

REVIEW

State-of-the-art of non-hormonal methods of contraception: I. Mechanical barrier contraception

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ABSTRACT Mechanical barriers, specifically male condoms, command renewed interest and are used today by more people. The worldwide prevalence rate of male condoms was about 6% in 2007 corresponding to 65 million cohabiting couples. The prevalence of female barrier methods, including diaphragms, cervical caps and female condoms has declined to less than 1% of women in North America and in north-west Europe. Even smaller percentages use female barriers elsewhere. First-year life table pregnancy probabilities of mechanical barrier methods range from 4 to 19 per hundred in clinical trials. The male condom is the only proved preventive tool against several sexually transmitted infections (STIs), especially HIV. The effectiveness of the diaphragm and cervical caps in this regard appears limited. Further research is needed to measure the efficacy of female condoms in disease prevention. Sponges are not known to protect against STIs. Because of their ease of use and availability, low short-term costs, relative freedom from side effects, and usefulness in combating STIs, mechanical barrier methods, especially condoms, will continue to be used on a large scale. For our literature search we used personal files, search engines such as Popline, Medline, PubMed and Google, and data bases of WHO, FHI and Cochrane Library.

KEY WORDS Mechanical barrier contraception; Male condoms; Female condoms; Diaphragm; Cervical cap; Contraceptive sponges

INTRODUCTION

To collect information and literature data on the topic, the authors utilised their own files, publications of the Cochrane Library, the Family Health International (FHI) and World Health Organisation (WHO) databases, and search engines such as Medline, Popline, PubMed and Google, employing

the following key words: mechanical barrier contraception, male condoms, female condoms, diaphragm, cervical cap and contraceptive sponges. Papers written in different languages were taken into consideration when having, at least, an abstract in English or German.

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THE METHODS

Mechanical barrier contraceptives prevent spermatozoa from gaining access to the upper female genital tract and thus prevent fertilisation. Male and female condoms block sperm from entering the vagina. Diaphragms and cervical caps prevent sperm present in the vagina from reaching the cervix. Male condoms and, to a lesser degree, female condoms and the diaphragm are barriers that reduce the risk of transmission of certain sexually transmitted infections (STIs).

History

The earliest known contraceptives are mentioned by the Petrie Medical Papyrus (also known as the Kahoun papyrus) around 1950 BC¹. These were primarily *spermicides* containing a mixture of extracts from different plants with honey and/or crocodile dung to form a vaginal contraceptive paste². In addition to their spermicidal effects, these paste mixtures and a vaginal suppository described in the Ebers papyrus¹ might have been the first mechanical barrier contraceptives due to their solid content.

In the 12th century, Moslem physicians recommended *suppositories* or *tampons* containing different spermicidal agents. Some hundreds of years later in Europe, a sponge moistened with diluted lemon juice was cited as an effective method when inserted into the vagina². Through the centuries and even up to the present time *home made pessaries* prepared from a wide variety of materials have been used³.

The inventor of the *condom* and even the country where it was invented are unknown. Some believe the name refers to an English physician, a Dr Condom who would have lived in the 17th century, and who allegedly provided King Charles II with a 'gadget' for preventing illegitimate offspring. Others cite the Latin word 'condus' that means 'receptacle' as well as the Persian 'kondu' or 'kendu', a name for containers made of animal intestines for grain storage^{4,5}.

The Italian anatomist Falloppio, in the 16th century, published the first description of a linen sheath, which some regard as the forerunner of the condom¹. Falloppio's goal was not contraception but prevention of the spread of venereal disease when the linen sheath was worn on the penis during sexual

intercourse⁴. Animal intestinal membranes (e.g., caecum of a sheep) were also used for such purpose in the Middle Ages⁴ and, later, for contraception as well. The first written documents appeared in the 18th century^{1,5}. The 'modern' condom era started in the mid-19th century when mass production of vulcanised rubber condoms became feasible. Further development of manufacturing processes in the 1930s brought the advent of latex rubber. Not only was there a great improvement in the quality of condoms, but also a drop in their price due to the less expensive production process.

Parallel with the expansion of latex condoms, 'skins' (condoms made from animal membranes) are produced and marketed even nowadays. Opinions that 'skin' condoms transmit sensation better and are of good quality with respect to contraceptive effectiveness and protection against STI proved difficult to test. Only limited numbers can be produced, and they are expensive⁵.

Although intravaginal barriers were first documented in ancient times, it was not until 1836 that the *cervical cap* described by F.A. Wilde, a German gynaecologist, as the 'cautchuk pessarium' entered the palette of vaginal methods. It was made of vulcanised rubber and customised to each woman from an impression of the cervix made in wax. Later, metal (silver or copper) and impermeable plastic caps in different formats were also manufactured and marketed^{6,7}. By now, most of these have been replaced by latex caps.

One of Casanova's methods, a squeezed half lemon inserted into the vagina covering the cervix, can be viewed as a predecessor of the present day *diaphragm*. The first 'scientific' publication describing the diaphragm was by C. Hasse of Germany and appeared in 1882⁶. This contraceptive device made of rubber with a spring moulded into the rim, was called the Mensinga diaphragm, and was the only brand available for many decades. The method spread from Germany through Holland to England and became known as the 'Dutch cap'. Early in the 20th century 14 sizes designed to fit various widths of vaginal canals were available⁶.

Other *intravaginal devices* from the middle of the last century such as the 'vault cap' and the 'vimule cap' combined the characteristics of the diaphragm and the cervical cap. They are often categorised as cervical caps⁶.

Although sponges have been used for centuries to prevent unwanted pregnancy³, development of 'modern' contraceptive sponges began only in the mid-1970s. The first *collagen sponge* contained no spermicide and was intended to be reusable. Contraceptive action was to be achieved physically by blocking the cervix and absorbing the ejaculate. Development was halted for several reasons: (i) trials found viable sperms in the vagina and cervical canal after coitus, and preliminary studies showed pregnancy rates as high as 35 to 50 per 100 woman-years of use; (ii) concern that the sponge could harbour infectious microbes; and (iii) side effects (e.g., vaginal dryness and discomfort during intercourse). Because of these concerns, developers combined the mechanical and chemical barrier characteristics by adding spermicide to a new device made of polyurethane that became known as the 'Today' sponge³.

The latest innovation in the field of mechanical barrier contraception is the *female condom*. It is made of polyurethane, which is a soft, impermeable material with good heat-transfer characteristics. It is not sensitive to oil-based lubricants and, compared to latex, it is less susceptible to deterioration during storage. The US Food and Drug Administration (USFDA) approved it in 1993⁸.

Prevalence of mechanical barrier methods

Little reliable data are available on contraceptive usage before the introduction of oral contraceptives (OCs) and intrauterine devices (IUDs) during the 1960s. After the First World War and through the Great Depression, birth rates fell in Western Europe to levels that were near or below replacement in some countries, and low birth rates persisted in much of Europe until the advent of modern contraception. In Western Europe the decline between the two world wars is attributed to the increasing use of withdrawal and diaphragms as well as to changes in age at marriage⁹. In the US, diaphragms and abstinence are judged to have been the principal contraceptive methods employed before condoms became widely available⁹. The magnitude of the role of abortion is guesswork.

In the two decades following the introduction of IUDs and OCs, and the refinement and legalisation of female and male sterilisation, condoms, diaphragms and cervical caps became less popular, while prevalence of the newer contraceptive modalities grew.

Condom

Two markedly different sources may be used for estimating condom usage. One examines manufacturing and distribution data. This is difficult because of the large number of manufacturing units and the still much larger number of distribution units throughout the world. Moreover, manufacture and distribution may precede sales and use by years (the shelf life of male condoms without lubricants is five years). There are still other drawbacks: male condoms are available 'over-the-counter' (OTC) and through vending machines without registering sales; manufacturers decline to release production figures; and distributors/retail outlets provide inaccurate information.

