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INVESTIGATION

Influence of the fixing technique on the quality of the cement mantle in knee arthroplasty. Experimental study on a synthetic model ☆

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KEYWORDS
Bone cement;
Total knee arthroplasty;
Synthetic model;
Digital image analysis

Abstract

Objective: To assess the quality of the cement mantle obtained with different fixation techniques in knee arthroplasty.

Material and method: An experimental study with synthetic bone models (16 tibias and 16 femurs), employing a PROFIX® prosthetic tool and high viscosity cement (Palacos R®), applied on the second and fifth minute after mixing the components using two fixation techniques: directly over the bone surface by digital pressure (technique M), or over the prosthetic implant (technique P). We performed a digital analysis on the photographs of the models, determining for each cut plane: mean penetration, percentage penetration and length of the cement mantle.

Results: Technique M applied in minute 2 achieved a better quality mantle, with a mean penetration of 4.44 mm and a percentage penetration of 79.36%; technique P in minute five obtained poorer results (2.12 mm and 45.79%), these differences being significant ($p=0.029$). The femur tangential fixation (anterior and posterior) was unstable, with a mean penetration of 2 mm. The mean length of the mantle in these two planes with technique M was 35 mm and 17.9 mm, compared with technique P (12.5 mm and 7.2 mm), which achieved a coverage of < 50% ($p=0.01$).

Conclusions: Cementing over the bone surface with digital pressure achieves a greater depth and percentage penetration than direct cementing over the prosthetic implant, with greater differences when the cement viscosity is higher. Tangential fixation of the anterior and posterior cuts is very unstable if it is cemented over the implant.

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PALABRAS CLAVE
Cemento óseo;
Artroplastia total de rodilla;
Modelo sintético;
Análisis digital de imagen

Influencia de la técnica de cementación sobre la calidad del manto de cemento en la artroplastia de rodilla. Estudio experimental sobre un modelo sintético

Resumen

Objetivo: Evaluar la calidad del manto de cemento obtenido con diferentes técnicas de cementación en la artroplastia de rodilla.

Material y método: Estudio experimental con modelos óseos sintéticos (16 tibias y 16 fémures), empleando instrumental protésico PROFIX® y cemento de alta viscosidad (Palacos R®), aplicado en el segundo y quinto minuto tras la mezcla de componentes mediante dos técnicas de cementación: directamente sobre la superficie ósea por presurización digital (técnica M), o sobre el implante protésico (técnica P). Realizamos análisis digital de las fotografías de los modelos determinando para cada plano de corte: penetración media, porcentaje de penetración y longitud del manto de cemento.

Resultados: La técnica M empleada en el minuto dos consiguió una mejor calidad del manto, con una penetración media de 4,44 mm y un porcentaje de penetración del 79,36%; la técnica P en el minuto cinco obtuvo los peores resultados (2,12 mm y 45,79%), siendo estas diferencias significativas (p=0,029). La cementación de los planos tangenciales femorales (anterior y posterior) resultó precaria, con una penetración media de 2 mm. La longitud media del manto de cemento en estos dos planos con la técnica M fue de 35 mm y 17,9 mm, en contraste con la técnica P (12,5 mm y 7,2 mm), que consiguió una cobertura < 50% (p=0,01).

Conclusiones: La cementación sobre la superficie ósea con presurización digital consigue mayor profundidad y porcentaje de penetración que con la cementación directa sobre los implantes protésicos, con mayores diferencias cuanto mayor es la viscosidad del cemento. La cementación tangencial de los cortes femorales anterior y posterior resulta muy precaria si se cementa sobre el implante.

Introduction

The biggest problem affecting the success of total knee arthroplasty (TKA) is the loosening of its components, mainly the tibial component, basically due to micro-mobility in the bone-cement interface. While the use of uncemented components in hip arthroplasty has earned itself enormous popularity, the same cannot be said for TKA. The use of uncemented components is attractive, but the best results so far in terms of the rate of complications and mean survival (> 95% after 15 years) have been achieved with cemented components.[1-4] Although recent papers such as that by Ferrer-Santacreu et al. have found high survival rates and excellent long-term functional results with uncemented implants,[5] others such as the 2009 meta-analysis published by Gandhi et al. reached the conclusion, after bringing together 15 controlled, randomized studies, a probability of implant failure due to aseptic loosening 4.2 times greater for uncemented fixation, without finding any statistically significant differences in terms of the functional result between both groups.[6]

Now that the theoretical advantage of cementation has been established, a whole spectrum of techniques has arisen for the application of bone cement, the same as has happened with hip arthroplasty, and makes it necessary to specify the method and optimize the steps.[7] Using current cementation techniques on available prosthetic designs, doubts have been raised in connection with the behaviour of the cement mantle regarding the distribution and penetration achieved for each of the applicable techniques. On the one hand, cement can be used in a more or less extensive manipulation and pressure time-window with a widely varying visco-elastic behaviour, depending on the apparent initial viscosity and the additives to the methyl acrylate compound. On the other hand, within the manual application technique and without including the use of devices such as a syringe or gun, the cement can be applied directly either entirely on the internal surface of the prosthetic implant or else on the pre-prepared bone surface, with a full range of intermediate possibilities for application distributed between the two surfaces.

The aim of the present study has been to assess the influence of the cementation technique on the quality of the cement mantle in TKA, starting from the conceptual hypothesis that the direct application on the bone surface with finger-pressure packing achieves a greater penetration of the cement mantle, and therefore better bone-cement interdigitation, than the direct application technique on the prosthetic implant; these differences are greater in the femoral planes with tangential cementation (anterior and posterior slices) and are decisive when it comes to application within the handling time-window.

