

directLINK®

Magazine for Arthroplasty · Issue: September 2014

»The weakest link is always the human factor!«

An interview with Prof. Dr. med. Thorsten Gehrke, Medical Director of the HELIOS ENDO-Klinik Hamburg, on the subject of periprosthetic infections, hygienic routine and the LINK® Endo-Model®

35 years in situ: Partial pelvic replacement from LINK

LINK® Endo-Model®: Dr. Francisco Maculé discusses stability, reliability and confidence





Mr. Link, can you do this, too?

This question from Prof. Hans-Wilhelm Buchholz to company founder Waldemar Link initiated the development of the St.Georg hip prosthesis. Previously, Prof. Buchholz had met the English orthopedic surgeon Sir John Charnley, who was trying out new materials for hip prostheses. The basic principles for the construction of a total hip prosthesis that were developed for the St. Georg model still apply today. The photograph shows Waldemar Link presenting the company's trade fair stand in the early days.



Dear Readers:

Discoveries and inventions may owe a lot to serendipity – as in the case of penicillin. But other important advances are down to daring pioneers such as Otto Lilienthal with his flying machine. Fortunately, when it came to developing LINK joint prostheses, there was no need to risk life and limb – even if the early days of arthroplasty in Germany, more than 50 years ago, were sometimes quite an adventure.

Today, LINK is able to draw on a wealth of experience, and new products are conceived and developed systematically. If there is a shortage of sound scientific studies dealing with a particular problem, it is helpful to consult with other experts in the field – for example, at the International Consensus Meeting, initiated by Prof. Thorsten Gehrke, on the problem of periprosthetic infections.

High quality at LINK benefits both patients and surgeons. This is demonstrated by the report on the LINK Partial Pelvis Replacement, which for 35 years now has not only kept an engineer on his legs, but has even kept him climbing mountains. His photo on a mountain peak is impressive proof that, as developers, we too should never stop looking forwards - and upwards!.

Enjoy this issue of directLINK. Regards.

Publication details

Published by: Waldemar Link GmbH & Co. KG · Helmut D. Link

Editor: Heike Urbschat · Tel.: +49 (0)40 53995-0 E-mail: redaktiondirectLINK@linkorthopaedics.com

Editing/Design/Production: medienärzte Gesundheitskommunikation · Hamburg · www.medienaeerzte.de

Photography/Graphics: Stefan Albrecht (cover, 2–4) · LINK (inside front cover, back cover, 1, 5, 8–11, 15, 17, 19, 20) · medienärzte (6, 13, 21) · Mathias Lange (14, 16), Fotolia (22), Bülent Topal (13, 20), Bernd Schlenker (19), Ingo Schwarz (21)

Disclaimer: The opinions of the interviewees do not necessarily reflect the views of the publisher.

Waldemar Link GmbH & Co. KG · Barkhausenweg 10 · 22339 Hamburg, Germany

Tel.: +49 (0)40 53995-0 · Fax: +49 (0)40 538 6929 · redaktiondirectLINK@linkhh.de · www.linkorthopaedics.com



»The rotational prosthesis is used primarily in cases of complete instability« – Prof. Dr. med. Thorsten Gehrke is Medical Director of the HELIOS ENDO-Klinik Hamburg, Germany

»The **weakest link** is always the human factor!«

An interview with Prof. Dr. med. Thorsten Gehrke, Medical Director of the HELIOS ENDO-Klinik Hamburg, on the subject of periprosthetic infections, hygienic routine and the LINK® Endo-Model®.

Professor Gehrke, you initiated and organized the International Consensus Meeting on periprosthetic infection in Philadelphia in 2013. How did it come about?

In 2012, my colleague Professor Javad Parvizi and I had discussed the fact that there were no prospective randomized controlled studies in the area of periprosthetic infections. Of course, patients with such problems cannot be assigned to random groups. They must all be given the best possible treatment. As it is not possible to generate clinical evidence via studies, we put together 200 questions to which we wanted to find answers by expert consensus.

400 experts from 52 countries, who represented over 100 national orthopedic associations, took part in the Consensus Meeting – quite a logistical feat.

You can say that again. Our staff combed through and evaluated more than 3,500 publications for contributions that were relevant to the subject. By the time everything was ready, we had exchanged

25,000 emails. The Consensus Meeting handbook is being translated into 21 languages.

»Pathogen resistance will continue to increase!«

A very worthwhile undertaking for tackling a growing problem.

Yes, because the incidence of periprosthetic infections is growing around the world in absolute terms as more and more primary hip and knee arthroplasties are being performed. The infection rate with primary arthroplasties is between one and two percent. At the ENDO-Klinik we treat a higher-than-average number of these cases because we are, essentially, a referral center for periprosthetic infection and patients from all over Europe are referred to us. We ourselves have an infection rate of 0.2 to 0.3 percent.

The ENDO-Klinik recently increased its capacity, and currently performs 6,000 interventions each year.

