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The Use of Polydimethylsiloxane for Injection Laryngoplasty

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Abstract
Background Injuries of the recurrent laryngeal nerve with consecutive vocal cord paralysis is a typical complication in chest, esophageal, thyroideal, and neck surgery. Glottic insufficiency secondary to such a lesion can be treated by endolaryngeal vocal cord augmentation (injection laryngoplasty). Many different substances have been used, often showing complications or disadvantages. This study reports on the use of injectable polydimethylsiloxane (PDMS), with special regard to the long-term results.
Methods In this prospective study, 21 patients with unilateral vocal cord paralysis underwent injection laryngoplasty using PDMS at a volume of 0.5–1.0 ml. Preoperatively, 6 weeks and 12 months after the injection the following parameters concerning patients' voice were evaluated: Glottic closure by videolaryngostroboscopy, maximum phonation time, voice range, voice dynamic, jitter, shimmer, noise-to-harmonic-ratio, and roughness, breathiness, and hoarseness (RBH). In addition, patients were asked to give their own evaluation of how satisfied they felt with their voice and of the handicaps it caused them.
Results Postoperatively an improvement was evident in all the parameters that were investigated, and this significant improvement was still in evidence for most of the parameters more than one year after the injection. In our study no complications were observed more than one year after injection.
Conclusion PDMS is a safe substance for injection laryngoplasty in unilateral vocal cord paresis. Objective and subjective parameters confirm its effectiveness. It is suitable for obtaining satisfying results in the reestablishment of the patient's voice and communication ability.

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Introduction

Lesions of the recurrent laryngeal nerve leading to a vocal fold paralysis occur not only in neck surgery, but they also are typical complications in chest, cardial, esophageal, and endocrine surgery. Unilateral vocal fold paralysis can remain asymptomatic if glottic closure or near glottic closure is achieved by a compensatory movement of the contralateral vocal fold. If this does not happen spontaneously, compensation can be induced by voice therapy. However, some patients undergoing voice therapy do not succeed in compensating. The voice then remains breathy, rough, and weak, often lacking resonance. Other patients want to achieve a normal voice within a short time. In these cases therapy focuses on medialization of the paralyzed vocal fold to achieve sufficient glottic closure. In these patients injection laryngoplasty is a safe and easy method. Since its introduction 1911 by Brüning (cited as quoted in [1]), a range of substances such as paraffin, autologous fat tissue, fascia, gelatin, calcium hydroxylapatite, hyaluronan acid, and Teflon® has been tried and most of them were abandoned due to resorption, migration, or complications [2, 3].

A promising substance is polydimethylsiloxane (PDMS), which has been widely used since 1989, for example, in urology in the treatment of vesicoureteral reflux or stress incontinence. As a suspension of textured silicone particles with a mean particle diameter of 200 μm in a polyvinylpyrrolidone hydrogel, it can be injected with a 27-gauge needle [1]. Since 1993 there have been sporadic reports about the

use of PDMS for injection laryngoplasty in individual cases, and later some instances of its use in the context of prospective studies with a limited number of patients and focusing on early postoperative results [1].

The aim of our study was to make a systematic analysis of acoustic and perceptive voice parameters as well as patients' subjective assessment of PDMS used for injection laryngoplasty on the basis of a larger number of patients and with particular regard to long-term effects at least 12 months postoperatively. Long-term results are especially important to rule out migration or foreign-body reactions.

Materials and methods

Twenty-one patients aged 41–86 years (mean = 62.4 years, standard deviation [SD] = 11.25 years) with unilateral recurrent laryngeal nerve palsy underwent injection laryngoplasty using PDMS elastomers between March 2002 and August 2006. Table 1 gives detailed information about the patients. The operation was performed 5–161 months (mean = 43 months, SD = 82 months) after diagnosis of vocal cord paralysis. For injection laryngoplasty VoxImplants® (Bioplasty BV, Geleen, The Netherlands) was used. Application was performed during a direct laryngoscopy under general anesthesia with jet ventilation or tracheal intubation using a small tube. The substance was administered deeply lateral to the thyroarytenoid muscle at a volume of 0.5–1.0 ml to obtain a straight and midline vocal cord edge. Even though the carrier material (polyvinylpyrrolidone) is resorbed, according to the manufacturer's product information the injected volume of PDMS does not shrink. Therefore, overinjection was strictly avoided.

