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Proposed Synthetic Tissues that Replace Human Cadavers for Training

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Abstract

In order to develop surgical skills required for cardiac surgeries, such as with surgeries of all types, years of practice and experience is required. Young cardiac surgeons need to improve technical proficiency in order to enrich the quality of care provided and to ensure patient safety. Realistic synthetic platforms and models are common resources for teaching and enhancing practical skills for both inexperienced as well as senior medical students, however are found particularly useful for young surgeons in training. Appropriate and available educational platforms can play an increasingly vital role in the training progression for young trainees in the area of cardiothoracic surgery. For example, the Coronary Artery Bypass Graft (CABG) surgery encompasses an extensive range of pathologic anatomies and surgical performances. In this chapter, we present original, synthetic, biomimetic models that allows for the accurate practice of surgeries such as the CABG surgery and aortic valve implantation. The prototype uses a polyvinyl alcohol (PVA) cryogel specifically designed to mimic the geometric properties of vasculature and the tissue of heart valve leaflets. The proposed models both visually resemble and feel like human tissue in addition to possessing relatively consistent mechanical properties. The technology and platform proposed have the potential for application in all cardiovascular-related reconstructive surgeries.

Keywords: hydrogel biomaterials, surgical tools, cardiac training, aortic valves, reconstructive surgery, bypass surgery, CABG

1. Introduction

The number of incidents of severe aortic stenosis in adults is remarkably high [1]. However, suitable timing of aortic valve replacement has the potential to avoid both early and late fatal events as well as result in improved functional status of the valve. Early diagnosis and
treatment will lead to increased preservation of regular ventricular function in addition to the possibility of regaining regular ventricular function from previously irregularly functioning valves. As the basis for the decision to proceed with surgical interventions is how the regular function and structure of the left ventricle, aortic valve and ascending aorta can be affected by appropriately timed and performed valve replacements, it is crucial to understand the implications of these factors.

Aortic stenosis is typically a progressive disease and with increasing stenosis severity there is an increased resistance during left ventricular outflow. In order for the left ventricle to compensate this high resistance while still maintaining normal systemic pressure and cardiac output, a higher left ventricular pressure is generated. This elevated pressure is achieved by concentric ventricular hypertrophy, an increase of mass and thickness in the wall of the left ventricle. Although this might be an effective temporary solution, the left ventricle will eventually exceed the limit of concentric hypertrophy and begin to dilate in order to maintain left ventricular pump function. This dilation leads to a change in the shape of the left ventricle which may induce significant and negative affects to the valves function. Factors such as ejection fraction and fiber shortening suggest that velocity may eventually be reduced, leading to congestive heart failure.

Both phases, that is, cardiac hypertrophy and ventricular wall dilation, could have possible effects on both the hemodynamic and metabolic alternations. As the ventricular wall experiences progressive dilation and increased hypertrophy, the end-diastolic and pulmonary venous pressure increase may lead to an increase in shortness of breath. In addition, as the myocardial wall tension increases due to hypertrophy, more oxygen is required and because the supply of oxygen remains unchanged, myocardial ischemia and the symptom of angina pectoris may occur. Further, the alteration in ventricular shape and dynamics caused from excessive dilation of the left ventricle may create a vicious cycle, inducing chronic congestive heart failure.

Aortic valve replacement will provide a significant reduction of these symptoms and enhanced function for patients with ventricular dysfunction. Even in cases of congestive heart failure and noticeable ineffectiveness of ventricular function, aortic valve replacement may lead to improvement in symptoms and ventricular function, resulting in the reversibility of ventricular dysfunction and improved survival. Hemodynamic assessment of the valve stenosis involves the determination of the valvular gradient and an estimation of both the aortic valve area and the aortic valve area index. If the ejection fraction and cardiac output are normal, severe aortic stenosis is detected by a pressure gradient across the valve with a value equal to or greater than 50 mmHg or by an aortic valve area index that is less than 0.75 cm$^2$/m$^2$ [1]. If the cardiac output is lower than normal, opposed to the pressure gradient the valve area index must be considered as the pressure gradient across the valve can be minimal for decreased cardiac outflow. Aortic valve replacement is recommended even in the presence of a left ventricular ejection fraction that is less than 25% as well as for symptomatic patients with moderate aortic stenosis in which the aortic valve area is in the range of 0.7–1.2 cm$^2$ [1].

