Evaluation of Clinically Relevant Operating Conditions for Left Ventricular Assist Device Investigations

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SUPPLEMENTARY MATERIAL

A1: Flow rate and pressure difference estimation in INCOR®

As described in the main article the flow rate and the pressure difference are estimated based on the axial position of the rotor within the magnetic bearing.

Within this chapter, the procedure and the accuracy are explained shortly.

a) Measuring possibility

Figure 1 of the main article shows the hydraulic components of the INCOR® pump. Due to the active control of the rotor within the magnetic bearing, the axial position (U) has to be measured at all times. As for all rotary pumps, also the rotational speed (n) is a known parameter. To be able to display the flow rate (Q) and pressure head (H) a possibility to calculate them is needed. Thus, the goal is to have functions to calculate them based on available data continuously: $Q = f(U, n)$ and $H = f(U, n)$. These functions are calibrated based on *in-vitro* measurement for each INCOR® pump before going to the clinics.

b) Generating data

An extended characteristic flow field is recorded for each INCOR® pump to generate a database for the functions $Q = f(U, n)$ and $H = f(U, n)$. »Extended« means that not only the data of the whole 1st quadrant of the HQ-field is recorded (normal pump operation condition) but also some data points within the 2nd and 4th quadrant. Within that whole field *U* and *n* are recorded by the pump. Additionally *H* and *Q* are measured by sensors in the mock loop.

c) Calculating coefficients based on multiple regression

Ten coefficients are needed to generate a cubic calculation specification for *H* and *Q* separately (That was possible due to the high density of data points within the operating field.):

$$\boldsymbol{H = a_1 * U^3 + a_2 * n^3 + a_3 * U^2 n + a_4 * U n^2 + a_5 * U^2 + a_6 * n^2 + a_7 * U n + a_8 * U + a_9 * n + a_{10}}$$

$$\boldsymbol{Q = b_1 * U^3 + b_2 * n^3 + b_3 * U^2 n + b_4 * U n^2 + b_5 * U^2 + b_6 * n^2 + b_7 * U n + b_8 * U + b_9 * n + b_{10}}$$

This is done by multiple regression. Since the flow behavior of the INCOR pump differs within the 2nd and 4th quadrant, additional coefficients are calculated (ten more for the 2nd quadrant and 3 more for the 4th quadrant). Altogether 33 coefficients are generated for each INCOR® and saved in the control unit.

d) Verify the calculated coefficients on new generated data

The operating range of the INCOR® is investigated similar to b) a second time to ensure that all coefficients are valid in use. The measured values of H and Q are compared to the calculated values after that second record. Figure A.1 shows a copy of plot of comparison in protocol of an INCOR® pump. The similarity of the calculated and measured plot can be seen. A more demonstrative plot in shown in figure A.2. In this figure only the differences of the calculated and the measured values are plotted. It can be seen, that all accuracies are much lower than the guaranteed of ± 0.4 l/min for the flow rate and ± 10 mmHg for the pressure head.

All those coefficient calculations are performed based on water glycerin solutions mixed to generate a dynamic viscosity of 3.5 mPa*s at a temperature of 37°C and a resulting density of 1.16 g/ml.

A2: Influence of viscosity on INCOR® flow behavior

Due to the changes of the hematocrit within the blood, the viscosity can vary either over time and/or between patients. Thus, it is important for this study to ensure that the influence of viscosity on the pump performance is low.

To investigate this influence, measurements of the characteristic flow field of an INCOR® pump was performed. Figure A.3 shows the outcomes of those measurements. The dynamic viscosity was set to 2 mPa*s as a worst case of low viscosity and to 6 mPa*s as the worst case for high viscosity, as well as to 3.5 mPa*s, for representing the normal viscosity expected in a VAD patient [5].

It can be seen from that figure that the influence of the viscosity is generally low, e.g. the 3.5 mPa*s and 2.0 mPa*s graphs are similar. For the high viscosity measurements, especially for high flows > 5 L/min, less pressure head for the same rotational speed and flow rate can be seen.

A characteristic effect can be from that figure: For low flow rates, the pressure head increases slightly when the viscosity is increased. This effect switches for high flow rates. This results into a »no dependency line« for medium flows.

Based on those investigations, the effect of the viscosity variance within the patients can be considered as low. Additionally it can be assumed, that the variance should get compensated because of the high number of patients.

