In vitro performance of the fixed and adjustable gravity assisted unit with and without motion – evidence of motion induced flow

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Abstract:

Background: Anti-Siphon devices and gravitational assisted valves have been introduced to counteract the effects of overdrainage after implantation of a shunt system. The study examined the flow performance of two gravitational assisted valves (shunt assistant – SA and programmable shunt assistant – proSA, Miethke & Co. KG, Potsdam, Germany) in an in-vitro shunt laboratory with and without motion.

Methods: An in-vitro laboratory setup was used to model the cerebrospinal fluid (CSF) drainage conditions similar to a ventriculo-peritoneal shunt and to test the SA (resitance of +20cmH_2O in 90°) and proSA (adjustable resitance of 0 to +40cmH_2O). The differential pressure (DP) through the simulated shunt and tested valve was adjusted between 0 and 60cmH_2O by combinations of different inflow pressures (40, 30, 20, 10 and 0cmH_2O) and the hydrostatic negative outflow pressure (0, -20 and -40cmH_2O) in several differing device positions (0°, 30°, 60° and 90°). In addition, the two devices were tested under vertical motion with movement frequencies of 2, 3 and 4Hz.

Results: Both gravity assisted units effectively counteract the hydrostatic effect in relation to the chosen differential pressure. The setting the proSA resulted in flow reductions in the 90° position according to the chosen resistance of the device. Angulation related flow characteristics was similar in the two devices in 30°-90° position, however, in 0-30° position a higher flow is seen in the proSA. Movement significantly increased flow through both devices. While with the proSA a 2 Hz motion was not able to induce additional flow (0.006±0.05ml/min), 3 and 4 Hz motion significantly induced higher flow values (3Hz: +0.56±0.12ml/min, 4Hz: +0.54±0.04ml/min). The flow through the SA was not induced by vertical movements at a low DP of 10 cmH_2O at all frequencies, but at DPs of 30 cmH_2O and higher, all frequencies significantly induced higher flow values (2Hz: +0.36±0.14ml/min, 3Hz: +0.32±0.08ml/min, 4Hz: +0.28±0.09ml/min).

Conclusion: In a static setup, both tested valves effectively counteracted the siphon effect according to their adjusted or predefined resistance. Motion induced increased flow was demonstrated for both devices with different patterns of flow depending on applied DP and setting of the respective valve. The documened increased drainage should be considered when selecting appropriate valves and settings in very active patients.

Keywords: overdrainage, adjustable gravitational assisted valve, shunt assistant, cerebrospinal fluid, hydrocephalus, ventriculoperitoneal shunt

Introduction:

Overdrainage is a well-known complication in patients treated with CSF diversion via a shunt. Although overdrainage may remain clinical asymptomatic, it can be the source of several long term sequelae. Known clinical signs and symptoms are subdural effusions, slit ventricle syndrome, induced microcephaly and fused cranial sutures, increased thickness of the calvarial bone among others [4, 18, 19, 24]. Overdrainage through an implanted shunt is due to the siphoning effect in upright position [6]. The clinical observation of radiological overdrainage in predominantly active children indicates a possible influence of the amount of activity on the extent of drainage through an implanted shunt system.

Valves, which incorporate anti-hydrostatic units, have been reported to counteract overdrainage and can be classified into anti-siphon, gravitational and flow regulated devices [7]. The introduced, adjustable gravitational valve (proSA, Miethke Germany) allows to set the resistance of the valve according to individual conditions – such as body length, assumed intra-peritoneal pressure and documented ventricular width. The presented study examined the flow performance of the gravity assisted shunt assistant and the adjustable shunt assistant (SA vs. proSA, Miethke & Co KG, Potsdam, Germany) using an in-vitro shunt laboratory and the influence of motion on the valves' flow characteristics.

Material and Methods

Experimental set-up

Flow conditions similar to a ventriculo-peritoneal shunt were simulated by an in-vitro laboratory setup as previously described [7]. Briefly, the intracranial compartment was represented by an overflow reservoir filled with 37°C isotonic solution and provided constant pressure and inflow into the connecting tube, which represented the shunt system with the inserted valve. The intraperitoneal compartment consisted in a second downstream overflow reservoir distal to the shunt system and guaranteed constant outflow. The draining fluid was collected to measure the draining volume over time. Both reservoirs could be adjusted to height of 0 to +40cmH_2O for the inflow reservoir and of 0 to -40 cmH_2O for the outflow reservoir in relation to the valve, thereby an overall hydrostatic differential pressure between 0 to 80cmH_2O was generated. The tested valves were fixed on a flexible wheel allowing positioning of the valve in any angle between 0° (horizontal position) and 90° (vertical position). Two pressure transducers in front (P1) and behind (P2) the tested valves displayed the respective pressure (in mmHg) on a monitor (IntelliVue MP30, Philips, Hamburg, Germany). Both pressure transducers were connected via a titanium shunt connector (Miethke, Potsdam, Germany - internal diameter 0.9 mm) and an 8 cm segment of a pediatric feeding tube (inner diameter: 1.5 mm) to the tested valve. The used catheters to connect from the pressure transducers to the reservoirs were commercially available infusion lines - from inflow reservoir to valve (Fresenius Kabi, Bad Homburg, Germany - length 175 cm, internal diameter 3.0 x 4.1 mm) and a second different line from the valve to the outflow reservoir (B.Braun, Melsungen, Germany - length 150 cm, internal diameter 1.5 x 2.7 mm; figure 1).

The flow over time through the tested valve was recorded by weight change at the outflow reservoir in g/min with a balance and a stopwatch (LC4801P; Sartorius, Göttingen, Germany). The measured flow values were converted to ml/min under the assumption that 1g of used isotonic fluid (Sterofundin; B. Braun, Melsungen, Germany – at 37°C) equals 1ml and has roughly the same specific weight (1.006) as the cerebrospinal fluid (1.005-1.007). The duration of a single measurement was 1 minute for each DP and positional valve setting.

Tested Valves

The shunt assistant (SA, 20cmH_2O, Miethke, Germany) is a gravitational assisted valve. The flow through the device is open in the horizontal (0°) position, the valve's resistance of 20

cmH_2O in the vertical (90°) position is generated by the weight of a tantalum ball, which acts against the flow.

