GUIDELINES FOR TRACHEAL STENT CUSTOMIZATION AND IMPLANTATION

MOHD. NORHAKEM BIN HAMID

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Faculty of Engineering
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DEDICATION

This thesis is dedicated to my lovely parents, Hamid Bin Bakar and Kamsinah Bte Ahmad Kadri, my brothers, Mohd Noorkhezan Bin Hamid, Mohd Norhairee Bin Hamid and Nor Hairul Faziz Bin Hamid and my friends who always encourage and support me to finish on this research.

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ABSTRACT

One of the treatments of tracheal stenosis is by stent implantation to reopen the constricted trachea lumen. However, post-stenting complications such as stent migration has been reported. This migration is due to undersized implanted stent. On the other hand, oversized implanted stent may pose excessive stress onto the wall of the trachea. Therefore, there is a need to customize the stent size according to the patients' requirements. Thus, this thesis proposes a correlation of a customized stent that addresses the two problems mentioned. The analysis of a healthy trachea is performed and the effect of the different locations of the stenosis is investigated. Then, the effects of implantations of selected stents are numerically studied. The stents are also subjected to several mechanical testing for failure analysis. The results show that the developed stent is able to withstand various mechanical loads and deformation. The currently developed stent performed better than that of the commercial stent by at least 60 percent in bending test, 10 percent in radial compression test and 15 percent in torsional test. The stent is then tested at various tracheal stenosis locations. For a stenosed trachea, the location of the stenosis at the bottom part will pose the highest risk to breathing problems. Post-stenting results show that the developed stent is able to revert the flow inside the trachea to the original flow conditions. The flow rate distributions to the right bronchus were reduced by more than 30 percent as compared to flow rate distributions in healthy trachea. Finally, a correlation is proposed to enable stent customization that best fits patients' requirements. This customized stent is predicted to be able to address the stent migration problem and excessive stress exerted to the trachea wall.

ABSTRAK

Salah satu rawatan stenosis trakea adalah dengan pemasangan stent untuk membuka semula lumen trakea yang tersekat. Walau bagaimanapun, komplikasi selepas pemasangan stent seperti pergerakan stent telah dilaporkan. Pergerakan ini disebabkan oleh pemasangan stent bersaiz kecil. Sebaliknya, pemasangan stent yang bersaiz besar boleh menimbulkan tekanan yang berlebihan pada dinding trakea. Dengan itu, terdapat keperluan untuk menyesuaikan saiz stent mengikut keperluan pesakit. Oleh itu, tesis ini mencadangkan korelasi stent tersuai yang menangani kedua masalah yang dinyatakan. Analisis trakea yang sihat dilakukan dan kesan lokasi stenosis yang berbeza dikaji. Kemudian, kesan pemasangan stent terpilih dikaji secara numerik. Stent juga tertakluk kepada beberapa ujian mekanikal untuk analisis kegagalan. Keputusan menunjukkan bahawa stent yang dibangunkan mampu menahan pelbagai beban mekanikal dan perubahan bentuk. Stent semasa yang dibangunkan menunjukkan prestasi yang lebih baik daripada stent komersial dengan sekurang-kurangnya 60 peratus dalam ujian lenturan, 10 peratus dalam ujian mampatan jejarian dan 15 peratus dalam ujian kilasan. Stent yang dibangunkan kemudiannya diuji di pelbagai lokasi stenosis trakea. Bagi trakea stenos, lokasi stenosis di bahagian bawah akan menimbulkan risiko tertinggi kepada masalah pernafasan. Keputusan pasca stent menunjukkan bahawa stent yang dibangunkan mampu mengembalikan aliran di dalam trakea kepada keadaan aliran asal. Pengagihan kadar aliran ke bronkus kanan telah dikurangkan lebih daripada 30 peratus berbanding dengan pengagihan kadar aliran dalam trakea yang sihat. Akhir sekali, satu korelasi dicadangkan untuk membolehkan penyesuaian stent bagi memenuhi keperluan terbaik pesakit. Stent tersuai ini dijangkakan dapat menangani masalah pemindahan stent dan tekanan berlebihan yang dikenakan terhadap dinding trakea.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

3D	-	Three-dimension
ANSYS	-	Analysis of Systems
CAD	-	Computer-aided Design
CFD	-	Computational Fluid Dynamics
CT	-	Computerized Tomography
DMLS	-	Direct Metal Laser Sintering
PIV	-	Particle Image Velocimetry
UTM	-	Universiti Teknologi Malaysia
GIT	-	Grid Independence Test

LIST OF SYMBOLS

L	-	Litre
ρ	-	Density
F	-	Force
v	-	Velocity
p	-	Pressure
N	-	Newton
%	-	Percent
Re	-	Reynold Number
σ	-	Stress
μ	-	Viscosity
mm	-	Millimetre

CHAPTER 1

INTRODUCTION

1.1 Background of Research

Tracheal stenosis is a constriction of the trachea in an uneven pattern. Injuries to the trachea, which are frequently induced by intubation, are the most common cause of tracheal stenosis. Other reasons of tracheal stenosis include external traumas, malignancies, bacterial infections, and surgical complications (Mostafa *et al.,* 2021). Patients with tracheal stenosis experience difficulties breathing or paralysis as a result of the restriction. Invasive surgical repairs are performed as part of the treatment for stenosis.

