US 20230347050A1

(19) United States
(12) Patent Application Publication
(10) Pub. No.: US 2023/0347050 A1
(43) Pub. Date: Nov. 2, 2023
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(54) **SYNTHETIC THYROID METHODS AND APPARATUS**

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(21) Appl. No.: **17/734,024**

(22) Filed: **Apr. 30, 2022**

Publication Classification

(51) **Int. Cl.**

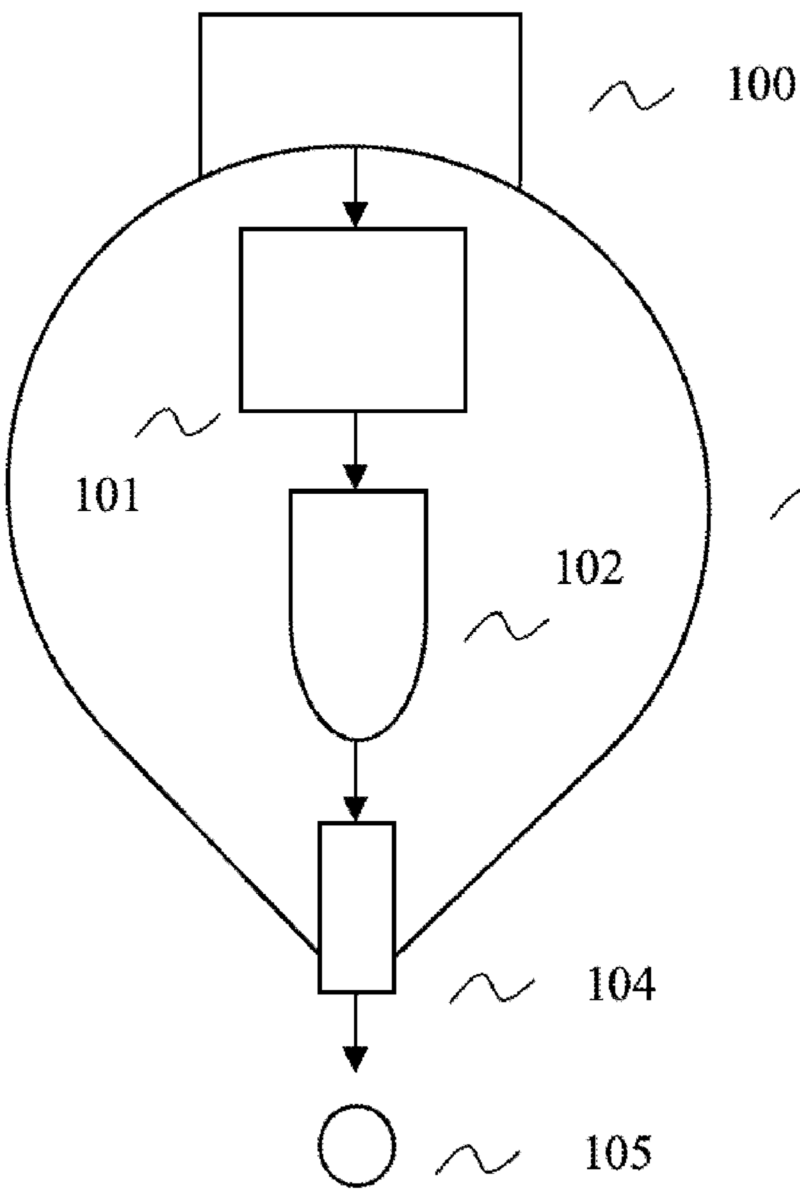
A61M 5/172	(2006.01)
A61L 27/54	(2006.01)
A61L 27/36	(2006.01)
G16H 20/17	(2006.01)

(52) **U.S. Cl.**

CPC ***A61M 5/1723*** (2013.01); ***A61L 27/54*** (2013.01); ***A61L 27/3604*** (2013.01); ***G16H 20/17*** (2018.01); *A61L 2300/43* (2013.01); *A61M 2230/20* (2013.01)

(57) **ABSTRACT**

A method and apparatus for thyroid hormone control using a synthetic module containing thyroid hormone and an intelligent valve control device. In embodiments, the invention consists of an iterative process with three steps. First, blood is measured to detect thyroid hormone concentration. Second, the measured concentration is compared to a target thyroid hormone concentration. Third, the intelligent valve control device optimizes thyroid hormone delivery, correcting for differences between the measured concentration and the target concentration.



