Analysis of the Mechanical Behavior of the Nijdam Voice Prosthesis

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The valveless Nijdam prosthesis is a new voice prosthesis for laryngectomized patients using tracheoesophageal speech. An "umbrella-like hat" covers the esophageal side of the tracheoesophageal fistula and is deformed during speech by air pressure. To decrease pressure loss during speech, a good understanding of the mechanical behavior is essential. In the present study, the Finite Element Method (FEM), used in engineering to analyze the mechanical behavior of complex structures, was applied to analyze eight possible improvements of the Nijdam prosthesis. This study found that, during speech, deformation of hat and soft tissue occur. Distinct differences in the hat's deformation of the eight models also were found. It is concluded that complex structures like the Nijdam prosthesis can be analyzed by FEM. An optimal model was found to decrease pressure loss while stresses in the device remain safe.


INTRODUCTION

Voice prostheses have been clinically used over the past 16 years to restore speech after total laryngectomy.1-3 Voice prostheses are inserted in a surgically induced fistula in the tracheoesophageal wall. At initiation of voice, the tracheostoma has to be occluded manually or by means of a tracheostoma valve.2,4 Expiratory air will flow into the esophagus and causes vibration of the pseudoglottis, which leads to phonation.

Two types of voice prostheses can be distinguished: nonindwelling and indwelling devices. The former devices can be replaced by the patient; the latter stay in place until malfunctioning of the device occurs, which is generally indicated by either leakage or increased pressure loss. The indwelling prostheses should be replaced as an outpatient clinic procedure by an otorhinolaryngologist.

The indwelling Nijdam prosthesis is a new voice prosthesis. It consists of a tracheal flange and a smaller esophageal flange, connected by a shaft (Fig. 1). On top, an "umbrella-like hat" is connected to the esophageal flange by three small columns. It differs from other indwelling voice prostheses by the fact that it does not have a distinct valve construction of its own. The hat of the Nijdam prosthesis covers the esophageal side of the fistula (Fig. 2). The edge of the hat is in contact with the esophageal mucous tissue. The combination of these two structures forms a valve. The Nijdam prosthesis has been clinically applied in the ENT clinic of Nijmegen and Maastricht (The Netherlands) since 1988.5

In vitro studies showed that, when the shaft length of the Nijdam prosthesis corresponds exactly to the tracheoesophageal wall thickness, the trans-device pressure loss is comparable to the Provox prosthesis.7 One can question whether this situation is possible in vivo, and if so, whether it will result in a leakage proof situation under all circumstances. If a 1-mm shorter Nijdam prosthesis is selected, the tighter fit will still result in a very acceptable pressure loss resembling the resistance of the Low Resistance Groningen Button.8 Aspiration will most probably not occur in this situation.
OBJECTIVES

One of the disadvantages of the Nijdam prosthesis is the sensibility to changes in tracheoesophageal wall thickness that interferes with the valve mechanism. To limit the resulting increase of pressure loss, the mechanical valve behavior had to be studied. It was assumed that air pressure deforms the hat and enables airflow to the pseudoglottis. Objectives of this study were to check this hypothesis and to develop strategies to decrease pressure loss.

MATERIALS AND METHODS

The prosthesis (Fig. 3) is made from medical-grade silicone rubber and is molded in one piece. It is available in five shaft lengths, varying from 4 to 8 mm, and two shaft diameters, 7 and 8 mm, to meet the individual differences in wall thickness and diameter of the fistula. It is produced and distributed by Medin Instruments (Groningen, The Netherlands).

Although the geometry of the hat is not very complex, the interaction between hat and soft tissue wall makes it rather difficult to study the valve behavior analytically. Therefore we used a numerical tool, the Finite Element Method (FEM), often used in mechanical engineering to analyze deformation of complex structures. FEM divides a complex construction into a network of simple elements. Deformation of such an element can be calculated analytically. The summarized deformation of all individual elements approaches the deformation of the complete construction. The larger the number of elements, the better the predicted deformation will be. With FEM the internal stresses can be calculated as well. This makes it possible to predict if the construction will collapse under the applied load.

When applying FEM on the Nijdam prosthesis, soft tissue characteristics have to be included as well, because the combination of both structures creates the valve function. Figure 4 shows the Nijdam prosthesis and tracheoesophageal wall, divided into simple beams. Besides geometry, material characteristics define deformation under a load. For this study, silicone rubber and soft tissue of the tracheoesophageal wall were considered to be isotropic, nonviscous, and Hook's linear elastic. Modulus of elasticity of silicone rubber is 1 MPa; for the tracheoesophageal wall 10 kPa was used. To decrease pressure loss, the hat's thickness was varied between 1 (the original wall thickness), 0.8, 0.6, and 0.4 mm (models 1 to 4). Also the influence of a different shape of hat and columns was studied by varying the wall thickness of the essential parts—the flat middle part of the hat, the rim of the hat, and the columns (models 5 to 7, see Table I).

