Long-term results of the custom-made hip endoprostheses Evolution K® and Adaptiva®: A prospective cohort study

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Abstract

The aim of our study is to evaluate clinical long-term results and determine changes in periprosthetic bone density of the custom-made hip prostheses Evolution-K® and Adaptiva®. Periprosthetic bone density were evaluated by means of DEXA (Lunar-iDXA-Prodigy® bone densitometer) with a long-term follow-up of 16 (15-18) years (Evolution-K®) in 24 patients and 13 (13-15) years (Adaptiva®) in 41 patients. Evolution-K® had a survival rate of 92% and yielded 79/100 points in Harris Hip Score, a mediocre result. Adaptiva® had a survival rate of 99% and achieved a good score of 88/100 points. Bone density measurements demonstrated the greatest loss of bone density in the proximal regions of interest (ROI) for both prosthesis types (Evolution-K®: -25.8% ROI 1, -40.3% ROI 7; -8.3% ROI 2, -10.4% ROI 6; Adaptiva®: -29.8% ROI 7, -6.8% ROI 6, +14.3% ROI 3, +3.1% ROI 4). Adaptiva® yielded a good clinical result as compared to Evolution-K® with only average clinical results. Both prostheses clearly showed signs of "stress shielding". Here, the Adaptiva® achieved reduced bone density loss as compared to the Evolution-K®.

Introduction

Nowadays cement-free standard hip prostheses provide very satisfying long-term clinical outcome.[1] With these prostheses, primary stability is achieved immediately after surgery by "press fit," while secondary stability greatly depends on integration of the prosthesis into the bone. The successful bone integration process itself depends on various factors, such as quality of the bone itself,[2] anchoring technique, design of the prosthesis and surface characteristics[3] that influence "bony ongrowth" or "bony ingrowth".[4] A certain primary stability is needed to avoid unwanted micromovements that could result in reduction of bone integration and aseptic loosening.[5] This can be achieved via the "press fit" or "form fit/fill and fit" technology. The "form fit" or "fill and fit" technology aims to improve the primary stability via maximum three-dimensional anatomical adaptation of the shaft to the marrow space.[4]

All designs and modifications aim to reduce stress shielding, which results from altered biomechanical properties after implantation of the prosthesis.[6] The primary load area of force transmission runs through the prosthesis and not along the physiological biomechanical route, leading to reduced force load around the proximal part of the prosthesis and thus to bone modification and stress shielding.[7,8]

The second-generation custom-made prosthesis (CMP) Evolution-K® (CMP-EK) (Fehling, Karlstein, Germany) has a microporous surface corundum-blasted proximal prosthesis shaft that increases surface area. It is fitted to the marrow space three-dimensionally ("fit and fill") in order to provide the greatest possible contact area and optimal fitting.

Third-generation CMP Adaptiva® (CMP-A) (Fehling, Karlstein, Germany) is a two-dimensionally fitted prosthesis with a rectangular design. Increased rotational stability and even force transmission are further enhanced via three vertical ribs in the proximal ventral shaft. The small width in the sagittal plane allows for spongiosa-sparing implantation, which improves bony ingrowth.[9,10]

The primary endpoint of this study is to examine clinical and osteodensitometric long-term results of CMP-EK and CMP-A obtained with the Harris Hip Score (HHS) and the DEXA measuring method. Secondary endpoints are comparison of the two prostheses with each other and with other custom-made prostheses.

Materials and Methods

In this prospective cohort study clinical and osteodensitometric data were collected following implantation of a custom-made femoral stem prothesis.

In the Evolution-K® collective (EK-C) 50 patients were recruited from 05-10/1993 at the Department of Orthopedic Surgery, Tübingen University Hospital. The follow-up measurements four and five years postoperatively were performed in a collective of 43 patients. The remaining seven patients were excluded due to death (n=2), septic or aseptic loosening leading to replacement of the prosthesis (n=3) or because they had moved away (n=2). Table 1 shows the collective size at the time of the recent follow-up examination 16 years postoperatively, for which 24 patients were enrolled.

In the Adaptiva® collective (A-C) 59 patients were recruited from 01-11/1997 at the Department of Orthopedic Surgery, Tübingen University Hospital. A total of 18 patients had to be excluded for the 13-year postoperative measurements listed in Table 1. Characteristics of the study collective and indications for CMP implantation are also shown in Table 1.

