AWARD NUMBER: W81XWH-19-1-0043

TITLE: Development of Virtual Surgery Technology Platform for Obstructive Sleep Apnea

PRINCIPAL INVESTIGATOR: Goutham Mylavarapu

CONTRACTING ORGANIZATION: Cincinnati Children's Hospital Medical Center

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6. AUTHOR(S)

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5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

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Cincinnati, OH 45229

8. PERFORMING ORGANIZATION REPORT NUMBER

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

Obstructive sleep apnea (OSA) is a common sleep disorder characterized by partial or complete obstruction of airway during sleep. This results in impaired health and quality life. With limited effective non-surgical treatments for OSA, most patients with OSA eventually need surgical intervention for a complete cure. However, surgical outcomes with OSA are far from satisfactory as the surgical planning is often subjective and based on the experience of the clinical team. In this study, we are developing a software framework to (1) virtually perform different surgeries on a representative anatomical model of the patient's airway and (2) evaluate different plans and predict surgical outcomes. At the time of this report, we build basic frame work and integrated tools to extract centerline of the airway anatomy, endoscopic view of the airway, basic tools necessary for virtual surgery, display velocity and pressure data from computational fluid dynamics simulations on the patient scans. We scanned 4/15 subjects so far. We are working to integrate haptic interface for a more realistic touch-feedback experience during virtual surgery.

15. SUBJECT TERMS

Upper airway, sleep apnea, Magnetic Resonance Imaging (MRI), virtual surgery, technology development, computational fluid dynamics

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRDC
Unclassified	Unclassified	Unclassified	Unclassified	17	19b. TELEPHONE NUMBER *(include area code)*

TABLE OF CONTENTS

1. **INTRODUCTION:** *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

Obstructive sleep apnea (OSA) is associated with partial or complete occlusion of the upper airway during sleep resulting in impaired quality of life and health. As the non-surgical treatments for OSA do not offer complete cure, most OSA patients eventually opt for surgery. However, the success rates for most OSA interventions is poor. At present, the choice of OSA surgery is subjective and entirely guided by the experience of the clinical team. This application will develop a *virtual surgery* platform for a personalized OSA surgical planning and test it in 15 patients. The proposed study will provide a novel tool for evaluating the efficiency of different OSA surgical plans, *non-invasive* using computer models and prior to an actual intervention. The technology, methodology developed in this work will be used to pursue the long-term goal of improving clinical outcomes for patients with OSA.

2. **KEYWORDS:** *Provide a brief list of keywords (limit to 20 words).*

Upper airway, obstructive sleep apnea, Magnetic Resonance Imaging (MRI), virtual surgery, opensource, software development, tonsillectomy, adenoidectomy, glossectomy, computational fluid dynamics

3. **ACCOMPLISHMENTS:** *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

What were the major goals of the project?
List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

Specific Aim 1: To develop a visualization rendering software for performing virtual OSA intervention(s)

Major task 1: Obtain upper airway scans of OSA patients

Subtask 1 [100%]: Submit documents for IRB approval (Target: Month 1; Submitted in Month 2; All regulatory approvals received in Month 7)
Subtask 2 & 3 [27%]: Recruit 15 patients for the study and complete pre-op and post-op scanning (Target: Months 2-15; Status: still recruiting. Enrolled 4/15 patients so far. Subtask start: Month 8)

Major task 2: Design and develop visualization software for virtual surgery

Subtask 1 [100%]: Write code for extracting centerlines of the airway (Target: Months 1-2)
Subtask 2 [100%]: Create endoscopy view to look inside the airway (Target: Months 2-3)
Subtask 3 [40%]: Add haptic interface for realistic surgical experience (Target: Months 3-4)
Subtask 4 [80%]: Add tools for performing virtual surgery (Target 4-7)

Major task 3: [0%] Perform virtual surgeries (Target: Months 6-14; waiting to schedule patients for post-op imaging post-shutdown because of pandemic)

