Numerical Computation Can Save Life: FEM Simulations for the Development of Artificial Hearts

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Cardiovascular diseases are the major cause of death worldwide. In conjunction with the restricted heart transplants due to the limited number of donor hearts, artificial hearts (AH) are the only therapy available for terminal heart diseases. Starting from the first design of an AH to its implantation into a human body, the AH has to pass several clinical trials, which result in redesigns and optimizations respectively. During this process, the dimensions, the weight and the required electromagnetic forces of the AH as well as blood damage, caused e.g. by shear forces or overheating, have to be considered. Thus, a coupling of analytical and numerical approaches permits an accurate design process to investigate force characteristics and losses of the drive. This contribution will give an example of an existing AH and provides exemplary the adoption of analytical and numerical approaches for the design of an AH developed by the authors. The presented heart prototype was already in operation during clinical animal tests.

***Index Terms*— Artificial organs, drive design, finite element method (FEM), linear electromagnetic actuators.**

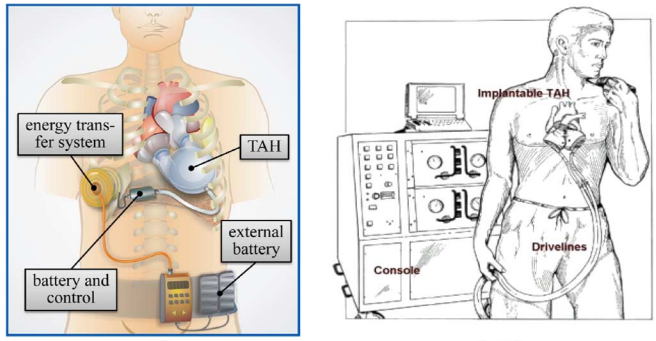
I. Introduction

DUE to the limited number of donor hearts, Artificial Heart (AH) systems are required for the therapy of terminal heart diseases. In medical technologies, two categories of AHs, the Total Artificial Heart (TAH) and the Ventricular Assist Device (VAD), are differentiated. While a TAH replaces the human heart, a VAD supports it. A VAD allows two therapy strategies at heart diseases, which are called bridge to recovery and bridge to transplant respectively. In the first strategy, it is expected that the heart recovers due to the support of the VAD, while the aim of the second strategy is to ensure the patient's survival until a donor or total artificial heart can be transplanted.

A concept of a TAH system is illustrated in Fig. 1(a). The patient wears a battery pack, which is connected to a transcutaneous energy transfer system, supplying an implanted battery in the human thorax. Thus, connections through the abdominal wall are avoided, which results in an annihilation of infection risks and a better quality of patient's life. Besides the battery, a TAH and its control are implanted into the human thorax. Due to the limited space, the volume and the weight of the TAH is restricted, especially for women and children. However, the TAH must be able to pump 6–7 l of blood per minute without exceeding limitations of blood damage, caused by shear forces or high losses, which result in an overheating of the blood and the surrounding tissue. Thus, high efficient concepts for blood pumps are required, achieving constraints such as minimized dimensions and weight as well as a long duration time.

II. State of the Art

Currently, most blood pumps are driven by rotary drives [2], which power density is higher when compared to linear drives,



a [1] b [3]

Fig. 1. Total artificial heart system. (a) [1] (b) [3]

inducing a continuous blood flow. On the other hand, a continuous blood flow does not represent the physiological conditions in the human blood circuits. For this reason, an optimization of current pulsatile blood pumps, especially concerning weight and durability, will be performed. In Fig. 1(b) the TAH CardioWest is presented [3], which is the only clinical approved system on the market. The implanted TAH is pneumatically actuated and therefore connected to a compressor via percutaneous drivelines. The advantage of the external compressor, which is integrated in the console, is the provision of high force densities for the blood pump, ensuring high rates of blood pressure. But regarding the dimensions of this system and the percutaneous drivelines, it is obvious that the patient's quality of life is affected and the risk of infections is increased.

