

LAPAROSCOPIC STERILIZATION
 WITH THE SPRING CLIP:
 INSTRUMENTATION
 DEVELOPMENT AND
 CURRENT CLINICAL
 EXPERIENCE

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Laparoscopic sterilization with the spring clip: Instrumentation development and current clinical experience

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Since the original spring clip sterilization studies were reported, a number of clinically important modifications to the spring clip and applicator have been developed. The spring-loaded clip, manufactured by Richard Wolf Medical Instruments Corporation of Chicago, Illinois, and Rocket of London, Inc., London, England, and New York, New York can be applied with either a one- or two-incision applicator and the clips and applicators currently available incorporate improvements to the original prototypes in design, manufacture, and quality control. The two-incision applicator is associated with significantly fewer misapplications and the high pregnancy rates reported with the original clip and applicator have not occurred with the current designs. Comparative studies between the clip and band have revealed less operative bleeding and pain associated with the clip. The method is appropriate to all women requesting sterilization but especially to those in the younger age group who may subsequently request reversal because of divorce and remarriage (AM J OBSTET. GYNECOL 135:1016, 1979)

IN 1973, THE FIRST HUMAN STUDY using a spring-loaded clip and a one-incision laparoscopic clip applicator was published.¹ A number of clinical studies have subsequently been reported. In addition, two-incision clip applicators have been designed² and the original one-incision laparoscopic instrument has been improved. Because the early clinical data, using prototype clips and applicators, do not completely apply to the instruments currently being distributed, we would like

to record the development and current clinical status of these instruments.

History of experiments

The first human sterilization by spring-loaded clip was performed in September, 1972,¹ after a research program of animal studies funded by the Agency for International Development and the Rockefeller Foundation. The prototype one-incision applicator and clips were then assessed in an international trial and the results of this prospective collaborative study were reported with a one-year follow-up.³ The two-puncture applicator was developed in the United Kingdom² and the design of the clip improved. This instrument (Samaritan clip applicator) and the modified clips were evaluated in a multicenter study in the United Kingdom.⁴

A number of additional prospective random-distribution studies comparing the original prototype clip and applicator to coagulation^{5, 6} and the two-incision

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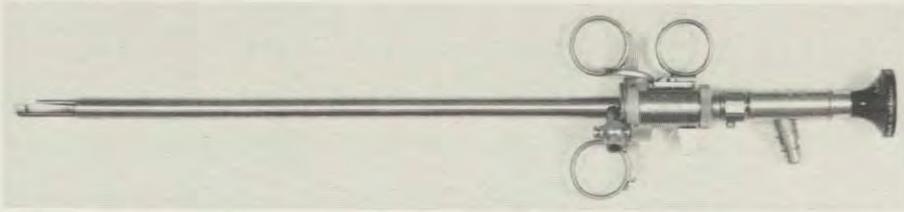


Fig. 1. One-puncture clip applicator with fixed optics. (Richard Wolf Medical Instruments Corporation).

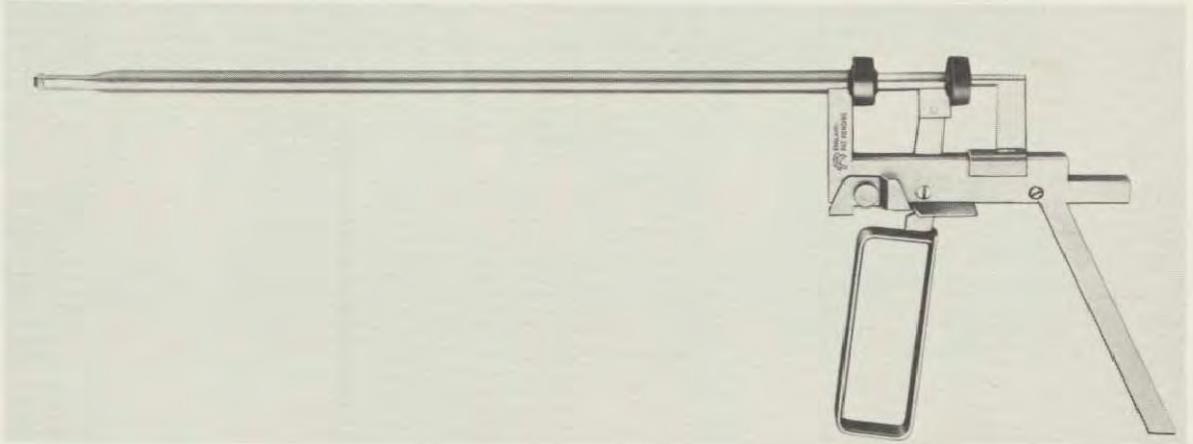


Fig. 2. Two-puncture clip applicator (Samaritan clip applicator, Rocket of London, Inc.).