We have taken on more surgeons and have also trained septic surgery specialists. That takes time because these colleagues must be extremely experienced. We now have a sepsis team comprising five specialists. In the past, we had 100 patients on our surgery list for sepsis cases, which meant a waiting period of three months. Today it's five weeks at most.

As a result of pathogen resistance, we are seeing the severity of periprosthetic infections increasing alongside the growth in the absolute number of cases. How serious is the problem?

Very serious. Pathogen resistance will continue to increase! Until five years ago we were able to control virtually all pathogens relatively easily with antibiotics – today we have to contend with multiresistant bacteria. MRSA is not really the problem because we know what weapons to use against it. But more and more bacteria are emerging all the time, such as 4MRGN¹, which only respond to cytotoxins like colistin. These are individual cases which we see quite frequently at the ENDO-Klinik, of course. But the number of these cases will increase.

Are there any failings on the part of the hospitals?

No, German hygiene standards are among the highest of all, and are enforced more strictly than anywhere else in the world. I feel confident in making this judgment because I perform surgery in many countries, and I am very familiar with operating room conditions from the USA and South America to Russia and India.

So what could be improved?

Everyone must try to perfect their hygienic routine. We are very strict about this at the ENDO-Klinik. For example, we ask our patients to go to the dentist at the diagnostic stage. We always wear two hoods and two pairs of gloves in the operating room. We have specialist hygiene staff and four physicians responsible for hygiene. If anyone is seen in a surgical gown outside the operating room, they are given an official warning. In the USA, some colleagues even go out to eat at the local diner without getting changed.

As regards the implant itself, do you see any means of fighting infections apart from silver coatings?

No, so far the silver coating is the best method of preventing periprosthetic infections. Almost all bacteria, with only a very few exceptions, respond to silver. In fact, we can't blame the implant at all for the infections that occur. The weakest link in this area is still the human factor!

»Discipline in the operating room is also part of infection prophylaxis!«

Why is that?

Just think about all the people who go in and out of the operating room. It's non-stop. Clearly that increases the infection risk and therefore should be stopped. Actually, such things are explained in the relevant literature, so operating room staff should



»German hygiene standards are amongst the highest of all, and are enforced more strictly than anywhere else in the world.«

Interview

be aware of them. Nevertheless there is potential for improvement. After all, it is down to people to implement infection prophylaxis for the patient's protection, which includes maintaining strict hygiene standards and optimizing operating room procedures. All that's really needed is for everyone to exercise a high level of discipline, from the surgeon through to the operating room nurse.

What role does surgery time play in infection prophylaxis?

The infection risk increases, the longer the operation takes. That is the only evidence that we have in this area. Surgeons who take three hours over a hip operation that can normally be done in half an hour or an hour increase the risk of infection. So surgical discipline is also an element of infection prophylaxis.



»Today our waiting time for sepsis cases is five weeks at most«

How important are rotational and hinge knee prostheses in the treatment of periprosthetic infections?

At the ENDO-Klinik, we use a rotational or hinge knee prosthesis in over 99 percent of cases involving periprosthetic infection. In around 85 percent, we perform a single-stage revision. Our success rate is very high, mainly because we carry out extreme debridement and radically remove any tissue suspected of being infected. When a knee prosthesis becomes infected, the stabilizing structures, such as the collateral ligaments, are often affected. In order to restore joint stability, it is necessary to implant a rotational or hinge knee prosthesis.

»The CCK requires a more complicated surgical technique and a longer surgery time.«

The Endo-Model® was developed together with LINK at the ENDO-Klinik.

That was 35 years ago, and there is still an incredible level of demand for it around the world. The reason is that the Endo-Model® permits very reliable and safe treatment with a very simple surgical technique and quite modest instrument requirements.

How does it compare with the CCK², in your view?

The CCK is undoubtedly a good knee prosthesis. But it is more complicated in terms of the surgical technique, requires considerably more instruments, and therefore a longer surgery time. However, the two implants have fundamentally different indications. The CCK can still be implanted in cases of pronounced instability. The rotational joint prosthesis is primarily used in cases of complete instability, that is to say when there is loss of the medical collateral ligament.

Professor Gehrke, many thanks for giving us this interview.

¹4MRGN = multiresistant gram-negative rods with resistance to four groups of antibiotics.

²CCK = Constrained condylar knee.

Very low risk of early aseptic loosening with the SP II[®] Hip Prosthesis Stem

With the anatomically adapted LINK[®] SP II[®] Hip Prosthesis Stem, the risk of early aseptic loosening is minimal. This is confirmed by a prospective study¹ conducted by the Orthopedic University Hospital at the Friedrich-Alexander University, Erlangen-Nürnberg, dating from 2013.

The study comprised 59 patients with an SP II[®] Hip Prosthesis Stem. Over a period of two years post-op, implant migration was analyzed, and the clinical results evaluated, by means of radiostereometric analysis (RSA) and Harris Hip Score (HHS).

