Meta-analysis of Six Excimer Laser Platforms for Safety and Efficacy in Myopic Laser-assisted *in situ* Keratomileusis

Christopher L Blanton, MD

President, Board of Directors; Chief Executive Officer, Inland Eye Institute Medical Group, Inc., Colton, California, US; Adjunct Assistant Professor of Surgery, Uniformed Services University of the Health Sciences, Bethesda, Maryland, US

Abstract

Purpose: To compare excimer laser platform outcomes for myopic laser-assisted *in situ* keratomileusis (LASIK). **Methods**: A peer-reviewed literature search was conducted using the terms "myopia," "LASIK," and "outcomes." Articles were selected based on inclusion/exclusion criteria. Data regarding Snellen visual acuity, refractive error ± 0.5 and 1.0 diopter (D) and loss of best-corrected acuity were extracted. US Food and Drug Administration (FDA) approval studies were used to fill in any data gaps. Statistical analysis was performed. **Results**: The Abbott laser outperformed the other five in multiple measures of visual acuity results at 1 and 3 months. The Nidek laser outperformed the other five lasers at the 20/16 level at 6 months. The Carl Zeiss/Meditec laser outperformed the other five at 6 months in terms of refractive outcome ± 0.5 D. The Abbott and Alcon lasers outperformed the other four lasers in the safety category (least amount of >2 line loss of best-corrected visual acuity [BCVA]) at the 1 month visit. There were no significant differences between the platforms, in the safety category, at all other time intervals. **Conclusion**: At all times, all lasers fell within the FDA guidelines for safety regarding loss of best-corrected acuity.

Keywords

Myopia, LASIK, outcomes, safety, efficacy, phase IV, peer-reviewed

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Correspondence: Christopher L Blanton, MD, 9481 Haven Ave, Suite 200, Rancho Cucamonga, CA 91730, US. E: Blanton007@aol.com

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Laser-assisted *in situ* keratomileusis (LASIK) for myopia is the most commonly performed corneal refractive procedure performed in the world today. The use of the excimer laser to reshape the cornea is accomplished utilizing an ultraviolet laser that contains sufficient energy per pulse to disrupt the organic bonds, which reside in the cornea. This allows corneal stromal tissue to be removed in very precise 0.25 micron increments enabling the surgeon to alter the shape of the cornea. Excess energy is dissipated in acoustic and photic forms. There are a number of excimer laser platforms available today for use by surgeons when performing this procedure. Although there have been sporadic articles comparing one or two laser platforms to another,[1–4] and rarely an article comparing several of the most commonly used excimer lasers,[5] there has not been a recent comprehensive comparison of currently available platforms looking at standard safety and efficacy data. This meta-analysis was undertaken to accomplish that goal.

Methods

An Internet-based search using SCOPUS, a system designed to screen and filter journal articles, was conducted. SCOPUS is the largest abstract and citation database of peer-reviewed research literature. The words "myopia," "LASIK," and "outcomes" were used to filter the articles in the categories of "article title," "abstract," and "keywords." The time period went from November 2013 retrospectively to January of 2007. Articles older than this were considered to be anachronistic. Inclusion criteria included the following: English-language, peer-reviewed journals for the surgical procedure of myopic LASIK. In addition, the following parameters were selected for inclusion: Snellen visual acuity at 1, 3, 6, and 12 months; efficacy regarding refractive error targeting: ± 0.5 diopters (D) at 3, 6, and 12 months; ± 1.0 D at 3, 6, and 12 months. Finally, the adverse event—loss of best-corrected visual acuity (BCVA) (>2 lines) at 1, 3, 6, and 12 months was also examined. Exclusion criteria were: any studies on eyes with 1) prior eye surgery, 2) pathology, or 3) for an

