**Dr. C. Walton Lillehei**
**Narrator**

**David Rhees**
**Interviewer**

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**St. Jude Medical**
**Little Canada, Minnesota**



**DR:** This is David Rhees. I'm here in the office of Dr. C. Walton Lillehei at St. Jude Medical in Little Canada, Minnesota. Today is May the 8th, 1998.

First of all, Dr. Lillehei, it's a real honor for me to be here with you and to have the opportunity to hear some of your recollections.

**CWL:** Well, thank you, David.

**DR:** Since we already covered most of the work leading up to the development of the external transistorized pacemaker in the video interview that we did last September, I thought maybe today we could focus on your work with heart valves, since that's been a major activity of yours.

**CWL:** Yes.

**DR:** Perhaps the easiest way to start is to ask you when did you first become involved in working with valve replacement?

**CWL:** Interest in valves began very early. The first operations inside the open heart were done in Minnesota, and the very first was done September 2, 1952, where John Lewis was the primary surgeon. He was a classmate of mine, a longtime personal friend. We were in the Army overseas about forty-four months and came back to the University of Minnesota to complete our training in surgery. We both decided that operations inside the open heart, which was not possible at that time, was a very fertile field for development. Dr. Lewis was impressed by a paper presented in 1950. I was sitting beside him actually in Colorado Springs at that meeting of the Thoracic Association [American Association for Thoracic Surgery.]

The presentation was by Dr. William Bigelow in Toronto, Canada, and he had pointed out in this article, with published results, that the limit the brain could go without blood safely was four minutes, but you could double that time to eight minutes if you reduced

the body temperature, including the brain, from thirty-seven degrees to thirty degrees centigrade. If you reduced it another five degrees to twenty-five degrees centigrade, you double the eight minutes to sixteen minutes. He felt that that was ample time for the simple defects inside the heart—he was talking at that time about the atrial secundum defect, which is a hole in the center of the upper chamber of the heart. People were dying of that probably in their twenties and thirties, about one third of the normal life expectancy, because that caused heart failure over a period of time. That could be closed by stitching, which should take five minutes or less. That patient's heart would be normal. So that was the first target of intracardiac surgery.

Dr. Bigelow presented quite a nice paper involving dogs, he had demonstrated this hypothermia was safe for that period of time. Strangely enough, he did not do any clinical cases, but Dr. Lewis and I, both in the audience, were very impressed and we said, "That's a place to begin." Dr. Lewis took the lead in that regard because I was more interested in developing some kind of an extracorporeal circulation, a heart-lung machine, if you will, for a longer period of time. We'll perhaps come to that eventually.

**DR:** I believe you covered a lot of that in the video interview.

**CWL:** In the video that we've done, yes. The first operation then, Dr. Lewis did about one or two hundred dogs with hypothermia and was very familiar with the mechanics of cooling the dog and ultimately the human, and clamping the inflow to the heart so there was no blood in the heart. Then, of course, that stopped the circulation to the brain as well. The first operation was September 2, 1952. It went extremely smoothly. It only took fifty-eight minutes from the skin incision in the chest to begin and the skin incision in the chest was closed in that length of time. The patient made an uneventful recovery.

The news of that method spread very rapidly through the grapevine, so to speak, and we began at Minnesota to use that method for closing atrial secundum defects two or three times a week. But the search went on, because you could not get more than fifteen or sixteen minutes by hypothermia, because if you went colder than twenty-five degrees centigrade you could not restore the heartbeat of a cold heart, and there was no way of warming the cold heart. We tried water in the chest as warm as you could without damaging the tissues, but cold blood entering the heart immediately was so strange or so important that you couldn't get the heart muscle to restore its beat. So that method was extremely useful for the simple defects.

The next thing we developed, and I think we've covered that in the past, was controlled cross-circulation, because the human use of the heart-lung machine had been a series of failures in application. Actually, the first use of the heart-lung machine in humans, or first in patients was at the University of Minnesota in April of 1951 by Dr. Clarence Dennis, one of our professors of surgery.

**DR:** Did you see that instrument in operation?

**CWL:** Yes. As a matter of fact, I saw the machine very often because Dr. Dennis's laboratory for research and my laboratory for research were in the attic of the physiology building, so we were next door, so to speak. That was a very cumbersome machine because it was thought necessary to do certain things that later proved unnecessary, but in the beginning, that machine was used twice and both patients died in the operating room. Dr. Dennis had gone then to New York to become professor of surgery at the [SUNY] Downstate Medical School of the New York University.

**DR:** Did he continue working on the heart-lung machine?

**CWL:** Well, when he moved, he apparently was involved with a lot of administrative duties, so it was a year or two before he started again. Yes, he did continue, but he did not have any successes in the immediate few years. The cross-circulation they use in the human donor, usually a parent to supply the fresh blood, the artificial lung, so to speak, with a pump to control flow, worked dramatically successfully and it became possible to close a number of birth defects in the heart that were previously not correctable, like ventricular septal defect, atrial ventricular canal. For the first time, total correction inside the heart of the blue baby, the common form of blue baby, which was called Tetralogy of Fallot was possible.

