Development of a new trans-oral endoscopic approach for mediastinal surgery based on ‘natural orifice surgery’: preclinical studies on surgical technique, feasibility, and safety

Thomas Wilhelm a,*, Wolfram Klemm b, Gunda Leschber b, Joris J. Harlaar c, Anton L.A. Kerver d, Gert-Jan Kleinrensink d, André Nemate e

Abstract

Objective: In recent years, several surgical disciplines adopted endoscopic techniques. Presently, natural orifice approaches are under exploration to reduce surgical access trauma. We have developed a trans-oral endoscopic approach for endoscopic mediastinal surgery and have tested this new technique in preclinical studies for feasibility and safety. Methods: We conducted an experimental anatomical study in fresh-frozen cadavers. By a midline, sublingual incision, we placed an optical scissor through a 6.0-mm trocar in the pretracheal region and created a working space; two additional trocars were placed by bi-vestibular incisions in the oral cavity. We visualized and followed the trachea down to the main bronchi. Paratracheal and subcarinal lymph nodes were resected bilaterally; the specimen could be removed through the midline channel. In an additional animal study in pigs, we tested the feasibility and safety for this surgical approach. Anatomical dissection allowed an estimate of collateral damage. Results: In all cases, we could reach the target region endoscopically, and no conversion was necessary. Landmarks (the brachio-cervical trunk, the azygos vein, and the pulmonary artery) were visualized easily and kept intact. A working space in the mediastinum could be established by the insufflation of air at 6–8 mm Hg. It was possible to harvest the specimen through the midline channel. Anatomical dissection of the cervical access route as well as of the mediastinal region showed no collateral damage. In the animal study, we encountered seroma of the surgical field due to the conditions of the animal model. The other outcomes with respect to pain and food intake were normal until the third postoperative day. No local infections occurred. Intraoperative gas exchange was normal and was not influenced by CO₂ insufflation with respect to blood gas analysis. Conclusion: These preclinical studies showed that the mediastinum could be reached by a trans-oral endoscopic approach, based on natural orifice surgery. Complete compartment resection of the paratracheal and subcarinal lymph node stations was possible in a well-defined and clearly visible working space. This approach may enhance the extent of mediastinal resections in oncologic surgery.

Keywords: Mediastinal surgery; Mediastinoscopy; Endoscopic; Trans-oral; Natural orifice surgery

1. Introduction

With the accumulation of malignant pulmonary and bronchial tumors in the first half of the last century, mediastinal surgery extended and an additional diagnostic need developed for clarification of operable findings.

With the developments of Eric Carlens, mediastinoscopy in 1959 became both safe and, within a few years, the standard method in the staging of malignant lung diseases, replaced explorative thoracotomy [1]. Difficulties were still encountered in diagnosing tumors of the anterior mediastinum and the contralateral N2-nodes in this area. In 1987, Ginsberg and colleagues recommended an ‘extended mediastinoscopy’ to reach all regions in the middle and...
anterior mediastinum [2]; this was already described by G. Specht in 1965 [3].

Cervical mediastinoscopy, despite the further developments in diagnostic imaging (computed tomography (CT), magnetic resonance imaging (MRI), and positron emission tomography (PET)) is still the gold standard in the staging of malignant lung and bronchial tumors [4]. The integration of video technology in mediastinoscopy by Sortini and colleagues in 1994 made working with two hands possible, and the technique of ‘video-assisted mediastinoscopy’ (VAM) was introduced [5]. In the years following, numerous studies have proved its superiority over conventional mediastinoscopy [6—8]. Now, the time had come to use the mediastinoscopy no longer as a purely diagnostic tool, but also therapeutically as a ‘video-assisted mediastinal lymphadenectomy’ (VAMLA) [9]. In addition, here too the benefits of this method could have been demonstrated [10—12]. With the combination of videothoracoscopy and other minimal access approaches evolving, a radical change toward minimally invasive surgical procedures in mediastinal surgery is taking place.

