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Magazine for Arthroplasty · Issue: September 2013

»I would do it again!«

Interview with PD Dr. Alexandra Claus about the length of training, leadership and quotas for women.

The extra mile: Registry Winners | **Megaprostheses:** Bridge between traumatology and arthroplasty | **EPRD:** Prof. Joachim Hassenpflug on bureaucracy and benchmarks

Better interaction

Calcium phosphate (CaP) coatings promote bone ongrowth on the implant more effectively than other surfaces. The photograph shows a LINK coating technician preparing implants for the electrochemical coating process and placing them on a contact frame.

Dear Readers:

There is no doubt about it: arthroplasty is a male preserve with only a small number of female surgeons. But why? To find out, we talked to a female medical director, PD Dr. Alexandra Claus. This interview revealed a lot about the length of training, female leadership and quotas for women – and about what needs to be done to achieve a greater balance. As a Welsh proverb says: "Nothing is good if better is possible."

This could also be the motto for our product philosophy. We at LINK tirelessly pursue the objective of continuously improving our products, even if it is only tiny details. What this approach can achieve is described in a report on our "Registry Winners". In addition, you can read interviews with the "makers and shakers" at two of the most important registers: Prof. Göran Garellick from the Swedish Hip Arthroplasty Register and Prof. Joachim Hassenpflug from the German Arthroplasty Register (EPRD).

Enjoy this latest issue of direct**LINK**.

Regards.

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»I would **do it again!«**

Why are there so few female surgeons in the field of arthroplasty? Interview with PD Dr. Alexandra Claus about the length of training, leadership and quotas for women.

When we put together a list of female medical directors for this interview, we found very few names. Why is arthroplasty an almost entirely male specialty?
Tradition is certainly a factor, but also the time it takes to achieve your first managerial post. It's a very long process: university and specialist training, then a period as a senior surgeon. So it is inevitable that there are few women who make it to the final rungs on the career ladder.

How many female surgeons work in arthroplasty today – and will choose to stick with it?
At our hospital, women make up 33 percent, including myself. Apart from me, there is one other female colleague who is interested in training for arthroplasty. The classic specialties for women in orthopedics and traumatology are, as is well-known, hand and foot surgery and pediatric orthopedics.

Why did you choose arthroplasty?
I did my doctorate in orthopedics, on the subject of acetabular cups, so I definitely wanted to go into surgery. In my specialist training, general and visceral surgery did not appeal to me particularly. Because of my pragmatic mindset, I found an objective radiograph a lot more helpful in diagnosing a patient correctly and proposing the appropriate treatment than the clinical or sonographic examination findings in visceral surgery, which I found more difficult to interpret due to a lack of experience. During my specialist training in orthopedics, I went to the USA for two years as a research assistant, and my work there focused principally on hip prostheses. When I returned, I was very keen to perform arthroplasties as much as possible. And as it turned out, I stayed in arthroplasty.

»In a sense, my leadership style is different to my male colleagues.«

Did you emulate any of your male superiors?
I learned a great deal medically from my superiors, in terms of dealing with both patients and colleagues. For example, I learned that certain situations may demand a directive style of leadership. In the past, I was critical of my superiors when they suddenly became very directive in a particular matter. Today I understand much better why they did that.

As a medical director, do you nevertheless have a female leadership style?
In a sense, my leadership style is different to my male colleagues. You could certainly say that I adopt a more collective approach. It's no secret that women are more team-oriented than men. I always try to integrate my team in medical decisions. But, at the end of the day, I carry the responsibility for all the decisions at our hospital.

»You're the boss, and you're the person I want to talk to!«

What do you do differently from your male colleagues?
I try to avoid the classic authoritarian and hierarchical style of leadership. My aim is to ensure that all my staff have the same information at their disposal, by holding twice daily discussions of X-rays, for example. I also make sure that the reasoning behind the decisions I take is clear, transparent and logical for everyone. For me it is important that each member of my staff understands why, when and how I am making a particular decision.

Did your patients ever doubt that you were qualified to be a medical director?
Patients generally picture the medical director as being a male orthopedic surgeon. When I began as medical director, many probably thought: Is this little lady really cut out for the job? But if you do your job confidently and to a high standard, sooner or later patients will come to you and say: "You're the boss, and you're the person I want to talk to!"

And what about your male colleagues?
With male colleagues you always have to demonstrate your medical expertise – in what you say and, of course, at the operating table. At the same time, being in the position of the superior makes it important to be able to say: My senior surgeon can actually do this or that better than me.

Did the management at your hospital have any reservations about your appointment?
No, they chose me, after all. But at the preliminary interviews, at the recruitment agency appointed to recruit candidates for the post of medical director, I was asked what could count against me as a person for this post. My reply was that there were two things: my age – I was 39 at the time – and my gender. I can't change either of them, and either people accept me as I am, or they don't.

How did the referring physicians react?
In an exposed rural location like this, the physicians tended to observe me at the beginning. They would send me especially difficult cases to see how I handled them. But it would be no different for a man in my position. It's just that it is unusual to see a female medical director in this field of medicine.

Have you ever been given preferential treatment in your working career because you are a woman?
No, in my career, I have taken on the same tasks as my male colleagues in the same position. If there was a particularly tall or heavy patient undergoing surgery, nobody said: You're too small, you mustn't do it. Instead, they would say: Tell us if you need a hand. If you are good at your job, nobody worries about whether you're a man or a woman. So I never felt uneasy with my colleagues during my specialist training.

What is your view on the discussion about quotas for women?
In our specialty, we have so few women who aspire to senior positions, we do not need quotas. In any case, quotas do not solve the problem of

"I tell my staff not to do anything medically ill-judged!" – **PD Dr. Alexandra Claus,** Medical Director at the Department of Orthopedics and Orthopedic Surgery, Obermain District Clinical Center, Kutzenberg, Ebensfeld

balancing family and profession. Who is going to take a colleague seriously if they know that she is a quota woman and not a merit woman?

Do physical demands play a part for women in arthroplasty?
Not nowadays. We have enough technical aids, surgical techniques and tricks to enable us to do our job without enormous physical strength. What the surgeon needs, whether man or woman, is

»They would send me especially difficult cases to see how I would handle them.«

endurance. You have to be able to stand at the operating table for long periods of time.

Is it easy to plan your working time when you have family and children?
During my specialist training, it was virtually impossible to plan my working time. At least, I couldn't have imagined having a family with children at the same time as my work and doing justice to both. Today the situation is different because the staff have different expectations. I think that is the right approach. I make sure that my staff have enough time to devote to their families.

Do you perceive a trend towards more women in arthroplasty?
Yes, there is a slight increase. At our hospital, we have a relatively large number of female applicants in specialist training because there are more female medical students. Of course, there's no way of knowing whether they will all become arthroplasty surgeons.

Do you advise your young colleagues to choose a surgical specialty?
Yes definitely, elective arthroplasty is a dream job! The patient has joint pain, you analyze the problem, make your diagnosis, advise the patient and implant a prosthetic joint. Then, if your diagnosis and patient selection were correct, the patient is free of pain and returns to his or her normal life. We are privileged in this branch of surgery because we do something with our hands for which people are very grateful. This positive feedback from the patient gives you a great sense of satisfaction with a job well done. Many colleagues in other fields of surgery are not so lucky. I try to motivate my female colleagues to choose a surgical specialty, but I also tell them what to expect.

What advice do you give a member of staff who leaves your hospital?
Not to do anything medically ill-judged! Seriously, I tell them to always be true to their quality standards, listen to the patient, be prepared for all surgical situations, and always have a plan B. And they need to display strong nerves and humility.

Would you choose the same career again, and still opt for arthroplasty?
I would do it again. No question.

Dr. Claus, many thanks for giving us this interview.

The **Registry Winners**

If there was such a thing as an Oscar in the category of joint survival rates, it would have been awarded to a LINK product several times already. We present three of the possible winners.

Lubinus® SP II® Hip Prosthesis, LINK® Unicondylar Sled Prosthesis, and C.F.P.® Hip Prosthesis top the rankings in the Swedish Arthroplasty Registers[1] and the Italian R.I.P.O.[2] due to their outstanding results for the survival rate.

