

INTERVIEW

»PATIENTS TODAY ARE WORRIED ABOUT INFECTIONS!«

Prof. Dr. med. Carsten Perka on the subject of revisions and why training is key to successful treatment of periprosthetic infections.

Case Report

Coupling of LINK® Endo-Model® Rotational Knee Prosthesis and MP® Reconstruction Prosthesis by means of RescueSleeve®

Quo vadis, LINK?

Interview with the management about current and future challenges

LINK® Endo-Model®

Prof. Carlos María Autorino interviewed about good proprioception following implantation of a LINK® Endo-Model® Hinge Knee Prosthesis



Staphylococcus aureus

and *Staphylococcus epidermidis* are two of the most common pathogens involved in periprosthetic infections (secondary electron image with 50,000x magnification)

Source: Agricultural Research Service, United States Dept. of Agriculture USDA (public domain)



Dear Readers:

Value chain is a widely used term in the world of economics. What it signifies is a sequence of activities which a business performs in order to develop, manufacture, sell and deliver products and to serve its customers.

Trust is an important link in the value chain, and its effects are felt both within a company and beyond.

Patients trust hospitals and doctors, who in turn trust their personnel. All of them trust the manufacturers of implants, such as LINK. For our part, we at LINK trust the qualities of our employees and, not least, we trust in the surgeons to use our products optimally. Trust is the corner stone of our company's success. It is also the starting point and basis of any good partnership.

If patients today are worried about infections, as you can read in the interview with Professor Carsten Perka about the treatment of periprosthetic infections, then it is the task of all of us to regain their trust and to show them that their fears are groundless in the great majority of cases.

LINK plays its part through our commitment to developing and producing nothing but high-quality implants. Furthermore, we control the value chain from development through to production of our joint prostheses, which enables us to guarantee consistently high quality. We also attach great importance to close and intensive collaboration with our customers so that their patients are able to benefit from unconventional arthroplasty solutions and the outstanding long-term results achieved with our prosthetic joints.

I hope you enjoy reading this issue of directLINK

Regards,

Helmut D. Link



»Patients today are worried about infections!«

Interview with Prof. Dr. med. Carsten Perka on the subject of revisions and why training is key to successful treatment of periprosthetic infections.

»Clinicians increasingly look for excellent registry data when selecting implants.«

Prof. Dr. med. Carsten Perka



Professor Perka, it is said that the number of knee and hip revisions is growing significantly. Can you confirm this?

You read that everywhere, but I don't actually believe it's true. In my view, today's joint prostheses are very good. Increasingly clinicians look for excellent registry data when it comes to selecting implants. As a result, the incidence of aseptic loosening as the main reason for revisions will decrease over the coming years.

Even though the absolute number of arthroplasties is rising?

The number of hip and knee arthroplasties is at a very high level, and will therefore only increase by 3 percent a year, at most. But this is not reflected in a growth in revision cases, due to the durability of the implants.

What is the situation with periprosthetic infections as the cause of revisions?

Currently, the declining incidence of aseptic loosening has to be set against an increase in cases of periprosthetic infections and fractures. In these areas, we will see more revisions, but in the final analysis there is no significant increase in revisions.

Periprosthetic infections are a core problem for the next few years. What are the reasons for this?

Some periprosthetic infections occur in connection with the surgery, by which I mean when the surgeon's skills and the capabilities of the implant are overestimated, leading to early infections. Optimization of the implants, combined with simpler handling, has in theory reduced the incidence of such infections. On the other hand, diagnostics have improved greatly, so more cases are now detected. Last but not least, modern implants have a higher survival, and this is a factor because hematogenous infections become more common with increasing age.

Is there also a problem with regard to specialist training?

Yes, the main problem is correct diagnosis of a periprosthetic infection, even though our methods are better than ever. If the patient's only symptom is pain – many low-grade infections are only detected because of pain – they are only given physiotherapy which they don't actually need. In other cases, a joint puncture is performed, but the synovial fluid is only cultured for two days instead of two weeks, even though only around 30 percent

INTERVIEW

Prof. Dr. med. Carsten Perka is Medical Director of the Center for Musculoskeletal Surgery at the Center for Orthopedics of the Charité – Universitätsmedizin Berlin, Campus Mitte.

of the bacteria will in fact grow in the first two days. There are many things that need to be considered. Specialist training for surgeons is tremendously important.

What specifically do hospitals need to change?

Hospitals must create the necessary conditions for correctly diagnosing and treating periprosthetic infections. The DRG system of hospital reimbursement specifies that each hospital has to deal with their own complications so that one is incentivized to do better next time. However, this does not work if patients suffering from complications are not just treated at the hospital which caused the

complications. That is also a major problem.

What do you want to see happen?

The treatment of periprosthetic infections is extremely complex. For that reason, it would be wrong, in my view, for complications to be treated at the hospital where they occurred in the first place. Considering the resources needed for effective infection therapy, the orthopedic surgeon is integrated into a team of specialists, including microbiologists, for example, who are experienced in the relevant diagnostics. Then you need an infectious disease specialist who initiates and monitors the high-dose antibiotic

therapy, a pathologist who can evaluate the tissue samples during the surgery, etc. There are many factors which determine whether treatment of periprosthetic infections is successful, but not every hospital can afford the extra specialist staff. So I would like to see large, central institutions with a high level of expertise. Furthermore, there must be appropriate financial rewards which at least makes it possible to break even.

What are the challenges in terms of specialist training?

Training is the greatest challenge faced by orthopedics and traumatology, especially in Germany. In Canada and the USA, the training is paid. Those countries have paid trainees plus additional funding because everybody knows that training costs money. That's not the case here in Germany. Under the DRG system, only those hospitals that are highly specialized and have large numbers of patients actually earn anything.

What needs to change?

Training must be much more widespread. A specialist in orthopedics and traumatology must be able to perform joint-preserving measures. They must know what can be done, from arthroscopy all the way to pelvic osteotomy, in order to preserve a hip joint, for example. One should also understand that the causes of many orthopedic problems are not always located precisely where the patient is experiencing pain. But this means that you need to have trained in the whole field, from hand and shoulder surgery to spinal surgery and traumatology. Unfortunately, that is not the case in Germany at the present time.

Why is that?

Because many hospitals are not interested in offering joint-preserving pelvic surgery, for example, as they would lose money if they did. In addition, specialist training means sacrificing free time, and

not every surgeon is willing to do that anymore. The number of junior doctors who regularly attend such training is shrinking drastically. The surgical intervention is not difficult, but you do have to learn how to do it. Unfortunately, our current training system is not ideal.

What is the current trend with regard to revision implants?

These implants are becoming better and better, both the material and the surfaces. Modular prosthesis systems have already made great progress. This means that we have increasing flexibility to adapt a prosthesis intraoperatively to suit the bone defect. That's extremely good! The other factor is the surfaces. They integrate into the bone much better than in the past. For revisions the implant situation is close to becoming ideal.

