

Worldwide method effectiveness of the Today[®] vaginal contraceptive sponge

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Abstract

The Today[®] vaginal contraceptive sponge is made of polyurethane and contains 1 gram of the spermicide nonoxynol-9. Following preclinical and phase I and II clinical trials, extensive worldwide phase III trials were conducted. These multiclinic trials were conducted according to a common protocol with regularly scheduled follow-up visits and examinations. The cumulative first year method effectiveness rate (life table) was 90 per 100 women. The second year rate was 97 per 100 women.

No statistically significant difference was found in method failures between nulliparous and parous women. No serious complications occurred in over 1000 women-years of sponge use.

Introduction

The Today[®] contraceptive sponge was designed to overcome some of the disadvantages of available vaginal contraception. After several years of preclinical testing and phase I and II clinical trials, extensive worldwide phase III comparative trials were started on the sponge in 1979. The data from these trials formed the basis for various governmental approvals of the sponge: Singapore (1981), the United Kingdom, the Netherlands and Norway (1982), Switzerland and the United States (1983). The sponge is now available to consumers in the United States and the United Kingdom as an over-the-counter contraceptive.

The results from the phase III clinical trials of the sponge have been presented in several publications that have provided information on its overall effectiveness [1-3]. Since the effectiveness of any vaginal method of contraception is dependent on whether the method is consistently and correctly used, it is important to evaluate pregnancy rates in terms of those that occurred because of user failure (user effectiveness) and those that occurred because the method failed even though it was consistently and correctly used (method effectiveness). From the point of

view of the user, method effectiveness is more important than either user or overall effectiveness. This paper discusses the method effectiveness of the Today® contraceptive sponge based on data from the phase III clinical trials.

Methods and materials

The Today® sponge is made of proprietary polyurethane and contains 1 g of the commonly used spermicide nonoxynol-9. The sponge contains small amounts of citric, sorbic and benzoic acids as preservatives; these acids also lower its pH to about 4-5. The sponge has a diameter of 5.5 cm and is about 2.5 cm thick (Figure

