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Concepts and designs of life support systems

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Abstract: Although total artificial hearts (TAHs) available on today's market can sustain a patient's life, their quality of life does not reach the potential of a donor heart transplant. The main reasons are device size and weight, as well as durability and the risk of blood clot formation. Additionally device-related infections pose a threat to a patient's life. A totally implantable TAH is developed in Aachen, which addresses these problems. One focus is set on improving durability, as failure is an immediate threat to a patient's life. The desired lifespan of the TAH should exceed 5 years. This can be achieved by reducing the number of moving, wear-prone components. In contrast to rotary motors with conversion gears, linear motors only need one moving part. Thus, a new TAH with a linear drive is developed, based on a detailed list of requirements. The potential of a linear motor as a TAH's drive is shown by a first prototype. Based on this prototype, two new drive concepts are developed and compared. The superior concept has been manufactured and force measurements have been performed in a test stand.

1 Introduction

Heart failure has been the major cause of mortality in industrialised countries for several decades. If sufficient perfusion of the body cannot be maintained by medication, heart transplantation becomes the only therapeutic option. Because of a severe shortage in donor hearts, more and more patients die while waiting for a heart transplant. To offer an alternative to those patients, total artificial hearts (TAHs) are developed. Obviously, certain requirements must be fulfilled by TAHs to ensure reliable operation and quality of life:

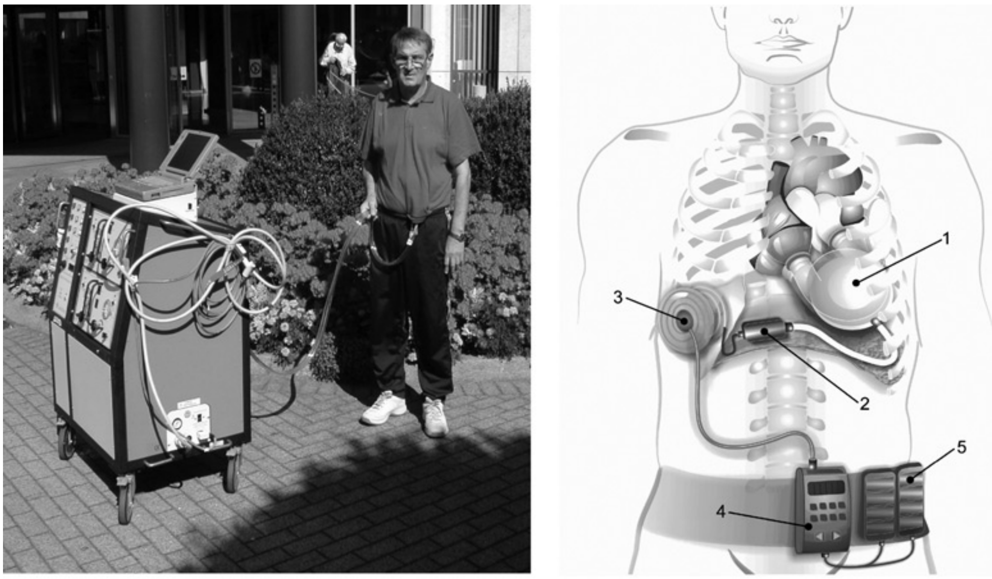
- The prevention of blood damage and blood clotting.
- A pulsating flow of blood according to the natural heart.
- The prevention of active blood suction.
- External components should be designed to maintain the patient's mobility.
- Penetrations through the skin should be avoided to reduce the risk of infections.
- The durability of TAH's life should be at least 5 years.

The main reason for blood damage and clotting are shear stresses and stagnation areas, respectively. Both are optimised by finite element computational fluid dynamics and verified by particle image velocimetry.

The implantation of a TAH is a severe medical intervention of the cardiovascular system. Although the influence of pulsatile against continuous blood flow on the human body is not well known, a minimal change of the physiologic situation is desired. Hence, a pulsatile operating system was chosen.

In the natural heart, the blood is flowing passively into the ventricle without suction. Active suction may result in an arterial collapse and, consequently, low pump output.

