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ACCURACY AND CONFIDENCE IN THE EVALUATION OF VAULT MEASUREMENTS IN SCLERAL LENSES: A COMPARATIVE STUDY OF NOVICE AND EXPERIENCED FITTERS UTILIZING A VAULT ESTIMATION GUIDE

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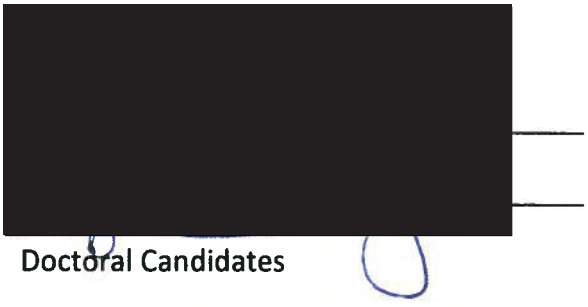

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by

Alyssa Spalding and Allison Middleton

Has been approved

May, 2013

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Alyssa Spalding and Allison Middleton

This paper is submitted in partial fulfillment of the
requirements for the degree of

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ABSTRACT

Name(s) of student(s): Allison Middleton & Alyssa Spalding

Names(s) of faculty advisor(s): Amy Dinardo, OD, MBA, FAAO

Date: April 25, 2013

Project Title: Accuracy and Confidence in the Evaluation of Vault Measurements in Scleral Lenses: A Comparative Study of Novice and Experienced Fitters Utilizing a Vault Estimation Guide

Background: *In hopes of increasing the number of scleral lens fits performed in practice, it is believed that the accuracy and confidence level of the fitter needs to be increased. The study attempted to determine the amount of accuracy and confidence that the utilization of a vault estimation guide can provide to a fitter.*

Methods: *The study was conducted through critical evaluation of the results of an online survey. 156 participants responded to the survey including both optometric students/novice scleral lens fitters and experienced scleral lens fitters. The first part of the survey included 4 photographs of scleral lens fits which the participant estimated the vaults of and rate their perceived confidence in that estimation. The second portion included 4 photographs to estimate vault, but also included a scleral lens vault measurement guide to utilize in their estimation of vault and confidence level. The photographs used in the survey are scleral lens fits that had vault measurements calculated by anterior segment OCT.*

Results: *Evaluation of the study determined and compared the overall accuracy and perceived confidence in both novice and experienced fitters with and without the guide, as well as a comparison of those values between the two groups of fitters. It will help determine the usefulness of the guide to increase confidence and accuracy in vault estimation of novice fitters. Variables in this study include the experience of the scleral lens fitter, the presence or absence of the scleral lens vault measurement guide and its usefulness in vault estimation, and the participant's confidence in estimating vault depth both with and without the guide. The collected data was analyzed with statistical software, and indicated statistically significant increases in many of the groups' accuracy and confidence ranking in evaluating scleral lens vault depth.*

Conclusions: *This study attempts to determine if a scleral fitting guide is useful in improving confidence and accuracy in fitters of all experience levels, especially novice fitters. In conclusion, a scleral lens fitting guide can improve both accuracy and confidence of scleral lens fittings in both novice and experienced fitters. Ultimately, this may encourage novice scleral lens fitters to increase the number of fits performed in practice by utilizing a scleral lens vault measurement guide.*