The second and major source of data on usage and contraceptive data in general derives from national probability household sample surveys. These are usually conducted by governmental statistical or health agencies, or specialised institutions or organisations that receive grants or contracts for collecting such data. Many surveys restrict interviews to women only or to women in union. Unless otherwise stated, data on female barrier methods derive from direct or telephone surveys that attempted to determine what the current or most recently used contraceptive method had been.

Global prevalence of the use of male condoms is indicated for all geographic regions of the world (Table 1) and for Europe (Table 2). World use of condoms in 2007 was 5.7% of women in union, or 64.7 million couples¹⁰. Male condom use is, as a percentage of the corresponding populations, more than three times as large in more developed areas (13.9% of couples) than in less developed areas (4.1%). Nevertheless male condom users in developing countries (43.1 million) greatly outnumber those in more developed countries (21.5 million). By continent, North America and Europe have the highest rates of condom use, between 11 and 12% of couples, while by far the lowest rate is found in Africa (1.7%). By country, Japan has the highest prevalence of condom use, with 41% of the couples using condoms. The only other country reporting condom prevalence above 30% is Uruguay (31.3%). The semi-autonomous region of Hong Kong, in China, is estimated to have a prevalence rate among couples of 34.5%.

Northern Europe, which by the United Nations (UN) definition includes the United Kingdom (UK),

Table 1 World prevalence of use of any or of modern contraceptives, of most popular contraceptive, and of male condoms among women in union, aged 15–49 (source: *World contraceptive use 2007*¹⁰)

Area	Women in union (10 ⁶)	Methods of contraception				
		Any (%)	Modern (%)	Most prevalent method		Condoms (%)
				Type	%	
<i>World</i>	1134.6	63.1	56.1	Tubal occlusion	19.7	5.7
<i>By economic status</i>						
More developed areas	154.5	67.4	56.1	OC	16.5	13.9
Less developed areas	980.2	62.4	56.1	Tubal occlusion	21.5	4.1
<i>By area</i>						
Europe	96.8	67.5	52.5	OC	18.6	11.2
Africa	148.1	28.0	21.4	OC	7.4	1.7
Asia	750.7	67.9	61.7	Tubal occlusion	24.0	5.3
East Asia	290.3	87.6	86.4	IUD	40.4	6.9
South-central Asia	321.3	54.3	45.8	Tubal occlusion	28.4	5.0
South-east Asia	103.3	59.9	51.0	IUD	49.7	2.1
West Asia	35.6	54.5	34.4	IUD	15.4	5.3
Latin America	94.8	71.4	64.5	Tubal occlusion	28.5	6.8
North America	40.2	73.0	68.8	Tubal occlusion	22.2	11.9
Oceania	4.1	52.9	48.9	OC	17.7	7.5

OC, oral contraceptive; IUD, intrauterine device.

Table 2 European prevalence of use of any, of modern contraceptive method, and of condoms among women in union, aged 15–49 (source: *World contraceptive use 2007*¹⁰)

Area	Women in union (10 ⁶)	Any method (%)	All modern methods (%)	Condoms %	Condom users (10 ⁶)
<i>Europe</i>	96.8	67.5	52.5	11.2	10.84
Eastern Europe	44.3	63.7	41.7	11.0	4.88
Northern Europe	9.9	77.3	74.1	18.0	1.78
Southern Europe	19.6	62.6	45.5	16.5*	3.23
Western Europe	23.0	74.8	70.2	3.9	0.97
<i>Largest countries</i>					
Russia	21.5	65.3	47.1	NA	NA
Germany	9.9	70.1	65.8	1.1	0.11
Ukraine	7.7	67.5	37.6	13.5	1.04
France	7.5	81.8	76.5	4.7	0.35
Italy	7.1	60.8	38.9	13.7*	0.42
United Kingdom	5.7	82.0	82.0	25.0	1.42
Spain	5.6	71.7	66.0	27.0*	1.51
Poland	5.3	49.4	19.0	9.1*	0.48

*The condom is the most widely used contraceptive in the country or region.

has the highest European prevalence of male condom use, 18.0%, while Western Europe has the lowest, 3.9% (Table 2). The European countries with the

highest use of condoms are Spain (27%) and the UK (25%). The countries with the lowest reported rates of condom use are Albania (2.1%) and Germany (1.1%).

None of the data in Tables 1 and 2 based on UN criteria reflects male condom use by women not living with a partner.

By the early 1980s, modern contraceptive methods had taken hold in most of the world reducing the proportion of users of barrier methods. Then fears of side effects of IUDs and OCs including infection, cardiovascular and thromboembolic disease, and later concern about the transmission of HIV/AIDS and other STIs, began slowly to change the array of contraceptives in use. Repeated national surveys in the US (National Survey of Family Growth – NSFG)¹¹ and the UK (Omnibus Survey)¹² show gradual growth in condom prevalence in recent years.

Table 3 displays US national survey data on use of male condoms in 1982, 1995 and 2002¹¹. Panel 3A describes prevalence of three barrier methods in terms of the percentage of all US women aged 15–44. If a

woman is currently using more than one method, the US NSFG strategy is to report the most effective of the two or three methods in current use. Prevalence of male condoms grew from 6.7% in 1982 to 13.1% and 11.1% in 1995 and 2002, respectively. Panel 3B describes prevalence using a denominator of women currently applying contraception rather than all women to define the role of condoms and other barrier methods. Male condom use rose, in this perspective, from 12% of women using contraception in 1982 to 20.4% in 1995 and slid back a little to 18.0% in 2002. Panel 3C tells perhaps the most dramatic story, showing that over the lifetime of interviewed women who have ever been sexually active, the use of condoms (at least once) increased from 52% in 1982 to 82% in 1995 and to 90% in 2002.

In the UK, over the past decade, the Omnibus survey has monitored contraceptive prevalence an-

Table 3 Trends in the use of barrier methods by American women (Source: Mosher et al.¹¹)

(A) Current contraceptive use of condoms, diaphragms, and other barrier methods as a percent of all women aged 15–44: United States in 1982, 1995 and 2002

<i>Method</i>	<i>1982 Percent (SE)</i>	<i>1995 Percent (SE)</i>	<i>2002 Percent (SE)</i>
Male condom	6.7 (0.6)	13.1 (0.4)	11.1 (0.5)
Diaphragm	4.5 (0.4)	1.2 (0.1)	0.2 (0.1)
Other barrier*	2.7 (0.3)	1.1 (0.1)	0.6 (0.1)

(B) Current contraceptive use of condoms, diaphragms, or other barrier methods as a percent of all women aged 15–44 currently using contraception: United States in 1982, 1995 and 2002

<i>Method</i>	<i>1982 Percent (SE)</i>	<i>1995 Percent (SE)</i>	<i>2002 Percent (SE)</i>
Male condom	12.0 (0.6)	20.4 (0.5)	18.0 (0.7)
Diaphragm	8.1 (0.6)	1.9 (0.2)	0.3 (0.1)
Other barrier*	1.3 (0.3)	1.7 (0.2)	0.9 (0.2)

(C) Ever use of condoms, diaphragms, and other barrier methods by sexually experienced women aged 15–44: United States in 1982, 1995 and 2002

<i>Method</i>	<i>1982 Percent (SE)</i>	<i>1995 Percent (SE)</i>	<i>2002 Percent (SE)</i>
Male condom	51.8 (1.0)	82.0 (0.5)	89.7 (0.6)
Diaphragm	17.1 (0.8)	15.2 (0.5)	8.5 (0.6)
Female condom	NA	1.2 (0.1)	1.9 (0.2)
Other barrier*	9.3 (0.6)	0.3 (0.1)	1.0 (0.1)

SE: standard error of the mean; NA: not applicable.

* Includes female condom, cervical cap, and other barrier methods

nually¹². Data from this survey on barrier method prevalence are shown in Table 4. (In case of use of multiple methods, the Omnibus survey reports each contraceptive used). A regression analysis for nine years of data (from April 2000 through March 2009) showed that a statistically significant rise in male condom use (from 21 to 25%, $p < 0.02$) took place.

