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Abstract
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Investigation of the Use of the Piggy-back Contact Lens System on Keratoconic Patients

May 1, 1978

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Submitted in partial fulfillment of the requirements for the Doctor of Optometry degree
INTRODUCTION:

Keratoconus has been characterized as a non-inflammatory dysplasia of the axial portion of the cornea. This process results in a disruption of the normally smooth refracting surface of the cornea, causing a visual deterioration related to the degree of progression. A characteristic of this condition is a thinning of the cornea, normally in the central portion. This thin portion of the cornea is then unable to withstand the intraocular pressure, resulting in a protrusion of the cornea in the thin area. It has been suggested that the terms "kerato-hyperbola" or "hyperbolic cornea" might be more appropriate since the cornea never assumes a true conical shape; as the corneal apex becomes conical the periphery tends to flatten. ¹

Keratoconus usually appears in youth or adolescence, progresses for five or six years after onset, and then enters a quiescent stage. It is not rare for acute relapses to occur in the 35-45 age group.

There are many and varied reports on the incidence of keratoconus in the normal human population. Hofstetter in 1959 conducted a study which revealed that approximately 0.6% of the adult population and 0.1% of the 0-1½ year age group were classified as keratoconic.² Various studies report the incidence from a low of 0.07% to a high of 8.75%. The condition seems to be more prevalent in some geographical areas than others. Keratoconus appears to be equally divided between male and female groups.
Clinical manifestations of keratoconus normally appear in youth or adolescence. In the majority of the cases the disease is full term by age 27. It cannot be assumed that the condition does not appear in later years. Many cases have become manifest between 40-50 years of age.

The etiology of keratoconus is uncertain at present. Many theories have been advanced, some based on scientific studies, others on clinical intuition. It would appear to be a degenerative condition, possibly secondary to a disease process, a state of malnutrition, or constant mechanical irritation (e.g. eye-rubbing) may be a factor. Other possibilities include heredity, hormonal imbalances, disturbed calcium metabolism, increased intra-ocular pressure, aberration of local metabolic processes in the cornea, or contact lens wear, although there is no verification of the latter.

Characteristic histological findings are: 1- Fragmentation of the basement membrane of the corneal epithelium, fibrillation of Bowman's membrane and the anterior stroma in the early stages. 2- Marked thinning and bulging of the central cornea. 3- Wavy appearance of Bowman's membrane with multiple narrow gaps filled by newly formed connective tissue or by epithelium. 4- Folds and buckles in Descemet's membrane and its overlying deep stroma. 5- Rupture of Descemet's membrane.

This pathological picture may be explained by the liberation of proteolytic enzymes from dead epithelial cells, leading to a loss of collagen fibrils and formation of the cone.

Various tissue changes occur during the course of the disease.
All of these tissue changes may not necessarily be observed in one particular case, and some changes are not found exclusively in keratoconic eyes. The main categories of observable changes are: 1- Thinning of the cornea at the apex of the cone. This is best viewed with an optic section on a biomicroscope. 2- Reflex from the endothelial cup. This is a brilliant reflex that occurs in the early stages of the disease, accounting for the characteristic "dew drop" or "piece of crystal" appearance of the apex of the cornea. This reflex is caused by the increased concavity of the posterior corneal surface at the apex, acting as a convex mirror on the incident light. 3- Striae represent themselves as a series of oblique or vertical lines, occurring in the stromal lamellae. 4- Irregular superficial corneal opacities form in the apex of the cornea with a resultant loss in visual acuity. They begin as discrete dots in Bowman's layer and increase in size, becoming opaque with the invasion by fibrillar connective tissue. 5- Ruptures in Descemet's Membrane. 6- Increased visibility of nerve fibers, possibly due to changes in nerve density rather than a profusion of nerve fibers. 7- Fleischer's Ring - is a complete or partial distended ring encircling the base of the cone. The color of the ring varies from yellow-green to olive-green and is located in the posterior layer of the stroma. The ring is considered to be due to a deposition of hemosiderin in the stromal tissue.

Keratoconus normally develops in one eye before the other. The onset may precede the contralateral eye by as much as five or six years. Almost always the first eye affected has the most
pronounced keratoconus.

Keratoconus is considered a self-limiting condition, but the conclusion of the progression may result in corneal irregularities mild to severe. The progression is often very rapid, many times lasting for a period of five to six years, followed by a period of quiescence. The condition, left untreated, has not been shown to enter a period of partial or complete remission.