An artificial platform which can be used to simulate aortic heart valve replacement or coronary artery bypass surgery does not exist. Current possible options are based on synthetic models that lack adequate realism or animal models which are not available for repetitive practice. It should also be noted that there are multiple limitations in using animal models which do not occur with our proposed synthetic models.
In this study we design and develop synthetic models of ascending aorta which have similar mechanical properties and geometry to those of porcine tissue. The aortic valve, root and other sections, which are made all in one piece, bear physical resemblance to their counterparts of the porcine ascending aorta tissue. In addition to appearing similar to porcine tissue, our proposed models also feel like the tissue so that when sutures are performed it resembles a realistic platform as is experienced in an actual surgical operation. Additionally, we propose synthetic phantoms of coronary artery vascular grafts with objectively analogous geometrical properties. These phantoms also have reliable mechanical properties to that of the native tissue. The proposed platform is an outstanding tool which may be utilized for the simulation of anastomosis as implemented in coronary artery bypass surgery.

2. Method

2.1. Part A: aortic valve replacement surgery

In this study, the human ascending aorta made of cryogel-based biomaterials is proposed. To develop the geometry of the root, an innovative surfacing method related to the de Casteljau technique which is used for developing Bezier surfaces is implemented. The 3D geometry of this model is developed using 2D images attained from the axial dissection of a young adult porcine aortic root. The biomaterial implemented for the aortic valve is a blood-compatible cryogel made of polyvinyl alcohol (PVA-c) which is strengthened by bacterial cellulose (BC) natural nanofibers in a mixture of 15% PVA-c and 0.5% BC by weight fraction and the biomaterial implemented for the root is 10% PVA-c. The tensile properties of the fabricated PVA-BC were measured and are similar to those of the porcine aortic valve leaflet tissue in the two radial and circumferential directions. We also attained a near match of the stress-strain curves for the aorta in the circumferential and axial directions by applying 10% PVA-c with 75% initial strain after cycle 3 [2]. A cavity mold was designed and manufactured and the proposed polymeric valve was then fabricated. An extensive finite element analysis was performed in order to optimize the final product (please see the appendix). The proposed model may be further used for animal trials.

2.1.1. Preparation of the hydrogel biomaterial

Hydrolyzed PVA, 99+% (Sigma-Aldrich) with a molecular weight of 146,000–186,000 is used as the main ingredient for the solution preparation. A suspension of 0.877 wt% BC in distilled water is then added to the PVA solution. The BC solution is produced in shake flasks by a fermentation process using the *Acetobacter xylinum* bacterium. The BC suspension was prepared and added to the PVA solution. The new solution contains 15% PVA and 0.5% BC by weight fraction while the rest is distilled water as shown in Figure 1 [3].

The final solution was dispensed into three metallic molds and placed in a heated/refrigerated circulator (15L Heating Bath Circulator Model SD15H170-A11B). The molds were cycled once between 20 and −20°C at 0.1°C/min for the solution to solidify and gain a deterministic shape (cycle 1). In order to impose anisotropy to the samples, a 75% strain was applied to all three
samples while they were placed back into the mold to reach the maximum anisotropy [3, 4]. The direction of stretch was selected to be in the direction with the higher stiffness, however one of the samples was kept non-stretched as a control. The molds were cycled using the freeze-thaw procedure for six cycles where one of the molds was removed at the end of each cycle. The above procedure and PVA-BC were applied for the preparation of the hydrogel implementation in the leaflet structure and a similar procedure was applied for the aortic wall, however as less stiffness is required for the aortic wall, BC fibers were not used and only 10% PVA was implemented.

2.1.2. Tensile testing

The results of the experimental tensile tests are reported in the form of load versus extension. These values are converted into stress-strain values by using the dimensions of the samples and the initial gauge length after preconditioning. Given that the samples undergo large deformation, the stress-strain curves obtained for all samples are nonlinear and hyperelastic. To fit the data obtained, an appropriate constitutive model is applied such that [2],

$$\sigma = y_0 + A \exp (B \varepsilon),$$

where $\sigma$ is true stress, $\varepsilon$ is true strain and $y_0$, $A$, and $B$ are constants.

