Incidence and Risk Factors for a Malpositioned Intrauterine Device Detected on Three-Dimensional Ultrasound Within Eight Weeks of Placement

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Objectives—To estimate the incidence of intrauterine device (IUD) malpositioning detected on three-dimensional (3D) transvaginal ultrasound within 8 weeks of placement and identify risk factors for malpositioning.

Methods—Retrospective study of women who had an IUD placed at a large obstetrics and gynecology practice from January 1, 2015, to December 31, 2020. All patients underwent two-dimensional ultrasound at the time of insertion and routine three-dimensional ultrasound within 8 weeks. Baseline characteristics and potential risk factors were compared between women with correctly positioned and malpositioned IUDs. Odds ratios were calculated by logistic regression to identify risk factors independently associated with malpositioning.

Results—A total of 763 IUD placements were included, and 127 malpositioned IUDs were identified representing an overall rate of malpositioning of 16.6% (95% confidence interval [CI] 14.0–19.3) with 8.8% (95% CI 6.8–10.8) requiring removal. Patients with malpositioned IUD had higher rates of morbid obesity (13.4% versus 3.8%, adjusted odds ratio [aOR] 2.46, 95% CI 1.10–5.50), prior uterine window or rupture (9.0% versus 2.2%, aOR 2.78, 95% CI 1.06–7.30), copper IUD placement (64.2% versus 47.4%, aOR 1.99, 95% CI 1.31–3.03), and symptoms such as bleeding or pain at follow-up (35.8% versus 20.1%, aOR 2.58, 95% CI 1.67–3.98). Parity, breastfeeding, difficult insertion, and uterine size and positioning were not significant.

Conclusions—The incidence of malpositioned IUD within 8 weeks of placement on 3D ultrasound is 16.6%, with 8.8% requiring removal. Significant risk factors for malpositioning include morbid obesity, prior uterine window or rupture, and copper IUD placement. These findings support the importance of routine follow-up 3D ultrasound after seemingly successful IUD placement.

Key Words—intrauterine device; intrauterine device malposition; long-acting reversible contraception; three-dimensional ultrasound; ultrasound

Received August 8, 2021, from the Department of Obstetrics, Gynecology, and Reproductive Science, Icahn School of Medicine at Mount Sinai, New York, NY, USA (C.T.C., N.S.F.); and Maternal Fetal Medicine Associates, PLLC, New York, NY, USA (N.S.F.). Manuscript accepted for publication September 14, 2021.

All of the authors of this article have reported no disclosures.

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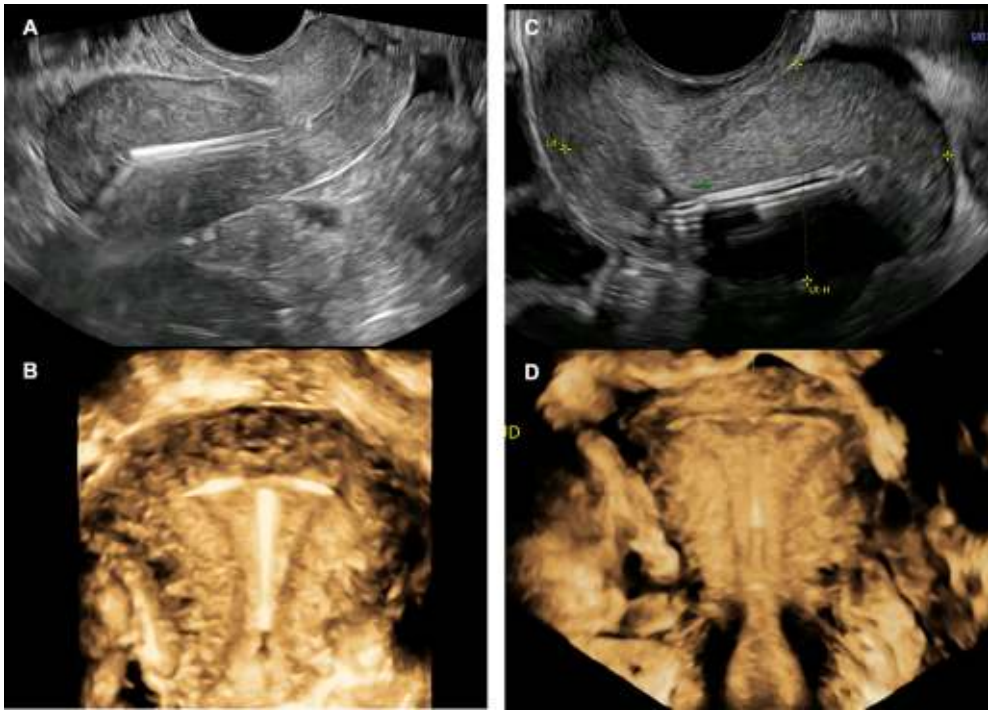
Abbreviations

2D, two-dimensional; 3D, three-dimensional; AIUM, American Institute of Ultrasound in Medicine; aOR, adjusted odds ratio; BMI, body mass index; CI, confidence interval; Cu-IUD, copper intrauterine device; IUD, intrauterine device; LNG-IUD, levonorgestrel intrauterine device; TVUS, transvaginal ultrasound

doi:10.1002/jum.15836

Intrauterine devices (IUDs) are effective long-acting reversible contraceptives that are becoming increasingly utilized due to their high efficacy, ease of use, and ability to be placed postpartum.[1] However, IUD migration can occur after insertion, with rates of malpositioning ranging from 10.4% to 25%.[2-6]

Figure 1. Properly positioned Intrauterine devices (IUDs) visualized on sagittal two-dimensional (2D) and coronal three-dimensional (3D) transvaginal ultrasound. **A** and **B**, Copper IUD. **C** and **D**, Levonorgestrel IUD.



