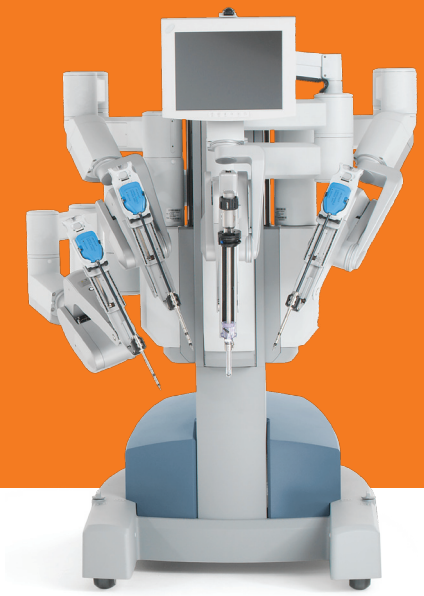
da Vinci®

TRANSORAL SURGERY

Procedure Guide



INTUITIVE SURGICAL®

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Disclaimer

The following material has been reviewed and approved by independent surgeons, who are not Intuitive Surgical employees:

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This procedure guide is provided for general information only and is not provided as formal medical training or certification. Intuitive Surgical trains only on the use of the *da Vinci* Surgical System. Intuitive Surgical does not provide clinical training nor does it provide or evaluate surgical credentialing or train in surgical procedures or techniques. This material presents the opinions of and techniques used by the above surgeons and not those of Intuitive Surgical. Before performing any clinical procedure utilizing the System, physicians are responsible for receiving sufficient training and proctoring to ensure that they have the requisite training, skill and experience necessary to protect the health and safety of the patient.

For technical information, including full cautions and warnings on using the *da Vinci* System, please refer to the System User Manual. Read all instructions carefully. Failure to properly follow instructions, notes, cautions, warnings and danger messages associated with this equipment may lead to serious injury or complications for the patient.

While clinical studies support the use of the *da Vinci* Surgical System as an effective tool for minimally invasive surgery, outcomes cannot be guaranteed, as surgery is patient and procedure specific.

The use of the *da Vinci* Surgical System for Transoral Surgery has not been cleared by the U.S. Food and Drug Administration.

1. Introduction

da Vinci® Transoral Surgery (TORS) is perhaps the most effective minimally invasive surgical treatment for diseases of the head and neck available today. The *da Vinci* Surgical System (standard and S models) allows the surgeon to provide the patient with procedures equivalent to traditional transoral surgery, but with the advantage of 3D high-definition visualization of the laryngopharyngeal structures, and the precision and dexterity afforded by robotic instrumentation. Additionally, *da Vinci* TORS allows the performance of endoscopic procedures that otherwise would be performed through an open approach, therefore minimizing morbidity and improving functional outcome as compared to an open approach.

Potential Patient Benefits

When compared to other surgical approaches, *da Vinci* Transoral Surgery may offer the patient numerous potential benefits, including:

- Avoidance of disfiguring mandibulotomy
- Minimization or elimination of need for chemoradiation therapy[1,2]
- Avoidance of tracheostomy[1]
- Quicker return to normal speech and swallowing[2]
- Significantly less pain[1]
- Less blood loss[1]
- Less risk of wound infection[1]
- Shorter hospital stay[1]
- Shorter recovery time[1]
- Minimal scarring[1]

Potential Surgeon Advantages

- General Advantages
    - Enhanced 3D HD visualization allowing precise dissection
    - With the angled telescopes and wristed instrument, issues of line-of-sight required for standard microscopic transoral laser surgery are eliminated
    - Maximum preservation of function and enhanced definition of safe margin for complete tumor removal
    - *da Vinci* technology provides enhanced possibility to adapt the surgical procedure to the intraoperative findings without compromising oncological principles
    - Tremor-free laser probe application available as an alternative to electrocautery, when indicated

- Advantages Specific to *da Vinci* Transoral Surgery (TORS)
    - Avoidance of significant morbidity of a translabial mandibulotomy, including lip and chin scars in selected cases
    - Avoidance of the need for combined chemotherapy and radiation in selected cases

[1] O'Malley BW, Weinstein GS, Snyder W, Hockstein NG. Transoral robotic surgery (TORS) for base of tongue neoplasms. Laryngoscope. 2006 Aug;116(8):1465-72

[2] Weinstein GS, O'Malley BW Jr, Snyder W, Sherman E, Quon H. Transoral robotic surgery: radical tonsillectomy. Arch Otolaryngol Head Neck Surg. 2007 Dec;133(12):1220-6.

- Potential to improve swallowing function due to added surgical precision
- Avoidance of malocclusion and chronic aspiration in selected cases
- Potential to avoid tracheostomy
- Visualization and reach of deepest structures with robotic instruments
- Transoral suturing capability for enhanced reconstruction capability

da Vinci **TORS applications**

The main anatomical areas for which TORS may be applied to a wide variety of procedures are:*

- Oropharynx and skull base
  - Tonsil
  - Tongue base
  - Palate
  - Pharyngeal wall
  - Parapharyngeal space

- Larynx and hypopharynx
  - Supraglottis
  - Glottis
  - Pyriform sinus
  - Pharyngeal wall

*This list is limited to those anatomical areas that have been reported in the literature.

This procedure guide will use an example procedure in the oropharyngeal and laryngeal area to detail the variations in *da Vinci* System setup. The patient positioning, *da Vinci* System setup and instrumentation is similar for all procedures performed in one anatomical area. Once the surgeon has familiarity with the proper setup for each of the areas, setup for procedures not described in this procedure guide should be apparent to the surgeon.

Portions of this procedure guide are synopsized from the book *Transoral Robotic Surgery (TORS)*, G. Weinstein and B. O'Malley, Plural Publishing, San Diego, CA. (www.pluralpublishing.com/publications_tors.htm)

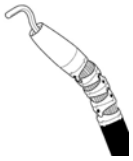
2. Instruments & Accessories

- OR equipment and robotic supplies
    - Equipment that must be available in room:
        - Warming blanket (Bair Hugger)
        - Cautery unit (set at 15-20 W for COAG) with Bovie pedal and bipolar pedal - one pedal next to assistant for suction cautery
        - Two Bovie pads
        - Reusable bipolar cord
        - Intuitive Surgical high-magnification camera head (45 FOV)
        - Intuitive Surgical wide-angle camera head (60 FOV)
        - Ikegami high-definition 3D imaging system (*da Vinci*® *S*™ only)
        - 30 degree Intuitive Surgical endoscope
        - 0 degree Intuitive Surgical endoscope
        - Surgical headlight
        - Three chairs that have a foot pedal for adjusting up and down - two at bedside (for the nurse and the bedside surgical assistant) and one at surgeon console
        - Three rectangular OR instrument carts and one small square OR instrument cart

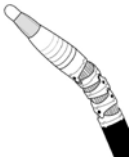
    - Medications/pharmacologicals:
        - Methylene Blue – for marking margins on specimen
        - Afrin® – for topical application transorally
        - Topical hemostatic agent
            - Surgiflo® – Agent (Baxter Healthcare) for topical hemostasis or
            - FloSeal® - (Johnson and Johnson, New Brunswick, NJ) for topical hemostasis

- Recommended 5mm *EndoWrist*® Instrumentation:
    - One Monopolar Cautery, PN 400142/420142

        - with Hook Tip, PN 400156



        - with Spatula Tip, PN 400160



    - Two Needle Drivers, PN 400117/420117

- One DeBakey Forceps, PN 400145/420145

- One Round-Tip Scissors, PN 400141/420141

- One Curved Scissors, PN 400146/420146

- One 5Fr Introducer Instrument (for laser application), PN 400225/420225

- 1 Maryland Dissector, PN 400143/420143

- 2 x 5mm Flared Cannula, PN 420262, *da Vinci* S only

- Alternative 8mm *EndoWrist* Instrumentation:
  - Fenestrated Maryland Bipolar, PN 400172/420172
  - Large Needle Driver, PN 400006/420006
  - DeBakey Forceps, PN 400036/420036
  - Round-Tip Scissors, PN 400007/420007
  - Permanent Cautery Spatula, PN400184/420184

