History and Principles of Surgical Stapling

Introduction

From the earliest days of surgery, there was concern about the amount of time required and the extent of tissue trauma associated with certain procedures, particularly those involving the abdominal organs. Indeed, it was only in the late nineteenth century that surgeons began confidently to undertake closure of wounds in the bowel and to perform intestinal anastomoses.

Restoration of function, effective hemostasis, reduction of tissue trauma and the prevention of postoperative sepsis and other complications were primary goals.

Early Development of Mechanical Stapling Devices

Although numerous devices for closing abdominal wounds or joining organs were developed during the 1800s, it was not until 1908 that the first mechanical device using staples was demonstrated by a Hungarian surgeon, Professor Humer Hültl.

This device—designed for use in distal gastrectomy—placed two double rows of fine steel wire staples so that the stomach or duodenum could be transected, leaving a double row of staples on both sides of the transection.

The instrument was widely acclaimed even though it was heavy and the assembly of its many parts was difficult and time-consuming. The design incorporated three principles that are still used in modern internal stapling devices—B-shaped configuration of closed staples; placement of staples in double staggered rows; and use of fine wire as the staple material.

In 1924, Aladar von Petz, another Hungarian surgeon, developed an instrument for gastrointestinal anastomosis. Silver-wire staples were individually inserted in two parallel rows in one jaw of what was essentially a giant Payr clamp. The staples were formed by anvil grooves in the other jaw. Although simpler and lighter than the Hültl device, the von Petz instrument still weighed over seven pounds and was cumbersome to prepare and use. Nevertheless, the von Petz clamp received worldwide acceptance.

Another major milestone occurred in 1934, when Dr. H. Friedrich of Germany introduced the first stapling instrument to feature a replaceable, preloaded staple cartridge.

Despite the success of these and other early devices, staplers were viewed as providing only temporary closure, since they were thought to close at a necrotizing pressure. The tissue was manually inverted and secured with sutures.

Russian Contributions

During the 1940s, the USSR began the first systematic program to develop stapling instruments with the establishment of the Scientific Institute for Experimental Surgical Apparatus and Instruments in Moscow. As a result, the Russians subsequently became the leaders in the field of surgical stapling.

Their first instrument, designed for vascular surgery, was introduced in 1951. Many other devices were developed, each intended for a specific stapling application (e.g., bronchus, gastrointestinal tract) and utilizing a specific staple form, size and pattern. During a procedure the surgeon selected the appropriate type of instrument for each application.

In general, the Russian staplers were complicated; many had to be loaded by hand and assembled before each use. Some later models used preloaded cartridges.

The United States

The first stapler was introduced in the United States in 1967. The design of this reusable instrument was licensed from a Russian patent, as were many of the other early devices.

American manufacturers eventually developed staplers that were simpler, lighter and more reliable, and took over leadership in the field.

One major improvement was the disposable staple cartridge, available preloaded with staples of different sizes and patterns. The surgeon could obtain the optimal configuration for a procedure by simply inserting the appropriate reloading unit.

In 1978, ETHICON, INC. introduced the first preassembled disposable device—the PROXIMATE* disposable skin stapler. Other types of disposable instruments soon followed, including, in 1980, the PROXIMATE* ILS Intraluminal Stapler.

Most recently, "single-patient-use-reloadable" staplers have appeared. These instruments provide the convenience and potential cost savings of the preloaded, disposable types. In addition, the capability of using disposable reloading units for subsequent applications during a case results in a lower average cost per firing.

Advantages of Stapling

Clinical experience has shown that stapling of internal organs can be faster than traditional suturing techniques, hence reducing operating time. Furthermore, stapling can reduce tissue trauma by minimizing tissue handling. In addition, the availability of stapling instruments has fostered the development of procedures that were difficult with traditional techniques because of limited access.

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Many studies have shown that stapled tissue and anastomoses heal as reliably and rapidly as sutured anastomoses. Although experimental studies of the bursting strength and resistance to tension of stapled anastomoses in animals have produced equivocal results, clinical experience indicates that stapling produces reliably strong, leakproof closure.

A cautionary comment: The use of stapling, per se, does not guarantee a successful outcome of a surgical procedure. Effective and safe use of mechanical stapling devices depends upon good basic surgical technique, including clean, atraumatic dissection, careful hemostasis, attention to tissue condition and blood supply, and creation of tension-free anastomoses. "If you wouldn't sew it, don't staple it," is a maxim that is worth remembering.

