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Real-time robotic airway measurement: an additional benefit of a novel steady-hand robotic platform.

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Abstract

Objective: Describe the secondary capability of a robotic system to provide real-time measurements of airway dimensions with high fidelity.

Methods: Seven unique phantoms of laryngotracheal stenosis (LTS) were modeled using a computer aided design tool and were three-dimensionally printed; these stenoses were of different dimensions and orientations, some purposefully oblique. The dimensions of the stenoses were then measured with the novel Robotic ENT Microsurgery System (REMS), as it is capable of tool position memory in 3D space. Five participants (two Laryngologists, two Otolaryngology – Head & Neck Surgery residents, one Neurotology fellow) measured each axis of stenosis (anterior-posterior, lateral, and cranio-caudal), three times for each of the seven stenosis phantoms. These measurements were then compared to the known design dimensions. Mean magnitude of error (MOE) and inter-rater-reliability (IRR) using an intraclass correlation coefficient (ICC) were then calculated.

Results: Mean MOE and standard deviation for all measurements was 0.306 ± 0.247 mm. Mean MOE was 0.374 ± 0.292 mm, 0.300 ± 0.237 mm, and 0.244 ± 0.185 mm for the anterior-posterior, lateral, and cranio-caudal dimensions of stenosis respectively. 82% of all measurements had MOE < 0.5mm. ICC was 0.945 (95% CI: 0.847–0.989), 0.995 (95% CI: 0.984–0.999), and 0.993 (95% CI: 0.987–0.999) for anterior-posterior, lateral, and cranio-caudal dimensions respectively, indicating excellent agreement among participants.

Conclusions: The REMS can be used to reliably and accurately measure airway dimensions in three dimensions regardless of the orientation of stenosis. This ability may be easily extrapolated to the measurement of any airway lesion during laryngotracheal surgery.

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Disclosures:

The technology described herein is currently under a license agreement between Galen Robotics, Inc., and the Johns Hopkins University. Dr. Taylor is entitled to royalty distributions on the aforementioned technology. Dr. Taylor is a paid consultant to and owns equity in Galen Robotics, Inc. Paul Wilkening is a paid employee of Galen Robotics, Inc. These arrangements have been reviewed and approved by the Johns Hopkins University in accordance with its conflict of interest policies. The authors have no other funding, financial relationships, or conflicts of interest to disclose.

Keywords

Robotic surgery; airway modeling; 3D-printing

Introduction:

Laryngotracheal stenosis (LTS) is a disease that affects both pediatric and adult patients with etiologies ranging from congenital to iatrogenic to idiopathic.^{1,2} Regardless of the cause, management requires long-term follow-up with serial examinations and interventions, often in the operating theatre.³ As such, quantifying the severity of stenosis is vital in both choosing the appropriate modality of intervention and determining treatment efficacy.⁴ Though many systems have been previously described to perform airway measurements, all have limitations in either their accuracy, their ability to provide real-time data, or ability to measure only in planes at a right angle to the axis of visualization.

The Cotton-Myer grading scale, where endotracheal tubes of varying size are used to estimate degree of stenosis, was the first described system and continues to be the most widely used to date.⁵ However, this method only provides estimated age-appropriate relative data and not absolute measurements, limiting its overall utility. Computed tomography (CT) and flexible bronchoscopy are subject to inaccuracies in measurement in the length of stenosis⁶, with one study finding CT to have an error of > 5mm in the length of stenosis in 75% of cases when compared to laryngotracheal resection specimens.⁷ As such, CT and flexible bronchoscopy are considered complimentary tools in airway evaluation and dimension definition.⁷ More recently, Sharma et al. described a system utilizing Kirschner (K) wires as measuring sticks of airway dimensions. Although practical and with the ability to provide real-time data, this system has a resolution of 2–3-mm owing to the spacing of the hash marks and the length of the shortest 90° bend on the measuring sticks.⁴ In neonates, where LTS is the third most common congenital laryngeal abnormality with subglottic diameters on the order of 4 mm, this would represent an error of up to 50–60%.⁸ Other techniques utilizing videobronchoscopy and photodocumentation of the stenosis next to an instrument of known length can be unreliable in subjective real-time qualitative assessment⁹ or require challenging post-procedure image-analysis to provide quantitative data.^{10–12} Similarly, systems utilizing optical coherence tomography (OCT) can require complex data post-processing with manual segmentation.¹³ Measurements with OCT, and similarly ultrasound, can also be limited by artifact and variability in image quality that can negatively impact resolution.^{13,14} As such, a system that can provide real-time quantitative airway measurements with a high level of accuracy has yet to be described.