How do you become a registry winner?

There is no set formula for becoming a registry winner – otherwise everyone would come out on top. There are, however, some fundamental rules for achieving success in the rankings: "When we develop a prosthetic joint, we start from tried and tested design principles", says company proprietor Helmut D. Link. "With our current registry winners, we shall once again learn something, which will be incorporated into forthcoming product developments at LINK."

The extra mile

In the development of joint implants, we constantly see what advantages 50 years of experience can offer. The fact that LINK manufactures these implants entirely itself in Germany is another important factor. "LINK is, as it were, the 'anatomy company' amongst the implant makers because it is not only from our registry winners that we have learned how important it is to precisely incorporate biomechanics into implant design", explains Helmut D. Link. "Ultimately, it always comes down to the question of whether or not you go the extra mile in the development process."

You can also read the interviews with

- Prof. Dr. Göran Garellick, Director of the "Swedish Hip Arthroplasty Register", on page 10
- Prof. Dr. Joachim Hassenpflug, Managing Director of the German Arthroplasty Register (EPRD) GmbH, on pages 8–9

[1] The Swedish Hip Arthroplasty Register, www.shpr.se; The Swedish Knee Arthroplasty Register, www.knee.nko.se.

[2] Regional Register of Orthopedic Prosthetic Implantology (R.I.P.O. 2011), https://ripo.cineca.it.

Lubinus SP II®
Hip Prosthesis

Place: 1st place, with a survival rate of 95.9 percent
Register: The Swedish Hip Arthroplasty Register, 2011*

Reasons: The Lubinus SP II® Hip Prosthesis Stem and the Lubinus Acetabular Cup or IP Acetabular Cup together form an anatomical hip prosthesis for cemented implantation.

Anatomically shaped SP II® Hip Prosthesis Stem with Lubinus Acetabular Cup

In Sweden, the Lubinus SP II® Hip Prosthesis is the most frequently used cemented implant, as is confirmed by the Swedish Annual Hip Report 2011*. This indicates that it is also the safest implant: for the LINK hip prosthesis system, the Register shows that, based on 50,588 implants placed at a large number of centers during the period under report, the survival rate was 95.9 percent after ten years (2002–2011).

Facts

- Anatomical stem shape ensures centered seating in the femoral canal
- Uniform cement coating in the entire stem area
- S-shape of the stem counteracts rotational forces
- Large collar transfers physiologic forces back into the femur
- Physiologic anteversion in the prosthesis stem
- Safe implantation technique
- Numerous versions permit adaptation to anatomical conditions
- 3 standard stem lengths, 4 additional lengths of 200 mm to 350 mm for revisions
- 3 CCD angles, an extra-long prosthesis neck, and up to 4 head-neck lengths for an anatomically correct hip reconstruction
- New, harmoniously coordinated instrument set

* Annual Report 2011, The Swedish Hip Arthroplasty Register, page 74, www.shpr.se.

LINK®
Unicondylar Sled Prosthesis

Place: 1st place, benchmark for low revision risk
Register: The Swedish Knee Arthroplasty Register, 2012**

Reasons: Continuously enhanced, the LINK® Unicondylar Sled Prosthesis has delivered outstanding results in everyday clinical use for years now. In combination with the minimally invasive surgical technique MITUS®, this knee replacement minimizes bone removal and preserves soft tissue.
In the Annual Report 2012** of the Swedish Knee Arthroplasty Register, the Sled Prosthesis is a benchmark for low revision risk.

** Annual Report 2012, The Swedish Knee Arthroplasty Register, page 35, www.knee.nko.se.

Sled prosthesis with tibial plateau – with metal base

Facts

- Bone-conserving design
- Full range of movement
- Short rehabilitation time
- Optimal implant-cement bond due to globular macrostructure on the inner surfaces of the prosthesis
- UHMWPE tibial plateaus with and without metal base
- Minimally invasive and conventional implantation techniques are possible
- Patella-friendly due to thin construction

LINK® C.F.P.®
Hip Prosthesis

Place: 1st place, with a survival rate of 99.3 percent
Register: R.I.P.O. 2011 (Regional Register of Orthopedic Prosthetic Implantology)*

Reasons: The C.F.P.® Hip Prosthesis Stem* and the T.O.P.® Acetabular Cup form a bioharmonious hip system for cementless implantation, which conserves the femoral neck. It was developed specifically for young, active patients, whose long life expectancy means that they must expect an above average rate of aseptic loosening with a conventional hip prosthesis.
The design of the C.F.P.® Hip Prosthesis Stem incorporates biomechanical loading and anchoring principles, conforming to the hip anatomy and physiology. This ensures stable, stress-resistant anchoring of the prosthesis, which in turn creates optimal conditions for later interventions.

Facts

- Minimal bone resection by preserving the femoral neck and compressing the cancellous bone without removing bone in the proximal femur
- Cementless implantation with up to 87 percent prosthesis bone contact
- Anatomical stem shape (allowing for physiologic anteversion in the prosthesis stem)
- Various stem curvatures in the frontal plane to support the prosthesis over a wide area at the Shenton's line
- Collar for transmitting physiologic compressive forces back into the femur
- Maintenance of blood supply to the femoral neck by protecting the ramification of the circumflex femoral artery by high resection

* Annual Report of R.I.P.O. 2011 (Regional Register of Orthopedic Prosthetic Implantology), page 73, https://ripo.cineca.it.

C.F.P.® Hip Prosthesis Stem with cementless Acetabular Cup

»Our **product database** is unique in the world!«

Since October 2012, the German Arthroplasty Register (EPRD) has been in trial operation. Interview with Managing Director Prof. Dr. Joachim Hassenpflug on matters of data validity, minimizing bureaucracy, and the opportunity to set a benchmark with the EPRD.

Prof. Hassenpflug, how is the trial going?
Very well! We are principally testing the pooling of data from various sources. We approached 40 hospitals about participating in the trial, and 32 of them are currently involved. From this pool, we collected data on the implant, the surgical procedure, and any comorbidities in 4,000 patients. Another 300 hospitals have expressed interest in participating in the register, even though it's not really up and running yet.

How many manufacturers and health insurers are on board?
At present, we cover 95 percent of the implants used in Germany, and other manufacturers are being added, too. The Federal Association of the AOK and the Verband der Ersatzkassen e.V. (both representing major German statutory health insurers) are involved on behalf of their members. Our next step is to talk to the private health insurers, who have also expressed great interest in the arthroplasty register.

»The system would not work without the technical expertise of our partners.«

What is the incentive for these different bodies to participate in the arthroplasty register?
They all share the same objective: to acquire reliable information about the quality of prosthetic joints implanted in Germany. Each partner in the arthroplasty register can contribute their own particular skill set: the manufacturers are providing product databases, the health insurers give information on invoicing, the surgeons at the hospitals input the data, the BQS Institute for Quality & Patient Safety ties the data together and evaluates it, and the DGOOC (German Society of Orthopedics and Orthopedic Surgery) is responsible for the scientific side. I find it fascinating that we are working together to create such a high-quality product. But the system would not work without the technical expertise of our partners.

How is the collected data validated?
The data is very reliable because, in addition to scanning the bar codes on the prostheses themselves, the routine invoicing data is also included. Of course, there is no hospital that does not invoice an implanted prosthesis. We are talking about hard facts here. Nobody is going to document a replacement as a primary implantation because the reimbursement from the health insurers is different.

And what about data protection?
We are dealing with personal data, so we encrypt and pseudonymize it in such a way that the person from whom the data stems cannot be identified at any point in the system. If the results reveal something that requires action to be taken, this data can be reverse extrapolated with the patient's permission, to identify which patient has an implant that is a cause for concern. This feedback system is one of the more important tasks of the register.

Given that 400,000 arthroplasties are performed each year, won't we end up with a bureaucratic nightmare?
Of course, data validity and data volume are key to the quality of a register. Data on the products and comorbidities have already been gathered. In the longer term, it is conceivable that the results of patient surveys could be included – admittedly, with 400,000 a year, that is a considerable quantity of data. But we have designed the process for reporting to the EPRD so as to minimize bureaucracy and make it easy for surgeons to integrate reporting into their work routine. And the data is not entered manually, but read in digitally from bar codes on the implants. The system is intentionally paperless. The various data sources are combined then.

