.

**Table 2. Laryngoscopy and Intubation Characteristics**

	No MILS	MILS
Glottic view, n		
1	5	1
2	4	3
3	0	4
4	0	1
Intubation success, n	9	7*
Intubation time, sec (n = 8)†	21.9 $\pm$ 8.4	27.2 $\pm$ 6.8

Data are presented as mean  $\pm$  SD (median, range) unless otherwise indicated.

\* In patient 5, an esophageal intubation occurred with MILS. In patient 6, with MILS, the intubation attempt was abandoned because of poor glottic visualization. † Data from 8 patients for whom an intubation attempt was made with MILS and without. Patient 6 was excluded because the intubation attempt with MILS was abandoned.

MILS = manual in-line stabilization.

with conventional DL, glottic view with MILS was worse in six patients (one grade worse in two patients, two grades worse in three patients, three grades worse in one patient) and was unchanged in three patients. Without MILS, all patients were successfully intubated. With MILS, an esophageal intubation occurred in patient 5; in patient 6, the anesthesiologist did not attempt intubation because of poor glottic visualization. Patient 6 also sustained minor injury to an upper incisor. There were no other study-related adverse events. For the eight patients in whom intubation was attempted with MILS and without, the mean time required for endotracheal tube insertion was greater with MILS.

Laryngoscope pressure measurements are summarized in table 3, and examples are shown in figure 2. This study's predefined primary outcome measure, maximum pressure (any transducer) at final position (best glottic view) as designated by the anesthesiologist was greater with MILS than without (717  $\pm$  339 mmHg *vs.* 363  $\pm$  121 mmHg, respectively; n = 8; *P* = 0.023). In these eight patients, the center of pressure at final position (best glottic view) was not significantly greater with MILS than without, but it showed a tendency toward a more proximal (cephalad) pressure application. *Post hoc* inspection of the data showed that laryngoscope pressures vary widely among sensors and, in some patients, inspection showed moderate to marked oscillations during DL and intubation (fig. 2, patients 3 and 6). To incorporate these elements, the continuous pressure-time curve from each transducer was numerically integrated over the entire intubation sequence, and the integrated values were summed; this value is the total work of intubation. Total work of intubation was greater with MILS than without (658  $\pm$  144 mmHg  $\cdot$  sec *vs.* 287  $\pm$  124 mmHg  $\cdot$  sec, respectively; n = 8; *P* = 0.008).

*Post hoc* inspection of the data also showed the time designated by the anesthesiologists as final position (E3, best glottic view) usually did not correspond to maxi-

**Table 3. Laryngoscope Pressures**

	No MILS	MILS	P Value
Maximum pressure at final position (best glottic view) designated by anesthesiologist, mmHg; (n = 8)*	363 ± 121	717 ± 339	0.023
Laryngoscope center of pressure at final position (best glottic view) defined by anesthesiologist, cm from distal tip; (n = 8)*	4.5 ± 0.9	5.1 ± 1.0	0.148
Summed pressure-time integral from all transducers (total work) for intubation, mmHg · sec; (n = 8)*	287 ± 124	658 ± 145	0.008
Maximum pressure any time after epiglottis seen, mmHg; (n = 9)†	751 ± 438	1278 ± 426	0.027
Time-adjusted summed pressure, mmHg; (n = 9)†	14 ± 5	25 ± 9	0.016

All values reported as mean ± SD.

\* Data from 8 patients for whom this point (Event 3) was designated by the anesthesiologist during both intubations. Patient 6 was excluded because, with MILS, the intubation attempt was abandoned. † Data from all 9 patients for whom laryngoscopy was performed, regardless of intubation attempt and/or success. MILS = manual in-line stabilization (MILS).

imum pressure occurring during intubation. Commonly, the transducer with the greatest pressure value had a discrete pressure peak 2–3 s before the anesthesiologists' designation of final position (E3, best glottic view). This pressure peak was followed by a progressive 15–50% decrease in pressure over the next 2–3 s to a plateau value (fig. 2, patients 3, 4, and 5). Therefore, as a secondary outcome measure, we compared maximum laryngoscope pressures with MILS and without (any transducer) at any time after visualization of the epiglottis, regardless of whether or not intubation was attempted. Maximum pressure at any time after the epiglottis was seen was greater with MILS than without ( $1278 \pm 426$  mmHg *vs.*  $751 \pm 438$  mmHg, respectively; n = 9;  $P = 0.027$ ). There was an association between change (deterioration) in glottic view with MILS and the increase in maximally applied laryngoscope pressure (n = 9; Spearman rank correlation coefficient = 0.702;  $P = 0.030$ ). Finally, for all patients, the summed pressure-time integral was divided by the total time of laryngoscopy, regardless of intubation attempt or success. This calculation produced a summed pressure that was independent of pressure distribution, pressure oscillation, and laryngoscopy duration. This time-adjusted summed pressure was greater with MILS than without ( $25 \pm 9$  mmHg *vs.*  $14 \pm 5$  mmHg, respectively; n = 9;  $P = 0.016$ ).

