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Comparison of Hydroxyapatite-Coated Stems in Total Hip Arthroplasty after a Minimum 10-Years Follow-up

TEP kyčle s hydroxyapatitovým povrchem – porovnání výsledků

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ABSTRACT

PURPOSE OF THE STUDY

Hydroxypatite coating (HAC) was introduced into total hip arthroplasty (THA) practice to improve the fixation interface between bone and prosthesis. To test this assumption however, long-term follow-up investigations are needed. In this study, we present data for two consecutive series of THA stems with HAC and a minimum ten-year follow-up.

MATERIAL

Overall, 249 patients (271 hips) were included in the study, of these 122 (135 hips) had Walter hip arthroplasty (WHA group) with a two-layered TiO2/HAC at the proximal part of the stem and 127 (136 hips) had ABG I prostheses (ABG I group) with a single-layered HAC at the proximal part of the stem. Mean length of follow-up was 11.4 years (0.8-13) and 9.8 years (4-12) in WHA and ABG I groups, respectively. Mean age at the time of surgery was 62 years (23-79) and 47 years (21-65) in WHA and ABG I groups, respectively.

METHODS

Probabilities of implant survival were estimated using the Kaplan-Meier method. Radiographic data were included to construct the worst-case scenario. Differences in survival curves were evaluated by Gehan's Wilcoxon test. Harris hip score was used to compare preoperative status with that of final follow-up.

RESULTS

The overall survival of WHA was significantly better than the ABG I (0.85 versus 0.66; $p < 0.05$). The main reason for a high revision rate in ABG I was periprosthetic osteolysis followed by aseptic loosening. With regard to stems, the survivorship curve for the Walter stem was significantly better than for the ABG I stem even when radiographic results were included ($p = 0.0002$). In the WHA group, two stems (1.5%) were revised due to sepsis, in contrast to thirty-one stems (23.5%) revised in the ABG I group due to osteolysis and aseptic loosening ($p < 0.05$). Significant improvement was achieved in both groups under study in terms of Harris hip score.

DISCUSSION

Data presented here appear surprising at first glance because the differences between the stems under study are only minor. The failure in ABG I was most probably caused by poor polyethylene quality and poor locking mechanism of polyethylene liner in the metallic shell. In addition, HAC used in ABG I prosthesis was not able to prevent the development of polyethylene disease stimulated by high wear rate.

CONCLUSION

This study revealed excellent survivorship for WHA stems after a minimum ten-year survival and significantly poorer survivorship for the ABG I stems. This may be explained at least particularly by combined two-layered HAC used in WHA stems which provide simultaneously endurable bone interlocking and effective barrier against expansion of polyethylene disease.

Key words: total hip replacement, hydroxyapatite, Walter hip arthroplasty, ABG I, survival analysis, polyethylene disease, osteolysis.

INTRODUCTION

The occurrence of gaps, instability or fibrous membrane at the fixation interface of implants is considered the key pathway in the initiation of periprosthetic osteolysis (OL) and aseptic loosening of total hip arthroplasties (THA), (11, 31). In these cases, the hydroxyapatite coating (HAC) is believed to be a progress owing to increased bonding between the implant and its bone bed (5, 21). Preclinical studies have demonstrated increased bone ingrowths in animal models for initial gaps of up to 1 mm and micromotions of up to 500 μm (30). Even when polyethylene (PE) particles were added, HAC provided better bone ingrowths and protection of the bone-implant interface than pure plasma-sprayed porous coating (25).

During the 1990ties and at the beginning of the present century, several studies were published which evaluated the clinical behavior of different implants with HAC (7). In some of these, the superiority of HAC over non-HAC porous-coated stems in terms of achieving stable bone fixation as well as durability compared to similar designs with and without HAC, was questioned (28). Several studies reported poor results for THA with HAC but the cup not the stem was the problem in a majority of them (26). In addition, HAC was queried as a potential source of third bodies that might accelerate the PE wear, resulting in OL and aseptic loosening (27). This seems to be in clear contradiction to the rationale for introducing HAC into the clinical practice. As a result, an accurate and reliable reporting from different centers is required to obtain sufficient evidence for the continuation of HAC use. The purpose of this paper is to compare a minimum 10-year survival for a consecutive series of two anatomical stems with HAC manufactured using different HAC technologies.