When will the register start to provide useful information?
I am working on the basis of a minimum observation period of two years. By then our data should have stabilized, and a reliable database should enable the first tangible conclusions to be drawn.

»The reliability of data generation via a paperless system is state of the art.«

What role will the German Arthroplasty Register play internationally?
No other country in Europe implants as many prosthetic joints as Germany. Even in the USA it will be organizationally difficult to aggregate data across state lines. In view of this, our register will become more important in the future, particularly because of the product database, which is unique in the world, containing, as it does, some 30,000 product details. You have to remember that the database is not just a collection of numbers, but is specifically categorized: polyethylene, highly crosslinked polyethylene, rough surface, smooth surface, etc. Apart from which, the reliability of data generation via a paperless system is state of the art.

Could the EPRD become the benchmark for registers?
Possibly in the long term. Our concept of gathering and evaluating validated data in an uncomplicated fashion and with powerful data protection has already attracted attention in political circles. The German Arthroplasty Register could also be a model for other fields in which implants are used. But right now we are very busy with development work, because we want to establish a wide basis for the register in hospitals and with the health insurance providers. 70 percent of insured persons are already involved via the two main associations of health insurers – but, of course, we want the other 30 percent, too.

Prof. Hassenpflug, thank you for this interview.

"We already cover 95 percent of the implants used in Germany" – **Prof. Dr. Joachim Hassenpflug** is managing director of the German Arthroplasty Register

"We interpret the results of our work on a purely scientific basis" – **Prof. Dr. Göran Garellick,** Director of the "Swedish Hip Arthroplasty Register" and President of the "International Society of Arthroplasty Registers"

»We can't afford not to have a **register!**«

The "Swedish Hip Arthroplasty Register" is regarded as a model for defining the long-term quality of hip prostheses. We put five questions to the director of the Register, Prof. Dr. Göran Garellick.

Prof. Garellick, how do you explain the high international regard in which the "Swedish Hip Arthroplasty Register" is held?
Since 1979 we have recorded data on all primary total hip arthroplasties and revisions in Sweden, and we carry out a detailed analysis of any problems that occur. Our feedback to the hospitals has led to dramatic improvements in the long-term outcomes of hip arthroplasties, and Sweden has the lowest revision rate in the world.

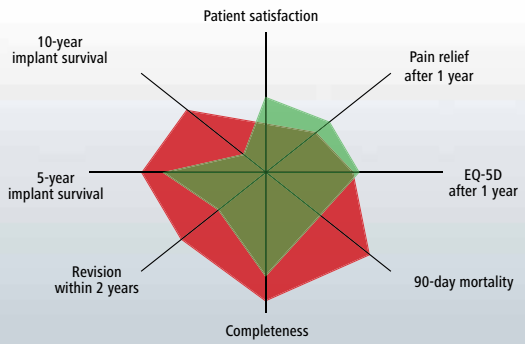
Does the work done by the Register help to reduce costs?
Yes, in the last ten years alone, the Swedish health system has been able to save over € 175 million in direct medical costs. As for indirect costs, which result from incapacity for work and early retirement, they are very difficult to measure, but the savings are many times greater. We cannot afford not to have a register.

Only six types of implant are used for hip replacements in Swedish hospitals. Is the feedback from the Register the reason for this?
Compared to the 200 or more implant types used by arthroplasty surgeons in Germany, it is, of course, an extremely small number. But we interpret the results of our work on a purely scientific basis, and do not make any recommendations concerning the choice of implants. Swedish surgeons take their own independent decision as to which implants to use for hip arthroplasties.

What variables does the Register publish?
The work of the Register provides hospitals in Sweden with information which helps arthroplasty surgeons tackle the causes of problems in a targeted manner, including statistically unusual and serious complications. In order to visualize this information, we prepare a "value compass", comprising eight parameters, for each hospital. This means that the hospital can instantly recognize the parameters in which they are better or worse than the national average.

Can the data from the Register be a substitute for clinical trials?
We carry out a lot of clinical research, and this year alone we will publish around 20 studies. So the data in the register contains very meaningful medical research findings. Nevertheless, our data is not intended as a substitute for clinical studies. A great strength of the Register is its generalizability – because it looks at the entire country and not just individual surgical departments.

Prof. Garellick, thank you for this interview.



Value compass for hospitals (example).
Red: national averages; green: hospital values

Megaprostheses: a bridge between **traumatology** and arthroplasty

A case report by Prof. Giorgio Maria Calori, head of the "Orthopedic Reparative Surgery Department" of the Gaetano Pini Institute at the University of Milan, and president of several orthopedics and traumatology societies, including the "European Society of Tissue Regeneration in Orthopedics and Trauma ESTROT", which he founded. He specializes in the treatment of extensive post-traumatic and post-infection bone substance defects

When critical bone defects resulting from trauma cannot be restored by conventional methods, the use of megaprostheses is an option. It offers the possibility of surgical treatment with reduced healing time and a better healing rate instead of further operations and lengthy rehabilitation with an uncertain outcome.

Pseudarthroses, which can occur following trauma with critical bone defects or bone necrosis, present major surgical challenges – comparable to the extensive bone resections performed in the case of tumors or infections.

Risk factors for the process of bone healing, which may be delayed greatly, include age, sex, medication and the patient's physical state – particularly diabetes mellitus, osteoporosis, muscle mass, lifestyle, diet, smoking and alcohol. In addition, there are local risk factors, which may result from, for example, the soft tissue state, neurovascular injuries, inadequate blood supply and infections. The following are regarded as the limits as from which bone defects are quantified as critical: 3 cm for the lower arm, 5 cm for the femur and tibia, and 6 cm for the humerus.

NUSS classification facilitates the choice of treatment

In 2008, we developed a classification system which enables the relevant risk factors affecting the patient, bone and soft tissues to be recorded and assessed, and which can be used to derive prognoses for treatment indications. This system is called the Non Union Severity Score (NUSS). The NUSS employs a score between 0 and 100 to enable surgeons to identify four groups of pseudarthroses and, in cases of critical bone defects, to weigh up the treatment options of bone preservation and restoration of biomechanical function:

- **Group 1** (score < 25): shockwave therapy, optimization of osteosynthesis etc.
- **Group 2** (score 26–50): external fixator, re-osteosynthesis etc.
- **Group 3** (score 51-75): microvascular grafting, growth factors, osteogenic cells, "biological chamber" etc.
- **Group 4** (score 76-100): arthrodesis, amputation, megaprosthesis

In the case of pseudarthroses with a NUSS score of 76 to 100, the severity of the injury and the clinical conditions are so serious that, usually, the surgical options of arthrodesis and amputation are implemented. But pseudarthroses in this group not only present a major challenge for the surgeon. The patient's quality of life is severely restricted: often the patient can no longer work as before, may have psychological and social problems, and has hardly any mobility. Furthermore, the health system has to provide considerable resources, including medical and nursing staff, rehabilitation time, and lengthy hospitalization, since numerous follow-up operations are often necessary. What's more, many of these patients are relatively young and therefore have high expectations, not only in terms of their current medical and surgical care. The direct and indirect costs for them and for society are particularly high in this patient group

– particularly in view of the demanding revision arthroplasty for the subsequent decades.

Megaprosthesis: alternative to the "gold standard"

Up to now, pseudarthroses with a NUSS score of 51 or higher have usually been treated with autologous materials for bone regeneration. But in such cases, the patient often suffers complications such as pain and sepsis at the harvest site. The use of an external fixator is effective for severe lesions, but patient acceptance is low. Techniques of tissue regeneration with bone growth factors, multipotent mesenchymal cells and scaffolds of chemical and physical compositions are further options. Megaprostheses such as the LINK® Megasystem-C® provide an alternative. The advantages are not only improved patient compliance and lower cost of surgery, but also the reduced healing time and improved healing rate which may be expected. Three case studies of pseudarthroses with multiple treatment failure demonstrate the value of the megaprosthesis concept. In all three cases, our decision to implant a megaprosthesis was based on the intention of restoring the biomechanical functions of the extremities as quickly as possible, and thus realizing the advantages mentioned above. The principle of maximum bone preservation was deliberately given a lower priority in view of the expected gain in quality of life for the patient.

