*Eye & Contact Lens 29(1S): S54–S56, 2003*



# Retrospective Case Series of Therapeutic Applications of a Lotrafilcon A Silicone Hydrogel Soft Contact Lens

Jésus Montero, M.D., Jane Sparholt, M.D., and René Mély, M.D.

**Purpose.** To report a series of consecutive cases for which a lotrafilcon A silicone hydrogel soft contact lens was used in therapeutic applications. **Methods.** Three practitioners in Spain, Denmark, and Germany supplied 41 consecutive case reports on 39 patients for whom a lotrafilcon A silicone hydrogel soft contact lens was used in therapeutic applications for erosion or recurrent erosion, bullous keratopathy, corneal edema, corneal dystrophy, neurotrophic corneal ulcer, entropion, and after corneal surgeries. Practitioners reported their judgements of pain relief, change in corneal signs by slitlamp evaluation, additional complications, and success of therapeutic lens treatment. Twenty cases that had completed treatment and 21 that remained under ongoing treatment were reported. **Results.** Complete pain relief was reported for 78% of cases with 94% reporting pain relief of 50% or more. Corneal signs were restored to normal for 74% of cases with 100% showing at least partial improvement. No additional complications were reported in 83% of cases. Therapeutic contact lens application was judged fully successful for 71% of cases with 93% showing at least partial success. **Conclusion.** The high-Dk lotrafilcon A lens met or exceeded the outcomes reported from historic reports of therapeutic applications of low-Dk soft contact lenses. Whereas the case reporting conditions may vary among the historic studies and from the current study, there is the indication that success may be improved with the lotrafilcon A high-Dk lens.

**Key Words:** Therapeutic contact lens—Bandage contact lens—Silicone hydrogel contact lens—Corneal erosion—Recurrent corneal erosion—Corneal edema—Bullous keratopathy—Entropion—Pain relief.

Shortly after the development of the first soft contact lens (SCL), reports of its use as a therapeutic contact lens (TCL) began to appear in the professional literature. Many reports have followed that described applications for TCLs, which include acting as a pressure bandage, pain relief, protection, and drug delivery.

Reports of the benefits of TCL vary. Success of TCLs may be reduced by their application to a cornea that is already compromised, and the criteria and judgement of success may vary. Amos[1] found that 71% of patients studied had moderate or significant pain relief and 51% had moderate or significant improvement in visual acuity (VA). Lindahl et al.[2] reported that 90% of their patients expressed improvement in symptoms and that 87% demonstrated objective improvement in corneal appearance. Dohlman et al.[3] reported full or partial success for 56% of patients. All of these studies were with low oxygen permeable (Dk) SCLs.

The need for adequate oxygen delivery to the normal cornea during contact lens wear was recognized early,[4] and thresholds of 87 barrers and 125 barrers/mm were established for Dk and oxygen transmissibility to avoid corneal compromise. These thresholds have been met by the development of high-Dk SCL materials. In addition to oxygen delivery, other criteria for a successful contact lens include deposit resistance, sufficient movement for tear and debris exchange, and wettable surfaces.

The introduction of the Focus Night & Day lens (CIBA Vision, Duluth, GA), which is a high-Dk fluoro-silicone hydrogel SCL, has resulted in many reports of clinical and subjective benefits with normal contact lens wearers.[5–7] Many international eye care practitioners have asked about and used this lens as a TCL under their scope of medical practice. Their theory was that more Dk would stimulate improved healing or reduce complications of hypoxia as compared with low-Dk materials. The objective of this trial was to report on a multinational, retrospective, consecutive series of patients for whom a high-Dk lotrafilcon A SCL was used in TCL applications.

## MATERIALS AND METHODS

Three practitioners in Spain, Denmark, and Germany supplied 41 consecutive retrospective case reports on 39 patients for whom a lotrafilcon A SCL was used in therapeutic applications. Practitioners were selected for geographical diversity and to increase the potential for reporting on a range of cases by avoiding specialization in one practice. Consecutive case reporting was used to provide data that is unbiased for outcome.

The lens used for all cases was the Focus Night & Day silicone hydrogel SCL that is manufactured from the *United States Adopted Names* material lotrafilcon A. This material is 24% water and has a Dk of 140 barrers. It is available in 8.4-mm and 8.6-mm base curves and in powers from +6.00 to −10.00 diopters (D).

Case report forms were completed based on medical records from the initial treatment visit available. Patient and treatment profile information including sex, age, days of treatment, contin-

This work was supported in part by CIBA Vision Corporation, Global Clinical Affairs, which supplied project management, monitoring, and data management services.

From the-C.E. Oftalmologicas, Sevilla, Spain (J.M.); Rønne, Denmark (J.S.); and Saarlouis, Germany (R.M.).

Address correspondence to: Jesus Montero, M.D., c/o Bill Long, CIBA Vision, 11460 Johns Creek Parkway, Duluth, GA 30097-1556. Phone: (678) 415-4207; fax: (678) 415-2686; e-mail: bill.long@cibavision.novartis.com.

