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HEALTH ECONOMICS & POLICY

OUTCOMES RESEARCH

IMPLANT MATERIAL

Ceramics for the Benefit of Patients and Healthcare Systems

Dear colleagues,

The Corona pandemic has affected our lives and our work severely. Elective surgeries have been postponed, with a massive negative impact on orthopaedic care in general and also on the financial situation of many hospitals. We still do not know when we can return to something that resembles normality. Nevertheless, our professional focus as surgeons has not changed. Under any circumstances, our goal will be further to increase benefits for the patient. Arthroplasty is not only about pain relief but also about performance, long-term

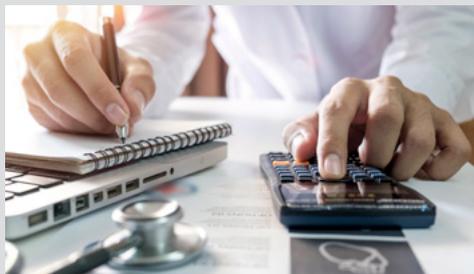
success (lifelong if possible), and cost efficiency. In the field of revision, 3D printing and customization offer new chances adequately to treat even the most difficult cases. Advanced bearing materials allow us to achieve long-term survival. As the number of primary and revision procedures keeps increasing continuously, we must be aware that we are riding a tiger! In revision cases, the choice of implant is especially crucial. In my department, we have been using ceramic femoral heads exclusively for all our patients for more than 20 years. (...)



*Professor Francesco Traina
Rizzoli Orthopaedic Institute
Bologna, Italy*

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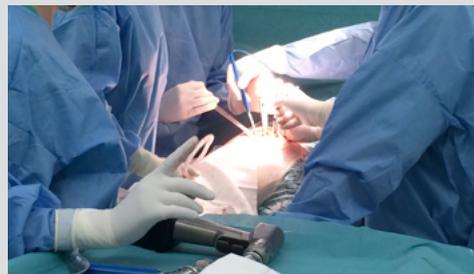
Burden of Disease: Can the Curve Be Flattened?



The growing number of hip arthroplasty procedures requires solutions and adequate planning to reduce the future burden of disease and its economic consequences. As revision has a severe impact on the patient's quality of life and the healthcare economy, implant solutions with proven superior outcomes should be regarded as best practice.

[Understand the background](#)

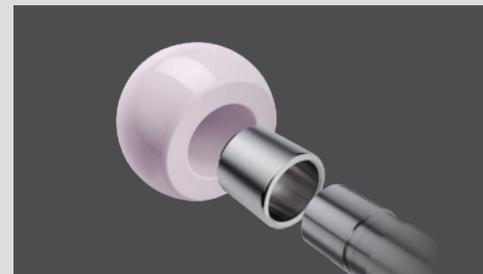
Excellent Outcomes with BIOLOX®delta in Revision: Don't Forget the Sleeve



Introduced to the market over 15 years ago, BIOLOX®delta ceramic hip implants have been widely used in primary THA ever since. Recent studies support their value as a reliable solution in hip revision, too. Placing a BIOLOX®delta head on a retained stem without an adapter is a matter of risk mitigation. Stay on the safe side by using a sleeved femoral head.

[Comprehend the relevance](#)

Sleeved Ceramic Heads: Versatile, Essential and Proven



In hip revision, the metal taper of an otherwise intact and well-fixed stem can exhibit varying types of damage which may be attributed to assembly or disassembly damage as well as black debris indicating fretting or even corrosion. Depending on the grade of the taper damage, the use of a sleeved ceramic head can offer a possibility to retain a well-fixed stem.

[Check the evidence](#)



Ceramics for the Benefit of Patients and Healthcare Systems



Professor Francesco Traina
Rizzoli Orthopaedic Institute
Bologna, Italy

Dear colleagues,

The Corona pandemic has affected our lives and our work severely. Elective surgeries have been postponed, with a massive negative impact on orthopaedic care in general and also on the financial situation of many hospitals. We still do not know when we can return to something that resembles normality. Nevertheless, our professional focus as surgeons has not changed. Under any circumstances, our goal will be further to increase benefits for the patient.

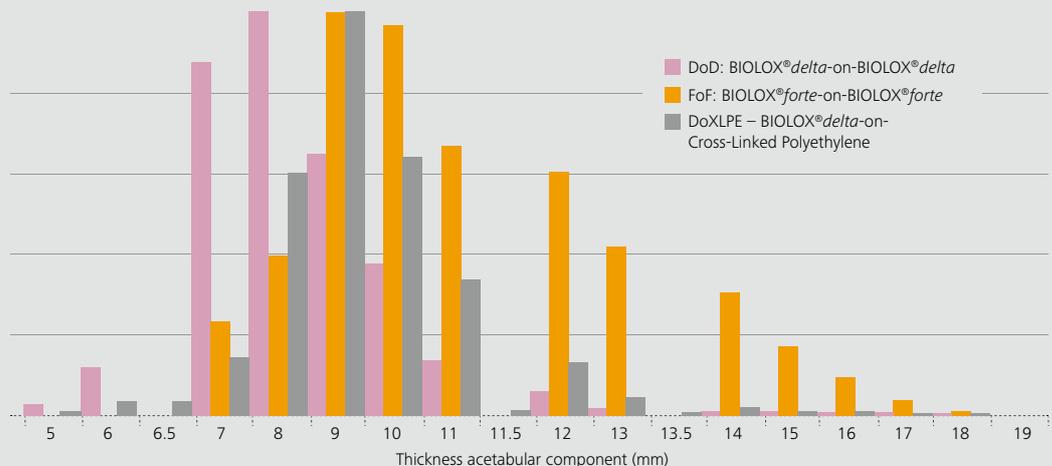
Arthroplasty is not only about pain relief but also about performance, long-term success (life-long if possible), and cost efficiency. In the field of revision, 3D printing and customization offer new chances adequately to treat even the most difficult cases. Advanced bearing materials allow us to achieve long-term survival. As the number of primary and revision procedures keeps increasing continuously, we must be aware that we are riding a tiger!

