A thin tracheal silicone washer to solve periprosthetic leakage in laryngectomies: direct results and long-term clinical effects

Hilgers, F.J.M.; Soolsma, J.; Ackerstaff, A.H.; Balm, F.J.M.; Tan, I.B.; van den Brekel, M.W.M.

Link to publication

Citation for published version (APA):

Hilgers, F. J. M., Soolsma, J., Ackerstaff, A. H., Balm, F. J. M., Tan, I. B., & van den Brekel, M. W. M. (2008). A thin tracheal silicone washer to solve periprosthetic leakage in laryngectomies: direct results and long-term clinical effects. *The Laryngoscope*, *118*(4), 640-645. https://doi.org/10.1097/MLG.0b013e31816067d5

A thin tracheal silicone washer solving periprosthetic leakage

in laryngectomees; direct results and long-term clinical effects

Frans JM Hilgers[1,2,3], Jessica Soolsma[1,2], Annemieke H Ackerstaff[1],

Fons JM Balm[1,2], I Bing Tan[1,2], Michiel WM van den Brekel[1,2]

[1]Department of Head and Neck Oncology and Surgery

The Netherlands Cancer Institute – Antoni van Leeuwenhoek Hospital

Plesmanlaan 121, 1066CX Amsterdam, the Netherlands,

[2]Academic Medical Center, University of Amsterdam

[3]Institute of Phonetic Sciences/ACLC, University of Amsterdam

Correspondence: Frans Hilgers, The Netherlands Cancer Institute – Antoni van
Leeuwenhoek Hospital, Plesmanlaan 121, 1066CX Amsterdam, The Netherlands; Tel.
+31205122550; Fax +31205122554; E-mail f.hilgers@nki.nl.

Abstract

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: 3-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), placed behind the tracheal flange either in combination with prosthesis replacement or later.

Results: immediate solution of periprosthetic leakage in 88 PLEs (median 38, mean 53 days; range 8-330 days), and in 6 PLEs with the washer still in situ at the date of analysis (median 75, mean 97 days; range 38-240 days). No solution for periprosthetic leakage in 13 PLEs. Thus, totally 94/107 PLEs (88%) were successfully solved. In 29/32 patients (91%) the washer solved the problem at least once. 12/32 Patients, including all 3 washer-failures, also required other interventions to ultimately solve the problem. The vast majority of patients (80%) did consider placement of the washer not to be inconvenient.

Conclusions: Considering 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.

Keywords: 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 of prosthetic voicing is the 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 itself[2], but sometimes elicited by an esophageal underpressure during breathing and/or swallowing[3]. Periprosthetic leakage, the topic of this paper, mainly occurs when the fistula is too wide, due to 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 11-27% 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 in such an instance is that there is a slight protrusion of the prosthesis into the trachea, which may be mistaken for the device

being too long. If not suspected and/or anticipated on, 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 instance a too short prosthesis is inserted, this will aggravate the problem and extrusion of the prosthesis or closure of the esophageal side of the fistula tract may result.

If adequate sizing turns out to be ineffective, several other options are conceivable to decrease the diameter of the fistula in order to treat the periprosthetic leakage. The placement of a purse-string suture[6] or the augmentation of the party wall by injection of various substances in the fistula wall, such as GM-CSF[8], autologous fat[9], bioplastique[10], collagen[11] or cymetra[12] 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 2-3 months, forcing the patient temporarily to use an alternative communication method, mostly Electrolarynx speech[13].

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 et al[14], or glued onto the esophageal flange of the prosthesis, as described by Kress et al [4]. 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 seems 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, and based on earlier experiences and discussions with others (e.g. Fábio Pupo Ceccon, personal communication[15]), we developed a thinner (0.5 mm) wider diameter (18 mm) silicon washer that can be put in position secondarily, i.e. after a prosthesis is already 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 this 0.5 mm 18 mm diameter silicone washer placed 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 in our institute, whereas 9 were especially referred for prosthesis or fistula related problems. In 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 own laryngectomy patient population.