Accepted September 23, 2002.

DOI: 10.1097/01.ICL.0000042266.17736.31

**TABLE 1.** *Diagnoses for therapeutic contact lens application*

| | Completed | Ongoing | Total |
|---|---|---|---|
| Erosion-recurrent erosion | 15 | 1 | 16 |
| Bullous keratopathy-postcataract bullous keratopathy | 0 | 9 | 9 |
| Corneal edema-postcataract and postcorneal transplant | 1 | 7 | 8 |
| Corneal dystrophy | 2 | 1 | 3 |
| Neurotrophic corneal ulcer | 2 | 1 | 3 |
| Entropion | 0 | 1 | 1 |
| Edema after alkali burn | 0 | 1 | 1 |
| Total | 20 | 21 | 41 |

uous lens wearing time, number of visits, and treatment status were collected. The case report sample consisted of 24 (59%) women and 17 (41%) men of average age 45.5 ± 13.2 years. Twenty of the 41 cases reported had completed treatment, and 21 remained under treatment at the time of reporting. The diagnoses for which the TCL was applied are summarized in Table 1.

The primary variables for this trial were practitioner judgements of pain relief, corneal changes by slitlamp evaluation, additional complications, and success of therapy. Pain relief was reported as 100%, 75%, 50%, 25%, or none as judged by practitioners. Corneal changes by slitlamp evaluation were reported as restored to normal, partially improved, worsened, or unchanged. Additional complications were either present or absent and were also reported as induced by TCL application or not. Additional complications were also noted in the case reports. Success of therapy was reported as fully successful, partially successful, or unsuccessful. For unsuccessful cases, the reason was also reported.

Secondary variables included VA and overall fit of the TCL. Visual acuity data varied from counting fingers or light-dark discrimination to measurable Snellen values. Changes in VA have been summarized as improved, none, or decreased. Overall fit of the TCL was reported as acceptably loose, optimal, or acceptably tight.

Additional variables reported included the treatment goal, concomitant therapy, and powers and base curves of lenses used. Treatment goals included pain relief, improvement in corneal signs, or corneal protection. Frequently, multiple treatment goals were noted. Pain relief was the primary treatment goal for 21 (51%) cases. Improvement in corneal signs was the primary treatment goal for three (7%) cases. Both pain relief and improvement in corneal signs were treatment goals for 16 (39%) cases. The TCL was used for corneal protection for one (2%) case. A range of concomitant therapies was used in conjunction with TCL application. Concomitant therapies included prophylactic antibiotic drops, nonsteroidal antiinflammatory drugs, steroids, lubricants, and glaucoma medications. Lens powers ranged from −6.00D to +1.00D, and both the 8.4-mm and 8.6-mm base curves were used.

Data were entered in a Microsoft Excel (Microsoft, Bellevue, WA) spreadsheet and summarized using Microsoft Excel pivot tables. There were no inferential hypotheses for this trial, thus no further statistical analyses were pursued.

## RESULTS

Therapeutic contact lens application was most often solely used for pain relief, constituting 21 (51%) of 41 applications. Pain relief in conjunction with improving corneal signs were the goals for 16 (39%) of the cases reported. Improvement in corneal signs as a sole reason for TCL application was reported as a treatment goal for three (2%) cases.

**TABLE 2.** *Pain relief when primary or additional treatment goal*

| (%) | Completed (%) | Ongoing (%) | Total (%) |
|---|---|---|---|
| 100 | 89 | 68 | 78 |
| 75 | 0 | 11 | 5 |
| 50 | 6 | 16 | 11 |
| 25 | 0 | 5 | 3 |
| 0 | 6 | 0 | 3 |
| ≥50 | 95 | 95 | 94 |

Among the 37 cases in which pain relief was the sole or a combination treatment goal, the TCL was judged as successful for 78% of all cases, 89% of completed cases, and 68% of cases under ongoing treatment. When pain was relieved by 50% or more, TCL application was effective for 95% of completed and 95% of ongoing cases. These data are summarized in Table 2.

Improving corneal signs was a treatment goal for 19 cases. Corneal signs were restored to normal for 74% of the cases reported and 93% of completed cases. As would be expected, no case under ongoing treatment was reported as restored to normal. When partially improved cases were considered, all cases were judged successful. These data are summarized in Table 3.

No additional complications were reported in 34 (83%) of 41 cases. Of these, 18 (90%) were among the 20 completed cases, and 16 (76%) were among the 21 ongoing cases. Non-TCL induced complications were assessed for three cases, and TLC-induced complications were assessed for four cases.

Two cases from one practitioner that developed additional complications were TCL-induced complications. These two cases were reported as caused by suspected but unconfirmed contamination of anesthetic drops that were used when the therapeutic lens was inserted. A symptomatic corneal infiltrate developed in one of these patients and a corneal ulcer in the other. Both were treated with diclofenac and ofloxacin. The patients recovered with small scars but no loss of VA. The practitioner judged the TCL for these two cases as unsuccessful.