In revision cases, the choice of implant is especially crucial. In my department, we have been using ceramic femoral heads exclusively for all our patients for more than 20 years. Our clinical results with BIOLOX®*forte* ceramic bearings at Rizzoli were excellent compared to other materials¹, showing very good results even in difficult cases like DDH, Poliomyelitis or Legg-Calvé-Perthes disease, Slipped Capital Femoral Epiphysis (SCFE)²⁻⁵. Our regional hip registry (RIPO) documents twenty years of long-term results with a very low rate of ceramic failure in ceramic-on-ceramic. The rare cases of failure were mostly related to mishandling⁶⁻⁹.

With the next generation of ceramics, BIOLOX®*delta* introduced in 2003, new geometries became possible. The possibility to reduce the thickness of the acetabular liner and increase the diameter of the head was, in my mind, a true game-changer in our clinical practice. The introduction of sleeved ceramic heads for revision gave us an additional treatment option.

Bearing distribution according to the thickness of the acetabular component

Regional Register of Orthopaedic Prosthetic Implantology (RIPO),
1st January 2000 – 31st December 2013
Evaluation based on figures from RIPO for CeramTec GmbH





[To the video >>>](#)

Ceramics is the second hardest material after diamond. [It is also very tough](#). Only punctual and local stresses can lead to damage under extreme circumstances. Small metal elevations on the worn surface of the metal taper or micro-movements between head and taper may lead to the fracture of a ceramic component.

However, this risk is extremely low when we compare the fracture risk of a ceramic head with the risk of polyethylene wear or instability due to a small head diameter. This is clearly shown by the evidence we collected over the years. And if I have to choose between a material releasing toxic ions, compromising the immune system of already weakened patients on the one hand and ceramics on the other, my choice will clearly be for the second. A fractured ceramic component can be revised. Damage by metal intoxication cannot.

Ceramics in Revision – Treatment Algorithm

In revision, I usually choose the largest head diameter (>36mm) available to increase implant stability, and to date I can report very good clinical outcomes. Furthermore, large heads increase positive proprioceptive sensations for the patients¹⁰. I have never faced any cases of trunnionosis related to a large ceramic head, and I am not aware of any clinical studies or case reports stating the opposite¹¹.

In our recently published study, Delta-on-Delta bearings showed reliable outcomes in revision at mid-term, with no fractures¹². These outcomes were confirmed also in smaller case series involving total hip revisions or isolated acetabular revisions, and even in specific cases as metal-on-metal revisions¹³.

At Rizzoli, we have very few cases of patients with noise issues. None of them had to be revised and therefore, squeaking is not rated as a risk factor in our institution. In my opinion, the only true limit for ceramics in revision surgery is set by the cases in which good implant stability cannot be achieved. Implant manufacturers strongly advise the use of a titanium sleeve on the damaged taper, in order to recreate the pristine trunnion and still allow a uniform distribution of the stresses on the ceramic head.

In finite-element simulations the fracture strength of Delta heads strongly decreased on tapers showing small metal elevations¹⁴. On the other hand, the fracture strength of sleeved heads did not decrease significantly on severely damaged tapers¹⁵.

In conclusion, our extensive clinical experience supported by the data collected in the RIPO regional registry demonstrates that the use of Delta-on-Delta ceramic bearings in revision surgery shows very promising results at a mid-term follow-up. The Australian registry suggests that the use of prostheses with improved performance has a positive impact on the incidence of revision. At Rizzoli, we observed that even the number of re-revisions decreases with the use of ceramic bearings. As revisions have a strong impact on patients' quality of life and also on the healthcare system, implants with proven outcomes should be considered as best practice and as a valuable strategy to reduce healthcare expenditures in the long term.



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Burden of Disease: Can the Curve Be Flattened?

The growing number of hip arthroplasty procedures requires solutions and adequate planning to reduce the future burden of disease and its economic consequences.

