Widespread demand for simple, effective, and inexpensive female sterilization procedures which can be performed on an outpatient basis has encouraged both medical practitioners and researchers to evaluate existing methods of tubal occlusion and to develop new ones. Recent research has concentrated on:

• modification and improvement of older methods of tubal occlusion, such as ligation and fulguration;
• application of clips and bands to the tubes;
• introduction of chemicals and plugs into the tubes.

Invention of equipment such as endoscopes and specially-tailored cannulae which now permit a variety of approaches to the tubes has contributed to the development of new methods of tubal occlusion. As a result, the traditional large abdominal incision for sterilization (laparotomy) has been replaced by a tiny abdominal incision (minilaparotomy) or puncture (laparoscopy) and by transvaginal (colpotomy, culdoscopy) or transcervical approaches (hysteroscopy, blind delivery) which require no incision.

These approaches permit occlusion of any part of the fallopian tube. For example, the infundibulum (distal, fimbrial end of the tube) can be excised, buried, plugged, or capped; the ampulla or isthmus (middle of the tube) can be tied, cut, excised, fulgurated, clipped, banded, or buried; and the interstitial portion of the tube (near the uterotubal junction) can be coagulated or blocked with chemicals or plugs (see Fig. 1).

The choice of approach and the method of tubal occlusion often depend upon the physician's prior training, degree of skill, and knowledge regarding the safety and effectiveness of the various methods. Endoscopic approaches, for example, generally require more training and skill than other approaches, while most transcervical approaches are still considered experimental and are less effective than those performed by other approaches. Likewise, cautery and some chemicals are associated with a higher risk of damage to structures adjacent to the tubes than ligation, clips, bands, or plugs. Methods performed through the vaginal cul-de-sac (e.g. colpotomy) are associated with a higher rate of infection than abdominal approaches. Finally, methods which interrupt (cut through) the tubes are associated with higher morbidity (e.g. bleeding) than those in which tube continuity is maintained.

Potential for reversibility may be a factor in selecting a particular method of tubal occlusion. Experience in both developing and developed countries indicates that most women desiring sterilization prefer a permanent method, but many, particularly in the younger age groups, might welcome a means of sterilization that could be reversed. Although some plugs offer potential for reversibility because theoretically they may be withdrawn from the tube, reversibility has not been adequately assessed by tests in humans. In animal experiments, the tubal epithelium is sometimes destroyed beyond repair when plugs are removed. Clips or bands, on the other hand, destroy a narrow segment of tube, but there is virtually no experience with reversibility. Reversal would require a second operation to cut out the crushed section of tube and...
anastomose (join) the two remaining ends. Ligation is the procedure most often reversed successfully, but the same operative procedure for anastomosis is required. The use of cautery makes reversibility virtually impossible to achieve because a large segment of tube is destroyed. Likewise, most chemical methods are not reversible because the epithelium is permanently damaged.

Comparisons of the effectiveness of the various tubal occlusion procedures are difficult to make. In many cases, there are insufficient data and investigators do not consider life tables or the Pearl Index* in computing failure rates (see Population Reports, Series H, Number 4, January 1976). Thus, there is no basis for comparison among studies and only estimates can be made from published information.

While great strides in knowledge about tubal physiology and in biomedical engineering have been made, more research is needed to determine the practicality, effectiveness, and applicability of the newer methods of tubal occlusion, such as use of chemicals. Until then, traditional methods (e.g., ligation) are likely to remain popular.

### LIGATION

Tubal ligation (tying the fallopian tubes) to prevent passage of sperm and ovum is one of the oldest forms of tubal occlusion. Nearly a century of experience with this method has eliminated the least effective techniques and the outcome of most of those remaining is now predictable. Traditionally performed through a large 10 cm (3-4 inches) abdominal incision (laparotomy), today the tubes are ligated through a 2.5 cm abdominal incision (minilaparotomy) or a 3-5 cm vaginal incision (colpotomy). The amount of skill required to perform ligation, the approach used, and effectiveness vary according to the type of ligation procedure performed (see Table 1).

<table>
<thead>
<tr>
<th>Major Advantages</th>
<th>Major Disadvantage</th>
</tr>
</thead>
<tbody>
<tr>
<td>• only average skill is required for most procedures;</td>
<td>• low morbidity;</td>
</tr>
<tr>
<td>• only simple instrumentation is required;</td>
<td>• high failure rate (up to 20 percent);</td>
</tr>
<tr>
<td>• morbidity is usually low.</td>
<td></td>
</tr>
</tbody>
</table>

*Ligation techniques can be classified into one or a combination of the following categories according to the extent of action on the fallopian tubes:

- simple ligation;
- ligation and crushing;
- ligation, division, and burial;
- ligation and resection;
- ligation, resection, and burial.

**SIMPLE LIGATION.** Simple ligation is seldom performed today because of the high failure rate associated with its use. First proposed by Lungren (USA) in 1860, simple ligation preceded other ligation methods by almost two decades. In 1895, Dührensen (The Netherlands) used a double ligature on each tube in an effort to prevent the failures associated with single ligatures (119). However, subsequent investigations have shown that hydrosalphinx (collection of fluid) frequently develops between the two ligatures and, as a result, reports of double ligation have disappeared from the literature. In one of the few recent reports on simple ligation, Purandare (India), who performs colpotomy for interval sterilization and laparotomy for pelvic sterilization, uses nonabsorbable linen thread to tie the tubes at the junction of the lateral one-third and medial two-thirds of the tubes. Purandare recognizes the possibility of failure with his technique and backs up the procedure by abortion. He has not recently published failure rates or the percentage of abortions required among the total number of procedures performed.

<table>
<thead>
<tr>
<th>Major Advantages</th>
<th>Major Disadvantage</th>
</tr>
</thead>
<tbody>
<tr>
<td>• simple to perform;</td>
<td>• high failure rate (up to 20 percent);</td>
</tr>
<tr>
<td>• low morbidity;</td>
<td></td>
</tr>
<tr>
<td>• high potential for reversibility.</td>
<td></td>
</tr>
</tbody>
</table>

**Ligation and Crushing**

**MADLENER TECHNIQUE.** This technique, first reported in 1919, is easier to perform and results in less bleeding than more extensive ligation procedures (144). However, like simple ligation, the failure rate is higher than for those techniques in which tubal continuity is interrupted. In the Madlener technique, the midsection of the tube is picked up to form a loop, and the base of the loop is crushed with a clamp and ligated with nonabsorbable suture material (e.g., silk, cotton) (see Fig. 2). In a modification of this technique adopted by some practitioners, the top of the loop is cut off.
Like simple ligation, the Madlener technique may be performed by the abdominal or vaginal route. Recently its performance on an outpatient basis was reported in Taiwan where Ou uses a "one finger technique" which involves inserting a finger through a minilaparotomy incision (2.5 cm) to bring the tube onto the abdomen (102). However, Chen (Taiwan) reports that the tubes are sometimes difficult to locate by this blind technique (12). The Madlener technique has also been performed via laparoscopy using a prolene loop to ligate the tubes, but this procedure requires endoscopic expertise and a high degree of skill to manipulate the instruments (39).

Failures following Madlener ligation are probably due to the reanastomosis and regeneration of tissue at the crushed portion of tube following penetration by the ligature. Thus tubal patency is restored. For this reason, the International Planned Parenthood Federation Panel of Experts on Male and Female Sterilization (Bombay, 1973) recommended that the tube not be crushed and that use of a nonabsorbable ligature alone would yield better results (67).

The failure rate varies according to the approach used: It remains low with laparotomy or culdoscopy, but increases with colpotomy (10). The reason for this difference has not been explained. Accounting for all approaches, investigators have reported failure rates ranging from 1-2 percent (43, 52, 90).

<table>
<thead>
<tr>
<th>Major Advantages</th>
<th>Major Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low morbidity;</td>
<td>Variable failure rate (depending on approach used).</td>
</tr>
<tr>
<td>Simple to perform;</td>
<td></td>
</tr>
<tr>
<td>May be performed by a variety of approaches.</td>
<td></td>
</tr>
</tbody>
</table>

**Ligation, Division, and Burial**

Ligation procedures which involve division of the tube and burial of the stumps are nearly 100 percent effective, but are slightly more difficult to perform than ligation and division or ligation and resection. In addition, the more extensive a tubal occlusion procedure (e.g., those requiring burial) is, the higher the rate of morbidity, such as bleeding. Among the techniques in use today are those of Irving and Wood.

**IRVING TECHNIQUE.** Although it requires more time to perform than most ligation procedures, Irving's technique is highly effective. As he reported in 1924, the tubes are divided between two absorbable ligatures and the proximal stump is buried in the uterine myometrium (58) (see Fig. 2).

In 1950, Irving reported no failures among 814 women sterilized by his ligation procedure (59). There were also no failures among 1,056 procedures in a literature review by Garb (43), and only one failure (0.5 percent) in 1,966 procedures reviewed by Merz (90).

