Patient-specific models of human trachea to predict mechanical consequences of endoprosthesis implantation

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Nowadays, interventions associated with the implantation of tracheal prostheses in patients with airway pathologies are very common. This surgery may promote problems such as migration of the prosthesis, development of granulation tissue at the edges of the stent with overgrowth of the tracheal lumen or accumulation of secretions inside the prosthesis. Among the movements that the trachea carries out, swallowing seems to have harmful consequences for the tracheal tissues surrounding the prosthesis. In this work, a finite-element-based tool is presented to construct patient-specific tracheal models, introducing the endotracheal prosthesis and analysing the mechanical consequences of this surgery during swallowing. A complete description of a patient-specific tracheal model is given, and a fully experimental characterization of the tracheal tissues is presented. To construct patient-specific grids, a mesh adaptation algorithm has been developed and the implantation of a tracheal prosthesis is simulated. The ascending deglutition movement of the trachea is recorded using real data from each specific patient from fluoroscopic images before and after implantation. The overall behaviour of the trachea is modified when a prosthesis is introduced. The presented tool has been particularized for two different patients (patient A and patient B), allowing prediction of the consequences of this kind of surgery. In particular, patient A had a decrease of almost 30 per cent in his ability to swallow, and an increase in stresses that were three times higher after prosthesis implantation. In contrast, patient B, who had a shorter trachea and who seemed to undergo more damaging effects, did not have a significant reduction in his ability to swallow and did not present an increase in stress in the tissues. In both cases, there are clinical studies that validate our results: namely, patient A underwent a further intervention whereas the outcome of patient B’s

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surgery was completely successful. Notwithstanding the fact that there are a lot of uncertainties relating to the implantation of endotracheal prostheses, the present work gives a new insight into these procedures, predicting their mechanical consequences. This tool could be used in the future as pre-operative planning software to help thoracic surgeons in deciding the optimal prosthesis as well as its size and positioning.

**Keywords: trachea; finite-element method; tracheal endoprostheses; Dumon prosthesis; granuloma; deglutition**

### 1. Introduction

The trachea is a cartilaginous and membranous tube, extending from the lower part of the larynx, at the level of the sixth cervical vertebra, to the upper border of the fifth thoracic vertebra, where it divides into two bronchi, one for each lung. The trachea is nearly, but not quite, cylindrical, being flattened posteriorly; it measures approximately 11 cm in length; its diameter, from side to side, ranges from 2 to 2.5 cm, being greater in males than in females. The trachea is a fibroelastic tube with 15–20 C-shaped slightly separated cartilaginous rings along its length. Cartilages are aligned with each other, and posteriorly, where the trachea is apposed to the oesophagus, they are deficient. This space is filled by the tracheal muscle. The hyaline cartilage helps to maintain the patency of the central lumen during inspiration (Holzhauser & Lambert 2001; Lyubimov 2001).

The trachea can be exposed to different pathologies that usually lead to a common effect: the obstruction of air flow, either owing to loss of its wall’s rigidity (malacia) or owing to the decrease in its free section (stenosis). Tracheal stenosis, which is the most common tracheal injury (Grillo et al. 1995), is usually caused by a tracheotomy intubation with unsuitable pressure. Prolonged ischaemia and infection cause necrosis of the tracheal wall and deterioration of the cartilaginous structure through the formation of granulation tissue. This granulation may lead to the collapse of the tracheal wall (Huang 2001).

Many methods are available to deal with tracheal stenosis, such as tracheal dilation, excision of the stricture and anastomosis (end-to-end joining after resection of a tracheal part) or reconstruction, but, after treatment, the stenosis may reappear, especially when the stenosis is more than 2 cm long (Rob & Bateman 1949; Belsey 1951; Huang 2001; Grillo 2002).