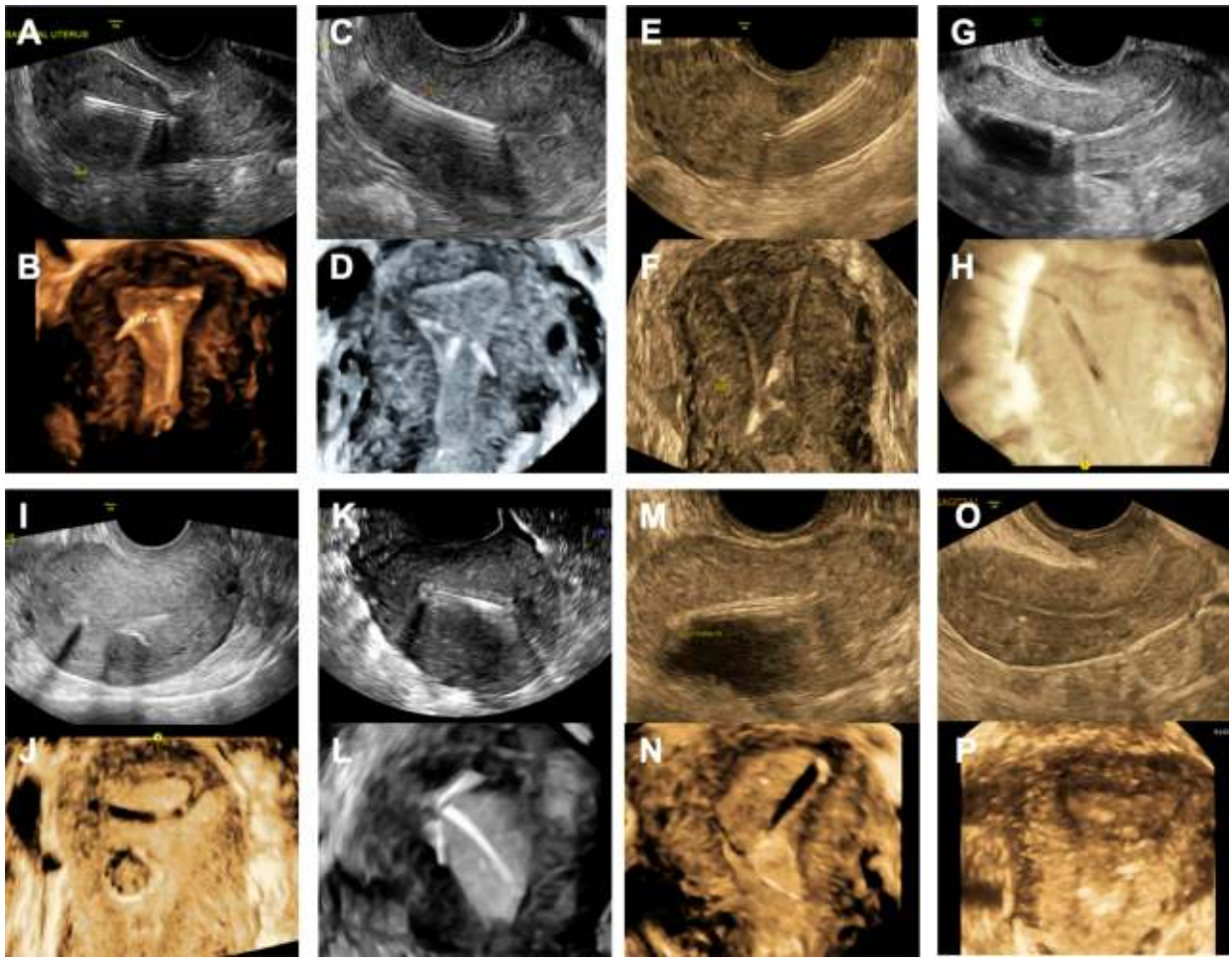
This can be associated with pain, bleeding, potentially decreased contraceptive efficacy, and expulsion.[2,7] IUD positioning was historically evaluated with a string check by the patient or physician after insertion and more recently with routine two-dimensional transvaginal ultrasound (2D TVUS). While 2D imaging can confirm intrauterine positioning, it is often difficult to visualize the arms of the IUD, and it has been shown that an IUD that appears to be correctly placed on 2D ultrasound may actually be embedded or otherwise malpositioned.[8] Furthermore, 2D ultrasound is inferior in detecting levonorgestrel-IUDs versus copper IUDs.[4]

With the emergence of three-dimensional TVUS (3D TVUS), a reconstructed coronal view of the uterus can be obtained. This allows for imaging of the entire IUD including both arms and its orientation within the uterine cavity, which provides an improved ability to detect subtle changes in positioning such as embedment and malrotation.[8-10] Three-dimensional imaging has also been shown to have significantly better diagnostic accuracy than 2D imaging[11] and allows measurement of uterine cavity width on the coronal plane, which is important for women who are nulliparous and have a narrower mean width that may not accommodate a standard IUD.[8] Despite these benefits, IUD placement is still not routinely evaluated with 3D ultrasound imaging by all physicians.

Prior studies suggested that uterine retroflexion, congenital uterine anomalies, fibroids, symptoms such as bleeding and pain, suspected adenomyosis, prior cesarean section, uterine diameter, endometrial thickness, higher body mass index (BMI), and breastfeeding are all associated with an increased risk for malpositioning.[2,3,5,6,12-16] However, few routinely used 3D TVUS to evaluate malpositioning and many were limited in scope, focusing only on specific subtypes of malpositioning (such as perforation or low in the uterine cavity) or examining a narrow array of risk factors.

The objective of our study was to estimate the rate of IUD malpositioning detected on routine 3D TVUS within 8 weeks of insertion in individuals with seemingly correct placement, including 2D ultrasound, and to identify risk factors for malpositioning

Figure 2. Different types of malpositioning identified on three-dimensional (3D) transvaginal ultrasound. **A** and **B**, Paragard (Copper IUD [Cu-IUD]) embedded in myometrium. **C** and **D**, Paragard (Cu-IUD) low in the uterine cavity. **E** and **F**, Paragard (Cu-IUD) in the endocervical canal. **G** and **H**, Liletta (levonorgestrel IUD [LNG-IUD] 52 mg) misaligned with the right arm of the IUD in the right fallopian tube. **I** and **J**, Liletta (LNG-IUD 52 mg) misaligned, transverse at the uterine fundus. **K** and **L**, Paragard (Cu-IUD) misaligned, with the arms of the IUD in the right cornua. **M** and **N**, Liletta (LNG-IUD 52 mg) misaligned, inverted in the uterine cavity. **O** and **P**, Paragard (Cu-IUD) perforation. 3D transvaginal ultrasound shows an empty uterine cavity. The IUD was located in the left adnexa.

