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Development of Transvaginal Uterus Amputation Device for Laparoscopic Hysterectomies in Gynecologic Surgeries

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Abstract: 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. During total laparoscopic hysterectomy, first uterine vessels and ligaments are cauterized respectively, and then cervicovaginal connections are cauterized and coagulated to remove uterus completely. 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 and amputation of the uterine cervix. A new transvaginal uterine manipulator may overcome these two important drawbacks of these currently available devices. For this reason, a3D scanned technique was used to get uterus sizes 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. Moreover, performances of different caps and LED systems will be evaluated. Furthermore, after integration of self-cutting and self-suturing mechanisms into our system, final prototype will be produced by using titanium which is biologically and mechanically appropriate. Therefore, aim of this study was to design and produce a new uterine manipulator with three dimensional movements, LED illumination, self-cutting and self-suturing systems to facilitate laparoscopic hysterectomy.

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Kadın Doğum Cerrahisinde Laparoskopik Histerektomilerde Kullanılmak Üzere Transvajinal Uterus Ampütasyon Cihazının Geliştirilmesi

Anahtar Kelimeler
Laparoskopi
Histerektomi
Rahim
Uterus
Manipulatör
Biyomedikal Mühendisliği

Özet: Histerektomi günümüzde en çok uygulanan ameliyat olup rahmin alınmasını ifade eder. Laparoskopik histerektomi (LH), operasyon sırasında kan kaybının, çevre doku/organ hasarının, post-operatif enfeksiyon ve ateş görülme sıklığının düşük olması, operasyon, hospitalizasyon ve ameliyat sonrası normal aktiviteye dönüş süresinin kısa olması gibi avantajları nedeniyle sıklıkla uygulanmaktadır. Total laparoskopik histerektomi (TLH) sırasında uterin damarlar ve ligamentler, koterize edilip uterus serbestleştirildikten sonra, TLH'nin en zor aşaması olan servikovajinal dokunun koterizasyonu gelmektedir. Bu aşamada hem uterusun manipülasyonu, hem de servikovajinal dokunun laparoskopik olarak yerinin belirlenmesinde uterus manipülatörleri kullanılmaktadır. Bu çalışmadaki amacımız, uterusun karın boşuğunda üç eksende hareket ettirilmesini sağlayacak ve servikovajinal dokunun karın boşuğundan rahatça algılanıp koterizasyonunu kolaylaştıracak yeni bir manipülatör tasarlamaktır. Bilgisayar ortamında tasarlanan paralel manipulatör ve özel LED'ler ile çevrelenmiş uterus başlığının 3B tarayıcı ve 3B yazıcı gibi hızlı protoipleme cihazları yardımı ile üretimi yapılmıştır. Sistem için tercih edilen LED'ler özel olup transvajinal olarak ışıma yapıp servikovajinal dokudan geçerek laporiskopik kamera ile algılanabilecek şekildedir. Üretilen prototip rahmin üç eksende hareketini ve servikovajinal bileşkenin LED ile tayinini başarıyla sağlayabilecek teknolojidedir. Farklı başlık ve LED aydınlatma tasarımları denenmesi ile verimlilikleri karılaştırılacak, sisteme entegre edilecek kendi kendine kesim ve dikim mekanizması ile birlikte nihai prototip üretimi hem mekanik hem biyolojik olarak uygun olan titanyum malzemeden yapılacaktır. Üretimin ardından dizayn edilen deney kabini ile rahmin vücut içerisindeki ortamı simüle edilecek ve etik izinleri alınmış olan fresh kadavra testleri yapılacaktır.

1. Introduction

Hysterectomy is the most common major gynecologic surgical procedure and refers to removal of uterus (Kondo et al., 2010; Gurin et al., 2012). Approximately 600.000 hysterectomies are performed in the United States each year (Keshavarz et al., 2002; McCracken et al., 2006). Although, there is no exact data to show prevalence of hysterectomy in Turkey it is thought that this number is about 150.000 hysterectomies per year (Statistics by Country for Hysterectomy, 2014). Benign diseases such as menstrual disorders, myomas, chronic pelvic pain and uterine prolapse are responsible for more than 70% of the indications for hysterectomy (Kondo et al., 2010). Moreover, gynecologic cancers related with endometrium, uterus, uterine cervix, uterine tuba and ovaries can be reasons for hysterectomies (Gurin et al., 2012). From past to present, three types of hysterectomies are being performed that are chronologically; vaginal, abdominal and laparoscopic hysterectomy (LH) (Sutton, 1997).