Does this mean that revisions have also become simpler?

Yes, today's revision prostheses allow a high degree of intraoperative flexibility. With the LINK® MEGASYSTEM-C®, for example, it is possible to build up everything, from knee to pelvis. The robustness and simplicity of these implants are unbeatable – these are important advantages, in my view.

So the drivers for successful revisions are materials, surfaces, modularity and training?

Yes, but training is the number one priority. Revisions are relatively simple to perform if you are systematic and utilize the capabilities offered by the implants. When problems occur in revisions, it is almost never due to a lack of surgical skills, but rather it is for conceptual reasons. Before every surgery, a surgeon must ask himself certain questions: What is the nature of the situation? Which prosthesis do I need, and which instruments? What are all the things that can theoretically happen? Every time you operate, you need a plan A, but also a plan B and C.

Let us turn to multiresistant bacteria. What is the current situation there?

MRSA and MRSE are often talked about as major problem bacteria, but we have got these under control relatively well. There are other bacteria that are often more difficult to deal with, but which are not encountered so frequently.

What does your hospital do to avoid infections?

For us, decontamination has proved extremely successful. Patients are given a disinfectant, with which they shower the day before surgery, possibly again on the actual day, and for up to five days afterwards. We believe that this can reduce the incidence of periprosthetic infections by a factor of two.

Does this mean that the source of infections has shifted from the hospital to the patient?

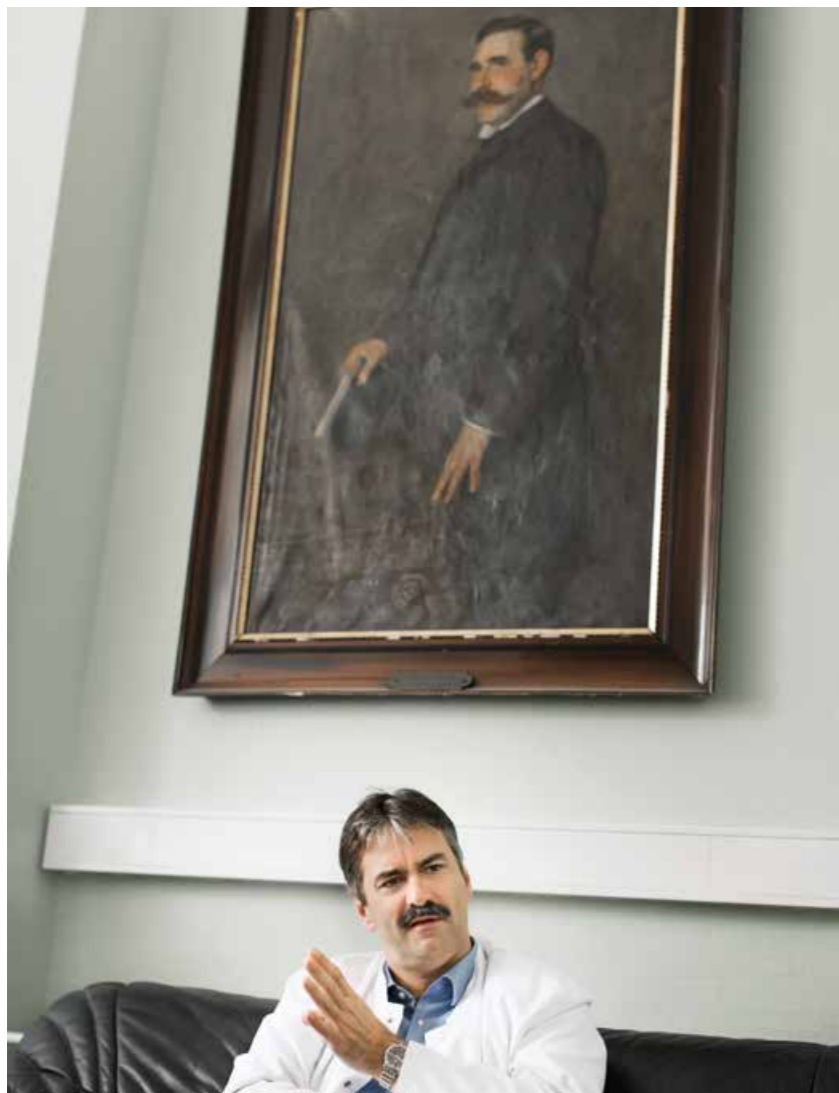
It is indeed often the case that the patient is carrying the bacteria on some part of their body. We now know how often infected teeth or a chronic urinary tract infection, for example, can represent a problem. But something will definitely change because patients have increasingly high expectations. Ten years ago, our patients were worried about pain. Today their greatest fear is infections.

Professor Perka, many thanks for this interview.



»The treatment of periprosthetic infections is extremely complex!«

Prof. Dr. med. Carsten Perka





»A key to any successful arthroplasty is an excellent surgical technique!«

A conversation with Dr. Rafael Llopis Miró about knee arthroplasties in Spain, and how to prevent periprosthetic joint infections.

INTERVIEW

Dr. Rafael Llopis Miró is Director of the Instituto del Aparato Locomotor of the Sanatorio San Francisco de Asís in Madrid, which is a reference clinic for knee and hip surgery in Spain. Dr. Llopis Miró is regarded as a pioneer of orthopedic surgery in the development of new techniques for the treatment of osteoarthritis of the hip and knee through the replacement of these joints.

Dr. Llopis Miró, you implant the LINK® GEMINI® SL® Total Knee Replacement in primary cases, and the LINK® Endo-Model® Rotational and Hinge Knee Prosthesis in revision cases. What is your opinion of these prostheses?

In my experience, they are both very good implants and the surgery is very easy to perform. I also use the LINK® MP® Reconstruction Prosthesis in difficult revision cases.

What role does the unicondylar knee replacement play in your country?

I think the market for unicondylars in primary arthroplasties in Spain is less than five percent of total knee replacements, despite of the many advantages. They are extremely bone-preserving on the femur, they preserve the ligamentous apparatus well, and they require a short rehabilitation time. Even so, in Spain, only few surgeons are convinced of this.

Is there any age limit for a unicondylar knee prosthesis?

No, I think a unicondylar knee prosthesis can be the best choice for older as well as

younger people. But the right indication is mandatory, which is osteoarthritis in the medial or lateral compartments alone, with no osteoarthritis in the femoral patella joint or on the other side of the joint. The key to any successful arthroplasty is the right indication and an excellent surgical technique.

Why do you think Spanish surgeons stay away from unicondylar knees?

Lack of proper training. The operation is quite difficult to perform when you are not very experienced. However, once you establish a routine with a sufficient volume, implanting a unicondylar knee prosthesis feels easy. Also, there are very good instruments that support an easy implantation.

