

Progress in Contraceptive Delivery Systems

Volume 4

IUD TECHNOLOGY

Edited by

E. S. E. Hafez and A. J. M. Audebert

Progress in Contraceptive Delivery Systems

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VOLUME IV

IUD TECHNOLOGY

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Foreword

Science and research continues to strive for the totality of means used to provide appropriate methods necessary for human contraceptive sustenance and comfort. Searching for total safety and effectiveness of contraceptives continually stimulates new research. Most methods presently under study are used or could be used if made available, or are at a stage of development where their usefulness is likely to be assessed over the next few years.

In particular, this volume deals with the widespread application of intrauterine contraceptive devices - the IUD - which did not occur actively until the 1960s. Since then, the devices in existence have made remarkable improvements. The contributors to this volume presented their papers at the International Symposium on *IUD Technology* which was held from July 3-5, 1980, in Bordeaux, France. All research efforts have strived to make IUDs as effective as possible while at the same time minimizing the existence of side-effects. One approach to improving the effectiveness, safety and acceptability is to develop methods of delivery that provide programmed medication. This is based on knowing that side-effects are generally dose dependent and that the degree of risk changes in proportion to the dose. The preferred dose is one that evokes contraception with minimal risk.

To promote widespread successful application, the physician must put the benefit-risk ratio of the IUD in a proper perspective. By obtaining a thorough knowledge of the practical results with all available devices and by utilizing the objective scientific data accumulated in the process of development, the physician can then adequately provide appropriate contraception to all those desiring it.

This volume concentrates on present knowledge obtained in the areas of inert and medicated IUDs, applications and complications of IUDs, and IUDs and family planning. To develop long-acting contraceptive systems, the application of more sophisticated technology is required, as is a wider diversity of technological expertise. The multidisciplinary approach to research requires centralization of advanced expertise and a broad funding base to be totally effective.

The editors would like to express their sincere appreciation to all the contributors of this volume, who so meticulously prepared their chapters and who share in the general goal of providing safe and effective contraception to the world. Thanks are also due to Jackie Mucci, who assisted in the editing and assembling of this volume; to Jackie Smieska for her helpful assistance; and to MTP Press for their fine preparation of this publication.

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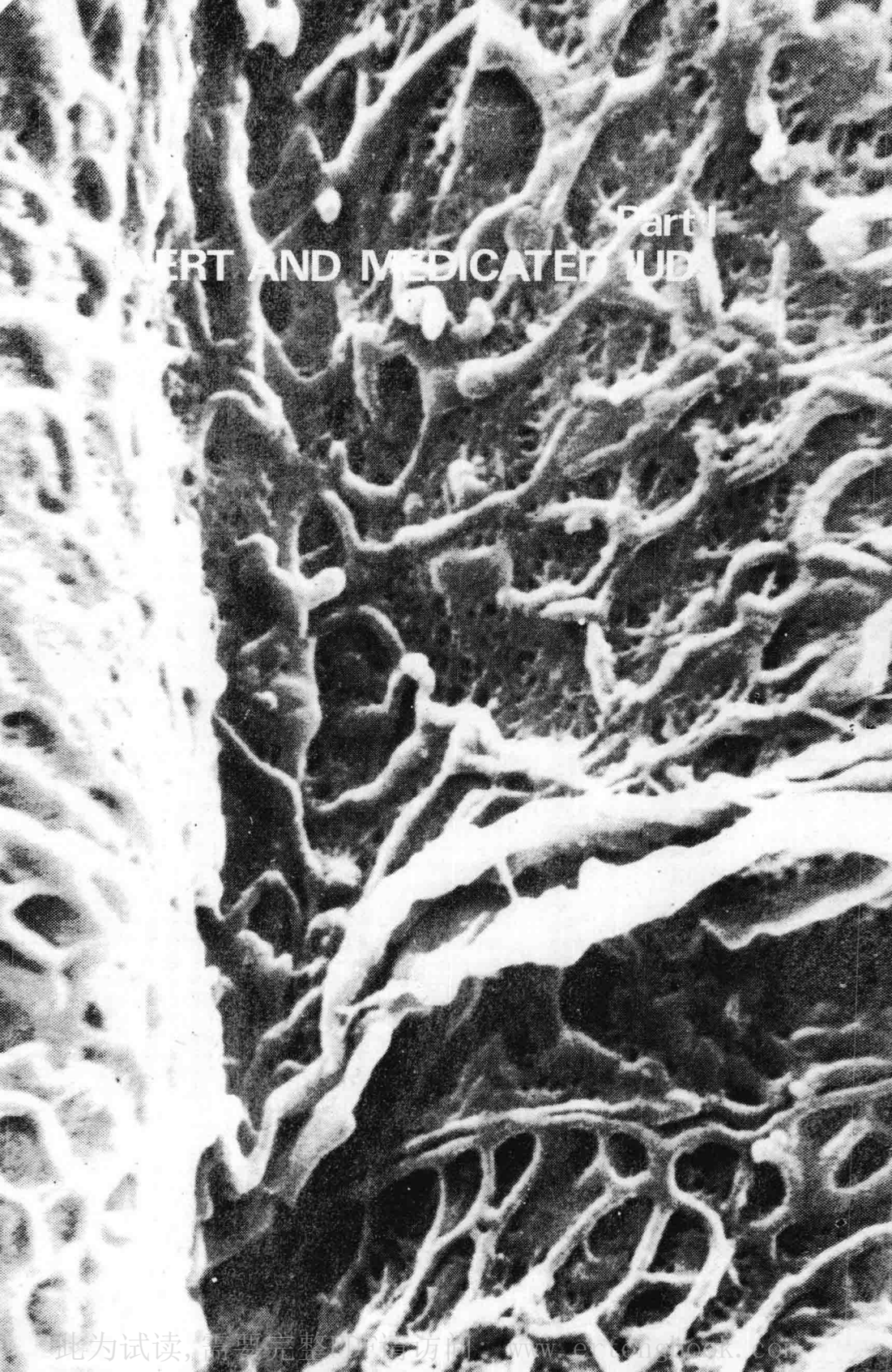
E. S. E. HAFEZ
Series Editor