- Recommended non-robotic instrumentation:

Qty.	Product Description	Catalog No.	Manufacturer or Vendor
1	Weder Tongue Depressor	55-0517	Gyrus
1	Right Clip Forceps	8225R	Karl Storz
1	Left Clip Forceps	8665L	Karl Storz
1	Regular Metzenbaum 7" Scissor	54-1027	Codman
1	8" [Long Suture] Sims Scissor	54-5503	Codman
1	9" Vascular Needle Driver	QG7-05-35-4941	Pilling
3	6¼" [Kelly] Rochester - Pean	32-4071	Codman
2	7¼" [Criles] Schmidt Clamps	30-4291	Codman
2	Curved Allis	N7013	Karl Storz
4	Towel Clips-Non Penetrating 3½"	33-5016	Codman
2	Penetrating Towels Clips 5.5"	33-5005	Codman
1	Blue Burner [9½ Pilling Insulated]	34-2982-B	Pilling
2	Velvet Eye Laryngeal Suction	50-7030	Pilling
3	Baby Yankauer Suction	16-2310	Pilling

- Recommended mouth gags/retractors
  The main consideration when choosing a mouth gag or retractor for *da Vinci* TORS is whether the device provides adequate exposure to the anatomical structures without compromising the workspace necessary for the *da Vinci* System arms and instruments.

  - Feyh-Kastenbauer (FK) Retractor
    The FK-Laryngo-Pharyngoscope System (Feyh-Kastenbauer Retractor) from Gyrus ACMI (www.gyrus-ent.com)/Explorent GmbH, Tuttlingen Germany (www.explorent.de) offers significant potential advantages with its lateral retractor attachments and its variety of tongue blades. The “cutout” blades and vallecular blade of the FK with three-dimensional adjustment capability provide the most versatility for achieving ideal exposure, and it is therefore the recommended retractor system for *da Vinci* TORS for exposure of the hypopharynx, larynx and — at times — for tongue base exposure.

Qty.	Product Description	Catalog No.	Manufacturer or Vendor
1	FK Basic Frame (Feyh-Kastenbauer)	640001	Gyrus
1	Attachment for connection of frame to chest support	640003	Gyrus
1	Tongue Blade Curved 22cm (for all applications)	640013	Gyrus
1	Tongue Blade Curved to Right, 22cm	640016	Gyrus
1	Tongue Blade Curved to Left, 22cm	640017	Gyrus
2	Cheek Retractor, flexible, 22.5cm	640011	Gyrus
1	Wollenberg Laryngeal Blade, concave, 17cm	640019	Gyrus
1	Wollenberg Diverticuloscope Blade, concave, 22cm	640050	Gyrus
1	Simon Mandible Blade, 14cm	640020	Gyrus

- Crow-Davis Mouth Gag
  Utilized for oropharyngeal exposure; the primary retractor for the exposure of the tonsillar region and the tongue base. The mouth gag listed below allows for wider mouth opening than other products.

  - The Storz tongue blades listed below feature integrated suction tubing for smoke evacuation. (www.storz.com, www.karlstorz.com)

Qty.	Product Description	Catalog No.	Manufacturer or Vendor
1	Crow-Davis Mouth Gag Right	N7451	Bausch & Lomb/Storz
1	Crow-Davis Mouth Gag Left	N7550	Bausch & Lomb/Storz
1	Davis-Meyer Tongue Blade size 2.5	743925	Karl Storz
1	Davis-Meyer Tongue Blade size 3	743930	Karl Storz
1	Davis-Meyer Tongue Blade size 3.5	743935	Karl Storz

  - Dingman Mouth Gag
    Utilized for oral cavity exposure
    (www.cardinalhealth.com/mps/brands/vmueller/vmcatalog/vmueller.html)

Qty.	Product Description	Catalog No.	Manufacturer or Vendor
1	Dingman Mouth Gag Frame	MO130-001	V. Mueller
1	Dingman Mouth Gag Blade No.1, 2 ½" x 1"	MO130-002	V. Mueller
1	Dingman Mouth Gag Blade No.2, 2 ¾" x 1¼"	MO130-003	V. Mueller
1	Dingman Mouth Gag Blade No.3, 3 ¼" x 1¼"	MO130-004	V. Mueller

- Additional mouth gags

Qty.	Product Description	Catalog No.	Manufacturer or Vendor
1	Jennings Mouth Gag	70202	Pilling
1	Side Biting Mouth Gag/Sluder Jansen Mouth Gag	70232	Pilling

- Additional equipment for mouth gag application
  - Metal holding arms that mount on the OR table to support mouth gag retractor:
    - 2x holding system w/ articulated stand (PN28172HA), socket (PN28172HK) and flexible clamping jaw (PN28172KFA) or clamping jaw instrument (PN28172KSA) (all at www.karlstorz.com)
  - Laryngoscope Holder and Chest Support for Adults (8575 GK) (www.karlstorz.com)

- Required sutures
    - 2-0 PermaHand Silk, SH needle (Ethicon Inc., http://ecatalog.ethicon.com) or
    - 2-0 Sofsilk, V-20 needle (www.syneture.com)
    - 3-0 Vicryl Coated, SH needle (Ethicon Inc., http://ecatalog.ethicon.com) or
    - 3-0 Polysorb, V-20 needle (www.syneture.com)

- Operating room disposables
  - Plastic Yankauer suction
  - Suction tubing (three)
  - Tonsil sponges
  - Steri-Drape™ Instrument Pouch – (www.3M.com)
  - Disposable suction coagulator – 11.00" (www.aemedical.com) (Catalog # - 050-035)
  - Optigard® Eye Protection Goggles – (www.dupacoinc.com) (Catalog # - 28310)
  - Clips for use with forceps 8665LR, Titan LT 200: medium, 5 mm, sterile, box with 36 cartridges, 6 clips each (8665T) (www.karlstorz.com)

- Supplies for postoperative care
  - No *da Vinci* TORS-specific supplies necessary
  - Usual post-operative regimen for transoral microsurgical surgery per individual hospital standards

3. Patient Selection, Positioning and Docking

- **Patient types for early cases:**
  - Choose an early tonsillar or supraglottic case initially with a localized lesion without extensive involvement of surrounding structures
- **Indications**
  - Patients must present with indications for diagnostic or therapeutic approaches for benign and malignant diseases of the oral cavity or laryngopharynx
- **Contraindications**
  - The standard contraindications for head and neck surgery, both conventional and minimally invasive, should be practiced when selecting patients for transoral robotic procedures including:
    - The presence of medical conditions contraindicating general anesthesia or transoral surgical approaches
    - Inability to adequately visualize anatomy to perform the diagnostic or therapeutic surgical approach transorally (methods for preoperative visualization are specific to site and procedure and are available either in the text below or attached references)
    - Unresectability of involved neck nodes
  - Specific contraindications for *da Vinci* TORS procedures regardless of region or procedure:
    - Mandibular invasion
    - Tongue base involvement requiring resection of greater than 50% of the tongue base
    - Pharyngeal wall involvement requiring resection of more than 50% of the posterior pharyngeal wall
    - Radiologic confirmation of carotid artery involvement
    - Fixation of tumor to the prevertebral fascia
  - Experienced teams have operated on patients with the following disease states which should be considered relative contraindications until greater experience level is achieved:
    - Pyriform sinus carcinoma
    - Skull base tumors

- **OR configuration**

  The following figure [Figure 1] shows an overhead view of the recommended OR configuration for *da Vinci* TORS. The surgeon console should be situated on the same side of the operating table as the assisting surgeon to allow for easier communication between assistant and console surgeon. Care should be taken to allow enough space for the patient cart to come in at an angle of ~ 30˚ during roll up to the patient from the right.

