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A Nine Months Follow-up Study of Hemodynamic Effect on Bioabsorbable Coronary Stent Implantation

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ABSTRACT Coronary artery disease has emerged as one of the major diseases causing death worldwide. Coronary stent has great effect to improve blood flow to the myocardium subtended by that artery, in which bioresorbable vascular scaffolds are new-generation stents used by people. However, Coronary stents implantation has a risk of restenosis, which is relative to hemodynamic parameters. Most of existing literatures studied in this issue have not taken into account such important factors as the strut thickness and lumen profile, and has yet to analyze the time effects among hemodynamic parameters over a certain period of time based on individual models. In this research, we proposed a framework to assess the chronic impact of hemodynamic on coronary stent implantation. In the framework, the optical coherence tomography (OCT) is combined with angiography to reconstruct patient-specific models of bioresorbable vascular scaffolds. Then, the hemodynamics parameters are extracted through the simulated 3D models, obtaining the distribution of wall shear stress (WSS), relative residence time (RRT) and oscillatory shear index (OSI). Finally, the changes of these parameters representing the effectiveness of hemodynamics exerted on the implanted stent can be assessed to estimate the chronic impacts. By a 9-month follow-up case study, it is observed that the difference of hemodynamic parameters are not significance. Both at baseline and 9-month follow-up experiments show that the hemodynamic parameters remain normal and similar, proving that the coronary stent implantation nowadays appears to have a robust and everlasting curative effect.

INDEX TERMS Bioabsorbable vascular scaffolds, optical coherence tomography, computational fluid dynamics, hemodynamic parameters at baseline, nine months follow-up.

I. INTRODUCTION

With the improvement of people's living standard and longer life expectation, more and more people suffer from cardiovascular diseases because of individual health condition, age, hypertension and poor lifestyle habits, among which coronary artery disease is the most common diseases. According to the statistics released by the World Health Organization in early 2015, an estimation of 17.5 million people died from cardiovascular diseases (CVD) in 2012, representing 31 percent of all global deaths [1].

The dominating account of cardiovascular disease is atherosclerosis, which causes narrowing or obstruction of the vascular, resulting in myocardial ischemia, hypoxia

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or necrosis. Atherosclerosis is characterized by a thickening and loss of elasticity of the arterial wall [2]. Fat, cholesterol or other substances accumulate in the arteries to form plaques that narrow the artery channels and reduce elasticity, eventually causing arterial blockage, and leading to diseases such as heart disease and stroke [3]. Therefore, coronary stent implantation is widely used as one of the most effective methods to treat acute vascular occlusion. Coronary stent is a wire mesh or cut tubular structure inserted into a stenosed or blocked coronary artery to improve blood flow to the myocardium subtended by that artery [4]. The metal stent is permanently placed in the coronary artery lesion. And then the vascular wall is supported through balloon dilation or self-expand to keep the coronary artery lumen dilated, contributing to the low mortality of acute myocardial infarction. The new-generation stents are called bioresorbable vascular scaffold (BVS) [5]. Bioresorbable coronary devices have been rapidly developed in recent years to overcome the limitations of the state-of-the-art drug-eluting permanent stents, including the risks of target lesion revascularization, neo-atherosclerosis, hindrance of late lumen enlargement, and the lack of reactive vasomotion in the stented vessel [6]. Bioabsorbable vascular scaffolds can be fully absorbed, thus decrease the risk of stent thrombosis.

Stent implantation in coronary bifurcations imposes unique effects to the blood flow patterns [7]. And the biological processes that can lead to In-stent restenosis(ISR) have been found to be partially flow dependent with the local hemodynamics at the arterial wall of crucial importance [8]. ISR manifested as a re-narrowing of the arterial lumen post-implantation of a stent, is a detrimental limitation of stent technology. However, restenosis may also occur after coronary stent implantation. Hence understanding and consequently devising ways of reducing the frequency of ISR has been a continuing goal of research into improved stent designs. Using intravascular ultrasound (IVUS) is a common practice for inspecting the implanted stents. The results of IVUS showed that restenosis after stent implantation was mainly caused by hyperplasia of neointima. Previous studies have implied that blood flow patterns such as low WSS are favorable to the development of intimal thickening in the normal carotid artery and abdominal aorta [9]. Variations in the local hemodynamic environment after bioresorbable stenting result in alterations of WSS [10], RRT, and OSI, which can invoke a different response around the stent struts.

