IZMIR KATIP CELEBI UNIVERSITY ★ GRADUATE SCHOOL OF NATURAL AND APPLIED SCIENCES

DEVELOPING A NEW UTERINE MANIPULATOR (TRANSVAGINAL UTERUS AMPUTATION DEVICE) FOR TOTAL LAPAROSCOPIC HYSTERECTOMIES IN GYNECOLOGICAL SURGERIES

M.Sc. THESIS

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Department of Biomedical Technologies

Thesis Advisor: Assist. Prof. Dr. Hakan OFLAZ

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İZMİR KATİP ÇELEBİ ÜNİVERSİTESİ ★ FEN BİLİMLERİ ENSTİTÜSÜ

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YÜKSEK LİSANS TEZİ

Serkan DİKİCİ
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Tez Danışmanı: Yrd. Doç. Hakan OFLAZ

OCAK 2016

Serkan Dikici, **a M.Sc.** student of **IZMIR KATIP CELEBI UNIVERSITY Graduate School of Natural and Applied Science** student ID Y130101011, successfully defended the **thesis** entitled "**DEVELOPING A NEW UTERINE MANIPULATOR (TRANSVAGINAL UTERUS AMPUTATION DEVICE) FOR TOTAL LAPAROSCOPIC HYSTERECTOMIES IN GYNAECOLOGICAL SURGERIES**", which he prepared after fulfilling the requirements specified in the associated legislations, before the jury whose signatures are below.

Thesis Advisor:	**Assist. Prof. Dr. Hakan OFLAZ** **İzmir Katip Çelebi Üniversitesi**	**......................................**
Jury Members:	**Prof. Dr. Adnan KAYA** **İzmir Katip Çelebi Üniversitesi**	**......................................**
	Assoc. Prof. Dr. Bülent YILMAZ **İzmir Katip Çelebi Üniversitesi**	**......................................**
	Assist. Prof. Dr. Özgün BAŞER **İzmir Katip Çelebi Üniversitesi**	**......................................**
	Assist. Prof. Dr. Mehmet SARIKANAT **Ege Üniversitesi**	**................................**

Date of Submission: 13 January 2016

Date of Defense: 6 January 2016

To all my family,

FOREWORD

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ABBREVIATIONS

AAGL:	Association of Gynecologic Laparoscopists
ABS:	Acrylonitrile Butadiene Styrene
AM:	Additive Manufacturing
CAD:	Computer Aided Design
CT:	Computer Aided Tomography
FDM:	Fused Deposition Modelling
FEA:	Finite Element Analysis
FEM:	Finite Element Method
FOV:	Field of View
LED:	Light Emitting Diot
LENS:	Laser Engineered Net Shaping
LH:	Laparoscopic Hysterectomy
LOM:	Laminated Object Manufacturing
MRI:	Magnetic Resonance Imaging
PLA:	Poly lactic Acid
PWM:	Pulse Width Modulator
RMS:	Root Mean Square
RP:	Rapid prototyping
SLS:	Selective Laser Sintering
SL / STL:	Stereolithography
TLH:	Total Laparoscopic Hysterectomy
2D:	Two Dimensional
3DP:	Three Dimensional Printing
3D:	Three Dimensional

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DEVELOPING A NEW UTERINE MANIPULATOR (TRANSVAGINAL UTERUS AMPUTATION DEVICE) FOR TOTAL LAPAROSCOPIC HYSTERECTOMIES IN GYNECOLOGICAL SURGERIES

SUMMARY

Hysterectomy, that is removal of uterus, is one of the most common major operations in gynecologic surgeries. Laparoscopy technique is preferred in hysterectomy because of its advantages such as lower intra-operative blood loss, decreased surrounding tissue/organ damage, less operating time, lower post-operative infection and frequency of fever, shorter duration of hospitalization and post-operative returning time to normal activity.

Firstly uterine vessels and ligaments are cauterized respectively, and then cervicovaginal connections are cauterized and coagulated to remove uterus completely during laparoscopic hysterectomy. Uterine manipulators are used during laparoscopy to maximize the endoscopic vision of surgeons by moving related organs. However, conventional uterine manipulators have important drawbacks particularly to move uterus in three dimensions and to show cervicovaginal landmark during laparoscopic circular cauterization which is difficult and hand skill required process, and amputation of the uterine cervix.

A new transvaginal uterine manipulator may overcome these important drawbacks of these currently available devices. For this reason, a 3 dimensional (3D) scanning technique was used to obtain real world data such as uterine dimensions and computer aided design software is used in designing of the new manipulator and then 3D printer was used in prototyping. Special light emitting diodes (LEDs) were mounted on the cervical cap of the manipulator to guide light beams from inside of cervicovaginal tissue to abdominal cavity to facilitate the visualization of tissue landmarks.

In brief, structural synthesis, CAD and rapid prototyping of parallel manipulator with 2-dof and which allows the uterus to be manipulated in both anterior posterior and lateral axis was performed in the scope of this thesis. Furthermore, a circular LED system was designed and implemented on system to ease the determination of cervicovaginal landmark.

In the light of the findings acquired from the thesis, designed manipulator has 80° range of motion in sagittal and 80° in coronal planes. Moreover, LED illumination system which can be detected easily by the laparoscope is successfully implemented on the manipulator’s cervical cap.

JİNEKOLOJİK OPERASYONLARDA TOTAL LAPAROSKOPİK HİSTEREKTOMİ OPERASYONLARI İÇİN YENİ BİR UTERUS MANİPULATÖRÜ (TRANSVAJİNAL UTERUS AMPÜTASYON CİHAZI) GELİŞTİRİLMESİ

ÖZET

Rahmin alınması anlamına gelen histerektomi, jinekolojik ameliyatlar içerisinde en sık uygulanan operasyonlardan biridir. Histerektomilerde laparoskopi tekniği, operasyon esnasında düşük kan kaybı, daha az çevre doku/organ hasarı, daha kısa operasyon süresi, operasyon sonrası enfeksiyon ve ateş görülme sıklığının düşük olması, düşük hospitalizasyon ve operasyon sonrası normal aktiviteye dönüş süresi gibi avantajları nedeniyle tercih edilir.

Total Laparoskopik Histerektomi (TLH) esnasında, ilk olarak uterin damarlar ve ligamentler sırasıyla koterize edilir ardından rahmin tamamen serbestleşmesi için servikovajinal bağlantılar koterize ve koagüle edilir. Uterus manipülatörleri laparoskopik histerektomi (LH) esnasında ilgili organı hareket ettirerek cerrahın endoskopik görünümünü maksimize etmek için kullanılır. Bununla birlikte mevcut uterus manipülatörleri özellikle uterusu üç eksende hareket ettirme, zor ve el becerisi gerektiren bir işlem olan sirküler koterizasyon ve uterusun ampütasyonu esnasında servikovajinal kesim bölgesinin tayini gibi alanlarda eksikliklere sahiptir.

Yeni bir transvajinal uterus manipülatörü, mevcut manipülatörlerin bu önemli eksikliklerini giderebilir. Bu amaçala ilk olarak, uterus ölçüleri gibi gerçek verilerin elde edilmesi için üç boyutlu tarama tekniği ve yeni manipülatörün dizaynı için bilgisayar destekli tasarım programları kullanıldı. Tasarımın ardından prototip üretimi için eklemeli üretim tekniklerinden yararlanıldı. Özel ışık yayımlayıcı diyotlar (LED) doku kesim bölgesinin görünümünü kolaylaştırmak için servikovajinal dokunun içinden, abdominal kaviteye belirleyici ışık olarak manipülatörün servikoavajinal başlığı etrafına konumlandırıldı. Ayrıca farklı başlıkların ve LED sistemlerinin performansları karşılaştırılarak değerlendirildi.

Özetle tez kapsamında LH'yi kolaylaştırmak amacıyla iki eksende hareket kabiliyetine sahip ve uterusun anterior posterior ve lateral eksenlerde manipulasyonuna imkan veren, ayrıca serviks üzerinde kesim bölgesinin belirlenmesine yardımcı olmak amacıyla LED aydınlatma sistemine sahip bir uterus manipulatörü tasarlanmış ve prototip üretimi gerçekleştirilmiştir.

Tez sonucunda varılan bulgular ışığında, manipulatörün anterior posterior eksende 80° ve lateral eksende 80° manipulasyona imkan sağladığı görülmüştür. Öte yandan, laparoskop tarafından kolaylıkla belirlenebilecek ve kesim bölgesinin belirlenmesini kolaylaştıracak olan LED aydınlatma sistemi manipulatöre başarıyla entegre edilmiştir.

1. INTRODUCTION

1.1. Anatomy of Uterus

Uterus is a female reproductive organ which is shaped as pear and about 7,5 cm in length, 5cm max diameter and has an avarage weight of 30 – 40g (up to 200g) and it is immobilized by ligaments. Uterus consist of three main parts as fundus, body and cervix. Body part is the largest part and the fundus is the rounded section of the body next to the conneciton of the uterine tubes. Cervix is the lower region of uterus and nearly 2 – 3cm long. In adults, uterus can bent forward approximately 170°. Uterus wall is consist of three layers which are inner endometrium, muscular myometrium and the covering of these two layers, perimetrium. In adult woman who have not delivered, the uteruine wall has a thickness of 1,5cm (Martini, Bartholomew et al. 2000, Ellis 2005, Scanlon and Sanders 2007). Anatomy of uterus is given in the Fig.1.1.

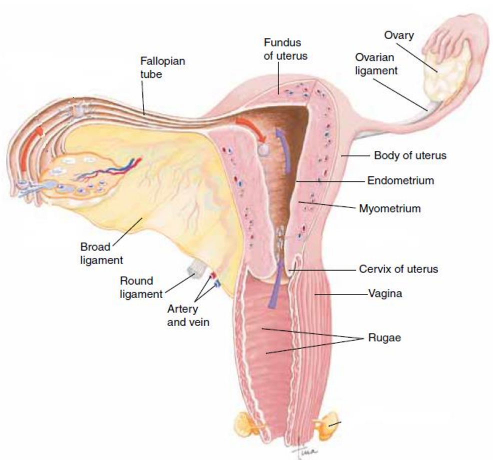


Figure 1.1: Anatomy of Uterus (Scanlon and Sanders 2007)

1.2. Laparoscopic Hysterectomy

Hysterectomy is the most commonly performed major gynecologic procedure around the world and means surgical removal of uterus. Benign diseases are responsible for more than 70% of the indications for hysterectomy and include menstrual disorders, fibroids, pelvic pain and uterine prolapsus (Whiteman, Hillis et al. 2008). Also endometrial diseases, reproductive system cancers and genital endometriosis localized in myometrium are other indications to perform hysterectomy.(Lethaby, Ivanova et al. 2006, Wu, Wechter et al. 2007)

Traditionally the uterus has been removed by an abdominal or vaginal route. In spite of the lower complication rate in vaginal hysterectomies (Dicker, Greenspan et al. 1982), abdominal hysterectomy has been the main method of hysterectomy in many countries (Easterday, Grimes et al. 1983, Luoto, Kaprio et al. 1994, Davies, Vizza et al. 1998). Optimum surgical conditions for removal of uterus consider three main advantages such as clear visualization and ease of manipulation of the adnexal structures, which are advantages of abdominal route, and avoidance of a large incision which is related with vaginal route. Laparoscopic hysterectomy (LH) combines these advantages and offers a short recovery time (Garry 1998). Despite all of these advantages, laparoscopy is a hand skill technique which really requires experience and attention. There are some difficult steps such as cauterization and coagulation of all connections between uterus and surrounding tissues and blood vessels. Removal of uterus is not an easy procedure as the vital organs such as colon, rectum, ureter and urinary bladder may be damaged during cauterization which is used frequently to separate uterus from its surrounding tissues (Einarsson and Suzuki 2009, Kondo W., Zomer M.T. et al. 2010) .Damage to these vital organs is seen particularly during the separation process of uterine cervix from the apex of the vagina. (Dikici S., Aldemir B. et al. 2014)

In 1989, Reich et al. described the first total laparoscopic hysterectomy, which is an alternative for traditional techniques of hysterectomy. Laparoscopy is an operation based on monitoring internal organs by inserting a camera and illumination system abdominally and which is performed under general or local anesthesia and first human laparoscopy is performed by Jacobaeus in 1910 by using pneumoperitoneum and a Nitze cystoscope which is developed by Nitze in Germany in 1877. By development of lens systems and external cold light sources improved the visibility which affects LH directly. But in 1970s still a limited number of surgeons were using laparoscopic techniques (Gomel 1989, Nezhat, Nezhat et al. 1992, Sutton 1997, Garry 1998, Dikici S., Aldemir B. et al. 2014). Harry Reich performed the first LH in January, 1988. Operation time was about 180 minutes and the procedure involves coagulation of the ligaments and uterine vessels with bipolar forceps and cutting with scissors. Opening of the anterior vagina by using a unipolar cutting current and the posterior vaginal fornix by using laser. Then the uterosacral ligaments were clamped and divided vaginally and the uterus was removed. The vaginal cuff was closed vaginally. The uterus weight was 230 g and the patient was discharged on the fourth postoperative day (Reich, Decaprio et al. 1989).

Laparoscopy technique is preferred in hysterectomy because of its major advantages such as less blood loss during operation, lower surrounding tissue and organ damage, shorter hospitalization duration, lower postoperative infections, frequency of fever and lower postoperative return time to normal activity (Nassif and Wattiez 2010, Gurin A.l., Kostiahin A.E. et al. 2012).

In the earlier time of LH, cost of this procedure was higher than abdominal or vaginal hysterectomies because of expensive disposable instruments. On the other hand hospitalization duration is much higher in abdominal hysterectomy and it is increasing the hospital expenses. Also after abdominal hysterectomy, patient should visit hospital often than LH (Dorsey, Holtz et al. 1996, Weber and Lee 1996). According to a Belgian work LH was stated as the cheapest method for hysterectomy when reusable instruments were used (Nisolle and Donnez 1997).

Complications of LH is consist of complications that occurs during laparoscopy and hysterectomy separately. Major complications are major bleeding, organ damage such as bowel, bladder and ureter, pulmonary embolism, anesthesia problems, vaginal cuff dehiscence (Garry, Fountain et al. 2004). Nonetheless minor complications are minor bleeding, infections, hematoma, venous thromboembolism, cervical stump and minor anesthesia problems and also predisposing factors such as being at later ages, medical diseases, obesity can cause a rise in complications. Also there some other risk factors such as cigarette, menopause, vaginal cuff infections and hematomas. (Kowalski, Seski et al. 1996, Croak, Gebhart et al. 2004, Hur, Guido et al. 2007, Jeung, Baek et al. 2010).

1.3. Equipment Used in Laparoscopic Hysterectomy

1.3.1. Vaginal Speculum

Vaginal Speculum (Fig 1.2) is a bivalved instrument, with two blades used to hold open the vaginal opening for inspection of the vaginal cavity before placement of uterine manipulator (O'Toole 2012).

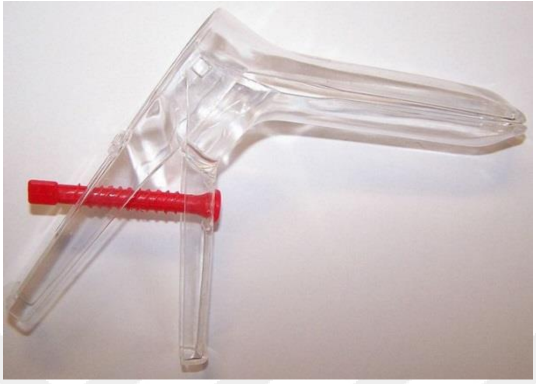


Figure 1.2: Disposable and Reusable Vaginal Speculum

1.3.2. Trocar

Trocar (Fig 1.3) is used to pierce the skin and the wall of abdominal cavity, to aspirate fluids, install a laparoscopic device or guide the placement of a soft catheter. It is consist of a sharp and pointed rod that fits inside a tube (O'Toole 2012).

Figure 1.3: 10-mm Trocar (Nezhat, Nezhat et al. 2008)

1.3.3. Catheter

Catheter is a hallow flexible tube which can be inserted into a vessel or cavity of the body to instill fluids (O'Toole 2012).

1.3.4. Uterine manipulator

Uterine manipulator (Fig 1.4) is a device that is used for uterine cannulation and manipulation process (Kondo W., Zomer M.T. et al. 2010).