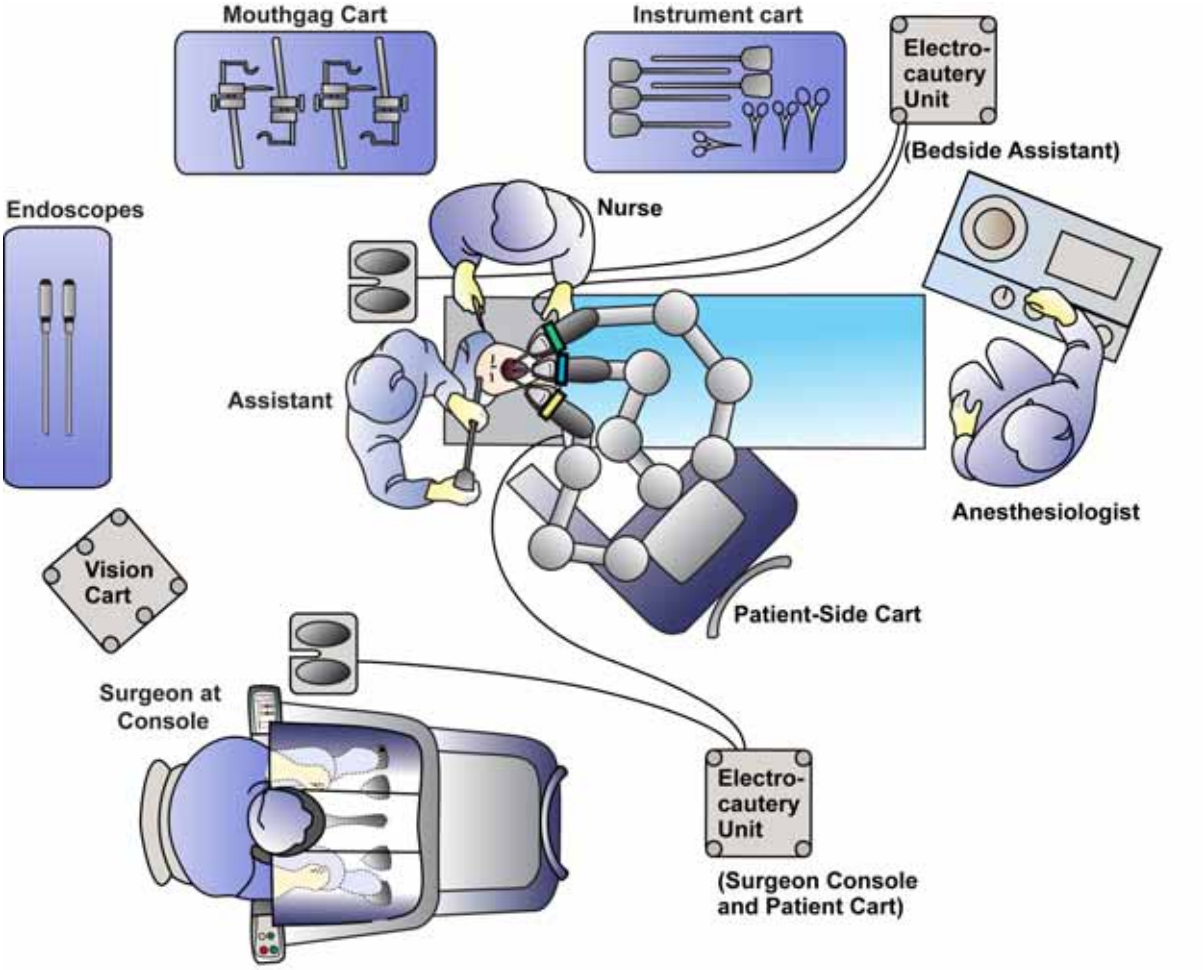


Figure 1: Operating Room Setup for *da Vinci* TORS

- Because of the position of the *da Vinci* patient cart arms over the patient's head, the anesthesia cart is placed at the foot of the patient to facilitate anesthesia management with minimal interference (patient's head is turned 180 degrees from anesthesia). [Figure 2]
- With some very heavy patients, and on some operating tables, placing the patient's head at the foot of the bed may change the control of the gravity of the bed, creating instability. One way to address this is to place an adjustable stool under the foot of the bed for extra support or alternatively, a stack of operating room platforms may be used under the foot of the bed.

- The patient-side surgical assistant works seated at the patient's head and has direct access to the surgical site with handheld instrumentation. The surgical assistant performs important functions during the case, such as:
    - Suction
    - Retraction
    - Application of hemoclips [Figure 2]

Figure 2: OR room setup with anesthesia management at foot end

- To facilitate quick mouth gag placement and robotic instrument changes, the scrub nurse is seated on the opposite side of the bed from the patient cart, facing the surgical assistant.
- The most ergonomic approach is to utilize three rolling rectangular draped operating room carts for instrumentation: The endoscope cart is positioned behind the surgical assistant at right angles to the patient bed. The camera, 0 and 30 degree endoscopes and a box of disposal surgical gloves for the surgeon and the assistant are placed on the endoscopic cart. The mouth gag cart [Figure 3] and the surgical instrument cart [Figure 4] are positioned adjacent the scrub nurse.
- These carts can be moved in or out of position relative to the scrub nurse depending on the point in the case. In the beginning of the case when the mouth gag is positioned (or later in the case if the mouth gag needs to be changed), the mouth gag cart is rolled in

and the various mouth gag options are readily available to the surgical team. Following positioning of the mouth gag, the mouth gag cart is moved out and the instrument cart is moved in, giving the surgical team access to all additional instruments utilized in the case. The third cart is the small square cart, which may hold the light source for traditional laryngoscopes used both for endoscopy — if deemed necessary at the start of the case — and, if required, to change the endotracheal tube at the end of the case to a larger bore tube for postoperative intubation.

Figure 3: Mouth gag cart

Figure 4: Surgical instrument cart

- Keep the patient-side monitor in the patient-side surgical assistant's line-of-sight to optimize hand-eye alignment. A second monitor is recommended, to provide easier viewing by anesthesia and the scrub nurse.

Patient preparation

- Anesthesia setup:
  - Peripheral IV
  - Single lumen wire-reinforced endotracheal tube is routinely utilized for non-laser cases and for oropharyngeal cases. For laser cases or for hypopharyngeal or laryngeal lesions where there is a risk of the cautery tip touching the endotracheal tube, a laser resistant endotracheal tube should be utilized.
  - Plastic patient safety goggles are used in all cases to protect the eye during the case. [Figure 5]

Figure 5: Optigard® Eye Protection Goggles in place

- If the surgery will be performed using a laser, then standard patient protective measures should be instituted. For eye protection, the following is recommended:
    1. Tape the eyes shut
    2. Place saline-soaked gauze and eye patches over the tape
    3. Wrap the head in moistened green operative towels.

