Genesis of an Innovator: Michael E. DeBakey and the Sleeve-Valve Transfusion Syringe

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The life and career of Michael E. DeBakey, M.D., are primarily associated with his many years as the Chief of the Department of Surgery at Baylor College of Medicine in Houston, Texas. While there he became widely known for his many contributions to the understanding and treatment of cardiovascular diseases. In addition to his pioneering work in defining new techniques and approaches to surgical intervention for arterial occlusive disease, aneurysms, and dissections, DeBakey was an innovator with regard to novel technologies. He made seminal contributions related to prosthetic arterial substitutes, new surgical instruments, and artificial cardiac pumps. Prior to this groundbreaking work, however, DeBakey spent twenty-two years of his adult life affiliated with Tulane University in New Orleans, Louisiana. These were years of personal and professional growth and maturation, but also of significant and lasting contributions on his part to clinical medicine and surgery. The first of these was his invention of the sleeve-valve transfusion syringe.

Eighteen-year-old Michael DeBakey arrived at the campus of Tulane University in New Orleans in September, 1926. The valedictorian of his high school class, DeBakey enrolled in the university’s Premedical Course, a two-year undergraduate track designed to prepare students for the rigors of the Tulane Medical School. Accustomed to perfect marks, DeBakey was mortified when his first term report was studded with B’s. After some soul-searching he returned for the second session with a new determination to excel. His father, Shiker Morris, was a tireless worker and astute businessman who built a small empire of dry goods and drug stores in the family’s hometown of Lake Charles. From this point on, through the rest of his life, DeBakey took up his father’s Spartan example and worked exceptionally long days, seldom sleeping more than four or five hours a night. This effort paid off in the classroom, where DeBakey earned high grades in his courses in zoology, mathematics, physics and most of the remainder of the curriculum.

During the spring of DeBakey’s first year of medical school, in 1929, he took an introductory class in surgery taught by Tulane’s new Professor and Chief of the subject, the mercurial and young Alton Ochsner. DeBakey was bewitched by the South Dakota transplant’s obvious talents as a clinician and educator, and soon became convinced that his career path lay in the field of surgery. His performance in
medical school was characterized by continued excellence, and he finished in 1932 in the top 10% of his class.\textsuperscript{4} DeBakey then decided to train in surgery with Ochsner.

DeBakey saw a blood transfusion for the first time while still a medical student on clinical rotation at New Orleans’ famous Charity Hospital. In the days before blood banks this procedure bore some semblance to a major operation; indeed, much of the time it was performed in the operating room. With a very few exceptions, transfusion was direct from donor to recipient. Each patient had a needle placed into an arm vein, then the donor’s blood was either pumped directly into the recipient via a syringe and rubber tubing or, with some early commercial devices, into an intervening bottle containing sodium citrate and saline solution to inhibit clotting. In even more primitive versions, the syringe was simply filled with donor blood and injected into the recipient. In any case, the procedure was not notable for its elegance: needles were frequently dislodged, blood inevitably splattered everywhere, and clotting mid-transfusion was the norm. Death was not rare. Small wonder that DeBakey thought he could improve on the process:

At that time they did it in a very awkward way. […] They had to do it direct from an individual. They had to take it out with a syringe and then inject it and I said well there must be better way to do it than that. That just is terrible—blood all over the place. So I went to work on a blood transfusion machine.\textsuperscript{5}

In his adolescence DeBakey had enjoyed tinkering on his father’s automobiles. Drawing on this prior experience in an entirely different arena, the now-23-year-old recalled an engine design that incorporated the concept known as the sleeve valve. Invented around the turn of the century by Charles Yale Knight (who was annoyed by the excessive noise of conventional poppet valves) these engines featured metal sleeves which sat within the cylinder and slid as the piston moved, causing ports in the sleeves to line up with holes in the walls of the cylinder at specific times during the engine’s cycle to expel combustion gases and draw in air.\textsuperscript{6}

DeBakey reasoned that this design should work with any fluid, including blood, and that the intake and exhaust phases of the engine were analogous to the two limbs of the transfusion process. Together with one of his medical school classmates, William Gillentine, he set to work adapting automotive engine technology to the hospital ward (Fig. 1).

