CONTRACEPTIVE TECHNOLOGY UPDATE®

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JULY 2003
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Extended-use contraception offers revolution in reproductive choices

Approval of dedicated product could eliminate barriers to acceptance

A young woman sits before you. She has an active lifestyle that requires her to travel a great deal. She is not interested in having children within the next year, and she is looking for convenient, effective contraception. What choices do you offer?

If any of the methods in your counseling strategy include extended use of hormonal contraception, then you join a growing number of clinicians who are responding to patients' requests for birth control methods that reduce or eliminate the number of withdrawal bleeds.

To date, no oral contraceptive (OC) has been packaged for extended or continuous use. This may change this summer, though, if the Food and Drug Administration (FDA) approves Seasonale, the first extended regimen oral contraceptive. Under FDA review at press time, the proposed product, manufactured by Barr Laboratories of Pomona, NY, is designed with 84 continuous days of pills containing 150-mcg levonorgestrel and 30-mcg ethinyl estradiol, followed by seven placebo pills. **(CTU reported on Seasonale in the May 1999 article, "4-periods-per-year pill eyed for use in U.S. market," p. 51, and the August 2002 article, "4-periods-per-year OC: Comparable to pill," p. 87.)**

Special focus issue: Extended contraception

This issue of *Contraceptive Technology Update* offers a special focus on extended use of contraception. With the first extended-regimen oral contraceptive now under review by the Food and Drug Administration, interest is increasing in methods that reduce or eliminate the withdrawal bleeding and cyclic symptoms. By reviewing this material, clinicians will be able to provide women needed counseling for acceptance and proper use of extended methods. ■

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Editor: **Rebecca Bowers**.
Vice President/Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@ahcpub.com).
Editorial Group Head: **Valerie Loner**, (404) 262-5475, (valerie.loner@ahcpub.com).
Senior Managing Editor: **Joy Daughtery Dickinson**, (229) 377-8044, (joy.dickinson@ahcpub.com).
Production Editor: **Nancy McCreary**.

Editorial Questions

Questions or comments? Call **Joy Daughtery Dickinson** (229) 377-8044.

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EXECUTIVE SUMMARY

Clinicians are responding to patients' requests for birth control methods that reduce or eliminate the number of withdrawal bleeds.

- To date, no oral contraceptive has been packaged for extended or continuous use. This may change this summer, if regulatory approval is given to Seasonale, the first extended regimen oral contraceptive. Investigation is under way in extending the regimens for the contraceptive vaginal ring and the transdermal contraception.
- Surveys indicate that many women — regardless of age — would prefer to eliminate menses completely or reduce the frequency to less than once a month.

Researchers also are looking at extended use of the NuvaRing contraceptive vaginal ring (Organon, West Orange, NJ) and the Evra transdermal contraceptive (Ortho McNeil Pharmaceuticals, Raritan, NJ).

"Although women's health clinicians have known for decades that the schedule used to prescribe OCs can be varied to reduce bleeding, the availability of dedicated extended OC packaging, and hopefully, educational programs to support this, will make choices regarding reduced bleeding much more available to women in the U.S.," says **Andrew Kaunitz**, MD, professor and assistant chair in the obstetrics and gynecology department at the University of Florida Health Science Center/Jacksonville. (Clinicians can learn more about extended contraception by attending one of the Washington, DC-based Association of Reproductive Health Professionals' visiting faculty program sessions of "Choosing When to Menstruate." **See the resource box on p. 76 for more information.)**

Women want the choice

Recent surveys indicate that many women — regardless of age — would prefer to eliminate menses completely or reduce the frequency to less than once a month. The percentage of women desiring to stop having their periods increased with age, with more than half of menstruating women older than 45 preferring no periods at all.[1] ***(Contraceptive Technology Update* has reported on this trend in two articles: "Menstruation on hold? More women favor option," May 2003, p. 54; and "Research eyes extending the menstrual**

When to menstruate: what women want

What are women's preferences when it comes to frequency and characteristics of menstrual bleeding in relation to reproductive status and oral contraceptive use? Here are highlights from a 2002 survey of some 500 women ages 18-49, conducted for the Washington, DC-based Association of Reproductive Health Professionals.[1]

- When asked if their period let them know whether they are "healthy," more than two-thirds of women surveyed said no.
- Given the opportunity to determine how frequently they would menstruate, 44% of all women surveyed would prefer never to menstruate, and this number increases to 59% for women ages 40-49.
- More than one in four women respondents said their period, menstrual cramps, or other menstrual effects, have caused them to miss professional, social, athletic, or family-oriented events.
- 70% of women say they use or have used oral contraceptive pills in their lifetime.
- Less than 20% of women surveyed have ever used oral contraceptives to delay or stop their period for any length of time.

Reference

1. Association of Reproductive Health Professionals. Extended regimen oral contraceptives. Harris Poll. June 14-17, 2002. ■

cycle," January 2002, p. 3.)

In 2002, ARHP commissioned a telephone survey to check women's preferences on the frequency and characteristics of menstrual bleeding. The survey data showed that nearly two-thirds of women do not rely on their monthly periods to let them know if they are pregnant, able to have children, or are healthy.[2] More than one in four women surveyed reported they have missed professional, social, athletic, or family-oriented events because of their period, menstrual cramps, or other menstrual effects.[2] **(See above article for survey highlights.)**

Using hormonal contraception for induced amenorrhea is not a new concept, points out **John Guillebaud**, MA, FRCSEd, FRCOG, MFFP, emeritus professor of family planning and reproductive health at University College in London. The concept has been around since at least the 1970s, with publication of research on reducing the frequency of menstruation with oral contraceptives, he notes.[3]

Further observations on the subject were spurred by the 1999 publication of the book *Is Menstruation Obsolete?*[4] Co-author **Sheldon Segal**, PhD, distinguished scientist at the New York City-based Population Council, extends the argument in his new publication, *Under the Banyan Tree: A Population Scientist's Odyssey*.[5] Control of when or whether to menstruate is a new reproductive freedom that should be available to modern women, he says.

Clinicians are familiar with the long-term impact of the progestin-only contraceptive injection (depot medroxyprogesterone acetate or DMPA, marketed as Depo-Provera, Pharmacia Corp., Peapack, NJ) on bleeding profiles. During the first year of DMPA use, 30%-50% of women are amenorrheic, and by the fifth year, that number increases to 80%.[6] The levonorgestrel intrauterine system (Mirena, Berlex Laboratories, Montville, NJ) also impacts the bleeding profile. In a long-term study, cessation of menstruation occurred in 47% of women.[7]

Providers also have become accustomed to manipulating the 21/7 packaging regimen of combined oral contraceptives to help bypass withdrawal bleeding for healthy women competing in athletic competitions or going on their honeymoons, as well as for women for whom bleeding poses a severe sanitary problem, such as for individuals with severe mental disabilities.[8]

Review physiology

In discussing extended contraception, it is important that clinicians and patients understand that a woman using OCs — or another combined hormone method — does not have an ovulatory cycle; it is stopped, and remains stopped, whether the hormones are taken on a 21-day schedule or for a longer regimen, observes **Felicia Stewart**, MD, adjunct professor in the department of obstetrics, gynecology, and reproductive sciences at the University of California, San Francisco and co-director of the Center for Reproductive Health Research & Policy.

