Long-Term Results and Subjective Outcome After Gland-Preserving Treatment in Parotid Duct Stenosis

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Objectives/Hypothesis: To assess the objective long-term results and subjective outcome after treatment of Stensen's duct stenosis.

Study Design: Retrospective study at a tertiary center.

Methods: The long-term results after treatment with a minimally invasive regimen focusing on sialendoscopy were assessed in 82 patients with 98 parotid duct stenoses after primary gland-preserving treatment. A questionnaire was used to assess the patients' perception of success, including clinical parameters and a visual analogue scale (VAS) assessing pain, symptoms, and salivary gland–related quality of life (QOL). Patients were invited to present for clinical and ultrasound examinations and sialendoscopy.

Results: The average follow-up period was 98.48 months. Fifty percent of the patients reported having recurrent gland swelling; but only 19.5% reported recurrent pain and the VAS scores for current symptoms and pain were low. Independent of the type of stenosis, the VAS scores showed a significant reduction in symptoms and improvement in the perceived QOL after the treatment ($P = 0.0001$ each). Follow-up examinations were carried out in 20.73% of the patients, and sialendoscopy was performed in 12.1% of the patients. After diagnosis, recurrent stenoses (n = 8, 9.75%) were successfully reopened in all cases. The glands were preserved in all of the patients.

Conclusion: Long-term evaluation after minimally invasive treatment of stenoses of the parotid duct indicates that high success rates, high rates of gland preservation, and an acceptable subjective patient outcome can be achieved.

Key Words: Salivary gland, obstruction, Stensen's duct, stenosis, stricture, sialendoscopy, treatment, minimally invasive, long-term results.

Level of Evidence: 4.

INTRODUCTION

Obstructive diseases in the salivary glands are associated with considerable impairment of the quality of life (QOL) for the patients affected. Up to 75% of stenoses of the salivary ducts are located in the parotid duct, and these cause approximately 15% to 25% of all unclear salivary gland diseases.[1,2] Fundamental changes have taken place in the treatment of parotid duct stenoses after the development of minimally invasive and gland-preserving treatment protocols.[3–11] Nowadays, stenoses can be visualized using sialendoscopy (SE), which allows for assessment of the tissue characteristics and exact measurement of the stenosis.[9–11] Successful SE-based treatment with preservation of the gland in more than 90% of cases has been reported in several studies with short- to medium-term follow-up periods.[2,12–18] However, thus far there have been no reports evaluating long-term outcome after this form of treatment. Following a previous report on the short- to medium-term results with a minimally invasive treatment regimen in different types of stenosis,[17] the same group of patients was evaluated to assess the long-term success rates and follow-up. A key issue was to investigate the subjective outcome for the patients and their acceptance of the results with this treatment regimen.

MATERIALS AND METHODS

A total of 111 stenoses of the parotid duct in 93 patients were treated during the period from 2001 to 2006.[17] The present study was approved by the local ethics committee. All of the patients were invited to attend for a follow-up clinical and ultrasound examination, in combination with SE if necessary or desired. All patients who were included were asked to complete a questionnaire inquiring about the following parameters:

- Current symptoms or pain: if yes, what symptoms, how often—and with an assessment of their severity using a visual analogue scale (VAS) (0 = minimum to 100 = maximum)
- Current comorbid conditions. If pain with assessment of its severity using an VAS (0 = minimum to 10 = maximum).
- Assessment of the value of the treatment (negative or positive effect) and change in the subjectively perceived quality of life after the treatment (much worse—worse—unchanged—better—much better).

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The authors have no funding, financial relationships, or conflicts of interest to disclose.