Material and method

An experimental study has been conducted using third-generation synthetic models validated for use as a study material for instruments and testing devices in the field of

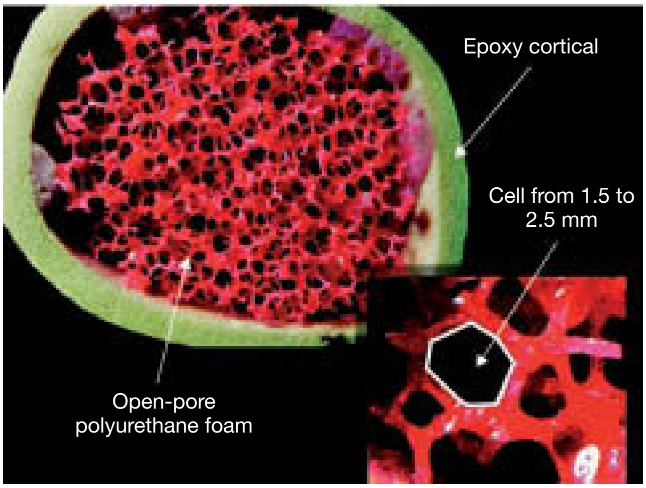

Figure 1 Detail of the synthetic bone analogue (Sawbone®): cortical and trabecular tissues simulated using epoxy resin and open-pore polyurethane foam, respectively.

orthopaedics by numerous articles,[8-11] as well as by the international ASTM standard.[12] These models act as anatomical replicas (16 left tibias and 16 left femurs) comprising a fibre cortex based on polyepoxide resin to imitate bone cortex, wrapped around a semi-rigid open-pore polyurethane foam comprising multiple 1.5 to 2.5 millimetre cells (Fig. 1), by way of trabecular bone tissue (models 1130-130 and 1117-131 by Sawbones®, Pacific Research Laboratories, Inc., Malmo, Sweden). The items were cut using the respective instrument cutting blocks for Profix® model knee prosthesis (Smith&Nephew, Memphis, Tennessee, USA), fixed in anatomical position to reproduce real working conditions during TKA, and following the usual steps reflected in the surgical technique described by L. Whiteside, using intramedullary guidance. Following pulsed washing of the parts, it was possible to eliminate the cutting residue and reproduce a wet setting that is similar to biological conditions.

The bone cement used in this study was fast-setting and high-viscosity Palacos R® polymethyl methacrylate (PMMA) (Heraeus Medical GmbH, Wehrheim, Germany). This cement was stored and prepared in an environment with controlled temperature and relative humidity. The cement's components were not subjected to prior chilling and were prepared manually by mixing on a tray at a mean ambient temperature of 19.5°C and a relative humidity of 55-60%. The manufacturer's instructions were followed during the mixing process. Each ampoule with 20 mL of monomer was mixed with a sachet of 40 g of polymer, added in that order and then mixed in a clockwise direction at a steady frequency for 30 seconds timed by a watch. Each cement tray allowed cementing of two tibial or femoral parts.

Four cementing groups were established for both the tibial and the femoral parts, with four elements in each group (n=4), depending on the technique for applying the cement and the apparent viscosity of the preparation. Thus "technique M" was established as direct manual cementing on the bone surface with finger-pressure packing, exerting pressure perpendicularly to each cut plane, and "technique P" was uniform cementing on the whole internal surface of the prosthetic implant. In terms of the cement viscosity, two groups were cemented in minute two following the mixing of the components (M2 and P2) and another two in minute five (M5 and P5) (Fig. 2). In order to facilitate the re-use of the prosthetic components and to make the cementing process of all the parts more dynamic, they were covered with an 11 μm thick layer of unlaminated aluminium foil, impregnated with pure vaseline on its internal face. As prosthetic implants, a 150 x 50 x 5 mm steel plate was used in the case of the tibial parts and a size 5 prosthetic shield on the femoral parts. The cemented models were cut using a 0.25 mm diamond band saw in an identical sagittal plane 20 mm from the medial margin of the tibial parts, and at the mid-point of the external condyle of the femur, 20 mm from its lateral margin.

Digital photographs were taken parallel to the slice in the parts at a distance of 25 cm from the same, using an Olympus E-510 digital reflex camera with a 14-42 mm lens, obtaining 10 megapixel images with a resolution of 314 ppi (points per inch) in JPEG format (EXIF 2.2). For the digital analysis of the image, the Adobe Photoshop CS4® programme was used. The first step was the re-scaling of the images, using a printed millimetric scale as a reference attached to the surface of the cemented part (Fig. 3). Using this scale, the small differences in proportion of each photograph were adjusted, the pixels were converted to millimetres and the magnification of the digital template of the femoral shield could also be adjusted to present it on the photograph of the femoral parts.

For the measurement of the tibial cement mantle, a rectangular layer 38 x 10 mm was defined, delimited at the top by a reference line presented on the anterior and posterior cortical limits of the tibial cut plane (Fig. 4), whereas for the femoral parts five measurement areas were created corresponding to the five cut planes on these parts, using as a reference the template of the prosthetic shield (area 1=anterior, area 2=anterior bevel, area 3=distal, area 4=posterior bevel, area 5=posterior). Using the "Curves" tool, the histogram of the image was worked on within the respective analysis areas, with an entry value of 50 and an exit value of 0 as the limits for the whites, and entry value of 52 and an exit value of 100 as the limits for the blacks, thus achieving a "Duotone" image in which the cement mantle was clearly defined as a homogeneous white area. Using the "Magic wand" tool, adjusted to a tolerance value of 1, the cement area was selected for each analysis area. The resulting layer of subtraction of the cement mantle (Fig. 5) was superimposed by transparency on the original image to verify that only the cement mantle was selected. Finally, using the "Record measurements" tool, the mantle's measurements were recorded for the following variables: total area of the cement mantle (At), area penetrated (Ap), maximum height of the mantle (Al), maximum width (An), mean depth of penetration (Pr, calculated as the ratio of Ap to An) and the penetration percentage (%P, calculated as the ratio of Ap x 100 to At).

