A Thin Tracheal Silicone Washer to Solve Periprosthetic Leakage in Laryngectomies: Direct Results and Long-Term Clinical Effects

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Objectives: Assessment of the immediate results and long-term clinical effects of a thin silicone washer placed behind the tracheal flange of voice prostheses to treat periprosthetic leakage.

Patients and Methods: Three year retrospective analysis of 32 laryngectomized patients with 107 periprosthetic leakage events (PLEs). Custom-made silicone washers (outer diameter 18 mm, inner diameter 7.5 mm, thickness 0.5 mm) were placed behind the tracheal flange either in combination with prosthesis replacement or later.

Results: There was immediate resolution of periprosthetic leakage in 88 PLEs (median, 38 d; mean, 53 d; range, 8–330 d) and in 6 PLEs with the washer still in situ at the date of analysis (median, 75; mean, 97 d; range, 38–240 d). There was no resolution for periprosthetic leakage in 13 PLEs. Thus, in total, 94 of 107 PLEs (88%) were successfully resolved. In 29 of 32 (91%) patients, the washer resolved the problem at least in one PLE successfully. Twelve of 32 patients, including all 3 with washer failures, also required other interventions to ultimately solve the problem. The vast majority of patients (80%) did not consider placement of the washer to be inconvenient.

Conclusions: In consideration of the high success rate and limited inconvenience for patients, this simple thin silicon washer application provides a good first option for the treatment of periprosthetic leakage.

Key Words: Total laryngectomy, prosthetic voice rehabilitation, periprosthetic leakage, silicone washer, tracheal flange.

INTRODUCTION

Prosthetic voice restoration is presently the most favored technique for vocal rehabilitation after total laryngectomy. After removal of the larynx, a tracheoesophageal fistula is created to hold a voice prosthesis.1 The one-way valve construction of such prostheses allows the passage of air for voicing and prevents aspiration. Voicing is achieved through mucosal vibrations induced by pulmonary air passing through the prosthesis into the pharyngoesophageal segment or neoglottis.

The most frequent inconvenience with prosthetic voicing is possible leakage of fluids (i.e., aspiration), which, if uncontrollable, forms the main indication for replacement of these devices. Leakage can either be device related (i.e., transprosthetic) or fistula related (i.e., periprosthetic). Transprosthetic leakage accounts for approximately 80% of all leakages and is mainly the result of insufficiency of the one-way valve mechanism, most likely caused by biofilm and Candida deposits on the valve itself2 but sometimes is elicited by an esophageal under-pressure during breathing or swallowing.3 Periprosthetic leakage, the topic of this paper, mainly occurs when the fistula is too wide because of atrophy of the periprosthetic tissues, scarring of the fistula tract, granulation tissue formation, local tissue inflammation, or the formation of a so-called esophageal pouch. Periprosthetic leakage accounts for 11% to 27% of all replacement indications for prosthetic devices.4–6 Most cases of periprosthetic leakage can be managed by downsizing of the device.7 However, in case of a too wide or scarred fistula tract, this is not always achievable, either because the shortest prosthesis is still too long or the fistula tract is not completely round and...
gaps between the prosthesis and the fistula wall remain open. Inserting a (slightly) too short device is also not an option in the latter cases because increased pressure of the flanges of the device on the party wall may cause local irritation and granulation formation. Another occasional cause of periprosthetic leakage is the presence of an esophageal pouch. This condition is defined as excess mucosal tissue that has formed over the esophageal flanges of a prosthesis, creating a diverticulum-like cavity in which the esophageal flange is buried. Typical for such instances is a slight protrusion of the prosthesis into the trachea, which may be mistaken for the device being too long. If esophageal pouch is not suspected or anticipated, accurate sizing of the prosthesis (i.e., insertion of a longer prosthesis to encompass the complete fistula tract including the pouch) might not be accomplished. And, if in such instances a too short prosthesis is inserted, the problem will be aggravated, and extrusion of the prosthesis or closure of the esophageal side of the fistula tract may occur.

If resizing turns out to be ineffective, several other options are available to decrease the diameter of the fistula to treat the periprosthetic leakage. Placement of a purse-string suture or the augmentation of the party wall by injection of various substances in the fistula wall such as granulocyte-macrophage colony-stimulating factor (GM-CSF), autologous fat, bioplastique collagen, or cymetra are among the most frequently used techniques. Temporary removal of the prosthesis to stimulate spontaneous shrinkage of the fistula is another and, for many clinicians, often the first option. However, if the periprosthetic leakage persists, ultimately, the fistula has to be closed, followed by a secondary tracheoesophageal puncture after 2 to 3 months, forcing the patient temporarily to use an alternative communication method, usually electrolarynx speech.