MATERIAL AND METHODS

Patients

The first group of patients was operated on consecutively at the First Orthopedic Clinic of Charles University, Prague, Czech Republic, in the period from 1990 to 1994. There were 122 patients (74 women and 48 men) with 135 cementless Walter hip arthroplasty (WHA group). The mean age of the patients at the time of the surgery was 61.5 years (range, 23 to 79 years, SD 12.7). The primary diagnosis in this group is shown in Figure 1. The mean length of follow up was 11.4 years (range, 0.76 to 13.1, SD 2.22) for this group. None of the patients missed any follow-up but eight patients died during this period. None of these had undergone revision surgery thus their data were taken into clinical evaluation, resulting in complete follow-up for all 135 hips.

The second group included 84 women and 43 men with 136 cementless total hip replacements Anatomique Benoist Girard type I (ABG I group), which were operated on consecutively at the Department of Orthopedics of Palacký University Hospital, Olomouc, Czech Republic, in the years 1994 and 1995. The mean age at the time of surgery was 46.5 years (range, 21 to 65 years, SD 6.7) which was significantly lower than in the WHA group (t-test, $p < 0.05$). A survey of primary diagnosis is included in Figure 1; the mean length of follow-up was 9.82 years (range, 4.18 to 11.68, SD 1.9). Three patients could not be located for follow-up (four hips; 3%) and four died during this period (five hips; 3.8%) with none having revision hip surgery. Hence, the data of the dead patients were taken into the clinical analysis. Complete follow-up was thus obtained for 124 patients (132 hips).

All procedures were performed by experienced surgeons using the Watson-Jones anterolateral approach. Patients were protected by a prophylactic dose of antibiotic for 48 hours after the surgery. Partial loading of the body weight was allowed on the fourth week after surgery while full weight-bearing was permitted after twelve weeks.

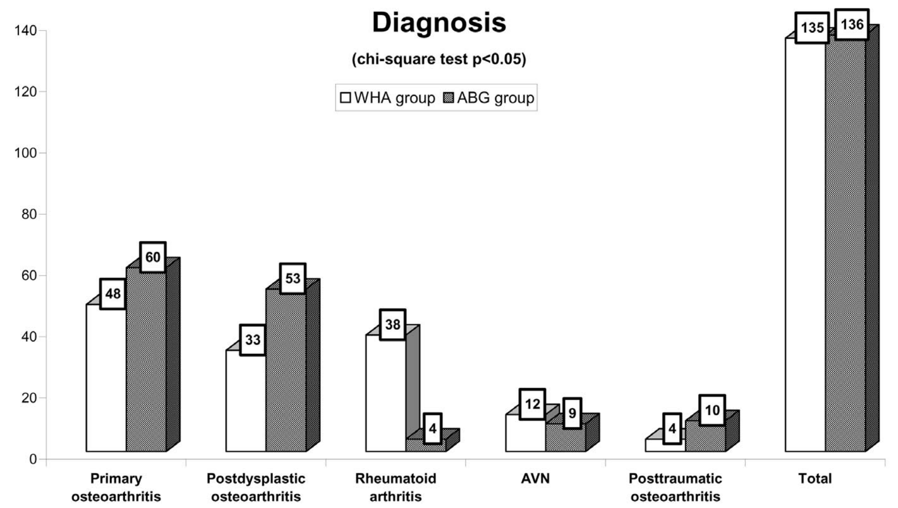


Figure 1. Comparison of primary diagnosis (AVN- avascular necrosis of the femoral head)

