

UC Davis

UC Davis Previously Published Works

Title

Understanding the mechanical behavior of intrauterine devices during simulated removal

Permalink

<https://escholarship.org/uc/item/0n15t07w>

Authors

La Saponara, Valeria

Wan, Shuhao

Nagarkar, Bhagyashree

et al.

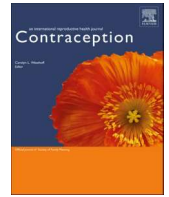
Publication Date

2024-05-01

DOI

10.1016/j.contraception.2024.110399

Peer reviewed



Understanding the mechanical behavior of intrauterine devices during simulated removal^{☆,☆☆}



Valeria La Saponara^a, Shuhao Wan^a, Bhagyashree Nagarkar^a, Faress Zwain^a, Mitchell D. Creinin^{b,*}

^a Department of Mechanical and Aerospace Engineering, University of California, Davis, Davis, CA, USA

^b Department of Obstetrics and Gynecology, University of California, Davis, Sacramento, CA, USA

ARTICLE INFO

Article history:

Received 4 February 2024

Accepted 11 February 2024

Keywords:

Force
Fracture
Intrauterine device
Strain
Stress

ABSTRACT

Objective: To evaluate differences based on intrauterine device (IUD) frame geometry in force, and stress, and strain at the stem/arms junction during simulated IUD removal.

Study design: We manufactured injection-molded frame models for three Nova-T IUDs (Mirena [model M]; Liletta [model L]; Kyleena [model K]) and a Tatum-T IUD (Paragard [model P]) at two-times scaling. We created a custom fixture to simulate the uterus and used a screw-driven machine to pull models at various displacement rates through the 10 cm fixture cavity to measure force and strain and calculate stress at the IUD stem/arms junction. We tested models at 30 mm/min and higher displacement rates for exploratory analyses. We used Mann-Whitney U test for statistical testing.

Results: We completed testing at 30 mm/min using five of each Nova-T model and nine model P samples. Resistance against the cavity walls created significantly more force on model P (11.83, interquartile range [IQR] 11.61–12.31) than any Nova-T model samples ($p < 0.001$). The smaller model K created slightly more median stress (MPa) than the larger model M (0.36 [IQR 0.33–0.38] and 0.79 [IQR 0.76–0.80], respectively, $p = 0.008$); model P samples generated significantly more median stress than other models (1.70 [IQR 1.67–1.77], $p < 0.001$). Strain plots demonstrated permanent deformation for some samples during IUD removal simulation. We tested 20 samples at various higher displacement rates up to 2500 mm/min, with stress notably increasing for model P samples with increasing rates. No fractures occurred.

Conclusions: Force and stress at the stem/arms junction are higher with Tatum-T-shaped compared to Nova-T-shaped IUD models under the same testing conditions, and a higher speed of extraction causes more stress.

Implications: Sharp corners create vulnerability under static and fatigue loading in structural components due to increased local stresses. Our findings suggest that IUDs with Tatum-T frames should be removed slowly to minimize the stress at the stem/arms junction. Future studies can provide more information if performed with commercially available products.

© 2024 Elsevier Inc. All rights reserved.

* Conflicts of Interest: Dr. Creinin is a consultant for Medicines360. The Department of Obstetrics and Gynecology, University of California, Davis, receives contraceptive research funding for Dr. Creinin from Medicines360 and Sebel. All other authors report no conflicts of interest.

** Funding: University of California, Davis Department of Obstetrics and Gynecology Family Planning Research Funds. No pharmaceutical companies supplied study product or were involved in the conduct of the study.

* Corresponding author.

E-mail address: mdcreinin@ucdavis.edu (M.D. Creinin).

1. Introduction

The first intrauterine devices (IUDs), developed in the early 1900s, came in various shapes and sizes that did not match the shape of the uterine cavity [1]. The configurations caused significant pain, heavy bleeding, and expulsion, which researchers hypothesized was from the uterus trying to conform to the IUD. In 1967, Howard Tatum developed a T-shaped IUD to allow the IUD to conform to the uterine cavity, resulting in fewer expulsions and removals compared to other inert plastic IUDs [1,2]. In 1969, Zipper et al. [3] reported improved effectiveness by adding copper to the new IUD, creating the new “Tatum-T” copper IUD.

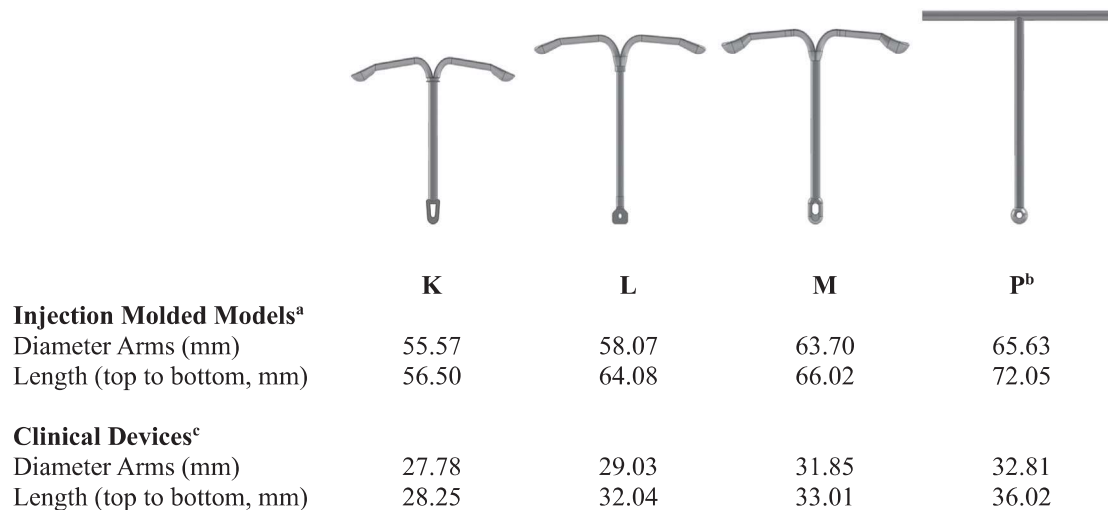


Fig. 1. Computer-aided design drawings of intrauterine device model frames. K: Kyleena; L: Liletta; M: Mirena; P: Paragard. ^aModels are scaled up samples used for study testing. ^bThe eyelet for the model is modified to be located axially; the eyelet in the Paragard clinical devices is slightly off-axis. Clinical devices were purchased commercially available products used to create the samples through computer-aided design/computer-aided manufacturing.

