A Comparison Between Fractured Xience-like and Palmaz-like Stents Using a Novel Computational Model

Josip Tambača,* Sunčica Čanić[†] and David Paniagua [‡] *Department of Mathematics, University of Zagreb, Bijenička 30, Croatia [†]Department of Mathematics, University of Houston, Houston, TX 77204, USA [‡]Cardiac Catheterization Laboratory, Michael E. DeBakey Veterans Medical Center and Baylor College of Medicine, Houston, TX 77030, USA

Abstract-We developed a novel mathematical model to study the mechanical properties of endovascular stents in their expanded state. The model is based on the one-dimensional theory of slender curved rods. Stent struts are modeled as linearly elastic curved rods that satisfy the kinematic and dynamic contact conditions at the vertices where the struts meet. A Finite Element Method for a numerical computation of its solution was developed and used to study mechanical properties of two commonly used coronary stents (Palmaz-like and Xience-like stent) in their expanded, fractured state. A simple fracture (separation), corresponding to one stent strut being disconnected from one vertex in a stent, was considered. Our results show a drastic difference in the response of the two stents to the physiologically reasonable uniform compression and bending forces. In particular, deformation of a fractured Xience-like stent (with one strut separated from one vertex) is significantly larger than that of a fractured Palmaz-like stent when exposed to uniform compression and bending. This presents conditions which may be a precursor for the clinically observed complications associated with in-stent thrombosis and in-stent restenosis of fractured coronary stents.

I. METHODS

Mathematical and computer modeling of endovascular stents is an efficient way to improve their design and performance [1-11]. Currently available computational tools include "off the shelf," commercial software which is based on various three-dimensional Finite Element Method structure approximations of stent struts that form a three-dimensional stent mesh. Accurate, three-dimensional approximation of stents is often computationally very expensive in terms of time and memory requirements. This is why we developed a novel mathematical and computational algorithm which approximates three-dimensional stents as a **mesh of onedimensional, elastic curved rods** [12].

Stent struts were modeled as linearly elastic, slender curved rods that satisfy the kinematic and dynamic contact conditions at the vertices where the struts meet. A weak formulation for the stent problem was defined and a Finite Element Method (FEM) for a numerical computation of its solution was developed in [12]. The resulting FEM algorithm is incomparably simpler and faster than any corresponding three-dimensional solver, thereby enabling simulations of a large number of stent configurations in a short time. We have been working with frames consisting of 100-250 vertices, giving rise to matrices of the discretized system of differential equations which are of dimension up to 2000. The time to solve the problem for one stent configuration numerically varied from 0.3 to 5 seconds on a server with one Intel Xeon 3.00 GHz processor and 2GB of RAM. This is to be compared to the three-dimensional FEM simulations which require at least one day for a numerical simulation of one stent configuration.

Using this algorithm, we studied elastic deformation of stents **in their expanded state**, exposed to the physiologically reasonable pressure loads of 0.5 atm [12] causing compression, expansion and bending. In particular, in this work we compared the mechanical response to compression and bending of two commonly used coronary stents: a Palmaz-like stent and a Xience-like stent, shown in Figure 1.



Fig. 1. The figure shows photographs of Xience stent by Abbott (left) and Palmaz stent by Cordis (right).

Furthermore, a fracture (separation) was introduced prior to the computer simulations, corresponding to a separation of one stent strut from one vertex in the stent frame. Stent fractures and separation of coronary stent components are relatively rare (although fracture of stents used in larger arteries such as those of the legs, are more common) but they cause potentially serious complications of coronary artery stenting [13], [14]. Patients whose coronary stents suffer from stent fracture may present non-specific symptoms of angina as a result of restenosis or in-stent thrombosis, or both [14], [13]. In order to insure proper recognition and treatment of this problem, physicians must be aware of its existence and of the stent behavior under these circumstances [15]. In this manuscript we present a few scenarios that shed light on the mechanical behavior of two commonly used coronary stents under the assumption of a disconnection of one of the struts in the stent frame. The following is a short summary of the results.



Fig. 2. The figure shows numerical simulation of a non-fractured Xience-like stent (top) and Palmaz-like stent (bottom) exposed to the same bending forces. Stent struts are colored based on the magnitude of contact moment. Much higher bending rigidity can be observed in the Palmaz-like stent (bottom).

II. RESULTS

Drastic differences between the mechanical responses to uniform compression and bending of the Xience-like stent and of the Palmaz-like stent were detected:

1. Palmaz-like stent is much stiffer than a Xience-like stent both under uniform compression and under bending force, see Figure 2. This, in turn, implies less deformation of a fractured Palmaz-like stent than the Xience-like stent, as shown in Figure 3,

2. Large contact moments in the fractured Xience-like stent introduced by a disconnection of a strut from the stent frame were observed (see Figure 3), providing potential for further stent fractures and component separation.



Fig. 3. The figure shows numerical simulation of a fractured Xience-like stent (top) and Palmaz-like stent (bottom) exposed to the same bending forces. The disconnected vertex lies at the bottom center of each stent (denoted by the black dot in the Palmaz-like stent at the bottom panel).

3. Disconnection of a horizontally placed strut in a Xiencelike stent may lead to catastrophic deformation, as shown in Figure 3 (top), when such a stent is located in a tortuous (curved) geometry, such as, for example, the one shown in Figure 4, which is a typical application of Xience-like stents.



Fig. 4. Blockage in a right coronary artery at bending point which requires stenting with a flexible stent that conforms to the artery morphology.

4. Disconnection of any one strut in a Xience-like stent causes protrusion of a stent strut into the lumen of a stented artery by around 30% of its expanded radius, providing an environment that promotes coronary in-stent thrombosis and restenosis as clinically observed in [13], [14]. See Figure 5.



