Three-dimensional printing vaginal pessary to treat pelvic organ prolapse: A pilot study

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Abstract

Objective Pelvic organ prolapse (POP) is a common gynecological condition and pessaries are offered as a first line management, however, each woman presents with unique anatomy and thus the effectiveness of commercially available pessaries may be limited by lack of customization. This study aims to apply three-dimensional (3D) printing technology in seeking resolution. Design, setting, population and methods This was a pilot study, 6 patients with mean age 68 years (57 to 74) were treated with Gellhorn pessary for symptomatic POP were enrolled in our study. We put the Gellhorn-type pessary into the vagina to restore the prolapsed parts and under transvaginal ultrasound (US) guided to evaluate the gap which Gellhorn pessary can't cover. Ototoform (an impression silicone) was used to make a sphere-shape mode and have it hooked onto Gellhorn pessary (template). We collected template and then applied 3D printing to customize silicone vaginal pessary. Results All 6 patients were satisfied with the customized made pessaries. No patients complained of adverse effects, such as discomfort, expulsion of the pessary, urinary incontinence, difficulty in urination or bowel movement, and vaginal bleeding during the study. Conclusions Our study demonstrates that a tailor made pessary may offer better solution for women with POP. A customized pessary can be made with the help of transvaginal US and 3D printing technology. Any local clinic can use simple tools (i.e. transvaginal US and pessary) with assistance from a 3D printing center to create a well fit pessary. With our innovation, distant is not a boundary.

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ABSTRACT

Objective Pelvic organ prolapse (POP) is a common gynecological condition and pessaries are offered as a first line management, however, each woman presents with unique anatomy and thus the effectiveness of commercially available pessaries may be limited by lack of customization. This study aims to apply three-dimensional (3D) printing technology in seeking resolution.

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Results All 6 patients were satisfied with the customized made pessaries. No patients complained of adverse effects, such as discomfort, expulsion of the pessary, urinary incontinence, difficulty in urination or bowel movement, and vaginal bleeding during the study.

Conclusions Our study demonstrates that a tailor made pessary may offer better solution for women with POP. A customized pessary can be made with the help of transvaginal US and 3D printing technology. Any local clinic can use simple tools (i.e. transvaginal US and pessary) with assistance from a 3D printing center to create a well fit pessary. With our innovation, distant is not a boundary.

Keywords Pelvic organ prolapse, pessary, customized pessary, Gellhorn pessary, transvaginal US (ultrasound), 3D (three-dimensional) printing, 3D scanner.

Introduction

Pelvic organ prolapse (POP) is a common gynecological condition among aged, postmenopausal, and parous women. It has been estimated that up to 50% of parous women experience some degree of POP [1]. Women with POP may have symptoms including vaginal bulging, heaviness, and voiding/defecatory/sexual

dysfunction that adversely affect their quality of life. In addition, women with POP are relative old, usually live alone and feel embarrassed to talk to someone else about their bothering.

Pessaries, having been used for thousands of years [2] are offered as a first line management of POP to all women and as the only option for women who are poor surgical candidates. Pessaries are categorized as either supporting or space filling devices. Support pessaries, such as the ring, are generally easier to remove, cause less risk of erosions, and require fewer office visits. Space-filling pessaries, such as the Gellhorn, are reserved for advanced prolapse [3]. A high rate of discontinuation was observed within 1 year with 56% of ring pessary users experiencing complications, including bleeding, extrusion, severe vaginal discharge, pain, and constipation [4]. However, our data indicated that self-management Gellhorn pessary was safe and relatively effective and that it increased patients' autonomy and ability to manage their POP [5].