The only difference between the schedules is

RESOURCE

The Washington, DC-based Association of Reproductive Health Professionals (ARHP) has scheduled several 2003 sessions of its visiting faculty program, "Choosing When to Menstruate." To check session dates, go to the ARHP web site, www.arhp.org; highlight "Healthcare Providers," then "Visiting Faculty Programs," then click on "Choosing When to Menstruate." Under "Visiting Faculty Program," click hyperlink to see list of locations. ARHP also has devoted an entire issue of its publication, *Clinical Proceedings*, to the subject. Review the issue online at the web site; highlight "Healthcare Providers," then "Online Publications," then click on "*Clinical Proceedings*." Click on "April 2003, Choosing When to Menstruate: The Role of Extended Contraception."

how often withdrawal bleeding occurs, explains Stewart. Bleeding in this situation occurs not because of a "cycle," but because the hormone level in the woman's body (which comes from the OC) declines as soon as she stops taking the OC, and the decline causes whatever lining there is in the uterus to be shed, she states.

"The hormone dose in low-dose OCs, as well as patches or rings, is low enough that lining build-up is less than most women have with ovary hormone cycles, and as time goes on with extended use, the lining may become thin enough that the 'shedding' is too little to see, [with] little or no visible blood," Stewart observes.

Clinicians may want to avoid the phrase "suppressed menses," because what is suppressed is ovulation, and that is true whether OCs are used in 21-day cycles or in longer cycles, Stewart suggests. She also believes that it may be misleading to talk about "regulating" a cycle. Using OCs or other combined hormonal methods actually eliminate the cyclic ovulatory changes, and "regulate" implies that "cycles" still are occurring, but just on a more predictable timetable, Stewart says.

Clinicians may be surprised at how meaningful involvement in decisions about pill-taking could affect a woman's adherence to her chosen pill regimen, points out **Anita Nelson**, MD, professor in the obstetrics and gynecology department at the University of California in Los Angeles (UCLA) and medical director of the women's health care clinic and nurse practitioner training program at Harbor-UCLA Medical Center in Torrance in a 2000 review of the history of the Pill.[9]

"Can we imagine how well women would take their pills if they could use them to control when [and if] they menstruated?" wrote Nelson. "I think today would be a good day to find out."

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Researchers explore extended contraception

Extending the traditional 21/7 regimen of several forms of hormonal contraception has captured the attention of research scientists, and results of their investigations may lead to new approved uses of birth control drugs.

For some women, the unpleasant side effects of hormone withdrawal and the withdrawal bleed that accompanies it are inconvenient or problematic. For these women, administration of continuous hormone therapy for longer periods (42 to 96 days) may permit a much improved quality of life and relief from side effects associated with the shorter regimen.[1]

Since the recent approvals of the NuvaRing contraceptive vaginal ring (Organon, West

EXECUTIVE SUMMARY

Investigation is under way on extending the use of the combined oral contraceptive (OC), the contraceptive vaginal ring, and the transdermal contraceptive.

- Although it has been 25 years since the first research was published on extending the 21/7 OC regimen, relatively little research has been done to examine the effectiveness, safety, and acceptability of extended regimens.
- More investigation is needed to determine if extended therapy influences any of the noncontraceptive health benefits of OC therapy, including prevention of osteoporosis and protection from ovarian and endometrial cancers.

Orange, NJ) and the Evra transdermal contraceptive (Ortho McNeil Pharmaceuticals, Raritan, NJ), both companies are pursuing studies to determine if the methods can be used beyond their Food and Drug Administration-approved regimens.

"The reason that we are interested in extended use or continuous use is because since NuvaRing provides a very low dose, steady state release of hormones without the usual ups and downs, the peaks and valleys, that you would get from oral contraceptives," says **Nancy Alexander**, PhD, director of medical affairs for contraception at Organon.

Organon is sponsoring a multicenter study of the ring, which includes 10 research sites. According to one of the investigators, **Larry Seidman**, DO, MBA, of Philadelphia Women's Research, the company's protocol calls for women to be assigned to one of four use categories, allowing Organon to test extended and continuous use of the method. The trial is about midpoint, he estimates. While results are not final, patient acceptability appears high, he notes.

Investigators affiliated with Ortho-McNeil Pharmaceuticals also are conducting research on extended use regimens of the Evra transdermal contraceptive. However, the company is declining to comment on its work at this point, says **Mona Terrell**, company spokeswoman.

Revamp the OC regimen

Despite many modifications in dose and formulation, the standard oral contraceptive (OC) regimen has changed little in the Pill's 43-year history.[2] While women may consider the withdrawal bleed experienced during the oral contraceptive's pill-free interval as "natural," it is medically induced and has no proven physiologic or health benefits.[3]

Researchers now are looking at revamping the conventional OC regimen. In one study, designed to measure acceptance and use of shortening the hormone-free pill interval to reduce the frequency and severity of hormone withdrawal symptoms, the majority of women chose to stay on an extended regimen to relieve associated symptoms.[4] Of 267 patients who initiated such a regimen, 57 discontinued OCs, 38 returned to a standard regimen, and 172 were extending use at the last follow-up. Forty-six percent of the women continued extended use for at least five years. All women in the study used a monophasic 30-35 mcg pill.[4]

In another study, which looked at use of a combined 20 mcg ethinyl estradiol/100 mcg levonorgestrel pill taken with and without a hormone-free interval, findings indicate that continuous use of the drug is associated with less bleeding requiring protection, and more amenorrhea than standard administration.[5] Although both groups of women reported a high level of satisfaction with bleeding patterns and side effect profiles, women in the continuous group reported significantly fewer days of bloating and menstrual pain.[5]

A just-published paper that compares bleeding profiles of a traditional 28-day oral contraceptive pill cycle with continuous administration suggests that extending the pill regimen resulted in significantly fewer bleeding days.[6] Amenorrhea or infrequent bleeding was present in 68% of continuous users during cycles 1-3 and increased to 88% during cycles 10-12. Spotting during cycle days 1-21 increased initially with continuous use but reduced over time, and by nine months was less than the spotting reported by cyclic users, investigators found. The study used a 20-mcg ethinyl estradiol/100 mcg levonorgestrel pill.

More research needed

Although it has been 25 years since the first research was published on extending the 21/7 OC regimen, relatively little research has been done to examine the effectiveness, safety, and acceptability of extended regimens. More investigation is needed to determine if extended therapy influences any of the noncontraceptive health benefits of OC therapy, including prevention of osteoporosis and protection from ovarian and endometrial cancers.[1]

According to **Leslie Miller**, MD, assistant professor of obstetrics and gynecology at the University of Washington and family planning medical director at Public Health-Seattle and King County, both in Seattle, focus also should be given to a head-to-head comparison of extended and continuous pill regimens.

Miller, who now centers her research on continuous use of low-dose oral contraceptives, also would like to see some form of registry to track the effects of the Pill in long-term use on such areas as bones, breasts, and fertility.

"If you do continuous, will there be protection against breast cancer?" Miller hypothesizes. "It is possible that using these really low doses and having it be continuous so you don't cycle at all, is that more protective for the breast?"

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Help educate for success with extended pill use

For patients who are considering extended or continuous use of combined oral contraceptives (OCs), thorough counseling is an important aspect of ensuring success with the method.