Other options reported in the literature to treat periprosthetic leakage are the use of silicon washers, either of 2 mm thickness inserted behind the tracheal flange, as described by Bunting, or glued onto the esophageal flange of the prosthesis, as described by Kress et al. Although these authors indicate reasonable success rates with their methods, both options pose some inherent problems. The insertion of a 2 mm thick washer at the tracheal side might put some undue pressure of the esophageal flange on the fistula tract. The washer on the esophageal side, although this would appear to be the logical location, has to be in place before the insertion, requires extra gluing, and might make the insertion procedure less straightforward. Therefore, based on earlier experiences and discussions with others, we developed a thinner (0.5 mm), wider diameter (18 mm) silicon washer that can be put in position secondarily, that is, after a prosthesis has already been inserted. This washer is not intended to make a too long prosthesis shorter but to function as an extra flange that adheres to the mucosa by surface tension, thus potentially limiting the chance of periprosthetic leakage. In this paper, we describe the direct results and long-term clinical effects obtained with placement of a 0.5 mm thick, 18 mm diameter silicone washer behind the tracheal flange.

PATIENTS AND METHODS

Patients

Thirty-two laryngectomized patients received at least one washer between August 2004 and August 2007. Of these 32 patients, 23 originally were laryngectomized at our institute, whereas 9 were referred for prosthesis or fistula-related problems. At our institute, approximately 200 patients with a voice prosthesis are in long-term follow-up, which means that the 23 “washer patients” form approximately 12% of our laryngectomy patient population.

Of the 32 included patients, 27 were male and 5 female, with a mean age of 62 (range, 39–83) years. The median time since surgery was 5 (range, 0.6–21) years, and the median time between laryngectomy and the placement of the first washer was 4 years (range, 1 mo–20 yr). All but 1 patient were radiated, 19 prior to surgery and 12 after surgery. The pharynx was reconstructed in 12 (38%) patients, in 10 patients with a pectoralis myocutaneous flap and in 2 patients with a radial forearm flap. In the remaining 20 patients, the pharynx was closed primarily. Twelve (38%) patients were known to have had a pharyngeal stenosis, for which, in 11 patients, dilatations were performed. All 32 patients used a Provox2 prosthesis, and 15 of them were also familiar with the Provox ActiValve (8 of the 23 original Netherlands Cancer Institute patients and 7 of 9 referred patients). Twenty-one of 30 (70%) patients were known to have had fistula problems (i.e., granulation formation, hypertrophic scarring, or infection) in the past, some time before they received a first washer (in 2 patients, no information was available on this issue). During the 3 year period, one patient died of intercurrent disease. Patient characteristics are given in Table I.

Periprosthetic Leakage Events

There were, in total, 117 periprosthetic leakage events (PLEs) in which a washer was applied. Although the periprosthetic leakage stopped immediately after washer application, 10 PLEs were excluded from further analysis because adequate follow-up was too short or lacking (with some of the outside referrals) and categorization into one of the four outcome categories (see below) was not possible, leaving 107 PLEs for further analysis in this retrospective study. In 9 of these 107 PLEs, a double washer (mostly applied during earlier stages of the study) was placed, but because of the small numbers, this is not further analyzed. During the study period, the vast majority of patients (94%) also required one or more downsizing of the prosthesis; only two patients never had their prostheses resized to smaller versions. Twelve patients also underwent one or more additional interventions, other than the use of a washer, to treat periprosthetic leakage, including temporary prosthesis removal (3 patients), purse-string suture (8 patients), silicone injection (6 patients), and closure of fistula followed by repuncture (2 patients). Six patients had a combination of two or more these interventions, and, in six patients, one of these four interventions was carried out.

Washers

The washers were custom made with a special punch (Fig. 1). With this punch, washers were produced from a 0.5 mm thin nasal silicon sheath (Silatos Silicone Sheetings, Atos Medical, Hörby, Sweden). Initially, three outer diameters of the washers were tested, 16, 17, and 18 mm, all with an inner diameter of 7.5 mm, to ensure some distension outside the tracheal flange (15 mm diameter) and good fit around the shaft of a Provox prosthesis (22.5 F, which equals a diameter of 7.5 mm). After the first few patients, it became obvious that an outer diameter of 18 mm was the best addition to the flange diameter of the prosthesis itself, allowing the washer to follow the contours of the tracheal wall.
and to adhere to the mucosa. In addition to the punch, Figure 1 shows the various steps of washer placement behind the tracheal flange of the prosthesis in situ with the help of two hemostats and also shows the washer in situ.

