Many newborn boys in the United States are circumcised. The American Academy of Pediatrics, while acknowledging that some advantages may be derived from neonatal circumcision, has expressed the opinion that these potential benefits are not yet demonstrated to the point at which formal advocacy of the procedure is warranted. Although the medical benefits of neonatal circumcision remain in dispute, the method used to perform the operation is well known and recognized by most urologists. The common technique involves the use of a specialized device under local anesthesia. The device assists in controlling the amount of prepuce to be removed and aids in hemostasis. The most popular of these devices in the United States are the GOMCO clamp (U.S. Patent 119180), Hollister Plastibell (U.S. Patent 3056407), and Mogen clamp (U.S. Patent 2747576). Of these, the oldest is the GOMCO clamp, which originated in Buffalo, New York. Created more than 60 years ago by Hiram S. Yellen, M.D. and Aaron A. Goldstein, the device is a model of excellence in design and innovation.

Brief Description of the GOMCO Clamp

The GOMCO clamp is composed of four parts: a bell, a base plate, an arm or yoke, and a screw nut. After the patient is anesthetized, the glans is exposed. The bell is then placed on the glans and the prepuce drawn over it. The penis and bell are passed up through the hole in the base plate. The yoke is then positioned to catch the bell under its two small studs. The screw nut is then applied so that it exerts a crushing force on the prepuce at the junction of the bell and plate. After a time, the trapped prepuce is cut away. The clamp is then dissembled. The clamping action creates a hemostatic seal along the cut edge, and no sutures are usually necessary.

Although primarily designed for newborns, larger adult sizes are available. Originally made of brass with a nickel-chrome plating, later models were fabricated of stainless steel with a chrome finish. The screw nut had a small fiberboard washer to help it seat down on the arm. Both were later replaced by a permanent autoclavable plastic washer. The fundamental design has not changed in six decades of continuous service and manufacture.

When considered from an engineering standpoint, the device is a force multiplier. The clamp is an amalgamation of two classic simple machines: the lever and the inclined plane. The arm is a lever with the fulcrum placed to yield a two-to-one mechanical advantage. The screw nut is a modified inclined plane. Its mechanical advantage is calculated as $2 \times \frac{\pi \times \text{radius of the nut divided by the distance between the threads}}{100}$. There are 32 threads per inch on the screw nut, and it has a radius of 0.5 in. This yields a further mechanical advantage of $32 \frac{\pi}{100}$, or roughly 100-fold. When these mechanical advantages are combined, they yield a 200-fold ($2 \times 100$) increase in force. The average adult can exert 40 to 100 lb of force turning the dominant wrist in a pronation-supination action to drive the screw nut. The GOMCO clamp converts this force into 8000 to 20,000 lb of hemostatic force against the prepuce.

Hiram S. Yellen, M.D. and Aaron A. Goldstein created the GOMCO clamp. Yellen, an obstetrician-gynecologist in Buffalo, New York, sought an improved method of neonatal circumcision. Goldstein was a prolific local inventor and manufacturer. They were not close friends, but may have known each other from religious or social affiliations. Friends and family recollect that Yellen was unhappy with the results of some neonatal circumcisions and believed that a better method could be found. The clamp may have been inspired when Yellen observed a levering tool used to change the solid rubber tires on a Ford Model T. These de-
VICES were not part of the original Ford Model T kit, but were later manufactured as accessories.10

THE DOCTOR AND THE INVENTOR

Hiram Samuel Yellen was born on January 25, 1894.11 The family immigrated to the United States in 1897. He grew up in Buffalo, New York, graduated from the University of Michigan in 1915, and obtained a doctor of medicine degree from the University of Buffalo Medical School in 191712,13 (Fig. 1). After an internship in Buffalo, he served in World War I as the medical officer in a machine gun battalion. After the war, he served an obstetrics and gynecology assistantship.14 From 1920 to 1941, Yellen was an attending obstetrician and gynecologist in Buffalo.14 He became a Fellow of the American College of Surgeons in 1933.14 Around this time, he developed and began to use the GOMCO clamp. A couple known to Yellen gave birth to a son in 1933 and asked him to perform the circumcision. That occasioned his first use of the clamp.13 With World War II, he rejoined the U.S. Army Medical Corps and commanded military hospitals in the European and Pacific Theatres of Operations. For his wartime services, he received the Legion of Merit and the Conspicuous Service Cross. On separation at the war’s end, he returned to Buffalo and resumed his practice. He joined the faculty of the University of Buffalo Medical School in 1949 as a volunteer faculty associate consultant.16 Except for the paper on the GOMCO clamp, Yellen had no other known publications.16 An active practitioner, he had delivered more than 5000 babies by 1958.16 Yellen never married and had no children. He was still practicing, when, at the age of 75, he died on September 2, 1969 of an intracerebral hemorrhage.11

