Regenerative medicine
Shaping transplantation and beyond

Digital exclusive
Olympian Chris Klug shares his story of transplantation

NEW FRONTIERS IN MEDICINE

Comedian and actor George Lopez talks candidly about his kidney transplant procedure and feeling healthy for the first time.

While you are waiting......................

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As we enter a time where there is a growing gap between the number of lives that can be saved by transplantation and the number of available organs, we need to look deeper into the advancements and solutions being made through technology and medical science.

Defeating the waiting list

For patients suffering from end-stage organ failure (kidney, liver, heart, lung and pancreas), transplantation offers a second chance to resume a normal and productive life and saves millions of dollars in healthcare. The American Society of Transplantation (AST) is grateful for this opportunity to recognize the importance of transplantation and promote public awareness of organ donation, a commitment to public action that we call the “Power2Save.”

Transplantation is the intersection of two human beings where the immune system of the patient must recognize and ultimately accept the donor’s gift. To accomplish this amazing feat requires the use of powerful drug combinations and the coordination of teams of professionals drawing on their special expertise in transplant medicine, immunology and surgery.

But transplantation and organ donation are also profoundly human events that for patients and families on both sides are life changing, frightening and dramatic. Thus, it is also critical to recognize the compassion and dedication of all professionals working tirelessly with these sick patients and their families. In fact, the entire endeavor is directly linked to the success of finding and transplanting enough donor organs. To underscore this fact, consider that there are 118,000 Americans awaiting a transplant today, many will wait more than five years for the chance and thousands will die every year because their chance never came. What can we do to address this critical medical challenge? One answer is to take every opportunity to advance awareness of the life saving importance of organ donation, the “gift of life.”

But transplantation is not standing still. There are many exciting new advances developing in our nation’s laboratories: the pioneering transplantation of new limbs and faces changing the lives of wounded warriors, tissue engineering of new organs from renewable stem cells, amazing technologies from the Human Genome Project to discover the genes and proteins that regulate our immune responses and the next generation of safer and more powerful immunosuppressive drugs.

Ultimately, the truth is that individual citizens and corporate America pay for all health care and the end stage organ failure that we are treating. We need your support to achieve our mission to advance the miracle of transplantation and we promise to continue to advocate for the needs of all our patients and their families.

Daniel R. Salomon, M.D.
President of the American Society of Transplantation, Professor at The Scripps Research Institute, Department of Molecular and Experimental Medicine, and Program Medical Director of the Scripps Center for Organ Transplantation.

Photo: The Scripps Research Institute

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#FUTUREOFTRANSPLANTS
"My new heart
gave me a
new chance
at life."

At the age of 20, Kareen Momo was shocked to be diagnosed with congestive heart failure. A virus had attacked his heart muscle, leaving him with the heart function of a 90-year-old man. Without a transplant, his life expectancy was less than a year. In an emergency procedure at Baylor University Medical Center at Dallas, an IV pump was inserted in Kareen’s arm to deliver medications to support his heart and a defibrillator was implanted in chest to shock his heart if it stopped. A year later, he received a heart transplant at Baylor Dallas. Back in college, Kareen enjoys playing sports again. “Thanks to Baylor, my future looks really, really bright.”

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Success in transplant includes having a realistic financial plan

Transplant procedures account for eight of the top 10 most expensive medical procedures in the United States.

Average first-year expenses for a transplant are more than $650,000.

While the transplant surgery may be covered by health insurance, pre-transplant medical services and post-transplant maintenance are often uncovered, leaving patients and families with huge out-of-pocket expenses.

It is increasingly common for a transplant center to require a deposit or a down payment for pre-transplant evaluation or transplant eligibility.

Fundraising offers a solution for patients and families with uninsured transplant expenses—both medical and non-medical.

Fundraising with a nonprofit offers the transplant center and patient supporters assurance that funds will be used as intended—to pay transplant medical and related expenses only.

George Lopez, recipient of a donor kidney, speaks on prevention, awareness and new discoveries, giving hope to all.

