

## ORIGINAL RESEARCH

# Design, development, and face validation of an intubation simulation device using real-time force data feedback

Gopikrishna M. Rao<sup>1</sup>  | Vishwanatha M. Rao BE<sup>2</sup> | Jeremy Juang MD<sup>3</sup>  |  
Justin Benoit MD<sup>3</sup> | Allen L. Feng MD<sup>4</sup>  | Phillip C. Song MD<sup>4</sup> 

<sup>1</sup>Department of Medicine, Tufts Medical School, Boston, MA, USA

<sup>2</sup>Department of Biomedical Engineering, Columbia University, New York, NY, USA

<sup>3</sup>Department of Anesthesiology, Massachusetts Eye and Ear Infirmary, Boston, MA, USA

<sup>4</sup>Department of Otolaryngology, Massachusetts Eye and Ear Infirmary, Boston, MA, USA

## Correspondence

Phillip C. Song, Department of Otolaryngology,  
Massachusetts Eye and Ear Infirmary,  
243 Charles Street, Boston, MA 02114, USA.  
Email: [phillip\\_song@meei.harvard.edu](mailto:phillip_song@meei.harvard.edu)

## Abstract

**Objectives:** To develop a novel laryngoscope device capable of dynamically measuring force and torque measurements in real-time during intubation and to explore the efficacy of such a device through a face validation simulation.

**Methods:** The torque sensor laryngoscope is designed for use during intubation and is modeled after a standard, single-use plastic laryngoscope. After device calibration, a face validation study was performed with intubation experts in the field. Quantitative data (intubation force metrics) and qualitative data (expert feedback on the device) were collected from three intubations using a Mac blade and three intubations with the Miller blade.

**Results:** Three experts (two anesthesiologists and one otolaryngologist) participated in the study. The mean maximum force exerted with the Mac blade was 24.5 N (95% confidence interval [CI], 22.3–26.8). The average force exerted was 13.6 N (95% CI, 11.7–15.5). The average total suspension time was 13.1 s (95% CI, 10.4–15.8). The average total impulse was 164.6 N-s (95% CI, 147.9–181.4). The mean maximum force exerted with the Miller blade was 31.6 N (95% CI, 26.4–36.8). The average force exerted was 15.8 N (95% CI, 13.8–17.9). The average total suspension time was 11.3 s (95% CI, 9.9–12.6). The average total impulse was 216.2 N-s (95% CI, 186.5–245.9). The mean maximum force ( $p = .0265$ ) and total impulse ( $p = .009$ ) were significantly higher in the Miller blade trials than in the Mac blade trials. Survey results found that this device, while bulky, intubated similarly to standard-use models and has potential as an intubation teaching tool.

**Conclusion:** The torque sensor laryngoscope can measure and display real-time intubation force metrics for multiple laryngoscope blades. Initial validation studies showed a significantly lower maximum force and total impulse when intubating with

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the Mac blade than with the Miller blade. Face validation survey results were positive and suggested the potential for this device as a teaching tool.

**Level of Evidence:** Level 5.

**KEYWORDS**

airway simulation, biomechanical analysis, device design, endotracheal intubation, face validation, laryngoscope, torque sensor

## 1 | INTRODUCTION

Endotracheal intubation is a critical and potentially life-saving skill taught to medical students and many health care providers. In most instances, it is a routine process. However, there are many potential risks with intubation that relate to user technique and comfortability. In inexperienced hands, this can lead to complications and life-threatening situations, especially when managing the airway of a critically ill patient.<sup>1-3</sup> Previous studies from our group have shown that excessive forces exerted through laryngoscopes during suspension microlaryngoscopy are associated with soft tissue injuries within the oral cavity and other postprocedure complications like pain and neuropathy.<sup>4-6</sup> During intubation, excessive forces have been hypothesized to be a causative factor in postprocedure complications. Little research has been performed to quantify the force needed to cause such symptoms.<sup>7</sup> However, various methods have been used to approximate these forces exerted by a laryngoscope during intubation.<sup>8,9</sup>

Dynamic simulators and devices are currently being built to characterize these metrics. Mannikins and medical devices are being developed to provide real-time active feedback based on user application.<sup>10-13</sup> These devices include visual and force feedback as metrics of interest. While this provides methods to quantify intubations *ex vivo*, there is an unmet need for a device capable of accurately measuring intubation in the field.

