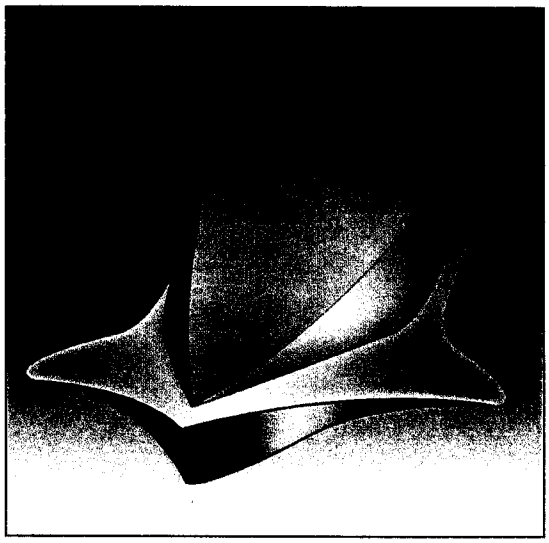
Ultra-Glide®

Corneal Transplant Sutures



Sharpoint®

The Surgeon's Edge

Ultra-Glide® Corneal Transplant Sutures

Ultra-Glide® Corneal Transplant Sutures were specifically designed to meet the performance requirements of the corneal transplant surgeon:

- Unique "lift and cut" design action
- Reduced tissue drag, ensuring tightly sealed closures that do not leak
- Needle strength prevents curvature change, providing for exact suture placement
- Precision sharp cutting edges provide for effortless penetration throughout the procedure
- Non-glare finish reduces flash from microscope light

To learn more about Sharpoint® Ultra-Glide Corneal Transplant Sutures, contact our Customer Service Team at 800-523-3332 or 610-404-1000.

"CUTTING EDGE" NEEDLE TECHNOLOGY FROM SHARPOINT®

NYLON BLACK MONO — ULTRA-GLIDE

NEEDLE	DESCRIPTION		SUTURE LENGTH	SUTURE SIZE 11-0	SUTURE SIZE 10-0	ALCON NEEDLE	ETHICON NEEDLE	MICROTECH NEEDLE
DGL6	¾ Circle Curvature 140 Length 6.15 mm	Radius 2.54 mm Chord 4.82 mm Wire .15 mm	4"/10 cm		AA-2673N	CU1 AU1 NU1	TG140-6 CS140-6	MI-135
2xDGL6	¾ Circle Curvature 140 Length 6.15 mm	Radius 2.54 mm Chord 4.82 mm Wire .15 mm	12"/30 cm		AA-2627N	CU1 AU1 NU1	TG140-6 CS140-6	MI-135
HGL5	½ Circle Curvature 160 Length 5.51 mm	Radius 2.03 mm Chord 4.06 mm Wire .15 mm	4"/10 cm		AA-2674N	CU5 AU5 NU5	TG160-6 CS160-6	MI-160
2xHGL5	½ Circle Curvature 160 Length 5.51 mm	Radius 2.03 mm Chord 4.06 mm Wire .15 mm	6"/15 cm	AA-2713N	AA-2712N	CU5 AU5 NU5	TG160-6 CS160-6	MI-160
2xHGL5	½ Circle Curvature 160 Length 5.51 mm	Radius 2.03 mm Chord 4.06 mm Wire .15 mm	12"/30 cm		AA-2626N	CU5 AU5 NU5	TG160-6 CS160-6	MI-160
2xHGL7	½ Circle Curvature 175 Length 6.99 mm	Radius 2.29 mm Chord 4.57 mm Wire .15 mm	12"/30 cm		AA-2714N	CU2 AU2	TG175-8 CS175-8	MI-175
2xBGL5	Bicurve Curvature 90/50 Length 4.83 mm	Rad 1.52/2.79 mm Chord 3.71 mm Wire .15 mm	8"/20 cm		AA-2716N	CU8 AU8 NU8	TG6-3 CSB-6 CSC-6	MI-500
2xBGL5	Bicurve Curvature 90/50 Length 4.83 mm	Rad 1.52/2.79 mm Chord 3.71 mm Wire .15 mm	12"/30 cm		AA-2675N	CU8 AU8 NU8	TG6-3 CSB-6 CSC-6	MI-500

