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TRANSORAL ROBOTIC SURGERY FOR HILO-PARENCHYMAL SUBMANDIBULAR STONES: STEP-BY-STEP ICONOGRAHIC AND REASONED APPROACH

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Abstract:	The conservative trans-oral approach to hilo-parenchymal submandibular stones has been proposed as an alternative to traditional sialadenectomy; the main purpose is to obtain gland preservation and to eliminate the risk of the cervical scar and the damage of the marginal mandibular branch of the facial nerve. The spread of transoral robotic surgery favoured its application not only for oropharynx but also for the anterior oral cavity. We describe a transoral robotic approach for hiloparenchymal submandibular stones. Two patients with a right and a left hiloparenchymal submandibular stone of 15 and 8 mm, respectively, underwent the removal of the stone with transoral robotic surgery using the Si Da Vinci Surgical Robot. The procedure was successfully performed and tolerated with one-night hospitalization; no complications such as lingual nerve damage, painful gland swelling, infection and ranula were encountered. The patients were followed up clinically and ultrasonographically in the first three months to verify symptom relief and the persistence of stones but no symptoms or stones were found. The transoral robotic surgical approach seems to be safe and adequate for the conservative management of large hiloparenchymal submandibular stones; an adequate diagnosis together with a proper docking and approach to the oral floor is mandatory.

Cover letter

Managing Editor
International Journal of Oral and Maxillo-Facial Surgery

Milan, 18th May 2019

Dear Editor,

herewith enclosed the revised manuscript titled “TRANSORAL ROBOTIC SURGERY FOR HILO-PARENCHYMAL SUBMANDIBULAR STONES: STEP-BY-STEP ICONOGRAHIC AND REASONED APPROACH for the publication in the journal “International Journal of Oral & Maxillofacial Surgery”.

All reviewer’s suggestions were pointed out: the text was shortened by putting Patients and Methods, surgical procedure and follow-up altogether and by eliminating useless sentences by the text. Figures 3a, 3c and 3d were deleted by leaving only Figure 3 as an intraoperative photo. A track change manuscript was also added to the submission with all corrections highlighted in bold type.

This study is the result of the integration of two different long-term experiences on minimally invasive salivary gland management and transoral robotic surgery.

Looking forward to receive any information from you.

Sincerely yours,

Pasquale Capaccio, MD
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*Declaration Form

Journal: INTERNATIONAL JOURNAL OF ORAL & MAXILLOFACIAL SURGERY

Title of Paper:
TRANSORAL ROBOTIC SURGERY FOR HILO-PARENCHYMAL SUBMANDIBULAR STONES: STEP-BY-STEP ICONOGRAHIC AND REASONED APPROACH

Declarations

The following additional information is required for submission. Please note that failure to respond to these questions/statements will mean your submission will be returned to you. If you have nothing to declare in any of these categories then this should be stated.

Please state any conflict of interests. A conflict of interest exists when an author or the author's institution has financial or personal relationships with other people or organisations that inappropriately influence (bias) his or her actions. Financial relationships are easily identifiable, but conflicts can also occur because of personal relationships, academic competition, or intellectual passion. A conflict can be actual or potential, and full disclosure to The Editor is the safest course.

Competing Interests

none

Please state any sources of funding for your research

none

DOES YOUR STUDY INVOLVE HUMAN OR ANIMALSUBJECTS? Please cross out whichever is not applicable

YES x

NO

If your study involves human or animal subjects or records of human patients you MUST have obtained ethical approval. Ethics approval or exemption are required for retrospective studies on patients' records

Please state whether Ethical Approval was given, by whom and the relevant Judgement's reference number.

The study has been approved by the appropriate local Ethical Committee according to the principles stated in the Declaration of Helsinki

Patient Consent – please state whether written patient consent has been obtained. Please note that patient consent is always required to publish clinical photographs. If patient consent was not required, please state this. The Journal may request a copy of this consent prior to acceptance

The patients gave informed consent to the study

Please add a statement to confirm that all authors have viewed and agreed to the submission

All authors confirm that have viewed and agreed the submission

This information must also be inserted into your manuscript under the acknowledgements section prior to the References.

Ethics approval

CEIIAV COMITATO ETICO IRST IRCCS AVR

SERVIZIO SANITARIO REGIONALE EMILIA-ROMAGNA

Sede Operativa c/o Istituto Scientifico Romagnolo per lo Studio e la Cura dei Tumori IRST - IRCCS Srl - Via Piero Maroncelli 40, 47014 Meldola (FC)

Reg. sperimentazioni n. 1335

Prot. 2576/2015
I.5/66

Meldola (FC), 20 APR. 2015

Parere espresso nella seduta del 16.04.2015

Questo Comitato Etico, istituito ai sensi del D.M. 08.02.2013 con Delibera IRST IRCCS n° 11 del 28.06.2013, opera conformemente alle modalità previste dal Decreto Legislativo n. 211 del 2003 e nel rispetto delle norme di Buona Pratica Clinica (GCP-ICP) e degli adempimenti previsti dall'allegato 1 al Decreto Ministeriale del 15/07/97 e successivi aggiornamenti.

