Northwestern and Other Historical Vignettes regarding the Vascular Anastomotic Coupling Device

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INTRODUCTION

Innovation is a process whereby an unfilled need is addressed via human ingenuity. In surgery, there is a requirement for the movement and revascularization of large blocks of tissue. This need fostered the development of the vascular anastomotic coupler—a wonderful story involving a large number of colorful surgeons and researchers who spanned 100 years. It is a story that illustrates the innovation process, as well appropriately attributing the credit for important medical devices that we often take for granted each day in the care of our patients.

EARLY DEVELOPMENT OF THE SUTURELESS VASCULAR ANASTOMOSIS

At the turn of the 19th century, it became clear that the manipulation of blood flow could lead to advances in medicine. Virchow had already postulated that the vessel injury led to thrombosis, and so the flowing blood across a newly constructed anastomosis would require a minimally injured vessel wall. To this end, Carrel developed atraumatic suture techniques for which he was awarded a Nobel Prize in 1912. Even before this accomplishment, in 1894, Abbe worked on a prosthetic hollow glass conduit that was placed intraluminally and secured with ties exterior to the vessel wall for allowing the blood flow across a gap.¹

Any time there is thought to be a medical or surgical innovation, one must be sure to check the early German medical literature. For the vascular anastomotic device that approximates blood vessels without sutures, this truism holds. Dr. Erwin Payr was an Austrian–German surgeon who was born in Innsbruck and worked during his illustrious career for a time with Dr. Carl Nicoladoni in Graz. Perhaps he was influenced to investigate blood vessel anastomoses by the work of his chief, Dr. Nicoladoni, the first surgeon to perform a toe to thumb transfer (although performed as a pedicle transfer). Payr devised 2 distinct means to join blood vessels without sutures, with the second design employing pins held in place by a circular ring made of slowly dissolving magnesium to hold the everted lumen. When the 2 rings are brought together, this looks unmistakably similar to current technology (Fig. 1).² One small difference is that only the “male” ring held pins, while the “female” end of the device maintained lumen eversion with sutures. Unfortunately, this particular concept of lumen eversion pins held by a circular ring that remained on the vessel wall was essentially lost for the next 60 years.

Elements of the Payr design were used in 1910 in a Northwestern University laboratory for an improved vascular anastomosis. Victor Darwin Lespinasse, a Chicago urologist (famous for early studies in testicular transplantation),³ described in great detail the use of magnesium metal rings with multiple pinholes placed on the outside of vessels in the same manner as Payr. Termed a “magnesium ring blood vessel anastomosis,” the sutures passed through the metal holes and the vessel wall, with the metal rings preventing suture pull-through and maintaining intimal eversion (Fig. 2). Rings with multiple holes
Fig. 1. Sutureless anastomosis diagram by Payr.2

Fig. 2. Diagram of magnesium rings of Lespinasse.4

Fig. 1—A ring, a flat piece of metallic magnesium, with edges rounded off and eight holes punched in it equidistant. These holes are counter sunk so that their edges will not cut the threads.

Fig. 2—Vessel sewed into the ring, using every other hole; the sutures are triple 0 silk.

Fig. 3.—The two rings and one of the four approximating sutures of then passed. Three others are passed in exactly the same way.

Fig. 4.—The two rings drawn together and three of the approximating sutures tied while the fourth one is drawn up ready to be tied.
for passage of the 3-0 silk sutures were a critical aspect of the design, but clearly there are no pins present to hold the vessel walls. The article provided interesting details on the use of magnesium rings—chosen for their dissolvability in tissues over time. The rings should be sterilized in Lake Michigan water, due to its low mineral content, as opposed to well water. One milliliter of hydrogen gas would be expected to be released for each milligram of magnesium, and so, for a 3.5-mm diameter ring, 60 ml of hydrogen gas would be released, although the authors stated that this would be well tolerated over the dissolving time of the magnesium metal of 2–3 months. This work links the design of Northwestern laboratory with the modern design of the anastomotic couplers, but this was not the only contribution of a Northwestern laboratory as will be seen.

