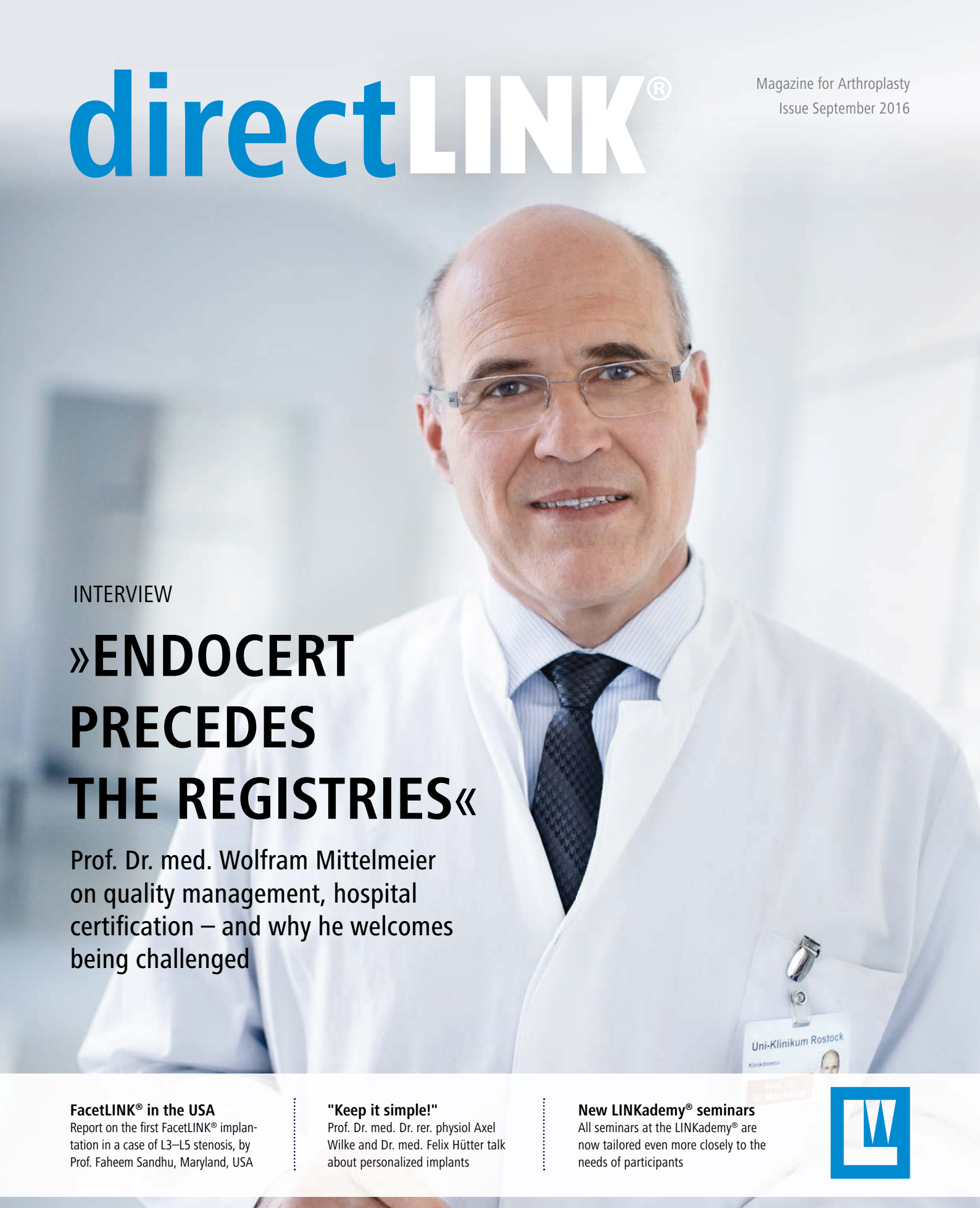
directLINK®

Magazine for Arthroplasty
Issue September 2016



INTERVIEW

»ENDOCERT PRECEDES THE REGISTRIES«

Prof. Dr. med. Wolfram Mittelmeier on quality management, hospital certification – and why he welcomes being challenged

FacetLINK® in the USA
Report on the first FacetLINK® implantation in a case of L3–L5 stenosis, by Prof. Faheem Sandhu, Maryland, USA

"Keep it simple!"
Prof. Dr. med. Dr. rer. physiol Axel Wilke and Dr. med. Felix Hütter talk about personalized implants

New LINKademy® seminars
All seminars at the LINKademy® are now tailored even more closely to the needs of participants

Quality is often in the detail.

The pronounced rib design and the extremely strong LINK® Tilastan®-S alloy mean that the SP-CL® stem offers not only material elasticity but also outstanding constructive elasticity, which reduces stress shielding. The result is excellent primary and secondary stability. The LINK® HX® (CaP) osteoconductive coating permits especially swift bone ongrowth.

Dear Readers:

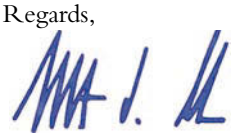
Quality is often in the detail. That is considered to be a cliché – unjustly so, in my view. To guarantee quality, many factors have to come together: a passion for technology, for example, as well as concentration on details, openness to ideas and the discipline to discard them again when doubts arise. When it comes to quality, surgeons and implant manufacturers often share the same objectives, for instance seeking to conserve even more bone during surgery.

Determination and courage can also be drivers of quality. An impressive example of this was provided by Prof. Dr. sc. Johannes Hellinger. Back in 1982, when he was Head of the institution once known as the Orthopedic Clinic of the Medical Academy "Carl Gustav Carus" in Dresden, he wanted to save a patient's leg from being amputated. So he turned to the West German company LINK, even though he was based in the former East Germany (GDR) in those days. The decision to put the well-being of a patient before politics deserves great respect. Please see page 20 for the case report.

Quality can also be achieved through simplicity - a topic discussed by Prof. Dr. Axel Wilke and Dr. Felix Hütter in an interview on page 14. Their motto "Keep it simple!" underlines the fact that complex implants are not automatically superior. We are therefore delighted that they intend to make surgeries with our anatomically adapted cementless SP-CL® hip prosthesis a standard procedure at their hospital. Possibly the best cemented hip prosthesis in the world: this is how they describe the LINK® SP II®, so spurring us on to greater efforts. Quality is in the detail, but can still be improved even further.

I hope you enjoy reading this issue of directLINK

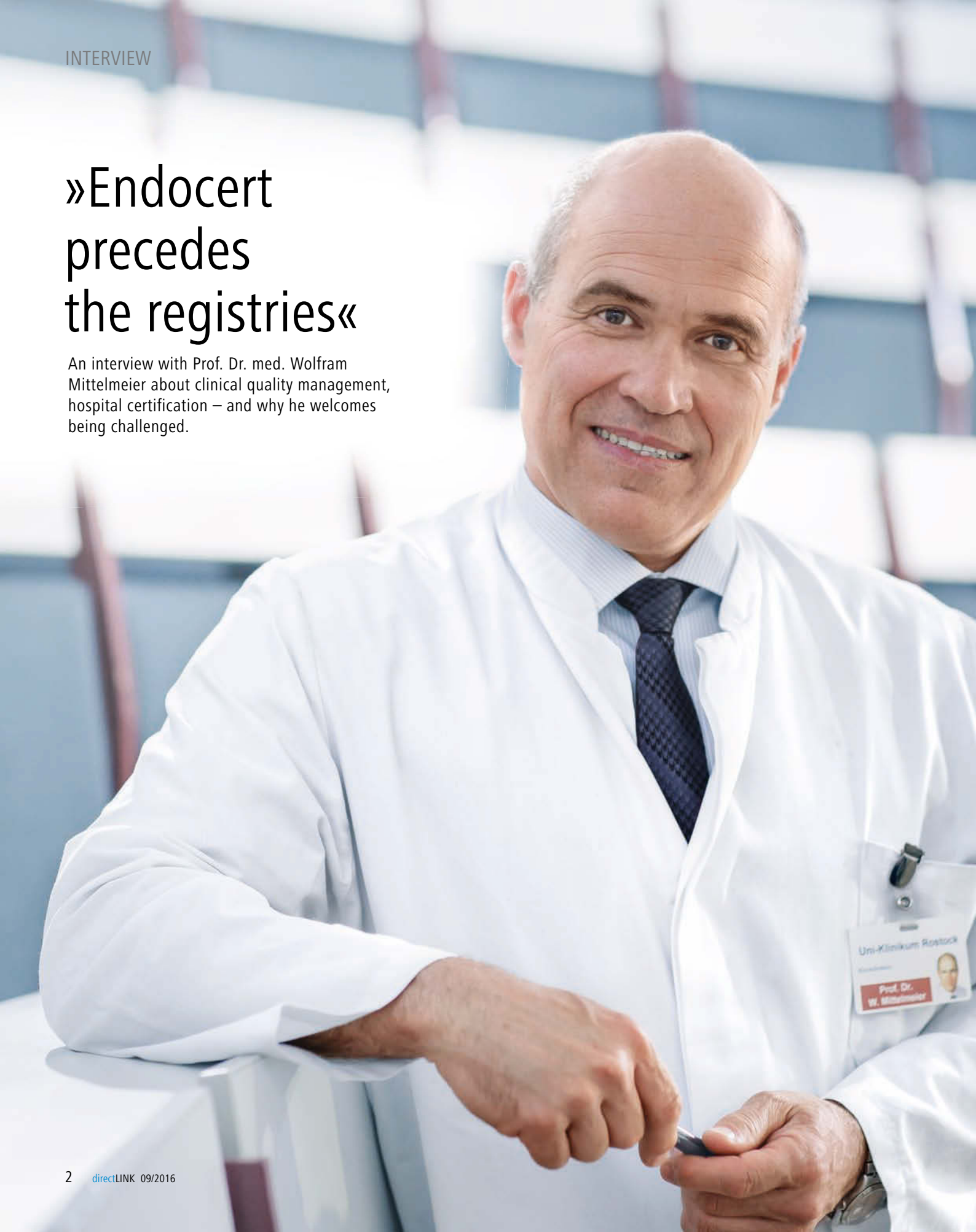
Regards,



Helmut D. Link

»Endocert precedes the registries«

An interview with Prof. Dr. med. Wolfram Mittelmeier about clinical quality management, hospital certification – and why he welcomes being challenged.



»When colleagues challenge me, but still come on board with me and respect our system, I find that a good thing.«

Prof. Dr. med. Wolfram Mittelmeier

AN INTERVIEW WITH

Prof. Dr. med. Wolfram Mittelmeier is Director of the Department of Orthopedics at the University of Rostock as well as Deputy Chairman of the Endocert Certification Commission (www.endocert.de), the world's first certification system set up by the German Association of Orthopedics and Orthopedic Surgery (DGOOC) in cooperation with the professional association for Orthopedics and Traumatology (BVOU) and the German Arthroplasty Association (AE). In his research he focuses on biomaterials, regenerative medicine, biomechanics, worst-case simulations and clinical quality management.

