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**COVER FEATURE**

## Cornea Artificial corneas much improved

by **Michelle Dalton** EyeWorld Contributing Editor

*Compared to earlier versions, today's artificial corneas are much less likely to fail, giving corneal surgeons safer options for their graft failure patients*

**EW WEEK No. 11**

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Call it a keratoprosthesis, call it an artificial cornea. Whichever term is preferred, the devices available in the United States play a substantial role in combating corneal blindness in patients who are no longer candidates for penetrating keratoplasty (PK). The Boston K-Pro (also called the Dohlman-Doane, developed at Massachusetts Eye and Ear Infirmary, MEEI, Boston) has been in development since the 1960s, and was approved for use in the United States in 1992. Another artificial cornea, the AlphaCor (developed by Argus Biomedical, Australia) has been available in the United States since 2002.

Earlier versions of keratoprostheses had high rates of severe complications, such as tissue necrosis, leakage, endophthalmitis and extrusion. The improvements in design have renewed interest in device development, and several organizations are working towards other types of artificial corneas (see sidebar). The Boston K-Pro is made of clear plastic with excellent tissue tolerance and optical properties, MEEI notes on its Web site. It consists of two parts, but when fully assembled in the eye looks more like a collar button. The device is inserted into a corneal graft, which is then sutured into the patient's cloudy cornea in a surgical procedure similar to a standard transplant. The AlphaCor is a curved flexible plastic disc; the central part of the disc is transparent. The rim, or skirt, of the device resembles a sponge and acts to secure the device into place by allowing the patient's own tissue to grow into it and hold it in place.

**Advantages and disadvantages**

"The most critical issue in the design of a keratoprosthesis device is finding a solution to the engineering dilemma, i.e., how to create a piece of a prosthetic structure that both likes (has a high affinity for) and dislikes (has a low affinity for) recipient host tissue at the same time. Alphacor engineers attempted to solve this problem by designing a device that has two distinctly different and separately located zones, i.e., a host-tissue friendly outer skirt that has a high affinity for recipient rim tissue (the skirt is porous, which encourages host tissue to grow into it, vascularize, adhere and anchor), and a host-tissue unfriendly central clear optical region made up of a polymer material that has a low affinity for host tissue, thereby discouraging host tissue attachment, adhesion and migration over the central optical region of the prosthesis. This is a unique design, solving the dual requirements of a keratoprosthesis, namely the need of having opposing tissue affinity, by locating them in different parts of the device. Additional advantages of the Alphacor also include:

- 1) It most closely resembles the appearance of an actual human cornea;
  - 2) It can be implanted within the cornea, thereby causing less ocular structural distortion;
  - 3) Its anterior optical curvature can be engineered to fit the patient's eye condition (aphakic versus phakic, or pseudophakic).
- Overall, compared with the traditional hard keratoprosthesis, Alphacor has shown to have a higher retention rate, better visual outcome and a bit more satisfactory cosmetic appearance," said Ming Wang, M.D., Ph.D., medical director of refractive surgery, Aier Eye Hospital System, the People's Republic of China, and clinical associate professor of ophthalmology, University of Tennessee, Nashville.

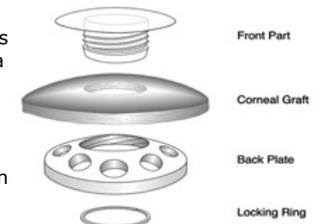
"It's an extra-ocular procedure; the implant is placed within the cornea stroma," said James V. Aquavella, M.D., professor of ophthalmology, the University of Rochester Eye Institute, New



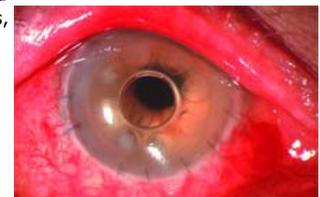
**Boston keratoprosthesis in herpes simplex (20/25 vision).**



**A painted soft contact lens (right eye) can enhance cosmetic appearance of the keratoprosthesis.**



**Principles of assembly of the Boston keratoprosthesis into a carrier corneal graft.**



**The Boston KPro Type 1 in situ. Source: Photos courtesy of MEEI**

York. "The potential candidates are [primarily] those who have failed an initial corneal transplant."

