ORTHODYNAMICS

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25th February 2011

Dear [redacted]

Re: ESKA Adapter (cementless) Femoral Stem Prosthesis and ESKA Bionik Resurfacing Femoral Head

I am writing in response to your letter to ESKA Australia of the 17th January 2011 regarding your observation of higher than expected revision rates for the ESKA Adapter (cementless) Femoral Stem Prosthesis and the ESKA Bionik Resurfacing Femoral Head.

I would firstly like to thank you for granting an extension of the reporting period to the 28th February, the additional time has provided us with the opportunity to carry out a thorough review of the issues raised in your letter of the 17th January to [redacted] I would also take this opportunity to advise you that information supplied by ESKA Australia in September 2010 had not been verified or reviewed by Orthodynamics GmbH

Whilst ESKA Australia is the distributor of the implants identified in your letters, you may be aware that the manufacturer of these devices was ESKA Implants AG, although this company ceased to exist on 31st March 2010.

The assets of ESKA Implants AG were acquired by The Summit Medical Group on the 31st March 2010, and a new entity was formed "Eska Orthodynamics GmbH". This business was subsequently rebranded as "Orthodynamics GmbH" in October 2010. Orthodynamics GmbH continues to manufacture and supply the above devices to the Australian market via our distributor ESKA Australia.

In response to your invitation to further review and expand on information previously supplied, the executive management at Orthodynamics GmbH commissioned a comprehensive review of the products currently being placed on the market in Australia. This review was conducted by Regulatory Affairs, Design and Development and Customer Services Managers at our facility in Lübeck, Germany. Additional product testing by [redacted] Director of Surgery and Orthopaedic Laboratories at UNSW, was also commissioned. ESKA Australia is currently in liaison with [redacted] in order to obtain the final version of this test report; it will be forwarded to you as soon as it becomes available. The main report attached does reference the findings of this test report, based on early communication of the results from [redacted]

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It is our view that this report provides data and reasoned arguments to demonstrate that these devices provide a safe and effective solution in the management of clinical procedures for which they are indicated and as such should remain available to surgeon and patients in the Australian market.

Should you have any questions regarding the report, or require any further information, please do not hesitate to contact me directly.

Yours sincerely,

[redacted]

[redacted]

[redacted]

[redacted]

c.c. [redacted] ESKA Australia

Investigation into Australian Orthopaedic Association National Joint Replacement Registry Data for the ESKA Adapter (cementless) Femoral Stem Prosthesis and the ESKA Bionik Resurfacing Femoral Head

The Australian Orthopaedic Association National Joint Replacement Registry (NJRR) demonstrates a higher than expected revision rate for the ESKA Adapter (cementless) Femoral Stem and Bionik Resurfacing Femoral Head.

Interpretation of Adapter stem joint registry data

The Adapter stem has a revision rate of 2.11 revisions/100 obs. years compared to 0.78 revisions/100 obs. years for conventional total hip arthroplasty[1].

Detailed investigation into the Adapter stem NJRR data shows that the majority of its usage in Australia (63%) has been with a large metal-on-metal bearing combination. The metal-on-metal bearing also accounts for 17 of the 23 revisions (74%). It is well documented throughout the industry that this bearing combination has been associated with higher revision rates. This has led to a Medical Device Alert for all metal-on-metal bearings in the UK[2], and increased vigilance by the FDA[3].

The UK National Joint Registry demonstrates a revision rate of 7.7% at five years with large head metal-on-metal bearings compared to 3.4% for cementless total hip arthroplasty[4]. This compares to an overall revision rate of 4.1% for the Adapter stem between 2005 and 2009 as reported by the NJRR (4.8% for metal-on-metal bearings, and 2.8% for cementless total hip arthroplasty).

It could be argued that it is therefore slightly misleading to compare the performance of the Adapter stem to conventional total hip arthroplasty. The UK National Joint Registry demonstrates that the Adapter stem falls within reported revision rates at five years when compared with other large metal head bearings, and cementless hip arthroplasty (both of which are demonstrated to have a higher revision rate than conventional cemented hip arthroplasty).

However, there is also reason to believe that there may be design factors associated with the Bionik femoral head which could account for a higher than expected revision rate. In July 2007, the external geometry of the Bionik femoral head was modified upon feedback from the Australian surgeons to avoid irritation of the iliopsoas tendon[5]. This was followed by a further design change of the Biosurf surface in September 2008 to improve wear results (this is discussed further in the Bionik resurfacing head section). A review of the NJRR data for cementless adaptor stems and large Bionik femoral heads[6] shows a strong correlation between stem and head revisions, and a reduction in revision rate since the implementation of the latest design in 2008[7].

Reviewing the reasons for revision in the NJRR demonstrates that the Adapter stem's performance is directly comparable to other total conventional hip prostheses in Australia for loosening, dislocation, infection and fracture (the four most common causes of revision). The incidence of revision due to pain is higher with the Adapter stem, but that could be attributed to many factors including wear particles from the metal-on-metal articulation rather than purely complications with the stem (given that three quarters of the revisions are on joint replacements with a metal-on-metal articulation).

This argument is strengthened when investigating the types of revision. This demonstrates that there were eight femoral stem revisions (excluding one case of infection which cannot be attributed to the implant). The remaining fourteen revisions all involved replacement of bearing components, rather than the stem. This gives the Adapter stem a revision rate of 0.73%/100 obs. years which is below the 0.78% reported for conventional total hip arthroplasty in the NJRR.

There was also a significant design change to the liner which was implemented into the Australian market in February 2009[8]. This design change introduced a locating pin to the liner to ensure that the liner is centrally positioned within the metal shell. This design change is also likely to have contributed to the decline in revision rates reported by the NJRR in 2009.

The Adapter stem has been widely used in the German market, in far larger numbers than those reported in Australia, with very low incidence of complaints and adverse incidents[9]. However, the use of the Adapter stem with large metal heads is not common in the German market, which may account for the discrepancy of results when compared to those witnessed in the Australian market and described in the NJRR.

Adapter stem clinical literature

Published clinical literature to support the Adapter stem is limited, although one abstract presented at the 56th Annual Meeting of the Association of South German Orthopaedic Surgeons in Baden-Baden May 2008 demonstrated good results[10]. This followed up 42 surgeries to a period of up to four years with excellent clinical outcomes, as measured by the Harris Hip Score of 98, and 100% survivorship.

The same design of taper cone adaptor is also used on the G2 Adapter stem marketed in Europe. The G2 Adapter stem is very similar in design to the GHE Adapter stem, and can be considered equivalent when looking at the stem/modular taper interface[11]. Zurstegge[12] followed up 100 stems over four years and concluded that the taper/stem connection was effective with no evidence of fractures or loosening.

As well as the Adapter stem, Orthodynamics GmbH manufactures a monoblock variant which is identical in geometry to the Adapter stem, but without the modular neck taper. This stem has clinical publications of larger cohorts which demonstrate that the stem design is clinically safe and effective.

Kinner et al[13] followed up 200 surgeries up to four years and showed three revisions, none of which were directly attributable to the stem. Patient outcome was good with a high Harris Hip Score of 97, and the three revisions account for a revision rate of 1.5%. Ogawa et al[14] followed up 48 stems for a period of just over six years. They witnessed no revisions and an average Merle d'Aubigne score of 16.1. Similarly, Kusaba et al[15] also followed up a cohort of 166 patients for a period of just over six years. They also witnessed no revisions, and good clinical outcomes with a Harris Hip Score of 91.

Overall, these three studies of the monoblock GHE stem followed up over 400 patients and witnessed just three revisions at a minimum of four years follow-up (none of which could be attributed to the stem). This amounts to a low revision rate of 0.7% for the monoblock variant of the Adapter stem.

As well as the published clinical data in support of the Adapter stem and its variants, Orthodynamics GmbH has also obtained surgical testimonies from experienced Adapter stem users in our domestic market[16,17]. This is further evidence that the Adapter stem is achieving satisfactory clinical results, although again it should be stressed that these users are not using the stem in combination with metal-on-metal bearings as is often the case in Australia.

Adapter stem mechanical testing

A review of the pre-clinical testing for Adapter stems showed that whilst the worst case stem, taper, head combination had been fatigue tested to ISO 7206-6, the testing had not been conducted in saline. Upon reviewing the NJRR data, Orthodynamics GmbH commissioned a further fatigue test in saline to determine if fretting corrosion could lead to mechanical failures of the Adapter stem. This test[18] was performed by an eminent, independent party in Australia, Professor Bill Walsh of the University of New South Wales, to 3.5kN and 10m cycles (beyond the ISO 7206-6 requirements).

The results showed that the stem exceeded the fatigue requirements of ISO 7206-6. Analysis of the taper adapter after testing showed that there was evidence of fretting, particularly on the medial side of the taper adapter, and the corresponding area of the female femoral stem connection. However, fretting is observed in all modular taper connections after fatigue testing. The amount of fretting documented varies with Kretzer et al[19] observing low amounts of Titanium release (in the region of µg) and Traina[20] et al witnessing Titanium release in the region of 0.6mg/million cycles. Both studies conclude that the amount of wear debris and associated risk of fretting is acceptable, given the clinical benefits of modularity. Grupp et al[21] demonstrate that a Cobalt chrome modular neck adapter, as utilised with the Adapter stem, offers significant reductions in fretting when compared to Titanium neck adapters. A subjective comparison of fretting witnessed with these accepted levels in the published literature shows no evidence of increased risk associated with the Adapter stem. The level of wear particles is certainly low when compared to those witnessed from metal-on-metal bearings[22] ($1mm^3$ is equivalent to 8.28mg).

Adapter stem conclusion

A review of the joint registry data shows there to be identifiable factors and reasons to explain the higher than expected rate of revision for the Adapter stem when compared to conventional hip arthroplasty.

Firstly, the high revision rate is believed to be linked to the comparatively high metal-on-metal usage in Australia, and problems with earlier designs of large metal heads irritating the iliopsoas tendon and potential high wear rates. However, the five year results are favourable when compared to the UK National Joint Registry data where there has been large metal-on-metal implant usage, and there is a clear downward trend in revisions being recorded by the NJRR as a consequence of the design changes to the Bionik femoral head and liner.

Aside from pain, which is believed to be linked to metal-on-metal wear particles from the metal-on-metal articulation, the Adapter stem has a comparable record with the conventional hip replacement results reported in the NJRR. Breaking down the data to femoral stem revisions, shows a revision rate of 0.73 revisions/100 obs. years (lower than the standard for conventional hip arthroplasty of 0.78 revisions/100 obs. years).

The successful clinical performance of the stem is supported by good clinical results and published data in Europe, with lower revision rates than those witnessed in Australia. Again, this is believed to be attributable to the fact that the stem is not used with a large metal-on-metal bearing in Europe.

Whilst the stem/adapter stem interface has shown evidence of fretting during mechanical testing, this is believed to be comparable to similar products and acceptable for a modular implant. Wear rates associated with taper junctions are very low for cobalt chrome taper adapters when compared to the wear rates seen in metal-on-metal articulations.

The NJRR and UK NJR analysis, the published literature, the surgeon testimonies and the fatigue test results all demonstrate that the Adapter stem is clinically safe and effective when used for its intended purpose of primary hip arthroplasty. The NJRR data which demonstrates a higher than expected revision rate for the Adapter stem has been distorted by metal-on-metal failures which can be attributed to a former design of the femoral head component and liner.

Given the low risk associated with the Adapter stem, and the clinical benefits of the modular neck system, it is Orthodynamics GmbH's belief that there is sufficient data to enable continued usage of the device in the Australian market.

Interpretation of Bionik resurfacing head registry data

The Bionik resurfacing head has a revision rate of 2.75 revisions/100 obs. years compared to 0.99 revisions/100 obs. years for all hip resurfacing[23].

The Bionik resurfacing system data supplied by the NJRR covers four different types of femoral component[24]: a conventional hip resurfacing component, a conventional hip resurfacing component with "BioSurf", a femoral head shell "Onlay" with "Biosurf", and a Cera-Metal device (no longer supplied to the Australian market).

The Cera-Metal device was a ceramic coated metal head, but it has never been manufactured or supplied by Orthodynamics GmbH and is no longer available on the market worldwide. There was one Cera-Metal failure in the market, but the revision rate was 11.11 revisions/100 obs. years. This figure obviously distorts the remaining Bionik resurfacing data and should be discounted. The revision rate for the other Bionik resurfacing variants is 2.52 revisions/100 obs. years.

The data is also potentially skewed by a 20% revision rate in Tasmania (2 revisions from 10 implantations, at 7.67 revisions/100 obs. years). Although it is clear that the revision rate is higher than expected when compared to other resurfacing data from the NJRR, there have only been nine revisions of the Bionik resurfacing head. New South Wales and Tasmania account for 131 of 178 implantations (73%), and have witnessed all of the revisions. Even discounting the Bionik data, these

centres have the highest resurfacing revision rates of 1.11 revisions/100 obs. years and 2.77 revisions/100 obs. years respectively.

The UK National Joint Registry reports a resurfacing revision rate of 6.2% at five years[4]. The NJRR data shows that the Bionik resurfacing head has a revision rate of 5.1%.

The NJRR data also demonstrates that all of the revisions involved the femoral component, and that conventional resurfacing Biosurf and femoral shell Onlay Biosurf components account for 75% of the revisions excluding Cera-Metal (3 conventional revisions and 3 Onlay revisions). The dimpled Biosurf surface is identical on the conventional resurfacing and Onlay devices, and is also used on the Bionik femoral head. It is believed that earlier design iterations of the Biosurf components could have led to higher than expected revision rates due to high wear (see mechanical testing section below for further information). The earlier design of liners without the centralising peg could also be a factor causing slight elevations in wear. These factors were also discussed as reasons for the higher than expected revision rates of the Adapter stem.

The case for metal wear particles being a cause for revision is strengthened by the fact that 5 of the 9 revisions (56%) are due to loosening or lysis. The other predominant failure rate is fracture; this was the cause of 3 of the 9 revisions (33%). However, the incidence of fractures is in line with those witnessed in the NJRR for resurfacing at around 1.5%. The cause of fractures may be more related to the general resurfacing surgical technique rather than specific implant features.

The resurfacing components have been widely sold into the German market, but currently the revision rate appears to be much lower than that reported in Australia[25]. 9 of 181 stems sold into Australia have been revised (4.97%) compared to 17 of 1973 worldwide (0.86%).

Bionik resurfacing head clinical literature

The clinical literature for the conventional resurfacing and Onlay resurfacing prostheses is good. Gerdesmeyer's most extensive follow-up is of 104 surgeries at 3 years[26]. The follow-up is conducted on an Onlay device with Biosurf and shows excellent clinical outcomes with a good Harris Hip Score of 98 and a revision rate of 0.96%. The one revision is due to femoral neck fracture, and therefore not strictly implant related. This relates favourably to the revision rate reported in the NJRR data.

Gerdesmeyer et al[27] performed a second study that investigates the same device but with a minimally invasive approach. This time 31 surgeries were followed up at one year. Again, the clinical outcome was very good with an excellent Harris Hip Score of 97 and no revisions.

Rudert et al[28] followed up 20 patients with the conventional hip resurfacing and Biosurf to 1.5 years. The clinical outcomes were satisfactory with Harris Hip Scores of 92, but a high revision rate of 10% was reported. It is believed that this data is skewed by the low numbers in the study. Of the two revisions, one was due to dislocation and the other was due to femoral neck fracture. There were no implant failures due to loosening as reported in the NJRR.

Literature suggests that implant positioning and alignment is of increased importance during hip resurfacing procedures, and this can significantly affect the long-term results[29]. This may also be a factor in the differences in revision rates reported in Germany compared to Australia.

Bionik resurfacing head mechanical testing

The Bionik femoral and resurfacing heads were brought to market on the basis of a successful hip simulator wear test to ISO 14242 in 2003[30]. Conventional resurfacing parts were used, one with Biosurf and one without. The results of the test were 2.1mg/million cycles for the Biosurf and 5.5mg/million cycles for the non-dimpled surface. These were converted into volumetric wear rates of 0.25mm^3/year and 0.66mm^3/year, and shown to be comparable with the lower end of reported wear rates in the literature[21]. Based upon the successful wear test, established cobalt chrome bearing materials, and established manufacturing tolerances[31], the Bionik femoral heads were CE marked.

Following design changes to the external geometry of the Biosurf surface, a further wear test was commissioned in 2007[32]. This test was performed using three conventional femoral heads. The results identified a higher mean wear rate of 10.83mg/million cycles which equates to 1.31mm^3/year. These wear results are in the middle range of the reported values in the literature. The results were also inconsistent with a large standard deviation.

Concern about these results led to an improvement in polishing of the Biosurf components and a further test of four components[33]. This testing demonstrated a significantly higher wear rate again, and a wider range of results. The wear rate varied from 2.2mg/million cycles to 52.2mg/million cycles. Conversion of these results gives a **mean** volumetric wear rate of 3.29mm^3/year which is beyond the levels reported in the published literature[22].

Due to the wide range of results witnessed, it is not clear whether this problem related to all parts that had been previously manufactured or just the latest design iteration. The devices were left on the market by Eska Implants AG until a design change was approved in September 2008. This remains the latest design iteration, and it was approved on the basis of achieving three consistently low results from the wear simulator testing for both surfaces[34,35]. These latest wear results of 1.51mg/million cycles for the Biosurf and 1.81mg/million cycles (0.18mm^3/year and 0.39mm^3/year) for the conventional surface were lower than those seen in the original testing, and are at the low end of reported results in the literature.

The design was improved by moving the region of the dimples closer to the equator and reducing the number and depth of the dimples[36]. Following the successful wear results, the latest design of device replaced all previous issue stock in the Eska Implants warehouse and all previous issue consigned European stock. It is understood that Australian stock was not replaced by the then owners of Eska Implants AG and/or Eska Australia. It should be stressed that this action was performed long before the change of ownership, and is in no way condoned by Orthodynamics GmbH. A review of stock currently held by the Australian distributor, Eska Australia, and their customers, confirmed that there were still previous issue femoral heads in stock at their facility. Arrangements have now been put in place to ensure that this previous issue stock is returned to Orthodynamics GmbH to prevent its usage in the Australian market.

Bionik resurfacing head conclusion

The NJRR data demonstrated that even allowing for the small numbers, there is a higher than expected revision rate for the Bionik revision femoral head. However, given the low numbers and possible reasons for a slightly higher rate such as Cera-Metal and poor results at one centre, the revision rate of 5.1% is not excessive for resurfacing devices, as demonstrated by the UK National Joint Registry data.

The NJRR data indicates that there may be a problem with femoral heads, with them being revised in all 9 cases, and with Biosurf, as that product was involved in six of the eight metal revisions. The fact that loosening and lysis is higher than expected also suggests that metal wear particles may be a contributory factor.

The clinical literature does not match the conclusions of the NJRR with predominately positive clinical results published. The sales and complaint data from the rest of the world also indicate more positive results than the high revision numbers from the NJRR.

The mechanical testing results indicate a possible problem with potentially high and unreliable wear rates for earlier designs of the Biosurf femoral head. It is not clear whether this will affect all previous Bionik femoral head designs, but there is certainly evidence that heads manufactured in 2007 and before September 2008 could have a higher than normal wear rate. It is believed that this could be a contributory factor to the higher than expected revision levels of the Bionik resurfacing head and the cementless Adapter stem when used with a metal-on-metal bearing.

However, the problem was rectified by a design change in September 2008, and the NJRR is reporting lower revision rates, certainly for the Adapter stem and conventional Bionik femoral head, since the design change. It can be confirmed that our distributor has advised there is no stock available for implantation in Australia to the previous issue design, so Orthodynamics GmbH would expect to witness an increase in survivorship of all of its metal-on-metal bearing combinations over the next few years.

Even assuming the potential high wear rate, the clinical data gathered by Professor Dr. Gerdesmeyer et al and Dr. Rudert demonstrates that good clinical results are obtainable with this device when it used correctly and for suitable indications.

Given that the higher than expected revision rate can be attributed to a former design of femoral head, and the successful clinical and mechanical test results outside of the NJRR data, it is believed that the Bionik resurfacing head is clinically safe and effective for its intended use, and this information is sufficient to enable the continued usage of the device in the Australian market.

Report completed by:

[redacted]

Quality Management and Regulatory Affairs Manager - Implants
23rd February 2011

[1] Adaptor (cementless) Total Conventional Hip Femoral Prosthesis – Extract from NJRR 2010
[2] Medical Device Alert Ref: MDA/2010/033 issued 22nd April 2010
[3] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetalHipImplants/default.htm
[4] Table 3.2 of UK NJR report 2010
[5] Change report 16-07 for Bionik femoral heads
[6] Bionik Total Conventional Hip Acetabular Prosthesis – Extract from NJRR 2010
[7] Graph comparing revisions of Adapter stems and Bionik femoral heads – Compiled from NJRR data 2010
[8] Change report 09-06 for Bionik liners
[9] Orthodynamics sales and complaint data – Adapter stem
[10] Thomas, S.; Scholz, J., & Latif, B, Die metallspongiöse Hüftendoprothese mit Konusadapter - Erste klinische Erfahrung einer radiologischen Nachuntersuchung, 56. Jahrestagung der Vereinigung Süddeutscher Orthopäden e.V., 2008, 1-15
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[16] Professor Rudigier's cemented Adapter stem testimony
[17] Dr. Seifert's cementless Adapter stem testimony
[18] Characterisation of taper surfaces following fatigue loading of the modular Orthodynamics stem and adapter
[19] Kretzer, J.P.; Jakubowitz, E.; Krachler, M.; Thomsen, M.; Heisel C., Metal release and corrosion effects of modular neck total hip arthroplasty, International Orthopaedics (SICOT) (2009) 33:1531-1536
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[22] Volumetric wear rates of metal-on-metal articulations – extract from Orthodynamics technical file
[23] Bionik/Bionik Total Resurfacing Hip Investigation – Extract from NJRR 2010
[24] Overview of Bionik femoral options
[25] Orthodynamics sales and complaint data – Bionik resurfacing femoral head
[26] Gerdesmeyer, L., Manuskript Gerdesmeyer_Confirmation AAOS 2008, 2009
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[32] Endolab test report 05.070904.10.963, June 2008
[33] Endolab test report 05.071113.10.981, July 2008
[34] Endolab test report 05.080109.10.1000, May 2008
[35] Endolab test report 05.070731.10.944, January 2008 (Non-Biosurf surface)
[36] Change report 05-08 for Bionik femoral head

Medical Device Alert

Action

Ref: MDA/2010/033 Issued: 22 April 2010 at 14:00

Device

All metal-on-metal (MoM) hip replacements.

Problem

The MHRA has received reports of revisions of MoM hip replacements involving soft tissue reactions. These reactions may be associated with unexplained hip pain.

Action by

- Medical directors
- Orthopaedic departments
- Orthopaedic surgeons
- Staff involved in the management of patients with joint replacement implants.

CAS deadlines

Action underway: 21 May 2010
Action complete: 17 June 2010

Note: These deadlines are for systems to be in place to take actions and not for the completion of patient follow-up and testing.

Action

Put systems in place for the follow-up of patients implanted with MoM hip replacements including, where appropriate, blood metal ion measurements and cross sectional imaging.

Issued: 22 April 2010 at 14:00 Ref: **MDA/2010/033**

Problem

The majority of patients implanted with MoM hip replacements have well functioning hips and are thought to be at a low risk of developing serious problems.

A small number of patients implanted with these hips may, however, develop progressive soft tissue reactions to the wear debris associated with MoM articulations. The debris can cause soft tissue necrosis and adversely affect the results of revision surgery. Early revision of poorly performing MoM hip replacements should give a better revision outcome.

Following extensive consultation with orthopaedic experts and using information from the National Joint Registry for England and Wales, the MHRA is issuing this interim advice to healthcare professionals involved in the management of patients implanted with MoM hip replacements.

The MHRA is continuing to monitor the situation in consultation with orthopaedic experts and may issue further advice.

Action

For patients implanted with MoM hip replacements:

- follow up patients at least annually for five years postoperatively and more frequently in the presence of symptoms. Beyond five years, follow up in accordance with locally agreed protocols
- investigate patients with painful MoM hip replacements. Specific tests should include evaluation of cobalt and chromium ion levels in the patient's blood and cross sectional imaging including MRI or ultrasound scan
- consider measuring cobalt and chromium ion levels in the blood and/or cross sectional imaging for the following patient groups:
  - > patients with radiological features associated with adverse outcomes including component position
  - > patients with small component size (hip resurfacing arthroplasty only)
  - > cases where the patient or surgeon is concerned about the MoM hip replacement
  - > cohorts of patients where there is concern about higher than expected rates of failure
- if either cobalt or chromium ion levels are elevated above seven parts per billion (ppb), then a second test should be performed three months after the first in order to identify patients who require closer surveillance, which may include cross sectional imaging
- if imaging reveals soft tissue reactions, fluid collections or tissue masses then consider revision surgery.

Note: Measurements of cobalt or chromium ions should be carried out by laboratories participating in the Trace Elements External Quality Assessment Scheme (TEQAS) (http://www.sas-centre.org/home.html).

Distribution

This MDA has been distributed to:

- NHS trusts in England (Chief Executives)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Chief Executives)
- NHS boards and trusts in Wales (Chief Executives)
- Care Quality Commission (Headquarters)
- Primary care trusts in England (Chief Executives)

Onward distribution

Please bring this notice to the attention of all who need to know or be aware of it. This may include distribution by:

Trusts to:

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Clinical governance leads
- Medical directors
- Nursing executive directors
- Orthopaedic departments
- Orthopaedic surgeons
- Outpatient clinics
- Outpatient theatre managers
- Outpatient theatre nurses
- Pathologists
- Radiology departments
- Radiology directors
- Risk managers
- Theatre managers

Care Quality Commission (CQC) (England only) to:

The MHRA considers this information to be important to:

- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

Primary care trusts to:

- Directors of public health
- General practitioners
- NHS walk-in centres

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2010/033 or 2010/004/019/291/007**

Technical aspects

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Fax: 020 7084 3111

Email: susanne.ludgate@mhra.gsi.gov.uk

How to report adverse incidents

Please report via our website http://www.mhra.gov.uk

Further information about **CAS** can be found at https://www.cas.dh.gov.uk/Home.aspx

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
Health Estates Investment Group
Room 17
Annex 6
Castle Buildings
Stormont Estate
Dundonald BT4 3SQ

Tel: 02890 523 704
Fax: 02890 523 900

Email: NIAIC@dhsspsni.gov.uk

http://www.dhsspsni.gov.uk/index/hea/niaic.htm

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website http://www.dhsspsni.gov.uk/niaic

Further information about **SABS** can be found at http://sabs.dhsspsni.gov.uk/

Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
Health Facilities Scotland
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh EH12 9EB

Tel: 0131 275 7575
Fax: 0131 314 0722

Email: nss.iric@nhs.net

http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

Wales

Enquiries in Wales should be addressed to:

Dr Sara Hayes
Senior Medical Officer
Medical Device Alerts
Welsh Assembly Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk

U.S. Food and Drug Administration

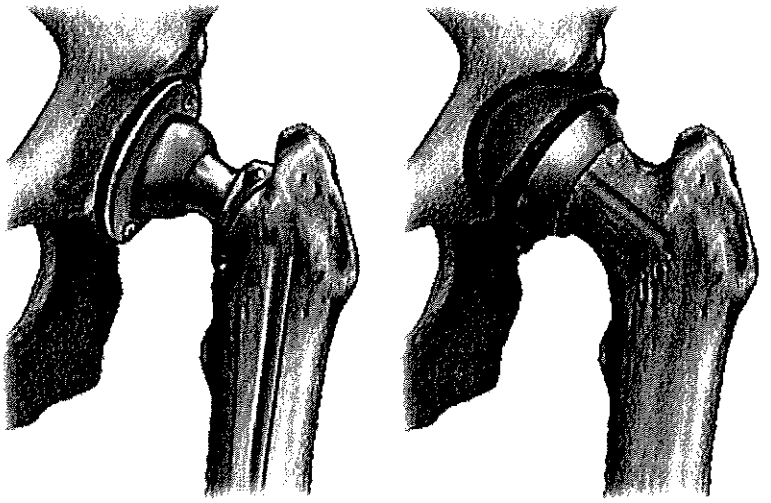
Medical Devices

Metal-on-Metal Hip Implants

Hip joint deterioration can lead to symptoms such as pain, stiffness or difficulty walking. When symptoms do not respond to conservative treatment, patients may be advised to undergo total hip replacement or hip resurfacing. Patients may receive a "metal-on-metal" hip implant in which the "ball and socket" of the device are both made from metal.

Metal-on-Metal Hip Implant Systems

Total Hip Replacement | Hip Resurfacing



A.D.A.M.

In this website, the FDA describes hip implants, how metal-on-metal implants differ from other hip implants and gives information and recommendations for patients and physicians about the benefits and risks of these products.

Links on this page:

Table 3.2 Revision at three and five years for primary hip replacement procedures, undertaken between 1st April 2003 and 31st December 2009, which were linked to a HES/PEDW episode.

Category	Number of patients	Revision rate at three years[23] (95% CI)	Revision rate at five years[23] (95% CI)	Hazard ratio[24] (95% CI)
Prosthesis type				
Males <55 years				
Total replacement using cement	1,669	2.7% (1.9% to 3.8%)	4.4% (3.2% to 6.0%)	1
Total replacement not using cement	3,858	2.9% (2.3% to 3.6%)	4.0% (3.1% to 5.1%)	1.10 (0.77 to 1.57)
Hybrid total replacement	1,498	1.8% (1.2% to 2.7%)	2.6% (1.7% to 3.8%)	0.68 (0.42 to 1.09)
Hip resurfacing	4,215	3.6% (3.0% to 4.3%)	5.6% (4.5% to 6.9%)	1.37 (0.98 to 1.92)
LHMoM THR	1,564	4.5% (3.3% to 6.1%)	6.4% (4.5% to 8.9%)	1.52 (1.01 to 2.28)
Males 55 - 64 years				
Total replacement using cement	5,560	1.7% (1.3% to 2.1%)	2.6% (2.1% to 3.2%)	1
Total replacement not using cement	8,035	2.8% (2.3% to 3.2%)	3.5% (2.9% to 4.2%)	1.56 (1.22 to 2.01)
Hybrid total replacement	2,990	1.8% (1.3% to 2.4%)	2.7% (2.0% to 3.7%)	1.09 (0.78 to 1.52)
Hip resurfacing	3,852	3.3% (2.7% to 3.9%)	4.5% (3.6% to 5.6%)	2.14 (1.63 to 2.80)
LHMoM THR	1,857	4.0% (2.9% to 5.4%)	5.5% (3.9% to 7.8%)	2.19 (1.56 to 3.07)
Males 65+ years				
Total replacement using cement	27,694	1.5% (1.3% to 1.7%)	2.0% (1.8% to 2.3%)	1
Total replacement not using cement	14,499	2.5% (2.2% to 2.8%)	3.1% (2.7% to 3.6%)	1.73 (1.48 to 2.02)
Hybrid total replacement	7,748	2.2% (1.9% to 2.6%)	3.0% (2.4% to 3.7%)	1.48 (1.22 to 1.80)
Hip resurfacing	980	5.4% (4.1% to 7.3%)	6.0% (4.4% to 8.2%)	3.85 (2.83 to 5.23)
LHMoM THR	1,444	3.4% (2.2% to 5.1%)	6.4% (3.7% to 11.0%)	2.21 (1.55 to 3.16)
Females <55				
Total replacement using cement	2,174	2.5% (1.8% to 3.4%)	3.6% (2.7% to 4.8%)	1
Total replacement not using cement	5,082	2.7% (2.2% to 3.3%)	4.3% (3.4% to 5.5%)	1.22 (0.89 to 1.71)
Hybrid total replacement	1,840	2.2% (1.5% to 3.1%)	4.0% (2.8% to 5.8%)	0.97 (0.64 to 1.48)
Hip resurfacing	2,647	5.4% (4.5% to 6.5%)	8.3% (6.8% to 10%)	2.32 (1.67 to 3.21)
LHMoM THR	1,037	6.3% (4.6% to 8.6%)	9.2% (5.9% to 14.1%)	2.22 (1.48 to 3.32)
Females 55-64				
Total replacement using cement	8,239	1.6% (1.3% to 2.0%)	2.5% (2.1% to 3.0%)	1
Total replacement not using cement	10,735	2.5% (2.2% to 2.9%)	3.7% (3.1% to 4.4%)	1.54 (1.24 to 1.91)
Hybrid total replacement	4,474	1.6% (1.2% to 2.1%)	2.9% (2.2% to 3.8%)	1.06 (0.79 to 1.43)
Hip resurfacing	1,854	5.4% (4.4% to 6.6%)	7.9% (6.3% to 9.8%)	3.61 (2.78 to 4.68)
LHMoM THR	1,526	6.7% (5.2% to 8.7%)	9.5%(7.4% to 12.3%)	3.73 (2.80 to 4.96)
Females 65+				
Total replacement using cement	54,023	1.1% (1.0% to 1.2%)	1.6% (1.5% to 1.8%)	1
Total replacement not using cement	20,728	2.3% (2.0% to 2.5%)	3.0% (2.7% to 3.4%)	2.21 (1.94 to 2.53)
Hybrid total replacement	13,112	1.5% (1.3% to 1.8%)	2.0% (1.6% to 2.4%)	1.43 (1.20 to 2.53)
Hip resurfacing	305	7.1% (4.5% to 11.1%)	8.8% (5.2% to 14.7%)	6.59 (4.17 to 10.41)
LHMoM THR	1,454	3.6% (2.5% to 5.2%)	10.5% (6.1% to 17.8%)	3.65 (2.67 to 5.00)
Patient physical status				
P1 – fit and healthy	37,244	2.3% (2.2% to 2.5%)	3.4% (3.1% to 3.7%)	1
P2 – mild disease not incapacitating	138,701	1.9% (1.9% to 2.0%)	2.8% (2.6% to 2.9%)	1.06 (0.98 to 1.16)
P3+ – incapacitating systemic disease or worse	40,748	2.1% (2.0% to 2.3%)	2.8% (2.6% to 3.1%)	1.29 (1.16 to 1.43)
Type of provider				
NHS hospital	180,937	2.1% (2.0% to 2.2%)	2.9% (2.8% to 3.0%)	1
NHS treatment centre	13,554	1.8% (1.5% to 2.1%)	2.9% (2.4% to 3.4%)	0.83 (0.73 to 0.96)
Independent hospital	13,378	2.0% (1.7% to 2.4%)	2.6% (2.2% to 3.1%)	0.85 (0.73 to 1.00)
ISTC	8,824	2.3% (1.8% to 2.8%)	2.9% (2.2% to 3.9%)	1.09 (0.91 to 1.31)

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FB Konstruktionsänderungsbericht

ESKA IMPLANTS

Betrifft QS und Konstruktion	Betrifft
Bericht Nr.: 16/07	Datum: 02.08.2007
Art.-Bez.: Metallkopf Biosurf silver "BS" AD = 38/44/48 mm	Unterschrift [redacted]
Index: _03_ ACHTUNG! Index der ges. Prod.-Gr. dem neuen Index anpassen!	Art.-Nr(n).: siehe Anlage
Veranlasst durch: [redacted]	
Art der Änderung (Beschreibung/Begr. siehe Anlagen)	**Anlagen**
[redacted] Änderung der Bezeichnung Konstruktive Änderung Funktionelle Änderung	[redacted] Zeichnung Skizze Andere:_____

Betrifft Geschäftsleitung: *Maßnahmen zur Lagerbereinigung*		Auf-brauchen	Nach-arbeiten.	Vernich-ten	Nicht anwend-bar	Anmerkungen / Bestätigung der Maßnahme
Vorpro-duktion	Wachse				X	
	Belegte Wachse				X	
	Wachsformen				X	
Pro-duk-tion	Rohware				X	
	WIP		X			soweit noch möglich
Fertig-ware	ESKA-Lager	X				Sicherstellung ESKA Australia nur Index 03 nach Komplettem Tausch der Ware
	Konsigna-tionslager	X				
Ver-kaufte Ware	Klinikware	X				
	Warenrücksen dgn./ Retouren	X				[redacted]
Erstaussttg. Neukunden		☒ Nur Neuware ☐ Mischware neu/alt				
Datum und Unterschrift GL:						[redacted] 15.8.07

Betrifft	Betrifft L[redacted]
Erforderliche Maßnahmen: ☒ Risikoanalyse gem. Anh. I EG-RL 93/42/EWG ☐ Neue Artikelnummer ☒ Zeichngs.-änderung ☒ Alte Zeichng. ungültig ☐ Alte Zeichng. erhalten ☒ Neuer Artikelnummernindex ☒ Instrumentenänderung ☒ Änderung der produktbegl. Dokumentation ☒ Kunden/Händler informieren ☒ Überprüfung der Zulassung ☒ Inland ☒ Ausland ☒ Aktualisierung[1] ☒ Musterbibliothek ☒ Prospektbibliothek ☐ Sonstiges, siehe Anlage [1] in der Verantwortung des Marketings Datum, Unterschrift: [redacted] [redacted]	Zur Kenntnis gen. und Maßnahme eingeleitet, Kürzel/ Datum GL (NA) [redacted] Vertrieb Marketing Q-Wesen Versand Produktio[redacted] Instr.-bau Prod.-Planung Konstruktion Wachserei SoKo Modellbau Q-Manageme[redacted] Schleiferei Gießerei.....