The tensile properties are measured by a servohydraulic testing machine (INSTRON 8872) with a precise load cell that has a maximum capacity of 1 kg. In order to remain consistent with the realistic bio-environment of the samples, all measurements are carried out inside a container filled with distilled water at body temperature. The strain rate for the performed tensile tests is set to 40 mm/s with a maximum of 60% strain. The preconditioning test was achieved for all samples in 10 cycles with an amplitude of 5 cm and a frequency of 2 cycles/s [5, 6]. The mechanical properties obtained for the aortic valve and the ascending aorta are shown in Figure 2a–d. A close match in mechanical properties for the applied PVA-c samples and the porcine aorta was obtained. Figure 2e shows the stress-strain curves of the aorta in both principal directions and the anisotropic PVA-c sample after cycle 3 at 75% initial strain.

2.1.3. The design and fabrication of the ascending aorta

For the design of the geometry of both the ascending aorta and the aortic valve, an advanced and novel surfacing technique based on the de Casteljau method is applied on the Bezier-based
The 3D geometry was developed by stacking 2D images obtained by the axial dissection of an adult human aortic root and aortic valve. It should be mentioned that the valve used for this purpose was a Mitroflow bioprosthetic valve. The 2D images are digitized surfaces. The 3D geometry was developed by stacking 2D images obtained by the axial dissection of an adult human aortic root and aortic valve. It should be mentioned that the valve used for this purpose was a Mitroflow bioprosthetic valve. The 2D images are digitized
and converted into a finite number of control points. This is determined by mapping the 2D geometry of each section using a coordinate measuring machine (CMM) with a laser scanning system such as 3D Digital Corp, 3D scanner cyberware.

The control points are then applied to construct the corresponding Bezier curves to complete the digitization of the 2D images which are used as the bases for the production of the final Bezier surfaces. The main advantage of this technique is that the final surface obtained is easily and quickly tunable. In order to increase the surface quality and apply any desired changes, Bezier curves are accustomed through a trial and error procedure by removing, relocating or interpolating the initial control points. The final surfaces are then brought to a CAD software environment by using a command as known as shell, for example, command Shell of I-Deas. As we are developing 3D and physical models, the thicknesses of the valve leaflets and ascending aortic wall and their respective variation is of particular importance. For this purpose, two surfaces are independently designed to form the top surfaces of both the male and female parts of the mold for each model. Even though the produced shells of the Bezier surfaces possess uniform thicknesses individually, the final products are 3D and have proper variable thicknesses as intended [6–8].

The thickness of the model is developed by the gap in the final design of the mold which is created due to the distance between these two surfaces. We used Mechanical Desktop V2013i CAD software for the perfection of the models throughout testing. As mentioned earlier, the geometry of the proposed aortic valve is inspired by a design modification on the Mitroflow bioprosthetic valve.

A major advantage of this new design is that the variable thickness of the leaflets is considered (0.7 mm on the free edge and 1.2 mm on the attachment with the stent) which is defined by applying a comprehensive finite element structural analysis and using the related optimized computational methods for further enhancement. The final model of the proposed valve consists of three identical cusps for which the leaflets are symmetrical about their own midlines. The fabricated model and the final prototype for the proposed aortic valve prosthesis composed of PBS thermoplastic material are shown in Figure 3. The valve is then added to the ascending aortic wall model to develop a complete synthetic model (made of PBS thermoplastic material) including the sinuses, two outlets for the right and left coronary arteries and the valve in only one component. The final model of the ascending aorta is shown in Figure 4.

2.1.4. Final models made of the proposed hydrogel

The developed material which possesses similar mechanical properties to those of the ascending aortic wall and the porcine heart valve leaflet tissue is implemented in the final models. The designed and fabricated molds were filled with the proposed hydrogels (PVA-BC for the valve leaflet and PVA only for the aortic wall) and the final models were manufactured. These models are similar in geometry and mechanical properties to that of the native tissues and can be an excellent tool for the simulation of aortic heart valve surgery (Figure 5).