However, it is hard to segment struts in IVUS due to its limited spatial resolution and various kinds of noises, where OCT has become a common alternative. OCT is a non-invasive imaging modality, which a low-coherence interferometry is used to produce a two-dimensional image of optical scattering from internal tissue microstructures in a way that is analogous to ultrasonic pulse-echo imaging [11]. It has the characteristics of suppressing scattered light, high resolution and high sensitivity. It can also accurately observe the ultrastructure of tissue.

Another stream of researchers are investigating the dynamics of coronary arterial blood flow to replicate real stenting procedures following clinical indications, for example, in [12], Brindise et al used image-based reconstructions of coronary bifurcations to implement a patient-specific model. They also investigated the impact of different stent designs on local hemodynamics in stent arteries, furthermore, they found that the hemodynamics changes associated with stent malposition in an idealized coronary artery. In [4], Chen used three-dimensional computational modelling and computational fluid dynamics methodologies to analyze the hemodynamic characteristics in curved stented arteries using some kinds of common stent models. And in [13], a model was produced by Malek in order to understand the focal propensity of atherosclerosis in the setting of systemic factors. There are also some researches based on clinal cases, as [14], which replicated real stenting procedures following clinical indications.

However, most researchers studied straight and curved stented arteries under ideal conditions, the above studies did not take into account such important factors as the strut thickness and lumen profile, nor analyzed the differences of hemodynamic parameters over a certain period of time based on a individual model, so as to effectively investigate the effect of stent implantation.

Our study aims to analyze and compare between patient-specific hemodynamics at nine months from the intervention using coronary artery reconstruction technique, so as to improve the knowledge of the effect of bioabsorbable coronary stent implantation and thus effectively avoid the occurrence of restenosis. The changes in WSS, RRT, and OSI are the major hemodynamic factors explored in this study.

The main contributions of the paper can be summarized as below:

a. We propose a framework to assess the chronic impact of hemodynamic on coronary stent implantation. By comparing the changes of hemodynamic parameters, the stent implantation effective can be assessed.

b. A 9-month follow-up case study is piloted. From the study, it can be seen that the stent implantation has not been impacted significantly in 9 months' time and no sign of stent restenosis occur.

c. The fusion of Intravascular Optical Coherence (IVOCT) images and angiography for patients is applied to reconstruct vascular specific model and simulate numerical fluid mechanics.

d. The relationship between hemodynamic parameters and coronary restenosis is used to infer the effectiveness of bioabsorbable stent implantation.

The remaining part of the paper is organized as following: We will describe in detail the methods and how to analyze hemodynamic parameters in section II; experiments and results are given in Section III; Section IV are detailed discussions and Section V concludes the paper with future work.

II. METHOD

In this section, we'll elaborate the experimental method of our research. We first introduce the experimental data sources, then describe the procedures of reconstruction of 3D blood vessels. Moreover, a section is used to introduce the 3D vascular reconstruction model of the patient. Finally, we give the method of hemodynamic parameters calculation and analysis.

A. DATABASE

The OCT and angiography image data were collected from the Department of Cardiology, Tongji hospital affiliated to Tongji University. We chose the left anterior descending (LAD) branch of the coronary artery as research object. The bioabsorbable stent was implanted near the middle of the left anterior descending coronary artery. The bioabsorbable scaffold is 28 mm in length.

IVOCT images were collected by commercial c7-XR Fourier-Domain OCT systems [15] and C7 Dragonfly imaging catheter which developed by Jude Medical. Imaging tube filling velocity of about 18 mm/s, frame rate is about 180 frames/s.

B. 3D RECONSTRUCTION METHOD OF INDIVIDUAL MODEL

In order to investigate the hemodynamic changes of coronary artery after the implantation of bioabsorbable stent, we apply IVOCT image fusion and angiography for patients with vascular specific modeling and numerical simulation of fluid mechanics, and then examine the changes of hemodynamic parameters of the baseline and 9-month follow-up. This method consists of the following five steps, as shown in Fig. 1:

1.Detect and extract the vascular lumen contour and bioabsorbable scaffold column points of optical coherence sequence images. An automated characterization method is utilized to detect newly implanted bioabsorbable structs based on a region-growing algorithm.