Konstruktionsänderungsbericht - Anlage 1

Bericht-Nr.: **16/07** **Datum:** 02.08.07

Art.-Bez.: Metallkopf Biosurf silver "BS"
AD = 38/44/48 mm

Index: 03

Beschreibung der Änderung:

Der metallische Großkopf Biosurf "BS" mit 12/14er Steckkonus wird seit mehreren Jahren erfolgreich eingesetzt und findet Verwendung in hemiprothetischen Versorgungen, in Paarungen mit Polyethyleninlays und in Metall-Metallpaarungen. Hier ist insbesondere die Möglichkeit der Revision von Kappenprothesen zu nennen, bei der unter Erhalt der Pfannenversorgung auf einen Standard- bzw. Adapterhüftstiel mit einer Großkopf-ME-ME-Paarung umgerüstet werden kann.

Im Jahr 2007 hat ESKA insbesondere aus dem australischen Markt Rückmeldungen über klinische Beschwerden von derart versorgten Patienten erhalten, die von den Klinikern aufgrund anderer fehlender Ansatzpunkte einer Reizung der Iliopsoas-Sehne durch die Kante des Großkopfes zugeordnet werden. Der Mechanismus wird mit den Anwendern weiterhin kontrovers diskutiert, die anatomische Möglichkeit könnte jedoch gegeben sein. Allein diese Vermutung hat uns veranlasst, eine Änderung der Geometrie der Großkopfprodukte einzuleiten.

Des weiteren ist von unseren klinischen Partnern der Wunsch geäußert worden, eine zusätzliche Kopflänge zur Verfügung zu stellen, um eine weitere Option zur Einstellung des Bandapparates zur Stabilisierung der Versorgung zu haben.

Im Rahmen der konstruktiven Überarbeitung wird die Bauhöhe der Großköpfe "BS" nach distal entsprechend H = D/2 + 10 vergrößert, so dass eine großzügige Verrundung möglich wird. Die untere umlaufende Kante der Großkopfprodukte der Durchmesser 38 mm wird mittels eines Radius 7,5 mm (respektive 8 mm bei 44 und 48 mm Durchmesser) verrundet (s. Abb. 1). Die Gestaltung der spezifischen "Biosurf"-Oberfläche ist hiervon nicht betroffen.

Gleichzeitig wird dazu der innere Rezess im Durchmesser von 32 mm auf 24 mm reduziert. Die Radiusumfangsfläche ist nicht Artikulationsfläche im Gelenk und wird daher nicht feingeschliffen. Durch die Vergrößerung der Bauhöhe und die Reduzierung des Rezesses erhöht sich das Gewicht der Großköpfe um 4,5 bis 6%.

Die beschriebene konstruktive Änderung der Großköpfe "BS" beinhaltet zudem, dass der Offsetsprung zwischen der Halslänge medium und short von 3,5 mm auf 2,5 mm verringert wird (s. Abb. 1), d.h. der Mittelpunkt verschiebt sich 1 mm nach proximal.

Diese zusätzliche Änderung ist aufgrund der möglichen Kombination des Großkopfes "BS" mit der Cut "A"-Prothese erforderlich, da es bei der Verwendung eines Großkopfes der Halslänge short sonst zur Kollision mit der Prothese bzw. dem Schenkelhals und somit zu keiner konischen Verklemmung von Kopf und Konusadapter kommen kann.

Durch die Reduzierung des Offsets ist gewährleistet, dass die Kombination mit dem 10° bzw. 20°-Adapter der Größe medium uneingeschränkt möglich ist. Die Kombination eines Großkopfes "BS" der Halslänge short mit Konusadaptern für Cut "A" mit 10° und 20° der Größe short ist aufgrund der oben beschriebenen Begebenheit zukünftig nicht mehr möglich.

Die Produktgruppe der Großköpfe 38, 44 und 48 mm in short, medium und long wird durch jeweils eine x-long-Version ergänzt, bei der der innere Konus um 3,5mm versetzt gefertigt wird. Durch diese Ergänzung wird im Vergleich zum Produkt XL-28 und XL-32mm-Kopf keine kritische Erhöhung der Länge und damit auch keine maßgebliche Steigerung der Biegebeanspruchung der Prothese erzeugt, da die Großköpfe konstruktiv bereits 2,5 mm „kürzer" als die 28 und 32 mm-Köpfe ausgeführt sind (s. Abb. 2). Somit ist auch der Wunsch der Anwender nach der Option der Halslänge XL zu erklären.

Für die veränderte Ausführung der Großköpfe "BS" sowie für die zusätzliche Halslänge XL sind neue Probeköpfe für das Instrumentarium herzustellen. Zur Information der Anwender über die Einschränkung der Verwendung des short-Großkopfes "BS" mit dem Cut "A" in Kombination mit einem short-Konusadapter ist ein entsprechender Anwenderhinweis zu erstellen.

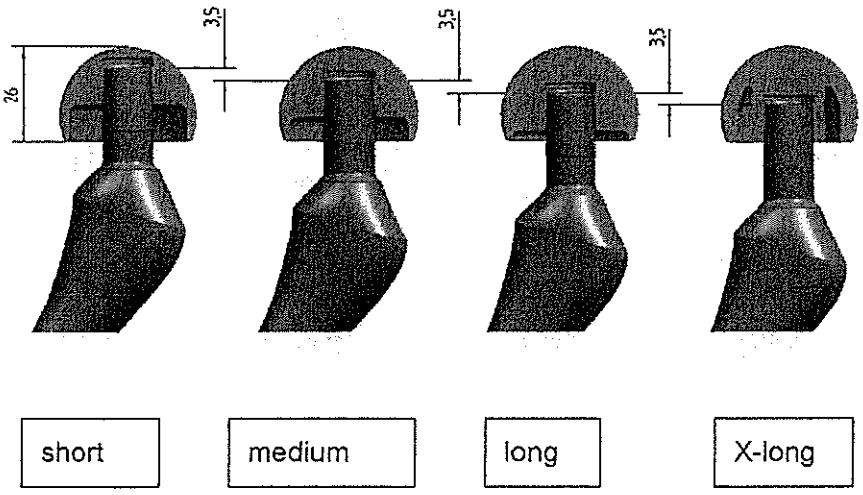
Die vorliegende Änderung verursacht kein zusätzliches oder erhöhtes Risiko bei der Herstellung, Handhabung oder Anwendung. Durch die Änderung werden aktuellen Erkenntnissen Rechnung getragen, um so die Produktqualität und –sicherheit zu erhöhen.

Das Risiko durch die eingeschränkte Verwendung der Großköpfe short mit der Schenkelhalsprothese Cut "A" kann durch eine umfassende Information der Anwender und durch Zusatzinformationen zum Produkt minimiert werden.

Modifizierung Metallköpfe Biosurf „BS“
Ø38, Ø44, Ø48

Ausfertigung „ALT“ (Index 02): (Beispiel Ø38)

H=26, Größensprung 3.5mm



Ausfertigung „NEU“ (Index 03): (Beispiel Ø38)

H=D/2 + 10 = 29 (Beispiel Ø38), Größensprung von short zu medium 2.5mm, weitere 3.5 mm

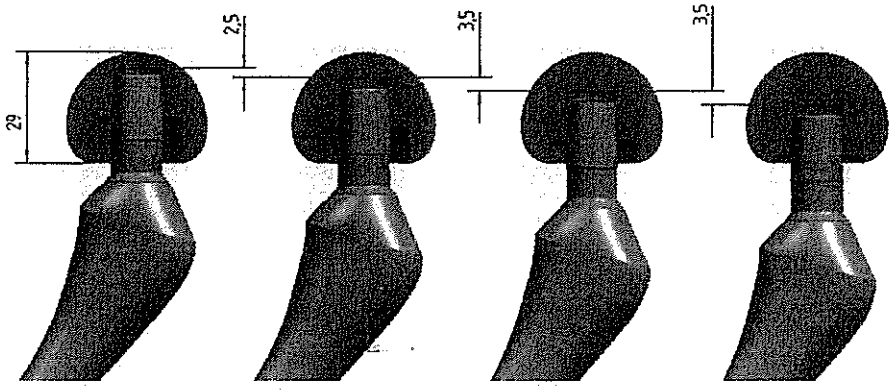


Abb. 1: Vergleichende Darstellung der neuen (Index 03) zur alten Ausführung (Index 02) (Darstellung Metallkopf silver "BS")

Modifizierung Metallköpfe Biosurf „BS“
Ø38, Ø44, Ø48

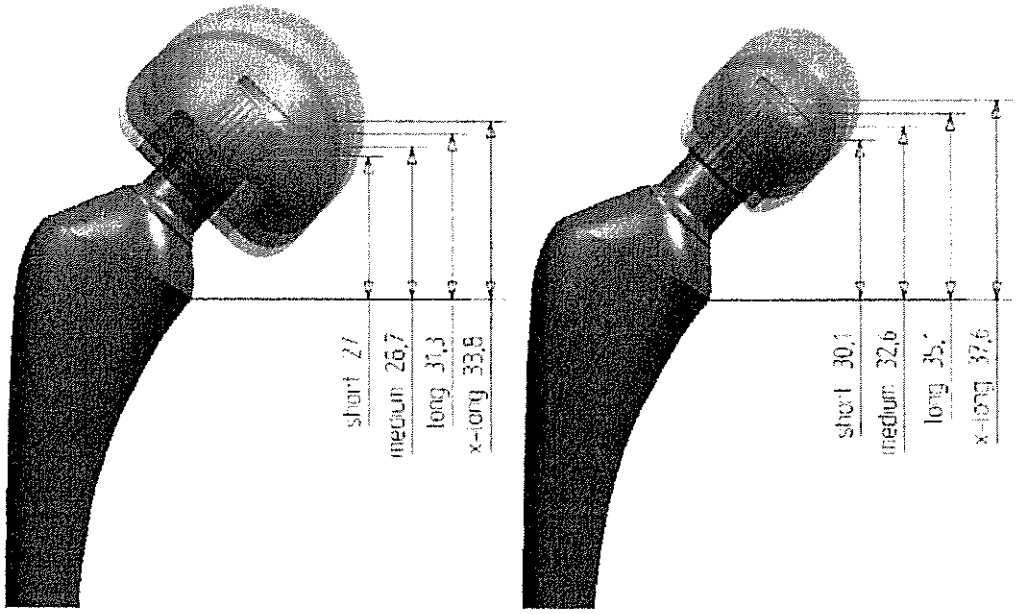


Abb. 2: Vergleich der Offset-Maße für verschiedene Halslängen beim Metallkopf "BS" und Standardkopf (∅ 28/32 mm)

Artikel - Übersicht

Artikel	Bezeichnung	Größe Seite	Fert.-KZ
10250138 10250138	METALLKOPF BIOSURF SILVER "BS" K12/14 AD=38MM	SHORT	
10250144 10250144	METALLKOPF BIOSURF SILVER "BS" K12/14 AD=44MM	SHORT	
10250148 10250148	METALLKOPF BIOSURF SILVER "BS" K12/14 AD=48MM	SHORT	
10250238 10250238	METALLKOPF BIOSURF SILVER "BS" K12/14 AD=38MM	MEDIUM	
10250244 10250244	METALLKOPF BIOSURF SILVER "BS" K12/14 AD=44MM	MEDIUM	
10250248 10250248	METALLKOPF BIOSURF SILVER "BS" K12/14 AD=48MM	MEDIUM	
10250338 10250338	METALLKOPF BIOSURF SILVER "BS" K12/14 AD=38MM	LONG	
10250344 10250344	METALLKOPF BIOSURF SILVER "BS" K12/14 AD=44MM	LONG	
10250348 .0250348	METALLKOPF BIOSURF SILVER "BS" K12/14 AD=48MM	LONG	
10250438 10250438	METALLKOPF BIOSURF SILVER "BS" K12/14 AD=38MM	X-LONG	
10250444 10250444	METALLKOPF BIOSURF SILVER "BS" K12/14 AD=44MM	X-LONG	
10250448 10250448	METALLKOPF BIOSURF SILVER "BS" K12/14 AD=48MM	X-LONG	

Dahlke

Von: Heißenberg
Gesendet: Montag, 30. Juli 2007 12:58
An: Alscher; Apelt; Baasch; Bertram; Dahlke; Eisenblätter; Foerster; Frank; Goegel; Goetze; Günther; Hahm; Hennig; Knorr; Kock; Krey; Krezic; Krotowski Fr.; Krotowski Hr.; Kwasniok; Liebsch; Lohrke; Nassutt; Okonnek; Reiher; Riechert; Rieck; Roßteutscher; Schlupp; Schmidt; Schmitz; Schröder; Schuett; Setzke; Silberstorff; Sperfeld; Tzola; Wenskus; Wittler; Wordell; Borchert; Treyde; QSInstru; Hunger
Betreff: Artikelanlage Großköpfe "BS"

Das Sortiment der Großköpfe wird mit der Kopfhalslänge "X-Long" erweitert.

Herr Wittler: Bitte um Freigabe der Liefersperre

ARTNR	ETIBEZ1	ETIBEZ2		GROESSE	SEITE
10252438	METALLKOPF SILVER "BS"	K12/14	AD=38MM	X-LONG	
10252444	METALLKOPF SILVER "BS"	K12/14	AD=44MM	X-LONG	
10252448	METALLKOPF SILVER "BS"	K12/14	AD=48MM	X-LONG	
10250438	METALLKOPF BIOSURF SILVER "BS"	K12/14	AD=38MM	X-LONG	
10250444	METALLKOPF BIOSURF SILVER "BS"	K12/14	AD=44MM	X-LONG	
10250448	METALLKOPF BIOSURF SILVER "BS"	K12/14	AD=48MM	X-LONG	

ESKA IMPLANTS

Anlage zum Änderungsbericht Nr.: 16/07

Die Änderung betrifft:	***=> bitte jeweils ankreuzen***	**ja**	**nein**
I. ALLGEMEINE ANFORDERUNGEN			
1.	PRODUKTAUSLEGUNG	X	
2.	PRODUKTSICHERHEIT	X	
3.	PRODUKTAUSLEGUNG, LEISTUNG UND FUNKTION	X	
4.	RISKANTE ÄNDERUNG DER PRODUKTEIGENSCHAFTEN WÄHREND DER LEBENSDAUER		X
5.	LAGERUNG UND TRANSPORT		X
6.	UNERWÜNSCHTE NEBENWIRKUNGEN		X
II. ANFORDERUNGEN AN DIE AUSLEGUNG UND KONSTRUKTION			
7. CHEMISCHE, PHYSIKALISCHE und BIOLOGISCHE EIGENSCHAFTEN			
7.1	Werkstoffauswahl - Toxizität, Biokompatibilität		X
7.2	Schadstoffarmut		X
7.3	Risiken bei Lagerung, Transport und Anwendung		X
7.4	Arzneimittel auf dem Produkt		X
7.5	Entweichende Stoffe		X
7.6	Eindringen von Fremdstoffen		X
8. INFEKTION UND MIKROBIELLE KONTAMINATION			
8.1	Infektionsrisiko durch Herstellungsverfahren und Produktauslegung		X
8.2	(Tierisches Gewebe)		X
8.3	Aufrechterhaltung der Sterilität		X
8.4.	Validierung des Herstellungsverfahrens steril ausgelieferter Produkte		X
8.5	Voraussetzung für die Sterilisation - sterile Produkte		X
8.6	Voraussetzung für die Sterilisation - unsterile Produkte		X
8.7.	Steril-Kennzeichnung		X
9. EIGENSCHAFTEN IM HINBLICK AUF DIE KONSTRUKTION UND DIE UMGEBUNGS-BEDINGUNGEN			
9.1	Verbindungsstelle zu Anschlussprodukten	X	
9.2	Risikominimierung	X	
9.3	(Brand- und Explosionsrisiko)		X
10. PRODUKTE MIT MESSFUNKTION			
10.1	Messtoleranzen		X
10.2	Ablese-Ergonomie		X
10.3	Gesetzliche Einheiten		X
11. SCHUTZ VOR STRAHLUNGEN			

Checkliste Grundlegende Änderungen

ESKA IMPLANTS

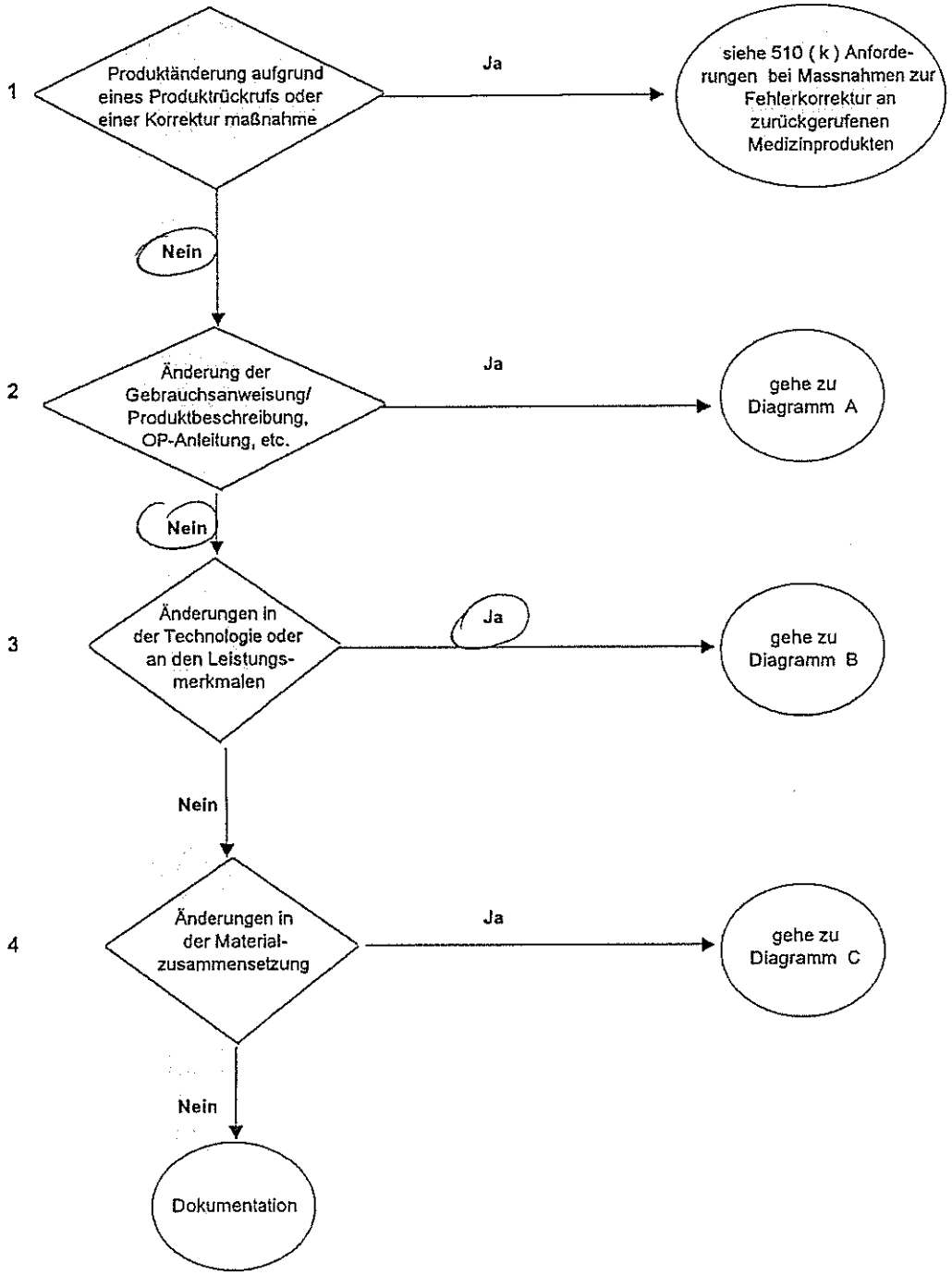
Anlage zum Änderungsbericht Nr.: 16/07

Die Änderung betrifft:	***=> bitte jeweils ankreuzen***	**ja**	**nein**
12. ANFORDERUNGEN AN PRODUKTE MIT EXTERNER ODER INTERNER ENERGIEQUELLE			
12.7	Schutz vor mechanischen und thermischen Risiken		X
12.7.1	Festigkeit und Stabilität, bewegliche Teile		X
12.7.2	Schwingungsdämpfung		X
12.7.3	Lärmreduzierung		X
12.7.4	Anschlüsse für externe Energiequellen		X
12.7.5	Schutz vor Wärme		X
12.8	Schutz vor Risiken infolge der Abgabe von Energie oder Stoffen an den Patienten		X
12.8.1	Justierung der Stoffabgabe		X
12.8.2	Störungsalarm		X
12.9	Markierung von Bedienungseinrichtungen		X
13. BEREITSTELLUNG VON INFORMATIONEN DURCH DEN HERSTELLER			
13.1	Kennzeichnung, Gebrauchsanweisung	X	
13.2	Symbole		X
13.3	Kennzeichnung		X
13.4	Zweckbestimmung		X
13.5	Identifizierung	X	
13.6	Inhalt der Gebrauchsanweisung	X	
14. KLINISCHE PRÜFUNG UNERWÜNSCHTER NEBENWIRKUNGEN			
Für jede der o.g. Fragestellungen, die mit "ja" beantworten wurde, ist für den entsprechenden Abschnitt der Risikoanalyse eine erneute Bewertung durchzuführen. Ist demnach eine Neubewertung erforderlich?		X	
FDA-Anforderungen: Grundlegende Aspekte der Sicherheit und Funktion des/der Produkte(s) sind betroffen => Eine neue/ erweiterte/ geänderte 510(k)- Zulassung ist erforderlich !			X

[redacted]

Anlage zu Bericht Nr.: 16107

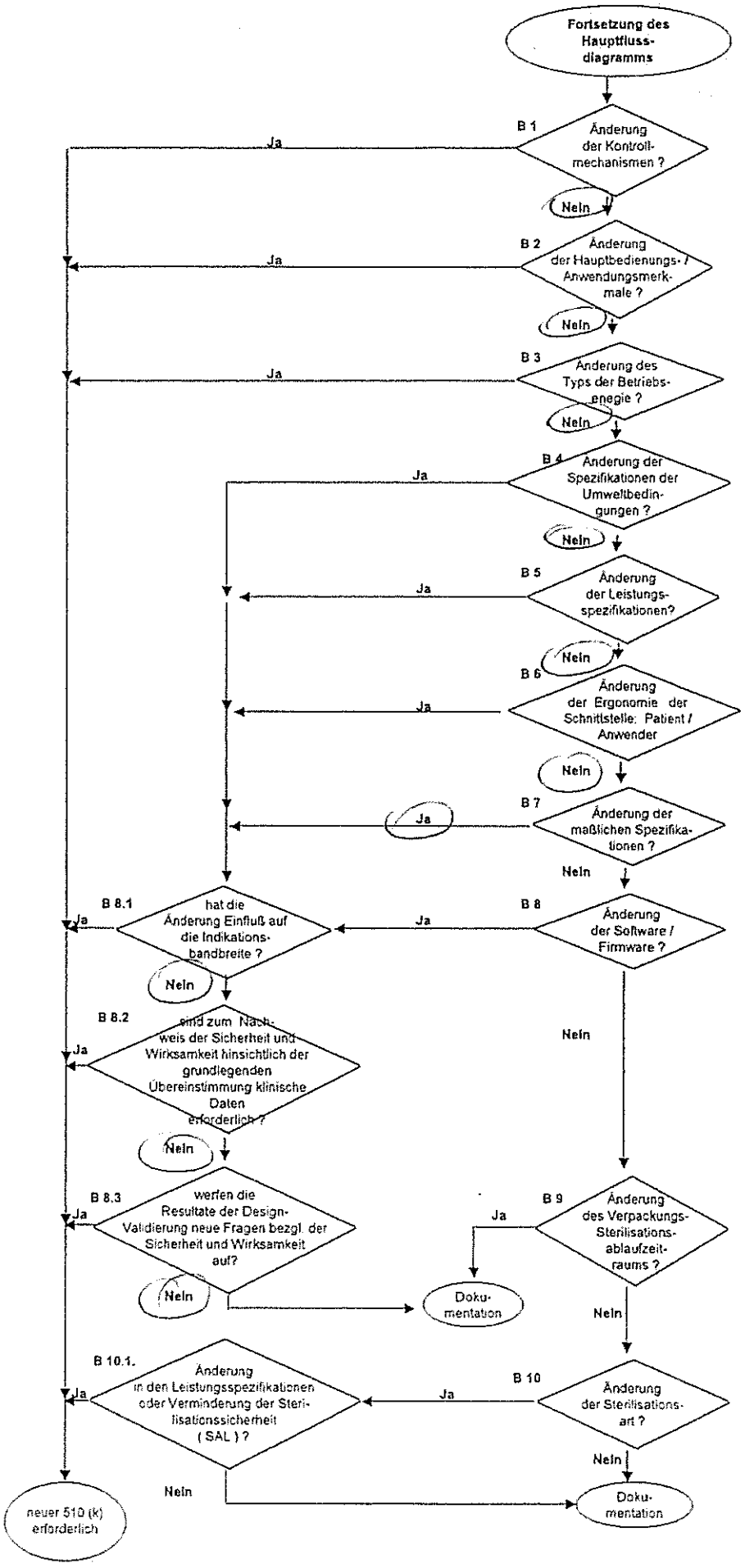
HAUPT - FLUSSDIAGRAMM ZUR ENTSCHEIDUNGSFINDUNG HINSICHTLICH EINER 510 (k) ZULASSUNGSERWEITERUNG NACH ÄNDERUNG EINES ZUGELASSENEN MEDIZINPRODUKTES



16107

097

FLUSSDIAGRAM "B" : LIEGEN ÄNDERUNGEN IN DER TECHNOLOGIE ODER DEN LEISTUNGSMERKMALEN VOR ?



Bionik Total Conventional Hip Acetabular Prosthesis

This analysis compares the Bionik Total Conventional Hip Acetabular Prosthesis with all Other Total Conventional Hip prostheses. This Acetabular Prosthesis 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 Conventional Hip Replacement

The ***Revision Rate*** of the Bionik Total Conventional Hip Acetabular Prosthesis is compared to all Other Total Conventional Hip prostheses.

Table 1: Revision Rates of Primary Total Conventional Hip Replacement

Component	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Bionik	28	565	1103	2.54 (1.69, 3.67)
Other Total Conventional Hip	5049	170539	651215	0.78 (0.75, 0.80)
TOTAL	**5077**	**171104**	**652317**	**0.78 (0.76, 0.80)**

TABLE 2

Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement

The ***Yearly Cumulative Percent Revision*** of the Bionik Total Conventional Hip Acetabular Prosthesis is compared to all Other Total Conventional Hip prostheses.

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

CPR	1 Yr	3 Yrs	5 Yrs	7 Yrs	9 Yrs
Bionik	3.2 (2.0, 5.2)	6.9 (4.6, 10.2)			
Other Total Conventional Hip	1.5 (1.5, 1.6)	2.7 (2.6, 2.8)	3.5 (3.4, 3.6)	4.4 (4.3, 4.5)	5.4 (5.1, 5.7)

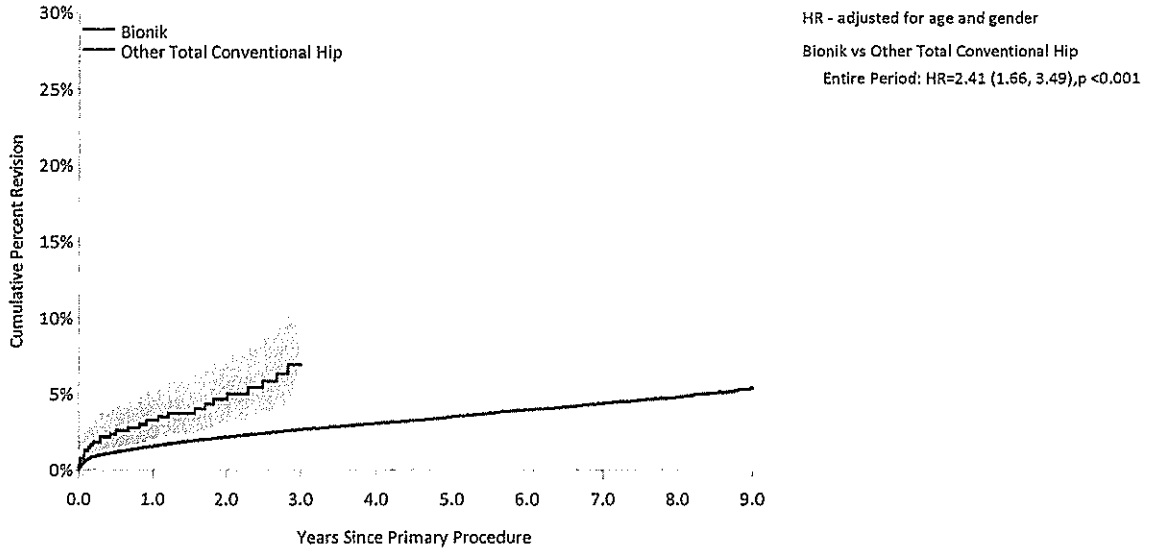
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement

The ***Yearly Cumulative Percent Revision*** of the Bionik Total Conventional Hip Acetabular Prosthesis is compared to all Other Total Conventional 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 Conventional 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	565	412	267	132	10	0	0	0	0	0
Other Total Conventional Hip	170539	142248	117869	96119	75962	57166	40037	24821	11582	2968

TABLE 3

Primary Diagnosis for Revised Primary Total Conventional 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 Conventional Hip prostheses.

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

	Bionik		Other Total Conventional Hip	
Primary Diagnosis	Number	Percent	Number	Percent
Osteoarthritis	27	96.4	4257	84.3
Avascular Necrosis			253	5.0
Fractured Neck Of Femur	1	3.6	249	4.9
Rheumatoid Arthritis			96	1.9
Developmental Dysplasia			87	1.7
Failed Internal Fixation			32	0.6
Tumour			32	0.6
Other Inflammatory Arthritis			29	0.6
Fracture/Dislocation			7	0.1
Arthrodesis Takedown			5	0.1
Other			2	0.0
TOTAL	**28**	**100.0**	**5049**	**100.0**

TABLE 4

Revision Rates of Bionik Primary Total Conventional 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 Primary Total Conventional Hip Replacement by Fixation

Fixation	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Cemented	0	2	5	0.00 (0.00, 76.12)
Cementless	22	481	942	2.34 (1.46, 3.54)
Hybrid	6	82	156	3.85 (1.41, 8.37)
TOTAL	**28**	**565**	**1103**	**2.54 (1.69, 3.67)**

TABLE 5

Revision Rates of* Bionik *Primary* Total Conventional Hip *Replacement by Bearing Surface.

This analysis is provided as some prostheses are combined with a variety of different bearing surfaces. All bearing surfaces used with this Acetabular Prosthesis are listed.

Table 5: Revision Rates of Bionik Primary Total Conventional Hip Replacement by Bearing Surface

Bearing Surface	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Ceramic/Ceramic	1	8	4	25.87 (0.65, 144.1)
Ceramic/Polyethylene	1	43	75	1.33 (0.03, 7.38)
Metal/Metal	22	418	885	2.49 (1.56, 3.77)
Metal/Polyethylene	4	96	139	2.88 (0.78, 7.37)
TOTAL	**28**	**565**	**1103**	**2.54 (1.69, 3.67)**

TABLE 6

Type of Revision Performed for Primary Total Conventional Hip Replacement

This analysis identifies the components used in the revision of the Bionik Total Conventional Hip Acetabular Prosthesis and compares it to the components used in the revision of all Other Total Conventional 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 Conventional Hip prostheses i.e. is there a difference in the type of revision undertaken for the Bionik Total Conventional Hip Acetabular Prosthesis compared to all Other Total Conventional Hip prostheses.

Table 6: Primary Total Conventional Hip Replacement - Type of Revision

	Bionik		Other Total Conventional Hip	
Revision Type	Number	Percent	Number	Percent
Femoral Only	7	25.0	1481	29.3
Acetabular Only	5	17.9	1260	25.0
THR (Femoral/Acetabular)	4	14.3	623	12.3
Cement Spacer	1	3.6	244	4.8
Removal of Prostheses			41	0.8
Reinsertion of Components			6	0.1
Bipolar Head and Femoral			2	0.0
Saddle			2	0.0
N Major	**17**	**60.7**	**3659**	**72.5**
Head/Insert	7	25.0	920	18.2
Head Only	1	3.6	285	5.6
Minor Components			82	1.6
Insert Only	1	3.6	70	1.4
Head/Neck	2	7.1	30	0.6
Neck Only			2	0.0
Neck/Insert			1	0.0
N Minor	**11**	**39.3**	**1390**	**27.5**
TOTAL	**28**	**100.0**	**5049**	**100.0**

TABLE 7

Reason for Revision of Primary Total Conventional 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 Conventional 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 Total Conventional Hip Acetabular Prosthesis and all Other Total Conventional Hip prostheses.

Table 7: Primary Total Conventional Hip Replacement - Reason for Revision

	Bionik			Other Total Conventional Hip		
Revision Diagnosis	**Number**	**% Revision**	**% Primary**	**Number**	**% Revision**	**% Primary**
Loosening/Lysis	7	25.0	1.2	1512	29.9	0.9
Prosthesis Dislocation	7	25.0	1.2	1393	27.6	0.8
Infection	3	10.7	0.5	843	16.7	0.5
Fracture	2	7.1	0.4	742	14.7	0.4
Pain	5	17.9	0.9	99	2.0	0.1
Other				67	1.3	0.0
Leg Length Discrepancy	1	3.6	0.2	63	1.2	0.0
Metal Sensitivity	1	3.6	0.2	61	1.2	0.0
Malposition				54	1.1	0.0
Wear Acetabulum	1	3.6	0.2	51	1.0	0.0
Implant Breakage Stem				35	0.7	0.0
Implant Breakage Acetabular	1	3.6	0.2	32	0.6	0.0
Incorrect Sizing				29	0.6	0.0
Instability				28	0.6	0.0
Implant Breakage Head				20	0.4	0.0
Heterotopic Bone				8	0.2	0.0
Tumour				8	0.2	0.0
Avascular Necrosis				2	0.0	0.0
Synovitis				2	0.0	0.0
N Revision	**28**	**100.0**	**5.0**	**5049**	**100.0**	**3.0**
N Primary	***565***			**170539**		

FIGURE 2

Revision Diagnosis Cumulative Incidence by Time to Revision for Primary Total Conventional 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 Total Conventional Hip Acetabular Prosthesis . A comparative graph is provided of the cumulative incidence for the same reasons for revisions for all Other Total Conventional Hip prostheses.

Figure 2: Cumulative Incidence Revision Diagnosis for Primary Total Conventional Hip Replacement

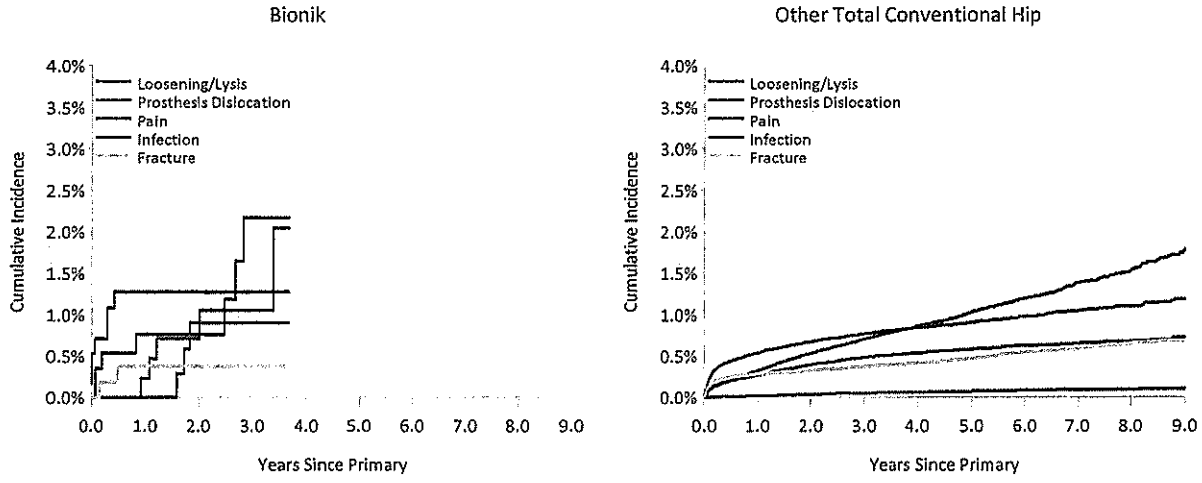


TABLE 8

Revision Rates of Primary Total Conventional Hip Replacement by State

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

This analysis is undertaken for similar reasons as those outlined above for Table 8.

