Introduction of a simple artificial kidney in the United States

Result of International Cooperation

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IN the fall of 1964 while visiting the medical department of Dr. Hippocrates Yatzidis in Athens, Greece, to see his 'charcoal' artificial kidney, I noted a 'wind-it-yourself' artificial kidney that greatly impressed me. It had a large coil that could be wound easily, with a cellophane tube in it, and the hospital technician or nurse newly wound the coil every time an artificial kidney was needed. The principle of a wind-it-yourself coil has appealed to me since 1948 when I saw it first applied by Bodo von Garrelts.

Until inexpensive, disposable units become available in drugstores throughout the country, the wind-it-yourself artificial kidney offers a partial solution to the financial burden of thousands of patients who will depend on hemodialysis for the rest of their lives.

The design of the 'Greek' artificial kidney had actually been reported by Hillenbrand, Hoeltzenbein, and Schmandt[1] in Germany, and at one time was produced commercially; it is not now being manufactured. The German manufacturers were no longer interested in the product, therefore I communicated with one of the inventors of this artificial kidney, Dr. Josef Hoeltzenbein, and invited him to visit us in Cleveland. Before he came, efforts to make simpler kidneys had been well underway at the Cleveland Clinic.

During the last few years we had kept an eye on all the new artificial kidneys whenever and wherever they were developed. Great impetus was derived from the experiences in the dialysis center of Mount Sinai Hospital in Cleveland. Dr. Victor Vertes, Mr. Marion M. S. Levy, and their co-workers perfected the technic of unrolling the commercially available twin-coil kidneys so that they could be reloaded with new cellophane and be reused. By doing so they greatly reduced the overall cost of dialysis. One technician can recondition 10 twin-coil kidneys per day. The reduction in cost can be easily realized. Yet the procedure is cumbersome.

Additional incentive was derived from the careful studies by Dr. Jack R. Leonards, at The School of Medicine of Western Reserve University in

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Fig. 1. The barrels of concentrate for the dialyzing solution. (Dr. W. J. Kolff and Mr. Diederich van Dura, chief technician.)

Cleveland, who adapted some technics from the soft-drink industry. During the last few years Leonards[2] proved that dialyzing fluid prepared from clean tap water in absolutely clean polyethylene tanks stays sufficiently free of bacteria, even at room temperature, to be used as dialyzing fluid for more than 24 hours. He has also found that water at 37 C which has been standing for eight or nine hours is safe to use. Leonards advocates the use of sodium hypochloride, to clean and to sterilize the equipment. Adaptation of Leonards' technic makes it possible to prepare for storage a large volume of dialyzing fluid by mixing commercially available concentrate with a known volume of tap water. The empty polyethylene tanks in which the concentrate is shipped are satisfactory for use as dialysis tanks (*Fig. 1*). They can contain 180 liters, sufficient fluid for one dialysis for a patient of average weight.

Dr. Yukihiko Nosé, head of experimental surgery in the Department of Artificial Organs, who devotes most of his time to research on artificial hearts, brought a wind-it-yourself kidney (the so-called bamboo kidney)[3] with him from Japan (*Fig. 2*). Dr. Josef Erben[4] from Czechoslovakia joined the Department, and imported a novel way of determining the distribu-

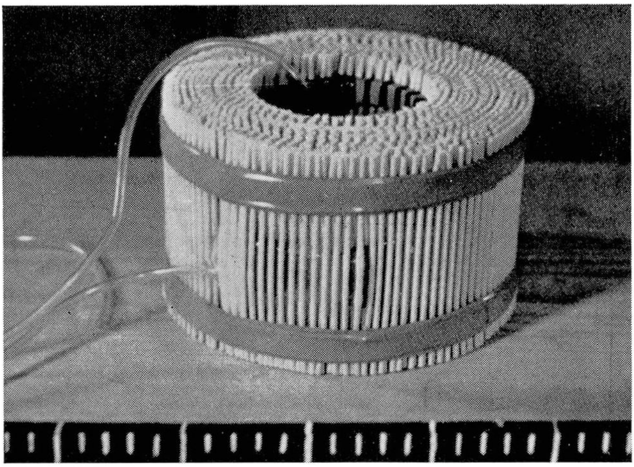

Fig. 2. 'Bamboo' kidney, made not of bamboo but from small plastic rods. These rods could easily be wound and the cellophane tubing was inside. Dr. Y. Nosé brought it with him from Japan.