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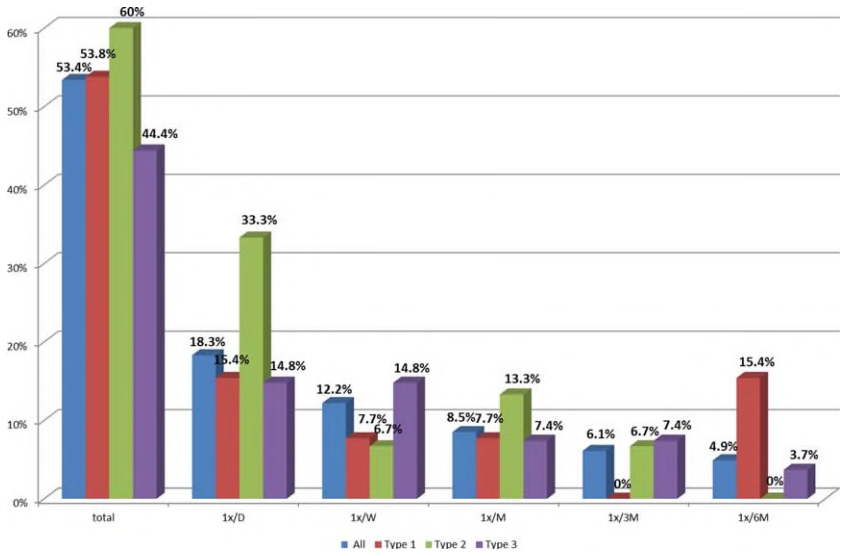

Fig. 1. Frequency/interval of symptoms (not differentiated between pain or swelling) in 82 patients in all stenoses and subdivided according to the type of stenosis after treatment (percentages). D = day; W = week; M = month. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

- Comparison of subjectively perceived symptoms before and after treatment, using a VAS in each case (0 = minimum to 100 = maximum).
- Comparison of the subjectively perceived QOL before and after treatment in relation to salivary gland symptoms, using a VAS in each case (0 = minimum to 100 = maximum).

At presentation, all of the patients were examined using high-resolution ultrasound (Sonoline Acuson Antares 2000; 5–10 MHz; Siemens Medical Solutions USA, Inc., Malvern, PA). Hypoechoic changes in the parenchyma, with enlargement of the gland volume and duct dilation, were regarded as significant signs of gland obstruction on ultrasonography.[17,19] SE was carried out when there were symptoms, signs of obstruction on ultrasound, and/or if desired by the patient.

Various diameters of endoscopes included in the Erlangen sialendoscopy set were used to assess the location, length, and degree of stenosis. New stenoses were grouped into types 1 to 3 using the classification described (type 1: inflammatory; type 2: fibrous, associated with webs and with tendency to formation of megaduct; type 3: fibrous with involvement of the entire ductal wall). Grade 1 stenoses were passable with the 1.1 mm and grade 2 stenoses with 0.8 mm endoscope, each with forced power. Grade 3 stenoses showed a filiforme residual lumen that was not passable with any endoscope without instrumental dilation; and in grade 4 stenosis no lumen was visible.[19] If types 2 and 3 were observed simultaneously, the patient was included in the group with type 3 stenoses relative to the questionnaire evaluation. Patients who had a change of grade in cases of recurrent stenosis were classified according to the highest grade.

Primary treatment consisted in irrigation and intraductal cortisone application, in interventional sialendoscopy with endoscopic controlled instrumental dilation using basket and/or microdrill (intSE), or a combination of intSE with transoral duct surgery (TDS).[17,19]

The results were analyzed separately according to the type of stenosis. Patients who TDS + SE/intSE (representing a subgroup with type 3 stenoses), were also evaluated separately.

Primary outcome measures were the state of the gland (preservation vs. resection) and the results of the questionnaire (status of clinical symptoms of patients, patients' subjective outcome scores). Clinical findings (salivary flow), findings after control SE (type/grade of stenosis), or findings after ultrasound examination (ductal dilation) were considered as secondary outcome measures.

Statistical Analysis

Testing for significant differences in scores of the questionnaire was carried out using the Wilcoxon rank test for matched samples. Testing for significant differences between the different types of stenosis—including the degree of change in these parameters—was carried out using the Kruskal-Wallis analysis of variance (ANOVA) test for independent samples. The significance level was $P = 0.05$. Data are given as means plus or minus standard error of the mean (SEM). The software program SPSS, version 21 for Windows (SPSS Inc., Chicago, IL), was used.

