Clinical Use of Therapeutic Bandage Contact Lenses

Bruce Baldwin, OD, PhD, FAAO
Fellow, Scleral Lens Education Society
Associate Fellow, Aerospace Medical Association
LtCol (Ret), USAF, BSC
Associate Professor
UNC Ophthalmology

OBJECTIVES
Review, with case reports, bandage lens use, with emphasis on types of patients that might been seen in various specialty practices.

- Retina
- Glaucoma
- Peds
- Optometry
- Oculoplastics
- Cornea
- Neuro

39F, Central abrasion, 14mm SiHy

Re-epithelialization Studies: Serial Photographs

...SIZE MATTERS

Masked comparison of silicone hydrogel lotraflacon A and lotraflacon A extended-wear bandage contact lenses after photo refractive keratectomy.

METHODS: In the prospective study, 100 patients received PRK in both eyes. Each patient received a BCL composed of lotraflacon A (Acuvue [ACV]). Valeon Inc. (14.0 diameter, 8.48 base curve) in 1 eye and lotraflacon A (Focus Night and Day [NOD]). Ciba Vision (13.8 diameter, 8.8 base curve) in the fellow eye. The patient was masked to the lens type in each eye. The postoperative medication regimen was the same with both lenses. The epithelial defect size and subjective level of discomfort were measured at surgery and daily after surgery until both eyes had epithelialized and the lenses were removed.

RESULTS: The mean epithelial defect size at surgery was similar with both BCLs (ACV 57.07 mm²) and NOD 57.5 mm²). On postoperative days 1 and 2, the mean defect size was significantly smaller in eyes with the NOD.
32F, EBMD, Recurrent erosions

1 Week F/U wearing 14mm SiHy

29 Day F/U

Discontinued Therapeutic Lenses

<table>
<thead>
<tr>
<th>LENS</th>
<th>MANUFACTURER</th>
<th>H₂O</th>
<th>Dk (O₂)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plano-T</td>
<td>B &amp; L</td>
<td>38%</td>
<td>9.2</td>
</tr>
<tr>
<td>O4</td>
<td>B &amp; L</td>
<td>38%</td>
<td>9.2</td>
</tr>
<tr>
<td>Optima FW</td>
<td>B &amp; L</td>
<td>38%</td>
<td>9.2</td>
</tr>
<tr>
<td>CSI-T</td>
<td>CIBA Vision</td>
<td>38.6%</td>
<td>13</td>
</tr>
<tr>
<td>Permalens</td>
<td>Cooper Vision</td>
<td>71%</td>
<td>34</td>
</tr>
</tbody>
</table>

FDA Approved Therapeutic Lenses

<table>
<thead>
<tr>
<th>LENS</th>
<th>MANUFACTURER</th>
<th>H₂O</th>
<th>Dk (O₂)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oasys</td>
<td>Vistaken</td>
<td>38%</td>
<td>103</td>
</tr>
<tr>
<td>Air Optix NBD</td>
<td>Alcon/CIBA</td>
<td>24%</td>
<td>140</td>
</tr>
<tr>
<td>Purevision</td>
<td>B &amp; L</td>
<td>36%</td>
<td>99</td>
</tr>
</tbody>
</table>

www.fda.gov/MedicalDevices/
P890006/5007 5/27/05

BAUSCH & LOMB® PureVision™ [bifilcon A] Visibility Tinted Contact Lens for Therapeutic Use Bausch & Lomb, Rochester, NY

Approval for adding a therapeutic indication for the PureVision Contact Lens. The device, as modified, will be marketed under the trade name BAUSCH & LOMB® PureVision™ [bifilcon A] Visibility Tinted Contact Lens for Therapeutic Use and is indicated for therapeutic use as a bandage contact lens for corneal protection and corneal pain relief during treatment of ocular pathologies as well as post-surgical conditions. Applications of the PureVision Contact Lens include but are not limited to:

1) For corneal protection in conditions such as entropion, trichiasis, tarsal scars, recurrent corneal erosion and post surgical ptosis for corneal protection; 2) For corneal pain relief in conditions such as bullous keratopathy, epithelial erosion and abrasion, filamentary keratitis, post-keratoplasty; 3) For use as a bandage during the healing process of conditions such as chronic epithelial defects, corneal ulcer, neurotrophic keratitis, neuroparalytic keratitis, chemical burns, and post surgical epithelial defects; and 4) For post surgical conditions that include bandage use such as LASIK, PRK, PK, PTK, lamellar grafts, corneal flaps, and additional corneal surgical conditions. Pure Vision Contact Lenses for therapeutic use can also provide correction during healing if required.