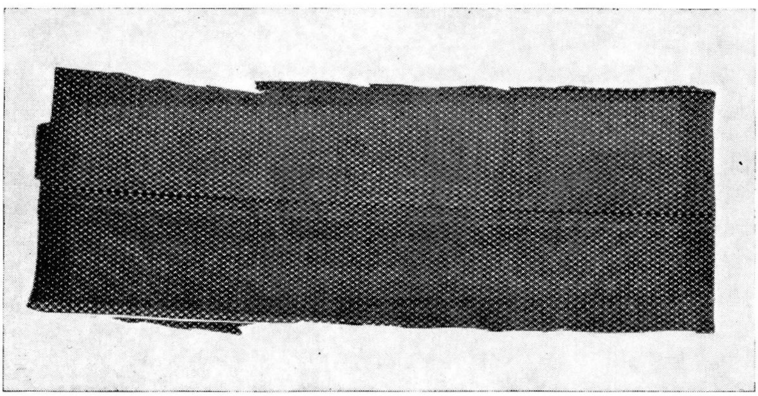

Fig. 3. An autogram made with Evans blue dye added to the dialyzing fluid indicates exactly by white spots where parts of the metal screen prevented the dialyzing fluid from touching the cellophane.

tion both of blood and of dialyzing fluid along the cellophane membrane in artificial kidneys. Erben and co-workers mixed Evans blue dye with the blood or dialyzing fluid. Evans blue does not go through the cellophane, but stains it, producing an autogram. Air pockets, screening, and dead areas are readily defined as uncolored areas in the cellophane.

Working with these physicians from faraway countries, an American engineer, Mr. Frank Rose, developed a number of kidneys, and when these were satisfactory they were tested in Dr. Satoru Nakamoto's dialysis

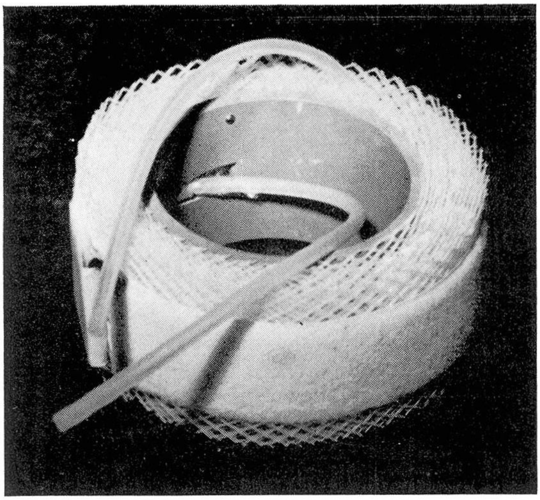

Fig. 4. A coil kidney wound. Four of these coils are needed in one washing machine.

program and under the critical eye of the chief technician, Mr. Diederich van Dura.

The best screens we could find in the United States were stainless steel screens.* One kind of screening seemed promising.

We wound several artificial kidneys with it. On the autogram with Evans blue, the dye proved that only a small portion of the dialyzing membrane was obstructed by the screen (*Fig. 3*). However, the screen brought by Hoeltzenbein from Germany was a much better screen than the one we had. His screen,† made of polyethylene, is not actually woven in the sense that the threads go over and under, but it is heat-sealed so that each crossing thread stays in its own plane. When this screen is wound on a coil, the cellophane tubing is occluded only at the points where the threads cross. No matter how tightly the coil is wound, it cannot obstruct the blood flow, and no spacers are required (*Fig. 4*).

