Mid-semester Report '11

Cervical Biopsy Device

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Abstract
Cervical biopsy procedures are performed after an abnormal PAP smear indicates abnormal cell growth. The most common cervical biopsy procedure is a punch biopsy, which utilizes devices like Tischler forceps and Kevorkian forceps. These biopsy devices are not effective at adhering to the surface of the cervix prior to pinching off the tissue sample, leading to tearing, bleeding, and increased patient discomfort. In order to make improvements upon these current devices, a scoop cervical biopsy device will be developed. This device will utilize the mechanical force of a scooping blade to make a clean cut against the cervix, allowing for a more consistent sample size while minimizing patient discomfort.

Background
In developed countries around the world, the incidence of cervical cancer has been reduced by about 50% due to cervical cancer screening programs, the most common of which is a PAP smear[1]. Each year, about 2-3 million PAP smears are found to be abnormal, meaning there are signs of abnormal or cancerous cell growth[2]. Upon discovering abnormal cells, the doctor will likely recommend a colposcopy and cervical biopsy, a combined procedure that utilizes a colposcope to obtain a better view of the patient's cervix as well as extracting 2-4 cervical tissues samples for pathological analysis.

Cervical Biopsy Procedure
During the cervical biopsy, the doctor can chose to perform either a cone biopsy or a punch biopsy. A cone biopsy involves using a scalpel to cut and remove and cone-shaped wedge of cervical tissue while a punch biopsy uses a punch instrument to remove small biopsy samples from the surface of the cervix[3]. Before starting the procedure, it is standard for the doctor to swap the surface of the cervix with vinegar or an iodine-based solution. Using vinegar will allow all of the abnormal cells to turn white in color and thus become much easier for the doctor to remove a sample of this abnormal tissue[4]. A pathologist then tests the cervix tissue sample for cancerous cell growth. Various treatments, depending on the severity, are then considered should it be determined that the cells are cancerous.

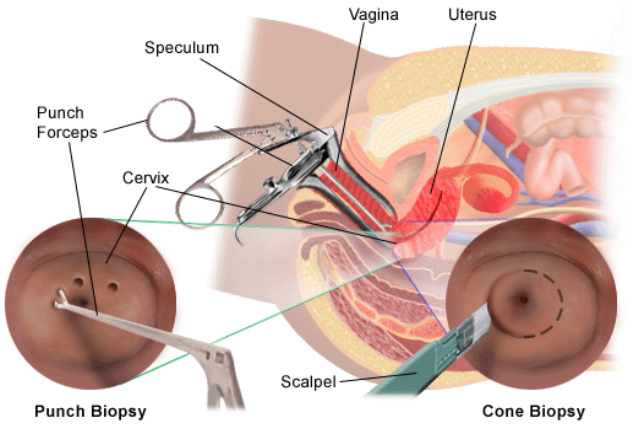

Figure 1: Visualization of cone and punch biopsy procedures[3].

Competition
There are currently several devices on the market that doctors can use for cervical biopsy procedures, the most common being Tischler and Baby Tischler forceps (Figure 2) as well as Kevorkian forceps. Both of these devices are very similar in their mechanics as well as how they obtain the biopsy sample. The ends of these devices, since they are used for punch biopsies, have a mouth-like opening that clamps down on the tissue of the cervix when the handle end is compressed. While these devices are easy for doctors to use and manipulate, it is often difficult to get the device secured against the surface of the cervix prior to taking a sample. This is

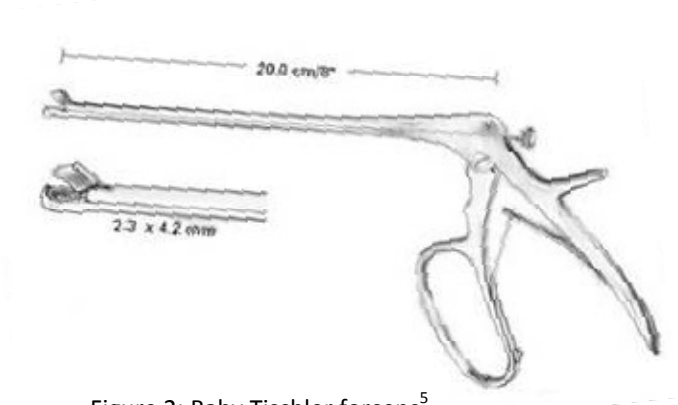

Figure 2: Baby Tischler forceps[5].

largely de to the slippery, mucus-covered surface of the cervix. Ultimately, this leads to increased patient discomfort due to the tearing and ripping of the cervix tissue before actually obtaining a biopsy sample. As well, this limitation affects the consistency of the biopsy sample size, which typically has dimensions of about 3mm x 3mm x 2mm[6]. However, since no one tool absolutely dominates the market, this allows for vast improvements to be made on any one of the currently used devices.