The adjustable shunt assistant (proSA, Miethke, Germany) is a gravitational assisted valve with variable resistance values in vertical position. The pressure of a sapphire ball against the inflow channel is regulated in the respective position by the tension of a tantalum pendulum. Due to gravity the tantalum pendulum adds resistance when the valve is brought towards the vertical position. An adjustable spring further regulates the effective pressure of the tantalum pendulum which allows settings of the valves' resitance between 0 and 40 cmH_2O in the vertical position (figure 2).

Measurement protocols

A baseline flow curve through the experimental setup was measured as control measures by replacing the to be tested valve by a piece of a pediatric feeding tube (4cm length, internal diameter 1.5 mm; Medicoplast, Düsseldorf, Germany) and by the application of differential pressures of 0-60 cm H_2O.

The first protocol under static condition was designed to compare flow characteristics of SA (20cmH2O) and proSA without movement. Two valves were tested in four angular positions (0°, 30°, 60°, 90°) under differential pressures of 10, 20, 30, 40, 50 and 60cmH_2O – generated by respective adjustment of the position of the inflow reservoir above and the outflow reservoir below the device. The resistance of proSA was set at 0, 10, 20, 30 and 40 cmH_2O and tested for these settings under all four angulations and DP variants.

The second protocol under motion was designed to characterize the two valves (SA, 20cmH_2O, and proSA set on 20cmH_2O) under constant vertical motion simulating shunt patients walking, jogging or running. A differential pressure (DP) of 10, 20, 30, 40, 50 and 60 cm H_2O was generated by the adjustment of the height of the inflow and outflow reservoir in relation to the valves' position. The two devices were fixed each in the vertical (90°) position on a mechanical construction (Fischertechnik GmbH, Waldachral, Germany) that oscillates in vertical direction with an amplitude of 3 cm. An electrical motor (Fischertechnik GmbH, Waldachral, Germany) controlled the frequency of oscillation. Both valves were tested with oscillation frequencies of 2Hz, 3Hz and 4Hz, respectively. To characterize the flow through the proSA under motion the proSA was tested in the vertical (90°) position by adjusting valves resistance to 0, 10, 20, 30, 40 cmH_2O and by applying a DP of 20 and 40 cmH_2O.

For each positional and pressure setup the flow data were repeatedly measured three times for 1 minute for each valve. Additionally, three differing devices of each valve were tested; thereby generating nine single data values for each setup.

Statistical analysis

Prism 6 software (GraphPad Software Inc., La Jolla, USA) was used to test for possible statistical differences. Differences in flow at a single DP levels were calculated using one-way ANOVA, followed by Tukey's multiple comparison test. A p-value less than 0.05 was considered statistically significant. All results are given as mean ± standard deviation.

Results:

The static protocol

The first measurement protocol was designed to characterize the flow of the SA and proSA without motion. The baseline flow through the experimental control setup was dependent on the applied DP and increased in a linear fashion from 1.1±0.03 ml/min at 4cmH_2O to 21.5±0.03ml/min at 60cmH_2O DP (figure 3). In a horizontal position (0°) the flow of the SA linearly increased from 2±0.0ml/min at 10cmH_2O to a flow of 16.4±0.2ml/min at 60cmH_2O DP, correspondingly the flow through the proSA linearly increased from 3.8±0.0ml/min to 19.6±0.4ml/min (figure 3). There was significantly less flow through the SA at a DP of 10 to 60 cmH_2O and proSA at a DP of 40 to 60 cmH_2O ($p<0.001$).

In the vertical position (90°) the flow through either SA and proSA (set at a resistance of 20 cmH_2O) was minimal when a DP of less than 20 cm$H_2$0 was applied. With increasing DP there was a linear increase of flow through both valves resulting in a peak flow of 9.8 ml/min at 60 cmH_2O DP with SA and a peak flow of 8.0 ml/min at 60 cmH_2O DP with proSA (figure 4). The flow through either valve was significantly less at either applied DP in the vertical position compared to the horizontal position ($p<0.0001$). Stepwise reduction of the angle of the valve from 90° (vertical position) to 0° (horizontal position) resulted in a non-linear increasing flow through either SA or proSA at the applied DPs of 10 to 40 cmH_2O with significantly different measures between both valves predominantly at positions approaching the horizontal position and at lower DPs as presented in table 1.

The motion protocol

The second measurement protocol was designed to characterize the flow of the SA (20 cmH_2O) and proSA (set on 20 cmH_2O resistance) when exposed to a vertically directed motion of 2Hz, 3Hz and 4Hz frequency with an amplitude of 3cm. The flow of the SA was unchanged at 10 cmH_2O DP for all tested frequencies, at 20 cmH2O for 2Hz and at 50 cmH2O for 4Hz, but was increased for all other DPs and frequencies ($p<0.01$). In detail, a significantly increased flow was measured in the SA at 20cmH_2O DP with 3 and 4Hz vertical oscillation (the difference in flow: +0.40±0.04, +0.58±0.06ml/min; $p<0.001$), at 30 cmH_2O DP with 2, 3 and 4 Hz (+0.24±0.05, +0.46±0.07, +0.42±0.06ml/min; $p<0.001$), at 40 cmH_2O DP with 2, 3 and 4 Hz (+0.88±0.09, +0.46±0.08, +0.29±0.06ml/min; $p<0.001$), at 50 cmH_2O DP with 2 Hz (+0.43±0.11ml/min; $p<0.001$) and 3 Hz (+0.19±0.07ml/min; $p<0.01$), at 60 cmH_2O DP with 2, 3 and 4 Hz (+0.58±0.09, +0.40±0.07, +0.32±0.09ml/min; $p<0.001$) (figure 5).

On contrary, flow through the proSA when set on 20cmH_2O was not altered with 2 Hz vertical oscillation for all tested DP levels, but significantly increased flow through the proSA at 10 cmH_2O DP with 4 Hz vertical oscillation (the difference in flow: +0.38±0.02ml/min; $p<0.001$) and at 20 cmH_2O DP with 3 Hz (+0.33±0.04ml/min; $p<0.01$) and 4 Hz (+0.47±0.07ml/min; $p<0.001$), while at 30-60 cmH_2O DP with 3 Hz (+0.54±0.07 to +0.9±0.15ml/min; $p<0.001$) and 4 Hz (+0.59±0.01 to +0.69±0.30ml/min; $p<0.001$) an even higher increase in flow was demonstrated (figure 6).

