Bionik Resurfacing Femoral Head when used in conjunction with the Bionik Acetabular Component

Sponsor: ESKA Australia
Manufacturer: ESKA

NJRR Data:

# Implanted	# Revised	Revision Rate (%)
175	9	5.1
13307	*548*	*4.1*
Observed Compt Yrs	**Revns/100 Comp Yrs**	**CL on revs/100 c.yrs**
327	2.8	1.26 - 5.23
55420	1.0	*0.90 - 1.06*

The numbers in shaded italics are the comparison figures for the same type of implant. In most cases this is the numbers for all implants of the same type received by the NJRR

Number of implanting hospitals: 25
Number of hospitals where revisions occurred: 5

Reason for Revision	N	%
Loosening/Lysis	5	55.6
Fracture (Bone)	3	33.3
Pain	1	11.1
Total	9	100%

Type of Revision	N	%
Femoral and Acetabular	6	66.7
Acetabular Only	3	33.3
Total	9	100%

TGA Observations on NJRR Data

Loosening/lysis and fracture are the main reasons for revision of the Bionik Implant, Losening/lysis and pain are over-represented. That is the proportion of Bionik implants that are revised for these reasons is greater than the proportion of implants revised for this reasons in all other implants of the same type. Femoral neck fracture is a common cause for revision with this type of implant. Femoral neck fracture is considered to be related to the implant because preservation of the femoral neck is part of the design phylosophy of this type of implant (The cummulative revision rate of the implant appears to be increasing and diverging from the revision rate curve for all oter implants, but once again the certainty of this trend is difficult to establish due to the relatively low number of observed years.

TGA Observations on Manufacturers Reply

There are 9 revisions reported by the NJRR in this series. The sponsor states that 1 was a ceramic on ceramic implant and the remaining 8 were metal on metal. The Sponsor dismisses them all as not being implant related:

> The revision of the ceramic on ceramic implant was due to a femur fracture due to AVM.
>
> Of the implants that the sponsor claims were metal on metal hips, 3 revisions were due to neck of femur fractures (2 of which are claimed to be due to trauma), 3 revisions are due to malposition of the acetabulr cup and in two cases the femoral heads were not in the varus position.

Note that this does not completely account for all revisions and is not consistent with the NJRR data, which cites 3 fractures, not 4.

ESKA have also supplied some published papers and abstracts about the performace of the ESKA implant. The following are some observations about this literature.

In a general article about hip joint surface replacement Rudert et al report a case series of 20 Bionik surface replacement prostheses inserted between 2003 and 2005. At an average follow up period of 18 months there were no infections of aseptic loosening, but there was one femoral neck fracture and one dislocation, placing the revision rate at approximately 10% (or (100 x 2 revisions / 1.5 years x 20 implants = 6.6 revisions/100 component years).

ESKA has provided a "Data Summary" on a series involving 248 patients (number of implants not stated). Enrolments began in February 2003 and patients were followed until February 2006 (estimated average follow up of 1.5 years). During that time ESKA reports that there were 7 revisions for various reasons - mostly femoral neck fracture. The revision rate is not calculted, but based on the information provided above, an estimate would be 100 x 7 revisions / 1.5 years x 248 implants = 1.88 revisions/100 component years.

Beaulé et al report a retrospective review of 94 cases for which the mean follow up was 4.2 years. 13 patients are reported to have had a bad outcome. A bad outcome is defined as conversion to THR, radiolucency of greater than 1mm or narrowing of the femoral neck by greater than 10%. It is not clear whether all 13 required revision, but if they did then the revision rate was 3.29 revisions/100 component years. To achieve the same revision rate as the average revision rate of similar implants in Australia, the number of implants that were revised should can be no greater than 4. However, Beaulé et al made an important observation: The number of failures is related to a neck shaft angle < 130°. The relative risk of problems with Bionik hips where the neck shaft angle is < 130° is 6 times that wwhere the neck shatf angle is > 130°. It is not clear whether this piece of information is conveyed to surgeons through product literature or training.

The paper by Gerdesmeyer et al on minimally invasive surgery reports that in a series of 31 patients using a minimally invasive approach, no instances of loosening or dislocation or other sequelae were observed after 12 months of follow up.

Two abstracts to papers are submitted with no accompanying citation... and are not discussed further here.

In summary the Sponsor asserts that none of the revisions reported in the NJRR against the Bionik implant are related to the design of the implant. ESKA has also provided papers and citations as evidence of implant performance elsewhere in the world, but the revision rates reported in the literature provided appears to be higher – sometimes much higher than the revision rate reported by the NJRR for this implant.

One author noted the importance of neck shaft angle - The TGA seeks the advice of the OEWG as to whether this affects all similar resufacing implants and whether this is a commonly known in the orthopaedics field.

[redacted]

Bionik/Bionik Total Resurfacing Hip Investigation

This analysis compares the Bionik/Bionik Total Resurfacing Hip Combination with all Other Total Resurfacing Hip prostheses. This Combination has been identified as having a significantly higher revision rate.

For a detailed explanation of the process used by the Registry that results in identification of prostheses that have a higher than anticipated rate of revision please refer to the ' Prostheses with Higher than Anticipated Rates of Revision ' chapter of the most recent AOANJRR Annual Report, http://www.dmac.adelaide.edu.au/aoanjrr/publications.jsp.

TABLE 1

Revision Rate of Primary Total Resurfacing Hip Replacement

The ***Revision Rate*** of the Bionik/Bionik Total Resurfacing Hip Combination is compared to all Other Total Resurfacing Hip prostheses.

Table 1: Revision Rates of Primary Total Resurfacing Hip Replacement

Component	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Bionik/Bionik	9	175	327	2.75 (1.26, 5.23)
Total Resurfacing Hip	539	13132	55093	0.98 (0.90, 1.06)
TOTAL	**548**	**13307**	**55420**	**0.99 (0.91, 1.08)**

TABLE 2

Yearly Cumulative Percent Revision of Primary Total Resurfacing Hip Replacement

The ***Yearly Cumulative Percent Revision*** of the Bionik/Bionik Total Resurfacing Hip Combination is compared to all Other Total Resurfacing Hip prostheses.

Table 2: Yearly Cumulative Percent Revision of Primary Total Resurfacing Hip Replacement

CPR	1 Yr	3 Yrs	5 Yrs	7 Yrs	9 Yrs
Bionik/Bionik	3.8 (1.7, 8.4)	6.6 (3.2, 13.6)			
Total Resurfacing Hip	1.8 (1.6, 2.1)	3.2 (2.9, 3.5)	4.5 (4.1, 4.9)	6.1 (5.5, 6.7)	7.4 (6.4, 8.6)

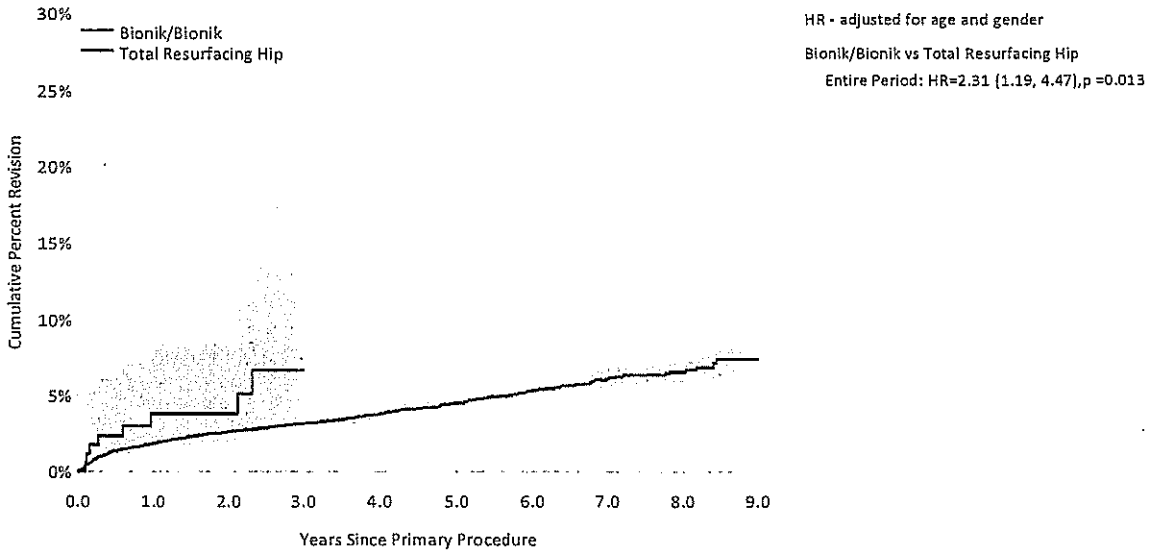
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Resurfacing Hip Replacement

The ***Yearly Cumulative Percent Revision*** of the Bionik/Bionik Total Resurfacing Hip Combination is compared to all Other Total Resurfacing Hip prostheses. In addition, Hazard Ratios are also reported.

Hazard Ratios are reported for specific time periods during which the Hazard Ratio is constant. This is done to enable more specific and valid comparisons of the risk of revision over time. The pattern of variation in risk has important implications with respect to the underlying reasons for any difference.

Figure 1: Cumulative Percent Revision of Primary Total Resurfacing Hip Replacement



Number at Risk	0 Yr	1 Yrs	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs	8 Yrs	9 Yrs
Bionik/Bionik	175	117	73	43	12	0	0	0	0	0
Total Resurfacing Hip	13132	11736	10239	8597	6883	5090	3457	2000	703	88

TABLE 3

Primary Diagnosis for Revised Primary Total Resurfacing Hip Replacement

This table identifies the diagnosis of the primary procedure which was subsequently revised. This information is provided as there is a variation on outcome depending on the primary diagnosis. It is therefore important when considering the reasons for a higher than anticipated rate of revision that there is identification of the primary diagnosis. This information should be compared to the primary diagnosis for the revisions of all Other Total Resurfacing Hip prostheses.

Table 3: Primary Diagnosis for Revised Primary Total Resurfacing Hip Replacement

	Bionik/Bionik		Other Total Resurfacing Hip	
Primary Diagnosis	Number	Percent	Number	Percent
Osteoarthritis	9	100.0	481	89.2
Developmental Dysplasia			35	6.5
Avascular Necrosis			13	2.4
Other Inflammatory Arthritis			6	1.1
Rheumatoid Arthritis			4	0.7
TOTAL	**9**	**100.0**	**539**	**100.0**

TABLE 4

Revision Rates of Bionik/Bionik Primary Total Resurfacing Hip Replacement by Fixation.

This analysis is provided as some prostheses have more than one fixation option. Additionally there are prostheses where an alternative to the recommended approach to fixation was used e.g. a cementless prosthesis that has been cemented or vice-versa.

Table 4: Revision Rates of Bionik/Bionik Primary Total Resurfacing Hip Replacement by Fixation

Fixation	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Cemented	0	1	1	0.00 (0.00, 349.1)
Cementless	1	15	44	2.27 (0.06, 12.67)
Hybrid	8	159	282	2.84 (1.23, 5.59)
TOTAL	**9**	**175**	**327**	**2.75 (1.26, 5.23)**

TABLE 5

Type of Revision Performed for Primary Total Resurfacing Hip Replacement

This analysis identifies the components used in the revision of the Bionik/Bionik Total Resurfacing Hip Combination and compares it to the components used in the revision of all Other Total Resurfacing Hip prostheses.

The reason this analysis is undertaken is to identify whether there is one or more components which are being replaced that differ from the components replaced for revisions of all Other Total Resurfacing Hip prostheses i.e. is there a difference in the type of revision undertaken for the Bionik/Bionik Total Resurfacing Hip Combination compared to all Other Total Resurfacing Hip prostheses.

Table 5: Type of Revision for Primary Total Resurfacing Hip Replacement

	Bionik/Bionik		Other Total Resurfacing Hip	
Revision Type	Number	Percent	Number	Percent
Femoral Only	3	33.3	284	52.7
THR (Femoral/Acetabular)	6	66.7	195	36.2
Acetabular Only			41	7.6
Cement Spacer			15	2.8
Removal of Prostheses			4	0.7
N Major	**9**	**100.0**	**539**	**100.0**
TOTAL	9	100.0	539	100.0

TABLE 6

Reason for Revision of Primary Total Resurfacing Hip Replacement

This is reported in two ways; a percentage of all revisions and also as a percentage of all primary procedures.

This analysis includes a comparison of reasons for revision to all Other Total Resurfacing Hip prostheses.

This analysis is undertaken to identify if there are differences in the reasons for revision and the number of revisions performed for those reasons between the Bionik/Bionik Total Resurfacing Hip Combination and all Other Total Resurfacing Hip prostheses.