Median follow-up in the EK-C was 16 (15-18) and 13 (13-15) years in the A-C.

Clinical examination included HHS, a standardized method aimed at quantifying various parameters, with which 91 points can be achieved from subjective criteria such as pain or functional impairment, and nine

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points from objective criteria such as range of motion or deformities.[11] This was supplemented by a precise questionnaire and clinical examination.

Osteodensitometric measurements were conducted with the GE Lunar iDXA-Prodigy® apparatus (GE Healthcare, Madison, WI, USA) and permit quantitative statements to be made largely irrespective of consistency and quantity of the surrounding soft tissue. The resulting BMD denotes bone mass per scanned area as g/cm.[2,12] For means of comparability of periprosthetic BMD, Gruen-analysis was performed.[13] For this purpose, the regions surrounding the prosthesis stem are divided into seven regions of interest (ROI) (Figure 1). ROI 7, the medial proximal ROI, was then modified by reducing the frontal surface, so that the area resected during femoral neck osteotomy is not considered. The cranial margin of this ROI was congruent to the end of the osteotomy line. This guaranteed pre- and postoperative comparability.

The statistical analysis was performed with "EXCEL 2010" (Microsoft, Redmond, WA, USA) and "SPSS for windows" (SPSS Inc., Chicago, IL, USA).

First, normal distribution was checked using the Kolmogorov-Smirnov test followed by testing the homogeneity of variance using the Levene test. For testing significance Student's T test or the Mann-

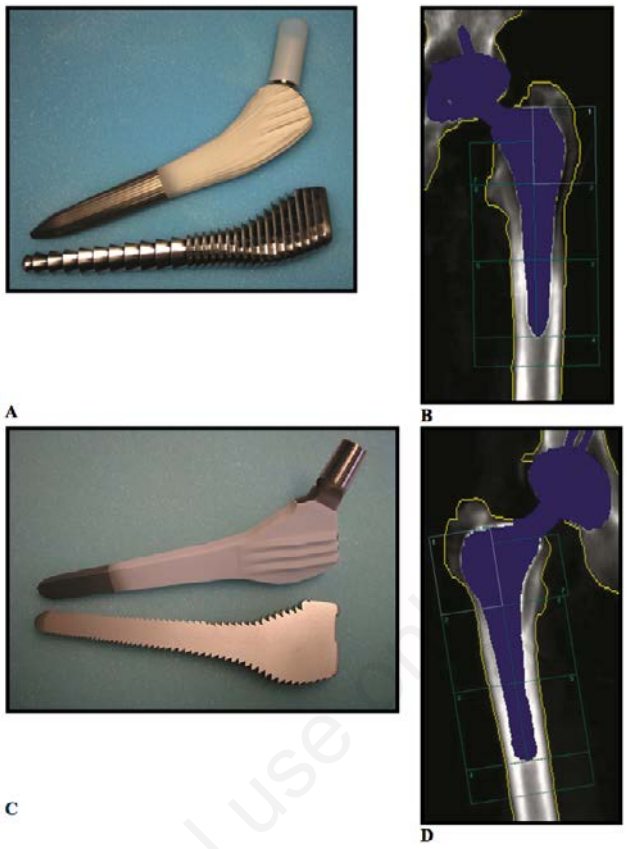

Figure 1. A: CMP-Evolution-K®; B: Regions of interest 1-7 in the osteodensitometric measurement (Evolution-K®); C: CMP-Adaptiva® (from Leichtle et al.10), D: Regions of interest 1-7 in the osteodensitometric measurement (Adaptiva®).

Table 1. Patient and study collective.

