directLINK®

Magazine for Arthroplasty · Issue: January 2016

»The LINK® MP® is an implant we trust!«

An interview with Dr. David G. Lewallen and Dr. Rafael J. Sierra about the increasing use of the LINK[®] MP[®] Reconstruction Prosthesis in the USA



The new cementless, anatomically adapted **SP-CL® Hip System from LINK** – to find out more, simply scan this QR code with your smartphone.

Megasystem-C[®]: LINK tumor prosthesis replaced by LINK[®] Megasystem-C[®] after 31 years LINK[®] Endo-Model[®]: earlier postoperative weight bearing, better long-term gait



A custom-made implant from LINK

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begins with a surgeon inquiring about a customized implant solution. Using precise, true-to-scale X-rays, our specialists from the department specializing in custom-made implants discuss the first details. The photograph shows the width of the tibia being measured to within a tenth of a millimeter. Some 2,000 custom-made implants are ordered from LINK each year.



Dear Readers:

Long-lasting technical developments do not happen every day. But they often remain in daily use for decades. An outstanding example – you might even say a "high-flier" – is the Boeing 747. The first steps in the development of this wide-body airliner were taken in 1965. Two years before that, Professor Hans-Wilhelm Buchholz and my father launched Germany's first total hip replacement.

Since those pioneering years, LINK has been developing and manufacturing implants that are used around the world – such as our MP[®] Reconstruction Prosthesis. In this issue, orthopedic surgeons Dr. David G. Lewallen and Dr. Rafael J. Sierra from the Mayo Clinic in Rochester, Minnesota, USA, report on the reasons why this prosthesis is chosen for revisions. In August, they visited our company and teamed up with distinguished European colleagues in our *Hip Revision Developer Group* with the aim of finding new solutions to familiar challenges.

The importance we attach to the development of long-lasting implants is also illustrated by our recruitment of Dr. Paolo Dalla Pria. In a personal interview, Dr. Paolo explains his passion for designing prostheses.

Enjoy this issue of directLINK. Regards.

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Helmut D. Link

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»The LINK[®] MP[®] is an implant we trust!«

At LINK's invitation, renowned orthopedic surgeons from the UK, Germany, and the USA met this summer in Hamburg to form the Hip Revision Developer Group with the aim of finding new solutions to old problems. We took the opportunity to talk to Dr. David G. Lewallen and Dr. Rafael J. Sierra from the Mayo Clinic in Rochester, Minnesota, about their hip revision philosophy, modular junction fractures, and the use of the LINK[®] MP[®] Reconstruction Prosthesis in the United States.

Dr. Lewallen, Dr. Sierra, do orthopedic surgeons in the USA have a special philosophy regarding hip revisions?

Dr. Sierra: Our philosophy is to preserve as much bone as possible. Around the femur, it is sometimes best to do an extended transfemoral osteotomy. In this way, you normally get the best fixation. By adopting a proximal approach, especially in more severe cases, we sometimes end up sacrificing valuable bone instead of preserving it. Dr. Lewallen: In the USA, well over ninety percent of revision hip arthroplasties are cementless. The trend over the past decade has confirmed the success of diaphyseal fixation on the femoral side. The main strategy to this end has been the extensive use of porous-coated, monoblock stems and modular tapered titanium stems such as the LINK® MP® prosthesis. With registry surveillance of implant performance, we now recognize that the best implants are those that have a good performance track record¹ of a decade or longer.

What ensures the high stability of the MP[®] prosthesis in hip revisions?

Dr. Lewallen: We learned very quickly that the LINK[®] MP[®] is a tool you can adapt to many different circumstances. We are also very pleased with the modular connection and have not encountered any major problems, such as fractures. That's a huge advantage.

Dr. Sierra: We trust the LINK[®] MP[®] because we know how good it is through the results we've achieved. Similar implants on the market have had some problems. From a safety perspective, we know that the LINK[®] MP[®] is an implant we can use.

¹ Rodriguez et al. – Reproducible fixation with a tapered, fluted, modular, titanium stem in revision hip arthroplasy at 8-15 years follow-up, The Journal of Arthroplasty 29 Suppl. 2 (2014) 214-218.



»In cases of severe bone loss, it is easier and safer to use a modular implant« – Dr. David G. Lewallen (left) and Dr. Rafael J. Sierra are members of the expert orthopedic surgery team at the Mayo Clinic in Rochester, Minnesota, USA



»I hope we will find solutions to some of the problems – for example, the balance between good osseointegration and revision friendliness. Implant fractures, however, are very rare. I do not see them as a relevant problem« – **Prof. Dr. med. Georg Matziolis** heads the Clinic for Orthopedics and Traumatology at Waldkrankenhaus Rudolf Elle in Eisenberg, Germany, and is a member of the Hip Revision Developer Group



»Concerning the LINK[®] MP[®] Reconstruction Prosthesis, we need to discuss some of the successes. It works well and the fixation is very good. There are a few areas, though, that we need to dive deeper into to find out what can be improved« – **Mr. Jonathan Miles** is Clinical Director of The Royal National Orthopaedic Hospital in Stanmore, UK, and is a member of the Hip Revision Developer Group

Generally speaking, are modular junction fractures in modular systems an issue in the USA?

Dr. Sierra: Our concern relates to fractures and corrosion which result from a combination of dissimilar metals and can involve fretting of the connections. As the MP[®] features broad contacts and identical metals, such as titanium, instances where any little bit of debris occurs in a titanium connection seem to be of no biological significance. In contrast, the chrome-cobalt modular connections are under intense scrutiny in that area right now. *Dr. Lewallen:* With regard to the unique MP[®] junction, we haven't really seen any problems with fractures or corrosion. The modular junction has been very good.