Furthermore, the influence of the motion effect on the flow through the proSA in dependence of the adjustment of the proSA was tested for a DP of 20cmH_20 and 40 cmH_2O. Interestingly, the set valve's resistance had in influence on its susceptibility to vertical motion. When a continuous DP of 20 cmH_2O was applied, a proSA adjusted to 30 or 40 cmH_2O resistance effectively blocked flow with no or 2 Hz vertical motion, while 3 and 4 Hz motion overcame the blockade and some flow was initiated. At proSA settings of 0 and 10cmH_20 and a DP of 20 as well as 40cmH_2O the application of motion had an inverse effect, resulting in decreased flow through the valve with increasing frequency of motion from 2 to 4Hz. (figure 7).

Discussion:

Overdrainage of an implanted CSF shunt system is a recognized adverse effect and might lead to numerous acute and long term complications. Acute complications might be subdural effusions or positional headaches while chronic overdrainage will lead to decreased size of the ventricular system, thereby, increased risk of ventricular catheter obstruction, and secondary changes as microcephaly, increased thickness of the cranial bone and enlarged pneumatized paranasal sinus [1, 5, 9, 12, 22]. Some of the symptoms form the slit-ventricle syndrome, which is characterized clinically by headaches, repeated ventricular catheter obstructions and radiologically by slit-like ventricles [13, 17, 19-21].

Recognition to the sequelae of chronic overdrainage has led to the development of technical devices to counteract the effect of overdrainage [8, 14, 23, 25], which derives from a hydrostatic effect in vertical position when the level of the CSF filled ventricles is higher than the receiving peritoneal cavity [15]. The magnitude of the hydrostatic effect is dependent on several factors like the height of the patient, the resistance within the shunt system and the characteristics of the hardware of the shunt, such as length and the diameter of the tube [3, 21].

Devices to counteract the hydrostatic effect can be classified according to their working mechanisms. The examined SA and proSA belong to the group of gravity regulated devices and have been used widly in clinical practice [10, 11, 23]. In order to test the flow characteristics of the two devices a setup simulating a shunt system with adjustable DP from 0 to 60 cmH_2O between an inflow and outflow compartment was utilized as previously described [7]. Both gravity regulated units effectively counteracted the siphon effect in the vertical position compaired with the control flow through the tube alone a demonstrated abolished flow through the device, if an DP less than the either predefined (SA) or adjusted (proSA) of $20cmH_2O$ resistance was applied. At DPs exceeding the resistance of the device a linear increase of the flow through both devices was demonstrated. In the horizontal position for both devices a linear increase of flow was seen with both devices – while the proSA demonstrated similar flow as the control setup at DPs from $10\text{-}30cmH_20$ and only reduced flow at higher DPs of 40 and $60cmH_2O$, the SA allowed at all examined DPs less flow. This effect was confirmed by changing the angles of the valve from horizontal to vertical, when it comes to angles approaching the horizontal position and in the horizontal position itself, the SA allowed significantly less flow through the device at similar applied DP of 10 to 40 cmH_2O. This is the first notable observation of this study and confirms previously published results of laboratory testing for the proSA [2]. In this evaluation study we tested three deffering devices of each valves and three times for each devices, as a result we could get little standard error of the mean (0.02 to 0.61 ml/min) we could get consistent results. the amount of devices semms to be enough. The differing behavior of the two valves can be explained by their differing designs and working mechanisms of the gravitational units. First the smaller design of the SA´s design incorporates a slightly higher resistance itself. Second in the SA the tantalum ball falls freely on the outlet with increasing gravity towards the upright position the resistance increases in nearly sinusoid fashion, while in the proSA the gravity of a tantalum pendulum is reduced by the spring adjusted to lower levels. When the proSA is set at 0cmH_2O the tantalum pendulum is not able to fall in vertical position, thus causing no additional resistance in flow. At settings between 10 and 30cmH_2O the spring´s tension reduces and enables the tantalum pendulum to fall, however, the lower the valve is set, the later the resistance can be established at angles towards 90°. This might explain lower flow through the SA compared to the proSA at the same setting of +20cmH_2O.

The influence of motion on the flow characteristics through both devices were tested as well. With both SA and proSA there was a significantly increased flow when a vertical oscillation of a small amplitude of 3 cm was applied; however, there were certain differences. A vertical oscillation of a 2 Hz frequency did not influence the flow through the proSA, but with higher frequency of 3 and 4 Hz a significantly increased flow through this device was demonstrated at all applied DP levels. This is a relevant finding since even at DP less than the chosen resistance of the valve, a vertical oscillation would overcome the gravity mechanism of the valve and allow flow. The SA blocked flow at a DP of 10cmH_2O and at 20cmH_2O, however with increasing DPs and frequency of oscillation a significant additional flow through the device was shown. This demonstrated induction of flow through both gravity regulated devices by vertical oscillation constitutes an important finding because of its clinical relevance. The frequency of walking was reported to be approximately 2 Hz; the frequency of normal jogging (slow running) range of 2.4 to 2.7Hz and running (for sprinting) range of 3.5 to 5Hz [16]. Therefore, the tested frequencies simulated natural movement patterns. However, with jogging and running or jumping the amplitude of vertical oscillation might be even larger than the tested 3cm amplitude, which would result in a greater potential energy of the elevated water column within the shunt tubes amplifying the effect of motion. But even the documented increase of flow rates of approximately 0.5 ml/min (equals 30ml/h) would allow a substantial additional amount of CSF drainage induced by episodes of activity. In children with VP shunts, who can display a very active behavior with running and jumping, the demonstrated effect would contribute to clinical overdrainage. The influence of the amount of activity to the clinical problem of overdrainage is currently not widely appreciated in the treatment of shunted patients and should therefore be considered when selecting the appropriate devices and settings.