2. Extract the patient-specific luminal centerline of the angiogram. The middle points of the cross section are selected as the center line points, by connecting which the centerline can be obtained.

3.The contour plane of the optical coherence tomography image in each frame is perpendicular to the centerline of angiography. Arrange the IVOCT images in each frame in sequence along the centerline according to the acquisition sequence.

4. Reconstruct the coronary artery models using the 3D computer-aided software Autodesk Inventor Professional (2017)

5. The finite element model is used to simulate the inflow boundary conditions and Computational Fluid Dynamics (CFD) analysis is carried out.

C. 3D VASCULAR RECONSTRUCTION MODEL OF CORONARY ARTERY

Through smoothing operation on the reconstructed coronary artery, we export the final models in STL format.

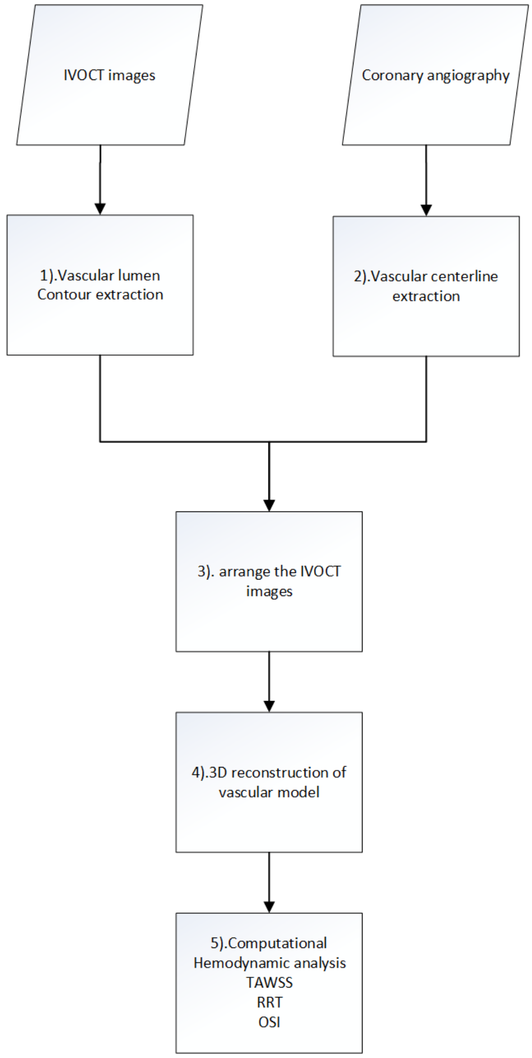


FIGURE 1. 3D printing and hemodynamic analysis framework flowchart based on specific vascular modeling.

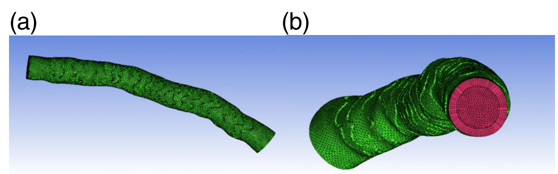


FIGURE 2. (a) 3D geometry of the coronary artery at baseline (b) Local enlargement of volume meshes at baseline.

Hexahedral meshes were generated for the vascular wall, and the lumen of the coronary artery was divided into tetrahedral and hexahedral elements [16]. Meshes are created successfully in Fig. 2(at baseline) and Fig. 3 (9-month follow-up).

And Fig. 4 shows the profile of inlet flow waveforms during the cardiac cycle.

D. HEMODYNAMIC PARAMETERS CALCULATION

The governing equations of fluid mechanics include energy equation, continuity equation and momentum equation [17].