The only approved TAH, CardioWest (Syncardia) [1–3], is pneumatically actuated by an external compressor. Because of the inefficient pneumatic principle of the compressor, it is very large and heavy, restricting mobility and the patient's comfort, Fig. 1*a*. Its two drive lines penetrating the skin are a main source of infection. The linear drive provides smaller dimensions because of higher efficiency. Thus, the whole drive can be implanted into the human body, Fig. 1*b*. Energy supply is performed inductively by



a *b*

Figure 1 *Heart and Diabetes Center and totally implanted TAH*

a CardioWest by Syncardia,© Heart and Diabetes Center North Rhine-Westphalia, Bad Oeynhausen
b Totally implanted TAH: 1 TAH, 2 implanted converter, controller and buffer battery, 3 inductive transcutaneous energy transmission, 4 external controller, 5 external battery pack

transcutaneous energy transmission. The energy is taken from a compact external battery pack and transmitted to an implanted buffer battery and, thereby, no leads through the skin are needed, and the system provides maximum mobility.

Present systems such as MiniACcor (AME) [4], Abiocor (Abiomed) [5] or Magscrew [6] employ rotary motors with a conversion gear. They consist of many wear-prone parts, limiting life expectancy. The linear direct drive concept has only one moving component. The remaining wear parts are the linear bearing and potentially the energy supply lines to the actuator. In contrast to conversion gear bearings, the linear bearing does not have to support the actuator force but only the weight of the actuator and, thereby, the bearing forces are reduced by a factor of thirty and durability is significantly increased.

Compared with rotary and pneumatically driven systems, the linear drive concept has the best potential to fulfil all demands simultaneously.

2 Development approach

At the beginning of the design process, a list of requirements for the linear drive has been set up, derived from the demands listed above:

- Space in the thorax is limited, especially for women and children. Therefore the TAH's dimensions should not exceed 85 mm in diameter and 95 mm in length.
- Because of experience with transplantation of TAHs, the weight should be below 800 g, compared with 300–400 g of the natural heart.
- The average pumping capacity should reach 6 l/min against 100 mmHg with an additional overload capacity.
- Because of the heat tolerance limits of the human body, the thermal losses should be $<$20 W.
- The maximum force of the linear drive should amount to 70 N.
- The stroke of the actuator should be about 18 mm.
- Redundancy is desired in all system components to ensure failure-free operation.

The TAH replaces the natural heart in the thorax. Because of the implantation of a TAH in the human body, its dimensions are severely limited. The averaged dimensions should not exceed a cylindrical volume of 85 mm in diameter and 95 mm in length. For women and children, even smaller dimensions are preferable.

The weight of the natural heart amounts to 300–400 g. Because of fixation problems of a TAH, its weight should be below 800 g.

Under normal conditions, such as walking or non-intensive exercise, an average pumping capacity of 6 l/min against 100 mmHg provides sufficient blood perfusion for the body. Under geometrical restrictions, each of the two

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pump chambers of the developed TAH has a stroke volume of 50 ml, resulting in a required pump frequency of 120 beats per minute.

The TAH's power consumption is limited by heat dissipation and the capacity of the implanted buffer battery. As the blood and tissue of the human body only tolerate temperatures <42°C, the TAH's surface must not exceed this temperature limitation. The average losses tolerated are estimated to be <20 W to fulfil thermal requirements.

Fig. 2 illustrates the required force over the stroke of the linear drive for left and right pump chamber (shaded area). The force against the displacement curve has been deducted by measurements of the MiniACcor [4] performed in a cardiovascular simulator. The maximum force is estimated to be 70 N.

Although the TAH's maximum length amounts to 95 mm, only about one-third of this length is available for the linear drive. The desired stroke volume of 50 ml requires pump chambers with an overall installed size of the same dimension as the drive.

A TAH's failure is an immediate threat to a patient's life. Thus, redundancy is desired wherever possible to ensure reliable operation.

All these requirements cannot be fulfilled simultaneously by conventional linear drives.

