Medical Engineering & Physics 36 (2014) 345–353

Contents lists available at ScienceDirect

Medical Engineering & Physics

journal homepage: www.elsevier.com/locate/medengphy

Improving peri-prosthetic bone adaptation around cementless hip stems: A clinical and finite element study

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ARTICLE INFO

Article history:
Received 2 April 2013
Received in revised form
20 November 2013
Accepted 1 December 2013

Keywords:
Cementless hip arthroplasty
Bone mineral density
Finite element analysis
DEXA

ABSTRACT

This study assessed whether the Symax™ implant, a modification of the Omnifit® stem (in terms of shape, proximal coating and distal surface treatment), would yield improved bone remodelling in a clinical DEXA study, and if these results could be predicted in a finite element (FE) simulation study.

In a randomized clinical trial, 2 year DEXA measurements between the uncemented Symax™ and Omnifit® stem (both $n = 25$) showed bone mineral density (BMD) loss in Gruen zone 7 of 14% and 20%, respectively ($p < 0.05$). In contrast, the FE models predicted a 28% (Symax™) and 26% (Omnifit®) bone loss. When the distal treatment to the Symax™ was not modelled in the simulation, bone loss of 35% was predicted, suggesting the benefit of this surface treatment for proximal bone maintenance.

The theoretical concept for enhanced proximal bone loading by the Symax™, and the predicted remodelling pattern were confirmed by DEXA-results, but there was no quantitative match between clinical and FE findings. This was due to a simulation based on incomplete assumptions concerning the yet unknown biological and mechanical effects of the new coating and surface treatment.

Study listed under ClinicalTrials.gov with number NCT01695213.

1. Introduction

Successful biologic fixation of uncemented total hip prostheses is inevitably associated with resorptive bone remodelling, because of load sharing and stress protection of bone by the implant. This has been a concern in the early generations of stems where proximal femoral bone loss up to 62% was detected, both experimentally as well as clinically [1,2]. This bone resorption may in the long term compromise implant support, cause periprosthetic bone fracture and challenge revision procedures. Therefore in the development of new total hip designs, a need is felt for diagnostic tools that can discriminate between superior and inferior implants. Such tools should be able to predict unacceptable clinical outcome like excessive bone loss, high risk of loosening and revision, in an early postoperative or even preoperative stage.

For this purpose finite element analysis (FEA) has been used to estimate loads and stresses in periprosthetic bone and interfaces [3,4]. Through Numerical Shape Optimization (NSO) the optimal geometry and material of an implant were calculated, based on predefined goals in terms of maximally acceptable strains and stresses in the bone and interfaces [5].

The major limitation of the FE-technique is that it remains a computer model that makes several assumptions on implant material properties, bone properties [6], implant–bone interface conditions [7], and loading-boundary conditions (interface loading forces during daily activities, hip and muscle forces) [8]. It is obvious that because of all these assumptions, the extent to which FE-models can realistically simulate failure mechanisms, is uncertain.

Despite these limitations, it is generally accepted that FEA can adequately predict qualitative bone remodelling around implants as these FE-models are suitable to address the relationship between mechanical stimuli and bone remodelling [9]. Bone remodelling is often expressed as the postoperative change in periprosthetic bone mineral density (BMD) as measured by dual energy X-ray absorptiometry (DEXA). In recent years several studies have been performed to retrospectively correlate 2-D and 3-D FEA predictions with the effects on bone density [10–12]. Attempts were focused

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http://dx.doi.org/10.1016/j.medengphy.2013.12.006

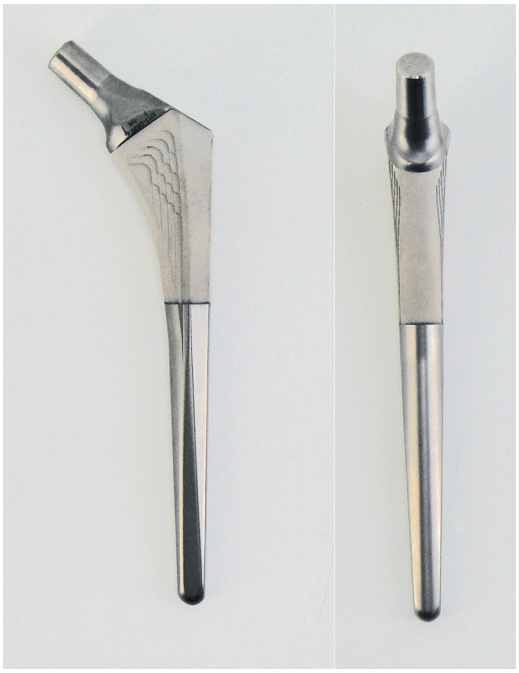

Fig. 1. The HA Omnifit® hip stem, geometrically a straight double wedge design, is made of Ti-alloy, has a macro-textured surface of which the proximal 40% is plasma sprayed HA-coated, and has a distal matte finish, all aimed at proximal fixation. The HA-coating is highly crystalline (65%) explaining slow resobability.

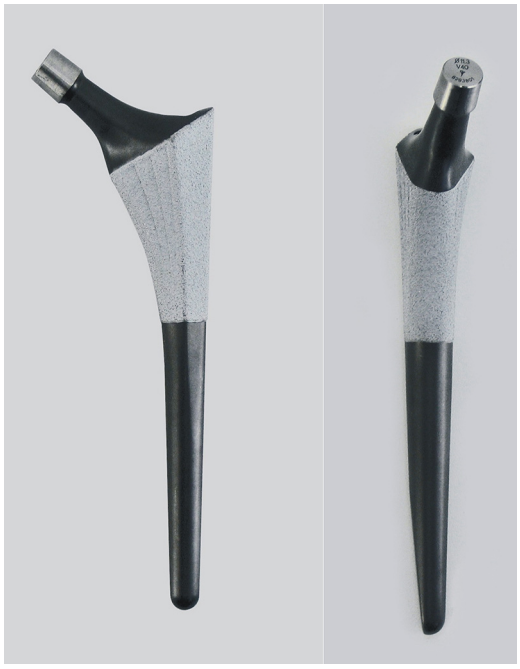

Fig. 2. Illustrations of the Symax™ stem in AP (left) and lateral (right) vue, showing a straight stem with the neck in an anteverted position. It features a proximal plasma-sprayed CP titanium layer, with a biomimetic electrochemically deposited BONIT®-HA coating of very high porosity of 60%, and only 10–20 μm thick. Distally the stem is treated with the Dotize® surface process, which reduces distal bone apposition and osseointegration.

