

# An assessment of the first 3 years' use of Implanon® in Luton

Anjali Agrawal, Christine Robinson

## Abstract

**Objectives** Implanon® was introduced in the UK in September 1999. We present here the results of our first 106 Implanon insertions, performed over a period of 18 months. The aims of the study were to study the clinical and demographic profile of Implanon users, to assess the continuation rates of Implanon in the local population, and to identify the reasons for removal.

**Methods** This was a case note-based study in which the data were transferred to a standardised pre-tested proforma.

**Results** The age range of the 106 Implanon users was 15–43 years. Eighty-six of these clients had their Implanon removed and the Implanon status of 20 clients is not known since they were lost to follow-up by our service. Of these 86 cases, 26 had completed the full 3-year period; therefore, the continuation rate at 3 years was 30.2%. The continuation rate at the end of 1 year was 69.8% and at 2 years was 44.1%. Of the 60 women who had their Implanon removed before the recommended 3-year period, the most common reason was for bleeding irregularity (24 cases, 40%).

**Conclusions** This is the first published study set in the UK within a real-life setting to follow up a cohort of Implanon users for the full 3-year period. No contraceptive failures were found, replicating previous clinical trials. The continuation rate in this real-life situation was quite low compared to clinical trials. This is frequently the case when comparing real-life situations with clinical trials and may be in part due to higher motivation on the part of clinical trial participants.

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## Key message points

- The continuation rate for Implanon® at 3 years was only 30.2%, whereas the continuation rates at 1 and 2 years were 69.8% and 44.1%, respectively.
- Irregular bleeding was the main reason for discontinuation (40%). Mood swings and weight gain accounted for 10% each.

## Introduction

Implanon® has several advantages over other methods of contraception including high efficacy, the need for minimal maintenance, absence of oestrogen, and rapid return of fertility after discontinuation. It was introduced in the UK in September 1999. Because of its relatively recent introduction, there have been no published studies in the UK to date investigating the continuation rates of a sample of users for a full 3-year period until recommended removal. We present here our findings of the first 106 Implanon insertions performed between January 2000 and July 2001, which were followed until 31 July 2004. The objectives of this study were three-fold: (1) to study the clinical and demographic profile of Implanon users, (2) to assess the continuation rates of Implanon in the local population and (3) to identify the reasons for removal.

## Methods

This was a case note-based study, which was conducted at the Family Planning and Reproductive Health Care Centre, Luton Primary Care Trust (PCT), Luton, UK. The project proposal was submitted to the Evidence-Based Practice Group of Luton PCT and was approved. The project proposal was subsequently modified and resubmitted when it was realised that some of the clients did not return for removal of their Implanon after the 3-year expiry date. The option of writing to or phoning these clients or their general practitioner (GP) was considered but it was decided not to do so in view of lack of prior consent from clients and also due to the fear of potential breach of confidentiality.

Between January 2000 and July 2001, 106 clients had an Implanon device fitted by our service. We followed this group of clients until July 2004 so that each of them could complete the full 3-year period.

The demographic and clinical profile of Implanon users (e.g. age, ethnicity, parity, smoking status, medical and contraceptive history, weight at insertion and removal, date of insertion and removal, and reasons for removal) were collected from the case notes. The data were transferred to a standardised pre-tested proforma. The data were analysed using Microsoft Excel and SPSS v.12 (SPSS Inc., Chicago IL, USA).

## Results

Of the 106 clients who commenced Implanon, 86 have had their device removed in this time period. The Implanon status of the remaining 20 is unknown since they were lost to follow-up by our service. Therefore, the demographic profile relates to 106 clients, whereas the continuation rates and reasons for removal relate to 86 clients.