	Evolution-K®	Adaptiva®	P
Examined at current time	24	41	
Deceased	9	7	
CMP replaced (aseptic loosening)	4	1	
Emigrated	3	0	
Health limitations	5	5	
Failure to contact/other	5	5	
Total		50	59
Gender (n/%)			0.924
Male	12 (50)	21 (51)	
Memale	12 (50)	20 (49)	
Age (years)	70.5 (50-80; IQR: 9)	70 (55-79; IQR: 13)	0.851
Height (cm)	166 (148-185; IQR: 15)	171 (147-185; IQR: 11)	0.721
Weight (kg/m^2)	26.6 (18.3-45.7; IQR: 20)	28.4 (17-40.2; IQR: 26)	0.961
Comorbidities (n/%)			
Orthopedic	22 (92)	38 (92)	0.887
Medical	19 (79)	30 (73)	0.588
Side of study prosthesis (n/%)			0.457
Right	14 (58)	20 (49)	
Left	10 (42)	21 (51)	
Preoperative diagnoses (t=PE) (n/%)		0.088	0.088
Idiopathic coxarthrosis	26 (60)	45 (76)	
Secondary coxarthrosis	17 (40)	14 (24)	
Preoperative diagnoses (t=CE) (n/%)		0.121	0.121
Idiopathic coxarthrosis	13 (54)	30 (73)	
Secondary coxarthrosis	11 (46)	11 (27)	

PE=Previous examination. CE=Current examination.

Whitney U test was applied depending on the presence or absence of normal distribution. The requirements for using Student's T test are normal distribution and homogeneity of variety of data. The Mann-Whitney U test is a parameter-free statistical homogeneity test with the homogeneity of variance requiring homogeneity of variance, but not normal distribution of data.

Ethics approval for conduct of the study in compliance with protection of the rights and welfare of human subjects participating in medical research according to the World Medical Association Declaration of Helsinki was obtained (Ethics review board of Tübingen University, Germany, 164/97) and complies with the criteria of the STROCSS guideline for cohort studies in surgery.[14] The study is registered in the German Clinical Trials register (DRKS00023140). Before commencing the study informed written consent was obtained.

Results

Overall survival rates (SR) were 92% at CMP-EK with four revisions and 99% at CMP-A with one revision due to aseptic loosening (Table 2).

With regard to clinical outcome, CMP-EK resulted in an HHS of 78.7 (25.5-96.7; 17.2) points and CMP-A in 87.7 (45.6-99.6; 13.1) points (p=0.032).

Pain was reported by 41.7% of CMP-EK patients as opposed to 19.5% of CMP-A (OR 2.95; 95 %CI 0.96-9.03; p=0.055). Pain in the EK-C was characterized as stress-related by 41.7% and constant by 12.5% of the cohort. In the A-C 9.8% of the cohort experienced stress-related pain and 2.4% reported constant pain.

Occasional use of analgesics was higher in the EK-C (16.7%), while sustained use was lower (4.2%), as compared to the A-C. In the latter cohort, occasional analgesic consumption was reported by 4.9% of the patients and permanent use by 9.8%. No significance difference was seen between patients who needed analgesics and patients who did not need analgesics (p=0.52). In order to rule out other reasons for pain medication intake, orthopedic and medical comorbidities were evaluated. No significant differences within the collectives were found regarding orthopedic ailments (p=0.883) or ailments from the internal medicine spectrum (p=0.591). Load capacity of the hip was surveyed, too and showed that 62.5% of the EK-C as compared to 39% of the A-C reported practicing sports regularly, while 50% versus 24.4%, respectively, reported regularly participating in a special hip gymnastics or physiotherapy program.

Walking distance was unimpaired in 79.2% (Evolution-K®) and 82.9% (Adaptiva®) of the patients, with 4.2% (Evolution-K®) and 7.3% (Adaptiva®) quantifying their walking distance at approximately 500 m, 12.5% (Evolution-K®) and 7.3% (Adaptiva®) at approximately 300 m, and finally 4.2% (Evolution-K®) and 2.4% (Adaptiva®) at a walking distance of only one room. No patient in either collective was unable to walk.

Analysis of the osteodensitometric follow-up measurements of the periprosthetic BMD of the CMP-EK showed a continuous downward trend with regard to the 10-day postoperative measurements, especially in the proximal ROI 1, 6 and 7, with a decrease of up to 25.8% (ROI 1) and 40.3% (ROI 7). The measurements conducted in the A-C showed a decrease in BMD only in ROI 6 and in ROI 7, namely 6.8% and 29.8%, respectively. The other ROI revealed an increase of up to 14.3% in BMD (ROI 3) (Table 3).

