International Orthopaedics (SICOT) (2015) 39:1065–1071
DOI 10.1007/s00264-014-2623-4

ORIGINAL PAPER

# Results of total hip arthroplasty using a bionic hip stem

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Received: 6 November 2014 / Accepted: 26 November 2014 / Published online: 9 December 2014


**Abstract**
*Purpose* The trabecular-orientated bionic hip stem was designed to mimic the natural force transmission through the femur in total hip arthroplasty, resulting in supposedly longer prosthesis survivability. The aim of this study was to compare the second-generation bionic hip stem to a standard uncemented hip stem.
*Methods* A group of 18 patients (21 hips) who underwent total hip arthroplasty with a bionic stem (bionic group) was compared with a historic group of 12 patients (12 hips) treated with standard anatomic hip stem (control group). During the first year after the procedure, the densitometric measurements of the bone around the prosthesis were taken. Radiographic and clinical assessments were additionally performed preoperatively and at the three month, six month, one year and three year follow-ups in the bionic group.
*Results* In the bionic group, one patient was revised for aseptic loosening and 16 patients (19 hips) were available to the final follow-up. A significant decrease of bone mineral density was found in Gruen zones 3, 4 and 5 in the bionic group, and in zone 7 in both groups. The bionic group had a significantly higher bone mineral density in Gruen zone 1 at the one year follow-up. At the final follow-up, all prostheses were radiologically stable in both groups.
*Conclusions* Provided that a good implant position is achieved, comparable short-term results can be obtained using a bionic stem. Still, a decrease of bone mineral density in Gruen zone 7 occurred in both groups. Further studies are required to determine survivability of the bionic stem.

**Keywords** Total hip arthroplasty · Bionic hip · Densitometry · Bone mineral density · Periprosthetic bone loss

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## Introduction

The conservation of periprosthetic bone stock over time is one of the crucial elements that enable the longevity of an endoprosthesis. Following total hip arthroplasty (THA) periprosthetic bone undergoes adaptive remodelling due to the biomechanical changes caused by the inserted implant [1]. The bone loss is most prominent in the first six months after THA, when bone mineral density (BMD) deficit may reach over 30 %, preventing optimal osseointegration [2, 3]. Periprosthetic BMD loss, caused by stress shielding which may also contribute to aseptic loosening with eventual implant destabilization [4], may be diminished by appropriate stem shape, size, material and coating [5, 6].

Holz and Copf have developed the so-called trabecular femoral hip prosthesis using a mainly metaphyseal fixation principle [7–10]. The stem of the first generation prosthesis was a coarse-meshed netting made from cobalt-chrome-molybdenum. Because of the very unusual design, this prosthesis drew considerable interest in the Central European orthopaedic community. However, osseointegration of the first generation smooth uncoated stem was unreliable [11]. A second generation "bionic" stem was ultimately made from titanium alloy and a heavier ribbed structure, which retained the

fenestrated design, and was additionally grid-blasted for better osseointegration. To the best of our knowledge, we could not find any recordings evaluating the performance of this type of prosthesis in vivo.

The main aim of the present study is to provide prospectively gathered short-term results, comparing periprosthetic BMD changes between patients treated with second generation Holz-Copf trabecular stems and proximally hydroxyapatite-coated cementless femoral stems.

## Materials and methods

### Study design and population

Twenty-eight patients (31 hips) were evaluated in this prospective study. Patients were selected consecutively from the official waiting list for total hip replacement. The inclusion criteria were unilateral degenerative hip changes necessitating cementless total hip arthroplasty (THA). Exclusion criteria included perioperative complications, revision surgery, and history of disorders known to affect bone or mineral metabolism. All patients provided written informed consent before inclusion and the study was approved by the National Medical Ethics Committee of the Ministry of Health and performed according to the ethical principles stated in the Helsinki Declaration.

Surgery was performed by two experienced surgeons in a single orthopaedic centre using the direct lateral approach. Original instruments and rasps provided from the manufacturers were used in all cases in both groups. Following their THA, the patients were allowed to walk with crutches with partial weight bearing during the first six weeks, and then progressed to full weight bearing over the next six weeks.