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

Component	State	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Bionik	NSW	18	306	610	2.95 (1.75, 4.67)
Bionik	VIC	3	75	145	2.07 (0.43, 6.04)
Bionik	QLD	1	20	55	1.81 (0.05, 10.08)
Bionik	WA	0	22	11	0.00 (0.00, 32.84)
Bionik	SA	0	5	5	0.00 (0.00, 69.02)
Bionik	TAS	6	136	276	2.18 (0.80, 4.74)
Bionik	ACT/NT	0	1	0	0.00 (0.00, 1773)
Other Total Conventional Hip	NSW	1401	50349	180275	0.78 (0.74, 0.82)
Other Total Conventional Hip	VIC	1378	46238	176180	0.78 (0.74, 0.82)
Other Total Conventional Hip	QLD	867	27406	105373	0.82 (0.77, 0.88)
Other Total Conventional Hip	WA	647	18995	76125	0.85 (0.79, 0.92)
Other Total Conventional Hip	SA	462	17571	74846	0.62 (0.56, 0.68)
Other Total Conventional Hip	TAS	162	6112	24253	0.67 (0.57, 0.78)
Other Total Conventional Hip	ACT/NT	132	3868	14161	0.93 (0.78, 1.11)
TOTAL		**5077**	**171104**	**652317**	**0.78 (0.76, 0.80)**

TABLE 9

Number of Revisions of Bionik Primary Total Conventional Hip Replacement by Year of Implant

This analysis details the number of prostheses reported each year to the Registry for the Bionik Total Conventional Hip Acetabular Prosthesis. 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 Primary Total Conventional Hip Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2005	0	11
2006	13	147
2007	6	136
2008	5	137
2009	4	134
TOTAL	**28**	**565**

TABLE 10

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

	Catalogue Range	Catalogue Description
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
Bionik	10202154-10202164	METAL SHELL CEMENTLESS DYSPL. TINB C. SCREW FIX

Acetabular Range	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
10201050-10201064	1	23	54	1.84 (0.05, 10.23)
10201150-10201164	6	126	271	2.22 (0.81, 4.83)
10201248-10201264	4	52	101	3.95 (1.08, 10.12)
10201346-10201366	17	361	672	2.53 (1.47, 4.05)
10202154-10202164	0	3	4	0.00 (0.00, 87.78)
TOTAL	**28**	**565**	**1103**	**2.54 (1.69, 3.67)**

TABLE 11

Revision rates of Bionik Primary Total Conventional Hip Replacement by Component

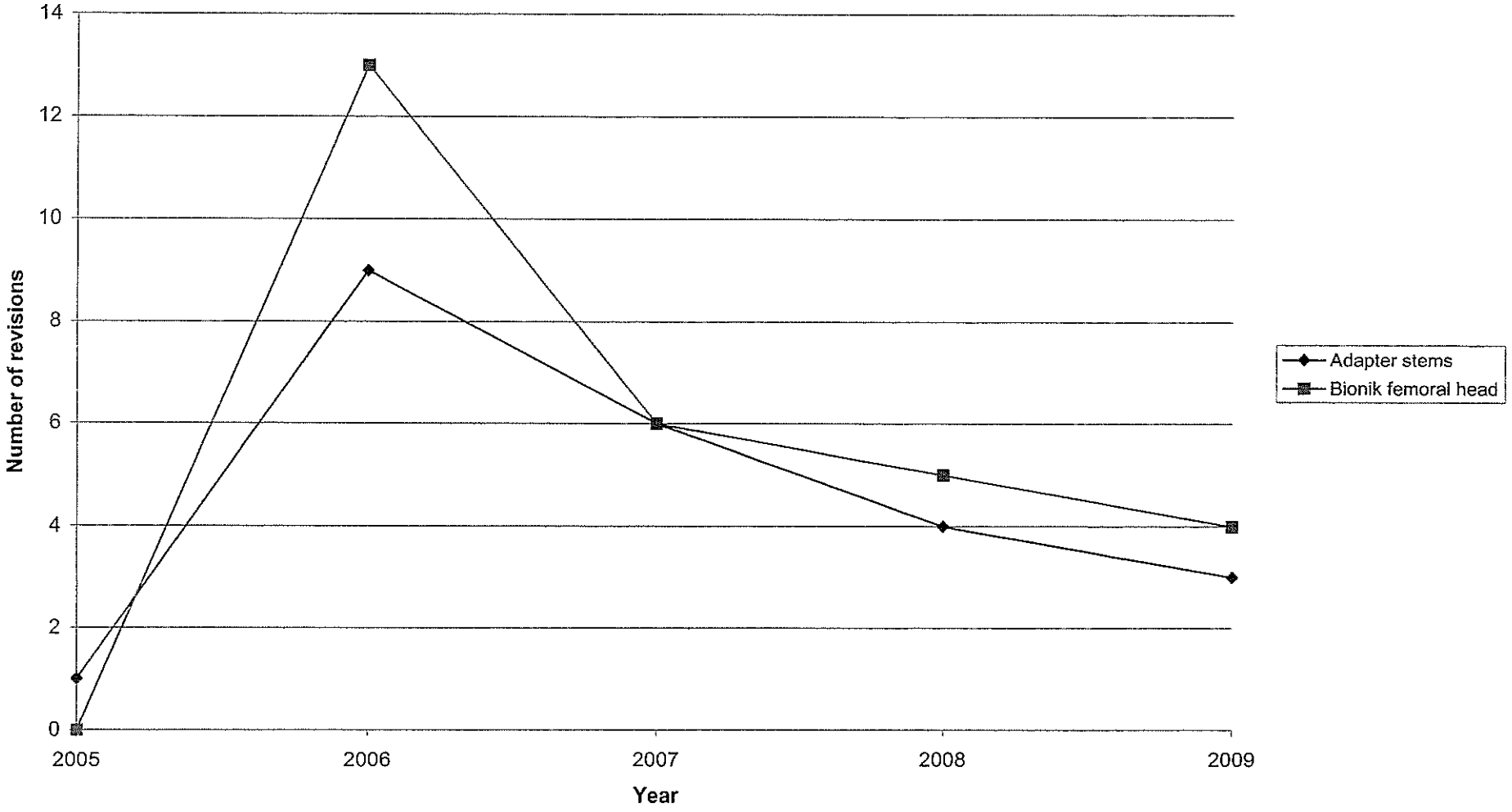
A prosthesis may be combined with multiple components.

This analysis has been undertaken to determine if the revision rate varies according to the component with which it is combined.

Table 11: Revision Rates of Bionik Primary Total Conventional Hip Replacement by Femoral Stem Component

Femoral Stem Component	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Adapter	27	560	1097	2.46 (1.62, 3.58)
Corail	0	1	0	0.00 (0.00, 806.8)
Custom Made (Eska)	0	1	1	0.00 (0.00, 246.8)
Edinburgh	0	1	3	0.00 (0.00, 128.1)
K2	1	1	0	1304.46 (33.03, 7268)
S-Rom	0	1	1	0.00 (0.00, 687.4)
TOTAL	**28**	**565**	**1103**	**2.54 (1.69, 3.67)**

Graph comparing revisions of Adapter stems and Bionik femoral heads



FB Konstruktionsänderungsbericht

ESKA IMPLANTS

Betrifft QS und Konstruktion	Betrifft Betriebsleitung
Bericht Nr.: 09/06	**Datum:** 15.05.2006
Art.-Bez.: Metall-Inlay "BS"	**Unterschrift:** [redacted]
Index: _01_____ **ACHTUNG!** Index der ges. Prod.-Gr. dem neuen Index anpassen	**Art.-Nr(n).:** siehe Anlage
Veranlasst durch: Dr. Grundei	

Art der Änderung (Beschreibung/Begr. siehe Anlagen)	Anlagen
☐ Änderung der Bezeichnung ☒ Konstruktive Änderung ☐ Funktionelle Änderung	☐ Zeichnung ☒ Skizze ☒ Andere:_____

Betrifft Geschäftsleitung: *Maßnahmen zur Lagerbereinigung*		Auf-brauchen	Nach-arbeiten.	Vernich-ten	Nicht anwend-bar	Anmerkungen / Bestätigung der Maßnahme
Vorpro-duktion	Wachse				X	
	Belegte Wachse				X	
	Wachsformen				X	
Pro-duk-tion	Rohware				X	[redacted]
	WIP		X			
Fertig-ware	ESKA-Lager	X				
	Konsigna-tionslager	X				
Ver-kaufte Ware	Klinikware	X				22. MAI 2006
	Warenrücksen dgn./ Retouren	X				
Erstaussttg. Neukunden	☒ Nur Neuware ☐ Mischware neu/alt					[redacted]
	Datum und Unterschrift GL:					23. MAI 2006

Betrifft Betriebsleitung	Betrifft Leitend
Erforderliche Maßnahmen: ☐ Risikoanalyse gem. Anh. I EG-RL 93/42/EWG ☐ Neue Artikelnummer ☒ Zeichngs.-änderung ☐ Alte Zeichng. ungültig ☐ Alte Zeichng. Erhalten ☒ Neuer Artikelnummernindex ☐ Instrumentenänderung ☒ Änderung der produktbegl. Dokumentation ☒ Kunden/Händler informieren ☐ Überprüfung der Zulassung ☐ Inland ☐ Ausland* ☒ Aktualisierung [1] ☐ Musterbibliothek ☐ Prospektbibliothek ☐ Sonstiges, siehe Anlage [1] in der Verantwortung des Marketings Datum, Unterschrift: [redacted]	Zur Kenntnis gen [redacted] Assist. GL Vertrieb Marketing Q-Wesen Versand Produktion Instr.-bau Prod.-Planung Konstruktion Wachserei SoKo Modellbau Q-Managemei Schleiferei *.....

Konstruktionsänderungsbericht - Anlage 1

Bericht-Nr.: **09/06** **Datum:** 15.05.06

Art.-Bez.: Metall-Inlay "BS"

Index: 01

Beschreibung der Änderung:

Aus den operativen Erfahrungen ist die Notwendigkeit konstruktiver Korrekturen für das Metall-Inlay "BS" abgeleitet worden. Zum sicheren intraoperativen Setzen der Inlays wird am Boden ein Zapfen als Zentrierhilfe vorgesehen, der in die Gewindebohrung des Metallsockels eingeführt wird und ein Verkippen der Inlays verhindert (Abb. 1). Die konstruktive Ausführung des Zapfens erfolgt in Anlehnung an das PE-Inlay "BS" unter Berücksichtigung der Bauhöhendifferenz der Inlays.

Intraoperativ entfällt bei Verwendung eines Metallinlays mit Zapfen (Index 01) die Verschlußschraube für den Metallsockel "BS".

Konstruktionsänderungsbericht - Anlage 2

Bericht-Nr.: **09/06 - Nachtrag** **Datum:** 20.07.2006

Art.-Bez.: Metall-Inlay "BS"

Index: 01

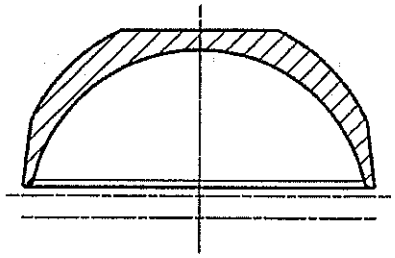
Beschreibung der Änderung:

Der **Index 00** bleibt aus zulassungstechnischen Gründen für den **australischen Markt** vorerst gültig.

[redacted]

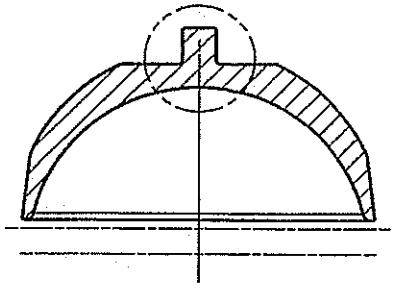
Metall-Inlay Silver "BS"

Fertigungsindex 00



Metall-Inlay Silver "BS"

Fertigungsindex 01



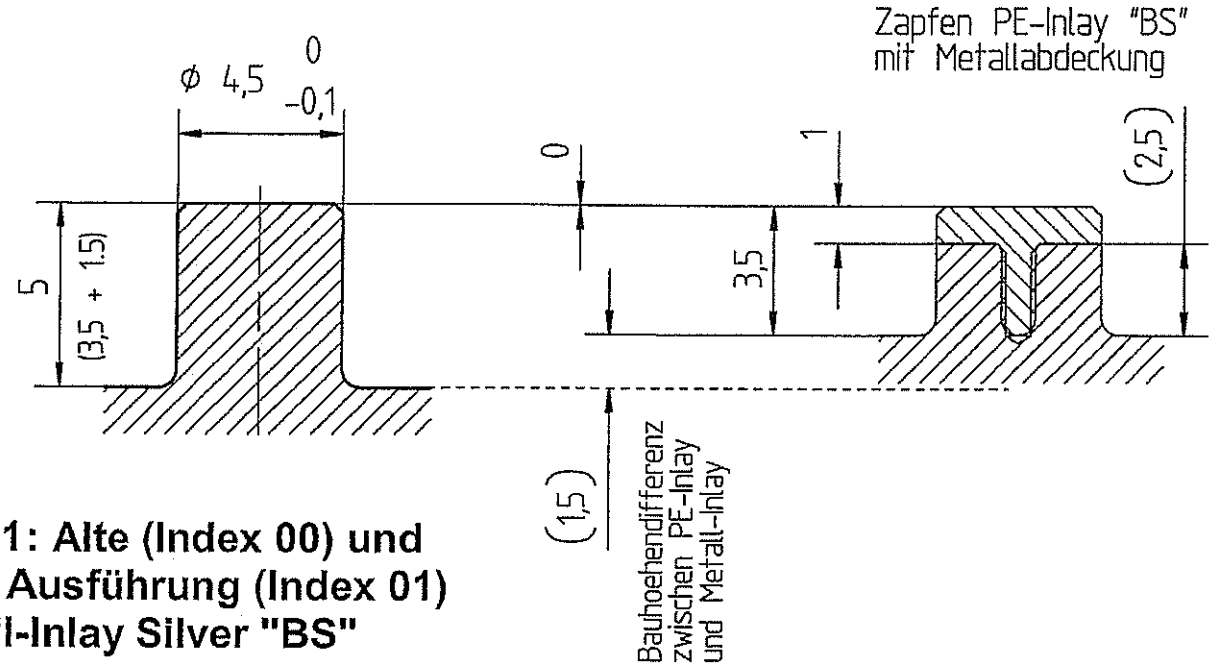


Abb. 1: Alte (Index 00) und neue Ausführung (Index 01) Metall-Inlay Silver "BS"

Artikel - Übersicht

Artikel	Bezeichnung		Größe Seite
10220038 79110038	METALL-INLAY SILVER FÜR AD=46MM	"BS"	ID=38MM
10220040 79110040	METALL-INLAY SILVER FÜR AD=48MM	"BS"	ID=40MM
10220042 79110042	METALL-INLAY SILVER FÜR AD=50MM	"BS"	ID=42MM
10220044 79110044	METALL-INLAY SILVER FÜR AD=52MM	"BS"	ID=44MM
10220046 79110046	METALL-INLAY SILVER FÜR AD=54MM	"BS"	ID=46MM
10220048 79110048	METALL-INLAY SILVER FÜR AD=56MM	"BS"	ID=48MM
10220050 79110050	METALL-INLAY SILVER FÜR AD=58MM	"BS"	ID=50MM
10220052 79110052	METALL-INLAY SILVER FÜR AD=60MM	"BS"	ID=52MM
10220054 79110054	METALL-INLAY SILVER FÜR AD=62MM	"BS"	ID=54MM
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10224838 79114838	METALL-INLAY SILVER FÜR AD=48MM	"BS"	ID=38MM
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Checkliste Grundlegende Änderungen

ESKA IMPLANTS

Anlage zum Änderungsbericht Nr.: 09/06

Die Änderung betrifft:	*=> bitte jeweils ankreuzen*	ja	nein
I. ALLGEMEINE ANFORDERUNGEN			
1.	PRODUKTAUSLEGUNG	X	
2.	PRODUKTSICHERHEIT		X
3.	PRODUKTAUSLEGUNG, LEISTUNG UND FUNKTION		X
4.	RISKANTE ÄNDERUNG DER PRODUKTEIGENSCHAFTEN WÄHREND DER LEBENSDAUER		X
5.	LAGERUNG UND TRANSPORT		X
6.	UNERWÜNSCHTE NEBENWIRKUNGEN		X
II. ANFORDERUNGEN AN DIE AUSLEGUNG UND KONSTRUKTION			
7. CHEMISCHE, PHYSIKALISCHE und BIOLOGISCHE EIGENSCHAFTEN			
7.1	Werkstoffauswahl - Toxizität, Biokompatibilität		X
7.2	Schadstoffarmut		X
7.3	Risiken bei Lagerung, Transport und Anwendung		X
7.4	Arzneimittel auf dem Produkt		X
7.5	Entweichende Stoffe		X
7.6	Eindringen von Fremdstoffen		X
8. INFEKTION UND MIKROBIELLE KONTAMINATION			
8.1	Infektionsrisiko durch Herstellungsverfahren und Produktauslegung		X
8.2	(Tierisches Gewebe)		X
8.3	Aufrechterhaltung der Sterilität		X
8.4.	Validierung des Herstellungsverfahrens steril ausgelieferter Produkte		X
8.5	Voraussetzung für die Sterilisation - sterile Produkte		X
8.6	Voraussetzung für die Sterilisation - unsterile Produkte		X
8.7.	Steril-Kennzeichnung		X
9. EIGENSCHAFTEN IM HINBLICK AUF DIE KONSTRUKTION UND DIE UMGEBUNGS-BEDINGUNGEN			
9.1	Verbindungsstelle zu Anschlussprodukten	X	
9.2	Risikominimierung	X	
9.3	(Brand- und Explosionsrisiko)		X
10. PRODUKTE MIT MESSFUNKTION			
10.1	Messtoleranzen		X
10.2	Ablese-Ergonomie		X
10.3	Gesetzliche Einheiten		X
11. SCHUTZ VOR STRAHLUNGEN			X

Checkliste Grundlegende Änderungen

ESKA IMPLANTS

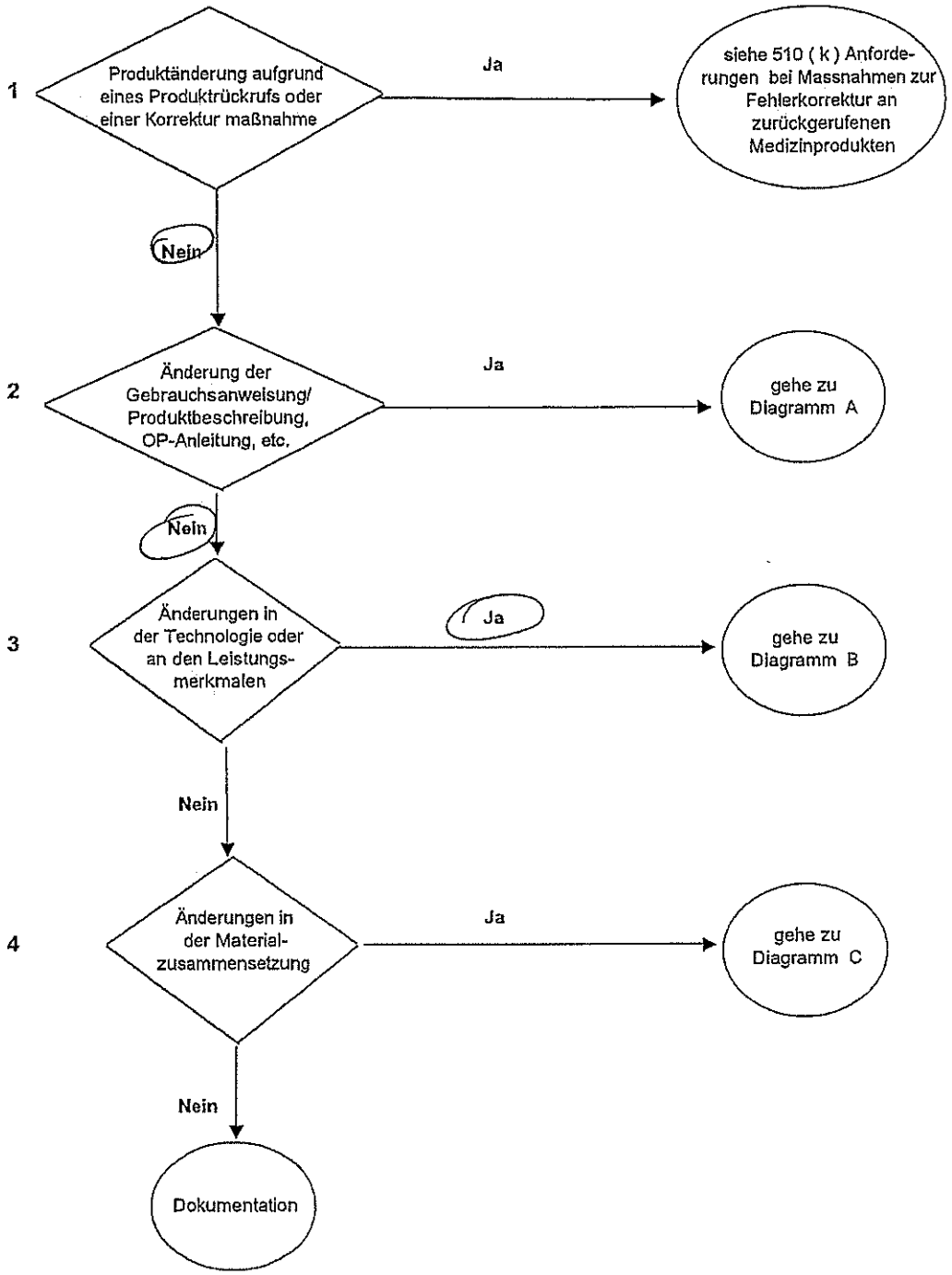
Anlage zum Änderungsbericht Nr.: 09/06

Die Änderung betrifft:	***=> bitte jeweils ankreuzen***	**ja**	**nein**
12. ANFORDERUNGEN AN PRODUKTE MIT EXTERNER ODER INTERNER ENERGIEQUELLE			
12.7	Schutz vor mechanischen und thermischen Risiken		X
12.7.1	Festigkeit und Stabilität, bewegliche Teile		X
12.7.2	Schwingungsdämpfung		X
12.7.3	Lärmreduzierung		X
12.7.4	Anschlüsse für externe Energiequellen		X
12.7.5	Schutz vor Wärme		X
12.8	Schutz vor Risiken infolge der Abgabe von Energie oder Stoffen an den Patienten		X
12.8.1	Justierung der Stoffabgabe		X
12.8.2	Störungsalarm		X
12.9	Markierung von Bedienungseinrichtungen		X
13. BEREITSTELLUNG VON INFORMATIONEN DURCH DEN HERSTELLER			
13.1	Kennzeichnung, Gebrauchsanweisung		X
13.2	Symbole		X
13.3	Kennzeichnung		X
13.4	Zweckbestimmung		X
13.5	Identifizierung	X	
13.6	Inhalt der Gebrauchsanweisung		X
14. KLINISCHE PRÜFUNG UNERWÜNSCHTER NEBENWIRKUNGEN			X
Grundlegende Aspekte der Sicherheit und Funktion des/der Produkte(s) sind betroffen => neue/ erweiterte/ geänderte 510(k)- Zulassung ist erforderlich !			X

[redacted]

Anlage zu Bericht Nr.: 09106

HAUPT - FLUSSDIAGRAMM ZUR ENTSCHEIDUNGSFINDUNG HINSICHTLICH EINER 510 (k) ZULASSUNGSERWEITERUNG NACH ÄNDERUNG EINES ZUGELASSENEN MEDIZINPRODUKTES



09106

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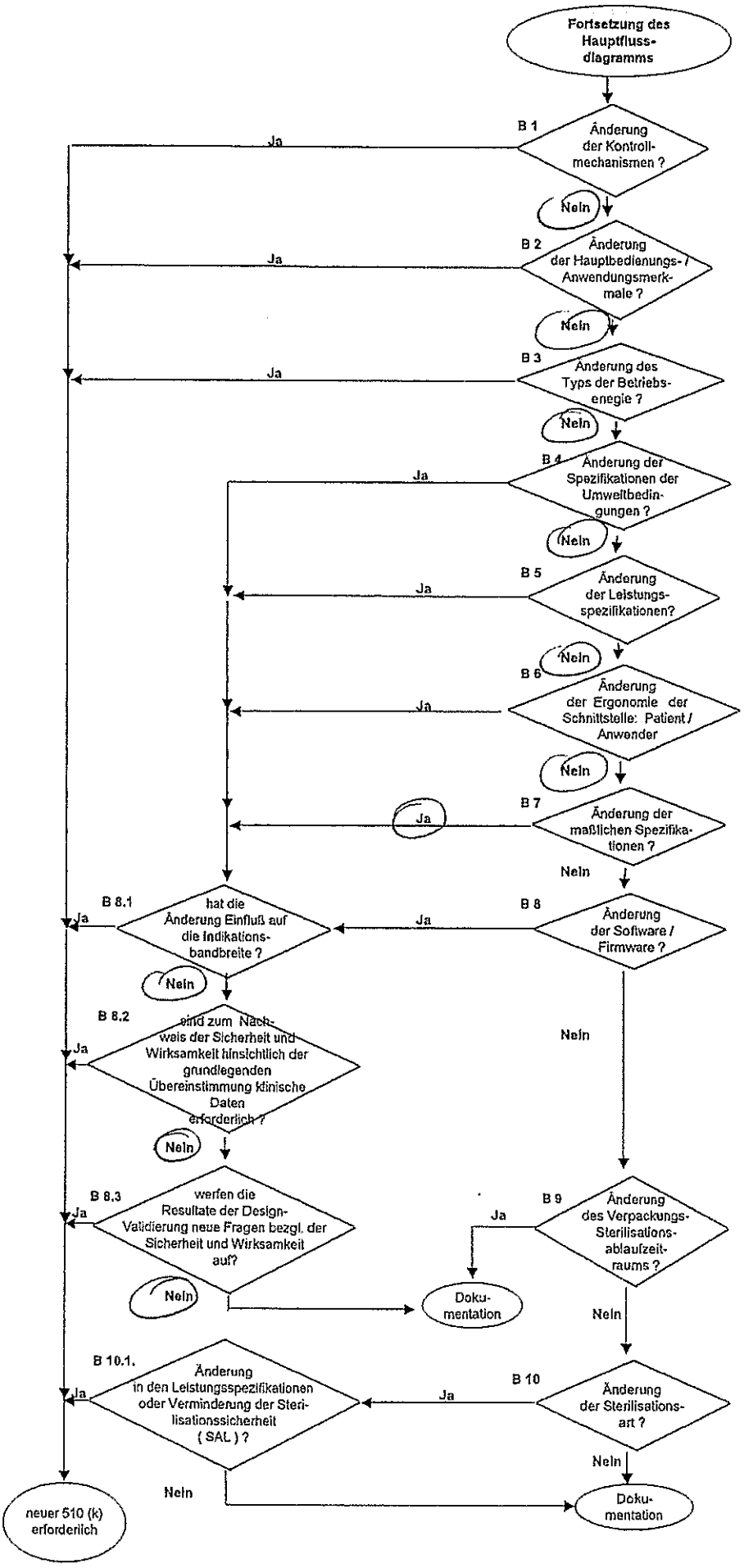
FLUSSDIAGRAM "B" : LIEGEN ÄNDERUNGEN IN DER TECHNOLOGIE ODER DEN LEISTUNGSMERKMALEN VOR ?



Orthodynamics GmbH Sales and Complaints Data - Cementless Adapter Stem

Year	Product Name	# supplied in Australia	# supplied World Wide	# of complaints in Australia	# of complaints World Wide (incl. Australia)	# of Adverse Events in Australia	# of Adverse Events World Wide (incl. Australia)
2005	Adapter (Cementless) Femoral Stem	20	475	0	0	1	1
2006	Adapter (Cementless) Femoral Stem	143	338	0	0	9	9
2007	Adapter (Cementless) Femoral Stem	136	398	0	0	6	6
2008	Adapter (Cementless) Femoral Stem	129	351	0	0	4	4
2009	Adapter (Cementless) Femoral Stem	169	427	0	0	3	3

56. Jahrestagung der Vereinigung Süddeutscher Orthopäden e.V.

1. bis 4. Mai 2008
in Baden-Baden

Wissenschaftliche Leitung:
Univ.-Prof. Dr. med. H. Reichel, Ulm

Kurzreferate der Vorträge

Sonderausgabe
der ORTHOPÄDISCHEN PRAXIS

MEDIZINISCH LITERARISCHE VERLAGSGESELLSCHAFT MBH
Postfach 11/51/ 11 52, D-29501 Uelzen

onen. Intraoperativ traten 3 Schaftfissuren auf, bei 6 Patienten lockerten sich Pins des Fixateurs. Es traten 4 Nervenläsionen, 3 Frühinfekte und ein Spätinfekt auf.

Vortrag Nr. 14

Offset- und Beinlängenrekonstruktion mit modularen Steckhälsen – wie viel Modularität wird im klinischen Alltag benötigt?

P. Aldinger, H. Ulrich, K. Kramer, G. Aldinger, Heidelberg

Einführung: Die durch die Modularität verbesserte Biomechanik in der primären Hüftendoprothetik hat das Potential die Operation zu vereinfachen und die Gelenkrekonstruktion zu verbessern. Wie viel Modularität wird im klinischen Einsatz benötigt, um das Offset und die Beinlänge exakt zu rekonstruieren? Kann die Luxationsrate durch deren Einsatz verringert werden?
Material und Methoden: Wir untersuchten die ersten 154 konsekutiven Implantationen eines zementfreien Geradschaftes mit einem Steckhals, der in 12 verschiedenen Geometrien erhältlich ist. Es besteht eine Auswahl von zwei Schaftvarianten, 4 Halslängen, 3 Offsetvarianten sowie 5 Anteversionen (European Hip System [EHS)/Profemur E, Wright Medical Technology Inc., Arlington, TN, USA). Prä- und postoperativ wurden radiologisch die Beinlänge und das Offset im Vergleich zur Gegenseite gemessen. Die Luxationsrate im 10-Jahreszeitraum wurde gemessen.
Ergebnisse: Das Offset konnte mit dem modularen Steckhalssystem in 98 %, die Beinlänge in 94 % der Fälle korrekt rekonstruiert werden. Es traten im Zeitraum von 10 (9–13) Jahren keine Luxationsereignisse auf. Offset-Rekonstruktion: Frauen prä-OP 40,1 (31,6–48,3) mm, post-OP 44,4 (35,3–52,2) mm; Männer prä-OP 44,5 (35,7–53,3) mm, post-OP 49,4 (40,4–58,4) mm. Die gemessene Offsetvergrößerung resultierte aus der Verwendung von Pressfitpfannen, die den Drehpunkt zentralisieren. Beinlängendifferenz: Frauen prä-OP 0,8 (0–2,8) mm, post-OP 0,2 (0–0,7) mm; Männer prä-OP 0,9 (0–2,6) mm, post-OP 0,3 (0–1,2) mm. Verwendete Implantate: Schaft: Standard 59 % (91), Plus 41 % (63); Schaftgrößen: 7,5 1 %(1), 10,5 10 % (16), 11,5 25 % (39), 12,5 27 % (41), 13,5 25 %(38), 14,5 7 % (11), 15,5 5 % (8). Steckhalsversion: varus 68 % (105), gerade 15 % (23), valgus 1 % (2), Retroversion 8°/15° 4/3 % (6/4), Anteversion 8°/15° 5/5 % (7/7); Halslänge: extra kurz 10 % (16), kurz 18 % (27), mittel 1 % (1), lang 71 % (110). Kopf: kurz 45 % (69), mittel 26 % (40), lang 29 % (45).
Schlussfolgerung: Die Rekonstruktion der Gelenkmechanik bezogen auf die gemessenen Parameter Offset und Beinlänge war mit dem Steckhalssystem in über 90 % der Fälle exakt möglich. Steckhälse können durch die große Auswahl an verschiedenen Halsgeometrien dazu beitragen, die Gelenkmechanik zu verbessern und die Luxationsrate zu senken.

Vortrag Nr. 15

Die metallspongiöse Hüftendoprothese mit Konusadapter – Erste klinische Erfahrungen einer radiologischen Nachuntersuchung

S. Thomas, J. Scholz, B. Latif, Berlin

Einleitung: Metallspongiöse Endoprothesen werden von uns seit 1983 verwendet. Bei diesem Prothesensystem handelt es sich um eine Hüftgelenktotalendoprothese aus einer Chrom-Kobalt-Molybdän-Basislegierung mit einer makroporösen Oberflächenstrukturierung. Das Implantat war im Bereich der Hüftgelenkstiele bis 2004 in einer Standardvariante mit einem CCD-Winkel von 135° und in einer lateralisierten Variante vorhanden. Um größere Variationsmöglichkeiten zu erreichen und die Lagerhaltung im Bereich der Klinik zu reduzieren, wurde entschieden, den Konus – Euro-Konus 12/14 – als Doppelkonus zu konstruieren und somit eine Adapter-Situation zu schaffen, die es dem Operateur ermöglicht, in einer 0°-, 10°- und 20°-Variante den CCD-Winkel zu beeinflussen und in einer Offset-Variante den Offset zu gestalten. Mit dieser klinischen Studie soll überprüft werden, ob die

Adapter-Variante des Stiels in der frühen klinischen Nachuntersuchungszeit im Vergleich zum Festkonus eine Verbesserung des klinischen Outcomes bringt und inwieweit mechanische Probleme der Doppelkonus-Situation entstehen können.
Methode: Zur Beantwortung dieser Fragestellung wurden im HELIOS Klinikum Emil von Behring, Stiftung Oskar-Helene-Heim, 40 Patienten klinisch und radiologisch nachuntersucht. Die klinische Nachuntersuchung erfolgte nach dem Harris Hip Score. Die Patienten wurden radiologisch durch ein Standard-Röntgenbild in zwei Ebenen nachuntersucht.
Ergebnisse: Der durchschnittliche Harris Hip Score betrug für 40 Patienten mit 42 Hüftendoprothesen 98 Punkte. Dabei reichte die Variationsbreite von 87 Punkten bis 100 Punkte.
Radiologische Ergebnisse: Die Überprüfung des Sitzes der Endoprothesenstiele und der Endoprothesenpfannen ergab in 41 von 42 Endoprothesen keinen Anhaltspunkt für eine Prothesenlockerung. In keinem Fall kam es zu einer Dislokation des Konus oder zu einem Bruch des Konus.
Schlussfolgerung: Die Variante des Doppelkonus im Sinne des Adapterstiels hat in der frühen klinischen Erprobungsphase keine negativen Begleiterscheinungen mit sich gebracht. Die Konen wiesen weder Konusbrüche noch vermehrt metallischen Abrieb im Lager auf. Das klinische Nachuntersuchungsergebnis mit einem durchschnittlichen Harris Hip Score von 98 Punkten belegt, dass durch die Variationsmöglichkeit der CCD-Winkel und der Adapterkonen die primäre anatomische Situation besser nachgestaltet werden kann und somit ein besseres klinisches Outcome zu erzielen ist.