	Presente	Assente
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Dr.ssa Anita Zeneli Rapp.te area professioni sanitarie	■	□

I membri del Comitato dichiarano che si asterranno dal pronunciarsi su quelle sperimentazioni per le quali possa sussistere un conflitto di interessi di tipo diretto o indiretto.

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Protocollo	ORL 02 15 SWALLOWING
Titolo studio	Studio clinico osservazionale valutativo della deglutizione nei pazienti operati con tors per sindrome delle apnee notturne ostruttive
Fase	n/a
EudraCT	n/a
Proponente	AUSL Romagna
Ricercatore	Dr. Vicini, U.O. Otorinolaringoiatria – Forlì, AUSL Romagna
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Documentazione presa in esame:

- Lettera di Intenti_swallowing
- Protocollo di Studio_swallowing Versione 1.0 del 25/02/2015
- Sinossi del protocollo_swallowing vers. 1.0 del 23.02.2015
- Modulo di Consenso Informato con consenso al trattamento dei dati personali_swallowing Versione 1.0 del 25/02/2015
- Foglio Informativo per il paziente_swallowing Versione 1.0 del 25/02/2015
- Lettera informativa per il Medico Curante_swallowing Versione 1.0 del 25/02/2015
- CV del Principal Investigator
- Dichiarazione di studio-no profit _swallowing
- Studio NO PROFIT - Modulistica a cura dello Sperimentatore_swallowing
- Modulo Piattaforma_swallowing

Il Comitato Etico, esaminata la documentazione sopra elencata, che rispetta i requisiti della normativa in materia di ricerca no-profit, esprime il seguente parere:

☒ Approvata
☐ Approvata con osservazioni
☐ Non approvata per le motivazioni indicate
☐ Sospesa in attesa delle richieste

Si richiede che questo Comitato Etico sia informato dell'inizio della sperimentazione, della sua conclusione o di eventuale interruzione, nonché di ogni successivo emendamento al protocollo e degli eventi avversi, seri o inattesi, insorti nel corso dello studio, che potrebbero influire sulla sicurezza dei soggetti o sul proseguimento dello studio.

Si rammenta inoltre che, ai sensi della Cir. Min. Salute n. 6 del 02/09/2002 e del D.M. 12/05/2006, è compito dello Sponsor/Promotore della sperimentazione al termine della sperimentazione rendere pubblici i risultati della ricerca entro i termini stabiliti.

Prof. Stefano Cascinu
Presidente

Approval of Ethical Committee

CEIIAV Ethical Committee IRST IRCCS AVR Regional Health System Emilia Romagna

Experimentation Reference no. 1335

Opinion expressed during meeting on 16-04-15.

Observational Clinical study on swallowing for patients undergoing transoral robotic surgery (TORS) for OSAS proposed by Dr. Claudio Vicini.

The ethical Committee, after examination of all listed documents, that respect all rules of non profit research, approves the proposal.

Prof. Stefano Casdinu

President of Ethical Committee

Point-by-point answer to reviewer’s suggestions of the manuscript titled “TRANSORAL ROBOTIC SURGERY FOR HILO-PARENCHYMAL SUBMANDIBULAR STONES: STEP-BY-STEP ICONOGRAHIC AND REASONED APPROACH”.

1) the text was shortened by putting Patients and Methods, surgical procedure and follow-up altogether;
2) the text was written in a more concise way and by eliminating useless sentences by the text.
3) Figures 3a, 3c and 3d were deleted by leaving only Figure 3 as an intraoperative photo.
4) A track change manuscript was also added to the submission with all corrections highlighted in bold type.

TITLE PAGE

TRANSORAL ROBOTIC SURGERY FOR HILO-PARENCHYMAL SUBMANDIBULAR STONES: STEP-BY-STEP ICONOGRAHIC AND REASONED APPROACH

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Running title: Transoral robotic surgery for submandibular stones

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ABSTRACT

The conservative trans-oral approach to hilo-parenchymal submandibular stones has been proposed as an alternative to traditional sialadenectomy; the main purpose is to obtain gland preservation and to eliminate the risk of the cervical scar and the damage of the marginal mandibular branch of the facial nerve. The spread of transoral robotic surgery favoured its application not only for oropharynx but also for the anterior oral cavity. We describe a transoral robotic approach for hiloparenchymal submandibular stones.

In January 2019 two patients with a right and a left hiloparenchymal submandibular stone of 15 and 8 mm, respectively, underwent the removal of the stone with transoral robotic surgery using the Si Da Vinci Surgical Robot.

