Clinical applications of Telerobotic ENT-Head and Neck surgery

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ABSTRACT

Objective: To review the published clinical data in Telerobotic ENT-Head and Neck surgery, evaluate the benefit of existing clinical applications and identify areas for potential development.

Methods: A qualitative review was performed of publications in PubMed, Medline and the Cochrane Database identified from the following keyword searches: Telerobotic/Robotic ENT, Otorhinolaryngology, Head and Neck surgery, Thyroid and Parathyroid surgery. Preclinical studies and non-clinical review articles were excluded.

Results: Forty-five publications were identified including 7 review articles. Transoral robotic surgery (TORS) was reported in 20 clinical studies, robotic-assisted thyroidectomy in 13 studies, parathyroidectomy in 4 studies and skull base surgery in 1 study. The majority of TORS publications relate to oropharyngeal malignancy which were Stage III and IV. Clinical benefits include avoidance or dose reduction of adjuvant chemoradiotherapy and improved swallow function. The primary clinical advantage of robotic-assisted neck surgery is the avoidance of a neck scar. The learning curve for robotic thyroidectomy is 50 cases. Body habitus is an important factor for assessment of robotic feasibility in transoral and neck surgery.

Conclusion: The application of robotic-assisted parathyroidectomy, thyroidectomy and TORS suggests promising improvements in patient care. Randomised control trials are needed to assess clinical outcome, cost effectiveness and patient benefit in the existing applications. Continued development of robotic technology will expand the viable clinical applications in this specialty.

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1. Introduction

Telerobotic surgery was developed by NASA in 2001 and initially envisaged for use in the battlefield by the US Department of Defence. Over the last decade it has become the established clinical practice in several surgical specialties. Imperial College London has been at the forefront of developing and assessing clinical applications in the UK since 2004.1–3

The daVinci surgical system is a master–slave Telerobotic platform which consists of a console, surgical cart and manipulator unit (Fig. 1). The console surgeon views a three-dimensional magnified image and controls 4 endowristed robotic arms which enhance manual dexterity.4 The surgeon’s hand movements are motion scaled and physiological hand tremor is abolished. The ability to recreate an open surgical experience, minimise surgical trauma and improve precision are the primary advantages. This has translated to improved patient care in several specialties including urology, gynaecology, cardiothoracic and paediatric surgery.5,6

In ENT-Head and Neck surgery the existing endoscopic techniques have several limitations. In transoral surgery, this includes a confined operative field, limited range of instrument motion, line of sight issues and poor depth perception.

In endoscopic thyroid and parathyroid surgery limitations include video camera platform instability, restricted motion of straight endoscopic instruments, 2-dimensional imaging and suboptimal operator ergonomics.7

Robotic surgery has the potential to improve patient care in ENT similar to that witnessed in other specialties. However, the inherent anatomical constraints which do not occur in open cavities such as
the abdomen, pelvis or thorax create unique technical challenges. Significant adaptation to the positioning of the robotic arms and operating room reconfiguration is necessary. The essential preclinical transoral robotic surgery (TORS) studies were performed by Weinstein et al. in 2005. An increasing number of clinical applications have subsequently been reported in TORS (Fig. 2).

The primary focus of the robotic ENT programme at Imperial College Healthcare NHS Trust over the last 18 months was to devise and evaluate a robotic-assisted parathyroidectomy (RAP) technique which avoids a neck scar to treat patients with Primary Hyperparathyroidism.

The purpose of this review is to evaluate the existing clinical applications, assess their advantages in terms of patient benefit and identify areas for potential application in ENT-Head and Neck surgery.

2. Methods

A qualitative review was performed of articles in the English language following keyword searches of PubMed, Medline and the Cochrane Database. The search terms used were: Telerobotic/robotic/robotic-assisted otorhinolaryngology, ENT, head and neck, thyroid and parathyroid surgery. These included prospective clinical trials, case series and case reports. Preclinical studies (cadaveric and animal studies) and non-clinical review articles were excluded. The specific aspects which were evaluated included existing clinical applications and feasibility, exclusion criteria, morbidity, mortality, length of stay, cost and the learning curve.

