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Intradductal Fragmentation in Sialolithiasis Using Pneumatic Lithotripsy: Initial Experience and Results

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Abstract

Objective. To report initial experience in using a pneumatic lithotripter to treat salivary stones.

Study Design. Level IV retrospective study.

Setting. University hospital and tertiary referral center.

Methods. A pneumatic lithotripter was used to treat salivary stones after these were diagnosed. Probes with diameters of 0.7 mm were used. Total fragmentation was intended in all stones. Stone fragments were removed using several instruments in serial sialendoscopies to achieve complete stone clearance.

Results. A total of 62 patients with 77 stones were treated. Forty-three submandibular stones were treated in 34 patients, and 34 parotid stones were treated in 28 patients. An operating pressure of 2.5 bar and a single frequency mode were used. Complete fragmentation was achieved in all but one of the treated stones in both glands (98.7%). Among the patients, 90.32% became stone free and 100% symptom free. Multiple stones were treated in 24.19% of the patients, and multimodal therapy was also carried out in 24.19%. All of the glands were preserved.

Conclusions. The pneumatic lithotripter proved to be effective in the treatment of sialolithiasis. Stone size, location, and the gland involved were important clinical factors. The device was sufficient to achieve success without any increased risk for complications in the patients or damage to the sialendoscopes.

Keywords

sialolithiasis, treatment, salivary gland, sialendoscopy, pneumatic lithotripsy, intraductal lithotripsy

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Treatment for sialolithiasis, which is the cause in 60% to 85% of all patients presenting with obstructive sialadenitis,[1-4] has undergone fundamental changes in recent decades.[5-9] Sialendoscopy-controlled extraction is now regarded as the treatment of first choice. As more than 80% of the stones are impacted, immobile, and/or too large, they have to be fragmented using various methods such as extracorporeal shock-wave lithotripsy (ESWL), interventional sialendoscopy with mechanical fragmentation, and intraductal shock-wave lithotripsy (ISWL).[5,7-21]

Results improved again markedly after the development of suitable sialendoscopes, instruments, and devices. ISWL performed using laser lithotripsy (LL)[22-35] led to success rates of 90% or more. With regard to intraductal pneumatic lithotripsy (IPL), fewer reports have been published, but success rates of >90% have been described.[33,36] One of these studies used a mobile handheld pneumatic lithotripter,[36] and the other used an immobile device.[33] Our own research group obtained good results with the handheld pneumatic lithotripter.[36] However, the device is not currently being supplied to new adopters interested in it. To test another device providing a "cold technique," we decided to carry out a study to describe our initial experience in using an alternative device to treat salivary stones. The aim was to describe the procedure and success rates, complications, and short-term follow-up.

Patients and Methods

This retrospective study was carried out in the Department of Otorhinolaryngology, Head and Neck Surgery at the Friedrich-Alexander University of Erlangen–Nuremberg, Germany. The study was conducted in accordance with the Declaration of Helsinki; approval was obtained from the local institutional review board of the Friedrich-Alexander University of Erlangen–Nuremberg, and all of the study participants provided informed consent.

From February 2019 to October 2020, patients presenting with sialolithiasis, which was diagnosed in all cases using high-resolution ultrasound (Siemens ACUSON S2000 and S3000; Siemens Medical Solutions USA), were included. Treatment was performed using the Vibrolith (ELMED Medical Systems; **Figure 1A,B**). The device is approved for renal and urinary tract stones and was used with a special

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certification for salivary stones. The device currently has a certification of the European Commission (EC) according to the Medical Device Regulation for the treatment of salivary stones. The introduction to the market under a different brand name currently is in process. The indication for performing IPL was established in accordance with the department's well-tried treatment algorithms[7] and based on experience after performing intraductal lithotripsy using other devices.[34-36] A flowchart illustrating the decision tree in such cases is shown in **Figure 2**.

All of the IPL procedures were carried out with the patient under local anesthesia (5-15 mL articaine 2%/Ultracain; Sanofi-Aventis) and after application of 15 to 30 drops of tilidine (Valoron; Aliud Pharma GmbH).

Sialendoscopes with a diameter of 1.6 mm and a working channel of 0.8 mm (Erlangen Set; Karl Storz)[19,34-36] were used.

