

Eye Banking:

A Labor of Love That's Come a Long Way

Although corneal transplants are the most common type of transplant, they do not get as much media attention as others.

BY ROCHELLE NATALONI, CONTRIBUTING EDITOR

A generation ago, corneal transplants were similar to vital organ transplants: the waiting list was long and when an acceptable donor cornea finally became available, the challenges included speedy transportation to ensure its ultimate viability, quickly assembling a surgical team, and scheduling an emergency procedure for the recipient.

In the United States, this picture has changed dramatically in a relatively short period of time. The evolution is due to an organized constellation of 85 eye banks across the country and the hub around which they revolve—the Eye Bank Association of America (EBAA), as well as the donation of time, money, and talent from corporate sponsors, eye care associations, and surgeons. “Today, we have adequate donor tissue in America to cover all of the need that exists, which is about 50,000 corneal transplants a year,” says Richard L. Lindstrom, MD. “To service that need, we harvest about 100,000 corneas, which are preserved and then screened for disease, and then we connect that tissue with the patient. That chain of events happens quite seamlessly because of the network of eye banks.”

Patients who have Fuchs dystrophy, keratoconus, and pseudophakic keratopathy comprise most of those who benefit from the increased sophistication and connectivity of eye banks, but the practice of ophthalmology as a whole reaps the rewards of advances in research that are performed at or funded in part by the EBAA and the entities with which it partners. For instance, money provided by the Lindstrom Fund for Corneal Research, which is underwritten by an agreement between Dr. Lindstrom and Bausch + Lomb, allow EBAA to award roughly \$50,000 per

year for research pertaining to eye banking and/or corneal transplantation. Dr. Lindstrom played an integral role in developing methods of corneal preservation including Optisol GS, which he patented and Bausch + Lomb markets. “I licensed my patents and chose to share a significant portion of my royalties with EBAA, which created the funding that is now called the Lindstrom Fund for Corneal Research,” he explains. “Those funds have been used through the years in various settings by the EBAA to support research as well as other special projects.”

In 2013, some of these research grants were awarded to projects such as gene therapy to protect corneas during storage after transplantation, nanoparticle-based targeted therapy of corneal inflammation, and in vivo imaging-guided risk assessment for corneal graft rejection in dry eye disease. “I like to support the research of young corneal doctors, particularly fellows,” says Dr. Lindstrom. “I received those kinds of grants when I was a fellow, and it got me started on my research. This is like payback: creating that opportunity for others.”

THE EYE BANK IS YOUR PARTNER

Kevin Corcoran, EBAA president and CEO, suggests that surgeons should consider the EBAA their partner in the process of sight restoration. “There are many stages and players that are required for a successful transplant, from donor registry and donor family contact through tissue recovery, testing and preparation, and finally, the exquisite skill of the surgeon. All of these are essential to facilitate nearly 50,000 corneal transplants per year in the United States. That’s why we studied the entire process and integrated the costs and

benefits of every stage, in our analysis; because without this infrastructure, neither the eye bank nor the surgeon can have the same impact on society.”

Mr. Corcoran is referring to the EBAA’s recent cost-benefit analysis of corneal transplantation, which demonstrated a net lifetime benefit of over \$100,000 per person, across all ages and types of corneal transplants.¹ The study compared the medical cost of transplant procedures to the direct and indirect lifetime costs of the alternative: living with blindness or severe vision impairment. With a corneal transplant, an individual avoids the direct expenditures that come with vision loss such as higher routine medical and long-term care costs and the indirect costs of potential years of lost productivity to patients and their family caregivers. Eye disorders are the fifth costliest illness to the US economy after heart disease, cancer, emotional disorders, and pulmonary conditions. The 6-month study found that corneal transplants performed in the United States in 2013 resulted in nearly \$6 billion in total net benefits over the lifetime of the recipients.

The lifetime direct medical benefits alone, independent of indirect economic benefits, outstripped the costs of transplant surgery by more than \$50,000, according to corneal surgeon and chair-elect of the EBAA, David Glasser, MD. “In every single subcategory, there was a significant net economic benefit of surgery,” he points out.