Vortrag Nr. 16

Periprothetische Knochendichteveränderungen nach Implantation zementfreier und zementierter Endoprothesenstiele mit identischem geometrischen Design

R. Decking, R. Bieger, H. Reichel, Ulm

Fragestellung: Die Reduktion der periprothetischen Knochendichte ist ein oft beschriebenes und vieldiskutiertes Problem nach Implantation zementierter und zementfreier Endoprothesenstiele. Während eine Reihe von Publikationen die Knochendichteveränderungen unterschiedlicher Schäfte im longitudinalen Verlauf verfolgt hat, gab es bis dato keinen publizierten Vergleich zwischen zementierter und zementfreier Versorgung bei Schäften mit identischem geometrischen Design.
Patienten und Methoden: In einer prospektiven Studie wurden 25 Patienten mit einem „anatomisch adaptierten" zementfreien Stiel und weitere 18 Patienten mit einem geometrisch identischen zementierten Stiel versorgt.
Beide Patientengruppen wurden über 12 Monate sowohl klinisch als auch radiologisch nachuntersucht. Die periprothetischen Knochendichteveränderungen wurden mittels DEXA longitudinal über den gleichen Zeitraum erfasst.
Resultat: In beiden Gruppen kam es zu einer deutlichen Reduktion der Knochendichte im Verlauf der ersten 12 postoperativen Monate. Während diese Reduktion beim zementfreien Schaft proximal medial und lateral sehr ausgeprägt war (-18 und -16 %), war die Reduktion im proximalen Schaftbereich bei den zementierten Endoprothesen vor allem auf die mediale Seite beschränkt (-16 %), während vermutlich die homogenere Krafteinleitung über den ganzen Schaft hinweg zu einer Knochenreduktion auch in den Grünschen Zonen 2 bis 6 führte.
Sowohl die zementierte als auch die zementfreie Verankerung führt bei dem untersuchten anatomisch adaptierten Schaft zu einer Knochenresorption, die sich jedoch in ihrer Verteilung deutlich zwischen zementfreiem und zementiertem Implantat unterscheidet.

ORTHODYNAMICS

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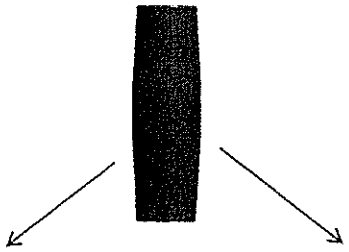
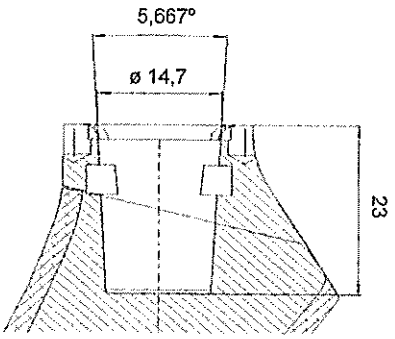
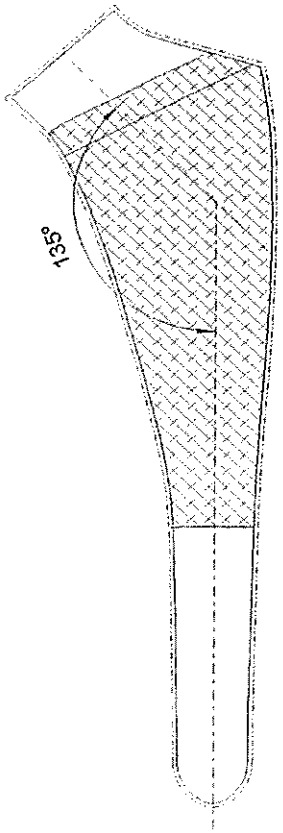
equal design characteristics of adapter hip stem "G2" and "GHE"

Dual cone
for all adapter hip stems
(example 0°)

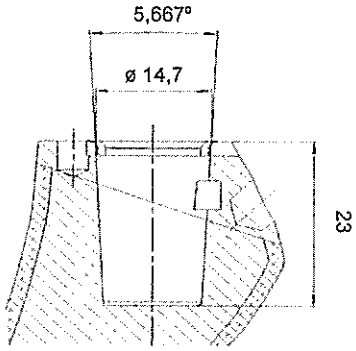


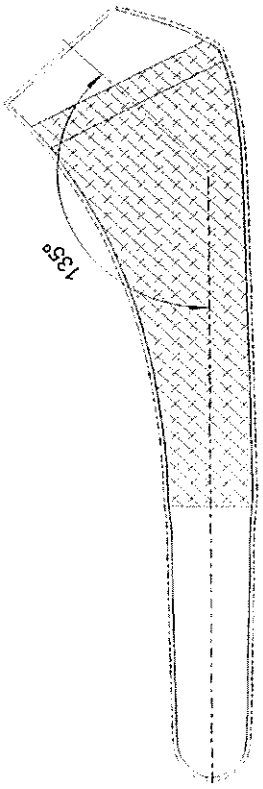
Adapter hip stem
"G2"





Adapter hip stem
"GHE"





ASKLEPIOS
Stadtklinik Bad Tölz

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Klinische Einschätzung von modularen Adapterhüftstielen „G2“ mit Konusadaptern von ESKA Implants AG

In der orthopädischen Abteilung der Asklepios Stadtklinik Bad Tölz implantieren wir Adapterhüftstiele „G2“ mit entsprechenden Konusadaptern. Im Zeitraum von Januar 2006 bis Ende August 2009 haben wir ca. 100 Patienten mit diesen Adapterhüftstielen versorgt.

Indikationen und Anwendung von Adapterhüftstielen

Die verschiedenen Konusadapter bieten nach der Hüftstielimplantation unterschiedliche Offset- bzw. durch das konische Design frei wählbare Torsionseinstellungen.

Es wurden vier verschiedene Konusadapter mit CCD-Winkeleinstellungen von 0°, 10° und 20° zum Ausgleich von Varus-/Valgus-Fehlstellungen und lateralisierende Konusadapter zur Offsetkorrektur verwendet.

Ein großer Vorteil von Adapterhüftstielen ist, dass ein entsprechender Konusadapter patientenindividuell anhand der möglichen Luxationstendenz, des Bewegungsumfanges und der vorliegenden Weichteil- bzw. Bandspannung ausgewählt werden kann, wodurch eine schnelle und optimale Einstellung des Gelenkzentrums sowie eine luxationssichere Versorgung ermöglicht werden. Unter Berücksichtigung der Weichteilspannung können sowohl die Gelenkstabilität als auch die Beinlänge und die Beweglichkeit individuell angepasst bzw. rekonstruiert werden. Die Beinlänge kann wie bei Standardhüftstielen mit Hüftköpfen verschiedener Halslängen korrigiert werden. Die präzise Anpassung und Einstellung des Gelenkzentrums erfolgt durch eine Probereposition mit Probekomponenten und definitivem Hüftstiel, wobei mit entsprechenden Konusadaptern auch etwaige geringfügige Fehlpositionierungen der bereits liegenden Prothesenkomponenten intraoperativ ausgeglichen werden können.

Die variablen Einstellmöglichkeiten durch die verschiedenen Konusadapter haben sich vor allem bei starken anatomischen Deformationen als sehr nützlich erwiesen.

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Sitz der Gesellschaft: HR Königstein Nr. 5707
Sparkasse Bad Tölz - Wolfratshausen • BLZ 700 543 06 • Kto.-Nr. 810 000 992
Geschäftsführer: Arnulf Mehren, Bernd Hirtreiter, Dr. Tobias Kaltenbach
Steuernummer: 0322849062 • Ust-IdNr.: DE 236792342

Bei Revisionsoperationen kann femurseitig der Konusadapter ausgetauscht und erneut ein Standard-Keramikkopf aufgesetzt werden. Der Zugang zum Acetabulum kann im Bedarfsfall durch Abnehmen des Konusadapters erleichtert werden.

Spezielle Indikationen und Kontraindikationen von Adapterhüftstielen
Entsprechend unserer Erfahrungen sind die Adapterhüftstiele für folgende Indikationen besonders geeignet:

1. Varus- und Valgusfehlstellungen des Schenkelhalses
2. Torsions-/Rotationsfehlstellungen
3. Hüftpfannenfehlbildungen

Spezielle Kontraindikationen von Adapterhüftstielen/Konusadaptern sind:

- Adipositas permagna

Klinische Erfahrungen und klinische Einschätzung
Im Zeitraum von Januar 2006 bis August 2009 wurden in unserer Klinik ca. 100 Patienten mit dem CL-Adapterhüftstiel „G2" versorgt. Hauptsächlich wurde der Hüftstiel mit einem lateralisierenden Konusadapter (86%) kombiniert.

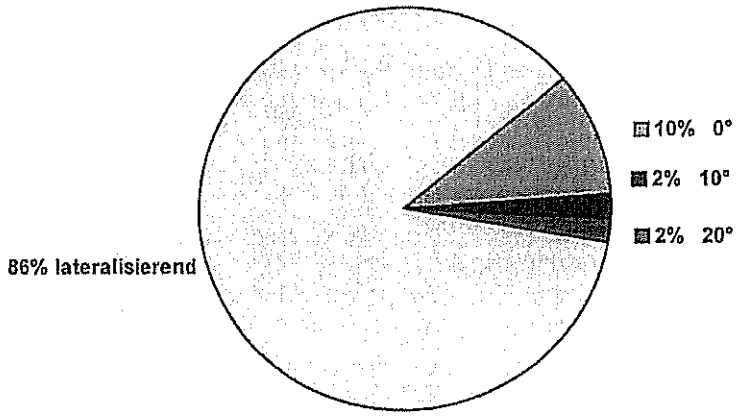

Abb. 1: prozentuale Verteilung der implantierten Konusadapter

Klinische Ergebnisse:

- gute bis sehr gute klinische Ergebnisse bezüglich Bewegungsumfang und Stabilität
- einfache Handhabung der Konusadapter, gutes Gelenkalignement

Komplikationen:
In genanntem Zeitraum traten keine Brüche oder Lockerungen der eingesetzten Konusadapter auf.

Fazit

Unsere Erfahrungen mit dem modularen Adapterhüftstiel „G2" sind sehr gut. Es sind bei den von uns seit 2006 implantierten Konusadaptern keine Brüche oder Lockerungen aufgetreten.
Wir sahen bis dato auch keine Brüche von Konusadaptern, die vor 2006 implantiert wurden.
Die Adaptertechnologie ist für uns eine sehr gute Option zur individuellen und optimalen Versorgung des Patienten. Die Risiken und Komplikationen sind mit denen nicht modularer Standardhüftstiele vergleichbar, doch bietet der Konusadapter die o. g. operationstechnischen Vorteile.

Aus unserer Sicht ist das klinische Versagensrisiko von Konusadaptern bei korrekter Indikationsstellung und sachgemäßer Anwendung unbedeutend. Dies ist mit dem eigenen Krankengut unstrittig zu belegen.

Bad Tölz, 11.01.2010

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2

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Erfahrungen mit einer Hydroxylapatit-beschichteten, makroporös strukturierten Hüftendoprothese

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[2] CeramTec AG, Plochingen

Enke

Erfahrungen mit einer Hydroxylapatit-beschichteten, makroporös strukturierten Hüftendoprothese

B. Kinner[1], *G. Willmann*[2], *S. Storz*[1], *J. Kinner*[1]
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[2] CeramTec AG, Plochingen

Zusammenfassung

Fragestellung: Makroporös strukturierte, zementlose Hüftendoprothesen haben die an sie gestellten Erwartungen nur bedingt erfüllt. Mittelfristige Ergebnisse zeigen im Vergleich zu zementierten Implantaten oft nicht die erhofften Vorteile, da die sichere Sekundärstabilität durch feste knöcherne Einheilung nicht immer gewährleistet ist. Es galt daher zu klären, ob eine zusätzliche Beschichtung mit Hydroxylapatit die Ergebnisse verbessert.
Methode: 200 aufeinanderfolgende Patienten (9/1992–3/1996), die mit einer Hydroxylapatit beschichteten Hüftendoprothese mit makroporöser Oberflächenstrukturierung versorgt wurden, konnten prospektiv verfolgt werden.
Postoperativ wurden die Patienten klinisch und radiologisch gemäß der Kriterien von *Johnston* et al. (1990) nachuntersucht. Als Maß für das klinische Ergebnis wurde der HHS berechnet, zur radiologischen Beurteilung der Score n. *Engh* herangezogen.
Ergebnisse: 91% der Patienten konnten regelmäßig und vollständig untersucht werden. Bisher war keine Revision aufgrund einer aseptischen Lockerung nötig. Femorale „Anpassungsschmerzen" sind nicht mehr aufgetreten. Der mittlere HHS nach 2 Jahren betrug 97.
Die radiologische Untersuchung zeigte eine frühe und komplette knöcherne Einheilung aller Prothesenkomponenten.
Schlußfolgerung: Unsere Ergebnisse haben uns ermutigt dieses Endoprothesenmodell weiter anzuwenden. Es bietet neben der Primärstabilität eine sichere und frühzeitige sekundäre Stabilisierung als Voraussetzung für eine dauerhafte Fixation der Prothese.

Schlüsselwörter: Hüftendoprothese – Oberflächenstrukturierung – Hydroxylapatit

Experience with a Hydroxypatik-Coated and Macroporous-surfaced Hip Prosthesis

Introduction: Cementless hip arthroplasty is not completely satisfactory – even with macroporous structured surface. Medium term results are sometimes disappointing because of insufficient secondary stability. Thus our aim was to improve fixation by additional coating with hydroxyapatite.
Methods: 200 consecutive patients who had hydroxyapatite-coated cementless hip replacement with a macroporous hip prosthesis (09/92–03/96) were studied prospectively. All patients were included in a prospective follow up scedule according to the criteria of *Johnston* et al. As measure of clinical outcome we calculated Harris Hip Score as well as Enghs Score to assess radiologic fixation and stability.
Results: 91% could be followed up regularly. No revision because of aseptic loosening had to be done. Analysis of clinical results showed almost painless patients from early after the operation – especially no thigh pain. Average HHS after 2 years was 97.
Radiological evaluation showed early and complete osteointegration of all components. According to *Engh*-Score they are stable and well fixed.
Conclusion: HA coated macroporous implants provide some striking advantages, which encouraged us to continue with this system. By early and secure bony ingrowth a fibrous interface is avoided and thereby also long-lasting thigh pain.

Key words: Hip arthroplasty – surface structure – hydroxyapatite

Einleitung

Zementlose Hüftendoprothesen haben unsere Erwartungen zwar bedingt erfüllt, sind aber noch verbesserungsfähig. Das zeigen nicht nur die Auswertungen der skandinavischen Endoprothesenregister [11,12], sondern auch die bisherigen Erfahrungen mit der von uns verwendeten, makroporös strukturierten Prothese (Fa. ESKA/S&G).

Sielewicz et al. (1997) berichten mit dieser zementfreien Hüftendoprothese eine Revisionsrate von 6% nach 10 bis 12 Jahren. Wenn wir die Prothesen dazuzählen, die noch nicht gewechselt wurden, aber gewandert sind oder sonstige Zeichen einer Lockerung zeigen, muß man von einer Lockerungsrate von bis zu 16% in o. g. Zeitintervall ausgehen. Das deckt sich mit einer Rate von 21% mäßiger bis schlechter klinischer Resultate [17] und entspricht auch unseren eigenen Erfahrungen.

Bei genauerer Betrachtung der Revisionsfälle und der Explantate bzw. des entsprechenden Interfaces konnten wir eine bindegewebige Fixierung der Prothesen mit unzureichender Sekundärstabilität feststellen (Abb. 1a u. b) [10].

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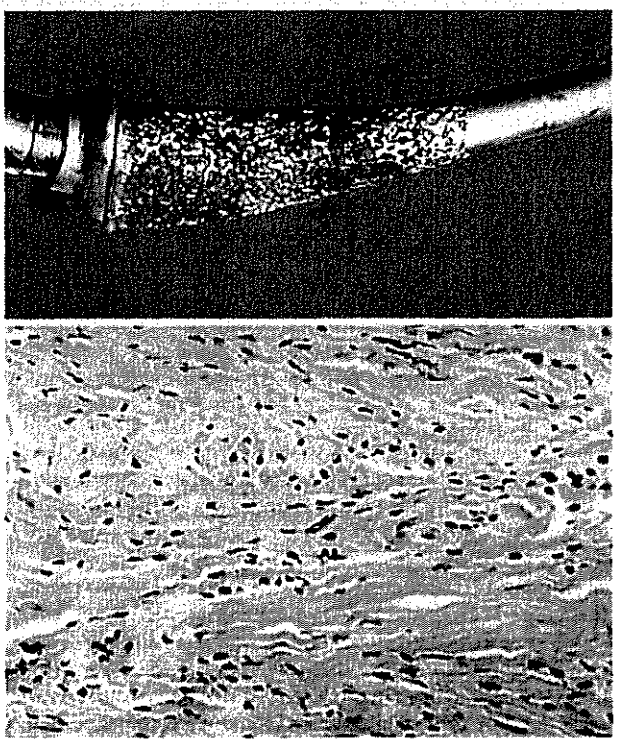

Abb. 1a u. b Schaftwechsel wegen andauernder Oberschenkelschmerzen (ohne Beschichtung), **a** Explantierte Prothese, **b** Interface Prothese – Wirtsknochen. Histologischer Schnitt
Überwiegend bindegewebige Fixierung des nicht-beschichteten Schaftes

Abb. 2 HA-beschichtete ESKA-Prothese; anatomisch geformter Schaft aus einer CrCoMo-Legierung mit teilstrukturierter Oberfläche. Modulares Pfannensystem aus Metallsockel und Insert – wahlweise PE oder Biolox forte® (16). Sphärische Pfanne, mit zwei Antirotationsflügeln zur Rotationssicherung. Beschichtung jeweils nach Korundstrahlung mit Osprovit® (CeramTec) durch das Plasmaspritzverfahran (Air plasma-spraying). Schichtdicke ca. 80 µm

In Kenntnis dieser Fälle muß man auch all jene Patienten kritisch betrachten, die lange postoperativ über Schaftschmerzen klagen. Auch hier ist von einer bindegewebigen Fixation bzw. biomechanisch unzureichenden knöchernen Einheilung auszugehen. Diese knöcherne Teileinheilung kann darüber hinaus eine äußerst schwierige Wechseloperation nach sich ziehen, bei der die punktuell knöchern fixierte Prothese schwierig aus dem Implantatbett zu lösen ist.

Dies war Anlaß für uns, über Modifikationen der ESKA-Prothese nachzudenken, ohne das Prinzip einer biologischen Verankerung der Prothese mittels interkonnektierender makroporöser Oberfläche aufzugeben, indem zur Gewährleistung einer sicheren Einheilung und Vermeidung des bindegewebigen Interfaces eine HA-Beschichtung (Osprovit®) aufgebracht wurde (Abb. 2 u. 3).

Dieses HA-beschichtete Implantat ist nun seit über 5 Jahren im klinischen Einsatz. Es ist daher Zeit eine Zwischenbilanz zu ziehen und eine Versagensanalyse und -prognose abzugeben.

Optimierung der Fixation eines Implantates

Es gibt verschiedene Möglichkeiten, die Fixation zementfreier Implantate im Implantatbett zu verbessern (Tab. 1).

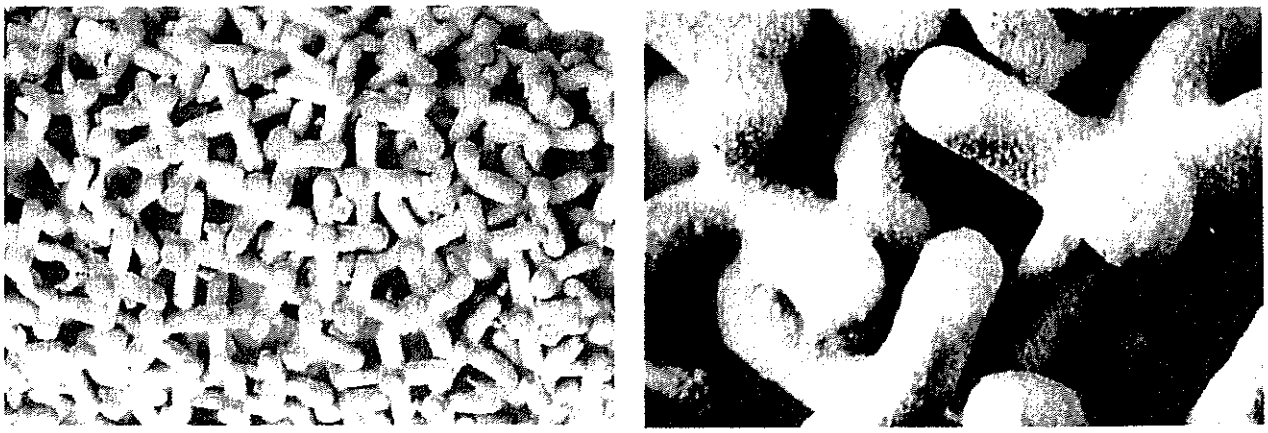

Abb. 3 Detail-Aufnahme der Oberfläche nach Beschichtung mit Osprovit®: Grundeinheit der Oberflächenstrukturierung: aufgesinterte Tripoden, aus jeweils 6 trabekelähnlichen Stegen. Maximale Bauhöhe 3 mm, interkonnektierende Poren von 1–3 mm Weite, Porosität 80%

Tab. 1 Möglichkeiten zur Verbesserung der Fixation zementfreier Implantate

Maßnahme	Ziel
1. großflächige proximale Krafteinleitung	kein stress shielding
2. anatomisch gestaltete Implantate	keine punkt- oder linienförmige Krafteinleitung
3. gute Primärfixation	Unterbindung von Mikrobewegung
4. zweizeitige Implantationstechnik (in der Endoprothetik nicht möglich)	Unterbindung von Mikrobewegung Einheilung ohne Belastung
5. strukturierte Oberfläche, z. B. beads, mesh, Tripoden-Struktur, rauhe Oberfläche durch Beschichtung mit Titan oder Korundstrahlen	bony in-growth statt bony ongrowth Maximierung der Kontaktfläche
6. bioaktive Oberfläche (osseokonduktiv)	bony in-growth, Verbundosteogenese
7. osteoinduktive Effekte	Neubildung von knöchernem Gewebe am Implantat (z. B. mit BMP)

Dabei ist wohl die wesentlichste Voraussetzung die Bildung eines bindegewebigen Interfaces zwischen Implantatbett und Implantat zu verhindern. Hier dürften die wichtigsten Maßnahmen die Ruhigstellung des Implantates und die Unterbindung von Mikrobewegung sein.

Dies kann z. B. mit einer strukturierten Implantatoberfläche erreicht werden:
- Makroporöse Gestaltung der Implantatoberfläche, z. B. aufgesinterten Kügelchen (beads), aufgebrachten Netzstrukturen (mesh), der Spongiosa nachgestellten makroporösen Strukturen (Spongiosa-Metall®, Metallspongiosa®, Corallo-Metall® oder Tripo®-Metall (Tripoden-Struktur) [13])[1].
- mikroporöse Gestaltung der Oberfläche, Aufrauen der Oberfläche, z. B. durch Beschichtung mit Titan oder Korundstrahlen.

Will man jedoch eine Verbundosteogenese (=bony ingrowth) erreichen, dann muß man die Oberflächen der Implantate bioaktiv [24] gestalten. Stand der Technik ist seit etwas mehr als 10 Jahren die Beschichtung mit bioaktivem Hydroxylapatit [4, 6, 7].

Kombiniert man eine makroporöse Oberflächenstruktur (z. B. Tripoden-Struktur) mit einer bioaktiven HA-Beschichtung, dann erhält man die beste Option, ein bony in-growth zu erreichen. Der Knochen wird durch die osseokonduktiven Eigenschaften des HA an die Implantatoberfläche herangeführt und er kann in die Makroporen einwachsen [8].

Mit diesem Konzept kann auch die Übertragung von Zugkräften zwischen Implantat und Implantatbett beschleunigt und deutlich verbessert werden. Für HA hat bereits Osborn auf diese Option hingewiesen. Er hat für die Größe der Makroporen postuliert und nachgewiesen, daß sie einen Durchmesser von über 0,2 mm haben sollen [15].

[1] Diese Begriffe werden bzw. wurden von der Firma ESKA und S&G für ihre strukturierten Oberflächen benützt.

Hydroxylapatit – Stand der Kenntnisse und der Technik

Es gibt viele Beweise durch Tierversuche und klinische Erprobung, daß das Konzept der HA-Beschichtung die Fixation eines Implantates zielführend beeinflußt [4, 7, 18].

Hydroxylapatit (HA) ist aufgrund mangelnder mechanischer Festigkeit [22] für lasttragende Funktionen von Implantaten nicht geeignet, als HA-Beschichtung ist aber die attraktive Bioaktivität des Hydroxylapatits nutzbar [4, 7, 15, 18, 21, 22].

Der Stand der Technik bei der HA-Beschichtung ist wie folgt: Alle Biolegierungen (Edelstahl, cp-Titan, Titan- und Kobalt-Chrom-Legierungen) und alle Oberflächenstrukturen (z. B. mesh, Spongiosametall® bzw. Tripoden, porous coating, aufgerauhte Oberfläche etc.) können heute ohne technische Probleme beschichtet werden. Richtwerte für die Eigenschaften von HA können der einschlägigen Literatur entnommen werden [13].

Die Dicke der HA-Beschichtung wird üblicherweise zwischen 0,05 mm und 0,25 mm gewählt. Es wurden in vivo keine Probleme mit Abplatzern oder Delaminationen beobachtet [4, 7, 18, 23]. Über die optimale Dicke der HA-Beschichtung wurde bisher noch keine Einigkeit erzielt. Technisch ist alles im Bereich von rund 0,05 bis 0,25 mm möglich [22].

Ist beim ESKA-System durch die Tripoden-Struktur knöchernes Gewebe in die Makroporen mit Hilfe des HA hineingeführt worden, dann ist die Prothese sekundär gut fixiert und die Beschichtung mit HA hat eigentlich ihre Funktion erfüllt. Für das ESKA-System hat man sich, dieser Argumentation folgend, für HA-Schichten um 0,1 mm entschieden.

David et al. fanden durch Messung des Ausdrehmomentes beschichteter Schanz-Schrauben, daß alle die Osteointegration beherrschenden Prozesse nach 4 Wochen völlig abgeschlossen waren [2]. Bei beschichteten Schrauben war das Ausdrehmoment rund 8mal so hoch wie das von unbeschichteten. Dies ist ein schlüssiger Beweis für die gute Osteointegration von HA-beschichteten Implantaten. Dabei erfolgt die Einheilung ohne bindegewebige Zwischenschicht, auch wenn Mikrobewegungen am Implantat stattgefunden haben [18, 19].

Heute ist eine Reihe von Langzeituntersuchungen mit HA-beschichteten Endoprothesen verfügbar. Das gleiche gilt für aktuelle Reviews mit mittelfristigen klinischen Ergebnissen [4, 7]. Diese beweisen den Erfolg und die Verbesserungen durch HA-Beschichtung.

Patienten u. Methodik

200 aufeinanderfolgende Patienten, die zwischen September 1992 und März 1996 mit einer HA-beschichteten, ana-

tomischen Hüftendoprothese mit offen makroporöser Oberfläche versorgt wurden, konnten prospektiv verfolgt werden (Abb. **2** u. **3**).

Alle Prothesen wurden von einem standardisierten posterolateralen Zugang implantiert. Die peri- und postoperative Thrombo-Embolieprophylaxe erfolgte mit LMWH. Intraoperativ wurden 2 g Cefotiam zur Infektionsprophylaxe gegeben. Ab dem ersten postop. Tag erhielten die Patienten eine fraktionierte Röntgentiefenbestrahlung (insges. 16 Gy, Orthovolt) in Kombination mit 100 mg/d Diclofenac zur Prophylaxe periartikulärer Ossifikationen für insgesamt 3 Wochen.

Die Mobilisation der Patienten erfolgte früh-postoperativ mit einer Teilbelastung von 20 kp über 3 Wochen.

Das mittlere Alter der Patienten bei der Operation betrug 64 (34–81) Jahre. 17 Patienten waren jünger als 55 und 6 Patienten älter als 75 Jahre. Die Geschlechterverteilung war m:w = 1:1,6.

Wir operierten unsere Patienten unter den in Abb. **4** dargestellten Diagnosen. Die Indikation zu einem zementlosen Hüftgelenksersatz stellten wir ausschließlich aufgrund des präoperativen biologischen Alters und Aktivitätslevels.

Alle Patienten wurden in ein Nachuntersuchungsprotokoll aufgenommen, das sich an den Kriterien von *Johnston* et al. [9] orientierte.

Wir konnten unsere Patienten sowohl klinisch als auch radiologisch (Beckenübersicht und Hüfte axial) regelmäßig nach 3, 6 und 12 Monaten, dann jährlich nachuntersuchen. Dazu diente ein nach den Kriterien von *Johnston* et al. (1990) standardisierter Erhebungsbogen. Als Maß für das klinische Ergebnis wurde der Harris-hip-score berechnet. Zur Beurteilung der radiologischen Stabilität und Festigkeit zogen wir den Score n. *Engh* [3] heran. Dieser Score berücksichtigt neben röntgenmorphologischen Kriterien auch meßtechnische Daten (Abb. **5**). Die Auswertung erfolgte entsprechend der *Gruen*-Zonen am Schaft bzw. der *DeLee-Charnley*-Zonen an der Pfanne.

Die Schaftsinterung berechneten wir nach *Engh* et al. [3], indem jeweils die Distanz zwischen Spitze d. Trochanter major und Prothesenschulter in der Beckenübersichtsaufnahme gemessen wurde. Als signifikantes Ergebnis wurde eine Wanderung von >2 mm gewertet. Eine Wanderung der Pfanne analysierten wir nach der Methode von *Nunn* [14].

Die mittlere Nachuntersuchungszeit betrug 4 (2–5) Jahre. Die exakten Daten des follow up sind in Abb. **6** wiedergegeben. Die Untersuchung ist als Langzeitstudie angelegt.

Ergebnisse

Die Komplikationen sind in Tab. **2** wiedergegeben. 2 Patienten starben während der postoperativen Phase, 2 weitere während des Beobachtungszeitraumes, ohne daß es

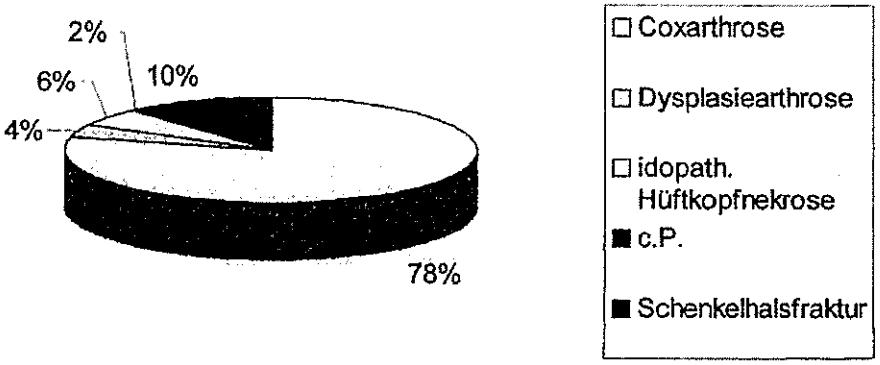

Abb. 4 Präoperative Diagnose

Reaktive Seite		Nicht zu beurteilen	
Veränderungen an der beschichteten/strukturierten Oberfläche (reaktive Linie, Saum)	Ausgedehnt (>50%) -5,0	0	Fehlt +5,0
Spot welds	Fehlt -2,5	0	Vorhanden +5,0
Stabilität Seite			
Veränderungen an der glatten Oberfläche	Ausgedehnt (>50%) -3,5	0	Fehlt +5,0
Pedestals	Vorhanden -3,5	0	Fehlt +2,5
Calcar modeling	Hypertrophie -4,0	0	Atrophie +3,0
Implant detoriation (Zunahme des Saums, vom Implantat divergierende radiolucente Linien)	Vorhanden -2,5	0	Fehlt +2,5
Migration	Vorhanden -5,0	0	Fehlt +3,0
Particle shedding (z.B. durch das Abscheren von HA-Partikeln)	Vorhanden -5,0	0	Fehlt +1,0

Abb. 5 *Engh*-Score

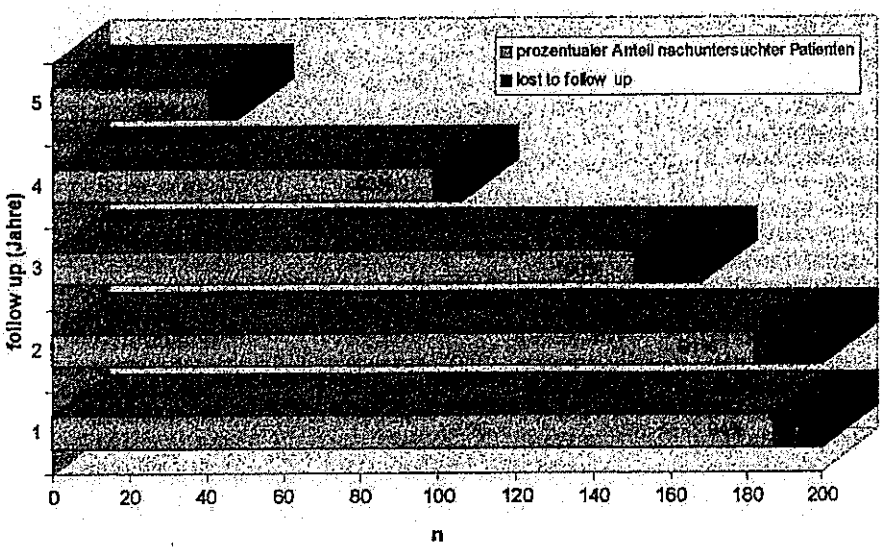

Abb. 6 Follow up

Tab. 2 Komplikationen

Luxation	4 (2,0%)
revisionsbedürftige Luxation	1 (0,5%)
Serom	1 (0,5%)
Hämatom	1 (0,5%)
Wundinfekt	2 (1,0%)
Thrombose	3 (1,5%)
Lungenembolie	3 (1,5%)
Pneumonie	3 (1,5%)
unklares Fieber	3 (1,5%)
Harnwegsinfekt	6 (3,0%)
Tod	2 (1,0%)
Niereninsuffizienz	3 (1,5%)
keine	168 (84,0%)

einen Zusammenhang zu der operierten Hüfte gegeben hätte. Ein Patient mußte aufgrund rezidivierender Luxationen revidiert und mit einem längeren Hals, bzw. exzentrischem Insert versorgt werden. 2 weitere Revisionen waren aufgrund eines Hämatoms bzw. Seroms notwendig.

Klinische Ergebnisse

Bisher war keine Revision wegen einer aseptischen Implantatlockerung notwendig. 97% der Patienten sind mit dem Behandlungsergebnis zufrieden oder mehr als zufrieden. Der Harris-hip-score während des Nachuntersuchungszeitraumes ist in Abb. **7** dargestellt.

Besonders niedrig war das Auftreten von Schmerzen von Beginn an. Bereits 3 Monate postoperativ gaben 76% der Patienten an, schmerzfrei zu sein, 18% hatten noch minimale bis leichte Schmerzen und 6% klagten über mäßige Beschwerden. Kein Patient gab an, unter erheblichen Schmerzen zu leiden. Nach 2 wie nach 4 Jahren gaben 89% der Patienten an schmerzfrei zu sein, 6% klagten über minimale und 5% über leichte bis mäßige Schmerzen. Insbesondere klagte kein Patient über Oberschenkel-Schaftschmerzen.

Wenn Schmerzen angegeben wurden, bezogen sich diese auf Narbenschmerzen, Wetterfühligkeit, Probleme über dem Trochanter major bzw. uncharakteristische, nicht genau lokalisierbare Beschwerden.

Ähnlich günstig waren die funktionellen Ergebnisse. Kein Patient hatte eine Einschränkung der Gehstrecke aufgrund der operierten Hüfte. Die mittlere Hüftbeugung nach 2 Jahren betrug 120°(80–140°).

Radiologische Ergebnisse

Bereits nach 3 bis 6 Monaten waren leichte, aber typische knöcherne Reaktionen des Implantatlagers im konventionellen Röntgenbild zu verzeichnen.

Zunächst kam es zu einer Spongiosaverdichtung in den Gruen-Zonen 2 und 6 [9, 13] – d. h. am Übergang zwischen strukturiertem/beschichtetem und glattem Schaftteil – die stetig über den Beobachtungszeitraum zunahm. Diese Spongiosaverdichtung erscheint typischerweise in der Form sog. Spot welds [3, 5], d. h. Knochentrabekeln, die in Richtung makroporöse Oberfläche wachsen. Stellvertretend sei die Verteilung dieser Spot welds nach 2 Jahren in Abb. **9a** und **10a** dargestellt.

