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Oves® contraceptive cap: Short-term acceptability, aspects of use and user satisfaction

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Abstract

Objective*. To assess the short-term acceptability, aspects of use and user satisfaction with the Oves® cap.*

Design, setting and subjects*. A multicentre observational study, commissioned by Veos Ltd, manufacturers of the Oves® cap, was carried out by the UK Family Planning and Reproductive Health Research Network in collaboration with the Institute of Population Studies, University of Exeter, Exeter, UK. Women from ten Network centres and one collaborating centre were invited to participate. Following an assessment by vaginal examination women were fitted with the cap and taught self-fitting by a doctor. The women were asked to use the cap six times in 8 weeks. Participants were asked to complete four questionnaires on various aspects of cap use including Likert-type measures and open-ended questions on experiences with the cap. Doctors were asked to complete a first visit and follow-up questionnaires. Women were self-selected clients in the participating centres. Women aged 18 years and over, gynaecologically healthy, using hormonal contraception or sterilised were eligible for the study. Thirty-five women were enrolled and fitted with the cap; 20 chose to participate in the study.*

Main outcome measures*. Ease of fitting and removal of the cap expressed in structured and open-ended questions by both cap users and doctors; satisfaction of women and partners with the cap, measured by desire to use the cap in the future and by premature withdrawal from the trial.*

Results*. Twenty women used the cap on a total of 84 occasions. Four women completed the trial of six uses. While most doctors did not have difficulty with fittings or removals, 10/20 Oves® cap users reported some difficulty in fitting it over the cervix and 12 reported some difficulty removing it in the first three uses. Fewer women had difficulty in fitting in uses 4–6 but nearly half continued to have some difficulty with removals.*

Conclusions*. Few women indicated that they would use the cap in the future. However, most women were satisfied with their current method of contraception. The study raises the question whether women using non-barrier methods of contraception and satisfied with their current method of contraception are the appropriate target recruits for a trial such as this, even in the absence of robust efficacy data.*

Key message points

- The Oves® cap is a disposable silicone cap that can be left in situ for 72 hours.
- Ease of fitting of the Oves® cap increased with increased use, but some women continued to experience difficulty in removing the cap.
- Women recruited to this acceptability study were already using non-barrier contraception.
- The Oves® cap may offer an additional choice of contraception for some women, when UK efficacy data is available.

Introduction

Oves®, a new cervical cap, was introduced in the UK in Spring 2001, an addition to the current range of female barrier methods of contraception. Only about 1% of women of reproductive age in the UK use female barrier methods, despite the availability of several types of diaphragm and cap free on prescription. Female barrier methods do have some benefits. There are no established health risks. They are under a woman's control and they may protect against some sexually transmitted infections (STIs).

The Oves® cap, made of medical-grade silicone, is soft, pliable and does not support bacterial growth; it is non-allergenic, can be kept in situ for 72 hours and is disposable. The sizing and first fitting of the cap (available in sizes 26, 28 and 30 mm) should be carried out by a health professional.

The Oves® cap has been licensed for use in accordance with European Union 'medical device' regulations since July 1997 and is available in France. Phase I and II trials and a small-scale efficacy study (unpublished data) have been carried out in the US. Information on product acceptability was deemed important by the manufacturers and ourselves.

The present study was an in-depth investigation of the short-term acceptability of the Oves® cervical cap to women using the cap six times in a period of 2 months. Unless otherwise specified, 'cap' is assumed to be the Oves® cap.

Methods and participants

Women eligible for inclusion in the study were those aged 18 years and over, currently using hormonal contraception or sterilised, currently sexually active, with no past evidence of cervical dysplasia or reported symptoms or evidence of cervico-vaginal infection.

Though intrauterine device (IUD) use was an exclusion criterion, one GyneFix user was recruited, completed the trial and is therefore included.

Following multicentre and local research ethics committees' approvals, women were invited to participate in the trial in ten UK Family Planning Research Network clinics and practices and in one collaborating centre in London. Posters and information sheets, displayed in clinics, invited interested women to volunteer for the study. The study target was 60 women. Women who expressed interest were given additional information by nurses and doctors. The enrolment period was extended from 3 to 8 months because of delays in obtaining approval from Ethics Committees and slower than expected recruitment.