Table 1. Details for the cups and balls under study

Characteristics	WHA	ABG I
Alloy	Titanium (VT-6 ASTM F-136)	Titanium Alloy (Ti-6Al-4V)
Geometry	Conical	Hemispherical
Holes	No	Yes (12 holes for spikes)
Fixation	Self-tapping thread	Press-fit
Surface roughness	Grit blasting (Ra=1.36 μm)	Ti/HA (Ra=6 μm)
Coating	Uncoated	Ca10(PO4)6(OH)2
Details of coating	Not applicable	Identical to stem
Polyethylene (PE)	UHMWPE (Chirulen) ISO 5834. part 2	Hostalen GUR 4150
Sterilization	Gamma irradiation in air	Gamma irradiation in air
Locking mechanism	By shape and three plugs	Central plug, snap fitting
Thickness of the PE	Range from 4 to 8.5 mm	Range from 4.9 to 11.9 mm
Ball material	Ceramic (Al_2O_3)	Cobalt alloy or zirconia
Diameter	32 mm	Range 22 to 32 mm

Table 2. Details for the stems evaluated in the study

Characteristics	WHA	ABG I
Alloy	Titanium (VT-6 ASTM F-136)	Titanium Alloy (Ti-6Al-4V)
Geometry	Anatomical	Anatomical
Fixation	Press-fit	Press-fit
Surface roughness	Grit-blasting (Ra=1.36 μm)	Macro-relief scaled surface
Coating	Composite	Single layer
Details of coating	1st layer: porous titanium alloy (Ti-6Al-4V) 2nd layer: $Ca_{10}(PO_4)_6(OH)_2$, a minimum α tricalcium phosphate	$Ca_{10}(PO_4)_6(OH)_2$
Location of coating	Proximal part	Proximal part
Thickness of coating	Appr. 1.0 mm	Appr. 0.070 mm
Porosity	Range from 15 to 70%	2% (maximum)
Pore size	Range from 75 to 300 μm	NA
Thickness of HA layer	0.05 mm (appr.)	0.06+0.01 mm
Crystallinity of HA	80% (appr.)	Range from 98% to 99%
Purity of HA	More than 99.0%	More than 99.99%
Tensile strength of HAC	Range from 31 to 41 MPa	Range from 62 to 65 MPa
Shear strength of HAC	Range from 14 to 17 MPa	NA

Appr.= approximately NA= not assigned

Prosthesis

The implants for the WHA group were manufactured by Walter (Czech Republic). The acetabular component consists of a cone-shaped metal anchoring cup with self-tapping thread and PE liner. The femoral stem mimics the anatomy of the proximal femur as much as possible to allow high quality primary fixation by way of "pressfit". Half of the proximal part of the stem is coated with a two-layer surface which is described in detail elsewhere (22).

The design of the ABG I prosthesis is also described elsewhere (10). The details for both WHA and ABG I implants are overviewed in Tables 1 and 2.

Clinical and radiographic analysis

Clinical and radiographic evaluations of both groups were performed preoperatively and at 3, 6 and 12 months postoperatively. The patients were then followed-up annually for the WHA group, while in the ABG I group regular follow-up was not as frequent except for the last follow-up. Routine physical examination and completion of the Harris Hip Score (HHS) were done for each assessment.

Radiographic evaluation was performed with immediate postoperative radiographs and at the last follow-up (29). The analysis included determination of the prosthetic stability and investigation for OL, radiolucent and/ or sclerotic lines. Components were graded as stable, potentially loose or unstable according to the rules of Dorr (34), (for the cup) and Engh (8), (for the stem). OL was defined as sharply demarcated radiolucency surrounding the bone-prosthesis interface that extended at least 5 mm in diameter. DeLee and Charnley (6) and Gruen (14) topography was utilized to locate the OL and radiolucent lines. Based on this, radiographic failure was defined as evident prosthetic migration, complete radio-

