

directLINK®


Magazine for Arthroplasty · Issue: November 2012

»Surgeons can learn from pilots!«

Interview with Dr. Stephan Kirschner about the future of arthroplasty beyond prosthesis design

LINK customized solutions: Plate and femoral fracture in an in-situ hip and knee prosthesis – What to do? **Looking into the future:** What does the »iProsthesis« offer?





PoroLINK[®], shot-blasted

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¹J. D. Bobyn, R. M. Pilliar, H. U. Cameron and G. C. Weatherly, "The Optimum Pore Size for the Fixation of Porous-Surfaced Metal Implants by the Ingrowth of Bone," Clinical Orthopaedics and ²Related Research, No. 150, Jul.-Aug. 1980, pp. 263-270.

²o.f.u. Gesellschaft für Oberflächen-und Festkörperuntersuchungen mbH, test report.



Dear Readers:

Since Barack Obama took office in January 2009, passing a health care reform bill had been one of his top domestic priorities. After in June 2012 the U.S. Supreme Court found the underlying law to be constitutional and now, that he has been re-elected as President of the United States, the »Obama Care« will be realized. The future will prove if that legislation will have positive or negative impact on the quality of care.

Quality responsibility, and security are also matters of major importance to LINK. In our cover story, Dr. Stephan Kirschner, from Dresden, calls for the sort of techniques used in pilot training to be adopted for surgeons. To enable an expert exchange of views and experience, LINK invited Chinese surgeons to Berlin and sent Dr. Robert Krause, a German arthroplasty surgeon, to China. In this issue, Dr. Krause reports on his fascinating visit. In large countries like China and the USA, safeguarding the health of the population as a whole is increasingly important both politically and economically.

We in Germany would like to make a global contribution: with high-quality products, international knowledge transfer, and an open ear for challenges in the field of arthroplasty around the world.

Enjoy this latest issue of directLINK. Regards.

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»Surgeons can **learn from pilots!**«

Dr. Stephan Kirschner is chief physician of the Orthopedic Clinic at the Carl Gustav Carus University Hospital in Dresden. He spoke to us about matters affecting arthroplasty in the future, beyond prosthesis design and surgical techniques. The wider perspective.

Dr. Kirschner, you have an excellent reputation as an orthopedic surgeon, but you are also researching into matters concerning patient satisfaction. Why is that?

Because sometimes we are faced with an apparent paradox following implantation of prosthetic joints. Some patients have a very good surgical outcome, as indicated by the X-ray images, and yet they are unhappy. Others have imperfect radiological results, but are extremely satisfied. So our aim is to achieve an improved outcome, specifically from the viewpoint of the patient.

What does that mean in practical terms, and how do you go about it?

First, we have to accept that there are two perspectives regarding the outcome of treatment: that of the surgeon and that of the patient. They do not necessarily coincide, but the more closely they agree, the higher the level of patient satisfaction. That's why, here in Dresden, we have begun asking patients about their expectations before surgery is conducted. We also talk to them about our previous experience of the relevant treatment. This creates a realistic picture which enables the patient to have a better understanding of the outcome of surgery.

»I read the press reports that patients read« –
Dr. Stephan Kirschner on his way to the hospital ward

In the technology-driven world of arthroplasty, that is a relatively unusual approach.

Yes. Of course, we are also continuously working on technical optimization. What matters most is for the patient to have the postoperative mobility that he or she expected before undergoing surgery.

»It's all about improving the outcome – from the patient's viewpoint.«

In order to understand patient expectations, you need a more holistic understanding of the patient. How do you achieve that?

Well, I read the press reports that patients read, for example. Health-related stories in magazines, information leaflets that you pick up at the pharmacy and health websites on the Internet. These are the sources of information patients use to form a picture of their illness and the available treatment options. Often what a patient hears from friends and relatives also plays a part. It is very helpful to understand what hopes and expectations arise from all this.

What implications does this have for patient information and consent?

There is a statutory side to patient information and consent, and that is not a problem. What is interesting is another aspect which the legislator is seeking to strengthen, namely explanation of the available treatment options. Patients in their sixties and seventies often say: »Doctor, you decide; you know what's best for me.« Others think their body is like an automobile: you take it to a garage to have it repaired, and everything is as good as new again. Younger patients are most likely to take on board the sort of approach envisaged in the legislation. They find out relevant information, ask questions and make their own decision. This means that in future it will be increasingly important to establish a sort of partnership between doctor and patient, even if this is unaccustomed for both parties at first.

When it succeeds, does it improve the outcome?

Definitely. Because the patient understands many things better. They can assess more accurately what an artificial joint is capable of, and how active a life they will be able to lead, what type of sport is advisable, and whether they will have to adapt their working life accordingly. It is irrelevant whether a patient has very high or very low expectations. As soon as our discussion with the patient succeeds in harmonizing expectations with medical options, postoperative patient satisfaction increases.

Has any scientific research been done on the subject of expectation management?

It's a new field. Some questionnaires have been produced, and we are also developing our own. We have identified interesting differences in expectations between the sexes from a cohort of patients requiring a knee prosthesis. Men give great importance to how knee replacement will affect their driving, for example, while for women in their sixties and seventies, that is of no interest at all. They would rather know whether and how they will be able to use public transport.

»Manufacturers should provide patients with direct access to relevant information.«

What can the manufacturers do to improve patient information?

I think that no manufacturer should be content to only provide information via third parties. In other words, they should also communicate directly with the patient to a certain degree. That does not mean seeking to promote their products, but providing information that patients can understand. Information from the German Arthroplasty Register in language that patients can understand would be desirable.

You are a chief physician and know all about budgets, staffing plans and the often heavy work-loads. Is it actually possible for surgeons to invest more time in patient consultations?

If we consider the medical side of arthroplasty in isolation, then yes. But doctors are also required to do other jobs which cost time. For example, matters concerning business development. Training is another drain on the available time. This is something that cannot be refinanced at the present time. Our European neighbors have already recognized the problem and are financing specialist training opportunities via publicly funded programs. We do not have that here – and the result is that a training hospital with ten junior doctors does the same work as a non-training hospital with eight specialists. We have yet to find a good solution to the problem.

In England there are established, highly structured training schemes for traumatologists and orthopedic surgeons. Wouldn't that be a good model for Germany?

We are close to achieving just such a model. There is a joint curriculum for orthopedic surgeons and traumatologists, in which times and tasks are defined.

And yet distinguished surgeons constantly complain that many joint prostheses are implanted

by people who do not have the required skills – and this tarnishes the reputation of the profession as a whole. What is the reason for this?

The health insurers and legislators wanted to create competition between hospitals in order to reduce waiting times for patients. That has been achieved, but it has also brought about some negative treatment outcomes. The DGOOC (German Association of Orthopedics and Orthopedic Surgery) drew up a proposal for certifying arthroplasty centers in order to achieve reliable and good treatment outcomes with the aid of quality indicators and the expertise of surgeons. Moreover, in the context of specialist training, we must learn to assess skill levels realistically. Not every person with the ambition to become a surgeon has the necessary manual dexterity. Where this is the case, a mutual solution must be found whereby the candidate can discontinue training and transfer to a field in which his or her skills are better employed.

