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EVOLUTION OF THE CERVICAL ARTIFICIAL DISC

First Generation, Second Generation, and Beyond

Although artificial discs are fairly new to the U.S. market, these discs have had 17 years of clinical results in other parts of the world, mainly in Europe. While these devices are still being introduced into the United States, their designs, materials, and technologies were invented more than 20 years ago. A new wave of designs has already emerged with the singular purpose of improving upon that first generation of moderately successful artificial discs. But measuring this improvement is the subject of widespread debate. What constitutes a design enhancement and what renders an artificial disc a "second-generation" prosthesis? Are kinematics that mimic the natural disc paramount? Are streamlined surgical instruments and minimally invasive techniques evolutionary? How important is the potential for improved performance and reliability? Must a second generation design be adaptable to multiple levels? What about ease of revision? To sort out these questions it is helpful to start where artificial disc designs are now.

First Generation

First generation discs (see Table) as a group are constrained designs and, in comparison to a healthy human disc, have biomechanical limitations. First generation artificial disc designs generally allow no more than three independent degrees of freedom—rotation, flexion-extension, and lateral bending. Reginald J. Davis, MD, Head of Neurosurgery, Greater Baltimore Medical Center (Baltimore, MD), says, "first generation designs are basically mechanical approximations of the normal disc." A natural disc allows for six independent degrees of freedom, which also includes anterior-posterior and lateral translation, as well as axial stretching and compression. First generation discs, with their constrained designs, do not and are therefore unable to properly replicate natural disc motion. Although some surgeons believe that a design that limits movement to only allow critical spine movement is desirable, the majority of surgeons believe the artificial disc should try to recreate as much of the natural spine motion as possible, while working with adjacent discs to avoid undue forces on the implant or other areas of the spine and body. According to Ralph F. Rashbaum, MD, Orthopedic Spine Surgeon, Texas Back Institute (Plano, TX), "the bottom line is trying to protect the next segment from breaking down. The best way to do that is to absolutely mimic as closely as possible the mobile disc as to its flexibility, flexion-extension and its elasticity." Despite their limitations, early designs have enjoyed a fortuitous start, and, as stated by Dr. Rashbaum, "imagine what the second and third generations will be."

With first generation discs having achieved acceptance, they made it possible for surgeons and engineers to improve upon that generation—to create the second generation of artificial discs. Simple enough, but how do you determine what is considered an improvement worthy of being called "second generation?"

Second Generation

Spine experts agree that a design aim for a second generation artificial disc includes a more natural replication of natural anatomic movements. According to Dr. Davis, "duplicating the normal disc kinematics is probably one of the more important criteria of the second generation." Hyun Bae, MD, Research Director, Spine Institute (Santa Monica, CA), agrees: "we are all looking for that magic goal of improved kinematics. Trying to improve the kinematics as well as reducing the

wear and stress put on the prosthesis would be a second generation disc objective."

It is evident that both surgeons and patients can benefit from the more highly developed second generation discs and instrumentation that makes disc surgeries not only easier, but safer. Dr. Davis agrees: "as you look at the various classes of discs, the first generations of discs were cumbersome, the instruments were unrefined and the introduction techniques were fiddlesome. I think that the second generation discs refined the instrumentation and the implantation technique and by doing so also improved revision strategies."

With the variety of artificial discs available, there are those attributes of a disc which make it superior and which will provide simple and reproducible surgical technique. If bone invasion could be minimized (such as keels and screws), it would allow a disc to be utilized in multi-level applications or would simplify its removal in case of a necessary revision or repositioning. One limitation of more constrained designs is that they must have invasive primary fixation, such as screws or keels, to ensure the prosthesis can resist the natural movement of the spine. These mechanical fixators can greatly reduce the ability for these designs to have application in multi-level surgery. As stated by Dr. Davis, "we're trying to learn from the predecessors in the first generation discs, where multi-levels were somewhat of a challenge. Easy implantability for a multi-level surgery is an important attribute of second generation designs as it is one of the better indicators for doing successful disc replacement in the cervical spine."

The Future—Third Generation

It is generally agreed that third generation discs will optimize mechanical approximation by utilizing new materials, new bearing surfaces, elastomer cores and advanced instru-mentation with computer-guided assistance. New bearing surfaces alone are not sufficient to make a disc third generation, as these are present in some second generation discs (see Table). Further, third generation discs must also offer six independent degrees of freedom. The notion is that these concepts and materials will lead to more successful outcomes for patients. In Dr. Bae's view, "it is difficult to project what will happen with the third generation discs. That generation is going to be built on what we find from the second generation discs, with some built-in flexibility. Most of the discs right now are metal on metal or metal on poly, but they're not spongy. So whether there is an elastomer or some other type of core, we think that the third generation discs will have some type of compliance, which will better mimic the biologic disc."