The pneumatic lithotripter (PL) used is a handheld device connected to a gas source, which may be mobile or fixed. The supply pressure was 5 bar and was provided by a mobile custom-made bottle filled with CO_2 gas. The preset operating pressure was 2.5 bar. The release of the pneumatic energy was triggered using a foot pedal. The handheld device is connected to a probe made of stainless steel. In all cases, a probe measuring 0.7 mm in diameter was used, which fitted through the working channel of the 1.6-mm sialendoscope (**Figure 1B**). The tip of the probe was positioned in direct contact with the surface of the stone, and fragmentation was performed under direct visual control. A single-pulse mode was used in all of the procedures. The number of pulses applied was counted continuously. Irrigation was performed during stone fragmentation and extraction of the fragments. The fragments were removed with the basket, grasping forceps, and/or microdrill. In case of very small fragments, spontaneous washout was awaited. Stent implantation was regarded as necessary if pronounced denudation of the duct epithelium was noted and/or to treat an accompanying stenosis.[34-38]

Aftercare and follow-up examinations were performed as described in our previous publications.[7,34-36] A follow-up investigation was planned 4 to 12 weeks later. It was checked if the salivary secretion after gland massage was abundant and clear or not. High-resolution ultrasound of the unstimulated/stimulated gland and control sialendoscopy were performed. If a patient was unwilling or unable to attend the follow-up examination, the local ear, nose, and throat (ENT) practitioner was consulted and a phone interview was carried out.

The patients' data were recorded and reviewed, including epidemiologic data, status of the disease, treatment settings, and clinical outcomes. Analyses of parameters were calculated on the basis of individual stones or per patient. Outcomes such as complete fragmentation rate, stone-free rate, symptom-free rate, and gland preservation rate were calculated on the basis of patient numbers as well as symptom-free status and complication-free status.

Statistical Analysis

The software program SPSS Statistics, version 24 (SPSS, Inc) was used. All data are given as means plus or minus standard error of the mean (SEM), range, and median. Bivariate correlations were calculated using the Pearson correlation coefficient. Differences between groups were calculated using the Mann-Whitney *U* test. The significance level was $P \leq .05$.

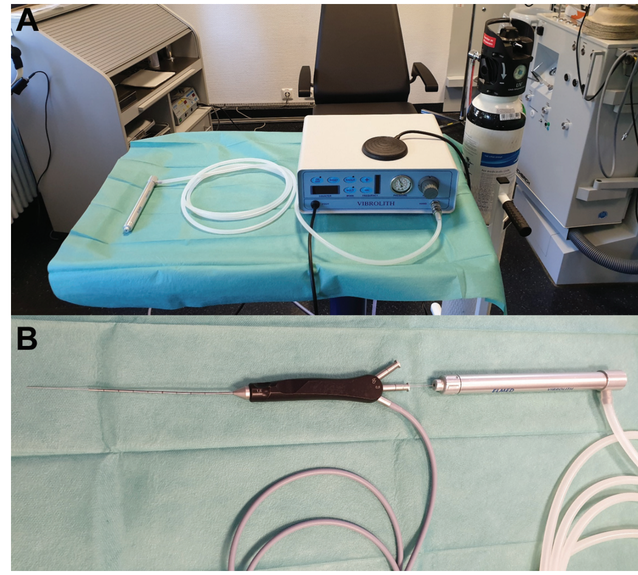

Figure 1. Treatment setting. (A) The handheld lithotripter, foot pedal, and gas bottle containing CO_2 gas. (B) A 0.7-mm probe inserted into the working channel of a 1.6-mm sialendoscope.

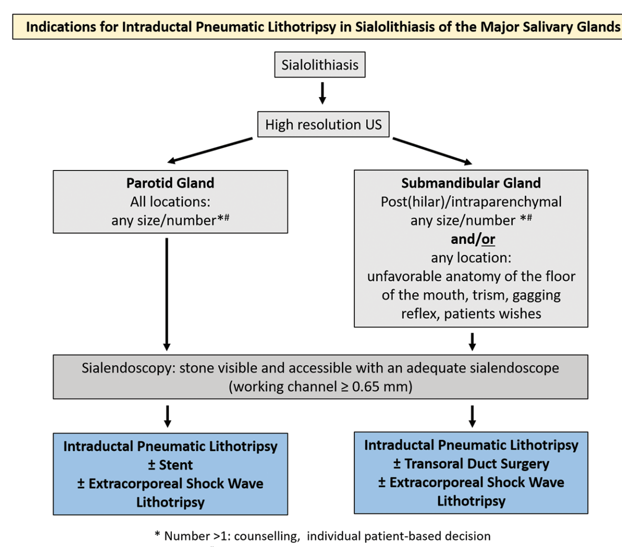

Figure 2. Flow diagram showing the indications for intraductal pneumatic lithotripsy in a treatment algorithm.