## Discussion

### Key Findings and Clinical Relevance

Prievously conducted studies of intubation forces have used transducers placed in the laryngoscope handle.<sup>7,14–17</sup> This study is the first to measure applied pressures distributed along the length of the laryngoscope blade during DL and intubation and to assess the effect of MILS upon these pressures. This study shows DL with MILS results in a doubling of applied pressure as compared to conventional DL.

Pressures applied to airway tissues by the laryngoscope blade are secondarily transmitted to the cervical spine and result in cranio-cervical motion (extension).<sup>18</sup> By definition, unstable spines move abnormally in response to physiologically normal forces. Consequently, when applied to an unstable cervical spine, forces of DL can result in pathologic movement of bony structures, resulting in nerve root and/or spinal cord compression. Consequently, although rare, DL and intubation in the presence of cervical instability may cause neurologic injury.<sup>19,20</sup> Because of this concern, Advanced Trauma Life Support guidelines have stated for more than 20 yr that MILS is to be used when DL and intubation are needed in patients with known or suspected cervical instability.<sup>1</sup> However, it may be time for a reappraisal of MILS.<sup>21</sup>

In patients with normal cervical spines, MILS has been shown to decrease cervical motion (extension) by approximately 50% compared to conventional DL.<sup>5</sup> In contrast, in the presence of *unstable* cervical segments, the evidence that MILS decreases abnormal cervical motion as compared to conventional DL is exceedingly weak. In fact, there is only a single study that suggests any benefit with MILS during conventional DL.<sup>22</sup> In five cadavers with C<sub>5,6</sub> instability, subluxation and angulation at the unstable segment were numerically less during DL with MILS than without.<sup>22</sup> However, no statistical comparisons were made because of a small number of data points and incomplete data. In contrast, in 16 cadavers with partial (largely posterior) instability at C<sub>4–5</sub>, MILS did not decrease abnormal angulation at the unstable segment during DL as compared to conventional DL alone.<sup>11</sup> In a subsequent study in 10 cadavers with complete (anterior and posterior) instability at C<sub>4–5</sub>, intubation with MILS significantly *increased* the amount of subluxation at the unstable segment as compared to conventional DL alone.<sup>23</sup> In this latter study, increased subluxation with MILS can only be explained by increased force application across the unstable segment with MILS.

In our study, we observed a significant correlation between change (worsening) in glottic view with MILS