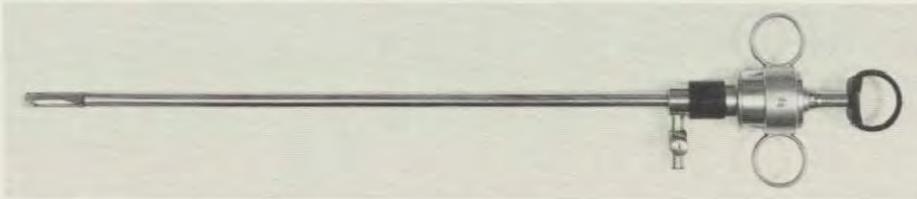


Fig. 3. Two-puncture clip applicator (Richard Wolf Medical Instruments Corporation).

clip applicator and modified clips to the silicone rubber band have been undertaken.⁷

History of applicator design

The original clip and applicator were designed by Hulka and Clemens. This one-puncture applicator with fixed optics is now commercially available after improvements by Richard Wolf Medical Instruments Corporation of Chicago, Illinois.

A two-puncture applicator was developed by Lieberman² and Rocket of London, Inc., London, England, and New York, New York. Hulka also designed a two-puncture applicator activated by one thumb rod, utilizing mechanically interlocking internal springs to achieve the complex sequences required for clip application and release. This design, like the one-puncture Richard Wolf Medical Instruments Corporation and the two-puncture Samaritan applicators, underwent

extensive clinical testing before being released for distribution in 1977.

The currently available clip applicator is shown in Figs. 1 to 5.

History of clip design

The original design. The first 200 clips were designed and assembled by Clemens. An additional 2,000 clips were then manufactured and distributed by KLI* until weak springs were detected in clips removed from women who became pregnant after sterilization (Fig. 6). The remaining clips were recalled and the manufacture of these experimental clips was undertaken by IPAS.† These clips were distributed to investigators until 1977, when four additional pregnancies led to the

*KLI, Inc., Iveyland, Pennsylvania.

†International Pregnancy Advisory Service, Chapel Hill, North Carolina.

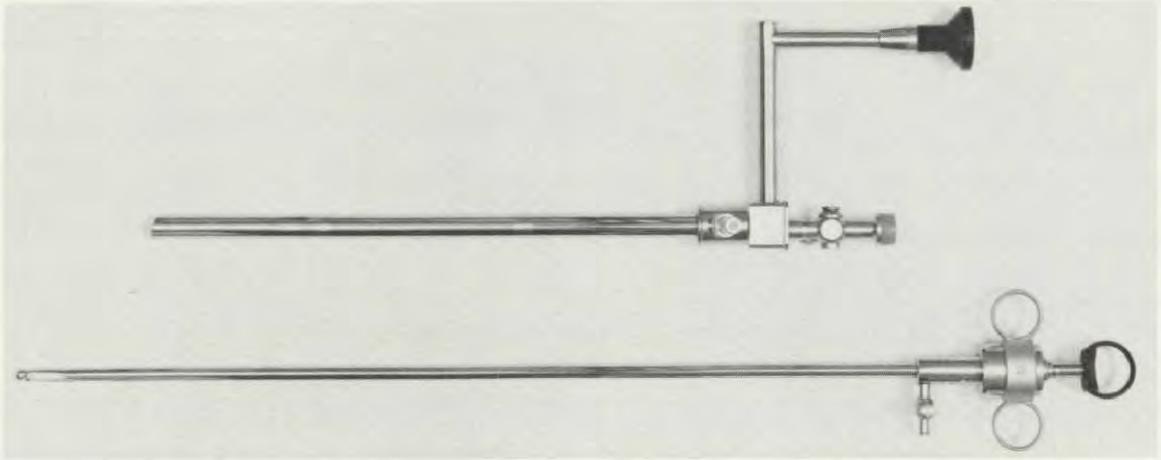


Fig. 4. Same applicator as in Fig. 3, lengthened for one-puncture operating laparoscope (Richard Wolf Medical Instruments Corporation).