...indicated for therapeutic use as a bandage contact lens for corneal protection and corneal pain relief during treatment of ocular pathologies as well as post-surgical conditions.

include but are not limited to: entropion, trichiasis, tarsal scars, recurrent corneal erosion and post surgical ptosis for corneal protection; bullous keratopathy, epithelial erosion and abrasion, filamentary keratitis, post-keratoplasty; chronic epithelial defects, corneal ulcer, neurotrophic keratitis, neuroparalytic keratitis, chemical burns, and post surgical epithelial defects; LASIK, PRK, PK, PTK, lamellar grafts, corneal flaps.

**Lenses for therapeutic use can also provide correction during healing if required.**
Approval for an additional indication for therapeutic use for the VISTAKON®…ACUVUE® OASYS™...

5) For structural stability and protection in piggy back lens fitting where the cornea and associated surfaces are too irregular to allow for corneal rigid gas permeable (RGP) lenses to be fit. In addition the use of the lens can prevent irritation and abrasions in conditions where there are elevation differences in the host/graph junction or scar tissue. Lenses prescribed for therapeutic use may be worn for daily or extended wearing periods.

www.fda.gov/MedicalDevices/
Painful bullae

Indications for PK

<table>
<thead>
<tr>
<th>Rank</th>
<th>2012</th>
<th>2011</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Unknown, unreported, or</td>
<td>Unknown, unreported, or</td>
<td>Ectasia/Thinings (Keratoconus)</td>
</tr>
<tr>
<td></td>
<td>unspecified 9.70%</td>
<td>unspecified 8.72%</td>
<td>4.71% (2.1%)</td>
</tr>
<tr>
<td>2</td>
<td>Ectasia/Proffings (Keratoconus)</td>
<td>Ectasia/Proffings (Keratoconus)</td>
<td>Other causes of endothelial</td>
</tr>
<tr>
<td></td>
<td>8.60% (3.1%)</td>
<td>7.50% (2.1%)</td>
<td>dysfunction 4.65% (2.1%)</td>
</tr>
<tr>
<td>3</td>
<td>Repeat corneal transplant</td>
<td>Repeat corneal transplant</td>
<td>Repeat corneal transplant</td>
</tr>
<tr>
<td></td>
<td>4.460 (22.2%)</td>
<td>4.771 (22.2%)</td>
<td>4.771 (22.2%)</td>
</tr>
<tr>
<td>4</td>
<td>Other causes of corneal</td>
<td>Other causes of corneal</td>
<td>Post-cataract surgery</td>
</tr>
<tr>
<td></td>
<td>dysfunction or distortion</td>
<td>dysfunction or distortion</td>
<td>exsuln 3.090 (18.9%)</td>
</tr>
<tr>
<td></td>
<td>(inc-incutable)</td>
<td>(non-incutable)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3.795 (20.7%)</td>
<td>4.113 (21.1%)</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Post-cataract surgery</td>
<td>Post-cataract surgery</td>
<td>Other degenerations or</td>
</tr>
<tr>
<td></td>
<td>exsuln 3.710 (20.7%)</td>
<td>exsuln 3.710 (20.7%)</td>
<td>dystrophies 1.050 (8.5%)</td>
</tr>
</tbody>
</table>

TOTAL PK 39,574 36,144 22,382

2012 Eye Banking Statistical Report
Eye Bank Association of America, www.restoresight.org

2009 Eye Banking Statistics Reported by U.S. Banks:
Distribution of Tissues
78 U.S. Eye Banks Reporting

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Corneal Grafts Total</td>
<td>51.78</td>
<td>57.94</td>
<td>50.02</td>
<td>49.26</td>
<td>49.39</td>
</tr>
<tr>
<td>Penetrating Keratoplasty</td>
<td>23.39</td>
<td>23.52</td>
<td>34.06</td>
<td>38.06</td>
<td>43.82</td>
</tr>
<tr>
<td>Stromal Grafts Keratoplasty</td>
<td>774</td>
<td>1,072</td>
<td>950</td>
<td>106</td>
<td>860</td>
</tr>
<tr>
<td>Stromal Grafts Keratoplasty</td>
<td>18,221</td>
<td>17,468</td>
<td>14,150</td>
<td>6,072</td>
<td>4,129</td>
</tr>
<tr>
<td>Stromal Grafts Keratoplasty</td>
<td>120</td>
<td>173</td>
<td>207</td>
<td>138</td>
<td>179</td>
</tr>
<tr>
<td>Stromal Grafts Keratoplasty</td>
<td>92</td>
<td>122</td>
<td></td>
<td>176</td>
<td></td>
</tr>
<tr>
<td>Stromal Grafts Keratoplasty</td>
<td>7,624</td>
<td>5,514</td>
<td>4,694</td>
<td>4,018</td>
<td>3,386</td>
</tr>
<tr>
<td>Sclera</td>
<td>2,053</td>
<td>980</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Long-Term Preserved Corneas</td>
<td>14,547</td>
<td>13,730</td>
<td>13,824</td>
<td>11,845</td>
<td>14,332</td>
</tr>
<tr>
<td>Research</td>
<td>5,113</td>
<td>5,385</td>
<td>4,804</td>
<td>4,038</td>
<td>3,477</td>
</tr>
</tbody>
</table>

