



## The uncemented Isoelastic/Isotitan total hip arthroplasty A 10-15 years follow-up with bone mineral density evaluation

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The present study analyses the long-term outcome of isoelastic hip prostheses and their influence on the extent of periprosthetic bone remodeling. Ninety-two patients (102 hips) with Isoelastic/Isotitan uncemented total hip arthroplasty were evaluated after an average of 13.4 years. The average age of patients at surgery was 42.5 years. The clinical outcome was assessed based on the Harris hip score, complications and thigh pain. Bone mineral density (BMD) of the proximal femur in the seven Gruen zones was evaluated by dual-energy X-ray absorptiometry (DEXA) scans with the contralateral hip serving as a control. The average Harris hip score at the most recent follow-up was 72 points, with 72 hips (70%) rating completely pain free. Eight stems required revision whereas none of the cups showed any evidence of loosening. The change in the mean BMD values between the femora on the operated side and the contralateral femora averaged 15% for all zones. Although the isoelastic stems are no longer used owing to their high loosening rate, it appears that this prosthesis preserved periprosthetic bone better than reported for cemented or uncemented metallic implants. Besides, the provision of a titanium coating on the isoelastic stem, comparable to that on the RM cup, would presumably have improved its long-term fixation by encouraging bony ongrowth.

**Keywords :** total hip arthroplasty ; cementless ; isoelastic ; bone mineral density.

### INTRODUCTION

Uncemented metal implants have a stiffness at least five to twenty times that of normal bone, which may result in stress-shielding, bone resorption and ultimately implant failure (24). To avoid stress-shielding atrophy, an isoelastic femoral stem was developed by Robert Mathys in 1973 (18). The aim of isoelasticity was to ensure that the implant and bone deform as one unit, loading the bone in a more physiological way and maintaining its structure better (3). The potential for maintaining better bone stock through uniform stress distribution sparked the initial interest in exploring an isoelastic type of hip prosthesis (3). Ang *et al* (4) reported better preservation of bone mineral density in the periprosthetic bone at one year after implanting flexible stems in comparison to rigid metallic

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implants as evidenced by the dual-energy X-ray absorptiometry (DEXA) scans. However, the long-term clinical experience with isoelastic stems was not encouraging owing to a high rate of stem loosening and migration requiring frequent stem revisions (2, 20), and they are no longer used now.

The initial recommendation was to remove all cancellous bone and to implant the stem with the largest possible diameter, to ensure rigid mechanical fixation in strong cortical bone (3). However, the process of long-term biological fixation by bone ongrowth can be compromised not only by mechanically inadequate cancellous bone but also by the precarious endosteal circulation following excessive medullary reaming (15). Jasty *et al* (13) distinguished precise fit from tight press fit and concluded that precise fit results in the most normal strain pattern. Reiter *et al* (22) noted significant decrease in the bone mineral density with the use of large Bicontact stems compared to smaller sized stems. The senior author (ONN) modified the surgical technique for implanting the isoelastic hip prosthesis by performing medullary reaming in such a way as to ensure more cancellous bone around the prosthetic stems and using precise fit with relatively narrow stems and in addition employed impaction grafting of autologous bone. Our preliminary experience with this technique was encouraging and the results were better than those reported in the literature (19). The present retrospective study aims to analyze the long-term outcome of the isoelastic hip prosthesis implanted with this modified surgical technique and to assess whether this had influenced the extent of periprosthetic bone remodeling, with a comprehensive literature review to outline the usefulness and pitfalls of this prosthesis.