The procedure was successfully performed and tolerated with one-night hospitalization; no complications such as lingual nerve damage, painful gland swelling, infection and ranula were encountered. The patients were followed up clinically and ultrasonographically in the first three months to verify symptom relief and the persistence of stones but no symptoms or stones were found.

The transoral robotic surgical approach seems to be safe and adequate for the conservative management of large hiloparenchymal submandibular stones; an adequate diagnosis together with a proper docking and approach to the oral floor is mandatory.

Key words: *Submandibular stones; transoral surgery; transoral robotic surgery; CBCT*

INTRODUCTION

Most of salivary stones involve the submandibular gland (80-90%) and the most frequent locations are the distal tract of the duct, the hilum, and the hiloparenchymal area (1,2,3,4). Although sialadenectomy is still the most widely used procedure to treat proximal and hiloparenchymal submandibular stones (HPSMS)(5,6) with its known risks (6,7), the conservative transoral approach has emerged as a valid alternative (8,9,10,11) and this trend has increased after the introduction of interventional sialendoscopy (12). In fact, it has been shown that the trans-oral removal of large (>7 mm) and deeply located submandibular stones is safe, effective (11,13,14,15) and highly successful in terms of stone removal and symptom relief (13,14,15), especially if an adequate diagnostic process based on clinical oral floor palpation, ultrasonography (US) and cone beam tomography (CBCT) is adopted (16,17,18,19). Several stone recurrences have been described after performing a transoral surgical approach by means of loupes lens-guided surgery (13,14). A possible partial explanation of this finding is the difficulty of the main surgeon in obtaining an adequate visualization of anatomical landmarks in the oral floor after parenchymal incision due to the narrow and deep surgical field. The possibility to undergo a sialendoscopic check through the main preserved duct after the removal of the hiloparenchymal stone can help the surgeon in reducing the risk of leaving residual stone fragments in the parenchyma but, the narrow, deep and bloodish surgical field do not guarantee a clear vision. Recently, the application of robotic technology in the head and neck field (20,21,22,23,24) and, in particular, the transoral robotic approach has favoured the spread of this procedure not only for oropharyngeal disorders (20) but also for anterior oral floor diseases (25). A transoral robot-assisted management of large submandibular gland stones and a transoral robotic submandibular gland removal have been recently described in case reports or small and heterogeneous series of patients (26-29); these initial experiences appear very interesting although they do not clearly specify certain steps of the procedure such as docking that, in our opinion, should be considered one of the mainstay of the surgical robotic technique (21). Our main goal was to provide a step-by-step reasoned description of all phases of the transoral robotic approach to hiloparenchymal submandibular stones through the oral floor.

PATIENTS AND METHODS

In January 2019 a male patient (56 years' old) with a right hiloparenchymal submandibular stone (15 mm) and a female patient (43 years' old) with a left hiloparenchymal submandibular stone (8 mm) underwent a transoral robotic surgical removal by means of a Si Da Vinci surgical robot at the Head and Neck Department, ENT & Oral Surgery Unit of G.B. Morgagni – L. Pierantoni Hospital, Forlì, Italy. The patients underwent pre-operative US and Doppler US assessments (Hitachi H21, 7.5 MHz, Hitachi High Technology Corporation Ltd., Tokyo, Japan), a cone beam 3D CT (Figure 1a and 1b), and a clinical evaluation to establish the size of the stone and its location, which was clinically defined as hilo-parenchymal when only the distal margin of the stone was detectable during bimanual palpation of the oral floor (13). **The exclusion criteria were an inability to open the mouth sufficiently and non- palpable stones (13,14).** The study has been approved by the appropriate local Ethical Committee according to the principles stated in the Declaration of Helsinki; the patients gave informed consent to the study.

The procedure was performed under general anesthesia with a nasotracheal tube and a Molt mouth gag was introduced. The Si Da Vinci surgical robot (Intuitive Surgical, Sunnyvale, CA, USA) was docked behind the head of the patient with an angle of 30° (Figure 2) and a 30° endoscope downward facing was placed into the scope holder. Two robotic five-millimetre instruments, the Maryland dissector and monopolar cautery with spatula tip were placed into arms 1 and 3 according to the side of the stone. A squarish tongue retractor, covered by a rough gauze, was positioned to retract the tongue to the contralateral side and to flatten the oral floor. The location of the stone was marked on the mucosal surface by means of palpation**. The robotic surgeon sat at the surgical console and the assistant surgeon was positioned at the contralateral side of the affected gland and used suction and tongue retractor.** The duct was identified and cannulated using a salivary probe (Bowman probes, Karl Storz, Tuttlingen, Germany). **Using the monopolar cautery of the robot set at 15W of coagulation, an oblique mucosal incision was made over the marked area near the papillar region of Wharton's duct, along the floor of the mouth toward the second**