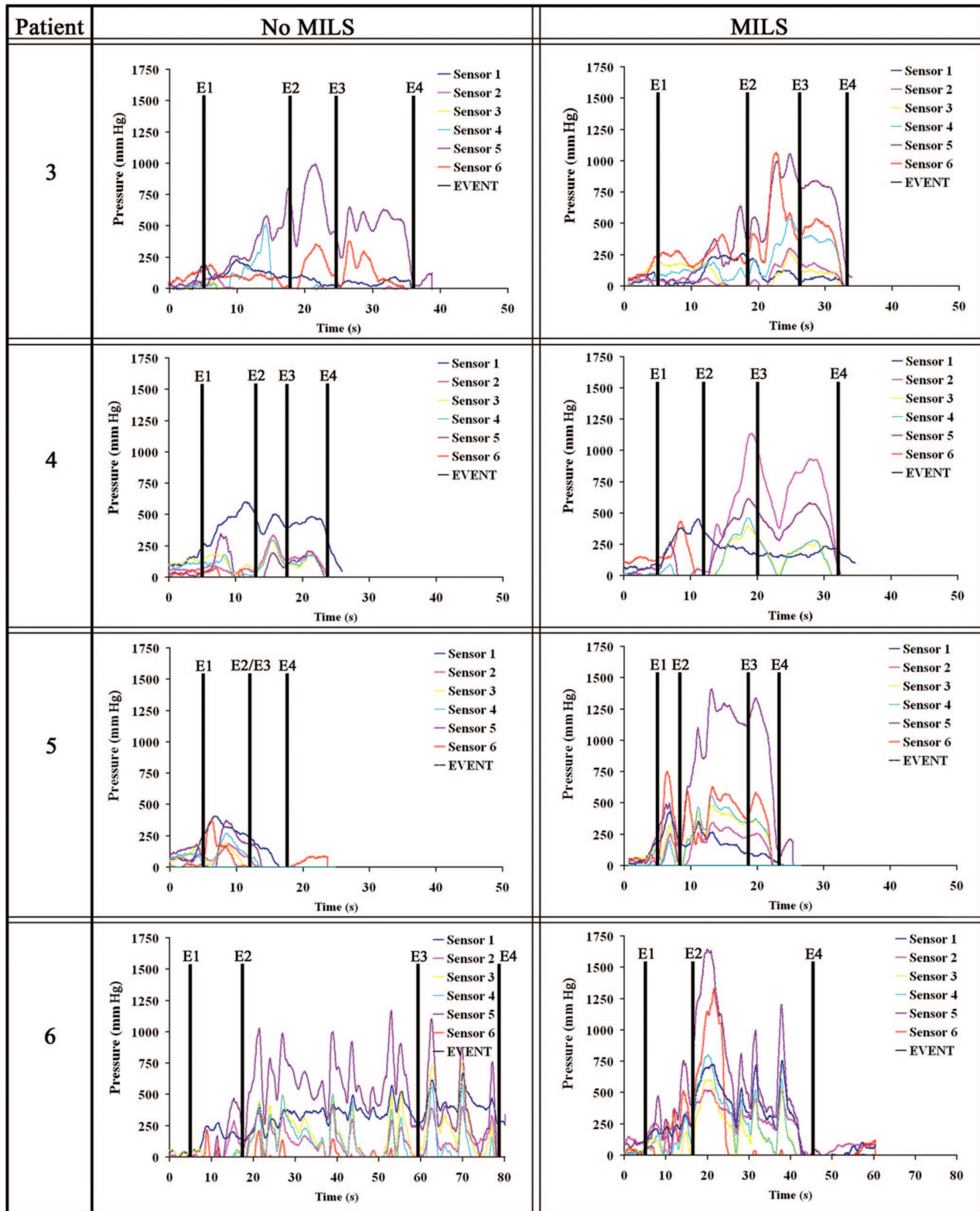


Fig. 2. Examples of laryngoscope pressure recordings obtained during intubations without manual in-line stabilization (No MILS) (*left*), and with MILS (*right*). The pressure values for each sensor are color coded as shown in the figure (e.g., sensor 3—yellow, sensor 6—red). Black vertical event markers indicate points in the intubation sequence designated by the anesthesiologist: E1 = starting intubation, E2 = epiglottis first seen, E3 = final position (best glottic view) immediately before endotracheal tube insertion, and E4 = intubation complete. For patient 5 (no MILS), E2 and E3 were reported simultaneously. For patient 6 (MILS), E3 is missing because the intubation attempt was abandoned because of poor glottic visualization.

and the associated increase in maximum applied pressure. Thus, this study establishes that with deterioration of glottic view, MILS results in an increase in the pressure applied by the laryngoscope blade as compared to conventional DL and intubation alone. Approximately twice as much pressure was applied during intubation with MILS than without it. Therefore, with MILS, impaired glottic visualization and secondary increases in force application have the potential to actually *increase* rather than decrease pathologic spine movement in the presence of cervical instability.

This concept is supported by the study of Gerling *et al.*, conducted in 14 cadavers with complete instability at C<sub>5,6</sub>.<sup>24</sup> Conventional DL and intubation were not performed; instead, intubation was performed with MILS or in the presence of rigid cervical collar and head fixation. Intubation with MILS was associated with significantly less subluxation at the unstable segment compared to intubation with collar/head fixation.<sup>24</sup> Notably, glottic visualization was significantly worse with collar/head fixation than with MILS. The authors suggested worse glottic visualization with collar/head fixation as compared to MILS may have resulted in additional force application with the laryngoscope and in increased pathologic motion. Thus, *external* cervical stabilization methods (e.g., MILS, collars) appear to have limited capacity to offset the increased force application that they engender secondary to limited glottic visualization. One reason why this may be so is that increased intubation forces are applied *internally*, whereas stabilization forces are applied externally.

Therefore, when DL and intubation are needed in patients with known or suspected cervical instability, clinicians must consider the drawbacks of MILS—impaired glottic visualization, greater intubation time, greater likelihood of intubation failure, and greater laryngoscope pressure application—against a standard that has literally no objective evidence of benefit.

