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Eugene Balogh
Pacific University

Eric Bohjanen
Pacific University

Michael Mavencamp
Pacific University

Brannon Mills
Pacific University

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Abstract

Two different procedures involved in the proper fitting of orthokeratology lenses were compared to one another to assess whether one technique was superior overall in determining the fit and function of the contact lens. The two procedures compared were the use of Paragon CRT software with the Humphrey's Corneal Atlas Topographer versus the use of the Slide Rule Method (SRM). The parameters used to determine superior fit and function included the evaluation of centration, treatment zone, edge lift, and lens movement as determined by each technique. These evaluations were then combined to tabulate a final score for each fitting technique. The CRT software method was awarded a superior total fit score one-third of the time, the slide rule method was awarded a superior total fit score one-third of the time, and the two methods were awarded an equal total fit score one-third of the time. The results of the study showed that neither technique was overall superior to the other in its ability to ascertain a best fit lens for the patient.

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ASSESSING THE EFFECTIVENESS OF FITTING PARAGON CRT LENSES WITH THE AID OF HUMPHREY'S CORNEAL ATLAS TOPOGRAPHER VERSUS THE SLIDE RULE METHOD

By

EUGENE BALOGH

ERIC BOHJANEN

MICHAEL MAVENCAMP

BRANNON MILLS

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Advisor:

Patrick Caroline

EUGENE BALOGH

ERIC BOHJANEN

MICHAEL MAVENCAMP

BRANNON MILLS

PATRICK CAROLINE

BIOGRAPHIES

Eugene Balogh graduated from the University of California at Davis earning a bachelors degree in Biology. Upon completion of his B.S., he earned a teaching credential from Humbolt State University. He worked as an elementary school teacher in the Willits Unified School District for two years while teaching second and third grade. He is currently completing his fourth and final year of professional study at Pacific University College of Optometry. While attending Pacific University, Eugene has been an active member of Amigos Eyecare. While with Amigos he has participated in local vision screenings and fundraising activities, and has served as an equipment organizer for a non-profit charitable mission to El Salvador. Eugene plans to practice primary care optometry in a private partnership setting following graduation in 2005.

Eric Bohjanen graduated from the University of Michigan with a B.S. in Biology. He is currently a fourth year optometric intern with Pacific University College of Optometry, and is on schedule to graduate in May 2005. While attending Pacific University he has held positions such as Vice President of Amigos (a non-profit charitable eyecare organization) and Class Representative for the National Optometric Student Association (NOSA). He has organized several school sponsored vision screenings, and been a student leader on an Amigos mission to El Salvador. Eric hopes to pursue a career in optometry in a private partnership setting where is able to provide quality primary care.

Michael Mavencamp graduated from Saint Mary's University in Texas with a B.S. in Biology. He is currently completing his fourth and final year in the Pacific University College of Optometry program. While at Pacific University he has been the optometry representative to the Disciplinary Committee for Graduate Schools, a member of the charitable eyecare group Amigos, and a member of the Sports Vision Club. Upon graduation in May of 2005, Michael plans to practice primary care optometry in his home state of Alaska.

Brannon Mills graduated with honors from Biola University in Southern California earning a B.A. in History. Upon completion of his undergraduate degree, he returned home to Southern Oregon where he worked in the timber industry, and continued his education in the human sciences in order to attend a health profession school. He is currently a fourth year Optometric Physician Intern in Pacific University's College of Optometry and plans to graduate May 2005. While at Pacific University he was a member of Amigos Eyecare, Oregon Optometric Physician Association, American Optometric Student Association, Pacific University Sports Vision Club, and American Optometric Association's Political Action Committee. Brannon intends to practice primary care optometry in a rural, private partnership setting in his home state of Oregon.

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ABSTRACT

Two different procedures involved in the proper fitting of orthokeratology lenses were compared to one another to assess whether one technique was superior overall in determining the fit and function of the contact lens. The two procedures compared were the use of Paragon CRT software with the Humphrey's Corneal Atlas Topographer versus the use of the Slide Rule Method (SRM). The parameters used to determine superior fit and function included the evaluation of centration, treatment zone, edge lift, and lens movement as determined by each technique. These evaluations were then combined to tabulate a final score for each fitting technique. The CRT software method was awarded a superior total fit score one-third of the time, the slide rule method was awarded a superior total fit score one-third of the time, and the two methods were awarded an equal total fit score one-third of the time. The results of the study showed that neither technique was overall superior to the other in its ability to ascertain a best fit lens for the patient.