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Part I

INERT AND MEDICATED IUD

1

Fertility regulation and modern technology

E. S. E. HAFEZ

Fertility regulation and family planning are both essential factors in developing a 'natural economy', maintaining the 'quality of life', and protecting both maternal and child health. Family planning is encouraged in densely populated areas, whereas appropriate measures are adopted to increase the population in sparsely populated minority areas. People will be encouraged to marry late, and families will be encouraged to plan only one or two children at most, with a 3-year gap between children (Figure 1.1).

A dramatic culture revolution now exists which includes an overall increase in cohabitation and a decrease in birth rate as well as a natural increase in growth rate, and decrease in death rate. An equilibrium between these factors is highly critical in maintaining a natural economy and quality of life. In both men and women, sexual behavior in middle age is greatly influenced by socio-cultural background. Cohabitation is common in various parts of the world and is becoming more popular. Concepts and methods of contraception therefore vary accordingly.

In parts of Africa, as elsewhere, a woman is not expected to have any more children after she has a married daughter, or otherwise becomes a grandmother. In parts of Hindu India, the idea of manhood may be to marry at age 25, to have 25 years of fertile life and then to abstain from sex thereafter. As men often marry younger brides, it is not uncommon for women to abstain from intercourse well before they reach the end of their fertile years. In some parts of Asia, coital frequency in couples between ages 40 and 50 is significantly lower than among those in the West.

The impact of contraception on population growth varies considerably in different countries as a result of various factors such as culture, religion, socio-economic condition, education, general health and standard of living. These differences are apparent when contrasting the Middle East with Latin America; and Africa with China. One of the most important demographic events in human history is that China has cut its birth and growth rates approximately in half during the last decade. Family planning in China has

