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Original Article

Migration and strains induced by different designs of force-closed stems for THA☆

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ABSTRACT

Objectives: Subtle differences in stem design can result in different mechanical responses of the total hip arthroplasty. Tests measuring migration of the stem relative to the femur, as well as the strains in the cement mantle and on the femur can detect different mechanical behavior between stems.

Methods: In this article, conical, double and triple tapered stems were implanted in composite femurs and subjected to static and cyclic loads. Stems differed mainly on taper angle, calcar radius and proximal stiffness. Stem migration and strains on the femur and in the cement mantle were achieved.

Results: Significant differences ($p < 0.05$) were noted in the permanent rotation between double and triple tapers, in the strains on the proximal medial femur between triple and both conical and double tapers, and in the strains on the lateral proximal femur between double tapers and both conical and triple tapers.

Conclusion: The proposed mechanical tests were able to detect significant differences in the behavior of these resembling stems. Stem proximal stiffness and the calcar radius of the stem influence its rotational stability and the strain transmission to the femur.

☆ Study developed at the Laboratory of Physical Metallurgy, Department of Metallurgy, Post-Graduate Program in Metallurgical Engineering, Mining and Materials, Universidade Federal do Rio Grande do Sul (UFRGS), Porto Alegre, RS, Brazil.

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Migração e deformações induzidas por diferentes hastes do tipo force-closed para ATQ

RESUMO

Palavras-chave:
Artroplastia de quadril
Desenho de prótese
Fenômenos mecânicos

Objetivos: Diferenças sutis no projeto da haste podem resultar em diferentes respostas mecânicas da artroplastia total do quadril. Testes que meçam a migração da haste em relação ao fêmur, bem como as deformações no cimento e no fêmur, podem salientar as diferenças entre diferentes projetos de hastes.

Métodos: Neste artigo foram implantadas hastes cônicas, hastes duplamente afiladas e triplamente afiladas em fêmures compósitos e submetidas a cargas estáticas e cíclicas. As hastes diferenciaram-se principalmente em relação aos afilamentos, ao raio do calcar e à rigidez proximal. A migração das hastes e as deformações tanto no fêmur quanto no cimento foram medidas.

Resultados: Foram observadas diferenças significativas ($p < 0,05$) na rotação permanente entre as hastes duplamente e triplamente afiladas, nas deformações do nível proximal medial do fêmur entre as hastes triplamente afiladas e ambas cônicas e duplamente afiladas e nas deformações do nível proximal lateral do fêmur entre as hastes duplamente afiladas e ambas cônicas e triplamente afiladas.

Conclusão: Os ensaios mecânicos propostos foram capazes de produzir diferenças significativas no comportamento dessas hastes semelhantes. A rigidez proximal da haste e o raio do calcar influenciam a estabilidade rotacional e a transmissão de deformação da haste ao femur.

Introduction

Polished, collarless, tapered cemented stems work as a taper lock system, the so-called *force-closed* behavior.[1] Force-closed stems such as Exeter have been showing excellent long-term results.[2] The stem migrates due to the cement creep, and it provides the load to be transferred throughout cement mantle to bone in a more homogeneous fashion.[1,3]

Different subtle design changes of the force-closed stems have been conceived in the last decades. Examples of such changes are the double tapered Exeter Universal and the triple tapered C stems.[4] Changes in the stem shape such as the cross-sectional and proximal geometry, angles and planes of tapering may interfere with the stem stiffness and stability, as well as with the load transmitted to the cement mantle and bone. All these aspects can influence to the potential for stem survival.

Mechanical tests have been previously proposed to compare the mechanics of total hip stems designed with great conceptual differences.[5] However, studies of the mechanics of the arthroplasty due to subtle differences in shape of a specific concept as the force-closed stems are scarce. Numerical simulation was achieved to predict the damage on the cement strains.[6] However, mechanical tests monitoring the stem migration and strains in the cement mantle and the femur may also contribute to the understanding of the mechanical response of such a concept of total hip arthroplasty.

The objective of this study was to determine if mechanical tests could be able to detect differences regarding to the load transmission and migration of force-closed stems that have subtle design differences.

