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ORIGINAL ARTICLE

Is there any difference between tapered titanium stems with similar geometry and hydroxyapatite coating?

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Abstract

Purpose Several tapered stems with similar geometry and extensive hydroxyapatite coating have recently been introduced. It is not clear, however, whether they share the same design or whether they exhibit any difference that might affect their clinical performances. In this study, we analysed five tapered stems fully coated with hydroxyapatite to establish whether they exhibit similar geometric features and may therefore be used indifferently when a cementless stem is indicated.

Methods The length of the stem, the coronal and sagittal diameters, the length of the stem shoulder and the metadiaphyseal angle were measured. The ratio between the proximal and distal coronal diameters of the stem and that between the proximal and distal cross-sectional areas were calculated as a flare index and tapered index, respectively.

Results The proximal coronal diameter ranged between 24.9 and 28 mm in the smaller size and between 34 and 38.4 mm in the largest sizes. The proximal sagittal diameter ranged between 10.2 and 11.8 in the smallest size and between 14.4 and 17.2 in the largest. A significant difference was found between stems of different brands in the flare index, tapered index, length of stem shoulder and metadiaphyseal angle.

Conclusions Lookalike tapered stems with extensive HA coating actually exhibit significant differences in several geometric features potentially affecting their clinical performances. As a result, these stems should not be used indifferently, but rather they should be selected on the basis of the femoral morphology of the operated patient.

Keywords Tapered titanium stem · Hydroxyapatite coating · Stem geometry · Total hip arthroplasty · Stress shielding

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Introduction

The tapered titanium femoral stem with extensive hydroxyapatite coating (TTS-EHAC) has yielded a high rate of satisfactory results in the medium- and long-term follow-up [1–3]. The stem geometry was designed to provide immediate stability and prevent loading concentration in the distal femur, while the extensive hydroxyapatite coating was aimed at stimulating metaphyseal and diaphyseal osseointegration and homogeneous stress distribution at the bone–stem interface [3]. Early concerns were possible complications related to such extensive HA coating, including HA resorption, delamination, osteolysis and early wear [4–6], as well as the risk of subsidence in collarless stems [7]. However, long-term results have shown that the risk of coating-related complications is low [1–3], while stem subsidence may occur with different effects on the clinical outcome [8–11].

Several TTSs-EHAC have been introduced on the market in recent years. These stems resemble the original one in terms of geometry and extension of the HA coating, with no apparent differences between them. As no manufacturers have, to our knowledge, reported any peculiar features of their TTS-EHAC compared to the others and no studies have analysed possible differences in the geometry of the various TTSs-EHAC, the surgeon may select the stem to implant according to factors other than the stem's peculiar features, such as the cost and quality of the service provided.

In the present study, we compared the geometry of the original TTS-EHAC with that of 4 similar stems recently introduced; our hypothesis was that these new stems, despite appearing to duplicate the original one, actually have a different geometry that may affect their clinical indications.

Materials and methods

The coronal and sagittal geometry of the original Corail (CO) (DePuy, Johnson & Johnson, USA) and of four similar TTSs-EHAC, i.e. TrendHip (TH) (B.Braun-Aesculap, Germany), H-Max (HM) (Lima Corporate, Italy), POLARSTEM (PS) (Smith & Nephew, USA) and Avenir Muller (AM) (Zimmer, USA), was analysed (Fig. 1). The configuration of all the stems was standard, with a cephal-diaphyseal angle of 135°; no high-offset stem configurations were analysed.