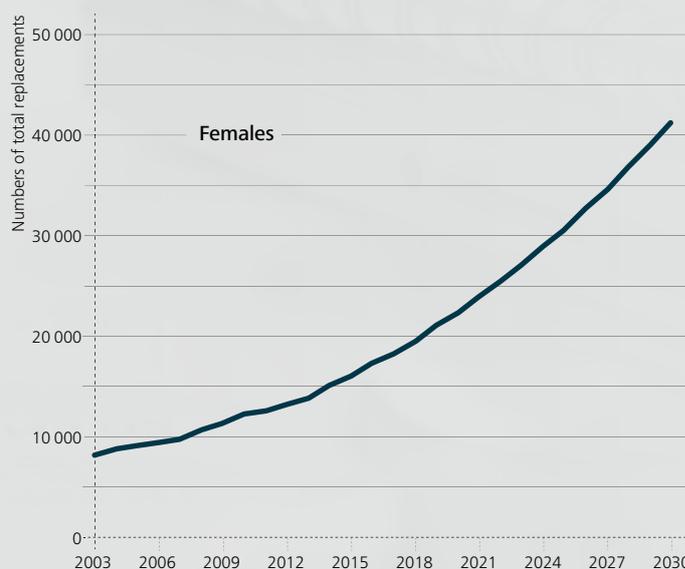
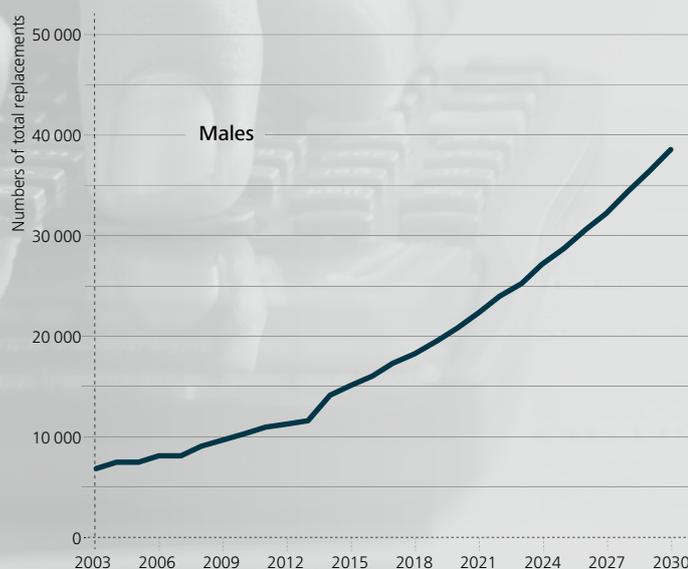
Global THA Trends

The number of hip replacement procedures increased significantly over the past decades, even beyond previous expectations. It is expected to rise further over the next two decades according to the projections in several studies^{1,2,3,4,5,6}. Demographic change, aging populations with a growing percentage of patients with poor health status, a growing obesity rate and paradoxical, the great clinical success of hip arthroplasty are some of the major causes for this development. Clearly, a notable impact on healthcare resources and economics is inevitable.

Australia

The data collected by arthroplasty registries can provide a valuable tool to calculate further increases in hip replacement, the ensuing economic burden and the sustainability of healthcare structures. **Ackerman et al.**¹ analyzed **Australian Arthroplasty Registry** data from 2003–2013. Based on the growth rate of THA for osteoarthritis in that decade, they expect the figures to rise by 208%, from 25,945 procedures in 2013 to 79,795 in 2030. The predicted growth in THA will mainly be driven by population aging and soaring rates of obesity.

Projections for hip replacement (indication OA), based on Australian registry data from 2003–2013.



Ackerman IN, Bohensky MA, Zomer E, et al. The projected burden of primary total knee and hip replacement for osteoarthritis in Australia to the year 2030. *BMC Musculoskelet Disord.* 2019;20(1):90. doi:10.1186/s12891-019-2411-2419. Evaluation based on additional files 3 and 4.



USA

Singh et al.² report a similar increase of arthroplasty procedures for the USA where the population is expected to grow in the coming years. Based on **National Inpatient Sample** data, the authors predict soaring numbers for primary THA for male and female in all age groups, female and patients in age group 45–85 being more affected:

*Overall Projections to 2040
Primary THA in the US
(comparison year from 2014)*

Year	THA growth rate
2020	34%
2025	75%
2030	129%
2040	284%

Based on: Singh JA, Yu S, Chen L, Cleveland JD. Rates of total joint replacement in the United States: future projections to 2020–2040 using the National Inpatient Sample. *J Rheumatol.* 2019;46(9):1134-1140.

Germany, Sweden, UK

In Germany, where the population is expected to shrink and age, Rupp et al.³ calculated the number of THA based on population projections and estimates of future healthcare expenditures as a percent of the **gross domestic product (GDP)**. The authors predict a 23% increase from 2016 to 2040. The greatest rise is expected to occur in elderly patients.

A similar surge is estimated for Sweden and the UK: 25% increase in THA numbers between 2013 and 2030 for Sweden^{4,5}, 32% between 2015 and 2035 in the UK⁶.

The Rise of Revision Figures

It is reasonable to assume that these trends will result in a rising number of revisions. Schwartz et al.⁷ analyzed the **National Inpatient Sample (NIS)** database and forecast an increase of revision THA numbers between 43% and 70% from 2014 to 2030 in the USA. The share of expenditures for revision procedures could grow even faster, heavily impacting the healthcare system. A growing number of primary arthroplasties will be performed on younger and more active patients in the near future, putting this cohort at a high risk for multiple revisions in their lifetime. The number of revision procedures is expected to increase in the 55–64 age group explicitly, with infection being one of the most important drivers.