intended result of "monovision." Finally, the best data, with regards to visual acuity and loss of BCVA, were presented for each platform. At the conclusion of the database search there were 613 articles. One hundred and seventy-four articles were removed due to the fact that they did not examine the parameters in the categories of 1) visual acuity, 2) ± 0.5 D or ± 1 D of refractive accuracy, or 3) loss of >2 lines of BCVA. Seventy-four articles were excluded because they did not concern myopic LASIK for emmetropia. Seventy-one articles were excluded because they were on previously operated eyes. Ten articles were excluded because they were on pathologic eyes (amblyopia for example). Four articles were excluded since they were not in the English language. After application of the inclusion/exclusion criteria, there were 281 usable journal articles with six separate laser platforms with sufficient data for analysis.[6–34] If data were lacking with regards to these parameters for a particular platform, we reverted to US Food and Drug Administration (FDA) approval studies.[35–39] This was a common occurrence and even after including FDA-approval data there were still some platforms with no data points in the literature. For example, only two platforms have 20/10 visual acuity data at the 3-month post-op time frame.

The Six Platforms Compared

A comparison analysis of visual outcomes between these six common excimer platforms was performed. These lasers included the following capabilities at the time of use in the journal articles used.

Abbott-Star-S4IR

Capable of performing conventional (phoropter-based) and wavefront-guided (aberrometer-based) ablations using a Hartmann-Shack aberrometer. Speed of the laser is variable but maximized at 20 Hz. The laser uses a pattern known as variable spot scanning in which pulses of different diameters are calculated, using a Fourier algorithm, and used to remove corneal stromal tissue. Pupil tracking and iris registration are available.

Alcon Wavelight 200/400 Hz Wavefront Optimized/ Wavefront Guided

These devices are capable of performing both conventional and wavefront-guided ablations. The wavefront-guided ablations are driven by a Tscherning principle-based aberrometer. Conventional ablations are placed in an "optimized" fashion by applying a correction profile designed to maintain the natural prolate shape of the cornea. A scanning spot technology is used. The speed of the most recent version available at the time of this article was 400 Hz. Pupil tracking is available.

Carl Zeiss/Meditec Mel 80

This performs conventional, topography-, and wavefront-guided excimer laser surgery with a Hartmann-Shack type aberrometer. The speed of the laser is 250 Hz. The device uses flying spot technology to deliver excimer laser ablation. The platform can be set to correct for induced spherical aberrations. Eye tracking and iris recognition are available.

Nidek EC5000

This performs conventional and wavefront-guided excimer laser ablations with scanning slit technology. Ablation profiles can be delivered attempting to create a prolate corneal profile over the mesopic pupil while targeting zero or mildly negative spherical aberration. Additionally, a conventional profile can be used with a small optical zone coupled with an aspheric transition zone that is at least 3 mm larger than the optical zone. The aberrometer is a time-based device using dynamic skiascopy. The speed of the laser is 40 Hz. Pupil tracking and torsion error detection are available.

Schwind Esiris/Amaris

This is the only laser in this analysis that is not FDA approved, but it so commonly used globally and was therefore included. The laser is capable of conventional and wavefront-guided treatments. A Hartmann-Shack aberrometer is utilized. Ablation profiles can take into account keratometry readings and can deliver aspheric profiles. The speed is 500 Hz and has pupil tracking and dynamic cyclotorsional tracking technology.

Technolas-217Z

This model is capable of performing both conventional and wavefront-guided excimer ablations with a speed of 100 Hz. The platform uses a Hartmann-Shack type of aberrometer. The ablation can be delivered using an aspheric module. Uses flying spot technology to deliver excimer ablation. Pupil tracking and dynamic iris recognition are available.

The final results underwent a statistical analysis in the following manner: we used a one-tailed two-sample Z-test about proportions. Observed proportions were placed in descending order, then we iteratively tested each against the remaining platforms. If observed proportions were equal: the sample size was the "tie-breaker" as a potential discriminator against lower observed proportions.

Results

Visual Acuity at 1 Month

Comparison of Platforms

The following data were recovered from the eligible articles:

Abbott excimer platform—20/10—22 %,[6] 20/12.5—81 %,[6] 20/16—95 %,[6] 20/20—99 %[6]
Alcon excimer platform—20/12.5—21 %,[35] 20/16—64 %,[12] 20/20—92 %[18]
Carl Zeiss excimer platform—20/16—65 %,[16] 20/20—96 %[16]
Nidek excimer platform—20/20—81 %[24]
Schwind excimer platform—no data
Technolas excimer platform—61 %—20/16,[36] 20/20—86 %[36] (see *Figure 1*)

The Abbott platform was significantly superior to all the other platforms at acuity levels 20/12.5, 20/16 and 20/20 (see *Table 1*).