RESULTS

Eight patients were excluded from the final evaluation: seven had died and one was lost to follow-up. A total of 82 patients were ultimately included in the study, representing 88.2% of the initial cohort.[17] Three patients after gland resection due to primary therapy failure were not reevaluated but counted as failures (3.6%, 3/85).

A total of 43.9% of the patients were men (36/82). The patients' average age was 48.83 years (median 48, range 15–75). The mean follow-up period for these patients was 98.48 ± 2.02 months (median 94, range 73–152).

Follow-up Results of Questionnaire

Fifty percent (41/82) of the patients reported symptoms: All of these patients had recurrent gland swelling, but only 19.5% (16/82) of the patients were suffering pain. Patients with type 2 stenoses reported the highest rate of symptoms (Fig. 1). A total of 51.2% (42/82) of patients reported a much better QOL; 25.6% (21/82) of patients reported a better QOL; and 23.2% (19/82) of patients reported an unchanged QOL, but none of the patients described any deterioration. The average VAS score for the current level of symptoms was 23.54 ± 2.86, and for current pain it was 1.38 ± 0.26. The average VAS score for pretreatment symptoms was 70.25 ± 2.41,

TABLE I.
Data (grade, location, type of recurrent/new stenosis and current symptoms) in Patients After Interventional Sialendoscopy Due to Symptomatic Recurrent Stenosis (n = 8/82).

Patients (n)	Grade of Stenosis	Type of Stenosis	Location of Stenosis	No. of SE	No. of IntSE	Complaints	Swelling	Pain	Remarks
1	3	3	distal to middle	5	5	yes	yes	yes	Primary 2 stenoses type 2 and 3 unilateral, after combined treatment (TDS + intSE) Recurrent stenosis, type 3, length > 2 cm
									Treatment: dilation + stent implantation; patient can cope currently with gland massage and self-bougienage
2	3*	3	proximal	4	2	no	no	no	From grade 2 to 3*
3	3	3	proximal	2	2	yes	yes	no	Complaints only in case of cold weather
									Patient can cope with gland massage
4	2	3	middle to proximal	2	1	yes	yes	no	Length < 2 cm
									Jelly-like secretion
									Patient can cope with gland massage
5	3 (right s.) 2 (left s.)	3 and 3	distal (both sides)	8	5	no	no	no	Dilation both sides
									In addition, therapy of suspected cranio-mandibular dysfunction recommended
6	2 and 3†	3	middle (right side)	4	3	no	no	no	Dilation both sides
									New stenosis left side, grade 3
			proximal (left side)						Former stenosis right side, grade 2
7	2	2	middle	4	1	no	no	no	Dilation of stenosis on one side
8	2*	3	middle	3	2	no	no	no	Grades 3 to 2*
Total n = 8	–	–	–	32	21	37.5% (3/8)	–	–	–

*Reclassification: change of grade of stenosis.
†New stenosis in the duct system of the same side.
SE = Sialendoscopy; IntSE = interventional Sialendoscopy; TDS = transoral duct surgery.

significantly higher than posttreatment scores (22.09 ± 2.71, $P = 0.0001$). The average VAS score for pretreatment QOL was 54.87 ± 3.21, significant lower than the posttreatment scores (86.71 ± 1.63; $P = 0.0001$; Table I).

Patients who reported no symptoms in the questionnaire had significantly lower VAS scores for current symptoms and pain ($P = 0.0001$ each). Preoperative scores did not differ significantly from patients with symptoms, but when the preoperative and postoperative scores were compared, significant differences were evident ($P = 0.0001$ each; Table I). In addition, patients with no symptoms described a significantly greater improvement in QOL (4.60 ± 0.123 vs. 3.92 ± 0.131; $P = 0.001$). Nearly all of the patients stated that they were able to cope with the disease by carrying out the recommended gland massage after stimulation. In addition to this, it was important for them to have the confirmation that no "serious disease" was responsible for the discomfort.

