Mechanical Intrathecal Pump for Leptin Delivery for Type 1 Diabetes

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Introduction

Type 1 Diabetes (T1D)

- Lifelong disease
- Millions affected globally, $15.45 billion in 2024

Current Treatments

- Regular insulin shots
- Devices that constantly check blood sugar levels

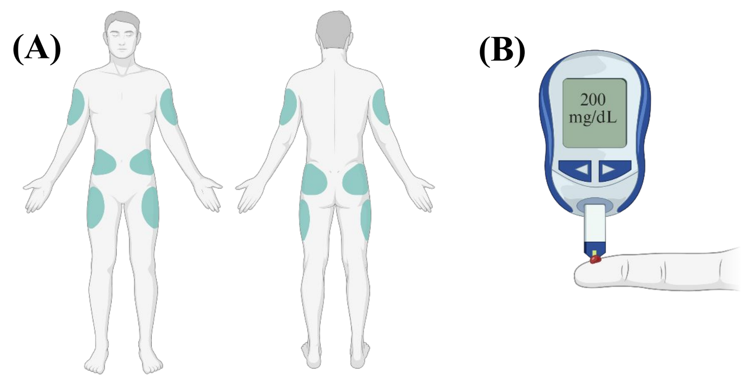


Figure 1. Current treatments for T1D. Figure 1A shows the injection sites for insulin. Figure 1B is a device that checks blood sugar levels. Made on BioRender.

The Problem with Current Treatments

- ✘ Uncomfortable, hard to manage, expensive
- ✘ Unwanted side effects, like fatty lumps or loss of fat tissue at injection sites [1]

Our Solution

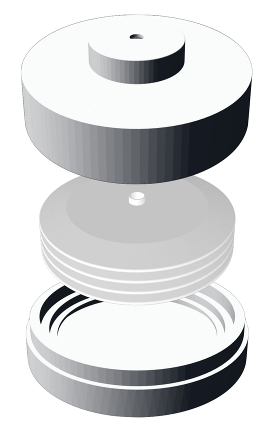


Figure 2. Exploded view of the mechanical intrathecal pump for leptin delivery.

We have developed a prototype consisting of a small, mechanical pump to deliver leptin through cerebrospinal fluid (CSF) around the spine (intrathecal area).

- Leptin: hormone with potential to correct diabetes [2]

Our aims with CSF-mediated delivery of leptin include:

1. Targeting the central nervous system
2. Regulating glucose homeostasis
3. Improving the body's response to insulin

Benefits of Pump

- ✔ Less invasive
- ✔ Reduces need for constant monitoring
- ✔ Reduces frequency of injections
- ✔ More manageable/affordable compared to current treatments.

With our pump, delivery of leptin directly into the intrathecal CSF enables euglycemia, addressing blood sugar level regulation issues present in patients with T1D.

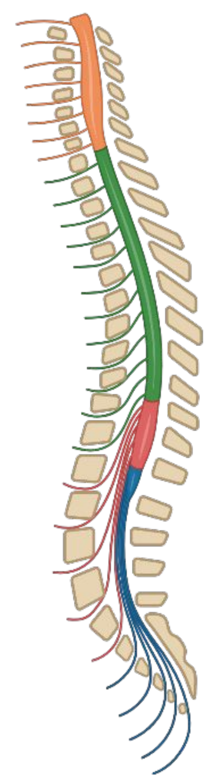


Figure 3. Lateral view of human spinal cord and vertebrae. Made from BioRender.

Materials and Specifications

These listed materials are being used for our final prototype:

- Platinum Cure Silicone
- PLA Filament (testing/casting)
- ABS Filament
- SIL Poxy

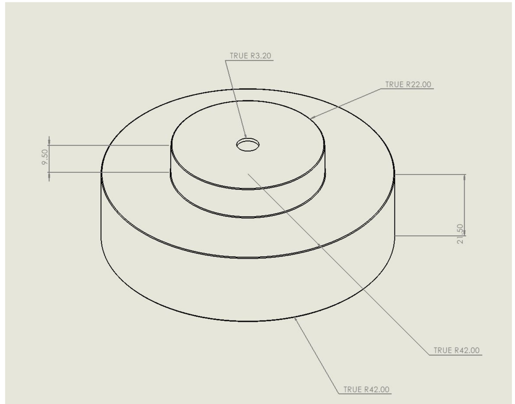


Figure 4. Isometric view of the mechanical intrathecal pump with dimensions. Created through SolidWorks.