Ackerman et al.⁸ suggest that the use of implant systems with a lower risk for revision and the use of value-based payment models could be effective strategies for reducing healthcare expenditures in the long term. The authors assume that the use of a hip implant with a 1% absolute reduction in the cumulative revision rate may allow Medicare to save almost a third of the resources needed for revision, not to mention the huge benefit for the patients involved.

Reduced Revision Numbers with High-Quality Implants

The **Australian Arthroplasty Registry** reports a reduction in revision hip replacement over the years since the registry has been in operation⁹. Similar trends can be observed in the NJR report: since 2012 the number of revisions decreased despite the growth of primary procedures. In the latest report, the authors emphasize the increasing usage of ceramic-on-polyethylene bearings as the bearing of choice, showing encouraging outcomes after extended follow-up. According to the NJR dataset, the longer the survival of the primary implants, the lower the risk of revision and re-revision¹⁰. The introduction of the fourth generation of ceramics for THA, and of highly crosslinked polyethylene has proven to play a crucial role in improving the performance of hip implants.

One of the standard objections against ceramic couplings is related to high costs. However, a significantly lower rate of postoperative complications with CoC/CoP bearings may lead to lower overall costs compared to other bearing couples. Several health economy studies have shown that ceramics show a great potential for cost-effectiveness in hip arthroplasty. According to three US studies, ceramic bearings have already proven to be cost-effective for a wide population. **Kurtz et al.** describe bearing surfaces to be “among the least important drivers of hospital cost”. Ceramic bearings (CoP/CoC) are both cost-effective implant choices for patients under 87 years in primary THA^{11,12,13}.

In summary, arthroplasty is expected to grow over the next years due to multiple reasons. At the same time, data-based projections point out that replacement procedures will progressively involve younger patients. It is likely that in the future many revision procedures will be needed and many re-implantations will be performed in younger patients. As revision has a severe impact on the patient’s quality of life and the healthcare economy, implant solutions with proven superior outcomes should be regarded as best practice.

Incidence of all hip revisions per 100,000 between 2003 to 2018



Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR). Demographics of Hip, Knee & Shoulder Arthroplasty: Supplementary Report 2019 – Table SH3. Adelaide: AOA, 2019:13.



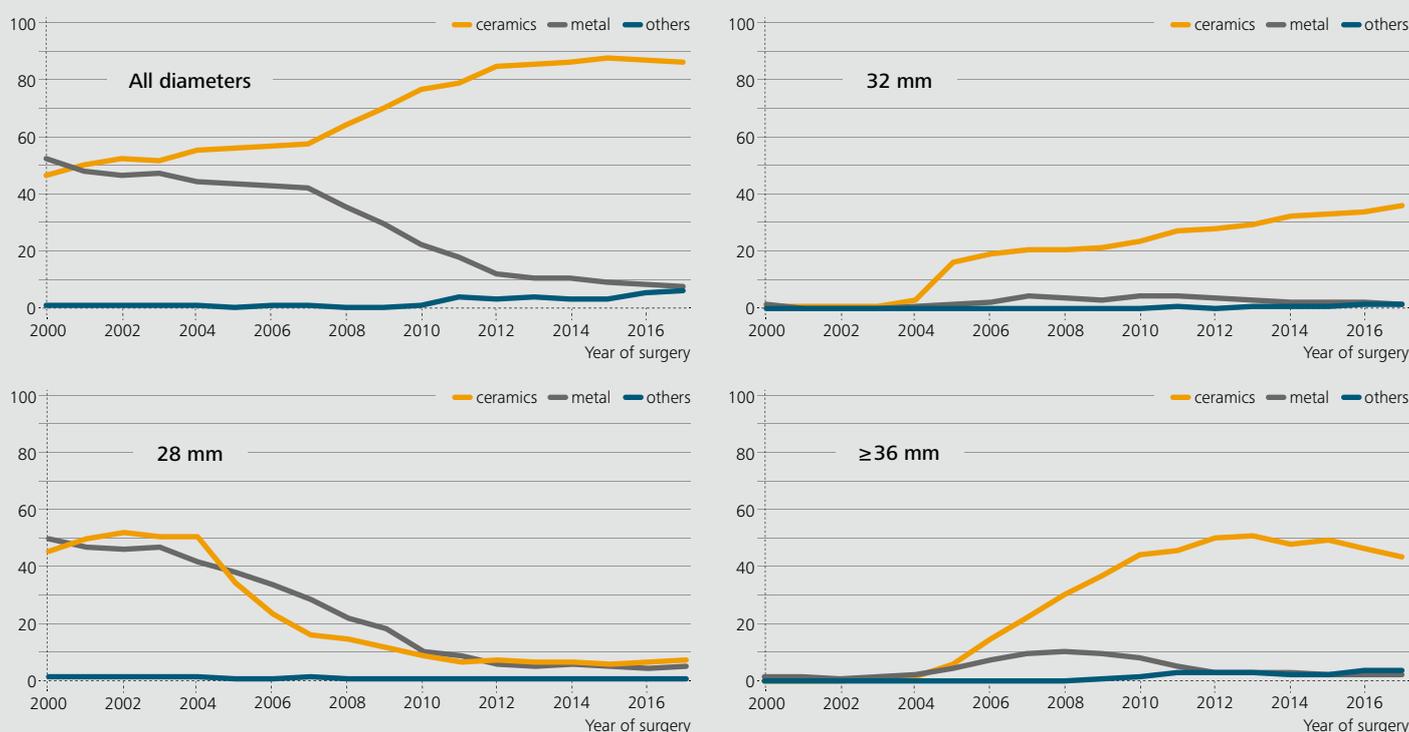
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Excellent Outcomes with BIOLOX[®]delta in Revision: Don't Forget the Sleeve

Introduced to the market over 15 years ago, BIOLOX[®]delta ceramic hip implants have been widely used in primary total hip arthroplasty ever since. Their clinical performance is well documented in clinical studies and implant registries, with abundant evidence supporting their efficacy and safety. The collected data support the value of BIOLOX[®]delta as a reliable option in hip revision, too.

