RESNA SDC Submission
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Eye Spy Design Brief

I. PROBLEM STATEMENT/ RESEARCH QUESTION AND BACKGROUND

Type I diabetes is a chronic condition in which the body produces little or no insulin, a hormone which is needed to produce energy from glucose [1]. Our client is an older woman who has managed her Type I diabetes for over 60 years. She experiences two common long-term complications of diabetes: visual impairment and slight neuropathy (loss of sensation in her fingertips) [2]. Since the advent of insulin-based diabetes treatment is a relatively recent historical phenomenon, there are only about five thousand individuals in the world who have managed Type I diabetes for as long as our client has [3]. Even though visual impairment and neuropathy are common among individuals who have had diabetes for many years, current diabetes management devices like insulin pumps and needle insertion kits have not been designed with these two complications in mind.

Many steps involved in managing diabetes primarily rely on sight. Because our client has years of experience managing her own care, she is comfortable completing the majority of these steps using strategies she has memorized. However, she currently requires assistance from a neighbor when changing her infusion site every 2-3 days. Specifically, our client needs a way to insert the pump's needle into her abdomen at the right angle and depth, without straining her vision.

Precise insertion of the pump's needle is required for successful regulation of blood sugar. If the needle is inserted at too shallow an angle and depth, the insulin will diffuse only through the dermal layer of the skin and will not reach the blood stream. This may result in a dangerous blood sugar spike. If the needle is inserted at too deep an angle and depth, the muscle wall may be dangerously punctured, and insulin will not diffuse properly. Our client needs a solution individually tailored to fit her needs: she is thin, requiring a shallower angle of insertion than the industry standard and other insertion devices on the market [4], and she has built up scar tissue in her abdomen, requiring an insertion method that allows her to feel resistance at specific spots and adjust infusion sites accordingly. Thus, the goal of this project is to develop a method and device that will allow the client to independently insert her pump's needle at the right angle and depth for proper insulin diffusion.

II. METHODS/APPROACH/SOLUTIONS CONSIDERED

In terms of design specifications, a successful design will work with the Medtronic pump system to insert the needle consistently at a proper angle and depth. After talking to the client, she specified that she normally tries to insert her needle at 10 degrees and at a depth of 6mm. Additionally, as the client changes sites on her abdomen for the needle and insulin every 2-3 days, it must be reusable and have the ability to be used on multiple sites from various orientations. Lastly, it must be compatible and simple to use with slight neuropathy and a visual impairment. A successful design will abide by all of these constraints with the ultimate goal of her inserting the needle into her abdomen for proper insulin diffusion simply and independently.

With these critical features in mind, we first looked into video magnification systems to see if this could aid the client. We tested a variety of webcam and webcam software and ultimately concluded that although the client could now see where the needle was and identify landmarks on her abdomen with this video equipment, she still could not see if the needle was resting against her abdomen and could not use the video system for accurate insertion. As the client was more comfortable with feeling and control over her insertion, we decided that redesigning the current devices on the market to fit her angle and depth were not adequate due to the spring like all-or-nothing mechanism for insertion. Ultimately we settled on 3D printing a ramp and box that would hold the needle in place in which the client could use her hands to slide the ramp a precise depth. This way if the client inserted the needle into scar tissue or felt pain when inserting, she could feel the needle enter and immediately remove it before it was the full 6mm in her abdomen. Each prototype was presented to the client and through multiple iterations based on the client's feedback and ease of use a final design was reached.

III. DESCRIPTION Of FINAL APPROACH AND DESIGN

We have created a solution that will enable the client to independently change infusion sites. We designed in Solidworks and 3D printed a device that meets the client's need to insert her needle at the proper angle and depth without sole reliance on vision. The device is compatible with client's patented Medtronic pump system, and is made to hold her specific brand of Silhouette needles in place.

