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Recovery of gland function after endoscopy-assisted removal of impacted hilo-parenchymal stones in the Wharton's duct

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Abstract. The aim of this study was to evaluate the gland function of patients following endoscopy-assisted removal of impacted hilo-parenchymal stones in the Wharton's duct. The study cohort comprised 115 patients who had undergone successful endoscopy-assisted lithotomy for hilo-parenchymal stones (mean diameter 7.7 mm). Gland function was evaluated at a mean 12 months after surgery using ultrasonography, sialography, and/or sialometry. Postoperative ultrasonography of 51 affected glands revealed a regular gland size in 58.8%, normal parenchyma density in 51.0%, and ductal ectasia in 80.4%. Postoperative sialograms of 109 affected glands were scored as type I (approximately normal) in 13 cases, type II (saccular ectasia of the hilo-parenchymal duct with/without stenosis, and no contrast retention) in 64, type III (saccular ectasia of the hilo-parenchymal duct with/without stenosis, and mild contrast retention) in 23, and type IV (poor shape of the main duct with evident contrast retention) in nine cases. The existence of ductal ectasia corresponded well to larger stone cases ($P = 0.002$). In the postoperative sialometry of 35 patients with unilateral stones, differences between the two sides were insignificant ($P > 0.05$). For patients with hilo-parenchymal submandibular gland stones, endoscopy-assisted surgery and extended postoperative follow-up help preserve the gland with good function.

Keywords: Submandibular gland; Calculi; Ultrasonography; Sialography; Salivation.

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Sialolithiasis is the leading cause of unilateral obstructive salivary gland disease, with a reported prevalence of 1/10,000 to 1/30,000 in the general population.[1] Approximately 80–90% of sialoliths are located in the submandibular gland (SMG).[2–5] Following the development of sialendoscopy-assisted minimally invasive techniques for the treatment of SMG stones over the past decade, the gland preservation rate has increased substantially, accompanied by satisfactory clinical outcomes.[6–9]

Several studies reported to date have focused on the subjective assessment of postoperative gland function recovery, using the chronic obstructive

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sialadenitis symptom (COSS) questionnaire and quality of life questionnaires, which are based mainly on the subjective evaluation of symptoms and signs.[10–14] Postoperative gland function varies greatly depending on the preoperative impairment and intraoperative injury to the ductal system and parenchyma. An objective and accurate evaluation of gland function might help optimize intra- and postoperative management. Objective evaluations include ultrasonography, sialography, scintigraphy, and sialometry. High-resolution ultrasonography devices provide detailed information about the ductal system and glandular parenchyma.[15,16] Sialography directly provides a map of the ductal system, and the evacuation of the contrast medium provides an indication of gland function.[17,18] Sialometry and scintigraphy are quantitative evaluation methods.[19–22] However, few studies have investigated SMG function after the removal of impacted hilo-parenchymal stones using combinations of these methods.

The aim of this study was to objectively evaluate the SMG function of patients postoperative, following endoscopy-assisted removal of impacted hilo-parenchymal stones in the Wharton's duct, using ultrasonography, sialography, and sialometry, based on a relatively large sample size.

Materials and methods

Patients

From January 2008 to December 2021, 785 patients (792 glands) with impacted hilo-parenchymal stones in the Wharton's duct underwent endoscopy-assisted lithotomy at Peking University School and Hospital of Stomatology, with a 92.7% success rate. The stones were classified as hilar (at the hilum), post-hilar (intraglandular stone, 0–5 mm proximal to the hilum), or intraparenchymal (intraglandular stone, ≥5 mm proximal to the hilum).[23] The surgical approaches included transoral duct slitting, basket retrieval, transcervical lithotomy, and laser lithotripsy. After successful removal of the stone, daily gland self-massage and the use of a sialagogue were recommended. Intraductal saline irrigation was performed once a month for at least 3 months. Patients who returned to the clinic were invited to undergo postoperative evaluation of glandular function by ultrasonography, sialography, or sialometry, or combinations of these. Inclusion criteria for the study sample were (1) patients who had undergone successful stone removal by transoral approach, (2) the affected SMG was preserved with a good or acceptable clinical outcome, (3) at least 3 months after surgery. Patients with severe operation-related side effects, such as permanent lingual nerve injury, ranula, duct atresia, or stone recurrence (approximately 5% of all patients) were excluded. The study design was approved by the Institutional Review Board of the Peking University School of Stomatology (PKUSSIRB-202059175). Informed consent was obtained from all participants.

