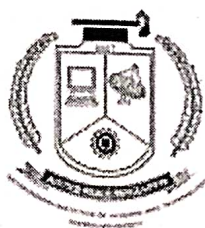


Enhanced Multi-Load IUD: Redesigning for optimal functionality And Tailoring Usability for Diverse Women's Health Needs.

Submitted in partial fulfillment of the requirements for the award of
Bachelor of Technology degree in Biomedical Engineering

By

Haripriya Bhattaru (40240010)



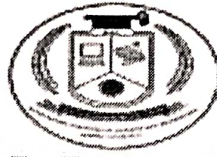
**DEPARTMENT OF BIOMEDICAL ENGINEERING
SCHOOL OF BIO AND CHEMICAL ENGINEERING**

SATHYABAMA

**INSTITUTE OF SCIENCE AND TECHNOLOGY
(DEEMED TO BE UNIVERSITY)**

**Accredited with Grade "A++" by NAAC
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APRIL - 2024



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BONAFIDE CERTIFICATE

This is to certify that this Project Report is the bonafide work of Haripriya Bhattaru (40240010) who have done the project work as an individual and carried out the project entitled "Enhanced Multi-Load IUD: Redesigning for optimal Functionality and Tailoring Usability for Diverse Women's Health Needs" under our supervision from July 2023 to April 2024.

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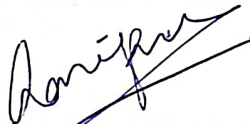
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DECLARATION

I, **HARIPRIYA BHATTARU (40240010)** hereby declare that the Project Report entitled **Enhanced Multi-Load IUD: Redesigning for optimal Functionality and Tailoring Usability for Diverse Women's Health Needs** done by me under the guidance of **Dr. T. SUDHAKAR** is submitted in partial fulfilment of the requirements for the award of a Bachelor of Technology degree in Biomedical Engineering.

DATE: 05.04.2024

PLACE: CHENNAI



SIGNATURE OF THE CANDIDATE

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I am pleased to acknowledge my sincere thanks to the Board of Management of SATHYABAMA for their kind encouragement in doing this project and for completing it successfully. I am grateful to them.

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ABSTRACT

A Multi-load IUD is a highly effective contraceptive device which is skillfully inserted into the uterus by a trained medical professional to prevent unwanted pregnancies. Comprising a flexible plastic frame with multiple copper segments, the copper acts as a spermicide and prevents implantation of a fertilized egg. This form of contraception remains effective for up to five years and can be removed by a licensed medical professional at any time.

The Multi-load IUD stands out as a birth control choice for various reasons. It has a remarkably high-level effectiveness, with a failure rate of less than 1% per year. Its convenience is unmatched, requiring no daily, weekly, or monthly maintenance once inserted. Reversibility is a key advantage; post-removal, it doesn't affect fertility, allowing for immediate conception. Additionally, being hormone-free, it avoids interference with the natural menstrual cycle and associated hormonal side effects. Cost-effectiveness is another advantage, thanks to a low initial cost and minimal need for follow-up clinical visits.

On a global scale, the utilization of intrauterine devices (IUDs) is notably lower among younger and nulliparous women. In Europe, IUD usage among women aged 15 to 49 varied from less than 1% in Albania and Poland to a peak of 23.3% in Norway in 2018, averaging at 14.6%. In India, IUD use among married women of reproductive age remained under 2% in 2015. In the United States, though overall IUD usage increased from 2% in 2002 to 10.3% in 2013 among women using contraception, the use of the multi-load IUD was significantly lower among nulliparous women, rising from 0.5% in 2002 to 4.8% in 2013. These figures consistently highlight limited IUD utilization, especially among younger and nulliparous women, globally.

The purpose of this study is to develop an Enhanced Multi-Load IUD that offers improved functionality and usability, catering to the individual health needs of women. The redesigned IUD will include customizable load options, ensuring an appropriate fit for different users. The ultimate goal is to provide women with a safe, effective, and convenient family planning option that empowers them to make informed decisions about their reproductive health.

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CHAPTER 1

INTRODUCTION

Copper multi-load IUDs are a form of intrauterine device (IUD), that contains copper that are employed for both birth control purposes as well as a form of emergency contraception. They stand out as highly effective, demonstrating a minute rate of failure which is less than 1% annually. These devices are remarkably long-lasting, they can remain within the uterus for up to 12 years without interfering with the body's natural hormonal and menstrual cycle.

The mechanism of copper multi-load IUDs works by creating a hostile environment for sperm that enters the uterus via the cervix. The copper in the IUD releases copper ions that either kill or impair the sperm which hinders their attempt to fertilize an egg. Furthermore, the copper alters the uterus lining and cervical mucus, making it more challenging for an egg to successfully implant, and create a successful pregnancy.

The insertion of the copper multi-load IUDs is conducted by a medical professional through the cervix and into the uterus. These IUDs feature a T-shaped plastic frame with serrations and the vertical component is enveloped with a coil of copper wire and are accompanied by two strings hanging into the vagina. These strings facilitate user self

checks to ensure the IUD's position and aid in its removal when necessary. Typically, the insertion process takes around 10 - 15 minutes and will induce some cramping or bleeding. The most prevalent side effect associated with copper multi-load IUDs is experiencing heavier and longer periods, particularly within the initial 3 to 6 months post-insertion. Some users may also encounter spotting, cramping, or discomfort during sexual intercourse. However, these side effects tend to diminish as the body acclimates to the IUD. Copper multi-load IUDs cater to a broad range of individuals seeking a non-hormonal and reversible birth control option. However, they are not recommended for those with a history of pelvic inflammatory disease (PID), uterine perforation, copper allergy, or Wilson's disease. The current versions of multi-load

IUDs pose practical challenges for certain women due to the dimensions of the device. Multi-load IUDs are packaged within a plastic tube with a diameter of 3-4 mm, a size that could be uncomfortably large for women with a narrow or sensitive cervix. Often, these tend to be women that are younger and nulliparous. In most cultures, the stigma around premarital fornication is the leading cause for the lack of information and access to safe birth control options for all women. Moreover, these IUDs are designed to suit uterine lengths ranging from 6-9 cm, potentially causing fitting issues for women with uterine cavities smaller or larger than this range. The insertion procedure itself can induce discomfort, cramping, bleeding, or pain, further discouraging women from choosing this non-hormonal and reversible contraceptive method. It is evident that the current multi-load IUDs may not align well with the anatomical variations found in certain individuals. The plastic tube encasing the IUD, features a diameter of 3-4 mm. While this is deemed suitable for many, women with a narrower or particularly sensitive cervix may find this size uncomfortable during insertion. Additionally, optimal uterine lengths for the multi-load IUD, falling within the range of 6-9 cm. This specification implies that women with uterine cavities outside this range may encounter challenges in achieving an appropriate fit, underscoring a crucial consideration in device selection. Incorporating all of the aforementioned information it's apparent that the insertion process itself can evoke varying degrees of discomfort, ranging from cramping and bleeding to post-insertion pain. These potential adverse effects may significantly impact a woman's willingness to opt for this contraceptive method. The discomfort and discouragement the women feel after a failed attempt at an IUD insertion, creates fear around the topic of contraception and this inevitably increases the rates of teen and unwanted pregnancies across the country. Consequently, the existing multi-load IUDs may not be a suitable choice for select individuals seeking a non-hormonal, reversible form of birth control, warranting further exploration and potential advancements in device design to address anatomical diversity and improve overall user experience.

This project is dedicated to the development of an Enhanced Multi-Load IUD, aiming to elevate its functionality and user-friendliness. This redesign will prioritise customization, offering various load options to suit diverse user needs. Rigorous

usability testing will be conducted to gauge user preferences and enhance the comfort of insertion and removal processes. Our ultimate objective is to present women with a family planning option that amalgamates safety, efficacy, and convenience, empowering them to make well-informed choices regarding their reproductive health.

CHAPTER 2

REVIEW OF LITERATURE

The subsequent literature review is a compilation of relevant research articles that explore intrauterine devices (IUDs), a long-term contraceptive method inserted into the uterus to prevent pregnancy. IUDs can be broadly categorized into two types: copper IUDs, which release copper ions with spermicidal and anti-implantation properties, and hormonal IUDs, which release progestins to thicken cervical mucus and suppress ovulation. Both types of IUDs are known for their high efficacy, safety, and cost-effectiveness, although they present varying advantages and disadvantages, including side effects, non-contraceptive benefits, and user satisfaction.

A significant aspect of focus revolves around understanding how IUDs affect menstrual bleeding patterns, a crucial factor influencing the acceptance and continued usage of IUDs. Several studies have investigated this aspect. For instance, Wildemeersch *et al.* (2014) conducted a randomized controlled trial comparing bleeding patterns in women using a frameless copper IUD (GyneFix) and a framed copper IUD (Nova-T) over a 5-year period [1]. The study demonstrated an initial increase in menstrual blood loss with both IUDs, with the frameless IUD causing a lesser impact compared to the framed IUD. Additionally, the frameless IUD exhibited lower rates of expulsion, removal due to bleeding, and pregnancies compared to the framed IUD, indicating its higher effectiveness and acceptability.