Figure 2. Kaplan-Meier curves showing acetabular component survival

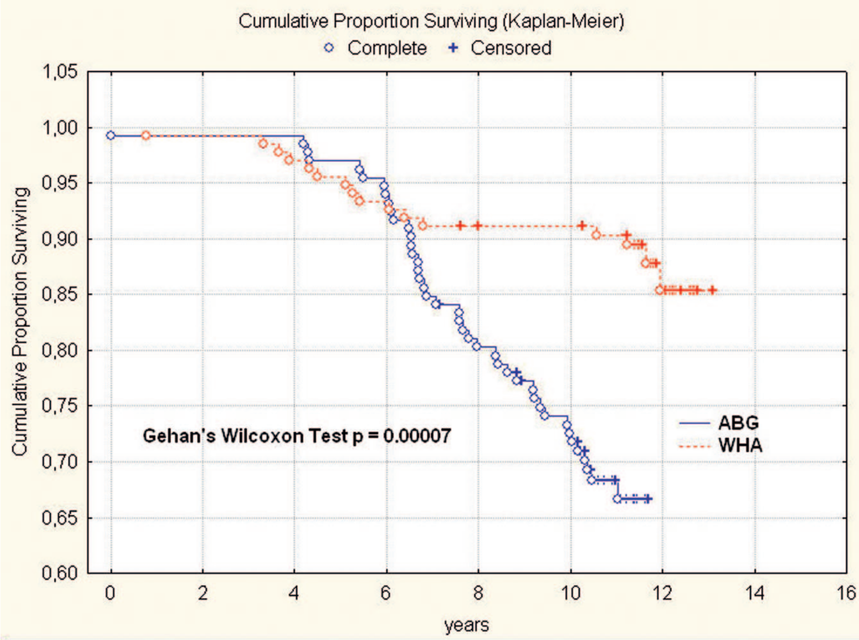
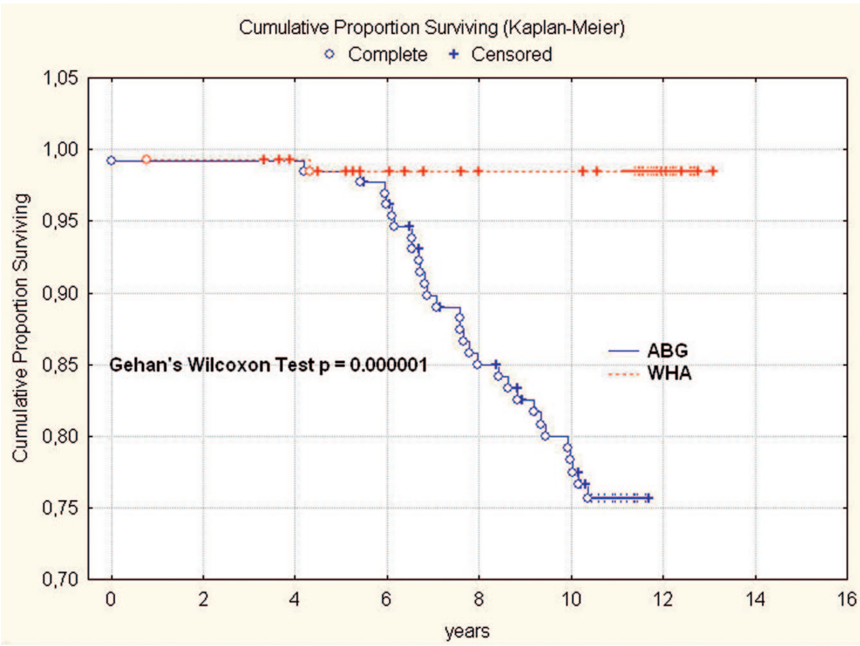


Figure 3. Kaplan-Meier curves showing femoral stem survival



lucency, gross OL extending at least one zone or impending fracture through the OL lesion.

Statistical analysis

This two-centre study was conducted to compare long-term survival of two different stems with HAC. Probabilities of implant survival were estimated using the Kaplan-Meier method. The prosthesis revision for any reason was taken as the end-point. Patients without revisions were censored at the date of the last follow-up or death. Differences in survival curves were evaluated using the Gehan's Wilcoxon test. Differences in the variables under study were assessed with a two-tailed Student t-test, Fisher's exact test, and chi-square test. A p value of less than 0.05 was considered as significant.