Data from both the US NSFG and from the Omnibus study in the UK also provide evidence that surveys based on couples in union strongly underestimate the prevalence of the male condom use for contraceptive reasons as indicated below.

Table 5A indicates that among all American women aged 15–44, those under the age of 30 have higher prevalence rates of condom use than do women over that age. When the denominator is current users of contraception rather than all women (Table 5B), the proportion of American women using condoms exceeds 20% in each of the three age groups less than 30 years old and is below 20% in each of the three age groups above 30 years of age. Starting from the youngest age group the decline in condom use is monotonic through each subsequent age group.

Data from the UK¹² (Table 6) show as do the US data (Table 5) a decline in condom use with age. Table 6 also demonstrates the important place that the condom has: 80% of men and more than 60% of the women aged less than 30 had used the method within the past year.

Table 7 shows barrier method use by marital and cohabitating status in the US. Panel B indicates that

Table 4 Percentage of women aged 16–49 currently using the male condom, the female condom, or the diaphragm or cervical cap at the time of the survey in the UK. (Survey years begin 1 April of the year cited and end 31 March of the following year. Source: Lader¹²)

Year	Male condom %	Female condom %	Diaphragm or cervical cap %
2000	21	0	1
2001	21	0	1
2002	20	0	1
2003	23	0	1
2004	22	0	1
2005	21	0	1
2006	22	0	1
2007	24	0	0
2008	25	1	0

condom use is highest (38.4%) among never married women currently employing contraception, a far higher percentage than found for cohabiting women. This finding emphasises the necessity that contraceptive surveys include all women of reproductive age. Table 7 also provides information on the percentages of women who use the male condom in conjunction with other contraceptives. Among US never married women who currently used condoms, half simultaneously used other contraceptives, notably the pill. This strongly suggests that for this group, a large proportion of condoms were likely to have been used primarily to prevent STIs, with pregnancy prevention shared with other contraceptives.

Limited data from Switzerland and Germany suggest that male condom use is more frequent than it would seem from the UN prevalence estimates. There are several reasons for this discrepancy: the time when the UN's estimates were made, the fact that the more recent national data pertain to all women within the age group studied rather than solely to couples in union and, finally, the age groups studied. Swiss data from 1994/1995 collected by the Swiss Federal Statistical Office estimated that 14.2% of couples aged 20–49 were using male condoms¹³. In 2007, the Federal Statistical Office selected a sample of women 15–44 years old, whether cohabiting or not, and estimated that male condoms were used by the partners of 27.4% of those women¹⁴. The German male condom data from 1992 used by the UN (Table 2) were derived from a study of cohabiting couples. A survey of German men and women aged 20–44 undertaken by the Society for Social Research¹⁵ in 2003 included 1501 randomly selected men and women. The survey examined several aspects of their use of contraception. Twenty-two percent of the respondents (both sexes) were current users of condoms. The evidence at hand indicates that in Western and Northern Europe as well as in North America over the last two decades male condom use has increased.

Diaphragms and cervical caps

Diaphragms and cervical caps were popular contraceptives in Europe and the USA until the 1960s. After the introduction of OCs and IUDs relatively fewer women used diaphragms and caps. According to a 1959 survey in England, 12% of couples applying a

Table 5 Age and barrier method use in the United States, 2002 (Source: Mosher et al.¹¹)

(A) Women currently using barrier methods of contraception as a percentage of all women by age group

Method	Age (years)						All 15–44
	15–19	20–24	25–29	30–34	35–39	40–44	
Male condom	8.5	14.0	14.0	11.8	11.1	8.0	11.1
Diaphragm	–	0.1	0.3	0.1	–	0.4	0.2
Other barrier*	0.6	0.2	0.4	0.4	0.5	1.1	0.6

(B) Women whose current partners use male condoms as a percentage of all women currently applying contraception by age group

Method	Age (years)						All 15–44
	15–19	20–24	25–29	30–34	35–39	40–44	
Male condom	27.0	23.1	20.5	17.1	15.7	11.5	18.0

*Includes female condom, cervical cap, and other barrier methods.

Table 6 Percentage of men and of women, currently in a sexual relationship, who had used the male condom within the year preceding interview, by age group, UK 2008/9 (Source: Lader¹², recalculated from Omnibus 2008/9*)

Gender	Age (years)				
	16–29	30–39	40–49	16–44	16–49
Men	80	58	31	63	57
Women	63	44	36	54	51

*The table is from Omnibus 2008/9 where we took the weighted sample and the percentages for each age group, obtained the number of users by age, and put them together in a different fashion from the Omnibus, excluding men older than 44 or 49.

contraceptive method were using the diaphragm. By 1973 this figure had dropped to 5% in England and Wales⁶; similar trends were observed in other countries including the USA^{3,6}. Usage by the mid-1980s remained at much lower levels than 20 years before³. National statistics on barrier contraceptive use in the UK suggest that throughout the first decade of the 21st century, 1% of women of reproductive age used female barrier methods (Table 4). The majority employing female barrier methods used diaphragms or cervical caps in the earlier years of the decade. Today

the female condom has become the principal female barrier method, but only a very small percentage of women use it¹².

In the US, the decrease in diaphragm usage observed between 1960 and 1982 continued thereafter. In 1982, 4.5% of women of reproductive age were using diaphragms, considerably less did so in 1995, and very few employed this method in 2002 (Table 3A). When the computation of prevalence is based on all users of contraception, the drop in usage appears steeper because a smaller proportion of women in 2002 were using the diaphragm along with a second method of contraception (Table 3B). More ominous for the future of diaphragms is the fall in lifetime use of the method. The 1982 NSFG shows that more than one out of six American women (17.1%) had ever used the diaphragm. In the 1995 survey, lifetime usage had declined to 15.2% (Table 3C); by 2002, lifetime diaphragm use had dropped to 8.5% with little usage by younger women: only 0.1% of American women 20–24 years old were using the diaphragm in 2002, and an even smaller fraction of the women aged 15–19 had ever used it (Table 5A).

National surveys in Switzerland^{13,14} also indicate the near disappearance of the diaphragm in that country. Whereas it was estimated that 0.9% of Swiss women used it in 1994/1995, its prevalence could no longer be reliably determined in the 2007 survey¹⁴

Table 7 Marital and cohabiting status and barrier method use in the United States, 2002 (Source: Mosher et al.¹¹)

(A) Women currently using barrier methods of contraception as a percentage of all women of by marital and cohabitation status

Method	Currently married, cohabiting	Currently not married, cohabiting	Never married	Formerly married	All women 15–44
Male condom	12.0	13.1	10.3	8.0	11.1
Diaphragm	0.2	0.0	0.2	0.0	0.2
Other barrier	0.7	0.8	0.2	0.9	0.6

(B) Women currently using male condoms alone or in combination with other contraceptives as a percentage of all women using contraception by marital and cohabitation status

Method	Currently married	Currently cohabiting	Never married	Formerly married	All women 15–44
Condom only	12.7	13.9	19.2	11.2	14.3
Condom + OC	1.3	3.7	11.4	1.3	4.1
Condom + withdrawal	2.6	3.4	3.6	0.8	2.7
Condom + other	1.7	4.1	4.2	2.8	2.7
Any condom use	18.3	25.1	38.4	16.2	23.8

because so few women were still resorting to this method. Overall, in this recent survey, female barrier methods had a prevalence of 0.4%, mainly accounted for by female condoms.

Female condom

Even from large surveys, only limited data are available about usage of this relatively new method. Records from the late 1990s indicated about 30 million female condoms (FCs) had been sold worldwide since 1992, and distribution was growing rapidly⁸. This total number of sales would correspond to 200,000 to 300,000 woman-years of use, worldwide, a rather small number compared to that of users of male condoms. In the UK the percentage of users was nearly 0% each year between 2000 and 2007 and was about 1% in 2008 (Table 4)¹².