Materials and methods

Three groups of force-closed stems were manufactured from stainless steel ASTM FI38 and supplied by the manufacturer (MDT Implants, Rio Claro, Brazil). The groups differed concerning the stem shape (Fig. 1). The most relevant differences between the stems are as follows: stem A, (Spoac®): 1°15′ conical distal shape designed to give an auto-centralization with the medullar cavity; stem B (Maxima®): double-taper (4°30′ and 1° respectively at the lateral and medial sides, showing in the frontal plane, 3°12′ at the lateral plane), rectangular cross-section with rounded comers; stem C (Spoac NG®): triple-taper (3°, 3°30′, 3°53′, respectively at the frontal, lateral and transverse planes), rectangular cross-section with rounded comers. Stem A has a narrow shoulder. The transition between the proximal and medial level of the stem B occurs through a smaller curvature radius of the medial side (the calcar radius). The calcar radius of the stems A, B and C are respectively, 120 min, 40 mm and 60 mm. Therefore, stem B has the lower proximal stiffness, followed by the stem A. Four specimens for each group were implanted in twelve large composite left femurs (3306 Pacific Research Labs.)

Appropriate stem size was selected according to templates. Medullar cavity was locked by polyethylene restrictor 20 mm from the stem tip. Bone cement (Simplex P, Stryker-Howmedica-Osteonics, Allendale, NJ) was applied at the recommended proportion of 2 g of powder for 1 ml of liquid.

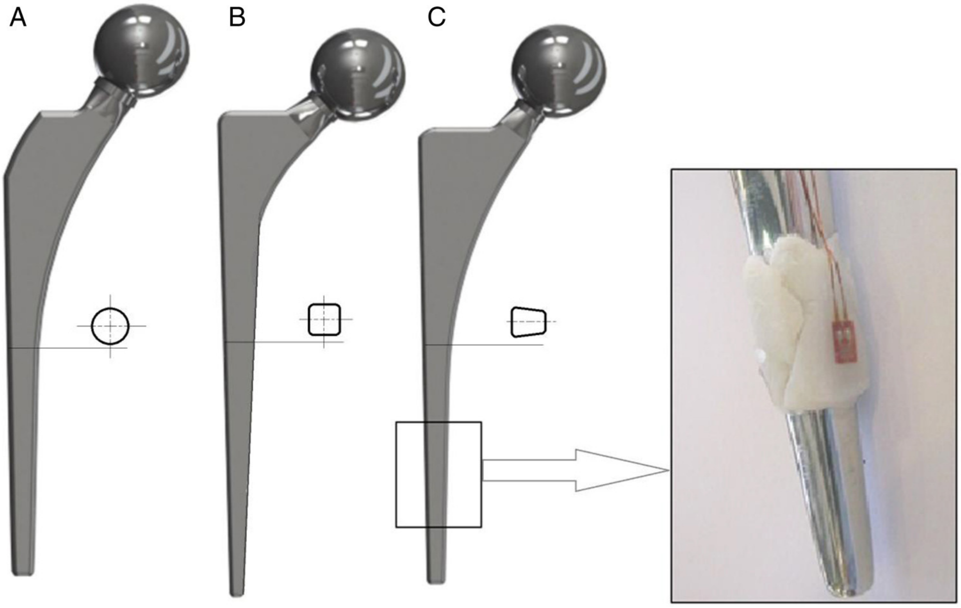

Fig. 1 – The three prosthetic models. From left to right, the conical nail A, double-tapered nail B and triple-tapered C-Stem. The cross-section of the nails is represented. The highlighted figure on the right shows a strain gauge fixed at the cement layer on the distal part of the nail. The head of the nails has a diameter of 28 mm.

Cement was introduced into the medullar cavity at retrograde fashion by syringe. Implantations were evaluated always by the same experienced surgeon (LSMG).

The distal portion of the femurs was attached to a device, that ensured a posterior inclination of 9° and a lateral inclination of 10 degrees, both with respect to the axis of the composites (Fig. 2). After proper positioning and adequate fixation of the condyles with screws, the distal 50 mm of the composites were soaked by PMMA. Samples were mechanically loaded in a servohidraulic machine (MTS 810, MTS Corporation, Eden Prairie, MN, USA). Static loads were applied to the composites in three different test situations: (a) on the head of the intact femurs before implantation, (b) on the head of the stem after implantation and (c) on the head of the stem after cyclic loads. Blocks of 10 static loads were applied at a rate of 2300 N/min, followed by one minute of load sustaining and one minute for load relieve. Strain and displacement variations due to static loads were taken as the mean values measured in the 10 static loads. The sinusoidal cyclic load with a frequency of seven Hz for one million cycles was applied within the range of 230 and 2300 N.