Professor Mittelmeier, clinical quality management is one of your key areas of research. How did this come about?

I noticed the many sticking points in clinical procedures at an early stage. So I began by looking at how to improve processes in the perioperative system, such as preparation for surgery and patient discharge. We have been measuring these processes for ten years now in order to specifically minimize any inefficiencies.

In 2006 the concept of quality management was still undoubtedly frowned upon.

"I'm an experienced surgeon and I'm not going to be told what to do!" – That's what some colleagues were saying at the time. But it soon became clear that many activities at the hospital functioned better if process standards were decided jointly. When the provision of information to patients and their preparation for surgery are standardized, and medical staff are given training with the implants, everyone can then concentrate on the essentials.

Critics also say quality management creates a mountain of paperwork.

Some quality managers do overload us with documents. The aim of quality management is to ensure that regularized processes are established for all aspects of surgery. What we mean here is rules that guide patients properly through the procedures. They must, however, offer physicians and medical staff freedom to use their own discretion.

For example?

We've ensured that every patient is given a minimum of good physiotherapy. We have defined goals that patients are expected to achieve on each specific day after surgery. At the pre-discharge appointment, a specially trained person discusses with patients whether there is going to be someone at home to look after them, whether rehabilitation has been arranged, what paperwork is outstanding, and so on.

Have you also defined further training as a process?

Yes, because no patient should be exposed to increased risk because a junior doctor has to gain practical experience. This is why we've introduced the principle of the lead surgeon. During every operation

»Important data put into the external quality assurance systems is merely reported by the hospitals themselves. This data should, however, be more reliable.«

there is an experienced surgeon in charge. Junior doctors are of course familiarized with the implant beforehand by means of standardized training courses.

Does quality management have many advantages to offer?

Yes, medical directors benefit from safer, less hectic working practices at their hospital because many things run more smoothly. Administrators have a better understanding of what the staff actually achieve. Patients have access to a reliable, trained team, and can be sure of being treated by an experienced lead surgeon.

But there are also disadvantages.

The hospital administration has to free up a position for quality management. It's not enough just to look at whether the figures add up. You also need to check whether processes function properly, ensure staff training and help make forms simpler.

It may also be a problem that new rules result in greater transparency.

Some older colleagues don't like it if the director's X-ray images also come in for criticism. At our hospital all X-rays taken that day are shown at the afternoon meeting and discussed. People don't mince their words if something needs to be improved. My images are assessed as well.

So you don't mind if your colleagues challenge you?

If they still come on board with me and respect our system, I find it a good thing. As the director I have to face up to discussions of quality like everyone else: otherwise we're not living out the principle of quality. As soon as you stop criticizing yourself, you feel you're the best, but mistakes still happen. I find it very important that my staff sometimes tell me: "Boss, I'd have done that differently." The key thing is for everything to culminate in objective criticism. It's the procedure that needs to be evaluated, not the person.

In 2009 you set up Endocert, an initiative created by doctors to certify medical facilities for arthroplasty. What has happened since then?

Endocert has far exceeded our expectations. We've become an extremely fast system, with the orthopedic specialists, trauma surgeons and administrative staff involved in the program demonstrating real passion – a fascinating sight. A key role is played here by the lead surgeons, who have to submit minimum figures and training courses in large joint arthroplasty completed each year. But there is still plenty to do to improve the quality of care in this field and ensure the performance of high-quality surgery. So the next step is for us to introduce a shoulder and a tumor module, followed by certification of the evaluation of patient questionnaires. Number three on our list is the internationalization of Endocert.

Hospitals can apply to be certified by Endocert as a Center for Arthroplasty (CAP) if they demonstrate in an audit that they satisfy the process quality requirements. How can an audit guarantee quality?

In the years following initial certification, the Endocert auditors then regularly perform random checks of hospital documentation. They see what was reported and what wasn't. And if they find serious mistakes, the Endocert quality seal may be revoked.

»We don't want salesmen who merely rattle off the ostensible benefits of implants. What we need is highly qualified customer advisors who know about medical devices and can also point out the risks, limitations and complications involved.«

Is Endocert competing with the registries?

No, but the registries only supply implant-specific information. They don't tell users whether an implant failed because it wasn't implanted properly, or the processes that accompany surgery didn't function correctly. In addition, important data put into the external quality assurance systems is merely reported by the hospitals themselves. This data should, however, be more reliable and therefore be verified by means of audits, since many patients fall through the net. This is why audit quality control on site is an important part of Endocert. Endocert precedes the registries, but does not aim to compete with them.

Are discrepancies between the data from the audit and the German Arthroplasty Register (EPRD) critically appraised?

We're looking to organize feedback between the EPRD and Endocert in certain areas very soon. The EPRD is not, however, a statutory process, and does not yet include private patients or many hospitals. I think that the registry will only become an important source of information if it covers all arthroplasty operations, 100 percent. So anyone who wants to have the Endocert quality seal must register with the EPRD.

How can manufacturers support clinical quality management?

Hospitals must submit evidence that staff who use implants in their work have been properly trained. So we don't want salesmen who merely rattle off the ostensible benefits of implants. What we need is highly qualified customer advisors who know about medical devices and can also point out the risks, limitations and complications involved.

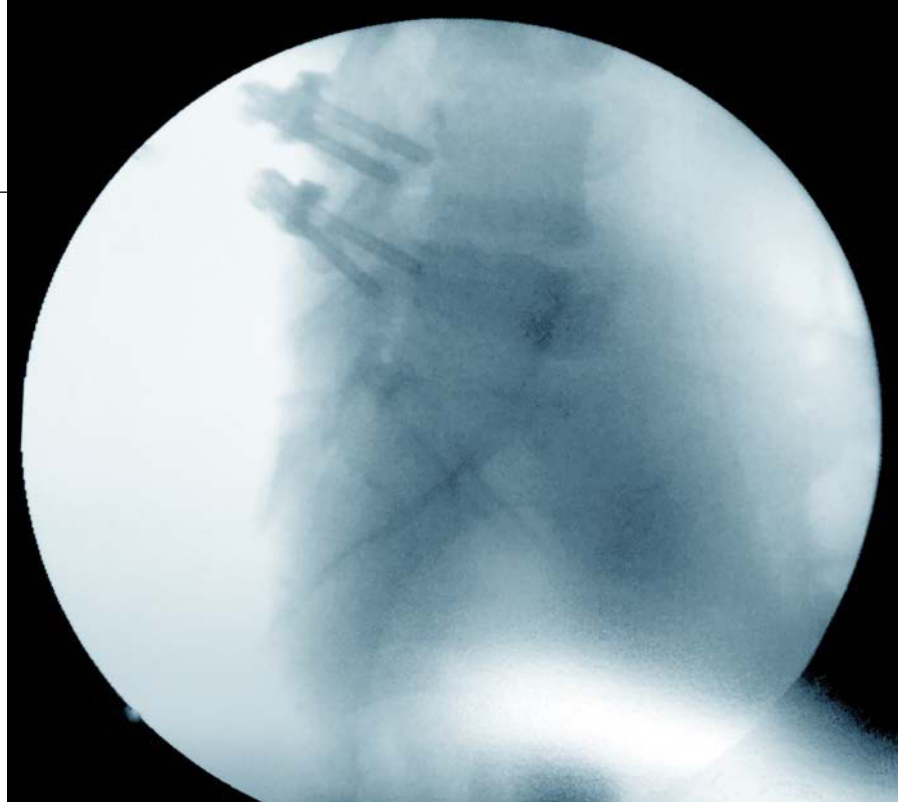
What direction is clinical quality management currently taking?

I hope that even more unnecessary formalities are whittled away, and that Endocert can become a system that is recognized and supported by the general public and politicians. The quality assurance activities forming the basis for this must at last be refinanced, because hospitals will otherwise be forced to make savings in medical and nursing care if they are to practice quality management. It's fascinating to see the speed at which this essentially voluntary system has spread, which is indicative of the sense of responsibility among senior physicians and hospital managers. Over 400 hospitals are now certified in Germany, and Austria, Switzerland and Luxembourg have also started to work with the system. At the end of the day patients will benefit here.

Professor Mittelmeier, many thanks for giving us this interview.

CASE STUDY

A 68-year-old man with severe central and lateral recess stenosis of L3 through L5 concomitant with degenerative spondylosis presented complaining of neurogenic claudication with associated radicular pain. As conservative therapy proved unsuccessful, a FacetLINK® HEMI was implanted in the patient in late 2015.
Report by Dr. Faheem Sandhu, MD, PhD, Professor of Neurosurgery and Director of Spine Surgery, MedStar Georgetown University Hospital, Washington, USA.



The failure of conservative therapy prompted the patient to opt for decompression and fusion of L3 through L5 with FacetLINK® HEMI

First FacetLINK® implant for L3–5 stenosis in the USA

The patient was suffering from severe neurogenic claudication, which did not respond to conservative therapy. Faced with instability in L3–L5, we recommended fusion over two planes. While we weighed up whether to use TLIF, the patient's osteopenic bones and severely collapsed intervertebral disks led us to decide against inserting a cage, since it would most probably have given way. We ultimately performed microsurgical decompression of L3–L4 and L4–L5 on the left and applied the crossover technique to decompress the contralateral sides. The surgery was performed at the MedStar Southern Maryland Hospital Center in Clinton, Maryland, USA.

Autologous bone collected during decompression

A high-speed reamer was used for the decompression, as well as a separate aspirator, connected to an osseous coagulum trap to collect the autologous mix of blood and bone. Following decompression of the spinal canal and recess stenosis, we then determined the correct implant size with the help of a resection guide. We measured an implant width of 8 mm and selected the appropriate implant. Starting in the lateral plane, we targeted the ipsilateral guide wire. As we wished the initial trajectory to be slightly further to cranial, we corrected the positioning in the A.P. view. We then made the pilot hole with a cannulated drill and inserted

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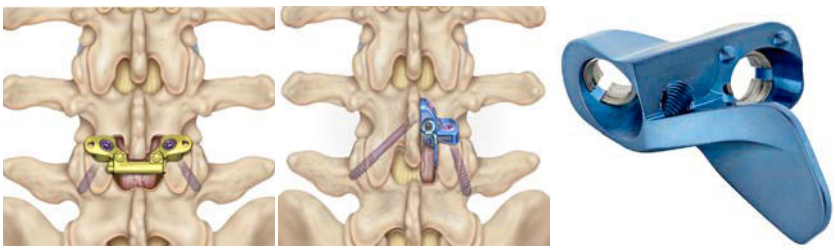
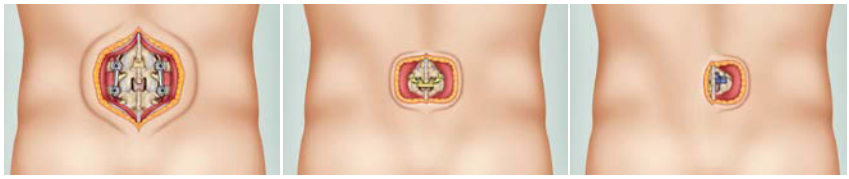
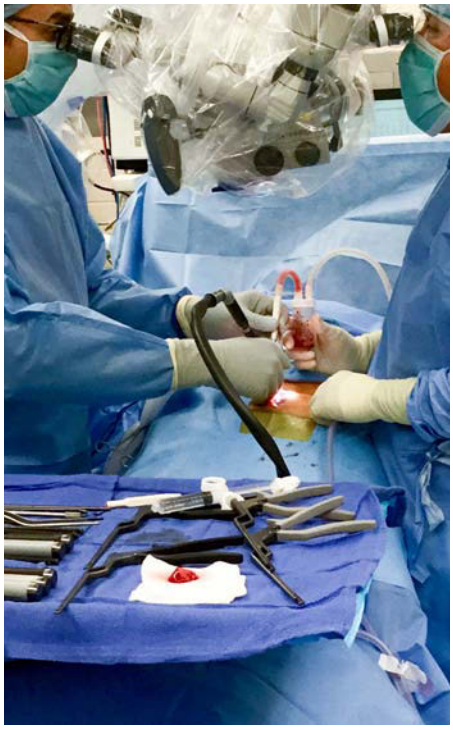