Figure 1.4: RUMI II Uterine Manipulator with KOH Colpotomizer System

1.3.5. Laparoscopic Ablation Equipment

1.3.5.1.Electrosurgery

Electrosurgery is the application of a high-frequency electric current to biological tissue to cut, coagulate, desiccate, or fulgurate the tissue. Electrosurgical ablation can be monopolar or bipolar according to its purpose of use (Massarweh, Cosgriff et al. 2006, Glover, Bendick et al. 2007).

1.3.5.2. Laser scalpel

A laser scalpel is used for cutting or ablating tissues by the energy of laser light. In soft tissue laser surgery, a laser beam ablates or vaporizes the soft tissue with high water content (Glover, Bendick et al. 2007).

1.3.5.3. Ultrasonic (harmonic) scalpel

Ultrasonic (or harmonic scalpel) is a surgical ablation device which uses high frequency mechanical energy and is used to simultaneously cut and cauterize tissue (Siperstein, Berber et al. 2002, Glover, Bendick et al. 2007).

1.3.5.4. Plasma scalpel

A plasma scalpel (or plasma cutter) works by streaming pressurized gas (i.e. argon) through a narrow tube, where it acquires an electrical charge, transforming it into a blade of plasma traveling nearly 2500 km/h. Plasma cutters generally use cold plasmas to cauterize the tissue on direct contact but the heat surrounding cells is about 36^0C (Glover, Bendick et al. 1982, Glover, Bendick et al. 2007).

1.3.6. Laparoscope

Laparoscope (Fig 1.5) is a type of endoscope consisting of an illuminated tube with an optical system. It is inserted through abdominal wall to examine the peritoneal cavity (O'Toole 2012).

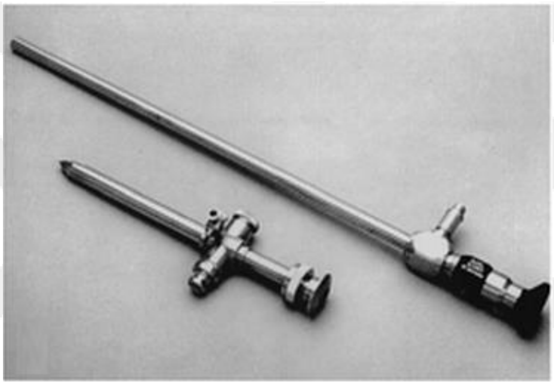


Figure 1.5: Laparoscope and trocar (Nezhat, Nezhat et al. 2008)

1.4. Surgical Procedure of Laparoscopic Hysterectomy

1.4.1. Positioning

The patient is positioned in dorsal decubitus, under general anesthesia. The legs are positioned in 30° flexion; the arms along the body, and the buttocks extending slightly over the edge of the surgical table (Fig 1.6) (Kondo W., Zomer M.T. et al. 2010).

Figure 1.6: Positioning of the patient for LH (Kondo W., Zomer M.T. et al. 2010)

1.4.2. Uterine Manipulation and Cannulation

Uterine cannulation and manipulation process is performed with a specific device called uterine manipulator. There are several uterine manipulators on market to assist LH. Widely used are Cohen-Cannula, Clermont-Ferrand (Fig 1.7), EndoPath, TINTARA, RUMI (Fig 1.8), ForniSee, SecuFix (Keriakos and Zaklama 2000, Mettler and Nikam 2006, Choksuchat, Getpook et al. 2008, Sauer 2013)

Figure 1.7: Clermont-Ferrand Uterine Manipulator (Kondo W., Zomer M.T. et al. 2010)

Figure 1.8: The RUMI Uterine Manipulator (Eltabbakh G. 2010)

An uterine manipulator should have some characteristics to ease the LH procedure. Such as being easy to assemble and use, inexpensive, easily placable to cervix and stay in place all through the procedure, not breakable or fragmented during operation, having a wide range of motion for uterine manipulation. (Eltabbakh G. 2010) They are used to overcome those problems which can occur during the LH procedures (Tanprasertkul and Kulvanitchaiyanunt 2010). An uterine manipulator should provide basic functions as follow (Eltabbakh G. 2010); a) Raises the uterus and makes it closer to the laparoscopic surgical instruments to ease the procedure, b) Manipulates the uterus according to operators desired motion, c) Increases the distance between the uterus and the bladder, the ureters, and the rectum, thus reducing the chance of injury, d) Could be used to remove the uterus vaginally after its complete detachment, e) Eases identification of the uterovesical peritoneum, the cul-de-sac, and the vaginal cuff which is located below cervical connection.

In brief, the uterine manipulators which are used for LH should have many different tasks in order to provide a safe and successful outcome. Their main function is mobilizing the uterus as wide as possible (Mettler and Nikam 2006). Two popular and widely used uterine manipulators were compared according to its specifications (Table 1-1).

Table 1.1: Comparison of RUMI and Clermont-Ferrand Uterine Manipulators.

RUMI System		Clermont-Ferrand	
Advantages	**Disadvantages**	**Advantages**	**Disadvantages**
High movement capacity allows to rotate the tip through a 140°	Some difficulties on placing device	Movement angles 140° in the anterior plane, 90° in the posterior plane	Because of tip design cervix should be dilated up to no. 9 (Hegar dilator)
Well-designed pneumoperitoneum	Complex assembly and high cost because of disposable parts	Extra movement with the help of internal shaft which is moving independently	Complex assembly and requirement of practice
Cervicovaginal cap can be used with harmonic or other ultrasound energy systems	Elevation of uterus is limited	Sterilizable / Reusable	High cost

1.4.3. Inflation of Abdominal Cavity

The pneumoperitoneum is insufflated to a pressure of 12 to 14 mmHg by CO_2 for a better manipulation and visualization (Einarsson and Suzuki 2009). Inflated abdominal cavity is given in the Fig 1.9.

Figure 1.9: Inflation of Abdominal Cavity.

1.4.4. Positioning the Trocars

After the inflation of abdominal cavity, four trocars are positioned. Their positions can be differ according to LH and uterus type. Usually, a 5-mm trocar is placed on the right side and a 12-mm trocar on the left side. Additionally, a 5-mm trocar is placed approximately 8 cm above and parallel to the lower left trocar site (Fig 1.10) (Einarsson and Suzuki 2009, Eltabbakh G. 2010, Daniilidis A., Hatzis P. et al. 2011)

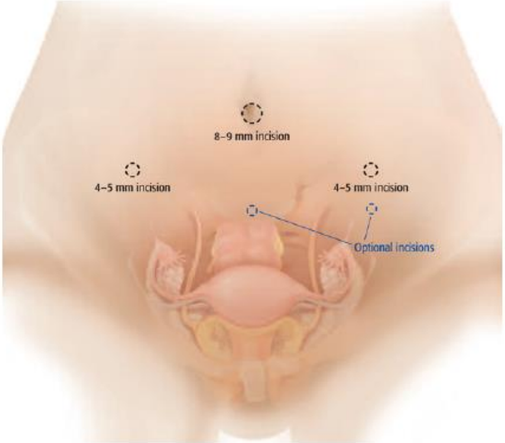


Figure 1.10: Trocar Positioning in LH (Doll S. 2012)

1.4.5. Coagulation and Section of the Round Ligament

The coagulation of the round ligament is performed by using a bipolar cautery and the section is performed with the laparoscopic scissors (Fig 1.11) (Kondo W., Zomer M.T. et al. 2010)

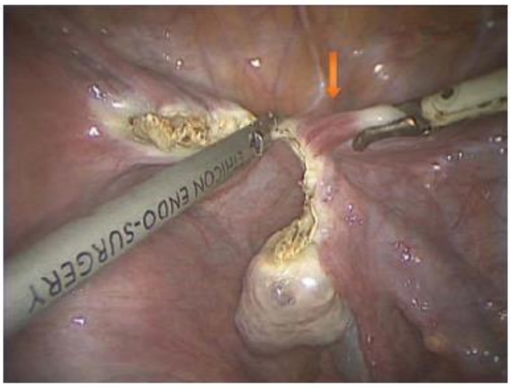


Figure 1.11: Coagulation and section of the round ligament (Einarsson and Suzuki 2009)

1.4.6. Separation of the Anterior and Posterior Leaves of the Broad Ligament

The interior leaflet of the broad ligament is coagulated with help of bipolar forceps and separated from the round ligament (Fig 1.12) (Einarsson and Suzuki 2009, Kondo W., Zomer M.T. et al. 2010).

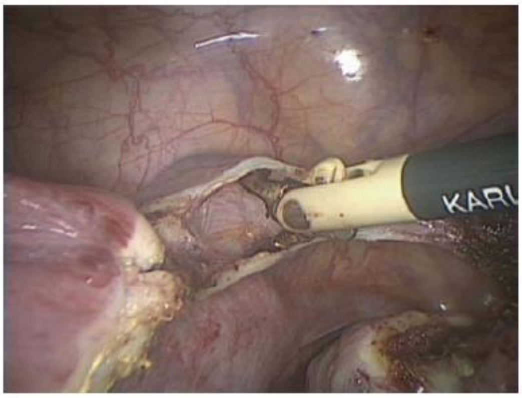


Figure 1.12: Separation of the anterior and posterior leaves of the broad ligament (Einarsson and Suzuki 2009)

1.4.7. The Segmentation of the Anterior Leaf of the Broad Ligament

The segmenting of the anterior leaf of the broad ligament continues anteriorly, thus enabling dissection of the bladder from the lower uterine segment (Fig 1.13) (Einarsson and Suzuki 2009).

Figure 1.13: The dissection of the anterior leaf of the broad ligament

1.4.8. Securing the Uterine Vessels

After complete mobilizing of uterus, it would be helpful and safe to skeletonize the uterine vessels by using harmonic scalpel or bipolar cautery (Fig 1.14) (Einarsson and Suzuki 2009).

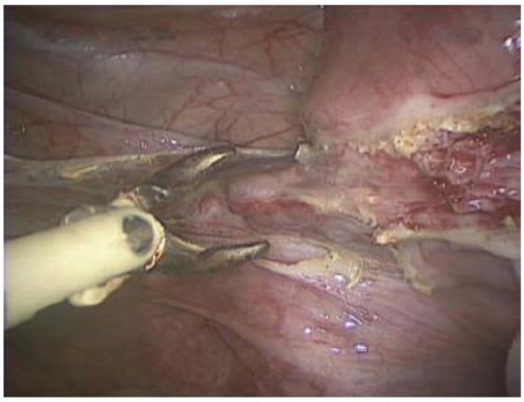


Figure 1.14: Securing the Uterine Vessels (Einarsson and Suzuki 2009)

1.4.9. Separation of the Uterus on Cervix

After the anterior and posterior colpotomies are opened, the uterine vessels are skeletonized, sealed, and divided, uterus and cervix should be separated for a complete removal of uterus (Lange S.S. 2013). Cervicovaginal landmark should be cauterized circularly with help of cervicovaginal cap of the uterine manipulator and surgeon's tactile senses (Fig 1.15).

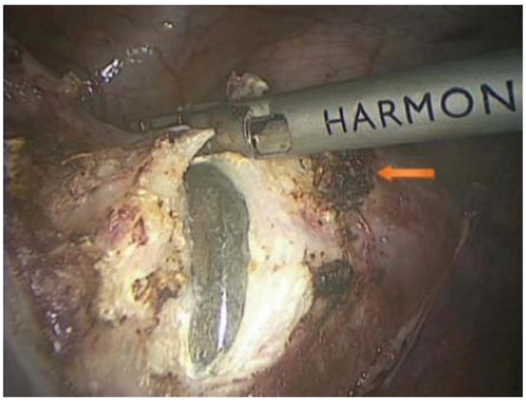


Figure 1.15: Separation of uterus and cervix

1.4.10. Removal of Uterus

Following the cauterization of uterine vessels, ligaments and cervicovaginal landmark, uterus can be pulled out from vagina to be removed from body with help of uterine manipulator’s tip anchorage system (mechanism or balloon etc.) (Einarsson and Suzuki 2009, Kondo W., Zomer M.T. et al. 2010, Lange S.S. 2013)

1.4.11. Vaginal Cuff Closure

After removal of uterus, formed vaginal cuff can be sutured either by vaginally or abdominally.

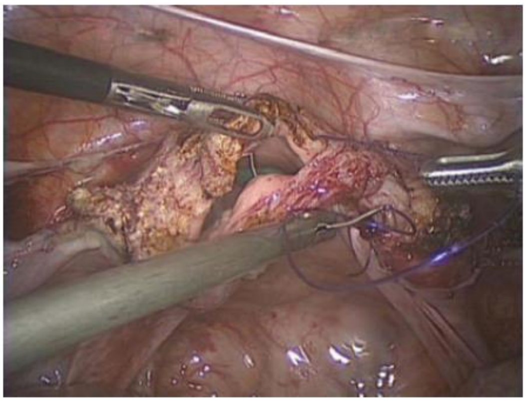


Figure 1.16: Vaginal Cuff Closure (Einarsson and Suzuki 2009)

1.5. Engineering Approaches on Biomedical Device Design

According to the European Medical Device Directive, a medical device is any instrument, material etc. that can be used alone or in a combination with other technologies for human beings for the purpose of;

- Diagnosis,
- Prevention,
- Monitoring,
- Treatment,
- Investigation,
- Replacement etc.

Basic engineering process life cycle can be summarized as design, prototyping, analyzing and manufacturing. In medical device industry, the products are quite complex and require several iterations of design. Thus, modelling, prototyping and analyzing phases are essentials for medical device design process (Scacchi W. and Mi P. 1997, Cetin 2004).

The existence of CAD based design systems are really effective for design process of a medical device. By the use of that systems, it is possible to check the final product before it is manufactured, therefore, CAD systems are mostly preferred by manufacturers from varying disciplines. Unfortunately, it is not always possible to design a complex products by only using 3D sketching software. Modelling of living organism parts such as bone, tissue, organs and limbs are more difficult than mechanical parts. Therefore, external and internal 3D scanning systems are now being used for modelling complex structures and some complicated biomedical structures can be modelled by using 3D scanning systems. Computer aided modelling process as an engineering approach either by using CAD or scanning are frequently used at every stage of a biomedical device design.

1.5.1. Computer Aided Design

Computer Aided Design (CAD) can be defined as the use of information technology (IT) in the design process. The technique initiated in the MIT from Ian Sutherland with SketchPad and it was based on 2D-sketching. Mid 1980’s, 3D modelling systems become popular and started to be used by many industries such as aerospace and automotive. Current systems, especially for mechanical industries are 3D systems and they are getting popular day by day. 3D modelling can be wireframe, surface or solid modelling. Most of the CAD systems are Parametric and Feature Based Solid Modelling systems (Bilalis N. 2000).

Nowadays, design process of biomedical equipment and devices are mostly performed by using computers as well as other disciplines. CAD is now being used in lots of biomedical applications such as clinical medicine, customized medical implant design, biomedical device and equipment design and even tissue engineering (Sun W., Starly B. et al. 2005). Computer aided design is not only important for simplifying the design of biomedical equipment but also enabling computer aided analyzing of the models before manufacturing. Therefore, CAD is getting popular in biomedical field as well as in other fields because of its advantages which can be summarized as being very accurate, fast and easily modifiable.

1.5.2. 3D Scanning Technology

According to its purpose of use and structure of the object, two different method can be used to generate 3D models (Ciobanu, Soydan et al. 2012);

- 3D model generation by using computer aided design (CAD) software such as SolidWorks and Autodesk Inventor
- 3D model creation by capturing images of target object by using scanners such as 3D Scanner, magnetic resonance imaging (MRI), computer aided tomography (CT)

Geometrical complexity of objects obstruct to create its 3D model by using CAD software (Demir Y.B. and Ertürk S. 2006). In recent years computer graphics has made major progress in visualizing 3D models. Many techniques have been developed and are being transferred to hardware and now it is possible to create 3D models of complex objects (Pollefeys M. 2003).

3D scanner (Fig 1.17) is a device which analyses a real object to collect data about its shape and appearance. The aim of a 3D scanner is generally to create a point cloud of geometric samples on the surface of the subject. Also these points can then be used to extrapolate the shape of the subject. 3D scanning will give a point cloud result and can be converted to solid 3D models. This process has been widely used for many years and is called reverse engineering (Bernardini and Rushmeier 2002).