Eine weitere typische röntgenmorphologische Erscheinung ist das Auftreten sog. reactive lines [3, 5]. Hierbei handelt es sich um eine zarte röntgendichte Line um die nichtbeschichtete Prothesenspitze. Die Verteilung reaktiver Linien nach 2 Jahren ist in Abb. **9b** und **10b** dargestellt.

Sog. Pedestals – d. h. endostale Knochenneubildung [3] um die Schaftspitze – traten in 7% um deren laterale Zirkumferenz auf, ohne daß sich eine Korrelation zu Schmerzen oder weitere Zeichen einer Schaftlockerung gezeigt hätten.

Regelmäßig kam es zum Remodelling am Calcar, im Wesentlichen in Form einer Abrundung (86%). Nie trat eine Calcarhypertrophie – im Sinne der Definition von *Engh* et al. [3] – auf.

Auch zur Kortikalishypertrophie kam es nur in 14%. Zum einen Teil (7%) zusammen mit einer Spongiosahypertro-

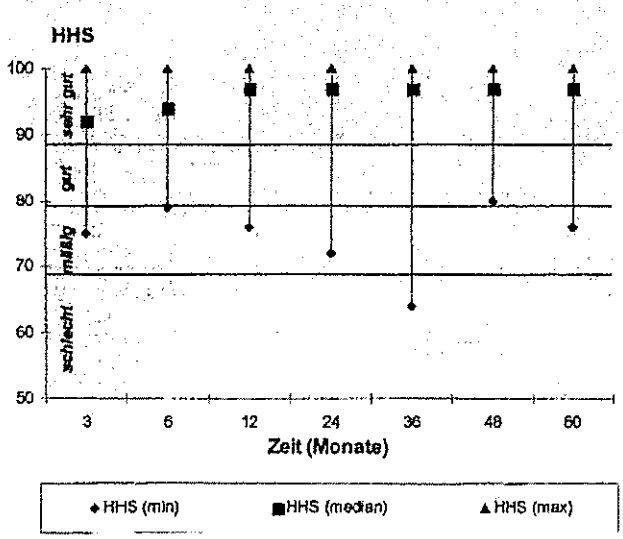

Abb. 7 Harris-hip-score als Maß für das klinische Ergebnis

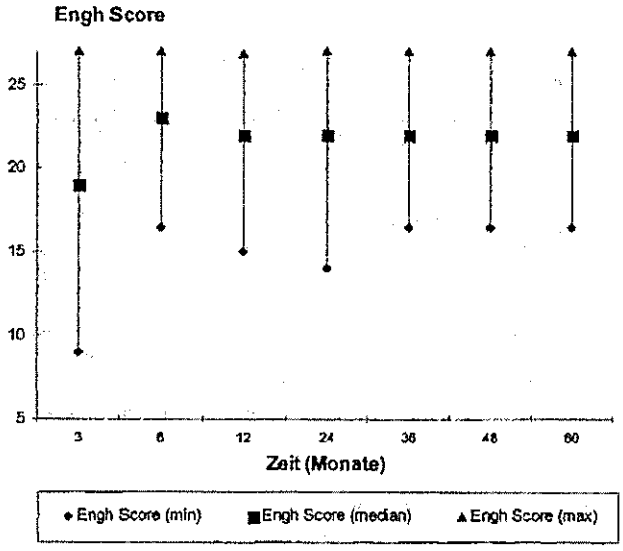

Abb. 8 *Eng*-Score als Maß für die radiologische Einheilung und Stabilität

phie in Zone 2, 6, zum anderen zusammen mit oben beschriebenen Pedestals (7%), nie jedoch in Verbindung zu reaktiven Linien um die Beschichtung.

Im Bereich der Zone 1 war es bei 64% (2 Jahre) der Patienten zu einer milden Reduktion der Knochendichte gekommen als Ausdruck der eher etwas distaler – am Übergang des beschichteten zum nicht-beschichteten Schaftanteil – gelegenen Krafteinleitung.

Die knöchernen Reaktionen um die Pfanne sind sehr ähnlich, lediglich in ihrer Ausprägung noch feiner. Auch hier kommt es frühzeitig (nach 6–12 Monaten) zur Ausbildung sog. spot welds, typischerweise an 3 Stellen: Zone I lateral, sowie am Übergang der Zonen I/II und II/III nach *DeLee* u. *Charnley* (Abb. 9 u. 10).

Bis jetzt kam es zu keiner Ausbildung eines Saums oder reaktiver Linien im gesamten strukturierten/beschichteten Bereich – weder an der Pfanne noch am Schaft. Die Knochenstruktur dort ist – wie oben dargestellt – v. a. durch das Vorhandensein von spot welds bestimmt. Genauso wenig war es zu einer signifikanten Wanderung von Prothesenkomponenten gekommen. Dies bezieht sich sowohl auf eine mögliche kraniale und mediale Wanderung der Pfanne (>2 mm) als auch auf eine Veränderung der Pfannenkippung oder Elevation. Auch eine signifikante Schaftsinterung (>2 mm) konnte nach Ausmessen der Röntgenbilder ausgeschlossen werden.

Anzeichen für ein Abscheren von HA-Partikeln gab es ebensowenig wie ein Brechen der sog. Tripoden. Das Ausmessen der Kopfposition in bezug auf das Pfannenzentrum ergab keinen Anhalt für einen wie auch immer gearteten Abrieb.

Besonders niedrig war auch die Rate periartikulärer Ossifikationen prophylaktisch behandelter Patienten; vergleichsweise niedriger, als für ähnliche in der Literatur beschriebene Prothesen [6]. Die exakten Ergebnisse werden an anderer Stelle dargestellt.

Als Maß für die Stabilität und Festigkeit läßt sich der Score nach *Engh* [3] anhand o.g. Kriterien berechnen. Ein Wert von >10 Punkten gilt als sichere knöcherne Einheilung. Die entsprechenden Ergebnisse während des Verlaufs sind in Abb. 8 wiedergegeben. Demnach sind alle Prothesen bereits nach 6 Monaten als sicher knöchern eingeheilt zu bewerten.

Abb. 9 Radiologisches Ergebnis nach 2 Jahren, **a** ausgedehnte spot-weld-Formation in den *Gruen*-Zonen 2 und 6, **b** Reaktive Linien in den *Gruen*-Zonen 2 und 6

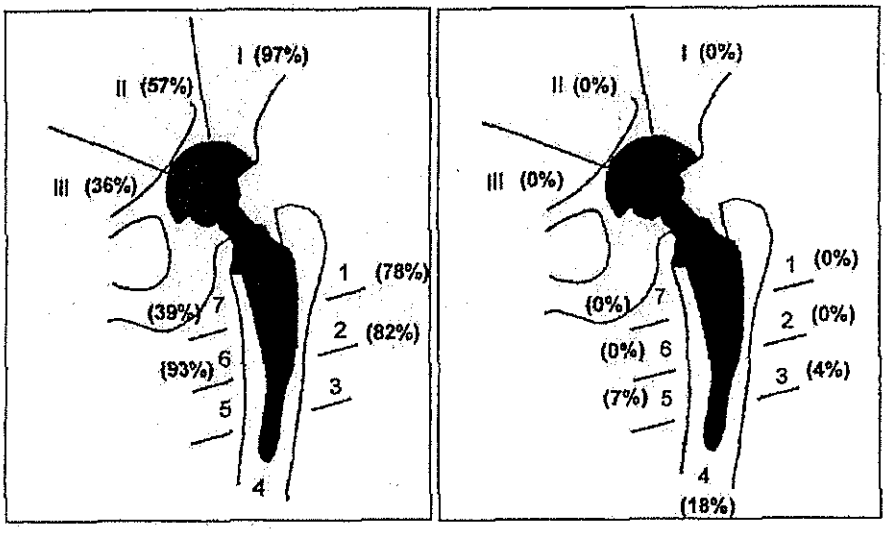

Abb. 10 a Verteilung der spot welds nach 2 Jahren, b Verteilung reaktiver Linien nach 2 Jahren

Diskussion

Entsprechend den heutigen Standards der Endoprothetik fand sich eine sehr niedrige Komplikationsrate, vergleichbar mit anderen Untersuchungen und Prothesenmodellen [18]. Spezifische HA-bezogene Komplikationen sind nicht aufgetreten.

Insbesondere kam es in keinem Fall zu einer Delamination von HA. Wir widersprechen daher der Meinung von *Bauer* [1], es sei schwierig eine qualitativ hochwertige Beschichtung auf makrotexturierten Implantaten herzustellen.

Die klinischen Ergebnisse zeigen, daß sich mit dem untersuchten Modell der sog. Schaft- oder Anpassungsschmerz sicher vermeiden läßt. Dies wird in ähnlichem Ausmaß auch von anderen Autoren berichtet [6] und ist ein Zeichen für die frühe und sichere knöcherne Einheilung, die nach radiologischen Kriterien in jedem Fall erreicht wurde. Die Fixation der Implantate vollzieht sich nicht über ein bindegewebiges Interface, das in vielen Fällen für die Schmerzen verantwortlich gemacht werden muß und eben auch bei makro- und mikroporös-strukturierten Prothesen, wie eingangs dargestellt, auftreten kann.

Damit wird aber auch die in manchen Fällen notwendige und von vielen gefürchtete aufwendige Wechseloperation wegen einer, mit Schmerzen einhergehenden, unzureichenden knöchernen Fixierung vermieden.

Radiologisch zeigen sich alle Kriterien einer sicheren knöchernen Einheilung und Stabilität, die von *Engh* et al. (1990) beschrieben wurden: Fehlen kompletter reaktiver Linien, fehlende Implantatwanderung, spot welds an der Übergangszone beschichteter/unbeschichteter Teil des Schaftes.

Regelmäßig traten reaktive Linien um die Schaftspitze auf. Die Ursache dafür ist nicht endgültig geklärt, aber typisch für proximal HA-beschichtete Prothesen [5]. Die meisten Autoren sehen darin einen Ausdruck des Elastizitätsunterschiedes zwischen Knochen und Prothese und den bei fehlender Beschichtung auftretenden Mikrobewegungen (sog. Windshield-whiper sign [5, 6]). Sie können aber auch als Ausdruck einer dynamischen Fixation der Prothese weit proximal im spongiösen Knochen sein.

Diese radiologischen Kriterien werden dadurch erfüllt, daß das HA das Knochenwachstum direkt und tief in die Makroporen der Tripoden-Oberfläche leitet.

Diese Eigenschaft des Hydroxylapatits führt auch dazu, daß Prothesen mit suboptimalem Sitz oder unbefriedigender Implantation fest knöchern einheilen können. Experimentelle Untersuchungen haben gezeigt, daß die knöcherne Heilung auch über Spalten zwischen Knochen und Prothese von >1 mm erfolgt (4, 8). Wie *Geesink* [6] wollen wir daher den fehlerverzeihenden Charakter HA-beschichteter Implantate betonen.

Darüber hinaus haben experimentelle Studien gezeigt, daß auch unter Infektbedingungen ein Einheilen der Prothese möglich ist. *Wielke* et al. [20] diskutieren sogar, ob eine infizierte HA-beschichtete Prothese in jedem Fall explantiert werden muß.

Die Funktionsfähigkeit eines Implantates hängt nicht nur von der Bioaktivität seiner Oberfläche ab. Vielmehr ist das Zusammenspiel aller Einflußgrößen – Biomechanik, Oberflächenstrukturierung und Bioaktivität – entscheidend.

Aufgrund eigener Erfahrungen sowie der Literatur [5, 13] halten wir es für besonders günstig, eine makroporös strukturierte Prothese zu beschichten. Diese Strukturierung erhöht die Widerstandsfähigkeit der Beschichtung gegen reine Scherkräfte [5]. Eine tiefe oder innige Osteointegration (bony ingrowth) ist nur bei makroporöser Oberflächenstruktur zu erreichen. Bei mikroporösen Oberflächen wird lediglich ein Heranwachsen des Knochens an die Prothese erreicht (bony ongrowth). Mit einer erhöhten Lockerungsrate muß hierbei nach Jahren gerechnet werden.

Weiterhin besteht Besorgnis darüber, wie der Knochen-Prothesenkontakt aussehen mag, wenn die HA-Beschichtung resorbiert ist – und davon, das beweist die Literatur ebenfalls, ist in jedem Fall je nach Beschichtungsstärke

auszugehen [4]. Im Fall oberflächenstrukturierter Implantate bleibt der feste und tiefe Knochen-Prothesen-Kontakt erhalten [8]. Wir sehen daher im HA vor allem die Starter-Funktion [4], die uns eine sichere knöcherne Heilung gewährleistet, indem das sog. kritische „Interperiodikum" [15] überbrückt wird. Die sekundäre Stabilität wird nach wie vor durch die interkonnektierenden Knochen-Prothesentrabekel, die zu einer dynamischen Aufhängung der Prothese im Prothesenlager führt, gewährleistet. Aufgrund der zu erwartenden Resorption des HA sind daher in ganz besonderem Maß makrostrukturierte Implantate als Grundlage für eine Beschichtung geeignet.

Bedenken gegen Beschichtung makrostrukturierter Implantate (z.B. beads) aufgrund technischer Probleme [4] sind mit modernen Verfahren unseres Erachtens haltlos. Experimentelle Untersuchungen (pull-out-Versuche) sowie die Qualitätskontrollen der eigenen Beschichtung haben durchweg bessere Resultate im Vergleich zu glatten Oberflächen ergeben [2].

Einen weiteren Vorteil HA-beschichteter Implantate sehen wir wie andere Autoren [4, 6, 8] in der möglichen „Versiegelung" des Femurs gegen das Einwandern von PE in das sog. Interface, das bei Vorhandensein eines fibrösen Interface maximal ist [4].

Diese Vorteile sollten zu einer deutlichen Verkürzung des Krankenhausaufenthaltes, einer schnelleren Rehabilitation sowie Wiedereingliederung in den Arbeitsprozeß führen. Weiterhin ist eine niedrigere Revisionsrate, ein geringerer Analgetikaverbrauch sowie eine Reduktion von Arztkontakten möglich. Es ist daher von diesem Implantat ein hoher Kosten-Nutzen-Effekt trotz initial höherer Implantatkosten zu erwarten. Diese Hypothese muß allerdings durch Langzeitstudien bewiesen werden.

Schlußfolgerung

200 aufeinanderfolgende Patienten, die mit einer Hydroxylapatit beschichteten Hüftendoprothese mit makroporöser Oberflächenstrukturierung versorgt wurden, konnten prospektiv verfolgt werden. Bisher war keine Revision aufgrund einer aseptischen Lockerung nötig. Femorale „Anpassungsschmerzen" sind nicht mehr aufgetreten. Der mittlere HHS nach 2 Jahren betrug 97 und die radiologische Untersuchung zeigte eine frühe und komplette knöcherne Einheilung aller Prothesenkomponenten.

Unsere Ergebnisse haben uns daher ermutigt, dieses Endoprothesenmodell weiter anzuwenden. Es bietet neben der Primärstabilität eine sichere und frühzeitige sekundäre Stabilisierung als Voraussetzung für eine dauerhafte Fixation der Prothese. Ob eine bessere Fixierung durch die Verbindung einer makroporösen Oberfläche mit HA-Beschichtung sich langfristig bestätigt, wird durch das weitere follow up zu beweisen sein.

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Osteoblastic response to osteoarthrosis of the hip does not predict outcome of cementless cup fixation

79 patients followed for 5–11 years

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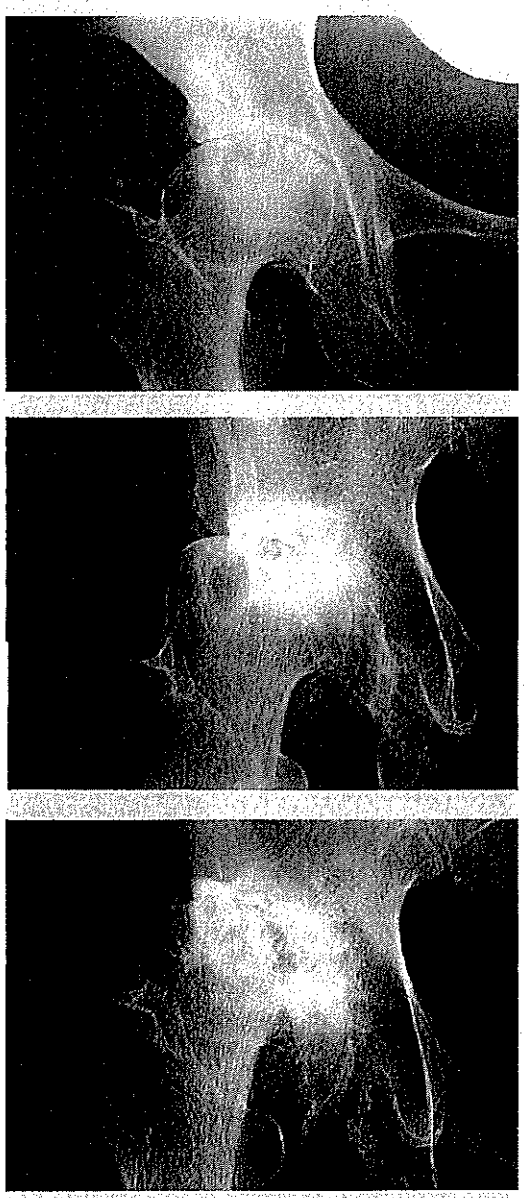
ABSTRACT – We evaluated the influence of osteoblastic response to osteoarthrosis of the hip on the outcome of cementless acetabular cup after 91 total hip replacements in 79 patients. Of the 91 hips, 23 were atrophic, 37 normotrophic, and 31 hypertrophic, according to Bombelli's criteria. There were no clinical or radiographic differences among the three groups at the final follow-up (average 7 (5–11) years), when stable bone growth had been achieved by all of the acetabular cups in patients with the atrophic type, 35/37 of the normotrophic type, and all the hypertrophic type. Revision of the acetabular cup was performed on 1 hip of the normotrophic type, in connection with severe polyethylene liner wear and progressive osteolysis.

Osteoblastic response by host bone to implant surface may be an important factor affecting longevity of total hip arthroplasty (THA). In patients with osteoarthrosis (OA), the type of osteoblastic response, in terms of Bombelli's (1983) classification, has been reported to predict loosening of the cemented acetabular socket (Saito et al. 1987, Kobayashi et al. 1997). The atrophic OA type hips showed a higher incidence of unsatisfactory clinical results and radiographic loosening of the cemented cup than did the hypertrophic or normotrophic OA type hips. The influence of osteoblastic response on cementless THA has not been studied. We thought that cementless fixation may need a higher osteoblastic response to achieve good bone ingrowth or ongrowth fixation. Therefore we investigated whether there was any association between osteoblastic response and outcome in cementless THA, as previously reported in cemented THA.

Patients and methods

Between 1987 and 1993, a cementless THA, using the Spongiosa Metal Total Hip System (ESKA, Lübeck, Germany), was performed in a consecutive series of 100 hips for 87 patients with OA. All the cases were secondary to acetabular dysplasia or congenital subluxation or dislocation of the hip. No cases of primary osteoarthrosis, or completely dislocated hip were included. The stem and metal socket of this system are made of cobalt chrome molybdenum alloy with the entire surface covered by a spongy metal structure similar to cancellous bone. The metal cup has a hemispherical shape with two spikes wedged into the anterior and posterior acetabular rims and one peg inserted into the ischium. The curved stem with a collar anatomically matches the medullary canal of the proximal femur. An interior polyethylene liner (ESKA, Lübeck, Germany) and a modular aluminum ceramic head, having a diameter of 28 mm (Biolox: Ceramtech, Plochingen, Germany), are used for the articulation. As a rule, the cup was placed in the anatomical position of the acetabulum, and a block bone graft from the resected femoral head was used in 14 hips and chip grafts in 23 hips to fill the superolateral bony defect in the acetabulum. Partial weight bearing was started at



Morphological types of osteoarthrosis of the hip according to Bombelli's criteria: a) atrophic OA type, showing poor osteophyte formation and gradual reduction in size of the femoral head, b) normotrophic OA type, showing a moderately sized osteophyte formation, c) hypertrophic OA type, having large osteophytes on the margins and floor of the acetabulum as well as around the femoral head.

6 weeks and full weight bearing was allowed at 12 weeks after the operation. Clinical and radiographic assessments were done annually.

2 patients, accounting for 3 hips, died within 5 years after surgery due to causes unrelated to the hip. Deep infection occurred in 1 hip 4 years postoperatively, and both the acetabular cup and stem were removed. 5 patients (5 hips) were lost to follow-up within 5 years after surgery, but they showed excellent clinical and radiographic results when last reviewed. The remaining 91 hips of 79 patients were the subjects for subsequently analyzed with a minimal follow-up of 5 years. The average age of the patients was 52 (29–67) years at the time of operation, and the average follow-up 7 (5–11) years.

The clinical assessments were based on the Merle d'Aubigné and Postel (1954) hip score, which allocates up to 6 points for each type of pain, mobility, and function, with a total of 18 points given to a normal hip. Osteoblastic response of the arthrotic hips was evaluated with Bombelli's (1983) criteria on preoperative radiographs (Figure). These radiographs were interpreted blindly by two of the authors without knowledge of the clinical and radiographic outcomes. Both observers had the same view about 78 hips, but came to an agreement about the remaining cases. 23 hips were classified as atrophic OA type (A-type), 37 as normotrophic OA type (N-type), and 31 as hypertrophic OA type (H-type). All patients were female, except 1 in the A-type group and 2 in the N-type group. The follow-up period was about the same in the three groups (mean months (SD): 85 (20) in the A-type group, 85 (19) in the N-type group, 87 (15) in the H-type group). The patients' ages at operation differed significantly: 56 years (SD 6) in the A-type group, 53 years (7) in the N-type group, 49 years (8) in the H-type group, the latter being younger than the A-type group ($p = 0.003$, Scheffe test).

At the annual postoperative follow-ups, anteroposterior and lateral radiographs were evaluated for evidence of radiolucent lines, implant fixation, and osteolysis by a zonal interface analysis of the acetabular cup with DeLee and Charnley's method (1976). Fixation of the cup was evaluated by a modified DeLee and Charnley classification (McPherson et al. 1995), according to which fixation by bone ingrowth (type 1) has three subtypes: 1A means the absence of radiolucent lines or migration of the cup, 1B has a radiolucent line in one zone, and 1C has a radiolucent line in two zones. Stable fibrous fixation (type 2) has a com-

Incidence of radiolucent lines around the acetabular cup and cup fixation at the final follow-up

Type of osteoarthrosis	Radiolucent line				Cup fixation				
	Present in one or more zones	Zone 1	Zone 2	Zone 3	1A	1B	1C	2	3
Atrophic	2/2 (CI 0–0.22)	2/2	0	0	20/21	2/2	0	0	0
Normotrophic	7/7 (CI 0.06–0.35)	1/1	4/4	5/5	27/29	4/4	1/2	0	2/2 (CI 0–0.14)
Hypertrophic	3/3 (CI 0.02–0.24)	0	0	3/3	24/28	3/3	0	0	0

Values are number of patients/hips, CI = 95 % confidence interval of incidence ratios

plete radiolucent line less than 2 mm in width. Unstable fibrous fixation (type 3) has a complete radiolucent line equal to or greater than 2 mm in width, a progressive zone 3 radiolucent line, or cup migration by more than 2 mm.

Statistical analysis was performed with StatView software (version 5.0; SAS Institute, Cary, North Carolina) and a p-value less than 0.05 was considered significant.

Results

Clinical results

The mean Merle d'Aubigné and Postel hip score of all patients improved from 7.6 (pain 1.2, mobility 3.7, function 2.7) before operation, to 17 (pain 5.9, mobility 5.3, function 5.6) 2 years postoperatively, and to 17 (pain 5.9, mobility 5.3, function 5.5) at the final follow-up. All three groups achieved good hip score improvement from preoperative examinations to the final follow-up: from 8.0 points to 17 in the A-type group, from 7.7 to 17 in the N-type group, and from 7.2 to 17 in the H-type group. There was no statistically significant difference in the hip scores among the three groups at the final follow-up (one-way analysis of variance). The resuls were unsatisfactory, indicated by a total score of 14 or less, in 2 N-type hips due to stem fracture or disability from osteoarthrosis of the contralateral hip, and in 1 H-type hip due to disability from lumbar spondyloarthritis.

Radiographic results

Radiolucent lines in one or more zones around the acetabular cup were seen in 2 patients in the A-type group, 7 patients in the N-type group, and 3 patients in the H-type group at the final follow-up (Table). When adjusted for other factors, including age, sex, follow-up period, and performance of block bone graft, osteoblastic response type showed no significant correlation with the occurrence of a radiolucent line (logistic regression analysis). Satisfactory fixation of the acetabular cup was achieved in all 3 groups at the final follow-up. All patients in A-type and H-type groups, and 32 patients in the N-type group showed bone ingrowth fixation (grades 1A, 1B, or 1C). Osteolysis around the acetabular cup was most marked in the N-type group (6 patients), while only 1 patient in the A-type group and none in the H-type group showed osteolysis.

Two revision operations were performed during the study: 1 hip in the N-type group underwent a revision of the acetabular cup due to unstable fibrous fixation, and 1 hip in the N-type group underwent revision of the femoral stem due to stem fracture without loosening of the cup.

Discussion

The morphological type of osteoarthrosis is said to affect the outcome of cemented THA (Saito et al. 1987, Kobayashi et al. 1997): atrophic type hips had a high incidence of unsatisfactory clinical results and acetabular loosening. Histological

examinations showed that bone specimens from hypertrophic type hips had many osteoblasts with few osteoclasts on the surface of subchondral trabeculae, while bone specimens from atrophic type hips had many osteoclasts with fewer osteoblasts (Saito et al. 1987).

These findings suggest that the results with morphological types of osteoarthrosis may be similar to those with acetabular cups after cementless THA. Hernández-Vaquero et al. (1996) compared the outcome of threaded acetabular cups after cementless THA among the atrophic, normotrophic, and hypertrophic types of hips at a mean follow-up of 6 years, and found that periprosthetic radiolucent lines and loosening of the acetabular cups occurred significantly oftener in the atrophic hips. Our study, however, showed no significant differences in clinical results, incidence of radiolucent lines or cup fixation after 7 years among the three groups. The discrepancy between the findings of Hernández-Vaquero et al. (1996) and ours may be due to the tendency of threaded cups to fail after a few years (Snorrason and Kärrholm 1990, Yahiro et al. 1995). Adequate bone ingrowth and long-term fixation of the acetabular cup can be achieved only by stable initial fixation into the acetabular bone. If stability is insufficient, minimal bone ingrowth can be expected because of weak osteoblastic activity in atrophic type hips. Here we used a press-fitting technique with underreaming to obtain stable fixation of the acetabular cup. The results half-way through the study using this technique for cup fixation were satisfactory (Morscher 1992, Dorr et al. 1998). Linder et al. (1988) showed that osseointegration with the implant surface was usually attained even in patients with compromised bone quality, such as osteoporosis and rheumatoid arthritis, and adequate initial stability with the acetabular cup we used should have resulted in adequate subsequent bone ingrowth fixation and a successful outcome, even in hips of the atrophic type.

Our study has certain limitations: almost all patients were female, and osteoarthrosis secondary to dysplasia or congenital subluxation or dislocation of the hip was evaluated exclusively because these are the main causes of osteoarthrosis in our country. This may have affected the relation between the outcome of the arthroplasty and the osteoblastic types of hip. We found no significant difference among the three groups as regards clinical and radiographic outcomes. However, there may be a true difference among the groups (type II error), because of the limited sample size (Freedman and Bernstein 1999). Further studies in more patients including more males and various causes of osteoarthrosis are needed to increase the reliability of the statistical analysis and extrapolate the findings to the usual type of osteoarthrosis of the hip or a population with more males.

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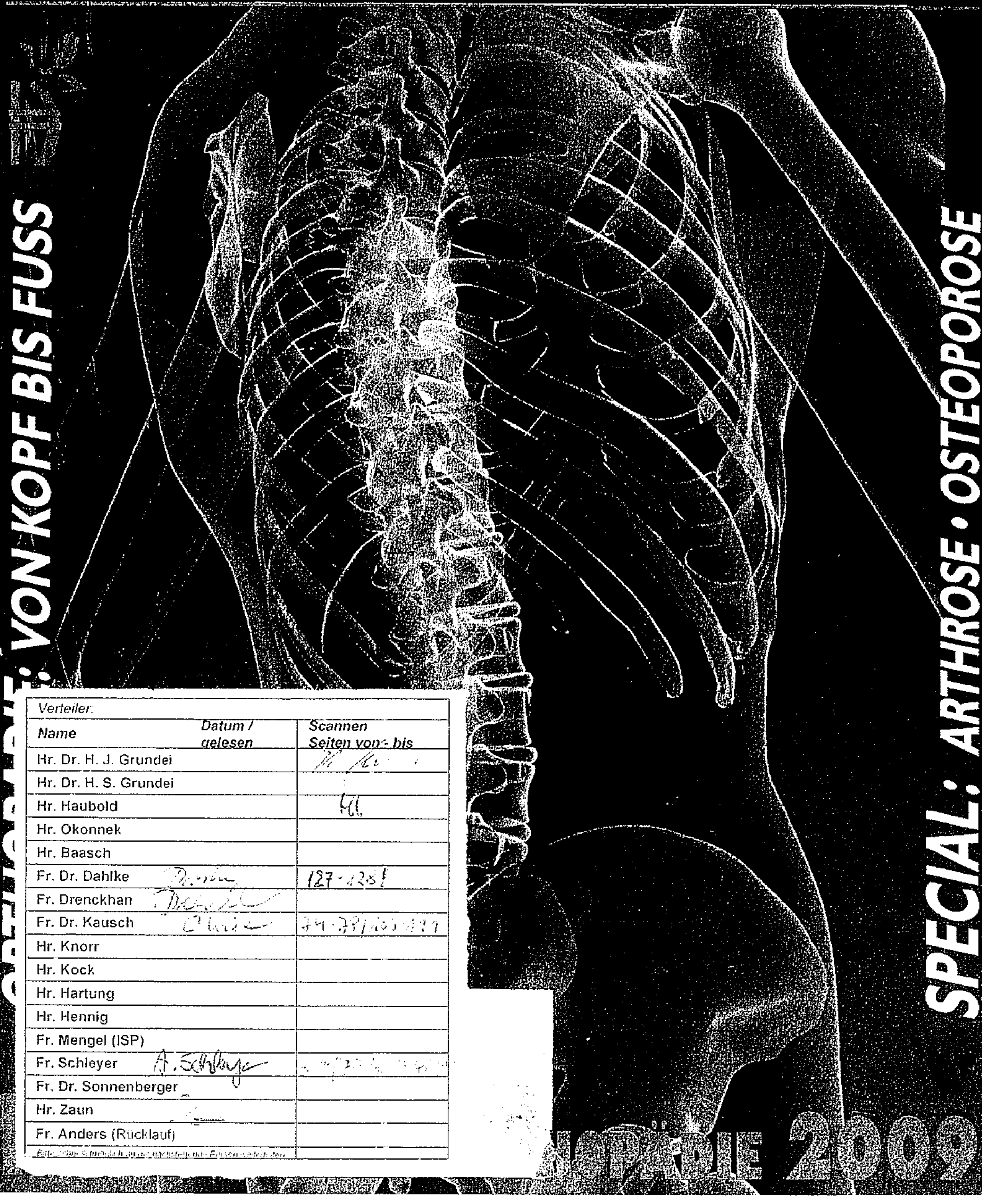
- RHEUMATOLOGIE + TRAUMATOLOGIE -



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5 bis 9 Jahre Nachuntersuchungsergebnisse der zementfreien Keramik/Keramik-Totalendoprothetik bei Dysplasiecoxarthrosen

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Schlüsselwörter:
Dysplasiecoxarthrose, Aluminiumoxidkeramik, zementfreie Keramik.

Einleitung

Die aseptische Lockerung ist langfristig ein Hauptproblem der zementfreien Hüftendoprothetik. Die Versorgung junger und aktiver Patienten mit Dysplasiecoxarthrose stellt hierbei eine Herausforderung dar. Seit 10 Jahren verwenden wir das modulare Spongiosa Metal II® Endoprothesensystem (ESKA Implants, Lübeck) mit einer Aluminiumoxidkeramik-Gleitpaarung (BIOLOX®forte, Kugelkopf 28 mm, CeramTec AG, Plochingen), da wir ein besseres Abriebverhalten und eine längere Lebensdauer der Endoprothese erwarten [1].

Material und Methoden

Von Oktober 1998 bis Dezember 2007 wurden 1153 primäre Totalendoprothesen mit einer Keramik/Keramik-Gleitpaarung eingesetzt. Bei 151 Patienten mit Dysplasiecoxarthrose erfolgten 166 Implantationen. Dabei verteilte sich das Patientengut auf 4 männliche und 147 weibliche Patienten. In allen Fällen ergab die präoperative Diagnose eine Dysplasiecoxarthrose, darin eingeschlossen 10 fehlgeschlagene Osteotomien, 3 Femurkopfnekrosen (Kalamchi und McEwen Typ II) [2] und 2 Dislokationen (Klassifizierung nach Crowe, Grad IV) [3]. Der Altersdurchschnitt zum Operationszeitpunkt lag bei 57 (44-75) Jahren. Die durchschnittliche Operationsdauer betrug 78 (38-159) Minuten. Um die größte Pfanne (d.h. ein Keramikinsert mit maximaler Wandstärke) verwenden und das Hüftzentrum entsprechend wiederherstellen zu können, wurde das Acetabulum bis zur Lamina interna ausgefräst. Bei 8 Hüften erfolgte zusätzlich eine Pfannendachplastik mit Schrauben. Ein autologes Knochentransplantat wurde am Pfannenrand bei 60 Hüften verwendet. Bei 30 Hüften wurde eine Adduktorentenotomie durchgeführt. Ein ausgedehntes Weichteilrelease erforderten 5 Hüften. Osteophyten wurden sorgfältig entfernt, um Impingement zu vermeiden. Der Nachuntersuchungszeitraum lag bei durchschnittlich 6,3 (5-9) Jahren.

Abb. links: A.p.-Aufnahme präoperativ. Abb. rechts: A.p.-Aufnahme 1 Jahr postoperativ. Das Acetabulum wurde bis zur Lamina interna ausgefräst.

Klinische und radiologische Ergebnisse

Der Harris Hip Score (HHS) hat sich bei allen Patienten verbessert. Der durchschnittliche HHS erhöhte sich von präoperativ 62 (30-83) Punkte auf 91 (69-100) Punkte postoperativ. Die Überlebensrate betrug für Pfanne und Schaft 100%. Kein Patient benötigte eine Revision. Es traten keine Dislokationen oder Geräusche [4] auf. Es zeigten sich keine implantatspezifischen Komplikationen. Tiefe Thrombosen, Lungenembolien oder Infektionen waren nicht zu verzeichnen. Der durchschnittliche Inklinationswinkel betrug 39 (29-49) Grad, der Anteversionswinkel im Durchschnitt 18 (10-30) Grad. Im Beobachtungszeitraum waren alle Prothesen stabil [5]. In einem Fall kam es innerhalb der ersten 2 Jahre nach Implantation zu einer geringfügigen Positionsänderung des Schaftes (Varuskippung), die sich jedoch im weiteren Verlauf stabilisierte. Radiologisch fanden sich Lysesäume bei 4 Hüften (2%) im Pfannenbereich (Zone III), bei 20 Hüften (12%) in den proximalen Schaftzonen. Osteolysen wurden nicht beobachtet.

Diskussion

Der Vorteil von Keramik/Keramik-Gleitpaarungen besteht in ihrem ausgezeichneten Abriebverhalten [6]. Keramikabriebpartikel zeigen ein bioinertes Verhalten und es kommt selten zu Osteolysen [7, 8]. In einer Studie unseres Institutes zeigte sich, dass Osteolysen weniger oft bei Prothesen mit Keramik/Keramik-Gleitpaarungen als vergleichsweise mit Keramik/Polyethylen-Gleitpaarungen auftraten [1]. Diskutiert wird das Bruchrisiko von Keramikkomponenten [9]. In unserem Patientengut der Studie trat bisher keine Fraktur auf. Nach Garcia-Cimbrelo et al. wurde bei 319 Hüftendoprothesen nur in einem Fall ein Bruch einer Keramikkomponente bekannt [10]. Bizot et al. verwiesen darauf, dass sowohl der Innenkonus der Metallpfanne als auch die Keramikkomponente beim Einsetzen des Keramikinserts in die Pfanne beschädigt werden können [11]. Um das Frakturrisiko zu minimieren sollten Operateure darauf achten, dass Pfanneninnenkonus und Schaftkonus nicht mit Instrumenten in Berührung kommen oder durch Gewebereste verschmutzt sind. Yoo et al. wiesen darauf hin, dass bei einer Fehlpositionierung der Pfanne oder exzessiver Weichteilspannung während der Operation Keramikkomponenten beschädigt werden könnten, mit der Folge eines erhöhten Bruchrisikos und vermehrten Abriebs [12, 13]. Nach Lusty et al. beeinflusst die Positionierung der Implantate das Abriebverhalten keramischer Gleitpaarungen [6]. Bader et al. empfehlen die Verwendung von Keramik/Keramik-Gleitpaarungen nur bei günstiger Implantatposition, um Impingement und mögliche Folgen wie Materialversagen (z.B. Randabplatzer oder Bruch) und Dislokation zu vermeiden [9].