Preoperatively, 6 weeks postoperatively, and at least 12 months (range = 12–27 months, mean = 18 months, SD = 6 months) after injection laryngoplasty, the following parameters of larynx and voice function were measured: glottic closure by videolaryngostroboscopy, maximum phonation time of the vowel /a/, and roughness, breathiness, and hoarseness (RBH) using scores from 0 to 3 [4]. The acoustic analysis was performed by a voice range profile: The voice range was measured in half-tones and dynamic in dB calculated as the difference between the loudest and the faintest tone of the phonetogram. Jitter, shimmer, and noise-to-harmonic ratio (NHR) were

Table 1 List of patients

Patient no.	Gender	Age at injection (years)	Side	Diagnosis/cause of paresis	Preop voice therapy (No. sessions)	Postop voice therapy (No. sessions)	Latest control (years after injection)
1	m	58	r	Operation of cervical spine	20	3	2.3
2	m	67	l	Bronchial carcinoma, pneumonectomy	15	0	Died
3	m	62	l	Bronchial carcinoma, palliative	3	0	Died
4	m	60	l	Esophageal carcinoma, surgery	24	6	1.9
5	m	59	l	Bronchial carcinoma, pneumonectomy	10	0	1.6
6	m	51	l	Esophageal carcinoma, surgery	10	0	1.9
7	m	76	l	Cerebrovascular insult, central paresis	25	0	Died
8	m	41	l	Brainstem glioma	21	0	1.6
9	m	53	r	Esophageal carcinoma, surgery	7	0	Died
10	m	61	l	Bronchial carcinoma, partial pneumonectomy	7	7	1
11	f	47	r	Idiopathic	37	0	1
12	m	52	l	Aortic arch surgery	21	0	1.7
13	m	64	l	Bronchial carcinoma, pneumonectomy	12	0	Died
14	m	66	l	Bronchial carcinoma, palliative	4	0	Died
15	m	74	l	Aortic arch surgery	16	7	1
16	m	58	l	Idiopathic	12	0	1
17	m	63	r	Esophageal carcinoma, surgery	0	0	1
18	m	72	l	Aortic arch surgery	26	0	1
19	m	57	r	Bronchial carcinoma, pneumonectomy	12	0	1
20	f	82	l	Idiopathic	30	0	1
21	f	86	r	Idiopathic	20	0	1

r = right; l = left; m = male; f = female

Table 2 Questionnaire for subjective evaluation

1. Satisfaction: With my voice – as it is at the moment – I am					
Very content	Fairly content	Moderately content	Not very content	Not content	Not at all content
☐	☐	☐	☐	☐	☐
6	5	4	3	2	1
2. Handicap in private life: My voice – as it is at the moment – handicaps me in private life					
Not at all	Only a little	Moderately	Quite a lot	Greatly	Very greatly
☐	☐	☐	☐	☐	☐
6	5	4	3	2	1
3. Handicap in work life: My voice – as it is at the moment – handicaps me in work/professional life					
Not at all	Only a little	Moderately	Quite a lot	Greatly	Very greatly
☐	☐	☐	☐	☐	☐
6	5	4	3	2	1
4. Liking: My voice – as it is at the moment – pleases me					
Very much	Quite a lot	Moderately	Not much	Not	Not at all
☐	☐	☐	☐	☐	☐
6	5	4	3	2	1

calculated using MDVP (Multidimensional Voice Program, Kay Elemetrics Corp., Lincoln Park, NJ, USA).

The subjective evaluation was carried out by the patient answering a questionnaire containing four questions adapted from the voice handicap index regarding their voice (3 questions for retired patients) to be answered on a six-step scale (Table 2) [5]. The examination that was planned to be held at least 12 months postoperatively has been carried out in 15 patients. Meanwhile, six patients have died from the palliative situation of their basic illness. Preoperatively, 20 patients had 3–37 lessons of voice therapy (mean = 15.6, SD = 9.7); postoperatively, 4 patients had 3–7 more lessons of voice therapy (mean = 1.2, SD = 2.5).

The prospective study was performed with the informed consent of the patients and with the approval of the institutional review board.

Statistical evaluation was done using Wald-type, Hotelling F-type, and ANOVA-type tests of the SAS software (SAS Institute, Cary, NC, USA).

Results

Glottic closure during phonation

Glottic closure was incomplete in 20 patients preoperatively, and one patient showed a small dorsal insufficiency. Six weeks after the operation complete glottic closure was observed in 11 patients and a small dorsal insufficiency in 9 patients. One patient still showed glottic insufficiency. In the 15 patients who have been examined 12 months after their operation, 9 still showed complete glottic closure. In six patients the dorsal gap remained unchanged compared to the examination conducted 6 weeks after the operation. Postoperative videolaryngostroboscopy, even 12 months postoperatively, did not indicate any migration or granuloma formation.