The age range of the 106 Implanon users was 15–43 (mean, 25.2) years and 36.8% were nulliparous. The pre-insertion weight exceeded 70 kg in 41% of cases. Some 67% of clients were white Caucasian women, 17% were Asian and 16% belonged to other ethnic groups. Eighty-six of these clients had their Implanon removed. Twenty (18.9%) clients were lost to follow-up by our service, which means they did not return to our service for Implanon removal after the 3-year expiry period. Of these 86 cases, 26 completed the full 3-year period; therefore, the continuation rate at 3 years was 30.2%. The continuation rates at 1 and 2 years were 69.8% (60 cases) and 44.1%

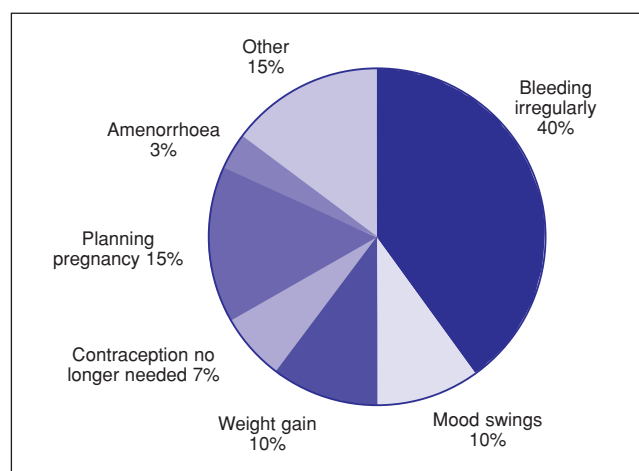
South East Hertfordshire Primary Care Trust, Welwyn Garden City, UK

Anjali Agrawal, MRCOG, MFFP, Associate Specialist in Family Planning

Southwark PCT, London, UK

Christine Robinson, FRCOG, MFFP, Consultant in Family Planning

**Correspondence to:** Dr Anjali Agrawal, Family Planning Service, Parkway Health Clinic, Birdcroft Road, Welwyn Garden City, Herts AL8 6EH, UK. E-mail: anjaliagrawala@hotmail.com



**Figure 1** Reasons given for Implanon® removal before completion of the 3-year period (n = 60)

(38 cases), respectively. Of the 26 women who had their Implanon in place for 3 years, 16 (61.5%) had their Implanon replaced with a new one. Two clients retained their devices for 3 and 8 months, respectively, beyond the device's expiry date as they could not remember the planned removal date, but still there was no failure of the method.

Of the 60 cases with Implanon removal before the recommended 3-year period, the most common reason for removal was for bleeding irregularity, which occurred in 24 (40%) cases. Other reasons for removal were to plan pregnancy (nine cases, 15%), mood swings and weight gain (six cases, 10% each), contraception no longer required (four cases, 6.7%), amenorrhoea (two cases, 3.3%) and other reasons (nine cases, 15%). No failure of the method was found with Implanon use even though 40 (37.7%) women were in the 70–100 kg weight range and four (3.8%) exceeded 100 kg.

## Discussion

### Demographic profile

The age range of the 106 Implanon users was 15–43 (mean, 25.2) years and 36.8% were nulliparous. These observations are similar to the observations made by Rai *et al.*<sup>1</sup> who found a mean age of 25 years with 36% being nulliparous women. The mean weight gain was 3.15 (range, –14 to +23, SD 6.48) kg. This is comparable to observations made by Davies *et al.*<sup>2</sup> who reported a 3.7 kg weight gain (maximum 22 kg, minimum 1.5 kg) by the end of the first treatment year.

The ethnic origin of those using Implanon was similar to the ethnic mix of the overall family planning clinic attendees at Luton.

### Continuation rate

Our continuation rates at 1, 2 and 3 years were 69.8%, 44.1% and 30.2%, respectively. Edwards and Moore<sup>3</sup> reported an overall continuation rate of 82% for Implanon use for 24 months. However, it should be borne in mind that this continuation rate was for a clinical trial population and not for a clinic population as in the present study.

To date, the other published studies based on real-life situations have provided only estimates of continuation rates for Implanon use.<sup>1,4</sup>

### Efficacy

All clients weighing above 100 kg were advised to have their Implanon removed at 2.5 years.<sup>5</sup> Four clients' weight exceeded 100 kg. Two cases had early removal,

but the other two had removal after 2.5 and 3 years and also had immediate reinsertion of another Implanon device. There are some concerns about contraceptive efficacy for women weighing over 100 kg; although we had only two cases in our study, no failure of the method occurred.