The assessment of the stem geometry included the measurement of the medio-lateral and antero-posterior diameters in the coronal and sagittal planes at the level of the proximal medial extension of the HA coating, 10 mm proximally to the distal tip of the stem and in the middle between the two points (Fig. 2). The relationship between the three diameters (proximal, intermediate and distal) and size of the stems was analysed to assess whether a linear correlation exists between the stem size and diameters. The total length of the stem, the length of the stem shoulder, defined as the tilted portion of the proximal and lateral side of the stem, and the angle between a line tangent to the stem shoulder and the diaphyseal portion of the stem were analysed (Fig. 2). The flare index (FI) of the stem was defined as the ratio between the coronal diameter of the stem measured at the level of the proximal medial extension of the HA coating (A diameter, Fig. 2) and the coronal diameter measured 1 cm proximal to the tip of the stem (C diameter, Fig. 2). The tapered index (TI) was calculated as the ratio between the cross-sectional area measured at the level of the proximal medial extension of the HA coating and the cross-sectional area measured 1 cm proximal to the tip of the stem (Fig. 2).

As the stems analysed are available in 8 to 11 different sizes, depending on the brand, in order to compare implants with similar geometric features, we selected the stems whose diameter in the intermediate portion (B diameter, Fig. 2) was equal or similar. In particular, stem sizes were considered to be comparable when the difference in the B diameter was within 0.7 mm in the small and medium sizes and within 1 mm in the largest sizes. To assess any differences in stem geometry between brands, the coronal and sagittal diameters, flare indexes and tapered indexes were compared in all the sizes available for each brand as well as in the subgroup of comparable sizes.

Measurements were performed on all the sizes of each brand on digitized images of stem templates provided by the manufactures using AUTOCAD software. In order to detect any differences between the geometries of the original stem

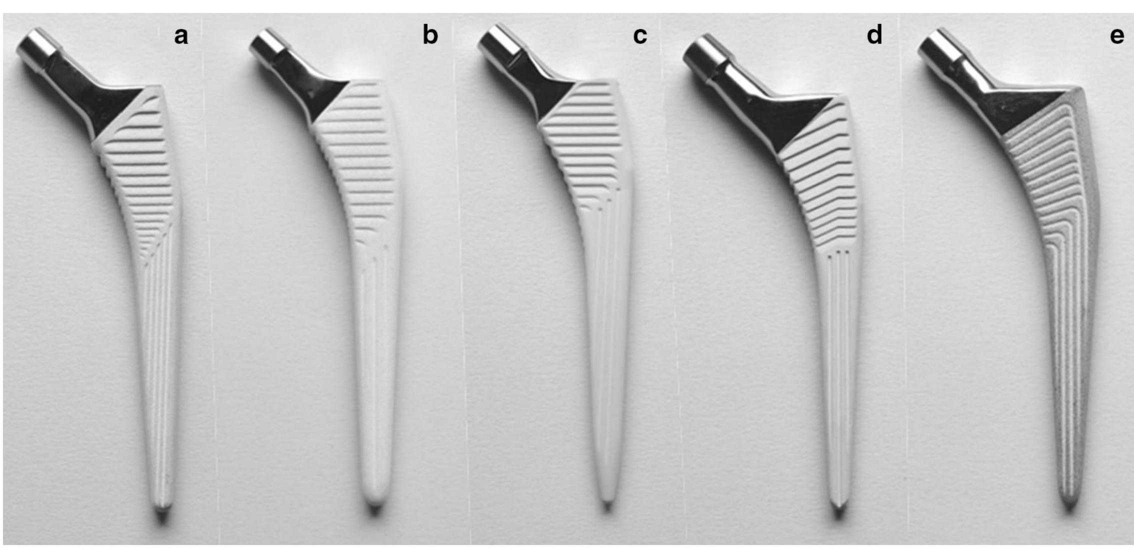

Fig. 1 Five TTSs-EHAC analysed including **a** Corail (CO) stem, **b** TrendHip (TH), **c** H-Max (HM), **d** Avenir Muller (AM), **e** POLARSTEM (PS)