Adding a device to the shunt in order to counteract the hydrostatic effect is a logical consequence to reduce overdrainage related complications. Both tested devices were reliably capable to exhibit this capacity in accordance to the set resistance of the valves. Comparing the devices, the proSA bears the advantage of being adjustable, therefore reducing the need for potential operative revisions in order to change the settings of the gravitational unit. However, with the application of vertical motion some important differences were demonstrated. Under movement, the SA abolished flow at DPs less than its predefined resistance, but with increasing DPs motion induced significant flow through the device. Contrary, a 2 Hz motion did not influence the flow through the proSA (set on 20 cm H_2O), but increasing the frequency of motion induced flow at all tested DPs from 10 to 60 cmH_2O – including DPs of 10 and 20 cmH_2O at which the valve should be closed. A further notable effect was the demonstrated dependence of the proSA under motion on the setting of the valve – where the flow through the valve decreased by motion at settings at 0 and 10cmH_20 and increased by motion at higher valve settings. The specific mechanical construction of the device explains this demonstrated effect. At lower settings the pressure of the tantalum pendulum on the sapphire ball into the inlet is firm. At higher settings the adjustable spring is loose and acceleration/deceleration of the valve might induce movements of the pendulum and brief opening of the inflow channel might occur. On the contrary, at lower settings the channel through the gravitational valve is open and oscillation might provokes movements of the sapphire ball against the inflow channel which might hinder continuous flow through the valve. In comparison, the anti-gravity mechanism of the SA depends on the weight of the tantalum ball alone, which seemed capable to counteract completely any effect of motion at DPs smaller than the valves predefined resistance.

The findings of the study are of clinical importance, when it comes to clinical situations of documented overdrainage. While both valve counteract the hydrostatic effect in a vertical position in accordance to their given resistance, both are differently influenced by motion. In an upright position both valves demonstrated an increased flow induced by motion at certain frequencies and settings. The SA seems to be less influenced, especially at DP acting on the valve which are lower than the set resistance, therefore this valve might be a good first choice of gravitational assisted valves. If, however, the chosen setting of the SA is not sufficient, it might be reasonable to add a proSA, instead of replacing it, in order to allow further stepwise increase of the total resistance in an upright position.

In our present study we had tested only the SA (20cmH_2O) but further resistance units might need to be taken into account considering the clinical situations.

Conclusion:

In a static setup, both tested valves effectively counteracted the hydrostatic effect according to their adjusted or predefined resistance. Motion induced increased flow was demonstrated for both devices with different patterns of flow depending on applied DP and adjustment of the respective valve. This increased drainage capacity should be kept in mind when selecting appropriate valves and settings in very active patients.

