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Contraception 76 (2007) 35–39

Contraception

Original research article

Removal of etonogestrel contraceptive implants in the operating theater: report on 28 cases

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Received 21 December 2006; revised 21 February 2007; accepted 27 March 2007

Abstract

Objectives: We describe removal procedures for etonogestrel contraceptive implants in the operating theater. In addition, we discuss the management of removal of contraceptive implants that are difficult to palpate or are impalpable.
Design: We conducted a retrospective single-center case series analysis of Implanon™ removals conducted at a university hospital between January 2002 and April 2005.
Materials and Methods: We analyzed case notes for 28 patients who had their contraceptive implant removed in the operating theater.
Results: Intermenstrual bleeding was the principal reason for removal (52.4%). Ten patients already had one attempted removal of their implant. Preoperative ultrasound localized the implant in all cases. Half of the removals were done under local anesthetic, with three cases progressing to general anesthesia (11%). Thirty percent of the implants had migrated from their initial implantation, 37% were in intramuscular tissue and 11% were in the humeral neurovascular sheath. The only postoperative complications were one small seroma and transient paresthesia in the territory of the ulnar nerve. The implant was not found in one case.
Conclusions: The removal of an implant that is not palpable or difficult to palpate should take place in the operating theater following localization by ultrasound. Patients must be fully informed about the procedure, including its complications and the risk for failure.

Keywords: Contraceptive implant; Etonogestrel; Difficult removal; Ultrasound guidance

1. Introduction

The contraceptive implant Implanon™ (Organon, Puteaux, France) has been available in France since May 2001. The implant is a small cylinder that is 40 mm long and has a diameter of 2 mm. It contains 68 mg of etonogestrel, the active metabolite of desogestrel. It is inserted subdermally in the upper medial aspect of the nondominant arm. This mode of contraception lasts for 3 years and does not require any further patient compliance. Many studies have demonstrated its efficacy, and some have reported a Pearl index of zero [1–9]. In September 2005, the Organon Laboratory reported sales of 400,000 implants in France and of 1.5 million implants in Europe. Soon after Implanon™ was launched in the market, physicians were confronted with occasional difficulties with removing the implant. The Organon Laboratory nominated a referral team in each French town to deal with difficult retrievals. We form one of those teams. The aim of this report was to describe difficult removals in order to define the management of implants when they are difficult to palpate or are completely impalpable.

2. Materials and methods

We conducted a retrospective study at the gynecology department of a university hospital (i.e., SIHCUS-CMCO). We analyzed case notes for patients who had to have their Implanon™ removed in the operating theater between January 2002 and April 2005.

The data collected include each patient's age, the level of experience of the physician who inserted the Implanon™, the site of implantation, the time between implantation and

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doi:10.1016/j.contraception.2007.03.012

Table 1
Reasons given by the patients for having their etonogestrel implant removed

Reason	*n* (%)
Metrorrhagia	11 (52)
Beyond expiry time	8 (38)
Headache	5 (24)
Weight gain	3 (14)
Spotting	2 (9.5)
Oligomenorrhea	1 (5)
Irritability	1 (5)

The total exceeds 100% because several reasons could have been cited by the same patient.

retrieval, the patient's reason for removal, the level of experience of the physician who attempted the removal, the difficulties encountered at palpation, the information collected during surgery (e.g., type of anesthesia, location of the implant, difficulties during the operation and operative time), postoperative complications and type of contraception used after retrieval of the implant.

3. Results

Twenty-eight cases of Implanon™ retrieval in the operating theater were identified during the study period.

The mean age of the patients was 31±7.5 years (range, 20–44 years). Their mean body mass index was 23.1±4.9 kg/m^2 (range, 17–33 kg/m^2).

The implant was inserted by a French gynecologist in 8 cases, by a general practitioner (GP) in 4 cases, by a non-French gynecologist in 3 cases, by a GP trainee in 1 case and by a trainee in obstetrics and gynecology in another case. This information was missing for 11 cases. Seven implants were inserted in a hospital setting, and 11 were inserted in a private practice office. This information was missing for 10 cases.

