

# Long-term Outcomes and quality of life following parotidectomy for benign disease: A cohort study

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## Research

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# Abstract

**Background:** Parotidectomy may be burdened by numerous complications that may worsen subjects' quality of life (QoL). So far, the literature still lacks of long-term data (>10 years) answering to the question what impacted the patients the most on QOL after parotidectomy compared to well-published short-term data.

**Methods:** A prospective long-term follow-up study was carried out. Participants were divided into three groups concerning the follow-up: short-term (ST; 6 postoperative weeks), long-term (LT; 13 years postoperative) and short- and long-term (SLT) on same patient collective. QOL was assessed by the Parotidectomy Outcome Inventory (POI-8). Demographic and clinical data were collected from all patients. Operative reports were used to classify all parotidectomies as great auricular nerve (GAN) "preserving" or GAN "sacrificing" surgical preparations.

**Results:** 74 LT, 57 ST and 33 SLT patients were enrolled in this study. Hypoesthesia posed the major short- and long-term problem whereas facial palsy posed the minor problem. Pain ( $p < 0.01$ ) and hypoesthesia ( $p < 0.001$ ) significantly improved from six weeks to 13 years after parotidectomy as well as the overall POI-8 score ( $p = 0.04$ ). The disease-specific impairment rate decreased from short ( $\gg 70\%$ ) to long-term ( $\gg 30\%$ ) follow-up. Sacrifice of the auricular nerve was associated with hypoesthesia in the ST-cohort ( $p = 0.028$ ).

**Conclusion:** To our knowledge, this study represents the longest follow-up of patients undergoing parotidectomy. Hypoesthesia significantly improved but still remains on long-follow-up without impacting QOL. As part of the preoperative informed consent, prolonged or permanent hypoesthesia should be explicitly emphasized.

**Trial registration:** This study was prospectively approved and registered by the local Ethics Committee (Project Trial No: S-300/2007 and S-443/2018).

## Introduction

Tumours of the parotid gland constitute approximately 3% of the head and neck tumours, and about 80% of them exist as benign pathologies. Benign tumours like pleomorphic salivary adenoma, cystadenolymphoma or basal cell adenoma, inflammatory and autoimmune diseases are indications for surgery [1]. The aim of parotid surgery in benign diseases is the partial or total removal of the gland while preserving the facial nerve function and preventing tumour recurrence [2]. The overall complication rate is about 21.6% [3, 4]. Post-operative numbness, pain, dermal problems, mouth dryness and scar-related problems are the important complications that affect quality of life (QOL) [5]. Health-related quality of life (HRQoL) measurements are gaining increased importance in clinical medicine. The Parotidectomy Outcome Inventory (POI-8) is the first reliable and valid instrument for measuring health-related QoL in patients after parotidectomy for benign disease [6]. Several studies reported no changes in QoL in a short

observation period after parotidectomy - usually 6 months to 1 year [2, 5, 7-10]. However, little is known about the long-term disease-specific QOL after parotidectomy.

The aim of this retro- and prospective study was to determine the long-term surgery-affected QOL using the disease-specific POI-8 questionnaire and to compare those to well-published short-term data. In order to get more objectivity, data research was performed in different (LT-versus ST-cohort) and same patients collectives (SLT-cohort).