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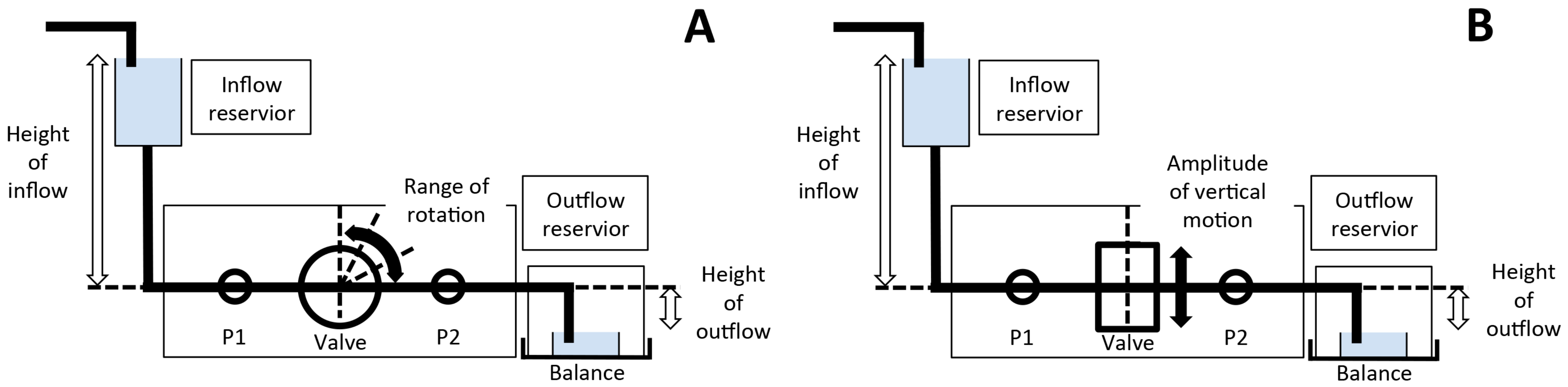
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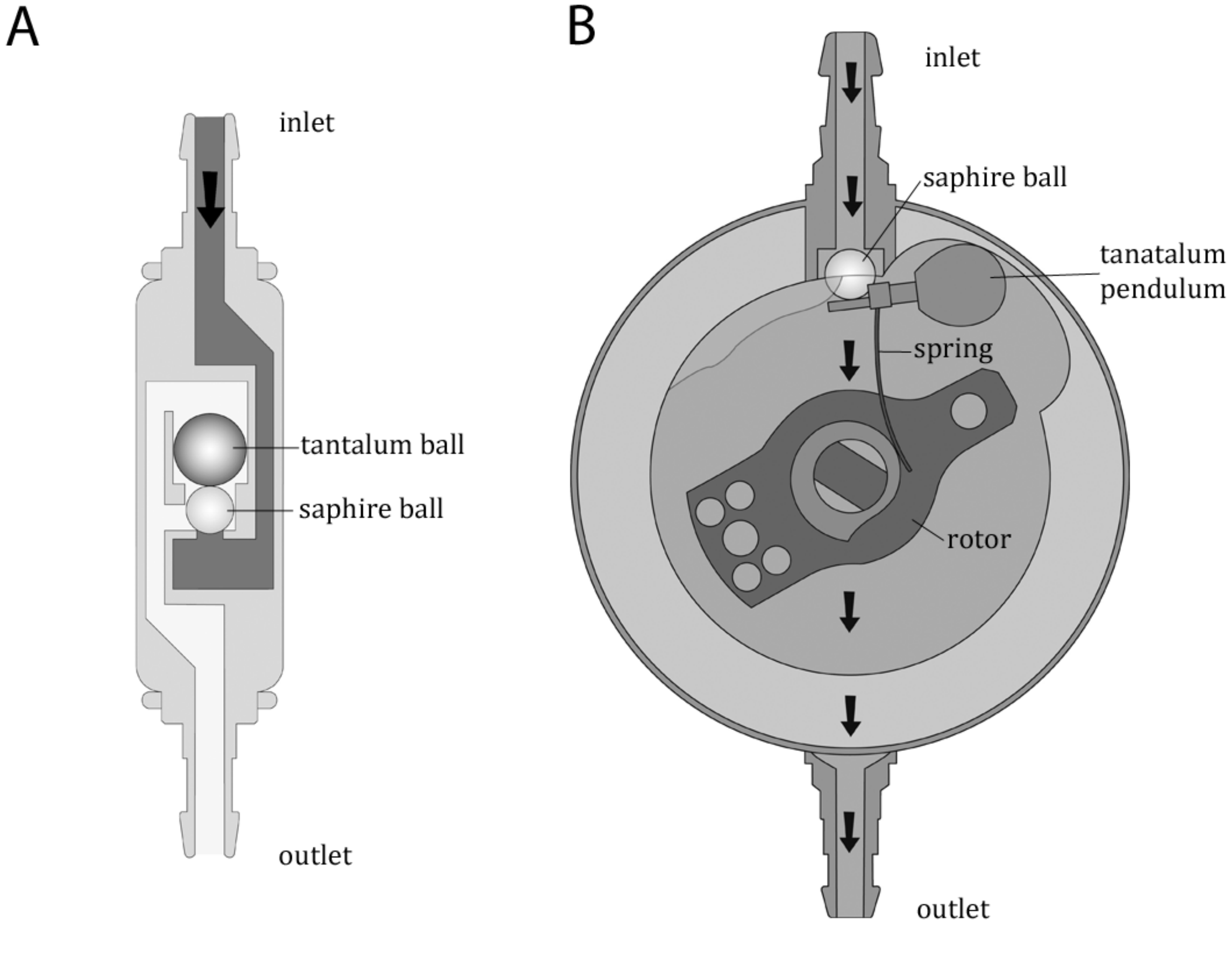
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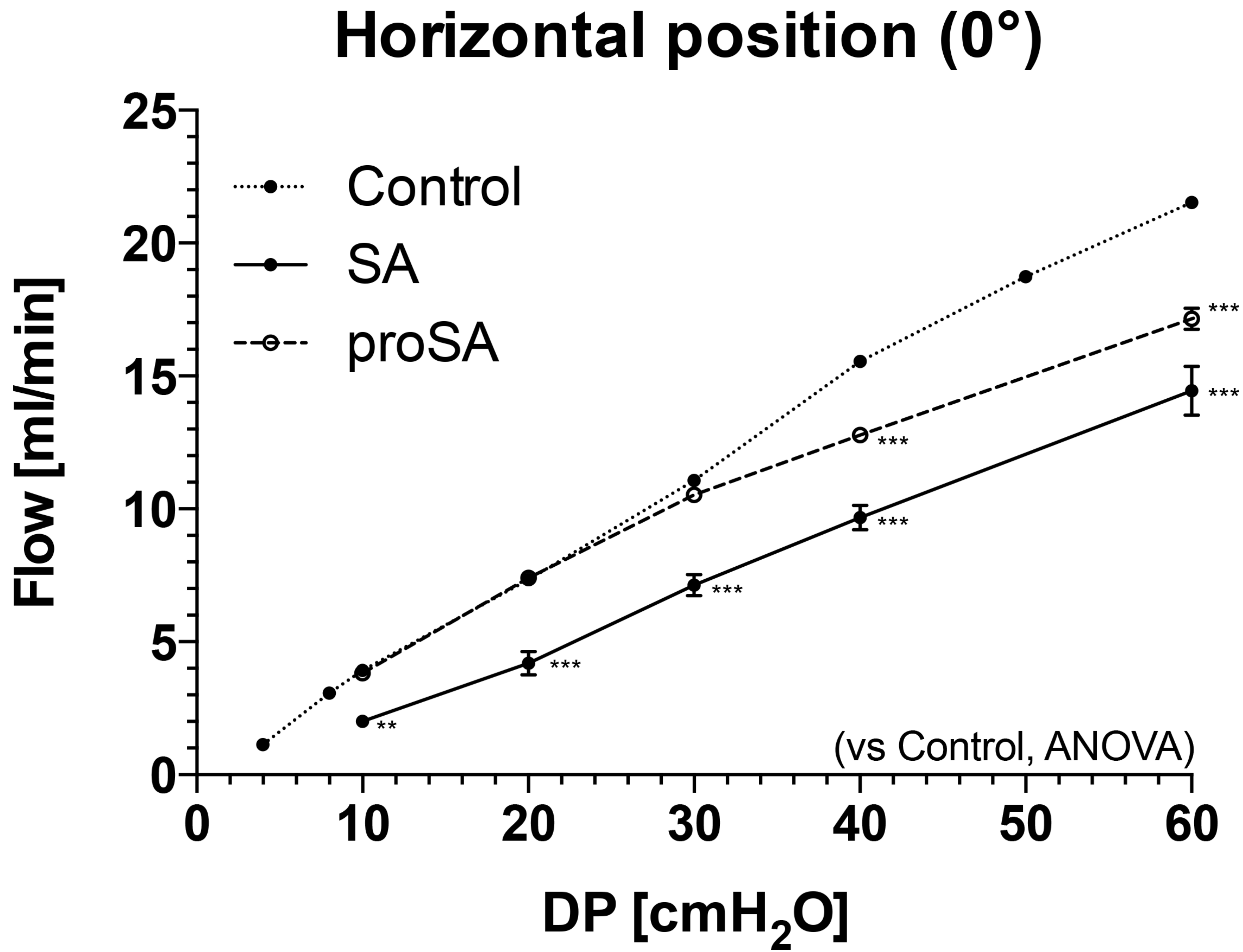
Horizontal position (0°)
Control
SA
proSA
Flow [ml/min]
0