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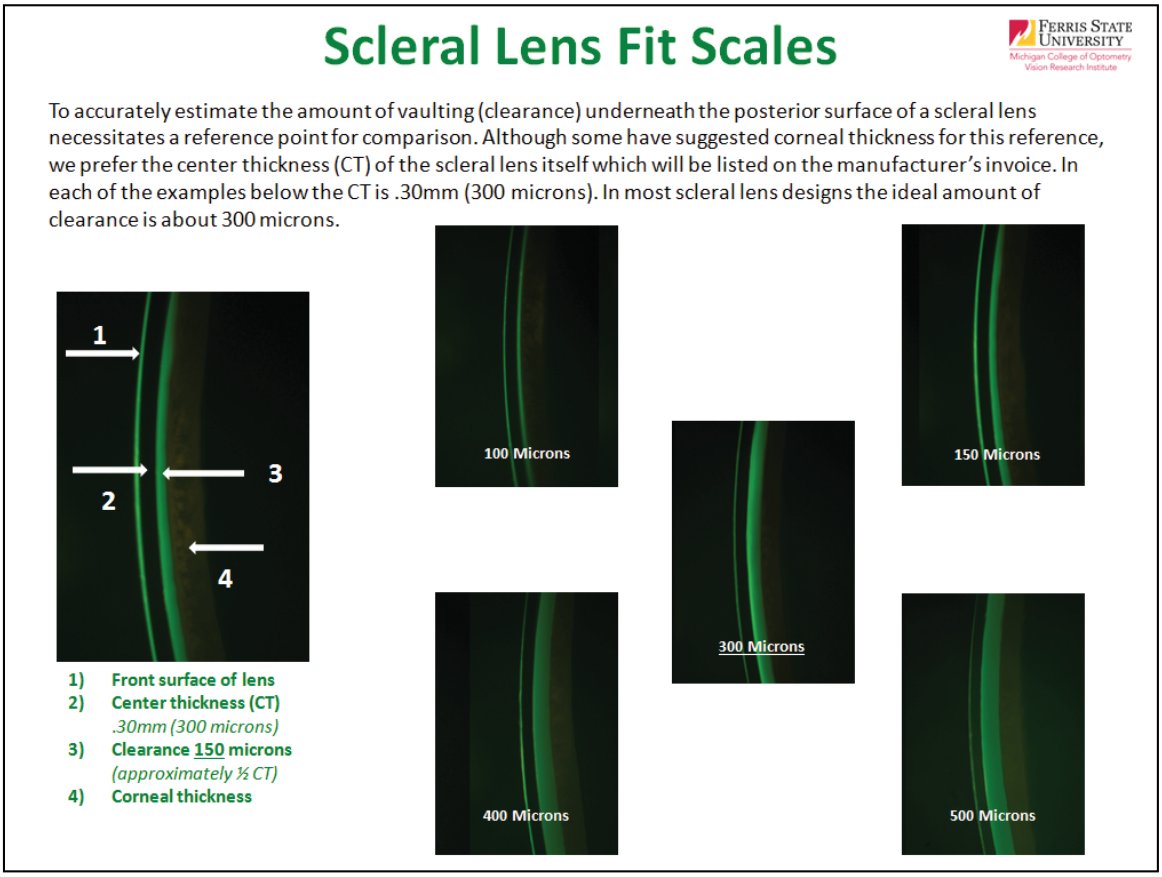
Figure 1 – The Michigan College of Optometry, Scleral Lens Central Vault Estimation Guide



TABLES

Table 1 - Demographics of participants

Demographics	n	%
current student	29	19%
1-5 years of practice	22	14%
6-10 years of practice	8	5%
11-15 years of practice	19	12%
16-20 years of practice	11	7%
21-25 years of practice	12	8%
>25 years of practice	55	35%
residency trained OD	47	31%
non-residency trained OD	76	76%
zero fits performed	24	24%
<50 fits performed	59	59%
>50 fits performed	74	74%

Table 2 - Confidence in estimating the central vault of a scleral lens fit

Comparing pre-guide confidence to post-guide between students and non-students, residents and non-residents, and all participants