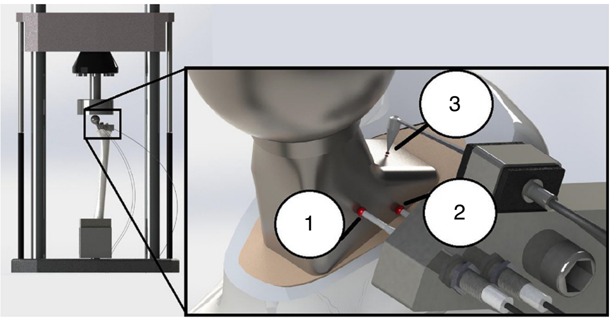

Fig. 2 – Test apparatus and displacement gauges to measure nail rotation (L1, L2) and axial migration (L3).

Evaluation method

Strains on the outer surface of the femurs were measured through six axial electrical resistance strain-gauges (Kyowa KFG 2-120-C1-11-N15-C02, Tokyo, Japan) at the three test moments. The strain gauges were attained to the femurs as well as to the cement in a similar manner as described in a previous protocol.[7] The gauges were arranged in the direction of the femoral axis. The positions of the gauges were measured by an altimeter (0.1 mm resolution). Strains in the cement mantle were measured by four axial electrical resistance strain-gauges during the static loads after implantation, and during the final static loads after the cyclic loads. During cyclic loading, strains in the cement mantle were also monitored to evaluate permanent deformations. Bone cement layers were applied in the proximal and distal levels of each stem. Cement layers were sanded until a thickness of one mm was achieved, measured with a caliper (0.1 mm resolution). The gauges were applied to the cement layer on the medial and lateral sides. Fig. 1 shows a strain gauge attached to the distal aspect of a stem, prior to implantation. Table 1 describes the positions of all strain gauges used in this study. Fig. 3 shows the positions of the strain gauges in relation to both the cement mantle and the femur. The deformations were measured with a signal conditioner (HBM MGCplus, Dannstadt, Germany). To increase data reliability all the strain gauges were calibrated using a precision electrical resistor.

The axial and rotational migration of the stems in relation to the femurs were measured through a displacement gage (0.01 mm resolution) and two linear variable displacement transducers (0.02 mm resolution) to evaluate, respectively the

Table 1 – Position of deformation strain gauges.

Gauge	Position
1	Adhered to the medial aspect of the cement, at 130 mm of the nail end
2	Adhered to the medial aspect of the cement, at 20 mm of the nail end
3	Adhered to the lateral aspect of cement, at 130 mm of the nail end
4	Adhered to the lateral aspect of cement, at 20 mm of the nail end
5	Medial aspect of the outer surface of the femur, at 63 mm of the greater trochanter end
6	Medial aspect of the outer surface of the femur, at 98 mm of the greater trochanter end
7	Lateral aspect of the outer surface of the femur, at 40 mm of the greater trochanter end
8	Lateral aspect of the outer lateral surface of the femur, at 102 mm of the greater trochanter end
9	Anterior aspect of the outer surface of the femur, at 35 mm of the greater trochanter end
10	Posterior aspect of the outer surface of the femur, at 65 mm of the greater trochanter end

axial migration and the rotation of the stem. The displacement gauges were supported by an aluminum device attached to the greater trochanter through bolts and an epoxy mantle to ensure good stiffness fixation (Fig. 2). The gauge used to measure the axial migration was attached to the upper surface of the stem shoulder. The transducers to measure the rotation were arranged separately and at 14 mm from each other, orthogonally on the front surface of the proximal portion of the stems. The rotation angle was then calculated through trigonometric relations between the difference of displacements measured by the two transducers and the distance of 14 mm. Thus, the rotation measurements had a resolution of 0.16°. The migrations were measured using a signal conditioner (HBM Spider8, Darmstadt, Germany). The permanent migrations of the stem were monitored during cyclic loading.

The analysis of variance (one-way ANOVA) was used to detect significant differences between the groups in all tests ($p \leq 0.05$). According to Cristofolini et al.,[5] at least three samples from each group are required to yield a significant difference in the measured variables. The present study used four samples for each group.