As a proof of concept, a first linear drive prototype was developed and set up, Fig. 3*a*. Analogous to the natural heart, TAHs comprise two blood chambers (6, 7). To pump the blood into the aorta/pulmonary artery, these blood chambers are compressed by pusher plates (4). Active suction and the risk of arterial collapse are avoided by a passive filling of the blood chamber. The membranes of the pump chamber are not mechanically fixed to the pusher

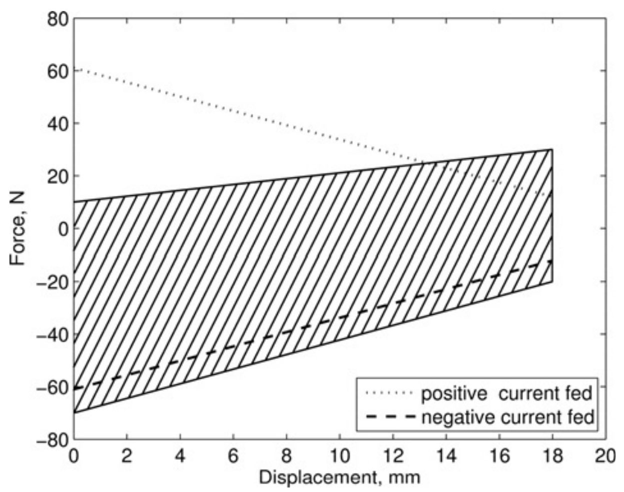

Figure 2 *Required force (shaded area) and measured force (lines) – force against displacement curve of prototype*

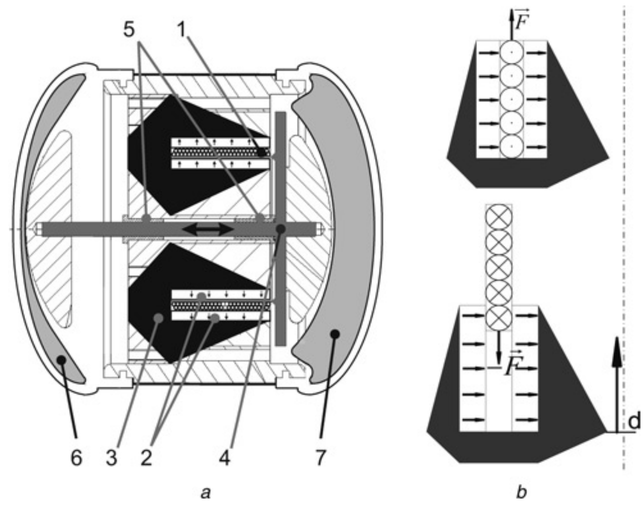

Figure 3 *Components of prototype TAH and their operation mode*

a Components of prototype TAH: 1 coil, 2 permanent magnet rings, 3 back iron, 4 coil support with pusher plates, 5 bearings, 6 left pump chamber, 7 right pump chamber
b Operation mode of prototype

plates, and so during diastole, the membrane can freely move back as blood enters the chambers.

The prototype is axisymmetric. It consists of two radially magnetised cylindrical permanent magnets (2) placed concentrically on both sides of a long thin coil (1). A back iron with saturation induction of 1.8 T closes the magnetic circuit (3). The electrical contact for the movable coil is ensured by specially designed flat springs. The measured force at 20 W copper losses is displayed in Fig. 2 as a function of displacement. The required forces for the left pump chamber have a negative sign as the displacement direction is negative. The left forces are higher than the right forces as pressure in the aorta is higher than that in the pulmonary artery.

Fig. 3*b* depicts the operation mode of the prototype. Only those parts of the coil placed between the permanent magnet rings produce force to drive the pusher plates. Hence, the force decreases with increased displacement. This force against the displacement characteristic can be improved by dividing the coil into different electrical circuits. Here, only those parts of the coil segments, which are powered, are placed between the permanent magnet rings. Hence, force can be increased at constant thermal losses of 20 W. This result will be taken into account for further development.

Although in a wide range, forces are too low and the weight exceeds limitations because of the thickness of the back iron, the prototype demonstrates that it is possible to realise a TAH with a linear drive if the device is well optimised. The main fields of optimisation to achieve all requirements simultaneously are the geometry and materials.

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3 Modified direct linear drive concepts

An actuator consists of a stator and a mover. Either the magnets or the coils are part of the stator or mover. To achieve a higher reliability, it is useful to avoid a moving coil, because the electrical contacts for the coil are additional, wear-prone parts. On the other hand, a moving coil can dissipate heat by conduction via the pump diaphragm to the flowing blood. In a static coil concept, heat is mainly transferred to the surrounding tissue. As their impact on the human body is not well known, both principles, moving coil and moving magnets, are investigated at a thermal dissipation of 20 W. The design process of the concepts started with analytical computations followed by 3D static nonlinear finite-element method (FEM) calculations with the solver iMOOSE [7].