- Patient Positioning and OR Table Considerations
    - Patient in supine position
    - Before positioning the patient on the OR table, the surgical team should assess whether the base of the table will interfere with the base of the patient cart when rolled in at a ~30° angle. For example, using the Amsco 3085SP Surgical Table (www.steris.com) limits how close the patient cart can be rolled in.
    - Since the relationship between the robotic cart and the bed is the same in every case, a useful shortcut is to place indelible marks on the OR floor corresponding to the foot of the bed and the front of the robotic cart: This will save some time during setup and positioning.
    - To avoid collisions between the base of the cart and the OR table base, the patient's head is positioned towards the feet of the OR table (so patient is backwards on the table, as is done in otologic cases). Then, the OR table is spun 180° with feet towards anesthesia. This is to allow the base of the *da Vinci* System patient cart to fit under the table, avoiding collision with the OR table column/post while bringing the arms into proper position for surgery. [Figure 6]

Figure 6: Relationship between the foot of the patient cart and the surgical bed pedestal

- Ground the patient with two grounding pads. Ground pad #1 will be for the electrosurgical generator controlled by the patient-side assistant (suction cautery); ground pad #2 is for the unit controlled from the *da Vinci* surgeon console.
- The console surgeon uses the foot pedal from the electrocautery unit, not the foot pedal on the console, as there is no cutting foot pedal on the *da Vinci* console (*da Vinci* standard and *da Vinci S* models).
- For laser cases, the neck and face should also be covered with moistened operative towels and the patient prepped and draped in the standard fashion.
- Following placement of the drapes, an instrument pouch [Figure 7] is positioned on the left side of the patient, within easy reach of both the nurse and the bedside surgical assistant. The pouch contains the blue burner forceps, the various suction tips, the suction cautery and standard cautery.

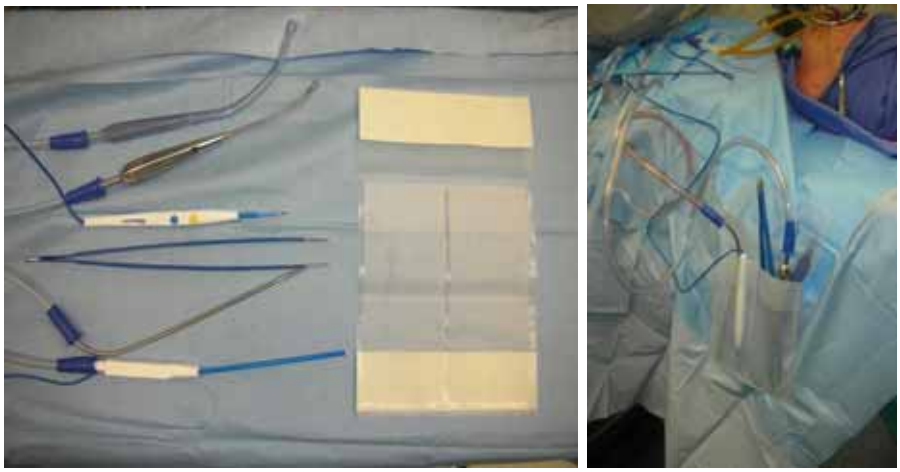


Figure 7: Bedside instrument pouch

- *da Vinci* **Setup and Docking**
  - Before roll up of the patient cart, identify the "sweet spot" on the camera arm and instrument arms to allow for correct patient cart setup. The camera arm setup joint should be placed towards the right to avoid collisions with the left instrument arm during docking.
  - The *da Vinci* patient cart is rolled in at ~30° angle. The position of the foot of the patient cart relative to the OR table is shown in Figure 6. The patient cart center column should be in line with the camera arm and the midline of the mouth gag. The patient cart is rolled in until the camera arm cannula adapter is located in the area above the patient's left shoulder, with the camera arm setup joint in the sweet spot.
  - At this point, the surgeon should put on a headlight and place the appropriate mouth gag.
  - Before insertion of the *EndoWrist* instruments, verify that there is sufficient clearance between the camera arm and the instrument arms.
  - At this point, prior to inserting the instrument arms, move the *da Vinci* patient cart arms into position over the patient's head. If they are not in good alignment, it is

easier at this point to undock the operating table and swivel the head of the bed away or towards the *da Vinci* patient cart to find the optimal position. Then, lock the operating room bed into position.

CAUTION: Once the robotic patient cart is moved into position and the instrument arms positioned intraorally, the OR table should no longer be moved.

- **Camera arm and instrument arm docking**
  - First, the camera arm is positioned in a vertical line over the patient's chest and inserted midline through the mouth gag. The camera arm insertion angle should be perpendicular to the angle of the mouth gag to allow for immediate visualization of the structures once docked.
  - Always start with the camera arm positioned as high on the robotic cart pedestal as possible. The higher this arm is, the less likely collisions will occur among the arms.
  - The camera cannula tip is positioned intraorally to provide good visualization of the operative field, as seen on the monitor. Sufficient room must remain between the incisors in the dentate patient or the upper alveolus in the edentulous patient to separate these structures from the scope while adjusting its position during the case. It is important for the bedside assistant to ensure that the endoscope is not resting on the upper teeth or the lower molars during the case to avoid damaging these teeth.
  - Position the endoscope on the camera arm intraorally and now, if need be, lower the arm on the cart pedestal to allow for maximal magnification of the primary site. For deeper lesions, such as Pyriform, supraglottis and glottis, the arm may need to be lowered, whereas this is rarely the case for tonsil or soft palate.
  - The right instrument arm is brought in and positioned with the cannula remote center (thick black line) well outside the mouth and the cannula tip roughly at the level of the mouth gag frame. Keeping the distance between the camera arm and right instrument arm setup joints at a maximum avoids external collisions of the robotic arms.
  - The insertion angle of the right instrument arm is adjusted so that the trajectory of the instrument, once inserted, can be seen just past the tip of the endoscope.
  - The left instrument arm has to cross over the patient and be positioned around the camera arm through the mouth gag. Similar to the placement of the other instrument arm, the left arm is positioned with the cannula remote center (thick black line) well outside the mouth with the cannula tip roughly the level of the mouth gag frame.
  - Next, the insertion angle of the left instrument arm is adjusted so that the instrument tip, once inserted, can be seen at the tip of the endoscope.