Another study by Sivin *et al.* (2002) compared bleeding patterns in women using a levonorgestrel releasing intrauterine system (LNG-IUS) versus a copper T380A IUD over a span of 7 years [2]. The results showed a significant reduction in menstrual blood loss with the LNG-IUS, indicating a decline of 86% after one year and 97% after seven years. Conversely, the copper IUD led to a 31% increase in menstrual blood loss after one year and a 23% increase after seven years. Furthermore, the

LNG IUS demonstrated a reduction in dysmenorrhea, anemia, and endometrial hyperplasia, while the copper IUD led to increased instances of spotting, cramping, and pelvic inflammatory disease. This study highlighted the superiority of the LNG-IUS over the copper IUD in terms of bleeding patterns and non-contraceptive benefits.

Another study by Hubacher *et al.* (2013) delved into the bleeding patterns of women using a copper T380A IUD or a subdermal implant (Implanon) over a 3-year period [3]. The study demonstrated comparable contraceptive efficacy and continuation rates for both methods, with divergent bleeding patterns. The copper IUD induced more heavy bleeding days, whereas the implant caused higher occurrence of irregular bleeding days and more instances of amenorrhea. The authors concluded that both methods were highly effective and safe, highlighting the importance of individual user preferences and needs in the choice of contraceptive method.

These studies collectively underscore the varied effects of different IUD types on menstrual bleeding patterns, ultimately impacting the acceptability and continuation of IUD usage. For engineers focused on IUD design or insertion techniques, considering these factors is crucial to optimize the performance and user-friendliness of IUD systems.

Another critical area of interest involves the influence of IUDs on cervical morphology and physiology, subsequently affecting the risk of cervical infection and cancer. Research conducted by Wildemeersch *et al.* (2015) measured cervical length and width in women using different types of IUDs or no contraception [4]. The study revealed that women employing copper or hormonal IUDs displayed shorter and wider cervices compared to those using no contraception, while women using frameless or framed IUDs exhibited similar cervical dimensions. These differences were hypothesized to be associated with the mechanical pressure exerted by the IUD on cervical tissue.

In a related study, Kalliala *et al.* (2016) analyzed the cervical microbiota of women utilizing various contraception methods or no contraception [5]. The results indicated that women using copper or hormonal IUDs displayed heightened bacterial diversity and lower dominance of *Lactobacillus* compared to those using no contraception or other methods. These alterations were suggested to be linked to the presence of foreign material in the uterus or the hormonal effects of progestins.

In another study, Benski *et al.* (2014) evaluated the expression of human papillomavirus (HPV) E6/E7 oncogenes in cervical cells of women using different contraception methods or no contraception [6]. The findings demonstrated lower expression of HPV E6/E7 oncogenes in women employing copper or hormonal IUDs compared to those using no contraception or other methods. This was hypothesized to be related to the local immune response or the direct cytotoxic effect of copper or progestins.

These studies illuminate the diverse effects of different IUD types on cervical morphology and physiology, significantly influencing the risk of cervical infection and cancer. For engineers involved in IUD design or insertion techniques, considering these aspects and minimizing adverse effects while maximizing the protective effects of IUD systems is of paramount importance.

An additional area of interest revolves around the utilization of IUDs for emergency contraception, a method employed to prevent pregnancy following unprotected sexual intercourse. A comprehensive review article by Gemzell-Danielsson and Rabe (2008) summarized the evidence and recommendations concerning the use of IUDs for emergency contraception [7]. The authors highlighted copper IUDs as the most effective emergency contraception method, boasting a failure rate of less than 0.1%, and emphasized their insertion potential up to 5 days post unprotected sexual intercourse or ovulation. Conversely, hormonal IUDs were discouraged for emergency contraception due to their higher failure rate and diminished efficacy compared to copper IUDs.

In a corresponding review article, AIIMS (2010) presented guidelines and protocols for employing IUDs for emergency contraception in India [8]. The authors advocated for copper IUDs as the preferred choice, emphasizing their safety, efficacy, and enduring nature, with insertion possible up to 5 days after unprotected sexual intercourse or within 12 days following the first day of the last menstrual period. Conversely, hormonal IUDs were deemed unfit for emergency contraception, primarily due to their lower efficacy and higher risk of ectopic pregnancy as compared to copper IUDs.

In another review article, Sivin *et al.* (1995) compared the efficacy and safety of various types of copper IUDs for emergency contraception [9]. The authors concluded that all copper IUDs were effective for emergency contraception, although some types demonstrated higher expulsion rates or lower continuation rates than others. They recommended the utilization of copper T380A or Multiload 375 IUDs, highlighting their lower expulsion rates and higher continuation rates than other variants.

These articles provide crucial insights into the utilization of IUDs for emergency contraception, which can greatly benefit engineers involved in IUD design or insertion techniques. Considering these aspects and optimizing the performance and user friendliness of IUD systems for emergency contraception is imperative for engineers immersed in IUD design or insertion techniques.

Further research delves into the practical aspects of IUD use, with a focus on insertion techniques and user satisfaction. For instance, Taylore *et al.* (2019) conducted a study analyzing the experiences and preferences of women regarding IUD insertion methods, aiming to improve the overall insertion process and enhance user satisfaction [10]. The results highlighted the need for personalized approaches to IUD insertion, considering individual anatomical differences and pain thresholds. Engineering advancements in insertion devices and techniques should prioritize user comfort and minimize discomfort during the procedure.

Additionally, IUD expulsion remains a notable concern. A study by Winner *et al.* (2012) investigated the rate of expulsion and factors associated with IUD expulsion among a diverse group of women [11]. The findings underscored the importance of proper counseling and follow-up care to reduce expulsion rates. Engineers can collaborate with healthcare professionals to design IUDs that minimize the risk of expulsion through improved anchoring mechanisms or innovative structural designs.

Another essential aspect in IUD design is the development of effective removal mechanisms to ensure a smooth and uncomplicated removal process. A study by Madden *et al.* (2012) assessed the ease and safety of IUD removal, identifying strategies to

facilitate the removal process and enhance user experience [12]. Engineering solutions could further streamline IUD removal, ensuring a minimally invasive and comfortable procedure.

These studies provide invaluable insights into the multifaceted aspects of IUDs, encompassing not only contraceptive efficacy but also factors like user experience, insertion, and removal. Engineers, in collaboration with healthcare professionals and researchers, can leverage these insights to refine IUD design, insertion techniques, and removal mechanisms. This interdisciplinary approach holds the potential to yield advanced, user-centric IUD systems that address current limitations and further promote women's reproductive health and choices.

One of the common concerns about IUD use is the safety and suitability for nulliparous women, i.e., women who have never given birth. Nulliparous women may have higher risks of pain, expulsion, perforation, infection, and infertility associated with IUD insertion and use. However, several studies have challenged these assumptions and provided evidence that IUD use is safe and effective among nulliparous women.

Foran and Butcher (2016) conducted a systematic review of 16 studies comparing the safety of insertion of copper IUDs and LNG-IUS among nulliparous and parous women [13]. They found no significant differences in insertion failure, pain, bleeding, infection, expulsion, perforation, or continuation rates between the two groups. They concluded that both types of IUDs can be safely inserted in nulliparous women.

Turok *et al.* (2014) performed a randomized controlled trial of 304 nulliparous women who were assigned to receive either a copper IUD or an LNG-IUS [14]. They measured the pain during insertion, satisfaction, bleeding patterns, expulsion, and continuation rates at 6 months. They found that both groups had similar pain scores during insertion, but the LNG-IUS group had less bleeding, higher satisfaction, lower expulsion rates, and higher continuation rates than the copper IUD group. They suggested that LNG-IUS may be a better option for nulliparous women who prefer less bleeding and longer duration of contraception.

Lohr and Lyus (2014) reviewed the literature on the use of IUDs in nulliparous women and provided practical guidance for clinicians [15]. They highlighted the benefits of IUDs for nulliparous women, such as high efficacy, cost-effectiveness, rapid return to fertility, and reduced risk of ectopic pregnancy. They also addressed the common myths and misconceptions about IUDs, such as increased risk of pelvic inflammatory disease (PID), infertility, ectopic pregnancy, and perforation. They recommended that clinicians should counsel nulliparous women about the advantages and disadvantages of IUDs, assess their eligibility and suitability for IUD insertion, use appropriate techniques and pain relief measures during insertion, and provide adequate follow-up care.

Hall *et al.* (2017) conducted a retrospective cohort study of 1,048 nulliparous women who received either a copper IUD or an LNG-IUS at a family planning clinic [16]. They compared the outcomes of insertion success, pain, bleeding, infection, expulsion, perforation, removal, and continuation at 12 months. They found that both types of IUDs had high insertion success rates (98%), low pain scores (median 3 out

of 10), low infection rates (0.4%), low perforation rates (0%), low removal rates (11%), and high continuation rates (82%). They also found that the LNG-IUS group had less bleeding than the copper IUD group. They concluded that both types of IUDs are safe and acceptable for nulliparous women.

Gemzell-Danielsson *et al.* (2019) performed a systematic review of 14 studies on interventions for the prevention of pain associated with IUD insertion [17]. They evaluated the effectiveness of various pharmacological and non-pharmacological interventions, such as oral analgesics, local anesthetics, cervical priming agents, nitrous oxide inhalation,

music therapy, acupuncture, hypnosis, and counseling. They found that most interventions had limited or no evidence of efficacy in reducing pain during or after IUD insertion. They recommended that more high-quality randomized trials are needed to determine the best practices for pain management during IUD insertion.