Migration values far below the clinically relevant threshold values

The SP II[®] Hip Prosthesis Stem remained stably fixed throughout the study period. Migration was significantly below the levels regarded as clinically relevant, at 0.04 ± 0.83 mm.² The HHS rose from 42 ± 11 postoperatively to a level of 79 ± 16 after two years, while the Charnley values were $n = 71$ postop and $n = 67$ after two years. It may be concluded from the results that the SP II[®] Hip Prosthesis Stem is associated with only a very minor risk of early aseptic loosening within the study period.

The study confirms the consistently good results from the Swedish Hip Arthroplasty Register.³ Furthermore, according to the authors, the study is based on probably the largest sample to be RSA-measured and examined under standardized clinical conditions, thus underlining its clinical character and making the SP II[®] Hip Prosthesis Stem a reference for new RSA-measured implant designs.

Individual adaptation to anatomical conditions

The key feature of the LINK[®] SP II[®] Hip Prosthesis Stem is its anatomical shape, which allows a centered fit in the femoral canal and preservation of the intramedullary bone substance. The S-shape of the stem counteracts rotational forces, while the

modular system allows individual adaptation to the anatomy.

Together with the LINK[®] Lubinus[®] acetabular cup, which has been used in thousands of patients, the LINK[®] SP II[®] Hip Prosthesis Stem forms an optimal cemented total hip prosthesis.

¹ Wierer T, Forst R, Mueller LA, Sesselmann S.: Biomed Tech (Berl). 2013 Aug; 58(4):333-41. doi: 10.1515/bmt-2012-0038, Radiostereometric migration analysis of the Lubinus SP II hip stem: 59 hips followed for 2 years

² Garellick G, Karrholm J, Rogmark C, et al.: Swedish Hip Arthroplasty Register Annual Report 2008. Sweden Department of Orthopaedics, Sahlgrenska University Hospital 2009

³ The Swedish Hip Arthroplasty Register, page 75, www.shpr.se.



Minimal risk of early aseptic loosening: Anatomically shaped SP II[®] Prosthesis Stem with Lubinus[®] acetabular cup



»I want to achieve the greatest possible comfort for my patients« – **Dr. Francisco Maculé** is Director of the Knee Department at the Hospital Clínic de Barcelona

»I have confidence in the **rotational knee!**«

How does an experienced surgeon rate the LINK Endo-Model® Rotational Knee Prosthesis in comparison with the CCK*? An interview with Dr. Francisco Maculé, Director of the Knee Department at the Hospital Clínic de Barcelona, on the subject of stability, reliability and confidence.

Dr. Maculé, you perform up to ten total knee replacements in a week. Which of your patients are given an Endo-Model® Rotational Hinge Knee Prosthesis and which a CCK?

Essentially, the objective state of the knee ligaments is the key factor in deciding whether to implant a rotational knee prosthesis such as the LINK Endo-Model® or a CCK. In the case of revisions, I usually choose a rotational knee prosthesis. For primary arthroplasty in patients with severe varus or valgus deformities and loose ligaments, I have to weigh up whether a CCK is adequate to ensure stability in the knee joint. The choice of system is always a case-by-case decision.

Do you ever change your mind during the course of the operation?

Yes, if the intraoperative anatomy demands it. For example if, contrary to expectation, the medio-

lateral ligament is very loose. I know from experience that in such cases a rotational knee prosthesis is more suitable than a CCK.

Some arthroplasty surgeons believe that a CCK is always adequate both for complex primary cases and for revisions.

No, you have to make a careful distinction here. If the patient has a severe valgus deformity, for example, it is scarcely possible to achieve reliable stability with the CCK. In such cases I prefer a pure hinge knee prosthesis because I can reliably ensure stability in the joint.

Can you explain more precisely what you mean by reliable stability?

Reliability and confidence in a prosthetic joint are key, in my view. I know from many years of experience that very good, reproducible results can be

achieved with a rotational knee prosthesis. So I have confidence in this system. I do not have the same confidence in the CCK. There are too many variables which affect joint stability. The state of the ligaments, for example.

Reliability and confidence in a prosthetic joint are key, in my view.

As a surgeon, does your confidence in an implant transfer to the patient?

Yes, also consciously. I want the greatest possible comfort for my patients. The feeling of stability in the knee joint is a very important criterion in this respect. Furthermore, with a CCK, the patient has to wait two days before starting with postoperative walking exercises. He must also do physiotherapy for six months until the ligaments and muscles have adapted to the point where they give him the feeling of stability in the knee. With a rotational knee prosthesis, the walking exercises can start three hours after surgery, and physiotherapy is only required for a few weeks, if at all.

When a patient has had a CCK for several years, the knee ligaments are usually very loose, which makes the joint unstable. Does this mean that a rotational knee prosthesis might be the better option from the outset?

That only applies to some ligaments, such as the posterior and mediolateral. Besides, it also depends on the underlying disorder. In the case of rheumatoid arthritis, with the future changes to the soft tissue, and in the case of chronically loose ligaments, it is advisable to perform the primary replacement with a rotational knee prosthesis in order to ensure long-term joint stability. If the patient only suffers from osteoarthritis, my judgment would probably be different.