For the purposes of this study, the following classification system shall be used: 1- Grade 1(incipient) keratoconus - keratometric findings are possible but there are distortions of the mires; the mires are of unequal size and cannot be completely aligned. Spectacle lenses will correct nearly all of the refractive error. Difficult to diagnose by ophthalmoscopy or retinoscopy. 2- Grade 2(medium) keratoconus - keratometric findings are not accurate and must be approximated, usually with minimal accuracy. The refractive error can be corrected only by contact lenses. Ophthalmoscopy and retinoscopy are somewhat abnormal. 3- Grade 3(severe) keratoconus - can be diagnosed by inspection (i.e. Munson's sign). Biomicroscopy reveals corneal thinning and opacities.

The early stages of keratoconus cause subjective symptoms difficult for the patient to interpret. Objects are more distorted than blurred. Young patients will report that near and far vision seem reduced. One letter may be confused with another or parts of letters or words appear to be missing or distorted.

The patient may have many pairs of spectacles, none of them satisfactory. There may be a recent increase in photophobia,
reports of halos around lights, diplopia or polyopia.

External examination of the cornea from the side may reveal an apparent ectasia of the vertical meridian even in incipient conus. The horizontal meridian is observed by having the patient depress his gaze so the lower lid is approximately at the principal horizontal meridian of the cornea. In this position the cone will cause an outpouching of the lid (Munsen's sign).

Cophthalmoscopy will reveal a circular, oblong, or dumbbell shaped shadow within the reflex. Fundus details may be indistinct and difficult to observe due to corneal distortion.

Keratometry is very important in the detection of incipient conus. There are more distortions, with the principal meridians not at right angles to each other but, rather, oblique. The corneal readings are nearly always high - usually 48.00D or higher.

Biomicroscopy will reveal some or all of the seven observable tissue changes previously mentioned.

Retinoscopy will reveal the same shadows observed in cophthalmoscopy. Keratoconic eyes give the impression of shadow movement in several directions at once, a swirling motion due to the irregular refracting surface of the cornea.

The refractive end point is often indeterminate. This suggesting the possibility of amblyopia in combination with myopia.
In most cases of keratoconus a high degree of irregular astigmatism is present that is uncorrectable with spectacle lenses. This condition is usually fitted with a PMMA hard contact lens in order to give a spherical refracting surface and provide some support for the thinning cornea. Hydrophilic lenses are occasionally used where there is a significant degree of corneal cylinder. They generally provide a lessened amount of corneal insult and a greater degree of patient comfort.

The steep and irregular corneas associated with keratoconus often give problems of abrasion and edema with hard contact lenses. This results in a shortened daily wearing schedule for a patient who may have difficulty functioning with only a spectacle prescription. It is these patients who can benefit from the "piggy-back" combination of a hard lens placed on top of a hydrophilic lens. This pairing is to give the comfort and lessened corneal insult for increased wearing time and the improved acuity from correction of the residual astigmatism showing through the soft lenses.

Most of the literature on the subject of fitting keratoconus with a combination of hydrophilic PMMA lenses is limited to a few case reports. Through trial and error several practitioners have successfully fitted a number of patients who have been unable to achieve satisfactory wear with either hard or soft lenses by themselves.

The major purpose of the "piggy-back" system is to give the comfort and extra wearing time associated with soft lenses
combined with the improved acuity, due to the lessened residual astigmatism, of the hard lenses. Most of the cases reported were attempts to reduce physiologic and traumatic damage to the corneal apex by PMMA lenses. These corneas usually contained a significant cylindrical component that hydrophilic lenses alone were unable to compensate for.

