Discussion

Dr Valavanur Subramanian (New York, NY). Very elegant. I have a few questions. How do you adjust your amount of folding into your clip or do you have different sizes, number one?

Dr Feins. We have multiple clip sizes that we use. For the purposes of this in vivo study, we found that almost all animals except I required just the smallest size clip we have, which I can back up to show you based on the scale from my slides. One animal did require a larger clip.

The clips themselves are fairly fixed in the amount of leaflet tissue that they can plicate, which you can see is probably defined by the maximum opening state of the clip itself. However, it is a fairly trivial matter to create variable size clips for the purposes of plicating different amounts of leaflet tissue.

Dr Subramanian. In the animals, do you look at the flared gap, how much of a flared gap you had before you had a successful clip deployment?

Dr Feins. I’m sorry, could you repeat the question?

Dr Subramanian. The flared gap, how much of a prolapse from the annular plane, because there are limitations there.

Dr Feins. What we had tried to do was maintain the chordae that were supporting the segments of the leaflet between the P2 and P3 scallops and the P1 and P2 scallops, with the goal of having some leaflet tissue of P2 that still had chordal support so that when we plicated the central segment we would have some supporting leaflet tissue to maintain valve function.

Generally speaking, our goal was to create prolapse in just the central portion of P2, which essentially was about 3 or 4 mm. I would say between 3 and 5 mm in terms of the length of the coaptation line for the valve itself.

Dr Song Wan (Shatin, Hong Kong). Congratulations for this innovative design and excellent experimental result. I have one comment and one question. The comment is, your idea appears to me to be more advanced than MitraClip, however, it didn’t overcome the intrinsic critical drawback of MitraClip, namely, it only addresses the leaflet but not the annulus, and without proper annuloplasty, the long-term durability is reduced, as all of us know already.

The question is, your device seems more suitable for the chronic, for example, P2 prolapse, with excessive valve tissue and maybe myxomatous change. However, your animal model is an acute model with chordal cutting, and the leaflets are more or less normal in this setting. Do you think your device can be used in acute MR, like a sudden rupture of the chordae, exactly mimic your animal model?

Dr Feins. Thank you for your comments and question. I certainly think that there is some limitation to our animal model with regard to the type of lesion that we were creating. Not all prolapses are created equal, and this is a very different lesion than a myxomatous valve with excessive leaflet tissue. This is a limitation of our model. You could envision various scenarios where you would create a more clinically similar type of lesion, and that may involve augmentation of the leaflet and then surviving animals to create a dilated anulus that mimics the clinical scenario.

The purposes of this study were mainly to assess the clip in an acute setting, not because this would necessarily be a replacement to a chordal replacement, for example, but simply as a way of seeing if the ex vivo findings that we had could be reproducible in an acute model. And I suspect in the setting of what you are describing, which is excessive leaflet tissue with redundancy, which we see in a more chronic setting, that this leaflet plication clip would arguably have even better results than in an acute chordal rupture model.

And just in response to your comment, I completely agree. Our intention for not including an annuloplasty was simply to assess...
the sole effect of the clip in isolation. I think we can all agree that an annuloplasty in addition will improve outcomes. And while the clip doesn’t add an annuloplasty, and in that way is not an improvement on the current MitraClip, I think it is fair to say that one of the reasons that mitral valve reparative surgery has improved over the past several decades is due to the breadth of reparative techniques we have: annuloplasty, edge-to-edge repair, and the various ways to address the leaflet and the chordae. This represents one way of doing that by plicating the leaflet rather than simply involving the other leaflet segments.

Dr Mathew Williams (New York, NY). What are your plans for putting this in a catheter-based approach?

Dr Feins. We are currently developing some of the minimally invasive methods for implanting this, and there is a wide range of applications. I think when we developed this, we saw this not just as a percutaneous or catheter-based technique. There are also transcardiac ways of implanting it, as well as implantation in the open heart. One could argue that in conventional heart surgery, having a device such as this allows for a more reproducible way of plicating the leaflet instead of suture-based techniques.