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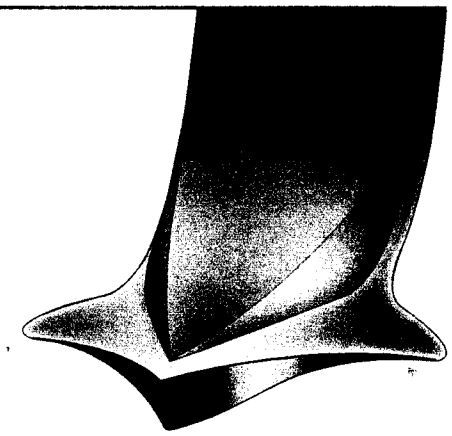
Sharpoint®
The Surgeon's Edge

Achieve Clinically Advanced Outcomes with the Right Needles



DermaGlide oculoplastic needles

Producing needles for oculoplastic surgical procedures is one of the greatest quality challenges facing manufacturers.

Traditional cuticular needles have three facets of equal cutting-edge angles (60-degree) that form a triangular point. The needles are triangular not because this shape provides any benefits to the patient, but because it's simple to produce.

To achieve enhanced cutting with minimal trauma and scarring, ophthalmic lancets offer superior geometry. Lancets cut with two edges rather than three, and the angle of each cutting edge is far less than 60 degrees, creating a sharper needle. Sharpoint DermaGlide needles are based on this technology, ensuring a clinically superior oculoplastic needle.

DermaGlide needles are produced with the same proprietary grindless blade-making process developed by Surgical Specialties Corporation. The needle tips resemble miniature vitrectomy knifes — the very finest tips available — which produce the following significant clinical advantages:

- Curved tips track properly.
- Concave facets reduce tissue drag during penetration.
- Tips transition directly into an oval needle body to prevent lifting the incision during passage.

The tips on DermaGlide needles are formed, rather than ground, ensuring that each tip is positioned centrally to the needle body. The most significant clinical benefit is the ability of DermaGlide needles to penetrate the skin with less than half the force of the best competitive product available on the market today — without sacrificing strength or malleability.

UltraGlide corneal transplant needles

Since the introduction of UltraGlide Corneal Transplant Sutures, many surgeons have come to appreciate their unsurpassed performance characteristics.

Corneal tissue has a tendency to "roll under" and follow the needle if it lacks sharpness. Any distortion of the cornea causes the fibrous layers to "delaminate" and lose clarity.

The UltraGlide needle has concave facets to minimize tissue contact and friction. The tip has an angle of approximately 45 degrees for strength and precise placement, and a smooth, "spiraling" transition into 30-degree cutting facets at the widest cross-section of the point. Complementing this cutting geometry is a unique "lift-and-cut" ramp that gently directs corneal tissue upward and prevents it from rolling under itself.

The "lift-and-cut" ramp also keeps a minimal degree of tension on the tissue to facilitate the incising process.

How Do You Determine Quality?

Each type of surgical needle must incorporate distinct quality characteristics into the design. Three characteristics are universal to all surgical needles.

Penetration, or sharpness, describes the ease with which the needle passes through tissue.

Stiffness is the ability to resist bending. The required stiffness relates inversely to the needle's penetration quality.

Ductility, or malleability, is the ability to bend without breakage. Stiffness and ductility are inversely related. Design features or heat treatments that make the needle more ductile generally make the needle less stiff.

Both stiffness and ductility are influenced by raw-material selection, body shape and heat treatment.

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The art of corneal transplantation: How to make everything come up roses

by Maxine Lipner Contributing Editor

With the seeds of improved technology and techniques, corneal transplantation [illegible]

Take a look around our gardening shed for some ideas on how to get better growth from the corneal transplantation technique.

Corneal transplantation has come a long way in a relatively short time, but for many practitioners, it often has less-than-optimal results. Practitioners don't have to have a green thumb to make the procedure work; however, they can best serve patients if they do the proper spadework. Reviewing the procedure's history and peering over the shoulder of a corneal transplant gardening guru would be helpful.

Laying the groundwork

Corneal transplantation has been around for a number of years, but wasn't taken seriously until recently, Joel Sugar, MD, professor, University of Illinois, Chicago, told American Academy of Ophthalmology meeting attendees in Dallas last year.

"While the first successful penetrating keratoplasty took place near the onset of the last century, corneal grafts were not done in great numbers until ... the mid-20th century," Sugar said. "Twenty-five years ago, approximately 10,000 penetrating grafts were done annually in the United States, while in 1999, close to 40,000 were done."

