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The short-term effects of PMMA and RGP contact lens wear on keratometric behaviour: a pilot study*

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Abstract

This article represents the preliminary findings of a larger study that included 24 subjects that were equally divided into three groups, namely, the PMMA (polymethyl methacrylate) group, the RGP (rigid gas permeable) group and the control group. The aim of this study was to establish the short-term effects (if any) of PMMA and RGP contact lens wear on keratometric behaviour. A control subject was also included in the study to establish a reference for normal diurnal changes in keratometric behaviour. Fifty successive auto-keratometric measurements were taken before and immediately after three hours of rigid contact lens wear for the first subject in the PMMA group and the first subject in the RGP group (experimental samples). Fifty successive auto-keratometric measurements were also taken on the first subject of the control group before and immediately after three hours of no lens wear (control sample). Data collected were analysed using multivariate statistical methods that in the past have been used infrequently in this area of study. This investigation revealed that, at least in these two randomly selected subjects, rigid contact lens wear appears to influence keratometric behaviour (PMMA contact lenses more so than RGP contact lenses). (*S Afr Optom* 2010 **69**(4) 173-181)

Introduction

Placing a contact lens onto the cornea is an invasive procedure inducing pressure on the corneal surface. The contact lens is a foreign body, hence, it is expected that the eye could react in some way. Literature has revealed that the general reactions of the eye to contact lens wear include initial tearing, alteration of the tear layer, corneal oedema and acidosis due to reduced oxygen transmission, topographical changes and so on[1-4]. Most of these changes are transient and disappear with adaptation. What exactly occurs under a contact lens remains an enigma which contact lens researchers have strived to uncover over the past century.

Contact lenses either completely or partially cover the cornea which is a vital component of the refractive mechanism of the eye. The curvature of the front surface of the cornea is required to determine the correct contact lens base curve (posterior surface) for

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an individual. There are many instruments (such as manual or auto-keratometers) available to measure corneal curvature or topography[5], however, the auto-keratometer (Nidek ARK-700) was the instrument of choice for the purpose of this study because the auto-keratometer provides less variation and bias than the manual keratometer[6]. Furthermore, the accuracy of the auto-keratometer has been established in previous investigations[7, 8].

The consequence of contact lens wear is a vast area of research and can best be investigated by focusing on one aspect at a time. Our understanding of the influence of contact lens wear on keratometric behaviour (the overall change in an individual's keratometric state over time which is influenced by both known and unknown factors which cause continuous fluctuations[9]) is limited. The aim of this study is to investigate keratometric behaviour following RGP and PMMA contact lens wear by using an auto-keratometer to take keratometry measurements before, and after, three hours of contact lens wear. Data will be analysed correctly using multivariate statistical methods.

Method

Twenty-four healthy students with no previous history of contact lens wear or ocular compromise were randomly and equally divided into three groups of eight subjects per group. Subjects in the first experimental group wore PMMA contact lenses, the second experimental group wore RGP contact lenses and the last group served as the control (no lens wear). The study sample was not confined to any one ethnic group and consisted of eight male and sixteen female students from the University of Johannesburg between the ages of 21-46 years. Subjects were excluded from participation in the study based on the following criteria: current or recent contact lens wear, keratoconus, compromised corneal integcompromised corneal integrity, any ocular pathology, corneal astigmatism of more than 2 D or recent eye surgery. Subjects who were taking medication that might have influenced the tears and/ or the cornea were also excluded from the study. This information was obtained by means of a questionnaire and preliminary tests that are described below. The study had five stages and will be explained accordingly.

Stage one: preliminary testing

All 24 subjects had to undergo preliminary testing which included habitual visual acuity, slit lamp evaluation, ophthalmoscopy and three auto-keratometric measurements. These auto-keratometric measurements were taken to rule out corneal astigmatism exceeding 2 D and to provide a starting point to determine the base curve required to provide an "on alignment" contact lens fit (according to well known general contact lens fitting principles) for each subject in the experimental groups.

