

Effect of Modified Peristaltic Phacoemulsification Device on Efficiency and Post-Occlusion Pressure Surge

Reiker G Ricks ^{1,2}, Ivan A Cardenas ^{1,2}, Emilie L Ungricht ^{1,2}, Randall J Olson ¹, Jeff H Pettey ¹

¹Department of Ophthalmology and Visual Sciences, John A. Moran Eye Center, University of Utah, Salt Lake City, UT, USA; ²University of Utah School of Medicine, Salt Lake City, UT, USA

Correspondence: Jeff H Pettey, John A. Moran Eye Center, University of Utah, 65 Mario Capecchi Drive, Salt Lake City, UT, 84132, USA, Tel +1 801-581-2352, Fax +1 801-581-3357, Email jeff.pettey@hsc.utah.edu

Purpose: To evaluate efficiency of grooving, nuclear fragment removal, and changes in pressure control in the Oertli Faros using traditional peristaltic and Speed and Precision (SPEEP) features. The SPEEP mode uses novel peristaltic technology permitting independent control of flow and vacuum.

Methods: A porcine lens model was used with an enclosed chamber simulating the anterior segment. Grooving efficiency is evaluated with flow rates of 10, 30, and 50 mL/min using whole lenses. Lens cubes were emulsified at 20, 40, 60, 80, and 100% power with both SPEEP and non-SPEEP modes. Surge was evaluated with pressure gauges placed on the irrigation tubing and aspiration tubing. Pressure readings were recorded per the following: fluid and vacuum were initiated for 15 seconds, vacuum tubing was occluded for 5 seconds, tubing patency was then re-introduced for 15 seconds. Differences between sensors were recorded.

Results: No significant increase in efficiency was seen with increasing flow rate from 30 to 50 mL/min using SPEEP. No significant differences were shown in lens fragment removal in SPEEP and non-SPEEP modes at any power tested. Pressure difference measurements were not significantly different with SPEEP and non-SPEEP modes.

Conclusion: We showed that lower flow rates show comparable efficiency of grooving when using the SPEEP mode. The SPEEP function did not show increased efficiency in nuclear fragment removal when compared to traditional mode. Surge control was also comparable with both SPEEP and non-SPEEP modes. We suggest that the SPEEP function included in the Oertli Faros may have some advantages.

Keywords: cataract, grooving, pump, nuclear fragment removal, power, machine setting optimization

Plain Language Summary

We looked at a new device that is used for taking out cataracts. For a long time, cataract removal devices have used a peristaltic setting, which uses rollers that squeeze the tubing, causing fluid and lens tissue to be pulled from the eye. The new kind of setting, called Speed and Precision (SPEEP), functions similarly but allows for more control of fluid movement when operating. Using pig lenses, we examined how well the device can remove cataracts and whether peristaltic or SPEEP is better. We also studied if surge, which is a possible complication of cataract surgery, is better prevented by using the SPEEP setting rather than the peristaltic setting. To do this we placed pressure sensors on the tubing and measured how much of a difference we saw when the tubing was blocked and then after removing the blockage. We did not find any differences when comparing the two settings. This means that SPEEP may be better than peristaltic in some ways. However, our results show that advantages in efficiency and surge prevention with SPEEP are not likely.

Introduction

Phacoemulsification (phaco) has been used as the predominant method of choice in high-income countries for lens removal in cataract surgery.¹ New technology is constantly being developed to optimize the use of phaco in a number of surgical scenarios, to provide greater efficiency, and produce better patient outcomes. An area of focus for many companies is

developing new strategies for aspiration by modifying current aspiration pump technology. Traditionally phaco systems are separated into two categories, namely venturi pump systems and peristaltic systems.^{2,3} Novel modifications of pump functionality seek to incorporate the advantages of both pump modalities to provide surgeons with more options for a variety of surgical scenarios.⁴