Hoeltzenbein also invented a new way of fixing the cellophane tubing to the blood tubing. He pulled a Silastic tube through a narrow opening and the cellophane tubing was simply sealed by the pressure of the Silastic against the rim of the opening; there were no strings and no knots.

Hoeltzenbein[5] wound concentrically four coils around one cone. No one in the past has ever been able to do so.‡

* *The W. S. Tyler Company, Woven Wire Screen Division, Cleveland, Ohio, screen 1/16-inch mesh, courtesy of Mr. Walter Malek.*

† *Polyethylene screening, Norddeutsche Seekabelwerke, Nordenham, West Germany.*

‡ *Hoeltzenbein shared with others his inventions, and I am glad that he had the opportunity to describe them at the meeting of the American Society for Artificial Internal Organs, in April 1966. That report established his priority and also safeguarded him against possibly unscrupulous patent hunters.*

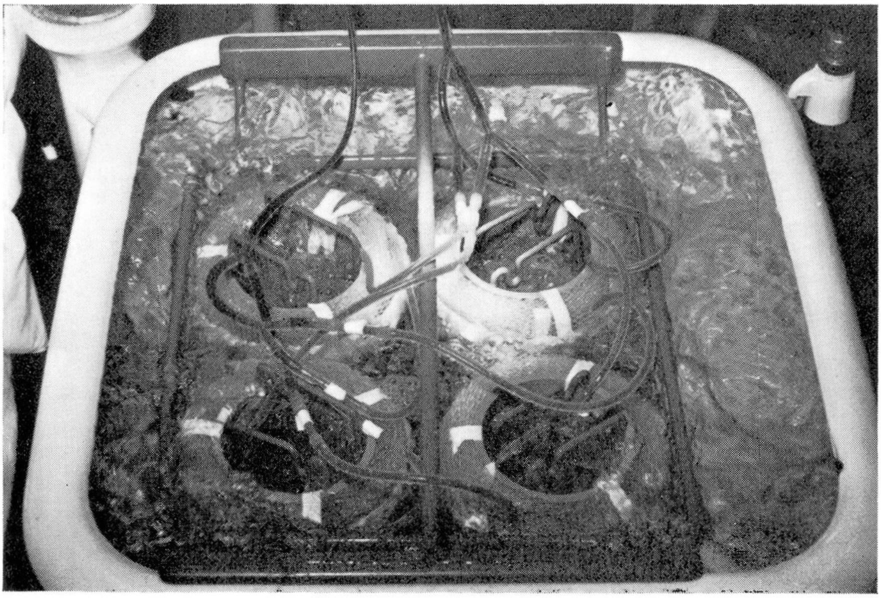

Fig. 5. Four coils in the washing machine. How the dialyzing fluid can slosh in and around the coils is clearly visible.

Travenol, subsidiary of Baxter Laboratories, who recognized the potential importance of disposable artificial kidneys long before other manufacturers did, adopted some of Hoeltzenbein's designs. Mr. Howard Janneck of Baxter Laboratories brought the first Hoeltzenbein artificial kidneys to this country. We used these artificial kidneys clinically and noted that: the blood-priming volume was small (from 400 to 500 ml); the blood flow rate without a blood pump was fair (around 120 ml per minute); the clearance rate was good (about 70 to 90 ml per minute); and the patients liked this type of artificial kidney. The Hoeltzenbein kidney comes closer to the requirements of a good disposable artificial kidney than any other type now available.