Specific Aim 2: To test and validate the virtual surgery system for predicting OSA surgical outcomes

Major task 1: Perform morphological and CFD data analysis in 15 patients

Subtask 1 [10%]: Obtain morphometrics of airway size and shape changes before and after virtual surgery (Target: Months 8-15; Status: Still in progress. Performed analysis in 3/15 pre-op;)
Subtask 2 [7%]: Perform CFD simulations on pre-op, post-op and post-virtual airways (Target: Months 8-16; Status: still recruiting. Performed analysis is 3/15 pre-op;)
Subtask 3 [0%]: Statistical analysis for intra-observer and inter-observer reliability of virtual surgeries (Target: Month 16)

Major task 2: Add upper airway functional metrics to the software

Subtask 1 [100%]: Display CFD flow features on scans (Target: Months 8-10)
Subtask 2 [20%]: Add display boxes on the GUI based on the clinical team feedback (Target: Months 9-10)

Major task 3: Predict surgical outcomes

Subtask 1 [0%]: Predict outcomes in 15 OSA patients based on morphological and functional data (Target: Months 13-15; didn't start)
Subtask 2 [0%]: Compare actual and predicted outcomes (Target: Months 13-15; didn't start)

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

1. **Major activities:** The year 1 of this project focused on obtaining all regulatory approvals (See Table 1 for chronological order of administrative events) and building basic building blocks for software development such as centerline extraction, endoscopic view, virtual surgery basic tools such as paint, cut, smooth and display CFD simulated results of pressure and velocities on the patient scans. We recruited 4/15 subjects so far.
2. **Specific objectives:** The objectives of this study from Specific Aims 1 & 2 can be summarized into (A) Regulatory approvals, (B) Patient recruitment, (C) Virtual surgery software development, (D) Analysis: Perform virtual surgery and predict outcomes.
3. **Significant results:**
   - **(A) Regulatory approvals:** We obtained regulatory approvals from local IRB and HRPO and even obtained renewal approvals, which is valid until 07/27/2021. See Table 1 for chronological order of administrative events.
   - **(B) Patient recruitment:** After an initial HRPO approval on 12/16/2019, we began enrolling patients briefly in Jan-Mar 2020 only to be suspended between Mar-June 2020 due to pandemic. So far, we recruited 4 against a target of 15 patients. See Table 2 for the status on these 4 subjects. We had another 7/15 patients who consented to participate in the study but could not start because of the pandemic (Table 3). We will try to consent these patients along other eligible new patients with the resumption of clinical and research sleep MRI operations in the last week of June 2020.

		Date
1.	Grant awarded	05/01/19
2.	Local IRB submission	06/14/19
3.	Local IRB review stated the study is ”greater than minimal risk” and clarifications were asked	07/23/19
4.	Revised IRB documents submitted	08/29/19
5.	Local IRB approval letter received	08/30/19
6.	Submitted docs for HRPO approval	09/05/19
7.	HRPO initial review received	10/30/19
8.	HRPO clarifications to initial review submitted	11/08/19
9.	HRPO approval letter received	12/16/19
10.	Patient recruitment started for the study	12/17/19
11.	First patient consented and scanned	01/17/20
12.	Consented patients started cancelling or ”no shows” due to Covid19	Early March
13.	Clinical & research MRI operations suspended at our institution due to Covid19	03/22/20
14.	Clinical and research scan operations resumed	06/20/20
15.	Local IRB renewal application submitted	06/24/20
16.	First patient recruited and scanned since shutdown	07/09/20
17.	Local IRB renewal approved	07/28/20
18.	Renewal IRB docs submitted to HRPO	07/29/20

Table 1: Chronological order of administrative events

	Pre-surgery			Surgery	Post-surgery		
Subject #	PSG date	AHI	scan date		PSG date	AHI	scan date
VS_01	12/03/19	10.6	01/17/20	05/08/20	09/01/20		
VS_02	04/27/19	85	03/13/20	08/03/20	12/05/20		
VS_03	12/17/19	8.4	07/09/20				
VS_04	02/22/20	9	07/16/20				