**Outcome Categories**

Outcomes were classified into four categories: category 1, the periprosthetic leakage was immediately cured for at least 7 days, but eventually recurred; category 2, the next replacement (later than 7 d) was for transprosthetic leakage, meaning that the “natural” end of the device-life had been reached; category 3, the next replacement was for a fistula-related problem other than periprosthetic leakage; categories 1, 2, and 3 were considered successful solutions of the periprosthetic leakage, in contrast with the last category, category 4, no immediate solution of the periprosthetic leakage was achieved or this leakage recurred within 7 days. Those washers still in situ at the date of analysis (and minimally at 7 d) also were considered to be successful and will be described separately. Patients often received more than one washer and therefore could fall into more than one of these four categories. Patients were considered to be treated successfully if at least one washer was in one of the first three categories. When no washer attempts were successful, the patient was considered to be unsuccessfully treated for periprosthetic leakage. Thirty-one patients (given that 1 patient died during the 3 yr period of this study) were questioned either by telephone or while visiting the outpatient clinic for a routine follow-up about possible inconveniences they experienced during placement of the washer.

**Statistics**

Statistical analyses primarily included tabulations and descriptive analyses. Statistical associations were calculated by Pearson’s correlation coefficient. A two-tailed P value of less than .05 was taken to indicate statistical significance. Generalized equation models were fitted to relate the different outcome categories with clinical parameters (pharynx reconstruction, neopharynx stenosis, radiotherapy, sex, and age), taking into account that there were repeated observations of patients.

**RESULTS**

This analysis is based on the 107 PLEs with adequate follow-up, and, in these instances, the washer was placed 91 times (85%) in combination with a Provox2 prosthesis and 16 times (15%) with an ActiValve. The washer was placed at the time of the replacement of the prosthesis in 47% (n = 50) of cases and at a later moment than prosthesis replacement in 53% (n = 57), with a median interval of 10 (range, 1–193) days. The two longest intervals (137 and 193 d) were to salvage otherwise well-functioning Provox ActiValves, which stayed in place for another 15 and 98 days, respectively. In 31 PLEs in 13 patients, a 4.5 mm prosthesis was in situ, for which further downsizing of the prosthesis to solve the periprosthetic leakage was no longer an option. In the remaining 76 PLEs in 30 patients, the washer was placed with a 6 mm or longer prosthesis in situ. Because of the variation in fistula length over time, some patients obviously can fall into both the 4.5 mm and the 6 mm and longer categories. There is no difference in
Prosthesis length between the immediate and delayed placement categories nor is there between the Provox2 and Provox ActiValve (latter data not shown). Characteristics of the prostheses combined with a washer are given in Table II.

At the date of analysis, washers have been removed after 101 PLEs, and in 6 PLEs, the washer was still successfully in situ. Table III shows the survival times of the washers in the four outcome categories, and Figure 2 shows these as a boxplot. The first outcome category (periprosthetic leakage cured for at least 7 d) comprised 28 PLEs in 15 patients; periprosthetic leakage recurred after a median and mean of 31 and 46 (range 8–229) days, respectively. The second category (periprosthetic leakage cured and next replacement required for transprosthetic leakage) comprised 28 PLEs in 14 patients; next prosthesis replacement occurred after a median and mean of 45 and 56 (range, 12–145) days, respectively. The third category (periprosthetic leakage cured and next replacement required for fistula problem) comprised 32 PLEs in 21 patients; next prosthesis replacement was required for granulation formation/hypertrophic scarring (n = 13), infection (n = 4), formation of an esophageal pouch (n = 9), or extrusion of the device (n = 6) after a median and mean washer lifetime of 41 and 55 (range, 9–330) days, respectively. The 88 washers from categories 1 to 3 together were replaced after a median and mean of 38 and 53 (range, 8–330) days. Finally, the fourth category comprised 13 PLEs in 10 patients; the washer placement was not successful, that is, there was persistent periprosthetic leakage either immediately (n = 4) or within 7 days (n = 9) (median and mean of 1 and 1.4 d, respectively; range, 0–5 d). These 13 cases appeared to be still solvable by downsizing (n = 9) or with replacement for a prosthesis of the same size (n = 2) or required upsize because of an initially overlooked esophageal pouch (n = 2). The washers in six PLEs were still in situ at the date of analysis, after median and mean of 75 and 97 (range, 38–240) days, respectively.

