ADDITIONAL MECHANICAL TESTS OF BONE CEMENTS

D. HANSEN, J. STEEN JENSEN

A revision of the ISO-standard for bone cement testing has been proposed to include compressive strength after 24 hours in air and 4-point bending testing after 50 hours in a 37° water bath.

Nine commercially available bone cements were tested in accordance with the new program. Compressive strength varied from 78 to 100 MPa, bending strength from 48 to 74 MPa and bending modulus from 2.2 to 2.8 GPa. The highest strengths, but also the highest stiffness, were encountered with Simplex® brands and low-viscosity cements.

Keywords : bone cement ; biomaterials.
Mots-clés : ciment ; os ; biomatériaux.

INTRODUCTION

A direct relationship between the initial properties of bone cement and its longevity has been suggested (3, 5, 7), Saha and Pal (6) have given a comprehensive review of the literature concerning a wide range of mechanical characteristics of bone cement. Testing procedures have varied considerably, and comparative testing included only a few brands.

Standards for bone cement (1, 4) only required testing of compressive strength, but a revision of the ISO-standard proposed in 1987 also added bending modulus and bending strength. Our purpose was to provide data on the mechanical properties of nine commercially available bone cements tested according to the revised program, and to investigate the influence of the testing velocity.

MATERIALS AND METHODS

The following bone cements were tested : Cerafix® (low viscosity ; Ceraver, France), CMW 1® and CMW 3® (standard and low viscosity ; CMW Laboratories Ltd., UK), Palacos E® (low viscosity), Palacos G® (gentamycin-containing), and Palacos R® (standard ; Kulzer and Co GmbH, Germany), Simplex P® with or without radiopacifier (Howmedica Inc., USA), and Zimmer-D® (Zimmer Inc., USA).

The liquid MMA-monomer and the PMMA powder were mixed manually in a cartridge (one beat/sec) in accordance with the manufacturers' recommendations. At the commencement of the dough time test specimens were molded at room temperature from two samples of each brand. Specimens with visible air inclusions or molding errors were discarded.

Mean values and standard deviations were calculated and the results compared applying the Mann-Whitney two-sample rank sum test ($P = 0.05$).

For *compressive strength testing* cylindrical specimens ($\varnothing = 6.0 \pm 0.1$ mm, $L = 12.0 \pm 0.1$ mm) were molded in empax steel molds and the ends grounded with silicone carbide abrasive. Testing was performed after 24 hours of storage at room temperature by constantly increasing load (M5 testing machine, Nene Instruments Ltd., UK) with simultaneous recording of load versus deformation. The average compressive strength was calculated from at least 6 specimens, using the load to cause fracture, the 2.0% offset load, or the upper yield point load, whichever occurred first, as required by the standard. A constant cross-head speed of 20 mm/min (strain rate $2.0 \cdot 10^{-3}$ sec^{-1}) was applied in accordance with the standard. In order to investigate the influence of lower velocity, tests at cross-head speeds of 12 mm/min (strain rate $1.7 \cdot 10^{-3}$ sec^{-1}) and 2 mm/min (strain rate $0.28 \cdot 10^{-3}$ sec^{-1}) were also performed.

Department of Orthopaedics U-2162, Rigshospitalet, University of Copenhagen, DK-2100 Copenhagen Ø, Denmark.
Correspondence and reprints : J. Steen Jensen.

For determination of *bending modulus and bending strength*, 6 flat, smooth plates of each brand were molded in Teflon moulds (length = 75 mm, width = 10 mm, depth = 3.3 mm) and grounded on the edges and top face, but not on the bottom face, which was used as the tensile face during bending. In accordance with the revised standard the specimens were immersed in a 37° water bath for 50 hours. Testing was applied in a 4-point bending rig using a cross-head speed of 5 mm/min, and the average bending modulus and bending strength were calculated as described in the standard.

RESULTS

The compressive strength exceeded the standard requirement of 70 MPa in all cases (table I). The low-viscosity cements and the two Simplex® brands were, however, significantly stronger, and the Zimmer-D® cement was the weakest. The addition of gentamycin by the manufacturer to Palacos® did not affect the strength.

The variation between test specimens was rather small in the Palacos R® series, especially with respect to the highest and lowest load for the same specimen, although this brand had the widest range (table II). The compressive strength increased nonlinearly with increasing strain rate, as did the deflection (table III).