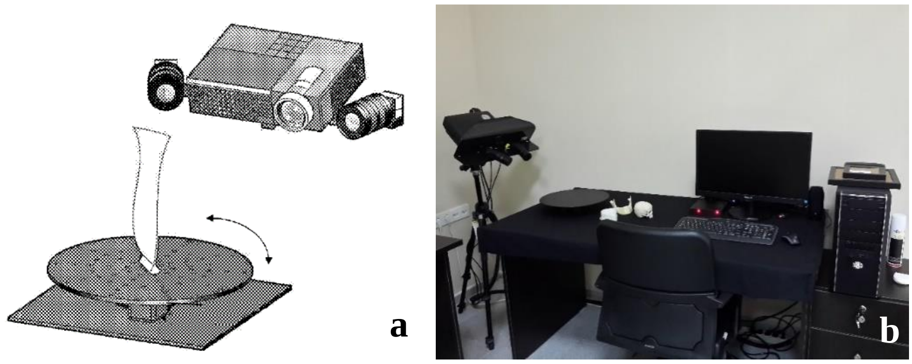


Figure 1.17: (a)Basic 3D scanner illustration based on structural light (Mannan M. and Scotton T. 2013) and a 3D scanner system (b).

The first 3D scanning technology was created in the 1960s. The early scanners include lights, cameras and projectors to perform this task. However, due to limitations of the equipment it was time consuming and difficult to scan objects accurately. After mid-eighties they were replaced with scanners that use white light, lasers and projectors to capture a given surface. 3D scanning technology was first used for capturing humans for animation industry by Cyberware Laboratories in the eighties. In the mid-nineties, they have developed a full body scanner for same purpose (Fig 1.18) (Ebrahim 2011, Breuckmann 2014).

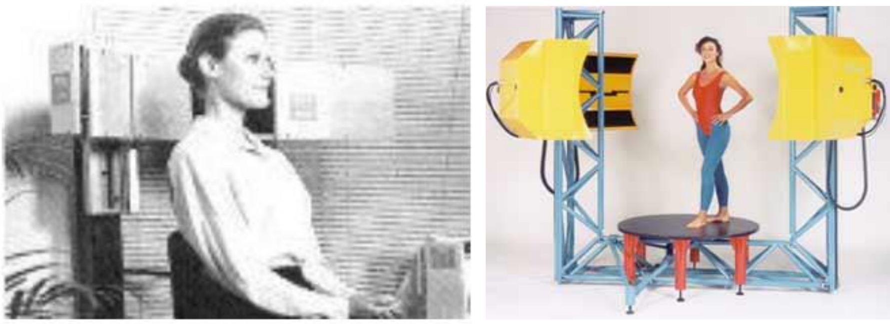


Figure 1.18: Head scanner on the left and full-body scanner on the right by Cyberware Laboratories Los Angeles.

In 1994, a fast and highly accurate 3D scanner, Replica, is launched and marked significant progress in laser scanning. In 1996, first manually operated arm and stripe are used in 3D scanning technology (Fig 1.19). It brings a fast and flexible solution and also produces complex models with color (Ebrahim 2011).

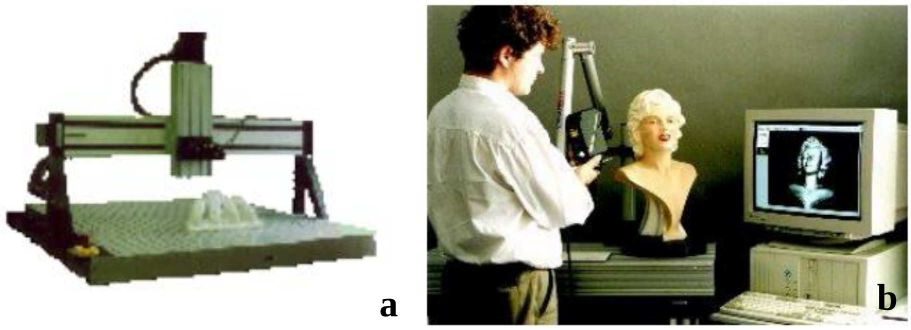


Figure 1.19: Replica 3D Laser Scanner on left (a) and manually operated 3D scanner on right (b).

3D scanning can be categorized as active and passive scanning techniques. 3D models are created by using only object images in passive scanning technique, besides in the active scanning, patterns which is created by projector are reflected on the target object and 3D model information is determined with help of engineering software (Besdok E. and Kasap B. 2006).

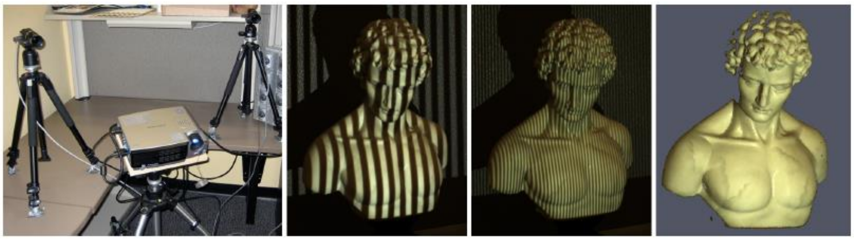


Figure 1.20: Structured light for 3D scanning. From left to right: a 3D scanner system with a pair of camera and a projector, two images of structured light on target object, 3D model of scanned object (Lanman D. and Taubin G. 2009).

Before the creation process of 3D models of desired objects by 3D scanning, camera calibrations should be done which complete the transformation between 3D coordinate system and 2 dimensional (2D) image plane. Calibration is a correlation method between real value of measured magnitude and the result taken by device and in many cases, the overall performance of the machine vision system strongly depends on the accuracy of the camera calibration (Heikkila and Silven 1997, Zhang 2004).

There are several methods for camera calibration but usually a checkerboard (Fig 1.21) is used to determine both interior and exterior geometry of cameras including focal length, distortion parameters, positions and rotations of cameras according to each other. Certain number of images should captured in different positions for corner determination and calibration (Dikici S., Aldemir B. et al. 2014).

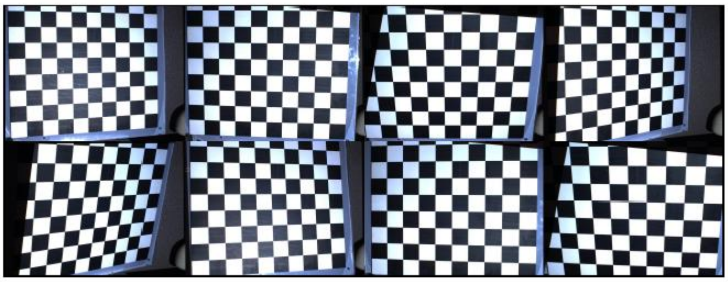


Figure 1.21: Multiple views of a checkerboard at various positions for camera calibration (Lanman D. and Taubin G. 2009).

As mentioned in the previous sections, biomedical complex geometries need to be modelled by using 3D scanning technology due to their complicated and insolvable structures which cannot be drawn by using CAD software. For this reason usage of scanning systems are the best option for collecting real world data and geometry of that kind of models and reverse engineering approaches.

1.5.2.1. 3D scanning parameters that affect quality of model

Accurate and high resolution 3D scanning depends on some parameters and their correlations (Rocchini, Cignoni et al. 2001, Breuckmann 2014).

- Field of View (FOV): Larger FOV will reduce resolution and accuracy
- Camera Resolution: High camera resolution will affect accuracy and total resolution of the scanning process positively. Also in a higher FOV, camera resolution will suppress the decrease in scanning quality.
- Triangulation Angle: Larger triangulation angles may require more scans but they result in a better depth resolution.
- Calibration: Before scanning process camera calibration should be done. A strong correlation exists between calibration and quality of scan.

1.5.2.2. 3D scanning limitations and problems

- Surface scanning technology does only give a cloud volume data therefore, output is not a solid model.
- Deep holes, undercutting and detailed zones are difficult to scan and triangulation.
- Due to limited light sources, large areas cannot be illuminated well enough.
- Ambient light may be problem for scanning especially in large FOV’s.

- Shiny, transparent and dark colored object cause undesirable scanning results (Fechteler, Eisert et al. 2007, Breuckmann 2014).

1.5.3. Additive Manufacturing Technology (3D Printing Technology)

Additive manufacturing (AM) is a manufacturing technique using 3D digital models to produce the object in successive layers, each one adhering to the previous layer (Bandi, Dufva et al. 2013).

3D printing (3DP) which he named sterolithography (SL) was first described in 1986 by Charles W. Hull. In this method, lasers were used to heat and merge layers of resin together to create a three dimensional object. SL was a prototype and later an improved model was improved in 1988, the SLA-2502 (Wong and Hernandez Hoyos 2012, Bandi, Dufva et al. 2013).

In 1987, Selective Laser Sintering (SLS) was developed by B. F. Goodrich. SLS process involves high intensity laser melting of powder substances to produce a 3D object. In 1988, Scott Crump invented fused deposition modelling (FDM). The first FDM machine became available on market in 1992 (Excell J. and Nathan S. 2010, Bandi, Dufva et al. 2013)

First 3DP machine which uses a powder and a binder and applies respectively layer by layer, was patented in 1993 by MIT and licensed to Z-corp carried out the idea in 1996 as Z402 printer. After a few years a self-replicating 3D printer called RepRap which can produce a new 3D printer device by printing itself, is announced in 2006 and went on sale in 2008 (Junji 2013).

According to its phase, AM can be categorized into three main groups as

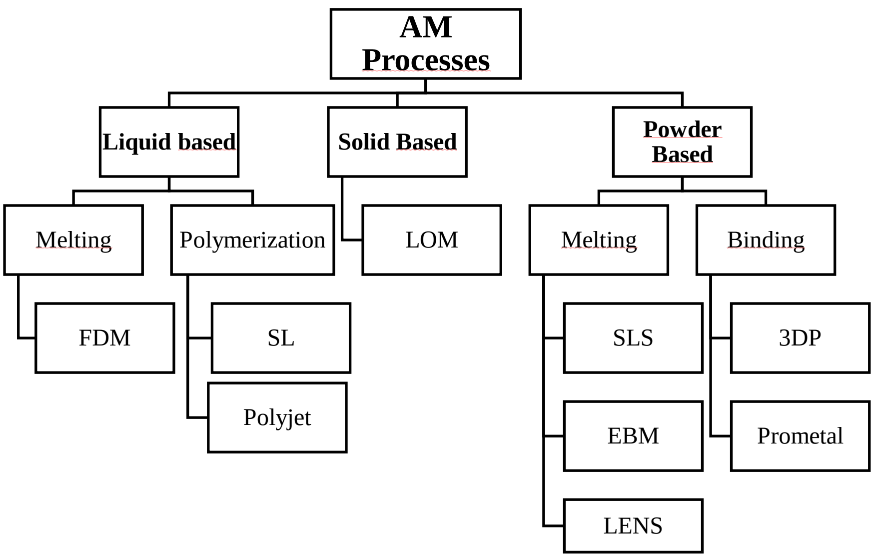


Figure 1.22: AM Categorization according to raw material phase (Wong and Hernandez Hoyos 2012).

liquid, solid, powder based (Fig 1.22).

Additive manufacturing has non-negligible advantages such as

- High complexity model production
- Production of variable models at the same time
- No assembly requirement
- Fast manufacturing
- Scale-up or scale-down of models
- Minimum waste
- Material variety
- Sustainable production
- Cost effectiveness

As mentioned above, additive manufacturing methods are outstanding alternatives for conventional manufacturing methods with its major advantages. For this reason, AM is useful for fabrication of biomedical instruments and devices which can be complicated models and require remanufacturing due to the alteration of design dynamically during whole processes.

1.5.3.1. Stereolithography

Stereolithography (SL) (Fig 1.23) was the first and most widely used process of AM technique in which a photosensitive polymer is solidified, layer by layer, using ultraviolet laser (Wong and Hernandez Hoyos 2012, Bandi, Dufva et al. 2013).

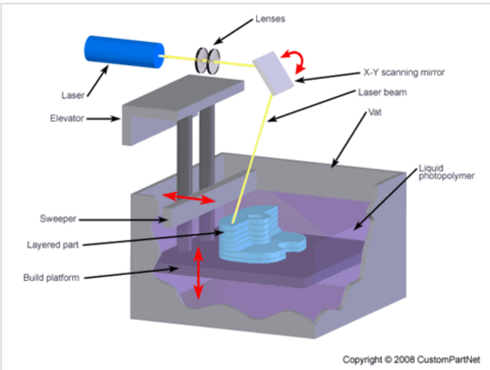


Figure 1.23: Stereolithography (Custompart 2015)

1.5.3.2. Fused deposition modelling

Fused Deposition Modelling (FDM) (Fig 1.24) is an additive manufacturing technique in which a thin filament of plastic material feeds the FDM machine where a print head melts it and extrude it in a thickness typically of 0.25 mm. FDM has some advantages like no require for chemical post-processing, no resins to cure, less expensive than other techniques, high quality and being ready to use as prototype.

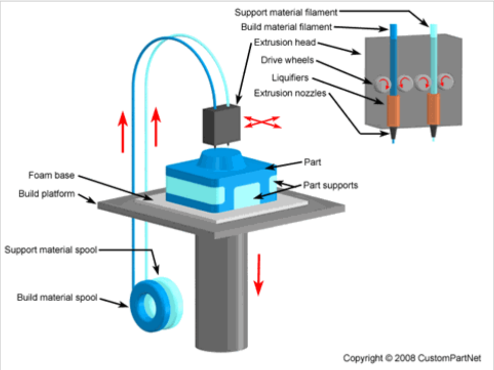


Figure 1.24: Fused Deposition Modelling (Custompart, 2015)

1.5.3.3. Selective laser sintering

Selective Laser Sintering (SLS) (Fig 1.25) is a powder based technique in which a metal powder placed on a build chamber, is sintered by CO_2 laser according to desired shape and geometry. The chamber is preheated to nearly the melting point of the material. The laser sinter the powder at a specific design for each layer. The particles are found in a chamber, which is controlled by a piston, that is lowered the same amount of the layer thickness when a layer is finished (Wong and Hernandez Hoyos 2012, Bandi, Dufva et al. 2013, Junji 2013).

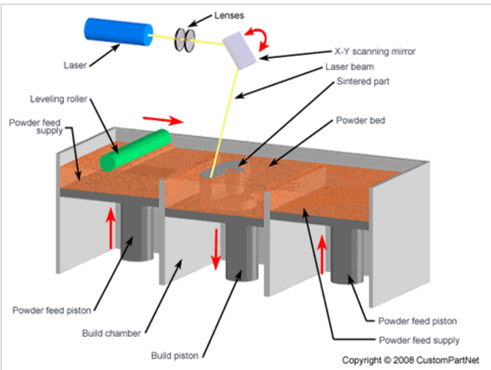


Figure 1.25: Selective Laser Sintering (Custompart, 2015)

1.5.3.4. Laminated object manufacturing

Laminated Object Manufacturing (LOM) (Fig 1.26) uses a combination of the additive and subtractive manufacturing techniques. In this process materials come in sheet form. The layers are bonded together by pressure and heat application and using a thermal adhesive coating. A carbon dioxide laser cuts the material to the geometry of each layer according to information taken from 3D model from the CAD or sterolithography (STL) file. Advantages of LOM are no post-processing and supporting structure required, no deformation and phase change occurring, low cost, possibility of building large parts. (Wong and Hernandez Hoyos 2012, Bandi, Dufva et al. 2013)

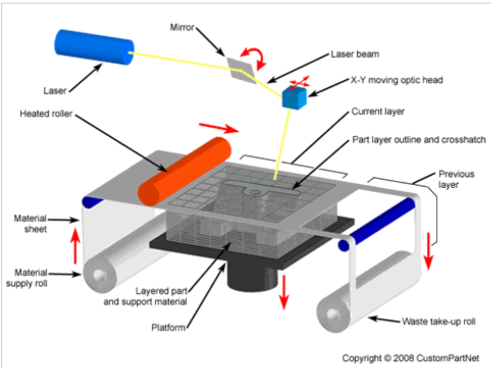


Figure 1.26: Laminated Object Manufacturing (Custompart 2015)

1.5.3.5. Polyjet (inkjet printing)

Polyjet (Fig 1.27) is an additive manufacturing process that uses inkjet technologies to manufacture physical models. During creation of models, inkjet head moves horizontally depositing photopolymer, on which ultraviolet light will be applied after each layer is finished according to specific design. Polyjet is using a high resolution technology so layer thickness is about 16 µm. But as a disadvantage, parts produced by polyjet, are weaker than the parts produced by other techniques. Also a gel-type support material is needed during process (Wong and Hernandez Hoyos 2012, Bandi, Dufva et al. 2013, Gibson, Rosen et al. 2015).

