



FOR IMMEDIATE RELEASE – June 24, 2002

AVAILABLE FOR INTERVIEWS:

- L. Stephen Gordon, M.D., Director of Pediatric Cardiac Catheterization and Cardiac Intervention
- Freddy and Reanna Contreras, Parents of Nicole Contreras, 6, one of the first pediatric patients at Cedars-Sinai to receive an ASD Closure Device.
- Saibal Kar, M.D., Adult Interventional Cardiologist
- Ayelet Kotel, 26, of Woodland Hills, Patient (adult)

HIGHLIGHTS:

It looks like a yo-yo, but it can stretch, flatten out, “swell up” and even “self-center,” depending on what it needs to do to adjust itself to plug holes in the heart that make up some of the most common congenital heart defects. In the past, treating such heart defects required open heart surgery, but thanks to these high-tech titanium devices that look like toys, surgery is no longer necessary. Amplatzer closure devices, long in use in Europe, received FDA approval earlier this year and are now being implanted non-surgically into both adults and children at Cedars-Sinai Medical Center – with outstanding results.

AVOIDING OPEN HEART SURGERY: NEW MINIMALLY INVASIVE CLOSURE DEVICE HELPS KIDS AND ADULTS WITH ATRIAL OR VENTRICULAR SEPTAL DEFECTS, AS WELL AS PATENT FORAMEN OVALE DEFECTS

LOS ANGELES, CA (June 24, 2002) – It looks like a yo-yo, but it can stretch, flatten out, “swell up,” or even “self-center,” depending on what it needs to do to adjust itself to plug holes in the heart that make up some of the most common congenital heart defects. In the past, treating such heart defects required open heart surgery, but thanks to these high-tech titanium devices that look like toys, surgery is no longer necessary. Amplatzer closure devices, long in use in Europe, received FDA approval earlier this year and are now being implanted non-surgically into both adults and children at Cedars-Sinai Medical Center – with outstanding results.

Nicole Contreras, age 6, who lives in Ontario, CA, was diagnosed with an atrial septal defect (ASD) when she was less than a month old. Ayelet Kotel, age 26, of Woodland Hills, was diagnosed with a hole in her heart while she was pregnant. The 6-year-old and the 26-year-old have become some of the first patients at Cedars-Sinai to have their heart defects treated non-surgically with the new closure devices.

Previously, both would have required open heart surgery, but instead they had the new devices implanted non-surgically. Nicole’s procedure, done under general anesthesia because of her age, took about an hour, and by the next day she was back to her usually bouncy self. Ayelet’s procedure, done using only a local anesthetic

took about 35 minutes. According to her cardiologist, Saibal Kar, M.D., she was asking to go home two hours later.

When as an infant, Nicole was diagnosed, her pediatrician explained to her parents, Freddy and Reanna, that Nicole had a hole between two chambers in her heart. Nicole was referred to L. Stephen Gordon, M.D., a pediatric cardiologist with offices in Arcadia and Beverly Hills, and Director of Pediatric Cardiac Catheterization and Cardiac Intervention at Cedars-Sinai. Because there was no immediate threat, Dr. Gordon decided not to intervene, hoping that over time, a small flap of tissue in Nicole's heart would heal over the hole, closing the defect on its own. He saw her every six months, monitoring the defect, but it remained open.

As a toddler and then as a child, Nicole was active, but she was less so than her twin sister, Lauren, and was also significantly smaller and thinner than her twin. Dr. Gordon explained that this was because her heart was having to work much harder due to the defect. As she grows older, it would also mean that she would be at higher risk for life-threatening events such as stroke.

Until very recently, treating ASDs required open heart surgery, but Dr. Gordon told the Contreras's about a new procedure he believed the FDA would soon be approving. The new ASD Closure Device was currently in use in Europe and had proven to be very effective. Best of all, it would mean that Nicole would not have to have surgery; she would recover very quickly and she wouldn't have the large scar that accompanies open heart surgery.

At first, Nicole's parents were nervous, but Dr. Gordon explained in detail what he would be doing during the procedure. Instead of being done in a typical operating room, Nicole's procedure would be performed in the heart catheterization laboratory. Nicole would lie on an x-ray table and an x-ray camera would move over her chest during the procedure. In addition, he would use ultrasound imaging which would allow him to see the hole in Nicole's heart and position the closure device in it properly.

Because of her age, Nicole would have a general anesthesia, but adults often choose to remain awake throughout the procedure, having only a local anesthetic. Dr. Gordon explained that he would then insert a catheter, or tube, through a large vein in Nicole's groin and navigate it through some of her body's largest veins until it reached her heart. He would then perform an angiogram (x-ray of blood vessels or heart chambers) to visualize her heart and the closure device. Next, he would measure the pressure and oxygen content in different chambers of Nicole's heart and measure the size of the hole in her heart.

He would then choose an appropriately-sized closure device – made of nickel and titanium alloy so it can be molded and stretched – and attach it to a tiny cable that would be threaded through the catheter until it reached the site of Nicole's heart defect.. At that point, he would push the closure device out of the catheter and into the defect, positioning it centrally in the hole, so that the two disks of the "yo-yo" would rest on each side of the hole. Once he was satisfied with the positioning of the device, he would release it by unscrewing the cable that had been used to slide it through the catheter. The cable and catheter would then be removed and the implant would be complete.

The whole procedure, Dr. Gordon explained, would take about 60-90 minutes, compared to about 3 hours for open heart surgery. If they chose the surgical option, the surgeons would need to stop Nicole's heart and use the heart-lung machine, putting her blood through a special pump. Overall recovery would take a few weeks instead of a few hours. And there would be a large scar.

After considering carefully, and doing their own additional Internet research, Reanna and Freddy decided that the advantages of the new procedure far outweighed the possible risks. In fact, Reanna now laughingly says,

“I can’t believe that I was skeptical at first. I guess I was just afraid because it was new, and because Nicole was one of the first pediatric patients at Cedars-Sinai to receive the device.”

And Nicole’s results have been outstanding. According to Reanna, the procedure took about an hour and by the next day, Nicole was back to her normal self – skipping and jumping. “She felt great – so good in fact, that Dr. Gordon asked us to try to slow her down a little,” says Reanna. However, even the “slow-down” was temporary. Less than a month after her procedure, Nicole received permission from Dr. Gordon to go back to jumping on her trampoline and swinging on the monkey bars.

“I would have really regretted it had I not had her heart defect repaired in this way,” says Reanna.

Since the closure devices were approved by the FDA earlier this year, Cedars-Sinai cardiologists have implanted more than two dozen.

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