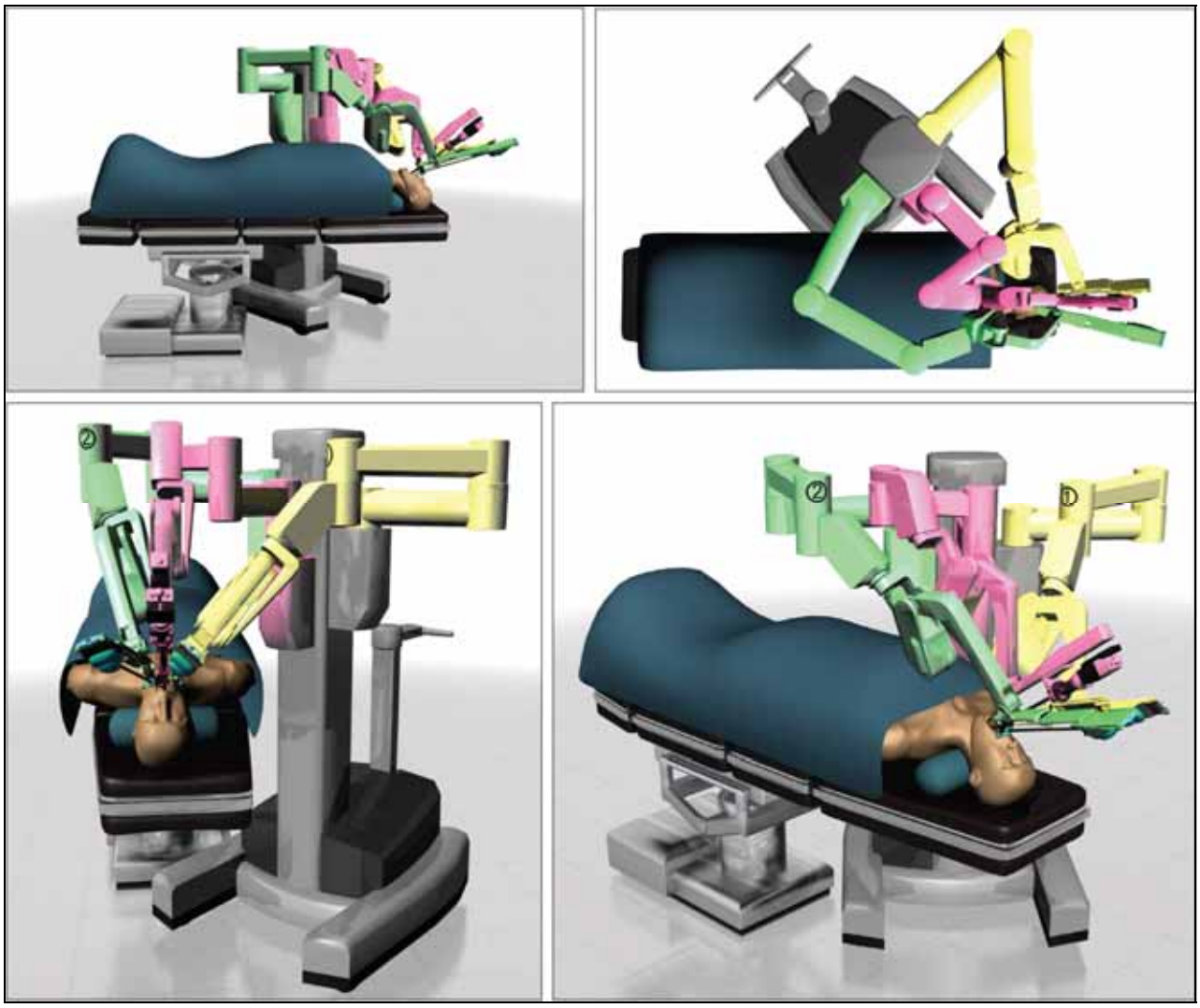


Figure 8: Patient positioning and system setup

Figure 9: Patient positioned with assistance at bedside and at the head of the bed

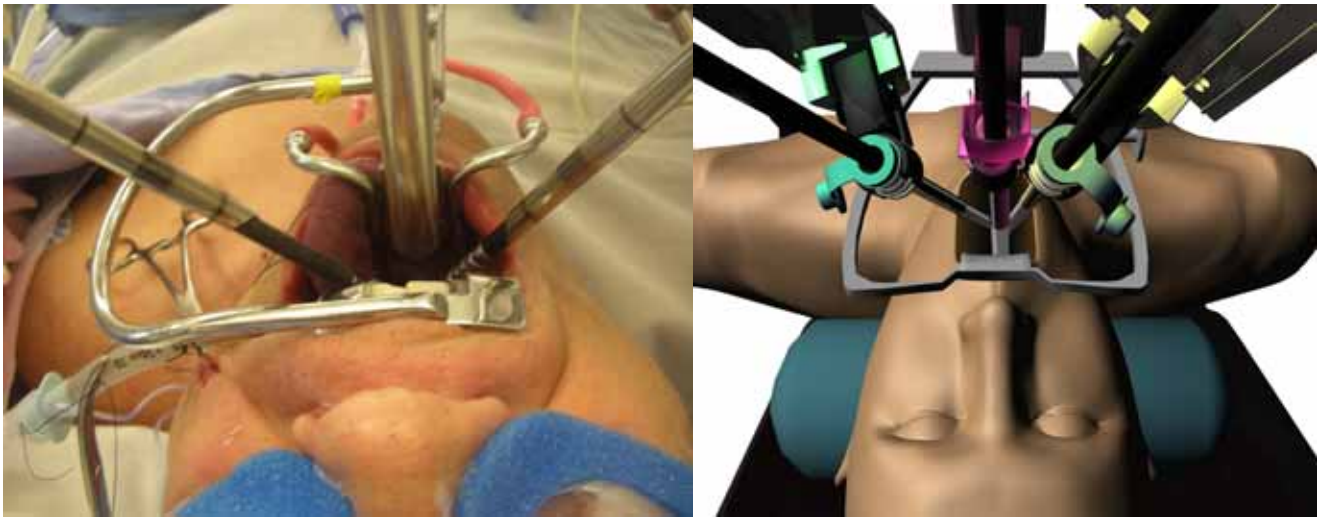


Figure 10: Position of the cannula, camera and instrument arms relative to the mouth gag and oral cavity

- Either the Intuitive Surgical high-magnification camera head (45 FOV) or the 3D HD system (Ikegami/Panasonic) is recommended for *da Vinci* TORS. This is because with the high-magnification cameras, you can maintain a close-up of the surgical site while avoiding instrument interference by pulling the endoscope tip back. If the Intuitive Surgical high-magnification camera head is used, be advised that the field of view is smaller (45° viewing angle versus 60° viewing angle for the Intuitive Surgical wide-angle camera head), which will require more camera rotation and movement during the case to visualize the target anatomy. The Ikegami camera system provides a wide 16-9 view and digital zoom without above-mentioned limitations.

4. Procedure Examples

Surgical Site Exposure

- The exposure must be achieved with a mouth gag and not a laryngoscope.
- In some tonsillar, palatal and other high oropharyngeal cases it will be evident, based on the outpatient office exam and radiology, that *da Vinci* TORS can be readily accomplished. All primary tongue-base, larynx and hypopharyngeal lesions should undergo a separate staging endoscopy in order to assess whether adequate exposure for *da Vinci* TORS can be attained. The patient should be informed that a staging endoscopy is needed to triage them between non-surgical treatment, open surgical treatment, laser resection via laryngoscopes or *da Vinci* TORS. During the staging endoscopy, the various mouth gags that would be used during *da Vinci* TORS are placed and the surgeon predicts if *da Vinci* TORS is possible. Separate staging endoscopy can be avoided in many tonsillar carcinomas. If it is decided that the optimal treatment in this case would be *da Vinci* TORS, then this is performed as a separate procedure at a later date.
- If, at the time of staging endoscopy, it is predicted that the planned surgical (or non-surgical treatment if surgical approaches are found not to be indicated) would result in prolonged dysphagia, then a percutaneous gastrostomy (PEG) can be performed at the time of staging endoscopy. Alternatively, the PEG can be done on the day *da Vinci* TORS is performed. If the duration of the dysphagia is expected to be very short, then a nasogastric tube can be used in lieu of a PEG. Finally, some patients may be able to eat by mouth postoperatively and no feeding tube is indicated. Nonetheless, while many patients may be able to eat by mouth following radical tonsillectomy, tongue base resection, supraglottic partial laryngectomy, we prefer at least a couple of weeks of tube feeds following these types of resections. The rationale of temporary tube feeding in these cases is that while many of these patients may be able to swallow some food and liquids without serious risk of aspiration, it is likely that they will not be able to take adequate nutrition by mouth to avoid malnutrition and dehydration. In addition, eating immediately postoperatively may result in excessive coughing and throat clearing, which may result in postoperative bleeding.
- While the surgeon can move directly on to *da Vinci* TORS and forego the step of staging endoscopy, there is a risk is that the *da Vinci* TORS case must be cancelled either because of lack of adequate exposure or because it is found that an alternative treatment may be optimal.
- A 2-0 silk suture is placed through the midline of the oral tongue, as a deep half-mattress suture (to avoid tearing the tongue). A hemostat is placed on the end of this suture and used to retract the tongue during the placement of the mouth gag. Following the placement of the mouth gag, the hemostat on the suture is allowed to hang freely and never suspended to the mouth gag itself to avoid tongue necrosis. An additional suture is placed intraorally on the contralateral side of the cancer to retract the endotracheal tube laterally; again, this is left long, and a hemostat is attached and allowed to hang freely. This hemostat serves as a reminder to remove the stitch at the end of the case.
- The best mouth gag that we have utilized for exposing the larynx and hypopharynx during TORS is the FK retractor system. [Figure 11]

Figure 11: FK retractor (Feyh-Kastenbauer system)

- For base-of-tongue and tonsillar procedures, the mouth gag of choice is the Crow-Davis [Figure 12], with the FK retractor system being used occasionally to expose the portion of the tongue base adjacent to the vallecula.

