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# The Learning Curve of Sialendoscopy With Modular Sialendoscopes

## *A Single Surgeon's Experience*

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**Objective:** To assess the learning curve of sialendoscopy with modular endoscopes based on operative parameters and a postoperative performance rating.

**Design:** Prospective study, case series.

**Setting:** Tertiary referral hospital.

**Patients:** The study included 50 consecutive patients who underwent sialendoscopy by a single surgeon (J.C.L.) between September 2007 and March 2009 at University Hospital of Cologne, Cologne, Germany. The patients were chronologically arranged into 5 groups of 10 patients.

**Interventions:** Diagnostic and interventional sialendoscopy using local anesthesia.

**Main Outcome Measures:** Operative parameters and postoperative performance ratings.

**Results:** The average operative time was 39 minutes, with a ratio of diagnostic to interventional sialendoscopy of 62%:38%. There was a significant improvement in the average operative time ( $P < .001$ ) and in the average performance rating ( $P = .007$ ) after the first 10 patients and again after the first 30 patients ( $P = .003$  and  $P = .01$ , respectively). A continuous decrease in operation time was measurable up to the last patients. Performance ratings reached a level of excellence within the last group of patients.

**Conclusions:** The performance of sialendoscopy improves with time and experience. With endoscopes of a modular design, the surgeons have a remarkable learning curve. The surgeons' learning curve in this study required 30 cases to reach satisfactory operation times and performance ratings. Both parameters showed continuous improvement and a leveling off after 50 cases.

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**I**N THE PAST, SYMPTOMATIC SALIVARY gland stones that could not be successfully treated by conservative treatment or intraoral duct incisions close to the ostium most often required surgical removal of the whole gland. Since its introduction into clinical practice more than a decade ago, the modern technique of sialendoscopy has evolved in clinical application and has become the diagnostic tool and treatment of choice for ductal disorders of the salivary glands.<sup>1</sup> Sialendoscopy aims to diagnose and treat salivary duct diseases by means of a semirigid endoscope that is inserted into the salivary duct system via the natural ostium inside the oral cavity. It is a minimally invasive procedure that can be carried out with the patient under local anesthesia. The procedure may be performed in an outpatient setting because complication rates are low and recovery time is short.<sup>2</sup> In the hands of an experienced surgeon, the sialolith extraction rate is roughly 75% according to the literature.<sup>3</sup> The likelihood of removal of an

intraglandular stone depends on the stone's size, form, mobility, and location inside the duct system as well as on the experience and manual skills of the surgeon who is performing the procedure.<sup>1</sup> In certain cases, and especially in those involving immobile stones greater than 5 mm, a combined endoscopic-external approach can be an option.<sup>4</sup> For large or fixed sialoliths that are located close to the ostium, intraoral removal can be a primary treatment option, ideally followed by a sialendoscopic procedure to exclude further calculi in the deeper duct system.<sup>5</sup> As yet, the technique is available in only a few clinical centers.

The general technique of sialendoscopy has been repeatedly described in literature; however, some questions still remain unanswered, and there is a lack of sufficient clinical experience and research.<sup>1,6,7</sup> It is the general belief that sialendoscopy requires extensive practical experience before success rates reach a level comparable to those reported in the literature.<sup>1,3</sup> Because sialendoscopy is con-

sidered to be a technically challenging procedure, it is best performed, or supervised, by an experienced surgeon. However, how many cases a surgeon should perform to become proficient in this technique is still unknown. Because sialendoscopy differs from other endoscopic procedures in many points (eg, smaller endoscopes, new working tools, endoscopy in a fluid-filled branched system, local anesthesia), and because acquisition costs for the instruments involved are rather high, the learning curve should be of special interest to surgeons who are considering performing sialendoscopy in their clinic. Herein, we describe the learning curve of a single surgeon (J.C.L.) during the first 50 sialendoscopies and report on quantitative (duration of sialendoscopy) and qualitative (performance rating) measurements.

## METHODS

Sialendoscopy was performed between September 2007 and March 2009 on 50 consecutive patients by a single surgeon in a tertiary referral center. During every procedure, supervision and assistance were given by an advanced surgeon with wide experience in the field of sialendoscopy. The primary surgeon's level of education was the third year of training for general otolaryngology. Preparation for the primary surgeon consisted of attendance at a sialendoscopy training course at the European Sialendoscopy Training Centre, Geneva, Switzerland, which included practical training on pig heads. All 50 procedures were conducted with the patients under local anesthesia in an ambulatory care setting. Approval was obtained from the ethics committee of the University Hospital of Cologne, Cologne, Germany.