<table>
<thead>
<tr>
<th>Major Advantage</th>
<th>Major Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nearly 100 percent effective.</td>
<td>Performed by laparotomy requiring abdominal incision and hospitalization;</td>
</tr>
<tr>
<td></td>
<td>More complicated than many ligation procedures;</td>
</tr>
<tr>
<td></td>
<td>Poor potential for reversibility.</td>
</tr>
</tbody>
</table>

**WOOD TECHNIQUE.** A microsurgical technique (performed under magnification) of ligation, division, and burial—first reported by Wood (Australia) in 1973—requires above-average skill, but it is highly effective and potentially reversible. The procedure, termed "atraumatic midampullary sterilization," involves division of the ampullary portion of the tube, ligation of the cut ends with absorbable suture, and burial of the medial stump in a pocket cut in the mesosalpinx (portion of the peritoneum enclosing the tube).

Thus far the technique has only been used in Australia with a few patients. However, there have been no failures among 18 women, most of whom have been followed-up for two years (151). Although reversal has not yet been attempted, the Wood technique is potentially reversible because there is:

- No excision of the tube;
- Minimal interference with the blood and nerve supply to the tube;
- Treatment of the ampulla (widest part of the tube).

<table>
<thead>
<tr>
<th>Major Advantages</th>
<th>Major Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potentially highly effective (data inadequate to date);</td>
<td>Above average skill required;</td>
</tr>
<tr>
<td>Potentially reversible.</td>
<td></td>
</tr>
</tbody>
</table>

**Ligation and Resection**

Procedures involving ligation and resection (removal) of a segment of tubal are easier to perform and, therefore, are more widely used than those that require burial of the stumps. Many techniques have been developed since Fritch first proposed ligation and resection in 1898. While some techniques have virtually disappeared from current practice, among those still reported in the literature are:

- Salpingectomy;
- Pomeroy;
- Fimbriectomy.

**SALPINGECTOMY.** Of the ligation and resection techniques, salpingectomy—removal of the tube distal to a nonabsorbable suture placed near the uterus—is least often performed. Because the procedure is extensive, it offers little chance of reversibility and is associated with higher morbidity (e.g., bleeding) than many other ligation
<table>
<thead>
<tr>
<th>Method</th>
<th>Part of Tube Treated</th>
<th>Possible Approaches</th>
<th>Potential for Reversibility</th>
<th>Done with Standard Equipment</th>
<th>Degree of Skill Required</th>
<th>In Experimental Stage</th>
<th>Cost</th>
<th>Range of Failure Rate</th>
<th>Incidence of Morbidity</th>
<th>Possible as Outpatient Procedure</th>
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<tr>
<td>LIGATION</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<td>yes</td>
<td>yes</td>
<td>above average</td>
<td>no</td>
<td>high**</td>
<td>(higher when performed by culdoscopy)</td>
<td>low</td>
<td>no</td>
</tr>
<tr>
<td></td>
<td></td>
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<td>yes</td>
<td>yes</td>
<td>above average</td>
<td>no</td>
<td>high**</td>
<td>nil</td>
<td>low</td>
<td>yes</td>
</tr>
<tr>
<td></td>
<td></td>
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<td>no</td>
<td>high</td>
<td>yes</td>
<td>high*</td>
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<td>low</td>
<td>yes</td>
</tr>
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<td></td>
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<td>low</td>
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<td>above average</td>
<td>no</td>
<td>high**</td>
<td>nil</td>
<td>low</td>
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</tr>
<tr>
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<td></td>
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<td>yes</td>
<td>above average</td>
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<td>high**</td>
<td>nil</td>
<td>low</td>
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<td>no</td>
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<td>nil</td>
<td>low</td>
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<td></td>
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<td>yes</td>
<td>above average</td>
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<td>high**</td>
<td>nil</td>
<td>low</td>
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<tr>
<td></td>
<td></td>
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<td>low</td>
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<td>(higher when performed by colpotomy)</td>
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<tr>
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<td>no</td>
<td>high**</td>
<td>(higher when performed by colpotomy)</td>
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<td>no</td>
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<td>0.1-2</td>
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<td>no</td>
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<td>0.1-2</td>
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<tr>
<td>coagulate &amp; divide</td>
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<td>coagulate &amp; excise</td>
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<td>Spring-loaded</td>
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<td>no</td>
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<td>0.2-0.6</td>
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<td>high**</td>
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<td>low</td>
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<td></td>
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<td>high*</td>
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<td>low</td>
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<td></td>
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<td>Falope Ring™</td>
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<td>minilaparotomy</td>
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<td>high</td>
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<td>high*</td>
<td>nil</td>
<td>low</td>
<td>yes</td>
</tr>
</tbody>
</table>
procedures. It is performed via the abdominal or vaginal routes.

In 1973, Stoot (The Netherlands) reported combining salpingectomy and cautery via colpotomy. Two linen sutures were tied around the tube close to the uterus. The more distal suture was also tied around the mesosalpinx. The tube was then cut and the remaining stump cauterized. Hysterosalpingograms performed three months following the procedure showed one tube was patent in two (1.9 percent) of 106 women (140). However, in a previous review of the literature, Garb (USA) found that investigators reported no failures following salpingectomy (43).

**Major Advantages**  
- effective (0-1.9 percent failures);  
- can be performed by either abdominal or vaginal routes.

**POMEROY TECHNIQUE.** The Pomeroy technique of tubal ligation is the most frequently performed of all ligation techniques. Although Pomeroy developed this technique in the early 20th century, it was not until after his death that a description of it was published by his colleagues (7). The technique's simplicity and high degree of effectiveness have made it popular in all countries. The technique requires picking up the tube near the midportion to form a loop, ligating the base of the loop with absorbable suture, and cutting off (resecting) the top of the loop. As the suture material is absorbed, the ends of the tube pull apart (128) (see Fig. 2).

The IPPF Panel of Experts recommended the Pomeroy technique for tubal ligation, using traditional abdominal or vaginal approaches (62). For many years, the technique has been the procedure of choice in the immediate periparum at which time it is performed via laparotomy. For interval sterilization, Pomeroy ligation is performed via laparotomy, colpotomy, or culdoscopy, and recently by minilaparotomy and laparoscopy.

Clark, Loeffler, Greene, and Alexander have described Pomeroy ligation via laparoscopy whereby the tube is either tied within the abdomen or brought out through the abdominal puncture site for ligation (2, 14, 45, 81). However, the procedure is complicated, thus making this approach less attractive than simpler ones, such as minilaparotomy.

Although the usual failure rate for Pomeroy ligation is low (0-0.4 percent) (43, 90, 110, 152), some investigators have reported failure rates ranging from 2.5 to 5 percent when the technique is performed at the time of cesarean section (43, 103, 110). No account has been given for the high failure rate when the technique is used at this time. However, in 1970 Husbands reported that, among his patients, the failure rate for the procedure performed at cesarean section is comparable to that for interval Pomeroy ligation. He reported one failure (0.2 percent) in 400 patients, 202 of whom were followed up for three years (57).
FIMBRIECTOMY. Fimbriectomy, removal of the distal (fimbrial) end of the tube, can be easily performed by the vaginal route and is highly effective as an interval procedure. Developed in 1935 by Kroener and reported in 1959 by his son, the technique involves placement of a double silk ligature near the distal one-third of tube and excision of the fimbrial end (see Fig. 2). Despite treatment of the distal part of the tube, there is no interference with the ovarian blood supply.

Fimbriectomy for interval sterilization is associated with a low failure rate. For example, Kroener encountered no failures among 145 women followed up for a minimum of six years (107).

Although fimbriectomy may be performed either through the abdomen or vagina, the IPPF Panel of Experts favored the vaginal route as an interval procedure or following vaginal abortion because only the distal end of the tube needs to be exposed. However, the Panel stated it should only be performed when a nonreversible method is desired (67).

Uchida, well known for his own tubal ligation technique, has also developed a modification of the Kroener technique to prevent failures from recanalization associated with postpartum fimbriectomy. In the Uchida technique, the cut distal end of the tube is covered with serosa (a thin membrane), thereby providing an extra block to sperm or ova (145,146). Using this technique, Uchida encountered no failures in 405 postpartum fimbriectomies and no failures in 120 fimbriectomies performed following cesarean section (175).

Major Advantages
- nearly 100 percent effective as interval procedure;
- easily performed via vaginal route (also possible via the abdominal route).

Major Disadvantage
- less effective when performed abdominally postpartum.

UCHIDA TECHNIQUE. The Uchida technique of tubal occlusion is often performed in Japan where it proved to be effective. The technique is also performed in some other countries (e.g., USA), but on a more limited scale.

Uchida (Japan) developed his technique of tubal ligation, resection, and burial in the mid-1940s. It requires that the tube be brought out onto the abdomen through a small 1 cm or less suprapubic incision (minilaparotomy). Epinephrine-saline solution (1:1,000) is injected beneath the serosa in the ampulla of the tube which produces local vascular spasm and ballooning of the mesosalpinx, thus separating the serosal surface from the muscular portion of the tube. The serosa is incised and stripped back, a 5 cm segment of the proximal tube severed, the short stump ligated with nonabsorbable suture, and a segment of tube removed. The ligated stump automatically bury themselves beneath the serosa. The edge of the serosal incision is then gathered around the distal end of tube and tied in a purse-string ligature so that the tube is left projecting into the abdominal cavity (145, 146) (see Fig. 2). Using his technique, Uchida claims he has seen no failures in 21,000 cases, though many patients have not been followed up after tubal ligation.