III. Total Artificial Heart Accor

In Fig. 2 the TAH ACcor is shown, a pulsatile blood pump, developed at the Chair of Applied Medical Engineering of the RWTH Aachen University. The TAH is connected to the human blood circuit by two inlet and outlet valves, regulating the blood flow in the systemic and the pulmonary circuit. On each side of the drive a blood chamber with a capacity of 50 ml is attached. In theory, 120 beats per minute (bpm) are required to achieve a blood flow rate of 6 l/min. The rotation of the electrical motor is transformed by a coupled gear into a linear movement of the

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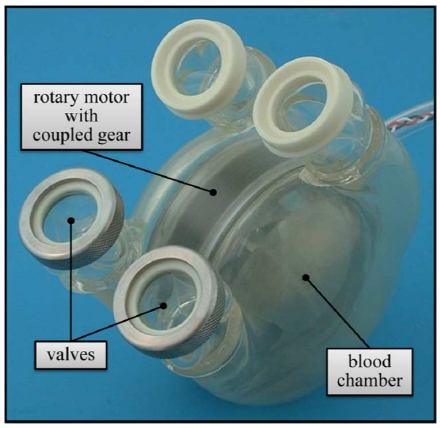

Fig. 2. ACcor.

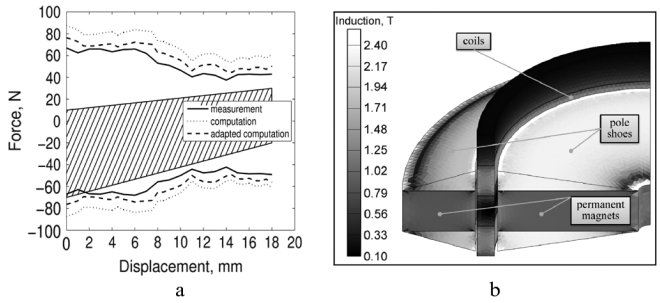

Fig. 3. Required forces (a) and distribution of the induction (b).

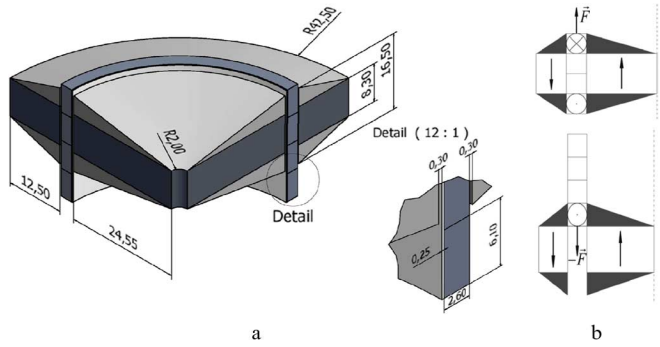

Fig. 4. CAD drawing (a) and operation principle (b).

pusher plates, emptying the blood chambers alternating and inducing a pulsatile blood flow. During initial in-vitro tests, the coupled gear failed due to it's fragile and wear prone components. Hence, this concept is not applicable as TAH drive. Before starting a redesign of the ACcor, an initial list of requirements, based on previous experiments and a literature research, was established:

- Due to the limited space in the human thorax, the dimensions of the TAH should not exceed 85 mm in diameter and 95 mm in length.
- The total weight of the TAH should be less than 800 g, compared to 400 g of the natural heart.
- The average pumping capacity should amount to 6 l/min against a medium aortic pressure of 100 mmHg and provide an additional overload capacity.
- The electrical losses have to be less than 20 W to avoid blood damage due to heat tolerance of the human body.
- The linear drive has to provide a maximum force of 70 N.
- A long durability (>5 years) of the TAH by a wear free and/or redundant system is desirable.

IV. Redesign of the ACcor

Before a TAH or VAD is clinical approved, it has to pass laboratory tests, animal experiments and clinical trials, which is a time consuming and expensive process. In order to shorten the development time and costs, an accurate TAH model from the beginning of the design process is required. Thus, the number of time-consuming and expensive in-vitro and in-vivo tests can be reduced to a minimum.