Group	Pre-guide confidence			Post-guide confidence		% Change
	level	responses	percent	responses	percent	
student	not confident at all	17	15.32	5	4.63	-10.69
	somewhat confident	74	66.67	78	72.22	5.56
	extremely confident	20	18.02	25	23.15	5.13
non-student	not confident at all	57	11.90	7	1.51	-10.39
	somewhat confident	261	54.49	248	53.45	-1.04
	extremely confident	161	33.61	209	45.04	11.43
residency trained OD	not confident at all	16	8.51	2	1.06	-7.45
	somewhat confident	115	61.17	113	60.11	-1.06
	extremely confident	57	30.32	73	38.83	8.51
non-residency trained OD	not confident at all	58	15.03	10	2.72	-12.31
	somewhat confident	210	54.40	203	55.16	0.76
	extremely confident	118	30.57	155	42.12	11.55
all participants	not confident at all	74	12.37	12	2.07	-10.31
	somewhat confident	339	56.69	330	56.90	0.21
	extremely confident	185	30.94	238	41.03	10.10

Table 3 - Confidence in estimating the central vault of a scleral lens fit

Comparing pre-guide confidence to post-guide based on the number of fits performed

Group	Pre-guide confidence			Post-guide confidence		% Change
	level	responses	percent	responses	percent	
zero fits	not confident at all	38	43.18	5	6.17	-37.01
	somewhat confident	42	47.73	50	61.73	14.00
	extremely confident	8	9.09	26	32.10	23.01
< 50 fits	not confident at all	29	13.24	6	2.78	-10.46
	somewhat confident	152	69.41	144	66.67	-2.74
	extremely confident	38	17.35	66	30.56	13.20
>50 fits	not confident at all	7	2.44	1	0.36	-2.08
	somewhat confident	141	49.13	132	47.31	-1.82
	extremely confident	139	48.43	146	52.33	3.90

Table 4 - Confidence in estimating the central vault of a scleral lens fit

Comparing pre-guide confidence to post-guide based on number of years in practice

Group	Pre-guide confidence			Post-guide confidence		% Change
	level	responses	percent	responses	percent	
< 5 years in practice	not confident at all	4	4.82	2	2.50	-2.32
	somewhat confident	39	46.99	34	42.50	-4.49
	extremely confident	40	48.19	44	55.00	6.81
6 - 10 years in practice	not confident at all	0	0.00	0	0.00	0.00
	somewhat confident	24	75.00	26	81.25	6.25
	extremely confident	8	25.00	6	18.75	-6.25
11 - 15 years in practice	not confident at all	9	12.50	0	0.00	-12.50
	somewhat confident	56	77.78	54	75.00	-2.78
	extremely confident	7	9.72	18	25.00	15.28
16 - 20 years in practice	not confident at all	7	17.50	4	11.11	-6.39
	somewhat confident	14	35.00	11	30.56	-4.44
	extremely confident	19	47.50	21	58.33	10.83
21 - 25 years in practice	not confident at all	7	14.58	0	0.00	-14.58
	somewhat confident	36	75.00	32	69.57	-5.43
	extremely confident	5	10.42	14	30.43	20.02
> 25 years in practice	not confident at all	30	14.71	1	0.93	-13.78
	somewhat confident	92	45.10	91	84.26	39.16
	extremely confident	82	40.20	16	14.81	-25.38

Table 5 - Accuracy in estimating the central vault of a scleral lens fit

Comparing pre-guide accuracy to post-guide between students and non-students, residents and non-residents, and all participants

Group	Pre-guide accuracy			Post-guide accuracy		% Change
	accuracy	responses	percent	responses	percent	
student	correct	23	20.72	21	26.92	6.20
	incorrect	88	40.74	57	73.08	32.34
non-student	correct	128	26.89	202	43.16	16.27
	incorrect	348	87.88	266	56.84	-31.04
residency trained OD	correct	48	25.67	91	48.40	22.74
	incorrect	139	58.16	97	51.60	-6.56
non-residency trained OD	correct	100	26.04	156	41.94	15.89
	incorrect	284	93.11	216	58.06	-35.05
all participants	correct	151	25.38	255	43.66	18.29
	incorrect	444	94.47	329	56.34	-38.13

Table 6 - Accuracy in estimating the central vault of a scleral lens fit

Comparing pre-guide accuracy to post-guide based on the nummber of fits performed