One such modification developed by Oertli (Oertli Instrumente AG, Berneck, Switzerland) uses a novel Speed and Precision (SPEEP) peristaltic pump which allows the surgeon control of both aspiration flow rate and vacuum pressure during surgery with the foot pedal.³ Conventional peristaltic systems are generally controlled with a foot pedal that can be depressed to 3 different positions. Position 1 is irrigation which is determined by the bottle height and this is active as long as the foot pedal is in position 1. The second position is aspiration. Settings for aspiration are set to a specific rate and a linear increase in flow rate is created with increased depression of the foot pedal. In position 2, vacuum is also introduced which is a set maximum pressure that is achieved under occlusion of the phaco tip. Conventional peristaltic systems do not allow for control of vacuum pressure while under occlusion, rather a maximum pressure is achieved under occlusion. In the SPEEP pump, the vacuum pressure can be manipulated with the position of the foot pedal which causes fine forward and backward movements of the pump. This allows the surgeon to adjust vacuum to a desired pressure while under occlusion. Purported advantages would include increased control of vacuum in a peristaltic system translating to increased efficiency while preserving anterior chamber stability. While previous studies have evaluated the efficiency of traditional peristaltic platforms,^{5–8} much is unknown with regard to Oertli's SPEEP pump. This study seeks to evaluate the performance of Oertli's SPEEP pump in grooving and nuclear fragment removal efficiency, and post-occlusion surge, using a porcine lens model and the Oertli Faros device. We examine the effect of increasing aspiration flow rates on grooving efficiency while the device is set in SPEEP mode. We also evaluate the effect of increasing power on efficiency in both SPEEP and non-SPEEP peristalsis. Finally, we evaluate the effects of using the SPEEP pump on post-occlusion surge magnitude.

Materials and Methods

Since this study did not involve human subjects, we did not request Ethics Committee approval.

Lens Preparation

A total of 70 whole pig eyes purchased from Visiontech, Inc. were transported to the John A. Moran Eye Center, Salt Lake City, Utah, USA. Porcine lenses were extracted from the gross specimens within 48 hours of arrival and soaked in 10% pH neutral formalin for two hours at room temperature. The lenses were rinsed three times with a balanced salt solution (BSS) and then immersed completely in BSS for storage at room temperature for 24 hours.⁹ Lenses were used within 24 hours of formalin fixation. Care was taken during the extractions to preserve both the cortex and nuclei of the lenses to ensure uniform lens hardening. Crushing studies have shown that lenses prepared by this method are comparable to grade 3–4+ human cataractous lenses.^{9,10}

Surgical Procedures: Grooving Efficiency with Increasing Flow Rates

Sixty porcine lenses were selected at random following the lens hardening process. Each lens was placed individually in a groover device developed at the Moran Eye Center. The groover is composed of a cylinder with a concave surface which holds the lens in a fixed position. A convex plastic cover is placed over the lens which has a small, sealed opening for insertion of the surgical handpiece. The groover device holds the lens in a fixed position with minimal movement (Figure 1).

Grooving procedures were performed using the Oertli Faros with the easyPhaco handpiece.¹¹ The handpiece was fitted with the Oertli easyTip, 2.8 mm with 30 degree bevel (VV806840) for all experiments. The parameters for lens grooving efficiency evaluation were set at longitudinal power 80%, vacuum 400 mmHg, gravity forced infusion (GFI) 67 mmHg, and aspiration flow rates of 10, 30, and 50 mL/min. The power, vacuum, and GFI were selected from commonly used settings for the grooving step of phacoemulsification. Aspiration flow rates were set as a low, medium, and high rate to clearly differentiate between the outcomes at each setting. Phaco settings were linear longitudinal ultrasound (US). Trials were performed, and the device was placed in SPEEP mode. To mitigate bias, whole lenses were selected at random and placed in the groover device, with lenses having ruptured capsules being excluded. There were 60 total pig lenses used for the lens grooving portion of the study. Twenty lenses were randomly chosen for 10 mL/min, 20 were