**Mediaplanet: When did you find out you needed a kidney transplant and what was your reaction?**

**George Lopez:** Unfortunately for me, I didn’t find out until my late 30s that I had kidney disease, but throughout my life, there were signs that I wasn’t 100 percent. But my grandparents came from a culture where you really didn’t go to the doctor unless there was a problem— I think that’s a mistake. If I had gone to the doctor, they probably would have found out that I was born with narrowing ureters. We can prevent a lot of illnesses if we take a proactive approach to our health. Culture should not be an excuse for not taking care of your body.

**MP: Since your transplant, how has life changed for you?**

**GL:** To be completely honest with you, when I was sick, I was really, very, very sick, and I continued to do my work. I remember telling my doctor that I did not want to be the poster boy for kidney disease. I just wanted to get in, get out, and get on with my life. But after I had my transplant, literally less than two days later, I woke up and I felt better than I’d ever felt in my life, because I was really healthy for the first time. At that moment, that morning, I decided that I could not turn my back on spreading the message of organ donation, of prevention, and of taking an interest in your health and in the health of your family. After all, it is your life and it is the only one that you have.

**MP: What kind of work do you do with your foundation around this cause?**

**GL:** My foundation helps people to understand kidney disease. But also, I wanted to help families with kids who have kidney disease with a camp they have; this wonderful Painted Turtle Camp. I wanted to have kids with kidney disease come to this camp that has all of the facilities they need for their health—dialysis, great doctors—it allows them to be kids for the summer and in the fall, and their families to come, and get them out of their hospitals, and get them to be regular kids, surrounded by other kids who are in the same situation that they are. You see kids who have advanced kidney disease, and kids that need transplants. When you see the faces of the kids and of the families [at the camp], you realize that it’s an amazing thing that they keep going.

**MP: What advice do you have for others in terms of the future of transplants?**

**GL:** I would say that you cannot think that it’s not going to happen to you. You can’t think that you will never be affected. The best thing we can do as humans is help other people in need. By doing that, were helping ourselves. To assume that no one in your family is going to get sick or need help is something that no one should ever do. If you’re proactive and you’re helping and your connected and staying aware of your own health, I think we are taking a step forward.

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From life partner to living donor

In 1993, when Gregory Smith was a sophomore in high school, he was "on top of the world." A well-rounded athlete, who played a sport-year-round, Greg had just fallen "madly in love" with fellow student, Randi Foraker, who was equally athletic and optimistic.

During a routine physical at school, Greg’s blood pressure tested high. Greg could not play sports until he got the all-clear tested high. Greg could not play school, Greg’s blood pressure kidney function had declined to 20 percent. The transplant was scheduled for December 12th at Wisconsin Medical Center at Ohio University. Greg was feeling very ill. "My biggest concern," says Randi, "was that without a kidney transplant, including increased energy and well-being. Using compatible spouses is very emotionally difficult. VADs increase patients’ lives of survival until a heart transplant. If VADs did not exist, thousands of hearts would have been donated each year. But now, thanks to medical technology, many children who would have died without a VAD are surviving. Many children are growing up and leading normal lives because of VADs." It is a mechanical circulatory pump used in patients with heart failure. "Heart failure is very rare in children, but the prevalence of this condition is increasing," says Dr. VanDerpluym. "Thanks to medical technology, many children born or with congenital abnormalities who would have had new survivors. However, some of those children eventually develop heart failure.

bridging the demand-supply gap with VADs

"Through the heart transplant list is growing, the number of hearts available has remained stagnant. Getting a heart on the transplant list is very difficult. VADs increase patients’ odds of survival until a heart transplant. After receiving the VAD, Kyah did not feel as tired. She was back at school and feeling much better.

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2. Kyah received the device (VAD) Kyah would not live. "Heart failure is very rare in children, but the prevalence of this condition is increasing," says Dr. VanDerpluym. "Thanks to medical technology, many children born or with congenital abnormalities who would have died without a VAD are surviving. Many children are growing up and leading normal lives because of VADs."