The developments in laparoscopic surgery led to the goal of minimizing surgical access trauma with new approaches on the conceptual basis of ‘natural orifice surgery’. Since 2008, we established experimentally a trans-oral endoscopic access route for thyroid resections [13—15], which could be meanwhile implemented clinically: [16,17] with this direct access to anatomically defined fascial layers and planes of the neck, a bloodless and gentle surgery under endoscopic view and magnification is possible. The patients reported no swallowing disorders after surgery and neither local or regional infection nor a visible scar was seen.

Therefore, the idea was born to expand the access path into direction of the mediastinum. In conventional as well as the extended mediastinoscopy, difficulties result from the accessibility of the different mediastinal lymph node stations; this is addressed by different rearrangements of the patient during surgery. The typical complication of the procedure, palsy of the left recurrent nerve, is caused by the surgical technique itself: after local skin incision, the tunnel to the mediastinum is firstly preformed digitally and eventually enlarged with the mediastinoscope. This can cause stretching of the nerve with complications varying form temporary conduction block up to complete palsy of the recurrent laryngeal nerve [18]. Such manipulations are not necessary in a trans-oral endoscopic access because we enter the anatomical layers directly and create a working space under direct vision with endoscopic instruments and without tension on surrounding tissues.

The following questions arise when entering the mediastinum by means of a trans-oral endoscopic approach:

- Is a trans-oral endoscopic approach to the mediastinum feasible?
- Can we identify and protect intrathoracic vessels and nerves?
- Is it possible to create a ‘working space’ within the mediastinum for lymph node dissection and resection?
- Is this method feasible and safe in an animal study?
- Is respiration and gas exchange in an animal model affected by mediastinal CO₂ insufflation?

To answer these questions, we first tested the principle of entering the mediastinum by means of a trans-oral endoscopic approach in a human cadaver study. To prove feasibility and safety in vivo, we carried out a short-term survival animal study.

2. Material and methods

The instruments used in this endoscopic approach were standard instruments (3.7 mm diameter) for laparoscopic procedures as well as Hopkins endoscopes of 2.7 (0°) and 5.0 mm (30°) diameter (Karl STORZ Company, Tuttingen/Germany). Trocars were adapted to the special needs of this type of endoscopic surgery: they had a diameter of 6.0 mm and a working length of 200 mm.

2.1. Description of the surgical technique

Subjects are positioned in a supine position flat on the operation table without reclination of the head. A sublingual sagittal mucosal incision, 10.0 mm in length, is placed between the papillae of the Wharton duct in the midline (Video 1). The muscles of the floor of the mouth (geniohyoid muscle, mylohyoid muscle, and anterior belly of the digastric muscle) are divided directly in the midline by Metzenbaum scissors to reach the plane beneath the superficial fascia of the neck and the platysma muscle. The ligaments that keep the subcutaneous tissue fixed to the hyoid bone in the upper third are divided with scissors.

Under vision (optical scissors), we pass the thyroid cartilage of the larynx, and the plane of the pretracheal strap muscles becomes visible. Above the strap muscle, a working space is created and CO₂ is insufflated at 6.0 mm Hg pressure.

The mucosa in the vestibule of mouth is incised bilaterally 1 cm lateral to the buccal fold at the level of the canine teeth for a length of 5—10 mm. Care has to be taken not to injure the mental nerve, which runs very superficial, and is thus visible easily. The trocar is directed straight below the platysma muscle into the infralaryngeal working area. As

![Fig. 1. a) Setup during operative procedure. b) Instruments used for trans-oral endoscopic mediastinal surgery (1: suction-irrigation canula, 2: grasping forceps, 3: dissectors, 4: monopolar scissor, 5: 5.0 mm 30° Hopkins endoscope, 6: optical scissor including 2.7 mm 0° Hopkins endoscope, 7: 6.0 mm trocars 190 mm length, 8: LANGENBECK-hook, needle holder, JANESON- and METZENBAUM scissor, surgical tweezers; all instruments supported by Karl STORZ Company, Tuttingen/Germany).](image-url)
shown already in previous anatomical studies, there are no vascular or neural structures at risk in this trans-oral route [13].

