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TESTING OF A MODIFIED CONTRACEPTIVE DIAPHRAGM: ACCEPTABILITY STUDY

by

Janet Catherine MacGregor

A Thesis Submitted to the Faculty of the
SCHOOL OF HOME ECONOMICS
In Partial Fulfillment of the Requirements
For the Degree of
MASTER OF SCIENCE
In the Graduate College
THE UNIVERSITY OF ARIZONA

1982
STATEMENT BY AUTHOR

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This thesis has been approved on the date shown below:

S. R. Jorgensen
Assistant Professor of
Home Economics

November 17, 1982
Date
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ABSTRACT

A comparison study was conducted using a diaphragm made of two layers of thin collagen sponge and the regular rubber diaphragm in order to evaluate the acceptability of the sponge diaphragm as an intra-vaginal contraceptive method. The study was designed as a preliminary trial to generate feedback from the users in order to implement improvements in the design and to indicate appropriate techniques in the proper use of the sponge diaphragm. The factors governing acceptability were considered to be items such as ease of preparation and insertion, ability to feel the cervix through the positioned diaphragm, comfort during and after intercourse, absence of odor and dripping, and ease of removal. The sponge diaphragm was rated more highly on ease of preparation. The incidence of dripping, normally associated with use of the rubber diaphragm, was not reduced with the sponge diaphragm. The overall acceptability of the sponge diaphragm was found to be about the same as that of the rubber diaphragm.
CHAPTER 1

INTRODUCTION

The explosive growth in world population during this century has demonstrated the urgent need for fertility control. Although organized family planning was first implemented in "developed" countries, the need for active planning is more obvious today in the "developing" countries where the fertility rates threaten to double the population in a relatively short period of time. In some South American countries this doubling time is 22 years, although in the city of Cali, Colombia, it is calculated to be as little as 12.5 years. These rates can be compared with those in the United States and other technologically advanced countries where the population doubling time is closer to 100 years (Barnes, 1978).

It has become apparent that a large variety of contraceptive methods have to be available due to differences in individual tolerance, ethnic and religious traditions, and age differences. In the United States alone, at least 12 different contraceptive methods are practiced. Another important reason for a variety of contraceptives to be made available is the variation in the risk-benefit rations, which vary from one society to the next, including real and perceived health risks among fecund women as well as consideration of the contraceptive potential of the different methods.
The development of contraceptives that are safe, highly effective, readily available, and convenient to use is of great importance for the future of humanity. Two major discoveries of the 1960s and the early 1970s, the birth control pill and the intrauterine device (IUD) have subsequently suffered from adverse publicity. In light of recent medical research, both the pill and the IUD have been implicated in the development of health problems in certain women, and caution has been advised in the use of both contraceptives.

Prior to the introduction of these two new contraceptive methods, the condom, diaphragm, and rhythm were the popular means of birth control (Table 1). Wider acceptance of the need for contraceptive information and improved access to the condom and diaphragm may account for the decline in douche users. The use of the oral contraceptive and the IUD continued to rise in the early 1970s with an accompanying decline in diaphragm and condom use. Studies in the late 1970s indicated an upward swing in diaphragm use with the diminished popularity of the oral contraceptive pill. The trend toward vaginal barrier methods of contraception was also indicated in the documented increase in use of spermicides.

Statement of the Problem

It is now considered by many that the future of contraceptives lies in developing more sophisticated modifications of the vaginal barrier methods such as the collagen sponge, the diaphragm, and the cervical cap (Zatuchni, 1979). The conventional rubber diaphragm has been used by many couples for over a hundred years. Although safe, the
Table 1. Percent distribution by method for women aged 13–44 in the United States using contraception other than sterilization. — Data from Freedman (1959), Westoff and Jones (1977, Ford (1978), and Dryfoos (1982)

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<th>Method</th>
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<th>1955(^a)</th>
<th>1965(^a)</th>
<th>1970(^a)</th>
<th>1976(^a)</th>
<th>1978(^b)</th>
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<td>Oral contraceptives</td>
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<td>0</td>
<td>31.2</td>
<td>41.1</td>
<td>45.9</td>
<td>41.5</td>
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<tr>
<td>IUD</td>
<td>0</td>
<td>0</td>
<td>1.3</td>
<td>8.7</td>
<td>12.5</td>
<td>11</td>
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<tr>
<td>Condom</td>
<td>20</td>
<td>29</td>
<td>24.2</td>
<td>17.2</td>
<td>14.8</td>
<td>14.5</td>
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<tr>
<td>Diaphragm</td>
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<td>26</td>
<td>11.5</td>
<td>6.6</td>
<td>5.9</td>
<td>10</td>
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<tr>
<td>Rhythm</td>
<td>11</td>
<td>24</td>
<td>12.6</td>
<td>8.3</td>
<td>6.9</td>
<td>5.7</td>
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<tr>
<td>Douche</td>
<td>44</td>
<td>11</td>
<td>3.7</td>
<td>2.7</td>
<td>1.4</td>
<td>2</td>
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<td>Spermicide (used alone)</td>
<td>4</td>
<td>4</td>
<td>3.4</td>
<td>7.7</td>
<td>6.1</td>
<td>9.7</td>
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<tr>
<td>Withdrawal</td>
<td>5</td>
<td>6</td>
<td>4.4</td>
<td>2.7</td>
<td>4.1</td>
<td>4.5</td>
</tr>
<tr>
<td>Other</td>
<td>6</td>
<td>7</td>
<td>7.8</td>
<td>5.0</td>
<td>2.2</td>
<td>1.0</td>
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\(a\). Figures apply to married women only

\(b\). Figures apply to sexually active, fecund women.
diaphragm has not been considered as effective or convenient as the pill or the IUD. The effectiveness of this method is increased greatly by the use of spermicidal creams, foams, or jellies applied to the convex side of the latex and to the ring reinforcing the diaphragm structure. However, the addition of spermicide introduces the disadvantage of "messiness." Another disadvantage of the use of spermicide with the regular diaphragm is the need for its reapplication for complete protection with repeated intercourse. It now appears that prolonged use of spermicide has an associated health risk (Chvapil et al., 1980). Evidence has emerged to indicate that the use of intravaginal spermicidal agents such as nonoxynol 9 can lead to adverse effects on the developing fetus and the liver and kidneys of the women due to the systematic resorption of the spermicide. If the spermicidal moiety is used in the form of jelly, cream, or foam, most of the active drug (detergent) is transvaginally absorbed (Chvapil et al., 1980). Apart from the evidence relating to health risks for such spermicides, the inconvenience of messiness accompanying insertion and use have led to a decline in the popularity of the diaphragm (see Table 1).

One of the oldest documented forms of contraception is a type of vaginal sponge (Keown, 1977; Tatum and Connell-Tatum, 1981). Recent work with collagen sponge has updated this ancient method, but the studies also demonstrated the significant disadvantages of bulkiness, odor, and dripping (Chvapil, 1976). More recently, a modification of the diaphragm contraceptive method has been developed to overcome the problems associated with the use of the rubber diaphragm and the collagen sponge: the sponge bilayer diaphragm. This method
was designed to (a) eliminate most of the inconveniences of the regular diaphragm such as messiness due to the need for the application of spermicidal jelly or cream and dripping of liquified ejaculate, (b) reduce the potential risk associated with prolonged use of spermicide with a lower dose of spermicide and retrieval of nonused spermicide, and (c) possibly increase the contraceptive effectiveness when compared to other vaginal barrier methods due to better mechanical and chemical fit on the circumference in contact with the vaginal wall. The sponge diaphragm allows for sustained release of spermicide into the upper vagina, and the detergent present on the rim of the sponge will also diffuse around the edges of the sponge bilayer.

The basic criteria for the ideal contraceptive are simplicity of use, safety, convenience, and efficacy (Sciarra, 1981). Considering these factors, the sponge bilayer diaphragm would appear to meet many of the criteria for an ideal intravaginal contraceptive. As a barrier to the movement of sperm into the uterus, the collagen sponge bilayer diaphragm is porous and permeable to fluids and air, as well as being highly absorbent of fluids such as ejaculate and cervical mucus, which become trapped in the sponge meshwork. It is resilient, and its size and shape should conform well to the anatomy of the upper vagina with close adherence to the walls. Insertion does not require medical assistance. The collagen is nonirritating to the tissues and is sufficiently soft to avoid interference during sexual intercourse. It has the added advantage of safety and reversibility.

It is expected that the sponge diaphragm will appeal to women in one or more of the following categories and will thereby be attractive
to a growing section of the contraceptive market in the United States because some women

1. Cannot tolerate the IUD.
2. Have used oral contraceptives for an extended period and have been advised to try an alternative.
3. Are seeking a natural contraceptive free of any systemic side effects.
4. Dislike the drip and messiness of foams and suppositories.
5. Felt comfortable with their own bodies and do not object to inserting and removing vaginal barrier devices.

**Purpose of the Study**

The purpose of this study was to examine the acceptability of the new sponge bilayer diaphragm among a small number of subjects. The sponge diaphragm was alternated with the regular diaphragm a total of 10 times, each diaphragm being tested 5 times. These women, ages 18–40 years, were interviewed twice during the study, at the beginning and end of the research period, with a self-administered questionnaire completed after two trials with each diaphragm. The overall goal of the study was to determine the acceptability of this modification of the diaphragm as compared with that of the rubber diaphragm.

**Hypothesis**

It is hypothesized that the sponge bilayer diaphragm will be as equally acceptable as the rubber diaphragm but with the following exceptions:
1. The sponge bilayer diaphragm will be easier and more convenient to prepare by the user.

2. The sponge bilayer diaphragm will demonstrate less dripping during use than will the rubber diaphragm.

Importance of the Study

1. This investigation is to help define the acceptability of a modified contraceptive device that promises to overcome many of the deficits in other vaginal barrier methods and could possibly popularize the diaphragm method of contraception.

2. This method of investigation is to help define the nature of the problems associated with the modified method so that corrective steps can be taken for the future of the sponge bilayer diaphragm.

The regular rubber diaphragm is considered to be one of the safest forms of contraception, although less effective than oral contraceptives or IUDs. It is also somewhat inconvenient in that it needs to be applied prior to each sexual act along with the spermicidal jelly or cream. It is also essential that the contraceptor be fitted with a ring of the appropriate size, necessitating a medical consultation.

Limitations of the Study

For the purposes of this study, the following limitations were identified:

1. The sample was small and drawn in a purposive fashion; therefore generalizations to any group of women outside this sample are not possible.
2. The sample was limited in that it largely reflects the perceptions of women only.

3. The sample was small due to the time limitations of the research workers, including the gynecologist, nurse practitioner, and research assistant. The cost of the survey was an additional consideration.

4. The volunteers used this form of contraception in addition to their regular contraceptive method, and it therefore had a degree of nuisance value.

5. The study depended on the cooperation of both the male and female partners, and a dissolution of this partnership led to failure to complete the trials.

Assumptions

For the purpose of this study, the following assumptions were made:

1. All subjects were equally motivated to participate in the program and to complete it.

2. All subjects were able to learn the contraceptive techniques.

3. All subjects who were using additional contraception were able to identify and separate the perceived effects of the new modified contraceptive device.
CHAPTER 2

REVIEW OF LITERATURE

As far as written history extends, there is documentation of the attempts by many cultures to prevent conception. These efforts have taken many forms with varying degrees of effectiveness, which is not surprising in view of the recency and overall inadequacy of our scientific knowledge about reproduction.

History of Vaginal Barrier Methods of Contraceptions

Vaginal barrier methods were among the earliest contraceptives, and from ancient manuscripts it would appear that intravaginal contraception has a history extending beyond 38 centuries with the first known references appearing in Egyptian writings (Keown, 1977). These describe pessaries made of crocodile dung mixed with honey for insertion into the vagina. Because concentrated sugar or honey has a spermidical and antiseptic action, this pessary was undoubtedly somewhat effective.

Many other agents used as contraceptives in earlier times have become the forerunners of modern-day physical barriers and chemical spermicides. Some of these such as quinine, rock salt, and alum possess strong and immediate sperricidal action. During the Crusades, the first purely mechanical type of female contraceptive barrier was introduced: the chastity girdle. However, the intravaginal methods of
contraception have probably been the most widely practiced up to the present.