Results

Seventy-seven stones in 62 patients were treated using the PL. Thirty-six of the patients were men and 26 were women, with a mean age of 51.4 years (median, 53.5 years; range, 27-80 years). Forty-three stones were located in the submandibular gland (SMG; **Figures 3-4**; see Supplemental Video 1 in the online version of the article) and 34 in the parotid gland (PG;

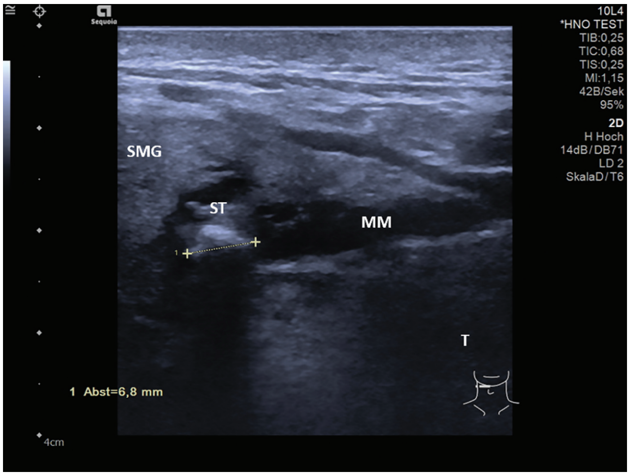

Figure 3. Case (SMG). Ultrasound view, showing a posthilar stone, measuring 6.8 mm. MM, mylohyoid muscle; SMG, submandibular gland; ST, stone; T, tongue; WD, Wharton's duct.

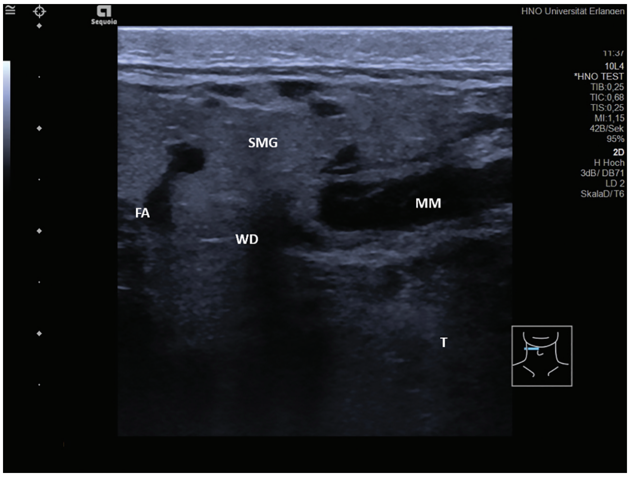

Figure 4. Case (SMG). Ultrasound view 8 weeks later without evidence for any residual fragments. FA, facial artery; MM, mylohyoid muscle; SMG, submandibular gland; T, tongue; WD, Wharton's duct.

see Supplemental Figures 1-6 in the online version of the article).

The stones were a mean of 6.14 mm in size (**Table 1**). The location of the stones treated using IPL differed significantly between the glands (P = .0001)–paralleling and reflecting differences in indications relative to our treatment algorithms. The size of the stones did not differ between the glands (**Table 1**).

One IPL procedure was performed in 88.3% of the patients, 2 in 10.4%, and 3 in 1.3%. The mean duration of the 77 procedures performed was 50.29 (range, 12-105) minutes, and the mean total duration of treatment per stone (all IPLs/stone) was 50.96 (range, 12-176) minutes. The procedures were tolerated at least well by the patients and could be finalized in all cases as planned.

