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Original Research Article

Safety and efficacy of a suction cervical stabilizer for intrauterine contraceptive device insertion: Results from a randomized, controlled study☆,☆☆

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ABSTRACT

Objectives: To compare patient-reported pain, bleeding, and device safety between intrauterine contraceptive device (IUD) insertion procedures employing a suction cervical stabilizer or single-tooth tenaculum.
Study design: This was a randomized, prospective, single-blinded study conducted at two centers, enrolling women aged 18 years or older, eligible for IUD insertion. The primary end point measure was patient-reported pain, measured on a 100-mm Visual Analogue Scale. Safety was assessed on the amount of bleeding, adverse events, and serious adverse events.
Results: One hundred women were randomized, 48 to the investigational device and 52 to control. There were no statistically significant differences between the groups in factors potentially associated with pain on IUD insertion. IUD insertion was successful in 94% of all subjects. Subjects in the investigational device group reported pain scores ≥14 points lower than in the control group at cervix grasping (14.9 vs 31.3; $p < 0.001$) and traction (17.0 vs 35.9; $p < 0.001$), and smaller differences in pain scores at the IUD insertion (31.5 vs 44.9; $p = 0.021$) and cervix-release (20.6 vs 30.9; $p = 0.049$) steps. Nulliparous women experienced the greatest pain differences to control. Mean blood loss was 0.336 (range 0.022–2.189) grams in the investigational device group and 1.336 (range 0.201–11.936) grams in the control group, respectively ($p = 0.03$ for the comparison).

One adverse event (bruising and minor bleeding) in the investigational device group was considered causally related to the study device.
Conclusions: The suction cervical stabilizer had a reassuring safety profile and its use was associated with significant reductions in pain during the IUD insertion procedure compared with standard single-tooth tenaculum use, particularly among nulliparous women.
Implications: Pain can be an important barrier to greater use of IUD devices among prescribers and users, particularly nulliparous women. The suction cervical stabilizer may provide an appealing alternative to currently available tenacula, filling an important unmet need.

1. Introduction

Intrauterine contraceptive devices (IUDs) represent a highly effective, long-acting, well-tolerated, and safe reversible contraceptive method. IUDs are associated with lower contraceptive failure rates than other reversible methods [1] and typically have very high user satisfaction rates [2–5]. Most recommendations from medical authorities place IUD in the highest Medical Eligibility Criteria recommendation categories 1 and 2 for women without specific complicating conditions [6–8].

Despite this authoritative support, IUDs are used by a fraction of those women who opt for birth control and healthcare providers are

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sometimes reluctant to recommend their use [9,10]. One important barrier to increased IUD uptake is pain—whether actual or feared—and anxiety before and during the procedure [10–14]. For insertion, the uterus, cervical opening, and vaginal canal need to be aligned, which often necessitates the use of a cervical tenaculum. This is associated with pain both during the procedure and postprocedurally [15,16] and may also induce bleeding. The highest patient-reported pain scores are for the two steps uterine sounding and IUD insertion using a tenaculum [17]. The degree of pain has been reported to be greater in nulliparous than in multiparous women [18], which may be a reason for the lower uptake of IUD in younger women [10,19,20].

There is no consensus on effective analgesics to reduce pain [15], nor on the use of different tenaculum designs [17]. Hence, there remains a significant unmet need for IUD insertion procedures associated with less pain and discomfort, in order to reduce barriers to IUD use, especially among nulliparous and younger women.

We have recently reported on an open-label pilot study with an investigational soft-suction device for atraumatic stabilization of the cervix during IUD insertion [21]. The device was associated with very little pain and with high overall satisfaction rates among those participants who achieved IUD insertion. The results supported the conduct of a randomized trial to compare the device with the use of a standard tenaculum in a larger population. We here report the main results of this study.

2. Methods

2.1. Design

This was a randomized, prospective, single-blinded, interventional study with the primary objectives to compare patient-reported pain, bleeding, and device safety between procedures employing the Aspivix suction cervical stabilizer (Aspivix SA, Renens, Switzerland) and commonly used single-tooth cervical tenaculum. The study was conducted at the Department of Woman, Child & Adolescent, University Hospitals (HUG) Geneva, Switzerland, and the Department of Women, Mother & Child, University Hospital (CHUV) Lausanne, Switzerland, from April 30, 2021 to February 16, 2022.