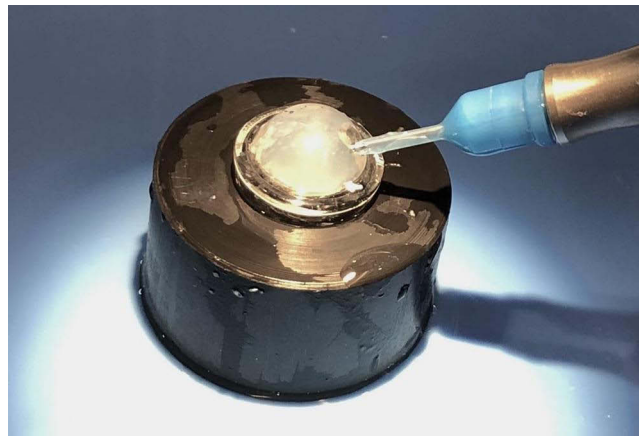


Figure 1 Porcine lens placed in a groover device designed to simulate the anterior segment. Whole lens specimens or lens cubes are placed in the groover for experimental procedures.

randomly chosen for 30 mL/min, and 20 were randomly chosen for 50 mL/min. Twenty trials were completed at each of the three flow rates, and the other surgical parameters were conserved with each trial. The same researcher performed all trials to ensure the same surgical technique was performed for each trial. This researcher who grooved all the lenses was blind to both the flow rate and elapsed time. A second researcher randomly assigned flow rates and timed the grooving using a stopwatch. This second researcher instructed on when to begin the procedure and counted down three seconds prior to the stop time, at which point the trial ended. Grooving time was measured from the beginning of phaco to the complete division of the lens.

Surgical Procedures: Efficiency with Increasing Power and SPEEP vs Peristaltic Pump

To evaluate if differences exist in efficiency of nuclear fragment removal in SPEEP and non-SPEEP peristalsis, we examined the effect of increasing power. Both SPEEP and non-SPEEP procedures were performed using the Oertli Faros with the easyPhaco handpiece (Oertli). The Oertli easyTip, 2.8 mm with 30 degree bevel was also used.

Surgical parameters for comparison of SPEEP and traditional modes were set at 450mmHg vacuum, 67 GFI, and 45mL/min flow rate. Power levels of 20, 40, 60, 80, and 100% were used for both SPEEP and non-SPEEP peristalsis. Ten formalin fixed porcine lenses were placed in a cubinator device developed at the Moran Eye Center and anatomized into 2.0 mm cubes.¹² The cubes were then placed into BSS and stored at room temperature. Randomly chosen 2.0 mm porcine lens cubes were placed in the simulated anterior chamber groover device as previously mentioned and individual lens cubes were emulsified and aspirated. Twenty lens cubes were used for each power setting for both SPEEP and non-SPEEP phaco settings; and surgery was performed by the first experimenter, who was blind to SPEEP vs non-SPEEP, power levels, and elapsed time. The pump type and power were randomly assigned by a second experimenter who also timed the procedure using a stopwatch. The efficiency was measured from the start of phaco to complete lens cube removal.

Surgical Procedures: Post-Occlusion Surge

Each procedure was performed using the Oertli Faros with the easyPhaco handpiece. The Oertli easyTip, 2.8 mm with 30 degree bevel was used for all experiments. Two Dwyer digital pressure gauges were placed in series, one on the irrigation tubing and the other on the aspiration tubing and set to record (Figure 2). The tip of the Oertli Faros with SPEEP handpiece was inserted into a closed chamber, with the machine settings at 80% longitudinal, intraocular pressure (IOP) 50 mmHg, and 40 mL/minute flow. Pressure readings were recorded for the following: fluid and vacuum were initiated for 15 seconds, then the vacuum tubing was occluded for 5 seconds, with the vacuum tubing patency re-introduced for 15 seconds. This occurred 20 times each with and without the SPEEP setting. The pressure prior to occlusion, during