During the one year observation period, all patients were periodically assessed. Measurements were done with a dual energy X-ray absorptiometry (DXA), guaranteeing the best possible sensitivity, precision and reproducibility to date [12–14]. Additionally, patients with trabecular stems were clinically and radiologically followed for three years after surgery.

### Implants

In 18 patients, 21 Unibionix (Unior Bionic, Zreče, Slovenia) trabecular femoral stem prostheses were consecutively implanted (bionic group). Twelve patients received 12 ANCA-Fit (Cremascoli Ortho Group, Milan, Italy) proximally hydroxyapatite-coated femoral implants (control group). Acetabular implants used were of cementless press-fit cup design. The MultiCup (Merete Medical, Berlin, Germany) was implanted in the bionic group and ANCA-Fit cup (Cremascoli Ortho Group, Milan, Italy) in the control group. All cup inlays and femoral heads in both groups were made of alumina ceramic (Biolox Forte; CeramTec, Plochingen, Germany). Femoral stem technical characteristics are presented in Table 1.

### Bone mineral density measurements

BMD scans were performed in both groups at one week (baseline), three months, six months and 12 months postoperatively using a dual energy X-ray absorptiometry (DXA) on the same machine (QDR-1000plus; Hologic, Waltham, MA, USA). In the implanted femur, BMD was measured in each of the seven regions of interest (ROIs) based on Gruen zones in the proximal femur, as well as in the total proximal femur [15]. In the contralateral femur, BMD was measured in the neck and in the total proximal femur. BMD of the lumbar spine was also measured at the same time points. The coefficient of variation of the DXA machine was 0.34 %. Computer software (prosthetic hip and metal software version 6; Hologic, Waltham, MA, USA) was used to measure the periprosthetic BMD in the seven ROIs.

### Clinical and radiographic evaluation

The clinical outcome in bionic group was evaluated by Harris Hip Score (HHS) at six months, 12 months and 36 months postoperatively [16].

The bionic group received additional radiographic evaluation. Two orthopaedic surgeons not involved in the patients' operations independently reviewed the serial radiographs. Early radiographic analysis consisted of: anatomical specifications of proximal femur in two standard projections pre-operatively, prosthesis position on the AP roentgenogram at day 1 after implantation including comparison of biomechanical parameters to the contralateral hip, and the three months post-operative AP and lateral roentgenogram assessment following the recommendation of Johnston et al. [17]. Late radiographic analysis was conducted on control roentgenograms in two standard projections at six months, one year and three years postoperatively. Predictive signs of early femoral stem failure were sought after the criteria established by Kobayashi et al. [18]. Charts from the control group were reviewed and the latest radiographs were also analysed using the same criteria [18].

### Statistical analysis

Friedman's test was used to look for significance among data measured at different time intervals in each groups. Statistical significance was a $p$ value of less than 0.05. Mean values of demographics, BMD and baseline-normalised BMD were compared between the bionic and control groups at each time point using the Mann–Whitney test, with a level of significance of 0.05.

**Table 1** Femoral stem technical characteristics

| | Bionic stem (Unibionix) | Control stem (ANCA-Fit) |
|---|---|---|
| Material | TiAl6V4 | TiAl6V4 |
| Coating | – | Proximal third only, 80 μ crystalline HA (plasma sprayed) |
| Stem lengths | 69.6 mm (size 30) to 97.2 mm (size 80) | 119.5 mm (size 9.5) to 138.5 mm (size 17.5) |

## Results

Thirty patients (33 hips) were initially eligible for the trial and agreed to participate. Of these two patients (two hips) in the bionic group did not complete the follow-up: one was excluded from the study due to revision surgery and the other died from unrelated causes. Patient sampling for DXA measurement is shown in Fig. 1.

Apart from median age, there were no significant differences between baseline characteristics in the bionic and control groups (Table 2).

### BMD changes in the bionic and control groups

Both groups presented significant temporal total periprosthetic BMD decrease. Corresponding lines in Fig. 2 show the greatest decrease occurring at three months postoperatively followed by a slow and incomplete recovery from the 3rd to 12th month.

Within the bionic group, significant temporal BMD decreases were found in ROIs 3, 4, 5 and 7. The greatest decrease of 15 % was found in ROI 7, the femoral calcar region, at 12 months, with a persistently declining trend.