Over the next decade, Finnish researchers developed a variation of the T-frame shape to minimize displacement and maintain fundal position, hoping these changes would result in lower copper IUD pregnancy rates [4]. The new “Nova-T” frame was more flexible and the arms bent up for loading, opposite the Tatum-T. In 1977, investigators first reported using this new frame with the stem holding a silastic rate-controlling membrane containing norgestrel for hormone delivery [5].

IUDs with these frames are the only ones marketed in the U.S. today, with the available copper IUD on a Tatum-T frame and the 4 available hormonal IUDs on a Nova-T frame. A rare complication of these IUDs is fracture, noted typically at the time of removal. A recent Food and Drug Administration Adverse Event Reporting System database evaluation for IUD breakage reports from 1998 through February 2022 found Tatum-T frame copper IUDs had greater odds of breakage compared to Nova-T hormonal IUDs (adjusted OR 1.93 [95% CI 1.74–2.15]) [6]. From 2014–2021, annual breakage reports were approximately two- to four-fold higher for copper IUDs. We lack contemporary evaluations of the frames to understand any inherent structural issues that may contribute to fracture. We performed this study using injection-molded models to evaluate differences based on frame geometry in force (load), stress (force/unit area), and strain (deformation) at the stem/arms junction to help us better understand potential inherent causes of breakage.

2. Materials and methods

2.1. IUD models

We manufactured injection-molded models for the frames of both commercially available levonorgestrel 52 mg IUDs, Mirena (Bayer Healthcare, Whippany, NJ [model M]) and Liletta (Medicines360 and Abbvie, San Francisco, CA and North Chicago, IL [model L]), the levonorgestrel 19.5 mg IUD, Kyleena (Bayer Healthcare, Whippany, NJ [model K]), and the copper 380 mm² IUD, Paragard (Cooper Surgical, Trumbull CT [model P]). The models and their dimensions are demonstrated in Figure 1. According to World Health Organization (WHO) documentation, the copper 380 mm² IUD T frame must include a blend of low-density polyethylene (LDPE) with mechanical properties of density of 0.92 g/cm³, an elongation at break of 600%, tensile strength of 13 MPa, and a 15%–25% content of barium sulfate [7,8]. Although Nova-T frames are

also LDPE, we could find no similar standardized structural requirements.

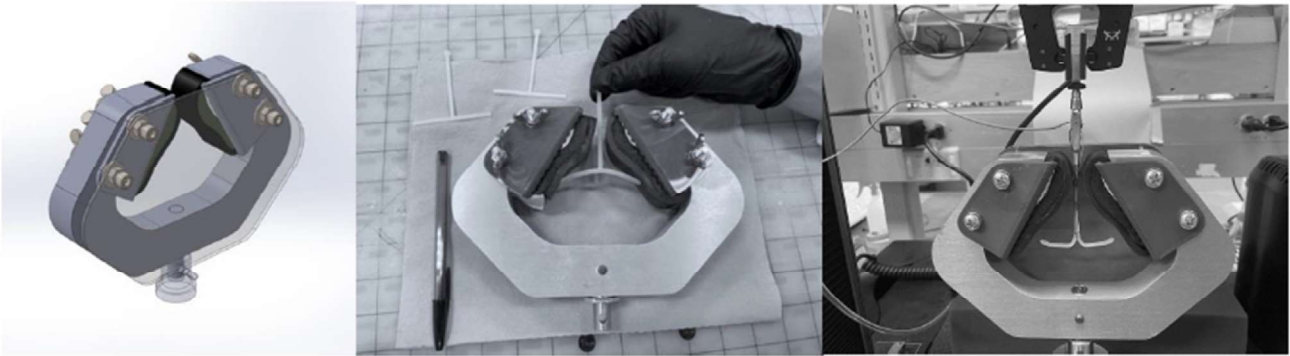
To mold the models, we used LDPE pellets (LDPE 20, type PPR-LDPE02, Premier Plastic Resins, MI, USA) commercially available for purchase for laboratory testing. We attempted to match the WHO recommended properties [7] as closely as possible; our LDPE had elongation at break of 300%, density of 0.92 g/cm³, and nominal tensile strength at yield of 10 MPa. Our materials had an elongation less than the WHO recommended materials and the same density; the tensile strength was slightly less than the WHO-recommended 13 MPa. Overall, these differences would favor a slightly higher chance of breakage with the injection-molded models compared to any manufactured using WHO recommended materials. Because barium sulfate is incorporated for X-ray opacity and not for stress bearing, we did not acquire barium sulfate-loaded LDPE. Barium sulfate-loaded LDPE used for commercial IUD production is solid white while our models were semi-transparent, which allowed visual inspections with a 150 W focused halogen light for imperfections. For the injection molding process, we used computer-aided design/computer-aided manufacturing (CAD/CAM) drawings (Solidworks, Dassault Systèmes, Waltham, MA) to reverse engineer the geometries of the entire frame, including the ring where the thread is attached. To accommodate strain sensors which would not fit actual size IUDs, we used the CAD/CAM drawings to create injection-molded models with a scale-up to increase the diameter by a factor of 2 (Fig. 1), resulting in models with arms/stem junction areas measured at the narrowest part of the joint of 1.32 × 10⁻⁵ m² for Model M, 1.29 × 10⁻⁵ m² for Model L, 6.79 × 10⁻⁶ m² for Model K, and 6.94 × 10⁻⁶ m² for Model P. We noted that the Paragard frame eyelets are off-axis, while all Nova-T devices are axial. For our injection-molded models, we changed the location of the model P eyelet to be in the center of the axis to allow all models to have the same symmetric boundary and axial loading conditions during testing.