All IPLs were performed using the 0.7-mm probe and 1.6-mm sialendoscope, with an effective gas pressure level of 2.5 bar. Comparison of the groups showed no significant differences between them in relation to the number of stones, duration of the IPL procedures per stone, or number of pulses needed to fragment the stones (**Table 1**). However, significant associations were observed only in the SMGs between stone size and the number of pulses (P = .0001), number of IPLs (P = .026), and duration of IPLs (P = .003). No other correlations were observed for any other parameters for any glands.

All but 1 of the stones (98.7%) that were assessed were completely fragmented in both glands (see below). No significant differences were noted between the glands in relation to fragmentation rates or fragment extraction rates (**Table 1**).

Multiple stones were present and treated in 15 of 62 patients (24.19%). IPL formed part of multimodal treatment in all patients with multiple stones. In 10 of these patients, a total of 24 stones were treated using IPL alone (2 each in 6 patients and 3 each in 4 patients) (**Table 2**).

Multimodal therapy was performed in 20.96% of the cases (13/62), for single stones in 6 cases and for multiple stones in 7 cases, including stones not treated with IPL. Single stones had to be treated using multimodal therapy, including IPL, in 6 cases.

In 22 of 62 patients (35.48%), SMGs were treated after or in combination with transoral duct surgery (TDS). Simultaneous or combined TDS was performed in 6 cases, in 2 of these cases due to a narrow duct, in order to remove a larger impacted fragment trapped inside a basket. Stones were treated after TDS had been performed in 16 cases (all SMG; **Table 2**).

Five cases were treated in combination with or after ESWL (3 in the SMG and 2 in the PG). Interventional sialendoscopy was performed in addition to IPL in 6 cases, all due to multiple stones and in most of these cases as part of multimodal treatment. In 1 of the cases, an additional stone with an extraductal location near the papilla was removed with forceps (PG; **Table 2**).

In 1 case, an incipient smooth and impacted stone (3 mm in size) in the accessory gland was treated after navigation to the location via simultaneous ultrasound. In 1 case, treatment with the PL proved ineffective (proximal duct, PG; see below).

Complete fragmentation was achieved in 76 of 77 stones (98.7%). In 1 case, the device proved ineffective. The stone had a remarkably hard and hyaline composition, and the tissue was of a very elastic consistency, which both reduced the effectiveness of IPL (see above). A switch was made to LL, which led to successful fragmentation of the stone. Fragments of 74 of 77 stones (96.1%) were extracted completely (in 1 case after additional LL). In 3 cases, 1 or 2 small residual fragments (1-4 mm) were washed too far proximally into the intraparenchymal duct system, and the complete extraction rate for fragmented stones after application of the PL was therefore 95.16%. All of the patients ultimately became symptom free, and 90.32% (56/62) were stone free. No differences between the different groups of glands were observed in relation to any of these parameters (**Table 1**).

Table 1. Initial Experience With the Pneumatic Lithotripter.[a]

Characteristic	All glands (patients, n = 62; stones, n = 77)	Submandibular glands (patients, n = 34; stones, n = 43)	Parotid glands (patients, n = 28; stones, n = 34)	Mann-Whitney *U* test, PG vs SMG
Sex, male/female, No.	36/26	22/12	14/14	
Stone size, mm	6.14 ± 0.35 (6.0; 2.5-16.7)	5.87 ± 0.37 (6.0; 2.5-16.7)	6.50 ± 0.44 (6.0; 3.0-16.7)	NS
Location of stones				*P* = .0001
Distal	6 (7.8)	—	6 (17.6)	
Middle	10 (13.0)	—	10 (29.4)	
Proximal-hilar	17 (22.07)	—	17 (50.0)	
Hilar-posthilar	33 (42.86)	32 (74.41)	1 (2.94)	
Posthilar to intraparenchymal	11 (14.28)	11 (25.58)	—	
Number of IPL/stone	0.98 ± 0.06 (1.0; 0.25-3)	1.11 ± 0.09 (1.0; 0.3-3)	1.08 ± 0.08 (1.0; 0.25-2)	NS
Duration of IPL/stone, min	50.96 ± 3.42 (46; 12-172)	49.28 ± 4.55 (41; 17-150)	53.09 ± 5.25 (49.50; 12-172)	NS
Number of pulse/stone	366.54 ± 39.86 (250; 23-1790)	363.63 ± 59.85 (235; 23-1790)	370.23 ± 50.19 (270; 38-1067)	NS
Stones with complete fragmentation	76/77 (98.7)[b]	43/43 (100)	33/34 (97.05)[b]	NS
Stones with complete fragment extraction	74/77 (96.1)[c]	39/42 (92.85)[c]	35/35 (100)[c]	NS
Stone-free patients	56/62 (90.32)[b,d]	30/34 (88.24)[b,d]	26/28 (92.85)[b,d]	NS
Complaint-free patients	62/62 (100)	15/15 (100)	28/28 (100)	NS

Abbreviations: IPL, intraductal pneumatic lithotripsy; NS, not significant; PG, parotid gland; SMG, submandibular gland.