With that success, we had enough knowledge about perfusion of the heart that one of my associates which I had put to work on this problem, Dr. Richard DeWall. (He was a young surgeon that joined us for training in surgery, and he was a very inventive fellow.) I had asked him to run the pump during these cross-circulation operations which we were doing about twice or three times a week and, in between, develop an artificial means, an artificial lung that we could use with the same pump to purify the blood. I told him that we had done some preliminary experiments in the immediate period prior to cross-circulation, using oxygen to purify the blood, which is the way it's purified in the lungs, but using bubbles of oxygen in the desaturated or venous blood.

Now, in the field working in this endeavor to develop means of working inside the open human heart were probably fifteen or eighteen centers around the world: United States, several places in Europe, England, Germany, Brussels, Belgium, Russia, and in the Far East, in Japan particularly. Amongst those investigators, there was not consistent agreement about how to work inside the heart because nobody had done it successfully with a heart-lung machine.

The one thing they did agree on was it was not possible to consider a bubble oxygenator to purify the blood because the brain was so sensitive to bubbles that you could never expect to maintain a patient for any length of time without damaging the brain. Well, Dr. DeWall is a very inventive fellow, and he also wasn't one that did go to the library to

read up on the problem. Often that's a way to start a problem and it's probably a very good way to start in order to see what other people have done, but had he done that, I'm afraid he would have been totally depressed about a bubble oxygenator. I didn't tell him anything about the failures or the articles about the dangers of bubbles. He knew the dangers of bubbles to the brain. So he started working, and within about three months developed a very feasible bubble oxygenator in the laboratory that maintained dogs.

**DR:** You said he was very inventive. Did he have a background in engineering or invention?

**CWL:** No.

**DR:** Isn't it a little unusual for a physician? Was he a surgeon by training?

**CWL:** No, he had just graduated from medical school at the University of Minnesota and had gone to Chicago for an internship and come back to Minnesota. He was in general practice, actually, in Anoka, Minnesota, and he was not very happy there in general practice because he had an inventive sort of mind and he wanted to be in research. So he used to come over to the laboratory, my laboratory, on his days off, which was usually Wednesday or Thursday, and put on a scrub suit and pitch in. I could see by his help that [when] he saw a problem, he had a solution for it. I mean, some people are naturally inventive, but he had no training in engineering and no background that certainly you would have thought to have been a big help, but he was not of that category. As a matter of fact, his grades in medical school had been very low, passing, but low, and when he came back and started working for me, I suggested that he enroll in the graduate school so he could get credit perhaps towards an advanced degree, a Master's degree or a Ph.D., but interestingly enough, his grades were not sufficient to enroll in the graduate school at that time. Later when he developed this bubble oxygenator and people were asking him to come to France and to come to England to help them with their first case, a graduate school remitted him so he could be a suitable candidate. That's a little byproduct. But with the knowledge of the very effective bubble oxygenator that was first used at the University of Minnesota in May of 1955 on patients, it was dramatically successful.

We had many visitors at that time from all over the world, because the only place that was doing open-heart surgery on a regular basis from 1952 through 1955 was the University [of Minnesota] here in Minneapolis. In 1955, about May, my good friend Dr. John Kirklin started open-heart surgery at Rochester, so visitors that came to Minnesota had a fruitful time. They could see two places, the only two places in the world at that time, with only a short distance between them to travel, so we had many hundreds of visitors.

With the success of the bubble oxygenator, for the first time they said that we needed to do something about the adult patients that were dying of heart disease. One of the most

common forms of heart disease at that time that afflicted adults were diseases of the valves, many other things, of course, but valvular disease was a common problem.

**DR:** Before you move on to that, I was just wanting to ask about the bubble oxygenator. Was that ever commercially produced?

**CWL:** Yes, the bubble oxygenator, we patented it.

**DR:** You and Richard DeWall?

**CWL:** Yes, and gave the patent to the University of Minnesota, who licensed a company called Travenol to make this oxygenator and distribute it in a sterile form around the world. So a group ordering this oxygenator just needed to unpack it, hang it up and prime it with the blood, usually, and go to work. So that had an explosive effect on the spread of open-heart surgery because the previous heart-lung machines that had been used and failed were very complex. They usually filled one stall of an automobile garage and weighed 1,500 to 2,000 pounds, whereas the bubble oxygenator was three pieces basically of polyethylene tubing with some needles for creating the bubbles. It was heat sterilizable, and we threw it away after each use because it was so inexpensive.

Fortunately, at that time polyethylene tubing was just coming into existence. There was a company in Minneapolis that was making this for the creamery business, because they like to use tubing which was disposable and heat sterilizable for separating milk and cream. That was Mayon Plastics. They supplied the tubing. It later became one of their primary products exceeding the dairy industry.