Because many patients over time had more than one PLE, they often fell into several categories, and only in three patients was the use of a washer never successful. Ultimately, 94 of 107 (88%) washer placements could be considered successful, and 29 of 32 (91%) patients were successfully treated with a washer at least once, whereas 19 of the 32 patients had 2 or more washers placed with success. However, as already mentioned, it is also important to realize that, in 12 patients, one or more other interventions were additionally needed to solve their periprosthetic leakage.

Prosthesis length appears to have no statistically significant influence on device life when used in combination with a washer (i.e., problems with shorter prostheses were not more successfully treated than with longer versions or vice versa). In questioning patients about their experience with washers, one patient was not able to remember placement of a washer (which was placed 2 yr earlier). In the remaining 30 patients, 24 (80%) considered the placement not inconvenient at all, 2 reported it to be a bit inconvenient, 1 as rather inconvenient, and 3 as very inconvenient.

From the generalized equation models, fitted to relate the outcome category to the clinical parameters pharynx

**TABLE II.** Characteristics of Prostheses With Washer (n = 107).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prostheses combined with washer</td>
<td></td>
</tr>
<tr>
<td>Provox2</td>
<td>91 (85)</td>
</tr>
<tr>
<td>ActiValve</td>
<td>16 (15)</td>
</tr>
<tr>
<td>Prostheses directly combined with washer (n = 50)</td>
<td></td>
</tr>
<tr>
<td>4.5 mm</td>
<td>20 (40)</td>
</tr>
<tr>
<td>6 mm</td>
<td>19 (38)</td>
</tr>
<tr>
<td>8 mm</td>
<td>9 (18)</td>
</tr>
<tr>
<td>10 mm</td>
<td>1 (2)</td>
</tr>
<tr>
<td>12.5 mm</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Prostheses later combined with washer (n = 57)*</td>
<td></td>
</tr>
<tr>
<td>4.5 mm</td>
<td>11 (19)</td>
</tr>
<tr>
<td>6 mm</td>
<td>22 (38)</td>
</tr>
<tr>
<td>8 mm</td>
<td>18 (32)</td>
</tr>
<tr>
<td>10 mm</td>
<td>5 (9)</td>
</tr>
<tr>
<td>12.5 mm</td>
<td>1 (2)</td>
</tr>
</tbody>
</table>

*Delayed application of washer: median 10 (range, 1–193) days.

**TABLE III.** Medians, Means, and Ranges of Survival Times of Washers (in Days) per Replacement Category.

<table>
<thead>
<tr>
<th>Category</th>
<th>Washer In Situ Until . . . (n)</th>
<th>Survival Times of Washers in Days, Median, Mean (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Periprosthetic leakage (28)</td>
<td>31, 46 (8–229)</td>
</tr>
<tr>
<td>2</td>
<td>Leakage through (28)</td>
<td>45, 56 (12–145)</td>
</tr>
<tr>
<td>3</td>
<td>Fistula problem (32)</td>
<td>41, 55 (9–330)</td>
</tr>
<tr>
<td>4</td>
<td>No success (13)</td>
<td>1, 1.4 (0–5)</td>
</tr>
</tbody>
</table>

n = numbers of patients per category.
reconstruction, neopharynx stenosis, radiotherapy, sex, and age, only sex appears to be related to category 4 (P = .037), with women significantly less represented in category 4 than men. Taking all four outcome categories in the model and leaving the in situ group aside so that only “closed intervals” are taken into account, categories 1, 2, and 3 are significantly different from category 4 (P = .0087). Leaving the “failure category” 4 aside, the duration in situ between the three “success categories” are statistically not significantly different (P = .97). However, sex plays a statistically significant role, with women showing a shorter “washer survival time” in both models (category 4 included or left aside, P = .0024 and P = .0047, respectively). The other factors, pharynx reconstruction, neopharynx stenosis, radiotherapy, and age, do not play a role in either model.

DISCUSSION

This study clearly shows that periprosthetic leakage poses a significant and recurring problem. Most patients in this series, comprising approximately 12% of our total long-term follow-up population, already have an extensive history of local fistula problems, of which, unlike as commonly suggested, atrophy of the party wall is the least of their problems. More often, they have suffered from local infections, leading to increased fistula lengths, with subsequent shrinkage of the fistula caused by subsiding of inflammatory reactions and ultimately scarring of the fistula tract, which causes periprosthetic leakage. Nevertheless, with an immediate halt of the leakage in 88% of the PLEs (94 of 107 PLEs) and a clinical effectiveness of 91% (29 of 32 patients with at least 1 successful washer placement) and 59% (19 of 32 patients with more than 1 successful washer), it is obvious that the 0.5 mm thin silicone washer is an effective instantaneous method for the treatment of periprosthetic leakage. Even if the 10 PLEs that had to be excluded from further analysis because of inadequate follow-up are considered failures, which probably most of them were not given the initial solution of the periprosthetic leakage, the success rate is still 79%. Although 12 patients also required one or more other interventions to ultimately solve their leakage problem, the usefulness of the washer is still obvious in our view because it provides an easy, straightforward, and instant solution in the vast majority of PLEs.

