

Measurement of Phacoemulsification Vacuum Pressure in the Oertli CataRhex3

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Purpose: To determine the actual vacuum pressure generated by the Oertli CataRhex 3[®] (Oertli), using an external measuring system.

Methods: The effective vacuum pressure created by the Oertli was measured with a pressure device that was continuous with the vacuum tubing system while closed to the external environment. Measurements were taken with the machine set to 300 and 500 mmHg at flow rates of 20, 35, and 50 mL/min and at bottle heights of 60, 80, and 100 cm. Pressures were recorded after the foot pedal was depressed to vacuum setting (second position), and the pressure was allowed to stabilize. Subsequently, it was compared to the pressure value displayed by the machine.

Results: Externally measured vacuum pressure was on average 13.02% greater (39.05 mmHg) than displayed vacuum pressure at 300 mmHg ($P < 0.005$) and 8.60% greater (42.98 mmHg) than displayed vacuum at 500 mmHg ($P < 0.005$). The average difference between displayed and measured pressure increased with increasing bottle heights.

Conclusion: On average, the vacuum pressure generated in the Oertli was found to be significantly higher than the machine's reading when the machine was set at 300 mmHg and 500 mmHg. Adjusting vacuum had variable effects on the measured versus displayed pressure readings.

Keywords: phacoemulsification, Oertli CataRhex 3, vacuum pressure, bottle height, flow rate

Plain Language Summary

While cataract surgery is one of the most commonly performed surgeries and considered quite safe, complications do arise. By controlling vacuum pressure during phacoemulsification, cataract surgeons may be able to better protect their patients. We investigated whether the vacuum pressure reported by the Oertli CataRhex3 could be verified by an independent pressure gauge, and if not, what the actual pressure was. We found that the pressure was higher than reported by the machine. We also found that changes in the bottle height and flow rate impact the pressure. Being aware of this information can help surgeons make prudent decisions about their phacodynamic settings in order to create the safest possible operating environment.

Introduction

Removal of cataracts by phacoemulsification (phaco) remains one of the safest and most common surgical procedures in the United States, but it is not without risks.^{1,2} Post-occlusive surge is a well-known complication of phacoemulsification,^{3,4} leading to collapse of the anterior chamber and increased risk of posterior capsule rupture.⁵⁻⁷ The likelihood of intraoperative complications can be reduced through careful control of vacuum pressure. Thus, an accurate measurement of the vacuum generated by a phaco machine is an important safety issue.

It has been over a decade since the accuracy of a phaco machine's displayed pressure was assessed by an external measuring system, and previous work largely found that the displayed pressure matched measured values.⁸ These earlier studies revealed not only significant differences between machine listed pressure but the ways in which other machine settings can influence surgical efficiency.⁸⁻¹⁵ Since then, new machines and models have replaced those studied back in 2006.⁸⁻¹⁵ This experiment is the first in

a series, which aims to provide an important update to earlier data, and to provide cataract surgeons with external measurements regarding the actual vacuum pressure of the machines in use today, so that surgeons can minimize risk and improve outcomes for their patients.

In this study, we evaluated the pressure generated by the Oertli CataRhex3[®] (Oertli) at various surgical settings. It is a portable 5-kg machine, which is well suited for surgery in low-resource settings, and which utilizes a peristaltic pump to generate vacuum pressure.¹⁶ The Oertli reduces the risk of surgical complications, namely post-occlusion surge, with a system that maintains the irrigation-to-aspiration ratio at 6:1. This differs from other machines, which utilize an aspiration bypass system (ABS), which utilizes an additional hole approximately 3.0 mm from the tip to allow for fluid removal in the case of tip occlusion.^{7,17} The unique fluidics of the Oertli highlight the importance of understanding the machine's vacuum dynamics.

Materials and Methods

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

A Dwyer DPGA-08 digital gas pressure gauge (Dwyer Instruments, Inc., Michigan City, IN, USA) was modified to validate the vacuum measured at the phaco tip. This was done using sealed tubing with 1/8 inch inside diameter (I.D.) and 3/16 inch outside diameter (O.D.) (clear vinyl tubing Model #T10004001 [The Home Depot, Inc., Atlanta, GA, USA]) to connect with the handpiece, and four white plastic Pawfly Naludo-UL125 aquarium air valves, to connect to the outflow tubing. These two tubes were connected to a Dwyer DPGA-08 digital gas pressure gauge using a Tee Quick Connect Coupling joint manufacturer model #70682C (W. W. Grainger, Inc., Lake Forest, IL, USA), placing the pressure line in an uninterrupted series with a vacuum outflow. All adaptors and joints were sealed with epoxy glue to ensure that they were airtight (Figure 1).