Is a rotational knee prosthesis quicker for you to implant than a CCK?

Definitely. In primary cases, I only need an hour, at most. For revisions it is somewhat longer because the loss of bone mass, which is often an

accompanying problem, also takes up time. With the CCK, both operations can take considerably longer in some cases due to the many variables.

At your hospital, you have established a protocol for implantation of a total knee prosthesis. What does it comprise in essence?

First of all, we determine the indication. For the rotational knee prosthesis, in primary cases, this principally means deformities and severe joint instability. In the case of revisions, the indication is very loose collateral ligaments and severe loss of bone mass. In the second step, we seek to achieve a steep learning curve. For the rotational knee prosthesis you need around ten implantations in order to master the system. With the CCK, it takes at least 20 operations, due to the variables. The third step is, of course, ongoing analysis of our results because our aim is to improve continuously.

For the rotational knee prosthesis you need around ten implantations in order to master the system properly.

What conclusion do you draw from a comparison of the two knee prosthesis systems?

The rotational knee prosthesis is a very reliable system that reproducibly delivers good results, so I have great confidence in it. Another advantage is that it can solve complex cases in a single intervention – which reduces the overall cost. In addition, the shorter surgery time compared to the CCK reduces the infection risk. In my experience, patients with a rotational knee prosthesis regain confidence in their knee particularly quickly. If the patient then believes his knee is stable, that's really due to the implant. One could also say that the rotational knee prosthesis has an ›intrinsic stability‹.

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

Reaming instead of sawing: MIRETO™¹ instrument set for intracondylar hinge knee prosthesis systems

Following the principle of »reaming instead of sawing«, LINK has optimized the instrument set for its intracondylar Endo-Model® knee prosthesis systems and also added a bone-conserving reaming technique. With the new MIRETO™ reaming process, only the cartilage is removed from the condyles for primary implantation – the load-bearing subchondral bone is largely preserved.

MIRETO™ saves bone substance

With the MIRETO™ instrument set and the new innovative reaming technique, the term »total knee replacement« is finally becoming a reality in regard

to condylar implant bed preparation. The Endo-Model® knee prosthesis systems can thus be implanted reliably, reproducibly and with high precision, while also conserving bone substance. In the case of primary implantations, the new reaming technique saves a third² of bone substance in comparison with a standard condylar resection. Therefore more bone is conserved for revision procedures. The instrument set offers various options for checking the implant alignment and restoring the position of the joint line in revision cases.



MIRETO™ with the innovative reaming technique is suitable for all intracondylar Endo-Model® knee prosthesis systems

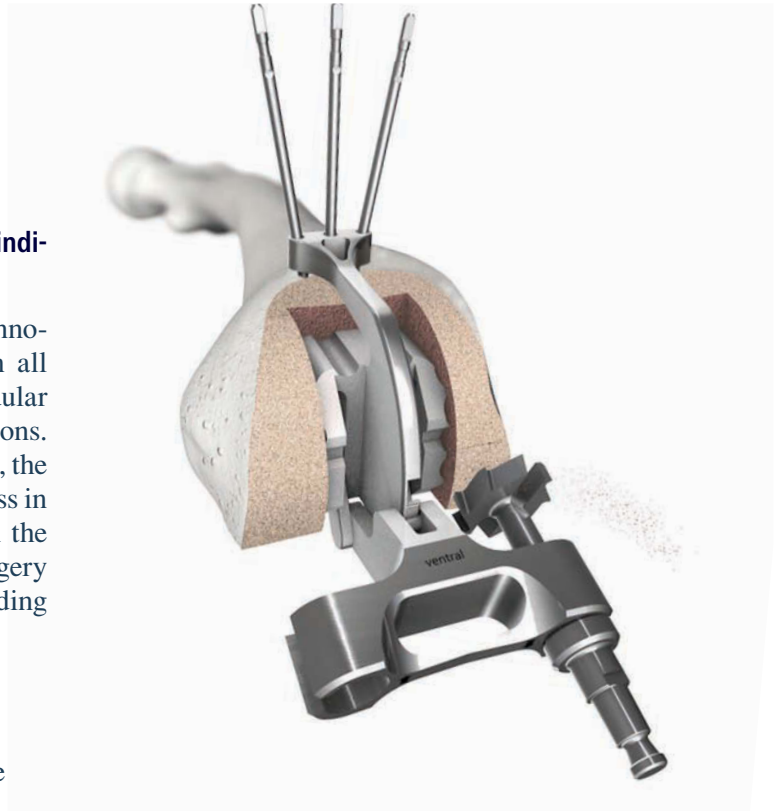
Endo-Model® knee prosthesis: Also with PorEx® (TiNbn = titanium niobium nitride) surface modification for patients with metal hypersensitivity

MIRETO™ is suitable for primary and revision indications

The new MIRETO™ instrument set, with its innovative reaming technique, can be used with all intracondylar Endo-Model® standard and modular implants for primary and revision indications. From storage through to hygienic reprocessing, the instrument set is designed with user-friendliness in mind. This ensures reproducible handling in the operating room and enables the planned surgery time to be adhered to, even in more demanding cases.