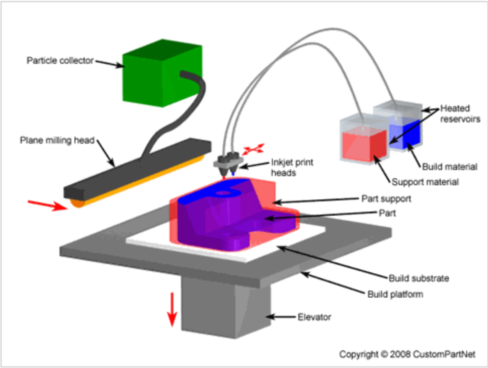


Figure 1.27: Polyjet (Inkjet Printing)(Custompart 2015)

1.5.3.6. Laser engineered net shaping

In Laser Engineered Net Shaping (LENS) (Fig 1.28), a part is built by melting metal powder which is injected into a specific location. It becomes molten by using a high-powered laser. The material solidifies when it is cooled down. The process occurs in a closed chamber with an argon atmosphere (Griffith, Keicher et al. 1996, Wong and Hernandez Hoyos 2012, Bandi, Dufva et al. 2013).

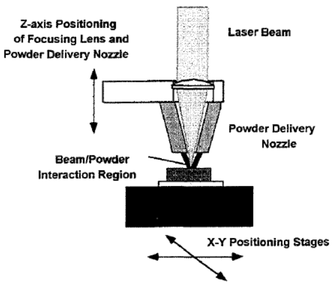


Figure 1.28: Laser Engineered Net Shaping (Griffith, Keicher et al. 1996)

1.5.3.7. 3D printing

3D Printing (3DP) (Fig 1.29) is a powder-based technique in which a liquid binder is supplied onto a thin layer of the material according to specific design. In process, one thin layer of powder material is dispersed on a platform, following that the binder is sprayed into the powder. The binder binds the powders to form a layer. This process occurs many times to produce layer by layer structures (Lichte, Pape et al. 2011).

At the end of the printing process, it is possible to apply some post processes to increase quality of scaffolds. Post-printing manipulation, depowdering, coating, sintering and infiltration are some of the post process applications. Depowdering is removal of loose powder with brushing, blowing air, vacuuming, vibration, wet depowdering (ultrasonicating, microwave-induced boiling and CO_2 bubble generation in soda water). Coating is usually done with polymer-particle paste or slip casting to improve surface. Sintering and infiltration is applied to increase strength of structures. In sintering, scaffolds are exposed to temperature and shrink to consolidate. Dipping part, aerosolizing infiltrant, spraying the part are infiltration techniques to get high density structures without the large shrinkage (Utela, Storti et al. 2010).

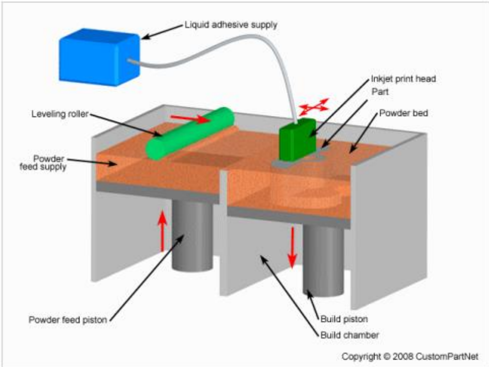


Figure 1.29: 3D Printing (Custompart 2015)

Main advantage of 3DP is having a resolution is similar or better than the other techniques. Also this technique offers an opportunity to modify the system about powder and binder selection. Post-processing requirements are nearly same with the other techniques. In addition, manufacturing is cheaper than most of the other processes because of cheaper raw material (Utela, Storti et al. 2010, Wong and Hernandez Hoyos 2012).

1.5.4. Finite Element Analysis

Finite element analysis (FEA), sometimes can be referred as finite element method (FEM), is a computational (or numerical) method to acquire the approximate solutions of problems in engineering and physics. FEA is based on subdivision of a complex problems into simpler parts which is called finite elements. In other words FEA cuts a solid structure into many elements and then reconnects them at nodes by using mesh generation techniques (Hutton D. 2004). The process of FEA starting from the physical problem and an example of FEA results of a dental implant is given respectively in the Fig 1.30 and 1.31.

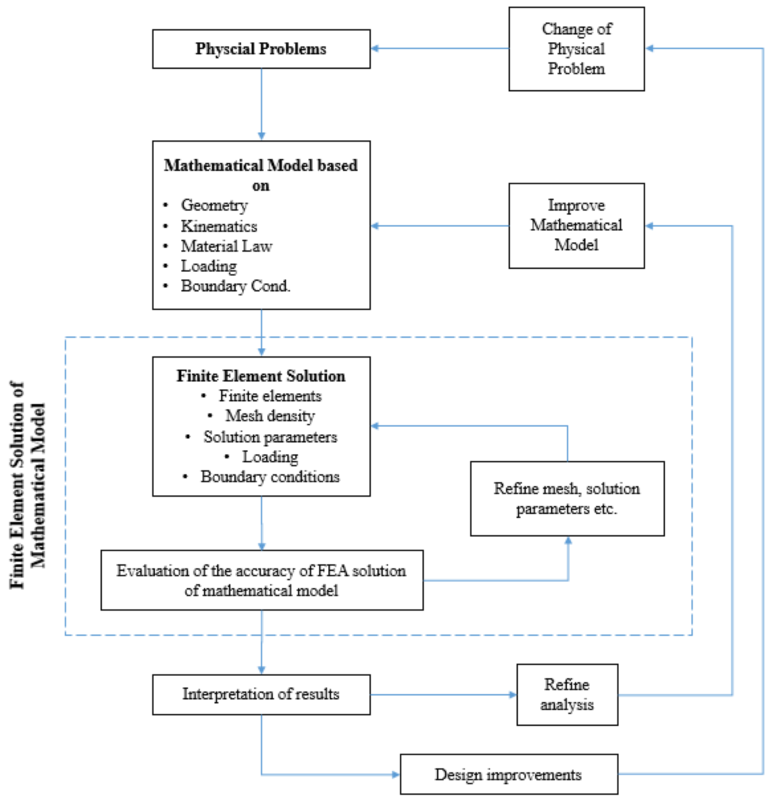


Figure 1.30: The process of FEA(Bathe 1996).

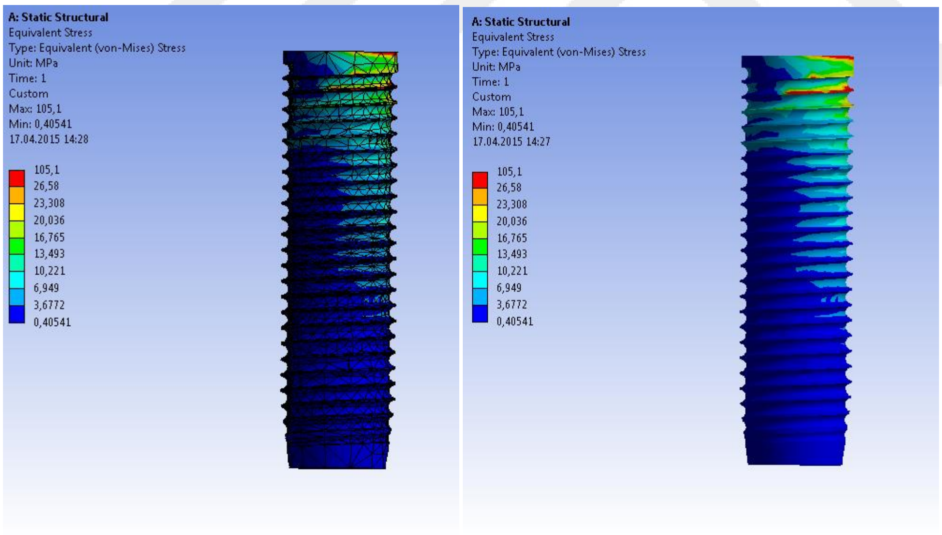


Figure 1.31: FEA Example of a dental implant.

As can be seen in the image given on the left, model is divided into numerous triangular elements. After FEA and solving the model, stress distribution can be seen as chromatic dispersion and numerical values in the image on the right. Stresses are depicted with colors according to stress gradients, where red zones the highest stresses and blue the lowest.

FEA is a powerful tool for biomedical applications. These applications can be exemplified as mechanical simulation and analysis of dental systems, orthopedic implants and bone remodeling, hearth valves, device design etc. FEA is preferable not only to determine material and design specifications before manufacturing but also check the mechanical properties, stability and functionality of the system by simulating the real environment. IT can be thought as a guide during design process of a biomedical instrument. In brief, FEA can analyze the design in detail, save time and money by reducing the number of required prototype.

2. MATERIALS AND METHODS

2.1. Design

Transvaginal uterus amputation device was modelled by using CAD software (Autodesk Inventor 2016, USA) to design and modify the parts and 3D scanning system (3D3 Solutions HDI Advance R2, Canada) to obtain real world data. A cervical cap of conventional uterine manipulator has been scanned and analyzed by regarding cervix anatomy. After matchup processes 3D engineering software was used to make modifications on cap and model the new cap. At the end of the design phase, core system was analyzed by using FEA software (Ansys Workbench 15, USA) under static load conditions by simulating real environment forces before prototyping.

Additive manufacturing techniques has been found suitable and determined for the rapid prototype production and 3D printer (3DS Projet 160, USA) has been used for the very early prototype production. First prototype manufacturing was performed on the purpose of testing adaptation of the parts to each other and assembly relationships. After that, FDM (Ultimaker 2 Extended, Netherlands) with different filament compositions has been used to manufacture rapid prototypes by PLA. FDM technology has been selected as rapid prototyping method because of various advantages such as being inexpensive, rapid, accurate and sensitive.

In the scope of this section, design of the parts, LED illumination system and computer aided assembly of the system will be discussed.

2.1.1. Parallel Manipulator Design

As one of the main outcomes of this study is to design a new uterine manipulator enabling the uterine movement in three dimensional workspaces, design procedure has begun with the structural synthesis. Considering the design constraints with respect to the surgeons' comments on the flaws of the current designs on the market and the operation difficulties, two degrees of freedom spatial parallel manipulator has been chosen to be designed. Due to the fact that axial rotation of the uterus is not important during the operation, two degrees of freedom orientation manipulator will provide enough articulation to the uterus in order to be moved in a desired three dimensional workspace. Kinematic representation and the CAD of the selected manipulator can be seen in Fig 2.1 and 2.2.

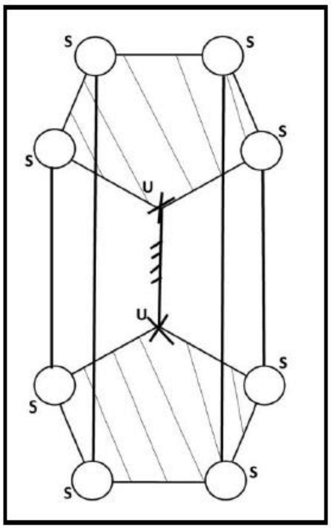
Using Alizade's universal mobility equation,

$$M = \sum fi - \lambda\,(N - C - B) + q - Jp$$

$$M = 28 - 6\,(10 - 4 - 2) + 2 - 4$$

$$M = 2 = (DOF)$$

Where M is the mobility of the manipulator, fi is the total degrees of freedom of the i^{th} joint, N is the platform type, C is the connections between platforms, B is the number of platforms, λ is the subspace or space of the independent loop, q is the total number of excessive links and Jp is the total number of passive joints; mobility of the manipulator can easily be calculated as shown in Figure 2-1.



$$M = \sum fi - \lambda\,(N - C - B) + q - Jp$$

$$M = 28 - 6\,(10 - 4 - 2) + 2 - 4$$

$$M = 2 = (DOF)$$

Figure 2.1: Structural synthesis of parallel manipulator.

After the structural synthesis procedure, CAD software (Autodesk Inventor, USA; SolidWorks, USA) were used to simulate designed spatial parallel manipulator with respect to the results of structural synthesis.

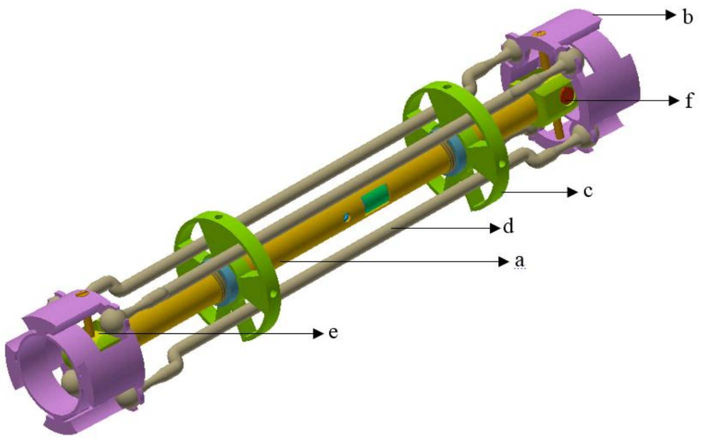


Figure 2.2: CAD of Parallel Manipulator with 2-DOF. (a) Main inner shaft, (b) Platforms, (c) Shaft Platforms, (d) Double spherical ended curved shafts, (e) cardan cube, (f) cardan u.

Designed parallel manipulator with 2-dof motion capacity is consist of a main inner shaft (Fig2.2a), two platforms (Fig2.2b), two shaft platforms (Fig2.2c) which guides the double spherical ended curved shafts (Fig2.2d), cardan cube (Fig2.2e) and cardan u (Fig2.2f) systems. Working principle of the manipulator is to transmit the starting movement from first platform to second platform by the help of carrier shafts with two degrees of freedom. Design parameters such as length and diameter of the manipulator were determined by regarding limitations of woman anatomy. Furthermore, minimum diameters of the platforms and measurements of the cardan cube and u systems were optimized according to desired range of motion of the manipulator.

2.1.2. Cervicovaginal Cap Design

Cervicovaginal cap is an apparatus which is placed on cervix and indicate the vaginal fornices that is the correct ablation region by the help of LED illumination system. Modelling of cervical cap is one of the most important aim of this thesis by regarding limitations of cervical anatomy of uterus such as minimum and maximum diameter ranges. A 3D scanning system (3D3 Solutions – HDI Advance, Canada) has been used during the data collecting and modelling stages.

3D scanning technology was used for collecting real world data to construct digital 3D models. Before the scanning process, camera calibration is required to determine cameras' geometry both interior and exterior. Interior and exterior geometry of cameras include; focal length, distortion parameters, positions and rotations of cameras according to each other. This work was done by eighty one captures of 5mm checkerboard. After the process, calibration level was calculated approximately 78%.

3D scanner system was used in designing the cervicovaginal cap of the manipulator and modelling the uterus. 3D scanner software (FlexScan, Canada) was used in revising the design and modelling. Then, some modifications were performed on CAD software (Autodesk Inventor, USA; SolidWorks, USA) and LED illumination mounting canal (Fig2.3a) and cable carrier tunnel (Fig2.3b) and were constituted on the cervicovaginal cap design. Moreover, scanned .stl data repairing was performed by 3D data repair software (Geomagic Studio 12, USA). After all, the design was exported to rapid prototyping format and transferred to 3D printer software.

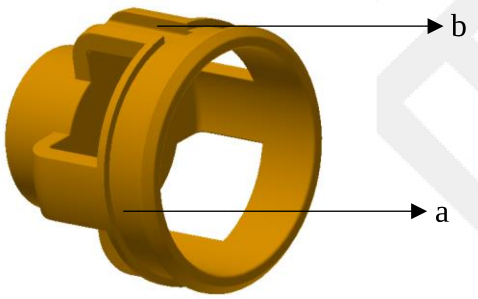


Figure 2.3: CAD of Cervicovaginal Cap with cautery and LED pathway. (a) LED illumination mounting canal, (b) cable carrier tunnel.

Cervicovaginal cap design was performed with respect to cervix anatomy and caps with various diameters has been designed for better settlement of the cap on cervix. Also, mounting canal for LEDs (Fig2.3a) were planned according to decided LED measurements. For this purpose, 1,1mm depth and 0,6mm width, which are the exact dimensions of our LEDs, has been selected and applied on cervical cap.

2.1.3. LED Illumination System Design and Implementation

LED illumination system which will surround cervicovaginal cap acts like a marker for determination of correct ablation region on cervix during LH. For this aim a special LED system shape and location is determined and integrated on modified cervicovaginal cap according to safety and performance specifications.