Irregular bleeding during the first months of use is to be expected, so counsel women on this fact, advises **Leslie Miller**, MD, assistant professor of obstetrics and gynecology at the University of Washington and family planning medical director at Public Health-Seattle and King County, both in Seattle. She operates her own web site, www.noperiod.com, which provides information for female patients and providers on how to use continuous OC regimens. **(Miller's free patient handout, "Continuous Birth Control Use," is available at www.contraceptiveupdate.com. Your user name is your subscriber number from your mailing label. Your password is ctu, then your subscriber number again. Use lowercase letters and no spaces. At the web site, click on "toolbox" to see this and other useful forms.)**

EXECUTIVE SUMMARY

As with any contraceptive choice, counseling plays a significant role in ensuring success with extended use of hormonal contraceptives.

- While breakthrough bleeding/spotting is common with extended regimens of oral contraceptives (OCs), educate patients that occurrences will lessen as the body adjusts.
- Women are exposed to more hormones with an extended or continuous regimen; the annual consumption in milligrams of estrogen and progestin is 23% greater in women using a trimonthly OC regimen vs. the standard 21/7 regimen. However, this level of exposure is still below that of women using 50 mcg ethinyl estradiol pills.

Miller, who has worked with both types of regimens,[1,2] says she tells women to expect some bleeding up into six months of use.

"There is a light at the end of the tunnel," she notes. "By six months, 70% don't have bleeding; by one year, 90%."

In her practice, Miller says she may switch a patient with persistent bleeding who is on continuous use of pills from Alesse (Wyeth-Ayerst Laboratories, Philadelphia) to Loestrin 1/20 (Galen Holdings, Rockaway, NJ), believing that the difference in progestins may lessen the symptom. She holds to using no higher than 20-mcg ethinyl estradiol pills for continuous regimens.

"I find it works better, with less bleeding," Miller comments. "Since one is taking it every day, it is more than an cyclic 20 mcg dose, so theoretically a 30 mcg ethinyl estradiol pill taken every day could expose the woman to the equivalent of a higher estrogen dose, which could mean more risk of thrombosis."

Women need a basic explanation of physiology

to understand the absence of withdrawal bleeds, which occur during traditional regimen use, says **Larry Seidman**, DO, MBA, of Philadelphia Women's Research. He is an investigator in the extended regimen trial of the contraceptive vaginal ring NuvaRing (Organon, West Orange, NJ).

Counsel that the bleeding that oral contraceptive users experience each month bears little biological resemblance to a menstrual period; indeed, there is little built-up uterine lining to be shed for these women.[3] The bleeding women experience during the pill-free interval results from a drop in the hormone levels after the 21st day when active tablets have been completed and placebo pills are used.[3]

How to get pills?

How do you prescribe pills past the 21/7 regimen? Miller says she writes the prescription a certain way, first specifying the brand, then indicating "one birth control pill every day, active drug only, no spacer pills," and giving a medical reason for menstrual suppression, such as endometriosis, dysmenorrhea, or premenstrual syndrome (PMS). She then specifies 84 pills with four refills.

"One concern women have is getting enough pills to do it," says Miller. "Going to the pharmacy every 21 days is a barrier."

Until there is a dedicated OC product with an approved regimen outside the traditional 21/7 framework, women may have concerns about the safety and efficacy of such drug use. The Washington, DC-based Association of Reproductive Health Professionals (ARHP) has developed a free patient handout, "Frequently Asked Questions on Extended Contraception," to answer frequently asked questions on the method. (The handout is included in the April 2003 issue of the ARHP publication *Clinical Proceedings*. **See the resource box, above right, on how to obtain the issue.** The handout also is available on the *Contraceptive Technology Update* web site, www.contraceptiveupdate.com.)

Women are exposed to more hormones with an extended or continuous regimen; the annual consumption in milligrams of estrogen and progestin is 23% greater in women using a trimonthly OC regimen (84 days of hormones followed by seven placebo days) vs. the standard 21/7 regimen.[4] However, this increased level of exposure is still below that of women using 50 mcg ethinyl estradiol pills.[4]

No study has examined the long-term safety of an extended OC regimen.[4] According to published reports, about 350 women from the Phase III trial of Seasonale, the extended-regimen pill under review by the Food and Drug Administration at press time, will be followed for another two years to assess side effects and continuation rates.

"A woman who would choose to use the new product, Seasonale, would be exposed to, over the course of several months without a break, far less steroid medication than her mother did on a three-week-on, one-week-off regimen," says **Sheldon Segal**, PhD, distinguished scientist at the New York City-based Population Council and co-author of the book *Is Menstruation Obsolete?*[5] "As for the risk on ovulation and menstruation suppression without interruption, we know from the large experience with Depo-Provera and Norplant, for example, that this is not a health risk."

Women do need to realize that because they will be eliminating the pill-free intervals, they will be using more packs of pills, says **John Guillebaud**, MA, FRCSEd, FRCOG, MFFP, emeritus professor of family planning and reproductive health at University College in London.

"If I were marketing a [pill] like this, I would want to say to the woman up front, 'You will be taking more hormones per year,'" he says. "But if you feel the advantages of not bleeding, not having to use tampons, are enough to compensate for that question mark, that small question mark, go for it."

RESOURCE

"Choosing When to Menstruate" is the focus of the April 2003 issue of the Washington, DC-based Association of Reproductive Health Professionals' (ARHP) publication *Clinical Proceedings*. Review the issue on-line at the ARHP web site, www.arhp.org; click on "Healthcare Providers," "Online Publications," "*Clinical Proceedings*," and then "Choosing When to Menstruate."

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GUEST COLUMN

A new season: Extending the 21/7 pill regimen

By **Robert A. Hatcher**, MD, MPH
Professor of Gynecology and Obstetrics
Emory University School of Medicine
Atlanta
Chairman, *Contraceptive Technology Update* Advisory Board

Since 1960, women have been instructed to take 21 hormonally active pills followed by seven placebo pills (or seven days of taking no pill at all). Throughout the remainder of this commentary, this pattern will be referred to as 21/7, 21/7, 21/7. The one exception to this pattern is the pill marketed as Mircette (Organon, West Orange, NJ). After 21 hormonally active pills, a woman on Mircette takes no hormones for two days followed by five days of an estrogen-only pill with 10 mcg of ethinyl estradiol.

No pill has been marketed that has instructed a woman to take more than 21 consecutive pills that are hormonally active. The new pill, Seasonale (Barr Laboratories, Pomona, NY), under review by the Food and Drug Administration (FDA) at press time, will instruct women to take 84 consecutive pills, each with 30 mcg of ethinyl estradiol and 0.15 mg of levonorgestrel, followed by seven placebo pills. Four of these 91-day cycles will last 91 x 4, or 364 days (one day short of a year). Four times a year a woman will have a period, hence the name: Seasonale.

There are two types of combined oral contraceptive pills: monophasic pills, which provide exactly the same hormones every day, and phasic pills, where the strength of the hormones changes during the 21 days a hormonally active pill is taken.