Of the 32 included patients 27 were male and five female, with a mean age of 62 years (range 39-83). The median time since surgery was 5 years (range 0.6-21) and the median time between laryngectomy and the placement of the first washer was 4 years (range 1 month-20 years). All but one patient were radiated, 19 prior to surgery and 12 after surgery. The pharynx was reconstructed in 12 patients (38%): 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 patients (38%) were known to have had a pharyngeal stenosis, for which in 11 patients dilatations have been performed. All 32 patients used a Provox2 prosthesis and 15 of them were also familiar with the Provox ActiValve (8 of the 23 original NKI patients and 7/9 referred patients). Twenty-one of 30 patients (70%) 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 this 3-year period, one patient died of intercurrent disease. Patient characteristics are shown in Table 1.

Periprosthetic leakage events

There were in total 117 periprosthetic leakage events (PLEs) in which a washer was applied. 10 PLEs were excluded from further analysis, although the periprosthetic

leakage was immediately stopped after washer application, because adequate follow-up was too short or lacking (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 in the earlier stages of the study) was placed, but because of the small numbers this is not further looked into. During the study period, the vast majority of the patients (94%) also required one or more times downsizing of the prosthesis; only two patients never had their prosthesis resized to a smaller version. Twelve patients also have undergone 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 6 patients one of these four interventions was carried out.

Washers

The washers were custom made with a special punch (see figure 1). With this punch, washers were produced out of a 0.5 mm thin nasal silicon sheath (Silatos^{TM} Silicone Sheetings, Atos Medical, Hörby, Sweden). Initially, three outer diameters of the washers were tested, i.e. 16, 17, and 18 mm, all with an inner diameter 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 Fr, which equals a diameter of 7.5 mm). After the first few patients it became obvious that the outer diameter of 18 mm gave 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. Besides the punch, figure 1 further shows the various steps of the placement of the washer behind the tracheal flange of the prosthesis in situ with the help of two hemostats, and the washer in situ.

Outcome-categories

The outcomes were classified into 4 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 days) was for transprosthetic leakage, meaning that the 'natural'

end of the device-life was reached. Category 3: the next replacement was for a fistula-related problem other than periprosthetic leakage. Category 1, 2, and 3 were considered successful solutions of the periprosthetic leakage, in contrast to 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 on the date of analysis (and minimally 7 days) also were considered to be successful and are described separately. Patients often received more than once a washer and therefore could fall in more than one of these 4 categories. Patients were considered to be treated successfully if at least one washer fell in one of the first three categories. When no washer attempt at all was successful, the patient was considered to be unsuccessfully treated for periprosthetic leakage.

Thirty-one patients (as one patient died during the 3-year period of this study) could be questioned either by telephone, or while visiting the outpatient clinic for a routine follow-up, about possible inconveniences felt while placing 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 <.05 was taken to indicate statistical significance. Generalized equation models were fitted to relate the different outcome-categories to clinical parameters (pharynx reconstruction, neopharynx stenosis, radiotherapy, sex, and age), taking into account that there are repeated observations in patients.

Results

The analysis is based on the 107 periprosthetic leakage events (PLEs) with adequate follow-up and in these instances the washer was placed 91 times in combination with a Provox2 prosthesis (85%) and 16 times with an ActiValve (15%). The washer was placed at the time of the replacement of the prosthesis in 47% of cases (N=50) and at a later moment than the prosthesis replacement in 53% (N=57) with a median interval of 10

days (range 1-193). The two longest intervals (137 and 193 days) were to salvage an otherwise well functioning Provox ActiValve, 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 not an option any longer. In the remaining 76 PLEs in 30 patients the washer was placed with a 6 mm or longer prosthesis in situ. Due to the variation in fistula length over time, some patients obviously can fall both in the 4.5 mm and in the 6 mm and longer categories. There is no difference in prosthesis length between the immediate and delayed placement categories, nor is there between Provox2 and Provox ActiValve (the latter data are not shown).The characteristics of the prostheses combined with a washer are shown in Table 2.

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

to an initially overlooked esophageal pouch (N=2). The washers in 6 PLEs were still in situ on the date of analysis, after median and mean of 75 and 97 days (range 38-240), respectively.