Other advantages of the instrument set are:

- Fully guided instrumentation
- Reproducible, reliable and extremely precise bone resection
- Quick and easy assembly and disassembly
- Small number of instrument trays combined with enhanced application modularity.
- Simple hygienic reprocessing
- Accelerated surgical procedure
- Low investment and reprocessing costs



Reaming instead of sawing: With the new MIRETO™ instrument set, more bone is conserved for later revision procedures

¹ MIRETO™: Minimal Resection Total Knee.

² Source: internal measurement.



Video at: www.linkorthopaedics.com

Greater **reliability** and **precision**: MITUS[®] RS instrument set for the LINK[®] Sled Prosthesis

LINK has enhanced the instrument set for its unicondylar LINK[®] Sled Prosthesis to enable precise, controlled femoral resurfacing. The new MITUS[®] RS (Resurfacing) instrument set enables reproducible alignment of the components and resection in a single step. An additional advantage of the instrument set is a high level of bone conservation.

Anatomically adapted reconstruction

Bone-conserving resection and minimization of soft tissue damage are important factors for the success of unicondylar arthroplasty. The basis for the outstanding survival rates achieved with the unicondylar LINK[®] Sled Prosthesis² is bone-conserving positioning of the femoral component. Fol-

lowing removal of the cartilage from the femoral condyle, the femoral implant is simply placed over it like a shell. The reconstruction is anatomically adapted by means of the polycentric design of the femoral implant. Another feature of the implant is the thinness of the »shell«, which reduces the risk of patellar impingement.



Unicondylar LINK[®] Sled Prosthesis: Only minimal bone resection is required to accommodate the femoral and tibial components



Unicondylar LINK[®] Sled Prosthesis: With PorEx[®] (TiNbn = titanium niobium nitride) ceramic-like surface modification for patients with metal hypersensitivity

Maximum bone conservation and minimum soft tissue damage

The LINK® MITUS® RS instruments for implantation of the sled prosthesis assist bone-conserving resection and help to protect the soft tissues because they enable control of the cutting depth on the tibia and exact adjustment of the desired resection height in the sagittal and horizontal planes. The features of the new MITUS® RS instrument set for the unicondylar sled prosthesis makes it even easier to implement the key intraoperative factors for successful treatment:

- Alignment of the femoral cutting template according to the anatomy
- Minimum bone resection – maximum bone conservation
- Full control over the tibial resection height
- Choice of different implant sizes after testing with trial implants.
- Uniform cement mantle achieved by smooth, even surface preparation with minimal bone removal
- Homogeneous load transmission ensured by uniform anchorage
- Precise adjustability permits exact, reproducible component alignment
- No tools required for disassembly for sterilization



Resurfacing with greater precision than ever: MITUS® RS

¹ MITUS®: minimally invasive technique for the unicondylar sled prosthesis.

² Source: Annual Report, The Swedish Knee Arthroplasty Register, <http://www.myknee.se/en/>.



Video at: www.linkorthopaedics.com

»There's **still a lot** for me to do!«

An interview with Prof. Dr. med. Heinrich Thabe, former Medical Director at the Diakonie hospital in Kreuznach, Germany; on the subjects of certifications, bowing and his own knee joint replacement.

Prof. Thabe, after more than 35 years in senior positions, you recently entered retirement. What are you doing now?

Something that I have always enjoyed a lot: organizing and structuring. In 1998 I was one of the first medical directors in Germany to obtain certification for my Orthopedic Department at the Diakonie Krankenhaus in Kreuznach. And that is something I have been involved with ever since.

With lasting success, evidently.

My staff were pleased to have clear treatment guidelines. Suddenly we all had a third more time for our patients, and that was achieved by working systematically, both individually and as a team. In 2006, the entire hospital obtained certification.

Now you are passing on your experiences of certification to others.

Yes, I decided to train as an auditor and, since the end of last year, I have been engaged in certifying orthopedic hospitals. That's what I know best, after all.

Do you miss being a surgeon?

No, I prepared myself mentally for doing my last operation, and said to myself that, from that day onwards, I would have time for other things. For example, supervising scientific projects, preparing data for publications, and lots more.

You performed your last operation in China, a country with which you have a special relationship.

That's right. In 1995 I began inviting colleagues from China to our hospital in Bad Kreuznach. We were soon receiving visits on a two-weekly basis. I went over to China more than 20 times myself. Most recently last November for the Congress of the Chinese Orthopedic Association (COA) in Beijing. I gave talks at the invitation of the COA and LINK's Chinese partner.

One result of your involvement with China is the Thabe-Endo-Club.

