Assistive device for the insertion of subcutaneous contraceptive implants

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1 Background

Providing access to family planning services in low- and middle-income countries (LMICs) is a major focus of the global health community [1]. The World Bank estimates that only 45% of the demand for contraceptive services in sub-Saharan Africa is satisfied [2]. The availability of long-term contraceptive methods is particularly important for women who prefer to space pregnancies by two or more years.

Intrauterine and subcutaneous implant contraceptive methods are the most effective reversible contraception methods available [3]. Subcutaneous implants are single (or double) rods that contain etonogestrel and are inserted subdermally on the inner side of a woman's non-dominant arm [4]. Single-rod devices (e.g., Implanon, Nexplanon) can prevent pregnancy for up to three years while two-rod devices (e.g., Jadelle, Sino-implant) can prevent pregnancy for up to five years. In addition, implants do not require maintenance or effort on the part of the user, allow women to return to fertility quickly, and have very low failure rates [5].

While the benefits of implantable contraceptives are significant, major barriers exist that prevent wider usage; namely, the training and skill required for performing insertion/removal procedures. This barrier is exacerbated in rural areas where access to health clinics, medical devices, and trained clinicians is more limited. This paper details the design of an innovative task shifting device that enables community healthcare workers to insert subcutaneous contraceptive implants. The ultimate goal of this work is to lower the barrier to adoption of long-term contraceptive implants for rural women in LMICs.

2 Methods

During August 2013, design ethnography techniques were performed at St. Paul's Hospital in Addis Ababa, Ethiopia to identify and characterize unmet maternal health needs. Eighty-five needs were identified including the need for a device to assist healthcare providers with the insertion of subcutaneous contraceptive implants.

User requirements including accuracy, safety, and ease of use were elicited from key stakeholders and additional requirements were identified using clinical literature and benchmarks. Requirements were translated into engineering specifications and prioritized using survey results administered to key clinical stakeholders.

A functional decomposition was performed to facilitate concept generation. Nine subfunctions were identified through this process: 1) locates insertion site, 2) guards against sharps, 3) transforms user input into motion, 4) prepares skin for insertion, 5) breaks skin, 6) moves implant into final position, 7) deploys implant, 8) prevents second use without sterilization, and 9) retains implant before deployment. Concept generation resulted in approximately sixty designs that were assessed using Pugh charts, based upon the requirements and specifications.

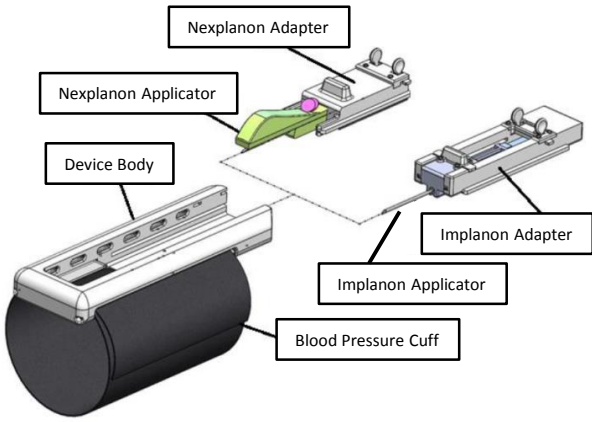

Figure 1: Overview of device components

The selected concept is shown in Figure 1. The device is composed of two main parts: the device body (which is attached to a blood pressure cuff) and the applicator adapter (one for the Implanon and one for Nexplanon). The adapters allow for both Implanon and Nexplanon insertion procedures to be performed. The insertion process for the selected concept is illustrated in Figure 2. The blood pressure cuff is inflated to a predetermined pressure causing the skin and subcutaneous tissue to be raised into a hollow cavity inside of the device's body (injection window). The skin/tissue displacement is controlled by the height of the injection cover thereby allowing the Implanon/Nexplanon applicator needle to be inserted at an accurate depth and parallel to the skin.

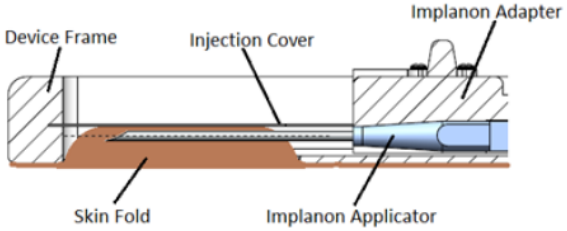

Figure 2: Method by which device controls implant injection depth.