Major Advantages
- highly effective.
- more complicated to perform than most ligation procedures.

Fulguration (burning a segment of tube) is a tubal occlusion method used frequently in both developed and developing countries during the past 15 years. In some countries, such as the USA, it has become more prevalent than ligation for accomplishing interval sterilization (see Table 1). It is usually performed via an endoscope (a viewing scope) inserted into the abdomen (laparoscopy) or uterus (hysteroscopy), or through the vaginal cul-de-sac (culdoscopy). Using a special instrument (e.g., grasping forceps, probe), burning heat is applied to a small point on or within the tube by a concentration of electrical current. However, to date, there is no standardization of kind and amount of current or length of time it must be applied in order to destroy the tubal lumen.
Table 2—Failures Following Laparoscopic Fulguration of the Fallopian Tubes in Selected Studies, 1973-1976

<table>
<thead>
<tr>
<th>Author &amp; Date</th>
<th>Reference Number</th>
<th>Number of Patients</th>
<th>Technique of Tubal Occlusion</th>
<th>Failures Number</th>
<th>Percent</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edgerton 1974</td>
<td>27</td>
<td>2,018</td>
<td>coagulation, division, and excision</td>
<td>12</td>
<td>0.6</td>
<td>9 luteal phase pregnancies*</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3</td>
<td>2.0</td>
<td>3 operator errors</td>
</tr>
<tr>
<td>El-Serour 1975</td>
<td>28</td>
<td>82</td>
<td>coagulation and division</td>
<td>70</td>
<td>10.0</td>
<td>operator error</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>coagulation only</td>
<td>3</td>
<td>2.0</td>
<td>recanalization</td>
</tr>
<tr>
<td>Wheelless 1973 &amp; 1976</td>
<td>149,150</td>
<td>1,000</td>
<td>coagulation only</td>
<td>11</td>
<td>1.1</td>
<td>1 luteal phase pregnancy*</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>coagulation, division and recoagulation of the cut ends</td>
<td>1</td>
<td>0.1</td>
<td></td>
</tr>
<tr>
<td>Yuzpe 1974</td>
<td>158</td>
<td>335</td>
<td>coagulation only</td>
<td>0**</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

*Procedure performed during luteal rather than proliferative phase of the menstrual cycle at which time patient was pregnant.
**No failures occurred following use of bipolar equipment.

Major Advantages

- effective;
- outpatient procedure;
- does not require large abdominal incision.

Major Disadvantages

- risk of burns and perforation injury to adjacent structures;
- special equipment required (electrical source, fulguration equipment);
- equipment difficult to maintain.

Laparoscopic Fulguration

Of all fulguration approaches, laparoscopy is the most popular because in the hands of a properly trained physician, it is not only quick but also highly effective. Laparoscopy was first proposed as an approach to tubal occlusion by E.T. Anderson (USA) in 1937 (4) and described by Power and Barnes (USA) in 1941 (111). Although the technique was improved by Palmer (France) during the 1940s, it was not until the 1960s, following development of modern laparoscopes which use fiberoptic light bundles to transmit cold light from an external source directly into the abdomen, that laparoscopic fulguration of the fallopian tubes became widely used.

Once the abdomen is insufflated with 2-4 liters of gas (pneumoperitoneum) and the tip of the laparoscope is introduced into the abdomen through a small puncture, the fulgurating instrument can either be inserted through a special channel in the scope or through a second tiny puncture (see Fig. 3). The tube is then picked up and either coagulating or cutting current applied. The choice of current depends upon whether or not the practitioner intends to divide the tube. Coagulation current causes cellular dehydration and charring without division while the intense heat of cutting current causes the tube to divide. Both kinds of current are potentially dangerous: coagulating current may produce sparks which burn adjacent structures (37, 124, 130) and cutting current may also result in bleeding from the cut ends of the tube (37, 124, 130). Edgerton, an experienced laparoscopist, uses a mixed current for both electrocoagulation and cutting. This produces blanching, hemostasis, and cutting with very little charring and without the sparking which causes burns (27).

Because burns of the bowel or other adjacent structures have been reported following laparoscopic fulguration, many investigators now prefer to use bipolar instruments (current passes only between two closely placed electrodes) or equipment employing only low voltage current, both of which reduce the hazard. Although laparoscopic fulguration is highly effective (0.1-2.0 percent failure rate) work is being done to eliminate failures and reduce morbidity. In this respect, practitioners using the laparoscopic approach to tubal occlusion have been most concerned with the number of times a tube must be burned and whether the tube should be transected and/or a piece removed (see Table 2). The debate over which method is best still continues because the most effective procedures are often associated with high morbidity rates and the safest procedures with high failure rates. In 1975, 1,000 physicians from around the world were asked by the American Association of Gynecological Laparoscopists to state the tubal procedures they preferred (108). Results follow:

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Number</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coagulation only</td>
<td>214</td>
<td>21.4</td>
</tr>
<tr>
<td>Coagulation and division</td>
<td>404</td>
<td>40.4</td>
</tr>
<tr>
<td>Coagulation and excision of a segment</td>
<td>306</td>
<td>30.6</td>
</tr>
<tr>
<td>Other procedures</td>
<td>27</td>
<td>2.7</td>
</tr>
<tr>
<td>Not answered</td>
<td>6</td>
<td>0.6</td>
</tr>
<tr>
<td>No sterilization performed</td>
<td>43</td>
<td>4.3</td>
</tr>
<tr>
<td></td>
<td>1,000</td>
<td>100.0</td>
</tr>
</tbody>
</table>

The AAGL survey data must be interpreted cautiously since results of the different procedures chosen by the
Although early reports of coagulation alone revealed high failure rates, some practitioners now claim that if a segment of tube is adequately fulgurated (i.e., blanching is visible on each side of the fulguration instrument), failure is unlikely and there is thus no advantage in dividing the tubes.

Studies conducted in 1974 reveal that electrocoagulation without division using the new bipolar instruments may be as effective as dividing the tube. Performing coagulation alone with a bipolar instrument, Yuzpe encountered no pregnancies in 335 women, many of whom had been followed up for 10 months after sterilization (158). Broader experience is needed to determine the true efficacy of this technique.

Wheeless (USA) tested the effectiveness of coagulation alone versus coagulation and division with conventional equipment. Among 1,000 women who were sterilized by coagulation alone, there were 11 failures (1.1 percent), most of which were due to recanalization of the fallopian tube in the area of electrocoagulation (149). In contrast, the three-burn technique—where a portion of the tube is excised and the two remaining ends coagulated—resulted in no recanalization failures (150). The failure rate remained low (0.25 percent) in Nepal where this technique was used in 2,000 women, but 35 patients (1.7 percent) experienced tubal hemorrhage. All but two of the bleeding complications were controlled by recoagulation through the laparoscope; the remaining two required laparotomy to control the bleeding (149).

Safer and equally effective sterilization by the coagulation and division technique has been achieved by a few practitioners using low thermal current (74, 129, 137). Prior to insertion of the fulguration instrument which is heated from the inside by a wire, the operator selects the amount of heat and length of time it is to be applied. Because low voltage (6 volts) and low temperatures (usually under 140°C) are used, the risk of burns to nearby structures, such as the bowel, during fulguration is reduced. When the maximum temperature is reached and applied to the tube for the selected time, the coagulating forceps cools automatically. Thus, there is also little danger of burns from inadvertent contact with nearby structures following fulguration. One millimeter of the tube is burned on each side of the fulguration instrument; then, the tube is divided and hemostasis ascertained for the remaining ends. Only those vessels in the mesosalpinx immediately adjacent to the segment of tube treated are coagulated. Therefore, the risk of bleeding is also minimized. Using this technique, Semm has performed over 270 sterilizations without accidents (129), but the technique is still experimental and only limited experience with low thermal coagulation has been reported. Because only a small section of tube is destroyed, potential exists for future reversal by surgical reanastomosis of the remaining ends (137). The fact that only low voltage is required—the amount supplied by a car battery—suggests that this procedure might be used in areas where sophisticated electrical equipment is unavailable (129).

Because excision of a segment of tube is the most complicated of the fulguration procedures and associated with higher morbidity from mesosalpingeal tears which cause bleeding, Soderstrom (USA) indicates it should only be undertaken by a surgeon experienced in operative laparoscopy (132). Most practitioners who use this technique remove a segment of tube to confirm histologically that they have fulgurated the tube and not an adjacent structure (e.g., round ligament). However, in an April 1975 meeting in London, the IPPF Panel of Experts on Sterilization made the following statement regarding excision of a segment of tube:

"The panel does not recommend the removal of parts of the uterine tube for biopsy and histological examination as a check on the success of the operation. Such a procedure may add an otherwise avoidable risk of hemorrhage, make reversibility more difficult, burden the pathological service, and increase the cost of the operation to the patient or the service. Even when established practice in the community is to remove tissue for biopsy, the panel does not consider this an essential part of female sterilization. (68)".