Pessaries products on the market have specific sizes to choose from and some women may not be able to find the right size. Each patient presents with unique anatomy and thus the effectiveness of commercially

available pessaries may be limited by lack of customization. Recently, as a novel technology, 3D (three-dimensional) printing has been widely adopted in various fields of medicine [6]. However, the technology has only just begun to branch into the fields of gynecology and obstetrics [7 -12]. Stitely et al. conducted a proof-of-concept study using 3D printing to fabricate a tubing connector for dilation and evacuation in a surgical procedure [7]. Sandrini et al. reported their experience in 3D printing of fetal models of congenital heart disease derived from micro-focus computed tomography [8]. Baek et al. used a 3D printer to create anatomical replicas of real lesions and tested its application in cervical cancer then used to plan and simulate the surgery [9]. Mackey et al. used 3D printed uterine model for surgical planning of a cesarean delivery complicated by multiple myomas and actually showed the model accurately represented the number, size, and locations of uterine myomas, therefore improved surgical planning and optimize outcomes for patient [10]. Garcia de Paredes et al. also reported two cases that highlight the utility of a 3D printing technique to aid in ex utero intrapartum treatment procedures during cesarean delivery [11]. Nevertheless, only one article addressed the importance of a customized pessary [12]. Barsky et al. reported the successful insertion of a customized 3D-printed pessary in a patient. They though this idea is feasible and may extend to patients with anatomy incompatible with commercially available pessaries. We think this issue has not been assessed robustly.

The aim of this prospective study was to evaluate 3D printing technology in helping this minority group of women who need more concern.

Materials and Methods

This was a pilot study performed at a tertiary referral center and conducted after obtaining the Institutional Review Board approval (TYGH109052). All researchers involved in the study agreed to treat the data confidentially in accordance with the General Data Protection Regulation

Study design

Six patients with mean age 68 years (57 to 74) were treated with Gellhorn pessary (Panpac Medical Products, Corp., New Taipei City, Taiwan) as a first-line treatment for symptomatic POP were enrolled in our study. They had been used Gellhorn pessary before entering our study and our study period was from January 2021 to June 2021. They were eligible patients attending the urogynecology clinic during the study period; they all had POPQ stage [?] II symptomatic anterior, apical, and/or posterior

prolapse according to the POP Quantification System (POP-Q)/International Continence Society (ICS) [13] and opted to use a pessary for treatment.

Pessary fitting trial

Each patient will receive the Gellhorn-type pessary fitting trial before entering our study. A pessary fitting trial was conducted at our urogynecology department within the female pelvic health center, where a trained physiotherapist (Chiang CC) helped in fitting each patient with the tailor-made pessaries. The customized pessary was inserted into each patient's vagina. The pessary should be retained during physical activities such as standing, coughing, and straining, and the patient should experience no discomfort/expulsion/difficulty in urination or defecation. Pessary fitting was considered unsuccessful if the physiotherapist failed to obtain an adequate fit after at least 3 attempts, when the pessary caused pain, or if the patient did not plan to use the pessary after fitting. An in-home pessary trial then followed for 1 week. In addition, a patient's family members or home-care assistants, if available, were taught to assist. Patients were taught how to clean and maintain the pessary on their own every day. The pessary was removed and cleaned when the patient bathed and was reinserted and maintained as needed.

Template create

We put the Gellhorn-type pessary into the vagina to restore the prolapsed parts and using transvaginal ultrasound (US) to evaluate the gap (Fig. 1) which Gellhorn pessary can't cover [14]. We then use Ototoform [15] to make a sphere-shape mode and have it hooked onto Gellhorn pessary (Fig. 2), thus the template is

complete. Each patient might use different size of Gellhorn pessary because of unique anatomy. Otoform is an impression silicone for molding interdigital wedges, separators, dorsal toe protectors and orthodigital splints and is putty-like silicone used with splints, burn garments or gloves to aid in scar remodeling and healing. Based on its' clinical utility, safety and available in clinics that's why we choice Otoform for mapping the image gap captured in transvaginal US.

Customized pessary management

The Gellhorn pessary (Panpac Medical Products, Corp., New Taipei City, Taiwan) was offered to patients who presented with symptomatic POP. Based on our prior studies, the results showed a high long-term success rate for advanced POP [5,16], with merits including easy to use, a concave design to provide suction, a wide pessary base that adequately supports proximal prolapse, and significant improvements in quality of life [5].

