

A CERVIX DILATION DEVICE USEFUL IN PRESENCE OF MINIMAL RESOURCE SETTINGS.

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Conflict of Interest: None

Funding: NewGen Innovation and Entrepreneurship Development Centre, National Science and Technology Entrepreneurship Development Board (NSTEDB), Department of Science & Technology (DST), Government of India

Abstract

Cervical dilators are used to dilate the cervix in an efficient manner. It is done during labor, miscarriages, abortion or for any gynaecological surgery. During gynaecological surgery procedures, it is necessary to open the cervix to get access to the uterus and fallopian tubes and this can be achievable using a dilator. The device is useful as it decreases the risk of cervical injury during surgery. There are a number of cervix dilators used by the Gynaecologists around the world including mechanical dilators, drugs inducing cervical dilation and osmotic dilators. Balloon catheters are used in mechanical dilation while hygroscopic dilators are the osmotic dilators. For drug induces dilation, there are several drugs available in the market. The current paper focuses on the mechanical type of cervix dilators.

Keywords - Cervix, Cervical Dilation, Rapid Cervical Ripening Device, Foley Catheter, Childbirth, Induced Abortion.

Introduction

In pregnancy the opening of the cervix is blocked by thick mucus (to prevent bacteria from entering the cervix). During normal child birth when dilation starts this plug is loosened, it may either come as one piece or thick mucus discharge from vagina. After the loosening of mucus plug we arrive at the second stage. Here blood comes out of vagina. During this process Prostaglandins is released into the cervix which help in ripening and dilation of cervix [1]. All these processes happen in normal pregnancy and in 9th month of delivery (3rd trimester). But for some reasons there are complications in pregnancy and may need termination. Generally complications in pregnancy are identified in second trimester. So cervical dilation during 2nd trimester abortion is achieved by mechanical means and specific medication. Mechanical means include catheters and osmotic dilators. Catheters are silicone based tubes with balloon at one end. After inserting the catheter in the cervix the balloon is expanded. Osmotic dilators are the made of hygroscopic material that absorbs the moisture inside the cervix and they expand inside the cervix. In both the cases, like when balloon expands or osmotic dilator expands it apply mechanical pressure on the internal linings of cervix and hence starting the dilation process. Medical means include use of various drugs and medicines.

There are various reasons for cervical dilation process, some of them are intrauterine death of baby, fatal anomalies [2], infection to baby, premature birth of baby. Intrauterine fatal demise describes the death of the foetus in the uterus at or after 20th week of pregnancy. The concept of fatal demise is different around the globe and it depends on the foetus age and weight [3]. Fatal anomalies, often referred to as birth defects, are structural changes to one or more parts of the foetus' body that increase the chance of stillbirth and can cause deficiencies in the child's health, development and quality of life [4]. Premature birth is a birth that occurs before the 37th week of pregnancy. The gestational period is approximately of 40 weeks. Premature birth may result in improper development of lungs, difficulty in maintaining body temperature, sluggish weight gain [4].

Problem Statement

The aim of development of the device is to increase the efficiency of dilator and reduce the time of dilation. The project had two domains. The first to design and manufacture the new type of catheter based on Anchor Bolt mechanism. And second to develop a Cervical Ripening Device that helps to make the dilation process faster using flexible silicone.

Literature Survey

The Foley catheter and a 3 mg dinoprostone pessary (Prostin E2) were compared in a study for cervical preparation. The catheter was compatible and it dilated the cervix more with good cervical compliance. The Foley catheter gives the impression to deliver a freely accessible and effective means of cervical dilation and preparation [5].

The period of 14th – 28th week is the mid-trimester period. In the mid-trimester, screenings of the foetus for presence of any fatal anomalies are executed and if the anomalies which are incompatible are diagnosed, pregnancy termination is suggested to the family. 50 patients were administered misoprostol only (Group 1), 30 patients were administered single dose of misoprostol and then received cervical Foley catheter (Group 2), and 32 patients received Foley catheter only (Group 3). Even though medical approaches might seem more efficient in

the procedure of pregnancy termination, mechanical methods are more consistent in relations to reliability. Specifically mutual methods can be implemented to intensify the efficiency and to decrease complications [2].

In a patent named “Cervical Canal Dilator” the dilator assembly includes a plastic shaft, a first inflatable member, and a second inflatable member. The shaft can range from being rigid to being highly flexible. The second inflatable member is fabricated of a non-elastic material and is configured to have a maximum inflatable diameter. The second inflatable member is configured to have a predetermined maximum inflatable diameter ranging from 4 to 20 mm. The dilating assembly can also be at least partially covered by a sheath [2].

In a patent named “Fluid-filled Cervical Dilator” a cervical canal dilator comprising an elongate tubular or cylindrical shaft having a distal end and a proximal end; the interior of the shaft being provided with internal cavities that communicate with anchor and dilation balloons in such a manner as to permit the separate inflation thereof; the anchor balloon being positioned on the distal end of the shaft and being capable of anchoring the dilator against the bottom of the cervix when inflated after the dilator is inserted in a cervix and the remaining dilation balloons being positioned between the distal and proximal ends so as to effect optimum dilation of the cervical canal when inflated after the device is inserted and anchored in place by inflation of the anchor balloon [6].