With both working trocars in place, we divide the strap muscles in the midline and the thyroid gland becomes visible. If necessary, the isthmus of the thyroid gland can be divided in the midline; in human application, the use of the harmonic scalpel (Ultracision®, Ethicon Endosurgery, Norderstedt/Germany) is be advocated for this step because this reduces the risk of hemorrhage securely [16,17].

We follow the trachea down to the mediastinum (Fig. 1(a)), where the innominate artery (brachiocephalic trunk) becomes visible and has to be spared. By proceeding further, the azygos vein as well as the pulmonary artery is visualized during dissection of the mediastinum (Video 1). The complete paratracheal lymph node stations are separated in the midline to achieve a resectable specimen on both sides. Then, the tracheal bifurcation is fully visible with both main bronchi, and thus the lymph nodes of station 7 are defined. The pressure of the insufflated gas is kept at 6–8 mm Hg consequently.

When resecting the paratracheal lymph node stations, care has to be taken not to harm the vagal nerve on the right and recurrent laryngeal nerve on the left side. In vivo, they can easily be detected and monitored by active stimulation with a neuromonitoring system. Station 7 lymph nodes are dissected down to the esophagus. After complete dissection of all lymph node stations, the scope is passed through a lateral trocar. Specimens are removed through the midline optical tunnel after withdrawal of the midline trocar. Finally, the operation field is checked for bleeding or remaining parts of the specimen prior to removal of all trocars. Incision sites sublingually and in the vestibule of the mouth are closed with resorbable sutures.

2.2. Anatomical studies

Anatomical studies were performed between 26 and 31 October 2009 at the Department of Neuroscience and Anatomy of Erasmus MC, University Medical Centre Rotterdam, the Netherlands. Five male human specimens (mean age 78 years; range 66–84 years) were used for this feasibility study. The nutritional status ranged from cachectic to mild obese. Three had no history of thoracic surgery; two others have had previous aortocoronary bypass surgery.

In all cases, the surgical procedure was performed as described earlier.

To qualitatively determine damage to anatomically relevant structures, all five cadavers were dissected after performing the surgical procedure. The anatomical dissections were performed based on surgical planes: first, the skin, subcutaneous tissue, and platysma muscle were removed. Beyond the superficial fascia, the vascular architecture and the nerves of the anterior triangle of the neck were separated from the connective tissues and lymph nodes. Then, the passage through the floor of the oral cavity to the sublingual space was shown. The anterior region of the neck, including the thyroid gland, was dissected. Afterward, the sternum was resected by bilateral thoracotomy. We removed the thymus completely and opened the anterior mediastinum. The aortic arch, brachiocephalic artery, and subclavian artery were dissected as well as the azygos vein and pulmonary artery. The middle mediastinum was checked for complete removal of the lymph nodes. In addition, the aortopulmonary window was visualized, and the extent of resection was estimated.

All relevant steps of the dissections were documented by a digital SLR-camera (Canon EOS 400D), and image processing was performed with Adobe Photoshop CS4 Extended Version ©.

2.3. Animal study

Permission to perform this experimental trial was granted by the Regional Administrative Authority (Institutional Ethics Committee) Frankfurt/Oder, Germany (Landesamt für Verbraucherschutz, Landwirtschaft und Flurneuordnung, Frankfurt/Oder, Germany, genehmigte Tierversuchsangez 23-2347-20-2009, 18.11.2009). All animals received humane care in compliance with the European Convention on Animal Care.

When compared with human anatomy, the porcine anatomy is identical regarding structure and alignment of the suprahoyoidal muscles as well as superficial layers of the pretracheal muscles. Underneath these structures lies the thymus in pigs; in humans, one would find the thyroid gland. Dorsal to the pig’s thymus is a second muscle layer (pretracheal muscles), and dorsal to these the rather small thyroid gland is observed, with the trachea underlying it. Therefore, the porcine model is a suitable model for our experimental purposes. Lymph node stations in the mediastinum are comparable to human conditions, even if in the very young healthy animals used in this study, they were not visible.

