Device for Automatic De-epithelialization

09/17/20
Client: Dr. Carol Soteropulos
Advisors: Dr. Krishanu Saha, Todd Le
Team: Josh Giarto, Young Kim, Colleen Cuncannan, Tatum Rubald, Noah Ruh, Michael Chiariello

Function: In many plastic surgeries, specifically breast reconstruction with free tissue transfer and breast reduction, surgeons must use de-epithelialization to remove the epidermis from the skin. However, the current methods used are both time consuming and the results are inconsistent due to lack of tension in the skin flaps. This product aims to efficiently and safely remove the epidermis from the skin while creating enough tension to cut at a consistent depth.

Client requirements:

- The device must be efficient and decrease the time it takes for surgeons to de-epithelialize the skin.
- The device must also be easy to use. There cannot be a significant learning curve for surgeons using this device for the first time.
- The device must be able to cut at a uniform depth by keeping tension on the skin so as to ensure the safety of the patient and a positive surgical outcome.

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*:

I. The device must be able to remove the epidermal layer of skin during surgery
II. Although it will be specifically beneficial for Bilateral Breast Reduction (BBR) surgeries, this device will be able to be used for any surgical procedure in which the epidermis must be removed
III. The current amount of time it takes for manual deepithelialization during a BBR is about 15.5 minutes. [1] Therefore, the device must be noticeably faster than 15.5 minutes.
IV. The current method of deepithelialization is physically taxing for the surgeon. The device must ease the common physical demands and should be comfortable for the operator.
V. The device must keep tension on the skin and cleanly remove the epidermis without damaging or disturbing the dermis.

b. *Safety*:

I. The device must remove the epidermis, which has a thickness of approximately 0.1 millimeters.
II. Damage to the dermis or subdermal complex could be dangerous to the patient. Therefore,

there should be no damage to the dermis or subdermal plexus caused by the device.

III. Before every use, blades should be changed in order to ensure the sterile nature of the device.
IV. After every use, the device should be sterilized as a whole and the sterilizing process should not affect the device in any way.
V. Device malfunction and user error are also possible sources of risk.

c. *Accuracy and Reliability*:

I. The device must completely remove the 0.1 millimeter thick epidermal layer without disturbing the dermis or subdermal plexus.
II. Because manual removal of the epidermis with a scalpel already exists, this device must be both absolutely precise and accurate in order to be incorporated into surgeries. The operator of the device must be able to trust that this device will assist them with deepithelialization, without concern that the device may yield inconsistent results.

d. *Life in Service*:

I. The device will be used regularly for multiple operations per day.
II. Blades must be replaced before every use of the device.

e. *Shelf Life*:

I. This device should last for upwards of 5 years in a dry, sterile, and non-corrosive environment.
II. The blades used on the device will last upwards of 5 years.

f. *Operating Environment*:

I. This device will be used within an operating room.
II. The device will be fully functional within standard operating room conditions. These include a relative humidity of 20 to 60%, and a temperature between 68 and 75 °F. [2]
III. It should be stored in a designated sterile storage room.

g. *Ergonomics*:

I. The device should be easily gripped by the operator to ensure maximum control.
II. Vibrations caused from the motor should be minimized.
III. Post operation, this device should be easily inserted into an autoclave for sterilization.
IV. When not in use, the device should be easily stored away in a storage room.

h. *Size*:

I. The device should not exceed 12 inches in length, 4 inches in width, and 3 inches in height.
II. The handle should be under 3 inches in diameter.

i. *Weight*:

I. Should weigh around 800 g.
II. Should not exceed 1000 g which is around the weight of the best competing device that fits the requirements of the client [3].

j. *Materials*:

I. Materials should be lightweight, water resistance, and non-corrosive

k. *Aesthetics*, *Appearance, and Finish:*

I. Aesthetics should not add unnecessary weight or be a movement limiter for the device
II. The device should be as ergonomic as possible to decrease hand stress for users

2. Production Characteristics

a. *Quantity*:
One device is needed.

b. *Target Product Cost*:
$300, however this is slightly flexible. A similar product on the market, the *Zimmer Skin Graft Blade,* is sold for $6,886.99 [4].

3.Miscellaneos

a. *Standards and Specifications*:
If the device reaches clinical use, the design and manufacturing of the device would need to be approved by the FDA and follow all regulations in place for medical devices including [5];

I. Establishment Registration - 21 CFR Part 807
II. Investigational Device Exemption (IDE) - 21CFR Part 812
III. Quality System Regulation (QS regulation) - 21 CFR Part 820
IV. Labeling - 21 CFR Part 801
V. Medical Device Reporting - 21 CFR Part 803

b. *Customer*:
Customers of this device would be surgeons interested in removing the epithelial tissue without removing any tissue underneath that layer. In order to keep patients safe, this device must be

effective, precise, and accurate.

c. *Patient-related concerns*:
The device must be covered during use, and the heads need to be sterilized and remain sterile until use. The device will need to be accurate and safe so that the patient will not receive excessive injuries beyond epidermal removal.

d. *Competition*:
There is currently a device put out by Zimmer Biomet known as a ‘Dermatome’ which is used to remove skin for transplants [6]. This device is similar to the device that the team plans on creating, however the skin needs to be taught for this device to work well, which is what the team is trying to overcome with the new device.

References:

[1] Iwuagwu OC, Drew PJ. Deskinning versus deepithelialization for inferior pedicle reduction mammoplasty: a prospective comparative analysis. *Aesthetic Plast Surg*, 6-June-2005. [Online]. Available: https://pubmed.ncbi.nlm.nih.gov/15959690/ [Accessed: 16-Sep-2020]

[2] Weigel, B., 2020. Controlling Operating Room Temperature And Humidity, And Managing Expectations. [online] Buildingenergy.cx-associates.com. Available at: <https://buildingenergy.cx-associates.com/2014/12/controlling-operating-room-temperature-and-humidity-and-managing-expectations/> [Accessed 16 September 2020].

[3] Ozmedix. 2020. *Humeca Cordless Battery Electric Dermatomes*. [online] Available at: <https://ozmedix.com.au/humeca/dermatomes/#:~:text=The%20small%20head%20of%20the,to%20an%20exceptional%20985%20grams.> [Accessed 16 September 2020].

[4] Serfinity Medical. 2020. *Auxo Medical Padgett Electro Model B Dermatome System 120 V - AM-PADGETT-Bpack Of 1*. [online] Available at: <https://serfinitymedical.com/products/padgett-electro-model-b-dermatome-system-120-v-auxo-medical-am-padgett-b-796443?variant=30775986716747> [Accessed 16 September 2020].

[5] Center for Devices and Radiological Health, "Overview of Device Regulation," *U.S. Food and Drug Administration*, 04-Sep-2020. [Online]. Available: https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation. [Accessed: 16-Sep-2020].

[6] "Zimmer Biomet® Electric Dermatome," *Skin Grafting | Zimmer Biomet® Electric Dermatome*. [Online]. Available: https://www.zimmerbiomet.com/medical-professionals/surgical-and-operating-room-solutions/product/electric-dermatome.html. [Accessed: 16-Sep-2020].