Staple Configuration

Internal Staplers

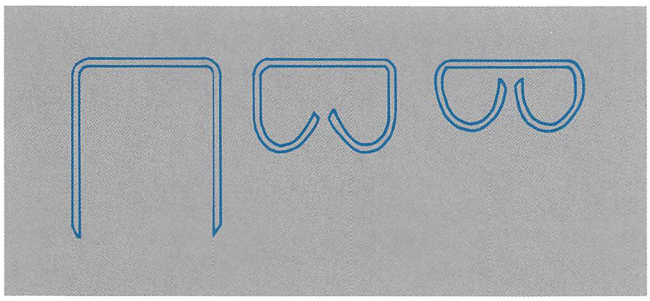

Figure 1. *Open and closed shape of staples used to approximate internal tissue.*

Internal staplers join tissue with B-shaped staples of fine stainless steel wire (Figure 1). As the instrument is fired, the open legs of the staple are driven through the tissue and formed into a B shape in a corresponding anvil indentation.

Placement of staples in a staggered double row provides effective closure of tissue. The B-shaped staple form is used because it allows small vessels to pass through the openings in and between the staples, allowing the tissue margin between the staple line and the cut edge to remain viable.

It should be noted that such staple lines are not in themselves hemostatic. When an appropriate closed staple height is used, modern staples apply a clamping pressure of approximately 8 grams/mm^2, a level that promotes normal hemostasis, yet prevents leakage.

Indeed, the slight, transient seepage along the transected edges of a stapled closure can be considered an indication of adequate blood supply to the tissue margin. The occasional frank bleeder can be controlled with electrocautery or suture ligature.

Skin Stapling

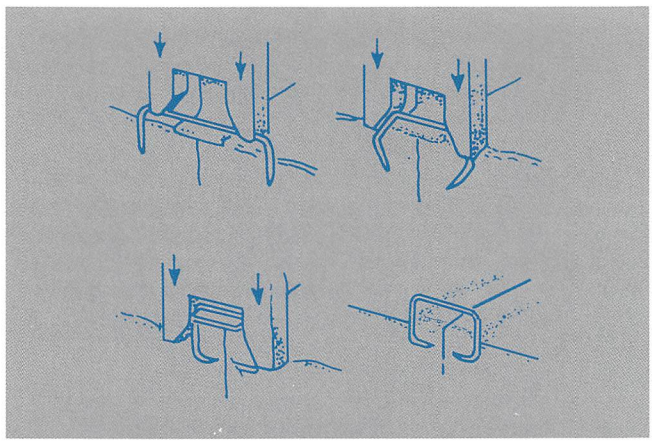

Figure 2. *Skin edges are approximated by rectangular staples.*

Staplers used to close skin form staples into a rectangular configuration that approximates and everts the edges (Figure 2). As the instrument is fired, the staple is forced against an anvil located in the nose. This action gradually bends the staple, causes it to enter the skin edges, and to assume its final configuration. This rectangular shape resists rotation and allows easy removal.

Everted Versus Inverted Closure

In some applications, tissue is joined in an everted, mucosa-to-mucosa fashion. This would seem to violate the long-held principle of using only inverted, serosa-to-serosa closure. As a result, in the early days of stapling, many surgeons manually inverted or covered everted staple lines with adjacent tissue. Clinical and experimental experience has now shown that everted staple closures heal as well as the traditional inverted closures.