After using standard procedures for surface cleaning and preparation, we secured strain sensors, on the stem/arms junction of each model, and connected them to the strain acquisition equipment (Online Appendix 1, Fig. 1).

2.2. Mechanical testing instrumentation and procedures

The full mechanical testing details are described in Online Appendix 1. We first designed and machined a custom-made fixture to simulate the uterus (Fig. 2; Online Appendix 1, Fig. 2). The fixture

A



B

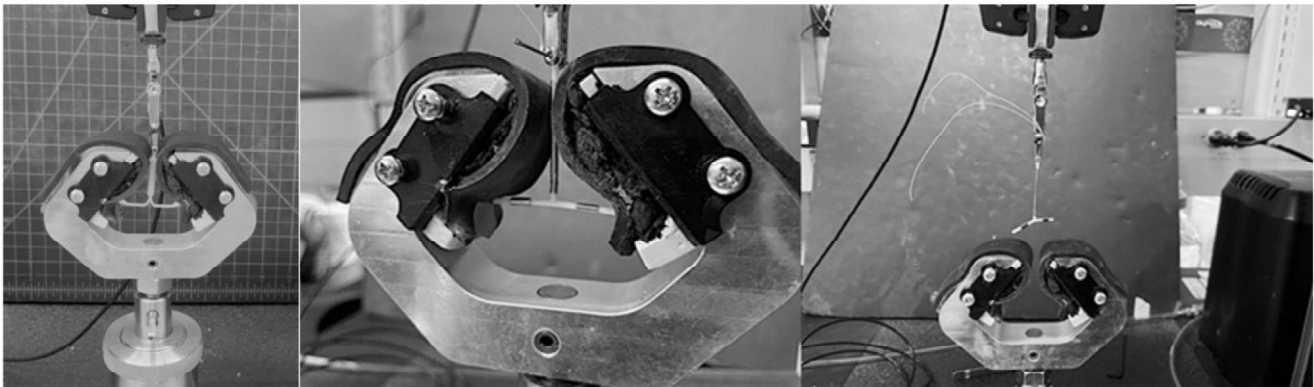


Fig. 2. Custom fixtures used to simulate the uterus and measure IUD model stress and strain. (A) Fixtures for injection-molded IUD model testing. Left: computer model; Middle: fixture with injection-molded Tatum-T shaped model. Right: fixture aligned with testing equipment and an injection-molded Nova-T shaped model. (B) Fixtures for clinical IUD testing. Left: fixture with Mirena IUD; Middle: Paragard IUD placed symmetrically in the fixture; Right: Paragard IUD twisting during removal. IUD = intrauterine device.

was lined with polyurethane with nominal tensile strength of 1.03 MPa, approximating the mechanical properties of the uterus [9–11]. We programmed an instrumented screw-driven testing machine (Instron 5965 model) to pull the model at various displacement rates.

The two data acquisition machines (Online Appendix 1, Fig. 3) measured force (or load, the effort needed to remove the IUD model from the fixture) and strain (deformation of material at the stem/arms junction). With these measurements, we could calculate stress (force per unit area where the strain gauge was attached at the junction) along the IUD axis; because each IUD is a different size, this calculation allows comparisons between IUDs. In addition, the equipment measured time and displacement as quality control to verify the removal rate over a set distance of 100 mm.

All tests started with the IUD models placed at the same position with respect to the fixture, with no interference with the fixture walls, and zero force (load). The total distance for the model to travel was 100 mm, with the model beginning to touch the fixture walls at 10 mm and exiting the fixture before 100 mm, depending on the model length.

To guide displacement rates for testing, we reviewed WHO specifications for testing LDPE mechanical properties. These specifications do not require LDPE testing in the shape of an IUD frame but, rather, recommend using an ASTM International Standard D638 Type I rectangular “specimen bar” with a 50 mm/min displacement rate [8]. Conversely, the ASTM International Standard Test Method for Tensile Properties of Plastics specifies that the displacement rate for testing should be the slowest of those required for the rectangular geometry (namely 5, 50 or 500 mm/min), which will give

rupture between 0.5 and 5 minutes of testing [12]. We planned initial testing to select a displacement rate for evaluation of a geometric IUD frame (rather than a rectangle) that would allow enough strain data points at a sampling rate of 2 Hz for the primary analyses and allow syncing of the two data acquisition machines.

We performed the first three tests at different displacement rates using models randomly selected from those initially available to identify a best rate. After testing a model M at 20 mm/min, a model P at 30 mm/min, and a model M at 50 mm/min, we selected the 30 mm/min speed as optimal for data collection.

Our goal was to test five of each model at the 30 mm/min displacement rate (3.3 minutes extraction) and additional models, as available, at higher displacement rates as exploratory analyses of force, and to calculate stress, depending on the initial results. We based our sample on the ASTM International Standard D638 protocols which recommend testing at least five specimens per condition [8].

