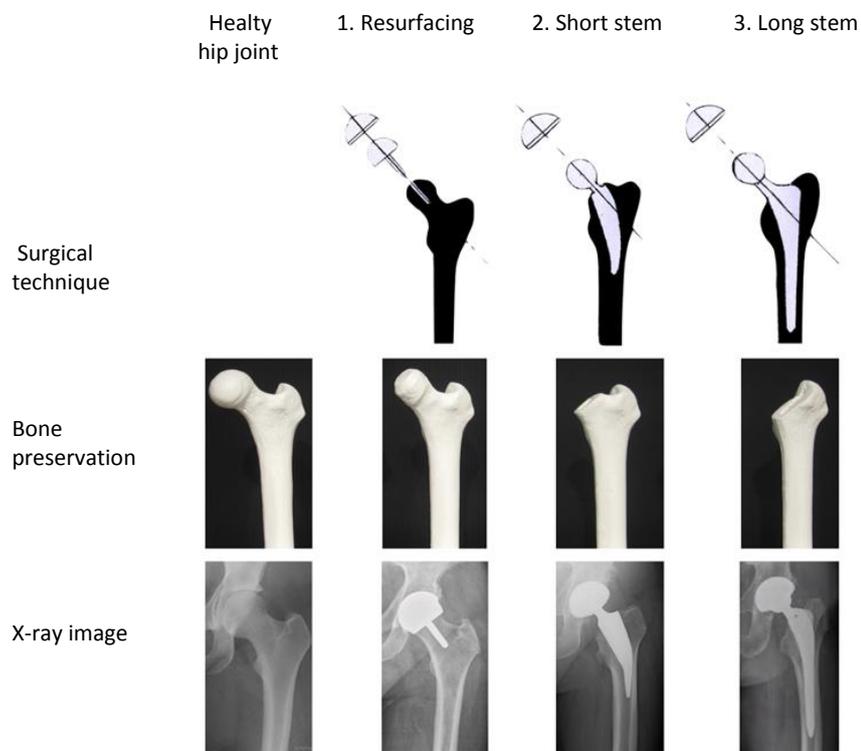


**Welcome to our homepage and thank you very much for your interest!**

The most common reason for considering the implantation of an artificial hip joint (hip endoprosthesis) is an uncontrollable pain condition of the affected hip in high-grade hip osteoarthritis. The artificial hip replacement is one of the most successful surgical procedures in modern medicine. However, this procedure always represents the last treatment step.

Although the risks of such an intervention are very low, a complication such as an infection or vascular / nerve injury can have serious, possibly permanent consequences for the patient. Therefore, the options of conservative (= non-surgical) therapy methods should be exhausted as long as possible. If the hip endoprosthesis is ultimately unavoidable, excellent hip endoprosthesis systems are available today:

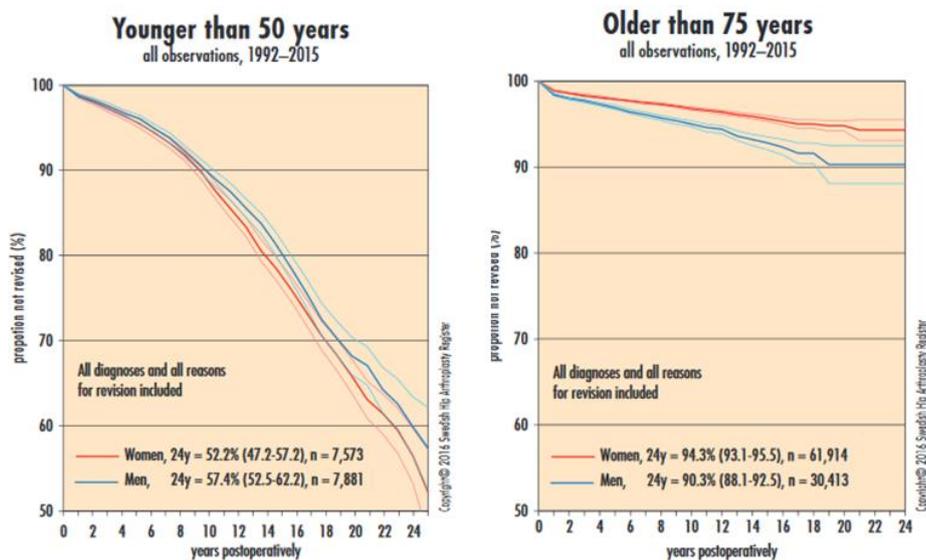
1. Surface replacement (resurfacing) hip endoprostheses
2. Stem-based hip endoprosthesis / short shaft hip endoprostheses
3. Stem-based hip endoprosthesis / long shaft hip endoprostheses



