Earl Bakken and Dr. C. Walton Lillehei
Narrators

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Interviewer

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(former location of Operating Room J)

CWL: Well, right after World War II, you know, jobs for engineers were not easy to get, or not? You decided to go on your own.

EB: Yes, I had several other offers, but I took an interest [in this], because [I had been interested in] my early days [in electricity and] Frankenstein and other things. You know I wanted to be in medical electronics, and there weren't courses in it then.

CWL: There were courses?

EB: There weren't.

CWL: Well, I wouldn't think so.

EB: There were a few. I think Tulane had something going, but very few. Here [at the University] you could put something together if you pieced it out.

CWL: Well, there wasn't much biomedical engineering.

EB: Well, it just coming in from the science that had been developed during World War II.

CWL: A lot of that, of course, wasn't particularly applicable to medicine, as I recall. But anyway, I know you were making instruments with physiology [the Physiology Department.]

EB: Yes, I was just talking coming down the hall, maybe I can find some of the old instruments I made, an integrator or an animal respirator.

CWL: These are the anesthesia labs, Earl, right here.

Okay. You entered the first operating room through here. I think we had about ten operating rooms here, I don't remember exactly. I didn't look up above. They've covered the dome off entirely.

EB: Yes, I suppose.

CWL: These were all operating rooms.

EB: In those early days, I didn't have any office at Medtronic, I was just over here all the time, but mostly in the animal labs.

CWL: Well, your office was your garage. [Laughter]

EB: Well, yes, but that didn't have any office.

CWL: Well, there was no Medtronic, other than your little company, which is—what was the guy, your partner's name?

EB: Hermundslie.

CWL: Hermundslie and your wife. His wife and your wife, right?

EB: Well, they didn't do much, but his— [Hermundslie's wife and Bakken's wife were sisters.]

CWL: They were supposed to be secretaries.

EB: My wife was working at Northwestern Hospital as a medical technician. She had kept us eating.

CWL: You told me one time, when you were getting started, that was the early years of TV, they had a lot of the early sets, do you remember, Earl? We used to—our main operating rooms were in the building they tore down to build this one, part of it.

EB: Yes.

CWL: We did the first open-hearts in that other part of the building.

EB: Yes, in 1954.

CWL: Well, 1952, was the first, and then through '54, '55. I think we moved in '56, it's not important, I think, for this, but I was going to look that up.

EB: Up until when did you use a parent as the oxygenator?

CWL: Yes, up until July of 1955. We started in '54, used it about fifteen months. The only reason we used it that long, was we started the [bubble] oxygenator in May of '55, and it seemed to be working very well. This was a very radical thing, you remember. "Bubbles" was the worse thing you could say to a surgeon. "Bubbles." So we were using the bubble oxygenator on the easier cases, and I remember we were reserving cross-circulation for the really high risk, complicated cases. The last patient I used it on was a boy from Paris, whose father was a famous explorer, Paul Victor. He had a very high pressure VSD [Ventricular Septal Defect], and, fortunately, it went beautifully. His mother was the donor. That was July of '55. [Richard DeWall invented the bubble disposable oxygenator.]

EB: One of the questions, when I talked about that to young people, I think they were fifth graders, and I said they used either the mother or the father. They asked, well, could it be an older brother or sister?

CWL: Sure. Matter of fact, we did forty-five cross-circulations and six—put it another way to start out. In a natural family birth, the child, all the children, at least, will be blood-compatible with one or sometimes both parents. Adopted children, of course, you wouldn't have that. In six patients that needed an operation, in a couple of them the only parent that was compatible had some history of heart disease, and even though the donor wasn't very much a strain, we didn't want to tempt fate. But two or three, apparently they were not legitimate children. [Laughter] We didn't raise a problem with the parents, but we could tell from the blood type that neither one was the parent.

DR: Were those cross-circulation operations conducted here in this room?

CWL: Yes, [operating room] J. I think all of them were here. Let's see, first or second or third might have been in the old part, but I'd have to look that up, but the vast majority were in this new building.

DR: Can you tell us a little bit about that?

CWL: Well, I spent hundreds, maybe thousands, of hours here, and Earl has spent at least hundreds of hours in this room.

EB: Yes, I had my locker, surgical locker, here. It's more than I had at Medtronic.

CWL: At first glance, it doesn't look at all familiar, with the play things around and the equipment for the children's rehab, but as you look around, obviously, it was an operating room. The old operating table they've left there for sentimental reasons, the tile floors, things like that, and the layout. As you look at it carefully, they've put in some extra walls here, which changes the outward appearance. But, no, it looks very familiar.

One thing that we used to have, which was considered quite an advanced feature at the time when this hospital was built, was a dome in the operating room roof. It was glass, of course, and sealed, but it was quite low, and the visitors could see quite well into the operative field. Trained surgeons like to stand right behind the other surgeon and ask them questions and so on, so they weren't very enthused. But for many groups of people, and schoolchildren, even, more advanced schoolchildren, this dome served a very worthy and effective purpose for demonstrating heart surgery. Since it was sealed off, they didn't have the fear of being—some people didn't like to be in a real operating room, they felt they wouldn't be compatible with the sight of blood and things like that. There was an intercom that you talk back and forth.

DR: Earl, what are your memories of this room?

EB: Like I said before, my memories are being in here with the Sanborn equipment, and particularly when there was a human patient, a human oxygenator, a mother or father, and the risk of losing one or both, it was so important to keep the monitoring equipment and the recording equipment working well and accurately. I remember we used to accumulate rolls and rolls of paper. I don't know what they ever did with it, but, of course, they wanted to study.

CWL: We stored it for a while, but it got out of hand.

EB: The systems then weren't available to tape record it or anything at the time you were doing it; it was just the paper recording.