For the early cultures who lived by sea, sponges were used for many centuries. They were placed in the vagina as a barrier to sperm penetration of the cervix. The advantages of this form of vaginal barrier became quickly apparent; a sponge, even in its natural state is relatively clean and highly absorbent and can be rinsed out and reused often. A reduction in the number of sperm reaching the cervix would have been effected even without the addition of some spermicide.

The Greek–Roman texts dating from the second century of the modern era mention the use of soft wool inserted into the vagina where it could serve both as a tampon and as a method of birth control. The Hebrews, too, allowed birth control by this method, although the Far Eastern cultures do not seem to have emphasized intravaginal contraception. A Sanskrit text refers to a suppository of salt, oil, and ajowan seeds but fails to mention the appropriate time of insertion. In Chinese and Japanese texts only one method seems to be recorded, and this refers to an intravaginal device consisting of a disc of oiled silk paper placed against the cervix (Tatum and Connell-Tatum, 1981). This is considered to be the earliest known precursor of the contraceptive diaphragm and cervical cap. In Europe and Russia, linen cloths and molded wax wafers also came to be used as contraceptives.

In Islamic countries, pessary contraception was more widely used than elsewhere, and often the pulps of various plants such as cabbage were used to absorb the semen. Methods of contraception used in the Middle Ages in Europe have been difficult to document and would
seem to have been surrounded by mystery and superstition. Better documentation of contraceptive practices in the seventeenth century is evident, but details are limited. However, mention is made of the use of the sponge in association with various astringents and disinfectants.

Casanova is credited with the discovery of the first cervical cap when he halved lemons, removed most of the pulp, and had his partners insert them vaginally. His other favored methods of contraception were the use of gold balls and the condom. Francis Place led the movement in England toward mass contraception in the early nineteenth century. He distributed handbills extolling the virtues of the use of the intravaginal sponge as a contraceptive device. Towards the end of that century, Anne Besant was also recommending the sponge as a reliable contraceptive along with the cervical cap and suppository (Keown, 1977).

The discovery of the vulcanization of rubber in the 1840s led to the development of rubber cervical caps in Germany, to be followed 40 years later by the development of the rubber vaginal diaphragm by a Dr. Hasse (using the pseudonym Mensinga). In 1882 Dr. Hasse (cited by Tatum and Connell-Tatum, 1981) wrote a philosophic treatise in support of the voluntary control of fertility, including case histories on the use of the diaphragm. As his work became known, the diaphragm became popular in Europe and was introduced to the United States by Margaret Sanger early this century.

Dr. Marie Stopes (1933), who worked in birth control clinics in Britain, stated that as early as 1918 she had believed that contraception was best accomplished in the normal situation by the combination of a
vaginal rubber cap and some chemical spermicide. In the 1930s there was widespread use of the diaphragm used in conjunction with a spermicide, and in 1932 Stopes (p. 133) was also endorsing the use of the contraceptive sponge, identifying its chief advantages as being "cheap, safe, very easy to manipulate, easily understood. . . . it does not require accurate adjustment . . . and it can be used by the woman herself without the cooperation of her husband." The sponge is also the most suitable contraceptive for various types of cervical abnormalities. Stopes suggested that the sponge be soaked in ordinary olive oil as a spermicide, using the now-commonplace rubber sponge rather than the sea sponge.

Of the commonly practiced contraceptive methods today, the vaginal barrier methods used in the United States can be broadly classified to include the diaphragm, spermicidal detergents (creams, jellies, foams, suppositories, and foaming tablets), and sponges. Cervical caps are also used in Great Britain and on the European continent. Other methods of contraception not classified as vaginal barrier methods include the douche, the condom, withdrawal, and extended breastfeeding. Developments in this century have led to widespread use of male and female sterilization, the birth control pill, the intrauterine device, injections of serum (Depo-Provera, Upjohn Company, Kalamazoo, Michigan), and the use of rhythm, basal body temperature, and mucus identification as methods of contraception. Interestingly, the sponge has been used well in the 1960s as a popular method in folk medicine (Keown, 1977).
Use of the Vaginal Barrier Methods in the United States

Studies begun in the 1950s and 1960s would seem to indicate a revival in the use of vaginal barrier methods of contraception (Zatuchni, 1979). In the third quarter of 1976, in the 16 largest affiliates of the Planned Parenthood Federation of America, 12.7% of both married and unmarried patients chose to use the diaphragm as compared with 6.7% during the same period of 1975 (Lane, 1978). This movement toward the greater use of vaginal barrier methods was accompanied by a greater acceptance of such methods. Scientific interest in the use of vaginal contraceptives is increasing with an urgent need seen to develop modifications that are medically safe and culturally acceptable and do not require the intervention of health professionals (Zatuchni, 1979).

The condom has had the stigma of illicit sex attached to its use, largely effected by its wide-scale distribution by medical authorities earlier in the century in their efforts to reduce the prevalence of venereal disease in the armed forces overseas. The use of the diaphragm has been neglected because the authorities failed to see it as a viable alternative for many women (Sciarra, 1979).

By 1965 IUDs and oral contraceptives were used by 16% of all married couples in the United States, and by 1973 this figure had doubled (Zatuchni, 1979). However, studies conducted in 1978 showed a decline in the use of the IUD and the oral contraceptive pill in the United states, whereas the use of vaginal barrier methods had increased
slightly' (Dryfoos, 1982). This increase in the use of traditional methods can be attributed to several risks among other factors.

1. **Risk in using oral contraceptives.** Over the past 10 years many studies have explored the possible long-term effects of the continued use of the oral contraceptive pill. There are many indications that extended use of this method carries with it some hazard to health. However, considering efficacy of the pill and facilitation of more satisfactory sexual relations, many workers in the family planning field claim that the benefits outweigh the risks, particularly for nonsmoking women 30 years of age and younger (Jaffe, 1977). Conversely, many women are averse to ingesting chemicals, the full action of which is unknown and which may lead to changes in the body as undocumented or substantiated.

2. **Risk in using the IUD.** Studies have shown that there is reason for caution in the use of intrauterine devices because it is possible for perforation of the uterus to occur, resulting pelvic inflammatory disease and subsequent sterility (Eschenbach, 1978).

3. **Risk in using spermicidal detergents.** Caution is beginning to be exercised in the use of spermicidal detergents, as recent studies have shown that these agents can pose some risk, both topically and systemically (Chvapil et al., 1980). The presence of spermicidal agents in the milk of lactating mother may also be a concern.

Wide publicity of these risks have led many contracepting couples to look to other alternatives, particularly if sterilization is not appropriate. By the early 1970s, surgical sterilization had become the
most commonly used method of contraception. In 1973, twice as many
married couples elected sterilization as their method of fertility control
than in 1965. This also contributed to the decline in the use of vaginal

Today there are indications that the number of couples favoring
vaginal contraceptive methods over the IUD, hormonal contraceptives,
or sterilization is increasing. There would appear to be a positive shift
in the acceptability of vaginal methods reflected in the increased will-
ingness of couples to accept the greater inconveniences and higher risk
of pregnancy when confronted with the permanence of sterilization and
the perceived risks of intrauterine devices and oral contraceptives
(Taylor et al., 1979). Along with the initial increased use of IUDs, the
oral contraceptive pill, and sterilization has come the realization that
their greater effectiveness in fertility control has another price:
increased incidence of venereal disease. This factor has also contrib­
uted to a renewed interest in vaginal contraceptives (Pratt, 1979).

Theoretical and User Effectiveness of
Vaginal Barrier Methods

Effectiveness of any contraceptive is defined using two types of
effectiveness rating:

1. Theoretical effectiveness, which reflects the maximum effective-
ness when used perfectly.

2. Actual user effectiveness (Hatcher et al., 1979).
Theoretical effectiveness has improved as advances in contraceptive
technology have taken place. However, user effectiveness rates can
vary for the same method, depending on many variables affecting
acceptability for any one individual, including such items as religious beliefs, consistency of use, knowledge, previous experience with contraceptives, and partner's perceptions and behavior. For the purposes of this study, the vaginal barrier methods are considered to be the diaphragm, the sponge, the cervical cap, and spermicidal detergents. Although the sponge and cervical cap are not commonly used in the United States, they are currently in the forefront of much research in the development of acceptable vaginal barrier methods.

Diaphragm

Contraceptive diaphragms in current use are soft rubber vaginal cups with metal spring-reinforced rim, varying in both size and structure with diameters ranging from 50 to 105 mm. There are four types that are best known and commonly used. These are the coil spring (as used in this study), the flat spring, the arcing diaphragm, and the Matrisalus (also referred to as the "bowbent"). It is considered that the device acts primarily as a container for spermicide and secondarily as a mechanical barrier (Wortman, 1976). If used with spermicide, the use of the rubber diaphragm should result in no more than 2-3 failures per 100 woman-years. The theoretical effectiveness of the diaphragm would put it in the highly effective group of contraceptives, along with the IUD, condom, and minipill (Wortman, 1976). The diaphragm has been found to be less effective than sterilization, oral contraceptives, and injectables but more effective than rhythm, local chemical contraceptives, and withdrawal. Because the diaphragm depends on correct fit and proper use, user effectiveness of
the rubber diaphragm is much lower than its theoretical effectiveness. Estimates of the failure rate, due primarily to human error, place the user effectiveness in the range of 6–25 failures per 100 woman-years (Wortman, 1976). Studies have shown that as the duration of use increased, the failure rate declined, with failure rates among older women being generally lower than those among young women. This is attributed to several factors: the older women are more experienced, are more motivated, experience less frequent intercourse, and experience a decrease in ovulation. Causes of the failure in the use of the rubber diaphragm include poor motivation, wrong size of diaphragm resulting in improper fit, displacement during coitus, defect in the diaphragm (uncommon), lack of knowledge regarding proper insertion and/or placement of spermicide on diaphragm before insertion, use of inadequate quantity of spermicide, and poor timing in use.

Sponge

Although the sponge has a long history of use, its effectiveness as a contraceptive has never been a distinguishing feature. The natural sea sponge used for thousands of years has been replaced in this century by latex rubber and other synthetic materials with their effectiveness considerably improved by addition of spermicide (Tatum and Connell-Tatum, 1981). The contraceptive revolution, which began with the introduction of the oral contraceptive pill and the IUD, has continued to develop with a resurgence of interest in the vaginal methods of contraception. Specifically, renewed focus on the sponge as a contraceptive has been largely the work of Chvapil (1976), whose
research with the collagen modification has received much recognition and has resulted in the development and extensive testing of a polyurethane sponge modification (Taylor et al., 1979).

The theoretical and user effectiveness of the traditional sea sponge and later the rubber sponge has been low. The modified sponge used today, however, has a dual chemical and physical mode of action, being both a barrier to the passage of sperm and a container for the slow release of spermicide. For this modification, the theoretical effectiveness would appear to be at least as high as that of other barrier methods (Taylor et al., 1979). The user effectiveness was found to be 94%. It is considered that this failure rate of 6% was most likely due to wrong use of the sponge and incorrect washing (Serlin, 1981). It is interesting to note that testing in Yugoslavia resulted in a failure rate of only 1.1% (Taylor et al., 1979).

Cervical Cap

The cervical cap is a smaller but deeper version of the diaphragm, as well as being more rigid and held in place by suction rather than by spring tension. Most versions are made of acrylic resin, although some may be manufactured from rubber or metal. The mode of action of the cap is primarily mechanical, as even without spermicide the cap provides a block against sperm's entering the cervix. If used with spermicide, the effectiveness of the cap would appear to be similar to that of the diaphragms, but few studies have been conducted to document this. In the United States, this method of contraception has not been widely publicized or promoted by family planning authorities. The
U.S. Food and Drug Administration (FDA) has prohibited their sale pending appropriate clinical evaluations that establish their safety and efficacy. Another reason cited for the lack of promotion is the need to fit each woman individually to ensure that the cap is molded to the shape of the cervix.

Spermicidal Detergents

Spermicidal detergents are used as vaginal barrier contraceptives in the form of jellies, creams, foams, suppositories, foaming tablets, and soluble films. The passage is physically blocked by the presence of an inert-base material, which also serves as a carrier for the spermicide (Wortman, 1976). The theoretical effectiveness of spermicides is 95%, but because the user may fail to apply the products correctly and consistently, the user effectiveness is closer to 85%. Hatcher (1976) considered that the theoretical failure rate of vaginal foam is 3%, but that the user effectiveness of 78% represents a very biased figure. He noted that very low failure rates have been reported: as low as 1.55–3.15 pregnancies per 100 woman-years.