In addition to patient descriptive data (age, sex, type of gland, site of performance, and type and duration of preoperative symptoms), we recorded the following data for each procedure to keep track of the surgeon's personal progress: time until the ostium was detected (part 1), time until the duct lumen was endoscopically visible (part 2), and overall time for the whole sialendoscopy (part 3) (all in minutes). We also recorded the number of minor duct injuries, duct perforations, breakaways of the dormia basket, and retracted stones. Furthermore, the primary surgeon and an experienced supervisor (M.D., J.P.K, and D.B.) independently and subjectively rated each performance using a 5-point numerical scale (1, insufficient; 2, room for improvement; 3, average; 4, good; and 5, excellent). To analyze the learning curve of the trainee, the 50 patients were arranged according to their chronological order into 5 groups of 10 patients.

Statistical analysis was performed with a SPSS statistics software package (Version 17.0.0; SPSS Inc, Chicago, Illinois). To compare groups, *t* tests and the Mann-Whitney *U* test were used as applicable. The interrater agreement for the procedure rating was measured with a  $\kappa$  coefficient calculation. An univariate analysis of variance was calculated to compare groups, and a Bonferroni post hoc test was calculated to determine the statistical significance between groups. Data are presented as mean (SD [minimum and maximum]). Differences were considered significant at  $P < .05$ .

Routine preparations consisted of premedication with a benzodiazepine (7.5 mg of midazolam or 2 mg of flunitrazepam) 45 minutes before the procedure. After infiltration of the mucosa that surrounds the papilla with 1 mL of lidocaine hydrochloride and epinephrine, 2%, the ostium was widened with probes of increasing size and a conic dilator. Sialendoscopy was then started with a 1-mm endoscope placed in a diagnostic single-channel device with a 1.3-mm outer diameter (Nos. 11577

A and KA; Karl Storz AG, Tuttlingen, Germany). For interventional sialendoscopy (stone extraction, stenosis dilatation), we changed to a 0.75-mm endoscope in a double-channel device (total outer diameter, 2.4 mm) (Nos. 11576 A and KF; Karl Storz AG). The rinsing solution consisted of lidocaine, 2%, and sodium chloride, 0.9%, at a ratio of 1:5. For the working channel, we used grasping baskets, dilatation balloons, and forceps (Nos. 11575 L and 11576 BP and TJ; Karl Storz AG).

All operation videos were saved and analyzed after surgery. The whole process was divided into 3 parts: (1) finding the ostium; (2) dilating the ostium until fitting of the probe size 5 (No. 11745855; Karl Storz AG), preparing the endoscope in terms of white balance, optical alignment, and focus, inserting the small diagnostic endoscope, and visualizing the duct lumen on the screen; and (3) performing the sialendoscopy. The supervisor assumed control over the endoscopy whenever necessary and to guarantee success of the procedure and optimal treatment of the patient.

## RESULTS

### PATIENTS

Thirty-three women and 17 men (age, 49.0 [20 and 79] years) underwent sialendoscopy. The site of origin was the parotid gland in 31 cases (left,  $n = 19$ ; right,  $n = 12$ ) and the submandibular gland in 19 cases (left,  $n = 9$ ; right,  $n = 10$ ). The patients' preoperative symptoms were as follows: postprandial swelling of the gland ( $n = 32$ ), gland swelling independent of ingestion ( $n = 16$ ), recurrent sialadenitis ( $n = 15$ ), pain in the region of the gland ( $n = 26$ ), and fetor ex ore ( $n = 11$ ). Symptoms lasted an average of 34.0 months (64.1 [0.5 and 300.0]). The ratio of diagnostic to interventional sialendoscopy was 31:19 (62%:38%).

### PERFORMANCE

For the parotid gland, it took an average of 0.7 (1.3 [0 and 8]) minutes to detect the ostium of the Stensen duct. Detection of the Wharton duct ostium (part 1) took an average of 3:30 (2:42 [0 and 10:00]) minutes. Preparation of the ostium and the endoscope until the first visualization of the duct lumen on the screen (part 2) took an average of 6 (3:30 [2:0 and 15:00]) minutes for the parotid gland and 6:36 (3:48 [2:00 and 13:00]) minutes for the submandibular gland. Diagnostic sialendoscopy (part 3) took an average of 36:00 (17:12 [7:00 and 80:00]) minutes, and interventional sialendoscopy took an average of 45:00 (33:00 [10:00 and 160:00]) minutes. The rate for minor duct injuries was 14% ( $n = 7$ ). There was 1 case of duct perforation, and a dormia basket was lost behind an immobile stone in 2 cases.