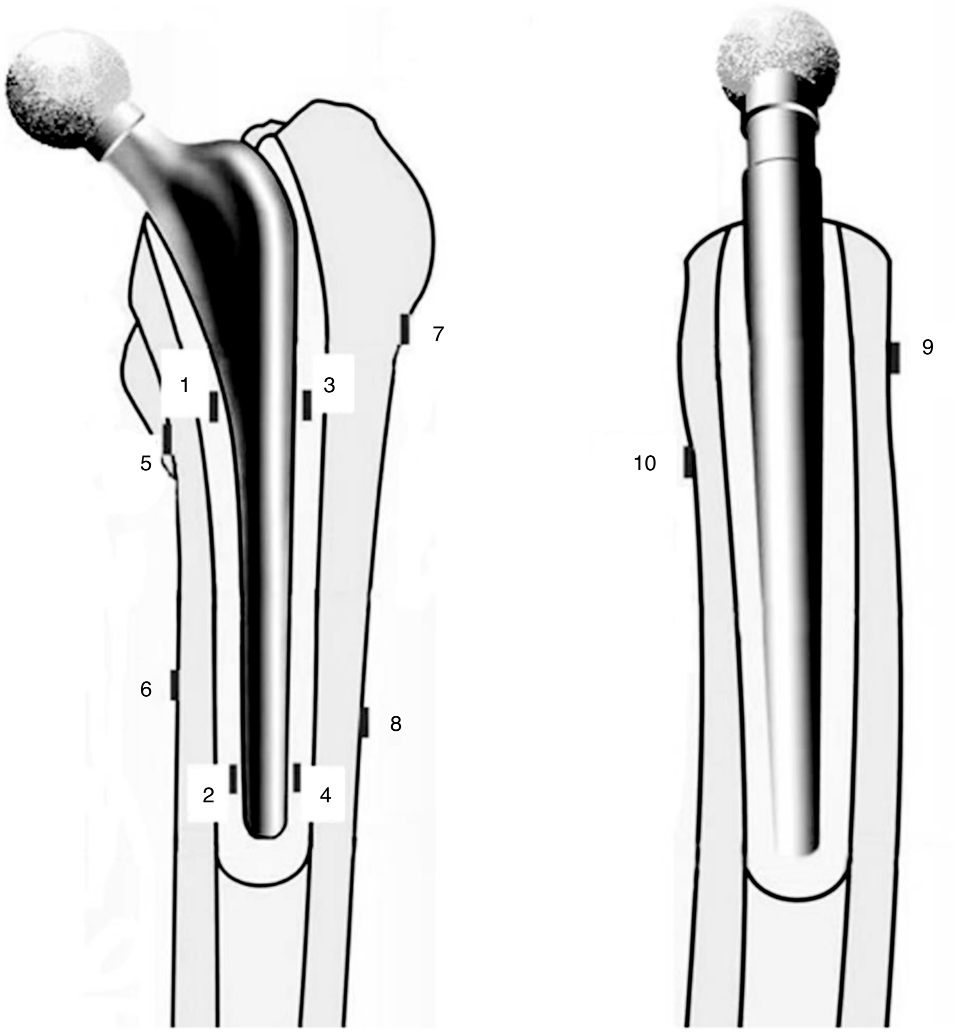

Fig. 3 – Strain gauges embedded in the cement mantle arranged from the tip of the nail (1, 2, 3, 4) and femoral gauges arranged from the end of the greater trochanter (5, 6, 7, 8, 9, 10). gr3.

Table 2 – Mean deformation (standard deviation) measurements in composites. The positions (5-10) were defined in Fig. 3.

Position	Medial 5	Medial 6	Lateral 7	Lateral 8	Anterior 9	Posterior 10
Deformation (μm/m)	−2249 (34)	−1378 (26)	473 (16)	1387 (24)	−562 (14)	−852 (18)

Results

The measured deformations in intact femurs during the first period of testing are shown in Table 2. The deformations were negative on the medial, anterior and posterior aspects, while the deformations on the lateral aspect were positive. Regarding the cement mantle deformations, negative values were found on the medial side (gauges one and two), without significant differences between the groups (Fig. 4). Some gauges in the positions three and four were damaged during implantation and hindered the statistical analysis of cement deformations on the lateral portion. Regarding femoral deformations after implantation, a reduction in deformation under static loads was detected. The results were shown as residual deformations, that is, the association between the deformations measured after implantation and those previously measured for each strain gauge in the intact femurs. The triple-tapered C-Stem showed 33% of residual deformation in the medial proximal aspect (gauge five), with a significant difference from both, conical stem A (43%) and double-tapered Stem B (49%), as shown in Fig. 5. In the proximal lateral aspect, the double-tapered stem B showed 18% of residual deformation, with a significant difference from both conical stem A (27%) and triple-tapered stem C (36%).