Pulse width modulator (PWM) signal which is created by using NE555 entegrated PWM generator was amplified with 7667 mosfet driver entegration and applied to IRF1358 mosfet. To optimize Root Mean Square (RMS) value of the output voltage duty ratio of the PWM was changed by using potantiometer. Therefore, brightness of LEDs which are connected to output can be configured. Duty ratio can be adjusted between 10% and 100% interval. PWM LED driving circuit and Output PWM signal are given below.

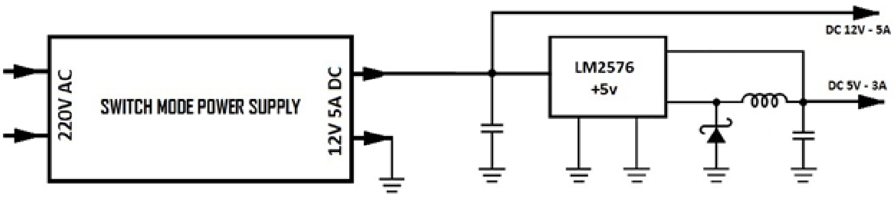


Figure 2.4: Power supply circuit.

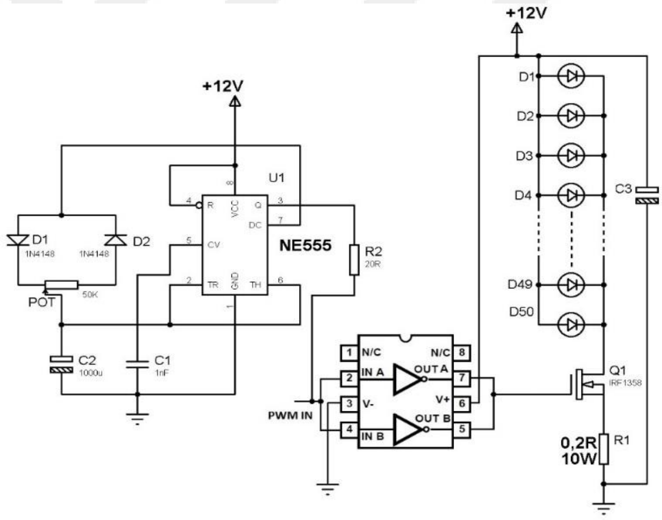


Figure 2.5: PWM LED driving circuit.

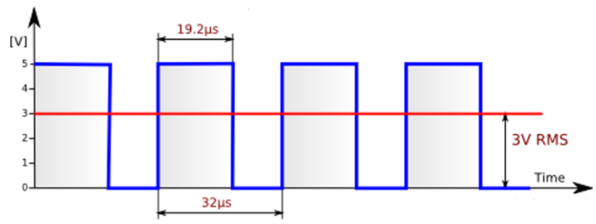


Figure 2.6: Output PWM signal. Frequency is 30 KHz and duty ratio is 60%.

Desired specifications of the LED illumination system are related with safety, enough illumination through vaginal tissue, temperature while LEDs are working and power requirements. LED choice has been performed by regarding these conditions. Selected LED characteristics are stated in the Table 2.1.

Table 2.1: LED Specifications

Specifications	**Value**
Power	0,5 W
Voltage	DC: 2,8 - 3,8 V
Current	150mA
Lumen	45-55 LM
Dimensions	5,7 x 3,0 x 0,8 mm

3D model of LED illumination system integrated cervicovaginal cap is created by using CAD software (Autodesk Inventor 2016, USA) and given in the Fig 2.7. LEDs (Fig2.7a) were implemented onto recently designed cervicovaginal cap and the cables (Fig2.7b) were placed on cable carrier tunnel.

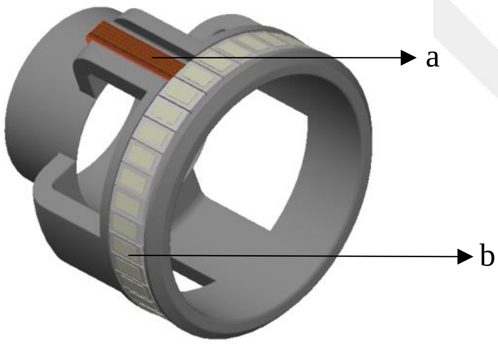


Figure 2.7: CAD of LED illumination system integrated cervicovaginal cap. (a) LEDs, (b) LED cables.

Light transmission through cervical tissue of a conventional uterine manipulator's LED illumination system during a LH operation is given in the Figure 2.8 for better identification of the intended system. LED illumination system of the manipulator identifies the vaginal fornices and the light transmission through vaginal tissue (Fig 2.8a) enables the detection of the region during LH by laparoscope.

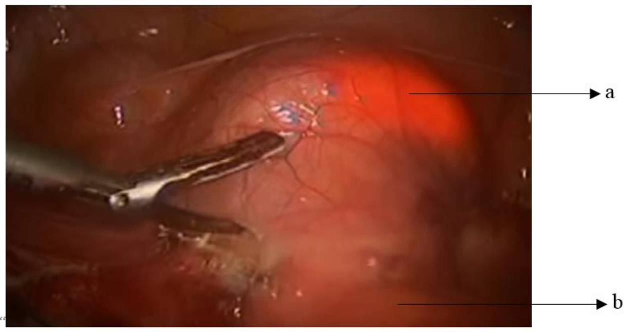


Figure 2.8: Identification of ablation region by using LED illumination system. (a) Light transmission through vaginal tissue, (b) uterus.

2.1.4. Handle Design

Designing a handle is an important process and should be efficient to use, safe, and attractive to buy. Handles are generally too small, too stiff, sharp, awkwardly placed, and sometimes confusing to use (Patkin 2001).

It is possible to categorize handles according to its intended purpose. They can be classified as;

- Power grip
- Pinch
- External precision grip
- Internal precision grip

2.1.4.1. Power grip

In this type of handles, fingers are bunched around an object and overlapped by the thumb (Fig 2.9).

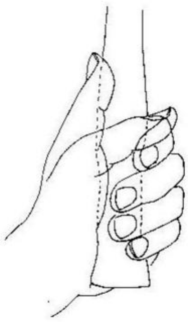


Figure 2.9: Power Grip Handle (Patkin 2001).

2.1.4.2. Pinch grip

In this type of grip between the thumb and the side of the index finger is used for picking up small objects. Common example for pinch grip is keys (Fig 2.10).

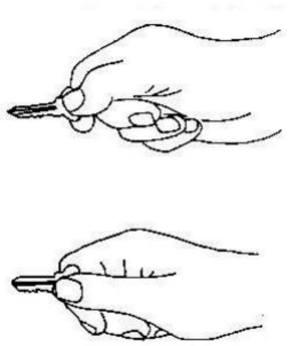


Figure 2.10: Pinch Grip(Patkin 2001).

2.1.4.3. External precision grip

This grip is for fine work such as writing. It has a similar mechanism with pinch grip but with two extra support component (Fig 2.11).

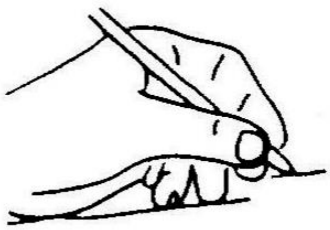


Figure 2.11: External Precision Grip(Patkin 2001).

2.1.4.4. Internal precision grip

Contrary to external grip, in internal grip the tool handle is held parallel to the work surface rather than at an angle to it.

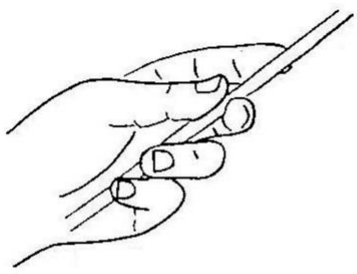


Figure 2.12: Internal Precision Grip (Patkin 2001).

During handle design process some parameters should be regarded (Patkin 2001);

- Size
- Shape
- Surface
- Safety
- Stiffness
- Siting
- Cost efficiency

One of the major drawbacks of uterine manipulators is uncomfortable and non-ergonomic handle design. Due to this lack of design quality, uterine manipulation is being more difficult for surgeons. To overcome this problem, an ergonomic, light and durable handle was designed and produced. Sharp corners were rounded and a thumbhole (Fig 2.13a) is placed on the top of handle to increase the manipulation. Sub-section of the handle (Fig 2.13b) on which surgeon places his/her palm was designed properly by regarding real hand design. Moreover, finger settlement gaps (Fig 2.13c) were adapted on system to increase the ergonomy. CAD of handle is generated by 3D sketch software (SolidWorks, USA) (Figure 2.13).

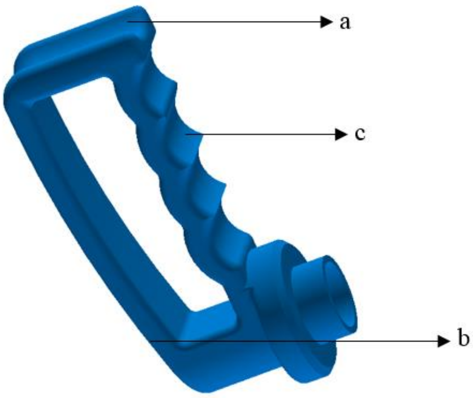


Figure 2.13: CAD of Handle. (a) Thumbhole, (b) Sub-section of the handle, (c) Finger settlement gaps.

2.1.5. Cover Design

Designed parallel manipulator was closed with a cylindrical cover which is consist of an upper part (Fig2.14a) and a lower part (Fig2.14b). A trapezium shaped canal (Fig2.14c) was designed inside the upper side of the cover to create a path for LED illumination cables. Canal geometry was determined as trapezium because of the settlement of cover on shaft platforms. Six ISO M3 screw holes (Fig2.14d) were drilled on the upper and lower parts of cover to fix them on shaft platforms. CAD of cover is showed in the Fig 2.14.

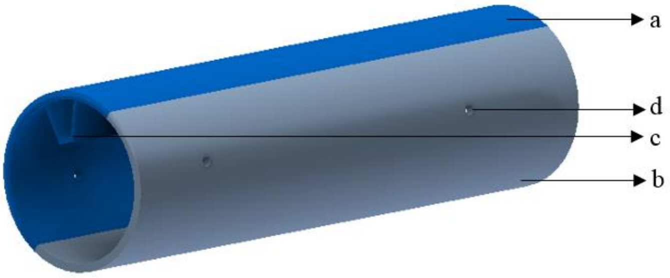


Figure 2.14: CAD of Cover. (a) Upper part with cable canal, (b) Lower part of the cover, (c) Trapezium shaped canal, (d) ISO M3 screw holes.

2.1.6. Computer Aided Mechanism Assembly

All parts of the uterine manipulator were rearranged and assembled by using 3D CAD software (Autodesk Inventor, USA). Constrains were assigned according to real life assembly specifications. Installation of the mechanism was performed and given in the Fig 2.15.

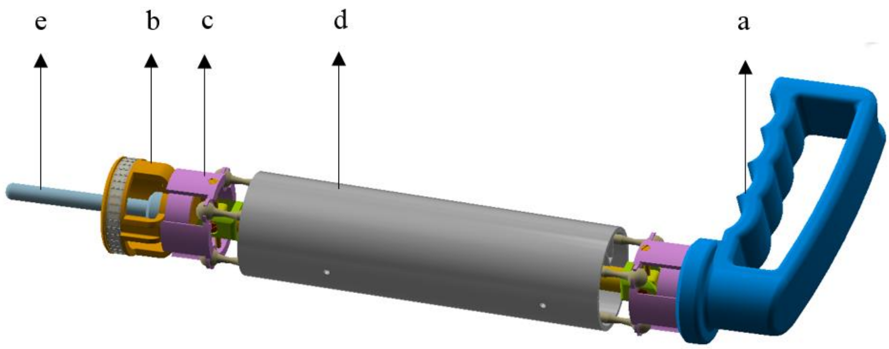


Figure 2.15: CAD of TUAC. (a) Handle, (b) Cervicovaginal cap, (c) Platform, (d) Upper and lower part of the cover, (e) Tip.

Handle (Fig 2.15a) and cervicovaginal cap (Fig 2.15b) was connected to platforms (Fig 2.15c) by the 10mm shrink fit junctions. Upper and lower part of the cover (Fig 2.15d) were screwed to shaft platforms and provide not only protection but also immobilization of the system. Tip (Fig 2.15e) was assembled into the cervicovaginal cap by screwing method. For this purpose, junction of the tip was turned into ISO M6 screw and ISO M6 groove was created into the cervical cap.

2.2. Finite Element Analysis

Before final prototyping, parallel manipulator was analyzed under simulative forces by using finite element analysis (FEA) software (Ansys 15.0, USA). For the FEA of manipulator, four different horizontal force (20N, 50N, 100N and 200N) was determined and applied on load bearing components which are the double spherical ended curved shafts of the system. Before the analysis, external geometry of the designed model (Fig 2.16a) was imported to software and mesh optimizations have been done and the statistics of nodes and elements are given in the Fig 2.16b.

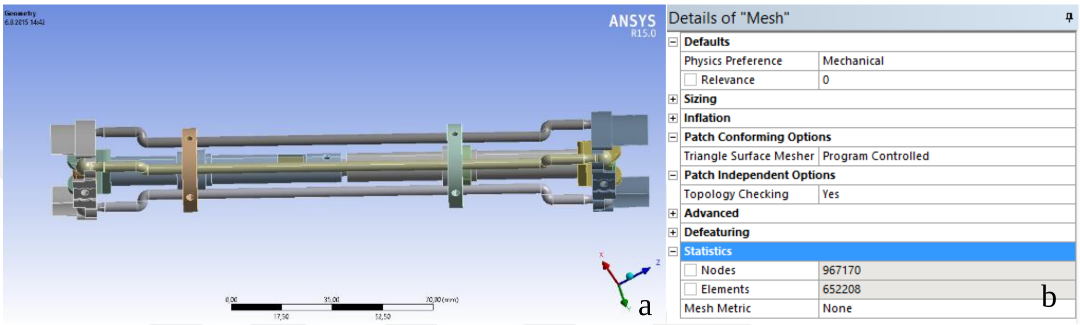


Figure 2.16: Imported External Geometry of the Designed Parallel Manipulator.

Mechanical properties of stainless steel was assigned to model with a Young's modulus of 1,93E+11 and Poisson's ratio of 0,31. Stainless steel was selected as the material of the system because the device was planned to be manufactured from stainless steel as a future aspect.

Simulative horizontal forces were applied onto surface of the spherical ended curved shafts as load carrier structures. 20, 50, 100 and 200N forces have been chosen as simulative forces for different scenarios which can be encountered during LH operation. Forces were divided equally on each for shafts, but the directions were opposite for upper and lower two shafts. Applied horizontal forces and their directions are given in the Fig 2.17.

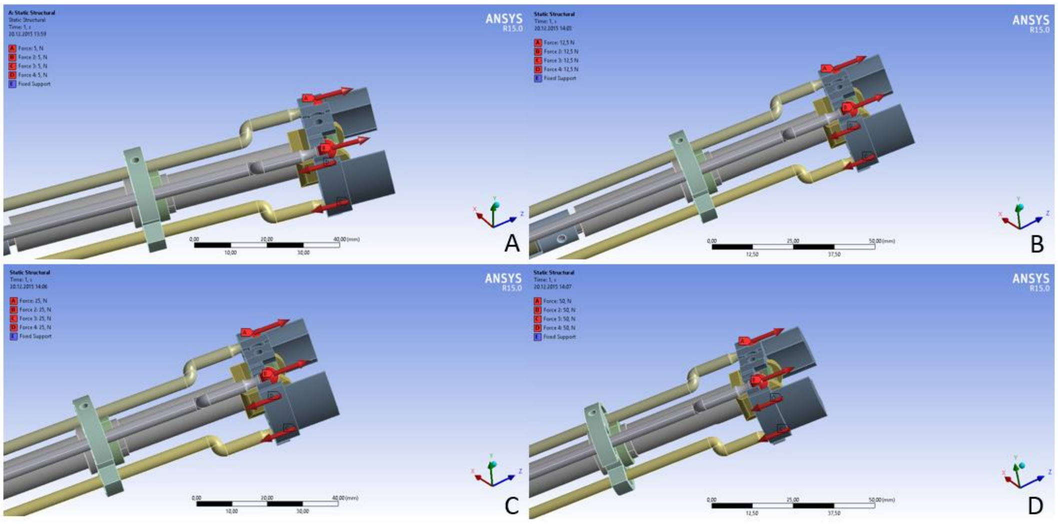


Figure 2.17: Applied horizontal forces on spherical ended shafts. (A) 20N, (B) 50N, (C)100N, (D) 200N.