DeBakey envisioned two metal cylinders which fit together snugly. The inner cylinder would be mostly solid, but with a flow channel in the center, extending to an opening in the side – it would function as a piston. The outer, hollow cylinder (the sleeve) would have two ports, a top one for receiving the donor blood and a bottom one for expelling it to the recipient. Sliding the piston up or down exposed its side hole to the appropriate sleeve port depending on the stage of operation. The piston attached to a syringe.

Accordingly, after attaching the sleeve ports to rubber tubing connected to intravenous needles in the two patients, the transfusionist would merely slide the piston to expose the donor port, pull back on the syringe to fill it with donor blood, then slide the piston forward, covering the donor port and opening the recipient one, finally expelling the syringe contents. In practice there was no need to move the piston; pulling back and pushing down on the syringe plunger did it automatically because of the friction involved and the viscosity of blood.\textsuperscript{7}

\textsuperscript{5} Michael E. DeBakey, Don A. Schanche Interviews DeBakey, 1972 Jan-Sep, Michael E. DeBakey Archives. 1903-2010. Located in: Archives and Modern Manuscripts Collection, History of Medicine Division, National Library of Medicine, Bethesda, MD; MS C 582. [Hereafter, Michael E. DeBakey Archives, NLM] Series 1:2:10.
\textsuperscript{7} Becton, Dickinson & Co. correspondence, Michael E. DeBakey Archives, NLM. Series 2:4:28.
DeBakey and Gillentine drew up plans for the device on paper (Fig. 2, 3). They then approached the Charity Hospital carpentry shop about building the syringe, but were told that the work involved was beyond their capability. They were referred to several machine shops and scientific instrument repair facilities in New Orleans. One of these was the Marine Instrument Laboratory of F.A. Smith, on Girod Street near Lafayette Square. They paid Smith a $10 deposit to produce a prototype, with a further $10 due on completion.

The first clinical use of the new instrument was on November 4, 1932, when DeBakey and Gillentine were “internes” at Charity. Before long word got around about the young physicians and their new, improved method of transfusion, and the demand for their services escalated. The indications were diverse. As DeBakey and Gillentine later noted, “All types of conditions have been treated, including postoperative hemorrhages, and infections, complications of pregnancy and the puerperium, typhoid fever, osteomyelitis, malignant cachexia, primary anemia, secondary anemias of various origins, traumatic injuries of the viscera, bacterial endocarditis, hyperemesis gravidarum, bichloride poisoning, any primary disease or secondary complication, in short, for which transfusion might be indicated.”

The greatest volume that was transfused at one setting was 750ml for patients who had nearly exsanguinated from acute issues. For chronic anemias of the various types the internes preferred to give repeated transfusions in the range of 250ml. By April of 1933 DeBakey and Gillentine had performed seventy-five transfusions on fifty-two patients, with great success. They were ready to begin reporting their results, with the help of some well-known faculty. Ochsner introduced DeBakey and Gillentine at the April 10 Quarterly Meeting of the Orleans Parish Medical Society. They delivered their paper, “A New Syringe Method for Blood Transfusion” in a twenty-minute presentation and demonstrated the device to enthusiastic approval. The published version of this paper, slightly altered to “New Method of Syringe Transfusion,” appeared later in the year in the New Orleans Medical and Surgical Journal. This was Michael DeBakey’s first publication.

Urban Maes, at this point the Chairman of Surgery at the new Louisiana State University School of Medicine and Senior Visiting Surgeon at Charity, also became aware of the transfusion efforts of DeBakey and Gillentine and suggested they publish a paper in a national journal about their new device. He penned a brief letter to the editor of the American Journal of Surgery in New York as an introduction:

Dear Dr. Welton:

A series of disillusion has taught me to be very wary about endorsing new equipment of any sort, particularly when it has to do with blood transfusion. So when I was told that two of the internes at Charity Hospital here had devised a very effective syringe for direct transfusion I was very polite, but very skeptical. Well, I stand converted. I have seen it in action several times, and heard the reports of others who have seen it in action, and there isn’t any desirable quality it does not seem to possess; it is simple, accurate, quick, safe and apparently fool-proof.