The initial deformations remained at 42% for all the stems on the anterior aspect. A smaller reduction was found on the posterior aspect, in which the double-tapered stem B showed 98% of residual deformation, with no significant difference regarding both conical stem A (71%) and triple-tapered stem C (80%), as shown in Fig. 6. Both gauges embedded in the cement mantle and the migration gauges showed, respectively, permanent deformation and permanent migration, and stabilized between 0.2 and 0.6 million cycles. There were no significant changes in cyclical amplitude during the monitoring. Fig. 7 shows the deformation variation of gauge two in one of the stems C during cyclic loading. It is possible to observe the permanent deformation stabilizing at around 0.6 million cycles, whereas the deformation amplitude remained unchanged. No significant differences were found in the permanent axial migration of the nails. The distal migration, known as subsidence, occurred in the mean interval of 0.06 mm for the triple-tapered stem C and 0.12 mm for the double-tapered stem B (Table 3). There was a significant difference in the permanent rotation between the double-tapered stem B and the triple-tapered stem C, respectively, with 1.1° and 0.22° (Table 3). Stem rotation generally occurred in retroversion. However, the stem C showed mean rotation in anteversion.

Table 3 – Axial and rotational migration of the nails. Standard deviation in parentheses.

Nail migration	Nail A	Nail B	C-Stem
Axial (mm)	−0.08 (0.12)	−0.12 (0.19)	−0.06 (0.08)
Rotation (degrees)	0.32 (0.59)	1.10 (0.73)	−0.22 (0.51)

Discussion

Several mechanical tests have been previously published to compare stem designs for total hip arthroplasty. However, in general, the studies aimed at deformations or stem migration measurement. Moreover, previous studies generally focused on comparing stems with significant design differences, such as the study of Cristofolini et al.[5] that compared the stem (Lubinus SPII), which showed good clinical outcomes, with the Müller, curved stem, which showed poor clinical outcomes. In this study, three force-closed stems types that have subtle design differences were compared. Stem migration, as well as deformations in the cement mantle and the femur was assesse during static and cyclic loading conditions. The suggested test protocol showed significant differences between the stems.

The analyses should be performed keeping in mind the use of composite femurs, without the presence of biological reactions. The frequency of seven Hz applied in the cyclic tests may be used without damaging the bone cement constitutive properties[8] and with the benefit of shorter time spent during testing, compared with cyclic tests of lower frequency. The

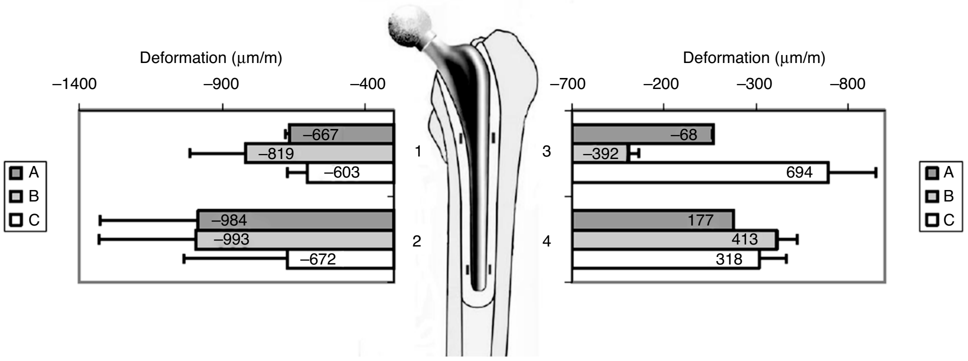

Fig. 4 – Deformations measured during the initial static loads in positions (1, 2, 3, 4) of the cement mantle.

