

# EVA NEXUS-Phaco performance study

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## Abstract

• **AIM:** To investigate a novel phacoemulsification system “EVA NEXUS” (D.O.R.C., Dutch Ophthalmic Research Center) in comparison to the existing system “EVA” in clinical use. And to compare both phacoemulsification systems in terms of efficiency, safety and postoperative inflammatory activity.

• **METHODS:** In this study standardized cataract surgery was performed on both eyes of the study participant, using the “EVA system” (control group,  $n=20$ ) on one eye and the “EVA NEXUS system” (intervention group,  $n=20$ ) on the other eye. Only patients with cataract LOCS Grading 1-3 and no accompanying eye diseases were included in this study. A total of 20 patients were included in this study, with each treatment arm including 20 eyes. During surgery a 0.1 mL aqueous humor sample was collected 1min after phacoemulsification to measure the total prostaglandin E2 concentrations using an enzyme-linked immunosorbent assay. The endothelial cell count, visual and refractive outcomes, and anterior chamber flare were evaluated preoperatively, and 1d, 1wk, and 3mo postoperatively.

• **RESULTS:** There were no statistically significant differences between both groups regarding intraoperative safety parameters including effective phacoemulsification time ( $P=0.904$ ), balanced saline solution flow ( $P=0.701$ ) and total surgery time ( $P=0.565$ ). Postoperative prostaglandin E2 levels, anterior chamber flare as well as endothelial cell loss tended to be lower in the NEXUS-Group, however not being statistically significant ( $P=0.718$ ; 0.164; 0.486). Both systems provided similar clinical outcomes, regarding best corrected visual acuity and refractive parameters, showing no statistically significant differences between both groups.

• **CONCLUSION:** Both systems show a high level of safety and efficiency with similar results in terms of safety parameters including postoperative inflammatory activity and endothelial cell loss as well as visual and refractive

outcomes. Although statistically not significant, the EVA NEXUS system tends to cause less postoperative inflammation with lower prostaglandin E2 levels and lower anterior chamber flare values.

• **KEYWORDS:** cataract surgery; phacoemulsification; fluidics; instrument

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## INTRODUCTION

The development of a cataract is the most common cause of treatable blindness. Regardless of the cause, the only option for treating cataracts is cataract surgery. Since the development of phacoemulsification (phaco) by Charles Kelman in 1967 it has become the preferred technique for cataract surgery worldwide<sup>[1-2]</sup>. In addition to the surgeon's individual technique and experience, the clinical outcome depends to a large extent on the settings of the phaco system<sup>[3-5]</sup>. Several factors can affect the success of surgery, leading to intraoperative and postoperative complications. One critical factor is the anterior chamber stability during phaco<sup>[6]</sup>. The fluidics of a phaco-system are one of the key factors to achieve good results, as they have a significant impact on the behavior of the anterior chamber during surgery and determine how the fragments of the lens move toward the phaco-tip<sup>[7]</sup>.

Modern phaco-machines use pumps to control fluidics mainly in one of the two ways: vacuum-based or flow-based<sup>[8-9]</sup>.

In order to create a vacuum, the pressure must be reduced below the atmospheric pressure. In ophthalmic devices the most common and low-cost method of creating the vacuum is a venturi pump, which operates on compressed air and reduces the pressure in the cartridge of an ophthalmic device. The speed at which the vacuum is created is mainly depended on the volume of the cartridge as a larger volume will result in slower vacuum response times.

Another method to create a vacuum is the displacement of fluid directly in the aspiration line. Displacing the fluid in the aspiration line creates a pressure difference between the infusion pressure and the aspiration line, whereupon this pressure difference creates an aspiration flow. Because this