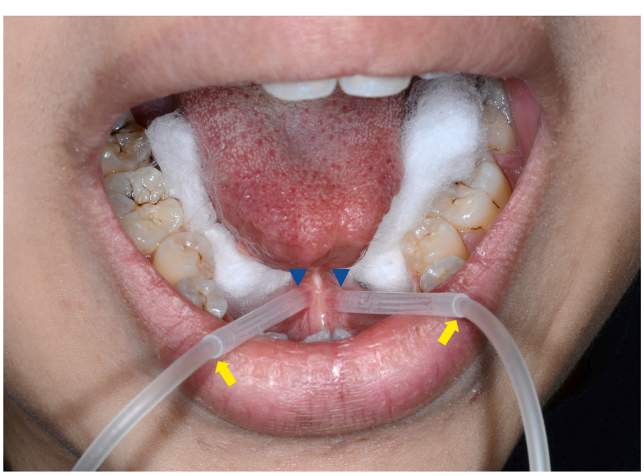

Fig. 1. During sialometry, a 7-gauge scalp needle tube coated with its plastic outer sheath (yellow arrows) was suctioned onto the ostium (blue arrowhead) and then connected to a saliva storage device.

Sialendoscopy was performed under local anaesthesia using an endoscope (PD-ZS-0084; PolyDiagnost, Hallbergmoos, Germany). Postoperative ultrasonography examinations were performed and interpreted by an experienced physician. Sialography and sialometry were performed by two researchers who were well calibrated.

Ultrasonography

The ultrasound examinations were performed using a Mindray Resona 7 S ultrasound system (Mindray, Shenzhen, China) with a linear transducer of L11–3 U. The bilateral submandibular glands were comparatively scanned to evaluate the size, density, and ductal features of the affected glands. The gland size was scored as normal, enlarged, or reduced after comparison between the two sides. When looking at the parenchymal structure, the gland density was graded as normal, hyperdense, or hypodense. Moreover, the existence of ductal ectasia in the hilo-parenchymal region was also evaluated.

Sialography

After dilatation of the orifice, 1.0–1.5 ml of contrast was carefully infused. Subsequently, a lateral view and a 5-minute emptying film were taken. The ductal morphology on filling films and contrast medium retention on functional films were analysed. Each film was analysed independently by two experienced oral radiologists who reached a consensus by discussion. The sialograms were categorized into four types, as follows: type I, approximately normal; type II, saccular ectasia of the hilo-parenchymal duct with or without stenosis, and no persistent contrast on functional films; type III, saccular ectasia of the hilo-parenchymal duct with or without stenosis, and mild contrast retention; type IV, poor shape of the main duct with evident contrast retention. Regarding gland function, types I and II were scored as 'good', type III was scored as 'fair', and type IV as 'poor'.

Sialometry

The salivary flow rate was measured at 9–11 a.m. Before saliva collection, water and alcohol consumption and smoking were prohibited for at least

1 h, and the patient rinsed their mouth twice with clean water. Submandibular saliva was collected using a 7-gauge scalp needle tube coated with its plastic outer sheath, which was suctioned onto the ostium and then connected to a saliva storage device (Fig. 1). The resting and stimulated salivary flow rates were each measured for 5 min. After saliva collection, the saliva weight was measured on an analytical balance with a precision of 0.1 mg. The total saliva flow over the 10 min was calculated by adding the resting saliva flow and the stimulated saliva flow.

Statistical analysis

The statistical analyses were conducted using IBM SPSS Statistics version 25.0 (IBM Corp., Armonk, NY, USA). The mean and standard deviation or median (range) were calculated for continuous variables, and compared using the independent *t*-test or Wilcoxon rank sum test. Categorical variables were expressed as percentages and compared using the χ^2 test or Fisher's exact test. Differences were considered significant for a *P*-value less than 0.05.

Results

A total of 115 patients (including two with bilateral affected glands) who returned to the clinic and agreed to undergo one or more of the objective tests were enrolled. Of these 115 patients, 70 were female and 45 were male. They ranged in age from 13 to 89 years. Among them, 97 patients had only hilo-parenchymal stones; 18 patients had hilo-parenchymal and ductal stones concomitantly. The mean diameter of the stones was 7.7 mm. Stone removal was performed successfully via transoral duct slitting (105 glands), basket retrieval (nine glands), or laser lithotripsy (three glands). Postoperative gland function was evaluated 3–94 months (mean 12 months) after the operation. Seven of the 115 patients underwent ultrasonography alone, 49 underwent sialography alone, one underwent sialometry alone, 24 underwent ultrasonography and sialography, 15 underwent sialography and sialometry, and the remaining 19 underwent all three tests.

