Technical realization of medical requirements: Electromagnetic design of Artificial Heart systems

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Abstract- **According to the World Health Organization cardiovascular diseases are the major cause of death in industrialized countries. For some patients', suffering from terminal heart failure, a heart transplantation is the last medical therapy option. While the demand for the required donor hearts is rising, the number of available donor organs is decreasing. Therefore artificial heart systems are essential to sustain the life of the patients. In general these systems can be classified as Total Artificial Hearts (TAH), which are able to replace the natural heart, and Ventricular Assist Devices (VAD), which support the heart to generate a sufficient perfusion of the human body.**
In this contribution the technical specifications for Artificial Heart systems are deduced from the medical requirements for the therapy of cardiovascular diseases and the physical constraints of the human body. For example, in a TAH, which should bridge the time until a donor heart is available, dimensions are important. If the TAH is inappropriate large, it is impossible to implant the donor organ into the human thorax. On the other hand, if the TAH dimensions are too small, the surrounding tissue will grow into the free space of the thorax and therefore a heart transplantation is impossible. The TAH and a VAD system, developed at the RWTH Aachen University, are introduced and the realization of the medical requirements for the electromagnetic design of their drives is demonstrated. Challenges in the artificial heart development of the future are pointed out in the paper.

I. Introduction

In industrialized countries cardiovascular diseases are the mayor cause of death [1]. If drug based therapies fail, a heart transplant is one of the last therapy options for terminal heart diseases. This option is limited because the amount of required donor hearts exceeds the number of available and suitable organs [2]. Another possibility are artificial hearts (AHs), which are classified as Total Artificial Hearts (TAHs) and Ventricular Assist Devices (VADs). The TAH replaces the human heart completely. Therefore it is used as a bridge to transplant and sustains the life of the patient until a donor heart is available. If the TAH achieves a sufficient durability, which is defined as at least five years in current research [3], it is an alternative to heart transplantation. A VAD extracts blood from the veins and pumps it in the left (LVAD), right (RVAD) or both (BiVAD) ventricle(s) and therefore support the human heart to achieve a sufficient perfusion of the body. In this way the human original heart is unloaded, what yields its recovery for some patients. Otherwise the VAD is used as bridge to transplant such as the TAH.

Currently there are three generations of AHs studied in research. While the first generation induces a pulsatile blood flow similar to the physiological constraints in the human body [4], the other two generations of AHs provide a continuous blood flow. Although the question if a pulsatile or non pulsatile blood flow achieves a better and physiological perfusion is discussed for more than 30 years [5], a final answer is not found yet. The durability of second generation AHs is regarded as limited, due to its conventional and wear prone bearings. For this reason third generation AHs [6], [7] are operated with contactless bearings. This example provides an idea how to consider the physiological constraints of the human body for the design of an AH. Besides durability an AH operation without blood and tissue damage is essential.

II. Medical Constraints For Artificial Heart Design

In order to derive technical constraints for designing Ahs, the most important physiological constraints of the human heart and blood circuits are explained. The weight of a heart and its volume amount up to 400 g and 800 ml. respectively, while the pumping capacity of the left and right ventricle sum up to a maximum of 140 ml. When the pressure in the left ventricle exceeds the diastolic pressure of the aorta, the left ventricle is evacuated. It is filled with blood again when the systolic pressure of the aorta exceed the pressure of the left ventricle. This process is in principle the same for the right ventricle. In this way a pulsatile perfusion of up to 6 litre at a frequency between 60 and 80 bpm (beats per minute) of the human body is achieved. Due to the larger height differences the systolic/diastolic pressures (120/80 mmHg) of the systemic blood circuit exceeds the pressures of the lung/pulmonary blood circuit (25/15 mmHg). For this reason the left ventricle mostly is weakened first, if the human heart is overloaded. In medicine the important causes for blood damage are hemolysis, thrombogenicity or denaturation. High shear forces, stagnation of the blood, not biocompatible material and coarse surfaces are the main factors yielding hemolysis and thrombogenicity. In the human body denaturation starts at body temperature of 40˚C and is irreversible for temperatures above 42˚C. Denaturation yields a deformation of the bimolecular structure of the proteins in the blood causing its destruction.