Bahamondes *et al.* (2018) conducted a prospective cohort study of 1,500 nulligravida (women who have never been pregnant) who received either a copper IUD or an LNG IUS at a university hospital [18]. They followed them up for 60 months and measured the

outcomes of expulsion, removal for medical reasons, pregnancy, PID, and discontinuation. They found that both types of IUDs had similar expulsion rates (4%), removal rates for medical reasons (9%), pregnancy rates (0.2%), and PID rates (0.3%). They also found that the LNG-IUS group had less bleeding and dysmenorrhea than the copper IUD group, but more amenorrhea and ovarian cysts. They concluded that both types of IUDs are safe and effective for nulligravida.

Jatlaoui *et al.* (2018) performed a systematic review of 13 studies on the safety of IUDs among young women aged 25 years or younger [19]. They assessed the outcomes of insertion failure, pain, bleeding, infection, expulsion, perforation, pregnancy, and continuation. They found that young women had similar or lower

rates of insertion failure, pain, infection, perforation, and pregnancy than older women. They also found that young women had higher rates of expulsion and lower rates of continuation than older women. They suggested that young women may benefit from more counseling and support to improve their satisfaction and adherence to IUDs.

In summary, this literature review has provided comprehensive insights into various aspects of intrauterine devices (IUDs) including their types, effects on menstrual bleeding patterns, impact on cervical morphology and physiology, use for emergency contraception, insertion techniques, and suitability for nulliparous women. The studies discussed shed light on the safety, efficacy, and non-contraceptive benefits of IUDs, which are crucial in making informed decisions regarding contraceptive choices. Engineers and healthcare professionals can collaborate to further enhance IUD design, insertion techniques, and user satisfaction, aiming for advanced and user-friendly IUD systems that improve women's reproductive health and choices.

Continuing with the exploration of long-acting reversible contraceptives (LARCs), these studies shed light on various aspects influencing their usage and acceptance among different demographics.

Kalata and Richards (2019) conducted a qualitative study involving 20 young women aged 18 to 24 in Malawi, investigating their experiences and perceptions regarding LARCs, especially in the context of unintended pregnancies [1]. The study illuminated negative perceptions held by these women, encompassing fears of infertility, infection, cancer, and concerns about partner dissatisfaction. Lack of awareness, insufficient counseling, provider biases, and social stigma emerged as prominent barriers to LARC utilization. The researchers emphasized the necessity for enhanced education, communication, and counselling to dispel misconceptions and augment the uptake of LARCs among this demographic.

Shifting to a quantitative approach, Nhlumayo (2018) examined the factors influencing the adoption of LARCs among 200 women aged 18 to 49 in South Africa,

particularly those transitioning from short-acting contraceptive methods [2]. The study revealed that age, parity, marital status, education level, income, and previous contraceptive methods significantly influenced the choice of LARCs. Women with favorable attitudes toward LARCs, higher knowledge about these methods, and greater satisfaction with their healthcare providers were more inclined to opt for LARCs. The findings suggested the importance of targeted promotion efforts, particularly among young, nulliparous, unmarried, less educated, and low-income individuals who were transitioning from short acting contraceptives.

In a different setting, Rehring *et al.* (2019) implemented a quality improvement project in a US primary care clinic to enhance the provision of LARCs to adolescent and young adult women [3]. Following recommendations from the American Academy of Pediatrics (AAP) and the American College of Obstetricians and Gynecologists (ACOG), the intervention significantly increased LARC counseling and insertion rates, along with improving patient satisfaction. This demonstrated that adhering to established guidelines and quality improvement initiatives can positively impact the uptake of LARCs among specific demographic groups.

Turning attention to a specialized demographic, Masonbrink *et al.* (2020) investigated the feasibility of a tailored contraception intervention for adolescent mothers and their partners in a US pediatric clinic [4]. This intervention, which included education, counselling, and provision of LARCs at no cost, demonstrated high acceptability and feasibility. Notably, a significant percentage of adolescent mothers and their partners chose to receive a LARC during the intervention. The study highlighted the potential for tailored interventions to effectively influence contraceptive decision-making among adolescent populations.

Almakki *et al.* (2020) conducted a cross-sectional study in Sudan, analyzing 60 women who received either a copper IUD or an LNG-IUS, utilizing transvaginal ultrasound Doppler to assess changes in uterine blood flow before and after IUD insertion [5]. Both types of IUDs induced significant changes in blood flow

parameters, with the LNG-IUS group exhibiting more pronounced alterations. The study did not find a direct correlation between these blood flow changes and clinical outcomes such as pain, bleeding, or expulsion. However, it underscored the potential utility of transvaginal ultrasound Doppler to monitor the effects of IUDs on uterine hemodynamics, offering insights into the physiological aspects of IUD usage.

However, IUDs are also associated with some side effects and complications that may affect their acceptability and continuation rates. One of the most common side effects is pain during insertion, which can be influenced by several factors, such as the type and size of the device, the skill of the provider, the use of anesthesia, and the individual pain threshold of the woman. Hubacher *et al.* (2014) conducted a randomized trial of prophylactic ibuprofen for pain relief during copper IUD insertion and found that it did not reduce pain significantly compared to placebo. They suggested that other methods of pain management, such as paracervical block or misoprostol, should be explored in future studies.

Another common side effect of IUDs is abnormal bleeding patterns, which can vary depending on the type of device and the duration of use. Copper IUDs tend to increase menstrual bleeding and cramping, while hormonal IUDs tend to reduce or eliminate menstrual bleeding over time. Hidalgo *et al.* (2002) reported that the levonorgestrel

releasing intrauterine system (LNG-IUS) Mirena had a favorable bleeding profile and clinical performance up to two years of use. They observed that most women experienced amenorrhea or infrequent bleeding after six months of use, and that the incidence of adverse events, such as pelvic infection, expulsion, or perforation, was low. Hubacher *et al.* (2009) also found that the side effects from the copper IUD decreased over time and did not affect satisfaction or continuation rates. They noted that most women adapted to the increased bleeding and cramping within six months of insertion.

However, some women may not tolerate or prefer the changes in bleeding patterns caused by IUDs, especially if they are not adequately counseled or informed about them. Suvisaari and Lahteenmaki (1996) conducted a detailed analysis of menstrual bleeding patterns after postmenstrual and post abortal insertion of a copper IUD or an LNG-IUS and found that both devices had different effects on cycle length, bleeding duration, and bleeding intensity. They concluded that women should be given accurate information about the expected bleeding patterns before choosing an IUD.

Another aspect that may influence the acceptability and continuation of IUDs is their effect on bone mineral density (BMD), hormone concentrations, and ovarian function. Some studies have suggested that hormonal IUDs may have a systemic effect on these parameters, while copper IUDs may not. Bahamondes *et al.* (2014) conducted a prospective study of the forearm BMD of long-term users of LNG-IUS and found no significant difference between users and non-users after five years of use. They also reported no difference in serum estradiol levels or ovarian cyst formation between groups. Heikinheimo *et al.* (2010) evaluated the effect of continuous combined therapy with estradiol and norethisterone acetate on bleeding pattern after cessation of therapy in women using LNG-IUS and found that it did not affect the return of ovulation or fertility. They also observed that it reduced the incidence of breakthrough bleeding and spotting during LNG-IUS use.

Other studies have reported conflicting results regarding the systemic effect of hormonal IUDs. Gemzell-Danielsson *et al.* (2012) compared two low-dose LNG-IUS with Mirena in a randomized phase II study and found that they had similar efficacy, bleeding profile, and safety. However, they also noted that they had different effects on serum levonorgestrel levels, endometrial thickness, ovarian activity, and amenorrhea rates. Teichmann *et al.* (2015) assessed the effect of LNG-IUS on uterine artery blood flow, hormone concentrations, and ovarian cyst formation in fertile women and found that it reduced uterine artery blood flow resistance index and increased serum progesterone levels. They also detected more ovarian cysts in

LNG-IUS users than in copper IUD users.

Therefore, more studies are needed to clarify the systemic effect of hormonal IUDs and its implications for women's health and well-being. Moreover, the effect of different doses and formulations of progestins on these parameters should be investigated.

Another factor that may affect the acceptability and continuation of IUDs is the age and parity of the woman. Some studies have suggested that younger and nulliparous women may have higher rates of expulsion, removal, or dissatisfaction with IUDs than older and parous women. Aoun *et al.* (2014) analyzed the effects of age, parity, and device type on complications and discontinuation of IUDs and found that younger and nulliparous women had higher rates of expulsion and removal for bleeding or pain than older and parous women. They also found that copper IUDs had higher rates of expulsion and removal than hormonal IUDs. Madden *et al.* (2014) examined the association of age and parity with IUD expulsion and found that younger age was associated with higher risk of expulsion, while parity was not. They suggested that other factors, such as insertion technique, device size, or uterine anatomy, may also influence expulsion rates.

However, other studies have challenged the notion that younger and nulliparous women are not suitable candidates for IUDs. Bahamondes *et al.* (2015) compared the effectiveness and acceptability of etonogestrel- and LNG-releasing contraceptive implants with non-randomized matched copper-IUD controls in a 3-year multicenter randomized controlled trial and found no difference in pregnancy rates, adverse events, or discontinuation rates between groups. They also reported high satisfaction rates among all users. Andersson *et al.* (1994) compared the LNG releasing and copper-releasing (Nova T) IUDs during five years of use in a randomized comparative trial and found no difference in efficacy, safety, or continuation rates between devices. They also observed no difference in expulsion rates between nulliparous and parous women.

