New modalities in the management of human sialolithiasis

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Summary. Sialolithiasis is the most common disease of the great salivary glands with an incidence of 1.2%. New minimal-invasive methods like extracorporeal shockwave application or intracorporeal laser lithotripsy have changed the established ways of treatment of human sialolithiasis during the last years. Twenty per cent of our patients ($n = 402$) suffered from parotid duct stones and 80% from submandibular duct calculi. The typical symptoms were post-prandial pain and swelling of the glands. Until now there has been no proof of a metabolic disorder which could be responsible for coincidental stone development (6%) in the urinary tract or the bile duct system. Concrements are diagnosed by B-scan ultrasonography in nearly 100% of all cases. After our basic *in vitro* and *in vivo* investigations two systems of shockwave treatment are useful for clinical application: extracorporeal shockwave lithotripsy (piezoelectric) and intracorporeal laser lithotripsy (Rhodamine-6G-dye-laser), both supported by auxiliary measures (slitting and widening of the duct, dormia-basket extraction, sialagogues and gland massage). Due to our experiences with these minimally-invasive methods a new management of sialolithiasis is recommended depending on the localization of the calculi and their maximal diameters. Submandibular stones should be treated by extracorporeal lithotripsy, if the stone is located in intraglandular parts or in the hilum. Stones of the hilum also can be treated by laser lithotripsy. In the distal parts and near the orifice papillotomy and stone extraction should be tried independent of the stone size. If the maximum diameter is more than 12 mm and the concrement is detected in the intraglandular parts of the duct system or deep in the hilum, submandibulectomy is necessary. Calculi of the parotid gland should only be treated by extracorporeal lithotripsy, regardless of their size and location. Because of severe duct stenosis papillotomy is not indicated. Parotidectomy should be carried out only in cases reluctant to minimally-invasive measures.

Keywords: Sialolithiasis, minimally invasive therapy, lithotripsy

Epidemiology

Among the diseases of the large salivary glands in the head and neck region sialolithiasis accounts for more than 50% of the overall number of cases and is thus the most common cause of acute and chronic infections [1] (Figure 1). According to Rauch [2], the prevalence of sialolithiasis is about 1.2%. Salivary calculi predominate in patients in their thirties and forties and preferentially occur in male patients.

In our own study comprising 402 patients, however, manifestation of sialolithiasis was noted in 16 patients below the age of 20. Eighty per cent of all salivary duct stones develop in the submandibular (Wharton's) ducts, followed by about 20% which occur in the parotid (Stensen's) ducts. A formation of sialoliths in the sublingual gland or in the smaller salivary glands is rarely observed (0–2%).

A simultaneous lithiasis in more than one salivary gland

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Figure 1. Salivary duct calculi of different shapes, colours and diameters.

is uncommon [3], though four of our patients suffered from a concomitant disease of both parotid glands ($n = 2$) or both submandibular glands ($n = 2$).

Pathophysiology

Generalized stone development in the urinary tract, the bile duct system or the salivary ducts has been documented in 6–10% of the patient population. Until now there is no proof to corroborate the assumption that a metabolic disorder predisposes to this coincidental formation of concrements in different organ systems.

The clearly predominant occurrence of stones in the sudmandibular duct may result from the secretion of the submandibular gland being more mucinous than that of the parotid gland (4). In addition, Wharton's duct forms an angulation in its course around the mylohyoid muscle and exhibits numerous diverticula in its distal segment. This can promote a stagnation of secretion, thus increasing the possibility of stone formation [5]. In spite of the large number of investigations on salivary gland disorders the exact cause of sialolith formation still remains unclear. On one hand, inflammations – which may affect the colloidal equilibrium and cause subsequent gel-formation ('mucoidgel') and a consecutive incorporation of inorganic material – are held responsible for the development of sialoliths [6].

Moreover, foreign bodies could act as nuclei of crystallization [4, 7]. It is to be assumed, though, that local factors play a decisive role in lithogenesis, since only one salivary gland is affected in most cases. Solitary concrements are found in 80% of all salivary stones, whereas in 20% more than one stone is detected in the salivary duct [2].

The composition of stones of the parotid duct differs from that of stones of the submandibular duct. While parotid duct stones are composed of 51% of organic material and 49% of inorganic material (the latter with a calcium contribution of 15%), the organic component of submandibular stones is only 18%, whereas the inorganic component is 82% (with a calcium contribution of 46%). The inorganic components are predominantly, weddellite, whitelockite and brushite [8, 9].