Five male pigs (race: country pig, large white, Piatrain) were used to evaluate feasibility and safety of the trans-oral endoscopic mediastinal surgery through the floor of the mouth. Intravenous anesthesia was induced with ketamine, midazolam, and azaperone, and pancuronium as relaxant. After oral intubation, an intravenous prophylactic single shot of 1500 mg cefuroxime was applied. Ventilation was controlled with a standard ventilation system (Evia XL, Dräger, Lübeck/Germany). Standard laparoscopic instruments were used as described above (Karl STORZ Company, Tuttinglen/Germany).

After use of skin and mucosal disinfectant, the surgical technique was performed as described in the previous section. The trachea was easily identified and followed down to the mediastinum (Video 2). An electric surgical knife (Erbe, Tübingen, Germany, type and mode of action: VIO 300D, Effect 3, swift-coag, 50–90 W) was used where necessary. The mediastinal fatty tissues, according to the lymph node stations, were dissected properly, and the right upper bronchus as well as the both main bronchi identified. The vascular structures within the thoracic aperture and in the anterior mediastinum (common carotid artery bilaterally, brachiocephalic artery, azygos vein, and pulmonary artery) were identified and separated. The incision sites were closed with absorbable sutures (Vicryl® 3/0, Ethicon, Norderstedt/Germany).

At the beginning of the procedure, when entering the mediastinum and at the end of the operation, venous blood
gas analyses (Radiometer ABL800 Flex, Radiometer Company, Willich/Germany) were performed to estimate alterations in the respiration and gas exchange.

The animals woke up breathing spontaneously and were brought back to their stables after 3 h. For the next 2 days, all animals were observed regarding pain reactions and oral feeding (Video 2). On the third postoperative day, all animals were euthanized and a complete dissection was performed, including the complete surgical field, to detect infections, hematomas, or other collateral damage.

3. Results

In the cadaver study as well as in the animal study, we could reach and enter the middle mediastinum by the surgical technique described here. The instruments used in these studies proved suitable for our kind of trans-oral endoscopic mediastinal surgery (TOEMS).

3.1. Anatomical studies

The five male specimens used were fresh-frozen human cadavers; two of them had died within 8 days prior to the experiments and three within 1 year. All surgical interventions were performed with the purpose of accessing the middle mediastinum: this proved to be possible in all cases despite the fact that two (#3 and #5) had a history of cardiovascular bypass surgery with median sternotomy. Even in this condition, no problems occurred when entering the mediastinum. In case #4, scar tissue was observed in the right paratracheal space during the endoscopic procedure. Further endoscopic dissection of this region was impossible.

In every case, the preoperatively determined anatomical landmarks were clearly identified: the brachiocephalic artery, the azygos vein and the pulmonary artery. Trachea and main bronchi could easily be followed down to the tracheal bifurcation. Lymph node compartments (station 2 and 4 on both sides, and station 7) could be identified and resected within the borders of the mediastinum (Fig. 2). The vagal nerve on the right side as well as the recurrent laryngeal nerve on the left side were visualized and spared (Fig. 3(b)).

The dissected specimens were harvested through the midline tunnel. This was done according to the lymphatic stations. Resected lymph node compartments had an average volume of 11.6 ml (range 4.4—24.6 ml, Table 1). Cases #3—5 had died more than a year before investigation, and autolysis was seen during endoscopic surgery: the lymph nodes were discolored and deliquescent. Therefore, harvesting was problematic as the lymph nodes disintegrated when extracting them with a grasping forceps. Consequently, in the in vivo situation, the use of a harvesting bag is strongly recommended.

After completing the endoscopic procedure, an anatomical dissection of the floor of mouth, the anterior neck region, and the mediastinum took place. It could be shown that the targeted anatomical space underneath the platysma muscle and the superficial cervical fascia was reached in every case. The tunnels created for the working and optical trocars ended at the level of the hyoid bone. The ligaments that connect the subcutaneous tissue with the hyoid bone proved to be the bottleneck of the procedure (Fig. 3(a)). These have to be dissected gently in the early phase of the procedure to create a tunnel, to simplify the harvesting of the specimen.

