ASSESSING A NEW INTRAUTERINE DEVICE INSERTOR

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INTRODUCTION & AIM

Despite proven benefits, including affordability and efficacy, Intrauterine Device (IUD) technology has suffered from a lack of innovation. Current insertion procedures are often complicated and issues persist, including pain, risk of pelvic infection and uterus damage[1]. Recommendations to improve the procedure fail to meet the expectations of both women and providers, especially for patient pain management[2] and the easiness of IUD insertion. Thus, there is a true unmet medical need.

The main issue encountered for IUD insertion procedure is the difficulty to pass the cervix and access the uterine cavity. Very often, this step requires the use of a tenaculum to grab and straighten the cervix and a measurement of the uterine cavity with a hysterometer. To overcome this painful step, CEMAG CARE has developed a new IUD, Yanae®: composed by a Y shape 380 copper IUD associated with an innovative CrossGlide™ insertor. The CrossGlide™ insertor has been specifically designed to allow an easy access to uterine cavity without using a tenaculum/vulsellum. Yanae® was designed to provide an Intrauterine Contraceptive Solution combined with a painless solution to access the uterine cavity.

The aims of this pilot study are:

- Assessment of Yanae® successful insertion
- Evaluation of patient pain and satisfaction
- Evaluate provider satisfaction after using Yanae®

MATERIALS & METHODS

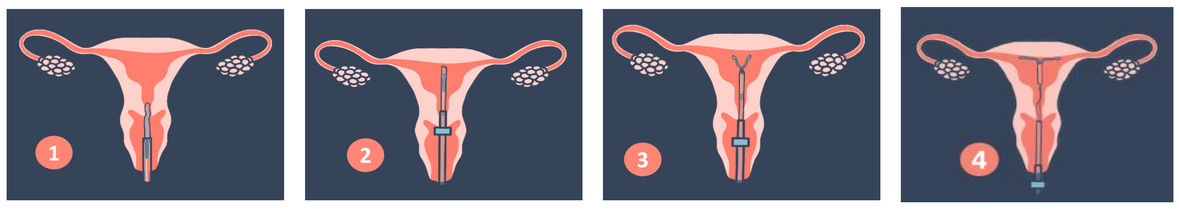
In this pilot study, the IUD insertion procedure using Yanae® was assessed on 3 extirpated uteri and in 26 patients[3] by an ob-gyn not familiar with the technology.

Table 1: *Patient information*

Details for patients having had an IUD insertion procedure (N=26)	
Patient's mean age	**27 years**
Nulliparous women	**14 (54%)**
Women having had c-section deliveries	**10 (38%)**
Women having had vaginal delivery	**1 (4%)**
Women having had c-section and vaginal deliveries	**1 (4%)**

IUD insertion was performed according to Yanae® instructions for use and without the use of a tenaculum (Figure 1). Procedure was immediately followed by an ultrasound examination to confirm placement of the IUD. Patient pain was immediately assessed after IUD insertion using a VAS-10 cm scale. Provider and patients completed satisfaction surveys after procedure.

Figure 1: *Description of Yanae® IUD insertion procedure.*



1-Cervical access with the inflatable membrane. *2-Allocation of IUD at the fundus.* *3-Deployment of the IUD.* *4-IUD at the fundus and withdrawal of the insertor*

RESULTS

1- Assessment of Yanae® insertions:

After having performed 3 successful Yanae® IUD insertions on extirpated uteri, 26 Yanae® IUD insertions were performed in women:

- 24 insertions were successful with a correct fundal placement and did not require the use of a tenaculum neither a hysterometer, to measure the uterine cavity;
- For 2 women, IUD insertion failed: one failure was related to the presence of adherences in the cervical canal (visible by ultrasound) and one to a misuse of the device by the provider.

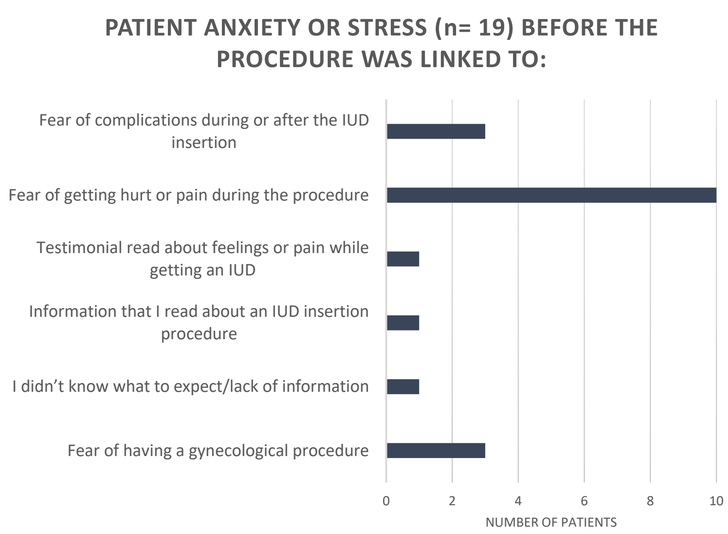
Table 2: *Yanae® insertion successful rate.*