Conclusion

In cases of critical bone defects, the patient's life situation and his/her level of compliance must be taken into account. The NUSS score is suitable for critically assessing whether bone preservation or rapid restoration of biomechanical function is the appropriate treatment strategy. The traditional techniques of stabilization have their place here. Biotechnological methods and/or megaprostheses are an option for more complex cases because they reduce the healing time and improve the healing rate. As a reliable, "permanent" surgical treatment, they reduce long-term costs. These patients should be treated in specialist centers, where all the technologies have been tested and undergo continuous improvement.

Possible indications for megaprostheses

- Aseptic loosening of the prosthesis components due to mechanical implant failure. In most cases, the components are badly worn, and severe periprosthetic osteolysis is evident. If the bone defect is so serious that a normal revision prosthesis is contraindicated, implantation of a megaprosthesis may offer a solution.

- Septic complication after arthroplasty with critical bone loss, usually combined with a severe local inflammatory reaction and necrosis of osseous tissue. The two-step procedure (1.: resection, wound toilet, and spacer implantation with antibiotics, 2.: Removal of the spacer and implantation of LINK® Megasystem-C®) appears to be the best choice in terms of preserving function, improving quality of life and preventing systemic sepsis.

- Periprosthetic fracture or pseudarthrosis. Most patients present with poor bone quality and/or severe periprosthetic bone loss with loosening of stem and acetabulum components. If osteosynthesis is not assured, implantation of a megaprosthesis may be advisable.

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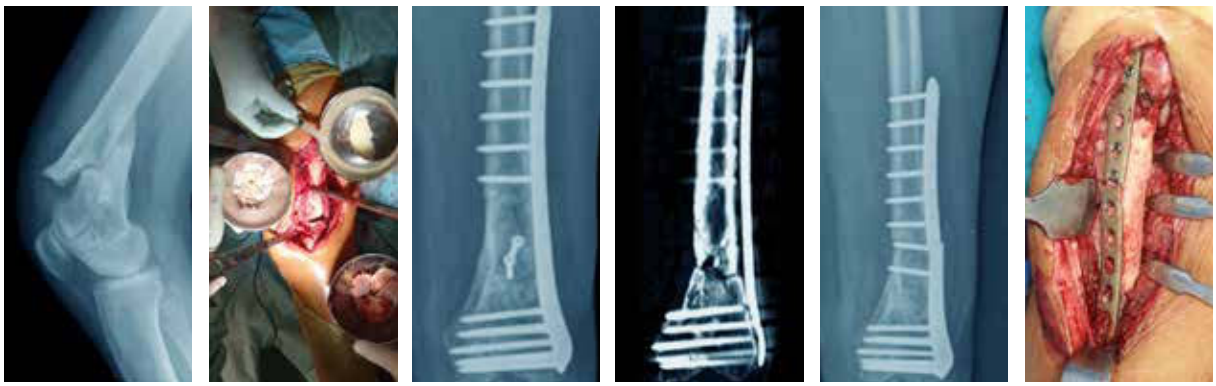
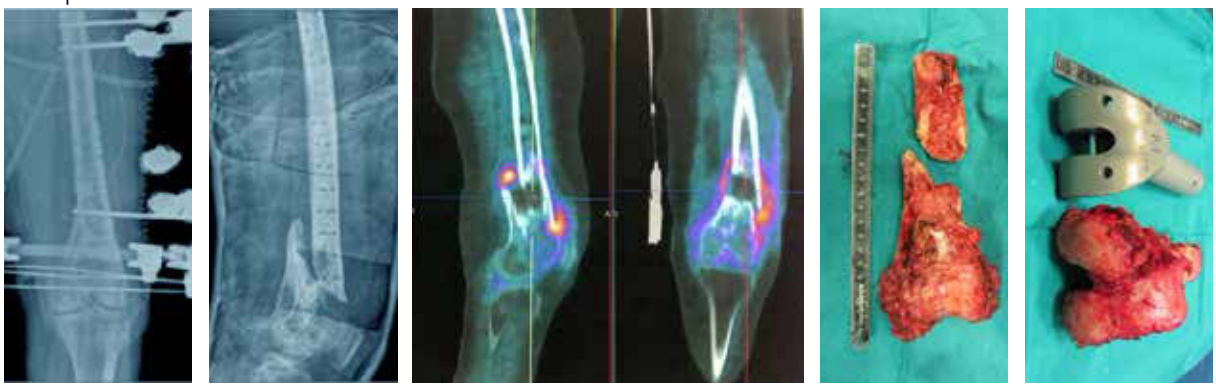
Case study I

45-year old patient

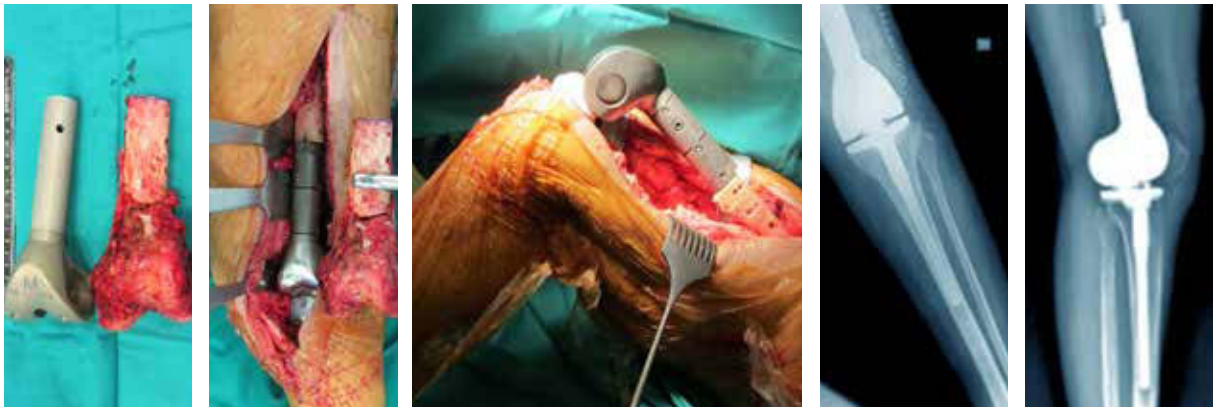
Critical meta-epiphyseal fracture (NUSS score 70) of the left femur, multiple treatment failure, single-stage surgical procedure



Images l. to r.: Preoperative radiograph / Treatment of the fracture with autologous materials and osteosynthesis plate / 3 months post-op / MRI scan 9 months post-op / Failure of the osteosynthesis plate 4 months later / Removal of the osteosynthesis plate



Images l. to r.: Use of external fixator / Removal of external fixator and treatment with a cast, NUSS score now 78 / PET scan to assess bone vitality: Decision to restore biomechanical function as quickly as possible with a megaprosthesis / Implantation of megaprosthesis LINK® Megasystem-C®

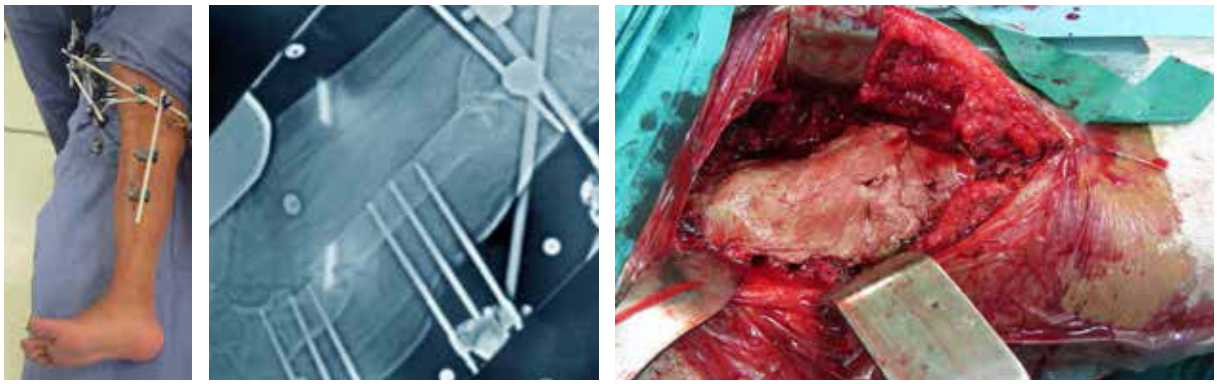


Images l. to r.: Implantation of megaprosthesis LINK® Megasystem-C®/Post-op radiograph / 3 months post-op