Available as STANDARD and MINI for bilateral decompression, and as HEMI for unilateral decompression: the new minimally invasive FacetLINK® Stabilization System for the lumbar spine



Placement of the FacetLINK® implant system (center: MINI; right: HEMI) can be performed via a smaller access port than with bilateral pedicle screw and rod systems (left) – which, in turn, can mean a shorter recovery time, less postoperative discomfort and faster postoperative healing than with pedicle screws.



a tension screw, 25 mm by 4.5 mm thick and featuring a partial thread. This was followed by positioning of the contralateral guide wire with an excellent result. We were finally able to insert a tension screw 40 mm in length. The screws were finally locked with a torque-limiting screwdriver. We also selected an 8 mm FacetLINK® HEMI implant for the L4–L5 level. As with L3–L4, we implanted a 25 mm x 4.5 mm tension screw with a partial thread on the ipsilateral side, and a 40 mm x 4.5 mm tension screw with a partial thread on the contralateral side.

Highly satisfied with the surgical technique

In our view the highlights of the system are excellent screw fixation, including with osteopenic bone, the intuitive surgical technique, as well as the extremely low hardware profile. We were also impressed by the fixation philosophy of the system, as the screws do not encroach on the adjacent facet joint. We would be interested to learn whether this will lead to fewer problems in neighboring segments. In this case we required 60 minutes for insertion of the FacetLINK® HEMI implants.

After implantation we enriched the bone mass from the osseous coagulum trap with demineralized bone matrix and introduced the composite mix for dorsal fusion at the opened facet joints. After surgery, the patient displayed complete remission of his neurogenic claudication and radicular pain and was thus very pleased with the outcome of surgery.

Time required very similar to conventional pedicle screws and rods

As a neurosurgeon focusing on minimally invasive procedures, I prefer treatment methods that minimize the destruction of tissue and surgical morbidity. I therefore find the FacetLINK® portfolio especially interesting.

Insertion of the contralateral screw during our first FacetLINK® HEMI implantation procedure seemed relatively free of problems. The bisegmental decompression and fusion took a total of 150 minutes, so making the system, in my view, a competitive alternative to the minimally invasive bisegmental decompression and placement of six pedicle screws with rods. I am confident that the length of time required for surgery will fall even further as we gain experience with the system.

We are extremely satisfied with the FacetLINK® platform and are eager to see the complete product portfolio, which will permit use on a wider range of patients.

Report: Dr. Faheem Akram Sandhu, MD, PhD







REVISION

INTERNATIONAL SYMPOSIUM 2016

in Berlin, from 25 to 26 January, 2016

LINKADEMY






32 nations at the 2016 International LINK® Revision Symposium

In January 2016 over 230 participants and 20 speakers from 32 countries came to Berlin for the two-day program. This ensured fascinating discussions, so making LINK's International Revision Symposium an event of global importance in the field of revision arthroplasty. A short report now follows.

"This year we chose the topics for the symposium from purely practical points of view," explains the symposium's Scientific Director, Prof. Dr. med. Thorsten Gehrke, Medical Director of the HELIOS ENDO-Klinik Hamburg. "Discussion basically always revolved around the following issues: What exactly are the problems of revision surgery, for example with an infection or luxation? What is the precise defect situation, and which implant can be used in each case?"

Optimal solutions and viable alternatives

"Another aspect that came into play when selecting the program topics is the fact that not every country is able to provide patients with high-quality implants," comments Prof. Gehrke. "It was therefore important to me that the debate not only covered ideal solutions for specific challenges of revision, but also viable alternatives."

This includes, for example, impaction allografting with knee prostheses. "The literature forecasts that from 2010 to 2030 the revision frequency for knees will have risen by 600 percent." In the future, orthopedic surgeons and traumatologists performing replacements will be faced with the challenge of how to fixate implants securely. "Impaction grafting can also be used in countries whose health systems are less well funded," comments Prof. Gehrke.

Cemented or cementless knee revision

Prof. Dr. Davide Maria Donati, Director of the Orthopaedic and Onchologic Department, Istituto Ortopedico Rizzoli, Bologna, Italy, wants every patient undergoing knee revision to receive the perfect solution. "I've had good experience with cementless stems for patients both young and old if there is sufficient stability of the knee joint," says Donati, explaining his fundamental approach when performing knee revisions. "But if a patient only has minimal joint stability and poor bone quality, I'm always looking for an especially reliable solution and I implant a cemented stem in the diaphysis," explains Prof. Donati.

Prof. Dr. Brett R. Levine, Assistant Professor, Rush University Medical Center, Chicago, USA follows a similar approach with his revision surgery. "When it comes to worst-case scenarios, the cemented implant is in my experience far more forgiving than the cementless version. For the LINK® Endo-Model® my ratio is, for example, 65 to 35 percent for the cemented version," states Prof.

"With over 230 participants from more than 30 countries, LINK's International Revision Symposium has become one of the largest revision surgery symposia in the world" Prof. Dr. med. Thorsten Gehrke, HELIOS ENDO-Klinik Hamburg

"We can always choose whether to use a press-fit version or not. But with older patients it's always best to be cautious, as you can seldom rely on good bone quality" Prof. Dr. Davide Maria Donati, Orthopaedic and Onchologic Department at the Istituto Ortopedico Rizzoli, Bologna, Italy

"Whether I use cemented or cementless stems depends for me on the individual patient" Prof. Dr. Brett R. Levine, Rush University Medical Center, Chicago, USA

"The advantage of an interposition sleeve (Rescue Sleeve) for an interprosthetic fracture is that none of the joints involved need to be opened, nor the implants replaced. This means patients are mobile again very quickly"
Dr. med. Akos Zahar, HELIOS ENDO-Klinik Hamburg

"The LINK® Endo-Model® is easier to implant than extensive modular resurfacing prostheses and ensures excellent loading stability"
Prof. Arnaldo José Hernandez, Instituto de Ortopedia e Traumatologia – Faculdade de Medicianda Universidade de São Paulo, Brazil

Levine. "I'm highly satisfied with the results. To date we have seen no septic loosening, and the implants function perfectly."

Stability and reliability are the deciding factors

The surgeons at one of Brazil's largest orthopedic centers only recently became familiar with the LINK® Endo-Model® for primary and revision surgery. "The Endo-Model® is easier to implant than extensive modular resurfacing prostheses and ensures excellent loading stability," remarks Prof. Arnaldo José Hernandez from the Instituto de Ortopedia e Traumatologia – Faculdade de Medicianda Universidade de São Paulo, Brazil.

Dr. Gurava Reddy, Managing Director and Chief Joint Replacement Surgeon at Sunshine Hospital, Hyderabad, India, has also enjoyed positive experiences with the LINK® Endo-Model®. "Every year we perform some 4,000 arthroplasties, including many serious cases, and the revision rate is significant," states Dr. Reddy. "Constrained knee prostheses like the LINK® Endo-Model® have proved to be extremely reliable here – the perfect solution for such cases."

"Constrained knee prostheses like the LINK® Endo-Model® have proved to be extremely reliable – the perfect solution for our cases" Dr. Gurava Reddy, Sunshine Hospital, Hyderabad, India

LINK's interposition sleeve is also suitable for special situations. "Following interprosthetic fracture, the interposition sleeve (Rescue Sleeve) is a fast and elegant solution for elderly patients with a long-stem knee and hip prosthesis in situ," comments Dr. med. Akos Zahar, senior physician at the HELIOS ENDO-Klinik Hamburg. Patients are also mobile again very quickly, since it is not necessary to open any of the joints and revise implants. "We have had excellent experience with the interposition prosthesis," claims Dr. Zahar.

Symposium on demand!

Video recordings of all 45 presentations made at the symposium as well as impressions of the two days in Berlin are available at www.revision.linkorthopaedics.com. Alternatively, you can scan this QR code with your smartphone.

New training concept at the LINKademy®

At the beginning of 2016 the LINKademy® launched a new concept. Its seminars are now tailored even more closely to the qualifications and needs of participants.

Learning from each other for the benefit of patients. This philosophy of orthopedic surgeons is also part of the daily routine at LINK and the LINKademy®. The LINKademy® has revamped its training concept to cater even better for the qualifications and needs of the participants. The high-quality orthopedic and traumatology seminars are held under realistic conditions.
Certain workshops now last one and a half days, take place at two work stations and are taught by either one or two instructors plus assistants. Training focuses on safe use of the LINK® Endo-Model®, the associated MIRETO® instrument set and the LINK® MEGASYSTEM-C®.

The course concept is based on four sequential levels:.

- **Level 1** is for physicians with initial experience in primary and revision surgery.
- **Level 2** will interest physicians with experience in revision surgery who wish to deepen their theoretical knowledge and practical skills in knee revisions.
- **Level 3** is aimed at experienced physicians who are looking for more in-depth theoretical knowledge and practical skills in treating severe bone substance losses and periprosthetic infections. Physicians wishing to intensify the subject matter covered by the Level 2 courses can likewise opt for the Level 3 program.
- **Level 4** consists of a certified training concept aimed at international instructors and speakers.

You can find more information online at **www.linkorthopaedics.com.**

Advancing knowledge: LINKademy® seminars, workshops and fellowships

»Advanced age is not a contraindication for a Sled Prosthesis«

An interview with Dr. med. Jens Müller about sled prostheses, problems for novices and the new MITUS® ART surgical technique for the LINK® Sled Prosthesis.

AN INTERVIEW WITH

Dr. med. Jens Müller is an orthopedic surgeon and traumatologist practicing in Berlin-Adlershof. As a consultant and hospital-affiliated physician, he specializes in joint diseases of the knee and hip. His main areas of surgical expertise include the complete spectrum of knee and hip arthroplasty, in particular the implantation of sled prostheses.

Dr. Müller, you implant some 100 sled prostheses a year, with LINK accounting for over half of them. What is your impression of the LINK® Sled?