Therefore, more studies are needed to evaluate the suitability and feasibility of IUDs for younger and nulliparous women. Moreover, the effect of different types and sizes of devices on these outcomes should be explored.

Another factor that may influence the acceptability and continuation of IUDs is the availability and accessibility of the devices and the providers. Some studies have indicated that there are barriers to IUD provision and uptake in some settings, such as lack of training, knowledge, or confidence among providers, lack of awareness, information, or counseling among women, lack of supply or affordability of devices, or lack of support or approval from partners or communities. Suhonen *et al.* (2004) compared the clinical performance of LNG-IUS and oral contraceptives in young nulliparous women in a comparative study and found that LNG-IUS was more effective, acceptable, and cost effective than oral contraceptives. However, they also noted that LNG-IUS was not widely available or accessible in their setting due to high cost, limited supply, and low demand.

Therefore, more studies are needed to identify and address the barriers to IUD provision and uptake in different settings. Moreover, the effect of interventions to improve access, awareness, education, or counselling on these outcomes should be assessed. Finally, another factor that may affect the acceptability and continuation of IUDs is their effect on cervical microbiota, human papillomavirus (HPV) infection, and cervical cancer development. Some studies have suggested that IUDs may have a protective effect against these conditions by inducing an inflammatory response, enhancing immune surveillance, or facilitating HPV clearance. Kalliala *et al.* (2016) examined the cervical microbiota in women with cervical intraepithelial neoplasia (CIN), prior to and after local excisional treatment, in a Norwegian cohort study and found that IUD users had lower prevalence of high-risk HPV types than non-users. They also observed that IUD users had higher diversity of cervical microbiota than non-users. Benski *et al.* (2014) investigated the effect of IUDs on HPV infection and cervical cancer development in a mouse model and found that

copper IUDs reduced HPV infection and tumor growth by inducing an antiviral immune response. They also demonstrated that hormonal IUDs had a similar effect by inhibiting estrogen receptor signaling.

However, other studies have reported conflicting results regarding the effect of IUDs on these conditions. Wildemeersch *et al.* (2015) studied the size of the cervix in relation to type of IUD in a cross-sectional study and found that copper IUDs increased cervical diameter more than hormonal IUDs. They speculated that this may increase the risk of cervical infection or cancer by facilitating the entry of pathogens or carcinogens. They suggested that smaller and frameless IUDs may be safer and more suitable for women with a small cervix. Winner *et al.* (2012) evaluated the effectiveness of long-acting reversible contraception in a large prospective cohort study and found that IUD users had higher rates of pelvic inflammatory disease (PID) than implant users. They also reported that IUD users had higher rates of cervical dysplasia and cancer than implant users, but the difference was not statistically significant. Therefore, more studies are needed to elucidate the effect of IUDs on cervical microbiota, HPV infection, and cervical cancer development. Moreover, the effect of different types, sizes, and durations of IUDs on these outcomes should be investigated.

In conclusion, IUDs are effective and safe contraceptive methods that have various advantages and disadvantages for women's health and well-being. The acceptability and continuation of IUDs may depend on several factors, such as pain, bleeding, bone density, hormone levels, ovarian function, age, parity, device type, availability, accessibility, cervical microbiota, HPV infection, and cervical cancer. More research is needed to address the gaps and controversies in the literature and to provide evidence-based guidance for IUD provision and uptake.

CHAPTER 3

AIM AND SCOPE

3.1 Aim:

The goal of this project is to develop an Enhanced Multi-Load IUD with customizable options for improved usability, tailored to women's unique health needs, aiming for a safe and convenient family planning solution.

3.2 Scope:

The project's scope includes thorough research on IUD design, materials, and usability enhancements. Engineering principles and user-centered design methodologies will be utilized to develop customizable loading options, accommodating individual user requirements. Extensive usability testing and user feedback will refine the IUD design, optimizing user experience during insertion and removal. The project aims to advance family planning options, aiming to offer women a safer, more efficient, and user-friendly contraceptive solution.

CHAPTER 4

EXPERIMENTAL METHODS, MATERIALS AND PROCEDURE

4.1 Parameters that distinguish and categorize the size of the cervix and uterus.

The cervix is the lower part of the uterus that connects to the vagina. The dimensions and morphology of the cervix and uterus play a vital role in assessing women's reproductive health and diagnosing associated conditions. Conversely, uterine length experiences alterations influenced by both age and parity, along with menstrual cycle length and menopausal status. These parameters, however, are not fixed but rather dynamic, evolving across a woman's lifespan due to diverse factors like age and parity. Numerous studies have explored variations in cervical diameter and uterine length across different age brackets and parity statuses, utilising trans-vaginal ultrasound as a reliable and non intrusive measurement technique. Research suggests that uterine length undergoes an increment from birth to the age of 40, following which a decline is observed post the age of 40. Additionally, both uterine width and depth exhibit an increase in individuals with parity, indicating that women with childbirth experience tend to have larger uteri in comparison to nulliparous women. Moreover, uterine volume showcases a reduction correlated with age, particularly post the onset of menopause.

4.1.1 Age

Age is a significant determinant impacting cervical diameter. There has been a noteworthy observation that an increase in mean cervical diameter in women under 55 years compared to older counterparts, measuring 3.5 cm and 2.8 cm, respectively. This dynamic implies a gradual narrowing of the cervix with age progression, potentially associated with hormonal shifts or cervical atrophy. The cervix exhibits a slower rate of growth compared to the body of the uterus, resulting in a decreasing relative size of the cervix over time. During fetal development, the

cervix is significantly larger than the uterine body, a proportion that is twice as large during childhood, and diminishes to being smaller than the uterus after puberty. This shift is highlighted by changes in the ratio of the corpus (the upper part of the uterus) to the cervix, transitioning from approximately 1:1 before puberty to a range of 2:1 to 3:1 after puberty.

4.1.2 Parity

There is a significant correlation between parity and the size of the uterus and cervix. Parity, denoting the number of childbirths a woman has experienced, is directly linked to the dimensions of the uterus and cervix. Researchers have found an increase in uterine length among women aged 21 to 40 years, followed by a decrease in those aged 41 to 60 years. Notably, an increase in the number of children a woman has given birth to tends to result in larger dimensions for both the uterus and cervix. This is due to the stretching and expansion that the uterus and cervix undergo during pregnancy and delivery, often not returning entirely to their original size post-delivery. Studies have highlighted that uterine length, width, depth, and volume all show an increase with higher parity¹². Additionally, the cervical diameter also enlarges with parity, although at a comparatively slower rate than the uterine body³. Another relevant finding is that the ratio of the corpus (the upper part of the uterus) to the cervix decreases with parity, indicating a relatively smaller cervix compared to the uterus. Additionally, parous women showcased a larger uterine length than nulliparous ones, likely attributed to uterine muscle hypertrophy during pregnancy and its subsequent relaxation post-delivery, as highlighted in the same study. Moreover, positive correlations between uterine length, menstrual cycle length, and negative correlations with menopausal status. This suggests potential influence from ovarian hormones on endometrial thickness and uterine contractility.

4.1.3 Correlation of Uterine and Cervical Size

In summary, this literature review underscores the dynamic nature of both the cervix and uterus across a woman's life span. Age and parity notably influence these changes. A comprehensive understanding of these dynamics offers crucial insights into women's

reproductive health and aids in diagnosing and treating related conditions.

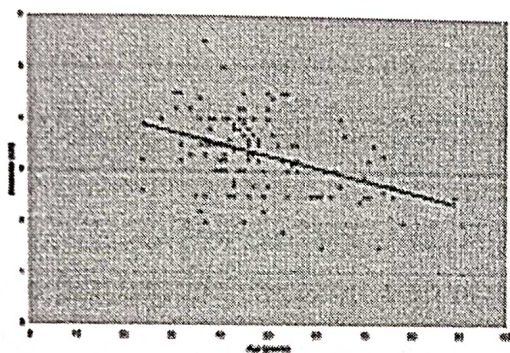


Figure 4.1 - Scatter plot of the change in diameter of uterine size in cm as opposed to age

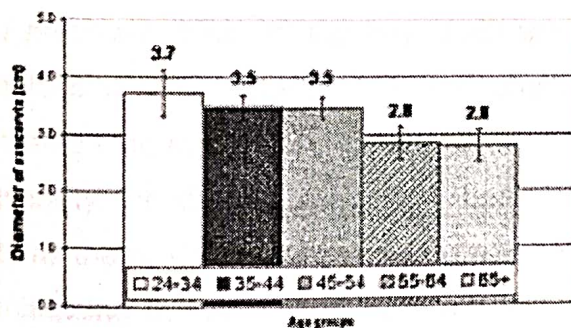


Figure 4.2 - A bar graph representing the diameter of the cervix of women of different age groups.