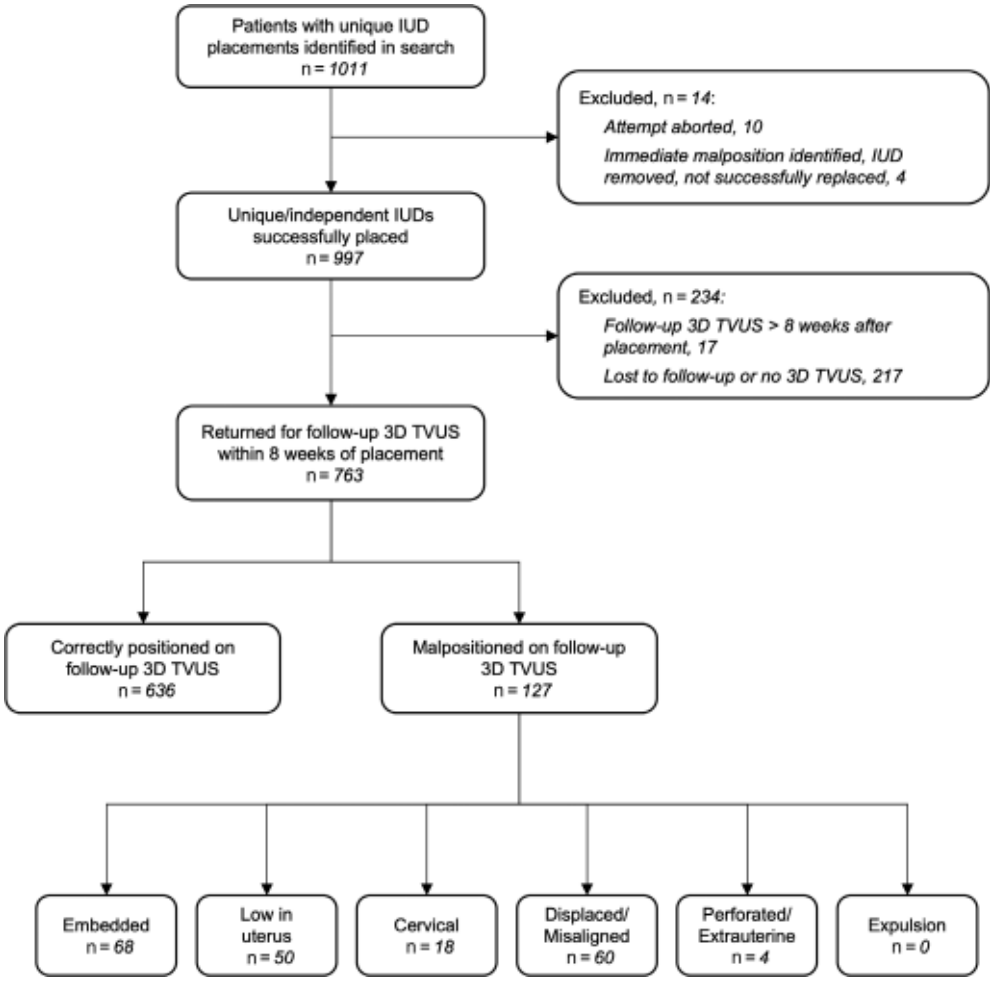


in a large cohort of women undergoing IUD placement in an outpatient setting.

Materials and Methods

This was a retrospective case–control study of women with an IUD placed at a single obstetrics and gynecology practice in New York City between January 1, 2015, and December 31, 2020. This human study was approved by the Biomedical Research Alliance of New York Institutional Review Board. The study had a waiver of informed consent, as it was a retrospective study. We identified all patients who had an IUD placed at our practice by querying our billing database for the current procedural terminology (CPT) code 58300 (IUD insertion). At our office, 2D bedside ultrasound is available and is used to verify IUD positioning immediately after insertion via a transabdominal and transvaginal approach, as needed. If positioning on 2D ultrasound appears abnormal, the IUD is removed and re-attempt at placement is

Figure 3. Flowchart depicting intrauterine device (IUD) placement inclusion and exclusion criteria. IUD malpositioning was categorized as embedded, low in the uterine cavity, endocervical, misaligned (including rotated, laterally displaced, cornual, transverse, inverted, transverse, arms folded or not deployed), perforated/extrauterine, and/or expulsed. IUDs could be categorized as multiple types of malpositioning.



performed at the discretion of the provider and patient. During the study period, we routinely recommended that all patients return for a follow-up 3D TVUS within 2 to 8 weeks of placement to verify correct positioning, in accordance with our practice's standard recommendation for all patients who undergo IUD placement.

All IUDs were placed by attending physicians board-certified or board-eligible in obstetrics and gynecology. All 3D ultrasounds were performed by sonographers certified by the Registry for Diagnostic Medical Sonography in an ultrasound unit accredited by the American Institute of Ultrasound in Medicine (AIUM) with AIUM 3D certification and were read by board-certified specialists in obstetrics and gynecology with subspecialty training in maternal fetal medicine and diagnostic ultrasound. Three-dimensional ultrasounds were performed using GE Voluson E6, E8, and E10 ultrasound machines.

For our study, we included patients with a confirmed IUD insertion who presented for a follow-up 3D TVUS within 8 weeks of insertion. Individual patients could be included in the study multiple times if they had unique IUD insertions separated temporally by IUD removal for any reason other than

malpositioning (eg, patient preference, desiring conception) within the study time period. We excluded failed attempts at IUD placement, patients who were lost to follow up, or those who came for a follow-up visit but did not receive a 3D TVUS for any reason, including gross malpositioning identified on pelvic examination or expulsion at home.

