HFA3 SITA FASTER RESULTS ARE EQUIVALENT TO SITA FAST AND SITA STANDARD

Authors: Thomas Callan, OD, Gary C. Lee, PhD, Eric Larson, Carl Zeiss Meditec, Inc., Dublin, CA USA

Introduction

ZEISS recently introduced a new visual field test strategy for the HFA3 known as SITA™ Faster. The SITA Faster 24-2 test has been shown to run 30% faster compared to SITA Fast, and 50% faster compared to SITA Standard. This white paper provides additional information to demonstrate that SITA Faster results are comparable to the established SITA Fast and SITA Standard tests and thus may be suitable for use instead of 24-2 SITA Standard or SITA Fast strategies.

A study was conducted at Carl Zeiss Meditec, Inc., to assess comparability of SITA Faster, SITA Fast, and SITA Standard with the primary endpoint of Mean Deviation (MD) and an acceptance criteria of <± 1.00 dB. A total of 25 normal subjects and 25 glaucoma subjects participated in the study. Measures reported are:

1. The agreement of the MD parameter between SITA Faster 24-2, SITA Fast 24-2, and SITA Standard 24-2 threshold visual field tests.

2. The similarities in the flagging of total and pattern deviation probability symbols between SITA Faster 24-2, SITA Fast 24-2, and SITA Standard 24-2 threshold visual field tests.

3. The test times between the SITA Faster 24-2, SITA Fast 24-2, and SITA Standard 24-2 threshold visual field tests.

Study results and discussion

- **MD Based Equivalence**

For the normal group, the MD average difference for "SITA Faster – SITA Fast" was -0.144 dB; and for the glaucoma group, the mean difference was just 0.002 dB, Table 1.

Comparison of SITA Faster results to SITA Standard also show that SITA Faster was well within the ± 1.0 dB equivalence limit range. For the normal group, the MD average difference for "SITA Faster – SITA Standard" was 0.175 dB, and it was 0.301 dB for the glaucoma group, Table 1.

Agreement of MD Between SITA Faster, SITA Fast, and SITA Standard

Parameter	N	Mean (SD)					
		SITA Faster	SITA Fast	SITA Faster – SITA Fast Difference (95% CI)	SITA Faster	SITA Standard	SITA Faster – SITA Standard Difference (95% CI)
Normal							
MD (decibels)	25	0.749 (1.11)	0.892 (1.09)	-0.144 (0.712) (-0.387, 0.100 p <0.001	0.749 (1.11)	0.574 (1.11)	0.175 (0.953) (-0.152, 0.501) p <0.001
Glaucoma							
MD	25	-2.83 (5.33)	-2.83 (5.36)	0.002 (0.749) (-0.259, 0.254) p <0.001	-2.83 (5.33)	-3.13 (5.56)	0.301 (0.907) (-0.009, 0.612) p <0.001

Table 1

In both groups, the MD average difference was significantly lower than the limit of ± 1.00 dB. Therefore, for this study cohort, all three studies generated comparable results on MD.

- **Total Deviation and Pattern Deviation Probability Symbol Analysis**

The MD average difference shown in Table 1 is the criteria used to confirm equivalence. Additional support for equivalence is shown in the similarity of number of flagged points on the total deviation (TD) and pattern deviation (PD) plots and compared between the SITA Faster, SITA Fast, and SITA Standard tests.

Descriptive statistics of the number of flagged points are provided separately for the probability levels of <5%, <2%, <1%, and <0.5% in Table 2. These descriptive statistics summarize the total number of flagged points for the SITA Faster, SITA Fast, and SITA Standard tests.

Agreement of Pattern Deviation Points Between SITA Faster, SITA Fast, and SITA Standard