[a]Size and location of stones, number of intraductal pneumatic IPLs per stone, duration of IPLs per stone, number of pulses per stone, number of stones with complete fragmentation, rates of complete stone extraction after fragmentation, stone-free rate, and symptom-free rate in 62 patients with 77 stones were classified relative to the major glands. Values are presented as parameter mean ± SEM (median; range) or number (%) unless otherwise indicated.

[b]Three patients with recurrent stones prior treatment with another IPL (SB = StoneBreaker® (COOK Medical, IL, USA)).

[c]Two patients with fragments impacted within a basket demanding simultaneous transoral duct surgery (all SMG).

[d]Three patients with intraparenchymal stones (not accessible, 1 SMG, 2 PG).

Table 2. Initial Experience With the Pneumatic Lithotripter.[a]

Characteristic	All glands (patients, n = 62; stones, n = 77), No. (%)	Submandibular glands (patients, n = 34; stones, n = 43), No. (%)	Parotid glands (patients, n = 28; stones, n = 34), No. (%)	Mann-Whitney *U* test or χ^2 test, PG vs SMG
Stent implantation (n cases)	23 (37.09)	0	23 (100)	*P* = .0001
Gland function insufficient (n cases)	7 (100)	3 (42.86)	4 (57.14)	NS
Complication (n cases)	3 (100)	3 (100)	—	—
After prior TDS (n cases)	18 (25.8)	18 (52.94)	0 (0)	*P* = .0001
Residual (n stones)	3 (4.83)	3 (4.83)	—	—
Persistent (n stones)	2 (3.22)	2 (3.22)	—	—
Recurrent (n stones)	13 (20.96)[b]	13 (20.96)[b]	—	—
Combined with ESWL				
Preinterventional (n stones)	1 (1.62)	1 (2.32)	—	—
Simultaneous (n stones)	1 (1.62)	1 (2.32)	—	—
Postinterventional (n stones)	3 (4.83)	1 (2.32)	2 (7.14)	—
Treatment of multiple stones (n cases)	15 (24.19)	9 (26.47)	6 (21.43)	*P* = .050
Monomodal (IPL only)	10 (16.13)	5 (14.71)	5 (17.86)	NS
Multimodal (with or without IPL)	5 (8.06)	4 (11.76)	1 (3.57)	NS
IPL as part of multimodal treatment (single or multiple stones, n cases)	15 (24.19)	(26.67)	(2.94)	*P* = .026
Interv SE + IPL	1 (1.16)	—	1 (3.57)	—
IPL and LL	1 (1.16)	—	1 (3.57)	—
Interv SE + TDS + IPL	3 (4.83)	3 (8.82)	—	—
Interv SE + ESWL + IPL	2 (3.22)	—	2 (7.14)	—
ESWL + IPL	1 (1.16)	1 (2.94)	—	—
TDS + IPL	5 (8.06)[c]	5 (14.71)[c]	—	—
TDS + IPL + ESWL	2 (3.22)	—	2 (7.14)	—

Abbreviations: ESWL, extracorporeal shock wave lithotripsy; Interv SE, interventional sialendoscopy; IPL, intraductal pneumatic lithotripsy; LL, laser lithotripsy; NS, not significant; PG, parotid gland, SMG, submandibular gland; TDS, transoral duct surgery.

[a]Rates of stent implantation, insufficient gland function, complications, treatment of multiple stones, and patients/stones treated with combined and/or multimodal treatment in 62 patients with 77 stones classified relative to the major glands.

[b]Three patients with recurrent stones prior treatment with another IPL (StoneBreaker).

[c]Two patients with fragments impacted within a basket demanding simultaneous TDS (all SMG).