Stage two: contact lens parameters

All contact lenses used in the study were tricurve in design and had the same power (**O** D), total diameter (9.2 mm), optic zone diameter (7.2 mm) and centre thickness (0.19 mm). The base curve, however, was dependant on individual keratometric measurements. All subjects from the experimental groups were required to attend a contact lens fitting session. During this session the auto-keratometric measurements recorded in stage one were used as a starting point in finding a contact lens base curve that would most likely fit on alignment. Fluroscein was used to evaluate the fit of the trial lenses and enabled us to determine when an on alignment fit was established. The PMMA contact lenses were made from gas impermeable polymethyl methacrylate and the RGP contact lenses were made from Fluroperm 90 which has a dk of approximately 90×10^{-11} cm^2/s (ml O_2/ml mm Hg).

Stage three: test eye

Fifty auto-keratometric measurements were taken with a Nidek ARK-700 on a test eye. This was done on three occasions. The first set of measurements was taken before measurements were taken on the PMMA group, the second set was taken before the RGP group measurements and the last set was taken before the control group measurements. This was done in an attempt to ensure calibration of the auto-keratometer and to establish the variation present within the instrument itself so as not to confuse it with the keratometric variation exhibited by the subjects.

Stage four: data collection

Once preliminary tests were completed and a suitably fitting contact lens was obtained (for subjects in the experimental groups) the final stage of the study was executed. Keratometric measurements were taken on three subjects per day on average and this was done in a staggered fashion to allow for the time taken to obtain the measurements. Each measuring session lasted approximately 15 minutes. The subject was seated in front of the auto-keratometer with their head positioned securely on the chin rest and forehead bar. Fifty auto-keratometric measurements were taken on the right eye of each subject with both eyes open. No instructions were given regarding blinking, however, subjects were instructed to focus on the target in the instrument. After each measurement was taken, the subject was asked to sit back while the measurement was being printed out. This allowed the examiner to re-focus the instrument after every measurement. The auto-keratometer records the measurements in radii of curvature (in millimetres) along the principal meridians (in degrees).

Experimental groups: the PMMA and RGP groups then had the predetermined contact lens inserted in their right eye. All subjects were given the same instructions, that is, to return after three hours (the generally accepted tolerance trial period for any new contact lens wearer in which the examiner would be able to determine if the patient can tolerate using contact lenses) for the next set of measurements and to refrain from doing any strenuous physical activity as this has been shown to influence keratometric behaviour[10].

When the subject returned three hours later the contact lens was removed and the cornea examined using a slitlamp to establish if there had been any corneal compromise during the three hour period. Immediately after that another 50 auto-keratometric measurements were taken as described above.

Control group: 50 auto-keratometric measurements were taken as described for the experimental groups. These subjects were also instructed to return after three hours and also refrain from strenuous physical activity. Thereafter another set of 50 auto-keratometric measurements was taken.

As mentioned previously, this paper presents the preliminary results of a larger study conducted by the first author therefore only the results of the first subject from each of the three groups were considered for analysis.

Stage five: data analysis

Previous studies of this nature[11-15] made use of incomplete or incorrect statistical methods. In these studies keratometric data in its conventional form (sphere, cylinder and axis) were treated as three independent components. When dioptric power is represented by a matrix[16, 17] it is possible to analyse such data with multivariate statistical methods which are complete. The raw keratometric data collected in this study (radii of curvature along principal meridians) were first transformed into conventional powers using a nominal refractive index of 1.3375 and then converted into dioptric power matrices[18]. The dioptric power matrices were then used to generate 3-dimensional stereo-pair scatter plots. This was achieved using software that was specifically developed for this purpose by Harris and Malan and modified by Rubin[19-21]. Keratometric data can be represented graphically with 3-dimensional stereo-pair scatter plots, ellipsoidal surfaces of constant probability density (distribution ellipsoids) and ellipsoidal confidence regions for mean dioptric power. These graphical methods make it possible to visualize and analyze variation[18-21]. With multivariate transformation of dioptric power, standard statistical calculations such as means, standard deviations and variances can be determined thus making hypothesis testing possible[22].