PSG: Polysomnography; AHI: Apnea-Hypoapnea Index;

Table 2: Patients recruited in the study and their status

Subject #	Pre-op AHI	Pre-op scan date	Enrollment status
1	13.3	02/21/20	No show
2		02/25/20	Cancelled due to Covid19
3	99.5	03/02/20	Cancelled due to Covid19
4	14.2	03/05/20	Cancelled due to Covid19
5	29.8	04/10/20	Cancelled due to Covid19
6	10.8	03/12/20	Cancelled due to Covid19
7	7.0	07/24/20	No show

* These eligible patients will be consented again for the research study, when they schedule their clinical scans.

Table 3: Patients enrolled but could not start (*)

(C) Virtual surgery software development. While we were waiting for the regulatory approvals and recruiting patients for the study, we made major progress in developing the framework and necessary modules proposed for the virtual surgery software.

C1. Centerline extraction of the airway

To provide an endoscopic view for a more realistic experience to the surgeons, a centerline path that translates along the length of the airway is essential. To this end, we developed a workflow and integrated a centerline workflow to our software framework. As shown in Fig.1 (a-c), we segment the airway to include both oral airway (Location 1-2) and pharyngeal airway (Location 3-8) using local thresholding and growth-cut algorithms. A three-dimensional rendering of the airway is obtained based on this airway segmentation. Three seed points as shown in Fig.1(d) at the entrance to the mouth (location 1), at the nasopharynx (approximately at location 3) and the inferior end of the airway model in the trachea are given. Centerlines are generated inside the airway lumen as three curves between locations 1-2, 3-2 and 2-8.

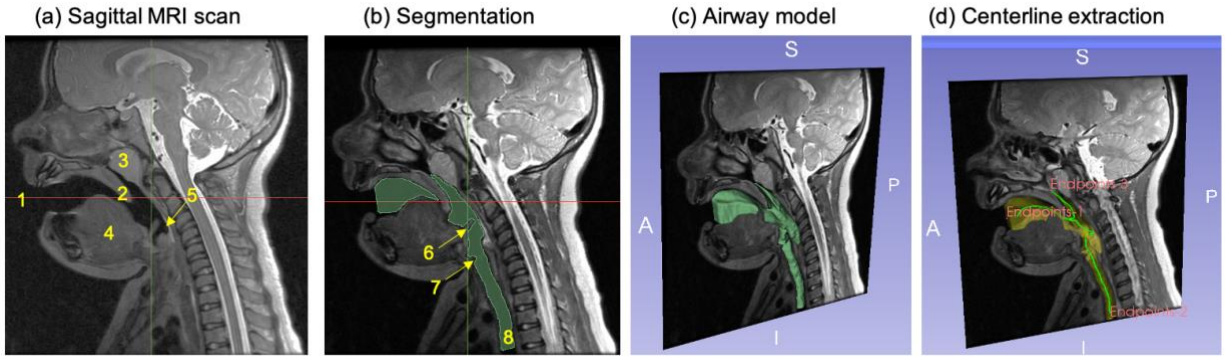

Fig.1: Workflow for extracting centerlines in an airway. (a) mid-sagittal Magnetic Resonance Image (MRI) scan; (b) Segmentation of upper airway; (c) 3D rendering of airway anatomical model; (d) Centerlines generated for the airway model based on 3 seed points. Anatomical locations 1-8 are marked in (a) and (b). 1: Oral airway opening; 2: Velum, oropharyngeal junction; 3: Adenoid; 4: Tongue; 5: Posterior vallecular space opening into esophagus; 6: Epiglottis; 7: Larynx; 8: Trachea.