The anatomy of the aortic valve is shown in Figures 6 and 7. Figure 6 shows the valve from above, with the orientation as is usually seen throughout a standard transverse aortotomy [9].
2.1.5. Surgical procedure

A transverse aortotomy is made which is normally placed approximately 15 mm above the level of the right coronary artery. This specific placement is to reduce the possibility of jeopardizing the

Figure 3. (a) The mitroflow bioprosthetic valve of which the design of the proposed valve is inspired, (b) the final CAD model of the proposed valve, (c) the designed and fabricated mold and its parts for the new design of the PVA-BC polymeric trileaflet valve. A: casing, B: caps ×2, C: main female part, D: main male part, E: the assembled mold, (d) and (e) are the first prototypes of the valve made of PBC thermoplastic material.
Figure 4. (a) The 3D CAD model of the ascending aorta, (b) the fabricated mold and its part of the proposed final CAD model, (c) the prototype of the ascending aorta made of PBC thermoplastic material including the left and right coronary arteries, the sinuses and the aortic valve in a singular component.
right coronary artery (caused by low incision placement) which can lead to technical complications in valve seating and aortotomy closure. Avoiding higher incision placement has decreased importance as the aortotomy can easily be angled downward and the anterior lip caused by a high incision can be quickly pulled back. The aortotomy is suggested to be extended to about 10 mm above the commissure between the left and right coronary leaflets and to a similar distance above the commissure between the left and the noncoronary leaflets [9].

Figure 5. (a) The final aortic valve made of PVA-BC and (b) the final aortic root including the valve and sinuses with similar mechanical properties and geometry to that of the native tissue.
After retractor s are located, the valve can be seen, and the approach for excision is identified. The calcified tissues are completely excised, ensuring to not injure the bundle of His or the aortic wall. In many severely calcified valves, leaflets are free of calcification at the site of attachment prior to the annulus so the incision line can be positioned exactly on the calcium-free ribbon near the annulus. If a calcium-free ribbon near the annulus does not exist, the excision can be made on a hypothetical ribbon relatively close to the annulus. This is to prevent inadvertent excision of a portion of the annulus as such severe calcification may cause damage to the annulus and part of it may be inadvertently removed. A polymer aortic valve prosthesis is designed and fabricated slightly smaller (normally 1–2 mm smaller) in diameter than the diameter of the patient’s annulus. The sinuses are removed in a way that only a rim of aortic

Figure 6. The anatomy of the human aortic valve including the right, left and noncoronary cusps (leaflets) as well as the main branches of left and right coronary arteries—top view. The top image is a typical diagram of the ascending aorta and the lower image is the synthetic ascending aorta proposed in this study which is one piece of the aortic root including the valve and coronary outlets.
Three sutures are placed through the prosthesis and the patient’s annulus (Figure 8A1, 2 and B1, 2) and the prosthesis is then lowered into the patient’s annulus and inverted into the left ventricle (Figure 8B3). The sutures should then be run...
toward each commissure and firmly tied ensuring the suture line is kept slightly below the patient’s annulus. In the case of bioprosthesis, special care must be taken to avoid the conduction tissue under the commissure between the right coronary and the noncoronary cusps, however this is not required for the polymeric valve. Following this, the valve is then everted and sutures are initiated at the low points of the sinuses and are brought up to the commissures (Figure 8A3, 4 and B4–B6) [9].

2.1.6. Congenital aortic stenosis

The left and right cusps are fused together at the commissure which is considered as a relative underdevelopment of the right coronary leaflet (cusp) and the orifice is typically a cut between the left- and noncoronary cusps. The commissure between these two cusps is typically well-developed, however the other commissure may be dissimilar in degree of development and
may merely be a primitive raphe. A simple incision is typically made in one (or two) commissure(s) of the right coronary leaflets (cusps). Incision of the other commissure may depend on its degree of development as well as the extension and depth of the right coronary leaflet (cusp).

2.1.7. Surgical procedure

In the first step, a transverse aortotomy is prepared and the valve is uncovered with small cusp retractors. Forceps are used to hold the leaflets and an incision is made on the well-developed commissure all the way to the annulus (Figure 9A1 and A2). The assessment is carefully made on the depth of support and the degree of development of the right coronary leaflet. Due to the fact that the right coronary leaflet develops a coaptation area with the other leaflets (and not prolapse), the other commissure is carefully incised. In the last step, the subvalvular area is carefully checked to ensure there is no subvalvular stenosis underneath. The procedure on the proposed synthetic model is shown in Figure 9B1–B4.