The MP[®] stem improves on the Wagner stem in terms of geometry and surface structure. Does that become evident in primary or secondary bone fixation? *Dr. Sierra:* For primary surgery, there are occasional issues aside from subsidence problems, but it's hard to argue that certain surfaces have gigantic advantages over others. The issue becomes much more critical when you have more limited areas of bone contact. In this case, the challenge involves the surface and the interface's mechanical stability. No matter what the material is, if it moves, the bone won't adhere to it. The MP[®] exceeds the interface requirements in terms of stability. We know that the more rigidly fixed and stable the interface is in the initial few weeks, the better chance the bone has of growing in and integrating into it. Osseointegration depends on the interface mechanics and the material. I think both are highly favorable with the MP[®] design.

»We trust the LINK[®] MP[®] because we know how good it is through the results we've achieved.«

When do you indicate the MP[®] stem at Mayo Clinic? *Dr. Sierra:* In 1999, the main revision stem used at our institution was a fully porous-coated, cylindrical, cobalt-chrome stem that is pretty rigid. Over time, the indications have expanded to include using fluid titanium stems like the MP[®] prosthesis. Today, we indicate both stems for the more complex cases.

To tell the truth, we also indicate the MP[®] for simpler cases. The light stem is very easy to implant and its modularity offers the versatility that comes with changing versions. It's also easier to teach it in simple cases. I teach it to fellows so they can use it when they have a harder case. I use the MP[®] almost exclusively except for straightforward revisions.

Dr. Lewallen: In cases of severe bone loss, it is easier and safer to use a modular implant. In the event of a proximal periprosthetic fracture or when a femoral osteotomy is required such that the proximal femur is open, it becomes much easier and safer to have a stem that properly fills the distal diaphysis. The stem also has a slight bend in it to accommodate the anatomical curvature of the femur. The most difficult cases, where I worry most about causing a fracture during implantation, involve more intact femora. However, in such situations we overcome this challenge by using shorter stems.

»We haven't really seen any problems with fractures or corrosion of the junction.«

Are there fixed rules for one-stage and two-stage revisions in the US?

Dr. Lewallen: We rarely perform two-stage operations that don't involve infection. The tools have improved such that the one-stage procedure fits almost all situations of bone loss or other difficulties. We have so many tools and such expanded options in terms of implant combinations that twostage procedures which do not involve infection are rarely needed.

Dr. Sierra: We're always going to be stuck with a certain number of two-stage exchanges. But given the higher risk involved, the approach needs to be individualized. In our institution, we perform some one-stage reconstructions for infection, but they're a little different. They tend to be done for elderly patients who may have medical comorbidities that make having several operations a really big deal.

Are there age requirements for primary and antiluxation implants in the US?

Dr. Lewallen: This is controversial. We have tried virtually all the constrained liners available and have seen failures with all of them. We continue to use them occasionally when the soft tissues are extremely deficient. For the most part, however, we have migrated, along with many other surgeons in the USA, toward expanded use of dual-mobility articulations. Our use of them tends to be in the revision setting for patients at extremely high risk for dislocations – for example, in the case of hip muscle paralysis, or something of similar extremity. It's very rare to see this in a primary setting.

Dr. Sierra: I think the frontier in this area will be going beyond the practice of trying to hit the average target for implant positioning. Surgeons don't always hit it. In the future we will have an individualized target. With pelvic tilt or degenerative scoliosis, for example, it'll be a different answer for the right hip and the left. What's the ideal target? We will be able to understand that and will have improved techniques for hitting the target. That will really be the next jump forward in preventing and treating dislocation.

How long do your patients stay hospitalized after an average revision surgery?

Dr. Sierra: We tend to mobilize the patients quickly in the hospital. We have them sit at the edge of the bed on the night after the surgery, unless it has been a very long operation where, for instance, there might have been blood loss. But in general, patients get up the next day and, with therapy, they are protected from mishaps. We don't have these long five, six, or seven days of bed rest that other institutions have.

Dr. Lewallen: Patients having more complicated revisions may be in hospital four or five nights. We live in the Midwest. Many people have intact families and support systems. Most of them are able to go home and take care of themselves with today's implants because we can fix the implants securely. We get them up walking and have them put at least partial weight on their hip. They work on exercises later.

Dr. Lewallen, Dr. Sierra, thank you.



powerlock

LINK[®] power**lock** – the better solution.

LINK[®] MP[®] Reconstruction Prosthesis.

Safety – No Morse Taper – no modular junction fatigue fractures
Strong – tested under worst-case scenario conditions without any proximal bone support
Fully proven – documented results since 1993 with more than 40,000 implantations¹ worldwide
Versatility – Full modularity in situ for every patient



»For all processes there is an optimum, if standards are agreed.« **Dr. Gunter Trojandt** is CEO of Surgical Process Institute Deutschland GmbH (SPI)

»Top-class medicine requires specific standards governing **processes!**«

Structured, digitized workflows in operating rooms can create considerable cost savings. An interview with Dr. Gunter Trojandt on the subject of processes, standards – and why your boiled egg is the result of optimized processes.

Dr. Trojandt, many hospitals in Germany are having to find savings, but not all of them succeed. Why is this? Some hospitals are already quite successful in identifying and implementing savings, but others are not, unfortunately. The problem is often that while many senior physicians have gained an understanding of the hospital administrator's job, too few administrators have familiarized themselves sufficiently with the medical procedures. Knowledge of workflows and processes is, however, a prerequisite for successful collaboration, which in turn generates cost savings.

In which areas is there still untapped potential for savings?

The first area to mention is that of processes. Today, patients are able to choose which hospital they go to for treatment because there is cut-throat competition out there. Whoever has the best concepts will gain the upper hand. If I'm in a position to promise the best medical care available any day of the week, then I will soon have more patients than my competitors. So the first priority is to be attractive to patients, and to fulfill the commitment to deliver top-class medicine at all times. But to achieve this you need specific standards governing processes in every department of the hospital.

»Today, patients in Germany can choose which hospital to go to for treatment. Whoever has the best concepts will gain the upper hand.«

How do standardized processes translate into cost savings?

Efficiency, which for hospitals means revenue minus costs, is determined by various process-related factors. For example, the length of time patients stay

in hospital, turnover times in the operating room, or the procedures for surgical interventions.

How might such a process look for implantation of a knee prosthesis?