All images from the follow-up 3D TVUS as well as the accompanying report written by the physician who originally interpreted the scan were re-reviewed, and patients with malpositioned IUDs were identified as cases and patients who had correct IUD positioning were identified as controls. IUD positioning was determined to be correct if the IUD shaft was midline in the uterine cavity, the IUD arms were fully deployed at 90°, and the top of the IUD sat within 3–4 mm of the uterine cavity[3] (Figure 1). Any deviation from this position was considered a malpositioning and categorized as embedded, low in the uterine cavity, in the endocervical canal, misaligned, perforated, and expulsion (Figure 2). An IUD was considered embedded if the arms or shaft of the IUD penetrated into the myometrium but not through the serosa. An IUD was classified as low in the uterus if it was more than 3–4 mm from the uterine fundus and as cervical if any component was in the cervix. Misaligned IUDs encompassed any IUD that was rotated, laterally displaced, inverted, transverse, cornual, in the fallopian tube, or had arms that were folded or not fully deployed. Perforations included any IUD that penetrated through both the myometrium and serosa as well as IUDs that were completely extrauterine and/or intra-abdominal. An IUD was considered expulsed if it was completely expelled through the cervical os.

Demographic and baseline characteristics were collected from electronic medical records, including age, race, BMI, obstetrical history, postpartum or postabortion status, prior IUD placement, prior IUD malpositioning or failure, and standard versus difficult placement. Patients were considered postpartum if IUD placement occurred within 6 months of delivery and postabortion if placement occurred within 6 months of an abortion or pregnancy loss, including IUDs placed immediately after a dilation and curettage. At our practice, postpartum IUDs are placed at or just after the 6-week postpartum visit. No IUDs were placed at the time of delivery. An IUD insertion was defined as difficult if it required live transabdominal ultrasound guidance during placement, cervical stenosis was noted, multiple attempts were needed for placement, or the patient was brought to the operating room for placement under sedation. As we reviewed the ultrasound imaging and reports, we verified uterine positioning (retroverted, anteverted, or neutral), uterine dimensions (length, width, height, and volume), endometrial thickness, and absence or presence of any structural uterine anomalies. Uterine volume was calculated as length × width × height. We also collected data from the electronic medical records regarding symptoms, including the presence of bleeding and pain, patients reported at time of follow-up and the management course for malpositioned IUDs, including if the IUD was removed, if replacement was attempted, and how many attempts were ultimately required to attain correct positioning. The clinical decision to remove the IUD was made by the physician and patient together after considering the type of IUD, severity of malpositioning, likelihood malpositioning would affect contraceptive efficacy, and symptom presentation.

Our primary outcome was the overall rate of IUD malpositioning. Our secondary outcomes were subtypes of malpositioning as well as malpositioned IUDs that required removal. We compared baseline characteristics and potential risk factors between the case and control groups. Potential risk factor variables included presence of uterine anomalies, breastfeeding, prior

Table 1. Description of Malpositioned Intrauterine Devices (IUDs)

	All Malpositioned IUDs
Number of patients (n)	127/763 (16.6%; 95% CI 14.0–19.3)
Type of malposition	
Embedded in the myometrium	68 (53.5%)
Low in the uterine cavity	50 (39.4%)
In the endocervical canal	18 (14.2%)
Misaligned (rotated, laterally displaced, inverted, transverse, cornual, arms folded/not deployed)	60 (47.2%)
Perforation/Abdominal/ Extrauterine	4 (3.1%)
Expulsion	0 (0.0%)
Management	
Removed	67/127 (52.8%)
Not removed	60/127 (47.2%)

Data are presented as n (%).

Table 2. Risk Factors for Malpositioned Intrauterine Devices (IUDs)

	Controls, Correctly Positioned IUDs, n = 636	Cases, Malpositioned IUDs, n = 127	Odds Ratio (95% CI)
Age (years)	**34.66 ± 6.23**	**32.99 ± 6.08**	**0.96 (0.93, 0.99)**
White race	557/630 (88.4%)	111/124 (89.5%)	1.12 (0.60, 2.09)
BMI	25.27 ± 4.72	26.03 ± 5.16	1.03 (0.99, 1.07)
Obesity	83/628 (13.2%)	24/127 (18.9%)	1.53 (0.93, 2.52)
Morbid obesity	**24/628 (3.8%)**	**11/127 (8.7%)**	**2.39 (1.14, 5.01)**
Nulliparous	57 (9.0%)	11 (8.7%)	0.96 (0.49, 1.89)
Multiparous	579 (91.0%)	116 (91.3%)	1.04 (0.53, 2.04)
Prior vaginal delivery	452 (71.1%)	91 (71.7%)	1.03 (0.68, 1.57)
Prior cesarean delivery	220 (34.6%)	49 (38.6%)	1.19 (0.80, 1.76)
Prior term birth	541/632 (85.6%)	105/125 (84.0%)	0.88 (0.52, 1.50)
Prior preterm birth	172/632 (27.2%)	33/125 (26.4%)	0.96 (0.62, 1.48)
Multiples ever delivered	73 (11.5%)	16 (12.6%)	1.11 (0.62, 1.98)
Postpartum (delivery within 6 months)	**355 (55.8%)**	**84 (66.1%)**	**1.55 (1.04, 2.31)**
For postpartum only: Time between most recent delivery and IUD insertion (weeks)	9.83 ± 4.63	10.01 ± 5.68	1.01 (0.96, 1.06)
For postpartum only			
Most recent delivery vaginal	238/355 (67.0%)	60/84 (71.4%)	1.23 (0.73, 2.07)
Most recent delivery cesarean	117/355 (33.0%)	24/84 (28.6%)	0.81 (0.48, 1.37)
For postpartum only			
Most recent delivery singleton	325/355 (91.5%)	75/83 (90.4%)	0.87 (0.38, 1.96)
Most recent delivery twins	30/355 (8.5%)	8/83 (9.6%)	1.16 (0.51, 2.62)
For postpartum only			
Most recent delivery term	302/355 (85.1%)	67/83 (80.7%)	0.74 (0.40, 1.36)
Most recent delivery preterm	53/355 (14.9%)	16/83 (19.3%)	1.36 (0.73, 2.53)
For postpartum only			
Breastfeeding	227/355 (63.9%)	54/84 (64.3%)	1.02 (0.62, 1.67)
Postabortion/pregnancy loss within 6 months	22 (3.5%)	3 (2.4%)	0.68 (0.20, 2.29)
For postabortion only: Time since abortion (weeks)	5.59 ± 5.74	7.24 ± 2.40	1.05 (0.86, 1.28)
Uterine anomaly	10 (1.6%)	4 (3.1%)	2.04 (0.63, 6.60)
Fibroids	46 (7.2%)	4 (3.1%)	0.42 (0.15, 1.18)
History of short cervix	40 (6.3%)	11 (8.7%)	1.41 (0.70, 2.84)
History of cerclage	16 (2.5%)	6 (4.7%)	1.92 (0.74, 5.01)
Prior uterine rupture	**5 (0.8%)**	**5 (3.9%)**	**5.17 (1.48, 18.14)**
Prior uterine window	8 (1.3%)	3 (2.4%)	1.90 (0.50, 7.26)
Prior uterine rupture or window	**13 (2.0%)**	**8 (6.3%)**	**3.22 (1.31, 7.94)**
Prior cervical excision procedure (LEEP or cone)	22 (3.5%)	3 (2.4%)	0.68 (0.20, 2.29)
Prior IUD malposition or failure (ie, pregnancy)	25 (3.9%)	4 (3.1%)	0.80 (0.27, 2.32)
IUD placement requiring real-time ultrasound guidance	27 (4.2%)	8 (6.3%)	1.52 (0.67, 3.42)
Copper IUD	**293 (46.1%)**	**80 (63.0%)**	**1.99 (1.35, 2.95)**
Hormonal IUD	343 (53.9%)	47 (37.0%)	0.50 (0.34, 0.74)
IUD type			
Paragard	293 (46.1%)$^{+}$	80 (63.0%)$^{+}$	Reference
Mirena	187 (29.4%)$^{+}$	18 (14.2%)$^{+}$	0.353 (0.21, 0.61)
Liletta	135 (21.2%)	29 (22.8%)	0.787 (0.49, 1.26)
Skyla	17 (2.7%)	0 (0.0%)	NA
Kyleena	4 (0.6%)	0 (0.0%)	NA
Difficult placement	36 (5.7%)	10 (7.9%)	1.43 (0.69, 2.95)
Time from IUD insertion to follow up 3D ultrasound (days)	17.26 ± 7.06	16.15 ± 5.93	0.97 (0.94, 1.01)
Uterine positioning			
Anteverted	483 (75.9%)	107 (84.3%)	Reference
Retroverted	115 (18.1%)	16 (12.6%)	0.63 (0.36, 1.10)