Once experience is gained in identifying the tube, mistakes rarely occur. Thus, most physicians now simply coagulate and divide the tube without obtaining a specimen (see Fig. 4).

Fig. 3. During laparoscopic fulguration, the operating laparoscope (for single puncture laparoscopy) is inserted through lower rim of umbilicus. The fallopian tube is grasped by the fulgurating instrument, inserted through a special channel in the scope.
Hysteroscopic Fulguration

Although most physicians consider hysteroscopy easier to perform than laparoscopy because it requires less equipment, tubal fulguration by hysteroscopy has been generally unsatisfactory because of the high incidence of failure and morbidity. To occlude the tubes, a hysteroscope (fiberoptic scope) is inserted via the cervix into the uterus, and an electrode inserted through a channel in the hysteroscope is passed into the tubal orifices at the uterotubal junction. An electrical coagulating current is then applied (see Fig. 5).

Early attempts at cornual occlusion involved the blind insertion of a cautery sound into the upper angle of each uterine horn. Although first attempted by Kocks (Germany) in 1878, it was not until 1929 that the first patient series of any size was reported. At that time, Dickinson stated he had performed "cautery stricture of the uterine ends of the tubes" in 65 women. Current was passed for 10 to 30 seconds—the longer period of time used for women with more vascular uterine linings. If the tubal vestibules were difficult to locate, X-rays were used to visualize the cornua (25). Dickinson reported the "new hysteroscopes" would permit direct visualization of the uterotubal junction and might improve the transcervical route to sterilization (25). Gauss and Mikulica-Radecki (Germany) and Freund (Germany) in 1928 and Schroder (Germany) in 1934 noted some difficulty in attempting tubal electro-coagulation using a hysteroscope. Subsequent improvement in instrumentation and experiments with media (e.g., nitrous oxide or dextran) to distend the uterus made it easier to locate and place an electrode directly into the tubal orifices under direct vision, thus increasing the safety and effectiveness of fulguration.

Failures may be caused by technical difficulties. Uterine anomalies such as polyps, deep uterine horns, or a uterine septum can prevent passage of the electrode into the tubal orifices (114). Another technical difficulty occurs after cauterization of one tube if tissue adheres around the probe, insulating it so that fulguration of the second tube is less effective. To increase the effectiveness of the second fulguration, Lindemann uses a different probe on the second tube (78).

In a review of 10 hysteroscopic sterilization studies involving a total of 524 women, Darabi reports a failure rate ranging from 12.5 to 82.8 percent. In the total series, there were 105 failures (35.5 percent), 175 of which were discovered during postoperative tubal occlusion tests. Eleven pregnancies occurred following tests for tubal occlusion. A 23.7 percent failure rate was noted among women who were not tested postoperatively (19).

Failures in the form of interstitial (within the interstitium of the tube) or cornual (within the myometrium of the uterine cornua) pregnancies have occurred following hysteroscopic fulguration. Israngkun reported eight such pregnancies (3.1 percent) among 251 women sterilized by this procedure (61). Because these pregnancies may rupture and lead to severe hemorrhage and are thus hazardous to the patient's life, he determined that hysteroscopic fulguration should not be done in rural areas of developing countries where backup medical facilities are not available (61).

Lindemann, who discovered interstitial pregnancies in two patients two months after fulguration, hypothesized that high frequency current does not destroy enough tube and its deep penetration into tissue causes necrosis and enlargement of the tubal openings which can lead to failure of the sterilization (79). Subsequently, he used a
low-voltage-current thermoprobe (a sound heated from the inside) in which temperature can be predetermined and accurately controlled, thus minimizing the risk of burns to other than tubal tissue. No ectopic pregnancies resulted, but the overall effectiveness rate (88 percent) in terms of tubal occlusion had not improved (79, 129).

Most investigators now recognize that timing the passage of current and regulating voltage are important to provide sufficient damage to the tubal ostium without spreading current beyond the uterine muscles and tubes. Nevertheless, use of controlled temperatures and of time durations has not greatly improved the effectiveness of hysteroscopic fulguration (133, 134). Although investigations are continuing in an effort to find the optimal procedure (see Table 3), many physicians have abandoned hysteroscopic fulguration in favor of introducing chemicals or trying different approaches to tubal occlusion.

### CLIPS

Since clips to occlude the fallopian tubes are associated with low morbidity, are easy to apply by the abdominal or vaginal route, and may result in a potentially reversible tubal occlusion, their use in female sterilization is gaining wider attention. However, clips are not used as often as ligation or laparoscopic fulguration methods because of the prevalence of reported failures, including ectopic pregnancies, with some models.

In 1953, Evans (USA) suggested that clips were a simple, safe, and quick way to occlude the fallopian tubes (33). In the 1960s when the use of cautery for tubal occlusion became popular and reports of burns to structures near the tube began appearing in the literature, a number of physicians began experimenting with clips as a less hazardous method of tubal occlusion.

Despite the simplicity of clip application, animal experiments conducted in the 1960s showed that clips often are less effective than conventional methods, either because they expand after application renewing tubal patency or because they become dislodged from the tube (83, 100). Despite failures, researchers were encouraged by the minimal damage to the tissues which makes the procedure potentially reversible. In one of the first animal experiments, reported by Neumann and Frick in 1961, patency was restored in 50 percent of the fallopian tubes of baboons after clips were removed (96). However, in 1974 experiments by Ma and Wong (Hong Kong), only 2 (9

### Table 3—Female Sterilization by Hysteroscopic Fulguration in Selected Studies, 1974-1976

<table>
<thead>
<tr>
<th>Author &amp; Date</th>
<th>Reference Number</th>
<th>Number of Patients</th>
<th>Kind of Fulguration</th>
<th>Current</th>
<th>Number of Seconds Applied</th>
<th>Coagulation Temperature</th>
<th>Failures Indicated by Tubal Patency</th>
<th>Failures Indicated by Pregnancy</th>
<th>Total Failures (Percent)</th>
<th>Effectiveness (Percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isnangkun</td>
<td>1976</td>
<td>61</td>
<td>261</td>
<td>high frequency</td>
<td>30 watts at 2-3 volts</td>
<td>45-60</td>
<td>NR</td>
<td>NR</td>
<td>48 (8 ectopic or cornual preg.)</td>
<td>19 81</td>
</tr>
<tr>
<td>Lindemann</td>
<td>1976</td>
<td>79</td>
<td>48</td>
<td>low thermal</td>
<td>2 watts at 6 volts</td>
<td>60-90 90-10°C</td>
<td>10 unilateral</td>
<td>1</td>
<td>48 52</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(314)**</td>
<td></td>
<td></td>
<td>high frequency</td>
<td>25-30 watts at 6 volts</td>
<td>90°C</td>
<td>21 unilateral</td>
<td>12 bilateral</td>
<td>11 89</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(216)**</td>
<td></td>
<td></td>
<td>high frequency</td>
<td>2-3 watts at 5 volts</td>
<td>90°C</td>
<td>17 bilateral</td>
<td>13 bilateral</td>
<td>11 89</td>
<td></td>
</tr>
<tr>
<td>March</td>
<td>1976</td>
<td>87</td>
<td>27(23)*</td>
<td>high frequency</td>
<td>30 watts</td>
<td>12</td>
<td>NR</td>
<td>NR</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Quinones</td>
<td>1976</td>
<td>113</td>
<td>800(70)*</td>
<td>high frequency</td>
<td>27.8 watts</td>
<td>4</td>
<td>NR</td>
<td>18</td>
<td>26 74</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(179)*</td>
<td></td>
<td></td>
<td>high frequency</td>
<td>27.8 watts</td>
<td>6</td>
<td>NR</td>
<td>30</td>
<td>17 83</td>
<td></td>
</tr>
<tr>
<td>Sugimoto</td>
<td>1974</td>
<td>141</td>
<td>38161*</td>
<td>high frequency</td>
<td>30 watts or 40 watts</td>
<td>3-4</td>
<td>NR</td>
<td>0</td>
<td>0 100</td>
<td></td>
</tr>
</tbody>
</table>

*Number of patients followed up appears in parenthesis.

** Of 18 patients, 11 had sinus tracts which could lead to later recanalization failure.

NR = Not Reported

percent) of 22 rabbits became pregnant following clip removal and nine months of breeding (83). The investigators hypothesized that interruption of the blood supply to the tube may have caused permanent injury making reversal impossible (83).

Realizing that tubal physiology and fertility rates in animals are different from those in humans, several investigators began applying clips to human fallopian tubes. Researchers used the approach to the tubes most familiar to them—laparotomy, laparoscopy, colpotomy, or culdoscopy. Particular consideration was given to the number of clips applied to the tube, where they were applied, and the material used to make them (132) (see Table 4).

**Tantalum Clips**

Most of the clips used by investigators in the last two decades have been made of tantalum, a non-tissue-reactive metal. The most frequently used model is simple in design with grooves on the inner surface to secure its grip on the tube. It is applied to the tube via a specially designed pliers or applicator (see Fig. 6).