CWL: I might say, the forty-five cross-circulations, were an extremely important event in open-heart surgery, because these patients survived in a very high percent when you had cross-circulation. Previous attempts with an artificial heart, they had all died. So the belief throughout the profession, throughout the world, at that time, for those working in this field was that the problem was not the oxygenator. It was a sick human heart, because these early patients, most of them children, babies, many of them, were extremely sick and this was sort of a last resort to open their heart and fix the problem. Of those forty-five cross-circulations, I'm happy to say, there was no donor mortality or deaths.

EB: How did you have the courage to go ahead with these pioneering-type experiments?

CWL: As I think, when I look back, that was part of the Wangensteen training system. We don't probably have time to go in to the chief of surgery from 1932 until 1967, Owen Wangensteen, but he was a unique person in many regards. One [aspect of his] uniqueness was his training system. He had a great faith in research, animal or other types of laboratory research. He felt that the results of his research gave the young investigator the courage to challenge accepted beliefs and go forward, which you would not have had, as I look back, as a young surgical resident. That's why many of the great universities didn't produce much in the way of innovative research, because they were so steeped in tradition. Wangensteen had a wide-open mind. If research showed some value, then you should pursue it.

EB: When he was alive, he worked with us quite a bit on the library, with his library and our library, the Bakken.

CWL: Historical—

EB: Well, you know that, it's the Wangensteen Library [at the University of Minnesota—Twin Cities]. Now that our museum is all torn up [being renovated], I guess one of our librarians is working here in the Wangensteen Library.

CWL: Why is your museum torn up, are you revising it?

EB: Well, we're adding a big addition to it, so that we can have laboratories and classrooms and more exhibition space, but mainly our thing is to be mentoring some young people before they come over here and get in the MD/Ph.D. program. Give them some hands-on, and try to teach them a little bit of your kind of philosophy that I call, "ready, fire, aim." You got to do something before you can find out how it affects the problems that might come out. But we're starting mentoring, even without the building.

But to put this big addition on, we had to close it up and put all the exhibits in storage, or put all the books and stuff in storage. But we'll be open again next September or October a year from now. It will give us a lot more functioning [space], and [help us] do a lot more for young people.

CWL: The reason that the cross-circulation, the circulation between the patient and a mother or father was so important, as we look back and we appreciated at the time, when you subject a patient that's in severe heart failure to a big operation, opening the chest, and in this case, opening the heart and stitching and all of the things that you do, you create a number of metabolic derangements both in the bloodstream, in the liver, the kidneys, and the lungs. We knew virtually nothing about those at that time, and that's the reason that the early patients all died with the heart/lung machine.

They blamed the patient, and it seemed so logical to blame the patient because these patients were at death's door. But cross-circulation, the patient came off of their connection to the donor with normal pH, electrolytes, passive, all of the things that we learned later were so important to the heart function, and they recovered with this surprisingly high percentage. So that changed the whole outlook. We didn't ever expect to use cross-circulation for any length of time, but just a matter of, with that knowledge, that these operations were possible in a sick patient, to go back and look at what we were using for a heart/lung machine.

All these heart/lung machines in the early days were all developed in the dog lab, working on dogs, and the thought was, the dog had a normal heart, so the heart/lung machine worked pretty good. Then when you took the same heart/lung machine into the operating room and all the patients died, obviously it was the patient, as the belief was. So that was the important thing that had to be appreciated. We appreciated it very quickly, and, of course, as we were doing the work, but the knowledge spread rapidly throughout the world.

EB: When I talk about your early work, that you were interested in saving patients that were going to die and to do something for them to try to give them life, whereas today the FDA [Food and Drug Administration] won't let you do those sorts of things, they just want to kill people, let them die. I saw a paper recently where the FDA has killed over 100,000 people in the last couple of years by delaying—

CWL: I'll tell you the author of that, William Cothe, who's the inventor of the artificial kidney, so he's been around a number of years. He wrote in one of our important journals, the *ASAIO Journal* [American Society for Artificial Internal Organs,] I think it was last November, I think he said 97,000 patients per year were killed by the FDA. That's no surprise to us, trying to work with the FDA. They were set out to protect the patients against abuses, but they've turned out to be the abuser, and it has to be changed. So many important problems that will require an act of Congress, so many important problems involving Congress these days, that it doesn't look like any early change is in the—

EB: Back in those days, of course, the FDA didn't have control of devices; that wasn't until 1975. I remember being at some conference out in Washington where a person from the FDA spoke of what they were going to do when they got control of these companies that were foisting these useless products on unknowing elderly people. I was almost a teetotaler before that, but that's the night I went out and got totally stoned on Black Russians. [Laughter] I pictured the war of the future.

CWL: Well, you were probably prescient, because we didn't know in the early days what a problem the FDA was going to develop into.

EB: Well, I recognized it that night, and it was worse than I anticipated.

CWL: Well, we don't want to get too involved in that. The sad thing about the FDA is that, in the first place, the abuses were not very common back in those early days. I was right in the middle of all this work, as you were, and there were very few. There were some, obviously, and there's some now with the FDA, but it didn't require a draconian act, which as I said, was designed to protect patients against abuses. You can't be against that.

EB: No.

CWL: What it's turned out to be is protect them against progress.

EB: Yes. Today you've got to have lawyers make the decision of what's right or wrong, not doctors. The government now is paying hospitals not to train doctors, and it's like the lawyers just want to do away with doctors and take over the whole system.

CWL: Well, we're here to discuss, I guess, pacemakers, but I agree with all that. It's pretty easy to get discouraged about some of these difficulties that are imposed. One of the last things I want to say about the FDA, it takes millions of dollars and years of time to get a new device on the market, so a person working in their garage, like Earl did in the early days, couldn't possibly finance [an innovation now].

EB: Well, there's an interesting story about that, to carry on on that theme. When we first made the first implantable pacemakers, we coated them with a silicone covering, and we got that silicone from Dow Corning. That had been developed during World War II for helping repair soldiers that were injured.

