DEVELOPMENT OF A SHEATH FOR AN ULTRASOUND PROBE USED TO MONITOR COAGULATION DURING PROSTATE CANCER TREATMENT

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INTRODUCTION

Prostate cancer is the leading cause of death amongst the various cancers in men. Furthermore, it is the 3rd most prevalent cause of death due to cancer itself [2]. There are several treatment options that are used by clinicians today. Active Surveillance (AS) is one option where no actual treatment takes place unless a change in the patient is observed. This precautionary option helps maintain the patient's current lifestyle until any aggressive treatment options are needed. [2]. Aggressive treatment options include radiation, surgery or a combination of the two, both of which target the entire prostate. Given the proximity of several critical structures (urethra, rectum, nerves) to the prostate, any overtreatment can also affect these structures, causing significant reduction in the quality of life for the patient [2].

Recently, an alternative approach referred to as focal therapy is being investigated, in which only the dominant cancerous lesion in the prostate is targeted. One treatment modality under investigation for focal therapy is laser interstitial thermal therapy (LITT), in which NIR light energy is delivered through interstitial optical fibers to the zone of interest. This energy effectively destroys the cancerous portion through thermal coagulation. [1] Through trans-rectal ultrasound (TRUS) guidance and co-registration with a pretreatment MRI scan, the boundaries of the prostate are defined that lead to targeting a specific portion of the prostate. However, the need to consistently monitor the coagulation is necessary, as it would be undesirable for the coagulation to reach the rectal wall [2].

Several groups have shown that light scattering increases by a factor of ~4 upon coagulation. [1] Diffuse Optical Tomography (DOT) images tissue based on variations in tissue optical properties such as absorption and scattering. Light directed into the body is scattered according to the functional and structural characteristics of the tissue [4] and detected as it exits the tissue. DOT serves as the ideal imaging modality to monitor the coagulated tissue.

The requirement of fiber optic cables to be placed in the rectum was eminent, as the rectal wall is the closest structure to the prostate. Since the TRUS is inserted into the rectum during LITT, an integration of DOT with the TRUS was explored. A sheath that would be placed over the TRUS with embedded fiber optic cables is being researched. The actual orientation of the fibers on the sheath is being explored in a separate project. However, the spacing between fibers will be in the range of 1-2 mm with an overall range of 10-20 mm.

METHODS

To take this project towards completion, various phases or steps were considered and are in the process of implementation.

I - Prototype and Final Design

The prototype had four main requirements: i) the material is biocompatible, ii) the device can be easily placed onto the TRUS, iii) the device

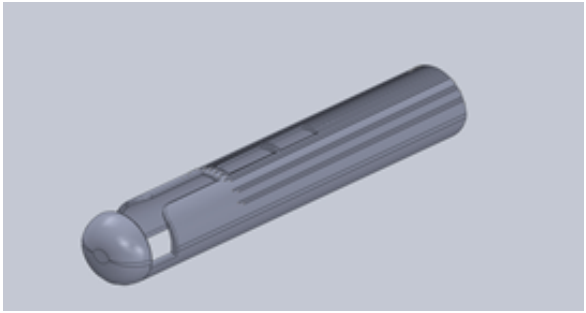

Figure 1: Prototype Design of the Sheath

does not interfere with the functionality of the TRUS and iv) the device does not cause any adverse effects to the patient. With these requirements in mind, a prototype was designed using SolidWorks (Figure 1). To meet biocompatibility requirements, the material ABS-M30 was chosen. This material was available in black, is compatible with various sterilization methods [5] and is non-toxic [6], making it suitable for medical applications. For the second requirement, the hollow cavity allows for the sheath to be placed on and taken off the TRUS with ease. For the third requirement, the TRUS's sagittal and axial scanning windows are left relatively unobstructed by the sheath, which causes minimal interference with the TRUS images. This will be discussed in further detail in the TRUS imaging section. Lastly, for the fourth requirement, the sheath is void of any edges or points. The roundness of the sheath ensures no adverse effects will affect the patient.

II - Fiber Placement

Fibers for light delivery and collection were side-firing and with a 0.33 mm core (FiberTech Optica, Waterloo, ON). In order to embed the fibers into the sheath, grooves were incorporated into the design of the sheath. However, to determine the ideal groove diameter and how much of the groove's diameter is in the sheath, test blocks were made with varying groove diameters and different percentage of diameters which were in the sheath (Figure 2).