In this study, a novel laryngoscope was designed to measure real-time force values exerted during endotracheal intubation. This article describes a force-sensing laryngoscope's design, development, and initial validation and testing on an airway mannikin. The device was tested in load cycles to characterize its accuracy before qualitative and quantitative testing in a face validation trial. Several intubation metrics were investigated, including maximum force, average force, total suspension time, and total impulse. Qualitative feedback was collected from several experts in the field.

## 2 | METHODS

### 2.1 | Device design and implementation

The torque sensor laryngoscope was designed to measure the force the user exerts on the patient during intubation. The device consists of three parts: (1) an upper piece that serves as the handle, (2) a

torque sensor (RST1 Torque Sensor, Loadstar Sensor Inc., California), and (3) a bottom piece that houses the light and interfaces with the laryngoscope blade. The upper housing was designed to imitate a classic laryngoscope handle, while the bottom housing was designed to allow quick attachment of a laryngoscope blade. A computer-aided design (Onshape CAD, Onshape, Massachusetts) of this model is shown in Figure 1. When in use, torque measurements captured by the sensor were displayed using custom data acquisition software.

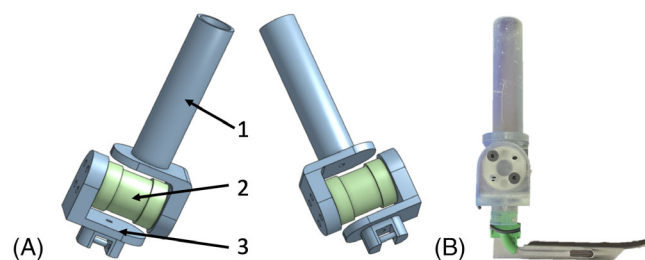
A free-body diagram of the forces in question is included in Figure 2. The torque sensor measures the net torque as seen by the center of rotation, which is in line with the handle of the laryngoscope. The moment generated by the laryngoscope interacting with patient tissue is exerted at an offset distance, which determines the corresponding magnitude of the torque. Torque measurements are calculated by multiplying the moment arm distance with force exerted at that point:

$$\tau = R * F * \sin\theta, \quad (1)$$

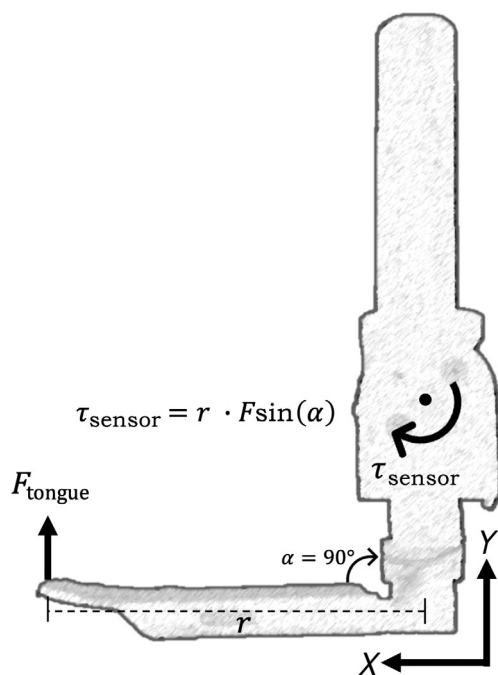
where  $R$  is the moment arm length,  $F$  is the force exerted, and  $\theta$  is the angle formed between the force and the moment arm.

### 2.2 | Initial calibration

Static analysis was performed to assess device functionality over a broad range of forces exerted at every quarter-point along the blade. For these tests, both the Miller and Macintosh blades were



**FIGURE 1** (A) Computer model illustrating the three parts of the torque sensor laryngoscope, including (1) the handle, (2) the torque sensor, and (3) the bottom connector. The third part contains an interface through which the laryngoscope blade will snap onto. (B) A picture of the fully assembled torque sensor laryngoscope



**FIGURE 2** Free body diagram of the torque sensor laryngoscope

individually tested in three separate load cycles. During each trial, the force exerted on the blade, measured by a force gauge, was changed from 0 to 20 N in a 1 N step-wise fashion. At every step, a response from the torque sensor was recorded. Each trial generated calibration models that were compared to theoretical curves representing the true torque given the force and the moment arm. The linear model is identified as:

$$\tau = RF + \tau_0, \quad (2)$$

where  $R$  is the moment arm length in meters,  $F$  is the force exerted in N, and  $\tau_0$  is the torque offset generated by the sensor in N-m. The resultant data were analyzed to determine the performance of the device. Non-repeatability, hysteresis, and non-linearity were calculated and averaged to determine the accuracy of the device readings. The positive and negative deviation from expected outputs was then calculated from these metrics to determine the accuracy error of the device. The root of summed squares method was used to determine accuracy based on the three independent factors listed above.<sup>7,8,14</sup> The equations and the device-specific calculations used to derive these values are outlined in Appendix A.