Is pressure from the health insurers when poor outcomes occur also a factor?

If a patient is hospitalized for revision surgery a short time after the original operation – and the proportion of such patients is growing – the health insurers demand to see the records in order to identify any possible errors made during surgery.

And that is one reason why more and more contracts between surgeons and health insurers specify a two-year guarantee.

Whether or not this guarantee clause is well advised is another question. I fear that we will witness risk selection. In some patients, ancillary illnesses increase the probability of complications, for example with therapeutic anticoagulation or diabetes mellitus. If the figure is 10 percent or higher, it is not reasonable to expect the surgeon to bear the financial responsibility alone.

Shouldn't qualified and experienced specialists do even more to ensure that improved outcomes are achieved?



»We should not allow patients to run into **problems** which may already be known«



»Not every person with the ambition to become a **surgeon** has the necessary manual dexterity«

They should be prepared to constantly keep abreast of new implants and surgical techniques. Much depends on their willingness to do this. The design of training programs probably needs to be adapted. It's not just the surgeon who has to know what he's doing; the entire team in the operating room must be up to speed.

»The learning curve should be as flat as possible.«

In your view, does this also apply to visiting surgeon programs?

Yes, most definitely. It would be advantageous if not only the surgeon participated, but also the surgical nurses. The wider the exchange of knowledge and experience, the better. The aim is to keep the learning curve as flat as possible for everyone. Written information is also valuable in this respect, by the way. My wish would be that understandable instructions from the manufacturer, in their language, were provided with new implants. Fellow surgeons who introduce something new into the treatment regime should systematically collate their experiences and make this information available. Patients and surgeons all want to participate in progress. When new techniques are introduced, one should ide-

ally know about the problems and difficulties that have already occurred elsewhere – including solutions for avoiding them.

But what surgeon likes to admit to difficulties?

We can learn from aircraft pilots. They undergo exhaustive simulator training in how to react in critical situations. That doesn't happen in medicine yet. But it is valuable to deliberately create training situations for which the implant is not suitable, or in which the surgeon needs to take additional measures if implantation is to be successful. This information should be made available to future users of implants. We still do not conduct such simulation even though it would be a very valuable training tool. The surgeon will then be able to deal with the simulated critical situation if it occurs in reality.

Many young doctors are going abroad because they see better opportunities. Are there worries about the next generation of orthopedic surgeons?

Not to the same extent as in other fields of medicine. No doubt, that is partly because we deal with illnesses which the patient understands. The patient has to endure pain and restricted mobility. If we find a good solution, the patient response is very positive. That's what makes orthopedics so attractive. On the other hand, it is true that surgeons will become an increasingly scarce »re-source« in the future, if only because of the demographic changes we are witnessing. So we must make every effort to enhance the work environment and to free the profession from extraneous burdens, such as financial tasks.

A famous American surgeon once said: I only take on people who are better than me.

(Laughs) Yes, if you can find them, that is certainly a recipe for success.

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



Dr. Zeng Yirong, Dr. Liu Yujie, Helmut D. Link, Dr. Sun Shui, Lin Yingzhao (Naton Medical Group) (l. to r.)

Distinguished visitors from China

In response to LINK's invitation, a delegation of distinguished clients from China were pleased to visit the 13th EFORT Congress, held in Berlin in May 2012. And they brought some very interesting presentations with them.

In its business with China, LINK places importance on enduring and, most importantly, personal relations. Consequently, some 300 Chinese doctors take up LINK's invitation to Germany each year for the Academic Sino Friendship Symposium and also other symposia and visiting surgeon programs.

Dr. Zhu Tianyue from Beijing University First Hospital in China, and his colleagues accepted LINK's invitation to attend the 13th EFORT (European Federation of National Associations of Orthopedics and Traumatology) Congress in Berlin. Dr. Zhu recalls: »I visited Berlin as a student back in 1987. I was studying medicine at the University of Essen and gained my doctorate there«. His first contact with LINK was in 1995, when LINK was just finding its way in the Chinese market. »I was introduced to the Naton Medical Group, who are LINK's joint venture partner in China, and I helped in finding the first offices to lease in Beijing«, Dr. Zhu explains.

The MP® Reconstruction Prosthesis marked the beginning.

Dr. Liu Yujie, from the General Hospital of PLA,

Beijing, is also of the view that the close collaboration established between manufacturers and surgeons in China are an important success factor. »By learning from each other, the standard of medicine in China will be further improved«, states Dr. Liu. His presentation on the subject of »Evaluation of arthroscopy in unicondylar knee replacement« was followed with great interest by a large number of EFORT visitors. Dr. Liu went on to say: »We believe that preoperative arthroscopy is becoming the gold standard for surgeons in order to assess the joint gap prior to surgery«. His first contact with LINK was in 1998: »We were faced with a very problematic revision when LINK introduced its MP® Reconstruction Prosthesis«. »The patient is still doing well to this day – and the MP® Reconstruction Prosthesis is now one of the most frequently implanted in China.«

The VACUCAST investment foundry makes a lasting impression

Dr. Sun Shui from Shandong Provincial Hospital, Jinan, also has great confidence in LINK products. He and some of his colleagues visited

LINK's in-house investment foundry VACU-CAST[®], in Berlin, on the day before the congress. »I was impressed by the precision casting techniques employed by LINK, and I now have even greater confidence in the quality of LINK products«, says Dr. Sun.

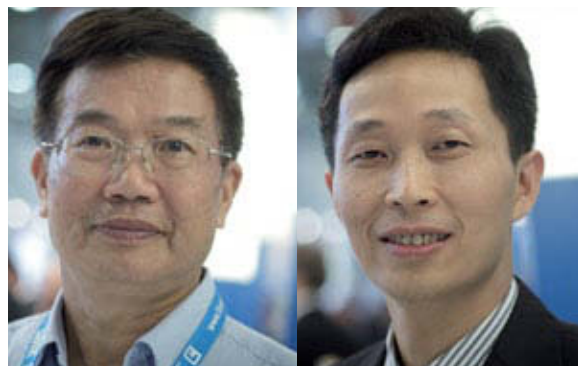
His well-attended presentation on the subject of »Solution for serious deformities: LINK[®] Endo-Model[®] Rotational and Hinge Knee Prosthesis« was also concerned with quality. »In the very complex and difficult cases of deformities, postoperative rehabilitation was quicker than with other products, and all the patients were very satisfied with the outcome«. This is how Dr. Sun summarized his study. The surgeon's first contact with LINK was in Hamburg in 2000. »I was a visiting surgeon in Hamburg for a year and began working with LINK products. Today I am still using LINK implants and am very satisfied with the results.«

A solution for 15 million young Chinese with femoral head necrosis

Dr. Zeng Yirong from The First Affiliated Hospital of Guangzhou University of Chinese Medicine, Guangzhou is also satisfied with the results of his research. His work concerns



Dr. Liu Yujie, The General Hospital of PLA, Beijing (left);
Dr. Sun Shui, Shandong Provincial Hospital, Jinan (right)