The Robotic Ear, Nose, and Throat Microsurgery System (REMS) (Galen Robotics Inc.) is a novel robotic platform designed specifically for Otolaryngology – Head & Neck Surgery (OHNS). Previously we have demonstrated its feasibility and utility in performing simulated microsurgical and microlaryngeal tasks with heightened precision and dampened tremor.^{15,16} The REMS operates via a cooperative-control mechanism, where the user and robot manipulate the surgical instrument together. Conventional surgical instruments ranging from microvascular needle drivers to microlaryngeal forceps are fitted with custom adapters to

articulate with the gantry arm of the REMS. Given that the positioning of the gantry arm is known at all times by the robot, by extension the position of the instrument tip maneuvered with the robot arm is also known. Measurement of lesions, then, can be done by simple calculation of the spatial difference from one point to another, which is not limited by orientation of the plane of measurement. The following study demonstrates the functional utility of this capability in providing real-time three-dimensional (3D) measurements with great precision in simulated airway models.

Materials & Methods:

The REMS

Details of the REMS platform, its design, and its function have been previously described within both the robotic and OHNS literature.^{15–19} In brief, the technology was developed at the Johns Hopkins Laboratory for Computational Sensing and Robotics and is now under a licensing agreement with Galen Robotics, Inc. It consists of a robotic gantry arm that stabilizes the user's primary instrument along six-degrees of freedom. The base – the delta stage – allows for movement in the x, y, and z planes. Roll motion and tilt motion belts (roll & tilt stages) provide rotational movement about the x and y axes respectively. Conventional instrumentation is modified with custom-built adaptors allowing articulation with the distal end of the REMS. Rotation about the z-axis of the user's unactuated primary instrument provides the sixth-degree of freedom. (Figure 1) A force sensor in the instrument exchange unit at the distal end of the gantry arm senses forces and torques exerted by the surgeon on the instrument, and the robot moves the tool to comply. As the robot is moving the instrument, the motion is very precise and unaffected by hand tremor. The responsiveness of the robot to forces exerted by the surgeon is proportional to the amount of depression of an admittance gain foot pedal, with full depression allowing for faster instrument motion. The position of the platform at any given time is known with a high level of precision and stereotactic accuracy based on the kinematic design and the resolution of the relative encoders used to manufacture the REMS.^{18,20}

Three-Dimensionally Printed Airway Models

Seven unique phantoms of LTS were modeled using a computer-aided design (CAD) tool Creo 4.0 (PTC, Needham, MA) for the purposes of 3D-printing. Dimensions of the phantoms were based on a “normal” tracheal diameter of 20 mm.²¹ From this, five phantoms of elliptical stenosis of varying proportions and lengths were modeled (25, 40, 50, 60, and 75% cross-sectional stenosis). The remaining two phantoms were modeled to have oblique stenoses that were situated at an angle (15°, 30°) relative to the axial plane of the trachea. The length of stenosis (cranio-caudal dimension) ranged from 10–15 mm across phantoms. The exact dimensions of stenosis for each phantom can be found in Table I. The models were then 3D-printed using a fused deposition-modeling printer (Stratasys uPrint SE, Eden Prairie, MN USA). Each phantom was designed to interchangeably fit within a larger laryngotracheal complex, which was printed in the same fashion as above and designed based on the laryngeal dissection station described by Klein et al.²² (Figure 2)