III. Total Artificial Heart Systems

Fig. 1 represents the idea of the AbioCor TAH system [8]. Via a transcutaneous energy transfer (TET) system, an implanted internal battery and control are supplied. This battery powers an electrically driven TAH. As the only clinical approved TAH CardioWest [9] (s. Fig. 2) is actuated with compressed air, it requires drive lines, penetrating the human abdominal wall, which are directly connected to a console, containing the required compressor and control. Therefore this system has an increased risk of infections and the mobility of the patient is limited when compared to the previous TAH system. Although the medical constraints like weight, dimensions, sufficient perfusion of the body et cetera, the described disadvantage prevents a sufficient durability. For this reason an electrical driven TAH in combination with a TET system is desirable. As this paper focuses on the electromagnetic drive design for AHs, only denaturation as a cause for blood damage is included in the following list, containing the design goals under consideration of the medical requirements. Further information on electromagnetic based TET systems can be found in [10].

a) 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, yielding a maximum volume of 540 ml.
b) The average pumping capacity should amount to 6 l/min against a medium aortic pressure of 100 mmHg and provide an additional overload capacity.
c) The total weight of the TAH should be less than 800 g, compared to 400 g of the natural heart.
d) The electrical losses have to be less than 20 W to avoid blood damage due to heat tolerance of the human body.
e) The linear drive has to provide a maximum force of 60 N.
f) A long durability (>5 years) of the TAH by a wear free and/or redundant system is desirable.

In Fig. 3 the TAH ReinHeart is shown, which is devoleped at the RWTH Aachen University as a cooperation between the Institute of Electrical Machines (IEM) and the Chair of Applied Medical Engineering (AME).

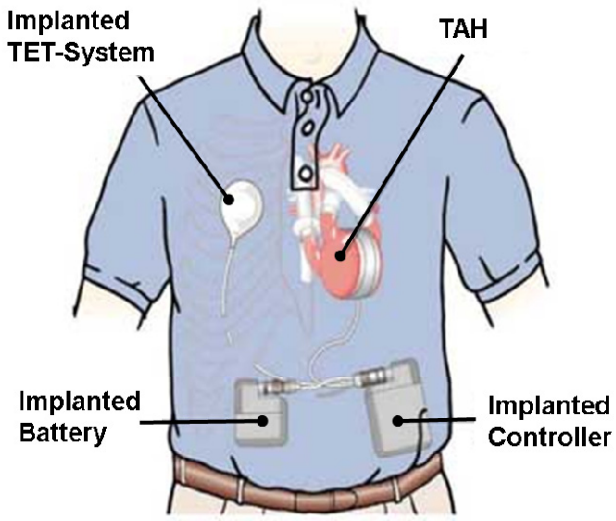

Fig. 1: Idea of a Total Artificial Heart System.

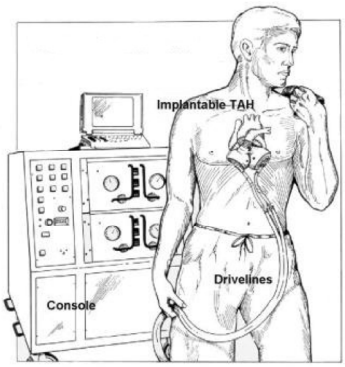

Fig. 2: TAH CardioWest [8].

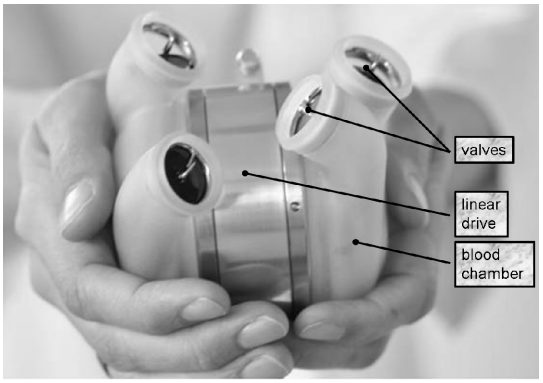

Fig. 3: TAH ReinHeart from RWTH Aachen University.

For a first seizing of the device the dimensions from a) have been taken. The left and right blood chambers are attached opposed to each other, separated by the linear drive located in the middle. In comparison with the human heart this assembly yields two mayor differences. First the chambers are evacuated in alternating operation instead of simultaneously and the shape is different. But experiences in TAH design have proved this assembly as the most suitable design. Each blood chamber has a capacity of 65 ml. In theory 100 beats per minute (bpm) generate a blood flow of 6 l/min, compensating flow losses due to delayed operation of the valves. The valves at the inlet and outlet of the chambers regulate the blood flow, yielding a pulsatile perfusion. When knowing the capacity of the blood chambers and the active membrane area of 3525 mm^2, the length of the required stroke can be calculated to 18.5 mm. Due to the required volume of the chambers and thickness of the used material a maximum length of 36 mm are left for the drive unit including the length of the stroke. Therefore the maximum dimensions for the drive are 36 mm in length and 85 mm in diameter a).