Dr. Zhu Tianyue, Beijing University First Hospital, Beijing (left);
Dr. Zeng Yirong, The First Affiliated Hospital of Guangzhou University of Chinese Medicine, Guangzhou (right)

treatment for osteonecrosis of the femoral head in young patients using the technique of bone transplant and a »free iliac flap«. »We have been using this method for over 20 years now, and the number of operations performed is growing because the incidence of osteonecrosis in China is very high, at 15 million cases a year«, explains Dr. Zeng. He was delighted at the enormous interest which his presentation generated among the delegates to the congress. »We employ the method in order to delay joint replacement surgery, and we even have patients who have managed well for 25 years without a joint prosthesis.«

Dr. Zeng has had contact with LINK since 2005. »In contrast with many American companies, LINK supplies products with an anatomical design. In more than 1,000 hip and knee operations using LINK products, I have not had a single case of implant loosening«, reports Dr. Zeng. For the future, Dr. Zeng would like to see products being developed which are tailored to the smaller stature of the Chinese, particularly in the province of Guangdong. »People in the province of Guangdong have smaller bones than the average German, so suitably adapted implants would be a great help to us«, Dr. Zeng stated.

From **Airport to OR** and **sea cucumbers**

Any surgeon who travels to China for LINK is in for an experience! A travel report by Dr. Robert Krause, head of extremity surgery at the Oberlin Clinic in Potsdam.

China – a country I had never been to, either on vacation or as a surgeon. Then I had a week there, at the end of August 2011, with a very tight schedule: flight from Copenhagen to Beijing for a whirlwind visit, then on to Central China, Luoyang, and from there to the coastal towns of Yichang, Wuhan, Weihai and finally Weifang.

You can tell immediately whether you're inland or on the coast because the air quality is drastically different. I'm a keen jogger, but that's not a sport that you can normally do inland in China. But I still gave it a go, and strangely I sometimes was the only person in the park who was running forwards. Many Chinese practice running backwards in the morning in the hope that it will improve their cerebral ability and coordination.

I was very curious to find out more about this country – its medicine and hospitals, but also the people and culture. Of course, I tried to prepare myself as well as possible. I was sent X-rays of the patients on whom I was to operate, but you can't know what it's going to look like in the operating room, or how working in the team will prove to be? I had prepared four presentations but, as it turned out, only one of them was in demand: an illustration of the complications that can occur in arthroplasty. In dynamically developing and technology-loving China, the focus is

on new surgical techniques. Primary treatment in the form of implants is really what it's all about. So there was great interest in the experience we have gained over decades. The Chinese surgeons know that they will be faced with a great deal of revision surgery in the medium term.

Of course, I was prepared, but ...

It's a bit embarrassing, really, but a German surgeon officially visiting a Chinese hospital is almost treated like a visiting head of state. That includes being welcomed by the hospital director, being presented with a large bouquet of flowers, having your name emblazoned on large banners, and sitting down to a meal together. I was amazed at how many medical staff were present at meal times in honor of a guest – I could scarcely have organized something on that scale at my own hospital. I was no less astonished at the almost excessive intensity with which I was quizzed about medical details and techniques. The sheer drive of the Chinese to always learn more and widen their knowledge is impressive.

In China, everything is on a different scale to Europe. You basically have to double everything. The airport at Beijing is simply huge. Then there's the skyscrapers, the traffic and the sheer number of people. A normal hospital has around 1,000 beds, which is more like a large hospital

第二届环渤海关节、脊柱及运动医学高峰论坛合影留念 2011.9.27



complex in Germany. Chinese houses boast all the latest technology. The surgeons, at least at the large medical centers, are so highly qualified that they are on a par with our own. That is remarkable, really, considering that they do not have the instant access to all specialized information that we do. Free, uncensored Internet access is only available in the large hotels as far as I could see. It is reserved for international visitors.

Chinese hospitals are state of the art in terms of equipment and facilities

The health system is very different to ours. Evidently, only traumatology for emergency cases is covered by health insurance. Arthroplasty has to be paid for privately, and there are a large number of cases because many people work either sitting, crouching or kneeling. Patients are often tended by their family. So you see relatives waiting outside the door while surgery is going on. They bring the patient in and out, and also bring food and tea to the hospital ward. The fact that prosthetic joints have to be paid for privately has a consequence that is not based on medical considerations, as far as I was able to observe: Patients tend to have complete replacements, while partial implants are rather rare. In Europe surgeons would be more inclined to adopt conservative treatment. Traditional Chinese medicine no longer plays any part at all in hospitals. Instead, it has become the medicine of the poor, who cannot afford evidence-based, western medical treatment.

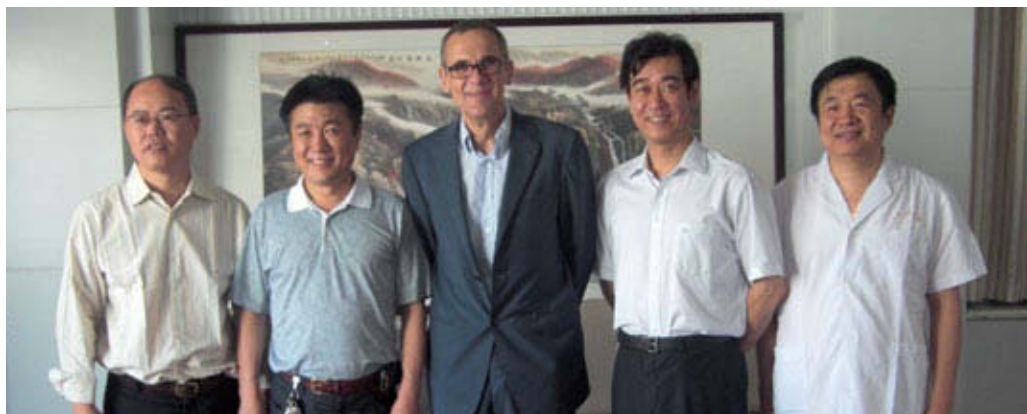
Sea cucumbers were completely new to me

Naturally, on such a trip you encounter a few rather odd things that are best tackled with humor and a degree of improvisation. One

example: The surgical gowns are much too small for Europeans. By the end of my visit I had become quite adept at lengthening my sleeves with tubular bandages. A second example: Chinese GPS navigators for automobiles do not manage to keep pace with new road building. So we often found ourselves in the middle of nowhere – facing a concrete wall or an unknown freeway exit, and such like. A last example: As a visitor, you're never quite sure what may find on your plate at lunch or dinner. The range of sea food, types of meat and methods of food preparation seems almost limitless. And to avoid being impolite, you simply have to be prepared for a few culinary adventures. Sea cucumbers, which belong to the same family of creatures as starfishes and sea urchins, were new to me in terms of culinary delicacies.

It was a short visit with a lot to pack in and plenty of work to do, but I would certainly go back to China any time. The contacts I made are sure to lead to reciprocal visits to Germany sooner or later. Western arthroplasty surgeons have a lead in terms of their knowledge and experience of complications and revisions. But when it comes to surgical techniques, Chinese surgeons are absolutely the equal of our own surgeons. In a word, they are colleagues.