Table 6: Reason for Revision of Primary Total Resurfacing Hip Replacement

	Bionik/Bionik			Other Total Resurfacing Hip		
Revision Diagnosis	Number	% Revision	% Primary	Number	% Revision	% Primary
Fracture	3	33.3	1.7	192	35.6	1.5
Loosening/Lysis	5	55.6	2.9	178	33.0	1.4
Infection				45	8.3	0.3
Metal Sensitivity				39	7.2	0.3
Pain	1	11.1	0.6	28	5.2	0.2
Avascular Necrosis				17	3.2	0.1
Prosthesis Dislocation				15	2.8	0.1
Malposition				12	2.2	0.1
Other				6	1.1	0.0
Implant Breakage Head				3	0.6	0.0
Instability				1	0.2	0.0
Leg Length Discrepancy				1	0.2	0.0
Synovitis				1	0.2	0.0
Tumour				1	0.2	0.0
N Revision	**9**	**100.0**	**5.1**	**539**	**100.0**	**4.1**
N Primary	**175**			**13132**		

FIGURE 2

Revision Diagnosis Cumulative Incidence by Time to Revision for Primary Total Resurfacing Hip Replacement

This figure details the cumulative incidence of the most common reasons for revision.

The five most common reasons for revision are included as long as each of these reasons account for more than 10 procedures or at least 5% of all revisions for the Bionik/Bionik Total Resurfacing Hip Combination. A comparative graph is provided of the cumulative incidence for the same reasons for revisions for all Other Total Resurfacing Hip prostheses.

Figure 2: Revision Diagnosis Cumulative Incidence by Time to Revision for Primary Total Resurfacing Hip Replacement

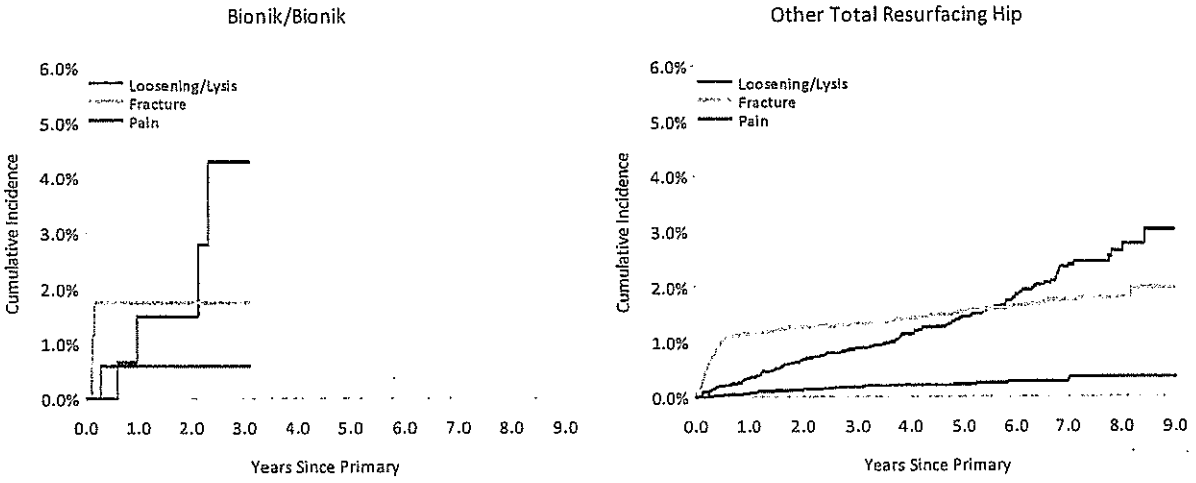


TABLE 7

Revision Rates of Bionik/Bionik Primary Total Resurfacing Hip Replacement by Hospital

This table details the rates of revision in each of the individual hospitals in which the Bionik/Bionik Total Resurfacing Hip Combination was used. The hospitals are identified by number only.

The purpose of this analysis is to determine if the higher than anticipated rate of revision has widespread distribution between hospitals. If there is widespread distribution then the reason for the higher than anticipated rate of revision is unlikely to be surgeon specific. If the prosthesis has been used in only a small number of hospitals it is not possible to distinguish if the higher than anticipated rate of revision is related to the prosthesis, surgeon, technique or patient.

Table 7: Revision Rates of Bionik/Bionik Primary Total Resurfacing Hip Replacement by Hospital

Hospital Number	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
1	0	2	7	0.00 (0.00, 52.96)
2	0	21	16	0.00 (0.00, 23.13)
3	0	4	11	0.00 (0.00, 34.82)
4	2	6	15	12.92 (1.56, 46.66)
5	0	3	4	0.00 (0.00, 85.44)
6	0	1	1	0.00 (0.00, 528.4)
7	0	12	35	0.00 (0.00, 10.60)
8	0	2	3	0.00 (0.00, 141.5)
9	0	3	3	0.00 (0.00, 112.6)
10	2	10	11	17.83 (2.16, 64.41)
11	0	4	5	0.00 (0.00, 67.30)
12	0	4	6	0.00 (0.00, 60.88)
13	0	1	2	0.00 (0.00, 168.2)
14	0	22	51	0.00 (0.00, 7.17)
15	0	1	0	0.00 (0.00, 8982)
16	0	3	3	0.00 (0.00, 108.9)
17	0	2	4	0.00 (0.00, 98.93)
18	0	2	5	0.00 (0.00, 75.40)
19	1	25	53	1.90 (0.05, 10.61)
20	0	1	0	0.00 (0.00, 2750)
21	1	15	11	9.04 (0.23, 50.36)
22	3	23	68	4.39 (0.91, 12.83)
23	0	1	1	0.00 (0.00, 344.6)
24	0	5	6	0.00 (0.00, 63.17)
25	0	2	5	0.00 (0.00, 75.10)
TOTAL	9	175	327	2.75 (1.26, 5.23)

TABLE 8

Revision Rates of Primary Total Resurfacing Hip Replacement by State

This enables a state by state variation to be identified for the Bionik/Bionik Total Resurfacing Hip Combination and provides the comparative data for each of the states for all Other Total Resurfacing Hip prostheses.

This analysis is undertaken for similar reasons as those outlined above for Table 7.

Table 8: Revision Rates of Primary Total Resurfacing Hip Replacement by State

Component	State	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Bionik/Bionik	NSW	7	118	225	3.12 (1.25, 6.42)
Bionik/Bionik	VIC	0	24	53	0.00 (0.00, 6.91)
Bionik/Bionik	QLD	0	2	7	0.00 (0.00, 52.96)
Bionik/Bionik	WA	0	21	16	0.00 (0.00, 23.13)
Bionik/Bionik	TAS	2	10	26	7.67 (0.93, 27.70)
Total Resurfacing Hip	NSW	180	3899	15823	1.14 (0.98, 1.32)
Total Resurfacing Hip	VIC	189	4747	21507	0.88 (0.76, 1.01)
Total Resurfacing Hip	QLD	80	2212	8156	0.98 (0.78, 1.22)
Total Resurfacing Hip	WA	16	370	1845	0.87 (0.50, 1.41)
Total Resurfacing Hip	SA	49	1268	5560	0.88 (0.65, 1.17)
Total Resurfacing Hip	TAS	9	83	279	3.22 (1.47, 6.12)
Total Resurfacing Hip	ACT/NT	16	553	1923	0.83 (0.48, 1.35)
TOTAL		**548**	**13307**	**55420**	**0.99 (0.91, 1.08)**

TABLE 9

Number of Revisions of Bionik/Bionik Primary Total Resurfacing Hip Replacement by Year of Implant

This analysis details the number of prostheses reported each year to the Registry for the Bionik/Bionik Total Resurfacing Hip Combination. It also provides the subsequent number of revisions of the primaries reported in that year.

Primary procedures performed in later years have had less follow up time therefore the number revised is expected to be less than the number revised in earlier years. For example, a primary procedure performed in 2009 has a maximum of one year to be revised, whereas a primary performed in 2007 has a maximum of three years to be revised.

Table 9: Number of Revisions of Bionik/Bionik Primary Total Resurfacing Hip Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2005	0	12
2006	3	33
2007	4	33
2008	0	43
2009	2	54
TOTAL	9	175

TABLE 10

Revision rates of Bionik/Bionik Primary Total Resurfacing Hip Replacement by Catalogue Number Range

Many prostheses have a number of catalogue ranges. The catalogue range is specific to particular design features; more than one catalogue range usually indicates a minor difference in design in a particular Bionik/Bionik prosthesis.

This analysis has been undertaken to determine if the revision rate varies according to the catalogue number range.

Table 10: Revision Rates of Bionik/Bionik Primary Total Resurfacing Hip Replacement by Catalogue Number Range

	Catalogue Range	Catalogue Description
Head		
Bionik	10260050-10260050	HIP RESURFACING CEMENTLESS SILVER
Bionik	10270042-10270058	HIP RESURFING CEMENTED SILVER
Bionik	10270238-10270258	CERAMIC HEAD HIP SURF. REPLACEMENT
Bionik	10280046-10280050	HIP RESURFACING CEMENTLESS SILVER
Bionik	10280142-10280156	HIP SURFACE REPLACEMENT CEMENTED BIOSURF SILVER
Bionik	10280642-10280654	HIP RESURFACING CEMENTLESS SILVER CAP-COAT
Bionik	10282038-10282058	FEMORAL HEAD SHELL BIOSURF CEMENTED
Acetabular		
Bionik	10201050-10201064	METAL SHELL BS TINB COAT
Bionik	10201150-10201164	METAL SHELL BS TINB COAT SCREW FIX
Bionik	10201248-10201264	METAL SHELL CEMENTLESS TINB COAT SCREW FIX
Bionik	10201346-10201366	METAL SHELL TINB CAP SCREW FIX

Head Range	Acetab Range	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
10260050-10260050	10201150-10201164	0	1	4	0.00 (0.00, 85.01)
10270042-10270058	10201150-10201164	0	6	23	0.00 (0.00, 15.72)
10270042-10270058	10201248-10201264	0	4	16	0.00 (0.00, 23.28)
10270042-10270058	10201346-10201366	2	11	36	5.51 (0.67, 19.90)
10270238-10270258	10201150-10201164	0	1	1	0.00 (0.00, 343.7)
10270238-10270258	10201248-10201264	0	1	1	0.00 (0.00, 471.1)
10270238-10270258	10201346-10201366	1	9	7	14.32 (0.36, 79.77)
10280046-10280050	10201050-10201064	0	1	4	0.00 (0.00, 83.69)
10280046-10280050	10201150-10201164	0	1	4	0.00 (0.00, 83.90)
10280142-10280156	10201050-10201064	0	1	3	0.00 (0.00, 107.4)
10280142-10280156	10201150-10201164	0	3	10	0.00 (0.00, 38.45)
10280142-10280156	10201248-10201264	0	10	22	0.00 (0.00, 16.80)
10280142-10280156	10201346-10201366	2	46	87	2.30 (0.28, 8.31)
10280642-10280654	10201050-10201064	0	2	7	0.00 (0.00, 50.24)
10280642-10280654	10201150-10201164	1	2	7	15.23 (0.39, 84.83)
10280642-10280654	10201248-10201264	0	3	8	0.00 (0.00, 46.30)
10280642-10280654	10201346-10201366	0	7	18	0.00 (0.00, 20.84)
10282038-10282058	10201150-10201164	1	3	6	15.58 (0.39, 86.82)
10282038-10282058	10201248-10201264	1	36	31	3.18 (0.08, 17.73)
10282038-10282058	10201346-10201366	1	27	30	3.34 (0.08, 18.58)
TOTAL		**9**	**175**	**327**	**2.75 (1.26, 5.23)**

[redacted]

29/10/2010 13:25

To [redacted]
cc [redacted]
bcc

Subject ESKA's reponse in regards to high revision rate product - BS Resurfacing Head

DOCUMENT NOT YET CLASSIFIED

Dear [redacted]

My apologies for not sending this email to you earlier due to the technical problem of my computer.

Please find attached my response to your questions and support clinical data for the Bionik Resurfacing System. As you can see from the first spreadsheet (type of complaints/revision), none of the reverse events occurred due to the failure of the product. The enclosed clinical data also show that the ESKA Bionik Resurfacing System has an excellent survival rate in the short-, mid- and long-term results.