Talking about difficult cases: What is the situation with periprosthetic joint infections in Spain?

We don't have very good data yet, but in our hospital the incidence of periprosthetic infections is less than 0.8 percent. In our institution, we are very focused on prevention and strict adherence to the protocols.

How do you reduce the risk of periprosthetic joint infections?

Our first step is a strict policy of closed doors in the operating rooms. Second, we thoroughly prepare the patient, with pre-operative washing with chlorhexidine 48 hours prior to surgery. We also screen patients for infection foci such as urinary and oral infections. If necessary, we delay the surgery until the patient is clear of infection. Steps three and four in our protocol are to perform a very clean surgery, and to provide very good post-operative care.

In case of a severe periprosthetic joint infection, do you prefer a one- or a two-stage revision?

I prefer two-stage exchanges, because at

the moment they are giving us much better results. My personal point of view is that hospitals who perform one-stage exchanges mostly do it because of the cost implications. But perhaps protocols do not allow everyone to do one-stage surgery. Special training is a prerequisite for this kind of surgery too, and you need to have a specialized team.

What is your advice for younger surgeons?

It's very important to know what you are going to do in an operation, and to have a very good training base where you can find everything you will need in surgery. Bring the patient into the hospital before surgery to screen and prepare him well. A good surgical technique and very good post-operative care with a special rehabilitation program are important too.

Dr. Llopis, thank you for the interview.



»The Sanatorio San Francisco de Asís in Madrid focuses on surgery of the upper and lower limbs, especially hips and knees. We take difficult cases from other regions in Spain and sometimes even from overseas« **Dr. Rafael Llopis Miró**

»Once you know how to implant a unicondylar knee prosthesis, it's easy!«

Dr. Rafael Llopis Miró



Dr. Héctor M. Depetris

»The excellent survival rate of the LINK® SLED Prosthesis convinced me!«

Dr. Depetris, you have been using unicondylar knee replacement implants for more than 18 years. Since 2013, you have been using the LINK® SLED Prosthesis. What led you to choose this implant?

The Swedish Knee Arthroplasty Register* shows that the LINK® SLED Prosthesis has an excellent 10-year survival rate. Moreover it is used as a reference product for measuring the performance of all other unicondylar knees. These were my main reasons for using the unicondylar knee from LINK as soon as it became available in Argentina three years ago. I perform about 50 UKA per year, and the LINK® SLED Prosthesis is the main implant in my portfolio.

What is the main advantage of the LINK® SLED Prosthesis?

Good bone preservation is one of the main advantages of unicondylar knees in general. The unicondylar knee from LINK is extremely bone-preserving on the femoral side, and it is very good on the tibial side too. That enables me to restore the normal biomechanics of the patient's knee and improve the patient's mobility in an optimal way. In connection with the minimally invasive surgical MITUS®-technique, the LINK® SLED Prosthesis not only preserves bone but also avoids damaging the soft tissue.

That leads to a shorter recovery time after surgery and a faster discharge from hospital?

Yes, that is correct. After the surgery is finished and the spinal anesthesia has worn off,

my patients are normally allowed to perch on the edge of the bed. Shortly after that, they can walk and bear their full weight as long as they use crutches. Soon the patients begin noticing that their leg is in the correct alignment and that their knee is more stable than before. With this implant, the patient's satisfaction levels are great.

Dr. Depetris, thank you very much for talking to us.



In the Annual Report 2015 of The Swedish Knee Arthroplasty Register the LINK® SLED® Prosthesis features the lowest revision risk with 2,321 implantations in the time period from 2004 to 2013
www.myknee.se/en/

INTERVIEW

Dr. Héctor M. Depetris is an orthopedic surgeon specializing in hip and knee pathology. He is the Director of the Hip and Knee Depetris Center in Rosario, Argentina.

»A strict search and destroy protocol is key for a low MRSA burden!«

Dr. Wagenaar, the MRSA burden in Holland and Scandinavia is 1.2 to 1.6¹ percent, significantly lower than in any other country in Europe. Why?

The key is the commitment to a strict »search-and-destroy« protocol for potential MRSA patients and a strictly regulated antibiotic regime for hospitals and general practitioners. Both have been customary in Holland for several years.

How does the search-and-destroy approach work?

Our goal is to prevent as many MRSA transmissions in hospitals as possible. We check patients but also health care workers, and our protocol cornerstones are active surveillance, adequate quarantine, and proper treatment of MRSA carriers. All patients and health care workers are screened for their MRSA risk. When at high risk, they are tested, treated and quarantined until they are decolonized. They are considered free of MRSA only after they have been tested several times with negative results. Patients from hospitals abroad are put into quarantine until the MRSA cultures return to negative.

Are hospital doctors in Holland stricter with antibiotics due to the guidelines?

They are generally strict with antibiotics. Each antibiotic prescribed in a hospital in Holland is screened by the microbiologist and pharmacist, who controls it, checks it, and gives advice on dosage and type of antibiotic.

Other countries have guidelines too.

Applying guidelines requires a complete change of attitude from surgeons, from veterinarians who deliver too many antibiotics to livestock, and from patients who buy antibiotics over the internet without prescription. But it takes time to raise awareness about proper antibiotic use.

How often do MRSA infections occur with a periprosthetic infection?

In one study², MRSA and MRSE accounted for 14 percent of infected total knee arthroplasties. Another study³ reported that 34 percent of periprosthetic joint infections were caused by MRSA or MRSE. When the periprosthetic joint infection rate is higher than 2 percent, I believe you should look for factors that could account for the higher percentage of infections. In Holland we have a low infection rate of 1.1 percent for hip and 0.6 percent for knee arthroplasties. Of these infections, only 1.4-1.6% involve a multiresistant pathogen, including MRSA.

What do you think about silver coatings for the prevention of biofilm, like PorAG® from LINK?

It's a very interesting concept and could be a valuable addition given the potential advantages. But I think it's still too early to use it routinely. We will see!

Dr. Wagenaar, thank you very much for talking to us.



Dr. Frank-Christiaan Wagenaar

INTERVIEW

Dr. Frank-Christiaan Wagenaar is a consultant orthopaedic surgeon at OCON Orthopedic Clinic, a national referral centre for periprosthetic joint infections and revision arthroplasty surgery in Hengelo, Holland. His prime speciality is knee arthroplasty and revision knee arthroplasty, including infections. He is also one of the initiators of the workgroup on orthopedic infections of the Dutch Orthopedic Society.

¹ www.ecdc.europa.eu
² Parvizi J. et al. Periprosthetic infection due to resistant staphylococci: serious problem in horizon. (2009) Clin Orthop Relat Res 467(7):1732-1739.
³ Mittal Y. et al. Two-stage reimplantation for periprosthetic knee infection involving resistant organisms. (2007) J Bone Joint Surg Am 89(6):1227-1231.