Stratification of the Results Relative to Different Stenosis Types

In type 1 stenoses (n = 14, 15.9% of the patients), symptoms were present in 46.2% of the patients; pain was present in 23.1% of the patients (Fig. 1). The QOL was reported to be much better by 46.2% of the patients, better in 23.1% of the patients, and unchanged in 30.8% of the patients. The current VAS score for symptoms was 30.67 ± 7.67 and for pain it was 1.88 ± 0.85. The preoperative VAS scores for symptoms were significantly higher compared to the posttreatment values ($P = 0.008$). The patients gave a significantly higher score for their perceived QOL after the treatment ($P = 0.012$; Table I).

In type 2 stenoses (n = 21, 18.3% of the patients), 60% of the patients reported symptoms and 26.7% of the patients reported pain (Fig. 1). QOL was reported to be much better by 53.3% of the patients, better by 13.3% of the patients, and unchanged by 33.3% of the patients. The current VAS score for symptoms was 31.3 ± 7.93 and for pain it was 1.6 ± 0.68. The preoperative VAS score for symptoms was significantly higher in comparison with the posttreatment values ($P = 0.002$). The patients gave a significantly higher score for their perceived QOL after the therapy ($P = 0.005$; Table I).

In type 3 stenoses (n = 63, 65.9% of the patients), 48.1% of the patients reported symptoms, but only 16.7% of the patients reported pain (Fig. 1). The QOL was reported to be much better by 51.9% of the patients,

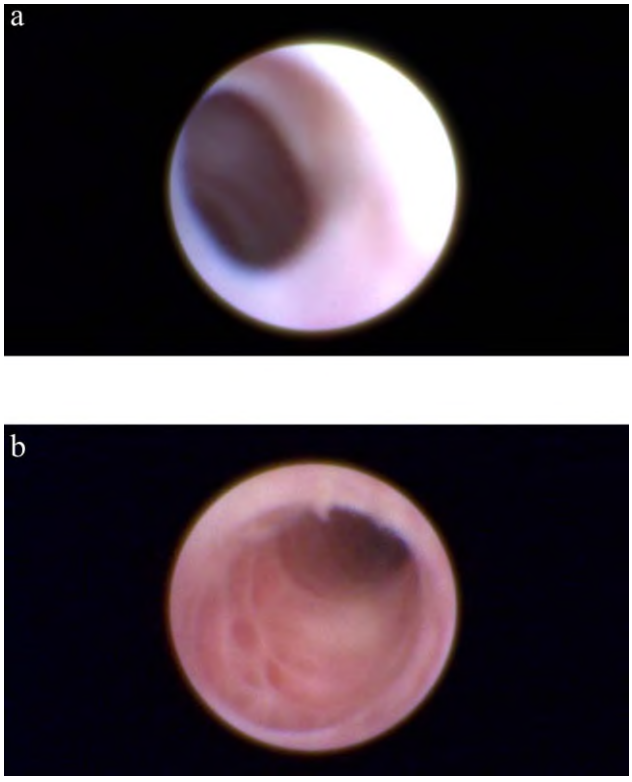

Fig. 2. a–b. Situation after instrumental dilation of a stenosis type 3: The duct system after repeated treatment of stenosis type 3 and grade 3 at the end of the distal duct on the right side (follow-up 7 years and 8 months; 4 months after last treatment: 4 SE, 3 intSE on this side [Table I: Patient 5]). The lumen has not a normal diameter, but is wide enough to allow unhindered salivary flow (a). In the remaining duct system, the wall is markedly thickened, in part by scarring tissue, and shows a subacute inflammation with adherent plaques (b). Int. = interventional; SE = sialendoscopy. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

better by 27.8% of the patients, and unchanged by 20.4% of the patients. The average current VAS score for symptoms was 19.63 ± 3.22, and for pain it was 1.20 ± 0.29. The preoperative VAS scores for symptoms were significantly higher compared to the posttreatment values ($P = 0.0001$). The patients gave significantly higher scores for their perceived QOL after the treatment ($P = 0.0001$; Table I). In all patients after TDS + intSE included (9/11), treatment was successful in the long-term follow-up (105.44 ± 5.76 months, median 100, range 83–127). Only one patient reported moderate pain, and the current level of pain was low (0.11 ± 0.11). After treatment, QOL results were very positive in five patients, positive in two patients, and unchanged in two patients. Preoperative VAS scores regarding complaints were significantly higher compared to posttherapeutic values ($P = 0.011$). The patients gave a significantly higher score for their perceived QOL after the treatment ($P = 0.018$; Table I).