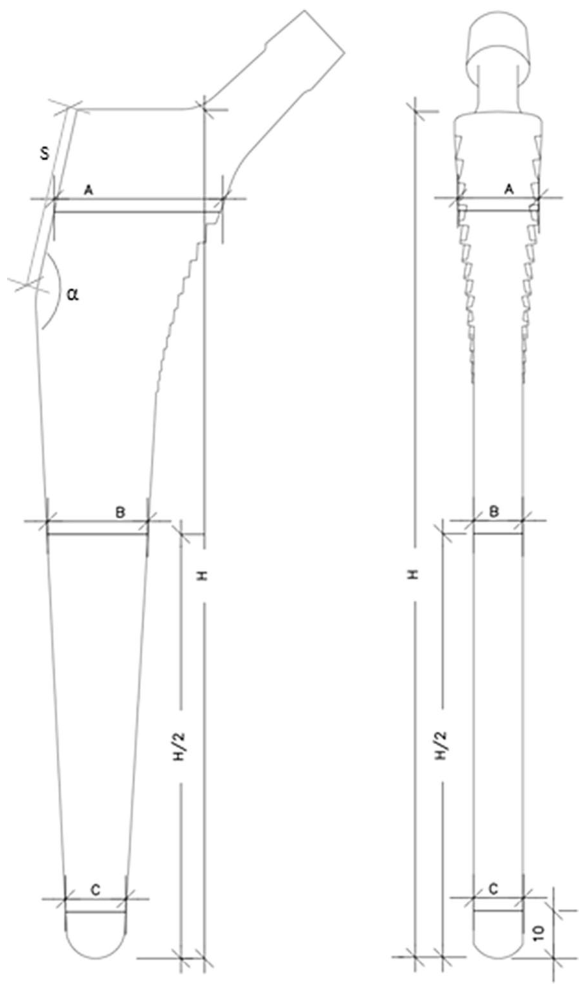

Fig. 2 Measurements performed on the coronal and sagittal planes. A, B and C represent the diameters taken at the proximal, intermediate and distal levels, respectively. S = stem shoulder. α = angle between stem shoulder and the diaphyseal portion of the stem (metadiaphyseal angle)

and its template, a comparison was made between the stem length measured on digitized templates and that provided by the manufacturer; if a difference greater than 1 mm was detected, the measurements were repeated.

The reliability of measurements was tested using the intraclass correlation coefficient (ICC) in 30 randomly selected digitized templates in which the coronal and sagittal diameters were measured by two observers. A test–retest was conducted for intra- and interobservers variability 3 weeks after the first assessment.

Data analysis

Nonparametric tests, including Kruskal–Wallis and Mann–Whitney, were used to detect any differences between the coronal and sagittal diameters, flare index and tapered index between stems of the five brands. A correlation analysis was performed to assess the relationship between changes in the size and diameters of each stem. The statistical analysis was performed using SPSS for Windows, release 22.0. The statistical significance was set at $p < 0.05$.

Results

Eleven sizes were available for the CO, HM and PS stems, 9 for the AM stem and 8 for the TH stem. The ICC for interobservers and intraobserver variability for the measurements of the coronal and sagittal diameters was 0.94 and 0.98, respectively. The range of coronal and sagittal diameters of each manufacturer is reported in Table 1.

The measurements of coronal diameters of the brands analysed showed that, at the proximal level (A diameter), the medio-lateral diameter ranged between 24.9 mm (CO) and 28 mm (HM) in the smallest size and between 34 mm (TH) and 38.4 mm (HM) in the largest size; at the distal level (C diameter), it ranged between 4.9 mm (PS) and 7.2 mm (TH) in the smallest size and between 10.3 mm (HM) and 13.7 mm (AM) in the largest size. The measurements of sagittal diameters of each brand showed that, at the proximal level (A diameter), the antero-posterior diameter ranged between 10.2 mm (HM) and 11.8 mm (PS) in the smallest size and between 14.4 mm (AM) and 17.2 mm (TH) in the largest size; the diameter at the distal level (C diameter)

Table 1 Range and difference, in brackets, between minimum and maximum coronal and sagittal diameters in the 5 brands examined at the proximal, intermediate and distal level