on finding a quantitative relationship between absolute values of stress in the bone at implantation, and subsequent remodelling changes in terms of BMD-values. By analyzing bone remodelling around a known implant one can propose changes to its design in order to improve the load transfer between implant and bone and reduce bone resorption.

As an example the Symax™ stem has been developed from the Omnifit® design in order to modify the press fit characteristics of the proximal stem geometry. A more bioactive biomimetic BONIT®-HA coating, applied to the proximal part of the stem, should also result in faster, deeper and more extensive bone–implant contact, as could be confirmed from a recent human retrieval study [13], and from experimental studies in animals [14]. It has been shown that osteoconductive coatings like hydroxyapatite may be used to promote proximal stress transfer, diminishing effects of stress shielding [1,15,16]. Furthermore the Dotize® treatment on the distal part of the stem was used to prevent bone apposition in that area, and enhance loading of the proximal femur [13].

In this study periprosthetic bone stock preservation around the two stem designs was compared in a prospective randomized clinical trial (RCT). Secondly it was assessed whether the results of the clinical trial could have been predicted by the FE simulations.

2. Materials and methods

2.1. Implants

The Omnifit® HA stem (Stryker®, Mahwah, New Jersey, USA) is forged from Ti6Al4V alloy, has a macrotextured surface and a plasmaspray HA-coating on the proximal 40% of the stem (Fig. 1). The HA coating has a thickness of 50 μm (45–65) with a porosity of <3%. The HA after spraying has a relatively high crystalline phase of 65%. The implant is a successful and well documented uncemented HA-coated stem [17–19].

The uncemented Symax™ hip stem (Stryker® EMEA, Montreux, Switzerland) was based on shape optimization of the Omnifit® stem. Preclinical design studies consisted of CT-investigations combined with finite element analyses to optimize fit and fill with even stress distribution without peak stresses in the bone and at the interface. It is also made of Ti6Al4V, features a proximal plasma-sprayed CP Titanium coating with an open porosity of 20–40% to enhance initial stem fixation, and a biomimetic electrochemically deposited BONIT®-HA coating with a high porosity of 60%, and 10–20 μm thick (proprietary to DOT GmbH, Rostock, Germany) (Fig. 2) [20]. The adhesion strength of both HA-coatings is comparable and about 65 MPa

Distally the stem is treated with the Dotize® surface process, an electrolytic conversion of titanium surfaces in which the thin native oxide film is replaced by a thicker oxidized surface layer that reduces protein adsorption and consequently distal bone apposition and osseointegration [20].

2.2. Clinical Trial Study

2.2.1. Design and patient selection

A prospective, individually randomized, two group, parallel comparative trial was performed between the uncemented Symax™ ($n = 25$) and the Omnifit®-HA stems ($n = 25$). The indication for total hip arthroplasty (THA) was in all cases osteoarthritis (OA) of the hip. Exclusion criteria were a history of hormonal therapy, any medication or illness known to affect bone metabolism, and a Quetelet index (BMI) higher than 35. After signing the appropriate informed consent forms, patients were allocated at random to one of either group in a 1:1 randomization ratio. The allocation sequence was generated by an independent trial bureau and concealed from the operating surgeon. Participants were enrolled from sequentially numbered, identical, opaque, sealed envelopes just before the operation, the surgeon being unaware of the content and sequence of the envelopes (allocation concealment). Both groups were comparable in terms of patient demographics (see Table 1). The study was approved by the local Institutional Review

Table 1
Patient characteristics and baseline demographic data.

	Omnifit®	Symax™
Mean age at operation in years (range)	60.4 (39–71)	60.2 (46–72)
Weight in kg (range)	78.5 (60–96)	82.2 (54–105)
Body Mass Index (range)	27.2 (22–32)	27.8 (22–37)
Male/female	15/9	12/13
Normal start BMD	16	17
Osteopenic/osteoporotic start BMD	7/1	7/1

Board prior to the start of the study (registration no.: 02-072), is listed in the Clinical Trials Registry (ClinicalTrials.gov identifier: NCT01695213), and was carried out in line with the Seoul amendment (2008) of the Helsinki declaration.

2.2.2. Surgical protocol and postoperative management

All operations were performed randomly by the same 2 staff surgeons (R.t.B. or R.G.) according to completely identical and standardized orthopaedic procedures using the postero-lateral approach. Patients were treated with 24 h intravenous antibiotic prophylaxis (Augmentin®), DVT prophylaxis with a small molecular heparin (Fraxiparin®) during 6 weeks and standard prophylaxis against heterotopic ossifications with an NSAID (Indocid®) for 14 days. Patients were allowed to full weightbearing from day 1.

2.2.3. DEXA protocol

In the first postoperative week the baseline BMD measurement was performed with the Hologic QDR 4500A densitometer (Hologic Inc., Waltham, MA, USA) according to the protocol, including exact positioning of the leg with stabilizing rotation using standard knee and foot support devices. Quality control of the densitometer was executed through daily automatic self-calibration, not showing any significant drift during the study period. Considering a difference in length of HA-coating between the stem-designs, the periprosthetic regions of interest (ROI) were placed around the stem according to adapted Gruen zones in such a way that ROI 1 and 7 covered comparable bone areas, and ROIs 2–6 were equally divided around the rest of the stem (Fig. 3). All DEXA-scans were done by the same independent analyst.

