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Background

- Workflow efficiency in ophthalmology operating rooms is critical because the global demand for retina surgeries is expected to outpace the supply of workforce.
- UNITY® Vitreoretinal Cataract System (UNITY VCS) received US-FDA 510k clearance in June 2024. The UNITY VCS is indicated for use during anterior segment and posterior segment ophthalmic surgery.
- A bench time trial was conducted on August 2023 to compare the mean duration of console set-up and tear-down time for vitreoretinal functionality with UNITY VCS and the current standard of care device, CONSTELLATION® Vision System (CONSTELLATION).

Methods

- A time trial included 9 ophthalmic technicians/nurses with a mean (SD) experience of 19.50 (12.15) years as either a technician or a surgical/scrub nurse, including 17.94 (10.35) years of supporting retina surgery.
- All participants worked at a practice with multiple surgeons, with 4 (44%) supporting retinal surgeries in an Ambulatory Surgical Center (ASC) while 5 (56%) serving ASCs and Hospital Outpatients Departments. Four (44%) worked at a practice where CONSTELLATION was first installed more than 10 years ago, 5 (56%) worked at a practice where CONSTELLATION was first installed more than 4 years ago.
- Each participant performed system setup and tear-down workflows of UNITY VCS and CONSTELLATION for vitreoretinal surgery. Participants were timed by observers with a stopwatch after 30 minutes of shared hands-on time with UNITY VCS. Start and end for each step and console were defined in Table 1.
- T-test for the paired two samples was conducted to test the difference of matched pairs. Given the small sample size, Wilcoxon Signed Rank Test was also conducted to verify the robustness of the analysis.
- Four participants further responded to the validated ten-item System Usability Scale (SUS), ranking their agreement on a scale from one to five.<sup>1</sup>

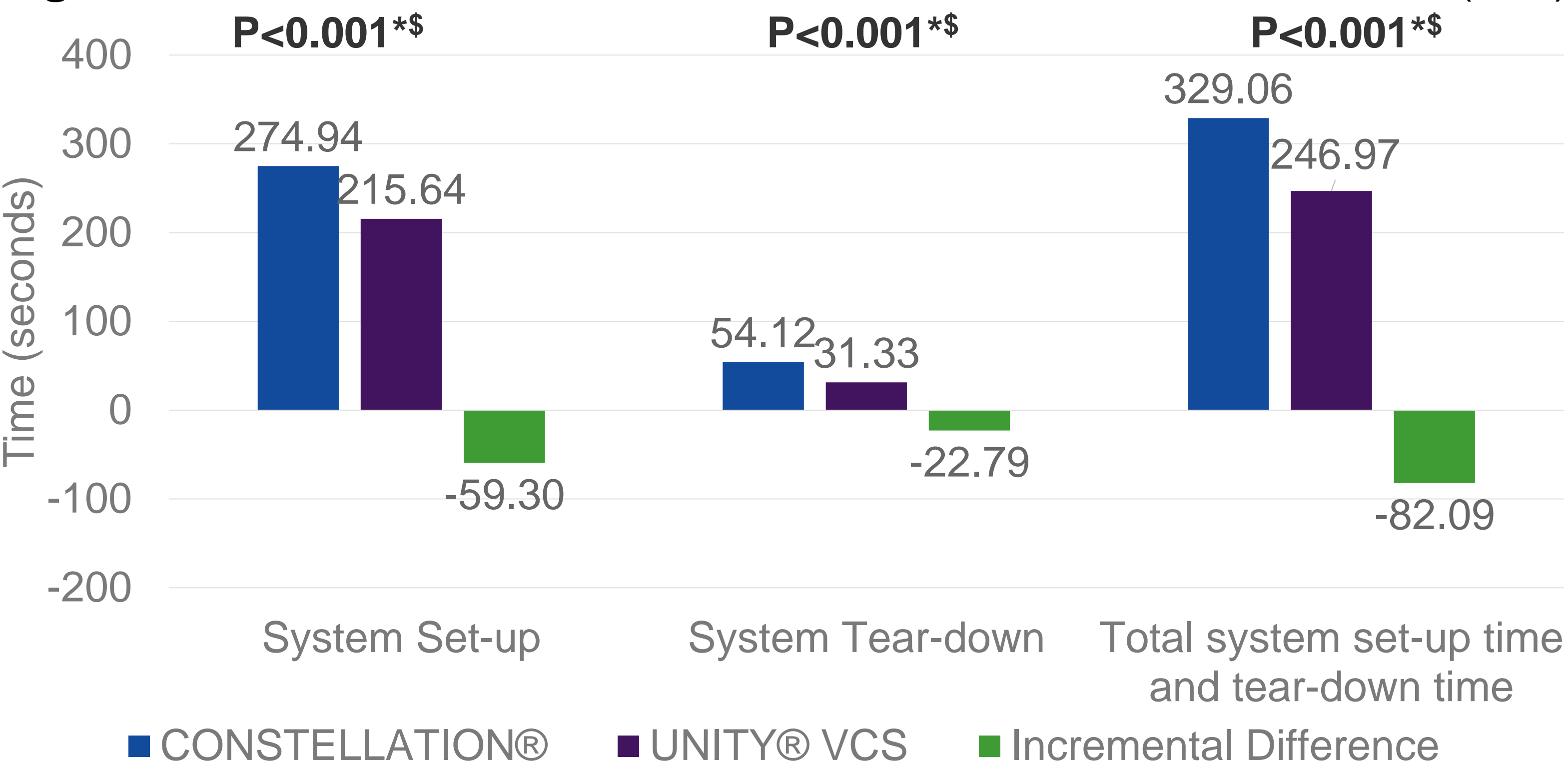
Table 1: Definition of Start and End Steps of Each Surgery System

