MedCrave
Step into the World of Research

Obstetrics & Gynecology International Journal

Short Communication

Open Access

Preliminary evidence for the safety and efficacy of a novel method for removal of contraceptive implants: a pilot RCT

Abstract

Contraceptive implants are the most effective form of long-acting reversible contraception (LARC). Implant insertion is standardized; however, the recommended removal method, the pop-out method, may be problematic if the implant does not easily pop-out. We evaluated an alternative removal method with a modified incision location, the To method, in a single-blind pilot randomized control trial of 21 patients. Pain differences, success rates, and procedure time between methods were examined. Results demonstrated that the To method was faster and less painful than the pop out method. This study provides preliminary evidence to support using the To method for contraceptive implant removal.

Keywords: contraception, long-acting reversible contraception, contraceptive implant, to method, nexplanon

Volume 15 Issue 3 - 2024

Juliet Prieto MD, Luna Zhang MD, Valerie O'Besso MD, Luke Keating MA, Aldona Chorzepa MS, Ivan Ngai MD, Mengyang Sun MD, Ervin Rene Riano Marin MD, Justin To MD

OBGYN Department, Flushing Hospital Medical Center, USA

Correspondence: Juliet Prieto, MD, OBGYN Department, Flushing Hospital Medical Center, 4500 Parsons Blvd, Queens, NY 11355, USA, Tel 718-670-5000, Email juliet.m.priet@gmail.com

Received: May 18, 2024 | **Published:** May 31, 2024

Introduction

Unplanned or unwanted pregnancies are a public health problem.[1] In the US, estimates from 2008 to 2011 showed that 45% of pregnancies were unplanned and estimates from 2017 to 2019 showed 38% of births were unplanned.[2] Estimated costs of unplanned pregnancies range from $4.7 billion to $12.6 billion.[3] Unplanned pregnancies are associated with adverse maternal and fetal outcomes including preterm birth, low birth weight, maternal depression, and maternal experience of interpersonal violence.[2] Long-acting reversible contraception (LARC), including intrauterine devices and contraceptive implants, is the most effective form of contraception and can prevent unplanned pregnancy and associated complications.

Contraceptive implants are the most effective LARC, with a 0.05% failure rate, and are used by 4% of sexually active women aged 18 to 44.[4] Implant insertion is conducted using a standard procedure and the implant is palpable in 99.7-100% of patients after the insertion.[5] However, there are multiple removal methods. Most removal methods were developed for use with Norplant implants and differ in the tools used. Removal methods include the pop-out method, the Emory method, and the U technique. For Nexplanon implant removal, the manufacturer recommends the pop-out method. Unlike other methods, the pop-out method does not require a hemostat, as the implant is pushed through the incision and pulled out.[6,7] Reports suggest this method may be time consuming and/or difficult if the implant slips from grasp while injecting anesthetic.[8]

Improvements to contraceptive implant removal procedures may save providers and patients time and reduce patient pain/discomfort. Attempts to improve contraceptive implant removal procedures are largely limited to deeply inserted implants and are less relevant to superficial Nexplanon implants.[9] These methods focus on using ultrasound guidance techniques for removal.[10] None have modified incision location. To date, no novel methods for superficial and palpable Nexplanon contraceptive implant removals have been evaluated.

Our study aims to evaluate a new alternative method of Nexplanon removal with a modified incision location, called the To method, and compare its effectiveness and efficiency to that of the pop-out method.

Material and methods

This study was a single-blind pilot randomized controlled trial. Patients ≥ 18 years old at a New York City community hospital presenting for contraceptive implant removal were recruited between March 2022 and March 2023. Patients with non-palpable implants were excluded from the study. No formal power analysis was performed as this was a small pilot study. All subjects provided written informed consent. Institutional Review Board (IRB) approval was obtained from the hospital IRB prior to initiation of this study.