The upper aperture of the thoracic cavity was not an obstacle: the diameter ranged in width from 1.94 cm to 3.22 cm and height from 0.8 cm to 1.49 cm (Table 2). This

<table>
<thead>
<tr>
<th>Trial</th>
<th>Right side</th>
<th>Left side</th>
<th>Median/paramedian</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>St. 2</td>
<td>St. 4</td>
<td>St. 2</td>
<td>St. 4</td>
</tr>
<tr>
<td>1</td>
<td>—</td>
<td>—</td>
<td>14.9</td>
<td>3.0</td>
</tr>
<tr>
<td>2</td>
<td>3.7</td>
<td>3.1</td>
<td>1.2</td>
<td>0.5</td>
</tr>
<tr>
<td>3</td>
<td>3.2</td>
<td>2.5</td>
<td>1.8</td>
<td>1.3</td>
</tr>
<tr>
<td>4</td>
<td>—</td>
<td>—</td>
<td>0.9</td>
<td>1.6</td>
</tr>
<tr>
<td>5</td>
<td>0.7</td>
<td>2.7</td>
<td>0.4</td>
<td>0.6</td>
</tr>
</tbody>
</table>

Fig. 2. Endoscopic view during cadaver experiments (1: left main bronchus, 2: right main bronchus, 3: anterior esophagus, 4: dissected lymph node station 7).

Fig. 3. Dissection in human cadavers: a) Anterior neck region from left below (1: infrahyoidial strap muscles, 2: anterior belly of the left digastric muscle, 3: hyoid bone, blue arrow indicating the hyoidal ligaments). b) Middle mediastinum complete dissected (1: anterior esophagus wall, 2: entry point in the upper thoracic aperture, *: innominate artery [brachiocephalic artery] transected, white arrow: left recurrent laryngeal nerve).
proved to be a sufficient space to enter the thorax during this endoscopic trans-oral approach.

No collateral damage was noticed; all intrathoracic vascular structures were kept intact as well as the neural structures (Fig. 3(b)). All mediastinal lymph node stations could be resected, except in case #4, where massive scarring of the right paratracheal space precluded further intervention in this area during the endoscopic procedure. On dissection, we found a massive scarring of unknown origin of the right mediastinum and the pleura (perhaps sarcoidosis).

As demonstrated by the anatomical studies, all lymphatic stations of the middle mediastinum are reachable, even the more distant.

3.2. Experimental study in the porcine model

The operative setup in the animal experiments was the same as in the anatomical studies (Fig. 4(a)). In all experiments, no intraoperative problems regarding anesthesia or the operative procedure itself occurred. In case #2, oral intubation was problematic but successful at least: 3 h after operation this case experienced stridor on inspiration and expiration. Glucocorticoids (10 mg dexamethasone) were administered subcutaneously with release of symptoms. No minor or major bleeding complications were noticed. In all cases, the mediastinum was reached and the tracheobronchial system down the main bronchi was displayed (Fig. 4(b)). Vascular structures could also be dissected and spared. In case #4, minor problems occurred while entering the upper aperture of the thorax: the optical trocar was primarily placed at the right side of the larynx. This resulted in a via falsa out of the midline, and the common carotid artery on the right side became visible by endoscopic dissection. After replacing the trocar to the correct median position, the pretracheal muscles and the thyroid gland became visible and the mediastinum could be entered. This minor problem resulted in a longer cut-suture time. Over all, the cut-suture time decreased from the first to the last experiment (Fig. 5).

Due to the relative youth of our experimental animals (4 month, weight: 30–40 kg, average 33 kg), no mediastinal lymph nodes were found during the endoscopic procedure and, therefore, harvesting of specimen was not possible.

During the entire surgical procedure, venous blood gas analysis showed normal levels (Fig. 6); in case #3 and case #4, at suture time no blood samples could be obtained. It can be concluded that the gas exchange and ventilation were not affected by the insufflation of CO2 at a pressure of 6–8 mm Hg to the mediastinum.