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 (Soper et al., 2004). LH refers to removal of uterus by laparoscopic procedures. LH is first performed in 1989 (Reich et al., 1989) and it becomes more popular because of its major advantages. Recently, it is performed frequently. Its major advantages are in 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 et al., 2010).

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 seperate uterus from its surrounding tissues (Kondo et al., 2010; Einarsson et al., 2009). Damage to these vital organs is seen particularly during the separation process of uterine cervix from the apex of the vagina.

The last step of the LH is closure of the vaginal incision which is carried out via abdominal or vaginal route using different type of sutures. Vaginal cuff separation (dehiscence) is a rare complication of total hysterectomy. It is potentially morbid complication and may cause evisceration of pelvic organs which eventually results with peritonitis, bowel injury and necrosis, and sepsis. Closing the vaginal cuff via abdominal route is more difficult and related with more complication particularly cuff dehiscence when compared to vaginal route during LH (Uccella et al., 2011)

Thus, purpose of this study was to design and produce a new uterine manipulator with three dimensional movements, LED illumination, self-cutting and self-suturing systems to facilitate laparoscopic hysterectomy.

2. MaterialsandMethods

2.1. Parallel Manipulator Design and Rapid Prototyping

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 drawing of the selected manipulator can be seen in Figure 1 and 2.

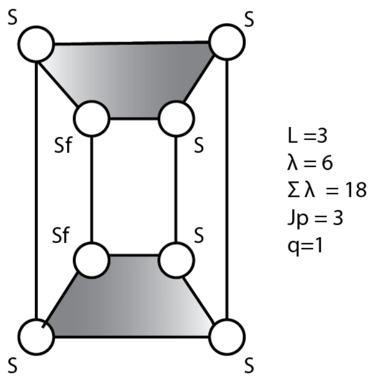

Figure 1. Structural synthesis of parallel manipulator

Using Alizade's universal mobility equation,

$$M = \sum_{i=1}^{j} fi - \sum_{k=1}^{L} \lambda k + q - Jp \quad (1)$$

$$M = 22 - 18 + 1 - 3 = 2$$

where M is the mobility of the manipulator, j is the total number of joints, fi is the total degrees of freedom of the i^{th}joint, L is the number of independent loops, λk is the subspace or space of the k th 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,

After the structural synthesis procedure, CAD softwares (Autodesk Inventor, USA; Solidworks, USA) were used to simulate designed spatial parallel manipulator.

After adding one more excessive link to the design for fault tolerance, it was exported to the rapid prototyping format (.stl file format) and transferred to the 3D printer software (Catalyst EX software, USA). Manipulator was rapid prototyped from acrylonitrile butadiene styrene polymer by using 3D printer (Stratasys Uprint SE, USA).

2.2. Cervicovaginal Cap Design and Rapid Prototyping

Three dimensional (3D) scanning technology is 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 (3D3 Solutions – HDI Advance, Canada) was used in designing a cervicovaginal cap of the manipulator and 3D scanner software (FlexScan, Canada) was used in revising the design. Then, some modifications were performed on CAD softwares (Autodesk Inventor, USA; Solidworks, USA) and LED illumination mounting gaps were constituted on the cervicovaginal cap design. After all, a design was exported to rapid prototyping format and transferred to 3D printer software (3DP software, USA). Cap was rapid prototyped from calcium sulphate powder by using 3D printer (3DS Projet 160, USA).

2.3. Cautery and LED Illumination Design and Implementation

The cautery device is going to be designed as a compatible device with the novelty uterine manipulator which was described above. The power of the device is going to be designed adequately with the ranges between 100 and 200W so as to perform removal and easily coagulation on uterine tissue. Since the uterine tissue which is going to be removed and cauterized is not suitable to be in between active electrode and neutral electrode, the device is going to be designed as monopolar structure.