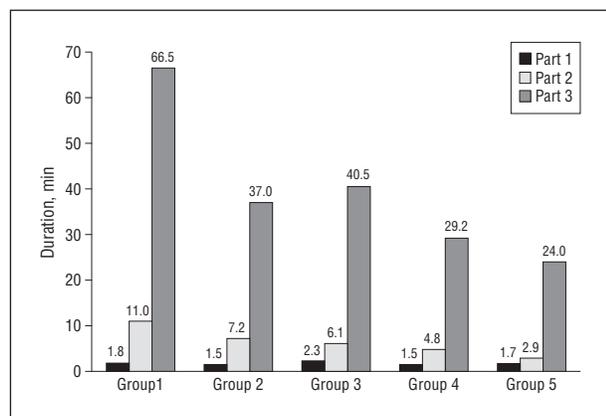
In 19 patients (38%), sialolithiasis was the underlying cause of the symptoms. In total, 25 sialoliths were found during sialendoscopy. Of these, 14 sialoliths were classified as removable compared with 11 sialoliths that were classified as nonremovable owing to size, immobility, or location deep in the gland. In total, the primary surgeon was able to remove 10 of the 14 removable stones (rate, 71.4%); the remaining 4 stones were removed by the supervisor.

During 9 sialendoscopies (18%), the supervisor intervened to ensure the optimal result for the procedure,

with 6 of these interventions occurring during the first 10 cases. The primary surgeon's rating for his personal performance was on average 3.6 (1.1 [1 and 5]); the supervisor rated the primary surgeon's average performance slightly better (3.7) (1.0 [1 and 5];  $\kappa=0.67$ ). The **Figure** shows the time development over the 5 groups for each part of the sialendoscopy.

### LEARNING CURVE

An univariate analysis of variance was calculated to compare the 5 groups. The time for part 1 of the procedure (time needed to find the duct entrance) changed only slightly between patient groups 1 and 5, while the time for part 2 (time needed to prepare the duct) and part 3 (time needed for the overall procedure) decreased significantly. The performance rating by both the primary surgeon and the supervisor improved significantly over time ( $P < .001$  for each). For part 2, the results of group 1 were found to significantly differ from all other groups (group 1 vs group 2,  $P < .009$ ; all other groups,  $P < .001$ ). Group 5 also differed significantly from groups 2 ( $P = .002$ ) and 3 ( $P < .001$ ). Other comparisons were not statistically significant (group 2 vs group 3,  $P > .99$ ; group 2 vs group 4,  $P = .29$ ; group 3



**Figure.** Duration of each sialendoscopy part in minutes in reference to chronologically arranged groups (5 groups, each comprising 10 patients). Part 1 (time until ostium is found), part 2 (time until duct is visible on screen), and part 3 (duration of overall sialendoscopy procedure).

vs group 4,  $P = .43$ ; and group 4 vs group 5,  $P = .81$ ). For part 3, the results of group 1 were found to significantly differ from groups 2 ( $P = .02$ ), 4 ( $P = .002$ ), and 5 ( $P < .001$ ). No differences were found between groups 1 and 3 ( $P = .06$ ) or among groups 2 through 5 (group 3 vs group 5,  $P = .78$ ; all other comparisons,  $P > .99$ ).

The performance rating showed a good interrater agreement within all groups of patients. A continuous improvement of the performance rating for both the primary surgeon and the supervisor was measurable over all 50 cases. A significant improvement in the performance rating occurred after the first 30 patients (Bonferroni post hoc test,  $P < .05$ ). Toward the end of the case series, the performance ratings reached a level of excellence, with an average rating of 4.7 for the last group of patients. The **Table** displays all results in total numbers.

### COMMENT

Because sialendoscopy requires specific expertise, the surgeon's level of training and experience are key factors in achieving a successful outcome. To our knowledge, no study to date has defined a learning curve for diagnostic or interventional sialendoscopy. Learning curves for other endoscopic procedures are reported to involve up to 40 (interventional gastroscopy),<sup>8</sup> 150 (diagnostic colonoscopy),<sup>9</sup> or 200 (endoscopic sinus surgery)<sup>10</sup> cases. For sialendoscopy, we assumed a shorter learning curve for 2 reasons: (1) otolaryngologists are commonly experienced with endoscopic procedures in general; and (2) the experienced supervisor supported the process by direct feedback and practical help. In our study, among the first 10 surgical procedures, the experienced supervisor took control in 6 cases. These interventions were related to the detection of the Wharton duct, to the maneuvering of the endoscope inside the duct system, or to the technical handling of sialolith removal. The low rate of complications in our study corroborates the belief that sialendoscopy is a low-risk procedure and supports the opinion that this operation can be safely taught to trainees by an advanced surgeon. It should be noted that different supervisors may bias our study results.