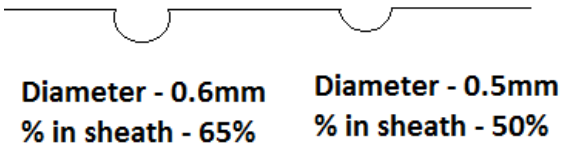

Figure 2: Examples of different groove diameters and different percentages of the diameter in the sheath

These initial results gave an indication of the appropriate groove diameter and percentage which is required for our application. As table 1 indicated, a groove diameter of 0.65 – 0.7 mm with greater than 80% of the groove in the sheath enabled easy translation of the fiber in the groove, while ensuring it was fixed in position. At 50% groove in the sheath did not allow the fiber to be threaded into the groove.

Table 1: Initial Groove Study Observations

Diameter (mm)	% of Hole in	Takeaway Observations
0.650	50.0	Unable to thread the wires
0.650	96.1	good fit, fibers were completely submerged in the groove, no part of fiber was sticking out of the surface
0.650	88.4	similar observations as above
0.700	92.8	similar observations as above
0.700	85.7	similar observations as above

To guide and position the fibers into the grooves, a jig was assembled consisting of a translational stage for fiber translation (Model 562-XYZ, Newport, Irvine, CA), a rotating disk

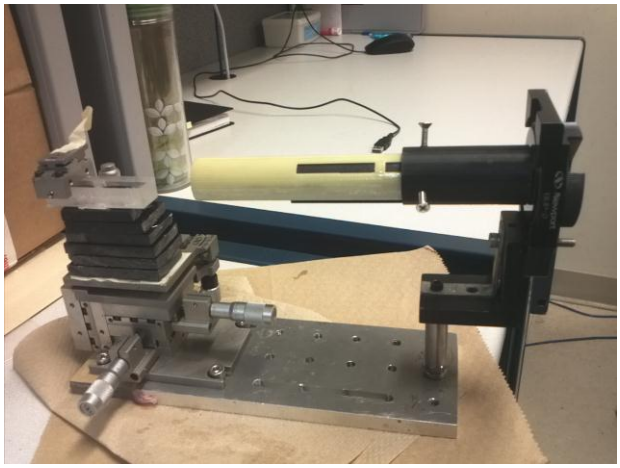

Figure 3: Assembly used to guide the fibers into the sheath

(Model BUP-2, Newport, Irvine, CA) for sheath rotation and a fiber rotator (Model HFR007, Thorlabs, Newton, NJ) plus custom parts to hold the sheath in place (Figure 3).

UV cured, optically transparent epoxy (Model OG603, Epotek, Billerica, MA) was used to fix the fibers onto the sheath [7] since this provided flexibility in controlling when and where the epoxy was applied. The following steps were taken to put the fibers into the groove: 1) Thread fiber into the groove, 2) Clamp the fiber, 3) Adjust the fiber using the translational platform for greater accuracy, 4) Place epoxy onto a Q-tip, 5) With fiber in the groove, carefully applied the epoxy at different spots along the length of the fiber, 6) Place entire setup in under the UV lamp, and finally 7) Repeat steps 1-6 for all the fibers. Figure 4 shows the final product. Further work is required to control the rotation of the fiber in the groove. A prototype version has been assembled but requires testing. Further testing is also required for inserting fibers while the groove is bent.

Figure 4: Sheath with the fibers attached

III - Effect on sheath during TRUS imaging

It is imperative that the sheath does not hinder the clarity of the images from the TRUS. However, two bridges were included in the design of the sheath. Due to the high number of fibers used for this study, some of the fibers ran over the ultrasound window. These bridges were added into the design to provide additional mechanical stability to the fibers. Thus, the effects of these bridges were tested. We utilized an Ultrasound Prostate Phantom (Model 053, CIRS, Norfolk, VA) to observe these effects. The sheath (Figure 4) was placed onto the TRUS (Model 8848, BK Medical, Peabody, MA). This entire setup was then