The largest diameters of the salivary stones are in the range of 0.1 mm to 30 mm [10]. The mean stone diameters found in our patients were 6.7 mm in the case of submandibular concrements and 5.2 mm in the case of parotid concrements.

Symptoms

The set of clinical complaints which accompanies sialolithiasis forms a typical pattern: if the duct system is partially or completely congested, colicky post-prandial pain (resulting from induced secretion) and some very severe pain attacks, as well as swelling of the parenchyma of the affected glands, become manifest, with a variable degree of pain intensity between the attacks [5].

If the concrement does not disappear spontaneously, an ascending retrograde infection of the duct and gland is promoted by the persisting congestion. In addition, continued retention of saliva not only leads to a dilation of the duct system but also to an increasing atrophy of the glandular parenchyma. Histologically, the changes occurring in the final stage of this chronic obstructive sialadenitis are similar to those observed in gland atrophy caused by instrumental duct ligation or occlusion by a protein solution [11, 12].

Diagnosis

In general, the classification of clinical findings in patients presenting with sialolithiasis is typical: during examination and palpation a distinct and partly painful swelling is detected in the region of the affected salivary gland.

In conventional radiography 80% of the submandibular stones and 20% of the parotid stones are detectable (Figure 2). Due to their mineralogical components 20% of the submandibular stones and 80% of the parotid stones are radiolucent [13, 14].

The excellent axial resolution of high frequency ultrasound scanners allows concrements with diameters exceeding 1.5 mm to be detected in virtually all cases, independent of their mineralogical composition. Therefore, sonography should be the diagnostic imaging method of choice if sialolithiasis is suspected [15] (Figures 3a and 3b). In inflammation-free intervals sialography may, in certain cases, provide additional information. With modern mini-endoscopes (external diameters of

Figure 2. Conventional X-ray of a sialolith of the right submandibular gland.

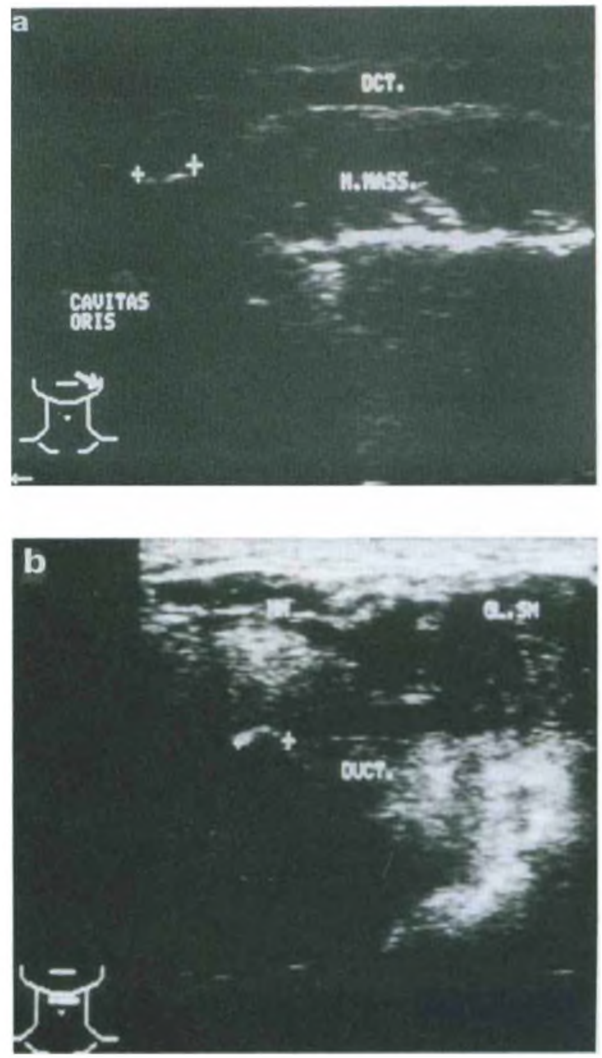


Figure 3. (a) Sonographical image of a parotid duct stone (+ . . . +; 6.6 mm in diameter) in the vicinity of the orifice of Stensen's duct, with the dilated duct (DCT) behind, above the masseteric muscle (M. Mass.). (b) Sonographical image of a concrement (+ . . . +; 7.2 mm in diameter) in the floor of the mouth congesting left Wharton's duct (DUCT). GL. SM = submandibular gland, MM = mylohyoid muscle.

0.6–2.0 mm) it is possible to examine the distal parts of the ducts and to verify the diagnosis by direct stone imaging. Scintigraphy of the salivary glands can give some general indications as to the secretory function of the afflicted gland. In this context it should be emphasized that the secretory function can regenerate completely after removal of the obstruction [16, 17].