Maximum phonation time

Maximum phonation time increased significantly 6 weeks postoperatively ($p < 0.000005$). A further significant increase was observed during the first 12 months postoperatively compared with the preoperative data ($p = 0.00016$) as well as with the 6 weeks' postoperative data ($p = 0.03$). The detailed results are given in Table 3.

Roughness (R), breathiness (B), hoarseness (H)

Before the operation patients had very rough, breathy, and hoarse voices. Six weeks after injection laryngoplasty, each of the parameters—roughness, breathiness and hoarseness—was significantly lower ($p < 0.000005$ each). One year after the operation the results remained significantly better than before the operation (R: $p = 0.00006$, B: $p = 0.00002$, H: $p = 0.00006$) and they remained unchanged from the results 6 weeks after the operation (R: $p = 0.66$, B: $p = 0.10$, H: $p = 0.40$). Details are shown in Table 3. Figure 1 shows the relationship between hoarseness and glottic closure.

Voice range, voice dynamic

Voice range increased significantly from a mean of 12.5 half-tones before the operation to 20.5 half-tones 6 weeks after operation ($p = 0.00001$) and to 22.9 half-tones 12

Table 3 Maximum phonation time, RBH

Patient no.	Maximum phonation time (s)			Roughness (0–3)		Breathiness (0–3)		Hoarseness (0–3)	
	Preop	6 weeks postop	12 months postop	Preop	12 months postop	preop	12 months postop	Preop	12 months postop
1	12	21	26	1	0	1	0	1	0
2	4	10	Died	2	Died	3	Died	3	Died
3	11	12	Died	3	Died	3	Died	3	Died
4	3	4	9	3	1	3	1	3	1
5	6	17	20	3	2	3	1	3	2
6	9	12	21	3	1	2	0	3	0
7	4	20	Died	3	Died	3	Died	3	Died
8	4	7	7	2	2	3	3	3	3
9	3	7	Died	3	Died	3	Died	3	Died
10	6	13	14	3	2	3	2	3	2
11	14	17	14	1	1	2	1	2	1
12	4	8	5	2	1	3	1	3	1
13	3	20	Died	3	Died	3	Died	3	Died
14	4	10	Died	3	Died	3	Died	3	Died
15	14	18	21	2	1	2	0	2	0
16	3	4	5	3	2	3	2	3	2
17	6	17	25	3	1	2	1	3	1
18	5	11	17	2	1	2	0	2	0
19	3	4	11	3	1	3	2	3	2
20	6	4	12	3	2	3	0	3	2
21	3	12	18	3	1	3	1	3	1
Mean	6.0	11.8	14.7	2.6	1.3	2.7	1.0	2.8	1.2
SD	3.7	5.7	8.3	0.7	0.6	0.6	0.9	0.5	0.9

months after laryngoplasty ($p = 0.0086$). No significant increase was found between the two postoperative examinations ($p = 0.60$).

Voice dynamic increased significantly from a preoperative mean of 14.5 dB to 24.6 dB 6 weeks after operation ($p < 0.000005$) and 26.0 dB after 12 months ($p = 0.0094$). Both postoperative results showed no significant difference ($p = 0.74$) (see details in Table 4).

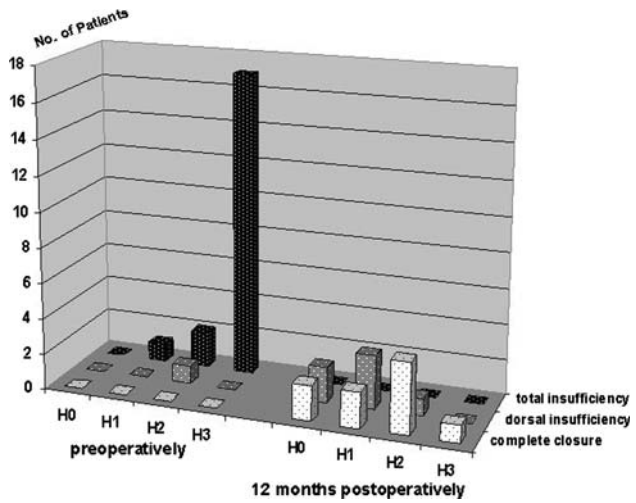

Fig. 1 Influence of glottic closure on grade of hoarseness

Jitter, Shimmer, NHR

Both postoperative results of jitter were significantly lower than before the operation ($p = 0.00031$ resp. $p = 0.035$). No significant difference between the postoperative results was found ($p = 0.71$).