Previously, the clip was used to provide hemostasis (stop bleeding) during surgery and was highly effective when used for that purpose. However, the clip is less effective when used for tubal occlusion. Failure rates of more than 10 percent, particularly among puerperal patients, have been recorded (49). Failures usually result when a clip:

- migrates off the tube;
- opens slightly, renewing tubal patency (may be caused by normal buildup of intraluminal secretions);
- cuts through the tube leading to recanalization;
- opens subsequent to the pressure produced by a hysterosalpingogram or injection of dye used to test tubal occlusion.

There is also danger of subsequent ectopic pregnancy when a clip opens wide enough to permit passage of sperm but not a fertilized ovum (49, 97, 106). In an effort to reduce this hazard and increase effectiveness, Wheeless and other investigators applied two clips to the tubes, but the failure rate remained unacceptably high (11.2 percent) (148). The highest effectiveness rate (0.9 percent failure rate) was achieved by Gutierrez-Najar who applied two clips and then cut between them. However, as with all procedures where the tube is transected, there is greater risk of bleeding from the cut ends of tube.

### Major Advantages
- simple in design and application;
- potentially reversible;
- inexpensive;
- application possible by a number of approaches.

### Major Disadvantages
- high failure rate (0.0-11 percent);
- risk of ectopic pregnancy.

Reports of failure with tantalum hemoclips have led a few investigators to develop new designs to improve the efficacy of clips. One of the most recent designs is being developed by Filshie (Great Britain) in cooperation with the Simon Population Trust. The clip has an outer surface of tantalum and a soft-ridged inner core of Silastic. It has been tested successfully in animals and human trials are to begin soon (11).**

**Spring-loaded Clips**

In extensive clinical trials a spring-loaded clip designed in the 1970s by Hulka and Clemens (USA) has been judged more effective than the tantalum clip. The clip has two plastic-toothed jaws which are hinged by a metal pin and are locked closed around the tubes by a stainless steel...
spring (see Fig. 7). Although the clip may be placed on the isthmus of the tube by any route, its applicator was originally designed for laparoscopic use (see Population Reports, Series C, Number 4, March 1974).

As of March 1974, the spring clip had been applied in over 1,000 women at nine different locations with a minimum one-year follow-up (56). The majority of clip applications was done as interval sterilization. A few procedures were done following a first or second trimester abortion, but because the tubes are edematous after second trimester abortion, two clips were applied.

In a follow-up study of 907 patients, 24 failures occurred: 11 were due to operator error; 3 were luteal phase pregnancies; 3 occurred in early experiments using a prototype clip with incorrect spring tension; and in 7 the cause of pregnancy was unknown. On reexamination of 2 of these 7 patients, clips had been properly applied (56). Hulka reports that if properly manufactured clips are correctly applied to the tube, the pregnancy rate will be about 2/1000 or less (53). He suggests that the failure rate is likely to be slightly higher than that for fulguration because the tube must be caught properly in the jaws of the clip. Thus, there is greater chance of operator error.

Only minor morbidity has occurred following spring-clip application. Although a vagal reflex (nausea, faintness, bradycardia, hypotension) occurred in 8 percent of University of North Carolina patients, the most often reported side effects during or following clip application were abdominal pain and cramps (26 percent of patients). In countries where more sedation and local anesthesia are used, operative pain has not been a reported problem. In other series, the application of local anesthesia to the tube has eliminated operative pain. Cramps lasting up to 48 hours following the procedure are thought due to the pressure of the clip on nerve endings in the tube and mesosalpinx and are treated with analgesics.

To reverse occlusion produced by the spring-clip, the section of tube under the clip which has undergone necrosis is cut out and the two remaining ends of tube

![Fig. 6. A tantalum Weck Hemoclip® being applied to fallopian tube by means of a special laparoscopic clip applicator. (Photo courtesy of Dr. Hans Frangenheim, Chief of the Women's Clinic, Kostanz, Federal Republic of Germany. Weck Hemoclips are manufactured by: Edward Weck & Company, Inc., 49-33 31st Place, Long Island City, New York 11101, USA.)](image)

![Fig. 7. A spring-loaded clip in its laparoscopic applicator prior to closing on fallopian tube. (Courtesy of Dr. Jaroslav Hulka, University of North Carolina, Chapel Hill, USA.)](image)

joined. To date, reversal by reanastomosis with Dexon® suture has only been attempted in 8 pigs, six months following clip application. Six of the eight pigs became pregnant. Therefore, a 75 percent restored fertility rate occurred which compares favorably to an 80 percent fertility rate for pigs under normal husbandry conditions (55).

**Major Advantages**
- low morbidity;
- outpatient application possible;
- potentially reversible;
- effective (0.2–1.5 percent failure rate).

**Major Disadvantages**
- high cost of clip and applicator;
- technically difficult.

**Plastic Clip**

Use of a plastic clip to occlude the fallopian tubes is being investigated by Bleier in Germany. The clip is 10 mm long and 4 mm wide. Between 1970 and 1973, the clip was applied to the fallopian tubes of 600 women via colpotomy, laparotomy, or minilaparotomy. No mortality was reported and the only morbidity was slight bleeding from the fallopian tube and ovary. It is possible that bleeding results from tears of the vessels in the mesosalpinx which occur as the clip's latch snaps shut (53). No adhesions formed following clip application. Technical difficulty was encountered in a few cases (number unreported) in which the clip broke at its joint during application. In 1975, two failures (pregnancies) were reported as resulting from operator error in which the clip was placed onto the mesosalpinx instead of the fallopian tube. Reversal of sterilization following clip application has not yet been attempted (6).

**BANDS**

The use of bands is a recent addition to tubal occlusion methods. To date, they are utilized in only a few clinical centers around the world. The best known of the current

*Davis and Geck, American Cyanamid Co., Pearl River, New York 10965, USA.*
designs—the Falope Ring™ (also known as the Yoon band)—has been tested clinically only within the past three years. Like clips, bands may be applied by any approach, except the transcervical, to occlude the fallopian tubes by the external application of pressure. The amount of continuing pressure which will allow bands to adapt to tubal changes without expanding too widely or cutting through the tube is an important factor in determining their effectiveness.

**Falope Ring™**

Experiments using a silicone rubber band developed by Yoon (USA) began in 1973. The Falope Ring is a small (1 mm inner diameter) silicone circle which exerts 0.3-0.4 pounds per square inch. It will revert to 90-100 percent its normal size and shape after application if not stretched beyond 6 mm (156).

The Ring can be applied to the tube by a variety of routes—laparotomy, minilaparotomy, culdectomy, colpotomy, or laparoscopy. To date, however, most have been applied by one- or two-puncture laparoscopy (see Fig. 8). The Ring was developed to eliminate the hazards of electrocautery during laparoscopy and, at the same time, provide a simple tubal occlusion method surpassing the effectiveness of tantalum hemoclips. After the Ring is slipped onto the base of a loop of the tube via a special applicator, the loop blanches white as the blood supply is cut off and eventually undergoes fibrosis (154, 156).

When the Ring is applied via laparoscopy, there is no danger of burns since electrocautery is not required. In addition, only a small amount of insufflation gas (1.5–2 liters) is needed.

Nearly 4,000 women have been sterilized by the Falope Ring since 1973. Over 900 procedures were performed at the Johns Hopkins University; the rest were carried out in Seoul (Korea) and Manila (the Philippines). Whenever the Ring was properly applied, there were no failures. Of the 3 reported failures among the 500 cases evaluated, 1 was caused by operator error when two Rings were applied to the same tube; 1 resulted from an uncompleted procedure due to adhesions; and the third was a luteal phase pregnancy. Tubal transection (10 in 370 cases) was most likely to occur when pelvic inflammatory disease or adhesions were present (156). Transection of the tube can also result from pulling it too strongly toward the applicator rather than lowering the tip of the instrument toward the tube to lessen tension. If the tube is transected, a Ring can be applied to the end of each segment, or the ends can be electrocoagulated. Lower abdominal cramping lasting up to 48 hours occurred in 32 of 567 cases and may be due to avascular ischemia of the treated knuckle of tube. Application of an anesthetic jelly to the tube during the application procedure has eliminated pain. In 8 cases the Ring was dropped into the abdomen by the operator. Because the Ring is non-tissue-reactive, it is not essential that it be retrieved (156).

In a comparison of the Falope Ring, fulguration, and the spring-loaded clip methods of tubal occlusion performed via laparoscopy, Brenner reported no failures among Falope Ring cases and a lower failure rate for fulguration cases (0.4 percent) than for spring-loaded clip cases (1.5 percent). The incidence of technical difficulties was also lower for the Falope Ring, but operative and postoperative complication rates were slightly higher than for the other two procedures:

<table>
<thead>
<tr>
<th></th>
<th>Falope Ring</th>
<th>Fulguration</th>
<th>Spring-Loaded Clip</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complications (%)</td>
<td>1.6</td>
<td>3.5</td>
<td>12.2</td>
</tr>
<tr>
<td>Difficulties (%)</td>
<td>1.6</td>
<td>6.5</td>
<td>15.5</td>
</tr>
</tbody>
</table>

The only operative complication reported for the Falope Ring was bleeding from the tube or mesosalpinx requiring cautery or the application of another Ring. Early postoperative complications were due to pelvic or wound infections (9).