Data from studies undertaken during the development of Implanon<sup>6</sup> included a core dataset of 13 studies that met the requirements for good clinical practice. These studies, involving 1716 women in at least 10 different countries, contributed 4103 woman-years of use of Implanon in which no pregnancies occurred. The reported failure rate of Implanon was therefore zero. There are insufficient data on the influence of age and weight on the effectiveness of this contraceptive device.<sup>7</sup>

### Reasons for removal

Of the 60 cases with Implanon removal before the recommended 3-year period, the most common reason for removal was bleeding irregularity (40.0%). Other reasons for removal were planned pregnancy (15%), mood swings and weight gain (10% each), contraception no longer required (6.7%), amenorrhoea (3.3%) and other reasons (15%).

The above findings are comparable to observations made by Smith and Reuter<sup>4</sup> who reported reasons for removal as bleeding problems (34%), mood swings (24%), weight gain (12%), planned pregnancy (10%) and other reasons (27%); however, their study did not follow a cohort for a full 3-year period.

In Europe, the discontinuation rates due to vaginal bleeding pattern disturbances in comparative trials were 30.2% for Implanon and 22.5% for Norplant<sup>®</sup>.<sup>8</sup>

All studies to date show that irregular bleeding is the most common reason for discontinuation. This is understandable since unpredictable and prolonged vaginal bleeding can be a considerable nuisance and can adversely affect women's daily lives.

### Insertion or removal complications

Edwards and Moore,<sup>3</sup> in a review of clinical studies of Implanon, noted complications of Implanon insertion in 0.6% (10/1716) in all studies; these complications involved mainly bleeding at the insertion site or failure of the implant device. They also reported complications of Implanon removal in 1.3% (12/1616) of women in all studies. The 21 complications involved six deep insertions, six with fibrous adhesions, four where there was difficulty finding the implant, three broken implants and two other problems.<sup>3</sup>

In the present study we did not notice any insertion or removal complications except in one case where the Implanon snapped spontaneously *in situ* 3 months before its expiry period. The client knew the Implanon had broken but was unperturbed by this fact. She attended 2 months later for removal as well as reinsertion of a new device. The removal procedure was uncomplicated except that the Implanon had to be removed in two pieces. To the best of our knowledge, this is the first case of an Implanon device snapping into two halves spontaneously *in situ*.<sup>9</sup> The only other case reported in the literature is one in which an Implanon device had fractured halfway across its width during a game of 'rough and tumble'.<sup>10</sup>

### Limitations of the present study

As mentioned earlier, 20 clients were lost to follow-up. We speculate that this may be attributed to the movement of the population to and from the Luton area. Because of the lack of prior consent from clients, and also due to the fear of

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potential breach of confidentiality, we did not think it appropriate to send a reminder by post.

### Summary and conclusions

The results of the study can be summarised as follows:

1. In this group of clients using Implanon no pregnancies occurred.
2. In our experience, the continuation rate at 3 years was only 30.2%. However, the continuation rates at 1 and 2 years were 69.8% (60 cases) and 44.1% (38 cases), respectively.
3. Irregular bleeding was the main reason for discontinuation (40%). Mood swings and weight gain accounted for 10% each.
4. Of the 26 women who had their Implanon in place for 3 years, 16 (61.5%) women had their Implanon replaced with a new one.
5. Twenty (18.9%) clients failed to return to our service for removal of their implant after the 3-year period and the reasons for this are unknown. Two clients returned after the 3-year period for device removal. We may need to implement a recall system to ensure that all women return for implant removal at the appropriate time.
6. Incidentally, 44 women were overweight; 40 (37.7%) women were in the weight range 70–100 kg and four (3.8%) exceeded 100 kg. Although Implanon has proven to be an effective contraceptive for women in this weight range, the efficacy of Implanon in this subgroup of women needs further exploration.

### Recommendations for practice

Based on the present study, we can make the following recommendations:

1. On giving the Implanon card (showing the due date for removal) to the client it is important to stress that it is her responsibility to return, since we do not have a reminder system in place. This fact can also be documented in the client's notes.