All postmenopausal women were offered local intravaginal estrogen application prior to and after pessary treatment unless it was contraindicated or if the patient refused this treatment. Outpatient follow-up evaluations were scheduled at 1, 3, and 6 months. Evaluations included pelvic examination and patients were asked about adverse effects, such as discomfort, expulsion of the pessary, urinary incontinence, difficulty in urination or bowel movements, and vaginal bleeding. The pessary was then removed and cleaned, and the vagina was examined for erosions. If the pessary fit well and no adverse effects were noted, the pessary was reinserted, and the next follow-up was scheduled.

3D printing process

We collected the template and then applied 3D printing to customize silicone vaginal pessary. With regard to the 3D printing process, we use a non-contact active 3D scanner (both turnable table and handhold type) to capture the object, followed by texture mapping and 3D-matching.

Handhold Laser (EinScan Pro+ supplied by Shinning3D) (Fig. 3) [17] creates a 3D image and is done by using a handheld device that projects a point of laser on or transmits linear laser to the object of detection. The distance from the surface of the object of detection to the handhold laser is measured with two or more detectors, i.e., optical coupler or location sensing element. Usually, a specific reference point is required. Such a point is usually an adhesive and reflective sticker for positioning and calibration of the scanner in space. The data obtained from this scanner will be imported to a computer and converted to a 3D model by software.

Results

All six patients completed the study. We briefly presented manufacture process then will be detail discussed in the discussion section later. The whole process included template captured, Otoform mapping, 3D printing, customize vaginal pessary fitting trial and patient reported outcome.

Template captured

For each patient we put Gellhorn pessary into her vagina to restore the prolapsed parts and using transvaginal US to evaluate the gap (Fig. 1) which Gellhorn pessary can't cover. Each patient might use different size of Gellhorn pessary because of unique anatomy.

Otoform mapping

We then use Ototoform to make a sphere-shape mode and have it hooked onto Gellhorn pessary (Fig. 2), thus the template is complete.

3D printing

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Customize vaginal pessary fitting trial

Once the customized vaginal pessary was born then a pessary fitting trial was conducted at our urogynecology department within the female pelvic health center, where a trained physiotherapist (Chiang CC) helped in fitting each patient with the tailor-made pessaries

Patient reported outcome

All 6 patients were satisfied with the customized made pessaries. No patient complained of adverse effects, such as discomfort, expulsion of the pessary, urinary incontinence, difficulty in urination or bowel movements, and vaginal bleeding during the study.

Discussion

Main findings

Our study indicates the idea that a customized made pessary offer better solution for women with POP if commercial pessary failed. A customized pessary can be made through the application of transvaginal US and 3D printing technology. In any local clinic, even in remote areas, provided that simple tools (i.e. transvaginal US and pessary) plus the help of 3D printing center, a customized made pessary can be made to improve patient satisfaction.

Strengths and limitations

The major strength of our study is the development of a practical way to answer their need among women with POP when conventional pessary fails. Our method can be applied to any patient already using an existing pessary on the market. Because conventional pessaries have only a limited number of fixed sizes, it is difficult to meet the needs of all patients. The only existent article [8] reported they performed the pelvic examination as the main guide to create the customized pessary. We know it's difficult to choose the suitable template if we only perform the pelvic examination for the patient. We know that such a method cannot be scientifically verified. Therefore, in our research, we find the best way to get to the anatomic position and come up with a proper size to create customized pessary. Only through the position of the Gellhorn pessary inside vagina, we can know the exact site of customized pessary should be located for this woman. By observing the position of the Gellhorn pessary in the vagina by US, we can determine the most suitable, neutral position for the patient. Then we observe the place that are not covered enough by Gellhorn pessary, which can be further provided as reference for subsequent 3D printing processing.

