Initial Evaluation of a Novel Nitinol, Low-dose Copper Intrauterine Contraceptive

Matthew F. Reeves[1,2], Bob Katz[1], Juan Canela[3], Mark Hathaway[4], Michael Tal[1,5]

[1]ContraMed (San Jose, CA, USA), [2]National Abortion Federation (Washington, DC, USA), [3]Clinica Canela (La Romana, Dominican Republic), [4]Unity Health Care (Washington, DC, USA), [5]Yale University School of Medicine (New Haven, CT, USA)

Abstract

Objective: ContraMed has developed VeraCept™, an intrauterine contraceptive with 175 mm² copper surface area on a flexible Nitinol frame. VeraCept is provided preloaded in a tapered-tip introducer with an external diameter of 3.7mm and with pre-trimmed retrieval strings. We report the initial experience with insertion and use of VeraCept.

Methods: A pilot study was performed to evaluate and refine VeraCept. We enrolled healthy fertile parous women desiring contraception in a single site with follow-up visits scheduled every 2-3 months. Hysterosalpingography and transvaginal ultrasound were performed at insertion and follow-up to assess device placement.

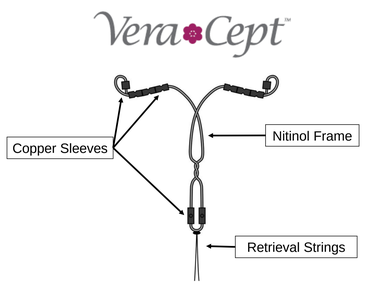
Results: We enrolled 463 women with a mean age of 25.5 years (range 18, 44), mean parity of 1.8 and 44% with a prior Cesarean. No complications occurred at insertion. No women developed clinical infection. No perforations or other serious adverse events were observed. After more than 4,600 woman-months, there have been no intrauterine pregnancies observed. One ectopic pregnancy was observed, giving a total pregnancy risk of 0.3 per 100 woman-years (95%CI 0.1, 1.2). At the 6-month follow-up, continuation was 92% (95% CI 85, 96%) and expulsions occurred in 2.1% (95% CI 0.3, 6.6%). VeraCept removal for increased bleeding or pain was 3.1% (95%CI 0.8, 8.1%).

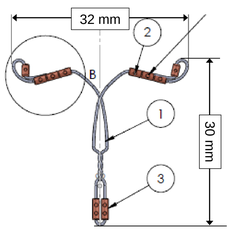
Conclusion: Initial clinical results of the VeraCept low dose intrauterine contraceptive demonstrate excellent contraceptive efficacy and safety profile with few side effects. Further clinical evaluation is needed.

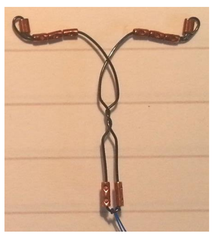
Background Information

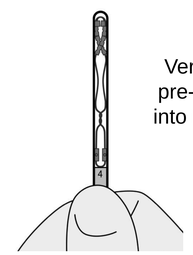
The VeraCept Intrauterine Copper Contraceptive

- A copper-based intrauterine device
  - 32 mm in width and 30 mm in height
- Frame made of Nitinol, a shape-memory, superelastic alloy
  - Anatomically compliant design provides the ability to seek the uterine fundus and conform to varying anatomical shapes
- 175 mm² of exposed copper surface area
  - Copper sleeves located near cornua & fundus and near cervix
- Compressed and preloaded in introducer
  - 3.7 mm diameter
  - With preformed, rounded tip
- monofilament polypropylene strings
  - Pre-cut at 7.8 cm in length
- Device changes were small sequential increases in spring constant to compress horizontal arms
  - Referred to as Device #1, Device #2, Device #3, and Final Device

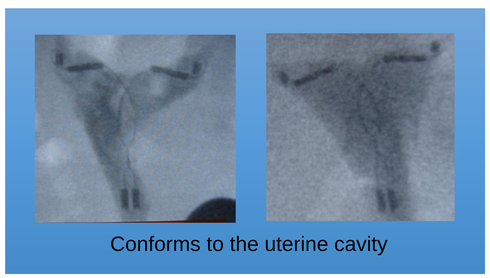


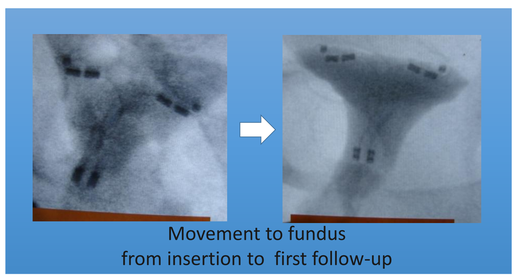


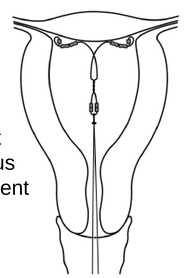




VeraCept pre-loaded into inserter







VeraCept in the uterus post-placement

Study Objective

To observe the safety, user tolerability and effectiveness of a new long acting reversible intrauterine contraceptive device utilizing a low-dose copper configuration on a shape memory Nitinol frame.