Ultrasonography features

A total of 51 glands (50 patients) underwent ultrasonography examination after the operation. They included 34 hilar, 13 post-hilar, and 4 intraparenchymal stone cases. The mean stone size was 8.0 mm. Follow-up sonography showed a regular gland size in 58.8% of cases and a normal parenchyma density in 51.0% of cases (Fig. 2); however, ductal ectasia was detected in 80.4% of cases (Fig. 3) (Table 1).

Sialography features

A total of 109 glands (107 patients) underwent sialography after the operation. They included 73 hilar, 28 post-hilar, and eight intraparenchymal stone cases. The average diameter of the stones was 7.7 mm. Sialography appearance was scored as type I in 13 cases (11.9%, Fig. 2), type II in 64 (58.7%), type III in 23 (21.1%, Fig. 3), and type IV in nine cases (8.3%, Fig. 4). Consequently, 100 glands (91.7%) with type I, II, and III sialograms were scored as good or fair, while the remaining nine glands with a type IV sialogram were scored as poor. Stone diameter differed significantly among the four sialogram types ($P = 0.002$). Specifically, stones with type II–IV sialograms were larger in size than the stones with a type I sialogram (Table 2). When looking at the 30 cases with large stones (≥10 mm in diameter), the sialograms comprised 18 type II (60%), eight type III (26.7%), and four type IV (13.3%) cases. Moreover, the 17 follow-up sialograms at ≥ 24 months after surgery were scored as type I in two cases (11.8%), type II in 11 cases (64.7%), and type III in four cases (23.5%).

Sialometry data

A total of 35 patients with unilateral affected glands underwent sialometry examination. They included 20 hilar, 12 post-hilar, and three intraparenchymal stone cases. The two patients with bilateral stones were excluded from this examination. Stone size was an average 7.1 mm. The sialometry data did not have a Gaussian distribution, so the Wilcoxon rank sum test was used for the comparisons. There was no significant difference in 5-minute resting saliva flow ($P = 0.101$), 5-minute stimulated flow ($P = 0.103$), or 10-minute total flow ($P = 0.060$) between the affected and control glands. Similar to the control glands, the 5-minute stimulated flow in the affected glands was significantly higher than the 5-minute resting flow ($P < 0.001$) (Table 3).

Discussion

In this study, three objective methods were used to evaluate the glandular function of the SMGs after endoscopy-assisted extraction of hilo-parenchymal SMG stones.

As a safe, simple and non-invasive approach, ultrasonography has been applied both in preoperative diagnosis and postoperative evaluation of gland function.[24,25] Capaccio et al.[15] performed a 3-year follow-up ultrasonography evaluation to investigate the outcomes of transoral removal of

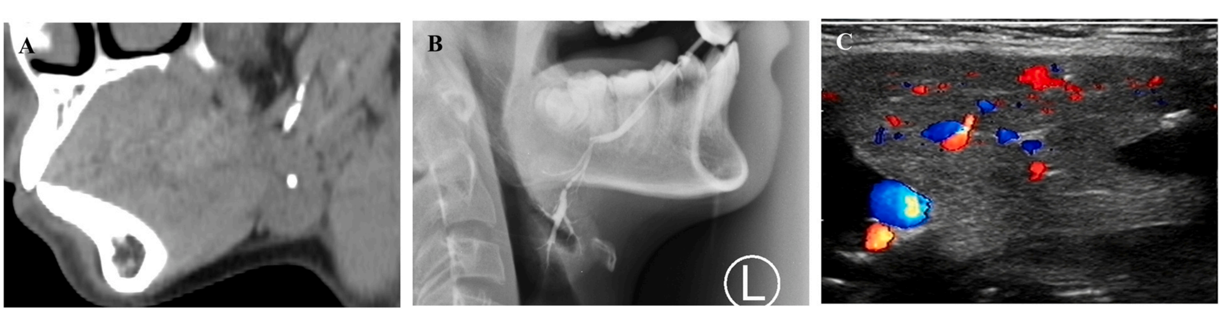

Fig. 2. A 13-year-old boy with an intraglandular submandibular gland stone. (A) Lateral computed tomography showed a 4-mm intraglandular stone in the left submandibular gland. Three months after stone removal, follow-up sialograms (B) and ultrasonography (C) showed an approximately normal appearance of the gland.