Shimmer was significantly lower 6 weeks after laryngoplasty ($p = 0.0011$). Twelve months later the results showed no significant difference compared to the preoperative results ($p = 0.079$).

NHR also showed a significant decrease only 6 weeks after the operation ($p = 0.00009$) but not 12 months after the operation ($p = 0.063$) (Table 4).

Subjective evaluation (self-assessment)

The question about the patient's satisfaction with his or her voice was answered preoperatively with "not very content." Six weeks and one year after the operation the

Table 4 Voice range and dynamic, jitter, shimmer, and noise-to-harmonic ratio

Patient no.	Voice range (half tones)		Voice dynamic (dB)		Jitter (%)		Shimmer (%)		NHR	
	Preop	12 months postop	Preop	12 months postop	Preop	12 months postop	Preop	12 months postop	Preop	12 months postop
1	22	25	23	22	5.2	1.5	29	9.4	0.60	0.19
2	3	Died	5	Died	20	Died	26	Died	1.2	Died
3	4	Died	10	Died	12	Died	17	Died	0.44	Died
4	23	25	22	29	5.0	1.3	13	4.8	0.22	0.13
5	19	20	24	26	2.3	7.3	13	26	0.23	0.79
6	14	30	9	27	1.9	0.73	14	3.7	0.30	0.14
7	11	Died	9	Died	6.5	Died	13	Died	0.40	Died
8	17	24	24	28	3.1	5.8	8.8	14	0.80	0.33
9	x	Died	x	Died	9.8	Died	19	Died	0.70	Died
10	5	23	9	23	4.7	1.2	11	3.0	0.24	0.14
11	14	20	22	27	1.3	0.60	3.0	4.2	0.11	0.10
12	16	18	19	20	0.73	1.9	5.7	8.8	0.16	0.16
13	25	Died	19	Died	9.1	Died	13	Died	0.42	Died
14	10	Died	17	Died	4.9	Died	10	Died	0.31	Died
15	23	34	19	33	1.7	0.59	7.1	6.1	0.12	0.17
16	x	11	x	26	7.6	2.1	10	5.1	0.42	0.14
17	14	19	23	33	0.77	0.39	6.0	4.5	0.14	0.13
18	24	21	18	26	2.3	0.98	6.9	5.6	0.18	0.12
19	8	32	12	23	12	1.4	15	6.2	0.37	0.18
20	x	20	x	20	17	5.3	23	14	1.0	0.23
21	8	16	24	20	2.1	1.5	14	6.1	0.62	0.17
Mean	13.9	23	17	26	6.2	2.2	13	8.1	0.40	0.20
SD	7.5	6.1	6.1	4.2	5.4	2.1	6.7	5.9	0.30	0.17

x = too hoarse to be measured

patients were "fairly content," which is significantly better ($p < 0.000005$ resp. $p < 0.0092$). The question about how much handicap was experienced in private life was answered preoperatively with "quite a lot." Postoperatively it was ranked as "only a little," which is significantly better ($p < 0.000005$ resp. $p = 0.024$). The question as to how the patients liked their voice was answered as "not much" before the operation and as "quite a lot," which is significantly better ($p < 0.000005$ resp. $p = 0.016$). The results for the patients asked about the handicap experienced at work were significantly better after the operation ($p = 0.014$ resp. 0.043) (for details see Table 5). Figure 2 shows the relation between patient satisfaction and glottic closure.

Complications

During the 24 h of postoperative monitoring, no complications such as excessive pain, dyspnea, or dysphagia were observed. Even during further observation, including endoscopic exams, no complications occurred such as foreign body reaction or inflammation. Minimum postoperative observation was 12 months, the longest 27 months (mean = 18 months, SD = 6 months), excluding patients who had meanwhile died from other diseases.