The references of relevant papers were evaluated as a source of further study. Personal communication of unpublished clinical data was sought from three experts in the field of ENT-Head and Neck surgery (N Tolley, C Vicini and G Weinstein) and from the American Cancer Society Department of Surveillance and Health Policy Research.

3. Results

There were 45 publications all within the last 5 years comprising 9 case reports, 29 case series and 7 review articles (Table 1). Six case series contained 50 patients or more and the largest series contained 1043 patients. The first clinical applications were reported in 2005 for thyroidectomy and TORS to remove a benign oropharyngeal lesion. The application of TORS in head and neck cancer was published the following year. TORS accounts for the largest number of publications (Fig. 3). There are 17 TORS case series/reports in head and neck cancer and 3 for benign conditions. There are 13 case series/reports of robotic-assisted thyroidectomy and 4 case series/reports of robotic-assisted parathyroidectomy (RAP) all for a mediastinal adenoma. A RAP feasibility study of 12 cases has been accepted for publication. In the other ENT subspecialties, there is 1 case report of robotic-assisted skull based surgery.
3.1. TORS: head & neck oncology

Seventeen studies report 319 cases of oral cavity, oropharyngeal, hypopharyngeal and laryngeal malignancy treated with TORS. Oropharyngeal and oral cavity cancer account for 85% of cases and the majority of these were stage III or IV disease (Figs. 4a and 5).

Table 2 summarises the 4 largest TORS studies. Mean follow up was 13 months. Failure due to suboptimal access occurred in 6.2% of cases. Contributing factors included a narrow mandible, full dentition, retrognathia and trismus.

Exclusion criteria included lateral or posterior tumour fixation, tumour adjacent to the carotid artery or involvement of the nasopharynx, lateral pterygoid muscle or mandible.

Morbidity: Complications include one neck haematoma necessitating return to theatre and development of an oro-cutaneous fistula (n = 4). A temporary tracheostomy was performed in 14% of cases. Moore et al. reported an equal distribution of tracheostomy irrespective of T stage. Predictive factors of poor swallow were an advanced T stage, preoperative nasogastric feeding and recurrent/2nd primary tumour resection. Resumption of oral intake occurred in approximately 70% of patients within 2 days increasing to 83% two weeks following surgery. At 12 months, 17% of patients were percutaneous endoscopic gastrostomy (PEG) tube dependent as was a similar proportion in the Mayo study. PEG dependent patients all had T4 disease and 90% of these involved the tongue base. Weinstein et al. reported a 2.4% PEG dependency rate in a series of 47 patients with oropharyngeal cancer at a minimum of 12 months follow up. Mortality: Perioperative mortality has not been reported. Recurrence: The Mayo study reported one (2%) contralateral tongue cancer and three (7%) regional neck recurrences. In Weinstein’s largest reported series, local control was achieved in 98%, regional control in 96% and distant control in 91% of cases at 18 months follow up. Adjuvant therapy: The Mayo Clinic group used a smaller dose of adjuvant chemoradiotherapy than conventionally administered although their protocol was not stated. In Weinstein’s series, 38% of patients avoided adjuvant chemotherapy and 11% avoided adjuvant chemoradiotherapy. In a recently updated publication of 31 oropharyngeal cases, 86% of patients with N1 disease and 30% of patients with N2 disease avoided concurrent chemohypermia. Of the N1 patients, 29% avoided radiotherapy or any adjuvant therapy altogether. The application of a flexible CO2 laser with TORS has been reported in 8 patients with early oropharyngeal or laryngeal tumours. Robotic-assisted free flap reconstruction in the oral cavity and oropharynx was reported in 2 cases. Image guided TORS using the BrainLAB AG navigation system was reported in 1 oropharyngeal and 2 parapharyngeal tumours.

3.2. TORS: benign head & neck

The first clinical application published in 2005 was marsupialisation of a vallecular cyst. In 2007, its application in paediatric ENT surgery for laryngeal cleft repair was reported in 2 patients. In 2010, Vicini et al. performed tongue base reduction, supraglottoplasty and uvulopalatoplasty in 10 patients with obstructive sleep apnoea or snoring. In 8 patients this was in addition to (non robotic) nasal surgery. All patients had a tracheostomy and nasogastric tube insertion. Successful decannulation and normal swallow function was achieved as was a significant reduction in Epworth score and Apnoea–Hypopnoea Index (AHI) postoperatively. Patient reported outcome measures included 90% satisfaction scores.