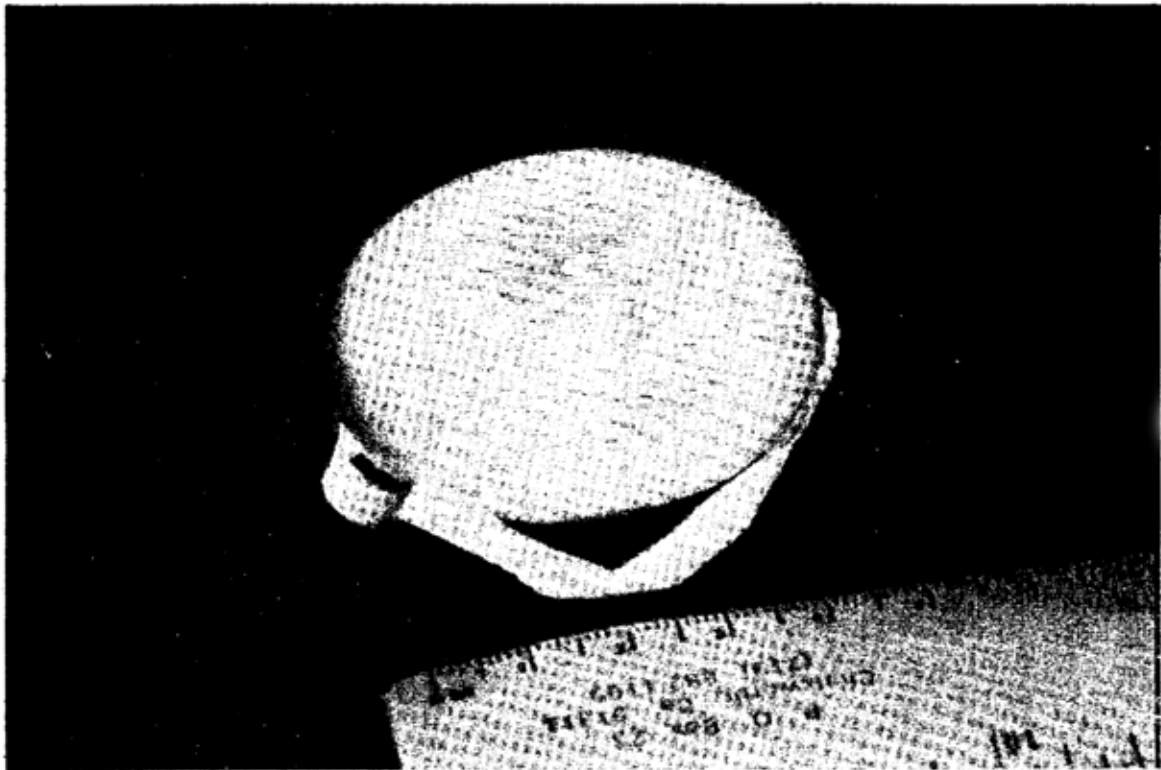


Figure 1 The Today® vaginal contraceptive sponge

1). An indentation on one side helps to ensure its placement against the cervix. An average of 125 mg of nonoxynol-9 is eluted from the sponge during a 24-hour use period [2]. A polyester retrieval loop attached to the sponge facilitates removal. The sponge is first wet and then inserted in a manner similar to that of the diaphragm and is effective immediately after insertion. It may be inserted up to 24 hours before coitus and should be removed no sooner than 6 hours after coitus.

Starting in 1979, international (Bangladesh, Canada, England, Israel, Taiwan, United States and Yugoslavia) clinical trials were undertaken to evaluate the effectiveness, associated complications and side effects, and user acceptability of the Today® contraceptive sponge (VLI Corporation, Irvine, California, USA). These studies were conducted at 20 clinics (13 in the United States) and included 1847 women who accounted for 12514 woman-months of sponge use. Five hundred

and seventy-nine women completed 12 months of sponge use. At all clinics the evaluation of the sponge was performed according to a common protocol. Study volunteers were required to be 18 to 40 years of age, sexually active, not known to be infertile, generally healthy and to have had at least one menstrual cycle since termination of their last pregnancy. Subjects were followed up every three months for one year. In some of the US clinics and in all international clinics, subjects were also followed up during the first month of sponge use.

At each participating clinic, pregnancies were classified as either user or method failures. User failures were defined as those pregnancies that occurred because the woman did not use the sponge in the manner prescribed in the user instructions. Method failures were defined as those pregnancies that occurred even though the sponge was consistently used in the manner prescribed. If the clinic staff did not know whether the pregnancy was due to the user or method failure, the pregnancy was classified as a method failure. The life table method was used for the statistical analysis of the pregnancy rates. Whenever statistical tests are used, only the significance level (*p*-value) associated with the test is given.

Results

Subjects

Most of the subjects enrolled in the studies were under 30 years of age (71.9%), currently married (52.5%), with parity 1 or more (50.6%) (Table 1). The contraceptive

Table 1 Selected sociodemographic characteristics

Characteristic	%
Age (y)	
<20	5.5
20-29	66.4
>29	28.1
Mean	26.8
Parity	
0	49.4
≥1	50.6
Nulligravid	31.0

practices of the subjects prior to enrolling in the study are shown in Table 2. Nearly 24% of the subjects were using vaginal contraceptive methods and nearly half of the subjects (44.2%) had previously used vaginal contraceptives.

There were both similarities and differences among subjects from the various clinics. For example, women who were enrolled in clinics in the United States were similar in age, parity, marital status, but a higher percentage were using vaginal contraceptive methods compared to women from Canada and the United Kingdom.