## MATERIALS AND METHODS

Between January 1990 and January 1996, 102 patients (120 hips) underwent primary total hip arthroplasty using the titanium-coated RM cup (Robert Mathys, Bettlach, Switzerland) and Isoelastic/Isotitan femoral component (fig 1 & table I). We used a 28-mm stainless steel head in 108 hips and a 28-mm ceramic head in 12 hips. Femoral stem no. 9 was used in 48 hips, no.10 in 52 hips and no.11 in 20 hips. The femoral com-

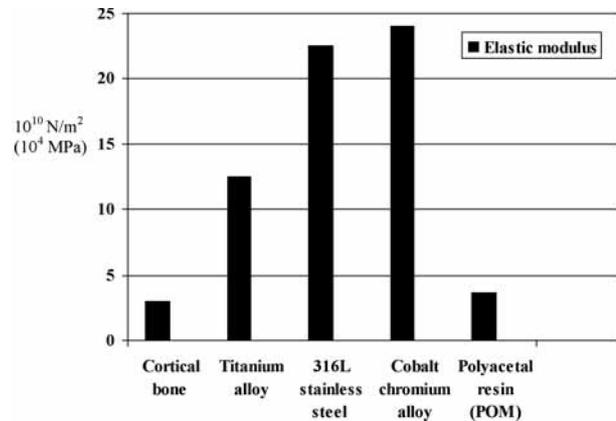


Fig. 1. — Graphic representation of the elastic modulus of implant alloys in comparison to cortical bone (Source : Robert Mathys Sr. Isoelastic hip prostheses. Manual of surgical and operative techniques. Hogrefe & Huber publishers, 1992).

Table I. — Typical physical and mechanical properties of polyacetal resin (POM)

Density (g/cm <sup>3</sup> )	1.43
Melting temperature (°C)	175
Water absorption (23°C) (%)	0.9-1.4
Tensile strength (MPa)	70
Elongation (%)	15-75
Tensile modulus (MPa)	3650

(Source : Robert Mathys Sr. Isoelastic hip prostheses. Manual of surgical and operative techniques. Hogrefe & Huber publishers, 1992).

ponent was a stainless steel reinforced third generation isoelastic femoral stem in 52 hips and a titanium alloy reinforced isoelastic stem (Isotitan) in 68 hips. Patients with marked pain and crippling deformities with restriction of daily-life activities were included in the study. The average age of patients at the time of operation was 42.5 (32-54) years. There were 70 male and 32 female patients. Eighteen patients underwent bilateral hip replacement. Sixty-six replacements were on the right side and 54 on the left. Pre-operative diagnosis was avascular necrosis in 56 hips, osteoarthritis in 52 hips, ankylosing spondylitis in 12 hips. All patients were operated through an anterolateral approach. No trochanteric osteotomy was performed in any case. The originally recommended technique for insertion of the

isoelastic hip prosthesis was modified by the senior author (ONN) in the early 1990s'. The medullary reaming was done such that it was ensured that a layer of cancellous bone was preserved. Autograft from the femoral head was prepared into a paste after milling it, and was inserted into the medullary canal with a smaller trial component and pressurized. The acetabular cup was positioned 5° more horizontal than originally recommended. All patients received two doses of preoperative intravenous antibiotics followed with postoperative antibiotics for five days. Anticoagulants were not used routinely except in cases with high risk for deep venous thrombosis. All patients were required to wear antithromboembolic stockings for eight weeks postoperatively. All patients were mobilised with partial weight-bearing with crutches after six weeks. They were regularly followed clinically after discharge at 6 weeks, 3 months, 6 months and thereafter yearly for at least the first five years – with a questionnaire and radiographs. The functional assessment was done using the Harris hip score (11). The incidence of thigh pain was graded on a 5-point rating scale as suggested by Krish *et al* (14).