molar. A blunt dissection of the loose areolar tissue was performed medially to the internal edge of the sublingual gland, which was rotated laterally to expose Wharton's duct (Figure 3). The lingual nerve is easily identified running obliquely from the tongue, passing under the duct, and then ascending medially through the tail of the sublingual gland over Wharton's duct. **The lingual nerve was mobilised from the duct and retracted medially to visualise the gland hilum, which was moved upward to the submandibular gland area by means of external finger pressure of the assistant surgeon who was also able to palpate the stone to verify the exact location before hiloparenchymal incision.** An incision was made over the hilar region to find out the calculus by means of the monopolar cautery; a gentle dissection with the spatula and the help of the Maryland dissector was done to detach and deliver the stone "en bloc" from the parenchyma **(Figure 3). The stone was then measured in size and compared to the shape obtained with the cone beam 3D CT scan (Figure 1b e 1d).** The docking was removed. The incisional cavity was irrigated with saline solution to clear any debris. The robotic surgical procedure was concluded and surgery continued by a traditional transoral approach by putting and a hemostatic and anti-microbial fibrillar surgical net (Tabotamp, Johnson & Johnson Medical Limited, Gargrave, Skipton, UK) over the hilar opening to avoid the risk of stricture or stenosis. Finally, the wound was irrigated with antibiotic solution (rifampicin), and the oral floor was sutured using resorbable stitches (3.0 Vicryl). The sialendoscopic check (0.8-1.1 mm, Erlangen sialoendoscopes, Karl Storz Co., GmbH, Tuttlingen, Germany, always available on the surgical table) was not done because of the perfect concordance between the removed stone and imaging. All of the patients received antibiotic therapy (amoxicillin and clavulanic acid) for one week after the operation; steroids were also administered in the case of oral floor oedema. **The patients were clinically re-examined after one week, one month and three months and they were also offered an US examination three months after the procedure in order to ascertain any possible ductal system dilation or residual stones.**

RESULTS

The stones were successfully removed by means of transoral robotic surgery (TORS); the stone located in the right submandibular gland was removed in multiple pieces while the one located in left submandibular gland was removed “en bloc”; in both cases there was a perfect concordance between size and shape of the stone and three-dimensional cone beam CT. The mean time duration of the procedure was 50 minutes (55 minutes for the right stone and 45 minutes for the left stone including 15 minutes for the robotic setting and 10 minutes for the suture). No intra-operative nor post-operative complications such as lingual nerve injury, duct stenosis, ranula, persistent gland swelling were encountered. The female patient only referred a mild, transitory painful gland few days after the procedure; interestingly, a ductal kinking at the proximal third of the duct was observed during the procedure. Both the patients were discharged the day after surgery. Neither residual stones nor duct dilation was observed at three months postoperative US evaluation.

DISCUSSION

The trans-oral approach nowadays represents an effective and gland-preserving alternative to sialadenectomy for deep hilo-parenchymal stones (9,11-15). The main limitations of previously published studies are that the majority of them describes heterogeneous series of patients in which stones located in the main submandibular duct are also encountered. At the same time, the so-called combined sialendoscopy-assisted trans-oral procedure (particularly useful if the main duct is incised during the procedure) has been advocated as the mainstay for parenchymal stones (13,14). However, it is questionable how post-operative sialendoscopy might influence the result of trans-oral stone removal, considering the bloodish and narrow intraoperative surgical field.

We describe a step-by-step iconographic and reasoned transoral robotic approach to hilo-parenchymal submandibular stones by assuming that all the anatomical structures encountered in the oral floor have to be preserved to obtain a successful result in terms of functional preservation of the gland. Two large hilo-parenchymal submandibular stones were successfully removed with TORS; the smaller stone (8 mm) was removed “en bloc” while the larger one (15 mm) was removed in multiple pieces. The piecemeal extraction of large parenchymal stones is relatively frequent during traditional transoral approach due to the fact that stones are impacted and adherent to parenchymal gland tissue and this partially justifies the 11,2% of residual stones after the transoral approach as the result of long term experience (13,14); in this regard, postoperative sialendoscopic check of the hilo-parenchymal incisional area is not always useful to identify deep residual microliths that had cracked during the removal of the main stone. Based on our long term surgical experience (14) a diagnostic process based on US and cone beam 3D CT has been adopted in order to compare intraoperatively 3D images to the size and shape of the extracted stone and to avoid the risk of leaving ancillary microliths near to the main stone, not detected during US, also in experienced hands.