Since many patients over time had more than one PLE, they often fell into several categories and only in 3 patients the use of a washer was never a success. Ultimately, 94 of 107 washer placements could be considered successful (88%) and 29 of 32 patients (91%) were successfully treated with a washer at least once, whereas 19 of the 32 patients had 2 or more washers placed with success. But, as already mentioned, it is also important to realize that additionally in 12 patients one or more other interventions were needed to solve their periprosthetic leakage.

Prosthesis length appears to have no statistically significant influence on device life in combination with a washer, i.e. the shorter prostheses are not more successfully treated than the longer versions or vice versa.

In questioning the patients' experience with washers, one patient was not able to remember the placement of a washer (which was in his case placed 2 years earlier). In the remaining 30 patients, 24 (80%) considered the placement to be not inconvenient at all, 2 reported it to be a bit inconvenient, 1 rather inconvenient and 3 very inconvenient

From the generalized equation models, fitted to relate the outcome category to the clinical parameters pharynx reconstruction, neopharynx stenosis, radiotherapy, gender, and age, only gender seems to be related to the category 4 (p=0.037), with woman significantly less represented in category 4 than man. Taking all 4 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 'failure-category' 4 aside, the *duration in-situ* between the three 'success-categories' are statistically not significantly different (p=.97). However, gender plays a statistically significant role, with woman showing a shorter 'washer survival time' in both models (category 4 included or left aside, p=.0024 and p=.0047, respectively). The other factors,

i.e. pharynx reconstruction, neopharynx stenosis, radiotherapy and age do not play a role in both models.

Discussion

This study clearly shows that patients with periprosthetic leakage pose a significant and recurring problem. Most patients in this series, comprising approximately 12% of our total long-term follow-up population, had already an extensive history of local fistula problems, of which, unlike 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 due to subsiding of the inflammatory reactions and ultimately scarring of the fistula tract, causing periprosthetic leakage. Nevertheless, with an immediate halt of the leakage in 88% of the periprosthetic leakage events (94/107 PTEs), and a clinical effectiveness of 91% (29/32 patients with at least one successful washer placement), and 59% (19/32 patients with more than one successful washer), it is obvious that the 0.5 mm thin silicone washer seems an effective instant 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 because of 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.

Considering the 3 categories separately, it is noteworthy that the next prosthesis replacement is fistula-related in 32/107 (30%) of the PTEs, i.e. in 21/32 (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 their pharynx reconstructed, 38% suffering from a pharyngeal stenosis for which in all but one patient dilations had been performed and 47% Provox ActiValve users (whereas 15% of all laryngectomized patients in our institution are using an ActiValve).[16] Since there is no statistical significant relation with any of the potential

clinical confounders except for gender (woman fail less often than man, but on the other hand have a shorter time-benefit of the washer), this periprosthetic leakage problem must be multifactorial with still not all suspected causative factors, like reflux, diabetes, hypertension, radiotherapy or local irritation fully understood.

Obviously, there is a learning curve for all health-care providers involved in the treatment of this complex problem of periprosthetic leakage. All clinicians of the 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 case of periprosthetic leakage. In 9 of the 13 as unsuccessful categorized washer placements, 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 for that occasion. On the other hand, it also underlines the ease of the washer application method and the cost-consciousness of the clinicians.

Literature about the use of additional flanges in the treatment of periprosthetic leakage is scarce. Bunting et al. describe the use of a 2 mm thick washer, without giving any results[14]. However, such a thick washer, as already 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 is probably wiser to insert a one-size (2 mm) shorter prosthesis, although salvaging an otherwise good functioning valve, always is appealing, especially in low income countries (Fabiò Ceccon, personal communication[15]).

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[4]. Although this seems to be the logical place for a washer, as mentioned already in the introduction, it has to be in place prior to the insertion, requires extra gluing and might make the insertion procedure less straightforward. Additionally, it is not a salvage solution for

periprosthetic leakage developing shortly after placement of new prosthesis, otherwise still functioning correctly, as was the case in almost half of our washer placements.

