Outcome of Minimally Invasive Management of Salivary Calculi in 4,691 Patients

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Objective: To evaluate the application of minimally invasive techniques in the management of salivary stones.

Background: The incidence of salivary calculi is 60 cases/million/year, with most stones situated in the mid or proximal duct. The current treatment of these stones is adenectomy. This paper reports the results of minimally invasive methods of stone removal that avoid gland excision.

Methods: Observational study of 5,528 consecutive patients treated by lithotripsy, endoscopy, basket retrieval, and /or surgery in five centers from 1990 to 2004 inclusive. A total of 567cases were excluded, leaving 4,691 patients (parotid n = 1,165, submandibular n = 3,526) for analysis.

Results: Salivary calculi were eliminated in 3,775/4,691 (80.5%) of cases and partly cleared in 782/4,691 (16.7%). Salivary glands were removed in 134/4,691 (2.9%) of patients with symptoms in whom treatment failed.

Conclusions: Minimally invasive techniques move treatment of salivary calculi to an outpatient or a day case setting. They are reliable ways of both retrieving stones and eliminating symptoms, and mean that the gland rarely has to be removed.

Key Words: Salivary stones, lithotripsy, sialendoscopy, minimally invasive therapy.

INTRODUCTION

Obstruction of the salivary glands accounts for about half of all benign salivary disease.[1] Its prevalence is unknown; in the United Kingdom an evaluation of symptomatic disease based on completed consultant episodes undertaken in the NHS suggests roughly 59 patients/million population are admitted to hospital annually with obstructive salivary gland disease (stones and chronic sialoadenitis) for up to 3 days each year.[2] This is about 3,850 admissions/year in and, if applied to the population of Western Europe, about 16,000 cases a year.

Current practice for removal of stones in the mid or proximal portion of the duct is excision of the submandibular gland. However, some European centers have now developed minimally invasive techniques, the results of which indicate that more than 70% of such stones can be retrieved successfully, and only about 2% of patients subsequently require excision.[3]

The object of this study was to evaluate outcome in five centers that worked independently, but had adopted a minimally invasive approach as routine for the management of stones in the salivary glands.

PATIENTS AND METHODS

During the period March 1990 to December 2004, 5,258 patients with 5,993 salivary stones were seen at five centers. Patients who were treated conservatively, by simple intraoral release of the stone at the orifice, or who refused treatment (241) were excluded, as were those with complete ductal stenosis (11), recurrent infective episodes, or multiple stones that required removal of the gland (63) or who were lost to follow-up after their initial assessment (15). Those patients who were treated early in the program by minimally invasive techniques that did not feature in our final protocol (such as intracorporeal lithotripsy) and mechanical fragmentation (237), were excluded. The remaining 4,691 cases were entered into a minimally invasive regimen, and data were collected prospectively from consecutive cases treated in each center (Table I). The data were pooled for analysis.

The minimally invasive techniques used were extra-corporeal shock wave lithotripsy, (Erlangen, London, Milan, and Paris), retrieval of stones by wire basket or microforceps (Ashkelon, Erlangen, London, Milan, and Paris) and gland-preserving surgery (Ashkelon, Erlangen, London, and Milan). At the present time no one technique is used exclusively, although inclusion and exclusion criteria have been developed and adopted (Table II).

The policy in the five centers was to treat symptomatic salivary disease by minimally invasive methods and remove the gland only as a last resort. Acute sialoadenitis was treated with antibiotics before intervention. Investigations were ultrasound

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TABLE I.
Number of Parotid and Submandibular Cases Treated by Center.

Center	Total No. of Patients	Submandibular	Parotid
Ashkelon	496	366	130
Erlangen	1,142	922	220
London	490	347	143
Milan	548	417	131
Paris	2,015	1,474	541
Total	4,691	3,526	1,165

evaluation in all centers supplemented with sialograms (London and Israel). Sialographic findings were available for 1,141 stones with 65.9% of calculi being radiopaque (parotid 139/367 [37.9%] and submandibular 613/774 [79.2%]). Data about multiple stones were available on 1,811 patients; the number of patients at presentation with a stone in one gland was 1,777/1,811 (98.1%), and in two glands 34/1,811 (1.9%), whereas no patients had stones in more than two glands.