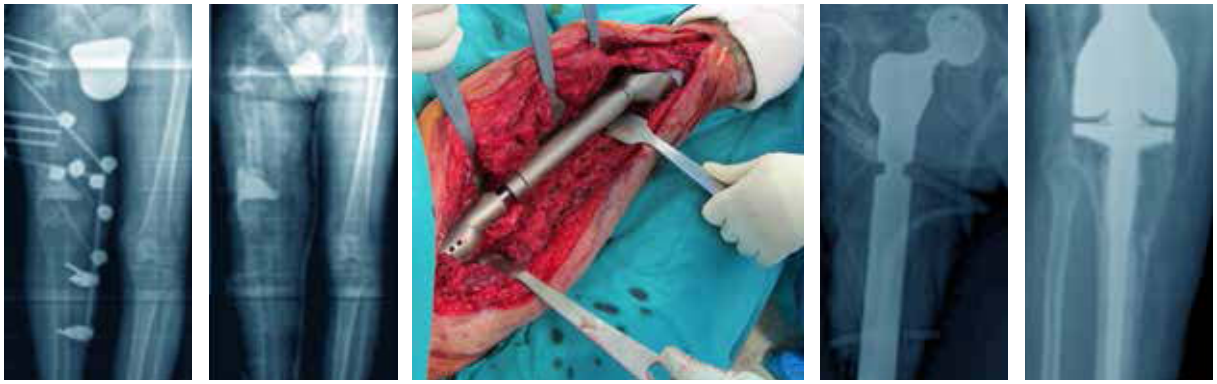
Case study II

43-year-old patient

Subtrochanteric and epiphyseal infected fracture (NUSS score 88) of the right femur, two-stage procedure due to septic conditions



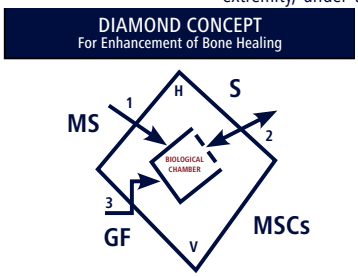
Images l. to r.: External fixator in situ / Treatment of the epiphyseal femur fracture with use of the "biological chamber" (diamond concept, see below)



Images l. to r.: Post-op radiograph, "biological chamber" in situ / Treatment of hip and knee joints with megaprosthesis LINK® Megasystem-C® (with LINK® PorAg® antimicrobial surface modification) / Post-op radiograph / LINK® Megasystem-C® in situ

Diamond concept and "biological chamber"

Bone regeneration in patients with bone defects and pseudarthroses presents a challenge for surgeons. But it also represents a therapeutic opportunity in the light of current knowledge about molecular mediators, cell populations and the cascade of events involved in osteogenic repair processes. The traumatologic concept of fracture healing at the molecular level, extended to include the factor of "mechanical stability" (see the Diamond Concept diagram) essentially supports the implantation of mesenchymal stem cells, a scaffold and a growth factor with the aim of bone regeneration. However, before these materials are implanted, it should be ensured that the molecular and physiologic processes can evolve in an ideal biological environment.



Diamond concept and the biological chamber, V = vascularity, H = host, MS = mechanical stability MSC = osteoprogenitor cells, S = scaffold, GF = growth factor, 1.Closed chamber; 2. Open chamber; 3. Partially closed chamber.

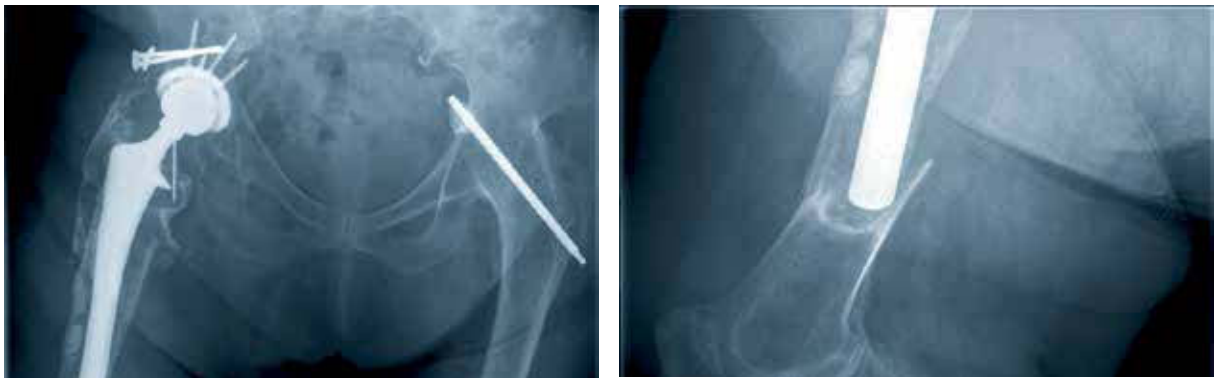
This environment, which we call the "non-union bed" is essential in order to generate undisturbed, successful osteogenesis,thus ensuring bone continuity, and therefore restoration of the biomechanical function of the extremity, under the conditions of serious bone defects. The "non-union bed", or the region of the bone defect, thus represents the location of highest biological activity, and therefore the "center"of the diamond concept. For this reason, we refer to it as the "biological chamber".

From a practical perspective, it has proven advantageous to employ a membrane in order to transform the "biological chamber" into a closed compartment, also in the literal sense, a "bioreactor", which can be removed in a second operation. In this way, contact with the prosthesis material is prevented, which additionally supports the described concept of an optimal biological environment.