Except for case #2, as described above, all pigs were breathing spontaneously after the surgical procedure, and could be extubated without complications. They recovered quickly, and no acute postoperative bleeding occurred. After 4–5 h, all animals started oral food intake without signs of pain. In the following 2 days, the animals were kept in their stables and were fed with standard pig food and water. There were no irregularities, especially no signs of pain or local (wound) infections.

On the third day postoperatively, all animals underwent a second anesthesia induction to examine the incision with special regard to local infections or wound breakdown, and these parameters were compared to the findings immediately after operation: in three cases, partial wound break-
down became visible, but no local infection. In four of five cases, a mild swelling over the anterior region of the neck was observed. The animals were euthanized and a complete dissection followed. There were no fresh bleedings, hematomas, or infections. The access path of the trocars could be identified in all cases and revealed no local complications.

After opening the pretracheal strap muscles in the midline, in all cases seroma (average 76 ml, range 30—175 ml), and in case #1, an offensive hematoseroma (45 ml) was observed. These seromata were attributed to the use of the monopolar scissors used for preparation and seems to be a specific problem of the porcine animal model as mono- and bipolar instruments used in conventional mediastinoscopy in humans almost never result in seroma formation. No other bleedings or infections were observed. The muscles of the floor of mouth as well as the pretracheal muscles were proven to be intact.

After opening the thorax, the intrathoracic relations were shown to be normal. All vascular structures were intact. Dissections demonstrated that the upper thoracic aperture is much smaller than in humans (Fig. 4(c)); this, however, did not cause problems in entering the mediastinum during endoscopic surgery.

4. Discussion

The integration of endoscopic operative techniques in minimally invasive laparoscopic procedures in the mid-1980s has been called ‘the second generation of visceral surgery’. This has been a revolution in surgical approach and, today, some surgical procedures in general surgery, gynecology, and urology are performed almost exclusively endoscopically.

Further development of sophisticated endoscopic instruments and increasing possibilities of camera- and videotechnology over the last 5 years resulted in a paradigm shift: the use of natural orifices of the human body as access route to endoscopic surgical procedures further minimize surgical access trauma. This approach may be called ‘third-generation surgery’. In principle, two different concepts can be distinguished: one uses flexible endoscopes and enters the body through natural orifices and cavities such as the stomach, the bladder, or the vagina (natural orifice transluminal endoscopic surgery: NOTES); the other technique is based on rigid endoscopes and standard laparoscopic instruments to perform surgery and utilizes natural orifices (natural orifice surgery: NOS) as well. Most of the previous surgical procedures in humans were carried out by NOS technology, as this technology allows a bimanual instrumental approach, which enables the surgeon to use the important triangulation principle. The flexible-endoscopic approaches are still in a stage of development: key barriers are the development of appropriate endoscopes, a sufficient endoscopic suturing technique, and the insufficient possibilities to apply the triangulation principle.

In the last 3 years, several attempts to access the mediastinum via a natural orifice pathway were performed: one technique used rigid endoscopes and a route from the urethra and bladder through the abdominal cavity and the diaphragm into the thorax [19]. Other research groups accessed the posterior mediastinum by flexible endoscopy in a transmural esophageal or hybrid approach via a suprasternal incision in animal models [20—25]. Until now, all these approaches were evaluated only in animal experiments; through these rigid and flexible endoscopic approaches, only minor surgical procedures were possible because, always, a single-port access was in use, and bimanual manipulation not possible. Only in the hybrid approaches were surgical procedures (Heller myotomy, esophagectomy) performed [25]. Therefore, NOS as well as NOTES techniques are still in their infancy, and are far from clinical application with respect to mediastinal surgery. In addition, these methods did not allow systematic surgical procedures in the mediastinum because they either did not reach the mediastinum [19] or were located in the posterior mediastinum with minimal access to the middle mediastinum [20—23]. Swanstrom and colleagues reported in their series on surgical interventions in an animal model about major hemodynamic changes due to gas insufflation: [25] they accessed the mediastinum by a conventional cervical incision and used an experimental, flexible, two-channel endoscope. These endoscopes have only a control for the air flow through the scope and, therefore, the pressure in the mediastinum could not be controlled. In our trans-oral endoscopic approach, the pressure in the target region is continuously monitored and kept at 6—8 mm Hg so that we did not experience such conditions as described by Swanstrom and colleagues.