Step	CONSTELLATION	UNITY VCS
System Set-up Time	Start: Hanging/placing the BSS bag	Start: Close door to BSS bag
	End: Screen updates to "Surgery Ready"	End: Screen updates to "Surgery Start"
System Tear-down Time	Start: Start FMS ejection	Start: Hit FMS ejection
	End: Waste bag removed	End: Waste bag removed

Results

- The mean (SD) system set-up time was 215.64 seconds (38.78) with UNITY VCS compared to 274.94 seconds (18.94) with CONSTELLATION, leading to 21.6% faster set-up time with UNITY VCS (mean difference of 59.30 seconds with SD of 29.65. P<0.001) as shown in Figure 1.
- The mean (SD) system tear-down time was 31.33 seconds (9.78) with UNITY VCS compared to 54.12 seconds (7.29) with CONSTELLATION, leading to 42.1% faster set-up time with UNITY VCS (mean difference of 22.79 seconds with SD of 9.44. P<0.001).
- The mean (SD) total system set-up and tear-down time was 246.97 seconds (42.83) with UNITY VCS compared to 329.06 seconds (21.11) with CONSTELLATION, leading to 24.9% faster total set-up and tear-down time with UNITY VCS (mean difference of 82.09 seconds with SD of 33.85. P<0.001).