3.3. Robotic-assisted parathyroidectomy (RAP)

In 2004, Bodner et al. reported robotic-assisted mediastinal parathyroidectomy using thoracoscopic ports. The parathyroid adenoma, located in the aortopulmonary window, was successfully removed although the patient developed temporary recurrent laryngeal nerve (RLN) paresis. There are 2 further case reports and 1
TORS Head & Neck Oncology: summary of 4 major clinical series.

<table>
<thead>
<tr>
<th>Level of evidence</th>
<th>No. of clinical cases</th>
<th>Tumour site (no. of patients)</th>
<th>Exclusions-unuitable access</th>
<th>Mean setup time</th>
<th>Mean surgical time</th>
<th>Blood loss (ml)</th>
<th>Length of stay</th>
<th>Follow up time</th>
<th>Return to normal swallow (%)</th>
<th>Airway management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boudreaux et al. 2009</td>
<td>III 29</td>
<td>Oral Cavity 2, Oropharynx 19, Hypopharynx 7, Larynx 1</td>
<td>3</td>
<td>N/R</td>
<td>99 min</td>
<td>2–150 (mean 51)</td>
<td>1–13 days</td>
<td>3 months</td>
<td>79% at last follow up</td>
<td>Planned tracheostomy-Decannulated prior to discharge 5 prolonged intubation (2 days)</td>
</tr>
<tr>
<td>Moore et al. 2009</td>
<td>III 45</td>
<td>Base of tongue 26, Tonsillar Fossa 19</td>
<td>0</td>
<td>1st 10: 68 min Subsequent: 22 min</td>
<td>71 min</td>
<td>N/R</td>
<td>1–10 days</td>
<td>3 months –2 years</td>
<td>100% at last follow up</td>
<td>Tracheostomies intraoperatively: 14 Mean decannulation at 7 days</td>
</tr>
<tr>
<td>Iselia et al. 2009</td>
<td>III 54</td>
<td>Oropharynx 6, Larynx 12, Hypopharynx 3</td>
<td>5</td>
<td>N/R</td>
<td>N/R</td>
<td>N/R</td>
<td>1–7 days</td>
<td>2 months –2 years</td>
<td>83% at mean 12 months follow up</td>
<td>Tracheostomies intraoperatively: 5 Mean decannulation at 8 days</td>
</tr>
<tr>
<td>Weinstein et al. 2010</td>
<td>IIb 47</td>
<td>Base of tongue 23, Tonsil 23, Soft Palate 1</td>
<td>3</td>
<td>N/R</td>
<td>N/R</td>
<td>220 ml (mean)</td>
<td>N/R</td>
<td>Mean 26 months</td>
<td>97.6% at last follow up</td>
<td>Tracheostomies: 5 3 planned and 2 unplanned</td>
</tr>
</tbody>
</table>

Table 2

3.5. Other applications

Skull base surgery has been evaluated in preclinical studies using a transnasal approach to the sella and TORS to access the cranio-cervical junction and atlantoaxial spine. There is one case report in the literature. TORS has been used to excise 3 parapharyngeal space tumours which avoided the morbidity associated with splitting the mandible for access.

4. Discussion

The application of Telerobots is a new, rapidly evolving field in ENT- Head and Neck surgery. In December 2009 FDA approval was granted for TORS in the oral cavity, oropharynx, hypopharynx and larynx.

4.1. TORS

Conventional transoral surgery can be technically challenging due to suboptimal target visualisation. Conversely, an open approach can involve debilitating surgery. In TORS, two 5 or 8 mm wristed instrument arms and a central 3D 8.5 or 12 mm endoscope are inserted transorally via a Boyle Davis mouth gag or FK retractor. The instruments are controlled by the console surgeon to perform multi-planar, en bloc resection. Less blood loss, reduced postoperative stay and improved functional outcomes have been reported.

