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TITLE: Criterion-Based Training to Reduce Surgical Errors

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14. ABSTRACT Technical skill is at the core of surgery. Surgical training typically lasts for a specified time period or number of procedures. This approach produces surgeons with considerably variable skill levels. Also, training on patients is becoming unacceptable for patient safety. In contrast, pilots and other non-medical personnel are trained to criteria on simulators to ensure skill proficiency in their MOS prior to reporting for duty. Proficiency levels are objectively established by experienced practitioners, and the trainee is required to consistently demonstrate that level of proficiency before progressing. We propose to use a surgical simulator (the ES3) to train surgical residents to criterion performance levels, and to investigate whether criterion-based training is superior to training for a fixed number of trials. Twenty-four otolaryngology residents will serve as subjects. Eight attending otolaryngologists will establish performance criteria and will serve as comparators for infra-operative assessment. Subjects will complete a battery of validated objective tests to assess visuospatial, perceptual and psychomotor abilities. An experimental group will be trained to criterion on the simulator, and then perform a procedure on a patient. A control group will train by repeatedly performing the same procedure on patients, with no simulator training. All procedures will be videotaped and objectively assessed for explicitly defined metrics. We hypothesize that prior training to established criteria will reduce surgical errors, and provide evidence for training on simulators before ever operating upon a patient.				
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Table of Contents

	<u>Page</u>
Introduction.....	4
Body.....	4
Key Research Accomplishments.....	5
Reportable Outcomes.....	None
Conclusion.....	None
References.....	None
Appendices.....	None

INTRODUCTION:

Technical abilities are highly individualistic, as shown by the wide range of ability characterizing different musicians, artists, and others. Given that the issue of creating a competent and safe surgeon is of paramount importance, we hypothesize that the objective measurement of a resident's progress is critical to both the achievement and the assessment of proficiency.

BODY:

Nine junior (postgraduate years 1, 2, and 3) Otorhinolaryngology residents were enrolled at the Montefiore Medical Center site as the subject group. All have undergone baseline skills assessment on the Endoscopic Sinus Surgery Simulator along with having performed a digitally recorded pre-training surgical procedure in the operating room. Eight residents have completed training to proficiency, indicated by achieving a score of greater than 94 on the Sinus Surgery Simulator three consecutive times, as previously determined by a panel of experts. Four of these residents have performed a digitally recorded post-training surgical procedure in the operating room and therefore have completed their participation in the study. The other resident will perform the digitally recorded post-training surgical procedure in the operating room as soon as an eligible surgery becomes available. One resident remains to be trained on the ES3 until proficiency is reached. Five remain to be recorded on their final surgical performance.

The control group is composed of nine junior Otorhinolaryngology residents from two collaborating institutions, Montefiore Medical Center and New York University Medical Center. Our efforts in establishing the control group had been extensively delayed while awaiting ORP approval for submission of an IRB to New York University Medical Center. We had originally sent the application to the ORP on February 15, 2007. The subject protocol for New York University Medical Center was resubmitted on July 29, 2008. The subject protocol for that institution was reviewed and accepted by the USAMRMC, ORP, and HRPO on July 30, 2008. Moreover, eligible cases for resident involvement are limited. Many sinus surgeries are disqualified because they do not reach our established criteria of being over 18 years of age with no previous endoscopic sinus surgeries and no obstructing pathology. Since approval of IRB submission to our collaborating institution, six of the seven junior residents at New York University Medical Center who will make up the control group had their base-line skills assessed. Two of these residents have completed all four live training OR video tapings while assisting in ESS cases and have completed their participation in the study. We will begin videotaping the live training of the four remaining residents at New York University Medical Center as soon as eligible surgeries are available. Two residents from Montefiore Medical Center also make up the control group. Both have had their base-line skills assessed. We will begin video taping their live training in the OR as soon as eligible surgeries become available as well.

We have videotaped the benchmark endoscopic sinus surgical procedures performed by two otolaryngology attending physicians. We plan on taping three more attending doctors shortly since this aspect of the study was also dependent on receiving ORP clearance for IRB submission.

We are also currently in the process of establishing intra-rater reliability of the expert sinus surgeons who make up the rater group. This will enable us to analyze the surgical procedure recordings as soon as the videotaping of the subject and control groups are complete.

Key Research Accomplishments:

- **Completion of initial assessment by 9/9 subject group residents on ES3**
- **Completion of initial recording of pre-training surgical procedure by 9/9 subject group residents**
- **Completion of training to proficiency by 8/9 subject group residents on ES3**
- **Completion of final recording of post-training surgical procedure by 4/9 subject group residents**
- **Completion of initial assessment by 8/9 control group residents on ES3**
- **Completion of initial recording by 2/9 control group residents**
- **Completion of recorded surgical procedure by 2/5 expert Endoscopic Sinus Surgeons**

Reportable Outcomes:

We do not, as of yet, have any reportable outcomes due to the delays delineated above. Anticipated time to completion is 6-9 months.

Conclusions:

N/A

References:

N/A

Appendices:

N/A

Supporting Data:

N/A

REPORT OF INVENTIONS AND SUBCONTRACTS
(Pursuant to "Patent Rights" Contract Clause) (See Instructions on back)

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5. "SUBJECT INVENTIONS" REQUIRED TO BE REPORTED BY CONTRACTOR/SUBCONTRACTOR (If "None," so state)

a. NAME(S) OF INVENTOR(S) <i>(Last, First, Middle Initial)</i>	b. TITLE OF INVENTION(S)	c. DISCLOSURE NUMBER, PATENT APPLICATION SERIAL NUMBER OR PATENT NUMBER	d. ELECTION TO FILE PATENT APPLICATIONS (X)				e. CONFIRMATORY INSTRUMENT OR ASSIGNMENT FORWARDED TO CONTRACTING OFFICER (X)	
			(1) UNITED STATES		(2) FOREIGN		(a) YES	(b) NO
			(a) YES	(b) NO	(a) YES	(b) NO		
None								

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(b) NAME OF EMPLOYER	(b) NAME OF EMPLOYER				
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