2. With the client's consent, her GP can be informed about the Implanon fitting.
3. The Implanon counselling sticker, which documents the various points discussed with the client during her consultation including the date by which the device should be removed, can also be attached to the client's notes.

### Acknowledgement

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### Statements on funding and competing interests

*Funding.* None identified

*Competing interests.* None identified

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## Book Reviews

**Chromosome Abnormalities and Genetic Counseling.** RJ McKinlay Gardner and GR Sutherland. New York, NY: Oxford University Press, 2004. ISBN: 0 19 514960 2. Price: £49.50. Pages: 555 (hardback)

This is a weighty specialist text, now in its third edition. Since the first edition in 1989, the text has expanded vastly to take in repercussions of assisted reproduction and of the Human Genome Project. Nevertheless, this book retains a very human face, the writers consciously remembering the clients who continue to ask essentially the same questions about the impact of chromosomal abnormality on their families.

Although written for genetic counsellors and cytogenetic laboratory scientists, this text has much to enlighten the practitioner in day-to-day reproductive health. The fascinating section on reproductive failure explains how frequently chromosomal anomalies are responsible for recurrent miscarriage and infertility. It also shows how the fragility of chromosomes in meiosis contributes to these problems. An excellent section on prenatal diagnosis looks at the details of screening for chromosomal defects by amniocentesis, chorionic villus sampling and preimplantation genetic diagnosis. These complex topics are explained clearly, and the human dilemmas of screening are never forgotten.

In this book, reproductive health care professionals can gain by revising the fundamentals

of human life and reproduction. They can also glimpse the difficult journeys that some of their clients make in wrestling with the hard choices chromosomal abnormalities can bring.

Reviewed by **Kate Weaver**, MB ChB, MFFP  
Staff Grade Doctor in Reproductive Health Care,  
Edinburgh, UK

**Pediatric and Adolescent Gynecology: Evidence-based Practice.** C Sultan (ed.). Basel, Switzerland: Karger, 2004. ISBN: 3 8055 7623 4. Price: £121.10. Pages: 269 (hardback)

*Pediatric and Adolescent Gynecology* has been written by an international group of experts in the field of adolescent gynaecology. It is part of a series of four books on endocrine development and has a strong focus on reproductive endocrinology. An initial overview gives an introduction to all aspects of a clinical examination of a child or adolescent and emphasises the importance of a multidisciplinary approach. Specific imaging techniques (mainly ultrasound) and findings are discussed in the following chapter. A well-illustrated dermatological overview demonstrates the common perineal involvement of many dermatoses.

This introduction is followed by detailed chapters of various pathologies encountered in prepubertal and adolescent girls. It does include an excellent overview of the management of ambiguous genitalia in the newborn, precocious puberty and hyperandrogenism in adolescent girls. The detailed discussion of signs and symptoms of sexual abuse in prepubertal children

and adolescents highlights the difficulties and pitfalls, as well as differential diagnoses. The following chapters include a summary of commonly encountered clinical problems, including menstrual irregularities, dysmenorrhea and the management of the ovarian mass.

The final chapters provide an overview of adolescent sexual health. A review from Finland highlights important aspects of sex and relationship education. Unfortunately, the chapter on contraception does not make any reference to the World Health Organization *Medical Eligibility Criteria for Contraceptive Use* (WHOMEC) and shows some discrepancies to guidelines developed by the Clinical Effectiveness Unit of the Faculty of Family Planning and Reproductive Health Care. The dosages and regimes of antibiotics mentioned in the chapter on sexual transmitted disease differ slightly from the recommendations made by the Royal College of Obstetricians and Gynaecologists. The guidance on cervical screening and the management of PAP smear abnormalities in adolescents differs from that of the British Society of Colposcopy and Cervical Pathology.

This is a readable and interesting book, addressing the most common paediatric and adolescent gynaecological problems. It offers a good introduction to the speciality, although as most authors are not UK-based, some of the diagnostics and management differ from current UK practice.

Reviewed by **Anja Guttinger**, MRCOG  
Subspecialist Registrar in Reproductive Health  
Care, Edinburgh, UK