Spermicides can be used alone, as in foam, but it would appear that jellies and creams are more effective if they are used in conjunction with the diaphragm, sponge, or cervical cap.

Comparison of Theoretical and User Effectiveness of Diaphragm and Spermicidal Foam with Other Methods

It can be seen from Table 2 that the diaphragm and spermicidal foam, both vaginal barrier methods, have a high theoretical effectiveness if used correctly and conscientiously and compare favorably with
Table 2. Theoretical and actual use rates for method effectiveness. -- Adapted from Hatcher et al. (1978)

<table>
<thead>
<tr>
<th>Method</th>
<th>Number of Pregnancies during First Year of Use per 100 Nonsterile Women Initiating Method</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Used Correctly and Consistently</td>
</tr>
<tr>
<td>Sterilization</td>
<td></td>
</tr>
<tr>
<td>Tubal ligation</td>
<td>0.04</td>
</tr>
<tr>
<td>Vasectomy</td>
<td>0.15</td>
</tr>
<tr>
<td>Oral contraceptive (combined)</td>
<td>0.34</td>
</tr>
<tr>
<td>IUD</td>
<td>1-3</td>
</tr>
<tr>
<td>Condom</td>
<td>3</td>
</tr>
<tr>
<td>Diaphragm</td>
<td>3</td>
</tr>
<tr>
<td>Spermicidal foam</td>
<td>3</td>
</tr>
<tr>
<td>Coitus interruptus</td>
<td>9</td>
</tr>
<tr>
<td>Rhythm (calendar)</td>
<td>13</td>
</tr>
<tr>
<td>Lactation for 12 months</td>
<td>25</td>
</tr>
<tr>
<td>Douche</td>
<td>?</td>
</tr>
</tbody>
</table>

* Reliable figures are not available for the sponge bilayer diaphragm or cervical cap.*
the IUD. The actual use rates, which can vary widely, depend on the individual and indicate incorrect or inconsistent use rather than failure of the method itself.

**Acceptability of Vaginal Barrier Methods**

Psychological and Social Acceptability

For this study, acceptability of the various vaginal barrier methods of contraception will be considered primarily for the United States unless stated otherwise. Characteristics of one method of contraception may be desirable in one society, but the same method may be inappropriate in another culture. Marshall and Polgar (1975) regarded an analysis of cultural values and family planning practices as having different values for particular aspects of these characteristics. Contraceptive methods have many different attributes, and the rejection or acceptance of the individual method depends on the acceptability of more than one of these characteristics, which can be divided into three categories (Scrimshaw, 1979):

1. Use-related attributes (e.g., requires handling of the genitalia).

2. Inherent attributes (e.g., color, odor).

3. Perceived attributes (e.g., easy to use, messy).

Perceived attributes are as significant as the use-related and inherent attributes in the overall social and psychological acceptability of any contraceptive method. For vaginal barrier methods to be as effective as possible, it is important that a satisfactory level of
husband–wife communication exist. Pohlman (1969) viewed conjugal role organization as a highly relevant concept to explain differences in the effectiveness of contraceptive practice. Those couples in "joint" marital role organization are seen as less sexually inhibited and more able to communicate freely. Consequently, they can work well together, particularly in such areas as contraception. Successful use of vaginal contraceptives is also affected by factors such as the enjoyment of sex, attitudes toward touching the genitalia, and acceptance of sexuality (Scrimshaw, 1979).

The traditional view is that the use of vaginal products depends entirely on the motivation and conscientiousness of the user, but the use of most cultural methods can be substantially influenced by the actions and attitudes of family planning personnel even though the initial psychological acceptability of any vaginal barrier method of contraception would appear to depend largely on upbringing. Women raised with rigid ideas concerning sexuality would appear to dislike contraceptive methods that involve genital contact or are coitus related (Scrimshaw, 1979). A growing group of women are psychologically opposed to the systemic and unnatural effects of the oral contraceptives. They may be unable to physically tolerate the IUD and are seeking a more natural form of contraception that is also reversible and lacking in side effects. The existence of a safe, effective, and convenient contraceptive device is considered to have some appeal to that group of people who are uncertain about whether to avoid or postpone their next conception (Marshall and Polgar, 1976).
It can be generalized that the main features of vaginal barrier contraceptives that act against their acceptability are the need to touch the genitals, messiness, storage, disposal, and direct relationship to coitus. Some couples also find unacceptable the planning and compulsiveness required for effective use of these methods. It can be assumed that the contraceptive effectiveness will be greater the stronger the desire to avoid conception (Pohlman, 1966). Conception can be avoided by changing to a more effective method once desired family size is reached or by more skillful, careful, and consistent use of the same contraceptive method during the period when contraception is not so important.

To date, studies of acceptability have been largely confined to the oral contraceptive pill, the IUD, and sterilization or have focused on the acceptability of family planning in general rather than on a specific method. Those studies that have looked at acceptability of vaginal barrier contraceptives have tended to assess safety and effectiveness rather than why the method is acceptable.

Perceived and Real Risks

**Diaphragm and Cervical Cap.** The diaphragm and cervical cap are considered together because of their similarity in risks. They represent two of the safest methods of contraception available. For full effectiveness, it is recommended that they be used in conjunction with a spermicide. Until recently, it was considered that nonoxynol 9, the spermicide frequently used in jellies and creams, was free of any harmful side effects. However, recent work by Chvapil et al. (1980) would
suggest possibilities of a health hazard in prolonged use of this spermicide. Allergic reactions, vaginal irritations, and infections have been known to occur in rare instances, and allergy to the latex itself has occasionally been a concern (Hatcher, 1978). Apart from the fear held by some women that the device could become lost in the vagina, the perceived risks seem few.

**Sponge.** The real risk from use of the sponge, as for the diaphragm, may be in its prolonged use in conjunction with a spermicide. A perceived risk could be toxic shock syndrome, with much recent publicity concerning that problem with some tampons. Some users have registered concern about its falling apart and becoming lost in the vagina.

**Spermicides.** Spermicides can be used alone as jellies, creams, foaming tablets, suppositories, or film. If nonoxynol 9 is used as the spermicide, the same real risk described above may exist. In addition, spermicides may cause allergic reactions or irritation, which can often be remedied by changing to another brand.

Risk–Benefit Ratios

There are many risks and benefits in the use of contraceptives. Studies show that at least a thousand men and women die from results of smoking for every woman who dies from use of the pill. The risks of contraceptive use can likewise be equated with the use of medications such as analgesics and tranquilizers, which have a far higher mortality rate than contraceptives. For both developed and undeveloped
countries it is considered that the actual risks of oral contraceptives are substantially less than risks incurred through uncontrolled fertility. If less effective methods are used, the risks of unplanned pregnancy are of the same order and magnitude as those from the use of the oral contraceptive pill (Potts, Speidel, and Kessel, 1979). Some family authorities advocate combining legal early abortion with the use of barrier methods as it is considered that the nonuse or incorrect use of these methods is their greatest risk. Others consider it important that the risk of nonuse or incorrect use be minimized by improving convenience of the barrier methods and by education supplemented with improved instructions accompanying the device.

Even within the United States the disadvantages and risks of any particular contraceptive method must be weighed against the benefits and advantages. Pregnancy carries with it a higher risk of complications or mortality than does use of the pill or abortion. Sciarra (1978) stressed the importance of control of fertility and population growth in considering contraceptive methods as the benefits are reflected in society's well-being and standard of living. Lane (1978) considered that both the diaphragm and condom are at present much underrated methods of fertility control in the United States, particularly so in consideration of their high ratio of benefit to risk if used correctly and conscientiously.

A summary of the advantages and disadvantages of the various barrier methods appears in Table 3.

It can be seen from a study of the disadvantages of the different vaginal barrier methods of contraception how necessary it is to
Table 3. Main characteristics of barrier methods

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Diaphragm</strong></td>
<td></td>
</tr>
<tr>
<td>1. Safer than pill, IUD or injectables</td>
<td>1. Spermicide may have some systemic or topical effect</td>
</tr>
<tr>
<td>2. Effective if used correctly</td>
<td>2. Has lower rates of use effectiveness than pill, IUD, or injectables.</td>
</tr>
<tr>
<td>3. Reversible</td>
<td>3. Requires a high level of motivation for correct use</td>
</tr>
<tr>
<td>4. Controlled by user</td>
<td>4. Requires assistance of qualified personnel to fit device</td>
</tr>
<tr>
<td>5. Used only when needed</td>
<td>5. Coitus connected, may affect spontaneity</td>
</tr>
<tr>
<td>6. Affords additional lubrication during intercourse</td>
<td>6. Can be messy; dripping of spermicide and liquified ejaculate</td>
</tr>
<tr>
<td>7. Can be used during menstruation</td>
<td>7. Requires washing and storage</td>
</tr>
<tr>
<td>8. No effect on lactation</td>
<td>8. Requires knowledge of female anatomy</td>
</tr>
<tr>
<td></td>
<td>9. Requires touching genitalia</td>
</tr>
<tr>
<td></td>
<td>10. Expense of spermicidal cream or jelly</td>
</tr>
<tr>
<td></td>
<td>11. Needs reapplication of spermicidal cream or jelly for repeated intercourse</td>
</tr>
<tr>
<td></td>
<td>12. Subject to human error: inadequate dose or incorrect placement of spermicide</td>
</tr>
<tr>
<td></td>
<td>13. Can occasionally be felt by partner during intercourse</td>
</tr>
</tbody>
</table>
Table 3. Main characteristics of barrier methods—Continued

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sponge</strong></td>
<td></td>
</tr>
<tr>
<td>1. Safer than pill, IUD, or injectable; may not need spermicide</td>
<td>1. Spermicide may have some systemic risk (possible risk of toxic shock syndrome)</td>
</tr>
<tr>
<td>2. Very effective if used correctly in conjunction with spermicide</td>
<td>2. Has lower rates of effectiveness than pill, IUD, or injectables</td>
</tr>
<tr>
<td>3. Reversible</td>
<td>3. Requires motivation for correct use</td>
</tr>
<tr>
<td>4. Controlled by user</td>
<td>4. Requires touching genitalia and knowledge of female anatomy</td>
</tr>
<tr>
<td>5. Absorbs liquified ejaculate; no dripping</td>
<td>5. Dryness of vagina</td>
</tr>
<tr>
<td>6. Used only when needed; can be independent of coitus</td>
<td>6. Requires washing and storage; bulky</td>
</tr>
<tr>
<td>7. Natural product, if sea sponge or collagen sponge</td>
<td>7. Problems with insertion and removal</td>
</tr>
<tr>
<td>8. No effect on lactation</td>
<td>8. If full of liquid, can feel heavy and uncomfortable; may leak</td>
</tr>
<tr>
<td>9. No need for reapplication of spermicide</td>
<td>9. Use of spermicide can create problems with odor</td>
</tr>
<tr>
<td>10. Discomfort during coitus for some</td>
<td>10. Problem with disposal</td>
</tr>
<tr>
<td>11. Size and appearance can put some off</td>
<td></td>
</tr>
<tr>
<td>12. Problem with disposal</td>
<td></td>
</tr>
</tbody>
</table>
Table 3. Main characteristics of barrier methods—Continued