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11 Ibid., 581.
12 Ibid., 581.
[...] I have therefore suggested to Dr. M.E. DeBakey and Dr. W.H. Gillentine, who devised it, that they let me write you about it, telling them that I felt sure you would be glad to publish a description of it...

With kindest personal regards,

Very sincerely yours,

Urban Maes, M.D.\textsuperscript{14}

On the strength of Maes’s letter the article, “A Syringe-Sleeve-Valve Transfusion Instrument: A New Method of Transfusion of Unmodified Blood,” appeared in the American Journal of Surgery in March, 1934. This was DeBakey’s first paper to be published in a national journal (Fig. 4).\textsuperscript{15}

Academic considerations aside, not a week passed after their first successful human transfusion with the new syringe before DeBakey and Gillentine began searching for a large-scale manufacturer for their machine. Neither of the internes had had any prior experience that was remotely similar to the patenting, licensing, and manufacture of a novel scientific instrument. Their eyes were soon opened, and any preconceived notions they might have had about the ease of the process was quickly dispelled.

They first approached the established northeast medical manufacturing firm of Becton, Dickinson and Company. Located just outside New York City, this manufacturer had been in business since the 1890s and was one of the leading producers of thermometers, hypodermic needles, and, notably, syringes. Ochsner made the initial overture, and, in response, DeBakey received an introductory letter from the company’s Research Department Manager, Oscar Schwidetzky (inventor of the still-ubiquitous ACE bandage):

Dear Dr. DeBakey:

Alton Ochsner was kind enough to write us regarding the blood transfusion apparatus which you have devised.

We are very much interested in blood transfusion apparatus (sic) and are very anxious to see the outfit which you have constructed. No doubt an arrangement – fair to Becton, Dickinson & Co. and fair to you – can be worked out.

Very truly yours,

Becton, Dickinson & Co.

O. O. R. Schwidetzky
Manager Research Dept.\textsuperscript{16}

On receipt of this very encouraging letter DeBakey and Gillentine composed a response that consisted of a detailed description of their instrument, compete with drawings, and an accounting of its clinical success (which was actually quite limited at the time). Under a separate cover they forwarded one of their prototypes.\textsuperscript{17}

They must have been surprised and disappointed by the next letter from Schwidetzky, dated November 21. After acknowledging the novelty of their design, the research manager went on to point out that there actually was a similar device already available, which utilized a stopcock to adjust direction of flow rather than a sleeve valve. He also tactfully noted that their blood-metal interface was less forgiving than one employing glass, and less gracefully asserted that Becton-Dickinson’s own existing transfusion device, which dated to 1922, was, in any case, superior to all. Schwidetzky closed by admonishing the internes to “take our advice and don’t spend a penny on patent papers.”\textsuperscript{18}

\textsuperscript{14} Urban Maes to Thurston Welton, April 7, 1933. Michael E. DeBakey Archives, NLM, series 2:4.
\textsuperscript{17} Ibid.
DeBakey and Gillentine’s response to this letter has not survived, but judging by the reaction of Schwidetzky, it was swift and harsh:

Dear Dr. DeBakey,

We are in receipt of your wire, in which you ask us to return the blood transfusion apparatus immediately…\(^{19}\)

Schwidetzky continued by apologizing for an aggravating delay in returning the device, then cheekily suggested some modifications, which included incorporating “Luer-Lok” fittings for attaching syringes (these were proprietary Becton-Dickinson connectors). He also reminded the New Orleans men that they should “not spend any money in patenting your present type machine.”\(^{20}\)

Not long after this, as their success with transfusions on the wards continued, the internes decided to ignore the pointed - and emphatically-repeated - advice of Mr. O.O.R. Schwidetzky and pursue a patent. They enlisted the services of a New Orleans attorney who contacted the firm of Alexander & Dowell in Washington, D.C. Lawyers there returned the information that between patent search fees, government charges, and legal compensation for preparing the application, the cost would be $170 (approximately $2500 in 2018 dollars).\(^{21}\) This exorbitant price tag appears to have convinced the impoverished internes to put their patenting ambitions on hold, at least temporarily.