	CO	AM	HM	PS	TH
Coronal diameters (mm)					
Proximal	24.9–37.3 (12.4)	25.3–35.3 (10)	28–38.4 (10.4)	26.5–36.6 (10.1)	27–34 (7)
Intermediate	11.8–22.8 (11)	11.3–23.8 (12.5)	11–18.2 (7.2)	9.5–21.3 (11.8)	7.9–12.4 (5.5)
Distal	6.7–13.8 (7.1)	6.8–13.7 (6.9)	5.8–10.3 (4.5)	4.9–12.6 (7.7)	7.2–11.2 (4)
Sagittal diameters (mm)					
Proximal	10.5–15 (4.5)	10.6–14.4 (3.8)	10.2–15 (4.8)	11.8–16.6 (4.8)	10.5–17.2 (6.7)
Intermediate	6.8–10.2 (3.4)	8–10.4 (2.4)	7–10.2 (3.2)	8–11.4 (3.4)	7.3–13.7 (6.4)
Distal	6.7–10.2 (3.5)	6.1–8.4 (2.3)	5.5–9.8 (4.3)	6.7–9.3 (2.6)	5.9–11.7 (5.8)

ranged between 5.5 mm (HM) and 6.7 mm (CO and PS) in the smallest size and between 8.4 mm (AM) and 11.7 (TH) in the largest size. No significant difference was found between coronal and sagittal diameters of different brands, with the exception of the coronal diameter of HM and AM which, at the proximal level, were found to differ significantly ($p=0.04$).

The length of the stem ranged between 115 mm (CO) and 132.8 mm (TH) in the smallest size and between 166.2 mm (TH) and 190 mm (CO) in the largest size. A linear correlation was found between the increase in all diameters analysed and the increase in size ($r=0.89$, CO; 0.97, TH; 0.97, HM; 0.98, PS; 0.98, AM) (Fig. 3).

When all the sizes of the various brands were considered, a significant difference was found in the overall flare index and in the tapered index ($p=0.001$ and $p<0.001$, respectively) (Fig. 4).

To measure stems of comparable size, we identified 6 classes of sizes for each of the 5 brands (total of 30 stems) which yielded a comparable diameter in the middle portion of the stem (B diameter). A significant difference was found in the flare index ($p=0.01$) and tapered index ($p=0.002$) of comparable sizes between the different brands (Fig. 5). When the stems of each brand were compared to each other, the flare index was still significantly different between TH and PS, CO and HM, TH and HM, PS and AM, and AM and HM; the tapered index was still significant between CO and PS, CO and AM, CO and HM, TH and PS, PS and AM, and AM and HM.

The length of the stem shoulder ranged between 33.3 mm (HM) and 39.4 mm (PS) in the smallest size and between

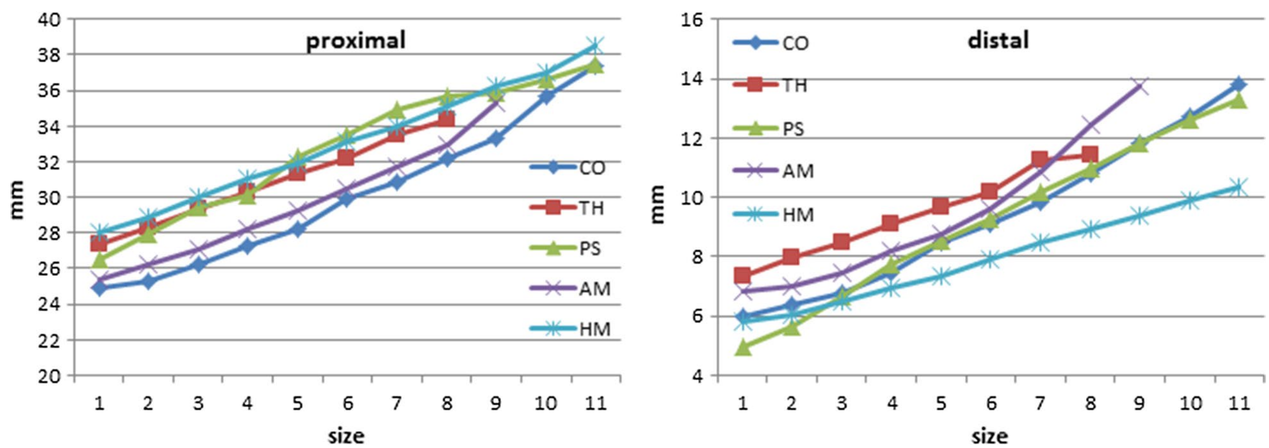

Fig. 3 Graphs showing correlation analysis between stem size and coronal diameters at the proximal (left) and distal level (right). A significant correlation was found between the increases in stem size and diameters in all brands