Comparison of the results for VAS scores between the different types of stenosis showed no significant differences (Table I).

Follow-up Results After Presentation

Most of the patients live at a considerable distance from our center ($\geq$ 200 km); therefore, only 20.73% of the patients (17/82) presented for follow-up: none after treatment for type 1 stenoses, 20% after treatment for type 2 stenoses, and 25.9% after treatment for type 3 stenoses.

At clinical examination, ultrasound showed signs of duct dilation (2–6 mm) and more or less echopoor changes of the parenchyma in these patients, but no clear signs of gland atrophy. A total of 58.8% (10/17) of the patients showed pronounced changes of salivary secretion: in nine the saliva was murky due to plaques and in one it was jelly-like. A check-up SE was performed in 12.1% of the patients (10/82). Patients with sialodochitis and plaques without any relevant stenosis were treated with intraductal cortisone therapy (Fig. 2).[17] Repeated and planned SE at intervals of 4 to 8 weeks were arranged on request for one patient in order to improve long-term control of the background inflammatory activity. IntSE was performed in 9.75% of the patients (8/82). A new stenosis (type 3 as the first one) was diagnosed in the unilateral duct system in only one patient. The type of stenosis did not have to be reclassified in any of the patients (Table I). Stent implantation had to be performed in one case (Table I).

Primary or secondary treatment for a total of 98 stenoses was ultimately administered in our 82 patients. Different types unilaterally were not observed in any of the patients, but a combination of different types of stenosis occurred bilaterally in one patient (type 3 and type 2; Table II). No patient had grade 1 stenosis. Forty-seven stenoses were grade 2 (six type 1, twenty type 2, twenty-one type 3); 42 stenoses were grade 3 (five type 1, one type 2, thirty-six type 3); and nine stenoses were grade 4 (three type 1, six type 3). A total of 141 SE were carried out, and 32.9% of the patients (27/82) had more than one SE (Table III). Eighty-two intSEs were performed. In 44 cases (53.7%), one procedure was sufficient (five type 1, seven type 2, thirty-two type 3), but in 15 patients (18.3%) more than one intSE was needed: two in 11 cases (one type 1, two type 2, eight type 3), three in 2 cases (all type 3), and in two cases 5 intSE (type 3

TABLE II.
Number and Type in 98 Primary or Secondary Stenoses, Diagnosed in 82 Patients.

	1 Stenosis	2 Stenoses	3 Stenoses	Total
Patients	68	12	2	82
Type 1 (no. of patients)	12	1	–	14
Type 2 (no. of patients)	9	6*†	–	21
Type 3 (no. of patients)	47	5*†	2	63
Total stenoses	68	24	6‡	98

*Six patients had bilateral stenoses (three type 2, three type 3).
†One patient with bilateral stenosis had type 2 on one side and type 3 on the other side.
‡Two patients with three stenoses: One patient had two type 3 stenoses on the right side and one type 3 stenosis on the left side. The other patient had two type 3 stenoses on the right side (one new grade 3 stenosis) and one type 3 stenosis on the left side.

TABLE III.
Number of Sialendoscopies During the Long-term Follow-up in 82 Patients.

	Sialendoscopies								Patients (n)
	1	2	3	4	5	8	11	Total	
Type 1	10	1	2	–	–	–	–	18	13
Type 2	10	2	–	2	–	–	1	33	15
Type 3	35	12	2	3	1	1	–	90	54
Sialendoscopies (n)	55	30	12	20	5	8	11	141	82

each) had to be carried out. Finally, in 46.2% of patients with type 1 stenoses, 60% of patients with type 2 stenoses, and 87.1% of patients with type 3 stenoses, instrumental dilation was necessary. All of the patients who received TDS ± SE/intSE also had a successful long-term course. This group of patients needed a total of 16 SE and 11 intSE (Table I).