Thank you for your assistance and should you have any further queries, please do not hesitate to contact [redacted]

Regards,
[redacted]

Regards,

[redacted]

ESKA AUSTRALIA

Suite 32A-B, 2-6 Chaplin Dr. Lane Cove NSW 2066 | Tel: [redacted] | Fax: [redacted]

Email: [redacted] | Web site: www.eskaaustralia.com.au

Attachment 1 -Hip joint surface replacement.pdf

Attachment 2 - Modular Approach in hip resurfacing with cemented and cement free prosthesis.pdf

Attachment 3 - Orientation of the femoral component in surface arthroplasty of the hip.pdf

Attachment 4 - Biomechanical investigations to determine primary stability of a new femur hip resurfacing system in THR.doc

Attachment 5 - The Onlay hip endoprosthesis - a controlled prospective study - mid term results.doc

Attachment 6 - The minimally invasive anterolateral approach combined with hip onlay resurfacing.pdf

Q1 Type of complaints & revision.xls Q2 Number of implants.xls Q3 Clinical Support.xls

Product	Type of Reverse	Number in Australia	Percentage in Australia	Number in World Wide	Percentage world wide	Reasons/Explanation
Bionik Resurfacing Head - Ceramic (10270238 - 10270258)						
	Surgeon revised the C-O-C hip resurfaing into a Total Hip Replacement	1	11.2%	0	0.0%	The patient fractured the neck of femur due to AVM. This wasn't a failure of the product.
Bionik Resurfacing Head - Metal (10270038 - 10270058, 10280138 - 10280158, 10280638 - 10280658, 10282038 - 10282058)						
	Surgeon revised the M-O-M hip resurfaing into Total Hip Replacements	8	88.8%	0	0.0%	We have 3 patients fractured the neck of femur (one felt down from the horse and one fell up from the ladder). 3 patients malposition of the cups. The femoral heads of the another 2 patients weren't varus position. Obiously they were either surgical errors that happened within the learing curve of the system or patient problems. Revision were not due to the failure of the products.

Product	Type of complaints	Number in Australia	Percentage in Australia	Number in World Wide	Percentage world wide	Regulatory action
Bionik Resurfacing Head - Metal (10260042)						
	Metalosis	0	0.0%	1	0.2%	n/a
Bionik Resurfacing Head - Ceramic (10270248)						
	Femoral Neck Fracture	1	1.8%	1	0.3%	n/a

Year	Product Name	# supplied in Australia	# supplied World Wide	# of complaints in Australia	# of complaints World Wide	# of Adverse Events in Australia	# of Adverse Events World Wide
2005	Bionik Resurfacing Femoral Head	12	455	0	0	0	0
2006	Bionik Resurfacing Femoral Head	34	432	0	0	3	0
2007	Bionik Resurfacing Femoral Head	33	374	0	0	4	0
2008	Bionik Resurfacing Femoral Head	47	404	0	1	0	0
2009	Bionik Resurfacing Femoral Head	55	308	0	1	2	0

Nr.	Author	Title	Design	Description	Aim	Population	Number of implants	Outcome Measures	Scores	Results
1	M. Rudert, L. Gerdesmeyer, H. Recht, P. Juhnke, R. Gradinger	Hip joint surface replacement	Comparative study	16 patients (average age 41 years) with exact indication were provided with 20 surface replacment prostheses (ESKA Bionik-system) between December 2003 and February 2005	To prove the new production techniques of metal-metal tribological pairing enable long-term prosthetic service life in hip surface replacement.	16	20	Simulated tests proved a significantly reduced abrasion in metal-on-metal bearings in comparison to metal-polyethylene tribological pring.	HHS	The ESKA-Bionik-system is implanted completely cement-free. Spongiosa Metal forms the contact to the pelvic bone as well as to the femoral neck. An insert consisting of forged metal is modularly inserted in the base and can be replaced in an exchange situation. This also enables the choice between an insert for large head articulation or PE or metal-on-metal with reduced head diameters. At an average follow-up period of 18 months, no infection or aseptic loosening was observed. The survival rate of the BS system is at appr. 90%.
2	J. Scholz, H. Wirth, R. Gradinger, W. Thomas	Modular approach in hip resurfacing with cemented and cement free prosthesis	Case Series	A prospective clinical study in multi centres were conducted by one single surgeon. 248 patients received the ESKA BS hip resurfacing replacement between February 2003 and January 2005.	A prospective clinical study on the ESKA-Bionik-System hip resurfacing replacement.	248	248	Study enrolments commenced February 2003 with total enrolments to January 2005 - 248 patients from 4 different centres.	HHS	248 patients received the hip resurfacing replacement by using ESKA-Bionik-System cemented or cement free prostheses. There were 7 revision cases. The short-term result was excellent.
3	P.E. Beaulé, J.L. Lee, M.J. Le Duff, H. C. Amstutz, E. Ebramzadeh	Orientation of the femoral component in surface arthroplasty of the hip	Randomised Control	In the clinic of the author 626 surgical procedures were performed between 1998 and 2003 using hip surface replacemnt in hybrid-technique. 94 cases have been examined in patients <40 years old which at least had been implanted for two years or had been explanted.	To find out the importance of the position of femoral component.	94	94	Measurements of the hip reconstruction were made on the anteroposterior pelvic radiograph. The correlation between the orientation of the femoral component and the outcome of the arthroplasty was evaluated, as were stresses within the resurfaced femoral head as a funciton of the orientation of the femoral component.	N/A	The study shows that the number of failure is related to a neck shaft angle ≤130°. The relative risk of an ealy problem is 6 times large than in cases where the neck shaft angle is<130°. This study also proved that the hip surface replacemnet is an effective solution in restoring the joint function in younger patients if an optimal positioning of the femoral component in valgus orientation is taken into account so that the load within the critical area is transferred to the femoral neck by the hip surface replacement.
4	L. Gerdesmeyer	Biomechanical investigations to determine primary stability of a new femur hip resufacing system in total hip replacemnt	Cadaver workshop	4 human cadavers were used to perform hip resurfacing on both sides. The onlay resurfacing system was used and all implants were fixed with specific bone cement.	The presented investigations were performed to analyze a new resurfacing concept regarding the primary stability.	4	8	To determine the primary stability increasing rotating forced was applied orthograde to the femoral neck until bone failure or implant loosening occurred.	Endpoint was defined as femoral neck fracture or implant loosening	Increasing rotation forces did not lead to implant loosening in one case. All subjects showed femoral neck fracture prior loosening in all cases. The mean rotation force at neck fracture was 59 Nm. The results were constant and reproducible. The new concept in hip resurfacing - onlay resurfacing, provides only marginal bone resection and hig primary stability.
5	L. Gerdesmeyer	The onlay hip endoprosthesis - a controlled prospective study - min term results	Comparative study	74 patients with primary osteoarthritis underwent hip onlay resurfacing. The onlay resurfacing system of ESKA Implants was used.	To evaluate the mid-term clinical and radiological results of the onlay resurfacing system when compared to the THA	74	74	In the group the HHS was recorded at 6 weeks, 6 month and 2 years after surgery.	HHS	In the onlay resurfacing group the HHS improved 6 weeks, 6 month and 2 years after surgery from 46 to 89, to 98 and 98. At 6 month and 2 years the SF12 score improved to normal. This result is much better than a THA. Only one neck fracture occurred in the Onlay resurfacing group. No implant failure occured. Blood loss was significant less after onlay resurfacing.
6	L. Gerdesmeyer, H. Gollwitzer, P. Diehl, B. Buttgereit, M. Rudert	The minimally invasive anterolateral approach combined with hip onlay resurfacing	Case Series	31 patients with osteoarthritis underwent onlay resurfacing via a minimally invasive approach.	The objective of the study is to examine the effecience of the hip onlay resurfacing approach.	31	31	To evaluate the clinical outcome the Harris Hip Score was used at follow-up. X-rays examinations 3,6 and 12 months aftersurgery were recorded.	HHS	The Harris Hip Score improved from 43.9 to 97 at 12 months after surgery. Adverse events such as fracture, dislocation, nerve or muscle lesions did not occurred, and clinically significant thromboembolism or infection was not observed.

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Hip Joint Surface Replacement

The endoprosthetic provision of hip joints is still one of the most successful orthopedic procedures. Longevity of implants of more than 90 % after 10 years is the rule for older patients [17]. If younger patients under the age of 55 years receive a hip prosthesis, the survival rate sinks to below 80 % after 10 years, according to the Swedish Endoprosthetic Register. However, higher longevity in younger patients with conventional hip endoprostheses has been described. One possible cause under discussion for an early failure is, among others, high activity in younger patients. Of further significance is the longer life expectancy of the younger patient, during which loosening may occur. So it seems expedient to develop joint replacement with as little destruction of the patient's bone as possible, relieving later exchange surgery. The logical consequence was the development of a form of surface replacement also known as Hip Resurfacing in Anglo-American areas.

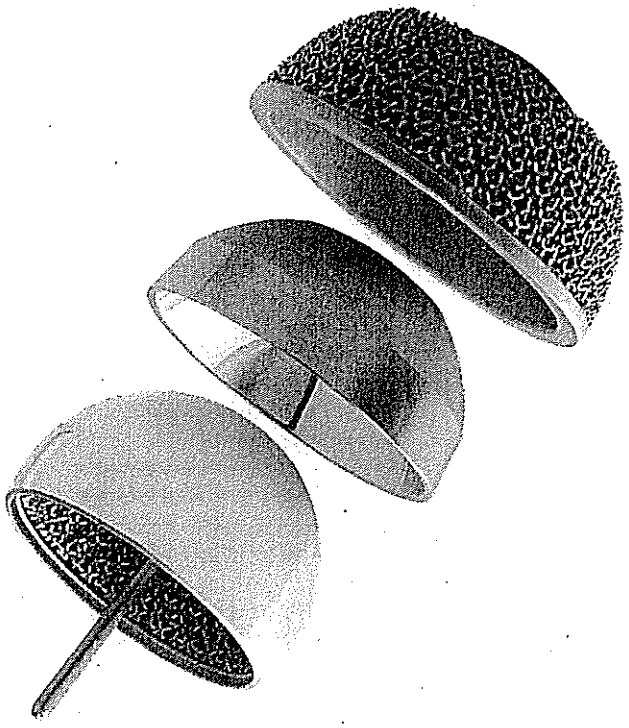
Historical Development

The concept of a hip joint replacement in form of surface replacement is not a novelty. An initial form of surface replacement was introduced by Chamley in the 1950s. He used Teflon shells, which featured early abrasion and proved useless [4]. In the mid-70s, Wagner began implanting surface replacements named after him. These consisted of metal or ceramics for the femur and polyethylene (PE) for the hip cup [31]. This form of joint replacement was often applied in Europe due to promising early results. However, high loosening rates were determined at a later stage, which lead to extensive failure and disrepute of this type of joint surface replacement. During a damage analysis of a total of 124 Wagner dual cups implanted at our clinic between 1977 and 1984, Rechl et al [24] were able to clinically and radiologically re-examine 85 % of the patients. At an average post-examination time of 107 months, 104 dual cups revealed loosening in a total of 53 cases. The thin-walled polyethylene cup was more often affected than the femoral components. The cup deformed under load and therefore lead to increased abrasion in connection with the large articulation area. This was made responsible for partly very large defects in the cup area, which required special revision implants and bone transplants. Strong abrasion also partly created granulation tissue, which lead from osteolysis to connective tissue restructuring of the entire femoral head. Although these loosening procedures were part of a multifactorial problem, the unfavorable material properties came to the fore. At the same time, Salzer [25] used cementless implanted ceramics-ceramics tribological pairing, which however was also abandoned at an early stage due to high loosening rates.

Only a few centers continued working on the development of surface replacement. Amstutz later implanted modular systems consisting of a metal head and a metal cup with a thin intermediate polyethylene layer. A Renaissance in surface replacement at the hip joint was created after the renewed introduction of metal-metal tribological pairing with better production techniques. Forged or cast components consisting of chrome-cobalt alloys with high carbide contents featured excellent abrasion properties [22, 33]. Prosthetic systems based on this technology were developed by Wagner [32] in Germany, Amstutz [26] in the US and McMinn [18] in England in the early 1990s.. Only a few of these models were implanted, whereby the design and anchoring technology changed constantly, as early loosening was still frequently observed. A hybrid fixation system with cementless cup and cemented femoral components in combination with the above-mentioned metal-metal tribological pairing finally asserted itself at the start of the new millennium.

Current state of development

These days, practically all large prosthetics manufacturers are providing a system for the so-called hip joint surface replacement. Common to all is metal-metal tribological pairing with high carbide contents, cementless fixation of the cup and usually cemented fixation of the femoral components. Variations do however exist, which not only determine the tribological properties.