In 1964, William W. Montgomery used for the first time a two-piece rigid acrylic stent during a surgical reconstruction of the cervical trachea to prevent post-operative tracheal stenosis; 1965, he improved it to a one-piece flexible silicone stent, called a T-tube stent, which is still being used today, albeit with some substantial modifications (Wahidi & Ernst 2003). The theory behind its use is to create a support on which the lesion scar can be modelled. Then, when the scaring process is stabilized, the prosthesis can be taken away. Since then, these stents have been the object of an unceasing evolution, from the simple tube design to more complex geometries (Noppen et al. 1999; Xavier et al. 2008), and from the static silicone stent to dynamic or expandable metallic stents.
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(Freitag et al. 1994; Madden et al. 2002; Noppen et al. 2005). However, in 1987, Dumon designed a flexible, studded, silicone prosthesis stent, with no metallic reinforcement to enhance flexibility and facilitate placement and removal. The studs are designed to prevent migration and limit contact with the mucosa (Dumon et al. 1996). The Dumon stent (Novatech; Aubagne, France; Noppen et al. 1999) is probably the most popular stent used nowadays in managing tracheal obstructive lesions, and is considered to be the most effective airway stent presently available worldwide based on both cost and safety factors (Mitsuoka et al. 2007).

Because of the clinical interest in the reasons for implantation of tracheal stents, few studies based on numerical models have been carried out on prosthesis/airway interaction; generally, research has focused on the experimental and clinical results of tracheal stent insertion (Dumon 1990; Grillo et al. 1995; Huang 2001). Most numerical studies have focused on the development of analytical models simulating an isolated tracheal ring formed by a cartilaginous ring and a muscular membrane (Holzhauser & Lambert 2001). In this line of research, a finite-element model of a lamb’s windpipe was constructed to predict the behaviour of the trachea before airway ventilation treatments (Costantino et al. 2004). Gustin et al. (1996) analysed the influence of the endotracheal prosthesis collocation through an axisymmetric model, which also used the finite-element method. Wiggs et al. (1997) presented a finite-element model free from the cartilaginous structure to analyse the mechanism of mucosal folding that occurs after smooth muscle shortening and which explains the difference in airway narrowing between asthmatic and control airways, based on the mechanics of the tracheal wall structure.

In contrast, the mechanical characteristics of the human trachea have not been completely determined; few studies have been carried out to understand the behaviour of its components (Rob & Bateman 1949; Belsey 1951; Grillo 2002; Trabelsi et al. 2010). In some of these studies, cartilage is considered to be a nonlinear material displaying higher strength in compression than in extension (Grillo 2002), but, in most of them, the isolated tracheal cartilage was considered to be a linear elastic material (Wahidi & Ernst 2003; Xavier et al. 2008). In the work carried out by Rains and colleagues (Rains 1989; Rains et al. 1992; Roberts et al. 1998), the stress–strain relations obtained for slices of human tracheal cartilage were considered linear for deformations up to 10 per cent of the initial length of the samples. In fact, there was negligible hysteresis and no residual strain in the specimens tested to a maximal applied strain of 10 per cent; beyond this limit, strain hysteresis and residual strain increased progressively (Rob & Bateman 1949). With respect to the mechanical properties of the tracheal muscle, most studies dealt with its plasticity, stiffness and extensibility (Yamada 1970; Maksym et al. 2005). Gunst & Ming-Fan (2001) investigated the effects of its length on the stiffness and extensibility at contractile time activation. Stephens et al. (1977) analysed the influence of temperature on force–velocity relationships. However, none of them except Trabelsi et al. (2010) analysed the mechanical properties of this membrane, which makes the collapse of the rings possible and therefore affects the pressure balance inside the trachea.

In this study, a patient-specific tool based on the finite-element method to analyse the behaviour of different tracheas before and after implantation of a prosthesis is described. Moreover, a real constitutive model for the tissues is
presented based on an experimental study of the mechanical behaviour of the principal tracheal constituents: cartilage and smooth muscle.

2. How to construct a patient-specific tracheal model

In this section, a complete description of the generation of a patient-specific tracheal finite-element model is presented. First, the experimental characterization of the tracheal tissues and their mathematical modelling is summarized from a previously published paper (Trabelsi et al. 2010). Then, the construction of patient-specific tracheal meshes will be explained. Finally, the estimation of the movement of the human trachea during swallowing will be presented. To collect all data, patients were fully informed about the objectives of the project, including information about the clinical and experimental protocols. The patient’s anonymity was guaranteed throughout the process.