**DR:** Is that company still in business?

**CWL:** Yes.

**DR:** Have you kept a relationship with them?

**CWL:** The president was Ray Johnson, who, as it turned out when they called him, had been a classmate of mine in high school. I didn't know him, because our high school class had about 800 students in it in West High School in Minneapolis. He became a longtime friend and is retired now, but he still lives out in the Lake Minnetonka district.

**DR:** Was Travenol a local company?

**CWL:** No.

**DR:** Where were they from?

**CWL:** They were in northern Illinois. I think they were a division of the Baxter Company. At least they became a division.

**DR:** How did you find them, or how did they find you?

**CWL:** Well, I don't know. I don't remember how we got in contact, but the news that we were doing this type of surgery, as I said, spread rapidly throughout the United States and the world, so it was no secret.

**DR:** Did that become a commercial success?

**CWL:** The commercialized form of the DeWall-Lillehei bubble oxygenator became available in 1956, called the sheet oxygenator. It had the same principal as the one that we put together by hand, but it was made in the form of a sheet, autoclaved and all ready to use.

**DR:** Did that continue in commercial production for some time?

**CWL:** Oh, yes. Most of the world used the bubble oxygenator because it was so readily available, so effective, and so inexpensive.

**DR:** How long did that continue before it was superseded?

**CWL:** Well it continued until, I suppose, the second half of the 1980s. The membrane oxygenator, disposable, which we first described actually in 1966, I think, Dr. A. J. Lande, one of my fellows and I described one. It was made commercially by the Edwards Company in California, but it didn't really catch on until about ten, fifteen years later when the bubble oxygenator was so effective. The only advantage, I suppose, of the membrane oxygenator is if you have to operate beyond two or three hours inside the heart, it's probably safer, but the vast majority of open-heart operations are done within the hour, but not always.

**DR:** Was that your first experience in working with a medical device company?

**CWL:** Yes.

**DR:** Was that a good experience?

**CWL:** Well, it worked out well. We had control of the patent, the University did, so they were by contract obligated to produce what we had agreed upon. They gave a royalty to the University of Minnesota, which was useful. Yes, I'd say it was very satisfactory, really.

**DR:** I interrupted you. You were about to start talking about valves and replacing them.

**CWL:** Well, we got into the oxygenator business because that had to be developed, and that early surgery was all on children with birth defects, babies and small children who were in extreme heart failure and were destined to die unless something could be done. So they were the early patients. But by late 1955, early 1956, we started to do open-heart surgery on patients with valvular lesions. We thought that opening up the heart, we could do much more effective operations than were being done, if at all. The only operations on patients with valvular heart disease at that time were done with a beating heart filled with blood, and you put a finger into the upper chamber, and if it was a narrow valve you could split it open sometimes if it didn't have deposits of bone, but that was the limit. By opening the heart, emptying the blood and opening the heart, you could do much more.

We developed a number of operations that were very effective. One of the ones that is still used is anuloplasty, when a mitral valve has been enlarged. The heart has been enlarged. The valve shrinks up because of fibrosis or scarring, so it leaks. We successfully put stitches in to narrow that widened opening back to normal, then you had a functioning valve if it had not been destroyed by calcium or bone. But many valves were not repairable and you could not, in those days, tell that ahead of time because the diagnostic methods were not nearly as precise as they are now. So often we were confronted with those emergencies after we had opened the heart, and we had to devise the best methods we could to lessen disease, but sometimes those were ineffective and the patient didn't survive, or if he did survive, was not particularly helped. So it was quickly apparent that we would need an artificial valve to substitute for the very diseased valve. So, immediately we began, and others did too, methods of developing artificial valves.

The first artificial valve that was widely applied and successful in patients was called the ball valve. It was developed by a surgeon named Albert Starr working with an engineer, Lowell Edwards. It was a ball with a cage on it, and it was kind of cumbersome, but most of these hearts were enlarged so that was not a limiting problem very frequently. If you could sew that valve in place either in the aortic or mitral area or the tricuspid area, or the aortic—there are only four valves in the heart—this valve was applicable to any of those four situations. But most of the disease that occurs in valves in humans is either the mitral valve or the aortic valve in the left side of the heart.

The ball valve, in general, was quite successful, but it had problems that were apparent as more patients had this valve in place. The main problems in the early months and years of this valve—incidentally, I think the first Starr ball valve was placed about 1960 by Dr. Starr, and we began using it at the University of Minnesota, as others did, and the successes were stimulating. The problems, of course, became apparent and that engendered efforts to improve valve function. The main problem with the artificial valve was where the heart beats one hundred thousand times every twenty-four hours, that's

something like thirty-six million times a year, and that's a lot of wear on a valve. These valves were made of titanium or various stainless steels with a silicone valve and they were quite durable, but the early models, some of them failed in three or four years.