2.3. Rapid Prototyping

Rapid prototyping (RP) which its techniques were discussed in previous sections is used to manufacture a prototype from a CAD data quickly. Before final prototyping or product production, RP can be used as a check guidance to test the mechanism. It is relatively inexpensive and fast. Our project group has two different RP option based on material. First one is a 3D printer (3DS Projet 160, USA) which uses calcium sulphate powder. Second is a FDM (Ultimaker, Netherland) that uses acrylonitrile butadiene styrene (ABS) or polylactic acid (PLA). Whole mechanism is rapid prototyped before final prototype production. 3D printer is used to check the mechanism about its assembly accuracy because of its cost and time effectiveness. On the other hand, FDM is used to create a functional, durable and inexpensive mechanism by using PLA. Two different PLA filaments (yellow and grey) which differ from each other by their qualities were used for RP. In the same vein, the grey filament is more durable and accurate in comparison with yellow one. Therefore, the grey PLA filament has been determined as the raw material of final rapid prototype.

2.3.1. Rapid Prototyping of Parallel Manipulator

At the beginning, the designed parallel manipulator was rapid prototyped by 3D printer to test the mechanism assembly criteria. According to assembly results, mechanism parts were found compatible to each other. 3D printed mechanism parts (Fig 2.18a) and assembled mechanism (Fig 2.18b) is given in the Fig 2.18.

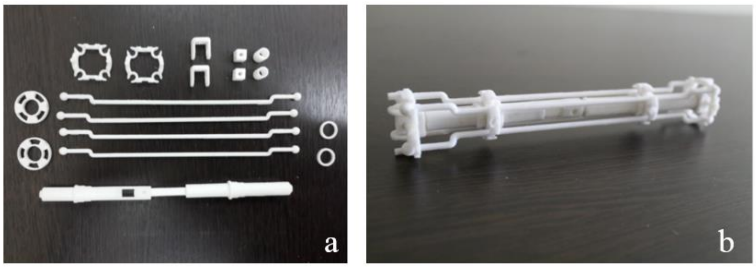


Figure 2.18: 3D Printed mechanism parts (a) and assembled mechanism (b).

After testing the matching of the parts to each other, the mechanism was rapid prototyped by FDM to check the functionality. PLA based rapid prototyped mechanism parts (Fig 2.19a) and assembled mechanism (Fig 2.19b) is given in the Fig 2.19. First PLA based prototype has been manufactured by using yellow filament which is less expensive but not the original filament. However, surface of the manufactured parts were rough and the sliding parts were prevented by it. Therefore, the system was remanufactured by using grey filament which is the original filament of our FDM printer. Since the surface of manufactured parts were much smoother than yellow filament, grey system was more functional than earlier prototypes. Manufactured parts and the assembled system is given in Fig 2.20.

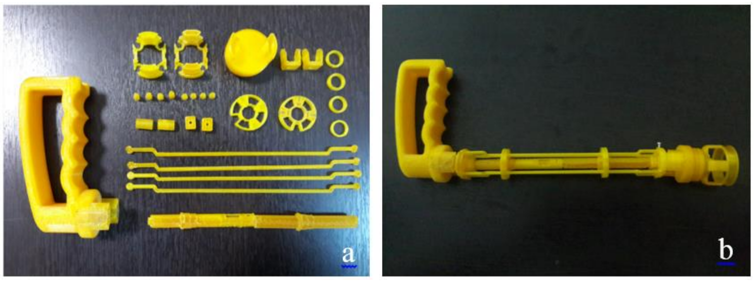


Figure 2.19: FDM manufactured parts by yellow filament PLA (a) and assembled mechanism (b).

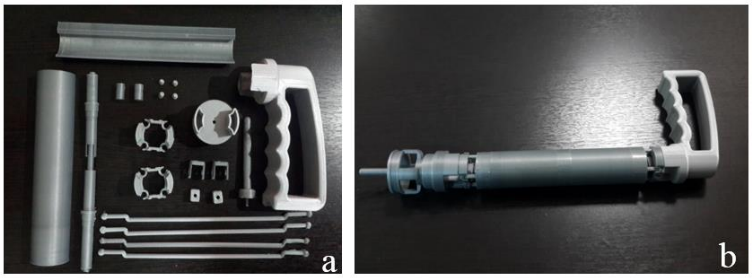


Figure 2.20: FDM manufactured parts by grey filament PLA (a) and assembled mechanism (b).

2.3.2. Rapid Prototyping of Cervicovaginal Cap

Cervicovaginal cap was designed according to uterus and cervix specifications and then rapid prototyped by using 3D printing to check the LED system pathway (Fig 2.21a) and also junction (Fig 2.21b) of the system. 3D printed rapid prototype by calcium sulphate powder is given in the Fig 2.24.

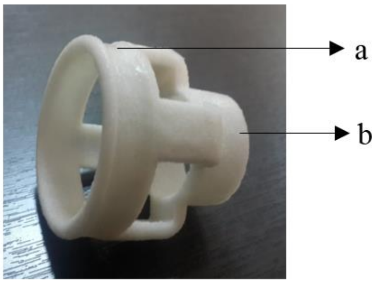


Figure 2.21: 3D Printed cervicovaginal cap by calcium sulphate hemihydrate. (a) LED system pathway, (b) Junction of the cap.

Furthermore, cap design is also rapid prototyped by PLA to implement to the mechanism and check the dimensions and compatibility. At the beginning, yellow filament was used because of its cost effectiveness. However, surface roughness and irregularity were obstacles for LED system implementation. Therefore, the cap was reproduced by using original grey filament for better surface properties. FDM manufactured cervicovaginal cap from yellow filament and LED system implemented cervical cap from grey filament are given respectively in the Fig 2.22 and 2.23.

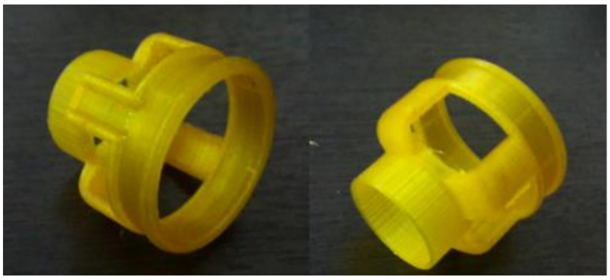


Figure 2.22: FDM manufactured cervicovaginal cap from yellow PLA filament.

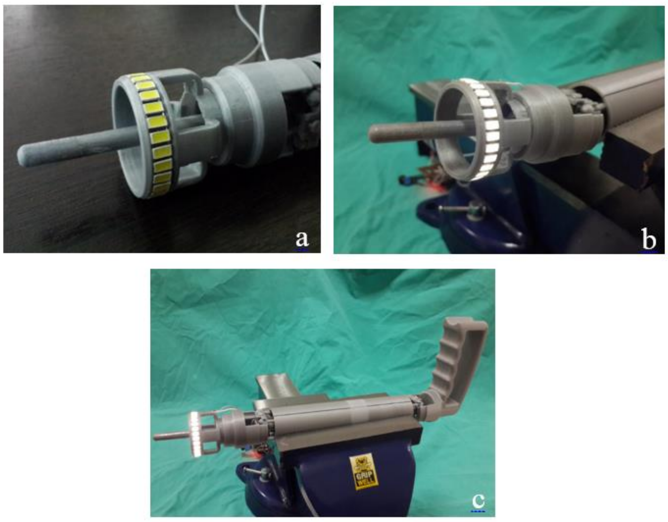


Figure 2.23: FDM manufactured cervicovaginal cap from grey PLA filament. (a) LED system integrated cervicovaginal cap, (b) LED illumination implementation, (c) Entire system.

2.3.3. Rapid Prototyping of Handle

Engineered handle was prototyped by FDM by using PLA. Handle properties were tested and implementation features were discussed before final product prototyping. Additionally, ergonomic design principles were evaluated.

Firstly, the handle was rapid prototyped by inexpensive yellow filament, but junctions were deformed due to low quality of filament, and the assembly of handle to platforms was troublesome. Thus, the handle was remanufactured by using high quality grey filament without any problem. Rapid prototyped handles were given in the Fig 2.24.

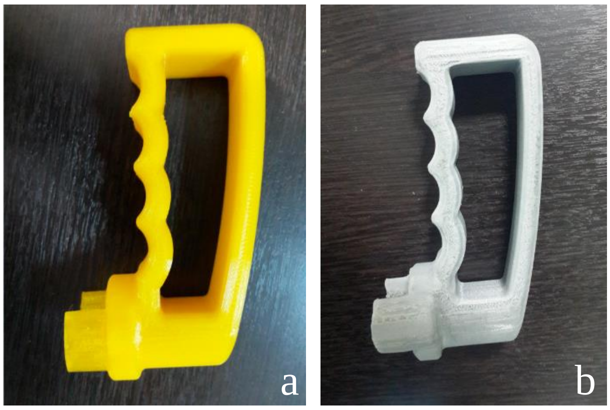


Figure 2.24: Rapid prototyped handles. (a) From yellow PLA filament and (b) grey PLA filament.

2.3.4. Rapid Prototyping of Cover

Cover is designed and produced by two parts for the assembly convenience. Lower part of cover (Fig 2.25a) was manufactured as hemi-cylinder. Upper part of cover (Fig 2.25b) was designed and manufactured as hemi-cylinder with a trapezium shaped canal (Fig 2.25c) for carriage of LED system cables. Rapid prototype of the cover parts were produced only by using grey filament in consequence of its strength, smoothness and durability. Manufactured cover parts are shown in the Fig 2.25.

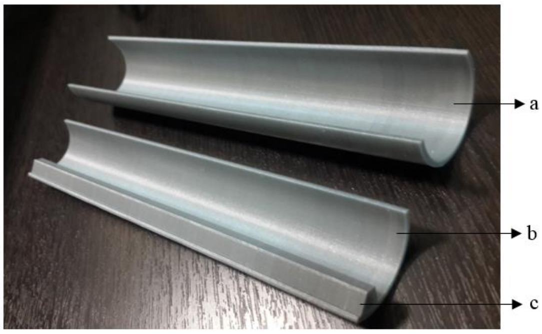


Figure 2.25: Cover prototype produced by PLA. (a) Lower part of cover, (b) Upper part of cover with cable canal, (c) Trapezium shaped canal

2.3.5. Final Rapid Prototyping of TUAC Uterine Manipulator by using SLS Technique

After modelling, analyzing and rapid prototyping trials developed manipulator has been decided to be manufactured by SLS from plastic by regarding accuracy, sensitivity, rapidness and cost effectiveness of SLS. Each component of the manipulator was controlled and the tongue and groove junctions were adjusted to 0,2mm which is recommended for SLS technique.

After production process, screw holes were created on necessary parts. Then, junctions of parts were validated and the system implementation was performed. Manufactured parts and the implemented uterine manipulator is given respectively in the Fig 2.26a and 2.26b.

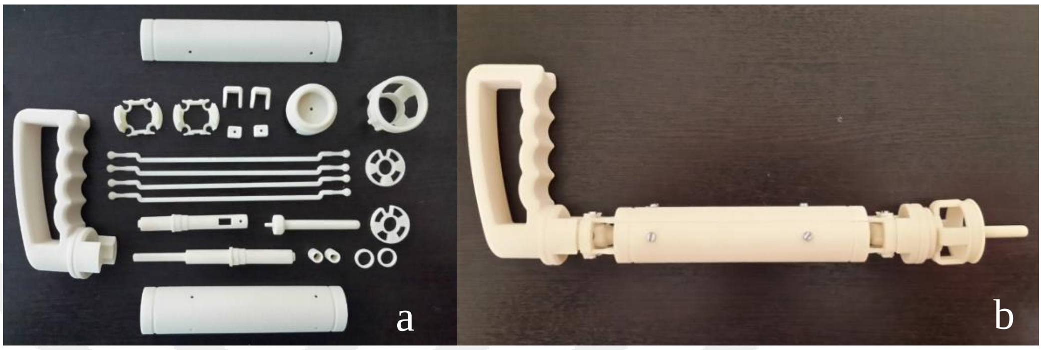


Figure 2.26: SLS Manufactured parts (a) and assembly performed system (b).

2.4. Manipulator Manufacturing

In consequence of design, analysis and rapid prototyping processes, functionality, stability, durability and convenience of transvaginal uterus amputation device have been assessed. Since the conventional manufacturing methods have some limitations, the parts which were not suitable to be manufactured by using this techniques were revised. Firstly, the design of handle was simplified by regarding available materials and time management. Also, platforms were revised according to CNC production requirements. At the end of the modification process, parts were approved for the metal prototyping.

Stainless steel which also used in many medical and operational devices was agreed as the main material because of various benefits such as being easily processable, durable, inexpensive, and corrosion resistant. On the other hand, disposable cervicovaginal cap was made of acetal copolymer (POMC) which is suitable for usage of monopolar, bipolar and harmonic ablation equipment.

Various manufacturing methods were used during prototyping processes of different parts. Turning lathe, computer numerical control (CNC) device, wire cut, and router were used for the production of parts such as cervicovaginal cap (Fig 2.27f), inner main shafts (Fig 2.27e), double spherical ended curved shafts (Fig

2.27d), shaft platforms (Fig 2.27c), platforms (Fig 2.27b), handle (Fig 2.27a) and the other parts. While circular basic parts were manufactured by turning lathe, complex parts were processed by CNC. After forming the rough structures, wire cut has been used to cut the parts in desired geometries. Furthermore, assembly of the uterine manipulation system was performed manually.

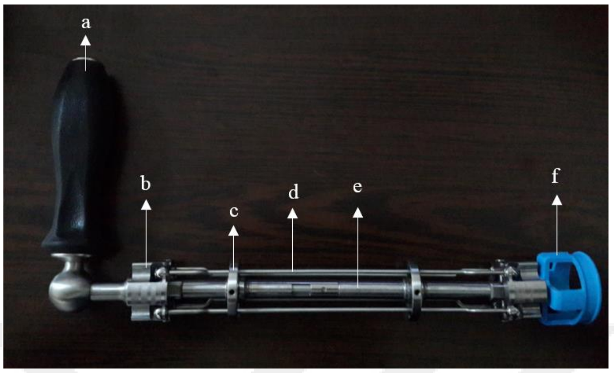


Figure 2.27: Metal prototype of TUAC. (a) Handle, (b) Platforms, (c) Shaft platforms, (d) Double spherical ended curved shafts, (e) Inner shafts, (f) Cervicovaginal cap.

Production of parts of the manipulator was performed mainly by using four devices which are turning lathe, CNC, router and wire cut. Most of the productions were performed by using two or more devices. Figures that represents manufacturing techniques that were used for the fabrication of parts of transvaginal uterus amputation device are given below.

Figure 2.28: Manufacturing techniques which are used for production of transvaginal uterus amputation device. (a) Turning lathe, (b) Wire cut, (c) CNC, (d) Router.

Manufacturing methods which were used for production of each part are summarized in the Table 2.2.

Table 2.2: Manufacturing techniques of parts.

Parts of Manipulator	Manufacturing Technique			
	Turning Lathe	CNC	Router	Wire Cut
Cervicovaginal Cap	X	X	X	
Handle	X		X	
Tip	X		X	
Inner Shafts	X	X	X	X
Platforms	X	X	X	
Shaft Platforms	X	X	X	X
Cardan U	X	X		X
Cardan Cube	X			X
Double Spherical Ended Curved Shafts	X			
Cover Parts	X		X	X
Adjustment Cylinders	X		X	X
Shaft Platform Stoppers	X			

Finally, brightness adjustable LED illumination system (Fig 2.29a) and the uterus tip (Fig 2.29b) was implemented on cervical cap after metal prototype manufacturing and assembly of the parts. LED system implemented transvaginal uterus amputation device prototype made of stainless steel is given in the Fig 2.29.

Figure 2.29: LED system implemented transvaginal uterus amputation device prototype made of stainless steel. (a) Cervical cap with LED illumination system, (b) Uterus tip.

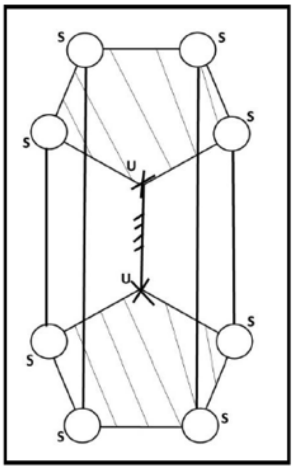
3. RESULTS AND DISCUSSIONS

3.1. Results

This section deals with the results from the design, modelling, mechanical analysis and the prototyping of the uterine manipulator.