Follow up evaluations were performed at 6 weeks, 3 months, 6 months, 1 year and 2 years, and analysis of all raw scans was independently done by one member of the research staff (R.H.) without involvement of the operating surgeon.

2.2.4. Statistics of the clinical trial

Longitudinal BMD results (in g/cm^2) per Gruen zone are expressed as relative values with the immediate postoperative DEXA measurement of the operated femur being the reference value, set at 100%. Absolute and relative BMD values are described by mean and standard deviation, demographic parameters by mean and range. Since no deviations from normal distribution could be observed, comparing the Symax™ and Omnifit® group in any of the ROIs, the one-sample t-test in cases of paired data (comparisons within a group) and the two-sample t-test in cases of unpaired data (comparisons between groups) was used.

The statistically required sample size is based on a power-analysis performed on the ability to detect a minimal mean difference of BMD-results between stem designs (δ). Based on earlier studies we assumed this difference to be 25%. By convention, an α-error rate of 0.05 was adopted, and the β-error was set at 0.20 (power $1-\beta = 80\%$). We were planning a study of a continuous response variable from independent control and experimental subjects with 1 control(s) per experimental subject. In a previous study the response within each subject group was normally distributed with standard deviation 25%. If the true difference in the experimental and control means was 20%, we would need to study

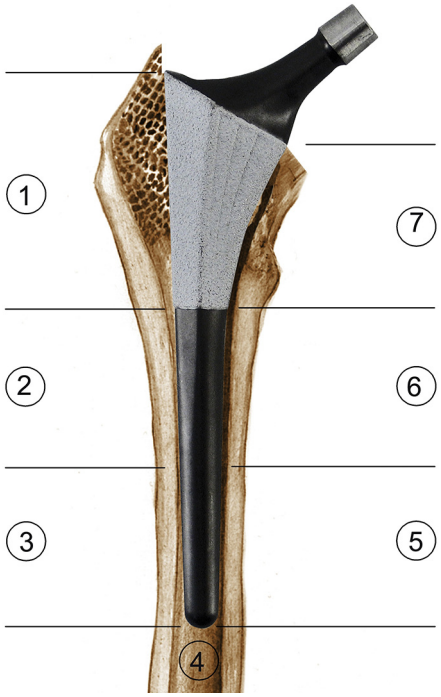

Fig. 3. Drawing showing delineation of Gruen zones 1–7 in the AP view around the Symax™ stem.

25 subjects in the Symax™ arm and 25 subjects in the Omnifit® arm to be able to reject the null hypothesis that the population means of these groups were equal with probability (power) 0.8. The type I error probability associated with the test of this null hypothesis was 0.05.

Microsoft Office Excel 2003 (Microsoft Corporation, Redmond, Washington, USA) and SPSS software 15.0 for Windows (SPSS Inc., Chicago, Illinois, USA) was used for data analysis.

2.3. Finite element bone remodelling study

2.3.1. Finite element model

We used a validated FEM-model of CT data of a human femur [21]. The bone was CT scanned along with a calibration phantom (solid, 0, 50, 100, 200 mg/ml calcium hydroxyapatite, Image Analysis, Columbia, KY, USA). The data was processed using a medical imaging software package (MIMICS 11.0). Subsequently, we created two uncemented THA reconstructions implanted with the Omnifit® and the Symax™ stem. The stems were positioned in the virtual bone by an experienced surgeon (R.t.B.), using in-house software (DCMTK MFC 10.8), which allows manipulation of a solid (stem) model within the visualized CT-data of the femur [21]. The models of the reconstructions were solid meshed using an FEA preprocessor (Mentat 2007r1, MSC Software), and they consisted of ~97,000 and ~18,000 linear four-noded tetrahedral elements for the bones and stems, respectively [22]. The isotropic properties of cortical and trabecular bone were derived from the calibrated CT data. The calibration phantom was used to convert Hounsfield Units (HU) to calcium equivalent densities (ρ_{CHA}). An in-house software package was used to assign a calcium equivalent density (ρ_{CHA}) to each element, based on the average ρ_{CHA} value of all pixels in the element volume. The ash density was computed using relationships specific to the type of phantom used ($\rho_{ash} = 0.0633 + 0.887\rho_{CHA}$). The elastic modulus ($E$, MPa) was computed for each element from ash density (ρ_{ash}) using correlations for trabecular and cortical bone [23]. The elastic modulus of the stems was set to 105 GPa. The Poisson's ratio for the bone and implant was set to 0.3 [24]. The reconstructions