Proprioception: »Patients with LINK Endo-Model® achieved the exact same scores as patients using PS knees with a mild deformity«

How does proprioception develop in patients with knee osteoarthritis after a total knee replacement (TKR), when comparing a posterior stabilized with a rotational hinge knee prosthesis? An Interview with Professor Carlos María Autorino.

Professor Autorino, you researched the proprioception before and after TKR, using a posterior stabilized (PS) and a rotational hinge knee prosthesis. What are your conclusions?

When we started our prospective multicentric study¹, our hypothesis was that the functional lower limb impairment, locomotor capacity, and proprioception improved after TKR using posterior stabilized or rotational hinge knee prostheses, such as the LINK® Endo-Model®. Our findings are that TKR improves knee joint proprioception which results in better functional performance, regardless of the type of constraint. That means that the LINK® Endo-Model® can improve proprioception in patients with greater deformities.

On what basis did you design the study?

We have a complex scenario because functional consequences of impaired proprioception may include shorter stride length, changes in gait pattern, and increased risk of falls with a potential consequence of bone fracture. As the risk of fall is directly related to sensory motor function, it inspired us to study the capacity for restoration that we can provide for patients with severe knee joint deformities.

What was the study design?

We gathered three groups of patients, all of whom had a diagnosis of osteoarthritis and were undergoing a TKR. All procedures were performed by the same trained

»Patients with the most severe deformity, who received the LINK® Endo-Model®, have quicker rehabilitation, even when starting with poorer scores.«

Prof. Carlos María Autorino

surgeons in the Hospital Universitario Austral and Banco de Prótesis. In the first two groups, altogether 64 patients received conventional PS knee implants from Exactech and DePuy. They had minor deformities with stable knees and sufficient bone stock. In the third group, there were 12 patients receiving the LINK® Endo-Model® Rotational Hinge Knee Prosthesis and all participants had a major deformity with more than a 20 degree varus/valgus deformity, ligament instability, and segmental uncontained bone stock loss.

How did you measure the impact the devices had on proprioception?

We preoperatively performed a questionnaire recording subjective perception of knee instability. Also, we measured functional evaluation, including the Knee Society Score (KSS), an angular deviation precision test, a Timed Up and Go Test (TUG), and a Four Square Step Test (FSST). All patients were evaluated preoperatively and postoperatively for 12 weeks. We assessed proprioception by asking the patients to reproduce a limb position in the sagittal plane at full extension, 20 degree and 40 degrees, and measured the angular deviation.

What were your results?

We recorded statistical differences between the three groups. All patients returned to normal after TKR despite the bad preoperative scores of patients with severe instabilities. This means that patients with LINK Endo-Model® achieved the exact same scores as patients using PS knees with a mild deformity.

What influence does postoperative rehabilitation have on proprioception?

It is very important to continue the rehabilitation program for at least six months for all patients. In patients with a lesser deformity, the restoration of proprioception increased after the third or

fourth month. Interestingly patients receiving the LINK® Endo-Model® have a quicker rehabilitation already at the second or third month compared to patients with PS knee. Finding out why will be the topic of our next study.

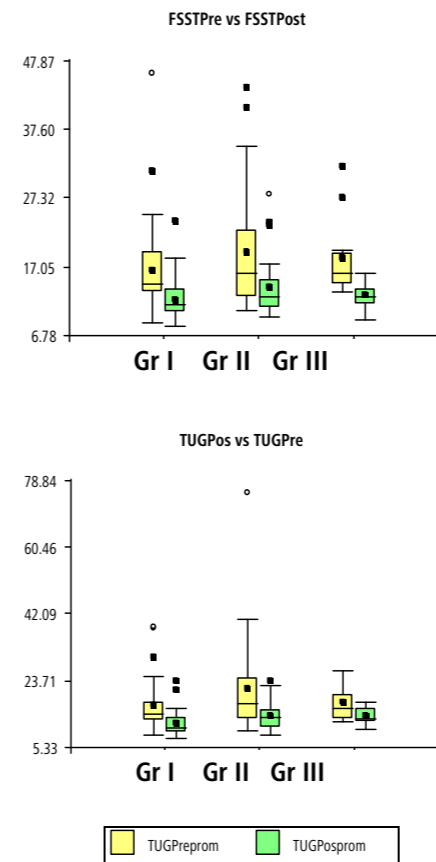
Does this study disprove the idea that higher constraint can mean worse proprioception?

Yes, there are surgeons who should use a hinge knee but don't. They instead use a PS design, thinking that the patient will have a freer and better proprioception. If they would know about the superior performance in proprioception, these surgeons will also be confident in indicating a LINK® Endo-Model®. They will have all the benefits of the stability and long-term results but also will have the benefit of good patient satisfaction. Proprioception plays an important role because you reduce the risk of fall and increase the satisfaction of the patient.

Does that also disprove the old concept of a rotating hinge knee being only a last resort when other knee revision surgeries have failed?

I would say so. The hinge knee has good patient satisfaction and can be used in a normal setting, alternative to a PS. Basically, higher constraint, in the case of the LINK® Endo-Model®, does not necessarily mean worse proprioception.

Professor Autorino, thank you very much for talking to us.



In all three groups, the TUG and FSST dynamic standing balance tests improved after surgery

¹ Autorino C. M., Alvarez Salinas E., Sormani M., Chiotta Romano M., Rivarola Etcheto H., Motta F.: COMPARISON OF POSTERIOR STABILIZED AND ROTATIONAL HINGED KNEE PROSTHESIS; Hospital Universitario Austral. Buenos Aires, Argentina; Banco de Prótesis. Montevideo, Uruguay



»Quickly restoring mobility with LINK® Internal Hallux Fixator!«

What is so special about the Internal Hallux Fixator from LINK? An interview with Dr. med. Holger Fröhlich about patients' worries, postoperative weight bearing and follow-up treatment.

Dr. Fröhlich, what worries and fears do patients have when they come to you presenting with a hallux valgus?

Patients are often unsure about what the best solution is. Many have friends or family members who have undergone surgery for hallux valgus and are not satisfied with the outcome. What patients expect is an aesthetic improvement plus freedom from pain and no complications.

What do you tell them?

First of all, I carry out clinical-radiological diagnostics and gather information about accompanying illnesses, such as circulatory disorders or diabetes mellitus, for example. Depending on the stage of the deformity, I decide which procedure

is suitable for the patient. In many cases surgical correction is necessary in order to achieve an optimal aesthetic and functional outcome for the affected foot.

You frequently use the LINK® Internal Hallux Fixator for correcting hallux valgus. Why is that?

