PRODUCT DESIGN SPECIFICATIONS: THE BIOPSY BADGERS

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Biomedical Engineering 400

Improving the precision of small human tissue biopsy processing

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Function

The purpose of this design is to improve the precision and consistency of processing small tissue biopsies for ex vivo wound healing studies. Current methods rely on manual tools such as surgical scissors or scalpels, which often leave residual fat layers and lead to variations of sample thickness that compromise culture viability. The client, Dr. Angel Gibson, requires a reliable method for reducing porcine tissue biopsies to a uniform thickness of 2 - 3 mm while maintaining perpendicular cuts across the sample. The design must be able to hold 12 mm cylindrical biopsies and allow for precise trimming of the lower fat with ease of usability to ensure that samples remain viable for extended culture. Overall, by standardizing sample preparation, the design is aimed to minimize variability through experiments, improve the desired outcomes, and fasten the workflows for the client in tissue engineering and wound-healing research.

Client Requirements

- ❖ Device must evenly cut cylindrical 12 mm diameter porcine tissue samples to a thickness of 2-3 mm
- ❖ Device must have a fixed blade that can be easily replaced
- ❖ Device must be portable
- ❖ Device must be able to cut cylindrical 12 mm diameter porcine tissue samples vertically down the center
- ❖ Device must be easily sterilizable
- ❖ Device must be able to cut up to 4 samples at a time
- ❖ Device must allow for sample visibility during cutting
- ❖ Device should be easily reproducible

Design Requirements

1. **Physical and Operational Characteristics**
    a. **Performance Requirements**

i. The device must remove the lower 2 mm of a 12 mm diameter pig skin biopsy sample in order to increase the sample's viability through fat removal.
ii. The device must be sterilizable by autoclave, UV radiation, or alcohol between each use.
iii. The blade of the device must be commonly sourced and easily replaceable in the device.

b. **Safety**

i. To best prioritize the safety of the user, the device must follow common laboratory cutting safety measures to limit possible harm to the user. During use, the device must secure on the lab table top without slipping. The blade of the device should be safely contained when not in use and must also be easily removable with minimal effort and contact with the user. The device should limit the user's contact with the blade to minimize the possibility of injury [1].

c. **Accuracy and Reliability**

i. The device must be able to cut tissue biopsy samples to a thickness of 2 to 3 mm from epidermis to dermis and allow variation of ± 0.2 mm. Cuts should also remain perpendicular to the biopsy surface within 2° to avoid tilted spaces that can compromise culture viability. The device system should perform at least 95% repeatability across experiments up to 48 biopsies and maintain cutting precision for a minimum of 200 samples before blade replacement is required.

d. **Life in Service**

i. The device should remain functional for at least one year of routine laboratory use under standard sterilization and cleaning purposes. With consideration of up to 48 biopsies per experiment and having around 20 experiments per year, each unit is expected to withstand approximately 1000 biopsy cutting cycles before requiring replacement of core components. For cutting performance, two blades are available: Tissue-Tek Accu-Edge High Profile Blades (PTFE-coated, designed for microtomy/cryotomy) and Standard Razor Blades (Stanley 11-515, high-carbon steel). Accu-Edge blades are optimized for dense tissues like pig skin and are expected to last around 200 cuts per blade according to histology practice. Standard razor blades are less durable and should be expected to last 100 cuts before dullness compromises cutting precision.

e. **Shelf Life**

   i. Non-disposable components of the device should maintain structural integrity, sterility, and usability when stored under a set range of ambient environments (20-25 °C, 20-80 % relative humidity) [2]. Disposable blades should be able to retain sharpness and sterility for 12 months when sealed and stored unopened. Following the common sterilization methods that includes autoclaving, UV irradiation, alcohol wiping), the device's materials should be able to resist corrosion and degradation. Small metal instruments autoclaved and stored in double-wrapped linen indicate that they can remain sterile up to 96 weeks while packaging integrity and storage conditions are maintained [3].

f. **Operating Environment**

   i. The device should be used exclusively for laboratory environments in controlled settings in biosafety cabinets. It should operate under ambient conditions identical to the ones stated in Shell Life criteria. Since sterility is critical for the success of tissue culture, the device should be able to withstand repeated sterilization by autoclaving at ≥ 121℃, UV radiation in biosafety cabinets, and chemical wipe-downs with isopropanol or ethanol without causing material degradation [2]. All exposed surfaces of the device should resist corrosion, moisture and contamination from biological fluids. Sharp edges should be protected to ensure operator safety during sample handling. For storage, environmental control guidance suggests maintaining 22-26 ℃ and ≤ 60% relative humidity in sterile supply areas to protect both reusable device components and packaged disposable blades [4].

g. **Ergonomics**

i. The device should be intuitive to use, with cuts able to be done in swift motions. Tissue samples should be held in place during cutting and be easily removable upon completion to reduce user involvement. All blades should have grippable handles and run on a track to increase user comfort, safety, and sample cut consistency. The device should incorporate a measurement system and clear sides to assist the user in preparing uniform samples without the need for individual measurement. Additionally, the device itself should firmly attach to a surface to reduce slipping upon blade engagement.