Where the femur is concerned, the LINK® Sled is the only implant that is extremely bone-conserving and, as such, enables genuine re-surfacing. The surgeon merely smooths off the bone before fitting the Sled Prosthesis. On the tibial side, the LINK® Sled also ranks as an especially bone-conserving prosthesis. These two reasons mean that it can be implanted even when bone is not of optimum quality.

Based on your experience, are you able to confirm the excellent long-term results given for the LINK® Sled Prosthesis by the Swedish Register*?

I can confirm the quality of the LINK® Sled. However, this implant is not suitable for novices. Anyone who is inexperienced will, for example, often have problems with aligning the femoral component of the implant properly and selecting the best size. However, with a bit more experience and professional training, the LINK® Sled is relatively simple to implant. Essentially, if you know how to do it, the procedure is quick and simple.

»The LINK® Sled is the only sled that enables genuine re-surfacing.«

You were involved in the development of the new MITUS® ART surgical technique for the LINK® Sled. How does it differ from the previous version?

Above all, the tibial instrument set offers even greater ease of use and improved tactile properties. The adjustment options on the tibial side have been optimized, as well as the possibilities for testing with trial implants. The new MITUS® ART surgical technique permits more precise adjustment, with significantly finer setting of the slope and joint line.

Many physicians believe that older patients should be given a total knee

»The LINK® Sled Prosthesis is relatively easy to implant. If you know how to do it, the procedure is quick and simple.«

Dr. med. Jens Müller

replacement rather than a Sled Prosthesis. You don't share this opinion – why not?

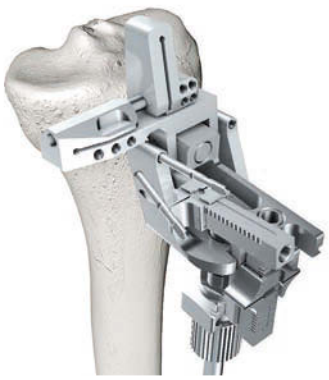
Yes, I take the exact opposite view here. It is above all older patients who stand to benefit from a sled prosthesis. After surgery they are normally mobile again faster and recovering their fitness. This reduces the level of risk, complication rate and side effects. For an 80-year-old patient it may be very important not to have to undergo major surgery. We shouldn't go overboard with the indication – but in my view, an advanced age is fundamentally no contraindication for a sled prosthesis.

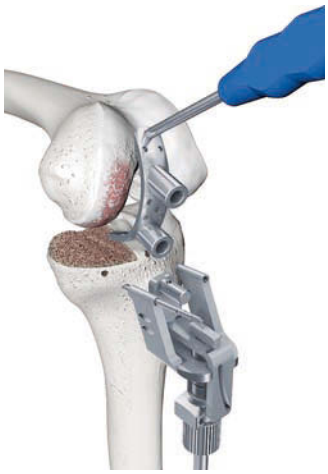
Dr. Müller, many thanks for this interview

**The Swedish Knee Arthroplasty Register, www.myknee.se/en/*

LINK® MITUS® ART instrument set for the minimally invasive surgical technique using the LINK® Sled Prosthesis

MITUS® stands for Minimally Invasive Technique for the Unicondylar Sled, and ART for Anatomic Reconstruction Technique. Bone-conserving resection and sparing of soft tissue are key factors for the success of unicondylar arthroplasty. Both these aims are supported by the MITUS® instrument set for implantation of the LINK® Sled Prosthesis – with full control over incision depth at the tibia and precise setting of the desired resection level in the sagittal and horizontal planes. For the benefit of the patient: a smaller wound, a smaller scar and faster restoration of mobility.





LINK® Sled Prosthesis delivers outstanding results

Unicondylar knee prostheses can be implanted with little bone destruction and well-preserved ligaments in the knee joint. Still undergoing continuous further development, the unicondylar LINK® Sled Prosthesis has delivered outstanding outcomes in everyday clinical practice for many years. When used in combination with the minimally invasive surgical technique MITUS® ART, this knee replacement minimizes bone removal and preserves soft tissue. Based on 2,321 implantation procedures between 2004 and 2013, the 2015 Annual Report* of the Swedish Knee Arthroplasty Register certifies the LINK® Sled Prosthesis as having the lowest revision risk.

»If the SP-CL® prosthesis from LINK lives up to what it promises, it will become a standard procedure at our hospital.«

Prof. Dr. med. Dr. rer. physiol. Axel Wilke

»Keep it simple!«

An interview with Prof. Dr. med. Dr. rer. physiol. Axel Wilke and Dr. Felix Hütter about customized implants for patients, digital planning of surgery and their study evaluating the LINK SP-CL®.

Professor Wilke, Dr. Hütter, You have been using LINK's new SP-CL® implant since the middle of 2015. How did this come about?

Prof. Wilke: We were looking for a cementless anatomical stem with a slender shoulder, and in our search we came across the SP-CL® Hip System. The stem is not too curved, nor is the shoulder of the SP-CL® too wide, so very little bone needs to be sacrificed on implantation. We like that.

What is your experience with the SP-CL® to date?

Dr. Hütter: We use the SP-CL® for younger patients, although there isn't any upper age limit. We have now implanted some 50 SP-CL® prostheses and can tell you that they function well. There have been no major complications. Our portfolio also includes the cementless C.F.P.® hip prosthesis from LINK, which we use on even younger patients.

How do the design features of the SP-CL® fit with your computer-aided digital planning?

Dr. Hütter: The implantation of an SP-CL® is very amenable to digital planning, which allows the prosthesis to be optimally tailored to the patient. However, a prerequisite here is a certain degree of surgical experience with the SP-CL®. The cancellous bone, for example, is not scraped out, but rather the prosthesis is impacted and anchored in it. The surgeon has to be familiar with such details and also take them into account when planning the size to be used prior to the procedure.

Is it more an advantage or disadvantage being able to choose between implants of many different sizes?

Prof. Wilke: It is always an advantage if you can choose between many sizes for a hip or knee implant. Nowadays, sizes that are very rarely used can be ordered

AN INTERVIEW WITH

Prof. Dr. med. Dr. rer. physiol. Axel Wilke is General Manager, Medical Director and Head Physician at Elisabeth-Klink in Bigge-Olsberg, one of Germany's oldest and largest orthopedic hospitals.
Specializing in orthopedics and traumatology, **Dr. med. Felix Hütter** is a senior physician and study director at Elisabeth-Klinik, Germany.

quickly and will be delivered the next morning. When selecting the implant, you need to remember that the prosthesis should be easy to use, particularly if a hospital only performs a small number of arthroplasties. For training junior doctors, the prosthesis should also be simple to handle when assisting in surgery. This will ensure success with both learning and teaching in a straightforward, reproducible manner. "Keep it simple!" – that's really important in arthroplasty.

Why is that?

Dr. Hütter: A scrub nurse must, for example, first assist in a hip surgery, next a cruciate ligament and then a cervical spine. If an implant is too complicated, the scrub and surgery nurses will not be able to cope – and at some point the surgeons will also struggle. The outcome may be affected if not even the surgeon is fully familiar with the prosthesis system.

"Keep it simple!" – does this also apply to the SP-CL® prosthesis?

Prof. Wilke: Yes, otherwise we wouldn't use the SP-CL®.

What do you think of implants that are custom-made to the patient's individual specifications?

Prof. Wilke: A special indication should exist for implants that are custom-made to the patient's specifications. This is generally for anatomical reasons and/or due to complicated previous surgery.
In these cases I consider such prostheses to be justified, although I feel generalized implantation of customized artificial joints isn't the route to take. Firstly, the scientific data for the majority of customized implants does not show the necessary benefit at a scientific level, and secondly, such a departure from the current standard also needs to be funded by the health service.

Would custom-made prostheses actually make any major difference?

Prof. Wilke: We cannot give a definite answer to this question at present. We lack scientific studies for customized prostheses, performed on a prospective, randomized basis over an observation period of undoubtedly at least 15 years. This would allow us to see whether custom-made prostheses are substantially better than standard implants. The use of customized prostheses may in fact show no significant improvement in patient-specific outcomes, as with the navigation sometimes employed with arthroplasty.

You are currently working on a study involving the SP-CL®. What is your objective?

Dr. Hütter: We are looking at 100 patients aged between 18 and 75 years suffering from coxarthrosis and treated with a cementless, anatomic prosthesis. Our aim is to investigate the accuracy of our preoperative planning in relation to the clinical and radiological outcome of the surgery. How well can these patients walk, what pain do they complain of, how satisfied are they? To determine this, they will be followed up at intervals of one, two and a half, and five years.
Prof. Wilke: If the SP-CL® prosthesis lives up to what it promises, it will become a standard procedure at our hospital. We are optimistic. The SP-CL® is a further development of the SP II®, LINK's cemented prosthesis system, which, in our view, is possibly the best cemented hip prosthesis in the world.

Professor Wilke, Dr. Hütter, many thanks for this interview.

»Implantation of the SP-CL® is very amenable to digital planning. But it depends on the experience of the surgeon.«

Dr. med. Felix Hütter

LINK® SP-CL® anatomically adapted hip system, cementless

- Versions and sizes available for standard and special cases
- S-shaped stem with integrated antetorsion
- Flattened, lateral profile for protection of the trochanter
- Pronounced rib design for integration of the proximal femur in the distribution of forces
- LINK® Tilastan®-S alloy and design to minimize stress shielding
- Osteoconductive coating LINK® HX® (CaP)
- Cancellous bone compressors

»My door is always open. Whether nursing assistant or senior physician, the boss has time for everyone.«

Prof. Dr. med. Stefan Endres

»We offer great job satisfaction!«

An interview with Prof. Dr. med. Stefan Endres about team-building, respect and the special challenges of the region where the borders of Germany, Switzerland, and France converge.

AN INTERVIEW WITH

Prof. Dr. med. Stefan Endres is Medical Director at the Orthopedic Surgery department of Rheinfelden District Hospital, Germany. He specializes in primary and revision arthroplasty, joint surgery, spinal surgery and limb traumatology. Prof. Endres also teaches at the University of Marburg.

Professor Endres, your hospital is located in the border region of Germany, Switzerland, and France. Do you feel any competitive pressure here?

You feel it every day. Sometimes good people are lured away, since the financial aspect is something where Germany cannot really keep up, including as regards pay scales. This makes it difficult to get staff close to the border, whether for the X-ray department, emergency room, surgery or the wards.

Difficult, but evidently not impossible. Since you took over as Medical Director three and a half years ago, things have been looking up. How have you managed that?

Although we are unable to keep up with pay rates in Switzerland, we offer very high levels of job satisfaction – because apart from offering good medical training, we are also a great team. We do not, for example, take a strictly hierarchical approach to our work. If tough decisions are needed, we try to find a solution

through cooperation. You see, what really counts here is authenticity and empathy – and that's something both patients and staff can sense.

Is the door to your office always open?

