

Original Study

Bits and Pieces: A Crowd-Sourced Series of 54 Cases of Fractured Hormonal Implants

Bonnie C. Crouthamel MD^{1,*}, Melissa A. Schiff MD, MPH², Anne-Marie E. Amies Oelschlager MD¹, Sarah W. Prager MD, MAS¹, Katherine E. Debiec MD¹

¹ Department of Obstetrics and Gynecology, School of Medicine, University of Washington, Seattle, Washington

² Department of Epidemiology, School of Public Health, University of Washington, Seattle, Washington

ABSTRACT

Study Objective: The fracture of hormonal implants, including Implanon, Nexplanon (both from Merck & Co, Inc), and histrelin acetate is rare. Our aim was to describe patient demographic characteristics, mechanisms, and consequences of fractured implants by surveying physicians' experience via listservs and social media.

Design, Setting, Participants, Interventions, and Main Outcome Measures: We developed a Research Electronic Data Capture survey for physicians regarding their experience with implant fracture, including patient characteristics, mechanism of fracture, changes in menstrual bleeding patterns, time from insertion to fracture, and time from fracture to seeking care. We distributed the survey to providers in listservs for the North American Society for Pediatric and Adolescent Gynecology, the Family Planning Fellowship, the Ryan Program, and the Facebook Physician Moms Group and Facebook OB-GYN Mom Group. We performed descriptive analyses.

Results: We received 42 survey responses, representing 54 discrete implant fractures of which 70% (n=14) were Nexplanon, 26% (n=38) were Implanon, and 4% (n=2) were histrelin acetate. Mechanisms of implant fracture included patient manipulation (23%, n=12), unintentional trauma (11%, n=6), interpersonal violence (8%, n=4), lifting/carrying (6%, n=3), fracture with removal (6%, n=3), and unknown (47%, n=25). Bleeding pattern was not altered in 78% (n=42) of cases. Time interval between placement and fracture was less than 2 years for 63% (n=34) of cases. Thirty-nine percent (n=21) of patients presented for care more than 1 month from the time of fracture.

Conclusion: Patients should be counseled about potential for hormonal implant fracture, advised against excessive manipulation of implants, and counseled to present for care immediately upon noticing an implant fracture. Surveying physicians through listservs and social media is an effective strategy to increase the reporting of rare complications and events.

Key Words: Contraception, Implant, Nexplanon, Implanon crowdsourcing, Fractured implants

Introduction

Hormonal implants, including Implanon and Nexplanon (both from Merck & Co, Inc), are safe and effective birth control methods, with a pregnancy rate of approximately 0.05%.¹ Implants are gaining in popularity, with an estimated 492,000 women in the United States using them for contraception in 2012.² Although the initial cost of an implant might be hundreds of dollars, their high efficacy prevents thousands of unwanted pregnancies, thus decreasing the medical costs of pregnancy, delivery, child-care, and abortion. In 2010, the Guttmacher Institute estimated that for every \$1 invested in helping women prevent unwanted pregnancy, \$7.09 were saved in Medicaid expenditures.² In addition to hormonal implants for birth control, histrelin acetate, a long-acting Gonadotropin Releasing Hormone (GnRH) agonist subcutaneous implant, distributed in the United States under the brand names Supprelin LA and Vantas (both from Endo Pharmaceuticals Inc), is effective for treatment of central precocious puberty in young girls and has begun to be used for halting pubertal

progression for transgender children.³ Despite the many benefits of hormonal implants, adverse events have occurred sporadically.

The fracture of a hormonal implant in situ is rare and little is known about the clinical consequences.⁴⁻⁶ Several case reports have described in situ fracture of implants, with each report describing only 1 or 2 cases.⁴⁻⁶ Some have occurred without local trauma to the area or a known inciting event, whereas others were due to accidental or intentional trauma. All of them were located in the inner aspect of the upper arm when removed. Some patients were asymptomatic after the implant fracture and did not present to have it removed, whereas others experienced clinical bleeding changes that prompted a physician visit. It is unknown if the rate of hormone release changes with a fractured contraceptive implant and if this affects efficacy or menstrual bleeding patterns. The only case report of a fractured GnRH implant was noted at the time of scheduled removal.⁴⁻⁹ Because implant fracture is rare, there is scant reported information about the circumstances that have led to any implant fracture. Furthermore, with regard to contraceptive implants, there is no official recommendation by the manufacturers on when to remove a fractured implant.¹⁰

The use of social media in medical research has diverse applications. Social media in medicine has been used for dissemination and acquisition of information, for

The authors indicate no conflicts of interest.

* Address correspondence to: Bonnie C. Crouthamel, MD, Department of Ob/Gyn, University of Washington, Box 356460, Seattle, WA 98195; Phone (206) 543-9626. E-mail address: bcroutha@uw.edu (B.C. Crouthamel).

marketing, and for medical research to recruit study participants.^{11–16} Crowd-sourcing is the concept of pooling resources for the purposes of aggregate research.¹⁷ The purpose of this study was: (1) to identify physicians with experience with implant fracture by crowd-sourcing through social media platforms and listservs; and (2) to survey the experienced physicians to understand the characteristics, circumstances, and consequences of fractured implants.