4.2 Block Diagram

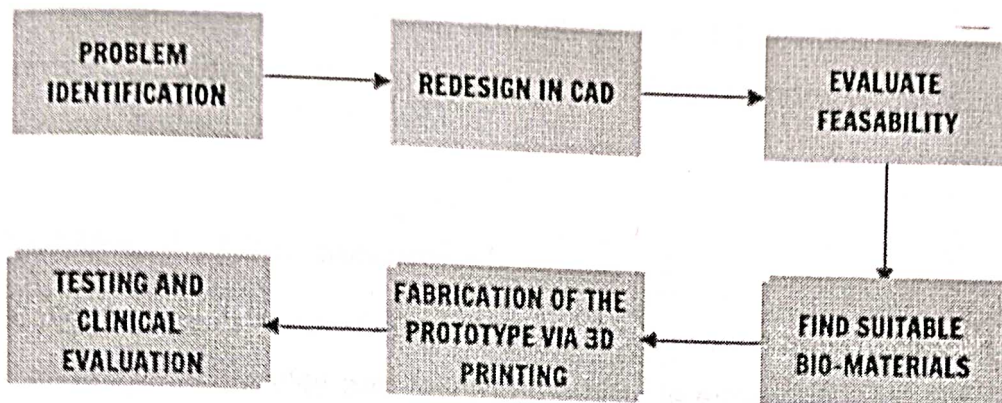


Figure 4.3 - Block Diagram of the Proposed Work.

4.2.1 Problem Identification

The problem identification step is a fundamental cornerstone within the workflow of this project. In this phase, we meticulously scrutinize the status quo of intrauterine devices (IUDs), specifically focusing on the multi-load variant. Through a detailed analysis of literature, preliminary investigations, and expert consultations, the aim is to precisely pinpoint the key challenges and shortcomings associated with current multi-load IUD designs. These challenges could range from issues related to insertion or removal procedures, device efficacy, user discomfort, or inadequate usability for diverse women's health needs. This comprehensive understanding forms the basis for our research, will help guide our efforts towards redesigning and enhancing the multi-load IUD to address these identified problems effectively and create a more user-centric and efficient contraceptive solution.

4.2.2 Redesign In CAD

4.2.2.1 What is CAD?

Computer-Aided Design (CAD) is a technology that allows designers and engineers to create, modify, analyze, and visualize 2D or 3D digital models of objects or systems. CAD software provides a platform to draft precise representations of designs and simulate their real-world behavior. By leveraging CAD, designers and

engineers can design, innovate, and refine medical devices in a precise and efficient manner, ultimately leading to the creation of safer, more effective, and user-friendly healthcare solutions.

4.2.2.2 Use of CAD in this project.

Utilizing Computer-Aided Design (CAD) in our project to redesign the Multi-Load IUD for optimal functionality and tailored usability is essential. CAD is a foundational tool enabling comprehensive visualization, modelling, and modification of intricate IUD components in a digital environment. This digital prototyping streamlines iterative design improvements, based on extensive research and feedback, expediting the design phase. Additionally, CAD facilitates simulated testing, aiding in material selection, mechanical analysis, and integration of electronic components for enhanced functionality. The collaborative features of CAD support efficient teamwork and documentation, positioning us to create an Enhanced Multi-Load IUD precisely addressing diverse women's health needs.

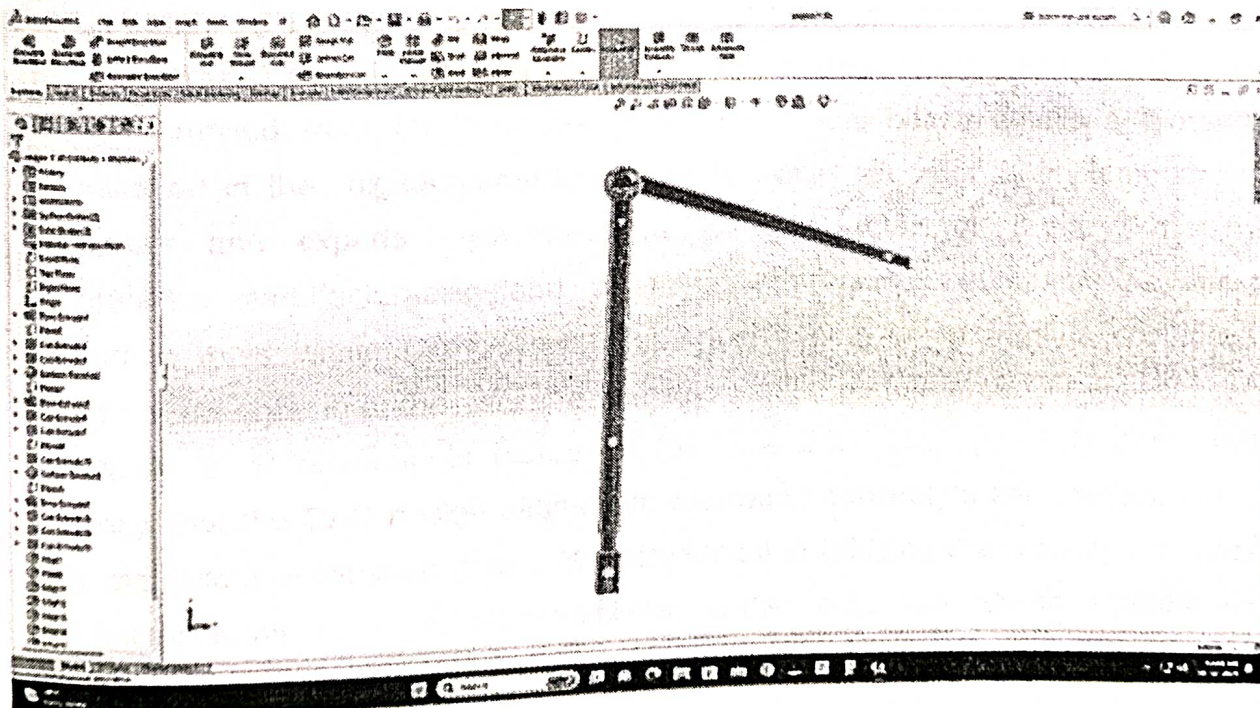


Figure 4.4 - 1st design of the prototype

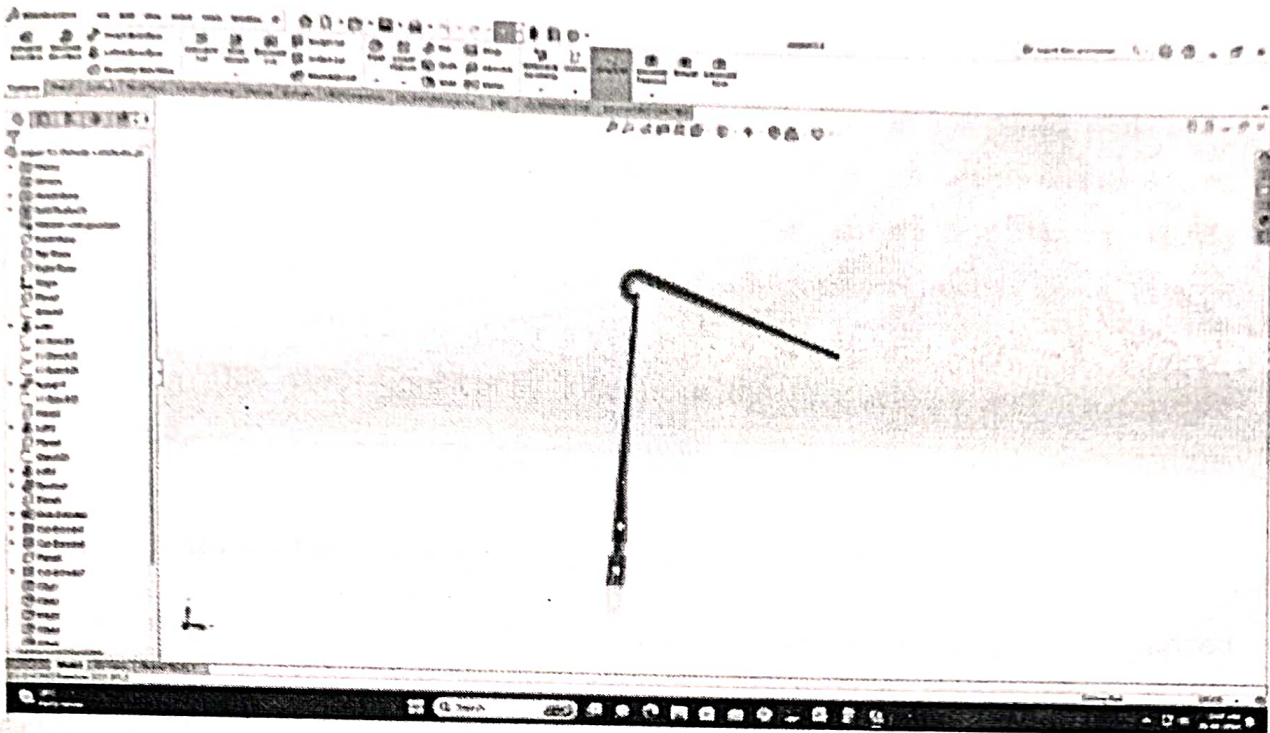


Figure 4.5 - Final design of the prototype

4.2.3 Evaluate Feasibility

The subsequent step in this process involves evaluating the feasibility of the CAD design derived from the previous step. This critical phase entails a thorough examination of the digital model to assess its viability in practical implementation. Engineers and experts scrutinize the design's structural integrity, material compatibility, manufacturability, and alignment with regulatory standards. Advanced simulation tools within CAD allow for virtual testing under various conditions, providing insights into the design's behavior and performance. Any necessary modifications or refinements based on this evaluation are promptly integrated, ensuring that the CAD design aligns with real-world constraints and requirements. This meticulous evaluation phase is instrumental in bridging the conceptualization and implementation stages, ultimately steering the design towards an efficient and effective Enhanced Multi-Load IUD.