ETHICS

This study followed protocol as reviewed by the Internal Review Board of Pacific University College of Optometry. All patients received, agreed to, and signed a consent form the same as contained herein. These procedures were in accordance with the ethical standards of the responsible committee on human experimentation and with the Helsinki Declaration of 1975, revised 1983. All protected patient information is confidential, and no animals were harmed before, during, or after the completion of this study.

INTRODUCTION

Orthokeratology (Ortho-K) is a non-surgical alternative to the reshaping of the cornea of the eye through the use of contact lenses. Ortho-K is currently effective in reducing and/or eliminating the refractive error of myopic (nearsighted) patients by effectively flattening the cornea. This flattening of the cornea allows for the reduction of focusing power of the eye and a shift toward ernmetropia (an eye that needs no corrective lenses for best vision). The contact lens gets its effectiveness using technology known as reverse geometry. This contact lens is worn each night (or during the patients normal sleeping hours), and then removed upon awakening. After the lens is removed the cornea retains its renewed shape for most, if not all, of the day (or waking hours). This retention of the renewed corneal shape allows the patient best vision without wearing a refractive correction. If the reshaping contact lens is not worn at night for any significant length of time, the cornea will return to its original pre-therapy configuration. Therefore, two advantages of this system are exposed: the ability to have best vision during waking hours without wearing a refractive correction; and, unlike permanent refractive sugeries, this procedure is completely reversible without permanent effect on the cornea or vision.

With the advent of any new surgical or non-surgical medical technique comes the arrival of learned and established protocol and the variability of said protocol to achieve the desired result using the technique. While these variabilities of protocol are generally similar, they can vary according to the individual performing the technique and/or the company developing the technology to perform the procedure. This is true for the application of Orthokeratology. These variations in protocol are the focus of this study and corresponding write-up. Which of the two primarily used fitting techniques for Orthokeratology is most effective in determining the best fit lens for treatment of a given patient?

The current gold standard for determining the best fit lens for Orthokeratology is assessing, through trial and error, the best flourescein pattern on the eye after lens insertion. However, this method is too time consuming to be of any practical use in a clinical setting. In an attempt to make the fitting of Ortho-K lenses more efficient, different techniques have been established. Of the techniques available, there are two that have gained widespread use and notoriety. They are the use of CRT software in conjunction with a Humphrey's Corneal Atlas Topographer or the use of the Slide Rule Method (SRM). This study seeks to compare the two techniques by assessing their ability to predict centration, treatment zone, edge lift, and lens movement. Thereby providing the practitioner with the ability to chose the most effective method of Ortho-K fitting technique for the patient.

MATERIALS AND METHODS

The participants were optometry students of Pacific University College of Optometry between 20 and 30 years of age. Roughly half of the participants were male and half were female. None of the participants had any from of ocular disease, dystrophies, trauma, or any other corneal disorders. The study consisted of 20 participants. All of the participants were chosen based on refractive error ranging from -1.00D to -6.00D of myopia. Anyone with cylinder >1.00D was eliminated from the study. Anyone with a corneal diameter greater than 12mm was eliminated from the study due to a high degree of difficulty fitting such subjects with the current CRT lenses.

The experimental setup began with a brief case history given to each subject. Each subject was asked to give their most current spectacle refraction. Since all participants were optometry students we felt that a verbal response to this question would be accurate and sufficiently current. All subjects responded that their most current refractions were no more than 6 months old. We also asked the subjects if they had any corneal problems currently or in the past. We specifically asked about corneal dystrophies, trauma, and laser surgeries. No subjects were found to have any of the aforementioned. We then asked the subjects if they had any allergic reactions to medications. This question was relevant to instillation of topical anesthetic they would later receive. All responses were negative.