3.1 Halbach concept

To completely avoid cogging forces without increasing device complexity [8], an ironless drive has been set up, Fig. 4*b*. The magnets are aligned in a special manner known as the Halbach array [9]. This array consists of permanent magnet rings, magnetised in an alternating axial and radial direction. Through this alignment, the magnetic flux density is augmented on the left/outer side, whereas it is partially cancelled on the right/inner side of the magnets, Fig. 5*a*. A back iron is not required in this configuration. Hence, weight and dimensions of the drive are reduced compared with the first prototype. The moving magnets are surrounded by segmented coils. Only those parts of the coil penetrated by high radial flux are powered. The required maximum force is decreased from 70 to 30 N with increased displacement, Fig. 4*a*. Thus, the coils and the Halbach array have the same length and, thereby, the number of coils penetrated by the radial flux of the Halbach array is reduced, resulting in a decrease of force against displacement. Hence, the required length of drive can be maintained.

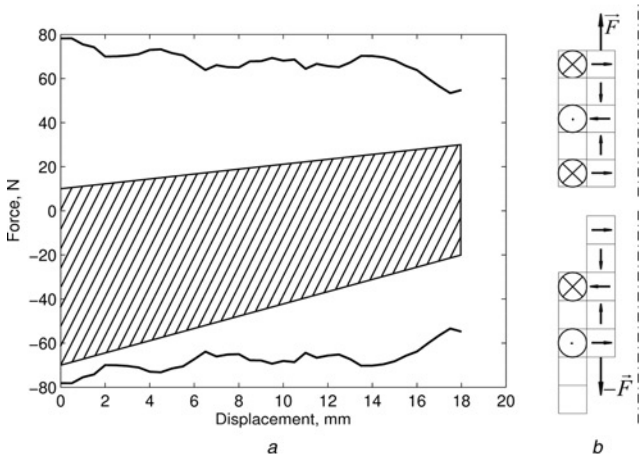

Figure 4 *Force against displacement curve of Halbach concept and their operation mode*

a Required force (shaded area) and computed force (lines) – force against displacement curve of Halbach concept
b Operation mode of Halbach concept

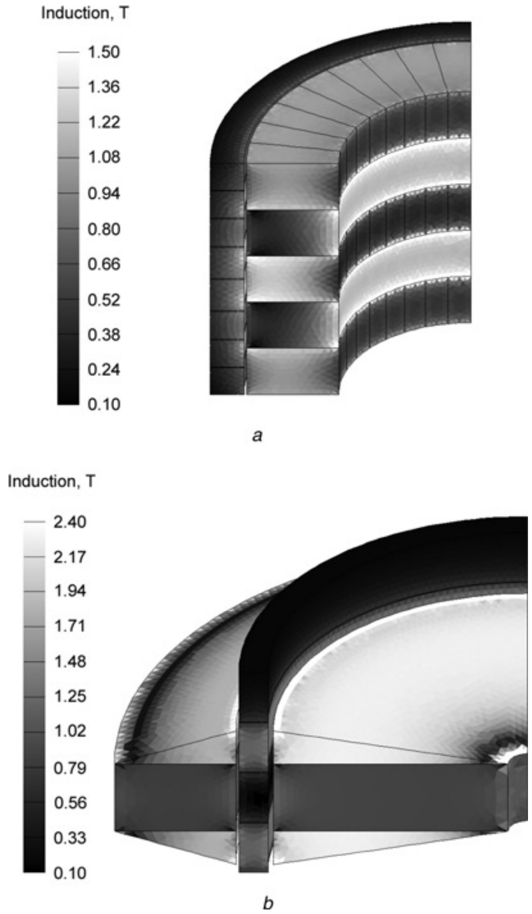

Figure 5 *Flux density*

a Halbach concept
b Flux concentrating concept

The simulated force – displacement curve of the Halbach concept achieves all requirements over the whole stroke. The force ripple can be reduced by increasing the number of coils or by modifying the current applied to the coils by means of pulse-width modulation (PWM).