The clinical procedure first involves marking the insertion site (8-10cm above the epicondyle on the underside of the arm). Next, the insertion site must be disinfected, and local anesthesia administered. After these steps have been accomplished, the device can be used to facilitate the insertion of the implant. The body of the device is wrapped around the woman's upper arm using the blood pressure cuff (aligning the window with the marked insertion site). The cuff is then inflated to 40mm Hg (pushing the skin and subcutaneous tissue into the insertion window). The appropriate adapter (for Implanon or Nexplanon) is selected and the applicator inserted into the adapter. The adapter is then placed into the body of the device, which positions the needle at the desired depth below the skin (just inside the subcutaneous tissue).

Proof of concept was demonstrated with two non-clinical studies. The first non-clinical study evaluated the effects of pressure applied by a blood pressure cuff on the skin/tissue deformation responses within the insertion window. This study was performed to determine the minimum pressure needed to ensure that the skin and subcutaneous tissue were consistently and correctly raised against the injection cover. A study team member's arm and a pork belly simulator were used to inform this pressure selection and three measurements were made at each pressure (Figure 2).

The second non-clinical study compared the unassisted versus assisted placement (depth) of implants by novice users (simulating community healthcare workers). Three novice users performed three repetitions of each insertion method using a pork belly simulator. The four insertion methods used were: unassisted insertion of Implanon (Baseline Im), unassisted insertion of Nexplanon (Baseline Nx), insertion using the Implanon assistive adapter and device (Prototype Im), and insertion using the Nexplanon assistive adapter and device (Prototype Nx).

3 Results

A prototype based on the selected concept was fabricated using 3D printing and allowed for the non-clinical studies to be performed.

The first non-clinical study revealed that adequate skin/tissue contact with the injection cover was achieved using 30 mmHg (Figure 3). To account for potential variability, 40 mmHg was established as the minimum recommended pressure.

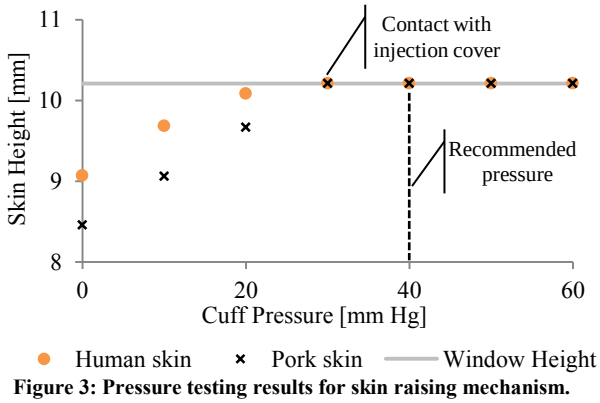

Figure 3: Pressure testing results for skin raising mechanism.

Table 1: Insertion depth results.

	Baseline		Prototype		Target
	Im	Nx	Im	Nx	
Depth (mm)	4.0 ±1.5	2.9 ±0.5	2.1 ±0.7	2.4 ±0.6	**1.7 ±0.6**

*Im = Implanon; Nx = Nexplanon

4 Interpretation

The insertion depth results shown above (Table 1) suggest that novice users can employ the prototype to successfully insert both Implanon and Nexplanon implants. Furthermore, novices were able to insert the implants at the desired insertion depth more consistently using the assistive device than using the conventional unassisted method. The device described in this paper has the potential to minimize a major source of user error (implant depth) when inserting contraceptive implants and could, therefore, facilitate task shifting of insertion procedures to community healthcare workers in LMICs, expanding access of this effective form of contraception to rural areas.

Subsequent usability and feasibility studies with key stakeholders including clinicians, rural healthcare workers, and ministry of health officials have revealed design shortcomings including: potential for cross-contamination (introduced by the reusable nature of the device), lack of assistance with anesthesia delivery, and the large dimensions of the prototype. Future iterations of the design will address these concerns and the revised device will be evaluated in pre-clinical and clinical trials.

Acknowledgments

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