Visual Acuity at 3 Months

Comparison of Platforms

The following data were recovered from the eligible articles:

Abbott excimer platform—20/10—23 %,[6] 20/12.5—80 %,[6] 20/16—96 %,[6] 20/20—98 %[6]
Alcon excimer platform—20/12.5—25 %,[15] 20/16—76 %,[15] 20/20—93 %[15]
Carl Zeiss excimer platform—20/16—50 %,[16] 20/20—96 %[16]
Nidek excimer platform—20/20—96 %[23]
Schwind excimer platform—20/10—23 %,[30] 20/16—71 %,[25] 20/20—97 %[30]

Figure 1: Visual Acuity—1 Month—Comparison of Platforms

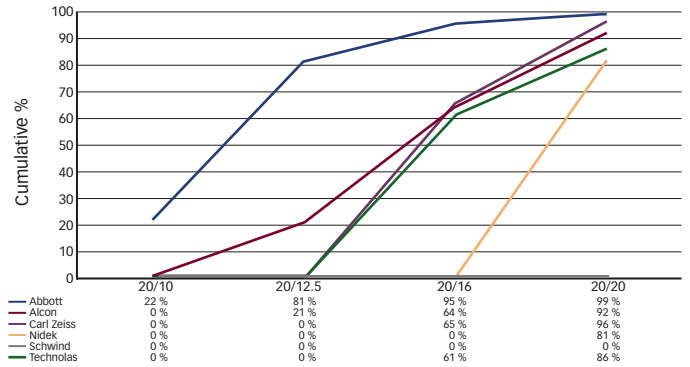

Figure 2: Visual Acuity—3 Month—Comparison of Platforms

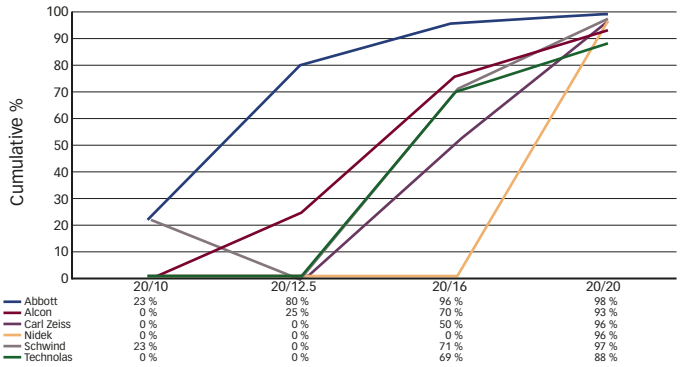

Table 1: Visual Acuity—1 Month p Values between Platforms

Visual acuity = 20/20—1 month

	Abbott	Carl Zeiss	Alcon	Technolas	Nidek	Schwind
Abbott						
Carl Zeiss	0.0256					
Alcon	0.0010	0.2184				
Technolas	0.0000	0.0148	0.1904			
Nidek	0.0000	0.0031	0.0856	0.1030		
Schwind						

Visual acuity = 20/16—1 month

Abbott						
Carl Zeiss	0.0000					
Alcon	0.0000	0.4665				
Technolas	0.0000	0.2771	0.3898			
Nidek						
Schwind						

Visual acuity = 20/12.5—1 month

Abbott						
Carl Zeiss						
Alcon	0.0000					
Technolas						
Nidek						
Schwind						

Visual acuity = 20/10—1 month

Abbott						
Carl Zeiss						
Alcon						
Technolas						
Nidek						
Schwind						

Table 2: Visual Acuity—3 Month p Values between Platforms

Visual acuity = 20/20—3 months

	Abbott	Carl Zeiss	Alcon	Technolas	Nidek	Schwind
Abbott						
Carl Zeiss	0.1584					0.3242
Alcon	0.0006	0.2006			0.1532	0.0009
Technolas	0.0000	0.0493	0.1009		0.0248	0.0000
Nidek	0.1134	0.5000				0.2802
Schwind	0.0994					