In the literature, the AlphaCor may have a failure rate as high as 20% in the first year.

The virtues of the Boston K-Pro "are its particular stability and retention, which is very high. In non-autoimmune diseases, the retention rate is almost 100% over many years," said Claes Dohlman, M.D., Ph.D., who is a co-developer of the K-Pro, professor of ophthalmology, emeritus, Harvard Medical School, Boston, and affiliated with MEEI. Dr. Dohlman is presently directing a large research program on the Boston KPro. A new design will be introduced in a few months.

"The main advantage of the Boston K-Pro is that it rapidly establishes good vision, the technique is straightforward and follows the usual corneal transplant procedure," Dr. Aquavella said. "We have done considerable testing and find that the quality of the optics with this device approximates that of the normal human cornea."

"The Boston K-Pro is much easier to implant from a physician's perspective," said Michael W. Belin, M.D., professor of ophthalmology and director of cornea & refractive surgery at Albany Medical College, New York.

When the AlphaCor was first introduced, surgical implantation was a two-step process, Dr. Belin said.

"Initially, you'd do an intralamellar dissection, put the prosthesis in and close it over [with a Gunderson flap]. About 3 months later, you'd go back in to open it up and expose the optic," he said.

Both lenses have disadvantages, the surgeons note.

"My main problem with the AlphaCor is the difficulty in obtaining good vision," Dr. Aquavella said. "There is no pupil effect and thus glare becomes a large factor."

Both Drs. Aquavella and Belin remained concerned about the AlphaCor's ability to stain as well.

The plastic in the AlphaCor "discolors easily from the use of several medications which are commonly used in the eye," Dr. Aquavella said.

"It's a limitation for the AlphaCor—it's a soft, flexible material, but there are numerous drops that will stain the device and cannot be used with it," Dr. Belin said. "The Boston K-Pro is PMMA (polymethyl methacrylate), so staining doesn't present the same difficulties."

"The Boston K-Pro is custom made and can correct for refractive errors including aphakia which is very advantageous especially in pediatric cases said Esen K. Akpek, M.D., associate professor of ophthalmology and director, Ocular Surface Diseases and Dry Eye Clinic at the Wilmer Eye Institute, Baltimore. "This makes the post-operative visual rehabilitation easier."

In addition, the AlphaCor lies within the plane of the original cornea without affecting other parts of the eye and can be replaced with human donor tissue or a new AlphaCor in the event of a complication, according to physicians with Advocate South Suburban Hospital, Hazel Crest, Ill. A donor graft performed after an AlphaCor is removed may fail but it will restore the patient to the pre-AlphaCor status in most cases, placing the patient in the same position as prior to the AlphaCor, they said.

The potential for subsequent corneal surgery is a main reason Dr. Wang said he prefers the AlphaCor in children and patients from developing countries.

#### Potential patient candidates

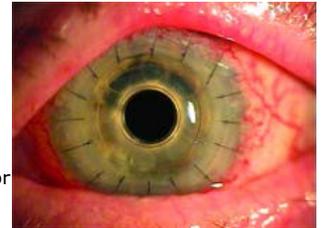
Generally, patients would be suitable for the K-Pro if they have had two failed grafts with a poor prognosis for subsequent grafts, vision less than 20/400 in the affected eye and lower than optimal vision in the contralateral eye, and no end-stage glaucoma or retinal detachment. Patients with autoimmune diseases such as pemphigoid, Stevens-Johnson syndrome, uveitis or Sjögren's syndrome are generally not good candidates for the K-Pro.

"The autoimmune and inflammatory diseases such as Stevens-Johnson and ocular cicatricial pemphigoid, have the worst prognosis for any surgical intervention, including K-Pro," Dr. Dohlman said. Patients are more likely to be candidates for the AlphaCor if they have severe corneal injuries or repeated corneal graft failures, said Dr. Wang.

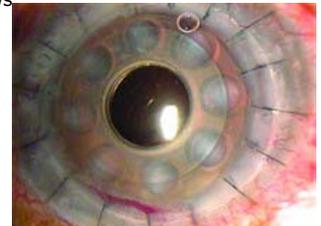
"The AlphaCor hasn't shown great results in patients with ocular surface diseases, severe dry eye or herpes infection," Dr. Akpek said. In fact, the AlphaCor is contraindicated in people with ocular herpes, as stromal melting is a potential side effect in patients with that disease.