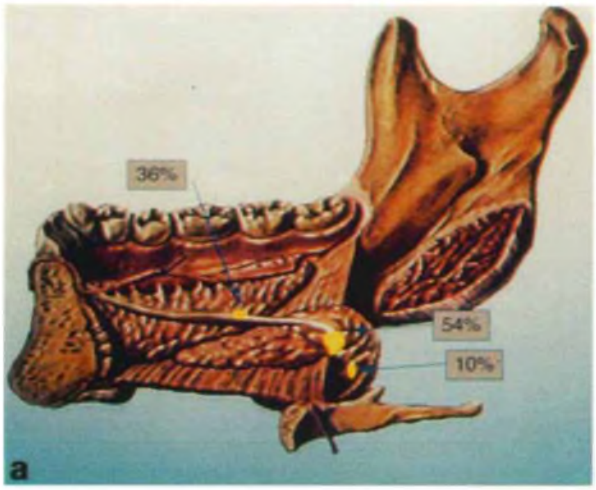
In the application of modern minimally-invasive treatment methods, it is essential not only to verify the diagnosis of a sialolithiasis and to define the specific nature of the disorder, but also to establish the exact localization of a concrement within the duct system – on the basis of a differential therapeutic approach which includes minimally-invasive therapy.

Approximately 36% of all concrements in the submandibular duct are detectable in the vicinity of the ostium or in Wharton's duct as it passes through the floor of the mouth. In 54% of the cases the stones are located in the hilum and in 10% they are found in the intraglandular duct system (Figure 4a).

Seventy per cent of the parotid stones are located in the distal part of Stensen's duct, 10% in the hilum and 20% in the intraglandular duct system (Figure 4b).

Established methods of therapy (see Table 1)

In the case of sialolithiasis no methods of dissolving concrements by medical therapy have become available to date, nor has diet prophylaxis proven effective – in contrast to the treatment of stone diseases affecting the urogenital tract and especially the bile duct system; therefore, therapy of sialolithiasis has to be aimed at complete stone removal. If stimulation of secretion, gland massage or dilation of the orifice remain unsuccessful, the patient will have to undergo an operation [18]. If the



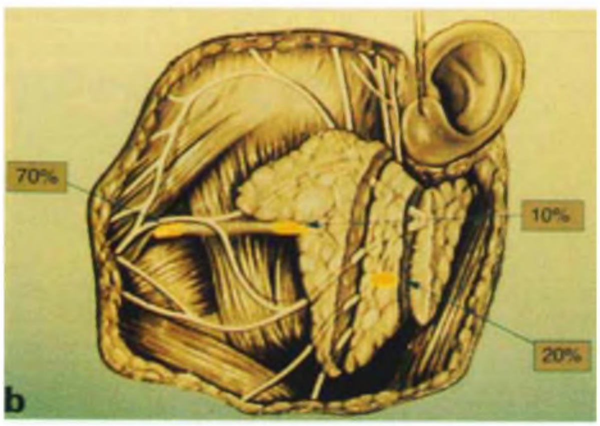


Figure 4. (a) Frequencies of the different locations of the sialoliths in the submandibular gland. (b) Frequencies of the different locations of the sialoliths in the parotid gland.

concrement of the submandibular gland is lodged in the distal part of Wharton's duct near the orifice, the ductal orifice is enlarged by incision and the stone removed (Figure 5). In the case of more proximally positioned submandibular stones near the hilum there is an imminent danger of injuring the lingual nerve when slitting the duct [19].

Stenosis of Wharton's duct is rarely observed after performing duct incision. We reject an incision if sialolithiasis is detected in Stensen's duct, because of the danger of

Figure 5. Salivary stone coming out of left Wharton's duct after incision of the orifice.

ductal strictures and stenosis resulting from scar formation [20]. Eight out of 10 stenoses, which we have seen during the last 4 years, occurring in the papillary region of the glandula parotis were the result of incisions in the orifice of Stensen's duct that had been performed at other hospitals.

Up to now, surgical excision of the afflicted gland was required, if removal of the concrement by careful probing and dilation or by incision of the duct was not successful. Complications that can arise during surgical removal of the submandibular gland – carried out under either general or local anaesthesia – include injuries of the mandibular branch of the facial nerve, of the lingual nerve and the hypoglossal nerve. These risks are well-described in the literature [21, 22, 23].