Author: Dr. Robert Krause





»Homologous bone, mixed with autologous blood and placed in the bone defect using the impaction grafting technique is the method of choice« – **Prof. Dr. Dieter Christian Wirtz** is Director of the Department of Orthopedics and Traumatology at Bonn University Hospital

»In ten years we aim to have a synthetic bone substitute material!«

Prof. Dr. Dieter Christian Wirtz is Director of the Department of Orthopedics and Traumatology at Bonn University Hospital. We spoke to him about reconstruction of bone defects, bone substitute materials, and what stem cells and growth factors can contribute.

Prof. Wirtz, a focus of your scientific work is biological regeneration of bone defects. Why is that?

More and more younger people are having prosthetic joints, which are subject to natural loosening over a period of years and therefore require revision up to three times during their lifetime. But every prosthesis that becomes loose causes a bone defect. In order to anchor future prostheses securely to the bone, these defects must be repaired. Biological regeneration of bone defects is, basically, the optimal complement to an implant system that covers everything with modularity, from the smallest to the largest defect.

What options for bone defect reconstruction are available at present?

You can restore a bone defect with cement or metal – or you can reconstruct it biologically. This can, of course, be done using either autologous or homologous bone, but autologous bone, as the »gold standard« is not available in the quantities required for large defects, especially on the acetabulum. What material is actually used, depends on the anatomy, amongst other factors.

Can you give us a practical example?

For the rear wall of the acetabulum, for example,

one requires a strong, force-transmitting base, so it is best to use a metal as the augmentation material. In the roof of the acetabulum, where there is a large quantity of cancellous bone structure and good vascularity, it makes more sense to augment with bone rather than cement and metal.

How does remodeling differ between these materials?

We conducted tests on 30 sheep with periacetabular bone defects, which we restored using autologous and endogenous bone and a ceramic bone substitute material; subsequently, the animals spent nine months out at pasture. The assessment has not been completed, but we can already state that all three materials do remodel. However, the quality of remodeling depends greatly on the technique used for placing the material.

What factors are involved?

If you merely restore the defect by inserting cancellous tissue, the bone does not remodel as effectively, in terms of quality or quantity, as when the impaction grafting technique for cement-free reconstruction is used. Homologous bone also remodels very well, both quantitatively and qualitatively, with impaction grafting.

What conclusion do you draw from this?

The findings of the animal tests show the method of choice to be homologous bone mixed with autologous blood and placed in the defect using the impaction grafting technique. But there is still room for improvement. We are investigating whether autologous stem cells or growth factors can further accelerate and improve bone remodeling, thus making the new bone even stronger.

Are there any results to report regarding autologous stem cells?

It's a bit too early for that. We are still in the process of clarifying some fundamental questions such as which stem cells, in which medium, in which concentration and which three-dimensional architecture have the potential to generate load-bearing bone at the graft site.

And what is the situation with growth factors?

There, it is principally the kinetics of action that still have to be clarified. How high is the rate of release of the growth factor? In what concentration must it be available? And how quickly is it decomposed by the body at the graft site? None of these questions have yet been adequately answered to allow use of the technique in human patients. Moreover, highly concentrated growth factors have considerable side effects, so one has to be very cautious.

Can you give us an idea of what may be possible in the future?

Our ten-year target is to produce a synthetic bone substitute material which can be inoculated with autologous stem cells, progenitor cells or a growth factor, and implanted in the bone defect in a moldable matrix. The aim is for this biological composite to be intraoperatively moldable to the shape of the defect. It should also heal as well as any fracture, but must not cause any immunological problems.

What will be the benefit of your research?

If we succeed in developing a composite material with which bone defects, in all their three-dimensional variations, can be rectified intraoperatively, then we would have reached

a new milestone in this problematic area. The main objective would be achieved, namely to be able to use a smaller implant when a joint is replaced again because the bone defect has become smaller. This would all go hand-in-hand with a simpler intervention and lower cost for the revision because – taking the example of the acetabulum again – it would no longer be necessary to fabricate a tailor-made partial pelvic replacement.

And for the patient?

The advantage for the patient is also clear. If you allow a bone defect to become larger and larger due to the second and third joint replacement, you eventually reach a point where it is no longer possible to anchor an implant. But if you can remodel the bone at the time of the first joint replacement so that the defect becomes smaller instead of larger, then you have created a far better situation for any revision, and thus for the lifetime of the prosthetic joint.

Prof. Wirtz, thank you for talking to us.

»Our Department of Orthopedics and Traumatology has its own research laboratory, where six research groups are currently working on a wide range of research projects.«

– Prof. Dr. Dieter Christian Wirtz

Diaphyseal partial replacement with sleeve coupling for interprosthetic femoral fractures

An 84-year-old patient with right knee and hip prostheses was treated with a plate osteosynthesis following an interprosthetic femoral shaft fracture. Two months post-op, the plate failed. The surgeon, Dr. med. Karl Schmoranz, chief physician at the Department of Orthopedics and Traumatology at the Martin Luther Hospital in Berlin, ordered a customized component from LINK to provide a strong connection for the prosthesis stems.

Findings

84-year-old female patient with right femoral shaft fracture between LINK SPII® Hip Prosthesis and LINK® Endo-Model® Rotational Knee Prosthesis, sustained due to a fall; treatment with plate osteosynthesis; plate failure with pseudarthrosis of the femoral shaft after two months; patient unable to walk.

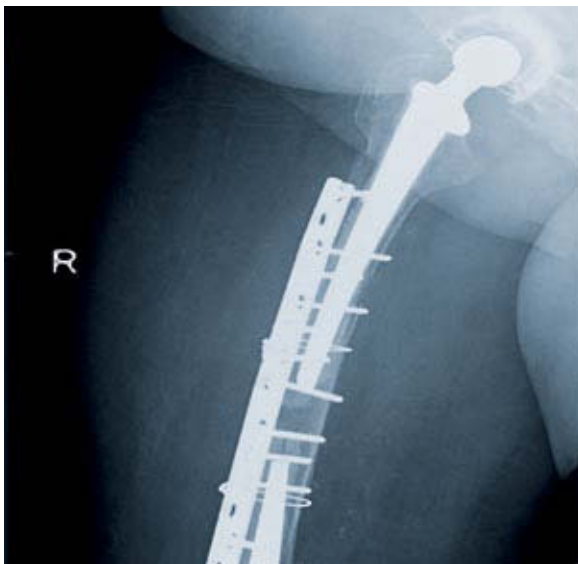
Requirements

Fabrication of a customized component in order to preserve the perfectly functional hip and knee joints and to achieve a strong connection of the

prosthesis stems. Postoperative mobilization of the patient in a wheelchair without full loading.

Customized solution

After assessing the X-ray images, a customized interposition double sleeve was fabricated. The sleeve comprises a proximal and a distal component, each with nine stem securing screws and two coupling locking screws, including two plastic stoppers.