In our case, the washer seems 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 been squeezed around the prosthesis and reaches the tracheal side of the fistula tract. Observations in patients actually have demonstrated this: the fluid often still appears along side the shaft of the prosthesis at the tracheal level, but does not enter the trachea itself and with the next swallow or inhalation, due to the underpressure in the esophagus, the fluid is sucked back.

It might sound repetitive, but as already mentioned in the introduction, adequate sizing still is the key to successful treatment of periprosthetic leakage, but if this turns out to be ineffective, several other options are conceivable to decrease the diameter of the fistula in order to treat the 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 leaving the patients with an open tract, with obvious aspiration and oral diet problems, for which the patient sometimes needs a cuffed-cannula and always a feeding tube. Not a very appealing instant solution. Nor are the placement of a purse-string suture[6] or the augmentation of the party wall by injection of various substances in the fistula wall, such as GM-CSF[8], autologous fat[9], bioplastique[10], collagen[11] or cymetra[12] are among the most frequently used invasive techniques. These methods all require treatment by a physician and often are not instantly available. Since in many countries, speech-language pathologists are the main responsible clinicians for this patient category, a solution like this immediate or delayed washer placement also applicable by these clinicians, is very attractive.

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

Table 1. Patient characteristics (N=32)

		N (%)
Gender	Male	27 (84)
	Female	5 (16)
Age (in years)	Mean	62.3
	Range	39-83
Pharynx reconstruction	Primary closure	20 (63)
	Pectoralis Major flap	10 (31)
	Radial Forearm Flap	2 (6)
Radiotherapy	Prior to Surgery	19 (59)
	Post Surgery	12 (38)
	None	1 (3)
Time since surgery (in years)	Median	5.0
	Range	0.6-21
Time until 1^{rst} washer since surgery (in years)	Median	4.0
	Range	0.08-20
PE-segment stenosis	No	20 (62)
	Yes	12 (38)
Voice prosthesis	Provox2 only	17 (53)
	Provox ActiValve at some time	15 (47)

Table 2. Characteristics of prostheses with washer (N=107); * delayed application of washer: median 10 days (range 1-193 days).

		N (%)
Prostheses combined with washer	Provox2	91 (85)
	ActiValve	16 (15)
Prostheses directly combined with washer (N=50)	4.5 mm	20 (40)
	6 mm	19 (38)
	8 mm	9 (18)
	10 mm	1 (2)
	12.5 mm	1 (2)
Prostheses later combined with washer (N=57)*	4.5 mm	11 (19)
	6 mm	22 (38)
	8 mm	18 (32)
	10 mm	5 (9)
	12.5 mm	1 (2)

Table 3. Medians, means, and ranges of survival times of the washers (in days) per replacement category; (N) are numbers of patients per category.

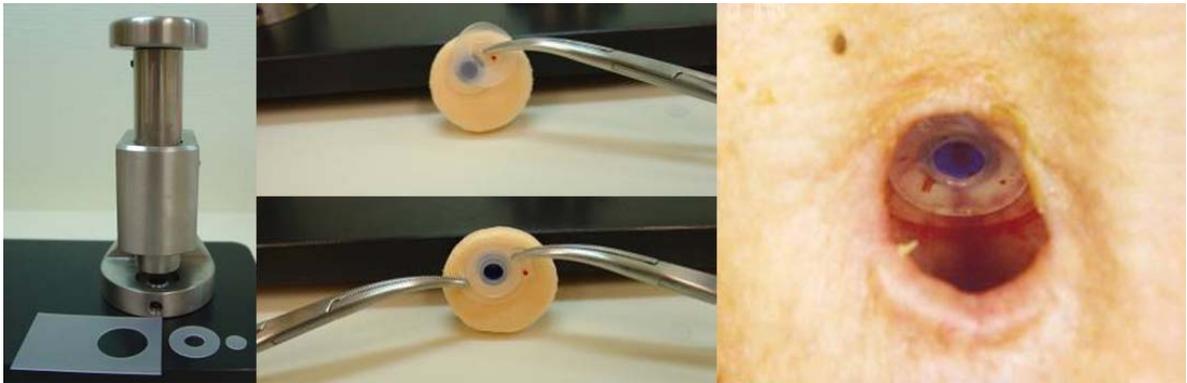| Category	Washer in situ until … (N)	Survival times washer in days, median and mean (range in days)
1	Periprosthetic leakage (28)	31 and 46 (8-229)
2	Leakage through (28)	45 and 56 (12-145)
3	Fistula problem (32)	41 and 55 (9-330)
4	No Success (13)	1 and 1.4 (0-5)