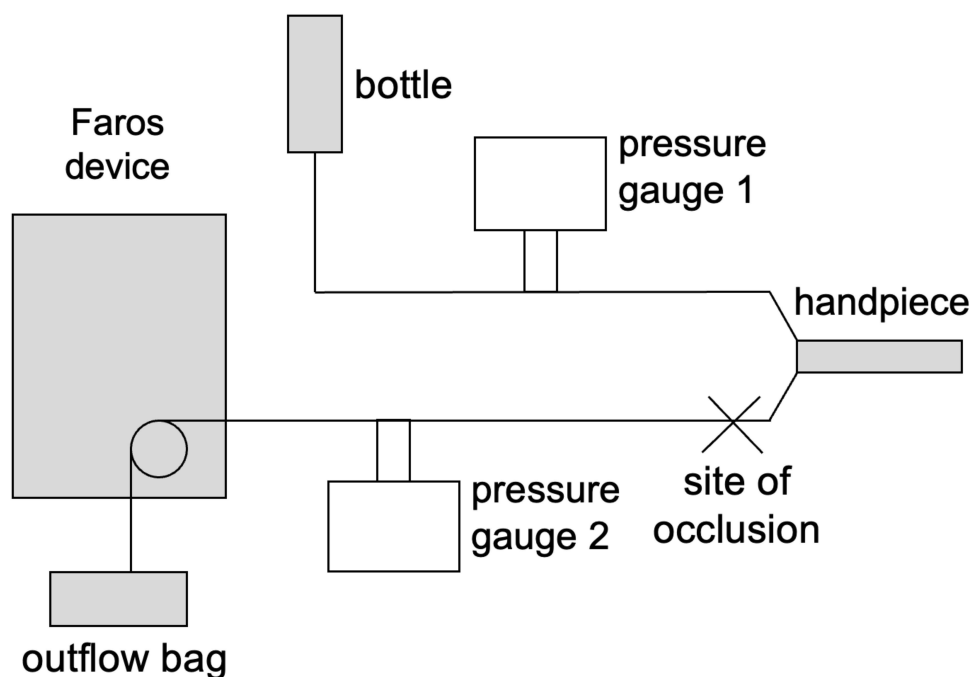


Figure 2 Simulated occluded surgical scenario. Two pressure gauges were placed in series with pressure gauge 1 on the irrigation tubing and pressure gauge 2 on the aspiration tubing. The outflow tubing was manually occluded after pressure gauge 2, and the difference between the two gauges was used to determine anterior chamber pressure.

occlusion, and post occlusion was measured. The difference between the pressure gauges was recorded and evaluated to determine the pressure within the anterior chamber.

Statistical Analysis

Replicate trials were averaged with standard deviations of the means, which were calculated using Microsoft Excel. This was done for each experimental procedure for flow rate, power, and pressure difference. Results were compared using a one-way analysis of variance (ANOVA).

Results

With increasing flow rate from 10 to 30 mL/min, we observed a slight inverse effect on grooving efficiency. Change in efficiency from 30 to 50 mL/min was minimal. The average grooving time for 10 mL/min was 26.53 ± 4.94 seconds; for 30 mL/min it was 29.05 ± 5.24 seconds; and for 50 mL/min it was 28.84 ± 5.91 seconds. Differences in average grooving times were not statistically significant between groups (Figure 3).

Simulated nuclear fragment removal with 2 mm porcine lens cubes showed a trend of increasing efficiency from 20 to 80%. At 100%, a decrease in efficiency was noted when compared to 80%. Differences were not statistically significant with SPEEP on or off at any power level (Table 1).

When evaluating post-occlusion surge, the average pressure in the anterior chamber prior to occlusion was 27.6 ± 1.43 and 27.6 ± 1.0 mm Hg with and without SPEEP, respectively, with no statistical difference between the two. The average pressure in the anterior chamber during occlusion was 4.6 ± 2.3 and 2.9 ± 1.37 mm Hg with and without SPEEP, respectively, with no statistical significance. The average pressure after occlusion in the anterior chamber was -24 ± 7.26 and -28.3 ± 5.03 mm Hg for SPEEP and without SPEEP, respectively, with no statistical significance (Figure 4).