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DP [cmH2O]
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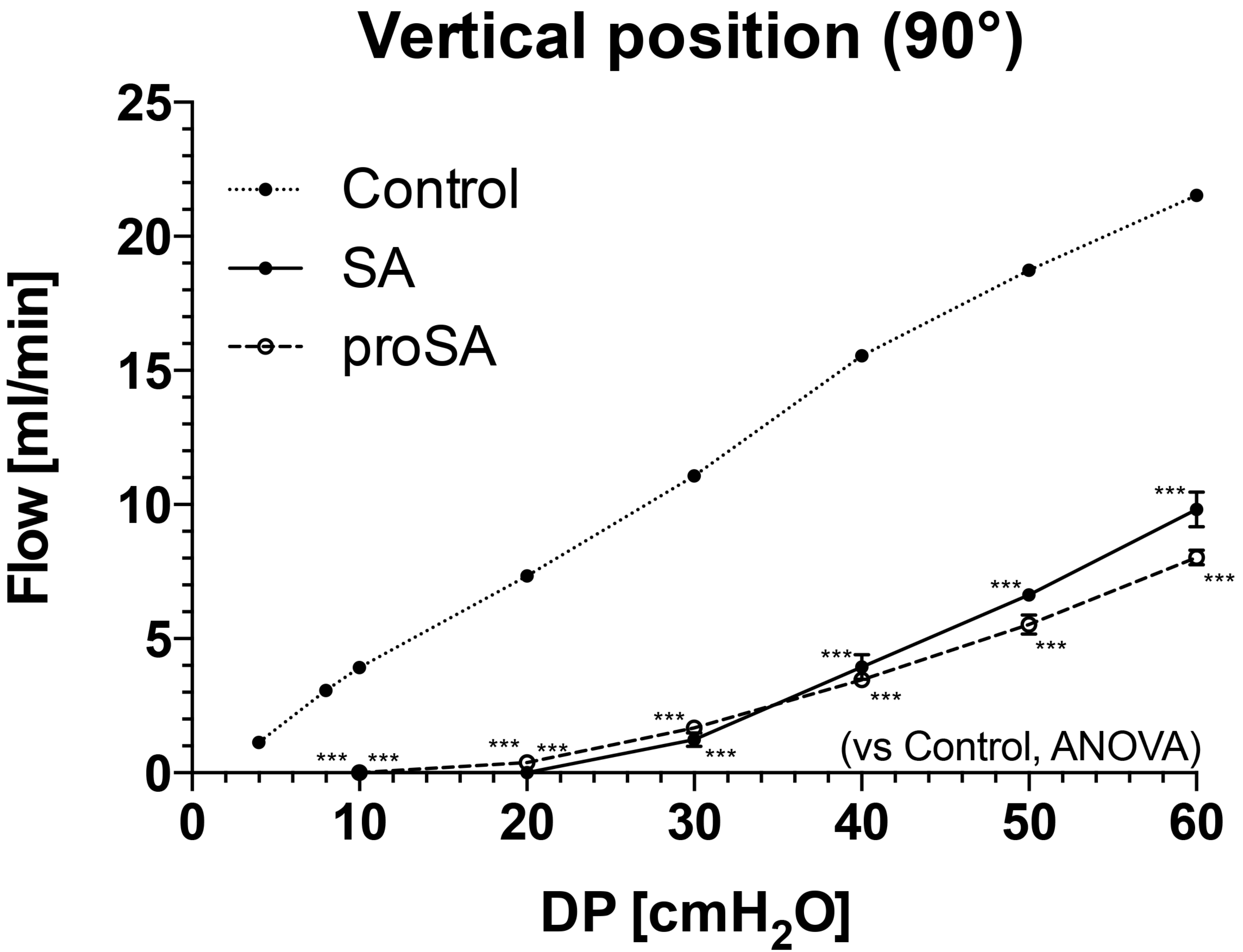
(vs Control, ANOVA)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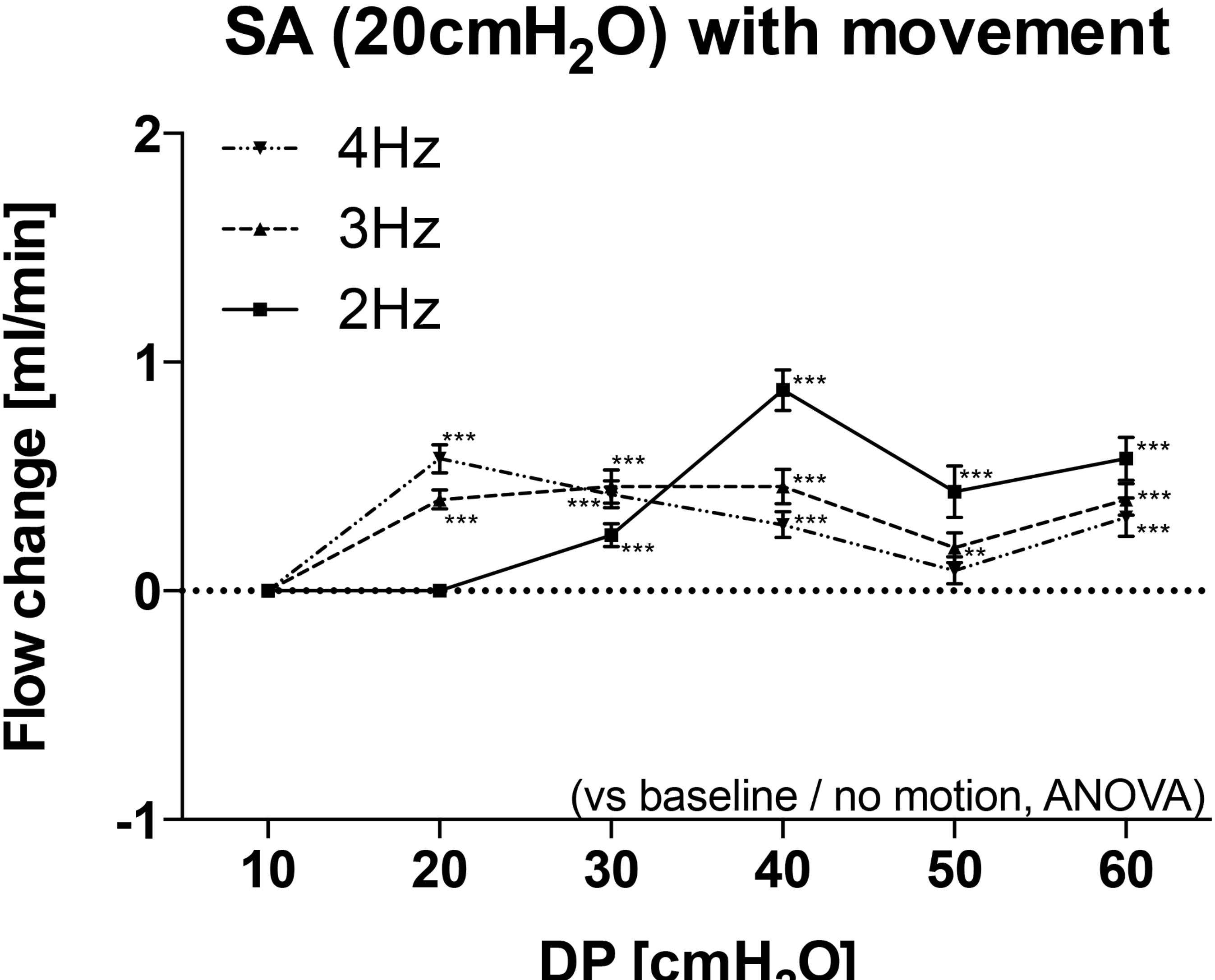
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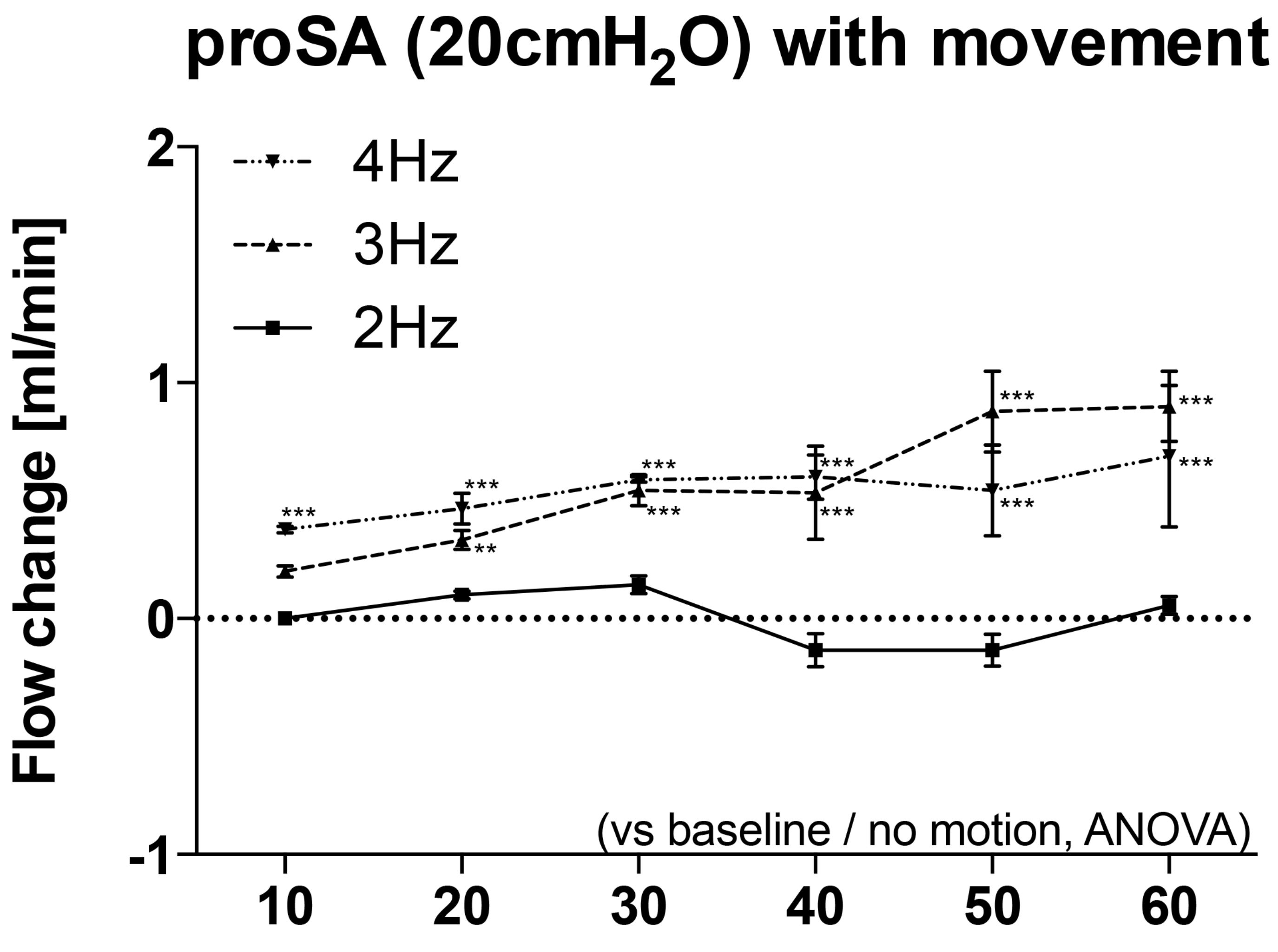