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cervical Cap</strong></td>
<td></td>
</tr>
<tr>
<td>1. Safer than pill, IUD, or injectables</td>
<td>1. Spermicide may have some systemic or topical risk</td>
</tr>
<tr>
<td>2. Effective if used with spermicide</td>
<td>2. Not as effective as pill, IUD, or injectables</td>
</tr>
<tr>
<td>3. Reversible</td>
<td>3. Must tailored to fit each cervix</td>
</tr>
<tr>
<td>4. Controlled by user</td>
<td>4. Self-insertion and removal can be difficult</td>
</tr>
<tr>
<td>5. Not related to coitus</td>
<td>5. Requires considerable handling of genitalia</td>
</tr>
<tr>
<td>6. Can be left in place during entire intermenstrual period</td>
<td>6. Requires knowledge of female anatomy</td>
</tr>
<tr>
<td>7. Usually cannot be felt by male during intercourse</td>
<td></td>
</tr>
<tr>
<td>8. Can be used even by women with anatomical and functional abnormalities of the vagina</td>
<td></td>
</tr>
<tr>
<td>9. Covers only the cervix and therefore does not require refitting if vaginal muscle tone changes</td>
<td></td>
</tr>
<tr>
<td>10. Is unlikely to be dislodged during intercourse</td>
<td></td>
</tr>
<tr>
<td>11. Is smaller than diaphragm</td>
<td></td>
</tr>
<tr>
<td>12. No effect on lactation</td>
<td></td>
</tr>
<tr>
<td>Advantages</td>
<td>Disadvantages</td>
</tr>
<tr>
<td>------------</td>
<td>--------------</td>
</tr>
<tr>
<td>Spermicides</td>
<td></td>
</tr>
<tr>
<td>1. Safer than pill, IUD, or injectables</td>
<td>1. May have some systemic or topical risk</td>
</tr>
<tr>
<td>2. Readily available; no need for prescription</td>
<td>2. Effectiveness much lower than pill, IUD, or injectables</td>
</tr>
<tr>
<td>3. Easy to use; user controlled</td>
<td>3. Requires motivation</td>
</tr>
<tr>
<td>4. Convenient to use; use only when needed</td>
<td>4. Coitus connected</td>
</tr>
<tr>
<td>5. Reversible</td>
<td>5. Must be applied shortly before each act of intercourse</td>
</tr>
<tr>
<td>6. Protective against VD and sexually related infections</td>
<td>6. Expensive used on a regular basis</td>
</tr>
<tr>
<td>7. Affords additional lubrication</td>
<td>7. Messy</td>
</tr>
<tr>
<td>8. Little touching of genitalia needed</td>
<td>8. Can taste unpleasant</td>
</tr>
<tr>
<td>9. No effect on lactation</td>
<td></td>
</tr>
<tr>
<td>10. Acceptable to women who might otherwise not use contraceptive</td>
<td></td>
</tr>
<tr>
<td>11. Appropriate for short-term use</td>
<td></td>
</tr>
<tr>
<td>12. Easy to understand</td>
<td></td>
</tr>
</tbody>
</table>
continue research in this field, particularly with the growing demand of women for personal fertility control that is safe, highly effective, easy to use, and reversible. No one method is going to meet all these requirements: the social, political, and religious considerations, the differing cultural expectations concerning sexuality, male and female roles and responsibilities along with variations in health status and stage of life, as well as being affordable, readily available, and legal (Sciarra, 1981).

Present methods of contraception need modification to more closely meet the needs of the contracepting population. Ongoing research is needed to develop new approaches to fertility regulation. A broad spectrum of methods of birth control is seen as the most realistic answer to the needs of society, and this study of a modification of the regular rubber diaphragm is an important contribution to the field.
CHAPTER 3

METHODS

For this study, designed as a preliminary trial requiring a considerable time investment from the research team, only a small number of volunteer subjects were used.

Selection of Subjects

Subjects for this study were recruited from the staff of the Health Sciences Center at The University of Arizona, both by word of mouth and through notices in the staff circular. Additional participants were found through publicity in the university daily newspaper. The sample was small: 16 women in the age group 18–40 years. Twenty-three subjects began the study, but only 16 completed all aspects.

The subjects were required to compare the acceptability of a well-known brand of rubber contraceptive diaphragm with the sponge bilayer diaphragm. It was not necessary that the women have previous experience with the rubber diaphragm, but it was mandatory that an additional contraceptive method be used by each individual, either the oral contraceptive pill, the IUD, or surgical sterilization of either partner. This was of the utmost importance because the effectiveness of the sponge bilayer diaphragm has not been established and for this acceptability study the diaphragm was not used with any spermicidal
detergent. All participants who completed the study received $60 to compensate for transportation costs and time.

**Research Design**

Because of the nature of the social setting of this experiment, it was necessary to select a quasi-experimental design in which there is repeated introduction of the experimental variable. No control group was possible, but this particular design has the strength of using each subject as its own control. The measures chosen in this study to operationalize the dependent variables are those commonly used in survey research, namely, the self-administered questionnaire and the interview. The design used here, although quasi-experimental, also has strong elements of survey research. A randomized two independent groups design could have been used, but its lower power would have required substantially more subjects than were available.

Each subject used each diaphragm five times, with the sponge diaphragm being alternated with the rubber diaphragm. The participants noted their reaction to each diaphragm after each use. However, to reduce the laboriousness of their role in the study (and therefore to maximize their likelihood of completion), their observations were recorded only twice. The initial observation was made after 4 trials and again upon completion of 10 trials. All participants were also interviewed prior to the beginning of the 10 trials.

The research design is closest to the Equivalent Time-Samples design discussed by Campbell and Stanley (1966), in which one group of individuals is used in the experimentation and two equivalent samples
of occasions are employed. One experimental treatment was compared with another experimental treatment on alternating occasions. The design was therefore a comparison of two treatments, $X_1$ versus $X_2$ without a control group. As these occasions were repeated five times, the design can be represented as follows:

$$X_1, X_2, X_1O_1, X_2O_2, X_1, X_2, X_1O_3, X_2O_4$$

where the $X$s represent the treatment and the $O$s represent the observational time periods.

Structurally, the design consisted of a shortened series of four observations with an initial treatment of both devices in alternating order and then a retreatment of both devices.

The Equivalent Time-Samples design is a quasi-experimental design controlling for most internal sources of invalidity. Consideration of the possible sources of invalidity, or alternative hypotheses, indicates that the effects of history are controlled in that each experimental variable was alternately introduced on 10 separate occasions. It would have been unlikely that any extraneous event occurring during this testing period would have influenced the use and evaluation of one diaphragm but not the other. Any changes effected by instrumentation would have been the same for each diaphragm method. Testing, likewise, would not have been a great problem in this design except for the possibility of some training effect, with the women's awareness of the questions prompting them to be more conscientious in their participation. Conversely, the questionnaires may have introduced an area of invalidity if the subjects' becoming aware of the questions posed caused
them to consciously or unconsciously give answers they felt were expected of them. To help control for some of these effects, the initial contraceptive method used by each subject was alternated.

Because the same subjects were involved for every treatment, neither the effects of statistical regression nor selection of subjects would be possible alternative hypotheses for the observed results. Likewise, the regression effect would have had no consequence as the selection process acted against extremes being studied. Mortality effects were a factor, as three women who found in the initial interview either or both methods of contraception unacceptable did withdraw from the study. The financial compensation offered was therefore not sufficient as a motivation in all circumstances. Four other subjects did not complete the study because of loss of their partners.

The main problems with research of this nature are in the sources of external validity. The alternating of the two stimuli could prevent adequate learning of the use of each diaphragm and there could occur confusion in the identification of the characteristics of each contraceptive method. It may have been difficult for the subjects to separate out the relevant acceptability factors. By introducing a self-administered questionnaire after each method has been used twice, it was hoped to overcome some of these effects. Multiple-treatment interference could have been a real problem, as the introduction of two different methods of contraception as experimental variables, in addition to the current method of contraception used by each woman subject, presented an artificial setting for the use of the experimental contraceptives. These were not used on an ongoing basis as would occur in a
natural setting, but their use was constantly juxtaposed with an alternative method. Therefore, there remains the possibility that the results of the study can be generalized only to conditions of repetitive and alternating use of the two diaphragms in women who have no real need for this form of contraception. Likewise, the interaction of the selection of subjects and the treatment were a concern in this study. With the use of only the staff and students of the university as a pool for subjects, a problem in generalizability arises. Had a less biased and more random sample been used, however, there exists the probability that the effects of these experimental variables would have been more generalizable.

One of the weaknesses of a study such as this is that it disturbs the lifestyle of the participating individuals and involves a considerable amount of their time and energy. Women who volunteered for this study were also unlikely to feel uneasy with their bodies and may therefore have represented a biased sample. It was not a simple straightforward study and had the additional limitations of the stimulus being applied by the subject alone. One of the strengths is that it was a relatively short study. The initial questionnaire can be seen as a form of training, with the final results being the best answer to the perceived differences.

**Procedures**

Each volunteer was examined by a physician, and a brief medical history obtained during the initial visit to the clinic. Each woman was given instructions in the use of each diaphragm, the correct
positioning of which was checked by a nurse practitioner. This was followed by an interview administered by the research assistant and a helper. The informed consent of each subject was received.

Six sponge bilayer diaphragms and one rubber diaphragm, including a tube of spermicidal jelly, were given to each volunteer along with a folder containing (see Appendix A):

1. Detailed instructions for use of the sponge diaphragm.
2. Detailed instructions for use of the rubber diaphragm.
3. Questionnaire comparing acceptability of each method.
4. Introduction to the study and explanation of its importance.
5. Phone number of the research assistant and nurse practitioner.

The rubber coil spring diaphragms were manufactured by Ortho Pharmaceuticals Corporation, Raritan, New Jersey, which also supplied the spermicidal jelly. The sponge diaphragms (Figure 1) were assembled by the research assistant and were constructed from materials approved by the Federal Drug Administration (FDA). The bilayer material consists of a layer of collagen sponge laminated with a self-adhering surgical membrane. To make the diaphragm, a bilayer pocket was sewn and the appropriate size of rubber ring inserted. These rings are standard diaphragm rings reinforced with a coiled steel spring and are manufactured by Ortho Pharmaceutical Corporation and Schmid Laboratory, Inc., Little Falls, New Jersey. Three sizes of O rings were used with the sponge bilayer, resulting in finished diaphragms of size 65, 75, and 85 mm (small, medium, and large).
Explanation

1. Exterior of sponge diaphragm
2. Stitches holding together the two bilayers
3. Rubber diaphragm ring
4. Opening to reveal construction
5. Adhesive backing reinforcing collagen layer
6. Collagen sponge layer
7. Rim of sponge diaphragm

Figure 1. Schematic representation of a sponge bilayer diaphragm made from collagen sponge
To enable the diaphragms to be easily manipulated, they were soaked in glycerin to soften the collagen sponge and give it pliability. The circumference of each diaphragm was then well lubricated with K-Y (Johnson-Johnson, New Brunswick, New Jersey) before being slowly dried at room temperature. Before use, it is necessary that the diaphragm be moistened with a little water to restore the lubrication and softness.

Each subject completed a self-administered questionnaire after each contraceptive method had been used twice. A second interview was conducted at the conclusion of the study to further assess acceptability. Future studies on the sponge diaphragm will require that the material be treated with spermicide for testing the release of the spermicidal detergent in the vagina and also for testing for viable sperm in postcoital studies. The diaphragm is designed to be disposable. Although the collagen sponge is biodegradable, the addition of the laminate and ring removes that property from the device.

**Variable Measurement**

In this study, the two main dependent variables under investigation were:

1. Acceptability of the sponge diaphragm.
2. Acceptability of the rubber diaphragm.

At the first interview, the subjects were questioned in the following areas to assess their relationship, if any, to the acceptability of both the sponge and rubber diaphragms (Appendix B):

1. Source of information about the study.
2. Reasons for interest in the study
3. Birthdate of subject and partner.
4. Occupation of subject and partner.
5. Ethnicity.
6. Marital status.
7. Religious affiliation
9. Income.
10. Education.
11. Birth control methods ever used.
12. Birth control methods used in the past year.
13. How often these were used.
15. Ability to check own cervix.

The two independent variables were operationalized by questions listed in a self-administered questionnaire and later in an interview-administered questionnaire. For the self-administered questionnaire five indicators were employed, measured on a scale of 1 to 7, a score of 7 indicating the highest degree of acceptability and a score of 1 representing the lowest level, or absence of acceptability (Appendix B). The five indicators were:

1. Ease of preparation of each diaphragm for insertion.
2. Ease of insertion of each diaphragm.
3. Acceptability during intercourse with each diaphragm.
4. Ease of removal of the diaphragms.
5. Comfort during the day following intercourse.

The first part of the final interview was identical with the initial questionnaire to increase reliability and to assess any changes in the acceptability of each method. It was considered important to keep the initial questionnaire brief, tapping only five of the most significant acceptability factors to encourage a high return rate of the papers. Three additional indicators of acceptability, measured on the scale of 1 to 7, were incorporated in the final interview/questionnaire:

6. Confidence in correct positioning.
7. Acceptability after intercourse with each diaphragm.
8. Overall acceptability.

For the final reaction, acceptability was also operationalized by seven questions demanding a yes/no response; only the first item was asked in both the self-administered and final questionnaires:

1. Ability to feel cervix through positioned diaphragm.
2. Discomfort with positioned diaphragm prior to intercourse.
3. Dripping at any time with positioned diaphragm.
4. Discomfort with urinating or bowel movements.
5. Diaphragm stayed intact with use.
6. Odor observed.
7. Odor offensive.