For implantation of a knee prosthesis, we at SPI have developed a standard process comprising 50 individual steps. We discuss this process with the surgeons in order to tailor it to their specific requirements and their operating rooms: Which suture thread and which instruments are used in which situation? When is a photograph taken? And so on. Our customized software solutions then help the surgeon to implement each step of the tailor-made process. This approach soon produces improvements of 20 to 25 percent in operating room turnover times or incision-to-suture times. These improvements can be converted into tangible cost savings.

Recent innovations in arthroplasty have mainly dealt with surface modifications and instruments. Is now the time for processes?

Yes, in my view, the future will involve more the improvement of processes. When is the hip replacement fully loaded? When does the patient start his rehab? But another very important process is answering the question as to which implant system is used for which indications and which patients. Furthermore, we often see far too many instruments on the trays because each surgeon uses his or her own scissors and forceps. That means higher sterilization costs. However, if you define a strict process for tray management and then incorporate it into a standard, this saves time and money.

»One process is answering the question as to which implant system is used for which indications.«

Can standardized processes also help improve the quality of medical care?

Yes, I believe they can. Let's take the example of the operating room again. It contains lots of different machines that have to be operated by numerous surgeons, technicians and other personnel. This man-machine interface, with the thousands of parameters that can be set correctly or incorrectly, is becoming ever more complex. If you adopt a checklist system, like airline pilots, with defined standards that are systematically ticked off for each machine, then you avoid many mistakes right from the outset. This means that standards are even an important prerequisite for providing each individual patient with good medical care.

What advice do you give to hospitals which are looking to develop and implement cost-saving potential?

There are several ways in which hospitals can go about this. If, for example, a new surgical unit is being built, the processes should be developed before the technology is installed. Unfortunately, it is the other way round in most cases. 20 operating rooms are fully equipped with the latest, expensive technology, but nobody has bothered to think about the processes. As a consequence, once the unit is up and running, the medical staff constantly have to improvise, and that costs a lot of time and money. So before you build an operating room, everyone involved should first sit down and discuss the processes.

Once processes have been decided, can they be amended or expanded at a later date?

Yes, of course! All processes can and should preferably be optimized on an ongoing basis. This gives you a self-improving system. Nature shows us what is possible because nature itself is highly structured and standardized. In the natural world, there are only processes and systems that have reached an optimum at some point. For example, the shell of your boiled egg is hard enough to protect it but porous enough to be air-permeable. The yolk is secured by spiral bands. What's more, the egg is not round but oval to prevent it from falling out of the bird's nest. In my view, there is an optimum for all processes, and it is achieved when standards are agreed.

Many thanks, Dr. Trojandt.

»With good physiotherapy, the LINK[®] Endo-Model[®] can improve the patient's **gait**!«

Does the LINK[®] Endo-Model[®] Rotational Hinge Knee Prosthesis enable particularly early postoperative loading, and thereby a long-term improvement in gait? Physiotherapist Jeannette Maric and medical director Dr. med. Erwin Lenz report on their experiences.



Dr. med. Erwin Lenz is medical director of the Department of Revision Arthroplasty, Customized Prosthetics and Septic Revision Surgery at Rummelsberg Hospital in Schwarzenbruck, Germany; **Jeannette Maric** (pictured on a proprioception training device) is a physiotherapist with years of experience at the hospital

Dr. Lenz, does the LINK[®] Endo-Model[®] Knee Prosthesis System enable postoperative loading much earlier than usual?

No studies into this question have been conducted to date. But my impression is that the many intelligent design details incorporated into the Endo-Model[®] reflect the manufacturer's enormous experience in this field. These details make a difference! In fact, they can enable the patient to achieve particularly early postoperative weight bearing on the knee. Given good physiotherapy, this can have a positive effect on the patient's gait.

»The many intelligent design details incorporated into the Endo-Model[®] reflect the manufacturer's enormous experience in this field.«

Which versions of the Endo-Model[®] does this apply to? In my opinion, it applies to all versions, both for revisions and for primary arthroplasties in which a bicondylar sled prosthesis is not adequate. The Endo-Model[®] SL[®] provides the option of first implanting the stems and then making a decision whether to use a rotational or pure hinge knee prosthesis. How relevant this actually is, and how important, is difficult to say with certainty due to the lack of unambiguous study results. But, in my view, it does offer an additional, advantageous variation that is not available with other systems.

»Especially after a revision, an experienced physiotherapist is important!«

Are there also reasons in terms of the surgical procedure?

Yes, the design of the Endo-Model® Knee Prosthesis permits particularly sparing, relatively conservative bone resection, and therefore less discomfort for the patient. The less postoperative pain the patient experiences, the sooner he or she will have the confidence to load the knee during physiotherapy.

Does physiotherapy play a major part in the success of the surgery?

Yes, definitely. Arthroplasty surgeons for whom the knee joint is a particular specialty regard physiotherapy as extremely important. If the rehab does not go well, you can never compensate for it. Especially after a revision, an experienced physiotherapist is important. Otherwise the entire operation will not be any use!

Ms Maric, why is postoperative physiotherapy so very important?

Because targeted proprioceptive training is necessary for stability in the knee joint. The proprioceptors in the knee are stimulated by loading. Earlier

weight bearing allows earlier coordination training, for example where the patient has to compensate for irregularities on the floor. This requires proprioception and therefore leads to a confident gait. At the same time, however, the essential requirements for successful treatment are a good surgical outcome, optimal collaboration between surgeon and physiotherapist and, last but not least, hard work and commitment on the part of the patient.

Thank you, Ms Maric and Dr. Lenz.



the rotational and hinge knee prosthesis are based on the Endo-Model® solution, which has been used successfully for hinge knee arthroplasties for decades

LINK® Endo-Model® with a 10-year survival rate of 95 percent

The LINK[®] Endo-Model[®] has a 10-year survival rate of 95 percent in primary arthroplasties, according to the findings of the UK National Joint Registry (NJR)¹. The NJR documents the clinical outcomes of all currently used knee prostheses in the UK (at least ten arthroplasties in the last twelve months; at least ten implants with potential follow-up > 3 years). The LINK[®] Endo-Model[®] has been documented in the NJR for the first time.