There are a variety of different fitting philosophies concerning parameters of the lenses involved. There are a few basic principles on which several of the reports agree. The hydrophilic lens should be steep enough so there is a contact between the posterior surface of the lens and the apex of the cone. The lens periphery rests on sclera throughout the entire circumference. The normal fitting procedure recommended by the manufacturer was used in most cases. The thinnest hard lens that is stable is the best choice for good centering. The periphery of the hard contact lens must fit snugly against the soft lens and have a thin edge to avoid lid sensation. While Gruber recommends a small slightly steep lens, Steele and others specify a larger than normal diameter. All cases indicated the use of a PMMA lens that was steeper than the keratometry readings obtained over the hydrophilic lenses. The degree of steepness varies from 0.50 D. to 2.00 D. over the flattest K reading. One method is to pick the midpoint between the flattest and steepest meridian. The major concern with size and steepness of the hard lens is the effect on tear flow under the hydrophilic lens. A hard lens that bears too heavily on its periphery can effectively seal off the tear exchange under the soft lens. The majority of failures with
the "piggy-back" system come from this anoxia of the cornea. The best fit for the hard lens appears to be about 1 mm of movement on the soft lens during a blink. Occasionally fenestrations in the hard lens have been used to attempt an increase in oxygen exchange.
CLINICAL FINDINGS

Patient: M. E.

11/8/77

Trial fitting OS: Hydrocurve 2 (H2); 9.50mm BC, 16.0mm, -3.00D, 2mm movement on blink (2mm movmt), slight inferior edge stand off due to conus

Ordered: -2.50D H2 of above parameters and dispensed.

11/21/77

Patient could not insert H2 lens (of 11/8) due to large diameter

Trial fitting OS: Naturvue 8.90mm BC, 14.5mm OAD, C.T. 0.22mm, -3.50D, centers C to C3, 2mm movmt, inferior edge stand off due to conus

12/10/77

Dispensed OS lens (of 11/21)

Trial fitting OD: Naturvue, 8.90mm BC, 14.5mm OAD, -3.50, 2mm movmt, centers C3

lens dispensed

12/21/77

12/10 lenses both tightened up somewhat, moving only 1mm or less on blinking. It was felt that this would be insufficient when hard lenses were placed on the soft lenses.

12/28/77

Trial fitting OD: AO Soft, Vault I, -0.75D, 1mm movmt, 4mm drop on upward gaze, inferior edge stand off, centers C

Trial fitting OS: AO Soft, Vault III, -0.75D, 1mm movmt, 4mm drop on upward gaze, slight inferior edge stand off, center C2

Ordered above lenses
1/27/78
Dispensed 12/28 lenses: movmt etc. same as trial fitting
chemical sterilization

2/7/78
Progress: wearing AO Softs 10 days, lenses subjectively comfortable, vision "OK", some difficulty at near
Both lenses same movmt etc. as on 12/28

Keratometer readings over soft lenses:

OD  43.00 @ 180 (7.84mm)
     36.50 @ 90 (9.24mm)
OS  48.50 @ 175 (6.95mm)
     38.75 @ 85 (8.70mm)

Hard lens trial fit (piggyback):

OD  Trial 1: BC 8.44mm (39.87D), -2.00, OAD 8.30mm
     OZD 7.30mm, CT 0.15mm, Fit is 3.37D steeper than Kf
     Fit is unstable: discontinued

Trial 2: BC 8.22mm (41.12D), -1.12D, OAD 8.55mm,
     OZD 7.50, Fit is 4.62D steeper than Kf
     Lens rides nasal and inferior (almost reaching the limbus), 3mm movmt on blink (hard), soft 1mm
     Over refraction: +1.75 = 20/20-3

Lens ordered: 8.2BC, +0.50, OAD 8.50,
     OZD 7.50, CT 0.14

OS  Trial 1:  8.22mm (41.00D) BC, -0.75D, CAD
     7.70mm, OZD 7.00mm, CT 0.16mm, Fit is 2.25D steeper than Kf
     Fit is unstable: discontinued

Trial 2:  8.08 (41.75D) BC, -0.12D, OAD 8.50,
     OZD 7.9, CT 0.15, Fit is 3D steeper than Kf
     Lens rides nasal and inferior (almost reaching the limbus), 3mm movmt on blink (hard), less than 1mm for soft
     Over refraction: -0.50 = 20/20

Lens ordered: 8.08 BC, -0.50D, OAD 8.50,
     OZD 7.90, CT 0.14mm
2/22/78

Dispensed hard lenses from 2/7/78 order

Possible reaction to chemical disinfection method last week. Red eye and discomfort OU - stopped wearing lenses but did not consult eye care practitioner.

