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virtual cavity as indicated in anatomy treatises<sup>4</sup>; therefore, the mirror is able to comfortably insert into the horizontal portion of the H and does not generate discomfort. It can be concluded from the present study that the practice of horizontal placement of a vaginal speculum is better for decreasing pain in patients.

# CONFLICTS OF INTEREST

The authors have no conflicts of interest.

# AUTHOR CONTRIBUTIONS

RAAP contributed to the study design and manuscript writing. MFLR was responsible for study design, patient data collection, and manuscript writing. SRO contributed to data analysis and manuscript writing. KASR was responsible for data analysis, and review of the manuscript. JMA contributed to the study Design, and patient data collection. All authors approved of and contributed to the final version of the manuscript.

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### REFERENCES

- Bloomfield HE, Olson A, Greer N, et al. Screening pelvic examinations in asymptomatic, average-risk adult women: An evidence report for a clinical practice guideline from the American College of Physicians. Ann Intern Med. 2014;161(1):46. http://dx.doi. org/10.7326/m13-2881
- Bennett KF, Waller J, Chorley AJ, Ferrer RA, Haddrell JB, Marlow LAV. Barriers to cervical screening and interest in self-sampling among women who actively decline screening. J Med Screen. 2018;25(4):211-217. http://dx.doi.org/10.1177/0969141318 767471
- Petravage JB, Reynolds LJ, Gardner HJ, Reading JC. Attitudes of women toward the gynecologic examination. J Fam Pract. 1979;9(6):1039-1045.
- 4. Latarjet M, Ruiz Liard A. Anatomía Humana. Vol 2. 3rd ed. Madrid, España: Editorial Médica Panamericana; 1999:1756-1761.

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Gynecology

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

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Globally, unmet contraceptive needs affect over 200 million women, resulting in over 50 million unintended pregnancies and 1.1 million infant deaths annually.<sup>1</sup>

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

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.<sup>2</sup>

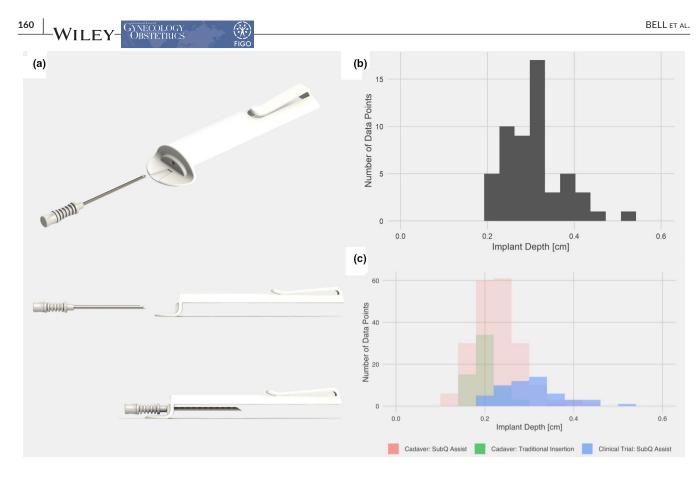


FIGURE 1 (a) SubQ Assist rendered images showing top and side view with trocar. (b) Implant depth results from clinical data. (c) Comparison between SubQ Assist insertions in cadavers, traditional free-hand method insertions in cadavers, and SubQ Assist insertions in human subjects (i.e., clinical data)

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.<sup>3</sup> A primary factor facilitating nonsurgical 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).<sup>4</sup> 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.<sup>5</sup> 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) 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.

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# CONFLICTS OF INTEREST

The authors have no conflicts of interest.

# 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.

# REFERENCES

- 1. Sedgh G, Hussain R, Bankole A, Singh S. Women with an unmet need for contraception in developing countries and their reasons for not using a method. *Occas Rep.* 2007;37:5-40.
- Tibaijuka L, Odongo R, Welikhe E, et al. Factors influencing use of long-acting versus short-acting contraceptive methods among reproductive-age women in a resource-limited setting. BMC Womens Health. 2017;17:1-13.

- 3. Pillai M, Gazet AC, Griffiths M. Continuing need for and provision of a service for non-standard implant removal. *J Fam Plann Reprod Health Care.* 2014;40:126-132.
- Mohedas I, Sarvestani AS, Daly SR, Sienko KH. Applying design ethnography to product evaluation: A case example of a medical device in a low-resource setting. 2015: 401-410.
- Jiang KC, Mohedas I, Biks GA, et al. Assessing the Usability of a Task-Shifting Device for Inserting Subcutaneous Contraceptive Implants for Use in Low-Income Countries. J Med Devices. 2020;14(1).

## SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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# Gynecolgy

# Telemedicine abortion: A channel to Brazilian women

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A recent article by Spillane et al.<sup>1</sup> discussed the experience of the Irish Family Planning Association in implementing early abortion care via telemedicine in Ireland during the COVID-19 pandemic. The study attests to the efforts needed to guarantee access to essential health services for women and girls during a public health emergency. A single community-level service in Brazil's countryside also worked collectively to ensure women and girls had access to care in a country with very restrictive laws on abortion. In Brazil, women have the legal right to an abortion if the pregnancy is the result of rape, if abortion is the only way to save a woman's life, or in cases of an anencephalic fetus. However, even in these limited situations, access is still difficult and services are scarce.

In Brazil, the declaration of a public health emergency due to COVID-19 has led to the administration of temporary regulations regarding telemedicine. A regional reference center for victims of sexual violence, located far from large urban areas in Brazil and coordinated by a female OBGYN, Dr. Helena Paro, was able to set up the first, and so far only, legal abortion service in the country that provides abortion for patients up to the ninth gestational week via a hybrid telemedicine system.<sup>2</sup> This is a free public

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