Next we took three topographical maps of the central cornea in one eye only, using the Humphrey's Atlas™ Corneal Topographer. Prior to the measurements, one drop of

Refresh Liquitears™ was instilled to reduce distortions in our topography results. One eye was chosen arbitrarily. We felt that one eye, and not both, would be appropriate for testing because many subjects would have too much symmetry between the two eyes and therefore confound our results. Once we obtained the three topographical maps, we analyzed them using two different criteria to choose the best map of the three. The first criterion was the quality of the image. Any breaks or distortions varying from the other maps would not be used. The second criterion was the simulated keratometry values. Any map with inconsistent keratometry values relative to the other two would not be used. If there was too much variation between all three maps, then we took three new topographical maps and reassessed them using the same criteria.

After choosing a reasonable topographical map, we used this map to obtain the appropriate Paragon™ CRT diagnostic lens employing two different methods.

Method 1: Slide-rule-method

From the simulated keratometry readings of the best selected topography map, we used the flat K value together with the subject's refractive error to find the proper lens parameters based on Paragon's™ slide rule.

Method 2: Paragon™ CRT Software method

From the best selected topography map, we used the Paragon™ CRT Software to translate the topographical image into the best fitting lens parameters. The software program also takes into account the subject's refractive error. All fitting parameters are based on axial maps.

Once the lenses were determined, we fit the subjects with our respective CRT diagnostic lenses from Paragon's™ fitting set. The fitting order between method 1 and method 2 was randomized for later review. All fittings were initiated with the instillation of the topical anesthetic 0.5% Proparicaine Hydrochloride Opthalmic Solution to the appropriate eye being fit. This was done to increase patient comfort during the fitting process. All lenses were disinfected with Boston™ RGP conditioning and cleaning solution prior to fitting. Once the CRT lens was placed on the eye, we waited 4-5 minutes for the lens to stabilize. After stabilization, a saline-moistened Flourescein strip was instilled to the upper conjunctiva while the subject maintained a downward gaze. The subject was positioned properly in a biomicroscope with a blue light to enhance the flourescein pattern. Room lights were dimmed. Each trial lens cap was recorded for later reference. The subject was then video recorded for 8 minutes using a slit lamp camera. While the subject was being recorded, they were asked to blink several times, look left and right, and the upper lid was held superiorly to allow proper assessment without lid interaction. Our goal was to not only assess stability, but simulate the closed eye environment which should have minimal blinking lid interactions. After recording was finished, we removed the diagnostic lens and let the patient relax for five minutes while we disinfected the lenses. We repeated these procedures for each lens fit. This project was testing for best initial fit and so no lenses were dispensed to any subjects.

After we had completed 20 subjects successfully, we analyzed the recordings of each fitting using a four parameter grading system. Two of the recordings were thrown out due to poor or incomplete recordings and this left us with a total of 18 useable subjects for analysis (36 contact lens fits). All recordings were analyzed by an assessment team of three. It's important to note here that though all trial lens caps were recorded for reference, the assessment team would not be aware of which method was used to choose the diagnostic lens being assessed. The assessment team used four parameters for grading the fit: 1) Centration 2) Treatment zone 3) Edge Lift and 4) Movement. Together, all parameters and their respective grades would add up to a total fitting score for each fit.

Centration: We graded this on a scale of 1-10. (Note: the other three were graded on a scale of 1-5) We felt that centration had the most impact on overall fit and so the grading would have to reflect that impact on total fitting score. A grade of 10 meant perfect centration with equal limbus to contact lens edge distance temporally and nasally as well as superiorly and inferiorly. A grade of 1 meant >4mm of decentration in any one direction. All grades in between followed 0.5mm increments of decentration.

Treatment Zone (TZ): We graded this on a scale of 1-5. A grade of 5 meant >4mm TZ indicated by the bull's eye pattern in the flourescein stain. A grade of 1 meant no TZ. Grades 2-4 are as follows: grade 2 = 1mm TZ, grade 3 = 2mm TZ, grade 4 = 3mm TZ.

