Project Design Specifications

#25 – Tissue Fragment Injection System

September 12, 2011

Team: Ashley Quinn, Emma Weinberger, James Dorrance, Andrew Osterbauer

Client: Dr. Chris Brace

Advisor: Dr. Randolph Ashton

Function:

Certain models of cancer require surgical implantation of tissue fragments. Percutaneous injection is the preferred method for implantation over open surgery because it is less invasive. Percutaneous methods have limitations including: difficulty suturing the site of incision, tumor seeding in unwanted areas, and backflow of tumor fragments during procedure. Our goal is to design an improved tissue fragment injection system that effectively eliminates these complications using biocompatible materials and biopsy needles, while also lowering the technical skill required to perform the procedure.

Client Requirements:

- Cost effective
- Efficient
- Ease of use

Design Requirements:

1. Physical and Operational Characteristics:
    a. *Performance Requirements:*
        i. Decrease inoculation time in order to lessen the stress experienced by the rabbits, therefore increasing the number of experiments that can be fit in one day.
        ii. Should be disposable or easily sterilized to surgical standards.
        iii. Needle must be able to reach a 5 cm insertion depth in order to reach the thickest part of the liver.
        iv. Must prevent unwanted cell seeding in the abdominal cavity.
    b. *Safety:*
        i. The device must be biocompatible in order to preserve long-term health and to preserve the environment the tumor cells grow in.
        ii. The device should be non-toxic to the user.
        iii. Needle must be able to fit into a biohazard needle disposal compartment.
        iv. The device must be sterile.

c. *Accuracy and Reliability:*
    i. Must consistently seed cells in the target area of the liver, which must be at least 2cm thick, with the assistance of sonographic imaging.
    ii. Must reliably prevent unwanted tumor cell seeding in the abdomen due to both residual cells on the injection needle, and tumor fragments slipping out of the liver into the abdominal cavity.
    iii. Needle must effectively enclose tumor fragments from the pathway during injection.
    iv. Device must prevent residual cells from seeding in the pathway during retraction.
d. *Life in Service:*
    i. Needle and other biomaterials will be used one time.
    ii. Device will be in use for years.
e. *Shelf Life:*
    i. Should be stored vertically to maintain calibrations if needed.
    ii. Should be stored at room temperature and off the floor.
        1. PLGA stored at -20 degrees Celsius for an extended period of time.
    iii. Needles are sealed and can be stored according to manufacturer's specifications.
f. *Operating Environment:*
    i. Device will be used at laboratory and operating room temperatures.
    ii. Device will be used in a sterile environment.
    iii. Device will be used in vivo, thus should be biocompatible.
g. *Ergonomics:*
    i. Materials must not react negatively with animal tissues.
    ii. Device must have a comfortable grip to allow for extended and repeated use.
h. *Size:*
    i. Device should be portable.
    ii. Device must be easily held by user for the duration of the procedure.
    iii. Needle should not exceed 18-gauge.
i. *Weight:*
    i. Device should not weigh more than 2 pounds so it can reasonably be used throughout the multiple procedures performed in one day.
j. *Materials:*
    i. Injected biomaterials must not be detrimental to the subject. ie. change in pH and enzyme activity.
    ii. Materials must be sterile.
k. *Aesthetics:*
    i. No specified aesthetic requirements.

2. **Production Characteristics**
    a. *Quantity:*
        i. One device.
    b. *Target Product Cost:*
        i. Client gave a flexible budget.
3. **Miscellaneous:**
    a. *Standards and Specifications:*
        i. Must be up to RARC standards.
    b. *Customer:*
        i. Client is interested in thermally expanding materials as a method to close the point of insertion.
        ii. Client is interested in a dissolvable material.
        iii. Client prefers a thin-walled needle, no larger than 18-gauge diameter.
    c. *Patient-Related Concerns:*
        i. Reduce the amount of anesthesia and stress on the animal, therefore increasing recovery time.
        ii. Must be sterilized or replaced in between uses.
    d. *Competition:*
        i. Existing percutaneous surgical methods.
        ii. Open surgery procedures.