Overall, preservation of the glands was possible in all 82 patients after an average follow-up period of more than 9 years (98.48 months, range 73–152). When the three patients after primary gland resection were included, in 96.4% of all cases gland resection was avoided (82/85).

DISCUSSION

In several publications, gland preservation rates subsequent to the treatment of salivary duct stenoses of 80% to 90% after short- to medium-term follow-up periods have been reported.[2,12,14–18] Our study group reported a significant reduction in symptoms in 92% of cases—and a gland preservation rate of 96.8% after an average follow-up period of 27.2 months.[17] We actually present the follow-up results subsequent to the treatment of 82 patients after a mean follow-up period of 98.48 and a minimum follow-up period of 73 months.

The results of the questionnaire indicate that the minimally invasive treatment approach was carried out with a high success rate during the primary procedures. A total of 74.4% of the patients perceived that it was worth having the treatment, and that their QOL had been improved by it. None of them perceived it as having had a negative influence. Scores for symptoms were significantly lower, and those for QOL relative to salivary gland symptoms were significantly higher after the treatment ($P = 0.0001$ each; Table I). Significant differences were also seen when the different types of stenosis were analyzed separately (type 1, $P = 0.008$ and 0.012; type 2, $P = 0.002$ and 0.005; type 3, $P = 0.0001$ each; Table I). No differences between the different types of stenosis were observed. This indicates that successful type-specific therapy is possible.

Fifty percent of the patients reported to have gland swelling, but no more than 19.5% reported pain (Fig. 1) and current scores for symptoms and pain were at a low level on the VAS (Table I). In comparison to the symptom-free patients, those with symptoms had similar preoperative VAS scores, but significantly worse postoperative VAS scores ($P = 0.0001$ each) and significant higher VAS scores for current symptoms and pain ($P = 0.0001$ each; Table I). Many patients stated that awareness of their diagnosis, exclusion of a serious or malignant disease, and the ability to improve the symptoms by carrying out conservative measures helped them cope with their situation. Recommendation of regular gland massage after stimulation even during symptom-free intervals proved to be helpful in controlling the background inflammatory activity in the ductal system, which seems to be associated with the formation of plaques and ductal obstruction.[5,10,17,20]

Despite overall significant positive effects of our treatment protocol on symptoms and life quality of our patients, a considerably percentage of the patients reported residual symptoms (Fig. 1). Twenty-three percent reported no change in their QOL, indicating that a definitive cure by our treatment measures was not achieved.

Reviewing the long-term follow-up, it can be seen that a total of 141 SE and 82 intSE were performed in these patients. Repeated SE was needed in 32.9% (Table III) of the patients, and 18.3% required more than one intSE. A total of 58.8% of the patients presenting for follow-up examinations had SE. Eighty percent of these (9.75% of all patients) needed intSE due to the symptomatic recurrent ductal stenosis. The stenosis was managed successfully and the glands were preserved in all cases (Table I). Patients with no stenosis, but with chronic sialodochitis and plaques, were adequately treated by SE and intraductal cortisone administration (Fig. 2). Due to the brevity of this procedure (5–10 minutes), with minimal stress for the patient, this strategy can be used repeatedly. These generally positive results are supplemented by the fact that, after combined surgical treatment, all of the patients had a satisfactory long-term course, with preservation of the gland in all cases (Table I).

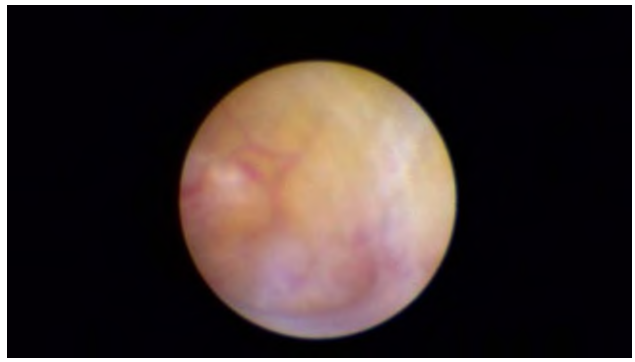

Fig. 3. Typical findings in duct systems of a patient with stenosis type 2: In the proximal duct, the vessels are shining through a very flimsy and transparent duct wall; the duct wall does not have not a reddish color. Yellowish tissue is shining through the duct wall (fat or parenchyma). The small muscle fibers seem to be absent, which may explain the weak excretory power in these duct systems. This may also explain the high frequency of gland swelling, without significant pain, continuing in most patients after successful instrumental dilation of the stenosis. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