Parotidectomy, which should be performed under general anaesthesia, bears the risk of causing irreversible injury to the facial nerve [24]. Frey's syndrome (gustatory

Table 1. Established therapies of sialolithiasis

Sialagogues
Duct dilation
Duct slitting
Gland extirpation
(Chorda tympany neurectomy)

Table 2. New methods of therapy

Lithotripsy		
Intracorporeal		Extracorporeal
Endoscopically		Sonographically
	Controlled	
	Auxiliary measures	

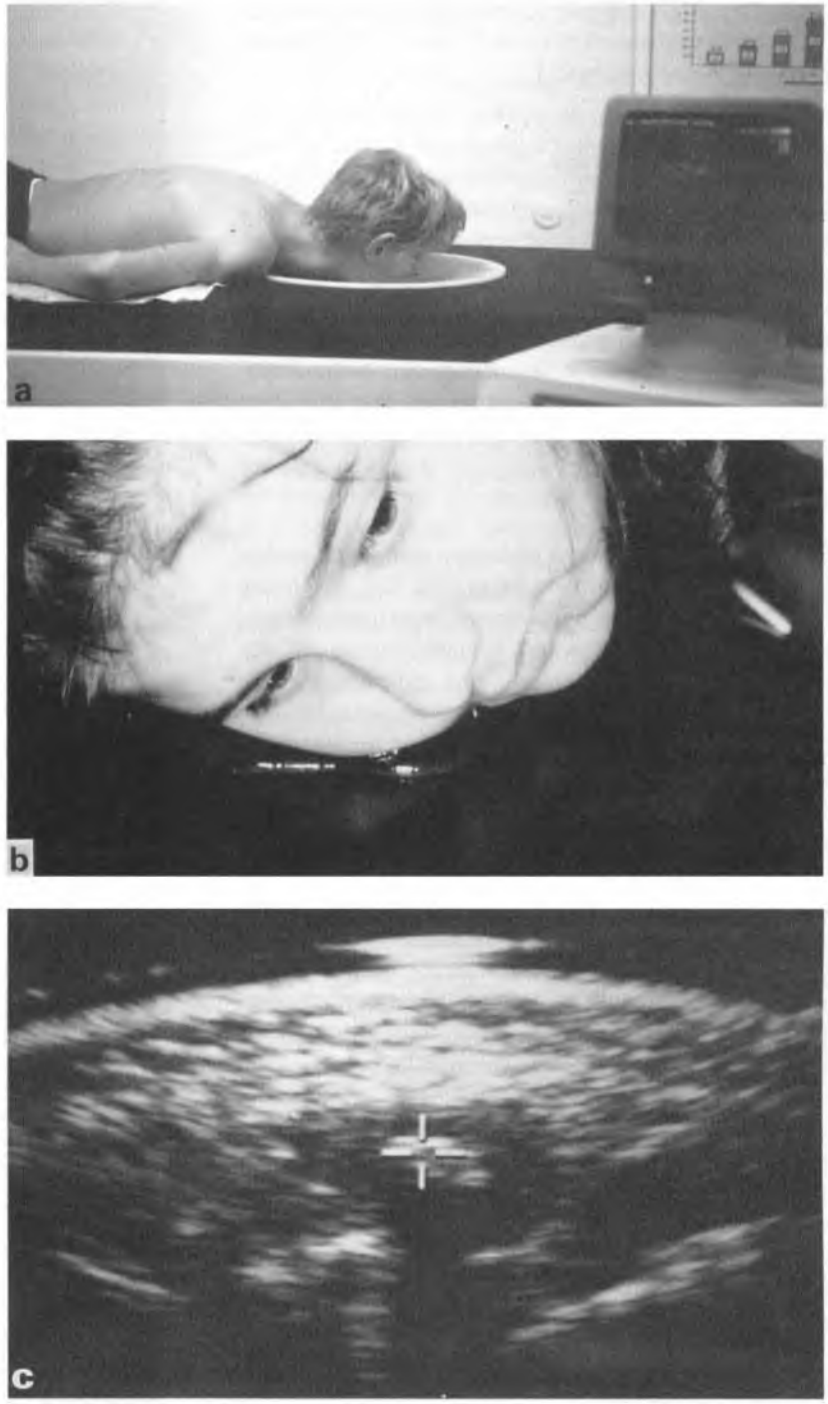


Figure 6. (a) Twelve-year-old boy positioned above the extracorporeal shockwave generator during therapy of a sialolithiasis of the submandibular gland. (b) 14-year-old girl with stone disease of the parotid gland positioned above the shockwave generator during extracorporeal lithotripsy. (c) Calculus of the same young girl, sonographically localized and positioned in the focus of the lithotripter (+).

sweating or auricular temporal syndrome) is subjectively noticable in 10% of the patients and objectively dectectable in nearly all patients [25].