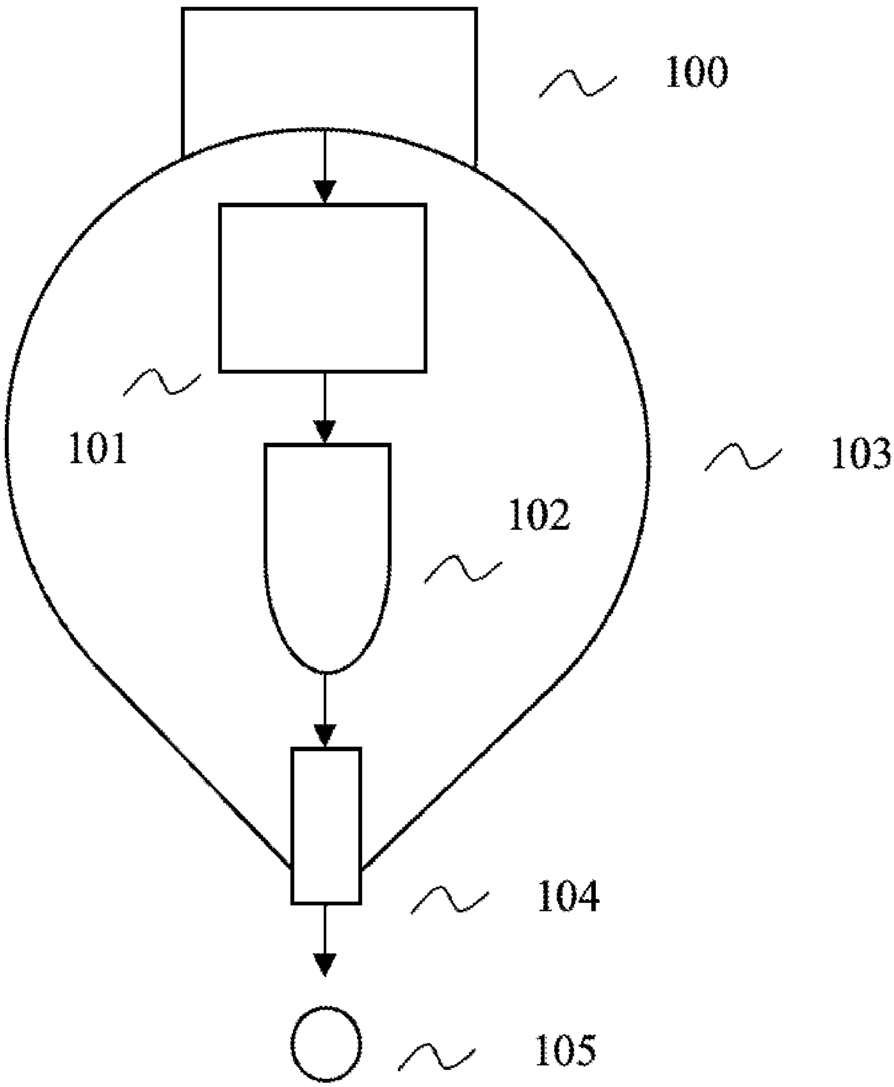


Figure 1

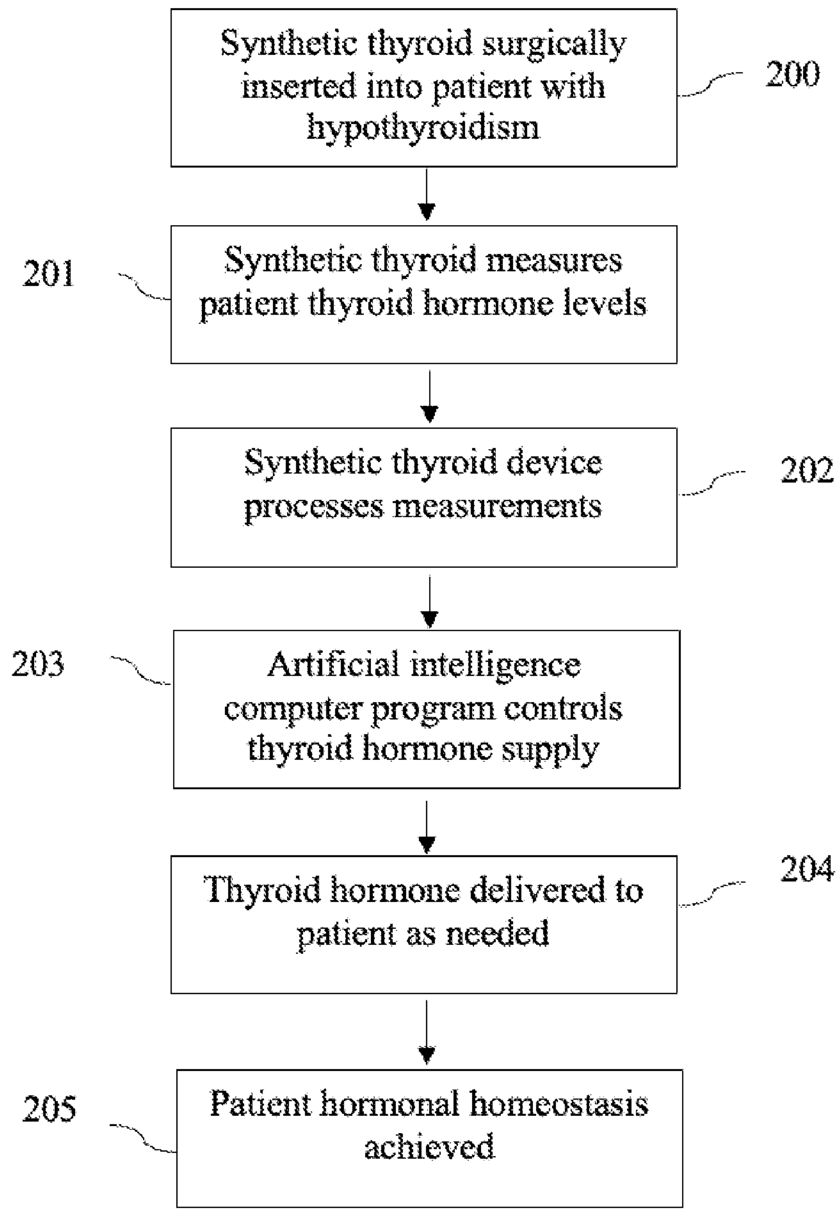

Synthetic thyroid surgically inserted into patient with hypothyroidism
200
Synthetic thyroid measures patient thyroid hormone levels
201
Synthetic thyroid device processes measurements
202
Artificial intelligence computer program controls thyroid hormone supply
203
Thyroid hormone delivered to patient as needed
204
Patient hormonal homeostasis achieved
205