Of course! Whether nursing assistant or senior physician, the boss has time for everyone. But mutual respect isn't everything, of course: the financial aspect also plays a role. If you want to advance and expand a hospital, a lot depends on extra commitment on the part of your staff. So we need employees who are willing to go the extra mile. But nowadays, you can't just ask for such commitment, you also have to recognize and reward it. The job market is simply too good: at the end of the day, physicians can choose where they want to work.

What else do you do differently?

My team includes 14 physicians plus surgical staff and the secretariat. In all, I have some 30 people working for me. We consciously try to bring everyone together. To encourage a team feeling, we regularly get together and undertake something that has nothing to do with the hospital. One winter, for instance, we headed for the Sauerland region, complete with après-ski hut. We've also gone on a diving course together, and take part in soccer tournaments. Normally staff in a hospital form their own little groups: physicians, nurses or physiotherapists. We are like one big family.

Switzerland and France don't fund treatment in Germany. So your patients only come from Germany, yet your hospital is expanding.

Our catchment area is limited by our location to the north-east. It nevertheless contains hospitals staffed by people with an outstanding reputation. In this rather unusual situation, we do a very good job, offering high-quality medical care. This is, in my view, one of the reasons for our excellent levels of patient satisfaction and patient loyalty.

And there are other reasons.

We are a provincial hospital providing general healthcare and have strong competition on our doorstep. Yet people still keep coming to us. My operating schedule is booked up for over ten weeks and is extremely varied: hip surgery for example, followed by spondylodesis, then an acetabular revision, next an operation on the cervical spine, and finishing with a total femoral arthroplasty. In some of these cases we really hold our own against the best. In terms of our structure, we're a bit like a university-based hospital.

What challenges do you expect to face in the next few years?

It will be interesting to see what direction Orthopedics and Traumatology take in future. I suspect it will merge, with the subspecialties becoming even more important. I can well imagine a department-based system with subgroup leaders, for example head of Arthroplasty, head of Arthroscopic Surgery, and so on. To remain competitive, we also have to keep pace with medical progress, as Switzerland is always abreast of the latest developments.

Professor Endres, many thanks for this interview.

»If you want to advance and expand a hospital, a lot depends on extra commitment on the part of your staff.«

Prof. Dr. med. Stefan Endres interviewed by LINK medical device advisor Gerhard Pischel

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LINK® Endo-Model® for complex knee deformity

CASE REPORT

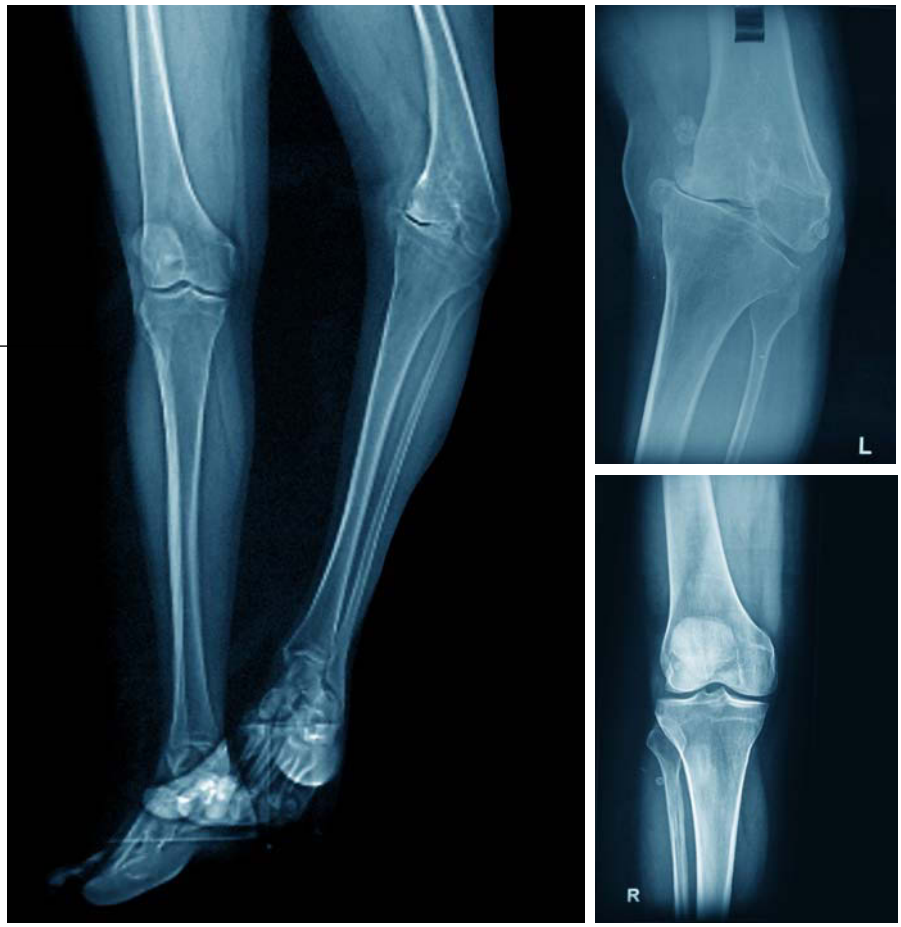
A 53-year-old temple priest with a complex deformity of the left knee had suffered pain for 20 years. This had become worse in recent years, leading to difficulty with walking and reduced mobility. The patient's medical history also included a distal femur fracture 25 years ago. This had been treated by a local hospital, and no further details were available.

Clinically, the patient presented with severe joint-cavity tenderness of the left knee. The tibia was internally rotated with a shortening of 7 cm, and a varus flexion deformity. The ROM (range of movement) was 0–5 degrees. No neurological defects were found on examination, nor was there any tenderness of the left hip.

Routine knee arthroplasty appeared impossible

We initially planned to perform a total knee replacement (TKR). Intraoperatively, however, the femur and tibia were found to be completely deformed, so that routine knee arthroplasty with a primary implant appeared impossible. We therefore decided to implant a LINK® Endo-Model® Rotational and Hinge Knee Prosthesis.

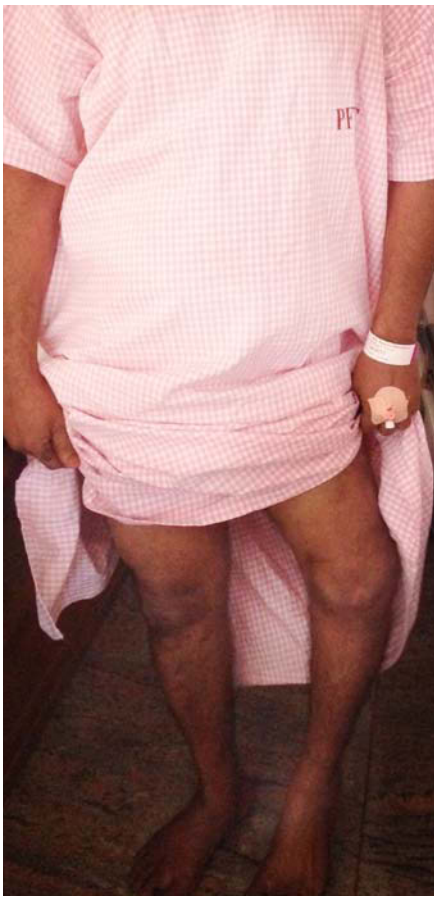
Postoperatively, the patient made an excellent recovery. On the second postoperative day he was able to walk with the help of a walker, and on the fifth day

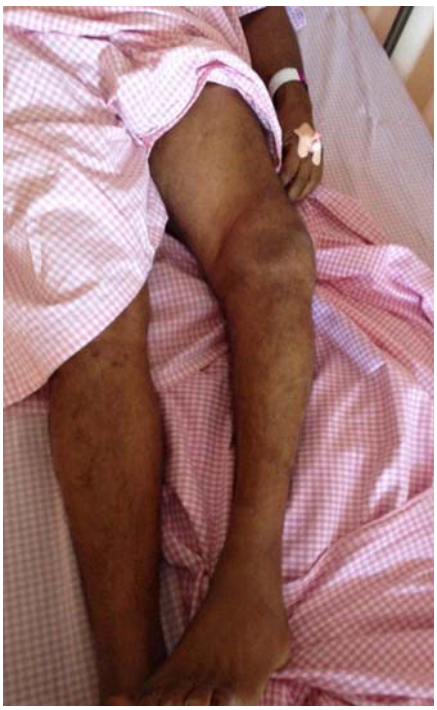


Preoperative imaging shows the complex flexion deformity of the left knee: Internal rotation of the tibia has resulted in shortening of 7 cm

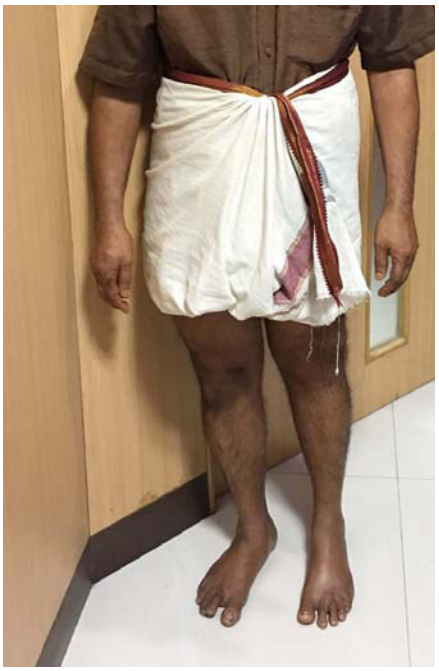
maximum flexion of the knee was 60 degrees. Wound healing was complete after two weeks, and the satisfied patient then discharged.

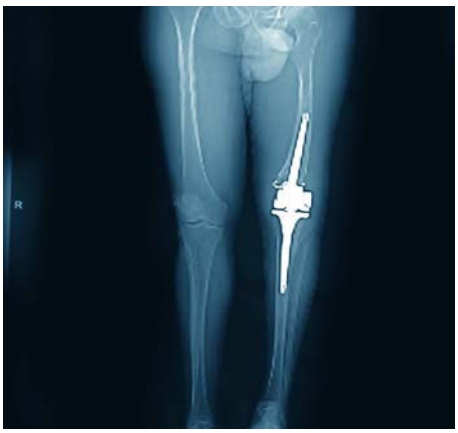
In the course of follow-up, he was first reviewed on a monthly basis. The patient was soon able to walk without support and returned to his job as a temple priest free of pain. From the sixth postoperative month he was reviewed every three months. After two and a half years the patient was still found to be pain-free, walking without support and enjoying a ROM of 0–60 degrees.