Results

In the stereo-pair scatter plots that follow one can appreciate the three-dimensional percept by viewing the scatter plots in an exo-position (eyes drifted apart). Each dot on the scatter plot represents one transformed keratometric measurement. Each of the following scatter plots has an axis length of 1 D and a tick interval of 0.25**I**, 0.25**J** and 0.25**K** D respectively. The origin of the axes differs but will be specified for each scatter plot.

Figure 1 is a representation of the keratometric data collected from the test eye on the three measuring occasions as described above. The origin was chosen to represent the power 42**I** D. Black data points represent the first set of 50 auto-keratometric measurements, red the second and blue the third. However, due to the scale that was chosen it is difficult to distinguish the three sets of data. Each set of data points has a 95% distribution ellipsoid included. The tight clusters illustrated in Figure 1 are an indication of the small amount of variation present within the instrument (compare Figure 1 with Figures 2a, 3 and 4). It is therefore probably safe to postulate that any variation observed in the other scatter plots is predominantly due to keratometric variation.

In Figures 2, 3 and 5 the black and red data points symbolize the 50 auto-keratometric measurements taken before and after three hours of contact lens wear respectively. In Figures 4 and 6, the black and red data points symbolize the 50 auto-keratometric measurements taken before and after three hours of no contact lens wear respectively.

Figure 2a represents the measurements taken on subject 1 in the PMMA contact lens group. The origin of this scatter plot is 41.85**I** D. Figure 2b makes it easier to see that the two sets of data points do not intersect. This may suggest that there is a difference in keratometric behaviour after lens wear. It would also appear that there is more variation present before the three hours of lens wear (black data points) and this is substantiated by comparing the volume of the distribution ellipsoid for P1 (sample taken before three hours of PMMA contact lens wear) and P2 (sample taken after three hours of PMMA contact lens wear) provided in Table 1 (0.062 D^3 versus 0.026 D^3 respectively). The three hours of lens wear has appeared to have increased the corneal curvature in the region of the stigmatic axis. Not much change in curvature occurred along the ortho-antistigmatic and oblique antistigmatic axes (compare scientific means for P1 and P2 in Table 1). When viewing Figure 2a one would notice that the orientation of the axes of both the ellipsoids do not correspond to the spread of the majority of the data points. This could be due to the one red data point and one black data point that appear to be far removed from their respective clusters. These two data points could be considered as possible outliers (assumed irregularities in the sample). When these possible outliers were removed from P1 and P2, the resulting distribution ellipsoids (Figure 5) reduced in size slightly (Table 2) and the orientation of the axes appear to correspond with the spread of the data points. The variation is still greater in P1 than in P2 even with the removal of possible outliers. Even though these changes occurred, the inferences made from Figure 2a are still applicable (compare the differences in Table 2).

The two sets of measurements taken on the first subject in the RGP contact lens group are represented by Figure 3 (origin: 42.50**I** D). Unlike P1 and P2, R1 (sample taken before three hours of RGP contact lens wear) and R2 (sample taken after three hours of RGP contact lens wear) do appear to overlap in some areas. Again, there is more variation present before lens wear as can be seen by the larger black ellipsoid (0.023 D^3 versus 0.011 D^3). The three hours of RGP contact lens wear seems to have caused a minimal decrease in curvature along the stigmatic axis. There also appears to be slightly more change along the ortho-antistigmatic and oblique-antistigmatic axes than was evident in the PMMA sample.