REMS-Assisted Dimension Measurement & Validation

Five participants, two fellowship-trained Laryngologists, two OHNS residents, and one Neurotology fellow were recruited to participate in the study. Two participants (one OHNS resident and the Neurotology fellow) had significant familiarity with the technology (experienced users), using it in a laboratory setting on a weekly basis. The other participants had cursory or no experience (novice users) using the technology for measuring applications prior to this study. Prior to beginning the study, novice REMS users were given a brief five-minute tutorial in regards to operation of the robot. Participants were then asked to provide measurements of the anterior-posterior, lateral, and cranio-caudal dimensions of stenosis for each of the above seven phantoms. To do so they utilized a 150 mm microlaryngeal ball-probe that was articulated with the REMS. (Figure 3) The position of the tip of the ball-probe in 3D space was known by the REMS, as described above, and could be recorded. The tool tip was then placed along the respective ends of each dimension to be measured and the resulting vector between each set of two points was calculated by the REMS in real-time. The values generated were the measured dimensions of stenosis for each phantom. Visualization of the laryngotracheal complex was achieved using a zero degree endoscope in the non-dominant hand with the REMS in the contralateral hand, simulating the operative setup/workflow that is often used clinically during treatment of tracheal stenoses. Participants were blinded to the true dimensions of each stenosis. Participants measured each dimension three times per phantom, for a total of 9 measurements per phantom; across all seven phantoms, each participant made 63 total measurements. Measurements were then compared to the known CAD design dimensions of each phantom, yielding a magnitude of error (MOE).

The mean MOE in each dimension and across all measurements was then calculated. The participants were then stratified based on clinical experience, with MOE of fellowship-trained laryngologists compared to the MOE of the remainder of participants using a linear regression model treating measures between individual participants as independent but accounting for intra-participant correlation in measurements across phantoms. Differences in MOE stratifying for experience with the REMS and differences in MOE in angled and non-angled models were evaluated using a similar linear regression model.

The inter-rater reliability (IRR) was determined by calculating the absolute agreement intraclass correlation coefficient (ICC) with a two-way mixed effect model, comparing mean recorded measurements for each phantom across participants. The following ranges of ICC were used to determine reliability: poor (ICC = 0.21–0.40), moderate (ICC = 0.41–0.60), good (ICC = 0.61–0.80), or excellent (ICC = 0.81–1.00).^{23,24} ICC was calculated for measurements in each dimension, and also across all measurements. Statistical analysis was completed in Stata Statistical Software: Release 15 (StataCorp LLC, College Station, Texas) using an alpha of 0.05 for statistical significance.

Results:

315 measurements were taken in total, representing 5 participants measuring each of the 7 stenoses in 3 dimensions, with 3 independent measurement of each dimension. The mean MOE across all dimensions and participants was 0.306 ± 0.247 mm (range .003–1.673 mm),

with 82% (259/315) of all measurements having a MOE less than 0.5 mm. Mean MOE across individual dimensions was 0.374 ± 0.292 mm anterior-posterior, 0.300 ± 0.237 mm lateral, and 0.244 ± 0.185 mm cranio-caudal respectively. (Table II) There was no statistically significant difference in mean MOE between fellowship-trained Laryngologists and non-Laryngologists (0.300 ± 0.259 mm vs. 0.312 ± 0.234 mm, $p=0.79$). Similarly there was no difference in mean MOE between experienced (0.291 ± 0.215 mm) and novice REMS users (0.316 ± 0.266 mm, $p=0.65$). There was also no difference in mean MOE between angled and non-angled phantoms (0.305 ± 0.253 mm vs. 0.306 ± 0.254 mm $p=0.99$) (Table III) The ICC among participants was 0.945 (95% CI: 0.847–0.989), 0.995 (95% CI: 0.984–0.999), and 0.993 (95% CI: 0.987–0.999) for anterior-posterior, lateral, and cranio-caudal dimensions of stenosis respectively. The ICC across all dimensions was 0.992 (95% CI: 0.986–0.997), with all IRR values representing excellent agreement/reliability.