After a first analytical design, FEM simulations are adopted to improve the accuracy of the models, taking non linearity such as saturation effects into account and provide the investigation of transient system behavior [4]. Although the ACcor did not achieve the requirements for long durability, measurements verified the linear concept. Thus, a sufficient flow rate was provided at a negligible amount of blood damage. Hence, alternatives to the rotary motor with the fragile coupled gear have to be found in terms of a direct linear drive. The redesign of the ACcor drive is based on the aforementioned requirement list for implantation and an assumed force displacement curve, which is presented by the shaded area in Fig. 3(a) as a function of axial stroke to compress the blood chambers. If the forces, given in this diagram, can be achieved, a sufficient perfusion of the human body is expected. First, a proof of concept is performed for various linear drive concepts, such as a Halbach array for magnetic excitation [5] or a flux concentrating concept. Each concept is transformed into a drive design and a computer model, meeting the given geometrical constraints [6]. As these concepts have a large air gap, an analytical approach does not provide accurate results. For this reason, solvers of IEM's in-house FE software package iMOOSE [7] compute the induction, the resulting forces and the losses of the models after assigning the characteristics of the used materials and the excitations. Each drive concept is virtually supplied with a current that yields the maximum tolerable electrical losses of constantly 20 W. Thus, the maximum force output can be determined for each concept.

The evaluation yields the drive shown in Fig. 3(b) and Fig. 4 as the best linear concept for this TAH application, which is based on a flux concentrating concept. The linear drive consists of two stationary, axial contrary magnetized permanent magnet rings, arranged concentrically along the moving path of four coils. Above and below the magnets, pole shoes, which are made of an iron vanadium cobalt alloy with a saturation induction of 2.4 T [8] concentrate the magnets' induction. The coils are connected to helical springs, stacked on each other while separated by insulating layers to supply the mover of the linear drive. The pusher plates, emptying the blood chambers alternating, are attached to the ends of the coils. When supplying the coils, penetrated by the concentrated induction, with a current, the amount and direction of the resulting force as shown in Fig. 4(b) can be obtained by the Lorentz force equation

$$\overrightarrow{F}_n(x) = I_n(x) \cdot \left(\overrightarrow{l} \times \overrightarrow{B}_n(x) \right). \tag{1}$$

While the wire length l of each coil n is constant, the resulting force $F_n(x)$, the currents $I_n(x)$ and the induction $B_n(x)$ are

dependent on the axial displacement x of each coil. For the calculation of the resulting forces, the coil currents and the distribution of the induction, penetrating the coils, are required. Because of an air gap width of 3.45 mm between the inner and outer permanent magnet ring, the counter effects of the field, excited by the coils, can be neglected. As the magnetic leakage flux is significant and the iron vanadium cobalt alloy is magnetically saturated, non linear FEM simulations are required for the computation of the distribution of induction in the air gap. Due to the low frequencies of about 2 Hz and the negligible counter effects of the coils, iron losses can be neglected. Thus, only electric losses, caused by the current supply of the coils, occur in the drive. Due to limitations in achievable remanent induction, depending on the magnets diameter, remanent induction is 1.4 T for the inner and 1.35 T for the outer permanent magnet ring. The pole shoes are operating in saturation at 2.4 T as depicted in Fig. 3(b), permitting highest air gap induction and low ohmic losses respectively. In order to reduce them further, all four coils can be supplied separately. For this reason, the force is maximized at given losses P_{sum}, if the current is distributed to the coils proportional to the average radial amount of induction $B_{r,n}$, penetrating each coil at a given axial displacement x

$$k_{I,n}(x) = \frac{\overline{B}_{r,n}(x)}{\sum_{n=1}^{4} \left|\overline{B}_{r,n}(x)\right|}. \tag{2}$$

Each coil current is computed by the current factor $k_{I,n}(x)$

$$I_n(x) = k_{I,n}(x) \cdot I_{sum}(x) \tag{3}$$

and the total amount of current

$$I_{sum}(x) = \sqrt{\frac{P_{sum}}{R \cdot \sum_{n=1}^{4} k_{I,n}^2(x)}}. \tag{4}$$

