

Clinical Evaluation of C-Film, a Vaginal Contraceptive

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C-Film is a novel presentation of a vaginal contraceptive in the form of a square, water-soluble, plastic film containing the spermicide, nonylphenoxy-polyethoxyethanol. The film was used as the sole contraceptive method by 237 women over a total period of 1,866 months. Fourteen pregnancies occurred, thus giving a pregnancy rate of nine per hundred woman-years. Most of these resulted from a failure to follow instructions; the true method failure being two per hundred woman-years. Life-table analysis of the results in 156 women observed for more than twelve months gives a pregnancy rate of 6.5%, and a continuation rate of 68.6%. The low continuation rate was largely a reflection of the women's distrust of the method. The study, however, indicates that C-Film is a good vaginal contraceptive, which is well tolerated and acceptably reliable though it should not be considered as an alternative to oral contraception or to an intra-uterine contraceptive device.

Introduction

Much more attention has been paid in the last decade to medical methods of contraception (oral contraceptives and the intra-uterine contraceptive device) than to the older, non-medical methods like the diaphragm, condom and spermicidal agent. Yet there have been useful developments in chemical contraception, not only as regards the type of spermicidal agents but also in the method of presentation.

Three basic forms of chemical contraception have been available for many years: suppositories, creams, jellies and pastes, all of which are squeezed out of a tube, and foams, either as a tablet or a pressurised aerosol. To these must now be added a water-soluble film, invented by Hotay and introduced into contraceptive practice by Csoma *et al* (1969). Hotay called this C-Film. It consists of a 5 × 5 cm piece of water-soluble plastic (polyvinyl alcohol) film, which serves

as the base for the spermicidal agent. The film is folded once, placed over the dry finger and inserted high into the vagina, or it may be folded over the tip of the erect penis just before intromission. More recently, the male method has been considered to be less reliable than digital insertion into the vagina (Pariser, 1974). After insertion, the film dissolves rapidly in the normal vaginal secretion to provide a spermicidal barrier in the region of the cervix.

In its original presentation, C-Film contained the spermicidal agent, cetylpyridine bromide. This has now been replaced by the surface active, non-ionic compound, nonoxynol-9 (nonylphenoxy-polyethoxyethanol). Non-ionic compounds are generally regarded as highly effective spermicides, probably superior to those previously in use. In its present form C-Film has passed the IPPF Agreed Test for Total Spermicidal Power (IPPF, 1965).

The new presentation of C-Film was assessed for its tolerance, acceptability and efficiency in preventing pregnancy at three family planning clinics in Sweden: the WHO Clinical Research Centre, Karolinska Hospital, Stockholm; Mentalvardsbyran, Stockholm; and the Department of Obstetrics and Gynaecology, Eskilstuna Hospital, Eskilstuna.

Materials and Methods

Presentation. C-Film was made available by the manufacturers in a package containing ten semi-transparent films, placed between silver foil interleaving (Figure 1).

Instructions. Each patient was carefully instructed to insert one film high into the vagina at least five minutes before coitus. Another film was to be inserted if coitus took place later than an hour after insertion. The same instruction applied to repeated acts of coitus. In the early part of the study the male method of introduction was recommended as an alternative but this was abandoned

following reports of an increased failure rate from other centres.

Patients. C-Film was offered to women attending a contraceptive clinic as a method which should prove as reliable as vaginal foam or barrier methods. The clinic doctors emphasized that the film would not provide the same degree of reliability as oral contraception or the intra-uterine device, but no attempt was made to limit acceptors to highly-motivated women who could be expected to use the method reliably. Women using other contraceptive methods were excluded from the study, as were those who stated a frequency of coitus of less than once a week.

Originally, 265 women accepted the method. Twenty-eight of them were subsequently excluded from the study, fourteen because they never used the method, twelve because they used it as an adjunct to other methods and two because they were impossible to trace either by telephone or letter. The remaining 237 women have been

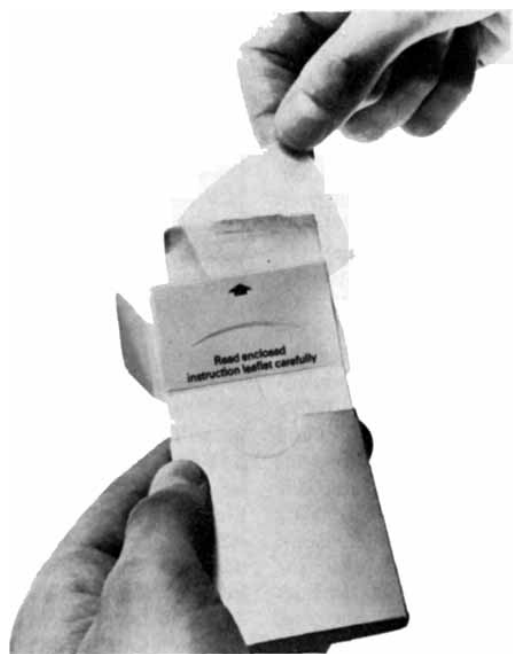
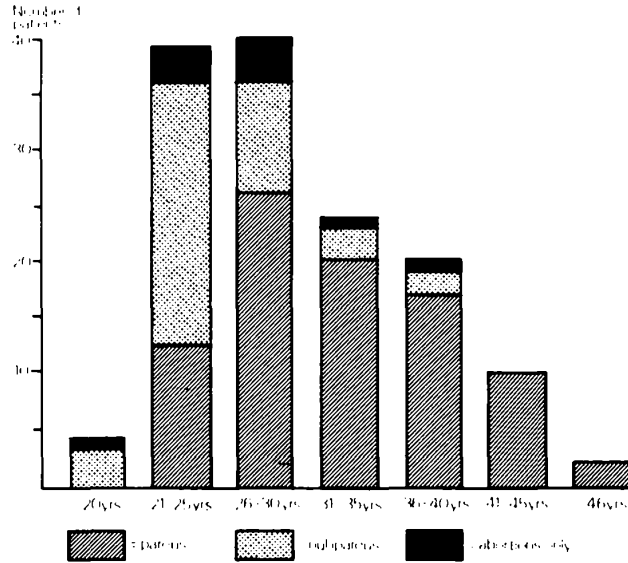