Someone at Dow Corning went to the FDA, because they were supplying liquid-type chemicals for medical purposes, and so they were closely working with the FDA. They went to the FDA and asked, "When Medtronic puts this silicone on these pacemakers and supplies them, is that a drug or a device?" [They asked] because they didn't have control of devices. The FDA came back, "Well, obviously it's a drug and Medtronic will have to go through a new drug application to sell those pacemakers."

Well, of course, as you've said, we couldn't have put the millions of dollars into an NDA [New Drug Application] at that time. So we went to Washington and talked to Hubert Humphrey, our senator at the time, and we got a letter back a few weeks later from the FDA that they had reconsidered and, indeed, it was not a drug, but a device, and we could go ahead and market them. Otherwise, we never would have gotten started.

CWL: That's interesting. I'd never heard that. But in the early days you could exert some influence, now you couldn't possibly do that, if you had the President or the Supreme Court calling the FDA, they would be just—

EB: Yes.

DR: That was a very different situation in the late fifties when you two first met. I wonder if you remember when you first met and how that came about.

CWL: Well, I first met Earl Bakken because he appeared one day and the supervisor of the operating rooms suites introduced me to him. It was her response to some vigorous, vociferous complaints of longstanding—I think six months or more—we started open-heart surgery with a heart/lung machine, then the bubble oxygenator, in '54. This was some time in late '54, or early '55, that Earl appeared.

My problems were in the operating rooms here. Once you started anesthesia, there were a dozen pumps and suction machines and special lights with sixty-cycle interference, and so electrocardiogram was a very important aid that sat beside the patient, that we could get strips off of the heart rhythm.

In those days, diagnosis was quite primitive, as was the surgery, so frequently the preoperative diagnosis was not correct, so the electrocardiogram was very important. Another device that was in the operating room, sitting beside the patient, was a Sanborn pressure recorder, because you put needles in various chambers to ascertain what the pressure was, and that would give you, many times, the answer to your diagnostic uncertainty.

I think Mr. Bakken—maybe Earl can say a few words. I think he was selected by Mrs. Sholtice because he was an expert in marketing the Sanborn pressure recorders, and he was willing to come in the operating room. Laypeople, some people around our laboratory, or workers, that were knowledgeable about some of this equipment, but they wouldn't come in the operating room when an operation was in progress.

DR: So many people wouldn't come into the operating room to work on the electrical equipment.

CWL: For example, electrical experts in the hospital, electricians, absolutely refused to come in the operating room when an operation was in progress. They said it was not part of their contract. Aside from that, it's understandable, they were laymen, they were frightened by it.

EB: Yes. In that time, too, the engineers knew very little about electronics, and so they were just scared to tackle anything electronic. Remember, this was just after World War II, and the electronic devices were just starting to move into laboratories and then into operating rooms and other areas. They were all vacuum tubes, and so they didn't know anything about those kinds of things. Now all hospitals have people that are bioengineers and can tackle electronic equipment.

CWL: My request to Mrs. Sholtice repeatedly was—her first name was Jenner—"Jenner, we need someone that can come into the operating room and be there when we need them." So Earl Bakken was that first and last person, as far as I was concerned. He was there for all the time that I was working here, and he'd come over for the operation, he knew the schedule, they'd telephone him, I guess. He came over for every open-heart operation. He was here at the beginning and stayed until the end, and back and forth out of the room, in the room, whatever necessary, and was a great help.

DR: I guess the sight of blood didn't bother you, Earl?

EB: Well, I had gotten over it long before then with spending time in the animal lab and working on the dogs, eating lunch over an open animal. It used to be very interesting down in the animal labs here with all the barking. Pretty interesting years, when you look back on them. I wish I had known more what pioneering work was going on that I was being a part of. I'm proud now to have been a small part of it.

CWL: I think a relatively large part, as it turns out.

DR: Can you touch on your background in electronics, how you got into electronics and medical electronics?

EB: Yes. Well, of course, I went from high school into the service, but I had a first-class radio telephone license that I obtained on my own study.

CWL: In the service, were you in a category where you were working in this field?

EB: Yes, I went into the Signal Corps to get into communications, radio communications. But then I was transferred to—well, before when I enlisted in the Signal Corps, they sent us to pre-radar here in town, at East High School. For a three-month course in electrical engineering, so in ninety days we came out as electrical engineers. It was interesting, when I came back and went three years, I did the same stuff I had already done when I was in the senior year, and I did it again.

DR: At the University of Minnesota?

EB: Yes.

CWL: Some of those crash courses that we did have in the army, hundreds of them, thousands of them, probably. Some of them were pretty good.

EB: Yes. In the service, I was in airborne radar, repairing airborne radar, and so it was all electronic, and I got to know all the things in electronics that came then into colorimeters and flame photometers and EKG [electrocardiogram] machines. When I first started repairing EKG machines, they were all the photographic-type units, and then the first direct writers, and then the two-channel machines, and then the four-channel machines, which we had here.

CWL: The machines were very susceptible to sixty-cycle interference, because they weren't made to be in a room with a lot of sixty-cycle—

EB: The pressures had to be very carefully calibrated.

CWL: I'm not certain, were you an engineer when you went in the army?

EB: No.

CWL: Were you undergraduate?

EB: No, I came back and went through the University in three years. Then I started coming over here.

CWL: So it's interesting, you were not an engineer.

EB: No. But I was an engineer, of course, when I got into graduate school, started graduate school, just barely; a good "B" student. But then I started spending time over here at the hospital, particularly first in the clinical lab, because my wife was a med tech, and then in the EKG department, over in the heart hospital. Then into selling Sanborn equipment, and that's where we got acquainted with the anesthesiologists and Mrs. Sholtice. We had set up a contract of some sort for servicing.

CWL: Yes, you had a service contract with the Sanborns, I know that.

EB: Yes.

DR: Who's Mrs. Sholtice?

CWL: She was the supervisor of this whole suite, a very important job.

