STRUCTURAL DESIGN OPTIMIZATION OF A PEDIATRIC STENT FOR PULMONARY ARTERY STENOSIS

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INTRODUCTION

Congenital cardiovascular defects occur in approximately one percent of live births annually. One example is pulmonary artery stenosis, a narrowing of the major artery connecting the right ventricle to the lungs. As a result, the blood flow towards the lungs is decreased, making it difficult for blood to be reoxygenated.

In order to remedy such a condition, pediatric cardiologists often opt for a minimally invasive procedure that is, inserting a stent, a tubular prosthetic to hold the artery open. However, the stents available that are inserted in the infant are adult stents designed for coronary artery disease. These adult stents do not accommodate from growth in children, therefore re-dilations of the implanted stent are required every three years or so. On the other hand, with current stenting technology, only about two redilations can be performed; eventually open heart surgery has to be performed to remove this no longer adequate prosthesis.

The goal of this project is to optimize a pediatric stent design the major characteristic of which is an open loop design that accommodates for the infant's artery growth. This design was generated following engineering design steps (problem definition, design embodiment, etc.) and will be optimized through numerical simulations, mechanical testing and in vivo experiments.

However, after a certain period of time, this treatment is no longer suitable, as it does not grow any further with the artery.

BACKGROUND INFORMATION

What is a stent?

A stent is a tubular prosthesis that is inserted into a narrowed artery and expanded. Its purpose is to keep the formerly stenosed artery open.

Stenting procedure

In stenting, a catheter is inserted usually through the groin (femoral artery) to the target location, in our case, the pulmonary artery (Figure 1a). Once this catheter is in place, an assembly consisting of a guide, a stent, and an angioplasty balloon is inserted through the catheter into the constricted region. The balloon is then inflated, causing the stent to expand and dilate the artery (Figure 1b). The stent is expanded into a plastic state so that it cannot collapse, allowing it to maintain the broadened arterial passage.

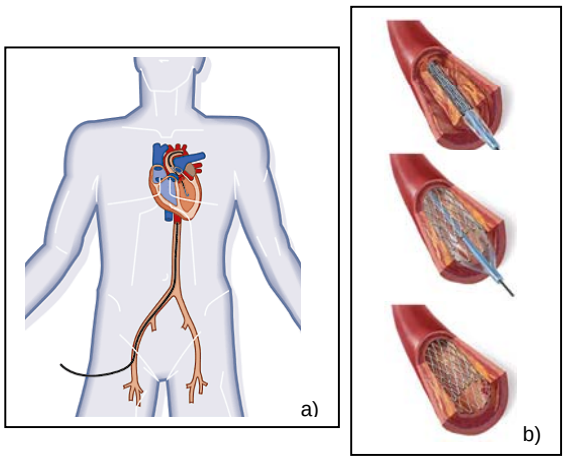

Figure 1: Stent a) Insertion b) Deployment

FIRST GENERATION DESIGN

General concept

An open structure, composed of a backbone with ribs extruding on both sides, is the key to our design. This concept is inspired from a snake skeleton (Figure 2). The geometry of the latter is known to provide strength and flexibility. Moreover, an open structure would accommodate for the artery growth. The biomaterial chosen is medical grade stainless 316L,

Figure 2: General design concept

which is used in other biomedical applications.

Structural Design Evaluation criteria

From a mechanical point of view, once deployed, the stent should be plastically deformed. That is, the material should be in the strain hardening phase to avoid recoil (reduction in stent diameter and obstruction of the artery lumen) once the balloon is deflated and the catheter assembly removed. In addition, the stent should provide sufficient coverage of the targeted surface area and be deployable to the desired final diameter.

NUMERICAL SIMULATIONS

Numerical simulations are used to predict the behavior of the stent prior to its fabrication, thus helping in the design optimization process. Various parameters have to be included in a numerical model including material properties, realistic boundary conditions and applied loads. The boundary conditions consisted in preventing both the translation along and the rotation about the stent central longitudinal axis. Pressures as high as 20 atm could be applied to achieve plastic deformation.

Two various scenarios are to be considered: First, the free expansion scenario studies the ability of the stent to deploy, whereas the stent/artery interaction scenario studies the ability of the stent to keep the artery open in a nearly circular fashion.

Free expansion

As described earlier, desired results are plastic deformation that is a von Misses stress greater than the yield stress (about 400 MPa for stainless steel 316L), and a significant opening of the ribs under the applied pressure. In figure 3, it can be seen that ribs are deployed and plastically deformed.

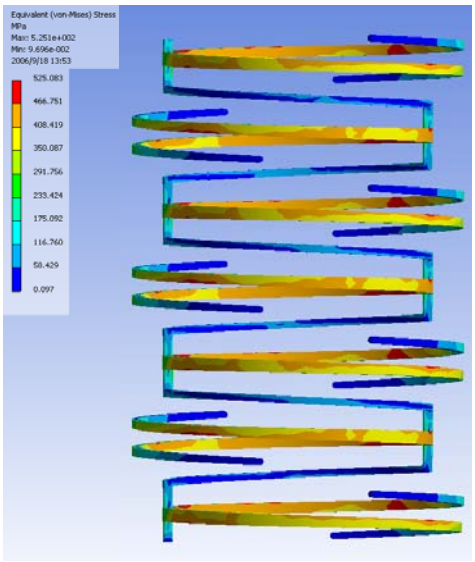

Figure 3: Equivalent stress

Artery/stent interaction

It can be seen from figure 4 that the artery seems to follow the same nearly circular shape the stent has in free expansion.

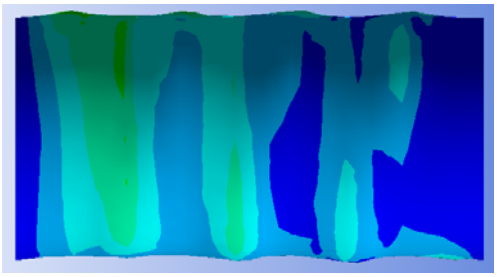

Figure 4: Stent/artery interactions

MECHANICAL TESTING

Once the design has been optimized and numerical simulations provided satisfactory results, stents are manufactured and deployed using angioplasty balloons to verify the numerical results. Below, microscope pictures of the deployment of the first generation of pediatric stents.

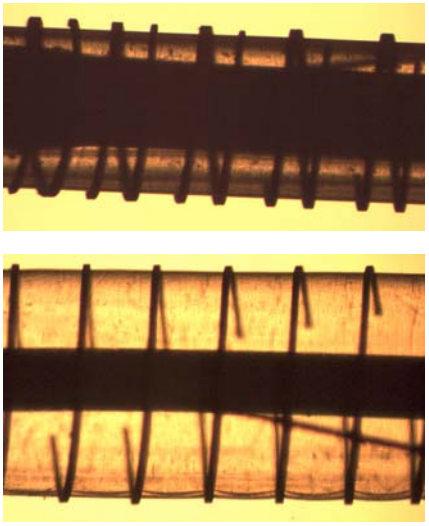

Figure 5: Stent undeployed (top), deployed (bottom)

FUTURE DEVELOPMENTS

Presented here were the results of previous stent generations. A current generation is under study and should be tested soon. In addition to deployment tests, fatigue tests will be carried out using the

appropriate equipment. Once the stents satisfy the structural design criteria, they will be tested in vivo at l'hôpital Laval at Quebec City.

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