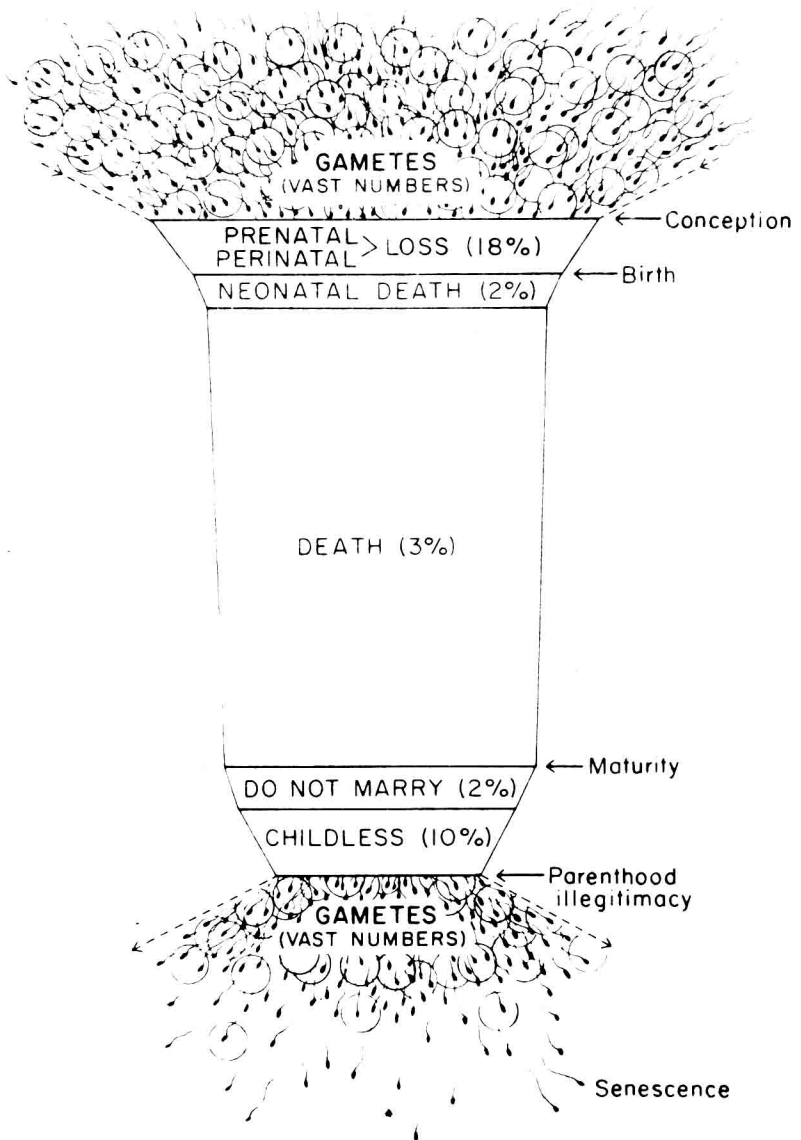


Figure 1.1 Diagram of life cycle, showing effect of sexual reproduction on variability. Gametes are produced in large numbers and suffer a large random loss. Prenatal and perinatal loss is estimated as 18%, neonatal death as 5%, and death before sexual maturity as 3%. Of survivors, 2% do not marry before the end of childbearing age. Of those who do marry, 10% are childless (From Sladen, B. K. and Bang, F. B. (eds.) (1969). *Biology of Populations: The Biological Basis of Public Health*, p. 188. (New York: American Elsevier).

been successful due to: (1) delay of marriage and reproduction until at least the mid-twenties; (2) full availability of all the most effective contraceptive

methods – IUDs, oral contraceptives, condoms, voluntary sterilization, and abortion; and (3) intense education and peer pressure for planned and reduced reproduction.

CONTRACEPTIVE REVOLUTION

Since the perfect contraceptive has not yet been developed, research continues. Attempts for improving contraceptive methods include new synthetic antifertility drugs for both male and female as well as the ability for women to easily and accurately determine their own fertile period. During the last decade, over 1500 chemical entities have been developed and/or tested. Although new formulas are always being discovered, most are not pursued beyond animal testing. Some of these compounds may have high antifertility activity, but it is difficult to prove their effectiveness and safety. The method of administering contraceptives is also important in improving fertility regulation. By reducing the drug burden on the body, a greater degree of safety can be achieved by substituting naturally occurring steroids for synthetic ones. Consequently, considerable progress has been made in the area of contraceptive delivery systems.

Experimental attempts to develop devices that will occlude the vas deferens or fallopian tubes to permit temporary or easily reversed sterilization have been less successful.

WHO NEEDS CONTRACEPTION?

Contraception is most important for professional women, disturbed women, teenagers, women in developing countries and for women who reach their desired number of children. A career women in her 30s who is professionally successful and financially secure may request contraception to maintain her present independence without having the fear of pregnancy. In developing countries, a woman's career may hold higher priorities for the betterment of the country, rather than choosing a family.

Disturbed women

The disturbed woman whether by the trauma of rape, fear of abortion, or perhaps mentally ill, may not desire the birth of a child and would therefore require some contraceptive method to minimize this emotional stress. Realizing the impossibility of being able to adequately raise a child would also determine one's acceptance to contraceptives.

Teenagers

In today's society, most teenagers find themselves pregnant without being prepared for the psychological, physical, or financial outcome. Many of these teenagers are not informed of available contraceptive choices that exist, and are often unable to obtain them without parental consent. Consequently, pregnant teenagers may either resort to inadequate abortion clinics, excessive drugs or else give birth to the child and place it for adoption, or raise the child under strenuous conditions. Therefore, major

emphasis should be placed on contraception, with accurate informants in the school system to provide the necessary knowledge to teenagers on various methods of choice.