Edge Lift (EL): We graded this on a scale of 1-5. A grade of 5 meant perfect edge lift with a bright 0.5 - 1 mm band running 360" around the edge of the contact lens. A grade of 1 meant no edge lift anywhere around the contact lens. Grade 2 meant some places of edge lift around the contact lens. Grade 3 meant at least half of the contact lens had edge lift. Grade 4 meant that there was three fourths of the contact lens with edge lift or complete edge lift around the contact lens but it was diminished.

Movement: We graded this on a scale of 1-5. A grade of 5 meant that there was 0.5mm of movement on blink. A grade of 1 meant that there was either no movement indicating that the contact lens was too tight, or that there was excessive movement > 4mm on blink. Grade 2 meant 3-4mm of movement. Grade 3 meant 2-3mm of movement. Grade 4 meant 1-2mm of movement.

Once each fitting was graded, a total fitting score could be obtained by adding the individual grades of each fit. The highest fitting score possible was a score of 25. In this way, we could assess not only how each fitting method compared in each parameter, but also to get an overall fitting comparison.

RESULTS

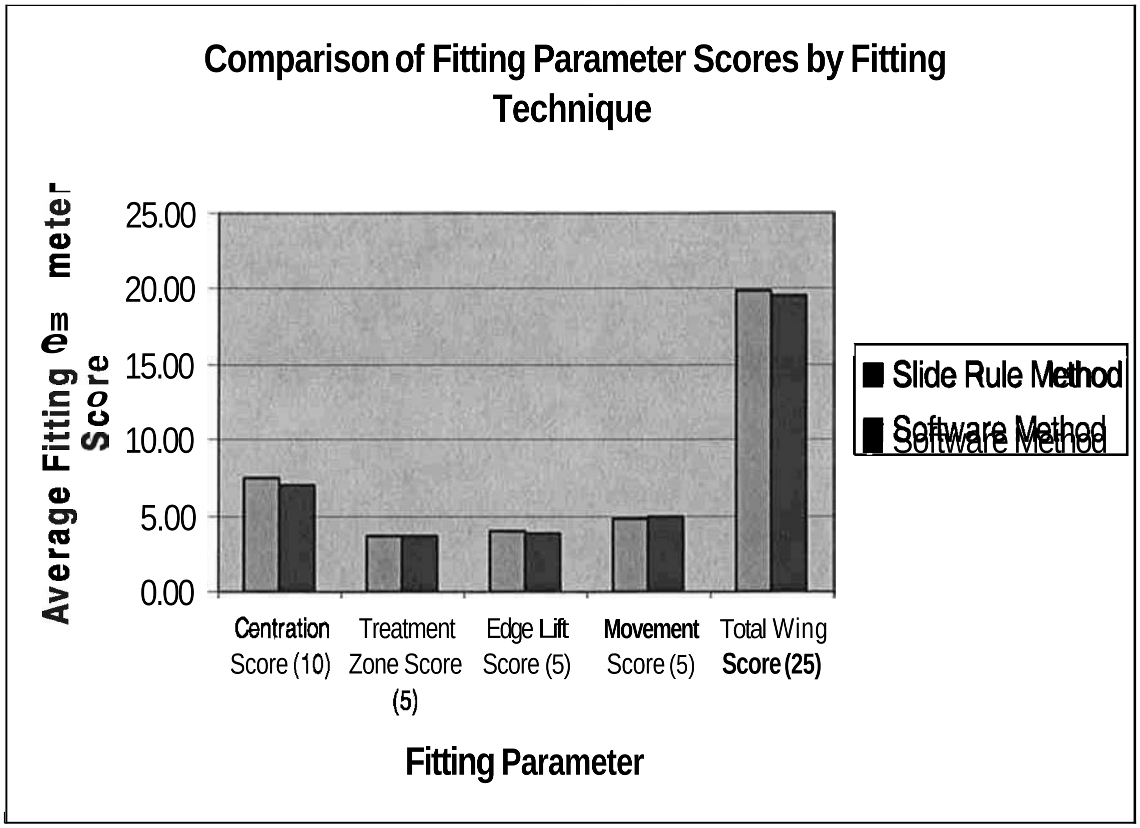

Figure 1

Figure 1 shows a comparison of average fitting scores by fitting technique and the maximum value possible for each category. For the first fitting parameter, lens centration, the slide rule fitting method produced an average score of 7.50 and the software method produced an average score of 7.06. Treatment zone scores were 3.61 by the slide rule method and 3.72 by the software method. Edge lift scores were 4.06 by the slide rule method and 3.89 by the software method. The slide rule method produced a movement score of 4.78 while the software method produced a movement score of 4.89. The total fitting scores are as follows, 19.94 for the slide rule method and 19.56 for the software method.