(Continues)

Table 2. Continued

	Controls, Correctly Positioned IUDs, n = 636	Cases, Malpositioned IUDs, n = 127	Odds Ratio (95% CI)
Neutral	38 (6.0%)	4 (3.1%)	0.48 (0.17, 1.36)
Uterine length (cm)	7.70 ± 1.40	7.74 ± 1.34	1.02 (0.89, 1.17)
Uterine width (cm)	5.41 ± 1.00	5.42 ± 1.05	1.01 (0.83, 1.23)
Uterine height (cm)	4.19 ± 0.90	4.07 ± 0.84	0.86 (0.68, 1.08)
Uterine volume (cm^3)	185.73 ± 108.31	185.70 ± 93.86	1.00 (0.9, 1.002)
Endometrial thickness (mm)	5.88 ± 3.07	5.63 ± 3.14	0.97 (0.91, 1.04)
Symptomatic at time of follow up ultrasound	**118 (18.6%)**	**46 (36.2%)**	**2.49 (1.65, 3.77)**

Values in bold indicate statistical significance. Data are presented as mean ± standard deviation or n (%).
BMI, body mass index; IUD, intrauterine device; LEEP, loop electrosurgical excision procedure.

gynecologic procedures, postpartum or postabortion status, uterine size and positioning, presence or absence of symptoms, and IUD type. IUD types included the copper IUD (Paragard, CooperSurgical, Inc., Trumbull, CT), levonorgestrel-releasing 52 mg IUD (Mirena, Bayer HealthCare Pharmaceuticals Inc., Whippany, NJ), levonorgestrel-releasing 52 mg IUD (Liletta, Odyssea Pharma, SPRL, Belgium), levonorgestrel-releasing 13.5 mg IUD (Skyla, Bayer HealthCare Pharmaceuticals Inc., Whippany, NJ), and levonorgestrel-releasing 19.5 mg IUD (Kyleena, Bayer HealthCare Pharmaceuticals Inc., Whippany, NJ). Fibroids were documented only if seen on transvaginal ultrasound at time of IUD follow-up to best ensure accuracy given the dynamic nature of fibroids in response to hormonal changes over time. Uterine rupture and uterine window were determined by direct visualization and report if the cesarean was done by our practice and by reviewing operative reports if the cesarean was performed by an outside provider. Uterine anomalies included arcuate uterus, septate uterus, bicornuate uterus, unicornuate uterus, and uterine didelphys and did not include adenomyosis, fibroids, or uterine polyps. Overweight was defined as a BMI ≥25 kg/m^2, obesity as a BMI ≥30 kg/m^2, and morbid obesity as BMI ≥35 kg/m^2. We performed a second analysis identifying cases as malpositioned IUDs removed and controls as correctly positioned IUDs plus malpositioned IUDs not requiring immediate removal and compared baseline characteristics and risk factors between these two groups.

Statistical analysis was conducted using IBM SPSS software version 27 (SPSS, Chicago, IL). Chi-square, Fisher's exact, and independent samples *t*-test were used, as indicated, and logistic regression was used to estimate crude odds ratios and 95% confidence intervals (CIs). Odds ratios for continuous variables were calculated and represent a change in odds for each unit of the variable. For example, for BMI the odds ratio reflects a change in odds for each 1 kg/m^2. A multiple logistic regression was then performed using the enter method to identify risk factors independently associated with malpositioning and malpositioning necessitating removal. Assessment of model fit for the regression was assessed with the Hosmer-Lemeshow goodness of fit test. For all analyses, a *P*-value <.05 was considered to be statistically significant.