Radiologically, the femoral component was assessed in seven zones as described by Gruen *et al* (10). Osteolysis was defined as a newly developing expansile cystic lesion, with endosteal scalloping not present in the immediate postoperative radiograph, and showing progression on subsequent radiographs. Stem subsidence was calculated by drawing a line along the long axis of femur. Another two lines were drawn perpendicular to this line, one through the center of the femoral head and the other from the tip of the lesser trochanter. Subsidence was measured as the reduction in the distance between the two perpendicular lines. Subsidence was regarded as significant if it exceeded 5 mm (16). Bone ongrowth was indicated by the presence of "spot welds", i.e. streaks of newly formed bone bridging the space between the implant and the endosteal surface of the femoral cortex. Cortical hypertrophy was indicated by a smoothly bordered "bump" disrupting the contour of the femur. The stability of the femoral stem was evaluated with the criteria suggested by Engh (7) with a few modifications. Accordingly, the radiographic stability was divided into three categories.

1. Stable stem without any radiolucent lines in the proximal cross-hatched area of the stem or if there was subsidence in neutral position (fig 2)
2. Unstable stem if there was varus tilt and lateral migration in addition to subsidence of the stem with or without screw breakage

3. Failed stem if there was perforation of lateral femoral cortex by the tip of the stem (fig 3)

Radiographic evaluation of the acetabular component was made using the method of DeLee and Charnley (6). Acetabular migration was evaluated by the method of Nunn *et al* (21) using the center of the femoral head and the interteardrop line as references. The acetabular component was considered to be unstable if there was definite migration or a change in the position. Heterotopic ossification was graded according to the classification of Brooker *et al* (5).

All patients who had completed ten or more years after index surgery were called for review, of which 92 patients (102 hips) responded. Three patients died in the follow-up period for reasons unrelated to the index surgery. Seven patients were lost to final follow-up. The demographics of this patient group are as given in table II. The functional outcome was analysed both clinically and radiologically on the basis of previously described parameters. Complications such as screw breakage, stem migration, implant cut-out, periprosthetic fractures, and revisions were documented.

At final follow-up, the bone mineral density (BMD) of the periprosthetic femur was measured in the coronal plane with a dual-energy X-ray absorptiometer (DEXA ; DXR-L ; Lunar, GE medical systems, WI, USA). During scanning, the patient was placed supine with standard knee and foot supports with the femur in neutral rotation. The scanner was equipped with the software for femoral periprosthetic bone mineral measurement. The software detected the interface between the bony part and the prosthesis stem on the basis of density change and simulated the stem in the form of a prosthesis mask, which was superimposed on the healthy side. The healthy hip was scanned at the corresponding level, and BMD in 7 regions of interest (ROIs) based on Gruen zones was analysed. The values were expressed as g/cm<sup>2</sup>. Periprosthetic bone loss was expressed as relative to that of the contralateral normal femur. It was calculated from the formula : (BMD of operated side – BMD of normal side/BMD of normal side × 100). We performed a precision study on 10 patients. The precision error in vivo was analysed as the coefficient of variation (SD/mean), expressed as a percentage (% CV). This error, which was mainly due to the position of the patient during the measurement, was found to be 0.62% in repeated investigations of uninvolved femora of 10 patients by one operator. The precision error increased to 1.4% when the analysis of the results of a single measurement was repeated by two experienced



**Fig. 2.** — **a.** Anteroposterior radiograph of left hip demonstrating stable bony ingrowth with no radiolucent lines at 12.1 years of follow-up ; **b.** A close-up view of the proximal femur at 7.2 years follow-up, showing bone condensation (?) consistent with bony ongrowth, in another patient.

radiologists. The results were analysed with an SPSS statistical software version 13.0 (SPSS Inc. Ill, USA). The significances of the differences were analyzed by using the paired t-test and the normality of the distributions was checked with M estimators. Kaplan-Meier survival analysis was performed to assess the longevity of isoelastic stems, with revision for any cause or Harris hip score < 50 points or radiological evidence of loosening of any component considered as endpoint or failures.

## RESULTS

### *Clinical evaluation*

The average Harris hip score improved from a preoperative score of less than 40 (7-40) to 72 (64-92) after an average follow-up of 13.4 years. The average thigh pain score was 1.4 points. Seventy patients reported no thigh pain, 9 mild, 8 moderate and 5 occasionally had severe pain. Five patients (5 hips) had superficial wound infections postoperatively that responded to oral antibiotics. There were no intra-operative fractures, post-operative dislocations or deep infections.