## Material And Methods

The Ethics Committees of University of Heidelberg (Project Trial No: S-300/2007 and S-443/2018) granted approval for the study. This long-term follow-up study based on the validation data of the German version of the Parotidectomy Outcome Inventory-8 (POI-8) questionnaire including 199 patients undergoing benign parotidectomy [6] between 2003 and 2006 in our Department for Ear, Nose and Throat, Head and Neck Surgery, University of Heidelberg, Germany of which 57 (28,6%) patients returned the POI-8 six weeks after parotid surgery. Surgical procedures included partial and total parotidectomies. All histopathological results were retrieved, and patients with malignant diseases were excluded. The prospective recruitment took place in 2018. In total, 199 patients who were included in the original retrospective study of Baumann et al. [6] were reinvited to participate in the study of which 74 (37.2%) responded in 2018, this means 12-16 years after surgery. 108 / 199 (54.3%) patients did not respond due to change of location or disinterest, 16 patients (8%) had already died and only one patient (0.5%) actively declined to participate in the study. For simplification, we assigned the study patients to different groups (**Figure 1**): patients who participated in our prospective study in 2018 fitted into the long-term cohort (**LT-cohort**, 74/199) because they replied 12-16 years after parotidectomy. 33 of them were already included in the original study of Baumann et al. in which the patients returned the POI-8 six weeks after parotid surgery [6]. Consequently, these responders who returned the completed questionnaires six weeks and 12-16 years after surgery were assigned to the **SLT-cohort** (short- and long-term cohort, 33/199). Both groups were compared to the original short-term data (6 weeks postoperatively) of Baumann et al. [6], which were titled here as **ST-cohort** (short-term cohort, 57/199). Taken together, the pro- and retrospective POI-8 data from a total of 98 (74 LT, 57 ST, 33 SLT) patients were available. Hence, the LT- and ST-cohort are not disjoint but overlapping. The set of overlapping patients has the size of the SLT-cohort. All patients were informed about the study aims and protocol, and participants were enrolled after giving informed written consent. The Parotidectomy Outcome Inventory-8 (POI-8) is a validated and reliable questionnaire for patient-reported QOL in parotid surgery [6]. It consists of eight Likert-type scaled questions from 0 to 5 (no – marginal – slight – moderate – severe – the worst problems) with a total score of 40. Low values for the POI-8 scales indicate high functionality and QoL. In addition to the POI-8, patients responded to global questions concerning the parotidectomy impairment (no – low grade – moderate – severe – very severe impairment), their satisfaction with the postoperative results and if they would recommend this operation to good friends and family members. Additionally, questions were answered regarding doctor rounds, rehabilitative measures and days of incapacitation for work in the last 6 months. Group comparisons were made between the Short (ST)- and long-term (LT) cohorts

(**intergroup**) as well as within the SLT-cohort (**intragroup**), short versus long follow-up measurements. Lastly, operative reports and clinic notes were used to classify all parotidectomies as “nerve preserving” or “nerve sacrificing” surgical preparations concerning the branches of the great auricular nerve (GAN).

## Statistical analysis

The data were analysed using R, Version 3.6.1. Metric variables are presented as means  $\pm$  standard deviation, while factorial variables are presented by their proportional distribution. Additionally, t-statistics for the comparison of mean values between variables were used to determine differences between the cohorts (intergroup comparisons). Furthermore, the distribution of particular variables were tested for relatedness/independence with other variables, using  $\chi^2$ -tests for intragroup comparisons. We decided on that particular procedure, since a) most of the variables that we compared are categorical and nominal distributed, b) the sample size was not too large to impact sensitivity of the test’s results in a way that would lead to false positive outcomes and c) it is the statistic that is most commonly used for such comparisons, which may lead to more accessible and understandable results [11]. A p-value less than 0.05 was considered statistically significant. The graphical displays that are shown, were programmed using the ggplot2 library of R.

## Results

### Patient cohorts

74 patients (41 men, 33 women) with an average age of  $66.4 \pm 12.2$  years at time of survey prospectively completed the POI-8 questionnaire. Average time span of follow-up was  $13.3 \pm 1.1$  (range: 12-16 years). The contributions of the benign histopathologic diagnoses were predominantly cystadenolymphoma (40.5%) and pleomorphic adenoma (28.4%), followed by chronically relapsing sialadenitis (6.8%) and parotid cyst (6.8%). 93.2% of patients underwent a lateral, 6.8% of patients a total parotidectomy. Details of the different patient’s cohorts and disease characteristics are shown in **Table 1**.

Table 1  
Surgical and clinico-pathological characteristics of the three different study cohorts.