Fig. 5. The figure shows numerical simulation of a fractured Xience-like stent under uniform pressure load, viewed from two different angles. Stent struts are colored based on the magnitude of the radial displacement. The circles on the figure denote the points corresponding to the fractured vertex of a stent. Under the uniform radially applied pressure load, the disconnected strut, shown in blue, protrudes into the lumen by around 30% of its reference radius, causing high potential for the clinically observed complications associated with in-stent thrombosis and in-stent restenosis [14], [15].

5. Disconnection of a diagonally-placed strut in a Xiencelike stent causes visible bending of the stent even when the stent is exposed to uniform compression forces.

III. CONCLUSIONS

We have developed and used a novel, simple, fast and efficient FEM-based computational software, to study the mechanical properties of endovascular stents in their expanded state. In this work we used this software to study the mechanical response of a Xience-like stent and a Palmazlike stent with a simple fracture (separation of one stent strut from one vertex) under physiologically relevant uniform pressure loads and bending. Both stents have been widely used in clinical practice, with the Xience-like stents now capturing over 50% of the market for coronary artery stenting [16]. Our numerical results showed that Xiencelike stents are much softer than Palmaz-like stents, which correlates with clinical experience. As a consequence, our numerical simulations showed that deformation of a fractured Xience-like stent (with one strut separated from one vertex) is significantly larger than the deformation of a fractured Palmaz-like stent when exposed to uniform compression and bending. Although fractures and separation of coronary stent components are relatively rare, they couase potentially serious complication of coronary artery stenting. The kind of deformation of a fractured Xience-like stent shown in our study (see Figures 3 and 5) presents conditions which may be a precursor for the clinically observed complications associated with in-stent thrombosis and in-stent restenosis of fractured coronary stents [14], [15].

IV. ACKNOWLEDGEMENTS

The authors wish to acknowledge the contributions of Mate Kosor for technical and programming assistance. This work was supported in part by the National Science Foundation under grant DMS-0806941, by the National Science Foundation and the National Institutes of Health under a joint grant DMS/NIGMS DMS-0443826, by the Texas Education Board Advanced Research Program - Mathematics 003652-0051-2006, by the University of Houston GEAR grant 2007, and by the MZOS-Croatia under grant 037-0693014-2765.

REFERENCES

- J.L. Berry, A. Santamarina, J.E. Moore Jr., S. Roychowdhury, and W.D. Routh. *Experimental and Computational Flow Evaluation of Coronary Stents* Annal of Biomedical Engineering 28 (2000) 386– 398.
- [2] C. Dumoulin and B. Cochelin. Mechanical behavior modeling of balloon-expandable stents Journal of Biomechanics 33(11) (2000) 1461–1470.
- [3] A.O. Frank, P.w. Walsh and J.E. Moore Jr. Computational Fluid Dynamics and Stent Design Artificial Organs 26(7) (2002) 614–621.
- [4] G. Hausdorf. Mechanical and Biophysical Aspects of Stents, in Catheter Based Devices for the Treatment of Non-coronary Cardiovascular Diseases in Adults and Children. Ed. P. Syamasundar Rao and Morton J. Kern. Lippincott Williams & Wilkins, Philadelphia 2003.
- [5] V. Hoang, Stent Design and Engineered Coating Over Flow Removal Tool, Team #3 (Vimage), 10/29/04.
- [6] KW Lau, A. Johan, U. Sigwart, JS Hung, A stent is not just a stent: stent construction and design do matter in its clinical performance, Singapore Medical Journal 45 (2004) 7, 305–312.
- [7] McClean Dougal R, MD, Eigler N, MD, Stent Design: Implications for Restensis, MedReviews, LLC 2002.
- [8] F. Migliavacca, L. Petrini, M. Colombo, F. Auricchio, R. Pietrabissa. Mechanical behavior of coronary stents investigated through the finite element method Jurnal of Biomechanics 35 (2002) 803–811.
- [9] J.E. Moore Jr. and J.L. Berry. *Fluid and Solid Mechanical Implications of Vascular Stenting*. Annals of Biomedical Engineering 30 (2002) 498–508.
- [10] A.C. Morton, D. Crossman, J. Gunn., The influence of physical stent parameters upon restenosis, Pathologie Biologie 52 (2004) 196–205.
- [11] L.H. Timmins, M.R. Moreno, C.A. Meyer, J.C. Criscione, A. Rachev and J.E. Moore Jr. *Stented artery biomechanics and device design optimization*. Med. Bio. Eng. Comput 45 (2007) 505–513.
- [12] J. Tambača, M. Kosor, S. Čanić, D. Paniagua. Mathematical Modeling of Vascular Stents. SIAM J Applied Mathematics. Conditionally Accepted 2009.
- [13] A. N. Makaryusm, L. Lefkowitz and A. D. K. Lee, Coronary artery stent fracture. Int J Cardiovasc Imaging 23 (2007) 305–309.
- [14] F. Shaikh, R. Maddikunta, M Djelmami-Hani, J. Solis, S. Allaqaband, and T. Bajwa. Stent fracture, an incidental finding or a significant marker of clinical in-stent restenosis. Cathet Cardiovasc Interv 71 (2008) 614-618.
- [15] A. Carter. Stent strut fracture: Seeing is believing. Cathet Cardiovasc Interv 71 (2008) 619-620.
- [16] MX Issues Update. "At TCT, New Studies Support Drug-Eluting Stents," 2008 Canon Communications LLC. http://devicelink.com/mx/issuesupdate/08/10/TCT.html