Two cases with additional TCL-induced complications reported corneal infection with symptoms of pain in both eyes of a patient who received TCL application bilaterally. The patient was treated with dexamethasone-tobramycin (TobraDex, Alcon, Fort Worth, TX), and TCL application was reported as fully successful although under ongoing treatment at the time of the case report.

Three additional complications were reported as not induced by TCL application. One neurotrophic ulcer case proceeded to stromal necrosis and perforation and symptoms of pain and was treated with topical exocin, dexamethasone, polyvidonum (CIBA Vision, Annonay, France), and systemic azathioprine (Imurel, GlaxoSmithKline, Marly-Le-Roi, France) and believed to be fully successful although still active at the time of reporting. One case with irritation and symptoms of pain was treated with lubricants,

**TABLE 3.** *Change in corneal signs by slitlamp observation*

| | Completed | | Ongoing | | Total | |
|---|---|---|---|---|---|---|
| | *n* | % | *n* | % | *n* | % |
| Restored to normal | 14 | 93 | 0 | 0 | 14 | 74 |
| Partially improved | 1 | 7 | 4 | 100 | 5 | 26 |
| Unchanged | 0 | 0 | 0 | 0 | 0 | 0 |
| Worsened | 0 | 0 | 0 | 0 | 0 | 0 |
| Total | 15 | 100 | 4 | 100 | 19 | 100 |

**TABLE 4.** *Success of TCL therapy*

| | Completed | | Ongoing | | Total | |
|---|---|---|---|---|---|---|
| | *n* | % | *n* | % | *n* | % |
| Fully successful | 14 | 67 | 15 | 75 | 29 | 71 |
| Partially successful | 6 | 29 | 3 | 15 | 9 | 22 |
| Unsuccessful | 1 | 5 | 2 | 10 | 3 | 7 |
| Total | 21 | 100 | 20 | 100 | 41 | 100 |
| Full + partial success | 20 | 96 | 18 | 90 | 38 | 93 |

TCL, Therapeutic contact lens.

judged partially successful, and remained under treatment at the time of reporting. One case with trichiasis and symptoms of pain was treated with Fucithalmic ointment (Leo Pharm Inc., Ajax, Ontario, Canada), judged fully successful, and remained under treatment at the time of reporting.

Therapeutic lens application was judged fully successful for 71% of all cases, 67% of completed cases, and 75% of ongoing cases. When full and partial successes are taken together, the results are 93% for all cases, 96% for completed cases, and 90% for ongoing cases. When the treatment goal was only for pain relief, 18 of 21 cases (86%) were considered fully or partially successful. When both pain relief and the reduction in corneal signs were treatment goals, 14 of 14 cases (100%) were considered full or partially successful. In three cases with the sole treatment goal as the reduction in corneal signs, full success was achieved, with two cases showing signs returned to normal and one case showing partial improvement of signs. However, this latter case was complicated by stromal necrosis unrelated to the bandage lens and has been summarized among the additional complications. In one case, the treatment goal was to protect the cornea from damage caused by entropion. Although the bandage lens was believed to be fully successful in this application, the case was complicated by trichiasis unrelated to the bandage lens and also summarized among the additional complications. Overall success is summarized in Table 4.

Visual acuity was improved for 46% of all cases, 45% of completed cases, and 48% of active cases. One investigator did not take the VA at the initial visit, and the change is unknown. When these cases are excluded, VA improved for 63% of all cases, 100% of completed cases, and 67% of active cases.

Acceptable fit was attained for all subjects, with 78% of fits being judged as optimal and the remainder as acceptably tight or loose. In two cases, the initially fitted 8.4-mm base curve lens was judged as acceptable but tight. These subjects were changed to the 8.6-mm base curve lens on the second day and continued in TCL wear.

## DISCUSSION

The new high-Dk silicone hydrogel lenses have been associated with improved clinical signs in several studies. Differences from low-Dk lenses have been reported for limbal redness,[8] bulbar and limbal redness,[9] and corneal edema.[10] These studies may indicate that improved oxygen permeability supports an environment for better ocular health.

The high-Dk lotrafilcon A lens met or exceeded the outcomes reported from historic reports of therapeutic applications of low-Dk SCLs. This series reported complete pain relief for 78% of all cases in comparison to Amos[1] who reported moderate or significant pain relief with 71% of his cases. Improvement in corneal signs was found for 100% of the cases treated with lotrafilcon A as compared with 87% reported by Lindahl et al.[2] Overall, 93% of the current cases were judged fully or partially successful, whereas Dohlman et al.[3] reported success with 56% of cases. Although the case reporting conditions may vary among the historic studies and from the current study, there is the indication that success in therapeutic applications may be improved with the lotrafilcon A high-Dk lens.

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