Researchers from the Rizzoli Orthopaedic Institute (Bologna, Italy) have recently analyzed the performance of BIOLOX[®]delta components in revision based on data from the regional Register of Orthopaedic Prosthetic Implantology (RIPO)^{1,2}. In 2018, 98% of all hip, knee and shoulder arthroplasties performed in the Emilia-Romagna region were captured. The latest report (2000–2017) offers a documentation of 111,856 primary total hip replacements and of 16,432 hip revisions. Ceramic-on-Ceramic (CoC) was the bearing couple most commonly used in primary total hip arthroplasty (45.6%). In revision, 25.5% of the hip with a CoC bearing. According to the registry, alumina composite ceramics and XLPE have become the preferred bearing materials for index surgery. The survival rate of all primary hip procedures at 17 years is 89.1%³.

Femoral head usage (%)
by material type
(RIPO 2000–2017)



Adapted from: Report of R.I.P.O. Regional Register of Orthopaedic Prosthetic Implantology Overall Data Hip, Knee and Shoulder Arthroplasty in Emilia-Romagna Region (Italy) 2000-2017 Version 1 July 22, 2019.

Clinical Performance at Mid-term Follow-up

In one study¹, the Rizzoli group analyzed RIPO data to evaluate the survival rate of 327 revision implants with BIOLOX[®]*delta*-on-BIOLOX[®]*delta* ceramic bearings (hereafter: Delta-on-Delta). The survival rate was 90.5% at 10 years (mean follow-up: 4.1 years). Twenty-three hips were re-revised and the reasons for failure were analyzed.

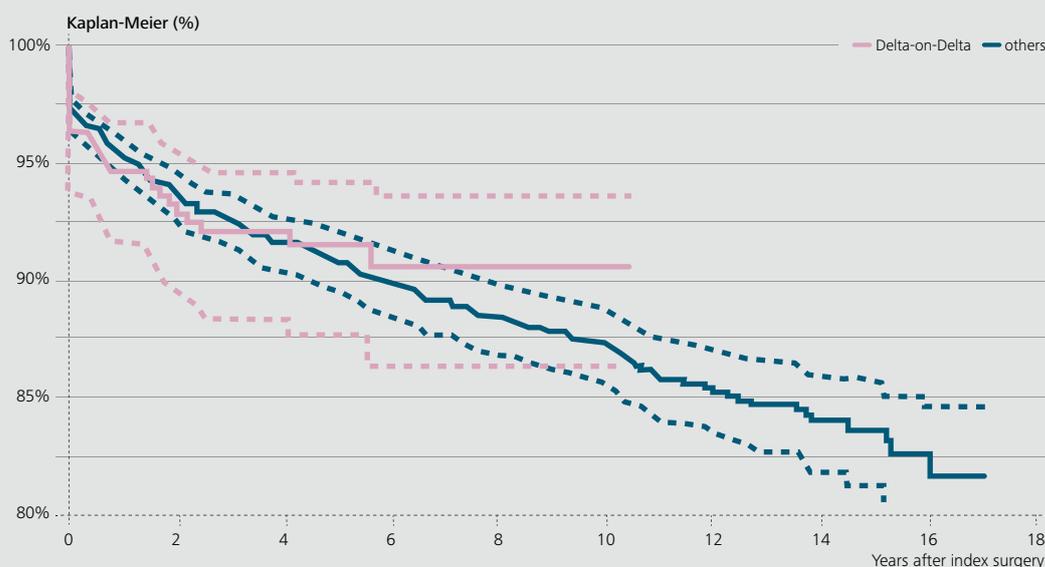
Recurrent dislocation was identified as the main reason for failure. Most of the re-revisions occurred within the first year after the original revision surgery. According to the authors, the prevalence of recurrent dislocations may be related to implant positioning or soft tissue quality/tension issues. Re-revisions for ceramic fracture or noise were not reported.

When compared to the control group with other bearing types, the researchers found a lower re-revision rate for implants with Delta-on-Delta. The ceramic composite bearings also showed a lower incidence of re-revision for aseptic and septic loosening. The authors concluded that revision procedures with Delta-on-Delta bearings show good and reliable clinical performance at mid-term follow-up.

These positive results are supported by a retrospective clinical study from Korea in 2018. **Chang et al.**⁴ evaluated the clinical and radiological outcomes of 47 patients (52 hips) treated with Delta-on-Delta in revision surgery with all components exchanged. None of the components required a re-revision at a mean follow-up of 7.3 years. The study reported no ceramic fractures or noise.

