2017

A Stationary Camera for Use with Other Implantable Medical Devices

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8-10% of Americans will have an implantable medical device inserted at some point in their life [1]. Defined by the FDA as “a device or tissue that is placed inside or on the surface of the body ”, implantable medical devices represent a wide range of technology, all with unique problems and challenges [1]. Currently, there are very few means of monitoring the performance of such devices after implantation, and usually conventional and costly exams such as MRIs or CAT scans are used. Furthermore, symptoms of device failure are often ambiguous and difficult to distinguish from disease or treatment symptoms. For example, biliary stents have a failure rate of almost 70% [3] after implantation. Coronary stents have a high success rate but sudden thrombosis (reclosure) remains a troubling symptom with a high mortality rate and no means of monitoring its advance. 50% of patients who have received total knee replacements continue to experience pain for years after the surgery [2]. Therefore, there is a need for more information about how these devices operate once implanted. I developed an optical system to provide information about the performance of implantable medical devices after they have been inserted into a patients body. This feedback can take two forms: information about the flow of bodily fluid through a device, or information about the development of tissue on the surface of an implantable device.

Originally, I planned to develop an implantable camera that would generate real time images. These images would then be used to determine the flow through a device or visualize the development of tissues on the device. The device would use a CCD to generate an image, which requires very good lighting and a guarantee that there are no obstructions. I came to the realization that the desired information could be easily collected using a photodiode and a focused light spot rather than a CCD. As the photodiode provides information on the position and intensity of light, the flow could be determined by measuring the fluctuation of light position. Furthermore, the development of tissues could be measured by determining the fluctuation of light intensity. Photodiodes simplify the circuitry required to wirelessly transmit data, are less expensive, and accomplish the goal in a more direct and efficient way.

Once the decision had been made to use a photodiode, I had to design the optical system to generate the focused light spot that would be interacting with the tissues. In order to generate a focused light spot, one must align everything precisely according to the Gaussian thin lens equation $(1/o) + (1/i) = (1/f)$, where o is the object distance, i is the image distance, and f is the focal length [4]. Although the equation is limited by the imperfect nature of the lenses in question, it suffices for this application. The focal length of the lens used in calculations depends on the size and thickness of the lens [4]. This is provided by the lens manufacturers. For some lenses (such as the ball lens used in this application) the focusing distance is so small that it is unnecessary to measure and one can simply place the lenses next to each other[4]. The other consideration when designing the optical system is the loss of light as it travels through. With each added element, more loss will occur. Therefore one must optimize for simplicity and consider carefully the benefit of adding a second lens compared to the loss of light intensity. However, for this application the light loss was not a pressing concern, as the photodiode is sensitive and can measure low light intensities.

I began with the simplest design that could generate a small light spot, using only a 6mm double convex lens and a light source. This generates a focused light spot to the size of the light source (which in this case was about .5 in by .5 in), which was not small enough for this application. It also lacked any versatility, which was important because the device was not designed for any specific implantable medical device. At this stage, the light source had to be aligned parallel to the double convex lens and precisely the focal distance away (about 24mm). I added a right angle mirror to direct the light into the system rather than keeping it parallel. Although I chose to have the light source perpendicular and above the system, it would be easy to use a different mirror and direct the light spot from any angle, therefore improving the versatility. I also decided to add a fiber optic in order to improve the versatility of the device. Fiber optics transport light from one location to the next with minimal loss because the inside of the cable is made of reflective material that does not let light escape. With the fiber optic, the light source could be a variable distance from the double convex lens. Furthermore, the light spot was now focused to the diameter of the fiber optic cable (about .5mm) which was the desired size. In this way, it also acts as an aperture. I then incorporated a ball lens to couple light from LED to fiber, which greatly improved efficiency and reduced loss of light. As briefly mentioned above, the ball lens was aligned so closely to the fiber that there was no need to account for a specific focal distance and they were treated as though they were touching.

Figure 1. Wooden platform aligning optical components.

Initially the light source, mirror, ball lens, fiber, and 6mm lens were aligned by hand on wooden platforms that I built (figure 1). Although this set up successfully verified the effectiveness of this alignment, it was very difficult to align things accurately. I designed a holder in SolidWorks that could hold everything together in the correct alignment. There was immediately a great improvement in efficiency and focus. The current iteration is designed for a 3mm double convex lens. This is an improvement because it reduces the size of the device by cutting the focusing length in half and also decreasing the width and height of the device.

Although the device could be used to measure both flow and the development of tissue growth on an implantable medical device, I chose to evaluate its potential to measure flow, which made more sense with the resources I had available and the scope of a summer project. I built a rotational mechanism to simulate flow and glued a small, reflective flow sensor (.4mm by 1mm) onto the rotating arm. The light spot was shined onto the flow sensor and the deflection of the light spot was measured qualitatively. I then placed skin phantoms on entrance and exit to determine if light intensity would change and also monitor ability of light to remain coherent after scattering. The light spot was still visible to the naked eye, verifying the potential for this system to work in conjunction with an implantable medical device.

The next step is to make the system self contained. Currently, nothing is wireless (the light source must be plugged in) and there is no way to wirelessly transmit data from the photodiode to the outside of the body, as will be necessary in a real life situation. I will use wireless radio frequency (RF) telemetry to transmit data from the photodiode to a receiver outside of the body. The 2-segment photodiode will be connected to an operational amplifier, which will amplify the difference in voltage generated by the light spot between the two diodes. The difference in voltage can be used to determine the relative position of the light spot on the face of the photodiode. This amplified signal will then be inputted into a voltage controlled oscillator and converted into a radio frequency carrier output. This frequency will be transmitted via an antenna to an external RF receiver and fed to an external processor through which data can be analyzed. The system will be powered by a lithium ion battery, which is common in many other medical applications (such as pacemakers) and is suitable for this application due to its long life span and small size. A timing and control unit (TCU) will serve the function of "turning on" the system when a patient is being examined. The TCU itself will be triggered by a magnetically actuated reed switch that can be controlled via a magnet external to the skin.

In conclusion, I designed an optical system for analysis of implantable devices. The final system consists of a 3mm double convex lens that focuses a light spot onto a tissue or implantable medical device. This light spot can then provide feedback on the movement of flow through a device or the development of tissue on the device, although my project focused solely on the flow application. The light spot is generated by an LED and directed using a half mirror. It is then focused using a ball lens, fiber optic, and the double convex lens. With this system the generated light spot met all criteria for versatility, size, and focus. Future work will focus on making the system self contained as mentioned above.

Sources

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