Piggyback Parameters:

OD
Hard: 8.2BC, +0.50D, OAD 8.50, OZD 7.5, CT 0.14
Soft: AO Soft Vault I -0.75D

Visual acuity 20/25, overrefraction plano, position C_{3N}_{3}, movement; hard 2 to 3mm, soft 1mm

OS
Hard: 8.08BC, -0.50D, OAD 8.50, OZD 7.90
CT 0.14
Soft: AO Soft Vault III -0.75D

Visual acuity 20/40, over refraction -0.25D

Instructions:

Soft wear time 8 hrs/day - hard 2hrs first day, 4 hrs until next visit
Use Adapt for wetting solution
Use heat asensor with preflex cleaner and Boil n Soak saline

3/1/78

Piggyback 1 week progress exam

Wearing piggyback 4hrs/night, comfort good, on weekend wore 4hrs on-2 off-4on.
Slit lamp- lenses moving as on dispensing, no edema seen although difficult because of reduced corneal transparency (previous)

Visual acuity:

OD 20/25
OS 20/40 - lowered acuity seems to be a function of approx. 2.00D residual cyl. and decentration of hard lens. Difficult to obtain any increase in VA

3/28/78

Patient missed previous appointment

Good deal of difficulty in inserting and removing piggyback system. Patient may have confused OD with OS soft contact
OD: "OK" (patient response)
OS: "Hard and soft lenses moved up"

Patient discontinued wearing piggybacks 4 days ago
"Uncomfortable and brow ache"

OD: Same as 3/1
OS: Soft lens riding up somewhat - hard lens also

Slit lamp: (no lenses)

Some very slight increase in perilimbal loops (OU)
Irregular thinning of cornea approximately the same as at the start of the study

Keratometer readings:

OD: 45.62/39.00 @95
OS: 53.00/38.50 @80

STUDY DISCONTINUED
Patient: J. S.

11/17&18/77

Trial fitting OS: Soft lens- B&L unacceptable

Hydrocurve II 9.80BC, 15.50AD, -3.25D, Ctr C1 to C3, movmt 1.5mm
on blink/2mm on upward gaze
OverRef. -0.50-3.50x05
OverK 39.50/42.75 @ 90

Hard (piggyback): BC 8.22 (41.00D), OAD 8.80, CT 0.14, -3.00D, OZD 7.80,
movmt C1 to C3
OverRef.+3.25sph
Lens fit 1.50D steeper than Kf

Ordered:

Soft: H II, -3.25D, OAD 15.5mm
Hard: BC 8.22, OAD 8.80, OZD 7.80,
CT 0.14, power= plano

11/29/77

Dispensed 11/17-18 lenses (OS):

OS: Centering- C2 to C3 (soft), C3 (hard)
movmt 1mm for soft and hard
OverRef. plano, VA 20/30-1, Retinoscopy plano

12/1/77

Trial fitting OD: H II, 10.1BC, 16.00AD, -2.75D, VA
20/25, Center C3, movmt 1mm
OverRef. +0.50, VA 20/15
OverK 38.00 @17/41.75 @107

12/2/77

OS

Patient could not wear hard contact lens more
than 15 minutes comfortably.

Slit lamp: Soft lens moving 1.0mm but no movmt
of hard lens independently of soft
Modification: Hard lens; OZD reduced from 7.80 to 7.50, OAD reduced from 8.80 to 8.60mm

Modification had little effect on hard lens performance. The soft lens appeared to tighten slightly with this change.

Trial fitting OS: Soft; 10.1BC, OAD 16.0, -2.75D, center C3, movmt 1.5mm
OverK 41.25/44.25 @80

Hard; BC 8.22 (41.00D), OAD 8.60, OZD 7.50, CT 0.14, -3.00D, movmt 2mm, 0.25 flatter than Kf

Trial fitting OD: Soft; HII 10.1BC, 16.0 OAD, -2.75D, movmt 2mm
OverK 38.12/41.62 @107

Hard; BC 8.54; OAD 8.80, OZD 7.70mm
CT 0.15mm, -4.75D; fit of hard lens 1.37D steeper than K, ctr C4, movmt 1 to 3mm depending on force of blink, overrefraction +3.25D(20/25)

Above hard lens ordered in -1.00D.

