EXPERIMENTAL DESIGN: Robotic Bone Drilling Assessment

Experiment title:
Evaluation of the Galen System in the Bone Drilling Procedure

People Involved:
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Date this document was prepared:
April 6, 2017

Date this document was last updated:
April 28, 2017

Experiment goal:
Compare the use of the Galen System to free hand use of the drill to evaluate the performance of the robot in assisting the bone drilling process.

Location of experiment:
Experiments will be conducted in the Swirnow Mock Operating Room in Hackerman Hall on the Johns Hopkins Homewood campus.

Levels of robotic assistance:
1. No assistance
2. Hand tremor elimination
3. Hand tremor elimination and virtual fixtures

Groups of test subjects:
1. Laymen (no prior surgical experience): 4 subjects
2. Surgeons in training: 2 subjects
3. Senior surgeons: 2 subjects

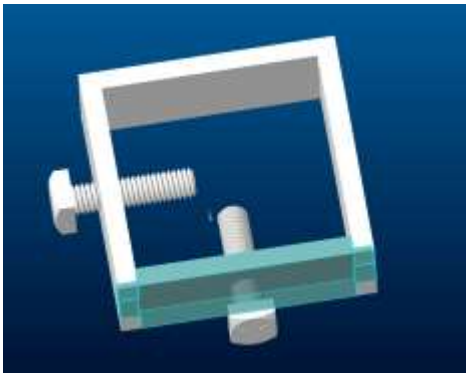
Replicates of experiments:
Each test subject will perform 2 trials under each robotic assistance level.

Randomization of experiment order:
The order in which each subject will operate under the different robotic assistance modes will be randomized based on random numbers generated before the session begins.

Phantom design:
The phantom will be 3D printed using white PLA filament. It contains a simulated facial nerve, and a simulated auditory canal to facilitate the locating of the facial nerve. The facial nerve will be printed as a

hollow channel, and a cable will then be inserted into the channel to represent the facial nerve. The cavity in the 3D printed model will be filled in with wax. Two colors of wax will be used. The top layer of red wax simulates the diseased tissue that participants will be asked to remove. The bottom layer of blue wax serves the purpose of warning participants that they have reached the boundary of the workspace.

The phantom will also have fiducials located at its four corners for registration purposes. A frame will be constructed to hold the phantom in place. The frame will be attached to a tray that will be used to hold water from irrigation.



Virtual fixture design:
We will create two planes to limit the user's motion, shown by yellow lines. As a result, the drill attached to the robot should be forbidden to enter the regions highlighted in yellow. This will help protect against damaging the facial nerve.

Data collection:
The motions of the robot, photos and video recordings of the experiment (not showing any identifiable portions of the study participant) will be recorded.

Performance evaluation criteria:
Safety

- An attempt will be deemed a failure if the simulated facial nerve is touched by the drill, and a success otherwise. The number of successes and failures will be recorded.
- If an attempt is successful, the closest distance the tip of the drill approaches the facial nerve during the experiment will be measured.
    - The robot system software is able to register the coordinate positions of the drill tip during the procedure. An algorithm will then be developed to compute the distance between the drill tip and the facial nerve at all instants, and the minimum distance will be reported.

Effectiveness

- Quantification of the extent of over-drilling and under-drilling compared to the pre-defined workspace
    - This is made possible by the color coding of the phantom. A photo of the top view of the phantom will be taken. Any red wax that is left over indicates under-drilling. Any white

region of the phantom that is revealed indicates over-drilling. The proportions of these three colors in the photo will be calculated using image analysis techniques.

- We recognize the strategy above is not perfect as it does not take into account depth information. However, due to the limited resources available to us (e.g. no access to CT scanner), this was considered a good alternative, since the area of the xy-plane is much larger compare to both the xz-plane and the yz-plane.

Example illustration:

Percent red (under-drilling): 10%
Percent white (over-drilling): 15%
Percent blue: 75%

Speed

- Time taken to perform procedure will be recorded.

Additional

- An expert surgeon will provide a qualitative assessment based on examination of the post-operative phantoms and of intraoperative photos and videos of the operative field.
- Participants will be asked to fill out an anonymous questionnaire about their experience with the robot once they have completed the experiment.