Schlussfolgerung

Die Spongiosa Metall II® Endoprothese ermöglicht bei Dysplasiecoxarthrosen eine exzellente Primärstabilität und erweist sich als geeignet in Kombination mit der keramischen Gleitpaarung. Auch bei stark dysplastischen Acetabula muss der Operateur eine gute Primärstabilität und Pfannenpositionierung gewährleisten. Daher sind korrekte Implantationstechnik und operative Sorgfalt [14] unerlässlich, um die tribologischen Vorteile der Keramik nutzen zu können und Komplikationen zu vermeiden.

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22nd February 2011

Re: GHE Adapter stems

Dear Mr. Meakins,

I can confirm that I have been using the cemented GHE Adapter stem for primary hip replacement since 2006.

During this time, I have implanted approximately 35 Adapter stems per year, over 150 implantations in total.

Whilst there has been no official follow-up of these devices, from my experience the incidence of problems is low and the implant survivorship is good. In my opinion, the cemented Adaptor stem offers a good clinical outcome that is comparable to other stems used to treat primary hip arthroplasty indications.

Yours sincerely,

Professor Rudigier

Offenburg

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Ihr Zeichen	Ihre Nachricht	Unser Zeichen	22nd February 2011

Re: GHE Adapter stems

Dear Mr. Meakins,

I can confirm that I have been using the cementless GHE Adapter stem for primary hip replacement since 2004.

During this time, I have implanted approximately 38 Adapter stems per year, over 200 implantations in total.

Whilst there has been no official follow-up of these devices, from my experience the incidence of problems is low and the implant survivorship is good. In my opinion, the cementless GHE Adaptor stem offers a good clinical outcome that is comparable to other stems used to treat primary hip arthroplasty indications.

Yours sincerely,

Dr. Seifert

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ORIGINAL PAPER

Metal release and corrosion effects of modular neck total hip arthroplasty

J. Philippe Kretzer · Eike Jakubowitz · Michael Krachler · Marc Thomsen · Christian Heisel

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Abstract Modular neck implants are an attractive treatment tool in total hip replacement. Concerns remain about the mechanical stability and metal ion release caused by the modular connection. Five different implant designs were investigated in an experimental set-up. In vivo conditions were simulated and the long-term titanium release was measured. Finally, the modular connections were inspected for corrosion processes and signs of fretting. No mechanical failure or excessive corrosion could be identified for the implants tested. The titanium releases measured were extremely low compared to in vivo and in vitro studies and were not in a critical range.

Résumé Dans les prothèses totales de hanche l'utilisation d'implants avec col modulaire est d'une utilisation fréquente et pratique. Néanmoins, cette utilisation laisse persister des doutes sur la stabilité mécanique et sur le relargage des ions métalliques. 5 différents implants ont été étudiés en reproduisant les conditions in vivo, en mesurant le relargage de titane et en évaluant la corrosion et les lésions du col. Ce travail n'a pas permis de mettre en évidence d'échec secondaire à une corrosion excessive, et les taux de titane sont restés extrêmement bas dans les limites de l'acceptable.

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Introduction

In current total hip arthroplasty, modularity between the head-neck connection of the femoral stem is well established [1]. More recently, implants with an additional modular connection between the neck and stem have become more popular. The ability to adjust the head centre relative to the stem axis intraoperatively, by connecting the neck in different positions, guarantees high versatility during surgery.

The mechanical loading conditions of the neck-stem connection fundamentally differ from the well-established head-neck connection. The forces at the established head-neck connection are transmitted centrally through the head resulting in low stresses. In contrast, the eccentric load on the modular neck-stem connection leads to higher stresses at the connection.

Fretting caused by micro-motion between the modular components may lead to particle and ion release to the surrounding tissue [4, 12, 21]. Titanium-containing particles may cause the release of cytokines that are associated with periprosthetic bone loss [25]. Such particles may get trapped between the articulating surfaces of the artificial joint resulting in third-body wear [21]. Furthermore, mechanically assisted crevice corrosion (as a combination of fretting and crevice corrosion) may attack the alloy and

lead to implant failure [7]. Modularity is often associated with corrosion effects and is seen as a weak link with a possible source of complications [24]. A multicentre retrieval analysis of 231 modular hip implants revealed corrosion processes at the modular head-neck connection in more than 28% of the cases [8].

The aim of this study was to analyse and compare the corrosion effects and to evaluate the particle and ion release of the modular neck hip implants currently used. The following questions were addressed: (1) Are there differences in the total titanium release between different implant designs? (2) How does the geometry of the taper influence the titanium release? (3) Are there differences in the titanium release over time?

Material and methods

Three implants were analysed (Fig. 1): Eco-Modular® (Endoplant, Marl, Germany), Varicon® (Falcon Medical, Mödling, Austria), Metha® (Aesculap, Tuttlingen, Germany) and SPS-Modular® (Symbios, Yverdon, Switzerland). All implants were made of Ti-6Al-4V alloy. Additionally, a universal modular neck adapter (Bio-Ball®, Merete, Berlin, Germany) which is connectable to standard hip stems (12/14 taper) was included. This adapter was combined with a CF30®-stem (Zimmer, Warsaw, IN, USA). The Metha® and SPS-Modular® taper shapes were oval, designed with a female stem connection. All other taper geometries were round and had a male stem connection (Fig. 1).

The stem and neck sizes were chosen on the basis of the femoral size of an average patient. Comparable biomechanical loading conditions were achieved by selecting similar femoral anteversion and head neck diaphyseal (CCD) angles and lateral offsets for all implants (anteversion: 6.8°; CCD: 133.1°; lateral offset: 46.5 mm).

The taper angles were determined using a coordinate measuring machine (CMM) (MarVision MS 222, Mahr, Göttingen, Germany; accuracy: ±2.3 µm) and the surface roughness was analysed using a roughness measurement instrument (Perthometer M2, Mahr, Göttingen, Germany; accuracy: 12 nm). The stems and modular necks of each design were randomly paired. The resulting taper angle differences (cone angle differences) were calculated and the total surface roughness of each couple was determined quadratically. All geometrical measurements were repeated five times.

The assembly load and environment play a major role in the initial stability of modular connections [16]. To simulate surgical conditions the modular connections were connected wet by a hammer stroke. The stems were orientated in 10° adduction and in 9° flexion resulting in bending and torsional loading of the stem and stem-modular neck connection according to ISO 7206 (Fig. 2). A sinusoidal load of between 0.3 kN (min.) and 2.3 kN (max.) was applied for 10×10^6 cycles. The frequency was repeatedly altered between 3 Hz (100,000 cycles) followed by 15 Hz (900,000 cycles).

The particles and ions released from the stem-modular neck connection were measured using a fluid reservoir filled with 800 ml calf serum (diluted to a protein content of 30 g/l, at 37°C, pH: 7.4). Serum was chosen because proteins are reported to affect the corrosion resistance of titanium alloy [11, 14]. The serum was continuously circulated by a peristaltic pump from the reservoir to a small simulation chamber which surrounded the modular connection (Fig. 2).

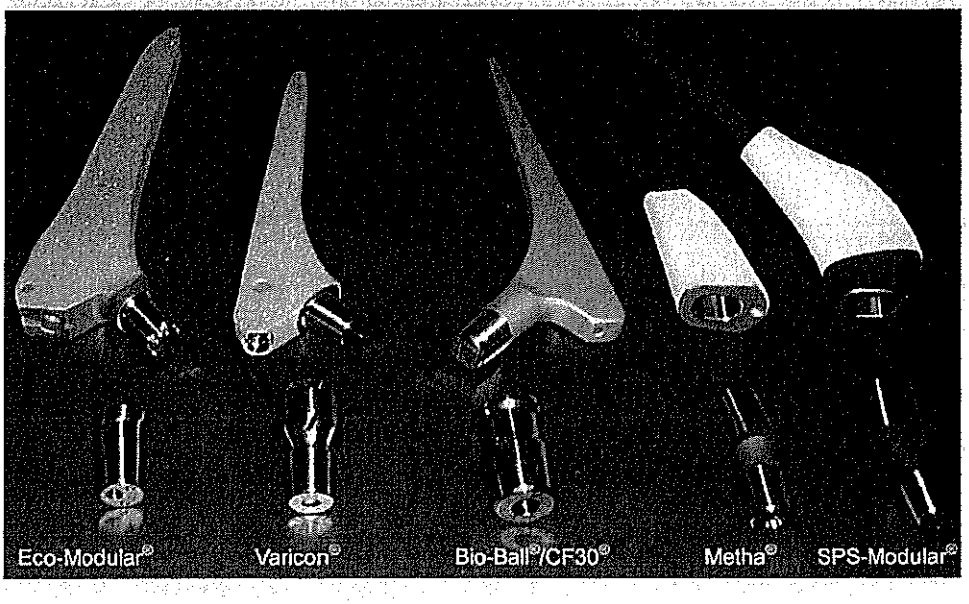

Fig. 1 Implant designs investigated. The oval modular taper of the two designs on the *right side* are female connections

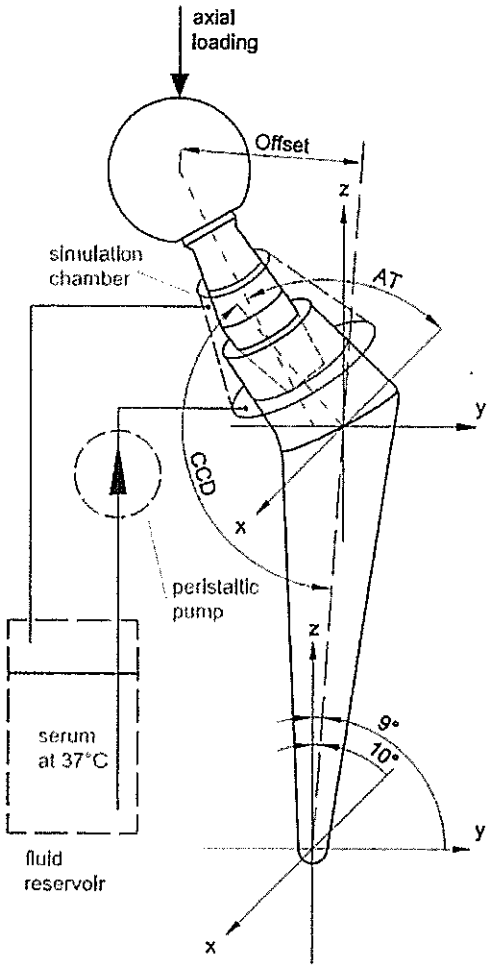

Fig. 2 Alignment of the stem and modular neck relative to spatial coordinates. The peristaltic pump continuously circulates serum between the fluid reservoir and simulation chamber

The titanium concentration of the serum was analysed using HR-ICP-MS (Element2, Thermo Fisher Scientific, Bremen, Germany) at intervals of 0, 1×10^6, 2×10^6, 4.5×10^6, 7×10^6 and 10×10^6 cycles. In order to detect not only ions but also particles in the serum, the samples were first digested with high purity nitric acid (HNO_3) and hydrogen peroxide (H_2O_2) following a standardised, well-established procedure [10]. The titanium mass was calculated based on the test medium's volume and the measured titanium concentration.

All data are presented as mean ± standard deviation (SD). An analysis of variance (ANOVA) was used to prove whether there were differences between the prostheses in total titanium release. Pearson's correlation test was performed to deal with geometrically related influences (total surface roughness, mean cone angle and delta cone angle) on total titanium release. Student's *t*-test was used to detect possible influences of the taper shape (round vs oval). Regression analysis was performed to demonstrate a progression in titanium release over time. All statistical analyses were performed using SPSS® software (SPSS® for Windows 16.0.1, SPSS Inc. Chicago, IL, USA). A p value < 0.05 was considered significant.

Finally, the tapers were carefully disconnected and inspected by scanning electron microscope (SEM) (Type 440, Carl Zeiss, Cambridge, UK) for corrosion effects.

Results

The total titanium release of all systems varied between 12 and 44 µg at the end of the test (Fig. 3). No significant differences in total titanium release were found between the tested implants ($p=0.66$). Table 1 summarises the results of the geometrical measurements. Neither the mean cone angle ($p=0.45$), the cone angle difference ($p=0.30$) nor the shape of the taper ($p=0.44$) had a significant influence on the total titanium release. Based on an almost significant ($p=0.06$) negative correlation coefficient of $r=-0.86$, the total surface roughness indeed seemed to have an effect. A significant linear progression in titanium release over time was found for the Eco-Modular® implant ($p<0.01$, $r=0.98$), the SPS-Modular® implant ($p<0.01$, $r=0.99$) and the Bio-Ball® implant ($p=0.04$, $r=0.90$). No linear correlation was found for the Varicon® implant ($p=0.30$, $r=0.59$) and the Metha® implant ($p=0.19$, $r=0.70$).

SEM revealed moderate signs of fretting in all tested connections. Figure 4 shows scars caused by micro-motion which perpendicularly obliterate machine lines. No severe corrosion effects were detected in any of the implants investigated.

Discussion

The literature unequivocally demonstrates that design- and material-related parameters influence micro-motion and

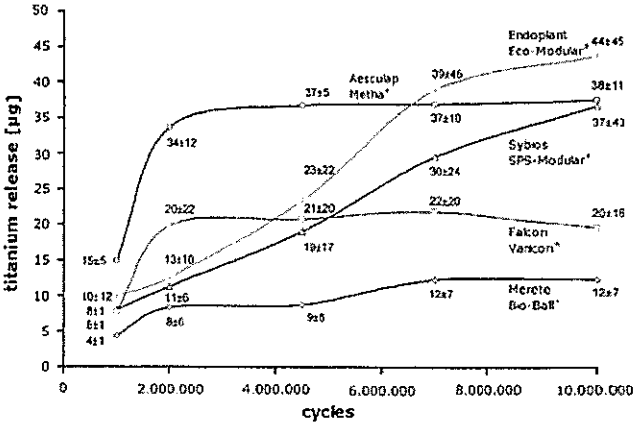

Fig. 3 Titanium release of the five implant designs during the course of simulation

Table 1 Results of the cone geometry measured

	Total surface roughness (μm)		Mean cone angle (°)		Cone angle difference (°)	
Endoplant Eco-Modular®	1.28	± 0.31	5.67	± 0.02	0.04	± 0.04
Falcon Varicon®	3.48	± 0.17	5.80	± 0.01	0.31	± 0.03
Aesculap Metha®	0.72	± 0.02	3.69	± 0.01	0.09	± 0.04
Symbios SPS®	0.34	± 0.01	5.01	± 0.01	0.10	± 0.02
Merete Bio-Ball®	12.15	± 0.39	5.68	± 0.00	0.11	± 0.03

fretting of implant connections [8, 9, 11, 13, 15]. However, no differences in total titanium release were found for the implant designs tested here. Compared to other studies the titanium release of all systems investigated in this study is low. A similar study on a modular neck hip implant design made of a titanium alloy revealed material loss of between 280 and 1,640 μg after 5.5×10^6 loading cycles [22]. Another study on a titanium plate-screw connection resulted in a titanium release of 849 μg after 1.2×10^6 loading cycles [13]. Lower concentrations ranging from 3 to 21 μg were also reported for plate-screw connections [11]. However, this study was only performed for 0.4×10^6 loading cycles.

The surface roughness showed a negative linear correlation to the total titanium release. With increasing surface roughness the titanium release decreased. Higher surface roughness may locally increase and evenly distribute the contact pressure [2] and thus decrease micro-motions between both components. The reported effect of increased micro-motion and fretting depending on the cone angle difference [20, 23] was not seen in this study. The implants showed different patterns with respect to progression in titanium release over time. For the Symbios SPS®, Endoplant Eco-Modular® and Merete Bio-Ball® implants the titanium release proceeds in a linear manner. However, the Aesculap Metha® and Falcon Varicon® systems showed a titanium release which increased during the first 2×10^6 cycles and subsequently remained stable (Fig. 3). Similar progressions are reported for wear studies on metal-on-metal joint bearings in total hip replacement [10]. During the initial run-in phase of those implants, the surface geometries of both counterparts adapt to each other. Such a mechanism may also occur at the modular connection leading to decreased micro-motion and resulting in a more stable connection. The explanation for the measured steady-state titanium concentrations over time in two of the five tested implant designs may be related to a limited fluid transfer between the crevice of the modular connection and the surrounding fluid. If the fluid transfer is restricted, metal ions caused by fretting may not enter into the surrounding fluid. In this case mechanically assisted crevice corrosion as reported by Gilbert et al. [7] may occur. Based on fretting and subsequent repassivation of the titanium, the local concentration of free oxygen will drop and this will result in an increased concentration of free metal ions in the crevice. The excess of metal ions then attracts chloride ions to form metal chlorides. These metal chlorides will react with water to form metal hydroxide and hydrochloride acid, lowering the pH and resulting in a hydrochloric acid solution with a very low pH in the crevice. The metal then loses its passive film and becomes thermodynamically unstable. Subsequent failure of the modular connection might occur. However, in this study neither mechanically assisted crevice corrosion nor other severe corrosion effects could be identified by final SEM analysis. No gross material failure occurred.

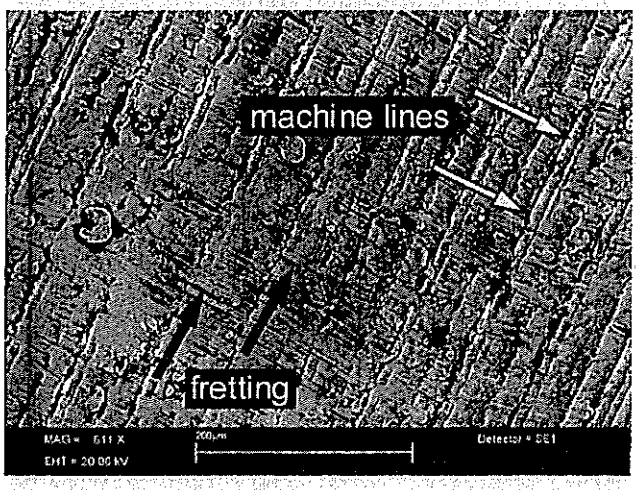

Fig. 4 Fretting scars run perpendicular to machine lines

Forces of normal gait were applied in this study [3]. For active or obese patients higher forces may occur in vivo, especially in combination with high offset necks.

Titanium is the commonly used implant material. In spite of its functional benefits and local biocompatibility, concerns exist about the long-term risks caused by the metal particles and ion release. Macrophage activation caused by titanium particles and increased cell mediator release has been observed in vitro and in vivo [18, 19]. In vitro chromosomal damage caused by high concentrations of titanium particles have also been reported [5, 6]. Nevertheless, such reactions depend strongly on the applied particle or ion concentration. Rogers et al. investigated the effect of different titanium particle concentrations on the cell mediator release and cytotoxicity [18]. They applied

particle concentrations of between 14 and 58 μg/ml to human monocytes in vitro and reported an increase in cell mediator release depending on the particle concentration. However, a significant toxicity was not seen in their study. Assuming a patient activity of 2×10^6 cycles/year [10], the mean titanium release of all tested systems in our study would correspond to an annual total titanium release of about 6 μg to the whole organism. Compared to in vivo or other in vitro studies this concentration is extremely low. Clinically, reactions to titanium are rare and in vivo studies also confirmed no genotoxicity or cytotoxicity of titanium [17]. Consequently, the authors believe that the clinical use of these implants would appear to be appropriate.

The titanium concentrations exhibited quite a high variability. The measurement of small values near the threshold of a specific measuring method generates wide ranges. Thus, the variability measured for some values in this study may be related to the low values generally measured.

Conclusion

The results of this study are promising and can support limited clinical use of these implants. Very low concentrations of titanium release were found. No differences between the different designs in total titanium were seen. However, the surface roughness of the taper connection seems to affect the total titanium release of the implants tested. Different modes of titanium release over time were measured. No mechanical failure or excessive corrosion processes could be identified on the implants tested. Compared to in vivo and other in vitro studies extremely low concentrations of titanium release were seen. From the authors' point of view the measured titanium concentrations are within a clinically non-critical range. The safety of the modular neck-stem connection still needs to be proven in clinical studies.

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Scientific Exhibit at the 71st AAOS Annual Meeting

MODULAR NECK PRIMARY PROSTHESIS: EXPERIMENTAL AND CLINICAL OUTCOMES

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INTRODUCTION

Modular acetabular designs, due to their versatility, are widespread used in primary total hip replacements while primary modular stem designs are rarely employed. Nevertheless primary stem modularity could be useful to manage difficult cases, when the anatomy is overthrown, and for mini-incision approaches. Stem modularity, as a matter of fact, provides an increased adaptability without any need for a large inventory of monoblock prostheses or expensive custom made prostheses. Besides the availability of a variable geometry stem could be useful to restore the leg length or the hip offset and to correct a pathological femoral anatomy.
While revision modular stems, with different interchangeable components[1,2,3] are every day more often employed and well documented, very little is reported on primary modular stems.

THE MODULAR PROSTHESIS

The stem employed for the pre-clinical validation and in the clinical practice is a titanium alloy stem (Ti6A14V) anatomically shaped (ANCA-Fit, Wright-Cremascoli), grit blasted (Ra 6 μm) and coated with 80 μm high crystalline plasma sprayed hydroxyapatite (Ca/P rate of 1.67±0.05; purity >97%; crystallinity >60%) in the proximal third. In the proximal end a double tapered housing for the modular necks is provided. The distal 2/3 of the stem are tapered and grit blasted (Ra 2 μm).

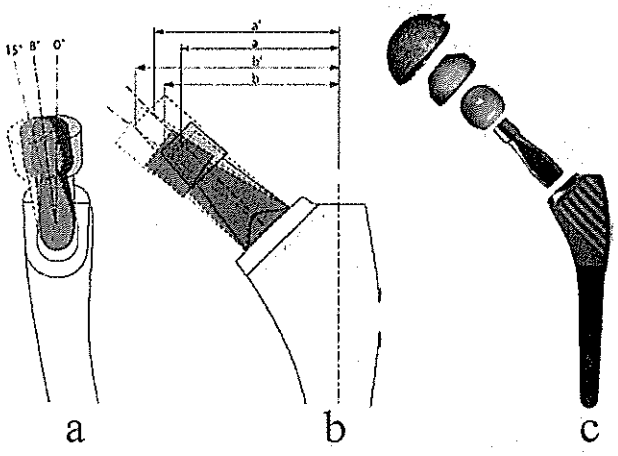


Fig. 1 a) Schematic drawing showing the possible implant solution with a straight, an 8° and a 15° retroverted neck. b) Different possible implant lengths and offset with a straight or a varus neck of the two lengths. c) Picture of the ANCA Fit hip system.

MODULAR NECKS

The modular necks are made of titanium (Ti6A14V), present an oblong section and a conical design to limit the risk of impingement. A thin titanium oxide layer (2-5 nm thickness) cover the whole neck surface providing an exceptional corrosion resistance. The neck is connected with the modular head by a cylindrical taper fitting, while is connected to the stem by a taper fitting having a rectangular cross section with semicircular short sides. Necks present two different lengths: short (28 mm) and long (38.5 mm). For both lengths there are 6 different models: straight, varus-valgus of 8°, antiverted-retroverted of 8° or 15°, the combination of 6° of varus and 4.5° of retroversion for the left and the right side. The modular heads are available in three sizes: short (-3.5 mm), medium (0 mm) and long (+3.5 mm) providing with the two necks a range of possible lengthening of 17.5 mm.

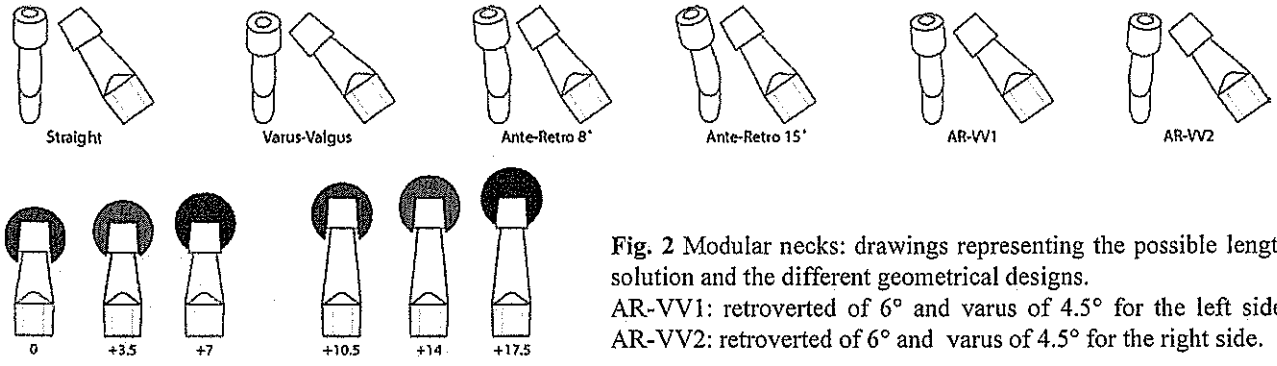


Fig. 2 Modular necks: drawings representing the possible length solution and the different geometrical designs.
AR-VV1: retroverted of 6° and varus of 4.5° for the left side;
AR-VV2: retroverted of 6° and varus of 4.5° for the right side.

AIM OF THE STUDY

The aim of the study was to present the pre-clinical validation and the clinical results of 1734 modular neck primary prostheses at 8 years of survival.

PRE-CLINICAL VALIDATION

The fretting-corrosion behaviour of the neck-stem coupling was investigated. A validated internal procedure[4,5], defined on the basis of the ISO 7206 recommendations for fatigue test of hip stem, was used. Different testing conditions were fixed to investigate the effect of the environmental condition, applied load, stem size, and test duration (that represents the *in vivo* prosthesis life) on the damage process of the coupling. The coupling surface underwent to microscope analysis to determine the morphology of the damage. Finally, the amount of particulate produced during the test was calculated by means of the weight loss of the neck.

Experimental Results

Although long load history (3300 N applied for 20 million cycles that conventionally represent 20 years of active patient use) or high load level (4200 N applied for 5.5 million cycles that would represent 5 years of jogging activity), **no mechanical fracture of the neck-stem coupling occurred during the tests**. The neck was firmly assembled to the stem at the end of the test.

The microscopical analysis of the coupling surface showed no evidence of primary corrosion also when the test was conducted in chemically aggressive environment ($FeCl_3$ solution). Flakes of spalled material were observed in the burnished areas suggesting the presence of a mechanical damage due to micromotion (fretting). Nevertheless, the extension of the damaged area was affected by the test environment suggesting a mechanical damage chemically enhanced. The damage extension is linearly related to the load level, the stem size and the number of applied load cycles. However, **the amount of fretted material was estimated 0.6 mg/million cycles**.

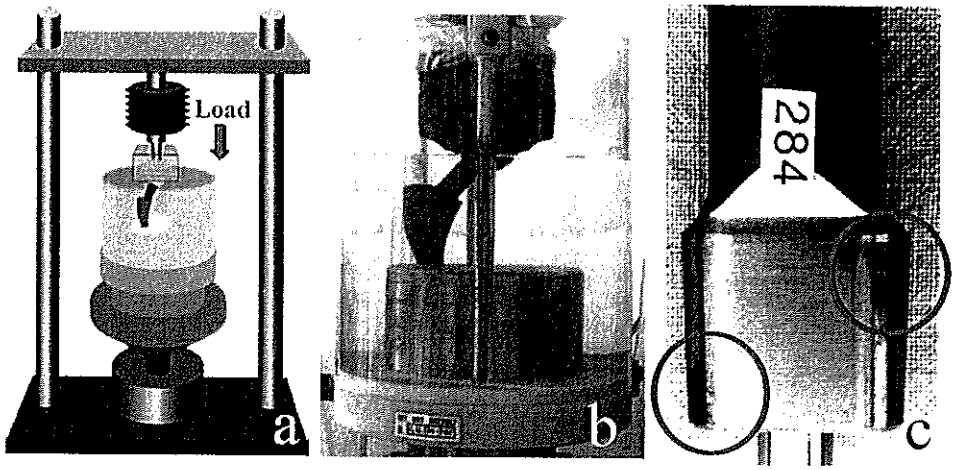


Fig. 3 a) Schematic drawing showing the experimental set-up. **b)** Picture of a modular neck during the tests. **c)** Modular neck after 5.5 million cycles at 3300 N: red circles show the burnished areas.

CLINICAL EXPERIENCE

From August 1995 to August 2003, 1752 primary surgeries were performed with a modular neck stem in our Hospital; all the prostheses present a ceramic coupling with 28 mm head. To evaluate the influence of the learning curve with modular neck prostheses the population was divided in two cohorts. The first 864 consecutive surgeries performed from August 1995 to December 2000 were included in the first cohort, and of these patient 16 were lost to follow-up leaving under observation 848 prostheses. The following 888 consecutive surgeries performed between January 2001 and August 2003 were included in the second cohort: in this group 2 patients were lost to follow-up leaving 886 prostheses under control. Summarizing 18 patients (1.02%) out of 1752 were lost to follow-up, the remaining 1734 patients were investigated.

Considering the pre-operative diagnosis, with the conventional related anatomical deformity of the hip joint, the 1734 prostheses were divided in 4 major groups: A) Normal hip morphology; B) Mild hip deformity; C) Moderate hip deformity; and D) Severe Hip Deformity (Figure 4).
The demographic features of the 2 cohorts and of the whole population are shown in Table 1: there is not any statistically difference for age, gender and pre-operative diagnosis between the three.
Modular neck distribution was investigated in relation to the four different groups of hip morphology and in relation to the surgeons' learning curve.
The modular stem survival was estimated by the Kaplan-Meier method[6]. All the patients considered followed up had at least one follow-up control in the last 18 months; patients who were not reviewed in the last 18 months were checked by phone to assess their clinical status and the survival of the stem. Patients who were not reached by phone were considered truly lost to follow-up.

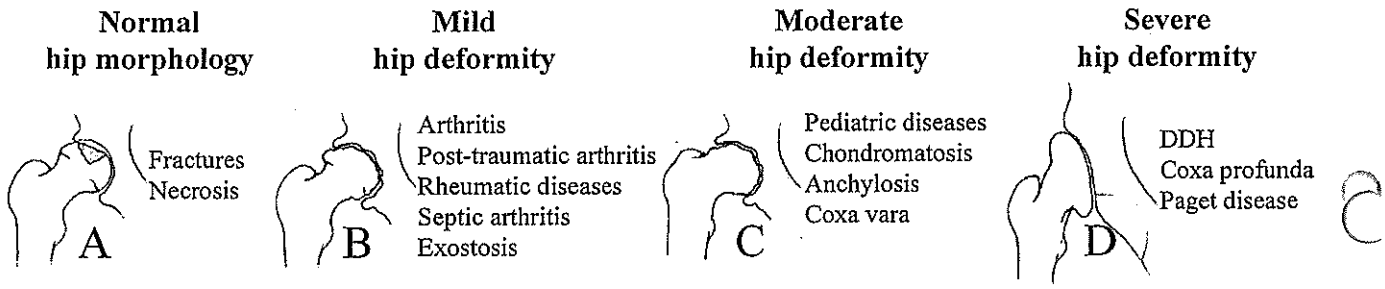
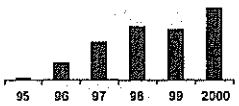
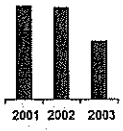
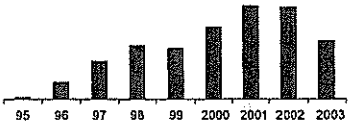
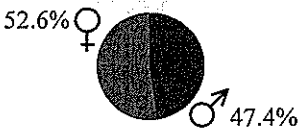
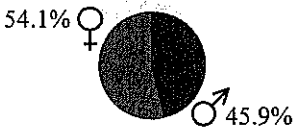
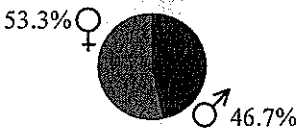
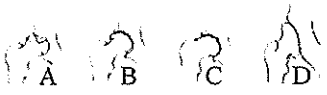
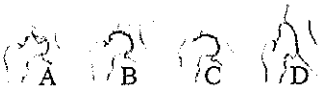
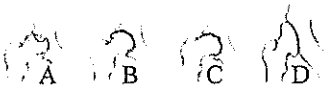


Fig. 4 Patients pre-operative diagnoses were grouped in 4 major categories considering the conventional related anatomical deformity.

	Aug 1995 - Dec 2000 848 prostheses	Jan 2001 – Aug 2003 886 prostheses	Aug 1995 – Aug 2003 1734 prostheses
Surgeries/year			
Average age	54.7 years (16-81)	56.4 years (14-86)	55.5 years (14-86)
Gender			
Pre-op diagnosis			
	6.6% 66.7% 1.8% 24.9%	9.3% 66% 1.5% 23.3%	8% 66.4% 1.6% 24%

Tab. 1 Demographic features of the two cohorts and the whole population.

Clinical Results

None of the 1734 prostheses needed revision for a modular neck failure. In our experience the straight neck was implanted in 56.5% of the cases of group A, 55.4% of B, 39.3% of C, and 21.6% of D (Figure 5). This distribution shows how modularity is always more over useful increasing the difficulty of the case, but also how frequently a non-straight neck is employed in easy or standard cases (A and B). Figure 6 shows how non-straight necks were more employed in the second 886 cases because of the increased familiarity of the surgeons with modularity opportunities.

Dislocation rate of the 1734 prostheses, with a ceramic coupling without a liner lip, was 1.4% (25 patients), 6 cases of recurrent dislocation leaded to revision surgery (0.3%). Eighteen implants failed, 6 for recurrent dislocation, 5 for late aseptic loosening, 3 for early failure (2 cases for intra-operative cracks leading to femoral fractures, 1 for stem undersizing), and 3 for septic loosening. The survival rate of the modular neck stem, without septic loosening, is 97.5% (C.I. 94.9-100%) at 8 years (Figure 7).