In a patent named “A Cervical Canal Dilation Device”, the device is aimed to controlled release of a liquid/gel to the canal of cervix to cause fixed cervical dilation with minimal discomfort to the patient. The liquid/gel is delivered into the cervix while the inner and outer orifices of the cervical canal are closed by the “dilating balloons”. An inflatable balloon at the tip or near the tip of the cervical canal dilation device anchors the device to the desired position in the cervix canal for the dilation treatment [7, 8].

Objective

The device was designed to proceed with this study. The factors that should be considered in the design process are summarized as follows

- 1) Design and manufacture a device with 4 flaps
- 2) Provide a balloon at the top for anchoring
- 3) Provide a covering on the flaps to eliminate the contact of propagation device with the linings of cervix
- 4) Make the design cost efficient
- 5) Cervical Ripening Device that helps to make the dilation process faster using flexible silicone.

Material

Material selection is very tough process. As the device is going to be used inside the human body, it should not cause damage to the internal organs of the body. The internal lines of cervix are very delicate. We cannot use metal or any other material with sharp edges. So we decided to go for medical grade silicone for both the devices. First we 3D printed the designed model on 3D printer with the help of PLA (Polylactic acid) and then coated it with Liquid Silicone Rubber. PLA thread was standard thread that is always used for 3D printers. Liquid Silicone Rubber was LSR 110 in two parts that is part A and part B.

- SILOCZEST LSR-110 is mainly used for making soft silicone products and its little harder than LSR-105, such as body organs , artificial limbs ,artificial breasts ,body breast enhancers , silicone toys , silicone simulation skin ,etc.
- Its food Grade Two-part silicon rubber: flowable addition cure silicon
- Medium fast curing. Cures at room temperature within 5-8 hours.
- An exceptional fluidity and good operability, easy to demould.
- Good tensile and tear strength, no shrinkage.

Method

The Problem Statement related to project was put forth by the medical guides and solution for the same was needed. Designing of new catheter is supposed to be based on flexible material and should reduce the time of dilation and easy to operate. Research related to existing solutions, drawbacks in them were identified and this was conducted under the guidance of medical and technical mentors. A brainstorming session was conducted where ideas and new inputs were taken. For the catheter 4 ideas were put forth in brainstorming. From these ideas the idea of Flaps Opening with the use of propagation device was finalized by discussing with mentors. Further the CAD modelling started. In first we started with 3 flaps system. After the suggestions of the mentors we shifted to 4 flaps. After the proper modifications and dimensioning the most suitable and most feasible CAD model was prepared. It includes (from the top) a balloon which works just like the Foley Catheter's balloon which will be used as an anchor on the interior part of the cervix. The middle portion is the main dilator part with 4 Flaps. They can open like the petals of the flower. Flaps are followed by the guiding tube which will also be useful at the time of inserting the catheter inside the cervix. Furthermore the propagation device will be passed through the guiding tube into the core of the flaps to push them apart which will put force on the cervix and will start the process of dilation.

Now for Cervical Ripening device the work started with taking the actual dimensions of the device [9]. These dimensions include outer diameter, inner diameter and height of the instrument and dimensions of the slit. Further by discussing with medical guide the size of the groove that we have to incorporate in the instrument was finalized based on the consistency of Dinoprostone gel. The CAD model was prepared based on the actual dimensions. The model was then shown to guides and was modified 6 times. After the 7th model which was to the scale and was feasible, it was 3D printed. Then it was coated with Medical Grade Liquid Silicone.

Result

In development of a new catheter, design is ready and we are searching for prototyping method.

In Cervical Ripening Device, after 6 failed designs we were able to achieve desired specifications in 7th design and after 3D Printing it and coating with silicone to prevent injuries and sterilizing it to test on patients. This device is used along with the Foley Catheter for cervical dilation.

Discussion:

Cervical dilation during 2nd trimester abortion is achieved by mechanical means and medical drugs. Mechanical means include catheters and osmotic dilators. Medical means include use of various drugs and medicines. Based on research done until now mechanical dilation is more suitable and an effective way for cervical dilation during 2nd trimester. There are various reasons for cervical dilation process. Tuncay Y et al discussed that although medical methods may seem to be more effective in the process of termination, mechanical methods seem more reliable in terms of reliability. Especially combined methods can be used to increase effectiveness and also to reduce complications.

However Gözde Demirezen et.al. states that during the termination of second trimester pregnancies time from induction of labor to delivery is shorter with the Foley catheter compared to double balloon catheter.

Hackett GA et.al. states (1) Foley catheter and a 3 mg dinoprostone pessary (Prostin E2) were compared as methods for cervical preparation before second trimester dilatation and evacuation. The catheter was well tolerated and provided significantly greater change in cervical dilatation and improved cervical compliance. The Foley catheter would seem to provide a readily available and efficacious means of cervical preparation. Deshmukh et. al. reported on use of Pg-e 2 Gel for cervical ripening in labour induction[10]. Similarly related articles were reported by Sharma and Tiwari [11], Singh et. al. [12], Acharya et. al. [13], Agrawal et. al. [14]. Evidences of needs were reported in different studies [15-20].

The mechanically induced dilation is more suitable, helpful, fast and preferred over medical methods. Other type of dilation methods like Osmotic dilation are time consuming and more painful. By using foley catheter along with other instruments is a successful practice.

Conclusion

For second domain the catheter itself is equipped with anchoring mechanism, dilation mechanism and guiding mechanism while propagating inside the uterus. It will be a multiuse device and no need to buy new device for every dilation process.

For first domain we can reduce the time required for dilation with medicines filed in grove and chances of injury are reduced when we replace the stainless steel component.

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