This is excellent news for corneal transplant surgeons, who are facing increasing pressure from Medicare and commercial third-party payers to reduce payment for corneal transplant surgery, according to Dr. Glasser. “Added to the existing cost-utility literature showing that corneal transplantation is a highly cost-efficient procedure in terms of quality-adjusted life years, the recent EBAA report gives surgeons a credible argument to convince payers to support transplant surgery,” he says.¹⁻⁵

Dr. Glasser says that reimbursement has already had a negative impact on the number of corneal surgeons who perform transplant surgery, and additional pressure is being placed on corneal transplantation. “Although some patients now have to travel further for their surgery, fortunately, there are enough transplant surgeons remaining to fill the need,” he adds.

Unlike Medicare, which pays separately for the cost of the tissue, commercial payers are increasingly bundling this cost into the facility fee that hospitals and ambulatory surgery centers (ASCs) receive for performing transplant surgery. “With the cost of the tissue exceeding the facility fee, some ASCs have had to abandon corneal transplantation. This has forced more cases to hospital outpatient departments, in turn forcing some patients to find another surgeon with privileges in those hospitals,” says Dr. Glasser.

He says this is a shortsighted decision on the part of com-

MORE INFORMATION ABOUT EYE BANKING

- www.areyouadonor.org
- www.lionseyeinstitute.org/ocular-research-center
- www.midwesteyebanks.org
- www.LionsEyeInstitute.org
- www.eyedonation.org
- www.lionseyebanknj.org
- www.restoresight.org

mercial carriers, even on a purely economic basis. “The payer’s overall medical costs are much lower for patients who have transplant surgery. For those who are forced to have surgery in a hospital outpatient department, the payer’s costs are much higher than when surgery is performed in an ASC. Physicians and ASC owners need to make this clear to the commercial carriers when it comes time to negotiate contracts, or the trend is likely to continue,” Dr. Glasser stresses.

Mr. Corcoran points out how important it is for surgeons to appreciate the impact that corneal transplantation has on individuals and society (see *More Information About Eye Banking*). “We recognize that most corneal surgeons perform relatively few transplant procedures as compared to their other patient care, so they might not give too much thought to this part of their practice, but the fact is that a single corneal transplant has a net lifetime benefit of nearly \$120,000, so I think there’s a benefit for them to understand the financial and social implications of their work.”

PUTTING THINGS IN PERSPECTIVE

The cornea is the organ most commonly transplanted; however, such procedures do not receive a lot of media attention because, sources say, hearts and lungs and kidneys are simply seen as a bigger deal. Mr. Corcoran says there are common misconceptions. “People often ask me if we transplant the entire eye; it happened again just last week while meeting with the health policy analyst for a member of Congress. This is what makes outreach and education efforts so important, whether they’re conducted by Donate Life America, by individual eye banks, or by EBAA through events such as the annual Run for Vision (see *Corporate Leaders Help Move Eye Banking Forward*). Keeping our message simple and delivering it consistently, will lead to greater understanding,” he said. “Interestingly,” he added, “we’ve found that once folks understand the message, they’re very receptive to it. Many of our eye banks report that over 50% of donor family members authorize the recovery of their loved one’s corneas after we have explained the recovery process and the benefits for recipients.”

Dr. Lindstrom points out, “In the United States,

CORPORATE LEADERS HELP MOVE EYE BANKING FORWARD

Eye banking efforts, from fundraising to research to donor tissue recovery and distribution, benefit both patients and the ophthalmic community at large. Lending a helping hand to this endeavor and encouraging others to do the same has been a priority for Bausch + Lomb for decades. "With thousands of patients in need of corneal transplants each year, eye care practitioners and their staff members, as well as eye care corporations, have a tremendous opportunity to bring the gift of sight to millions of people around the world by registering as eye, organ, and tissue donors and encouraging others to do the same," said Bausch + Lomb's Chief Medical Officer of ophthalmology and eye health, Calvin Roberts, MD.

Through its Grants and Charitable Contributions program, Bausch + Lomb supports projects related to eye banking through grant-supported research and education. "We also donate products, such as Optisol GS, to physicians around the world who provide corneal transplants for those in need," he explained. Optisol GS extends the viability of donor corneas from recovery to transplantation surgery. Surgeons rely on the agent to ensure that corneal tissue is well preserved during transport, storage, and laboratory evaluation prior to corneal transplantation. Bausch + Lomb manufactures and distributes Optisol GS.