To spare patients suffering from a submandibular lithiasis the strain of undergoing submandibulectomy, Zalin & Cooney [26] recommended a tympanic neurectomy to reduce salivary secretion to a minimum by parasympathetic denervation of the submandibular gland. Following this transtympanally executed neurectomy, a fairly rapid resolution of symptoms is noted, but this is accompanied by a partial loss of taste [27]. In addition, the concrement – as a possible source of consecutive infections – is left in the duct. Because of these disadvantages tympanic neurectomy has not been able to assert itself as a therapeutic option.

New methods of therapy

Efforts to establish minimally-invasive methods in the treatment of sialolithiasis, i.e. to dispense with or to minimize surgical intervention, led to the introduction of intracorporeal, endoscopically controlled lithotripsy and extracorporeal, sonographically controlled lithotripsy as new treatment regimes in the management of sialolithiasis (Table 2).

Extracorporeal shockwave lithotripsy of salivary duct stones (ESWL)

Extracorporeal shockwave lithotripsy was introduced in the treatment of kidney stones in 1980 [28]. Within the last 13 years 90% of all nephrotomies have been replaced by ESWL in the management of kidney stones [29, 30]. Extracorporeal, sonographically and radiologically controlled lithotripsy also provides an alternative to cholecystectomy in treating non-calcified stones of the gall bladder. Furthermore, given certain indications, ESWL has also proved its effectiveness in the treatment of biliary duct and pancratic duct stones [31, 32].

In view of the continuing technical development of the first generation of lithotripters it appeared possible to treat sialoliths by extracorporeal shockwave lithotripsy as well [33]. The small focal dimensions of the piezoelectric shockwave device (Piezolith 2500, R. Wolf Company, Knittlingen, Germany) appeared especially well adapted to applications in the head and neck region with its important and very sensitive peripheral and central nerve structures.

Within the scope of *in vitro* and animal experiments and other basic investigations, the feasibility of fragmenting sialoliths by piezoelectrically generated shockwaves was demonstrated [34, 35]. Moreover, animal experiments showed no structural damage and no severe tissue lesions in the head and neck region after exposure to piezoelectric shockwaves [34].

Extracorporeal shockwaves are transduced into the body of the patient from outside under sonographic control (Figures 6a and 6b). Exact sonographic imaging and positioning of a salivary duct concrement into the focus zone of the lithotripter are decisive preconditions for implementing shockwave lithotripsy systems in the treatment of sialolithiasis in human patients (Figure 6c). Clinical application of ESWL is possible without anaesthesia or sedoanalgesia, if these conditions are fulfilled.

The first successful implementation of extracorporeal lithotripsy in human sialolithiasis was performed in 1989 by our group treating a patient afflicted by a parotid stone measuring 12 mm [36].

In the scope of a prospective study [37] we treated 60 patients suffering from sialolithiasis, giving consideration to the following criteria:

1. the sialoliths had to cause clinical symptoms;
2. sonographic evidence had to be absolutely reliable; and
3. removal of the stones by other measures such as duct incision was not possible.

An acute episode of sialadenitis or previously performed duct incisions are contraindications for lithotripsy because of the danger of scarred ductal strictures. Out of a total number of 60 patients, 41 suffered from submandibular calculi and 19 from parotid calculi. While complete stone fragmentation was achieved in all patients afflicted by parotid stones, in seven patients out of 41 suffering from submandibular stones only partial fragmentation was shown by sonography after three ESWL sessions.

The only side-effects caused by extracorporeal shockwave lithotripsy were localized petechial bleedings and suggilations in the skin (13%), as well as temporary gland swellings (3%). During the average follow-up period of 12 months all patients (i.e. 100%) with parotid concrements and 85% of the patients with submandibular concrements remained free of symptoms. Complete elimination of stones was sonographically verified in 81% of the patients with parotid calculi (Figures 7a, 7b and 7c), whereas stone fragments were still imaged in 60% of the patients exhibiting submandibular calculi.

In summary, it can be conclusively stated that extracorporeal lithotripsy represents an effective minimally-invasive therapy method for treating sialolithiasis which ensures a high level of comfort for the patient. With the help of this new method, operations causing undesired side effects may be avoided. The experiences of our medical team are shared by Kater *et al.* [38].

