THE CREEP PROPERTIES OF THREE NEW LOW TEMPERATURE-CURING BONE CEMENTS:

A PRE-CLINICAL ASSESSMENT

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Introduction: Before new products are released on the orthopaedic market they should be analyzed at a pre-clinical stage and tested in restricted clinical trials [1]. That this process is not always adequately followed is demonstrated by unacceptable clinical results with some products which had to be withdrawn from the orthopaedic market [2,3]. In this study we assessed the creep properties of three new low temperature-curing bone cements (Cemex RX, Cemex System, Cemex Isoplastic) produced by one company (Tecres, Italy) and compared the results with those of Simplex P bone cement [4]. Determination of the creep properties of these new bone cements is important because if the cements creeps excessively, prosthetic stability can not be obtained and the cement should not be clinically used.

Methods: Three types of bone cements were considered. Cemex RX medium viscosity cement and Cemex Isoplastic high viscosity cement are delivered in the usual packages. Cemex System is a medium viscosity cement supplied as a closed disposable cartridge system designed to reduce the porosity in the cement. The bone cement was hand mixed according to the guidelines of the manufacturer and was hand packed in PTFE molds. The molds were sealed and the cement was allowed to cure for 15 minutes. In this way five standardized cylindrical compressive specimens (32 mm in length, 17 mm in diameter) were obtained for each cement type. The specimens were stored in saline solution at a temperature of 37°C for a period of at least one month to allow for full polymerization and water uptake. A dynamic sinusoidal compressive stress was applied ranging from zero to 20 MPa with a frequency of 1 Hz for a period of 250,000 cycles (Fig. 1). Testing environment was saline solution at a temperature of 38.5 °C to simulate the in-vivo temperature elevation during activities. The displacements were measured using an Instron extensometer with a resolution of 0.58 microns. The displacement and force signals were recorded and stored in a computer. After testing the relationships between the amount of creep and the number of loading cycles were determined and fitted to the equation:

$$\log \varepsilon_c = A * \log N + B \qquad (1)$$

where ε_c is the creep strain, N the number of loading cycles and A and B are the parameters to be determined. Statistical analyses were performed to assess the differences of the three new bone cements with Simplex P in terms of their creep strain at the end of the test (ε_{tot}), the parameters A and B of formula (1), and the elastic modulus (E) as determined by the dynamic strain and stress level at the beginning of the tests.

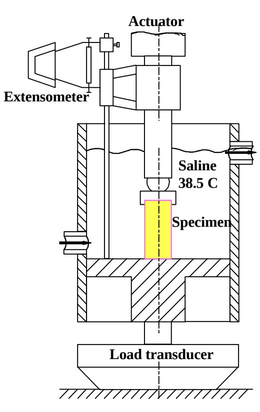

Fig. 1: The testing set-up of the dynamic compressive creep experiment

Results: The three types of bone cement showed typical creep deformation curves with relatively high initial creep rates, levelling off to a rather constant value (Fig. 2). At the end of the test, Cemex RX produced the most creep followed by Cemex System. Both had total creep strains that were significantly higher as compared to Simplex P cement (Table I). Cemex Isoplastic produced a creep curve which was almost identical to that of Simplex P. Parameter A and B were only different for Cemex System relative to Simplex P. The elastic moduli of the three cements were very similar to that of Simplex P bone cement.

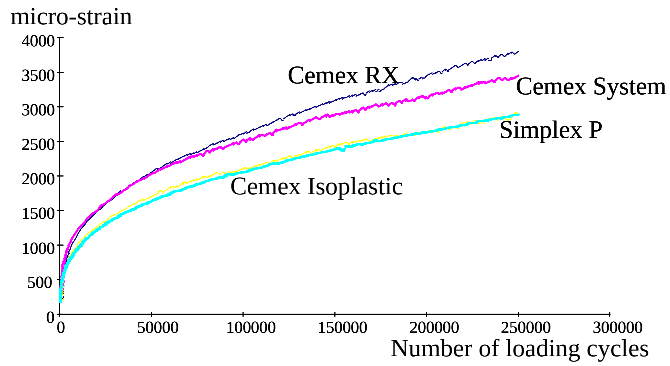

Fig. 2: Averaged creep strains versus number of loading cycles for the four cement types.

	ε_{tot}	A	B	E (MPa)
Cemex RX	3811 (sd=521) *	0.3743	-4.366	2153
Cemex System	3456 (sd=397) *	0.3101 *	-4.148 *	2131
Cemex Isoplastic	2906 (sd=173)	0.3386	-4.449	2252
Simplex P	2888 (sd=142)	0.3488	-4.426	2219

Table I: The various parameters of the four bone cements. '' indicates a statistical significant difference relative to Simplex P (p<0.05).*

Discussion: The creep rates of the three new bone cements were similar to that of Simplex P. Nevertheless, it is relevant to know whether these creep properties are at the lower or upper end of the acceptable range. If they are in the upper range, the new cement may allow for more prosthetic migration; if they are in the lower range, prosthetic migration may be more disturbing and may be associated with cement failure.The higher creep values of Cemex RX and Cemex System do indicate that, if creep indeed plays an important role in prosthetic migration, higher prosthetic subsidence rates may be expected with these cements. Two year results of a clinical trial with Cemex RX do not indicate that this is the case. On the contrary, early migration found with Cemex RX appeared to be smaller than that found with a conventional bone cement (Palacos R) [5]. This may indicate that cement creep does not play a major role in prosthetic migration.
Although Cemex RX and Cemex System produced higher creep rates as compared to Simplex P, these differences were not considered as excessive. Hence, although other tests are required to assess safety and efficacy of these new cements, the creep properties can be considered as adequate for clinical use.

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