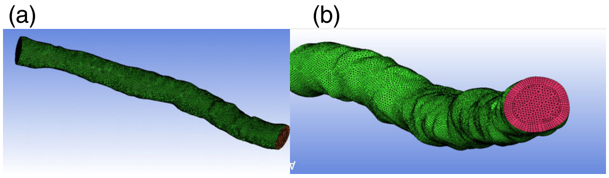


FIGURE 3. **(a) 3D geometry of the coronary artery 9-month follow-up (b) Local enlargement of volume meshes 9-month follow-up.**

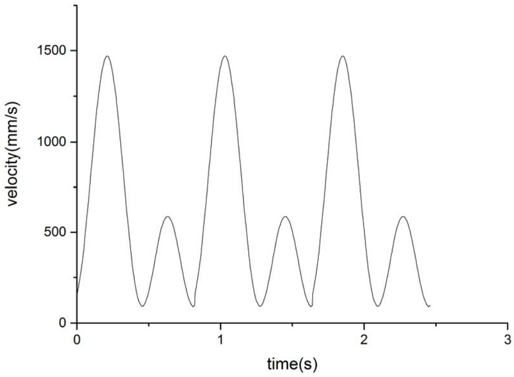


FIGURE 4. **Profile of inlet flow waveforms during the cardiac cycle.**

In this study, it is assumed that the blood is adiabatic, that is, the heat transfer is ignored, so the energy equation is not considered anymore. Blood flow obeys the law of conservation of mass and momentum, the continuity equation and the navier-stokes equation [18]

$$\nabla \cdot U = 0 \tag{1}$$

$$\rho(\frac{\partial U}{\partial t} + U \cdot \nabla U) + \nabla p - \mu \nabla^2 U = 0 \tag{2}$$

In the equation, ρ represents fluid density, t represents time, p represents blood flow pressure vector, U represents blood flow velocity vector, and μ represents fluid viscosity.

The hemodynamic characteristics of coronary artery were assessed using three fundamental metrics, i.e., TAWSS, OSI and RRT. Shear stress refers to the friction between blood flow and the intimal surface of blood vessel wall. It is generally believed in the industry that the change of vascular shear stress is the most important hemodynamic factor that affects the changes of morphology, structure and function of vascular endothelial cells. It is well known that both low WSS and high oscillatory patterns of WSS cause intimal wall thickening [16].

To evaluate the WSS on the vessel wall in pulsatile flow, the TAWSS is defined as follows [15]:

$$TAWSS = \frac{1}{T}\int_0^T |WSS(s,t)| \cdot dt \tag{3}$$

where T is the duration of a cardiac cycle, and WSS is instantaneous variables. WSS and s is the position on the vessel wall.

To measure the directional change of WSS during the cardiac cycle and describe the disturbance of a flow field, the OSI is introduced as [15]:

$$\begin{aligned} OSI &= 0.5[1 - \frac{|TAWSS|}{TAWSS}] \\ &= 0.5[1 - (\frac{\left|1/T \int_0^T WSS(s,t) \cdot dt\right|}{1/T \int_0^T |WSS(s,t) \cdot dt|})] \end{aligned} \tag{4}$$

To evaluate the residence time of particles near the vessel wall, the RRT is introduced as [15]:

$$RRT = \frac{1}{(1 - 2 \cdot OSI) \cdot TAWSS} \tag{5}$$

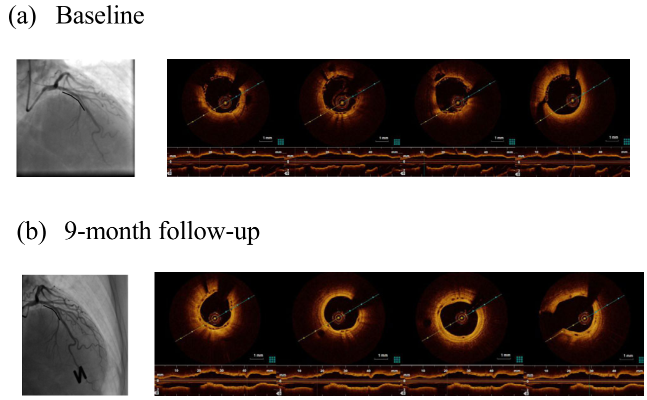


FIGURE 5. **Selected optical coherence tomographic cross sections of coronary artery lumen matching the centerline of coronary angiography.**

III. EXPERIMENT AND RESULTS

The 3D reconstruction is operated by fusing optical coherence tomography and angiography. In Fig. 5, four IVOCT images of interest segment and corresponding angiography images are compared between baseline and 9-month follow-up. It is shown that in IVOCT images, the effective dilation of the vascular lumen after stent implantation does not result in restenosis at 9-month follow-up.

