*Int J Fertil*, 30(1), 1985, p. 81-84
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Scandinavian Association for Studies in Fertility, and International Federation of Fertility Societies

# Use of the Today® Contraceptive Sponge in the United States

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**ABSTRACT:** Use of the TODAY® Contraceptive Sponge in the U.S. has been monitored in three ways since it became an OTC product in June, 1983:

1. The Phase III clinical trials in the U. S. were extended for a second year (Life Table method efficacy rate for a second year of use = 96.6%; N = 103).
2. The manufacturer has solicited comments and complaints from family planning professionals and from women who purchased sponges over-the-counter. One complaint has been received for every 33,000 sponges distributed, primarily related to removal difficulty, infection and allergy to spermicide. By December of 1984, there were an estimated 1.25 million sponge users in the U.S.
3. Voluntary, spontaneous reporting to regulatory or health agencies has tracked case reports of toxic shock syndrome (TSS) in sponge users. To date 13 cases have been reported with over 25 million sponges sold. The risk of TSS in sponge users is thus very small and may not represent an increased risk over baseline.

## INTRODUCTION

THE TODAY® CONTRACEPTIVE SPONGE received New Drug Approval from the United States Food and Drug Administration in April 1983. Since that time, it has become widely available to the general public as a nonprescription vaginal contraceptive. Information about the experience of sponge users has been obtained from three sources:

1. An extension of U.S. Phase III clinical trials at seven centers, involving 103 women, to monitor safety and efficacy in the second year of use.
2. A toll-free telephone "Talkline" provided by the manufacturer to supply information for the new user and to family planning professionals, and to receive reports of medical problems or product use difficulty.
3. FDA tracking of TSS cases in sponge users with case determination supplied by the Centers for Disease Control.

Data received from these three sources are summarized in this report.

Support for this study was provided by VLI Corporation. The contributions of clinical investigators who participated in these trials are gratefully acknowledged.

## MATERIALS AND METHODS

The TODAY® Contraceptive Sponge is composed of a soft polyurethane foam that contains 1 gram of the spermicide nonoxynol-9. It is concave on one surface to facilitate folding and placement over the cervix; a removal loop is attached. After adding water to activate the spermicide, the sponge is inserted deeply into the vagina immediately before (or up to 24

hours prior to) intercourse. Within the 24-hour wear time, a single sponge can be used for multiple episodes of coitus; removal is recommended 6 hours after the last coitus, for a maximum wear time of 30 hours.

In the United States, sponge safety and efficacy after 12 months of use were established by NIH sponsored Phase III Clinical Trials. Thirteen study centers enrolled 750 sponge users in a randomized comparative trial of sponge and diaphragm. The protocol is reported elsewhere.[1] Seven of the original 13 centers agreed to follow sponge users into a second year. One hundred three women volunteered for this extended Phase III trial. Volunteers were interviewed at 3-6 month intervals, and given a complete physical examination after 24 months of sponge use. Lab tests included pap smear, urinalysis, gonorrhea culture, CBC, UCG pregnancy test and VDRL. (Identical examinations had been conducted previously at admission and 12 months.) Method effectiveness (defined as correct and consistent use as reported by the sponge user) was calculated using the Life Table statistic.[2]

Monitoring of OTC sponge use by the general public was accomplished via a 24-hour toll-free telephone Talkline to the manufacturer (VLI Corporation, Irvine, CA; Toll-free number: 800-223-2329). The number was highly publicized and placed on every package and product insert. Trained operators recorded all information received. Written complaints or direct verbal reports were logged as well. Potential medical or safety problems were forwarded to VLI medical personnel and the FDA immediately for further evaluation.

Any serious medical complications in sponge users reported directly to local, state or federal health agencies, or to the manufacturer, are automatically forwarded to the FDA for investigation and risk assessment. The TODAY® Sponge is classified as a New Drug and therefore periodic reports of its postmarketing performance are required by U.S. law.

## RESULTS

### Extended Phase III Trials

Characteristics of women (N = 103) who enrolled in the extended Phase III study are shown in Table I. Seventy-five percent of these second-year volunteers completed 24 months of continuous sponge use. Six women discontinued due to product-related complaints; one was lost to follow-up (Table II). There was one discontinuation for medical reasons.

Life Table method effectiveness rate for these experienced sponge users in the second year of use was significantly higher than the rate reported for the first 12 months of use (Table III).

**TABLE I**
**Selected characteristics of subjects (N = 103).**

| | | |
|---|---|---|
| Age: | Under 25 | 38% |
| | 25-34 | 58% |
| | Over 34 | 4% |
| | Mean = 26.2 years | |
| Residence: | Urban | 87% |
| | Rural | 13% |
| Marital Status: | Married | 22% |
| | Single | 78% |
| Education: | High School | 15% |
| | 13 or more years | 85% |
| Nulliparous: | | 83% |

Results of physical examination at 24 months were unchanged from the admission examination.

### OTC Monitoring

Approximately 64,000 telephone calls were received on the Talkline in 18 months (through December, 1984). Over 25 million sponges were distributed OTC to an estimated 1.25 million users in the same period. The vast majority of these calls requested further information; reported medical problems totalled 754. This is one problem/33,000 sponges, or about one complaint per estimated 1,700 sponge users. The most common complaint categories were removal problems, vaginal infection, spermicide allergy and pregnancy (Table IV).