RESULTS

Survivorship curves derived by the Kaplan-Meier method and life tables are presented for cups and stems separately (Fig. 2, 3, Table 3). Gehan's Wilcoxon test confirmed that the survivorship curve for the WHA group was significantly better than for the ABG I group

Table 3. Life table analysis

	ABG stem				ABG cup			
Interval	Number	Cum. prop.	95% Confidence interval		Number	Cum. prop.	95% Confidence interval	
Start	exposed	surviving	lower bound	upper bound	exposed	surviving	lower bound	upper bound
0	132	1.00	1	1	132	1.00	1	1
2	131	0.99	0.98	1	131	0.99	0.98	1
4	130	0.99	0.97	1	131	0.99	0.97	1
6	122	0.96	0.93	0.99	124	0.94	0.90	0.97
8	103	0.85	0.79	0.90	104	0.80	0.74	0.85
10	48	0.78	0.73	0.84	50	0.72	0.67	0.78
	WHA stem				WHA cup			
Interval	Number	Cum. prop.	95% Confidence interval		Number	Cum. prop.	95% Confidence interval	
Start	exposed	surviving	lower bound	upper bound	exposed	surviving	lower bound	upper bound
0	135	1.00	1	1.00	135	1	1	1
2	134	0.99	0.98	1.00	134	0.99	0.98	1
4	134	0.99	0.97	1.00	131	0.97	0.94	1
6	133	0.98	0.96	1.00	125	0.93	0.89	0.97
8	133	0.98	0.95	1.00	119	0.91	0.87	0.95
10	74	0.97	0.95	1.00	78	0.91	0.86	0.95
12	7	0.97	0.94	1.00	17	0.86	0.8	0.92

not only in total, but also separately in stems and cups (Table 4).

In the WHA group there were sixteen acetabular (12%) and two femoral components (1.5%) revised, while forty-two cups (32%) and thirty-one stems (23.6%) were revised in the group of ABG I (chi-square test, $p < 0.05$).

Comparison of the reasons for revision (Table 5) showed that patients in the ABG I group were significantly more likely to develop OL with a stable prosthesis than those with WHA implant (Fisher's exact test, $p < 0.05$).

Radiographic and clinical follow-up evaluations were performed on 119 hips of the WHA group and 90 hips of the ABG I group that were not revised up to the time of their latest follow-ups. A one-year examination of all hips disclosed radiographic stability for both the acetabular and femoral sites. At the last follow-up, there was no case of any OL or radiolucency found at the femoral site among the WHA group. In contrast, in the ABG I group, extensive femoral OL was detected in four hips including one case with an impending fracture of the greater trochanter (5%). All of the osteolytic lesions were located in Gruen 1 and 7 zones which paradoxically corresponded to areas of HAC on the stem.

Incomplete radiolucent lines adjacent to the acetabular component together with a migration of up to 2 mm were seen in 28% of the WHA cups that were not revised at the time of the last follow-up. In the ABG I group, one cup was radiographically loosened with complete radiolucent line and migration above 2 mm (1%). Moreover, retroacetabular OL was seen in the same group in another ten hips (12%). When radiographic data were included into the Kaplan-Meier analysis the differences

Table 4. Comparison of cumulative surviving for both prostheses under study by Gehan's Wilcoxon test

	WHA group	ABG I group	Difference
Stem	0.97	0.78	p<0.05
Cup	0.86	0.72	p<0.05
Total	0.85	0.66	p<0.05