¹ UK National Joint Registry; www.njrcentre.org.uk.

Tumor prosthesis from LINK replaced by LINK[®] Megasystem-C[®] after **31 years**

In 1984 an administrative worker, who is now 48, underwent a partial femur replacement in the right leg. After 30 symptom-free years, the patient presented at the outpatient department of the Dietrich Bonhoeffer Hospital (DBK) in Neubrandenburg/Altentreptow in January 2015 with increasing pain in the right knee joint. A case report by Dr. med. Dirk Ganzer, Director of Orthopedics and Traumatology at the DBK.



Postoperative X-rays of the right knee joint, radiographic follow-up 1990: custom-made partial femur replacement from LINK in situ

Surgical implantation of a partial femur replacement was performed at what was then the Berlin-Buch Hospital in East Berlin, in 1984. A bone tumor of the distal femur is given as the reason for the operation, but the patient no longer has any information about the tumor status. The research carried out by our hospital was unsuccessful because medical records at Berlin-Buch were only kept for 30 years. Having been free of symptoms for 30 years, the patient had not presented as an outpatient at any other hospital during this period, and therefore the search for previous findings proved fruitless.

No sign of implant loosening after 31 years

When the patient presented at our outpatient department, he reported swelling in the right knee joint, which had begun 18 months earlier and seemed to be growing, an increasing varus malalignment and a minimized flexion ability of the affected knee joint. The initial examination revealed a pronounced varus malalignment of the right leg axis and considerable medial instability. The right knee joint was acceptably mobile with an extension/flexion of 0/0/90°. A considerable knee joint effusion was also noted. Radiography showed a badly worn inlay of a cemented distal partial femur replacement. Furthermore, the



Preoperative X-rays of the right knee joint, June 2015: custom-made partial femur replacement from LINK, dating from 1984, in situ



Postoperative X-rays of the right knee joint, September 2015: new partial femur replacement with LINK Megasystem-C[®] in situ

X-ray indicated a possible fracture of the coupling mechanism of the hinge knee joint implant. There were no radiographic signs of loosening of the implant. A knee arthrocentesis was performed to rule out any periprosthetic infection; the subsequent microbiological analysis of the synovial fluid was negative.

New partial femur replacement with LINK Megasystem-C[®]

Up to this point, we had no information whatsoever about the manufacturer of the in-situ femoral prosthesis. Intraoperatively, however, we discovered that it was a custom-made implant from LINK, which had been available in the former GDR back in 1984.

The surgery also revealed badly worn bearing bushes of the constrained knee prosthesis, which led to secondary damage to the implant components. The implant itself was, however, firmly anchored in the cement bed even after 31 years, and great effort was required to remove it.

For the revision procedure we selected the modlar tumor and revision system LINK[®] Megasystem-C[®], which has proved very successful and is frequently used at our hospital. The patient was given a distal partial femoral replacement, which was implanted with cementless anchoring in the femur and cemented anchoring in the tibia. The immediate postoperative progress and further convalescence were uneventful.

Confident, unaided gait without crutches

In September 2015, the patient presented at our outpatient department for a follow-up examination three months postop. The exam revealed irritation-free functioning of the knee joint with an extension/flexion of 0/0/110°. The patient was weaned from crutches and was eventually able to walk confidently and unaided. He will shortly be returning to work. The patient is highly satisfied with the surgical outcome achieved.

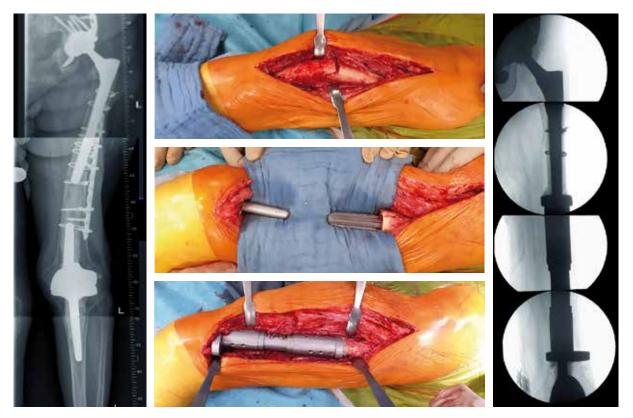


Contact:

Dr. med. Dirk Ganzer Director of Orthopedics and Traumatology Dietrich Bonhoeffer Hospital Neubrandenburg/Altentreptow, Germany ganzerd@dbknb.de

»Rescue Sleeves« from LINK permanently stabilize interprosthetic fractures!

Interprosthetic fractures can be successfully and permanently stabilized with special prostheses like the Rescue Sleeves from LINK – as confirmed by studies^{1, 2, 3, 4, 5}. Effective stabilization is also achieved when LINK prostheses are combined with implants from other manufacturers.



After interprosthetic fracture in situ: LINK Rescue Sleeves

The increasing use of stemmed prostheses today means that the stems of hip and knee prostheses often have to be coupled in the femur. According to Soenen et al.¹, the risk of interprosthetic fracture increases dramatically if the distance between the stem tips is less than 100 mm. Weiser et al.², on the other hand, concluded that the distance between the stem tips has scarcely any influence on the risk of fracture, but rather the bone quality of the cortex is the decisive factor.

Irrespective of the cause of these interprosthetic fractures, they can be effectively and permanently stabilized with custom-made prostheses. Very good results have been achieved with sleeve couplings, like the new Rescue Sleeves from LINK, for stemstem coupling.³ This applies both to LINK stems and to combinations of LINK prostheses with implants from other manufacturers.

Anatomical angle between the connection components is possible

Essentially, the sleeves can be either single-ended or double-ended (twin sleeve). In the case of the single-ended version, the component that is in contact with the sleeve can consist of an intramedullary stem or a joint component that anchors the prosthesis, which is held by the sleeve, in the medullary canal, or connects it to another joint. The double-ended sleeve, on the other hand, connects the two opposing stemmed prostheses following an interprosthetic fracture.