Other researchers worked on a sutureless anastomosis, no doubt seeing the need for a reliable blood vessel anastomosis with the ongoing World Wars. There are benefits of medical innovation, particularly when an instrument design can be patented. The patent literature produces a “time stamp” on knowledge with clear attributions on who was the first to “teach” a particular concept or design. With our review, the earliest patented surgical device for a ring with pins to pierce the vessel wall lumen was awarded to Soresi, who flamboyantly began his patent with:

> Be it known that I, ANGELO L. SORESI, a subject of the King of Italy, residing in New York, in the State of New York, have invented certain new and useful improvements in instruments for the Transfusion of blood, of which the following is a specification.

**P. I. ANDROSOV AND THE STAPLED VASCULAR ANASTOMOSIS**

From Germany before World War I, the story jumps to the Soviet Union and Dr. Pavel Iosofovich Androsov. Always referred to in the literature and Internet as “P. I. Androsov,” he was born in a village in the Kursk region, and he started his education in the local village school and proceeded to vocational school until 1925 when he was drafted into the army. He progressed to a medical school in Leningrad, where he methodically advanced up the medical ranks until 1928 when he was called into the army for imprisonment and exile in 1948 by Stalin. Perhaps this was not the only contribution of a Northwestern laboratory as will be seen.

During World War II, Yudin became “surgeon-in-chief” of the army and made significant contributions to the field of orthopedics, espousing wide and early debridement of gunshot wounds. The Anglo-American-Canadian surgical mission of 1943 visited his institute for the improved understanding of trauma organization for the war effort. Unfortunately, the fame of Dr. Yudin did not prevent his imprisonment and exile in 1948 by Stalin. Perhaps this was the change of letters and medical publications. In 1928, he travelled to the United States to visit 15 major US medical institutions, and his longest sojourn was with the Mayo Brothers in Rochester, Minn. He maintained that relationship with the Mayos by the exchange of letters and medical publications. In 1928, he became chief surgeon at the Sklifosovsky Institute where over time it became the central trauma hospital for Moscow. During World War II, Yudin became “surgeon-in-chief” of the army and made significant contributions to the field of orthopedics, espousing wide and early debridement of gunshot wounds. The Anglo-American-Canadian surgical mission of 1943 visited his institute for the improved understanding of trauma organization for the war effort.

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due to his never being a member of the Communist Party and his continued connection with westerners.

The transfer of knowledge during the Cold War between the superpowers on the potential for stapled vascular anastomoses circumstantially was due to the preexisting relationships among Yudin, the Skilosovsky Institute, and the Mayo Clinic. F. Henry (Bunky) Ellis, a general and a thoracic surgeon at the Mayo Clinic, in his second year of practice (and who was well known to my family15) became one of the first American surgeons to visit the Soviet Union after World War II for evaluation of their hospital systems and advancements in surgery. Exactly how this junior attending surgeon received this invitation is unclear. Ellis detailed the various surgeries he witnessed in Archives of Surgery, with 1 paragraph describing the work of the chief of the unit Androsov.13 The connection with Yudin is circumstantial, with Ellis praising Yudin and his abilities 3 times in his report, although Yudin at this point had already passed away the year before. In an editorial to the same article, Yudin was also praised by Dr. Waltman Walters, son-in-law of Dr. William Mayo and the editor of Archives of Surgery from 1938 to 1962. Perhaps Walters had met Yudin during the latter’s time in Rochester, as he was already married to Phoebe Mayo and a section chief at the time of Yudin’s visit in 1924.14 I suspect that the connection among the Mayo Brothers, Dr. Walters, and Dr. Yudin facilitated the invitation to Dr. Ellis by the Soviet Union, and this allowed Ellis to visualize Dr. Androsov’s vascular stapler in action. It was Dr. Walters in his role as editor who encouraged and published both the visit of Ellis as well as Androsov’s clinical series. Bunky Ellis would go on to have an illustrious career in thoracic surgery, ending his career as a section chief at the Lahey Clinic and the New England Deaconess Hospital.