Before collecting measurements, the gauge was first calibrated using the following process: First, the machine, including tubing and tip, was primed using the pre-op cycle without the pressure gauge attached. Then, the gauge was attached between the handpiece and outflow tubing. Next, the respective vacuum, flow, and bottle height settings were set; and the pedal was depressed to the second position, engaging both the machine's irrigation and vacuum for about five seconds, and then released, bringing the pressure reading on the gauge to within 4 mmHg of zero. Once calibrated, the pedal was depressed to the second position, and after five seconds the outflow tubing was occluded by kinking the inflow tubing and holding it closed with a hemostat. The vacuum remained engaged until the pressure reading on the gauge plateaued. The pressure measured by the gauge was recorded. This process was repeated 20 times.

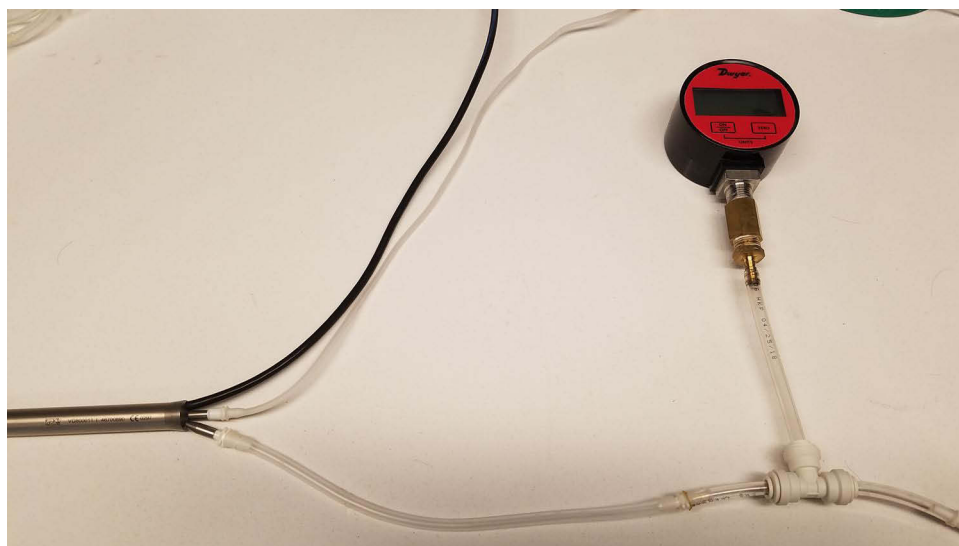


Figure 1 Independent vacuum pressure measurement device.

External vacuum measurements were taken with the machine set to 300 and 500 mmHg at flow rates of 20, 35, and 50 mL/min and at bottle heights of 60, 80, and 100 cm, resulting in pressure readings for each unique parameter combination. The absolute values of the pressure readings were recorded so that the data would be presented in an intuitive way.

Statistical Methods

If the data had a standard deviation of less than 1, trials were stopped before reaching 20 trials, as was done in previous studies.¹⁸ This was evaluated after each trial, with a minimum of 10 trials, before trials were stopped.

Microsoft Excel (Microsoft Corporation, Redmond, WA, USA) was used for the statistical analysis, using the Statistical Add-On. The average, sum, variance, standard deviation, and a single-factor ANOVA were calculated for 1) each displayed pressure, comparing the measured pressure readings obtained for one bottle height versus all flow rates to explore the effect of flow and 2) each pressure of interest, comparing the measured pressure readings obtained for a flow rate versus each bottle height to explore the effect of bottle height. A *P* value of less than 0.05 was used to determine the significance. Histograms were made for each of these scenarios, with a linear line-of-best fit added to approximate the impact of the respective independent variable on the dependent variable. R^2 values were calculated for each series. The average sum, variance, standard deviation, and a single-factor ANOVA were also calculated to compare the significance of the difference between the displayed pressure given by the Oertli and the measured pressure.