2.2. Part B: coronary artery bypass surgery

The wall thicknesses of the coronary arteries possess a range from 0.42 to 1.35 mm [10]. The thickness of the saphenous vein wall is approximately 0.79 ± 20 μm [11] and the outer diameter of the lower bound coronary artery is 1.2 mm [12], whereas the diameter of the upper bound harvested saphenous vein is 7 mm with a normal minimum diameter of 3.6 mm and a normal maximum diameter of 4.84 mm within one vessel length [12].

Figure 9. The exposure of the valve and incision of the well-developed commissure all the way back to the annulus (A1, A2)—top view. In the synthetic model, initially all three cusps are fused together. The practice is to make the main incision as discussed in the manuscript. (1) The valve is exposed (B1), (2) the incision line is determined (B2), (3) the incision is made all the way back to the annulus (B3) and (4) the incision is completed (B4).
2.2.1. Cryogel preparation

Polyvinyl alcohol cryogel (PVA-c), 99+% (Sigma-Aldrich) hydrolyzed with a molecular weight of 146,000–186,000 was implemented for the solution preparation which is outlined in more detail in our previous studies [10, 11]. The proposed cryogel material requires a thermal cycling procedure in order to physically crosslink the long molecules. Therefore, the design is limited to molds that can be implemented with the anti-freeze cooling bath which takes place within ethylene glycol solution with a temperature change of −20 to +20°C [12].

2.2.2. Mold design

Ten sizes of arteries, ranging from 1.5 to 7 mm are targeted in order to provide for all of the possible sizes implemented in CABG, which also includes internal mammary artery (IMA), saphenous vein (SVG) and radial artery (RA) grafting. The normal internal diameter for the human saphenous vein is 1.75 mm (without distention) and 2.18 mm (with distention) [5]. The diameter of artery and vein cores chosen for the design are from 1 to 2.5 mm. The length the vessels is simplified to a 10 cm long graft of continuous diameter and a wall thickness with no alterations.

In order to attain the precise dimensions, a flat plate design was implemented. This design consists of two flat symmetrical plates with the dimensions of each artery size fixed into a semicircular channel. When these compartments mate, a cylindrical graft is made (Figure 10a and b).

Another main issue addressed by this design is the capability for the cores to always remain concentric with the mold cavity. Our exclusive solution is to implement tension in the cores through a conical centering system. This feature ensures the cores remain centered regardless of orientation or disturbance imparted on the mold during the fabrication process. The conical mechanism is designed with a 45° taper on each end of the cylinder (Figure 10c).

2.2.3. Mold fabrication

The 3D rendering of the mold was fabricated on SolidWorks R2016 software. Renderings were printed using a Mojo (Proto 3000, Mississauga, Canada) 3D printer with a resolution between layers of 100 μm.

2.2.4. PVA cryogel models

The proposed material has similar mechanical properties to those of the coronary artery tissue. The molds were packed with 10% PVA-c and the final models were fabricated. These models are close in geometry and have similar mechanical properties to that of native tissues and are suitable to model vasculature for the simulation of bypass surgery (Figure 11). The circumferential strength of the proposed models reported here is 0.50 ± 0.12 MPa which is comparable to the native tissue (0.39 ± 0.07 MPa) [13, 14] with less than 5% discrepancy.

Using this procedure, vessels with a mean outer diameter of 1.30 mm and a mean luminal diameter of 600 μm can be produced where the dimension of the vessel thickness is 350 μm. These vessels have a normal vessel length of 60 mm and thus, vessels have efficaciously been
fabricated in small scales. We have the capability of reliably creating vessels with a diameter ranging from 1.5 to 7 mm, Figure 11 and Table 1.

![Figure 10](image1.png)  
**Figure 10.** (a) CAD design, (b) the prototype of the mold for the construction of synthetic grafts. Twelve grafts with variations of sizes are developed in the same batch and (c) tensioning mechanism, the conic fixture holds the cord constantly at the center and the spring behind it is for providing a minimal tension on the cord so it is continuously under stretch [17].