The grafts are used for different reasons now, as well. In the last 3 decades, Sugar said, there has been an increase in cases related to pseudophakic corneal edema and a corresponding decline in those resulting from aphakic edema. Also, there has been a persistent rate of keratoplasty for keratoconus and an increasing number of grafts done for Fuchs' dystrophy — probably due to improving outcomes. Indeed, the success rate has improved for clear grafts, from 31% in 1955 to close to 90% in 1996, and success rates for keratoconus in some series have reached 97%, Sugar said.

"Twenty-five years ago, approximately 10,000 penetrating grafts were done annually in the United States, while in 1999, close to 40,000 were done."

Joel Sugar, MD
Chicago

Techniques and technology have also changed from the square graft and double blade. Needles are finer and stronger with better tip configuration, suturing materials have evolved, and viscoelastics help preserve tissue. The handheld trephine Castroviejo introduced in the 1930s remains in frequent use — but the blades are now disposable and offer more-consistent sharpness and cutting quality, Sugar said.

Precision seeding

Precision is, more than ever, important when it comes to corneal transplants, said Kurt A. Buzard, MD, assistant clinical professor at Tulane University and the University of Nevada, as well as director of the Buzard Eye Institute

in Las Vegas. "In a corneal transplant, the biggest issue to remember is that a 0.1-mm difference between one direction and the direction 90° away will result in 1 D of astigmatism," he said. "It's not very hard to get 5 or 10 D of astigmatism, just by not being careful about how the graft is sewn or by leaving little pieces of tissue that aren't properly trimmed."

Buzard thinks that each aspect of the surgery needs to be approached in this meticulous manner. For instance, after the practitioner has made a hole in the cornea, it's very simple to take a punched piece of corneal tissue and turn the piece until the tissue best fits in the hole.

To more tightly control corneal transplant surgery from the start, Buzard recommends doing the procedure under general anesthesia. He thinks results with a retrobulbar block aren't as good, since patients can easily move or cough during the procedure.

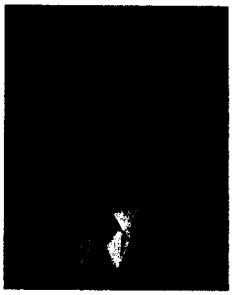
Buzard also thinks using a ring can help prepare for the trephination. He prefers a wider Pierce ring to the traditional Flieringa wire ring. "The wider ring gives me more support," he said. It allows him to examine each aspect of the transplant with a Trautman keratometer to be certain that it is a relatively round shape and that there aren't any stresses on the cornea.

Trephination tilling

In making the trephination, Buzard recommends using a Krumeich or Hanna trephine to get completely into the eye. He finishes the trephination with corneal scissors. These, he said, can create a beveled edge as they cut and may lead to astigmatism. To avoid this, Buzard trims the bottom edge so that it is vertical all the way around. "Now, I have an opening in the cornea that is centered on the pupil and is absolutely vertical in terms of the edge," he said.

In creating the button, when cutting the donor cornea from different sides, Buzard uses an 8.25-mm trephine for the donor tissue and an 8-mm trephine for the host. However, with the newer

Repotting problems: Understanding late graft failure



Despite plentiful advances in corneal transplant technique and technology, even those grafts that look as if they have been a complete success can turn out otherwise. The major cause of graft loss after the first 5 postoperative years is late endothelial failure (LEF) and, in a recent long-term study, William M. Bourne, MD, professor of ophthalmology, Mayo Clinic, Rochester, Minn., found that this accounted for 90% of failures after the 5-year mark.

Bourne analyzed 384 penetrating keratoplasty cases and found that preservation in surgery causes initial endothelial loss, which is followed by a steady decline of cell density during a 10-year period, during which endothelial cells become very large.

"During this time, with the loss of endothelial cells, there's a gradual loss of endothelial function," Bourne said. When the dual barrier and pump components of endothelial function were measured in the study, Bourne found that in 12 grafts, examined 7 to 18 years postoperatively, the grafts had very low cell densities, but were still clear and had no decrease in corneal thickness compared with the normal group. However, he did discover that the endothelial pump functions were at about half normal, although the corneal thickness remained the same. "With time, as these cells decrease further, these corneas gradually swell further and become compromised and develop what we call endothelial failure," he said. "I've defined this as a gradual graft decompensation, without apparent cause, unresponsive to corticosteroids, and with no recent history of a rejection episode."