In mediastinoscopy, as introduced by Carlens [1], triangulation is hindered by manipulating through the mediastinoscope, and movement of instruments, especially in bimanual activities, is restricted. Prior to the placement of the mediastinoscope, digital opening of the mediastinum is required; that can result in stretching of the recurrent laryngeal nerve, especially on the left side, which may cause postoperative recurrent nerve palsy [18].

Inspection of the different mediastinal lymph node stations may require repeated repositioning of the patient’s head during the operation. This is difficult, especially in the elderly, and in impaired mobility of the cervical spine in some circumstances. The trans-oral endoscopic minimally invasive approach seemed to solve these problems and restrictions.

In the preclinical studies presented here, we expanded our trans-oral endoscopic approach, which was primarily
designed for endoscopic minimally invasive thyroidectomy [13–17]. By accessing the anterior neck region through trocars placed sublingually and in the vestibule of mouth bilaterally, we were able reach the upper aperture of the thoracic cavity. The tractea was easily identified and was followed down to the mediastinum. With standard laparoscopic instruments and CO2 insufflation, a sufficient working space was created and all intrathoracic vascular and neural structures were identified and preserved. It was possible to perform compartment resections of the mediastinal lymph node stations.

An advantage of the technique is the working ‘in line’ with the structures at risk: no stretching of anatomical structures is necessary. Anatomically defined tissue layers are entered directly; this offered a ‘physiological’ and less traumatic access to target structures. By positioning the working trocars in the vestibule of the mouth, a sufficient triangulation enables an easy and comfortable handling of the endoscopic instruments. Due to endoscopic magnification and working by dissection, a lower rate of postoperative palsy of the recurrent laryngeal nerve as well as bleeding complications could be expected. Intraoperative neuromonitoring will also help to identify and preserve the function of the recurrent laryngeal nerve by direct stimulation, before taking further surgical steps. Finally, the technique of TOEMS can be combined with other minimally invasive techniques in thoracic surgery. Possible additional complications of the procedure seem to be negligible: the vestibular incision site may cause injury to the mental nerve with subsequent paraesthesia. In our clinical applications of this technique for thyroidectomy [16,17], we observed a reversible paraesthesia of the mental nerve in the first patients: the more lateral we placed the incision site the less this was observed.

Furthermore, we did not notice any regional infections caused by the access in human applications [16,17]. The risk of local infections seems to be very small, but a prophylactic administration of antibiotic agents preoperatively is advocated.

Harvesting of the resected specimen will perhaps be problematic under certain circumstances as the ligaments at the level of the hyoid bone can form the ‘bottleneck’ of the procedure. This disadvantage can be neutralized by proper transection of these ligaments in the early stage of surgery to create a sufficient wide midline access path. The dissected ligaments over the hyoid bone during clinical application for thyroidectomy were reattached by a temporarily plaster tape — no physiological or cosmetic changes were observed in the postoperative course and follow-up [16,17].

In case of a major bleeding, a standby for rapid sternotomy or thoracotomy is mandatory.

In conclusion, this new trans-oral endoscopic approach for mediastinal surgery was feasible in anatomical studies; the porcine, animal study with short-time survival demonstrated the safety of the procedure in vivo. Wound breakdowns, as observed in the animal study, were not followed by local/regional infections or mediastinitis. The expected benefits (less swelling disorders postoperatively, perhaps a lower rate of postoperative palsy of the recurrent laryngeal nerve) can only be estimated after the first application in humans; after these thorough preclinical investigational series, it seems to be the right time for this next step. Our experiences with minimally invasive thyroidectomy indicate that benefits are to be expected and likely.

References


Appendix A. Supplementary data

Supplementary data associated with this article (Video 1 and Video 2) can be found, in the online version, at doi:10.1016/j.ejcts.2010.09.028.