**Table 1 Key technical specifications of EVA NEXUS compared to the EVA System**

Feature	EVA	EVA NEXUS	Note
<b>Fluidics</b>			
Active IOP control	AIC and posterior	Smart IOP	The new fluidics module allows Smart-IOP and a more responsive AIC control for both phaco and vitrectomy
Dual infusion lines	No, only manual control	Yes, automatic control	EVA NEXUS offers two separate infusion lines automatically controlled when changing procedure steps
Dual aspiration pump	Yes	Yes	Proven dual pump technology with vacuum and flow control
Proportional Backflush	No	Yes	Both systems can apply proportional reflux to the aspirating instrument
BSS level detection	No	Yes	EVA NEXUS will inform the user when the BSS level gets low and stops aspirations when the level reaches 10 mL
<b>Phaco</b>			
Phaco ultrasound	Longitudinal	Longitudinal	Comparison has shown that the DORC 27G TDC Veloce offers an 20% increase to DORCs current cutter
Phaco frequency	40 kHz	40 kHz	Increased aspiration flow rate and increased stiffness

AIC: Aspiration flow rate; BSS: Balanced saline solution flow; IOP: Intraocular pressure.

method uses the displacement of a fluid volume, the flow can be controlled by alternating the speed at which this volume is displaced. In ophthalmic devices the most common method is the roller or peristaltic pump. The faster the fluid is displaced the faster the vacuum is created<sup>[10-11]</sup>.

With EVA NEXUS the company D.O.R.C. developed an advanced fluidics system called VacuFlow VTi Technology (Valve Timing intelligence). The VacuFlow fluidics system is an aspiration system which can work in two modes; the vacuum and the flow mode, hence the name VacuFlow. As mentioned before traditional ophthalmic devices have either a peristaltic pump, a venturi pump or both, each of these having their own flaws. A peristaltic pump causes unwanted intraocular pressure (IOP) pulsations while the venturi pump generates different flow rates at different viscosities and can be slow in the vacuum rise time.

The EVA NEXUS cartridge contains two fluid displacement chambers which can be compressed or expanded with the pistons of the VacuFlow Fluidics System. The combination of the piston and chamber can be seen as a syringe with plunger, pulling the plunger of a syringe will cause a liquid to fill the syringe. Pushing on the plunger will empty the syringe. Like the syringe expanding the chamber of the cartridge will create an aspiration flow into the chamber and compressing the chamber will result in emptying the chamber.

VTi is the acronym for Valve Timing intelligence and ensures the correct movement and timing of the valves and pistons in relation to the demanded aspiration flow and the measured pressure by the contactless sensors.

Each of the pistons and valves are driven by a direct drive motor. A direct drive motor is characterized by its accuracy, speed, force and silence. With the accuracy of these motors the VacuFlow Fluidics system is capable of controlling the flow with a precision of 0.1 mL/min. In the vacuum mode high flow rates are required in order to generate a fast vacuum rise time.

Due to the speed and force of the motors hundreds of mL/min can be generated resulting in an extremely fast vacuum rise time.

The VacuFlow system gives the surgeon the possibility to work with both modes-a flow mode without unwanted pressure pulsations and a vacuum mode with controllable vacuum response time. In combination with revised software and phaco handpieces, D.O.R.C. has introduced with EVA NEXUS its new generation of phaco devices.

The purpose of this study was to examine the EVA NEXUS system by the company D.O.R.C. with regard for its safety and efficiency in everyday clinical practice and to compare it with the previous model EVA. Table 1, provided by the same company, gives an overview of the most important features of the two models “EVA” and “EVA NEXUS”.

**SUBJECTS AND METHODS**

**Ethical Approval** This prospective, single center Investigator Initiated Trial (IIT) study was approved by the institutional review board on the University Hospital of the LMU Munich (approval number 21-0995). All patients signed informed consent before the surgery.

A total of 20 patients were randomly assigned to have standard phacoemulsification using the EVA System (control group, n=20) on one eye and the EVA NEXUS system (intervention group, n=20) on the other eye. All surgeries were performed by the same experienced surgeon (Mayer W) between October 2022 and July 2023. Only patient with cataract LOCS Grading 1-3 and no accompanying eye diseases were included in this study.