Nonetheless, patients are motivated to keep their hematocrit value within inconspicuously ranges by nutrition and medication. Thus, extreme values such as 2 mPa*s or 6 mPa*s are not commonly expected for a VAD patient.

A3: Explicit values of the dynamic BCs

The raw data is needed to enable the possibility to use the dynamic BCs also within other investigations at other working groups. Table A.1 shows the values of the representative dynamic flow rate and the pressure difference in relation to the normalized heartbeat waveform.

Figures and tables

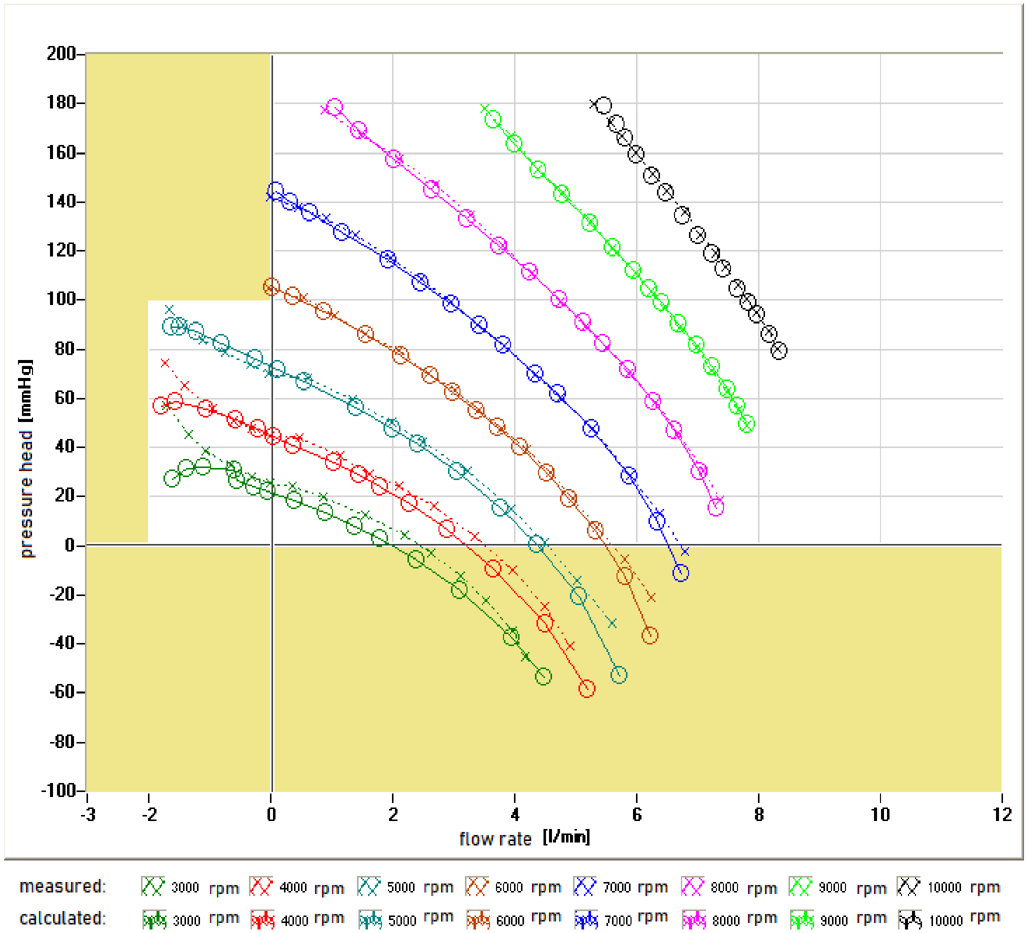

Figure A.1: Copy of the original comparison of the measured and calculated values within the coefficient calculating procedure of an INCOR® pump. It shows the pressure difference H (y-axis) and flow rate Q (x-axis) of the characteristic flow field and different rotational speed.

