Journal of Biomechanics 47 (2014) 1861–1868

Contents lists available at ScienceDirect

Journal of Biomechanics

journal homepage: www.elsevier.com/locate/jbiomech
www.JBiomech.com

Creation of an *in vitro* biomechanical model of the trachea using rapid prototyping

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ARTICLE INFO

Article history:
Accepted 11 March 2014

Keywords:
Compliant airway model
In vitro airway experiments
Endotracheal intubation
Endotracheal tube with inflatable cuff
Mucus leakage
Rapid prototyping

ABSTRACT

Previous *in vitro* models of the airways are either rigid or, if flexible, have not matched *in vivo* compliance characteristics. Rapid prototyping provides a quickly evolving approach that can be used to directly produce *in vitro* airway models using either rigid or flexible polymers. The objective of this study was to use rapid prototyping to directly produce a flexible hollow model that matches the biomechanical compliance of the trachea. The airway model consisted of a previously developed characteristic mouth–throat region, the trachea, and a portion of the main bronchi. Compliance of the tracheal region was known from a previous *in vivo* imaging study that reported cross-sectional areas over a range of internal pressures. The compliance of the tracheal region was matched to the *in vivo* data for a specific flexible resin by iteratively selecting the thicknesses and other dimensions of tracheal wall components. Seven iterative models were produced and illustrated highly non-linear expansion consisting of initial rapid size increase, a transition region, and continued slower size increase as pressure was increased. Thickness of the esophageal interface membrane and initial trachea indention were identified as key parameters with the final model correctly predicting all phases of expansion within a value of 5% of the *in vivo* data. Applications of the current biomechanical model are related to endotracheal intubation and include determination of effective mucus suctioning and evaluation of cuff sealing with respect to gases and secretions.

1. Introduction

Tracheal intubation requires the insertion of an endotracheal tube (ETT) through the oropharynx to form an artificial airway for the delivery of ventilation gases and aerosolized medications (Hess, 2002). Inflatable cuffs at the distal end of ETTs are often used to form an airtight seal within the trachea. ETTs with inflatable cuffs may include integrated suction ports for the removal of pooled secretions from the upper airway (Shah et al., 2005). The presence of the ETT affects pooling of mucus within the lungs, which can alter the effective distribution of gas delivery and increases the risk of infection. Additional risks of endotracheal intubation include damage of the airway during tube insertion, damage of tracheal tissue at the site of cuff inflation, and damage to epithelial cells from being pulled into mucus suction ports (Mujica-Lopez et al., 2010; Shah et al., 2005). A biomechanically accurate *in vitro* model of the tracheal airway region is needed to better evaluate the effectiveness of cuff sealing, mucus suctioning, and potential tissue damage complications associated with cuff inflation.

Tracheal biomechanical properties have been characterized by a number of numerical and experimental studies. Of particular interest are those studies that have modeled or measured tracheal compliance in healthy adult human airways, which is used in this study to guide the construction of an *in vitro* model. Numerical models have utilized symmetric, simplified approximations (Bagnoli et al., 2013; Begis et al., 1988; Holzhäuser and Lambert, 2001) and patient-specific geometries (del Palomar et al., 2010; Malve et al., 2011) to predict tracheal behavior under a variety of conditions, including standard mechanical ventilation (Malve et al., 2011), total liquid ventilation (Bagnoli et al., 2013), and implantation of an endotracheal prosthesis (del Palomar et al., 2010). However, only two numerical studies have reported estimates of human tracheal compliance. Holzhäuser and Lambert (2001) estimated tracheal compliance under a variety of strain conditions and found a strong dependence on the longitudinal stretch, using a two dimensional symmetric model. Begis et al. (1988) used a three dimensional symmetric model to estimate the variation of compliance during tracheal collapse.

Experimental studies that measure tracheal biomechanical properties utilize either *in vivo* (Baier et al., 1981; Hoffstein et al.,

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http://dx.doi.org/10.1016/j.jbiomech.2014.03.018
0021-9290/

1987; Newth et al., 1990; Williamson et al., 2011; Winter, 1985) or *ex vivo* data (Costantino et al., 2004; Lambert et al., 1991; Rains et al., 1992; Teng et al., 2007, 2009a, 2009b, 2008a, 2012, 2008b; Trabelsi et al., 2010) from human or animal subjects. Of these studies only Baier et al. (1981), Hoffstein et al. (1987), and Williamson et al. (2011) reported human tracheal compliance data. Baier et al. (1981) used fiber optic cinebronchoscopy to estimate tracheal compliance in healthy patients ($n=2$) as well as those with emphysema and pulmonary fibrosis, and reported trachea cross-sectional area as a function of transpulmonary pressure. The maximum specific compliance of the trachea, which is calculated as a normalized, non-dimensional cross-sectional area divided by a transpulmonary pressure difference, may be estimated from the figure in Baier et al. (1981) as 46×10^{-3} (cm H_2O)$^{-1}$, where the pressure is between 10 and 16 cm H_2O during inspiration. Hoffstein et al. (1987) characterized healthy adult tracheae ($n=8$) using an acoustic reflection technique, and reported specific tracheal compliance as $2.1\pm2.0\times10^{-3}$ (cm H_2O)$^{-1}$ for a pressure difference of 0 to 20 cm H_2O, which covered the range of pressures measured. Hysteresis was noted by both Baier et al. (1981) and Hoffstein et al. (1987), where the tracheal cross-sectional area was higher during expiration than inhalation for a given pressure. The large disparity in specific compliance reported by Baier et al. (1981) and Hoffstein et al. (1987) may be due to differences in methodology or sample size. A new technique, anatomical optical coherence tomography (aOCT) was validated by Williamson et al. (2010) where *in vivo* CT scan images were compared to aOCT images of four patients and close agreement was found, particularly for larger airways. Williamson et al. (2011) measured cross-sectional area of the trachea in 10 healthy adults using aOCT at applied airway pressures ranging from -10 to 20 cm H_2O. Williamson et al. (2011) also considered compliance for diseased cases and in more distal airways, both of which are not considered in the current study. They found that healthy patients had an average maximum specific tracheal compliance of approximately 33×10^{-3}(cm H_2O)$^{-1}$ in the range of transpulmonary pressure from 0 to 5 cm H_2O (Williamson et al., 2011) during an inhalation maneuver, which is similar to the findings of Baier et al. (1981). Regarding the different range of pressures where maximum specific compliance occurred, it is most likely due to differences in airway inflation protocol. Whereas the subjects in Baier et al. (1981) performed inspiratory and expiratory maneuvers while conscious, the Williamson et al. (2011) subjects were anesthetized and fitted with a laryngeal mask airway while pressure was manually increased from -10 to 20 cm H_2O.