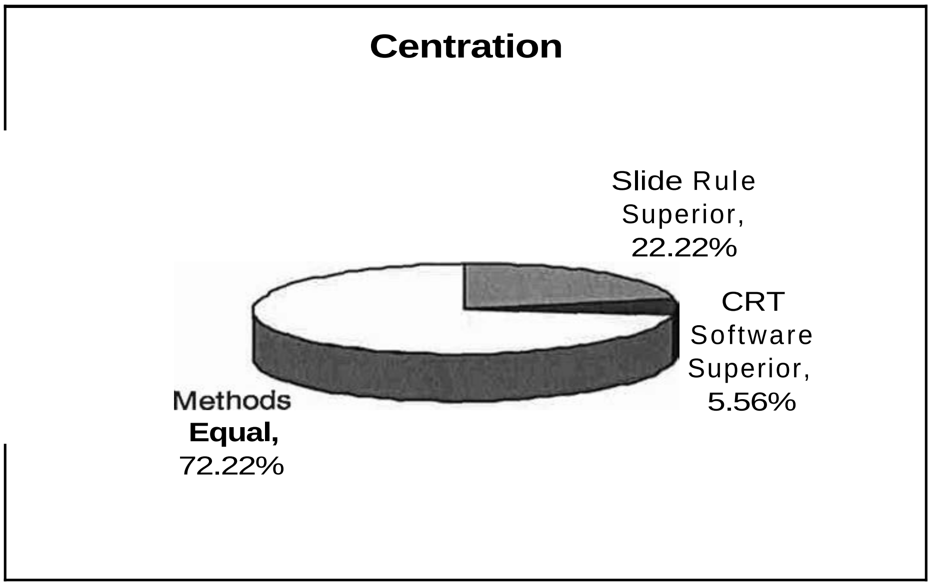

Figure 2

Figure 2 displays the frequency of time that each fitting method produced superior centration. The majority of the time (72.22%) the fitting methods were subjectively equal. 22.22% of the time the slide rule produced superior lens centration, and 5.56% of the time the software produced superior lens centration.

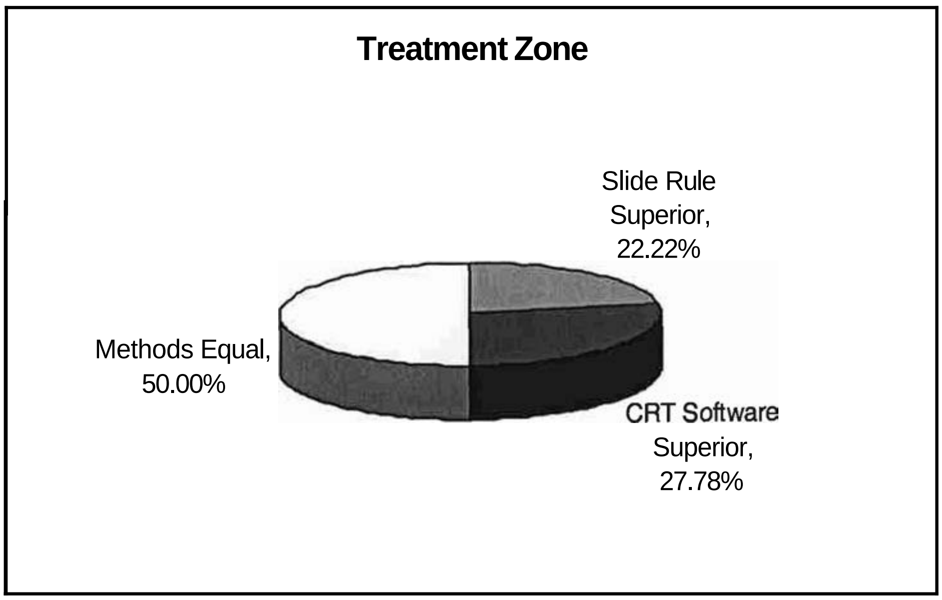

Figure 3

Figure 3 shows the percentage of the time that each method produced superior treatment zone. The slide rule and software methods were equal 50% of the time. The software was superior 27.78% of the time and the slide rule method resulted in superior treatment zone 22.22% of the time.