C2. Endoscopic fly-through view

We had integrated an endoscopic view module into the software framework, which allows a fly-through view (look inside) of the airway and provide access to anatomical regions of interest such as lingual tonsils, tongue tissue or the velopharynx during virtual surgery (see Fig. 2). As most OSA surgeries are accessed through oral opening, we simulated a similar line of flight to move freely along the centerlines and to provide visualization of the airway anatomy at desired depth inside the airway. Fig. 2 (c-d) provide endoscopic views at the beginning, above the epiglottis and to the inferior end of the airway model.

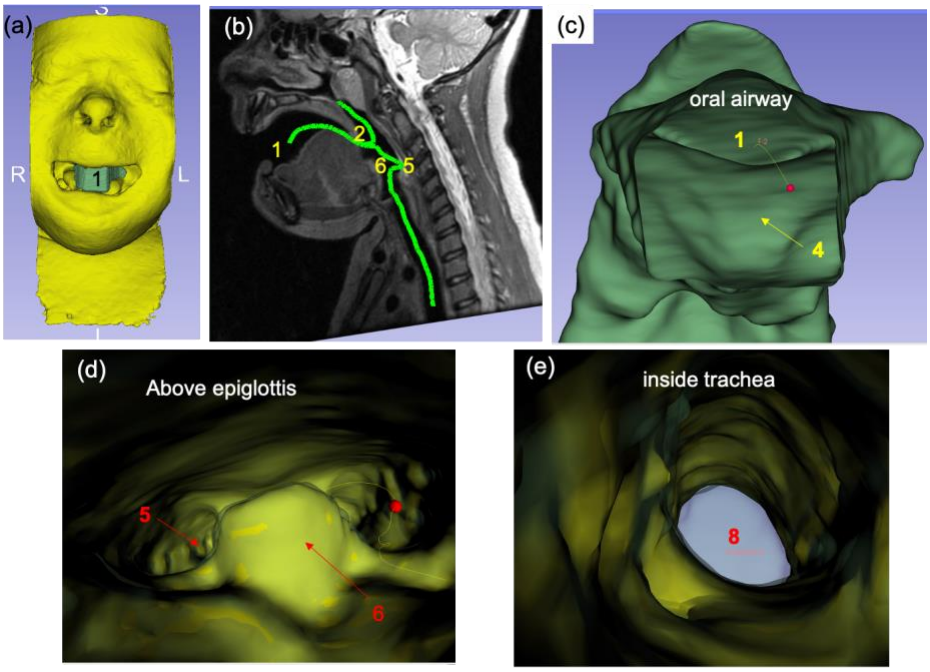

Fig. 2: Endoscopic view of the airway. (a) 3D rendering of the face (yellow) and airway (green). Location 1 marks the oral entrance to the airway; (b) Centerlines of the airway overlaid on the mid-sagittal scan; (c) Looking inside the airway downstream of oral opening; (d) fly-through view along the centerline slightly above the epiglottis (location 6); (e) fly-through view further downstream inside the trachea at a location below larynx;