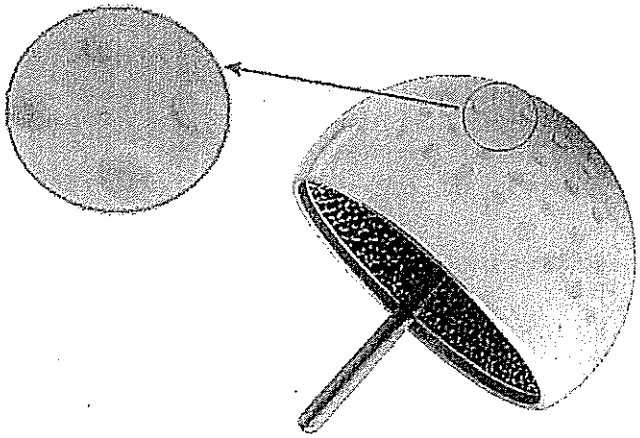


Fig. 2 Femoral resurfacing. The enlargement displays the indentations serving as reservoirs for the lubrication liquid

Fig. 1 Modular surface replacement for the hip joint with cementless anchoring and exchangeable metal insert (CL-Resurfacing „BS", CL-Metal Shell „BS", metal insert; *CL:* cementless, *BS:* Bionic System; Firma ESKA-Implants, Lübeck)

Simulated tests proved a significantly reduced abrasion in metal-on-metal bearings with <0,3 mm^3/year after the run-in period in comparison to metal-polyethylene tribological pairing with an abrasion of 30–100 mm^3/year [27]. Abrasion in metal-on-metal bearings is reduced after a certain run-in period. The same is said to apply for the situation in which the femoral component is replaced, while the cup remains in situ. Whether this poses a problem in the combination of „run-in" cups and new large ball heads is currently unknown. It has to be assumed that the combination of a new head and a run-in cup results in altered clearance, which in turn influences the lubricating film between the joint components. Individual manufacturers therefore supply the cup components with metal inserts, which enable the later replacement of articulated areas with completely new components (Fig. 1).

The role of the particles' size and morphology is unclear to date. Plitz [8, 23] assumes that although a reduced particle volume is created when compared to metal-PE tribological pairings, the reduced size of the particles creates a higher total of abrasion particles.

Already in the 1970s, increased serum concentration of metal-ion (chrome and cobalt) was proven in metal-on-metal bearings [5]. Further increases of ion concentrations in serum and urine were not discernable in surface replacements with large-diameter articulated components in comparison to conventional hip joint replacement with metal-on-metal bearings [14].

As chrome and cobalt compounds are eliminated in the kidney through glomerular filtration, patients with kidney disease should be excluded from these tribological pairings. The same applies to patients with evident metal allergies. However, verifiable data does not exist for either the increased concentration of metal compounds themselves nor for the presence of allergic reactions to these. A clear recommendation in this regard requires further observations. The same applies for the implant of metal-on-metal bearings in childbearing age. Although Brodner [3] was able to prove increased concentrations of metal compounds in the peripheral blood of pregnant women with this tribological pairing, an increased concentration in cord blood was not ascertained. It is also unclear, whether the increased metal concentrations could in time result in, for example, hypersensitivity and whether there is increased a danger of secondary degeneration development.

Wear depends on the macro-geometry (component size, fit), the micro-geometry (surface) and the lubrication between the components. The larger the components with the same other parameters, the less the abrasion.

[9, 29]. However, it would not be correct to say that larger component diameters also lead to larger range of motion dimensions. The dimension of movement is decisively formed by the ratio between the femoral head and neck diameter [2]. Nevertheless, the large femoral components clearly reduce the joint's luxation tendencies. The use of large components is said to lead to kinematics more similar to that of a healthy hip joint when compared to conventional joint replacement [20]. The authors of the trial do however concede that the results may have been influenced by a certain bias in patient selection.

Increased lubrication of components through a liquid film would benefit from large components with

as smooth a surface as possible [30].
Another method is surface modification with specific indentations, which serve as liquid reservoirs in the joint gap to keep the volume of lubrication film constant, therefore reducing abrasion to a minimum.
(→ Fig. 2).

The larger the femoral components the more extensive the bone loss will be during implantation of the matching cup. This situation seems logical. It also applies in comparison to conventional total hip replacements [16].

A large difference is currently ascertained in the fixation of the individual components and their surfaces. Implants with plasma-sprayed surfaces, chrome-cobalt beads and three-dimensional mesh spongy metal surfaces are currently predominant. So far no screws have been applied in anchoring as the cups, with the exception of those manufactured by ESKA, are not modular systems and holes for screw heads in the surface of the sensitive slide face would result in increased abrasion. Whether surface processing would influence long-term abrasion properties of the articulated areas remains to be seen. The same applies to the varying clearance or leeway between the components. A certain degree of clearance is required to permit a constant lubrication film between the bearing components. Modern production technologies ensure a reproducible clearance, which is measurable and within micrometer range for surface replacement. Implantation of thin-walled cups can however cause changes to this clearance and therefore to abrasion. The component abrasion tested in the simulator must therefore be considered as the ideal case.

On the femoral side, the approach to the hip joint, the preparation of the femoral head and anchoring play a specific role. With regard to blood circulation of the femoral head, the access to

Abstract

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Hip Joint Surface Replacement

Summary
Modern surface replacement is regarded as an attractive procedure for the replacement of a degenerative altered hip joint, specifically in young patients. The high expectations placed in this form of joint replacement are yet to be fulfilled. Earlier implants with similar forms of surface replacement have lead to high revision rates through early aseptic loosening in connection with a high degree of material abrasion and femoral neck fractures. These days, new production techniques of metal-metal tribological pairing enable the use of surface replacement with minimum abrasion, which in turn theoretically enables long-term prosthetic service life. Long-term results from the new generation of surface replacement is still outstanding. Femoral neck fractures and femoroacetabular impingement proved to be possible early complications. The implantation of these systems is technically demanding and requires a high degree of experience from the surgeon. Access-related traumatizing of muscles and hazards to the blood vessel supply of the femoral head face the positive effect of retaining femoral head bone substance and improved revision options in case of failure. The future will tell us if the young patient in particular will benefit from surface replacement despite his increased activity.

Key words
Hip arthritis - Endoprosthesis – Resurfacing arthoplasty – Metal-on-metal bearing

Resurfacing arthroplasty of the hip

Abstract
Resurfacing arthroplasty is regarded as an at- tractive method, especially for the young pa- tient who needs a hip replacement. Howev- er, the high expectations regarding this new technique in THR must first be met. Earlier experiences with similar forms of surface replacement have led to high revision rates with early aseptic wear induced component loosening and neck fractures. Technical pro- gresses in production techniques for metal- on-metal articulations with minimized wear have enabled the introduction of new surface replacements for the hip joint. Long-term results of these resurfacing arthroplasties are still due. Femoral neck fractures and femoro- acetabular impingement are possible early complications which require revision. The implantation of these systems requires a high degree of operative skill and experience on the part of the surgeon. Approach dependent trauma to the musculature and endanger- ing of the blood supply to the femoral head is balanced with the positive effect of the pres- ervation of femoral bone stock and better op- tions in case of revision. Whether the younger patient with a higher activity profile and an increased chance of implant loosening actu- ally profits from the resurfacing arthroplasty will be determined in the future.

Keywords
Hip arthritis · Endoprosthesis · Resurfacing arthroplasty · Metal-on-metal bearing

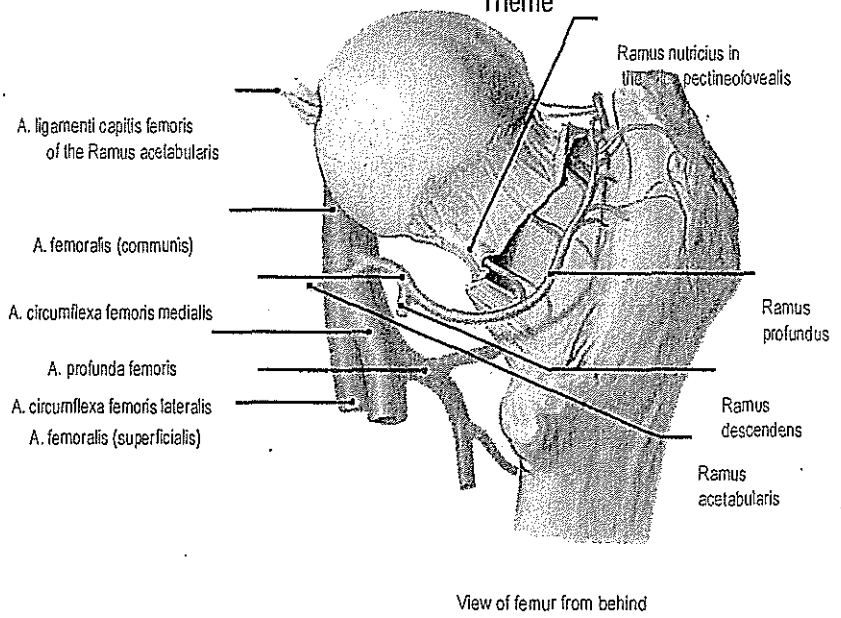

Fig. 3: Anatomical display of the dorso-lateral region of a right femur with R. profundus and the distribution of the Rr. nutritii, with clearly recognisable arcade formation. (Modified according to Tillmann (2005) Atlas of Human Anatomy. Springer, Heidelberg)

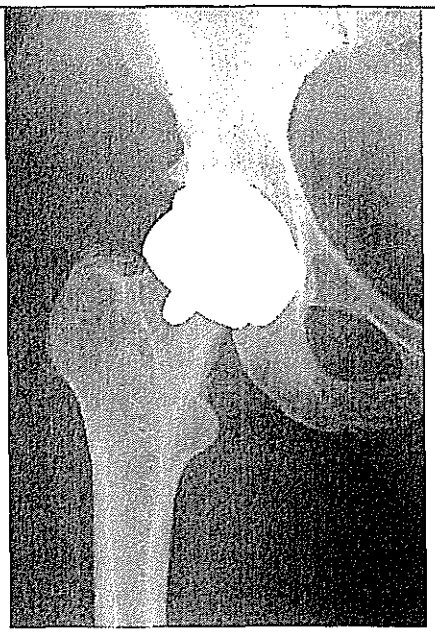

Fig. 5: X-ray of conventional surface replacement in cementless anchoring technique.

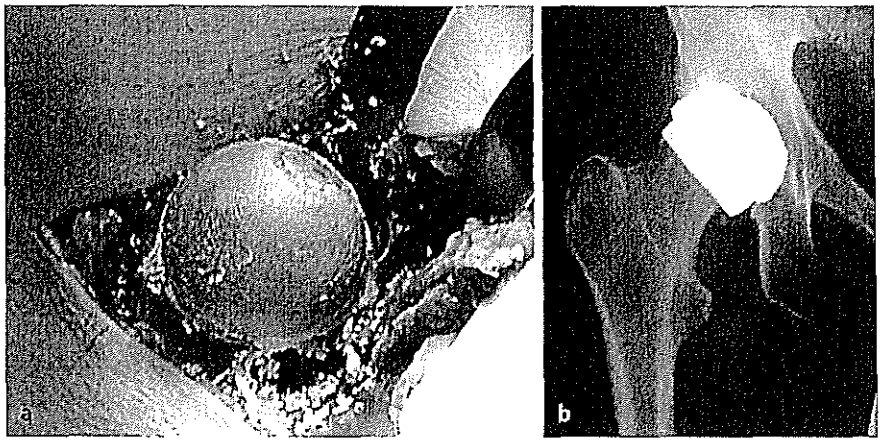

Fig. 4a Femoral head, where only the cartiledge surface was removed, with the exception of the corticalis, to achieve as physiological a force as possible, over a cemented cap. b X-ray of surface replacement implanted in the right hip joint with the technique described under Fig. 4a. The cementlessl anchored cup, the resurfacing fixed with low-viscosity cement
(Femoral Head Shell Onlay)

hip is of particular interest. Compromization of the blood circulation the femoral head can be assumed in case of destruction of the Ramus profundus of the A. circumflexa femoris medialis (Fig. 3). This branch is particularly threatened during the frequently used posterior approach, as it runs along the base area of the external hip rotators [10]. It lies beneath the ligament of the M. obturator externus. We therefore prefer the antero-lateral approach to the femoral joint, even if this occasionally complicates the exposition of the femoral neck. When compared to conventional endoprosthetic hip replacement, an extended solution of fibrous tissue is required to sufficiently display the acetabulum. otherwise the implantation path is covered and constricted too much by the retaining femoral head.