Eligible participants were randomly assigned to one of two conditions: contraceptive implant removal with the pop-out method or the To method. Implants were palpated and betadine preparation of the procedure site was performed. 1% lidocaine was injected in the planned incision site. A scalpel was then used to make a 5mm skin incision at the planned location. Incision location differed by procedure group. In the pop-out method group, the contraceptive implant was pushed toward the skin and an incision was made over the distal tip of the implant, parallel to its long axis. The implant was then pushed through the incision and removed. In the To method group, an incision was made over the implant, perpendicular to its long axis, about 1 cm from the distal tip. A small clamp was then used to grasp and remove the implant.

Our primary objective was to compare procedure times, pain scale ratings, and procedure completion rates between methods. Our secondary objective was to compare rates of complete pain freedom (i.e., a pain scale score of 0). Descriptive analyses on participants' sociodemographic and implant characteristics were reported. For all continuous variables under investigation, normality was assessed visually with the use of histograms. Sociodemographic variations in pain, implant depth, and procedure time were examined using bivariate correlation and analysis of variance (ANOVA). Group

differences in procedure time and pain scale scores were examined using multiple regression analyses. One aborted procedure was assigned the maximum observed procedure time for its condition to permit analysis. Statistical significance was defined by a two-tailed p value of < .05. Statistical analyses were performed using SAS.

Results

The sample consisted of 21 women presenting for Nexplanon removal (Table 1). The most common reasons for Nexplanon removal were irregular bleeding, expiration, and weight gain. The remaining reasons included pain/discomfort, mood side effects, and tubal ligation.

Bivariate analyses showed no significant differences in procedure time by age (p = .617), race (p = .070), or BMI (p = .828). Deep implants were associated with longer procedure time (p = .032). There were no significant group differences in implant depth (p = .604).

Results of primary analyses are presented in Table 2. Adjusting for implant depth, we found significant differences in procedure time, with the To method being associated with a shorter procedure time compared to the pop-out method (p = .032). We also observed significant differences in pain, with the To method being associated with significantly lower pain scale scores than the pop-out method (p = .021). 100% of To method procedures were successful, compared to 75% of pop-out method procedures. The To method was associated with greater likelihood of pain freedom (OR = 13.75, p = .046).

Table 1 Sociodemographic characteristics

Variables	Full Sample (n=21)	To Method (n=9)	Pop-out Method (n=12)
Age			
[M (SD) Range]	30.43 (7.19)	31.22 (7.41)	29.83 (7.30)
	Range: 18 - 44	Range: 18 - 40	Range: 20 - 44
BMI			
[M (SD) Range]	31.39 (6.45)	31.78 (3.59)	31.10 (8.13)
	Range: 23.23 - 51.58	Range: 27.40 - 38.26	Range: 23.23 - 51.58
Multipara			
No	n = 8; 38.10%	n = 3; 33.33%	n = 5; 41.67%
Yes	n = 13; 61.90%	n = 6; 66.67%	n = 7; 58.33%
Race/Ethnicity			
Asian	n = 2; 9.52%	n = 1; 11.11%	n = 1; 8.33%
Hispanic or Latino	n = 19; 90.48%	n = 8; 88.89%	n = 11; 91.67%
Removal Reason			
Irregular Bleeding	n = 8; 38.10%	n = 3; 33.33%	n = 4; 33.33%
Expiration	n = 7; 33.33%	n = 2; 22.22%	n = 5; 41.67%
Weight Gain	n = 4; 19.05%	n = 3; 33.33%	n = 1; 8.33%
Pain/Discomfort	n = 2; 9.52%	n = 1; 11.11%	n = 1; 8.33%
Headaches	n = 1; 4.76%	n = 0	n = 1; 8.33%
Mood Changes	n = 1; 4.76%	n = 0	n = 1; 8.33%
Tubal Ligation	n = 1; 4.76%	n = 1; 11.11%	n = 0
Implant Depth			
Shallow	n = 8; 38.10%	n = 4; 44.44%	n = 4; 33.33%
Deep	n = 13; 61.90%	n = 5; 55.56%	n = 8; 66.67%

Note: n's may not always add up to total sample N due to reports of multiple removal reasons.