The majority of TORS cases were in the T1 and T2 category (Fig. 4). This is not surprising as approximately 60% of patients with advanced stage oropharyngeal cancer recorded in the 2007 American National Cancer Database were T1 and T2. This is in addition to all patients with Stage I and Stage II disease which are, by definition, T1 or T2 tumours. Regardless of treatment, most studies of oropharyngeal cancer report that the majority of patients have T1 and T2 tumours. Therefore, the key issue regarding disease-specific survival is not T stage but rather the N stage. This drives the overall staging in oropharyngeal cancer and determines the need for adjuvant therapy following TORS or the use of chemotherapy and radiation if non-surgical therapy is used for the primary treatment modality. In this regard, the TORS treatment paradigm is similar to other studies as the vast majority of patients have advanced Stage III and IV disease.
Weinstein et al. (University of Pennsylvania) established the first TORS programme in 2004 and have the largest clinical experience. Preliminary results suggest equivalent rates of loco-regional recurrence compared with conventional treatment.\textsuperscript{19,56} Several meta-analysis studies report that the prognosis for locally advanced oropharyngeal disease with surgery and/or radiotherapy is 30–35% at 5 years.\textsuperscript{62} There is an additional survival benefit with altered fractionated radiotherapy and concurrent chemotherapy.\textsuperscript{63,64} Recent studies involving a primary surgical approach for T1 and T2 tumours with adjuvant radiotherapy when indicated report 98% survival in 47 reported.26,28 The laser tip is a few millimetres from the target and is the avoidance or dose fractionated radiotherapy and concurrent chemotherapy.\textsuperscript{63,64} Recent studies involving a primary surgical approach for T1 and T2 tumours with adjuvant radiotherapy when indicated report 98%.\textsuperscript{65} There is an additional survival benefit with altered fractionated radiotherapy and concurrent chemotherapy.\textsuperscript{63,64} Recent studies involving a primary surgical approach for T1 and T2 tumours with adjuvant radiotherapy when indicated report 98% survival in 47 patients who underwent TORS was 97%.\textsuperscript{56} Some of this cohort also received post operative IMRT (Intensity modulated radiotherapy) and/or adjuvant chemotherapy. Quon et al. have outlined the rationale for a trimodality treatment with TORS for oropharyngeal carcinoma.\textsuperscript{56} The robotic transoral approach permits en bloc resection which is not possible with TLM. This improves the ability to interpret the adequacy of the resection margins which is an important factor for determining whether adjuvant therapy is indicated. Compared with open resection TORS is associated with less morbidity. An additional benefit is the avoidance or dose reduction of adjuvant radiotherapy and chemotherapy due to clear resection margins and effective pathological risk stratification which a staged approach to the neck permits.\textsuperscript{18,56} In patients treated using TORS with N\textsubscript{1} disease in the neck there was an 86% avoidance of cisplatin postoperatively. This decreased to 30% for N\textsubscript{2} disease.

The oropharyngeal series reported by Weinstein et al. (n = 47) comprised entirely of Stage III and IV disease.\textsuperscript{19} 97.6% of patients swallowed normally at 12 month follow up. Similar outcomes have been reported in other centres including Moore et al, who reported a zero PEG dependency rate in their series.\textsuperscript{9} In comparison, swallowing complications at 2 years following primary chemoradiotherapy for oropharyngeal cancer has been reported as 13–43%.\textsuperscript{69–71} Randomised studies which compare TORS with established treatments such as transoral laser surgery and primary chemoradiotherapy are needed to further evaluate these potential advantages.

### 4.1.1. Feasibility

Appropriate case selection is important because inadequate access precludes TORS in at least 6% of cases. Triaging potential candidates with panendoscopy reduces this figure.\textsuperscript{55} Patients with snoring and obstructive sleep apnoea require a different assessment strategy. A TORSS (transoral robotic sleep surgery) pilot study conducted at Imperial College London evaluated feasibility in 5 patients. Preoperative sleep nasendoscopy was performed to identify patients with tongue base collapse most likely to benefit from a robotic approach.