The 38 women choosing to enrol were given a detailed information sheet describing the product, the study and what participation in the trial would entail. Confidentiality was assured. Signed consent was obtained. The clinic doctor carried out an initial speculum and bimanual vaginal examination to assess the appearance, size and shape of the cervix, position of the uterus, and signs of cervico-vaginal infection. Those women judged clinically suitable to use the Oves® cap were fitted with the appropriate size of cap by the doctor. Three women were excluded: two because of signs of infection and one because none of the cap sizes were appropriate. The 35 women finally enrolled in the trial were taught how to fit and remove the cap. Six women chose not to attempt a self-fitting in the clinic. Doctors completed a 'first visit' form for each woman describing the results of the vaginal examination and the practice fittings. At the 'first visit' each woman was given six Oves® caps and a supply of spermicide (nonoxinol-9) was provided to replicate normal use of the cap. They were given four questionnaires to be completed before, during and after cap use, stamped-addressed envelopes (SAEs), to return directly to Exeter, and a contact telephone number.

Women were asked a large number of questions (some 150 in all) in the four user questionnaires. Questionnaire 1 (Q1) was to be completed before using the cap and included sociodemographic questions and a brief obstetric and contraceptive history. Questionnaires 2 (Q2) and 3 (Q3) included questions on fitting and removal of the cap, time taken to fit, time the cap was retained before and after intercourse, comfort before, during and after intercourse and partner's impressions. Q2 was to be completed after 1–3 uses of the cap; Q3 was to be completed after 4–6 uses of the cap. Other than use of spermicide, there were no questions that applied to individual cap uses. For example, questions on fitting the cap in Q2 could apply to any use of the cap in the first three uses or to all uses. Q4 was to be completed by the cap user after six uses of the cap or 8 weeks after the woman's initial visit. This questionnaire included partner's and cap user's impressions and cap user's opinions on possible methods of provision.

The cap user was requested to return to her clinic/practice for a further vaginal examination after the six uses of the cap or 8 weeks after the first study visit. Doctors described the results of the vaginal examination and women's comments on the use of the cap in a 'second visit' form. After the recruitment period closed, a follow-up questionnaire was sent to each participating doctor asking her/him to compare their experience with the Oves® cap to that with other cervical caps and to comment on various aspects of the study, including difficulty in recruiting subjects.

Results

Characteristics of participants

Of the 35 women enrolled in the study, 20 went on to use the cap at least once, on a total of 84 occasions and completed user acceptability questionnaires. Age, parity, current use of contraception, and Oves® cap size of the 35 women enrolled and the 20 cap users are presented in Table 1. Most of the cap users were using the oral contraceptive (OC) pill (n = 12). Twelve cap users were fitted with the 28 mm cap, four were fitted with the 26 mm cap and four with the 30 mm cap. Nine of the 20 cap users had previously used a diaphragm but none had previously used a cervical cap (data not shown).

Table 1 *Summary of characteristics of women enrolled in the study and cap users*

	Enrolled (n = 35)	Cap users (n = 20)
Age (years)		
< 25	6	2
25–29	8	5
30–39	17	10
40+	4	3
Parity		
Nulliparous	21	12
Parous	13	8
Missing data	1	–
Current contraception		
OC pill	22	12
Injectables	8	4
Sterilised	4	3
Gynefix	1	1
Cap size (mm)		
26	7	4
28	22	12
30	6	4

OC, Oral contraceptive.

Cap use: instructions on use and remembering to 'insert' the cap in the first three uses

Unlike Lea's Shield®, the first fitting of the Oves® cap is intended to be carried out by a health professional. Four-fifths of the 20 users found the doctor's verbal instructions 'easy' or 'very easy' to understand and none had any difficulty with the manufacturer's detailed written and graphic instructions for use and removal. One-fifth of the cap users indicated that it was difficult to remember to insert the cap before sex.

Use of spermicide

Although the manufacturers of the Oves® cap recommend using spermicide, it was used in only 4/35 practice fittings by the doctors and 4/29 practice fittings by the women themselves (3/4 were the same women). In uses 1–3 spermicide was used in about two-thirds of uses and more frequently used in uses 4–6.

Cap use: fitting and removing the cap in clinic and uses 1–6

Ease of fitting and removal was measured by a five-point Likert scale in both the 'first visit' forms and in Q2 and Q3: 'very easy', 'easy', 'neither difficult nor easy', 'difficult' and 'very difficult'. Other open-ended questions asked the doctors and the women to comment on difficulties fitting or removing the cap.