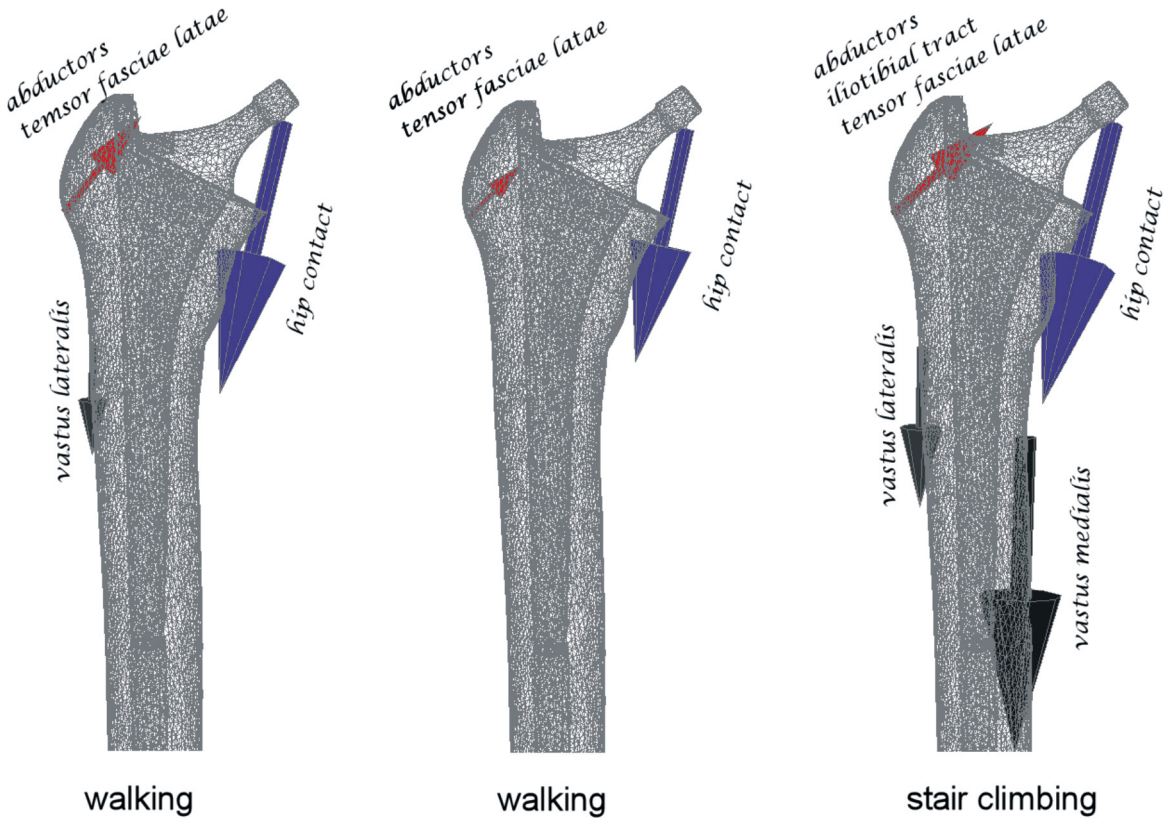

Fig. 4. The reconstruction was subjected to the loading condition of normal walking (toe off and heel strike) and the peak force during stair climbing.

were fixed distally and subjected to an alternating loading history of normal walking and stair climbing (Fig. 4 and Table 2) [25].

2.3.2. Bone remodelling and DEXA simulation

We used the strain adaptive remodelling theory to simulate changes in bone mineral density in time ($d\rho/dt$) [26]. The size of 'dead zone' and computer time unit were determined in our previous remodelling study in which we utilized the same bone model [21]. In that study the FE remodelling prediction around the EPOCH FullCoat stem was fitted to 2 year clinical DEXA data in order to define the adequate 'dead zone' and to determine the time unit in the simulation [27]. The best fit was obtained for dead zone value 0.35 and time unit 60 (meaning that 60 computer time units correspond to 2 year clinical reality). A further description of the remodelling theory used is given in our previous remodelling study [21]. These previously determined values of 'dead zone' and time unit were used here when performing the remodelling prediction in the reconstructions with the Omnifit® and Symax™ stems. To allow for clinically relevant interpretation of the remodelling results, we used an in-house software package (DCMTK MFC 10.8) to project the FE results of bone remodelling onto 2D virtual DEXA images. This in-house algorithm maps a 3D voxel mesh onto the FE reconstruction. Each pixel in 2D DEXA image has a calcium equivalent value corresponding to the summation of the calcium equivalent values of 3D voxels along the chosen DEXA scan axis. Detailed description of the in-house algorithm used here is also given in our previous study [21].

We defined the seven Gruen zones according with the guidelines [28], adapted for uncemented stems with proximal coating, and computed bone density (BMD) (g/cm^2) and local bone mineral content (BMC) (g) at one and two years postoperatively for each implant composition. The bone loss predicted by our simulations was defined as a percentage of the pre-operative bone mass.

2.3.3. Cases analysed

The design changes of Symax™ relative to the Omnifit® stem concerned three aspects: the shape, proximal coating and treatment of distal stem with Dotize® surface process. The geometry and distal surface treatment were modelled in our FE study, but the differences between proximal coatings of both stems were not simulated as both stems were assumed to be bonded at the coated locations. The difference in design (geometry, offset and stem length) was modelled based on CAD-files provided by the manufacturers. Equal loading conditions were applied to both stems. The radiography findings in the reconstruction with Symax™ reveal reactive lines around the anodized surface of the stem (Fig. 5). However, the actual effect of the distal surface treatment of the Symax™ stem would be difficult to predict pre-clinically. There-

Table 2
Details of joint contact and muscle force vector directions and magnitudes.

Loadcase	Walking (toe off)			Walking (heel strike)			Stair climbing		
Direction	Fx	Fy	Fz	Fx	Fy	Fz	Fx	Fy	Fz
Hip contact	−432 N	−263 N	−1833 N	−342 N	29 N	−1575 N	−475 N	−485 N	−1890 N
Abductors	518 N	122 N	646 N	375 N	6 N	369 N	664 N	237 N	618 N
Vastus lateralis	−7 N	148 N	−743 N	0	0	0	−18 N	179 N	−1081 N
Vastus medialis	0	0	0	0	0	0	−70 N	317 N	−2137 N

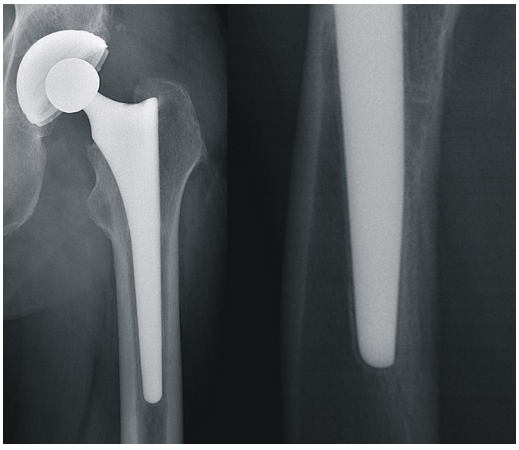

Fig. 5. X-rays showing reactive lines in Gruen zone 2 up to and including zone 6 (AP view, left), and zone 9 up to and including zone 13 (lateral view, right) around a Symax™ stem. This is a sign of absence of bone attachment in the distal anodized part of the stem.

