DEGRADABLE MAGNESIUM BASED CEMENT ADHERES STAINLESS STEEL SCREWS INTO BONE

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HYPOTHESIS: A biodegradable monopotassium phosphate, magnesium [Mg] oxide, tricalcium phosphate, injectable formulation will increase screw extraction torque and surface bonding compared to polymethylmethacrylate [PMMA], calcium [Ca] phosphate or no bone cement.

INTRODUCTION: Bone cements serve as bone void fillers and can cement structures, such as implants into bone. Bone cements are used to secure joint implants into bone cavities[1], lute plates and screws onto bone[2], and enhance screw pullout forces[3]. Mechanisms of action for enhancing security of the implants in these applications include hardening within the bone cavity and increasing surface contact area. None of the currently available cements (biodegradable or non-biodegradable) claim to adhere implants to bone, but this property could further enhance the security of implants in bone and reduce micromotion. A Mg-based formulation has demonstrated adhesive properties for bone to bone and tendon to bone,[4] and may therefore provide adhesion of implants to bone. The specific goal of this study was to determine if a Mg-based bone cement had adhesive properties to stainless steel screws compared to a Ca-based commercial product and PMMA. Implant security was quantified as peak extraction torque. Material distribution and bonding to the implant was assessed with high-detailed radiography and undecalcified histology. Extraction torque was selected to represent bone-material-implant bonding because interface failure, rather than failure of the material or bone, occurs at the loss of implant security.

METHODS: Sixteen paired radii were harvested from 8 mid-sized dogs. Four holes were drilled, equidistant, from cranial to caudal in the distal diaphysis.[5] (Fig 1) The bones were secured in a jig and drilled perpendicular to the surface with a 2.5 mm drill bit and the length of the hole measured with a depth gauge. The holes were manually tapped to be filled with a 316L stainless steel cortical bone screw [Synthes, Paoli, Pa] of appropriate length to a torque of 0.706 Nm [Qdriver2 Torque Screwdriver, Snap-on Inc., Kenosha, WI] according to the following assignments: Gp1-Control, No material; Gp2- Ca-based biodegradable bone filler/cement [Bone Source; Stryker Inc, Kalamazoo, MI]; Gp3- PMMA [Simplex™P, Stryker Inc., Kalamazoo, MI]; and Gp4- Mg-based biodegradable bone filler/cement [Bone Solutions, Dallas, TX]. Material was prepared and used to fill the assigned holes, which were rotated to control for hole position from proximal to distal. In rapid succession, the screws were placed and the material allowed to cure for 96 hrs. The extraction torque (Nm) for each screw was tested and measured using a Torque Sensor/Load Cell Display [Transducer Techniques Inc, Temecula, CA] connected with a torque wrench during derotation of screws. Peak values were recorded (Nm). Radii were digitally radiographed and the cemented area around each hole measured using an electronic pen [Osirix Medical Imaging Software] and recorded. (Fig 2) Screws were reinserted and bones were cut into slabs on either side of the hole, sectioned undecalcified [Exackt System, Zimmer, Warsaw, IND] cranial to caudal, and stained with Masson's trichrome stain. Histologic sections were evaluated qualitatively for interface gap, bone/screw/material contact, and material microscopic appearance.

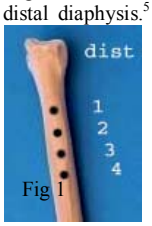


Fig 1

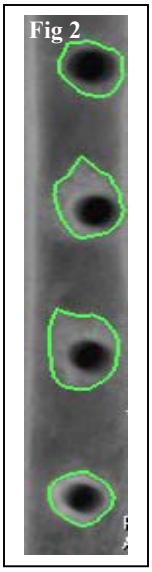


Fig 2

RESULTS: The Mg-based product (Bone Solutions) had significantly ($p<0.001$) greater extraction torque (mean 97.5+/- 17.7 Nm) than control, Ca-based product and PMMA. PMMA had significantly ($p<0.05$) greater extraction torque than Ca-based product. (Fig 3) An area of cement around the screw was identifiable in all materials, but significantly greater ($p<0.001$) in Mg-based product and PMMA than control or Ca-based product [Table 1] and was obvious grossly. (Fig 4)

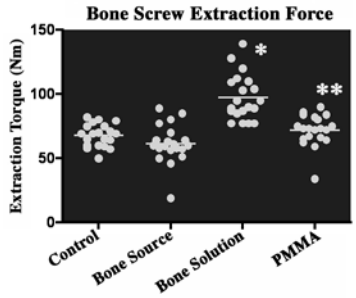


Fig 3. * significantly greater ($p<0.001$) than all other groups; ** significantly greater ($p<0.05$) than Ca-based product.

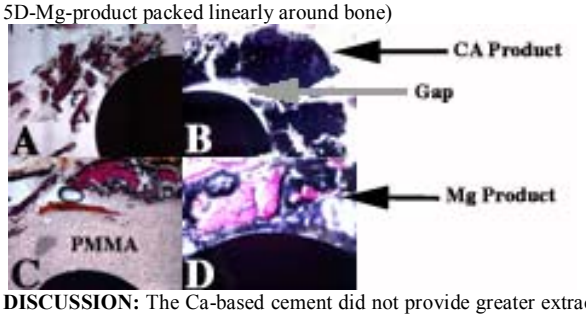
Table 1. Mean (+/- SEM) area (pixels^2) of cement present surrounding screws placed in canine radii.

Control	Ca-based Bone Source	Mg-based Bone Solutions	PMMA	
0 +/-0	519 +/-36	973 +/-100*	1309+/-179*	*P<0.001

Fig 4 Radii; Masson's trichrome stain

Histologically (Fig 5) the Ca-based product (5B) was granular, dense, homogeneous with a gap at the interface. The PMMA (5C) was finely granular, homogeneous and in contact at the interface. The Mg-based product (5D) was granular, non-homogeneous, in direct contact with screw an bone. The material was densely packed at the interface.

Fig 5A-Control with shards of bone only; 5B-Ca-product; 5C-PMMA; 5D-Mg-product packed linearly around bone)



DISCUSSION: The Ca-based cement did not provide greater extraction torque on the screw due to separation at the interface. PMMA diffused into the surrounding bone, provided a tight bond at the screw interface, and greater extraction torque than Ca-based cement or control, but is not biodegradable. Mg-based cement diffused into the surrounding bone, provided a tight bond at the screw interface, the greatest extraction torque and is biodegradable. The mechanism of superior adhesion to the implant appeared to include expansion and compression against the surface of screw and bone.

CONCLUSION: A biodegradable magnesium injectable cement was superior at securing stainless steel implants in bone.

REFERENCES: 1)Sporer and Paprosky. (2005)36:105;2)Anderson *et al.* Vet Surg (2002) 31:3;3)Griffon *et al.* Vet Surg (2005):34:223;4)Bertone *et al.* (2005)Trans ORS:1007;5)Linn *et al.* V.C.O.T. (2001)14:1-6.