Methodology

*Validation of device through **flow rate** and **durability and reusability** testing, under simulated physiological conditions*

Flow Rate

- Blanket warmed at three different temperatures to simulate when patient temperatures when normal, slightly elevated, or "sick"
  - 97° F - normal
  - 99° F - slightly elevated
  - 102° F - average flu temperature

Durability and Reusability

- Catheter placed in a tank to simulate the average CSF pressure of 18 cm H2O (1.77 Kpa).
- Daily discharge of the device measured for 4 days, compared to our desired flow rate of 0.3 ml/day.
- Completed device placed in a Universal Tensile Testing Machine, subjected to with three different pressure amounts
  - 10 kPa
  - 100 kPa
  - 200 kPa
  - 300 kPa
  - 500 kPa
- Scale of 1 (not repairable and not reusable) and 10 (structural integrity retained) in combination.

Results

1A. Flow Rate Testing

Temperature	Day 1	Day 2	Day 3	Day 4	Average Flow Rate
97°F	+0.28	+0.32	+0.29	+0.32	0.3025 mL/day
99°F	+0.31	+0.34	+0.32	+0.31	0.32 mL/day
102°F	+0.34	+0.36	+0.35	+0.37	0.355 mL/day

1B. Durability and Reusability Testing

	10kPa	100kPa	200kPa	300kPa	500kPa
Trail 1	10	10	10	10	9
Trail 2	10	10	10	10	9
Trail 3	10	10	10	9	9

Table 1. Results from device validation. Table 1A shows the average flow rate over the course of four days with the device exposed to three temperatures. Table 1B shows the structural integrity retention of the device under different pressures (10 kPa - 500 kPa) as determined through visual examination.

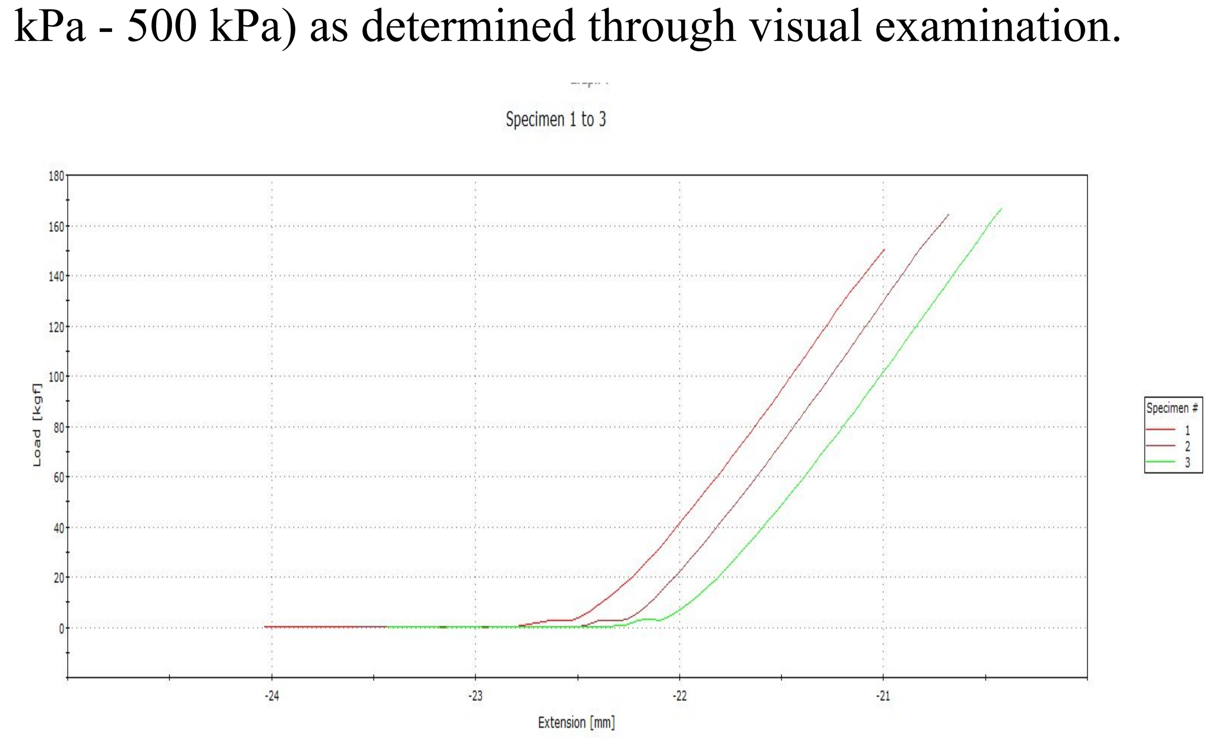
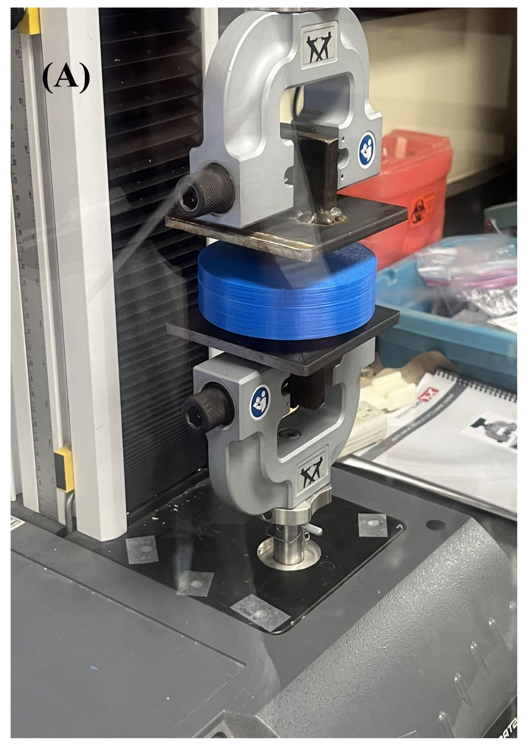