The other problem with a valve in the blood is artificial clotting around the valve, and those clots can have very deleterious effects. If they are extensive enough, they stop the motion of the valve, and that's fatal, or if they break off, they can go anywhere in the bloodstream and sometimes they go to innocent areas like a muscle, but other times they go to the brain or the kidney or the intestine, and you have a short period perhaps to remove that clot if you can, and save the patient, but other times, it's fatal.

So the research on valves began around the world, so to speak, by people using valves. We developed at the University of Minnesota three artificial valves, prosthetic valves, we called them, that we designed and tested to improve some of those problems with the ball valve. The first was a disk valve with a hole in the center like a doughnut. It moved up and down. Other workers had devised the disk valve with a solid disk that moved up and down. With a hole in it, we had better flow through the valve with less work on the heart. That was the Lillehei-Nakib valve.

**DR:** Who was Nakib?

**CWL:** [Ahmad] Nakib was a doctor that had graduated from medical school in Lebanon and had surgical training in Lebanon, but had come to Minnesota to work on open-heart surgery. He was trained eventually as a thoracic surgeon at the University of Minnesota.

**DR:** Did you have any engineering help as the doctor who had the ball valve did?

**CWL:** Well, I think we consulted with engineers, but we did not have any engineer working actively with us.

**DR:** Who actually built the valves?

**CWL:** Well, we had contracted that out to a company here in Minneapolis.

**DR:** Who was that? Maybe I have that name. Was that Washington Scientific Industries?

**CWL:** That [company] made the Lillehei-Kaster, but maybe they did that one, too. Washington Scientific did the next valve, which was the Lillehei-Kaster valve.

**DR:** In one of your articles it indicated that they did the Lillehei-Nakib valve.

**CWL:** Washington?

**DR:** Washington.

**CWL:** Okay, they did then.

**DR:** I'm just curious about that company. What were they making at the time?

**CWL:** They were making gun mounts for the Navy. The war was over and there were contractual withdrawals, and they were looking for new products.

**DR:** How did you get together with them?

**CWL:** I don't remember exactly. We became quite good friends with the president, and I think he had had some members of his family, as I recall, succumb from valvular heart disease, and he was very interested in working with us on the artificial prosthetic heart valve.

**DR:** They are still in existence. Who built the prototypes?

**CWL:** They did. We described what we wanted. The dog was a very valuable experimental method for studying heart valves. The other method that was very valuable was called a pulse duplicator, an artificial circuit outside the body with places you could measure pressure to establish the freedom of obstruction from flow. One of the young fellows who was working his way through engineering school, Mr. Robert L. Kaster, designed a pulse duplicator using the first of the computers called an analog pulse duplicator. It pulsated the blood like a normal pulse to study the flow of these prosthetic valves. Actually, when he graduated from mechanical engineering at the University of Minnesota, he was so enthralled with his work at our laboratory that he became a full-time engineer, biological engineer, we used to call them, because of dealing with biology, one of the first in that field. There are many now. When I moved to New York in 1967, I created a position for him at the Cornell Medical School as a biological engineer for work on many types of research problems that had engineering problems, which is quite frequent in working in the cardiovascular system, because we're really plumbers outside the body working inside the body with the same principles of flow.

**DR:** Did Kaster remain at New York after you came back to Minnesota?

**CWL:** No, he came back with me.

**DR:** Is he still in the area?

**CWL:** Well, he was hired by Medtronic, and for a while headed the Division of Heart Valves that they created, and then he left Medtronic and has been working on his own for the last fifteen or twenty years.

**DR:** Interesting.

**CWL:** He has not produced any new valves, or actually any new biological innovations. I've talked with him periodically every several years probably in between. He's readily available.

**DR:** Did you and he take out a patent on the pulse—

**CWL:** No, as far as I know. In many things, taking out patents we found was very time-consuming to sit down and go over each word in the patent and each drawing, and many things we did not patent; actually, other people patented. But I don't resent that particularly, because it was very time-consuming.

**DR:** The Nakib valve, you did patent that.

**CWL:** I think Nakib patented it.

**DR:** By the way, was that your first patent, the Lillehei-Nakib valve?

**CWL:** I guess so, yes. Well, no, the oxygenator was.

**DR:** You took a patent on that as well, of course.

**CWL:** The bubble oxygenator.

**DR:** I'm sorry I'm getting you out of the flow here. So, the Lillehei-Nakib valve was produced by Washington.

**CWL:** Scientific. It was used probably in somewhere between 1,500 patients, so in terms of the Lillehei-Kaster which followed, it was used in about sixty-five thousand patients, but the Kalke-Lillehei, which was developed in St. Jude, has been used in over eight hundred thousand patients, to give you some idea.