Results

On average, the vacuum pressure generated in the Oertli was greater than the machine's reading when the machine was set at both 300 mmHg ($P < 0.005$) and 500 mmHg ($P < 0.005$). When the machine vacuum was set to 300 mmHg, the average measured pressure was 339 mmHg (SD = 15 mmHg); and when it was set to 500 mmHg, the average measured pressure was 543 mmHg (SD = 16 mmHg). The pressure differences measured at both 300 mmHg and 500 mmHg were found to vary based on the settings used, including bottle height (Figures 2 and 3) and flow rate (Figures 4 and 5).

The average difference between the displayed pressure and measured pressure increased almost linearly as the saline bottle was moved higher up the pole when the vacuum was set at 500 mmHg at all measured flow rates ($R^2 = 0.99$ and 0.98, respectively) (Figures 2 and 3). Measurements taken with the machine set at 300 mmHg showed a comparable, albeit weaker, increasing trend with a flow of 20 mL/min ($R^2 = 0.75$) and an increase that plateaued at 35 and 50 mL/min ($R^2 = 0.75$ for both) (Figures 4 and 5).

A decreasing trend was seen at 500 mmHg with bottle heights of 80 cm and 100 cm ($R^2 = 0.87$ and 0.93, respectively) and when operating at 300 mmHg with a bottle height of 100 cm ($R^2 = 0.96$) (Figures 4 and 5). A lone increase in

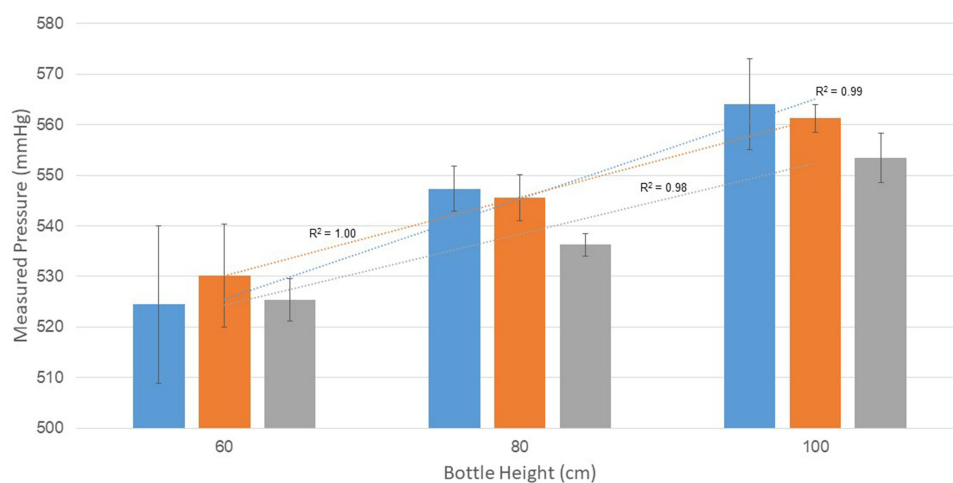


Figure 2 Measured pressures with machine set to 500 mmHg and varying bottle heights and flow rates. Blue: flow = 20 mL/min and R^2 , orange: flow = 35 mL/min and R^2 , gray: 50 mL/min and R^2 .

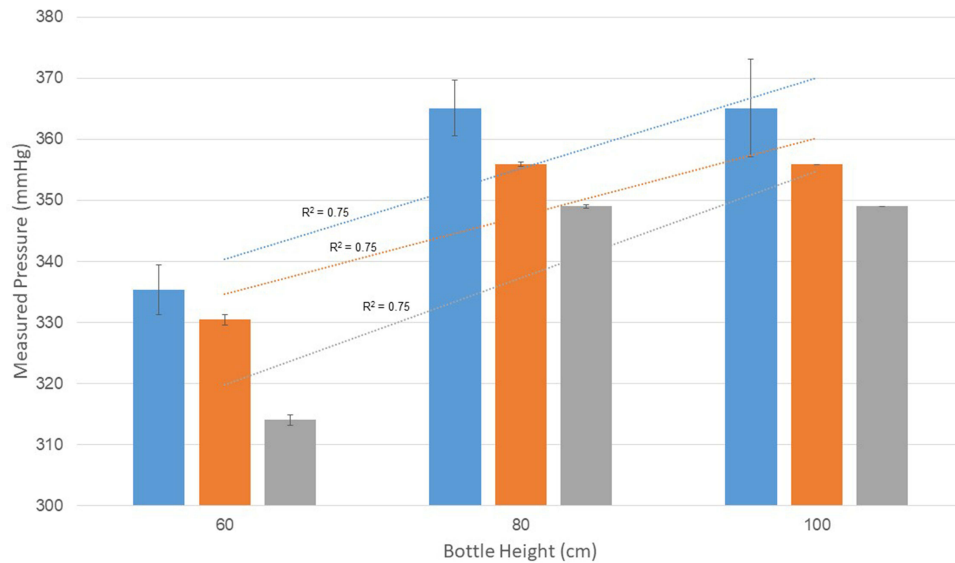


Figure 3 Measured pressures with machine set to 300 mmHg and varying bottle heights and flow rates. Blue: flow = 20 mL/min and R², orange: flow = 35 mL/min and R², gray: 50 mL/min and R².