C3. Multiplanar reformat of patient scans

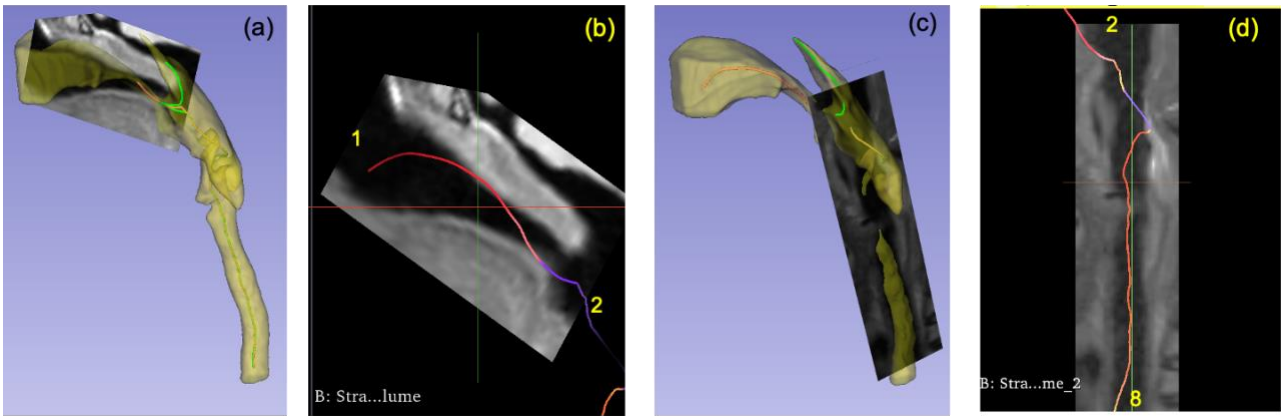

Fig. 3: Multiplanar reformatting of the patient scans along the centerlines. (a-b) Reformatted mid-sagittal plane along the centerline between locations 1 and 2 in the oral airway; (c-d) Reformatted mid-sagittal plane along the centerline between location 2 and 8 in the pharyngeal airway posterior to the tongue and into trachea.

Along with the endoscopic fly-through view, we integrated multiplanar formatting of volumetric imaging data into axial, sagittal and coronal planes along each of the centerline curves in the oropharynx (location 1-2), nasopharynx (3-2) and retroglossal (2-8) airways (see Fig. 3). This is an additional feature along with the endoscopic view during the virtual surgery.

C4. Overlay CFD calculated pressures and velocities on patient scans

Computational fluid dynamics (CFD) simulations of the airflow are performed in an OSA patient. Fig. 4(a) and 4(c) show the velocities inside the airway lumen and pressure on the airway wall respectively, for a simulated peak expiratory flow condition of 10 liters per minute (lpm). These simulations were run on the backend and the airflow functional output measures from CFD are exported in *vtk format into the software. We integrated a feature to display the velocity and pressure data on the frontend in the software in any user-defined anatomical plane of reference. This feature allows the clinicians to qualitatively assess the airflow changes before and after virtual surgeries. We are working to display quantitative metrics of change in cross-sectional area, diameters, airway resistance as a table on the frontend. Fig. 4(b) and 4(d) show velocity flow field and airway wall pressure in the mid-sagittal plane.

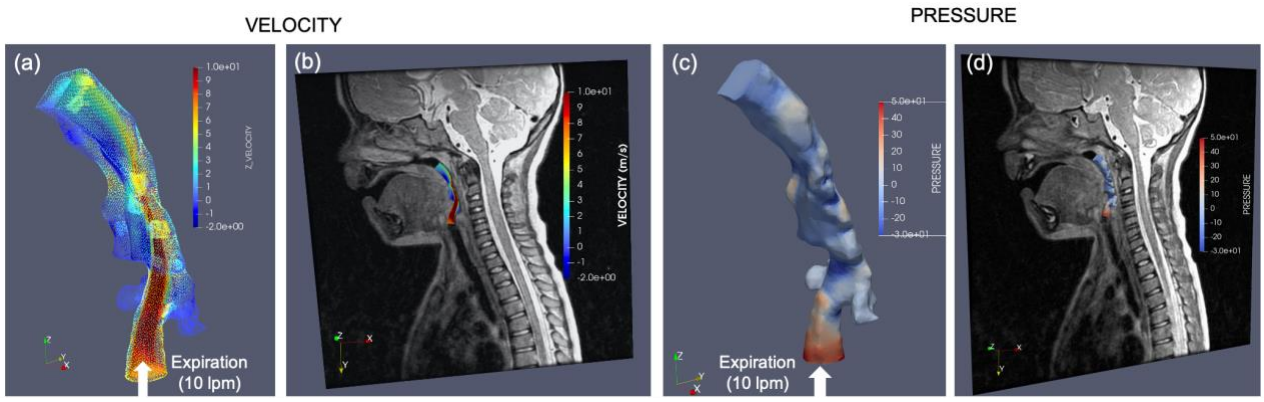

Fig. 4: Display velocity and pressures data from CFD on patient-scans. The CFD results were at simulated condition of 10 liters per minute (lpm) peak expiratory airflow; (a) Changes in velocity inside the airway lumen from nasopharynx to larynx; (b) Velocity in mid-sagittal plane displayed on the mid-sagittal patient scan; (c) Contours of the airway wall pressure; (d) Airway wall pressure aligned with the mid-sagittal plane;