The Run for Vision is another avenue through which Bausch + Lomb supports eye banking. Dr. Roberts explains, "For nearly 3 decades, Bausch + Lomb has helped raise awareness and generate support for eye banking through its sponsorship of a 5K benefit run/walk, held each year during the annual meeting of the American Academy of Ophthalmology." Since its inception, the race has raised more than a quarter of a million dollars in support of the Eye Bank Association of America (EBAA). Kevin Corcoran, president and CEO of the EBAA adds that the Run for Vision is a critical component of the Eye Bank's advocacy and outreach efforts. "It allows us to reach a very wide constituency, both inside the ophthalmic profession and in the broader community. It gives us a platform to bring together physicians and eye bankers, and to showcase our work to the media centers in the city where the race is held."

Mr. Corcoran goes on to say, "Bausch + Lomb under-



The 2013 Run for Vision: Kevin Corcoran (president and CEO of EBAA) and Brad Hurt (vice president, surgical sales for Bausch + Lomb) with Emily Schneider who was the female first place finisher (left). B + L Team at the Run for Vision (right).

writes 100% of the cost of the event, and all of the proceeds flow back to EBAA. These funds, more than \$250,000 over the life of the race, have made possible many of the association's activities. Currently, they help make possible our advocacy efforts on Capitol Hill, where we're educating legislators and their staffs on the value and benefit of eye banking and cornea transplantation."

Are You a Donor (AYAD) (www.areyouadonor.org) is another program through which corporations and associations support eye banking. Current Are You a Donor members include Abbott Medical Optics, Allergan Foundation, American Society of Cataract & Refractive Surgery, Bausch + Lomb, EBAA, and SightLife. The AYAD Project was developed through the partnership of the country's foremost ophthalmic companies and organizations to encourage eye, organ, and tissue donation. An estimated 42% of adults are currently registered as eye, organ, and tissue donors. The goal of the AYAD Project is to increase donor commitment by enlisting ophthalmologists and ophthalmic professionals to become eye, organ and tissue donors; encourage their peers and community to register as donors; and honor those who are already registered as donors.

AYAD has an excerpt from a letter written by a cornea recipient posted on its website (www.areyouadonor.org/about.html). It says "If I could talk to my donor's family, I would try to express the miracle they and their loved one gave me. I would say thank you a hundred times over. They may hope a little piece of their loved one lives on in me, and so it does. I see the world through your eyes, and the view is fantastic."

Dr. Roberts, who is a donor himself, stresses how gratifying it is to positively influence people's lives in such an important way. "One donation can not only transform the life of the organ recipient but their families, as well."

3.5 million cataract surgeries are performed each year, in comparison to just 50,000 corneal transplants, but a significant cohort of corneal surgeons is performing 50 to 100 corneal transplants per year. They are doing a great service for their patients. It's not very lucrative. It's a lot of work. Nobody makes a living just doing corneal transplants. We all have to do cataract surgery or refractive surgery or something else to balance this out."

Like Dr. Lindstrom, Charles J. Pivoney, chief operating officer, Midwest Eye-Banks, has experienced firsthand the evolution of eye banking in the United States. In the 29 years that Mr. Pivoney has been involved in the process, he suggests that the biggest impact that eye banks have had is enabling the scheduling of transplants on an elective

basis. "When I first started, patients were waiting an average of 18 months for a cornea, and procedures were performed on an emergency basis, which was less than optimal for the patients, the surgeons, and the surgical facilities. Now, we have time to perform preoperative testing, and patients can make arrangements for their family, among other things, because they know in advance when the surgery will take place," says Mr. Pivoney. Through its locations in Ohio, Illinois, Michigan and New Jersey, Midwest Eye-Banks recovers, evaluates, and distributes human eye tissue for transplantation. Part of its mission, according to Mr. Pivoney, is supporting preliminary research into the causes and cures of blinding eye conditions. "Through public and professional education programs, we encourage people to learn about

LEITR: HARNESSING THE POWER OF DONOR DATA

Organized eye banking has made monumental strides over the past 30 years, and nowhere is that more evident than the Lions Eye Institute for Transplant & Research (LEITR), in Tampa, Florida. As a research institute in addition to an eye bank, LEITR offers high-volume, high-quality human ocular tissue for study, collaboration, and clinical advancements.

"[LEITR] is the largest eye bank in the world, honoring each donor and donor family by passing on the gift of sight to recipients around the world," says Jason Woody, president and CEO of LEITR.

"We do everything except the cornea transplant," he explains. "We work directly with the hospitals. We screen the donor to make sure that the cornea is suitable, we do the recovery, we do the blood testing, we evaluate the tissue, and then we provide it to the surgeon." Roughly 30% of the donated tissue is not able to be used because of things that come up during this quality assurance process, according to Mr. Woody. "Our goal is that no tissue that's useable goes unused," he adds.