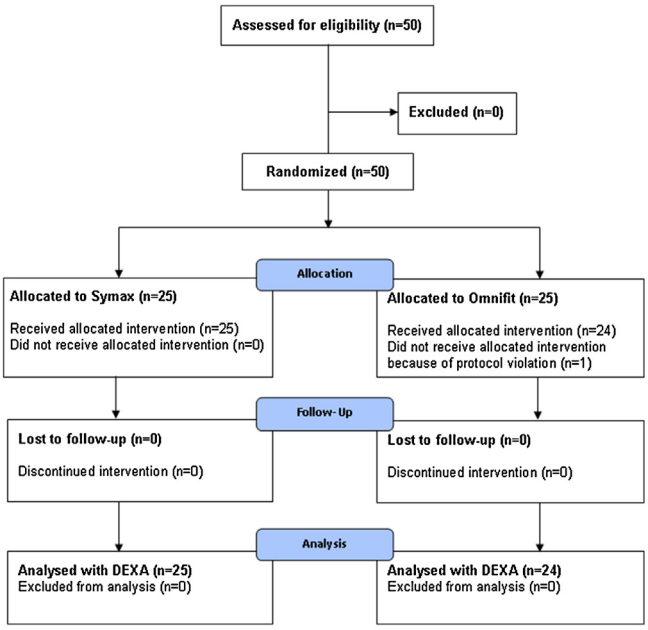

Fig. 6. Patient enrolment flow diagram.

fore, we simulated two extreme cases for the Symax™ stem (with a gap of 0.5 mm around the distal part of the stem, and without a gap assuming a frictional contact ($\mu = 0.3$) between implant and bone distally). While, in the reconstruction with Omnifit® stem the distal implant–bone interface was modelled by assuming a frictional contact ($\mu = 0.3$) between implant and bone [29]. Hence, we simulated one case for the Omnifit® stem and two cases for the Symax™ stem (either with or without a distal gap).

3. Results

3.1. Clinical DEXA results

There was no statistical difference in the demographic details and initial bone quality between patients in either group, confirming that preoperative conditions between the two groups were comparable (Table 1). There was one patient (Omnifit®) withdrawn from the study because of protocol violation, no further patients were lost to follow-up (see flow chart Fig. 6). There was no difference in physical activity among patients postoperatively, as assessed with the Harris Hip Score.

All patients had all their scans performed during the entire follow-up and within the predefined timeframe. At one year follow-up all stems showed radiological evidence of stable bone ingrowth according to the classification of Engh et al. [30]. Evolution of BMD in both implant groups is represented graphically in Fig. 7. A decrease in BMD was detected with both stems in all Gruen zones except zone 4, at 3 months after surgery, varying between −1.9% and −9.5% for the Symax™ prosthesis and between −1.0% and −13.0% for the Omnifit® prosthesis. Starting between 3 and 6 months postoperatively, complete recovery of bone loss was initiated in zones 2, 3, 5 and 6. In zone 1 and particularly zone 7 however there was additional bone loss, increasing to −20.3% for the Omnifit®, and −14% for the Symax™. Only in zone 7 the difference in bone loss between the two stem designs was statistically significant during the entire follow-up, starting from 6 weeks and in favour of the modified stem, with p-values of 0.05 (at 1 year) and 0.01 (at 2 years). In all other zones (1–6) there was no statistically significant difference in remodelling, although BMD values were consequently higher in the modified stem group.

3.2. Remodelling prediction versus clinical findings

There were considerable differences in predicted bone loss between the simulated Symax™ reconstructions with and without direct distal contact between stem and bone (Fig. 8). In the reconstruction without a distal gap (= simulating frictional stem–bone contact), bone resorption was considerably greater especially in Gruen zone 6 and 7. Bone loss at 2 years postoperatively was 35% in the Gruen zone 7 for the Symax™ reconstruction without a gap and 28% in the reconstruction with a distal gap. FE remodelling prediction for the Symax™ reconstruction with a gap was better correlated with clinical findings than the prediction for the Symax™ reconstruction without a distal gap. Thus, the Symax™ reconstruction with a distal gap was more suitable for FE remodelling prediction, especially as the clinical and retrieval findings confirmed no direct contact between implant and bone distally for the Symax™ reconstructions.

There were differences in FE-predicted bone loss between the Omnifit® stem and the Symax™ stem. In Gruen zone 7 slightly greater bone loss at 2 years was predicted for the reconstruction with the Symax™ stem with a distal gap (−28% for Symax™ versus −26% for the Omnifit® stem, see Fig. 8). However, in zones 1–6 the Symax™ stem was expected to cause less bone resorption than the Omnifit® stem.

This FE-predicted pattern of bone remodelling matched the clinical findings only partially. The correlation between clinical data and FE-predictions was rather poor for the Symax™ in zone 7, and for the Omnifit® in zone 6 (both at 2 years). In Gruen zone 7 DEXA-measured bone loss at 2 years was significantly smaller for the Symax™ (−14% versus −20.3% for the Omnifit®, $p = 0.01$), while FE simulations had predicted a slightly larger bone loss (−28% for the Symax™ versus −26% for the Omnifit®).

4. Discussion

In the clinical part of this study it was tested if the design changes implemented in the modified (Symax™) stem would result in less bone resorption (DEXA) in the proximal Gruen zones when compared to the Omnifit®. Secondly, we investigated if a FE model would yield similar results as seen clinically for both stems.