Intracorporeal shockwave lithotripsy (ISWL)

Besides extracorporeal lithotripsy, the technique of intracorporeal lithotripsy is also currently available for treatment of salivary stones. With this method shockwaves are applied directly – under endoscopic control – to the surface of the stone lodged within the duct. An essential precondition for performing intracorporeal lithotripsy within the salivary ducts was the development of suitable mini-endoscopes with external probe diameters of 1.5 to 2.0 mm. In addition, a working channel of at least 0.5 mm for the laser probes and water irrigation has to be ensured (Figure 8).

In the field of intracorporeal lithotripsy different principles of shockwave generation can be distinguished. Laser systems are being implemented on one hand, and on the other hand electrohydraulic shockwave generation systems are also in use. In laser lithotripsy, basically four different systems are available: the Excimer-Laser, the Neodymium-YAG-Laser, the Alexandrite-Laser and the so called Rhodamine-6G-Dye-Laser. Within the framework of detailed *in vitro* and animal experiments [39, 40] it was shown that the Nd-YAG (1064 nm) and the Alexandrite (755 nm) laser systems were not able to achieve fragmentation of calculi. With the Excimer-Laser (308 nm) it was indeed possible to achieve complete disintegration of salivary stones, but at a high risk of duct perforation, if the tip of the probe comes into contact with the duct tissue. Tissue contact cannot always be avoided, especially in the narrow main salivary ducts with a maximum diameter of 1.2–1.8 mm. Although the Excimer-Laser is reliable in stone fragmentation, tissue lesions which might lead to consecutive scarred duct stenosis have to be anticipated.

With the Rhodamine-6G-Dye-Laser (595 nm, Lithognost, Telemit-Company, Germany) a system with an integrated stone/tissue detection system has become accessible. This laser is able to differentiate between tissue and stone material at the tip of the probe by optical analysis of fluorescent light which is emitted during laser-induced shockwave application. If tissue is detected in front of the probe, the laser pulse is terminated and shockwave emission is interrupted. Thus, this system can be applied without causing tissue lesions. After verification *in vitro* that salivary stones can be reliably disintegrated using the Rhodamine-6G-Dye-Laser, clinical application of this system for the treatment of sialolithiasis appears possible. Preconditions for the implementation of intracorporeal laser-induced lithotripsy are as follows:

1 a symptomatic disease;
2 the concrement cannot be extracted by duct dilation or incision; and
3 endoscopic visualization of the calculi.