The average time between insertion and removal of Implanon™ was 22.8±12 months (range, 5–40 months).

The reasons given by the patients for having their implant removed are listed in Table 1. The most frequently cited reasons for Implanon™ removal because of side effects were metrorrhagia in 52.4%, headache in 23.8% and weight gain in 14.3%. In a third of cases, removal was performed because the Implanon™ had reached the end of its period of efficacy (8/21 cases).

Ten patients already had at least one attempted retrieval. Eight of them underwent an unsuccessful removal in a clinic, one had an attempt in the operating theater and another patient had two attempts in the operating theater (Fig. 1A and B).

A radiologist performed preoperative ultrasound with a 7.5-Mhz high-frequency probe. In two cases, identification was difficult, with doubt about the presence of the implant in one case. In that case, the blood level of etonogestrel was detected and the patient underwent a magnetic resonance imaging (MRI) scan. A second ultrasound examination allowed us to locate the implant.

We were able to determine from the patient records that 15 implants were not palpable and that 11 were palpable albeit with difficulty in the preoperative examination.

Seventeen patients (61%) had local anesthesia initially; however, for three of them, it was necessary to proceed to the use of general anesthesia. Eleven patients had general anesthesia initially (39%). The average length of the procedure was 21.5±19 min (range, 5–70 min) for the 11 cases for which the information was available (mostly for patients who had general anesthesia).

During the surgical procedure, we found that 19 implants had not migrated from their initial implantation. Eight implants did migrate outside the original site (30%), including 1 that moved to the root of the axillary area. One set of notes did not contain this information. Fourteen implants were in a subdermal position, and more than a third (11/28) were in an intramuscular position, most often under the muscular aponeurosis. Three implants were located in a

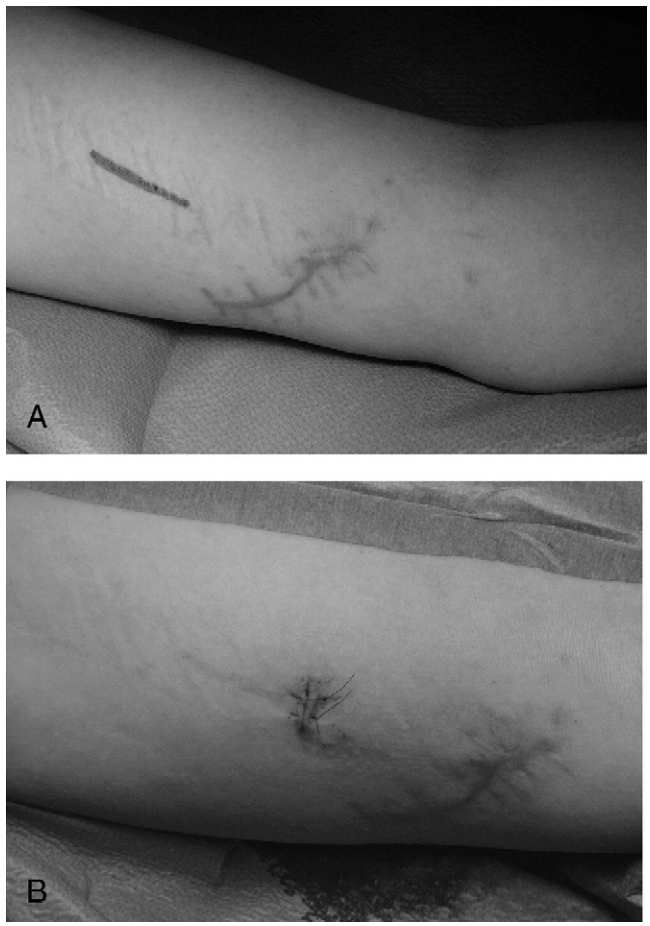

Fig. 1. (A) Unsightly scars after two failed attempts at removing Implanon™. The scars are distant from the Implanon™, whose position is marked by a dark line on the skin and which was identified by ultrasound. (B) Immediate postoperative appearance in the same patient. The implant was removed by a small transverse incision.

perivascular position, near or touching the brachial artery (11%). Of the 27 cases for which the implant was retrieved in the operating theater, only 5 were documented as being difficult to retrieve. In one case, in which the Implanon™ was in a deep intramuscular position, the implant was not found and left in place.