Based on this dimensions a concept study has been performed to find the drive design yielding the highest possible forces at constant losses of 20W d), because during test bench operation these losses did not cause an overheating of blood or surrounding tissue [3]. In order to achieve the desired durability f) all concepts are based on a linear drive system to avoid as many mowing components such as a gear as possible. In Fig. 4 the most promising design of the studied concept is presented, which is based on flux concentration. The mover consist of four separately supplyable coils. This provides the

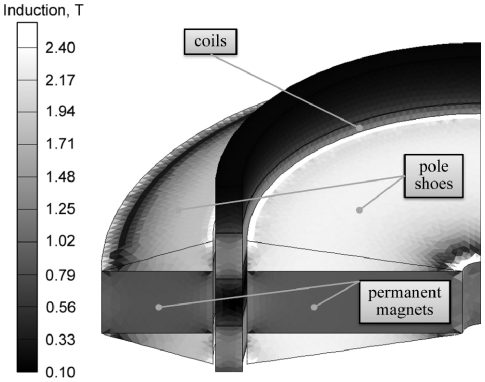

Fig. 4: CAD drawing of linear drive operating ReinHeart.

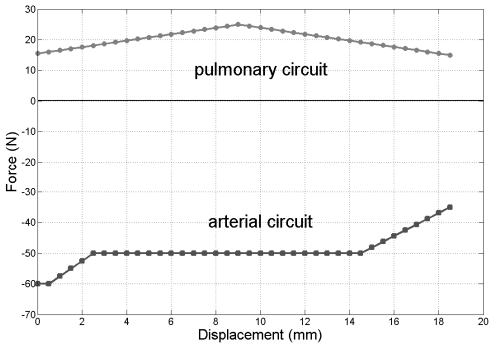

Fig. 5: Required force for sufficient perfusion.

possibility to supply the coils in dependency of the flux density penetrating them. According to the Lorentz force equation

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

an optimized coil supply can be applied to reduce the copper losses. While the wire length l of all coils is constant, the required coil current I_n of each coil and the required force F_{sum} have to be determined in order to yield an optimal design. The resulting radial flux density $B_{r,n}$ is generated by an inner and outer permanent magnet ring, made of neodymium iron boron (NdFeB). Due to manufacturing the remanent induction of the inner ring only amounts to 1.38 T, instead of 1.43 T of the inner ring at room temperature. The pole shoes, which are attached above and beyond the magnetic rings, concentrate the magnetic induction in the air gap. They are made out of an iron vanadium cobalt alloy with a saturation induction of 2.35 T. But the resulting weight of 1127 g of this TAH design exceeds the given limit of c). Although the weight sets the limit, the problem is the fixation of the TAH inside the human thorax. When the body is moving high forces are acting on the connections.

With 616g the drive is the heaviest component of the TAH. In order to reduce its and therefore the resulting TAH weight, the magnetic exploitation of the drive design should be maximized by decreasing its dimensions. Therefore the optimization objective is to provide a sufficient perfusion b) without exceeding the loss limit of 20 W d) and to reduce the weight of the drive as much as possible. For this reason in [11] the required force (Fig. 5) for a sufficient perfusion has been experimentally determined. According to the physiology of the heart the pressures in the arterial or systemic blood circuit exceeds the pressures in the pulmonary circuit. This yields different shapes and maximum absolute force for the two circuits, which have to be generated by the drive. Although the distribution of the induction B (Fig. 4) and the coil length l are dependent the drive design, they can be determined by Finite Element (FE) simulations and analytical equation for every design variation.

The required forces are given by Fig. 5, which according to equation 1 are dependent on the coil supply I_n. As the resulting copper losses are rising with the square of the coil supply, an optimum supply scheme has to be found, yielding the required forces for a minimum of losses.