Materials and Methods

We performed a crowd-sourced case series by collecting physician reports of fractured implants. We distributed an online survey to providers who are subscribers to the following listservs (with member count at the time of distribution): (1) North American Society for Pediatric and Adolescent Gynecology (213 members); (2) the Family Planning Fellowship Listserv (377 members); and (3) the Ryan Program Listserv (285 members). We distributed our survey to the Facebook groups for the Physician Moms Group (62,000 members) and OB-GYN Mom Group (2100 members) after approval from listserv and social media site administrators. The institutional review board of the University of Washington determined that the study was exempt from human subjects approval.

Study data were collected and managed using Research Electronic Data Capture (REDCap) tools hosted at the Institute of Translational Health Sciences.¹⁸ REDCap is a secure, Web-based application designed to support data capture for research studies, providing: (1) an intuitive interface for validated data entry; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages; and (4) procedures for importing data from external sources.

The anonymous survey consisted of 11 questions regarding the characteristics of the patients who experienced an implant fracture, including age, weight, and body mass index (BMI). Other questions included type of fractured device, timing of fracture including time from insertion to fracture and time from fracture to seeking care, mechanism of the fracture, method for diagnosing the fracture, changes in menstrual bleeding pattern after the fracture, and the state of implant upon removal. Respondents were able to complete the survey for more than 1 patient. All questions were multiple choice except for age, weight, BMI, and mechanism of fracture, which were open-ended. Age was categorized into 2 groups: 21 and younger and older than 21 years. Weight was categorized into 100 pounds or less, 101-150 pounds, 151-200 pounds, 201-250 pounds, and more than 250 pounds. BMI was categorized into underweight (≤ 18), normal (19-25), overweight (26-30), obese (31-35), and morbidly obese (> 35). We evaluated the open-ended responses for the mechanisms of fracture and categorized them as: unintentional trauma, intimate partner violence (IPV), patient manipulation, lifting/carrying, fracture at time of removal, and unknown. We performed descriptive analysis with counts and percentages using STATA version 14.0 (StataCorp).

Results

We received 42 survey responses, representing 54 discrete implant fractures. Most patients with reported data were 21 years of age or younger (54%, $n=13$; Table 1). Twenty-one percent ($n=4$) of participants had a normal BMI, 16% ($n=3$) were overweight, 11% ($n=2$) were obese, and 53% ($n=10$) were morbidly obese.

Seventy percent ($n=38$) of the fractured implant cases involved Nexplanon, 26% ($n=14$) involved Implanon, and 4%

Table 1
Demographic and Implant Characteristics of Patients Who Experienced a Fractured Hormonal Implant (N = 54)

Characteristic	n (%)
Age, years	
21 or younger	13 (54)
Older than 21	11 (46)
Weight in pounds	
Less than 100	0 (0)
101-150	4 (29)
151-200	5 (36)
201-250	3 (21)
More than 250	2 (14)
Body mass index	
Underweight	0 (0)
Normal	4 (21)
Overweight	3 (16)
Obese	2 (11)
Morbidly obese	10 (53)
Type of device	
Implanon	14 (26)
Nexplanon	38 (70)
Histrelin acetate	2 (4)
Interval since placement	
Less than 1 year	22 (41)
1-2 years	12 (22)
More than 2 years to 3 years	13 (24)
More than 3 years	1 (2)
Unknown	6 (11)
Interval from fracture to seeking care	
Less than 1 week	5 (9)
1 week to 1 month	16 (30)
More than 1 month to 3 months	8 (15)
More than 3 months	13 (24)
Unknown	12 (22)
Method of diagnosis	
Palpation	46 (85)
X-ray	1 (2)
Seen on removal	6 (11)
Ultrasound	1 (2)
State of device on removal	
Bent, not fractured	7 (13)
1 piece, fractured	23 (42)
2 separate pieces	16 (30)
More than 2 separate pieces	8 (15)
Mechanism of fracture	
Patient manipulation	12 (23)
Accidental trauma	6 (11)
Intimate partner violence	4 (7)
Lifting/carrying	3 (6)
Fracture at removal	3 (6)
Unknown	25 (47)
Fracture caused by intimate partner violence	
Yes	5 (9)
No	44 (82)
Unknown	5 (9)
Bleeding pattern altered	
Yes	4 (7)
No	42 (78)
Not applicable	2 (4)
Unknown	6 (11)

Some counts do not add to the total due to missing data. Nexplanon and Implanon from Merck & Co, Inc.

Download English Version:

<https://daneshyari.com/en/article/8782044>

Download Persian Version:

<https://daneshyari.com/article/8782044>

[Daneshyari.com](https://daneshyari.com)