The sleeve can be designed so that an anatomical angle (varus/valgus) is provided in the lock of the connecting components. Sleeve connections of this kind entail a certain bone loss of 170-200 mm, but the coupling is so strong that the held prosthesis stem usually fractures before the connection fails. Furthermore, the joint regions in the knee or hip are not impaired by the intervention. Tests on the stability of the sleeve connection were performed by Professor Morlock, Director of the Institute of Biomechanics at Hamburg University of Technology (TUHH).⁴

To create the coupling, the holding sleeve is first filled with bone cement, then the prosthesis stem is

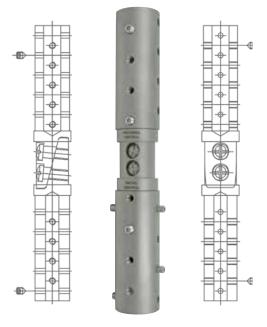
Study: Interposition sleeve (Rescue Sleeve) as a treatment option for interprosthetic femoral fractures

An interposition sleeve is an option for the treatment of interprosthetic femoral fractures when osteosynthesis is not possible or uncertain due to a major bone defects. This is the conclusion of a study ⁶ in which the six LINK[®] Lubinus Classic Plus[®] Hip Prostheses and LINK[®] Endo-Model[®]-M Knee Prostheses with different stem lengths were implanted with cement in bone specimens. Interprosthetic femoral fractures were then induced using a 4-point bending test. The fractures were repaired with an interposition sleeve from LINK before repeating the 4-point bending test. The load-to-failure of the prostheses prior to fracture was significantly higher than after treatment with the interposition sleeve (10681 N versus 5083 N; p = 0.002). The failure mechanism of the femurs in the bending test was a deformation of the hip and knee prostheses. The interposition sleeve did not fail with any construct.

pushed into the holding sleeve while the cement is still soft. Primary fixation of the stem is then achieved with the circumferentially arranged fixation screws. Once the cement has hardened, the result is a stable, loadable connection between the in-situ prosthesis stem and the sleeve prosthesis. Patel et al.⁵ describe a similar method, in which the stem of one prosthesis component has a sleeve at the anchoring end, and the sleeve is cannulated to provide better adhesion of the cement to the internal wall. The revision rate after 5.6 years is described as 6.7% for 15 patients.⁵

The new LINK "Rescue Sleeves" are available as custom-made products for individual patients.

- ² Weiser, L. et al "The role of interprosthetic fractures of the femur", JBJS Vol 96-B, No 10, Oct 2014, pp 1378-1384.
- ³ Citak, Mustafa et al "Treatment of interprosthetic femoral fractures with an interposition prosthesis", Acta Orthpedica 2013, 84 (3): 326-327.
- ⁴ Internal report by Prof. Michael M. Morlock, Publication in preparation.
- ⁵ Patel, Nirav K. et al "Custom-made Cement-Linked Mega Prostheses: A Salvage Solution for Complex Periprosthetic Femoral Fractures", The Journ. of Arth. 29 (2014) 204-209.



Available as a custom-made product: The **LINK twin sleeve** (**Rescue Sleeve**) consists of two parts which are adapted to the interprosthetic distance and fixed together by means of a connecting element

⁶ Weiser L., Korecki, M. A., Sellenschloh, K., Fensky, F., Püschel K., Morlock M.M., Rueger J.M., Lehmann W.: The interposition sleeve as a treatment option for interprosthetic fractures of the femur: a biomechanical in vitro assessment (Int Orthopaedics (SICOT), April 24, 2015).

¹ Soenen, Marc et al "Stemmed TKA in a Femur with a Total Hip Arthroplasty. Is there a safe distance between the stem tips?", Journ. of Arth., 28 (2013) 1437-1445.

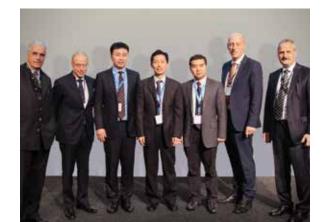


Learning about products, developing ideas, initiating projects – as every year, the LINK stand at the DKOU was the place where customers, colleagues and friends met for in-depth discussions

The **SP-CL® Hip System** and visitors from **China** are the focus of the **DKOU**

The new, anatomically adapted, cementless SP-CL[®] Hip System and the "Sino-German Academic Exchange" were the focal point for LINK at the German Congress of Orthopedics and Trauma Surgery (DKOU), held in October 2015 in Berlin. Visitors to the LINK stand were greeted with a fascinating holographic 3D presentation of the SP-CL[®] Hip System in HD quality. At a user symposium, a talk about the SP-CL[®] was given by Prof. Dr. med. Thorsten Gehrke, and was followed by a discussion of various aspects in connection with the new implant from LINK. Prof. Gehrke is Medical Director of the HELIOS ENDO-Klinik Hamburg and co-developer of the SP-CL[®].

Another highlight of the DKOU was a series of high-level presentations by a delegation of 57 orthopedic surgeons and traumatologists from China, who came to the DKOU under the umbrella



of the "Sino-German Academic Exchange". Cooperation between Chinese and German orthopedic surgeons has a long and successful track record. The aim is to build on this through close collaboration between Chinese and German orthopedic organizations such as the Chinese Orthopaedic Association (COA) and the German Society for Orthopaedics and Trauma (DGOU). LINK is actively promoting closer cooperation with Chinese orthopedic surgeons and their representative bodies, also with the aim of creating a counterbalance, with German influence, to the onesided Anglo-Saxon dominance in the world of orthopedics.



The new cementless, anatomically adapted **SP-CL® Hip System from LINK** – to find out more, simply scan this QR code with your smartphone.

