Is New Always Better?

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The advancement of urologic care depends on research and innovation. New surgical techniques, devices, and medications have kept our field at the forefront of medicine. But do all new products presented to us really represent an advancement or are they sometimes a step into the unknown? Even more troubling, might they be a step backwards?

Though there may be examples of this throughout the various subspecialties within urology, here I address those with which I am most familiar, within female urology and voiding dysfunction. Over the years the treatment of female stress urinary incontinence has evolved. Various studies and the American Urological Association guidelines of 1997 demonstrated the long-term superiority of open retropubic bladder neck suspensions and slings (primarily autologous fascial) when compared with other methods of repair. Soon there was an explosion in the number of kits and other types of materials available that were expected to reproduce the outcomes of the autologous fascial slings. Unfortunately many of these were introduced via the 510(k) route, which allows devices that are "at least as safe and effective, that is, substantially equivalent, to a legally marketed device" (http://www.fda.gov/cdrh/devadvice/314.html) to obtain US Food and Drug Administration approval with minimal review. Many urologists began to use these kits and other materials without a body of evidence supporting their equivalent efficacy to the autologous fascial sling. As we all know, many of these devices and materials have fallen out of favor, and some, namely the ProteGen sling (Boston Scientific, Natick, MA), resulted in lawsuits against the companies that produced them and the physicians who implanted them.

The introduction, in the late 1990s, of the tension-free vaginal tape (TVT) (Gynecare, Somerville, NJ) midurethral sling revolutionized both sling material and technique. Over the past 10 years, multiple studies have attested to the efficacy of the TVT sling and the minimal rate of untoward outcomes. In order to capture a portion of this market, no fewer than 10 other companies have introduced their version of this type of sling. Unfortunately, the products are usually brought to the market with minimal human outcomes data. Frequently the urologist is shown a company-produced glossy monograph demonstrating that after 3 months of implantation in a rabbit's flank there is minimal reaction. Usually one is told that it is the same polypropylene type of mesh as the original TVT. When studies are available, they are generally short-term. Although ultimately some of these products do prove equivalent, many do not. It is interesting to note how many of the companies are rapidly introducing newer, better meshes. This begs the question: What was wrong with the original, proven mesh?

Similar issues have arisen with the recent procedural modification in which the transobturator approach is used rather than the retropubic approach. Do we have good long-term data that this approach is superior to the "tried and true" retropubic approach, justifying an across-the-board switch from one approach to the other? In addition to the innovative, new, transobturator approach, one of these kits, the Obtape (Mentor Corp., Santa Barbara, CA), purported to have a newer, better mesh as well. The Obtape mesh was a thermally bonded, nonwoven, polypropylene mesh that was represented as an advancement over the TVT type of mesh. Based on very limited data, many urologists switched. Unfortunately, reports soon appeared documenting vaginal erosion rates as high as 20% as well as cases of significant soft tissue infection. This mesh is no longer marketed. Recently a new kit, the TVT SECUR (Ethicon Women's Health and Urology, Somerville, NJ), was introduced to the market with essentially no significant human outcomes data. The first human implantations were done just months before marketing began. Since introduction of the kit, there have been slight modifications in the technique in an effort to match the outcomes of the original TVT. I suggest that it would have been better had the need for these modifications been recognized during a study period prior to widespread marketing so that the "ideal" technique could have been introduced and taught from the start.

The introduction of the collagen implant (Contigen; C.R. Bard, Murray Hill, NJ) was another revolution in the treatment of stress urinary incontinence. For patients who are thought to be candidates for a bulking agent, collagen is a simple-to-use, relatively effective material. Over time