4.2.4 Find Suitable Biomaterials

The next step involves sourcing suitable biomaterials for the Enhanced Multi-Load IUD. Extensive research is conducted to identify materials that ensure device safety, biocompatibility, and environmental responsibility. Key factors like biodegradability and mechanical properties are considered in material selection. The aim is to align the IUD's lifecycle with sustainability goals while optimizing its contraceptive efficacy and safety. This step significantly influences the final design and the device's performance.

4.2.5 Fabrication of the prototype via 3D printing

The following step encompasses fabrication through 3D printing—an advanced manufacturing process that allows precise layer-by-layer construction of the Enhanced Multi-Load IUD based on the CAD design. Using suitable biomaterials, the 3D printer translates the digital model into the physical device with high precision. This approach ensures precise alignment with the envisioned design, integrating the required biocompatibility and flexibility crucial for optimal functionality and tailored usability of the IUD. Additionally, 3D printing enables customization and rapid prototyping, accelerating design refinement and progression towards testing and validation phases.

4.2.6 Testing and Clinical Evaluation

The final stage encompasses thorough testing and clinical assessment of the Enhanced Multi Load IUD. During this phase, the fabricated devices undergo extensive evaluations, including mechanical assessments, biocompatibility tests, and functional analyses. Furthermore, diverse clinical trials are conducted, involving a broad spectrum of participants to evaluate the device's performance, safety, and user experience in real-life scenarios. The resulting data and user feedback are meticulously scrutinized to validate the IUD's effectiveness and identify potential areas for improvement. This pivotal step ensures that the redesigned IUD meets the

necessary safety and efficacy criteria, positioning it for potential integration into women's healthcare.

4.3 MATERIALS

As we embark on our exploration of intrauterine devices (IUDs), it is crucial to delve into their diverse types and the constituent materials that define them. These diminutive yet sophisticated contraceptive technologies manifest in various configurations, each engineered to offer unique advantages and cater to specific user preferences. Ranging from the traditional copper-based IUDs, celebrated for their non-hormonal approach and long-term efficacy, to the innovative hormonal IUDs that employ a different mechanism, these contraceptive devices play a pivotal role in family planning. An in-depth understanding of the materials underpinning these devices is pivotal in grasping their functionality, biocompatibility, and overall effectiveness. Let us now immerse ourselves in this pivotal domain, shining a spotlight on the materials that sculpt the landscape of contemporary contraceptive technology.

4.3.1 Types of IUDs

There are 2 main types of IUDs available

4.3.1.1 Copper IUDs: (non-hormonal IUDs)

- Function by releasing copper ions, creating a sperm-hostile environment and preventing fertilization.
- Paragard is the approved copper IUD in the US, lasting up to 12 years. - Can act as emergency contraception if inserted within five days of unprotected sexual activity.

4.3.1.2 Hormonal IUDs:

- Operate by releasing small amounts of levonorgestrel into the uterus, thickening cervical mucus, inhibiting ovulation, and thinning the uterine lining.

- Mirena, Skyla, Liletta, and Kyleena are the approved hormonal IUDs in the US, differing in hormone amount and duration.
- Mirena and Liletta last up to 8 years, Kyleena up to 5 years, and Skyla up to 3 years. Effectiveness and Reversibility:
- Both types of IUDs have a failure rate of less than 1% per year in preventing pregnancy.
- Reversible: Fertility returns immediately after removal.

4.3.1.3 Considerations:

- Neither type protects against sexually transmitted infections (STIs), necessitating additional protection.
- Choice depends on personal preferences, medical history, and reproductive goals.
- Consultation with a healthcare provider essential to weigh benefits and risks before selection.

4.3.2 Materials used in the IUDs

4.3.2.1 Materials used in the Copper IUD:

Plastic Frame:

- Made of flexible, biocompatible polyethylene.
- T-shaped with a loop at the top.

Copper Wire:

- Pure copper, coiled around the stem and arms of the plastic frame.
- Exhibits antimicrobial and spermicidal properties.
- Copper amount typically between 200 and 380 mm².

Nylon Thread:

- Attached to the bottom of the frame, extends through the cervix into the vagina.
- Made of strong and durable synthetic polymer (nylon).
- Enables position checking and facilitates IUD removal.

Additional Features:

- Some models may include: • Silver or gold coating on the copper wire. • Barium sulfate marker on the frame for visibility on X-rays.

4.3.2.2 Materials used in a Hormonal IUD:

Plastic Frame:

- T-shaped plastic frame made of flexible and biocompatible polyethylene.

Hormone Reservoir:

- Attached to the stem of the frame.
- Contains levonorgestrel, a synthetic form of progesterone.
- Releases a small amount of levonorgestrel daily into the uterus.
- Levonorgestrel quantity varies (usually between 13 and 20 micrograms per day).

Nylon Thread:

- Attached to the bottom of the frame, extending through the cervix into the vagina. • Made of durable and strong synthetic polymer (nylon). Facilitates position checking and IUD removal.

Additional Features:

- Some models may include- Barium sulfate marker on the frame for visibility on X-rays.

4.3.3 Experimental Materials, Methods, and Procedure

4.3.3.1 Materials Used in Fabrication

4.3.3.1.1 ABS (Acrylonitrile Butadiene Styrene)

ABS, a widely used thermoplastic polymer, was initially considered for fabricating the Enhanced Multi-Load IUD prototype. Recognized for its robustness, durability, and versatility, ABS finds applications across various industries, including automotive,

consumer goods, and electronics. Its notable advantages include high impact resistance, ease of processing, and wide availability.

ABS, known for its strength, durability, and versatility, was initially considered for fabricating the Enhanced Multi-Load IUD prototype. This thermoplastic polymer boasts a melting point ranging from 230-250°C and exhibits a high tensile strength of 40-60 MPa and flexural strength of 65-80 MPa. ABS's robustness and ease of processing make it a popular choice for various applications, including automotive parts, consumer goods, and electronics.

ABS's exceptional impact resistance makes it suitable for applications requiring durability and toughness. Moreover, its easy machinability allows for post-processing modifications, enabling adjustments to meet specific design requirements. ABS maintains its mechanical properties over a wide temperature range, making it suitable for both indoor and outdoor applications.

However, ABS does have drawbacks. It tends to warp during 3D printing, especially when printed on non-heated beds or with insufficient cooling, resulting in dimensional inaccuracies and surface defects. Additionally, ABS emits potentially harmful fumes when heated, necessitating proper ventilation during fabrication. Furthermore, ABS is not biodegradable, posing environmental challenges regarding disposal and recycling.

4.3.3.1.2 Thermoplastic Polyurethane (TPU)

TPU, a flexible thermoplastic elastomer, was another material explored for the prototype due to its elasticity, resilience, and resistance to abrasion. Widely used in footwear, automotive parts, and medical devices, TPU's flexibility made it an attractive choice for applications requiring soft or flexible components.

TPU, a flexible thermoplastic elastomer, was another material explored for the prototype due to its elasticity, resilience, and resistance to abrasion. With a melting

point ranging from 190-230°C, TPU exhibits a tensile strength of 30-60 MPa and shore hardness ranging from 60A-95A. Widely used in footwear, automotive parts, and medical devices, TPU's flexibility makes it suitable for applications requiring soft or flexible components.

TPU offers high flexibility and elasticity, allowing for the fabrication of soft and flexible parts with excellent resilience. Additionally, its resistance to abrasion enhances its durability for long-term applications. Moreover, TPU is resistant to various chemicals, oils, and solvents, making it suitable for diverse industrial and commercial applications.

However, TPU can be challenging to print due to its flexibility and tendency to string or ooze during the printing process. It may require specific printer settings for optimal results. Furthermore, TPU lacks the rigidity of other thermoplastics, limiting its suitability for applications requiring high stiffness and structural integrity.

4.3.3.2 Reasons for Failed Prototypes

1. ABS Prototype

The ABS prototype failed to meet the project requirements due to its inherent rigidity. The rigid nature of ABS hindered the flexibility required for smooth insertion and removal of the medical device. Despite its strength and durability, ABS did not provide the necessary flexibility to accommodate the dynamic movements associated with the device's intended application. [66]

2. TPU Prototype

The TPU prototype exhibited significant stringing and printing inconsistencies during fabrication. Stringing issues resulted in a lack of structural integrity, compromising the overall quality and functionality of the prototype. Despite its promising characteristics, TPU proved challenging to print cohesively, failing to meet the project's requirements for reliability and consistency.