**TABLE II**
**Discontinuations second year (N = 103).**

| | | |
|---|---|---|
| Pregnancy: | Method Failure | 3 |
| | Use Failure | 2 |
| | Planned | 2 |
| Product Related: | Method Inconvenient | 3 |
| | Safety Concerns | 2 |
| | Vaginal Discharge | 1 |
| Other: | Partner With Vasectomy | 1 |
| | Moved From Area | 2 |
| Study Ended Before 24 Mos. Of Use | | |
| Completed: | | 10 |
| Lost to Followup: | | 3 |

**TABLE III**
**Second year Cumulative Life Table pregnancy rates (per 100 Women).**

*Method Failure = 3.4 ± 1.9 s.e.
†Overall Failure = 5.4 ± 2.3 s.e.

*Pregnancies that occur with correct and consistent use of contraceptive method.
†All accidental pregnancies, including those occurring with incorrect or inconsistent use.

## TSS Reporting

Thirteen toxic shock syndrome cases in sponge users (fulfilling the case definition of the Centers for Disease Control)[3] had been reported to the FDA by December, 1984. This represents one case for every 2 million sponges distributed, or about one case per estimated 100,000 sponge users.

## DISCUSSION

The TODAY® Vaginal Contraceptive Sponge has been widely available over-the-counter in the U.S. since June 1983. The experience of the estimated 1.25 million women who have used the Sponge in this time was closely monitored via 64,000 telephone calls and reports. This form of voluntary, spontaneous reporting was actively solicited by the manufacturer and by the Centers for Disease Control.[4] Reported medical problems totalled 754, which is equivalent to one problem for every 33,000 sponges distributed. Removal difficulty was reported most often, followed by infection and allergy. Assuming a ten-fold underreporting rate (64,000 calls probably represent approximately 5% of the total estimated user population), we can estimate that one problem is experienced for every 1,700 sponges used.

**TABLE IV**
**Product field experience June 1983 through January 1985.**

| *Medical* | *Number* |
|---|---|
| Allergic reaction | 69 |
| Bleeding | 14 |
| Cervical abrasion | 1 |
| Cramping, pain | 7 |
| Infection | 106 |
| Pregnancy | 160 |
| Rash | 1 |
| Removal with medical assistance | 387 |
| TSS-like symptoms | 5 |
| Urinary retention | 1 |
| Vaginal ulceration | 1 |
| PID | 2 |
| Total Medical | 754 |

Since the Sponge became available OTC, the only potentially serious complication of sponge use that has been discussed is toxic shock syndrome. Using the case definition established by the CDC,[3] 13 nonmenstrual cases of TSS have been reported in women who were also sponge users. None have been fatal. In this same period, over 25 million sponges were distributed. There is considerable disagreement about whether or not these cases are numerous enough to represent an increased risk for sponge users relative to the baseline risk for women to develop nonmenstrual TSS. TSS does occur in nonmenstruating women, in men and in children. Nonmenstrual TSS accounted for 22% of cases voluntarily reported to the CDC in 1982.[5] Active surveillance studies in the U.S. designed to estimate actual TSS incidence have focused on menstrual cases exclusively; the actual baseline rate of nonmenstrual TSS is unknown. Because of this uncertainty, attempts to calculate precise risk of TSS in sponge users are not useful.[6] However, because the actual number of cases is small (one for every 2 million sponges), most authorities agree that this does not represent a significant health risk—especially in view of the obvious, significant contraceptive benefits to health.[4]

It is also reassuring to note that nonoxynol-9 (the spermicidal agent contained in the Sponge and other spermicidal products) demonstrates antimicrobial properties[7,8]—including anti-*Staphylococcus aureus* activity. Specifically, the TODAY® Sponge demonstrates significant inhibition of *S. aureus* growth and exotoxin production after 24 hours incubation under various *in vitro* conditions.[9,10]

Additional data on efficacy rates are also reported here, from an extension of the U.S. Phase III clinical trials. Women who had successfully completed one year of sponge use were followed for a second year. The efficacy rate for the second year of use was 96.7% for these experienced users. This is a significent ($p < .05$) increase over the first year rate of 89.9% for new (inexperienced) users. In the same clinical trials, inexperienced diaphragm users demonstrated a similar improvement in efficacy with time, and rates for diaphragm users were not significantly different from sponge users.[11] Improvement in efficacy with ex-

perience has also been demonstrated for other barrier methods.[12]

In summary, the TODAY® Contraceptive Sponge has demonstrated medical risks and efficacy comparable to other spermicidal, vaginal methods of contraception. Because of its OTC availability, extended wear time, and ease of use, it may provide an important contraceptive option for women unable or unwilling to access professional family planning services.

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# Announcement

## Antifertility Effects of Gossypol (CDS Task Force)

*A joint basic research between the Peoples Republic of China and the USA will deal with the pharmacology and toxicology of gossypol.* Phase I will be limited to occurrence mechanisms of development of hypokalemia, toxicological effects on endocrine system, lifetime carcinogenesis, gossypol analog with satisfactory antifertility and minimal toxic effects. This Task Force is co-sponsored by the World Bank, Chinese Academy of Population Sciences, University of Missouri, Columbia, and Reproductive Health Center, Kiawah Island, South Carolina. For information, CDS pre-doctoral and post-doctoral fellowships and computerized research protocols, write to: Editor-in-Chief, Contraceptive Delivery Systems, Dr. E.S.E. Hafez, Reproductive Health Center, 78 Surfsong Road, Kiawah Island, South Carolina 29455, USA, telephone (803) 768-5556.