On the other hand Becton-Dickinson’s rejection, although disappointing, did not dissuade DeBakey and Gillentine in their effort to get the invention on the market. In January, 1933 they sent out a barrage of letters of introduction to various other manufacturers, trumpeting their idea. Their introductory paragraph read:

We have designed a blood transfusion apparatus which has proven clinically to be entirely satisfactory, and is looked upon by able clinicians here to be the best and most practical syringe transfusion method in use at present. We refer you to Dr. Alton Ochsner, professor of surgery, Dr. Roy Turner, assistant professor of experimental medicine, and Dr. P.H. Jones, assistant professor of clinical medicine, all of Tulane University, who have seen the instrument in clinical trial. We have been persuaded by these men and other able clinicians who have seen the instrument in use, to have it manufactured and sold, so that it will be available to the profession.\(^{22}\)

Subsequent sentences described the apparatus, its operation and advantages, and were tailored to the manufacturer in question. George B. Pilling and Son Company of Philadelphia, J. Sklar Manufacturing Company of Brooklyn, the MacGregor Instrument Company of Needham, Massachusetts, and V. Mueller and Company of Chicago were among the targeted firms.\(^{23}\)

As was the case with Becton Dickinson, the internes’ efforts met with staunch, if not necessarily surprising resistance. After expressing initial interest Pilling refused even to consider the device until it had been patented. Sklar indicated, like Becton-Dickinson, that there was already a device on the market of an essentially identical design (there was not). MacGregor lamented that they thought the sleeve-valve syringe had merit, but they were contractually obligated not to market a transfusion device other

\(^{20}\) Ibid.
\(^{22}\) For example, see M.E. DeBakey and W.H. Gillentine to George B. Pilling Co., January 23, 1933. Michael E. DeBakey Archives, NLM, series 2:5:35.
\(^{23}\) See letters to multiple firms, Michael E. DeBakey Archives, NLM, series 2:5:26, 29, 35, and 39.
than the one they were already manufacturing. With the nation in the throes of the Great Depression the risk of investment in new ideas was, to some companies, clearly insurmountable.\footnote{Ibid.}

V. Mueller was the exception. The Chicago company, which manufactured hospital and office furniture in addition to surgical instruments at its West Side factory, qualified its initial interest by invoking the by-now-familiar patent hurdle. Unlike the other firms, though, Mueller offered to help. They did their own patent search, which showed that the concerns of the Becton-Dickinson and Sklar representatives, if they were genuine, were unfounded. Mueller went further, too, and also recommended that DeBakey and Gillentine register their device with the American Surgical Trade Association. This was a sort of gentleman’s agreement among manufacturers of surgical instruments – not statutory or in any way enforceable – to respect the priority rights of a new apparatus for five years. There were other legal hoops to be jumped through, and much ink to dry, but V. Mueller gradually came on board.\footnote{G.W. Wallerich to M.E. DeBakey and W.H. Gillentine, December 19, 1933. Michael E. DeBakey Archives, NLM, series 2:5:29.}

Not long after DeBakey and Gillentine’s article appeared in the American Journal of Surgery in the spring of 1933, requests for examples of the new transfusion device began descending on the internes at Charity Hospital.\footnote{M.E. DeBakey to G.W. Wallerich, January 6, 1934. Michael E. DeBakey Archives, NLM, series 2:5:35.}


Within a few months of the release of his sleeve-valve syringe, DeBakey produced a modification of the roller pump which turned out to be an even more effective device for transfusion. The DeBakey Roller Pump was successfully patented, and commercially produced by Aloe and Company.\footnote{H.F. Baer to M.E. DeBakey, May 27, 1936. Michael E. DeBakey Archives, NLM, series 2:5:34.}

By the late 1930s, however, advances in blood banking technology, especially refrigeration, had rendered patient-to-patient transfusions obsolete, and these ingenious devices were abandoned for their originally intended purposes.

