Biomechanical Strength of Bone Allografts Following the *AllowashXG*™ Allograft Sterilization System

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INTRODUCTION:

Allograft bone has been used in spine surgery for years. Due to the low but real risk of disease transmission, many cleaning and processing systems have been developed in an effort to improve graft safety and efficacy. Among the more common and successful treatments include cleaning solutions, chemical sterilants and irradiation. Other systems include gas plasma, ethylene oxide (ETO) and e-beam irradiation. Each of these systems have pros and cons. Chemicals are useful for removing blood and fats from the tissue as well as inactivating a wide range of organisms, however, it is difficult to ensure that the chemicals have fully penetrated the graft. Gamma irradiation has been used successfully for years, but has raised questions about the mechanical strength of grafts undergoing this treatment. Plasma systems and e-beam technology are relatively new and have limited use.

Many studies exist which investigate the use of gamma irradiation on allograft bone[1,2,3,4,5]. Most of these studies have shown that doses of more than 2 Mrad (20 kGy) significantly weaken the graft, rendering it unsuitable for implantation. The current study was performed to characterize the biomechanical properties of cortical and cortical-cancellous grafts treated with the new *AllowashXG*™ allograft sterilization system. *AllowashXG* is a series of chemical and mechanical cleaning steps followed by a low-dose gamma irradiation targeted at 1.0 Mrad (with a range of 0.95 to 1.32 Mrad.) The treatment group is compared to a control group processed with the *Allowash* cleaning system that has in use since 1995[6].

Biomechanical tests were performed on three VERTIGRAFT™ configurations at the biomechanical labs of DePuy Spine (Raynham, MA). VG2™ Cervical Allograft, VG2 PLIF Allograft and VG1™ ALIF Allograft, processed by LifeNet (Virginia Beach, VA) were tested in axial compression, compressive shear and static torsion following the guidelines of ASTM standard F2077[7]. Standard *Allowash* treated controls were compared to those treated with the new *AllowashXG* system.

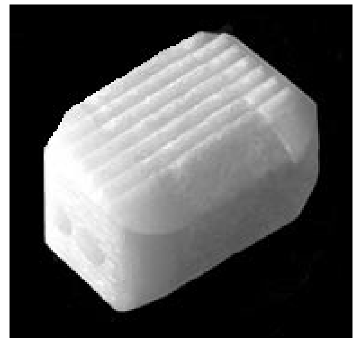

Figure 1: VG2 Cervical Allograft. LifeNet/DePuy Spine

MATERIALS AND METHODS:

The VG2 Cervical Allograft (VG2C) and VG2 PLIF Allograft (VG2 PLIF) are machined, frozen, cortico-cancellous allografts comprised of two cortical planks of bone flanking a cancellous center, held in place with bone pins. The cortical planks provide strength for anterior column support, while the cancellous bone provides an osteoconductive lattice for bone remodeling. VG2C is used for anterior cervical discectomy and fusion. VG2 PLIF is used in a posterior lumbar interbody fusion. VG1 ALIF Allograft (VG1 ALIF) is a solid cortical allograft processed from cortical rings. VG1 ALIF is used in anterior lumbar interbody fusion procedures.

Frozen VG2C, VG2 PLIF and VG1 ALIF samples were processed in a series of chemical and mechanical cleaning steps by LifeNet and shipped to a qualified irradiation facility for treatment. The frozen grafts were irradiated with a “worst case” target dose of 1.5 Mrad and received an actual dose of 1.58 Mrad. The validated AllowashXG system targets the irradiation dose of 1.0Mrad, therefore the 1.5 Mrad represents a higher than normal dose. The frozen grafts were shipped to DePuy Spine laboratories for testing. Each graft was reconstituted in saline (0.9% NaCl) for one hour prior to testing. Six or more samples per loading condition were tested in axial compression, compressive shear (45°) and torsion to determine ultimate strength. Axial compression and compressive shear tests were performed on an electromechanical Instron-4204 test frame and torsion was performed on an MTS-858 biaxial servohydraulic test frame. The maximum load for each test was reported and statistical comparisons between treatments were made using the Student's t-test with a p-value of 0.05. In addition, the strength of each graft was compared to published data on the strength of cervical or lumbar vertebral bodies and loads in the cervical or lumbar spine.

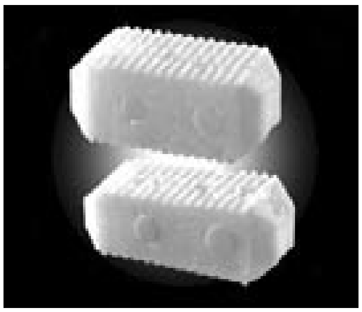

Figure 2: VG2 PLIF Allograft. LifeNet/DePuy Spine

RESULTS AND DISCUSSION:

As shown in Tables 1-3, for all graft types (Cervical, PLIF and ALIF) tested in axial compression, no statistical differences were found between the *AllowashXG* versus those that had been treated with the standard *Allowash* (Control) (P<0.05). VG2C grafts treated with *AllowashXG* had an average compressive strength that was 4.6 times that required to crush a whole cervical vertebral body (2,000 N)[8]. In reality, however, the graft is placed in the center of the disc space in contact with the trabecular bone of the adjacent vertebrae. Mosekilde et al. measured the compressive strength of vertebral trabecular bone to be 1-5 MPa from donors ranging in age from 15 to 91 years old[9,10]. The load that can be borne by the vertebral trabecular bone in contact with the graft can be calculated as follows:

Load = contact area X trabecular bone strength

Therefore, assuming a 5 MPa trabecular bone strength and a VG2C graft with a footprint area of 155 mm^2 (as tested in this study), the graft would subside into the vertebral endplate at a load of 775 N. The strength of the VG2C is nearly 12 times this value.