The cause remains unknown. Bourne does not believe that it is immunologic, since autografts lose endothelial cells at the same rate as allografts and he could find no signs of rejection in these grafts. Also, other studies have shown that recipient corneas lose cells at the same rate as the donor and chronic endothelial cell loss is not increased in LEF.

Bourne found that grafts that failed from LEF had statistically fewer endothelial cells to begin with. "These grafts started out with fewer cells after transplantation than the remainder and they lost them at the same rate," he said. "So, they reached the critically low level sooner than the other grafts."

In addition to endothelial cell loss, Bourne noted a decline in keratocytes, which he thinks plays a role in graft problems. While these keratocytes decrease in normal corneas over time, the level is statistically lower in transplanted cases. Also, he has seen a change in the morphology of keratocytes as early as the first week, when they start to show cell bodies. This can interfere with vision. "These cells, with their cell bodies visible, I think are responsible for some of the visual loss, because they are reflecting more light," he said.

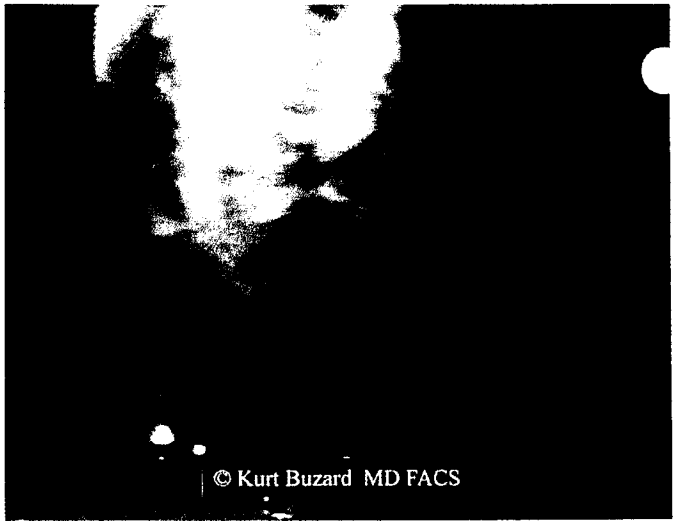
To prevent LEF, Bourne said that it is necessary to improve donor preservation, decrease surgical trauma, and increase endothelial cell density. While he sees the first two as having limited potential, accounting for only about 10% of average cell loss, Bourne thinks the idea of artificially increasing cell density with growth factors or targeted gene therapy has real merit. He predicts such methods may even be used to prevent the need for transplants in cases of endothelial deficiency in the first place.

Hanna or Krumeich trephines, in which you are cutting from the same side, he uses the same size trephine for both. This allows for less worry about astigmatism and better corneal cuts.

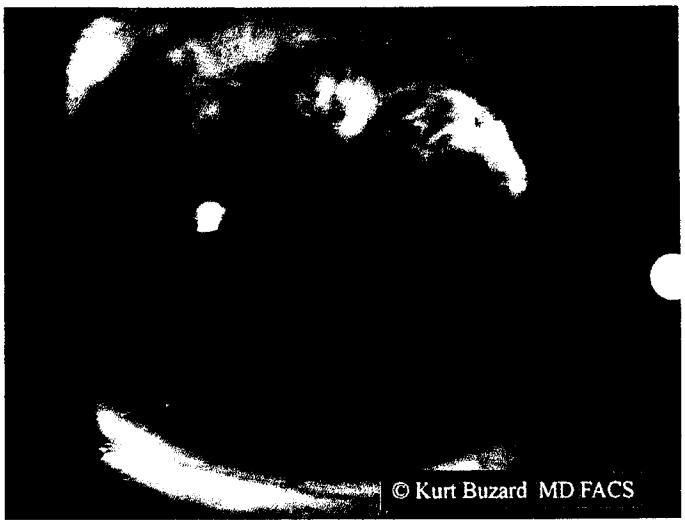
The fine points of technique can make the difference, Buzard thinks. He advises practitioners who are using a traditional punch method to get all the fluid out from under the cornea and trephine in the middle of the donor cornea to avoid ending up with a piece of sclera or a hard area of pannus. "As you push down to create the donor button, you want to apply a light pressure prior to actually going through the cornea — that will squish out everything and sort of settle the cornea down ... then punch through," Buzard said. Once the donor tissue is put in the eye, he recommends trying to get a bubble of viscoelastic in the middle of the cornea, since it is a long operation. "This scatters the bad light rays and it makes the visual recovery much faster."