No reliable American data on current use of female condoms have been published as the small number of current users is grouped together with women who use cervical caps, the Today Sponge and other (presumed) barrier methods. The US NSFG¹¹ determined the percentage of lifetime users of female condoms in 1995 and in 2002. In 1995, only two years after the FDA approved the method, 1.2% of women aged 15–44 had used the female

condom at least once in their lifetime; the figure had risen to 1.9% in 2002.

Surveys assessing only women in union (cohabiting or married; Tables 5–7) will underestimate the prevalence of condom use. This is because younger women, who are not cohabiting and hence would not be interviewed, use male condoms more often than do older, cohabiting women.

Continuation rates

Few estimates of continuation rates of barrier methods have been derived from national probability surveys in Europe or North America in recent years. According to Trussell, whose estimates for the US are derived from the 1995 NSFG, first year continuation rates were 53% for male condoms, 57% for diaphragms, and 49% for female condoms¹⁶. Clinical trials of cervical caps indicate similar one year rates. Moreau et al.¹⁷ estimated that the median duration of use of male condoms was 6.6 months, a figure implying a one year continuation rate of about 25–26 per 100 women. Continuation rates for barrier methods appear to be considerably lower than those of IUDs but not altogether dissimilar from those of many hormonal contraceptive delivery systems.

Pregnancy rates

Trussell's estimates of contraceptive failure rates, principally derived from national survey data, have been accepted by the US FDA and are widely considered authoritative¹⁶. Trussell presents two types of life table pregnancy rates during the first year of contraceptive use. One set of rates measures pregnancy probabilities in typical *users*, meaning all first year users. The second set measures pregnancy probabilities in *perfect users* (first year users who consistently and correctly follow instructions for use). For typical use, Trussell estimates that first year pregnancy rates for male condoms, diaphragms and female condoms are, respectively, 15, 16 and 21 per hundred women initiating use of the method. For perfect use Trussell estimates that the one year rates are 2, 6 and 5 per 100, respectively, at the end of one year. Method failure (e.g., when the condom breaks or slips off completely during intercourse) often is a large component of the perfect use pregnancy rate, but is uncommon for latex male condoms^{16,18}. These rates have limitations in that they are not standardised by age or parity, and they do not represent the experience of women beyond the first year of use or into later second and third segments of use of the same type of contraceptive. Effectiveness of each method is discussed more at length below.

Male condoms

A condom consists of a thin sheath, which is placed over the glans and is unrolled to cover the shaft of the penis. It acts as a *physical barrier* preventing sperm from being deposited in the vagina during coitus.

Condoms exist in a wide variety of shapes and textures. Strait-sided plain or teat-ended condoms in contoured, textured and rippled format, all coming in various colours are now available. Lubricated condoms are less likely to tear during handling or use and make penile penetration easier. The vast majority of male condoms that are marketed today are latex condoms.

Effectiveness

The criteria for selection of studies of condoms, diaphragms and cervical caps were that the loss to follow-up rate or non-response rate had to be smaller than 25% and the number of initiators greater than 99. Results from two randomised clinical trials of male

condoms of six months duration are mentioned in Table 8. The trials involved four brands and three materials (latex rubber, plastic and polyurethane). In each study more than 25% of the participants were not cohabitating with their partner, a situation that generally leads to lower coital frequency than cohabitation does. The six-month life table pregnancy rates ranged from 3.3 to 9.3 per hundred initiators. The upper 95% confidence limit ranged from above 5 to above 12 per hundred.

Table 9 summarises information from different nationwide studies carried out in Australia, the UK and the US. The UK study of Glass, with the lowest one year pregnancy rate (4.2 per 100 at one year) and the lowest rate of non-response or loss to follow-up, comprised a cohort of married women aged 25 years or older. Because all the other included studies recruited women aged either 15-44 or less than 30, it is not surprising that in all of these studies higher pregnancy rates were observed. These ranged from 7.2 to 15.8 per 100 at the end of the year. Remarkably, the estimates of 7.2 and of 15.8 per hundred were derived from the same study by two experts, who made substantially different estimates of unreported pregnancies among study participants.

Double protection: neither pregnancy nor disease

Neither sperm nor pathogenic microorganisms including HIV pass through high-quality male latex condoms. This widely known fact of 'double protection' raised the demand for male condoms after the advent of HIV/AIDS. Prospective studies undertaken on serodiscordant couples (one partner is infected with HIV and the other is not) show that, with consistent condom use, the HIV infection rate among uninfected partners is less than 1% per year^{18,28}. A Cochrane review indicates that consistent use of condoms results in 80% reduction in the risk of HIV transmission, but the estimated reduction has wide confidence limits (95% confidence interval [CI]: 35-94%)^{29,30}. A prospective study from Peru³¹ shows that consistent use of male condoms offers reductions in acquisition risk of gonorrhoea and chlamydial infection estimated as 62% and 26%, respectively. Evidence has also accrued that consistent use of condoms is associated with a sharp reduction in the acquisition by monogamous women of herpes simplex type 2 virus from their infected partners³². However, there is little evidence that

Table 8 Pregnancy rates of latex and other male condoms from prospective 6-month clinical trials

First author	Brand (type)	Year	N	Life table rate	LFU* (%)	Characteristic
Nelson ¹⁹	Ramses [®] (latex)	1997	383	6.4	4.7	31% not cohabiting
Nelson ¹⁹	Avanti [®] (plastic)	1997	384	5.0	4.6	31% not cohabiting
Steiner ²⁰	Kimono Select [®] (latex)	2003	436	3.3	5.8	28% not cohabiting
Steiner ²⁰	eZ-on [®] (polyurethane)	2003	442	9.2	5.1	27% not cohabiting

* LFU, Loss to follow-up.

Table 9 Pregnancy rates of latex and other male condoms from national surveys

First author	Year	N	Life table rate	LFU* (%)	Characteristics
Glass ²¹	1974	2057	4.2	2.9	All married, age > 25y
Vaughan ²²	1977	696	10.1	19	All married, age 15–44
Schirm ²³	1982	1223	9.6	18	All married, age 15–44
Grady ²⁴	1986	526	13.8	20.6	All married, age 15–44
Bracher ²⁵	1992	262	8.1	25	81% <30y, first use of condoms
Jones ²⁶	1992	1728	7.2	21	Age 15–44
Trussell ²⁷	1992	1728	15.8	21	Reanalysis of Jones

* LFU, Loss to follow-up.

condoms provide protection against the human papilloma viruses.

Advantages of the male condom

Male condoms need no medical supervision and are easily available. Except for the rare occurrence of true latex allergy¹⁸, condoms are essentially devoid of systemic side effects; they may even prevent premature ejaculation. When used correctly with every act of sexual intercourse they prevent pregnancy, including ectopic pregnancy, and protect against various STIs, including HIV/AIDS. This knowledge may increase mutual sexual enjoyment because there is little need to worry about pregnancy or STIs. Male condoms can be used soon after childbirth, and can be stopped at any time. They enable men to take greater responsibility in the prevention of pregnancy and disease.

Disadvantages of the male condom

A supply must be at hand, and the user must take the time to put the condom on correctly before sex. Male condoms may decrease sensation resulting in less enjoyable sex for either partner. There is a small chance that the condom may tear or slip off during

sex. Improper storage (too much heat, sunlight and humidity), use long after shelf life expiration, or using oil-based lubricants can cause the condom to deteriorate. Some people may be allergic to latex or to the lubricant on some brand of condoms.

Constraints and opportunities

Male condoms have a poor image in many cultures and areas, stemming from their associations with sex workers or premarital or extramarital sexual relations. Many people are unfamiliar with the product and may be embarrassed to buy or to handle it. The condom also has a persistent reputation of being unreliable although there is little factual back-up for such allegation.

Health services also face constraints when dealing with male condoms. These include inadequate staff training, lack of time to spend with each patient, lack of privacy and space, and poor attitudes of staff.

These constraints – whether personal or institutional – can be minimised through careful counselling and client-friendly office setup (creating positive attitudes of clinic staff, helping anxious and fearful clients open up about their lack of condom knowledge and use). This is very important because anyone can

use condoms safely and effectively, and condom users' attitudes, knowledge and behaviour are as important with regard to condom effectiveness as the quality of the condom itself.