"The Boston K-Pro can be implanted in those patients, even though the outcome may not be ideal," she said.

Dr. Aquavella has implanted more than 200 Boston devices "in a variety of conditions ranging from severe autoimmune disease and infants, through ocular inflammation and chemical injuries, down to the more common transplant failures and even as a primary procedure in noninflamed eyes to establish vision rapidly rather than wait the year or more involved with a corneal transplant."



One week after implantation of the Boston Type 1 artificial cornea.



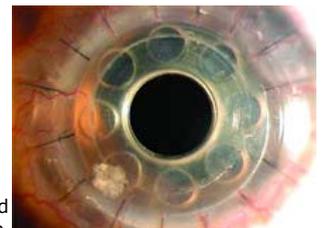
The Boston KPro Type 1, in situ.



The retainer ring of the Boston KPro.  
Source: Michael Belin, M.D.



A patient, on post-op day 1 after implantation with the Boston KPro.



The same patient, 2 months post-op.



The Alphacor artificial cornea.  
Source: Michael Belin, M.D.

He said his experience with the AlphaCor is more limited, as the eight implant procedures he performed about 5 years ago all required explantation.

"Clearly, even if I used AlphaCor I would not do so in cases with glaucoma, inflammation or autoimmune disease," he said. He has exclusively used the Boston K-Pro for several years and has no plans to convert back to using the AlphaCor.

"In our setting, the K-Pro has been incredibly exciting and our patients have done very well," said Elisabeth J. Cohen, M.D., director of Wills Eye Cornea Service, Philadelphia. "We've had very dramatic results. The AlphaCor, however, has been disappointing. We had one patient in whom we implanted an AlphaCor and subsequently had to explant it and put in a K-Pro instead. In that patient, the device didn't fuse initially, and then the visual acuity was only 20/400."

At Wills, "a number of patients" with failed grafts or glaucoma (presuming no ocular surface disease) have done well after K-Pro implantation, and Dr. Cohen estimates that of the 25 implantations, "about half" had great vision outcomes.

"Vision is limited by a prior glaucomatous optic nerve damage. For glaucoma patients, either they already have had tubes implanted, or we'll implant one at the time of the keratoprosthesis surgery," she said.

Patients with severe surface diseases "have a worse prognosis" than patients who have simply failed prior PK, said Dr. Belin.

"Clearly when the data is stratified, patients with chemical burns and surface disease have worse outcomes," he said.

In the first collaborative multicenter effort to evaluate the Boston Type 1 K-Pro, Dr. Belin and colleagues evaluated 141 surgical procedures; an average follow-up of 8.5 months showed a retention rate of 95%.<sup>1</sup>

"We have a number of patients seeing better than legal driving vision," he said. "When something works, you tend to try and expand it beyond its original indications. We're now studying using it in other conditions such as severe surface disease or chemical burns, even though that's not what it's indicated for."

A study of the AlphaCor in 14 patients with a mean follow-up of 13.3 months found the probability of retention beyond 1 year of 80% in nonherpetic eyes.<sup>2</sup> Further, the authors found if patients were prescribed medroxyprogesterone 1%, the probability of successful implantation at 1 year was 100%.

"In our setting, the patients all have pre-existing conditions," said Dr. Akpek. "These include no fornices, terrible dry eye, non-healing corneal epithelial defects, atopic keratoconjunctivitis—they are all very complicated surgical cases, and the patient usually has to undergo multiple surgeries such as fornix reconstruction before the eye is prepared to receive an artificial transplant. Majority of Dr. Akpek's patient population comprises those with trachoma (usually from the Middle East), and those patients would receive the Boston K-Pro as they are not eligible for the AlphaCor, she said.

### Surgical techniques

Surgical implantation of the AlphaCor remains a two-step process, said Dr. Wang. In the first step, the surgeon creates a lamellar pocket, within the stroma of the recipient corneal tissue. Then the surgeon punches through the posterior lamellar, to create a central 3-mm opening from the pocket into the anterior chamber. The surgeon places the AlphaCor in the pocket and "zips" close the pocket opening, Dr. Wang said.