The difference in the 10-day postoperative measurements calculated for ROI 1-3 and 5 for both prosthesis types in the 16- or 13-year postoperative measurements were significant (ROI 1: p=0.002; ROI 2 and 3: p=0.009; ROI 5: p=0.006). The remaining ROI did not demonstrate a significant difference (ROI 4: p=0.155; ROI 6: p=0.693; ROI 7: p=0.153) (Table 4).

The osteodensitometric results for lumbar vertebrae 2-4, as compared to the 10-day postoperative measurements, did not reveal a significant difference (p=0.870), namely 0.12 (-0.2-0.41; 0.16) g/cm^2 for the CMP-EK and 0.1 (-1.37-0.9; 0.39) g/cm^2 for the CMP-A.

Osteoporosis, diagnosed with the Z Score, was found in 8.3% of patients in the EK-C and 17.1% in the A-C (standard deviation >-1). The difference between the two collectives was not significant (p=0.59).

When comparing the results of male and female patients (both n=12) in the EK-C, no significant differences in BMD within the various ROI were detected. In the A-C, however, the 21 male and 20 female patients revealed significant differences in the various periprosthetic BMD (p<0.05) (Table 3). Comparison of periprosthetic BMD of non-osteoporotic (n=34) and osteoporotic patients (n=7) in A-C showed no significant differences in ROI 1 or 3-7 (p>0.05). Only ROI 2 showed a significant difference (p=0.023).

Discussion and Conclusions

Lower revision rates of uncemented standard prostheses[15] and longer survival rates were reported, especially in patients under the age of 55,[16] as compared to cemented prostheses. There are only few studies comparing them to CMP.

The most important quality criterion for evaluation of CMP is clinical outcome. EK-C achieved after 16 years of follow-up a mediocre result while after 13 years A-C showed a good HHS result. Both collectives demonstrate a worsening of the clinical result over the study period. A noticeable finding was the number of patients with stress-related or permanent pain at the time of follow-up. This underlines the significant

Tabel 2. Results of CMP.

Prosthesis	Author	Year	A	B	C	D	E	F	G	H
Evolution-K®		2015	16 (15-18)	54.5 (34-64)	50	5	79	4	4	92
Adaptiva®		2015	13 (13-15)	57 (42-66)	59	5	88	1	1	99
CAD-CAM®	Muirhead-Allwood *et al.*	2010	13 (10-17)	46 (25-62)	112	6	90	0	0	100
	Sewell *et al.*	2011	10 (4-18)	38 (18-61)	43	3	80	2	1	93
	Benum et Aamodt	2010	10	48 (20-65)	83	0	-	2	0	98
	Al-Khateeb *et al.*	2014	10 (5-15)	33 (23-55)	17	0	80	0	0	100
Symbios®	Flecher *et al.*	2010	10 (5-16)	40 (18-50)	232	0	97	6	2	97
	Pakos et al.	2015	10 (8-12)	48 (41-55)	86	0	-	4	2	98
CT3D-A®	Akbar et al.	2009	14 (10-16)	35 (22-40)	72	0	87	0	0	100

A: Mean follow-up period [years]. B: Median age of the collective [years]. C: Collective size [n]. D: Lost to follow up [n]. E: HHS-result [points]. F: Number of revisions [n]. G: Number of revisions due to aseptic loosening [n]. H: Survival rates [%].

differences in the HHS. For CMP generally, HHS of 80-97 points can be found in the literature and reveal similar results (Table 2).[17-23] Here, only the "Symbios-CMP" by Flecher *et al.* scored an excellent 97 points. However, the slightly shorter follow-up period should be taken into account, despite this being the largest collective. Akbar *et al.* showed lower clinical results with 87 points, but have the longest follow-up period, namely 14 years. CMP reaped better results in the above-mentioned studies compared to cement-free standard prostheses. However, the CMP-EK with only 79 points had one of the lowest results, while the CMP-A compared well with 88 points.