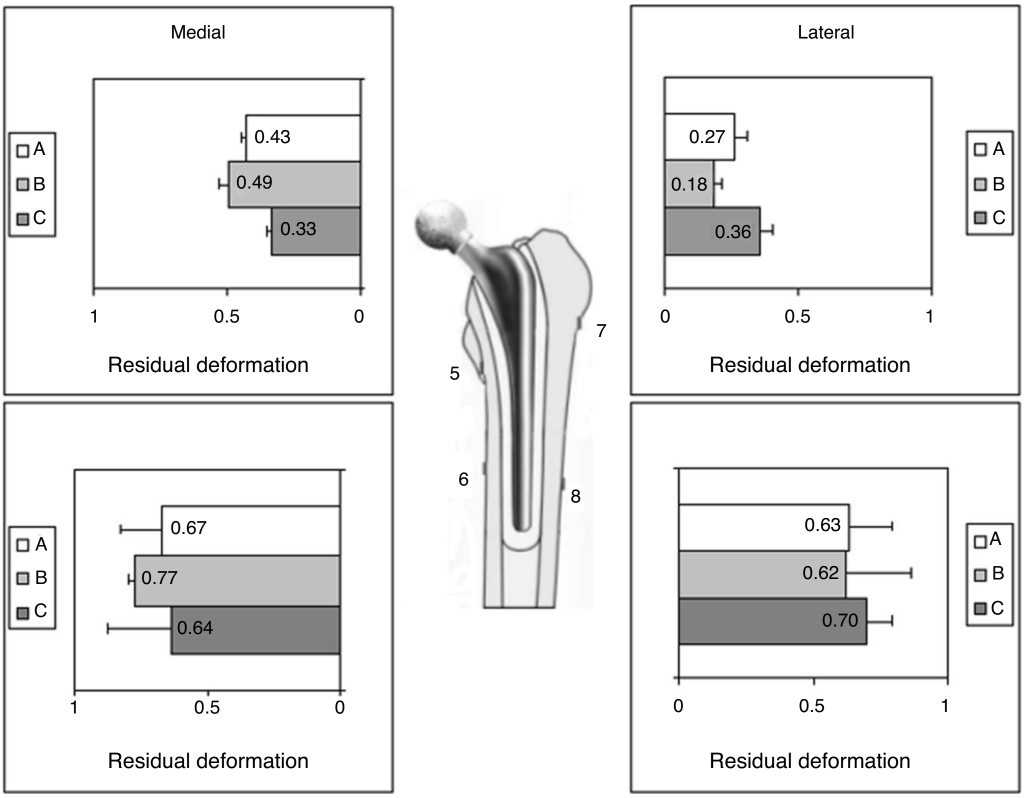

Fig. 5 – Residual deformations on the medial and lateral aspects of implants under initial static loads.

tests were performed without the presence of muscle forces. Although a sudy[9] showed the importance of muscle forces applied to the greater trochanter for a better assessment of the distribution of stress due to total hip replacement, this study was effective in producing significant differences in both migration and deformation. While some deformation gauges in positions three and four were damaged during implantation and hindered the statistical analysis of cement mantle deformation only in the lateral region, we were able to compare cement deformations in the medial region of all stems. No significant differences were found between the three stems with respect to cement deformation. The permanent displacements and deformations measured in our cyclic tests showed a decreasing rate that stabilized between 0.2 and 0.6 million cycles. The imposed load on the cement mantle during the *in vivo* postures results in the flow of cement. The flow rate decreases with time (or the cyclic loads), and although it remains for a long time, it may become insignificant in the long-term.[10] According to Nelissen et al.[11] stabilizing the migration rate of a double-tapered stem occurs within six months of *in vivo* use. Therefore, it is possible to compare our cyclic loading with such a period of *in vivo* use.

According to Stolk et al.[12] the rotation is the primary mode of migration in such concepts of force-closed stems for total