Group	Pre-guide accuracy			Post-guide accuracy		% Change
	accuracy	responses	percent	responses	percent	
zero fits	correct	21	24.14	37	44.05	19.91
	incorrect	66	54.55	47	55.95	1.41
< 50 fits	correct	55	25.23	86	39.81	14.59
	incorrect	163	68.49	130	60.19	-8.30
> 50 fits	correct	75	26.22	131	46.79	20.56
	incorrect	211	58.29	149	53.21	-5.07

Table 7 - Accuracy in estimating the central vault of a scleral lens fit

Comparing pre-guide accuracy to post-guide based on number of years in practice

Group	Pre-guide accuracy			Post-guide accuracy		% Change
	accuracy	responses	percent	responses	percent	
< 5 years in practice	correct	26	31.33	44	55.00	23.67
	incorrect	57	89.06	36	45.00	-44.06
6 - 10 years in practice	correct	7	21.88	19	59.38	37.50
	incorrect	25	54.35	13	40.63	-13.72
11 - 15 years in practice	correct	21	29.17	30	41.67	12.50
	incorrect	51	83.61	42	58.33	-25.27
16 - 20 years in practice	correct	10	25.64	16	44.44	18.80
	incorrect	29	70.73	20	55.56	-15.18
21 - 25 years in practice	correct	12	25.00	18	37.50	12.50
	incorrect	36	40.91	30	62.50	21.59
> 25 years in practice	correct	52	25.74	75	37.50	11.76
	incorrect	150	100.00	125	62.50	-37.50

INTRODUCTION

It is widely known in the optometric profession that contact lenses are a viable option for many different types of patients. Not only are contact lenses good for patients concerned about aesthetics, level of physical activity, ease of use, and convenience, but they are often the only option for visual clarity, comfort and health in numerous ocular diseases and dysfunctions.

In the early years of contact lens usage, technology – as viewed today – was in its infancy. Even into the late 19th Century, contact lenses were made of blown-glass[1] and were similar to the design of current large-diameter scleral lenses. These lenses were developed to fully encase the corneal surface and reach out to the sclera. When a liquid tear film was present between the back surface of the lens and the front surface of the cornea, the patient's refractive error could be neutralized.[1,2] Unfortunately, the process of fitting these types of lenses was involved, time-consuming, expensive and hard to come by – as only highly trained and skilled individuals were able to perform fits.[1]

As technology increased in material development, glass was replaced by polymethylacrylate (PMMA) as the material of choice. PMMA's ability to be produced and machined more easily, allowed for better practitioner and patient access. Diagnostic fitting sets were developed and the ability to customize lenses with anterior segment impressions, molds, and lathe cutting continued to further the contact lens industry.[1] Lenses were able to be made smaller, and newer, oxygen-transmissible materials revolutionized the rigid gas permeable corneal lens. As soft hydrogel and silicone hydrogel materials were produced, the large diameter scleral lenses began to fall out of use – only saved for the most advanced and last resort fittings.[2]

Corneal ectasias and pathologies – such as keratoconus, pellucid marginal degeneration, irregular/high corneal astigmatism, excessive corneal scarring, graft and post refractive surgery complications, as well as exposure keratopathy and extreme dry eye – are all conditions that optometrists deal with on a fairly regular basis. To achieve acceptable vision and comfort, especially in patients exhibiting these corneal ectasias and keratopathies, large diameter rigid lenses are the best option available to neutralize the refractive error created by the irregular surface as well as provide for a microenvironment that can protect the corneal surface.[3,4] Benefits of scleral lenses also include minimal discomfort and ease in new wearers due to limited interaction between the lens edge and the lid margin, unlike in small corneal rigid lenses.