Total of IUD insertions performed	**N = 26 (100%)**
IUD insertion successful	**24 (92%)**
At 1st insertion attempt	22 (85%)
After 2 insertion attempts	1 (4%)
After 3 insertion attempts	1 (4%)
IUD insertion fails	**2 (8%)**

2- Evaluation of Patient's feelings, pain and satisfaction:

Before IUD insertion, 19 women reported to be anxious and stressed, in particular of getting hurt or having pain during the procedure. After IUD insertion, 14 women reported having felt medium or light anxiety or stress (Figure 2). Only 17 women correctly complete the pain survey. Mean Patient pain level was mild pain (score from 1 to 3) on a 10 point scale (Figure 3). All women were satisfied by the IUD procedure insertion and 92% (n=22) of them will recommend Yanae® to a friend/family member.

Figure 2: *Patients anxiety or stress before and after IUD insertion procedure*



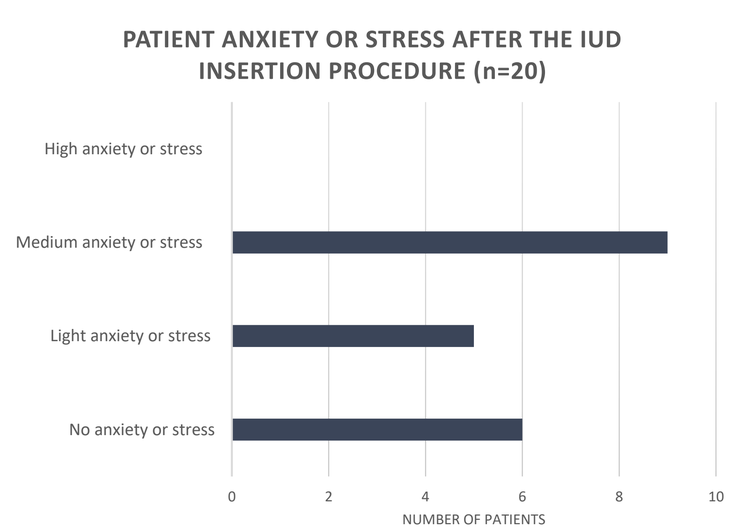


Figure 3: *Evaluation of pain during Yanae® insertion. Pain score rate was completed by the patient using a visual analog scale, 0 corresponding to no pain and 10 to the worst pain possible. Only 17 women correctly complete the pain survey.*

	Pain score	Nb of patients (n=17)
No pain	0	2 (12%)
Mild pain	1	1 (6%)
	2	5 (29%)
	3	3 (18%)
Moderate pain	4	4 (24%)
	5	2 (12%)
Very severe pain	6	0 (0%)
	7	0 (0%)
	8	0 (0%)
	9	0 (0%)
Worst pain possible	10	0 (0%)

3- Evaluation of provider's satisfaction :

Provider satisfaction survey revealed a very significant improvement of the insertion procedure practice in comparison with his usual practice with other IUD with standard inserter. Provider reported that the use of Yanae® could improve patient conform.

SUMMARY / CONCLUSION

This evaluation is the proof of concept of the ability of this new device to pass the cervix, enter the into the uterine cavity and deploy the IUD with a correct fundal placement without using a tenaculum and with no prior uterine cavity measurement[4].

In comparison with IUD standard inserter and usual IUD insertion procedure, provider noticed a significant improvement of the procedure practice and patient comfort. Patients' feedback showed a good satisfaction and a mild pain score during the procedure.

The patients reported that the anxiety and stress they may feel before the IUD insertion procedure is mainly related to the fear of getting hurt or having pain. Our results suggest that our technology may improve IUD insertion patient experience by reducing the anxiety and stress levels.

A prospective controlled study should confirm these encouraging results.

REFERENCES / COI

References:

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