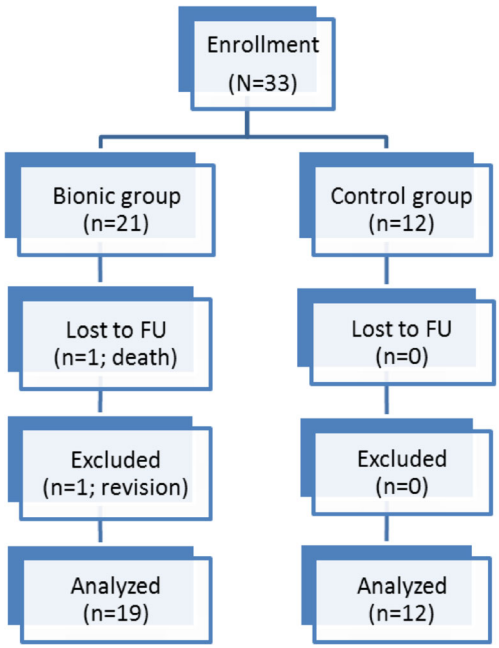


**Fig. 1** Flow chart presenting patient sampling for DXA measurements. *N* or *n* number of hips

Following a similar pattern, the most pronounced BMD reduction of 15 % also occurred in ROI 7 in the control group at 12 months postoperatively. This was the only statistically significant BMD deviation recorded within the control group.

Significant BMD increase in the bionic group was found in ROI 1 at 12 months. This hypertrophy occurred with a constant positive inclination from 3rd to 12th month postoperatively.

Statistically significant differences between the two groups were found in ROI 4 at three and six months and in ROI 1 at six and 12 months. In ROI 1, BMD progression trend could be shown in the bionic group reaching 110 % at one year, as opposed to BMD loss observed in the control group. In ROI 4, a constant BMD level near the baseline could be shown in the control group, as opposed to BMD loss in the bionic group.

In the contralateral femur as well as in the lumbar spine, there were no significant temporal BMD changes within the bionic and control groups.

### Clinical results in the bionic group

The HHS score improved from a mean of 41 pre-operatively to a mean of 82.5 after six months. HHS score further increased to a mean of 88 at 12 months postoperatively, but dropped to a mean of 74 points at 36 months postoperatively. These changes were significant compared with the pre-operative scores ($p$=0.018, Friedman's test) (Fig. 3).

### Radiographic evaluation

Early radiographic analysis showed that 15 out of 19 patients (79 %) in the bionic group had the prosthesis implanted in an

**Table 2** Patients' demographical data

| | Bionic group ($n$=19) | Control group ($n$=12) | $p$ value |
|---|---|---|---|
| Age (median, (range)) | 60 (47–78) | 49 (38–61) | 0.003[a] |
| Gender (M:F) | 8:11 | 8:4 | 0.273[b] |
| BMI (median, (range)) | 28 (19–35) | 29 (24–33) | 0.372[a] |
| Side (R:L) | 13:6 | 5:7 | 0.262[b] |
| Total spine BMD (g/cm$^2$) | 1.015 | 0.998 | 0.669[a] |