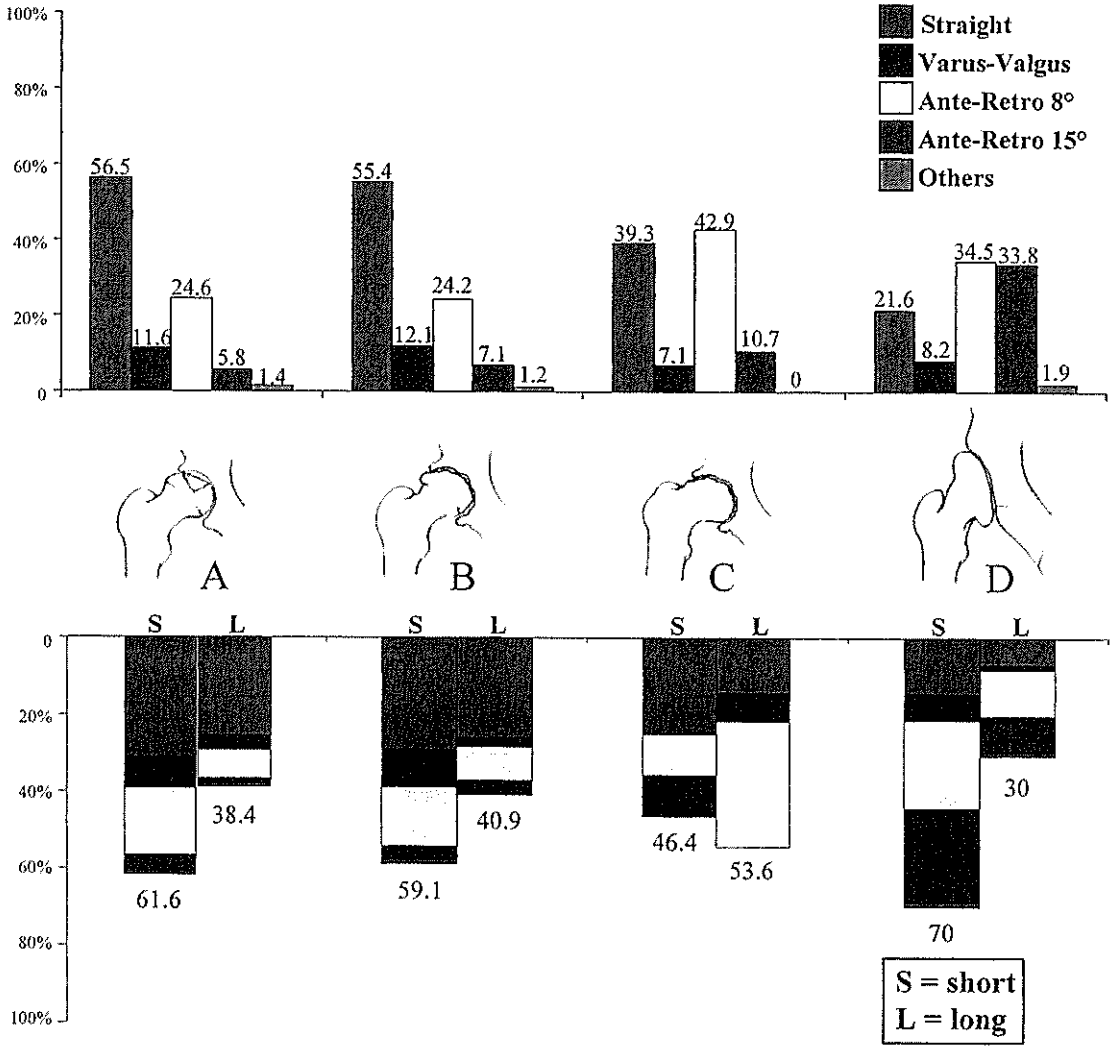


Fig. 5 Necks distribution for different anatomical deformity. **Top:** non-straight necks were used mostly for difficult cases (C-D) but also in about 45% of the easier cases. **Bottom:** Neck length choice is not related to the preoperative diagnosis.

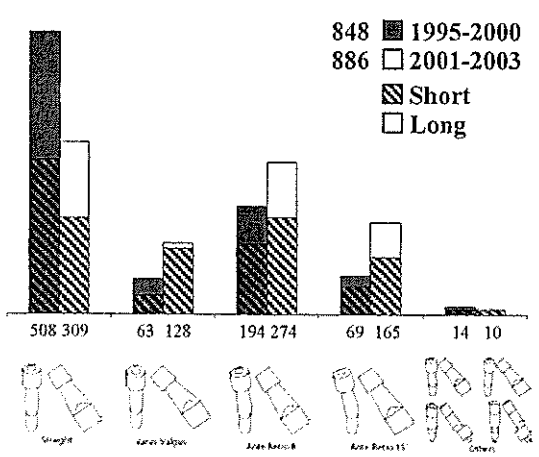


Fig. 6 Necks distribution in relation to surgeons learning curve. Non-straight necks were more employed in the second cohort when surgeons familiarity with modularity opportunities increased.

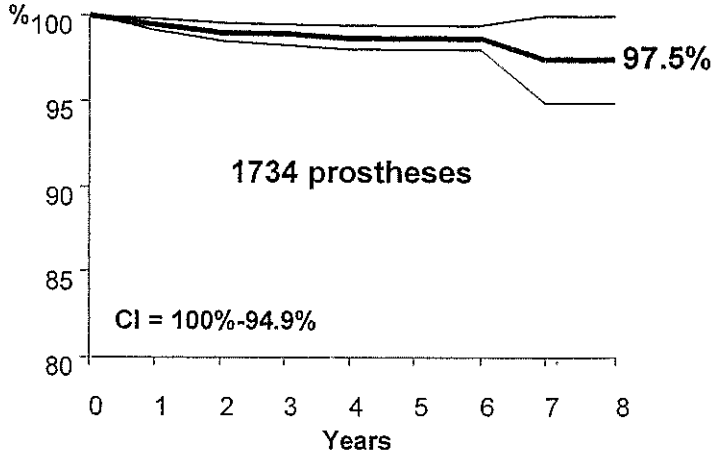


Fig. 7 Survival analysis at 8 years of the modular neck stem. No stem failure was due to the modular neck.

MODULAR NECK CLINICAL ADVANTAGES

Modular necks present several advantages, the 2 neck lengths and the 3 head lengths enable a good modulation of the implant length and offset: indeed, the former can vary between 24.5 mm (28 mm - 3.5 mm) and 42 mm (38.5 mm + 3.5 mm) considering the 2 different neck lengths matched with the available 3 head lengths. Furthermore, neck modularity allows the surgeon to correct intra-operatively the implant configuration, based on intra-operative trials of the hip range of motion, reducing the risk of impingement (Figure 8). Besides, different neck designs allow the correction of a pathological anatomy respecting the hip center of rotation or, in very difficult cases, allow to change the hip center of rotation respecting the hip offset (Figure 10). In addition, the modular prosthesis allows the surgeon to replace only the modular components of the implant; in case of revision this could be very useful, for example, for revisions due to recurrent dislocation when a very easy substitution of the neck could be the only surgery needed.

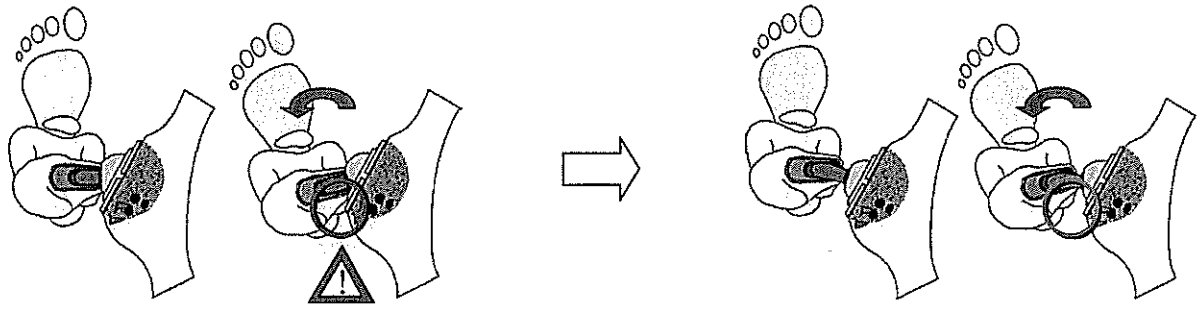


Fig. 8 In the drawing is shown how modular necks could be useful in case of impingement: a long retroverted neck prevents the impingement inducible extra-rotating the leg with a short straight neck.

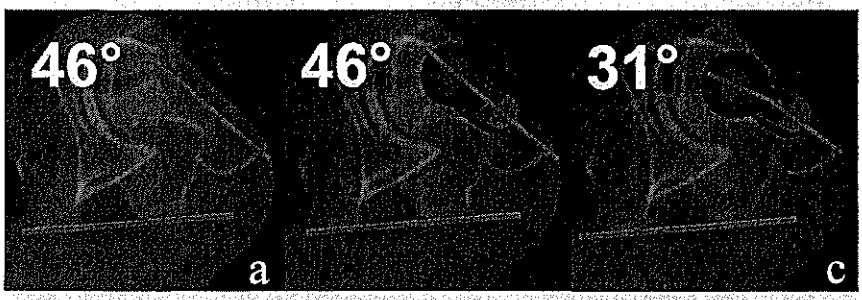


Fig. 9 a) Two superimposed CT scan slices of a DDH case showing a highly pathological femoral neck anteversion.
b) a straight neck does not allow an anatomic reconstruction.
c) a 15° retroverted neck allows the correction of the deformity.

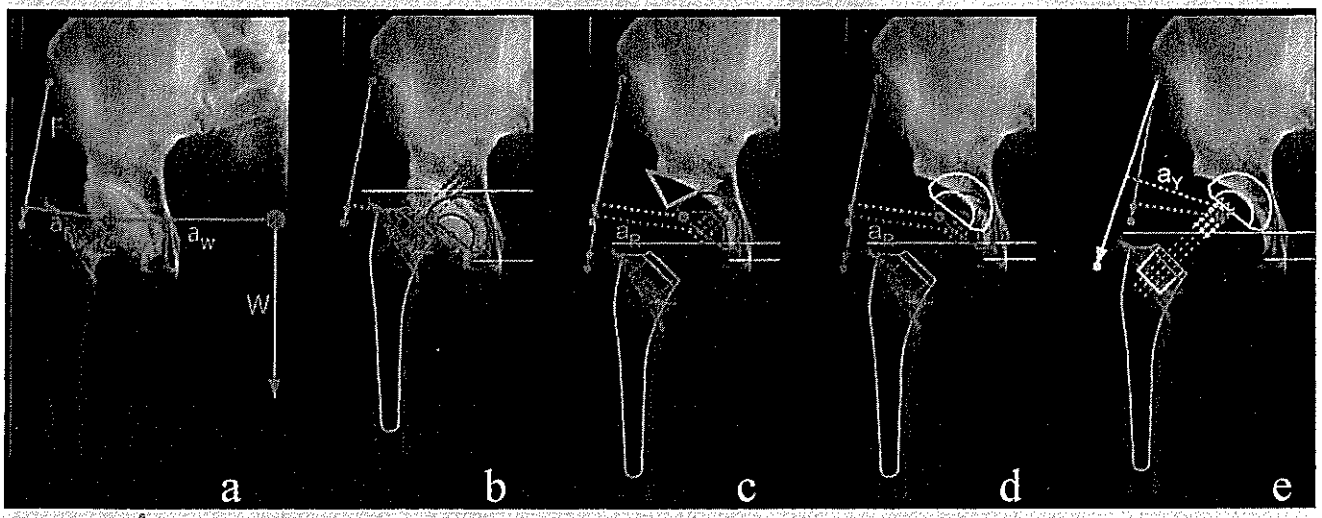
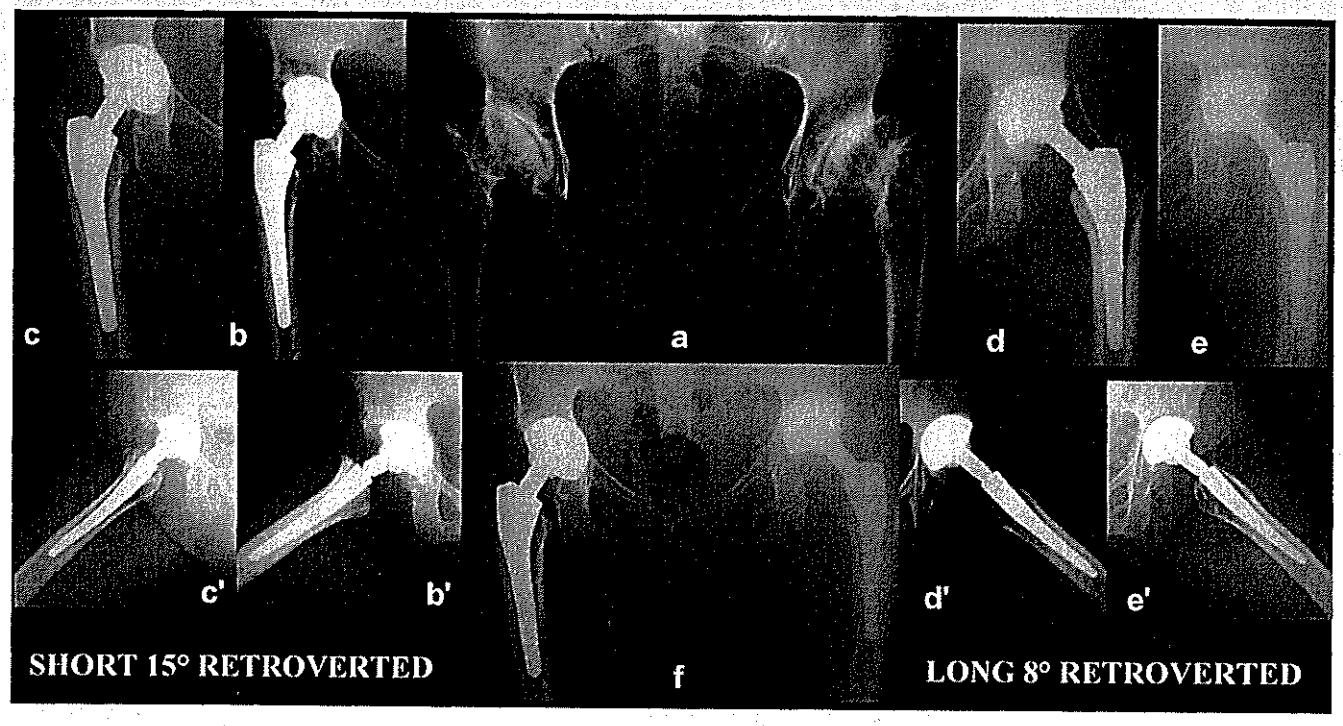


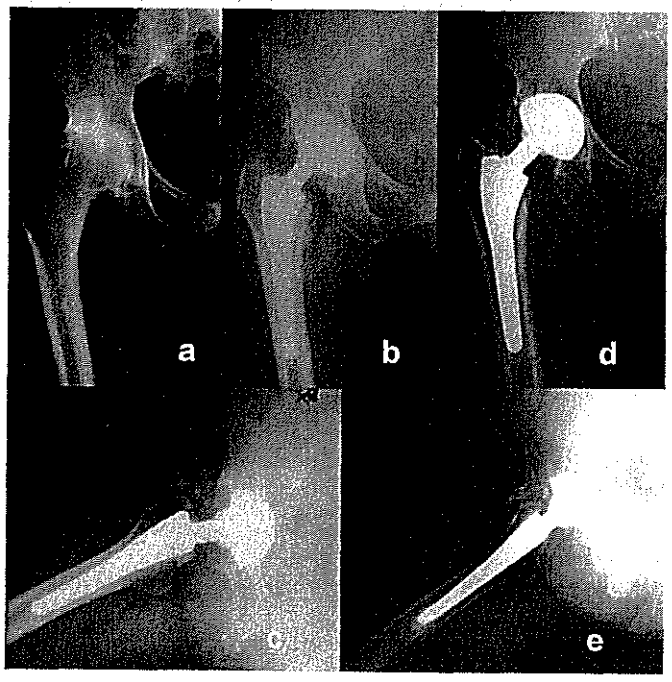
Fig. 10 a) X-ray of a DDH: Single leg stance. C: hip center of rotation; F: resultant force of abductor muscles; W: body weight; a_F: moment arm of the abductor muscles force; a_W: moment arm of the body weight. The condition for the rotational equilibrium of the pelvis about C is $F \cdot a_F = W \cdot a_W$. b) Ideal solution of hip replacement with a straight short neck and the cup in the ideal hip center. c) By this solution the hip offset is restored and a good leg lengthening is achieved, but an augmentation technique with a bone graft is needed for the cup stability. d) To avoid bone grafting the cup should be implanted with a higher center of rotation. e) Despite the high hip center of rotation, with a long varus modular neck, the hip offset, the leg lengthening and the moment arm of the system are respected ($a_R = a_Y$).

CASE REPORTS



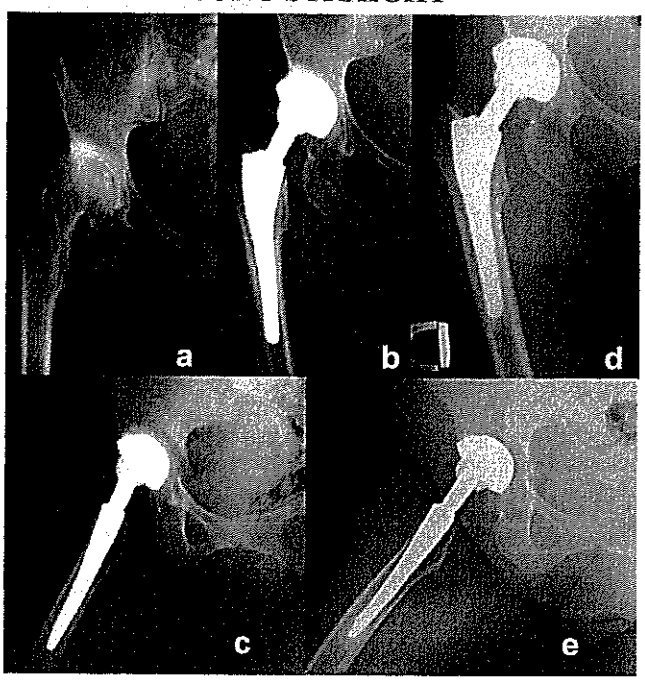
Case 1. Female, 54 years old, showing a bilateral DDH.
Right hip: **a)** Pre-op frontal view; **b)** Post-op frontal view: a short 15° retroverted neck was employed; **b')** Post-op frog view; **c)** and **c')** 7.5 years follow-up.
Left hip: **a)** Pre-op frontal view; **d)** Post-op frontal view: a long 8° retroverted neck was employed; **d')** Post-op frog view; **e)** and **e')** 6.5 years follow-up;
f) frontal view at the last follow-up.

SHORT VARUS



Case 2. Female, 64 years old, primary arthrithis.
a) Pre-op frontal view; **b)** Post-op: a short 8° varus neck was employed; **c)** Post-op frog view; **d)** 8 years follow-up; **e)** Follow-up, frog view.

LONG STRAIGHT



Case 3. Female, 57 years old, primary arthritis.
a) Pre-op frontal view; **b)** Post-op: a long straight neck was employed; **c)** Post-op frog view;
d) 7 years follow-up; **e)** Follow-up, frog view.

DISCUSSION AND CONCLUSION

Modular prostheses allow the surgeon to correct the length of the lower limb by choosing the offset, the length and the anti-retroversion of the neck; besides, this is possible avoiding the long-waiting times and high costs of custom-made prostheses, and assuring the reliability of mechanical tests (done on standard prostheses). Such modularity is particularly useful in cases where the femoral deformity is threatening (only in the 21.6% of group D and in the 39.3 % of group C a straight neck was employed) but also in standard cases as shown in Figure 5. Indeed in about 45% of the prostheses implanted with a normal or a mild anatomically deformed hip (groups A and B) a non-straight neck has been employed. This results show the poor predictive value of a 2D templating that usually underestimate the femoral neck anteversion and is not useful to predict the possible causes of impingement. Furthermore the impingement due to a cup malpositioning is usually corrigible, during surgery, by a modular neck. Besides, the possibility of increase the stem length enhances the implant stability, this is particularly useful with the old age patients with muscular weakness and in the cases where the acetabular anatomy is badly compromised (group D). Indeed in our series the rate of dislocation is only 1,4% and there is not any significant difference between patients over and under 65 years old and between the 4 joint morphological cohorts (A; B; C; D) contradicting what was expected considering the letterature.

In spite of these advantages, a modular prosthesis has some concerns related to the risk of corrosion, fretting[7,8,9,10,11], dislocation of the modular components[12,13,14] and mostly of fracture of the modular neck[15]. These potential problems risen in presence of two coupled components (head-neck) could be worsened in case of a further modularity between the neck and the stem. The experimental study tried to address the causes of concern. The investigated modular necks have shown a good mechanical behaviour *in vitro*. The neck-stem coupling undergoes to a fretting damage process. However, the amount of produced fretting debris (0.6 mg per million cycles) seems negligible considering that a stable prosthesis is likely to produce more than 10 mg/year of metal debris[4,5].

These experimental findings are in agreement with the clinical outcomes. Besides, among the 1734 modular necks implanted in our hospital, out of more than 50.000 modular necks already implanted in Europe, no one needed a revision for mechanical failure. In the explanted cases, the cause of revision was not related to the neck-stem modularity. Furthermore, the comparative analysis between retrieved necks and those experimentally studied confirmed the absence of corrosion[16] and the completely absence of periprosthetic metallosis. These good results are to be related to the corrosion resistant features of the titanium-titanium coupling and the design of the taper.

In conclusion the use of a modular prosthesis should be routinely reserved for difficult primary surgeries or revision surgeries, where the non-modular prostheses could be not satisfactory. Nevertheless in our experience modular necks are very useful even for standard procedure to achieve a good implant stability and the best implant offset.

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Modular titanium alloy neck adapter failures in hip replacement - failure mode analysis and influence of implant material

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Abstract

Background: Modular neck adapters for hip arthroplasty stems allow the surgeon to modify CCD angle, offset and femoral anteversion intraoperatively. Fretting or crevice corrosion may lead to failure of such a modular device due to high loads or surface contamination inside the modular coupling. Unfortunately we have experienced such a failure of implants and now report our clinical experience with the failures in order to advance orthopaedic material research and joint replacement surgery.

The failed neck adapters were implanted between August 2004 and November 2006 a total of about 5000 devices. After this period, the titanium neck adapters were replaced by adapters out of cobalt-chromium. Until the end of 2008 in total 1.4% (n = 68) of the implanted titanium alloy neck adapters failed with an average time of 2.0 years (0.7 to 4.0 years) postoperatively. All, but one, patients were male, their average age being 57.4 years (36 to 75 years) and the average weight 102.3 kg (75 to 130 kg). The failures of neck adapters were divided into 66% with small CCD of 130° and 60% with head lengths of L or larger. Assuming an average time to failure of 2.8 years, the cumulative failure rate was calculated with 2.4%.

Methods: A series of adapter failures of titanium alloy modular neck adapters in combination with a titanium alloy modular short hip stem was investigated. For patients having received this particular implant combination risk factors were identified which were associated with the occurence of implant failure. A Kaplan-Meier survival-failure-analysis was conducted. The retrieved implants were analysed using microscopic and chemical methods. Modes of failure were simulated in biomechanical tests. Comparative tests included modular neck adapters made of titanium alloy and cobalt chrome alloy material.

Results: Retrieval examinations and biomechanical simulation revealed that primary micromotions initiated fretting within the modular tapered neck connection. A continuous abrasion and repassivation process with a subsequent cold welding at the titanium alloy modular interface. Surface layers of 10 - 30 μm titanium oxide were observed. Surface cracks caused by fretting or fretting corrosion finally lead to fatigue fracture of the titanium alloy modular neck adapters. Neck adapters made of cobalt chrome alloy show significantly reduced micromotions especially in case of contaminated cone connection. With a cobalt-chromium neck the micromotions can be reduced by a factor of 3 compared to the titanium neck. The incidence of fretting corrosion was also substantially lower with the cobalt-chromium neck configuration.

Conclusions: Failure of modular titanium alloy neck adapters can be initiated by surface micromotions due to surface contamination or highly loaded implant components. In the present study, the patients at risk were men with an average weight over 100 kg. Modular cobalt chrome neck adapters provide higher safety compared to titanium alloy material.

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Background

Total Hip Arthroplasty (THA) has become a successful clinical treatment to restore the function of the joint, with a positive impact on the patient's quality of life. Modular connections for hip prostheses have been used since the early 70ies for heads with different neck sizes or diameters. Later in the 90ies, modular neck adapters have been introduced [1,2] for intraoperative adjustment of collum-caput-diaphysis (CCD) angle and femoral anteversion to optimise offset and leg length, irrespective of the hip stem implanted. These solutions have been proven their relevance in total hip arthroplasty [3,4]. Several failures of modular connections in hip replacement including primary and revision stem components [5-8] were reported. Long-term experiences with modular heads made of cobalt-chromium alloy (CoCr29Mo6) in combination with the cone of the stem out of titanium alloy (TiAl6V4) have revealed, apart from traces of fretting corrosion, no adverse events such as fractures of the tapers in clinical use [9-17]. Failures of modular neck adapters have been rarely documented [5-7]. In 2007, we reported three cases of a failure of a modular short hip stem [8]. The purpose of this paper is to present the state-of-the-art research and the recent findings of the failure analysis.

Case history

The failed neck adapters were implanted between August 2004 and November 2006. After the third incident, the titanium neck adapters were replaced by adapters out of cobalt-chromium [8]. A typical x-ray of a failed titanium neck adapter is shown in Figure 1.

The failure of the neck did not cause further damage on the acetabulum side. Subsequently, there was no need to revise the cups in all of these cases. Modular cup inserts were replaced in some cases due to visible signs of damage originated by the neck failure or for reasons of precaution. About 5000 hip joints have been implanted with the titanium stem and titanium neck adapter material combination. Until the end of 2008 1.4% (n = 68) of the titanium alloy neck adapters failed after an average time in vivo of 24 months (Figure 2). All, but one, patients were male and most patients (59%) had a weight above 100 kg and an average body mass index (BMI) of 31.6 (24 to 42) (Figure 3).

An overview about the average age, weight and post-operative time until failure of the titanium alloy neck adapter in 68 patients and the distribution of neck adapter geometry, head size and length is given in Table 1. The implant size did not have a detectable influence on the occurrence of neck failure. The neck adapter failures were divided into 66% with a CCD angle of 130°, 34% with a CCD angle 135° and none with 140°.

A Kaplan-Meier survival analysis (Statistica 7, StatSoft Europe GmbH, Hamburg, Germany) was undertaken with revision due to failed neck adapter as an endpoint (confidence interval ± 95%). A cumulative survival rate of 98.6% was calculated with fractured neck adapter as the causative factor of failure (Figure 4).

There was no correlation between implant failures and a specific clinic or surgeon.

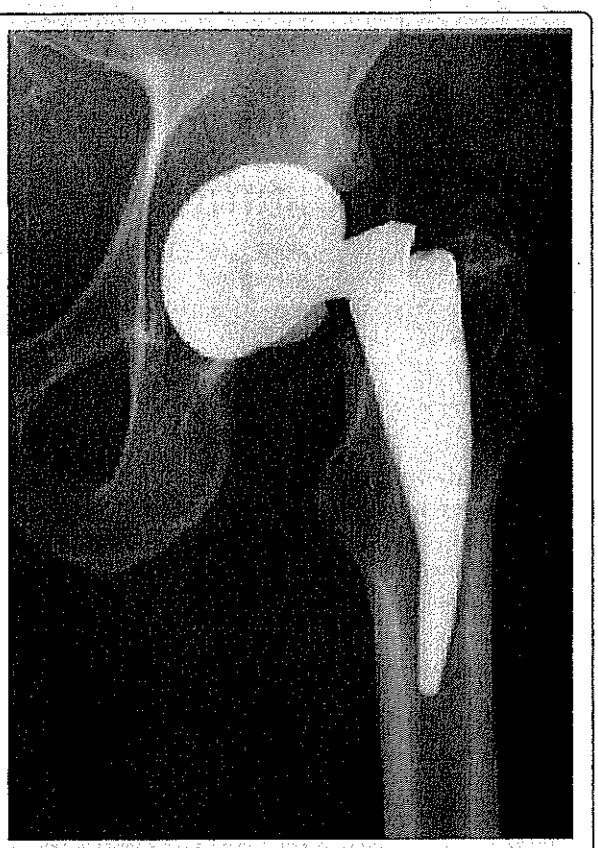


Figure 1 X-ray of a hip with a failed neck.

Methods

Implant component description

The modular neck adapters and stems used in our study were in all cases the Metha Short Hip Stem Prosthesis (Aesculap AG, Tuttlingen, Germany). Adapters and stems were made of titanium alloy. With its circumferencial pure titanium porous coating and additive thin layer of dicalcium phosphate dehydrate (Plasmapore® µCaP, Aesculap, Tuttlingen, Germany), the stem is designed for cementless anchorage (Figure 5). The modular neck adapters were used in three different CCD-angles (130°, 135° and 140°) in combination with neutral, anteverted and retroverted (± 7.5°) versions to adjust the CCD-angle intraoperatively [4].

Retrieval analysis

In the retrieval analysis, the failed neck adapters were subjected to a detailed examination to which most

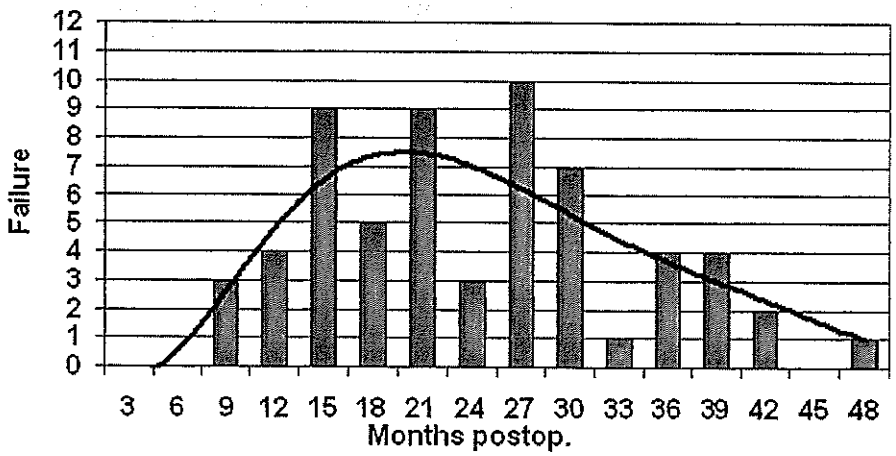


Figure 2 Occurrence of clinical neck failures in a postoperative time period in months.

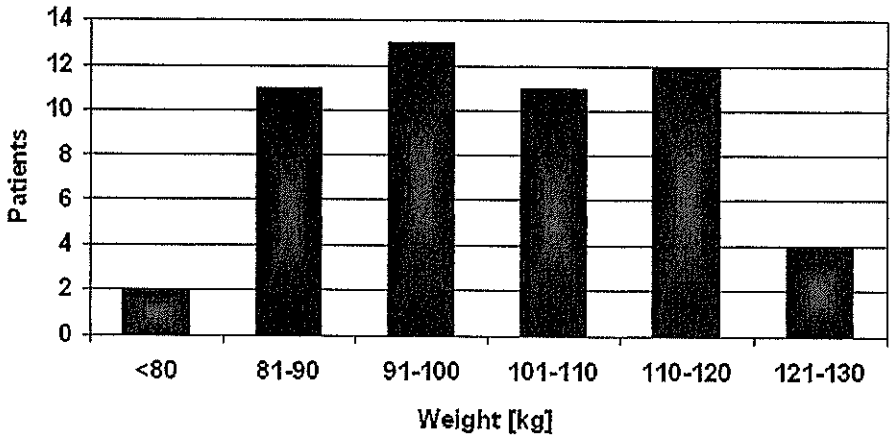


Figure 3 Correlation weight of patients and failures.

Table 1 Overview about the average age, weight and time in vivo until failure of the titanium alloy neck adapter in 68 patients and distribution of neck adapter and combined head geometry

age	Ø 57.2 years (36 - 75 years)					
weight	Ø 102.3 kg (75 to 130 kg)					
time in vivo	Ø 24 months (8 to 48 months)					
neck adapter (CCD-angle)	130°/0°	130° ± 7.5°	135°/0°	135° ± 7.5°	140°/0°	140° ± 7.5°
	29	16	18	5	-	-
head length	S	M	L	XL	XXL	unknown
	4	22	26	7	6	3
head diameter	28 mm		32 mm		36 mm	
	11		50		7	
head material	CoCrMo		Biolox forte		Biolox delta	
	13		53		2	

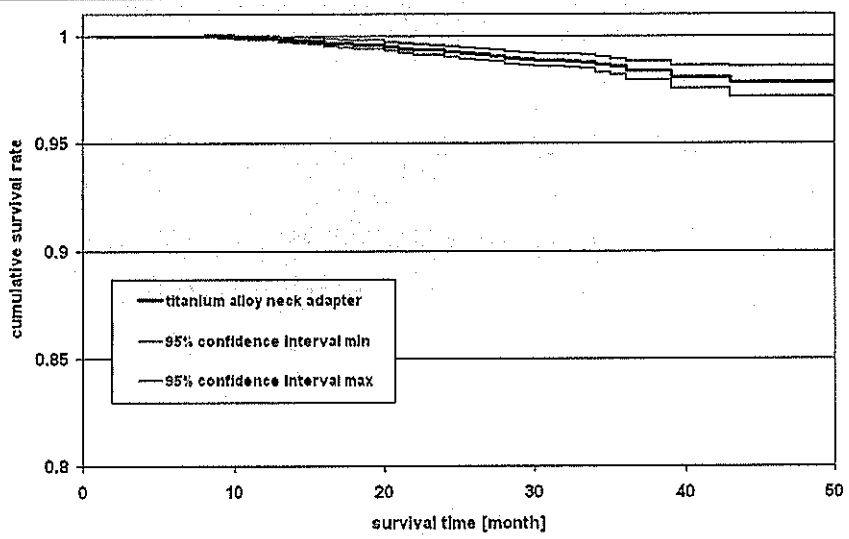


Figure 4 Kaplan-Meier survival analysis for failed neck adapter as reason of revision (± 95% confidence interval).

patients consented. The analysis is in every case based on the failed neck adapter and the hip stem including the remaining distal part of the neck adapter. The revised modular heads and cup inserts were in most of the cases not available and not subject of this examination. The present report is based on the retrieval analysis of 47 devices, the complete investigation data being compiled at the end of 2008. The fracture and modular

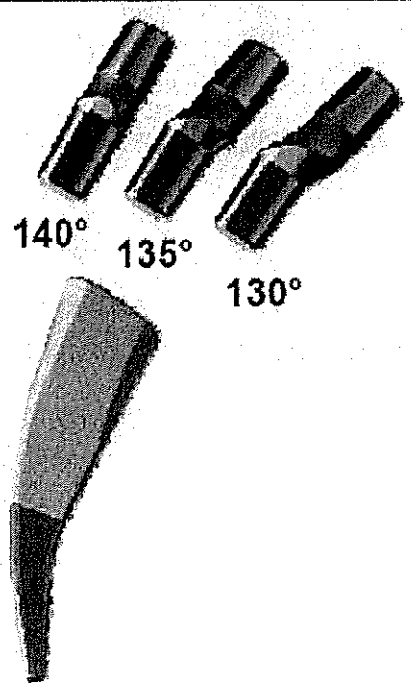


Figure 5 Metha Short Hip Stem System.

connection surfaces were evaluated using light microscope and scanning electron microscope (SEM) (Zeiss EVO 50, Carl Zeiss NTS GmbH Oberkochen, Germany).

The fragment of the broken adapters which remained inside the shaft was cut through axially. One half of the adapters was cautiously removed from the shaft to examine the contact zone between the two components. The other half was left inside the shaft to enable the metallographic investigation of the interface and the microstructure of the materials. To enable the metallographic investigation of the neck adapter/stem interface the samples were prepared by mechanical cutting using a cut off-wheel (Secotom 10 Struers A/S, Denmark). After embedding into epoxy resin (Polyfast Struers A/S, Denmark) the cross section was prepared by grinding, polishing and etching according to the method by Kroll (composition 100 ml distilled H_2O, 1 ml HF, 3 ml HNO_3). The investigation was performed by light microscope (Wilde M3Z Herrenbrugg, Switzerland) with a magnification up to 500-times.

The chemical composition of the abrasive substances found in the crevice of the cone connection was determined using energy dispersive analysis (EDX) (Oxforth EDX-Analysensystem INCA 7059 Oberkochen, Germany) and wet chemical digestion. The surface of the cone was rinsed cautiously using dilute acid. After hot digestion and dilution the analysis of the elements was performed using inductively coupled plasma optical emission spectrometry (ICP-OES Horiba Ultima II Jobin Yvon Longjumeau, France).

Micromotion analysis of the modular neck stem interface

To quantify the relative motion in the interface of the modular hip stem out of titanium alloy a total of eight

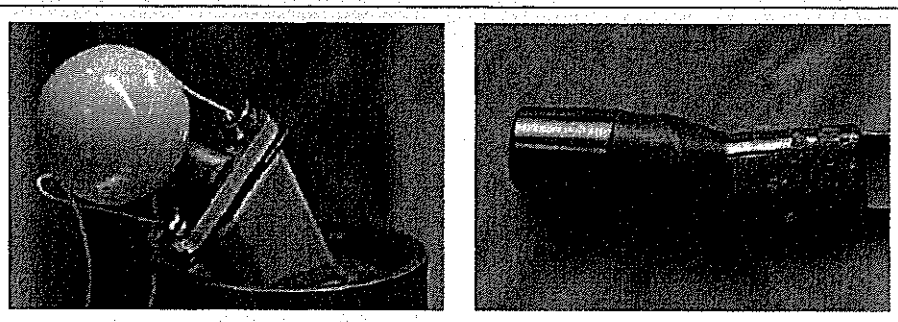


Figure 6 Test setup for measurement of micromotions in the modular cone connection (left) and particle-contaminated joining area (right) [18,19].

specimens with neck adapters out of titanium alloy and cobalt-chromium alloy were examined. As it appears that intraoperative contamination of the cone connection with bone particles has an considerable impact on the magnitude of fretting in the interface due to increased micromotions, a specific test setup was developed at the Biomechanics Section of the Hamburg University of Technology (Prof. Michael M. Morlock) and each device being tested with a clean and with a particle contaminated joining area (small porcine bone grafts approximately 1 mm in diameter) [18,19]. To determine the relative motion between neck adapter and stem a contactless measurement system (Micro-Epsilon Type U05(78) Messtechnik Ortenburg, Germany) was used. Two sensors with a range of 500 μm and a sensitivity of 0.025 μm were fixed on an aluminium plate and mounted on the neck adapter. Two steel plates fixed on the resection plane of the stem served as targets for the sensors (Figure 6).