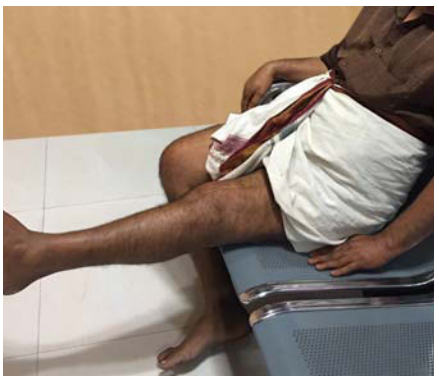


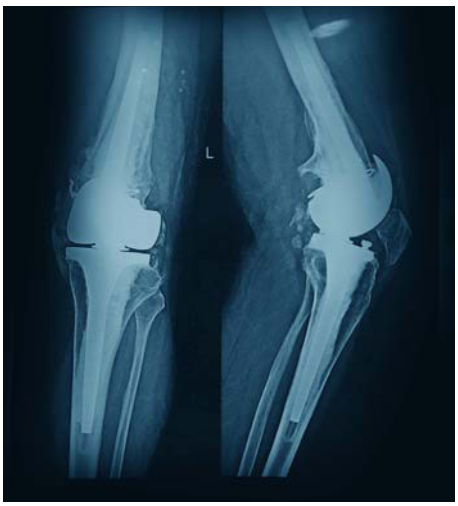


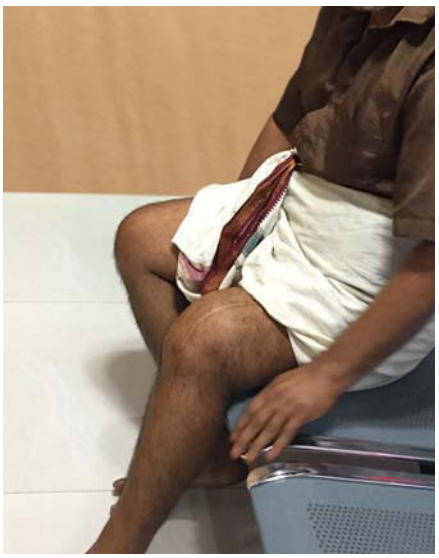
53-year-old patient with severe deformity of his left knee, resulting in pain, difficulty with walking and reduced mobility



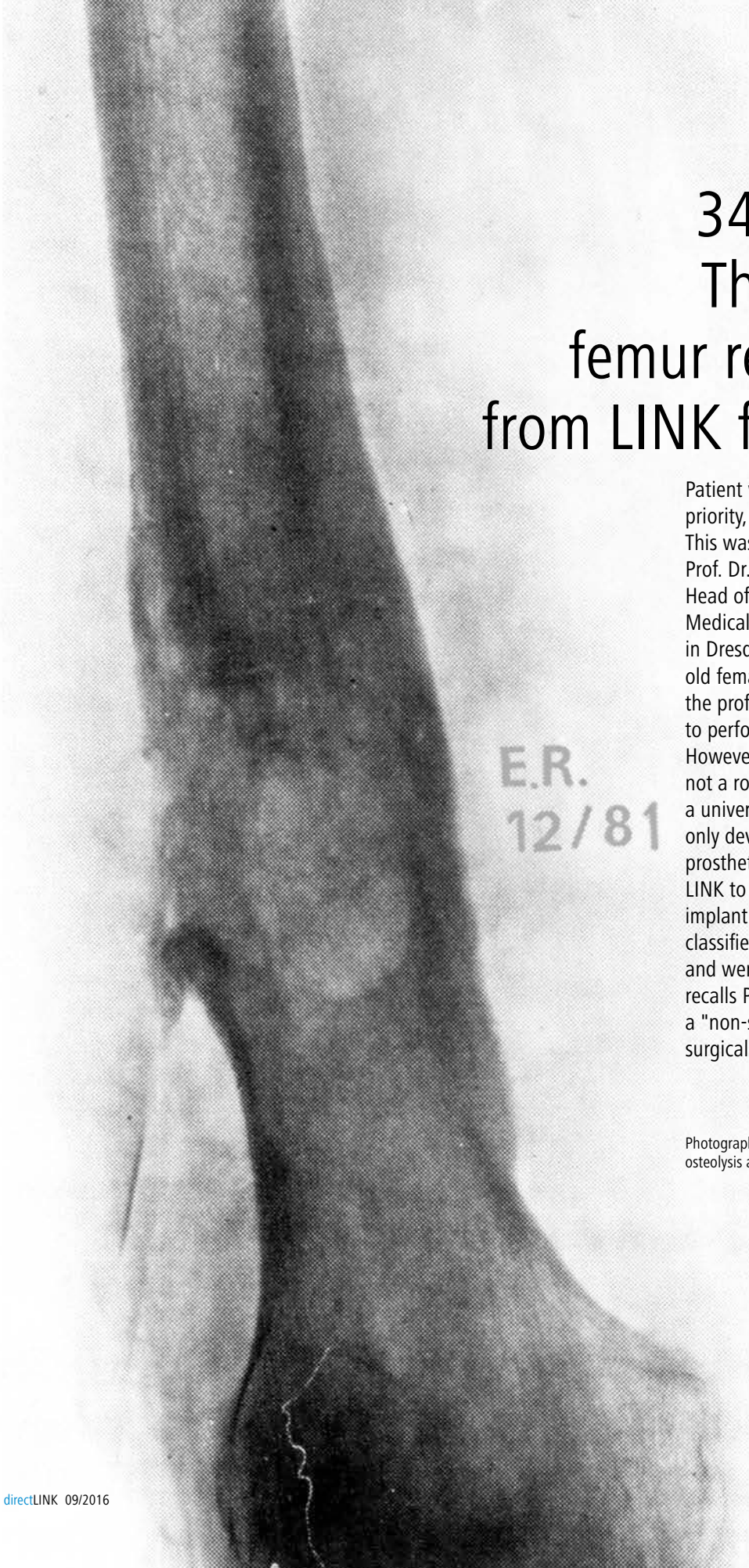








Postoperative images show the LINK® Endo-Model® Rotational and Hinge Knee Prosthesis in situ. 2.5 years postop the patient remains pain-free, with a ROM of 0–60 degrees, and walking without support



34 years ago: The first total femur replacement from LINK for the GDR

Patient well-being is always the priority, even ahead of power politics. This was demonstrated in 1982 by Prof. Dr. sc. med. Johannes Hellinger, Head of the Orthopedic Clinic of the Medical Academy "Carl Gustav Carus" in Dresden. In the case of a 73-year old female patient with osteosarcoma, the professor of orthopedics planned to perform a total femur replacement. However, in the early 1980s this was not a routine operation, even for a university hospital, and the GDR only developed standard models of prosthetic joints. So Hellinger asked LINK to produce a custom-made implant. "Joint prostheses were classified as medical devices in the GDR and were subject to import licenses," recalls Prof. Hellinger. With the help of a "non-socialist foreign country" the surgical procedure was successful.

Photograph: A.P. view of the right distal femur, with osteolysis and atypical sclerosis around the tumor

»However high the cost, the benefit to the patient compared with a high above-knee amputation was perfectly obvious: short rehabilitation time and preservation of the limb.«

Prof. Dr. sc. med. Johannes Hellinger

PROFILE

From 1974 to 1983 Professor of Orthopedics **Prof. Dr. sc. med. Johannes Hellinger** was Director of the Orthopedic Clinic of the Medical Academy "Carl Gustav Carus" in Dresden, Germany. He was responsible for the introduction and development of many new treatment techniques which shaped advances in orthopedics at the time, including internationally. He thus played a role in driving forward the progress of arthroplasty. In 1990 he set up his own practice as an orthopedic surgeon and also worked as a physician affiliated to Munich's Novamed-Klinik (today ISAR Klinikum). Prof. Hellinger ended his career in medicine with retirement from that hospital in 2011.

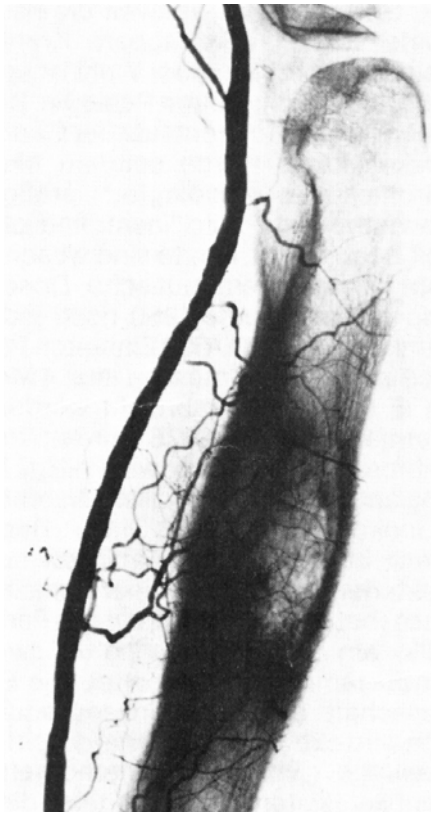
In the surgical treatment of primary malignant bone tumors in the 1970s and 1980s, the trend was towards preserving function while still performing radical removal of the tumor. And the GDR was no exception here. But it was generally only allografts prepared in various ways that were used to replace the bone, which resulted in lengthy immobilization periods for patients in the course of after-treatment. And where patients of an advanced age were concerned, this was not indicated due to the high risk of complications.

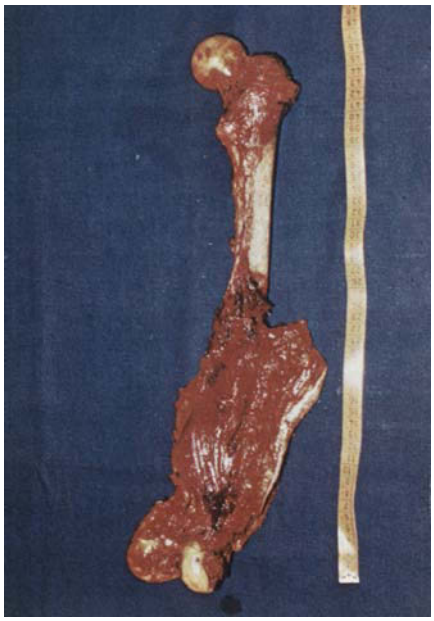
The alternative of amputation then came under discussion. "I was, however, of the opinion that in certain cases amputation could be replaced by a procedure that preserved function using alloplastic implants," explains Prof. Hellinger. "Fortunately, even in those days it was possible to preserve an entire bone plus adjacent joints if a skillful surgical technique was combined with high-quality joint prostheses fabricated on the basis of X-ray images. Thanks to its creativity, LINK was the right partner for such cases, including for surgeons in the GDR."

Thanks to its creativity, LINK was the right partner, including for surgeons in the GDR.

