Challenges in Spinal Repair and Regeneration

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Four out of five Americans will suffer back pain during their lifetime and each year approximately 33 million people will undergo some form of treatment, ranging from pain medication to physical therapy to surgery. Back pain can result from a number of different causes including osteoporosis, tumors, scoliosis and trauma. By far the largest cause, however, is disc degeneration, possibly induced by other factors but presenting as pain due to changes in the natural disc resulting ultimately in pressure on a nerve. For many years, and even today, there has been intense debate over the appropriate way to alleviate this pain. Advocates of non-surgical treatments have maintained that bed rest, coupled with appropriate physical therapy is as effective as surgery but without the risk. On the other hand, spine surgeons point to studies which indicate that surgery is a safe and effective form of treatment and allows for faster rehabilitation.

Regardless of the ongoing debate, each year almost 1.2 million spinal procedures are performed in the United States. Most of these procedures are either disc resection (so called discectomy) or disc fusion. Disc resection involves the surgical removal of any portion of the nucleus pulposus which may have been extruded through the annulus so that it causes pressure on the spinal cord. Disc fusion is generally a more severe operation and attempts to alleviate pain by removing the entire disc and inducing the adjacent vertebrae to fuse together, thereby limiting motion. Over the last 10-15 years, major advances in surgical techniques have been developed in both procedures. Today's discectomy is generally performed using only small incisions which allow same day discharge of the patient while disc fusions now use a variety of hardware, ranging from pedicle screw constructs to interdiscal cages to synthetic bone blocks, which provide superior stability and long term clinical results.

The major problem with both discectomy and fusion is that normal motion of the spine is not restored. Discectomies remove, but do not replace, the nucleus pulposus and therefore make the individual spinal segment more susceptible to subsequent degradation. Likewise, fusions limit the mobility of the spine at that level and require the adjacent levels to move more to compensate for this lack of mobility. As a result, implant developers are evaluating devices which may allow normal spinal motion to be restored. These devices include nucleus replacement which is intended to be used after a discectomy to replace the resected nucleus, artificial discs which replace the entire disc in place of fusion and therefore allow normal motion to be restored, facet joints which replace the natural facets in the posterior spine and combinations of all of the above.

Beyond these new implants, the opportunity exists for any number of biological solutions to disc degeneration involving either tissue engineered systems or gene therapy. These opportunities include cellular based strategies to replace the nucleus pulposus, the annulus fibrosus and even the entire disc. However in order for these approaches to operate successfully, a large number of fundamental challenges will need to be solved. Foremost amongst them is the recognition that degenerative disc disease is precisely that, a disease. Consequently the environment under which cellular based systems will be required to operate is not that of a normal disc but rather is dehydrated with a low partial pressure of oxygen. This makes it extremely challenging for viable cell growth. Furthermore the mechanical stress under which tissue engineered devices for the spine will be subjected is likely to exceed almost all current scaffold materials, particularly since even current metallic systems are prone to failure over time. Introduction of a clinically successful tissue engineered device to treat spinal disease will require significantly greater understanding of both the mechanical and physical environment under which they must operate.

From my own involvement with many of these newer spinal implants, one factor above all has become clear and that is the importance of ensuring that each new device is designed to satisfy the unique demands of the spine rather than simply being an extension of available technology. These 'technology pushes' have generally failed to recognize the specific requirements, both mechanically and surgically, inherent in the spine and therefore have achieved less than ideal clinical results. It is to be hoped that an increased understanding of the spine, coupled with greater experience in the design of spinal implants, will prevent these mistakes in the future.