

## KyphOs FS™ Calcium Phosphate for Balloon Kyphoplasty: Verification of Compressive Strength and Instructions for Use

J. Schwardt<sup>1</sup>, T. Slater<sup>1</sup>, S. Lee<sup>1</sup>, J. Meyer<sup>2</sup> & R. Wenz<sup>2</sup>

<sup>1</sup> Kyphon Inc., Sunnyvale, CA, USA. <sup>2</sup> Sanatis GmbH, Rosbach, Germany

**INTRODUCTION:** KyphOs FS™ Calcium Phosphate Bone Substitute is a biomaterial for use during balloon kyphoplasty (BKP) treatment of type A1.1, A1.2 or A3.1 fractures of the vertebral body (VB). During BKP, a collapsed VB is restored with an inflatable bone tamp, and the resulting void is filled with a biomaterial to support the surrounding bone and prevent further collapse. This report describes results of in vitro compressive strength tests that verify the utility of KyphOs FS for its intended use, and help prescribe intra-operative and post-operative instructions for use. The study aimed to answer the following research questions: (1) Within a reasonable period of time after implantation into a fractured VB, will KyphOs FS attain an appropriate weight-bearing compressive strength, thus allowing safe transfer of the patient from the procedure table? (2) Will KyphOs FS attain its expected final compressive strength after undergoing a significant early load during the initial setting period?

**METHODS:** Cylindrical specimens (6 mm diameter x 12 mm) of KyphOs FS were prepared, immersed in 37°C water for various setting times, and compressed under displacement control at 1 mm/min. In the first protocol, specimens were tested after setting times of 5 minutes to 24 hours. In the second protocol, specimens underwent a single non-destructive load of 1 MPa at early times of 10, 20, and 30 minutes, then returned to the water bath and loaded again to failure after 2 hours. A Tukey-Kramer HSD test was used to detect statistically significant (p<0.05) differences among strength values.

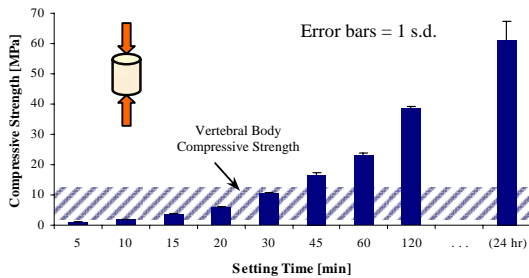


Fig. 1: Mean compressive strength (n=6) of specimens at various setting times, compared to the reported 2-12 MPa strength of a VB [1,2].

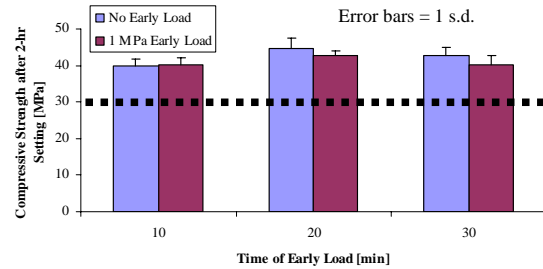


Fig. 2: Mean 2-hour compressive strength (n=6), with and without early load. 30 MPa is the minimum expected strength.

**RESULTS:** The compressive strength of KyphOs FS increased over time: 1.8 ± 0.2 MPa after 10 minutes, 3.4 ± 0.3 MPa after 15 minutes, 5.9 ± 0.3 MPa after 20 minutes, 38.5 ± 0.8 MPa after 2 hours, and 61.2 ± 6.1 MPa after 24 hours (Fig. 1). The 2-hour setting strengths in specimens with early loads of 1 MPa are not statistically different than controls with no early loads (Fig. 2).

**DISCUSSION & CONCLUSIONS:** The results suggest that KyphOs FS can attain compressive strength comparable to that of an intact VB within 15-20 minutes after implantation. Thus, the biomaterial is sufficiently strong for safe transfer of the patient within a reasonable setting time. The early load of 1 MPa used in the second protocol is similar to the compressive stress in a lumbar VB of a standing subject [2,3,4]. With or without an early load, the biomaterial attains its expected compressive strength.

Based on these data, KyphOs FS instructions for use have been prescribed as shown in Table 1.

Table 1. Timing Sequence in Instructions for Use

Time Interval	Activity
<b>4 min : 45 sec</b>	<ul style="list-style-type: none"> <li>▪ Mix Powder &amp; Liquid</li> <li>▪ Transfer to Bone Filler Devices</li> <li>▪ Deliver to VB</li> </ul>
<b>20 min</b>	Waiting period <i>after delivery to VB</i> before moving patient.
<b>24 hr</b>	Bed rest before weight-bearing.

**REFERENCES:** <sup>1</sup>L. Mosekilde (1990) *Bone* 11(2):67-73. <sup>2</sup>K. Singer et al. (1995) *Bone* 17(2):167-174. <sup>3</sup>A. Nachemson (1976) *Spine* 1:59. <sup>4</sup>H.J. Wilke et al. (1999) *Spine* 24(8):755-62