These results correspond to the outcome in a small case series (18 hips, 16 patients) by the already mentioned **Rizzoli group**. In this clinical study, **Castagnini et al.**⁵ report very good clinical results of highly porous titanium cups with Delta-on-Delta bearings with an adapter-sleeved head.

*Survivorship of Delta-on-Delta bearings in THA revision compared to control group**



* Courtesy of RIPO

Sixteen patients with metal resurfacing cups were revised. They received isolated acetabular revision cups and a Delta-on-Delta bearings. All patients showed elevated metal ion concentrations at the time of surgery. The clinical outcome of the revisions was evaluated at a minimum follow-up of 5 years. None of the 16 patients had to be re-revised, no patient was lost to follow-up. The metal-ion level in both blood and urine continually decreased after revision.

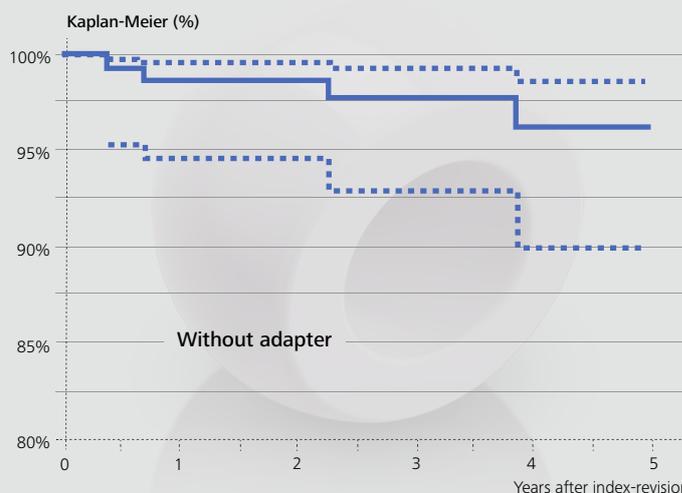
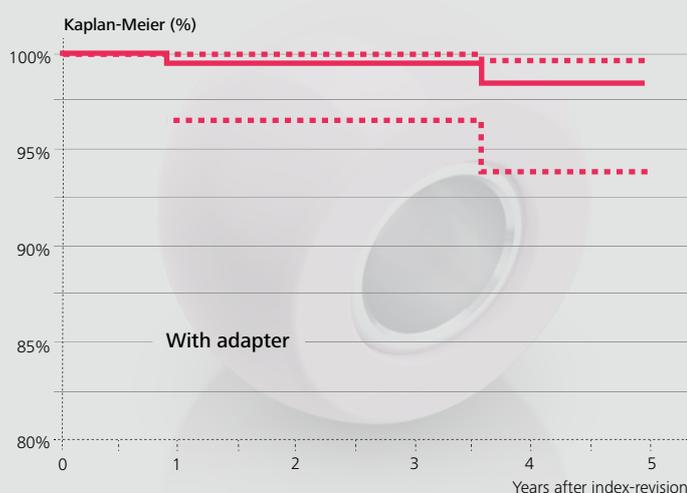
In an earlier study from 2016, **Plummer et al.**⁶ report similar results in a small cohort of patients at short term follow-up: ALTR patients revised with a sleeved ceramic head had significantly decreased cobalt and chromium ion concentration in the blood compared to ALTR patients revised with a metal head. Based on these results, the authors suggested to retain a well-fixed femoral stem and to use sleeved ceramic heads in ALTR patients.

However, some surgeons raise concerns about the addition of a titanium sleeve between the stem and the ceramic head as potential trigger of fretting corrosion at the stem/sleeve interface.

Preuss et al.⁷ addressed this question and performed in-vitro fretting corrosion tests according to ASTM F1875. Titanium alloy, cobalt chrome and stainless steel stems were evaluated with a sleeved BIOLOX[®]OPTION head. The authors did not find “any sign of excessive surface deterioration or progressive degradation.” This was confirmed clinically by **Eichler et al.**⁸. The Canadian research group measured the cobalt, chrome and titanium ion levels in the whole blood of 36 primary THA patients treated with Delta-on-Delta with large-diameter (sleeved) heads (40mm–48mm) and a preassembled acetabular component. After 5-years follow-up, the ion levels were low and no significant changes were noticed over time. No signs of trunnionosis were detected.

An analysis of retrieved BIOLOX[®]OPTION sleeved heads at the Hospital of Special Surgery, New York, performed by **Koch et al.**⁹ also showed that BIOLOX[®]delta sleeved ceramic heads are safe in terms of fretting corrosion. An investigation of retrievals at Drexel University, Philadelphia (**MacDonald et al.**)¹⁰ also supports their use.

Cumulative re-revision survivorship of BIOLOX[®]delta heads with and without adapter*



* Courtesy of RIPO



To Sleeve or Not to Sleeve Is a Matter of Risk

The international orthopedic community still seems to be divided on the necessity of placing a sleeve on a used taper although the implant manufacturers recommend this expressively.

Placing a BIOLOX®*delta* head on a retained stem without an adapter is a matter of risk mitigation. Stay on the safe side by using a sleeved femoral head.

In an observational study based on RIPO data, **Affatato et al.**² investigated the impact of adapter sleeves on re-revision rates of hip revision procedures with retained stems. Metal heads were mostly used without sleeves, about two thirds of the ceramic heads were implanted with sleeves.