### 2.3 | Face validation trials and data collection

A face validation trial was conducted with three board-certified physicians (two anesthesiologists and one otolaryngologist). Each of the experts provided informed consent regarding their participation in this study. The device was assessed and compared to standard single-use laryngoscopes. A series of intubations on an airway mannikin was

performed to determine how realistic the device was compared to standard single-use laryngoscopes. The study was presented to the participants before interacting with the force-sensing laryngoscope. Each expert then conducted a trial on a training mannikin (SimMan Essential 3G, Laerdal Medical, New York). Each trial consisted of intubation of the mannikin with a single-use plastic laryngoscope immediately followed by intubation with the force-sensing laryngoscope. Each expert performed six trials—three with a size 3 Mac blade and three with a size 3 Miller blade. During the study, data was collected on each intubation through the Loadstar data collection interface. The subjects were blinded to force recordings. At the end of the study, the subjects were instructed to complete a validation survey where they could give feedback on the design, weight, and overall feel of the experimental laryngoscope compared to the single-use model on a 5-point Likert scale. The subjects indicated which blade they preferred to intubate with and which blade on the force-sensing laryngoscope model felt easier to use.

### 2.4 | Survey metrics

The poststudy survey was designed on a 5-point Likert scale (1–5) and asked the experts questions regarding their trial with the experimental device compared to the control. Survey questions include ease of use, realism, willingness to use, and future potential. These questions were asked after the trial concluded, and the experts were asked to assess these variables in both absolute terms and relative to the standard laryngoscope. Data from these surveys were compiled, and two-sample  $t$  tests were used to determine significant differences between control and experimental device feedback. The survey questions are outlined in Appendix B.

### 2.5 | Data analysis

The force–time curves were captured continuously across different trials using the calibrated torque gauge with its integrated software system (Loadstar Sensors Inc., California). The signal was recorded at a rate of 10 Hz and low-pass filtered to eliminate noise generated during the trial. The curves were analyzed to determine the maximum force, average force during intubation, total time of intubation, and total impulse (the area under the force–time curves) using MATLAB (MATLAB, MathWorks, Massachusetts). In these trials, the start time was recorded by the first non-zero reading after the blade tip crossed the plane of the oral cavity. The expert confirmed the end time after successful intubation. Any periods of relaxation of the forces or manipulation of the mannequin head to gain better access were included in the average force, total time, and impulse calculations. The force–time curves were analyzed to determine the magnitudes of the force variables collected from each trial. Comparisons between trials were evaluated through a two-sample  $t$  test, with significance being attributed to a  $p$ -value less than or equal to .05.

**TABLE 1** Summary of the scores given to the normal intubation versus intubation with the experimental device.

Criteria	Mean (SD)	
	Normal	Experimental
Force used (1 = low, 5 = high)	2.00 (.82)	3.00 (.82)
Ease (1 = easy, 5 = hard)	1.66 (.47)	2.66 (.94)
Realism (1 = not real, 5 = very real)	2.50 (1.1)	2.30 (.94)

**TABLE 2** Summary of scores given to overall impressions of the device and an evaluation of the device as a potential intubation teaching tool for novices

	Mean (SD)
Overall impressions	
Effectiveness	3.30 (.94)
Willingness to change force given feedback	2.80 (.62)
Willingness to use device	2.00 (1.4)
Handling properties	3.00 (1.4)
Teaching tool	
Mannequin intubation difficulty	3.33 (.47)
Usefulness in teaching intubation	3.66 (.47)
Potential to decrease force exertion	3.66 (.47)
Potential to improve intubation procedure	4.00 (.82)

### 3 | RESULTS

#### 3.1 | Survey results

Feedback specific to the operator experience of the experimental device (assessed through product effectiveness, realism, and handling properties) compared to using a standard laryngoscope is summarized in Table 1. When comparing the standard and force sensing laryngoscopes, none of these variables were significantly different. The experts assigned a mean score (out of 5) of  $3.30 \pm .94$  (SD) to effectiveness,  $2.30 \pm .94$  to realism, and  $3.00 \pm 1.40$  to handling properties of the force-sensing laryngoscope, compared to a score of  $2.00 \pm .82$  to effectiveness,  $1.66 \pm .47$  to realism, and  $2.50 \pm 1.10$  to handling properties of the single-use laryngoscope. Other variables of interest, focused on the utility and adoptability of the device, are summarized in Table 2.