Therefore to calculate the resulting losses, a toolchain has been established in [11]. The generated radial magnetic induction is determined by FE-simulation. Due to the general drive design a static three dimensional and non linear solver from the IEMs inhouse software package iMoose [12] has been applied for the simulation. For each displacement of the mover, the magnetic flux coupling of each coil can be calculated. Investigation performed in [11] proved, that electric losses are minimized if the coils are supplied according to the relation, referred as $k_{I,n}(x)$ in the following, of between the magnetic flux coupling of each and all coils. Therefore the overall and position dependent current $I_{sum}(x)$,

$$I_{sum}(x) = \frac{F_r(x)}{\sum_{n=1}^{4} \overline{B}_{r,n}(x) \cdot k_{I,n}(x) \cdot l} \ , \qquad (2)$$

and by applying ohm's law the position dependent losses can be calculated. By integrating theses losses over one cycle, the average losses are determined.

When applying this toolchain to the design of the drive prototype the average losses sum up to 8W, allowing an increase of losses d) for the weight reduction and increasing the magnetic exploitation of the drive. During variation calculations, design parameters like the outer diameter, coil thickness and diameter as well as inner coil diameter were varied in fixed steps of 1 mm. By applying the toolchain a weight vs. losses characteristic can be obtained for every design parameter. Further a hierarchic order is established yielding the best parameters to be applied for the drive optimization. Variation Calculations are limited, because only one parameter can be investigated at the same time. Therefore the effect of the interdependencies between the parameters is not considered by this approach.

This problem is addressed by applying the Differential Evolution Algorithm [14],[15], which is an algorithm based optimization method. Therefore a fully parameterizeable computer model for the drive design is set up. Then a generation of models is created, which design parameters are initialized with random values. By applying a cost function the quality of each model is evaluated in terms of weight and losses, yielding a list with the sequence of the best members. Based on the best member a new generation of models is created and evaluated. The lists of the two generations are merged by comparing the models of the same hierarchic order. After several iterations the best possible drive design is found.

The results of the optimization processes are compared in Table 1 [16] with the parameters of the initial prototype. While the Variation Calculations only varied the radial geometry parameters, the DEA also considered the height of the permanent magnet rings and the pole shoes. As the inner and the outer dimensions for both methods are nearly identical, no further improvement potential is seen here. Nevertheless, the magnetic exploitation of the static drive part has been increased by the DEA yielding the maximum weight reduction of -156 g, when compared to the prototype. For both methods the losses amount to nearly 10W. The given limit of d) was not exploited, because the expected losses of the inverter are not included yet and the TET system is easier to apply for lower power requirements.

Table 1
Comparison of the optimized and the prototype´s drive.

Paramerter	Prototype	Variation Calculations	Differential Evolution
Weight	616 g	517 g	460 g
Losses	8 W	9.94 W	9.99 W
Inner radius	7 mm	8 mm	8 mm
Outer radius	42.5 mm	38.5 mm	38.45 mm
Height max.	16.5 mm	16.5 mm	15.6 mm

VAD REINVAD

The pressures in the systemic blood circuits exceed those of the pulmonary blood circuit. For this reason an overloading oft he left ventricle is more likely than an overloading of the right or both ventricles. If the heart remains with sufficient perfusion capabilities a recovery of the heart is possible for some patients by unloading the left ventricle with a supporting LVAD. Fig. 6 shows the components of a LVAD system by the example of the HeartMateII, developed by the Thoratec Cooperation. The internal pump unit is integrated in the systemic blood circuit. An external controller and battery supply is connected to pump via a skin penetrating driveline. For a short term cardiac assist the risk of infections is tolerable, but for a long support the same problems,

Fig. 6: LVAD HeartMateII [17].

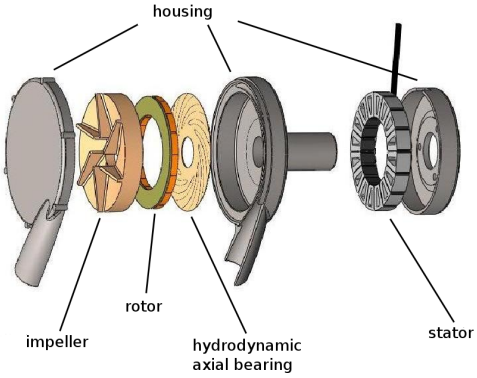

Fig. 7: Assembly of a VAD.

described before for the TAH system, occur. In Fig. 7 the general assembly of the third generation and radial blood flow VAD ReinVAD is shown. The pump unit consists of the rotating impeller and the in- and outlet, which is integrated into the VAD housing. For driving the impeller an axial flux brushless dc drive, which design is described in the following, is applied. The hydrodynamic bearing relies on a thin film of blood and therefore works without contact allowing cardiac assist for a long term.