Every visiting surgeon from China automatically became a member of the Club. Over the years, a network was established which still exists today. At our symposia, we implant joint prostheses and transmit the operations to the auditorium. Later we analyze the cases scientifically. We also exchange X-ray images via the Internet and discuss cases, and I answer questions. The Club has around 1,300 members, almost all of whom hold senior medical positions in China. So a lot of German expertise is implemented in Chinese hospitals.

How did the contact with China come about?

Professor Yan Wang, president of the Chinese Orthopedic Association, was one of our first visiting surgeons. We got on very well, and he liked the ideas behind our work. He then invited me to China. My first operation was at the People's Liberation Army General Hospital.

... the most important hospital in Beijing, and the size of a small town?

Yes, I soon became familiar with the huge scale of things in China. The operation was transmitted not only to 600 colleagues in the auditorium, but also to 75 universities around the country. After that, I was known all over China. The final breakthrough was made in 2001, when we implanted a knee prosthesis in a difficult patient in an operation lasting less than an hour. Nobody in China had believed it was possible until then.

You also have several visiting professorships.

In 1996 I became China's first visiting professor of orthopedics from outside of Asia. Since then I have been given a further six professorships at university hospitals.

»No unfulfilled wishes, but lots to do« –

Prof. Dr. med. Heinrich Thabe



How do you find your Chinese colleagues?

Extremely eager for knowledge, inquiring and dedicated. China must not be seen as a developing nation in terms of orthopedics, where you have to teach the basics. At China's major teaching hospitals, a lot of innovative work was going on from an early stage. For example, in the 1930s, hand transplants were being performed at the Guangzhou University Hospital.

The Chinese bow when they enter the room.

In China, people have a natural respect for the achievements of a colleague, something that has dwindled away a bit here in Europe. It is simply a way of acknowledging someone with many years of experience. In China, it's not unknown for a venerable old surgeon to be rolled onto the stage in his wheelchair to open a conference. Furthermore, I treated everyone as equals, and was always forthright, but at the same time I never tried to play the schoolmaster.

Since 1995 you have made numerous visits to China for LINK and performed many live operations there. But you also have a LINK® GEMINI® SL® Total Knee Replacement yourself.

That's correct. The first generation, the GEMINI MK I, was designed by a friend of mine. The MK II

was developed by the former LINK Managing Director Arnold Keller together with myself. The senior physician at my hospital implanted my own development, the MK II, for me in 2012.

Are then any wishes yet to be fulfilled in your career?

No, I've had a very full and enjoyable life as an orthopedic surgeon. The gratitude of my patients was always the biggest motivation. My key aim has always been to pass on my knowledge and to help as many colleagues as possible in their careers. In my 29 years as medical director, I have been able to provide senior physicians to fill 25 posts as medical directors of hospitals in their own right. Now I pass on my knowledge through the Thabe-Endo Club and in my certifications, for example.

So you will keep in close contact with the industry and with China?

Yes, certainly. Many contacts in China have developed into friendships which I am keen to maintain. And then I have my visiting professorships. I don't have any unfulfilled wishes, but lots to do!

Prof. Thabe, thank you for talking to us.

Left: The Club has around 1,300 members, almost all of whom hold senior medical positions in China; center: Chinese colleagues visiting the Diakonie Krankenhaus in Kreuznach; right: »I was always forthright, but equally I never tried to play the schoolteacher« – **Prof. Dr. med. Heinrich Thabe** will continue his visits to China even in retirement





»Good developers know whether something makes sense or not« – **Helmut D. Link** has headed up the company since 1972

»We thought about it, and then said **No!**«

More than 50 years of arthroplasty in Germany with LINK. An interview with Helmut D. Link about pioneering spirit, the qualities of the developer, and the value of experience.

Mr. Link, you were there when your father and Professor Hans-Wilhelm Buchholz¹ created the first total hip prosthesis in Germany in 1963. Was everyone aware at the time of just how momentous a development it would prove to be?

For my father it was just one new development of many. He was an instrument maker and often produced specialized instruments for surgeons. The importance of the prosthesis was soon made clear by the enormous interest expressed by the surgeons. Up until then, there had been no real method of alleviating the pain suffered by patients with coxarthrosis. Just think about hip arthrodesis! Patients needed special chairs to be able to sit.

The pioneers of hip arthroplasty also had a talent for organization.

That's true. The British orthopedic surgeon Charnley² discovered a great material for the acetabular cup, namely ultra-high-molecular-weight polyethylene (UHMWPE). Professor Buchholz consulted him and then obtained a block of the material from BASF. My father had an acetabular cup machined from the block, and this was used in combination with the Moore joint prosthesis from the American firm Howmedica³. That's how the first German total hip prosthesis came about. The bone cement for implantation was provided by a dental company. The hip prostheses became known as the

»St. Georg« because at that time, Professor Buchholz was head of bone surgery at the St Georg Hospital in Hamburg.

How were the first implantations carried out?