The surgical technique was equal in all cases. After a 2.2 mm clear cornea incision, a first aqueous humor ophthalmic viscoelastic device was delivered inside the anterior chamber. Continuous curvilinear capsulorrhexis was made with a bent cannula followed by hydrodissection and hydrodelineation with balanced saline solution (BSS). A chopping technique was used in all cases followed by phaco. One minute after phaco an

0.1 mL aqueous humour sample was collected for subsequent prostaglandin E2 (PGE2) level analysis. Phaco power was set to 60% and maximum vacuum level was set at 600 mm Hg. Intraoperative measurements at the end of the surgery included effective phaco time (EPT), BSS flow and total surgery time.

To analyze PGE2 levels an enzyme-linked immunosorbent assay (ELISA) was used in accordance to the manufacturer's protocol (PGE2 high sensitivity ELISA kit, Enzo Life Sciences GmbH, Lörrach, Germany). In brief, 50 µL aqueous humour were incubated for 24h at 4°C. After three washes, 200 µL of the substrate solution was added to each well and incubated at 37°C for 1h. For readout, the optical density was measured at a wavelength of 405 nm and a reference at 690 nm using the SpectraMax 190 ELISA reader (Molecular Devices, San Jose, CA, USA).

Clinical measurements included postoperative autorefraction including distance corrected best visual acuity (AR-1S, NIDEK Co. Ltd., Gamagori, Japan), endothelial cell count (EM-3000, Tomey GmbH, Nurnberg, Germany), and anterior chamber flare (Kowa FM-600 Laser-Flare-Meter, Kowa Europe GmbH, Duesseldorf, Germany) at the following study visits: preoperatively, one day, one week and three months postoperatively.

**Statistical Analysis** All data were gathered on an Excel (Microsoft Corporation, Redmond, WA, USA) spreadsheet and statistical data analysis was performed using SPSS software for Windows (version 27.0, IBM Corp.). The normality of data samples was evaluated with Kolmogorov-Smirnov and Shapiro-Wilk tests. When parametric analysis was possible, the Student *t*-test for paired data was used for comparisons. When parametric analysis was not possible, the Wilcoxon rank-sum test was applied to assess the significance of such differences.

**RESULTS**

Intraoperative evaluated parameters including EPT ( $P=0.904$ ), BSS flow ( $P=0.701$ ) and total surgery time ( $P=0.565$ ) showed no statistically significant differences between both groups (Table 2).

The analysis of the PGE2 level in the aqueous humour sample which was collected 1min after phaco in both groups showed a tendency to be lower in the NEXUS group with a mean value of 24.60 pg/mL compared to the EVA group with a mean value of 47.24 pg/mL. However, with a *P* value of 0.718, this was statistically not significant (Table 2).

Other clinical safety parameters including objective measurement of the anterior chamber flare (Figure 1) using a Laser-Flare-Meter ( $P=0.164$ ) and endothelial cell count, respectively the endothelial cell loss (Figure 2) with a loss of 170 cells/mm<sup>2</sup> in the NEXUS group compared with 210 cells/mm<sup>2</sup> in the EVA group ( $P=0.486$ ), likewise showed no statistically significant differences between both groups (Table 3).

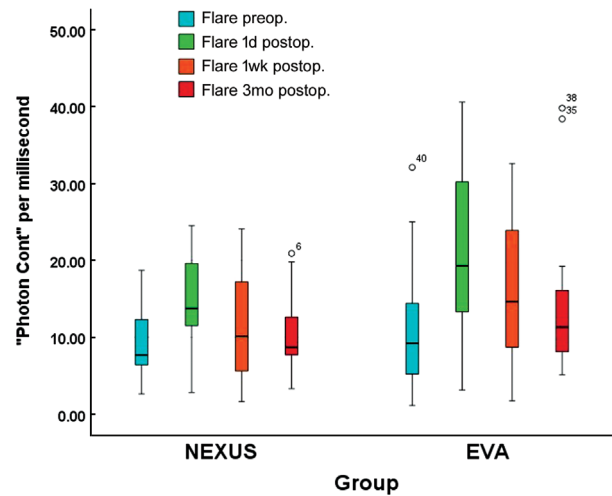


Figure 1 Comparison of anterior chamber flare between both groups.

