A successful disc will not behave like a hip, knee, toe or finger.

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EDITORIAL

Next-Generation Discs

Less balls, fewer sockets.

John A. Engelhardt, Founding Member, The Institute for Orthopaedics™

Last month, we detailed disc technologies that have been put into humans and therefore might provide a good representation of first generation devices. (See "Discs Move to Market in the U.S.," *Ortho-Know*, 6/04.) This month, we endeavor to provide a glimpse of what the future of disc replacement will look like. Exhibit 1 on the following pages details technologies that are currently marching towards clinical use.

My past criticisms of the first generation devices stem from the fact that they do not represent reasonable biomechanical approximations of the disc itself. They have focused on motion rather than kinematics, on movement rather than the stability that the natural disc provides. It is no surprise, then, that the majority of next-generation discs have design rationales that aim to provide six degrees of freedom of motion, but also of stiffness and damping, thereby mimicking the properties of the structures being replaced. I must confess a bias towards this philosophy.

Sons of Acroflex?

Upon studying some of these devices, a few of you may be inclined to say, "Sounds like Acroflex to me. Didn't that concept fail?" The answer is no, the concept didn't fail, but some early devices did, although a good number of them are still working well. The failures were technology issues. If we had stopped developing total hips when the first stems broke, we would now be living in the orthopaedic stone age. Ditto for pedicle screws. We developed better materials and optimized designs. Perhaps the biggest irony of Acroflex is that it was the brain child of a joint replacement surgeon: Arthur Steffee.

Dr. Steffee described himself many times as a hand surgeon who dabbled in spine. He had designed a number of joint replacement systems for the hand, shoulder and others. He knew that the disc was not a joint, and replacement of it would require non-joint replacement concepts, materials and design criteria. The Acroflex philosophy was to mimic, as closely as possible, the properties of an intact disc. The next generation of devices pays homage to Dr. Steffee's belief that a successful disc will do just that, and not behave like a hip, knee, toe or finger. It is hard to disagree with this concept, at least in theory.

This is all not to even mention the fact that we are eliminating the nucleus, annulus, anterior longitudinal ligament and sometimes the posterior longitudinal ligament. The future of disc design will take into account the functions of these structures, as well as the complex interplay with the posterior elements.

Based on the evolution of skeletal repair technology, we can expect to see a matrix of products designed for a particular set of indications or pathologies. This has been astutely envisioned by the work of Vertebron, whereby constrained and non-constrained devices share the product matrix.

Perhaps the take home point is that we are embryonic in our knowledge of what really matters in disc replacement, although we should not disregard over 100 years of empirical experience. This is perhaps the most exciting era of skeletal reconstruction in history. Many call it the final frontier.

The future will see a broad matrix of products from minimally invasive nucleus augmentation to disc/facet replacement systems to total motion segment replacement technologies. Patients will enter the treatment continuum sooner, and stay longer. Documented clinical results will dramatically improve, and the benefits to society will be unprecedented. Let's hope society gets the message.

John A. Engelhardt has designed and developed or lead teams in the design and development of hip, shoulder, elbow, wrist, ankle, finger and toe implants, as well as trauma products, artificial ligaments, interbody fusion devices, spinal instrumentation and artificial discs. He owns a small equity investment in AxioMed and Interpore/Biomet. The parent company of Pearsalls is a client of Knowledge Enterprises, Inc. Mr. Engelhardt can be reached at 440 247 9051 or john@orthoworld.com.

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Discs...

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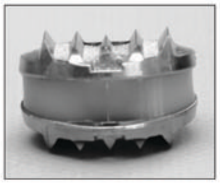
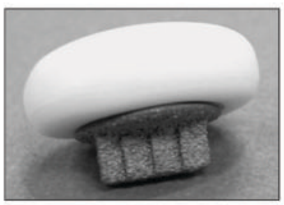
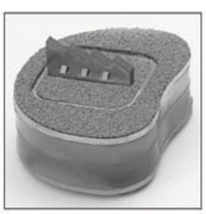
EXHIBIT 1
NEXT-GENERATION DISCS

Image	*Product/ Company*	*Description*	*Status*
	Freedom Lumbar, AxioMed Spine Corporation	Proprietary polymer between Titanium endplates, porous coated on fixation surfaces. Polymer mimics mechanical properties of natural disc.	Begins human clinicals 1st half of 2005.
	NeoDisc Cervical, Pearsalls, Ltd.	Polymer core inside capsule of engineered embroidery of polyester. Capsule and anterior flange encourage organized tissue growth to replace the function of the annulus and A.L.L. No endplate preparation.	Begins human clinicals 7/04 in the U.K.
	Min T Disc (**M**inimally **In**vasive **T**otal Disc), Interpore Cross, a Biomet Company	Zirconia ceramic dome, fixed to inferior body by titanium keel, articulates with superior endplate. Keel is affixed peri-operatively via locking taper.	Begins human clinicals 3Q04 in Australia.
	Takiron Co. Ltd.	Three dimensional matrix of woven polyethylene fibers has engineered anisotopy. Fixation surfaces are HA-impregnated.	In animal trials.
	Lumbar, Theken Surgical, LLC	Proprietary elastomer between titanium endplates, porous coated on fixation surfaces. Polymer mimics mechanical properties of natural disc. Integral micro-electronics produce information datastream.	Begins animal trials in 2004; human trials in 2005.
	Cervical, Spinal Innovations, Inc.	Hard-on-hard, free-floating bearing contained in an elastomeric ring, which provides damping and a centering force when displaced.	Files IDE in 4Q04.

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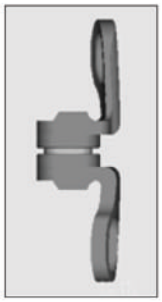
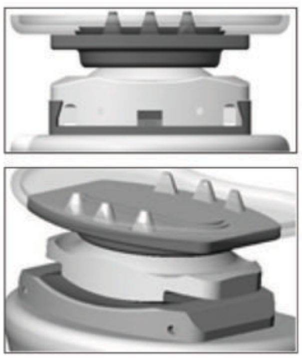
Please note:

Absence of a particular product indicates that the company did not respond to requests for information or that the product was deemed to be too early in development.

Discs...

(Continued from page 5)

EXHIBIT 1, continued
NEXT-GENERATION DISCS

Image	*Product/ Company*	*Description*	*Status*
	CMP (**C**ervical **M**otion **P**reservation), VERTEBRON, INC.	Articulated anterior cervical plate design meant to minimize learning curve. MoM bearing. Ti/HA-coated fixation surfaces.	Begins human clinicals early 2005 ex-U.S.
	AMP (Lumbar **A**nterior **M**otion **P**reservation), VERTEBRON, INC.	Semi-constrained (AMP-S, left top) has fixed UHMWPe bearing. Unconstrained (AMP-U, left bottom) has free-floating inserts. Each have Ti/HA-coated fixation surfaces.	Begins human clinicals early 2005 ex-U.S.

Learn more about the companies behind these technologies.

Find them online in the Directory of Orthopaedic Companies at *www.orthoworld.com/members/manufacturers/companiesA.htm*.