Table 5. List of reasons for revision of prostheses included in study

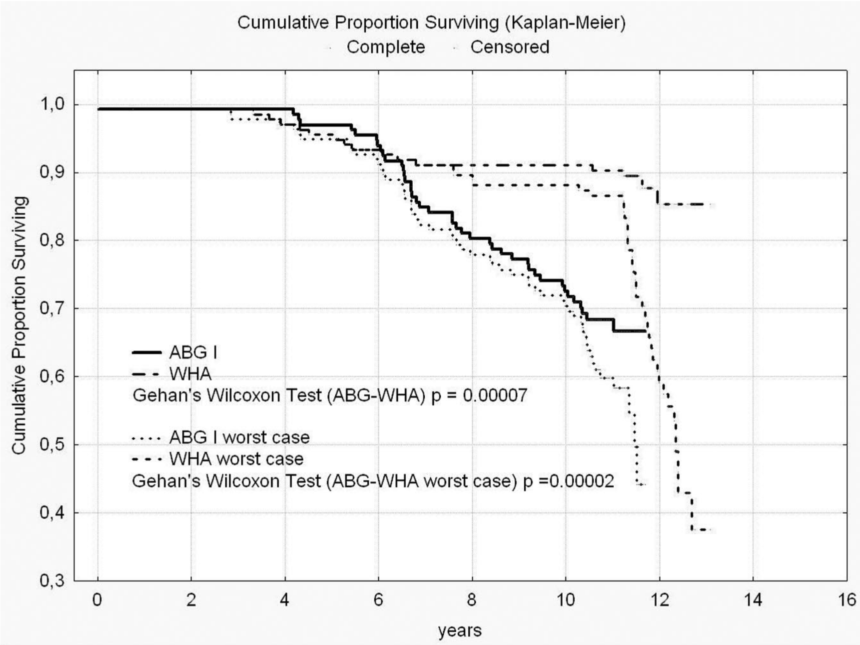
Component/	Cup		Stem	
Reasons	ABG	WHA	ABG	WHA
OL around stable prosthesis	25 (19%)	0 (0%)	27 (20.5%)	0 (0%)
Aseptic loosening	13 (10%)	14 (10%)	1 (0.8%)	0 (0%)
Instability	3 (2.3%)	0 (0%)	0 (0%)	0 (0%)
Periprosthetic fracture	0 (0%)	0 (0%)	2 (1.5%)	0 (0%)
Infection	1 (0.8%)	2 (1.5%)	1 (0.8%)	2 (1.5%)
Total	42 (32.1%)	16 (11.5%)	31 (23.6%)	2 (1.5%)

OL = osteolysis

in failure rates between both prostheses were also significant (Fig. 4).

In the unrevised hips, the HHS improved from an average of 34 (range, 27 to 57, SD 6.33) and 55 (range, 43 to 77, SD 6.08) points to an average of 96 (range, 88 to 100, SD 2.98) and 86 (range, 64 to 95, SD 6.34) points in WHA and ABG I groups (Fig. 5), respectively. The HHS improvement was statistically significant for both groups (t-test, $p < 0.05$). Moreover, the majority of patients with either implant were satisfied with the outcome of their surgeries.

Figure 4. Kaplan-Meier curves showing cumulative survival after radiographic data inclusion (worst-case scenario)



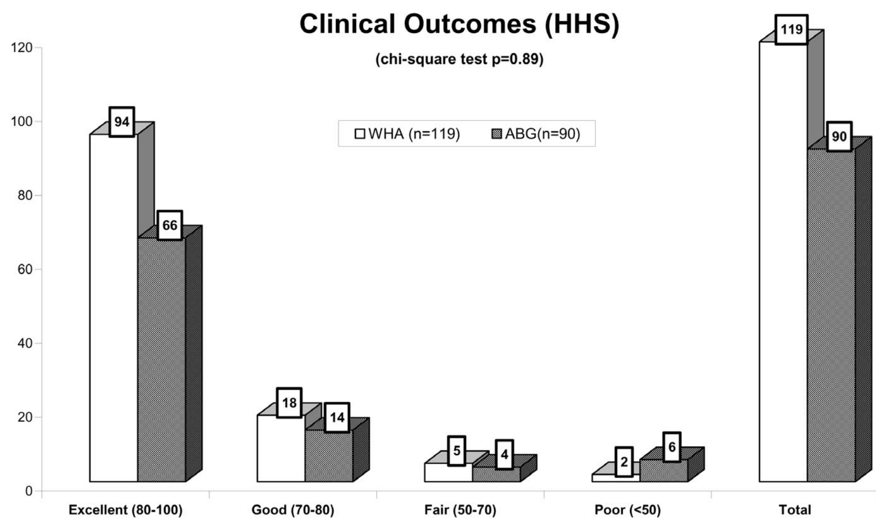


Figure 5. Comparison of clinical outcomes in terms of Harris Hip Score

DISCUSSION

Synthetic hydroxyapatite which is very similar to the inorganic component of the bone, has been found to be osteoinductive, i.e. it is capable of supporting ingrowth of osteoprogenitor cells into graft or implant (12). For this reason, HAC was introduced into clinical practice in the eighties with the hope of solving the problem of prosthetic fixation. Surprisingly, after more than twenty years of basic research and clinical studies, the debate continues about its presumed benefits. Moreover, some authors claim that HAC cannot offer better fixation than porous coated prosthetic surfaces which also provide good fixation (4, 9, 16, 23, 35).