Visual acuity = 20/16—3 months

Abbott						
Carl Zeiss	0.0000		0.0001	0.0019		0.0016
Alcon	0.0000					
Technolas	0.0000		0.0446			0.3236
Nidek						
Schwind	0.0000		0.1446			

Visual acuity = 20/12.5—3 months

Abbott						
Carl Zeiss						
Alcon	0.0000					
Technolas						
Nidek						
Schwind						

Visual acuity = 20/10—3 months

Abbott						0.5000
Carl Zeiss						
Alcon						
Technolas						
Nidek						
Schwind						

Technolas excimer platform—20/16—69 %,[36] 20/20—88 %[34] (see *Figure 2*)
The Abbott platform was significantly superior to all the other platforms at acuity levels 20/12.5 and 20/16 (see *Table 2*).

Visual Acuity at 6 Months

Comparison of Platforms

The following data were recovered from the eligible articles:

Abbott excimer platform—20/20—88 %[8]
Alcon excimer platform—20/12.5—25 %,[35] 20/16—62 %,[9] 20/20—92 %[9]
Carl Zeiss excimer platform—20/20—93 %[37]
Nidek excimer platform—20/12.5—15 %,[21] 20/16—85 %,[21] 20/20—97 %[21]
Schwind excimer platform—20/12.5—3 %,[28] 20/16—65 %,[26] 20/20—98 %[26]
Technolas excimer platform—20/12.5—2 %,[31] 20/16—70 %,[36] 20/20—87 %[33]
(see *Figure 3*)

The Nidek platform was significantly superior to all the other platforms at acuity level 20/16 (see *Table 3*).

Figure 3: Visual Acuity—6 Month Comparison of Platforms

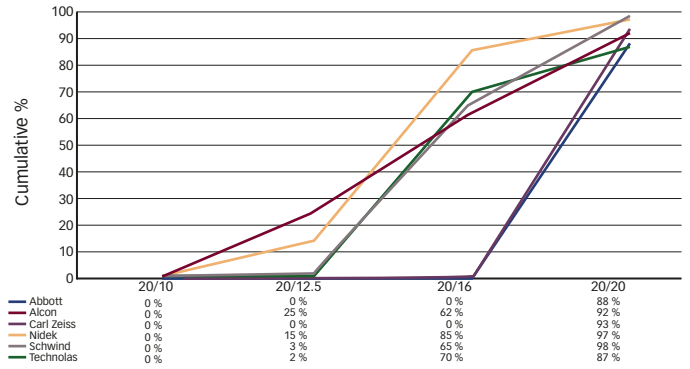

Figure 4: Visual Acuity—12 Month Comparison of Platforms

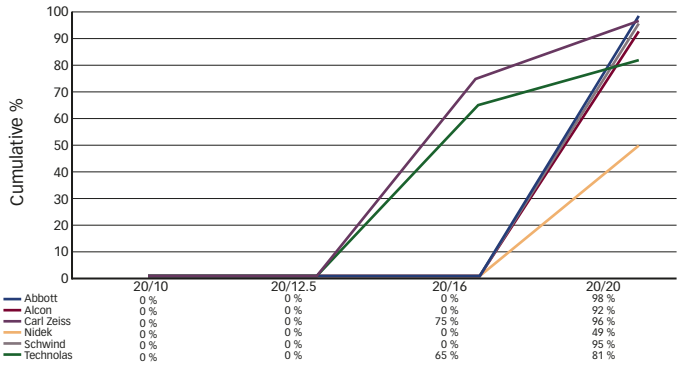

Table 3: Visual Acuity—6 Month p Values between Platforms

Visual acuity = 20/20—6 months

	Abbott	Carl Zeiss	Alcon	Technolas	Nidek	Schwind
Abbott		0.0692	0.2585		0.0607	0.0000
Carl Zeiss					0.1791	0.0007
Alcon		0.4108			0.1751	0.0142
Technolas	0.4185	0.0221	0.2058		0.0445	0.0000
Nidek						0.3449
Schwind						