Figure 5. Graph from device validation testing. The results show that the device can survive 500+ kPa multiple times in a short time span with out breaking.



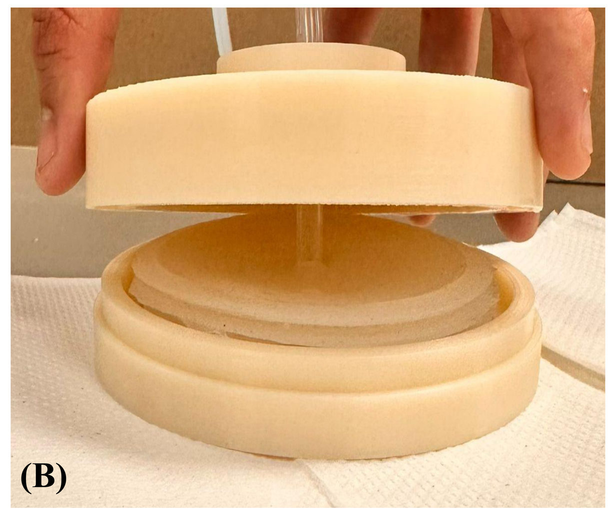


Figure 6. Images of the mechanical intrathecal pump prototype. Figure 6A shows the prototype in the universal tensile testing machine. Figure 6B shows the 3D-printed shell connected with the tubing.

Conclusion

- Device minimizes flow rate fluctuations from various physiological temperatures, which is desired
- Easy-to-use, easy-to-print device that supports intrathecal leptin delivery for T1D management
- Utilizes improved, up-to-date catheter materials
- Employs a mechanical pump for steady and precise flow rate through CSF
- Seamlessly incorporates perfluorodecalin through precise tubing
- All components work together with precision and reliability

Recommendations

- Add a **flow rate sensor** capable of wireless communication with patients' phones and physicians' computers.
- Cast the **inner tubing and bellow together** to improve the flow of the substance from the bellow to the catheter.
- Switch to **steel molds** (instead of PLA molds) for casting silicone to achieve:
  - More consistent sites
  - Improved structural integrity of silicone components

References

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- **Cite 3:** Leptin, diabetes, and the brain https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3602981/
- **Cite 4:** Leptin Action in the Ventromedial Hypothalamic Nucleus Is Sufficient, But Not Necessary, to Normalize Diabetic Hyperglycemia https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3749482/#:~:text=Collectively%20these%20findings%20suggest%20that,acts%20to%20promote%20glucose%20homeostasis.

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