As the optometry profession is beginning to see increased value in fitting patients with corneal vaulting lenses, new technology concerning ease of fit, evaluation of fit, and design parameters is on an upswing. While research on the actual number of scleral lens fittings being performed across the profession is not readily available, there has been much attention to the fact that the process is making a comeback. Contact lens

conventions are now showcasing scleral lens improvements, knowledge, and fitting tools relating to scleral lenses than there has been before. The many new technologies and techniques that have been developed to aid the optometrist in fitting a patient with scleral lenses include new scleral lens designs and diagnostic fitting sets being developed for specialized use, anterior segment optical coherence tomography (OCT) utilization to choose a starting diagnostic lens as well as being able to see the real time interactions of the lens with the corneal surface, scleral surface and tear lens.[5] Unfortunately, some of the newest technology and techniques available to optometrists are often too expensive for purchase in some practices – challenges with fitting and evaluating patients still exist.[3]

While fitting of scleral lenses has been recently integrated into optometric contact lens curriculum, it is the thought of this study's authors that many new optometry graduates and novice practitioners lack the confidence in their judgment and accuracy in evaluating certain lens parameters. A number of relatively new practitioners have not received formal training on performing scleral lens fits. Of course technology such as anterior segment OCTs would help in their accuracy and confidence, but often access for these optometrists is extremely limited.[4] In an effort to increase the novice practitioner's confidence and accuracy in office, as well as assisting existing optometrists in the goal of increasing the prevalence of scleral lens fits and improving patient standard of care, the contact lens faculty and students of The Michigan College of Optometry, in conjunction with members of the Vision Research Institute, has developed a novel fitting guide. This fitting guide attempts to simplify the evaluation of one parameter often difficult to judge in a scleral lens fit – central corneal clearance, or vault.

Although there are many different scleral lens designs which lend their own characteristics in the mix, scleral lenses are generally fit by looking at four specific parameters. These parameters include the centration, central corneal clearance or vault, the landing zone and the lens edge.[1] Though each parameter is important to the overall fit and total success of a scleral lens, it is the vault of the lens that is the parameter which enables the scleral lens to perform in all its functions and benefits. Sterile saline is placed into the bowl of the lens and then the lens is applied to the eye. To create the tear lens or reservoir, the lens must rest on the sclera and vault over the cornea completely. The front aspect of the cornea should never touch the posterior aspect of the lens.[1,6,3] A clearance that is too thick can cause subpar vision, bubbles, and seal off of the lens, revealing a surrounding ring of conjunctival vessel blanching and discomfort. Too thin or too thick of a tear film can cause a decrease in oxygen transmission, leading to possible compromise of the cornea.[4] A study performed by Sonsino and Mathe, indicated that there is a large, acceptable range of central clearance in a scleral lens. Successful fits, based on 1 month or more of comfortable wear with acceptable visual acuities, averaged 380µm [+/-110µm] of central clearance [using a customized, Jupiter scleral contact lenses that had diameters of 18.2 mm or greater].[4] This result is essentially in line with the conventional practice of aiming for a central vault clearance goal of 200-300µm, post lens-settling.[1,7]

There are numerous techniques to estimating and measuring the central vault of a scleral lens fit. Among these include evaluating the fluorescein brightness and reactivity level, comparison of the tear lens with the patient's cornea thickness, comparison between the tear lens thickness and the calibrated central thickness of the lens (fitting sets include these parameters), as well as measuring the tear lens thickness directly by anterior segment optical coherence tomography[4]. With exception of directly measuring the thickness by OCT, all of these techniques are very subjective and can reveal varying estimates between optometrists and at times may be completely inaccurate.

The Michigan College of Optometry, Scleral Lens Central Vault Estimation Guide, was developed to be used in a clinical setting to help practitioners compare a patient's resulting scleral lens central clearance to an accurate representation. The main goal of this study is to determine the effectiveness of the new pictorial guide on novice and experienced scleral lens fitters' accuracy in evaluating and estimating the central clearance, as well as measuring the perceived confidence in the estimation before and after use of the fitting guide. It is the hope that in each group, the guideline will improve both variables.