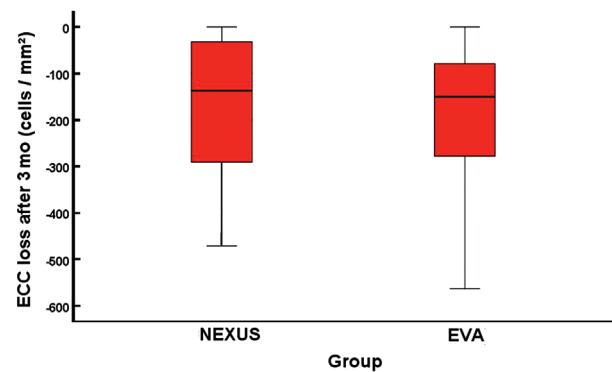


Figure 2 Comparison of endothelial cell loss 3mo postoperatively between both groups ECC: Endothelial cell count.

Table 2 Comparison of intraoperative parameters between both groups

Parameter	NEXUS group (n=20)	EVA group (n=20)	mean±SD	<i>P</i>
EPT (s)	1.33±0.84	1.26±0.72		0.904
BSS (mL)	65.53±12.66	63.00±13.71		0.701
Surgery time (min)	11.63±2.43	13.05±4.35		0.565
PG A.C. (pg/mL)	24.60±28.06	47.24±47.48		0.718

EPT: Effective phaco time; BSS: Balanced saline solution flow; PG A.C.: Prostaglandin level measured in the anterior chamber.

Table 4 represents further clinical parameters including visual and refractive outcomes showing comparable results in both groups with no statistically significant differences.

**DISCUSSION**

Maintaining a stable anterior chamber depth during phaco is crucial to minimize complications such as damage to the cornea, iris or posterior capsule that are related to a shallow anterior chamber. An important approach during phaco is to control the IOP so it stays close to the physiologic range, as maintaining a too high pressure during surgery can lead to increased postoperative corneal edema, decreased ocular perfusion, accelerated glaucomatous optic nerve damage and stress on weakened zonules<sup>[12-15]</sup>.

**Table 3 Comparison of clinical safety parameters between both groups** mean±SD

Parameter	NEXUS group (n=20)			EVA group (n=20)			P <sup>a</sup>
	Preoperative	1wk	3mo	Preoperative	1wk	3mo	
A.C. flare (photoncount/ms)	7.94±4.63	9.69±6.19	11.04±5.74	9.76±8.12	15.69±9.42	15.78±10.31	0.164 <sup>a</sup>
ECC (cells/mm <sup>2</sup> )	2491±304	2337±425	2325±386	2467±341	2262±410	2251±427	0.681 <sup>a</sup>
ECC loss (cells/mm <sup>2</sup> )		-156±172	-170±146		-166±172	-210±165	0.486 <sup>a</sup>

A.C. flare: Anterior chamber flare; ECC: Endothelial cell count; <sup>a</sup>P values were determined for the preoperative data compared to the 3mo postoperative data.

**Table 4 Visual and refractive outcome between both groups** mean±SD

Parameter	NEXUS group (n=20)			EVA group (n=20)			P <sup>a</sup>
	Preoperative	1wk	3mo	Preoperative	1wk	3mo	
CDVA (decimal)	0.47±0.16	0.77±0.15	0.85±0.0	0.48±0.17	0.79±0.16	0.88±0.15	0.726 <sup>a</sup>
SE (D)	-2.55±5.08	-0.63±0.88	-0.30±1.06	-2.94±5.77	-0.51±0.82	-0.47±1.13	0.566 <sup>a</sup>
Cyl (D)	-1.49±1.52	-0.99±0.61	-0.85±0.50	-1.44±0.95	-0.80±0.64	-0.96±0.68	0.746 <sup>a</sup>

CDVA: Corrected distance visual acuity; SE: Spherical equivalent; Cyl: Cylinder. <sup>a</sup>P values were determined for the preoperative data compared to the 3mo postoperative data.