Though it is possible to evaluate the mechanics of tracheal intubation using numerical or *in vivo* methods, an *in vitro* model is desirable because it allows for rapid, relatively inexpensive testing of ETT designs. Moreover, it is an ideal method for testing cuff sealing and mucus suctioning due to the relative difficulty of numerically characterizing such interactions, and the problems associated with visualizing these processes using an *in vivo* method. For evaluating the mechanics of intubation, the standard *in vitro* approach is to implement a rigid tubular geometry (Shah et al., 2005; Wright et al., 1989). In a more advanced model of the trachea, approximately 1/3 of a relatively rigid tube was made flexible using a thin rubber membrane to represent a compliant posterior section next to the esophagus (Mujica-Lopez et al., 2010). This model demonstrated that the flexible wall membrane could occlude the mucus suction port at certain mucus suction flow rates (Mujica-Lopez et al., 2010). However, this analysis was not performed to evaluate a flexible tracheal model with regard to accurately reproducing the biomechanical properties of the trachea.

Rapid prototyping provides an effective technique for generating anatomically accurate models of the anatomy. Considering the respiratory airways, rapid prototyped models are typically rigid and inflexible (Golshahi et al., 2011; Grgic et al., 2004; Holbrook and Longest, 2013; Longest et al., 2012; Robinson et al., 2009; Tian et al., 2011). Several recent studies have implemented rapid prototyping to aid in the creation of flexible airway models (Berg and Robinson, 2011; Berg et al., 2010; Kacmarynski et al., 2012; Longest and Oldham, 2008; Oldham et al., 2000; Robinson et al., 2006). These previous studies typically generate flexible airway models by first creating an internal solid and then using a casting technique to produce the flexible hollow. However, no reported studies have created flexible models that match the biomechanical properties of the airways. Furthermore, reported studies have not used rapid prototyping to directly produce flexible models that match biomechanical properties of *in vivo* tissue for the respiratory or circulatory systems. The objective of this study is to use rapid prototyping to directly produce a flexible hollow model that matches the biomechanical compliance of the trachea.

2. Methods

2.1. Airway geometry

The airway model used to create the *in vitro* model consisted of a previously developed characteristic mouth–throat (MT) region, the trachea, and a portion of the main bronchi (Fig. 1a). The MT model was previously developed by Xi and Longest (2007) and approximates cross-sectional profiles with elliptical curves to match the hydraulic diameters reported in the measurement study of Cheng et al. (1997). The trachea and main bronchi geometries were previously reported by Tian et al. (2011) and are based on airway measurements by Yeh and Schum (1980) and scaled to an adult with an inhaled tidal volume of 0.5 L and functional residual capacity of 3 L. Cartilaginous rings were included in the tracheal geometry based on the measurements of Russo et al. (2008). The tracheal model and part of the larynx were scaled by a factor of 1.54 to match the average initial cross-sectional area of the *in vivo* experimental data (Williamson et al., 2011) used for compliance testing. The resulting airway dimensions were within the range of average adults based on the anatomy analysis of Walenga et al. (2013) for the construction of aerosol transport models. Inclusion of the MT region in the computational model allows for

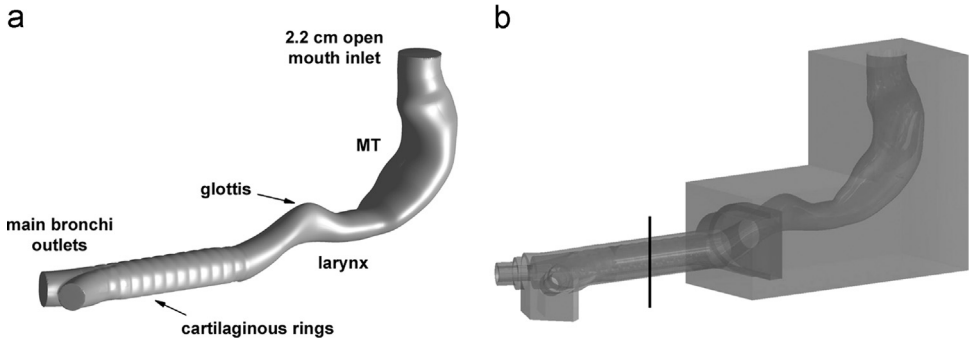

Fig. 1. Upper airway model from the mouth–throat (MT) through the main bronchi outlets presented as the (a) digital internal airspace and the (b) digital hollow model. A solid black line is drawn at the cross section of interest in the digital model.