Dear Editor,

We appreciate Dr Colvin’s thoughtful review and agree “that current anchoring devices suffer from unpredictable lead retention, possible lead fracture and discomfort due to being bulky.” As noted, our study was intended to analyze leads following maximal tension applied to suture loop anchors. The leads were subsequently examined under gross microscopy and tested for impedance changes. This was not a longitudinal study and interpretation of our results was therefore limited.

Anecdotally, we recently explanted a lead in a patient who had a spinal cord stimulator system in place for over 1 year. At the time of implant, the lead was anchored with 2.0 silk loop anchors. Following explantation, the lead was sent for electron microscopic (EM) analysis found to have significant microfractures at the loop anchor site in the outer polyurethane layer. However, analysis demonstrated that the lead was still perfectly functional with normal impedances at all contacts with no leakage of dye into the individual conductors. It is unclear if the microfracturing occurred in the first few weeks or over the subsequent 12 months following implantation. It is also not clear if the lead was destined to fail, and if so, over what time period. We questioned whether a larger diameter suture would distribute pressure over a larger area of the lead and we have subsequently begun using 0 silk for direct suture anchoring for our trial cases.

Recently, we have begun using EM analysis to examine explanted trial leads anchored with 0 silk. Four leads from two patients have been examined so far and we have seen no evidence of microfractures in the polyurethane. Granted, these short-term 5-day trials in two patients offer limited insight and long-term studies are needed. We plan on continuing to examine our trial leads with EM analysis to determine if any microfractures or gross lead damage can be appreciated. Trial leads may offer an effective short-term model as many of our patients inadvertently pull the trial leads in the performance of their daily routines, which imposes significant stress on the suture loop anchor. As we currently use a double chest tube tie along with the larger 0 silk suture, we hope this combination may help avoid damage through distributing tension over a large enough surface of the lead. Only further study will tell.

Our concern in using silicone medical adhesive relates to the 24-hour cure time. We have heard of a number of cases where lead migration occurred in the first 24 hours following implantation. If the lead could be securely anchored during the first 24 hours while the silicone was curing, it would be a more appealing solution. We are considering the application of octyl-2 cyanoacrylate to the lead-silicone suture sleeve interface, which may add strength to the anchor-lead complex while the silicone adhesive is curing. This is another potential area of study.

Dr Colvin has offered an articulate and concise summary of the historical issues involving lead anchoring. At the present time, no single approach is beyond reproach. Implanting clinicians must be aware of these controversies as well as the lack of definitive data to support one approach over another. Although it may be useful to note that we have been using direct suture anchoring exclusively for over 7 years without a single lead failure that we know of, focused and longitudinal data are required to know which approach to lead anchoring is best.

Paul G. Kreis, MD, Professor, and Scott M. Fishman, MD, Professor
University of California, Davis
School of Medicine