Figure 2

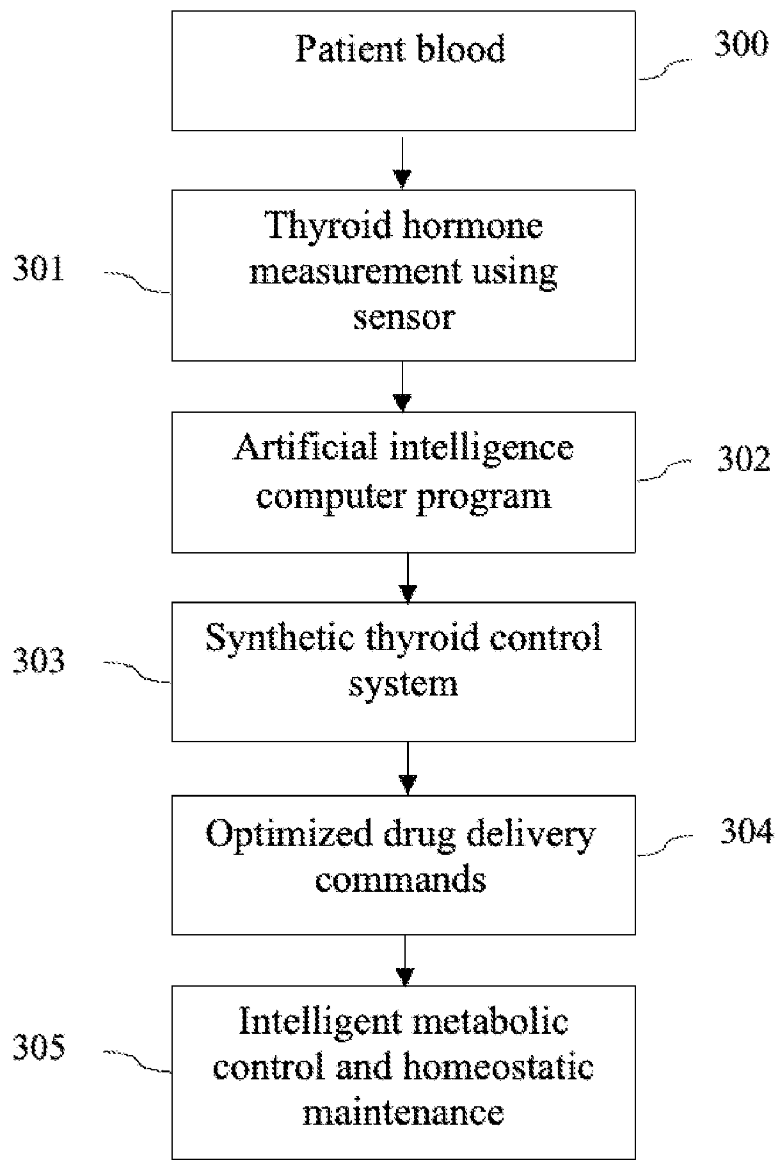

Patient blood
300
Thyroid hormone measurement using sensor
301
Artificial intelligence computer program
302
Synthetic thyroid control system
303
Optimized drug delivery commands
304
Intelligent metabolic control and homeostatic maintenance
305

Figure 3

SYNTHETIC THYROID METHODS AND APPARATUS

BACKGROUND TO THE INVENTION

[0001] The field of the invention rests at the intersection of two broader fields, artificial intelligence and endocrinology. Endocrinology is a medical branch concerned with endocrine glands and hormones, including the thyroid and thyroid hormones. Artificial intelligence refers to computational processes mirroring the human mind's thoughtful deliberation, decision making, and action-oriented behavior. Specifically, the field of the invention is artificial intelligence for drug delivery to patients with hypothyroidism, the most common thyroid disease in the United States.

[0002] Hypothyroidism is an endocrine disease affecting an estimated 9,900,000 people in the United States, 37,070,000 in Europe, and 104,000,000 people globally. Conventional methods for curing the disease fail for various reasons leading to ongoing patient symptoms including weight gain, depression, and anxiety. Further, medical reports suggest a common trend is that more than half of patients with hypothyroidism are undiagnosed and untreated. Moreover, there are several hypothyroidism types. For example, Congenital Hypothyroidism (CH) is defined as thyroid hormone deficiency present at birth. Another example is Hashimoto's Disease, a hypothyroid condition in which the immune system attacks the human thyroid gland preventing adequate Thyroxine (T_4) production.

[0003] The thyroid is a bilobal gland located at the base of the neck in front of the windpipe. The thyroid's functionality, essentially synthesizing thyroid hormone, is meticulously modeled through a feedback loop. The pituitary gland and thyroid communicate instructions for controlling hormone production and stabilization. The system works on an iterative loop where cells in the pituitary gland determine the body's normal hormonal range, known as the set point. In other words, the thyroid produces hormones, which are secreted into the blood and then carried to every tissue in the body. As such, the Thyroid produces a hormonal variety governing the human body's metabolism.

[0004] Thyroid hormone synthesis is a three-step process. First, the hypothalamus produces Thyroid Releasing Hormone (TRS), stimulating the pituitary gland to release Thyroid Stimulating Hormone (TSH), Thyrotropin, which in turn activates the thyroid gland. Second, the thyroid gland excretes Thyroxine (T_4) to the bloodstream. Third, T_4 converts to Triiodothyronine (T_3) through deiodination in peripheral tissues. This synthesis is critical for metabolic control in the human body.

[0005] Thyroxine (T_4) converts to the active Triiodothyronine (T_3) within cells and peripheral tissues by deiodinases. As such, in contrast to Thyroxine (T_4), the Triiodothyronine (T_3) molecule contains three iodine atoms. Triiodothyronine (T_3) is the physiologically active thyroid hormone. It controls myocardium properties, heart rate, and vascular function. In fact, Triiodothyronine (T_3) affects almost every process in the body. Some suggest the thyroid gland produces T_3 directly. Although, thyroid disease is typically not treated with Triiodothyronine (T_3) supplementation. However, speculate a Thyroxine (T_4) and Triiodothyronine (T_3) combination might be better. Molecular structures are important because clinical effects resulting from thyroid hormone imbalance are observable at the cellular level.

[0006] As such, Thyroid hormone maintenance is extremely critical for adult metabolic activity, and thyroid hormone abnormalities in adolescence can have catastrophic consequences. Thyroid hormone imbalance can have profound effects on the central nervous system. Interestingly, Thyroid hormone receptors are located throughout the brain, highlighting their importance in central nervous system's development and function. Indeed, Triiodothyronine (T_3) and Thyroxine (T_4) also provide feedback to the brain and anterior pituitary gland to regulate thyroid hormone.