Table 3. Multivariate Logistic Regression for Malpositioned Intrauterine Devices (IUDs)

	Unadjusted Odds Ratio (95% CI)	Adjusted Odds Ratio(95% CI)
Age	0.96 (0.93, 0.99)	0.97 (0.94, 1.00)
Morbid obesity	2.39 (1.14, 5.01)	2.46 (1.10, 5.50)
Postpartum (within 6 months of delivery)	1.55 (1.04, 2.31)	1.11 (0.72, 1.70)
Prior uterine rupture or window	3.22 (1.31, 7.94)	2.78 (1.06, 7.30)
Copper IUD	1.99 (1.35, 2.95)	1.99 (1.31, 3.03)
Symptomatic at time of follow up ultrasound	2.49 (1.65, 3.77)	2.58 (1.67, 3.98)

Results

A total of 1011 unique IUD placements were identified at our practice during the study period. Of these, 997 IUD placements were successfully completed without an immediate malposition identified

Table 4. Risk Factors for Malpositioned Intrauterine Devices (IUDs) Requiring Removal

	Controls, Correctly Positioned + Malpositioned IUDs Not Removed, n = 696	Cases, Malpositioned IUDs Removed, n = 67	Odds Ratio (95% CI)
Age (years)	**34.59 ± 6.19**	**32.20 ± 6.29**	**0.94 (0.90, 0.98)**
White race	609/687 (88.6%)	59/67 (88.1%)	0.95 (0.44, 2.05)
BMI	25.31 ± 4.68	26.30 ± 5.83	1.04 (0.99, 1.09)
Obesity	**92/688 (13.4%)**	**15/67 (22.4%)**	**1.87 (1.01, 3.46)**
Morbid obesity	**26/688 (3.8%)**	**9/67 (13.4%)**	**3.95 (1.77, 8.83)**
Nulliparous	64 (9.2%)	4 (6.0%)	0.63 (0.22, 1.78)
Multiparous	632 (90.8%)	64 (94.0%)	1.60 (0.56, 4.53)
Prior vaginal delivery	497 (71.4%)	46 (68.7%)	0.88 (0.51, 1.51)
Prior cesarean delivery	**238 (34.2%)**	**31 (46.3%)**	**1.66 (1.00, 2.75)**
Prior term birth	587/690 (85.1%)	59/67 (88.1%)	1.29 (0.60, 2.79)
Prior preterm birth	186/690 (27.0%)	19/67 (28.4%)	1.07 (0.61, 1.87)
Multiples ever delivered	81 (11.6%)	8 (11.9%)	1.03 (0.48, 2.23)
Postpartum (within 6 months of delivery)	**387 (55.6%)**	**52 (77.6%)**	**2.77 (1.53, 5.01)**
For postpartum only: Time between most recent delivery and IUD insertion (weeks)	9.95 ± 4.78	9.24 ± 5.28	0.97 (0.91, 1.03)
For postpartum only			
Most recent delivery vaginal	263/387 (68.0%)	35/52 (67.3%)	0.97 (0.52, 1.80)
Most recent delivery cesarean	124/387 (32.0%)	17/52 (32.7%)	1.03 (0.56, 1.91)
For postpartum only			
Most recent delivery singleton	352/386 (91.2%)	48/52 (92.3%)	1.16 (0.39, 3.41)
Most recent delivery twins	34/386 (8.8%)	4/52 (7.7%)	0.86 (0.29, 2.54)
For postpartum only			
Most recent delivery term	329/386 (85.2%)	40/52 (76.9%)	0.58 (0.29, 1.17)
Most recent preterm	57/386 (14.8%)	12/52 (23.1%)	1.73 (0.86, 3.50)
For postpartum only			
Breastfeeding	249/387 (64.3%)	32/52 (61.5%)	0.89 (0.49, 1.61)
Postabortion/pregnancy loss within 6 months	24 (3.4%)	1 (1.5%)	0.42 (0.06, 3.19)
For postabortion only: Time since abortion (weeks)	5.78 ± 5.55	6.00 (n = 1)	1.01 (0.70, 1.45)
Uterine anomaly	12 (1.7%)	2 (3.0%)	1.75 (0.38, 8.01)
Fibroids	48 (6.9%)	2 (3.0%)	0.42 (0.10, 1.75)
History of short cervix	46 (6.6%)	5 (7.5%)	1.14 (0.44, 2.97)
History of cerclage	18 (2.6%)	4 (6.0%)	2.39 (0.79, 7.28)
Prior uterine rupture	**6 (0.9%)**	**4 (6.0%)**	**7.30 (2.01, 26.56)**
Prior uterine window	9 (1.3%)	2 (3.0%)	2.35 (0.50, 11.10)
Prior uterine rupture or window	**15 (2.2%)**	**6 (9.0%)**	**4.47 (1.67, 11.93)**
Prior cervical excision procedure (LEEP or cone)	24 (3.4%)	1 (1.5%)	0.42 (0.06, 3.19)
Prior IUD malposition or failure (ie, pregnancy)	26 (3.7%)	3 (4.5%)	1.21 (0.36, 4.10)
IUD placement requiring real-time ultrasound guidance	**28 (4.0%)**	**7 (10.4%)**	**2.78 (1.17, 6.64)**
Copper IUD	**330 (47.4%)**	**43 (64.2%)**	**1.99 (1.18, 3.35)**
Hormonal IUD	366 (52.6%)	24 (35.8%)	0.50 (0.30, 0.85)
IUD type			
Paragard	330 (47.4%)[+]	43 (64.2%)[+]	Reference
Mirena	196 (28.2%)[+]	9 (13.4%)[+]	0.352 (0.17, 0.74)
Liletta	149 (21.4%)	15 (22.4%)	0.773 (0.42, 1.43)
Skyla	17 (2.4%)	0 (0.0%)	NA
Kyleena	4 (0.6%)	0 (0.0%)	NA
Difficult placement	**38 (5.5%)**	**8 (11.9%)**	**2.35 (1.05, 5.27)**
Time from IUD insertion to follow up ultrasound (days)	**17.26 ± 7.09**	**15.19 ± 3.97**	**0.94 (0.89, 0.99)**
Uterine positioning			
Anteverted	537 (77.2%)	53 (79.1%)	Reference

(Continues)

Table 4. Continued

	Controls, Correctly Positioned + Malpositioned IUDs Not Removed, n = 696	Cases, Malpositioned IUDs Removed, n = 67	Odds Ratio (95% CI)
Retroverted	119 (17.1%)	12 (17.9%)	1.02 (0.53, 1.97)
Neutral	40 (5.7%)	2 (3.0%)	0.51 (0.12, 2.16)
Uterine length (cm)	7.70 ± 1.40	7.78 ± 1.33	1.05 (0.87, 1.25)
Uterine width (cm)	5.39 ± 1.00	5.56 ± 1.09	1.18 (0.92, 1.51)
Uterine height (cm)	4.17 ± 0.90	4.14 ± 0.87	0.96 (0.72, 1.28)
Uterine volume (cm^3)	184.92 ± 107.13	194.13 ± 93.82	1.00 (1.00, 1.00)
Endometrial thickness (mm)	5.85 ± 3.09	5.67 ± 3.00	0.98 (0.90, 1.07)
Symptomatic at time of follow up ultrasound	**140 (20.1%)**	**24 (35.8%)**	**2.22 (1.30, 3.78)**