In this study we found significantly better hip survival of ten years for one of the two stems with HAC (Fig. 3, Tables 3 and 4). This might look like a paradox at first glance because the differences in design and material features between both stems used in the study were not conclusive enough to explain such differences. In fact, both of the stems were designed for proximal fixation and both were anatomically shaped to enable better filling in the metaphysis bone on cross-section.

In our previous study we reported excellent results for the first fifty WHA stems (22). The current study included more than double the number of hips and the rate of failure remained the same after a follow-up of 11.4 years. In contrast, the ABG I stems were revised more frequently. However, the main reason for failure was not aseptic loosening but periprosthetic OL which could also be interpreted as a long-term failure of the sealing effect of HAC. What caused this to happen, given the evident ability of HAC to accelerate osseointegration of the implant and achieve full osseointegration much sooner than particle disease would be able to exert any significant influence (25)?

One reason may lie in the gradual degradation of HAC over time which is not always followed by new bone formation of sufficient quality in the areas of HAC resorption. Based on the retrieval analysis done with the ABG I stems, HAC is slowly removed over time in situ without compromising the osseointegration up to 9.5 years postoperatively (13). In fact, bone trabeculae were seen in direct contact with the deeper layers of coating or even with pure titanium, without any occurrence of fibrous membrane. Hence, removal of hydroxyapatite seems to be an integral part of bidirectional bone growth and remodeling which runs around the stems with HAC being managed by osteoclasts, activated macrophages and osteoblasts (32). Some clinical studies support this concept with up to 15 years of follow-up (2, 7). On the other hand, regions with missing bone in the areas of HAC resorption were observed by us and others (33).

Secondly, periprosthetic OL is strongly associated with PE wear (19, 31). Generally speaking, the higher the PE wear-rate the greater the chances for a highly advanced polyethylene disease. In this regard, critics of

HAC argue that fragments of HAC could be another source of third body PE wear but this has not been proved for the ABG I prosthesis (24). On the other hand, accelerated PE wear has been reported for the ABG I prosthesis by us (10). Taken this into account, the periprosthetic bone must remodel under both the influence of polyethylene disease pathways which simultaneously influence bone homeostasis in favor of resorption, and mechanical factors such as joint fluid pressure that cause direct bone resorption (20). In this respect, one may speculate that high-grade polyethylene diseases such as those observed in the hips with ABG I can overwhelm the HAC barrier. However, the complete presence of bone attachment to the prosthetic surface around the joint is considered a reliable barrier against expansion of effective joint space. Taken together, the most important concern in HAC THA should be both the parameters of HAC and surface under HAC that influences the quality and durability of periprosthetic bone (32).

Interestingly, in the WHA stem, HAC porosity had increased progressively in the direction from implant/coating interface to the outer surface of the coating (from 15 to 70%). The bone interlocking of such HAC surface could guarantee significantly better long-term barrier against expansion of effective joint space in contrast to ABG I in which HAC porosity was equal or less than 2%. Moreover, these facts suggest that the amount of PE wear need not play a critical role in the events of OL around stable implants. In support, we observed several hips in our WHA group in which PE insert was almost worn-through after ten years of functioning but the stems had been steadily integrated without any radiolucent lines.