For thoracolumbar intervertebral joints, cadaveric studies have shown damage at compressive loads of 9.02 ± 1.08 kN[11]. Failures were observed at the endplates at average axial loads between 4,500 and 8,250 N, depending on the vertebral level[8]. When two VG2 PLIF grafts (13mm tall and 9mm wide) are used, their combined compressive strength is 2.5 times the highest of these endplate failure loads. VG1 ALIF grafts (20mm tall) alone were 4.4 times that of the 8,250 N total endplate failure load. Again, assuming that the grafts will be placed adjacent to the trabecular bone of the vertebrae, subsidence would be expected to occur at 1,890 N for two PLIF grafts of the size used in this study (9x21mm footprint) and at 962 N for the VG1 ALIF graft assuming a diameter of 27mm and wall thickness of 5 mm.

Table 1: VG2C Axial Compression

VG2C		Control n=6
	9,203	7,784
Std Dev	2,768	1,158
P = 0.20		

Table 2: VG2 PLIF Axial Compression

VG2 PLIF		Control n=6
Average (N)	10,314	11,002
Std Dev	1,909	802
P = 0.44		

Table 3: VG1 ALIF Axial Compression

VG1 ALIF		Control n=9
Average (N)	36,098	38,163
Std Dev	9,435	6,470
P = 0.572		

As shown in Tables 4-6, for all graft types (Cervical, PLIF and ALIF) tested in 45° compressive shear, no statistical differences were found between grafts that had been treated with AllowashXG versus those that had been treated with the standard Allowash (Control) (P<0.05). The average compressive shear strength of VG2C grafts was 1.6 times the whole cervical vertebral body compressive strength[8] and 6 times the load expected to cause subsidence into the trabecular bone. Two VG2 PLIF grafts had a compressive shear strength that was twice the maximum in vivo load measured in the lumbar spine during heavily lifting with back bent and knees straight (3,400 N)[12] and 5 times the expected trabecular bone subsidence load. Compressive shear strength of the VG1 ALIF was 1.2 times the maximum in vivo lumbar load and 6 times the load expected to cause subsidence into the vertebral trabecular bone.

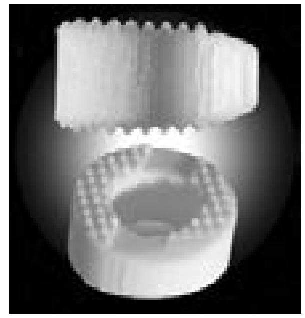

Figure 3: VG2 ALIF Allograft. LifeNet/DePuy Spine

Table 4: VG2C Compressive Shear

VG2C		*Control* n=6
Average (N)	3,277	3,513
Std Dev	396	630
P = 0.457		

Table 5: VG2 PLIF Compressive Shear

VG2 PLIF		*Control* n=6
Average (N)	3,383	2,637
Std Dev	497	1,333
P = 0.229		

Table 6: VG1 ALIF Compressive Shear

VG1 ALIF		*Control* n=8
Average (N)	4,144	3,828
Std Dev	1,202	1,253
P = 0.603		

The average torsional strength of the VG2C graft was 2.5 Nm (Table 7). The lower torsional strength of the *AllowashXG* treated grafts compared to the Control was statistically significant. However, Panjabi et al. reported that only 1.5 Nm of torque was required to produce a full range of motion in the cervical spine[13] and 5 Nm in the lumbar spine[14,15] without damaging soft tissue structures. Therefore, the torsional strength of the VG2C graft is still 1.6 times the torque required to produce a full range of motion in the cervical spine. Furthermore, in this loading condition, it is expected that relative motion at the interface between the graft and the vertebral body endplate would precede ultimate failure of the graft. Two VG2 PLIF grafts could withstand a maximum torque of 11.2 Nm, which is 2.2 times the torque required to produce a full range of motion in the lumbar spine.

Table 7: VG2C Torsion

VG2C		*Control* n=6
Average (N-m)	2.50	3.95
Std Dev	0.31	1.47
P = 0.039		

Table 8: VG2 PLIF Torsion

VG2 PLIF		*Control* n=6
Average (N-m)	5.64	6.71
Std Dev	0.87	0.88
P = 0.060		

The *AllowashXG* treatment group received a higher dose than will be administered during normal processing of these grafts. This safety factor also plays a part in the evaluation of these grafts and determination of their safety to use in spine surgery for their intended application.

CONCLUSIONS:

Since it is expected that the graft/endplate interface will fail prior to the graft in a torsional loading scenario, compression modes are the primary loading modes for setting design requirements. Taking into consideration the non-homogeneity of the donor bone raw materials, a safety factor of 2.5 should be considered. The test results presented here demonstrate that the VG2 Cervical Allograft, VG2 PLIF Allograft and VG1 ALIF Allograft, treated with a low-dose irradiation as part of the *AllowashXG* cleaning system surpassed this requirement with a safety factor of more than 2.5 times the design requirements for compressive loading modes. Therefore, the *AllowashXG* sterilization system is safe for use with VERTIGRAFT Allografts.

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68-20-035 Rev.00

OB02-60-000 9/04 DS/CSM