All participants provided written, informed consent. The study was conducted in compliance with the Declaration of Helsinki, ISO EN 14155 and all local legal and regulatory requirements. The protocol was approved by the Ethics Committees Vaud and Geneva and the Swiss Agency for Therapeutic Products (Swissmedic). The study was registered with clinicaltrials.gov (NCT04441281).

2.2. Study population

We enrolled women 18 years old or older presenting at the participating clinics for insertion of standard copper IUDs or levonorgestrel-releasing IUDs, in ordinary outpatient procedures. Patients were excluded if they were contraindicated for IUD insertion, were currently on oral anticoagulants, had a history of cervical operations or severe vaginal bleeding of unknown origin, or were receiving analgesics within 12 hours of the procedure. Preprocedure the practitioner assessed the presence of routine contraindications for the study devices (e.g., cervix diameter < 26 mm, Nabothian cyst, cervical myomas, or cervical abnormalities). The decision whether a cervix stabilizer was required for IUD insertion in each individual patient was taken according to the standard procedures at each center. Crossover was possible if deemed necessary by the operator.

Eligible subjects were randomized in blocks of size four, six, or eight stratified by site and using a computer-generated sequence. Patients were blinded to the type of insertion device used. The operators were staff and residents at the centers, with no selection criterion.

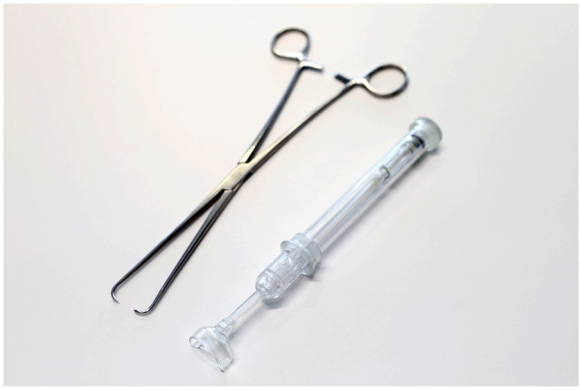

Fig. 1. The investigational soft-suction device for atraumatic stabilization of the cervix during IUD insertion used in the randomized controlled trial at Geneva and Lausanne evaluating a suction cervical stabilizer versus single-tooth tenaculum from April 30, 2021 to February 16, 2022 (below) with a standard tenaculum (above) for comparison.

2.3. Study device and procedures

The Aspivix suction cervical stabilizer (Fig. 1) is an investigational, atraumatic single-use device which uses suction force to hold the cervix during IUD insertion. The device has been described earlier [21]. A vacuum is created within the main body of the device. Operators were instructed to allow 10 seconds between vacuum deployment and cervix manipulation. Tissue is released by simple release of the vacuum. All four interventionists had previous experience with IUD insertion using single-tooth tenaculum, and one had experience of the suction cervical stabilizer. The number of insertion attempts with the study devices was at the discretion of the operator. Use of analgesics was allowed during the insertion if necessary. No prophylactic cervical anesthesia was used during the entire procedure.

2.4. End points

The primary end point was patient-perceived pain measured at seven steps throughout the IUD insertion: at baseline (before the procedure), immediately after speculum placement, at study device/tenaculum (placement on the cervix), at cervical traction, IUD insertion, at release of the device/tenaculum, and 5 minutes after speculum removal. We measured pain scores by using a 0- to 100-mm Visual Analogue Scale (VAS).

Secondary end points included operator-assessed effectiveness and satisfaction with the investigational device group, and patient satisfaction with the procedure, all measured on a five-point Likert questionnaire. Safety was assessed on the amount of bleeding, adverse events (AEs) and serious adverse events (SAEs). To measure total cervical blood loss, we subtracted the dry mass of the used compresses from their total mass. We collected subjects' experiences at the end of the consultation and at one follow-up telephone call at the end of the study, between days 3 and 5 post-IUD insertion. On this follow-up call, subjects reported on pain, bleeding, and AEs or SAEs occurring on each day postprocedure, from day 1 up to the day of the phone call.