The stem was combined with neck adapters with 130° CCD angle, embedded in bone cement (Palacos R, Heraeus Medical GmbH Wehrheim, Germany) and tested on a servohydraulic testing machine (MTS 850.2, MTS Systems Corporation Eden Prairie MN, USA). A sinusoidal axial force between 50 and 2500 N was applied via a ceramic head with neck length L at a frequency of 1 Hz for 2000 cycles to measure the relative displacement between neck adapter and stem with regard to irreversible settling and micromotions. A statistical analysis was performed to distinguish between independent groups (clean and particle contaminated joining area) (paired Student's t test) for both neck adapter materials (SPSS 15.0).

Pre-clinical fatigue testing

To determine the endurance properties of the neck region comparative tests were performed according to ASTM F 2068-03 and ISO 7206-6:1992(E) (MTS Mini Bionix II, MTS Systems GmbH Berlin, Germany). The hip contact force was set at 5340 N with a sinusoidal loading mode (ratio F_{min}/F_{max} = 0.1). In a saline medium (0.9%, pH 7) the number of cycles was set at 10 million load alterations at a frequency of 15 Hz. In a worst case scenario using a 32 mm diameter XL head, neck fatigue was tested on the smallest modular stem in combination with neck components with 130° CCD angle and 7.5° retrotorsion out of titanium and cobalt-chromium alloy, respectively. A paired Student's t test was used to differentiate the fatigue behaviour of the two neck adapter materials (Statistica 7, StatSoft Europe GmbH, Hamburg, Germany).

To evaluate the coaction of the stem/neck modularity with the hip stem, the modular stems were tilted both in the frontal plane (α = 10°) and in the sagittal plane (β = 9°). Based on CT scans on several human femurs and the specific stem design the level of embedding was set to 45 mm below the centre of the head to simulate a deficiency of proximal support due to bone loss in the neck and trochanter region (Figure 7).

For these customised test, the hip contact force was set at 2300 N for 5 million cycles according ISO 7206-8:1995(E) followed by a stepwise load increase (Locati method 500 N, 1 million cycles) until failure. These customised test setup was introduced to analyse if the mode of fatigue failure occurs in the modularity or in the stem region outside of the neck/stem connection.

To simulate the clinical failure modes in vitro, parameters for the titanium neck adapters were varied as shown in Table 2.

The resultant hip contact force was set at 3800 N to simulate a higher strain as in overweight or active patients. The test frequency was decreased from 15 Hz to 1 Hz to detect a possible influence on fretting corrosion in the modular neck interface. To simulate the patient's situation in daily life more realistically frequent stress phases alternated with rest phases. Taking into account the clinical conditions of hip replacement assembly, the connection was contaminated with blood, serum and cortical bone particles (approximately 1 mm in diameter) to provoke a mechanical disturbance in the interface. Additionally, the surrounding chemical

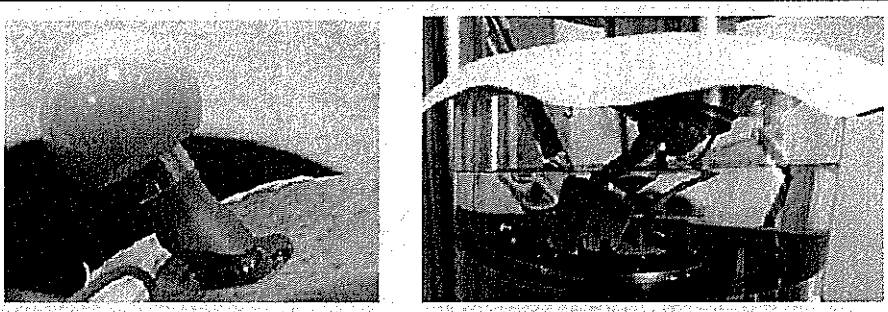


Figure 7 Test setup for neck test (left) and stem test (right) with reference electrode to measure corrosion potential.

conditions were altered by modifying pH values and enhancing chloride concentrations with the use of NaCl, $CaCl_2$ and $FeCl_3$ to accelerate any eventual tribochemical processes. To determine the continuous abrasion and repassivation of the titanium alloy surfaces in the neck/stem connection the redox potential was measured (InLab® 301 Mettler Toledo Balingen, Germany).

Results

Findings of the retrieval examination in clinical failures

All retrieved modular adapters showed similar breakage cross-sections. The fatigue fracture starts in the anterolateral area at the upper part of the conical connection, the area subjected to maximum biomechanical stress. The fatigue fracture is followed by the residual forced fracture (Figure 8).

Metallographic analyses showed that microcracks developed on the surface of the cone in the clamping range (Figure 9). It appears that these microcracks induced the fatigue crack which finally led to the implant failure. Microcracks were analyzed using a scanning electron microscope. Figure 9 shows a potential micro crack in an area where fretting marks can be seen on the surface of the cone.

The examination did not indicate any product deviation, manufacturing failure or batch correlation, thus excluding any manufacturing influence as cause for implant breakage. In the majority of cases, the surface of the cones was significantly modified and showed signs of fretting corrosion. Among the forty-seven of the revised cones available for examination, a total of 87% presented substantial fretting overlaid by laminar corrosion of different intensity (Figure 10).

Table 2 In vitro model to simulate the clinical failure modes with various parameters

Hip contact force	3800 N
Frequency	1 Hz/15 Hz
Stress and rest phases	1,000 cycles, 1.5 minutes rest, 1,000 cycles, 1.5 minutes rest repeat
Contamination	Dry, Blood, Serum, Cortical bone particles
Surrounding medium	Saline 0.9% pH 7 Saline 1.8% pH 2 $CaCl_2$ solution pH 2 $FeCl_3$ solution pH 0.5

The findings of the corrosive alteration apart of fretting have not been corroborated by biomechanical tests so far [8,14]. Metallographic cross sections of the cone show a 20 μm up to 30 μm thick layer developing in the modular joining area of most of the revised implants (Figure 11), a layer composed of different abrasive and corrosive substances including a high amount of titanium dioxide. The layer was formed due to abrasion of the passive oxide layer protecting the titanium alloy against corrosion. Continued abrasion and repeated repassivation of the titanium alloy surface produced the oxide layer's characteristic thickness.

Additionally in some cases this process accelerated through crevice corrosion as the reduction of the pH to values of about 2-3 indicates.

In one patient weighing 100 kg, a revision had to be carried out after 26 months to improve the offset due to cup loosening, thus providing the possibility to examine a faultless titanium adapter. (Figure 12).

The surface of the cone adapter which was not cleaned after revision was examined using a scanning electron

Figure 8 Fatigue fracture surface of a clinically failed titanium neck adapter.

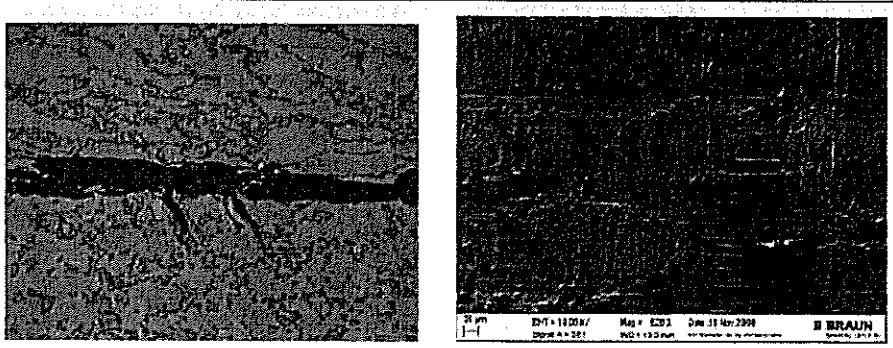


Figure 9 Metallographic analyses revealed microcracks on the cone surface (left) and a potential microcrack in a fretting area (right).

microscope. No calcium or phosphor could be detected. There was no indication of a contamination of the cone connection by bone particles. Besides mild abrasion on the surface, no signs of fretting corrosion could be found.

Influence of micromotions on the modular neck stem interface

The major part of the observed displacement was caused by elastic deformation of the neck adapter. The micromotions of the titanium neck adapter were in a clean condition 6 ± 4 μm (medial) and 6 ± 2 μm (lateral) and with particle contamination 18 ± 3 μm (medial) and 15 ± 4 μm (lateral). In each contaminated joining area, the displacement and the micromotions were larger than in a clean condition. The fully uncontaminated components showed a distinct and definitive settling within the first 20 cycles. In case of a contaminated joining area the settling process of the neck adapter did not come to an end and lasted over the entire test duration (2000 cycles) (Figure 13).

The titanium alloy neck adapter showed a significant increase of micromotions in the interface of the particle-contaminated joining ($p < 0.01$) in comparison to clean conditions (Figure 14). The micromotions of the neck adapter out of cobalt-chromium were in a clean condition 3 ± 1 μm (medial) and 3 ± 1 μm (lateral) and with particle contamination 5 ± 6 μm (medial) and 3 ± 2 μm (lateral).

In the case of the cobalt-chromium alloy neck adapter, the contamination of the joining area did not influence the micromotions significantly ($p = 0.43$).

In vitro fatigue behaviour of the stem/neck modularity

The neck adapters made of titanium and of cobalt-chromium alloy showed significantly different ($p = 0.009$) endurance behaviour. The Ti6Al4V adapters combined with a 28 L Biolox forte head failed after 2.45 million cycles (range 0.189 to 4.43). No failure occurred with the cobalt-chromium adapters (32 XL Biolox option) up to 20 million cycles.

Simulating a deficiency in proximal stem support the fatigue behaviour of the coaction of the stem/neck modularity with the hip stem was examined in a customised test setup. The titanium alloy neck adapters fulfilled the ISO 7206-8: 1995(E) requirements (2300 N for 5 million cycles) and failed during a stepwise increase of the applied force (Locati method) at a high load level of 5300 N after 0.7 million cycles (range 0.63 to 0.75). In a

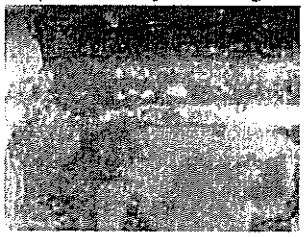
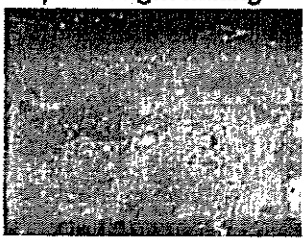
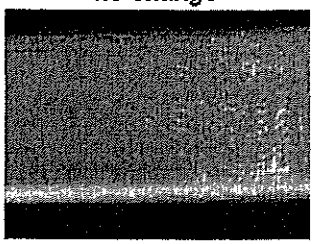
surface morphology	*partial large flaking*	*partial light flaking*	*no change*
			
amount of the cones	23 %	30 %	13 %
time to failure	10 – 36 month	8 – 39 month	16 – 38 month
averaged time	24 month	22 month	27 month

Figure 10 Overview of interface characteristics and time to failure of the retrievals.

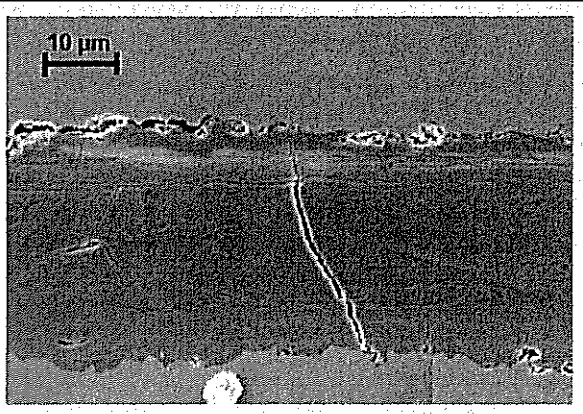


Figure 11 Brittle layer in cone connection between stem and neck adapter.

direct comparison, the cobalt-chromium neck adapters did not fail in the Locati test until the stem fractured at 6800 N load after 0.3 million cycles (Figure 15). Furthermore, the cobalt-chromium neck components did not fracture at 5300 N during 10 million cycles.

Contamination with cortical bone particles in the interface was found to be the main influence factor on the fatigue behaviour of the titanium alloy neck adapter. With a hip contact force of 3800 N the contaminated titanium alloy neck adapters failed after 3 million cycles (range 2.7 to 3.3) while no failure occurred under clean interface conditions (run-out limit 10 million cycles). This is mainly due to the increase of micromotions and the resulting fretting corrosion in the modular neck interface. In clean conditions, the load has to be increased up to 5300 N to provoke a similar failure mode. The redox potential measures fretting corrosion and repassivation on metallic surfaces. It shows impressively that introducing cortical particles into the modular neck interface generates a mechanical disturbance which triggers repassivation processes in high frequency (Figure 16).

Discussion

This study confirmes that the failure of the adapter cannot be attributed to any material or processing deviation or incorrect dimensioning. A twisted assembling of the adapter can also be excluded.

Due to mechanical perturbation in the modular connection, micro-movements caused fretting on the surface. Microcracks developed in the fretting zone, ultimately leading to the dynamic fatigue fracture of the implant. In 87% of the cases, fretting was accompanied by corrosion [17,20-25] as it initiates crevice corrosion [26,27]. The combination of fretting and crevice corrosion destroys the passive layer permanently. The electrochemical reactions provoke a shift in the pH value into the acidic range. The corrosion process generates a fissured surface of the connecting cone and can also generate microcracks. The examinations revealed that corrosion does not trigger the implant failure but does accelerate the process [26]. Cone adapters free from corrosive attack last the longest period up to failure (Figure 10).

In general, the titanium alloy provides excellent corrosion resistance and high biocompatibility because it quickly develops a thin passive layer with a thickness under 1 µm. Under inadequate conditions of cone assembling and in case of micro-movements within the modular connection, the protective passive layer is abraded initiating a continued abrasion and repassivation process which depletes the oxygen inside the crevice [17]. The metallic surface in the crevice becomes anodic relative to the outer surface, thus triggering an electrolytic process. The presence of chloride ions which disturb the passivity, induces pitting corrosion in the crevice leading to a quick dissolution of the metal

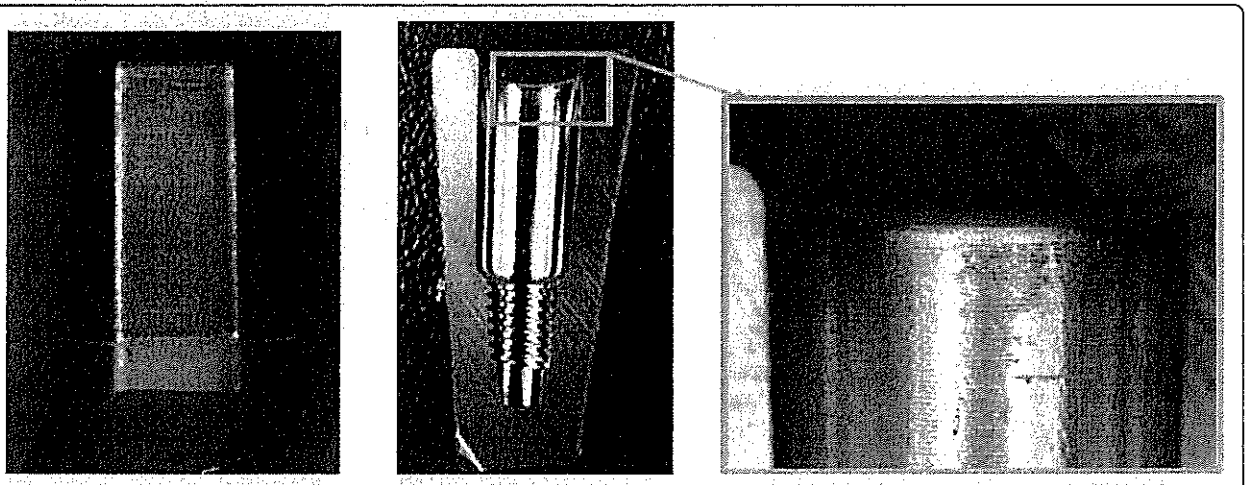


Figure 12 Retrieved faultless titanium alloy neck adapter (left) and stem (right) without contamination and any signs of corrosion.

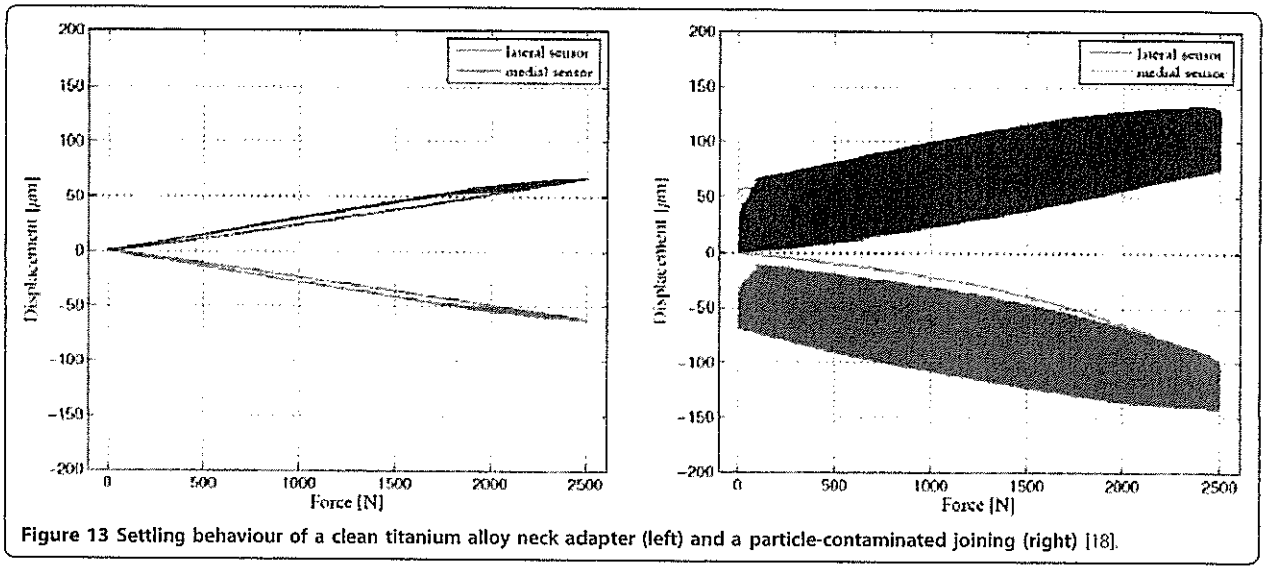


Figure 13 Settling behaviour of a clean titanium alloy neck adapter (left) and a particle-contaminated joining (right) [18].

accompanied by an acidification of the electrolyte [12,20,21,28].

Inside the layer, the elements calcium and phosphor could be detected and verified by different analytical methods. The crystalline composition of the calcium phosphate compound seems to indicate that the wear debris contained bone particles. Impurities which get inside the cone during intraoperative assembly may contribute to a mechanical perturbation which manifests itself as micro-movements which initiates fretting.

The study suggests the following hypothesis as to the cause of the damage. Fretting occurs when two surfaces in contact experience small amplitude oscillary relative motion; damage is induced on the fretting region. If the fretting fatigue strength of the material is exceeded, microcracks develope on the surface. In addition, tribochemically activated particles can discharge their content from the surface. These particles react with oxygen spontaneously, thus leading to fretting corrosion.

The severity of corrosion depends mainly from the frequency of the fretting action. For lower cyclic rates such as in a hip implant, the debris is usually oxidized if the environment is chemically active. The repeated removal of oxide films due to continued abrasion and repassivation produces thick oxide layer's. Such oxides are normally harder than the virgin titanium alloy

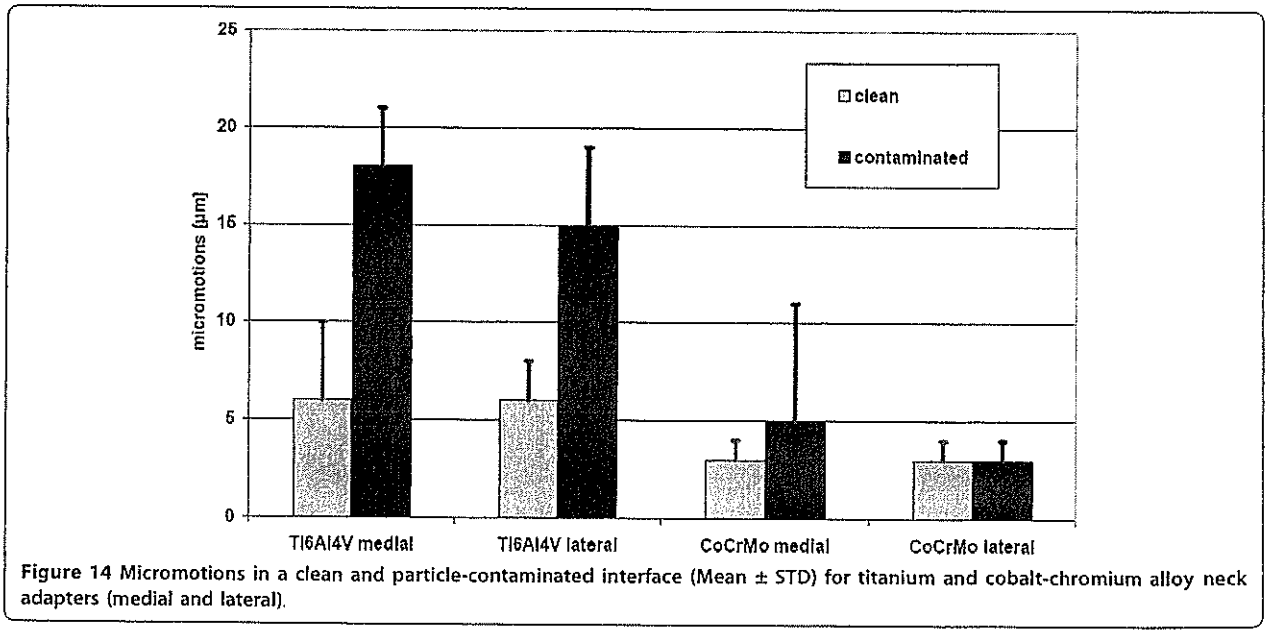


Figure 14 Micromotions in a clean and particle-contaminated interface (Mean ± STD) for titanium and cobalt-chromium alloy neck adapters (medial and lateral).

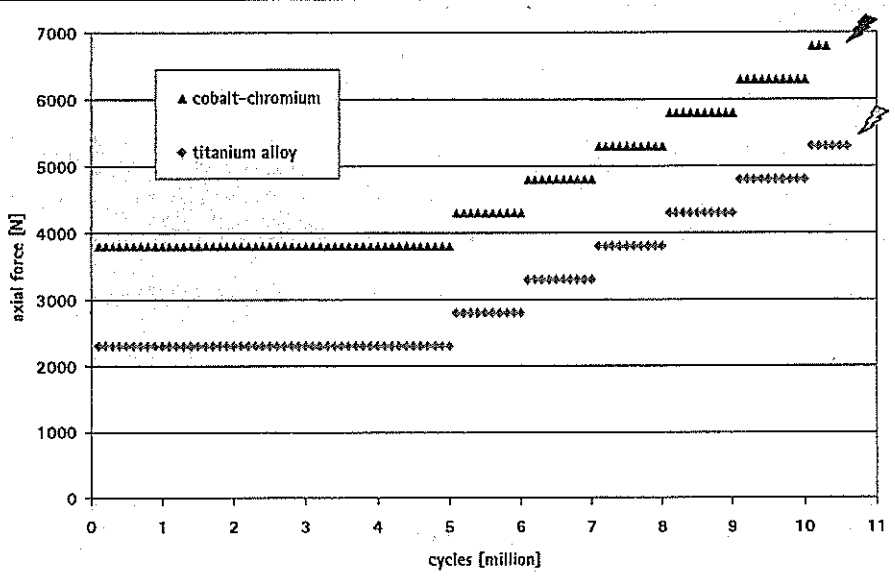


Figure 15 Endurance behaviour of the modular stem and different failure mechanisms for neck components made of titanium (failure of the neck adapter) and of cobalt-chromium alloy (fractured stem at a level below the embedding).

leading to greater surface damage [29-31] These damages then accelerate the crack nucleation [32,33].

Fretting reduces the fatigue strength of the titanium significantly [34]. To a great extent, this can be avoided by using of cobalt-chromium. The criteria listed in Table 3 show the comparison of the different materials which have been verified by biomechanical investigation. At a load of 5300 N the adapter made of the cobalt-based alloy did not break. At this high load level, the titanium adapter fractured after 2.45 million cycles.

The surface damage of the titanium alloy adapters caused by the microcracks or by corrosive deterioration accelerates the propagation of cracks by the cyclic loads bringing about the dynamic fatigue failure of the adapters. Micro-movements cause fretting in the cone connection. They can be increased by contamination of the cone connection through tissue or other particles intraoperatively. To anticipate this process any contamination of the connection should be avoided and the components dried before assembling. For this purpose

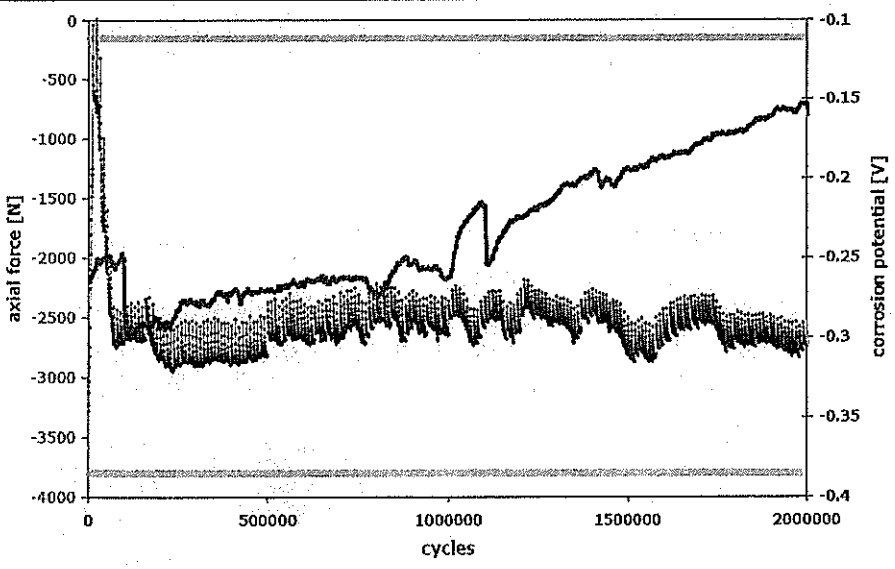


Figure 16 Free redox potential with frequent repassivation processes in the particle-contaminated modular neck interface (red curve) compared with a clean joining (blue curve).

Table 3 Assessment of the cone adapter made of the different materials - (ooo = excellent oo = good o = moderate)

	TiAl6V4	CoCr29Mo6
mechanical properties		
fatigue strength	ooo	ooo
stiffness/modulus of elasticity	oo	ooo
notch sensitivity	o	ooo
crack propagation	o	oo
abrasion	o	ooo
corrosion characteristics		
passive layer	ooo	ooo
re-passivation	ooo	oo
fretting corrosion	o	ooo
crevice corrosion	ooo	oo
allergic potential	ooo	o

abrasion-resistant cleaning rods are supplied together with the implants.

Conclusions

The change of the material of the adapter from titanium alloy to a cobalt-based alloy (CoCr29Mo6) increases the safety of the cone connection significantly. The combination of the cobalt-based alloy and the titanium alloy of the shaft shows a considerably higher rigidity. The smaller micro-movements reduce abrasion. Furthermore, the highly stable passive layer of the cobalt-based alloy provides an improved resistance against fretting. Due to its structure, the cobalt alloy has a much lower notch sensitivity compared to the titanium alloy. This enhances fatigue strength.

Among patients treated with the titanium alloy neck adapter, a combination of different parameters was identified as risk factors of implant failure. The parameters are intraoperative particle contamination of the cone connection, excessive loading due to a patient weight above 100 kg or high activity level, and male gender. In addition, the risk for failure rises with CCD angles of the cone adapter of 135° and smaller.

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Authors' contributions

The authors TMG, TW, WB, HPK have made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) TMG, TW, WB, HPK have been involved in drafting the manuscript or revising it critically for important intellectual content; and 3) TMG, TW, WB, HPK have given final approval of the version to be published.

Competing interests

The authors TMG, TW, WB, HPK are all employees of Aesculap AG Tuttlingen, Germany

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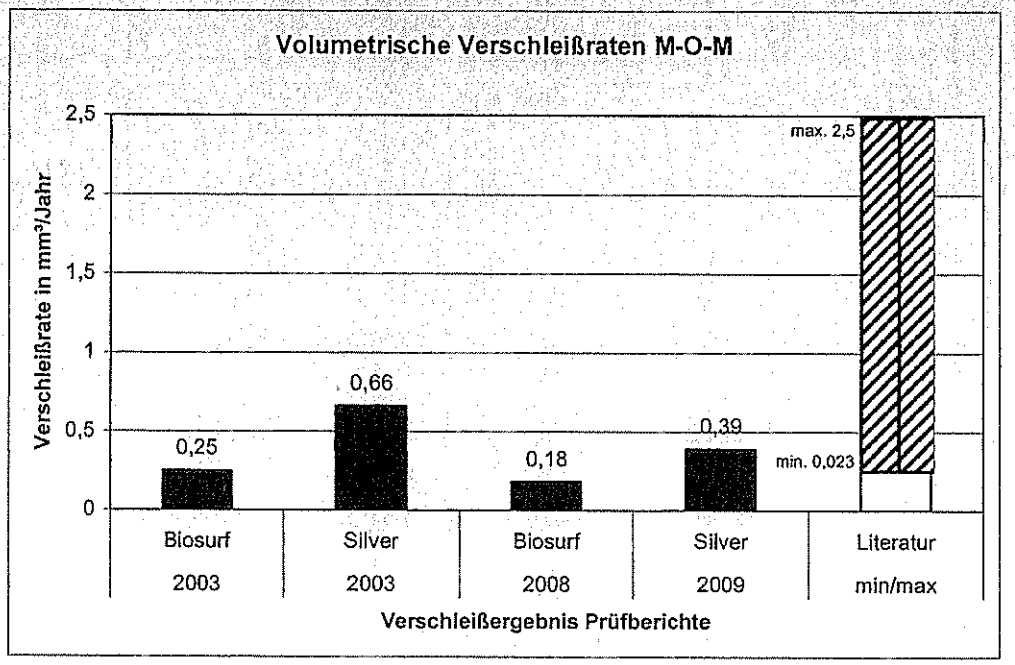

5.3.3 Verschleiß, Gleitpaarung Metall / UHMWPE

Lineare bzw. volumetrische Verschleißraten für die Hart-Weich-Paarung Metall / PE werden in der Literatur mit 0,07 - 0,5 mm/Jahr [12; 23; 25; 31; 36; 40; 41] bzw. 37 - 104,9 mm³/Jahr [22; 23; 27; 31] angegeben.

Eine aktuell im Jahr 2009 nach ISO 14242 durchgeführte Prüfung im Medical Center der University of Nebraska der Metall / UHMWPE Gleitpaarung ergab eine Verschleißrate von 0,05082 mm/Jahr bzw. 77,25 mm³/Jahr (73,81 mg/Jahr). [37]

Die ermittelten Verschleißwerte liegen somit innerhalb bzw. unterhalb und damit besser als die in der Literatur angegebenen Referenzwerte. Daher werden die Produkte von ESKA als sicher eingestuft.

Adapter (cementless) Femoral Stem Prosthesis

Sponsor: **ESKA Australia**
Manufacturer: **ESKA**

NJRR Data:

# Implanted	# Revised	Revision Rate (%)
567	23	4.1
171104	*5077*	3.0
Observed Compt Yrs	**Revns/100 Comp Yrs**	**CL on revs/100 c.yrs**
1092	2.1	1.34 - 3.16
652317	0.8	*0.76 - 0.80*

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: 34
Number of hospitals where revisions occurred: 10

Reason for Revision	N	%
Loosening/Lysis	5	21.7
Dislocation	5	21.7
Pain	4	17.4
Infection	3	13.0
Fracture (Bone)	2	8.7
Leg Length Discrepancy	1	4.3
Metal Sensitivity	1	4.3
Wear Acetabulum	1	4.3
Implant Brakage Acetabular	1	4.3
Total	23	100%

Type of Revision	N	%
Femoral Only	6	26.1
Acetabular Only	5	21.7
Femoral and Acetabular	2	8.7
Cement Spacer	1	4.4
Head/Insert	5	21.7
Head/Neck	2	8.7
Head Only	1	4.3
Insert Only	1	4.3
Total	23	100%

TGA Observations on NJRR Data

The revisions seem to be evenly distributed among using hospitals, which would imply that if there is a problem it is not technique or surgon related. The cummulative revision rate appears to get steadily worse and diverging from the cummulative revision rate of all other similar implants. Pain, leg leg discrepancy, metal sensitivity, wear and implant breakage are all over-represented as reasons for revision in this set.

TGA Observations on Manufacturers Reply

In this case the sponsor approach has been to explain, on a case by case basis why the implants have been revised, and then to provide published literature that suggests that this femoral stem prosthesis has had excellent results elsewhere in the world.

The 6 femoral only revisions and the 5 acetabular only revisions are said not to be due to "the failure of the device", but rather due to the "learning stage of the surgeons". However no supporting such as the manufacturer's own investigation records etc are provided to back up the statement, and the NJRR report contains no information about the surgeons who put these implants in or when.

One of the total revisions is blamed on the "high level of chromium that the patient had" requiring a change from a metal on metal bearing to a ceramic on ceramic bering – the sponsor considers this not to be implant related. The second total revision is said to have happened because an inexperienced surgeon chose to use too small an acetabulum, the revision was required to rectify this. (Note: this explanation was provided for one of the two femoral + acetabular revisions.

The sponsor provides an explanation for all all of the revisions in the "Type of Revision table in terms of surgical error, but no supporting evidence for the assertions (eg a cross reference to investigation reports, implant retrieval analysis etc is provided) is provided. However, the sponsor states that he has received no complaints about the Adapter stem and 23 adverse event reports. Presumably this means that the sponsor has received an adverse event report from a surgeon that matches every revision cited by the NJRR. The sponsor states that there have been no complaints or adveserse events reported elsewhere in the world.

As with other sponsors, ESKA have supplied a table summarising the available literature and copies of key publications.

Closer inspection of the paper by Sielewicz et al - reveals that the studies described in that paper were not without their complications (eg loosening, intraoperative stem fracture, pain). Also the relationship between the stem used by Sielewicz in 1983-88 and the Adapter stem is not clear other than the fact that both have a spongy surface.

Gollwitzer et al reports very good results with an ESKA hip system - presumably Adapter (76 hips, mean follow up 7.9 years, 1 femoral component revision and 2 acetabular component revision and good hip scores).

Götze et al report a cummulative survival rate on 90 ± 8 % at for the acetabular and 86 ± 5 %for the stems at 14.9 years. 137 patients were followed in this study and the authors stage that four prosthesis (a relatively large number) were revised dure to implant fracture. These are not great results. The authors conclude that

> "The long term results of the spongy metal cup are good, whereas the high loosening and fracture rate of fully coated stem are a source of concern especially with regard to the difficult revision scenario with frequent massive bone loss."

Götze et al state that the stem has since been modified to proximal coating only but it is not clear how similar the Adapter stem is to the stem used in this study.

Sholtz et al reviewed 165 consecutive ESKA hip arthroplasties conducted between 1983 and 1985. 32 patients had died of unrelated causes, 14 hips had been revised. The minimum follow up was 12 years the mean follow up time was 13 years. Of the 14 that were revised: 1 was due to infection – 11 (femoral only) were due to loosening – 1 was due to stem fracture and one (acetabulum only) doue to loosening. The survival rate was calculated to be 88% at 15 years with good hip scores.

Powerpoint slides of the Scholtz data set were also provided.

[redacted]