In addition to the usual descriptive statistics, inferential analysis as performed using non-parametric tests: Kruskal-Wallis for the comparison of more than two populations and the Mann-Whitney test for the contrasting of two

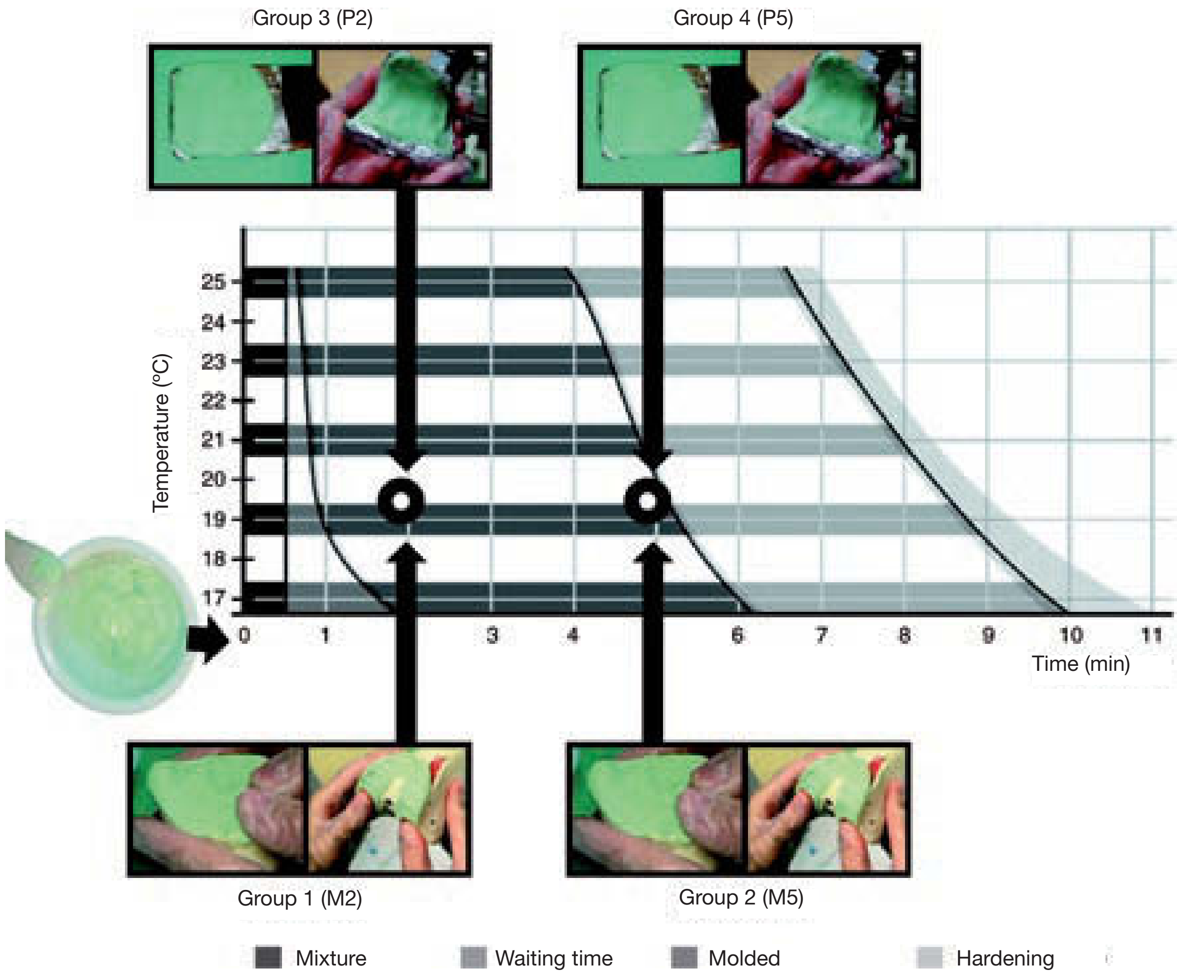

Figure 2 Cementing groups by technique and minute of application of the bone cement. M2 and M5: cementing on the bone surface with digital pressure in minute two and in minute five. P2 and P5: cementing on the prosthetic implant.

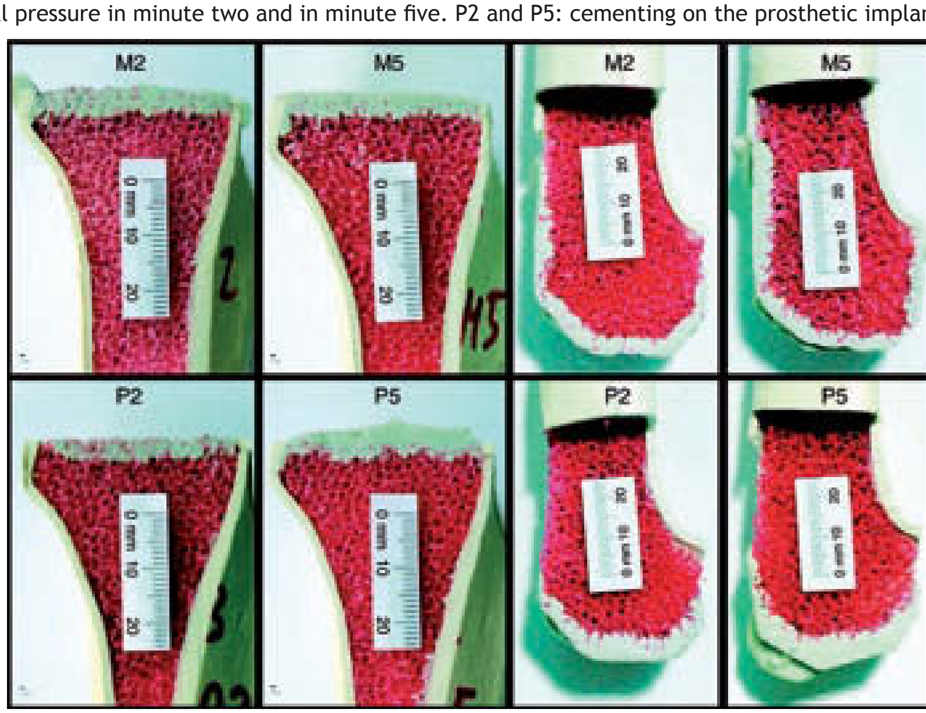

Figure 3 Digital photographs of tibial parts (left) and femoral parts (right) for each cementing group, already cut and presented with a millimetric graphic scale. Each image was centred and re-scaled for subsequent analysis.