We in the Department of Artificial Organs have slightly modified the design and, at least for the time being, prefer four separate coils (*Fig. 5*) instead of the concentric winding of the coils as done by Hoeltzenbein. With four separate coils it is easy to detect a leaky coil and to exclude it without interrupting the dialysis. We also favor the wind-it-yourself principle. When the patient is indigent, it is difficult for him to pay $20 for each dialysis with a disposable artificial kidney. We thought it would be easier to wind single cellophane loops on individual cores than to wind four cellophane loops on the same core. The cost of a rewound kidney is little more than that of the cellophane ($.75) and the blood lines.

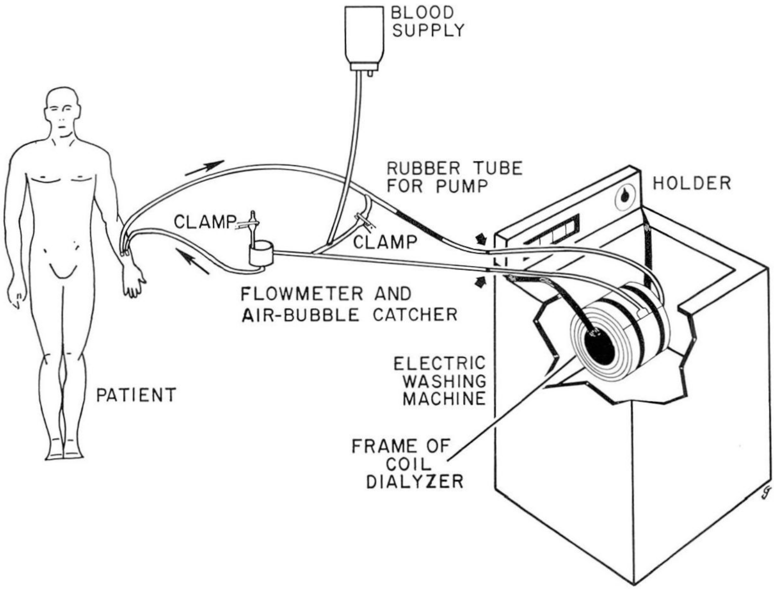

Fig. 6. A diagram of the use of the Japanese coil kidney inside a washing machine in the patient's home, as done by Dr. Y. Nosé in Japan. (Courtesy of Nosé, Y.: Discussion, page 15, Tr. Am. Soc. Artif. Int. Org. 11, 1965; and of the *Transactions of American Society for Artificial Internal Organs*.)

Nosé and his co-workers in Japan in 1961 had placed artificial kidneys in the washing machine at the patient's home (*Fig. 6*). Nosé mixed the appropriate salts with warm tap water and suspended the artificial kidney in the patient's own washing machine. This was achieving dialysis at home many years before it was tried in the United States. Having seen the effectiveness and simplicity of a coil kidney hanging in the sloshing dialyzing fluid in a commercial washing machine, Nosé, persuaded the regional representative of the Maytag Company in Cleveland to give us a Maytag washing machine. In this washing machine Erben tested numerous artificial kidneys, among which were the traditional twin-coil, and the coils that Rose made. Erben found that indeed the dialyzing fluid percolated perfectly. Financially, the washing machine artificial kidney is by far the least expensive design. A household washing machine stripped of the wringer, not necessary for dialysis, can be bought for about $80.00.

A single coil costs less than $12.50. A simple rig* (*Fig. 7*) on which to wind the artificial kidneys was built by Rose and Mr. Charles Blumle. A

* *Ten of these rigs were made available to us by the Pesco Division of Borg Warner through the courtesy of Mr. Ed Thorne.*