The postoperative complications were a 2-cc seroma, which necessitated drainage, and paresthesia in the ulnar nerve area, which spontaneously resolved within 72 h.

The types of contraception chosen after removal of the implant were the combined oral contraceptive pill in seven cases, a progestogen-releasing intrauterine system in two cases, a copper-bearing intrauterine contraceptive device in one case, the progestogen-only contraceptive pill in one case and high-dose progestogen administered intramuscularly in another case. Four patients asked for a new Implanon™ to be inserted.

4. Discussion

With a Pearl index of 0.006 (range, 0.004–0.08), Implanon™ is a safe and reliable method of contraception [9]. Nevertheless, there can be problems with retrieving the implant. Removal may be necessary because the implant is no longer effective after 3 years (2.5 years in the case of obese women) or because of side effects.

Having irregular menstrual cycles is the most common reason triggering patients to request for early removal of their Implanon™ [3,10,11]. Affandi [10], in a Europe-based meta-analysis, reported a rate of 23% for removing the Implanon™ within 2 years of its insertion for irregular cycles. Intermenstrual bleeding was the principal cause of implant removal (50% of cases). In France, Sergent et al. [3] reported abnormal cycles in 83% of 182 patients with an Implanon™. In this study, intermenstrual bleeding was the main cause of premature removal of the implant (41% of 29 premature removals). Irregular cycles seem to be less frequent in Chile and Southwest Asia [6,10]. Our removal rate due to intermenstrual bleeding is approximately 50%, which is in keeping with rates reported in most of the occidental literature. Other patients required removal of the implant because of other well-known side effects: headache, weight gain and irritability. Weight gain and irritability are due to the androgenic activity of the etonogestrel and, along with acne, are the most often reported side effects after irregular cycles [7,12,13].

If a patient wishes so or after 3 years of use, Implanon™ must be removed from the arm because it is not biodegradable. It is correct insertion in a good subdermal position that will determine the implant's ease of removal. Usually, removal is performed in a clinic by palpating the implant and making a 2-mm incision at its caudal end and then pushing the implant toward the incision. One end will come out and is grasped with forceps/clips — this is known as the pop-out technique [14]. It is recommended to inject the local anesthetic under the implant to avoid its disappearance under the edema after the infiltration.

Times for removing an Implanon™ are short according to the literature — between 2.1 and 5 min [6,7]. A meta-analysis compared the length of time of removing Implanon™ (633 patients) with that of removing Norplant™ (137 patients), which is a similar but older levonorgestrel-based device and that which includes six elements to insert. The mean time for the removal of Implanon™ was 2.6 min, versus that of 10.2 min for the removal of Norplant™ [15].

Data regarding difficult retrievals of Implanon™ are rare. For Sergent et al. [3], 10 of 29 removals under local anesthesia were deemed to be difficult by the patients. Two were ultimately performed under general anesthesia. Affandi et al. [6] reported on one difficult case from among 200, whereas Croxatto et al. [7] did on 19 of 205 cases (3%). One case of difficult localization of Implanon™, necessitating ultrasound, computed tomographic scan and MRI, triggered a national pharmacovigilance survey in France [16]. In 16 months, 11 cases of difficulty with or failure of Implanon™ removal were reported, giving an incidence of 1/100,000 implants (range, 0.05–0.181). Only 9 of the implants were finally removed, 2 of them under general anesthesia. To our knowledge, our series is the largest published to date concerning removal of Implanon™ in the operating theater. However, it has the obvious limitations of retrospective descriptive studies.