The second and equally important strength of this investigation is that we did not use any expensive instruments or special technologies, but instead started with US, a common tool every obstetrician-gynecologist is all familiar with. Almost all the clinics have US machines. As long as the US image is displayed on the US screen after the pessary is inserted into the vagina, we can take a picture as template for the subsequent 3D production center to manufacture. Combining the vaginal US and commercial available pessary, we are able to demonstrate a scientific, reproducible way to create each customized pessary. As the world is emerging from the worst situation of the COVID-19 pandemic, our study shows critical value there are no limits and boundaries for our discovery. When considering the cost of a customized made pessary it is almost the same price as a commercial available pessary.

The limitations of this study were that they were a relatively small number of patients and that we had to use Otoform to aid for the template production in order to send the parameters needed in the 3D printing process.

Interpretation

Actually, before we begin this pilot study, how to create the template employed to later 3D printing use was the most challenging issue. In our first approach we applied Otoform directly to the prolapsed part. The problems with using Otoform are: 1). The shaping timing must be very exact. Whether the time is too short or too long, shaping cannot be completed. 2). Since the tissue of the prolapsed part is soft, it is difficult to

adhere. 3). Even though it did attach to it, the thickness of the attachment part was difficult to control. In the second approach we use 3D scanner (Handhold Laser) [Fig. 3] to scan the prolapsed portion directly. The disadvantages of external scanning are: 1). It is difficult to estimate or grasp the precise condition of the prolapsed part. 2). The width of the vagina cannot be accurately evaluated. Finally, the last one we put Gellhorn-type pessary into the vagina and use transvaginal US to evaluate the possible gap which Gellhorn pessary can't cover. We then use Ototoform to make a sphere-shape and hook to Gellhorn pessary which later proved to be more reliable and practical. In addition, we think going through pessary fitting trials ahead and having a skillfully trained physiotherapist on hand are essential to the success of our study.

Currently 3D printing technology has a broad range of applications within the medical field including medical equipment manufacturing, diagnosis and surgical planning, simulated surgery, medical education, tissue engineering and lastly, the potential of individualized medical usage. Barsky et al. [12] reported the successful insertion of a customized 3D printed pessary in a patient with stress urinary incontinence in 2018 and actually it is the only one article appearing in literature so far. They thought this way was feasible and their utility may extend to the patient with anatomical parts incompatible with commercially available pessaries. They chose the template based on physical examination and fit the previously unfit pessaries and used a fused deposition modeling printer to create the mold. In addition, the grade silicone elastomer was chosen for pessary fabrication.

Our original idea was to find a more reliable and easy way to create the template which a general obstetrician-gynecologist can make. US offers a better understanding of disease entity and due to its ease use, noninvasiveness, and absence of radiation exposure, it is currently the most convenient imaging method available [14]. Transvaginal US is a basic skill all obstetricians-gynecologists have acquired throughout their residency training. A device can be applied to restore the prolapsed part of the patient and have to be easy available. So combining the use of transvaginal US and placement of Gellhorn pessary inside vagina composed of our original concept. We also apply 3D US to see if there is any substantial benefit for the making of customized pessary and abandon this approach due to cost and unavailability at a local clinic. We do know the benefit of perineal (translabial) or introital US approaches can prevent distortion of the anatomy of the lower urinary tract [14], however, not available at a local clinic also a problem.

3D printing for customized made pessary

We would like to explain the way we applied 3D printing for customized made pessary. Our team had applied 3D printing in clinical application by using handhold laser on the patients with fracture and achieved a very good result [18]. In our study we employed the previously-built automated model creation system [18] to create the appearance model from the template we got. Then we made a customized design and produced a physical object with 3D printing. An industrial handhold laser EinScan Pro+ supplied by Shinning3D was used for the operation of the process. This scanner has an accuracy of 0.1 mm and weighs only 0.8 kg, very suitable for the scanning of the parts of the body. The scan rate is 550,000 in./sec; scan distance is 300×170 mm and files can be exported to the different formats (OBJ, STL, ASC, and PLY). Since the output accuracy is higher, the requirements for the equipment are also higher. The requirements for the graphics card are NVIDIA (NVIDIA CORPORATE, 2788 San Tomas Expressway, Santa Clara, CA 95051) GTX660 or above, with a CPU of i5 and a RAM of 8 G.