INOKUCHI’S VASCULAR STAPLER

Professor Kiyoshi Inokuchi of the Department of Surgery at Kyushu University in Japan began to work on his version of a vascular stapling device in 1956 and first reported his design in 1958 in Archives of Surgery.15 The use of the device clinically for end-to-side anastomoses was published several years later.16 While he refers to Androsov’s work, he described his “mechanized vessel suture” as of his own design, and he only learned of the Russian device “...which I happened to learn in the course of my experimentation....” A patent was awarded in 1960, but no reference was given to Androsov.17 Years later in his 1975 Atlas of Applied Vascular Surgery, he did write that Androsov was his inspiration.18 At least 250 of these devices were distributed, and over 1,000 cases performed. An entire chapter of this well-illustrated book illustrates replacements of the esophagus with revascularized bowel, as well as other sizeable reconstructive procedures.

This engineering marvel, produced by the Senko Medical Manufacturing Co. was described by Inokuchi as being simpler and easier to handle than that designed by Androsov (see video, Supplemental Digital Content 1, which demonstrates the Inokuchi stapler, http://links.lww.com/PRSGO/B41). A key was the “scissors-type handle loops” for improved grasping of the coupler. The stapler relies on 3 pairs of semicylinders (bushings), with the 2 halves coming together to form a ring with sizes 1.5–5 mm. Exactly analogous to a common paper stapler, there is a plastic semicylindrical “stitching head” to hold the staples, a metal semicylindrical plunger that fit within the stitching head for a manual deployment by the surgeon by a lever, and a set of semicylindrical anvil with matching engraved pits to receive and to bend the ends of the staples to create a physical hold. Each staple would cover approximately 0.5 mm, with 4 staples used for a 1.5-mm anastomosis and 10 staples used for a 5-mm diameter lumen. The device came in 7 sizes, 1.5, 2, 2.5, 3, 3.5, 4, and 5 mm. Specialized forceps or “nippers” were provided with the instrument for individually gripping the staples and placement into the stitching head. Three millimeters of vessel was required to protrude past the face of the bushing to achieve eversion. Eversion is achieved with either forceps or a surgeon’s fingertip to fold the vessel onto itself. There are no protruding pins with this system, but rather adjacent to the bushings, there are atraumatic levers to hold the vessel walls in eversion. Finally, there is a vessel bulldog attached to the outer aspect of each arm of the device to hold the artery securely. Direct measurement shows that a minimum of 5 cm of total vessel length (1.5 cm on each side of the open lumen) was required to perform an anastomosis as this is the separation between the 2 bulldog clamps.

A key improvement that Inokuchi claimed was a sliding clamp that held the 2 pieces of the device in firm apposition. This allowed for the surgeon to push the 2 lever arms that would cause the plunger to deploy the staples into the receiving anvil. Inokuchi wrote that the ability to hold the device was far improved with the addition of the outer metal rings. Inokuchi also praised his device for the ease in switching the bushings for changes in vessel diameter and in cleaning. Excluding the bushings, Inokuchi’s device comprised 8 separate parts, while Androsov’s device came apart into 21 pieces that were detached and reassembled for each case.

Video Graphic 1. See video, Supplemental Digital Content 1, which demonstrates the Inokuchi stapler. This video is available in the “Related Videos” section of the Full-Text article on PRSGlobalOpen.com or available at or at http://links.lww.com/PRSGO/B41.
THE NORTHWESTERN CONTRIBUTION TO MICROSURGERY