The transoral robotic surgical removal of submandibular parenchymal stones was safe as no intraoperative or postoperative untoward effects such as tingling of the tip of the tongue, ranula, persistent lingual nerve injury or recurrent sialadenitis due to hilar stenosis were observed as otherwise reported in other clinical experiences (11). The successful result in terms of safety is in part due to the fact that the three dimensional view of the surgical field in the robot console permitted the main surgeon to have a clear anatomical delineation and enhanced depth perception of the oral floor, lingual nerve and Wharton's duct, sublingual gland and hiloparenchymal submandibular area. Woo et al. (30) described their experience on transoral approach for deep stones by removing a piece of sublingual gland; this approach appears to be risky and harmful for the potential occurence of ranula. Another interesting observation of our initial experience is that the blunt dissection with the spatula supported by the gentle take of the Maryland forceps guaranteed a clean surgical field with small amount of blood visible thus favouring a better view of the deep surgical plane. Very few information about the docking of the robot in the operating theatre for the removal of parenchymal submandibular stones can be extracted from literature (26-28). In our experience (21-23) an adequate docking of the robot is essential for a precise robotic procedure; contrarily to what is currently performed for other transoral procedures, the robot should be positioned behind the head of the patient and on the opposite side with respect to the involved gland and an angle of 30°. Finally, to obtain a better view of the posterior part of the oral floor a 30° endoscope downward facing was inserted in the arm 2 of the robot. As previously described in the literature (13,14), traditional transoral loops lens-guided surgery is performed with the help of three surgeons, i.e. the main surgeon and two assistant surgeons (one for the oral field and one for the push up of the submandibular gland from the neck). In our initial experience, we observed that the assistant surgeon can do simultaneously the suction, the tissue traction, and the push up of the gland from the neck to better expose the parenchyma in the oral floor thus avoiding the need of the third surgeon; furthermore, all the surgical steps can be observed by the surgical staff by video monitoring. Finally, the robotic surgical time was relatively fast (20 and 30 minutes); in our opinion, by increasing the number of robotic procedures, the surgical time will further reduce thus minimizing the tissue damage of the oral floor and subjective patient complain.

CONCLUSIONS

The transoral robotic surgical removal of large (>7 mm) hilo-parenchymal submandibular stones is a safe and effective conservative surgical procedure, in line with other initial experience (26-28). Thanks to the three dimensional and enhanced depth perception of the oral floor, the robotic approach preserves the main submandibular duct, the sublingual gland, and the lingual nerve and allows the stone to be removed through a minimal incision in the hilo-parenchymal region, thus guaranteeing the functional preservation of the obstructed gland. The preservation of the Wharton's duct allows to undergo a sialendoscopic access through the natural ostium in the case of residual microliths or to perform a new conservative transoral approach to the parenchyma in the case of a discrete stone recurrence. An adequate pre-operative clinical and radiological assessment by means of US and cone beam 3D CT evaluation is always advisable in order to locate the stone precisely and minimise the risk of failure. A proper docking of the robot together with a precise endoscopic view is mandatory to help the surgical staff in reaching a successful conservative result.

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All authors confirm that have viewed and agreed the submission.

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FIGURE LEGENDS

Figure 1. 1a) Cone beam CT 3D reconstruction of the right 15 mm submandibular parenchymal stone; 1b) Shape of the right stone removed by robotic surgery; 1c) Cone beam CT 3D reconstruction of the left 8 mm submandibular parenchymal stone; 1d) Shape of the left stone removed by robotic surgery.

Figure 2. Docking of the Si Da Vinci Robot positioned behind the head of the patient on the opposite side of the affected gland with an angle of 30°.

Figure 3. The stone extracted from the parenchyma and the relationship with the Wharton’s duct and the lingual nerve.

TITLE PAGE

TRANSORAL ROBOTIC SURGERY FOR HILO-PARENCHYMAL SUBMANDIBULAR STONES: STEP-BY-STEP ICONOGRAHIC AND REASONED APPROACH

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Running title: Transoral robotic surgery for submandibular stones

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ABSTRACT

The conservative trans-oral approach to hilo-parenchymal submandibular stones has been proposed as an alternative to traditional sialadenectomy; the main purpose is to obtain gland preservation and to eliminate the risk of the cervical scar and the damage of the marginal mandibular branch of the facial nerve. The spread of transoral robotic surgery favoured its application not only for oropharynx but also for the anterior oral cavity. We describe a transoral robotic approach for hiloparenchymal submandibular stones.

In January 2019 two patients with a right and a left hiloparenchymal submandibular stone of 15 and 8 mm, respectively, underwent the removal of the stone with transoral robotic surgery using the Si Da Vinci Surgical Robot.

The procedure was successfully performed and tolerated with one-night hospitalization; no complications such as lingual nerve damage, painful gland swelling, infection and ranula were encountered. The patients were followed up clinically and ultrasonographically in the first three months to verify symptom relief and the persistence of stones but no symptoms or stones were found.

The transoral robotic surgical approach seems to be safe and adequate for the conservative management of large hiloparenchymal submandibular stones; an adequate diagnosis together with a proper docking and approach to the oral floor is mandatory.