12/29/77

Dispensed OD,OS piggyback systems

OD: Soft; 10.1BC, OAD 16.0, -2.25D,
Hard; 8.54BC, OAD 8.80mm, OZD 7.70mm, -2.00D, CT 0.14mm
movmt: soft; 1 to 1.5mm, hard; C2 to C4 with blink.
overrefraction +1.50D(uncertain endpt.)
acuity thru +1.50D; 20/30
acuity thru piggyback; 20/30

OS: Soft; 9.80-BC, OAD 15.5mm, -3.25D
Hard; 8.22BC, OAD 8.80mm, OZD 7.50mm,
plano power, CT 0.14mm
movmt: soft; 1 to 1.5mm, hard; C3 to C4.
acuity 20/40
overrefraction -0.50D -1.00Dx 20(20/25)
1/4/78

Eyes tire, become red after 3-4 hours.

acuity: OD 20/25, OS 20/50
movmt: OD; hard C2 to C3 on blink,
soft less than 1.5mm.
OS; hard 1mm or less(at C4),
soft less than 1.5mm.

To determine the effect of a hard lens base curve change, OD and OS lenses were reversed OD to CS, CS to OD.

acuity: OD 20/30, OS 20/40
overrefraction: OD +0.50D(20/30),
OS -0.75D(20/30)
movmt: OD, CS hard lenses 2mm

1/26/78

Eyes still tire, become red after 3 hours

acuity: OD 20/30, OS 20/40
movmt: OD; hard 1mm, soft 1mm
OS; hard 1mm, soft 1mm

J.S. was to discontinue wearing piggyback system till returning from a one month vacation. We have been unable to re-establish clinical appointments since his return.
M. E. is a 57 year old self employed carpenter with onset of keratoconus noted approximately three years ago. He is mildly hypertensive and has had eczema (physician diagnosed) since childhood. He also has a trichiasis problem in both eyes. M. E. was formerly fit with an extended wear soft contact on his left eye by an ophthalmologist. This attempt failed. At the start of our study he was wearing hard lenses on both eyes. These lenses were fit with apical bearing, giving good acuity (20/20 O. D. and O. S.), but with discomfort and slight corneal breakdown. This was particularly evident in the left eye. It was thought that the piggyback system would increase the patient's comfort while decreasing the corneal problems and maintaining good visual acuity.

M. E. is classified as Grade 2 (see introduction) keratoconic in both eyes with the left eye more advanced. Both eyes have corneal apices that are down and in from the visual axis. Corneal thinning is seen in this area. Keratometric readings at the beginning of the study were: O. D. 45.50/38.50 @90, O. S. 53.00/40.50 @102. The mires were distorted on both eyes and they were almost impossible to estimate with any accuracy on the left eye. Both corneas show some decrease in transparency which could be considered normal for the patient's age, but there are two or three areas centrally in each eye which show a more obvious localized area of translucency.
PATIENT PROFILE:

J. S. is a 32 year old social worker. He has worn contact lenses for 12 years. The patient has not been able to see well through his spectacle Rx for 6 years. He also has light distortion when not wearing his contact lenses. His keratometric readings in 1966 were: 40.37/41.62 @90 O. D., 40.62/41.50 @110. Originally he was fit, by a private practitioner, with 9.0 OAD lenses on the flattest K with powers of -2.50 O. D. and -2.75 O. S. Acuity with these lenses was 20/20 O. D. and O. S. with either contact lenses or spectacles. The patient was examined in September 1976 after 3 weeks of discontinued wear of his left lens. Keratometer readings in the next month showed variation with an average of 40.25/43.50 @105 O. D., 43.75/50.50 @90 O. S.. The patient was referred to an M. D. and diagnosis of keratoconus was confirmed in the left eye. J. S. was fit with hard contact lenses of the following parameters: 8.10 B.C., -3.25, 8.2 CAD in the right eye, 7.60 B.C., -4.50, 7.0 CAD in the left eye. A satisfactory fit was obtained with 20/20 acuity in each eye. There was slight discomfort of the left lens.

The piggyback system was tried on J. S. to give the comfort of the soft lens and still attain good acuity.

J. S. is classified as Grade 1 keratoconic O.U.
DISCUSSION OF CLINICAL TRIALS:

M. E. was originally trial fit with the B & L soft lens on his left eye. This lens did not prove acceptable due to decentration. A Hydrocurve II lens was trial fit and dispensed for the left eye. The patient and family could not insert the lens so this lens was discontinued. Naturvue lenses were tried and an acceptable initial fit was achieved on both eyes. On the next check the lenses had reduced movement and it was felt that with a piggyback combination it would not provide sufficient oxygen to the cornea. These soft lenses were worn until the next lenses were dispensed. A O Soft lenses were trial fit and dispensed the next time the patient was seen. These lenses appeared to be an adequate fit when the patient returned for a progress evaluation.