3.2 Flux concentrating concept

3.2.1 Simulation: The force density and the efficiency of a drive can be improved by maximising air gap flux density. Hence, in this concept, flux concentration is the main objective, Fig. 6*b*. Because of geometrical requirements, the coil has to be part of the mover whereas the magnets and back iron are placed in the static part. The magnets are axially magnetised and the pole shoes guide the flux into the radial direction. As the pole shoes are made of Vacoflux [10] with a saturation induction of 2.35t, the air gap flux density can be maximised, Fig. 5*b*. Thus, the height and the weight can be reduced. Current is only applied to coil

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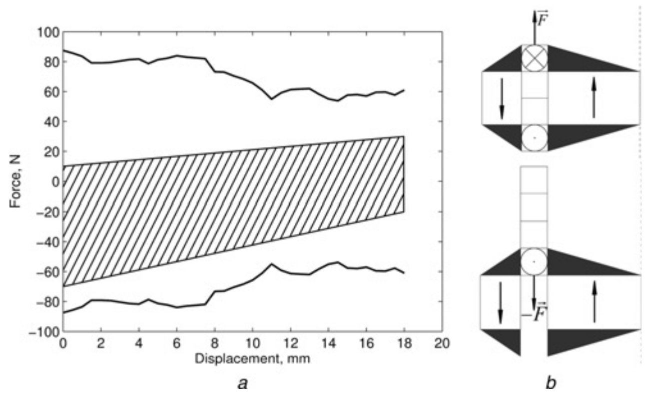

Figure 6 *Force against displacement curve of flux concentrating concept and their operation mode*

a Required force (shaded area) and computed force (lines) – force against displacement curve of flux concentrating concept
b Operation mode of flux concentrating concept

segments located between the pole shoes. As the maximal force is only needed at one end of the stroke, Fig. 6*a*, additional coil segments placed beneath the coil assembly can be left out, analogous to the Halbach concept. Additional segments would help avoid the decreasing maximum force observed in Fig. 6*a*, but they also would add unnecessary weight and increase the length of the drive.

The simulated force – displacement curve of the flux concentrating concept achieves all requirements. Analogous to the Halbach concept, the force ripple can be reduced by increasing the number of coils or by modifying the current applied to the coils (PWM). In comparison with the previous concepts, the force is increased and the weight reduced once more. The only disadvantage of the flux concentrating concept compared with the Halbach concept is the energy support of the moving coils. Additional wear-prone flat springs are required, Fig. 7*a*. To achieve the desired durability of 5 years, the springs must be designed to withstand 400 million cycles. Long-running experiments at a test stand have currently exceeded 180 million cycles without any indication of wear or fatigue of the material.

In summary, the flux concentrating concept best achieves all requirements. According to this simulated concept, a TAH prototype was set up and measured in a test stand.

3.2.2 Measurement: Fig. 7*b* displays the TAH prototype, consisting of the flux concentrating linear drive, the two pump chambers and the four heart valves. The maximum force against the displacement curve of the linear drive was measured in a tensile testing machine at thermal losses of 20 W. Only those coils penetrated by the magnetic flux of the pole shoes were supplied with current. The displacement of the coils relative to the stationary part was determined by an optical working position detecting system.

Figure 7 *Flat springs and TAH prototype*

a Flat springs for energy support of moving coils
b TAH prototype of flux concentrator with pump chambers and heart valves

Fig. 8 depicts the measured force – displacement curve of the flux concentrating prototype. Although the curve progression fits well, the measured force amounts to only

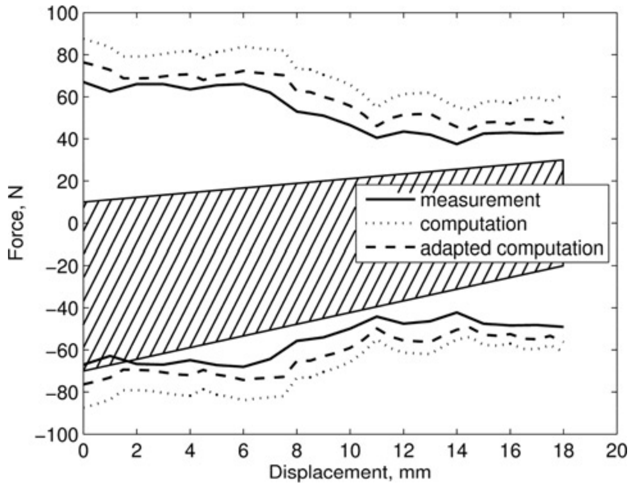

Figure 8 *Measured forces of TAH prototype of flux concentrator compared with computed forces*

about 70% of the computed force. Several reasons have been found for the reduction of force in measurement.