The sleeve-valve transfusion syringe was the first in a long line of innovations devised by Michael DeBakey in a career that would extend more than seven more decades. The development of this apparatus was his first exposure to the process of creating, patenting, and bringing a medical device to the market. DeBakey would go on to author some 1,600 publications, perform more than 60,000 operations, and train thousands of surgeons before his death at age ninety-nine in 2008. His friend, colleague, and co-inventor of the sleeve-valve syringe, William H. Gillentine, joined the faculty of Tulane and the staff of Charity Hospital as an internist following completion of his training. He specialized in diabetes treatment, and died in 1954.\footnote{Obituaries, Diabetes 3, no. 3, (May 1954): 260.}

Figures (All photos are used with permission of the History of Medicine Division of the National Library of Medicine, Bethesda, MD.)
Figure 1: Michael DeBakey and William Gillentine as internes at Charity Hospital in 1932-33.
Figure 2: Early hand-drawn sketch of transfusion syringe
Figure 3: Sketch and notation of improvements to sleeve-valve transfusion syringe.

- Finger ring
- Washer which fits over plunger and screws into ring cap thus fastening it into place.
- Spring strip which increases plunger-syringe friction by pressing on cap.
- Screw cap
- Thin brass tubing & offset pieces containing screw threads for cap & valve piston.
- Slide to adjust outward motion of plunger.
- Brass tubing to contain four windows to permit visibility of syringe.

7 Parts to assemble

Improvements in the syringe case and friction adjusting mechanism & slider to limit outward motion of the piston.
Figure 4: Article on the device as it appeared in the *American Journal of Surgery*.

NEW INSTRUMENTS

A SYRINGE-SLEEVE-VALVE TRANSFUSION INSTRUMENT

A NEW METHOD OF TRANSFUSION OF UNMODIFIED BLOOD

MICHAEL E. DEBAKEY, M.D. AND WILLIAM H. GILLETTE, M.D.

NEW ORLEANS

The principles of transfusion were established many years ago and the problem of the procedure today is a purely mechanical one, the transfer of the blood from the veins of the donor to the veins of the recipient within the shortest possible time and over the shortest possible pathway, so that there shall be no risk of clotting en route. To achieve these results many instruments have been devised, some of which are exceedingly ingenious but all of which are open to some objection: either the mechanism is so complicated that they are difficult to operate and keep in order, or they are so expensive that their purchase and maintenance is a distinct burden. None of them, in addition, offers entirely adequate protection against the risk of clotting. The instrument we have devised is, we believe, free from all of these disadvantages and risks, and it offers several advantages, in our opinion, over any other apparatus now available.

DESCRIPTION

The instrument (Figs. 1 and 2) consists of a 5 c.c. syringe and a sleeve valve. While any standard syringe would probably be satisfactory, we have chosen the 5 c.c. Sana-Lok syringe because it is easy to procure and because it offers the Luer-Lok attachment. A piston (A) contains a channel which communicates at the upper end with the syringe tip and at the lower end with the “port” of the donor (β) and of the recipient (α); these plugs are fitted into the sleeve (a). A taper pin (r) fits snugly into the sleeve and passes through a slot in the piston, the up and down motion of which is thereby limited. This mechanism ensures exact approximation of the port in the piston with that of the donor in the extreme up position (Fig. 1), and with that of the recipient in the extreme down position (Fig. 2). The separate parts of the apparatus are shown in Figure 3, and the assembled instrument in Figure 4.

Blood is a highly viscid fluid, and in actual clinical practice a reversal of the flow is therefore scarcely likely to occur. The theoretic possibility exists, however, and special precautions have been taken to guard against it. A rubber washer, placed at the top of the syringe, tightly surrounds the plunger shaft and increases the friction of the syringe over the friction of the sleeve valve; as a result, the valve always moves before the syringe plunger begins to move in the same direction. Errors of operation are thus absolutely guarded against.

TECHNIQUE

The parts of the instrument are sterilized in the autoclave or by immersion in 95 per cent alcohol and sterile liquid petrolatum is applied to the piston as a lubricant. The instrument is then assembled by slipping the piston into the sleeve, inserting the taper pin, and attaching the syringe to the Luer tip of the piston. Two small rubber