### 4.1.2. Future developments

Robotic phonsurgery, subglottic surgery and skull base access are limited by the existing Telerobotic platform and mouth gags. Instrument and endoscope miniaturisation is necessary. The development of robotic technology designed for single port surgery and multi backbone snake-like robotic units promise to expand clinical applications.\textsuperscript{54,72}

The combination of flexible CO\textsubscript{2} laser with TORS has been reported.\textsuperscript{26,28} The laser tip is a few millimetres from the target and...
the flexible delivery system improves dissection capability. Advantages include less peripheral thermal injury compared to monopolar diathermy. However, existing laser fibres are fragile and require an integrated delivery channel.

Image guided TORS has been shown to facilitate tumour resection. Guidance is two-dimensional and relies on fixed bony landmarks. However, the relationship between the soft tissue and these landmarks can change with excessive patient manipulation; for instance during mouth gag insertion. Research is on-going at Imperial College London to develop an Augmented Reality (AR) three-dimensional image guidance system which improves surgical accuracy.73

4.2. RAP & RAT

Robotic parathyroid and thyroid surgery use a lateral rather than the conventional anterior neck approach. In RAT the ipsilateral arm is abducted at the shoulder to minimise the tunnelling distance between the axilla and neck. Three robotic arms holding the endoscope and two 8 mm instruments are introduced through an axillary incision. A 4th arm, used for thyroid retraction, is inserted through the same incision or via a separate anterior chest or peri-areolar breast incision.38,40 The primary advantage is the avoidance of a neck scar. Scars in visible areas such as the anterior neck have a detrimental effect on body image.74 This is supported by findings in a robotic thyroidectomy case control study at 3 months.37 The arm position can cause over-traction and a 0.3% incidence of brachial plexus neurapraxia is reported in the largest series.14 Temporary shoulder discomfort was reported in approximately 12% of patients in another series although there was no difference in pain between robotic and control thyroidectomy groups.37 Swallow function appears better with the robotic approach. This may be because the lateral approach avoids midline strap muscle dissection, para-oesophageal traction is minimal and because 3D magnification enables precise tissue manipulation. The 4.3% temporary RLN rate in RAT is equivalent to conventional surgery. The 0.5% incidence of permanent RLN palsy is attributed to pathology greater than 6 cm and thyroiditis. Permanent hypocalcaemia was not reported although the incidence of transient hypocalcaemia ranges from 18 to 40%.12,21,38 Blood loss was not recorded but only 5 patients (0.5%) developed a muscle flap haematoma of which 1 patient required surgical intervention.13 The preliminary functional outcomes of RAP and RAT are encouraging. Long term prospective outcome data are imminent and randomised clinical studies are warranted to evaluate potential advantages. There is little published in the literature which evaluates patient perception of scar cosmesis in thyroid and parathyroid surgery. In the last decade, several scar-less in the neck surgical approaches have been reported.75–78 Whether patients prefer a scar-less in the neck approach is an important issue in determining whether these techniques become accepted in parathyroid and thyroid surgery. The morbidity associated with these approaches must also be shown to be at least equivalent to the established minimal access techniques.

4.2.1. Feasibility

Body habitus is a crucial factor for performing successful RAP and RAT. Patients with an anterior larynx are technically challenging when a total thyroidectomy is performed robotically due to difficult access to the contralateral lobe. Thyroiditis and nodules greater than 6 cm are associated with a higher incidence of RLN injury.

4.3. The robotic learning curve

The learning curve has implications for patient care, clinical workload and training.79 Robotic surgery has a shorter process of skill acquisition compared to endoscopic surgery in other specialties.80,81 A prospective multicentre study of robotic thyroidectomy in 644 cases suggests that the learning curve for total thyroidectomy plateaus after 50 cases.36 The TORS learning curve has not been formally published although in individual case series, the setup and docking times reduce as clinical experience grows. The setup time in the first reported case was 75 min compared to 9 min in Weinstein’s series.16,21

4.4. Robotic training

Effective training models address issues such as lack of haptic feedback and are essential for optimising surgical outcome.82 The University of Pennsylvania has an established training programme in TORS. This includes observation in clinic and the operating theatre. The laboratory component involves practising standardised tasks on a virtual reality trainer, porcine models and surgeon led cadaver training.55