Considering the DEXA-findings of successive generations of uncemented stems with bone loss varying between 15% and 70%, we found the results of the modified stem promising, with regard

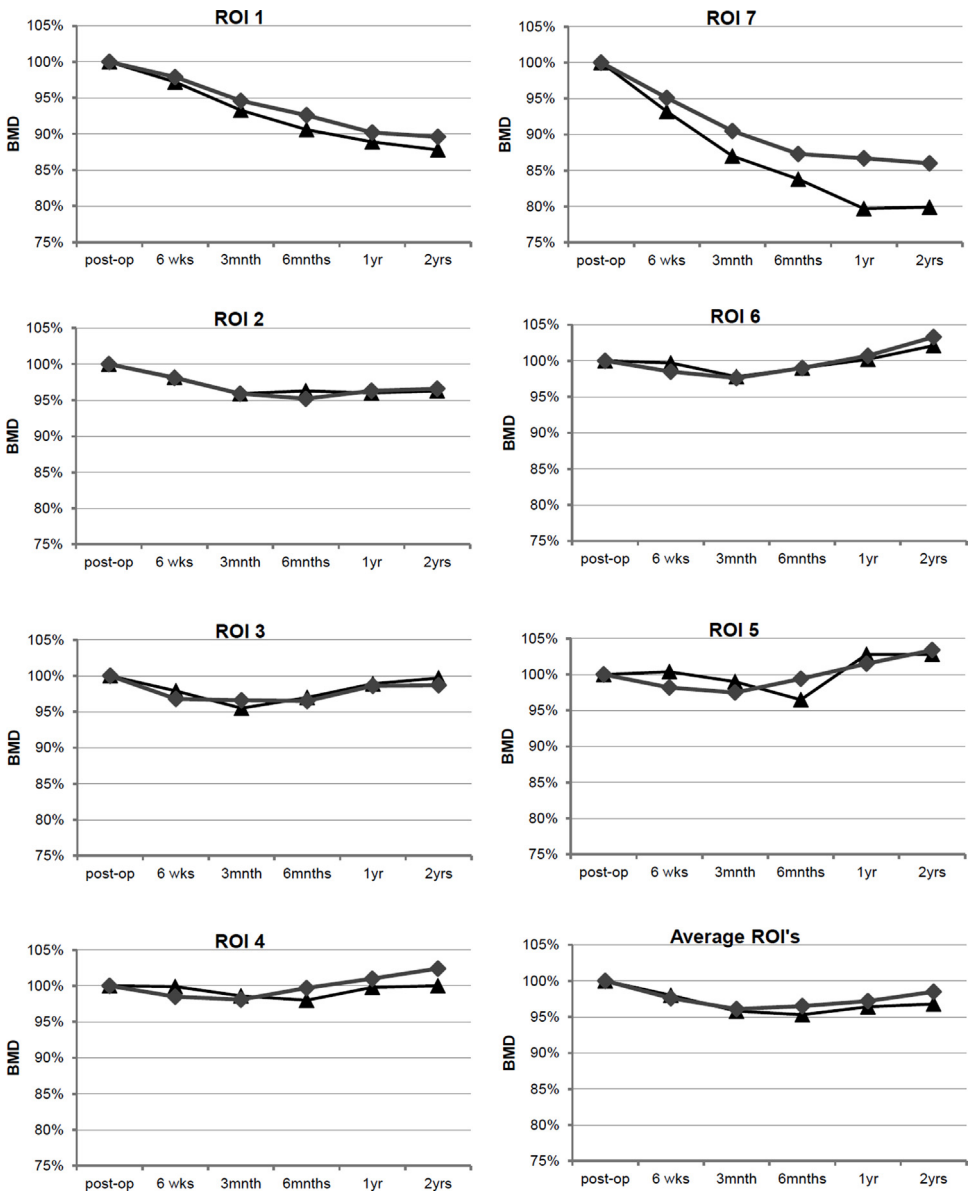

Fig. 7. Graphs showing BMD course of the ROIs 1–7 and net average in a longitudinal study for 2 years, comparing the Symax™ (♦) and the Omnifit® (▲) stem, with the immediate postoperative BMD set at 100% (= baseline reference). Only for the differences in ROI 7 statistical significance ($p < 0.05$) was seen at all postoperative time points.

to preservation of bone quantity. There was only a modest maximal bone loss (calcar area 14%, greater trochanter 10.4%), which is a normal representation of proximal osseointegration, but it illustrated improved metaphyseal bone loading compared to several other designs. More distally there was hardly any BMD loss at all indicating excellent preservation of bone in the regions where no osseointegration was intended. It could therefore be confirmed that the geometry of the modified stem, based on the proximal "fit and fill" principle, in combination with the proximal BONIT®-HA coating and the distal Dotize® surface treatment, were able to improve stress transfer from the implant to bone in the important zone 7. DEXA results for the Omnifit® in our clinical trial were similar with earlier assessment performed by Sluimer et al. (16% and 20% at 2 years for zone 1 and 7 respectively, versus 13% and 20% in the present study) [31]. This confirmed reliability and validity of our clinical DEXA data.

In contrast to the clinical findings, the FE simulation calculated greater bone loss in Gruen zone 7 for the Symax™ stem. Furthermore, in the other Gruen zones FE simulation showed greater bone loss for the Omnifit® when compared to the Symax™ (reconstruction with a distal gap), while clinically no considerable differences were found. Even though the FE remodelling prediction did not yield the same results in individual Gruen zones as the clinical DEXA study, the effect of design changes in the Symax™ stem could be seen in the reduction of bone loss around this stem in the reconstruction with a distal gap.