EB: You didn't get to see Lillehei or people unless you went through her. [Laughter]

CWL: For many years she was the supervisor of all of the—I think there were ten or twelve operating rooms in this suite, and there was several hundred nurses. She had to deal with the doctors, which was always difficult, I'm sure. We were always complaining about lack of something, or we wanted something changed, and she did a marvelous job, as a matter of fact. She's still alive, I just found out. I haven't communicated with her for about ten or more years. I've got her address, I don't have a phone number. I hope she's coherent and able to talk.

EB: Yes, she somehow trusted me. I had open access—I could come anyplace in surgery, or in the recovery rooms.

CWL: Not one of those complicated badges that they have now.

EB: Yes.

DR: You had your own locker with the surgeons.

EB: Yes, I had my locker. I spent a lot of time with the surgeons, and the young surgeons down in the animal labs, Vincent Gott and just the whole series.

CWL: Dick DeWall.

EB: Dick DeWall.

CWL: That was one of my successors. I won't try to name them now, I guess.

EB: Those "insignificant" residents that all became heads of surgery around the world.

CWL: Perhaps we should get to the point. You've got the background where Earl and I were well acquainted, because we used to sit right out here in the hall on the litter sometimes, waiting for the patient to get to sleep with the anesthesiologist and get all the drapes, just talking about affairs of the day and things like that, as well as, I think, we may have talked some science.

EB: Yes.

CWL: One of the early complications of open-heart surgery was—in the first place, I should say for the film, the first successful open-heart surgery in the world was done here at the University of Minnesota. In 1952, my classmate, Dr. John Lewis, close friend, we were army buddies for four years and close friends socially, came back from the war, as I did, and started training in Wangensteen's department. We were both interested in open-heart surgery, and he was impressed by a very simple method described by a surgeon in Canada called William Bigelow, of lowering the body temperature. First Bigelow's work was all in animals.

For each seven degrees you lower the body temperature, seven degrees Centigrade, about ten degrees Fahrenheit, you double the time the brain can go without oxygen. Normally, the brain can go without oxygen for four minutes, so when you take the temperature down from thirty-seven—which is normal body temperature—Centigrade, to thirty, you double that to eight minutes. Well, eight minutes is bordering on maybe you could do something in the heart, but if you go another five degrees centigrade, down to twenty-five, you double the eight to sixteen. That's pretty good for a simple hole.

Now, there were some problems with hypothermia. You couldn't go colder than twenty-five, about, Centigrade, because a cold heart could not be restored to a beating rhythm with a shock, you understand, defibrillator in the room. So you could not gain much more than fifteen or sixteen minutes to work in the heart. But fifteen minutes was ample time to do what Dr. Lewis did for the first time on September 2, 1952, he closed a hole about the size of a fifty-cent-piece in the upper chamber of a seven- or eight-year-old girl that was in severe failure with a birth defect, of course. The hole between the upper chambers, we call an atrial secundum-type defect. It only took about seven minutes, and the whole operation took only fifty-eight minutes.

So after the extensive experience in dogs that he had had, which was part of the Wangensteen training system, incidentally, he had the confidence to go ahead. Bigelow, who had described this technique in animals, never went ahead in humans until later, for reasons that—

EB: An engineer by the name of Jack Hopps, in Canada, they wanted a pacemaker to keep the hearts beating better during the cooling procedure, and Jack Hopps made an external pacemaker by a wire into the heart of the animal. Of course, they did postulate that it might sometime be used on humans. But they just stimulated the atrium, they didn't stimulate the ventricle. [John] Callahan, who was the surgeon involved, said if they had pushed the wire two more inches, they would have been famous, but they ended up just stimulating the atrium. But Hopps, now, himself, is still alive and has a Medtronic pacemaker in him. So it's kind of come full circle that way.

CWL: I had the opportunity of helping John Lewis, as did Dick Varco, another surgeon that figured prominently in these early days, on that first case. It went smoothly, of course, and that engendered great enthusiasm locally, but word spread rapidly around the world. Atrial septal defects, beginning in 1952, started to be performed here regularly, two or three a week, at least. But the minute you tried to use this technique for anything in the lower chambers, the ventricles, they all died. Even the ostium primum-type atrial defect, which is low down near the ventricles, they all died.

So it was great for atrial secundum defects and congenital valvular lesions in the pulmonary and aortic valves. But it was very apparent that we were going to confirm—reconfirmed, I should say—the fact that those of us who were dreaming of open-heart surgery, and there were not a lot, but there were various groups around the country and around the world, thinking and trying to work on this problem, reconfirmed the need that you were going to need cardiopulmonary bypass, some kind of an artificial heart/lung to get more time.

The first artificial heart/lung operation in humans was done here at the University of

Minnesota in 1951, not in this operating room, because it wasn't built yet, but in the old operating room in the University hospital, by Dr. Clarence Dennis, who was a member of the Department of Surgery here. He had started working on a heart/lung machine during the war, but he didn't have much time. He was not in the service, as he was here, until the war was over and then he expanded that program. By 1951, the experience in the dog lab with his machine was quite good, fifty percent of the dogs would survive a thirty-minute period, which in those days was thought pretty good.

So he applied it in two patients in April and May of 1951, the heart/lung machine, and both died in the operating room for reasons that would be apparent now. But his heart/lung machine was very complicated. It was a film-type oxygenator, and it weighed about a thousand pounds, and would fill a one-car garage with the pumps and the elaborate system you need to oxygenate blood by filming it. That was part of the problem, of course, as we knew later.

But at that time then he was due to move to New York to become chairman of the Department of Surgery at [SUNY] Downstate [Medical Center] in July of 1951, so he did not do any more patients here. Well, I was not part of his team, but I was in the operating room, barely in it, because there was a large number of people, and I could hear some of the problems that were going on.

I was convinced, by that and other experiences, that we must develop some simple method of oxygenating the blood. Pumps were no problem; you could pump blood quite easily in those days, as we do now. But the purification of the blood, getting the carbon dioxide out, the oxygen in, everybody that was working on it in the world agreed—and it was very few things that they all agreed on—but they all agreed on that you had to have a film-type oxygenator, or maybe a membrane.

