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CIS II: Group 12

Critical Review: Danger points, complications and medico-legal aspects in endoscopic sinus surgery

1 Project Review

Our project consists of three distinct subprojects, though the context of this paper review is only particularly relevant to one of them: the IRB Validation Study using the Robotic Ear Nose and Throat Microsurgery System (REMS). The primary goal of this study is to determine if robotic surgical assistance with the REMS improves surgical skill compared to conventional (unaided) surgery. Participants will be asked to navigate a tracked instrument to contact specific anatomical targets in the sinuses of a cadaver head. The study will involve 20 novice (untrained) participants and 5 expert (professional) surgeons. The 20 novices will be randomly divided into two groups of ten. One group will be trained conventionally and one group will be trained using the robotic method. At the end, the groups will be assessed with a standard evaluation method to determine if robotic surgical assistance increases surgical skill.

Simple adherence to the study protocol and requisite training in the operation and use of the REMS is sufficient to complete the tasks and goals laid before us in our project. However, by actually investigating and understanding the motivation behind this study and the REMS development in general, we hope to go above and beyond the required minimum to really ensure that the study quality is excellent. To this end, we have compiled an extensive and broad bibliography to enhance our understanding of the context of the greater REMS project. The paper I have selected for the seminar presentation and this critical review is precisely relevant to our learning: *Danger points, complications and medico-legal aspects in endoscopic sinus surgery*.

2 Paper Selection

The paper, titled *Danger points, complications and medico-legal aspects in endoscopic sinus surgery*, was published in December 2013 by W. Hosemann and C. Draft, both part of the Department of Otorhinolaryngology, Head and Neck Surgery at University Greifswald in Greifswald, Germany. The paper, across the span of 61 pages, provides a comprehensive review of all complications, minor and major, of endoscopic surgery of the paranasal sinuses. Discussion of complications also includes review of the symptoms associated with each complication, as well as their respective therapeutic/contingency regimens. The paper further presents a brief discussion regarding the medico-legal considerations surrounding these surgeries and also regarding the established and prospective surgical training and education methods.

Because the paper is more an encyclopedia than it is a presentation of a novel algorithm or method, it is an excellent resource for me and my group members. The discussion of complications

informs us of the common pitfalls associated with paranasal sinus surgery – pitfalls that the REMS is designed to help surgeons avoid. The presentation of issues and considerations in surgical training is also highly relevant to us, as part of our task involves the training of the study participants (with or without REMS).

3 Discussion of Complications

The bulk of content discussion in this paper is dedicated to the review of all major and minor complications in paranasal endoscopic surgery. This is over 35 pages out of the 40 pages of discussion – 34 complications are discussed in total. This breadth and depth of information is helpful to the group, but is impossible to discuss thoroughly in the scope of this critical review. Instead, I will discuss only the "Injury of the carotid artery."

Table 1: Complications of endonasal sinus surgery (based on: [62]).

Localization/overall type of injury	"minor complication"	"major complication"
Orbital complicaton	• Orbital emphysema • Ecchymosis of the eylid	• Orbital hematoma • Reduced visual acuity / blindness • Enophthalmos • Injury of the nasolacrimal duct
Intracranial complication	• Uncomplicated CSF fistula	• CSF leak • (Tension-) pneumocephalus • Encephalocele • Brain abscess • Meningitis • Intracranial (subarachnoid) hemorrhage • Direct injury of brain tissue
Bleeding	• minor bleeding (stopped with nasal packing, no need for blood transfusion)	• Injury of the ant. ethmoidal artery • Injury of the sphenopalatine artery • Injury of internal carotid artery • Bleeding in need of transfusion
other	• Synechiae • Slight exacerbation of pre-existing bronchial asthma • Hyposmia • Local infection (osteitis) • Postoperative MRSA-infection • Atrophic rhinitis • Paraffinoma • Myospherulosis • Temporal irritation of the infraorbital nerve • Hypoesthesia of the lip or teeth	• "Toxic shock syndrome" • Anosmia • Severe exacerbation of a pre-existing bronchial asthma or bronchospasm • Death