METHODS

156 people participated in this study. Each participant completed a survey consisting of 20 questions. Two variables were assessed by the survey; the confidence and accuracy of the participant in evaluating a central vault clearance, both before and after being introduced to a fitting guide. The first four questions of the survey inquired about the background of the participants including: location, school attended, years in practice (with a current student option), residency training, and approximate number of scleral lens fits performed. [A summary of responses to these background questions can be found in tables and graphs section] The participants were then shown four, two-dimensional photographs depicting an optic section view of a scleral lens fit. Multiple choice options were given to the participant to estimate the vault depth shown in the photograph, as well as a perceived confidence scale to rate their answer. Midway through the survey, the participants were instructed to review the Michigan College of Optometry Scleral Lens Fit Scales guide [See List of tables/images]. The guide broke down the four components included in the images: front surface of lens, center thickness of lens, clearance/tear film, and corneal thickness. The guide then showed five images of different vault depths and instructed participants on how to use the central lens thickness as a reference point to estimate vault depth. Four more photographs were shown after the fitting guide. Participants were again asked to estimate vault depth and rate their level of confidence after having reviewed the fitting guide.

The two-dimensional photographs included in the study were obtained using a Haag-Streit slit lamp with an IM900 camera and EyeCap v5 imaging capture system at the Michigan College of Optometry. Exact vault depths were determined using a Zeiss Visante

anterior segment OCT. A chi-squared analysis was used to analyze the responses of the survey.

RESULTS

The 156 participants were broken down for comparison three different ways: 1) years in practice 2) residency versus non-residency trained and 3) number of scleral lens fits the participant has performed. 47 participants were residency trained while 76 were not. Of those who revealed what their residency training included, 13 participants responded that they were trained in contact lenses, 2 in pediatrics, and 2 in primary care. Of the participants, 24 had performed zero scleral lens fits, 59 had performed less than 50 fits, and 74 had performed greater than 50 fits.

First we will look at confidence before and after the fitting guide was exposed. "Pre" will refer to questions answered prior to the fitting guide being introduced, and "post" will refer to questions answered after the fitting guide was introduced.

Overall, responses of "not confident at all" decreased from 12.4% pre to 2% post; somewhat confident stayed approximately the same at 56.6% pre and 56.8% post, while responses of "very confident" increased from 30.9% pre to 41% post. For the entire group, confidence was shown to have increased by a statistically significant amount, $p<0.5$.

In the non-student group, 11.8% of the participants, pre-guide, responded as "not confident at all", compared to 1.5% of responses post-guide responding as "not confident at all". "Very confident" responses increased from 33.6% pre to 45% post in non-students. "Not confident at all" responses decreased from 15.3% pre to 4.6% post and "very confident" responses increased from 18% pre to 23% post. In the current student group, "not confident at all" responses decreased from 15.3% pre to 4.8% post. "Somewhat confident" responses increased from 66.7% to 72% post guide. Responses of "very confident" increased from 18% pre to 23.1% post. These percentages reveal that both students and non-students' confidence was increased by a statistically significant amount by using the fitting guide; however students confidence did not increase as much as non-students. This could be due to a lack of formal training on scleral lens fitting in the non-student group. In the residency trained group, "not confident at all" responses decreased from 8.5% pre to 1% post, and "very confident" increased from 30.3% pre to 38.8% post. Non-residency trained responses to "not confident at all" decreased from 15% pre to 2.7% post, and "very confident" increased from 30.6% pre to 51.7% post. There was essentially no change in the "somewhat confident" responses pre and post fitting guide in residents and non-residents.

In people who had performed zero scleral lens fits, "not confident at all" responses decreased from 43% pre to 6% post. The zero fit groups' "very confident" responses increased from 9% pre to 32% post. In the less than 50 fittings group, "not confident"

responses decreased from 13.2% pre to 2.7% post, and "very confident" increased from 17.4% pre to 30.6% post. In the group who had performed 50 or greater fits, "not confident" responses decreased from 2.4% pre to .04% post. "Very confident" responses in this group increased from 48.4% pre to 52.3% post. The "somewhat confident" responses remained approximately the same in all of the groups above both pre and post.