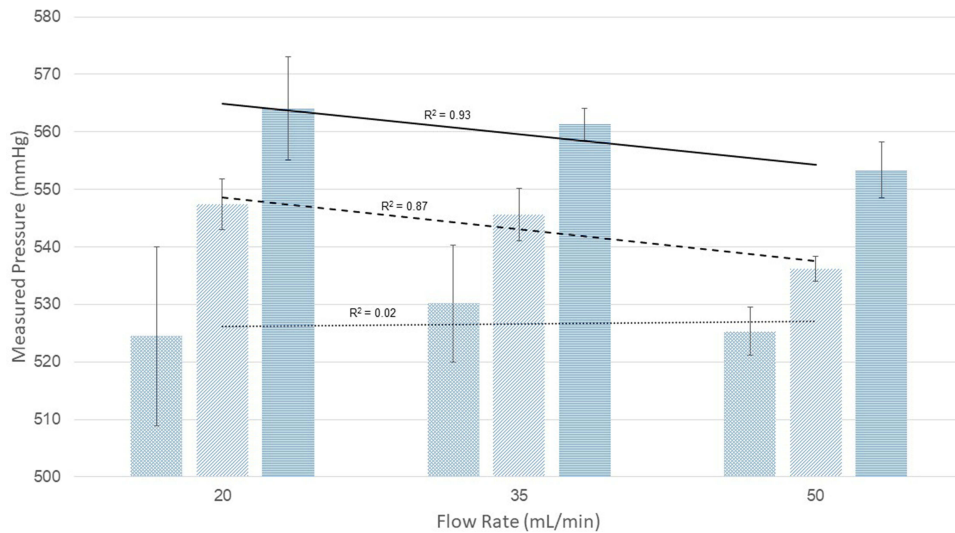


Figure 4 Measured pressures with machine set to 500 mmHg and varying bottle heights and flow rates. Cross-hatch: bottle height = 60 cm and dotted line R², diagonal: bottle height = 80 cm and dashed line, and horizontal: bottle height 100 cm and solid line R².

correlation between pressure difference and flow rate was seen when operating the machine at 300 mmHg with a bottle height of 80 cm ($R^2 = 0.99$) (Figure 5).

The flow rate had no statistically significant correlation with the measured pressure when the vacuum was set to 500 mmHg and the bottle height was 60 cm ($P=0.204$) (Figure 4).

Discussion

The most salient result from this study was that when vacuum pressure was measured independently of the phaco machine at 300 mmHg and 500 mmHg, it was higher than the value displayed by the machine. A deeper look into the data provides valuable insights into the forces governing vacuum pressure on a peristaltic pump machine.

We have noted that increasing the height of the bottle correlated with increasing the difference between measured vacuum pressure and the displayed pressure. Additionally, with the exception of the pressure at 500 mmHg with a 60 cm