#### 3.2 | Accuracy error and validation results

The results of the accuracy error calculations for the device with the Mac and Miller blades are summarized in Table 3. The Mac blade had a non-repeatability of 6.90%, a hysteresis of 1.33%, a non-linearity of 4.01%, and an accuracy error value of 8.27% at the tip of the device. The Miller blade had a non-repeatability of 10.95%, a hysteresis of 2.05%, a non-linearity of 14.40%, and an accuracy error value of

**TABLE 3** Summary of the accuracy measurements of the experimental device using the Miller blade and the Mac blade separately, measured at every quarter point (q) along the blade

1q	Miller	Mac
Non-repeatability	10.62%	15.81%
Hysteresis	1.25%	1.35%
Non-linearity	11.44%	18.92%
Accuracy error	15.66%	24.69%
Middle (2q)	Miller	Mac
Non-repeatability	6.66%	18.44%
Hysteresis	1.10%	1.55%
Non-linearity	5.31%	19.38%
Accuracy error	8.59%	26.80%
3q	Miller	Mac
Non-repeatability	5.62%	16.47%
Hysteresis	1.45%	1.30%
Non-linearity	11.56%	15.83%
Accuracy error	12.94%	22.88%
Tip	Miller	Mac
Non-repeatability	10.95%	6.94%
Hysteresis	1.33%	2.05%
Non-linearity	14.40%	4.01%
Accuracy error	18.14%	8.27%

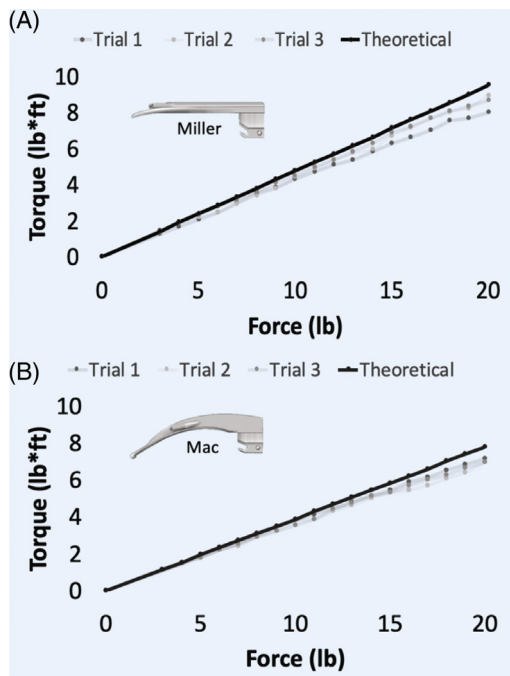
18.14% comparatively. A breakdown of the data collected from every quarter point of the blade is further summarized in Table 3.

Both the Mac and Miller blades experienced falloffs in accuracy as loading forces increased, illustrated in Figure 3. The maximum difference between actual data from the theoretical model was .63 N for the Mac blade and 1.50 N for the Miller blade.

#### 3.3 | Force analysis

The experts were comfortable using both Mac and Miller blades; however, they expressed a mild pre-test preference for using the Mac blade. The mean maximum force exerted through the Mac blade was 24.5 N (95% confidence interval [CI], 22.3–26.8). The average force exerted was 13.6 N (95% CI, 11.7–15.5). The average total suspension time was 13.1 s (95% CI, 10.4–15.8). The average total impulse, the area under the curve of the force–time plot, was 164.6 N-s (95% CI, 147.9–181.4). Figure 4 represents a typical force–time curve recorded by the torque laryngoscope. Methods of assessing the four variables previously listed are illustrated on the graph.