More information was required in the final interview, and the substance of these additional questions was:

1. Length of time between insertion and intercourse.
2. Any difference with repeated intercourse.
3. Frequency of intercourse.
4. Choice of method if both the sponge diaphragm and rubber diaphragm were available and one had to be chosen.
5. Partner's preference and his perceptions.
6. Likelihood of choosing the sponge diaphragm from all available contraceptives.
7. Comparison with other methods of contraception.
8. Packaging of sponge diaphragm.

Unless the above questions required a yes/no response or a comment, the answers were measured on a 7-point scale. The response categories used in these differentials for the scaled items were:

1. Difficult (1), somewhat difficult (4), easy (7)
3. Unlikely (1), somewhat unlikely (4), likely (7).
4. Much worse (1), same (4), much better (7).
5. Rubber diaphragm very much preferred (1), no preference (4), Sponge diaphragm very much preferred (7).

Both variables were analyzed independently and then compared.

It was postulated that the use of both the self-administered questionnaire and the interview-administered questionnaire would enhance the reliability of the responses, as both tap the same dependent variables with similar questions. A high response rate is typical in an interview-administered questionnaire, and it was expected that would overcome some of the deficiencies in the self-administered questionnaire,
as the interviewer can ensure that there is no confusion or misunderstanding of questions.

A problem with reliability arising with the use of two interviewers was largely overcome by careful preparation to ensure that there was no ambiguity in the questions and that the questions were relevant and straightforward. Although the subjects did receive remuneration for their participation, it did not guarantee their integrity. Because the participants themselves applied the treatment and made the observations, the regulated use of the diaphragm (when it should be used and under what conditions) could not be governed by the researchers. These factors therefore introduced a potential degree of unreliability, which could not be measured or controlled.
CHAPTER 4

RESULTS

In this study, the following hypothesis was tested: The sponge bilayer diaphragm will be as equally acceptable as the rubber diaphragm but with the following exceptions:

1. The sponge bilayer diaphragm will be easier and more convenient to prepare by the user.

2. The sponge bilayer diaphragm will demonstrate less dripping during use than will the rubber diaphragm.

With regard to this hypothesis, eight indicators of acceptable performance were employed, measured on a 7-point scale (see variable measurement, p. 38). Acceptability was also operationalized by seven questions requiring a yes/no response (Appendix B). The hypothesis was tested by calculating the difference between the response on the scale for the sponge bilayer diaphragm and the response for the rubber diaphragm. The data generated in the study were coded, and the overall level of satisfaction with the sponge bilayer diaphragm method of contraception and the rubber diaphragm method as determined on the scales was assessed. The hypothesis was tested for significance using paired two-tailed t tests at an alpha level of 0.05. In the tables, significance is presented in terms of the exact p values as achieved for each test.
Most subjects for this study were college students who were single, including those divorced, engaged, or separated (Table 4). Half had had previous experience with the rubber diaphragm as a method of contraception, but at the time of the study, 75% were using oral contraceptives, 19% had an IUD, and 6% were sterilized. All were involved in ongoing relationships with regular sexual activity. The financial compensation ($60) was an obvious incentive to participate in the study.

The study design included an initial questionnaire to be completed by the subjects and mailed in after testing two of the sponge bilayer diaphragms and two rubber diaphragms. The results of the final interview, administered when all 10 trials were complete, were markedly similar to those of the first questionnaire, the only significant difference being in the acceptability during intercourse with the sponge bilayer diaphragm. Comfort improved significantly with familiarity of use. There were 80 trials of each type of diaphragm.

When the initial reaction to the sponge bilayer diaphragm was compared with the initial reaction to the rubber diaphragm (Table 5), the ease of preparation of the sponge layer diaphragm was the only statistically significant finding. This finding was repeated when the final reaction to the preparation of the two diaphragm types was compared (Table 6). There was no statistically significant difference in ease of insertion of either diaphragm type for either the initial or final reaction. Likewise, no significant difference in acceptability during intercourse was determined, but it was found that the rubber diaphragm was more comfortable to remove after use than the sponge bilayer
Table 4. Characteristics of the group studied. -- n = 16.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Category</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Under 20</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>20-24 yr</td>
<td>50</td>
</tr>
<tr>
<td></td>
<td>25-29 yr</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td>30-34 yr</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td>35-39 yr</td>
<td>6</td>
</tr>
<tr>
<td>Highest level of education completed</td>
<td>Some college</td>
<td>56</td>
</tr>
<tr>
<td></td>
<td>College degree</td>
<td>38</td>
</tr>
<tr>
<td></td>
<td>Some graduate</td>
<td>6</td>
</tr>
<tr>
<td>Marital status</td>
<td>Single</td>
<td>50</td>
</tr>
<tr>
<td></td>
<td>Engaged</td>
<td>12.5</td>
</tr>
<tr>
<td></td>
<td>Married</td>
<td>12.5</td>
</tr>
<tr>
<td></td>
<td>Divorced</td>
<td>12.5</td>
</tr>
<tr>
<td></td>
<td>Separated</td>
<td>12.5</td>
</tr>
<tr>
<td>Income</td>
<td>&lt;$ 5,000</td>
<td>57</td>
</tr>
<tr>
<td></td>
<td>$ 5,000-$10,000</td>
<td>31</td>
</tr>
<tr>
<td></td>
<td>$10,000-$15,000</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>$15,000-$20,000</td>
<td>6</td>
</tr>
<tr>
<td>Previous experience with rubber diaphragm</td>
<td>Yes</td>
<td>50</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>50</td>
</tr>
<tr>
<td>Current contraceptive method</td>
<td>Birth control pill</td>
<td>75</td>
</tr>
<tr>
<td></td>
<td>IUD</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td>Sterilization</td>
<td>6</td>
</tr>
<tr>
<td>Frequency of intercourse</td>
<td>Once/day</td>
<td>12.5</td>
</tr>
<tr>
<td></td>
<td>&lt; Once/week</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td>Once/week</td>
<td>12.5</td>
</tr>
<tr>
<td></td>
<td>Twice/week or more</td>
<td>56</td>
</tr>
<tr>
<td>Average time interval between insertion and intercourse for both sponge bilayer and rubber diaphragms</td>
<td>1 hour or less</td>
<td>69</td>
</tr>
<tr>
<td></td>
<td>1-2 hours</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>4-5 hours</td>
<td>19</td>
</tr>
</tbody>
</table>
Table 5. Comparison of initial reactions to sponge bilayer diaphragm with those to rubber diaphragm. — Acceptability factors on 7-point scale, 0 = not acceptable and 7 = very acceptable. Variability is given by x + SEM.

<table>
<thead>
<tr>
<th>Item</th>
<th>Score by Diaphragm Type</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sponge Bilayer</td>
<td>Rubber</td>
<td>p</td>
</tr>
<tr>
<td>Ease of preparation</td>
<td>6.50 ± 0.63</td>
<td>5.25 ± 0.93</td>
<td>&lt;.0005</td>
</tr>
<tr>
<td>Ease of insertion</td>
<td>4.88 ± 1.63</td>
<td>5.44 ± 1.09</td>
<td>.278</td>
</tr>
<tr>
<td>Acceptability during intercourse</td>
<td>5.31 ± 1.92</td>
<td>5.94 ± 1.24</td>
<td>.145</td>
</tr>
<tr>
<td>Ease of removal</td>
<td>5.68 ± 1.85</td>
<td>6.31 ± 1.54</td>
<td>.055</td>
</tr>
<tr>
<td>Comfort day following intercourse</td>
<td>6.56 ± 1.26</td>
<td>6.56 ± 1.21</td>
<td>1.00</td>
</tr>
</tbody>
</table>

Table 6. Comparison of final reactions to sponge bilayer diaphragm with those to rubber diaphragm. — Acceptability factors on 7-point scale, 0 = not acceptable and 7 = very acceptable. Variability is given by x + SEM.

<table>
<thead>
<tr>
<th>Item</th>
<th>Score by Diaphragm Type</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sponge Bilayer</td>
<td>Rubber</td>
<td>p</td>
</tr>
<tr>
<td>Ease of preparation</td>
<td>6.75 ± 0.58</td>
<td>5.56 ± 1.03</td>
<td>.001</td>
</tr>
<tr>
<td>Ease of insertion</td>
<td>4.93 ± 1.57</td>
<td>5.18 ± 1.28</td>
<td>.665</td>
</tr>
<tr>
<td>Confidence in correct positioning</td>
<td>6.25 ± 0.25</td>
<td>6.44 ± 0.16</td>
<td>.423</td>
</tr>
<tr>
<td>Acceptability during intercourse</td>
<td>6.13 ± 1.63</td>
<td>6.50 ± 0.82</td>
<td>.359</td>
</tr>
<tr>
<td>Acceptability after intercourse</td>
<td>6.19 ± 1.22</td>
<td>6.38 ± 1.03</td>
<td>.646</td>
</tr>
<tr>
<td>Ease of removal</td>
<td>5.31 ± 1.45</td>
<td>6.19 ± 1.17</td>
<td>.008</td>
</tr>
<tr>
<td>Comfort during day following intercourse</td>
<td>6.75 ± 0.78</td>
<td>6.81 ± 0.75</td>
<td>.791</td>
</tr>
</tbody>
</table>
diaphragm, both in the initial reaction and significantly so in the final reaction. The average score for ease of removal of the rubber diaphragm (final reaction) was 6.19, whereas that for the sponge bilayer was 5.31. On the day following intercourse, comfort after removal of the diaphragm was found to be high for both diaphragm types and there was no statistically significance difference.

Confidence in correct positioning was an additional factor assessed in the final reactions of the respondents. Average scores for both types of diaphragms were high and of no statistical significance (Table 6), as were the average scores for acceptability of the diaphragms after intercourse.

Additional acceptability factors were analyzed (Table 7). Although most subjects were confident in the correct placement of the diaphragms, their ability to feel the cervix through the sponge diaphragms was not as great as for the rubber diaphragm: 69% were able to feel the cervix through the sponge bilayer diaphragm and 88% through the rubber diaphragm (p = .189). Discomfort prior to intercourse was reported only once, and that for the use of the sponge bilayer diaphragm. The dripping after intercourse so often associated with the rubber diaphragm was not eliminated as expected with the use of the sponge bilayer diaphragm, although its occurrence may be slightly diminished. The results indicated no significant differences. No respondent reported any discomfort with bowel movements or urination while either of the diaphragm types was in position. Three women recognized an odor in both the use of the sponge bilayer and rubber diaphragms, describing it as normal and not offensive.
Table 7. Comparison of acceptability factors for sponge bilayer and rubber diaphragms. -- n = 16.

<table>
<thead>
<tr>
<th>Acceptability Factor</th>
<th>Yes Response (%) by Diaphragm Type</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ability to feel cervix through positioned diaphragm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial</td>
<td>71</td>
<td>93</td>
</tr>
<tr>
<td>Final</td>
<td>69</td>
<td>88</td>
</tr>
<tr>
<td>Discomfort with positioned diaphragm prior to intercourse</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td>Dripping at any time with positioned diaphragm</td>
<td>50</td>
<td>57</td>
</tr>
<tr>
<td>Discomfort with urinating or bowel movements with positioned diaphragm</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Odor observed</td>
<td>19</td>
<td>19</td>
</tr>
<tr>
<td>Odor offensive</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
The overall acceptability of the sponge bilayer diaphragm as compared with the rubber diaphragm is shown in Table 8. The group as a whole showed no marked preference, but subgroups can be identified that preferred either the sponge bilayer or the rubber diaphragm; only one individual indicated "no preference" on the scale. The preference for the sponge bilayer or rubber diaphragm, if a choice were forced between the two, is represented in Table 9. Most of the men did not communicate their choice to the partner, but those who did tended to favor the rubber diaphragm. For the women, the choice was equally split.

The likelihood of choosing the sponge bilayer diaphragm from all available contraceptives was a question resulting in frequencies relatively uniformly spread over the 7-point scale, with a mean of 4.13 (Table 10), and was strongly related to sponge preference ($p < .001$). One factor was identified that could contribute to this preference: the volunteer's body image of "bodylike." A significant negative correlation was found between sponge preference and "bodylike" ($p = .047$; Table 11).