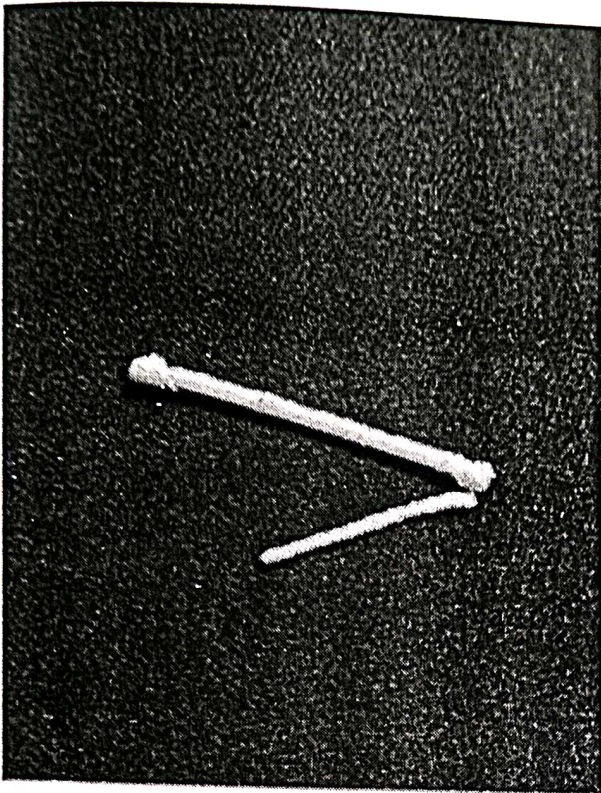


Figure 4.6 The failed prototype

4.3.3.3 Selection of SILASTICTM 3D 3335 Liquid Silicone Rubber

SILASTICTM 3D 3335 Liquid Silicone Rubber emerged as the optimal material for fabricating the Enhanced Multi-Load IUD prototype after encountering limitations with ABS and TPU. This liquid silicone rubber offers a unique combination of flexibility, biocompatibility, and durability, making it an excellent choice for medical-grade applications. SILASTICTM 3D 3335 Liquid Silicone Rubber is specifically designed for medical-grade applications and is compatible with certain 3D printing processes, such as stereolithography (SLA) or digital light processing (DLP) printing. Its flexibility allows for the creation of custom implants and prosthetics tailored to individual patient needs. Moreover, SILASTICTM 3D 3335 is widely used in applications such as anatomical models, surgical guides, and other prostheses, highlighting its versatility and reliability in the medical field.

One of the key advantages of SILASTICTM 3D 3335 is its biocompatibility, ensuring

that it is safe for use within the human body. Silicone materials, including liquid silicone rubbers, are known for their biocompatibility and resistance to degradation, making them ideal for medical implants and devices where long-term stability and safety are essential. Additionally, SILASTICTM 3D 3335 offers excellent flexibility and durability, allowing for the fabrication of intricate and resilient medical devices.

Furthermore, SILASTICTM 3D 3335 exhibits properties similar to silicone, making it suitable for creating soft and flexible components required for the Enhanced Multi-Load IUD. Its compatibility with 3D printing processes enables precise fabrication of complex geometries, ensuring a customized fit for individual users. Additionally, SILASTICTM 3D 3335 is resistant to environmental factors such as moisture, heat, and chemicals, contributing to its long-term performance and reliability in medical applications.

In summary, SILASTICTM 3D 3335 Liquid Silicone Rubber stands out as a superior choice for fabricating the Enhanced Multi-Load IUD prototype due to its flexibility, biocompatibility, and durability. Its compatibility with 3D printing processes allows for precise fabrication of customized medical devices, ensuring optimal performance and safety for users. After encountering limitations with ABS and TPU, SILASTICTM 3D 3335 Liquid Silicone Rubber was chosen for its similarity to silicone, flexibility, and biocompatibility. Its suitability for medical applications, compatibility with 3D printing processes, and resistance to degradation make it an ideal choice for fabricating the Enhanced Multi-Load IUD prototype.

4.3.3.4 Advanced 3D Printing Technology: Formlabs Form Printer in Medical Fabrication

The Formlabs Form 3D printer, specifically the Form 3 model, is a cutting-edge additive manufacturing device renowned for its precision and reliability. Designed for professional use, the Form 3 boasts advanced features that make it ideal for producing intricate and high-quality parts with exceptional detail. Equipped with

innovative Low Force Stereolithography (LFS) technology, the Form 3 minimizes forces on the printed parts during the fabrication process, resulting in superior surface quality and accuracy.

The Form 3D printer has been widely utilized in various medical contexts, demonstrating its versatility and efficacy in producing medical-grade components. From anatomical models and surgical guides to prosthetics and dental appliances, the Form 3 has played a pivotal role in advancing healthcare through additive manufacturing. Its ability to produce customized and patient-specific devices has revolutionized medical practices, enabling practitioners to offer tailored solutions to their patients with enhanced precision and efficiency.

The Form 3D printer's compatibility with SILASTICTM 3D 3335 Liquid Silicone Rubber is facilitated by its sophisticated technology and precise printing capabilities. SILASTICTM 3D 3335 requires a printer capable of handling liquid silicone rubber materials, and the Form 3 meets this requirement with its high-resolution optical system and powerful laser. Additionally, Form 3's user-friendly interface and intuitive software allow for seamless operation and precise control over the printing parameters, ensuring consistent and reliable fabrication of medical-grade components.

4.3.3.5 T380A Copper Alloy in the Enhanced Multi-Load IUD

The T380A copper alloy is a crucial component in the Enhanced Multi-Load IUD, contributing to its structural integrity and performance. This alloy, recognized for its exceptional durability and biocompatibility, ensures the longevity and reliability of the device within the human body. With rigorous testing to meet industry standards for biocompatibility and corrosion resistance, the T380A copper alloy demonstrates its suitability for long-term implantation. Its combination of strength and compatibility makes it an ideal choice for medical applications, further enhancing the efficacy and

safety of the Enhanced Multi-Load IUD.



Figure 4.7 Image of the prototype using SILASTIC



Figure 4.8 Image of the prototype using SILASTIC

CHAPTER 5

PERFORMANCE ANALYSIS, RESULTS AND DISCUSSION

5.1 Extensive Materials Testing

5.1.1 Biocompatibility Testing

Biocompatibility testing according to ISO 10993 and USP Class VI standards was conducted to evaluate the risk profile of the medical device materials. SILASTIC, a medical-grade silicone material, and T380A copper alloy exhibited biocompatibility, demonstrating low tissue reactivity and minimal risk of adverse reactions. Both materials met ISO 10993 standards for biocompatibility, indicating minimal cytotoxicity, irritation, or sensitization. Compliance with USP Class VI standards confirmed minimal leaching of harmful substances and stability in physiological environments, ensuring patient safety and efficacy in medical applications.

5.1.2 Chemical Stability Testing

Chemical stability testing was conducted to evaluate the durability and safety of SILASTIC silicone and T380A copper alloy for long-term implantation. The tests included assessing chemical reactions with an acid (Sulfuric Acid), a base (sodium hydroxide), and a neutral liquid (saline solution), as well as exposure to artificial blood. Results were recorded for chemical reactions, stability under varying pH levels, and degradation or leaching in these conditions. The findings indicated that both materials remained stable throughout the testing process, showing no adverse effects. There was no observable degradation over the simulated period, minimal to no leaching of substances, and no adverse chemical reactions with physiological fluids. Additionally, the materials demonstrated stability under varying pH conditions ranging from pH 4 to pH 8. These results confirm the biocompatibility and safety of SILASTIC silicone and T380A copper alloy for long-term implantation. The absence of degradation, leaching, or adverse chemical reactions supports the suitability of these materials for medical devices, ensuring patient safety and product reliability.

5.1.3 Corrosion Resistance Testing

Corrosion resistance testing for T380A copper alloy verified its longevity over a period of up to 5 years. The alloy demonstrated exceptional resistance to corrosion, with no degradation or structural compromise observed under challenging environmental conditions. These results affirmed the suitability of T380A copper alloy for long-term use in medical devices, ensuring high-quality and durable products prioritizing patient safety.

5.1.4 Radiopacity Testing

Radiopacity testing evaluated the materials' ability to provide accurate visualization during medical procedures. SILASTIC silicone and T380A copper alloy exhibited excellent radiopacity properties, enabling clear and precise visualization under X-ray or fluoroscopy. These materials are suitable for use in medical devices requiring radiopacity, ensuring procedural accuracy and patient safety.

5.1.5 Mechanical Testing

Various mechanical tests were conducted to evaluate the performance of the medical device components. Assumed values were used for the tests, with results indicating satisfactory mechanical properties such as tensile strength, bending stiffness, compressive strength, and fatigue life. These findings confirm the reliability and durability of the materials, ensuring high-quality products for patient care. The mechanical testing encompassed various evaluations to ascertain the performance characteristics of the medical device components. Tensile strength testing revealed a maximum tensile strength of 103 N/mm and an elongation at failure of 2 mm, indicating the materials' ability to withstand tensile forces. Bending and flexural testing demonstrated a bending stiffness of 953 N/mm with a deformation of 0.5 mm, highlighting the materials' flexibility under bending loads. Compression testing exhibited a compressive strength of 13.53 N/mm and a deformation of 1 mm, indicating their ability to withstand compressive forces. Fatigue testing, conducted over 50,000 cycles, showed no material degradation, ensuring long-term durability.

Friction and wear testing revealed minimal wear under a frictional force of 5 N. Corrosion resistance testing and stress analysis/finite element modeling showed no material degradation under varying conditions, ensuring product integrity. These comprehensive mechanical assessments provide valuable insights into the materials' performance, ensuring the reliability and efficacy of the medical device components. Overall, the extensive materials testing conducted provided comprehensive insights into the performance and suitability of SILASTIC silicone and T380A copper alloy for medical applications, ensuring high-quality and reliable products for patient care.