Figure 12: Crow-Davis mouth gag with Davis-Meyer Tongue Blade

- Before starting the *da Vinci* TORS procedure, there should be a final confirmation that the area of the laryngopharynx to be operated upon can be adequately visualized to perform the planned procedure. Depending on the individual exposure of the surgical field, the 0 degree endoscope is almost always inserted first to visualize the operative field; change to the 30 degree scope if and when it is necessary. The patient-side assistant can facilitate exposure with manual manipulation. [Figure 13]

Figure 13: Patient-side surgical assistant providing external neck pressure to move hyoid bone intraorally and provide improved exposure and suctioning

Resection methods

The general rule applied during *da Vinci* TORS is for the surgeon to be guided by the goal of achieving negative margins. Tumor resections are almost always performed utilizing electrocautery. If it is the opinion of the surgeon that there may be some benefit in utilizing the laser, the surgery may be accomplished with the *da Vinci* 5Fr Introducer Instrument that can carry a laser tool.

- When utilizing the electrocautery, the energy level on the electro-surgical generator should be set between 15-25W on **COAG and cut settings and the cutting should be set on "blend."**

- The most common combinations of instrumentation for the *da Vinci* System include:
  - 5mm *EndoWrist* instrumentation - Monopolar Cautery instrument combined with Maryland Forceps (see section 2, "Instruments & Accessories")
  - 8mm *EndoWrist* instrumentation – Any combination of monopolar cautery instruments and the Cadiere Forceps (contact your Intuitive Surgical representative for an instrument catalog)

- When utilizing the 5Fr Introducer Instrument (PN 400225/420225) for laser applications, follow the manufacturer's recommended guidelines for settings in accordance to the site and tissue being resected.

- In rare instances, the surgeon may feel that the optimal way to perform the resection is with scissors -- for instance, in the resection of a small superficial lesion in which either cautery or laser may damage the tissue in such a way as to preclude histopathologic diagnosis. In such instances, either the 5mm or 8 mm scissor may be utilized.

A. Oropharynx

da Vinci TORS Radical Tonsillectomy

The procedure is performed with electrocautery. The Crow-Davis mouth gag is utilized routinely for this procedure. The surgical steps are as follows:

- **Mouth gag placement** – The Crow-Davis mouth gag is placed so there is good visualization of the operative field. Ideally, the amount of tongue base that will need to be resected will be exposed from the start of the case to avoid the need for repositioning of the mouth gag later in the case. Suspension of the mouth gag is best done by using the Storz scope holder, which is attached to the side rail of the head of the operating table.

- **Scope Placement** - Initially the 0° endoscope is introduced in the midline through the Crow-Davis Mouth gag. The 30 degree scope may be utilized at the point during the case when tongue base exposure is needed in the area of the vallecula.

- **Instrument Placement** - After visualization of the pharynx, the Maryland Dissector (left instrument) and Monopolar Cautery with Spatula Tip (right instrument) are inserted and brought into endoscopic view.

- **Incision of Buccal Mucosa and the Pterygomandibular Raphe** - It is important that prior to this point, the surgeon has reviewed the preoperative anatomical scans — either computerized tomography (CT) scan with contrast or magnetic resonance imaging (MRI) with gadolinium. This is so the surgeon can understand the lateral extent of the cancer and the relationship of the cancer to the carotid arterial system, as well as the position of the carotid arterial system relative to the operative field.

  The first incision is made through the buccal mucosa at the level of the pterygomandibular raphe between the upper and lower molars using a 5 mm spatula cautery. The incision is carried superiorly through the anterior soft palate mucosa above the tonsillar fossa.

- **Identification of the Pterygoid Musculature** – After the pterygomandibular raphe is transected, the plane is developed along the lateral aspect of the constrictor muscles; laterally, the pterygoid musculature is identified. At this point in the operation, the dissection is brought to the level of the styloglossus and stylopharyngeous muscles without cutting these muscles. In addition, at this time, the floor of mouth is transected and brought anteriorly to a point adjacent to the tongue-base incision that will be performed later in the case. Whenever fascia is encountered, the surgeon should bluntly dissect the fascia to expose any underlying vessels, while avoiding directly cutting through undissected fascia.

- **Transection of Soft Palate and Superior Aspect of the Pharyngeal Constrictors** - The remainder of the soft palate is transected -- the extent is based upon the extent of cancer involvement. The resection is brought down through the soft palate musculature and the posterior tonsillar pillar to the level of the prevertebral fascia or

to the level of the pharyngeal constrictors posteriorly. The decision to transect and remove the pharyngeal constrictors over the posterior pharyngeal wall is based on how posteriorly the cancer extends. If the extent of the cancer requires the resection of the pharyngeal constrictors as a posterior margin, the horizontal transection is carried out by elevating the constrictor muscles off of the prevertebral fascia, utilizing blunt dissection with the 5 mm spatula cautery. Prior to resection of the constrictor muscles over the prevertebral fascia, it is critical that the surgeon has reviewed the preoperative anatomical scans to ensure that the carotid artery is not in a retropharyngeal position, thereby ensuring that incising this area will not put the carotid system at risk. Throughout the surgery, whenever muscle needs to be transected, every effort should be made to separate it from the surrounding tissues to avoid inadvertent transection of underlying blood vessels. As will be seen, this is not possible with the tongue-base musculature.

- **Identification and Transection of the Extrinsic Tongue/Pharynx Musculature with Protection of the Carotid Arterial System** – Attention now may be turned to transection of the tongue-base margin followed by identification and transection of the extrinsic musculature, including the palatopharyngeous, palatoglossus, styloglossus and stylopharyngeous muscles. Alternatively, based on the extent of the cancer, the anatomy, the flow of the surgery and the predisposition of the surgeon, the extrinsic musculature can be dealt with first, and then the tongue base margin can be resected.

  The position of the carotid arterial system is reconfirmed by evaluation of the preoperative CT scans and attention is focused on assessment of the carotid pulsations, which can often be visualized through the adjacent soft tissue in this area. The extrinsic muscles are bluntly dissected circumferentially. Alternatively, when circumferential dissection is not possible, at a minimum they are retracted away from the underlying deep structures and then carefully transected. Numerous transverse veins and arteries are encountered and clipped with three clips on the patient side and one clip on the tumor side, utilizing a Storz Laryngeal clip applier (Karl Storz, Tuttlingen, Germany) and cautery for smaller vessels. Care is taken to cut medially enough to avoid encountering the carotid arterial system.

  Of note, for almost all cancers in which significant trismus is not a symptom, the tonsillar cancer (which has had no prior treatment such as radiation or chemotherapy) rarely transgresses the constrictor muscles, and so the fascial and fat plane medial to the carotid artery is intact. Therefore, at this stage of the procedure, for cancers in patients without significant trismus, the fascia over the carotid artery should not be disturbed and the main trunks of the carotid arterial system should not be identified. If at the time of frozen section the lateral constrictor margin is found to be involved by cancer or have a close margin, the surgeon can return to the operating room and carefully dissect the next layer of fascia off of the carotid artery bluntly with the robotic instrumentation. This next layer of fascia and fat will be considered the lateral margin. As noted, when branches of the carotid artery to the tonsillar fossa are encountered, they should be carefully dissected and ligated utilizing the manual clip applier with two to three clips placed laterally and one on the tumor side (or just cauterization). Great care must be taken not to clip arteries that are traveling in the

caudad-cranial direction until the surgeon is entirely sure that this is not one of the major branches terminal of the carotid arterial system (i.e. the internal carotid artery).