Visual acuity = 20/16—6 months

Abbott						
Carl Zeiss						
Alcon				0.1584	0.0131	0.3615
Technolas					0.0291	
Nidek						
Schwind				0.1038	0.0085	

Visual acuity = 20/12.5—6 months

Abbott						
Carl Zeiss						
Alcon						
Technolas			0.0000		0.0010	0.3698
Nidek			0.0988			
Schwind			0.0035		0.0493	

Visual acuity = 20/10—6 months

Abbott						
Carl Zeiss						
Alcon						
Technolas						
Nidek						
Schwind						

Table 4: Visual Acuity—12 Month p Values between Platforms

Visual acuity = 20/20—12 months

	Abbott	Carl Zeiss	Alcon	Technolas	Nidek	Schwind
Abbott						
Carl Zeiss	0.1872					
Alcon	0.0567	0.1266				0.2784
Technolas	0.0004	0.0000	0.0831			0.0158
Nidek	0.0000	0.0000	0.0000	0.0001		0.0000
Schwind	0.1616	0.3622				

Visual acuity = 20/16—12 months

Abbott						
Carl Zeiss						
Alcon						
Technolas		0.1616				
Nidek						
Schwind						

Visual acuity = 20/12.5—12 months

Abbott						
Carl Zeiss						
Alcon						
Technolas						
Nidek						
Schwind						

Visual acuity = 20/10—12 months

Abbott						
Carl Zeiss						
Alcon						
Technolas						
Nidek						
Schwind						

Visual Acuity at 12 Months

Comparison of Platforms

The following data were recovered from the eligible articles:

Abbott excimer platform—20/20—98 %[38]
Alcon excimer platform—20/20—92 %[9]
Carl Zeiss excimer platform—20/16—75 %,[19] 20/20—96 %[13]
Nidek excimer platform—20/20—49 %[39]
Schwind excimer platform—20/20—95 %[29]
Technolas excimer platform—20/16—65 %,[32] 20/20—81 %[32] (see *Figure 4*).

No device was superior to all the other devices (see *Table 4*).

Refractive Accuracy at ± 0.5 Diopters

Comparison of Platforms

The following data were recovered from the eligible articles:

Abbott excimer platform—3 month—87 %,[38] 6 month—91 %,[8]

