Cortoplasty: Augmentation of Osteoporotic Vertebral Compression Fractures with Cortoss®

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Statement of Purpose: Cortoplasty is the low volume, interdigitated reinforcement of a fractured vertebral body, utilizing a precision start-stop, percutaneous injection of Cortoss® (Orthovita, Inc. Malvern, PA). Unlike traditional materials, such as polymethyl methacrylate (PMMA), Cortoss was engineered specifically for the augmentation of osteoporotic vertebral compression fractures (VCF). It is a high-strength, bioactive, non-monomer releasing, radiopaque, self-setting polymer with a low exotherm and a mix-on-demand application system that offers enhanced performance and safety. Replicating the physiologic structure and mechanics of vertebral bone, Cortoplasty is the state-of-the-art augmentation of osteoporotic vertebral bone.

VA is currently performed by either Percutaneous Vertebroplasty (PVP) or Kyphoplasty (KYPH) techniques with one of several commercial formulations of PMMA cement (Spineplex, Kyph-X, Vertebroplastic, etc.). The goal of VA is to stabilize the fractured vertebrae in order to alleviate the pain and to prevent further collapse of the vertebral body.

Materials: Table 1 compares Cortoss to commonly used Spineplex PMMA Cement with respect to several material properties important for VA.

	Cortoss	PMMA (Spineplex)
Compressive Strength (MPa)	201	81
Tensile Strength (MPa)	62	34
Bioactivity	Bone Apposition	Fibrous Tissue
Radiopacity (α)	115	96
Exotherm(°C)	59.7	96.1

Table 1: Comparison of mechanical, chemical and biological properties of Cortoss and Spineplex PMMA Cement

Methods: All biocompatibility testing was conducted in accordance with ISO 10993 using sterilized material. For detailed methods of comparative animal studies see reference (Erbe, EM. Euro Spine J. 2001; 10: S147-S152).

Results/Discussion: PMMA is a monofunctional thermoplastic polymer with moderate mechanical properties. It exhibits inefficient polymerization, which leads to the release of a significant amount of (unpolymerized) monomer (Kuhn Springer Verlag, 2000). This release of monomer is well reported in the literature and has been implicated in creating dangerous and sometimes deadly hypotensive conditions perioperatively (Mathis, JM AJNR 2003; 24(8):1697-1706). No monomer is released from Cortoss. As a result, the risks of a hypotensive effect or cardiac arrest associated with reaction to MMA monomer are eliminated.

Cortoplasty achieves a level of reinforcement that is not possible with other materials because Cortoss interdigitates with the trabeculae, as opposed to forming a bolus, as doughy PMMA does. The use of Cortoss also allows for start-stop precision when injecting the material into the vertebra. Vertebral bodies (VB) are highly vascularized which provides for many pathways for cement extravasation. Cement extravasation, though largely under reported (unless evaluated via post-op CT analysis), is believed to occur in almost every augmentation procedure (Yeom, J.S. JBJS 2003; 85(1): 83-89). Venous leaks may lead to pulmonary complications, as the veins drain into the inferior vena cavae. Posterior epidural leaks can potentially cause neurologic complications. The start-stop technique affords the clinician the opportunity to stop injecting as he/she wishes to allow already injected material to polymerize and block the leak without losing the ability to inject additional cement into another location. Additionally, the relatively low viscosity of Cortoss is such that even if a leakage occurs, the surrounding tissues are not displaced by the leaked material. Conversely, a herniating or disruptive displacement may occur when higher viscosity PMMA cement extravasations encounter adjacent tissues.

Cortoplasty is low volume by virtue of the trabecular interdigitation of Cortoss coupled with its high material strength. Because of the viscosity and bioactive nature of Cortoss, the bond responsible for augmentation starts as a micromechanical interdigitated reinforcement able to bear physiologic loads immediately and progressively strengthens as new bone apposition occurs (Erbe, EM. Euro Spine J. 2001; 10: S147-S152). No other injectable material exhibits this degree of strength and bioactivity.

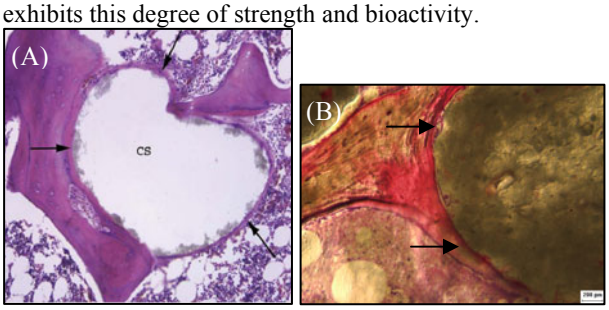

Figure 1: Histologies of vertebral bodies show A) fibrous encapsulation of PMMA and B) intimate apposition between bone and Cortoss.

Conclusions: The goals of VA are the alleviation of pain, immobilization of the fracture segments, and prevention of further collapse. Cortoss incorporates some characteristics described as 'ideal' for VA materials. It is non-monomer releasing, biocompatible, bioactive and structurally conforming to the physiology of the fractured vertebra. In addition, it is dose flexible, visualizeable and has optimized viscosity and setting characteristics which make it easy for surgeons to use. An FDA approved IDE clinical trial is currently underway in the U.S.