[0007] In adults, Hypothyroid symptoms include chronic fatigue, depression, impaired memory, and weight gain. In adolescents, Hypothyroid symptoms include poor growth trajectories, limited mental development, and delayed puberty. Additionally, hypothyroidism may cause problems such as sleep apnea, hypothermia, hypoventilation, neuropsychiatric syndromes, peripheral neuropathy, seizure, cerebellar ataxia, and coma.

[0008] Thyroid hormone replacement therapy may be a chronic and lifetime endeavor for treatment. Thyroid hormone dosage must be established for each patient individually. Usually, the initial dose is small, with amounts increasing gradually until clinical evaluation and laboratory tests indicate optimal response. The dose required to maintain this response is then continued. It is vital to patients physical and mental health that thyroid hormone treatment have the correct dosage. Under-treatment with thyroid hormone can have deleterious and disastrous consequences including neurochemical imbalances, depression, and fatigue.

[0009] Prior to the disclosed invention, the art reflected the idea that hypothyroidism could not be cured. Rather, since the year 1970s, the conventional wisdom has been that hypothyroidism is only treatable by replacing thyroid hormone deficiencies with orally administered levothyroxine (LT_4). And orally administered levothyroxine (LT_4) is still the standard treatment for hypothyroid patients despite its primitive conception five decades ago.

[0010] Another option for patients is T_3 or T_4 therapy options, such as thyroid armour. Thyroid armour is thyroid gland that has been dried and powdered for medical use. Typically, thyroid armour is made from animal thyroid glands. However, the most patients only use T_4 therapy. It remains unclear in the medical community whether combination therapy with T_3 or T_4 therapy is a better treatment option. In some cases, there may be worried that excessive T_3 could be associated with other health problems, such as arrhythmia. Ultimately, while T_4 is the predominant treatment option, each patient is different and requires careful analysis to get the best clinical results.

[0011] Now, artificial intelligence technologies are changing human health. For example, deep learning algorithms enable computer systems to have predictive power far superior to humans in various domains. Deep learning is a process by which machines learn using neural networks. Moreover, reinforcement learning algorithms provide an artificial intelligence structure for goal-oriented behavior. Typically, reinforcement learning programs have three parts. First the model defines an agent-environment relation. Second, a policy defines a decision-making process for the agent. Third, the reward defines the agent's goal, which is optimized according to the policy.

[0012] Despite advancements in other health disciplines, artificial intelligence has yet to have an impact for treating hypothyroidism. There are three major problems with daily oral levothyroxine for treating hypothyroidism: (1) Fluctuation in ingestion times and surrounding dietary conditions causes metabolic imbalance, (2) Fluctuation in patient needs causes metabolic imbalance, and (3) Fluctuation in brand name may cause metabolic imbalance. Thurs, there exists a need for new medical methods for patients to with hypothyroidism. The disclosed invention solves these three problems, providing methods for curing hypothyroidism with automatic monitoring and corrective release to maintain metabolic homeostasis.

SUMMARY OF THE INVENTION

[0013] The invention is a process and system for curing hypothyroidism using artificial intelligence to measure blood and command hormonal secretion through a valve delivery mechanism. First, blood sensors measure hormonal concentration in the blood, storing measurements in memory for further processing the measurement. The sensors measure blood to detect and commit hormone levels of memory, including: Thyroxine (T_4), Triiodothyronine (T_3), Free Thyroxine (FT_4), and other thyroid hormones. Second, the measurements are processed and compared to target hormonal levels, and subsequently produce an automatic command for a valve control and drug delivery mechanism. Third, the valve control subsystem motivates thyroid hormone delivery from a supply of reserved hormone in a module to the patient's bloodstream optimizing hormonal homeostasis.

BRIEF DESCRIPTION OF DRAWINGS

[0014] FIG. **1** illustrates embodiments of the disclosure as a drug delivery device.

[0015] FIG. **2** illustrates methods for stabilizing and maintaining patient homeostasis.

[0016] FIG. **3** illustrates embodiments of the disclosure as a process for intelligent metabolic manipulation in humans.