Table I. — Compressive strength of bone cements

	MPa	SD
CMW 1®	87	2,7
Palacos G®	86	1,1
Palacos R®	84	4,7
Simplex P®	100	1,9
Simplex RO®	99	3,0
Zimmer-D®	77	1,6
Low viscosity cements :		
Cerafix®	98	4,6
CMW 3®	100	2,5
Palacos E®	95	0,7

Table II. — Compressive load data for 6 Palacos R® specimens

Specimen	Peak load N	Upper yield load N	2% offset load N
1	2470	2470	2460
2	2450	2450	2450
3	2500	2490	2480
4	2490	2480	2480
5	2240	2230	2220
6	2160	2160	2140

Table III. — Compressive bone cement strength and deflection at different test velocities

	20 mm/min		12 mm/min		2 mm/min	
	MPa	mm	MPa	mm	MPa	mm
CMW 1®	87	1,0			69	0,9
Palacos G®	86	1,1			68	0,9
Palacos R®	84	1,0			67	0,9
Simplex P®	100	1,2	92	1,1	79	1,0
Simplex RO®	99	1,4	94	1,1	80	1,0
Zimmer-D®	77	1,0	69	0,9	60	0,8
Low viscosity cements :						
Cerafix®	98	1,2			78	1,0
CMW 3®	100	1,2	95	1,1	77	1,0
Palacos E®	95	1,2			75	1,0

Only the Zimmer-D® cement was at lower limit of the standard requirement of 50 MPa in bending strength, but the bending modulus exceeded the required 1,800 MPa (table IV). The highest strength was encountered with the two Simplex® brands and two low-viscosity brands (Cerafix® and Palacos E®), which also had the highest stiffness ($p < 0.05$), together with the third low-viscosity brand (CMW 3®).

Table IV. — Results of 4-point bending test of bone cements

	Strength MPa	SD	Modulus MPa	SD
CMW 1®	61	1,9	2317	18
Palacos G®	61	1,6	2237	77
Palacos R®	66	1,5	2348	77
Simplex P®	74	3,7	2522	137
Simplex RO®	71	2,0	2563	81
Zimmer-D®	48	2,8	2214	79
Low viscosity cements :				
Cerafix®	71	1,3	2528	75
CMW 3®	65	4,9	2771	138
Palacos E®	74	1,0	2647	19

DISCUSSION

Bone cements of PMMA are viscoelastic in nature and behave like a Kelvin body ; i.e. idealized as a serial connection of a linear spring and a dashpot. This means that the load-deformation curve is nonlinear, being asymptotic to a straight line, the slope of which is equal to the spring constant. Furthermore the rate of deformation, i.e. the strain rate, influences the slope of the curve and the peak load. A higher strain rate leads to a higher stiffness and a higher ultimate load (2, 6). This is the background for the standard requirements of testing at cross-head speeds in the narrow range of 20 to 25.4 mm/min, and the recording of the lowest load at the 2.0% proof load, the fracture load or the upper yield load whichever occurs first. The strain rate will be close to $3*10^{-3}$ sec^{-1} at this velocity.

Differences in strength between the brands can be attributed to variations in molecular weight, degree of polymerization, residual monomer content and packing of PMMA-beat. These factors are all influenced by the exothermal chemical reaction. In our study the highest strength values were encountered with low-viscosity cements, which can be explained by better packing and polymerization, as oxygen, which inhibits the chemical reaction, is more easily released. The high strength of Simplex® brands might result from the PMMA-styrene copolymer. The strongest bone cements also have the highest stiffness. The ideal modulus of elasticity is unknown, but too high stiffness might lead to disuse osteoporosis.

As pointed out in a comprehensive review (6), published data on strength cover a wide range, from 64 to 103 MPa in compression. The existing standards only require compressive strength testing to describe the mechanical properties of bone cements. Consequently various standards for plastic materials as well as related calculations of elastic modulus have been used for bending and tensile tests. Comparative data are difficult to generate. The currently accepted revision of the ISO-standard includes compressive strength after 24-hour storage in air as well as bending modulus and 4-point bending strengths after 50 hours in 37° water. These tests should give sufficient comparative data, if followed, as the proposed test specimens and procedures are not very susceptible to factors that increase stress, such as air inclusions and moulding errors. Consequently the test results reflect the properties per se and not the efficacy of the mixing procedure.

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SAMENVATTING

D. HANSEN en J. STEEN JENSEN. Aanvullende mechanische testen voor botcementen.

Een revisie van de ISO-criteria voor botcement werd door de auteurs voorgesteld, zodanig dat de resistentie versus compressie na 24 u in open lucht en een 4 punt flexietest na 50 u in een bad op 37°, ingeschakeld worden.
Negen botcementen uit de handel werden getest, volgens dit nieuw programma. De resistentie versus compressie schommelde tussen 78 en 100 MPa ; de resistentie versus flexie tussen 48 en 74 MPa en de flexiemodulus van 2,2 tot 2,8 GPa. De grootste resistentie, maar ook de grootste rigiditeit, werd gevonden bij Simplex® en bij de cementen met lage viscositeit.

RÉSUMÉ

D. HANSEN et J. STEEN JENSEN. Étude des propriétés mécaniques des ciments à os.

Une révision des critères ISO, en ce qui concerne le ciment osseux, est proposée par les auteurs, de manière à inclure une étude de la résistance à la compression après 24 h à l'air libre et un test de flexion à 4 points après 50 h dans un bain à 37°.
Neuf ciments commercialisés ont été testés selon ce nouveau programme. La résistance à la compression varie de 78 à 100 MPa ; le test de flexion de 48 à 74 MPa et le module de flexion de 2,2 à 2,8 GPa. La plus forte résistance, mais aussi la plus grande rigidité, fut observée pour le Simplex® et pour les ciments à basse viscosité.