Our device is reusable, can be used from both the right and left sides of the body, and is able to be sterilized with an alcohol wipe before use, following clean technique as specified by current clinical practice [5]. As shown in Fig. 1, the device consists of three main parts: the box, the ramp, and the clip. The box holds the ramp and clip, and makes contact with the client's abdomen. It has thumb grips to ensure easy placement on the abdomen and minimizes rocking so that the 10° angle is not compromised. The box also has guards to make sure that the needle is only slid the proper distance of 6mm, and there are rails on the sides to make sure the ramp will stay in place when used vertically on the plane of the abdomen. As per the client's request, the box also has extended arms to provide added stability when used.

The ramp part of the device slides along the box to insert the needle at the infusion site of choice. The ramp is fashioned at a 10° angle so that the needle is inserted according to the client's specifications. It has a raised ellipse-shaped guard that fits with the client's specific brand of Silhouette needles and holds the needle in place from the back.

Next, the red clip twists to hold the needle in place from the top and has a knob for the client to hold while pushing the ramp a distance of 6mm. The clip is printed in a bright contrasting color of PLA plastic so that the client can easily distinguish between the different parts of the device. The needle clip rotates on and off the needle for easy device removal once the needle has been inserted and the first half of the needle's adhesive has been secured to the abdomen. Figure 3 shows the client using this device to successfully insert her needle.

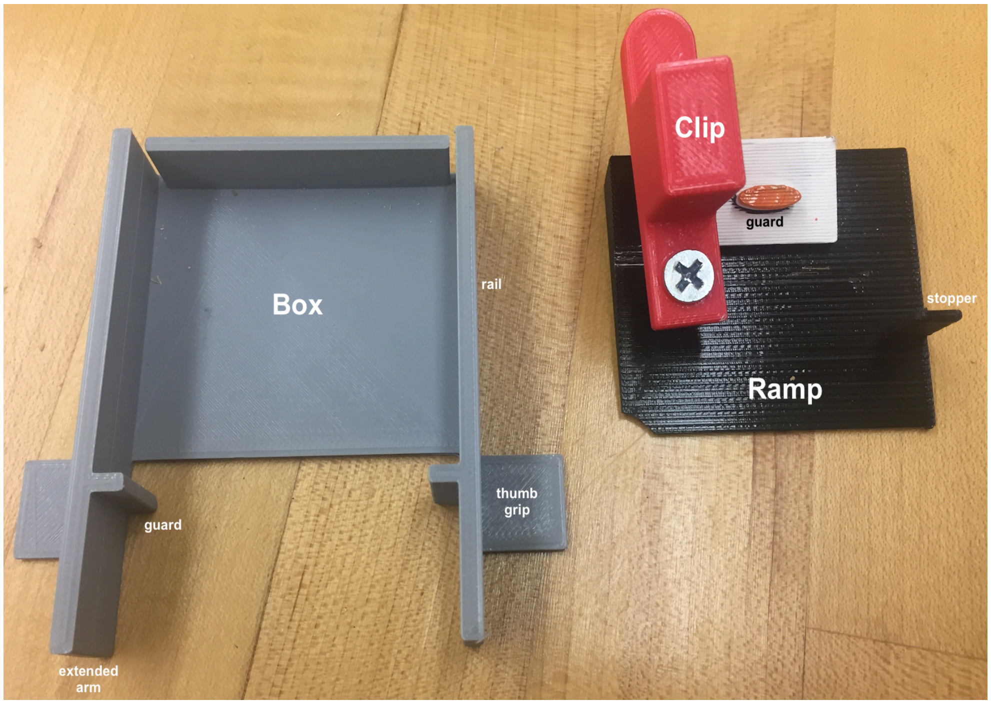
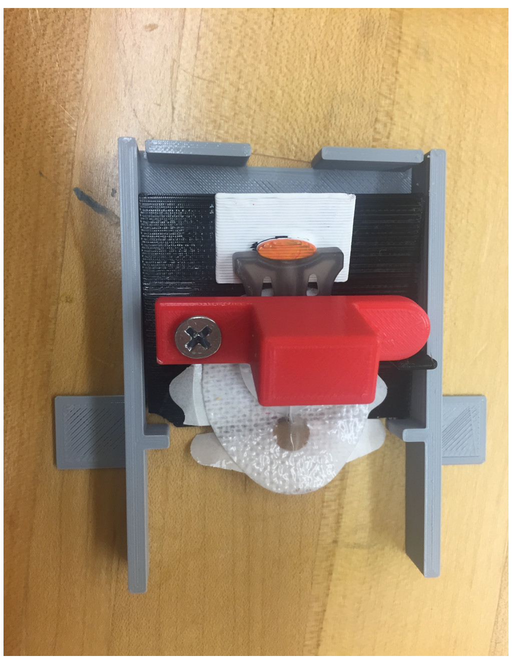


Figure 1. Prototype consisting of the box, the ramp, and the clip.