In all of the groups analyzed, confidence increased by a statistically significant amount. The groups that increased the least in confidence were students, residency trained optometrists, and those with 50 or greater fits which likely correlates with either formal training, experience, or both. Three other groups that did not show increased confidence by a statistically significant amount were those who had been practicing less than 5 years, 6-10 years, and 16-20 years (11-15 years did increase by a significant amount but not as high of an amount as some other groups and could be considered an outlier.) In comparison, students and those practicing greater than 20 years increased statistically. A few reasons for this could also be either formal training and used to utilizing/seeing guides, experience, or both.

While all groups increased in confidence, this does not necessarily correlate with overall accuracy. Only 40% of responses of "very confident" had correct vault estimations.

In terms of accuracy, all groups analyzed increased in accuracy by a statistically significant amount except the number of responses "not confident at all." This is likely because so few answered not confident post-fitting guide; 73 responses pre and 12 post (27% correct pre and 25% correct post.) Overall, there were a large percentage of incorrect answers pre-fitting guide; 444 responses were incorrect out of 595 total responses, or 74.6%. Post-fitting guide there were 329 incorrect responses out of 584 total, or 56.3% incorrect. Incorrect responses did improve/decrease post-fitting guide, however over half of the possible responses were still incorrect.

Non-students answered 73% of questions incorrectly pre, and decreased to 56.8% incorrect post. Students answered 79.2% incorrect pre and 52.7% incorrect post. Participants with residency training answered 74% incorrect pre and 58% incorrect post. Residency trained participants answered 74.3% incorrect pre and 51.5% incorrect post. Participants with zero fits answered 75.8% incorrect pre and 56% incorrect post. Those with less than 50 fits answered 74.8% incorrect pre and 60% incorrect post. Participants who had experience of 50 or greater fits answered, 73.8% incorrect pre and 53.2% incorrect post. Regardless of time in practice, number of fits, residency training, or student status all groups increased in accuracy by a statistically significant amount.

DISCUSSION

Overall there was a good number of responses to the survey, and a good representation of each experience level on the spectrum from extremely novice to expert scleral lens fitters.

As discussed above, the majority of groups (11 of the 14 groups or 80%) surveyed had an increased level of confidence in their central vault estimation. All of the groups increased in accuracy by a statistically significant amount. The conclusion that can be made is that a standardized scleral lens fitting guide can indeed be an asset to scleral lens fitters of all experience levels. While this guide only accounts for one aspect of the scleral lens fitting process, it is shown to improve the evaluation of that aspect. This may, in turn, lead to more practitioners being more comfortable with the scleral lens fit evaluation, and more likely to fit scleral lenses. This may increase the number of patients that can benefit from a scleral lens fit based on corneal health, refractive error, dry eye, etc and patient satisfaction in their optometrist and care.

A downside to this study was observed. While both confidence and accuracy did increase, they do not necessarily correlate. Accuracy did increase in all groups; however participants went from getting an average of approximately 75% of responses incorrect before utilizing the fitting guide to 55.5% incorrect after utilizing the fitting guide. Over half of all responses were still inaccurate and incorrect after utilizing a fitting guide. This brings up one downfall of the study, which is that the study was completed with 2-dimensional photographs as opposed to 3-dimensional videos or actually assessing a fit on a real patient in a clinical situation. It also only covered one aspect of the fitting process – the central corneal vault. This study reveals very promising for the usefulness and practicality of these types of fitting guides in the optometric profession. Based on the positive results found in this study, it is likely that more fitting guides – depicting other aspects of scleral contact lenses fits – will be developed for the use of optometrists in practice. It would also be interesting to test different types of guide media such as video guides or 3-D imaging to determine if accuracy can be achieved to a greater degree than the simple 2-D guide available now.

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