Given that the same bone model was used for two stems designs, our FE simulations allowed us to make comparisons considering the effect of shape and interface conditions on remodelling. In the present study we showed that the simulation was capable of capturing gross differences in bone remodelling between two THA reconstructions, but was likely not suitable for prediction of minor changes in load transfer patterns. There are several explanations for the discrepancy between these clinical findings and our FE calculations. Firstly, there are differences in bone quality and loading condition between the group of patients and the model. Secondly, we simulated remodelling around only one bone model implanted with one implant size, while the clinical results were averaged over

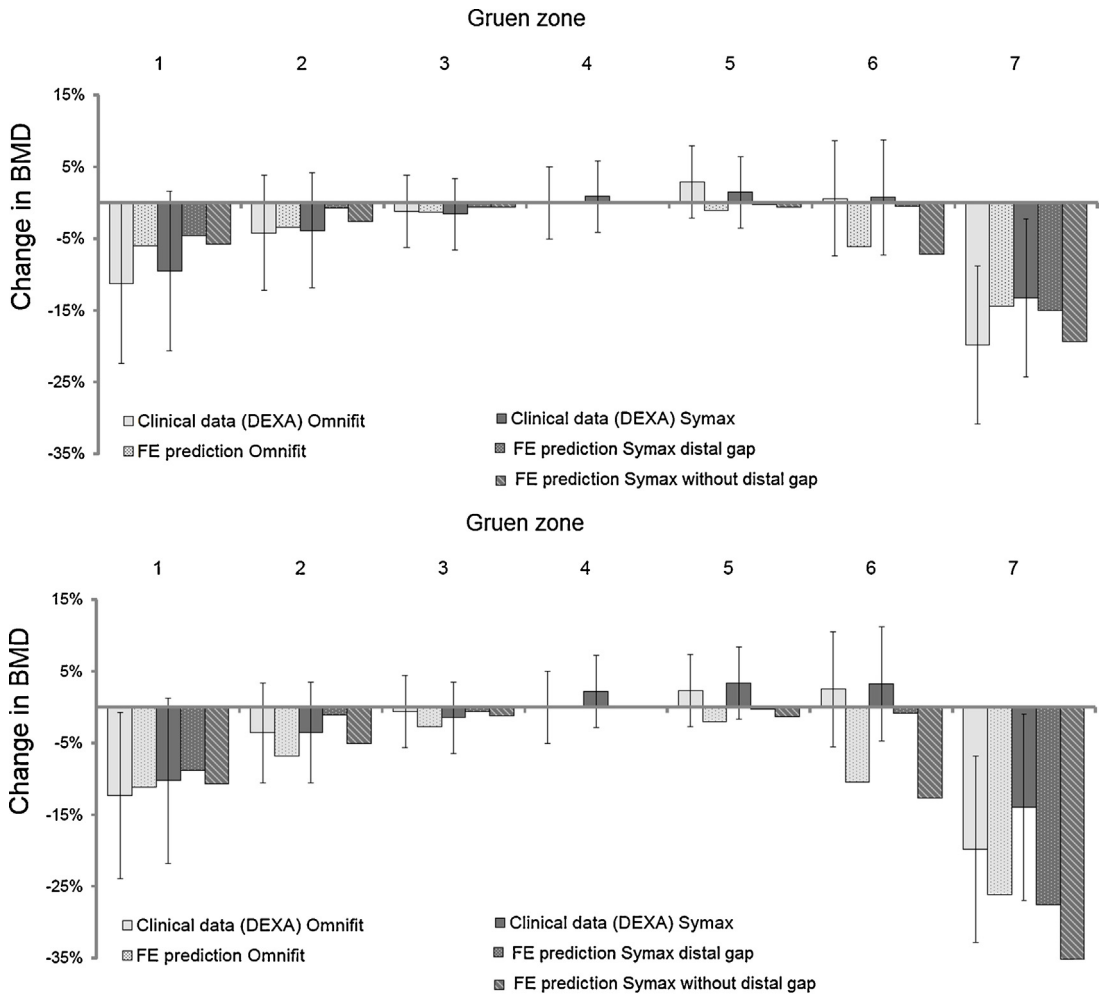

Fig. 8. Clinical DEXA data per Gruen zone (with standard deviation) around the Omnift® and Symax™ stem at 1 year (top) and 2 years (bottom) postoperatively, combined with the FEM predictions on remodelling. For the Symax™ predictions are given with a gap around the distal stem (no friction at the interface) and without a simulated gap around the distal stem (in other words with friction at the interface).

data of 25 patients with variable bone quality and implant size. Thirdly, the loading condition in our simulation was not changed between the pre and postoperative situation. In reality after the post-surgery rehabilitation period patients become more active, which may reduce the resorption rates around both stems.

There are more variables that influence DEXA changes than exclusively those incorporated in the strain adaptive bone remodelling concept. As stimulus to drive the bone remodelling we used the strain energy density, although some authors have suggested to include other stimuli as well such as micro-damage at areas where bone may be overloaded [32]. Inclusion of other stimuli will obviously alter the outcome, although with the types of stems analysed in this study the amount of micro-damage due to overload would probably have been modest. Furthermore, an immediate stimulus affecting bone remodelling can be expected from the surgical trauma of the reaming and implantation. This causes a catabolic reaction as a result of the inflammatory changes and degradation of bone [33]. This has to be repaired and neutralized before the (bio)mechanically induced bone apposition and resorption can exclusively be held responsible for further DEXA changes [34]. Therefore during the first three to six months there are more disturbing factors than exclusively biomechanical ones that determine DEXA results. This may explain why the match between FE predictions and DEXA results is not high during the first postoperative year. However, at two years the remodelling balance between apposition and resorption is restored and considered to be mainly mechanically determined. At that moment correlation between predicted and real bone density should be higher.