Figure 5: Refraction—± 0.5 Diopter Comparison of Platforms

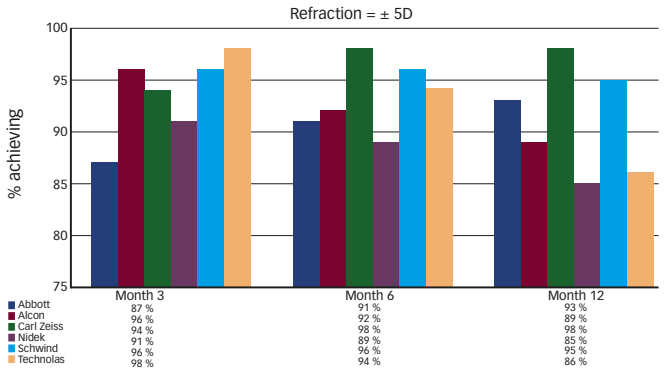

Figure 6: Refraction—± 1 Diopter Comparison of Platforms

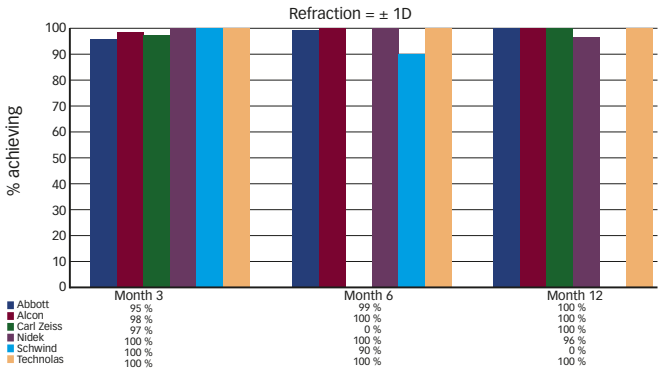

Table 5: Refraction—± 0.5 Diopter p Values between Platforms

	Abbott	Carl Zeiss	Alcon	Technolas	Nidek	Schwind
Refraction = ± 0.5 diopter—3 month						
Abbott		0.1266	0.0021	0.0000	0.0742	0.0019
Carl Zeiss			0.3095	0.0880		0.3088
Alcon				0.1314		
Technolas						
Nidek		0.2852	0.0356	0.0006		0.0340
Schwind			0.5000	0.1298		
Refraction = ± 0.5 diopter—6 month						
Abbott		0.0001	0.4294	0.2099	0.4395	0.0328
Carl Zeiss						
Alcon		0.0079		0.3318		0.1296
Technolas		0.0037				0.1788
Nidek		0.0005	0.4784	0.2690		0.0594
Schwind		0.0237				
Refraction = ± 0.5 diopter—12 month						
Abbott		0.1134				0.4085
Carl Zeiss						
Alcon	0.2325	0.0446				0.1920
Technolas	0.1117	0.0195	0.3482			0.0955
Nidek	0.0250	0.0076	0.2509	0.4335		0.0314
Schwind		0.1601				

Table 6: Refraction—± 1 Diopter p Values between Platforms

	Abbott	Carl Zeiss	Alcon	Technolas	Nidek	Schwind
Refraction = ± 1 diopter—3 month						
Abbott		0.3145	0.0596	0.0041	0.0002	0.0037
Carl Zeiss			0.3570	0.0214	0.0035	0.0199
Alcon				0.0485	0.0135	0.0461
Technolas					0.5000	0.5000
Nidek						
Schwind					0.5000	
Refraction = ± 1 diopter—6 month						
Abbott			0.2706	0.1210	0.2734	
Carl Zeiss						
Alcon				0.5000		
Technolas						
Nidek			0.5000	0.5000		
Schwind	0.0003		0.0245	0.0001	0.0261	
Refraction = ± 1 diopter—12 month						
Abbott						
Carl Zeiss	0.5000					
Alcon	0.5000	0.5000				
Technolas	0.5000	0.5000	0.5000			
Nidek	0.0294	0.0856	0.1074	0.1074		
Schwind						

12 month—93 %[38]
Alcon excimer platform—3 month—96 %,[10] 6 month—92 %,[9]
12 month—89 %[9]
Carl Zeiss excimer platform—3 month—94 %,[14] 6 month—98 %,[17]
12 month—98 %[19]
Nidek excimer platform—3 month—91 %,[22] 6 month—89 %,[21]
12 month—85 %[20]
Schwind excimer platform—3 month—96 %,[28] 6 month—96 %,[26]
12 month—95 %[29]
Technolas excimer platform—3 month—98 %,[11] 6 month—94 %,[31]
12 month—86 %[32] (see *Figure 5*)

The Carl Zeiss platform was superior to all the other platforms at 6 months (see *Table 5*)

Refractive Accuracy at ± 1.0 Diopters
Comparison of Platforms

The following data were recovered from the eligible articles:

Abbott excimer platform—3 month—95 %,[7] 6 month—99 %,[38]
12 month—100 %[38]
Alcon excimer platform—3 month—98 %,[11] 6 month—100 %,[9]
12 month—100 %[9]
Carl Zeiss excimer platform—3 month—97 %,[14] 6 month—no data,
12 month—100 %[19]
Nidek excimer platform—3 month—100 %,[22] 6 month—100 %,[21]
12 month—96 %[20]
Schwind excimer platform—3 month—100 %,[28] 6 month—90 %,[27]
12 month—no data

Technolas excimer platform—3 month—100 %,[34] 6 month—100 %,[31] 12 month—100 %[32] (see *Figure 6*).

No device was superior to all the other devices (see *Table 6*).