2.3. Validation testing

To validate the model testing, we performed similar evaluations of force and calculations of stress at 30 mm/min on three Mirena and three Paragard IUDs. We purchased the IUDs used for measurements to create the injection-molded models and the IUDs for validation testing at different times. The stem/arms junction diameter for the Mirena IUD purchased for model creation was 2.05 mm, while the diameters of the three purchased for validation testing were 2.32, 2.39, and 2.43 mm (average 2.38 ± 0.06 mm) or 16.1% greater. The diameter at the stem/arms junction for the Paragard IUD purchased

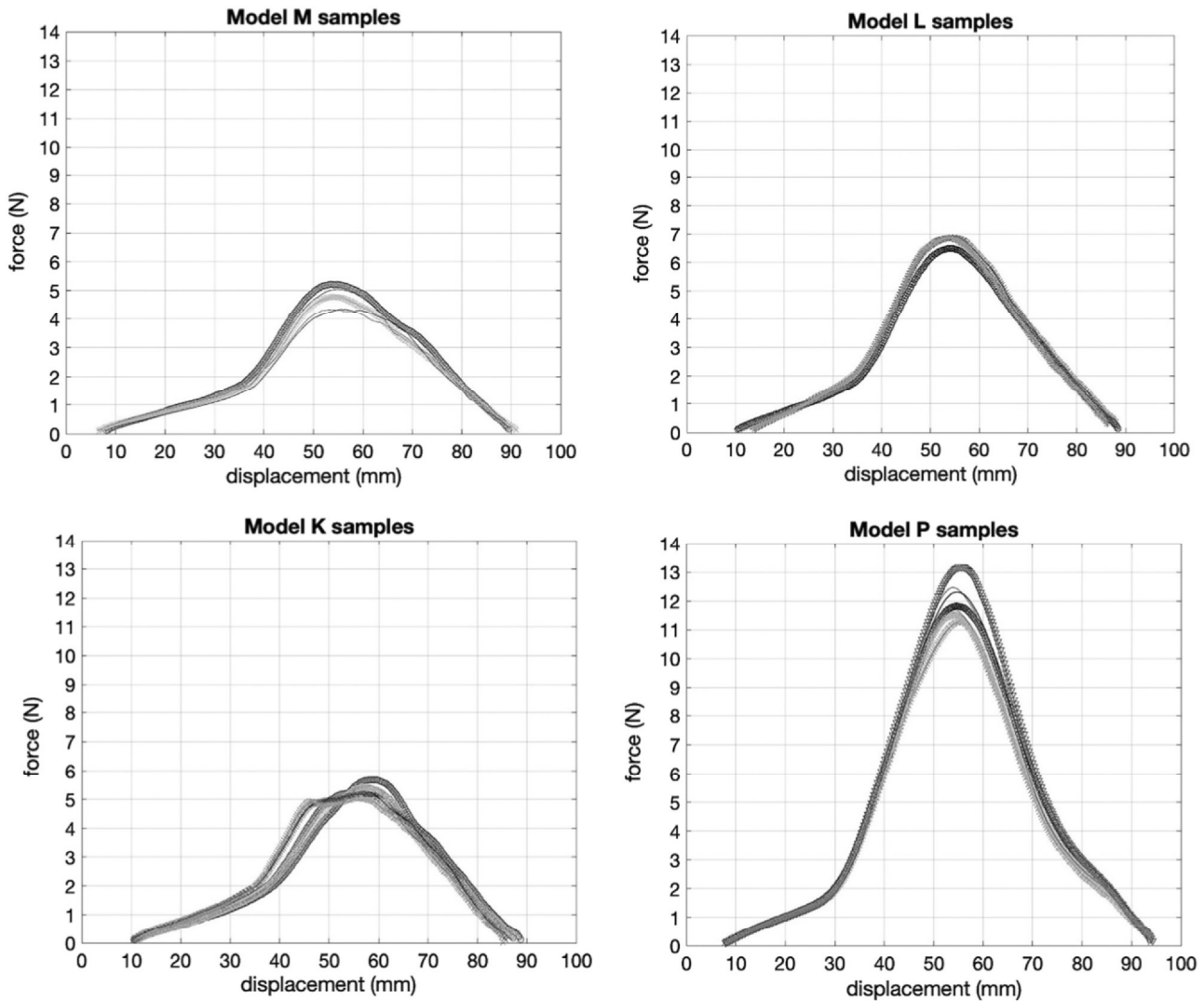


Fig. 3. Plots of force (load) versus displacements of IUD models at 30 mm/min. Model M: Mirena model ($n=5$); model L: Liletta model ($n=5$); model K: Kyleena model ($n=5$); model P: Paragard model ($n=9$). IUD = intrauterine device.

for model creation was 1.49 mm, while the diameters of the three purchased for validation testing were 1.49, 1.50, and 1.70 mm (average 1.56 ± 0.12 mm) or 4.7% greater. We custom-manufactured a half-size uterine fixture mimicking the larger fixture with a similar lining, allowing displacement over 50 mm. The fixture holding the IUD units did not change with respect to the fixture holding the injection-molded models. Details of this second fixture are provided in [Online Appendix 2](#).

2.4. Statistical testing

For the injection-molded models, we compared differences in force (load) and stress between models using Mann-Whitney U test with a $p < 0.05$ considered significant. For strain evaluations, we plotted strain vs calculated stress to create stress-strain curves. Because strain by itself has no context without stress (force per unit area), these curves are used to demonstrate the change in stress as strain increases, providing a display of the model's deformation in response to a tensile, compressive, or torsional load during the model's interaction with the fixture's walls.

For the validation testing, we compared median stress in clinical and our injection-molded units using a normalization formula: $\frac{\text{median}(\text{stress}_{\text{model}}) - \text{median}(\text{stress}_{\text{clinical}})}{\text{median}(\text{stress}_{\text{clinical}})} \times 100$. Although this type of testing had

not been evaluated previously for IUDs, we considered a normalized median stress difference of 20% or less as acceptable tolerance for validation.

3. Results

3.1. Number of models

We created 92 injection-molded samples of which 23 model M, 15 model L, four model K and six model P samples had defects (typically bubbles at the junction) or geometric inaccuracies, so were not used for testing. We initially completed testing at 30 mm/min using five of each model. We noticed minimal scatter during force (load) testing for models M, L and K but pronounced scatter for model P; thus, we performed four additional tests on model P at 30 mm/min. We tested 20 models at other displacement rates ranging from 20 mm/min to 2500 mm/min.