An impalpable implant must trigger three questions: Has it really been inserted? Is it in a subdermal or a subcutaneous or intramuscular position? Has it migrated? The noninserted implant is responsible for 77% of pregnancies occurring with Implanon™ [16]. In our experience, two patients were referred for an impalpable implant and were in the first trimester of their pregnancy. In these two cases, medical

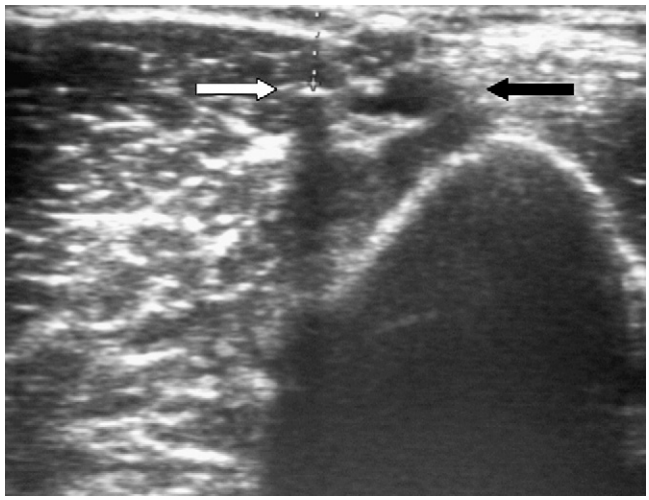

Fig. 2. The implant is best visualized by ultrasound on a transverse plane as an echogenic spot (white arrow) with a hypoechogenic shadow. The implant is in a deep intramuscular position. Note the close position of the brachial pedicle (black arrow).

imaging did not help with visualization of the implant. If in doubt, the etonogestrel blood level can be determined to confirm the presence of an implant. When present but not palpable, the device can be difficult to locate with medical imaging as it is radiotransparent [9]. This type of problem was already encountered with Norplant™ [9,17]. Ultrasound using a 7.5-Mhz linear probe allows for identification of the Implanon™, thanks to the presence of posterior acoustic shadowing [18] (Fig. 2). It has been suggested that the procedure be conducted in the ultrasound room, having marked the site on the skin, to facilitate the retrieval of the implant. This would avoid the difficulties caused by changing the position of a patient when she moves rooms [19]. For some authors, MRI is the best diagnostic tool for locating an implant not seen with ultrasound [20,21]. It should be noted that the implant is only visible with low-signal MRI.

Impalpable implants may trigger medicolegal actions. Difficult retrievals of Norplant™ were responsible for a drop in its use in the United States, following patient complaints [22,23]. In 2003, in France, two gynecologists and a GP had to utilize their professional insurance because they were being sued for badly positioning implants [24]. In 2004, three gynecologists and two GPs had similar experiences [25]. No complaint was made by any patient in our series. It is paramount to inform every patient when retrieval takes