Cultural and scientific aspects of closer cooperation between German and Chinese orthopedic organizations was at the heart of the "Sino-German Academic Exchange" at the DKOU – (l. to r.) **Prof. Dr. med. Wolfhart Puhl, Prof. Dr. med. Christoph Josten, Dr. Ma Jianbing, Dr. Zeng Yirong, Dr. Hou Zhiyong, Prof. Dr. med. Karl-Dieter Heller, Prof. Dr. med. Florian Gebhard**

At the invitation of LINK: 32 medical directors from China visit Germany



Medical Director **Dr. med. Klaus Lerch**, CEO **Nicolas von Oppen**, City Councillor **Rudolph Schnur** and the CEO of China's NATON **Lin Ying Zhao**, LINK Export Manager **Bülent Topal** and head of delegation **Prof. Huang Xiang Jie** (center, I to r) welcome the expert delegates in the ceremonial chamber of Landhut City Hall

At LINK's invitation, 32 orthopedic medical directors from China visited the Klinikum Landshut hospital. The aim of the meeting, which formed part of the 16th LINK Academic Sino-German Friendship Symposium, was to enable an exchange of knowledge and experience. During their stay, the guests from China were able to find out more about the latest prosthetic systems and various implantation techniques. In addition to the renowned tertiary referral centers at the HELIOS ENDO-Klinik in Hamburg and the Lubinus Clinicum in Kiel, another important institution in this field is the Department of Orthopedics and Traumatology at the Klinikum Landshut, headed by medical director Dr. med. Klaus Lerch. In the future, a LINK Academic Sino-German Friendship Symposium will be held as an annual event in Landshut.

Hans Georg Willert Prize 2015 for Professor Johan Kärrholm

Prof. Johan Kärrholm has been awarded the Hans Georg Willert Prize. Founded by Prof. Dr. med. Christoph Lohmann from LINK, the prize was presented by Helmut D. Link at the 63rd Annual Conference of the North German Association of Orthopedic Surgeons and Traumatologists (NOUV) held in Hamburg in June 2015. The Hans Georg Willert Prize has been awarded since 2012 in recognition of outstanding work in the field of arthroplasty. At the organizer's invitation, Helmut D. Link also gave a talk on implant protection against infections. The key message of his talk, held under the aegis of the AE (German Arthroplasty Association) Forum

Prof. Johan Kärrholm is head of the Department of Orthopaedics at Sahlgrenska Universitetssjukhuset at the University of Gothenburg; I. to r.: Prof. Dr. med. Christoph H. Lohmann, Helmut D. Link, Prof. Johan Kärrholm, Prof. Dr. med. Carsten Perka "Experts meet Experts. Prevention of periprosthetic infections", concerned infection prophylaxis as a decisive factor for the success of tumor and revision arthroplasty. Helmut D. Link informed the delegates about the positive clinical results achieved with the LINK surface modification PorAg[®]. His central thesis was, in summary: "The effectiveness of an oligodynamic surface modification is known and proven. It has a demonstrably lower toxicity, and with PorAg[®], no argyria occurred".

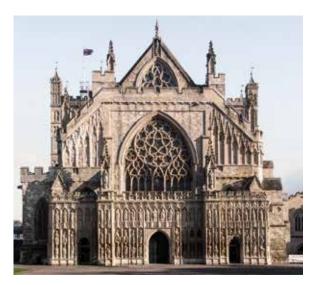


Leading Knee Experts at the »European Hinge Masters Meeting«

Leading experts from Europe met in June 2015, in Exeter, for the first "European Hinge Masters Meeting" to discuss selected aspects of knee arthroplasty. Below is a short report of this meeting.

Led by Mr. Andrew D. Toms, the participants discussed - among other aspects - knee and implant kinematics, soft-tissue reactions, fixation techniques, and the benefits of "hinge knees" with respect to the principle of "constrained condylar knees" (CCKs). Each expert put forward the case for his or her own views on selected issues. The focus of the meeting was the LINK[®] Endo-Model Rotational Knee Prosthesis and the CCK. Despite wide-ranging views on the indications for hinge knees, the experts agreed that the trend toward the use of such knee prostheses will continue. There was also a consensus agreement that - in terms of the force acting on the patella - the LINK® Endo-Model Rotational Knee Prosthesis is more akin to the natural knee joint than any other hinge knee prosthesis. However, some experts expressed their criticism on the over-frequent use of the CCK: "I revise a lot of CCKs; they have a lot more stress within a bone implant than a rotating hinge," said Dr. Pablo Sanz. "We use no CCK polyethylenes, just the implant with PS¹ or CR² polyethylene," Mr. Andrew D. Toms remarked.





The Cathedral Church of St. Peter in Exeter

Mr. Morgan Jones presented his position on knee ligaments: "If ligaments are there, balance them, if not, put a hinge in." Regarding the discussion to use shorter stems with the LINK[®] Endo-Model Rotational Knee Prosthesis to facilitate the use of less bone cement at a later revision, Mr. Keith Eyres recommended: "95 mm stems are short enough."

The next European Hinge Masters Meeting will be held in May 2016 in Verona.

¹ PS = Posterior-stabilized Polyethylene Insert. ² CR = Cruciate Retaining.

The participants of the first »European Hinge Masters Meeting« in Exeter were:

Mr. Simon Bridle – St. George's Teaching Hospital, London Mr. Tony Miles – Western Sussex NHS Foundation Trust, Sussex Mr. Peter Hull – Cambridge University Hospital, Cambridge Prof. Dr. Daniel Kendoff – HELIOS ENDO-Klinik, Hamburg Dr. Pablo Sanz – University Hospital Gregorio Marañon, Madrid Mr. Andrew D. Toms – Royal Devon and Exeter NHS Trust, Exeter Mr. Keith Eyres – Royal Devon and Exeter NHS Trust, Exeter Mr. Jonathan Phillips – Royal Devon and Exeter NHS Trust, Exeter Mr. R. Morgan Jones – University Hospital of Wales, Cardiff

Discussion within a select circle – the **European Hinge** Masters Meeting in Exeter, June 2015

»Spine Technology Award« and FDA approval for FacetLINK® in the USA

A successful year for FacetLINK[®]. LINK's new, minimally invasive stabilization system for the vertebral column, together with LINKSpine, a LINK subsidiary in the USA, has received the "Spine Technology Award 2015" in the "Minimally Invasive Spine Care" category. The annual award is presented for new technologies which have a high potential to improve treatment outcomes for patients. Only recently LINK received FDA approval for the system in the USA. The FacetLINK[®] components stabilize the segment of the spine that has undergone surgery, and support fusion. The HEMI implant allows stabilization and fusion of the segment to be performed via the decompression approach. The first HEMI implantation in the USA was performed in October 2015 by neurosurgeon Dr. Faheem Sandhu at the Medstar Southern Maryland Hospital Center in Clinton, Maryland. The patient was a 68-year-old man with degenerative spondylosis and severe central and lateral stenosis of L3–L5. Further information: Fabian Schöllchen, f.schoellchen@linkhh.de.

