ENGL 402-14

24 February 2014

Research Proposal

Integrated Sensor and Infusion Set for Use with Insulin Pumps

Introduction

Type one diabetes, also known as juvenile diabetes, occurs when the pancreas stops producing the hormone insulin, which regulates blood glucose levels. Before insulin was discovered in 1922, being diagnosed with type one was basically a death sentence. Children were put on starvation diets because doctors knew doing so would slow down the disease, but no one lived longer than a year like this. Two Canadian scientists, Frederick Banting and Charles Best, performed a series of experiments that ultimately showed that insulin is the only long-term effective treatment for type one, and since then the delivery method has been continuously improved upon from rudimentary (and massive) syringes to experimental artificial pancreases. The most popular delivery method, however, is the insulin pump.

Currently many diabetics use insulin pumps and continuous glucose monitors, but these are two separate devices, and require two different rotations to prevent scar tissue from building up. The problem with keeping them separate is the sharp decline in available sites where one can safely place either the infusion set or the sensor. There are specific zones on the body where these can be placed, and failure to rotate the sites results in increased insulin resistance. If left unchecked this resistance becomes a vicious cycle that results in excess weight gain, among other health problems.

The main limitation with integrating the sensor and the infusion set into one unit is the size. The sensor is currently larger and bulkier than the infusion set because the sensor relays the blood glucose level to the CGM receiver through wireless capability, and requires a small needle, which acts as an electrode, embedded beneath the skin. In contrast, the infusion set only needs a small cannula beneath the skin in order to deliver the insulin. Combining them would require an insulin

delivery method, an electrode to sense the glucose levels, and an appropriately small wireless chip to send the data back to the pump or to the CGM receiver. In addition, the set must be flexible in order to move with the body.

Literature Review

Medtronic, Animas, Omnipod, and Tandem all manufacture popular insulin pumps. Medtronic and Dexcom manufacture the CGM receivers. Most of the information will come from these manufacturers' websites, not printed sources, as the integrated sensor and infusion set is still a new idea in the diabetic community. Medtronic in particular is of interest because of their newest pump: the MiniMed 530 G, which became the only pump with the CGM receiver integrated inside the pump itself. They also have developed an experimental integrated set/sensor prototype which is still in early testing stages and not available to the public. We will utilize online resources from the American Diabetes Association, the Joslin Diabetes Center, the Juvenile Diabetes Research Foundation (JDRF), the United States Government clinical trials archive, and the pump manufacturers' company sites, among other reputable sources.

Methods

We will speak with a certified diabetes educator about the advantages and disadvantages of integration, and also ask how far she thinks manufacturers have to go before integration is marketable. We will speak with a participant in a research study for testing different sensors and ask her opinion on whose design is the most comfortable, and whether that design could be the basis of an integrated set/sensor. We will conduct a survey on a wide demographic of type one diabetics to determine the level of interest in an integrated sensor and infusion set, and also ask for suggestions for what could make it more appealing.

Results

The expected outcome of this project is to determine how far the major pump and CGM manufacturers have come in regards to producing market-ready integrated sensors and infusion sets, and determine the level of interest among the type one population. Determining the feasibility of this idea (whether insulin close to the sensor electrode causes false readings, and whether having

the insulin cannula close to the sensor electrode increases the rate of scar tissue development) is beyond the scope of this project because of limited access to the necessary resources.

Conclusion

Integrating the sensor with the infusion set is just another step towards manufacturing an artificial pancreas as a way to treat, but not cure, type one diabetes. This is also an important step forward, because, in lieu of a cure, it will tighten the control that diabetics need in order to remain healthy. I am qualified to do this study because I have been a type one diabetic since 1995. I am a member of a large network of type one diabetics, and have contacts within the diabetes treatment field. I am deeply invested in the outcome because it would help my own control which, though not life-threatening, is not perfect. Potential team members must be interested in the medical field as a whole or in this subject in particular. We prefer candidates with a working knowledge of diabetes or secondary knowledge from friend or family relationships. Candidates should have a thirst for knowledge and a positive attitude.

References

Note: the information about what diabetes is and the discovery of insulin comes from personal knowledge. References 1 and 2 provide more detailed information about these topics for further reading than can be included in this research proposal.

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4. "Feasibility Study of an Integrated Sensor and Infusion Set." *Clinicaltrials.gov.* U.S. National Institutes of Health, 4 Feb. 2013. Web. 13 Feb. 2014. http://clinicaltrials.gov/ct2/show/record/NCT01770561
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