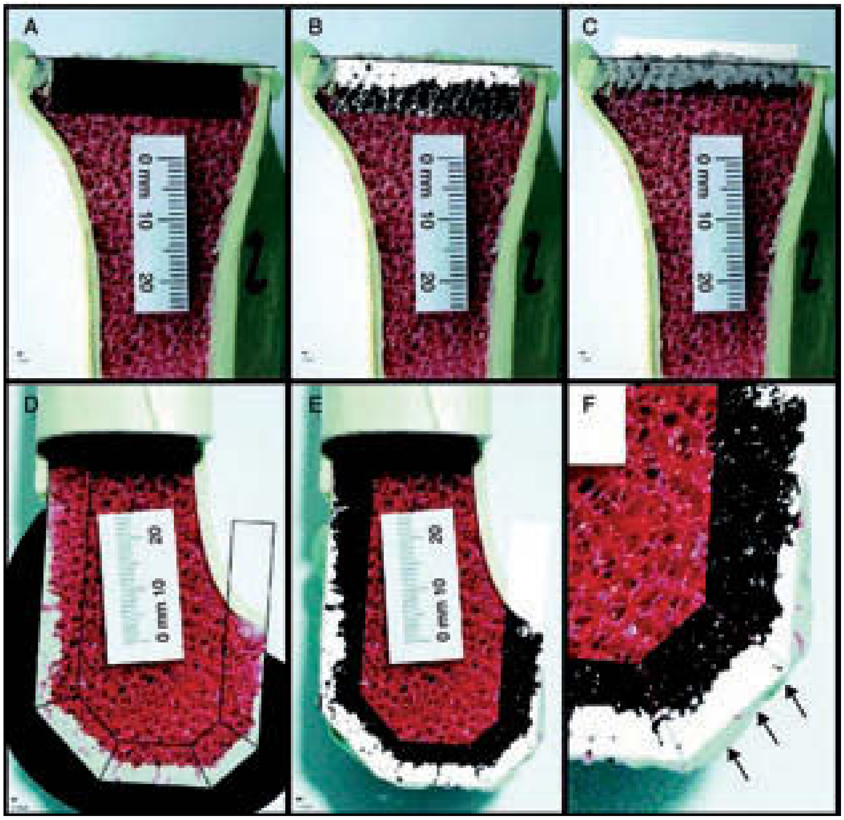

Figure 4 A) Measurement area for the tibial cement mantle, adjusted on cortical margins. B) Conversion of the area to a binary image (duotone). C) Measurement area for the calculation of the penetration percentage. D) Femoral part cemented with an adjusted prosthetic template. E) Delimitation of the five femoral areas for study, in binary image. F) Detail of the cement mantle not penetrated and not included in the measurement (arrows).

independent samples. The SPSS 18® computer package (PASW Statistics 18) for Microsoft Windows® was used, setting the significance level at p ≤ 0.05.

Results

In the tibial parts, the mean penetration (Pr) for the M2 group was 4.52 mm (3.97-4.77) and 2.95 mm (2,76-3,52) for the M5 group; for the P2 group it was 2.82 mm (2.27-3.08) and 2.14 mm (1.86-2.35) for the P5 group; these differences were statistically significant (p=0.007). In terms of the percentage of penetration (%P) for the cement mantle, the M2 group achieved a penetration of 79% (73-87%) in contrast with the P5 group which achieved 45% (39-52%) penetration (p=0.029). No significant differences were found between the M5 group with a penetration of 57% (49-62%) and the P2 group with a penetration of 69% (52-79%) (p=0.2) (Fig. 6). Nor were significant differences found in the percentage of penetration between the groups in which the cement was applied with the same viscosity, that is to say between M2 and P2 (p=0.34), or between M5 and P5 (p=0.06).

As for the results in the femoral parts, the first calculation was the mean penetration of the cement mantle for each area in the cementing of the femur, regardless of the cementing technique used (Fig. 7). Similarly, the mean penetration was calculated for groups by cementing technique, regardless of when it was applied, with the following mean values being found for the M2+M5 groups: 4.03 mm on the anterior plane (area 1), 3.20 mm on the distal plane (area 3) and 2.84 mm in the posterior plane (area 5); for the P2+P5 groups, on the other hand, area 1 had a mean penetration of 1.80 mm, in area 3 the mantle penetrated 4.47 mm on average, and in area 5 the average was 2.64 mm; these differences were sign (p=0.001). The mean length of cement mantle for the combined M2+M5 groups in area 1 was 36.15 mm and 18.69 mm in area 5, whereas for the P2+P5 groups it was 12.71 mm in area 1 an 7.17 mm in area 5, also significant differences (p=0.001) (Fig. 8).

By means of the simultaneous contrast of the four femoral cementing groups, stratified by cementing areas, significant differences were found for the following variables: area penetrated (Ap), length of the cement mantle (An) and mean penetration (Pr) in area 1 (p=0.008) ad in area 5 (p=0.009), and for the variables Ap and Pr in area 3 (p=0.0012), with no statistically significant differences being found in the areas corresponding to the bevels (areas 2 and 4), with p=0.068.