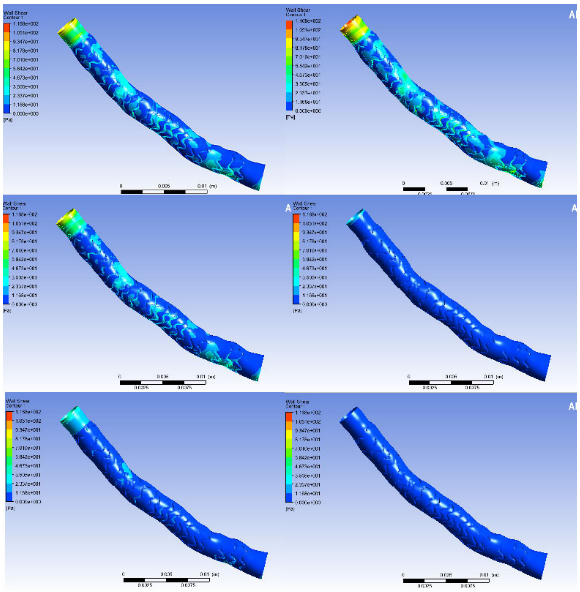
As shown in Fig. 5, the coronary angiogram at baseline and 9-month follow-up demonstrate that both the shape and size of the vessels in the two periods are similar, and the long-term effect of the operation is proved to be feasible.

Three complete cardiac cycles are used to simulate the hemodynamics of an individualized vascular model. Due to the fact that flow field rapidly achieves statistical convergence condition in the cardiac cycle, we collect hemodynamic parameters of important points in the second three complete cardiac cycle (I) - (VI), including TAWSS, OSI, RRT and blood vessel flow velocity, so as to compare the difference between baseline and 9-month follow-up.

A. WSS

In this part, 6 points at baseline and 9-month follow-up are randomly selected and then the corresponding distribution of WSS in the same timeline is depicted in Fig. 6.

(a) at baseline



(b) 9-month follow-up

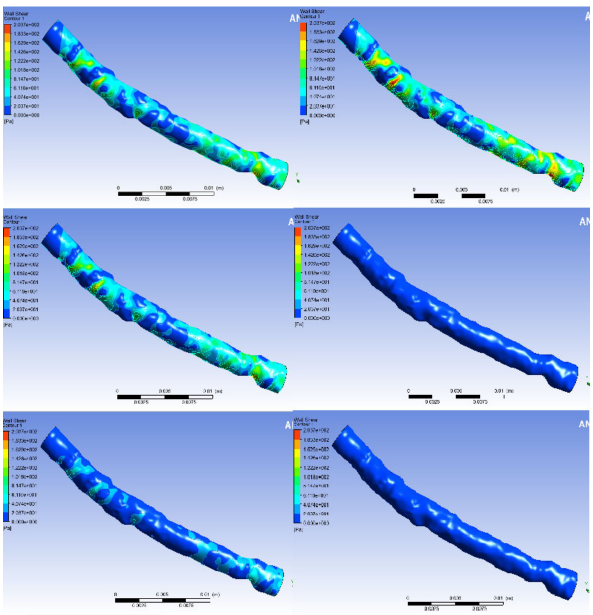


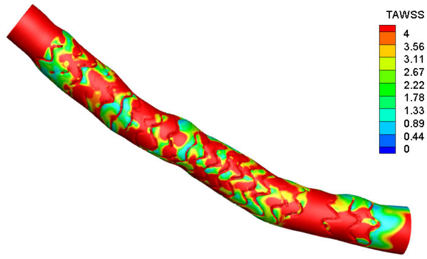
FIGURE 6. Wall shear of random selected 6 points.

B. TAWSS

Fig. 7 is the enlargement of the coronary artery, from where we can investigate the distribution of TAWSS of the vascular. It can be seen that the TAWSS of the majority areas of the coronary artery stabilizes at numerical value 4, and the difference between TAWSS at baseline and 9-month follow-up is not significant.

We take 4 points in different artery areas labeled by A, B, C, and D, which can present the overall TAWSS value in each region. The 4 points of the patient-specific model of time mean vascular wall shear stress (TAWSS) before and after stent implantation are shown in Table 1. According to the results in the table, it can be found that along the direction of blood vessel inlet to outlet, the shear stress on the blood vessel wall surface as a whole presents a gradually decreasing trend. High vascular WSS will result in a high risk of vessel stenosis. Meanwhile, compared with the results at baseline, the average WSS 9-month later increases, while the increased value is still within the normal range.