Sewing for success

After rotating the donor button to get the best fit, Buzard puts in basting sutures to hold the cornea in place, tying off each with a slipknot. "The first stitch I put in is usually at 6 o'clock, away from me. ... The choice of the needle is actually very important," he said. Buzard uses a fishhook-design needle, which dives deeply into the tissue and, with a little twist of the wrist, comes right back out and gives a very short deep suture. "Perry [S.] Binder [MD, associate clinical professor, University of California, San Diego] and others have shown that within 1 day or 2 of the surgery, this thin suture moves up into the cornea, and you get the apposition of the cornea in terms of the top/bottom that you can get no other way," Buzard said.



Corneal transplant in patient with previous radial keratotomy



Postoperative corneal transplant

The first suture in a corneal transplant is often the most difficult for an inexperienced surgeon, he said. If the practitioner who is grasping the tissue with forceps and putting the needle up to the graft is too far away from the needle, it will tend to push the tissue away and allow the graft to get away. "I grab the tissue [using atraumatic forceps] and very carefully put the needle just a smidgen behind where I am holding it and push it through."

Eric D. Donnenfeld, MD, of Ophthalmic Consultants of Long Island, and cochairman of Cornea External Disease at Manhattan Eye and Ear Hospital, believes that the most important aspect of suture alignment is the second suture. "I spend a lot of time making sure that the tension for that suture is bisecting the pupil and creating a cornea with a half on either side. I really don't think that making sure your wound is well-opposed has any real significant effect on long-term cylinder, once all the sutures are removed. I think it's how you place the cornea into the bed," he said. After the first two sutures, Buzard adds four basting stitches, for a total of six, making sure all are radial. "At this point, the cornea should hold water. If it doesn't, it's probably because your interrupted stitches aren't in right and you should go back and adjust them."

Once the basting stitches are place, Buzard recommends practitioners put in running sutures. He urges people to stay away from try-

"I spend a lot of time making sure that the tension for that suture is bisecting the pupil and creating a cornea with a half on either side."

Eric D. Donnenfeld, MD
Long Island

ing to use numerous interrupted sutures to close the wound. He said that in between these sutures, the wound doesn't heal and this induces a lot of astigmatism. Buzard also warns against taking sutures out early, calling it "suture roulette." "The problem is [that] this requires a lot of patient visits, and these interrupted sutures each have a knot that frequently breaks in the tissue and causes a vascularity to come up to that knot," he said.

The type of running suture technique used is also important. Buzard said, "A single running technique is better than no running technique and certainly better than an interrupted technique. But, the problem is that as the [single] running suture goes around, it tends to twist the graft." This causes a torque in the horizontal and vertical planes and weakens the wound. The forces on this type of stitch result in a seesaw pattern on the surface of the graft, which should be level across the area, Buzard said. To accomplish this, he does a double running suture with 18 needle bites in one direction, puts the suture in, and then does another 18 bites in the other direction. With this web of sutures, the wound will pooch up, because of all the forces on the inside pushing outward. "The way the forces are oriented across the wound, that web of sutures holds the top of the cornea down in a very uniform way."

Edward J. Holland, MD, director of Corneal Service at the Cincinnati Eye Institute and clinical professor of ophthalmology at the University of Cincinnati, has used a variety of sutures during his career. "I have gone from all interrupted sutures, when I first started as a fellow, to a combination of interrupted and running sutures, and then I was into all running sutures for a while. What I was impressed with is that I had a significant amount of irregular astigmatism with the running sutures, even after I took them out. And when I closely looked at that wound, saw that I did not have a uniform anterior wound alignment, and I thought it was the areas where the running suture was that distorted the wound alignment," he said.

Currently, Holland's suture pattern involves inserting the first eight sutures in on a temporary slipknot, re-forming the chamber, tying those original eight, and then going four-four with the additional sutures. "This allows me a much better early visual rehabilitation."

"I've also put 24 interrupted sutures in many patients. That gets a wonderful anterior wound alignment, because you can get a good depth at the donor and the recipient. I think you get great posterior wound closure, as opposed to a running suture," he said.