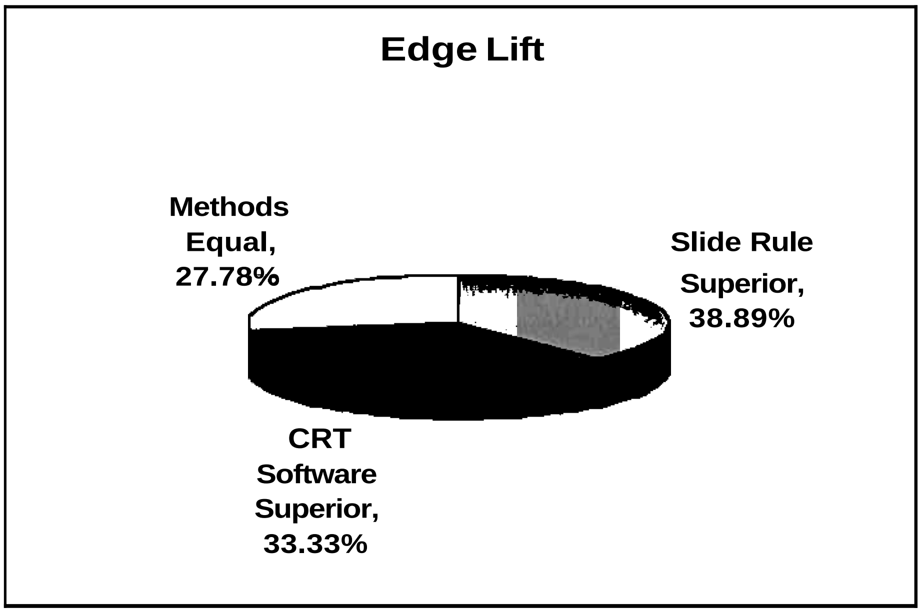

Figure 4

Figure 4 illustrates the percentage of the time that the fitting methods produce superior edge lift characteristics. The methods produced equal edge lift scores 27.78% of the time. The slide rule method produced superior results 38.89% of the time. The software fitting method resulted in superior edge lift 33.33% of the time.