Basic Types of Staplers

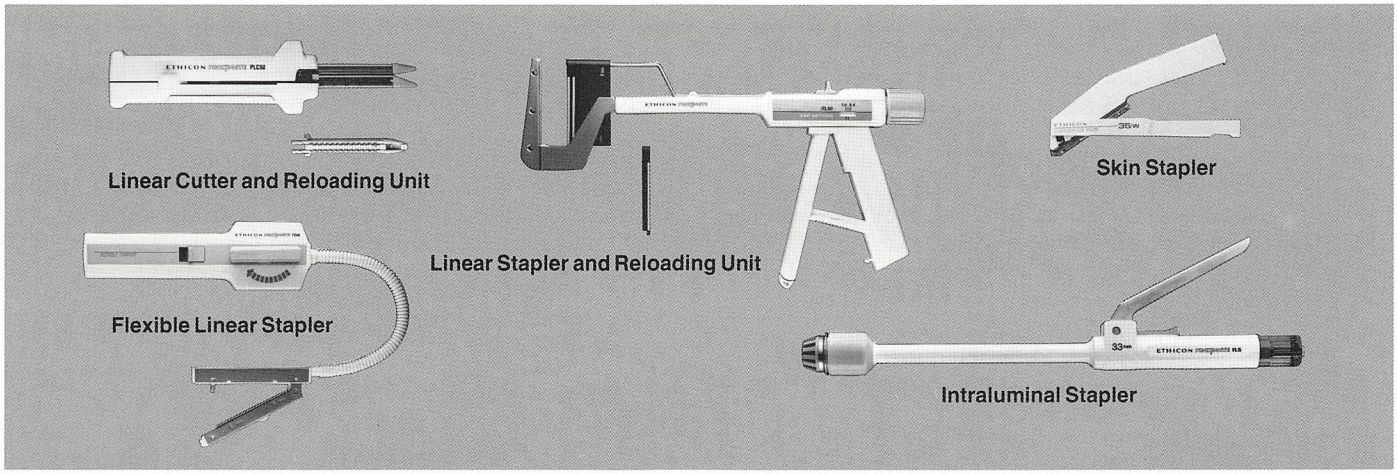

Figure 3. *Examples of basic types of surgical staplers.*

The currently available surgical staplers can be classified according to the configuration of the applied staple lines, whether they contain a knife blade for simultaneous transection of tissue, and whether they are designed for use on internal organs or for closing skin (Figure 3).

Many variations of these basic types are available for specific applications. "Special purpose" instruments usually differ in the gauge and size of staples, staple spacing and/or length of the staple line. For example, staplers intended for gastric applications employ heavier gauge staples with longer leg lengths in order to accommodate the greater tissue thickness of the stomach. Conversely, vascular staplers use finer, shorter staples applied more closely together.

Reusable, Reloadable and Disposable Designs

The earliest surgical staplers had to be cleaned, sterilized, assembled and loaded before each use. The development of disposable reloading units for use in a reusable body was a great improvement.

The introduction of preloaded, completely disposable devices provided the convenience of single patient use with a potential savings in cleaning and maintenance over reusable instruments.

The most recent design, "single-patient-use-reloadable," offers the convenience of a disposable with the potential cost-savings of a reloadable instrument.

Linear Staplers

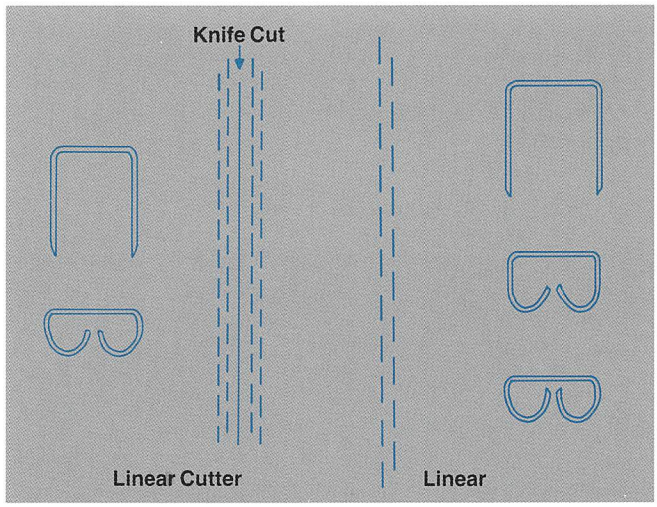

Figure 4. *Typical staple and staple line configurations of linear staplers used on internal organs.*

As the name suggests, a linear instrument places staples in one or two double staggered rows (Figure 4). It may have U- or V-shaped jaws, or separate forks (see Figure 3).

Linear staplers with parallel closing jaws usually place a single double staggered row of staplers, and do not contain a knife.

Forked staplers typically place two double staggered rows of staples, and usually (but not necessarily) contain a knife that transects the tissue between the two double rows. They are commonly called linear cutters.

The flexible linear stapler is another variation. It has a flexible shaft between the body and jaws that provides independent positioning of its components, thereby allowing more convenient access to certain operative sites, such as inside the rib cage.

NOTE: For more information on the design and operation of the PROXIMATE* Linear Stapler, Linear Cutter and Flexible Linear Stapler, see Section 1-B.