Further, the efficiency of the drive is improved by increasing the copper fill factor, using rectangular copper wire for the coils. Based on these conditions, the drive is analyzed by a combination of analytical and numerical computations to achieve accurate results in a minimum of computation time. Therefore, the magnetic field distribution $\overline{B}_{r,n}(x)$ in the air gap, depending on the geometrical dimensions of the stationary part, the excitation and the saturation effects of the pole shoes, is numerically computed by a 3d static problem-solver from the iMOOSE package [7]. Due to the negligible counter effects of the coils' field, force computations are performed analytically

$$F_{sum} = \sum_{n=1}^{4} \overline{B}_{r,n}(x) \cdot I_n(x) \cdot l. \tag{5}$$

Based on this procedure and the given requirements, the drive is optimized first by means of parameter variation manually. Therefore, force characteristics, depending on the axial displacement x, are computed as shown Fig. 3(a) and adapted to the, for the present assumed, force characteristic, illustrated by the shaded area. Thus, a force between 15 N and 30 N for the pulmonary blood circuit is expected to ensure sufficient lung perfusion according to a blood pressure of 30 mmHg at 6 l/min flow rate. Due to the higher medium pressure of 100 mmHg in the systemic blood circuit, higher forces between 30 N and 70 N are assumed in the opposite moving direction of the coils.

V. Experimental Evaluation

Based on the optimization results, a first prototype has been constructed. In general identical to Accor, the blood chambers and the valves have been modified. Thus, the pumping capacity was increased from 50 ml to 60 ml. Additionally, the wear prone components such as the fragile coupled gear and the ball bearings have been replaced by a linear bearing. Due to the ironless assembly of the linear moving part, the magnetic attraction forces between stator and rotor are avoided, minimizing the linear bearings load. Long duration tests of the bearing and the current supplying springs have yielded a duration time of more than five years.

In order to validate the simulated drive design, the force versus displacement curve of the prototype after optimization has been measured with a tensile testing machine. For this measurement, the coils have been supplied with the same currents applied to the previous simulations. The displacement of the coils in relation to the stationary part is detected by an optical working position sensor. Measurement results revealed that the assumed force characteristic can be achieved at any axial displacement except in the range between 0 mm and 2 mm for the arterial blood circuit, Fig. 3(a). However, when comparing the computation results with the measurements, the measured forces amounts to only about 70% of the simulation results.

The reasons can be found in the differences between the computation model and the assembly of the prototype. For the electrical connections of the coils as well as the fixation of the pole shoes to the magnets, holes have to be drilled through the pole shoes and the magnets. Due to the assembly of the linear bearing, the volume of the permanent magnets is reduced further. This decrease of the permanent magnet material yields a lower induction. Furthermore, during simulation the copper fill factor was assumed to be 90%. Although rectangular wire is used for the prototype, the hand wound coils only achieve a fill factor of 75%. According to (1), the resulting decrease of induction and wire length yields a lack of force. Thus, the simulation model is modified to consider these aspects.

When comparing the adapted computation to the measurement results as additionally depicted in Fig. 3(a), the average difference between the simulated and the measured forces amounts to 14%. As already revealed, the required force characteristic is not achieved at a displacement between 0 mm and 2 mm for arterial blood circuit without exceeding the assumed tolerable ohmic losses of 20 W. Thus, the coil supply has to be increased for this displacement range to meet the requirements. Nevertheless, an overheating of the drive, inducing thrombogenicity and hemolysis in the blood and the surrounding tissue, is not expected due to the thermal capacity of the drive and the average losses of less than 20 W during one beat cycle.

Additional tests have been performed in a circulatory mock loop, which simulates the aortal and pulmonary blood circuit under realistic conditions, Fig. 5. Long duration investigations revealed that average thermal losses of 20 W can be dissipated by the pusher plates to the blood without exceeding temperature limitations in the body of 42 °C. Thermal hotspots between the diaphragm of the pump chamber and the surrounding blood only amounts to a difference in temperature of about 1 °C. Furthermore, average thermal losses are only 11 W at 95 mmHg and a flow rate of 6 l/min, defusing the thermal problem. Neverthe-

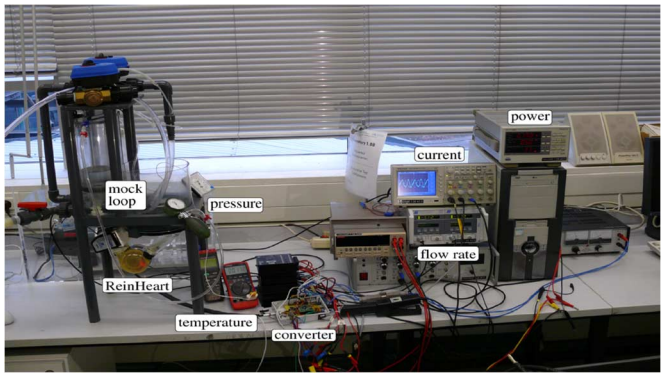

Fig. 5. ReinHeart in mock loop test.