There was no significant difference in the demographic details among centers. Stones were equally distributed between men and women, with a median age of 45 years at presentation (range = 9–91). The mean size of stone was 5.2 mm and 7.1 mm for the submandibular gland and parotid stones, respectively (Table III).

Extracorporeal Shock Wave Lithotripsy (ESWL)

For ESWL, a dedicated minilith sialolithotripter (Minilith SL1 Storz Medical, Kreuzlingen, Switzerland) was used in London, Milan, and Paris, and a piezoelectric lithotripter (Richard Wolfe Company, Germany) in Erlangen.[4–6] Both lithotripters have a small shock-wave focus that is suitable for salivary gland treatment. Patients were treated as outpatients, usually with a minimum rest period of a week between sessions. In Erlangen, patients remained in the hospital overnight, but this was a peculiarity of health funding in Germany, rather than a feature of lithotripsy. Treatment could be undertaken on 2 or 3 consecutive days if the patient lived a long distance from the hospital. The duration of each session was usually 1 hour, with no requirement for analgesia or anaesthetic. The shock waves were targeted with an ultrasound image (Storz 7.5 MHz; Wolfe 5200/economy: 7.5 MHz). They were delivered at a frequency of 2 per second up to a maximum pressure of 30 MPa for the Minilith and 80 MPa for the piezolith. The numbers of shock waves delivered during each session varied between 5,000 and 3,000. The initial course involved three to six treatment sessions (Erlangen total 12,000 shocks, London and Paris 15,000 shocks, Milan 18,000). If fragments of stone persisted, patients underwent a second course of lithotripsy. The outcome was assessed clinically and by ultrasound or sialographic evaluation, or both, 3 to 6 months after completion of treatment.

TABLE II.
Selection Criteria for Minimally Invasive Techniques.

Generic Inclusion Criteria

- Symptomatic disease
- At least one episode of purulent sialoadenitis
- No recovery after 3 months of conservative therapy
- Not amenable to simple intraoral release

Exclusion Criteria

Technique	Exclusion Criteria
ESWL	Inability to sonographically locate concretions
	Impaired blood coagulation
	Cervical spine problems with respect to posture during therapy
	More than two stones
Basket/microforceps retrieval	Known fixed salivary calculi.
	Calculi located within diverticulae.
	Calculi >50% wider than the distal duct especially in the parotid duct.
	Ductal stenosis distal to calculus
Gland preserving surgery:	
Submandibular	Stone not palpable intraorally
Parotid	Unable to negotiate duct with endoscope

ESWL = extracorporeal shock wave lithotripsy.

Retrieval by Basket or Microforceps

Retrieval of calculi by basket or microforceps was restricted to mobile stones that were usually no more than twice the diameter of the duct (normally <5 mm). Patients were operated on as outpatients under fluoroscopic, radiologic, or endoscopic control. The orifice was dilated, and a basket or microforceps was manipulated to engage the calculus. Once engaged, the stone was withdrawn slowly to the ostium, where a small incision facilitated its release.[7]

TABLE III.
Demographic Details of Patients by Center.

	Ashkelon	Erlangen	London	Milan	Paris	Overall
Ratio of men: women	0.98	1.11	1.03	1.04	1.02	1.04:1
Age (years)	45.0	42.6	45.8	45.5	45.5	44.77
Age (years) parotid stones	46.0	49.5	48.0	49.0	44.0	46.3
Age (years) submandibular stones	43.0	40.8	45.0	44.0	41.8	42.2
Size (mm) parotid stones	5.3	5.8	5.8	4.7	5.1	5.3
Size (mm) submandibular stones	7.1	7.7	7.3	7.0	6.9	7.2
Duration of symptoms (months) parotid stones	24.0	36.9	44.0	50.0	34.0	36.5
Duration of symptoms (months) submandibular stones	18.0	23.3	49.0	43.0	27.0	29.2

Data are mean values.