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With regard to the BHR® system (Birmingham Hip Resurfacing System) described below, there are no conflicts of interest with the manufacturing company Smith & Nephew® on my part. All previous scientific investigations, publications and patient information by my team and myself about the BHR® system have been carried out exclusively on our own initiative and at our own expense.

The survival of stem-based hip endoprosthesis systems of more than 90% after more than 20 years is the rule for older patients. The survival of stem-based endoprosthesis systems of the hip joint in patients under 50 years of age is scientifically proven to be worse. This is illustrated by the following graphs from the internationally recognized Swedish Endoprosthesis Register 2015, page 112 [<https://registercentrum.blob.core.windows.net/shpr/r/Annual-Report-2015-H19dFINOW.pdf>]:

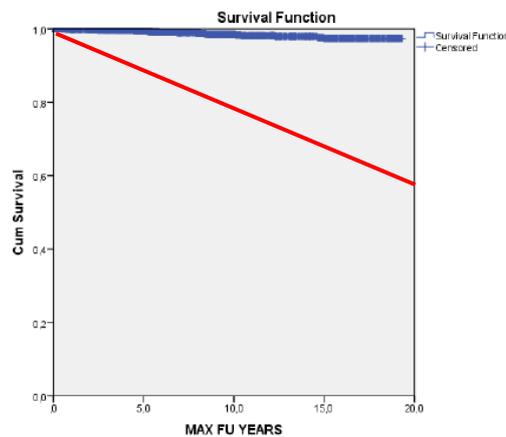


The graph on the left shows a significantly shorter durability (cumulative Kaplan-Meier survival curve) of all types of hip endoprosthesis (94% of which were stem-based prostheses) in the 24-year period 1992-2015 for patients younger than 50 years: on average 40% of the prostheses in these patients had to be replaced during this period. On the other hand, in patients over 75 years of age, these stem-based prostheses were still in place at an average of 95% after 24 years (right graph).

One of the possible causes of this early failure in younger patients after implantation of stem-based hip endoprosthesis is the high activity of younger patients. Therefore it was and is useful to develop and have available a joint replacement that has a longer survival in younger patients compared to stem-based endoprosthesis.