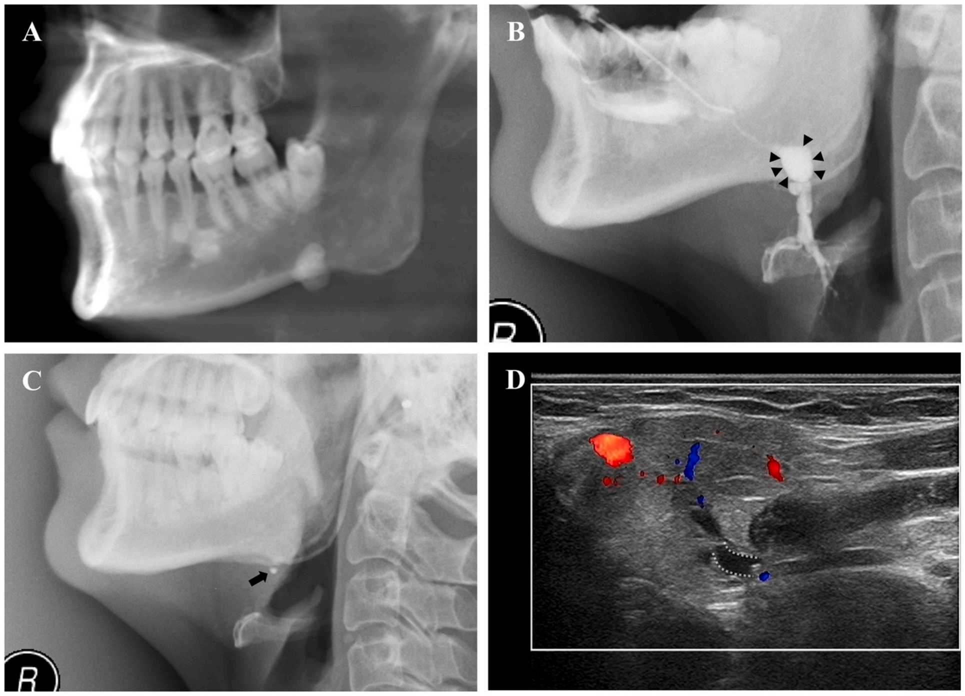

Fig. 3. A 43-year-old woman with a hilar submandibular gland stone. (A) Cone beam computed tomography showed a 12-mm hilar stone in the right submandibular gland. (B) (C) Four years after stone removal, follow-up sialograms showed saccular duct ectasia at the hilum (B, arrowhead) and mild contrast retention on the functional film (C, arrow). (D) Ultrasonography showed an approximately normal gland size, normal parenchyma density, and saccular ectasia of the hilum duct (dotted line).

large hilo-parenchymal submandibular calculi in a series of 37 patients, which showed a normal gland dimension in 72%, a regular ductal structure in 65%, and normal vascularization in 78% of the affected glands. Sproll et al.[16] applied a sonographic scoring system, which was adapted to the histopathological findings of resected SMGs , and the follow-up data showed a regular gland size in 70.8%, a parenchyma free of inflammation in 93.8%, without signs of fibrosis in 72.9%, and a regular structure of Wharton's duct in 68.7% of glands. Reichel et al.[26] reported that acoustic radiation force impulse (ARFI) imaging allowed the quantitative assessment of disease severity and the recovery of the diseased gland, and stated that this should be used in the initial examination and follow-up of sialolithiasis.

In the present study, the ultrasonographic parameters consisting of gland size, parenchymal density, and ductal morphology were used to evaluate the postoperative gland status. The results showed a normal gland size in 58.8% and a normal parenchymal density in 51.0% of the affected glands, while ductal ectasia was observed in 80.4% of the glands. It appears that the gland status was poorer than that reported by Capaccio et al.[15] and Sproll et al.[16] Several factors, including age, sex, race, symptom duration, and stone site, might have contributed to the differences in results. It should be stressed that all enrolled patients had radiographically verified hilo-parenchymal SMG stones, and patients with merely ductal stones that did not touch the genu of the main duct were excluded. Despite this, all of the enrolled glands were asymptomatic or had mild symptoms that could be self-relieved.

Although sialography is contraindicated in the case of a mobile stone for fear of its proximal movement, it can be used in cases with impacted stones for pre- and postoperative evaluation of the ductal morphology. Using endoscopy and replicated casts, Zheng et al.[27] found a high rate of hilar widening in patients with submandibular sialolithiasis and stated that this anatomical malformation may

Table 1. Postoperative ultrasonography features of 51 submandibular glands.