Study: **Knee arthrodesis** with coupled arthrodesis nail in the treatment of septic prosthesis failure

Knee arthrodesis is an acceptable method of limb preservation after failure of total knee arthroplasty due to infection. This is confirmed by a study ² in which 27 patients (10 female, mean age 68.8 years; 52 to 87), were treated with a single-stage LINK arthrodesis nail between 2002 and 2012. The mean follow-up duration was 67.1 months (24 tol43, n = 27), and the mean VAS score was 1.44 (SD 1.48). At the final follow-up, four patients had recurrent infections after arthrodesis (14.8%); of these, three patients were treated with a single-stage arthrodesis nail exchange. One of the three patients had an aseptic loosening which necessitated a third single-stage arthrodesis nail exchange. One patient underwent lower leg amputation due to uncontrolled sepsis at 108 months. All the patients stated that they would choose arthrodesis again. The data confirm that a single-stage knee arthrodesis offers an acceptable procedure for limb preservation procedure in cases of septic arthroplasty failure.

² Hawi N., Kendoff D., Citak M., Gehrke T., Haasper C.: Septic single-stage knee arthrodesis after failed total knee arthroplasty using a cemented coupled nail (Bone Joint J2015;97-B:649-53).

Study: **LINK[®] Endo-Model[®]** is a good option for elderly patients with instability following primary knee arthroplasty

Revision knee arthroplasty with a rotating hinge design is an option for the treatment of instability following primary knee arthroplasty. This was the conclusion reached by a study³ conducted by the Department of Orthopaedic Surgery, La Paz University Hospital in Madrid. The study evaluated 72 elderly women and 24 men who had received a LINK[®] Endo-Model[®] Knee Prosthesis System (Rotating Hinge) due to instability following primary knee arthroplasty. The average age of the patients was 79 (75-86); the minimum follow-up was 5 years (mean, 7.3 years; range, 5-10 years). The patients were evaluated clinically (Knee Society score) and radiographically (position of the prosthetic components, signs of loosening, bone loss). At a minimum follow-up of 5 years (mean 7.3 years, range, 5-10 years), the Knee Society pain scores improved from 37 preoperatively to 79 postoperatively. The function score rose from 34 to 53. ROM improved on average from -15° of extension and 80° of flexion before surgery to -5° of extension and 120° flexion at the last follow-up (p = 0.03). No cases of implant loosening were observed. One patient required re-operation because of a periprosthetic infection. Conclusion: Revision arthroplasty with a LINK[®] Endo-Model[®] Knee Prosthesis System provides substantial improvement in function and a reduction in pain in elderly patients with instability following primary knee arthroplasty.

³ E. Carlos Rodríguez-Merchán MD, PhD, Primitivo Gómez-Cardero MD, Ángel Martínez-Lloreda MD; Department of Orthopaedic Surgery, La Paz University Hospital, Paseo de la Castellana 261, 28046 Madrid, Spain; Journal of Clinical Orthopaedics and Trauma 6 (2015) 19-23

»LINK is growing fast in the **United States!**«

After a successful restart in the United States in 2013, LINK now sells premium implants to leading U.S. hospitals like the Mayo Clinic, Rush University Medical Center in Chicago, and the Hospital for Special Surgery in New York. Interview with LINK President and CEO Massimo Calafiore about products, sales figures, and why U.S. surgeons prefer LINK implants.

Mr. Calafiore, you are president and CEO of LINK-Spine and LINKBio in the United States. How do LINK products perform in one of the most challenging markets worldwide?

We started distributing LINK products directly again in the USA as of January 2013, when we decided not to renew the distribution agreement with Wright Medical and MicroPort. Since then we have been doubling our business every year with a staff of approximately 20 people.

What products does LINK sell in the USA?

Through LinkBio, we sell all LINK revision implants and all FDA-approved LINK primary products, as well as our surgical instruments. We recently obtained official approval to begin selling the LINK[®] Megasystem-C[®]. Our best-selling products are the LINK[®] MP[®] Reconstruction Prosthesis and Rotational Hinge Knee Endo-Model[®]. Of course, we also sell the new FacetLink[®] stabilization platform for the spine, which features fewer screws and smaller exposure. The FacetLink[®] system gathered great interest among U.S. spine surgeons. The system received FDA approval this year.



Does LINK pursue a special strategy in the USA?

The historical performance of LINK products speaks for itself. But we also have substantial evidence to show how well our products perform clinically. In addition, we try to differentiate ourselves from other companies. LINK is a familyowned company. We try to convey LINK's family values and culture to our surgeons and distributors. They like to be part of a close team in which everyone can make meaningful contributions to our projects. Our focus is on providing excellent product quality and supporting the people who make up our company. We want to show the world our abilities and prove to the market that we are here to become a major player. To that end, we are no longer seeking strategic alliances.

LINK sells its products to leading U.S. hospitals. Comparing LINK products to their U.S. competitors, what are the main differences?

U.S. surgeons are interested in and pay attention to our products because of the implants' performance and proven clinical success. They recognize that we come up with solutions that are more user-friendly in their view. We also own the entire production chain, which enables us to react to any change in the market quickly. Our management structure allows us to come up with quick answers to clinical needs and to develop new product ideas. Achieving this level of responsiveness in large companies is impossible.

Mr. Calafiore, thank you.

»LINKSpine works to develop simple, elegant solutions like Facet-LINK[®] for minimally invasive spine surgery.« Massimo Calafiore is president and CEO of LINKSpine and president of LINKBio. Helmut D. Link formed LINKSpine with the support of Massimo Calafiore in December 2010.