Discussion

Nowadays monitoring of the recurrent laryngeal nerve is quite common in chest, esophageal, and thyroid gland surgery, helping the surgeon to identify the nerve more easily even in difficult situations [6]. But vocal fold paralysis remains a typical complication in these fields of surgery, be it accidentally or because there is a need to resect lesions touching or even infiltrating the nerve. If hoarseness occurs after surgery, putting the recurrent laryngeal nerve at risk, the patient should be seen by an ENT specialist within a few days for differential diagnosis of vocal fold paralysis and vocal fold irritation caused by the endolaryngeal tube from anesthesia. In case of paralysis, voice therapy should be established within a few weeks. Most patients in good general health, such as young patients, who are undergoing thyroid gland surgery very

Table 5 Subjective evaluation

Patient no.	Satisfaction (1–6)		Handicap in private life (1–6)		Handicap in work life (1–6)		Liking (1–6)	
	Preop	12 months postop	Preop	12 months postop	Preop	12 months postop	Preop	12 months postop
1	2	6	3	6	2	6	2	6
2	2	Died	2	Died	3	Died	3	Died
3	1	Died	3	Died	6	Died	2	Died
4	1	4	1	4	1	3	1	4
5	3	4	4	4	3	3	3	4
6	2	6	2	6	1	6	3	5
7	4	Died	3	Died	x	Died	3	Died
8	3	4	3	2	x	x	2	1
9	4	Died	3	Died	2	Died	2	Died
10	3	5	5	5	3	6	3	4
11	3	6	4	5	3	5	3	6
12	4	5	4	5	4	5	4	4
13	4	Died	4	Died	x	x	4	Died
14	1	Died	1	Died	x	x	1	Died
15	1	5	2	6	1	6	2	5
16	4	4	2	3	x	x	2	6
17	4	5	4	6	4	6	3	5
18	5	6	5	6	3	5	5	6
19	2	5	2	5	x	x	2	6
20	1	4	1	4	1	4	1	5
21	2	4	2	5	2	4	4	6
Mean	2.7	4.8	2.9	4.8	2.6	4.9	2.6	4.9
SD	1.3	0.8	1.3	1.2	1.4	1.2	1.1	1.4

x = retired from work (due to age or illness)

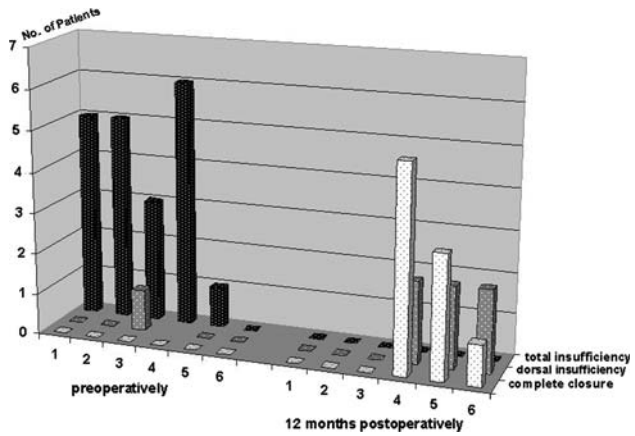

Fig. 2 Influence of glottic closure on satisfaction

often succeed very well in achieving a compensatory movement of the contralateral vocal cord. This may be why in our group no patients who had undergone previous thyroid gland surgery needed injection laryngoplasty.

However, in the case of patients whose condition is generally poor, e.g., after surgery for bronchial carcinoma, voice therapy is sometimes insufficient. In these patients surgical treatment can improve voice quality. A very common operation is thyroplasty which can be performed under local anesthesia. This technique shows immediate results during the operation giving the surgeon good control over how much to medialize the vocal fold. However, this technique needs an external approach to the larynx and requires the thyroid cartilage to be opened with a higher risk of complications [7].

By contrast, injection laryngoplasty is performed endolaryngeally with no external approach which would lead to a visible scar on the anterior neck. Because of the minimally invasive character of injection laryngoplasty compared to techniques using external approaches, the risk of infection is expected to be lower. However, thyroplasty is the technique of choice in patients with very severe glottic insufficiency, as seen in lesions of the vagus nerve, because the paralyzed vocal cord is then fixed in a more lateral position [8].

Since the first injection of paraffin oil into a paralyzed vocal cord (as quoted in [1]), different materials have been used for injection laryngoplasty. The ideal material should be easy to administer, show good biocompatibility, should

not be pyrogenic, toxic, carcinogenic, allergenic, or immunogenic, and it should be immobile and not resorbable. No material fulfilling all these criteria in an ideal way yet exists [9]. Since all these substances produce a medialization of the medial edge of the vocal folds, all of them show comparably good short-term results. However, because some of the substances used are slowly resorbed, good initial results for these substances often disappear after a few weeks or months, as described in more detail below. Other compounds showing no resorption often lacked biocompatibility, which led to chronic imflammation and granulomas, or over time slowly moved away from the site of injection.