It is true that I use the LINK® Internal Hallux Fixator most often because of the good outcomes and its versatility. The key advantage of this method is that the patient can fully load the foot immediately after the surgery. In contrast, many alternative procedures require complete or partial postoperative weight bearing on the treated foot for several weeks. Often a special forefoot relief shoe has to

»The key advantage of the LINK® Internal Hallux Fixator is that the patient is able to load the foot immediately after the procedure.«

Dr. med. Holger Fröhlich



The LINK® Internal Hallux Fixator is available in three versions (3, 5 and 7 mm) with the arm plane offset in order to achieve the desired lateralization of the metatarsal head (top). Implantation of the Internal Fixator gives internal splinting with three support points; functional loading ensures stable osteosynthesis (center). The arms of the implant are able to move in the longitudinal axis to accommodate the impaction of the metatarsal head caused by functional loading (bottom, E).

INTERVIEW

Dr. med. Holger Fröhlich is a specialist in General Surgery, Orthopedics, Special Traumatology and Sport Medicine. He has his own practice in Altenburg, Germany. The range of treatments provided comprises many ambulatory procedures, rehabilitative training therapies, treatment of industrial and travel injuries, medical assessments and a private orthopedic consultancy. An area in which he specializes is surgery for hallux valgus.

be worn. This is not necessary with corrective surgery using the LINK® Internal Hallux Fixator.

Why can the patient fully load the foot immediately after the operation?

The ability to fully load is thanks to the spring mechanism of the clasp of the Internal Hallux Fixator from LINK. This clasp is inserted into the metatarsal shaft via an intramedullary approach. The two undulating arms are pretensioned and therefore provide stable anchoring in the medullary canal, which prevents rotation and tipping. The distal end is screwed tightly to the metatarsal head, giving angular stability, and is impacted again, thereby creating firm contact. In order to lateralize the metatarsal head in the plane of the fixator arms, three different versions from 3 mm to 7 mm are available. I almost never have to shorten or adapt the clasp! The complete procedure takes 20 to 30 minutes.

When is an Akin osteotomy advisable in addition to the fixator?

If there is an axial deviation in the interphalangeal joint of the hallux in addition to the hallux valgus, an Akin osteotomy of the proximal phalanx is also required. This intervention is easily combined with implantation of the LINK® Internal Hallux Fixator. Although this has rarely been necessary in my patients to date, I have achieved very good surgical outcomes in this way.

How is the follow-up treatment?

The patient is fitted with a surgical shoe, and is then able to go home about an hour after corrective surgery with the Hallux Fixator. They are able to fully load the foot. I regularly prescribe postoperative lymph drainage, which ensures that any local swelling quickly recedes. Once the wound has healed, the patient can walk in trekking sandals, sneakers or simply a comfortable pair of shoes. Early functional follow-up treatment produces

rapid osseous integration. After four to six weeks, most patients are able to return to work. A jogger, for example, can start running again after around eight weeks. These are also important advantages of the LINK® Internal Hallux Fixator.

How long would it take to remove the implant again after the bone has healed?

Removing the fixator and screw takes around ten minutes. I always perform this procedure under local anesthetic and sterile conditions via a small stab incision, under x-ray control.

How are the long-term surgical outcomes?

Excellent! Our complication rate is minimal, even in older patients with accompanying illnesses. Postoperative swelling often occurs due to the localization of the surgical site, but that is a known phenomenon of forefoot surgery. Up to now I have not had to perform any revision procedures on account of pseudarthrosis. I'm convinced that the LINK® Internal Hallux Fixator will continue to prove itself in the coming decades!

Dr. Fröhlich, many thanks for this interview.



»Especially the core products from LINK are well received by surgeons in the USA.«

Norbert Ostwald

»LINK is a full service provider, and is growing three times faster than the market!«

In past years, LINK has invested heavily in research, development and production. How successful is this strategy?

Peter Willenborg Very successful. LINK has been growing by over 9 percent each year on average, which is three times faster than the market. In our focus markets, we are firmly established as a full-service provider. We are confident in maintaining this strong growth because we produce high-quality products very

efficiently. Many new LINK products are already on the market or about to be launched. Our investment is the basis for the successful long-term development of our company.

Norbert Ostwald In Germany we have been operating in a very difficult environment for years now because of falling prices, and also because buying groups and hospital chains are looking to reduce the number of suppliers they use. In spite of this, LINK is also achieving stable

growth here in Germany. In China, our largest focus market, we continue our market leadership with more than 20 percent share of the hospital market.

How is the US market developing?

Norbert Ostwald We have been very successful in the US market since we initiated a new strategy in 2014 and established direct sales through our own company there. Especially the core products from LINK, which produce outstanding results

and enjoy long-term success, are very well received by US surgeons because they demonstrate the quality that LINK is able to deliver. If we continue like this, we will soon be able to count the USA as one of our major markets. We will soon be seeing additional LINK products in the US market.

Mrs. Link-Lesniewicz, you are the principal shareholder of the LINK companies and also belong to the extended management team. How would you describe your role?

Rubia Link-Lesniewicz We have a shareholders' meeting up to four times a year, at which we deal with strategic matters and long-term planning. Since I do not live in Hamburg, I am not involved in the day-to-day running of the business. Nevertheless, I keep a close eye on the company's operations and ask lots of questions. For me it is important to ensure that we are always going in the right direction operationally, and know when and where to make adjustments if necessary. My father

is still active in the running of the business.

Mr Link, your family-owned business has a worldwide reputation for the very high quality of your products. Does that make the job of running the company easier?

Helmut D. Link Our customers expect quality from us, and that is what we deliver. Perhaps that makes it a bit easier for us than for the competition. In Europe, evidence-based medicine is becoming increasingly important. Consequently, in some countries, only products that offer outstanding long-term results are sold. That is something that especially benefits a company like LINK, as a well established supplier of very successful products. But at the same time, this has its pro's and con's.

Why is that?

Helmut D. Link The development of new implants almost always means evolution rather than revolution. For example, we have just developed a new acetabular cup system which at first sight, does not look

INTERVIEW

How well is family-owned LINK doing? What challenges do the years ahead hold in store? What strategy is LINK following in order to prepare for the future? An interview with LINK shareholders Rubia Link-Lesniewicz and Helmut D. Link and Managing Directors Norbert Ostwald and Peter Willenborg.



»In Germany, we have been operating in a difficult environment for years. In spite of this, LINK is also achieving stable growth here in Germany.« *Norbert Ostwald is the CEO of Waldemar Link GmbH & Co. KG, VACUCAST Feinguss GmbH & Co. Metall KG and the R&D company called DERU GmbH*



»Many new LINK products are already on the market or about to be launched. In our focus markets, we are well established as full-service providers.« *Peter Willenborg is the CFO of Waldemar Link GmbH & Co. KG and on the board of several foreign subsidiaries of in the LINK Group*

»New regulations are imposing such strict licensing requirements that some important products will simply disappear!«

Peter Willenborg



Asking questions and actively shaping the company – Rubia Link-Lesniewicz is the principal shareholder of the LINK Group

very different from the existing version, but in detail, it offers more than its predecessor. One always develops new products on the basis of existing models and their results. Unfortunately the regulatory bodies recognize this all too rarely. They regard every implant as if it were a completely new development. It doesn't make sense if products that have been very successful in the market for 20 or 30 years have to be tested again just to satisfy the bureaucrats.