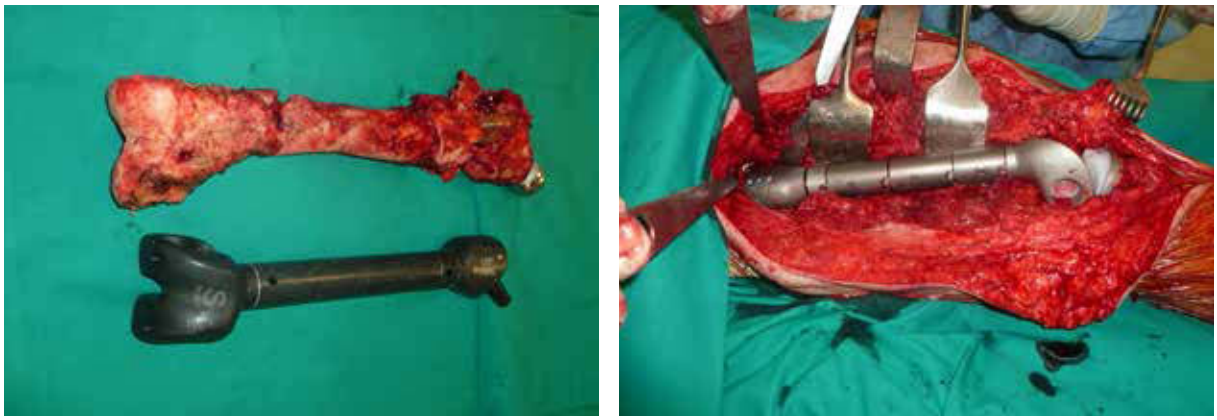
Case study III

89-year-old patient

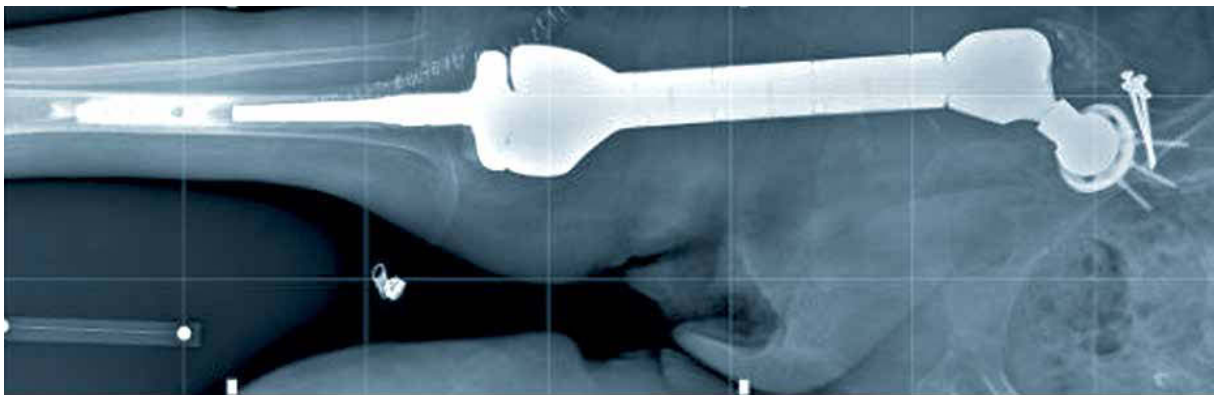
Periprosthetic fracture and severe bone loss on the right hip (NUSS score 90), single-stage surgical procedure



Preoperative radiographs show the periprosthetic fracture and severe bone loss on the right hip



Images l. to r.: Complete resection of the proximal femur segment, including stem components; the acetabulum component and the insert are in good condition, and were not explanted in order to avoid vascular problems (an acetabulum screw is located in the interior of the pelvis, see top radiograph) / Implantation of LINK® Megasystem-C® Total Femur



Post-op radiograph, LINK® Megasystem-C® Total Femur in situ

"We must be more acutely aware of seriously ill patients" – **Prof. Dr. Rudolf Ascherl,** Medical Director of the Department of Arthroplasty, Special Orthopedic Surgery and Spinal Surgery at the Zeisigwaldkliniken Bethanien Chemnitz Hospital

»We shouldn't always play the **blame game!**«

Is arthroplasty well equipped for the rapid increase in complex revisions? An interview with Prof. Dr. Rudolf Ascherl about microorganisms, skin screening and the significance of megaprostheses.

Prof. Ascherl, you are in charge of a center for special and revision arthroplasty and surgical infectiology. What new findings about complex revisions have there been in recent years?
The number of cases is rising. At the present time, we are doing more than 220,000 primary hip replacements and 180,000 knee replacements a year in Germany. Each year, at least 10 percent of patients come for a revision. Of the 40,000 revision arthroplasties, half were complex reconstructions involving large bone defects. Around 9,000 of them are infected, a third of them with organisms that are very difficult to combat.

Which organisms cause the greatest problems?
Apart from MRSA, we are seeing a continuing increase in MRSE, which is much more difficult to treat. Then there are Klebsiella, Proteus, Acinetobacter and Propioni. The latter causes acne, and is therefore a skin bacterium, and is classified as a "low-grade infection". However, the risk of recurrence is extremely high because the bacterium seems to have mutated.

What is the reason for the high infection rate with problem organisms?
It is not always about nosocomial organisms. The hygiene standards in German hospitals are not as poor as is sometimes suggested in the local media, you know. The problem is rather that patients often bring organisms with them when they are admitted. Patients' age is increasing and, due to their illness, personal hygiene may not always be optimal in all areas.

»We must screen all patients, and not just for MRSA.«

Could the problem be solved by skin screening before admission?
Yes, we must screen all patients, and not only for MRSA. Furthermore, we should examine patients' skin and nail care, and also check areas such as the groin, under the breasts, armpits, roots of the hair, in the mouth and paranasal sinuses for foci of infection that require attention.

To what extent is this already done?
We are already giving it a great deal of attention, but we need to improve – even if it is extremely expensive. Skin screening is only one aspect. In the field of arthroplasty we are too accustomed to short, easily managed interventions that are calculable - also with the regard to the financial benefit. Yet we physicians have a responsibility for the health of our patients. Above all, we must devote more attention than in the past to those patients who require complex interventions. The hospitals have their management teams to look after the other side of things.

Is there a general need to handle the complex cases differently?
Principally with regard to infections, we would say the hospital, the team, and the surgeon are responsible. But we mustn't always play the blame game. Loosening of an implant, periprosthetic fractures and infections are quite simply new disorders that require treatment.

Are arthroplasty departments ready for the increase in complex revisions?
In terms of surgical facilities and implant materials, certainly. But, partly for financial reasons, we do not have enough surgeons. It is important to understand that if we had a better training system, this would help to reduce costs because surgery would then be performed better, faster and more systematically.

What strategy might ensure that we have more well trained surgeons in the future?
The best incentive for young colleagues is a workplace in which medicine and people are the focus, not computers and documentation. In addition, surgeons should operate as much as possible so that they improve their surgical skills to the maximum, and also maintain that level.

»We are entering a phase in which megaprostheses are becoming increasingly important.«

Let us return to the practical aspect. Which classification systems for large bone defects and infections do you prefer?
We use the familiar classifications of Paprosky, Katthagen, AAOS, Endoklinik and Tsukayama. The underlying algorithms are, however, under discussion because important infection-related questions need to be answered more exactly: What is the best method of sealing the bone defects? With bone material, ready-made implants, or a combination of both? Or is it better to use custom implants like the megaprostheses?

Is there a paradigm shift on the horizon?
A good surgeon first reconstructs biologically. Only if that is not possible, does he resort to the megaprosthesis. We are entering a phase in which megaprostheses are becoming increasingly important because previous operations – the majority of our patients have already undergone surgery at least five times – have given rise to defects which require simple, quick, stable and aseptic repair. I believe that, in the future, custom prostheses will play an important role in the treatment of defects so that the implant can be kept as small as possible. Cost should be a secondary consideration. Our health insurers are increasingly willing to accept cost-intensive interventions for this type of patient.

What courses on revision surgery and opportunities to observe surgical procedures do you offer at your hospital?
We offer a course on revision surgery every two months, for which I and two or three colleagues perform live surgeries. I place great importance on authenticity, for example to show that even experienced surgeons are sometimes faced with difficult, but resolvable, situations. Observers are always welcome at our hospital. We are always pleased to receive visitors!

Prof. Ascherl, many thanks for talking to us.

LINKADEMY rev:ease

Revision surgery courses in Germany with Prof. Dr. Rudolf Ascherl

For the one-day **rev:ease** courses, participants arrive the evening before. An evening meal is taken together, during which Prof. Ascherl gives a talk about aseptic and septic revisions and presents complex cases that have occurred at his hospital. The aim of the course is to prepare surgeons for the growing number of revisions, which are increasingly affecting young, active patients.

The dates of the next courses can be found at: **www.linkorthopaedics.com.** If you have any questions, please contact linkademy@linkhh.de.

Enhanced **safety, precision** and intraoperative **control**

LINK made some important modifications to the instrument set for the Gemini® SL® Total Knee Replacement, which ensure greater precision, amongst other benefits.

Maximum safety, precision and reproducibility plus ease of use – these are the criteria which surgeons expect modern instruments for the implantation of knee prostheses to fulfill.

The instrument set for the Gemini® SL® Total Knee Replacement has been fundamentally redesigned by LINK in line with modern demands. The new set is easy to use, allows optimal alignment and soft tissue adjustment with reproducible results, and is arranged on new instrument trays in the correct surgical sequence to further assist the surgeon.

Precise adjustment to meet specific requirements, with correction options

The modifications focused on an even greater precision of alignment – both for tibial resection and for positioning the femoral component. Thus a high-precision tibial alignment has been developed, which allows the surgeon to carry out exact adjustment according to his specific requirements.