Interprosthetic femoral fracture caused by a fall: Plating of the femur shaft with in-situ LINK® Endo-Model® Knee Prosthesis and LINK® SPII® Hip Prosthesis



Two months after plate osteosynthesis: Fracture of the plate with interprosthetic femoral fracture

Implantation

During the operation, Dr. Karl Schmoranzner exposed 80 mm of each of the in-situ shaft ends. The sleeve components were filled with cement and slid into place. The fixation screws were then tightened in the still pasty cement. This allowed the in-situ shafts to be centered in the sleeve components and to be additionally fixed. To conclude, the two sleeve components were joined together. The interposition sleeve was preferred principally because it entailed a significantly smaller intervention than the otherwise necessary total femur replacement.

Conclusion

In order to restore mobility to the 84-year-old patient after failed plate osteosynthesis (following femoral shaft fracture) and plate failure, LINK manufactured a customized interposition prosthesis. This made it possible to stabilize the affected limb. After geriatric treatment, the patient is independently mobile on underarm crutches.



Left: **X-ray image with projected plan:** diaphyseal partial replacement (interposition sleeve)

Middle: **LINK customized solution:** diaphyseal partial replacement with sleeve coupling for hip and knee prosthesis stems, comprising a proximal and a distal component, each with nine stem securing screws and two coupling locking screws, including two plastic stoppers

Right: **Postoperative:** diaphyseal partial replacement with sleeve coupling for hip and knee stem in situ

Distinguished experts at the 2nd LINK Symposium in Granada

For two days, April 19 and 20, 2012, some 70 arthroplasty surgeons, pathologists and radiotherapists from Spain, Italy, Germany, Colombia and Argentina discussed the subject of musculoskeletal bone and soft tissue tumors and large bone defects. A snapshot.

The symposium, organized by LINK Spain, was held at the Virgen de las Nieves Hospital in Granada, Spain. At the suggestion of delegates at last year's symposium, the program focused on the practical requirements of arthroplasty surgeons in their daily work. The scientific director was Dr. José Luis Martínez Montes, head of orthopedic surgery at the hospital where the symposium was held.

Speakers emphasize the modularity of the LINK® Megasystem-C®

Around 20 distinguished international speakers updated the delegates on all relevant aspects of diagnostics, prognosis and therapy of bone and soft tissue tumors and large bone defects. In this context, numerous speakers emphasized the high degree of modularity of the LINK® Megasystem-C®. Prof. Rodolfo Capanna, co-developer of the LINK® Megasystem-C® and vastly experienced in the treatment of bone and soft tissue tumors, elucidated the functions of the modular tumor

and revision system and also the relevant indications and clinical results of his work. Prof. Christoph Lohmann, Prof. Thorsten Gehrke and Dr. Xavier Flores similarly presented their results obtained with the system during revisions, total femur replacement and large, septic bone defects. Other Spanish surgeons, such as Dr. Miguel Cuervo, Dr. Fermín Mandia, Dr. Francisco Baixauli and Dr. Isidre Gracia, reported on their first experiences with LINK® Megasystem-C®. Dr. Juan Carlos Martínez Pastor dealt with the controversial subject of metal allergy. The high scientific quality of the presentations together with the lively discussions and friendly international atmosphere made the 2nd LINK Symposium another highly successful event.

SCIENTIFIC DIRECTOR

Dr. José Luis Martínez Montes, Servicio COT¹, Hospital Univ., Virgen de las Nieves, Granada

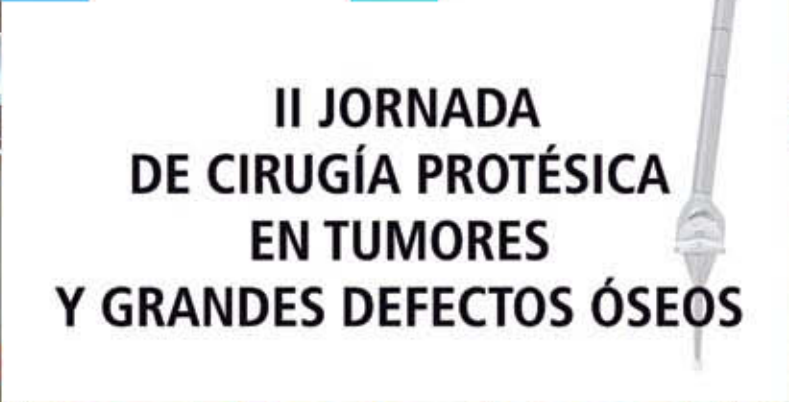
SPEAKERS

Dr. Luis Areizaga, Servicio COT, Hospital de Cruces, Barakaldo
Prof. Dr. Domenico Campanacci, Servicio COT, Centro Traumatológico Ortopédico, Florenz
Prof. Dr. Rodolfo Capanna, Servicio COT, Centro Traumatológico Ortopédico, Florenz
Dr. Pedro Cano, Servicio COT, Hospital Virgen del Rocío, Sevilla
Dr. Ángel Concha, Servicio de Anatomía Patológica, Hospital Univ., Virgen de las Nieves, Granada

Dr. Miguel Cuervo, Servicio COT, Hospital Gregorio Marañón, Madrid
Dr. Francisco Baixauli, Servicio COT, Hospital de la Fe, Valencia
Dr. José Expósito, Servicio de Radioterapia, Hospital Univ., Virgen de las Nieves, Granada
Prof. Dr. José Juan Fernández Martínez, Servicio COT, Hospital Arnau de Vilanova, Lleida
Dr. Francisco Fernández Serrano, Servicio COT, Hospital Univ., Virgen de las Nieves, Granada
Dr. Xavier Flores, Servicio COT, Unidad de sépticos, Hospital Vall D'Hebron, Barcelona
Prof. Dr. Thorsten Gehrke, Endo-Klinik, Hamburg
Dr. Isidre Gracia, Servicio COT, Hospital de la Santa Creu i Sant Pau, Barcelona

Prof. Dr. Christoph Lohmann, Orthopädische Otto-von-Guericke-Universitätsklinik, Magdeburg
Dr. Fermín Mandia, Servicio COT, Complejo Hospital Univ. de Santiago, Santiago de Compostela
Dr. Juan Carlos Martínez Pastor, Servicio COT, Hospital Clínic, Barcelona
Dr. Eduardo Ortíz, Servicio COT, Hospital Univ., La Paz, Madrid
Dr. Julio Ribes, Servicio COT, Hospital de la Ribera, Alzira

¹COT = Cirugía Ortopédica y Traumatología: Orthopedic Surgery and Traumatology.



**II JORNADA
DE CIRUGÍA PROTÉSICA
EN TUMORES
Y GRANDES DEFECTOS ÓSEOS**





»Specialist nurses must have very wide know-how in order to assist efficiently in the operating room« – OR manager **Carmen Domröse** (right) and OR nurse **Christfried Crämer** at the Zeisigwaldkliniken Bethanien hospital center in Chemnitz

»We must be willing to pursue continuing professional development!«

What are the jobs that today's nurses have to do in the arthroplasty operating room? How will their profession look in ten years time? These and other questions are answered by OR manager Carmen Domröse and OR nurse Christfried Crämer at the Zeisigwaldkliniken Bethanien hospital center in Chemnitz, Germany.