Over the past 43 years, it has not escaped the attention of women and their clinicians that pills *could* be taken for more than 21 days. Usually, a monophasic pill has been chosen since the fluctuating level of hormones in triphasic pills, if taken for more than 21 days, can cause spotting or breakthrough bleeding. Continuous use of monophasic pills for more than 21 days started with women being treated for endometriosis.[1]

Break out of the box

The availability of an FDA-approved product designed to be taken 84/7, 84/7, 84/7 will validate the taking of pills continuously and markedly increase the continuous use of pills, much as the FDA approval of Preven (Gynetics, Belle Mead, NJ) and Plan B (Women's Capital Corp., Washington, DC) increased use of combined pills as emergency contraceptive pills. The accompanying table outlines the different ways in which combined pills may be taken. **(See Table 1, enclosed in this issue.)** There still will be other variations. While any of the many monophasic-combined pills can be (and now are) used for more than 21 days, an FDA-approved product may quickly become the most commonly used pill to lengthen the number of days taking hormonally active pills.

In order to prescribe combined pills using FDA-approved instructions, we have been placed in a 21/7, 21/7, 21/7 "box" since 1960. Thinking outside this box has happened, but the availability of a pill labeled 84/7, 84/7, 84/7 is going to be important. The many ways of prescribing pills "outside the box" or outside of the "21/7, 21/7, 21/7 box" could be summarized this way: It means taking combined pills for any number of days beyond the usual 21 days. And it includes any number of hormone-free days from 0 to 7, but not more than seven hormone-free days.

Eye the pros and cons

What are the advantages of taking pills continuously?

- **Convenience.**

If a dedicated product is approved, there will be fewer packages of pills to obtain, open, and start on the correct day. With a continuous regimen, there are fewer days of bleeding and decreased expenditures for menstrual hygiene products.[2]

- **Compliance.**

The regimen is somewhat less complicated, and strict compliance may be somewhat less important.

- **Increased ovulation suppression.**

Missed pills may be less likely to lead to

ovulation and risk of pregnancy.[3] This may be particularly beneficial for women with complicated lives.

• **Benefit by certain illnesses.**

Women with endometriosis, porphyria, toxic shock, seizures or asthma, occurring exclusively premenstrually or exclusively during menses, may see relief.[2,4,5]

• **Minimization of cyclic symptoms.**

Women who regularly experience one or more cyclic symptoms in the course of their menstrual cycles may benefit from the elimination of some or all cycles.[2,4-6] **(See Table 2, enclosed in this issue.)**

• **Increased noncontraceptive benefits.**

Women on combined pills have been shown to have increased bone mass.[7] Taking pills continuously may increase this noncontraceptive benefit.

Increasing a woman's total exposure over time to combined pills may increase other documented noncontraceptive benefits of pills, such as the decreased risk for ovarian and endometrial cancer and improvement in acne.

What are the disadvantages of taking pills continuously?

• **Unnatural.**

Some women will not find the amenorrhea and irregularity of taking pills in one of the regimens described in Table 1 acceptable.

• **Expense during pill use.**

Use of any of the currently available monophasic pills continuously necessitates purchasing more cycles of pills. The retail and public sector/HMO price of Seasonale remains to be seen.

• **Expense if discontinued.**

The purchasing of enough pills at a time for one-fourth of a year (Seasonale, under FDA review at press time) will cost much more than a single cycle of pills providing 21 combined pills. Should a woman discontinue the pills before completing a package, she may have spent $50 to $75 on unused pills.

• **Additional counseling.**

Since there are so many different regimens and so many different approaches to managing spotting, prescribing pills continuously will require careful counseling.

Review these advantages and disadvantages, and consider the patient for whom an extended regimen might be appropriate, including women who find such pill-taking easier to remember, those with busy lifestyles, and women seeking relief from cyclic symptoms. Taking pills continuously offers women and their clinicians an important new contraceptive option.

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ASK THE EXPERTS

Safety and efficacy top clinicians' queries

Are low-dose oral contraceptives (OCs) a safe form of birth control for women with well-controlled hypertension? What is the impact of weight on contraceptive efficacy? Comments are offered by the following members of the Contraceptive Technology Update *Editorial Advisory Board:* ***Andrew Kaunitz****, MD, professor and assistant chair in the obstetrics and gynecology department at the University of Florida Health Science Center/Jacksonville;* ***Anita Nelson****, MD, professor in the obstetrics and gynecology department at the University of California in Los Angeles (UCLA) and medical director of the women's health care clinic and nurse practitioner training program at Harbor-UCLA Medical Center in Torrance; and* ***Susan Wysocki****, RNC, NP, president and chief executive officer of the Washington, DC-based National Association of Nurse Practitioners in Women's Health.*

Question: Is it within standards to start a well-controlled hypertensive client on a low-dose pill such as Alesse (Wyeth Laboratories, Philadelphia) as long as the blood pressure

stays within normal range?

Kaunitz: Even contemporary (lower dose) combined oral contraceptive formulations appear to increase blood pressure. Observational data have not clarified whether use of combined OCs in women with well-controlled hypertension (and no other vascular disease risk factors such as smoking or diabetes) increases the risk of heart attack or stroke.

Here is the language included in the Washington, DC-based American College of Obstetrics and Gynecology (ACOG) *Practice Bulletin*: "Women with well-controlled and monitored hypertension who are aged 35 years or younger are appropriate candidates for a trial of combination OCs formulated with 35 mcg or less of estrogen, provided they are otherwise healthy, show no evidence of end-organ vascular disease, and do not smoke cigarettes. If blood pressure remains well-controlled with careful monitoring several months after initiating OCs, use can be continued."[1]

In healthy, nonsmoking, perimenopausal women, use of combination OCs can regularize erratic cycles, suppress vasomotor symptoms, and prevent menopausal fractures as well as ovarian and endometrial cancer. Nonetheless, clinicians should recognize that hypertension increases as women (as with men) age. Accordingly, clinicians prescribing combination OCs to perimenopausal women should closely monitor blood pressure and should be proactive regarding OC discontinuation should blood pressure rise during OC use in this setting.

Finally, clinicians should recognize that progestin-only contraceptives, such as DMPA (Depo-Provera, Pharmacia Corp., Peapack, NJ), Mirena intrauterine system (Berlex Laboratories, Montville, NJ), and minipills, as well as intrauterine devices, represent safe contraceptive choices for hypertensive women, regardless of age or other vascular disease risk factors.

Nelson: This is a very complex question. If we endorse the use of estrogen-containing hormonal contraceptives for women with well-controlled hypertension, are we assuming that a well-controlled hypertensive woman has risk factors for arterial thrombosis that are equivalent to women who are normotensive? I personally offer low-dose contraceptives to such women, but usually only if other effective methods without estrogen are not appropriate. The Geneva-based World Health Organization (WHO) does not address this issue, but it does list mild hypertension as a Category 3, meaning that the risks generally outweigh the benefits. (To access the guidelines, "Improving Access to Quality Care in Family Planning. Medical Eligibility Criteria for Contraceptive Use," on-line, go to the WHO web site, www.who.int/en/, click on "WHO Sites," "Reproductive Health & Research," "Family Planning," and "Family Planning Materials." Click on the publication title, which then will allow you to browse the tables.)

Clearly, if the woman has other cardiovascular risks (such as obesity, diabetes, smoking, or dyslipidemia) then the concern about giving estrogen-containing hormonal contraceptives increases significantly.