**DR:** Washington Scientific Industries, did that company remain in the valve business?

**CWL:** No. I don't know. They were interested in other biological things, but I have not seen their name in any particular biology. I think they're mostly in industrial commercial engineering. I haven't talked with anybody from there for many years, but I have not seen their name in any of the advertisements for biological equipment.

**DR:** So this may have been just a one-time thing.

**CWL:** It was of interest to the people that were—the president particularly, and one or two of his engineers. It did not occupy a large number of people, because this type of research was a created product and then tested in animals and in the artificial circuits that we had and also by X-ray. Then if it looked feasible, and at that time there was no FDA approval necessary; you could move as your conscience dictated into use in the patients.

**DR:** So the Lillehei-Nakib valve enjoyed real success?

**CWL:** Limited success.

**DR:** But limited compared to the others.

**CWL:** All this occurred in a relatively short period of time, and the Lillehei-Kaster, which is a different principle to improve flow and reduce wear, was already being investigated in the laboratory. That became refined enough for use in humans beginning about 19—can you look it up?

**DR:** One of your articles said about 1967 for the Lillehei-Kaster.

**CWL:** Well, that's about right. The first description of the Lillehei-Kaster valve design was made in Stockholm in a meeting in 1967. That was the principle to be [unclear].

**DR:** This valve was—

**CWL:** Called the pivoting disk. It had a disk that was not hinged, it was free-floating, but kept in place by the design of the pivots. It was without a cage, and the disk rotated around the pivot so the wear was distributed circumferentially.

The chairman of that particular meeting in Stockholm was Dr. Viking Olov Bjork. He liked this design so much, he brought out a valve shortly after called the tilting disk, which was the Bjork-Shiley tilting disk. That was a similar design but didn't have the durability, and there were widespread failures with that design. The Lillehei-Kaster, fortunately, was sometimes called the DC-3 of heart valves because it worked and worked and worked and there was never—of these sixty-five thousand anyway, and some are still in existence—an example of it wearing out. It did have some clotting problems, less than the earlier valves, but not entirely eliminated. So the patients taking that valve, as the modern St. Jude valve, still need to take coumadin to reduce the clotting of the blood.

**DR:** Did you say that you did not patent the Lillehei-Kaster valve?

**CWL:** Yes, it was patented. We also gave that patent to the University.

**DR:** And it was produced by—

**CWL:** Washington Scientific, the Lillehei-Kaster.

The Kalke-Lillehei we did not patent ourselves. St. Jude patented the one aspect of the valve, the design of the pivot.

**DR:** I see. I'm sorry, I'm getting confused. So the Lillehei-Kaster valve, according to one of your articles, was produced by a company called Medical, Inc., in Inver Grove Heights, Minnesota.

Can you tell me a little bit about that company?

**CWL:** Yes. Well, that company was a company that made only this valve. It was run by an entrepreneur called [Marshall Kriesel]—mental block. Shut it off a minute. Give me that brochure a minute. The little brochure there.

**DR:** Let's see. That's the Kaster.

**CWL:** I was trying to think. His name is similar as my own name, but I get a mental block here.

**DR:** We can fill it in later if you'd like to go on.

**CWL:** He was the president and he had engineering training. He was not an engineering graduate. It was made essentially by machine-type lathes to produce this valve out of titanium, which is a very satisfactory metal. This valve had an orifice of titanium, but was the first valve to use pyrolytic carbon as the pivoting disk. This new material called pyrolytic carbon [came] from Dr. Vincent Gott, he was one of our students in the early periods. In fact, on the first cross-circulation operation in humans on March 26 of 1954, he was the intern on that case that scrubbed with us. He became very interested in the heart, and after finishing his training here, went to the University of Wisconsin for about two years, and from there to Johns Hopkins, where he's remained since then. He retired about a year ago, but he's still active in the Department of Surgery there.

**DR:** That was a very important breakthrough, wasn't it, the pyrolytic carbon?

**CWL:** Yes.

**DR:** How did he come across that?

**CWL:** Pyrolytic carbon was developed in the sixties, I think, basically, where there was a tremendous amount of money being spent and a tremendous amount of effort in the

Cold War. We were trying to outdo the Russians and they were trying to outdo us. This was the beginning of the Space Age and the first Sputniks were put up by the Russians, and I think our Mercury satellite, whatever the name was, was the first on our side. They were developing methods for various problems, and one of the problems from the stratosphere was reentry, because you develop a tremendous amount of heat with a projectile. I think they were going something like seventeen thousand, twenty thousand miles per second, I think, something, or maybe per minute.

Anyway, one of the materials that was developed by Gulf Atomic, an engineering outfit on the West Coast near San Diego, was this pyrolytic carbon. It was a form of carbon that was particularly hard and particularly resistant to heat. The idea was to coat the nose of the reentry vehicle with pyrolytic carbon. But they were going ahead on a number of different fronts because they had ample finances from the United States government and they didn't know exactly what they wanted until they developed it and tested it.