In Fig. 8 and Fig. 9 the stator and rotor of the ReinVAD drive are shown. The stator yoke is constructed of an ferromagnetic steel holding 18 coil, wounded with a rectangular shaped copper wire. There are 16 axially magnetized NdFeB magnets (1.4 T @ 20 ˚C) attached to the ferromagnetic rotor backiron. For this reason axial attracting force occur, which have to be compensated by the hydrodynamic bearing. When the stator coils are completely filled with ferromagnetic iron, the resulting axial forces can be compensated. For this reason the stator teeth height is reduced, yielding coils which are partially filled with iron and air. As

$$B \sim \frac{1}{\delta}, \tag{3}$$

the air gap induction and therefore the axial force decreases with the increasing air gap thickness δ. The resulting torque, depending on the radial component of the induction, decreased. Besides durability, dimensions and losses are technical limitations for the medical application of unloading the left ventricle. As the resulting torque depends on the outer rotor radius, the balance between torque and minimal dimensions has to be found. Additionally the electric losses, which consist of iron and copper loses, have to be within 3W.

Due to the multi objective design constraints, the DEA is applied again. The resulting forces and losses have been

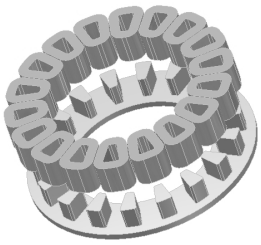

Fig. 8: Stator of ReinVAD.

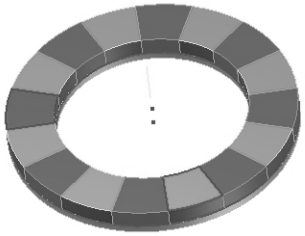

Fig. 9: Rotor of ReinVAD.

determined by transient and three dimensional FEM simulations, because high stray flux is expected due to the air gap thickness of 1mm between the top of the coils and the rotor. Table 2 collects the results of the drive design.

When the stator teeth height is 3.6 mm, the coils are filled with 70% iron and 30% air. This results in an average attracting force of 9.12 N, which can be compensated by the hydrodynamic bearing. The outer rotor diameter amounts to 39 mm and the copper losses are 0.66W, while generating a torque of 12 mNm at a rotational speed of 2500 rpm. Currently the iron losses have not been simulated yet, but are expected to be significant because of the solid stator yoke. Due to the rotational movement the reluctance force between stator and rotor is not constant, yielding ripples in the axial force and torque.

IV. Future Challenges

According to [18] the mayor challenges for the development of AHs are an increased durability to allow for destination therapy and a wide range of inexpensive blood pumps, classified by a high (TAH) and minimal invasive implantation (LVAD) technique, to cover the individual need for heart support systems. In order to increase the durability of the drive systems there are several well known options like avoiding wear by applying contact less working drives, using redundant components or an over seizing of the machine. But due to the design parameters weight and maximum dimensions, the last two possibilities are strongly limited.

When implanting an AH the surgeon performs a thoracotomy to gain access to the heart in most cases. Then the VAD is connected to pulmonary or arterial blood circuit with the help of artery catheters and bypass the correspondent blood circuit. This implantation procedure is stressful for the patient. Therefore a minimal invasive implantation technique should avoid the thoracotomy.

One idea is to insert the VAD in an artery close to the body surface. Then the VAD has to be placed for example in the upper apex. In surgery the placement of stents to widen for example coronary vessels is a well known procedure. So an transfer of this placement technique should be possible for the VAD. When considering the small dimensions, which are in the range between 3 and 6 mm in diameter and between 30 and 40 mm in length due to the human anatomy, the challenge lies in an innovative VAD design, which can be realized by available production technologies. The technical constraints such as a mechanical power of approx. 3W and torque about 10 mNm, a speed between 6.000 and 15.000 rpm can be deduced

Table 2
Drive design of the ReinVAD.

Paramerter	Prototype
Outer diameter	39 mm
Height of stator teeth	3.6 mm 70%
Axial force	9.12 N
torque	12 mNm
Copper losses	0.66 W

from the conventional VAD design. At this point some general aspects or questions of the drive design are discussed.

At first a motor with permanent excitation is expected to be the best choice for two reasons. First, the magnetic excitation replaces the cables for a current based excitation and therefore reduces the resulting copper losses. Secondly, the required machine volume is reduced and its dynamic performance is improved when compared to drives without magnetic excitation.