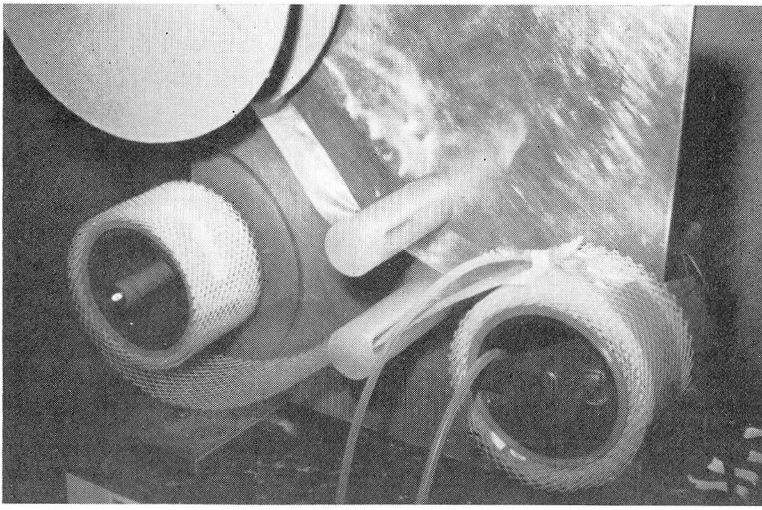

Fig. 7. A closeup of part of the winding rig on which the patients themselves can wind the coils for the artificial kidney.

student from Yale University School of Medicine, Mr. Lutz Schlicke,* joined the Department of Artificial Organs for the summer, and soon was able to wind four individual coils in 30 minutes.

Sterilization of the artificial kidney posed the next problem. First of all, I believe that if I had to be treated with an artificial kidney I would not sterilize it. Cellophane is sterile on the inside when it comes from the factory. If you insert sterile tubing, and wet the ends with either benzalkonium chloride or alcohol, in such a way as not to contaminate the inside of the cellophane, it is perhaps not necessary to sterilize the artificial kidney when you treat yourself. When you treat a patient you must sterilize it. Fortunately you can sterilize the coil and the blood tubing easily with ethylene oxide.† Sterilization can be done in the hospital ethylene oxide sterilizer, or the artificial kidney and the tubing can be placed in a polyethylene bag that is then filled with an ethylene oxide gas mixture and is allowed to remain there for 24 hours at room temperature. After this process, the inside of the artificial kidney is sterile. Before treating the patient with it, another day is required to allow the ethylene oxide to dissipate, otherwise hemolysis may occur.

The polyethylene screen for the artificial kidney can be used many

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† Made available by American Sterilizer, Erie, Pennsylvania, and by C. E. Bard Incorp., Murray Hill, New Jersey, in the form of ampules called Anprolene.

times. It is washed in the same washing machine with sodium hypochloride. Since contamination with hepatitis virus has become a recognized occupational hazard for personnel in charge of the artificial kidney, particular care is taken that the operator discards the cellophane that contained blood, without touching the blood with his hands.

In summary, artificial kidneys of the Hoeltzenbein type will be commercially produced as disposable equipment. They can be used in dialysis centers or by patients at home. The cost, hopefully, will gradually decrease. In the meantime, as long as social provisions to finance disposable artificial kidneys are not available in all the states of the Union, some hospitals and patients will prefer to rewind the artificial kidneys. Simple winding rigs will be made available for this purpose. As an initial courtesy, the Maytag Company made 21 washing machines available without cost for patients on home dialysis programs.

The first six of 25 wind-it-yourself washing machine artificial kidneys are now being tested in patients' homes; 25 more will be sent to hospitals here and abroad for clinical evaluation.

Home dialysis with this simple type of artificial kidney offers the possibility of frequent dialysis, which promises normal life and greater well-being for the patient than was formerly possible. There is a great need for simple safety devices. As soon as the home type of artificial kidney is known to be entirely dependable, it will be possible for the patient to manage dialysis himself and have it continue during his sleep.

Smaller and better artificial kidneys undoubtedly will be developed. However, until they become available we hope that many persons without renal function will be returned to useful lives, thanks to the persistence, ingenuity, inventiveness, and cooperation of many investigators—from foreign countries and in the United States. Among the talented investigators from overseas, Dr. Josef Hoeltzenbein and Dr. Josef Erben have made outstanding contributions.

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