The preparation of the femoral head should preferably allow alignment of the resurfacingp to the centre of the femoral neck. If this is not observed, the hip's range of motion dimensions are often restricted even further than is the case by the unfavorable relation between femoral neck and head diameter. One example would be the Coxa vara epiphysarea, which is accompanied with an eccentric position of the femoral head on the femoral neck. It this disproportion is maintained during implantation, . postoperative femoroacetabular impingement may occur more frequently, and in turn requires early revision. However, if a concentric abrasion does occur in physiological joint position, we currently see an indication for a newly developed surface replacement, in which only the femoral cartilage is reduced up to the corticalis, on which in turn a cap without stem is cemented. Femoral fixation is then usually performed with low-viscosity cement. The discussion on viscosity and thickness of the cement mantle is controversial. The excessive penetration of the cement in the trabecula may lead to bone necrosis in this area. . Stress shielding can also play a role here and osteolysis and consecutive fracturing of the femoral neck may be caused in connection with a short stem participating in femoral force. Therefore femoral neck fractures and impingement are currently responsible for early implantation-associated complications.

Results

From among our own patient material, 16 patients (average age 41 years) with exact indication were provided with 20 surface replacement prostheses (ESKA-Bionik-System) between December 2003 and February 2005. Compared to implants from other manufacturers, the system is implanted completely cement-free. Spongiosa Metal forms the contact to the pelvic bone as well as to the femoral neck. An insert consisting of forged metal is modularly inserted in the base and can be replaced in an exchange situation. This also enables the choice between an insert for large head articulation and an insert for standard articulation or polyethylene or metal-on-metal with reduced head diameters. At an average follow-up period of 18 months, no infection or aseptic loosening was observed in our patient material. On average, the Harris-Hip Score rose from 52 preoperative points to 92 postoperative points. One femoral neck fracture and one cup dislocation were recorded during the observation period. This placed the revision rate for our first surface replacement systems at approximately 10 % [15].

Literature specifies revision rates between 2 and 17 % [15]. Shimmin et al. [28] reported on 3497 Birmingham cups at an average post-examination period of 36 months via the National Australian Prosthesis Register.

. whereby 50 femoral neck fractures, 12 cases of aseptic cup loosening, 4 cases of femoral resurfacing loosening and 2 infections occurred. In total, the revision rate was 2 %. Witzleb reported on satisfactory results after 420 surface replacements (Birmingham Hip and Durom Cup). 238 patients were re-examined after an average of 2 years. The revision rate was 2.2 %. Patients provided with a dysplasia cup displayed as good an examples as those who received a standard cup.

Amstutz et al. [1] published the results of 400 hybrid surface replacements („Conserve Plus") in 355 patients with an average age of 48 after an average follow-up period of 3.5 years. After 4 years, 94.4 % remained without exchange surgery. The average Harris-Hip-Score was 93.5 points. 12 hips were replaced with conventional total hip prostheses. 3 patients displayed hip luxation. Heterotopic ossification (Brooker III-IV) occurred in 10 % of cases.

Gregoris [11] reported on 200 consecutive surface replacements (Durom System) with good results. The average age of the patients was 48 years, the post-examination period was 2.2 years. No luxation, infections or loosening occurred. Similarly good results were published by De Smet [7] on 200 patients, who had received Birmingham Hip Resurfacing. Only one femoral neck fracture was recorded at an average time of 1.1 years after implantation. The best results were reported by Daniel et al [6], who provided 446 patients below the age of 55 with Birmingham Hip Resurfacing. The average follow-up period was 3.3 years. Follow-up was conducted on the telephone and via questionnaires. Clinical or radiological controls were not conducted.

Table 1 * correctly translated on last page due to formatting problems

Vorteile	Nachteile
Knochensparende Technik am Femur	Leicht erhöhter Knochenverlust am Azetabulum
Geringere Luxationshäufigkeit	Gefahr der Schenkelhalsfraktur
Better revision options on the femur	Fehlende Langzeitergebnisse und Erfahrungen mit Revisionen
Joint replacement also possible in sub-capital or dia-	Metallabrieb und Metallionen im Organismus
Rare differences in leg length	Keine Rekonstruktion des Offsets

Conclusions

The early and medium-term results of modern surface replacements give rise to the hope that long-term results are equally positive. The clinical results are currently not comparable with those of conventional hip joint replacement. In comparison, the complication rate is also increased. From our point of view the primary causes for failure are femoral neck fractures and aseptic loosening of the femoral components as well femoroacetabular impingement. A critical aspect here is the correct positioning of the cup and the correct alignment of the cap to the femoral neck or the deformity of femoral neck and femoral head. An extremely exact indication and very presice surgical technique is required to ensure the implant's success. Advantages and disadvantages of surface replacement are displayed in

- Table in the form of an overview.

Early failure may be caused by the implantation technique, which may lead to micro-fractures with later pseudo-arthrosis under the femoral implant in the femoral neck [21]. A further risk factor for the femoral neck fracture is undersizing of the femoral resurfacing. This leads to notching of the femoral neck and therefore to a predetermined breaking point with questionable long-term results. Mont [19] therefore recommends implantation of the surface replacement with specially trained surgeons only. As a possible tool to shorten the learning curve, navigation could play a larger role in future.

The large diameter of the femoral neck presents an unfavourable relationship in the head-to-neck diameter. This causes a reduction in range of motion dimensions [2]. If the femoral neck impinges against the cup or the marginal bone, it will not only cause pain to the patient but also sub-luxation phenomena of the cap in the cup. These can be so pronounced as to require replacement of the femoral components.

The new generations of metal-on-metal bearings with large

diameter display excellent abrasion properties. However, these abrasive properties only come into effect if the components were optimally implanted and edge load does not occur, which could increase abrasion up to 500-fold [21]. The larger the head diameter, the larger the cup diameter [16] will be, something which opposed the objective of as bone-saving an operation as possible. If surgery is required due to failure on the femoral side, the cup will naturally not be exchanged, especially in the case of large dimensions. Most hip surface replacement systems display a monoblock cup, whose surface cannot be replaced, for example, on account of increased abrasion. Although simulator trials proved this to be relatively unproblematic [12], it is said to increase ion concentration indirectly indicating increased abrasion. We therefore prefer a modular system which, in the case of revision, enables the provision of a new inlay for the cup.

Practical conclusion

Hip joint surface replacement remains an attractive alternative to the very successful standard endoprosthetics. Increasing experience and information on error mechanisms playing a role in these systems will help to optimize the implants and to improve implantation techniques.

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Table 1

ESKA IMPLANTS

Title: **Modular Approach in hip resurfacing with cemented and cement free prosthesis**

Author: **Scholz J, Wirth H, Gradinger R, Thomas W**

Source: **Study Group ESKA Hip Resurfacing**

Data summary

Methods: Multi centre single surgeon prospective clinical study

Study enrolments commenced February 2003 with total enrolments to 31/1/06 – 248 patients

Implants are the:

- Metal Shell, cement less "BS"
- Modular liner Metal Insert silver "BS"
- Resurfacing component Hip Surface Replacement "BS" either applied cemented or cement less (spongiosa).

All components are manufactured by:

ESKA Implants, Lübeck, Germany.

Reference Centers enrolled in the Clinical Study

(1) Prof. Scholz, Zentralklinikum Emil von Behring, Berlin, Germany

(2) Prof. Wirth, Annastift, Hannover, Germany

(3) Prof. Gradinger, Klinikum rechts der Isar, München, Germany

(4) Prof. Thomas, Clinica Quisisana, Rome, Italy

Centre	Enrolled patients	Complications	Number of revisions	Remarks
(1)	130	3 femoral neck fractures	3	Complication occurred during initial period of learning curve
(2)	78	6	1	1 Loosening of femoral component 5 no sufficient bone stock for resurfacing – intraoperative change
(3)	20	2	2	1 Femoral neck fracture 1 Migration of shell
(4)	20		1	Revision case was made endoprosthesis with custom special surface coating.

Note: Data as per Jan 31st, 2006

Title: Orientation of the Femoral Component in Surface Arthroplasty of the Hip

Authors: P. E. Beaulé, J. L. Lee, M. J. Le Duff, H. C. Amstutz, E. Ebramzadeh

Source: The Journal of Bone & Joint Surgery, Volume 86-A, Number 9, September 2004

Background: Although the orientation of the femoral component has been shown to influence the outcome of total hip replacement, its effect on the clinical outcome of surface arthroplasty has not been studied, to our knowledge. The purpose of this study was to examine the relationship between femoral component positioning and the outcome of a surface arthroplasty of the hip.

Methods: We reviewed the results of ninety four hybrid metal on metal surface arthroplasties in patients who were forty years old or younger at the time of the operation and were followed for a minimum of two years or until the prosthesis failed. Measurements of the hip reconstruction were made on the anteroposterior pelvic radiograph. The correlation between the orientation of the femoral component and the outcome of the arthroplasty was evaluated, as were stresses within the resurfaced femoral head as a function of the orientation of the femoral component.

Results: The mean duration of follow-up was 4.2 years. Thirteen hips had an adverse outcome, defined as conversion to a total hip replacement, radiolucency of >1 mm in thickness adjacent to the femoral stem, or narrowing of the femoral neck of >10%. The mean femoral stem-shaft angle in the coronal plane was 138°, with the hips that had an adverse outcome having a significantly lower mean angle than the rest of the cohort (133° compared with 139°, $p = 0.03$). Hips with an angle of ≤130° had an increase in the relative risk of an adverse outcome by a factor of 6.1 ($p < 0.004$). In the entire cohort, stresses in the superior aspect of the resurfaced femoral head were substantially lower during slow walking than they were during fast walking (7.1 N/mm² compared with 14.2 N/mm²).

Conclusions: Optimizing the femoral stem-shaft angle toward a valgus orientation during the preparation of the femoral head is important when a hip is being reconstructed with a surface arthroplasty because the resurfaced hip transmits the load through a narrow critical zone in the femoral head-neck region and the valgus angulation may reduce these stresses.

Literatur

Early results of hip surface replacement using metal-on-PE as bearing option has not been sufficient because of high failure rates.
Now, interest is awakened again due to the advantages of modern metal-on-metal bearing options as alternate bearing option in conventional hip arthroplasty. Metal-on-metal shows significant advantages in wear behaviour, but other failures like osteonecrosis or fractures of the femoral head are of greater importance.

In the clinic of the author 626 surgical procedures have been performed between 1996 and 2003 using hip surface replacement in hybrid-technique (cemented hip surface replacement and cementlessly implanted acetabular component).

94 cases have been examined in patients <40 years old which at least hade been implanted for two years or had been explanted. Posterior approach was chosen except for two cases. It was aim of this study to find how position of femoral component and the result are correlated.

ESKA IMPLANTS

As a result the author summarizes that **the number of failure is related to a neck shaft angle ≤130°. The relative risk of an early problem is 6 time as large than in cases where the neck shaft angle is >130°.** Illustrations of forces involved, lever arms and calculation schemes are rendered by the authors.

This study shows that the positioning of the femoral component is of same importance as it is in conventional HTEP.
The positioning of surface replacement is of major importance because the anchorage surface is smaller.

Freeman, Jolley and Amstutz are quoted who recommend a rather valgus positioning with respect to the neck shaft angle.

The author finds hip surface replacement an effective solution in restoring the joint function in younger patients if an optimal positioning of the femoral component in valgus orientation is taken into account so that the load within the critical area is transferred to the femoral neck by the hip surface replacement.

Literatur

ESKA IMPLANTS

Title: Biomechanical investigations to determine primary stability of a new femur hip resurfacing system in total hip replacement.

Introduction: Femur hip resurfacing systems are more frequently used in total hip replacement. Some systems are based on different fixation techniques as well as different designs. The presented investigations were performed to analyze a new resurfacing concept regarding the primary stability.

Methods: 4 fresh human cadavers were used to perform hip resurfacing on both sites. The onlay resurfacing system we used was provided by ESKA implants (Lübeck/Germany). All implants were fixed with specific bone cement. After surgery the proximal femur were resected and fixed into the biomechanical testing system. To determine the primary stability increasing rotating forced was applied orthograde to the femoral neck until bone failure or implant loosening occurred. Endpoint was defined as femoral neck fracture or implant loosening.

Results: Increasing rotation forces did not lead to implant loosening in one case. All subjects showed femoral neck fracture prior loosening in all cases. The mean rotation force at neck fracture was 59 Nm. The results were constant and reproducible.

Conclusion: The new concept in hip resurfacing provides only marginal bone resection and high primary stability. A specific designed implant and implantation technique as well as the used bone cement characterized by a specific viscosity leads to a very high primary stability. Combined with minimal invasive surgery patients will be able to shorten the rehab phase significantly. Side effects as luxation, instability, length differences were expected to appear less frequently.

Title: The Onlay hip endoprosthesis – a controlled prospective study – mid term results.

Introduction:
Recently used hip resurfacing systems remove bone and reduce biomechanical properties of the femoral neck and ignore the individual joint congruency and position. As much bone was removed from the head as much the biomechanical properties decrease. The Onlay Resurfacing technique preserves complete bone stock and individual anatomy without any change in Offset or leg length.