Since doctors from the USA, Korea, the Philippines, India, Thailand, Egypt, Iran, and Mexico are receiving training in the Falope Ring procedure, data based upon broader experience are now being collected (1, 65). For example, the International Fertility Research Program (Research Triangle Park, North Carolina) has analyzed data from Bangkok, Singapore, Seoul, San Salvador, and the USA. Pregnancy failure rates using the life-table method were computed for those women who were not pregnant at the time of a completed sterilization that was successful according to the operator. Pregnancy rates per 100 women followed up at 12 months were 0.3 for the Ring (480 women followed up), 0.2 for fulguration (1,576 women followed up), and 2.1 for spring-loaded clip (949 women followed up) (65). Although both operative and postoperative complications appeared lower for the Ring than for fulguration or spring-loaded clip, a larger series of patients with Ring-occluded tubes is needed to provide an adequate basis for comparison with other methods.

![Fig. 8. Steps in application of Falope Ring™ to tube of a surgical specimen: 1) approaching tube with Ring resting at end of applicator, 2) grasping tube with tongs 2-3 cm from uterine cornu, 3) retracting loop of tube, and 4) final appearance of tube with Ring applied. (Courtesy of Dr. William Brenner, University of North Carolina, Chapel Hill, USA (9).)
Major Advantages
- outpatient procedure (discharge in 3-6 hours);
- low morbidity;
- low failure rate;
- potentially reversible (only a small segment of tube is damaged).

Major Disadvantage
- special applicator required.

### CHEMICALS

Several chemicals are now being used experimentally to occlude the fallopian tubes. While many chemicals have been tested in animals, only a few are being used in humans. These chemicals either act by solidifying in the tube, thus forming a plug (e.g., tissue adhesive), or by destroying the inner lining of the tube with subsequent fibrosis (sclerosing agent) (see Table 5). Investigations are underway to determine which substances are most effective, the proper dosage, and the best instrumentation for delivery. Advantages and disadvantages of some chemicals have not yet been fully determined.

Chemicals may be introduced through the cervix and instilled into the tubes at the uterotubal junction under direct vision via a hysteroscope or blindly via a catheter. They may also be introduced into the fimbrial end of the tube under direct vision via the abdominal or vaginal routes. The transcervical route to the uterotubal junction is used most often because it is simplest to perform and requires no incision.

### Table 5—Tubal Occlusion by Chemicals in Selected Experimental Studies, 1971-1976

<table>
<thead>
<tr>
<th>Author &amp; Date</th>
<th>Reference Number</th>
<th>Number of Subjects</th>
<th>Chemical Used</th>
<th>Formulation &amp; Dosage</th>
<th>Kind of Chemical Agent</th>
<th>Where Applied</th>
<th>Number of Failures Indicated by Patency</th>
<th>Effectiveness (Percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alvarado 1974</td>
<td>3</td>
<td>30(16)</td>
<td>quinacrine</td>
<td>1 gm in 6 ml H2O</td>
<td>sclerosing</td>
<td>uterine cornua</td>
<td>10 (6 unilateral &amp; 4 bilateral)</td>
<td>37</td>
</tr>
<tr>
<td>Benoit 1975</td>
<td>6</td>
<td>30</td>
<td>quinacrine &amp; atropine</td>
<td>0.4 mg</td>
<td>sclerosing uterus</td>
<td>17*</td>
<td>43*</td>
<td></td>
</tr>
<tr>
<td>Dafon 1976</td>
<td>18</td>
<td>8(4)</td>
<td>paraldehyde</td>
<td>0.5 cc of 16 molar suspension of 4.8 gm paraldehyde in 10 ml ethanol</td>
<td>sclerosing uterine cornua</td>
<td>1 (unilateral)</td>
<td>75</td>
<td></td>
</tr>
<tr>
<td>Davidson 1976</td>
<td>21</td>
<td>60(48)</td>
<td>quinacrine</td>
<td>5-6 ml suspension of 1 gm quinacrine in 7 ml H2O</td>
<td>sclerosing uterus</td>
<td>47 (of 96 tubes)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Erb 1974 1976</td>
<td>29, 31</td>
<td>19</td>
<td>silastic S-382</td>
<td>80 part medical tissue elastomer &amp; 20 parts 360 medical fluid + 1% stannous octoate</td>
<td>tissue adhesive</td>
<td>12 (1 pregnancy)</td>
<td>76</td>
<td></td>
</tr>
<tr>
<td>Isranghkun 1976</td>
<td>62</td>
<td>60</td>
<td>quinacrine</td>
<td>60 gr in 7 ml H2O</td>
<td>sclerosing uterine cornua</td>
<td>26</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lindemann 1976</td>
<td>79</td>
<td>50(16)</td>
<td>methyl-2-cyanoacrylate (MC)</td>
<td>0.5 ml</td>
<td>tissue interstitial &amp; 3 (unilateral)</td>
<td>3</td>
<td>81</td>
<td></td>
</tr>
<tr>
<td>Rakshit 1972</td>
<td>118</td>
<td>6</td>
<td>silastic S-3792</td>
<td>NR</td>
<td>tissue uteru s</td>
<td>8</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Richard 1971</td>
<td>121</td>
<td>14</td>
<td>silastic S-521</td>
<td>NR</td>
<td>tissue uteru s</td>
<td>3</td>
<td>86</td>
<td></td>
</tr>
<tr>
<td>Stevenson 1975</td>
<td>139</td>
<td>41</td>
<td>methyl-2-cyanoacrylate</td>
<td>0.2 ml of 10% hydrophilic ointment</td>
<td>sclerosing fimbria</td>
<td>0</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Zipper 1975</td>
<td>161</td>
<td>638</td>
<td>quinacrine &amp; potentiating agents</td>
<td>1.5 gr (various dosages)</td>
<td>sclerosing uterus</td>
<td>241 (50 pregnancies)</td>
<td>69</td>
<td></td>
</tr>
</tbody>
</table>

*after one instillation
**after two instillations
†after three installations

All studies involved human subjects except Erb who used rabbits.

All cases followed up appear in parenthesis.

NR = Not Reported
Ideally, chemicals should be:
- delivered by a single instillation;
- 100 percent effective;
- nontoxic;
- inexpensive;
- readily available;
- confined to the tubes (no intraperitoneal spillage);
- painless to the patient;
- stable, with unlimited shelf-life.

Chemicals which are toxic enough to cause tubal fibrosis may also damage peritoneum or viscera upon contact. If they enter the vascular system, they may end up in the lungs or elsewhere causing tissue damage. Therefore toxic chemicals require a delivery system which prevents intraperitoneal spillage (134).

Quinacrine

Quinacrine is the chemical most often used to occlude human fallopian tubes. It is a sclerosing agent, which was first used by Zipper (Chile) in 1961, and is usually delivered to the tubes through the cervix via a catheter or cannula (see Fig. 9).

In 1975, Zipper reported on studies conducted between August 1961 and September 1973 during which quinacrine was instilled into the fallopian tubes of 800 women. Of these women, 638 were observed for a total of 14,677 woman-months. Five different dosages or combinations of quinacrine with other pharmacological agents were studied. Considering all instillations, tubal occlusion was observed in 437 (68.4 percent) of the 638 women. The most effective combination for occluding the tubes was quinacrine plus xylocaine with or without epinephrine instilled in two successive cycles of the menstrual cycle. This combination of chemicals yielded a 94 percent tubal obstruction rate after two instillations (161). In the entire series, 2 patients experienced excitation of the central nervous system and were treated with barbiturates given intravenously. Sixteen other women experienced minor complications; 7 women had amenorrhea lasting three months; 4, intrauterine adhesions; 4, chemical vaginitis; and 1, a skin rash (161).

In a 1974 report, Moulding (USA) suggested that failure of a quinacrine suspension to enter the oviducts may be the cause of the high failure rate. He recommended additional experiments using a more viscous preparation and a cannula without an occlusive tip (93).

A number of investigators have attempted to improve the effectiveness of quinacrine by using instillation equipment which prevents reflux (drainage) of the chemical from the uterus. Despite the use of an indwelling catheter to prevent reflux and the administration of atropine sulfate to prevent spasm of the uterotubal junction, Benoit (Canada) achieved only a 77 percent tubal occlusion rate in 30 women after two instillations. Davidson (USA) obtained bilateral occlusion in 6 women following only one instillation of 680 mg of quinacrine using a flexible polyethylene cannula to prevent reflux. Only a 44 percent tubal closure rate, tested by hysterosalpingogram, was obtained by Israngkun and associates (Columbia University, New York, USA) who instilled 60 gr of quinacrine hydrochloride in 7 ml of water into 60 women via a Kahn cannula fitted with a device to prevent influx (62).

While instruments are still being developed to refine the blind (not under direct vision) instillation of quinacrine, Alvarado and Quiones (Mexico) tried instilling the chemical into 30 women under direct vision via hysteroscopy. However, the subsequent high failure rate (62 percent) caused the investigators to abandon this route for delivery of the chemical (3, 114).