You mentioned bubbles. We went into convulsions, because it was well known, for all of us, that a small amount of air in that circulatory system, maybe you can visualize a 10 cc syringe, if you fill that with air and inject it into the right atrium, you would probably not kill the patient necessarily, but he will be brain-damaged, go into convulsions and things. So a small amount of air in the brain is disastrous. So nobody felt that you could oxygenate blood by bubbles.

The reason I was attracted to bubbles is it was so simple, you could just take a plastic column of venous blood and put four or five hypodermic needles in the bottom and run oxygen through the needles, the bubbles would go up, and instantaneously the surface area of all these bubbles was—it was an instantaneous and rapid effective exchange of oxygen and CO_2 [carbon dioxide.] The question is, how to get those bubbles out.

Well, when we're doing cross-circulation, one of the things, early on, there was four of us in the team, myself, Dr. Varco and two residents in surgery, Dr. Morley Cohen from

Canada, and Dr. Herbert Warden, who was originally from California, and they had worked the cross-circulation out very well in over a hundred dogs, so they had the courage to go ahead and they felt that it could be done safely. Everybody else was failing with their heart/lung machines, because they thought that the problem was the patient. With the cross-circulation, we knew it wasn't.

But during those cross-circulation operations, I had hired a young surgical resident, Richard DeWall, to help run the pump and then work in the laboratory downstairs here in the research labs during the days that we weren't in the operating room. Because the pump was quite simple, but if you were part of our team, you were sterile and you couldn't make any adjustments.

The first few cases we relied on the anesthesiologist to make the adjustments, faster, slower, whatever. But they soon learned that during the time that the patient was on heart/lung machine, they were no great use, so they used to go out and get coffee and then there was nobody around. So Dick DeWall supplied that help. He was an extremely clever fellow. He was not a brilliant student. It's interesting, great ideas don't always arise in correlation with brilliant achievements in the classroom.

So I told Dick we needed a simple oxygenator, each sterilizable, disposable, and the only way we could do that was a bubble oxygenator. I showed him experiments we'd done earlier, how to oxygenate the blood. I said, "You need to work out a method to get the bubbles out." Within three months, he had a spiral helix de-bubbling arrangement that was working extremely well in dogs. It was working so well in dogs, and this now was very simple, just a couple links of plastic polyvinyl tube, an upright, slanted in a circular helix. Very inexpensive, heat-sterilizable, so you could autoclave it. The earlier oxygenators they could not autoclave, which was a real problem, but patients didn't live anyway, I guess, so infection was not a problem with those, as it would have been if they had lived. Very effective, this oxygenator. That was the origin of the bubble oxygenator.

DR: Did you use that on the so-called "blue babies" that were operated on?

CWL: Yes. We started using the DeWall bubble oxygenator of May of '55, and we were still using, as I said earlier, I don't know whether it was on the film, for the very technically complicated cases, our reliable cross-circulation. But for the easier cases, we started with the bubble oxygenator. It worked so well, by July of '55, the bubble oxygenator displaced cross-circulation.

The extremely effective way that the DeWall—very simple, I won't go into detail, because really the helix depended on gravity to separate the bubble-containing blood from the bubble-free blood, which is very predictable and simple. That spread rapidly, of course, around the world, and the bubble oxygenator displaced these cumbersome film oxygenators completely.

DR: So that allowed you then to work on a broad range of patients, including these blue babies with heart defects, and that's when you encountered the post-surgical problems with the electrical system, and that's how you two sort of came together, isn't it?

CWL: Yes. To fill that in a little bit, even with the cross-circulation, we had unexpected complication of this so-called heart block. Nobody knew much about heart block in those days. Even the so-called experts thought it was a very rare condition, only occurred occasionally in newborn babies that often didn't live very long, or was a terminal event in severe heart failure in adults. Just prior to death, the heart would become dissociated and have this block rhythm.

But one or two pathologists had predicted, one of them, Dr. Lev, expert pathologist in these things in Chicago at that time, told me, "Walt, if you're going to be working inside the heart, you're going to have a problem with heart block."

I said, "What's that?"

He explained it all. I'll elaborate a little; I don't think it requires a lot of knowledge. The heart has a nervous system, intrinsic, in itself. Most people don't realize that, because you can't see the nerves—they're not visible by eye—that is absolutely essential to its coordinated beat. If you disturb that intrinsic mechanism seriously, as we did in some of the repairs with stitching and cutting inside the area of the ventricle where this conduction system runs, you get heart block, and heart block is not compatible with life. That was the bad news; he predicted that, and it occurred.

The good news was that it only occurred in ten percent of our ventricular defects, it didn't occur in the atrial defects, because you were not near the important part of the conduction system. But ten percent of the ventricular defect closures, the blue babies, isolated ventricular defects in the so-called ostium primum developed heart block. In the first seventy cases we had seven heart blocks.

There was no treatment, except people said give adrenalin. Well, adrenalin would speed up the heart, but a little bit of adrenalin, a little overdose, the heart would be going 200, 250 [beats per minute], and you'd shut it down, and the heart would go to 50 or 40 or 30 or stop. Adrenalin didn't work, we couldn't keep them alive for any length of time. So all of those seven died, and that was a devastating complication to us.

That's when the crash program began in the dog lab on some means of treating the heart block. We tried a number of drugs, and one drug, in '55, had just come on the market, called Isuprel, it was used to treat asthma. It was a derivative of epinephrine, I think isoproterenol was the chemical formula, but the trade name as Isuprel. That had the effect of expanding the bronchi, which was very important in asthmatic patients, and did not cause the extreme elevation of blood pressure that epinephrine and ephedrine-type drugs did. But the side effect of Isuprel, which the people using it considering a complication, was it speeded up the heart. When we heard that, we said, "That's a drug we can possibly use." Doesn't affect the blood pressure, dilates the bronchi, that's all right, that's a tolerable side effect.