(a) Experimental characterization and constitutive modelling of tracheal tissues

First, a histological study was performed in order to relate the microstructure of the different tracheal tissues to their mechanical behaviour. Then, the experimental tests were carried out for cartilage and smooth muscle samples, and, finally, the experimental curves were fitted to a suitable constitutive model, which could represent their particular behaviour (for an extended description, see Trabelsi et al. 2010).

The specimens were mounted on a Instron MicroTester 5548 to perform tensile tests. For cartilage, since there is no preferential fibre orientation, a neo-Hookean model with strain density energy function (SEDF), \[ \psi = C_1(\bar{I}_1 - 3) \], was used to fit the experimental results. Regarding the smooth muscle, and taking into account that the histology showed two orthogonal fibre families, Holzapfel SEDF (Holzapfel 2000) for two families of fibres was used,

\[
\psi = C_1(\bar{I}_1 - 3) + \frac{K_1}{2K_2} \{ \exp[K_2(\bar{I}_{41} - 1)^2] - 1 \}
+ \frac{K_3}{2K_4} \{ \exp[K_4(\bar{I}_{42} - 1)^2] - 1 \} + \frac{1}{D}(J - 1)^2,
\]

where \( C_1 \) is the material constant related to the ground substance, \( K_i > 0 \) are the parameters that identify the exponential behaviour owing to the un-crimping of the two families of fibres and \( D \) is the tissue incompressibility volumetric modulus. The invariants \( I_{ij} \) are defined as

\[
\bar{I}_1 = \text{tr} \bar{C}, \quad \bar{I}_2 = \frac{1}{2}[(\text{tr} \bar{C})^2 - \text{tr}(\bar{C}^2)], \quad \bar{I}_{41} = \mathbf{a}^0 \cdot \bar{C} \mathbf{a}^0 \quad \text{and} \quad \bar{I}_{42} = \mathbf{b}^0 \cdot \bar{C} \mathbf{b}^0,
\]

where \( \mathbf{a}^0 \) is a unitary vector defining the preferential orientation of the first family of fibres and \( \mathbf{b}^0 \) the direction of the second family, both of which are in the reference configuration. Finally, \( \bar{C} \) is the modified right Green strain tensor defined as \( \bar{C} = J^{-1/3}C \), where \( C = F^T F \), \( F \) is the deformation gradient and \( J = \det(F) \).
Figure 1. Uniaxial tests performed with tracheal muscle samples. (a) Fitting of Holzapfel’s model to the experimental results obtained in a tensile test in the longitudinal direction of the trachea. (b) Fitting of Holzapfel’s model to the experimental results obtained in a tensile test in the transversal direction of the trachea. Grey shaded area, experimental data; grey line, Holzapfel’s model.

Table 1. Parameters of the constitutive models that characterize the mechanical behaviour of cartilage and muscular membrane.

<table>
<thead>
<tr>
<th>Material Parameters</th>
<th>$C_1$ (kPa)</th>
<th>$K_1$ (kPa)</th>
<th>$K_2$</th>
<th>$K_3$ (kPa)</th>
<th>$K_4$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cartilage</td>
<td>577.7</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Muscular Membrane</td>
<td>0.87</td>
<td>0.154</td>
<td>34.15</td>
<td>0.34</td>
<td>13.9</td>
</tr>
</tbody>
</table>

The longitudinal and transverse tensile behaviour of the tracheal muscle was analysed and the parameters of the SEDF were calculated by fitting the constitutive equation of Holzapfel to the experimental results obtained in our laboratory (figure 1); see also table 1 for a summary of the material constants used for the different tissues.

(b) Construction of patient-specific tracheal meshes

The purpose of this research is to construct a useful tool for surgeons to predict the consequences of implantation of a tracheal prosthesis in a specific patient. Therefore, it is necessary to create patient-specific meshes taking into account the huge geometrical variability among them. To develop these patient-specific models, an automatic adaptation of the mesh has been implemented.