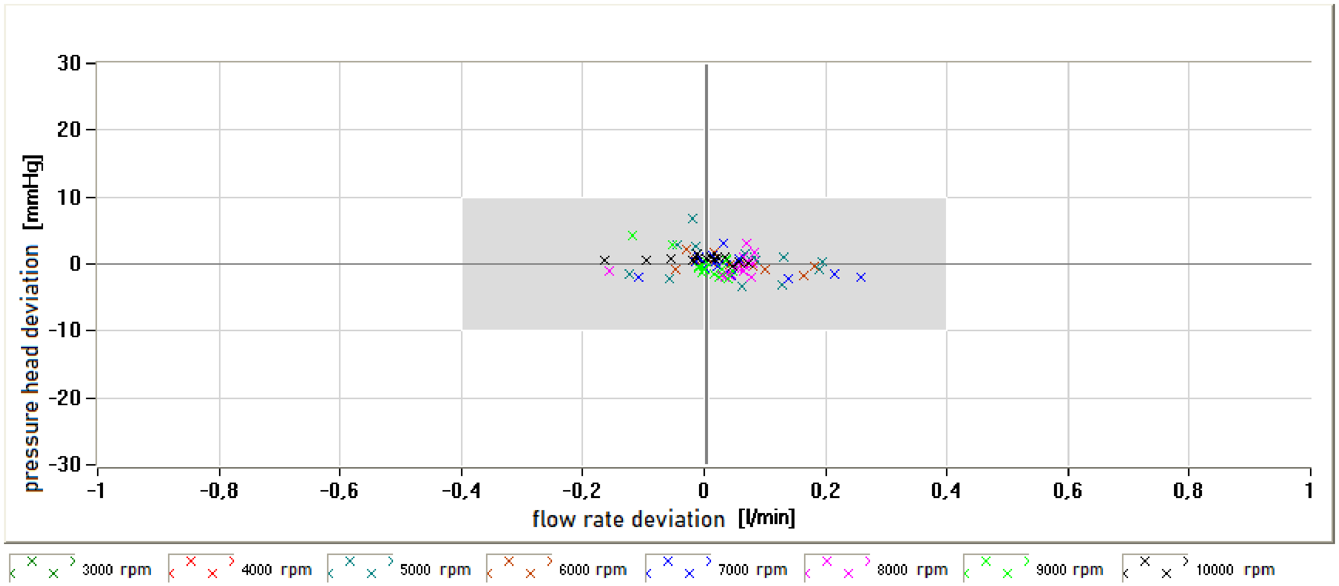

Figure A.2: Copy of the original analysis of the differences between the measured and calculated values within the coefficient calculating procedure of an INCOR® pump. It shows the differences in pressure difference H (y -axis) and flow rate Q (x -axis) and different rotational speeds.