Teenage pregnancy clinics do exist where a pregnant teenager (12-19 years old) can receive individual medical care and take part in group counseling sessions while continuing their education in a supportive atmosphere throughout their pregnancy. Once the baby is born, the mother and baby can return to the clinic for monthly visits with the social worker or psychologist. Support and guidance are offered by the social worker for continuing the mother's education if interrupted by the pregnancy.

Contraceptive counseling is most essential in school systems to advise and inform both teenage males and females of various contraceptive methods available, their effectiveness and side-effects. During the last decade, there has been an extraordinary increase in teenage promiscuity and sexual activity. In the USA, nearly half of all out-of-wedlock births are attributed to teenagers, and up to two-thirds of these are unwanted and unplanned births. Due to the rapidly changing sexual mores, the teenager feels trapped and confused by peer pressure, uncertainty, timidity, ignorance and misinformation. Consequently, the younger patient needs and deserves thorough counseling underlined with compassion, reassurance, and trust in many areas. These areas may range from the basic facts of reproduction and fertility to more serious subjects like venereal disease and consequences of pregnancy. Contraception is definitely a sensitive and controversial issue.

Due to the unavailability of proportionally sized IUDs for nulliparous teenagers, IUD use is restricted to such special cases as: (1) girls of unfavorable socio-economic background and/or uncontrollable ways of life; (2) mentally retarded girls without efficient supervision; (3) emotionally unstable girls with infrequent, irregular intercourse; and (4) where hormonal contraceptives are contraindicated. The small uterus of adolescents does not always support a normal-sized IUD.

MENSTRUATION AND CONTRACEPTION

A regular menstrual cycle reassures women whether they are pregnant or not. Consequently, any acceptable method of contraception must maintain a regular menstrual pattern. If regular menstruation is not important, a whole range of new methods of contraception will reduce the number of periods a woman has each year. This could prove to be an attraction rather than a deterrent to its use.

CONTRACEPTION FOR MIDDLE-AGED WOMEN

Owing to various social trends, fertility changes with age. In Europe, the birth rate of women over 35 years of age is 50%. This figure differs from 30% some 150 years ago. There are couples over the age of 35 who practice fertility control by sexual abstinence, contraception, or abortion.

The decrease in fertility at perimenopause may be due to the effects of age-related increases in the frequency of anovulatory cycles and inadequate luteal phases, and reduced frequency of intercourse. The incidence of

certain genetic disorders and congenital malformations, especially chromosomal imbalance in the fetus, increases with age of the mother. There may also be an increase in the number of gene mutations and some environmental factors, especially the early maternal environment which may become deficient.

Two hundred years ago when there was no contraception, 30% of all births occurred in women over 35 years of age. Even a decade ago, one in 10 births occurred in women of this age group. Today it is less than one in 20. Contraception invariably begins with the control of pregnancy in older age groups. Contraception in middle-aged women is highly recommended because of the high rates of mortality and morbidity associated with pregnancy. This is an important reason for providing adequate advice on contraception where sexual relations do persist in older women. Oral contraceptives are not totally recommended and IUDs are more suitable and becoming more acceptable except when irregular bleeding is feared. Sterilization has become increasingly popular in avoiding the risks of morbidity and mortality associated with pregnancy in older women. Coitus interruptus is widely practiced, but has a high failure rate and some illnesses in women may be traced to its use. Use of the diaphragm accompanied with various contraceptive foams and jels is also widely accepted and effective if properly used. The rhythm method is highly ineffective due to irregular menstrual cycles which prevent exact timing of the safe period.

The age of menopause varies between populations but the average age of menopause ranges from 50 to 52 years. In developing countries, the age of menopause, although quite variable, is less than 44 years due to nutritional factors. The length of the menstrual cycle decreases with age. A transitional phase just before menopause begins, which varies in different women, is characterized by having both unusually long and short menstrual cycles. Contraception should continue through this phase if desired, until the onset of permanent menopausal absence of menstruation.

CONTRACEPTION FOR BREAST-FEEDING MOTHERS

During the puerperium, non-nursing women can feel free to choose hormonal oral contraceptives. This kind of contraception, however, is not advisable for women when breast feeding since it may interfere with milk production. The hormone itself or its metabolites may be ingested by the baby through the milk which could consequently produce growth disturbances. When breast feeding, IUDs can be used with confidence since it does not interfere with milk production or any hormonal changes. In the future, it may be possible to use special biodegradable IUDs which would distribute various nutrients to the suckling baby.

Breast feeding has a temporary contraceptive effect. It is not an efficient method of contraception because the resumption of ovulation and menstruation in lactating women shows a high individual variability. A contraceptive method may therefore be necessary during lactation, and oral contraceptives are widely used for this purpose. The transfer of exogenous contraceptive steroids into human milk during established lactation is being investigated.