The four main processes incorporated in this study are described as below:

1. A fast and accurate customized scanning process

Due to the complexity of the human body structure, it is not possible to use fixed scanning equipment to scan a localized part of the body. A handheld scanner therefore must be used to obtain accurate digital information. Consequently, this study utilized an industrial and advanced handhold scanner EinScan Pro+ to perform scanning of the template. The template to be scanned should remain in a fixed gesture in scanning, which takes 1-2 minutes to complete. As the equipment used is the one for industrial scanning with a high level of accuracy, the 3D model obtained is also complete with a high level of fineness. The automated model creation system we used can simplify and speed up the editing on the mesh model obtained from scanning.

2. Digital model with simplified "parameter-based" editing

The digital model captured by 3D scanning is a point cloud information with a huge file size. Such information is then converted to a triangular 3D mesh model [19]. Mesh model is difficult or even impossible to be edited by 3D software. However, designing an assistive device that can fit the body better requires the conversion of meshes to editable non uniform rational b-spline (NURBS) model in model operation [20] [Fig 4]. It is intended to use the Grasshopper program, a parameter-based tool, for editing a tedious model conversion process. Simply importing the file from scanning can create an editable 3D model file right away and adjustable parameters that allow the user to make adjustments based on design requirements.

3. Appearance design model of "parameter texture"

Based on the NURBS model from conversion which allows the design of assistive device's appearance directly in Grasshopper parameter tool [21], our study creates a simple operation mode to allow a designer to create a customized digital 3D model of a pessary according to the patient's status and the doctor's clinical judgments and recommendations. The model created by this process can be used to make a physical model using 3D printing.

4. "Customized production" of a model using 3D printing

What makes the production process using 3D printing differs from mass-production by a factory is its ability to customize production in a smaller volume. Our study designs a fast printing disassembly method according to individual requirements of a pessary. In addition, various 3D printing techniques are also used to put out elements for study of material strength. This study was based on resin material made with the stereolithography (SLA) printing technique. Since a pessary must be placed within a vagina, this study utilizes for 3D printing, FABRIAL-R [22] as the 3D printing filament material developed by JSR of Japan [23] that is suitable for application on human skin and has been tested for irritation and skin sensitization in accordance with ISO 10993-10 standards. To make the material suitable for fused filament fabrication 3D printing, improvements have been made, including making it odorless during printing and reducing the deformation of printed items resulting from thermal shrinkage. This medical-grade silicone has a 35-durometer (a unitless measurement of polymer hardness; shore scleroscope hardness) and a tensile strength of 850 psi when cured, thus giving the pessary adequate mechanical strength. It is also intended to test the accuracy of the scanned sizes. Figure 5 shows a polylactic acid (PLA) model for 3D printing, obtained from scanning a customized pessary with a turntable table 3D scanner.

Future directions

We will continue our efforts and improvement will be made in the following ways: 1. Any type of pessary will do as long as it pushes the prolapsed part back. 2. Or not necessarily a pessary required if anything can push the prolapsed part back only if the US can distinguish and capture the template we need. By doing so we can send the message back to the 3D printing center thus anywhere in the world can do this without limitation.

Conclusion

The quality of life of patients with pelvic prolapse is very poor. Pessaries are the only option other than surgery. There are still a small number of patients who cannot use commercially available pessaries. So producing customized pessaries is extremely important to them. We've come up with a way to use US with a 3D processing to meet the needs of these patients. Hopefully our ideas will stimulate more obstetricians and gynecologists to make this goal a reality by providing better care and improving the quality of life for women with POP.

Authors' contribution

Lin Y.H. and Lim C.K. contributed equally to this work. Lin Y.H. and Lim C.K. wrote the paper; Chang S.D. and Tseng L.H. developed analytical tools and analyzed data; Huang C.H. and Chiang C.C. validated the results; Tseng L.H. supervised the project.

Details of ethics approval

The study was approved by the Human Research Ethics Committee at each participating institution (TY-GH109052)

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