proSA (20cmH2O) with movement
4Hz
3Hz
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Flow change [ml/min]
2
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-1
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(vs baseline / no motion, ANOVA)
10
20
30
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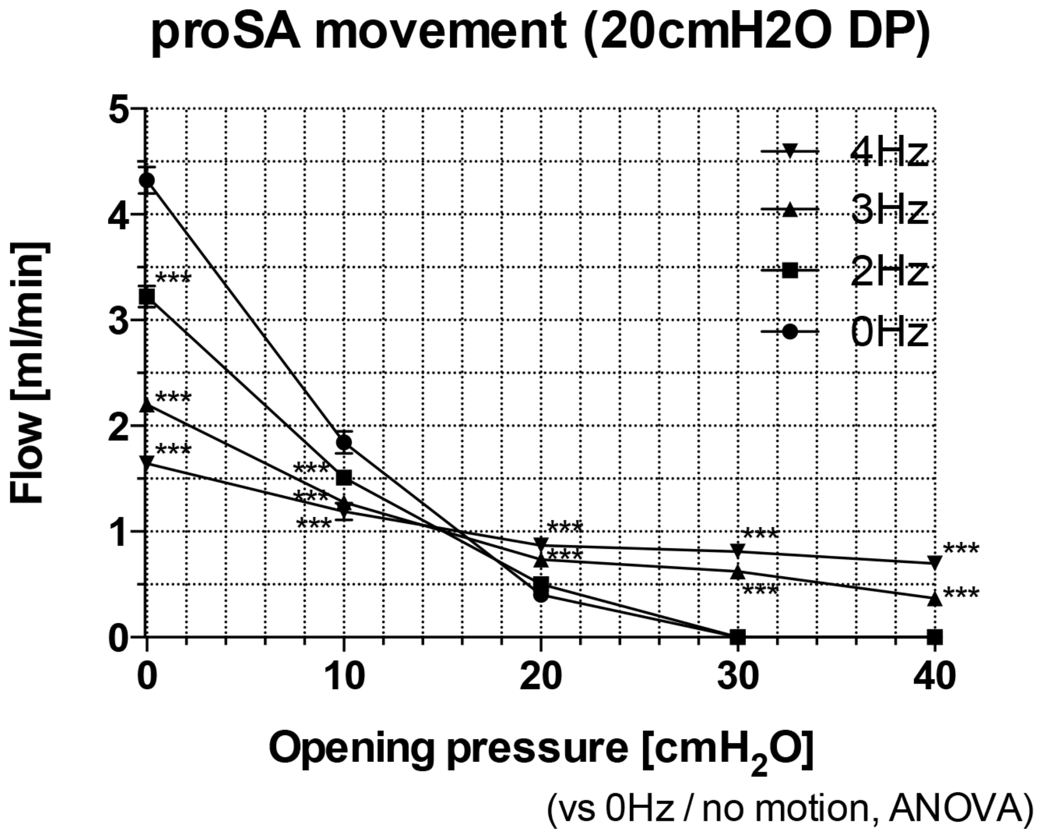
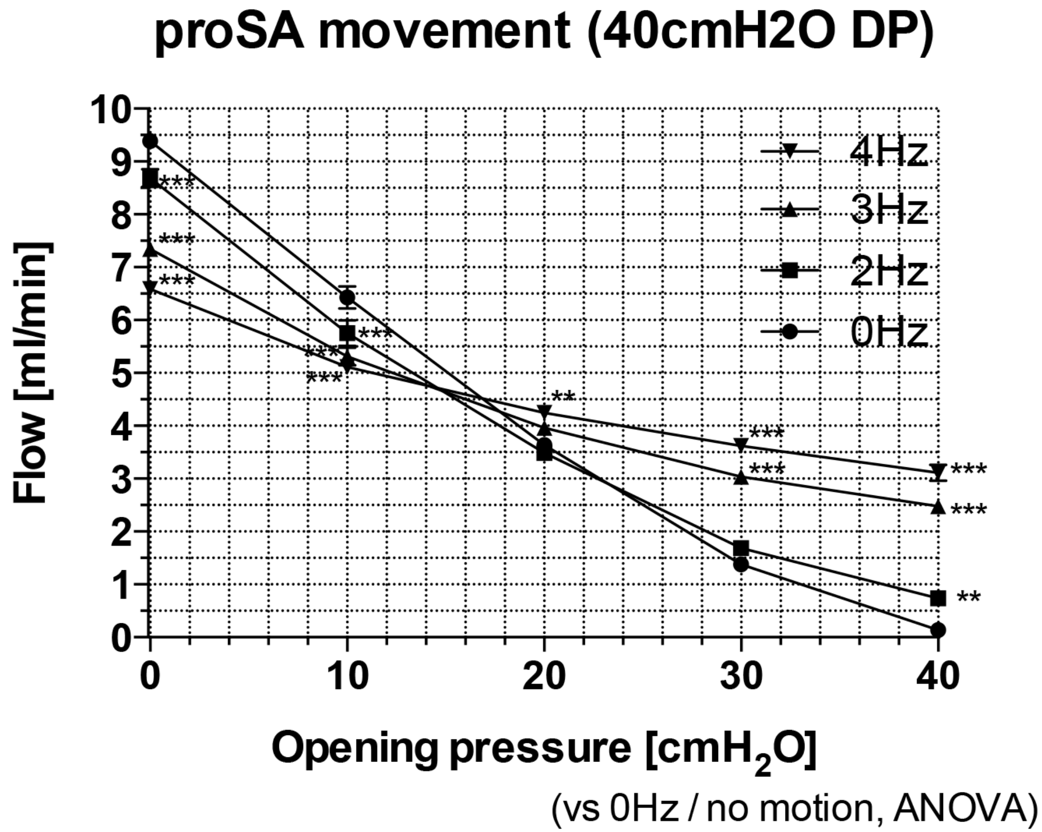
60
DP [cmH2O]