DETAILED DESCRIPTION OF THE INVENTION

[0017] In certain embodiments, the disclosure is a drug delivery device **103** including a sensor **100**, receiving information. The device processes the information with a microprocessor **101** and the processor generates instructions to command delivery of a thyroid hormone **102**. The synthetic thyroid includes a delivery mechanism **104** which continuously delivers thyroid hormone to a patient's bloodstream **105**.

[0018] In certain embodiments, the disclosure is methods for stabilizing and maintaining patient homeostasis where a synthetic thyroid is surgically inserted into the patient **200**. The synthetic thyroid periodically measures the patient's hormone levels **201** and processes the measurements **202**. The measurements are processed with a computer program **203** that produces instructions for thyroid hormone delivery **204**, such that patient hormonal homeostasis is achieved **205**.

[0019] In certain embodiments, the disclosure is a process where patient blood **300** flows to a sensor **301** for hormonal measurement using an artificial intelligence computer program **302** manipulating a Synthetic thyroid control system **303** and producing optimized drug delivery commands **304** for intelligent metabolic control and homeostatic maintenance **305**.

[0020] In certain embodiments, the disclosure is a drug delivery device **103** including a sensor **100**, receiving information and a micro-processor processing the information **101**. The processor produces instructions to command delivery of a thyroid hormone from an embedded supply **102**. Then, the instructions control a delivery mechanism **104** delivering thyroid hormone to a patient's bloodstream **105**.

[0021] In certain embodiments, the disclosure is methods for stabilizing and maintaining patient homeostasis where a synthetic thyroid is surgically inserted into the patient **200**. The synthetic thyroid periodically measures the patient's hormone levels **201** and processes the measurements **202** with an artificial intelligence computer program **203**. In turn, the artificial intelligence computer program produces instructions for thyroid hormone delivery **204**, such that patient hormonal homeostasis is achieved **205**.

[0022] In certain embodiments, the disclosure is a process where patient blood **300** flows to a sensor **301** for hormonal measurement using an artificial intelligence computer program **302**. The artificial intelligence computer program manipulates a Synthetic thyroid control system **303** and produces optimized drug delivery commands **304** for intelligent metabolic control and homeostatic maintenance **305**.

[0023] In certain embodiments, the invention is a process by which a patient with hypothyroidism uses a synthetic thyroid **103** to supplement thyroid hormonal deficiencies, effectively curing the patient for as long as the synthetic thyroid provides the patient's needed hormone. In such embodiments, the disclosed invention provides a sustainable cure to hypothyroidism. In turn, the invention allows patients suffering from hypothyroidism to live without stresses associated medication management including daily reminders, neurochemical imbalances, and prescriptions. Thus, in certain patient's hypothyroid symptoms are effectively cured without the need for further treatment except for the regular replacement of the synthetic thyroid.

[0024] In certain embodiments, the invention is a process where a synthetic thyroid draws a blood sample. The blood sample is collected, using a measurement device, passing the measurement to a computer processor **101** using a convolutional neural network and reinforcement learning algorithm to command drug delivery from a Thyroxine (T_4) supply **102**. The supply is loaded, to a release chamber and delivered to the bloodstream as a liquid drop. The delivery stabilizes hormonal homeostasis.

[0025] In certain embodiments, the present invention is a system for optimizing the hormone level of a patient wherein a data sensor **100** measures blood for hormonal concentration, and transfers a signal, to a processor with memory storage. Then, the hormonal measurement concentration is stored and processed, to subsequently deliver an open command, which is linked to a control valve via a computational coupling. This triggers thyroid hormone release, from a thyroid hormone store chamber containing thyroid hormone, to the bloodstream, by opening the control valve and subsequently commanding the control valve closed.

[0026] In certain embodiments, the synthetic thyroid uses a deep learning algorithm to control drug delivery **203** according to commands from a convolutional neural network. The information collected by blood measurements relating to thyroid hormone in the bloodstream may be processed with a neural network which predicts the needed dosing release. According to the prediction, the drug delivery system may deliver a specified amount of purified Thyroxine (T_4) to the bloodstream of the patient. In turn, the prediction ensures hormonal homeostasis for the patient over time by effectively linking the measurement and delivery mechanism in the synthetic thyroid via the neural network, which optimizes drug delivery.

[0027] In certain embodiments, the synthetic thyroid uses a deep learning algorithm to control drug delivery according to commands from an artificial intelligence computer program. The information collected by blood measurements relating to thyroid hormone in the bloodstream may be processed with an artificial intelligence **302** to predict the needed dosing release. According to the prediction, the drug delivery system delivers a specified amount of purified Thyroid Armor to the blood. In turn, the prediction promotes the stabilizing of hormonal homeostasis for the patient over time by effectively linking the measurement and delivery mechanism in the synthetic thyroid via the artificial intelligence computer program.