3.1.1. Results of Final Manipulator Design

2-Dof parallel spatial manipulator was designed and assembled with the other components by using CAD software. Parallel manipulator is redeveloped with two excess link and the design is reorganized with four passive hinge to provide working easiness. Mobility of the manipulator is calculated and the kinematic representation is shown in the Fig 3.1.



$$M = \sum fi - \lambda (N - C - B) + q - Jp$$

$$M = 28 - 6 (10 - 4 - 2) + 2 - 4$$

$$M = 2 = (DOF)$$

Figure 3.1: Kinematic Representation and the calculations of 2-dof parallel manipulator.

Entire dimensions of the manipulator was determined by regarding vaginal anatomy and by examining the conventional manipulators. Length of the final design was calculated approximately 340mm at all and 35mm maximum diameter without regarding cervical cap which will be available in varying sizes in our design with help of CAD software measurement tools. Measurement results of the assembled system are given in the Fig 3.2.

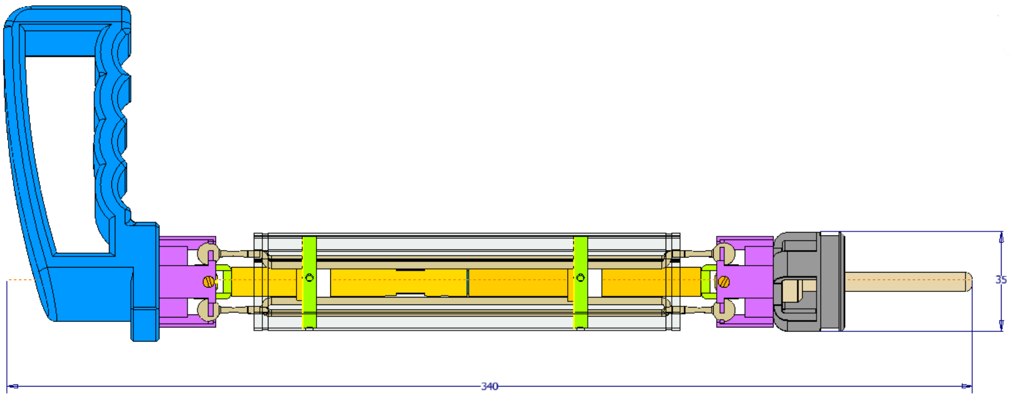


Figure 3.2: Dimensions of assembled uterine manipulator (dimensions are given in mm).

On the other hand, maximum range of motion was aimed to manipulate the uterus effectively. Design limitations and the desired range of motion were optimized and the manipulator's range of motion was determined both by using CAD software and defined 46° in sagittal and 46° in coronal planes (Fig 3.3). Simulation of two axis manipulation of the developed uterine manipulator was prepared by using sketch software (Photoshop CS6, Adobe, USA) to illustrate the range of motion of the manipulator and better understand the working principle and three dimensional motion. Illustration of the designed uterine manipulator are given in the Fig 3.4.

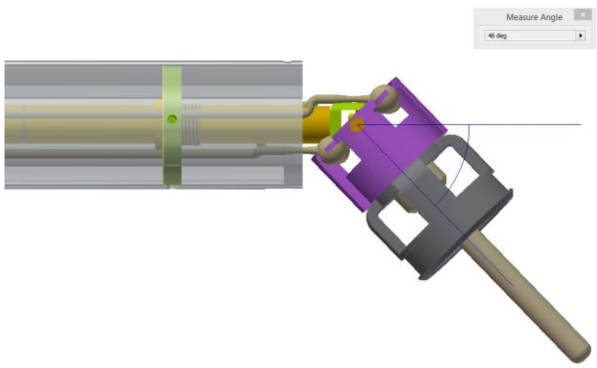


Figure 3.3: Anticipated range of motion of the TUAC system.

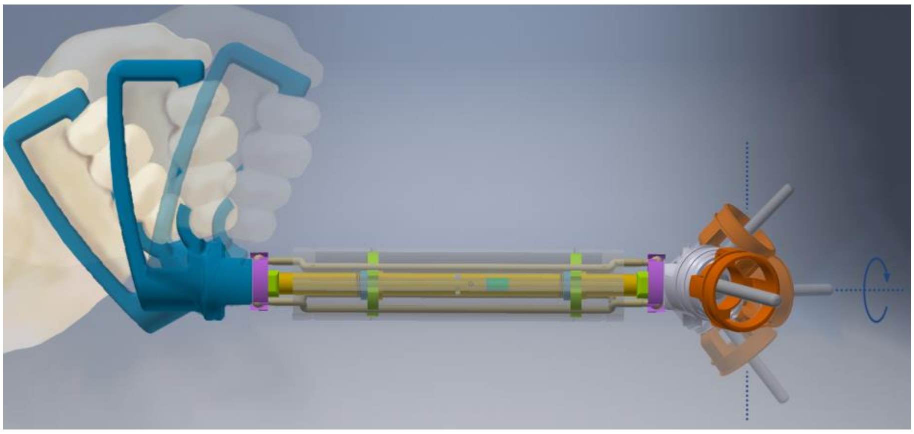


Figure 3.4: Simulation of two axis manipulation of the developed uterine manipulator.

3.1.2. Results of FEA of the Parallel Manipulator

Mechanical properties of stainless steel was assigned to model with a Young's modulus of 1,93E+11 and Poisson's ratio of 0,31. Stress distribution and the maximum stress accumulation of the varying forces on shafts are given in the following figures. Stresses are depicted with colors according to stress gradients, where red zones the highest stresses and blues are the lowest.

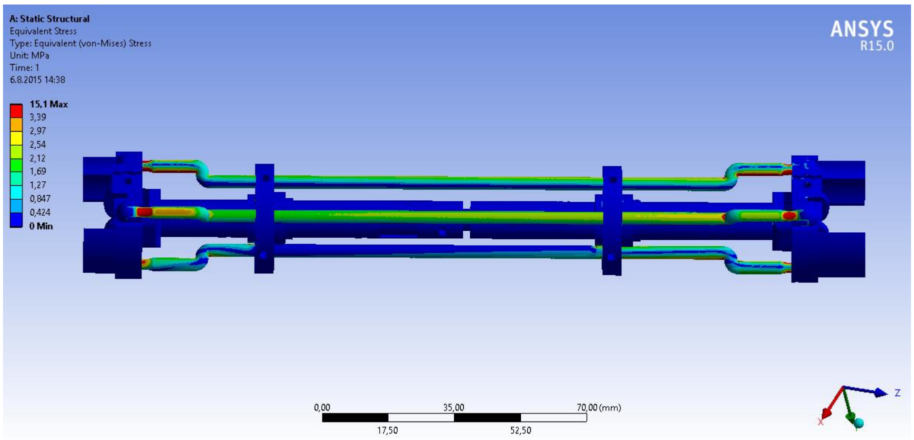


Figure 3.5: Stress distribution on system under 20N horizontal force.

Result of analysis shown that, under 20N horizontal force, stress accumulated on the apex of the spherical ended shafts with a maximum value of 15.1 MPa. Stress distribution is given in the Fig 3.5.

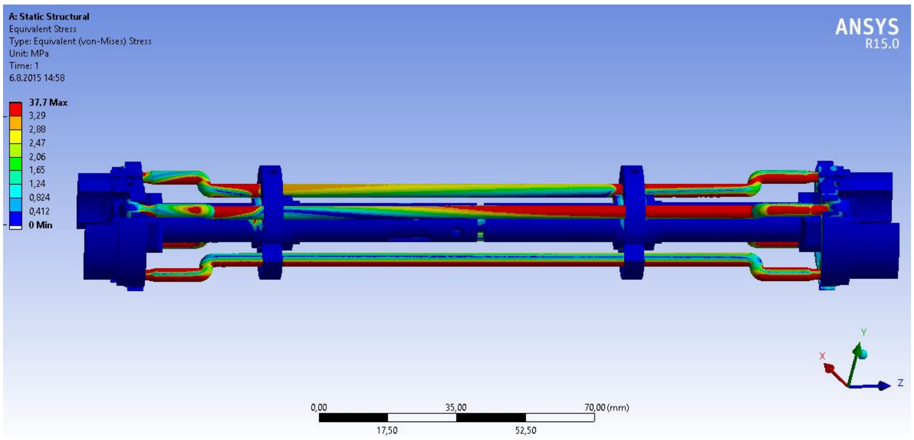


Figure 3.6: Stress distribution on system under 50N horizontal force.

In case the force is increased to 50N, results depict that stress accumulation shifted to the apex of the spherical ended shaft on the part of applied force direction which is the handle side of the manipulator. Maximum stress value was determined as 37.7 MPa and shown in the Fig 3.6.

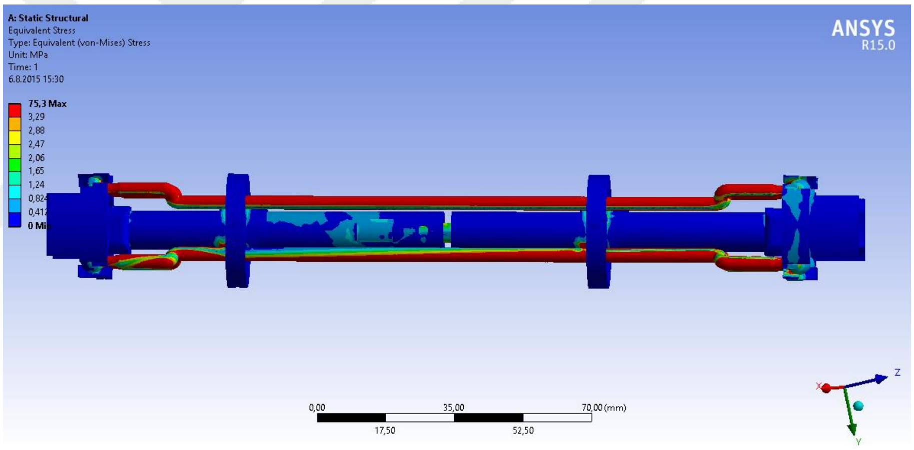


Figure 3.7: Stress distribution on system under 100N horizontal force.

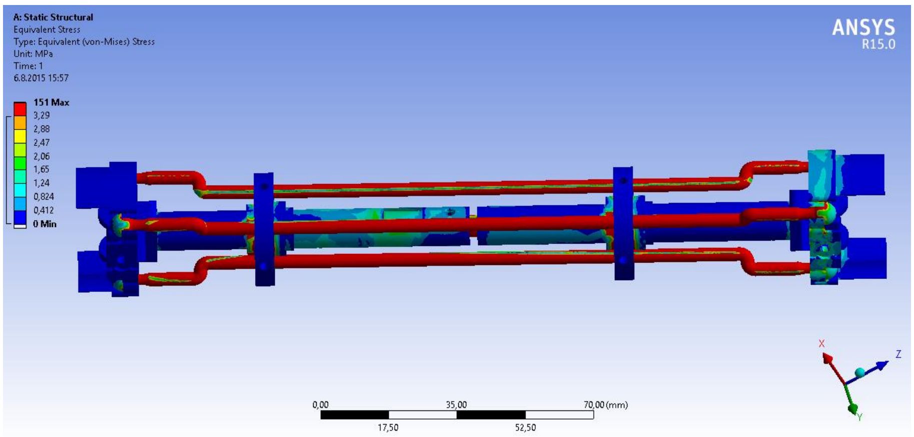


Figure 3.8: Stress distribution on system under 200N horizontal force.

Under 100N and 200N forces, stress intensity spreaded all over the shafts with maximum values respectively 75.4 and 151 MPa. Moreover, upper and lower shafts have been affected by the forces and the stress variation is given in the Fig 3.7 and 3.8 respectively for the 100N and 200N applied forces.

Ultimate compressive strength of stainless steel is approximately up to 310 MPa. In case 20, 50, 100 and 200 N forces were applied on double spherical ended curved shafts, maximum stress accumulation on system was determined as 151 MPa which was the result of applied 200N force as it was expected. In comparison to ultimate compressive strength of stainless steel, 151 MPa was evaluated as an acceptable stress accumulation. Maximum stress accumulations as a result of applied different forces were given in Table 3.1.

Table 3.1: Maximum stress accumulations on system as a result of applied forces.

Force (N)	Maximum Stress Accumulation (MPa)
20,0	15,1
50,0	37,7
100,0	75,4
200,0	151,0

3.1.3. Results of Manipulator Manufacturing

Transvaginal uterus amputation device has been manufactured subsequent to design, analysis and rapid prototyping processes. Various manufacturing techniques has been used for production and the manipulator was made of stainless steel which is inexpensive, easily processable, strong and convenient for medical device technologies.

Assembly of the system was mainly provided by using shrink fit junctions and screws. Junctions of the parts were adjusted approximately 0.05 mm for shrink fit connections. Moreover, fixation of the mobile parts were performed by using isometric screws with different measures. Handle of the manipulator has been immobilized on platforms with jamming screws for the purpose of better manipulation during operation. In the same manner, cover parts were attached to shaft platforms by using isometric screws. On the other hand, cervicovaginal cap which is a disposable equipment of the manipulator, was fixed into platform by using shrink fit junctions to provide easy demountability.

Updated version of the uterine manipulator, which was designed as suitable for conventional manufacturing techniques, is shown in the Fig 3.9. As mentioned before, shrink fit junction was adjusted between cervicovaginal cap and platform (Fig 3.9a), and jamming screws were used for fixation of the handle (Fig 3.9b). Also, two hemi-cylindrical cover parts were fixed on shaft platforms by using screws (Fig 3.9c).

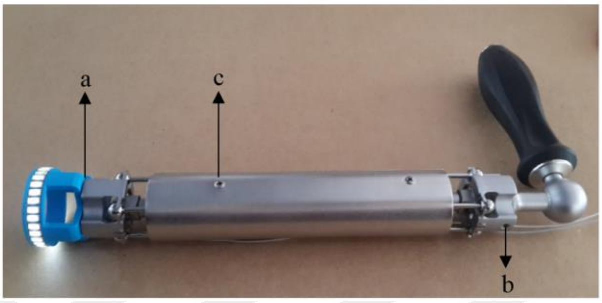


Figure 3.9: Updated version of the uterine manipulator, which was designed as suitable for conventional manufacturing techniques. (a) Shrink fit junction between cap and platform, (b) Jamming screws to fix handle to platform, (c) Fixation of hemi-cylindrical cover parts by using isometric screws.

Range of motion in sagittal and coronal planes of the manipulator was investigated and it was claimed that the system could not reach to 46° angle which was estimated by CAD software. The maximum manipulation angle of the manipulator was calculated approximately 80° in both sagittal and coronal planes. Limitations of conventional manufacturing techniques and performed design revisions might be possible reasons for decrease in range of motion of TUAC system. Movements of the manipulator in 2-axis were shown in the Fig 3.10.

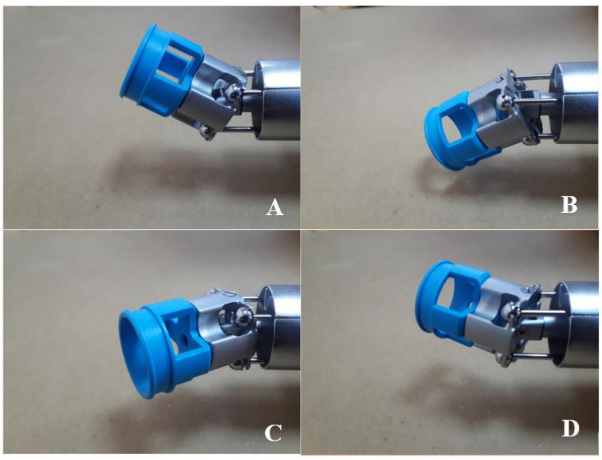


Figure 3.10: Range of motions of the manipulator in both sagittal and coronal planes. (A) Upwards, (B) Downwards, (C) Leftwards, (D) Rightwards movements.

LED system (Fig 3.11a) was designed as brightness adjustable by using a control knob (Fig 3.11b) to obtain different brightness levels. LED system integrated cervicovaginal cap was covered with an orange balloon to mimic the natural skin color and transmission of the light was emphasized in different levels as closed (Fig 3.12a), low (Fig 3.12b), high (Fig 3.12c) and maximum (Fig 3.12d). Furthermore, light transmission through both soft and hard tissue (fingers) was also examined and given in the Fig 3.13.