Tending astigmatism ground

When it comes to dealing with astigmatism following corneal transplant, Kurt A. Buzard, MD, assistant clinical professor at Tulane University and the University of Nevada, as well as director of the Buzard Eye Institute in Las Vegas, has developed the "additional suture technique." He goes back and adds stitches, which he thinks is beneficial.

Buzard reviews the patient's corneal topography for signs of a "microdehiscence," either a little blue spot on the topography or a V-shaped abnormality on the rings of the cornea. If he sees microdehiscence, it tells the patient that the graft wound isn't healing as well in this area as it is in others. This connection between wound healing and astigmatism, Buzard said, is a seminal one for corneal graft surgeons. "If the wound isn't healing in that area, you could take the suture out 90° away and say that suture is too tight," he said. "But in truth, what is happening is that you have two weak areas and what you really want to do is fix the bad area."

Buzard adds a stitch or two in that weakened area. "That draws the wound together and gets rid of the problem," he said. In addition to seeing an immediate improvement in the astigmatism, the result is lasting. "When all the stitches have been removed, the astigmatism is still reduced relative to the astigmatism that was present before — so it doesn't come back. ... We're fixing an abnormality and healing it."

By using this conservative technique, rather than weakening the wound and removing sutures, Buzard ends up with much more stable corneas. "My average corneal curvature is 43 D, which is absolutely normal," he said. "As opposed to corneal transplants done by surgeons with the selective suture removal, in which their average cornea is 48 or 49 D." This increased curvature can lead to 5 or 6 D of myopia, whereas Buzard said that just by fixing the astigmatism with the additional suture technique, 50% of his patients have 20/40 vision or better and are able to drive without glasses.

"The easy thing if you have some astigmatism is to sit the patient in a chair and cut a stitch — but then you have created two problems," Buzard said. "Moreover, you're going to cause the patient to have a weak wound with changing astigmatism over time." These patients, Buzard said, are poor candidates for further refractive surgery, like laser in-situ keratomileusis. They also require monthly follow-up visits to the doctor for a 3-year period. Buzard sees patients on day 1, at month 1, and then every 3 months until the stitches come out at 1 year.

Wilting reimbursement

Despite the annual need of approximately 46,000 patients for corneal transplants, many practitioners are becoming increasingly reluctant to take on such cases. "In this era of cost-containment, corneal transplants have become the poor brethren of other eye surgery," said Kurt A. Buzard, MD, assistant clinical professor at Tulane University and the University of Nevada, as well as director of the Buzard Eye Institute in Las Vegas. He thinks many corneal surgeons have opted not to perform them because they are complicated procedures with low reimbursement.

It has become a real economic quandary. While cataract surgery, which takes 10 minutes and needs limited follow-up, is reimbursed $750, corneal transplant surgery takes 1 hour or longer and requires the doctor to schedule frequent follow-ups during the first 3 months, but is reimbursed at just $1,200, Buzard said.

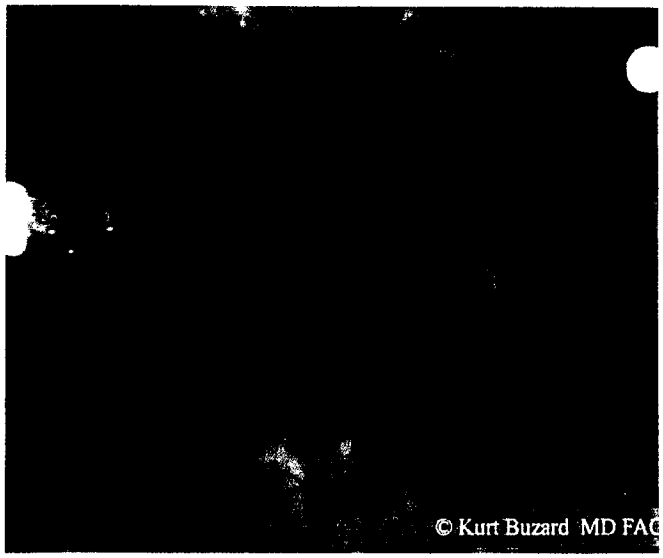
Roger F. Steinert, MD, assistant clinical professor, Harvard Medical School, Boston, continues to do the procedure because he finds corneal transplant surgery clinically satisfying, but he has limited his time. In crunching numbers, Steinert found that his practice was accruing just 10% of its revenue from the procedure, although it was amounting to about 33% of all postoperative visits. He said that many advances in the corneal transplant procedure have benefited patients, but they aren't compensated for.