Figure 1. Punch to produce a washer with an outer diameter of 18 mm and an inner diameter of 7.5 mm and a demonstration of the insertion technique, using 2 hemostats. The insertion of the washer is shown in an in vitro model. The washer is slipped over the first hemostat, which grabs the tracheal flange at its longest extension. The other hemostat is used to pull the washer over the tracheal flange, which due to the elasticity if the silicone material mostly slips over easily, even when the freedom of movement in a narrow stoma is somewhat restricted. The final in vivo result is shown on the lower right image.
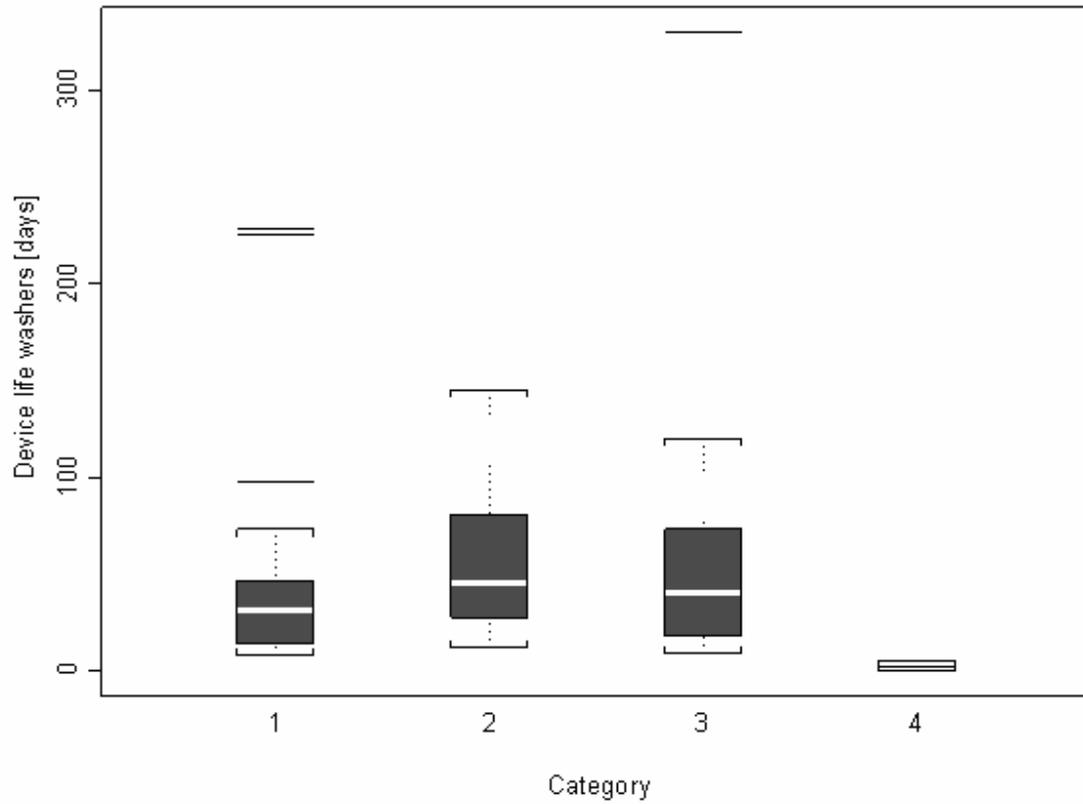
Figure 2. Boxplots of the device life of washers by category. Whiskers are drawn to the nearest value not beyond a standard span from the quartiles; points beyond (outliers) are drawn individually. The standard span is 1.5*(Inter-Quartile Range). The white line across the box represents the median. There is no statistically significant difference in device life between categories 1 to 3.