Data collected from the first subject in the control group are represented by Figure 4 (origin: 45.65**I** D). C1 (sample taken before three hours of no lens wear) and C2 (sample taken after three hours of no lens wear) are unlike the two experimental groups in that the majority of data points appear to lie in the same space. Also unlike the two experimental samples, variation of measurements is greater after the three hour period (red data points) rather than before (black data points). Even though most of the data points seem to occupy the same space and the means of the two samples are very similar (Table 1), the two distribution ellipsoids for C1 and C2 look quite disparate. In fact, the distribution ellipsoid for C2 is four times larger than the distribution ellipsoid for C1 (0.061versus 0.015). This might be due to the three red data points that lie outside the red ellipsoid. These three points may be considered as possible outliers and when they were removed, we found that the distribution ellipsoids looked more alike (Figure 6). The variation present in C2 has decreased with the removal of possible outliers, however, it is still greater than the variation exhibited by C1.

With regard to the possible outliers present in samples P1, P2 and C2: there were negligible differences in the conclusions drawn about the samples with and without possible outliers (Table 2) therefore all further analysis will be conducted on the original samples which include possible outliers. In our opinion, the inferences made will still be applicable regardless of the presence of possible outliers in the above mentioned samples.

Confidence ellipsoids

Confidence ellipsoids are generated from samples of dioptric powers and are plotted as stereo-pairs. According to Harris *et al*[23]: "a stereo-pair allows one to obtain a three-dimensional percept that gives a graphic representation of the most likely set of values of the mean dioptric power for the population". Confidence ellipsoids are useful in establishing if there are any changes in a "before and after" scenario as was the case for this study. In this instance, we constructed 95% confidence ellipsoids for samples from all three groups (Figures 7 to 9). This implies that we can be sure, with a 95% level of confidence, that the mean of the population lies within the confidence ellipsoid and we can infer if three hours of contact lens wear caused any change in keratometric behaviour.

The confidence ellipsoids for P1 and P2 are shown in Figure 7. As is clearly evident in the stereo-pair, the two confidence ellipsoids do not intersect therefore it is probable that there was some change in keratometric behaviour induced by the three hours of lens wear. The same can be said for the confidence ellipsoids representing R1 and R2 (Figure 8). However, the confidence ellipsoids generated by samples C1 and C2 (Figure 9) do intersect thus confirming that there was not as much change in keratometric behaviour during the three hour period of no lens wear than there was during lens wear.

Even though all six confidence ellipsoids vary in volume, they are essentially quite small therefore we can be confident about the accuracy of the mean in all six samples of keratometric measurements.

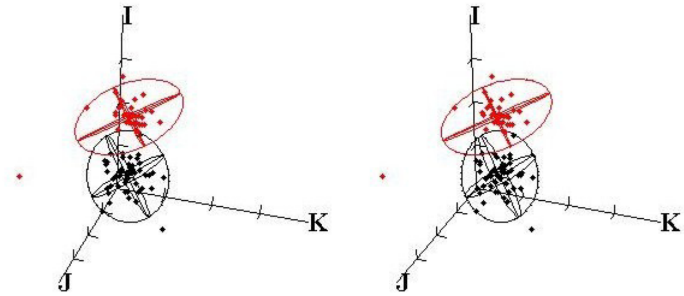

Figure 2a. Stereo-pair scatter plot (with included 95% distribution ellipsoids) of P1: 50 auto-keratometric measurements taken before (black data points) and P2: 50 auto-keratometric measurements taken after (red data points) three hours of PMMA contact lens wear. The origin of the scatter plot is 41.85**I** D.

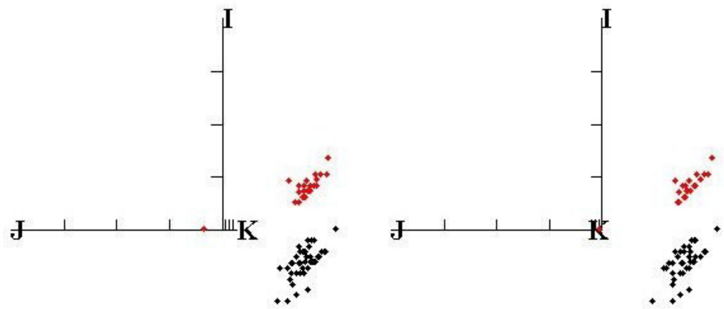

Figure 2b. Scatter plot (excluding the 95% distribution ellipsoids) of P1: 50 auto-keratometric measurements taken before (black data points) and P2: 50 auto-keratometric measurements taken after (red data points) three hours of PMMA contact lens wear. This scatter plot has been rotated so that the data points can be viewed looking down the oblique antistigmatic (**K**) axis. The origin of the scatter plot is 41.85**I** D.