Interestingly, the time needed for detection of the duct ostium was rather short even in the initial cases. We as-

**Table. Group and Performance Data in Chronological Order<sup>a</sup>**

Variable	Total	Group 1	Group 2	Group 3	Group 4	Group 5	P Value
Age, y	49.0	52.0	42.9	52.2	53.9	44.2	.20
Parotid/submandibular	31/19	8/2	8/2	4/6	8/2	3/7	NA
Diagnostic/interventional	30/20	7/3	8/2	6/4	5/5	4/6	NA
Part 1, min:s	01:48	01:48	01:30	02:18	01:30	01:42	>.94
Part 2, min:s	06:24	11:00	07:12	06:06	04:48	02:54	<.001
Part 3, min:s	39:24	66:30	37:00	40:30	29:12	24:00	<.001
Part 3, diagnostic/interventional, min	35/46	55/93	34/45	35/49	19/39	19/30	NA
Minor duct injuries	7/50	3	0	2	2	0	NA
Stone extraction rate (of stones classified as extractable), No. (%)	10/14	0/1 (0)	1/3 (33)	3/4 (75)	2/2 (100)	4/4 (100)	NA
Control assumption by supervisor	9/50	6/10	1/10	1/10	1/10	0	NA
Performance rating (trainee)	3.6	2.5	3.6	3.2	3.8	4.7	<.001
Performance rating (supervisor)	3.7	2.7	3.7	3.5	3.9	4.7	<.001

Abbreviation: NA, not applicable.

<sup>a</sup>Each group comprises 10 patients.

cribe this to the consequent use of an advanced technique to locate the duct ostium with medical dye.<sup>11</sup> Our study results show that the time needed for sialendoscopy decreases with the surgeon's individual experience. The remarkable decrease in time for both diagnostic and interventional sialendoscopy after the first 10 patients and again after the first 30 patients can be interpreted as noticeable steps in experience gained. After the first 30 procedures, both the trainee and the supervisor rated the performance significantly better compared with the first group of patients.

Supposedly, the learning curve correlates to the set of instruments being used. Certain difficulties, such as decreased shaft flexibility and a necessary change of instruments when transferring a diagnostic into an interventional procedure, are related to the use of sialendoscopes of modular design. Furthermore, endoscope maneuvering is more difficult with double-channel device endoscopes because of the scope's elliptical outer diameter. Also, the pointed tip of the device increases the risk for duct injuries when modular sialendoscopes are being used.

The latest generation of sialendoscopes ("all-in-one" endoscopes) include certain changes that might improve the ease of endoscope handling, decrease operating time and risks for minor and major trauma, and improve overall performance and success rates. Therefore, this article can state the learning curve only for sialendoscopes of a modular design. It could be argued that operating time is not a suitable indicator for a learning curve because sialendoscopy cases can significantly differ in the severity level of the pathology; consequently, the mixture of diagnostic and interventional procedures in our study could be criticized. However, in many cases, whether a sialendoscopic procedure will have pure diagnostic or interventional character cannot be foreseen. Moreover, both procedure types cross-stimulate each other concerning their experience gain; therefore, they contribute to the same learning curve. To our surprise, diagnostic and interventional sialendoscopy differed in time only marginally in our study ( $P=.08$ ).

In summary, we have shown a significant decline in operating time and an improvement in performance rating with time and increasing experience. In this study, the first 30 patients represent a noticeable step on the learning curve. However, the continuing decrease in time taken and rating improvement thereafter point to a continuing learning effect all the way to procedure 50. In the last cases of this study, the performance ratings reached a level of excellence (4.7 on a 5-point-scale). Likewise, the average operation time dropped to a rather low level compared with data in the literature.<sup>12</sup>

Our data support the use of operating time and performance rating as suitable markers for the learning curve. The outcomes suggest that the performance of sialendoscopy improves with time and amount of experience. In this study, the first 30 procedures represent the early stage of the sialendoscopy learning curve, with remark-

able performance improvement afterward. The actual end point of the individual learning curve is approximately close to the mark of 50 cases. Toward the end of the case series, the primary surgeon reached operation times comparable to those in the literature as well as very good performance results.

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**Additional Contributions:** Dr Luers had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. *Study concept and design:* Luers, Damm, Klussman, and Beutner. *Acquisition of data:* Luers, Damm, Klussman, and Beutner. *Analysis and interpretation of data:* Luers, Damm, Klussman, and Beutner. *Drafting of the manuscript:* Luers, Damm, Klussman, and Beutner. *Critical revision of the manuscript for important intellectual content:* Luers, Damm, Klussman, and Beutner. *Statistical analysis:* Luers and Damm. *Study supervision:* Klussman and Beutner.

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