"About 3 months later, you punch through a 3-mm opening in the anterior lamella, so that the anterior lamellar hole, the center of the AlphaCor and the posterior lamellar hole are all aligned," he said. "Light will then be able to penetrate through and reach the retina."

In general, the literature notes the most common complications with the AlphaCor were stromal melting, fibrous reclosure of the posterior lamellar opening and white intraoptic deposits, with incidences in 2005 of 11.4%, 5.1% and 2.6%.<sup>3</sup>

The Boston K-Pro currently has two versions, with slightly different surgical techniques, surgeons said. The Type I is incorporated into a fresh corneal graft and sutured into the eye much like a standard PK.

Design changes in the K-Pro "have improved nutrition and hydration to the overlying corneal tissue," Dr. Dohlman said, which greatly reduced the complication rate from earlier iterations. The Type I is typically used for low-inflammation graft failures and chemical burns while the Type II is more often used for end-stage autoimmune diseases, Dr. Dohlman said.

In Type II surgery, the K-Pro is implanted so that the nub is allowed to protrude through the closed lids. The fornices are cleaved to allow for the implantation of the graft; a small central notch is made in the upper lid and a tight permanent tarsorrhaphy is made on both sides of the protruding nub.

"Pre-operatively, we use no special treatment for either device," Dr. Aquavella said. "If the patient presents with mild glaucoma, medication is used post-operatively with the Boston device. If there is severe glaucoma, we use shunts before, during or after surgery."

Additionally, Dr. Dohlman said years ago, corneal melt of the tissue around the plastic was a "tremendous" problem.

"We have now made the K-Pro in such a way that the backplate holding the prosthesis is in the back, away from the cornea and we've put holes for nutrition on the top of the device. Melting is practically gone," he said. Add to that a regimen of vancomycin and earlier reports of endophthalmitis are no longer an issue, he said.

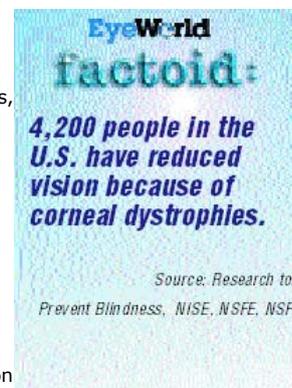
He notes the Type II "has about a 50% survival rate at 5 years. It's not 100% like it should be, but we are working quite heavily on that."

The Boston device "is versatile and has changed the whole subject of keratoprosthesis from an infrequently performed, highly complicated procedure to one which provides excellent visual rehabilitation rapidly in complicated as well as routine cases, and is often the procedure of choice," Dr. Aquavella said.

"Are these the 'ideal' keratoprostheses? No. It's a prosthesis, it's not human tissue," Dr. Belin said. "There's always some reaction to it. But results to date are beyond our initial expectations. When



A patient after the first stage of Alphacor implantation.  
Source: Ming Wang, M.D.



used in an appropriate patient, artificial cornea implantation is an excellent procedure.”

Dr. Akpek believes that artificial corneas will replace donor corneal transplantation altogether in the future for multiple reasons one of which is the difficulty to obtain and process good quality donor tissues even in the developed countries. I think we need to work harder on developing an ideal artificial cornea” Dr. Akpek said It should, ideally, be exactly like a human cornea; flexible, biointegrate into host tissue, covered by the patient’s own corneal epithelium shouldn’t cause other ocular problems, and chance of rejection or melt should be small.”

**Editor’s note:** None of the physicians has a direct financial interest in the aforementioned comments or devices mentioned.

**Contact information:**

**Akpek:** 410-955-7928; esakpek@jhmi.edu

**Aquavella:** 585-275-8957; James\_Aquavella@URMC.Rochester.edu

**Belin:** 518-475-1515; mwbelin@aol.com

**Cohen:** 866-337-7167; ecohen@willseye.org

**Dohlman:** 617-573-3996; Claes\_Dohlman@meei.harvard.edu

**Wang:** 615-321-8881; drwang@wangvisionistitute.com

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