America's Food and Drug Administration (FDA), which has a reputation for being very strict, apparently is less bureaucratic.

Helmut D. Link It's encouraging that the FDA is considering to include real-world data when assessing licensing applications. In the USA, they have recognized that trials and studies often deliver subjective results, while the knowledge gained from long years of practical experience with existing products is actually more significant, especially for recertifications. I would like to see the same approach adopted in Germany and the rest of Europe.

Does a difficult regulatory environment pose an obstacle to development?

Peter Willenborg It creates a serious obstacle



He has prepared his family-owned business for the next generation, but remains active in the day-to-day running of the company – Helmut D. Link

to development. New regulations are imposing such strict requirements that some important products for small numbers of treatments are unattractive and will soon disappear from the market. The current regulations for manufacturers almost defy belief, and the costs of regulatory approval are not consistent with the expected revenue. LINK has a range of such quality products which are often the last resort for surgeons, for example to keep a patient's leg from being amputated. Remaining sound in this difficult environment as a manufacturer of high-quality prostheses with a major commitment to R&D is our number one challenge!

Another challenge is the price pressure.

Norbert Ostwald Yes, price pressure will continue in the hip and knee segments. So, as a company, we are well advised to keep production costs under control and to streamline our organizational structures. For years, we have followed a clear strategy, and we do not intend to depart from it. In the field of hip and knee prostheses, we provide our customers a complete range, concentrating on our anatomically adapted products. Of course, we are also considering other joints and other market segments.



Together they ensure that LINK continues to flourish – Helmut D. Link, Rubia Link-Lesniewicz, Norbert Ostwald, Peter Willenborg

What will we be talking about in five years?

Norbert Ostwald There are lots of exciting new LINK products which will soon be ready for the market. And there are new production methods such as 3 D printing. That opens up new possibilities in terms of products and the production process. *Helmut D. Link* I hope that we will be able to tackle many of the issues and challenges in arthroplasty with these new technologies. Important developments from LINK will be targeted at periprosthetic infections and osseointegration, for example.

Mr. Link, two years ago you said in an interview that your family-owned business aims to one day join the ranks of the four major players in the sector. How close is LINK to achieving this objective?

Helmut D. Link On the product side, we have achieved this objective because we are a full-service provider with very diverse product groups and a wide choice within these groups. We are even further ahead with regard to the development of products that will drive medical advancement. In terms of sales, we are making much greater progress than a number of years ago. And, not least, a lot more highly skilled personnel from this sector are moving to us than in the past. This shows that we are a very attractive employer. So we're on the right path.

Norbert Ostwald LINK has several outstanding brands. If you ask anyone in Europe to name the best-known cemented hips, they will immediately mention the SP II® from LINK. Or ask anywhere in the world for the name of a revision knee joint prosthesis, and many orthopedic surgeons will cite the LINK® Endo-Model®. So I believe that the name LINK, and therefore the brand, already has the quality it takes to be mentioned in the same breath as the top four in this sector.

Mrs. Link-Lesniewicz, your company being mentioned in the same breath as the top four in the sector. What does that mean to you?

Rubia Link-Lesniewicz It makes me incredibly proud! Our company has always been like a big sister for me. Together with my father and our top-notch management team, we shall make sure that the big sister continues to flourish, and that we remain a very successful family-owned business.

Mrs. Link-Lesniewicz, Mr. Link, Mr. Ostwald, Mr. Willenborg – thank you all for talking to us.

»In the USA, the FDA has recognized that the knowledge gained from long years of practical experience with products is actually more meaningful than tests and studies.«

Helmut D. Link



LINK CEO Norbert Ostwald (4th from l.) with the BPJ founders Yingzhao Lin (4th from r.) and Yiwu Zhao (6th from r.) and BPJ members of staff

»We are looking forward to the next 20 years in China!«

LINK is in a market-leading position in China for imported prosthetic joints, and has a 20 percent market share in hospitals there. One reason for this success, is the close cooperation with BPJ (Beijing Power Joint) in Beijing. In 2016 LINK and BPJ celebrated the 20th anniversary of their successful partnership. LINK CEO Norbert Ostwald reviews how it came about.

The success story of LINK and BPJ in China began with an Export Manager from LINK and two Chinese university graduates. Back in 1996, they shared not only the vision to establish a successful business "Made in Germany" – but also the ambition and determination to realize the vision in the form of a joint venture.

The first step was taken when the founders of BPJ, Yingzhao Lin and Yiwu Zhao, together with four staff rented a

small office in a backlot in the Chaoyang district of Beijing. They chose the site very deliberately to be near to the city's most important hospitals.

20 years later, the first German-Chinese prosthetic joint start-up bears the name Naton Medical Group, of which BPJ is a division. The current workforce numbers 4,000, including 700 sales representatives.

Back in 1996, we were looking for a

partner to offer our premium products in China. We had the good fortune to meet the right people, at the right time, in the right place. LINK was one of the first importers of joint replacement prostheses in China.

Today LINK and BPJ together distribute premium LINK products and produce high-quality implants at their own plant, which opened in 2009.

The investment paid off for us; no other market served by LINK can boast the sort of continuous high growth that we enjoy in China. Our sales have multiplied since we took the first steps in the early years, to the extent that we are in a closely fought contest with our big American competitors for the position of China's Number 1 importer of joint prostheses.

The key factor in this great success has been the 20 years of continuous and close cooperation. This cooperation is centered on a permanent academic exchange program between Chinese and German surgeons.

There is huge demand for high-quality arthroplasty training in China. 2017 marks the 18th LINK® Academic Sino-German Friendship Symposium. Each year up to 70 Chinese surgeons come to Germany to attend presentations, workshops and live surgeries.

Further proof that the joint venture was a success is the growing academic network in China.

Many of the surgeons who came to visit us in Germany for the first time 20 years ago now hold very important positions at universities and major hospitals in China. Personal contacts are important, and this is especially true in China. So we meet our partners from BPJ and many of our Chinese friends personally at least every three months. In addition, the COA (Chinese Orthopaedic Association) Congress is an obligatory item on our calendar of visits each year.

LINK is on track for further success in the future.

The rising standard of living in China means that people there are able to spend more money on high quality. This is good news for our products manufactured both in Germany and at the Beijing plant. So we are looking forward to the next 20 years in China!