Animal experiments to reverse the effects of quinacrine have been conducted by Zipper and his associates. Tubal patency was restored in formerly obstructed tubes of rats by administration of an estrogen (estradiol benzoate) or progesterone between 1 and 28 days after instillation of quinacrine (159, 160). Similar results in monkeys were obtained by Malaviya (India) who injected estrogen (estradiol dipropionate) from days 16 to 20 following instillation. These investigators conclude that estrogen antagonizes the tubal occlusion action of quinacrine and is capable of reversing an already established occlusion (85).

Silver Nitrate

Although silver nitrate was one of the first chemicals investigated to achieve tubal occlusion, it is seldom used today. As early as 1849, silver nitrate was instilled into the uterine cornua of cesarean section patients via a sound (42). In 1971, more than a century later, Richart (USA) instilled 0.2 ml of 10 percent silver nitrate in hydrophilic ointment into the isthmus via the fimbria of 12 women by culdoscopy. Hysteroscopy conducted 8 to 12 weeks following the procedure disclosed bilateral tubal occlu-
Fig. 9. Quinacrine is delivered without direct vision high in uterine cavity near tubal ostium via a catheter or cannula.

In all patients (121). Despite its effectiveness, experiments using silver nitrate were discontinued because the chemical was difficult to deliver into the tubes and it tended to spill out the ends of the tubes into the pelvis. In addition all patients experienced abdominal pain for two to five days postoperatively (120).

**Silastic**

A number of adhesive substances—silastic (a silicone polymer), methyl-2-cyanoacrylate (MCA), and gelatin-resorcinol-formaldehyde (GRF)—have been instilled experimentally into the uterotubal junction to form a plug. These compounds are highly viscous (sticky) when instilled and polymerize (solidify) in place.

Silastic, first suggested in 1965 by Cortman and Taylor (USA) (15), is one of the most promising tissue adhesives in terms of effectiveness and reversibility. In 1967, Hefnawi investigated its effectiveness in animals. He instilled a highly diluted, low viscosity silicone (50 parts medical grade elastomer/50 parts medical fluid) into the oviducts of 37 rabbits. When the plug was retained, the procedure was 100 percent effective, produced no inflammatory reaction, and was reversible (50). However, many of the plugs did not remain in place, but were ejected from the distal end of the tube into the peritoneal cavity.

Rakshit in India was the first investigator to instill silastic in humans. Blind transcervical instillation of the silicone polymer S-521 into the uterine cavity of 30 women resulted in tubal occlusion in 21 (70 percent), doubtful occlusion in 6, and failure in 3. There was one failure among 10 women in whom S-521 was instilled transabdominally. In no case did tissue reaction occur. Rakshit observed that tubal peristalsis gave the silastic a segmented appearance as it solidified. This suggested the need for a catalyst that would promote rapid solidification and prevent intraperitoneal spillage of the silastic (116).

Erb (USA) found a means of preventing intraperitoneal spillage by mixing 1 percent stannous octoate with 80 parts medical elastomer (S-382) and 20 parts 360 medical fluid. Stannous octoate, a catalyst, transforms the viscous silastic liquid to a rubbery solid in about four minutes. Tests in animals have shown that while the silastic plug conforms to the tubal lumen and resists deformation and expulsion, its high tensile strength permits removal by pulling it out of the tube (29, 30, 31). However, because the human fallopian tube is more tortuous, removal may be more difficult if not impossible (120).

To date, Erb has conducted only animal experiments. There was 1 failure (5.3 percent) among 19 rabbits in which the silastic was instilled. The failure was probably due to poor instillation since no plug was found in the uterine horn where two fetuses were discovered. Fourteen of eighteen plugs were successfully removed in 9 rabbits, but fertility was restored in only 29 percent of the rabbits. Erb suggests that the low fertility rate after reversal was due to the temporary loss of functioning by those ciliated cells in the endosalpinx which came in contact with the plug. Thirty days following instillation there was no evidence of tissue damage or alteration and no inflammation of the tube (23). Tests conducted 56 days following instillation revealed that there was no expulsion of the plugs. An instrument to deliver the silastic plug in humans is now being developed (31) (see Fig. 10).

**MCA**

Results from animal and human experimentation involving methyl-2-cyanoacrylate (MCA) monomer, a tissue adhesive, indicate that it can be an effective but irreversible method of tubal occlusion. Experiments using MCA to occlude the fallopian tubes began in 1965 when Cortman instilled the chemical into the uterotubal junction of 9 rabbits. The resulting tubal occlusion was demonstrated by injection of saline containing methylene blue into the

*Fig. 10. A Silastic plug introduced into uterine cornua to block tubal ostia. (Courtesy of Dr. Robert Erb, Franklin Institute Research Laboratories, Philadelphia, Pennsylvania, USA (29).)*

<table>
<thead>
<tr>
<th>Major Advantages</th>
<th>Major Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Potentially reversible;</td>
<td>- Effectiveness in humans not investigated sufficiently;</td>
</tr>
<tr>
<td>- Non-tissue-reactive (minimal side effects);</td>
<td>- Requires sophisticated equipment;</td>
</tr>
<tr>
<td>- No incision required.</td>
<td>- Plug may break during removal.</td>
</tr>
</tbody>
</table>

*Dow-Corning Corporation, Midland, Michigan 48640, USA.*
weeks after instillation and confirmed histologically. By six weeks the tubal epithelium was destroyed and extensive fibrosis had taken place (16).

In 1975, Stevenson (USA) reported the results following transcervical instillation of MCA into the tubes of 41 women via an intrauterine catheter with a balloon (to prevent endometrial contact) on the seventh day following menstruation. Ten to fourteen weeks following instillation, the tubal lumen was obliterated by fibrosis, and by 24 weeks, no polymer was evident in the occluded tube. On follow-up tests 27 (66 percent) of the 41 women had bilateral occlusion following one instillation of MCA. The 14 other women who had one tube patent were given a second instillation and 10 of these had subsequent blocking. Two patients (5 percent) had bilateral tubal patency after the first attempt: 1 withdrew from the study, and in the other patient, only one tube was blocked following a repeat instillation. Therefore, the effectiveness rate was 92 percent (38 patients) after the second instillation of MCA. The women were followed-up from six months to one year after the first attempt: 1 withdrew from the study, and in the other patient, only one tube was blocked following a repeat instillation. Therefore, the effectiveness rate was 92 percent (38 patients) after the second instillation of MCA.

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According to Stevenson, women with endometrial irregularities should not receive MCA because polyps and other anomalies will deflect the chemical and prevent it from entering both tubes. In his study, instillation was confined to times when the endometrium was thin and the tubal ostia were at their widest (i.e., days 6–10 of the menstrual cycle). Experiments are now underway involving the instillation of saline prior to MCA to further distend the tubal ostia, but it is too soon to draw conclusions about this procedure (139).

Using a catheter filled with paraffin oil as a “push-transport medium,” Lindemann and Mohr (West Germany) injected 0.05 ml MCA monomer into 50 women via hysteroscopy. They suggested that carbon dioxide, rather than dextran, should be used as the uterine distention medium because contact with a liquid medium would result in polymerization of the MCA before it reached the tubes (77). The investigators observed that MCA destroyed 3–4 cm of epithelium. It took 5–10 seconds to polymerize and no spilling occurred. Of the 16 patients followed up for four to six weeks, 9 had bilateral occlusion at four weeks, while 4 additional patients showed bilateral occlusion at eight weeks. By 1976, Lindemann had instilled MCA into the tubes of 150 women. Bilateral tubal occlusion was achieved after 14 weeks in those cases where the solution was easily injected into the tubes without reflux into the uterus (77). Because tubal occlusion may take eight or more weeks to occur following treatment, patients must be maintained on contraceptives until occlusion is ascertained (79).

Major Advantage
- effective when reflux prevented;

Major Disadvantages
- not immediately effective;
- highly toxic (risk of injury to nearby structures on contact);
- irreversible.

Animal experiments with gelatin-resorcinol-formaldehyde (GRF), a biodegradable tissue adhesive, reveal that it may prove effective in blocking the fallopian tubes in humans. Resorcinol promotes adhesive strength and prevents immediate breakdown, while formaldehyde acts to solidify the gelatin-resorcinol solution and to promote adhesion between the glue and tissue.

The route for delivery of GRF is still under investigation. Although Falb (USA) acknowledged that GRF could be delivered by hysteroscopy, he expected this approach to eliminate its simplicity and the possibility of its delivery by nonphysicians. Therefore, investigations have begun to improve a cannulation device with a silicone tip for blind introduction of GRF (35).

Clinical trials of GRF in humans have not yet been conducted. However, use of the chemical to block the right fallopian tubes—the left tubes were untouched—and promote tissue ingrowth in rabbits was reported by Grode in 1971. None of the 4 animals subsequently bred became pregnant on the treated side (46).