Female condom

The female condom (FC) is made of polyurethane. It is a soft, loose-fitting, thin sheath or pouch having a length of about 17 cm^{8,33}. At each end there is a flexible ring. The movable ring at the closed end is compressed and inserted into the vagina, much like a diaphragm, to hold the device in place. The other ring at the open end of the sheath stays outside the entrance of the vagina covering the vulva. The inside of the condom is lubricated by a silicone-based material. The FC does not contain spermicides³³ and, like the male condom, it is intended for one time use only. The man or his partner should take hold of the penis and place it within the sheath; otherwise the penis may accidentally enter the vagina between the vaginal wall and the condom. The condom is removed immediately after intercourse.

Polyurethane FCs have proved to be impermeable to sperm and pathogenic microorganisms in laboratory tests⁸. But stereotypes, simplifications and strong opinions hamper the acceptance and the correct and consistent use of female condoms. This hinders the determination of their effectiveness in avoiding pregnancy and preventing HIV and other STIs.

Although early versions of the FC were available in the 1920s, it was not until the 1980s, that there was interest in its production. In 1992, a FC under the name Femidom[®] was launched in Europe; it was approved by the USFDA one year later. The FC is used in public health programmes in more than 90 countries and is commercially marketed in ten³³ carrying various other brand names including Reality[®], Dominique[®], Femy[®], Myfemy[®], Protectiv[®] and Care^{®33}.

Use is increasing. In 2005, 14 million units were sold worldwide; the corresponding figures for 2006 and 2008 were 25.9 and 34.7 million, respectively. However, female condoms account for only around 0.2% of global condom use. In 2005, nearly two thirds of all female condoms were used in Africa (mainly through donor agencies), and the next largest shares went to North America and Europe. Asia accounted for less than 1% of the global total in 2005³³.

Female condoms come in only one size; they are available without prescription but, compared to the male condom, are expensive. At present, a FC costs between \$2.50 and \$4 in the US retail market³⁴ and the bulk purchase price for use in developing countries is several times that of the male condom. This high price makes the FC unaffordable for many people, especially in developing countries, decreasing its preventive potential against sex-related diseases.

Contraceptive effectiveness varies according to how well the method is used. The one-year pregnancy rates with perfect use and with typical (including incorrect and inconsistent) use are 5% and 21%, respectively²⁷. The female condom thus is less effective than the male condom and somewhat more effective than spermicides²⁷.

For *disease prevention*, the female condom would appear as efficacious as any other barrier contraceptive provided it is used consistently and correctly³⁵. But, because of its recent introduction, insufficient clinical trial and epidemiological data are available to determine how effective it is against STIs in general populations. Research is needed to determine the method's degree of effectiveness in disease prevention³⁵.

The high price and the recommendation for a single use limit the wider application. Although a laboratory study on the effects of washing, drying and re-lubrication ten times found no significant deterioration in the structural integrity, USFDA has not approved the female condom for reuse. One reason could be that disease-causing organisms may remain on the surface of the device in spite of a thorough cleansing⁸. The FDA's policy is not to approve a device using a specific regimen without a large, well controlled clinical trial of the device and regimen. Laboratory studies alone do not suffice.

Because some women are reusing FCs, WHO released a document emphasising that there is no scientific evidence that any process, other than using a known disinfectant, will kill potentially infectious organisms. It also states that there is insufficient information available on the safety and efficacy of an alternative approach. Any protocol not requiring bleach disinfection is therefore not pursued, but may be reconsidered if more information turns up³⁶.

Advantages of the female condom

Unlike the male condom a FC can be inserted up to eight hours before intercourse, in which case it does not

interfere with the moment. Penile erection is not required. As it is not made of latex, oil-based lubricants may be used. A woman may be able to use the FC if her partner refuses to use the male condom. The female condom, if used correctly, provides some protection against pregnancy and probably against some STIs. No special storage requirements are needed because polyurethane is not affected by changes in temperature and dampness. In addition, this material is thin and conducts heat well, so that sensation is preserved.

Disadvantages of the female condom

Its outer ring covering the vulva being visible makes the FC unattractive for some potential users. It makes a noise (adding more lubricant can lessen this problem) and can be displaced during intercourse. Some women find the female condom hard to insert and to remove. It is expensive because of its recommended single-use, and availability is limited.

Diaphragm

The *diaphragm* is a shallow dome made of latex, with a firm, flexible rim³⁷. Sizes range from 50 to 105 mm in diameter, with increments of 2.5 to 5 mm⁶. Most women require a device of 70–80 mm. The diaphragm is designed with a flat-spring, a coil-spring, or an arcing spring embedded in the rim. The flat- and coil-spring designs fold flat forming a single plane when compressed for insertion. The arcing type forms an arc that many women find easier to insert³. After correct insertion the spring-strengthened rim, together with the vaginal muscle and the pubic bone, keeps the diaphragm in place. The lifespan of the diaphragm is up to two years, and its price ranges from \$15 to \$75 in the USA³⁷.

To determine the correct size for individual use, a pelvic examination is needed. The diagonal length of the vagina is measured between the posterior aspect of the pubic bone and the posterior vaginal fornix. The first fitting, serving as a demonstration for the benefit of the user, should be done by a qualified person (not necessarily a physician) who is motivated with regard to the method.

Even when correctly inserted, the diaphragm may not fit tightly enough to prevent sperm from seeping around the rim. Therefore many physicians recommend that it be used with spermicidal cream or jelly. When so used, the diaphragm acts both as a mechanical barrier blocking sperm migration and as

a carrier for the spermicide. For optimal protection, diaphragms should remain *in situ* for 6–8 hours after the last coitus. Douching is contraindicated with the device in place.

The diaphragm is a good alternative for women for whom contraindications exist to the use of hormonal contraceptives or IUD, or who do not wish to use other methods.

The prevalence of the use of the diaphragm began to decrease with the introduction of hormonal contraceptives and IUDs, but had occasional up-swings. Its prevalence of use continued to decrease in the US and the UK to the present when prevalence is at 1% or less (Tables 3A–C, 4, 5A, and 7A).

In spite of the dwindling interest for the method, service providers should be knowledgeable about it in order to properly counsel clients. A less effective or less popular method such as the diaphragm may fit the couple's needs, and hence be well accepted, correctly used and reasonably efficacious.

Factors, other than more modern contraceptives, also contributed to the decreasing use of the diaphragm: (i) service providers are no longer trained to fit the device; (ii) those who had proper training may not be keen on promoting it; (iii) there are few (if any) subsidised distribution programmes, and, as a result thereof, (iv) the diaphragm has become less available and more expensive than methods propagated by large subsidised programmes.

The diaphragm requires a high level of motivation for proper use. It is especially suitable for breastfeeding women (no effect on breast milk)^{6,37} and for those who do not need continuous protection because they engage in sexual intercourse infrequently⁶.

Clinical trial pregnancy data

As already mentioned, when the diaphragm is used consistently and correctly the first year pregnancy rate amounts to 6 per 100 initiators. Typical use (including both method and user failure) has a first year rate of 16 per 100 woman-years²⁷. First-year pregnancy rates of diaphragms, generally used with spermicides, have varied between 7.9/100 and 17.9/100 initiators according to studies conducted between 1967 and 1999^{38–42} (Table 10).

According to a Cochrane review, the efficacy of the diaphragm is the same, whether used by parous or nulliparous women⁴³. Another Cochrane review⁴⁴

found no significant difference in pregnancy rates (with either typical use or consistent use) or discontinuation rates between women using their diaphragm with- or without spermicide. Some more women got pregnant among those who used the diaphragm without spermicide, than among those who used it with spermicide; hence, there is no reason to change the practice of employing a spermicide with the diaphragm for those comfortable with its use.