The Miller blade exhibited higher forces during the intubation trials than the Mac blade. The mean maximum force exerted through the Miller blade was 31.6 N (95% CI, 26.4–36.8). The average force exerted was 15.8 N (95% CI, 13.8–17.9). The average total suspension time was 11.3 s (95% CI, 9.9–12.6). The average total impulse was 216.2 N-s (95% CI, 186.5–245.9). The mean maximum force



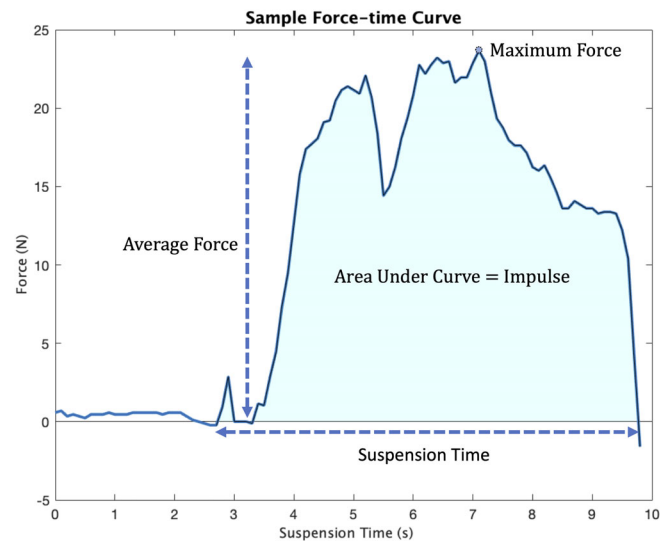
**FIGURE 3** Graphs showing the theoretical loading force (x-axis) versus torque measured (y-axis) compared to the measurements obtained from the device. Some drop-off is seen as the loading force is increased.

( $p = .0265$ ) and total impulse ( $p = .009$ ) were significantly higher in the Miller blade trials compared to the Mac blade trials. Table 4 summarizes the force measurements and intubation times recorded through the device.

## 4 | DISCUSSION

This study introduced a novel device that can produce real-time force feedback during intubation. There were several aims when designing this face validation trial: (1) to understand the force and time metrics related to endotracheal intubation in a simulated setting, (2) to explore variables that may impact these metrics, such as level of expertise and the types of blades used during intubation, and (3) to gather expert opinions on how realistic this model was compared to the current standard.

Such a device is useful in this field because it enables researchers to capture a dataset that is vital to the field of intubation training. A British Journal of Anaesthesia study that investigated intubation competence training assessed four variables—force during intubation, number of attempts, time to intubation, and hand position. Of those four variables, only force differences were found to distinguish experts from novice groups.<sup>15</sup> This study serves as a proof-of-concept for our experimental device, in that it showed force to be a significant variable of interest. By expanding the availability and depth of force analysis during intubation using our device, further comprehensive studies can be performed to expand on the aforementioned study.



**FIGURE 4** Sample force–time curve recorded from an expert intubation using the torque laryngoscope (solid line). Methods for assessing maximum force, average force, suspension time, and impulse are illustrated above.

**TABLE 4** Analysis of the force and suspension time variables collected through the intubation trials. The Mac blade had significantly lower maximum force and total impulse exertion on the mannequin during intubations.

N = 9	Mean (SD)	p
Maximum force (N)		
Mac	24.52 (3.46)	.0265*
Miller	31.62 (7.99)	
Average force (N)		
Mac	13.59 (2.94)	.1405
Miller	15.81 (3.13)	
Suspension time (s)		
Mac	13.11 (4.14)	.1079
Miller	11.28 (2.03)	
Total impulse (N s)		
Mac	164.57 (25.57)	.0090**
Miller	216.24 (45.52)	

Asterisk indicates statistical significance (two sample t-test, \* $p < 0.05$ ).

### 4.1 | Face validation data analysis

We demonstrated reasonable face validity of our device using a high-fidelity mannequin to simulate endotracheal intubation using the force measurements in a blinded prospective trial of experts. Our laryngoscope was developed using a torque sensor, three-dimensional printing technology, and commercially available laryngoscope blades. The experts who completed the face validation survey agreed that this device has potential as a teaching tool that provides quantitative benchmarks that students could use to measure progress, improve technical performance by decreasing force exertion and shorten the time to intubation.