Key words: *Submandibular stones; transoral surgery; transoral robotic surgery; CBCT*

INTRODUCTION

Most of salivary stones involve the submandibular gland (80-90%) and the most frequent locations are the distal tract of the duct, the hilum, and the hiloparenchymal area (1,2,3,4). Although sialadenectomy is still the most widely used procedure to treat proximal and hiloparenchymal submandibular stones (HPSMS)(5,6) with its known risks (6,7), the conservative transoral approach has emerged as a valid alternative (8,9,10,11) and this trend has increased after the introduction of interventional sialendoscopy (12). In fact, it has been shown that the trans-oral removal of large (>7 mm) and deeply located submandibular stones is safe, effective (11,13,14,15) and highly successful in terms of stone removal and symptom relief (13,14,15), especially if an adequate diagnostic process based on clinical oral floor palpation, ultrasonography (US) and cone beam tomography (CBCT) is adopted (16,17,18,19). Several stone recurrences have been described after performing a transoral surgical approach by means of loupes lens-guided surgery (13,14). A possible partial explanation of this finding is the difficulty of the main surgeon in obtaining an adequate visualization of anatomical landmarks in the oral floor after parenchymal incision due to the narrow and deep surgical field. The possibility to undergo a sialendoscopic check through the main preserved duct after the removal of the hiloparenchymal stone can help the surgeon in reducing the risk of leaving residual stone fragments in the parenchyma but, the narrow, deep and bloodish surgical field do not guarantee a clear vision. Recently, the application of robotic technology in the head and neck field (20,21,22,23,24) and, in particular, the transoral robotic approach has favoured the spread of this procedure not only for oropharyngeal disorders (20) but also for anterior oral floor diseases (25). A transoral robot-assisted management of large submandibular gland stones and a transoral robotic submandibular gland removal have been recently described in case reports or small and heterogeneous series of patients (26-29); these initial experiences appear very interesting although they do not clearly specify certain steps of the procedure such as docking that, in our opinion, should be considered one of the mainstay of the surgical robotic technique (21). Our main goal was to provide a step-by-step reasoned description of all phases of the transoral robotic approach to hiloparenchymal submandibular stones through the oral floor.

PATIENTS AND METHODS

In January 2019 a male patient (56 years' old) with a right hiloparenchymal submandibular stone (15 mm) and a female patient (43 years' old) with a left hiloparenchymal submandibular stone (8 mm) underwent a transoral robotic surgical removal by means of a Si Da Vinci surgical robot at the Head and Neck Department, ENT & Oral Surgery Unit of G.B. Morgagni – L. Pierantoni Hospital, Forlì, Italy. The patients underwent pre-operative US and Doppler US assessments (Hitachi H21, 7.5 MHz, Hitachi High Technology Corporation Ltd., Tokyo, Japan), a cone beam 3D CT (Figure 1a and 1b), and a clinical evaluation to establish the size of the stone and its location, which was clinically defined as hilo-parenchymal when only the distal margin of the stone was detectable during bimanual palpation of the oral floor (13). The exclusion criteria were an inability to open the mouth sufficiently and non- palpable stones (13,14). The study has been approved by the appropriate local Ethical Committee according to the principles stated in the Declaration of Helsinki; the patients gave informed consent to the study.

The procedure was performed under general anesthesia with a nasotracheal tube and a Molt mouth gag was introduced. The Si Da Vinci surgical robot (Intuitive Surgical, Sunnyvale, CA, USA) was docked behind the head of the patient with an angle of 30° (Figure 2) and a 30° endoscope downward facing was placed into the scope holder. Two robotic five-millimetre instruments, the Maryland dissector and monopolar cautery with spatula tip were placed into arms 1 and 3 according to the side of the stone. A squarish tongue retractor, covered by a rough gauze, was positioned to retract the tongue to the contralateral side and to flatten the oral floor. The location of the stone was marked on the mucosal surface by means of palpation. The robotic surgeon sat at the surgical console and the assistant surgeon was positioned at the contralateral side of the affected gland and used suction and tongue retractor. The duct was identified and cannulated using a salivary probe (Bowman probes, Karl Storz, Tuttlingen, Germany). Using the monopolar cautery of the robot set at 15W of coagulation, an oblique mucosal incision was made over the marked area near the papillar region of Wharton's duct, along the floor of the mouth toward the second molar. A blunt dissection of the loose areolar tissue was performed medially to the internal edge of the sublingual gland, which was rotated laterally to expose Wharton's duct (Figure 3). The lingual nerve is easily identified running obliquely from the tongue, passing under the duct, and then ascending medially through the tail of the sublingual gland over Wharton's duct. The lingual nerve was mobilised from the duct and retracted medially to visualise the gland hilum, which was moved upward to the submandibular gland area by means of external finger pressure of the assistant surgeon who was also able to palpate the stone to verify the exact location before hiloparenchymal incision. An incision was made over the hilar region to find out the calculus by means of the monopolar cautery; a gentle dissection with the spatula and the help of the Maryland dissector was done to detach and deliver the stone "en bloc" from the parenchyma (Figure 3). The stone was then measured in size and compared to the shape obtained with the cone beam 3D CT scan (Figure 1b e 1d). The docking was removed. The incisional cavity was irrigated with saline solution to clear any debris. The robotic surgical procedure was concluded and surgery continued by a traditional transoral approach by putting and a hemostatic and anti-microbial fibrillar surgical net (Tabotamp, Johnson & Johnson Medical Limited, Gargrave, Skipton, UK) over the hilar opening to avoid the risk of stricture or stenosis. Finally, the wound was irrigated with antibiotic solution (rifampicin), and the oral floor was sutured using resorbable stitches (3.0 Vicryl). The sialendoscopic check (0.8-1.1 mm, Erlangen sialoendoscopes, Karl Storz Co., GmbH, Tuttlingen, Germany, always available on the surgical table) was not done because of the perfect concordance between the removed stone and imaging. All of the patients received antibiotic therapy (amoxicillin and clavulanic acid) for one week after the operation; steroids were also administered in the case of oral floor oedema. The patients were clinically re-examined after one week, one month and three months and they were also offered an US examination three months after the procedure in order to ascertain any possible ductal system dilation or residual stones.