Adverse Event—Loss of Best Spectacle-corrected Visual Acuity >2 Lines

Comparison of Platforms

The following data were recovered from the eligible articles:

Abbott excimer platform—1 month—0 %,[6] 3 month—0.4 %,[6] 6 month—0 %,[38] 12 month—0 %[38]
Alcon excimer platform—1 month—0 %,[35] 3 month—0 %,[15] 6 month—0 %,[9] 12 month—0 %[9]
Carl Zeiss excimer platform—1 month—0.8 %,[37] 3 month—0 %,[14] 6 month—0.3 %,[37] 12 month—0 %[19]
Nidek excimer platform—1 month—1.5 %,[39] 3 month—0 %,[23] 6 month—0 %,[24] 12 month—0.7 %[39]
Schwind excimer platform—1 month—no data, 3 month—0.6 %,[26] 6 month—0 %,[26] 12 month—1.8 %[29]
Technolas excimer platform—1 month—1.5 %,[36] 3 month—1.2 %,[36] 6 month—0.6 %,[36] 12 month—3 %[32] (see *Figure 7*)

The Abbott and Alcon platforms were superior to all the other devices at the 1 month measurement. At all other time periods, no device was superior to any of the others (see *Table 7*). All devices remained below the 5 % FDA guidance figure.

Discussion

As with any meta-analysis, a legitimate criticism is that the different journal articles/studies reflect different study protocols with differing inclusion and exclusion criteria. Although this is a valid argument, there are several counterarguments. First of all, there are more similarities than dissimilarities when comparing these articles. Additionally, until the definitive prospective, randomized trial is conducted comparing all these available lasers, this is the best mechanism we have for comparing the currently available platforms. This article represents the current best compilation of data regarding the safety and accuracy of these six excimer platforms. Unfortunately, there are several examples where there are no data. Even after including FDA approval data, there are data gaps. This highlights the need for continuing phase IV studies with all of the platforms to fill in these data gaps. Because there is a meticulous referential database, each article can be obtained and read for its specifics allowing the reader to make a more detailed investigation and comparison. ■

Figure 7: Adverse Event Comparison of Platforms

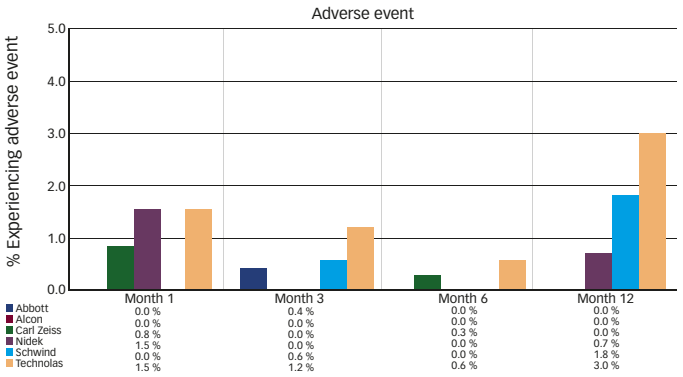

Table 7: Adverse Event p Values between Platforms

	Abbott	Carl Zeiss	Alcon	Technolas	Nidek	Schwind
Adverse event—1 month						
Abbott						
Carl Zeiss	0.5000		0.5000			
Alcon	0.5000					
Technolas	0.0024	0.1925	0.0484		0.5000	
Nidek	0.0024	0.1764	0.0483			
Schwind						
Adverse event—3 month						
Abbott		0.3600	0.1938		0.2632	
Carl Zeiss			0.5000		0.5000	
Alcon						
Technolas	0.0900	0.2666	0.0668		0.1355	0.0827
Nidek			0.5000			
Schwind	0.2848	0.3302	0.1447		0.2186	
Adverse event—6 month						
Abbott						0.5000
Carl Zeiss	0.1808		0.3693		0.2651	0.1550
Alcon	0.5000				0.5000	0.5000
Technolas	0.0983	0.2768	0.3183		0.1871	0.0754
Nidek	0.5000					0.5000
Schwind						
Adverse event—12 month						
Abbott		0.0871	0.1210	0.0533	0.3521	0.1442
Carl Zeiss			0.2867	0.2183		0.3048
Alcon				0.5000		
Technolas						
Nidek		0.2083	0.1829	0.1059		0.2060
Schwind			0.5000	0.5000		

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