2.5. Statistical methods

Data are presented descriptively as mean, standard deviation, median, range, and interquartile range for continuous data, or

number and percentages for discrete data. For comparisons between groups, we employed Student's t test for continuous and the chi-square test for discrete data. To correct for skewed distribution, we log-transformed blood loss data before applying the t test. Patient characteristics are summarized for the intent-to-treat population, defined as all enrolled subjects grouped according to their assigned study device regardless of which device was used in the actual procedure. The pain scores used for the intent-to-treat analyses were those for the actual IUD insertion procedure, regardless of device used, and patients remained analyzed according to their originally assigned group. If more than one placement attempt was needed, VAS was scored for the attempt when the provider was able to continue with the procedure. VAS scores were summarized by study arm, with scores between 70 and 100 categorized as severe pain [22]. For comparisons of scores at each procedural step between the study arms, we employed the two-sample *t* test supplemented by an analysis stratified according to study center and parity using analysis of variance and least-squares mean differences. The results are presented with 95% confidence intervals. Further analyses were performed stratifying for center and parity by analysis of variance and other regression models.

To calculate the sample size, we used the average pain score (34.3 ± 23 mm) with single-tooth tenaculum in the control groups of six published studies at the time of tenaculum placement [17,23–27] and the mean pain scores reported in the pilot study of the atraumatic suction device (7.7 ± 10.5 mm for device placement and 12.2 ± 11.3 mm when applying traction) [21]. Power calculations were conducted to demonstrate a difference of at least 14 mm between the two randomized groups with an assumed 23-mm standard deviation of pain scores (5% significance level, two-sided test) for steps C (cervix grasping) and D (cervix traction). To achieve at least 80% power to demonstrate noninferiority of 60% efficacy with a 21% equivalence margin would require 50 participants in each study group. We further assumed a 30% crossover rate from the study device to standard tenaculum. For the safety analysis, the sample size would provide 80% power to detect at least one serious device-related AE assuming a rate of 3.2% in the population and a binomial distribution.

A p value of < 0.05 was used to indicate significance for all comparisons.

All statistical calculations were performed using Stata v 13.1 software (StataCorp, TX).

3. Results

3.1. Study population

Figure 2 shows the participant flow. Out of 138 screened candidates, we randomized 100 subjects: 48 to the investigational device and 52 to control. Table 1 shows demographic characteristics at baseline. Median age was 30.0 years (range 18.6–51.4 years); 55 subjects (55%) were nulliparous. Similar percentages of women in both groups opted for smaller versus larger IUD insertion tube and arm diameters.

In total, IUD insertion was successful in 94% of enrolled subjects, with similar success rates in both groups. Insertion was successful in 40 subjects (83%) in the investigational device group using only the study device. Eight subjects were switched to tenaculum; in five of