The key features of the Gemini® SL® instrument set are:

- The dorsal slope can be optimally controlled and precisely adjusted (Fig. 1),
- The varus or valgus positioning can also be ideally controlled and precisely adjusted (Fig. 2),
- Seamless adjustment of the resection height (Fig. 3),
- The base frame allows pre-adjustment of the tibial cutting block in three degrees of freedom: Height, varus/valgus and slope,
- Positioning of the femoral components (external rotation) can be performed at individual or all three orientation points (Fig. 4):
  - Dorsal condyle tangent
  - Whiteside line
  - Epicondylar axis
- Allowance can be made for correction of the ligaments (Fig. 5),
- The instruments can be dismantled in a minimum of time and without tools – and are equally quick and easy to reassemble.

Fig. 1: Controlled and precise adjustment of the dorsal slope

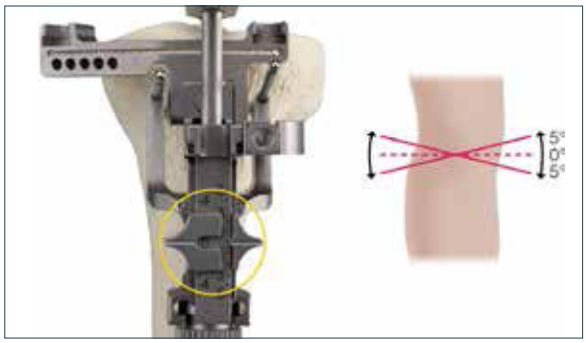


Fig. 2: Controlled and precise varus or valgus adjustment

Fig. 3: Stylus for determining the correct resection height and for precise seamless adjustment

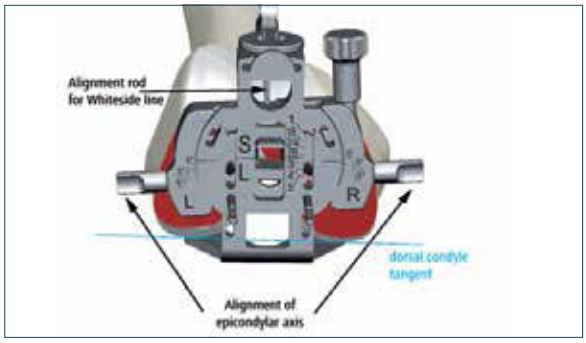


Fig. 4: Adjustment of the femoral external rotation using landmarks

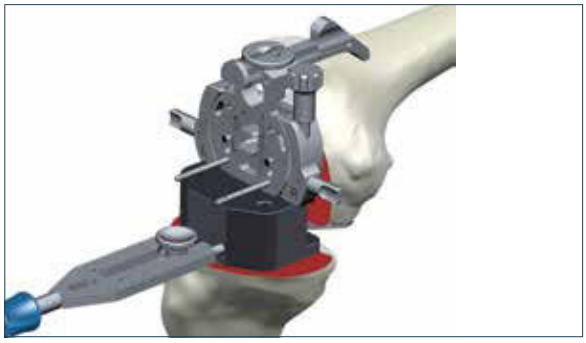


Fig. 5: Adjustment of the femoral external rotation on the basis of the ligaments

Investment casting – the secret of high-performance materials

LINK manufactures its joint prosthesis blanks with optimized investment casting technology, using high-purity titanium and cobalt/chrome base alloys exclusively. The VACUCAST® foundry in Berlin, which is part of the LINK® group, produces blanks from high-performance materials with excellent fatigue strength, which means high fracture resistance.

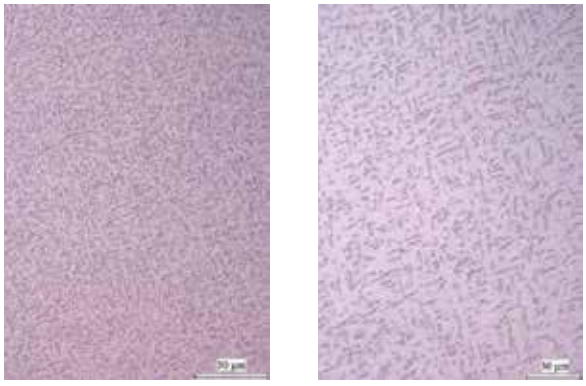
Even externally, the difference between a casted and a forged joint prosthesis blank is easy to see: Casting produces a blank which closely resembles its final form, whereas forging entails a series of forming steps. The material's micro structure and the shaping of the blanks determine the characteristics of the later joint prosthesis in actual use. Investment casting and forging each offer advantages.

If a metal component is forged, it is free of shrinkage pores: the material displays no microporosities which could reduce its mechanical strength. Furthermore, forging enables large numbers of blanks of simple design to be produced very economically. On the other hand, with investment casting there are virtually no limits in terms of complexity of design. In addition, investment casting produces blanks which can be machined without any forming operations. Even small batches can be profitably manufactured by the investment casting method.

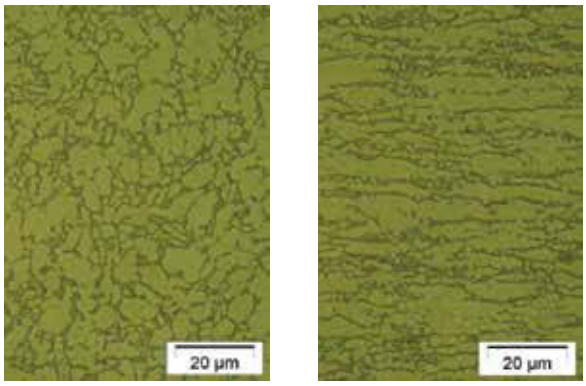
Investment casting: fatigue strength and fracture resistance in all directions

The most important advantage of the process employed by VACUCAST® is, however, that the decisive characteristic of the finished joint prosthesis – high fracture resistance – is isometric, i.e. omnidirectional. This means that the investmentcast joint prosthesis can always respond uniformly to applied loads. The strength of the material – such as titanium or cobalt/chrome – is always identical, irrespective of whether the force acts on the prosthesis from above, from the left, from the front or from below. This is because the material structure is not dependent on a forming operation, but is only created in the mold when the prosthesis is cast. What this means for the patient is essentially that the risk of fracture can be reduced because the designer knows that the mechanical properties of the material will not be affected by the shape of the prosthesis. In order to achieve these material properties, VACUCAST® has added some important steps to the investment casting technique. VACUCAST® uses specially developed chamber furnaces and a state-of-the-art

Cast blanks for hip prosthesis stems at VACUCAST®



Isotropic microstructure over the entire cross-section of an investment casting after thermochemical treatment at VACUCAST®. Left: 400x, right: 1000x



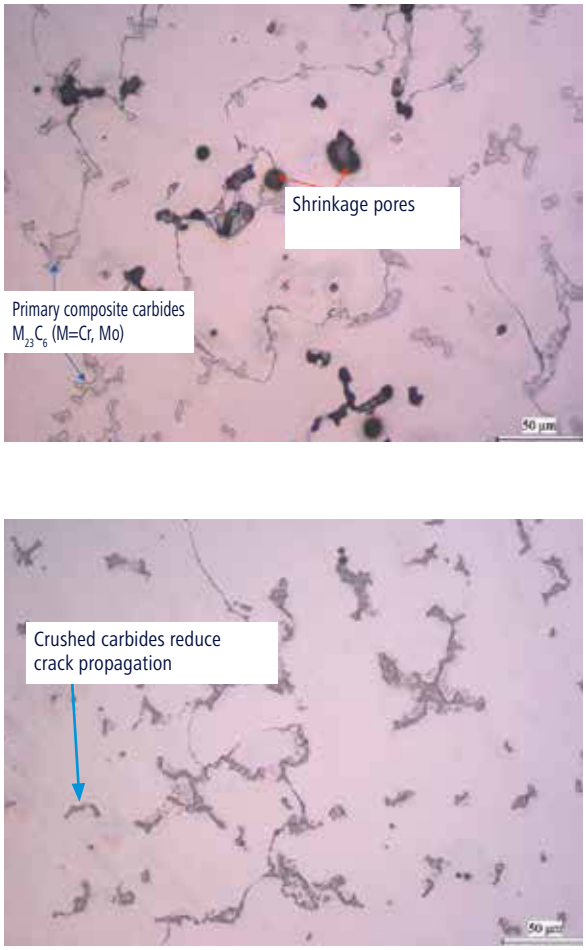
Two forging microstructures in a component (neck): globular (left); stretched (right). Left 400x, right: 1000x

HIP (hot isostatic pressing) plant, plus several vacuum and inert gas heat pretreatment systems. The purpose of the HIP process is to densify the cast blanks and thus eliminate the typical shrinkage porosity of castings.