<b>Characteristics</b>	<b>ST-cohort (n = 57)</b>	<b>LT-cohort (n = 74)</b>	<b>SLT-cohort (n = 33)</b>
<b>Age (years):</b> time of operation	55 14.9 (range: 17–78)	53 12.2 (range: 28–76)	55 12.7 (range: 30–76)
<b>Age (years):</b> time of survey	68 14.8	66.5 12.3	68 12.6
<b>Gender</b>	(range: 31–92)	(range: 40–90)	(range: 45–90)
- Female	30 (52.6%)	33 (44.6)	17 (51.5%)
- Male	27 (47.4%)	41 (55.4)	16 (48.5%)
<b>Operational extent</b>	53 (93.0%)	69 (93.2%)	30 (90.9%)
- Lateral	4 (7%)	5 (6.8%)	3 (9.1%)
- Total	32 (56.1%)	43 (58.1%)	20 (60.6%)
<b>Operation site</b>	25 (43.9%)	31 (41.9%)	13 (39.4%)
- Left	21 (36.8%)	30 (40.5%)	12 (36.4%)
- right	20 (35.1%)	21 (28.4%)	10 (30.3%)
<b>Histopathological diagnoses</b>	4 (7.0%)	5 (6.8%)	4 (12.1%)
- Cystadenolymphoma	5 (8.8%)	5 (6.8%)	2 (6.1%)
- Pleomorphic adenoma	2 (3.5%)	3 (4.1%)	1 (3.0%)
- Parotid cyst	1 (1.8%)	2 (2.7%)	1 (3%)
- Chronic sialadenitis	1 (1.8%)	1 (1.4%)	1 (3%)
- Basal cell adenoma	1 (1.8%)	1 (1.4%)	1 (3%)
- Epitheloid cell granuloma	0 (0%)	2 (2.7%)	0 (0%)
- Hemangioma	2 (3.5%)	2 (2.7%)	1 (3%)
- Myoepithelioma	0 (0%)	2 (2.7%)	0 (0%)
- Oncocytoma	39 (68.4%)	26 (35.1%)	25 (75.8%)
- Morbus Sjögren	17 (29.8%)	7 (9.5%)	7 (21.2%)
- Lymphadenitis	1 (1.8%)	1 (1.4%)	1 (3.0%)
<b>Marital status</b>	/	40 (54.1%)	/
- Married	25 (43.9%)	12 (16.2%)	12 (36.4%)
- Separated	11 (19.3%)	8 (10.8%)	7 (21.2%)

<b>Characteristics</b>	<b>ST-cohort (n = 57)</b>	<b>LT-cohort (n = 74)</b>	<b>SLT-cohort (n = 33)</b>
- Widowed	19 (33.3%)	13 (17.6%)	13 (39.4%)
- No data	2 (3.5%)	41 (55.4%)	1 (3%)
<b>Graduation</b>	12 (21.0%)	6 (8.1%)	6 (18.2%)
- Secondary school	2 (3.5%)	0 (0%)	0 (0%)
- Junior high school	2 (3.5%)	0 (0%)	0 (0%)
- High school	20 (35.1%)	11 (14.9%)	11 (33.3%)
- No data	18 (31.6%)	14 (18.9%)	13 (39.4%)
<b>Professional activities</b>	3 (5.3%)	40 (54.1%)	3 (9.1%)
- House work	14 (24.6%)	9 (12.2%)	9 (27.3%)
- Job seeking	19 (33.3%)	11 (14.9%)	10 (30.3%)
- College student	23 (40.4%)	13 (17.6%)	13 (39.4%)
- Retirement	1 (1.8%)	41 (55.4%)	1 (3.0%)
- Employed			
- No data			
<b>Smoking history</b>			
- Currently			
- Former			
- Never			
- No data			

### **Intergroup differences of POI-8 outcomes in ST- and LT-cohort**

Six weeks after parotidectomy, 77,2% of the ST-cohort characterized hypoesthesia as the most disturbing problem, followed by xerostomia (47.4%) and the appearance of the scar (45.6%). Facial palsy was posed as minor problem (87.7%). In the LT-cohort, hypoesthesia (54.1%), followed by fear of revision surgery (44.6%) and appearance of the scar (39.2%) posed the major problems. 95.9% of the patients described facial palsy not as problematic.

