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BRIEF COMMUNICATION

Preliminary clinical assessment of a task-shifting device for subcutaneous contraceptive implants

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Synopsis

Results from a small clinical trial suggest that the use of a task-shifting device for inserting contraceptive implants could increase access to safe, reliable, and reversible contraception.

https://clinicaltrials.gov/ct2/show/NCT03621787

Globally, unmet contraceptive needs affect over 200 million women, resulting in over 50 million unintended pregnancies and 1.1 million infant deaths annually [1].

Long-acting reversible contraception, including the subcutaneous implant, allows fertility preservation and family planning. Over 1.5 billion women in low- and middle-income countries live in rural settings. Despite efforts from global health stakeholders, the availability of long-term contraception remains limited in rural areas due to a lack of trained providers [2].

Traditional free-hand implant insertion consists of using a large bore needle to place rods (4 cm long, 2 mm in diameter) subcutaneously, administered by trained healthcare providers. Implants placed deeply require surgical removal [3]. A primary factor facilitating non-surgical removal is accurate, subcutaneous placement.

The SubQ Assist ("SubQ") standardizes subcutaneous implant placement by attaching to a conventional blood pressure cuff that when inflated, presses skin and subcutaneous tissue into the device cavity (Fig. 1A) [4]. Local anesthetic and implants are placed using the SubQ guide. Prior work comparing insertion depths during cadaver testing demonstrated that SubQ insertions were non-inferior to traditional insertions [5].

A small-scale clinical trial was performed to initially assess the performance of the SubQ in live tissue and compare insertion depths to those measured in cadavers. The clinical trial was approved by the University of Michigan Institutional Review Board and participants provided written informed consent prior to participation. Using the SubQ, two placebo implant rods were placed in nine human subjects by a certified obstetrician-gynecologist expert with a target depth of 0.30 cm as defined by experts. All implants were palpable. Ultrasound (Logiq V2 2016, GE Healthcare, Chicago, IL, USA) examination revealed a mean insertion depth of 0.31 cm (9 subjects, 18 implants, 3 data points per implant, Fig. 1B); 29 (53.7%) data points fell between 0.26 cm and 0.33 cm, and one measurement exceeded 0.50 cm.

A chi squared test revealed a statistically significant difference ($P < 0.001$) between implant depths placed using the traditional free-hand method in cadavers and SubQ-placed rods in human subjects (Fig. 1C). Potential factors which contributed to this difference included the insertion method used and the varying tissue characteristics

(e.g., thickness) between cadavers (older adults) and human subjects (young adults). Further research is needed to quantify the insertion depth threshold and compare the SubQ's performance to traditional free-hand insertions in human subjects. Preliminary testing suggests that with training, a healthcare extension worker using the SubQ could reliably and properly place the implant, thereby increasing access for millions of women to safe, reliable, and reversible contraception.

AUTHOR CONTRIBUTIONS

CB, IM, and KS designed and planned the study. CB, IM, and CS conducted the study. IM and CS analyzed the data. All authors contributed to the drafting, revision and writing of the final version of the manuscript.

CONFLICTS OF INTEREST

The authors have no conflicts of interest.

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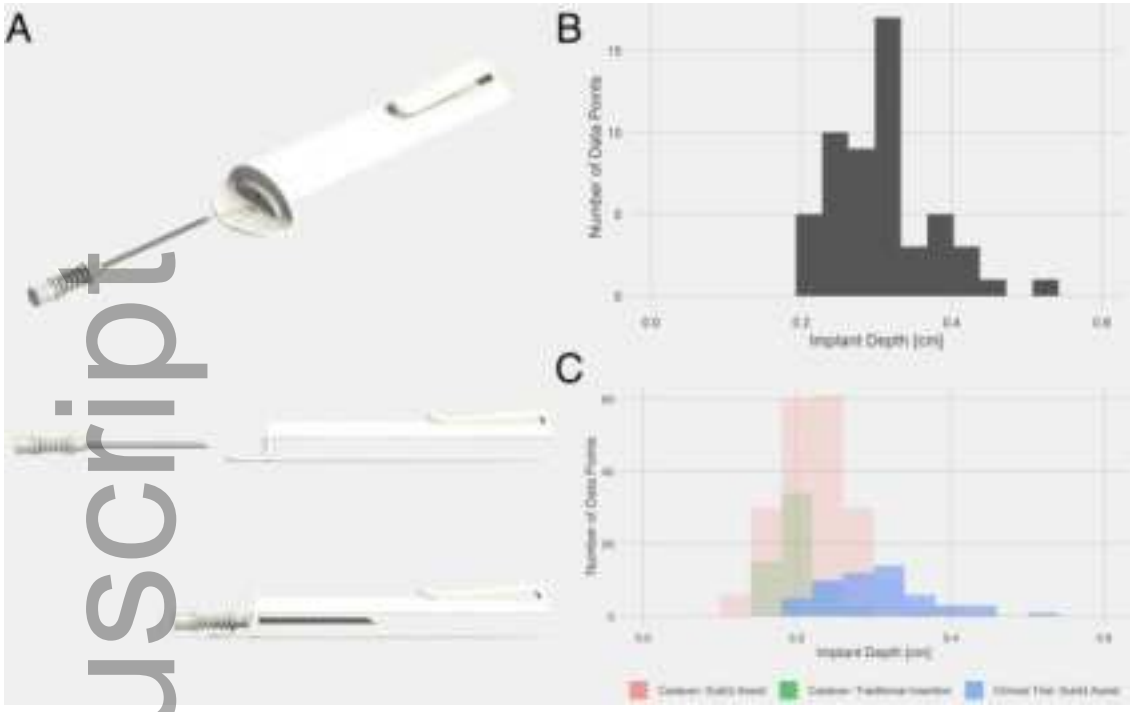
Figure Legend

Figure 1. A) SubQ Assist rendered images showing top and side view with trocar. B) Implant depth results from clinical data. C) Comparison between SubQ Assist insertions in cadavers, traditional free-hand method insertions in cadavers, and SubQ Assist insertions in human subjects.



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