The expert users did, however, note that the current iteration of the device was bulkier, heavier, and less ergonomic than a standard laryngoscope (Table 1). The experts proposed several design changes to increase realism and ease of use. The first proposal was to substitute the sensor with a narrower and lighter model. The second design proposal was to redesign the CAD model housing the device to (1) reduce weight, (2) contour around the hand better, and (3) move the bulk away from the hook base of the blade as most experts preferred that site to hold the device. Future experiments will build on this work with new design changes and a protocol that allows for force feedback to be seen by the user.

## 4.2 | Calibration and accuracy error analysis

The laryngoscope device exhibited a varied behavior as it was tested at different points along the blade. Closer to the handle, the Miller blade had a higher accuracy than the Mac blade. These findings were reversed at the laryngoscope blade's tip: the Miller blade's force measurement error was more than twice as high as the Mac blade (Table 3).

One explanation for this behavior is that the biomechanics of the two blades were fundamentally different—the Mac blade is shorter and curved compared to the Miller blade, and analysis was performed by placing forces on relative positions of the blades without controlling for total blade length. The shape and length differences between the blades may have also affected force readouts. Future studies with this device will also compare different sizes of the same blade type to further characterize this discrepancy in force measurement accuracy.

## 4.3 | Force–time data analysis

In this trial, 12 force–time curves were captured and analyzed to determine any change in force characteristics based on the type of blade used. A typical force–time curve and the associated measured variables are shown in Figure 4. This is similar to other force–tissue readings seen in prior studies.<sup>7,8</sup> Maximum force and total impulse were significantly lower when using the Mac blade than the Miller blade. This may be related to the curved shape of the Macintosh blade, which contours to the tongue and leverages the base of tongue and epiglottis to expose the vocal folds. Alternatively, the straight Miller blade requires direct vertical translation of the epiglottis to create a straight line-of-sight configuration toward the larynx. Prior studies by our group suggest that lower pressures are associated with fewer postoperative complications and a correlation between these forces and postoperative narcotic administration.<sup>4,5</sup> The studies also highlight the importance of real-time monitoring in reducing these complications. This suggests that lower forces exerted by the Mac blade may help minimize postoperative issues compared to the Miller blade.

Although the experts reported a preference for the Mac blade type, they were comfortable and proficient with both, which is

reflected in the similar time to intubation and success rates. Despite these similarities, there were significant differences in force measurements, which points to either an intrinsic difference due to blade design biomechanics or increased experience with one specific blade type. The latter is certainly possible, given that there were significant maximal force and total impulse reductions when intubating with the Mac blade.

While this study demonstrates significant differences in intubation biomechanics between blade types, several limitations exist. As with all simulations, clinical correlation is unclear, and the differences may be due to the biomechanics of the experimental device itself rather than the blade design or expert inclination. The process of intubation also may not have been as smooth, owing to the bulky nature of the experimental device. Given the novelty of the device and the low number of experts and trials, further experiments are needed to investigate the significance of the results of this study. Experts also found that the mannikin's tissue compliance and feel during intubation was rigid and did not respond as easily to blade adjustments inside the oropharynx. This may have affected how they viewed the device during the trials. While the experts found that intubating on a mannikin was generally challenging due to its material properties, they felt that limitations were not significant—all experts could intubate during each trial successfully.

This study highlights the importance of real-time force tracking during intubation and is a proof-of-concept of an idea that will be expanded into the educational setting. While the literature is replete with force evaluations during intubation, this device is capable of measuring real-time, sensitive changes that allow different, unique metrics to be serially tracked and will be used to do so in future studies with experts and novices.

## 5 | CONCLUSION

The torque sensor laryngoscope is a device capable of measuring and displaying real-time intubation metrics in an integrated device capable of multiple uses. Incorporating these metrics into currently existing laryngoscopes may also help mitigate postprocedure complications. Initial validation also found a significantly lower maximum force and total impulse when intubating with the Mac blade over the Miller blade. Face validation survey results showed no statistical differences in the Mac versus Miller blade. Still, qualitative feedback was positive and suggested that such a device would be a useful teaching tool.

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## ORCID

Gopikrishna M. Rao  <https://orcid.org/0000-0003-0133-3117>

Jeremy Juang  <https://orcid.org/0000-0002-7113-7042>

Allen L. Feng  <https://orcid.org/0000-0002-8040-5299>

Phillip C. Song  <https://orcid.org/0000-0003-0206-5441>

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## SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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