Ms Domröse, Mr Crämer, you are both old hands in the field of arthroplasty, if you'll pardon the expression ...

Carmen Domröse (laughs): Yes, we certainly are. The first prosthetic joints were implanted in our orthopedic department way back in 1976. In the meantime, we have performed up to 1,100 hip and knee arthroplasties per year.

Where did the prosthetic joints come from in 1976?

Christfried Crämer: They mostly came from abroad, from »non-socialist countries« as they were referred to back then. Prosthetic joints were classified as a form of medication, and there were »special requirements« to be met, in the form of import licenses. But in later years, the GDR (East Germany) did develop its own joint prostheses at the Hermsdorf ceramics factories.

What was the significant difference for you between the GDR days and today?

Christfried Crämer: Patients were often 65 years old already because the aim was to avoid having to replace prostheses. Back then we were

implanting standard models with the objective that a prosthetic joint must fit like a tailor-made suit! But that is a goal that has only really become achievable with today's implant models. As a specialist hospital, revision is now one of our key focuses.

Did you already use LINK implants before German reunification?

Christfried Crämer: Oh, yes! We used the Endo-Model® from LINK. For us it was always something special when we were able to open one of those light blue boxes from LINK. The packaging is still instantly recognizable – to this day.

Ms Domröse, you are responsible for managing the operating room; Mr Crämer you work at the operating table as a specialist nurse ...

Carmen Domröse: I also work at the operating table sometimes, for example if somebody is away. As OR manager, it is important to me to maintain these skills. It's essential for a complete understanding of important matters.

What is the focus of your work?

Christfried Crämer: Definitely correct instrumentation for each particular situation. I have to know the implants and the implantation procedure so well that I can hand the instruments to the surgeon before he asks for them.

Carmen Domröse: The specialist nurses must have very wide know-how in order to assist efficiently in the operating room. As OR manager, it's my job to organize everything connected with the operation itself: ensuring that stocks are replenished, dealing with suppliers, consulting with the surgeons.

What influence do you have on the choice of joint prosthesis?

Carmen Domröse: That is entirely the surgeon's decision. It's his prerogative. But I think our input does play a major part. Essentially it's about collaboration and teamwork. For example, we say what we think about the instruments – whether they are easy to recognize, and whether the instrument sequence is logical

What is your role with regard to purchasing?

Carmen Domröse: I prepare the negotiations with suppliers and, of course, I am assisted by our specialist staff in the Purchasing Department.

How important do you regard the relationship with prosthetic joint makers?

Carmen Domröse: Very important. A good example is revisions. Often these only involve partial implantations, for which we need the guarantee that spare parts will still be available in 20 or 30 years' time. LINK provides this guarantee, but other makers do not. It means that we do not have to replace the entire knee implant, which involves unnecessary expense and risks.

Christfried Crämer: In fact, the modularity of knee prostheses is something that we have only encountered with LINK. It is certainly very helpful. What is also important for me is that instrument sets are clearly structured and recognizable.

What message would you like to give to the makers? What needs to be improved?

Christfried Crämer: Just one small point: the labeling of the implant components should be as large as possible so that it is easy to read.

Carmen Domröse: Hospitals have to operate cost-efficiently. So it is important that the external packaging, the recoding, is free of charge. Otherwise that is an enormous cost factor. From my perspective, it is also desirable for the instructions for using the components are available in German.



Instantly recognizable – LINK packaging before 1993

Let's take a look in the crystal ball: How will your profession change over the next ten years?

Christfried Crämer: I think it will become more difficult to deliver an excellent service because of growing financial constraints.

Carmen Domröse: What worries me is staff turnover. Here, at the Chemnitz hospital things are very stable. Some of us have been working together for decades. But at many other hospitals there is a constant coming and going. That's a barrier to building up the necessary know-how. The ideal situation is when people stay – and come to terms with the need to constantly acquire more knowledge. The implants, the surgical techniques, everything is developing all the time. We must be willing to pursue continuing professional development.

You don't have any worries about financial constraints?

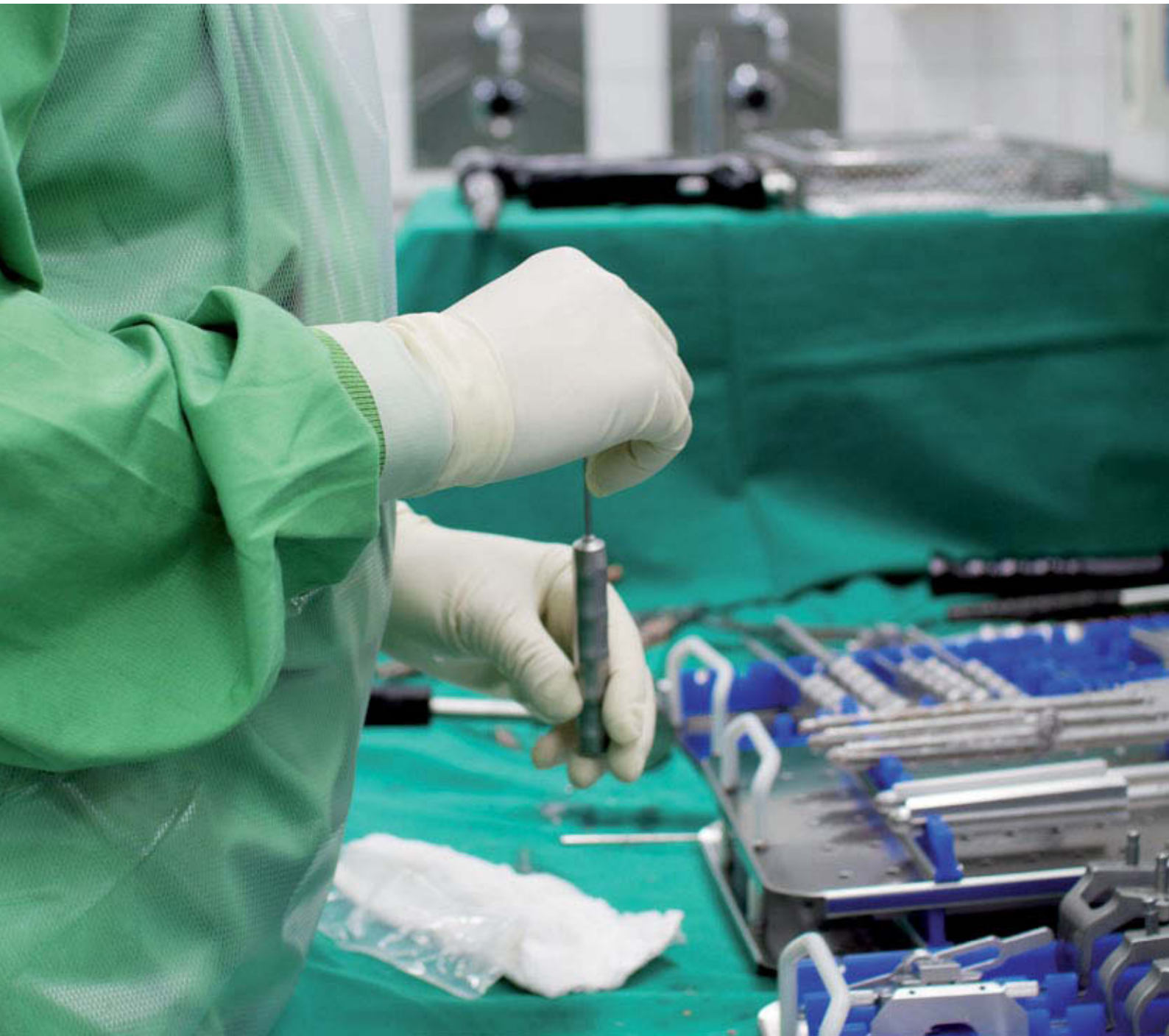
Carmen Domröse: We are already very careful with everything we use for cost reasons. In the GDR days we were equally careful – because everything was in short supply.