However, a good alternative is the PDMS used in this study, which has been used in urology for therapy of vesicoureteral reflux since 1989 and for injection laryngoplasty since 1993. Allergic reactions have not been observed in animals [10] or in humans [11]. Due to its minimum particle size of 100 μm, the PDMS elastomers cannot be phagocytized, which means that the material remains in place [1].

The results of this study indicate that a durable result can be achieved with this substance, which does not change significantly even after more than one year. Once achieved, glottic closure during phonation as well as maximum phonation time, voice range, voice dynamic, and the parameters jitter, shimmer, and NHR remain stable at the level achieved in long-term evaluation. Perceptive evaluation of voice quality on the part of the examiner (RBH classification) as well as the subjective evaluation on the part of the patient (questionnaire) already show an improvement shortly after the operation and this remains unchanged during the investigation period of up to 27 months.

Paraffin oil, as injected by Brüning, was soon abandoned due to migration, foreign body reaction, rejection, and recurrent inflammation [2]. Later in the 1950s the use of biological materials was recommended by Arnold, but autologous cartilage and bone flour appeared to be useless because of their rapid resorption [12]. Bovine and autologous collagen are resorbed more slowly but nevertheless almost completely; therefore, in addition to overcorrection making the results unpredictable, a number of reinjections were often necessary over time [1]. Even rare allergic reactions have to be taken into account for these materials [13]. Because of the risk of the transfection of prions which has not yet been ruled out, bovine collagen should be used with caution [14]. With respect to human collagen, the published results are divergent. Pearl et al. [15]. report a good subjective evaluation up to 3 months after injection of human collagen despite laryngoscopic signs of resorption. In contrast, Karpenko et al. [16] did not achieve an improvement in subjective evaluation even though glottic closure and maximum phonation time improved. Lundy et al. [17] achieved short-term results for jitter, NHR, and subjective evaluation 1 month after injection as good as those that have been described for type I thyroplasty. However, a methodical disadvantage of this study is the lack of long-term results.

Another autologous material is fat tissue. It can most often be harvested in abundance and its viscoelastic characteristics are comparable to those of the vocal cord [2]. An overcorrection is proposed because of its partial resorption, but this is problematic because the rate of resorption differs from patient to patient. According to a study by Shindo et al. [18], resorption is observed especially during the first 6 months after the operation. In contrast, resorption has been reported to be completely absent after overcorrection, making surgical removal necessary [19].

Hyaluronan acid is resorbed to a smaller extent, which is why, compared to collagen, the long-term results appear somewhat better [20]. Hyaluronan acid is available either as extract from rooster combs, so allergic reactions must be taken into account [21], or as an antigen-free biotechnologic product. For the latter, foreign body reaction with the formation of granulomas has been reported [21].

To solve the problem of resorption, Teflon® has been used since about 1960 and was at first regarded as the ideal material for injection laryngoplasty. However, it was soon observed that Teflon® does not remain in place but migrates, and it leads to chronic inflammation and granulomas of the foreign body type. Therefore, nowadays the use of Teflon® is opposed [3].

In contrast to the partly resorbable biological substances described above, the effect of PDMS is permanent, as has been demonstrated by studies regarding its use in plastic surgery [22]. Foreign body reactions, however, can be imagined with the use PDMS. The immunologic response is described as a "low-turnover foreign body response without granuloma formation" [11]. The formation of asymptomatic granulomas with the use of PDMS have been described [23]. However, it has to be mentioned that in the studies cited the granulomas occurred in the skin and caused a cosmetic problem; the granulomas themselves did not cause any other symptoms. Sittel et al. [1] did not observe granulomas of the vocal cords of seven patients in their long-term observation between 69 and 102 months after operation. In our patients no such granulomas have yet been observed; not even chronic inflammation has yet occurred in our patients. It should be pointed out that overcorrection, which may have unpredictable results, is not needed in PDMS. The absence of resorbability of PDMS described above has led to stable postoperative results in our patients 1 year after injection laryngoplasty, which remained unchanged from the results 6 weeks after injection. In this context the unchanged subjective

evaluation of the patients regarding their satisfaction with their voice after 1 year is especially important.

Conclusion

PDMS is a safe substance for injection laryngoplasty in unilateral vocal cord paralysis. Objective and subjective parameters confirm its effectiveness. It is suitable for obtaining satisfying results in the reestablishment of the patient's voice and communication ability.

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