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# INDICATIONS FOR REMOVAL OF ETONOGESTREL IMPLANT WITHIN TWO YEARS OF USE IN JOS, NIGERIA

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### **ABSTRACT**

**Background:** Implanon® is a new long-term and reversible sub-dermal contraceptive implant in Nigeria. It is a single rod containing 68mg of etonogestrel meant to offer contraception for three years and marketed by Organon.

Objective: To determine the indications for removal of Implanon® rods from clients within a two-year period.

*Design:* A retrospective review of 30 consecutive Implanon® removals within the study period.

Setting: The fertility regulation unit of the department of obstetrics and gynaecology of the Jos University Teaching Hospital, North-Central Nigeria.

Results: A total of 30 clients requested for and had their Implanon® rods removed out of 669 insertions constituting 95.5% crude continuation rate in the second year. The clients were of mean age  $31.4 \pm 6.2$  years, mean parity  $2.9 \pm 1.8$  and mean number of living children  $2.7 \pm 1.6$ . There was an average weight gain of 1.9 kg. The most common indication for removal was menstrual disruption (33.3%). Desire for another pregnancy closely followed (30.0%). Weight gain was another indication for discontinuation (13.3%). Two women were pregnant at insertion of the implant. There was one failure of the method with pregnancy as a result. Spousal disapproval was an indication for removal in two cases.

Conclusion: Like all progestin-only contraceptive methods, menstrual disruption was the most common indication for removal of implants. Inadvertent insertion of implants with existing pregnancy is of concern and should be avoided as much as is possible. In doubtful cases at insertion, this insertion should be deferred or serum  $\beta$ -HCG should be assessed to exclude chemical pregnancy.

## **INTRODUCTION**

Implants are sub-dermal contraceptive systems developed to increase the contraceptive method mix for women intending to use a modern method. They release low, stable amounts of contraceptive steroids from a suitably inert carrier such as silastic in Jadelle or ethylene vinyl acetate in Implanon (1,2).

In recent years, the most important trend in contraceptive research development has been the development of contraceptive methods designed to meet the needs of prospective users. Contraceptive implants are a proven method of contraception for long term prevention of pregnancy (1). Implanon® is such a product and is the trademark for etonogestrel. It is a progestin-only method of contraception suitable for a wide range of women (2).

The primary mechanism of action of Implanon@ is through ovulation inhibition, and in addition, also

increases the viscosity of the cervical mucus, thus having a dual contraceptive effect. Serum levels sufficient to inhibit ovulation are reached within eight hours (3). This means that it is efficacious within the first day of insertion.

The implant has been found to have un-surpassed efficacy, independence from user compliance and prompt return to fertility after removal. The exceptional efficacy has been attributable mainly to ovulation inhibition of Implanon®. It provides effective, reliable and reversible contraception for a maximum period of three years (4,5). Removal of the implant before three years is considered premature and the indications for such removals require evaluation.

The aim of the study was to determine the indications for these removals, and to be able to better counsel and inform new and/or prospective clients.

### MATERIALS AND METHODS

All the consecutive Implanon® rods removed within a three-year period were collated and analysed. The duration of study was between May 2006 and April 2009. The number of Implanon® rods inserted within the study period was also determined from the register. The age of the clients in years, parity, number of living children, weight at insertion and at removal of implants in kilogrammes, duration of the use of implant in months, indication for removal, marital status, educational status and history of previous contraceptive use before accepting Implanon® were collated and analysed. Epi Info 2002® Statistical software was used to determine averages, means, standard deviations and frequencies of the parameters. The figures were taken to the first decimal point.

## **RESULTS**

Thirty (30) Implanon® rods were removed out of total of 669 insertions within the period of review. This gives a continuation rate of 95.5% in the first two years. The clients were of the reproductive age, between 19 and 45 years with a mean of 31.4  $\pm$  6.2 years. The parity was between one and seven with a mean of 2.9  $\pm$  1.8. They had living children of between one and seven with a mean of 2.7  $\pm$  1.6. The clients weighed between 42 and 91 kg with an average of 64.8  $\pm$  12.7 kg at insertion. Their weights at removal ranged from 41-100 kg with an average of 66.7  $\pm$  13.3 kg. An average weight of 1.9 kg was gained, Table 1.

**Table 1**Parameters of clients with Implanon® removed (n=30)

Parameter	Range	Mean (SD)
Age in years	19-45	$31.4~\pm~6.2$
Parity	1-7	$2.9~\pm~1.8$
Number of living children	1-7	$2.7~\pm~1.6$
Weight at insertion in kg	42-91	$64.5~\pm~12.7$
Weight at removal in kg	41-100	$66.7\ \pm\ 13.2$

Within the period of two years of introduction of the implants, the thirty women that had the implants removed had used Implanon for duration of between 0.5 and 24.0 months with a mean of 13.4  $\pm$  6.8 months.

Twenty two (73.3%) of the clients wanted to have more pregnancies after discontinuing the implant while up to 26.7% did not want any more pregnancies and therefore using the implant as a long-term method of contraception.

Menstrual disorder was the most common indication for removal in 33.3%. This was followed

by the desire for another pregnancy in 30.0%. Four clients (13.3%) had the implants removed for weight gain. Two (6.7%) women were pregnant at insertion of the implant. There was one failure of the method with pregnancy as a result. Spousal disapproval and headache were indications for removal in two (6.7%) cases each. Some of the clients had more than one indication for removal of the implant, Table 2.

Majority of the clients (66.7%) had used a modern method of contraception before accepting the Implanon®. The condom and oral contraceptive pills (20% each) were the common methods of contraception used by the clients prior to accepting Implanon®. Four (13.3%) of them had used another implant (Norplant). Ten (33.3%) had not used any modern method of contraception before this time, Table 3.