Parameter	N	Number of Pattern Deviation Points Mean (SD) SITA Faster – SITA Fast					Number of Pattern Deviation Points Mean (SD) SITA Faster – SITA Standard				
		SITA Faster	SITA Fast	Difference	95% CI	P Value	SITA Faster	SITA Standard	Difference	95% CI	P Value
Normal											
# Points <5%	25	3.6 (2.4)	4.2 (3.4)	-0.6 (3.6)	(-2.079, 0.799)	0.568	3.6 (2.4)	3.9 (3.4)	-0.3 (3.0)	(-1.551, 0.911)	0.597
# Points <2%	25	1.2 (1.5)	1.1 (1.4)	0.1 (1.3)	(-0.430, 0.670)	0.657	1.2 (1.5)	1.6 (1.6)	-0.3 (1.7)	(-1.074, 0.354)	0.308
# Points <1%	25	0.6 (1.4)	0.6 (1.0)	0.0 (1.4)	(-0.525, 0.605)	0.885	0.6 (1.4)	0.5 (0.7)	0.04 (1.5)	(-0.585, 0.665)	0.896
# Points <0.5%	25	0.3 (1.2)	0.0 (0.2)	0.3 (1.2)	(-0.269, 0.749)	0.341	0.3 (1.2)	0.1 (0.3)	0.2 (1.3)	(-0.369, 0.689)	0.538
Glaucoma											
# Points <5%	25	11.4 (9.2)	12.0 (9.6)	-0.6 (3.5)	(-1.990, 0.870)	0.427	11.4 (9.2)	11.7 (10.5)	-0.2 (5.0)	(-2.33, 1.85)	0.814
# Points <2%	25	7.6 (9.4)	7.9 (9.7)	-0.3 (3.3)	(-1.667, 1.027)	0.628	7.6 (9.4)	8.0 (10.1)	-0.4 (3.9)	(-1.994, 1.194)	0.609
# Points <1%	25	6.1 (9.0)	6.1 (9.1)	0.0 (2.4)	(-0.990, 0.990)	1.000	6.1 (9.0)	6.4 (9.8)	-0.3 (2.8)	(-1.445, 0.865)	0.624
# Points <0.5%	25	4.3 (8.6)	4.3 (8.9)	0.0 (1.6)	(-0.653, 0.653)	1.000	4.3 (8.6)	5.2 (9.3)	-0.9 (2.0)	(-1.717, 0.043)	0.040

Table 2

Analysis of the total and pattern deviation plots from the SITA Faster, SITA Fast, and SITA Standard tests found that there were no statistically significant differences between the numbers of flagged points at any of the probability levels except the glaucoma < 0.5% level for SITA Faster and SITA Standard, which had a difference of only 1 point flagged (4 versus 5 points).

The findings of similar numbers of flagged points in both total and pattern deviation analyses indicate that the SITA Faster test results are equivalent with SITA Fast and SITA Standard test results, and therefore, the test results from any of these tests can be mixed together to assess visual field defect progression. This equivalence is important, particularly when following progression with the Guided Progression Analysis (GPA).

- **Test Time Analysis**

A second objective of this study was to compare the test times of the SITA Faster test strategy to the test times of both the SITA Fast and SITA Standard strategies for the 24-2 test pattern. The reduction in test time primarily comes from (in order of most significant to least) i) removing built-in delays following unseen stimuli, ii) optimizing starting values of test points, iii) eliminating the determination of the blind spot location, iv) and elimination of the false negative check stimuli. Table 3 shows the mean and SD values for the three test strategies and indicates the percent improvement in test time for SITA Faster over SITA Fast and SITA Standard.

Descriptive Statistics of Test Times

Parameter	N	Mean (SD)	SITA Faster time improvement over:	Min, Max
Normal				
Faster test time (sec)	25	106.6 (9.3)		90, 137
Fast	25	166.0 (16.5)	35.8%	133, 201
Standard	25	277.2 (21.8)	61.6%	232, 327
Glaucoma				
Faster test time (sec)	25	134.0 (37.8)		99, 245
Fast	25	198.8 (46.3)	32.6%	147, 344
Standard	25	321.0 (59.8)	58.2%	225, 487

Table 3

The SITA Faster mean test time was 36% faster than SITA Fast in normals and 33% faster than SITA Fast in the glaucoma group. The mean time difference between SITA Faster and SITA Standard was even greater. SITA Faster was 62% faster than SITA Standard in the normal group and 58% faster in the glaucoma group. These differences in test times were statistically significant.

Conclusions

The results of this study demonstrate the equivalence of the SITA Faster test strategy to both SITA Fast and SITA Standard in this cohort of normal and glaucoma subjects. SITA Faster showed very similar mean MD results for both groups studied and was easily within the equivalence limits established for the study. This indicates that a user should feel confident using the SITA Faster test strategy as an alternative to either the SITA Fast or SITA Standard strategies. The similar numbers of the flagged total deviation and pattern deviation points in SITA Faster, SITA Fast, and SITA Standard indicate that the SITA Faster test is equivalent when following visual field progression. Based on the findings of this study, the SITA Faster strategy is considered to be equivalent to SITA Fast as well as SITA Standard.

The improvement in test time with SITA Faster was shown to be greater than 30% over SITA Fast and greater than 50% over SITA Standard. The shorter test times should make the task of taking a visual field a better experience for many patients. A number of subjects in this study mentioned their preference for the SITA Faster test based on the reduced test duration.

The combination of equivalent test results to SITA Fast and SITA Standard, and the faster test times, will allow doctors to switch over their patients to the SITA Faster test and be assured that the test results are equivalent while their patients benefit from the shorter test times.

References

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