Some, like Marguerite B. McDonald, MD, clinical professor of ophthalmology at Tulane University in New Orleans, have stopped doing corneal transplantation in Medicare patients as a result. McDonald, whose practice is heavily corneal transplant oriented (up to 70%), found that Medicare reimbursement in this area was just too restrictive. She now refers transplant recipients older than 65 to other surgeons.

Refractive pruning

The advent and refinement of refractive surgery has dramatically improved the visual outcomes of penetrating keratoplasty. Donnenfeld outlines his experiences with refractive surgery in corneal transplant patients in the EW Interview on page 38.

Rick Palmon, MD, in private practice at Eye Centers of Florida in Fort Meyers, believes that refractive surgery permits the greatest benefit with best-corrected visual acuity in these patients. "Surgeons can have patients with 6 D to 8 D of cylinder, and anisometropia, and sometimes only a best-corrected visual acuity of 20/60 to 20/80. After reducing the cylinder with refractive surgery, their best-corrected visual acuity improves to 20/30 or 20/40, along with outstanding uncorrected visual acuity," he said.



Close-up of torque-antitorque suture

Torque-antitorque continuous suture pattern

Jonathan B. Rubenstein, MD, associate professor of ophthalmology at Rush Medical College in Chicago, believes that refractive surgery should be presented as a postoperative possibility from the start of the corneal transplant procedure. "I tell them in the beginning when I'm talking about transplant surgery that it actually can be thought of as a two-step procedure. One is providing them with normal corneal tissue in the corneal transplant surgery, and the second is the refractive adjustment that may be necessary afterwards, either with astigmatic surgery or something like LASIK," he said.

Indeed, LASIK does appear to be safe, effective, and predictable for the correction of residual ametropia following corneal transplant. Jean-Luc Febbraro, MD, attending surgeon at the Rothschild Foundation and in private practice in Paris, France, and Buzard performed a study that

His practice was accruing just 10% of its revenue from the procedure, although it was amounting to about 33% of all postoperative visits.

Roger F. Steinert, MD
Boston

included 26 eyes of 20 patients with a mean preoperative spherical equivalent of approximately –5 D and a mean preoperative astigmatism of 2.71 D. "The mean time from the primary penetrating keratoplasty was 4 years, ranging from a minimum of 15 months to 11 years," Febbraro said.

Control of the astigmatism component was first attempted in one group with selected addition or removal of sutures, and in a second by way of a relaxing incision or a wedge resection. In the first group, the astigmatism decreased from 6 D to 3.75 D, and in the second from 6.5 D to 3 D. Meanwhile, LASIK results showed progressive improvement. "Mean uncorrected vision was 20/50 at 1 month and increased to 20/30 at 12 months," Febbraro said. "Sixty percent of the eyes reach 20/40 at 1 month, and 86% of eyes reach 20/40 at 1 year."

LASIK predictability on PK eyes showed a correspondence with uncorrected vision. Researchers, however, did observe that PK patients tended to need more LASIK enhancements than typical patients, with a rate of close to 40%, compared with 10% to 15% in virgin eyes. There was no significant loss of endothelial cells at 1 year. Although 18% of eyes lost one line of best-corrected vision, 27% gained one line, Febbraro said. As for astigmatism, a slight undercorrection was noted. "The preoperative astigmatism was 2.71 D and at 1 year was 1 D, which meant a 70% correction of the astigmatism with the subtraction method," Febbraro said.

Future path

Overall, Buzard is optimistic about the future of corneal transplantation and thinks the surgery has entered the refractive era. "Whereas before you would not consider a cornea transplant on someone who, say, had a bad refractive surgery ... who can sort of get along ... well getting along isn't good enough," Buzard said. "For those people, you shouldn't be afraid to do a corneal transplant." He thinks most practitioners can do this well. "It's just a bag of tricks," he said. "If you listen to the tricks, corneal transplant can be the answer for people who have no other choice — and not just an end-of-the-line choice." Buzard does, however, add a caveat. "Corneal transplants are a serious business and if you can't achieve good results, you shouldn't be doing them," he said. "There are a lot of talented young corneal surgeons, and I think that corneal surgery really ought to be concentrated in the hands of those who want to do the surgery."

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