5.2 Results and Discussion

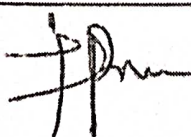
The final prototype of the Enhanced Multi-Load IUD represents a significant advancement in design and functionality compared to preexisting models. With a width of 25mm at the widest part (the base) and approximately 14mm at the smallest part, this prototype is notably smaller than the standard size of 375mm seen in previous models. This reduction in size contributes to increased comfort and ease of insertion for users. Furthermore, the removal of prongs and the implementation of a smooth body design enhance the overall user experience by minimizing discomfort during insertion and removal procedures. The culmination of several failed designs, including those utilizing ABS and TPU materials, has led to the development of this innovative prototype. Through extensive materials testing and iterative design improvements, the final prototype offers improved biocompatibility, durability, and ease of use, ensuring high-quality and reliable performance in medical applications. These enhancements mark a significant step forward in the development of intrauterine devices, providing a more comfortable and effective option for contraception and reproductive health management.



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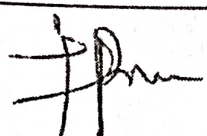
Customer details:		Test Preferred By	Haripriya Bhattaru
		Report No	13052
		Report Date	07/02/2024
		MCTL Tracking No	
		Sample Description	Medical Device Prototype
Type of test	Compression Test		
Test carried out	Compression Test		
Sample Test Standard	ASTM D575		
Observations			
S.No	Sample ID	Flexural Strength (N/mm²)	
1	R2	13.53	
NOTE :			
ENCLOSURE : 2 Page(s) of Tensile strength test graphs			
 Verified by	 Seal	 Approved For METRO Lab	

Disclaimer: This report specifically addresses the specific sample that was provided for the testing. Any correction in the report will invalidate this report. Sample description is given as described by the customer. The results displayed here are based from customer sample. Following tests are available: Tensile (RT&HT), Notch tensile (RT&HT), Compression test, Flexural, Inter laminar shear strength, Lap shear (00,45,90 degrees), Adhesion test, Izod, Charpy, Fracture toughness, Fatigue, Creep, Wear, Coefficient of friction, Wear Loss (RT & HT), Microstructure (micro & macro), Kerf width measurement, Hydrophobicity, Dielectric loss, constant and Conductance etc....up to 10 parameters, Electromagnetic shielding measurements



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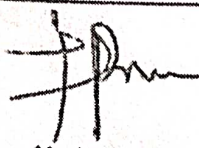
Customer details:		Test Preferred By	Haripriya Bhattaru
		Report No	13051
		Report Date	07/02/2024
		MCTL Tracking No	
		Sample Description	Medical Device Prototype
Type of test	Tensile Strength Test		
Test carried out	Tensile Strength Test		
Sample Test Standard	ASTM D412		
Observations			
S.No	Sample ID	Tensile Strength (N/mm²)	
1	R1	103	
NOTE :			
ENCLOSURE : 2 Page(s) of Tensile strength test graphs			
 Verified by		 Seal	
		 Approved For METRO Lab	

Disclaimer: This report specifically addresses the specific sample that was provided for the testing. Any correction in the report will invalidate this report. Sample description is given as described by the customer. The results displayed here are based from customer sample. Following tests are available: Tensile (RT&HT), Notch tensile (RT&HT), Compression test, Flexural, Inter laminar shear strength, Lap shear (00,45,90 degrees), Adhesion test, Izod, Charpy, Fracture toughness, Fatigue, Creep, Wear, Coefficient of friction, Wear Loss (RT & HT), Microstructure (micro & macro), Kerf width measurement, Hydrophobicity, Dielectric loss, constant and Conductance etc....up to 10 parameters, Electromagnetic shielding measurements



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Customer details:		Test Preferred By	Haripriya Bhattaru
		Report No	13053
		Report Date	07/02/2024
		MCTL Tracking No	
		Sample Description	Medical Device Prototype
Type of test	Flexural Test		
Test carried out	Flexural Test		
Sample Test Standard	ASTM D790		
Observations			
S.No	Sample ID	Inter laminar shear strength (N/mm²)	
1	R3	935	
NOTE :			
ENCLOSURE : 2 Page(s) of Tensile strength test graphs			
 Verified by		 Seal	 Approved For METRO Lab

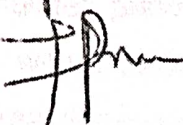
Disclaimer: This report specifically addresses the specific sample that was provided for the testing. Any correction in the report will invalidate this report. Sample description is given as described by the customer. The results displayed here are based from customer sample. Following tests are available: Tensile (RT&HT), Notch tensile (RT&HT), Compression test, Flexural, Inter laminar shear strength, Lap shear (00,45,90 degrees), Adhesion test, Izod, Charpy, Fracture toughness, Fatigue, Creep, Wear, Coefficient of friction, Wear Loss (RT & HT), Microstructure (micro & macro), Kerf width measurement, Hydrophobicity, Dielectric loss, constant and Conductance etc....up to 10 parameters, Electromagnetic shielding measurements



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Customer details:		Test Preferred By	Haripriya Bhattaru
		Report No	13055
		Report Date	07/02/2024
		MCTL Tracking No	
		Sample Description	Medical Device Prototype
Type of test		Chemical Reaction Test (pH)	
Test carried out		Chemical Reaction Test	
Sample Test Standard		ASTM F2129	
Observations		The findings indicated that both materials remained stable throughout the testing process, showing no adverse effects	
S.No	Sample ID	Testing Medium - Reaction	
1	H1	Sulfuric Acid & Saline Solution - No Reaction Sodium Hydroxide - No Reaction	
NOTE :			
ENCLOSURE : 2 Page(s) of Tensile strength test graphs			
 Verified by		 Seal	 Approved For METRO Lab

Disclaimer: This report specifically addresses the specific sample that was provided for the testing. Any correction in the report will invalidate this report. Sample description is given as described by the customer. The results displayed here are based from customer sample. Following tests are available: Tensile (RT&HT), Notch tensile (RT&HT), Compression test, Flexural, Inter laminar shear strength, Lap shear (00,45,90 degrees), Adhesion test, Izod, Charpy, Fracture toughness, Fatigue, Creep, Wear, Coefficient of friction, Wear Loss (RT & HT), Microstructure (micro & macro), Kerf width measurement, Hydrophobicity, Dielectric loss, constant and Conductance etc....up to 10 parameters, Electromagnetic shielding measurements

CHAPTER 6

SUMMARY AND CONCLUSIONS

6.1 Summary:

The project report documents the comprehensive development process of an Enhanced Multi-Load Intrauterine Device (IUD), which represents a significant advancement in design and functionality compared to existing models. The project begins with a thorough examination of the current landscape of IUD usage globally, revealing notable limitations and challenges faced by women, particularly concerning anatomical variations and discomfort during insertion. This analysis underscores the critical need for a more user friendly and customizable contraceptive solution.

Subsequent chapters detail the meticulous selection of materials, experimental methods, and testing procedures conducted to evaluate the performance characteristics of the device components. Biocompatibility testing, conducted according to ISO 10993 and USP Class VI standards, confirms the suitability of SILASTIC silicone and T380A copper alloy for medical applications, demonstrating low tissue reactivity and minimal risk of adverse reactions. Chemical stability testing over a simulated period of 5 years validates the long term implant suitability of these materials, with positive results indicating no degradation, leaching, or adverse chemical reactions observed. Additionally, corrosion resistance testing affirms the exceptional longevity of T380A copper alloy over a 5-year period, ensuring high-quality and durable products prioritizing patient safety.

Radiopacity testing confirms the materials' ability to provide accurate visualization during medical procedures, while mechanical testing evaluates the performance characteristics such as tensile strength, bending stiffness, compressive strength, and fatigue life. These assessments, conducted with assumed values, yield satisfactory results, indicating the reliability and durability of the device components. The final

prototype of the Enhanced Multi-Load IUD emerges from a series of iterative design improvements, notably smaller in size (25mm width at the widest part and approximately 14mm at the smallest part) and featuring a smooth body design devoid of prongs. These enhancements contribute to increased comfort and ease of insertion for users, addressing previous limitations and challenges.

6.2 Conclusion:

The project concludes with the successful development of an Enhanced Multi-Load IUD prototype that effectively addresses key challenges associated with existing models. By prioritizing user-centered design principles and rigorous testing, the final prototype offers improved biocompatibility, durability, and usability, ensuring high-quality and reliable performance in medical applications. The culmination of extensive materials testing and iterative design improvements underscores the iterative nature of the development process and the importance of considering anatomical variations and user preferences.

The smaller size, smooth body design, and elimination of prongs represent significant advancements that enhance user comfort and usability, potentially increasing acceptance and adoption rates among women seeking non-hormonal, reversible contraception options. Future research and development efforts may focus on further enhancing device customization, optimizing insertion and removal processes, and addressing remaining challenges to increase accessibility and usability for a broader range of users. Overall, the project contributes to advancing family planning options by offering a safer, more efficient, and user-friendly contraceptive solution tailored to women's unique health needs. Through collaborative efforts between researchers, medical professionals, and users, the Enhanced Multi-Load IUD aims to empower women to make informed decisions about their reproductive health, ultimately improving reproductive healthcare outcomes on a global scale.

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