Falb also conducted rabbit experiments using various adhesive formulas. The most effective contained 54 percent gelatin solids and 37 percent formaldehyde concentration and resorcinol which, after mixing, form a water insoluble mass. (Experiments adding quinacrine did not enhance the effectiveness of GRF.) The formaldehyde and resorcinol dissipate so that they are of low concentration in the final product. The compound was 100 percent effective in preventing pregnancy both initially and after subsequent breeding of the rabbits. A few months after application, GRF completely disappears from the tubes with no visual damage to the tubal lumen (34). Because the tubes are not occluded, the action of GRF in preventing pregnancy is not understood. Toxicity studies show that lesions form at the site of contact between GRF and various organs. Therefore, like MCA, it must be confined to the tubes to prevent injury to other structures.

Many investigators are optimistic about the potential of solid plugs for reversible sterilization. The consistency of plugs varies from soft to hard, but because they are solid, they may be directly inserted into or removed from the uterine or fimbrial end of the tube (see Table 6). However, instrumentation for their insertion needs to be simplified and reduced in cost. Because there has been less extensive clinical experience with solid plugs than with most other tubal occlusion methods, their advantages and disadvantages have not been fully ascertained.

Aside from possessing the ideal properties common to all tubal occlusion agents, plugs should:
- be compatible with tissue (nontoxic);
- possess properties for complete retention;
- be removable for the restoration of fertility;
- be inserted by a simple delivery system.

**Solid Silastic Intratubal Device**

The only solid plug which has received clinical trials is a silastic device with a nylon thread core designed by
Table 6—Experimental Use of Solid Plugs for Tubal Occlusion in Selected Studies, 1976

<table>
<thead>
<tr>
<th>Author &amp; Date</th>
<th>Reference Number</th>
<th>Kind of Plug</th>
<th>Point of Insertion</th>
<th>Approach</th>
<th>Number of Subjects*</th>
<th>Number of Failures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Craft 1976</td>
<td>17</td>
<td>porous ceramic</td>
<td>uterotubal junction</td>
<td>hysteroscopy</td>
<td>15</td>
<td>NR</td>
</tr>
<tr>
<td>Hosseinian 1976</td>
<td>51</td>
<td>polyethylene</td>
<td>uterotubal junction</td>
<td>hysteroscopy</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>Malinak 1976</td>
<td>86</td>
<td>aloplastic</td>
<td>mid-tube</td>
<td>laparotomy</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>Steptoe 1976</td>
<td>138</td>
<td>silastic</td>
<td>ampulla via fimbria</td>
<td>laparoscopy</td>
<td>40</td>
<td>1</td>
</tr>
</tbody>
</table>

* Craft and Steptoe used human subjects; Hosseinian and Malinak used baboons
NR = Not Reported

Steptoe (Great Britain) and intended for insertion into the ampulla of the tube via the fimbria. The plug is available in either 4 or 6 cm lengths, is 1 mm in diameter, and has 1.5 mm protuberances located at 1 cm intervals. Tantalum clips are applied between the protuberances to hold the device in place (see Fig. 11).

A number of approaches—minilaparatomy, laparotomy, colpotomy, culdoscopy, or laparoscopy—may be used to insert the plug into the ampulla through the fimbrial end of the tube. Steptoe has described a quick, 15-minute laparoscopic approach for insertion of the device. The major disadvantages of this approach are the need for a great deal of instrumentation (a special trocar and cannula to introduce the device and a special clip applicator with its own trocar and cannula) and for three punctures in the abdomen to insert these instruments.

The Silastic device has been placed in 40 women. The longest period of observation has been 2½ years during which no pain or menstrual disturbances have been reported. The device slipped out of one tube in one woman leading to failure (3 percent failure rate) as diagnosed by the presence of a normal intrauterine pregnancy. The normal pregnancy indicates the device does not injure the tube. Thus tubal occlusion is potentially reversible by removal of the device from the tube (137). To date, no attempts have been made to reverse the procedure (136, 138).

**Major Advantages**
- potential reversibility;
- application possible by abdominal or vaginal routes.

**Major Disadvantages**
- specially designed instrumentation required;
- above average skill required for insertion via laparoscopy.

**Polyethylene Plug**
Experiments are just beginning on a polyethylene plug which is inserted into the tube at the uterotubal junction. The plug is 10 mm long and 1 mm in diameter. Projecting from its base are spines made of elgiloy (a biocompatible metal) which penetrate the myometrium and fix the device in place. The plug is placed in the tubal lumen with a stainless steel inserter having a 37° angled flexible tip which fits through the operating channel of a specially-designed hysteroscope. Hosseinian (USA) has tested the plug in 7 baboons, with one tubal patency discovered four months following insertion. One device appeared out of position although both uterotubal junctions in that animal were blocked. Although reversibility has not been tested, investigators indicate that teeth on the end of the inserter can be used to grasp the base of the device and remove it from the tube (51).

**Ceramic and Proplast®**

Two plugs, one made of ceramic and one made of Proplast, have been tested for their tubal occlusion properties. Craft (Great Britain) has inserted a ceramic plug, made of alpha alumina, through the uterotubal junction of rabbits and hysterectomy patients. This plug has a solid core and porous head. Technical problems (e.g., displacement) were encountered in 5 of 15 women during insertion of the plug, making modification of the insertion procedure necessary. To date, only the insertion procedure has been tested. Evaluation of the plug’s fit or effectiveness in preventing pregnancy will be explored in future studies (17).

The Proplast plug has only been investigated in animals. The plug is saturated with autogenous blood, injected through a needle into the midportion of the tube and secured by suturing it in place. Follow-up tests on 4 baboons in which the plug had been introduced via laparotomy indicated that all oviducts were completely blocked. No adhesions or inflammatory reactions and no effect on the fallopian tubes other than obstruction were

**Fig 11. Diagram of solid Silastic intratubal device in situ. Device is held in place by application of a clip placed between protuberances on the plug. (Courtesy of Dr. Patrick C. Steptoe, Oldham, Lancashire, Great Britain.)**

*Bitek Inc., P.O. Box 6893, Houston, Texas 77025, USA.*
observed. Results have not yet been reported for animal studies in which the Proplast was inserted into the tube via the uterotubal junction (86).

**Dacron**® and **Teflon**® Plugs

Among the tubal occlusion methods tested by Hulka and Omran (USA) in 1970 was a Dacron® plug which was inserted into the tubes of 17 pigs. The plug was used alone or in combination with silver nitrate or electrocautery. Although the Dacron® plug was 100 percent effective in preventing pregnancies, there were a high incidence of infection, adhesions, and the development of cystic ovarian structures (54).

More recently, a notched Teflon® plug, developed by Meeker (USA), has produced minimal tissue reaction in baboons and rabbits and has been withdrawn from the tube to restore patency. The plug is inserted through the fimbrial end of the tube and anchored in place by sutures. Fertility was restored in 3 of 9 rabbits in which the plug was inserted for three months and then removed (89).

**OTHER TUBAL OCCLUSION METHODS**

Other tubal occlusion methods which do not fit into established categories are fimbriotexy and the use of the laser. While fimbriotexy has been used in medical practice for more than a decade, the use of a laser beam to occlude the fallopian tubes is a new method currently under investigation.

**Fimbriotexy**

Fimbriotexy—the placement of a cap or hood over the fimbrial end of the tube to prevent the ovum from gaining access—is a tubal occlusion method requiring additional research, especially in humans. In some cases reported, the end of the tube has been buried in or attached to the broad ligament to prevent the cap from dislodging (74). However, Clyman and Little (USA) have noted the presence of dense adhesions in some women in whom the caps were used. Little suggests the use of sterile devices, free from lint, to counteract the development of adhesions (74).

In animal experiments, Laufe (USA) removed fimbrial caps in 5 rabbits to test reversibility. Four subsequently conceived, while the fifth rabbit did not conceive in any state and may have been infertile (74).

<table>
<thead>
<tr>
<th>Major Advantages</th>
<th>Major Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>potential reversibility</td>
<td>risk of postoperative adhesions;</td>
</tr>
<tr>
<td></td>
<td>requires laparotomy;</td>
</tr>
<tr>
<td></td>
<td>may injure fimbria, making reversal difficult.</td>
</tr>
</tbody>
</table>

**Laser**

Use of a carbon dioxide laser to provide concentrated heat to a point on the tube resulting in destruction is currently being investigated by Halbrecht (Israel). The laser beam would eliminate the need to touch the treated area.

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*E. I. Du Pont de Nemours & Co., 1007 Market Street, Wilmington, Delaware 19898, USA.*

Lopez-Escobar (Colombia) reported that application of a laser beam to the uterotubal junction in rabbits via laparotomy resulted in later recanalization (142). Therefore, effectiveness, reversibility, and standards for length of time the beam must be applied to obtain the desired result need to be determined (38, 142). The use of smaller instruments and ways to reduce cost are also currently under study (104).

<table>
<thead>
<tr>
<th>Major Advantages</th>
<th>Major Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>damage to tube restricted;</td>
<td>requires cumbersome and expensive equipment;</td>
</tr>
<tr>
<td>low morbidity;</td>
<td>requires special training;</td>
</tr>
<tr>
<td>may be applied via laparoscope, hysteroscope, or laparotomy.</td>
<td>no standards of treatment yet established;</td>
</tr>
<tr>
<td></td>
<td>potential for reversibility unknown.</td>
</tr>
</tbody>
</table>

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