Values in bold indicate statistical significance. Data are presented as mean ± standard deviation or n (%).
BMI, body mass index; IUD, intrauterine device; LEEP, loop electrosurgical excision procedure.

necessitating removal, and 763 returned for a follow-up 3D TVUS within 8 weeks of placement (Figure 3). The distribution of IUD malpositioning and removal of these IUDs are shown in Table 1. There were 127 malpositioned IUDs (16.6%, 95% CI 14.0–19.3) and 67 required removal (8.8%, 95% CI 6.8–10.8). The most common category was embedment in the myometrium (53.5%) followed by misalignment (47.2%), low in the uterine cavity (39.4%), migrated into the cervix (14.2%), and perforated or extrauterine (4.1%). No expulsions were identified on 3D TVUS, as these patients presented with gross expulsion on pelvic examination or expulsion at home that did not warrant a 3D ultrasound. The 248 patients excluded from the study had similar characteristics to the patients included except for higher rates of history of cesarean delivery and prior spontaneous abortion (online supplemental Appendix 1).

Comparison between case and control groups are displayed in Table 2 and the results of the regression analysis are shown in Table 3. Risk factors independently associated with malpositioned IUD were morbid obesity (8.7% versus 3.8%; adjusted odds ratio [aOR] 2.462, 95%, CI 1.10–5.50), prior uterine window or rupture (6.3% versus 2.0%; aOR 2.78, 95% CI 1.06–7.30), copper IUD versus levonorgestrel-IUD placement (63.0% versus 46.1%; aOR 1.99, 95% CI 1.31–3.031), and symptom presence at time of follow-up (36.2% versus 18.6%; aOR 2.58, 95% CI 1.67–3.98). Parity, prior vaginal delivery, prior cesarean delivery, prior delivery of multiples, breastfeeding, congenital uterine anomaly, fibroids, history of short cervix or cerclage, prior cervical excision procedure, difficult placement, and uterine size and positioning were not significant risk factors for malpositioning.

Table 5. Multivariate Logistic Regression for Malpositioned Intrauterine Devices (IUDs) Requiring Removal

	Unadjusted Odds Ratio (95% CI)	Adjusted Odds Ratio (95% CI)
Age	0.94 (0.90, 0.98)	0.95 (0.90, 0.99)
Obesity	1.87 (1.01, 3.46)	0.90 (0.35, 2.28)
Morbid obesity	3.95 (1.77, 8.83)	4.40 (1.31, 14.75)
Prior cesarean delivery	1.66 (1.00, 2.75)	1.36 (0.76, 2.45)
Postpartum (within 6 months of delivery)	2.77 (1.53, 5.01)	1.83 (0.96, 3.47)
Prior uterine rupture or window	4.47 (1.67, 11.93)	2.61 (0.78, 8.75)
IUD placement requiring real-time ultrasound guidance	2.78 (1.17, 6.64)	1.95 (0.28, 13.67)
Copper IUD	1.99 (1.18, 3.35)	1.67 (0.95, 2.95)
Difficult placement risk factor	2.35 (1.05, 5.27)	1.12 (0.18, 6.89)
Time from IUD insertion to follow up ultrasound (days)	0.94 (0.89, 0.99)	0.94 (0.89, 0.99)
Symptomatic at time of follow up ultrasound	2.22 (1.30, 3.78)	2.07 (1.17, 3.68)

Comparisons between patients who did and did not require IUD removal are shown in Tables 4 and 5. Risk factors independently associated with malpositioned IUD requiring removal were younger age (32.20 ± 6.29 versus 34.59 ± 6.19; aOR 0.945, 95% CI 0.901–0.991), morbid obesity (13.4% versus 3.8%; aOR 4.40, 95% CI 1.31–14.75), shorter time from IUD insertion to follow up ultrasound (15.2 ± 4.0 versus

17.3 ± 7.1 days; aOR 0.94, 95% CI 0.89–0.99), and presence of symptoms on follow-up (35.8% versus 20.1%; aOR 2.07, 95% CI 1.17–3.68). Parity, prior vaginal delivery, prior delivery of multiples, breastfeeding, congenital uterine anomaly, fibroids, history of short cervix or cerclage, prior cervical excision procedure, and uterine size and positioning were not associated with malpositioning requiring removal.

For both the malpositioned IUD cohort and malpositioned IUD requiring removal cohort, we attempted to examine the significance of prior myomectomy, Asherman's syndrome, uterine prolapse, history of menorrhagia, endometriosis, prior uterine septum resection, prior endometrial polypectomy, and adenomyosis as risk factors, but these variables were too rare in each study population (<2% incidence) to result in a meaningful comparison.

Discussion

In this study, we found an overall rate of IUD malpositioning of 16.6% and a rate of IUD malpositioning requiring removal of 8.8% in patients who had a seemingly correct IUD placement at time of insertion, including on 2D TVUS. Morbid obesity, prior uterine window or rupture, placement of a copper IUD, and presence of symptoms at time of follow-up ultrasound were significant risk factors for malpositioning. Patients who had malpositioned IUDs that were ultimately removed also had higher rates of morbid obesity and symptoms at follow-up and were significantly younger and had a shorter time from IUD insertion to follow-up ultrasound. Our study reinforces the significance of IUD malpositioning detected on 3D ultrasound and identifies novel risk factors for malpositioned IUDs more likely to require removal.