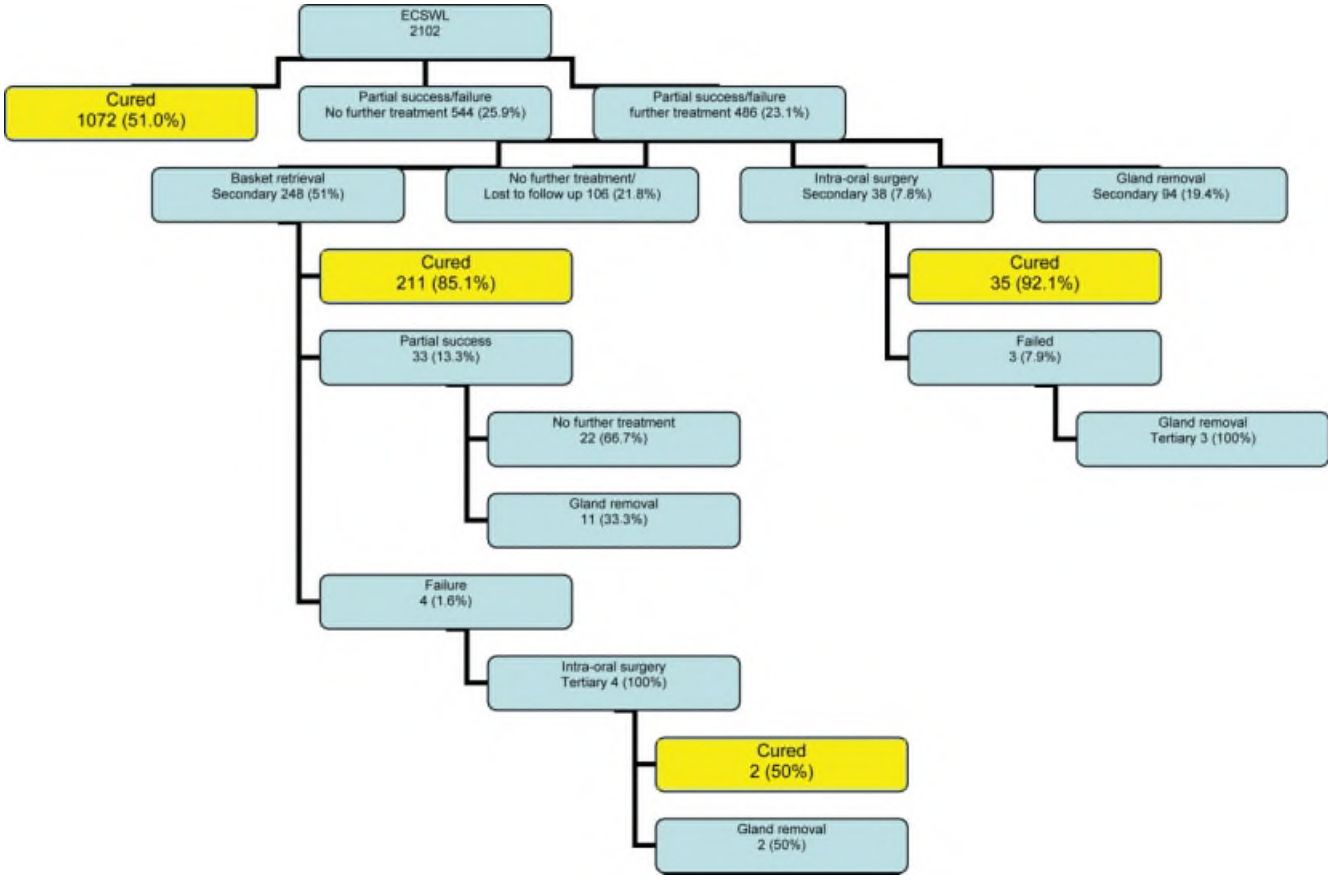

Fig. 1. Summary of treatment of 2,102 patients with extracorporeal shock wave lithotripsy as first line intervention. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

Minimally Invasive Surgery—Submandibular Stones

Stones were removed intraorally from the hilum or proximal portion of the submandibular duct during day-case admissions under either general or local anesthesia.[8,9] An incision was made in the floor of the mouth to expose the sublingual gland and the submandibular duct, which was traced back to the hilum of the submandibular gland. The technique used in Erlangen and Israel placed traction on the duct and opened it along its length until the stone could be seen and delivered. The duct was then laid open and sutured into the floor of the mouth. In London, the duct was opened over the surface of the stone, then continuity was reestablished with two or three sutures. Results were assessed clinically and by ultrasound, sialography, or both, 3 to 6 months after treatment.