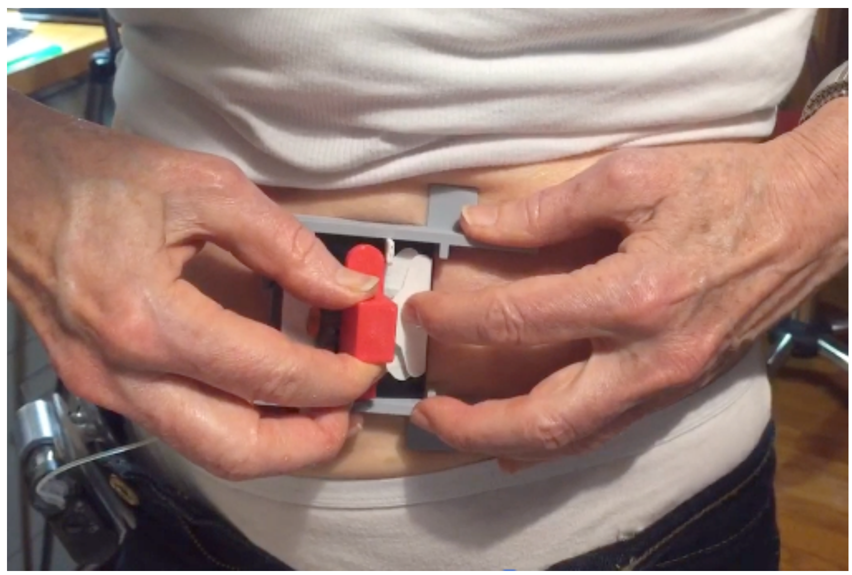


Figure 2. Device with Silhouette needle clipped into place, slid a distance of 6mm.

Figure 3. Client successfully testing device on her abdomen.

IV. OUTCOME

Many safety and hazards tests were performed outside of testing with the client. All tests, such as dropping (according to BSI Standards), were successful. Multiple client tests have demonstrated that our system enables optimal insulin infusion into the body, for the client's blood glucose levels after using our device to change infusion sites are consistent with levels she has achieved in the past with the help of a neighbor. Our client has used the final device over 10 times and is able to insert the needle easily into multiple sites of her abdomen. She has tested the device both with the assistance of a neighbor and completely by herself with success in blood sugar levels. Additionally, when asked a series of questions about the ease and design specifications in a client satisfaction survey, the client's average response was a 9.5/10 (with 10 being "very satisfied").

V. COST

The only cost for the production of this device is the PLA Plastic material for 3D Printing. As students of Duke University, this was paid in full by the Biomedical Engineering Department, but we approximate the cost for one device to be less than 10 dollars. Thus it is a device that can be easily reproduced and printed multiple times.

VI. SIGNIFICANCE

There are many people like our client who are beginning to suffer from visual impairments as a consequence of diabetes. Current diabetes management care is not compatible with this visual impairment, especially for people who have different body types and don't insert their needles the same depth and angle as current insertion products on the market. Our device has allowed our client to insert her needle at a consistent angle and depth and has allowed her more independence in her diabetes management care process. Since the components of the device were designed in Solidworks, the device's angle and depth can be easily adjusted, resulting in the potential to reach different clients in an effort to aid others in their insertion process as well.

VII. ACKNOWLEDGEMENTS AND REFERENCES

We would like to acknowledge the Duke Biomedical Engineering Department, our professor Kevin Caves, our teaching assistance Paul Thompson, our clinical advisor Nancy Lelle-Michel, and especially our client for their guidance on this design project.

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