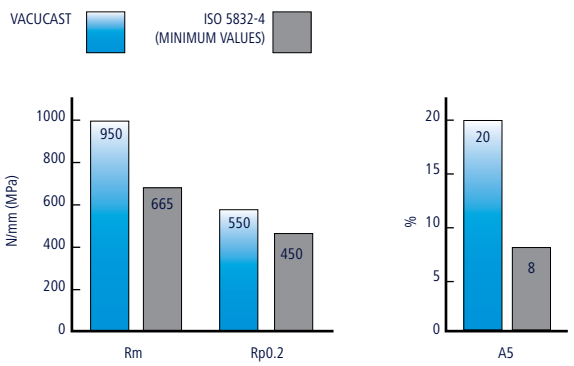
Very good fatigue strength, high fracture resistance and favorable friction and sliding wear characteristics

The quantity, shape and distribution of the microstructure components of the prosthesis material are enhanced by special temperature regulation in the HIP vessel. Thus VACUCAST® has optimized the production process chain, which comprises casting, HIP and heat treatment, to ensure homogeneity and excellent mechanical properties – including for materials that are difficult to cast, such as titanium and cobalt-based alloys. The end result is investment castings with a fine microstructure that is free of shrinkage porosity and therefore highly homogeneous. This in turn lends the joint prosthesis greater fracture resistance. In addition, the crushed carbides inhibit crack propagation, and produce favorable friction and sliding wear characteristics.

VACUCAST® uses a new, state-of-the-art HIP plant, in which the investment cast blanks for joint prostheses are hot-pressed and densified for several hours at above 1000°C and above 1000 bar in a vessel containing argon gas. This process eliminates even the finest porosity from the material. Titanium, which is naturally brittle, is given a homogeneous microstructure with a high level of fracture resistance



Microstructure of an investment casting blank made from CoCrMo in the as-cast state (top) and after treatment in the HIP vessel (bottom)



Comparison of typical mechanical properties of VACUCAST® BIODUR™ (CoCrMo cast alloy) with the required industry standard ISO 5832-4 (minimum values),
*Source: In-house VACUCAST® test

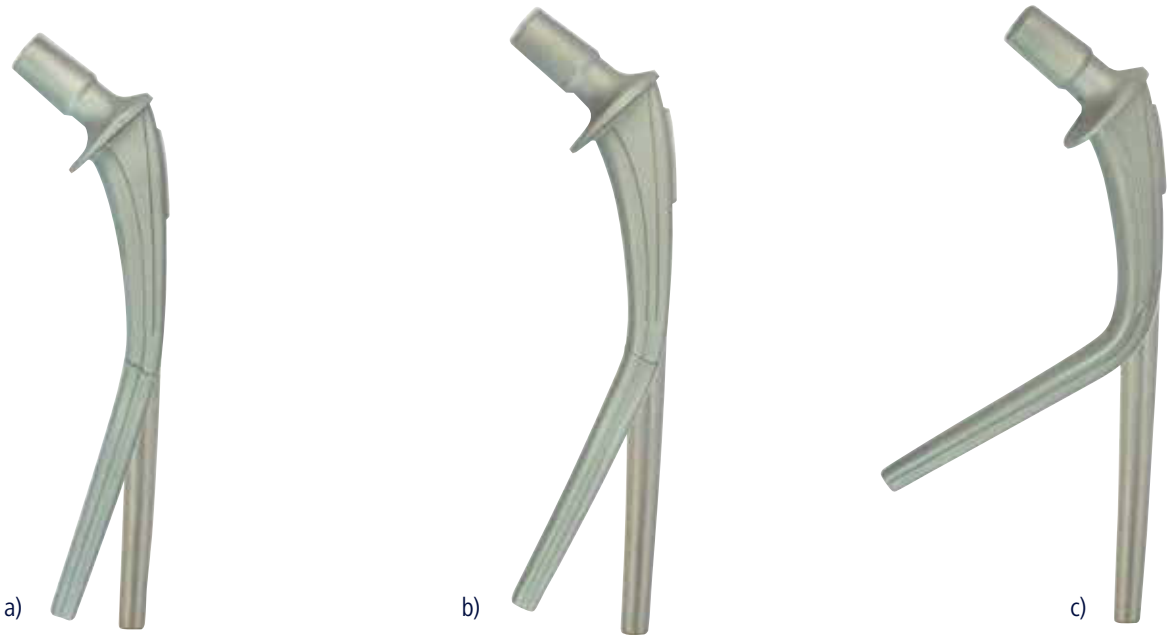
The effect which the VACUCAST® optimized investment casting technology has on the properties of joint prostheses is demonstrated by a bending test performed with LINK® Hip Prosthesis stems (material: CoCrMo alloy): In order to demonstrate the bending angle in the following illustrations, an unloaded SP II® stem, normal, CCD 126°, is shown in the background.

In-house laboratory analysis assures quality and continued technical development

To ensure that the material quality of the joint prosthesis blanks remains consistently high, VACUCAST® operates a comprehensive control and testing system. This comprises dimensional and visual controls at every stage of production plus spectrometric examination of the material composition, crack testing to detect surface defects, and X-ray examination to ensure there are no interior volumetric flaws or non-metallic inclusions.

VACUCAST® analyzes the mechanical characteristics of the materials with tensile and microhardness testing machines. Implant designs are subjected to pulsator tests with defined alternating loads to ensure that material and design combine to give the required fatigue strength. In the metallurgy lab, the material's structural formation undergoes metallographic examination by analysis of microsection scans.

A complete and fully traceable quality certificate is produced for each investment casting that passes through the production process. VACUCAST® is thus able to guarantee that the high quality standard is maintained – and prepares the way for new, increasingly optimized joint prostheses.



a) In the as-cast state: 16° bend angle up to failure **b)** After conventional HIP treatment: 24° bend angle up to failure
c) After HIP and heat treatment: 57° bending angle until shortly before failure

"We are aiming to further expand our position." – **Irina Hatsko** is Director of MedLINK, distributor for Waldemar Link GmbH & Co. KG in the Republic of Belarus

Belarus wins **award!**

A joint prosthesis makes a person stronger – which is why sculptor Corry Ammerlaan van Niekerk, from the Netherlands, gave the figure she created for LINK the title "Hochleben" ("Hurrah").

LINK awards the sculpture to representatives who have achieved exceptional sales success in their region. Irina Hatsko, for example, Director of MedLINK, distributor for Waldemar Link GmbH & Co. KG in the Republic of Belarus, who has worked for LINK since 1995.

Breakthrough in the Belarus market

MedLINK's excellent sales development in Belarus were only possible with the enormous personal commitment demonstrated by Irina Hatsko and the other members of the MedLINK team over the years. In spite of the complicated economic situation in the country, MedLINK have succeeded in increasing market share year on year, thus creating the leading position in the Belarus market. Today, implants from LINK are used in all the orthopedic hospitals in the country.

Extensive product range

"My colleagues in the Minsk office and I currently serve around 20 hospitals throughout Belarus", says Irina Hatsko. "Thanks to new LINK products, we now have an extensive product range, and are able to meet virtually every wish expressed by surgeons in our country regarding joint prostheses." What is the biggest challenge for the future? "We are determined to build on our current position. After all, we are not the only supplier in the Belarus market."

Optimal anchoring

CaP coatings are ideal for **cementless, biological secondary anchoring** of joint prostheses. To ensure optimal control of quality-relevant production processes, LINK now has its own CaP coating plant. The photograph shows how the implants are immersed in the coating tank containing CaP electrolyte solution.

A range of versions

LINK uses **CaP coatings on a range of implants.** Following completion of the development phase for CaP coatings, large-scale production of coated implants has begun at LINK. The photograph shows coated T.O.P.® acetabular cups before they are removed from the contact frame. The new plant enables us to coat 75,000 implants a year in single-shift operation.