Fitting the cap. Table 2 shows ease of fitting the cap by both doctors and women during the practice fitting in the first visit. (The total, n, refers to the number of fittings: six women did not carry out a self-fitting at the first visit.) Most fittings by doctors were carried out without difficulty; but in 8/34 fittings the doctor reported some difficulty (Table 2A). One doctor noted 'positioning was difficult ... uterus acutely retroverted, so size difficult to assess'. Another noted that lack of experience [with this cap] may have played a part and that the first cap (28 mm) was too small.

About one-third of the women carrying out a first or practice fitting experienced some difficulty, as reported by the doctor. However, only one was reported to be 'very difficult'.

Women were asked to assess the ease/difficulty of 'inserting the cap into the vagina' and 'fitting the cap into the correct place over the cervix' for both cap uses 1–3 and 4–6 (Table 2B and 2C). Eight of the 20 users reported that it was difficult to insert the cap into the vagina in at least one of the first three uses, but this fell to 3/13 in uses 4–6. Similarly, while half of the cap users reported that it was difficult to fit the cap over the cervix in one of the first three uses, only 4/13 reported this to be the case in uses 4–6. For some women the problems were limited to the first or first few uses. A number found it difficult to tell if the cap was over the cervix or 'in the right place'.

Removing the cap. Both doctors and cap users experienced problems removing the cap in the 'first' fittings. Six doctors reported having some difficulty (Table 2D). One doctor reported 'she could not find the ring'; another that the cervix was 'inaccessible'. For nine women the doctor noted that it was difficult for the cap user to remove the cap, for five it was reported to be 'very difficult'. Two could not remove the cap and several had problems finding the loop.

Removing the cap in subsequent uses remained a problem. Of the 20 women using the cap 1–3 times, 12 reported that it was difficult (five 'very difficult') (Table 2E). Unlike the pattern with fittings, ease of removal did not improve with use for a minority of women, nearly half (6/13) of those using the cap four or more times reporting some level of difficulty.

Comments centred on the difficulty of finding the loop, combined with strong suction; as an example: 'The suction was very effective! Extremely difficult to hook finger through loop to remove due to position of cap'. For some women problems removing the cap were only found 'at first'. However, of those women commenting on problems removing, over half discontinued use of the cap in the second part of the trial, i.e. uses 4–6.

Possible explanations for fitting and removal problems. Parity had an effect on both fitting the cap over the cervix and removal, with proportionately more nulliparous women experiencing problems with both: 10/12 nulliparous women had problems fitting the cap in the first three uses, in contrast to 3/8 parous women; 8/12 nulliparous women had problems removing the cap in contrast to 3/8 parous women.

Women fitted with the smallest cap were more likely to report difficulty fitting the cap over the cervix (3/4 of those using the 26 mm cap; all nulliparous) in contrast to 6/12 of those using the 28 mm cap and 1/4 of those using the 30 mm cap.

Position of the uterus also appeared to affect both fitting

Table 2 *Summary of the ease of fitting, insertion and removal of the Oves® cap by doctors and by users*

	Total (n)[a]	Very easy	Easy	Neither	Difficult	Very difficult
A. Ease of fitting by doctor and user (first fitting)						
Doctors	34	5	14	7	8	–
Users	29	1	10	7	10	1
B. Ease of insertion with use						
Uses 1–3	20	–	8	4	7	1
Uses 4–6	13	1	7	2	3	–
C. Ease of fitting with use						
Uses 1–3	20	–	4	6	7	3
Uses 4–6	13	1	5	3	4	–
D. Ease of removal by doctor and user (first fitting)						
Doctor	34	9	12	7	5	1
User	29	2	10	8	4	5
E. Ease of removal with use						
Uses 1–3	20	1	3	4	7	5
Uses 4–6	13	1	2	4	4	2

[a]Missing data in one doctor's fitting and one removal; six women had no practice fitting.

and removal, but the numbers in each position are small. While women with the uterus in the anteverted position were least likely to experience problems, 7/13 noted some problem both in fitting and in removing the cap in the first three uses.

Of the nine women who used spermicide in all three of the first three uses, only two reported difficulty fitting the cap over the cervix, in contrast to 4/5 who did not use spermicide in any of the first three cap uses. Use of spermicide did not, however, affect removals, with 3/5 of those who did not use spermicide and 5/9 of those who consistently used spermicide reporting difficulties.

Use of the cap during and after sex

Women were asked how comfortable the cap was during and after sex (a five-point Likert scale was again used). In cap uses 1–3 only one woman reported that the cap was uncomfortable during sex (in this case 'very uncomfortable') and three reported that it was to some degree uncomfortable after sex (two reported it was 'very uncomfortable'). Two women removed the cap because of discomfort.