42.1% of ST-cohort characterized pain on the site of surgery significantly more problematic with the mean POI-8 score of 0.93 than LT-cohort with the mean POI-8 score of 0.34 ( $p = 0.002$ ). 77% of LT-patients affirmed no pain or painful sensations 13 years after parotidectomy. Hypoesthesia improved significantly over the years but still posed a problem: 77.2% of ST-patients were disturbed by hypoesthesia six weeks

after surgery with the mean POI-8 score of 1.86 and 54.1% of the LT-cohort still named sensation loss as a problem with the POI-8 mean score of 0.88 ( $p < 0.001$ ).

The ST- and LT-cohort did not differ in POI-8 responses concerning scar ( $p = 0.07$ ), facial palsy ( $p = 0.21$ ), substance loss ( $p = 0.37$ ), Frey's syndrome ( $p = 0.64$ ), xerostomia ( $p = 0.14$ ) and anxiety of revision surgery ( $p = 0.73$ ). There was a significant change in the mean score of POI-8 detectable (ST-POI-8 of 7.47, LT-POI-8 of 5.15;  $p = 0.04$ ) (**Figure 2**).

In the ST-cohort, 64.9% of patients were - predominantly slightly - affected in disease-specific QOL after parotid surgery. 68.4% patients filled out to be "very satisfied" with operation results. In the LT-cohort, 27% of patients still described impairment after parotidectomy, thereof 4.1% as "severe". There was a long-term satisfaction rate of 81.8%. Negligible doctor visits (6.8%)/days of incapacitation (2.7%) and no rehabilitative measures were documented in the LT-cohort

### **Intragroup differences in POI-8 outcomes in SLT-cohort**

Six weeks after parotidectomy, 84.8% of the SLT-cohort characterized hypoesthesia as the most disturbing problem, followed by the appearance of the scar (54.5%) and pain (51,5%). Facial palsy posed the minor problem (87.9%). At 13 years follow-up, hypoesthesia still bothered 60.6% of them, but only 3% severely, as well as Frey's syndrome (48,5%) and fear of revision (42,4%). No one suffered from facial palsy in the LT-cohort. In the meantime, from 6 weeks to 13 years after surgery, hypoesthesia ( $p < 0.001$ ) and pain ( $p = 0.004$ ) had significantly improved from patient's perspective. Dissatisfaction with the scar ( $p = 0.13$ ), appearance due to substance loss ( $p = 0.17$ ), Frey's syndrome ( $p = 0.36$ ), xerostomia ( $p = 0.09$ ), fear of revision surgery ( $p = 0.75$ ) and facial palsy ( $p = 0.08$ ) did not significantly ameliorate after surgery. The total score of POI-8 significantly decreased from the mean POI-8 score of 8.24 six weeks after surgery to the mean POI-8 score of 5.15 13 years after surgery, indicating higher overall satisfaction ( $p = 0.04$ ; **Figure 2**).

Six weeks after parotidectomy, 72.7% of patients felt - mostly slightly - impaired by high satisfaction rate of 69.7%. In the long-term interval, 33,3% of patients felt impaired after parotid surgery, the satisfaction rate amounted 78.8%. No days of incapacitation, no rehabilitative measures and nearly no medical doctor visits (6.1%) were necessary in the last 6 months.

All group comparisons are graphically illustrated in **Figure 3**.

### **Preservation of the great auricular nerve (GAN)**

Based on all available surgical reports ( $n = 98$ ), 45.9% of the GAN could be technically preserved, 33.7% had been sacrificed and in 20.4% no information was found in the operation report.