First, a set of DICOM images from a CT scan performed on a 70-year-old healthy man were obtained. These images were used to configure our ‘reference patient’ model. The DICOM files from the scan provide a clear picture of the internal (black) cavity filled with air; however, the outer surface and therefore the thickness of the wall are difficult to detect. Because of this, a non-automatic segmentation of the CT scan was carried out to determine the real geometry of the trachea and to distinguish between the muscle membrane and the cartilage rings. The segmentation of the DICOM data was made using MIMICS. An IGES file of
the segmented geometry was created to construct the associated computational grid. Then, a full hexahedral mesh of 29250 elements was made using PATRAN (figure 2), in which the different tissues (cartilage and muscular membrane) can be distinguished. Both the internal and external surfaces of this ‘reference patient’ are then used to construct the new patient-specific meshes.

Once this ‘reference mesh’ has been constructed, it can be adapted to the actual geometry of the patient’s trachea to produce the patient-specific mesh. This adaptation process is based on the geometry of the internal and external tracheal surfaces of each patient. Thus, the geometry of these new surfaces can be detected using the DICOM files, as for the ‘reference’ ones.

First, the geometry of the reference is scaled in length to the new geometry. Then, to adapt the mesh, only the external and internal surfaces are deformed slice by slice (0.6mm distant), that is, each slice of the three-dimensional image of the ‘reference’ geometry is adapted to the patient-specific geometry (figure 3).

Finally, the previously applied transformations to the three-dimensional image slices are applied to the nodes of the reference mesh to achieve a new patient-specific mesh. As the definition of elements and nodes does not vary in this process, the same groups for the different tissues are conserved during adaptation, and, therefore, the resulting patient-specific mesh also includes the cartilage rings (the same number as in the reference patient) and the muscular membrane. Figure 4 shows two different patient-specific meshes from two datasets, called patients A (male, age 28) and B (male, age 62) in the following sections. These meshes were subsequently checked and sufficient accuracy was found.
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Figure 3. Adaptive algorithm to construct the patient-specific mesh using a reference mesh.

Figure 4. (a) The reference mesh used for adaptation. (b) Two examples of adaptation for two different patients.

(c) Implantation of the tracheal prostheses

The purpose of this work is to analyse the influence of a tracheal endoprosthesis on the overall behaviour of the trachea. Therefore, the prosthesis has to be accurately located inside the tracheal wall. The thoracic surgeons decide which kind of prosthesis is suitable for each patient. The most common one is the Dumon prosthesis that basically consists of a cylinder that can be of several diameters and lengths. Therefore, this information is available for every patient and, in particular, in this article for patients A and B. The prosthesis diameter has to be large enough to fit inside the trachea, remaining fixed to the wall and avoiding migration; thus, the surgeon chooses a prosthesis with a diameter a little greater than the tracheal diameter (for patient A, a Novatech Dumon prosthesis 16 × 50; for patient B, a Novatech prosthesis 14 × 30).
To be able to numerically simulate this process, the commercial software ABAQUS v6.9 (Hibbit, Karlsson and Sorensen Inc. 2009) was used. First, a smaller prosthesis than the one needed is located inside the trachea in the specified position, then the prosthesis is radially deformed to its real diameter (for patient A, 16 mm; for patient B, 14 mm) (figure 5) contacting the inner tracheal wall. The contact definition was defined element by element and a friction coefficient of 0.1 was defined in order to avoid migration and to represent the studs that firmly joined the prosthesis to the wall. With this new configuration, the real stress distribution in the tracheal walls due to the prosthesis insertion can be obtained.

(d) Tracheal movement

It has been seen clinically that the most dangerous tracheal movement when a prosthesis is implanted is swallowing. During swallowing, three steps can be distinguished: lip–mouth time, laryngeal time and oesophagus time (Robert 2004). It is during the second step that the pharyngolarynx and the trachea move upwards by the contraction of the larynx elevating muscles. This movement can be simulated by introducing the force exerted by these elevating muscles, but, although their directions can be estimated, the value of the developed active force is very difficult to measure. Therefore, in this study, these forces were estimated by measuring the displacement that different tracheas undergo during swallowing in different patients.
Figure 6. Measurement of the swallowing movement. Marking of the thyroid cartilage to detect the movement in patients A and B before and after implantation of a Dumont prosthesis.

