Method to capture viable cells via ultrasonic aspiration
(Under NDA)

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Background

Stryker tasked the team with finding a method for using their Sonopet IQ ultrasonic aspirator to capture aspirated tissues and cells while preserving viability. Brain tumor diagnoses affect over 25,000 adults each year (Cancer.Net, 2022). The tumors can be heterogeneous (Fisher et al., 2013), so the ability to take tissue samples for pathology at various points is important in deciding the treatment plan.

Practitioners commonly use the Sonopet IQ for brain tumor resections. It would be beneficial to the client to be able to use their ultrasonic aspirator to capture viable cells for use in a pathology analysis along with the resection. This could be an alternative to biopsy techniques.

The Sonopet IQ uses ultrasonic frequency vibration to remove tissues. Settings of power, suction, and irrigation are controlled with a console. Resected tissues are suctioned up through the handpiece and transported through tubing to a collection container. The suction and irrigation components of the handpiece are illustrated in Figure 1. Additional components of the Sonopet IQ system can be seen in Figure 2.

Constraints

The constraints for this project are focused upon protecting health and safety. The specific constraints of this project are as follows:

- Cause no harm to the patient
- Cause no interference with current usage of the Sonopet IQ

Standards from the ISO, IEC, and FDA must be followed. Some of these specific standards are:

- IEC 61847-1996 and ISO 10079-4:2021- Ultrasonic and suction equipment
- ISO 1135:2014- Sterilization
- ISO 10993-1-2018- Biological requirements

Tissue Selection

The design parameters for the resection material selection, from most to least important, were:

1. Initial viability of the tissue
2. Similarity to brain tumor tissue
3. Accessibility/Ease of obtaining
4. Cost

The materials considered were:

- Synthetic brain material
- Lab grown tissue
- Animal brain

After animal brain was determined to be the most applicable to all design parameters, the following species were considered:

- Monkey brain
- Pig brain
- Rat brain

The pig brain is gyrencephalic, as is the human brain (Lind et al., 2007), and is like the human in gross anatomy, growth, and development (Sauleau et al., 2009). For these reasons, along with the cheap cost and ease of accessibility, pig brain was chosen as the best option. An example of this material is shown in Figure 3.

Objectives

The objectives for this project are focused on developing and validating a method for capturing viable cells. The specific objectives were as follows:

- Capture a traceable amount of viable cells
- Collect at least 60 mg of material for each sample
- Identify changes in resection and collection process to improve viability percentage

Testing Procedure

The testing plan was based on varying power and suction while holding irrigation constant at 15 mL/min. The settings chosen were based on preliminary testing and client input. The focus was power variation, as preliminary testing indicated this had the highest effect on viability. The final testing plan is in Table 1.

Results & Conclusions

Testing Procedure Suggested Changes

In Figure 5, the standard tip 40/100 setting combination is a potential outlier. This is validated by the evidently different results shown in the graph, as well as other indicators in the testing process. This could be from variability in the testing done, or errors in the test kit for that sample.

Our results contained cells that did not have a more consistent higher proportion of 8-Hydroxy-2'-deoxyguanosine, which is a common biomarker for oxidative DNA damage, specifically of guanine. The test kit works by measuring the color change of a sample, which is proportional to the amount of DNA/RNA oxidative damage tracer that is bound to the sample well. This is inversely proportional to the amount of free 8-Hydroxy-2'-deoxyguanosine. So, a higher percentage in terms of pg/mL of 8-Hydroxy-2'-deoxyguanosine is indicative of a high amount of tracer, which means a low amount of free oxidatively damaged guanine. Therefore, a low pg/mL number means that there is a graph slope to the DNA, and a high number indicates less damage. The results for all tests with 50% and 100% suction with each tip are shown in Figure 5.

Suggested Changes

For future testing and eventual use in a clinical or surgical setting the team has suggested some changes. Some changes to the testing protocol are as follows:

- Further replications
- More samples from the same specimen
- Samples run simultaneously
- Samples packages as individual brains
- Packaging that protects each brain samples from air and light exposure

The team also has suggested changes for the design of the specimen sock. To be used in a surgical setting, the specimen sock would need to have an easier method of removing the sample without damage. This would involve an easier way to remove and open the sock. More effective prevention of liquid buildup would also be required. This could include testing other mesh materials that still collect material but allow more liquid flow.

Economics

The most expensive components of the project, including the Sonopet IQ and relevant components, were provided by Stryker. Many other testing items, such as gloves, scissors, lab spatula, biohood, and -80°C freezer were available in the testing laboratory. The only outside purchased item used in final testing was 200 mL of saline, which cost $42.99 on Amazon. It is important to note that the cost of pig brain material varies widely based on source.

Select References