With respect to tangential cementing areas, in area 1 the M2 group achieved a mean penetration of 3.79 mm (2.38-4.54) whereas the P2 group penetrated 1.91 mm

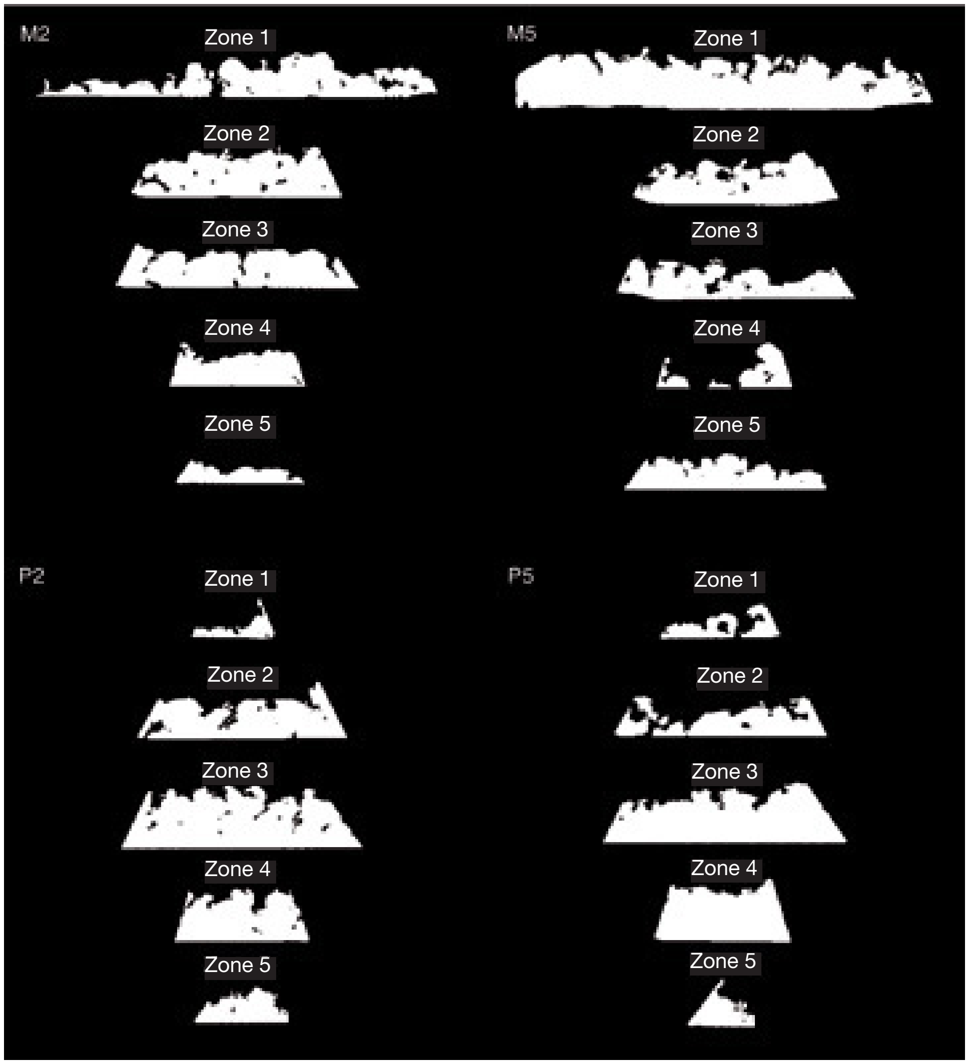

Figure 5 Representation of the cement mantle subtracted from each femoral analysis area, for each of the cementing groups. Note the differences in length in the tangential planes (areas 1 and 5).

(1.28-2.73) on average and the P5 group 1.69 mm (1.30-2.42); these differences were significant (p=0.029). In area 5, the M2 group had a mean penetration of 2.82 mm (1.38–3.92), whereas the implant cementing groups (P2 and P5) penetrated 2.48 mm (1.60-2.70) and 2.70 mm (2.40-3), respectively (p=0.029). The differences in cement mantle length for these two planes are represented on Figure 9 and statistical significance was also reached (p=0.029).

Discussion

This paper has tested the cementing of prosthetic components in a total knee arthroplasty using validated synthetic bone models. The decision to use these models was based on three reasons: availability, as they are identical synthetic pieces of the same size and side (something difficult to achieve with cadaver bone); consistency, as the use of synthetic models reduces the inter-specimen variability; and cost, which is also lower not only because of the price of the synthetic model with respect to a cadaver part, but also because, theoretically, a smaller sample size is required. In our study, the models used were prepared by pulsed washing to achieve a bone surface for cementing completely free from detritus, with the obvious limitation of the absence of bone marrow or bleeding pressure, and to simulate a slightly damp medium that reproduces better the behaviour of the analogue with respect to natural bone.[10]

Numerous factors have a significant influence on the tensile and shearing resistance of the bone-cement interface, but the fundamental aspect is its interdigitation.[13] Mann et al. carried out a study on proximal cadaver femurs to determine the influence of the cement's interdigitation on the mechanical properties of the interface, with a positive linear relationship being found between its tensile resistance and the amount of interdigitated cement.[14] In this respect, Walker et al. were among the first to describe, in a prospective study, the appearance of radiolucencies two years after surgery, finding a strong inverse relationship