The insertion of a stent in the stenosis region of the trachea is a less invasive treatment option. A stent is a tubular mesh or graft that is used to expand the area of stenosed tracheal arteries. Metallic or silicone stents are used in tracheal stents (Folch and Keyes, 2018). The stent acts as a scaffold to keep the trachea open once it has been dilated. In terms of efficacy, implantation of a trachea stent has showed promise. Although tracheal stents seldom cause difficulties, (Fernández *et al.,* 2015) found that stent migration occurs in more than one-fourth of patients.

Metal tracheal stent fracture, erosion of stent that leads to hemoptysis is also possible. Metallic stents can sometimes become encapsulated in the mucosa, making their removal very challenging. Granulation tissue is noted to occur in 15 to 20% of cases. On top of the migration problem, excessive stresses due to oversized stent can also occur. Therefore, the availability of customized stent could help to reduce or eliminate the two problems mention.

To improve patients' breathing function, more knowledge of tracheal stent failure is needed to reduce patient risk and the impacts of stent implantation. Thus,

the risk of tracheal stenosis and following stent implantation in tracheal airflow activity during exercise, normal, and sleep breathing situations is explored and analyzed in this study. The impact of stent implantation in tracheal stenosis on the severity of the patient's breathing is examined and compared. Computational fluid dynamics (CFD) analysis can help with this.

In this study, the process will be divided into two parts which is experimental and simulation work. For the experimental part, the fabrication of tracheal stent will be done using Direct Metal Laser Sintering (DMLS). Because this rapid prototyping technology can create complicated custom designed 3D parts with minimal post processing, it has the potential to be employed for stent production.

Two tracheal stents design is used in this study which is commercial stent and current stent. Then, three main mechanical tests on both tracheal stents included radial compression test, three-point bending test and torsion test will be done to determine mechanical performance of the stent in reducing the risk of the stent failure. All data from experiment will be examine and failure analysis will be done.

In simulation part, CFD analysis will be conduct by using computer software which is ANSYS Fluent is for the numerical study. Before CFD analysis, patient specific trachea model to be built by using Computed Tomography (CT) scan image. Then, the model must be mesh before setup the boundary condition. Next, run the simulation by using fluent solver to get the result. The result from CFD analysis will be compare with the result from the experimental to validation process.

1.2 Problem Statement

The incidence is estimated to be 1 in 64,500 people, with a mortality rate as high as 79 percent before the advent of current surgical techniques (Herrera et al., 2007). According to previous research, 5 out of 19 patients with tracheal stenosis have died (Tan and Tan, 2018). It proves that there are many cases of tracheal

stenosis and the dangerous of tracheal stenosis disease. Therefore, tracheal stenosis should be treated.

Implantation of tracheal stent has caused various complication such as stent fracture and wall perforation after the insertion of the airway stent into patient with trachea stenosis. Therefore, the customized tracheal stent has to be developed to overcome this complication and to increase the successful rate of implantation treatment for trachea stenosis patients.

However, the customized trachea stent has not yet been developed. In theory, stent should be strong enough to withhold the external compressive forces to maintain the lumen patency, biocompatible material use, can fit to all sizes, avoid stent migration, easily deployed and removed inside trachea while being flexible enough to various luminal abnormalities.

1.3 Research Objective

The objectives of this study:

1. To identify mechanical performance of the proposed current stent in comparison with commercial stent.
2. To developed customizable trachea stent strut configuration with respect to design requirements.
3. To quantify the risk in breathing difficulties due to different locations of stenosis and stent implantation with different flow rate intake.

1.4 Research Scopes

Toward achieving the objective, 5 research scopes have been determined and listed as follow:

1. All models are based on patient specific model.
2. Two stents design which is commercial stent and current stent.
3. Three main mechanical testing; radial compression, three-point bending and torsion test.
4. One healthy model and three different locations of stenosis and stented models.
5. Three different inlet flow rates are used which is 15 L/min (sleep), 60 L/min (normal) and 100 L/min (exercise).

1.5 Significance of the Research

For many people, tracheal stenting has a positive impact on quality of life. The tracheal stenting can be a lifesaver, especially when patient with tracheal stenosis disease.

The customized tracheal stent is able to relieve breathing difficulties and prevent further damage to your tracheal muscle for tracheal stenosis patient. It can also improve symptoms of tracheal disease, such as tracheal discomfort and shortness of breath. In many circumstances, you'll notice the advantages right away.

In some cases, stenting may eliminate your need for tracheal bypass surgery. The customized tracheal stent is much less invasive than bypass surgery and also able to reduce the risk of stent fracture, stent migration and granulation formation. The recovery time is also a lot shorter compared to bypass surgery.

The finding of this study will benefit the society especially medical practitioners in deciding suitable treatment and choosing the right size of tracheal stent for tracheal stenosis patient.

1.6 Summary of Chapters

This thesis consists of five chapters discussing on the customization of metallic tracheal stent by using experimental and numerical approach including this chapter of introduction as a Chapter 1.

Chapter 2 discuss about the literature review that covers topics connected to this study, ranging from the fundamentals of human trachea to tracheal stents through prior studies completed by numerous researchers that are valuable additions to this study.

Chapter 3 is explained in detail about the methodology of this study. The flow of the process from the preparing of the model to the data collection from experimental and numerical works.

Next, the discussion of the data collection is discussed in Chapter 4. All the data collection is plotted in graph and table. The findings on correlation between stent parameter also is presented in this chapter.

Finally, in Chapter 5, the study's conclusion is detailed, as well as some recommendations for further investigation on proposed current tracheal stent is used in this study.

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