**Fig. 3.** — Anteroposterior radiographs of left hip at 2 years and 7.2 years. **a.** At 2 years follow-up, stable fixation with good alignment; **b.** At 7.2 years follow-up, subsidence of stem with screw breakage and perforation of the stem tip through the lateral femoral cortex, requiring revision of the stem.

#### *Radiographic evaluation*

All except eight stems were placed within  $5^\circ$  of neutral alignment. Eight stems (5%) were placed in measurable varus alignment. Subsidence was  $> 5$  mm in sixteen hips and  $< 5$  mm in twenty seven hips. The tip of the femoral component migrated laterally in 33 hips. The migration was  $> 5$  mm in

sixteen hips and  $< 5$  mm in seventeen hips. Sixteen hips had femoral osteolytic lesions, mostly in Zone 4 and 7 at the latest follow-up. Three stems had implant cut out at their distal tip. Five stems had screw breakage. Eight stems required revision after a mean period of 6.8 years (4.2 to 9.3 years) from the index surgery. Revision was performed with

Table II. — Demographic data of 92 patients at follow-up

No. of hips	102
No. of patients	92
Male	62
Female	30
Diagnosis*	
Osteonecrosis	48
Osteoarthritis	42
Ankylosing spondylitis	12
Age at follow-up (years) <sup>†</sup>	56.8 (43-65)
Operated side	
Right	56
Left	46
No. of hips with Isoelastic stems	44
No. of hips with Isotitan stems	58
Follow-up (yrs.) <sup>†</sup>	13.4 (10.1-15.4)

\* The data are given as the numbers of hips.

<sup>†</sup> The data are given as the average, with the range in parentheses.

cemented Exeter (Howmedica Osteotronics, Howmedica, NJ, USA) stems. One patient had breakage of acetabular screws; however there was no clinical or radiological evidence of cup loosening. None of the acetabular cups required revision. Based on the modified Engh's criteria, 69 stems were stable with no radiolucent lines or with subsidence in neutral position, 30 had late subsidence with varus tilt of the stem. There were three failed stems that perforated the lateral cortex. Slight heterotopic ossification (Brooker stage I) was present

in 7 hips. The change in the mean BMD values of all zones between the femurs with a prosthesis and the contralateral intact femora averaged 15% (table III).

Except for Zone 2, the differences in the BMD values between the prosthesis and normal side were significant ( $p < 0.005$ ) in all zones. The greatest difference (24%) was observed in zone 6 and the smallest difference was (4%) noted in zone 2. When the proximal femur was analysed in terms of horizontal fields, the absolute value of the mean proximal-distal BMD increased evenly in both femora, while the change in mean BMD, expressed in percentages from the value of the uninvolved side, decreased rapidly from the most proximal to the lower fields. It was 25% in field I, 9% in field II, 11% and 5% in fields III and IV (table IV).

A comparison between the proximal zones showed the density in zone 1 to be lower than in zone 7 on the control side ( $p 0.001$ ), but not significantly so on the prosthesis side. A difference was observed in the BMDs between the proximal and distal zones laterally (zones 2-3) and medially (zones 5-6) around the stem both in the prosthesis and control side ( $p 0.003$ ).

Survival curves showed an 85% probability of survival of stems at 20 years and 74% probability of survival at 25 years (fig 4).