Based on this assumption various drive configurations, relying on an axial or radial flux flow are possible. Due to the limited dimensions only a limited number of coil layers is possible. Therefore, the torque generation is mainly dependent on the rotor radius r, according to the following equation.

$$\vec{T} = \vec{F} \times \vec{r}\,, \tag{4}$$

Therefore external motor rotors have advantages due to their working principle when compared to internal rotor motors, which can be easier fastened in the artery. Further the positioning of the drive is important In [20] the rotor (s. Fig. 10) of the so called MVAD has been integrated in the impeller. Flow channels have been milled in a solid cylinder. An additional hydrodynamic bearing been integrated as well by milling thin flow channels around the circumference of the cylinder. The rotor permanent magnets are inserted in the rotor blades.

For widening coronary vessels, stents are applied, which can be expanded. When integrating the VAD in a stent, the maximum possible diameter can be increased to be between 20 and 25mm, if the VAD is placed in the aorta, hopefully yielding an improved torque generation. In such an arrangement, the stator coils could be included in the stent housing. At this point there are two approaches for the rotor design. First the shaft could be made of a magnetic cylinder and therefore serving as a rotor. This design has a relatively thick air gap, weakening the magnetic coupling. The more challenging option is to realize an expandable rotor. High repulsive or attracting forces act on magnets, which are close to each other. For this reason a folding or expansion of such rotors is difficult to achieve. The same problem occurs when attaching the magnets to the stent housing.

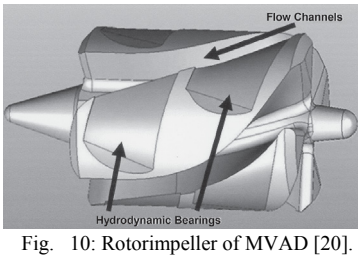

Fig. 10: Rotorimpeller of MVAD [20].

For the TAH system described before TET system for the wireless power supply are already available. In case of a VAD placed inside an artery, the realization of such a system is more challenging. The distance between the external submitting coil and the internal receiving coil sums up to be at least 30 mm. Further the artery is pulsating, resulting in constant changes of the angle between the coils, limiting the received power. Currently the incidence of right heart failure is regarded to be of minor importance when compared to left heart failure. For this reason it is treated with LVADs, because only a few RVAD systems like the Impella RD exist and have a limited durability. As the mean pressure in the pulmonary blood circuit is significantly lower when compared to the systemic blood circuit, LVAD are oversized for this therapy application. Therefore a VAD system adapted to the physiological constraints of the pulmonary blood circuit and allowing for long term cardiac assistance is desirable. Further it would be a good opportunity for the investigation and evaluation of the previously introduced minimal invasive implantable VADs, as the requirements are lower when compared to LVADs.

V. Summary and Conclusions

This paper explained the importance of the development of artificial heart systems, evolving from the insufficient number of donor hearts limiting heart transplants for the therapy of terminal heart diseases. Design constraints for AHs in general and their drives in particular have been deduced from the physiology of the human heart. Based on a concept study a linear drive relying on a flux concentrating concept has been introduced to operate the TAH ReinHeart. The initial design meets all constraints of the acquired constraint list except the specification of low weight. Further it is to be mentioned that the durability of the wear prone drive components have been tested separately, however, not the whole system. In order to reduce the weight of the drive, which is the heaviest part of the TAH, its dimensions and therefore its magnetic exploitation is optimized by two methods. In simulations and initial test bench operation the average copper losses were determined to 10 W for a drive with a weight of 460 g. As the pump and the housing is not adapted for the new drive design a further weight reduction for the TAH is expected. For this reason a TAH meeting all constraints is expected to be in reach in the near future. If some heart function is retaining, the heart is supported with a VAD, which can assist the left, right or both ventricles. For the introduced LVAD the drive is designed to allow for a hydrodynamic bearing, which can compensate axial attracting forces of 9N. This force depends on the axial magnetic induction, which itself depends on the air gap width. Therefore the stator tooth height is varied yielding coils which are filled with iron as well as with air. Due to the solid stator yoke high iron losses are expected due to the resulting eddy currents. The resulting losses will have to be simulated. The investigation of alternative materials such as soft magnetic composites is planed to reduce losses. As the hydrodynamic bearing works without contact a high durability is expected, but not proved yet. During initial in vitro and in vivo tests, the proof of concept was obtained for the ReinVAD as well as for the TAH ReinHeart.

The challenges of the future in the field of the electromagnetic design are mostly concerning the realization of minimal invasive implantable pumps. A feasible drive design has to be found with a high power density at small construction space allowing for the required torque generation. Another option might lie in the realization of an expandable motor concept.

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