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Linear stapler applications. Linear staplers are commonly used to close internal organs prior to transection and to close the common opening or enterotomy after creation of an anastomosis with a linear cutter or intraluminal stapler. Instruments loaded with larger, heavier staples are used in gastric procedures. Linear staplers can also be used to create end-to-end anastomoses by using the technique of triangulation.

Biopsy or wedge resection of the lung, completion of a lesser fissure and closing of the bronchus are some of the thoracic procedures in which linear staplers are commonly used. When loaded with finer, smaller staples, linear staplers are used to close pulmonary vessels prior to division.

Flexible linear staplers can be used instead of the parallel-jaw type for virtually all the same applications.

Linear cutter applications. Since the linear cutter transects as it staples, this device is commonly used to transect organs, and to create side-to-side and functional end-to-end anastomoses. When used to create a gastrotomy, the linear cutter applies a double staple line on the edges, which aids in hemostasis. The linear cutter is also used for lung biopsy or wedge resection, and to complete a lesser fissure.

A linear cutter without a knife can be used where a forked stapler would be particularly convenient, such as to secure intussuscepted tissue when creating a nipple valve.

Intraluminal Staplers

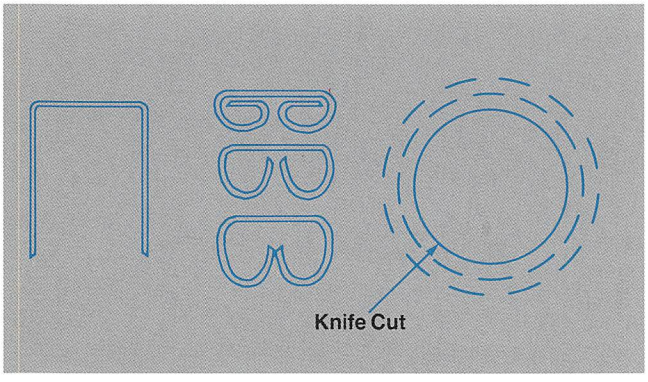

Figure 5. *Typical staple and staple line configurations of intraluminal staplers used to create anastomoses between hollow internal organs. These instruments place staples and simultaneously cut a uniform stoma in the joined organs.*

The intraluminal type of instrument places staples in a double staggered row but in a circular configuration (Figure 5). As the instrument is fired, the staples are driven through the tissue; simultaneously a circular knife cuts a uniform stoma in the joined tissue.

The round head of the intraluminal stapler (see Figure 3) is inserted into the lumina of the organs to be joined through an enterotomy or, for low anterior resections, through the dilated anus. Intraluminal staplers are available with various head diameters, permitting matching of instrument size to organ lumen.

Intraluminal stapler applications. This type of instrument has application for inverted end-to-end, end-to-side and side-to-side anastomosis throughout the alimentary tract, from the esophagus to the rectum.

NOTE: For more information on the design and operation of the PROXIMATE* ILS Intraluminal Stapler, see Section 1-B.

Skin Staplers

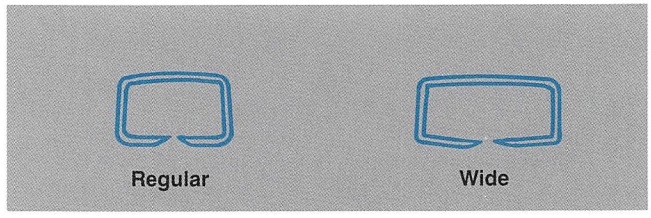

Figure 6. *Typical configurations of staples used to close the skin.*

Skin staplers are used to apply staples, one at a time, across the junction of skin edges, in a configuration entirely different from that used to close internal tissue. In order to approximate and evert the edges of the incision, and to allow easy removal postoperatively, the staples are formed into a rectangular shape (Figure 6). This form resists rotation, yet does not unduly compress the tissue, thereby providing good cosmetic results. The space between the staple crown and skin surface minimizes cross-hatching marks during healing and also facilitates removal.

Skin staplers are generally supplied preloaded with varying numbers (e.g., 15, 25, 35 or 55) of regular or wide staples (see Figure 6). The length of the incision to be closed usually dictates the most appropriate stapler.

Skin stapler applications. Intended for routine skin closure in a wide variety of operative procedures, skin staplers can be used virtually anywhere, regardless of the contour of the wound or incision. They are also used to secure skin grafts and to close skin lacerations in the emergency department.

NOTE: For more information on the design and operation of PROXIMATE* disposable skin staplers, see Section 1-B.

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