In the remaining cases, the surgeons opted for a non-sleeved BIOLOX®*delta* head. The authors found that the use of adapter sleeves significantly reduced the rate of re-revisions when all head materials were included (98.4% vs. 95.2% survival rate). Since there were no fractures of non-sleeved BIOLOX®*delta* heads at mid-term follow-up, the authors concluded that the use of the sleeve may play a “negligible role” in this respect.

Kim et al.¹¹ came to a similar conclusion. In a prospective clinical study, the Korean group implanted Delta-on-Delta bearings without using an adapter sleeve in 100 hip revisions. The revisions became necessary because of polyethylene wear and osteolysis with metal-on-polyethylene bearings. The tapers of the retained stems showed minimal to mild corrosion. The damage status of the taper was evaluated by three surgeons using a magnifying lens. Based on this visual inspection, they opted for non-sleeved heads.

After a mean follow-up of 12.8 years, no ceramic fractures were detected. Based on these results, the authors concluded that the use of adapter sleeves on stem tapers remaining *in situ* is not necessary.

Stay on the Safe Side

Even if these studies seem to support this option, implant manufacturers and CeramTec expressly caution surgeons to consider this decision carefully as it contravenes the Instructions for Use. The function of a sleeve is to recreate a pristine taper which is a prerequisite when engaging a new femoral ceramic head onto a slightly damaged stem taper.

The necessity of placing a sleeve has been recently addressed by **Morlock's research group in Hamburg**¹². The authors demonstrated that small local metal elevations at the edge of a scratch or at a damaged surface area of the taper can potentially lead to early failure of non-sleeved BIOLOX®*delta* ceramic heads despite their high fracture strength. Adapter sleeves allow an even distribution of contact stresses between stem taper and head, compensating local taper damage. Since local taper damage cannot be totally excluded by visual inspection, a sleeve should always be used on stem tapers remaining *in situ* in order to guarantee optimal conditions for BIOLOX®*delta* heads.



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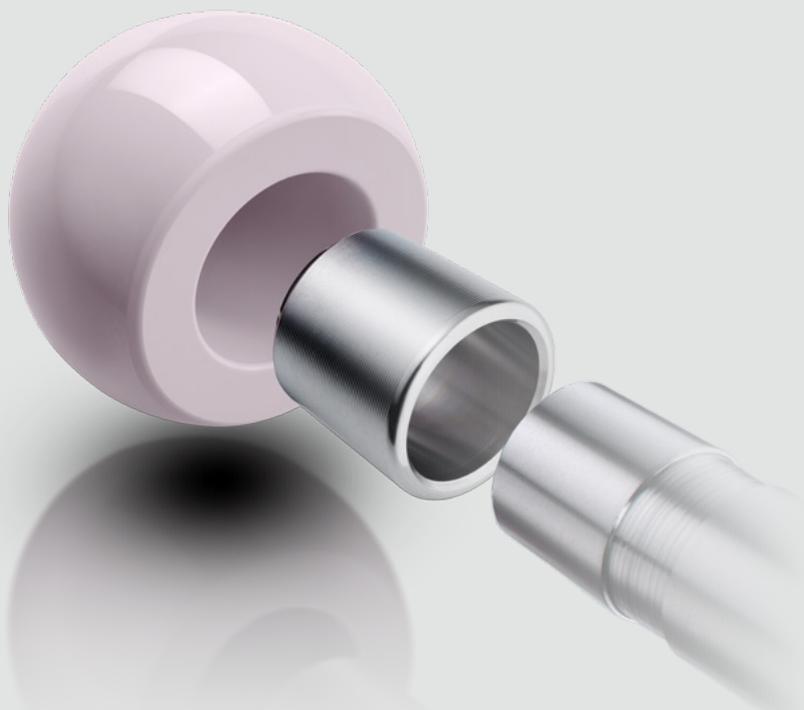
Sleeved Ceramic Heads: Versatile, Essential and Proven

Sleeved femoral heads made of BIOLOX®*delta* ceramic were introduced in 2005 with the brand name BIOLOX®*OPTION*. They offer the possibility of adjusting offset intraoperatively, but also revising a femoral head implant while retaining a well-fixed femoral stem with minor damages on the taper surface. The adapter sleeve was designed to create a pristine taper interface for the ceramic head before it is placed on a stem which remains *in situ*. Recent publications offer additional evidence on the protecting role of the sleeve.

Restoring the interface

In hip revision, the metal taper of an otherwise intact and well-fixed stem can exhibit varying types of damage: scratches, scars, flattened or burnished areas which may be attributed to assembly or disassembly damage as well as black debris indicating fretting or even corrosion¹. Depending on the grade of the taper damage, the use of a sleeved ceramic head can offer a possibility to retain a well-fixed stem.

The surface of a metal taper is manufactured with a special structure for optimal stress distribution. The adapter sleeve is intended to restore a pristine interface on its outer and to compensate slight damages on its inner side, to enable a secure head-taper lock and to avoid rotation of the new ceramic head.