Reference List

(1) Pou AM. Tracheoesophageal voice restoration with total laryngectomy. Otolaryngol Clin North Am. 2004;37:531-545.

(2) Mahieu HF, van Saene HK, Rosingh HJ, Schutte HK. Candida vegetations on silicone voice prostheses. Arch Otolaryngol Head Neck Surg. 1986;112:321-325.

(3) Hilgers FJ, Ackerstaff AH, Balm AJ, Van den Brekel MW, Bing T, I, Persson JO. A new problem-solving indwelling voice prosthesis, eliminating the need for frequent Candida- and "underpressure"-related replacements: Provox ActiValve. Acta Otolaryngol. 2003;123:972-979.

(4) Kress P, Schafer P, Schwerdtfeger FP. [The custom-fit voice prosthesis, for treatment of periprothetic leakage after tracheoesophageal voice restoration]. Laryngorhinootologie. 2006;85:496-500.

(5) Laccourreye O, Menard M, Crevier-Buchman L, Couloigner V, Brasnu D. In situ lifetime, causes for replacement, and complications of the Provox voice prosthesis. Laryngoscope. 1997;107:527-530.

(6) Op de Coul BM, Hilgers FJ, Balm AJ, Tan IB, van den Hoogen FJ, van TH. A decade of postlaryngectomy vocal rehabilitation in 318 patients: a single Institution's experience with consistent application of provox indwelling voice prostheses. Arch Otolaryngol Head Neck Surg. 2000;126:1320-1328.

(7) Leder SB, Sasaki CT. Incidence, timing, and importance of tracheoesophageal prosthesis resizing for successful tracheoesophageal speech production. Laryngoscope. 1995;105:827-832.

(8) Margolin G, Masucci G, Kuylenstierna R, Bjorck G, Hertegard S, Karling J. Leakage around voice prosthesis in laryngectomees: treatment with local GM-CSF. Head Neck. 2001;23:1006-1010.

(9) Perie S, Ming X, Dewolf E, St Guily JL. Autologous fat injection to treat leakage around tracheoesophageal puncture. Am J Otolaryngol. 2002;23:345-350.

(10) Lorincz BB, Lichtenberger G, Bihari A, Falvai J. Therapy of periprosthetical leakage with tissue augmentation using Bioplastique around the implanted voice prosthesis. Eur Arch Otorhinolaryngol. 2005;262:32-4.

(11) Hoffmann TK, Sommer P, Bier H. [Collagen injection for augmentation of periprosthetic leakage after tracheo-esophageal voice restoration]. Laryngorhinootologie. 2006;85:556-558.

(12) Seshamani MRCKSSMN. Cymetra injections to treat leakage around a tracheoesophageal puncture. ORL J Otorhinolaryngol Relat Spec. 2006;68:146-148.

(13)   Brasnu D, Pages JC, Laccourreye O, Jouffre V, Monfrais Pfauwadel MC, Crevier BL. [Results of the treatment of spontaneous widening of tracheo-esophageal punctures after laryngeal implant]. Ann Otolaryngol Chir Cervicofac. 1994;111:456-460.

(14)   Bunting GW. Voice following laryngeal cancer surgery: troubleshooting common problems after tracheoesophageal voice restoration. Otolaryngol Clin North Am. 2004;37:597-612.

(15)   Ceccon FP, Abrahão M, Cervantes O, Santos RO, Institution: Universidade Federal de São Paulo - Escola Paulista de Medicina. Treatment of leakage around tracheoesophageal prosthesis. 2003 Apr 9; p 271.

(16)   Soolsma J, Van den Brekel MW, Ackerstaff AH, Balm AJ, Tan IB, Hilgers FJ. Long-term results of Provox ActiValve, solving the problem of frequent Candida- and 'underpressure'-related voice prosthesis replacements. Laryngoscope. 2007;in press.