Thydaxa: Multilayer Hyrdogel Drug Delivery System to Treat Hypothyroidism

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Thydaxa

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Clinical Need

Critical Problem: The thyroid is responsible for controlling metabolism and producing essential hormones such as T3 and T4. Hypothyroidism is a disease in which the thyroid is unable to produce enough hormones, slowing the metabolic rate and overall bodily functions, which can lead to Hashimoto's Disease.

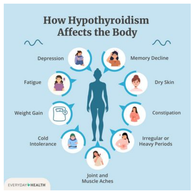

Figure 1: Possible side effects of uncontrolled TSH levels

Current Therapy Problems: Of the current limited therapies there are to treat hypothyroidism, only the oral tablet regulates TSH levels, ineffectively at that, and requires much effort for effiecency.

Mission Statement

The aim of Thydaxa is to provide new innovative ways to help the 35 - 60% Hypothyroidism patients which never reach ideal TSH levels to regulate their levels with convenience and comfort .

Market Analysis

Thyroid Disease Market Size	•2.45 billion to 3.14 billion [3]
Number of Patients Affected	•226 cases /100,000 individuals /year [4]
Added Cost of Hypothyroidism Patients	•$460 to $2555 per patient [5]

Final Specifications

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Hydrogel PEG 100-S (LxWxH)	6mm x 6mm x 2 um
PLA microneedle sheet	6mm x 6mm
Levothyroxine (T4 drug)	1.6 mcg/kg/day
silicone sheet	6mm x 6mm
skin adhesive sheet	10mm x 10mm
Product Lifespan	3-5 Days
Cost	< $120/day
Green Tea Extract	21 ug
Controlled Pore Size of Material	15 - 20 um
Product Shelf Life	> 6 months
Initial Drug Load	21 uM

- Our Projected Unit Cost: TBD

Prototype/Design Status

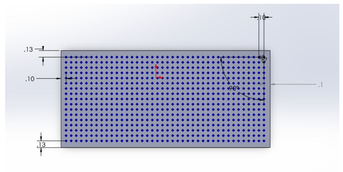

Figure 2: Model of Anticipated Product Design and Dimensions

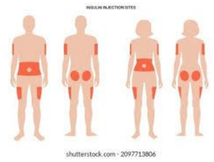

Figure 3: Anticipated areas of device application due to similar skin thickness

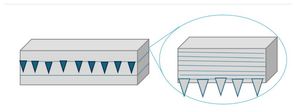

Figure 4: Physical Prototype design of hydrogel and hydrogel+skin

Validation Data

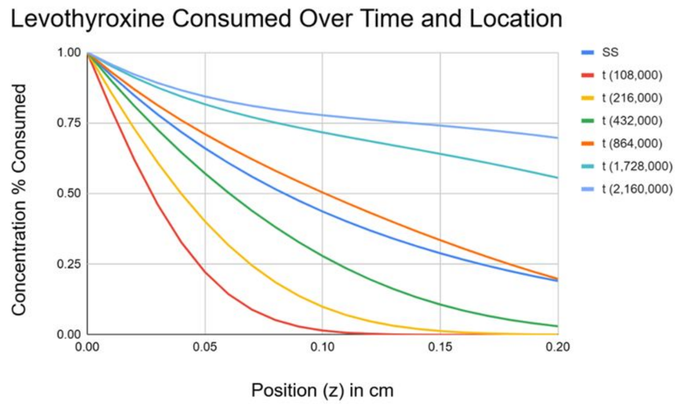

Figure 5: Graph of concentration of levothyroxine consumed by initial loading concentration percentage at different time points up to a few days past predicted half-life

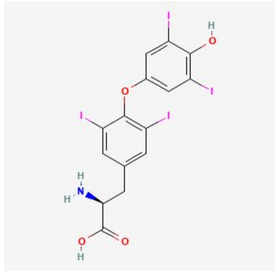

Figure 6: Chemical Structure of Levothyroxine. Molecular weight 776.87 g/mol. Average particle size 1 - 20 um. Slightly soluble in water and non-soluble in ethanol and benzene.

Technical Models

$$N_{i,x} = -D_{i,j}\frac{dC_i}{dx} + v_x C_i$$

$$\frac{dC_A}{dt} + \left(v_x\frac{dC_A}{dx} + v_y\frac{dC_A}{dy} + v_z\frac{dC_A}{dz}\right) = D_{A,B}\left(\frac{d^2C_A}{dx^2} + \frac{d^2C_A}{dy^2} + \frac{d^2C_A}{dz^2}\right) + R_A$$

$$\frac{dC_A}{dt} = D_{A,B}\frac{d^2C_A}{dy^2} - kC_A$$

$$0 = D_{A,B}\frac{d^2C_A}{dy^2} - kC_A$$

$$\frac{C}{C_0} = \frac{1}{2}e^{-z\sqrt{\left(\frac{k}{D}\right)}}\,erfc\left(\frac{z}{2\sqrt{Dt}} - \sqrt{kt}\right) + \frac{1}{2}e^{z\sqrt{\left(\frac{k}{D}\right)}}\,erfc\left(\frac{z}{2\sqrt{Dt}} + \sqrt{kt}\right)$$

Diffusion Coefficient (D)	0.00000000720	cm^2/s	[5]
1st Order Elimination Reaction (k)	0.000000493694573	1/s	[6]
Half Life (ln2/k)	1,404,000	s	[6]
Z max	0.2	cm	[7]

Figure 8: Fick's 2nd Law used to model the ratio of concentration of Levothyroxine used vs initial loading concentration model (fig 5) as well as values used for our constants.

Future Directions

Further Validation/ Verification → **Feedback and Alterations** → **Design Changes** → **Regulatory Approval Strategy** → **Market Device**

Figure 8: Progression of Future Development Stages

Regulatory Pathway:

This device will have to comply with the standard GP17-A31 to ensure lab safety and that proper guidelines are followed during manufacturing so that each patch is made consistent. As with all medical devices, ISO 13485 will establish a base for quality assurance throughout the manufacturing process. Additionally, ISO 10993 will assess biocompatibility, ISO 11607 will be the standard for sterilization, ISO 14971 for evaluating risk factor, 21 CFR Part 820 for quality system regulations by the FDA, USP 661.1 & 661.2 for chemical and physical safety requirements, and ISO 14644 if manufacturing takes place in a cleanroom to control contamination.

Intellectual Property

Based on prior art search, most individual components aren't patentable due to them pre-existing prior to our research, but combination of these components a thus far seems like unique intellectual property based on modeling and implementation of our device. This is mainly due to the focus in application we have chosen to go with, as there is little motivation in this field to find alternative methods for drug delivery.

Prior Art Search

Acknowledgements

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