Mitchell D. McCartney, PhD, joined the organization as its scientific director last year with a goal of developing partnerships and advancing research opportunities there. "LEITR provides the ability to have multiple concurrent studies in a confidential, neutral environment," says Dr. McCartney. "We have a repository of normal and diseased tissue, and we combine this tissue with a database of clinical and familial information. It is the only comprehensive database of its kind."

LEITR has a donor base with high rates of macular



Donor corneas being prepared for surgery.

degeneration, glaucoma, and other age-related diseases, which makes it an excellent source of information for a variety of studies. "We are amazed every day at the generosity of donors and their families," says Mr. Woody. "Most eye diseases are hereditary, so a lot of times when a family member is making the decision to be a donor, they are making the decision to help someone in their family down the road. They often say they feel like they are paying it forward. My grandmother had glaucoma, and she was in her 90s when her corneas were donated. When her corneas were recovered, the researchers said it was such a valuable donation because along with the corneas we provided all of the records describing what drugs and drops were used and how she responded. With animal tissue, you can't get that kind of information."

Providing researchers with the medical records of the donor enables them to learn the "history" behind the tissue. "Animal models have their place in science," said Mr. Woody, "but they do not offer any insight into how the disease will progress over the long term."

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eye, organ, and tissue donation, and we also provide humanitarian aid to those unable to afford transplantation procedures by waiving our tissue processing fees when a charitable need exists," he explains.

A SYMBIOTIC RELATIONSHIP

The relationship between eye banks and eye surgeons is symbiotic (see *LEITR, Harnessing the Power of Donor Data*). Ophthalmic surgeon John Barletta, MD, is on the board of the Michigan Eye Bank, one of the Midwest Eye-Banks' affiliates, and is active in fundraising and other outreach activities. He says, "I joined the eye bank because I wanted to give back to the community, but also because I wanted to give back to the eye bank that had been there for me throughout my career providing the tissue that my patients needed. Up to 95% of the time, they were able to get the tissue that my patients needed on time."

Helping to raise funds to support eye banking research is also a priority for Dr. Barletta. "Full-thickness transplants were the norm for 40 years, and the risk of rupture was high. Now with partial-thickness transplants, the recovery is quicker, the strength of the eye is stronger, and high refractive errors after transplant are greatly reduced. Partial-thickness transplants have been a significant improvement for surgeons and patients alike, and the eye banks have played a pivotal role in funding the research that culminated in these advances, and the eye banks have also provided tissue for these studies," he says.

Midwest Eye-Banks' board member William Constad, MD, points out that there are additional ways in which surgeons benefit from eye banks. "When a surgeon is interested in acquiring new skills and learning a new surgical technique and has taken the appropriate courses, he or she can sharpen and enhance those skills by doing surgery on eyes provided by the eye bank so that it approximates the real-life scenario," he said. "Surgeons sometimes have questions about how to handle a postoperative patient, and can call the medical director of the eye bank for information or advice." Dr. Constad is medical director of the Lions Eye Bank of New Jersey as well as the Midwest Eye-Banks.

Midwest Eye-Banks' Mr. Pivoney says the past 3 decades have advanced corneal donation to where it is today, with enough material to go around to enable elective surgery to all those affected by corneal blindness in the United States, and now the frontier lies in research. "The challenge is iden-

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tifying and recovering highly valued research tissue—eyes from donors with various eye diseases. The difficulty lies in the fact that many of the research protocols have very narrow criteria. So, unlike with transplant tissue, there is little financial support, and eye banks across the country are finding the programs unsustainable and therefore discontinuing their research services. We are working to leverage our extensive success in our donor cornea program and create a sustainable research donor system," he explains.

Although there is a sufficient amount of donor corneas to satisfy recipients' needs in the United States

and a handful of other countries, that is not the case across the globe. "We don't have a backlog of people blind in America because of [corneal disease] just like we don't have a backlog of people blind because of cataract in America, but if you go out into the world, there are approximately 10 million people blind from a corneal disease who would respond to a corneal transplant, particularly in countries such as India and Africa. In some cases, the issue is access to surgeons; but primarily the issue is inadequate availability of donor tissue," said Dr. Lindstrom. "The EBAA is now collaborating with member eye banks internationally and has decided to include in its mission statement the management of corneal blindness globally. The United States is secure at the moment, so we are reaching out." ■

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