As it turned out, pyrolytic carbon is not as effective for reentry as a softer material which burned up and flaked off, so the heat was dissipated, and so this was never used. It was sitting around the laboratory, and one of the engineers, Mr. [Jack] Bokros, thought—and I don't know exactly what stimulated him—that it might have some medical use. Somehow, and we'd have to ask Dr. Gott, he and Dr. Gott by that time, I think, were about to leave Wisconsin and go to Baltimore, but they got in contact. They did some experiments, Dr. Gott did, using this pyrolytic carbon. Mr. Bokros had demonstrated from the mechanical data from Gulf General Atomic that this was the hardest manmade substance known, harder than any analog of metal, tungsten alloys that they used on tanks and battleships for repelling projectiles. The only material that was harder in terms of wear was natural diamond, and, of course, natural diamond is a form of carbon. Pyrolytic carbon is carbon deposited on a substrate at two to three thousand degrees centigrade in a big vacuum tube. It was sort of a complicated substance to make, but could readily be made once you knew the formula.

So, this was the hardest material known to man, and Vincent Gott demonstrated it in dogs, putting the little rings of various substances in the right atrium of the living dog, he put material shaped like a wedding ring and he did a little projectile to hold it in the center of the bloodstream. He tested more than two hundred, maybe two hundred fifty various plastics, natural substances, synthetic substances to determine resistance of natural blood to clots, and he found pyrolytic carbon was far superior to any other material as far as resisting clot. So he was not in a position to do anything with valves at that time. He was a frequent visitor back here, he was one of our admired students, as a matter of fact. He told us, Mr. Kaster and myself, about this new material, it was so hard and so resistant to clots. It was ideal, we thought. As it turns out, that's still true, still being true twenty years later for heart-valve design.

**DR:** That's still true today?

**CWL:** Oh, yes. Prior to the St. Jude valve, when we modified the Kalke-Lillehei to become the St. Jude, we did three things. We opened the two disks that opened in the Kalke-Lillehei to sixty degrees, we opened them to eighty-five. The second is, we changed the titanium in the Lillehei-Kaster valve, we said if we're going to make a new valve, make it all pyrolytic carbon. The third thing was a change of necessity, because the pivot mechanism for the design of the Kalke-Lillehei valve was difficult to make in this new material because it was so hard that they had difficulty polishing it. So they developed the ear that made the pivot on the inflow side before the blood entered the valve. So those were the three changes made in the Lillehei-Kalke valve to become the St. Jude valve. The all-pyrolytic design, of course, was a big advance. You can keep that if you wish.

**DR:** Thank you.

**CWL:** That's the plastic design of the St. Jude valve. You could see the pivot mechanism, when they attempted to make it within the orifice, they couldn't get in to polish it, so they made this ear. You see the pivot, little pivot mechanism is in the ear on the inflow. The blood flows through the valve this direction. Opens, closes. It's an elephant model.

**DR:** That must have been a godsend then to discover this pyrolytic material.

**CWL:** Well, it was an important finding along the route. I suppose titanium would have been quite satisfactory, but we never used titanium for this valve, because titanium is extremely hard. It's a Space Age metal, really. Well, even the most advanced jet fighters now use carbon, of course. The Stealth fighter is almost all carbon.

**DR:** So the first use of pyrolytic was with the—

**CWL:** Lillehei-Kaster. In the disk.

**DR:** The disk in the middle.

**CWL:** The moving part. That's your titanium right there. Titanium is the orifice, where the dacron is attached, this carbon disk of the pyrolytic carbon. We got the pyrolytic carbon from Gulf Atomic. St. Jude was one of the first in the world to produce their own over here in Woodbridge. Well, it's over this way about half a mile.

**DR:** So this company Medical, Inc., was formed in order to make this valve, right?

**CWL:** We got the authorization from the University to use this patent. In fact, he didn't pay anything and the University had to sue him. About four, five years ago they won a

suit for six and a half million dollars at the University.

**DR:** How did you come into contact with the man who founded Medical, Inc.? I'm sure you'll remember the name later, but how did that relationship develop?

**CWL:** I think through the University that somehow he learned of this patent.

**DR:** So that valve, I think you said there was something like sixty-five thousand—

**CWL:** Yes, used in patients.

**DR:** So that continued up until fairly recently?

**CWL:** Well, let's see. We started using the valve, I think, seriously or consistently about 1969, as I recall. That valve actually is still being made with some certain modifications, but it has no real sales in the United States because of the more modern valves. They call it the Omniscience now. It's almost identical with the Lillehei-Kaster, but it's made out of pyrolytic carbon.

**DR:** Is that the name of the company or the valve?

**CWL:** The valve.

**DR:** Medical, Inc. still exists today?

**CWL:** Still in Inver Grove. Marshall Kriesel is his name. But he's out of the company now. He's the one that was displaced with the legal problems and so on, and there's an Egyptian running it. His name slips my mind now.