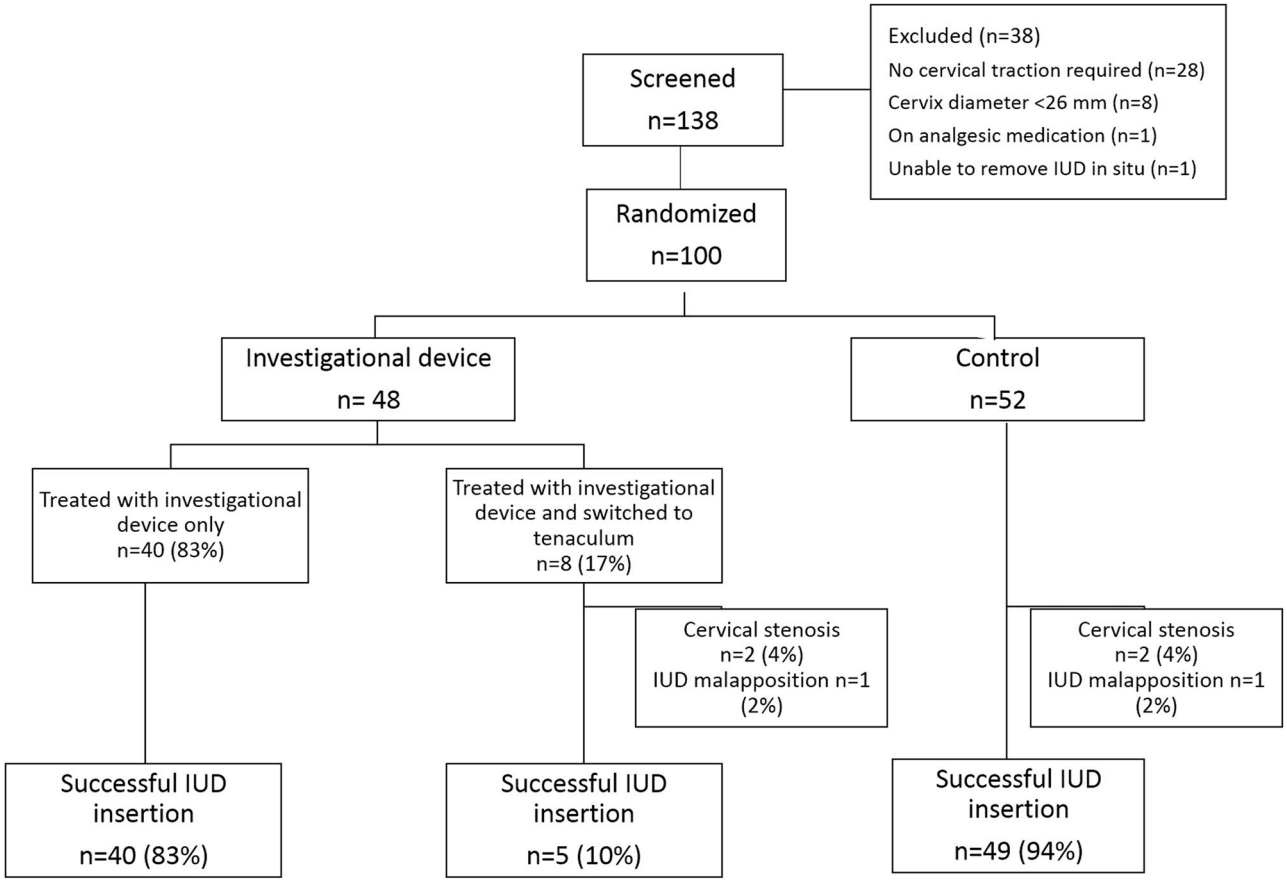

Fig. 2. Participant flow chart of subjects enrolled in a randomized controlled trial at Geneva and Lausanne evaluating a suction cervical stabilizer versus single-tooth tenaculum from April 30, 2021 to February 16, 2022.

Table 1
Characteristics of patients enrolled in a randomized controlled trial at Geneva and Lausanne evaluating a suction cervical stabilizer versus single-tooth tenaculum from April 30, 2021 to February 16, 2022

Characteristic	Investigational device (n = 48)	Control group (n = 52)
Age years, median [range]	29.3 [18.6–51.4]	29.0 [19.3–45.0]
Height cm mean ± SD	164.4 ± 6.6	162.5 ± 7.0
Weight kg, mean ± SD	66.3 ± 18.1	67.2 ± 17.3
Body mass index kg/m^2 mean ± SD	24.5 ± 6.3	25.4 ± 6.4
Parity		
0	28 (58%)	27 (52%)
1	9 (19%)	7 (13%)
2	7 (15%)	13 (25%)
≥3	4 (8%)	5 (10%)
≥1 vaginal delivery	14 (78%)	20 (80%)
Currently breastfeeding	8 (36%)	9 (31%)
Previous IUD	14 (29%)	19 (37%)
Change of IUD	7 (15%)	9 (17%)
Dysmenhorrea		
Never	37 (77%)	38 (73%)
Past	3 (6%)	2 (4%)
Current	8 (17%)	12 (23%)
Interval since last delivery (months)		
Not applicable	28 (58%)	25 (50%)
< 3	6 (13%)	6 (12%)
3–6	0 (0%)	7 (14%)
> 6	14 (29%)	12 (24%)
Interval since last menses (weeks)		
Not applicable[a]	12 (25%)	16 (33%)
< 1	11 (23%)	12 (25%)
1–2	8 (17%)	8 (17%)
> 2	17 (35%)	14 (29%)

[a] Participants who had the IUD inserted postpartum before they had their periods, or who were on hormonal IUD or continuous pills and not menstruating.

those, the IUD was successfully inserted. IUD insertion was unsuccessful in three subjects in each treatment group. Failures were due to the anatomy of the subjects. Use of analgesics was not indicated in any study subject. Cervical dilation was not attempted in any of the cases.