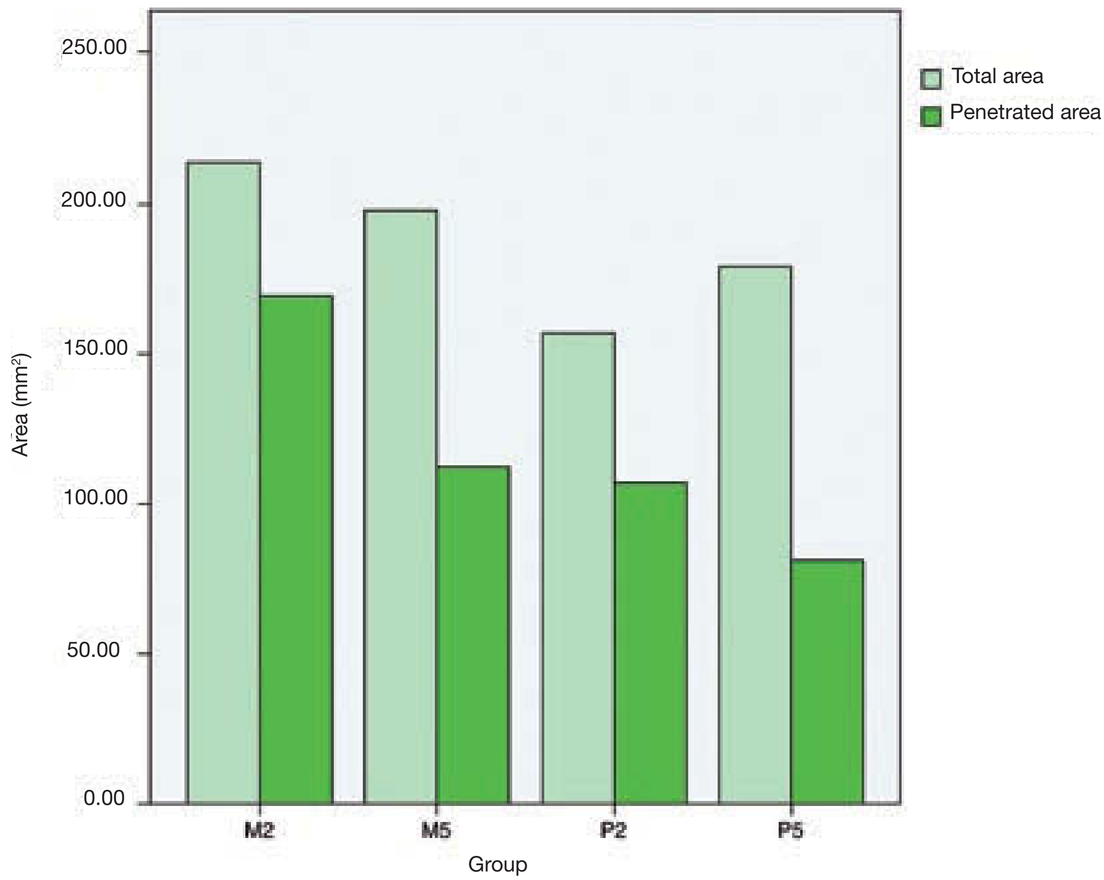

Figure 6 Representation of the total area (At) of the cement mantle in the tibia for each cementing group, together with the penetrated area (Ap).

between the initial penetration by the bone cement and the subsequent development of these lines, recommending an ideal penetration of two to four millimetres.[15] In their turn, Dorr et al. analyzed the factors influencing the intrusion of PMMA into the tibia using cadaver specimens, reaching the conclusion that applying high-viscosity PMMA between the second and third minute achieved an optimal depth of penetration, situated between two and four millimetres.[16] Thus, a penetration lower than one or two millimetres results in a very weak bone-cement interface, clearly predisposing to micromobility and subsequent aseptic loosening of the prosthesis. If the penetration exceeds five millimetres it may cause necrosis of the bone due to the thermal effect, and there is no increase seen international eh force on the interface.[17,18] In our study, the four tibial cementing groups achieve a mean penetration between the said values, with the M2 group showing an average of 4.44 mm, very close to the desired upper limit, and the P5 group (2.14 mm) close to the minimum penetration needed for correct interdigitation.

The cement is pressed into the spaces in the trabecular tissue and it is necessary to maintain a pressure of at least 76 kPa for 5 seconds to ensure adequate penetration of the cement into the bone bed.[19] If we take into account that the manual packing with the fingers may even exceed 100 kPa,[20] it can be seen how the manual pressure used with technique M achieves higher mean penetration figures in the cement mantle. In this paper, we have not used pressure packing with a pistol or any vacuum mixing, as there are published papers in which no significant differences have been found with the use of these techniques.[21]

In our study, no significant differences were found between the M5 group and the P2 group, which may be related to the capacity of high-viscosity cement to exceed the resistance to penetration exerted by the bone-cement interface itself.[22] As for the penetration percentage, it is worth highlighting the importance of the moment of application with respect to the proportion of the cement mantle truly interdigitated in the spongy tissue. At minute two, when the apparent viscosity of the acrylate is still low, it is possible to achieve between 30% and 40% more penetration than at the end of the cement application window (minute five), when the cement's viscosity is higher.

In general, the posterior condylar surface in a TKA receives poor cementing technique. Exposing and accessing this region to ensure correct preparation of the surface to be cemented is really difficult. The subsequent cuts for the femoral component are unique with respect to the other cementing planes, as implementing the prosthetic element moves it tangentially to the posterior plane. The adjustment of the part is tight and there is no mechanism to achieve