Minimally Invasive Surgery—Parotid Stone

Open surgery was the treatment of last resort for parotid stones, and was adopted only if the patient had persistent infection after failed lithotripsy.[10,11] The light tip of the endoscope is used as a beacon, and stones are retrieved through either a vertical skin incision made through the cheek directly over the stone, or made after lifting a preauricular skin flap.

RESULTS

In the period 1990 to 2004, 5,258 patients with 5,993 symptomatic stones presented for treatment. Of these, 4,691 were entered into the minimally invasive program. The outcome measures were cure (both stone and symptom free), partial success (symptom free but with residual stone fragments), and failure (symptomatic with residual stone/fragments). Calculi were successfully removed from 3,775/4,691 (80.5%). Treatment was partially successful in 782/4,691 (16.7%), and these patients received no further treatment or were lost to follow-up. Treatment failed, and salivary glands had to be removed in 134/4,691 patients (2.9%).

ESWL

This was adopted as primary treatment in 2,102 patients (Fig. 1) (1,364 submandibular and 738 parotid). Complete success was achieved in 1,072/2,102 patients (50.9%), the proportion differing between sites (submandibular 557/1,364, 40.8%, parotid 515/738, 69.8%). The technique was partially successful in a further 544 patients (25.9%) (half were submandibular, and a quarter were parotid stones) of whom 248 patients (33.6%) went on to be cured by other minimally invasive methods. The overall success rate was 1,320/2,102 (62.8%) with partial success in 672/2,102 (32.0%) and removal of the gland in 110/2,102 (5.2%).

Retrieval of Small Mobile Stones by Basket or Microforceps

No attempt has been made to distinguish between retrieval of calculi with a basket or forceps either under