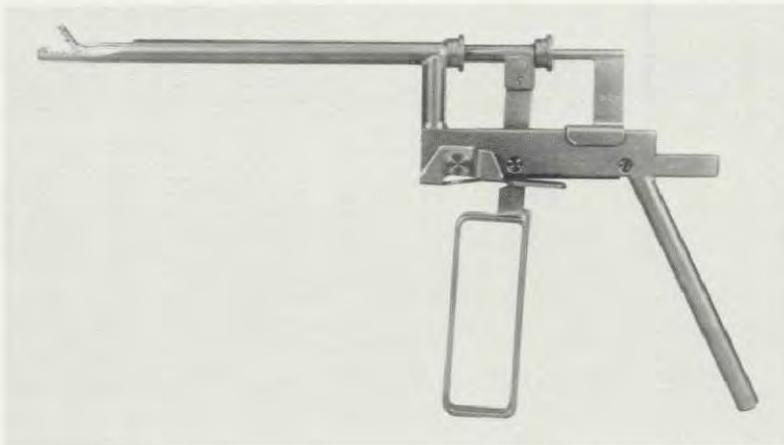


Fig. 5. Minilap clip applicator (Samaritan design, Rocket of London, Inc.).

detection of an occasional $\frac{5}{1,000}$ inch gap between the upper and lower jaws in some clips (Fig. 7). Because these gaps, originally felt to be within manufacturing tolerances, allowed recanalization to occur, the manufacturing specifications were restricted to permit no tolerance in the fit of the upper and lower jaws. Examination of the commercially available clips produced by Richard Wolf Medical Instruments Corporation and Rocket of London, Inc., did not reveal gaps to be present.

Modified design. The original design had a molded silicone rubber end, designed to present a smooth surface to the peritoneum, but was difficult to manufacture and assemble. The clip was redesigned to eliminate the silicone rubber and simplify assembly (Fig. 8). This modified clip is manufactured by both Rocket of London, Inc., and Richard Wolf Medical Instruments Corporation and is the only spring-loaded clip currently available.

Current clinical experience

As of 1977, over 2,000 patients have undergone clip sterilization in the United States, including the original groups studied in 1972 to 1975. Overseas, an additional 1,500 patients have been studied prospectively. All the overseas studies and initial United States groups used the original clip design, which is no longer available. The highest pregnancy rates were reported from this group,³ using the clip design and a fixed-optics, one-puncture applicator.

In England, over 750 patients have been studied prospectively by Lieberman and associates since 1975, using the modified clip design and the two-puncture applicator. A pregnancy rate of 1.8/1,000 using the improved clip and two punctures has been reported.

In random-assignment, single-blind comparative studies, the original clips have been compared to electrocoagulation.^{5, 6} Lieberman and colleagues⁷ compared the modified clip to the silicone rubber band. No

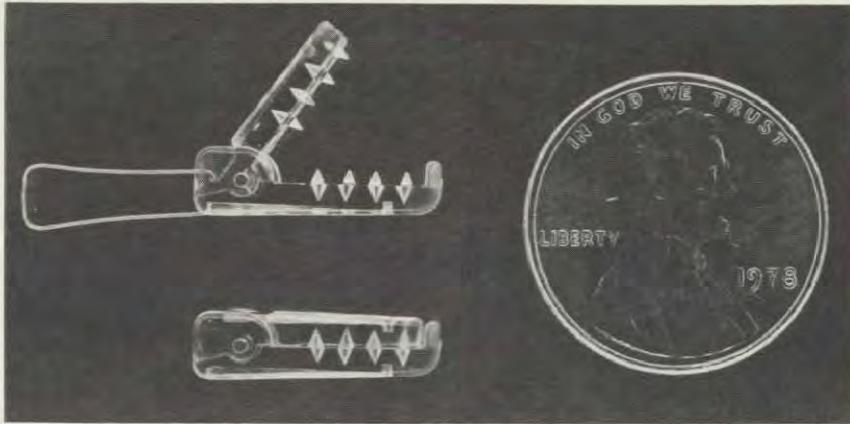


Fig. 8. Modified spring clips. The silicone rubber cap with its protective effect on the end of the clip was replaced by redesigning the lower jaw of the clip, simplifying manufacturing and assembly and minimizing the chance of manufacturing error.

reversal.⁹ The greatest number of requests for reversal of sterilization come from women in their late 20s or early 30s who underwent elective sterilization in their middle to late 20s after having completed their family with their first husband. Divorce and remarriage (occurring in 25% of United States couples today) led these women to seek reversal. It would be inadvisable to decline requests for sterilization by all women in this category just because 1% of these might seek reversal. It would seem more appropriate to offer them a permanent method of sterilization which destroys the least amount of tubal tissue, thus maintaining the highest potential for reversibility.