Aaron A. Goldstein was born in Utica, New York on September 5, 1899 to a family that emigrated from Lithuania in the 1880s.17 His education and early years are not well known, but he had a strong mechanical aptitude and a keen interest in inventions and manufacturing. From 1925 to 1929, he obtained a series of patents for a wide variety of devices. The earliest of these were simple metal cuff button designs and fasteners (U.S. Patent 1529539, issued March 10, 1925; U.S. Patent 1644720, issued October 11, 1927). From 1930 onward, Goldstein’s work turned to more complex and involved inventions. He first entered the medical field with a “sterilizing holder for clinical thermometers” (U.S. Patent 1777641). In 1931, he founded his own company, GOMCO (for Goldstein Manufacturing Company)18 (Fig. 2). Although he continued to design non-medical-related devices such as a fountain pen, by 1933, most of the firm’s efforts were medical (U.S. Patent 1838542). Sometime between 1932 and 1933, he began work on the GOMCO clamp with Yellen.

FIGURE 1. Hiram S. Yellen in 1917, from page 80 of the class yearbook of the University of Buffalo Medical School. It is not known who Mrs. Norton was.

FIGURE 2. Aaron A. Goldstein circa 1930 (?).
Yellen documented the date of introduction of the first working model in 1935: “about a year ago Aaron Goldstein of this city developed a clamp which we have used in many cases.”19 The clamp was an immediate success and established the firm financially. Through the end of the 1930s, GOMCO would introduce a series of electrically powered medical aspirator and suction pumps (U.S. Patent 2261648). Like the circumcision clamp, the GOMCO pumps (models 3810, 3840, and 480, Allied Healthcare Products) were a success and are still marketed to this day. Goldstein did not live to see the further success and expansion of GOMCO. He died on Feb. 26, 1945, at the age of 45, after a coronary thrombosis.17 He was survived by his wife and two children.

CIRCUMCISION INSTRUMENTATION

The GOMCO clamp fulfilled a recognized need for a simple, safe method of circumcision. Bertwistle20 wrote in the Lancet in 1935 of a “plea for a standardized technique.” The existing methods used standard surgical clamps to crush the prepuce for hemostasis before cutting. Calhoun21 in 1936 described cross-clamping the prepuce using a pair of bone-cutting forceps. Cogswell22 offered a similar method using a Kocher or Halstead clamp: “since the majority of circumcisions are done by general practitioners, a technique is here presented that does not entail any instruments other than those present in the average physician’s instrument cabinet.” This sentiment was echoed by Torpin,23 who also advocated a thorough understanding of preputial blood vessel patterns and careful application of hemostatic pressure. These cross-clamping techniques, although economic in not requiring specialized instruments, risked injury to the glans.

Circumcision instruments available around the time of the GOMCO clamp can be divided into three groups. Acutely curved forceps with a bend of 180° or more clamped the bleeding edge of the prepuce as it was cut from the penis.24 Cross-clamping devices replicated the action of a Kocher clamp and included an attached knife blade or scissors to remove the entrapped foreskin (eg, Harris Preputome, U.S. Patent 1918700; Stadle circumcision scissors, U.S. Patent 2212133). Cap devices placed a metal bell or cap over the glans for protection against injury and to catch the prepuce between two crushing surfaces (eg, LaBreck circumcision, U.S. Patent 20764968; Elias and Lemoine circumcision instrument, U.S. Patent 2296594). Most were minor devices that were used on only a few patients by their inventors. Some, however, were locally popular. The Harris Preputome, a cross-clamping scissors and clamp, was used on more than 1000 patients in the greater Philadelphia area.25

These devices tended to be awkward and hard to use. The potential for serious complications in that preantibiotic era fostered a less than enthusiastic view of these inventions. The conservative consensus was summed up by Winfield Scott Pugh in 1935.26 Given the risk of infection and significant hemorrhage, he advised treating circumcision as a major operation, avoiding the use of “suprarenal extract” when administering local anesthesia, ligating all bleeding vessels meticulously with plain catgut suture, and avoiding all circumcision clamps and devices. These, he wrote, provided only a “false sense of security” about hemostasis, and “if you possess any of the new-fangled clamps, place them on your museum shelves and treat your bleeders with proper surgical technic.”26

RESPONSE TO THE GOMCO CLAMP

In this environment of skepticism, Yellen and Goldstein brought forth their new clamp in 1935. Yellen’s concise article fully describes the device and gives precise instructions as to its use.19 He noted the advantages of being small, light, and easy to operate without an assistant and commented that the clamp was to be applied for 5 minutes before incision. The report described 500 neonatal circumcisions without infection or hemorrhage. The paper by Brodie27 in 1939 detailed 300 cases without complications. The GOMCO clamp combined some aspects of the earlier cap devices with a levering arm. The arm displaced the screwing action away from the shaft, thereby preventing torsion of the penile skin, which can lead to an uneven result. The arm also doubled the crushing force by granting one more level of mechanical advantage.

