

THE HORMONAL RING

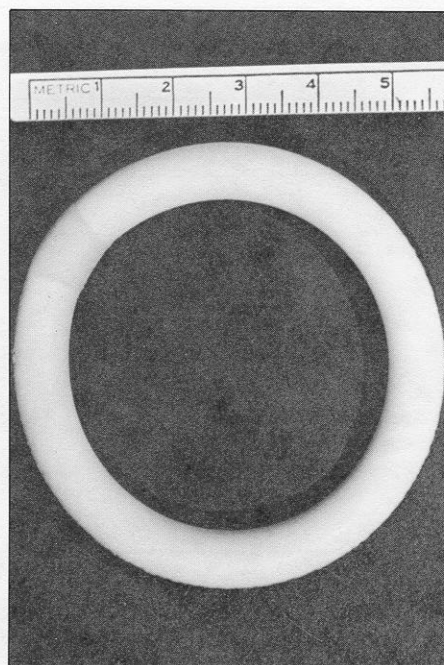
A NEW CONTRACEPTIVE GAINS ACCEPTANCE

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In many developing countries, meeting the demand for family planning services will depend on the development of contraceptive methods that are effective, acceptable, and can safely be delivered at a low cost by paramedical personnel without direct medical supervision. Encouraging results have been obtained in programs where contraceptive pills have been distributed by community leaders, vendors, or midwives without a physician's prescription or intervention, but the safety of such programs is being questioned as more evidence of the pill's side effects come to light.

The Population Council's International Committee on Contraceptive Research (ICCR) — a committee of nine scientists, four of whom are developing country nationals — has been working on an alternative hormonal contraceptive in the form of a vaginal contraceptive ring. The ring is 58 mm in diameter and consists of a core of Silastic® — a silicone rubber material that has been used for years in artificial vessels, prosthesis, etc. — covered by a thin layer of levonorgestrel (one of the steroids most commonly used in contraceptive pills) and estradiol (a hormone that prevents intermenstrual bleeding) and an overcoat of silicone rubber.

The ring is inserted into the vagina on the fifth day of the menstrual cycle, and withdrawn three weeks later for one week. The contraceptive steroids are released from the Silastic at a regular rate and readily absorbed through the vagina. Thus, the blood levels of contraceptive hormones reached during the use of the ring are sufficient to prevent ovulation but do not exhibit the great daily variations commonly observed in women on oral contraceptives. There are sufficient hormones in the ring to provide six months of contraception.



Preliminary research on Swedish and other developed country women indicates that the ring is as effective as, and safer than, the pill. Still, it was not known whether a method that involved handling the genitals twice a month and carrying a foreign body in the vagina for three weeks a month would prove acceptable to the poorer peri-urban and rural women in developing countries who were expected to benefit most from safe, reliable contraception.

In order to find out, IDRC agreed to support a study of the ring's acceptability in actual practice, carried out by the National Council on Population and the Family, Santo Domingo, Dominican Republic, and the Centre for Research on Maternal and Child Health, Campinas, Brazil. The ring was offered, along with other methods, in a number of clinics in each country where prescriptions, instruction, and follow-up were the responsibility of paramedical personnel. The study involved an observation period during which 150–200 ring acceptors in each country were to be enrolled and matched with pill users. A survey of the users, covering their demographic characteristics and satisfaction or dissatisfaction with the method, gathered information. Pill users were chosen for comparative purposes because both methods are hormonal, both require the same sequence of use and rest, and both tend to induce regular menses.

The survey findings indicated that ring users were slightly older than pill acceptors and that they and their partners tended to have more education. With regard to the method itself, 10 percent of ring users complained of difficulty associated with insertion, 20 percent of difficulty with removal. Forty-three percent worried about correct placement. Considering that women were told that the ring would

work however inserted in the vagina, this percentage is remarkably high. Thirty-three percent reported that the ring had caused vaginal pain and 10 percent reported having expelled it at some time or another. About half the women in each country said that the ring had changed colour during use and about a third of those who noted the change did not like it.

Ring users and pill users were asked whether they had experienced any problems while using the method. Twice as many ring users reported menstrual problems, but a significantly larger percentage of pill users (26 percent) as compared with ring users (17 percent) reported having other problems, such as headaches. Forty-two percent of ring users, compared with 62 percent of pill users, said they gained weight. Almost all (90 percent) of the Dominican women liked the weight increase, but 53 percent of the Brazilian women did not — probably a cultural difference explained by the fact that thin is associated with beauty in Brazil, while a full figure is considered a sign of good health and looks in the Dominican Republic.

As far as satisfaction with the method was concerned, a significantly larger percentage of the ring users (17 percent) than pill users (7 percent) considered their experience "very good," but the general level of satisfaction with both methods was similar.

An earlier study indicated that women liked the fact they had control over the use of the method, that they could insert and remove the ring at will, and that it was possible to remove it to have intercourse or wash it for hygienic purposes. Another positive finding that emerged from this study was that a decrease in the amount and duration of menstrual bleeding was welcomed by most users — as was the increase in body weight, at least by the Dominican women. Although these findings may be culturally related rather than universal, it is nonetheless encouraging to observe that in societies where malnutrition and anemia are not uncommon, contraceptive side effects that work against these problems are well accepted by the female population.

In addition, the information obtained from the study provides important data for the final design of the new method and the instructions that will accompany it. The concerns of the women regarding insertion, removal, and placement of the ring suggest that it may be worthwhile trying a narrower and more flexible model. In any case, detailed instructions, clearly stating that any place within the vagina is appropriate for the ring to be effective, should accompany the final model. Also, considering that a number of users were disturbed when the ring changed colour with use, correction of this factor might improve the ring's acceptability. □

The authors were members of the project team in Brazil and the Dominican Republic testing the contraceptive vaginal ring.