Norbert Ostwald



»In China, as elsewhere, our products are bought because of their quality« – LINK CEO Norbert Ostwald is one of the directors of the joint venture with BPJ

Conversion to a total femur replacement by means of RescueSleeve® from LINK

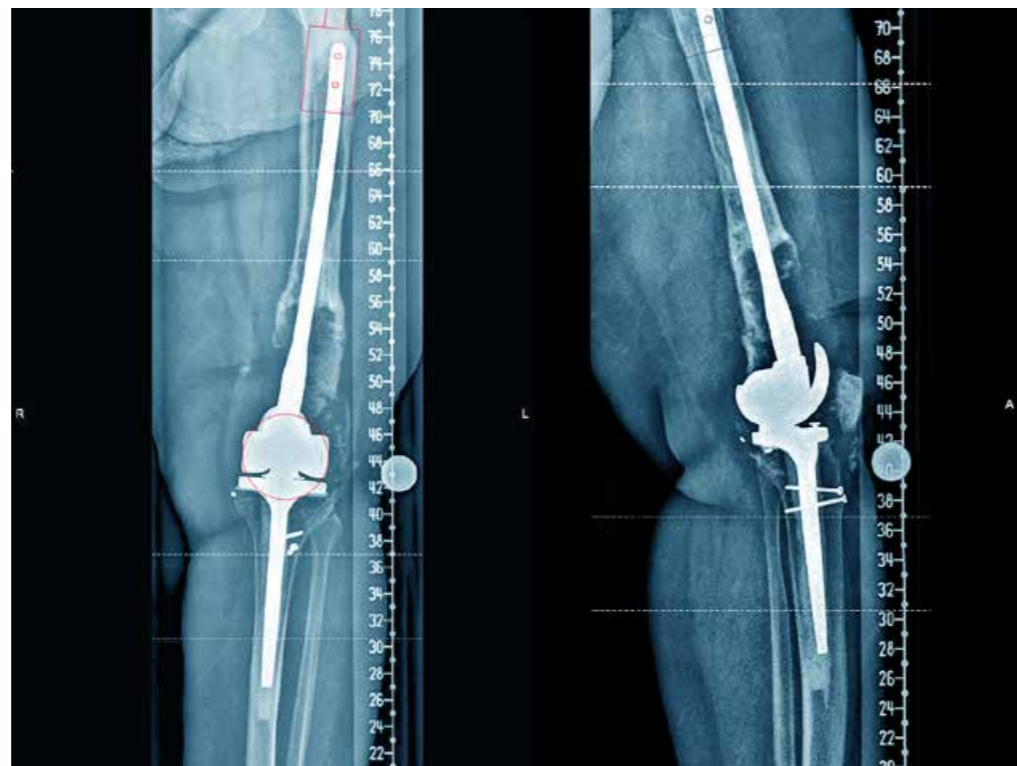
To perform a necessary hip replacement and to avoid revision of the in situ long stemmed knee prosthesis, a custom Rescue Sleeve® created a total femur replacement. Intraoperatively, approximately 50 mm of the in situ proximal knee stem end was exposed after opening. The sleeve component of the RescueSleeve® was then filled with bone cement and pushed onto the end

of the stem. Then the circumferentially arranged fixation screws were tightened in the still pasty cement so that the in-situ knee stem was centered in the sleeve and primary fixation was achieved. Once the bone cement hardened, there is a strong, weight bearing connection between the in-situ prosthesis stem and the RescueSleeve®, to permit a hip replacement.

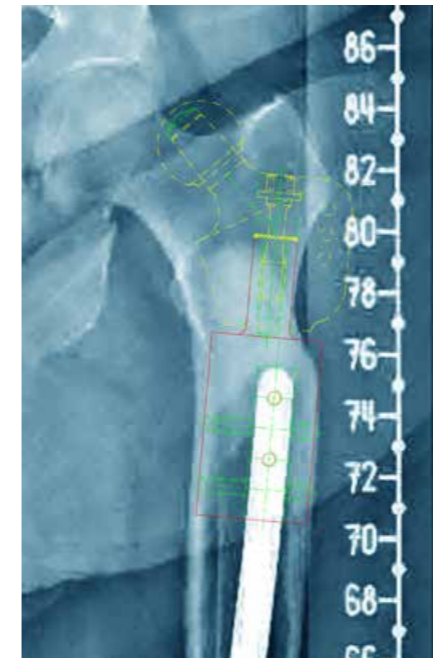
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CASE REPORT

A 67-year-old patient presented with a plasmocytoma-related osteolysis with loosening and lateral migration of the stem of a left-sided in situ, custom-made extra long stemmed LINK® Endo-Model® Rotational Knee Prosthesis. Due to local inoperability of the knee joint region following radiotherapy and postoperative infection at the time of the primary surgery, it was decided that a customized solution was required to preserve the knee joint prosthesis.



Pre-op X-ray: In situ long stemmed rotating hinge knee Prosthesis; distal osteolysis attributable to a plasmocytoma. The knee joint was implanted in 2000. Nowadays, LINK's Megasystem-C® provides such stems with a proximal connection to an MP® hip neck segment to facilitate hip replacement at a later date.



Post-op X-ray: Projection of the custom-made RescueSleeve® from LINK onto the proximal end of the in-situ LINK® Endo-Model® Rotational Knee Prosthesis from the year 2000



Custom-made RescueSleeve® from LINK: (left, from the year 2014) The off-center stem is the reason for the asymmetrically drilled hole in the sleeve (right, from 2016)



Post-op X-ray: Proximally the RescueSleeve® is connected via LINK's proprietary PowerLock connection to the neck segment of the MP® hip neck segment. Distally the sleeve is secured to the end of the knee stem with fixation screws and bone cement.

Orthopedic surgeons from 35 countries in Warsaw: LINKAcademy Symposium 2017

In February 2017, more than 240 delegates from 35 countries and 5 continents came together in Warsaw for two days to participate in the LINKAcademy International Symposium. In a relaxed atmosphere, they discussed the challenges facing knee and hip replacement. Herewith a summary of this event.

Chaired by Prof. Wolfram Mittelmeier and Prof. Marek Synder, a total of nine sessions with 46 presentations were devoted to aspects of primary and revision surgery of large joints. Exceptionally difficult cases were presented by several delegates from Poland and India. Proposed solutions were discussed not only with the panel of experts, but the audience was also involved via a wireless voting system.

In one of many highlights at the Symposium, Dr. Pawel Skowronek presented a simple and easily reproducible technique for direct anterior approach (DAA) for implanting the cementless, anatomically adapted LINK® SP-CL® Hip Prosthesis. This minimally invasive implantation technique does not require many special instruments.