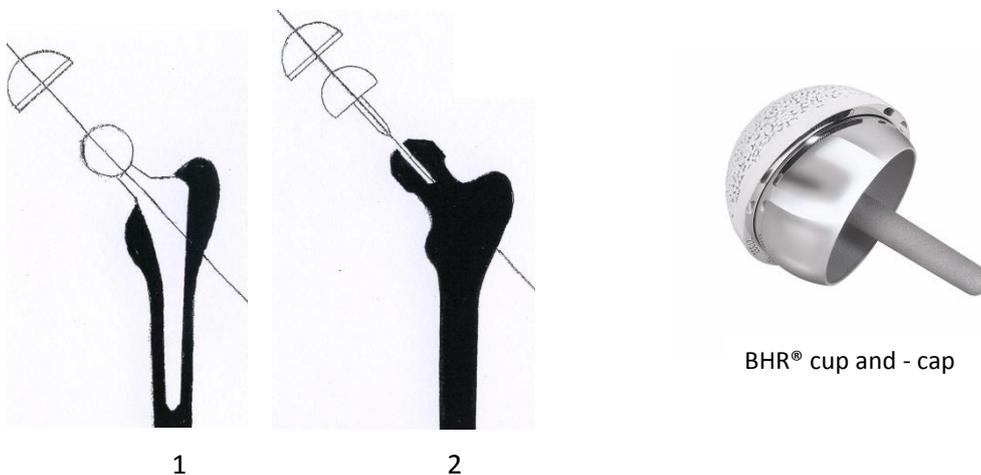
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The resurfacing of the hip joint using the example of the BHR® system can demonstrably offer this: An international study conducted by Catherine Van Der Straeten, MD, PhD, London et.al at the ISTA Congress including the results of the BHR® system (Birmingham Hip Resurfacing System), was presented in Seoul on September 30, 2017, and shows extremely encouraging results: International Hip Resurfacing Register Report 2017 [presentation/ISTA September 2017, Seoul]. The results of 11,386 hip surface replacement endoprotheses in patients under 50 years of age at the time of surgery were presented from 27 clinics in 13 countries. The BHR® system, which we use, was represented in this study in 2,714 cases in men  $\leq$  50 years in this study. According to Kaplan-Meier the cumulative survival rate of BHR® after 19 years was 97.7%. This means that after 19 years in this age group the BHR® system is still functional. The results in women will be discussed later.



Explanation of the above graphic: The blue bar shows the survival rate of BHR® in men  $\leq$  50 years (n = 2,714) according to the publication mentioned above by Catherine Van Der Straeten, MD, PhD, London, after 19 years: 97,7%. The red bar shows the survival rate of almost entirely stem-based prostheses in patients under the age of 50 years using the example of the Swedish Endoprosthesis Registry 2015 [<https://registercentrum.blob.core.windows.net/shpr/r/Annual-Report-2015-H19dFINOW.pdf>]. This is a very clear difference.

In contrast to the stem-based hip prosthesis systems (1), the BHR® retains the femoral head and neck (2):



1

2

BHR® cup and - cap

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Important to know: BHR is a metal-metal- glide pairing consisting of cobalt, chromium (no carcinogenic effect), molybdenum and nickel. The metallic femoral head moves in a metallic cup. In between there is a lubricating film, which is constantly produced by the joint mucosa. This glide pairing is sometimes discussed critically and therefore one must be well informed about this. Nowadays, stem-based prostheses have either ceramic-polyethylene or ceramic-ceramic glide pairings.

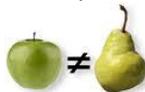


The x-ray image and the 2 models show that with the resurfacing endoprosthesis (image left) much more bone is preserved than with the stem-based total hip endoprosthesis (image right).

The BHR® system was first implanted in July 1997 and was approved for use in the United States by the Food and Drug Administration in 2006. Since its launch, more than 175.000 BHR® systems have been implanted worldwide by mid-2017. The BHR® system celebrated its 20th birthday in July 2017. More than 1820 BHR® systems have been implanted at Klinikum Friedrichshafen/Germany since February 2005 (status November 2018). Based on recent scientific studies on BHR® in men under 50 years of age, the BHR® system has a much better durability / survival rate compared to stem-based hip endoprotheses in this age group (see page 2). This has been demonstrated in the past by many other scientific studies (see pages 5 and 6).

You have to know: There are the "good hip resurfacing endoprotheses" and "bad hip resurfacing endoprotheses".

"Apples are compared to pears."



In the past 2 decades, some of the co-suppliers have been developing and selling replicas of the BHR®. However, after just a few years, these showed significantly worse results: shorter durability, metal ion abrasion. Today it is known, that these "bad replicas" had worse design features and poorer quality of the surface structure of the metallic gliding pair, which was the cause of their early failure.