Features	Number	Percentage
Size		
Normal	30	58.8
Increased	7	13.7
Decreased	14	27.5
Parenchymal density		
Normal	26	51.0
Hyperdense	–	–
Hypodense	25	49.0
Ductal ectasia		
Presence	41	80.4
Absence	10	19.6

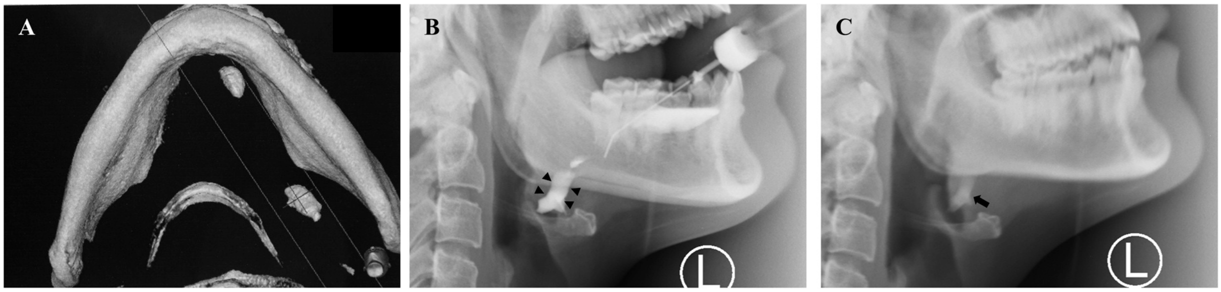

Fig. 4. A 32-year-old woman with multiple submandibular gland stones. (A) Three-dimensional cone beam computed tomography showed a 15-mm hilar stone and a concomitant 7-mm ductal stone in the left submandibular gland. (B) (C) Seven years after stone removal, follow-up sialograms showed saccular ectasia at the hilo-parenchymal duct (B, arrow) and evident contrast retention (C, arrow).

Table 2. Postoperative sialography features of 109 submandibular glands.

	Number (%)	Stone diameter (mm)			*P*-value
		Mean	SD	Median (range)	
Type I[a]	13 (11.9)	5.2	0.49	5.0 (3.0–9.0)	0.002
Type II[b]	64 (58.7)	7.5	0.38	7.0 (3.0–15.0)	
Type III[b]	23 (21.1)	9.3	0.85	8.0 (4.0–18.0)	
Type IV[b]	9 (8.3)	8.9	0.84	9.0 (4.0–12.0)	

SD, standard deviation. Type I, approximately normal; type II, saccular ectasia of the hilo-parenchymal duct with or without stenosis, and no contrast retention; type III, saccular ectasia of the hilo-parenchymal duct with or without stenosis, and mild contrast retention; type IV, poor shape of the main duct with evident contrast retention. a,bSame superscript letters indicate no significant difference.

Table 3. Postoperative sialometry results of 35 patients with unilateral stones.

	Mean	SD	Median	*P*-value Affected vs control side[a]	*P*-value RFR vs SFR[b]
Resting flow rate					
Affected gland	0.27	0.34	0.16	0.101	< 0.001
Control gland	0.31	0.27	0.30		< 0.001
Stimulated flow rate					
Affected gland	0.59	0.62	0.46	0.103	–
Control gland	0.78	0.68	0.58		–
Total flow rate					
Affected gland	0.86	0.91	0.67	0.060	–
Control gland	1.09	0.86	1.02		–

RFR, resting flow rate; SFR, stimulated flow rate; TFR, total flow rate; SD, standard deviation. Wilcoxon rank sum test results: acomparisons of RFR, SFR, and TFR between the affected and control sides; bcomparisons between RFR and SFR of the affected and control glands.

exacerbate the formation of sialoliths. Woo et al.[18] used sialography to investigate the anatomical recovery of the SMG duct after transoral removal of a hilar stone and found a normal ductal size in 79%, saccular dilatation in 14%, and partial stenosis in 3% of the cases. Su et al.[28] applied sialography to assess the radiographic anatomy of transplanted SMGs and found that the main duct had a regular shape in normal transplanted SMGs, while irregular dilatation and stricture of the duct were found in the transplanted glands with obstructive sialadenitis.