Discussion

Previous studies have demonstrated that pump type influences post-occlusive surge, with peristaltic pumps having less surge than Venturi pumps.¹³ The SPEEP pump has possible advantages during surgery due to decoupled control of the

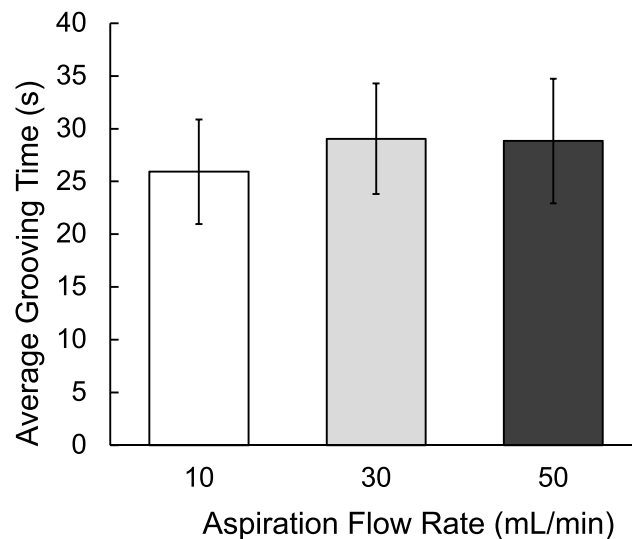


Figure 3 Average grooving times with increasing aspiration flow rate using SPEEP pump. Replicate trials (n=20) of grooving whole porcine lenses were averaged, and the average grooving time in seconds was compared across increasing flow rates. A one-way ANOVA showed no significant difference between the means.

vacuum level from the aspiration rate in a peristaltic system.⁵ The ability to modulate vacuum, or what is commonly referred to as holding power, can affect varying steps during phaco.^{14–17}

For the grooving step, we observed a non-statistically significant trend of decreasing efficiency as the flow rate was increased from 10 to 30 mL/min, with minimal increase beyond 30 mL/min. We suggest that a range of flow rates provides similar efficiency during grooving with or without the SPEEP feature on. It should also be considered that grooving has often been shown to be completed without occlusion.¹⁰ Since the SPEEP setting differences may manifest under times of occlusion where vacuum can be controlled, the SPEEP mode may have no advantage when compared to non-SPEEP mode during the grooving step of cataract surgery. However, we have shown that a possible advantage of the SPEEP mode is that surgeons do not have to sacrifice efficiency by operating at lower flow rates which may result in increased anterior chamber stability.^{8,10,16,17} These findings are also advantageous to surgeons using the SPEEP technology as studies in other devices have shown decreased aspiration during grooving reduces the chances of post-occlusion surge.^{6,8,10,16,17}

Efficiency in phaco procedures is of significant clinical importance. Previous studies have illustrated damage to structures within the anterior chamber from bouncing lens fragments and thermal energy.^{18–20} For this reason, it follows that phaco device features that increase efficiency while maintaining the safety and stability of the eye are eagerly sought after. The performance of Oertli's SPEEP mode did not reveal a significant difference in nuclear fragment removal efficiency when compared to the traditional peristaltic pump feature in the Faros platform. The differences between the SPEEP and non-SPEEP modes are likely limited to control of vacuum under times of occlusion; this may be helpful to a skillful surgeon in removing hard lens fragments

Table 1 Average Phacoemulsification Times for SPEEP and Non-SPEEP Peristalsis at Increasing Power Levels

Power (%)	Phacoemulsification Times (s)		P value
	SPEEP	Non-SPEEP	
20	6.43 ± 1.75	6.45 ± 1.07	0.16
40	4.51 ± 1.48	4.55 ± 1.26	0.64
60	3.94 ± 1.12	4.52 ± 0.96	0.65
80	3.88 ± 0.92	3.87 ± 1.04	0.74
100	4.3 ± 0.89	3.91 ± 1.11	0.53