STI prevention

The diaphragm, being a physical barrier, might be effective in the prevention of STIs. It may confer some protection against the human papilloma virus (HPV), which is implicated in the genesis of cervical carcinoma. Studies from the 1970s and 1980s demonstrated a lower risk of cervical neoplasia among diaphragm users. A protective effect of similar magnitude may apply to other STIs⁷. Later studies confirmed that the diaphragm provides some degree of protection against HPV and cervical intra-epithelial neoplasia (CIN)^{45,46}. However, good quality evidence is lacking with regard to the prevention of STIs achieved by mechanical barrier methods.

Contraindications

Certain conditions limit the use of the diaphragm. The latter can be used neither by women with an allergy to rubber, nor by those with certain anatomical defects (e.g., poor vaginal muscle tone, severe cysto- or rectocele, uterine prolapse, vaginal fistulae, deep lacerations of the vaginal wall, and perineal tears). There may be a psychological aversion to the spermicide, which may be considered messy, or reluctance to handle the genitalia. Lack of qualified

personnel to fit the diaphragm, inability to learn proper usage, and lack of privacy for insertion and removal are other limiting factors.

Side effects

Too large a diaphragm may result in pelvic discomfort and dyspareunia, whereas too small a diaphragm can be displaced during intercourse. Choosing the proper size or replacing the device with another one having a softer rim usually solves the problem.

Complications

Allergic reactions and/or vaginal irritation may occur in rare cases. Infection may occasionally supervene³. The pressure exerted on the urethra by the rim of the diaphragm may cause an irritation that mimics the symptoms of a true infection, or urine retention in the bladder thus promoting bacterial growth that will eventually result in a urinary tract infection. Contact with the perineal area is another factor as it may lead to the introduction of bacteria into the vagina and/or urethra. Finally, postcoital colonisation by *Escherichia coli* and other microorganisms with the diaphragm *in situ* (especially if left in place for a longer period than suggested) may lead to vaginosis and an increased risk of upper genital tract or urinary tract infection⁷.

Toxic shock syndrome (TSS) is a life-threatening disease which, very rarely, may occur among diaphragm users. Given the very small number of observed cases, the device does not appear to be a major risk factor. In every reported case the diaphragm had remained in the vagina for more than nine hours and, in some instances, for one to three days, when TSS developed³. According to statistics two to three cases of TSS per 100,000 women using vaginal barrier

Table 10 Pregnancy rates of diaphragms (generally used with spermicides) in clinical trials ($n > 99$, LFU* < 25%, no adjunctive contraception, first year only)

First author	Year	N	% LFU	First year rate	Characteristics
Tietze ³⁸	1967	1197	7.2	17.9	All married
Hall ³⁹	1973	347	16.0	10.6	c. 75% 20–24 yrs
Bounds ⁴⁰	1984	123	0.0	10.9	Most \geq 13 yrs educ
Loudon ⁴¹	1991	269	3.7	8.7 [†]	57% nulligravid
Mauck ⁴²	1999	403	4.2	7.9	25% nulligravid

*LFU, Loss to follow-up. [†]Pearl Index.

methods may be expected to occur yearly, resulting in 0.18 death/100,000 annually⁷.

Advantages of the diaphragm

The diaphragm is an effective contraceptive when used correctly, at every coitus. It does not interfere with coital sensations; if properly fitted, neither partner should be aware of its presence. It may help reduce the risk of transmission of certain STIs⁴⁷ and the incidence of pelvic inflammatory disease (PID), ectopic pregnancy, and tubal infertility⁷. It also may offer some protection against HIV/AIDS⁷ and cervical cancer⁷ but this has yet to be demonstrated. It protects against conceiving unwillingly just when needed, has no systemic side effects, does not influence breast milk production and quality, is easy to use with little practice, and may be placed by the woman up to 6 hours before coitus. Use of this method can be stopped at any time. Partner involvement is not required; consequently, the method may strengthen women's self-esteem and contribute to empowering them to make contraceptive decisions on their own.

Disadvantages of the diaphragm

The diaphragm needs an initial fitting by a family planning service provider, which necessarily involves a pelvic examination. Insertion requires putting fingers or an inserter into the vagina; it interrupts sex if not done beforehand. Severe obesity and arthritis may make insertion and removal difficult. Use of the method may be hard to conceal from the partner. Effectiveness depends on having the method at hand and taking correct actions before and after each coitus. The taste of the spermicide may discourage certain foreplay activities. Removal of the diaphragm is sometimes difficult and, rarely, it can tear when removed. The diaphragm should be washed after each use, and carefully stored to avoid deterioration. The woman may need a diaphragm of a different size after childbirth or following certain gynaecological operations.

Training

Proper use of the diaphragm is a key factor of effectiveness. Women need time to practise before relying on the method. Another reliable contraceptive

must be offered and used during the learning period at the end of which women should return for follow-up. Health professionals should then ascertain that users are comfortable with the diaphragm *in situ* before, during and for six to eight hours following intercourse; are able to recognise if it is correctly positioned; and have no intolerance for the spermicide.

But there is more to it than just training the client. Since the advent of the modern contraceptive methods in the second half of the last century most medical schools and postgraduate training centres have shown little interest in and have devoted little time, if any, to teaching students about the diaphragm and other 'non-modern' contraceptives. Physicians have become less knowledgeable about the method and less keen on promoting it. Simultaneously, through programmes conducted by family planning associations, nurses and midwives have learned how to fit the diaphragm and how to instruct women in its use⁶. Advantages of the diaphragm largely offset its disadvantages and rare side effects. The present prevalence of use is unreasonably low. More attention to this female barrier method on the part of teaching institutions would contribute to its wider utilisation.

Care of the diaphragm

The recommended life span of a diaphragm is one year but, when it is properly handled, it may be used for two years or more⁶. Before insertion, it should be checked for tears and holes, especially near the rim. If the diaphragm is damaged in that way or if it is puckered, it should be discarded, and a new one obtained. After removal, the diaphragm should be washed with lukewarm water and mild soap, rinsed out, dried and then kept in a container or in a clean sheet dusted with cornstarch or unscented talcum. Although there are concerns about the connection between talcum exposure and ovarian cancer, the evidence-based link is lacking. Scented powders and soaps may cause the latex to erode. Hot water, heat, oils, metals (e.g., copper, silver, zinc), and printing inks (newspaper!) may also decompose the latex.

Cervical caps

The cervical cap is a small thimble-shaped device that, unlike the diaphragm, blocks only the cervix^{6,48}. It was

as popular as the diaphragm in some European countries in the first half of the 20th century, but became much less used and hardly available by the turn of the millennium. In the USA, the cervical cap was classified by the USFDA as an investigational device in the mid-1980s, and hence was available only to women who participated in clinical trials. In the UK, Australia and some other countries the method was recommended only for women who gave barrier contraception preference over other methods, but could not use the diaphragm for some reason³. It is seldom touched upon in current literature, and if at all mentioned, then under 'other methods'. Its use in the USA has steadily declined since 1982; in recent years, its prevalence rate has been 1% or less in both the USA and the UK (Tables 3A–C, Table 4, Table 5A, and Table 7A).

Characteristics

Compared to the diaphragm, the cervical cap is deeper, but smaller; usually more rigid; and held in place by suction. Caps have been made of metal, rubber and plastic. At present, FemCap[®], the only cervical cap available in the USA is made of silicone and costs about \$60–75⁴⁸.

The three best-known *types* made of rubber are: (i) the thimble-shaped Prentif cavity-rim cap (the most commonly used) available in four sizes (inner rim diameter of 22, 25, 28 or 31 mm); (ii) the bowl-shaped, relatively shallow Dumas or vault cap available in six sizes (from 50–75 mm in 5 mm increments); and (iii) the bell-shaped Vimule cap with a flanged rim available in three sizes (42, 48 and 54 mm)³.

Effectiveness

For optimal efficacy, the cervical cap must be coated with spermicidal cream or jelly and be used consistently. Proper fitting and adherence to the guidelines are essential. At most half of the cap should be filled with spermicide before insertion. The cap should not be removed to reapply spermicide, and it should be left in place for at least six to eight hours after intercourse.