All patients of the LT-cohort ( $n = 40$ ; 23 men, 17 women), who documented a sensation loss in the POI-8 questionnaire, were contacted again and were asked about the location of the numbness. The area overlying the parotid gland and at the angle of the mandibule were slightly more affected than the area of

auricle and along the anterior border of the sternocleidomastoid muscle (55% versus 45%). In general, the patients did not feel limited in QOL: the majority of the patients described the hypoesthesia as “marginal” (55%) or “slight” (35%), but 10% of them felt “moderately”/“severely” or “very severely” affected. Concerning this selected collective here (n = 40), there were no correlations between the nerve’s sacrifice, the second POI-8 item, the operation procedure (lateral vs. total) and the affected area detectable ( $p > 0.05$ ). Sacrifice of the GAN was only associated with the second item of the POI-8 (hypoesthesia) in the ST-cohort ( $p = 0.028$ ), not in the SLT- or LT-cohort, using chi-square test.

## Discussion

This study provides first efficient data on short- (6 weeks) versus long-term (13 years) HRQoL after parotidectomy using the validated disease-specific questionnaire POI-8. Key goal in parotid surgical approaches for treatment of benign lesions is not only to remove the entire tumour and to minimize morbidity but also to maintain patients’ quality of life. However, only few studies address patients’ perspective on complications and the related QoL [5, 7-9, 12-14], but predominantly in a short follow-up after parotidectomy - usually 6 months or 1-2 years - and by using different symptom-specific QoL assessments. Beutner et al. [8] reported no changes in QoL in 34 patients one year after superficial parotidectomy for benign diseases compared with preoperative answers using the EORTC QLQ-C30 and EORTC QLQ-H&N 35. Nitzan et al. utilized a modified version of the University of Washington Quality of Life Questionnaire and could detect subjective sequelae like altered sensation, change in appearance, Frey’s syndrome and pain during at least 1-year follow-up period which did not significantly affect QoL [9]. New data of Bulut et al. described for the first time a significant increase in QOL in the long term (100 months postoperatively) compared to short term (2 weeks postoperatively) by focusing on sensory dysfunction resulting from great auricular nerve (GAN) sacrifice versus preservation in parotid surgery [14]. Since most studies have only a short follow-up, it raises the question what impacted the patients the most on QOL more than 10 years after parotidectomy. To our knowledge, this is the longest follow-up reported after benign parotid surgery. From patient’s perspective, hypoesthesia, followed by fear of revision surgery posed the major problems in long-term follow-up whereas facial palsy posed the minor problem. In the literature, numbness or uncomfortable sensations of the skin are well known as dominant, postoperative short-term sequelae after parotidectomy [5, 7, 9, 12, 15]. Indeed, hypoesthesia is of greatest concern to the patients 6 months (90%) and still 2 years after surgery (78%) [7]. Porter and Wood [16] observed that the majority of sensory improvement occurred in the first 6 months. Ryan and Fee described that at a mean point of 2 years, symptoms had either completely ablated or stabilized [17]. The great auricular nerve (GAN) originates from the cervical plexus at the levels of the second and third cervical nerves. It supplies sensation to the skin overlying the lower aspect of the pinna and angle of the mandible and is divided into anterior and posterior branches. The anterior branch is usually sacrificed whereas a posterior branch can technically be preserved [5]. That’s why, the area overlying the parotid gland and at the angle of the mandible were slightly more affected here than the area of auricle and along the anterior border of the sternocleidomastoid muscle. In this context, Bulut et al. reported that GAN preservation did significantly improve sensation in short- but not in long-term, nor did it increase QOL in

