NOVEL USE OF PRESSURE-SENSITIVE MICROCAPSULE FILM FOR PROSTATE CANCER SCREENING

Biomedical Engineering Senior Design Group 14
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Problem

All men above the age of 55 will endure prostate cancer screening. Current screening methods include the Digital Rectal Examination (DRE) and Prostate Specific Antigen Test (PSA). Both methods are inconsistent and subjective.

In theory, as the prostate grows erratically, as in the case of malignant tumors, PSA levels within a patient's blood will rise. Benign prostate enlargement and advanced age, however, also elevate PSA levels. And, tumor development can halt PSA generation entirely, resulting in deceivingly low PSA levels.

Infamously invasive, the DRE is the well-known, widely-disliked palpation of patients' prostates by insertion of a physician finger into the patient's anus. Physicians feel through the rectal wall for nodules and abnormalities. The practitioner's ability to effectively palpate the prostate is limited by his or her finger length, experience and the patient's anatomy.

Diagnostic imaging technologies are used to verify concerns raised by the PSA or DRE. Unfortunately, these technologies require separate appointments, highly trained staff, and expensive equipment.

Device Goals

Prostate cancer screening would benefit from a device that:

- Is inexpensive;
- Is consistent regardless of patient anatomy;
- Requires no advanced training or appointment;
- Maintains or enhances patient comfort during examination;
- And, offers objective visual data that is comprehensive even with limited practitioner experience.

Proposed Solution

Our device takes impressions of the prostate gland using PressureX Zero pressure sensitive film, which consists of two sheets: a developing and transmitting layer. This film can be analyzed to find the modulus of elasticity, topography, and the location of any nodules within a spatial resolution of one micrometer on the prostate. In order for the film to be activated and take an impression, both layers must be in contact with one another.

Our unique roller and gear design allows for the film to be inactive until the practitioner deploys the balloon. Once deployed, the activated film is then pressed onto the prostate with a non-elastic balloon, which theoretically provides constant deformation into the prostate. Implementation of the deployment and intake mechanisms in the device allow for multiple impressions to be taken with one roll of film without having to reinsert or reload the probe, minimizing the chance for error.

After the impressions are completed, the device is withdrawn from the patient, and the tip of the device is removed. The removal of the tip allows the film to then be extracted for quantification, and another film can be reloaded for the next patient.

Used film can be quickly scanned into a computer and then analyzed using a Matlab program we have developed. This program isolates the portion of the film that represents the prostate, removes potential noise, and then assigns an elastic modulus to every point on the film while highlighting areas of concern such as potential sites of cancer.

Our Device

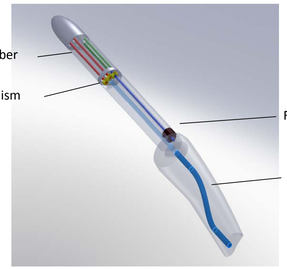


Figure 1: *A view of the interior of our device. The balloon catheter, axels and gears are all visible.*

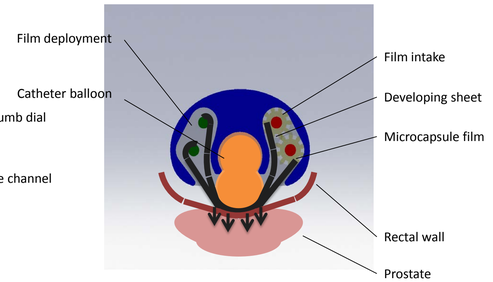


Figure 2: *Cross-section of our device's film chamber. The film is pressed onto the rectal wall by the expansion of the balloon. This exposes a window of the film to the prostate.*

Objective Results

Film Image of Prostate

Normal prostate

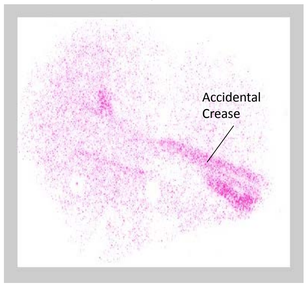


Figure 3: *Impression of a normal prostate. Film has a crease in the center of the image.*

Neoplastic prostate

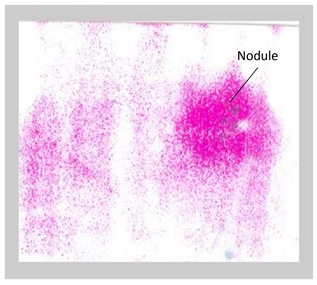


Figure 5: *Impression of prostate model with embedded nodule. This image was created using 5 balloon impressions.*

Film Analysis

Asymmetrical Prostate

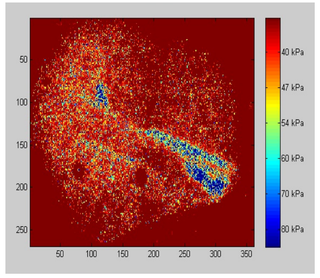


Figure 4: *Result of developed MATLAB image analysis program. Shows areas of pressure concentration . As expected crease is evident.*

Neoplastic prostate

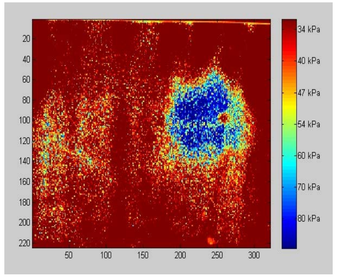
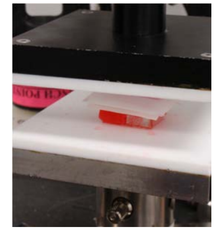


Figure 6: *Analyzed result of Figure 5. Highlights the nodule.*

Testing

The proposed device depends on a number of components that all must function in order for an accurate result to be obtained. Testing has shown that the balloon and the device can withstand many times the amount of pressure and force that will be applied to it when used. The film has shown to be accurate, even when applied to a deformable surface and used to pin point deformities (see figures below). The gear deployment fails due to the thickness and rigidity of the film, creating too much friction to be rolled up and then deployed in such a small area. With the current pressure film, deployment is limited to one impression per insertion.



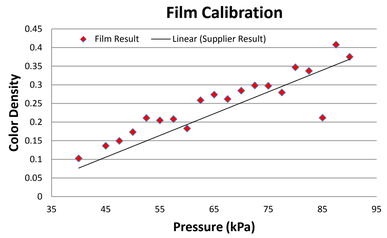


Figure 7*: MTS testing using film and PVA hydrogel.*

Conclusions

The major innovation within this device is the application of pressure-sensitive film in a biological setting to detect prostate cancer. Although we have not been successful in fully integrating the film within the rest of the device, we have shown through extensive testing that both components separately meet the device goals outlined in the beginning of this design process. In particular, the device design adhered to the specified dimensions as to ensure patient comfort. Furthermore, the imaging and analysis of the pressure-sensitive film create objective visual data that is comprehensive even with limited practitioner experience.

Further work would include developing a film that is inherently thinner and/or combine the film system into a single film. This would allow for better integration of the film into the rest of the device and greatly improve the film deployment and intake mechanism implemented within our design. Further testing should also be done to improve the balloon size, shape, and elasticity to optimize the surface contact with the prostate and subsequently the prostate image retrieved. Finally, once the aforementioned improvements can be made, the next milestone would be to test our device within physiologically relevant models. This would ultimately determine the feasibility of our design.

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