The current with high frequency, which originates from the removal probe on the tip of manipulator, is going to establish an electrical loop on patient's plaque by a capacitive transition. Besides, the current which is necessary for the LED illumination on the tip of manipulator and the related system are going to be controlled by this cautery unit. The front panel of the proposed device is going to contain removal, coagulation and blend selectors and their related power adjustment displays. The control of adjustment buttons, the control of LCD and other displays, the control of proper contact of patient's plaque, the generation of aural warning signals, the control of LED illumination on the tip of manipulator, the recall of preset user settings for different applications, and the control of all such similar functions which are necessary to be performed digitally are going to be achieved with an embedded system and its related software. During removal and coagulation operation, an extra manual or pedal command unit can be added to the design to obtain a more user friendly approach. Special LED system shape and location is determined and integrated to modified cervicovaginal cap according to safety and performance specifications.

3. Results

In the scope of thesis, CAD of parallel manipulator, rapid prototyped parallel manipulator, CAD of cervicovaginal cap and rapid prototyped, LED illumination system integrated cervicovaginal cap are shown in Figure 1, 2, 3 and 4 respectively and their specifications are given in Table 1.

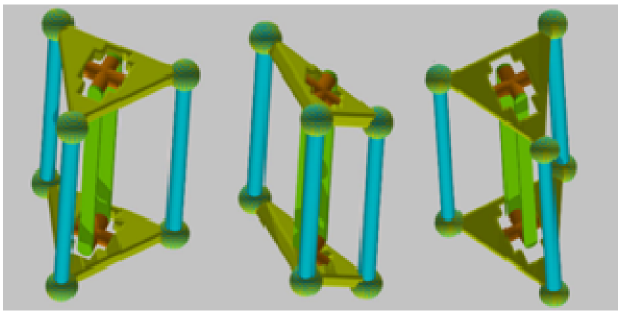

Figure 2. CAD of parallel manipulator

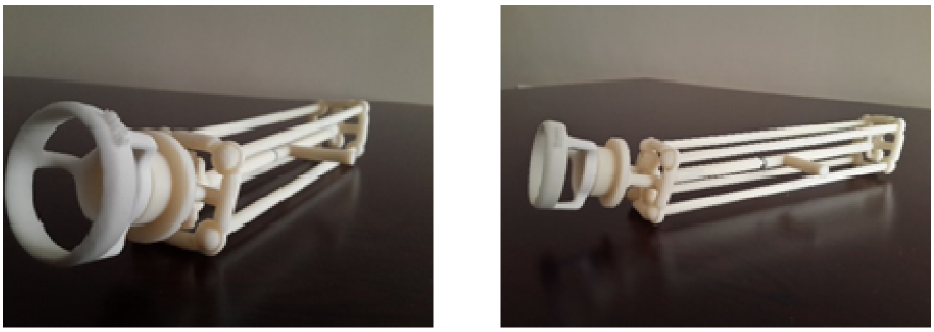

Figure 3. Rapid prototyped parallel manipulator

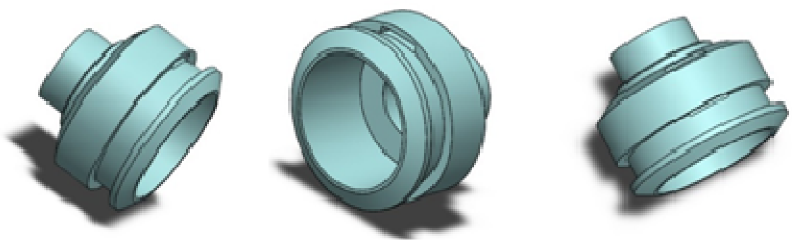

Figure 4. CAD of cervicovaginal cap

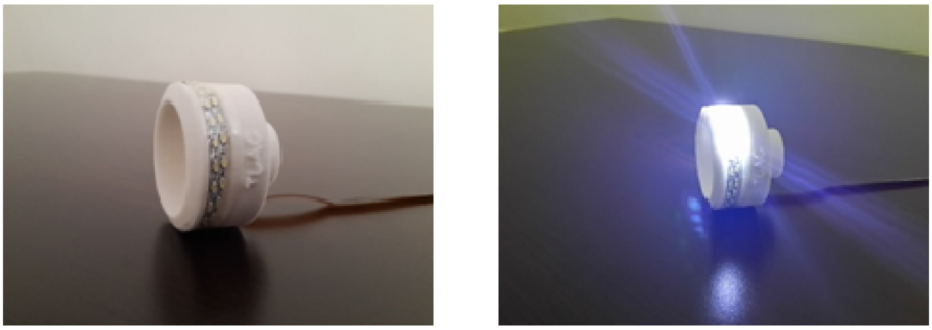

Figure 5. Rapid prototyped, LED illumination system integrated cervicovaginal cap

Table1. Design criteria of uterine manipulator

Parallel manipulator diameter	< 4cm
Parallel manipulator motion angles	Min -45 and +45
Cervicovaginal cap diameters	3cm-3,5cm–4 cm
LED power	0,5 W
Brightness	50– 55 lm (Pure White)

4. Discussion and Conclusion

Uterine manipulators are used to overcome those problems which can occur during the LH procedures (Tanprasertkul et al., 2010). An uterine manipulator should provide basic functions as follow (Eltabbakh, 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.

Nowadays, there are several uterine manipulators on markets. Widely used are Cohen-Cannula, Clermand-Ferrand, EndoPath, TINTARA, RUMI, ForniSee, SecuFix (Mettler and Nikam, 2006; Choksuchat et al., 2008; Keriakos et al., 2000; Sauer, 2013). However these commercial uterine manipulators have some disadvantages. Their common problems are limited motion capacity, expensiveness, including many disposable parts, insufficient motion capacity (Tanprasertkul et al., 2010; Mettler and Nikam, 2006). Moreover, they are insufficient to cut cervicovaginal tissue and suture vaginal cuff after removal of uterus.