Methods:
74 patients with primary osteoarthritis underwent hip onlay resurfacing. Men aged 51 yr, BMI 26.6. The onlay resurfacing system of ESKA implants (Lübeck/Germany) was used. The femoral component was cemented. All Onlay prosthesis have the Biosurf structure which provide less metal wear. A modular acetabular cementless component was used. The control group (n:74) got a standard cementless THA. All procedures were performed by one surgeon, minimal invasive approach was used, same post Op treatment in both groups.

Results:
In the Onlay Resurfacing group the HHS improved 6 weeks, 6 month and 2 years after surgery from 46 to 89, to 98 and 98. At 6 month and 2 years the SF12 score (mental and physical) improved to normal.
At 6 weeks, 6 month and 2 years the standard THA showed improvement in the HHS from 42 to 85, to 92 and 93. The SF12 showed normal level 2 years after Surgery. One neck fracture occurred in the Onlay resurfacing group, one DVT in the standard group. No implant failure in both groups. Blood loss was significant less after Onlay Resurfacing.

Conclusion:
The new concept in hip resurfacing provides only marginal bone resection and excellent early functional outcome. The outcome was better in the Onlay group compared to standard THA. Combined with minimal invasive surgery patients will be able to shorten the rehab phase significantly. Side effects as luxation, instability, length differences were expected to appear less frequently.

The Minimally Invasive Anterolateral Approach Combined with Hip Onlay Resurfacing

Ludger Gerdesmeyer[1,2], Hans Gollwitzer[2], Peter Diehl[3], Björn Buttgereit[4], Maximilian Rudert[1]

Abstract

Objective

Minimally invasive anterolateral approach in hip resurfacing with complete preservation of muscular integrity.

Indications

Primary or secondary osteoarthritis of the hip.

Contraindications

Approach:
- None.

Onlay implant:
- Females > 55 years with osteoporosis.
- Males > 60 years with osteoporosis.
- Severe varus deformity (CCD [collodiaphyseal] angle < 100°).
- History of metal allergy.
- Clinically relevant renal insufficiency.
- Radiologic appearance of avascular necrosis stage 3 and 4 according to Ficat.
- Femoral head cysts > 1 cm in diameter.

Surgical Technique

Supine position with possible overextension of the hip, longitudinal incision along the intermuscular septum and blunt intermuscular dissection between gluteus medius and tensor fasciae latae, partial resection of the anterior capsule and anterior dislocation of the hip with complete proximal release of the capsule. Dislocation of the femoral head and dorsal positioning, reaming of the acetabulum to implant the cementless acetabular component, exposition and reaming of the femoral head in extension/adduction and external rotation, implantation of the cemented onlay endoprosthesis.

Postoperative Management

Prophylaxis of thromboembolism and periarticular ossification. Rehabilitation with weight bearing as tolerated starting on the day of surgery, ergometer training from day 4 after surgery.

Results

31 patients with osteoarthritis underwent onlay resurfacing via a minimally invasive approach. The Harris Hip Score improved from 43.9 to 97.1 at 12 months after surgery. Adverse events such as fracture, dislocation, nerve or muscle lesions did not occur, and clinically significant thromboembolism or infection was not observed.

Key Words

Minimally invasive · Hip · Approach · Onlay · Prosthesis · Osteoarthritis · Resurfacing

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Der minimalinvasive anterolaterale Zugang zur Implantation einer Hüftoberflächenprothese

Zusammenfassung

Operationsziel

Implantation einer Hüftonlay-Femurkappenendoprothese über einen minimalinvasiven anterolateralen Zugang mit komplettem Erhalt der muskulären Integrität.

Indikationen

Primäre und sekundäre Koxarthrose.

Kontraindikationen

Zugang:
- Keine.

Onlay-Femurkappenendoprothese:
- Frauen > 55 Jahre mit Osteoporose.
- Männer > 60 Jahre mit Osteoporose.
- Schwere Coxa vara (CCD-[Centrum-Collum-Diaphysen-] Winkel < 100°).
- Metallallergie.
- Klinisch relevante Niereninsuffizienz.
- Hüftkopfnekrose Stadium 3 und 4 nach Ficat.
- Femurkopfzysten > 1 cm im Durchmesser.

Operationstechnik

Rückenlagerung mit der Möglichkeit, durch Aufklappen des Operationstischs das Hüftgelenk zu extendieren, gerader Hautschnitt entlang dem Septum intermusculare und stumpfe digitale Präparation der Muskellücke zwischen Musculus gluteus medius und Musculus tensor fasciae latae, partielle Resektion der vorderen Gelenkkapsel, Luxation des Femurkopfes nach ventral und komplettes Kapselrelease am Azetabulum. Luxation des Kopfes in die dorsale Luxationsstellung, Fräsen des Azetabulums für die zementlose Implantation der modularen azetabulären Komponente. In Extension/Adduktion und Außenrotation Darstellung des Femurkopfes und Formfräsen des Kopfes, Implantation der zementierten femoralen Komponente.

Weiterbehandlung

Prophylaxe einer Thrombose und periartikulärer Ossifikationen. Beginn der Mobilisation am Operationstag mit schmerzadaptierter Belastung, Ergometertraining ab dem 4. postoperativen Tag.

Ergebnisse

31 Patienten mit einer Koxarthrose wurden über einen minimalinvasiven anterolateralen Zugang mit einer Hüftonlay-Femurkappenendoprothese versorgt. Der Harris-Hip-Score verbesserte sich 12 Monate postoperativ von 43,9 auf 97,1 Punkte. Es traten weder Komplikationen wie Fraktur, Luxation, Nerven- oder Muskelschäden noch Thrombosen oder Infekte auf.

Schlüsselwörter
Minimalinvasiv · Hüfte · Zugang · Onlay · Prothese · Arthrose · Oberflächenersatz

Introductory Remarks

Resurfacing in total hip arthroplasty experiences a revival in modern orthopedics and becomes more and more popular. The concept itself has first been established in the 1980s [7]. Wagner described a bone-preserving technique already in the mid 1970s, which is still well known as the Wagner cup arthroplasty [8]. The approach was excellent, but poor tribological properties and failures of the polyethylene (PE) used as monoblock acetabular component resulted in a high early failure rate. Furthermore, small cement particles were generated due to significant deformation of the very thin PE acetabular components during weight bearing, and these cement particles initiated third body wear and consecutive failure [3, 4]. Improved technical knowledge and usage of advanced materials with better tribological properties have significantly increased survival rates and initiated a revival of hip resurfacing. All current implants used for resurfacing commonly require substantial bone resection at the femoral head, with loss of subchondral sclerotic bone [1, 2, 7]. Resection of subchondral bone – which shows the best biomechanical properties – is contradictory to the original concept of resurfacing. By contrast, the onlay resurfacing technique avoids bone resection, enables improved biomechanical properties, more anatomic relations of the femoral head, and an improved head/neck ratio. With the Biosurf surface topography of the femoral implant, a significant reduction of wear and metal debris can be achieved as well. High modularity of the components guarantees better options in the case of revision. However, complete preservation of the femoral head is automatically followed by a minimized intraoperative situs. An appropriate surgical approach is therefore mandatory. By using guidance systems such as Kirschner wires or templates, the approach has to be increased in size. Therefore, the dorsal approach has been used most frequently, which is associated with a high risk of avascular

necrosis as a result of cutting the perfusing vessels of the medial femoral circumflex artery [1, 7]. On the other hand, if the standard anterolateral approach, first described by Watson Jones, is used, the preserved femoral head prevents adequate exposure and preparation of the acetabulum and correct insertion of the acetabular component [5]. Suboptimal placement is often due to increased anteversion and inclination, leading to a significant increase of metal wear [6]. To prevent these approach-related side effects, we have developed a modified anterolateral approach to be described in this study. This new approach is characterized by excellent exposure of femoral head and acetabulum, prevention of avascular necrosis caused by vessel damages and complete preservation of bone and muscle, which makes fast-track rehabilitation feasible.

Surgical Principles and Objective

Resurfacing of the femoral head by using a modified anterolateral approach with minimally invasive surgical technique. Excellent exposure of the acetabulum and femoral head with complete preservation of surrounding muscles. Resurfacing without bone resection, but with reconstruction of the individual anatomic structures and relations.

Advantages

- Surgery is possible in supine position.
- Excellent exposure of the acetabulum und femoral head.
- No guidance system (Kirschner wire, navigation, X-ray) required.
- Protection and preservation of muscle insertions to the femur.
- Preservation of the anatomic head/neck ratio.
- Extension of surgical approach easy to perform.
- Preservation of the individual anatomy.

Disadvantages

- Extensive soft-tissue preparation.
- High learning curve compared to standard approach.
- No long-term follow-up data.
- Extended duration of surgery.
- Technically demanding in muscular patients.

Indications

- Primary and secondary osteoarthritis of the hip.

Contraindications

Modified Approach

- Obesity 3° according to the WHO classification..
- Previous surgery via anterolateral approach.

Onlay Resurfacing

- Females > 55 years with osteoporosis proven by bone mass measurement.
- Males > 60 years with osteoporosis proven by bone mass measurement.
- Severe varus deformity (CCD [collodiaphyseal] angle < 100°).
- Severe coxa vara epiphysaria so that roundness cannot be restored by reaming the head and the femoral component is seated without full bony contact.
- History of metal allergy.
- Clinically relevant renal insufficiency because of increased metal ion concentration due to wear.
- Avascular necrosis of the femoral head stage 3 and 4 (Ficat).
- Femoral cyst > 1 cm in diameter.

Patient Information

- General surgical risks, e.g., thromboembolism, infection, bleeding, delayed/complicated wound healing, dislocation, nerve lesions.
- Loosening of the implants.
- Implant without long-term follow-up data.
- Ectopic ossifications.
- Intraoperative change of the surgical strategy to another implant, if indicated.
- Metal wear.
- Induction of metal allergy possible.
- Fracture of femoral neck.
- Painful hematoma.

Preoperative Work Up

- Physiotherapy to improve range of motion and reduce contracture which facilitates the surgical procedure.
- Physical exercising.
- Reduction of weight.
- X-ray: anteroposterior and lateral according to Lauenstein.
- Presurgical peripheral catheter nerve block.
- Perioperative antibiotic prophylaxis with second- or third-generation cephalosporin i.v., single dose; in case of surgery duration > 2 h, second application of antibiotics is recommended.

Surgical Instruments and Implants

- Standard instruments for hip replacement.
- Specific instruments and implants for onlay hip resurfacing (ESKA Implants, Grapengießerstraße 34, 23556 Lübeck, Germany).
- Specific retractor set (MIOS, provided by Aesculap, Am-Aesculap-Platz, 78532 Tuttlingen, Germany) used for minimally invasive procedures in total hip arthroplasty with smooth and broad design, and curvatures from 30° to 90° to protect muscles.
- Minimized acetabular reaming system (optional).
- Jet-lavage system.
- Largely curved insertion instrument, minimally invasive socket impactor (ESKA Implants).

Anesthesia and Positioning

- Combination of general anesthesia with femoral nerve block is recommended.
- Patient-controlled analgesia [9].
- Supine position on operating table allowing 30° hip extension by bending the operating table.
- Contralateral stabilization of the patient with operating table fixation tools.
- Fixation of the contralateral leg.
- Disinfection and draping of the leg allowing full range of motion.

Surgical Technique

Figures 1 to 21

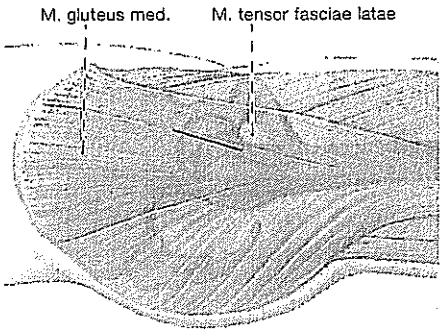


Figure 1
Patient placed in supine position allowing to hyperextend the hip up to 30° on the operating table. 10 cm skin incision between the tip of the greater trochanter and the anterior superior iliac spine, just above the intermuscular septum between the gluteus medius and the tensor fasciae latae.

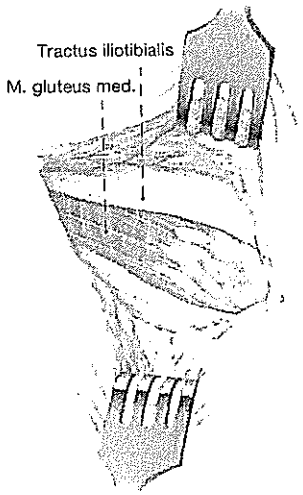


Figure 2
Incision of the fascia within the anterior aspect of the iliotibial band.