As the restricted dimensions of the distal ducts of the

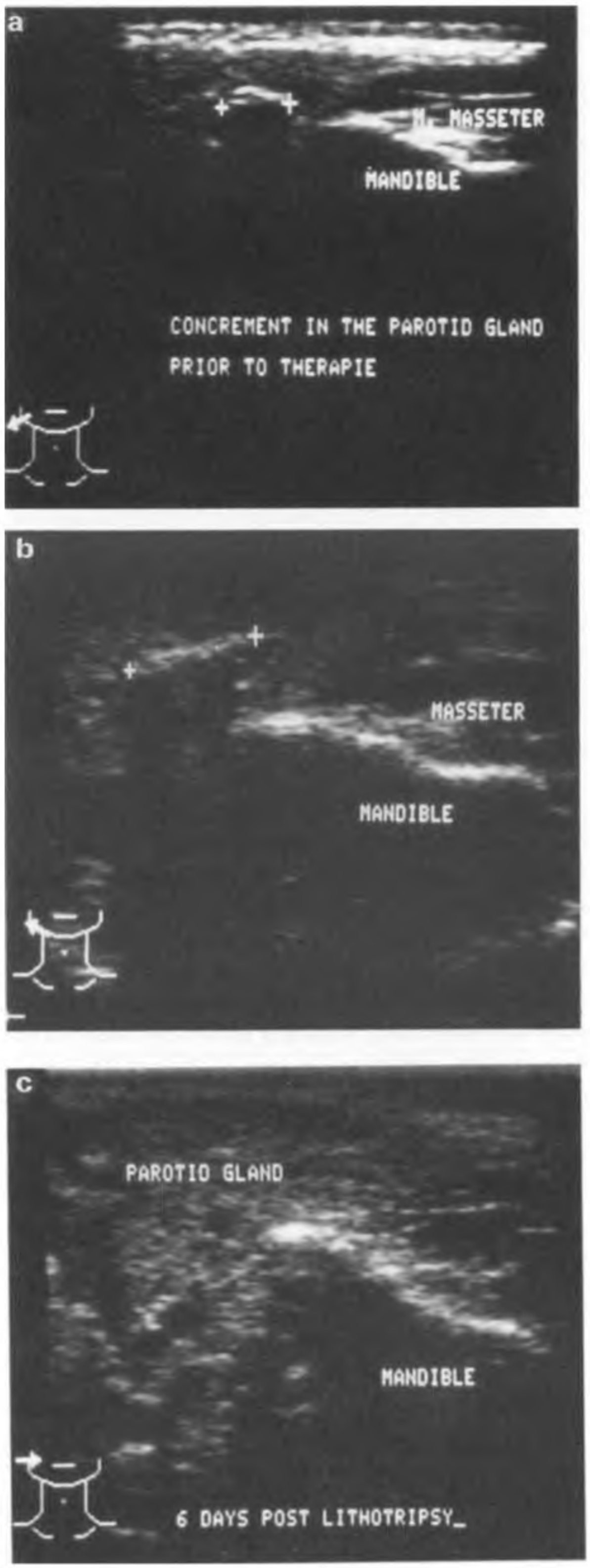


Figure 7. (a) Sonographic image of a right parotid duct stone located in the hilum immediately before extracorporeal lithotripsy (+ . . . +, 7.3 mm in diameter). (b) The same concrement 24 h after ESWL. Sonography shows a clearly enlarged stone signal (+ . . . +, 14 mm) as a sign of complete fragmentation. (c) Six days after therapy no concrement is detectable.

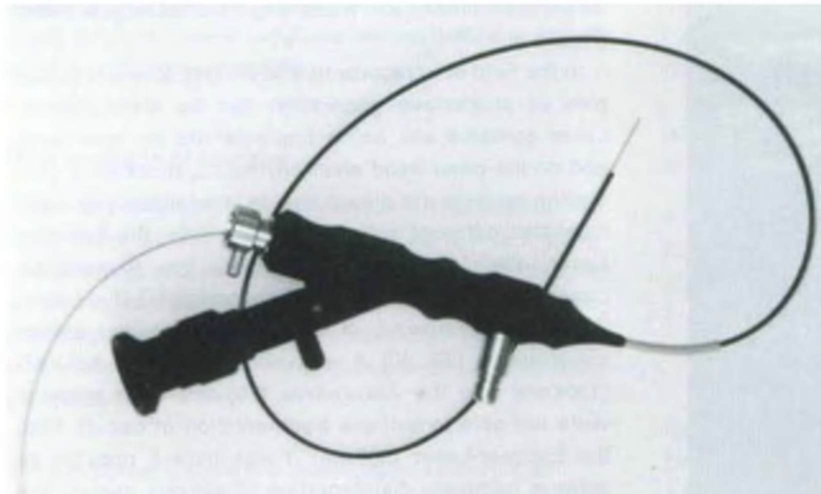


Figure 8. Mini-endoscope (1.6 mm in diameter) with an inserted laser probe for ISWL (400 μm in diameter).

large salivary glands – especially near the orifices – tend to make incision and slitting of the duct necessary, the indication for intracorporeal laser lithotripsy is limited primarily to submandibular duct stones (Figure 9). As pointed out above, an incision of the orifice of Stensen's duct should be avoided.

Like ESWL, ISWL can also be carried out under local anaesthesia. Complications of intracorporeal lithotripsy reported in the literature are intraglandular abscesses and acute episodes of sialadenitis [41].

Figure 9. Mini-endoscope introduced into Wharton's duct of a left submandibular gland for intracorporeal laser lithotripsy.

During the last 2 years various authors have reported on their experiences with intracorporeal laser lithotripsy of salivary stones. The percentage of patients with submandibular stones that can become free of symptoms after treatment is as high as 88% [41, 42]. At present there are no reports on stone clearance rates in patients who have received intracorporeal laser lithotripsy treatment.

Another method of shockwave generation and application besides laser lithotripsy is that of electrohydraulic intracorporeal lithotripsy. Whereas Königsberger *et al.* [43] reported on very satisfactory success rates in electrohydraulic intracorporeal lithotripsy of salivary stones, our own research results clearly showed that the probability of tissue lesions and duct perforations is immense [44]. For this reason the clinical use of intracorporeal electrohydraulic lithotripsy should definitely not be recommended, particularly in view of the fact that better and less dangerous alternative methods such as intracorporeal laser lithotripsy and ESWL are available for treatment of sialolithiasis.

