Applying What We Know About Stent Fractures

A summary of our clinical experience observing the incidence and impact of stent fractures.

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The debate surrounding the incidence and significance of stent fractures in the superficial femoral artery (SFA) is not a battle between physicians with differing opinions or companies with competing technologies—it's a competition between all of us and the SFA. In fact, there are few clinical settings more convincing than SFA disease in terms of its ability to show us if and how our technologies need improvement.

We have probably placed as many stents in the SFA over the last decade as any center in the country. I have had the luxury of using 16-slice and now 64-slice CTA, and I have had the opportunity to really look at stent fractures, and there is no debating that they do happen. I have seen some that are not harmful and others that are quite bad, and there are a lot of both. It is not my intention to criticize the use of stents in the SFA, but I do believe we need better stents.

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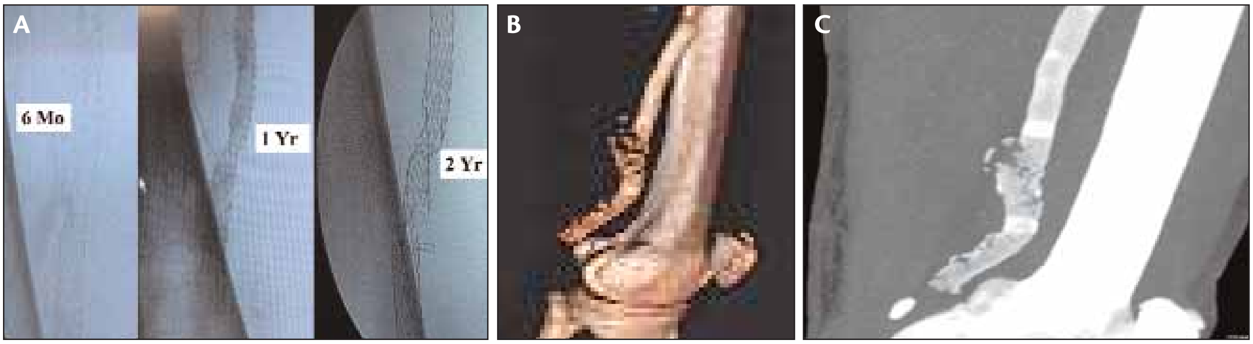

Figure 1. Two-year progression of a stent fracture (A). Type IV SFA stent fracture shown by 64-slice CTA (B, C). Angiogram of the same patient with the knee flexed (D). Final results after covered stent grafting (E).

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OUR EXPERIENCE

In 2000 to 2001, we started seeing some evidence for the first time that there were stent fractures and that they were a potential problem. We went back to our data, and we looked at 380 patients who had an SFA stent placed. Of those patients, 110 returned to our cath lab for some reason, which could have been follow-up for that leg or for a new procedure, and we took advantage of the opportunity to look at the originally treated SFA under fluoroscopy. This was nonrandomized, and it was really a nonselective analysis of all of our SFA stent patients who returned for any reason. What we saw was that 72 of those 110 (65%) patients had showed some incidence of stent fracture. In those patients, we looked for the fracture location, and whether there was any angiographic stenosis.

Most of the fractures were type I and type II fractures. However, we observed that ≥50% of our patients did have angiographic restenosis, especially the type III and type IV fractures. Patients who had more severe fractures were much more symptomatic and had angiographic problems. This correlation raises the issue that maybe stent fractures are not benign. Although the majority of the fractures we saw were more minor, if there is such thing as a minor stent fracture, this led us to ask is whether these minor stent fractures progress into more significant fractures. In some patients, continued follow-up showed that stent fractures can deteriorate over a period of time, as seen at 6 months, 1 year, and 2 years in Figure 1A through E. Notice the conformational changes that occur.

When we went back to the cases performed in 2000, our analysis found stent fractures occurring in all segments, even if they were cases in which a single stent was used. Most of the cases had more than one stent placed; however, we dealt with SFA disease much differently then, because we did not have the same tools that we have today. At that time, we would line the vessels (a full metal jacket, so to speak). We found approximately 35% of our patients had a full metal jacket, and twice that number had at least two stents (from two to five stents), which is a significant number.