If close or positive margins result in the need to take more tissue laterally in the proximity of the carotid, the dissection of the lateral tissue should be done gently and by "blunt" dissection with the spatula tip cautery and entirely freeing up the soft tissue prior to resection, to avoid inadvertent damage to the carotid system.

At this point, in most cases, a remnant of the styloglossus muscle is left in place at the level of the tongue base to avoid transecting vasculature that lies deep and lateral to this muscle. The surgeon returns to the remnant of the styloglossus following the resection of the tongue base margin.

- **Resection of the Tongue Base Margin** - Attention is now turned to resection at the level of the tongue base. The amount of tongue base resected is dependent on the inferior involvement of the tonsillar carcinoma into the tongue base. In those cases where there is no direct extension of cancer into the tongue base, a 1 cm margin will likely suffice. Alternatively, when the cancer extends deeply into the tongue base, up to half of the tongue base may be resected. It is important to predict preoperatively whether more than half the tongue base will need resection, as resection of greater than 50 percent of the tongue base is likely to lead to poor functional outcomes.

  The position of the mouth gag is now reassessed to ensure that there is adequate exposure of the amount of tongue base to be resected. An incision is made through the tongue base mucosa either starting medially or laterally, based upon the location of the cancer and the discretion of the surgeon.

  While the Maryland Forceps is excellent for most portions of the resection, the Schertel is superior in terms of its ability to grasp tissue and hold it under tension. However, the Schertel is inferior to the Maryland for fine dissection or to find and pick up the end of a bleeding vessel, so should only be used in the portion of the case where tissue retraction is critical.

  Tension is created on the tongue base by utilizing the Schertel Forceps to pull the tongue base posteriorly, utilizing the blade of the mouth gag as well as the assistant's Yankauer suctions to provide the counter tension. As one would with a standard transoral tonsillectomy, care must be taken to avoid touching of the electrocautery tip (which can get very hot) to the endotracheal tube to minimize potential for a tube fire. The assistant can help in this regard by retracting the endotracheal tube with a Yankauer suction when the electrocautery tip is in the proximity of the endotracheal tube.

  As the base of the tongue is resected to the level of the vallecula, an important consideration while progress is being made through the deep tongue musculature is to avoid making the cut too shallow, which may result in an inadequate resection. One way to avoid shallow resection is to remember to continue angling each progressive tongue-base muscle cut inferiorly toward the hyoid rather than cutting straight back

at right angles to the spine. To achieve the proper orientation, it may be useful for the bedside assistant to provide external pressure at the level of the tongue base in order to move the tissues into better view. In addition, using two baby Yankauer suction (one in each hand), the bedside assistant can retract soft tissue, the endotracheal tube and the tongue base to achieve better exposure. Finally, changing over to the 30 degree scope oriented in an upward direction allows good visualization of the progressive tongue base musculature cuts. Be advised that the surgeon must avoid the natural tendency to steer clear of deep cuts into the tongue base musculature that might result in transection of the lingual artery. While this may reduce the risk of potential bleeding from the lingual artery, it may also result in an inadequate cancer resection. The best way to ensure inadvertent transection of the lingual artery is slow, steady, progressive transection of the tongue base musculature.

- **Managing the Lingual Artery** - Care must be taken to avoid transecting the lingual artery. In the event the artery or one or more of its branches are encountered and need to be resected, three Storz laryngeal clips (Karl Storz, Tuttlingen. Germany) are applied on the patient side and either one clip or cautery on the tumor side prior to transection. If bleeding is encountered from the lingual artery, external neck pressure applied by an assistant at the level of the greater cornua of the hyoid decreases blood flow and allows for visualization of the bleeding point and application of Storz Laryngeal clips (Karl Storz, Tuttlingen. Germany).

- **Final Transection of the Junction of the Tongue Base and Extrinsic Musculature as well as the Posterior Pharyngeal Wall** - As mentioned above, a remnant of the styloglossus muscle is left in place prior to resection of the tongue base. This helps ensure that when the styloglossus is transected, it will be under tension as the surgeon pulls the entire tonsillar/tongue base specimen medially and superiorly into the lumen of the pharynx -- thereby avoiding transection of the underlying arterial vasculature. As in the rest of the procedure, when fascia is encountered, the surgeon should bluntly dissect through the fascia to expose any underlying vessels and should avoid directly cutting through non-dissected fascia. The posterior pharyngeal wall is then resected from the vallecula to the level of the soft palate. The tumor is mobilized en bloc and sent for final histopathology confirmation of negative margins. When significant soft palate resection is performed, pharyngoplasty may be performed by suturing the posterior palatal mucosa to the posterior pharyngeal wall with three or four 3-0 Polysorb, V-20 needle (www.syneture.com).

- **Final Hemostasis** - Hemostasis is verified using the Valsalva maneuver. The surgeon should visualize the carotid pulsation laterally, because when present, this is a valuable landmark that may help avoid this structure while achieving hemostasis. Cautery should not be applied deeply to avoid damaging underlying vasculature that may not be evident. Bleeding is controlled with electrocautery or hemoclips where indicated. A hemostatic agent such as Surgiflo® or FloSeal® is utilized routinely at the end of the case to minimize postoperative bleeding. The wound is copiously irrigated and evaluated for any additional bleeding that may need to be cauterized. Hemostasis may be time-consuming and should always be meticulous to avoid postoperative bleeding.

- **Assessment of Airway**
  The airway is assessed: If there is significant edema or concern that airway compromise might develop, the endotracheal tube is changed and the patient remains intubated for one to two days and then is extubated.

B. Larynx

da Vinci **TORS Supraglottic Partial Laryngectomy**

The patient should undergo a staging endoscopy to confirm that the exposure is adequate to perform. Either electrocautery or the robotic laser tool may be utilized per the desires of the surgeon. The surgical steps are as follows:

- **Mouth Gag Placement** – The FK retractor is utilized routinely. The initial view should include the epiglottis and vallecular mucosa. When using the *da Vinci* S System to resect larynx or pyriform lesions, the FK retractor should be suspended using the Storz (8575 GK Riecker-Kleinsasser Laryngoscope Holder and a Mayo stand over the patient's chest. When using the standard *da Vinci* system, there will be insufficient room between *da Vinci* patient cart arms and the chest to place a Mayo stand. So, in this case, two Storz scope holders are used attached to both sides of the OR table and both sides of the FK frame.

- **Scope Placement** - Initially the 0 degree endoscope is introduced in the midline through the FK retractor. The 30 degree scope is utilized at the point during the case when the surgeon has the sense that it would be beneficial. This may be at the outset of the case or not at all.

- **Instrument Placement** - After visualization of the larynx, the Bipolar Maryland Forceps (left instrument) and Monopolar Cautery with Spatula Tip are inserted and brought into endoscopic view.

- **Midline Transection of the Epiglottis** - The suprahyoid epiglottis and the median glossoepiglottic fold is transected in the midline in a sagittal plane and divided down to the level of the petiole.

- **Transection of the Vallecular Mucosa** - Next the transection is followed along one side of the vallecula, and the pre-epiglottic space is dissected from the region of the hyoid bone and thyrohyoid membrane.

- **Identification and Dissection of the Thyroid Cartilage** – At this point, the superior aspect of the thyroid cartilage is identified. Identification is done laterally by both visualization and palpation. The bedside assistant should apply intermittent pressure on the thyroid cartilage lamina during the dissection. This will allow the surgeon to see the movement of the top edge of the thyroid cartilage. The surgeon should then press on the top of the thyroid cartilage with the electrocautery while the bedside assistant palpates the cartilage to confirm that the structure being palpated is indeed the thyroid cartilage. Once the top of the thyroid cartilage is identified, the perichondrium is transected along the superior surface the full length from anterior to

posterior. The soft tissue of the supraglottis is dissected from the inner aspect of the thyroid cartilage at this stage.