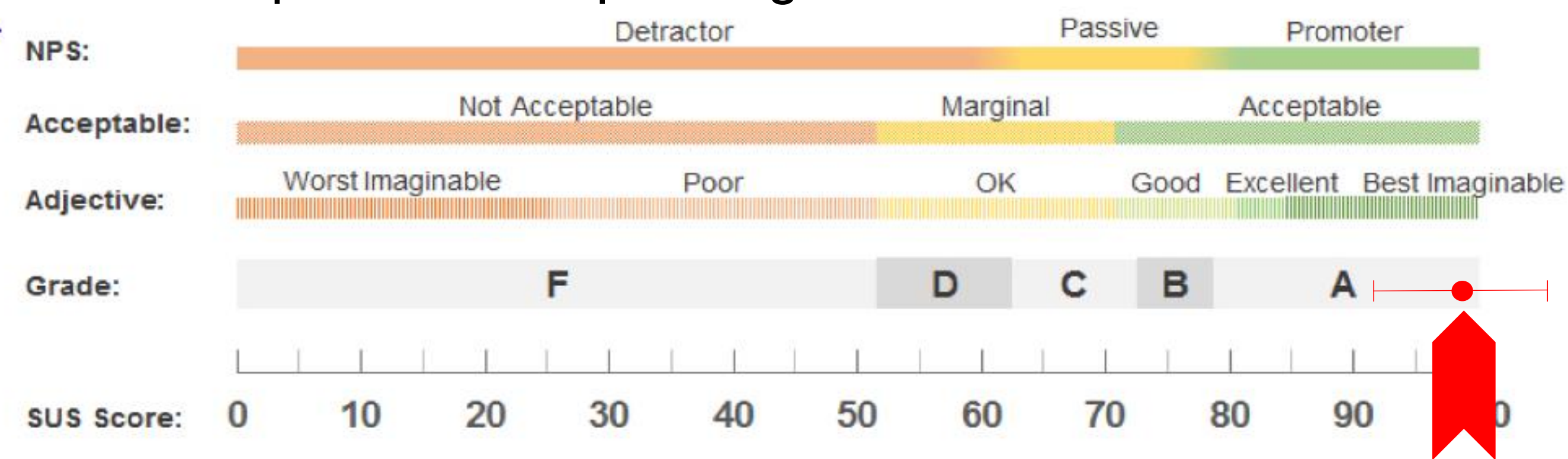
Figure 1: Mean Time Difference CONSTELLATION vs. UNITY VCS (n=9)



\*t-Test: Paired Two Sample for Means  
\*\* It was confirmed that all three were p-value <0.05 with Wilcoxon Signed Rank Test (Set-up time: p=0.004, Tear-down time: p=0.004, and Total time: p=0.004).

- The distribution of responses from four participants with SUS are presented in Table 2. These responses were transformed into the System Usability Scale Score (Maximum 100 points) using the defined algorithm<sup>1</sup>
- The mean (SD) SUS score was 89.38 (7.47).This score corresponds to the 97th percentile, which can be described as the “Best Imaginable” usability (Figure 2)<sup>2</sup>.

Figure 2: Descriptions corresponding to the SUS Score



Results Continued

Table 2: Distribution of Responses with SUS Dimensions (n=4)%

SUS Dimension	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
#1 I think that I would like to use the system frequently.				1	3
#2 I found the system unnecessarily complex	4				
#3 I thought the system was easy to use.				2	2
#4 I think that I would need the support of a technical person to be able to use the system.	3	1			
#5 I found the various functions in this system were well integrated.				1	3
#6 I thought there was too much inconsistency in this system.	3		1		
#7 I would imagine that most people would learn to use this system very quickly.				3	1
#8 I found the system very cumbersome to use.	2	1	1		
#9 I felt very confident using the system.			1	1	2
#10 I needed (or would need) to learn a lot of things before I could get going with this system.	3	1			

%: Scoring is done as following. 1 = Strongly disagree, 5 = Strongly agree. Odd numbered questions Point score = Response – 1 Even numbered questions Point score = 5 – Response. Point scores across all 10 questions are added (maximum = 40 points) and multiplied by 2.5 for a maximum of 100 points.<sup>1</sup>

Discussion & Conclusions

- This study showed that the new UNITY® Vitreoretinal Cataract System may deliver superior efficiency compared with the CONSTELLATION® Vision System. The total set-up and tear-down time UNITY VCS may release ~1.5 minutes of operating room turnover time per surgical case.
- The SUS scores also suggest that UNITY VCS may offer better system usability in system set-up and tear-down workflows including potential less learning curve for nurses/technicians.
- However, these should be interpreted with caution as it is based on data from only 9 time-trial participants and 4 SUS respondents.

References

1. Sauro J (2011) Measuring Usability with the System Usability Scale (SUS). Available online at: <https://measuringu.com/sus/>  
2. Sauro J (2018) 5 Ways to Interpret a SUS Score. Available online at: <https://measuringu.com/interpret-sus-score/>

**Disclosure:** YI and MD are employees of Alcon. DS and MAG were contracted by Alcon to conduct the time trial.