In considering the three categories separately, it is noteworthy that the next prosthesis replacement was fistula related in 32 of 107 (30%) of the PLEs (i.e., in 21 of 32, 66%, of the patients). However, it is important to keep in mind the negative selection of patients in this study group, with at least 70% of them already known to have had fistula problems in the past, 37% having had their pharynx reconstructed, 38% having suffered from a pharyngeal stenosis for which in all but one patient dilations had been performed, and 47% being Provox ActiValve users (whereas 15% of all laryngectomized patients at our institution use an ActiValve). Because there is no statistically significant relationship with any of the potential clinical confounders except for sex (women fail less often than men, but on the other hand receive a shorter time benefit from the washer), this periprosthetic leakage problem must be multifactorial, with suspected causative fac- tors not fully understood but including reflux, diabetes, hypertension, radiotherapy, or local irritation.

Obviously, there is a learning curve for all health care providers involved in the treatment of the complex problem of periprosthetic leakage. All clinicians at our department were involved in treating these patients, and from this retrospective study, it becomes clear that, in a busy practice, it can be difficult to immediately make the right diagnosis in cases of periprosthetic leakage. In 9 of the 13 washer placements categorized as unsuccessful, downsizing solved the problem, and most likely these can be considered the result of a suboptimal diagnosis (i.e., a judgment made too fast to use a washer as the best method on that occasion). On the other hand, this also underlines the ease of washer application and the cost consciousness of the clinicians.

Literature on the use of additional flanges in the treatment of periprosthetic leakage is scarce. Bunting describes the use of a 2 mm thick washer but did not provide any results. However, such a thick washer, as mentioned in the Introduction, might put undue pressure on the mucosa, especially on the esophageal side. Furthermore, if a prosthesis is so long that there is room for a 2 mm washer, it probably would have been wiser to insert a one size (2 mm) shorter prosthesis, although salvaging an otherwise good functioning valve is always appealing, especially in low income countries (Fabio Ceccon, personal communication).

Kress et al., reporting a comparable incidence of 13% of patients with periprosthetic leakage, describe the use of a 0.5 mm thin, 20 mm wide silicon ring, glued on the inside of the esophageal flange with a thin layer of medical grade silicone adhesive. Although this would appear to be the logical placement for a washer, as mentioned in the Introduction, it must be in place prior to insertion, requires extra gluing, and might make the insertion procedure less straightforward. In addition, this is not a salvage solution for a periprosthetic leakage developing shortly after placement of new prosthesis that is otherwise functioning correctly, as was the case in almost half of our washer placements.

In our experience, the washer appears to function through adhesion of the thin silicone material on the mucosa through surface tension, thus lengthening the distance the fluid has to travel once it has squeezed around the prosthesis and reaches the tracheal side of the fistula tract. Observations in patients have demonstrated this: the fluid often appears alongside the shaft of the prosthesis at the tracheal level but does not enter the trachea itself, and with the next swallow or inhalation, because of the under-pressure in the esophagus, the fluid is sucked back.

As mentioned in the Introduction, adequate sizing is key to successful treatment of periprosthetic leakage, but if this turns out to be ineffective, several other options are available to decrease the diameter of the fistula to treat periprosthetic leakage. Temporary removal of the prosthesis to stimulate spontaneous shrinkage of the fistula is still the first option for many clinicians. This has the inherent disadvantage of leaving patients with open tracts, with obvious aspiration and oral diet problems, for which the patient sometimes needs a cuffed cannula and
always a feeding tube. This is not a very appealing solution and neither are the placement of a purse-string suture or augmentation of the party wall by injection of various substances in the fistula wall such as GM-CSF, autologous fat, bioplastique, collagen, or cymetra, which are among the most frequently used invasive techniques. These methods all require treatment by a physician and often are not instantly available. Because, in many countries, speech-language pathologists are the primary clinicians responsible for this patient category, a solution such as immediate or delayed washer placement, also applicable by these clinicians, is very attractive.

In conclusion, in consideration of the high success rate and limited inconvenience for the patient, a thin silicon washer provides an easy and instant first-line option for the treatment of periprosthetic leakage that is not solvable by adequate sizing of a voice prosthesis alone.

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BIBLIOGRAPHY