Trial fitting of the hard lenses was begun on top of the A O Soft lenses. There was difficulty in finding a trial lens that had a flat enough base curve combined with the other parameters desired. A small enough overall diameter with a fairly flat base curve was a particular problem.

The first hard lens dispensed was 4.62D steeper than the flattest K on the right eye and 3.0D steeper than K on the left eye. This fitting relationship was determined by the stability and movement of the hard lens. When M. E. returned for a check he had not been wearing the lenses due to red eyes and discomfort possibly due to an allergic reaction to the chemical disinfection.
The patient had not sought professional attention but had stopped wearing the lenses. The patient showed variable acuity (20/20 to 20/40) with the combination at this time. Wearing was continued with heat sterilization of the soft lenses. Four to eight hours of daily wear with no significant problems was achieved.

The next time the patient was seen was one month later (patient missed previous appointment). Both lenses on the left eye were riding superiorly from the previous visits. The acuity was 20/40 on this eye partially due to residual cylinder and decentering and partially due to unknown causes. Objectively the right eye lenses were performing satisfactorily. The patient had discontinued wear of both sets of lenses due to discomfort and brow ache. He had been having a great deal of difficulty in inserting and removing the piggyback system. He also may have confused the right and left soft contact lenses.

The piggyback system was discontinued on this patient.
Bausch and Lomb Soflenses were the first lenses to be tried on J. S.. These lenses were chosen due to the thin center and edge thickness. Unfortunately these lenses were unstable or incomplete in corneal coverage. Hydrocurve II lenses were then tried because of their larger overall diameter; these also being of thin center thickness. The Hydrocurve II lenses had a tendency to tighten from the original optimal fit; even more so under the influence of the piggyback hard lens.

The right hard lens was originally (12/2) fit 1.37D steeper than the $K_f$ of the soft lens. Initially the visual acuity was 20/30-2. At the progress exam the visual acuity was 20/25. The movement of the hard lens with blinking decreased from 2mm on dispensing to about 1mm at the P. E.. The soft lens reduced from 1.5mm to 1.0mm.

The left eye hard lens was fit 1.50D steeper than the $K_f$ of the soft lens front surface on 11/29. Visual acuity through the piggyback system was 20/30-1 with an overrefraction of plano. At the 12/2 progress exam it was found that J. S. was unable to wear the hard lens more than fifteen minutes without discomfort. With the biomicroscope the hard lens was found to be moving with the soft lens, not independently. Modification of the hard lens, reducing the overall diameter (from 8.80mm to 8.60m-) and optical zone diameter (from 7.80mm to 7.50mm), had very little effect increasing the hard lens movement.
To determine the effect of base curve on fitting characteristics the right and left hand lenses were changed to left and right eyes respectively. This made the right contact lens 2.37D steeper than $K_r$ and the left contact lens 1.75D flatter than $K_r$ of the soft lens. Movement of the hard lenses on the blink was found to be 2mm in each eye.

At the next appointment (1/26), J. S. complained of "tired" eyes after three hours of wear. Visual acuity through the lenses was 20/30 in the right eye and 20/40 in the left. Movement of the lenses on blinking was 1mm of each lens on both eyes. At this point the patient went on vacation.
DISCUSSION:

The soft lens fitting on these keratoconic corneas was more difficult than with a normal cornea. Correction of refractive error was not of specific concern in this case as it usually is with soft lens fitting. Even without this problem the physical fit caused sufficient difficulties to the fitting of the soft lenses.

The philosophy of using the thinnest lenses available was used. The Bausch and Lomb lenses were not found to satisfactorily center. Hydrocurve II lenses were tried with varying success. These lenses were the only lenses large enough to provide good corneal coverage on J. S., but were too large and difficult to handle for M E. There was a problem with the physical fit due to the corneal topography. The steep central area and the relatively flat periphery tended to give edge stand off. After a few attempts an acceptable fit with the Hydrocurve II lenses was achieved with J. S.. Problems encountered in this fit included edge standoff and tightening of the lenses after a period of wear.