Figure 3
Dorsal retraction of the gluteus medius and gluteus minimus by a 60° curved Hohmann retractor. A blunt and broad retractor is placed medially of the femoral neck to retract the tensor fasciae latae anteriorly. A 90° retractor is placed close to the anterior rim of the acetabulum providing good exposure of the capsule.

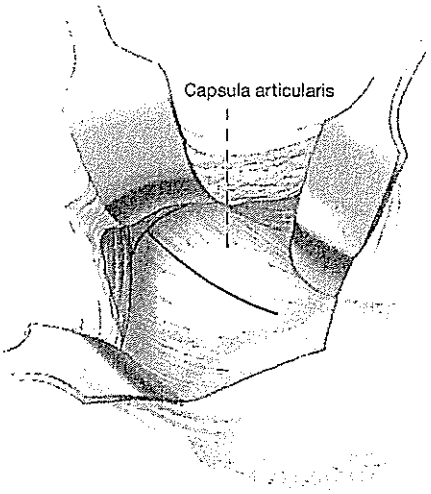


Figure 4
Incision of the capsule is performed in longitudinal direction of the femoral neck. Another incision is placed perpendicular along the anterior rim of the acetabulum to release the capsule as much as possible. Complete capsulotomy is essential for adequate exposure and to continue resurfacing.

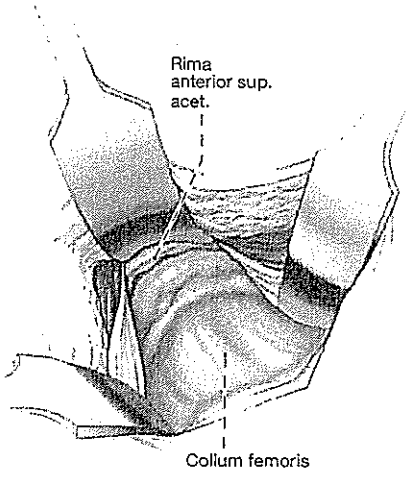
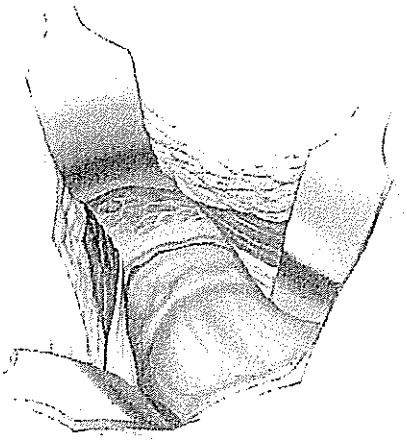
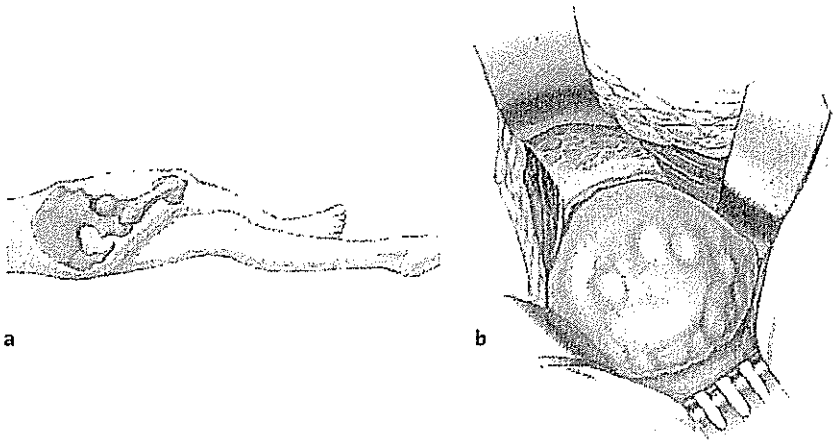


Figure 5
The gluteus medius and gluteus minimus are gently released from the lateral aspect of the pelvis. Abduction facilitates the detachment to create a dorsal muscular pouch for dislocation of the femoral head from anterior dislocation position to dorsal. This important step should be done digitally and gently to avoid muscle lesions.

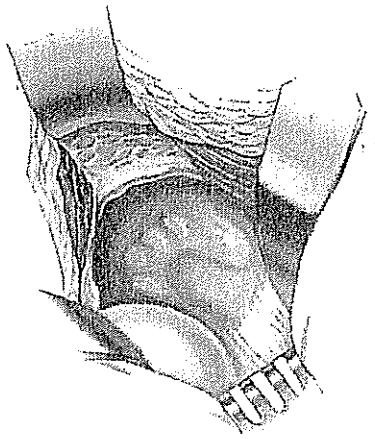


Figures 6a and 6b
Dislocation of the femoral head to an anterior position is achieved by adduction and external rotation (a). Resection of surrounding osteophytes is required, if luxation is not possible (b).

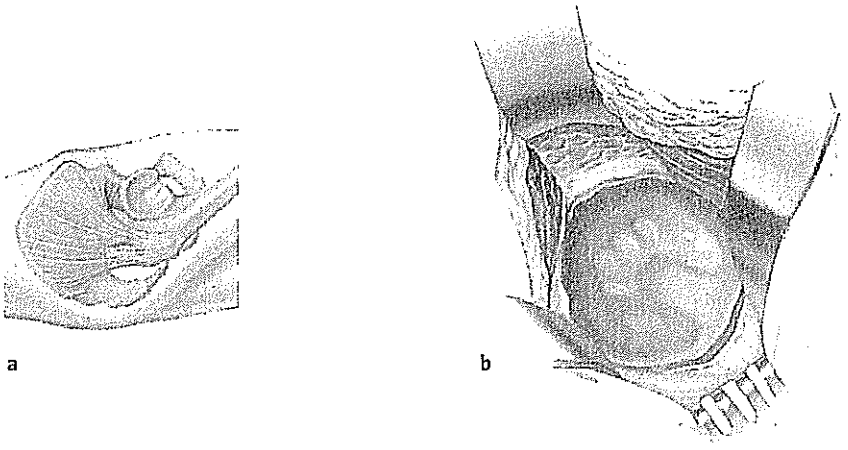


a b

Figure 7
The transfer of the femoral head between gluteus medius, gluteus minimus and the ilium from anterior to the dorsal dislocation position has to be done very gently by flexion and simultaneous rotations until the final dorsal dislocation position is reached. Then, the release of the capsule has to be completed to provide better mobilization of the femoral head. The release should be done very close to acetabular bone, completing a circumferential capsular release of 360°. If release is done within a wider distance to the bone, bleeding can occur.



Figures 8a und 8b
After capsular release has been finished, the femoral head is dislocated into the dorsal muscular pouch (a) allowing excellent exposure of the acetabulum (b).



a b

Figure 9
After complete exposure of the acetabulum has been achieved, reaming is started with the smallest size until the teardrop position is reached. Further reaming is done with size increasing in 2-mm steps until the size of the smallest possible implant is reached. The first reaming phase of the acetabulum ends with this step.

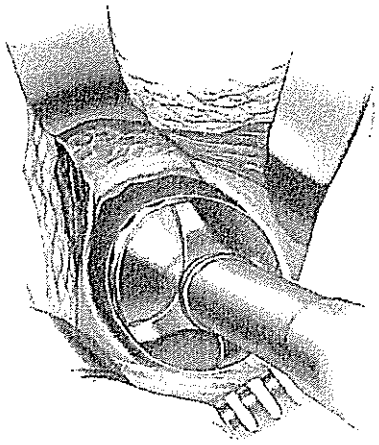


Figure 10
Repositioning of the femoral head into anterior dislocation by gentle abduction and external rotation. Extension of the hip is achieved, if the operation table is bent up to 30°; exposure of the head is much easier now due to relaxation of the gluteus medius and gluteus minimus in this position. Two 30° retractors are placed around the neck for complete exposure of the femoral head.

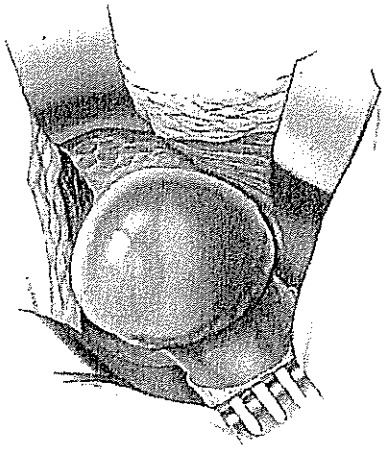


Figure 11
The reamer that fits the femoral head loosely has to be chosen first to start reaming until the osteophytes are removed and the head appears round.
After all osteophytes have been removed and the head is rounded, the next smaller reamer should be used to start final head reaming by 2-mm steps until all cartilage is removed. The last measured reamer corresponds to the largest size that can be implanted. Weakening of the subchondral bone stock occurs after extended or asymmetric reaming of the femoral head. If the femoral reamer is used in very close bone contact and reaming load is light, the subchondral bone is kept in excellent and unaffected condition.

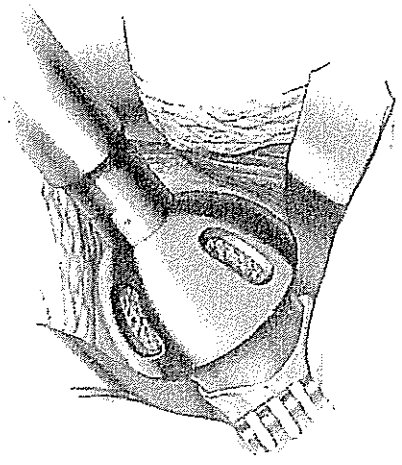


Figure 12
A trial implant is placed on the femoral head in press-fit technique to verify the reaming size. The trial implant is left in place while the femoral head is transferred back to the dorsal dislocation position for final reaming of the acetabulum.

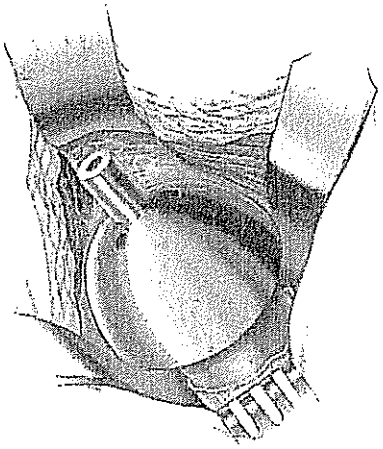


Figure 13
The second reaming phase starts with the reamer used before until the correct acetabular size is reamed (6 mm larger in diameter than the femur). The correct size is determined by the femoral size (femoral head reamer + 6 mm = correct acetabular reamer).
At the end of acetabular reaming, the subchondral cancellous structure is reached and subchondral sclerosis is opened to allow osseous integration of the implant.
If the acetabulum was overreamed while femoral head was decreased in size, a mismatch of the components could result because a specific femoral component needs to fit a specific corresponding socket and inlay. To avoid mismatch, we recommend to start reaming of the acetabulum first until the smallest socket which could be implanted is determined, followed by reaming of the femoral head to the largest size that fits the head. Then, the surgeon can easily continue reaming the acetabulum to the appropriated size.

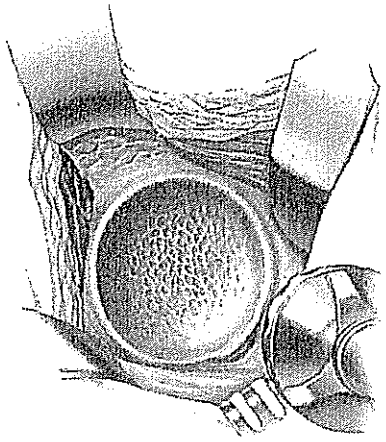
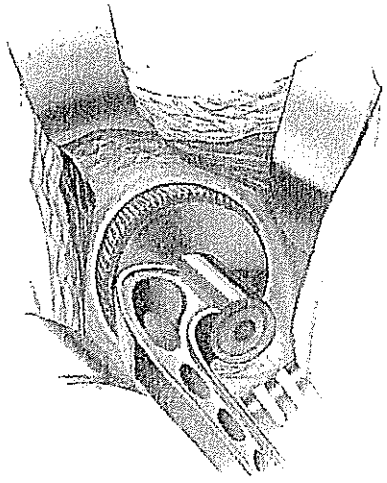


Figure 14
The acetabular implant is fixed on the curved impactor. Acetabular implant size = femoral implant size + 8 mm. The acetabulum has to be underreamed with the implant being oversized by 2 mm compared to the final acetabular reamer (socket size = femoral size + 8 mm). Malpositioning of the implants occurs, if exposition of the acetabulum is not completed. Large soft-tissue layers prevent exact positioning of the socket. Inadequate position commonly appears as increased inclination or anteversion or even both. A complete release of the capsule decreases the risk of malpositioning. Specific navigation systems could be an option to reduce the malpositioning risk.