*n* number of hips

[a] As determined by Mann–Whitney test

[b] As determined by Fisher's exact test

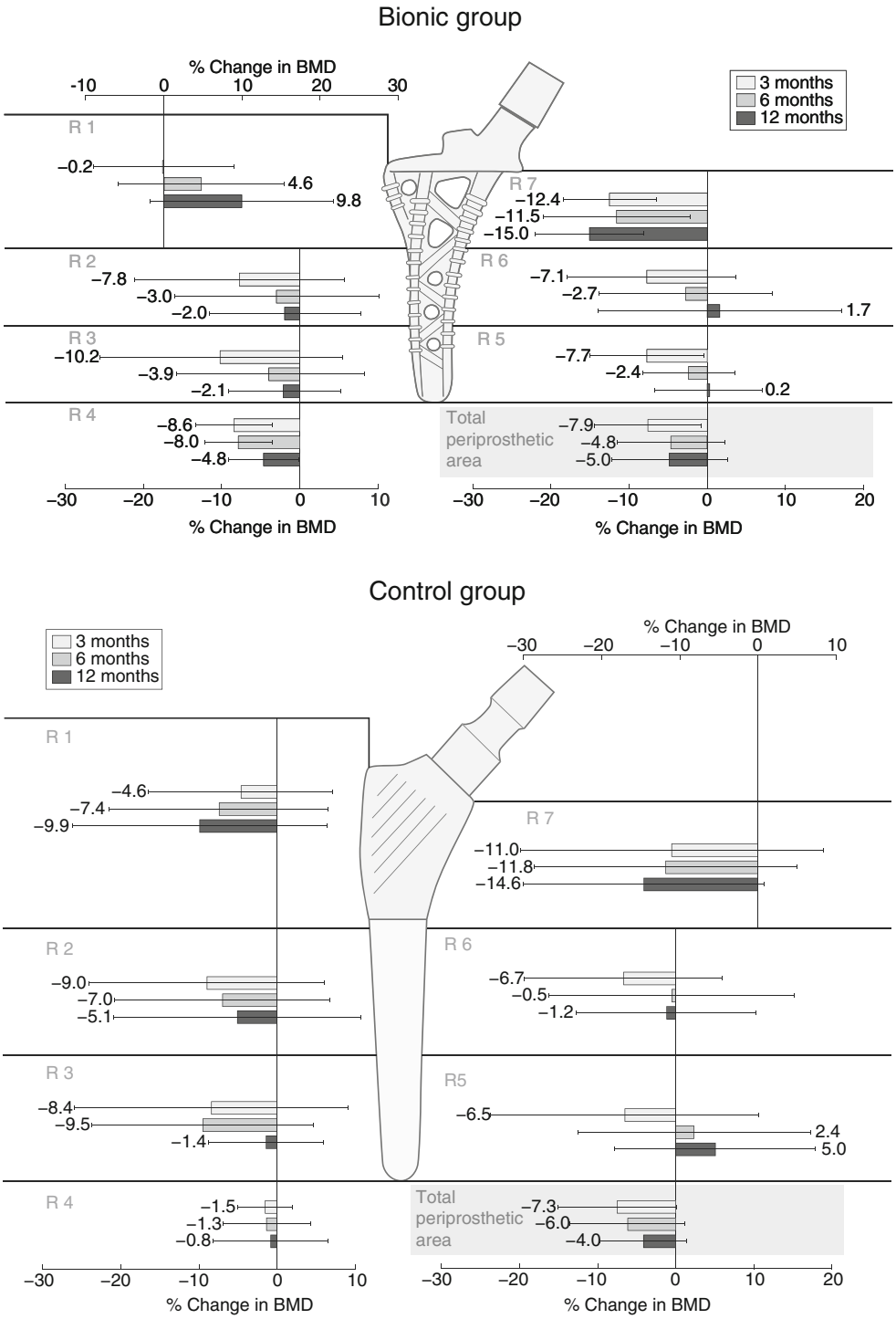


**Fig. 2** Temporal periprosthetic BMD changes in bionic and control groups in total periprosthetic areas and in the seven Gruen zones

ideal position (Fig. 4). In all four non-ideally placed patients, the base plate of the stem was not seated all the way to the femoral calcar. The main reason for this non-ideal position was the premature metaphyseal engagement of the shaft, preventing the base plate to slide down firmly on the femoral calcar (Fig. 5). Late radiographic analysis in the bionic group showed no predictive signs of early femoral stem failure. Heterotopic ossification was found in nine of 19 hips (47 %) in the bionic group: Brooker grade I (four hips), grade II (four hips), and grade III (1 hip), but no grade IV. In the control group, all femoral stems were stable and without radiolucent lines at latest follow-up at eight years (median, range seven to nine years) after THA. Heterotopic ossification was found in three of 12 hips (25 %) in the control group: Brooker grade I (2 hips), grade II (one hip), but no grade III and IV.