**DR:** So that was the late 1960s, and then the Kalke, and then at some point you—

**CWL:** Well, we described the Kalke-Lillehei valve in 1967—well, it was a series of descriptions. This was hemodynamic features of the double leaf, or rigid double leaf prosthetic valve, the new device. That was in 1967.[1] Then this was another one about that same time. I think this was the first hingeless double leaflet prosthetic heart valve for aortic, mitral, and tricuspid positions.[2] It still had a cage there. This was some of the testing data that showed it was so successful, better than the Lillehei-Kaster in the [unclear] flow through the valve.

This is the third one where we did this time, this is the report from the—[Shuffles through papers] I must have taken it out of the folder. This was a national conference of heart valves, and they published the results. That's not the right thing; maybe I have a reprint over there of the clinical model when we eliminated the cage. At that time, 1968,

Dr. Kalke had finished his training and finished in New York and got his Ph.D. degree from the University of Minnesota on this work, and then went back to India.

The picture is in here, the first description of this clinical model without the cage.[3] That original paper with the St. Jude valve shows—oh, here it is. This was early quality. We called it a clinical model. It was never used in patients, though we were planning to use that. I knew well, on a first-name basis, the CEOs of the three major mechanical valve company manufacturers in the United States. I went to each of them with the data to make a model to use in patients. They said, "Walt, we like you very well and this data's all very impressive, but the hinge is going to wear, going to clot." I said, "But it's pyrolite, going to be pyrolite." Well, they didn't know much about pyrolite, so nobody would make it until 1976.

Manny [Manuel] Villafaña incorporated the company, new company, called St. Jude Medical to make a valve. He decided with his advisory committee to make this design. That's the St. Jude valve. That first St. Jude valve was put in a patient October 4, 1967, and there have been eight hundred thousand since then. We had a twentieth anniversary, a one-day celebration last October.

**DR:** I attended that. It was quite a party.

**CWL:** You have this one [article], don't you?

**DR:** Yes, I do.

**CWL:** I'll make a note to put a Post-it on there and send you one in the mail. The final design of the Kalke-Lillehei, which became the St. Jude, sat on the shelf from 1968 till 1976, when it was refined and tested in animals, and through the latter part of sixty—all these dates. We designed the valve '68 till '76. The latter part of '76 and the first part of '77, and then it was considered ready for patients in October 1977.

It was slow to be accepted by surgeons. The surgeons looked at this and said, "It's going to wear out." It took eight years for the first hundred thousand to be used, and the second hundred thousand in three years, and the next hundred thousand in one year, and eight hundred thousand by 1997. I'm sure there's probably better designs of valves around and better materials, but to this date, nobody's described them, and the St. Jude valve was the gold standard of mechanical valves, and as you realize almost from the beginning—

[tape interruption]

**DR:** You were saying something about tissue valves.

**CWL:** From the beginning of this ball valve in 1960, it was investigators, surgeons,

cardiologists working with surgeons that suggested valve replacement, not by a mechanical device, but by a tissue device. The first tissue valve was the human valve recovered at autopsy under sterile conditions, called a homograft, because it's from the same species but different person. But they worked quite satisfactory up until, oh, seven, eight years they started to wear out. Then efforts were made using pig valves and different chemicals to denature the tissue to prolong its life. Now the tissue valve that's being used is the pig valve treated with glutaraldehyde and the new St. Jude valve, which is a pig valve treated with glutaraldehyde without a stent, because a stent tends to limit the flow and create turbulence. Turbulence is deleterious to tissue because it stimulates fibrosis, so this valve, stentless, is thought to extend the life of the tissue valves, which at this time is about twelve to fifteen years, at which time they usually need to be replaced by another operation, whereas the St. Jude valve, the gold standard of the mechanical valves, has a half-life of two hundred years. The half-life means that half of the carbon would be worn, but the valve would be very functional. It takes something like an estimated four hundred years. This is tested by using high-speed pumps to test the valve in this pulse-duplicator system.

**DR:** I'm just curious, you said you went to the three leading manufacturers, the CEOs of the three leading companies that made mechanical valves, after you developed the Kalke-Lillehei valve. Which companies were those?

**CWL:** That was the Edwards Company. Orville Edwards, he's the engineer that worked with Starr, created the company, and he subsequently died, but the company is still in existence, although I think they're part of Baxter now. I'm not sure of that, who owns it, but it's part of another company. Cutter Company was another valve-manufacturing company.

**DR:** Do you recall where they were located?

**CWL:** In California. Edwards was in California. Cutter, I think, was in California, and the third company [Surgitool] was in Pittsburgh. The engineer was Lewis. He called his company—I need to see that reprint of the one with the three valves described.[4] I think the name's in there. I said Lewis; actually his name was Harry Cromie, and the company was Surgitool, right down there. Harry Cromie. But he did make some prototypes of the Kalke-Lillehei for use in animals.