3.2. Testing at 30 mm/min

Figure 3 demonstrates the force needed to remove each model from the fixture with maximal force presented in [Table 1](#). Although similar in size and shape, the uterine fixture cavity walls created slightly more median force (resistance at the junction during

Table 1
Maximal forces measured and stress computed at the stem/arms junctions of the IUD models tested at 30 mm/min

Model	N	Force (N)	p-value ^a	Stress (MPa) ^b	p-value ^a
M	5	4.78 (4.34–5.05)	Referent	0.36 (0.33–0.38)	Referent
L	5	6.88 (6.78–6.90)	0.007	0.53 (0.53–0.53)	0.008
K	5	5.39 (5.18–5.43)	0.056	0.79 (0.76–0.80)	0.008
P	9	11.83 (11.61–12.31)	<0.001	1.70 (1.67–1.77)	<0.001

IUD, intrauterine device; model K, Kyleena model; model L, Liletta model; Model M, Mirena model; model P, Paragard model.

Data presented as median (interquartile range).

^a Mann-Whitney U test, compared to model M.

^b Stress: force/area at junction.

extraction) on model L (6.88 N [interquartile range (IQR) 6.78–6.90 N]) than model M (4.78 N [IQR 4.34–5.05 N]), $p=0.07$. Model P samples had the most resistance at the junction (11.83 N [IQR 11.61–12.31 N]), significantly higher than each Nova-T model ($p < 0.001$).

Median stress computed at the stem/arms junctions of the IUD models tested at 30 mm/min are presented in Table 1 and Figure 4. Although models K and M had similar force measurements, stress was significantly higher for model K at the junction because of the smaller surface area (Table 1). Model P samples had the highest stress, with median values 372%, 221%, and 115% larger than those of model M, L and K, respectively (all $p < 0.001$).

Strain is presented as strain plots (strain vs stress) in Figure 5 for testing in which the sensors remained attached throughout simulated IUD removal. Detachment typically occurs with higher strain, and we present the plots for all models (including those with detachment) in Online Appendix 3.

3.3. Testing at other displacement rates

We performed exploratory testing of force and stress at higher displacement rates using the remaining twenty injection-molded models (four model M, three model L, three model K and ten model P samples) available for testing. Maximal force during simulated

removal were similar for models M, L and K at all displacement rates compared to those measured at 30 mm/min (Online Appendix 4). However, for model P, as displacement rates increased, maximal force continued to increase; at displacement rates of 1200 and 2500 mm/min, maximal force ranged from approximately 17 to 20 N (Online Appendix 4), exceeding the approximately 11 to 13 N forces at 30 mm/min (Fig. 3). At rates of 50, 70 and 100 mm/min, we saw no considerable change in the stress at the junction of the arms and stem for any Nova-T frame, except one K sample at 100 mm/min (approximately 16% higher than the 30 mm/min median). Because model P demonstrated greater stress and strain at the junction with the initial testing, we tested that model at significantly higher displacement rates, with two replicates per rate. For model P, we observed even more stress at the stem/arms junction with increasing displacement rates (Fig. 4).

3.4. Validation testing

For the clinical Mirena IUDs, the maximum force experienced by the three units was 2.1, 1.9 and 1.4 N, while the clinical Paragard units reached 3.0, 3.0 and 4.0 N (Online Appendix 5). The maximum stress results are reported in Figure 4. The difference in medians for stress for Mirena (0.43 MPa) and the model M injection-molded units (0.36 MPa) was 16.3%. The difference in medians for stress for the Paragard IUDs (1.72 MPa) and the model P injection-molded units (1.70 MPa) was 1.2%, with two of the three data points overlapping (Online Appendix 5).

4. Discussion

This study demonstrates, through use of contemporary engineering methodology in a laboratory model, that the force and stress at the stem/arms junction of IUD geometries vary significantly during controlled IUD removal simulation. Most notable is the significant increase in force (load) and stress at this joint with Tatum-T shaped model P (Paragard) samples compared to Nova-T models under the same testing conditions, and that a higher speed of

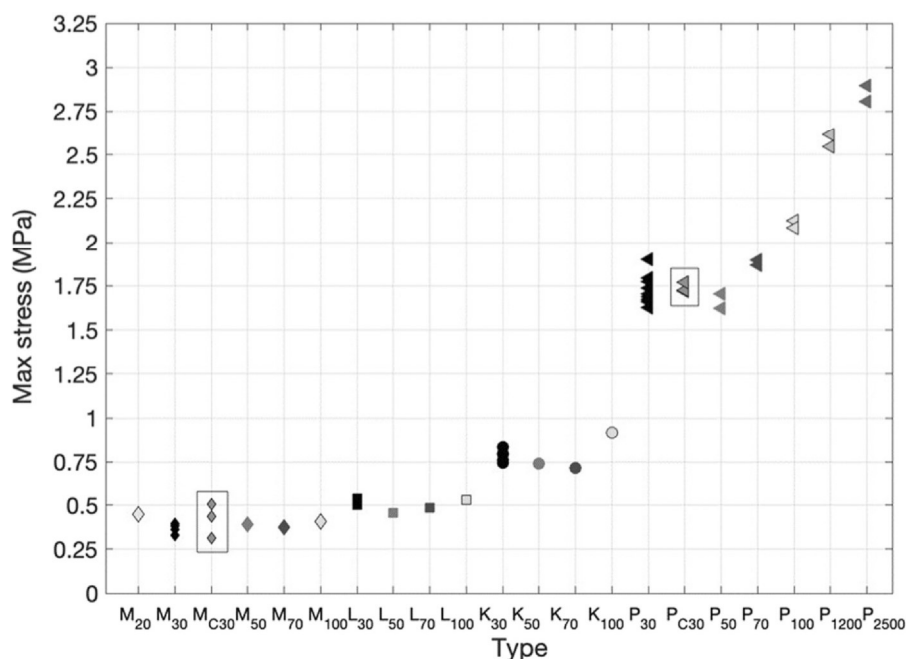


Fig. 4. Maximum stress (force/area at junction) occurring at the IUD stem/arms junction for IUD models at various displacement speeds. M: Mirena model; L: Liletta model; K: Kyleena model; P: Paragard model. Data in boxes are for clinical devices: MC30 (3 samples) are Mirena IUDs; PC30 (three samples, with two samples overlapping each other) are Paragard IUDs. Subscript numbers with model type represent speed of removal (displacement rate [mm/min]) during simulated removal through a fixture. IUD = intrauterine device.