Table 8. Comparison of overall acceptability for sponge bilayer and rubber diaphragms. — n in parentheses; mean = 4.7.

<table>
<thead>
<tr>
<th></th>
<th>Preferred</th>
<th>No Preference</th>
<th>Preferred</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rubber Diaphragm</td>
<td>1 2</td>
<td>3 4 5</td>
<td>6 7</td>
</tr>
<tr>
<td>Preferred</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sponge Bilayer Diaphragm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preferred</td>
<td>12.5%</td>
<td>25%</td>
<td>6.3%</td>
</tr>
<tr>
<td></td>
<td>(2)</td>
<td>(4)</td>
<td>(1)</td>
</tr>
<tr>
<td>Preferred</td>
<td>6.3%</td>
<td>37.5%</td>
<td>12.5%</td>
</tr>
<tr>
<td></td>
<td>(1)</td>
<td>(6)</td>
<td>(2)</td>
</tr>
</tbody>
</table>
Table 9. Comparison of preference by sex for sponge bilayer and rubber diaphragm if had to choose between the two types. -- n in parentheses.

<table>
<thead>
<tr>
<th>Preference</th>
<th>Men</th>
<th>Women</th>
</tr>
</thead>
<tbody>
<tr>
<td>None expressed</td>
<td>56.3% (9)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Sponge bilayer diaphragm</td>
<td>18.8% (3)</td>
<td>50% (8)</td>
</tr>
<tr>
<td>Rubber diaphragm</td>
<td>25.0% (4)</td>
<td>50% (8)</td>
</tr>
</tbody>
</table>

Table 10. Likelihood of choosing the sponge bilayer diaphragm from all available contraceptives. -- Mean = 4.13.

<table>
<thead>
<tr>
<th>Very Unlikely</th>
<th>Somewhat Likely</th>
<th>Unlikely</th>
<th>Very Likely</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>6.3%</td>
<td>18.8%</td>
<td>12.5%</td>
<td>25%</td>
</tr>
</tbody>
</table>

Table 11. Preference for sponge bilayer or rubber diaphragm in relation to "bodylike" on a 5-point scale. -- n = 16; correlation -0.5024; p = .047.

<table>
<thead>
<tr>
<th>&quot;Bodylike&quot; (on 5-point scale)</th>
<th>Diaphragm Preference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Sponge bilayer</td>
<td>12.5% (2)</td>
</tr>
<tr>
<td>Rubber</td>
<td>0</td>
</tr>
</tbody>
</table>
CHAPTER 5

DISCUSSION

In interpreting the findings of this study, the characteristics of the sample need to be remembered. The sample was small, as only 16 subjects actually completed all trials. The attrition of seven subjects was due to loss of partners or reluctance to participate as required. It needs to be noted also that the women were using this form of contraception, the sponge bilayer diaphragm or the rubber diaphragm, in addition to their regular contraceptive method. It is assumed that this test method justaposed on their method of choice had a degree of nuisance value and fostered a lack of motivation.

The perceived ease of preparation of the sponge bilayer diaphragm was significantly higher than for the rubber diaphragm. The sponge bilayer diaphragm required only a simple dampening with water before insertion, whereas the rubber diaphragm needed to be treated with the spermicidal jelly, requiring more motivation because of the messiness and the experience and time needed for proper placement of the spermicide. Although not significant, the ease of insertion was influenced by the slipperiness of the diaphragm. The rubber latex surface, coated with spermicidal jelly, seems to be more slippery than the sponge surface even when the sponge is pretreated with a solution containing 10% glycerin with lubricating jelly applied to the periphery of the sponge before drying. Another possible reason for the different
perceptions regarding the ease of insertion of both diaphragms is that the sponge diaphragm has a certain bulk due to two 2-mm-thick layers of collagen sheet and the inserted O ring 5 mm in diameter. For future use, a slimmer version using O ring 2.5 mm in diameter may be possible. A slimmer diaphragm may also be significant in the ease of removal of the sponge bilayer diaphragm.

Although this study would indicate a similar degree of acceptability for both the sponge bilayer and the rubber diaphragms, it should be noted that two of the subjects' partners perceived the sponge bilayer diaphragm to be uncomfortable during intercourse. This was not a problem with the rubber diaphragm.

The integrity of the sponge fabric has been a focus for a considerable portion of the research. Over half (56%) of the subjects experienced a rupture of the sponge layer of one or more of their sponge bilayer diaphragms, mainly during removal of the device from the vagina. It was observed by the research team midway through the study that moisture resulted in delamination of the adhesive backing of the sponge. (The lamination used with the tested sponges consisted of an adhesive-coated polyethylene membrane, 0.08 mm thick). This left the sponge layer unsupported and fragile and more subject to rupture. It was subsequently found that fixation of the polyethylene membrane to the sponge by a thermally melted polymer resulted in a reinforced collagen sheet structure that was resistant to moisture.

The data resulting from the question concerning the "likelihood of choosing the sponge bilayer diaphragm from all available contraceptives" would have been influenced by the fact that all subjects were
testing the two diaphragm methods alongside their method of choice. Apart from a professed interest in the research and the financial appeal, they had already currently decided against vaginal barrier methods for themselves. There would therefore be a strong likelihood that the sponge bilayer would be perceived as more preferable in a different group of women. The discomfort perceived by some subjects in the initial two trials of the sponge bilayer diaphragm could be a learning effect and could be attributable to insufficient moistening of the sponge or incorrect positioning, as there was a significant difference in the comfort perceived in the latter three trials.

The dripping normally associated with the use of the rubber diaphragm was not prevented by using the sponge bilayer diaphragm. It would seem that the sponge bilayer diaphragm becomes soaked with vaginal secretions, which prevents the adequate absorption of the liquified ejaculate. Most subjects were confident in the positioning of both the sponge bilayer and rubber diaphragms, but the ability to feel the cervix through the sponge fabric was reduced with the sponge bilayer diaphragm. This would appear to be a property of the bulk of the fabric, which may not be a problem with a slimmer diaphragm. Other checks for correct positioning may need to be used, e.g., running the finger around the rim of the positioned diaphragm. Removal of the sponge diaphragm could have been difficult due to the property of bulkiness also. When saturated with fluids, the sponge appeared to anchor itself firmly in the vagina and considerable force was required for removal because the rim of the diaphragm was difficult to grasp with the thumb and forefinger.
Finally, it needs to be stressed that this study served as a preliminary trial to generate feedback from users in order to implement improvements in the design and indicate appropriate techniques and manipulation in the proper use of the sponge bilayer diaphragm. This study definitely points to the necessity for further design improvements, which should include reducing the bulk of the device and obtaining a moisture-resistant thermoseal between the sponge and the lamination.

The significantly better rating of the collagen sponge in the ease of preparation was expected. We assume, however, that the uniformity of the distribution of the spermicide within the sponge matrix, mainly at the diaphragm circumference, and the possible continuous release of the spermicide into the vagina may both contribute to better contraceptive effectiveness. Addition of spermicide could further improve the ease of insertion due to its additional lubrication. The presence of the spermicidal detergent could possibly cause irritation of the vaginal wall as manifested by itching, burning sensation, and/or increased vaginal secretion with consequent dripping. This remains to be tested.

The favorable response to the sponge bilayer diaphragm was due in large part to its ease of preparation and its soft texture. The naturalness of the product had a strong appeal for the women. The need for alternative vaginal barrier methods has long been demonstrated, and this study would indicate that an improved sponge bilayer diaphragm could be highly competitive.
APPENDIX A

TESTING OF MODIFIED CONTRACEPTIVE DIAPHRAGM

Appendix A is a copy of the brochure given to each subject at the first interview. The time sheet is not included because some subjects failed to complete it and the data were therefore not used in the study.
# TABLE OF CONTENTS

1. Introduction to the Study  
2. Subject Consent Form  
3. Information about the Study  
4. General Instructions  
5. Instructions for Use of the Sponge Diaphragm  
6. Instructions for Use of the Rubber Diaphragm  
7. Questionnaire
Introduction to the Study

For thousands of years, efforts have been made to prevent conception, with varying degrees of success. One of the most ancient methods is the use of the vaginal sponge; those communities living by the sea having access to natural sea sponges. The Eighteenth Century saw the development of the rubber diaphragm as we know it today, and it has become a dependable form of contraception for many women, when used correctly and conscientiously and in conjunction with spermicidal cream or jelly. It does of course have its disadvantages. The sponge method, still used in some parts of the world, is much less reliable but it is very safe and does not require medical intervention.

After the initial excitement during the 1960s when the oral contraceptive pill and the intrauterine device were first introduced, there has developed considerable evidence that these two methods are not as ideal for all women as was first proclaimed. Recent studies show a renewed interest in the use of vaginal barrier methods of contraception.

The diaphragm which you are using in the study to compare with the regular diaphragm, is a modification of the rubber diaphragm incorporating the use of a naturally derived sponge with its high absorbent properties. It is hoped to develop a more natural disposable method of contraception which is aesthetically pleasing as well as safe and easy to use.
SUBJECT CONSENT FORM

TITLE: Testing of Modified Contraceptive Diaphragm

B. Acceptability

LAY SUMMARY

The purpose of this study is to determine if a diaphragm lined with a sponge made of pure fibrillar skin protein (collagen) and containing a sperm killing agent, placed in the upper part of the vagina against the cervix (the mouth of the womb) can prove to be an effective means of contraception by acting as a mechanical and chemical barrier to sperm.

You are being asked to participate in this acceptability study, which deals only with determining such factors as the convenience and comfort experienced in the use of the sponge diaphragm. To be eligible for this study you must be a woman who is currently using, as her method of contraception, either the oral contraceptive pill, an I U D, or sterilization of either partner. During this entire study, you should continue to use this contraceptive method as the sponge modification of the diaphragm could prove less effective than the method you are currently using. Your participation in the study will be terminated immediately if your current method is discontinued.

If you decide to participate, a physician will perform a vaginal examination and obtain a very brief history. If necessary, a culture will be done to determine the presence of infection. You will be asked to answer some questions during your visits to the clinic and will be given a questionnaire to evaluate the various aspects of the modification of the diaphragm as compared with the regular diaphragm. This is to be filled in at home. All information received will be coded and used in the further development of this diaphragm modification.
The signed consent form will be filed in an area designated by the Human Subjects Committee with access restricted to the principal investigator or authorized representatives of the particular department.

You should feel free to ask questions and receive answers at any time and may withdraw from the study at any time. Your refusal to participate in the project will not affect the quality of your care or treatment. There will be no cost to you; costs will be covered by research funds. There is no direct benefit to you, but you will be compensated $60 for loss of time, transportation costs and other inconveniences.

I understand that in the event of pregnancy or physical injury resulting from the research procedures, the sponsor of this project (Program for Applied Fertility Research) is not responsible for provision of medical care nor for compensation of any expenses associated with such injury. I also understand that the University of Arizona is not responsible for financial compensation for wages and time lost and that the costs of medical care and hospitalization are not covered and must be borned by the subject. Further information can be obtained by asking Dr. Droegemueller or Dr. Chvapil.

The nature, demands, risks and benefits of the project have been explained to me as well as the type of treatment known and available and I understand what my participation involves. Furthermore, I understand that I am free to ask questions and may withdraw from the project at any time, without affecting my medical care. A copy of this consent form is available to me upon request.

Subject ________________________________ Date _____

Witness ________________________________ Date _____
I have carefully explained to the subject the nature of the above project. I certify, that to the best of my knowledge, the subject signing this consent form understands clearly the nature, demands, benefits and risks involved in her participation in this study. A medical problem or language or educational barrier has not precluded a clear understanding of her involvement in this project.

________________________________________________________ Date ___________

Investigator's Signature
TESTING OF MODIFIED CONTRACEPTIVE DIAPHRAGM

Acceptability Study

Your help in this study is much appreciated. The sponge diaphragms are to be used a total of five times. Please alternate their use with that of the rubber diaphragm. We are asking that you use both diaphragms a total of ten times. (You have been given one extra sponge diaphragm. Please contact us if for any reason you need another to complete your part in the study.) The instructions for the use of each diaphragm are included in this folder. Please follow all the steps carefully. After use, the rubber diaphragm is to be washed and kept for reuse. Each sponge diaphragm is to be used once only. However, please save all diaphragms (which you may rinse and dry if you wish) and return them at the conclusion of the study, along with your completed questionnaire. Please also keep a record of the dates on which each method of contraception was used.