Each acetabular cup was sterilized by placing it in a metal bowl filled with Incidin®. After two hours, the cup was removed with sterile dressing forceps and rinsed off with a sterile saline solution. The surgeon then pressed the acetabular cup into the bone cement using a ball spike. From today's perspective it sounds a bit risky, but polyethylene is a very forgiving material.

»The risk-taking approach to development is a thing of the past – unfortunately and thank goodness!«

In those days, new developments demanded ideas and courage. And today?

Today a group of specialists develop products in several stages. Instead of models made of wood and modeling clay, there are 3D images, and everything is tested systematically. The risk-taking approach is a thing of the past – unfortunately, and thank goodness! Back then, development was much faster than today, but sometimes led to products that failed to meet requirements when put to the test. We, too, had to learn the hard way.

What makes a successful development today?

It begins with a precise analysis of whether it actually makes sense to develop a particular product. Many ideas sound great, but don't work in practice. Filtering of ideas is a very important aspect of development work. Good developers are very critical and do not slavishly follow the wishes of the person who came up with the idea. They know whether something makes sense or not, and can then implement the ideas, which are usually very rudimentary.

What motivates developers to achieve great things?

Open discussion, working together to think outside the box within the limits of anatomy and physiology, and also the freedom to innovate. Although,

as a firm, we have to be careful not to drift into pure research which cannot subsequently be translated into commercially viable products. I constantly have to restrain myself when confronted with interesting questions so that I don't start up a study out of sheer curiosity.

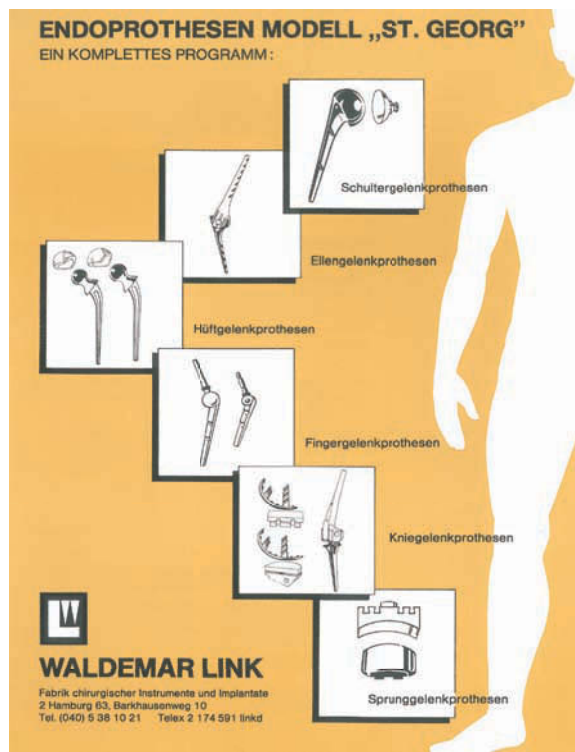
»Avoiding mistakes is an extremely important matter!«

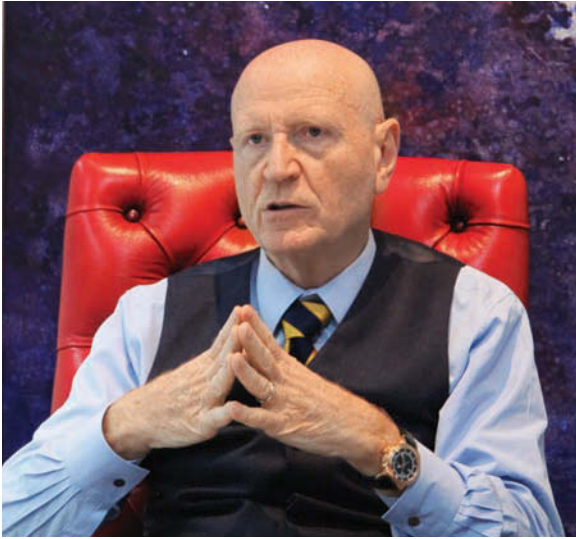
Steve Jobs, the deceased founder of Apple, made the following appeal in 2005, when addressing graduates at Stanford University: »Stay hungry, stay foolish!« Does that apply in the field of arthroplasty?

Actually, I have often argued along the same lines when it is claimed that something or other is not feasible. We have been to the Moon, so it must be possible to solve technically difficult challenges.

What have been LINK's greatest successes in terms of new developments?

The SPII® Hip Prosthesis and our rotational knee, which is now regarded as standard for revisions around the world. Also the Total Femur Replacement, the Partial Pelvis Replacement and our tumor prostheses. What was also very important for LINK was the lumbar and cervical intervertebral disc prostheses that we developed, and which we





»I hope that the firm will continue to expand to a point where, one day, it gets mentioned in the same breath as the big five in the industry«

introduced in the USA at the end of the nineties. You could say the same for the three-part Total Ankle Prosthesis developed with Prof. Hakan Kofoed: S.T.A.R.[®].

Were there any painful defeats?