3.2. Patient-reported pain

Figure 3 shows average patient-reported VAS scores. Data in the investigational device group were missing for the following reasons: at the cervix traction stage: one subject fainting, three cases of device malfunction, one insertion failure; at the insertion stage: one subject fainting and two insertion failures; at the cervix-release stage: two cases of device malfunction, two insertion failures, one subject fainting, and one unrecorded data gap; 5-minutes post-procedure**:** one subject fainting.

At most steps, subjects in the investigational device group reported lower VAS scores than those undergoing IUD insertion with standard tenaculum. Subjects in the investigational device group reported pain scores ≥14 points lower than in the control group at the cervix grasping (14.9 vs 31.3; $p < 0.001$) and traction (17.0 vs 35.9; $p < 0.001$) stages, and smaller differences in pain scores at the IUD insertion (31.5 vs 44.9; $p = 0.021$) and cervix-release (20.6 vs 30.9; $p = 0.049$) stages. Using commonly accepted thresholds for clinical significance [28], the differences in VAS scores were clinically significant at the grasping, traction, and insertion stages.

Postprocedure, pain scores were similar in both groups. On day 1, 69% of subjects in the investigational device group and 67% in the control group reported mild or no pain. On the follow-up telephone call made between 3 and 5 days after insertion, 82% and 86% of subjects in the two groups reported complete freedom from pain.

Figure 4 shows VAS scores in subgroups of nulliparous and parous subjects, respectively. Nulliparous women showed the greatest differences between the treatment groups, experiencing less pain with the suction cervical stabilizer at the key procedural steps. All these differences were highly statistically significant at $p \leq 0.001$. Parous women reported lower pain scores than nulliparous women with both treatment devices, and there were only statistically nonsignificant differences between the treatment groups (Fig. 4A and B).

At the extremes, a lower percentage of women in the investigational device group than in the control group reported severe pain. This was true for parous as well as for nulliparous women (Fig. 5).

A post-hoc analysis of results according to inserter diameter < 4 mm or > 4 mm showed no statistically significant influence of

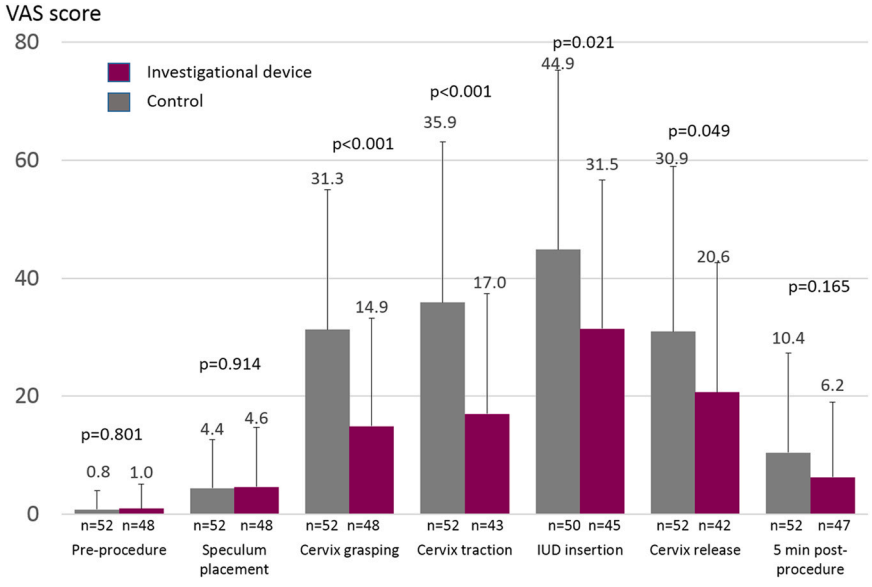

Fig. 3. Mean VAS scores (numbers above bars) at different steps of the IUD insertion procedures with the investigational device and standard tenaculum, respectively (ITT population) in subjects enrolled in a randomized controlled trial at Geneva and Lausanne evaluating a suction cervical stabilizer versus single-tooth tenaculum from April 30, 2021 to February 16, 2022. The lines indicate SD. P values refer to comparisons between the groups.