[0028] In certain embodiments, the drug delivery methods use a proximal policy optimization (PPO) algorithm, which is a type of reinforcement learning algorithm, to optimize drug delivery and homeostasis. In general, PPO works by computing an estimator of the policy gradient and iterating with a gradient optimization algorithm. In other words, the algorithm continuously updates the agent's policy based on the old policy's performance. Generally, the PPO update is a method of incremental improvement. In such embodiments, the proximal policy optimization algorithm may be trained in a simulation environment to develop a reinforcement learning agent. Then, the reinforcement learning agent is embedded to a processor inside the synthetic thyroid. In turn, the reinforcement learning agent sends commands to the drug delivery system according to an optimal decision-making algorithm **304**, which promotes delivery to maintain metabolic homeostasis in the patient **205**.

[0029] In certain embodiments, an artificial intelligence computer program **302** processes information relating to the patient's current thyroid hormone level. Then, the artificial intelligence program makes a prediction regarding the patient's needed thyroid hormone for maintaining homeostasis. Next, the prediction informs the amount of thyroid hormone pumped to a drug delivery chamber. Finally, the needed supply necessary for maintaining homeostasis is delivered to the patient's bloodstream **105**.

[0030] In certain embodiments, the synthetic thyroid uses carbon fiber nanotubes for drug delivery. First, a sensor **100** measures thyroid hormones in the patient's bloodstream **301**, which may include Thyroxine (T_4) and Free Thyroxine (FT_4) to identify patient need. Next, the sensor sends information to a drug delivery mechanism, which informs the measurement for thyroid hormone delivery. Then, the necessary thyroid hormone is delivered to the patient via carbon nanotubes, to ensure metabolic homeostasis **205**.

[0031] In certain embodiments, the synthetic thyroid **100** is constructed with nanotechnologies including nanosensors, microprocessors, and carbon nanotubes. The synthetic thyroid may be constructed with multiple carbon nanotubes for performing two essential functions. The first function is measuring the blood for concentrations of Thyroxine (T_4) and Triiodothyronine (T_3). The second function is using the measured information to inform supply **102** delivery and deliver Thyroxine (T_4) to the bloodstream. Once delivered, the blood will perform deiodinases on the Thyroxine (T_4) generating more Triiodothyronine (T_3). The various functions may be performed using commands from a processor within the synthetic thyroid, communicating with nanotubes via nano-wiring.

[0032] In certain embodiments, the invention is a process and system for curing hypothyroidism using artificial intelligence. First, blood sensors measure thyroid hormone concentration in the blood of the patient. The sensors detect and commit hormone levels of memory, including: Thyroxine (T_4), Triiodothyronine (T_3), Free Thyroxine (FT_4), and other thyroid hormones. Second, the measurements are processed and compared to target hormonal levels, subsequently producing an automatic command for a valve control and delivery mechanism. The commands control the valve control and delivery mechanism such that the open command delivers thyroid hormone to the patient's bloodstream and the close command terminates the delivery process **304**. Third, the valve control and drug delivery system command purified Thyroxine (T_4) delivery from a supply of reserved hormone in a module to the patient's bloodstream optimizing hormonal homeostasis **205**.

[0033] It is to be understood that while certain embodiments and examples of the invention are illustrated herein, the invention is not limited to the specific embodiments or forms described and set forth herein. It will be apparent to those skilled in the art that various changes and substitutions may be made without departing from the scope or spirit of the invention and the invention is not considered to be limited to what is shown and described in the specification and the embodiments and examples that are set forth therein. Moreover, several details describing structures and processes that are well-known to those skilled in the art and often associated with biotechnologies are not set forth in the following description to better focus on the various embodiments and novel features of the disclosure of the present invention. One skilled in the art would readily appreciate that such structures and processes are at least inherently in the invention and in the specific embodiments and examples set forth herein.