»I really like this job!«

Dr. Paolo Dalla Pria joined LINK a year ago to support the company as its International Research & Development Executive. In this interview he talks about his passion and motivation, and his philosophy when designing prostheses.

Dr. Dalla Pria, what is your job at LINK?

I am involved in developing new products, and also in improving existing products. For instance, I have quite an expertise in polyethylene, I work on finding better ways to sterilise and to crosslink this material.

What made you come from Italy to work with LINK?

LINK is the kind of company that I like working for. Not only because the people there are friendly and cooperative, but I really like it when a company is managed with a soul and a heart.

Why did you choose a career in implant technology?

When I was in high school, I had a passion for motorcycles and decided to become a mechanical engineer. Later I discovered an interest in medicine. So, I had to find something in between. Implant technology somehow merges mechanical engineering and medicine. This was in the mid-70's, and biomechanical concepts were not yet well known. That was very interesting for me!

What motivates you in your job?

I really like this job! I love designing prostheses. When I talk to a surgeon and he tells me that a prosthesis that I helped design works perfectly and that the patient is mobile again and happy – that is just the best satisfaction I can have in my professional life.

You also publish in scientific journals.

Yes, I like to communicate with surgeons, to receive questions from them and to discuss things with them. Surgeons have to understand some of the concepts of mechanical engineering and the



»As humans, we improve upon the past, always.« **Dr. Paolo Dalla Pria** supports LINK as its International Research & Development Executive. He lives in Udine, Italy

biology, physics, and biomechanics. So, for me as an engineer, it is my duty to find the right words and to talk to the surgeons.

What is your main philosophy when designing prostheses?

First, we have to know everything about the problems and the complications that have occurred. Then we need to know what works and what does not. In the end, we try to find a way to improve what already exists. As humans, we improve upon the past, always.

You are currently working on an upper limb tumor system. How is it going?

There are several tumor prostheses available in the market, but the prosthesis we at LINK are developing with Professor Rodolfo Capanna has something new. It incorporates some of the peculiar concepts of the lower limb tumor system. This really is an exciting project!

Dr. Dalla Pria, thank you.

»Our training never really ends!«

How does LINK train its sales representatives and product managers of the future? An interview with Angelika Müller and Björn Jäger about employers, training goals and aspirations.

10

ManCAs

Ms Müller, you recently completed a trainee program at LINK and are now a product manager. Where do you go from here?

I am now responsible for product management in the area of hand surgery and for surgical instruments from LINK. My personal goal is to expand the hand surgery portfolio and to deepen my knowledge in the field of surgical instruments and anatomy.

With your qualification in industrial business administration and your experience in arthroplasty, you had a choice of potential employers – so why did you choose LINK?

What is important to me is international contacts, a job that offers plenty of diversity, and direct contact with interesting people. I want to sell products that I can identify with, and implants have always interested me, ever since I began my training. LINK ticked all the boxes in terms of my job criteria.

Mr Jäger, you are a carpenter and a physiotherapist – having completed your trainee program, you are now starting out on a career as a medical device advisor in the LINK Sales department. How does that fit together? My great wish is to combine the technical side with the medical and also sales. I would like to work as part of a team and I enjoy traveling. It just happened to be in the field of arthroplasty that this came together. After six months I can safely say that applying for a job with LINK was a very good decision!

Why is that?

The corporate culture at LINK had a strong appeal. Members of staff are valued here, and that's something I quickly recognized. My colleagues are always willing to listen and I have found everyone very helpful.

Could you describe your traineeship at LINK?

Angelika Müller: I was given an overall training plan plus individual familiarization plans, and at the beginning I was also assigned a mentor. I then worked in various departments such as Quality Assurance and Production, and also attended surgical operations as an observer. I've seen everything from hip stems through to total femur arthroplasties. I was also given the opportunity to work without any supervision. "Learning by doing", in fact. That was excellent! *Björn Jäger:* It was much the same with me. For the first six months I alternated between inhouse training and visiting customers to give product presentations. Likewise, I always had an experienced colleague at my side.

What makes the Sales department at LINK so special for you, Mr Jäger?

We are always there when our customers need us. My impression is that everyone at LINK takes their job very seriously and goes about it with a passion and with creativity. Going the extra mile for the customer makes us a top-notch team of sales representatives and product managers. If we're in the middle of a training session, and the customer needs a specific implant, then we set about it immediately. You can rely on that.

Where do you see yourself in five years' time, Ms Müller?

Working and learning! Our training never really ends. We constantly have to demonstrate that we are capable of delivering what our customers expect from medical device advisors and product managers. In five years I'll certainly know even more about hand surgery and surgical instruments.

Many thanks Ms Müller and Mr Jäger.



»If our customers are able to give their patients optimal treatment, then we have achieved our goal« – Angelika Müller and Björn Jäger are setting out on their careers with LINK





SOM

A festival fit for a king!

The "King of Joint Prostheses" threw a party – and lots of other kings came along. Several hundred LINK staff members came to the Summer Festival held at the company premises on August 29, 2015. Many of them took the opportunity to take a look at LINK from a different perspective. The highlights included guided tours and a performance by the Hamburg cast of the musical "The Lion King". A big thank-you to everyone for their fantastic contribution to the success of LINK was expressed by the management, represented by Norbert Ostwald, Peter Willenborg and Rubia Link.



Production of a custom-made implant

keeps the team headed by precision engineers Günther Jendro (left) and Andreas Dänike busy for around two weeks. It involves numerous design and planning stages, computer-controlled machining, many hours of manual work, consultations with the surgeon who has ordered the implant plus several team meetings – like here at the X-ray viewer.

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Every LINK prosthesis fits perfectly!

There are no exceptions. So if the extensive LINK portfolio cannot offer the ideal prosthesis, a custom-made product is the best solution for the patient. The photograph shows the computer-generated 3D image of a LINK knee prosthesis with customized stems. Every year, LINK produces some 600 complete solutions like this for knee joints to customer specifications.