In comparison with fixation using plates and screws (ORIF), the LINK® Endo-Model® Rotational and Hinge Knee Prosthesis is a simple, safe and reliable solution for the treatment of distal femur fractures in older patients. This was demonstrated by Prof. Claudio Zorzi. He particularly emphasized the technically simple implantation of the LINK® Endo-Model®, the excellent and rapid stabilization, fast rehabilitation and resulting lower mortality rate. He summed up with the words: »This option should be the first choice for treating older patients.«

Dr. Pablo Sanz Ruiz presented the results of a comparative study of CCK type knee prostheses and hinge knee prostheses. According to his findings, rotational and

hinge knee prostheses such as the LINK® Endo-Model® enable faster and less costly surgery, especially for older patients. Furthermore the advantages are similar for revision procedures as for traumatology: rapid, efficient rehabilitation and better surgical outcomes, said Dr. Pablo Sanz Ruiz.

Another highlight was the presentation by Mr. Jonathan Miles. He summed up his vast experience in revision surgery in a presentation on the subject of implant removal. The talk focused on tips and tricks for safe removal of all types of all stems, cups and screws.

INTERNATIONAL SYMPOSIUM 2017

Current Challenges in Knee & Hip Surgeries

February 6 to 7, 2017 in Warsaw, Poland



Chairmen

Prof. Dr. med. Wolfram Mittelmeier
Clinical Director, Medical Faculty University Hospital Rostock, Germany
Prof. Marek Synder Clinical Director, Clinic of Orthopaedics and Paediatric Orthopaedics, Medical University of Lodz, Poland

Speakers

Dr. Carlos Maria Autorino Chief Physician, Hospital Universitario Austral, Buenos Aires, Argentina
Dr. Vincenzo Condello Consultant Orthopaedic Surgeon, Ospedale Sacro Cuore Don Calabria, Negrar Verona, Italy
Dr. med. Martin Darowski Consultant Orthopaedic Surgeon, Universitätsmedizin Rostock, Germany
Dr. med. Alois Johannes Franz Chief Physician, St.-Marien-Krankenhaus Siegen, Germany

Dr. Xavier Gallart Castany
Hip coordinator & President of the Spanish Hip Society University & Clinic Hospital in Barcelona, Spain
Dr. med. Alexander Huppertz
Senior Physician, Klinikum Ernst von Bergmann gGmbH, Potsdam, Germany
Prof. Dr. med. Daniel Kendoff
Chief Physician, HELIOS Klinikum Berlin-Buch, Germany
Brett R. Levine, MD, MS
Assistant Professor, Rush University Medical Center, Chicago USA
Helmut D. Link
Managing Director, Waldemar Link GmbH & Co. KG, Hamburg, Germany
Ass. Prof. Aare Märtson
Head of Orthopaedic Department, Tartu University Hospital, Estonia
Dr. Dariusz Marczak
Consultant Orthopaedic Surgeon, Samodzielny Publiczny Szpital Kliniczny, Otwock, Poland

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Clinical Director, Royal National Orthopaedic Hospital Trust, Stanmore, United Kingdom
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Chief Surgeon, Imam University Hospital, Tehran, Iran
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Senior Physician Campus Mitte (CCM), Berlin, Germany
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Consultant Orthopaedic Surgeon, OCON Orthopedische Kliniek Hengelo, The Netherlands
Prof. Dr. Claudio Zorzi
Chief Surgeon, Ospedale Sacro Cuore Don Calabria, Negrar Verona, Italy

LINK celebrates in Sweden and Spain

There was good reason to celebrate in both Northern and Southern Europe: The 20th and 25th anniversary of LINK's subsidiaries in Sweden and Spain. LINK operates worldwide! From Europe to the Americas and Australia, LINK sales companies on four continents ensure that LINK prostheses and LINK's expertise is quickly available around the world.



20th anniversary - the LINK team in Spain



25th anniversary – the LINK team in Sweden

More than 100 years!

This number of years is attained by a 92-year-old patient and the bilateral LINK SLED Prostheses, which were implanted at the ENDO-Klinik in Hamburg Germany in 1991. The patient has been free of symptoms ever since. An examination at the end of 2016 found depleted cartilage of the knee joint and also an intact Sled Prosthesis and firmly seated prosthesis components.



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LINK offers rapid treatment option for knee trauma patients

A new, fast, cost-sensitive treatment option for patients with traumatic knee injuries has been brought to market in Australia by LINK in cooperation with LifeHealthcare: the »LINK® Endo-Model® Distal Femoral Replacement for Fractures«, or Endo DFR-F.

The DFR-F was inspired by the continuing discussion about the optimal treatment for patients with traumatic knee joint fractures. An important consideration in the development of the implant system was that a fast method of treatment

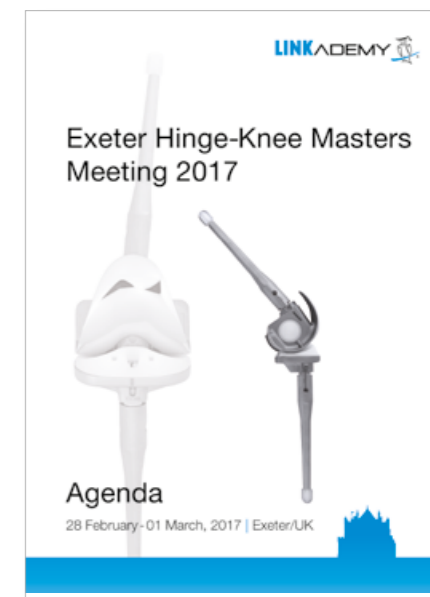
for serious knee trauma not only saves time and money, but can also reduce complications and thereby save the patient's life.¹ The DFR-F is completely modular, is available in sizes from 50 mm to 150 mm on four efficiently designed trays, and can be implanted in six surgical steps. If required, there is the option of expansion into the LINK® MEGA-SYSTEM-C®. Further information is available via Robert Bell, Head of Global Market Development at LINK (r.bell@linkhh.de).

¹ Schütz M. et al. Minimally invasive fracture stabilization of distal femoral fractures with the LISS: a prospective multi-center study. Results of a clinical study with special emphasis on difficult cases. Injury. 2001 Dec;32 Suppl 3:SC48-54.



Exeter Hinge-Knee Masters Meeting 2017

Discussions, live surgery, tips, tricks and interesting case reports featured at the »Exeter Hinge-Knee Masters Meeting 2017«, organized with the LINKademy at the end of February. At the annual meeting, leading international revision surgeons discussed the current challenges and the potential of hinge-knee prostheses in reconstructive knee surgery. All participants presented technically demanding cases.



TRUST.



Trust is the beginning and the basis for every good partnership. That is the cornerstone of our success and the reason why we will continue to rely on a strong and close collaboration with you in the future. This will allow you and your patients to profit from unconventional solutions and outstanding long-term outcomes, because trust is binding. **LINK** – Your Partner in Arthroplasty.