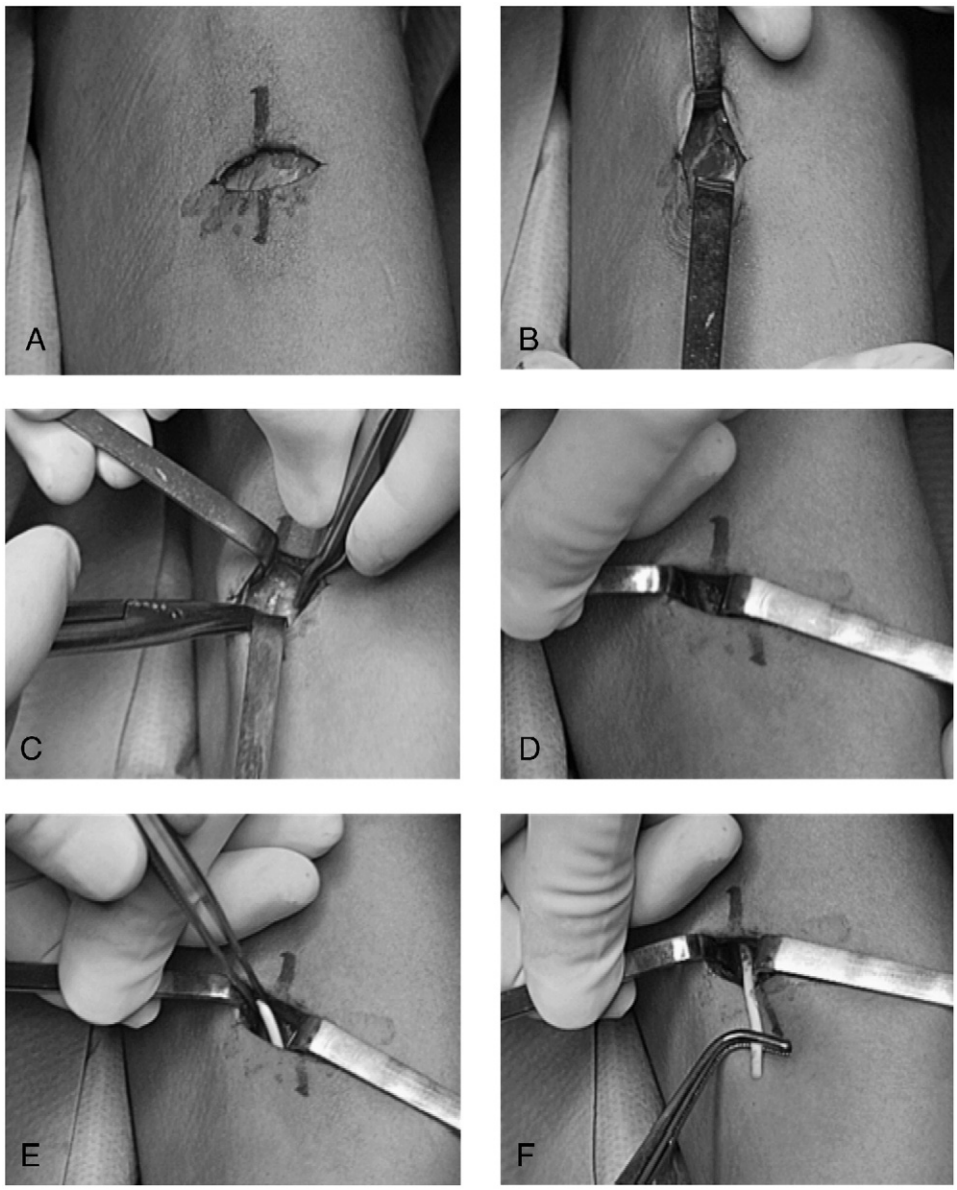

Fig. 3. Removal of an intramuscularly positioned implant near the brachial pedicle. (A) The implant was identified by ultrasound, and the skin was marked. After transverse skin incision across the implant, the aponeurosis was exposed. (B) Muscular exposure after aponeurosis incision. (C) Identification of the brachial pedicle. (D) The implant was more lateral, in an intramuscular position. (E and F) Removal of the implant.

place in a theater about potential difficulties and the risks for failure and scarring.

Once identified, an incision of 12–15 mm transverse to the implant is made (Fig. 3). This is performed near the most superficial end, which needs to be identified by the radiologist. The incision may need to be longer when the implant is deeper or near the humeral pedicle. The material required is not specific, but small retractors, such as Farabeuf retractors, may prove to be very useful. It is necessary to cut the subcutaneous tissue, and the incision of the muscular aponeurosis may often be necessary. The implant is often located just underneath it. In cases of deeper location, dissection needs to be progressive and gentle through the muscular fibers. The use of a right-angle retractor may be helpful, as is palpation with the pulp of the little finger in the incision. Insertion within the muscle is unusual. The dissection needs to be conducted carefully because of the presence of arteries and nerves, which appear white, like the implant.

It is worth noting that in the United Kingdom, the doctors allowed to insert and remove the implant must be specifically certified — and their certificate needs to be renewed every 5 years [26].

5. Conclusions

Removal of an impalpable or barely palpable implant must be performed in the operating theater after localizing the implant using ultrasound. Patients must be fully informed about the procedure, including its complications and the risk for failure.

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