Ms Domröse and Mr Crämer, thank you very much for giving us your time.

Training for surgeons

»Hands on! at the Megasystem-C® workshop«

Further training at the highest level under realistic conditions – that is what the LINKademy® offers new entrants and experienced arthroplasty surgeons alike. Report on a »hands-on workshop« for the LINK® Megasystem-C® tumor and revision system, held at the Department of Legal Medicine in Hamburg, Germany.



How a good workshop should be organized is easy to describe in theory. It should comprise work of a practical nature, with very high quality standards being set. What makes a good workshop in actual practice was experienced by those who attended the Megasystem-C® hands-on workshop held at the Department of Legal Medicine in Hamburg

Prof. Christoph Lohmann, Director of the Orthopedic University Hospital at the Otto von Guericke University in Magdeburg, was the distinguished instructor who was pleased to pass on his knowledge and experience to the six workshop participants. After a brief introduction and a talk by company proprietor Helmut D. Link on the subject of antimicrobial surface modifications, everyone adjourned to the autopsy room. The program for the day comprised two implantations of an Endo-Model® SL® Rotational and Hinge Knee Prosthesis in conjunction with the Megasystem-C®.

Tips and hints for a tumor and revision system offering maximum intraoperative flexibility

Prof. Lohmann demonstrated current surgical techniques on an anatomically prepared human body, discussed the implant design and gave valuable tips and hints. The participants had the opportunity to practice the technique and thereby discover in detail the high degree of intraoperative flexibility and range of applications of the Megasystem-C®.

Dr. Dirk Seifert, medical director at the Robert Koch Hospital, Apolda/Thüringen, summed up his impressions in the following words: »Practical hands-on training gives a better feel for the structure of tissue and bone«. Dr. Rauf Ahmadian, senior physician at the Rotes Kreuz Hospital in Kassel, particularly valued the directness of the experience. »Being able to discuss possible problems while standing at the operating table has great benefits in terms of improving one's technique, in my view«, he said.

Time enough for all questions

Dr. Maik Hoberg, senior physician at the König-Ludwig-Haus Orthopedic Hospital in



»I particularly liked the small group size and direct discussion with the expert« – **Dr. Iris Lasser**, senior physician at the Department of Orthopedics and Traumatology at the Klinik am Eichert in Göppingen, Germany



Discussion continued during the break: LINK Marketing Director **Thomas Benning**, Company Proprietor **Helmut D. Link** and **Dr. Maik Hoberg** (l. to r.)



Dr. Rauf Ahmadian, senior physician at the Rotes Kreuz Hospital in Kassel, Germany

Training for surgeons

Würzburg emphasized the benefits of involving the participants closely in the surgical procedure. His verdict on the workshop: »We were able to ask Prof. Lohmann absolutely any question, and that is a great advantage compared to events with a considerably larger number of participants«.

BioLab workshops with experts from leading international hospitals are part of the successful training opportunities offered by the LINKademy. You can find details of all the further training events at www.linkademy.de.



Dr. Dirk Seifert, Medical Director at the Robert Koch Hospital, Apolda



Original packaging – Only new LINK joint prostheses were used



»Our surgery courses are designed to benefit the living«

Prof. Dr. Klaus Püschel

is Director of the Department of Legal Medicine at the Hamburg-Eppendorf University Hospital. A particular area of expertise is

the systematic development of tissue donations with the permission of the deceased's family, in accordance with the statutory regulations governing human tissue donations.

Prof. Püschel, at your institute, surgeons receive practical training in the correct implantation of prosthetic joints using the bodies of deceased persons. Could you tell us why?

Surgeons do not want to train on living patients, but rather to use the donated body of a deceased person in order to help the living. The courses are designed to provide instruction in surgical techniques, and are thus scientifically based. The more often surgeons are able to practice difficult techniques, the better the outcomes achieved for patients. The surgery courses thus benefit medical science and patients' quality of life.

What are the advantages compared to using artificial bodies?

An artificial body does not provide the surgeon with the feel of natural tissues. It is almost impossible to practice placing access ports and handling osteoporotic hip bones, for example, if you are using a dummy. You do need the real anatomy. For this reason, the surgery courses represent the optimal form of training.

Where do the bodies come from?

In the cadaver labs, we use body donations from persons who have given their consent for their bodies to be used for scientific purposes after they have died. This is something we also do for other fields apart from arthroplasty. Training for the first heart transplants in Hamburg was conducted at our institute.



Thomas Benning graduated in Business Administration. After positions in product management and sales at Ethicon and Codman, he became Director of Orthopedic Sales and Marketing at DePuy and, most recently, Director of Marketing & Sales at Biomet Germany. In May 2012 Thomas Benning became Global Marketing Director at LINK.

»Our quality assurance does not end at the factory gate«

Mr Benning, you have been head of marketing at LINK since May. How were the first few weeks?

Exciting. I visited European subsidiaries – in Italy, Spain, Sweden and the Netherlands. After all, 70 percent of LINK's turnover is in other countries. That is something we must concentrate on more in our marketing effort.

What surprises did you have on changing job?

The US market is simpler in economic terms. Over there, higher prices are paid and unit sales are also higher. That makes life easier for our American competitors. In contrast, our home market in Germany is possibly the most competitive. We have to turn that to our own advantage.

Where do you see the drivers of the market?

In the industrialized countries, it is becoming increasingly important for the high standard we have achieved to be delivered more and more cost-effectively. But the appreciable expansion of our market will happen in the newly industrializing countries. On the product side, I see the greatest potential in the coating technologies.

What about the training of surgeons?

An extremely important area. On the one hand, financial pressures on hospitals means that a high degree of »productivity« is demanded from surgeons but, on the other hand, the increasingly specialized hospitals are finding it difficult to cover all aspects of orthopedics in the training they provide. The role of industry will increase

further, especially regarding complex products such as prosthetic joints.

Is that an advantage or a disadvantage from the marketing perspective?

Our quality assurance does not end at the factory gate. We aim to help surgeons to achieve the best possible outcome. That requires not only optimally developed products, but also training in the relevant implantation techniques.

What approach do you adopt in newly industrializing countries?