Table 2 Prior contraceptive use

<i>Contraceptive method mainly used before admission</i>	<i>%</i>
None	10.2
Oral contraceptives	31.5
Intrauterine contraceptive device	15.7
Diaphragm-cervical cap	17.1
Spermicidal foam, jelly, suppository, tablet	6.6
Condoms	10.1
Rhythm-withdrawal	7.1
Other	1.7
<hr/>	
<i>Prior experience with vaginal method</i>	<i>%</i>
None	55.9
Diaphragm-cervical cap	28.6
Spermicidal:	
foam	7.3
suppository	3.1
other	5.2

Termination rates for all reasons

Twelve-month cumulative life table rates per 100 women for events leading to discontinuation from the study for the combined data are given in Table 3. The

Table 3 Gross twelve-month cumulative termination rates (per 100 women)

<i>Termination reason</i>	<i>Rate</i>
Allergic-type reactions	2.1
Discomfort	8.9
Product-related	9.4
Planned pregnancy	6.4
Other personal	16.2
Other medical	3.1

'discomfort' category included vaginal and penile discomfort, soreness and itching. 'Product-related' events included problems related to insertion and removal problems, inconvenience of sponge use, and odor of the sponge. 'Other medical' events included mostly urinary tract and vaginal infections. The 'other personal' category included reasons given by the women as to why they no longer wished to continue in the study, including no longer sexually active, preference for other methods, objections of partner to method and moving from the clinic area.

Side-effect and complication rates

No serious or unexpected adverse reactions were reported by investigators at any of the clinics. Pelvic examinations given at the 6 and 12 month follow-up visits

did not indicate any significant changes that were attributed to use of the sponge. Over the course of the study no significant changes were observed in any of the laboratory parameters that were monitored (hematocrit, complete blood count, Papanicolaou smear, urinalysis, gonorrhea culture).

Pregnancy rates

The cumulative 12-month life table method pregnancy rates are given in Table 4 for the 13 clinics in the United States and the 7 international clinics. Also shown

Table 4 Gross cumulative life table effectiveness rates (per 100 women) of the Today® vaginal contraceptive sponge

Area	Number of centers	Method effectiveness at:	
		0-12 months	13-24 months
United States	13	88.8	—
	7	89.4	96.6
International	7	91.1	—
Worldwide	20	89.9	—

in this table are the method pregnancy rates for 7 of the 13 United States clinics, where investigators followed up some of their subjects for up to two years [3]. The method pregnancy rates were similar ($p > 0.10$) for the United States and international studies. At the end of one year of sponge use, the worldwide method effectiveness rate was 89.9, corresponding to the method pregnancy rate of 10.1 per 100 women. At the end of the second year the method effectiveness rate for the subset of US clinics was 96.6, corresponding to a pregnancy rate of 3.4 per 100 women. The method effectiveness rates were further analyzed to determine if there were factors (such as coital frequency, regularity of sponge use, prior experience with vaginal contraceptives) that might account for the variation in the effectiveness rates from the individual centers. None was identified. At each clinic, the method effectiveness rates were independent of the proportions of subjects who were determined to be lost to follow-up.

Table 5 Gross cumulative 12-month method failure rates (per 100 women) in nulliparous and parous contraceptive sponge users

	United States	International	Worldwide
Nulliparous	8.8 (539)	9.4 (376)	9.0 (915)
Parous	18.0 (183)	8.3 (756)	10.2 (939)

Using the combined data from all clinics, Table 5 shows that the method pregnancy rates were similar ($p > 0.10$) for nulliparous and parous sponge users (9.0 and 10.2 per 100 women, respectively).

Discussion

In evaluating the effectiveness of vaginal contraceptives, it is important to differentiate between user effectiveness and method effectiveness. One difficulty in the

evaluation of method and user effectiveness rates is the determination of whether each pregnancy was a user failure or a method failure. In the present evaluation, pregnancies were classified as method failures if the investigator was unable to determine the type of failure. For this reason, the method failure rates given in this paper overestimate the actual method failure rates. This is also evident from the pregnancy rates presented in Table 4, in that there is a decline in the method pregnancy rates during successive time periods. If the method pregnancy rates only included pregnancies that were true method failures, one would expect these rates to be constant over time. On the other hand, user pregnancy rates should decline over time, since women who do not consistently or correctly use the sponge may become pregnant or may elect to use other contraceptive methods.