Auxiliary measures

Once the salivary stones have been fragmented by extracorporeally or intracorporeally generated shockwaves, it is expected that the fragments will leave the ducts and the glands *per vias naturales*. The process of flushing out fragments can be facilitated by so-called auxiliary measures which are applied by the patients or the physician. The patient should take sialagogues (for example sour drops) and regularly massage the affected gland to produce a continuous flow of saliva. Discharge of the concrements through the orifice can also be enforced by dilation of the duct using embolectomy balloons or by slitting of the duct. Stone extraction can be

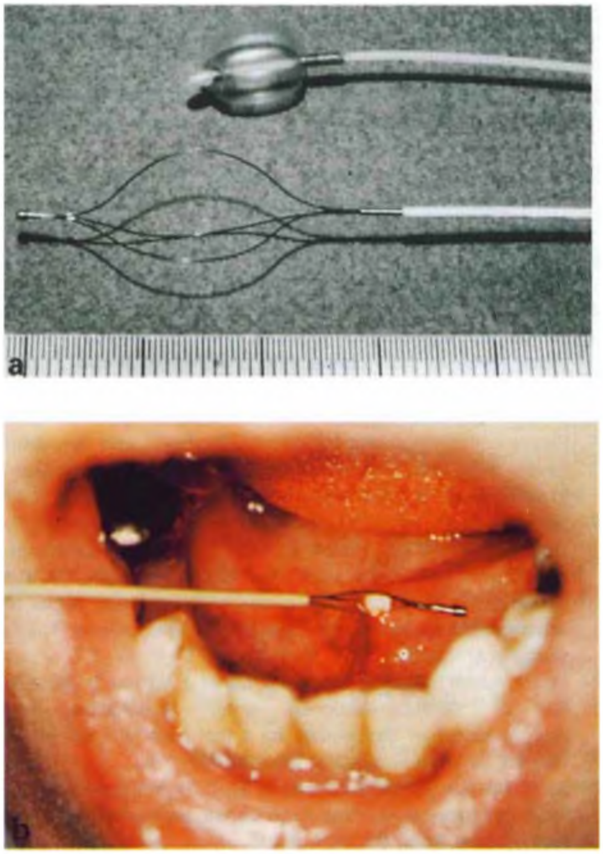


Figure 10. (a) Three-wire dormia basket and balloon catheter (auxiliary measures). (b) Removal of a stone fragment after ESWL with the help of a dormia basket.

Table 3a. Therapy of submandibular duct stones

Localization of the sialolith	Mode of therapy
Vicinity of the orifice	Extraction, slitting
Distal parts of Wharton's duct	Slitting and marsupialization
Hilum	Intra- or extracorporeal lithotripsy
Intraglandular duct system	
Stone diameter < 12 mm	Extracorporeal lithotripsy
Stone diameter > 12 mm	Extirpation of the gland

Table 3b. Therapy of parotid duct stones

Localization of the sialolith	Mode of therapy
Vicinity of the orifice	Extraction *without slitting*
Distal parts of Stensen's duct	Extracorporeal lithotripsy
Hilum	Extracorporeal lithotripsy
Intraglandular duct system, all stone diameters	Extracorporeal lithotripsy

achieved by using small three-wire dormia baskets (probe diameters: 2.7 French) or balloon-catheters (probe diameters: 2 French; volume 0.05 ml) (Figures 10a and 10b).

Conclusion

We use the following differential therapeutic scheme to manage salivary gland calculi – depending, of course, on the afflicted gland and the sonographically determined stone location:

Submandibular gland (Table 3a)

For stones located near the orifice in front of the papilla, extraction of calculi by duct incision with marsupialization or manual mobilization of the stones is always successful.

If the concrement is located in the distal sections of Wharton's duct, slitting of the duct and marsupialization will usually be the successful method of choice. Calculi of the hilum can be treated by extracorporeal or intracorporeal lithotripsy procedures.

If the calculus is located in the intraglandular parts of the duct system, ESWL is the only possible option, because the available endoscopes are not small enough in diameter to be able to accede these sections of the duct system.

If no success is reported after three treatment sessions within an overall period of 1 year (i.e. if the patient still exhibits symptoms) an extirpation of the submandibular gland has to be performed. Another indication for submandibulectomy is the size of the stone located in intraglandular regions. If the largest diameter of the stone reaches 12 mm in the sonographical image, the chances of successful lithotripsy might be less than 20%.

Parotid gland (Table 3b)

In treating parotid gland stones, slitting of the duct and incision of the orifice should be strictly avoided. Therefore, in our opinion, intracorporeal methods should not be implemented at the present time. Sometimes the removal of stones is possible by basket or balloon extractions.

Stones located in the distal parts of Stensen's duct, in the hilum or in the intraglandular duct system are treated only by extracorporeal lithotripsy – independent of their sizes.

Nowadays a parotidectomy should only be carried out for isolated cases of sialolithiasis resistant to minimally-invasive measures.

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