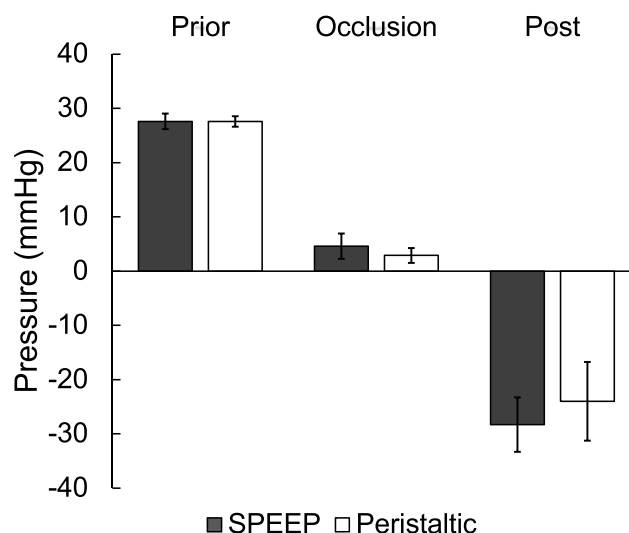


Figure 4 Pressure in simulated anterior chamber before, during, and after occlusion of the tip with and without SPEEP. Pressure was measured in both SPEEP and non-SPEEP peristalsis ($n = 20$) using Dwyer digital pressure sensors. Replicate results were averaged and standard deviation is represented by error bars. A one-way ANOVA showed no significant difference between SPEEP and non-SPEEP prior to, during, and post-occlusion.

where chatter is occurring or in other special circumstances.⁷ However, looking at classical parameters, we did not document a difference in lens fragment removal efficiency.

In terms of post-occlusion surge, our study did not reveal a statistically significant difference in pressures measured when using the SPEEP or traditional peristaltic modes. Although the SPEEP function allows surgeons to control the vacuum with the foot pedal under periods of occlusion, when maximum vacuum is achieved we show that sudden break in occlusion causes similar pressure changes whether the surgeon is using SPEEP or traditional peristalsis.

Acquired *in vitro* data presents certain limitations. In our study, our limitations included the use of a porcine lens model rather than human lenses for grooving and efficiency studies. Additionally, porcine lenses were hardened to the density of a 3–4+ grade, which limits the scope of surgical scenarios where these data apply. We did implement measures to mitigate bias, including blinding researchers to power levels, aspiration flow rates, and SPEEP and traditional phaco modes, as well as randomization of porcine lens nuclei and nuclear fragments.

Conclusion

The SPEEP function included in the Oertli Faros has possible advantages during the grooving step of cataract surgery including having similar efficiency at lower flow rates when compared to higher flow rates. However, our work does not show a difference between the SPEEP and non-SPEEP modes with regard to nuclear fragment removal or post-occlusion surge mitigation. Future studies *in vivo* may reveal differences under specific surgical situations with varying cataract grades.

Abbreviations

ANOVA, analysis of variance; BSS, balanced salt solution; GFI, gravity forced infusion; IOP, intraocular pressure; Oertli, Oertli Instrumente AG; phaco, phacoemulsification; SPEEP, Speed and Precision.

Acknowledgments

Susan Schulman assisted with editing and manuscript preparation.

Funding

This study was supported in part by an unrestricted grant from Research to Prevent Blindness, Inc., New York, New York, USA, to the Department of Ophthalmology and Visual Sciences, University of Utah, Salt Lake City, Utah, USA. The sponsor had no involvement in any of the stages from study design to submission of the manuscript for publication.

Disclosure

Dr. Olson is on the Board of Directors and equity owner of Perceive Bio and TMClear; Scientific Advisory Board and equity owner of Perfect Lens. Dr. Jeff Pettey reports a consulting agreement for Lensar and Zeiss, outside the submitted work. The authors report no other conflicts of interest in this work.

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