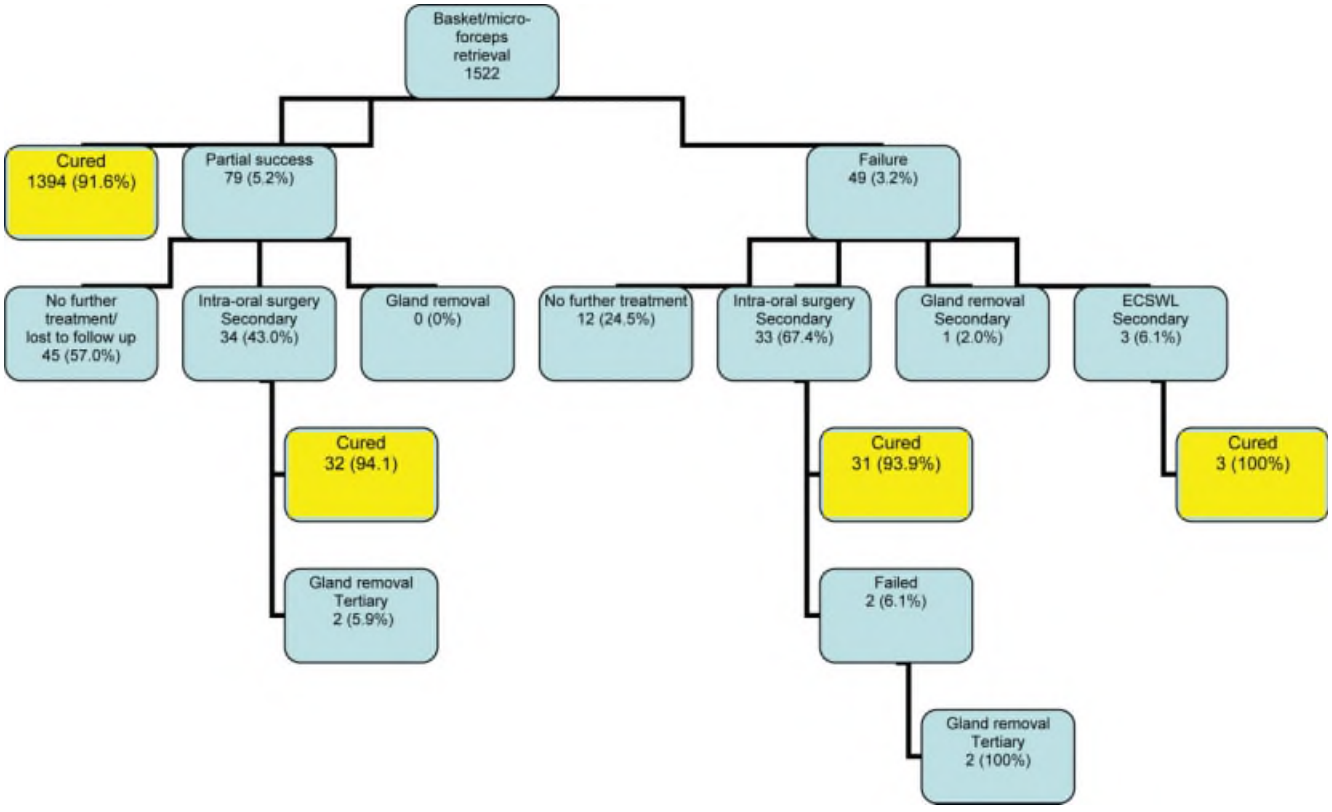

Fig. 2. Summary of treatment of 1,522 patients with basket or microforceps retrieval as first line intervention. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

radiologic or endoscopic control. A total of 1,522 patients were treated by these techniques primarily (Fig. 2). Stones were eradicated in 1,394 (91.6%); some stone fragments persisted, and partial success was recorded in 79/1,522 (5.2%) and treatment was unsuccessful in 49 (3.2%).

Seventy patients were subsequently treated by other techniques, and 52 refused further intervention or were lost to follow-up. After further treatment the overall success rate was 1,460/1,522 (95.9%), and partial success was achieved in 57/1,522 (3.7%). In 5/1,522 patients (0.3%) the salivary gland was removed.

Intraoral Removal of Submandibular Stones

Submandibular calculi were removed intraorally as a primary procedure from 1,021 patients (Fig. 3). Salivary calculi were eradicated in 949/1,021 primary cases (92.9%). The technique was equally successful when treating secondary or tertiary cases. Submandibular glands were removed in 18/1,021 cases (1.8%).

Endoscopically Assisted Release of Parotid Stones

Open release of parotid stones was an uncommon event (46), and was successful in 42/46 (91%). In three patients the parotid duct was damaged and had to be tied, with no ill effects, and the gland was removed because of persistent symptoms in one patient.

DISCUSSION

The current standard of care for symptomatic stones in the posterior portion of the parotid or submandibular ducts is excision of the gland. If the data regarding the incidence of salivary obstruction in England and Wales are correct, then many patients are having their salivary glands excised unnecessarily each year. As a result of adopting a minimally invasive policy in a large group of patients with salivary calculi, over 80% of stones were retrieved successfully, leaving a functionally intact salivary gland system; only 2.8% of patients required excision of the gland. The remaining patients have retained stone fragments, but these are not symptomatic. Our data covers a period of 14 years. Initial approaches to stone removal were not as effective as today, so current results are likely to be better than reported in this study. The success of minimally invasive treatment has been dependent upon the miniaturisation of instruments including microendoscopes, forceps, and dedicated lithotripters. This has been complemented by a change in surgical perspective toward the preservation of the gland.

The evidence suggests that after removal of a stone the function of the gland recovers, although not to its original level.[12–17] The general belief that obstruction of the proximal duct causes irreversible damage to the salivary glands does not seem to be borne out by studies in animals[4,5] or humans,[6–9] and is supported by the present data. We have shown conclusively that most stones

