American Journal of Otolaryngology–Head and Neck Medicine and Surgery xxx (2017) xxx–xxx

Contents lists available at ScienceDirect

American Journal of Otolaryngology–Head and Neck Medicine and Surgery

journal homepage: www.elsevier.com/locate/amjoto

Abrasion and blunt tissue trauma study of a novel flexible robotic system in the porcine model☆

Michael Z. Lerner [a,*], Michael Tricoli [b], Marshall Strome [b]

[a] Montefiore Medical Center, Department of Otolaryngology – Head and Neck Surgery, Bronx, New York, USA
[b] Medrobotics Corporation, Raynham, MA, USA

ARTICLE INFO

Article history:
Received 15 March 2017
Available online xxxx

Keywords:
Transoral robotic surgery (TORS)
Head and neck cancer (HNC)
Minimally invasive surgery (MIS)
Medrobotics
Flex robotic system

ABSTRACT

Objectives: The objective of this study was to determine if a flexible robotic system caused increased tissue reaction when accessing the oropharynx and hypopharynx compared to intubation controls in only 2 scenarios: high speed tissue impact and multiple unit insertions and retractions. The data obtained were submitted as part of the entirety of information submitted for FDA approval.
Methods: This study consisted of 5 groups of Yorkshire pigs (2 animals per group). On Day 0, all animals were intubated. For group 1 (control), a second endotracheal tube was advanced to just above the vocal cords. In abrasion groups 2 and 3, the flexible robotic system was advanced against the oropharyngeal and hypopharyngeal tissues, respectively. In blunt trauma groups 4 and 5, the flexible robotic system was advanced at maximum speed (22 mm/s) to collide with oropharyngeal and hypopharyngeal tissues, respectively. Pre- and post-procedure endoscopic assessments of tissue reaction were performed daily for 4 days. An independent reviewer graded tissue reaction using a 0–3 point scale.
Results: Tissue reaction scores at each observation time point for all test groups were less than or equal to control scores except for one instance of moderate scoring (2 out of 3) on Day 2 for an animal in the blunt trauma group where reaction was likely intubation-related rather than device impact related. Otherwise, all flexible robotic system-treated animal scores were less than 1 by Day 4.
Conclusions: In this limited study, the flexrobotic system afforded surgical access to the oropharynx and hypopharynx without an increased level of abrasion or tissue trauma when compared to intubation alone.

1. Introduction

Historically, there has been significant morbidity associated with surgical management of neoplasms of the oropharynx, hypopharynx and larynx. Prior to the widespread acceptance of minimally invasive transoral surgery techniques described by Vaughan in 1978 [1] and advanced by several others [2,3], traditional surgical approaches to these anatomically "hard-to-reach" subsites often required mandibulotomy, tracheostomy, along with other transcervical approaches. The more traditional and "invasive approaches", while still necessary in cases of advanced disease, have a greater potential for disfigurement of what some may argue is the most humanizing and visible part of their bodies, i.e., the face and neck, and a more detrimental effect on post-operative swallowing function [4].

With recent advances in robotic technologies, especially at the beginning of 21st century, transoral robotic surgery (TORS) has built upon existing transoral surgery techniques and has gained momentum as a valuable modality for reducing morbidity while optimizing oncologic management in select cases [5]. In 2003, Haus et al. [6] first evaluated the potential for robotic endoscopic surgery using a porcine model and in 2005, McLeod and Melder [7] introduced the da Vinci robot (Intuitive Surgical Inc., Sunnyvale, CA) for TORS in an initial report resecting a vallecular cyst. While TORS has continued to gain widespread acceptance over the past decade, certain limitations and shortcomings have been noted. Some of these limitations are specific to the configuration of the da Vinci surgical systems, for example, multiple arms and camera must negotiate the narrow conduit of the oral cavity toward the surgical site, the surgeon must sit in a console away from the patient, prolonged setup time, need for extensive operating room staff training and limited access to certain hard-to-reach subsites of the laryngopharynx [5], at least in part, due to the lack of a flexible camera.