## DISCUSSION

A potential cause of failure of the femoral stems is bone loss in the proximal femoral cortex follow-

Table III. — Mean BMD (S.D) values ( $\text{g}/\text{cm}^2$ ) in the seven Gruen zones of 92 patients

Zone	Normal Hip		Operated Hip		Difference <sup>1</sup>		95% Confidence Interval		p
	Mean	S.D	Mean	S.D					
1	0.86	0.12	1.03	0.19	0.16	19	-0.20	-0.12	0.000
2	1.52	0.13	1.43	0.43	0.09	4	-0.04	0.23	0.143
3	1.85	0.14	1.44	0.33	0.41	22	0.32	0.50	0.006
4	1.76	0.15	1.51	0.19	0.24	13	0.19	0.29	0.000
5	1.77	0.13	1.54	0.31	0.23	11	0.11	0.34	0.032
6	1.48	0.17	1.10	0.46	0.38	24	0.23	0.52	0.000
7	1.11	0.16	0.97	0.20	0.13	11	0.07	0.19	0.046

<sup>1</sup> Difference between means and difference as percentages. S.D. – Standard Deviation.

Table IV. — Mean BMD (SD) values (g/cm<sup>3</sup>) in 4 horizontal fields of 92 patients

Field	Normal Hip		Replaced Hip		Difference <sup>1</sup>		95% Confidence Interval	p
	Mean	S.D	Mean	S.D				
I	1.01	0.32	0.71	0.22	0.30	30	0.20 - 0.40	0.000
II	1.21	0.21	1.12	0.27	0.09	7	0.03 - 0.15	0.004
III	1.73	0.24	1.51	0.25	0.22	13	0.16 - 0.28	0.000
IV	1.77	0.41	1.66	0.21	0.11	6	0.06 - 0.16	0.000

<sup>1</sup> Difference between means and difference as percentages.

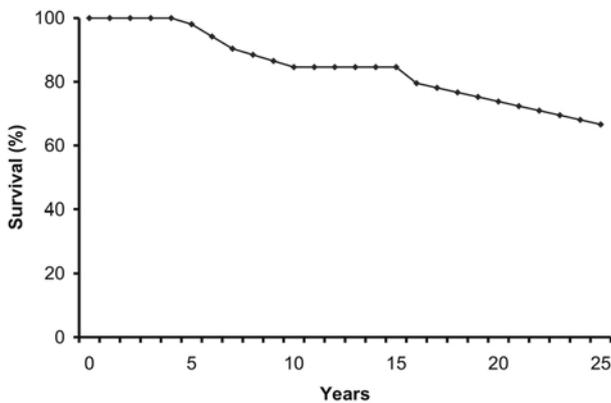


Fig. 4. — Survival curve for Isoelastic/Isotitan stems with revision as the end point (n = 102 hips).

ing hip replacement (14, 24). Cementless implants were thought to obviate this problem of aseptic loosening. However disuse osteoporosis of the proximal femur appears to be more pronounced when large metal femoral stems are employed, in particular those designed for biological ingrowth (7, 24). Animal models of total hip replacement have shown that cortical bone loss is reduced following the use of stems with a reduced stiffness (12).