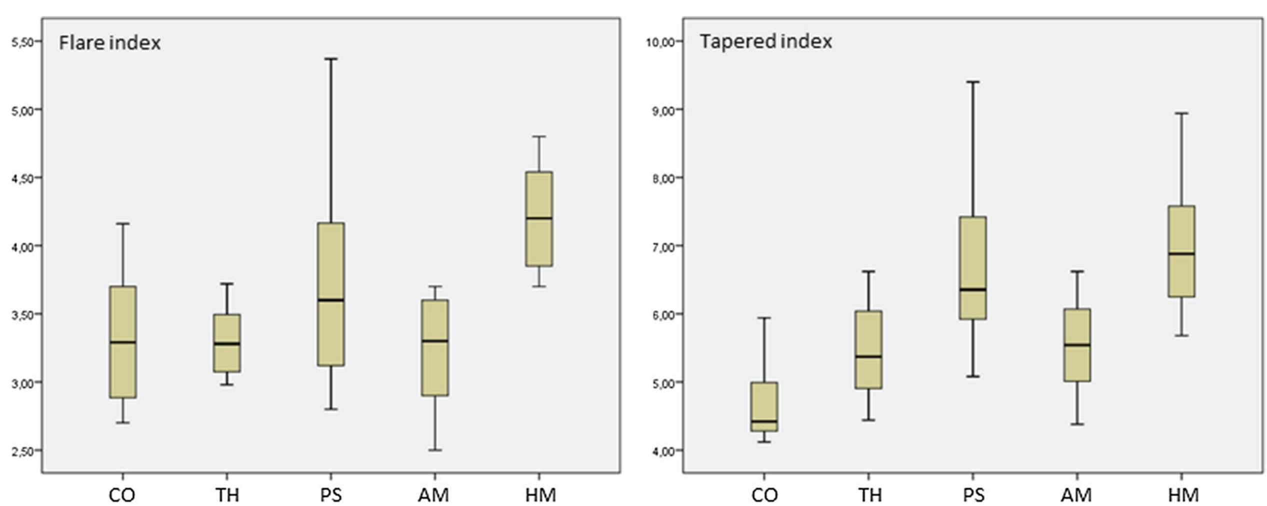

Fig. 4 Box plots showing the distribution of flare index and tapered index in all sizes of stems. The boxes represent the median (black line) and interquartile range (IQR), and error bars represent the range of data