The models of synthetic manufactured grafts made of 10% PVA-c [17].
We utilized a range of prolene (polypropylene) sutures (size: 2.0–6.0). The dull-witted marginal is incised with scissors (Figure 12a). A suture is passed (1) through the arterial wall, (2) through the vein and (3) through the arterial wall and (4) tagged. The other end is (1) brought through the vein and (2) the vein is again lowered into place. (3) The suture line is brought up to the right side. (4) The other suture is brought through the heel of the vein, (5) through the artery, (6) up the left side and around the toe, thus, completing the suture line, Figure 12b. In the end (7) a cannulation is utilized to ensure an excellent connection of the graft to the artery (Figure 12c–e).

### Table 1. Sizes of the proposed synthetic [17].

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<tr>
<th>OD (outer diameter) (mm)</th>
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**Figure 12.** Anastomosis of a graft to coronary artery on a pig heart. (a) Groundwork on the coronary artery and the approximation of the location of anastomosis, (b) the suturing graft to the location of anastomosis, (c), (d) and (e) represent the cannulation test. Blue water is perfused through graft by applying a suitable pressure and the location of anastomosis is tested and observed for leaks [17].
2.2.6. Side-to-side anastomosis

We utilized a range of prolene (polypropylene) suture of the same size. The grafts are organized, Figure 13a. Both grafts A and B are notched longitudinally, Figure 13b. The incision must be accurate as an unsuitable incision may cause narrowing on the graft at the location of anastomosis. The suturing procedure follows the same routine (Figure 13c–f). (1) A suture is guided inside-outside the artery on graft A and (2) labeled. (3) The suture line is brought up inside-outside the vein on graft B and (4) outside-inside the artery on graft A (Figure 13g and h). (5) The suture is brought up outside-inside the vein on graft B and (6) inside-outside the artery on graft A and (7) around the end of arteriotomy to complete the anastomosis (Figure 13i) [15, 16].

There are other methods which can be implemented for the side-to-side or the end-to-end anastomosis as shown in Figure 14a and b are not explained in detail.

In the final step, side-to-side anastomosis of a small-scale graft to the ascending aorta was simulated, Figure 15. The ascending aorta implemented in this study is made of the cryogel biomaterials,

![Figure 13](image-url)
This model contains the sinuses and the aortic valve placed in a singular piece. Then, side-to-side anastomosis of a small graft to the valve conduit was attained using the proposed platform.

3. Conclusion

This chapter summarizes a novel emerging technology by which a complex surgery can be accurately simulated. We proposed a novel model of the ascending aorta made of synthetic material which maintains similar mechanical properties and geometry to that of native tissue by which a complicated heart valve replacement surgery can be simulated step-by-step.

It is known that available surgical simulators lack fidelity or are not adequately lifelike, though in this chapter a high fidelity platform was designed and fabricated. This platform may be
used by young surgical residents or cardiac surgeons to develop expertise on the matter. More platforms will be developed so that other valve and ascending aorta related surgeries such as Yacob, David or Bentall procedures can be precisely simulated in a similar fashion.

Additionally to the best of the authors’ knowledge, for the first time a platform for fabricating artificial cryogel micro-vessels is demonstrated in order to address a lack of availability to coronary artery bypass practice materials. Previously, small cryogel vessels did not exist simply because of their complicated geometries. The vessels presented feature a biomaterial with mechanical properties and geometries which are not statistically different from human vessels and the models have been productively implemented to model a coronary artery bypass surgical procedure. The penetration ability and resistance to rupture the sutures with the diverse range of sizes from 2.0 to 6.0 was verified and deemed acceptable using prolene (polypropylene) suture. The proposed material appears to be well-matched with polyglactin (vicryl) sutures as well [17].

For forthcoming work, the suture penetrating ability and resistance to rupture by associating diverse sutures polyglactin (vicryl) versus prolene 5-0/6-0/7-0) by means of a semi-quantitative scoring method will be modeled. Suture retention by utilizing pull test data compared to the real tissues can be also considered. A short case study showing the appropriateness of the cryogel vessels in a virtual model to educate operators and its outcomes (which is essentially semi-quantitative scoring methods) will be implemented. The accessibility of practice tools for surgeons will contribute to improve their adroitness and self-reliance in cardiothoracic surgery.

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