A frequently expressed concern in the evaluation of pregnancy rates is that there may be an under-reporting of pregnancies if the group of women who are lost to follow-up experience a higher pregnancy rate than the group of women who continue in the study. The analyses of the data from the worldwide sponge studies showed that there was no relationship between the method pregnancy rates and lost to follow-up rates at each of the 20 clinics. The correlation between the two sets of rates was 0.04. This may be anticipated since most of the 20 clinics included in the evaluation also provided other health care services, including pregnancy counseling and abortion services.

In the US trials, a higher pregnancy rate was reported in parous women [2]. It has been suggested that the larger vaginal vault of parous women may result in higher risk of method failure and that a larger sponge may be desirable for these women [4]. This finding was not substantiated in the present worldwide evaluation of method pregnancy rates. The worldwide pregnancy rates were 9.0 per 100 nulliparous women and 10.2 per 100 parous women and were not statistically different (Table 5). A recent publication by Borko and co-workers [5] of 225 sponge users further substantiates no difference in pregnancy rates between parous and nulliparous women.

Variation in the method effectiveness rates of the sponge at the individual clinics (Table 5) was not unexpected. The variation in the method effectiveness rates probably is related to the designation of pregnancies that could not be classified as either user or method failures. The worldwide method effectiveness rate of 89.9 per 100 women at one year should be interpreted as an average rate based on the results of all clinics. The rates from individual studies can be expected to vary around this rate, which is in the range of effectiveness rates for other vaginal contraceptives.

Studies are currently being conducted in Europe to further evaluate the acceptability of the sponge and obtain additional data on its effectiveness in preventing pregnancy. These trials will also provide data on factors associated with user and method-related pregnancies.

References

1. Edelman, D. A., Smith, S. C. and McIntyre, S. (1983). Comparative trial of the contraceptive sponge and diaphragm. *J. Repro. Med.*, **28**, 781-784

2. Edelman, D. A., McIntyre, S. L. and Harper, J. (1984). A comparative trial of the Today® contraceptive sponge and diaphragm. *Am. J. Obstet. Gynecol.*, 150, 869-876
3. North, B. W. and Vorhauer, B. W. (1985). Longterm use of the Today® contraceptive sponge. Submitted to *J. Repr. Med.*
4. McIntyre, S. L. and Higgins, J. E. (1984). Factors related to pregnancy rates obtained by contraceptive sponge users. Paper presented at the annual meeting of the Association of Planned Parenthood Professionals, San Antonio, Nov. 3
5. Borko, E., McIntyre, S. L. and Feldbaum, P. J. (1985). A comparative clinical trial of the contraceptive sponge and Neo-Sampon tablets. *Obstet. Gynecol.*, 65, 511-515

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Resumé

L'éponge contraceptive vaginale Today® est en polyuréthane et contient 1 gramme du spermicide nonoxynol-9. Suite aux essais pré-cliniques et cliniques des phases I et II, on a entrepris des essais très poussés dans le monde entier dans le cadre de la phase III. Ces essais multicliniques ont été réalisés selon un protocole commun, et accompagnés de visites et d'examens de contrôle réguliers. Le taux d'efficacité cumulatif pour la première année (calculé par la méthode des tables de survie) a atteint 90/100 femmes, et 97/100 femmes pour la seconde année.

On n'a découvert aucune différence appréciable au point de vue statistique entre les nullipares et les femmes ayant eu un ou plusieurs enfants. Aucune complication grave n'est survenue durant plus de 1000 femmes-années d'emploi de l'éponge.

Resumen

La esponja vaginal anticonceptiva Today® está hecha de poliuretano y contiene un gramo de espermicida nonoxinol-9. Se efectuaron extensas pruebas de fase III en todo el mundo despues de haber hecho pruebas preclínicas y clínicas de fase I y II. Estas pruebas multiclinicas fueron hechas de acuerdo a un protocolo comun, con citas de seguimiento y exámenes. La tasa cumulativa del primer año de efectividad del método (tabla de vida) fué de 90 por 100 mujeres. En el segundo año la tasa fué de 97 por 100 mujeres.

No se encontró una diferencia estadísticamente significativa en los fracasos del método entre mujeres nulíparas y paras. No hubo complicaciones serias en mas de 1000 mujeres-año de uso de esta espanja.