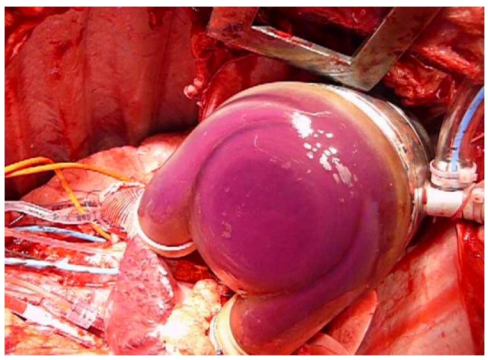

Fig. 6. ReinHeart implanted in a calf.

less, the aim to achieve a flow rate of 6 l/min at 100 bpm was not achieved until now.

Measurements revealed a flow rate of 6 l/min at 150 bpm, caused by flow losses in the valves, not sufficient stiffness of the pump chamber housing as well as not completely depleted pump chambers during one beat cycle.

For the validation of the drive concept under realistic conditions, the prototype of the ReinHeart TAH was implanted in the thorax of a calf, which anatomy is comparable to the human body, Fig. 6. During one hour in-vivo tests, the TAH provided a sufficient blood perfusion without thermal overheating. Thus, the calf already survived in the stadium of concept proof without further optimization of the drive. Hence, the linear drive concept was verified.

VI. Results

Although a first animal test was successful and demonstrated the potential of the new linear drive concept, the TAH is too heavy for the implantation in the human body with a weight of 1139 g. With 627 g, the drive is the heaviest component of the TAH. Hence, a reduction of drive's weight is required in order to meet the implantation requirements.

The heat dissipation of 20 W to the surrounding blood induces thermal hotspots of less than 1 °C temperature difference between pump chamber diaphragm and blood. Thus, thermal related blood damage such as hemolysis and thrombogenicity is not expected. The assumed force characteristic and ohmic losses of 20 W exceed the requirements, as laboratory tests revealed. Hence, the requirement list must be modified, based on further investigations concerning adapted force characteristic and thermal tests. Thus, the drive is oversized and will be minimized in further optimization.

TABLE I
Comparison of the Prototype and the Implantation Constraints

Parameter	ReinHeart	Implantation Constraint
Outer radius	85 mm	85 mm
Length	95 mm	95 mm
Weight	1139 g	< 800 g
Perfusion	6 l/min @ 150 bpm	6 l/min
Losses	11 W	< 20 W
Forces	70 N max	70 N max
Durability	?	> 5 a

VII. Conclusions and Future Work

This paper revealed the importance and the benefits of totally implantable TAHs. The ReinHeart, a further development of the ACcor, almost achieves any of these specifications but weight as shown in Table I. Further the required durability of the complete ReinHeart is not proven yet. As it is assumed that the springs have the highest failure probability, long term investigation have been performed, yielding a durability of more than five years. By means of coupling analytical and numerical computations, the innovative linear drive of the ReinHeart was developed time optimized. Extensive investigations at test benches as well as initial in-vivo tests verified the linear concept. Based on an assumed list of requirements, investigation results yielded a diffusion of the specifications, especially in force and tolerable losses.

In further development, the linear drive will be adapted to the modified list of requirements and will therefore be reduced in weight. Following investigations, performed by the proven numerical tool chain of iMOOSE, will affect manual parameter variations as well as optimization by means of differential evolution. Furthermore, extensive blood tests and fluid dynamic simulations will be performed in order to investigate blood damage, induced by thermal overheating, shear stress, or blood stagnation, and to optimize the blood chambers and valves.

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