Another limitation of the FE remodelling simulation is the fact that it neglects the dynamic process of osseointegration. Huiskes recognized that the degree of stress shielding is indeed affected by the bonding conditions of the implant–bone interface [35]. Therefore knowledge about the extent of osseointegration of a new uncemented implant, from retrieval analysis and histomorphometry, is paramount for generating realistic FE-remodelling predictions. As bone remodelling is a longer-term process (in the order of a few years), it is common in FE simulations to assume that coated areas can be considered as bonded [11,36,37]. Hence, in this study we also assumed that the surface area with the proximal coating was fully bonded in both stem cases. However, from retrieval studies this ideal situation has been shown not to be realistic. Porous coated prostheses usually show a bone–implant contact (BIC) of less than 20% [38,39]. BIC of HA-coated stems varies between 20% and 78% depending on the design [18,38,39]. Furthermore osseointegration is not a static but dynamic process in time and will depend on implant geometry, stem stiffness, surface treatment, type of coating and their degradation characteristics. The retrieval study of the Symax™ hip stem illustrated a progressive direct bone–implant contact in time increasing from 26.5% (at 3 weeks) to 83.5% (at 13 months) [13], which was different from that

of the Omnifit® [18]. Due to the plasmaspray technique the relatively thick (>50 μm) HA-coating occluded the low porosity surface of the Omnifit®, resulting in only superficial ongrowth of bone. However in case of the Symax™ the electrochemical deposition of the highly bioactive Bonit-HA created a thin (10–20 μm) coating of the entire pore depth of the highly (60%) porous TPS layer, leading to accelerated and deep bony ingrowth. This progressive bonding and osseointegration will have an effect on the amount of migration and load transfer from implant to bone, and on the resultant remodelling process, but this is typically not incorporated in finite element models. Furthermore it was found that normal contact stiffness and the friction coefficient increase several times as bone grows into the rough surface of the implant and mineralizes, thus providing a changing interface with improving secondary stability [40]. At this point, the effect of a gradually fixating bone–implant interface is difficult to estimate. On the one hand a debonded interface transfers higher local loads and therefore triggers more local bone apposition; on the other hand a proximally fixed interface promotes more proximal load-transfer on a more global scale. In any case, the assumption of a bonded interface at coated areas is over-simplified and probably should incorporate a time-dependent change of stem–bone bonding [41]. Dickinson et al. have proposed a FE based algorithm which combined implant–bone interface healing with bone remodelling and confirmed that a more clinically realistic bone remodelling is obtained when these two processes are simulated in concert [42].

Compared to the Omnifit®, the Symax™ is distinctly different in two ways; the geometry and the surface and coating characteristics. Literature has shown that the effects of geometry and material changes can be simulated reliably with the FE-technique. Amongst the many features held responsible for stress shielding, the mismatch in elasticity modulus between hip stems and bone is considered most important in causing stress mediated disuse atrophy of bone. Therefore focus has been on creating more flexible stems [43]. The metaphyseal fit-and-fill design of the Symax™, showing larger cross-sectional dimensions, and therefore being stiffer, was expected to cause more stress-shielding [26,44]. However this stem proves to preserve periprosthetic bone at least as good as flexible stems [45,46], and better than almost all proximally and entirely porous or HA coated stems [2,31,47]. This illustrates that interactions between various determinants of stress shielding and resulting bone remodelling are still not completely understood and hard to capture in an exclusively mechanical model. The same applies for the effect of the distal Dotize® treatment. The effects of new coatings on interface properties appear to be even more difficult to predict. To improve predictions, simultaneous ingrowth simulation and remodelling simulation should be performed. This would require quantification of the mechano-biological aspects of coatings after which this can be implemented in FE simulations. Subsequently, these studies need to be validated with results of retrievals and measurements of qualitative and quantitative bone changes. Various scenarios can then be simulated, and it can be tested how sensitive the FE-models are for changes in bonding conditions and for the dynamics of the osseointegration-process in time.

Several attempts have been conducted to simulate and predict adaptive periprosthetic bone remodelling in computer models that combine bone remodelling theories with finite element analysis. Validation of these FE-simulations were mostly based on animal experiments [48,49], post mortem retrieval studies [10], and retrospective clinical densitometry studies with DEXA [12,50] or 3D-volumetric CT-analysis [51]. Although correlation between predicted density changes and clinical data was mostly low, it was nevertheless concluded that bone remodelling after THA could be explained by a mechanical model [10,37]. Other studies have found higher clinical-modelling correlations, but these were obtained only after retrospective fitting of the model on DEXA results available from earlier studies [11,12,47].

This implies that preclinical FE-predictions in new designs triggering unquantified biological processes may be hazardous, because it remains difficult (as in our study) to anticipate on how biological tissues (like bone) will react on, for example, new implant properties (surface treatment, coating morphology, release of Ca-ions). In a recent review it was recognized that in models incorporating biological processes, the number of model parameters that have to be identified and translated into measurable physical or physiological quantities is high. Furthermore these parameters may show considerable variation between subjects of the research population. Therefore several levels of quantification and validation are required to improve the accuracy with which the model can predict physical phenomena [52].

We conclude that, based on the clinical DEXA results, the theoretical concept for improved proximal bone loading of the femur by the Symax™ stem is correct, and that the effect of distal stem treatment preventing bone ingrowth appears to have a positive effect on proximal bone maintenance. However, likely due to only partial modelling of differences in implant–bone interface conditions between both reconstructions, the FE-model could not completely match the clinical findings. Further quantitative data about biological phenomena are required to feed the FE-models in order to advance from case-specific simulations to reliable preclinical predictions of bone remodelling (or even implant survival) of new designs in averaged patient populations, particularly if multiple biological aspects are changed in a prosthetic design. Only then recommendations for multifaceted design changes of implants can be reliable.

Funding

No grants or funding were received for our research from any company or organization.

Competing interest

Two authors (J.J.A. and R.G.G.) are consultant for Stryker Orthopaedics, all other authors have no conflict of interest.

Ethical approval

The study was approved by the local Medical Ethics Committee (Institutional Review Board) prior to the start of the study (registration no.: 02-072), is listed in the Clinical Trials Registry (ClinicalTrials.gov identifier: NCT01695213), and was carried out in line with the Seoul amendment (2008) of the Helsinki declaration.

Acknowledgements

We acknowledge Liesbeth Jutten for data management and statistical assistance, Marc van Rijsbergen for his contribution to the FE part of the study, and Roel Hendrickx for analysis of the DEXA scans.

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