The displacements were obtained by capturing the tracheal movement with a sequence of fluoroscopic images. Here, the displacements of two different patients (patient A and patient B) will be reported both before and after implantation of the prosthesis (figure 6). Both patients underwent a long-term intubation (more than 15 days) that caused poor healing and left a fibrous stenosis. The total displacement that the trachea underwent during swallowing could be measured by marking the superior end of the thyroid cartilage in each image, which is a valid reference to track the movement along the antero-posterior and proximal–distal directions because this cartilage hardly undergoes deformation.

To see how the deglutition movement is performed, we show the magnitude of displacement for patient A before and after implantation of the prosthesis (figure 7). It can be seen that, when a patient swallows, two different peaks...
(points 3 and 5) of movement appear. In every monitored patient, this behaviour was seen. It can be related to the ‘barium meal’, which is difficult to swallow in only one deglutition cycle. The same trend could be seen for patient B, in whom, again, the ability to swallow was compromised when the endotracheal prosthesis was implanted. These movements were introduced as input calculations, to simulate using ABAQUS the deglutition movement of the trachea before and after prosthesis implantation.

3. Mechanical consequences of implanting a tracheal prosthesis

In this section, the stresses undergone in the trachea before and after implantation of a prosthesis are shown. First of all, the results for patient A are depicted. The deglutition movement was analysed before and after implantation. In figure 8, the displacements and the distribution of stresses are presented for the sequence of deglutition before implantation. It can be seen how the maximum stresses are distributed across the cartilage rings with a maximum value of 1.4 MPa for the maximum tracheal elongation. Moreover, it can be seen in the section of the trachea that there is not any stress concentration during the movement. The displacement of the trachea before implantation was 35 mm.

The influence of introducing an endotracheal prosthesis can be seen in figure 9. First, the prosthesis is located and then it is deformed as described in figure 5, then the deglutition movement is applied. In this case, the displacement (not shown in the figure) was 25 mm. The consequences of implanting a prosthesis can be easily seen in figure 9. The implantation provokes stresses in the internal surface of the trachea in the initial configuration (as can be seen at instant 0). In figure 9, the swallowing movement once the prosthesis is properly located is shown in order to compare the tracheal behaviour without and with the prosthesis. The maximum stresses during the movement are shown, and it can be seen how the maximum stresses (3.4 MPa) when the prosthesis was introduced nearly tripled. In addition, different local stress concentrations appeared in the internal surface of the trachea owing to the prosthesis contact.

Regarding patient B, the same analysis was performed. Once the mesh is adapted, the movement of the trachea can be analysed before and after implantation by introducing the captured displacements (figure 6). In figure 10, a summary of the obtained results before and after implantation is presented. In this case, as can be directly inferred from the fluoroscopic images, the ability of patient B to swallow is less compromised than in patient A, but the same trend is observed. Again, initial stresses owing to the adjustment of the prosthesis are produced in the trachea (figure 10c), but the overall behaviour of the trachea after implantation does not differ too much from that of the trachea before surgery.

4. Discussion

Based on clinical experience, thoracic surgeons classify swallowing as the movement that causes most harm to the trachea when a prosthesis is implanted. During swallowing, the trachea ascends accompanying the larynx, causing a
Figure 8. (a) Displacement and (b) maximum stresses undergone by patient A’s trachea during swallowing before implantation. Different stages of the movement (marked from 0 to 5) are plotted (see figure 7 for numbering).

non-homogeneous elongation of its segments. When a prosthesis is implanted, this movement is compromised because the stent stiffens these segments. This explains the inefficiency of the glottis closing that is sometimes observed after the placement of tracheotomy stents. At present, surgeons use their clinical experience to choose a suitable stent for each patient, but unfortunately most of the patients have to be reoperated more than twice.

In this work, the first step to constructing a pre-operative planning tool suitable for thoracic surgeons is presented. This first approach consists of using complex material models based on the experimental characterization of human tracheal tissues, obtaining patient-specific meshes by using an adaptive algorithm, introducing real movement of the patient-specific tracheas and analysing the
influence of locating a prosthesis in the exact position defined by the clinician. This procedure has been detailed for two different patients: patient A and patient B.