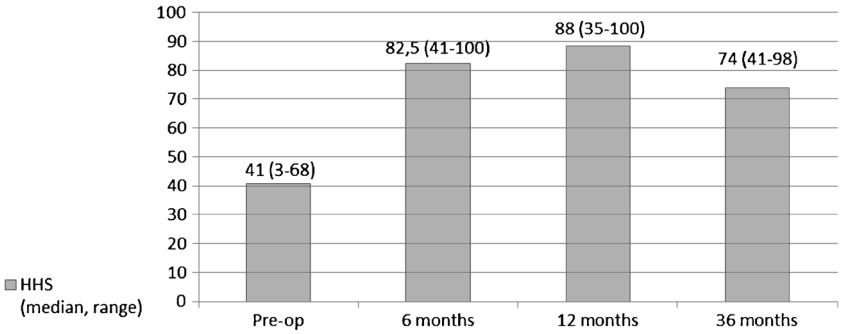


**Fig. 3** Clinical outcome in bionic group

Revisions

One hip was revised 16 months after primary implantation for aseptic femoral loosening (isolated revision of the bionic stem and the modular femoral head). A modular uncemented revision stem (MP Reconstruction prosthesis; Waldemar Link, Hamburg, Germany) was implanted and the patient's follow-up was uneventful. Histological examination revealed the connective tissue with moderate lymphocytic infiltrate, vascular proliferation and small areas of chondroid metaplasia. There were no revisions and no impending revisions at the most recent follow-up in the control group.

## Discussion

The Unibionix femoral implant was designed and marketed as an improved version of the bionic prosthesis developed in the 1980s [9]. Its short, anatomically shaped stem engages and loads the femur proximally. This should result in favourable force transmission on the proximal femur [10]. The specific shape of the Unibionix stem was thought to enable cancellous bone preservation, which should minimise the disruption of hydrodynamic, thermic and elastomechanic processes inside the proximal femur in comparison with the standard endoprosthetic stems. Currently, a slightly modified third generation of the trabecular-orientated endoprosthesis is entering the European market (Copf-Bionic, Ludwigsburg, Germany). For patient safety, it is important to report on bionic stem design behaviour in vivo.

Venesmaa et al. [19] have monitored the quantity changes in femoral bone mass after uncemented THA insertion with DXA for three years. The most remarkable decrease in BMD was found in ROI 7 at the end of the first year [19]. In our study, knowing that the plateau is reached 12 months postoperatively, one year periprosthetic BMD monitoring with DXA was chosen for the patient's convenience. Similar results with

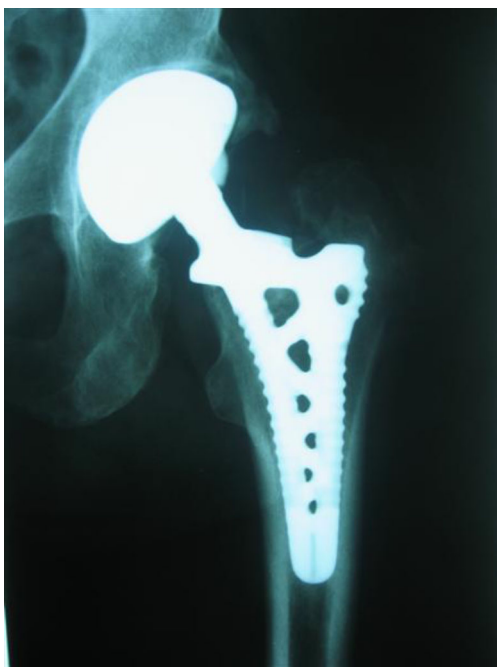

**Fig. 4** Anteroposterior radiograph 3 months after correctly implanted bionic THA

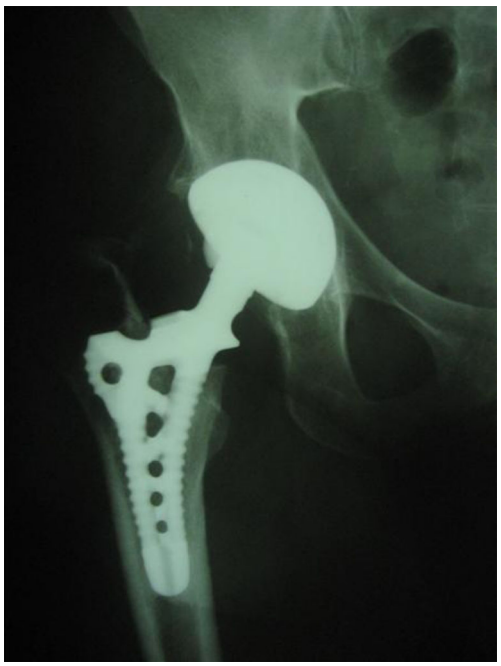

**Fig. 5** Anteroposterior radiograph 3 months after implanted THA. Note the gap between the base plate and femoral calcar