If you have any questions while you are participating in this study, please call

the research assistant, Janet MacGregor, Home 299-6853
or leave a message at the Surgical Biology office; secretary 626-6637
or call the nurse practitioner, Karen Betts,
Office 626-6591
Home 327-0674

IMPORTANT REMINDER: Please save all diaphragms.

Do not dispose of either the sponge or the rubber diaphragms.

PLEASE RETURN ALL DIAPHRAGMS TO THE CLINIC
AT YOUR LAST VISIT
INSTRUCTIONS

1. Questionnaire:

Please fill out the answers to the enclosed questions as soon as you have completed two trials of each diaphragm. This is a study of acceptability and as such we would appreciate it if you are as candid as you can be. For those questions which are accompanied by a scale, please place an X at the number you feel is the most appropriate. A stamped addressed envelope is included with this folder. Please mail back as soon as possible with your name and phone number for identification.

2. Time Sheet:

It would be helpful for us to know the time intervals between each use of the different diaphragms. Please write down the date you use each method.

3. Second Interview:

When you have completed all ten trials, please call as soon as possible to make an appointment for this extremely important follow up.

4. Diaphragms:

Please return all diaphragms at the time of your second interview.

Thank you very much for your participation.

Janet MacGregor
299-6853
INSTRUCTIONS FOR USE OF SPONGE DIAPHRAGM

IMPORTANT: THIS DIAPHRAGM WILL NOT PREVENT CONCEPTION
ITS USE IS SOLELY TO TEST ACCEPTABILITY

Inserting the diaphragm:
1. Remove the sponge diaphragm from the bag.
2. Moisten by sprinkling diaphragm with warm water until it is just damp. Run finger around both sides of rim to assist rehydration of lubricating jelly placed on the edge for ease of insertion. (Too much water will remove lubrication.)
3. Place one foot on toilet or chair, or sit on toilet with legs apart, or lie on your back with knees bent and apart . . . whichever seems most natural and comfortable for you. (The 'one foot up' method seems the most satisfactory.)
4. Compress opposite sides of diaphragm to form a flat figure 8.
5. Spread the lips of your vagina with your free hand and push the diaphragm gently inward as far as it can go.
6. Tuck the front rim of the diaphragm up behind the pelvic bone so that the diaphragm hugs the front wall of the vagina.
7. Check with the forefinger to be sure the diaphragm is in place covering the cervix. If properly inserted, you can perform any normal activity unaware of its presence or any discomfort.

The sponge diaphragm may be inserted up to 12 hours before intercourse and does not require additional spermicide for repeated intercourse in a 12 hour period.
Removing the diaphragm:

1. There is no urgency to remove the diaphragm. It may be left in position for up to 24 hours.

2. You should not remove the diaphragm nor should you douche for 6–8 hours after intercourse.

3. To remove the diaphragm, take front rim between thumb and forefinger and gently pull down and out. If it is difficult for you to reach the rim, bear down or contract your abdominal muscles to force the front edge down.

4. When you remove the sponge diaphragm, it is important for the purposes of this study that it be saved, and all samples be returned to the clinic at the conclusion of the acceptability testing. (If desired, you may rinse the diaphragm and leave to dry.)
INSTRUCTIONS FOR USE OF RUBBER DIAPHRAGM

Preparing for insertion

1. Urinate and wash your hands before inserting the diaphragm.

2. Place one or two teaspoonsful of contraceptive jelly or cream into the dome of the diaphragm. (Refer to package directions.) Spread the spermicide around the inner surface of the dome and also a small amount around the rim. The spermicide on the rim makes the diaphragm easier to insert and helps seal the diaphragm in place. Too much jelly or cream can make the diaphragm too slippery to handle during insertion.

3. You can insert the diaphragm while you are standing with one leg up, squatting or lying down. The position of the cervix and the walls of the vagina will be different depending on your position. If you are used to one position and then change to another, take extra care in positioning the diaphragm to be sure the cervix is covered.

Inserting the diaphragm

1. Hold the diaphragm with the dome down (spermicide up) and press the opposite sides of the rim together between your thumb and third finger. The diaphragm can be held from above or below (see booklet for diagrams).

2. Spread the lips of your vagina with your free hand. Hold the compressed diaphragm dome down (spermicide up) and push it gently inward along the rear wall of the vagina as far as it can go. Your index finger, kept on the outer rim of the diaphragm, helps you guide the diaphragm into place.

---
a. Copy of instructions included in package by Ortho Pharmaceuticals Corporation, Raritan, New Jersey.
3. With your index finger, push the front rim of the diaphragm up until it is locked in place just above the pubic bone.

4. Check with your index finger to be sure the diaphragm is in place and is holding the contraceptive jelly or cream over the cervix. It is important that the cervix be covered by the diaphragm and spermicide, and that the diaphragm be locked in place between the upper edge of the pubic bone and rear wall of the vagina. You should be able to feel your cervix through the rubber shield. You can feel the front rim of the diaphragm above the pubic bone, but you may not be able to follow the rim all the way around since your fingers may not be long enough.

5. If, after some practice, you still find insertion awkward or difficult, vary your body and hand positions slightly until you can insert the diaphragm comfortably.

Removing the diaphragm
1. You should not remove the diaphragm, nor should you douche, for six to eight hours after intercourse.

2. You need not feel any urgency about removing the diaphragm. It is safe to let it remain in position for 24 hours. Should you forget to remove it for some hours, or should removal be inconvenient at any particular time, that is no cause for concern. Just bear in mind that if you desire to have intercourse again, you must first apply more spermicidal jelly or cream.

3. To remove the diaphragm, put your index finger behind the front rim and pull the diaphragm down and out.

4. If you get up before it is time to remove the diaphragm and there is a discharge of cream or jelly, you may use a tampon or sanitary napkin.
INSTRUCTIONS FOR USE OF RUBBER DIAPHRAGM: Page 3

Care of the diaphragm

Clean your diaphragm after use with mild soap and water, rinse thoroughly in clear water and dry carefully. Store the diaphragm, unrolled, in its original container.

Except for mild, unperfumed soap, do not use any product on your diaphragm that is not made especially for use with the diaphragm.

Examine the diaphragm carefully before each use by holding it up to a bright light. Make sure that it has no cracks or tiny holes.
QUESTIONNAIRE

1. (a) How easy was the sponge diaphragm to prepare for insertion?

   Difficult 1 2 3 4 5 6 7 Easy
   difficult somewhat

   (b) How easy was the rubber diaphragm to prepare for insertion?

   Difficult 1 2 3 4 5 6 7 Easy
   difficult somewhat

2. (a) Please identify what it was that made it easy or difficult to
   prepare the sponge diaphragm for insertion. _______________________

   ________________________________________________________________

   (b) Please identify what it was that made it easy or difficult to
   prepare the rubber diaphragm for insertion. _______________________

   ________________________________________________________________

3. (a) How easy was the sponge diaphragm to insert?

   Difficult 1 2 3 4 5 6 7 Easy
   difficult somewhat

   (b) How easy was the rubber diaphragm to insert?

   Difficult 1 2 3 4 5 6 7 Easy
   difficult somewhat
5. (a) Please identify what it was that made the sponge diaphragm easy or difficult to insert. 
(b) Please identify what it was that made the rubber diaphragm easy or difficult to insert.

5. (a) Were you able to feel your cervix through the sponge diaphragm? YES ( ) NO ( )
(b) Were you able to feel your cervix through the rubber diaphragm? YES ( ) NO ( )

6. (a) Did you experience any problem during intercourse with the sponge diaphragm? 

(b) Did you experience any problem during intercourse with the rubber diaphragm? 

7. (a) If you had a problem with the sponge diaphragm during intercourse please describe it. 
(b) If you had a problem with the sponge diaphragm during intercourse please describe it.
8. Did you experience any problems removing
   (a) the sponge diaphragm?
   a big problem 1 2 3 4 5 6 7 no problem
   some problem
   (b) the rubber diaphragm
   a big problem 1 2 3 4 5 6 7 no problem
   some problem

9. (a) If you had a problem removing the sponge diaphragm, please describe it. 
      ____________________________

   (b) If you had a problem removing the rubber diaphragm, please describe it. 
      ____________________________

10. (a) Did you experience a problem the day following intercourse after using the sponge diaphragm?
    a big problem 1 2 3 4 5 6 7 no problem
    some problem

   (b) Did you experience a problem the day following intercourse after using the sponge diaphragm?
    a big problem 1 2 3 4 5 6 7 no problem
    some problem

11. (a) If you had a problem with the sponge diaphragm the day following intercourse, please describe it. 
      ____________________________

   (b) If you had a problem with the sponge diaphragm the day following intercourse, please describe it. 
      ____________________________
APPENDIX B

INTERVIEW GUIDES

Interview Guide # 1 was used at the first interview following the physical examination. Interview Guide # 2 was used at the conclusion of the 10 trials.
INTERVIEW GUIDE # 1

Identification number:

1. How did you find out about the study?

2. I would be interested to learn why you decided to participate in the research?
   a. Dissatisfaction with currently available contraceptive methods? ( )
   b. Curiosity? ( )
   c. Financial compensation? ( )
   d. Desire to be in control of own body? (Interest in Women's Movement) ( )
   e. Interest in research? ( )
   f. Other? ( ) (Please specify ____________________________)

3. What is your birthdate?

4. What is the birthdate of your partner?

5. What is your occupation? (Detailed description of duties) ______

6. What is your partner's occupation?
7. Please look at this card and tell me the number next to the category which best describes you. (Hand subject card #1)
   a. Black
   b. Mexican American
   c. Anglo
   d. Other (Specify _________)

8. What is your marital status? Are you . . .
   a. Single ( )
   b. Engaged ( )
   c. Married ( )
   d. Divorced ( )
   e. Separated ( )
   f. Widowed ( )

9. I would be interested to learn your religious affiliation. Are you .
   a. Catholic ( )
   b. Protestant ( )
   c. Jewish ( )
   b. Other ( ) Specify ________

10. Overall, how much would you say that your religion influences your daily life? (Hand subject card # 2)
    a. not at all ( )
    b. somewhat ( )
    c. quite a bit ( )
    d. a lot ( )

11. Please look at this card and tell me the number next to the category which best describes your personal income for the next year. (Hand subject card #3)
    a. less than $5000
    b. between 5,000 and 10,000
    c. between 10,000 and 15,000
    d. between 15,000 and 20,000
    e. between 20,000 and 25,000
    f. between 25,000 and 30,000
    g. between 30,000 and 35,000
    h. between 35,000 and 40,000
    i. above 40,000

(If married, give family income - before taxes.)
12. Please look at this card and tell me the number next to the category which best describes your highest level of education. (Hand subject card # 4)

a. 6th grade or less       e. college degree
b. some high school       f. some grad. school
c. high school grad.      g. professional (grad. degree)
d. some college or vocational
   training

13. Looking at this list, please tell me which of these methods you have ever used for birth control? (Hand subject contraceptive list)

a. _______  d. _______  g. _______  j. _______

b. _______  e. _______  h. _______  k. _______

c. _______  f. _______  i. _______  l. _______

m. others (specify ____________)

14. In the past year which of these contraceptives have you used?

a. _______  d. _______  g. _______  j. _______

b. _______  e. _______  h. _______  k. _______

c. _______  f. _______  i. _______  l. _______

m. others (specify ____________)
15. Of these you have mentioned, please tell me how often you have used them. (Hand subject card #5)
  a. seldom (a) ( )
  b. sometimes (b) ( )
  c. often (c) ( )
  d. always (d) ( )

16. How comfortable do you feel with your own body? (Hand subject card #6)

<table>
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<th>very uncomfortable</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>very comfortable</th>
</tr>
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<td></td>
<td>neither</td>
</tr>
</tbody>
</table>

17. Looking at this card, please tell me the letter which best describes how you feel. (Hand subject card #7)
  a. I dislike just about all aspects of my body.
  b. I dislike most aspects, but I like a few.
  c. I dislike some aspects, and like some aspects.
  d. I like most aspects, but I dislike a few.
  e. I like just about all aspects of my body.