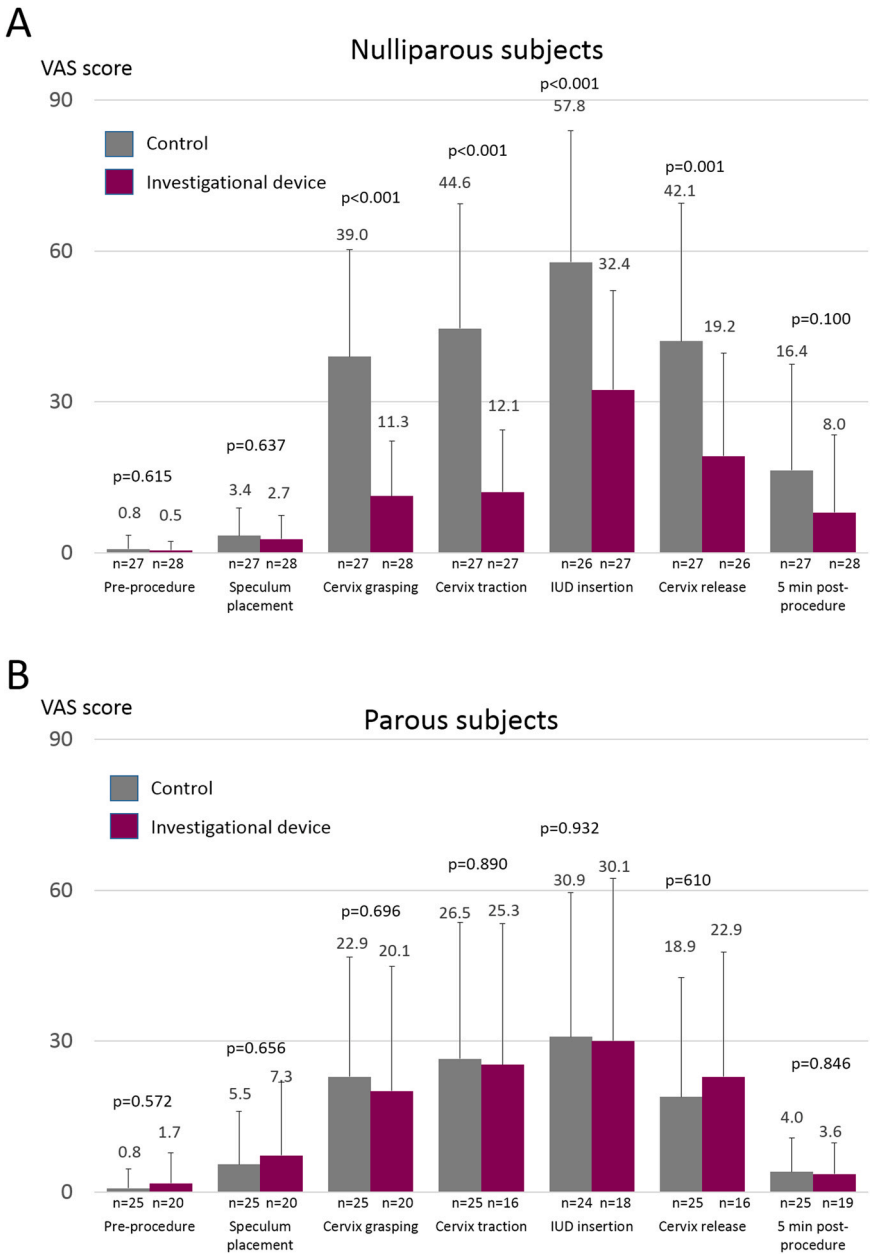

Fig. 4. Mean VAS scores (numbers above bars) at different steps of the IUD insertion procedures for nulliparous (A) and parous (B) subjects, respectively, with the suction cervical stabilizer and tenaculum, respectively, in subjects enrolled in a randomized controlled trial at Geneva and Lausanne evaluating a suction cervical stabilizer versus single-tooth tenaculum from April 30, 2021 to February 16, 2022. The lines indicate SD. P values refer to comparisons between the treatment groups.

inserter diameter on reported pain levels at all steps of insertion, regardless of parity.