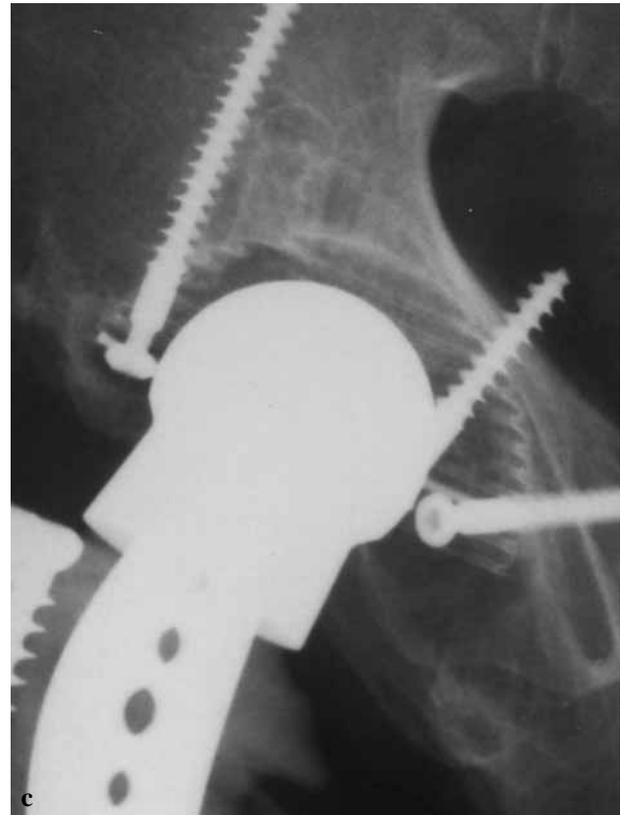
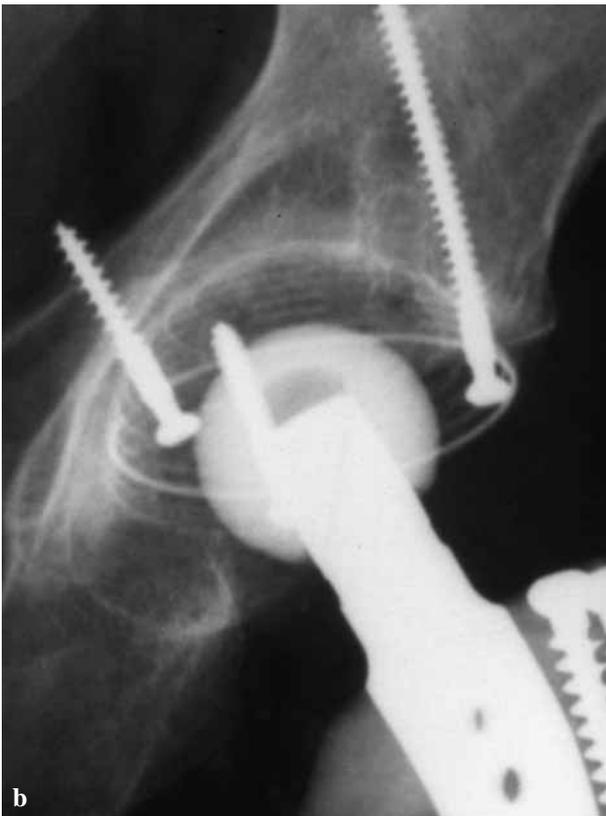
In the present study, the major limitation is that the evaluation of BMD was not performed prospectively, in a serial manner so as to have accurate measurement of bone loss. However, Niinimaki *et al* (20) in a similar study of 25 patients with isoelastic stems after 9 years confirmed that the bone mineral density in the proximal femur was better with isoelastic prostheses than with any uncemented or cemented metal prosthesis.

The early results for the isoelastic RM stem were promising. Andrew *et al* (3) reported good function in 92% of 400 patients at a mean follow-up of

28 months, with only two revisions for loosening. Trager (25) had excellent or good function in 86% of 71 cases at five to seven years but a 10% rate of loosening. However, Rosso (23) in his study of 92 cases with 93 isoelastic stems observed a high percentage (47%) of cases showing calcar resorption, loss of bone around the implant at the trochanter, and quiver formation around the stem. Niinimaki *et al* (20) found that 21 of 71 stems analysed after a mean follow-up of 8.2 years, were radiographically loose and ten showed osteolytic foci; they concluded that the results were worse than those reported for other uncemented stems and for cemented stems. In the present study also, there were sixteen stems with progressive osteolytic foci, however, only ten could be termed as radiographically loose.

Andrew *et al* (3) advocated that immediate mechanical stability of the prosthesis was essential for physiological loading. They recommended aggressive reaming with removal of cancellous bone and using the largest diameter stem possible to ensure rigid mechanical fixation in strong cortical bone. However, this may hamper the bony ingrowth and long-term biological fixation, as not only the living cancellous bone is removed but also the intramedullary circulation is compromised. In our preliminary study (19) of 46 patients followed up for an average period of 4 years and 10 months, except for one failure, all patients had significant improvement with better functional scores and radiological evidence of bone ingrowth. There was no stem with varus tilt or early subsidence.