C5. Virtual surgery tools

We have integrated basic tools necessary for paint, brush, cut, smooth to the framework. These basic tools will allow us to execute the virtual surgery tasks in our statement of work. We are waiting for the post-operative scanning of the study participants to test these tools and make any changes as necessary. We are still working on the haptic interface functioning for a touch feedback interface during virtual surgery operations such as drill, cut etc.

4. Discussion of stated goals not yet met.

We underestimated the time needed for regulatory approvals for the study. It took about 7 months against our target of 1-2 months. This delayed the patient recruitment necessary to test the virtual surgery software in Aim 2. We have regulatory approvals until 7/27/2021 now. We scanned of our first subject in month # 8 of this 18-month project. We had been working on the software development part during this time. As the patient recruitment was picking pace and we were hoping to still finish pre and post-op scan with minor delays, the unprecedented pandemic and operational shutdown for almost 3 months and slow recovery, thereafter, further delayed the patient recruitment, software testing and analysis. Patients have been returning to the clinics again and we will accomplish unfinished tasks in the next 12 months with a no-cost extension of this study.

What opportunities for training and professional development has the project provided?
If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

Nothing to report

How were the results disseminated to communities of interest?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

PI discussed the study objectives with the help of visual aids and a demo of the software in development with the parents of study participant, VS_01 who were nurses by profession. They expressed interest in learning about the final outcome of this study. Dr. Ishman, one of the co-investigators in this study along with her colleagues in the division conducts an annual *Upper Airway Clinic* community outreach program for OSA patients. This program was cancelled this year due to the pandemic. But investigators are planning to give a demonstration of the software and its application to OSA community for enhancing their understanding of this disease.

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

Over the next year, we will continue with the patient recruitment and test the software for its virtual surgery feature. We will perform *virtual surgeries* on all the patients as soon as they complete their post-operative scanning and analyze morphological and functional outcomes from CFD. The subtask in Aim 1, to integrate the haptic device for a more realistic surgical intervention experience will be completed. Also, another subtask to display CFD results computed in the backend, on the front-end of the software will be completed. We will continue to improve features already developed in Aim 1 depending on the clinical team feedback as they perform virtual surgeries.

4. **IMPACT:** D*escribe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

What was the impact on the development of the principal discipline(s) of the project?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

OSA is a common sleep disorder with unsatisfactory surgical intervention outcomes. With the funding support from DoD, our team is able to develop a software to perform and test personalized surgical plans in patients with OSA. We were able to generate software for generating centerlines through anatomical models, *see inside* the airways using a *fly-through* views along the centerlines. This feature provides a surgeon similar field of view of a patient's airway as in an operation theatre. Other tools to perform *virtual surgery* on a patient's airway and comparing functional outcomes before and after surgery scenario, should help optimize surgical planning by the clinical team.

What was the impact on other disciplines?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Although the software scripts were written with the primary goal of developing a virtual surgery software for OSA interventions, the centerline and endoscopy modules developed as part of this study are of great use in my other research to study lung airways and pulmonary vascular tree. The endoscopy module can be tested to develop a *virtual bronchoscopy* software with some additional work involving accurate segmentation of airways in the lung. Similarly, these tools can be used to study other tubular structures such as large and small vessels in aorta, brain, lungs etc. as well as the nasal and lower airways.