4.5. Cost effectiveness

Cost is a major issue in establishing any clinical robotic programme. The initial outlay is £1 million for the da Vinci system in addition to annual service cost which can be £80,000. This does not include the costs for consumables which are roughly £200 per case. Training costs for a robotic surgery unit can be as much as £100,000 depending on the number of individuals. Indirect costs take the form of prolonged initial operative times which lead to a reduced caseload.83 These may be off-set by the potential reduction in hospital admission times and the avoidance of HDU/ITU admissions. Evidence of cost effectiveness in the ENT literature has not yet been published. In Urology, the health economics associated with robotic-assisted prostatectomy have been compared with established techniques.84 The directly measurable outcomes were not significantly improved compared with laparoscopic or open procedures to off-set the substantial increased cost associated with robotic surgery. Further research is needed into cost effectiveness evaluating both direct and indirect potential advantages in ENT surgery.

4.6. Limitations

It is important to acknowledge the limitations of our methodology and also the robotic technology in its present form. This review only included clinical publications in the English language. This may introduce exclusion bias and underestimate the number of cases that were actually performed.

Weinstein et al. imposed strict exclusion criteria for patients undergoing TORS for oropharyngeal cancer due to the anatomical restrictions. These relate to the physical size of the instruments and arms of the da Vinci robot.55,56 Despite a reduction in the size of the original instruments this remains an important limitation in ENT surgery. Preoperative endoscopy under general anaesthetic was necessary to identify suitable patients, which represents an additional procedure.

The lack of haptic feedback is not a major limitation although this may contribute to the longer initial operating times and the relatively steep learning curve.75,21,29,55 The time taken to dock the robot can initially impact and prolong operating times. However, several groups report that this quickly improves particularly if the robotic programme contains a sufficiently high volume caseload.55 The practical aspect of the theatre space required to facilitate the use of the da Vinci robot is important and may preclude applications which involve day-case units where floor-space may be minimised. In order for robotic surgery to be cost effective the staff using it will
need to be proficient and experienced in troubleshooting any technical issues. There is not as yet a recognised training programme for surgeons or for theatre staff in the UK.

5. Conclusion

The application of Telerobotic-assisted ENT-Head and Neck surgery facilitates minimal access endoscopic techniques. The clinical studies reviewed report several potential improvements in patient care. These include reducing the morbidity associated with oropharyngeal cancer surgery such as the avoidance of a mandibular split, superior PEG dependence rates/swallow function and reduced length of hospital admission. In parathyroid and thyroid surgery, a robotic-assisted technique allows a scar-less in the neck approach. It also offers a new paradigm for the surgical management of patients with obstructive sleep apnoea. Randomised control trials are needed to evaluate clinical outcome and patient benefit in existing applications. The cost effectiveness in ENT applications must be evaluated. A robust framework for training, assessment and safe implementation is also crucial. The possibility for expanding the boundaries of minimal access techniques such as anterior skull base surgery will depend on further instrument and endoscope miniaturisation. The rapidly evolving field of robotic surgical technology promises to expand the clinical applications in this specialty. The lasting value of robotic-assisted surgery in otolaryngology, head and neck surgery remains to be seen.

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Author contribution
Mr Asit Arora: Conception and design of study, acquisition of data, analysis and interpretation; drafting the article and revising it critically for important intellectual content; final approval of the version to be published.
Miss Aileen Cunningham: Data acquisition, analysis and interpretation; drafting the article and revising it critically for important intellectual content.

Dr Gaurav Chawdary: Analysis and interpretation of data; revising it critically for important intellectual content.

Prof Claudio Vicini: Analysis and interpretation of data; revising it critically for important intellectual content; final approval.

Prof Gregory Weinstein: Analysis and interpretation of data; revising it critically for important intellectual content; final approval.

Prof Ara Darzi: Conception and design of study, revising it critically for important intellectual content; final approval.

Mr Neil Tolley: Conception and design of study, drafting the article and revising it critically for important intellectual content.

References