RESULTS

The stones were successfully removed by means of transoral robotic surgery (TORS); the stone located in the right submandibular gland was removed in multiple pieces while the one located in left submandibular gland was removed “en bloc”; in both cases there was a perfect concordance between size and shape of the stone and three-dimensional cone beam CT. The mean time duration of the procedure was 50 minutes (55 minutes for the right stone and 45 minutes for the left stone including 15 minutes for the robotic setting and 10 minutes for the suture). No intra-operative nor post-operative complications such as lingual nerve injury, duct stenosis, ranula, persistent gland swelling were encountered. The female patient only referred a mild, transitory painful gland few days after the procedure; interestingly, a ductal kinking at the proximal third of the duct was observed during the procedure. Both the patients were discharged the day after surgery. Neither residual stones nor duct dilation was observed at three months postoperative US evaluation.

DISCUSSION

The trans-oral approach nowadays represents an effective and gland-preserving alternative to sialadenectomy for deep hilo-parenchymal stones (9,11-15). The main limitations of previously published studies are that the majority of them describes heterogeneous series of patients in which stones located in the main submandibular duct are also encountered. At the same time, the so-called combined sialendoscopy-assisted trans-oral procedure (particularly useful if the main duct is incised during the procedure) has been advocated as the mainstay for parenchymal stones (13,14). However, it is questionable how post-operative sialendoscopy might influence the result of trans-oral stone removal, considering the bloodish and narrow intraoperative surgical field.

We describe a step-by-step iconographic and reasoned transoral robotic approach to hilo-parenchymal submandibular stones by assuming that all the anatomical structures encountered in the oral floor have to be preserved to obtain a successful result in terms of functional preservation of the gland. Two large hilo-parenchymal submandibular stones were successfully removed with TORS; the smaller stone (8 mm) was removed “en bloc” while the larger one (15 mm) was removed in multiple pieces. The piecemeal extraction of large parenchymal stones is relatively frequent during traditional transoral approach due to the fact that stones are impacted and adherent to parenchymal gland tissue and this partially justifies the 11,2% of residual stones after the transoral approach as the result of long term experience (13,14); in this regard, postoperative sialendoscopic check of the hilo-parenchymal incisional area is not always useful to identify deep residual microliths that had cracked during the removal of the main stone. Based on our long term surgical experience (14) a diagnostic process based on US and cone beam 3D CT has been adopted in order to compare intraoperatively 3D images to the size and shape of the extracted stone and to avoid the risk of leaving ancillary microliths near to the main stone, not detected during US, also in experienced hands.

The transoral robotic surgical removal of submandibular parenchymal stones was safe as no intraoperative or postoperative untoward effects such as tingling of the tip of the tongue, ranula, persistent lingual nerve injury or recurrent sialadenitis due to hilar stenosis were observed as otherwise reported in other clinical experiences (11). The successful result in terms of safety is in part due to the fact that the three dimensional view of the surgical field in the robot console permitted the main surgeon to have a clear anatomical delineation and enhanced depth perception of the oral floor, lingual nerve and Wharton's duct, sublingual gland and hiloparenchymal submandibular area. Woo et al. (30) described their experience on transoral approach for deep stones by removing a piece of sublingual gland; this approach appears to be risky and harmful for the potential occurence of ranula. Another interesting observation of our initial experience is that the blunt dissection with the spatula supported by the gentle take of the Maryland forceps guaranteed a clean surgical field with small amount of blood visible thus favouring a better view of the deep surgical plane. Very few information about the docking of the robot in the operating theatre for the removal of parenchymal submandibular stones can be extracted from literature (26-28). In our experience (21-23) an adequate docking of the robot is essential for a precise robotic procedure; contrarily to what is currently performed for other transoral procedures, the robot should be positioned behind the head of the patient and on the opposite side with respect to the involved gland and an angle of 30°. Finally, to obtain a better view of the posterior part of the oral floor a 30° endoscope downward facing was inserted in the arm 2 of the robot. As previously described in the literature (13,14), traditional transoral loops lens-guided surgery is performed with the help of three surgeons, i.e. the main surgeon and two assistant surgeons (one for the oral field and one for the push up of the submandibular gland from the neck). In our initial experience, we observed that the assistant surgeon can do simultaneously the suction, the tissue traction, and the push up of the gland from the neck to better expose the parenchyma in the oral floor thus avoiding the need of the third surgeon; furthermore, all the surgical steps can be observed by the surgical staff by video monitoring. Finally, the robotic surgical time was relatively fast (20 and 30 minutes); in our opinion, by increasing the number of robotic procedures, the surgical time will further reduce thus minimizing the tissue damage of the oral floor and subjective patient complain.