Fig 1 Packaging of C-Film



Age and parity of subjects entering trial (Life-table group)

observed for periods varying from five to twenty-three months.

Results

The 237 women used C-Film for a total of 1,866 months. During this time fourteen pregnancies occurred, which gives a use-effectiveness failure rate of nine per hundred woman-years. However, as can be seen from Table 1, eleven of the women failed to use the method as instructed. Thus the true method failure rate (theoretical effectiveness) is about two per hundred woman-years.

Of the total number of women, 156 have been observed for twelve months or longer. This permits an analysis of the data according to the life-table method (Tietze 1967). The overall pregnancy rate was 6.5% and the continuation rate 68.6%. The reasons for stopping using C-Film are listed in Table 2. About half of those who stopped using the method did so for "irrelevant" reasons, i.e. reasons not directly related to the acceptability or the efficiency of the method.

Among the "relevant" factors for stopping, apart from pregnancy, were difficulty in applying the film properly and minor complaints about the sharp edges of some of the

Table 1

Factors predisposing to pregnancy among 237 women using C-Film

Reason for pregnancy	Number of cases
Film not always used	7
No reason disclosed	3
Film used by male	2
Coitus within five minutes of introduction of C-film	1
Repeated coitus, no additional film used	1
Total	14

films. This seemed to happen after a package had been opened for a few weeks and could be attributed to air coming in contact with the individual films. Patients sometimes complained of difficulty in finding a film in a nearly empty package. A few patients inserted the interleaved silver foil as well as the film, a problem that highlights the need for careful instruction in usage. Most of them, however, found the film acceptable and easy to insert; problems like vaginal irritation or

Table 2

Reasons for stopping C-Film among 156 women using it for twelve months or longer

"Relevant" factors	Number of cases	"Non-relevant" factors	Number of cases
Pregnancies	10	Did not trust film	9
Difficulty in using	9	Wished to fall pregnant	6
Side effects	5	Leaving clinic area	6
Suspected pregnancy (later shown to be delayed period)	1	No further need for contraception	2
		No stated reason	1
Total	25	Total	24

complaints of a "runny" vaginal loss were encountered only rarely.

Discussion

The 237 women in this study did not constitute a particularly well-motivated group, who could be relied upon to use a chemical contraceptive according to instructions. Indeed, many of them had tried several other methods of contraception and found none that was acceptable or reliable. This fact alone could explain the low continuation rate as well as the relatively high failure in use-effectiveness. True method failure, on the other hand, was uncommon.

The results are clearly far better than those reported by Smith *et al* (1974) in a much smaller study. They recorded nine pregnancies among forty-five women during 175 cycles, a failure rate in use-effectiveness of 62 per hundred woman-years. This is about the same as would be expected among women using no contraceptives at all. Unfortunately, these workers failed to distinguish fully between method and patient failure. Some authors (Swyer 1968, Peel & Potts 1969) argue that all failures should be regarded as method failures, since intermittent use of a method implies dissatisfaction with it. We accept this view only in part, for it seems to us important to know how well a method works when properly used. Knowing the true method failure as well as the overall failure rate allows the individual prescriber to make a much better judgement about the results to be expected in routine contraceptive usage.

In our experience, C-Film offers good contraception for the reliable user, always provided she receives proper instruction. She should be warned to change the method if she finds it difficult to follow instructions. If she is familiar with her anatomy and can place the film high in the vagina in the region of the cervix, the reliability of the method is likely to be excellent. Nathan *et al* (1974) have shown that active spermicidal material penetrates far into the cervical canal only two minutes after high vaginal application of the film. Even among our group of women with less than perfect motivation, the results were comparable, if not superior, to those reported with other chemical or barrier methods (Marshall 1969). The low incidence of relevant side-effects confirms the findings of other studies on C-Film (Lichtman *et al* 1973).

Despite our generally satisfactory experience, C-Film should not be offered as an alternative to oral contraception or the intra-uterine device. However, it will almost certainly increase the reliability of the device, as well as that of the condom. It may also be used alone in certain circumstances—to postpone pregnancy for a few months, in women approaching the menopause and where absolute protection against pregnancy is not required.

C-Film is certainly more convenient to use, as well as more aesthetic, than foams, diaphragms or condoms, and offers a good alternative to any of them. Its introduction into family planning clinics should be welcomed, for the more varied the methods

available, the better are the chances of finding the most acceptable method for the individual.

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