As the vascular staplers of Androssov and Inokuchi gained notoriety, other groups including a Canadian Research Laboratory and the United States Army were simultaneously developing couplers. To this list of innovators, we add the underappreciated contributions of Gordon P. Holt, a fourth year medical student at Northwestern Medical School. Each senior medical student at that time had a requirement for a summer research project. Just before his fourth year in 1960, Gordon met Dr. Thomas Starzl, a young surgeon who had recently joined the Northwestern faculty (Gordon Payne Holt, telephone interview, February 9, 2018). Starzl was performing kidney transplants in animals and ran into the problem of small vessel thrombosis. He gave Gordon the task of creating a sutureless anastomosis where the lumen would be everted “like a trumpet.” Gordon was supervised by Dr. F. John Lewis, the first full-time member of the faculty of surgery at Northwestern and the first to perform a successful open heart surgery in 1952. Lewis was described as giving little direction but lots of encouragement. Neither Lewis nor Starzl gave Holt any literature as to how to construct this anastomosis, but they both insisted no foreign bodies could be present inside the vessel lumen. With some help from the machine shop, Holt began with a 6 mm in diameter Teflon ring, within which he drilled a central hole (Fig. 3). A finer drill was used to place 12 evenly spaced pin holes for each ring, with the alternating holes of each ring receiving 6 stainless steel wires. Holt settled on this design after having too much leakage from a design that used only 4 pins per ring. The rings were brought together with a modified “bullet removal” clamp and held together additionally with 1 or 2 sutures. Holt went to a jewelry store to buy fine forceps for the operations. Eighteen successful femoral arterial anastomoses of 2–3.5 mm in diameter were performed in dogs, with no thromboses or obvious signs of foreign body reaction when the histology was performed months later. Holt was proud that “the everted contact of the internal surfaces was replaced by new fibrous tissue and the inside lining was covered by a new smooth layer of intima.” His work was reported in the Chicago’s American newspaper in 1961, including the report of a human leg revascularization that was successful. After graduating from Northwestern, he spent time in the Army, followed by an internship in West Virginia and finally a residency in otolaryngology at the University of Iowa. He privately practiced otolaryngology in private practice in Arizona where he eventually retired. The idea of patenting this design was never discussed, and Holt had neither the ability nor the means to pursue protection of this idea. As the idea of pins and rings had already been published, Holt’s idea in isolation without a new mechanism to physically approximate the rings may not have been patentable. Between 1961 with the newspaper report and our telephone interview in 2018, Gordon Holt was never approached about his Surgical Forum publication, and he had no idea about his contribution to modern microsurgery regarding the development of the anastomotic coupler. He was understandably quite pleased to learn that his pin design is used widely today.

![Diagram of vascular anastomotic coupler of Holt](image.png)
NAKAYAMA, ÖSTRUP, AND THE CURRENT ANASTOMOTIC COUPLER DESIGN

Many authors give Nakayama credit for the current concept of the anastomotic coupler, being that of 2 rings, each with 6 pins and 6 holes. As in the modern anastomotic coupler design, the rings are adjusted, so that the pins of 1 member fit into the holes of the other. The operating surgeon brings the clamps together manually without any special additional devices or aids. The clamps holding the rings achieve bending of the ends of the pins, much as a stapler, to keep the rings apposed. While Nakayama’s US Patent application of 1962 does not mention Holt for his design, he published an image of Holt’s pins and cited the Surgical Forum manuscript in a contemporaneous clinical report. Like Yudin, Androsov, and Inokuchi, the clinical cases presented by Nakayama were for the treatment of esophageal cancer and the need to vascularize the intestinal segments for reconstruction.

Ostrup and Berggren greatly improved on the Nakayama rings by creating a means to bring the rings together. After working with the Nakayama device in both research and clinically in over 100 arteriovenous fistulas, the device was judged to be clumsy, with the ring holders being far too large and difficult to unite (Leif Östrup, personal correspondence). This team filed its Swedish Patent in June 1982 and its US Patent in 1988. The US Patent referenced Soresi of 1915, Nakayama, and Holt. The patentable feature of this design is not of the rings, but primarily the method to hold the rings and to subsequently align them to be joined. This design was originally manufactured as the “UNILINK” apparatus and then commercialized internationally as the “3M Precise Microvascular Anastomotic System (MAS).” Currently, the product is marketed by the Synovis Micro Companies Alliance as the GEM Microvascular Anastomotic Coupler.

CONCLUSIONS

It took over 100 years to develop the sutureless microvascular anastomosis device that we know and use today. It is a story of a clinical need, colorful personalities, personal relationships, and 1 lone medical student.

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