In uses 4–6, one woman reported the cap was uncomfortable during sex and none after sex. However in both 'use cycles' (uses 1–3 and uses 4–6) two women (2/20 in the first cycle and 2/13 in the second cycle) reported that the cap was uncomfortable the longer in position (in response to a yes/no question). Three women reported that the cap had become 'dislodged' in at least one of the first three uses. One woman reported that the cap became 'dislodged' in the second uses 4–6 ; two others reported 'slipping and moving'. One commented that the 'cap was hard to remove after the loop had moved around'.

Women were asked whether they or their partners could feel the cap during sexual intercourse and what effect, if any, this had on sexual pleasure. In the first three cap uses one-fifth (n = 4) of the women said that they could feel the cap, two said it 'decreased' sexual pleasure and two said it 'neither increased nor decreased' sexual pleasure. In uses 4–6, 2/13 women said they could feel the cap but that it did not affect sexual pleasure.

However, partners were more likely to feel the cap during intercourse. In the first cycle 8/20 partners felt the cap, and four felt that this decreased sexual pleasure. In the second cycle, seven felt the cap, of whom two said this decreased sexual pleasure.

Women were asked if they found sex with the cap more or less 'relaxed', 'enjoyable' and 'spontaneous' (based on closed-ended questions with categories 'more', 'less', 'no change'). Three-quarters of women in cap uses 1–3 found no change in sex in relation to its being relaxed and enjoyable. However, 12/20 (60%) found sex less spontaneous. Similarly, in cap uses 4–6 most women found 'no change' in sex being relaxed and enjoyable. However, 5/12 found sex less spontaneous.

Time cap left in situ (cap uses 1–3)

Women were asked the minimum and maximum time the cap was fitted before sexual intercourse and retained after intercourse, and to estimate the total time the cap was left in situ. Looking at the maximum time before, 6/16 answering this question said that they had fitted it less than half an hour before intercourse, and another six fitted the cap between 1 and 2 hours before intercourse.

Used as a contraceptive, the cap should be left in place for at least 6 hours after sex. Six of the 18 cap users reported they only retained the cap 2 hours after sex, four reported 7–8 hours after sex, five reported 10–12 hours after sex and three reported 24 or more hours. Only one user kept the cap in for 48 hours.

Women's comments on the cap

Women's open-ended comments on what they liked and disliked about the cap were considerably more positive than their comments on fitting/removal. Cap users liked the fact that the cap was non-hormonal. Several commented that a single-use cap was something they liked: 'no need to clean it afterwards, it is disposable'. 'Convenient' and 'handy' were used to describe the Oves® cap. One woman noted that it was 'streets ahead of condoms', others that it saved their partners needing to use a condom. Several women noted that that the cap gives women an alternative to existing methods, more choice.

Use in the future

Women were asked after all cap uses were completed (or 8 weeks after their first visit) whether they would use the Oves® cap in the future. Of the 15 women completing this questionnaire (Q4), who were not sterilised (therefore candidates for future use of the cap), six said 'no', three said 'yes' and six were 'not sure'. Asked if their partner would like 'you to use the cap as a future method', eight said 'no', four said 'yes' and three did not know.

Partner's impressions of the cap

Cap users were also asked in the final questionnaire (Q4) to give their partner's impressions of the cap. Five women said 'not favourable' another five said 'favourable' (one 'very favourable'), five reported that her partner was 'neither favourable nor unfavourable' and two women did not know.

Participating doctors' experiences with the Oves® cap

Doctors were asked to evaluate several features of the Oves® cap. All doctors thought it an 'advantage' that the cap was made from silicone, eliminating the problem of possible latex allergies; one noted that silicone is 'more resistant to heat and oil-based lubricants'.

While seven doctors reported that it was an advantage that the cap could be retained for 48 hours, three reported that it was neither an advantage nor a disadvantage. As an advantage, one doctor noted that it could be used 'going away overnight/weekend' another that users may find this 'more convenient'.

Doctors were less in agreement about the advantages of a disposable cap. Four reported this was an advantage, three a disadvantage, two neither and one noted it could be both an advantage and a disadvantage. On the positive side it was noted that this cap did not require washing and drying; the user could buy it when on holiday; and that this might make it more 'acceptable to subsets of the contracepting population'. However, several doctors noted that this would increase costs to women. Recruitment of women to the study was much slower than expected. Doctors were asked if they felt recruitment to the study was made 'more difficult because of the inclusion criterion of using hormonal contraception/sterilisation'. Nine doctors felt this was the case.