"Through the heart transplant list is growing, the number of hearts available has remained stagnant. Getting a heart on the transplant list is very difficult. VADs increase patients’ odds of survival until a heart transplant. After receiving the VAD, Kyah did not feel as tired. She was back at school and feeling much better. While VADs are used to keep patients alive and improve quality of life, they also allow patients to get stronger and become eligible for the heart transplant list.

Kyah’s in everyone’s heart

Kyah admits that she was scared, but she was also happy. Bused by the love and support of her family and community, Kyah underwent a successful heart transplant on March 30, 2012. On April 12, 2013, the Yarmouth Police Department escorted Kyah home, where she was greeted with a welcome-home parade. Now she is recovering at home and excited about starting high school in September. "Soon, I’ll be dancing again," she says.

Photos: Danielle DeSimone

Photo: heartWare
THE FUTURE OF TRANSPLANTS
Medical experts from around the nation talk about the procedures of tomorrow

THOMAS M. FISHBEGIN
MD, Executive Director, MedStar Georgetown Transplant Institute.

■ Mediaplanet: In your opinion, how has the field of transplantation changed in the past 10 years?
Thomas M. Fishbein: We have overcome most of the surgical hurdles. We can now perform liver transplants for two people from one liver, do more live donor transplants, have expanded the pool of organs we can use, and even perform multiorgan transplants with excellent success. We use less medications and have improved quality of life. We now have an ever increasing list of patients for whom transplants work, and have made the problem of organ shortage even greater.

■ MP: What innovations can be expected in the near future?
TMF: It is critical to maximally utilize the resources we have, some of which get discarded. Adoption of an “opt in” system of organ donation, rather than an “opt out” system, may be very helpful to find more organs. This has worked well in other countries.

■ MP: From your perspective, how can our society help to advance transplantation?
TMF: There are several ways we as a society can help, but the most important one is to recycle our organs once we are done with them. Supporting your local transplant center is also important. A single organ donor can save many lives. A single financial donor who supports his or her local center can save thousands.

GONZALO GONZALEZ-STAWINSKI
MD, chief, heart transplantation, Baylor Annette C. and Harold C. Simmons Transplant Institute

■ Mediaplanet: In your opinion, how has the field of transplantation changed in the past 10 years?
Gonzalo Gonzalez-Stawinski: The last 10 years of transplantation have seen a revolution in Mechanical Circulatory Support that allows patients to reach transplantation in a safer fashion.

■ MP: What innovations can be expected in the near future?
GGS: Innovations that can be expected in the near future relate to Mechanical Circulatory Support. These innovations will allow for the creation of miniaturized and fully implantable Mechanical Circulatory Support devices which will complement cardiac replacement therapy.

■ MP: From your perspective, how can our society help to advance transplantation?
GGS: Society can help the field of transplantation by educating themselves about the facts and myths that surround organ donation and becoming an organ donor.

MICHELLE ALTRICH
PhD, HCLD (ABB) Vice President and Clinical Laboratory Director, Viracor-IbT Laboratories.

■ Mediaplanet: How are innovative diagnostics improving patient outcomes?
Michelle Altrich: Diagnostics play a significant role in improving the prevention and management of transplant complications. For example, specialized tests can identify risk, indicate response to treatment, and provide early detection of serious infection or rejection. Today’s diagnostics performed at specialized labs are faster and more accurate than ever, with the ability to signal a problem before the patient experiences obvious symptoms. Advanced diagnostics support personalized treatment by providing a better understanding of unique patient needs.