The shaded numbers reflect tissues distributed and used within the U.S. only. Data for tissue distributed internationally did not include by surgery type. Data from previous years included U.S. and international distribution of tissues.

2013 Eye Banking Statistics Reported by U.S. Banks:
Use of Donated Tissues
76 U.S. Eye Banks Reporting

<table>
<thead>
<tr>
<th>Distribution</th>
<th>2013</th>
<th>2012</th>
<th>2011</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corneal Grafts Total</td>
<td>77,736</td>
<td>68,081</td>
<td>67,500</td>
<td>19,271</td>
</tr>
<tr>
<td>Penetrating Keratoplasty</td>
<td>16,398</td>
<td>16,716</td>
<td>16,144</td>
<td>25,308</td>
</tr>
<tr>
<td>Stromal Grafts Keratoplasty</td>
<td>2,029</td>
<td>1,853</td>
<td>1,778</td>
<td>1,041</td>
</tr>
<tr>
<td>Stromal Grafts Keratoplasty</td>
<td>7,716</td>
<td>14,277</td>
<td>21,287</td>
<td>15,127</td>
</tr>
<tr>
<td>Stromal Grafts Keratoplasty</td>
<td>110</td>
<td>97</td>
<td>97</td>
<td>109</td>
</tr>
<tr>
<td>Keratoplasties (K-P)</td>
<td>255</td>
<td>263</td>
<td>308</td>
<td>342</td>
</tr>
<tr>
<td>Glaucoma Short Patch or other</td>
<td>0</td>
<td>276</td>
<td>624</td>
<td></td>
</tr>
<tr>
<td>keratoplasty used</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other keratoplasty (surgical)</td>
<td>17</td>
<td>44</td>
<td>57</td>
<td></td>
</tr>
<tr>
<td>Unknown or Unspecified</td>
<td>1068</td>
<td>1,315</td>
<td>2,213</td>
<td></td>
</tr>
<tr>
<td>Sclera</td>
<td>3,093</td>
<td>3,477</td>
<td>5,567</td>
<td>6,786</td>
</tr>
<tr>
<td>Long-Term Preserved Corneas</td>
<td>4,040</td>
<td>4,435</td>
<td>3,303</td>
<td></td>
</tr>
<tr>
<td>Keratoplasty</td>
<td>499</td>
<td>325</td>
<td>276</td>
<td></td>
</tr>
<tr>
<td>Glaucoma Short Patching</td>
<td>4,040</td>
<td>4,435</td>
<td>3,303</td>
<td></td>
</tr>
<tr>
<td>Other Surgical Tissue</td>
<td>335</td>
<td>335</td>
<td>335</td>
<td></td>
</tr>
<tr>
<td>Research</td>
<td>18,354</td>
<td>19,320</td>
<td>19,230</td>
<td>17,260</td>
</tr>
<tr>
<td>Training</td>
<td>7,851</td>
<td>6,950</td>
<td>6,940</td>
<td>5,726</td>
</tr>
</tbody>
</table>

2013, 14mm SiHy q 4-6 weeks

Large abrasion, Long RD surgery Retina
Cornea Volume 26, Number 10, December 2007

**Infected and leaking filtering bleb Glaucoma**

20mm lens for tamponade

Bleb revision, 16mm, leak sealed in two weeks

Rub Glau, NLP, Ta 50
8.0, 3.7mm pupil, 14.5

Brain tumor, exposure keratopathy

Speculum may be needed for peds or adults

7yo F, Pencil trauma, aphakic
"Bandage lens" +1400 custom SiHy
Precautions for peds with vision loss?