Sample includes encounters for Nexplanon removal on n = 21 women desiring implant removal who presented to a NYC community hospital from March 2022 – March 2023.

Table 2 Regression analyses: procedure group predicting procedure time and pain scale scores

	B	β	SE	t	p
Procedure time (Seconds)					
Provider Reported Implant Depth	356.41	0.52	127.02	2.81	0.012
Procedure Group	-289.05	-0.43	124.65	-2.32	0.032
Pain scale scores					
Provider Reported Implant Depth	1.82	0.44	0.76	2.36	0.03
Procedure Group	-1.92	-0.48	0.77	-2.54	0.021

Note: Sample includes encounters for Nexplanon removal on n = 21 women desiring implant removal who presented to a NYC community hospital from March 2022 – March 2023.

Citation: Prieto J, Zhang L, O'Besso V, et al. Preliminary evidence for the safety and efficacy of a novel method for removal of contraceptive implants: a pilot RCT. *Obstet Gynecol Int J.* 2024;15(3):128–130. DOI: 10.15406/ogij.2024.15.00747

Discussion

This study provides preliminary evidence to support the use of the To method for contraceptive implant removal. We found that the To method was associated with shorter procedure times, less pain, and greater rates of pain freedom. There were no complications in either condition. These findings suggest that the To method may be a faster and less painful method of contraceptive implant removal.

Our findings are preliminary, as this single-blind pilot study reports on only 21 participants. Examinations in larger samples are needed in order to confirm generalizability. Future evaluation of the To method in larger samples should permit tests of interactions with implant depth, as the most efficacious method may differ by depth. Though future research is needed to comprehensively compare removal methods, our preliminary data suggest this alternative method may be beneficial.

Acknowledgments

Thank you to Flushing Hospital Medical Center's OBGYN and Research Education & Innovation departments for your support with this research.

Funding

None.

Conflicts of interest

The authors report no conflicts of interest.

References

1. Bahamondes L, Fernandes A, Monteiro I, et al. Long-acting reversible contraceptive (LARCs) methods. *Best Pract Res Clin Obstet Gynaecol.* 2020;66:28–40.
2. Nelson HD, Darney BG, Ahrens K, et al. Associations of unintended pregnancy with maternal and infant health outcomes: a systematic review and meta-analysis. *JAMA.* 2022;328(17):1714–1729.
3. Monea E, Thomas A. Unintended pregnancy and taxpayer spending. *Perspect Sex Reprod Health.* 2011;43(2):88–93.
4. Matos JE, Balkaran BL, Rooney J, et al. Preference for contraceptive implant among women 18-44 years old. *Womens Health Rep (New Rochelle).* 2021;2(1):622–632.
5. Rocca ML, Palumbo AR, Visconti F, et al. Safety and benefits of contraceptives implants: a systematic review. *Pharmaceuticals (Basel)*. 2021;14(6):548.
6. Zhang S, Batur P, Martin C, et al. Contraceptive implant migration and removal by interventional radiology. *Semin Intervent Radiol.* 2018;35(1):23–28.
7. Pymar HC, Creinin MD, Schwartz JL. "Pop-out" method of levonorgestrel implant removal. *Contraception.*1999;59(6):383–387.
8. Organon Global Inc. Removal of Nexplanon. 2021.
9. Sarma SP, Hatcher R. The Emory method: a modified approach to Norplant® implants removal. *Contraception*. 1994;49(6):551–556.
10. Jacques T, Brienne C, Henry S, et al. Minimally invasive removal of deep contraceptive implants under continuous ultrasound guidance is effective, quick, and safe. *Eur Radiol*. 2022;32(3):1718–1725.