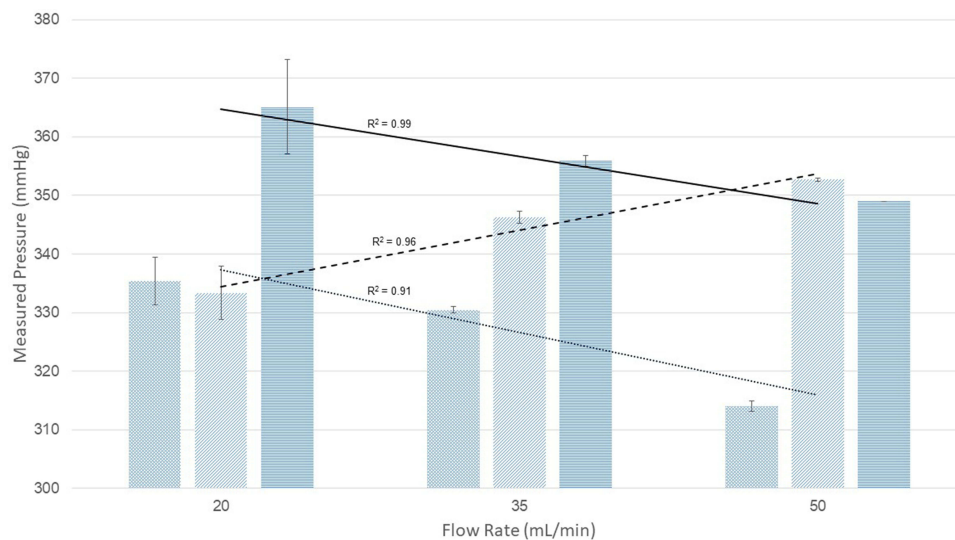


Figure 5 Measured pressures with machine set to 300 mmHg and varying bottle heights and flow rates. Cross-hatch: bottle height = 60 cm and dotted line R^2 , diagonal: bottle height = 80 cm and dashed line R^2 , and horizontal: bottle height 100 cm and solid line R^2 .

bottle height, the change in flow rate correlated with a change in measured pressure. With the exception of the two combinations of settings (vacuum pressure at 500 mmHg and bottle height at 60 cm and vacuum pressure at 300 mmHg and bottle height at 80 cm), increasing the flow was strongly correlated with a smaller difference between the machine's vacuum pressure and the pressure measured by the external gauge.

In order to understand these trends in the data, it is important to keep in mind the physics of the peristaltic pump used in the Oertli.¹⁰ In this system, vacuum is generated by “milking” fluid and air out of the closed space in the tubing system. Additionally, the infusion flow rate is controlled by adjusting the bottle height. As the bottle is raised higher, the force pushing fluid out of the tubing system increases. Thus, it is possible that increasing the bottle height may aid in stabilizing a high-pressure gradient and potentially increasing the vacuum's magnitude.

The relationship between flow rate, or the rate at which fluid is evacuated from the system, and vacuum pressure was not consistent across all bottle heights. However, in most cases, the correlation was inverted, showing that an increased flow rate correlated with a decreased difference between the measured and displayed vacuum pressures. This trend demonstrates the Bernoulli effect, which states that increased flow rate of a fluid decreases the magnitude of the pressure. This decreased fluid pressure lowers the difference between the machine's reading and that of the external gauge.

The primary concern during surgery is safety of the patient. When the pressure in the eye differs from the surgeon's intended pressure, there is potential for damage. The results of this study show that while the true vacuum pressure may in fact be higher than the machine-reported vacuum pressure on the Oertli, the pressure difference can be minimized by using a lower bottle height and higher flow rate. When possible, operating the vacuum at lower pressures may also reduce the discrepancy between the actual and machine-reported vacuum pressures. Operating with these considerations in mind may help surgeons have better outcomes when using the Oertli.

This study has several limitations. While every effort has been made to minimize error, we acknowledge the limitations of this work. For example, repeating this study with a variety of external gauges would likely add greater credence to our results. We also acknowledge that these results do not include information on other vacuum, bottle height, and flow settings. Performing the many experimental runs that this would necessitate was not logistically feasible. Finally, the fluid dynamics of the Oertli system are unique and may contribute to differences between the pressure measured at the tip and the pressure measured in the machine. Nonetheless, we feel that the statistically significant differences between the vacuum pressure displayed by the Oertli and the externally measured value, as well as the trends relating to bottle height and flow rate, remain useful to surgeons hoping to increase patient safety while operating this system.

Conclusion

The magnitude of the average measured pressure was consistently greater than the machine's stated pressure at 300 mmHg and 500 mmHg regardless of flow rate, bottle height, or pressure. This information may help surgeons reduce their risk for vacuum-related complications, such as capsular rupture while operating with this machine. We recognize that utilization of the Oertli varies throughout the world, and so we anticipate continuing our external measurements of vacuum pressure with other phaco systems so as to provide surgeons who use other machines with the same valuable information.

Abbreviations

Oertli, Oertli CataRhex3[®]; phaco, phacoemulsification; ABS, aspiration bypass system.

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Disclosure

Dr. Randall J Olson is on the Board of Directors of Perceive Bio and the Scientific Advisory Board of Perfect Lens. Dr. Jeff H Petty reports a consulting agreement for Lensar, outside the submitted work. The other authors report no conflicts of interest in this work.

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