Stent Fracture Resistance of a Cobalt Chromium Stent

Comparative studies are necessary to examine various devices' performance in the renal arteries.

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During the past 10 to 15 years, fractures of implanted metallic stents in various vascular and nonvascular beds have been reported. deVries et al reported fracture of a stent graft placed in the carotid artery of a 59-year-old man to treat a traumatic pseudoaneurysm 7 months after implantation.[1] Carrozza reported recurrence of symptoms due to the fracture of a balloon-expandable stent placed across an aortic coarctation.[2] Similarly, fractures have been reported in the coronary, subclavian, iliac, aortic, pulmonary, esophageal, tracheal, biliary, and venous stents, leading to late complications.

Although stent fractures have been observed in all of the anatomic territories mentioned above, those in the superficial femoral artery (SFA) have attracted the most attention and generated the most intense scientific investigations. This may be due to the higher incidence of this problem in the SFA, caused mainly by its unique changes during various activities and positions of the lower limb as well as stent characteristics. Fractures of various SFA stents and their frequencies have been reported previously.[3,4] Smouse et al analyzed biomechanical forces in the femoropopliteal arterial segment that could cause axial and bending fatigue of nitinol stents.[5]

Based on these biomechanical forces leading to stent fracture, disruption of stent integrity in renal arteries should be an exceedingly rare event, or is it? A review of the literature reveals that stent fractures have also been observed in the renal arteries. Bessias et al reported stent thrombosis in a 47-year-old patient with a single kidney and diseased renal artery who underwent placement of a balloon-expandable stent.[6] The patient presented 25 days after the procedure with renal insufficiency and uncontrolled hypertension. Angiography showed a thrombosed stent necessitating an aortorenal bypass. The explanted renal artery revealed a fractured incompletely expanded stent.

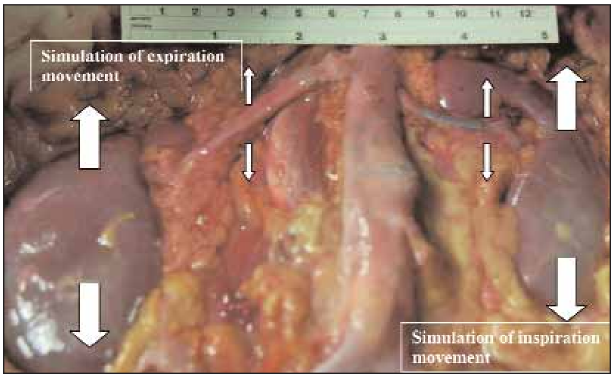

Figure 1. Simulation of the motion of the kidneys and the renal arteries during the respiration cycle.

Similarly, Sahin et al observed a fractured stent in a patient with mobile kidney.[7] The former case report underscores the possibility of "missed" fractures in renal stents that can lead to restenosis and/or thrombosis and the latter points to a possible mechanism.

In this article, we analyze the features of renal arteries that expose stents to strains and stresses that may cause strut fatigue and fracture. These include aortic pulsations and kidney motion during respiration. Craniocaudal movement and partial rotation of the kidneys during breathing causes a bend in the renal artery at or close to its point of fixation to the aorta. The impact of this bending motion on renal stents has not been sufficiently studied. We examined the renal stent bending fatigue performance and resistance of a cobalt-chromium stent (Abbott Vascular, Santa Clara, CA).

HUMAN OBSERVATIONS

During a single normal respiration, the kidney moves approximately 2 cm to 4 cm in the craniocaudal dimension. At aortic and renal angiography, empiric observations suggest a slightly more exaggerated vertical motion of the lower pole of the kidney as compared to its upper pole during the respiratory cycle. This implies occurrence of a slight rotation in addition to the vertical motion of the kidney. Based on a respiratory rate of 16 per minute for an average adult, more than 23,000 such movements occur in a single day and more than 8,000,000 in 1 year. Considering that the vertical kidney movement can be as much as 8 cm during deep inspiration/expiration, considerable stress can be exerted on stent struts over the course of just a few years.

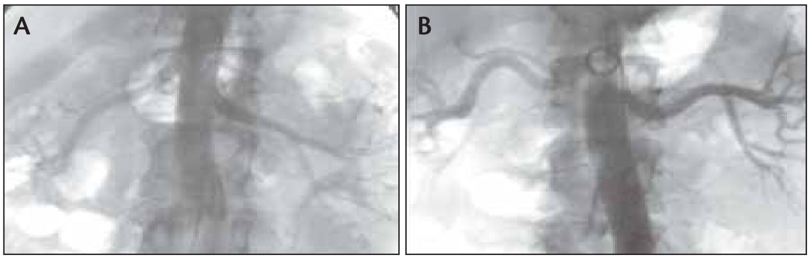

Figure 2. Inhalation (A) and exhalation (B) renal angiograms showing typical renal motion during the respiratory cycle.