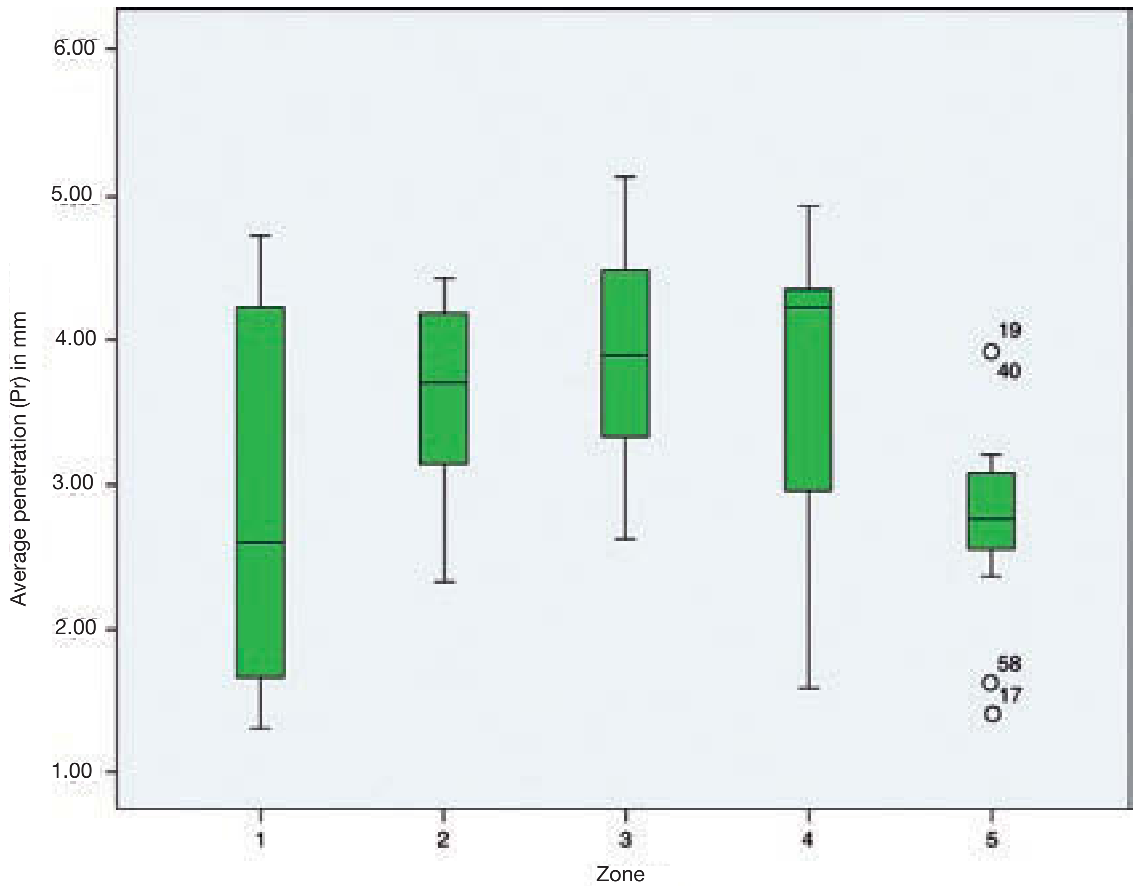

Figure 7 Box diagram representing the mean penetration in millimetres for each femoral area under study, regardless of the cementing technique.

active intrusion of the cement if it is initially placed on the component. King et al. were the first to describe the disproportionate rate of radiolucencies that appeared on the posterior femur after TKA,[23] concluding that the early loosening of the femoral implants resulted from the poor prosthetic fixation at the posterior condyle. In our paper, technique M, regardless of the moment of application, achieves a greater length in the anterior and posterior planes with respect to technique P, which does not reach 50% of coverage of the bone surface in these slices.

Our results coincide with those published in a recent paper by Vaninbroukx et al. also conducted on synthetic models, in which they concluded that the technique obtaining worst results in each of the three main planes, and basically on the posterior condyles of the femoral component is the technique of cementing on the prosthetic implant itself.[24] With a similar approach, but applied to hip coating arthroplasty, Scheerlinck et al. recently published a study carried out on bovine bone to assess the quality of the cement mantle depending on the cementing technique, also determining that the manual application on the bone surface of a medium viscosity cement was the technique that also achieved the most uniform coverage.[25]

As the limiting factors of our paper, we can highlight those inherent to an *in vitro* study, such as having used synthetic bone models which, albeit validated, limit the interpretation of results to a pre-clinical setting, in the absence of biological variables such as bleeding or the patient's body temperature. In addition, some parameters have not been standardized, such as the level of pressure applied when cementing. Nonetheless, the study comparing the different cementing techniques does not lose its validity as the controlled application conditions are homogeneous. Finally, with respect to the measurement method based on the analysis of a digital photograph of the parts, it is necessary to clarify that its intra- and inter-observer variability is unknown, although this method is similar to that used in other papers.[26-28]

Lastly, we can conclude that the cementing technique in TKA by means of direct application of the cement on the bone surface with finger packing achieves a greater mean penetration of the cement mantle and a higher percentage of penetration than with the direct application of the cement onto the prosthetic implants. The differences between the two techniques in terms of the penetration percentage become more notable the greater the viscosity with which the cement is applied. And in connection with the tangential cementing of the anterior and posterior femoral cuts, it should be noted that it is precarious when the cement is placed on the implant, and does not improve in this case by using cement with a lower viscosity.