3.3. Secondary end points

More than one positioning attempts were necessary in 11 patients (23%) in the investigational device group (median 3, range 2–8). Spontaneous device releases occurred in 18 of 48 subjects (38%) with a median of 3 (range 1–8) releases per subject. Spontaneous releases were more common in procedures with insertion failure or which required a switch to the single-tooth device.

Physicians' reported experiences of the investigational device were 'positive' or 'strongly positive' for between 72% and 91% of the procedures. Overall, operators found handling of the two devices to be comparable.

Study subjects' rates of dissatisfaction were 4% in the investigational device group and 8% in the control group.

3.4. Safety

Six AEs occurred, all classified as mild. One AE was considered causally related to the suction cervical stabilizer. The AE involved inability to remove vacuum and suction with the device, causing bruising and bleeding. One subject experienced a vasovagal reaction with transpiration and numbness of legs, possibly from multiple applications of the device due to difficulty maintaining suction sufficient for pulling.

There were significantly fewer occurrences of bleeding in the investigational device group (Table 2). In 89% of subjects, providers reported no bleeding compared with 40% in the comparator group ($p < 0.001$). No instance of substantial bleeding (> 3 minutes) was

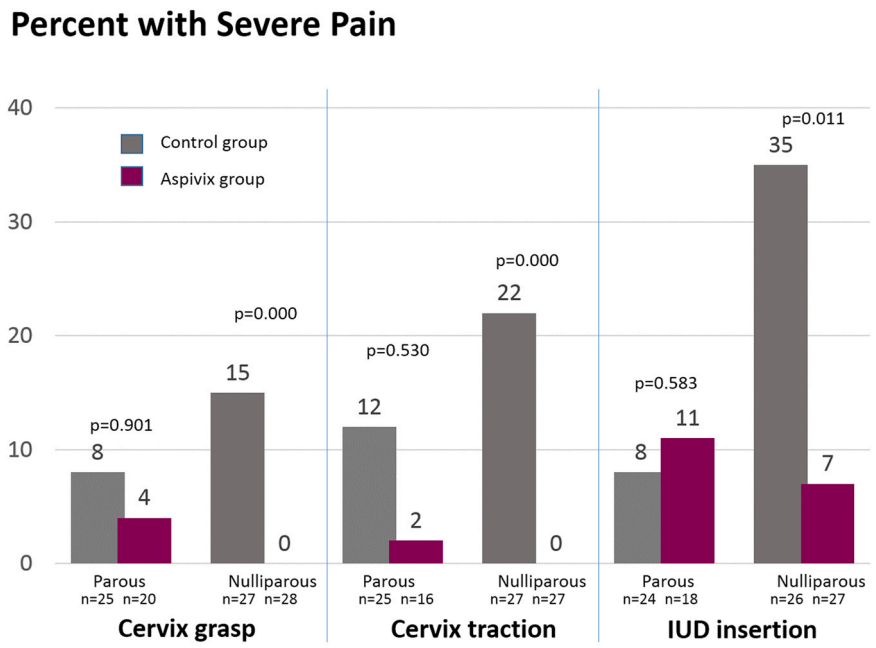

Fig. 5. D: Percentages of parous and nulliparous women, respectively, with severe pain during relevant procedural steps in subjects enrolled in a randomized controlled trial at Geneva and Lausanne evaluating a suction cervical stabilizer versus single-tooth tenaculum from April 30, 2021 to February 16, 2022.

reported. Eight participants in the investigational device group had ecchymosis compared with none of the patients in the control group. No new AEs were reported at the follow-up call. On day 1 post-procedure, 86% of subjects in the investigational device group and 79% in the control group had no or only light vaginal bleeding ($p = 0.257$). On the day of the follow-up call, these rates were 94% and 90%, respectively ($p = 0.942$).

Out of the 64 investigational devices employed in the study, 21 devices (32.8%) used in 12 patients had defects. The most common issue was problems with the slider, occurring with 10 devices.