M. E. was fitted with Naturvue lenses, but the movement proved to be insufficient after a few days of wear. Edge standoff was a problem with these lenses also. There was a difficulty with both the Naturvue and Hydrocurve II lenses in that a great deal of time was spent waiting for the lenses to arrive from the lab. M. E. was fit with A O Soft lenses and
an initial satisfactory fit was achieved. The lenses did not seem to change fitting characteristics over time as much as the other lenses during the first few weeks of wear.

In all cases the soft lenses produced a surface for fitting the hard lens that was considerably flatter than the corneal keratometer readings. Even lenses of low power gave flatter readings. This would indicate that the soft lenses were vaulting at least some of the areas that the keratometer was measuring.
Hard lens parameters (B.C., OAD, OZD) were determined by the apparent stability and movement on the soft lens during blink. The lenses were chosen as thin and as small in overall diameter as possible for increased tear movement under the lens. Because the soft lens front surface was considerably flatter than the cornea the OAD choice was somewhat restricted. There was a lack of small diameter (less 8.4) lenses in the trial set that had flat enough base curves.

Base curves used ranged from 0.25D flatter than $K_f$ to 4.62D steeper than $K_f$. With respect to movement it was found that changes in B.C, OAD, and OZD had less effect when a hard lens is applied to a soft contact lens surface than when applied to a corneal surface.

The hard lenses in general had a tendency to tighten with wear. There seemed to be a tendency to decrease in movement, an unexplainable "frictional" effect. This may be related to the wetting solutions used (Adapt & Adaptette). When the lenses were first coated with the above solutions, there seemed to be adequate movement. Possibly as the solution is removed from the lenses by the tears and the mechanical action of the lens there is an increased attraction of the hard lens to the soft lens.

There was an obvious difficulty in determining the hard lens' parameters effects on the tear exchange under the hard lens. Fluorescein could not be used because of its attraction
to gel lenses and inherent risks thereof. Moderate magnification and optic section illumination of the biomicroscope were used to help determine the fit, but were of limited value.

Adapt and Adaptettes were used as hard contact lens wetting solutions to decrease the possibility of adsorption into the soft lens of preservatives such as benzalkonium chloride, which in high enough dosage can be detrimental to corneal tissue.

The soft lens sterilization method used at first was the Preflex, Normal, Flexsol regimen. This method was chosen for simplicity of use. Later one patient (M.E.) had to be discontinued due to a possible chemical reaction, and was subsequently placed on the "heat" sterilization method.

Because of the number of lenses utilized at the same time and the lack of means of identifying the soft lenses, there was some difficulty in keeping the proper lens on the proper eye.
CONCLUSIONS

Although other investigators mentioned a relationship in which the base curve of the hard lens was fit slightly flat to slightly steep with respect to the front curvature of the soft lens, they did not always comment on the optical zone diameter of the lens. We did not find a lens fit with this philosophy to result in stability on advanced keratoconic eyes of high corneal curvature (M.E.), but it was valid in the case of less advanced keratoconic eyes (J.S.).

Even with adequate lens movement, there did not seem to be an adequate amount of oxygen distributed to the cornea. Soft contacts by themselves sometimes result in a deficient amount of oxygen to normal corneas. The addition of a hard lens over a soft lens reduces the oxygen transmission by an unacceptable amount (in this study). Smaller over all diameter lenses would increase the transmission of oxygen to the cornea, but were found unstable.

Without a better means to assess the back lens surface curvature (central, intermediate, and peripheral) effect on the tear distribution to cornea, it seems quite difficult to arrive at the parameters of the piggyback system that a patient is capable of wearing for any length of time.

In the near future, gas permeable lenses both hard and soft, may reduce the need for movement of the hard and soft lenses independently of each other. This would greatly simplify
the fitting concept. The practitioner would be more concerned with proper lens powers than optimal fit.

Patients for a study such as this must be selected carefully if success is to be obtained. They must realize that this is a time consuming process, with many failures possible. Patients must also be somewhat dexterious and meticulous to be able to handle the number of lenses involved in the piggyback system. Unfortunately the patients who really need this type of therapy may not be the patient best suited.

There is a need for a wetting solution for such a system. The solutions used seem to decrease in effectivity with wearing time. We can not be sure that the wetting solutions normally used with hard contact lenses are that much more effective. These solutions were not investigated because of their incompatibility with the soft lenses.
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7. Ibid.