Asked in what circumstances they would recommend the Oves® cap, doctors' responses varied. Some were quite positive. Comments included usefulness where there are allergies to latex, and cases where contraception is needed only occasionally. It was also noted that some women might prefer this cap to condoms. Several felt that they could not recommend the Oves® cap without further efficacy data.

Discussion

The requirement that women recruited to the study had also to use another form of contraception was intended to speed ethics committee approvals and was judged necessary as the product only had the 'CE' Mark, and less than robust efficacy data. This appears to have resulted in a less than fully motivated group of recruits. It was difficult to recruit women. Only 20/35 women enrolled went on to use the cap; of the 20 only four completed the trial, using the cap six times. Spermicide was recommended in order to simulate usual cap use, but was used inconsistently by most women, though when used it appeared to facilitate fitting. One of the important features of the cap, that it could be left in for 48 hours (now licensed for 72 hours pre-intercourse), was not taken advantage of in most cases. It is unlikely that women who are satisfied with their current contraception, as most of these cap users were, will be highly motivated to seek another contraceptive method, especially one which requires a vaginal examination, a medically supervised fitting and a number of uses of the cap. The small numbers of women recruited to the present study suggests that most women on hormonal methods are not interested in a new (or perhaps any) female barrier method. Indeed, in the final questionnaire completed by doctors, all but two agreed that 'recruitment of women to the study was made more difficult because of the inclusion criterion of simultaneous use of hormonal contraception/sterilisation'. However, while these small numbers may not be generalisable, cap uses numbered 83, sufficient to suggest the types of problems that will be encountered as this cap is used more widely.

Bounds and Guillebaud[1] have emphasised, in relation to Lea's Shield, that 'it is important to evaluate new devices in the populations for whom they are intended rather than relying solely on research findings obtained elsewhere', since efficacy and acceptability are influenced 'by many aspects other than merely product characteristics'. Women who are on hormonal contraception or another form of non-barrier contraception, and are satisfied with that method, are probably not the population for whom new female barrier methods are attractive. If they are not, then acceptability studies must be carried out on barrier method users or those who are interested in changing method. This has consequences for obtaining ethics approval in the absence of robust efficacy data and for recruitment, especially as the number of women using female barrier methods is small. The 'CE' Mark , which the Oves® cap has been given, is primarily concerned with safety of use. However, within the medical community, including family planning health professionals, there is debate about the acceptability of this certification for licensing new contraceptive devices.[2]

Women seeking to use a cap may need a longer period of instruction and a dedicated appointment or appointments for practice fittings to be certain that they use the cap correctly. Weiss et al.[3] argue that 'inability to master the technique of self-insertion is one of the reasons that women discontinue use of the cervical cap'. Caps may take more time in instruction for use than other contraceptive methods. This raises questions for the manufacturer, e.g. 'Will they provide sufficient caps for practice fittings at no charge to the women/ health practice?'; questions for health professionals providing the instruction, e.g. 'Will they be able to give sufficient time to fitting and will they seek appropriate training for new devices?'; and for women, e.g. 'Will they be sufficiently motivated to overcome what might be a steep learning curve if caps have to be purchased?' It is important to note that women's ability to fit and remove the cap without difficulty improved in cap uses 4–6 over uses 1–3. The UK Family Planning Association has suggested that the low level of use of caps may, in part, be the result of health professionals being untrained or lacking in confidence in fitting them.[4] The Faculty of Family Planning and Reproductive Health Care no longer requires trainees to be taught to fit caps and diaphragms, in part because of a scarcity of women seeking to use them. In the future, younger family planning trained doctors are unlikely to feel confident in fitting the cap and many nurses will have had no experience with caps. Any increase in cap use will need to be accompanied by a change in the attitudes of health professionals towards the cap. Women are unlikely to be encouraged to use caps in an environment where health professionals see few benefits in cap use and are not trained in their use.

The volunteers for the present study were not seeking an alternative method of contraception; however, a small number said that they would continue using the cap and a larger number identified advantages, which suggest that this additional method might suit some couples. The Oves® cap is therefore a potentially attractive option for some women. It is non-hormonal, may be preferable to the condom for some couples, may be attractive for those needing only occasional contraception and useful for those with latex allergies. However, there are hurdles to be overcome as it is introduced into the community. We await the results of a current UK efficacy study with interest.

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