"...oncocytic carcinoma arising in a pleomorphic adenoma involving lacrimal gland."  
Oculoplastics

Radiation orbitopathy

Non-healing epi defect after lid procedure

+1450 RGP  
With/without piggyback  20/50

Punctal plug  
20mm BSCL
Maintained on 14mm SiHy for 3+ years
Pain control, 20/200 PH 20/60

Ptosis surgery & revisions, lid scarring

Ptosis Surgery & Revisions, Exposure Keratopathy

82F, Uncomplicated phaco
PO day 3 weight lifting, leak

Choroidal effusion/Detachment

15mm edema, exchanged for 16mm
SLK, Lissamine Green

Pterygium, recurrent x 3
 Significant symblepharon with motility restriction and diplopia

Pterigectomy, conjunctival autograft
PERFECT: Pterygium Extended Removal Followed by Extended Conjunctival Transplant

http://www.aao.org/publications/eyenet/201202/cornea.cfm

One day post-op

Post-op day 14
20/60 chemosis resolving
Exchanged 18mm for a 20mm, 9.8
Bubble removed with manual slide technique

Post-op day 43
17F, Trauma, open globe, leak

PK, sulcus IOL, pupilloplasty UCVA 20/40

38M, CL Pseudomonus ulcer, perf, HM VA

Aug 2010
HM Va

Oct 2010

Oct 2010, Glue removed, 20/60

53F, LASIK OU with enhancements OU 2004

Multifocal IOL OS, broken haptic during surgery & IOL exchange 2010

Edema, pain, flap dehiscence

BCVA 20/200

Bandage lens x 13 months
14.4mm, 55% H20 BSCL for pain control and edema deturgescence

March 2011
Flap dehiscence, ragged endothelium

September 2011
BSCL

29F, CL, Pseudomonas aeruginosa
ER: erythromycin, ketorolac
MD: vanc/gent, Vig q4h
Beter & dexamethasone TID 3 days

Referred with failed PK x 2, HM VA for prosthetic hand painted SCL
After 16mm BSCL 20/70
Specimen A shows a thin layer of stratified nonkeratinizing squamous epithelium with no evidence of corneal/conjunctival intraepithelial neoplasia (CIN).

Specimen B shows a sessile papilloma. No CIN is identified.

Specimen C shows conjunctival epithelium with no evidence of CIN.

What Do You See?
Invasive SCC

Graves disease
Exposure

Posted for second orbital decompression
Neuro-ophthalmology

Exposure, risk of perforation
Use largest lens possible, 20mm

41M, SJS-TEN
Cough, OS conjunctivitis
Amoxicillin & Tobramycin drops OS
ICU then Burn ICU
BSCVA 20/80
**Piggyback**

*Oasys, 8.4, plano, 10.5mm RGP 20/50-30*

---

Mark Byrne, PhD, Auburn University

---

**imprinted hydrogel contact lenses**

Maryam Ali ¹, Shin Horkawa ², Siddarth Venkatash ³, Jishu Saha ⁴, Jong Wook Hong ⁵, Mark E. Byrne ⁶,⁷

¹ Economics & Behavioral Sciences, Electrical, Biomedical, and Drug Delivery Laboratory, Department of Chemical Engineering, Auburn University, Auburn, AL 36849, USA
² Institute of Life Sciences, Materials Science Research and Education Center, Department of Mechanical Engineering, Auburn University, Auburn, AL 36849, USA

---

**Ketotifen**

3 Days

---

Fig. 6. Zero-order fractional and cumulative drug release from imprinted lenses in a physiological flow. (a) The fraction of ketotifen fumarate and (b) cumulative mass released from poly(AA-co-AM-co-NVP-co-HEMA-co-PEG200DMA) lenses in artificial lacrimal fluid at 25 °C via steady in vitro physiological flow rate of 3 μL/min using the microfluidic device ($n=2$).
University of Florida

Biomaterials

Extended delivery of hydrophilic drugs from silicone-hydrogel contact lenses containing Vitamin E diffusion barriers

Cheng-Chun Peng, Jin-hui Kim, Anoj Chauhan

Department of Chemical Engineering, University of Florida, Gainesville, FL 32611-6104, USA

ACUVUE® ADVANCE™ (Johnson & Johnson Vision Care, Inc., Jacksonville, FL)
ACUVUE® OASYS™ (Johnson & Johnson Vision Care, Inc., Jacksonville, FL)
NIGHT&DAY™ (Ciba Vision Corp., Duluth, GA)
O2OPTIX™ (Ciba Vision Corp., Duluth, GA)
PureVision™ (Bausch & Lomb, Inc., Rochester, NY)

2 Weeks

Lenses Soaked in Vitamin E & Timolol

uncod@nc.rr.com