(a) at baseline



(b) 9-month follow-up

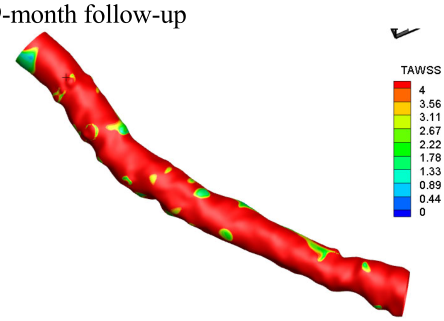


FIGURE 7. Distribution of time mean vascular wall shear stress.

TABLE 1. The comparation of TAWSS in four distributions in a specific vascular model.

Region	TAWSS at baseline	TAWSS 9-month follow-up
A	2.16	17.06
B	9.34	19.67
C	10.02	37.53
D	1.43	6.15

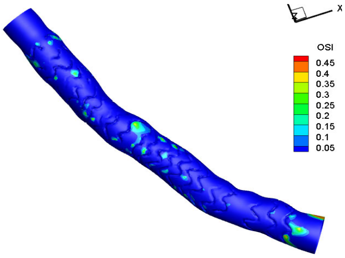
C. OSI

The distribution diagram of OSI at baseline and 9-month follow-up after the implantation of coronary artery stents is shown in Fig. 8. It can be seen that most of the numerical values are below 0.05, and there is no significant difference between the distribution and the value of the wall shear stress oscillators at baseline and 9-month follow-up, as they are still in the same order of magnitude.

D. RRT

The relative vascular retention time at baseline and 9-month follow-up are shown in Fig. 9 respectively. We can see that the relative vascular retention time at baseline is lower in most areas, but higher in a few areas with irregular distribution. After 9-month follow-up, the areas with higher relative retention time basically disappear and the average distribution is similar.

(a) at baseline



(b) 9-month follow-up

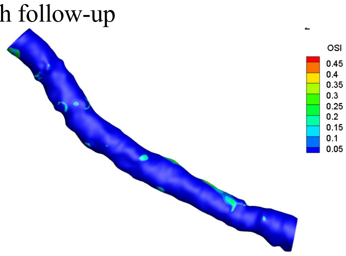
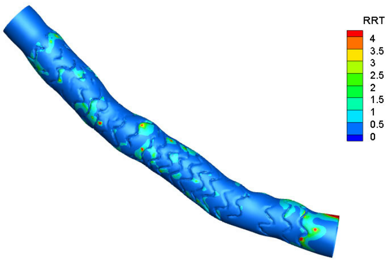


FIGURE 8. Distribution of oscillatory shear stress index.

(a) at baseline



(b) 9-month follow-up

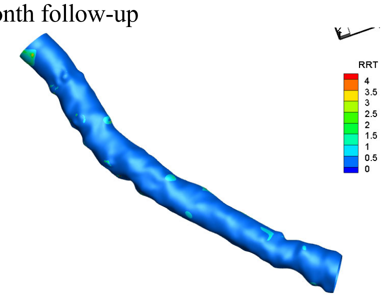
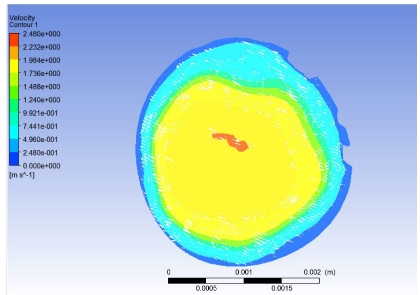


FIGURE 9. Distribution of relative residence time.

E. BLOOD FLOW VELOCITY

The blood flow in the center of the blood vessel is fleet, which near the wall of the blood vessel is slower. For the stenotic vessel segment, the stenosis part and the downstream segment are prone to eddy current during the systolic phase of cardiac cycle, and the eddy current becomes more obvious with the increase of inlet flow rate. In the diastolic phase of cardiac cycle, the eddy current continues to exist even if the flow rate decreases due to the obvious inertia characteristics of blood flow. Considering about the vascular segment after implantation of the bioabsorbable stent, it can be seen that the blood flow velocity changes slightly, and the eddy current in the blood vessel become not obvious. However, the stents will hinder the blood flow to some extent, as shown in Fig. 9, causing a disturbed flow.