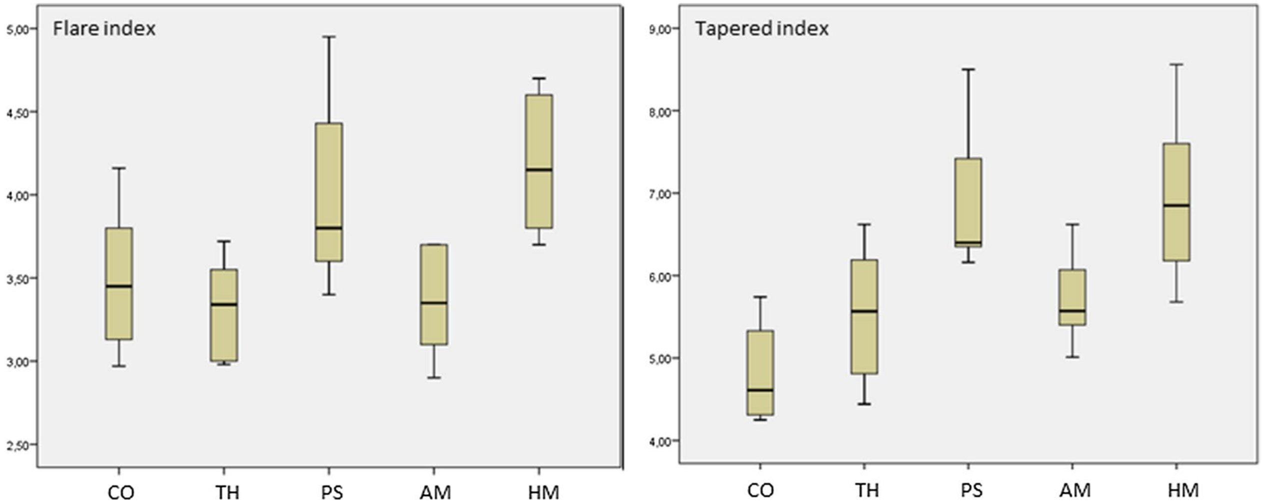

Fig. 5 Box plots showing the distribution of flare index and tapered index in comparable sizes. The boxes represent the median (black line) and interquartile range (IQR), and error bars represent the range of data

33 mm (HM) and 44 mm (PS) in the largest size. A significant difference was detected between the 5 brands in shoulder length ($p = 0.04$). The length of stem shoulder was found to increase with size by up to 9 mm in one brand (PS) and to be the same in all the sizes in another (HM). The metadiaphyseal angle ranged between 163° and 171° ($p < 0.001$). It was found to decrease as size increased in CO (from 171° to 165°), AM (from 170° to 163°) and PS (from 169° to 164°) or to remain the same as size increased in HM (167°) and TH (168°).

Discussion

Long-term follow-ups of Corail stem have shown high rates of satisfactory clinical outcomes [1–3], including a survival rate of 98 and 97% at 10 and 15 years, respectively, in 5456 stems analysed in the Norwegian Arthroplasty Register [2]. However, radiographic results appear to be less consistent than clinical outcomes. Progressive radiographic changes at the calcar level, including scalloping and osteolysis, have been found in up to 15% of Corail stems [3]; subsidence has been reported to range between −0.3 and 3.6 mm with RSA measurements [8] and between 0 and 26 mm when measured with standard radiographs [11]. The results have been even more discrepant in trauma and osteoarthritic patients, since a subsidence between 0 and 22 mm and between 0 and 5.5 mm has been reported in trauma and orthopaedics patients, respectively [10–12]. These results suggest that Corail stem may behave differently depending on the bone quality and the morphology of the femoral canal and that this aspect deserves to be investigated further since subsidence may increase the dislocation rate and be a cause of early revision [10].

Several TTSs-EHAC have recently been introduced on the market. Their geometry is similar and includes a tapered shape with a quadrangular cross section and a proximal flared portion in both planes. Horizontal and vertical groves are present on the porous coating, which is entirely covered with HA to enhance mechanical stability [3]. As these stems closely resemble each other and no investigation has previously been conducted to detect any differences between them, it might be assumed that any one of these stems can be used indifferently whenever a cementless stem is indicated. In this study, we analysed the geometry of 5 TTSs-EHAC to assess whether there is any significant difference between these stems. Measurements, including the coronal and sagittal diameters, flare index and tapered index, were taken at the metaphyseal and diaphyseal portion of each stem as well as halfway between these two portions. Our results have shown that stem diameters increase with size in all the stems. The coronal and sagittal diameters did not differ significantly between brands, possibly owing to the small number of stems available, even though a difference in coronal diameter of up to 3.1 mm in the smallest size and of up to 4.4 mm in the largest size at the calcar level, and of up to 2.3 mm in the smallest size and of up to 3.4 mm in the largest size at the distal level was detected. The flare index and tapered index yielded a significant difference when all the brands were considered; when each stem was matched with the others, the difference in flare index was still significant between HM and all the remaining stems except PS. The tapered index, which takes into account the ratio between the proximal and distal cross-sectional areas of the stem, differed significantly both when all brands were analysed together and when each stem was compared with the others, except for the difference between TH and AM and between PS and HM.