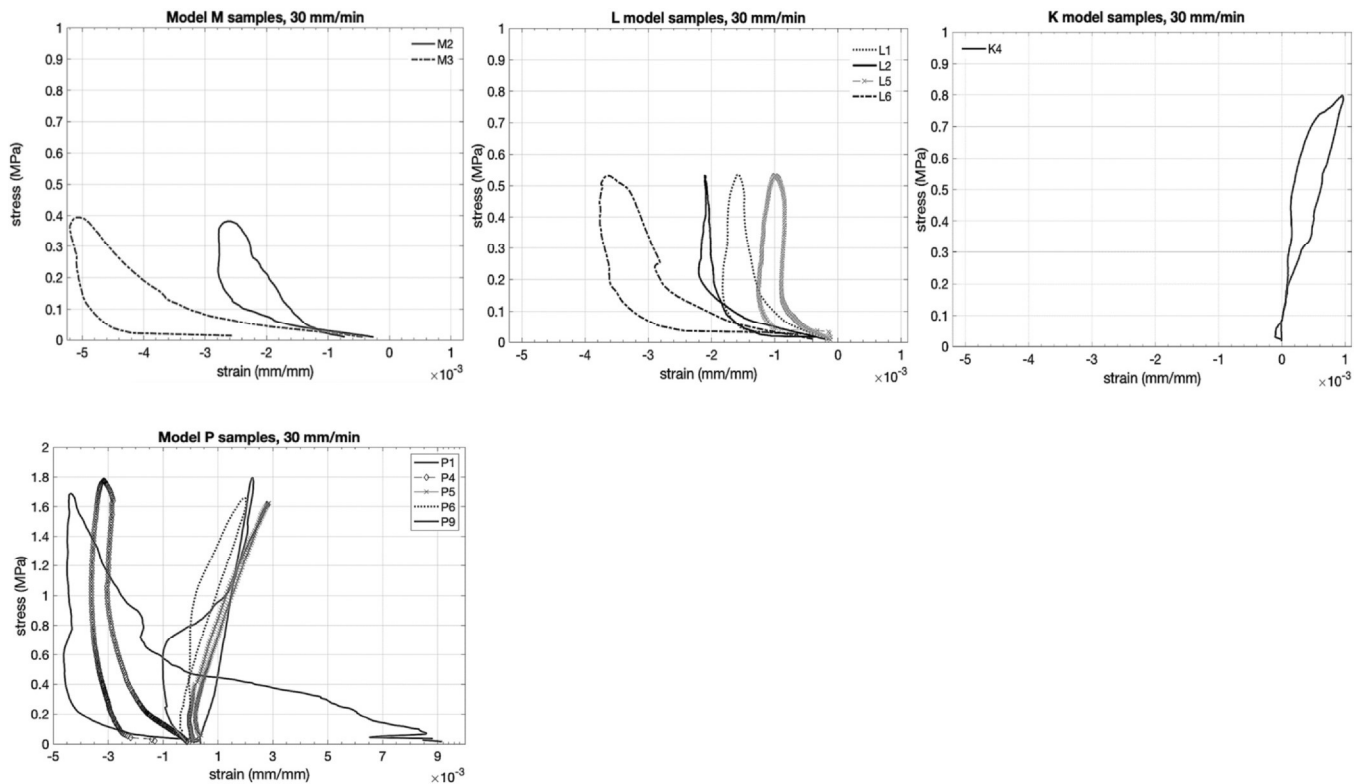


Fig. 5. Plots of stress versus strain of Models M, L, K, and P at 30 mm/min. Only includes strain tests in which all gauges remained attached throughout displacement through the fixture (model M: 2/3; Model L: 4/6; model K: 1/4; Model P: 5/9). Plots with all tests, including those in which the gauges did not remain attached, are in [Online Appendix 3](#). Model M: Mirena model; model L: Liletta model; model K: Kyleena model; model P: Paragard model. Model P stress scale (y-axis) maximizes at 2 MPa and other models at 1 MPa. Model P strain (x-axis) extends to much more positive levels for one test than other models; the variation in model P strain could reflect differences in injection molding which could happen in real life products. Models M and L are all similar (repeatable) and all negative, demonstrating compression at the stem/arms junction. Negative numbers imply compression at the stem/arms joint, while positive numbers imply tension (stretching). Some model P samples demonstrate compression and some do not. Samples in which the graph does not return to the starting point demonstrate permanent deformation (damage).

extraction causes even more stress. Structural engineers working with joints refer to the joint area where cracking is likely to start (because the stress is higher) as a "hot spot stress" location; the joint in Tatum-T-shaped frames exhibits more stress compared to Nova-T frames. The scatter in force (load) seen with model P, even at a low displacement rate of 30 mm/min, is consistent with unstable physical behavior inherent with T-joints. Because of differences in cross-sectional areas, stress is a better metric than force or strain to understand what is happening at the stem/arms junction.