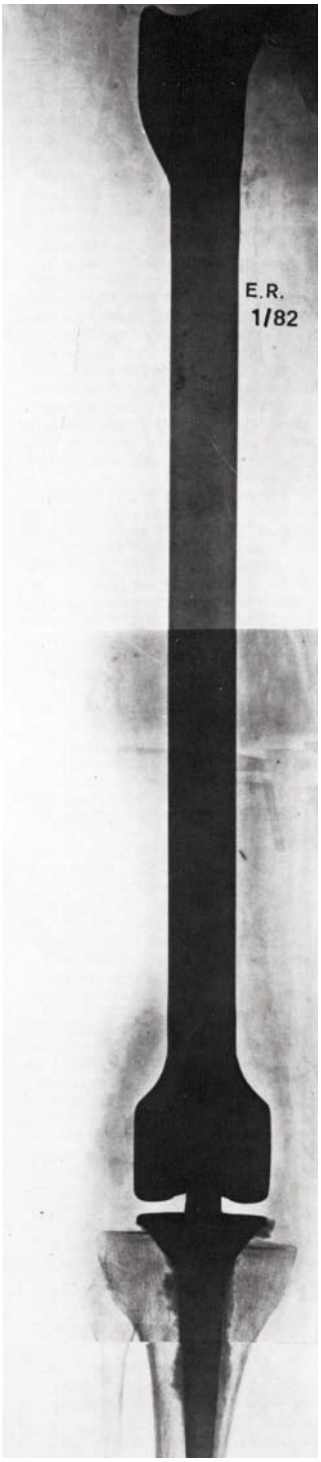
In 1982 cobalt-chromium cast alloys were already on the market. In a tried and tested combination with low-molecular low-density polyethylene and additional ceramic sliding bodies, they offered the requisite mechanical and tribological properties. "This was exactly what I was looking for," says Prof. Hellinger. "However high the cost, the benefit to the patient compared with a high above-knee amputation was perfectly obvious: short rehabilitation time and preservation of the limb."

Following removal of the tumor with the

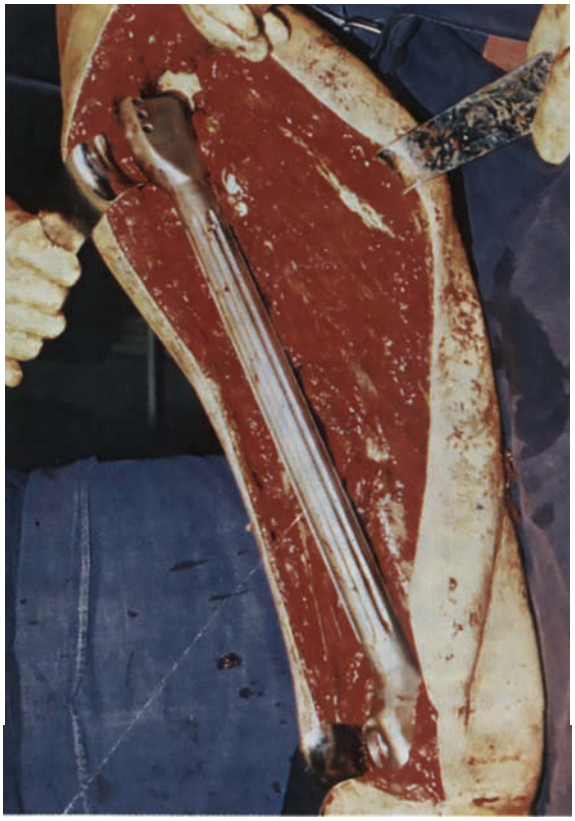


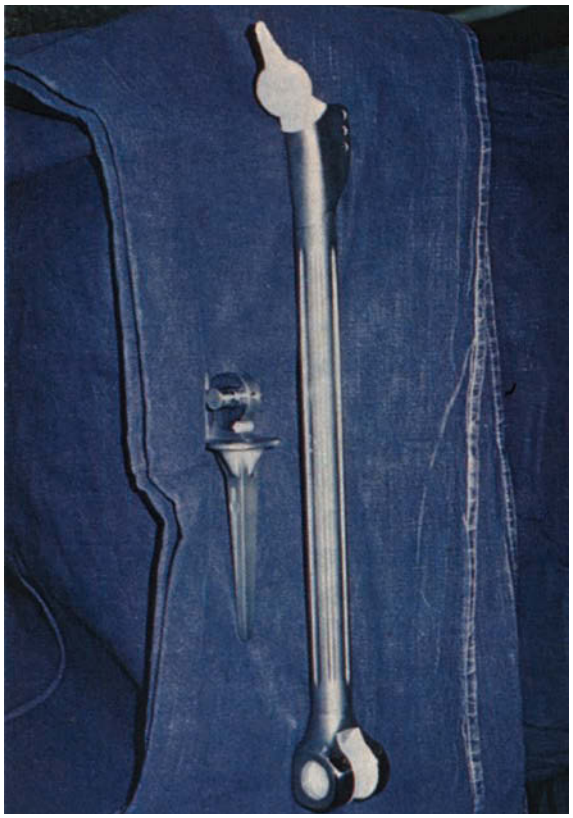


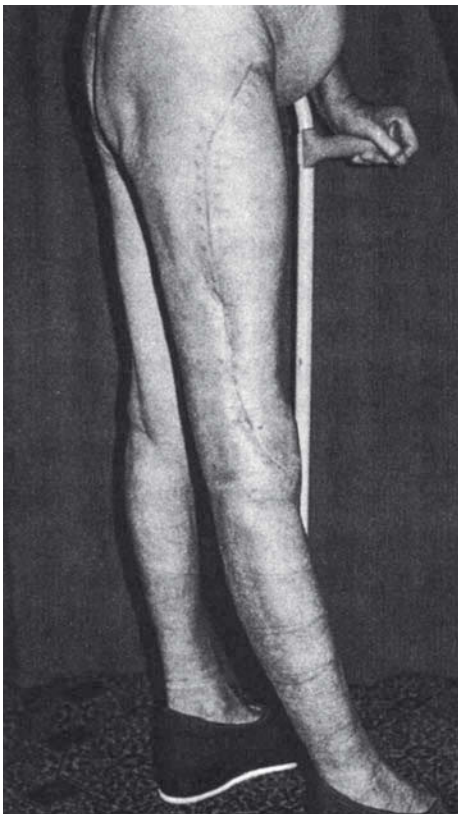
Photograph at top: Lateral angiogram of the distal femur, showing pathological vessels and displacement of the femoral artery, with arteriosclerotic changes (source: Radiology Department of Dresden Medical Academy)
Photograph at bottom: Extirpated right femur with excised skin and tumor in the distal section



Photograph at bottom: A.P. X-ray of the right femur, with total femoral prosthesis, cemented polyethylene acetabulum and knee joint hinge in situ (source: Radiology Department of Dresden Medical Academy)







femur in toto, the 73-year-old patient with osteosarcoma of the right distal end of the femur underwent total femur replacement with cementation of the knee and hip joint. Postoperatively, the patient experienced seroma formation and luxation of the prosthesis, but it was possible to overcome both complications. The patient was then supplied with walking aids and transferred to her local hospital for rehabilitation. The most recent radiographic follow-up showed that the prosthesis is well located. The patient went on to live for several more years, free of tumors and benefiting from an excellent functional outcome.

Photograph at top, center: Site of the operation with implanted hip and knee joint part
Photograph at bottom, center: Total femur replacement with a ceramic head, hinge joint for the knee joint supplied by LINK, and a polyethylene acetabulum (not shown here)
Photograph at bottom: Patient after wound healing, performing walking exercises

»An important factor for the outcome of the surgery is the ease with which good primary stability can be achieved.«

Prof. Dr. Kerem Basarir

INTERVIEW

Prof. Dr. Kerem Basarir is an orthopedic surgeon and Associate Professor at Ankara University, Turkey. In his clinical work he specializes in hip and knee arthroplasty, hip and knee revision surgery as well as femur and tumor surgery.

»The LCU® hip prosthesis system is simple to implant!«

An interview with Prof. Dr. Kerem Basarir about his impressions of the LINK® LCU® hip prosthesis system.

Professor Basarir, You have used the LINK® LCU® hip prosthesis system since 2013. What are your impressions of it to date?

I like this implant very much, above all when I choose the posterior access in complicated cases, such as with high luxations and severe deformities. In my view, however, the LCU® is also suitable for anterior access in uncomplicated primary cases. If the proximal metaphysis can be spared, I additionally use the LCU® for hip revisions with minimal bone defects.

What are the most important benefits of the LCU® hip prosthesis system?

In my opinion, the key benefits are the angled lateral shoulder, which permits preservation of the trochanter, and the HX® coating. The LCU® is also simple to implant, since the compressors are easily managed. If an implant system requires too many hand tools, it becomes more complicated to use, and teaching the relevant technique is also more difficult. The LCU® is simple and straightforward, so allowing the procedure to be carried out more quickly. It takes less than an hour to implant a cementless LCU® with a LINK® CombiCup® acetabular cup.

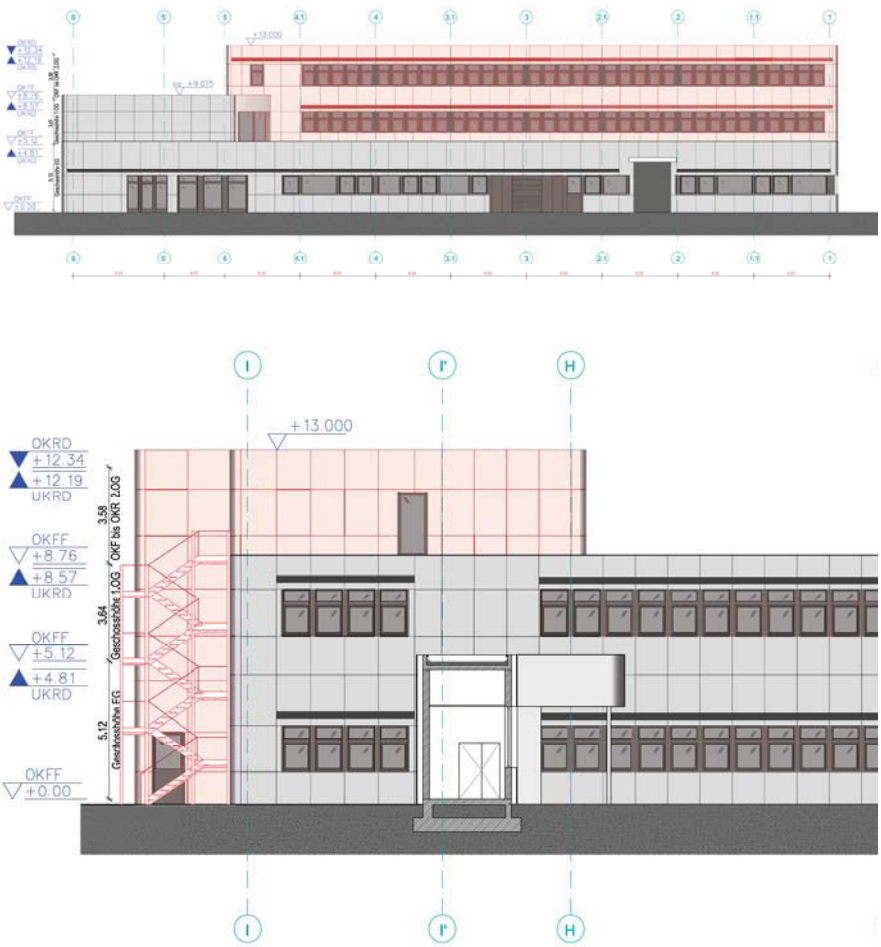
If we compare it with other cementless hip prosthesis systems of the Corail type, what are the differences?