a plateau reached at 12 months were obtained by Rahmy et al. [2], who measured periprosthetic BMD after two types of uncemented femoral implants with proximal hydroxyapatite coating for three years after THA. These authors found the largest BMD decrease in Gruen zones 1 and 7, with mean losses of 12.6 % and 16.3 % respectively in Anatomic Benoist Girard (ABG; Stryker, Newbury, UK) patients, and 10.9 % and 6.3 % in Mallory Head (MH; Biomet, Warsaw, IN, USA) patients, thus showing that prosthesis design influences periprosthetic bone loss [2]. The ABG stem has an anatomical press-fit, whereas the MH stem is straight and aims to three-point fixation. Both mentioned stems are made of titanium alloy (Ti6Al4V). The ANCA-Fit stem also aims to anatomically press-fit, is proximally HA coated, and is made from titanium alloy. Similar BMD decrease of ANCA-Fit stem in ROI 7 as reported for the ABG femoral stem is therefore not unexpected. Because of the different geometry of the bionic stem, better bone preservation in Gruen zone 7 could be expected. However, our results showed similar BMD decrease in Gruen zone 7 in the bionic group compared with anatomical stem designs.

Bionic stems are shorter than the conventional stem designs. Jahnke et al. [14] have recently measured changes of periprosthetic bone density after cementless short hip stem (Metha; B. Braun–Aesculap, Tuttlingen, Germany). BMD atrophy was shown in ROIs 1, 4 and 7; atrophy at 12 months was reaching −8.0 %, −1.8 % and −11.4 %, respectively. The main difference between these results and the results of our study, obtained in the bionic group, is in the ROI 1, the greater trochanter area. The bionic stem is unique in having a big lateral notch, giving the implant additional rotational stability. This notch requires larger greater trochanter resection during stem implantation. This may be the cause of greater trochanter hypertrophy measured with DXA, which was not found in other similar studies [1, 3]. Clinically, greater trochanter overload may be expressed as trochanteric pain, mostly responsible for slightly decreasing HHS at three years postoperatively, compared with HHS at 12 months. The lateral notch was reduced in the third generation of bionic stem design.

Special attention should be given to the patient, in whom revision surgery was performed for aseptic loosening of the bionic stem 16 months after primary THA. Removal of the prosthesis was relatively easy since the absence of ingrowth of cancellous bone into the fenestrated stem did not hinder the removal of this macroscopically loose and clinically symptomatic implant. The implant appears to be exposed to the identical problem as seen in other short hip endoprostheses: a high risk of bone overload as a consequence of a short stem being placed into poor quality bone. Bishop et al. [20] have clearly shown that bone stresses rise with decreasing implant length and diameter, varus implantation, incomplete engagement and high implantation forces. Hamadouche et al. [21] have recently confirmed that relative motion of stem tip of distally shortened cemented implants increased significantly compared with longer versions of the same batch. Although the bionic prosthesis is small, revision with a standard revision stem with diaphyseal anchoring was necessary in our patient because no metaphyseal bone has been left after unstable bionic stem removal. Others have shown that even with bone growth into Austin-Moore type fenestrations without completely filling them results in a loose prosthesis, which cannot be easily removed [11]. Therefore, the bionic stem may not conserve bone. It is possible, however, that this failure in our series appeared as a result of improper patient selection and surgeon's inexperience with this particular stem design due to a steep learning curve.

One of the major drawbacks of this study lies in the non-randomised patient selection which may include confounders. The other major drawback is the small cohort size. Even though correlations between age and BMD changes after THA could not be established, BMD changes are more frequent with older patients [22]. However, the study reported here showed for the first time the evidence of highly significant differences in regional adaptive remodelling between two different designs. Furthermore, this is also the first bionic study correlating DXA measurement with radiological and clinical data. We agree that 36 months is a short follow-up period for radiological and clinical results in a THA patient, but most of the dynamic remodelling processes are determinable within one year [23]. The effect of bone loss caused by the operation was also excluded using the initial postoperative BMD measurement as the baseline. Certainly, long-term studies have to be carried out before third-generation bionic prostheses could be introduced into routine clinical practice.

**Conflict of interest** The authors declare that they have no conflict of interest.

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