CONCLUSIONS

The transoral robotic surgical removal of large (>7 mm) hilo-parenchymal submandibular stones is a safe and effective conservative surgical procedure, in line with other initial experience (26-28). Thanks to the three dimensional and enhanced depth perception of the oral floor, the robotic approach preserves the main submandibular duct, the sublingual gland, and the lingual nerve and allows the stone to be removed through a minimal incision in the hilo-parenchymal region, thus guaranteeing the functional preservation of the obstructed gland. The preservation of the Wharton's duct allows to undergo a sialendoscopic access through the natural ostium in the case of residual microliths or to perform a new conservative transoral approach to the parenchyma in the case of a discrete stone recurrence. An adequate pre-operative clinical and radiological assessment by means of US and cone beam 3D CT evaluation is always advisable in order to locate the stone precisely and minimise the risk of failure. A proper docking of the robot together with a precise endoscopic view is mandatory to help the surgical staff in reaching a successful conservative result.

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All authors confirm that have viewed and agreed the submission.

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Figure 1a

Figure 1b

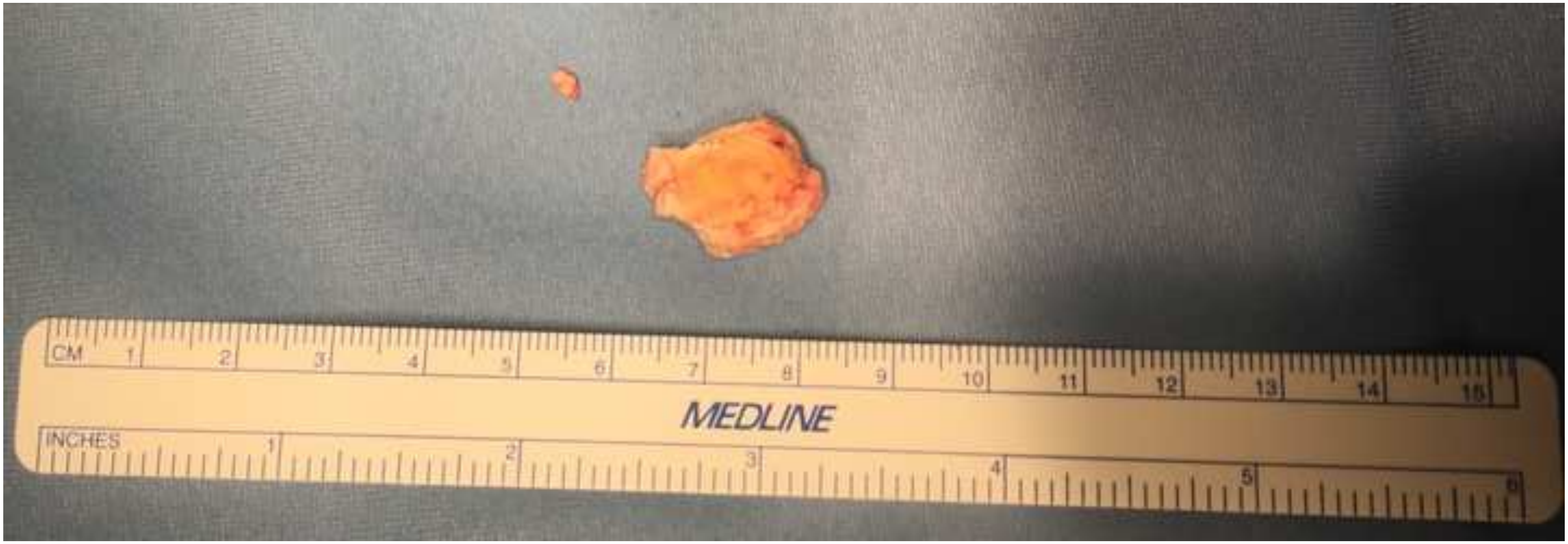

Figure 1c

Figure 1d

Figure 2

Figure 3