☆ **Institutions where work was performed:** Medrobotics Corporation, Raynham, Massachusetts, USA and CBSET, Inc. Test Facility, Lexington, Massachusetts, USA.**Attestation**: The principal investigator Marshall Strome, MD, MS, FACS had full access to all the data in the study and takes full responsibility for the integrity of the data and the accuracy of the data analysis.**Previous work:** Presented at the 2016 American Broncho-Esophagological Association in Chicago, IL from 5/18/16-5/22/16 as a poster presentation by Michael Z Lerner, MD.

* Corresponding author at: Department of Otolaryngology - Head and Neck Surgery, Montefiore Medical Center, 3400 Bainbridge Avenue, 3rd Floor, Bronx, NY 10467, USA.
E-mail address: michlern@montefiore.org (M.Z. Lerner).

http://dx.doi.org/10.1016/j.amjoto.2017.04.002
0196-0709/

The Flex® Robotic System is a robot-assisted platform based on a flexible and steerable scope technology that surgeons can use to navigate toward the surgical site using an integrated high-definition endoscopic system. Once positioned, the scope can become rigid to provide a stable platform through which flexible instruments can be deployed [8].

While the Flex® Robotic System design appears advantageous for TORS of the oropharynx and laryngopharynx, it was necessary to further characterize its safety for routine use as part of the FDA approval process. This study was designed to determine if the Flex® Robotic System caused increased tissue reaction when accessing the oropharynx and hypopharynx compared to intubation controls using a porcine model for only 2 specific surgical parameters.

2. Materials and methods

An innovative animal model was designed to compare the local tissue reaction caused by advancing the Flex® Robotic System through the upper aerodigestive tract to a standard technique, namely, intubation, which has known incidences of mucosal injury and is advanced in a fashion technically similar to that of the Flex® Robotic System. A large porcine model was chosen specifically, given the similarity in anatomic dimensions of the pig and human oropharynges. There also is precedent for using the porcine model for the study of transoral robotic surgical systems [9]. This study was performed as part of the submission process for FDA approval.

2.1. Animal welfare

This study was sponsored by Medrobotics Corporation and was performed at an independent test facility (CBSET, Inc.) in compliance with the Food and Drug Administration Good Laboratory Practice Regulations. The experiment was approved by the CBSET, Inc. Institutional Animal Care and Use Committee (IACUC) complying with all applicable regulations governing the care and use of laboratory animals. All procedures and conditions of testing were in compliance with the USDA, AWA [10]/AWR [11] and the National Research Council guidelines [12].

2.2. Anesthesia and perioperative procedures

Animals were pretreated with buprenorphine (0.01 mg/kg, IM) followed by inhalant isoflurane delivered via nosecone. Once sufficiently anesthetized, each animal underwent a pre-treatment assessment of the oral cavity, oropharynx and hypopharynx, which was video recorded by endoscopy. Next, animals were endotracheally intubated and maintained with isoflurane inhalant anesthetic. For the duration of the procedure and while under general anesthetic, animals were maintained in the dorsal recumbent position while monitoring body temperature, ECG and pulse-oximetry.

2.3. Study design, test device and procedure

The Flex® Robotic System is depicted in Figs. 1 and 2. Standard endotracheal tubes were used for intubation control animals. Mouth gags, which are used as standard practice in porcine transoral surgery, were only used in animals undergoing Flex® Robotic System access in the non-control groups. The senior author served as the operating physician and a blinded 3rd party physician with no company affiliation was tasked with grading tissue trauma based on captured images. All animals underwent a procedure on Day 0 under anesthesia, a pre-test assessment of the intended test areas was performed and then intubation with a standard endotracheal tube was performed. The number of flex insertion and removals were chosen to represent 2 theoretical

Fig. 1. The Flex® robotic system: the Flex® system included the Flex® cart, stand, base; Flex® scope; Flex® console. http://medrobotics.com.

Please cite this article as: Lerner MZ, et al, Abrasion and blunt tissue trauma study of a novel flexible robotic system in the porcine model, American Journal of Otolaryngology–Head and Neck Medicine and Surgery (2017), http://dx.doi.org/10.1016/j.amjoto.2017.04.002