[0034] One skilled in the art will readily appreciate that the present invention is well adapted to carry out the objectives and obtain the ends and advantages mentioned herein as well as those that are inherent in the invention and in the specific embodiments and examples set forth herein. The embodiments, examples, methods, and compositions described or set forth herein are representative of certain preferred embodiments and are intended to be exemplary and not limitations on the scope of the invention. Those skilled in the art will understand that changes to the embodiments, examples, methods and uses set forth herein may be made that will still be encompassed within the scope and spirit of the invention. Indeed, various embodiments and modifications of the described compositions and methods herein which are obvious to those skilled in the art, are intended to be within the scope of the invention disclosed herein. Moreover, although the embodiments of the present invention are described in reference to use in connection with artificial intelligence, ones of ordinary skill in the art will understand that the principles of the present inventions could be applied to other types of biotechnology for a wide variety of applications.

I claim:

1. A method for thyroid hormone control, the method comprising a synthetic thyroid containing one drug delivery system, the drug delivery system delivering thyroid hormone to the bloodstream, an artificial intelligence computer program controlling a delivery pump and valve with an embedded intelligence, programmatically optimizing thyroid hormone delivery, and one measurement device collecting and processing data, optimizing thyroid hormone dosing delivery according to defined parameters.

2. The method of claim **1**, wherein the artificial intelligence computer program is a trained proximal policy optimization algorithm, using a trained neural network to ensure the patient's bloodstream maintains homeostasis in thyroid hormone, delivering thyroid hormone to the patient according to a defined set point.

3. The method of claim **1**, wherein the defined parameters include a set point, defining the optimal concentration for thyroid hormone in the bloodstream, wherein the difference between a measured concentration is compared to the set point concentration, and an artificial intelligence program manipulates the drug delivery system, minimizing the difference between the measured concentration and set point concentration in the blood.

4. The method of claim **1**, wherein the thyroid hormone is purified Thyroxine (T_4).

5. The method of claim **1**, wherein the thyroid hormone is a composition containing Thyroxine (T_4) and Triiodothyronine (T_3).

6. The method of claim **1**, wherein the thyroid hormone is purified Triiodothyronine (T_3).

7. The method of claim **1**, wherein the artificial intelligence computer program is a proximal policy optimization algorithm, using a deep gradient optimizer, further comprising one convolutional neural network, iteratively improving the difference between a measured concentration of thyroid hormone, and set point concentration of thyroid hormone.

8. The method of claim **1**, where in the pump and valve are controlled with a classical computing system, optimizing drug delivery according to logical principles, performing computations without reference to the current thyroid hormone in the bloodstream.

9. A method for curing hypothyroidism, the method comprising a synthetic thyroid, measuring thyroid hormone in the blood, using an artificial intelligence program, predicting needed delivery dosage, the synthetic thyroid delivering thyroid hormone, according to the dosage defined by the artificial intelligence program, maintaining metabolic homeostasis in the patient by controlling thyroid hormone delivery to the bloodstream.

10. The method of claim **9**, wherein the artificial intelligence program is a convolutional neural network, further comprising an input layer, two hidden layers, and an output layer predicting needed dosage.

11. The method of claim **9**, wherein the artificial intelligence program is an embedded intelligence, calculating the needed dosage using statistical analysis, using intelligence from a human expert.

12. The method of claim **9**, wherein the thyroid hormone is purified Thyroxine (T_4).

13. The method of claim **9**, wherein the thyroid hormone is a composition containing Thyroxine (T_4) and Triiodothyronine (T_3).

14. The method of claim **9**, wherein the thyroid hormone is a composition containing Thyroxine (T_4), Triiodothyronine (T_3), and Free Thyroxine (FT_4).

15. The method of claim **9**, wherein the synthetic thyroid further compromises a carbon nanotube, concealing a thyroid hormone supply, delivering to the blood through a timed-release drug delivery system, according to commands from a micro computing chip, signaling delivery time according to programmed commands.

16. An apparatus for intelligent thyroid hormone delivery, the apparatus comprising a sensor, the sensor measuring thyroid hormone concentration in blood, receiving information and processing the information with a processor, further comprising a thyroid hormone supply, a pump and valve connecting a cylindrical tube for delivering the hormone supply to the bloodstream, the delivery happening according to an artificial intelligence program embedded on a microprocessor.

17. The apparatus of claim **16**, wherein the cylindrical tube comprises a carbon nanotube, with a lattice support structure.

18. The apparatus of claim **16**, wherein the thyroid hormone supply is purified Thyroxine (T_4).

19. The apparatus of claim **16**, wherein the thyroid hormone is a composition containing Thyroxine (T_4) and Triiodothyronine (T_3).

20. The apparatus of claim **16**, wherein the thyroid hormone is a composition containing Triiodothyronine (T_3).

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