So with Isuprel we managed to save the next group of patients, I think fifty-five percent lived, the next thirteen patients with Isuprel. But that was still almost a forty-odd-percent mortality. We used electrical stimulation on those early patients by virtue of a paper that [Paul] Zoll, in Boston, had written a paper that you could start a heart sometimes in a patient, whether it was dead or asystolic, without a heartbeat, by putting paddles on the chest and stimulating them with current, and it took 50 to 75 volts of current to stimulate the heart. We tried that on some of our heart block patients, and, sure enough, it stimulated the heart, but the amount of voltage required on the skin, these paddles, even though we taped them securely in place, was painful, number one; fifty or seventy shocks a minute was not very tolerable. The first thing you know, under the paddles you had burns, the burns got blisters and infections, so that was totally not effective.

We used to have conferences in this hospital, lots of conferences about patient outcomes, because you learn from your mistakes better than you learn from your accomplishments. One day we were in our Saturday morning conference discussing an infant that we had operated on—this would have been '55—who had died of heart block. The physiology people used to attend these, because Wangensteen had arranged them and had good relationships with physiology, admired the chief there, [Maurice] Visscher, and personally I spent, myself, in my training, almost two years in physiology.

He suggested, "We have an instrument in our laboratory (and I had known and I've seen it) for teaching students, called a Grass physiological stimulator." Grass was the name of a physiologist. G-R-A-S-S, just like the green grass, that's how it got its name. But it was a little instrument, like a small typewriter with a number of dials, you could adjust the amplitude of the current or the frequency of the current, but it had to be plugged into the wall; 110 volts was the source of the current. The transformers inside change it to whatever you wanted. We were using, well, as it turned out to stimulate, he said one of our student sessions is stimulating the hearts of frogs and so on and it takes only one or two volts.

Well, that was a revelation, it clicked, at least in my head, and Vincent Gott, he went over and borrowed a Grass physiological stimulator, and I think this was on a Saturday. You could easily create heart block in a dog. It's a marvelous animal to work with for many reasons, but this heart block work would have been impossible without the dog. You could easily create heart block, chronic heart block, in a dog. This dog heart would respond to one or two volts, ten or fifteen milliamps, I guess, of current drives it precisely and without problem to whatever rate that you set your pulse generator, your stimulating unit.

I think Vincent Gott was in charge of the research lab and my research lab, he did probably, I don't know how many dogs with this stimulator, the Grass physiological stimulator. Of course, I was well aware of what was going on. The next patient I had in the operating room had a heart block, and I asked them to telephone Dr. Gott to bring over the Grass physiological stimulator and we called it a myocardial—

[Tape interruption]

We sent it back one time. Periodically they needed servicing.

EB: I remember how we were criticized for calibrating the output in milliamps rather than volts. People said, "Who do you think you are, God? Changing the—"

CWL: You never got that from me, because milliamps, volts, what's the difference?

EB: No, I didn't get it from you, but I mean—

CWL: Most doctors didn't understand milliamps.

EB: The other machines, the Zoll and Morris, they were all calibrated in volts. But, to me, what you actually want to measure is current density, but you can't get that easily, so I just calibrated them in current.

DR: You were talking earlier about direct myocardial stimulation of the heart and that's what led eventually to your collaboration on the pacemaker. I wonder if you could tell us how that came about.

CWL: Well, I can continue with, you know, turn it over to Earl. The story, the revelation that a direct connection with a wire, called it, dignified it by electrode, it was just a piece of wire, didn't even have to be copper, it could be silver, whatever.

EB: Most were Teflon-coated suture wire, stainless steel suture wire.

CWL: Could drive the ventricles very accurately at any rate that you wanted, with a very small amount of current. This was entirely imperceptible to the dogs originally as we studied it, and then to the humans. It was only a couple of volts, varied a little because of the resistance and the connection, and it provided an ideal solution, so to speak, at that time for keeping the patients alive with heart block. If they kept them alive with stimulation, we found that in the first month, 89 percent reverted back to sinus rhythm. It was great. For those that didn't revert, that was still another problem that wasn't solved until we got the implantable one.

But to go back to my story, we treated about eighteen or twenty patients with the Grass physiological stimulator. It's not here, but it was a box—well, small typewriter, and it would be plugged into the 110 voltage, and the patient in heart block couldn't go for any time at all without stimulation, so they couldn't go down to X-ray, they couldn't go to the lab, unless you strung a wire.

EB: We used to run extension cords down the hall and pull one out at one end and plug another one in the other end to keep it going.

CWL: So it was lifesaving, but very cumbersome. At that time, as I said, the first patient with the wire in the heart was January 20, 1957. By probably April, or maybe even earlier, I said, "We've got to get some pacemaker (pulse-generator is another word for pacemaker) that's battery-driven."

EB: We had the major power failure here, where the electricity was off in the hospitals for three to four hours, and some of the patients got in trouble.

CWL: I don't think any died, but they got in trouble, all right.

EB: Some of them were supported with Isuprel.

CWL: Isuprel and [unclear].

EB: But following that, Lillehei came to me and said, "Isn't there some way we can have a battery backup to keep these going during a power failure and to move them easier?"

CWL: Well, part of the story that fits in with some of the film taken today. We had students that were in other fields, engineering, physics and even medicine, working in our dog lab, not as researchers, that's one group, but in the dog lab just to clean up and to take care of the dogs and feed them and so on. One of those was a physics student that I had known, he had a degree, he graduated four years in physics with an electrical major, and his name was Robert Bruss. I said, "Bob, we've got this great treatment and we need some kind of a battery-driven pulse generator that the patient could just wear like a holster. The current required is very minimal. Can you do that?"

He said, "Sure. Sure, I can do that."

So April, May, June, July, I'd periodically catch him. He lived in a rooming house and didn't have a phone, and was always hard to get a hold of. I'd come down to the lab sometime and talk to him and he got it all done, he said, in his head, the plans and so on. The companies were on strike and things were slow.