With regard to revisions due to aseptic loosening, CMP-A offers very good results with 99% not requiring such re-do operations. Therefore, it is comparable to the other listed CMP. CMP-EK, similar to the CAD-CAM prosthesis by Sewell *et al.,* offers only a survival rate of 92% and 93%. These two prostheses thus have the poorest survival rate of the listed prostheses (Table 2).[17-23] Overall, CMP demonstrated excellent survival rates in comparable collective sizes and comparable average age at implantation. At 92%, however, CMP-EK yielded a slightly reduced survival rate in our study, while having the longest median follow-up period of 16 years. CMP-A fits in well with the results published for other CMP with a survival rate of 99% in a follow-up period of 13 years.

The osteodensitometric results of CMP-EK reveal clear BMD reductions in the proximal ROI as compared to the 10-day postoperative measurement. The "fill and fit" concept is intended to reduce stress shielding, but these areas evidence remarkable stress shielding. The distal ROI showed declines of less than 4% in BMD. ROI 3 even showed unchanged BMD. This can be explained by the effect of stress shielding. This mechanism is thought to be responsible for pain in the thigh and aseptic loosening.[24]

When comparing changes in BMD after four or five years and ultimately after 16 years, it is noteworthy that the restructuring process of the BMD does not occur in an exponential fashion; it is much more likely to slow down. The follow-up measurements of the lumbar vertebrae 2-4, representing the systemic BMD, revealed in contrast a stable or slight increase in BMD and in the measurements of the opposite femur. Therefore, changes in the periprosthetic areas must be induced by the prosthesis. This increase, as well as the increase in systemic BMD in contrast to the age-related decrease in BMD, may have several causes, for instance improved postoperative mobility, pharmacological improvement of calcium metabolism due to osteoporosis prophylaxis, weight change in the collective or errors in pre- and postoperative measurements due to degeneration and osteophytes.

CMP-A also shows a remarkable decline in BMD, specifically in the proximal mid-ROI. Periprosthetic BMD, however, hardly deviated from the BMD of the previous measurements, indicating good biomechanical properties of this prosthesis. However, the depreciations in ROI 6 and 7 demonstrate that optimal force transmission and physiological biomechanical load are not yet fully established. The trend to increasing periprosthetic BMD described by Lebherz *et al*., especially in the distal shaft anchoring, was underlined by our measurements. Here a slight increase was seen during the 2-year follow-up measurements after an initial decline in the 6-month follow-up was measured. These observations were most striking in ROI 4 (1.7%) and ROI 5 (3.3%).[9]

Systemic BMD and BMD of the opposite femur did not differ significantly in the two collectives. Other factors leading to osteopenia or osteoporosis, which would therefore falsify the measurements, were ruled out with the T Score. However, periprosthetic BMD of the study prostheses in ROI 1-3 and ROI 5 differed significantly between the collectives (Table 4). This may be due to the bone transformations observed in CMP-EK, especially in the proximal ROI 1-2 caused by stress shielding, while this can not be detected in CMP-A. In ROI 5, a significant increase in BMD was observed with CMP-A. Consequently, the significant difference in ROI 3 and 5 between the two collectives resulted from more pronounced bone hypertrophy with CMP-A than with CMP-EK as a result of a wider area of contact during force transmission.

Table 3. CMP BMD-measurements and BMD-subgroup analysis man/woman.

	A	B	C	D	E	F	G	H	I	J	K
Evolution-K®											
ROI 1	O.97	-	0.76	-21.9	0.75	-22.9	0.72	-25.8	-0.24	-0.45	p=0.101
ROI 2	1.8	-	1.53	-14.9	1.51	-15.9	1.65	-8.3	-0.33	-0.39	p=0.932
ROI 3	1.96	-	1.86	-6.1	1.86	-6	1.96	0	-0.13	-0.35	p=0.242
ROI 4	1.86	-	1.72	-10.9	1.74	-9.8	1.8	-3.2	-0.20	-0.37	p=0.443
ROI 5	2.04	-	1.94	-5.4	1.98	-3.6	1.99	-2.5	-0.14	-0.45	p=0.332
ROI 6	1.73	-	1.57	-7.4	1.56	-7.9	1.5	-10.4	-0.36	-0.45	p=0.887
ROI 7	1.49	-	1.04	-27.5	1.0	-30.3	0.91	-40.3	-0.69	-0.71	p=0.755
Adaptiva®											
ROI 1	0.88	-	0.79	-10.8	-	-	0.95	8	0.29	-0.15	p=0.002
ROI 2	1.69	-	1.57	-6.8	-	-	1.89	11.8	0.50	-0.08	p=0.003
ROI 3	1.96	-	1.87	-4.9	-	-	2.24	14.3	0.50	0.09	p=0.003
ROI 4	1.92	-	1.86	-5.1	-	-	1.98	3.1	0.21	-0.05	p=0.042
ROI 5	1.93	-	1.87	-3.1	-	-	2.18	13	0.41	0.12	p=0.020
ROI 6	1.61	-	1.48	-8.0	-	-	1.50	-6.8	0.09	-0.36	p=0.003
ROI 7	1.51	-	1.15	-23.7	-	-	1.06	-29.8	-0.32	-0.61	p=0.010