Dr. Davis predicts there will be an "introduction of new materials, a better polymeric approximation of lumbar discs, getting closer to the native disc." Dr. Rashbaum adds that "in the lumbar spine, we'll innovate a third generation implant that features some type of a shock absorbing method. In the cervical spine, however, I think we're going to go from first to second to fourth generation. In other words, my prediction is we'll go right to orthobiologics and skip right over the third generation, as I'm not sure how an elastomer will work there." As the Table illustrates, there are a few third generation designs in development and many have yet to be proven safe or effective.

Much has been made of promising new elastomer core artificial discs. Essentially, these are discs that have a mass of rubber/polymer in the core. There is the hope that this shock absorbing material will more closely mimic the human disc and could one day be an appropriate application for some indications in patients. This technology shows potential and many companies are further testing this type of material. There is the general belief, however, that this group of discs is not in the second generation category and instead would be considered third or even fourth generation technology. The idea and approach is interesting and the science should be further developed via material, animal and eventually human testing.

And Beyond…

Fourth Generation

There are already discussions about fourth generation discs with wide speculation about what to expect. Many believe that fourth generation technology will be biologic augmentation and/or the combination of less device-oriented implants with biologic adjuncts to regenerate or stabilize the disc. This technology will attempt to restore and repair the disc to its natural state with as little disruption as possible, using both natural and synthetic materials. Drs. Bae, Davis and Rashbaum agree that this future generation of discs will be biologic and Dr. Davis opines, "this generation will incorporate either the native ability to heal or some stimulated ability to heal with growth products or stem cells." Dr. Rashbaum concurs: "we will be trying to get back to nature as our fourth generation. I'm not talking about injecting an elastomer. I'm talking about stem cells."

Generation	Manufacturer	Product	Description/Rational for Classification
Third	Nexgen Spine	Physio C	Variable modulus elastomer / metal endplates; elastomer core design
Third	Abbott	ISD	Elastomer core in woven cover core design
Second	Spinal Motion	Keneflex-C	Metal on metal; mobile core design, with retaining clip to contain core
Second	LDR Spine	Mobi-C	Metal on polyethylene; mobile core; mobile bearing design
Second	BioMet/EBI	Rescue	Pyrocarbon on pyrocarbon; reported to be a semi-constrained design
Second	Stryker	CerviCore	Metal on metal saddle; constrained design that provides axial movement dictated by rotation
Second	Nuvasive	Cerpass	Ceramic on ceramic; nucleus-like replacement device
Second	Globus	Secure-C	Metal on polyethylene with semi-mobile bearing
First	SeaSpine	Catalina	Ceramic or metal in polymer; ball and socket; constrained design
First	Cervitech	PCM	Metal on poly; large radius ball and socket; constrained design
First	Medtronic	Prestige LP	Ceramic on ceramic; ball and trough constrained design
First	Medtronic	Prestige ST	Metal on metal; ball and trough constrained design
First	Synthes	ProDisc-C	Metal on poly; ball and socket; highly constrained design
First	Vertebron	CMP	Metal on metal ball and socket; constrained design
First	Depuy	Discover	Metal on metal; constrained design inspired by Charite lumbar disc
First	Medtronic	Bryan	Metal on polyethylene ball and socket; constrained design

For now, we await a new wave of second generation cervical artificial disc designs that will seek to improve upon the moderately successful 17-year clinical history. There remains a mixture of controversy and enthusiasm associated with the currently available spinal artificial discs—both lumbar and cervical. Their recent entry into the U.S. market (note: only one lumbar AD, Depuy's Charite, is available thus far) has generated interest and excitement for both patients and spine surgeons. A new crop of companies have emerged professing to offer various levels of evolution in artificial discs and this rush of entries into the market, along with their various claims, have created differing levels of understanding and agreement on what constitutes meaningful evolution in the design of these products. Several companies have attempted to claim a label as "second generation" artificial discs. Industry analysts believe that a true second generation disc must offer real differentiation from the first discs marketed. Second generation discs must offer improved benefit to the patient and the surgeon.

In summary, to be considered second generation, an artificial disc should:

1. Have improved kinematics from original (first generation) discs.
2. Provide the potential for improved performance and reliability for the patient.
3. Offer instrumentation and a surgical technique that is more robust and repeatable.
4. Be able to be implanted in multiple levels.
5. Possess the ability to be more easily repositioned or revised if the situation warrants.

With this criteria in mind, we should continue to survey and assess the landscape of new offerings endeavoring to be called second generation. It appears the future is bright. There is a new wave of technology emerging that has the potential to improve patients' lives. These new products will offer surgeons new and hopefully better ways to address what is still an underserved patient need. Both patients and surgeons have much to look forward to with these new generation discs.

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