Methods

We conducted a single-arm prospective cohort evaluation of the VeraCept Intrauterine Copper Contraceptive in subjects recruited from a single clinical center, Clinica Canela in La Romana, Dominican Republic

The study was conducted in two phases:

1. Evaluation phase to evaluate the 175 mm² copper area and the spring constant of the frame, with enrolment from 7/12/2012 to 7/27/2013.
2. Confirmatory phase evaluating the final spring constant and the same 175 mm² copper area, with enrolment from 8/24/2013 to 8/25/2013

In both phases, we enrolled parous Women, at least 18 years of age, seeking long acting reversible contraception.

The primary safety endpoint was the occurrence of serious adverse events. Secondary safety endpoints were adverse events associated with VeraCept placement, peri-procedural events, and VeraCept tolerability.

We examined contraceptive effectiveness at 12 months.

This analysis includes data through 6/29/2014.

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Results

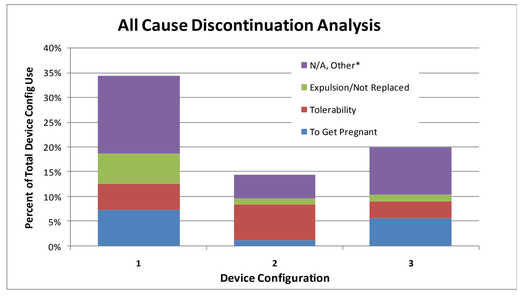
Study Population	Evaluation Phase	Confirmation Phase	Both Phases
N	365	98	463
Woman-months	5,812	894	6,706
Woman-years	484	75.4	559
Age (years)			
Mean	25	25	
Minimum	18	18	
Maximum	44	38	
Parity, mean	1.8	1.7	
Cesarean only	40.2%	41.8%	

Adverse Events	Evaluation Phase	Confirmation Phase
Pelvic Pain	43 (16.7%)	14 (15.9%)
Excess Bleeding	4 (1.5%)	0 (0.0%)
Pain+Bleeding	0 (0.0%)	1 (1.1%)
Vaginal Infection	0 (0.0%)	1 (1.1%)
Ovarian Cyst	4 (1.5%)	2 (2.3%)
Other	1 (0.4%)	0 (0.0%)
Total	52 (20.2%)	18 (20.4%)

Pregnancy Outcomes	Evaluation Phase	Confirmation Phase	Both Phases
Any pregnancy	1	0	1
Rate* (95% CI)	0.2 (0.05, 1.1)	0.0 (0.0, 4.0)	0.2 (0.04, 1.0)
Intrauterine	0	0	0
Rate* (95% CI)	0.0 (0.0, 0.6)	0.0 (0.0, 4.0)	0.0 (0.0, 0.5)

*Rate is pregnancies per 100 woman-years

Figure 3. Reasons for discontinuation.



Expulsion	Device iteration	Proportion
Evaluation Phase	#1	10.4%
	#2	1.9%
	#3	2.4%
Confirmation Phase	Final (at 12 months)	2.0%

Figure 1. Distribution of time of use by device type.

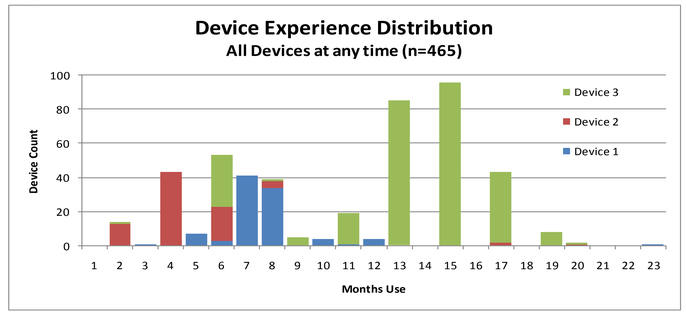
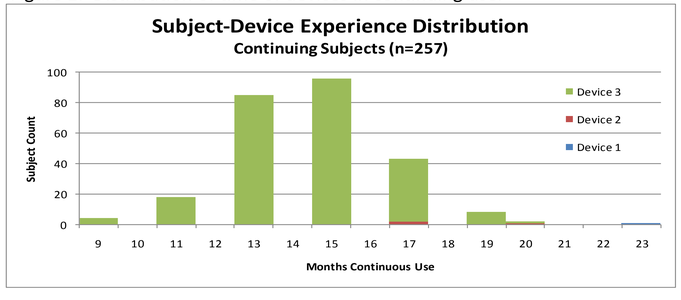


Figure 2. Distribution of time of devices in continuing use.



Conclusions

- VeraCept is a promising new intrauterine copper contraceptive
- A comparison study of VeraCept and the Copper T380S will provide additional data