Temporal Bone Dissection Simulation

E. Human Subjects

This study will be conducted under the IRB approved protocol, "The Investigation of the Use and Efficacy of Advanced and Virtual Computer Interfaces for Biomedical Applications" Donald Stredney, OSC, last approved August 11, 2003 under continuing review. This protocol is in complete compliance with all HIPAA regulations.

(1)
Subjects will be asked to sit and perform the basic techniques of temporal bone dissection using two different dexterous interfaces, and one visual interface (see Figure 2, Section C). Stereo images of the regional anatomy will be displayed. Two desktop speakers will play sounds of the simulated drilling. The dexterous interfaces will provide force reflection to the subject's hands.

The target population includes residents in their 2nd to 5th year of residency. Ages and health are not relevant and will not be considered for eligibility to participate. Inclusion and exclusion will be based solely on basic knowledge of surgical techniques. Pregnancy will not preclude participation and there is no know risk involved. No exclusions will be made on the basis of gender, or ethnicity. All subjects are reminded of their rights to terminate the study at any time, without cost or penalty to them.

(2)
Imaging data, (MR, CT) is acquired from fresh (non-profused) cadavers obtained from the Body Donation Program of the Department of Biomedical Informatics at The Ohio State University. All remains are returned to the program (see http://medicine.osu.edu/ame/bodydonation.html).

Data regarding interactive sequences including viewing parameters, tool selection, time to task, and amounts of tissue removed will be electronically recorded to computer disk. The time in the simulator will be dependent on the individual and their level of proficiency. Written instruments will be used to obtain summative data evaluating the simulator.

(3)
The specialized nature of otologic surgery limits the number of existing groups eligible for this study. Various individuals from applicable knowledge domains will be recruited for this study through the resident population of the Department of Otolaryngology at The Ohio State University College of Medicine. Additional subjects will be recruited through the institutions selected to participate in the study. The criteria for participation will be fundamental knowledge of the regional anatomy and basic otological dissection and surgery techniques. All subjects will be eligible for participation regardless of race, gender, age, body type, and physical or cognitive abilities. There is no finder's fee. Subjects will be recruited by personal contacts through the local and participating site populations. There will be no consequences to the participant for withdrawal from the study at anytime. Subjects will not be compensated for participation in the study.

One of the co-investigators will request written consent from the subjects prior to participation. A complete explanation of the session and study will be explained to the subjects.

(4)
There are essentially no known risks for the subjects. The interfaces to be used are of low voltage, low current devices (12V to 200mA) and pose no risks to the subjects. Nevertheless, the electronics will be appropriately shielded to prevent any contact with the subjects. The force reflection devices

are not capable of large forces (6.4 – 8.5N), so there is no inherent risk. If adequate force is applied, the devices will be overcome and become passive. However, it is unlikely that these forces would be reached in temporal bone dissection/surgery.

No treatment of any type is involved, only assessment of the subject's use of the interface and the associated limits of the computer environment as developed.

(5)
Strict codes of confidentiality will be observed with subjects linked with identifiers. Limited personal information regarding level of proficiency will be obtained. Videos used for documentation and numerical data will be acquired for each subject and will be maintained in a locked confidential file. Use of this material for either publication or teaching purposes will be under a code designation to preserve the subject's anonymity. Facial disguise will not be included in presented videos. However, every attempt will be made to limit exposure of the participants face.

(6)
There are no risks and direct benefits to the individual. The benefits will be principally to society. The results of the research are expected to provide information to design more intuitive synthesized environments for surgical training. This would directly facilitate education with implications to research in novel or unique surgical interventions and the documentation of pathological conditions.