Figures 15a and 15b
A disposable PE inserter has to be used to impact the acetabular implant (a) until correct positioning and depth of the socket are achieved (b). Eccentric impact leads to nonvisible deformities that induce peak load and increased debris rate and, thus, has to be avoided. If the final acetabular implant is seated (b) and correction of the implant is needed, an asymmetric impaction on the rim of the socket is not allowed. If any correction is needed, the socket-inserting instrument has to be used. Asymmetric impaction leads to a relevant deformation of the implant and the cone junction between inlay and socket is not possible anymore. If the inlay has been inserted in a deformed socket, the fixation of the inlay is no longer cone-based. Therefore, the specific impactor tools have to be used.

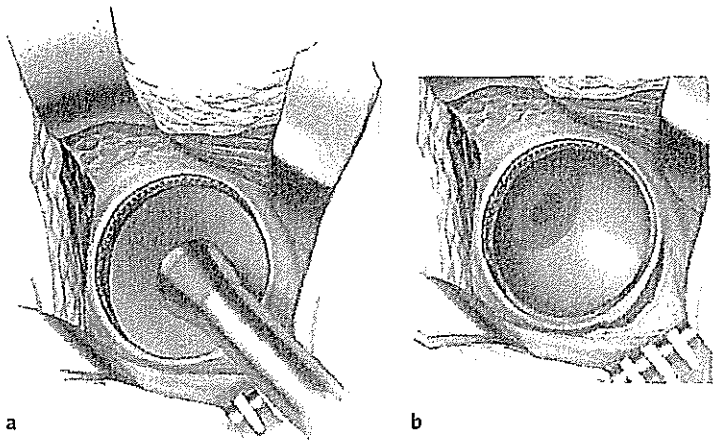


Figure 16
The insert should be inserted manually to avoid tilting followed by impacting the insert with the single-use PE impactor. Tilting of the insert must be avoided to guarantee an easy removal of the insert in case of revision.

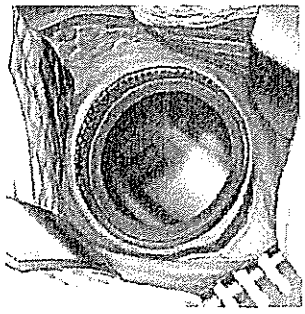


Figure 17
Repositioning of the femoral head into anterior dislocation for final reaming. To finalize reaming, the soft reamer is recommended. The size is determined by the acetabular implant (size of acetabular implant – 8 mm = reamer size to finalize the head).

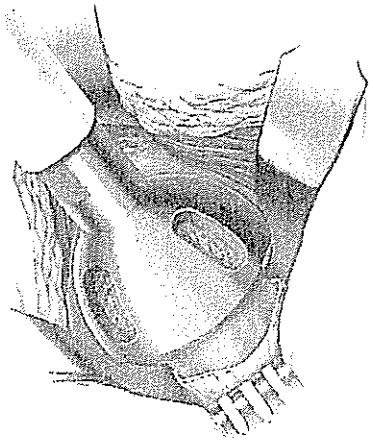


Figure 18
The trial implant is placed again in anatomically correct position guided by the individual neck-head junction. Then, the guiding hole is drilled and widened to facilitate and guarantee fast and reproducible implantation of the femoral component.

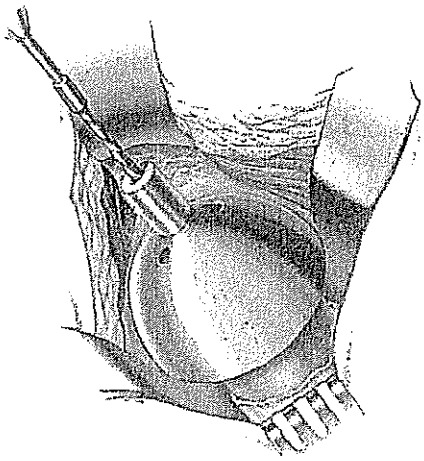
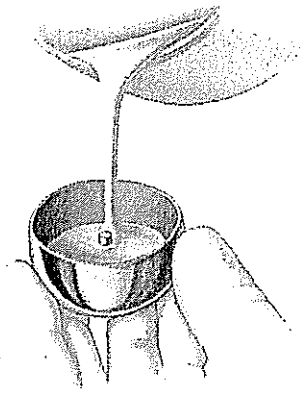
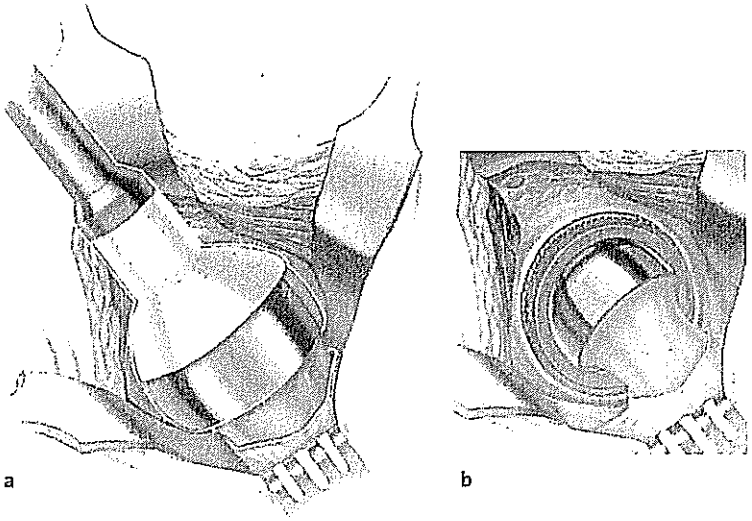


Figure 19
Jet lavage of the femoral head and preparation of the low-viscosity bone cement (Heraeus LV cement, Philipp-Reis-Straße 8/13, 61273 Wehrheim/Taunus, Germany). The cup has to be filled until 2 mm of the guiding pin are still visible. When the cement starts to be pasty, the onlay implant has to be placed on the femoral head.

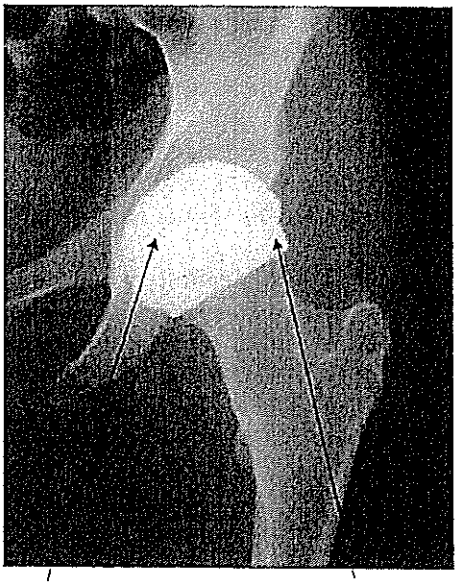


Figures 20a and 20b
The implant has to be seated with permanent pressure and gentle hammer impaction (a), cleaning of the head, jet lavage, and repositioning followed by examination of the range of motion (b). Femoroacetabular impingement must be avoided. Check for impingement by flexion and internal rotation of the hip. Femoroacetabular impingement is caused by osteophytes, located at the anterior aspect of the head-neck junction or the corresponding aspect of the acetabulum. If the osteophytes are removed, recheck for impingement before wound closure.



a b

Figure 21
Removal of all instruments. Now, the position of the implants can easily be verified by fluoroscopy. If correction of the implants is required, the specific impactor tools have to be used. Insertion of one drain and wound closure. Sterile dressing. X-ray control.



Postoperative Management

- Continuous passive motion starts on the 1st day after surgery and is continued until full range of motion is achieved and soft-tissue swelling has disappeared marking the start of the outpatient phase.
- Nonsteroidal anti-inflammatory drugs and metamizole as basic analgesics.
- Vital parameters observed continuously on the day of surgery.
- Mobilization with two crutches from the day of surgery with weight bearing as tolerated, increase of weight bearing up to full weight bearing as tolerated.
- We remove the drain on day 2 after surgery.
- Prophylaxis of thromboembolism until full weight bearing is achieved.
- Initiation of early rehabilitation on day 4 after surgery with 3 × 15 min of cycling on an ergometer (maximum 50 W, 80 rpm).
- Suture removal 12 days after surgery.

Errors, Hazards, Complications

- Bony defects of the acetabulum can occur, if reaming is not performed precisely in the central part of the acetabulum. Primary instability of the components results, if bony integrity of the acetabulum is lost: additional screw fixation is recommended.
- Transient disturbance of the femoral nerve, if retractors are placed at the anterior aspect of the acetabular rim: the retractors should be placed with bony contact to the anterior acetabulum.
- Lesions of small vessels of the gluteal region cause minor hematoma because the femoral head has to pass the interval between the dorsolateral aspect of the acetabulum and the gluteal muscles. These minor bleedings are difficult to coagulate because of the minimally invasive approach: the resulting hematoma is clinically of no relevance and resorbed spontaneously without any specific treatment. If preparation and luxation of the femoral head are done gently, bleeding risk can be reduced.
- Mismatch of the components, if the acetabulum was overreamed while femoral head was decreased in size: start reaming of the acetabulum first until the smallest socket which could be implanted is determined, followed by reaming of the femoral head to the largest size that fits the head. The femoral size determines the size of the socket. If both components cannot be adapted, the onlay procedure cannot be performed and surgery has to be changed to a standard resurfacing.
- Femoroacetabular impingement: resection of the osteophytes located at the anterior aspect of the head-neck junction or the corresponding aspect of the acetabulum.
- Neck fracture after surgery; resurfacing implants are associated with neck fractures known as peripros-

thetic fractures: conversion to a standard total hip. Due to the modularity of the acetabular component, the socket stays in situ and the inlay is only changed if necessary.
- Loosening of the femoral component: the head is resected, a short stem or standard femoral stem is implanted, and the inlay has to be changed to fit the new femoral component.
- Loosening of the socket: the socket should be removed and exchanged for a larger one that provides primary stability. A new specific inlay has to be implanted that fits the femoral component; otherwise, the femoral component has to be exchanged for a standard system to fit the new acetabular size.

Results

From December 2005 to June 2006, 31 patients (19 males, twelve females; mean age at the time of surgery 55 years [29–66 years]; mean body mass index 29.2 kg/m² [26.9–30.3 kg/m²]) underwent hip onlay resurfacing via a minimally invasive anterolateral approach using the ESKA onlay implant in all cases. 17 operations were performed on the right and 14 on the left side. Resurfacing was indicated because of primary or secondary osteoarthritis of the hip. Patients with ongoing osteoporosis were excluded. The primary outcome criterion was defined as a change at follow-up compared to baseline in regard of the Harris hip scoring system 12 months after surgery. The change in pain perception measured on a 10-scale visual analog rating system (VAS), the percentage of fractures and loosening were used as secondary criteria. 18 out of the 31 patients suffered from primary and 13 from secondary osteoarthritis (eight cases of dysplasia, three cases of posttraumatic osteoarthritis, and two cases of systemic rheumatoid arthritis). Mean duration of surgery was 81 min (54–145 min). Operating time was significantly longer (up to 145 min) in the first ten cases; mean blood loss was measured at 280 cm³ (140–510 cm³). Cell saving was performed in all cases. Autologous blood sampling was not required prior to surgery. To prevent heterotopic ossification, ibuprofen 600 mg was administered three times a day over a period of 10 days and standard thromboembolism prophylaxis was done until full weight bearing was achieved. Patients stayed in hospital for a mean of 7 (± 3) days, followed by 3 weeks of rehabilitation. Rehabilitation consisted of pain-adapted weight bearing within the full range of motion and ergometer training at a load of up to 50 W and a frequency of 80 rpm. Cycling was allowed from postoperative day 4, if no secretion was noted. The ergometer training was done three times a day to a total of 45 min and highly accepted by the patients.

12 months after resurfacing, functional outcome was excellent. The Harris Hip Score improved to 97.1 points compared to 43.9 points at baseline and subjective pain sensation was scored at 0.6 points on the VAS compared to 8.5 points at baseline. Severe side effects such as fracture, nerve or musculoskeletal lesions, thromboembolism or infection and approach-related side effects like delayed wound healing, limping or muscle insufficiency were not observed. Two patients showed relevant hematoma with load-related pain while cycling and walking without the need for revision or another specific treatment followed by spontaneous resorption.

Implant-related adverse events such as loosening, leg lengthening or dislocation were not found. All X-ray examinations 3, 6, and 12 months after surgery showed no change regarding positioning and loosening. Neither renal dysfunction nor metal-related allergic reaction were seen within 12 months after surgery.

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