Finally, about December, I was exasperated because we didn't have any wearable pulse generator. I left word in all of his rooming houses and his haunts where he was known to pick up messages, to meet me the first day after Christmas. "I'll be up in the operating room and see me between the first and second case," because I wanted to go over the plans. He turned up between the first and second case in this operating room J here, that was down at the end where we said the dictating room was. We were talking in there, and I realized that he really hadn't done anything, at least nothing tangible. I said, "Bob, you're fired from this project. Forget it."

Just as I talked to him, was firing him, Earl came walking around the corner to go down to room J, because we were doing a case, an open heart. I'd done a small case beforehand and then the open heart. As I walked down the hall with him—he knew that were treating these heart blocks with this physiological stimulator, because he was around all the time—I told him, "We need a wearable battery-driven unit, and I've just talked to somebody who has been working on it for several months, four, five, six months, no progress. Can you do that?"

He said, "Yes."

I said, "Fine."

I think the next day or maybe the same day, Vincent Gott, who was our chief doctor in the research laboratory at that time, took Earl down to the laboratory. Well, you can take on from there.

EB: Yes. When Walt asked for a battery backup on the pacemaker my first vision was, well, we had these pacemakers on large carts, because they were rather large units. Even the Grass was fairly large. I envisioned doing something real quickly by putting an automobile battery down on the shelf below and an invertor to supply the 110 volts to run the pacemaker, and then having a battery charger there. That way, if the power failed, you could move the patient to a place where there was current, emergency current.

So I went back to the garage to really just go out and buy the pieces and put that together, because they were all available. But that was 1957, and it was just after World War II, and during 1955 the transistors had come into play. They weren't used commercially yet to any extent, but they were available for home projects. So, as Walt said, we had determined you needed just a couple of volts to trigger the heart, so why go through a cartful of apparatus to get a little pulse of electricity.

That's when I looked up a circuit for a metronome in *Popular Electronics* magazine of that time. One of the home projects in there was to build a little box that would put clicks on a loudspeaker, the way a metronome sets clicks for timing music. [Demonstrates mechanical metronome.] It's interesting that a metronome has the same rate range as a normal heart. You can adjust it from 50 up to 100 or 150 or so pulses per minute. [Picks up prototype of Medtronic 5800, the first wearable pacemaker.]

So I plagiarized that circuit, in effect, modified it a little bit so it would be a one-millisecond pulse, and put it in a little box with a nine-volt photo-flash battery and a little neon bulb to show you if it was pulsing, and brought it over to the University, with Vince Gott. We tried it one day on a dog in the animal lab. I hadn't necessarily built this to be used on humans, but the next day I came over to the University and this was attached to a little child. I asked Walt about it and he said, well, he wasn't going to risk another power failure and losing a child to that when there was a problem.

CWL: Theoretically and practically, it was such an advance.

EB: So this was subsequently used on several children. It was a problem, because the knobs could be changed by the children. So when they would attach it to a child, they would cover it with tape to be sure that it didn't change its settings. It worked fine, except that it was not technically or not humanly oriented as to be properly used.

CWL: It was the dog model, we called it.

EB: We found, though, using this, starting to use it in the operating room, when the child was in the operating room, that cautery would set it off, start it running too fast, so we had to also shield the internal workings of the pacemaker.[Picks up one of the first clinical commercial models of the Medtronic 5800 pacemaker.] So we went on to, this is one of the very first ones we produced to actually sort of a commercial status at the University of Minnesota.

CWL: This is the first human model.

EB: Human model, okay. [Laughs] We recessed the knobs so that the little children couldn't get in there and turn the knobs, and made it difficult to turn on and off so that they couldn't accidentally do that.

CWL: You get these handmade knobs, Mr. Bakken made those, I think.

EB: These [refers to handles] were taken off of Sanborn electrocardiograph machines, so it was pretty crude, but it was more shielded, so it wouldn't run away during use of cautery. But it was black, which was not really appropriate for a hospital setting, so we went on to the white case, which is about the way most of them are made today. [Picks up a white Medtronic 5800 pacemaker.]

We were criticized quite a bit in those days for calibrating the output in milliamps, rather than volts, because everyone had been used to in dealing with the larger external pacemakers, of always using the term output in terms of volts.

But this was an interesting problem with this neon light, it took more current to flash the neon light than it did to run the pulse generator for stimulating a patient. I remember getting a call once from a nurse here at night, from the University, and she said, "The pacemaker is not working, it's not flashing."

I said, "What about the patient's pulse?"

She said, "Well, the pulse seems to be pretty near the setting on the pacemaker."

So I tried in the next days to figure out what that problem was, and I would take these pacemakers into a dark room, and, sure enough, they would appear to stop flashing. I said, is this an optical illusion or what is it? I finally discovered the neon light has to have ambient light shining on it to trigger it at a low level.

CWL: I didn't know that.

EB: So I just told the nurse, "Shine a flashlight on it and it will start pulsing." So that was an early solution to one of those nasty problems.

CWL: So beginning with this, this was the first Medtronic pacemaker developed for dogs, but used in humans and the subsequent models, and I think we wrote a paper—I wrote a paper with Earl in 1958. This started in April. Medtronic pacemakers started in April of '58, that's the first time we got that and we had done sixty-six by that time with these units, and the results were dramatically successful. Of course, other surgeons around the world were working on open-heart surgery.

EB: They said they never had heart block, but they started buying pacemakers. [Laughter]

CWL: [Laughter] That was an old joke that Earl and I had. Nobody had heart block, but I said, "Let me see. Were you shaping these—" Anyway, they did have heart block, and this was a dramatic improvement in the results. Also, I must say that we learned as we went on, good judgment comes from experience, I guess, and experience comes from bad judgment, how to put the stitches better to avoid heart block. But even today, occasionally, with all the knowledge that's accumulated, surgeons still get heart block. So you can reduce the incidence as compared to the early days, but the treatment was the saving grace for reducing the mortality and improvement of results.

EB: At that time at Medtronic we worked on producing a conduction system locator, a little tool with a probe. We worked on this with a surgeon who ended up in Milwaukee.