Question: My question is threefold:

• The Ortho Evra patch (Ortho McNeil Pharmaceuticals, Raritan, NJ) literature indicates weight more than 198 pounds may result in lower effectiveness rates. Is this something that precludes offering the method to patient who weigh more that this?

• Does this also apply to combined oral contraceptives (OCs) and the NuvaRing (Organon, West Orange, NJ)?

• We have read (not in the product literature) that weight over 150 pounds is a concern with the newer low-dose pills. Is this true, and how much do we have to worry about it?

Wysocki: For question one: Generally, the transdermal contraceptive would not be the first choice for a woman more than 198 pounds. However, if she is a poor pill taker, she might be better off with the patch that she will use consistently than the pill she won't.

For question two: There are no data on weight and NuvaRing. There is one study by Holt that showed a decrease in effectiveness with lower-dose pills and women more than 150 pounds.[2] However, the study has some problems in that

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it is retrospective and relies on patient recall of the pill they were on when they got pregnant and how much they weighed at the time. If one chooses to utilize the Holt data when counseling women who use OCs and weigh greater than 155 pounds, in terms of absolute risk, there is about a half percent increased risk of overall failure. Counseling about absolute risk may, in fact, be more realistic for our patients than the relative risk.

For question three: We can't say whether weight applies or doesn't apply to the pills or the ring with the limited data we have. **(*Contraceptive Technology Update* reported on the Holt, et al. research in its July 2002 *CTU* article, "Does weight play a role in effectiveness?" p. 81.** Scientists are further examining the weight issue, conducting a case-control study of pregnancies among current OC users. Investigators are obtaining information about women's weight before and during OC use, and also details of their pill-taking habits and concurrent illnesses and medications that might influence OC effectiveness. *CTU* will report on the findings when they are published.)

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CTU UPDATES
News ■ Resources ■ Events

News flash: Plan B files for OTC status

Over-the-counter (OTC) status for emergency contraception has moved a step closer with the Washington, DC-based Women's Capital Corp.'s April 2003 filing with the Food and Drug Administration (FDA) to switch its levonorgestrel drug Plan B from prescription to OTC status.

"We look forward to working with the FDA over the next 10 months as it reviews the safety and efficacy of OTC status for Plan B," says **Sharon Camp**, PhD, company founder and chief executive officer. "We believe that removing the prescription requirement is critical to giving women timely access to backup birth control."

If the FDA approves the application, U.S. women would be able to buy Plan B without a prescription sometime in 2004. Emergency contraception is available without a prescription in California, Washington, and several other states, but it remains a "behind-the-counter" drug that must be requested from a pharmacist, who provides counseling in its use. Similar "morning-after" contraceptives are available without prescription in Europe.

The 59-volume, 15,000-page application contains clinical study data on nearly 11,000 women who have taken the drug after sex to prevent pregnancy. The research encompasses the results of 39 studies, including the recently published label comprehension study[1] and the OTC actual use study, which has been accepted for publication by *Obstetrics & Gynecology*. The actual use study, which at press time was scheduled to appear as early as this summer, was designed to mimic OTC distribution.

The FDA approved Plan B in July 1999; Health Canada approved it in February 2000. Canada is considering nonprescription status for Plan B under an expedited review process.

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CE/CME instructions

Physicians and nurses participate in this continuing medical education/continuing education program by reading the articles, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers and refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this activity with the December issue, you must complete the evaluation form included in the December issue and return it in the reply envelope provided in that issue to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you. ■

CE/CME Questions

After reading *Contraceptive Technology Update*, the participant will be able to:

- Identify the progestin found in the 84-day regimen oral contraceptive, Seasonale, under regulatory review at press time. **(See "Extended-use contraception offers revolution in reproductive choices" in this issue.)**
- Name two new contraceptives that are being researched for potential use beyond their currently approved regimens. **(See "Researchers explore extended contraception.")**
- Cite a common side effect of combined oral contraceptives used in an extended regimen. **(See "Help educate for success with extended pill use.")**
- State the type of oral contraceptive traditionally used in extended regimens. **(See "A new season: Extending the 21/7 pill regimen.")**

1. What is the progestin found in the 84-day regimen oral contraceptive, Seasonale, under regulatory review at press time?

A. Norgestimate
B. Desogestrel
C. Levonorgestrel
D. Norethindrone

2. What new contraceptives are being researched for potential use beyond their currently approved regimens?

A. Transdermal contraceptive and contraceptive vaginal ring
B. Transdermal contraceptive and two-rod contraceptive implant
C. Contraceptive vaginal ring and contraceptive sponge
D. Contraceptive vaginal ring and combined contraceptive injection

3. What is a common side effect of combined oral contraceptives used in an extended regimen?

A. Nausea
B. Breast tenderness
C. Headaches
D. Initial breakthrough bleeding/spotting

4. What type of oral contraceptive traditionally has been used in extended regimens?

A. Triphasic
B. Biphasic
C. Monophasic
D. Progestin-only

Answer key: 1.C; 2.A; 3. D; 4.C.

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Table 1: Different Approaches to Taking Combined Pills Continuously (Outside the 21/7, 21/7, 21/7 Box)

Pill Used	Consecutive Days Taking Hormonally-Active Combined Pills #	Hormone-Free Days #	Comment
Seasonale	84	7	Under FDA review
Seasonale	84	3-6	Off- label
Seasonale	Until SPT or BTB	3-7	Off-label
Seasonale	Months to Years	0	Off-label
Seasonale	Enough to Manipulate Cycle*	3-7	Off-label
Any Monophasic Pill	42	3-7	Off-label; "bicycling"
Any Monophasic Pill	63	3-7	Off-label; "tricycling"
Any Monophasic Pill	Until SPT or BTB	3-7	Off-label
Any Monophasic Pill	Months to Years	0	Off-label
Any Monophasic Pill	Enough to Manipulate Cycle*	3-7	Off-label

SPT: Spotting
BTB: Breakthrough bleeding

* For honeymoon, vacation, exams, athletic event, trip, presentation, or special events.

Table 2. Cyclic Symptoms that May Improve in Women Taking Oral Contraceptives Continuously

During Menstrual Phase
- Cramping and pain
- Bleeding — nosebleeds
- Headaches of any kind
- Menstrual migraine
- Nausea, vomiting, diarrhea, dizziness
- Depression

At Midcycle
- Pain, sharp or dull
- Spotting
- Vaginal discharge
- Nausea

During Premenstrual Phase
- PMDD: Premenstrual Dysphoric Disorder
- PMS: Premenstrual Syndrome
- Breast fullness and tenderness
- Bloating
- Weight gain
- Anxiety, irritability, or depression
- Acne flare-ups

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Contraceptive Technology Reports

A supplement to *Contraceptive Technology Update* **July 2003, BB #S03162**

Evaluation of a Female-Controlled Intravaginal Barrier Device: The FemCap

Authors: **Linda Rogers, CRNP,** Research Program Coordinator, Johns Hopkins Bayview Medical Center, **Torri L. Ross, MPH,** Senior Research Program Coordinator, Johns Hopkins Bayview Medical Center, and **P.D. Blumenthal, MD, MPH,** Associate Professor, Johns Hopkins University, Director, Contraceptive Research and Programs, Johns Hopkins Bayview Medical Center.