Problem Statement

With the large number of abnormal PAP smears found each year, cervical biopsy procedures are becoming increasingly more common. As referenced in our discussion of the competition, current devices have proven to be rather difficult in securing a proper grip on the tissue of the cervix, ultimately making it difficult to obtain a biopsy sample and often leading to inconsistent biopsy sample sizes. This leaves a gap in the market that we hope to occupy by creating a device that solves many, if not all, of these shortcomings.

Design Constraints

The device must take uniform tissue samples measuring 3 mm x 3 mm x 2 mm as well as minimize the amount of patient discomfort. The biopsy should make good contact with the surface of the cervix to aid in achieving the goal of reliable tissue sample sizes. The device should be easy for the physician to handle during the procedure. Since the tool will eventually be implemented in the cervical biopsy procedure, the biopsy device must be sterile for each patient. Therefore, should the device be reusable, the material used to construct the tool should be sterilizable by an autoclave or be compatible with any other sterilization techniques that medical facilities may utilize.

Design Alternatives

Design One: Syringe Design

The first design alternative is based on the concept of a syringe. The device would be used by firmly pressing the steel tip against the tissue of the cervix. Pulling on the plunger handle would create suction, using the lower air pressure to pull some of the cervical tissue into the tube. Rotating the tube along the long axis would cut off a sample of the tissue with the gibbous-shaped razor blade slicing through the tissue that had been pulled into the tube. The syringe-like clear tube part of the device shown in Figure 3 would be a disposable plastic. The metal cutting tube and tip would be reusable and can be sterilized in an autoclave. This device ensures a better grip and contact with the surface of the cervix by employing suction to secure the best tissue sample. This secure contact should result in more uniform biopsy tissue

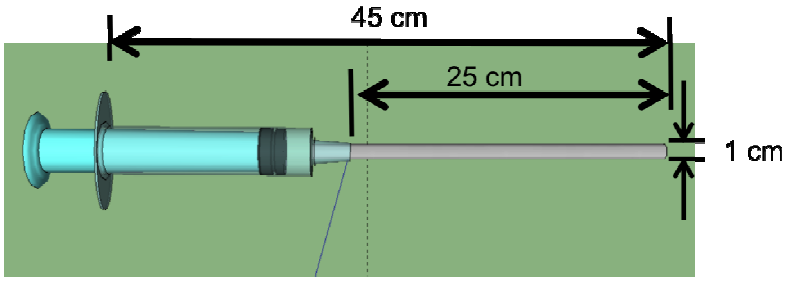

Figure 3: Syringe design.

samples. Construction of the device would be relatively simple since it uses concepts and technology that have been used in mass manufactured syringes for several years. To lessen the patient pain caused by the pinching of current devices, the devices uses a cutting technique to avoid unnecessarily clamping and tugging the epithelial tissue of the cervix, which could cause pain. However, this method of suction and cutting is not proven. Other popular tools in cervical biopsies do not utilize the same type of cutting motion so little is known about how much pain the technique might cause the patient. The tool would be largely dependent on physician technique and skill level, which would compound the difficulty assessing the pain experienced by the patient. Also, the device relies on blade sharpness, which is prone to dulling over time.

Design Two: Scoop Design

The third design is the scoop design (Figure 4). This design would be completely reusable and made entirely of metal. In between each use, it would need to be autoclaved before the next patient to be sterilized. This design would involve a similar base to that of the Kevorkian or Tischler forceps, with our focus primarily involving the tip of the device. This device would rely on a mechanical mechanism to complete the biopsy removal and retrieve a portion of the cervix rather than any manipulation of the device by a physician. By squeezing the base, this would retract the lower portion back towards the physician due to the squeezing of the base by the physician's hand. In turn, this would retract a narrow portion of that same piece (one solid piece from where the physicians hand would fit in all the way to the tip where a small portion extends up through the tip when no pressure is applied to the base by the physician's hand) from inside the tip of the device where it would be blocking the blade to one side, simultaneously compressing the spring. With the metal rod retracted from the tip, the spring would expand, creating the force necessary for the blade to complete the arc across the open top of the tip and slice through a small portion of the cervical tissue. Due to the hollow, hemi-spherical shape, the tissue sample would then be deposited with the movement of the blade into the tip.

