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Comparative fatigue validation of bone cement enriched with sodium fluoride

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Sodium fluoride (NaF) is an agent promoting bone formation around the hip implant and it can be used as an additive in poly(methyl methacrylate) (PMMA) bone cement. The influence of such an addition on the fatigue endurance of the material as used in biomedical applications was tested. Fatigue tests were performed to simulate the mode of loading that the cement mantle withstands *in vivo*. Tensile tests were conducted according to current standards and based on protocols being previously validated.

The results obtained prove that the addition of NaF (12% in weight) to PMMA bone cement does not have any detrimental effect on the fatigue resistance of the material. This percentage is higher than that normally used for $BaSO_4$ that is added to PMMA as a radiopacifier. This latter addition was proved to reduce the fatigue resistance of the material.

Key words: fatigue resistance, bone cement, sodium fluoride, bone formation

1. Introduction

Poly(methyl methacrylate) (PMMA) bone cement in cemented joint arthroplasties is the only material currently used for fixing the components and transferring loads from the artificial joint to the bone. Nevertheless, it is not without some mechanical drawbacks (Lewis [4]). It has been confirmed that in aseptic loosening of cemented hip implants the "weak link" is the cement mantle surrounding the femoral stem (Jasty et al. [3]). Disruption of cement–implant interface, cement–bone interface and bulk of the cement mantle act as the main initiating factors as far as prosthetic loosening is concerned (Jasty et al. [3], Topoleski et al. [8]). The cyclic nature of *in vivo* hip loading suggests a fatigue failure mechanism. Therefore, in a characterization of this acrylic material it is of a critical importance to focus our attention on its long term behaviour.

Sodium fluoride (NaF) is an agent that stimulates *in vitro* and *in vivo* activity of the osteoblasts (Amstutz [4], Magnan et al. [5]). Due to such a stimulation, sodium fluoride can be added in a crystal form to the PMMA bone cement powder before the *in situ* polymerization process. In this respect, the fluoride released by the cured cement to the surrounding bone tissue should be able to prevent *in vivo* bone resorption around the prosthetic implant (Magnan et al. [5]), which is a factor leading to aseptic loosening of arthroplasties (Amstutz [4]).

The influence of NaF on PMMA bone cement fatigue behaviour is currently unknown. The aim of this investigation was to test the influence of NaF on the mechanical long-term resistance of bone cement. Fatigue tensile testing was conducted on bone cement without additives (blank) and bone cement enriched with NaF of a high percentage by weight (12%).

2. Materials and methods

An experimental prototype PMMA bone cement with 12% sodium fluoride was tested. For comparison, PMMA without additives (blank) was tested under identical conditions.

For each of the cement types tested, all specimens were made from the same batch. The specimen dimensions and geometry were chosen according to the ISO 527-2 standard (figure 1). The mixing and seasoning were performed according to the ISO 5833 standard.

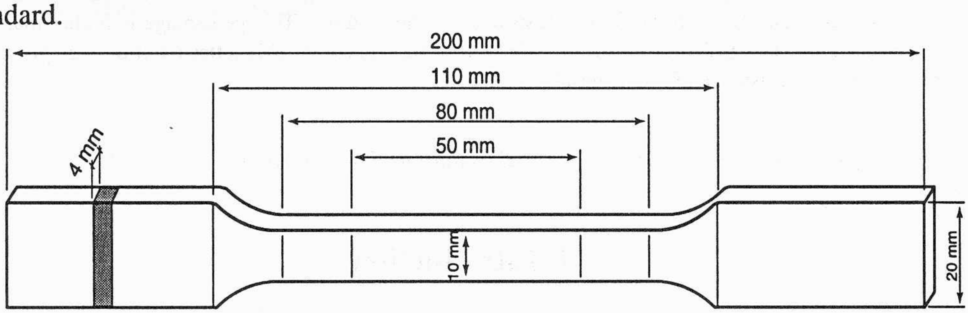

Fig. 1. Geometry and dimensions of the specimens (ISO 527-2-specimen type 1A) subjected to fatigue tests

Before fatigue tests, the pore size was measured on X-ray films under an optical microscope (magnification 20×). A criterion for specimen rejection previously validated and based on the size of internal pores was adopted (Cristofolini et al. [6]). This criterion has the advantage of reducing the scatter of results by discarding specimens with excessive porosity prior to testing.