Especially in those countries – Brazil, India and Indonesia, for example – training is the key to opening up the market. What good is the best product if nobody knows how to use it?

Isn't there a potential shortage of new recruits even here in Germany?

Yes, it is becoming increasingly difficult to find qualified personnel, and that applies both to hospitals and to manufacturers like us.

What do you plan to do?

Fortunately, LINK has its head office in Hamburg, a highly attractive location. That makes recruitment easier. Furthermore, we shall be making LINK more visible, including in the media, in order to position ourselves as an attractive partner in the labor market.

Mr Benning, thank you for talking to us.

What does the »iProsthesis« offer?

Tissue temperature, signs of loosening, information about implant model and manufacturer, and more besides. There's no doubt about it – equipping a joint prosthesis with all sorts of sensors and data storage devices has long been technically possible. But would such an »iProsthesis« actually be a good thing?

If you want to place a bet on the next digital megatrend, after Facebook and the like, you should consider the »self-tracking« movement. Members of the so-called Quantified Self Movement use a whole range of mini-sensors to measure body parameters such as heart rate, sleep rhythm, body position and body fat. Packaged in bits and bytes, the data is sent via smartphone apps to Internet data clouds, where they are discussed with experts in forums. The objective of the »self-trackers« is to adopt a healthier lifestyle by means of continuous statistical data analysis.

It may sound like a hobby for computer nerds, but it could in fact be just the start of the next megatrend worth billions. These data collections could be the first line drawings for a vision of the future, in which even complex medical tracking devices are measured in nanometers, yet are capable of alerting us to problems in the human body at an extremely early stage. In California, home to high-tech pioneers like Apple, Facebook and Google, start-up companies for the development of such nano measuring devices have already been established. It is possible that this technology will be extended to another field, namely joint prostheses.

Almost limitless measurement possibilities

At present, it is difficult to determine, for example, how well a hip prosthesis becomes integrated after implantation, or whether and why it works loose over a number of years. Similarly, when revision is required after a period of decades, it is often a time-consuming job for surgeons to find relevant data about the existing prosthesis. Consequently, some prostheses are removed completely as a precaution, when partial replacement would have sufficed.

An »intelligent« joint prosthesis, equipped with

all sorts of data storage devices, sensors and wireless LAN technology could provide precise information whenever required: exactly what model of implant it is, how well it is integrated, whether it has loosened, and what forces the stem, head and acetabular cup are actually subjected to in situ. Data analysis could, for example, provide the basis for recommending treatment to protect the loose prosthesis – and the success of the treatment could in turn be monitored via the sensors. The measurement possibilities are almost limitless. »Numerous tracking functions are conceivable, including for other joint prostheses and quite different implants«, says Hans-Jürgen Holland, an engineer at the Fraunhofer Institute for Photonic Microsystems IPMS in Dresden, in an interview with the German newspaper »Die Welt«. The institute is one of eight establishments and companies participating in the »Inhuepro« project funded by the German Ministry of Education and Research. The project integrates intelligent sensors into the hip prosthesis itself with the aim of avoiding unnecessary revisions in future. The first results are expected in the fall of 2012, after which patient testing can begin. The objectives of the project are, in part, similar to those of the »self-trackers«: to increase quality of treatment and quality of life, while keeping a lid on rising health costs due to demographic change.

It might, at last, be possible to assess the actual lifetime of a prosthetic joint accurately.

The question remains as to whether the »iProsthesis« would also be a good thing in practice. Prof. Rudolf Ascherl, Medical Director at the Center for Special and Revision Arthroplasty and Surgical Infectiology at the Zeisigwaldkliniken Bethanien hospital, is in no doubt: »If, during revision, we remove prostheses supplied by manufacturers that no



The smartphone for the »iProsthesis« – only an artist's impression for now

longer exist, the information necessary for obtaining the correct spare part is very difficult to get hold of. If a data storage device was integrated in every joint prosthesis, data regarding the type, size, alloy and original manufacturer would be available more quickly.«

But static data about the prosthesis itself is only one aspect of the »iProsthesis«. Apart from sensors which, for example, provide information about inflammatory processes via the periprosthetic temperature, it would also be possible to precisely document the actual useful life of a joint prosthesis by means of a force sensor to detect overloading or a pedometer. Prof. Ascherl also sees clear advantages here: »One person may walk 10,000 kilometres in the space of 20 years, while for someone else it may only be 1,000 km. Such a sensor would allow the actual lifetime of the prosthesis to be assessed correctly.«

Data protection legislation only applies if the data is matched up to the patient.

In spite of all the practical benefits of an »iProsthesis«, there are also critics. »The electronic components in the prosthesis would have to be fitted in such a way that they do not endanger the quality of the product, and that is a completely new challenge«, says Helmut D. Link, proprietor of Waldemar Link GmbH & Co. KG. Apart from which, the matter of data protection would also have to be addressed: Is it permissible to simply gather data from the prosthesis?



»Data protection legislation applies if the data is matched up to the patient« – **Prof. Dr. med. Dr. iur. Christian Dierks** is an expert in medical law, based in Berlin, Germany



»A sensor could help to correctly assess the lifetime of a prosthesis« – **Prof. Dr. med. Rudolf Ascherl** is medical director of the Center for Special and Revision Arthroplasty and Surgical Infectiology at the Zeisigwaldkliniken Bethanien hospital in Chemnitz, Germany

Prof. Dr. med. Dr. iur. Christian Dierks, an expert in medical law, takes a relaxed view on this question: »If and when such an »iProsthesis« becomes state of the art, the patient would be informed about it during the course of medical treatment. No special procedure is necessary because the patient is being treated in accordance with generally accepted medical practice.«

It only becomes critical if personal details are also gathered. Prof. Dierks explains: »Provided that the personal particulars are required for the treatment, the attending surgeon is permitted to obtain this data without a declaration of consent for the purpose of data protection. For the rest, the general rule applies that any use of personal data requires the consent of the person concerned under data protection law«. If, for example, the manufacturer of the prosthesis wanted to evaluate the data, agreement must also be reached about how the data is to be used. »Such data must only be used for the purpose for which it was originally obtained«, according to Prof. Dierks. »But these are matters that can be resolved.«

It is doubtful that »self-trackers« are already thinking about how to protect their data even today. After all, people exchange information via Facebook – and Facebook is renowned for the unabashed and liberal way in which it handles the data of its users.



PorEx® during final inspection

GEMINI® SL® knee prosthesis bearings, with gold-coloured titanium niobium nitride (TiNbN) surface modification, pass through manual final inspection. The hypoallergenic PorEx® surface modification has an even lower coefficient of friction than the CoCrMo surface, and therefore less Polyethylene wear. LINK offers PorEx® for all implants as a customized solution.



3D measurements

The curvature of a CoCrMo prosthesis head is measured using a 3D measuring machine. Our sphericity of 2-4 μm is well within the limits of the ISO 7206-2 standard, which specifies a maximum sphericity tolerance of 10 μm . The 4 mm red ball at the tip of the measuring probe is made of ruby. 36 prosthesis heads can be checked simultaneously in each measuring cycle.

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