**Table 2** Indications for Implanon® removal  $(n = 35^*)$  \* some clients had more than one indication for the removal

Parameter	Number (%)
Menstrual disorders	10 (33.3)
Prolonged (5)	
Heavy flow (3)	
Irregular flow (2)	
Desire for another pregnancy	9 (30.0)
Weight gain	4 (13.3)
Pregnant before insertion	2 (6.7)
Husband wants it removed	2 (6.7)
Headaches	2 (6.7)
Others	5 (16.7)

(Others = Acne - 1, Divorced - 1, Request by mother in law - 1, Request by cardiologist - 1, Had total abdominal hysterectomy - 1 and Failure of the method - 1.)

**Table 3**Previous method of contraception used by the clients (n = 35\*). \*Some clients had used more than one method

Previous method used	Number (%)
No method had been used	10 (33.3)
Condoms	6 (20.0)
Oral Contraceptive Pills (OCP)	6 (20.0)
Intrauterine Contraceptive Device (IUI	0) 5 (16.7)
Norplant implant	4 (13.3)
Lactational amenorrhoea method (LAN	A) 3 (10.0)
Injectable (Nor-ethisterone enanthate)	1 (3.3)

## **DISCUSSION**

Implanon® can be removed on client's request at any time, but after three years it should be removed. During the study period, first two years of introduction of the implants, 4.5% of the implants inserted were removed giving a crude continuation of 95.5%. The two-year continuation rate for Implanon® therefore was high among the clients. This was partly because of adequate pre-insertion counselling of clients on the perceived advantages or benefits which greatly outweigh the nuisance effects. This was higher than the pooled continuation rate of 90.1% after 12 months, 84.9% after 24 months for Norplant (6). During this period, the expiry time of three years had not been reached and therefore none of the indications for removal was for exipiry of the device. The thirty women whom had the implants removed had used Implanon for duration of between 0.5 and 24.0 months with a mean of  $13.4 \pm 6.8$  months.

The most common indication for removal of the implant was menstrual disruption. This constituted about one-third of the indications for removal in the first two years of use. Continuous progestin only contraceptive use alters the vaginal bleeding pattern and manifest as amenorrhoea, irregular bleeding and / or prolonged bleeding. Discontinuation of Implanon® due to bleeding disturbance in this study was 33.3%, and higher than that reported in Europe and Canada, 23.0% (7). This may be because our women are more concerned about vaginal bleeding and would want the implant removed in order not to interfere with their sexual relationships with their spouses.

Another indication for removal was the desire for another pregnancy. This is appropriate since majority of the acceptors (73.3%) were using the method as a temporary method of contraception. This group of women used the implants for an average of about 12 months after which they indicated the desire for another pregnancy and the implant thus removed.

Weight gain constituted another important indication for removal. This was in 13.3% of the clients. There was a mean increase in weight from 64.8 kg at insertion to 66.7 kg at removal of the implants (1.9 kg) in this study. Women are concerned about weight increase and will have it removed if this causes weight gain. Body weight is increasingly becoming an indication for removal of the implant. In another study, the mean body weight gain over a two year period observed a mean body weight of 2.4% and 2.9% for the intrauterine contraceptive device and Norplant respectively, and suggested that the body weight gain observed with Implanon® may not be much different from normal weight gain in women not exposed to exogenous sex steroids (8). That study however observed that the use of Implanon® for several years has a slight tendency to increase in body weight.

Two clients (6.7%) were actually pregnant before the insertion. The clients said they had menstruated just before they came for the implant. However, the pregnancy continued and they had to report back to the clinic. Ultrasound dating of the pregnancies confirmed that the pregnancies pre-dated the Implanon® insertion. The clients were further counselled and they opted to continue with the pregnancies by booking for antenatal care after removal of the implants. This brings about issues regarding screening of prospective clients for the implants and other contraceptive methods. The implants should be inserted within seven days of commencement of a normal menstrual period (1). In doubtful cases, chemical pregnancy should be ruled out by estimation of  $\beta$ -HCG in serum where available. Otherwise, postpone insertion for a menstrual cycle when urinary pregnancy test would have become positive or ultrasound scan with a vaginal probe may demonstrate gestational sac. There was one method failure as an indication for removal. This client was on Rifampicin for treatment of tuberculosis and discontinued the use of the condom contrary to advice from the physician.

Husband's disapproval of the method was the indication for removal in 6.7% of the clients. Headaches in combination with weight gain were the indication for removal in 6.7% of the clients. Other indications for removal, one in each case included acne, divorce, threats by mother-in-law and request by cardiologist and following hysterectomy. Some of the clients had more than one indication for removal of the implant. Social indications for discontinuation appear to be increasing among these clients. Husband, mother-inlaw and divorce contributed over 13% of the indications for discontinuation. This is alarming and requires that the male involvement should be incorporated in counselling issues regarding the implants. The disruption of the menstrual cycle, specifically prolonged menstrual loss may be a factor here since it interferes with coital pattern for the male.

A study has reported arm pain as an indication for removal of Norplant implants (9). This was not reported in this series. The reason for the non-reporting of this may be the small number of clients and the relatively short duration of use in these clients.

In conclusion, subjective side effects that lead to the discontinuation of Implanon® are similar to those of Norplant. Menstrual disruption is still the most common concern of majority of the clients. Inadvertent insertion of the implant when a client is pregnant is an issue worth taking seriously. When in doubt, client should be given another method of contraception and be re-evaluated after another menstrual cycle for pregnancy. The client should however be placed on a barrier method of contraception to avoid an unwanted pregnancy during the period of waiting.

Socialissues are also indicators for discontinuation and require male involvement during counselling if this aspect is to be reduced or eliminated.

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