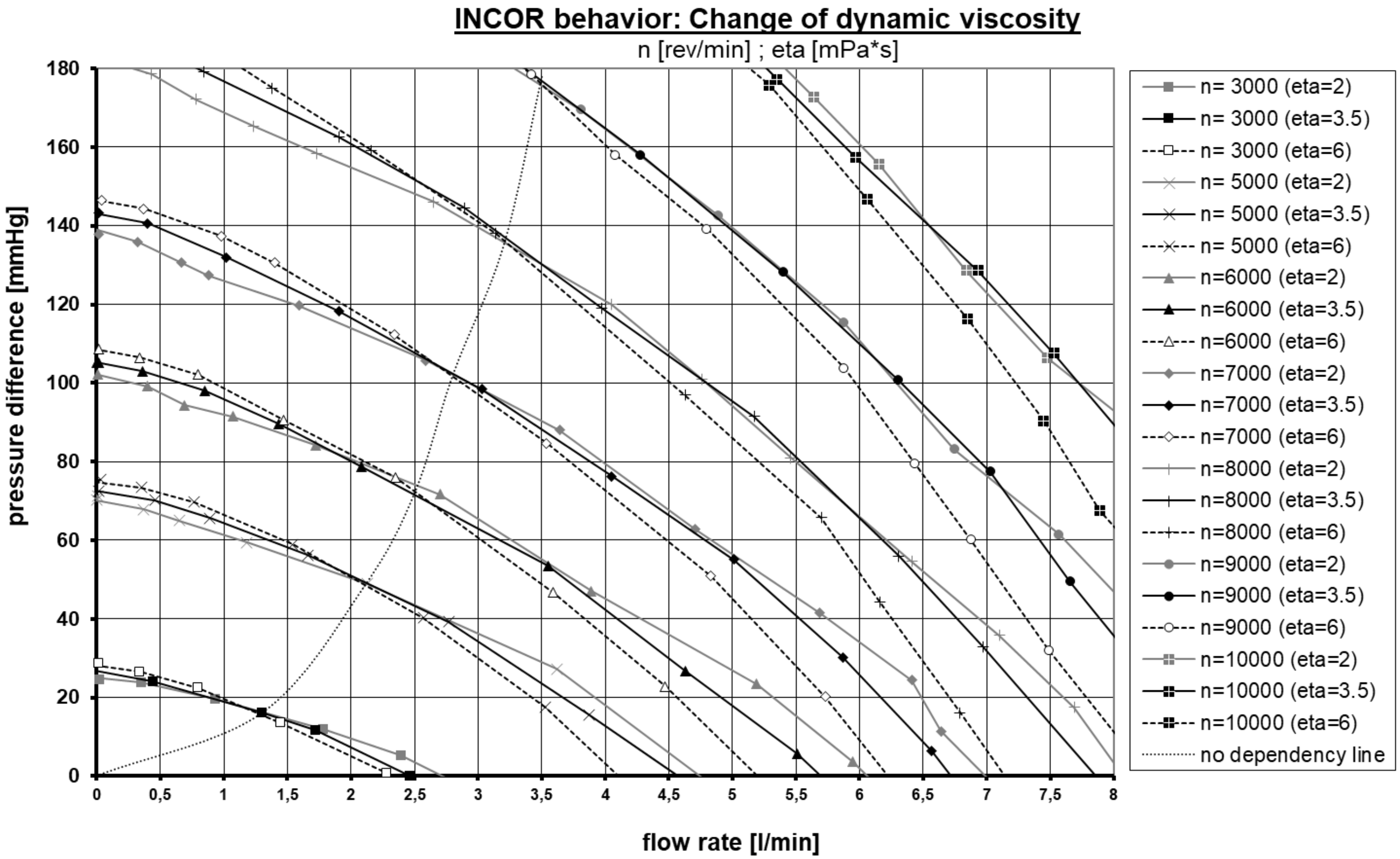

Figure A.3: Characteristic flow field of the INCOR® pump running in fluids of different dynamic viscosity. The rotational speed (n) varies from 3,000 rpm to 10,000 rpm and the dynamic viscosity (eta) varies from 2 mPa*s to 6 mPa*s. It can be seen, that for medium flow (for example near 3 l/min and 100 mmHg) there is a »no dependency line«, in which the viscosity has very little influence on the pumps characteristics.

time [normalized heartbeat]	pressure difference [mmHg]	flow rate [l/min]
0,00	59,76	4,429
0,02	55,42	4,615
0,04	51,20	4,762
0,06	46,93	4,916
0,08	43,48	5,048
0,10	40,98	5,136
0,12	38,87	5,206
0,14	37,83	5,228
0,16	37,38	5,250
0,18	37,05	5,262
0,20	37,77	5,242
0,22	39,21	5,185
0,24	41,62	5,093
0,26	44,78	4,976
0,28	48,73	4,819
0,30	52,90	4,672
0,32	56,86	4,501
0,34	60,44	4,362
0,36	64,45	4,191
0,38	67,43	4,064
0,40	70,37	3,929
0,42	73,02	3,811
0,44	74,62	3,735
0,46	75,36	3,701
0,48	76,10	3,667
0,50	76,49	3,649

time [normalized heartbeat]	pressure difference [mmHg]	flow rate [l/min]
0,52	76,59	3,627
0,54	76,63	3,623
0,56	76,50	3,634
0,58	76,45	3,651
0,60	76,16	3,657
0,62	75,67	3,679
0,64	75,19	3,695
0,66	75,14	3,697
0,68	75,13	3,695
0,70	74,62	3,705
0,72	74,06	3,714
0,74	73,88	3,749
0,76	73,74	3,754
0,78	73,39	3,765
0,80	73,56	3,749
0,82	73,76	3,738
0,84	73,77	3,744
0,86	72,98	3,797
0,88	72,75	3,808
0,90	72,01	3,839
0,92	70,37	3,916
0,94	68,49	4,022
0,96	65,72	4,164
0,98	62,31	4,310
1,00	59,76	4,429

Table A.1: Specific values of the representative dynamic flow rate and the pressure difference in relation to the normalized heartbeat.