Recent findings with BIOLOX®OPTION

Chaudhary et al.² from the Massachusetts General Hospital in Boston investigated the pull-off strength and seating displacement of BIOLOX®*delta* femoral heads and titanium taper sleeves. Two head diameters and two sleeve offset lengths were mated with trunnions at two different impaction forces. The sleeved heads showed a fixation strength similar to values published for non-sleeved heads. The pull-off force increased linearly with the assembly force as well. The head diameter did not have a significant effect on the measured parameters. Compared to short offset length, extra-long sleeves showed lower pull-off forces, particularly at higher impact forces. The authors confirmed that this may potentially result in better clinical outcomes by mitigating fretting corrosion.

Prof. Morlock's research group at the **Technical University of Hamburg (TUHH)** investigated the impact of stem taper damage on the fracture strength of sleeved ceramic heads. For this purpose, **Dickinson et al.**³ compared the fracture resistance of sleeved BIOLOX®*delta* heads while **Falkenberg et al.**⁴ simulated the fracture resistance of sleeved heads and compared them with non-sleeved BIOLOX®*delta* heads after impaction on severely damaged tapers.⁴ Four categories of severe taper damage were reproduced:

- a. Truncated
- b. Slanted
- c. Crushed
- d. Scratched

NOTE: With an already used stem taper, the surgeon has to make sure that the form of the taper remains unchanged and inspect it for damages such as severe abrasion/material loss, elevations and/or deep scratches ...

The categories of deformation reproduced at the TUHH are considered by manufacturers as unacceptable. Therefore, the use of sleeved BIOLOX®*delta* heads on such tapers is not allowed.

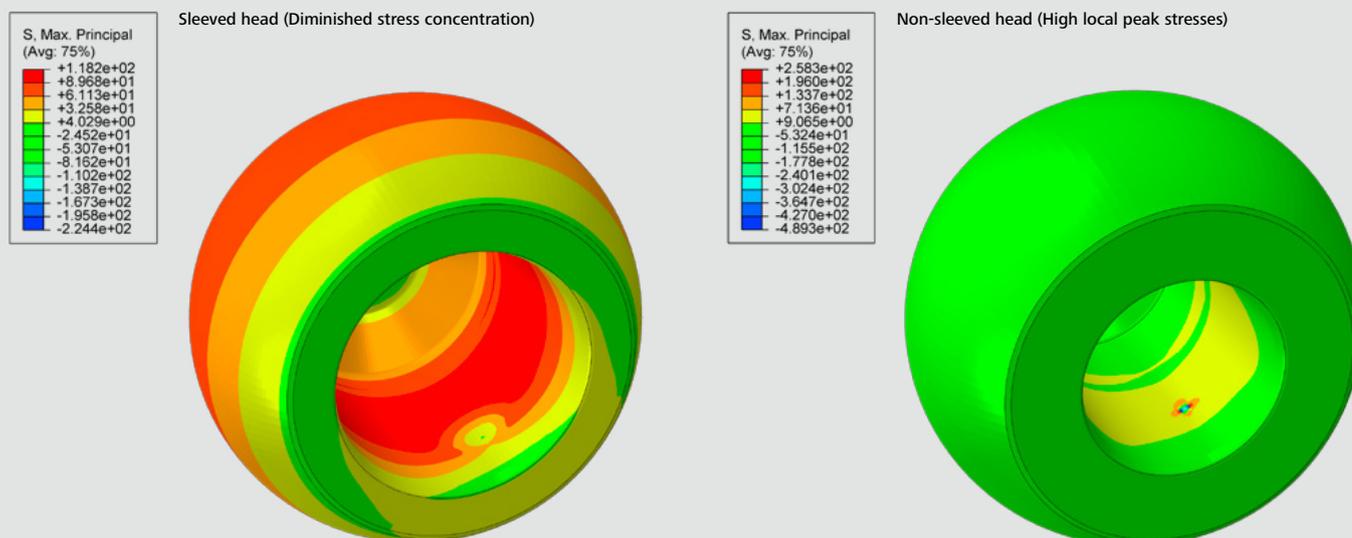
In both studies, the fracture strength of sleeved BIOLOX®*delta* heads measured with all investigated stem taper damage types was several times higher than the fracture force required by FDA recommendations. The heads were subjected to the ISO 7206-10 standard ultimate compression test, which is far from physiological loadings. The fixation strength of the taper junction depends on multiple factors which may vary in the clinical setting such as head diameter, assembly force and the angle, length and surface roughness of the taper. All these factors may influence the stress distribution and other conditions as the contamination junction⁵.

Uncompromised taper shape required

The unpredictability of these factors supports the manufacturer guidelines, which do not allow the implantation of sleeved heads in the extreme conditions tested in this study. Therefore, the surgeon must make sure that the shape of the taper is not compromised due to damage, such as severe wash-out areas, severe abrasion, material loss, deep scratches and ridges or similar defects.

The numerical simulations⁴ showed comparable fracture forces for truncated, slanted and crushed tapers for both sleeved and non-sleeved heads. However, the investigation showed that small local metal elevations at the edge of a scratch or at a surface damage can lead to early failure of non-sleeved ceramic heads despite their high fracture strength. Indeed, high local stress peaks generated by a small metal elevation ("scratch") drastically reduced the fracture strength of non-sleeved heads (-96%), whereas sleeved heads remained unaffected.

*The adapter sleeve compensates the punctual stresses caused by metal elevation of the retained stem taper and optimizes the stress distribution.**



* Courtesy of Professor M. M. Morlock, TUHH



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