(a) at baseline



(b) 9-month follow-up

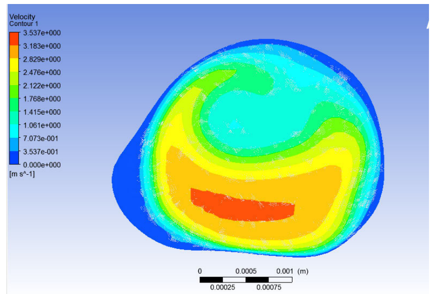


FIGURE 10. A cross section of blood vessel flow velocity.

IV. DISCUSSION

In this paper, we utilize the OCT images and computer technologies to build individualized accurate 3D reconstruction of coronary arteries and bioabsorbable coronary stents. Computational fluid dynamics techniques are exploited to simulate the hemodynamic parameters of the distribution of blood vessels and fluid dynamics parameters. Three major hemodynamic parameters at baseline and 9-month follow-up after coronary stent implantation are compared to demonstrate whether the effect of Coronary stent implantation is receptive.

In the pretreatment process of the experiment, we prepare the real data needed for the reconstruction of the three-dimensional model of blood vessels. And advanced image segmentation technologies are introduced to segment the contour of the coronary artery and semi-automatically detect the adherent and non-adherent states of the bioabsorbable stent. For the blood vessel models before and after stent implantation, advanced computational fluid dynamics tools are exploited to simulate the distribution of shear stress, blood vessel wall pressure and blood flow trace. A series of experimental results illustrate that our proposed method can improve the accuracy of hemodynamic analysis to evaluate the effect of bioabsorbable stent in the treatment of coronary atherosclerosis. Vascular WSS is generally considered as one of the most important hemodynamic factors affecting the structural, functional and morphological changes of vascular endothelial cells.

From the numerical simulation results of CFD, it can be seen that three important parameters of hemodynamic including TAWSS, OSI and RRT do not change significantly at baseline and 9-month follow-up. And the range of changes is also within the normal range and has the same order of magnitude. For instance, TAWSS changes from 1.43 to 6.15 at the selected point, still in the same order of magnitude. Moreover, through the analysis of the cross section of blood flow velocity, a series of experiments demonstrate that the blood flow velocity changes slightly, and the eddy current in the blood vessel becomes not apparent. However, the stents will hinder the blood flow to a certain extent, resulting in a ripple effect on the flow path.

Both the baseline and 9-month follow-up experiments demonstrate that the hemodynamic parameters remain normal and similar, indicating the coronary stent implantation nowadays appears to have a robust and everlasting curative effect.

V. CONCLUSION

In this study, an approach combining optical coherence tomography with angiography is proposed to reconstruct patient-specific models of coronary arteries. The conventional images obtained during percutaneous transluminal coronary intervention (PCI) is used to construct a patient-specific coronary artery model. The hemodynamics is numerically simulated to obtain the distribution and changes of WSS, RRT, OSI and flow lines in the blood flow field. On the basis, the hemodynamic parameters of the patients at baseline and 9-month follow-up are compared to verify the feasibility of our proposed method. Experiments demonstrate that implantation of bioabsorbable scaffolds can alleviate high WSS, which is proved to be an important tool for testing the mechanical properties of stents. Moreover, there is no significant difference between the hemodynamic parameters of patients at baseline and those of patients 9-month follow-up, indicating that stent implantation can effectively treat patients with coronary heart disease without causing stent restenosis. These remodeling and CFD assays will be useful in future studies for a larger patient population to study stent restenosis in bioabsorbable stents.

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(Yisha Lan and Yuanhang Zhou contributed equally to this work.)

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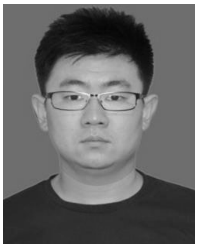

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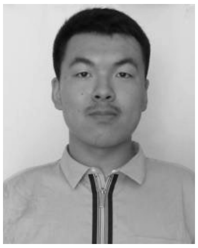

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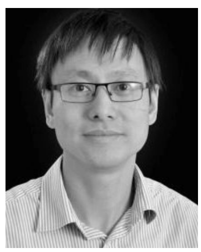

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