long term when compared to GAN sacrifice [14]. Based on the observation period of 12-16 years after parotidectomy, we could show that hypoesthesia significantly improved over the years ( $p < 0.001$ ) but still remains without limiting patients in QoL, a clinically relevant finding here. Indeed, 77.2% of ST-patients were disturbed by hypoesthesia six weeks after surgery with an overall impairment rate of 64.9% while 54.1% of the LT-cohort named sensation loss still as a problem with an impairment rate of 27%. In the LT-cohort, hypoesthesia was predominantly characterized as a “marginal” to “moderate” problem (51.3%) problem; only 2.8% of patients considered it as “severe” or “the worst problem”. Consequently, patients should be preoperatively informed about the possible prolonged or permanent hypoesthesia. According to data of Bulut et al. [14], we only found a positive association between intraoperative preservation of the GAN and improved hypoesthesia in the ST-cohort ( $p = 0.028$ ), not in the LT-cohort. Finally, we can conclude that patients seem to adapt to the postoperative functional impairment over time and focus less on the reduced ability to feel temperature and pain on the facial skin over the parotid gland and auricle. 42.1% of the ST-cohort characterized pain on the site of surgery significantly more problematic than the LT-cohort ( $p = 0.002$ ). Only 23% of LT-study patients affirmed pain and painful sensations 12-16 years after surgery, 13.5% of them described the pain as “marginal”, 9.5% of them as “slight” and “moderate”, no one as “severe” or as “the worst problem”. Wolber et al. [7] and Nitzan et al. [9] underlined our results by reporting an incidence of postoperative pain of 30-40% during a short follow-up. In accord with Kaya et al. [10], we can consequently argue that pain is an important early complication following parotidectomy which improves in the long-term. Strikingly, the ST- and LT-cohort did not significantly differ in scar, facial palsy, substance loss, Frey’s syndrome, xerostomia and anxiety of revision surgery. Due to the fact that the total POI-8 score significantly improved from the mean POI-8 score of 7.47 six weeks after surgery to the mean POI-8 score of 5.15 13 years after surgery ( $p = 0.04$ ), we can conclude that parotidectomy did not seem to be detrimental to QoL in the long run. Examinations on the same patient collective (SLT-cohort) underlined our results herein presented: hypoesthesia ( $p < 0.001$ ) and pain ( $p = 0.004$ ) had significantly improved from patient’s perspective with a significant POI-8 reduction from 8.24 to 5.15 13 years after surgery, indicating higher disease-specific QoL. Generally, global quality of life is a multidimensional construct with contributions from economic, social, interpersonal, physical and psychological aspects [8]. Thus, subjective perception of post-parotidectomy complications might be influenced by these mentioned factors unrelated to surgery [2] as disadvantage of self-reported measures. Besides, no objective testing method exists for accurate evaluation of QoL in the head and neck region [14]. Another limitation of our study is the different group size in the ST-, LT- and SLT-cohort. Consequently, further prospective studies with a larger sample size are needed. In summary, we see the strength of our study in the first reported, longest follow-up period of 12-16 years after parotidectomy, numerous group comparisons in different (LT, ST) and same patient cohorts (SLT\_short vs. SLT\_long), usage of a validated, commonly used patient-reported outcome measure POI-8 and in the retro- and prospective study design.

## Conclusion

To our knowledge, this is the longest follow-up study assessing QOL in patients undergoing parotidectomy, which showed an overall improvement of QOL after surgery with a significant reduction of POI-8 total score 12-16 years after parotidectomy. From patient's perspective, hypoesthesia and the appearance of the scar posed the major long-term problems (SLT/LT-cohort) whereas facial palsy posed the minor problem. Even though, hypoesthesia significantly improved over the years, it still remains without impacting QOL and should be mentioned as part of informed consent.

## **Declarations**

### **Authorship Contributions** □

All authors made substantial contributions to the study and have approved the final article.

MP: designed and coordinated the study, participated in data acquisition and analysis, interpreted the data and drafted the manuscript.

MS: is an accredited expert of survey analysis, who is working for GESIS - Leibniz Institute for Social Sciences with headquarter in Mannheim, and participated in data interpretation and statistical analysis.

PKP: participated in data interpretation.

IB: participated in data interpretation and revision of the manuscript.

KZ: designed and coordinated the study, participated in data acquisition and analysis, critically revised the manuscript for important intellectual content.

### **Conflict of interest**

All authors declare that they have no conflict of interest.

### **Informed consent**

Informed consent was obtained from all individual participants included in the study.