In previous studies by the current authors, sialography was used as a simple tool to evaluate the gland function for SMG and parotid stone cases.[17,23] In the present study, middle- to long-term postoperative sialography features were explored deeply, based on the largest sample size to date. The 109 postoperative sialograms were graded into four types (I–IV), with types I–III (approximately 92%) considered as 'good' or 'acceptable' function and type IV (approximately 8%) as 'poor' function. It should be noted that in a small number of patients, the clinical manifestations did not correspond well to their sialography findings; namely, although saccular dilatation and persistent contrast medium was evident in the sialograms of these patients, their subjective feelings and objective performance could be acceptably good after surgery. Overall, 88.1% of the affected glands had ductal ectasia (types II, III, and IV), mainly at the stone site, which is similar to our ultrasonography findings and the endoscopic findings by Zheng et al [27]; however, this frequency is higher than that reported by Woo et al.[18] Moreover, the existence of ductal ectasia corresponded well to larger stone cases (median stone diameter 7.0–9.0 mm). Strikingly, saccular ectasia persisted in 88.2% of the ≥ 24 months follow-up sialograms. Although it is uncertain whether the ductal ectasia preceded or was a consequence of stone formation, it is clear that saccular dilatation may be a longstanding characteristic after surgery. A widened hilo-parenchymal duct could cause excess stasis in salivary flow, and even the formation of mucus plugs, which could contribute to the recurrence of swelling, or even stone formation.[29–31] Consequently, an extended follow-up and the use of a sialogogue and self-massage would be helpful for the postoperative recovery of gland function, especially for those patients with larger or multiple stones.

Sialometry was performed in the resting and stimulated state. The resting state represents the baseline flow and the stimulated state reflects the flow rate of the salivary glands during chewing, tasting, or other stimulation.[32–34] Although the saliva flow rate has been shown to differ according to sex, age, and the environment, the bilateral glands usually show similar results. Differences between the two sides become significant if one gland has pathological changes.[35] Su et al.[20] used a polyethylene catheter introduced into the Wharton's duct to collect saliva. Their results showed a significant increase in glandular function in the affected glands postoperatively. Sproll et al.[16] measured the postoperative saliva flow of the SMG on both sides using a modified Schirmer test after external massage procedures. Compared with the contralateral glands, the affected glands showed a reduced flow rate in 45.8%, equal rate in 37.5%, an increased rate in 6.3%, and an undetectable rate in 10.4% of the cases.

In the present study, a modified SMG saliva collection device was used to examine the salivary flow rate of the bilateral glands for 5 min in the resting state and for 5 min in the acid-stimulated state. Both the resting and stimulated flow rates of the affected glands were lower than those of the control glands. For those patients with sialography-verified ductal ectasia, excessive saliva could be retained in the saccular dilatation, which might lead to an underestimation of sialometry results for the affected glands.[27] Based on this, external massage procedures might be helpful for the evacuation of the retained saliva and should be advocated in postoperative management. Despite this, no significant differences were observed between the two sides, which indicates that the postoperative gland function was substantially recovered, although it might be expected that the stone-related inflammation and intraoperative trauma could have severely damaged the gland function.[19]

This study has several limitations. Most of the patients who had undergone endoscopy-assisted lithotomy of hilo-parenchymal SMG stones were satisfied with the treatment outcome in their response to the telephone call or mailed questionnaire, and so were reluctant to return for the objective follow-up tests. Further, the follow- up rate varied greatly among the three testing methods. The heterogeneity of the data was attributed to several reasons: the retrospective nature of the study design, the COVID-19 pandemic, and patient resistance or reluctance to undergo the objective tests, which might require several hours of the patient's time and could lead to discomfort. Thus, a comparative study among the different methods could not be performed. The low objective follow-up rate was a notable limitation of the present study, therefore prospective studies using a larger sample size and sufficient comparative data are needed in the future.

In conclusion, for patients who had undergone successful endoscopy-assisted transoral lithotomy of hilo-parenchymal SMG stones, ultrasonography and sialography showed ductal ectasia in > 80% of the glands. Saccular dilatation appeared to be a longstanding characteristic after surgery, especially in larger stone cases, so long-term postoperative follow-up of the affected glands should not be neglected. Sialometry analysis confirmed a pronounced recovery of gland function. For patients with hilo-parenchymal SMG stones, endoscopy-assisted surgery and extended postoperative follow-up help preserve the gland with good function.

Ethical approval

The study design was approved by the Institutional Review Board of the Peking University School of Stomatology (PKUSSIRB-202059175).

Funding

None.

Competing interests

None.

Patient consent

All participants signed an informed consent.

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