Among the patients who did not become stone free, 3 (4.84%) had residual fragments after IPL (see above). In the 3 other patients (4.84%), additional stones were diagnosed in intraparenchymal locations that were not accessible with the sialendoscope. ESWL was the treatment of choice that was offered to all of the patients who were not stone free. In view of the lack of symptoms, further treatment was performed in 1 patient and was delayed in the remaining 5.

Twenty-three patients (37.09%) underwent stent implantation either during the primary procedure or during the further course, all in the PG (*P* = .0001; **Table 2**). In 19 cases (30.62%), stents were implanted during the primary procedure due to maceration, residual fragments, papillary swelling, or signs of insufficient gland function, and in 4 (6.45%), they were placed because of primary concomitant ductal stenosis. The stents were left in situ for a mean of 6.7 weeks (range, 4-9; median, 6.5).

Signs of insufficient gland function or even of a tendency toward gland atrophy, which were suspected in 7 patients by clinical and ultrasound examination, were associated with signs of duct obliteration in sialendoscopy. Prolonged stent implantation (>4-6 months) was indicated in the hope of glandular function recovering (4 cases; **Table 2**).

A denudation of the duct epithelium of various intensity was observable in the majority of cases, and if it showed a tendency to be circular, stent implantation was performed. Relevant complications relating to the duct or tissue next to it were noted in 3 cases (4.84%, all SMG). Duct perforation (hilar perforation with development of a temporary sialocele, conservative treatment), papillary stenosis (after papillotomy, successfully treated with stent implantation), and duct stenosis with no need for further treatment (probably due to insufficient gland function) were noted in 1 case each. No damage to the sialendoscopes used was noted. In 7 cases (11.29%; 3 SMG, 4 PG), the probes broke at the proximal end during the procedure—after repeated use in all of these cases.

Checkup endoscopies were carried out on the first and second days after primary IPL in order to remove residual fragments and/or fibrin plaques. Checkup endoscopies were performed after 8 to 12 weeks in all but 2 patients. The latter were not willing or able to attend for follow-up investigation but did not have any relevant symptoms. Phone interviews were carried out and a local ENT specialist contacted to confirm symptom- and stone-free status.

During the further course, 3 patients with stenosis, mostly with concomitant signs of insufficient gland function (as indicated by clinical and ultrasound examination), received prolonged stent implantation treatment at the checkup sialendoscopies.

Discussion

These results show that complete fragmentation rates of 98.7% and symptom-free rates of 100% were achieved. The stone-free rate, at 90.32%, was below the fragmentation rate, due to the presence of additional intraparenchymal stones or residual fragments (**Table 1**).

Out of the ISWL techniques, LL has been performed with success rates of more than 80% to 90%.[22-35] When electrohydraulic[39-41] and electrokinetic ISWL[14] were used, the results did not attract much attention. However, success rates of more than 80% or 90% have been reported with IPL in 2 recent studies, in 1 after use of the same device.[33,36] The present study shows that this device allows effective treatment of sialolithiasis (**Table 1**), confirming the results previously reported by another group.[33]

The size of the stones (both mean value and range) that were treated was similar to the data published earlier.[35,36] No differences in the size of the stones treated were noted relative to the different glands. Nor were any significant differences noted after comparison of the different glands in relation to the number of stones, duration of IPL procedures, or number of pulses needed to fragment the stones (**Table 1**), a finding that is comparable with the reported results using other lithotripters in our department.[35,36] In addition, the number of strikes required to achieve complete fragmentation did not differ between submandibular and parotid stones (**Table 1**). A possible reason for this may be that more patients (with 25.8% of all and 52.9% of submandibular stones) were treated following earlier extended TDS in the SMG, which improves access to recurrent stones and reduces the effort required.[34] However, the stone size was significantly associated with the number of pulses required (P = .0001), the number of IPL procedures (P = .026), and the duration of the IPL procedures (P = .003) only in the SMGs. The data presented here thus appear to indicate that ISWL is a more elaborate procedure in the SMG compared to the PG, as has also been reported and discussed previously.[34-36] The significant differences in the location of the treated stones between the glands (P = .0001) reflect the treatment indications that corresponded to well-established treatment algorithms.[7]