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### **Ethical approval**

The Ethics Committee of the Medical Faculty at the University of Heidelberg granted permission to conduct the study (Project No: S-443/2018).

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## Availability of data and material

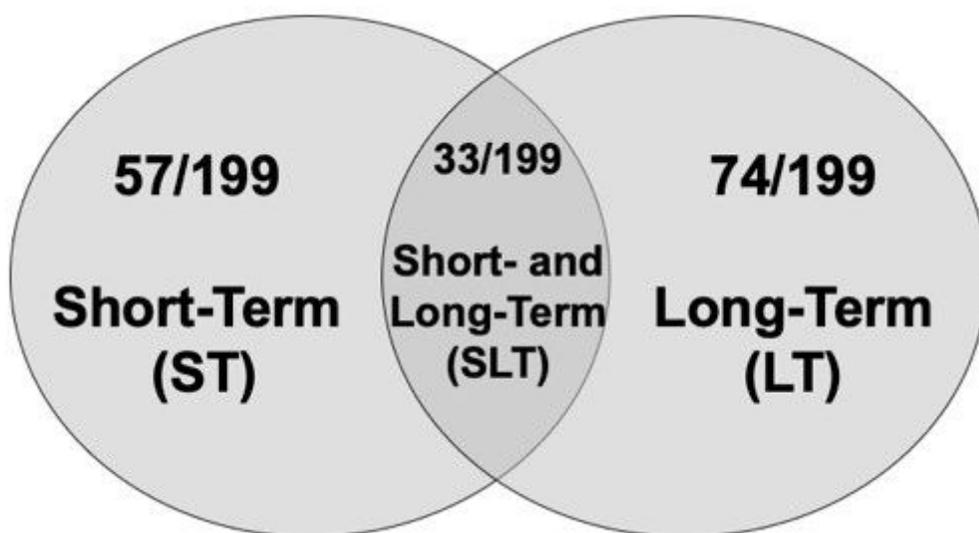
Data is available upon request from the author

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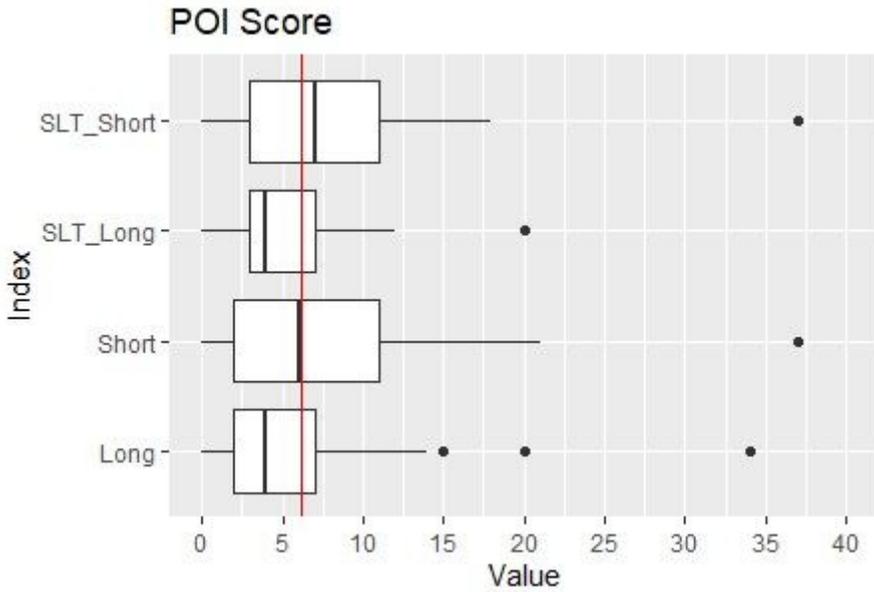
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## Figures