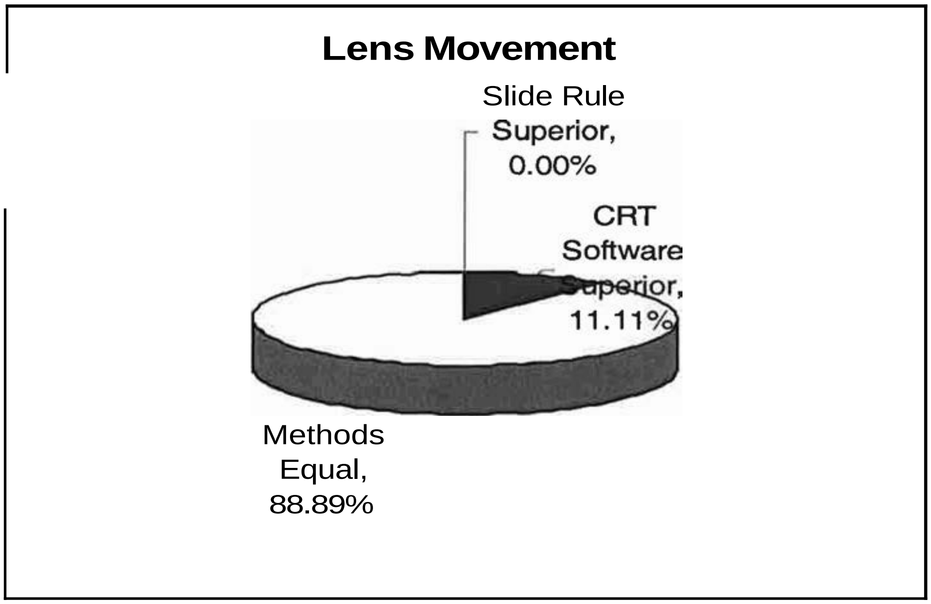

Figure 5

Figure 5 presents the percentage of time that each fitting method produced superior lens movment characteristics. The two fitting methods were produced equal lens movment scores 88.89% of the time. The fitting software was superior in this respect 11.11% of the time. The slide rule did not produce a superior lens movement score in our fitting trials.

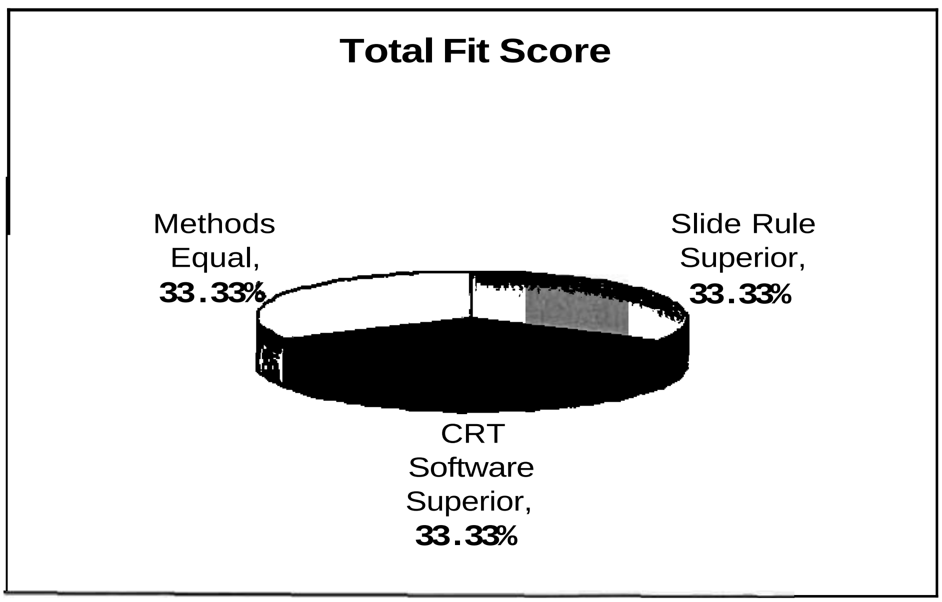

Figure 6

Figure 6 displays the percentage sf the time that each fitting method produced a superior total fit score. The methods were equal 33.33% of the time. The slide rule method was superior 33.33% of the time and the software fitting method was superior 33.33% of the time.

DISCUSSION

The primary goal of this study was to investigate and determine which of the two generally accepted methods of fitting orthokeratology contact lenses was more objectively accurate and reliable. As evidenced by the research presented herein, the two methods have shown themselves to be effectively equal overall. Fitting with the aid of the Paragon CRT software and Humphrey's Atlas Corneal Topographer has been shown to be slightly advantageous in the areas of superior treatment zones and superior lens movement; while fitting the orthokeratology lenses by the typical empirical method of slide-rule has proven slightly more effective in the areas superior centration and superior edge lift. Although these two methods each showed small superiorities in two of four arenas, neither method was able to prove itself more accurate and reliable than the other. The obvious conclusion from this study is that neither method shows objective superiority; and, therefore, the practitioner is free to choose which method he/she subjectively prefers to implement in the treatment of patients with orthokeratology.

Further research could be completed on this subject with a larger sample size of patients. It would be interesting to discover if the same tendencies were revealed between the two methods in a study population of one hundred or more. That information and evidence would likely give the practitioner further confidence as to which method to implement in clinical practice. Another clinically useful point of further investigation would be to divide the patients on the basis of flatter (<44 diopters) versus steeper (>44 diopters) corneas, and make an effort to determine which, if either, of the two aforementioned methods was superior for that given parameter (flatter or steeper cornea).