Peer Reviewer: **Mitchell D. Creinin, MD,** Associate Professor, Director of Family Planning and Family Planning Research, Department of Obstetrics, Gynecology, and Reproductive Sciences, University of Pittsburgh School of Medicine.

Over the last two decades, there has been a renewed interest in barrier methods due to their ability to protect against pregnancy and the transmission of HIV.[1] This is exemplified by the increase in the use of male condoms since the early 1980s when HIV first appeared in the United States.[2] Because the use of barrier methods other than male condoms has decreased, contraceptive research has focused on finding an acceptable female-controlled method serving the dual function of protecting against pregnancy and HIV. It is recognized that barrier methods are needed; particularly ones that offer HIV protection, and that are more convenient than those currently available. The condom needs to be used at the time of coitus and interferes with spontaneity. The diaphragm can be left in place for 24 hours, but a longer time frame may be more desirable for some women. Methods also are needed that are easier to insert and remove and that can be prescription-free.

Devices similar to the current cervical cap and diaphragm approved by the Food and Drug Administration (FDA) were designed and introduced in the United States in the late 1910s.[3,4] Since this time, these devices have evolved to address such issues as odor, dislodgment, difficulty, and time required to fit the device, insertion and removal, and discomfort to male and female partners, all of which have affected acceptability. Even with these improvements, these devices remain poorly utilized.

Several barrier methods developed over the last 10 years have attempted to address the problems with the currently available methods. In 1994, the female condom was introduced to the public. Unfortunately, after FDA approval, the female condom was found by many users to be undesirable because of slippage problems, difficulty of insertion, discomfort with use, appearance, and expense.[3] A newer barrier device, Lea's Shield, approved by the FDA in March 2002, was designed to fill the niche for women seeking an acceptable barrier method. It is a diaphragm-like device made of medical-grade silicone with a valve to allow for the escape of air and mucus and a loop to simplify insertion and removal. The latest barrier method on the market, approved in March 2003, is the FemCap; this method also was designed to address the inadequacies of the devices on the market when it was conceptualized.

Design/Mechanism of Action

The FemCap is a silicone device shaped like a U.S. Navy "sailor's" cap. The dome of the device fits over the cervix, the rim fits into the vaginal fornices, and the brim fits against the adjacent vaginal walls. One-half teaspoon of spermicidal gel is applied to the inside (the cervical side) of the cup and the brim, and one-half teaspoon is applied in the groove between the cup and the brim on the outside (the vaginal side). The device provides a physical barrier for the cervix from sperm and pathogens, and the spermicide provides a chemical barrier. There are three sizes of FemCap, which are determined by the diameter of the inner rim of the device. The smallest, the 22 mm, is designed for women who have never been pregnant. The medium (26 mm) is

Chairman:
Robert A. Hatcher, MD, MPH
Senior Author,
Contraceptive Technology
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and Obstetrics
Emory University School
of Medicine, Atlanta

David F. Archer, MD
Professor of OB/GYN
The Jones Institute for
Reproductive Medicine
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Perioperative Consultant/Educator
K&D Medical Center
Lewis Center, OH

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Howard County Health Dept.
Columbia, MD

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Assistant Medical Director
Planned Parenthood of New Mexico
Albuquerque, NM

Andrew M. Kaunitz, MD
Professor and Assistant Chair
Department of OB/GYN
University of Florida
Health Science Center
Jacksonville, FL

Anita L. Nelson, MD,
Medical Director,
Women's Health Care Clinic
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Torrance, CA

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Susan Wysocki, RNC, BSN, NP,
President
National Association of Nurse
Practitioners in Women's Health
Washington, DC

for women who have been pregnant but have not had a vaginal delivery, and the large (30 mm) is for women who have had a full term vaginal delivery. Parity alone has been found to be predictive for the appropriate size 85% of the time.[5]

The FemCap device was designed to combine some of the advantages of the diaphragm and the cervical cap. Like a diaphragm, it is relatively easy to insert. It is made of medical-grade silicone, which is stiffer than the latex in a diaphragm, but is not as rigid as the latex in a Prentif cervical cap. The silicone is less allergenic than latex and less likely to be harmed by petroleum-based lubricants and cleaning procedures. The device was designed to require less clinician time for fitting than the diaphragm or the cervical cap and comes in only three sizes, as opposed to the multitude of sizes for the diaphragm and four for the Prentif cervical cap. The cap fits less snugly over the cervix than a cervical cap and does not actively adhere to the cervix. The package labeling for the Prentif cervical cap requires that a pap smear be repeated after three months of use because an early trial found an increase in conversions from Class I to Class III (normal to dysplasia)[6] goes here pap smears at three months.[7] However, a subsequent re-analysis of that data found no statistically significant increase in abnormal pap smears at three months or at one year.[8]

The FemCap device that was approved by the FDA is a second-generation version of the original device that was used in the large U.S. randomized clinical trial. According to the manufacturer, several design changes were made to the device such as a strap that functions to facilitate removal by forcing the woman to push on the dome with her finger in order to slide her finger between the strap and the dome. This breaks the suction in the dome and also eases removal. Some other changes were made in an effort to improve the efficacy of the device. The "brim" portion that rests on the vaginal walls was lengthened to improve the barrier effect. With the first generation of the FemCap, a large proportion of the pregnancies in the trial occurred in parous women (i.e., those using the largest size cap). This cap was found to be slightly asymmetrical, and it was postulated that the movement of the cervix during coitus with the asymmetric device could have broken the contact of the brim and the vaginal wall (personal communication with Alfred Shihata, MD). The current large size FemCap has a slightly smaller dome than the original, a larger brim, and is perfectly symmetrical.

Fitting and Use

When providing a FemCap device, the fit should be checked by a clinician to ensure that it covers the entire cervix, extends into the vaginal fornices, and that the brim adheres to the vaginal wall. The device should not be easily dislodged, and the device should be comfortable for the woman. The FemCap is presently available only with a prescription and can be ordered directly through the company's web site (www.femcap.com) and sent to the patient's clinician. Fitting devices for providers and an instructional video also are available through the web site.

The FemCap can be left in place for up to 48 hours. Intercourse can take place as often as desired for up to 42 hours without the insertion of additional spermicide, because the device must be left in place for at least six hours after the last intercourse. In clinical trials, subjects were instructed not to use the device during their menses because of the theoretical risk of toxic shock syndrome, although the risk is not expected to be any higher than with the diaphragm. The odds ratio for toxic shock syndrome with a diaphragm is 11.7 compared to nonbarrier users.[9] To remove the device, the woman should push her finger into the dome of the device to break the suction and to allow room to grab on to the strap. She then can slowly pull the device out of her vagina by holding onto the strap. The FemCap should be washed with antibacterial hand soap, dried thoroughly, and stored in its plastic case.[10]

Efficacy and Acceptability

The randomized clinical trial on which FDA approval was based, compared the original FemCap and the Ortho All-Flex diaphragm. The treated population included 355 subjects who were randomized to the first generation design of the FemCap and 403 randomized to the diaphragm. Fifteen percent of the intent-to-treat population for the FemCap was excluded because of inability to insert or remove the device at enrollment, compared with 5% of the diaphragm group. Discontinuation rates for nonpregnancy reasons were not statistically different between the groups. Among women with previous diaphragm experience, those randomized to the FemCap were 2.5 times more likely to discontinue the study early. However, almost three-quarters of the FemCap subjects who