When the machine pulled the IUD models faster through the testing fixture, more stress occurred at this junction, most notably for the model P samples. The highest rates tested over the 100 mm displacement distance, 1200 and 2500 mm/min, equate to removal through the fixture over 5.0 and 2.4 seconds, respectively. Polymers such as LDPE are strain-rate dependent and our tests at various rates show that extraction speed is important. Our findings imply that, to potentially minimize chances of fracture, Tatum-T frame IUDs should be removed slowly to minimize the forces at the stem/arms junction.

Force (resistance at the stem/arms junction created by pressure of the uterine fixture walls on the arms) and stress varied between Nova-T models. We were surprised to find consistent differences, albeit small, between models L and M which are the same size and geometry, potentially reflecting slight differences in the architecture at the stem/arms joint (Fig. 1). The smaller model K frame sample demonstrated higher stress than the slightly larger model L and model M frames, even though force did not differ as compared to model M. The higher stress is related to the smaller frame having less area to withstand forces. Notably, the arms/stem area of Model K has a cross-sectional area similar to Model P but the shape of the joint (Nova-T frame) results in less stress intensity (hot spot stress) compared to the Tatum-T

frame. The commercially available Kyleena also has a small metal ring around the stem/arms junction; since we only tested outcomes on the injection-molded frames, testing of commercially available product would be needed to understand if this ring impacts load or stress.

None of our models fractured even though the material properties of the injection-molded models (elongation at break, density, strength at yield) would favor a slightly higher chance of breakage compared to IUDs manufactured using WHO recommended materials. Goldstuck et al. [13] reported testing of seven new and 22 used Multiload and Nova-T copper IUDs to assess forces required to avulse an arm from the stem. The investigators fixed the stem base via a clamp to the bottom of a water bath at 37 degrees Celsius, grasped an IUD arm with a forceps, and pulled upwards on the forceps with an attached force meter. For the Nova-T frame, the investigators reported fractures at about 7 N for the new Nova-T frame IUDs and about 16 N for the used IUD frames. This study does not simulate real-life removal scenario in which the stem base would be grasped and the arm would be potentially mobile (although could be restricted if embedded). In our laboratory testing, the maximal force for all the Nova-T models was 7 N or less at various displacement rates, and much higher for the Tatum-T model P samples, with forces of up to 20 N for samples tested at the highest rate (2500 mm/min); yet, we had no breakage. We primarily performed the tests to evaluate differences in stress at the stem/arms joint for different IUD frame geometries and not to see how much force would result in breakage. Our study helps us understand inherent differences in design between the Tatum-T and Nova-T that could lead to breakage. However, studies to determine actual forces required to cause breakage would require marketed products using contemporary engineering models.

We believe that controlled laboratory testing, as we performed in this study, is important to understand inherent properties of the IUD frame and

geometry that could lead to fracture, an uncommon but significant outcome. The comparison with the six clinical IUDs supports the suitability of our approach, especially for Model P. We also note that our Model P samples did not have an off-axis eyelet like actual Paragard devices. In real-world use, this axis shift could potentially cause the device to twist when pulling the thread during removal, as demonstrated in Figure 2.

Of note, the only testing recommended by the WHO is tensile testing of the materials (the rectangular bar) and not of the T-frame itself [8]. In civil engineering, tubular steel T-joint structures similar in shape to model P samples have been investigated for decades [14]. The typically welded intersection of stem and arms, like those in cranes, bridges, and high-rise buildings, are known locations of vulnerability under static and fatigue loading in structural components due to their increased local stresses and the consequently higher likelihood of crack growth from those sites. Similarly, we observed higher forces and stresses at the stem/arms junction in the Tatum-T frame model P samples compared to Nova-T frame samples as they interacted with the walls and exited the fixture. This situation could be further compounded in real-life by the challenges in achieving defect-free injection-molding in the stem/arms junction areas. The Nova-T frame geometries do not have sharp corners in the stem/arms joints and, within the limits of our study, sustain much lower loads and stresses and are likely less vulnerable to fracture.

We believe we selected an appropriate elastomeric liner for the fixture, which had a tensile strength of 1.03 MPa. The human uterus has a broad variability of location-dependent (anisotropic) and time-dependent (viscoelastic) properties that vary with age, hormonal changes, presence of fibroids, and pregnancy history [9–11,15]. Pearsall and Roberts [9] measured myometrium tensile strengths from an unknown number of uteri from hysterectomies, measuring 0.550–2.07 MPA at "modest strain rates" (corresponding to 12.7 mm/min). For clinical correlation, we recognize that the fixture (uterine model) only approximates real-life tissue, that IUD fracture can occur in the uterus or cervix, and the properties of these tissues will vary among patients based on numerous factors including age and number of prior pregnancies [10].

We used non-commercial manufacturing processes and materials to create the injection-molded models. We chose a two-times scale for the models to allow for assessment of strain. Most importantly, we chose these models instead of commercial product due to the high costs of obtaining these IUDs, which also limited our ability to test a large number of clinical units for validation. We did not expect the slight variation between the Mirena IUDs we purchased for creating the models and validation testing which resulted in a greater discrepancy in stress outcomes between the models and the clinical IUDs for Mirena (16.3%) than Paragard (1.2%). This finding may reflect that the accuracy of the model may be better for the Tatum-T than Nova T frames. The hormonal IUD models did not include the hormone-containing sleeve on the stem and this could, albeit unlikely, impact stress at the arms/stem joint. Within these limitations, we feel the testing still allows for a reasonably reliable comparison between frame geometries, highlighting the vulnerability of the Tatum-T frame joint.

Importantly, the testing we performed could not account for degradation with time, impact of uterine environment, or the possibility that barium sulfate nanoparticles have some effect on frame integrity. Although none of the models fractured, some strain plots did not return to zero, demonstrating permanent deformation when the model exits the fixture, which is when force (load) is removed. This permanent deformation implies material damage at the sensor location (the junction). Thus, similar tests using previously removed IUDs still may not reflect what happens when a commercial IUD is removed after a period of use. Of note, barium sulfate makes the frames opaque which makes it harder to detect inherent manufacturing defects. Such defects may matter more by geometry, especially with Tatum-T frames.