Surprisingly, several studies have reported survival rates for the ABG I stem similar to our WHA group (3, 15, 24). The reasons for this are not clear. Our readiness to revise mechanically stable stems with OL during cup revision might play a role here. Importantly, there was a higher rate of postdysplastic hips and younger patients in ABG I group compared to studies with better survival. As found previously, both of these variables might be associated with higher risk for failure (17). However, similar survival curves as for the ABG I group in our study have been published recently by others (1, 18). In fact, using ABG I prosthesis was ceased at the clinic early in 2000 after first revisions were performed on due to OL and excessive PE wear rate. Based of these data, all patients with ABG I implants should be tightly observed both clinically and radiographically. Finally, we recommend a revision should be indicated early rather than late to prevent development of extensive acetabular and femoral OL.

In conclusion, this study revealed excellent 10-year survivorship curve for WHA stem with HAC while the same for the ABG I stem was significantly poorer. The main reason for failure was OL in the latter group which may be interpreted as a result of sealing effect loss. This may be explained at least particularly by differences in the porosity profile of HAC which determines firmer and more endurable bone-prosthetic interlocking. In this way, the HAC on WHA stem probably provides a more resistant barrier against expansion of effective joint space with blocking of polyethylene disease formation and thus preventing premature implant failure from OL and aseptic loosening.

ZÁVĚR

Protézy s hydroxyapatitovým nástřikem byly zavedeny do klinické praxe v naději, že odstraní problémy fixačního rozhraní endoprotézy. K tomu, aby bylo možné vyhodnotit, zdali se tato koncepce osvědčila, je nutné publikovat výsledky s alespoň desetiletým sledováním. Cílem studie bylo porovnat chování dvou dříků TEP kyčelního kloubu s hydroxyapatitovým povrchem v dlouhodobém časovém horizontu.

Celkem bylo do retrospektivní studie zahrnuto 249 pacientů (271 kyčlí), z toho 122 pacientů (135 kyčlí) mělo endoprotézu Walter (skupina Walter) s dvouvrstevným kombinovaným TiO2/HA nástřikem v horní polovině dříku a 127 pacientů (136 kyčlí) mělo endoprotézu ABG I (skupina ABG I) s jednovrstevným HA nástřikem v horní polovině dříku. Průměrná délka sledování byla 11,4 roků (0,8-13) u protéz Walter a 9,8 roků (4-12) u protéz ABG I. Průměrný věk v době operace byl u pacientů s protézou Walter 62 roků (23-79) a u pacientů s protézou ABG I 47 roků (21-65).

Základním sledovaným parametrem byla pravděpodobnost přežití implantátu (Kaplan-Meierova křivka, „life-table“). Porovnáním předoperačního a finálního Harrisova skóre byly stanoveny změny v klinickém nálezu. Zhodnocení rentgenového nálezu se stalo vodítkem pro posouzení způsobu uvolnění.

Celkové přežití TEP kyčle Walter bylo signifikantně lepší nežli u protézy ABG I (0.85 versus 0.66; $p < 0.05$). Nejčastějším důvodem revize TEP ABG I byla periprotetická osteolýza následovaná aseptickým uvolněním implantátu. Křivka přežití pro dřík Walter byla významně lepší nežli pro dřík ABG I, a to i poté, co byly do analýzy přidány rentgenologické výsledky ($p = 0.0002$). Ve skupině Walter byly revidovány pouze dva dříky (1,5 %), zatímco ve skupině ABG I to bylo 31 dříků (23,5 %; $p < 0.05$). Významně vyšší bylo v souboru ABG I také množství revidovaných jamek ($p < 0.05$). V obou skupinách bylo dosaženo významného zlepšení Harrisova skóre oproti stavu před operací.

Hlavní příčinou selhání implantátu ABG I byla pravděpodobně nedostatečná kvalita polyetylenu a jeho špatné uzamčení v kovové jamce. Forma hydroxyapatitového nástřiku užitá u ABG I navíc nebyla schopna zablokovat rozvoj polyetylenové nemoci podporovaný rychlým otěrem polyetylenu.

V práci jsou prezentovány výborné výsledky dříku Walter ve srovnání s dříkem ABG I, a to v dlouhodobém sledování. Významný podíl na nich má zřejmě kvalitní kombinovaný dvouvrstevný povrch s hydroxyapatitem, který zajišťoval u dříků Walter optimální fixaci a současně bránil rozvoji polyetylenové nemoci.

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