proSA movement (20cmH2O DP)
Flow [ml/min]
Opening pressure [cmH2O]
4Hz
3Hz
2Hz
0Hz
(vs 0Hz / no motion, ANOVA)


proSA movement (40cmH2O DP)
Flow [ml/min]
Opening pressure [cmH2O]
4Hz
3Hz
2Hz
0Hz
(vs 0Hz / no motion, ANOVA)

Legend

Figure 1

Schematic drawing of the experimental setup (A) and the experimental setup with motion effects (B). (P1 and P2 - pressure transducers)

Figure 2

A: The gravitational called Shunt Assistant (SA, Miethke, Germany) adds no resistance in horizontal position, while in the vertical position the weight of a tantalum ball overlaying the sapphire ball must be lifted by e.g. 20cmH_2O before flow sets in. **B**: In the adjustable shunt assistant (proSA, Miethke, Germany) variable resistance values can be generated by setting the rotor position, which acts on a spring tension counteracting the weight of a tantalum pendulum that, itself, occludes the inlet flow by a sapphire ball when brought in vertical position. Hence, if highest spring tension is generated, the tantalum ball adds no resistance on flow (0cmH_2O), while at lowest spring tension full resistance can be added in vertical position (40cmH_2O).

Figure 3

Pressure-flow curve of the SA and the proSA in horizontal position (DP=differential pressure, ** $p<0.01$, *** $p<0.001$)

Figure 4

Pressure-flow curve of the SA and the proSA in vertical position (DP=differential pressure, *** $p<0.001$)

Figure 5

Induced flow through the SA by vertical motion (** $p<0.01$, *** $p<0.001$)

Figure 6

Induced flow through the proSA by vertical motion (** $p<0.01$, *** $p<0.001$)

Figure 7

Characterization of the dependence of the flow by the motion at various settings of the proSA at DPs of 20 and 40 cmH_2O(** $p<0.01$, *** $p<0.001$)

Table1

Influence of Valve Angulation on Flow
(DP=differential pressure, * $p<0.05$, *** $p<0.001$, vs SA, ANOVA)

	DP [cmH_2O]	Valve type	positional angulation [°] 0	30	60	90
Flow (mean±SEM) [ml/min]	10	SA	2.0±0.02	0	0	0
		proSA	3.8±0.03***	0.7±0.08***	0.1±0.03	0
	20	SA	4.2±0.44	1.0±0.26	0.1±0.04	0
		proSA	7.4±0.08***	2.4±0.11***	0.8±0.06*	0.4±0.05
	30	SA	7.1±0.40	4.0±0.61	1.9±0.32	1.2±0.25
		proSA	10.5±0.12***	4.5±0.16	2.4±0.17	1.7±0.07
	40	SA	9.7±0.47	6.7±0.52	4.7±0.48	3.9±0.46
		proSA	13.2±0.16***	6.7±0.17	4.4±0.19	3.5±0.14