Overall, our malpositioning rate was similar to that reported in the literature. Our results also reinforced several risk factors that have been demonstrated by prior studies. Presence of symptoms at time of follow was associated with both an increased risk of overall malpositioning and malpositioning prompting removal, consistent with studies by Gerkowicz et al and Benacerraf et al that also showed associations between vaginal bleeding and pain and IUD malpositioning.[3,5] We also found that morbid obesity was a significant independent risk factor for both overall malpositioning and malpositioning necessitating removal. A prior cross-sectional study by Moshesh et al had previously demonstrated a dose–response pattern of increased risk of malpositioning with increasing BMI.[6] However, this study only examined IUDs low in the uterine cavity or in the cervix. Morbid obesity may contribute to a more difficult initial placement secondary to body habitus or poor ultrasound imaging needed during insertion, as it is known that obesity can negatively impact imaging quality of both 2D and 3D ultrasonography.[8] It is also possible that obesity may independently contribute to increased rates of IUD migration over the first several weeks following placement. Our finding that postpartum status is not associated with an increased risk of malpositioning is reassuring and supports the findings of Braaten et al that IUD malpositioning was not associated with insertion at 6–9 weeks postpartum.[2] Furthermore, we did not find a relationship between postpartum patients' most recent delivery (vaginal versus cesarean delivery, singleton versus twin birth, or term versus preterm delivery) and malpositioning, which further supports the safety of placing an IUD during the postpartum period.

Our findings also identified several unique risk factors and opposed other risk factors acknowledged in previous studies. Specifically, history of uterine window or rupture was a novel finding associated with an increased risk of IUD malpositioning. The etiology underlying this association between prior uterine window or rupture and malpositioning is unclear. Because uterine rupture and window disrupt the integrity of the myometrium, it is possible that these uteri at baseline have less integrity and ability to withstand IUD migration. The subtypes of malpositioning associated with uterine window and rupture were embedded, low in the uterus, cervical, and misaligned. Interestingly, prior cesarean delivery, which also disrupts the myometrium, was not associated with an increased risk of malpositioning, and perforation was not a subtype of malpositioning associated with uterine rupture or window. A prior study had shown that higher rates of cesarean delivery were found in patients who had translocation of IUDs, but in our study we found that on regression analysis cesarean delivery was no longer significant for malpositioning requiring removal.[12]

Uterine size and positioning has been more extensively studied, with findings linking endometrial

thickness of 7.5 mm,[15] uterine retroflexion,[3] and a smaller fundal endometrial cavity diameter[14] with higher rates of malpositioning. A separate study found that nulliparous women had uterine cavity widths that were usually too narrow to accommodate the average IUD width.[17] While we found that placement of a copper IUD (width of 32 mm) is a risk factor for overall malpositioning, we did not find a significant relationship between uterine positioning, width, volume, or parity and IUD positioning. Furthermore, breastfeeding has been considered a risk factor in the past, with one study showing an increased risk of perforation in lactating patients.[16] However, we did not find any evidence to support an association between malpositioning and breastfeeding in our postpartum cohort.

While our overall rate of malpositioning was similar to previously reported rates in the literature, it may in fact reflect an overall higher than expected rate considering all women had 2D ultrasound immediately after IUD placement. This suggests that either 3D ultrasound can identify malpositioning not discernable on 2D ultrasound or IUDs can be placed correctly and then migrate to a different position over the next several weeks. We believe our data supports both of these possibilities, as many of the malpositioned IUDs seen on 3D imaging appear to be appropriately positioned on 2D ultrasound sagittal views (Figure 2). Our findings support the use of 3D imaging to assess IUD positioning, as well as some form of routine follow-up to confirm correct placement. Moreover, we found that parity, breastfeeding status, uterine size and positioning, and difficulty of insertion were not significant risk factors whereas prior uterine window or rupture, morbid obesity, and copper IUD placement were associated with higher rates of malposition. We believe this information can assist physicians in counseling patients prior to IUD placement on their risks of malpositioning and help identify which patients are more suitable candidates for an IUD.

Strengths of our study include a large sample size drawn from a single practice that followed a standardized follow-up ultrasound protocol post-IUD placement. Our 3D ultrasound imaging data is drawn from patients who were all brought in for routine ultrasound follow-up within 8 weeks of placement rather than follow-up for any other gynecologic indication. Moreover, by including all patients who were brought in for TVUS follow-up in the last 5 years and assigning them to the case and control groups as IUD positioning indicated, we limited potential selection bias in our case–control study design. Our practice also includes a significant obstetrics and maternal-fetal medicine component, which allowed our study to include a relatively large number of 439 postpartum IUD placements, comprising 57.5% of our study population.

In addition, our secondary analysis of malpositioned IUDs requiring removal versus correctly positioned IUDs plus malpositioned IUDs not removed is unique in attempting to identify which risk factors are specifically associated with higher rates of malpositioning requiring removal and may therefore be of higher clinical significance. In doing so, we believe that the risk factors we have identified are particularly relevant to clinical practice in helping to risk-stratify patients who would be low versus high-risk candidates for IUDs. There are few evidence-based management guidelines for patients with malpositioned IUDs and general uncertainty surrounding whether malpositioned IUDs should be removed, as demonstrated by a survey study of physicians by Golightly et al,[18] and our study design is well-suited to help inform these decisions.

Our study was limited by its retrospective design. Not all patients returned for follow-up ultrasound potentially representing selection bias. Our study was also not designed to track IUD migration after insertion, as our practice did not routinely recommend or follow patients with additional 3D ultrasounds after the first 3D TVUS. Therefore, we could not comment on the utility of expectant management and the potential for IUD malpositioning to spontaneously "resolve" or for correctly positioned IUDs to migrate after the 8 week study period. Furthermore, we did not track IUD failure or pregnancy rates, and it is uncertain which malpositioned IUD subtypes may ultimately reduce contraceptive efficacy and, if so, by how much. The ideal frequency and interval for 3D ultrasound assessments and whether they should be determined or differ by risk factor, such as IUD type or postpartum status, is unknown. Finally, our study population was mostly white, multiparous, and nonobese, which may limit the generalizability of our study.

In conclusion, the incidence of malpositioned IUD on 3D ultrasound within 8 weeks of insertion in patients who had seemingly successful placement is 16.6%, with 8.8% requiring removal. Significant risk factors for malposition include morbid obesity, prior uterine window or rupture, copper IUD placement, and symptoms of bleeding or pain at time of

follow-up. Our findings support the use of routine three-dimensional ultrasound follow-up to assess IUD positioning especially for patients with risk factors for malpositioning, although future studies are needed to examine rates of IUD migration after 8 weeks and the optimal frequency and interval for follow-up.

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