For a better understanding of some of the results, a closer look at the results stratified according to the various types of stenosis is needed. Although the data from the questionnaire did not reveal any significant differences after the primary treatment, a few discrepancies during the clinical course were recognizable. Type 1 stenoses showed the lowest recurrence rates (7.7%) and were associated with higher grades of luminal narrowing (grade 3 or 4) in 57.2% of cases. Primary SE-assisted irrigation with intraductal cortisone injection was sufficient in the majority of cases.[17] Inflammatory stenosis may be regarded as a specific type of stenosis or as an early stage of fibrotic (e.g., type 3) stenosis. The low recurrence rates may be a sign of effective and/or prophylactic treatment. Repeated cortisone administration and plaque removal appears to be a successful treatment strategy, even over the longer term.

Type 2 stenoses are characterized by circular or web-like encroachments and massive duct dilation. The duct wall appears very thin, which may be the reason for a weak excretory force (Fig. 3). A megaduct may then appear as a bulge on the cheek, which additionally can represent a cosmetic problem. It was no surprise that patients with type 2 stenoses reported the highest frequency of pain and symptoms (Fig. 1). Of interest, 95.3% of these patients had grade 2 luminal narrowing. Due to the reduced excretory force that results, lower-grade stenoses can cause symptoms; therefore, they should be treated by intSE (e.g., by cutting a stenosing web). Recurrences rates (13.3%) were between those observed in the other types. Most of the patients stated that, despite having current symptoms, they were able to cope with the situation. Gland massage after gland stimulation was reported to fix the symptoms at an acceptable stage and seem to compensate the apparently insufficient excretory function. This appears to be particularly important because no effective and gland-preserving alternative treatment options are currently available.[11,17]

Type 3 stenoses represented 64.28% of all stenoses (Table II), and two-thirds of them were high-grade stenosis. Therefore, over 80% had to be treated primarily using intSE.[11,17] Development of a massive duct dilation with a markedly thickened duct wall was observable in some cases as a result of long-standing severe obstruction. A total of 70.4% of all SE and 80% of all intSE were carried out in these cases. Type 3 stenoses also showed the highest recurrence rates, at 22.2%, and were consequently associated with the largest number of secondary treatment procedures (7/8 patients with recurrent stenosis).

Up to 11 SE and up to five intSE were performed in the present group of patients (Tables I, III), which indicates that stenosis of the parotid duct can be treated as often as needed. These data also seem to point out that instrumental opening of stenosis can improve symptoms but not provide a definitive cure of the underlying inflammatory gland disease. Nevertheless, finally in 96.4% of all patients in whom data were available, the gland could be preserved after a mean follow-up of nearly 10 years.

CONCLUSION

Successful symptomatic therapy can be carried out in primary or recurrent stenosis of the parotid duct with high long-term success rates. There appear to be no limits to the number of repeat (interventional) procedures that are possible. Regular daily conservative measures seem to provide an additional effect to instrumental manipulations.

Patients' acceptance of our treatment protocol was high: The majority of the patients stated that the treatment was beneficial. Scores on the VAS showed that the treatment significantly reduced symptoms and had a significant and positive impact on the perceived QOL associated with salivary gland symptoms.

The long-term success rates of therapy refers to the better control of symptoms, while a definitive cure of the underlying gland disease cannot currently be achieved by this treatment regime. Besides the treatment experiences, a better understanding of this condition may help put expectations on a realistic base. Nevertheless, due to the improvement of the symptoms, gland resection with all its risks and sequelae could be avoided in $>95\%$ of our patients in the long-term interval.

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