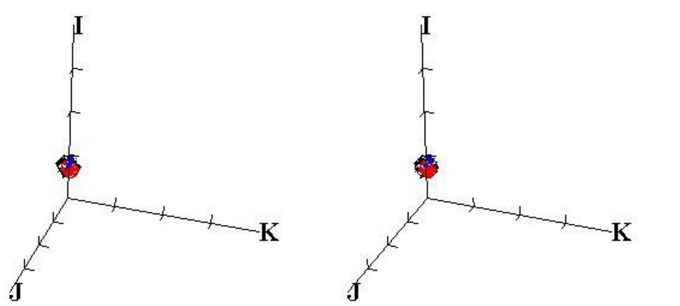

Figure 1. Stereo-pair scatter plot (with included 95% distribution ellipsoids) of the three sets of measurements taken on the test eye. The first set is represented by the black data points, the second set is represented by the red data points and the third set is represented by the blue data points. The origin is 42**I** D.

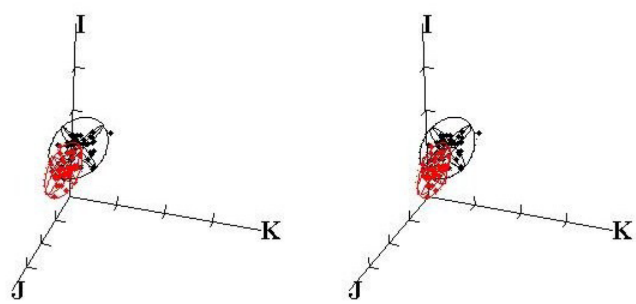

Figure 3 Stereo-pair scatter plot (with included 95% distribution ellipsoids) of R1: 50 auto-keratometric measurements taken before (black data points) and R2: 50 auto-keratometric measurements taken after (red data points) three hours of RGP contact lens wear. The origin of the scatter plot is 42.50**I** D.

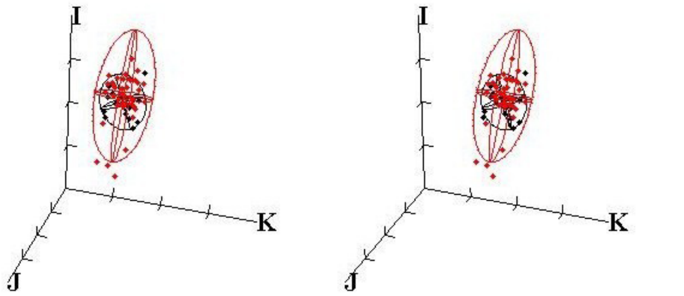

Figure 4. Stereo-pair scatter plot (with included 95% distribution ellipsoids) of C1: 50 auto-keratometric measurements taken before (black data points) and C2: 50 auto-keratometric measurements taken after (red data points) three hours of no contact lens wear. The origin of the scatter plot is 45.65**I** D.

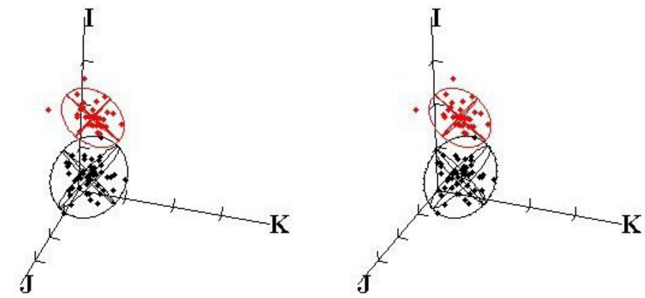

Figure 5. Stereo-pair scatter plot (with included 95% distribution ellipsoids) of P1 (black data points) and P2 (red data points) devoid of possible outliers. The origin of the scatter plot is 41.85**I** D.