18. Would you change your body if you could? ( ) Yes ( ) No ( ) Don't know

If response is YES) What would you change? ___________________
19. How comfortable do you feel about checking your own cervix?
(Hand subject card # 8)

very 1 2 3 4 5 6 7 very
uncomfortable neither comfortable

20. Can you touch your cervix? ( ) YES ( ) NO ( ) DON'T KNOW
If response is NO, why not? ____________________________
Interview Guide # 2

1. Looking at this card, please tell me the number which best describes how easy it was for you to prepare
   (a) the sponge diaphragm for insertion?

   Difficult  1  2  3  4  5  6  7  Easy
   somewhat
difficult

   (b) the rubber diaphragm for insertion?

   Difficult  1  2  3  4  5  6  7  Easy
   somewhat
difficult

(Hand subject card #1)

2. (a) Can you identify what it was that made the sponge diaphragm easy or difficult to prepare for insertion?  

   ________________________________

   (b) Can you identify what it was that made the rubber diaphragm easy or difficult to prepare for insertion?  

   ________________________________
3. Looking at this card, please tell me the number which best describes how easy it was for you to insert
   (a) the sponge diaphragm?

   Difficult  1  2  3  4  5  6  7  Easy
   somewhat
difficult

   (b) the rubber diaphragm?

   Difficult  1  2  3  4  5  6  7  Easy
   somewhat
difficult

(Hand subject card # 2)

4. (a) Please identify what it was that made the sponge diaphragm easy or difficult to insert. ____________________________
   (b) Please identify what it was that made the rubber diaphragm easy or difficult to insert. ____________________________
   (c) Did the ease of insertion differ at different times?
      YES ( ) NO ( )
   (d) To what can you relate the difference? ____________________________

5. (a) Were you able to feel your cervix through the sponge diaphragm?
      YES ( ) NO ( )
   (b) Were you able to feel your cervix through the rubber diaphragm?
      YES ( ) NO ( )
6. (a) Did you experience any problem with the sponge diaphragm during intercourse? (Hand subject card # 3)

A big problem 1 2 3 4 5 6 7 no problem

(b) Did you experience any problem with the sponge diaphragm during intercourse?

A big problem 1 2 3 4 5 6 7 no problem

7. (a) If you had a problem with the sponge diaphragm during intercourse please describe it. ___________________________

(b) If you had a problem with the rubber diaphragm during intercourse please describe it. ___________________________

8. a. Did you experience any problem with the sponge diaphragm after intercourse?

A big problem 1 2 3 4 5 6 7 no problem

a. Did you experience any problem with the rubber diaphragm after intercourse?

A big problem 1 2 3 4 5 6 7 no problem
9. a. If you had a problem with the sponge diaphragm after intercourse, please describe it.

b. If you had a problem with the rubber diaphragm after intercourse, please describe it.

10. Did you experience any dripping with:

a. the sponge diaphragm? Yes ( ) No ( )

b. the rubber diaphragm? Yes ( ) No ( )

If the volunteer describes a problem with dripping with the diaphragm:

a. Did the sponge diaphragm drip when inserted?
   Yes ( ) No ( )

b. How much water was used to dampen the sponge diaphragm?
   1. rinse only sprinkled with water ( )
   2. whole sponge sprinkled with water ( )
   3. sponge run under faucet ( )

c. Did the dripping occur with each diaphragm use?
   1. Sponge Yes ( ) No ( )
   2. Rubber Yes ( ) No ( )

d. If not how often did the dripping occur?
   1. Sponge 1x ( ) 2x ( ) 3x ( ) 4x ( )
   2. Rubber 1x ( ) 2x ( ) 3x ( ) 4x ( )
e. Can you identify when in your menstrual cycle the dripping occurred?
   early ( ) mid-cycle ( ) late ( ) during menses ( )

f. Was the dripping related to repeated intercourse?
   1. Sponge Yes ( ) No ( )
   2. Rubber Yes ( ) No ( )

g. How long had the sponge diaphragm been in the vagina?
   1. 6–8 hours after intercourse? ( )
   2. 8–16 hours after intercourse? ( )
   3. 16–24 hours after intercourse? ( )
   4. longer? ( )

11. Did you experience any discomfort with urinating or bowel movements while using:

   U.  B.M.

   a. the sponge diaphragm? Yes ( ) No ( ) Yes ( ) No ( )
   b. the rubber diaphragm? Yes ( ) No ( ) Yes ( ) No ( )
12. a. If you experienced any discomfort with urinating and/or bowel movements while using the sponge diaphragm, please describe it.

b. If you experienced any discomfort with urinating and/or bowel movements while using the sponge diaphragm, please describe it.

c. Was there any odor at any time with:
   a. the sponge diaphragm Yes ( ) No ( )
   b. the rubber diaphragm Yes ( ) No ( )

13. If YES, was the odor offensive?
   a. with the sponge diaphragm? Yes ( ) No ( )
   b. with the rubber diaphragm? Yes ( ) No ( )

14. If YES, how long had the diaphragm remained inserted after intercourse:
   a. sponge diaphragm
      (1) 6-8 hours ( )
      (2) 8-16 hours ( )
      (3) 16-24 hours ( )
      (4) longer ( )

   b. rubber diaphragm
      (1) 6-8 hours ( )
      (2) 8-16 hours ( )
      (3) 16-24 hours ( )
      (4) longer ( )
15. Did the sponge diaphragm remain intact during insertion, use, and removal? Yes ( ) No ( )

16. If NO, please describe damage. __________________________________________

17. Did you experience any problems removing (a) the sponge diaphragm? (Hand subject card # 4)

(a) the sponge diaphragm?

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<th>a big problem</th>
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<th>5</th>
<th>6</th>
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(b) the rubber diaphragm?

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18. (a) If you had a problem with removing the sponge diaphragm, please describe it. __________________________________________

(b) If you had a problem with removing the rubber diaphragm, please describe it. __________________________________________

19. (a) Did you experience any problem the day following intercourse after using the sponge diaphragm? (Hand subject card # 5)

(a) Did you experience any problem the day following intercourse after using the sponge diaphragm? (Hand subject card # 5)

<table>
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<tr>
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19. Continued

(b) Did you experience any problem the day following intercourse after using the rubber diaphragm?

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</table>

20. (a) If you had any problem with the sponge diaphragm the day following intercourse please describe it. _______________

(b) If you had any problem with the rubber diaphragm the day following intercourse please describe it. _______________

21. What was the average time interval between insertion of each diaphragm and intercourse? (Hand subject card #6)

(a) the sponge diaphragm? _______________

(b) the rubber diaphragm? _______________

(1) one hour or less (4) six to eight hours

(2) one to two hours (5) twelve hours

(3) four to five hours (6) overnight

22. Did you experience any discomfort during the wearing of the diaphragm prior to intercourse?

(a) with sponge diaphragm? YES ( ) NO ( )

(b) with rubber diaphragm? YES ( ) NO ( )
23. if YES, please explain.  
(a) 

(b) 

24. If you had intercourse more than once in any one day, were you aware of any differences:  
(a) with sponge diaphragm? YES ( ) NO ( ) 
(b) with rubber diaphragm? YES ( ) NO ( ) 

25. If YES, please identify the difference.  
(a) 

(b) 

26. On the average, how often do you have intercourse? (Hand subject card # 7)  
(1) once/day (2) about once/week (2) Less than once/week (4) two times or more/week 

27. How often did you have doubts that the diaphragm was properly placed? (Hand subject card # 8)  
(a) the sponge diaphragm?  
always  1 2 3 4 5 6 7 
sometimes never 

(b) the rubber diaphragm?  
always  1 2 3 4 5 6 7 
sometimes never
28. (a) Has your partner expressed a preference for either the sponge diaphragm or the rubber diaphragm:

YES ( ) NO ( )

(b) Which did he prefer and why? ________________________________

29. Did he have any other comments? ________________________________

30. Which of the two methods would you use if both were available in the future? (assuming that you had to choose one of them)

   ___ (a) the sponge diaphragm?
   ___ (b) the rubber diaphragm?

31. If you could choose among all available contraceptives, how likely is it that you would use:

   (a) the sponge diaphragm? (Hand subject card # 9)

   Unlikely 1 2 3 4 5 6 7 Likely
   somewhat unlikely

   (b) the rubber diaphragm?

   Unlikely 1 2 3 4 5 6 7 Likely
   somewhat unlikely
32. Considering all aspects, how comparable did you find the sponge diaphragm with the rubber diaphragm?

<table>
<thead>
<tr>
<th>rubber diaphragm very much preferred</th>
<th>1 2 3 4 5 6 7</th>
<th>sponge diaphragm very much preferred</th>
</tr>
</thead>
</table>

33. (a) From the following list, please tell me the three methods of contraception which you have used the most frequently.

(Hand subject contraceptive list)

1. ( ) Female sterilization       7. ( ) Douche
2. ( ) Male sterilization         8. ( ) Withdrawal
3. ( ) Birth Control Pills        9. ( ) Condom (rubber)
4. ( ) IUD                        10. ( ) Rhythm (calendar, mucus method, body temp.)
5. ( ) Diaphragm                  11. ( ) Extended breast-feeding
6. ( ) Foam/suppository/jellies    12. ( ) Injections
13. ( ) Other
33. (b) How would you compare the sponge bilayer diaphragm with these methods of contraception you have used in the past in terms of these factors:

(a) convenience of use  
(b) comfort  
(c) enjoyment of sex/spontaneity  
(d) effect on woman's body  
(e) effect on man's body  
(f) messiness  
(g) temperature effect  
(h) lubrication  
(i) confidence in effectiveness  
(j) care and storage  
(k) disposal

(Hand subject card # 10)

Much worse  1  2  3  4  5  6  7  Much better  
same

Method #  

(a) ( ) (f) ( )  
(b) ( ) (g) ( )  
(c) ( ) (h) ( )  
(d) ( ) (i) ( )  
(e) ( ) (j) ( )  
(f) ( ) (a) ( ) (k) ( )

(Hand subject card # 10)

34. How do you think these sponge diaphragms should be packaged?

(What would be most acceptable and convenient for you?)
35. Do you have any other comments?
APPENDIX C

PERMISSION FOR STUDY FROM HUMAN SUBJECTS COMMITTEE
Milos Chvapil, M.D., Ph.D.
Department of Surgery
Arizona Health Sciences Center

Dear Dr. Chvapil:

We are in receipt of the revised consent form for your project, "New Sponge-Bilayer Contraceptive Method" (HSC 880-06) (AKA: "Diaphragm-Colic Sponge Insert"). The changes reflected in this revision are minor and pose no further risk to the subjects involved. Therefore, approval of this revised consent form is granted effective 26 October 1981.

The changes approved are as follows:

1. Change in title to: "Testing of Modified Contraceptive Diaphragm"

2. Deletion of the daily body temperature measurement procedure.

3. Change in study population criteria to exclude women using a diaphragm and to include those women whose form of contraception is the contraceptive pill, an IUD, or sterilization of either partner.

4. Change of study sponsor from NIH to Program for Applied Fertility Research.

Approval for these changes is granted with the understanding that no further changes will be made in either the procedures followed or in the consent form used (copies of which we have on file) without the knowledge and approval of the Human Subjects Committee and the Departmental Review Committee. Any physical or psychological harm to any subject must also be reported to each committee.
A university policy requires that all signed subject consent forms be kept in a permanent file in an area designated for that purpose by the Department Head or comparable authority. This will assure their accessibility in the event that university officials require the information and the principal investigator is unavailable for some reason.

Sincerely yours,

Milan Novak, M.D., Ph.D.
Chairman
Human Subjects Committee

cc: Departmental Review Committee
HUMAN SUBJECTS RESEARCH STATEMENT

One copy of this form must be submitted with each Application for Candidacy or Master's Degree Study Program. Please sign one of the statements below:

1) The thesis/dissertation referenced on the attached form is based on research involving the use of human subjects. The project has been approved by the Human Subjects Committee. (Please attach a copy of the letter of approval received from the Committee.)

\[\text{Janet C. Brookfield} \quad \text{5/18/82}\]
Student
\[\text{Department Head} \quad \text{5/20/82}\]

2) The thesis/dissertation referenced on the attached form is based on research involving human subjects exempted from review by departmental or University Human Subjects committees by the National Research Act revision effective July 27, 1981.

\[\text{Student} \quad \text{Date}\]
\[\text{Department Head} \quad \text{Date}\]

3) The thesis/dissertation referenced on the attached form is based on research which does not involve the use of human subjects.

\[\text{Student} \quad \text{Date}\]
\[\text{Department Head} \quad \text{Date}\]

July 28, 1981
REFERENCES