To maintain a stable anterior chamber pressure during phaco, the inflow of BSS through the irrigation line must match the outflow of fluid from the aspiration line plus the possible leakage from the corneal incisions<sup>[16-17]</sup>.

In the beginnings the irrigation line inflow was mainly controllable using gravity-based infusion by raising or lowering the irrigation bottle. As technology advanced active fluidics complemented the way to control pressure changes, as motor-controlled plates squeeze an irrigation bag to compensate for flow-rate and pressure changes that are monitored by in-line sensors. It has been shown that active fluidics outperform gravity-based infusion systems, to maintain more stable target IOPs<sup>[18-20]</sup>.

With “EVA NEXUS” D.O.R.C. introduced a new fluidics system called VacuFlow VTi that enables a feature called SmartIOP™ using a phaco-tip that constantly measures the anterior chamber pressure. In this case only the base pressure is programed by the user and the phaco machine automatically compensates for the expected pressure loss in the instruments enabling a constant IOP during surgery and a more stable anterior chamber, even during post-occlusion breaks.

This study is the first clinical study to evaluate the newly developed EVA NEXUS surgical platform in clinical practice for cataract surgery compared to the previous surgical platform called EVA. The focus was set on clinical parameters, including inflammatory parameters.

A recent study has shown that a stable anterior chamber minimizes the risk of surgery-induced inflammation<sup>[21-22]</sup> which correlates with a higher risk of postoperative cystoid macular edema<sup>[23]</sup> and corneal edema<sup>[24]</sup>.

As the breakdown of the blood-aqueous barrier, whose clinical features are flare and cells in the anterior chamber we wanted to investigate if there are differences in the amount of flare and

inflammatory mediators, such as PGE2, between both groups. It is assumed that maintaining a stable intraoperative anterior chamber decreases the disturbance of the iris, thus reducing the damage to the blood aqueous barrier<sup>[25]</sup>. Although there seems to be a tendency to receive lower flare and PGE2 levels in the NEXUS group, we could not find a statistically significant difference. Compared to other studies who observed flare and prostaglandin levels after phaco<sup>[26-27]</sup>, our results reflect overall low measurements in both groups.

To further investigate the possible effect of anterior chamber instability on intraocular tissues such as the cornea, our study compared the postoperative endothelial cell loss in both groups, as phaco inevitably results in loss of endothelial cells, which are not renewable after damage<sup>[22,27]</sup>. Several studies have reported that intraoperative fluctuation of anterior chamber depths can lead to increased corneal endothelial cell loss<sup>[28-29]</sup>. We observed a postoperative reduction of endothelial cells in both groups, again with a tendency of causing less cell loss in the NEXUS group, however not statistically significant. During all surgeries there occurred no complications and intraoperative parameters including EPT, BSS flow and total surgery time demonstrated comparable results between both groups with overall low phaco energy needed.

These outcomes must be seen in the context of an experienced cataract surgeon who performed all surgeries.

In our study, no direct parameters regarding anterior chamber stability such as intraoperative IOP, anterior chamber collapse or surge were determined. This and the small sample size are important limitations of our study. We included only standard cataract cases in our study to make the results more comparable. The system could potentially be advantageous in more difficult cases or in the hands of less experienced surgeons. Regarding the study, however, this would lead to



less comparable results. Further studies with a larger study population as well as the comparison with other manufacturers and their current technology would be needed to find out possible advantages.

In conclusion, our data shows that both the EVA and the EVA NEXUS surgical platform for cataract surgery are equally safe and efficient when used by an experienced surgeon. However, we believe that especially in more difficult cases, such as mature cataracts, patients with a shallow anterior chamber, zonular weakness or other abnormalities the EVA NEXUS can show off its advantages. As it is usually more difficult in these cases to maintain an anterior chamber stability, EVA NEXUS might have the potential to further lower the risk for complications like corneal edema due to endothelial cell damage or capsular rupture. We see a further advantage in the use of EVA NEXUS in the hands of inexperienced surgeons who are less experienced to adjust the surgical parameters to the situation or different cases and could benefit from the possibilities that the platform provides with SmartIOP™ and VacuFlow.

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