A: BMD 10 d post-OP [g/cm²]. B: Difference based on the measurement 10 d post-OP [%]. C: BMD 4 y (Evolution-K®) / 2 y (Adaptiva®) post-OP [g/cm²]. D: Difference based on the measurement 10 d post-OP [%]. E: BMD 5 y post-OP [g/cm²]. F: Dif-ference based on the measurement 10 d post-OP [%]. G: BMD 16 y (Evolution-K®) /13 y (Adaptiva®) post-OP [g/cm²]. H: Dif-ference based on the measurement 10 d post-OP [%]. I: Mean subgroup "man" [g/cm²]. J: Mean subgroup „woman" [g/cm2]. K: Mann-Whitney-U-test (t-Test).

Table 4. Significant levels of measurement differences of ROI.

	A	B	C	D	E
ROI 1	-0.24	-25.8	0.07	8	p=0.002
ROI 2	-0.13	-8.3	0.22	11.8	p=0.009
ROI 3	0.05	0	0.3	14.3	p=0.009
ROI 4	-0.03	-3.2	0.08	3.1	p=0.155
ROI 5	-0.02	-2.5	0.27	13	p=0.006
ROI 6	-0.18	-10.4	-0.13	-6.8	p=0.693
ROI 7	-0.62	-40.3	-0.46	-29.8	p=0.153

A: Difference BMD [g/cm²] CMP-EK 16 years to 10 days postoperatively. B: Difference BMD [%] CMP-EK 16 years to 10 days postoperatively. C: Difference BMD [g/cm²] CMP-A 13 years to 10 days postoperatively. D: Difference BMD [%] CMP-A 13 years to 10 days postoperatively. E: Significance of differences of BMD.

Furthermore, CMP-A showed an increase in BMD also in the medial femur area, facilitating force transmission through this region. However, in CMP-EK a similar effect can be seen only in the lateral ROI 3, most probably caused by a leverage effect. This denotes a more unphysiological force transmission than with CMP-A.

Comparison with the listed studies regarding changes in BMD in CMP is hardly feasible, since they all acquired their data from radiological interpretations of anterior-posterior hip x rays with evaluation of heterotopic ossification based on the Brooker classification, lucid lines >2 mm as signs of loosening, osteolyses, stress shielding and stability criteria defined by Engh *et al*.[25]

Nevertheless, radiological interpretations are less precise and investigator-dependent than osteodensitometric examinations. Measuring changes in BMD and comparing them over such a long follow-up period is therefore unique to date.

A limitation of this study is the number of patients lost to follow-up. For clinical osteodensitometric study examination 24 EK-C patients and 41 A-C patients were evaluated (Table 1). Nevertheless, the long follow-up periods of 16 and 13 years must be taken into account.

In summary, CMP-A with its good HHS result after 13 years is superior to the CMP-EK with its average result after 16 years. With regard to the osteodensitometric results, both prostheses show signs of stress shielding in the proximal shaft areas despite their custom-made fitting. The two-dimensional, quadrangularly shaped Adaptiva®, however, showed far less stress shielding than did the three-dimensional and round-oval-shaped Evolution-K®. Clinical and osteodensitometric results of the CMP-A demonstrate the superiority of the medio-lateral form-fit concept with its press-fit procedure, augmented by three vertical ribs in the proximal and ventral area providing maximum rotary stability and smooth force transmission.

Long-term CMP results with a median follow-up period of 15 years are rarely published, but continue to gain in relevance in light of the increasing pressure on the health system to justify their use despite higher costs.

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