Sinusoidal uniaxial zero-tension loading was applied to each specimen with a servohydraulic testing system (MTS Mini Bionix 858, MTS Systems Corp., Minneapolis, Minnesota). The tests were carried out at 4 Hz in the air at a room temperature and ran to failure (the number N of cycles to failure being recorded). The test was stopped for the specimens that did not fail after 2×10^6 cycles and the corresponding stress level was estimated as the lower bond for the endurance limit.

The fatigue behaviour of bone cements tested was characterized by a Wöhler diagram, according to a previously validated method (Tanaka [7]). Data in the slope part of the Wöhler curve were plotted for the two materials. A slope value for each bone cement was calculated based on linear regression.

Finally, the slopes estimated for the two cements were statistically compared using Chi-squared distributions.

3. Results

The S–log N data in the slope part of the Wöhler diagram for the two materials are plotted in figure 2. The statistical analysis demonstrated the validity of the linear model ($p < 0.01$). The estimated values of R^2 were greater than 0.85, indicating the goodness of fit of the data to a straight line.

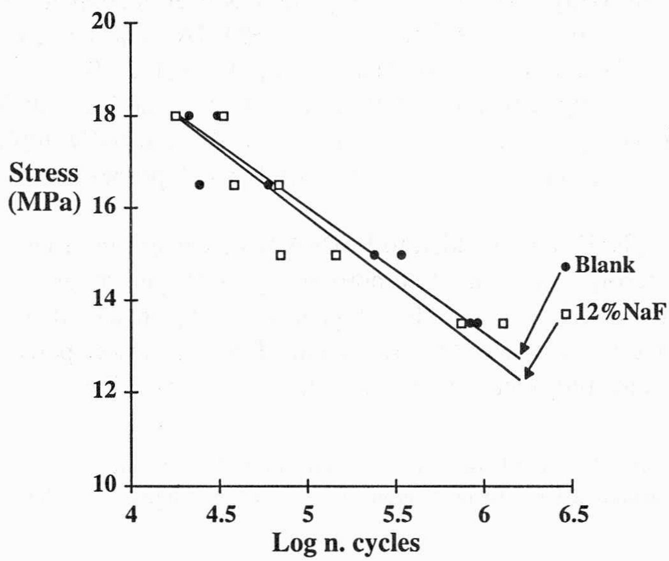

Fig. 2. Slope part of S–N diagram for the bone cement without additives (blank), and PMMA enriched with 12% NaF

There was no significant difference between the slope corresponding to the blank and that corresponding to the cement enriched with NaF when a confidence threshold

$p = 0.1$ was assumed. The same lower bond (i.e. 12 MPa) was estimated for the endurance limit corresponding to both materials.

4. Discussion

The lower bond for the endurance limit and the slope part of the curve obtained in the Wöhler plots provide information about the fatigue resistance of the materials tested.

The results obtained in this investigation show that there is no significant difference between the slope and the lower bond for the endurance limit of the two cement formulations tested. The same slope means that the same increase in the number of cycles to failure is related to a unitary decrease in the stress level associated. The same lower bond for the endurance limit provides a rough estimation of the maximum peak stress the two materials can withstand repeatedly without failure.

The results obtained in this study prove that the addition of NaF does not alter the long-term mechanical resistance of *in situ* polymerized PMMA used as bone cement in arthroplasties.

In a vast majority of PMMA bone cements, a radiopacifier (chiefly barium sulphate, $BaSO_4$) is added to the powder in 9–10 weight percentage, so as to render the material visible on X-ray films. Barium sulphate has been recognized as a factor contributing to the reduction of the fatigue life in PMMA bone cements, both *in vivo* (Topoleski et al. [8]) and *in vitro* (Tanaka [7], Topoleski et al. [9]).

Conversely, the fatigue results obtained show that the addition of NaF crystals in a higher percentage by weight (12%) compared to those usually applied to a radiopacifier does not influence the long-term mechanical properties of PMMA bone cement.

In conclusion, NaF can be added to PMMA bone cement in order to prevent periprosthetic bone resorption, without compromising its fatigue resistance. As far as the quantity needed is concerned, a study (Magnan et al. [5]) reveals that fluoride release by a PMMA bone cement with 6% by weight of NaF (a lower percentage than that tested in the present study) leads to a satisfactory bone formation.

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