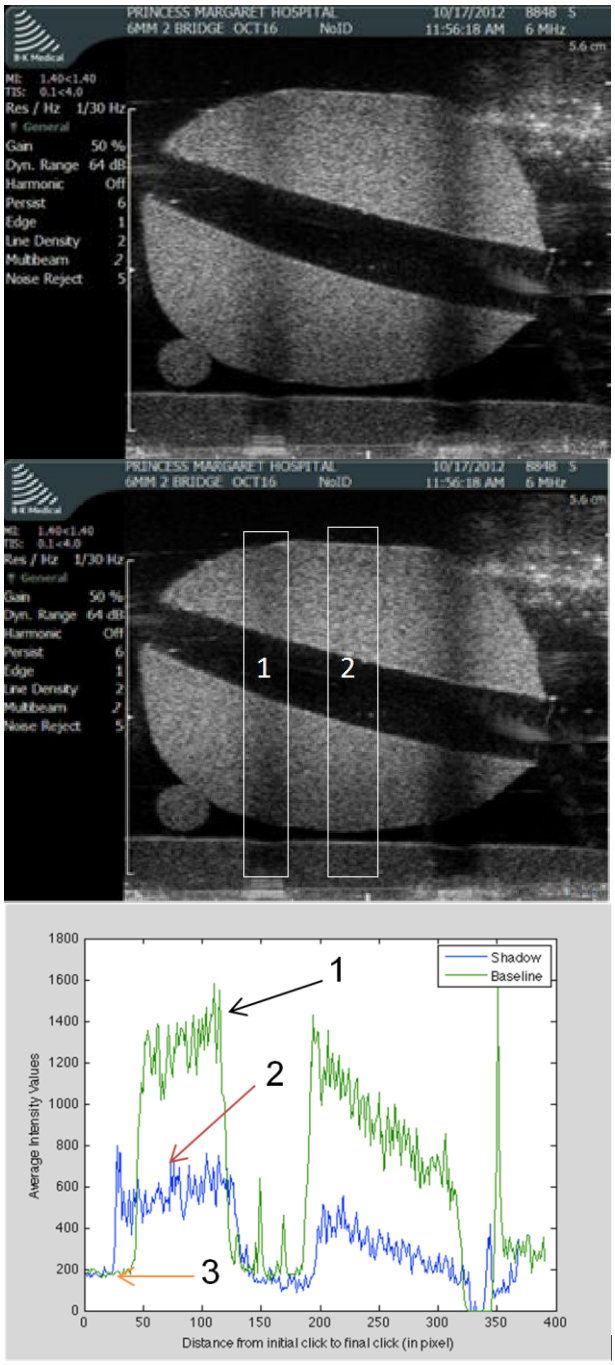

Figure 5a (above): TRUS image with the sheath on. Figure 5b (middle): TRUS image indicating the rectangles used. Figure 5c (below): Graph of the average horizontal intensity values

placed into the prostate phantom that resulted in the image in Figure 5a. Two distinct shadows, as a result of the bridges, are present on the ultrasound image. To further investigate

the effect of these shadows on the US image, the drop in contrast within the shadow region versus non-shadow region was measured. The TRUS is required primarily to define the borders of the prostate (and to guide the needle insertion). Therefore if the drop in contrast is acceptable to the physicians using this device, then the effect of the bridges should not critical for clinical use. First, two rectangles were segmented; one covered the shadow area on the TRUS image and the other, of similar size, that covered a non-shadow area (Figure 5b). Then, within each rectangle, US contrast in each row was averaged along the vertical extent of the rectangle, starting from the top of the rectangles. Figure 5c shows the results of the averaging algorithm.

The change in contrast was measured by comparing the change in signal from the baseline to the shadow**.** It was observed that the ratio between arrow 1 and arrow 3 was ~6 and the ratio difference between arrow 2 and arrow 3 was ~3. This indicated that in the bridge region, there was a 50% contrast drop. However, within Figure 5a, the ratio of 3 could still differentiate the prostate boundaries.

DISCUSSION

We have developed a clinic-ready prototype for trans-rectal delivery and collection of light integrated with a trans-rectal ultrasound probe. The device will be used as part of a diffuse optical tomography system to monitor focal thermal therapy in the prostate. Further studies aim to create test conditions to test for smaller diameters. The percentage of the hole in the sheath will be set above 80%. Further testing will investigate grooves with different bending ratios to account for a design scenario where the grooves must bend so that the fiber ends can form a line parallel to the long axis of the sheath.

While the sheath is independent of the TRUS, it must move with the TRUS. We are designing a method of attaching the sheath onto the TRUS setup so that it moves in sync with the TRUS.

Finally, we will validate the light delivery into the prostate region and collection of the scattered light, to indicate coagulated tissue. This will be done through in-house built phantoms that will mimic coagulated and non-coagulated tissue.

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