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To reveal any potential bias in this publication, we disclose the following: Rogers and Blumenthal (authors) reveal that they conducted research by participating in the clinical trial for FemCap. Ross (author) has no relationships with this field of study to disclose. Creinin (peer reviewer) reports no relationships related to this field of study.

had used both devices preferred the FemCap.[5]

The probability of pregnancy, using the six-month Kaplan-Meier cumulative unadjusted typical-use probability, was 13.5% for the FemCap users and 7.9% for the diaphragm users. The relative risk of pregnancy was 1.96 for the FemCap users compared with the diaphragm users, with the upper 95% confidence limit of 3.01. In order to demonstrate clinical equivalence, the study would have needed to demonstrate that the upper 95% confidence limit for the risk of pregnancy in the FemCap users was ≤ 1.73. Therefore, clinical equivalence was not demonstrated. The six-cycle perfect-use pregnancy probabilities (11.2% vs. 7.4%) also did not demonstrate clinical equivalence.[5] When the pregnancy rates were broken down by previous parity, the probability of pregnancy for nulliparous women was 9.5% for the FemCap (the small or the medium device primarily) and 9.1% for the diaphragm. However, for parous women, the pregnancy rates were 15.8% (primarily the large size device) and 6.9%, respectively.[5] It should be noted that the potential design problems with the first generation device have been addressed, and there currently are no data regarding pregnancy rates with the new design.

There are differences in the recommendations for use of the FDA-approved FemCap compared to the way the original device was used in the clinical trial, which may have a large effect on efficacy. The large randomized clinical trial was paid for by funds from the United States Agency for International Development, because officials of that agency are very interested in finding effective barrier methods for use by women in developing countries. For this reason, they did not want a videotape to be used to train women in the clinical trial to use the device as this technology often is not available in developing countries. However, the FDA has approved a videotape to be included with packaging which details instruction on use, insertion, and removal. Additionally, the manufacturer recommends that a backup method be used for the first few weeks while the woman is learning to use the device. This was not allowed in the clinical trial.

Side Effects and Safety

Cervical cytology was one of the outcome variables in the comparative study between the FemCap and the diaphragm. Women were excluded from the study at initiation if they had any abnormalities on their pap smears other than atypical cells of uncertain significance (ASCUS), inflammation, or infection. At the end of the six-month trial, 7.0% of the FemCap and 8.4% of the diaphragm users had ASCUS pap smears. Of the FemCap and diaphragm users respectively, 1.3% and 1.4% had low-grade squamous intraepithelial lesions (SIL), and 0.7% of FemCap users and 0.6% of diaphragm users had atypical glandular cells of uncertain significance (AGUS). None of these differences were statistically significant.

Coital logs were kept by all study subjects during the comparative trial. There were significantly more problems reported by the FemCap users compared to the diaphragm users. Of the FemCap users, 30.6% reported that the device moved or dislodged, as opposed to 6% of the diaphragm users. However, there was no statistically significant association between dislodgment of the FemCap and pregnancy. FemCap users (11.6%) had more difficulty removing the device than diaphragm users (3.8%). Problems that were not statistically significant, but were reported by slightly more FemCap users, were "difficulty inserting" (10.3% vs. 6.5%) and "partner could feel device" (7.1% vs. 2.5%). Slightly more diaphragm users reported coital pain (2.8%) than FemCap users (0.6%). All of the coitally related problems with the devices were reported in less than 2% of coital acts for both groups.[5]

Adverse events of the urogenital system were not statistically different between the FemCap group and the diaphragm group with two exceptions. More FemCap users reported blood found in the device (9% vs. 4%), and fewer FemCap users developed urinary tract infections (UTIs) (7.5% vs. 12.4%).[5] The increased risk of UTIs with diaphragm use has been consistent across multiple studies.[11,12] This increase may be due to the design of the diaphragm or because of the spermicide used with it. The FemCap does not impinge on the urethra because the size of the brim is much smaller than the diaphragm, and much less spermicide is used with the device.

Role of Method in the Contraceptive Marketplace

The FemCap use requires planning and the ability to understand complex instruction. This method would be fitting for women who do not want or cannot use hormonal contraceptives or for women who have contraindications to intrauterine devices (IUDs). Additionally, because the device is latex-free, the FemCap is an appropriate method for women and their partners who have latex allergies. Women who have done well with the diaphragm, but have had problems with UTIs, might be an especially suitable group for this method. Barrier methods such as FemCap might offer protection against HIV transmission if data emerging about the role of the cervix in acquisition of HIV are borne out, and if protection against HIV is demonstrated in clinical trials. If this were proven to be the case, this would contribute greatly to its marketability; however, more information is needed from studies before this can be concluded.

As with all contraceptive methods, there are women for whom this method is not appropriate. Consideration should be given before prescribing the device to women uncomfortable with genital manipulation or inserting and removing foreign bodies from their vaginas. These women are more likely to have higher failure rates with the FemCap. In addition, women whose sexual habits are unpredictable and spontaneous should be discouraged from using this method as it does require motivation and planning.

Benefits and Limitations of Method

The cost of the FemCap, at $49.95, is an important advantage of this method.[9] The device should last for two years, so the monthly cost is about $2 per month.[1] Based purely on commodity involved, the device is less expensive than hormonal contraceptives on a monthly basis. However, one must take into account the cost of an undesired pregnancy with the method's high rate of failure. Although some planning is required with the use of the FemCap, women can insert the device well before intercourse so as not to disrupt spontaneity when with their partner.

Not every woman can use the FemCap because one of the three sizes available may not fit correctly. Women with a cervix that is flush with the vagina after a cervical conization or with extremely large or a previously lacerated cervix may not be able to be fit with this device. The 13.5% six-month failure rate in the large clinical trial is higher than other barrier methods. More studies are needed to determine if the new design truly results in a lower pregnancy rate. As with all contraceptive methods, women should be fully counseled about the advantages and disadvantages before selecting the FemCap as their contraceptive method. **(See Table, Advantages and Disadvantages of FemCap, enclosed in this issue.)**

Conclusion

Although hormonal contraception and IUDs are highly effective, they are clearly not appropriate for all patients. The currently available female-controlled barrier methods are underutilized. The FemCap may be challenging for some women to use; for others, it may meet their needs in ways that enhance compliance and thus result in better efficacy than might have been achieved by a less acceptable method. This possibility alone can make this new, reasonably effective method a welcome addition to the contraceptive marketplace.

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CME Instructions

Physicians participate in this continuing medical education program by reading the article, using the provided references for further research, and studying the questions at the end of the article. Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this activity, you must complete the evaluation form provided and return it in the reply envelope provided in order to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you.

CME Objectives/Questions

After reading this article, the reader will be able to:

- List the benefits of using the FemCap.
- Define the limitations of the FemCap.
- Describe the procedure for fitting the FemCap.

1. The purported benefits of the FemCap include:

A. No need to use microbiocide or spermicide.
B. It is recommended for use during menses.
C. It can be used for as long as 48 hours.
D. It has efficacy similar to a condom.