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These "bad replicas" have since been withdrawn from the market. It is certainly right to publicize bad implants. However, the poor results of the "bad" hip resurfacing prostheses were unjustifiably transferred to all hip resurfacing prostheses. This has also been fueled by some colleagues who are exclusively concerned with stem-based hip endoprosthesis and do not have their own extensive experience with the principle of the resurfacing of the hip.

Controversy is important to move forward in discussions for the benefit of the patient. However, solidified prejudices lead to the fact that, for example, a defined group of patients with decompensated high-grade hip arthritis is deprived of a hip prosthesis system, namely the resurfacing principle, with which significantly better long term results can be achieved.

On the safety of the metal-metal-gliding pair in hip resurfacing is discussed in more detail on page 6.

Prejudices against the resurfacing prostheses of the hip joint are, among others:

- 1: "There are no long-term results..."
2. "It comes to harmful metal abrasion..."
3. "The bone under the cap is broken (femoral head necrosis)..."
4. "More bone is consumed at the pelvic bone compared to stem-based hip endoprosthesis ..."

Each of these claims can be clearly refuted on the basis of current scientific data - if one uses a "good" resurfacing system by correct indication and correctly position of the endoprosthesis components. In the following I address these common prejudices:

Ad 1: "There are no long-term results..."

I refer to the above mentioned scientific data of the international working group (van der Straeten C et al.). Furthermore, there are the following reputable scientific publications concerning long-term results (10-20-year results) after implantation of a BHR®:

Author	survival rate = Service life of the prosthesis after 10 and more years
Treacy RB et al.: Birmingham hip resurfacing: a minimum follow-up of ten years. <i>J Bone Joint Surg (Br)</i> <b>2011</b> ; 93: 27-33	survival rate ♂: 98,0%
McMinn D et al: Indications and results of hip resurfacing. <i>Int. Orthop</i> <b>2011</b> ; 35(2):331-237	survival rate ♂ : 98,0 % nach 13 J.
Murray DW et al: The ten-year survival of the Birmingham Hip Resurfacing: an independent series. <i>Bone Joint Surg (Br)</i> <b>2012</b> ; 94-B: 1180-1186	survival rate ♀ 74,0% ♂: 95,0%
Coulter G et al: Birmingham Hip resurfacing at a mean of tenyears: results from an indepent centre. <i>J Bone Joint Surg (Br)</i> <b>2012</b> ; 94-B: 315-321	survival rate ♀ 89,1% ♂: 97,5%
Holland JP et al: Ten-year clinical, radiological and metal ion analysis of the Birmingham Hip resurfacing: from an single, non-designer surgeon. <i>J Bone Joint Surg (Br)</i> <b>2012</b> ; 94-B: 471-476	survival rate ♀ 84,6% ♂: 94,6%