Few studies have evaluated the efficacy of the cervical cap and none was conducted in recent years. Nulliparae were the largest group assessed between 1981 and 1999^{42,49–51}; the first-year life table pregnancy rates in those studies ranged from 4.8/100

to 19.3/100, with the highest rate occurring in the study with the highest proportion (91%) of nulliparous women (Table 11). These rates may be considered comparable to or somewhat higher than those observed with the diaphragm (Table 10) and the male condom (Table 9).

There is only limited evidence with regard to the effectiveness of cervical caps in *preventing STIs*. As the device covers the cervix, one may assume that they exert such an effect. However, the vaginal wall is exposed to the pathogen; hence, the protective effect must be restricted and has yet to be proven.

Advantages of cervical caps

Women who cannot use the diaphragm because of some vaginal abnormality (e.g., cystocele, rectocele) often can use a cap. It can be inserted up to one day before coitus. Usually, it is not felt by the partner and is unlikely to be dislodged during intercourse. It can be left in place for more than 24 hours allowing repeated sexual intercourse without need for removing and re-inserting the device. According to some, the cap may remain in place during the entire intermenstrual period and need be removed only when menstruation is expected⁶ but, due to the colonisation by microorganisms, the prolonged presence of the cap *in situ* may cause a malodorous discharge to develop after a few days and the risk of TSS may increase.

Disadvantages of cervical caps

Initial fitting must be done by trained health care personnel. Insertion and removal can be difficult for some women. It may cause discomfort during intercourse for either partner and they may fear dislodgement of the cap. If left in place for a few days, a foul smelling discharge may develop. In many countries, cervical caps are not available and, when they are, qualified and motivated service providers are often lacking.

ALTERNATIVE OPTIONS AND NEW DESIGNS

Most mechanical barrier contraceptives are made of latex to which some people are sensitive or allergic. Alternatives are needed.

Table 11 Pregnancy rates of cervical caps (generally used with spermicides) in clinical trials ($n > 99$, LFU* < 25%, no adjunctive contraception, first year only)

First author	Type	Year	N	% LFU	First year rate	Demographic characteristics
Denniston ⁴⁹	Prentif	1981	110	20.9	8.0	70% nulliparous
Lehfeldt ⁵⁰	Prentif	1984	130	7.2	19.3	91% nulliparous
Shihata ⁵¹	FemCap	1991	106	0.0	4.8	NA
Mauck ⁴²	FemCap	1999	353	3.2	13.5	23% nulligravid

*LFU, Loss to follow-up. NA, not available.

Non-latex male condoms

Lambskin condoms

During its centuries of existence the condom has been made from all kinds of material, from linen to animal intestines, usually lamb caecum. The latter are called 'lambskin' or 'skin' condoms or simply 'skins'⁵. Being natural products, skin condoms, unlike other condoms, are not made to standard sizes. Their length ranges from 160–180 mm and their width from 63–80 mm when laid flat; their average thickness is about 0.6 mm. They neither stretch nor shrink. Because of this, 'skins' are heavily lubricated to secure a close, clinging fit. They are particularly indicated for persons who are sensitive to latex. Some people believe that 'lambskin' condoms are more 'natural' as they transmit heat and sensation better, but the validity of these opinions is difficult to test. They have been shown to prevent the passage of sperm and are considered effective contraceptives, but are associated with a greater risk of transmission of STIs compared to latex condoms. They do not protect against HIV/AIDS because of the presence of pores large enough (up to 1.5 μ) to allow infectious agents to pass through⁵². Because of this, the use of lambskin condoms should be restricted to monogamous couples seeking both heightened sexual feeling and reliable contraception. Use of 'skin' condoms for other than vaginal (e.g., oral, anal) intercourse is associated with a greater risk of damage to the condom. Lambskin condoms are considerably more expensive than other types and, because they are made of natural material, availability is limited.

Synthetic condoms

To counter the risk of transmission of STIs/HIV and because of the drawbacks of the male latex condom,

use has been made since the early 1990s of other materials such as *plastic* (synthetic elastomers) or *polyurethane*, in the manufacturing of condoms^{28,52}. These condoms are thinner, stronger and more sensitive than male latex condoms. They do not cause allergic reactions, are less constricting, can be used with any type of lubricants, and are less susceptible to poor storage conditions (they deteriorate more slowly than latex condoms)⁸. Limited data are on record concerning the performance of male non-latex condoms both in terms of contraceptive efficacy and prevention of STI transmission^{19,20} (Table 8). A 2006 Cochrane review⁵³ compared male condoms made of plastic, polyurethane or latex with regard to contraceptive efficacy, breakage and slippage, safety, and user preferences. The authors concluded: 'Although the nonlatex condoms were associated with higher rates of clinical breakage than their latex comparison condoms, the new condoms still provide an acceptable alternative for those with allergies, sensitivities, or preferences that might prevent the consistent use of latex condoms. The contraceptive efficacy of the nonlatex condoms requires more research'.

Other female barrier contraceptives

Sponges

In the late 1970s, following unsuccessful trials with the collagen sponge, clinical studies were launched with a sponge made of *polyurethane* containing a spermicide. Different formats with 10%, 20% and 30% solution of nonoxynol-9 (N-9) were tested as reusable contraceptives. In spite of clear instructions to users in this regard, the sponges on trial were washed too vigorously after each use, which lowered the N-9 content and increased the risk of failure. Therefore, it

was decided that the final version of the sponge would be a single-use, disposable product³.

Three brands of sponges are now available: the 'Today' sponge, Pharmatex 'vaginal tampon', and Protectaid sponge. They do not require medical supervision, can be purchased OTC or via internet in the USA. Pharmatex is principally available in France and Canada, while Protectaid is available in Canada and Europe.

The *Today sponge* is made of polyurethane; it is shaped as a mushroom cap and contains about one gram N-9. It absorbs the ejaculate, acts as a carrier for the spermicide (which is released by wetting of the sponge and by the action of intercourse), and blocks the external cervical os physically. The sponge may remain in the vagina for a maximum duration of 30 hours including 24 hours during which it is active and during which sexual intercourse may take place one or more times. Removal should not be attempted until the passage of six hours 'waiting time' following the last coitus. A built-in loop facilitates its removal. Being a disposable tool it must be discarded after use.

The Today sponge was introduced in the US in 1983. It became unavailable in 1994 due to manufacturing problems and remained off the market until a new manufacturer and owner reintroduced it in May 2009 into the USA; reintroduction was earlier in Canada.

Multicentre comparative trials conducted in the early 1980s showed failure rates ranging between 9.2 and 27.3 per 100 women (one year cumulative life table pregnancy rates)³. New sources quote either similar (9/100 to 16/100)⁵⁴ or somewhat higher figures (9–16/100 for nulligravidae and 20–30/100 for parous women)⁵⁵.

Present prevalence of use is low and is difficult to determine because evaluations and statistics group sponges and cervical caps under the common heading 'other barrier methods'. Taking this into account, the rate of use must be much below 1% in the UK and the USA (Tables 3A–C, 5A and 7A) and even lower in less developed areas. A package of three sponges costs \$9–\$15 in the USA⁵⁵.

The *Pharmatex sponge* is a foam cylinder (40 mm by 20 mm) impregnated with 60 mg of the spermicide benzalkonium chloride (BZK). It becomes effective on insertion and can remain in place for 24 hours; the sponge may be inserted up to 22 hours before sex and

must be left in place for at least two hours after the last act of vaginal intercourse. One can hardly find data on its effectiveness. A small clinical trial of the 'Pharmatex vaginal tampon' was conducted in France in the early 1980s, enrolling 105 women who completed 672 months of use. A low pregnancy rate was reported⁵⁶. According to a recent source, the 1st year failure rate is 19% with typical use⁵⁷. The *Pharmatex* sponge was introduced in 1984, in Europe.