To compare stems of similar size, the measurements were repeated on 30 stems, 6 for each brand, with a similar coronal diameter in the middle of the stem. A significant difference was found in both the flare and tapered indexes when all the brands were considered. When the stems of each brand were compared to each other, the flare index was still significantly different between TH and PS, between CO, TH and HM, and between PS, HM and AM. The tapered index of comparable size showed a significant difference between PS, AM, HM and CO, between AM, TH and PS and between AM and HM. The results indicate that some of these stems exhibit a significantly more pronounced funnel shape than others, thus suggesting that their biomechanical behaviour may vary in different morphologies of the proximal femur. Further differences were found in the length of the tilted portion of the stem, i.e. the stem shoulder, which was found to increase with size in 3 brands but was the same in the other two, as well as in the angle between the metaphyseal and diaphyseal portions of the stem, which was found to decrease as the size increased in 3 brands but was the same in the other 2. Since the length of stem shoulder and metadiaphyseal angle affect the lateral flare of the stem, these findings indicate that the filling of the lateral metaphysis varies significantly in the analysed TTSs-EHAC.

Previous investigations have shown that stem geometry may affect the biomechanical behaviour of cementless stems and their clinical performance [13–16]. In the clinical setting, a reduced metaphyseal filling along with diaphyseal fixation was associated with proximal bone remodelling, BMD reduction and thigh pain [17–20], whereas no, or very limited, proximal bone remodelling was observed in stems requiring pure proximal fixation [21, 22]. On the basis of these investigations, cementless stems should be selected so as to achieve an adequate fill and fit in the operated femur. The results of this study have shown that TTSs-EHAC, although apparently similar, actually show substantial geometric differences which should be taken into account in the preoperative planning. In particular, in patients whose proximal femur exhibits a fluted shape with a narrow diaphyseal canal (Dorr type A) [23], TTSs-EHAC showing a high tapered index, such as HM and PS stems, may provide a better fit and fill in the proximal and distal femur than stems with a low tapered index (CO and TH). The latter are more likely to result in pure diaphyseal fixation, with increased risks of proximal stress shielding and thigh pain. By contrast, in patients with a stove pipe femoral morphology with large diaphyseal canal (Dorr type C), TTSs-EHAC with a low tapered index, such as CO and TH, may attain more extensive proximal and distal endosteal contact, reduce the risk of calcar cracks and provide greater implant stability than stems with a pronounced funnel shape.

This study has certain limitations. First, as the measurements have been performed on digitized images, it is possible that a more accurate evaluation of the stem diameters can occur by making the same measurements on the original stem. Second, as the number of stem sizes for each brand ranges between 8 and 11, it may be difficult to compare stems of exactly the same size. We tried to solve this issue by identifying 30 stems, 6 for each brand, with a similar diameter in the middle of the stem and considering these as stems of comparable size. Although the results of the comparable stems were in line with those based on all the stem sizes, other parameters may be used to identify the group of comparable stems. Lastly, we analysed 5 TTSs-EHAC, but other stems with the same features are present on the market.

In conclusion, five lookalike tapered titanium stems fully coated with HA were analysed in order to assess whether they may be considered to share the same design or whether there are substantial geometric differences between them that may affect their clinical performances and, hence, their use in patients with different femoral morphologies. The results of the study have shown that as the flare index, tapered index and lateral flare of these stems differ significantly, they should not be considered to share the same stem design. We suggest that these stems are not used indifferently in any patient in whom a cementless stem is indicated but rather on the basis of a preoperative planning in which the stem showing the best fit and fill is selected.

Authors' contributions GC has planned the study, analysed data and written the manuscript. GM and FRR performed the measurements on the all series of stems; GLT performed statistical analysis and contributed to the data interpretation; GG was a major contributor in the planning of the study, analysis of data and writing the manuscript.

Compliance with ethical standards

Sources of support The involved companies provided the stems analysed.

Conflict of interests The authors declare that they have no competing interests in this section.

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