

Stryker and Osiris step into the bony void



[Elizabeth Cairns](#)

Biological grafts for orthopaedic applications have had a troubled history, with products from both Wright Medical and Medtronic getting caught out by safety concerns. But Osiris Therapeutics has form when it comes to cellular and biological products – back in 2012 it obtained the world's first approval for a stem cell therapy – and with help from its partner Stryker, may yet succeed in this contentious market.

Bio4, a bone allograft that contains both bone-forming cells and growth factors, was launched in the US at the weekend, three months after Osiris forged a licensing agreement with Stryker. Osiris is focusing hard on its biosurgery franchise, but reimbursement pressures are ever-present.

Bio4 was formerly known as OvationOS, and is a bone matrix designed to fill bony voids and to aid bone regeneration after foot and ankle surgeries. It is intended as an alternative to autografting, and has the advantage of avoiding the initial bone-harvesting procedure necessary for autografts.

Growth factors

According to Osiris, the graft provides a structural bone matrix, osteoinductive and angiogenic growth factors, and bone cells including mesenchymal stem cells and osteoblasts.

The growth factors are intriguing. Both Wright's Augment and Medtronic's spinal graft Infuse ran in to difficulties because they contained recombinant growth factors – platelet-derived growth factor and bone morphogenetic protein-2 respectively – that have been associated with cancer risk. It is not known which factors Bio4 contains.

Bio4 has at least passed muster at the FDA; it is approved for sale under regulations concerning cellular and tissue-based products. That said, it should be remembered that Infuse was FDA-approved too, despite later trials showing that it was no better than bone grafts and that it increased the risk of cancer ([Infuse trials backfire on Medtronic with negative findings, June 18, 2013](#)).

But Bio4 differs from these products in that it contains cells too. Here Osiris's core expertise comes into play; it launched OsteoCel, a preparation of allogeneic bone cells, including mesenchymal stem cells and osteoprogenitor cells, in 2005. And it sold the business to NuVasive, the fourth-largest player in bone fillers, for \$85m plus milestones three years later.

Allograft

Stryker puts the cellular allograft market at around \$200m, relative peanuts for the second-largest orthopaedics company in the world. But off-the-shelf, or allogeneic, grafts are appealing, reducing treatment time and avoiding the costs of the initial harvesting procedure.

Bio4 is cryopreserved and stored in special freezers at -80 degrees Celsius; customers have the product shipped to them on dry ice. This does involve management of a cold chain, but is still more convenient than autografting – Bio4 is ready to use as soon as it is unpacked.

Pricing, however, will be a concern, even with the marketing power of Stryker behind the technology. Being cheaper than autograft will be a start, but pressures on reimbursement are, as always, a fact of life.

This year the Centers for Medicare and Medicaid Services (CMS) reduced the bundled hospital outpatient department rate for Osiris's Graftix stem cell wound-healing product, and it would not be a surprise to see Medicare limiting its payment for Bio4 too. Stryker will have to judge this carefully if it wants to grow the market.

Established players in orthobiologic bone fillers

Company	Segment	Global sales (\$m)		
		2013	2020	CAGR
Medtronic	BMP Biologics	471	532	+2%
Integra LifeSciences	IsoTis DBM products	40	64	+7%
Integra LifeSciences	Synthetic Grafting products (Mozaik)	11	18	+7%
RTI Surgical	Bone Graft Substitutes	19	35	+9%
NuVasive	Allograft plus	22	25	+2%
NuVasive	AttraX/Progentix	1	1	-1%
Exactech	Biologics	16	13	-3%
Globus Medical	Biologics	5	11	+12%
Acelity	Allocraft DBM	2	3	+4%

Data sourced to EvaluateMedTech

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