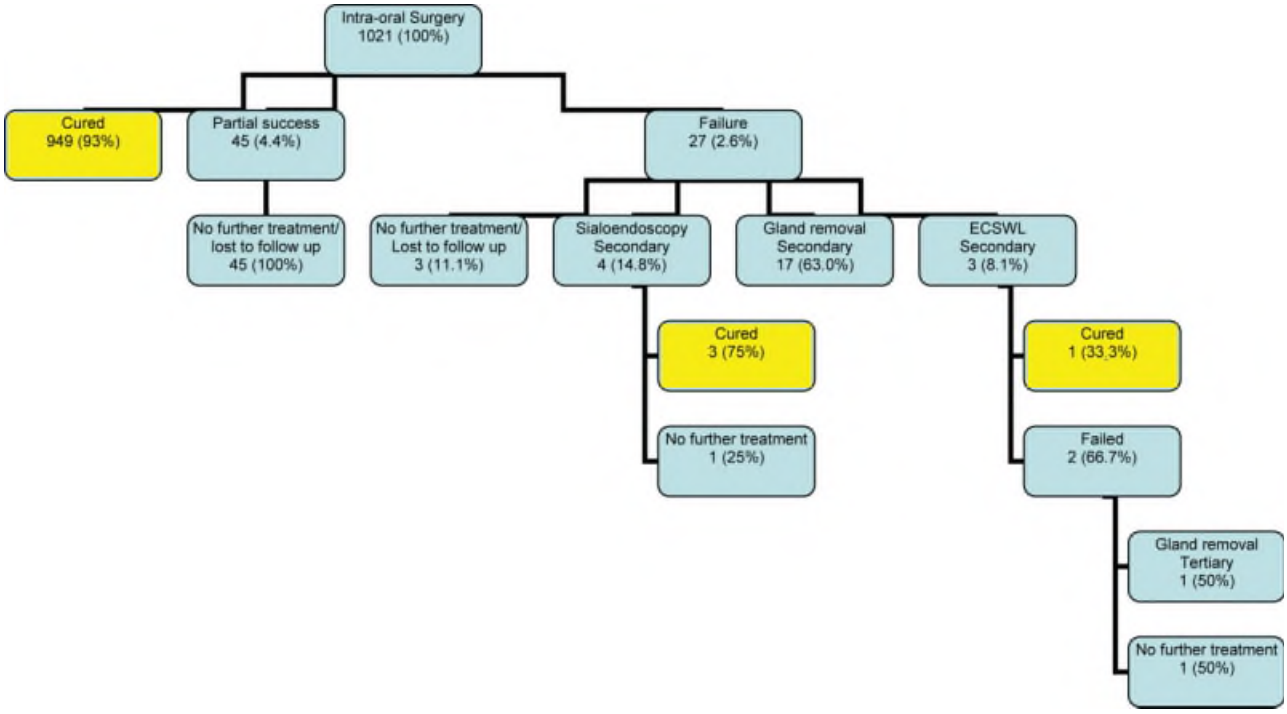

Fig. 3. Summary of treatment of 1,021 patients with intraoral Surgery as first line intervention. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

can be retrieved from the salivary glands, in many instances the patients being treated as day cases or outpatients, leaving a functioning gland in place.

As with renal calculi the four minimally invasive techniques are interchangeable, and the technique used first depends on clinical findings in each case. The choice is also influenced by the availability of equipment. High success rates can be achieved without access to all four treatment modalities (lithotripsy, endoscopic, or radiographic basket and microforceps retrieval, intraoral surgery, and extra-oral parotid surgery) because of the degree of overlap in their use. The centers with access to all four treatment modalities (Erlangen, London, and Milan) have independently moved toward similar protocols, whereas in Ashkelonl where no lithotripter was available, treatment has focused on intraoral endoscopic removal.

The protocol that has evolved is for small mobile stones to first be approached by basket or forceps under either radiologic or endoscopic control (1,522/4,691 [32.4%] of cases treated). The eradication of stones by extracorporeal lithotripsy is more effective in the parotid than in the submandibular gland.[3,18–20] and this modality is reserved mainly for fixed parotid stones of less than 7 mm in diameter[3,18] (738/4,691 [15.7%] of cases treated). In the submandibular gland the trend was to manage stones in the middle or proximal duct by intraoral surgery rather than lithotripsy[3] (1,021/4,691 [21.8%] of cases treated) because the treatment could be completed in one session. The approach to parotid gland stones was influenced by the risk of surgery to the facial nerve and the need for an extra-oral surgical approach, and so is avoided where possible. Lithotripsy is successful in the parotid with 60% of patients rendered stone free and a further 30% relieved of symptoms,[3,18,19] although retaining stone fragments. It is only recalcitrant symptomatic stones that require endoscopically assisted surgical removal.[10,11] This technique was used sparingly (46/4,691 [1%] of cases treated).

The implication of the present study is that the treatment of obstructive salivary stones will probably have to be centralized on a population of about 1 to 2 million. This will provide the experience necessary to use minimally invasive methods and, second, validate investment in staff and equipment to provide the service.

Although the current patients have been followed up for a median of over 5 years, further long-term assessment is required to confirm the benefits of the minimally invasive approach. Further research is also required to confirm the reparative powers of salivary glands after obstruction. At present, minimally invasive techniques seem to be the optimal way to manage salivary stones.

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