What was the impact on technology transfer?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to report

What was the impact on society beyond science and technology?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Once tested and validated, this software can be used for training of clinical residents and educating patients with OSA and their families to make informed decisions on their surgical plans.

5. CHANGES/PROBLEMS: *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:*

Changes in approach and reasons for change
Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

Nothing to report

Actual or anticipated problems or delays and actions or plans to resolve them
Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

Delay 1: The regulatory approvals from both local IRB and HRPO took about 6 months, delaying the patient recruitment for the study. We started enrolling eligible subjects since 12/17/19 (See Table 1 for chronological order of events).
Action 1: We have regulatory approvals until 7/28/21 to recruit subjects for this study.

Delay 2: Due to ongoing pandemic, clinical and research imaging of OSA patients was suspended by our institution taking into account the safety of the patients, their families and staff since 3/22/20. The operations resumed around 6/20/20 and patient scheduling has been slowly picking up pace, since then. Even before 3/22/20 and now, we had 4 consented patients who cancelled or didn't show up on the day of their scheduled scanning due to Covid (See Table 3).
Action 2: The clinical and research scans required for this study were resumed and operations are steadily coming to normalcy. Few of the subjected who consented to participate in the study, pre-Covid and being scheduled. They will be enrolled and reach again for consent. We have an annual turnover of around 100 OSA patients scheduled for Sleep MRI at our upper airway clinic. If we do not have another unprecedented shutdown as before, we do not anticipate any further problems in recruiting another 11 patients for this study. We'll request a no-cost extension for 12 months in order to complete patient recruitment and complete the rest of technology development and testing.

Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

Nothing to report

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

No changes to report

Significant changes in use or care of vertebrate animals

No changes to report

Significant changes in use of biohazards and/or select agents

No changes to report

6. **PRODUCTS:** *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."*

- **Publications, conference papers, and presentations**
  Report only the major publication(s) resulting from the work under this award.
  Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

  Nothing to report

Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to report

Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

Nothing to report

- **Website(s) or other Internet site(s)**
List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to report

- **Technologies or techniques**
Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

Nothing to report

- **Inventions, patent applications, and/or licenses**
Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to report

- **Other Products**

  Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

  - *data or databases;*
  - *physical collections;*
  - *audio or video products;*
  - *software;*
  - *models;*
  - *educational aids or curricula;*
  - *instruments or equipment;*
  - *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
  - *clinical interventions;*
  - *new business creation; and*
  - *other.*

Nothing to report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".

Example:

Name:	*Mary Smith*
Project Role:	*Graduate Student*
Researcher Identifier (e.g. ORCID ID):	*1234567*
Nearest person month worked:	*5*
Contribution to Project:	*Ms. Smith has performed work in the area of combined error-control and constrained coding.*
Funding Support:	*The Ford Foundation (Complete only if the funding support is provided from other than this award.)*

Name:	*Goutham Mylavarapu – no change*
Project Role:	*Principal Investigator*
Name:	*Stacey Ishman – no change*
Project Role:	*Co-Investigator*
Name:	*Raouf Amin – no change*
Project Role:	*Co-Investigator*
Name:	*Robert Fleck – no change*
Project Role:	*Collaborator*

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Goutham Mylavarapu (PI) has 40% effort in this DoD funded study. Since January 2020 and until December 2022, 60% of his remaining effort time is supported by an active grant from Cystic Fibrosis Foundation (CFF). Dr. Mylavarapu is a co-investigator on the CFF funded study and this does not impact his 40% effort in this project.

Raouf Amin (Co-I) has 1% effort in this DOD funded study. He is now a PI on the CFF funded study. His effort on the CFF funded study will not impact his effort in this project.

Stacey Ishman (Co-I) – no change

What other organizations were involved as partners?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:
Organization Name:
Location of Organization: (if foreign location list country)
Partner's contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

Nothing to report

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: *For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to* ***https://ers.amedd.army.mil*** *for each unique award.*

QUAD CHARTS: *If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.*

9. APPENDICES:

Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.