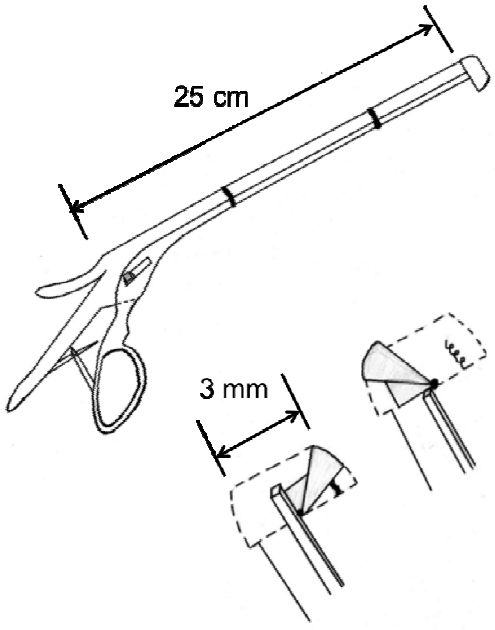

Figure 4: Scoop design.

The final position of the blade would also cover part of the top opening helping to ensure the biopsy sample did not fall out. This design ultimately depends on the spring creating an adequate degree of force to cut through the surface of the cervix and will require some to testing to ensure that a proper force is generated. However, despite this variable, this device will provide a consistent sample size due to the shape of the tip and the set path of rotation for the blade. The faster cut will also minimize the time required for the procedure and thus decrease the duration of patient discomfort.

Design Three: External Suction

The third design alternative is the external suction design (Figure 5). This design would be reusable with the exception of the very tip of the device, which can be screwed on to the end of the device's hollow tube. The device has a handle grip that allows the doctor to maneuver the device with greater ease. This handle is screwed into the hollow tube that extends about 25 cm when including the length of the tip attachment. The intersection between the handle and the tube also gives rise to a port for an external air auction device. A small tube leading to an external suction machine would be connected to the device at this junction, allowing all of the air in the hollow tube to be sucked out. This will effectively create suction between the device and the surface of the cervix. The removable tip has a gibbous-shaped razor blade, similar to the blade in the syringe design; thus, once suction is established, the device is rotated, slicing off the biopsy tissue sample. In order to prevent the sample from being sucked into the hollow tube, a filter will be placed between the hollow tube and the tip. This will allow suction to still be created while not sucking up the tissue sample. The many advantages to this design alternative include the fact that it uses a cutting motion instead of a clamping motion (like the Tischler or Kevorkian forceps) to obtain the tissue sample, which should lead to increased patient comfort during the procedure. Also, since external suction is utilized, the suction created with the surface of the cervix will be much more consistent and can also be adjusted, unlike the syringe design. The cutting blade of this device, however, is not found in other biopsy devices, so the effectiveness of the device would need to be tested. In addition, the addition of an external suction tube may hinder the doctor's ability to properly handle the device, especially since there are already many other surgical instruments in or around the vagina during the operation.

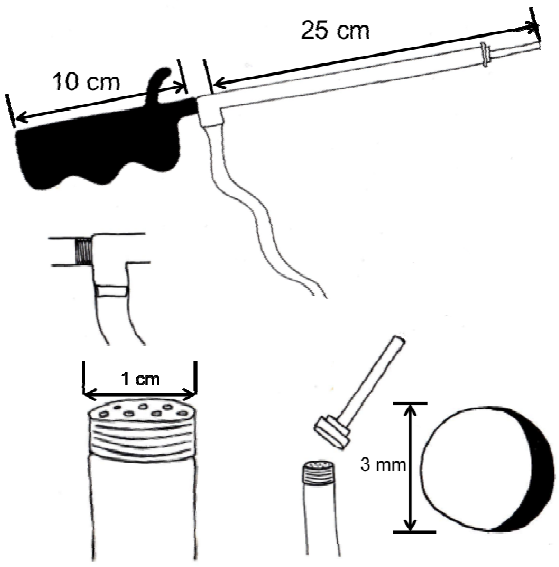

Figure 5: External Suction design.

Design Matrix

CATEGORIES	Weight	Scoop	External	Syringe

	(%)	Design	Suction	Design
Reliability	35	4	3	2
Manufacturability	20	2	3	4
Patient Comfort	15	5	3	3
Ease of Use	15	5	4	3
Relative Cost	15	4	3	3
Weighted Total		**3.9**	**3.15**	**2.85**

Figure 6. Completed design matrix comparing features of the three design alternatives.