Table 1. Statistics (means, variance-covariance matrices and ellipsoid volumes) for the first subject from the PMMA group, RGP group and control group.

PMMA:	**BEFORE LENS WEAR (P1)**	**AFTER LENS WEAR (P2)**
Conventional mean	42.09 / − 0.79 × 94	42.44 / − 0.81 × 94
Scientific mean (D)	41.70**I** − 0.39**J** − 0.05**K**	42.03**I** − 0.40**J** − 0.06**K**
Variance- covariance (D^2)	0.005 − 0.002 − 0.000	0.002 − 0.003 0.001
	− 0.002 0.003 0.001	− 0.003 0.005 − 0.004
	− 0.000 0.001 0.006	0.001 − 0.004 0.007
Volume of:		
95% distribution ellipsoid (D^3)	0.062	0.026
95% confidence ellipsoid (D^3)	0.0002	0.0001
RGP:	**BEFORE LENS WEAR (R1)**	**AFTER LENS WEAR (R2)**
Conventional mean	42.96 / − 0.83 × 95	42.82 / − 0.79 × 100
Scientific mean (D)	42.54**I** − 0.41**J** − 0.08**K**	42.42**I** − 0.37**J** − 0.14**K**
Variance- covariance (D^2)	0.003 − 0.001 0.001	0.002 − 0.001 0.001
	− 0.001 0.001 − 0.000	− 0.001 0.001 0.000
	0.001 − 0.000 0.003	0.001 0.000 0.002
Volume of:		
95% distribution ellipsoid (D^3)	0.023	0.011
95% confidence ellipsoid (D^3)	0.00008	0.00004
CONTROL:	**BEFORE LENS WEAR (C1)**	**AFTER LENS WEAR (C2)**
Conventional mean	46.58 / − 1.87 × 89	46.62 / − 1.87 × 89
Scientific mean (D)	45.65**I** − 0.93**J** 0.02**K**	45.68**I** − 0.93**J** 0.03**K**
Variance- covariance (D^2)	0.002 − 0.001 − 0.000	0.001 − 0.007 − 0.000
	− 0.001 0.002 0.000	− 0.007 0.008 0.001
	− 0.000 0.000 0.002	− 0.000 0.001 0.003
Volume of:		
95% distribution ellipsoid (D^3)	0.015	0.061
95% confidence ellipsoid (D^3)	0.00005	0.0002

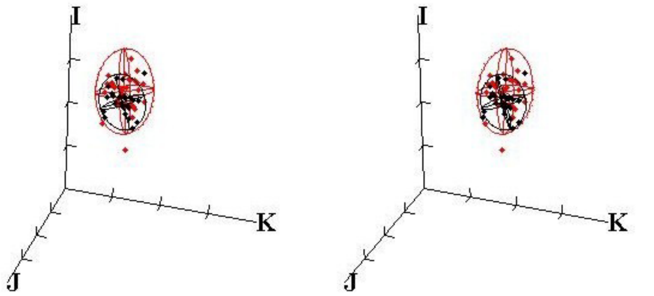

Figure 6. Stereo-pair scatter plot (with included 95% distribution ellipsoids) of C1 (black data points) and C2 (red data points) devoid of possible outliers. The origin of the scatter plot is 45.65**I** D.