Discussion

LTS is a pathology whose diagnosis and management can be greatly aided by serial quantitative measurements of airway dimensions. This information can facilitate patient-specific care by allowing surgeons to synthesize clinical symptoms with objective airway geometry. It is valuable in documentation of disease severity, response to therapy, and interval monitoring, ultimately enhancing patient care. Furthermore, the ability to gather this information real-time in the operating theatre helps prevent additional procedures, general anesthesia, and potential radiation exposure from imaging. Moreover, this information can also guide the optimal modality of intervention through tracking efficacy of prior interventions, as well as evaluating any immediate post-intervention change in airway caliber. Additionally it can direct sizing of instrumentation such as balloon dilators, preventing the unwrapping of inappropriately sized disposable products, which can be costly. The performance of more involved airway reconstruction procedures such as cricotracheal resections and slide tracheoplasties can also be assisted by knowing the length of the stenotic segments with a high degree of accuracy. Eventually, tissue-engineering applications with use of 3D printed scaffolds may also require precise airway measurements.^{25,26}

Real-time REMS-assisted measurements of airway dimensions were found to have a mean MOE of 0.306 ± 0.247 -mm. To our knowledge, the resolution of this system is superior to any previously described method of real-time airway measurement by nearly 10-fold.⁴ Moreover, the method of validation of REMS-assisted airway measurement is highly reliable. The ground truth dimensions used for validation were those that were designed and then 3D-printed, as opposed to dimensions measured with another instrument, which could introduce an additional source of error. Furthermore there was excellent IRR and no statistically significant difference in MOE when accounting for clinical experience or experience with the REMS. There was also no significant difference in MOE in angled vs. non-angled phantoms, suggesting that an additional benefit of this system as compared to those utilizing photodocumentation of the lesion alongside an instrument of known length, beyond real-time results, is the ability to measure in planes that are not orthogonal to the axis of the tracheal airway. Similarly, this system can measure length, which is not able to be precisely measured with k-wires or right angle probes. As such, these findings demonstrate

that REMS-assisted airway measurement is robust, repeatable, capable of handling complex geometrical stenosis, and not influenced by clinical experience or experience with the technology. This final point is in contrast to airway measurement modalities such as OCT or ultrasound, which require high levels of operational proficiency as image acquisition/quality can significantly impact resolution.⁴ Even when experienced ultrasonographers are used, prior studies have shown the IRR of sonographic airway measurements to be inferior to REMS-assisted measurements for the same airway dimension (ICC of 0.71; 95% CI: 0.57–0.81 vs. 0.995; 95% CI: 0.984–0.999).²⁷

Though the resolution of the REMS was superior to any other real-time measure of airway geometry to our knowledge, sub-millimeter error in measurements were still seen. While a conspicuous source of error would be inaccurate placement of the microlaryngeal ball probe, measurements were consistent and reliable among participants per ICC analysis, suggesting a source of systematic error. Potential sources include manufacturing errors in the commercial parts used to build the REMS. This would include dimensions/specifications in the relative encoders and/or machined parts that differ in any amount from published manufacturing specifications. A more likely source of error is compliance in the tool exchange system utilized to articulate various instruments with the robotic gantry arm. The calculations used to determine the theoretical error of the system assume fixation of an articulated instrument's axes and position in relation to the REMS. However, a portion of the current tool exchange system is rapid-prototyped with the compliance in the material utilized allowing for a small amount of relative motion between the instrument and the REMS. Future iterations of the REMS will be designed with a tool exchange system that limits/eliminates this compliance and therefore this source of error in resolution of instrument position. Additionally, future studies are needed to determine if these findings translate to an in vivo model where tissue pliability and irregular stenosis patterns may make measurement more challenging. As we have defined what the resolution capabilities of the REMS are, we can have a greater understanding of future in vivo REMS-assisted measurements in the context of other techniques such as OCT, rigid bronchoscopy, and direct ex vivo visualization once the technology has been approved for intraoperative use.