3.1 "Major Complication": Injury of the Carotid Artery

In the area of the paranasal sinuses, especially the sphenoid sinus, the stretch of carotid artery is known as the internal carotid. While the external carotid arteries supply areas of the head like the face, scalp, and skull, the interal arteries directly supply the brain itself: it is an extremely critical structure. Accidental injury of the internal carotid during surgery is therefore very serious and could easily result in death of the patient. The exact incidence rate of the injury is unknown, although it is very roughly

estimated by the authors at around 1%. The paper also states that the artery bulges from the anterior lateral wall of the sphenoid sinus in about 80% of cases, the large majority. In 15% of the cases, the protrusion is "very prominent" (this is not rigorously defined). On average however, the prominence is around .5mm. It is therefore critical that the path of the surgeon's tool be highly precise in order to avoid hitting and potentially rupturing the structure. The REMS assists in this area by providing the surgeon superior tool manipulation and also visualization compared to traditional non-robotic methods.

Although injury prevention is ideal, the authors also discuss the current emergency measures in the event of an injury. These steps are generally short-term and limited in effectiveness. While this is not immediately relevant to our IRB study, it further shows the importance of the REMS project. The steps described in the paper are as follows:

- Insertion of nasal packing coupled with suction (improper compression levels could result in even further damage, or inability to stop bleeding)
- Compression of the carotid in the neck (not reliable, and considered somewhat obsolete)
- Immediate establishment of IV lines around the body, blood transfusions to treat blood loss (a very short term and resource intense measure, fails to address the root issue)
- Neuroradiological intervention (not trivial – requires involvement of other specialists and likely requires transport of patient)

It is clear that the current methods are far from surefire solutions!

4 Discussion of Training Issues

The paper briefly discusses trends and developments in the area of surgical training, specifically for endoscopic procedures of the paranasal sinuses. It states that, given the increased desire for medical excellence and perfection over time coupled with a corresponding increase in strictness of medico-legal legislature, medical training must also improve. This also means that the primary forum for gaining surgical experience should be moved out of the operating room and into dedicated learning environments so as to minimize risk to patients.

The authors assert that "In order to learn and train endoscopic surgery techniques, endonasal, endoscopic dissections using cadaver specimens are certainly unmatched." They however go on to present virtual reality simulators as an alternative, due to possible lack of access to cadaveric specimens. The simulators would preserve the resources of the teaching clinic, and would also be more suitable for

junior residents. Some of the existing simulators described in the paper include the Endoscopic Sinus Surgery Simulator (ES3) and the Voxel-Man SinusSurg.

Figure 1: The Endoscopic Sinus Surgery Simulator

When considering simulators, one main issue is the convenience vs fidelity tradeoff. Virtual reality is more "portable" or lightweight than cadaveric/in vivo training. However, it is not a real procedure. For a simulator to be effective, it must effectively communicate anatomy (space) as well as haptic skills – one without the other is not sufficient. A notable advantage in simulators (and also our robotic REMS method) is that the environment is "controlled"/monitored – the computer stores information directly from the procedure. Results can be analyzed, quantified, and compared quite readily. This is advantageous compared to traditional evaluation methods, which are highly subjective. Tracking of training information over time is also valuable to monitor the progress of an individual. However, due to the developing nature of the field, the authors admit that not much has been conclusively demonstrated in terms of whether or not simulators (or other nontraditional training methods) actually increase surgical skill. Our project's study aims to show that there is indeed and improvement in surgical skill with the REMS robot!

5 ASSESSMENT

The paper very successfully accomplished its goal of presenting a comprehensive, detailed discussion and review of the risks and other considerations surrounding endoscopic paranasal sinus surgery. With over 700 unique paper references, the information in this paper is extremely well sourced. It is very simple to perform additional reading on virtually any claim or statistic the authors present. For the purposes of our group, this paper is unrivaled as a reliable source of thorough, technical information. Another positive aspect of the paper is that it has more than just in depth discussion of one subject – the scope includes discussion of even the legal aspects surrounding the surgery, as well as information regarding the state of surgical training.

One of the strengths of the paper is also a shortcoming – for a casual reader, there may simply be too much information here. Because it is so ambitious, the paper inevitably leaves some details undiscussed explicitly (these are sourced – it is up to the reader to go hunt down the referenced works and learn for themselves). Also, due to its size, there are also some organizational weaknesses. Within subsections, information is too often presented in an almost "stream of consciousness" fashion. It sometimes seems that the authors write down what they are thinking as they are thinking of it, without too much forethought to organization.