■ MP: What do transplant patients need to know about diagnostic tests?
MA: Specialized laboratories and tests are available to help physicians better manage transplant patients. Diagnostic tests can help physicians detect and treat complications quickly before they cascade into a potentially life-threatening situation. It’s important to talk with your physician about the availability and role of testing in your treatment plan.
My, how time flies. Astellas is entering its 20th year focusing on transplant immunology. Today we remain steadfast in our commitment to advancing the field. Tomorrow we will seek new possibilities for improving the transplant experience. Together, we celebrate the remarkable evolution in transplant history.
Regenerative Medicine:
One day organ donation will be unnecessary

What's the difference between the Bionic Man and a 21st century patient with a new bladder? The Bionic Man is part machine, but the 21st century patient has been restored using bio-based organs and tissues grown in a lab. There is a collective fantasy of cheating death by discarding old, sick body parts and getting new, fully functional organs. In fact, this seemingly far-fetched concept is already a medical reality. It's called regenerative medicine (RM), a medical field that aims to restore diseased or damaged tissue using the body's own healthy cells—or someone else's healthy cells.

Geoff MacKay, President and CEO of Organogenesis, Inc. and Chair, Alliance for Regenerative Medicine (ARM), says, “Currently healthy cells are being used to repair damaged organs, and this approach offers hope to patients with heart disease, hypertension, diabetes and other metabolic disorders.”

Cell therapy as a first step
Based on an ARM report, there are 60,000 stem-cell transplants each year for the treatment of cancer and blood disorders. But how do you get from cell-based therapy to growing completely new organs in the lab? According to Lee Buckler, Managing Director of the Cell Therapy Group, advancing cell-based therapies is part of the progression to full-functional organ creation. He cites islet cell transplantation as an example, which involves processes like diabetic patients getting cells transplanted from the pancreas of a recently deceased person. These healthy cells produce the insulin that the diabetic patient lacks, and there is a short-term cure. Eventually another transplant is needed. “This really represents progress,” Buckler says, “though the ultimate goal is to recreate patients’ organs in the lab, making exact replicas of kidneys, hearts, stomachs and other organs.”

The future is now
The current model of organ transplantation is challenging: There are more than 100,000 people on organ waiting lists and immune-mediated organ rejection is a problem. For example, 40 percent of transplanted lungs are rejected. However, on the positive side, there are already some compelling examples of fully functional organs designed through tissue engineering. For example, in 1999, Dr. Anthony Atala created synthetic bladders for young patients using a biological bag, seeding it with the patients’ cells and growing the bladder in a bioreactor. And in 2011, a patient who had cancer of the windpipe received a new trachea that was created by seeding the patient’s stem cells onto a synthetic surface—a scaffold—and “growing” it in a bioreactor. The patient lived.

Currently, there are 2,500 regenerative medicine trials underway, and 90 companies operating in this therapeutic arena. MacKay says, “I can’t think of an organ where regenerative medicine is not being researched.” Buckler adds, “We’re well on our way. This is not science fiction. It’s happening.”

Q&A
How is regenerative medicine being used right now?
In 2012, 160,000 patients were treated with commercially available regenerative medicine products (Source ARM 2013 Annual Report). These promising therapies are designed to treat diseases such as heart attack, spinal cord injury, wound repair and various cancers.

How has regenerative medicine and stem cell therapy proved successful thus far?
Regenerative Medicine is positioned to displace traditional medicines due to its curative effects as opposed to prolonged or lifetime medical treatments. This evolution of patient treatments can ultimately reduce the cost of medicines with a shift towards minimal patient-specific procedures.

In your opinion, how will regenerative medicine be used for treatment in 10 years from now?
One prominent shift in regenerative medicine is the development of induced pluripotent stem cells (iPS) by Dr. Shinya Yamanaka in 2007. iPS cells allow researchers to re-program basic human adult cells (i.e. skin cells) to function as early stem cells, allowing for advanced methods of treatment.

Dave Smith, Cell Therapy Innovator, Lonza
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- Sophia Castiglio, whose stem cells were used to rebuild her windpipe after a devastating tuberculosis infection;

- Mack Roberts, who was waiting for a heart transplant after a severe heart attack, when he was instead successfully treated with his own stem cells;

- Grigori Venadich, severely burned in a bombing, who was treated with a futuristic spray gun using his own stem cells to seed the growth of new skin;

- Damien Whitehall, blinded in one eye by ammonia, who had his cornea repaired with stem cells from the other.

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