#### Other Observations

In contrast to our preliminary observations with an intubation manikin, maximum laryngoscope pressure during DL and intubation did not correspond well to the point designated by anesthesiologists as final position (E3, best glottic view). Instead, maximum applied pressure often occurred 2–3 s before anesthesiologists' reports of best glottic view and followed by a progressive 10–50% decrease in pressure over that interval. This observation is consistent with the findings of Hastings *et al.*, who measured laryngoscope lifting force with a force transducer in the handle.<sup>7</sup> While maintaining a constant laryngeal view, Hastings *et al.* observed laryngoscope forces decreased to approximately 70% of peak values with a half-time of 4 s. The authors hypothesized that the decrease was the result of stress relaxation of pharyngeal tissues passively stretched during laryngos-

copy. Bucx *et al.* used a similar device, and their pressure tracings demonstrate the same phenomenon.<sup>14</sup>

We also observed that applied pressures were often not constant but were, instead, occasionally highly oscillatory. Although not specifically reported, the force tracings of Bucx *et al.* also demonstrate this phenomenon.<sup>14</sup> Therefore, it appears that anesthesiologists may differ in intubation technique, with some employing a repetitive lift-then-relax approach to visualize the glottis (fig. 2, patients 3 and 6) and others applying more constant pressure (fig. 2, patients 4 and 5). Another apparent difference in intubation technique involves application of maximum pressure along the length of the blade. Without MILS, three anesthesiologists applied maximum pressure with the more distal part of the laryngoscope blade (fig. 2, patients 4 and 5), whereas the remaining six anesthesiologists applied maximum pressure with the more proximal part of the laryngoscope blade. Thus, although the Macintosh-3 blade is in common use, there appears to be marked variability among anesthesiologists in *how* it is used.

#### Limitations

Several limitations must be kept in mind when considering the findings of this study. First, this is a small study, involving only a few patients and anesthesiologists. Nevertheless, on the basis of a preplanned interim analysis, we stopped this study after randomizing only 10 of the projected 20 patients. Because interim analysis carries an increased risk of a type 1 error, the threshold *P* value for significance should be adjusted to a more conservative value.<sup>15</sup> Our predetermined primary outcome measure, maximum pressure (any transducer) at final position (best glottic view) as designated by the anesthesiologist, satisfied this criterion. Most, but not all, of the secondary (alternative) outcome measures also satisfied this criterion. Because the MILS component of the protocol resulted in an esophageal intubation in one patient and a failed intubation and dental injury in another, we decided that the patient-related risks of continuing this protocol outweighed the statistical benefits of continuing.

We selected maximum pressure (any transducer) at final position (best glottic view) as our primary outcome measure because it was conceptually simple. However, our findings suggest that this outcome measure may not adequately characterize the complex variations in location and magnitude of applied pressures during DL. Furthermore, it is not currently known which index of laryngoscope pressure might be most biomechanically relevant in the setting of an unstable spine; specifically, it is not clear whether maximum, mean, or total pressure is most relevant and/or whether the duration of force application is also an important factor. Accordingly, we assessed the effect of MILS using a variety of secondary measures that incorporated variability in one or more of

these elements. Nevertheless, MILS was associated with increases in applied pressure with all of these secondary measures.

In clinical practice, cricoid pressure and/or external laryngeal manipulation are often used in concert with MILS to decrease the risk of aspiration and/or to improve glottic view. However, in our study, these maneuvers were not permitted. The rationale for this limitation was to ensure that all pressures applied to the airway could be measured. Wood *et al.* reported that cricoid pressure improved glottic visualization in 25% patients undergoing laryngoscopy with MILS.<sup>3</sup> Therefore, in our study, the absence of cricoid pressure likely maximized the impairment of glottic visualization resulting from MILS and, secondarily, increased applied pressures.

Patients in this study had clinically normal cervical spines and were selected for ease of intubation. Thus, our patients differed from patients who would most commonly require MILS during intubation—patients with known or suspected acute cervical spine injury and/or instability. With acute cervical spine injuries, changes can occur in the airway and perispinal tissues that can affect airway structure (*e.g.*, airway deviation from hematomas, prevertebral swelling) and/or intubation biomechanics (*e.g.*, muscle rigidity). These changes would generally be expected to unfavorably affect glottic visualization during DL. Therefore, patients who require urgent/emergent intubation in the setting of acute cervical spine injury are more likely to be difficult to intubate than the patients in this study. Accordingly, it is possible that the application of MILS in patients with acute cervical spine injuries may impair glottic visualization to an even greater extent than was observed in this study and may therefore be associated with even greater pressure application.

Although the choice and dose of anesthetic agents and paralytics differed among the patients of this study, all patients were fully pharmacologically paralyzed during both intubations. Because of this and because each patient served as their own control (being intubated with and without MILS), differences among patients in anesthetic agents and doses are not likely to have meaningfully affected the results and conclusions of this study.

Finally, our study population was disproportionately female. However, two studies have shown that, when adjusted for height and weight, gender does not influence the forces of laryngoscopy.<sup>15,17</sup> Therefore, it is not likely that gender imbalance meaningfully affected the results and conclusions of this study.

In summary, we observed that DL and orotracheal intubation with MILS resulted in a doubling of applied pressure by the laryngoscope blade. In the presence of

cervical instability, impaired glottic visualization and secondary increases in pressure application with MILS have the potential to increase pathologic cranio-cervical motion.

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