Although not specifically designed for this application, we have established the feasibility of the REMS in providing real-time airway measurements with high resolution. This finding in conjunction with our prior work demonstrating its benefits within simulated microlaryngeal tasks, exhibits the REMS' capability of becoming a valuable tool with wide-ranging application in microlaryngeal and airway interventions.

The cooperative-control technology of the REMS offers shared manipulation of instrumentation with preservation of current operative approaches/techniques as well as tactile feedback. With maintenance of familiar approaches and a relatively compact device footprint, the REMS has the potential for swift integration within existing operative workflows. Moreover, all existing microlaryngeal instrumentation can be fitted with custom-built adaptors to articulate with the REMS. These qualities suggest that the REMS not only has broad potential applications, but also favorable characteristics for widespread adoption.

The REMS continues to have functionality that has yet to be examined within simulated clinical settings. Most notably, the device has the capability to create workspace boundaries (virtual fixtures) preventing movement of the articulated instrument beyond a predetermined volume. This volume can be based on registration to patient anatomy from preprocedure imaging. A potential application within phonosurgery would be defining the depth and positioning of cordotomy. This feature is of particular relevance within other OHNS subspecialties including Otology, where a specific volume of tissue is to be removed, such as in a mastoidectomy. This exciting new technology may prove to be a valuable tool within OHNS, where other prior robotic technologies have had limited application. Future studies will continue to evaluate and delineate its full potential.

Conclusion:

REMS-assisted airway measurement can provide real-time data on laryngotracheal dimensions with a high degree of accuracy regardless of the orientation of stenosis/lesion. This is a secondary function of a promising robotic technology specifically designed for use within OHNS.

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Figure 1. The Robotic Ear, Nose, and Throat Microsurgery System (REMS). The REMS is capable of motorized movements along the “x, y, z” axes of the delta stage, and the roll and tilt stages, which are depicted.

Figure 2. Computer-aided design drawings of the modeled laryngotracheal complex and stenosis inserts. An example of the cross-section of an oblique stenosis phantom can be seen in the lower right.

Figure 3.

A. The microlaryngeal ball-probe with attached robotic instrument exchange adaptor.. B. The instrument articulating with REMS in the process of measuring the lateral dimension of stenosis in a laryngotracheal phantom.

Table I.

CAD Phantom stenosis dimensions.

Phantom Number	Antero-posterior Dimension (mm)	Lateral Dimension (mm)	Cranio-caudal Dimension (mm)	Angle from axial plane (degrees)
1	18.00	16.67	10.00	0
2	18.00	13.33	15.00	0
3	16.00	12.50	15.00	0
4	16.00	10.00	15.00	0
5	14.00	7.15	15.00	0
6	16.00	12.50	10.00	15
7	16.00	12.50	10.00	30

CAD; computer-aided design

Table II.

Mean error and ICC for all participants.

Dimension	Mean MOE $\pm$ SD (mm)	ICC
Antero-posterior	0.374 $\pm$ 0.292	0.945
Lateral	0.300 $\pm$ 0.237	0.995
Cranio-caudal	0.244 $\pm$ 0.185	0.993
All Dimensions	0.306 $\pm$ 0.247	0.992

MOE; magnitude of error, SD; standard deviation ICC; intraclass correlation coefficient

Table III.

Error stratification by clinical/robotic experience and phantom type.

Subgroup	Mean MOE $\pm$ SD (mm)	P value *
Laryngologists	0.300 $\pm$ 0.259	0.79
Non-laryngologists	0.312 $\pm$ 0.234	
Experienced REMS users	0.291 $\pm$ 0.215	0.65
Novice REMS users	0.316 $\pm$ 0.266	
Angled phantoms	0.305 $\pm$ 0.253	0.99
Non-angled phantoms	0.306 $\pm$ 0.254	

MOE; magnitude of error, SD; standard deviation

* Linear regression model accounting for intra-participant correlation in measurements