Tens of thousands of clamps were soon sold annually, and today the device remains a steady seller.3,28 The advertising of the GOMCO clamp attests to its successful introduction. The listing for the Atlantic City, New Jersey, Annual Meeting of the American Medical Association (AMA) for 1935 has an advertisement by GOMCO touting “Dr. Yellen’s Bloodless Circumcision Clamp,” stating that the device has been “adopted by over 1,500 physicians and hospitals in the past few months” (JAMA advertisement, vol. 104, p. 52, 1935). Buoyed by this response, GOMCO mounted an exhibit of its products in the 1936 AMA Annual Meeting in Kansas City, Missouri (JAMA advertisement, vol. 106, p. 1307, 1936). It announced that “the famous line of circumcision clamps will be shown and any questions pertaining to the technique required will be answered by capable persons in charge.” For a historical perspective, at the same meeting, the new
refreshing product, decaffeinated coffee, was introduced.

THE PATENT

The GOMCO clamp was not initially patented. At that time, U.S. patents lasted for 17 years (U.S. Government Patent and Trademark Office, http://www.uspto.gov). Patents had to be filed within 1 year of the first effort to commercialize or publish details of the invention. According to the original Yellen article in 1935, the device was in production and use for more than 1 year, and thus the period to patent it had elapsed.19 Goldstein, a savvy inventor, slightly altered the styling of the clamp and sought a design patent. A design patent covers the unique or ornamental design, visible shape, and characteristics of an object. Unlike a trademark, it applies to the actual shape, form, and appearance of the item, as opposed to an image. The key test differentiating a design patent from a utility patent is that the design must be ornamental and aesthetic in purpose. If by removing the design, the function of the item is altered, a design patent cannot cover it. A series of subtle, but distinct, modifications to the appearance of the clamp were therefore introduced. The original illustrations used in the Yellen article and the 1935 advertisement in JAMA are identical (Fig. 3). The drawing in the design patent reflected the new look of the clamp. There is a smooth curved arm in place of the old right-angled one and a subtle inset cut into the base where the bell is passed.

The patent is only in the name of Aaron Goldstein (design for a bloodless circumcision clamp, U.S. Patent 119180, issued February 27, 1940). The success of the device was apparently unanticipated. Goldstein’s prior work and patents demonstrate that he was aware of the patent laws and was intent on protecting the commercial rights to his work, no matter how small. Perhaps the poor general reputation of circumcision clamps at that time made him doubt its commercial viability and hence did not lead him to seek a patent before its initial use and publication.

In conversation with friends and family in later years, Yellen is said to have never voiced regret at his not profiting from the royalties generated by the clamp.8,9 Although we can only speculate as to why he did not want to profit from the invention, it should be recalled that at the time Yellen was studying medicine, it was a hotly debated topic as to whether doctors should be involved with medical invention patents. F. E. Stewart, a member of the AMA Section of Materia Medica, Pharmacy, and Therapeutics, put forth several objections, including the principal fear of what we now know of as a conflict of interest when he wrote: “The medical inventor who has a material substance for sale will unconsciously use his best endeavor to promote the sale of his goods, rather than make it his chief object to benefit his patients who may purchase his goods. This would change the nature of medical practice from a beneficent one to a distinctly commercial one, and while legitimate business is beneficent, in one sense of the term, the physician's vocation is peculiarly philanthropic, having as its chief end the relief of human suffering, and not the acquisition of money.”29 In the subsequent discussion, it was further noted that “the Association [AMA] sets its stamp of disapproval upon the holding of a patent by a physician.” During Yellen’s training, American medical

FIGURE 3. The illustration from the GOMCO clamp design patent. In the upper right-hand corner the designation is “Des 119180.” The inset is the figure taken, with permission, from Yellen’s article.19 It is identical to the one in the JAMA advertisement of 1935.
CONCLUSIONS

The GOMCO clamp is a noteworthy urologic invention because of its longevity and functional elegance. The device is entering its 68th year of continuous use and production. When it was introduced, polio was still a scourge, tuberculosis could only be ameliorated but not cured, rickets was not uncommon, and the antibiotic era was still more than a decade away. The simplicity in appearance and use of the GOMCO clamp belies its clever design and its history. Things that are encountered routinely and function unobtrusively tend to be unappreciated because of quiet familiarity. The products of human imagination do not generate spontaneously but grow from, and reflect the character, thoughts, experiences, and dreams of, their creators.

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