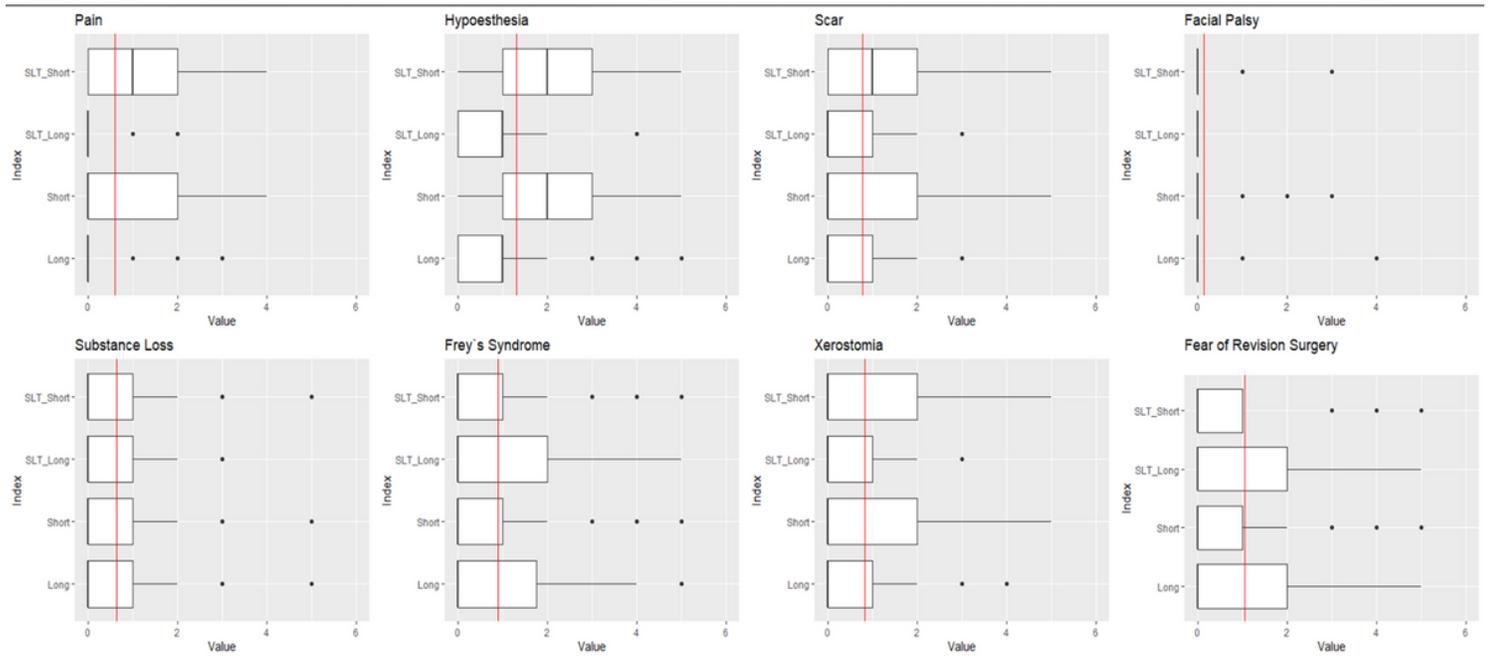
**Figure 1**

Overview of all short- and long-term study cohorts. 57 participants (short-term cohort = ST-cohort) filled out the POI-8 6 weeks postoperatively, 74 participants (long-term cohort = LT-cohort) edited the POI-8 13 years after surgery and 33 participants (short- and long-term cohort = SLT-cohort) completed the POI-8 in a short- (6 weeks after surgery) and in a long-term interval (13 years after surgery).



**Figure 2**

Group comparison of the Parotidectomy Outcome Inventory (POI-8) total score. The red line represents the overall mean POI-8 score of the combined results, measured at both times. The bold line describes each distribution’s median whereas the box represents the interquartile range. Dots resemble outliers.



**Figure 3**

Group comparison of the Parotidectomy Outcome Inventory (POI-8) items. The red line represents the overall mean of the particular item of the combined results, measured at both times. The bold line describes each distribution’s median whereas the box represents the interquartile range. Dots resemble outliers.