The *Protectaid sponge* is a foam disc impregnated with 5 mg of the F-5 gel containing three spermicidal agents: 6.25 mg of N-9, 6.25 mg of BZK and 25 mg of sodium cholate. It may be inserted up to six hours, but no less than 15 minutes, before sex and must be left in place for at least six hours after the last coitus (not to exceed 12 hours)⁵⁷. Contraceptive efficacy and acceptability was assessed in 1189 cycles of use of 129 women in a recent international clinical study⁵⁸, and the authors concluded: 'The overall efficacy rate was 77%, with no significant influence of age or parity. Acceptability was high, with 85% of subjects being symptom- or problem-free while using the sponge'. According to the above-mentioned source, the 1st year failure rate of Protectaid is 23% with typical use⁵⁷. The Protectaid sponge was introduced in 1996 in Canada and in 2000 in Europe.

Novel female barriers

New designs aim at being cheaper, easier, more comfortable and more pleasurable to use. They are made of latex or of other materials.

In 2005 a new female condom called FC2 became available³³; since 2007, it has been produced on a large-scale. It has the same design as the original FC (now called FC1) but is made of nitrile, which should make it cheaper to produce. The synthetic rubber latex, commonly referred to as nitrile rubber, is a terpolymer of butadiene, acrylonitrile and methacrylic acid, which is the widely used material for medical gloves. It is thin and conducts heat well, hence preserving sensation. Nitrile being unaffected by changes in temperature and humidity, the FC2 has no special storage requirements. The FDA approved the FC2 in December 2008³³. In a randomised cross-over trial conducted in South Africa, the performance and acceptability of FC2 was assessed against FC1. More than 200 women completed the study, in which

1,910 FC1 and 1,881 FC2 condoms were used. Several types of condom failure were investigated including breakage, slippage, misdirection and other failure modes, including pregnancy, named in the study protocol. There were no significant difference between the FC1 and FC2 models in total device related problems, which represented 5.1% and 4.2%, respectively, of the number of condom packages opened⁵⁹. According to the Technical Review Committee of WHO 'the design and physical characteristics of FC2, supported by the clinical data, suggest that the two devices are functionally equivalent, when used correctly' and the product is acceptable for bulk procurement by UN agencies⁵⁹.

The *VA w.o.w. Condom Feminine* (or *VA; w.o.w.* = worn-of-women) is still another new female condom³³. It is a latex pouch around 9 cm in length and 0.07 mm in thickness, with a rounded triangular frame at the open end and a sponge inside the closed end, which helps to anchor it in the vagina. The VA is lubricated but does not contain a spermicide. Oil-based lubricants should not be used with this female condom as they can damage latex. When in place, the VA lines the entire vagina³³. It has been distributed for HIV prevention in South Africa since 2004 and, more recently it has become available in Brazil, Indonesia and Portugal. Having the 'CE mark' for European marketing, it is expected that it will soon be available in other European countries as well. FDA approval for sale in the USA is also expected in the near future³³.

GENERAL CONCERNS

Effectiveness

Protection against unwanted pregnancy achieved by male and female mechanical barrier methods greatly depends on consistent and correct use, even more so than for other contraceptives. The gap between correct and typical use effectiveness is usually wider for barrier methods. Product failures are rare; most pregnancies result from poor compliance. Inconsistent use and the resulting failures are often related to attitudes and behaviours. Hence the provision of correct information, counselling and training to clients by qualified personnel is of paramount importance. Preparing the latter for this task is the responsibility of medical schools and schools for paramedical professions.

Lubricants

Spermicides increase effectiveness, act as lubricants and enhance pleasure. For years mainly N-9 was used to that effect. Detergents, like that compound, were thought to protect against STIs, including HIV. Later studies showed that N-9 actually might augment the risk of transmission of pathogenic agents. N-9 therefore is no longer used as a lubricant in condoms and less as a contraceptive on its own. Non-detergent molecules that could replace N-9 are presently being investigated⁶⁰.

Storage and care

Mechanical barrier contraceptives have a well-defined shelf life during which they retain their characteristics without losing effectiveness; it varies depending on the product and the material of which it is made. Exposure to a high temperature (as when a condom is carried in a pocket near the body for a long time), dampness or bright light hastens deterioration. Mainly latex is vulnerable in such circumstances; non-latex devices are more resistant.

Reusable devices, like diaphragms and cervical caps, need special care. Instructions regarding cleansing, drying and storing should be strictly observed. Oil-based lubricants such as Vaseline[®] and cocoa butter should not be used in conjunction with latex devices. Reusable barrier contraceptives should be inspected for holes and tears before each insertion and discarded if any is found.

Emergency contraception

Couples should be prepared for 'emergency situations' that may require emergency contraception (EC). Such situations arise when the device slips off or out, tears or is dislodged during sex, or when a diaphragm or cervical cap has been removed less than six hours after the last coitus. It is useful to have EC pills at hand. Alternatively, a copper IUD can be inserted at a nearby health care service.

Anatomical changes

Vaginal deliveries may widen the vagina, cause perineal tears and distort the cervix. Also gynaecological operations and marked weight gain or loss can

alter the anatomy of the lower genital tract. After any of these events, women using a diaphragm or a cervical cap should submit to a pelvic examination to evaluate whether a device of a different size should be used from then on.

Social marketing

One of the main reasons for contraceptive need being unmet is the price of contraceptives, especially in less developed countries. However, even in developed regions certain groups cannot afford reliable contraceptives. Social marketing programmes (SMPs) use established channels to distribute family planning products which are subsidised by donor agencies. Some programmes aim, in addition, at increasing knowledge, availability and usage³. When supported by a SMP, sales of condoms tend to increase rapidly. Another advantage of such programmes is that they are relatively inexpensive to operate⁶. Expanding female condom use, for instance, could be of great benefit: a study in 2006, found that the countrywide distribution of the FC2 in Brazil and South Africa would be 'useful and cost-effective' for preventing HIV³³. However, wider use of the female condom (and other contraceptives) in developing countries depends on the commitment of governments and other major donors. To achieve the full potential of SMPs, greater efforts are needed to promote the methods worldwide, and to make them more acceptable and accessible at a lower price.

CONCLUSION

Mechanical barrier methods have been used for millennia. They became increasingly popular in the 19th century with the advent of mass production at a relatively low price. For decades they were the methods most employed but with the appearance of the pill, IUDs and voluntary sterilisation, the prevalence of use of barrier methods steadily dropped. With the rising threat of STIs, particularly HIV since the early 1980s, use of the condom started to increase again, whereas female methods such as the diaphragm and the cervical cap got the smallest share. The worldwide prevalence rate of condom is now around 6% (14% in more developed and 4% in less developed areas). The use of the

diaphragm is less than 1% in the UK and the USA, figures for cervical caps and sponges being equally low. Less developed countries have the lowest rates. Only the recently developed female condom is used more frequently, with a prevalence rate in the UK around 1%. But globally the female condom accounts for only around 0.2% of total condom use³³.

The effectiveness of mechanical barrier contraceptives, which greatly depends on their correct and consistent use, is of the same order of magnitude, but male condoms appear to have the lowest pregnancy rates of the group, and sponges the highest failure rates. The first-year life table pregnancy rates for male and female condoms range from 4.2 to 21 per 100 users. The failure rates of the diaphragm vary between 7.9/100 and 17.9/100 in clinical trials, while those of the 'other barriers', also in clinical trials, vary from 4.8/100 to 27.3/100. These figures are higher than those applying to hormonal contraceptives, IUDs and sterilisation, but lower than the failure rates of spermicides and withdrawal⁶¹.

The protection against STIs achieved by barrier methods varies greatly. The male condom, when used consistently, provides the highest estimated reduction rate (80%) in HIV incidence²⁹. The protective effect of the diaphragm is limited, and further research is needed to confirm the effectiveness of the female condom and cervical caps in disease prevention. Sponges do not protect against STIs.

Advantages of mechanical barrier contraceptives outweigh their disadvantages. Increasing their use is an important issue. Improvement in knowledge, practice and attitudes through better information of lay people and greater commitment of service providers would contribute to achieve this goal.

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