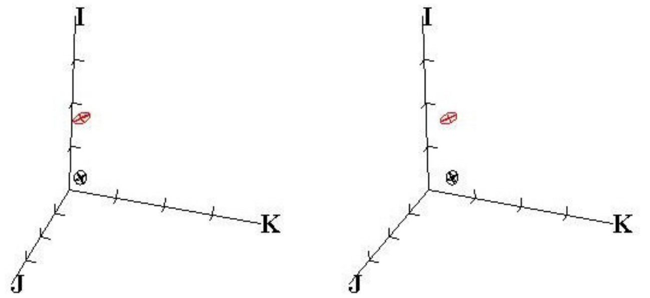

Figure 7. 95% confidence ellipsoids for the first subject in the PMMA group. P1 is represented by the black ellipsoid and P2 is represented by the red ellipsoid. Data points were not included to enhance visibility of the confidence ellipsoids. The origin is 41.85**I** D.

Table 2. Statistics (means, variance-covariance matrices and ellipsoid volumes) for samples P1, P2 and C2 with and without possible outliers.

PMMA: BEFORE LENS WEAR (P1)	**WITH POSSIBLE OUTLIERS**	**WITHOUT POSSIBLE OUTLIERS**
Conventional mean	42.09 / − 0.79 × 94	42.10 / − 0.80 × 94
Scientific mean (D)	41.70**I** − 0.39**J** − 0.05**K**	41.70**I** − 0.39**J** − 0.05**K**
Variance- covariance (D^2)	0.005 − 0.002 − 0.000 − 0.002 0.003 0.001 − 0.000 0.001 0.006	0.004 − 0.002 0.001 − 0.002 0.003 − 0.000 0.001 − 0.000 0.005
Volume of: 95% distribution ellipsoid (D^3)	0.062	0.053
PMMA: AFTER LENS WEAR (P2)	**WITH POSSIBLE OUTLIERS**	**WITHOUT POSSIBLE OUTLIERS**
Conventional mean	42.44 / − 0.81 × 94	42.45 / − 0.82 × 94
Scientific mean (D)	42.03**I** − 0.40**J** − 0.06**K**	42.04**I** − 0.41**J** − 0.05**K**
Variance- covariance (D^2)	0.002 − 0.003 0.001 − 0.003 0.005 − 0.004 0.001 − 0.004 0.007	0.002 − 0.001 −0.001 − 0.001 0.001 0.000 − 0.001 0.000 0.003
Volume of: 95% distribution ellipsoid (D^3)	0.026	0.011
CONTROL: AFTER NO LENS WEAR (C2)	**WITH POSSIBLE OUTLIERS**	**WITHOUT POSSIBLE OUTLIERS**
Conventional mean	46.62 / − 1.87 × 89	46.65 / − 1.90 × 89
Scientific mean (D)	45.68**I** − 0.93**J** 0.03**K**	45.70**I** − 0.95**J** 0.03**K**
Variance- covariance (D^2)	0.001 − 0.007 − 0.000 − 0.007 0.008 0.001 − 0.000 0.001 0.003	0.004 −0.002 −0.000 − 0.002 0.004 0.001 − 0.000 0.001 0.003
Volume of: 95% distribution ellipsoid (D^3)	0.061	0.040

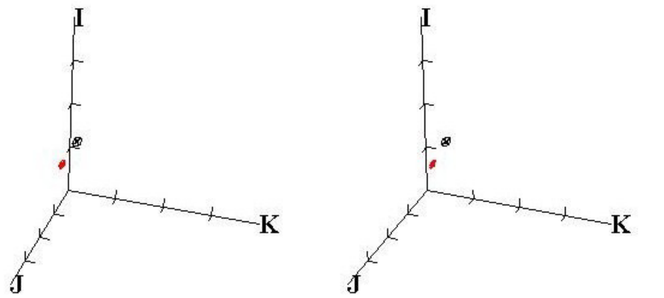

Figure 8. 95% confidence ellipsoids for the first subject in the RGP group. R1 is represented by the black ellipsoid and R2 is represented by the red ellipsoid. Data points were not included to enhance visibility of the confidence ellipsoids. The origin is 42.50**I** D.