The morphology of these tracheas was completely different. Both patients were male, but patient A was 28 years old while patient B was 62. In addition, patient B’s trachea was significantly shorter than average. The deglutition movement for each patient was recorded using fluoroscopic images before and after the intervention. It could be appreciated that both of the patients lost some ability to swallow after the surgery. This consequence was more evident in patient A, who underwent a decrease in his tracheal ascending movement of nearly 30 per cent.

Figure 9. (a) Displacement and (b) maximum stresses undergone by patient A’s trachea during swallowing after implantation. (a) Location of the prosthesis. Different stages of the movement (marked from 0 to 5) are plotted (figure 7 for numbering).
The deglutition movement was simulated for both patients before and after locating the stent. The dimensions and location of the stents were defined by the thoracic surgeons. Stresses were located in the tracheal wall tissue in contact with the superior edge of the stent. Three times higher maximal stress was obtained after introduction of the prosthesis in patient A. However, the stresses in patient B were hardly changed. It has been reported that granulation formation can occur at both ends of the stent, suggesting that this anomalous growth can be related to the mechanical stress (Dumont et al. 1996; Noppen et al. 2005). Therefore, using this hypothesis, patient A had developed some fibrous tissue at the superior edge of the stent, while patient B had not. In both cases, there was clinical validation.

Figure 10. Mechanical consequences of implanting a prosthesis in patient B. (a) Displacement and maximum principal stresses in patient B’s trachea before implantation. (b) Implantation of the prosthesis, showing the deformation of the prosthesis to reach its actual diameter. (c) Displacement and maximum principal stresses in patient’s B trachea after implantation.
of these results because both patients were monitored following implantation of the stents. Patient A underwent several reinterventions whereas patient B did not. Another important result that can be deduced from these simulations is the reaction force related to the imposed displacement. In both cases, the reaction force (which can be related to the forces exerted by the elevating muscles) was very similar. This implies that the same force for each patient could be introduced, and then the displacement of the trachea, which is related to the patient’s ability to swallow, would be another result of these simulations.

5. Limitations of the study

In spite of the good qualitative results that have been obtained in this work and the effort that has been made in constructing patient-specific models to predict the consequences of implanting an endoprosthesis, there are several assumptions that have been made and have to be pointed out.

Patient-specific tracheal meshes have been made using a mesh adaptation algorithm. A reference mesh is adapted to a specific tracheal geometry by transforming the reference geometry to the real one. This transformation is made slide by slide, conserving the definition and quality of the reference mesh. The first reason for this is to automate the definition of element groups regarding the different materials, although this implies conserving the same number of cartilage rings among patients, for instance, which would involve a loss of accuracy. Nevertheless, the goal of this work is to construct a tool that allows the thoracic surgeons to compare the behaviour of the trachea before and after implanting a prosthesis, or using different types of prostheses.

The experimental characterization of the human tracheal tissues has been made using samples from elderly people. It is known that biological tissues lose water and collagen with age owing to higher permeabilities and, therefore, their mechanical properties can be affected, so a wider experimental test with a higher range of ages should be performed to obtain non-age-dependent results. Moreover, there was a large variability from the mean value of the experimental curves and each of the isolated curves, a fact that can be related to the use of samples from different individuals. Therefore, more samples would be necessary to draw more accurate conclusions.

The boundary conditions used were based on two real cases of patients before and after implantation. The deglutition movement obtained from fluoroscopic images was obtained by marking the thyroid cartilage in a sagittal plane and tracking its position. Taking into account that the mobility of the trachea in the transverse plane is negligible, this movement would represent the overall movement of the trachea during swallowing. To be able to validate the simulated deglutition movement, the measurement of the movement of each cartilaginous ring would be valuable, but at present these rings cannot be distinguished on radiographic images.

Regarding the endoprosthesis itself, a rough approximation has been made assuming it is a perfect cylindrical surface. The Dumon prosthesis is actually a perfect cylinder; however, it has several studs that are used to fix it to the internal wall of the trachea. This effect has not been simulated, but the friction of the prosthesis–internal wall interface was high enough to avoid migration.
6. Clinical implications

Notwithstanding the fact that there are a lot of uncertainties in implanting an endotracheal prosthesis, the present work provides a new insight into these procedures, predicting their mechanical consequences. This tool could be used in the future as a support decision tool to help in the pre-operative planning of this kind of surgery.

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