IUD fragmentation is a rare and often unreported event [16]; studies such as this can help provide insight into different forces and

stresses that occur at the stem/arms junction of currently available IUD frame geometries. Future studies can provide more information if performed with commercially available products.

Acknowledgments

The authors thank R&D engineers José Mojica (Manager), David Kelhet, Sherry Batin and Shawn Malone, Michael Fish, UC Davis Engineering Student Design Center, for their help designing and machining the custom fixtures and ASTM D638 polyethylene samples for the validation of the testing procedure; Steven Lucero, Laboratory Manager for the TEAM Prototyping and Design Lab, UC Davis Biomedical Engineering, for his help with the injection molding process of the IUD models, and his design of the injection cavity molds; Tanya Garcia-Nolen, Laboratory Manager of the J.D. Wheat Veterinary Orthopedic Research Laboratory, UC Davis Veterinary Medicine, for her assistance and training with the Instron 5965 equipment; Chemical Engineering undergraduate student researcher Shivani Torres-Lal, for her assistance with the tests on the clinical devices.

Appendix A. Supporting material

Supplementary data associated with this article can be found in the online version at [doi:10.1016/j.contraception.2024.110399](https://doi.org/10.1016/j.contraception.2024.110399).

References

- [1] Tatum HJ. Intrauterine contraception. *Am J Obstet Gynecol* 1972;112(7):1000–1023. [https://doi.org/10.1016/0002-9378\(72\)90828-9](https://doi.org/10.1016/0002-9378(72)90828-9)
- [2] Tatum H., United States Patent 3,533,406. Available at: (<https://image-ppubs.uspto.gov/dirsearch-public/print/downloadPdf/3533406>); (accessed May 9, 2023).
- [3] Zipper JA, Tatum HJ, Pastene L, Medel M, Rivera M. Metallic copper as an intrauterine contraceptive adjunct to the "T" device. *Am J Obstet Gynecol* 1969;105(8):1274–8. [https://doi.org/10.1016/0002-9378\(69\)90302-0](https://doi.org/10.1016/0002-9378(69)90302-0)
- [4] Luukkainen T, Nielsen NC, Nygren KG, Pyörälä T, Allonen H. Combined and national experience of postmenstrual IUD insertions of Nova-T and Copper-T in a randomized study. *Contraception* 1979;19(1):11–20. [https://doi.org/10.1016/s0010-7824\(79\)80004-9](https://doi.org/10.1016/s0010-7824(79)80004-9)
- [5] Nilsson CG. Improvement of a d-norgestrel-releasing IUD. *Contraception* 1977;15(3):295–306. [https://doi.org/10.1016/0010-7824\(77\)90115-9](https://doi.org/10.1016/0010-7824(77)90115-9)
- [6] Latack KR, Nguyen BT. Trends in copper versus hormonal intrauterine device breakage reporting within the United States' Food and Drug Administration Adverse Event Reporting System. *Contraception* 2023;118:109909. <https://doi.org/10.1016/j.contraception.2022.10.011>
- [7] World Health Organization, United Nations Population Fund. The TCU380A Intrauterine Contraceptive Device (IUD): Specification, Prequalification and Guidelines for Procurement, 2010." Geneva, Switzerland, 2010. Available at: (https://www.unfpa.org/sites/default/files/resource-pdf/IUDbook_finalwlinks_042911.pdf); (accessed May 9, 2023).
- [8] World Health Organization, United Nations Population Fund. Annex 10: WHO/UNFPA technical specification for TCU380A intrauterine device." Geneva, Switzerland, 2010. Available at: (<https://www.who.int/publications/m/item/trs1044-annex10>); (accessed May 9, 2023).
- [9] Pearsall GW, Roberts VL. Passive mechanical properties of uterine muscle (myometrium) tested in vitro. *J Biomech* 1978;11(4):167–76. [https://doi.org/10.1016/0021-9290\(78\)90009-x](https://doi.org/10.1016/0021-9290(78)90009-x)
- [10] Zara F, Dupuis O. Uterus Ch. 15 In: Payan Y, Ohayon J, editors. *Biomechanics of living organs: hyperelastic constitutive laws for finite element modeling*. London, United Kingdom: Academic Press; 2017. p. 325–46. Ch. 15.
- [11] Fang S, McLean J, Shi L, Vink JY, Hendon CP, Myers KM. Anisotropic mechanical properties of the human uterus measured by spherical indentation. *Ann Biomed Eng* 2021;49(8):1923–42. <https://doi.org/10.1007/s10439-021-02769-0>
- [12] ASTM International. D638–22: Standard Test Method for Tensile Properties of Plastics, 2022. West Conshohocken, PA, USA. Available at: (<https://www.astm.org/standards/d638>); (accessed May 13, 2023).
- [13] Goldstuck ND, Hofmeyr GJ, Sonnendecker EW, Butchart A. In vitro study of fracture forces associated with the Copper T, Nova T and MLCu 250/375 intrauterine devices. *Contraception* 1990;41(6):583–9.
- [14] Hellier AK, Connolly MP, Dover WD. Stress concentration factors for tubular Y- and T-joints. *Int J Fatigue* 1990;12(1):13–23.
- [15] Rechberger T, Uldbjerg N, Oxlund H. Connective tissue changes in the cervix during normal pregnancy and pregnancy complicated by cervical incompetence. *Obstet Gynecol* 1988;71(4):563–7.
- [16] Wilson S, Tan G, Baylson M, Schreiber C. Controversies in family planning: how to manage a fractured IUD. *Contraception* 2013;88(5):599–603. <https://doi.org/10.1016/j.contraception.2013.07.007c>