- **Identification of the Neurovascular Bundle** - When the superior laryngeal neurovascular bundle in the pharyngoepiglottic fold is identified the vein and artery should be clipped utilizing the Storz Clip applier (Karl Storz, Tuttlingen, Germany). The vessels are transected by monopolar cautery. Although clips are preferable, at times cautery alone is utilized either with the suction cautery or the spatula cautery.

- **Transection of the False Cord** - The dissection is continued at the base of the aryepiglottic fold to the arytenoid by transecting the ipsilateral false cord. The false vocal cord is transected anteriorly and detached by dissection from the lateral ventricular mucosa anteriorly to posteriorly preserving the true vocal cord.

- **Final Resection at the Level of the Paraglottic Space and Arytenoid -** After mobilization of the ventricular mucosa, the false cord is separated from the attachments on the arytenoid cartilage down to the border and postero-lateral soft tissue, in the area of the paraglottic space. Care should be taken not to transect too deeply to avoid damaging either the arytenoid or the true cord.

- **Removal of Hemilarynx** - The entire left hemi-epiglottis is detached and removed en bloc and sent to pathology for pathologic examination of all margins.

- **Resection of Residual Supraglottic Tissue** - To prevent stenosis, the pre-epiglottic fat is mobilized with a soft tissue margin (2-3mm) from the hyoid bone, the thyrohyoid membrane and the inner aspect of the thyroid lamina, and sent to pathology to be included in the final pathologic margins.

- **Resection of the Contralateral Supraglottis** - For treatment of bilateral or midline tumors, the same procedural steps are then carried out on the opposite side.

- **Final Hemostasis and Assessment of Airway** - Hemostasis is verified using Valsalva maneuver. Bleeding is controlled with electrocautery where indicated. A hemostatic agent such as Surgiflo or FloSeal is applied to the wound routinely at the end of the case to minimize postoperative bleeding, and then removed after 120 seconds. The airway must be assessed: If there is significant edema or concern that airway compromise might develop, then the endotracheal tube is changed and the patient remains intubated for one to two days and then is extubated.

5. Post-Operative Care

- **Post-operative pain management**
  - Pain medication per usual post-operative regimen

- **Inpatient hospital follow-up and discharge**
  - Intubated patients are transferred to intensive care unit
  - Extubated patients are transferred to the recovery room and to the appropriate hospital inpatient setting
  - Antibiotic prophylaxis is mandatory
  - Patient should be monitored with oximetry around the clock
  - Patient continues percutaneous endoscopic gastrostomy (PEG) tube nutritional intake until full oral nutrition can be reintroduced into the diet
  - Patient discharged from hospital three to five days postoperatively if stable and if:
    - Free of bleeding
    - Afebrile
    - Free of major adverse events
    - Unless otherwise contraindicated, all patients are given six milligrams of dexamethasone q six hours while in the hospital

- **Outpatient hospital follow-up**
  - Unless otherwise contraindicated, all patients are discharged to home on tapering dose of steroids — per oral or via the feeding tube — as well as antibiotics.
  - Follow-up visit one week post-operatively
  - When indicated, plan for staged neck dissection(s) one-to-three weeks following *da Vinci* TORS. The rationale of staging the neck dissection is to avoid creating a connection between the pharynx and neck as well as to avoid additional laryngopharyngeal swelling that might result in the need for a tracheostomy.
  - In cases of malignancy following pathology review, counsel the patient concerning the need for additional therapy or adjuvant radiation, with or without chemotherapy, as indicated.
  - Following the neck dissection, have swallowing therapy begin with a speech language pathologist. In most cases, the preference is to have the patient use the g-tube for nutrition only for the first two to three weeks in order to minimize potential for coughing, which would cause repeated Valsalva and may predispose the patient to bleeding.

Author Biographies

Bert W. O'Malley, Jr., M.D. (at left) joined the University of Pennsylvania School of Medicine on August 1, 2003 as Gabriel Tucker Professor and Chairman of the Department of Otorhinolaryngology – Head & Neck Surgery. He is the Director of the Head and Neck Cancer Research Program, Co-Director of the Center for Head and Neck Cancer and Co-Director of the Center for Cranial Base Surgery, with joint appointments in the Departments of Neurosurgery and Radiation Oncology, respectively.

Dr. O'Malley previously served as Professor and Chairman of the Division of Otolaryngology – Head and Neck Surgery at the University of Maryland School of Medicine from February 1, 1999 through July of 2003 with joint appointments in the Department of Surgery and the Greenebaum Cancer Center. Prior to his appointment at Maryland, he held the position of Associate Professor and Director of Gene and Molecular Therapy in the Department of Otolaryngology – Head & Neck Surgery at the Johns Hopkins School of Medicine.

Dr. O'Malley leads a laboratory research group in the area of gene and molecular therapy, investigating both viral and non-viral based gene therapies for the treatment of head and neck cancer. He is also studying gene transfer of growth factors for repair and regeneration after muscle or nerve injury or surgical tissue transfer. The newest direction of this research is the use of molecular therapies to enhance the anti-tumor effects of chemotherapy and radiation while reducing the known toxicities of these standard treatments.

Dr. O'Malley has special clinical expertise in the area of skull base tumor surgery, head and neck and thyroid cancer and endoscopic sinus surgery. His clinical research focuses on the development of novel technologies such as image-guided surgery and robotic surgery. Dr. O'Malley co-founded the first human robotics head and neck and skull base program in the world and is co-principal investigator of the first IRB approved human clinical trial for robotic surgery in our specialty. He is actively developing novel robotics surgical procedures and instrumentation to advance the use of this technology in all aspects of Otolaryngology-Head and Neck Surgery.

Gregory S. Weinstein, M.D. (at right) joined the University Of Pennsylvania School Of Medicine in 1991 as a co-founder of the Penn Center for Head and Neck Cancer, of the Department of Otorhinolaryngology – Head & Neck Surgery. He is presently Professor and Vice Chair of the Department, Co-Director of the Center for Head and Neck Cancer, Director of the Division of Head and Neck Surgery, Director of the Head and Neck Surgery Fellowship, and Associate Director for Clinical Services and Programs at the Abramson Comprehensive Cancer Center.

Dr. Weinstein's clinical expertise is in the head and neck surgery including all aspects of cancer surgery of the oral, pharyngeal, laryngeal and neck cancer as well as special expertise in thyroid and parotid surgery. Dr. Weinstein's special interest is in organ preservation surgery for laryngeal cancer. He was the first surgeon in the United States to perform the larynx preserving surgery, the Supracricoid Partial Laryngectomy, and has been the primary instructor of this procedure nationally. His book entitled *Organ Preservation Surgery for Laryngeal Cancer* provides a guide for clinicians utilizing open and transoral surgery to save the larynx. Dr Weinstein has authored over 120 peer reviewed medical articles. Between 1993 and 2008, Dr Weinstein has given over 55 invited lectures both nationally and internationally.

An extension of Dr. Weinstein's special interest in organ preservation surgery has been clinical research in the area of Transoral Surgery (TORS) He was Principal investigator of the first IRB approved human clinical trial for robotic surgery in the field of Head and Neck Surgery. As co-founder of the world's first research program in human TORS he has been involved with clinical research in developing new techniques and instrumentation for robotic surgery. Dr. Weinstein has also been involved in establishing the first training program in TORS. He has authored numerous articles in the area of robotic surgery and is on the editorial board of numerous journals including the Journal of Robotic Surgery as well as Head & Neck: Journal for The Sciences & Specialties of The Head and Neck. Dr. Weinstein is a board member of the Minimally Invasive Robotic Association. (MIRA)