CADAVER STUDIES

Eighteen-mm-long balloon-expandable cobalt-chromium stents were deployed into the renal arteries of two cadavers through a transfemoral approach. Respiratory motion was simulated by manual manipulation of the kidneys (Figure 1). The extent of kidney motion was estimated based on the real-time human data collected during renal stent procedures (Figure 2). Stent bending angles were measured from fluoroscopic images obtained at various projections and finite element analysis was conducted using the measured bending angles as inputs.

Kidney motion during respiration results in bending of the renal artery, thereby deforming the longitudinal axis of the stent into a curved line. This bending motion exerts additional stresses on certain parts of the stent that do not normally occur.

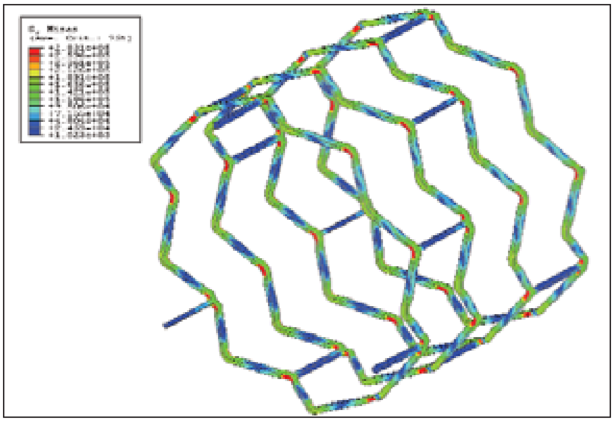

Figure 3. Contours of Von Mises stress for the studied renal stent.

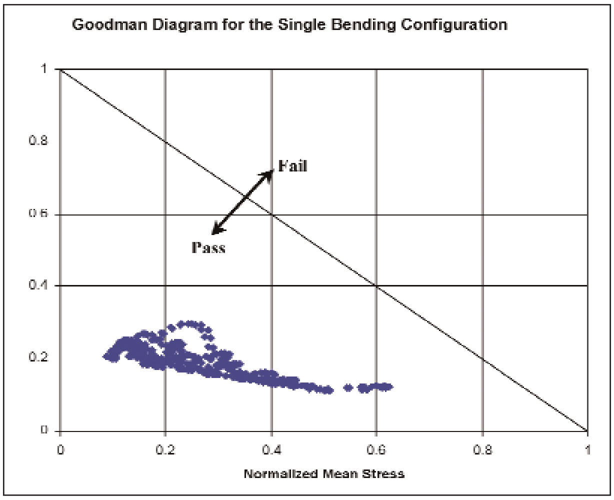

Figure 4. Goodman diagram for the studied renal stent under combined bending and radial fatigue.

FINITE ELEMENT ANALYSIS

Structural integrity and fatigue resistance of the balloon-expandable cobalt-chromium stent was evaluated under a combination of both bending and radial fatigue loading. The radial fatigue loading was designed to simulate pulsations during systole and diastole, while the bending fatigue loading was to simulate movements of the stented renal arteries. A computational model was developed to evaluate the stent response to various loading conditions it experiences during manufacturing (crimping), in vivo deployment (expansion), and clinical environment (systolic/diastolic pressure and respiration-induced bending).

Finite element results showed that the inner surfaces of the curved crown (the "W" and "U" struts) experienced the maximum stress and the maximum equivalent plastic strain, respectively (Figure 3). The Goodman diagram of the combined bending and radial fatigue is presented in Figure 4. Element integration points with the 400 lowest values of fatigue safety factor were plotted in the diagram. In this type of analysis, points falling below the failure line indicate acceptable fatigue resistance. These data calculated by finite element analysis were well below the failure line, suggesting

(Continued on page 35)

that the renal stent studied is capable of sustaining long-term respi-

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ration-induced bending due to its excellent flexibility.

CONCLUSION

Although rarely reported, stents in renal arteries are not immune to fracture. As previously described, the biomechanical forces that can lead to strut fatigue certainly exist in this location. Fractures may be hard to identify in the renal arteries and may be missed if they are not carefully looked for. The identification of the biomechanical forces in the renal arteries and recognition of their importance has led to improved stent designs. Although the tested stent passed the respiratory bending fatigue analysis, stents with different designs, material, and flexibility will likely perform differently. Longer stents or longer stented segments will experience increased stress and strain and may be subjected to a higher risk of fatigue, failure, and fracture. A comparative study is underway. ■

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