One important factor for the outcome of the surgery is the ease with which good primary stability can be achieved. For this reason, I think the most important differences are the excellent primary stability offered by the LCU® and the ease of implantation.

Professor Basarir, many thanks for this interview.

LINK® LCU® Hip System with HX® coating or PoroLink® surface modification. To date, the LCU® has been used all over the world in 100,000 implantations performed by surgeons in 37 countries. And new countries are regularly being added.

LINK expands production



With completion of its new business premises in the middle of 2016, LINK has increased the production space at its Norderstedt site by 1,100 m². "By extending our building, we have also catered for the steady growth of our company in terms of floor space," comments company director Peter Willenborg. "In the last four years LINK has, on average, grown three times as fast as the market, and we are constantly hiring new staff." In coming years the LINK management anticipates an annual growth rate of between 8 and 12 percent.

To enable the necessary expansion of production space at the Norderstedt site, two storeys were added to the existing plant. The majority of staff from Production Control and the departments Custom Production, Surgical Instruments and HR now work from the offices on the new floors. "This has enabled us to free up additional production space," explains Peter Willenborg. "We are also concentrating as many employees as possible at one site: that makes for easier communication."

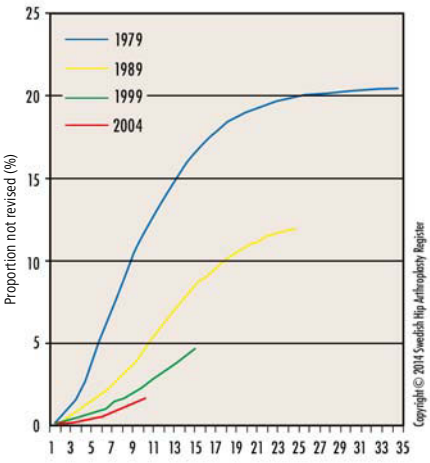
Health insurers promote the EPRD registry

Citing the success of the Swedish Register for revisions, health insurance providers in Germany now offer policyholders a first look into the EPRD arthroplasty registry in Germany. "If certain prostheses are defective, the registry could, for instance, act as an early warning system, so enabling hospitals to inform patients more quickly," commented Dr. Christoph Straub, Chairman of the Board at health insurer BARMER-GEK during a press conference held early February 2016.

In Sweden the number of hip revisions due to aseptic loosening fell from 18 percent in 1979 to 7.7 percent in 2006.[1] Besides improvements in surgical techniques, this positive development can also be attributed to the fact that Swedish orthopedic sur-

Aseptic loosening

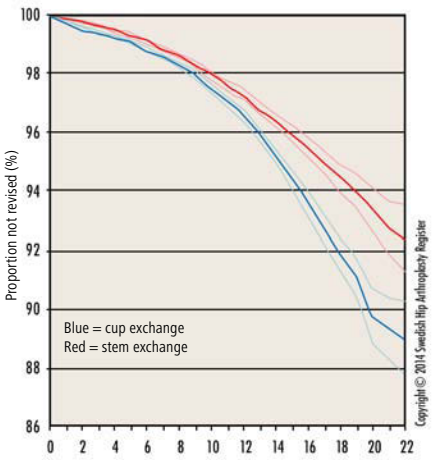
Cumulative revision frequency



In Sweden the number of hip revisions due to aseptic loosening fell from 18 percent in 1979 to 7.7 percent in 2006.

10,000 LINK® SP II® implanted in the Netherlands

LINK® SP II® Lubinus
Cup/stem revision - all diagnoses and all reasons



In Sweden the LINK® SP II® Lubinus® hip prosthesis was implanted in 86,643 cases from 1992 to 2013 and attained a survival rate of 92.4 percent at 22 years[2]

At Isala Klinieken in Zwolle, the Netherlands, a 70-year-old male patient recently underwent implantation of LINK's 10,000th SP II® Lubinus® hip prosthesis. The patient had also received an SP II® 25 years previously.

The LINK® SP II® stem is the most widely used cemented hip prosthesis stem in the Netherlands. Isala Klinieken has used implants from LINK for 30 years.

LINK SP II® stems are available in different lengths. Over the last 20 years, the "short" 130 mm stem has become the standard for primary and trauma surgery in the Netherlands.

In 2013 Dutch physicians published a study involving 932 SP II® stems which reported the 10-year outcomes for the 130 mm stem. According to this study, the "short" SP II® stems with a 10-year survival rate of 98.7 percent (95 percent CI: 99.7–97.7) functioned even better than the longer stems. The revision rate for the SP II® is thus lower than in Sweden, the home country of the arthroplasty registry. There the LINK® SP II® Lubinus® hip prosthesis had a survival rate of 92.4 percent after 22 years for a total of 86,643 implants.

The LINK® SP II® Lubinus® hip prosthesis has been awarded the 10A ODEP Rating.

LINK® SP II® Lubinus® model with the 130 mm stem

geons are increasingly concentrating on the most successful implants in the register. Where in 1979 some 60 different models of implant were available in Sweden, by 2001 there were just three, which accounted for over 90 percent of the market. The three top-performing implant models include the LINK® SP II® prosthesis, whose share far exceeds 50 percent.

Since 2013 the Swedish market has in fact been dominated by just two implants: leading the field is the LINK® SP II® with a market share of 56 percent.[3]

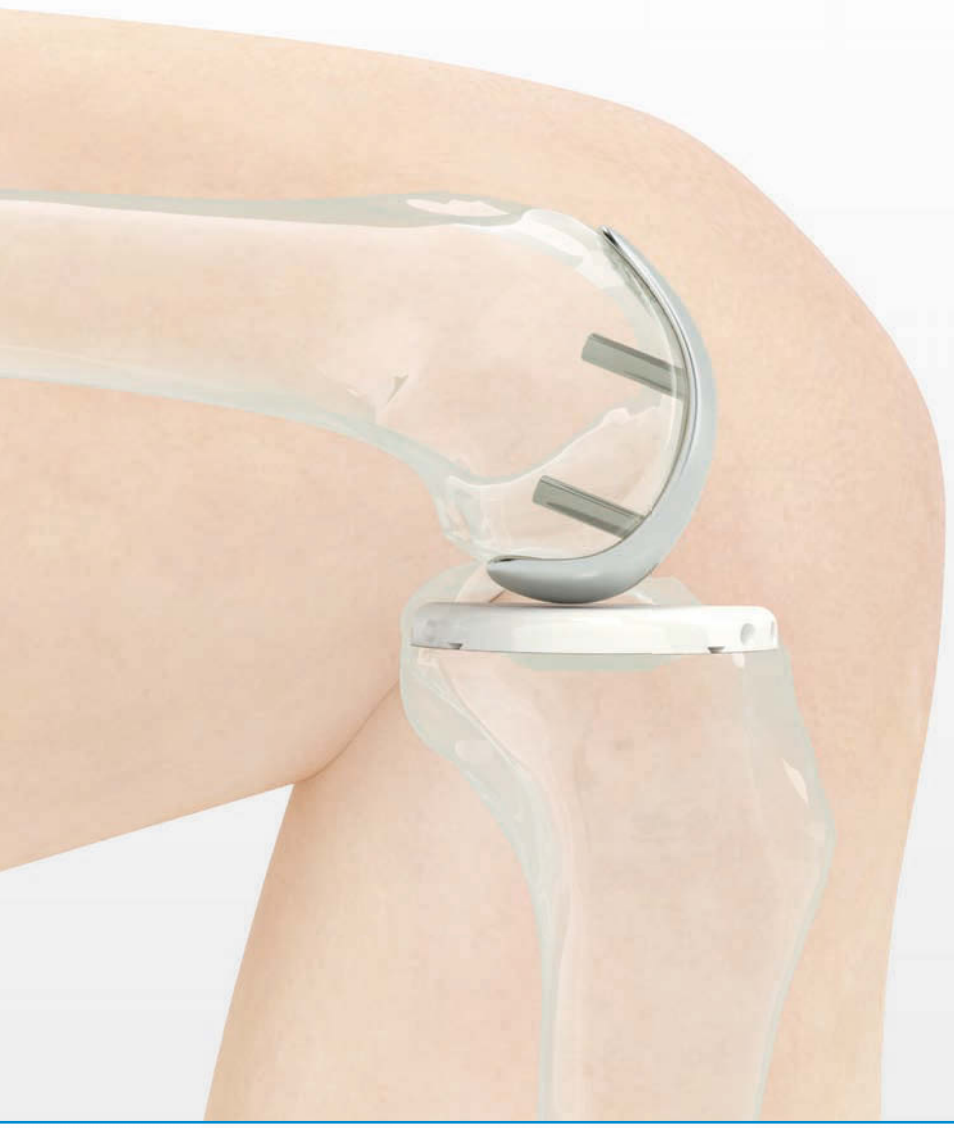
[1, 2, 3] Source: Annual Report 2013; Swedish Hip Arthroplasty Register; www.shpr.se.

[1] Source: Prins, Meijer, Kollen, Verheyen, Ettema: Excellent results with the cemented Lubinus SP II® 130-mm femoral stem at 10 years of follow-up; Department of Orthopedic Surgery and Traumatology, Isala Klinieken, Zwolle and Department of General Practice, University of Groningen, University Medical Centre Groningen, Groningen, the Netherlands; Acta Orthopaedica 2014; 85 (3): 276-279.

[2] Source: Annual Report 2013; Swedish Hip Arthroplasty Register; www.shpr.se.

Publication details

Published by: Waldemar Link GmbH & Co. KG · Helmut D. Link · Barkhausenweg 10 · 22339 Hamburg · Tel.: +49 40 53995-0 Fax: +49 40 5386929 · E-mail: redaktiondirectLINK@linkhh.de · www.linkorthopaedics.com · **Editor** (responsible): Heike Urbschat · Phone: +49 40 53995-0 · E-mail: redaktiondirectLINK@linkhh.de · **Editing/Design:** Dr. med. Michael Prang www.michaelprang.de · **Photography/Graphics:** Stefan Albrecht (Front cover, 1–5) · Prof. Dr. Kerem Basarir (25) · Prof. Dr. sc. med. Johannes Hellinger (22–24) · Markus Hertrich (10–12) · LINK (inside front cover & inside/outside back cover, 7, 15, 17, 25–26) · Dr. med. Michael Prang (13–14, 16, 18–19) · Prof. Faheem Sandhu (6–7) · The Swedish Hip Arthroplasty Register (26–27) · Dr. Kandasamy Velmurugan (20–21) · **Disclaimer:** The opinions of the interviewees do not necessarily reflect the views of the publisher.



LINK® SLED Prosthesis

NATURAL FIT

SIMPLE implantation • REPRODUCIBLE outcomes • RESULTS you can trust

The successful design of the LINK® SLED Prosthesis which was originally developed in 1969, has remained unchanged since its last modification in 1981. This extraordinary length of time and the outstanding long-term survival has been reported in *The Swedish Knee Arthroplasty Register**.

* Annual Report Swedish Knee Arthroplasty Register, www.myknee.se