4. Discussion

Pain and fear of pain during the insertion procedure are major barriers to increased IUD use worldwide [10–14]. The main findings of the current study with the suction cervical stabilizer are the significantly lower VAS pain scores compared with use of single-tooth tenaculum at all relevant steps of the procedure: cervix grasping, traction, IUD insertion, and cervix release. There was significantly less bleeding with the suction cervical stabilizer than in the control group. Such differences in pain scores have not previously been demonstrated for alternatives to the standard single-tooth tenaculum [17].

Ecchymosis occurred somewhat more frequently with the investigational device, and there remains scope for further reduction in malfunction rates experienced with the prototype device. The suction cervical stabilizer is a developmental device, and the lessons from this trial will feed back into design improvements. Overall the results appear promising, particularly for nulliparous women who experience the greatest need for more comfortable IUD fitting procedures. We found the greatest differences in VAS scores at the procedural steps during which patient-reported pain scores are highest and hence the need for improved procedures the greatest [17]. In the overall population, VAS scores with the tenaculum during IUD insertion, the most painful step of the procedure, were similar to those reported in other studies with mixed populations of parous and nulliparous women [17,29].

There is an important inverse relationship between pain and satisfaction with IUD procedures, which has been shown to be particularly strong for young women who experience higher pain levels [30], highlighting the importance of pain reduction in this population. The successful primary end point outcome in the current study was driven by large differences between the groups in nulliparous women. There may be several explanations why no significant differences were observed in the parous subgroup, but the lower pain scores with both treatment devices in this group will have left less scope for further reductions with the investigational device. It is notable that pain scores for parous women were 40% to 50% lower than for nulliparous subjects with either device at all painful stages of the procedure. Basically, use of the suction cervical stabilizer rendered the procedure less painful than use of tenaculum in all women, whatever their parous state.

Table 2
Occurrence and severity of bleeding and ecchymosis in a randomized controlled trial at Geneva and Lausanne evaluating a suction cervical stabilizer versus single-tooth tenaculum from April 30, 2021 to February 16, 2022

	Investigational device (ITT)	Control group (ITT)
Amount of blood loss, g, geometric mean (range)[a]	0.336 (0.022–2.189)	1.336 (0.201–11.936)
Ecchymosis size		
None	36[b]	52
1–5 mm	4	0
≥5–15 mm	3	0
≥15–40 mm	2	0

[a] $p < 0.05$ for the comparison between the treatment groups.
[b] Data are missing for three subjects in the investigational device group: two due to device malfunction and one to fainting.

The study device has previously been subject only to a small pilot study without a control group [21]. In the current population, there were far fewer switches to single-tooth tenaculum and success rates were higher than in the pilot study. This is possibly due to a combination of a learning curve and improvements to the device.

Although participants in both study groups showed high satisfaction levels, it is difficult to assess the relevance of the statements. Two-thirds of the subjects had not undergone IUD insertion previously and arguably did not know what to expect. Highly motivated women report higher satisfaction with the procedure, despite experiencing pain during the insertion procedure [30].

The study has limitations. Eight subjects (15%) were switched from study device to tenaculum. Data are missing for a (small) number of patients in the investigational device group for the core procedural steps. The study population may have been particularly motivated and it is possible that certain women played down their pain, although randomization would presumably have evened out such effects. Although subjects were blinded to the device and we paid special attention to handling the device out of sight of patients, we did not evaluate whether a patient could tell which device was used. Among strengths are the large number of study subjects, the interventionists' diverse levels of experience, the randomized design, use of a well-established technology in the comparator group, standardized assessment of bleeding, and the use of follow-up.

In summary, the suction cervical stabilizer was associated with a statistically significant reduction in pain during the IUD insertion procedure compared with standard single-tooth tenaculum use, particularly among nulliparous women. The safety profile was reassuring. With appropriate modifications to minimize the risk of malfunction, the investigational device may provide an appealing alternative to currently available tenacula, filling an important unmet need, particularly in nulliparous women who would greatly benefit from a more comfortable procedure. Potential other applications of the suction concept may be explored, for example, endometrial biopsies, vaginal or cervical exploration.

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