To date, actual human experience of clip excision and anastomosis by microsurgery has been small but encouraging. To our knowledge, eight women have undergone this procedure. Two women resumed oral contraception after surgery. Of the six remaining women, four have had intrauterine pregnancies. There have been, as yet, no ectopic pregnancies following reversal.

Addendum

As of June, 1979, of 13 women who have had anastomoses after clip sterilization and who wanted pregnancy, all have had intrauterine pregnancies.

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Fig. 6. Original spring clip. The silicone rubber cap covering the end of the spring presented difficulties in manufacturing and assembling the clip, resulting in weakening of the spring.

Table I. Summary of clip use: 1977

	<i>Original Clip</i>	<i>Improved Clip</i>
Prospective studies	2,191	655
Routine procedures	500	6,000*
Total	2,691	6,655

Grand total = 9,346.

*Estimated.

pregnancies occurred in any of these study groups but the clip was associated with less operative bleeding and pain.

In addition to these prospective studies, it is estimated that an additional 3,000 patients have recently undergone clip sterilization in England and Canada, and at least a similar number in Europe. These estimates are summarized in Table I.

Safety

The original one-puncture laparoscopic clip applicator was associated with numerous mechanical problems in separating the clip from the applicator, with consequent tearing of the tube as the applicator was removed.³ The applicators currently available have been greatly improved. There have been no reports of mesosalpingeal hemorrhage with the clips in contrast to the 2% hemorrhage rate reported with the silicone rubber band^{10, 11} and electrocoagulation and division of the tube.¹¹ Since the use of an electric current is avoided no skin or bowel burns have occurred.

Reversibility

Although the original research objective leading to the development of the spring clip was for "Simpler and More Reversible Sterilization," (Agency for International Development grant title), the objective of re-

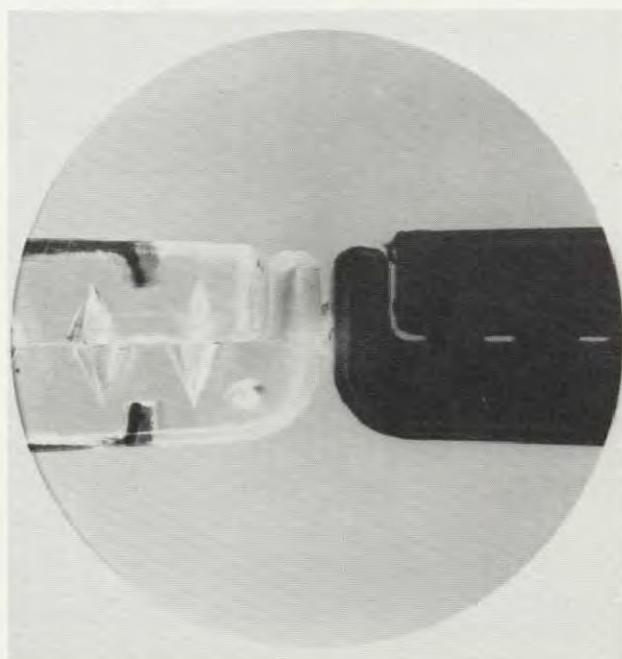


Fig. 7. Original prototype (dark) compared to current manufactured clip (light). The prototype clip photograph was removed from a pathology specimen where pregnancy had occurred. A $\frac{3}{1,000}$ inch gap is seen due to variation in tolerances of the plastic mold. The current manufactured clips have zero gap tolerance, as seen in the magnified view.

versibility, by means of intraluminal tubal devices, was abandoned in favor of a safe, permanent, nonelectric method of tubal occlusion. The clip was 3 mm wide and was designed to be large and strong enough to positively occlude pig oviducts⁸ yet small enough for laparoscopic application. Recent interest in reversibility has resulted from the popularity of female sterilization. In the United States, 600,000 women annually undergo elective tubal sterilization. A recent survey has estimated that about 1.0% of these women will seek