**DR:** But none of them would bite on producing the Kalke-Lillehei.

**CWL:** Harry Cromie was the closest. He said that he would do it if we advanced him fifty thousand dollars. Well, that's not a big amount these days, certainly, but they were busy with so many things. Most of the companies, if they agreed to do it, took it on as a contingency. I mean, if they thought it was good, they knew it was going to make money. This is before the FDA, of course.

**DR:** You said you were on a first-name basis, I think, with all those people. You had encountered them at professional meetings?

**CWL:** I think, yes, mostly, or when I was in the city and made an appointment to talk with them.

**DR:** So there was a small industry that was growing.

**CWL:** It was fairly big. Well, I don't know how big it's—compared to General Motors or General Electric maybe. They had sales of five to ten or twenty million a year, something like that.

**DR:** So it was a growing industry, but it wasn't here; it was all in Pittsburgh or California.

**CWL:** None were here until St. Jude.

**DR:** Let me pause at this point and ask you, it's 4:20 and we were supposed to end at 4:00.

**CWL:** Well, I'm sorry we were interrupted there for a while.

**DR:** Well, that's okay. That's quite all right. I'm just wondering if maybe we should make another appointment and I could come back sometime if you have other—

**CWL:** Well, I think we've done through the St. Jude valve, which has been a very dramatic success, both in terms of usage and patient benefits. It's often called by others the gold standard of mechanical valves, but this is an ongoing problem. We'd like to have a mechanical valve that you did not have to use coumadin. The use of coumadin has been far improved with the St. Jude valve because they call it the low dosage. The dosage that you used to use in the ball valve was several times greater than the dosage you need to prevent clots in the St. Jude valve, and that's beneficial because you have fewer bleeding problems.

**DR:** How did Manny Villafaña find out about the Kalke-Lillehei valve?

**CWL:** Manny Villafaña started the St. Jude valve at a time when he had just sold—Manny Villafaña is an entrepreneur. He had one or two years of engineering training in New York, but he was never an engineer per se. He worked for Medtronic in earlier years and was sent to Buenos Aires, actually, in the sixties, early sixties, to establish the first pacemaker distribution center there. That's when his first child was born, who had a very severe problem, almost died a number of times with difficulty in respiratory exchange,

born with a very soft trachea. They were not very well versed at that time in Buenos Aires, and finally after a few weeks and the child had nearly died several times from respiratory arrest, we put him on an airplane. He took an airplane with the baby and brought him to Mayo Clinic. [Brief interruption.]

At the Mayo Clinic the expert there stabilized the trachea, so the problem was solved. Mr. Villafaña named the child Jude. I had asked him later when we were talking about the name of this valve, he said that he would like to name this new valve that they were developing with the Kalke-Lillehei design the St. Jude valve, because he'd already named his company St. Jude, Incorporated. He had chosen St. Jude because he is of Puerto Rican descent, he was born in New York City in the Depression, in the inner city of New York, which is a very depressed area. His parents had come from Puerto Rico with no training and working at the lowest levels of remuneration. His father died when Manny was four or five years of age, so his mother was left to raise the several brothers in the family. He is Catholic descent.

It's not generally known, but one of the twelve disciples of Christ was St. Jude. Actually, the only disciple who was related to Christ. He was a cousin, because St. Jude was a son of Mary Cleophas, who was the sister of the Virgin Mary. At any rate, the St. Jude name has been confused in the literature with Judas, who betrayed Christ, also one of the disciples. So St. Jude was one of the least known of the twelve disciples, but he is in the Catholic literature, and in the liturgy of the Catholic Church is the saint to whom you pray when you need a miracle.

So Manny said that when he was praying in Buenos Aires for the salvation of this newborn, St. Jude told him to take him to the Mayo Clinic, and thus he named the child Jude, who has now, I think, graduated from college. He wanted to repay St. Jude by naming this new valve the St. Jude valve, and he said another reason is that most valves at that time had surgeons' names attached to them almost universally, and he said the same was true of pacemakers. When he used to sell pacemakers, he'd run into doctors who did not like the name on the pacemaker. [William] Chardack was one of the names on the early implantable pacemakers made by Medtronic, and [Wilson] Greatbatch. He said, "Who could hate a saint?" So he thought that that would be an excellent name for a heart valve, a saintly name. The sole proprietor of the name "St. Jude" is the Catholic Church, but they long lost any copyright endeavors. So you had two reasons for naming the heart valve the St. Jude. One is that you could pray for a miracle, and people would not have any displeasure with the name. That's how the name St. Jude was derived, which is an unusual name in the beginning at least. It's common now and nobody questions the origin—even though they don't know it, they know the St. Jude name so well. It's often confused with the St. Jude Church, I think Nashville, but they used the same name for the same reason, the hospital for children, where many are sent because they're dying, and hopefully a miracle will eventuate.

I think that's a good place to terminate.

**DR:** Okay. Thank you very much.

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