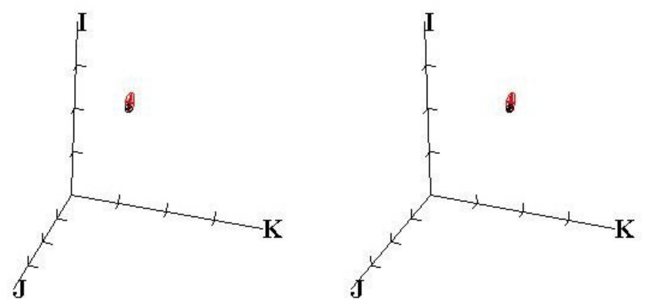

Figure 9. 95% confidence ellipsoids for the first subject in the control group. C1 is represented by the black ellipsoid and C2 is represented by the red ellipsoid. Data points were not included to enhance visibility of the confidence ellipsoids. The origin is 45.65**I** D.

Discussion

The increasingly extensive use of contact lenses advocates the need for thorough investigation of the consequences of placing this foreign body onto the eye. Previous studies of this nature have been done[11-15] and show, in general, an overall steepening of the cornea. However, the statistical analyses conducted at the time were incomplete or incorrect and some conclusions drawn from such research are questionable. A more recent study[24] which investigated the topographical changes under the influence of a PMMA contact lens used appropriate multivariate statistical methods to analyse the data and showed that not only was there an increase in stigmatic corneal curvature but there were also changes in the ortho-antistigmatic component as well.

Hypothesis tests[22] were done at a 95% confidence level on the means and variances of P1 and P2, R1 and R2 and, C1 and C2. The null hypothesis was rejected at the 5% level of significance. Even though the differences in keratometric behaviour were statistically significant for all three subjects, one could argue that the differences were not clinically significant. PMMA lens wear provoked a 0.33 D increase and RGP lens wear a 0.12 D decrease in the stigmatic component whilst no lens wear induced only a mere 0.03 D increase in the stigmatic component (Table 1). Changes along the ortho-antistigmatic and oblique antistigmatic axes were minimal for all three groups. Although one might consider the differences in all three subjects to be clinically insignificant, one should still note that the subject in the PMMA group experienced the greatest stigmatic change whilst the subject in the control group experienced the least change (0.33 D versus 0.03 D). The change that was observed in the subject in the control group could most likely be attributed to normal diurnal changes[6]. Considering that the stigmatic changes observed in the two experimental groups are greater than the changes in the control group, it is unlikely that normal diurnal effects are exclusively responsible for the changes observed in the experimental groups.

Conclusion

The control group (C1 and C2) differs from the experimental groups (P1, P2, R1 and R2) in two aspects. Firstly, there is a greater degree of comparison between the means of the control group than between the means of the PMMA and RGP groups (compare Figures 7 and 8 with Figure 9). Secondly, the variation of measurements is greater after the three hour period in the control group. Therefore, the presence of a rigid contact lens appears to have a two fold effect: (1) rigid contact lens wear provokes a change in mean in the sample taken three hours after lens wear and (2) the use of a rigid contact lens reduces the variation of the corneal curvature thus providing some sort of stability to the corneal surface. Both these effects imply that rigid contact lenses probably do have an influence over keratometric behaviour with PMMA contact lens wear provoking the greatest change.

Some of the samples (P1, P2 and C2) did contain possible outliers and the removal of these data points did adjust the size, shape and orientation of the respective ellipsoids. Whether or not these data points can be deemed as outliers is still vague, however, removing them did not impact on the inferences made from the original scatter plots.

Subject selection was not gender discriminate. Previous studies[6] thought of this to be a shortfall, however, gender based differences in keratometric behaviour have not been conclusively established to date[25-27]. Shortfalls of this article may include the minimal time allowed for lens wear and measuring each subject at only two occasions. Also, only three subjects are considered here but as mentioned in the beginning, the results presented in this paper form the pilot study for a larger study that includes 100 measurements taken on each of the 24 subjects used. Therefore, conclusions drawn from this initial set of results are yet to be augmented by means of a dissertation which is currently being compiled by the first author.

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