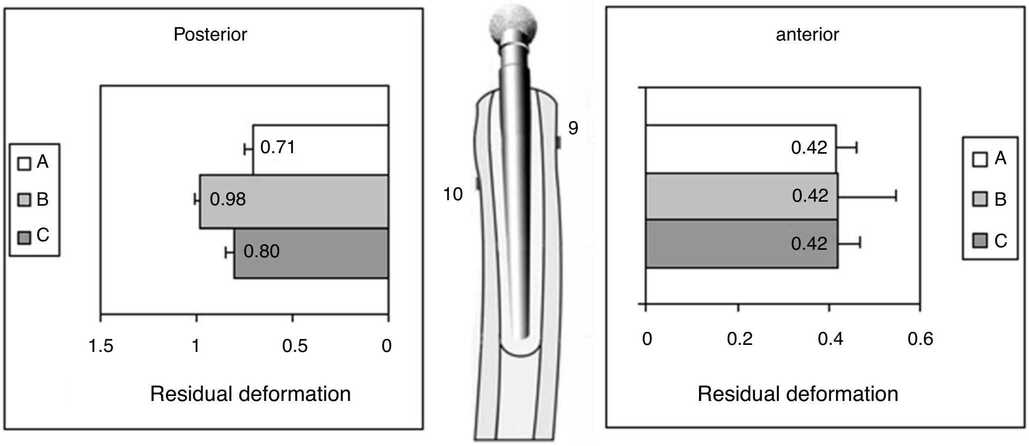

Fig. 6 – Residual deformations on the anterior and posterior aspects of implants under initial static loads. GR6.

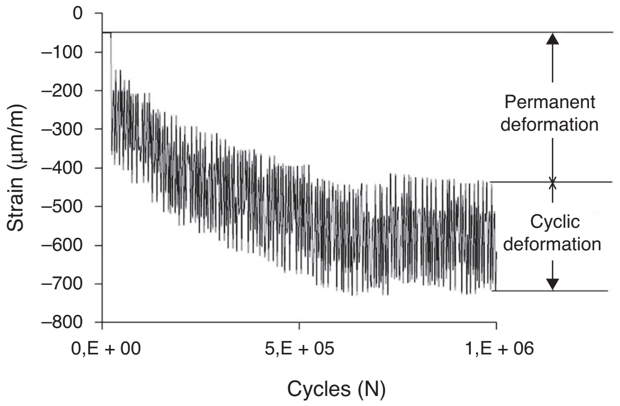

Fig. 7 – Deformation variation of gauge 2 in a C-Stem during cyclic loading. The permanent deformation stabilizes at around 0.6 million cycles, whereas the deformation amplitude remains unchanged.

hip arthroplasty. A significant difference in permanent rotation was observed for the double-tapered stem B compared to the triple-tapered stem C. Although there were no significant differences for the conical stem A when compared with the other two, a permanent rotation as high as 1.8° was observed fort he double-tapered stem B. This double-tapered nail is slimmer than the other two. It has lower proximal stiffness due to the smaller radius of the calcar, while having a greater dimensional association between the distal and the proximal lengths. Such aspects can increase the stem potential for rotation. The stem rotation can be harmful in the long term for polished and tapered stems, since the persistence of rotation over time can result in small spaces at the interface between the stem and the cement mantle. These spaces can be associated with osteolysis and fretting problems.[13]

We agree that the mechanical testing protocol cannot be used to decide the success of any of the tested stems models and, additionally, tests can only be validated by the results of the long-term clinical monitoring of the stems. However, one can expect that, if bone resorption-related problems are detected in the long-term clinical follow-up, such problems will occur in areas of lower deformation transmitted to the femur. After stem implantation, the deformation decrease was pronounced mainly on the proximal aspect of the femur, a region where the aseptic loosening is more evident after a long-term clinical follow-up for the Exeter nail,[2] an established model of force-closed stem.

Our results for reducing deformation in different positions (strain gauges 5–10) showed significant reduction in the initial deformation for the triple-tapered stem C on the medial proximal aspect (gauge 5). This was also the region where the lowest mean deformation was found in the cement fort he triple-tapered C-Stem. For the double-tapered nail B, we observed a marked reduction of the deformation on the proximal lateral aspect (gauge 7), again according to the tendency to cement deformation of this nail (gauge 3). The double-tapered stem B showed the lowest residual deformation on the proximal lateral aspect (18%), but the highest residual deformation on the medial proximal aspect (49%), whereas the triple-tapered stem C showed the opposite, i.e., the lowest residual deformation on the medial proximal aspect (33%) and the highest on the proximal lateral aspect (36%). The double-tapered stem B has the smallest calcar radius and the lowest proximal stiffness. This causes a higher flexion moment, increases the load transmitted against the calcar and reduces the load on the proximal lateral aspect of the femur.

Conclusions

Three designs of the force-closed stems were analyzed regarding deformations and migrations. The proposed test protocol was effective, as it demonstrated significant differences between the stems. The nails with lower proximal stiffness showed lower rotational stability. The nail with the smallest calcar radius increased the load transmitted to the calcar.

Conflicts of interest

The authors declare no conflicts of interest.

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