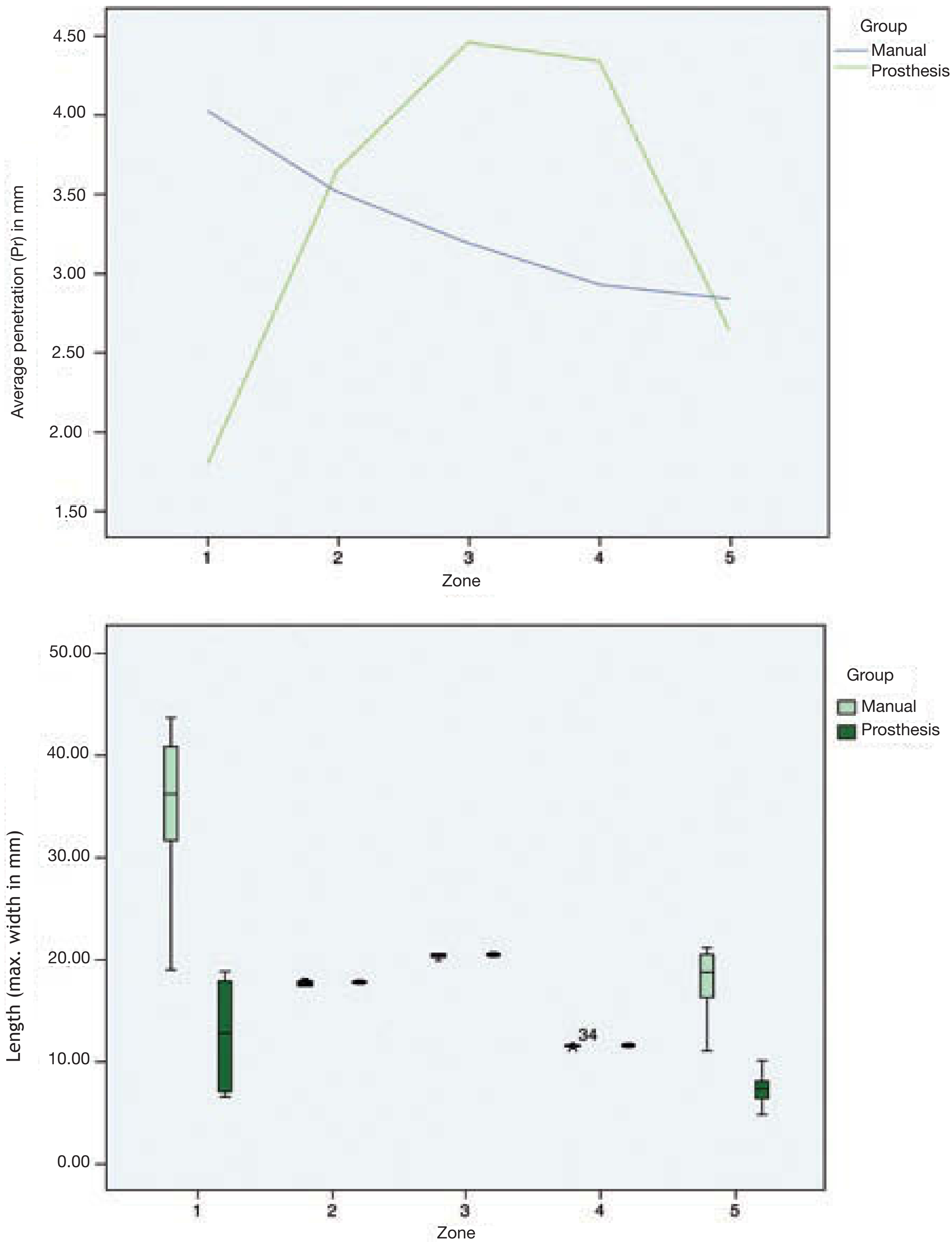

Figure 8 Representation of the penetration (top) and length of the cement mantle (below) in the manual cementing group (M2+M5) and the prosthesis cementing group (P2+P5), for each area in the femur.

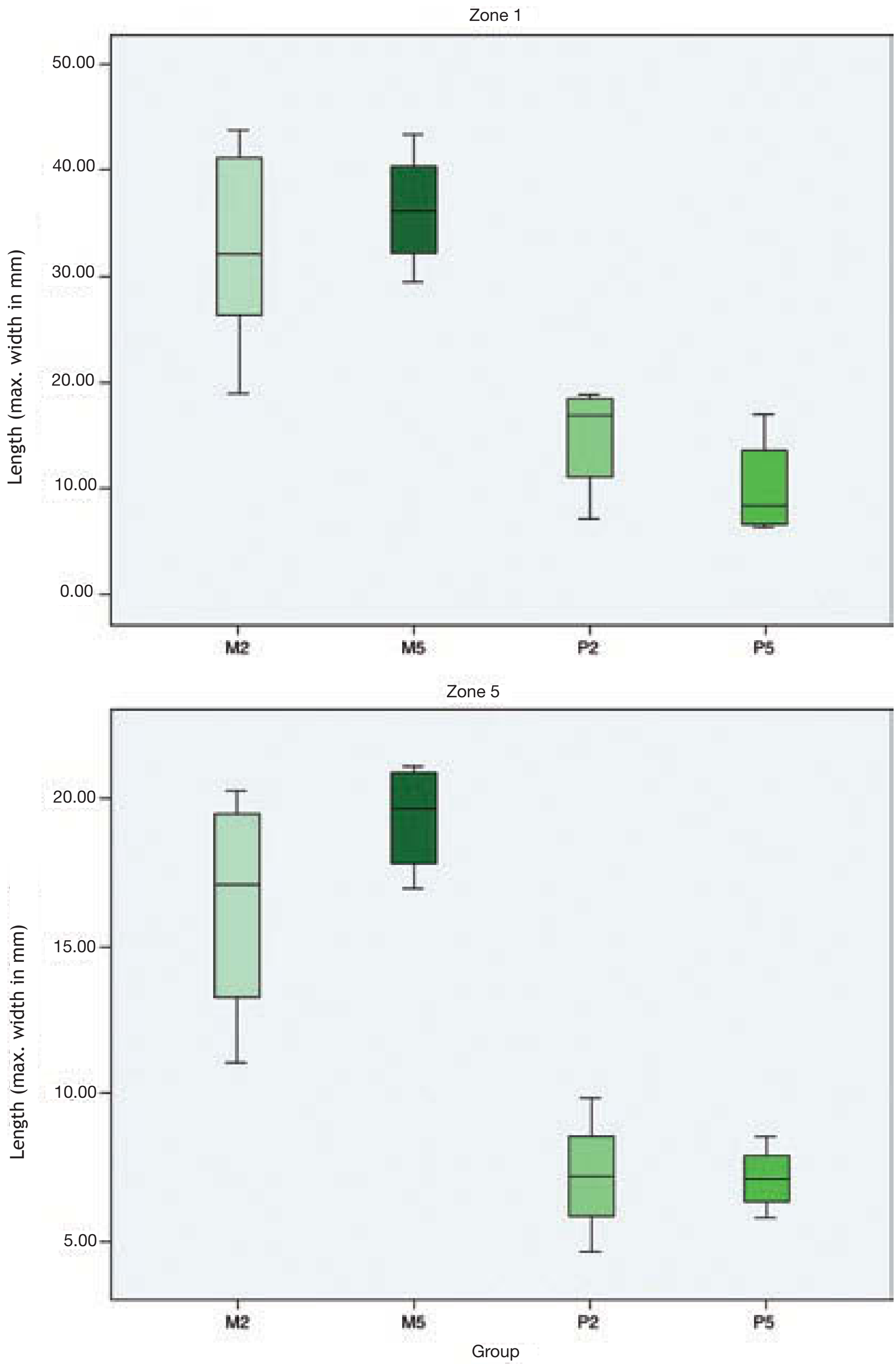

Figure 9 Box diagram representing the length of the cement mantle in the tangential cementing areas: area 1 (top) and area 5 (bottom), for each femoral cementing group.

Level of evidence

Basic research study. Level of evidence III.

Conflict of interest

The authors have stated that there is no conflict of interest.

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