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 deservingly 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, and expensive equipment.

Unfortunately, these technologies require separate appointments, highly trained staff, and expensive equipment.

“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 neoplastic growth. Film analysis can be used for quantification, and another film can be reloaded for the next examination. After the impressions are completed, the device is withdrawn from the patient, and the top of the device is removed.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.

Film analysis:

Normal prostate

Asymmetrical Prostate

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 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 a biological setting to detect prostate cancer. We’d like to thank Dr. Steven Saltzman, Dr. Nissrine Nalb, Dr. Badrinath Konety, Dr. Frederick Namer, Professor Shai Ashkenazi, Tom McPeak, Munt Reeves, Lucas Harder, Adam Gladen, Luke Schmeltzer, and Lance Nevala. Without their insight and assistance, our project would not be possible.