Experimental studies have shown that the composite hip stems compared quite well with conventional metallic hip stems with respect to axial migration and stem subsidence. However, Ali *et*



**Fig. 5.** — Radiographs demonstrating good osseous integration of titanium-coated isoelastic RM cups at different time periods of follow-up (a. 10.4 years, b. 11.6 years, c. 14.1 years, cup showing marked polyethylene wear).

*al* (2) noted a high incidence (41%) of lateral migration of the tip of the isoelastic stem. They attributed this to poor bone ongrowth onto polyacetal resin, bone resorption due to surgical trauma and early partial weight bearing. Studies have proved that higher interface shear stresses in the proximal region between the implant and the bone may increase with the decreasing stiffness of the implant. Excessive shear stresses can lead to mechanical instability and thus constitute a potential initiating mechanism of implant loosening through the failure of supporting tissue and/or the generation of debris. Rosso (23) opined that the physiological loading of the proximal femur occurred at the expense of micromotion between the stem and the surrounding bone and concluded that movement, rather than stiffening, causes more changes in the cortical bone of the diaphysis. Even in our cases, retrospectively, it would appear that leaving preferentially more cancellous bone around the stem might be construed as counterproductive, as osseointegration could anyway not occur, and

leaving cancellous bone in place rather weakened the initial fixation.

The prevalence of activity-related thigh pain following cementless total hip arthroplasty has been reported to be as high as 36% with some designs after an average duration of follow-up of twelve years (9, 14). This rate generally has been higher in association with cobalt-chromium stems and lower in association with titanium-alloy stems (3). Similarly, even after isoelastic cementless arthroplasty, activity-related thigh pain did persist, as reported in literature (1). In the present study, we noted a 6% incidence of activity-related thigh pain, which could be surmised to be related with varus migration of the tip of the stem and associated cortical hypertrophy. On the other hand, the performance of the isoelastic acetabular cups was excellent with no revisions required in any of the cases in the present series (fig 5). In our experience, we have found that the titanium-coated RM cup allows a harmonious load transfer because of its low and well-adapted modulus of elasticity and the titanium coating ensures osseous integration.

Aldinger *et al* (3) reported that the relatively flexible titanium stem used in their study transmitted load more proximally, resulting in less bone loss, in comparison to stiff uncemented components that transmitted load more distally, resulting in proximal bone loss. They stressed that isoelasticity of the stem is important to preserve the periprosthetic bone. Although its long term clinical results have not been satisfactory in the earlier studies, one point that all studies concur upon is that the isoelastic stems better preserved the proximal femoral bone stock in comparison to cemented or uncemented metal stems (8, 17). In the present study, although there was some bone loss in the proximal femur, this was less than that can be expected with other contemporary designs (8, 17).

The important factors for the long-term biological fixation of an uncemented implant are immediate stability to eliminate implant macro-motion, and a good surface condition to promote bone ingrowth or ongrowth. In line with earlier studies, this study showed that the Isoelastic/Isotitan stem preserved the proximal femoral bone stock on a long term basis. It has also been found to achieve

good primary stability, owing to its shape, collar and the lateral tension screws. The only major flaw was that the poor coating surface of the stem did not encourage long term bony anchorage, leading to late subsidence and migration. The provision of a uniform titanium coating might have aided in bony ongrowth, which perhaps could have totally changed the clinical outcome.

## CONCLUSION

The present study analyses the long-term outcome of isoelastic hip prostheses and their influence on the extent of periprosthetic bone remodeling. Although high failure rates have been reported with this implant, which is to the best of our knowledge no longer used now, it indeed reduced the extent of proximal femur bone loss. It could be surmised that the isoelastic stem, if provided with a uniform titanium coating would probably have matched the excellent clinical performance of the titanium-coated RM acetabular cup.

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