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We also frequently overlapped the stents. This was the way that we treated patients at that particular time. Naturally, the more stents that you actually use, the more overlap results, and the more difficult problem for the patient.

LESSONS LEARNED

Our conclusions were that these fractures certainly do occur. They were not benign in our particular hands because they were associated with angiographic findings and symptoms. They could really occur in any segment, but in our analysis, most of them occurred in the distal segment. The distal segment in the popliteal area is probably the area of most concern. Certainly, we did identify what is now well known—that overlap and the length of stents can be problematic, and we have modified our practice accordingly, as have most clinicians treating SFA disease.

Since that time, newer designs have come out, and it is logical to assume that there should be fewer fractures as the newer stent designs have entered the market. That certainly was what we have seen so far.

PLAQUE BURDEN AND STENT FRACTURE

The amount of plaque burden within the vessel may

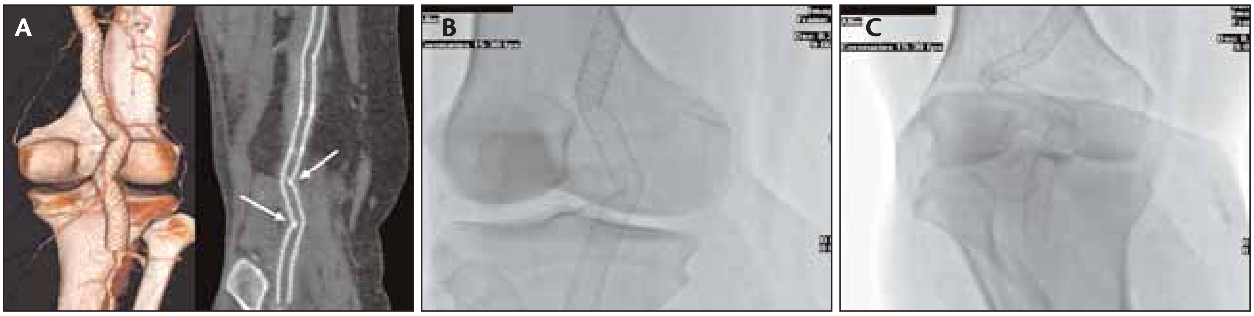

Figure 2. Type I (minor fracture) shown by 64-slice CTA (A). Fluoroscopy with 30° flexion (B). Fluoroscopy with 60° flexion (C). Note the severe kinking resulting in stent thrombosis (with minor stent fracture).

also have a lot more to do with stent fracture and the difficulty of with dealing with the SFA in general than we really know. As a surgeon by training, when I first started to stent these vessels I always asked myself, "Where are we going to put a 7-mm stent in a 7-mm vessel that is filled with 7 mm of plaque?" To me, that is 14 mm. The point is that we may be underestimating the amount and nature of plaque burden that is present, and we do not really know what impact it is having on the stents that we place. I believe SFA debulking prior to SFA stenting will improve the compliance of the SFA and may decrease stent fractures.

> "We are now experiencing what I call *beyond stent fracture*, which is the next biomechanical problem in femoropopliteal stenting, stent kinking."

CONCLUSION

I think there is little debate today, as opposed to 2003, that stent fractures occur, but there may still be some merit to debate the clinical relevance of minor stent fractures. SFA nitinol stents are much better today and, I suspect, fracture less with improved designs and technique, but I think all of us would rather have a fracture-proof stent, if possible. We are now experiencing what I call *beyond stent fracture*, which is the next biomechanical problem in femoropopliteal stenting, stent kinking (Figure 2A-C). Stents will have to be both fracture and kink resistant. There should be no debate about the significant challenges that the native femoropopliteal segment presents to all clinicians and industry that are involved with endovascular solutions for this vascular territory. ■

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