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v. der Straeten C et al.: Metal ion levels from well functioning BHR's decline significantly at ten years. J Bone Joint Surg (Br) <b>2013</b> ; 95-B:1332-1338	survival rate ♀ und ♂ (10 Jahre) : 92,4%
Matharu GS et al: The outcome of the Birmingham Hip Resurfacing in patients aged < 50 years up to 14 years postoperatively Bone Joint J <b>2013</b> (Br);95-B:1172-1177	survival rate ♂ unter 50 J. (14 Jahre) : 100%
Daniel J et al: Results of Birmingham hip resurfacing at 12-15 years: a single-surgeon series. Bone Joint J <b>2014</b> ;96-B:1298-1306	survival rate (15 Jahre): 95,8%
Haddad FS et al: A prospective comparative study of cementless THA an hip resurfacing in patients under the age of 55 years. Bone Joint J <b>2015</b> ; 97-B: 617-622	survival rate ♂ unter 55 J. (12 Jahre) : 100%
Brooks PJ et al: Hip resurfacing. A large US single surgeon series. Bone Joint J <b>2016</b> ; 98-B (1Suppl A)10-13	survival rate ♂ unter 55 J. (6 Jahre) : 100%
The Australian Orthopaedic Association National Joint Replacement Registry. Annual report <b>2016</b>	BHR ist the only hip resurfacing system with 15 years follow up, demonstrating the superior clinical outcome of a cumulative percent revision of 9.91 for all patients tracked
ODEP (Orthopaedic Data Evaluation Panel) <b>2017</b> www.odep.org.uk/products.aspx	BHR: ODEP 10A* rating = revision rate 5% or less at 10 years (10A* = beste Rating-Note)
van der Straeten C et al: Hip Resurfacing Arthroplasty in patients under 50 years. International Hip Resurfacing Register – Report 2017 [Vortrag / ISTA September <b>2017</b> , Seoul / Co-Autor: E. Winter	International group of authors, long-term results of 11386 patients under 50 years with hip-resurfacing
Gaillard M, Gross T: Metal-on-Metal hip resurfacing in patients younger than 50 years: a retrospective analysis <b>2018</b>	1585 cases, 12-year survivorship, hip resurfacing exceeds the stricter 2014 NICE survivorship criteria independently in men an women when performed on patients under 50 years old

Ad 2: "It comes to harmful metal abrasion..."

The question of a potentially harmful metallic abrasion of the metal-metal gliding pairing of the resurfacing hip endoprostheses is of paramount importance. There are numerous scientific papers on this question. These prove that when using a "good resurfacing hip endoprosthesis" such as the BHR® and with the correct implantation technique and the use of implant components with a cap size of 48 mm or larger, there is no questionable release of metal ions. The following is a selection of these studies:

Autor	Titel	Wiss. Zeitschrift
Back DL et al.	How do serum cobalt and chromium levels change after MOM hip resurfacing?	CORR <b>2005</b> ; 438:177-81
Daniel J et al.	Blood and urine metal ion levels in young and active patients after BHR arthroplasty.	J Bone Joint Surg Br. <b>2007</b> ; 89(2): 169-73
Daniel J et al.	Six years results of a prospective study of metal ion levels in young patients with MOM hip resurfacings.	J Bone Surg Br. <b>2009</b> ; 91(2): 176-9
Witzleb WC et al.	Exposure of chromium, cobalt and molybdenum from MOM THR and hip resurfacing arthroplasty.	Acta Orthop <b>2006</b> ; 77(5): 697-703
Holland JP et al.	Ten-year clinical, radiological and metal ion analysis of the BHR.	J Bone Joint Surg Br. <b>2012</b> ;94:471-476
van der Straeten C et al.	Metal ion levels from well functioning BHR's decline significantly at ten years	J Bone Joint Surg Br. <b>2013</b> ; 95:1332-8
Winter et al.	Oberflächenersatz des Hüftgelenkes. Metallionenanalyse bei BHR®-Trägern.	Orthopädische Nachrichten Endopoth. Spec. Jan <b>2014</b>
Haddad et al.	A prospective comparative study of cementless THA and hip resurfacing in patients under the age of 55 years.	J Bone Joint Surg Br. <b>2015</b> ; 97: 617-622
Enslé R, Winter E	Korrelation der BHR-Implantat-Position mit Chrom- und Kobaltwerten im Blut.	Dissertation Eberhard-Karls-Universität Tübingen <b>2018</b>

Ad 3: "The bone under the cap is broken (femoral head necrosis)..."