Because of geometrical requirements, such as the assembly of the linear bearings, the cross-section of the permanent magnets had to be reduced by 7% compared with that of computation.

The remanant induction of permanent magnets depends on their dimensions [10] and, hence, the outer permanent magnet ring could not be magnetised with the assumed remanant induction of 1.44 T; instead, the induction only amounts to 1.35 T according to the manufacturer's data. Both, the reduction of the permanent magnet's cross-section and remanant induction, result in a decrease of air gap flux penetrating the coils and, thus, a drop of force.

In simulations, the copper filling factor was assumed at 90% because of the use of wire with a rectangular cross-section. The hand wound coils only reached a filling factor of 75%, decreasing the ampere turns and, thus, force. Mechanical production may increase the filling factor to the assumed value.

The flat springs, required for energy support of the coils, additionally load a force to the mover. Depending on the mover's direction of movement, this force supports or works against the electromagnetic force of the drive. A total of eight springs is required for the independent energy support of the four coils, Fig. 7*a*. Their number and total spring constant can be reduced by integrating the converter into the mover. Taking the redundancy of two springs into account, the total spring constant could be decreased from 0.167 to 0.083 N/mm. Thus, the maximum force of the springs is reduced from 3 to 1.5 N at a displacement of 18 mm.

The simulation was modified by taking all these aspects into account. Fig. 8 depicts the adapted computation results. The remaining lack of force of the flux concentrating prototype amounts to 14% on average. At a constant value of copper losses of 20 W, measured forces achieve required forces, except for the displacement range from 0 to 2 mm. Hence, current can be increased in this range to fulfil the force requirements. Thermal losses would not exceed 20 W on average during one beat cycle.

4 Summary

The prototype of a flux concentrating concept prototype achieves all requirements. Hence, this concept will be used as a linear drive for a TAH. In further developments, the linear drive will be optimised mechanically and electromagnetically. Particularly, weight and dimensions should be reduced as much as possible. Redundancy and wear will be improved by integrating the converter into the mover. By modifying the currents applied to the coils, losses will be reduced and the force – displacement curve smoothed. Long-running tests will be performed to verify reliability, heat dissipation and power consumption. Therefore the prototype will be connected to a circulatory mock loop simulator and tested under realistic conditions. After successful laboratory tests, animal experiments will be performed.

5 Conclusion

Based on our experience with a first TAH prototype and magnetic force simulations, two concepts for a linear drive for a TAH were developed that accomplish force, weight and size requirements. Both demonstrate very good results in force simulation.

The Halbach concept with moving magnets has a small diameter and easy construction because of statically connectable coils. Compared with the flux concentrating concept, its weight is higher and the maximum force is lower.

The flux concentrating concept has a small height and weight and achieves the highest force densities. A minor disadvantage in this concept compared with the Halbach concept is the wear-prone connection of the moving coils. Long-running tests at a test stand did not indicate any wear or fatigue of the connection.

In summary, the flux concentrating concept best achieves all requirements. According to the simulation results, a TAH prototype of the flux concentrating concept was set up and measured in a test stand.

Although all simulation performances could not be implemented in the prototype, all requirements, especially the force – displacement curve at an average value of copper losses of 20 W, were fulfilled.

In future developments, the flux concentrating TAH prototype will be optimised mechanically and electromagnetically. Especially, the weight and size should be minimised as much as possible. Subsequently, long-running tests will be accomplished. Therefore the flux concentrating TAH prototype will be connected to a circulatory mock loop simulator and tested under realistic conditions. In this simulator, power consumption, heat dissipation and durability can be evaluated. After successful laboratory tests, animal experiments will be performed.

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