The design matrix (Figure 6) used to analyze our three devices was divided into the five categories of reliability, manufacturability, patient comfort, ease of use, and relative cost. To rank the designs within each category, each was graded from one to five with five being the highest. The weights, of each as well as each of the values assigned, can be found in the second column of Figure 5. We intended to incorporate client preference by getting our client's opinion on her evaluation of the relative importance of each of the categories, but she was not able to get back to our team in time to utilize her input. For our design, Reliability was the most heavily as the requirement for the device to result in a consistently sized sample during every biopsy was a key aspect of our design. As both the external suction and syringe designs relied on the physician's manipulation of the device to attain a sample, they were given slightly lower scores than the scoop design. This was decided as the scoop design relies on minimal movement to then initiate a mechanical response to actually take the biopsy. The external suction design rating was slightly higher than the syringe because it has the extra feature of an external suction source that constantly ensures a stronger hold on the tissue. Manufacturability was another heavily weighted category as, due to the small size of sample that needs to be acquired by the tool, it seemed could be a determining factor in deciding on a design. Here the designs were rated on complexity with the syringe, the simplest design, receiving the highest manufacturability rating and the scoop, which will require a number of small pieces working in sync, the lowest score. These two main categories were then followed by patient comfort, ease of use, and relative cost which were all weighted equally. Patient comfort was one area where we had to predict the device most suited to avoid patient discomfort. As the external suction and syringe designs both used the same type of blade and motion, we assigned them the same value. As a result of the quick and theoretically clean cut produced by the scoop, we gave this device the highest rating. Ease of use fell similar to reliability in terms of values for much of the same reasons. The scoop would involve no rotational motion to complete the biopsy while both the external suction and syringe design would. Furthermore, the syringe design would be harder to handle due to the ergonomics of the design of the base. When making a decision on relative cost, it was necessary to keep in mind the financial advantages of a reusable device verses a disposable one as with each use the cost of the reusable device would go down while a disposable device would have a constant fixed cost. These three categories were all seen as

important to use in the analysis of our design. However, they were not necessarily major deciding factors. From here, the overall weighted numbers were deduced based on the percent contribution of each category to the total. By the end, the scoop design had the highest rating followed by the external suction design and the then the syringe.

Ethical Considerations

Due the invasive nature of a cervical biopsy, patient safety and comfort are imperative design factors. The final design needs to ensure that the sharp blade will not cause accidental cutting of surrounding tissue. Since human anatomy severely limits the device's orientation, the device should be easily maneuvered. In addition, the device should minimize patient discomfort as well as procedural duration. This requires quick and clean cut of cervical tissue. After the sample has been cut, the design should also enclose the sample so that no loose tissue remains in the body. The physician should be more efficient by using the device.

Final Design

CATEGORIES	Scoop Design
Reliability	4
Manufacturability	2
Patient Comfort	5
Ease of Use	5
Relative Cost	4
Weighted Total	3.9

Figure 7: Overview of Scoop Design scores.

After totaling the values in our design matrix, it was clear that the scoop design was our final design (Figure 7). Although it scored low in manufacturing, we believe it will be highly reliable and provide a fast, clean cut minimizing patient discomfort. The similar style of base to current devices will also make it easier for physicians to adjust to our device with little need for new training. Although autoclaving the spring may be an area of some concern, we believe our design can be tweaked throughout the testing process, ultimately providing us with the most reliable and consistent device that relies on minimal manipulation by the physician while still being able to be adequately sterilized between uses. This will ultimately ensure the consistent size of biopsies taken. When it came to our two other designs, the need to manipulate the device in a circle while holding it in the same spot was a great concern for us. Without this occurring the tissue would not be completely removed and no biopsy would have been taken. The scoop design does not rely on such physician skill. We feel that our scoop device will adequately meet the demands of not only our client, but also fill a position in the current market for cervical biopsy devices. Thus, this is the design we will be looking into testing and manufacturing during the remainder of the semester.

Future Work

Since the team has decided on a final design, the next step is construction. The team will be using rapid prototyping to create the device. Furthermore, the team needs to purchase crucial components of the final design. They are the spring and the blade. The spring must be small enough to fit inside the hemisphere as well as exert enough force to cause a cutting action. In

addition, the blade has to been sharp enough for a clean cut and round enough to capture the sample. The team will continue to consult the client about funding. Next, the team will test certain features of the design. This includes the spring and the blade. Suggested by the client, testing will be done on unpeeled fruit such as kiwi. Testing will be done to determine the minimum force needed for the blade to swing across the opening of the hemisphere. Along with the force, the spring constant and upstretched length are also needed. After the blade and spring have proven to work appropriately, testing will be done to determine the consistency of sample sizes.

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