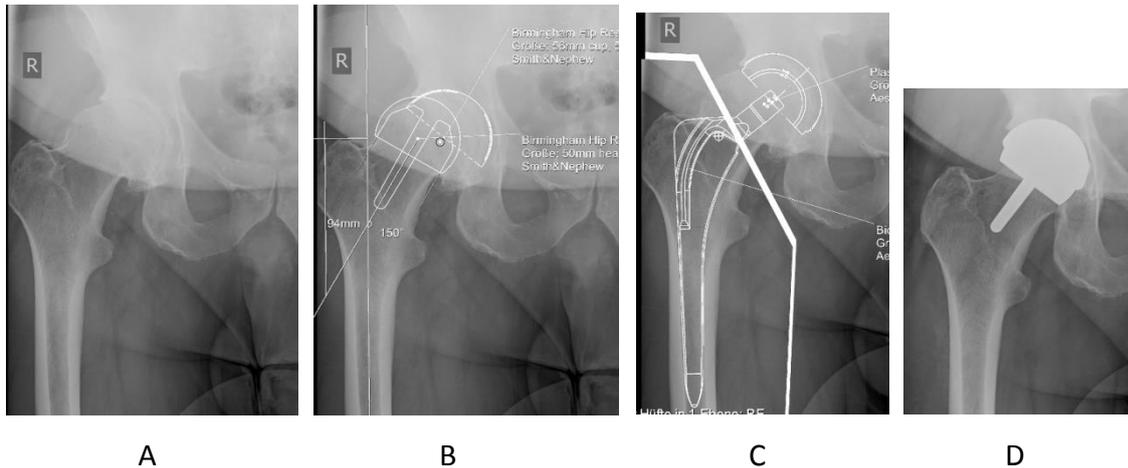
If that were so, the long-term results mentioned above would result in early failure of the prosthesis system in the appropriate indication group, but this is demonstrably not the case.

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Ad 4: "More bone is consumed at the pelvic bone compared to stem-based hip endoprostheses ..."

So far I've implanted well over 6000 stem-based hip endoprosthesis and performed over 1800 BHR® restorations. The average hip cap size in the BHR® system is in more than 90% a diameter of 50 mm and a cup diameter of 56 mm. From my experience I do not see any relevant difference compared to the size of the cup in stem based endoprostheses.

Example: Pat. A.A. born 1961



Patient example: A.A. born 1961: Decompensated 3rd - 4th degree and thus highest degree hip joint arthrosis on the right (A). Computer-aided planning resurfacing/ BHR® system (B). Computer-aided planning of a stem-based system (C). The prep. planning has resulted in a necessary cup size of 56 mm for both the resurfacing hip prosthesis and the stem-based hip endoprosthesis. The postoperative image (D) shows the implanted resurfacing prosthesis, cup diameter as planned 56 mm.

What if there is increased metal abrasion in the blood?

This can happen if "bad replicas" of the BHR® have been used or if the implant components of the BHR® have not been positioned correctly. For very small BHR® implant components, this may also occur with correct implantation technique / implant position: the smaller the components, the worse the "lubrication property" can be. This is currently in scientific clarification.

If there is increased metal abrasion, this can lead to tissue reactions: The abraded metal ions are recognized as foreign bodies, the body forms defense cells. This can lead to unpleasant tissue growths: Adverse reaction to metal debris (= ARMD). This tissue growth is also called "pseudo-tumor". Tumor means: tissue growth and does not immediately mean malignancy (cancer = malignant tumor). ARMD is a benign growth of tissue.

The limit from which such reactions can occur is determined internationally by scientific working groups: It amounts to 7.0 µg/l blood for each chromium and cobalt (Medical Device Alert issued 28 February 2012, MHRA (Medicines and Healthcare products Regulatory Agency), Department of Health, GB).

Very important for a reliable determination of the chromium and cobalt values are: special blood collection needle and special blood tube (metal trace), the correct determination method (ICP mass spectrometry) and the message

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to the laboratory that the patient is the wearer of an artificial hip joint. Unfortunately, the correct metal ion analysis for chromium and cobalt in laboratories in Germany is in high confusion regarding the correct analysis procedure and the correct interpretation of the values, which unfortunately causes the affected patients too much harm.