CWL: Lepley?

EB: Lepley. But it took too much time.

CWL: Yes, it didn't work very well, we tried it.

EB: It wasn't perfect, but it was pretty good, but it took so much extra time that it didn't turn out to be real practical.

CWL: I think I said earlier, the conduction system of the heart, these nerves are extremely important, but they're not visible to the eye. You know approximately where they're going to run, but you can't look carefully and avoid them. You have to know the anatomy and then with a little bit of luck, because they don't all—particularly in abnormal hearts, they don't all run where the previous studies have said they were going to run. So there was a vast amount of learning to go in to that early treatment of heart block. But the next step, Earl, I think, can take over here, is this unit. [Refers to white Medtronic 5800 unit.]

EB: Well, in '58, a doctor in St. Paul, Sam Hunter, started using these on Stokes-Adams patients, older patients that developed heart block as a result of disease, and not as a post-surgical procedure. So for the next few years up to about '62, we sold several thousand of these to be used permanently with the wires going in through the chest. You'd have to open the chest and connect the wires. There's a thousand stories of people wearing these, some of them getting into problems.

We had a little old lady who went in swimming with one in the salt water, and she fortunately had enough heart rate to keep her going. We had this veteran from the VA [Veterans Administration] Hospital out here who would go be released each weekend and he'd go up to northern Minnesota where they went square-dancing, and he would invariably break his wire, and then I'd get called to solder it together on Monday morning.

But it was working, and we showed that you could extend people's lives in an older heart-block patient. If you don't use pacing, 50 percent will die each year. With it, you find that their life expectancy is returned essentially to normal for anyone of that age. But it was cumbersome and you had to change the battery every thirty days, so several groups started working on making the unit implantable rather than wearing it externally.

I like to think that the fact of going from large AC-operated units to wearable units was quite a revolution. Going from a wearable unit to an implantable unit is kind of a logical evolution. We started working on implantables, and a group in New York, Dr. [William] Chardack and Wilson Greatbatch, were working on implantables and they had gotten a patent on the unit.

These are some of the [Medtronic] Chardack/Greatbatch units. The internal side of them was, you can see the ten cells and the two transistors. They were really not very much different than these, but you had to order them, the doctor had to order them at a given rate. They were not adjustable. But we did have a little program, or a little pigtail, hanging out separately that was buried in a different cavity than the one that the pulse generator was put in. If the unit started running away, you could go in here and short out the wires and stop it from running away.

CWL: This was not in the chest. It was implanted in the skin under the breast here or the abdomen. The wires went into the heart.

EB: These were all epicardial at that time with the platinum iridium coil springs. So this began the field of implantable pacemakers, and when we made them implantable and the local doctors could get them out of sight, then we started selling lots of them. When they were this kind, they were not very popular because they had to deal with them on a local level and were just scared.

CWL: The other thing I might interject at this point, when we got a good treatment for heart block, this myth that it was rare started to disappear. As it turns out, we look back in retrospect, there were literally thousands of patients dying each year around the world, millions—maybe that's an exaggeration—many hundreds of thousands, of heart block, they just called it a heart attack because most of these older patients that developed heart block, it was not due to surgery, were older, because it was through the coronary arteriosclerosis mostly that destroyed the nervous system of the heart. So all of a sudden, it was realized that these patients dying of heart attack were dying of heart block, and we could treat that. So that's why the number of these units started to escalate.

EB: It was interesting at that time, at Medtronic we had a larger company that offered to buy us out at three dollars a share. Our original stock was offered at a dollar and a half. We were essentially ready to sell, because we were having a tough time. But they went to the A. D. Little Company to get a market research study as to how many people would have heart block, and their study came back saying that the all-time worldwide number of heart blocks would be 10,000 units. Not per year—all time.

The Mallory Battery Company backed out of the deal at that point. But for us as a little company in a garage, 10,000 units seemed worth going after. Of course, now we sell over 200,000 per year ourselves, let alone what our competitors sell, another 200,000. So their market research, as Walt points out, you didn't see it. Doctors didn't know about it until they had some way of fixing it.

CWL: I imagine there's about four million, maybe you can correct me, maybe five million patients today living a normal life [with pacemakers.]

EB: Yes.

CWL: You can live a very normal life with a pacemaker.

EB: At least five million have been treated [with a pacemaker.] Many of them go on to die from other causes.

CWL: It doesn't create immortality.

EB: No. Some of them think it does, but—

DR: It must have been enormously satisfying for both of you to have played such an important role in launching this revolution right here from this room, just to think of all the children and older folks whose lives have been changed so much by this technology….

EB: Well, there have been people that have said that there has been no other single medical treatment that rehabilitates people so much as a pacemaker. It extends life and extends the quality of life.

CWL: It's interesting, it might refresh your memory, but I think about twenty years ago that the National Society of Professional Engineers had their fiftieth anniversary, and I think it was 1984, and they selected some committee and they publicized this, the ten most important inventions in the last fifty years in terms of human progress, benefits to humans, and pacemaker was one. Open-heart surgery was one. Laser was one.

EB: The computer was one.

CWL: Computers. Space travel. Ultrasonics was one. Pacemaker. They didn't try to equate which was most important. I think it would be very difficult. Atomic energy was one, for example. Pacemaker and open-heart surgery were two of those top ten.

DR: It's a wonderful achievement and I would like to thank you for taking the time to talk to us about it.

CWL: Well, thanks, Earl.

EB: Thanks, Walt.

CWL: You probably don't know, I never told you, we both are of Norwegian descent and the name Lillehei in Norway means "small hill," Lillehei. Bakken in Norway means a “small hill” or a “rounded hill.” So we were destined to work together, I guess. [Laughter]

EB: By the way, you should know that this is the original pacemaker, not one of the copies. [Refers to prototype.] That’s it.

CWL: That’s it. I don’t think you made more than one of these, the square one, did you?

EB: Yes, just one.

DR: Thank you so much.

CWL: I hope that is of help.