With regard to the gas pressure levels needed to achieve successful fragmentation, definitive values have not yet been reported in the literature. Serbetci et al[33] used a working pressure level of 3.5 bar. The results in the present study show that a preset working pressure of 2.5 bar was sufficient to achieve complete fragmentation in nearly all stones in both types of gland. In contrast to Serbetci et al,[33] we always continued with the IPL until complete fragmentation was achieved. However, the number of pulses needed was considerably higher in this study in comparison with other reports. Differences in the preset parameters (eg, a gas working pressure of 3.5 vs 2.5 bar) may be 1 possible reason for this. The quality of the probes used (stainless steel probes in this study), differences in the composition of the stones, the quality of the gland tissues, and the anatomy of the duct system may also be possible causes. It was evident in 1 patient in the present study that IPL was insufficient to achieve adequate fragmentation, due to extremely elastic gland tissue and a hyaline, hard consistency in the stone. It should also be mentioned that fewer numbers of pulses per stone were needed to achieve complete fragmentation when probes made of nitinol were used.[36]

As described in other publications,[32-36] damage of the duct epithelium of various intensities can be observed after ISWL in nearly all cases. It is caused by impaction of the stone and/or by the procedure itself. It is less often due to primary accompanying stenosis (less than 10% in the literature and 6.45% in the present study).[32-36] The duct system was stented in 55.1% of all patients—the parotid duct system in 23 cases, with no stenting in the submandibular ducts (P = .0001). Differences in the specificities of the duct anatomy, like the narrowness of the duct or duct bending in the SMG and a higher frequency of accompanying stenosis and insufficient gland function in the PG, were the main factors why stent implantation was performed only in the PG.

A substantial proportion of the patients were diagnosed as having difficult sialolithiasis, involving difficult locations of stones (all of the SMG and 52.9% of the PG stones) and the presence of multiple stones (24.19% of cases; **Table 2**). IPL contributed to successful therapy as a single modality in two-thirds of these cases, and in the remainder, it was a very important part of multimodal treatment. Multimodal treatment was performed in 24.19% of cases due to multiple sialoliths, also including additional stones that were not treated using IPL. Multiple stones were treated significantly more often in the SMG (P = .050). Cases of multiple sialolithiasis included 50% of the patients who were not stone free at the last evaluation and who had additional stones in intraparenchymal locations. Multimodal therapy was needed significantly more often in the SMG (P = .026), underlining the greater treatment effort required in that gland. However, the size of the stones did not have any influence on the indication for performing multimodal therapy in any gland.

Complications were rarely observed (4.84%), and no differences in the frequency of complications were noted between the SMG and PG, nor were there any correlations with major parameters such as stone size. In addition, no damage to the sialendoscopes used was observed. However, the probes broke at the proximal end during the procedure in 11.29% of cases (in all cases after repeated use). As larger sialendoscopes with wider working channels are needed, the natural ostium is often too narrow for these to be inserted into Wharton's duct, which then requires a papillotomy. A duct system that is too narrow, particularly in the parotid gland, is the most important limitation on performing IPL.

Conclusions

The results after using this PL confirmed the published literature results. As IPL is indicated mainly in difficult sialolithiasis, its effective use depends on the size, location, and accessibility of the stone and on the anatomic conditions in the duct (**Figure 2**). Effective fragmentation could be achieved while avoiding damage to the instruments and sialendoscopes used, as well as substantial tissue complications. The most appropriate preset parameters for achieving effective stone fragmentation will have to be determined in further studies.

Author Contributions

Michael Koch, surgery, substantial contributions to conception and design, acquisition of data, analysis and interpretation of data, acknowledgment of drafting the article and revising it critically for important intellectual content, final approval of the version to be published, agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved; **Mirco Schapher**, surgery, analysis and interpretation of data, revising the manuscript critically for intellectual content, final approval of the version to be published, agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved; **Matti Sievert**, contributions to conception and design, analysis and interpretation of data, revising the manuscript critically for intellectual content, final approval of the version to be published, agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved; **Konstantinos Mantsopoulos**, substantial contributions to conception and design, analysis and interpretation of data, acknowledgment of drafting the article or revising it critically for important intellectual content, final approval of the version to be published, agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved; **Heinrich Iro**, substantial contributions to conception and design, acquisition of data, analysis and interpretation of data, revising the manuscript critically for intellectual content, final approval of the version to be published, agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Supplemental Material

Additional supporting information is available in the online version of the article.

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