2. Possible limitations of FemCap include:

A. Risk of urinary tract infection is higher than with the diaphragm.
B. Risk of dislodgment is higher than with the diaphragm.
C. The FemCap can be left in place for only 24 hours.
D. Possible allergic reactions to the material used in the FemCap.

3. In respect to fitting the FemCap:

A. One size fits all.
B. It is similar to a diaphragm.
C. Size is dependent on patient's weight.
D. Size is dependent on parity: one size for nulliparous, one size for parous, and one size for patients who have had an abortion or C-section.

Answers: 1. C; 2. B; 3. D.

Table: Benefits and Limitations of FemCap

Benefits	Limitations
• Made of latex-free material that is durable and easy to clean • Inexpensive • Female-controlled nonhormonal method • Does not disrupt spontaneity because it can be inserted up to 42 hours before intercourse • Less clinician time needed for fitting compared to cervical cap • Instant reversibility of fertility • Modified design with strap makes removal easier • Can be left in place for up to 48 hours • Lower risk of urinary tract infections than with the diaphragm • Possible relative protection from sexually transmitted infections because of coverage of the cervix	• Less effective than hormonal methods of contraception • The FemCap cannot be used by all women • Must plan to insert before coitus • Need a prescription to use

Contraceptive Technology Update

2003 Confidential Salary Survey

This confidential salary survey is being conducted to gather information for a special report later in the year. Watch in coming months for your issue detailing the results of this survey and the overall state of employment in your field.

Instructions: Fill in the appropriate answer directly on this form. Please answer each question as accurately as possible. If you are unsure of how to answer any question, use your best judgment. Your responses will be strictly confidential. Do not put your name or any other identifying information on this survey form.

1. What is your current title?

- ☐ A. Admistrator
- ☐ B. Nurse practitioner
- ☐ C. Registered nurse
- ☐ D. Health educator
- ☐ E. MD
- ☐ F. Nurse midwife
- ☐ G. Physician assistant

2. Please indicate your highest degree.

- ☐ A. Some college
- ☐ B. Associate or 2-year
- ☐ C. Bachelor's degree
- ☐ D. Some graduate work
- ☐ E. Graduate degree
- ☐ F. Doctorate

3. How many people do you supervise?

- ☐ A. 0-3
- ☐ B. 4-6
- ☐ C. 7-10
- ☐ D. 11-15
- ☐ E. 16-20
- ☐ F. 21-40
- ☐ G. 41-60
- ☐ H. 61-80
- ☐ I. 81-100
- ☐ J. 101 or more

4. How long have you worked in your present field?

- ☐ A. less than 1 year
- ☐ B. 1-3 years
- ☐ C. 4-6 years
- ☐ D. 7-9 years
- ☐ E. 10-12 years
- ☐ F. 13-15 years
- ☐ G. 16-18 years
- ☐ H. 19-21 years
- ☐ I. 22-24 years
- ☐ J. 25 or more years

5. How long have you worked in health care?

- ☐ A. less than 1 year
- ☐ B. 1-3 years
- ☐ C. 4-6 years
- ☐ D. 7-9 years
- ☐ E. 10-12 years
- ☐ F. 13-15 years
- ☐ G. 16-18 years
- ☐ H. 19-21 years
- ☐ I. 22-24 years
- ☐ J. 25 or more years

6. What is your age?

- ☐ A. 20-25
- ☐ B. 26-30
- ☐ C. 31-35
- ☐ D. 36-40
- ☐ E. 41-45
- ☐ F. 46-50
- ☐ G. 51-55
- ☐ H. 56-60
- ☐ I. 61-65
- ☐ J. 66 or older

7. What is your sex?

- ☐ A. male
- ☐ B. female

8. What is your annual gross income from your primary health care position?

- ☐ A. Less than $30,000
- ☐ B. $30,000 to $39,999
- ☐ C. $40,000 to $49,999
- ☐ D. $50,000 to $59,999
- ☐ E. $60,000 to $69,999
- ☐ F. $70,000 to $79,999
- ☐ G. $80,000 to $89,999
- ☐ H. $90,000 to $99,999
- ☐ I. $100,000 to $129,999
- ☐ J. $130,000 or more

9. On average, how many hours a week do you work?

- ☐ A. less than 20
- ☐ B. 20-30
- ☐ C. 31-40
- ☐ D. 41-45
- ☐ E. 46-50
- ☐ F. 51-55
- ☐ G. 56-60
- ☐ H. 61-65
- ☐ I. more than 65

10. In the last year, how has your salary changed?

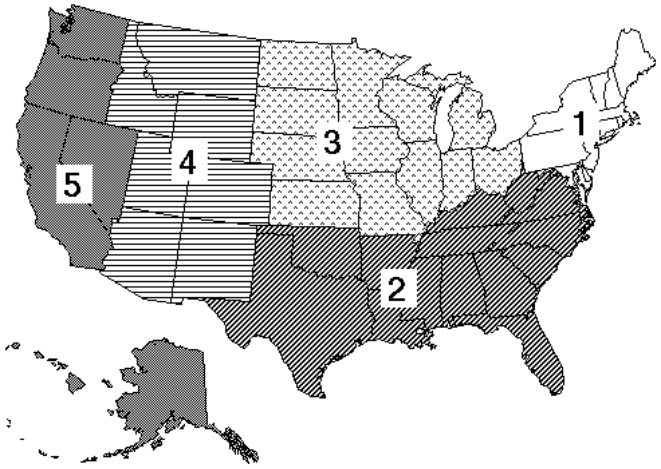
- ☐ A. salary decreased
- ☐ B. no change
- ☐ C. 1% to 3% increase
- ☐ D. 4% to 6% increase
- ☐ E. 7% to 10% increase
- ☐ F. 11% to 15% increase
- ☐ G. 16% to 20% increase
- ☐ H. 21% increase or more

11. Which of the following best describes the location of your work?

- ☐ A. urban
- ☐ B. suburban (outside large urban area)
- ☐ C. medium-sized community
- ☐ D. rural

12. Using the map (right), please indicate where your employer is located.

- ☐ A. region 1
- ☐ B. region 2
- ☐ C. region 3
- ☐ D. region 4
- ☐ E. region 5
- ☐ F. Canada
- ☐ G. other_____



13. Which best describes the ownership or control of your employer?

- ☐ A. college or university
- ☐ B. federal government
- ☐ C. state, county, or city government
- ☐ D. nonprofit
- ☐ E. for profit

14. Which of the following best categorizes the work environment of your employer?

- ☐ A. academic
- ☐ B. agency
- ☐ C. city or county health department
- ☐ D. clinic
- ☐ E. college health service
- ☐ F. consulting
- ☐ G. hospital
- ☐ H. private practice

15. In the past 12 months, how has the number of employees in your company or department changed?

- ☐ A. increased
- ☐ B. decreased
- ☐ C. no change

Deadline for responses: Aug. 15, 2003

Thank you very much for your time. The results of the survey will be reported in an upcoming issue of the newsletter, along with an analysis of the economic state of your field. Please return this form in the enclosed, postage-paid envelope as soon as possible. If the envelope is not available, mail the form to: Salary Survey, Thomson American Health Consultants, P.O. Box 740058, Atlanta, GA 30374.