h. **Size**

i. The size of the device must accommodate the small dimensions of the sample for accurate performance, as well as be large enough to be controlled by the user. It must contain a cylindrical porcine biopsy sample with a diameter of 12 mm and height ranging from 4 to 5 mm. To be easily used and not overoccupy the lab table area, the device should be within 3-5” in length and width. Furthermore, since the client stated that blades dull after 4-5 cut samples, the cutting component must be replaceable and thus the dimensions should allow for market product blades. The most common surgical blade is No. 10 with a blade length of 41.7 mm and thickness of .4 mm [5]. An average single edge razor blade length is 38.1 mm and thickness of .3 mm [6]. Thus, these dimensions should be implemented into the design for the ease of manufacturing and cost.

i. **Weight**

i. The device must be transportable for storage and movement around the lab for the user. Thus, the weight maximum of the total design must be 0.5 lbs.

j. **Materials**

i. The main requirements the materials need to meet are that it needs to be sterilizable, cheap, and sharp to cut the sample. For the blade, most market surgical products utilize stainless steel as it is sharp and corrosion resistant [7]. As for the rest of the design, since the client has access to a 3D printer, she recommended that it be utilized for ease of fabrication. Thus, Nylon

12 will be used for the design as it can be sterilized in many ways: autoclave, EtO, plasma, chemical, and gamma [8] [9, p. 3]. This is shown by its low fluid weight gain, .2% for both salt water and isopropyl alcohol when submerged for 24 hours, which makes it safe to be wiped down and come in contact with the sample media [10]. It also has a high heat deflection temperature of 171 degrees celsius at .45 MPa which makes the device safe for the autoclave which averages around 134 degrees celsius at .22 MPa [10] [11]. The way nylon is fabricated also makes it the best material to use as it does not contain microgaps that can harbor contaminants and bacteria if not sanitized properly.

2. **Production Characteristics**
   a. **Quantity**
      i. A single prototype of the design will be created for use in the client's lab. However, the device must be easily manufacturable for possible use on a larger scale in biopsy laboratory research.
   b. **Target Product Cost**
      i. The client has set a maximum budget of $500, though considering the cost of projected materials the estimated cost is likely to be around $100. To be potentially market competitive, the device must have a comparable price to existing biopsy punches and blades, ranging from $10 to $150 depending on blade quality [12][13].
3. **Miscellaneous**
   a. **Standards and Specifications**
      i. In addition to the client requirements, there are specific ISO and FDA standards the design needs to adhere to. Generally, surgical scalpels and blades must follow good manufacturing and quality control practices, proper registration and documentation, and need to meet labeling requirements [14]. Moreover, ISO 13402:2025 states the resistance of surgical instruments to corrosion, heat, and autoclaving, which is extremely relevant to the environment the design will be placed in. ISO

7153-1:2016 covers metallic materials for surgical instruments, specifically high-carbon stainless steel [15].

b. **Customer**

   i. Dr. Angela Gibson, MD, PhD, FACS, based in Madison, Wisconsin, is a surgeon, associate professor, and the Vice Chair of Research at the UW Hospital, and Medical Director of UW Health Wound Healing Services [16]. She specializes in surgically treating trauma and burns and performing surgical critical care. Dr. Gibson's RENEW (Regeneration, Engineering, and Novel Epidermal Wound-healing) Wisconsin Lab focuses on epithelial cell regeneration in burn injuries, the evaluation of skin substitutes, and human tissue model development for wound healing [17].

   ii. Ms. Bailey Donahue, BS, is a Research Technician in the RENEW Wisconsin Lab. Bailey oversees lab operations and helps conduct tissue experiments. She also contributes to the lab's research by investigating wound-healing mechanisms and working on therapies aimed at improving outcomes for burns and other injuries [18].

c. **User / Researcher-related Concerns**

   i. To guarantee viable tissue samples, each tissue biopsy taken needs to ensure complete fat removal such that the remaining thickness is 2-3 mm. All biopsies are contained within a 12 mm punch; the design needs to accommodate for this small, cylindrical shape while cutting down the sample to just the epidermis and dermis.

d. **Competition:**

   i. Acu-Punch - Disposable Skin Biopsy Punches [19]: These small, handheld tools cut precise biopsies and come from a complete set of fourteen sharp, sterile sizes, ranging from 1mm to 12mm. Each tool utilizes an ergonomic, ribbed handle for control and comfort. They are individually wrapped in sterile packaging, available in boxes of 10, 20, or 50. These range from $35.00-$156.80.

ii. Sakura Finetek USA - High Profile Microtome Blades [20]: These FDA Class I tools are designed for high profile blade holders and have sharp edges at a 35 degree angle to deliver high quality performance and durability. Each soft tissue blade is coated in a PTFE resin to reduce friction when sectioning, either in microtomy and/or cryotomy. These blades are available in a set of 50 for $190.65 [21].

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