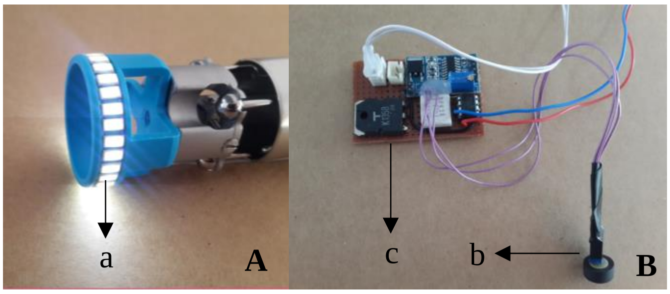


Figure 3.11: LED illumination system (A) and Brightness control unit (B) with control knob (b).

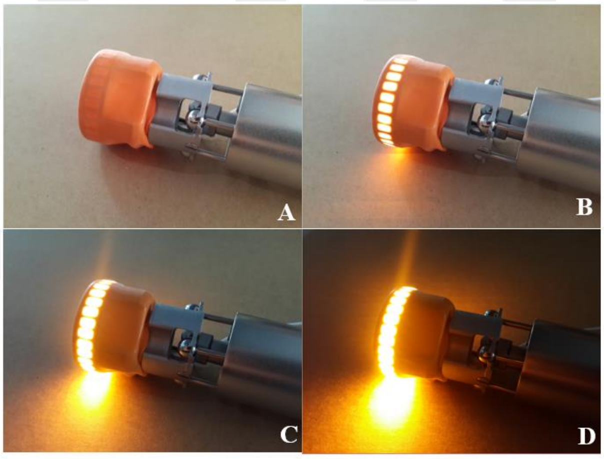


Figure 3.12: Light transmission through orange colored baloon in different level of brightness. (A) Closed, (B) Low, (C) High, (D) Maximum.

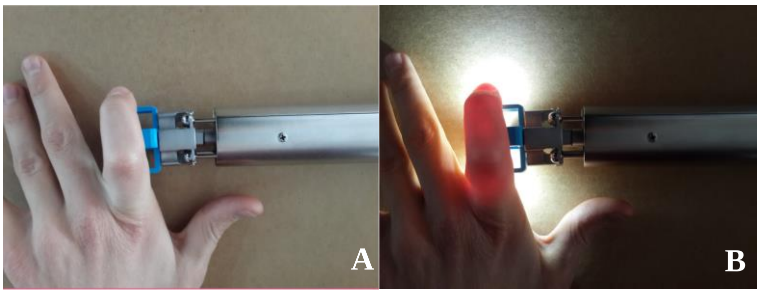


Figure 3.13: Light transmission through both soft and hard tissue (fingers). (A) LED system is off, (B) LED system is on.

3.2. Discussion

This chapter presents a discussion of the outcomes of the study and the comparison of the conventional uterine manipulators with TUAC. Also sterilization techniques of medical instruments will be discussed under this section for the future patient trials.

Approaching the operative field, uterine manipulators used in LH, have many different tasks in order to manipulate uterus safely and successfully. On the other hand, their main function is to mobilize the uterus for facilitating the LH operation (Mettler and Nikam 2006). For this purpose, various uterine manipulators are being used by surgeons in hysterectomies. Widely used uterine manipulators to assist LH are Clermont-Ferrand, EndoPath and RUMI on the market (Keriakos and Zaklama 2000, Mettler and Nikam 2006, Choksuchat, Getpook et al. 2008, Sauer 2013). All of these uterine manipulators have important advantages and drawbacks according to their design specifications and complexity. These drawbacks are particularly to move uterus in three dimensions, to show cervicovaginal landmark during laparoscopic circular cauterization which is difficult and hand skill required process, having uncomfortable and non-ergonomic handle design and amputation of the uterine cervix. An ideal uterine manipulator should be easy to assemble, inexpensive, easily placable to cervix and having a wide range of motions (Mettler and Nikam 2006, Eltabbakh G. 2010). However, none of the conventional uterine manipulators which are mentioned above provide these characteristics by oneself.

In this section, three different conventional uterine manipulators will be discussed in terms of range of motion, characteristics and usage aspects in detail and compared with TUAC.

3.2.1. Clermont-Ferrand Uterine Manipulator Specifications

The Clermont-Ferrand uterine manipulator (Karl Storz, Germany) offers a safe and easy manipulation and exact removal of uterus with a wide range of motion in anterior posterior plane up to 140° with five locking positions. The manipulator has a silicone sealing system to prevent gas leakage from vagina during the operation. Moreover, it can be used with both monopolar and harmonic cautery with help of semicircle shaped cervicovaginal cap made of ceramic.

Clermont–Ferrand manipulator (Fig 3.14) is an autoclavable instrument and reusable, which is important to reduce the operational costs. On the other hand, main disadvantage of this instrument is being complex to assemble before the operation and also its high cost. (Mettler and Nikam 2006, van den Haak, Alleblas et al. 2015)

Figure 3.14: Clermont-Ferrand Uterine Manipulator Components

3.2.2. EndoPath Uterine Manipulator Specifications

The EndoPath uterine manipulator (Ethicon, USA) (Fig 3.15) is a single use and lightweight device with a handle which allows a rotational control to surgeons. Its movement range is up to 210° in anterior posterior plane and with this range it has the greatest range of motion. Also it doesn't need an extra assistant for the manipulation of uterus by allowing one-handed operation. Alongside its reported advantages, it cannot maintain the pneumoperitoneum and being disposable increases the operation cost for each patient (Mettler and Nikam 2006, van den Haak, Alleblas et al. 2015).

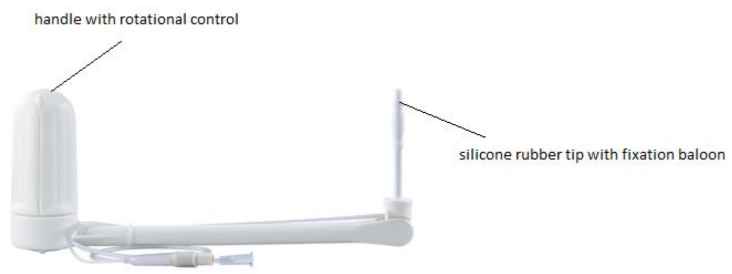


Figure 3.15: EndoPath Uterine Manipulator Components

3.2.3. RUMI Uterine Manipulator Specifications

RUMI uterine manipulation system (Cooper Surgical, USA) (Fig 3.16) is the most popular instrument and consist of a main shaft manipulator, KOH colpotomizer system, RUMI tip with five different lengths and colors (3,75cm, 6cm, 8cm, 10cm and 12 cm) and a cervicovaginal cap with different sizes (2,5cm, 3cm, 3.5cm and 4cm). It has a 140° wide range of motion in anterior posterior plane (Keriakos and Zaklama 2000, Mettler and Nikam 2006, van den Haak, Alleblas et al. 2015).

RUMI system has both disposable and reusable parts which brings an extra operational cost to patients for LH. Besides its advantages, RUMI cervicovaginal cap is made of polymeric resin which is not suitable to use with monopolar cautery. Also system instruments and disposable components are expensive.

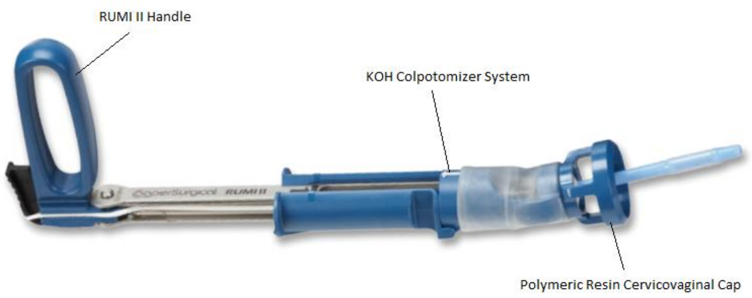


Figure 3.16: RUMI Uterine Manipulator Components

3.2.4. ForniSee Uterine Manipulator Specifications

The ForniSee uterine manipulation system (LSI Solutions, USA) (Fig 3.17) is a lighted uterine manipulator and consist of two main components which are the sound and device. The sound part is a reusable rod from stainless steel curved at the uterine end with varied lengths (6cm, 8cm, 10cm and 12cm). The device part is a disposable system with many components such as cervical cup, device shaft, handle, pneumo-occluder and light cord coupler (M. Gutierrez, K.W. Volker et al. 2013)

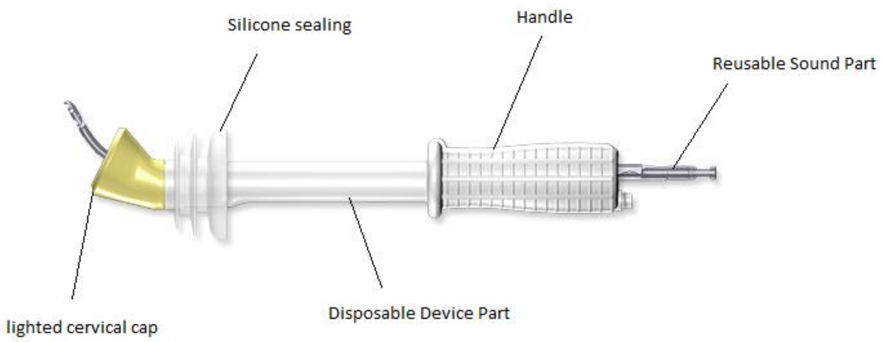


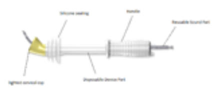
Figure 3.17: ForniSee Uterine Manipulator Components

3.2.5. Transvaginal Uterus Amputation Device (TUAC) Specifications

TUAC is the innovative and currently developed uterine manipulator with 2 axis motion up to 80° both in sagittal and 80° coronal planes. Since, the limited motion capacity in only one axis which is the most important drawback of the mentioned uterine manipulators create significant difficulties during LH especially in the segmentation of the ligaments and separation of uterus and cervix, the TUAC uterine manipulator with two axis motion capability will overcome this drawback and bring a new perspective on gynecology field.

In medical instrument sterilization, two main techniques are widely used. The first method is using autoclave which uses steam heated to approximately 120°C under pressure to sterilize the instrument (Dion M. and W. 2013). Furthermore, heat and/or moisture sensitive instruments such as plastic or rubber products can sterilize by using ethylene oxide (EO). Ethylene oxide sterilizers have a chamber with an air input, a steam input, gas conditioner, EO tank and a vacuum system for removal of gas from chamber (Mendes, Brandao et al. 2007). All system components were designed as reusable and sterilizable by autoclave or EO to reduce the operation costs. Moreover, a circular LED illumination system was integrated to cervicovaginal cap to provide visibility of cervicovaginal landmark through the cervical tissue during LH. Unlike other manipulators, this system will allow the surgeon to determine the exact cauterization region easily for separation of cervix and vagina which is one of the most difficult step of the operation. TUAC has an ergonomic power grip type handle design with five finger grasping regions to ease the manipulation of uterus by assistant.

Table 3.2: Comparison of Uterine Manipulators by regarding their characteristics (Greenberg 2013, van den Haak, Alleblas et al. 2015)

Uterine Manipulator		Range Of Motion		Characteristics				
		Sagittal Plane	Coronal Plane	Uterine Fixation Type	Reusable	Pneumoperitoneum	Cervicovaginal Landmark Indicator LED System	Costs
Clermont - Ferrand		**140°**	**-**	**Screw**	**Yes**	**Good**	**No**	**~2500 $**
EndoPath		**210°**	**-**	**Baloon**	**No**	**Bad**	**No**	**~100 $**
RUMI		**140°**	**-**	**Baloon**	**Partly**	**Good**	**No**	**~395 $**
ForniSee		**N/A**	**-**	**Anchorage Mechanism**	**Partly**	**Good**	**Yes**	**~240 $**
TUAC		**80°**	**80°**	**Baloon**	**Yes**	**N/A**	**Yes**	**N/A**

An ideal uterine manipulator should ease the operation by the way of having simple assemble structure and a wide range of motion in more than one axis, providing settlement on cervix with minimum effort as mentioned above. TUAC was designed and produced by regarding these specifications which have an important role on LH operation success. Although, none of the conventional manipulators has a motion in lateral axis, TUAC brought a complete manipulation opportunity to surgeon by adding one more axis to its motion capacity. Likewise, surgeons are having trouble with many uterine manipulators in terms of determination of cervicovaginal landmark by laparoscope. To overcome this drawback, a circular LED illumination system was integrated on cervicovaginal cap on the purpose of acting like a marker. Disposable medical instruments are beneficial for operations in many aspects however they increase the operation cost which will be reflected on both surgeon and patient. Obviously, reusable instruments are more preferable in comparison with disposable ones by regarding cost effectiveness. According to preferences given below, TUAC was planned, designed and manufactured as a reusable uterine manipulator.

Consequently, TUAC was derived from optimum manipulator requirements, drawbacks of the conventional manipulators and surgeons' demands. Design tasks and outputs were decided with a multidisciplinary team from varied disciplines such as medical sciences, engineering sciences and industrial partners.

Table 3.3: Comparison of Uterine Manipulators by regarding their advantages and disadvantages (Mettler and Nikam 2006, van den Haak, Alleblas et al. 2015)

Uterine Manipulator	Advantages	Disadvantages
Clermont-Ferrand	*Wide movement range (Up to 140°) *Reusable *Pneumoperitoneum is maintained	*Thick uterine manipulation tip with screw *Complex to assemble *Expensive purchase cost *Difficulties on determination of cervicovaginal landmark
EndoPath	*Wide movement range (Up to 210°)	*Disposable *Difficult pneumoperitoneum maintenance *Difficulties on determination of cervicovaginal landmark
RUMI	*Wide movement range (Up to 140°) *Pneumoperitoneum is quitely maintained	*Complex to assemble *Cervicovaginal settlement problems in case of narrow vagina *Pneumoperitoneum is maintained but lower preventation for leakage of gas *Expensive disposable components *Difficulties on determination of cervicovaginal landmark
ForniSee	*Inexpensive purschase cost *Lighted cervical cap *Pneumoperitoneum is maintained	*Expensive disposable components *Complex to assemble
TUAC	*Movement capacity in two axis up to 80° (saggital & coronal planes) *Reusable *Pneumoperitoneum will be maintained *LED illuminaiton system for the determination of cervicovaginal landmark	*Still in development progress *Movement ranges may be increased *Sterilization and impermeability conditions should be improved

4. CONCLUSIONS

This section discusses the primary objective posed in material and method in context with the results obtained during this study and the future expects of the thesis.

Most of the conventional uterine manipulators are based on the motion capability on anterior posterior plane. Moreover, determination of vaginal fornices are rely on surgeons' palpation skills. Thus, operation time is increasing, assistance is getting difficult, visibility of the ligaments and connections between uterus and abdominal tissues are restricted and determination of cervicovaginal landmark due to limited manipulation and the factors given above. Newly developed manipulator has possibility to overcome these problems by allowing the two axis manipulation of uterus, including a circular LED system for the determination of vaginal fornices and an ergonomic handle.

A 2-dof parallel manipulator with adequate range of motion will provide a manipulation in both anterior posterior and lateral planes. With help of this ability, LH operation procedures will be simplified and the visualization of cutting spots can be determined quite easy by the surgeon. Likewise, assistance of the LH will not be as difficult as with the current manipulators.

One of the challenging steps in LH is that to decide the separation region of uterus and vagina on cervix particularly in cancer inclusive cases. By regarding this, a circular LED illumination system is implemented on cervical cap in an attempt to simplify the monitorization of related section. In addition, variable light intensity is provided by considering the tissue thickness.

Everlasting manipulation process of uterus during LH increases the difficulties of handling for the assistant. Therefore, ergonomic requirements become crucial as well as functionality. To achieve a facile and safe manipulation, power grip type ergonomic handle with finger grooves for better fitting was designed and assembled to the manipulator.

By regarding the possible commercialization of the developed manipulator, it can be concluded that, artificial and the real uterus model tests should be done to correlate the design parameters with biological conditions before surgical trials. Following the completion of *in-vitro* experiments, it might be expected to use the uterine manipulator in real LH operations.

Despite all the current studies and uterine manipulators on the market, no significant researches with all the features mentioned above has ever been done. This study is a combination of many different uterine manipulation researches and give a new impulse to gynecological operations. Thus, it can be concluded that LH operation time and difficulties will be decreased, meanwhile operation success will be increased. It can be mentioned that significant research points posed in the thesis are concluded and clarified.

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