There are several important criteria in the designing phases of these manipulators. Main criteria can be summarized as being easy to assembly and staying in place during operation, inexpensive, not breaking apart during the procedure, having a wide range of motion in maximum number of axis (Eltabbakh, 2010; Mettler and Nikam, 2006). In the scope of the current study, a new uterine manipulator design will be done to overcome problems described above and increase the performance of LHs. Three dimensional motion of uterus will be provided and determination and cauterization of cervicovaginal tissue abdominally will be facilitated by new designed uterine manipulator.

Advantages of prototyped parallel manipulator and LED system integrated cervicovaginal cap which are in the scope of the study are discussed below as a comparison with current manipulators.

Existing manipulators have only 2D motion capacity but we provide 3D motion with transvaginal uterus amputation device (TUAC). It means easier manipulation of uterus in all directions. Current systems have insufficient assistance for determination and cutting process of cervicovaginal compound and suturing process of vaginal cuff after removal of uterus. Right cutting place must be determined by palpation which is a hand skill required process. One of the most difficult steps of laparoscopic hysterectomy would be overcome by designing LED system which will act as an indicator for determination of cervicovaginal tissue. Also for cutting and suturing process, we will design self-cutting and self-suturing mechanisms to reduce hand skill requirements and improve success of operation. Finally, most of current manipulators have many expensive disposable parts that increase the cost of a surgery and that mean a cost burden to patient for each operation. Reduced costs by decreasing number of disposable parts are one of the other advantages of the currently targeted manipulator.

Developed transvaginal uterine amputation device will constitute a basis in gynecologic diseases and delivery area. With help of designed new device, operation time will be reduced while operation success is increased. Also by increasing automation, laparoscopic hysterectomy will be easier and more popular. So patients will be treated with a less invasive operation. Also this project will be a step for new researches in robotic surgical area.

5. Future Works

Design of self-cutting and self-suturing mechanisms on cervicovaginal tissue which is the right cutting place for separation of cervix and vagina, is still going on. Performances of different caps and LED systems will be compared. After integration of self-cutting and self-suturing mechanisms into our system, final prototype will be produced by using titanium which is biologically and mechanically appropriate. After production, experimental cabin will be designed to simulate environment of uterus as in body and fresh cadaver tests (required ethical permissions have been possessed) will be done.

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