All models were loaded with 2 kPa, a typical tracheal pressure during speech. Mechanical stresses in the silicone rubber were calculated to predict if they exceed the maximal stress that can be resisted by silicone rubber (10 MPa). If they do, the silicone rubber could rupture.

<table>
<thead>
<tr>
<th>Model No.</th>
<th>Middle Part of Hat</th>
<th>Rim of Hat</th>
<th>Column</th>
</tr>
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<tr>
<td>5</td>
<td>1</td>
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<tr>
<td>7</td>
<td>0.4</td>
<td>0.4</td>
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</table>

TABLE I.

Wall Thicknesses (in mm) of the Three Different Parts of the Nijdam Prosthesis That Have Been Varied to Study the Influence of a Different Shape.
RESULTS

Figure 5 shows the calculated deformation of a device with a 0.4-mm wall thickness and the deformation of the tracheoesophageal wall due to the tracheal pressure. It is very clear that both the deformation of the hat and soft tissue makes airflow to the esophagus possible. Table II summarizes the calculated deformation of all models. The deformation of the soft tissue is summarized in Table III.

Varying the wall thickness of the essential parts (the flat middle part of the hat, the rim of the hat, and the columns) shows very different outcomes (Fig. 6). The mean deformation of the rim of the hat, which directly defines pressure loss during phonation, is summarized in Table II.

The highest stresses occur in model 4, 0.12 MPa. This, however, is still far below the maximal stress of silicone rubber, 10 MPa, so all models will withstand the load.

DISCUSSION

Most laryngectomized patients can regain their speech using a voice prosthesis. Although most laryngectomized patients are very enthusiastic about rehabilitation with voice prostheses, drawbacks still remain.
First, the lifetime of the prosthesis is limited because of adhesion of Candida and microorganisms and yeast on the valve surface. This causes leakage and/or increased pressure loss, requiring replacement of the prosthesis. Replacement of indwelling prostheses has to be done by a physician and thus is neither time-effective nor cost-effective. A prosthesis with a longer lifetime would be preferable. The lifetime of the Nijdam prosthesis is relatively long. Mean lifetime has been demonstrated to be 19 weeks. The same study presented a mean lifetime of the Provox and the Low Resistance Groningen Button of 13 and 15.8 weeks, respectively. The relative long device lifetime of the Nijdam prosthesis is probably due to the fact that the valve mechanism is less disturbed by the ingrowth of Candida and by the ingrowth of yeast microorganisms.

Second, high intratracheal pressure needed for phonation tires the patients. The intratracheal pressure is mainly caused by both the pseudoglottis and the prosthesis. Transdevice pressure loss should be low to decrease the intratracheal pressure. However, changing properties of the device could affect other qualities of the device.

The Finite Element Method predicts the mechanical behavior when properties are changed, so the trial and error method that requires building and testing several prototypes can be avoided, resulting in a faster product design and a better product.

**TABLE III.**
Mean Deformation in Axial Direction (in mm) of the Tracheo-Esophageal Wall As a Function of the Wall Thickness.

<table>
<thead>
<tr>
<th>Wall Thickness</th>
<th>Rim Deformation</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
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</tr>
<tr>
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<tr>
<td>6</td>
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<td>1.02</td>
</tr>
<tr>
<td>8</td>
<td>1.13</td>
</tr>
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</table>

Pressure loss can be reduced by changing hat geometry and thickness. If the thickness of the hat is decreased, deformation increases, resulting in a larger gap and lower pressure loss. Decreasing the hat thickness appears to be possible without increasing internal stresses. A second possibility is changing the hat’s geometry by a local change of wall thickness. The assumption, that silicone rubber and soft tissue of the tracheoesophageal wall can be considered to be isotropic, nonviscous, and Hook's linear elastic, is acceptable, because the results of the models are compared only relatively.

**CONCLUSION**

The Finite Element Method gives detailed information about the mechanical behavior of the Nijdam prosthesis. Soft tissue plays an important role, because its deformation during speech influences valve functioning. The optimal configuration of the Nijdam prosthesis appears to be model 7, because deformation of the hat’s rim is maximal and the stresses are acceptable.

**BIBLIOGRAPHY**