There are numerous scientific publications documenting the extremely low incidence of such tissue reactions in resurfacing endoprostheses. The Canadian Hip Resurfacing Study Group, for example, says in 2011 that almost 3,500 resurfacing endoprostheses of the hip joint were found to have a "pseudo-tumor" with a probability of 0.1%. (JBJS On 2011; 93 Suppl. 2: 118-121). In contrast, there are a few publications that report high pseudo-tumor rates of more than 5% (e.g. author group Bisschop, Groningen, Netherlands and author group Pandit, Oxford, GB). This leads understandably to an uncertainty of the affected patients. A closer look at the critical studies shows, however, that very low implantation numbers were described in some cases, that these procedures were performed by a large number of different surgeons in only a small number of cases, and that there were very high deviations from the optimal implantation technique, especially with regard to cup positioning.

After detailing the common prejudices against BHR®, I take the opportunity to discuss the benefits of the BHR® system:

- Many very good scientifically proven long-term results
- Scientifically proven clearly better long-term durability for persons under 50 years of age in the comparison with stem-based hip endoprostheses (see page 3)
- Bone preservation
- Preservation of normal biomechanics / force transmission in the proximal femur
- Preservation of the proprioceptors = depth sensors in the femoral head and femoral neck, there is still a normal joint feeling
- The femoral medullary space does not have to be opened, which means, among other things, less bleeding, less fat embolization risk
- No significant risk of femoral head necrosis
- No questionable metal abrasion with correct implantation technique
- Lower risk of leg length difference and dislocation (joint dislocation)
- With over 1,820 BHR® systems implanted in our clinic (as of Nov. 2018), we do not see any appreciably larger cup sizes compared to cup sizes for shaft-based hip endoprostheses

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Conclusion regarding BHR® / as of November 2018:

The BHR® system, which has been in use for 21 years, clearly shows scientifically proven better long-term results compared to shaft-based hip endoprostheses (see p. 3).

When using the BHR® system in sizes from 56 mm cup and 48 mm cap, no increased metal ion values for chromium and cobalt are to be expected with the correct implantation technique, which could lead to pathological effects on the organism (see p. 6).

The common prejudices against the BHR® system (see p. 5) are demonstrably untenable.

The BHR® system is a sophisticated surgical method that can and must be learned carefully.

At present, there are discussions as to whether the implantation of a resurfacing hip endoprosthesis can be carried out without hesitation an intensive consideration in women. The manufacturing company of the BHR® system excludes women from the indication group. According to the above-mentioned scientific study (van der Straeten C et al: Hip Resurfacing Arthroplasty in patients under 50 years. International Hip Resurfacing Register Report 2017 / Lecture / ISTA September 2017) women with the BHR® system showed 19-year long-term results of 86.8 %. Thus, the results with BHR® in women under 50 years of age are still significantly better compared to shaft-based hip endoprostheses (see page 2). However, it appears that the smaller the implant components of the BHR® system, the more likely it is that there will be increased metal abrasion. This is also shown by the results of a recent dissertation (Enslé R., Winter E., correlation of the BHR® implant position with chromium and cobalt values in the blood. Dissertation Eberhard-Karls-University Tübingen 2018)

The indication for the resurfacing hip endoprosthesis must always be set individually. There are clear contraindications for a resurfacing hip endoprosthesis: Excessive deformation of the femoral head, poor bone quality, cysts that are too large (bone dissolution) in the femoral head / acetabulum area, severe hip dysplasia (inadequate contact of the hip joint from birth), intolerance to the metal glide pair chromium, cobalt, nickel, molybdenum. If such a situation exists in younger patients, then a shaft-based hip endoprosthesis must be considered. If the patient concerned is careful with his shaft-based hip endoprosthesis, he can safely assume that his hip endoprosthesis will have a good service life.

If you have any questions, please do not hesitate to contact me: [e.winter@klinikum-fn.de](mailto:e.winter@klinikum-fn.de)

Yours sincerely, E. Winter