Performance of a New Dual Mode Phacoemulsification System

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INTRODUCTION

Background: The **VERITAS™** Vision System key features include: Improved chamber stability: Fluidics include 2 Procedure Packs with Advanced Tubing System (small bore & dual durometer aspiration tubing), Enhanced usability: ergonomics including swivel handpiece and foot pedal, Ease of use including touch monitor and remote control. The **VERITAS™** Vision System sub-modes allow the surgeon to also perform diathermy (electrical cauterization) and vitrectomy (a cutting action).

Purpose To evaluate the overall clinical performance and surgeon acceptability of a new phacoemulsification system (the **VERITAS™** Vision System).

METHODS

- Prospective, open-label clinical study
- One site in El Salvador (OUS) between September 29 – October 10, 2020
- Routine small-incision cataract surgery via phacoemulsification performed using the new dual mode phacoemulsification (phaco) system (**VERITAS™** Vision system)
- A total of 58 eyes (41 subjects) treated
- Two surgeons evaluated the clinical performance (i.e., chamber stability, cutting efficiency and system usability) and ergonomics by completing a questionnaire after each surgery using a 5-point rating scale:
  - (1- unsatisfied, 2- somewhat unsatisfied, 3- neither satisfied nor unsatisfied, 4- satisfied and 5- very satisfied)
  - The proportion and the associated 95% confidence interval were computed

INCLUSION / EXCLUSION CRITERIA

Study Inclusion Criteria:

- Minimum 22 years of age.
- Cataract extraction and posterior chamber IOL implantation have been planned
- Provide informed consent and authorization to disclose protected health information or equivalent documentation

Study Exclusion Criteria:

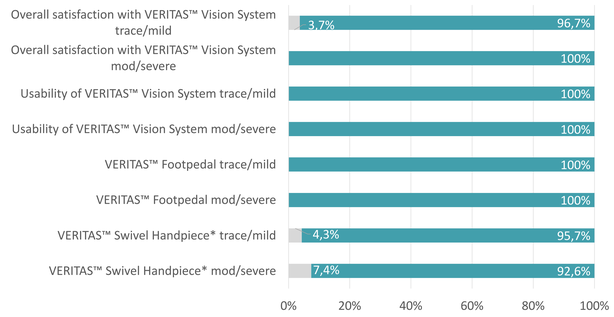
- Associated conditions with potential surgical difficulties or complications
- Conditions associated with increased risk of zonular rupture, including pseudoexfoliation, trauma, or posterior capsule defects
- Subjects with only one good eye (e.g. amblyopic condition etc.) or pupil abnormalities
- History or current use of alpha-1 antagonist medication (e.g., Flomax)

Table 1. Subject Demographics and Cataract Status

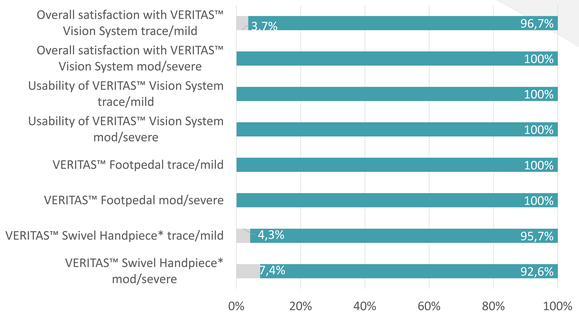
Demographics (N=41subjects)		%=n/N (Total) excluding not reported	
Age (years)	Mean ± SD	66.7 ± 8.3	-
	Range	51 – 87	-
	Median	67	-
Sex	Male	10	(24.4%)
	Female	31	(75.6%)
Race	Central and South American	41	(100.0%)
Ethnicity	Hispanic/Latino	41	(100.0%)
Cataract Status – Preop (n=58 eyes) Density:		58	100
+1 Trace		3	5.2
+2 Mild		24	41.4
+3 Moderate		23	39.7
+4 Severe		8	13.8

RESULTS & DISCUSSION

- **Surgeons rated the Overall Satisfaction** (scores of 4 or 5) **with the VERITAS™ Vision System in** over 96% of cases
- Surgeons rated satisfied/very satisfied (scores of 4 or 5) in 100% of cases for:
  - **Satisfaction with Usability of the VERITAS™ Vision System**
  - **VERITAS™ Footpedal**
- Surgeon satisfaction with the **VERITAS™ Swivel handpiece** was slightly lower at ≥92.6%.
- The Swivel handpiece rated as neither satisfied nor unsatisfied (rated 3) in 3 cases:
  - may reflect surgeon learning curve with the handpiece



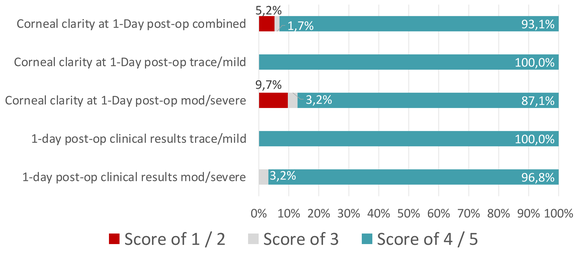
- Surgeons rated satisfied/very satisfied (scores of 4 or 5) in 100% of cases for
  - **Phaco (cutting) efficiency**
- Surgeons rated satisfied/very satisfied in over 95% of cases for the other clinical performance outcomes
- Overall <4% of cases rated as 3 (Neither satisfied, or unsatisfied) for **anterior chamber stability, followability and holdability**
  - Surgeon's first surgery in these cases



- Surgeons **satisfied with the overall clinical performance (including corneal clarity at 1-Day post op and clinical results at 1-Day post op)** of the new phaco system in over 93% of cases
- For the 3 cases rated as either 1-unsatisfied, or 2-somewhat unsatisfied with corneal clarity at 1-Day post operative dense cataracts were present in these cases

Adverse events and Complications

- Two intraoperative complications were reported (both capsule tears, one resulting in vitrectomy and classified as an adverse event)
- Both resolved without sequelae



CONCLUSIONS

The new dual mode phacoemulsification system with new swivel handpiece, gas forced infusion and ergonomics/ workflow improvements resulted in a high rate of user satisfaction with clinical performance and ergonomics.

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