We have never made any major mistake, I'm glad to say. My former Managing Director Arnold Keller was very experienced in material testing and he brought this expertise into the firm. That was a great help because avoiding mistakes is extremely important. In our early days, we developed a hinge knee for Professor Buchholz, and the upper section was made entirely of plastic. But the long leverages that occur in the femur resulted in too many periprosthetic spiral fractures. We then quickly changed over to metal.

»What matters is which product is needed and can be used safely.«

Clearly experience still plays a prominent role in development – and today?

Absolutely! Experience tells you what effects something can have, and whether it's better to discard an idea rather than pursue it. There are a

few examples where more experience at the development stage would have been beneficial, for example with metal-on-metal tribological pairings. We were also asked whether we wanted to manufacture these pairings. We thought about it carefully, and then said No. What matters to us is not just which product will be commercially successful, but also which product is really needed and can be used safely.

You have been personally involved in arthroplasty for over 50 years now. What still motivates you to come into the office every day?

First and foremost, the potential that I still see in joint prostheses. If you have the opportunity to analyze and read about the current state of arthroplasty, and to speak to people at conferences, then you constantly have ideas for improvements. I don't find it stressful at all. I hope that the firm will continue to expand to a point where, one day, it gets mentioned in the same breath as the big five in the industry. We have every prospect of achieving just that!

Mr. Link, thank you for talking to us.

¹ † 2002, founded the ENDO-Klinik Hamburg in 1975.

² † 1982, British orthopedic surgeon, regarded as the pioneer of hip arthroplasty.

³ Since 1998 Stryker Osteosynthesis.



»Stay hungry, stay foolish!«



Experts at the International LINKademy® Revision Symposium 2013: (l. to r.) Prof. Dr. Rodolfo Capanna, LINK proprietor Helmut D. Link, Prof. Dr. med. Thorsten Gehrke, Prof. Dr. Giorgio Maria Calori

LINKademy®

International Revision Symposia



The next international LINKademy® Revision Symposium will be held in Berlin on 27 and 28 November 2014. Like last year, the meeting will enable international revision experts to exchange their experiences.

The aim of the Symposium is to discuss solutions for difficult knee and hip revision arthroplasties on the basis of available scientific facts, with a view to finding a consensus and deriving treatment algorithms.

Following the extremely positive experience of 2013, this year's Symposium will again have a very interactive character. Prof. Dr. Thorsten Gehrke will again chair the Symposium and, as moderator, will ensure that all the participants are continuously involved in the discussions, and that their individual fields of interest are given due consideration. To this end, each subject will be introduced with a real case, and then intensive discussion will follow. The aim is to conclude each case by coming up with a specific solution and deriving a treatment algorithm.

Registration is now open for the LINKademy® Revision Symposium 2014 in Berlin via www.linkademy.de.



Partial Pelvis Replacement from LINK in situ for 35 years

In 1978, an engineer, who is now 71, was diagnosed with a malignant osteoblastoma. He received a partial pelvis replacement and a hip prosthesis from LINK. Over 30 years later, all that was required was a revision arthroplasty of the acetabular cup insert, hip stem and acetabular head. A case study.

In March 1978, a localized osteoblastoma in the region of the pelvis and right hip was diagnosed. In April of the same year, a surgeon resected the hip and parts of the pelvis in a multi-stage operation. In addition, the patient was given a hip prosthesis and a custom-made partial pelvis replacement made of stainless steel by LINK. Postoperatively, hepatitis C was diagnosed and later successfully treated with interferon.

The patient is even able to go mountain hiking using a walking aid.

After 20 weeks of rehab in the space of three years, the patient was able to get into a car unassisted using a metal-leather frame, move around his home, and even go mountain hiking using walking aids. In the subsequent years, accidents resulted in two thigh fractures in the proximity of the stem, each with partial dislocation of the hip stem. However, no revision of the implants was required.

33 years after implantation, the acetabular cup insert was replaced.

It was not until April 2011 that, due to pain and a right leg length difference of two centimeters, the worn out acetabular cup insert had to be replaced. At the same time, the hip stem (long stem) and acetabular head were revised. The partial pelvis replacement remained in situ, as only a crack in the material at the level of the ischium was detected. Shortly afterwards, due to several postoperative luxations, a re-revision was performed with an acetabular cup relocated further outwards and a larger acetabular head. A third revision was required 18 months later, when luxations again occurred. This time, the acetabular cup was lateralized further still so that the acetabular head sat even deeper and was

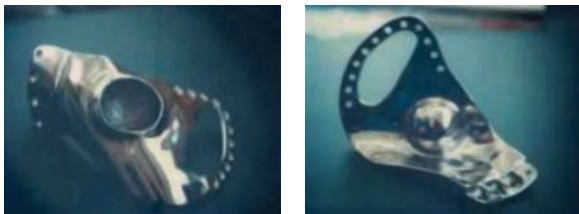
thus better protected against luxation. The partial pelvis insert from 1978 again remained untouched in this operation. It should be noted that even after 35 years, LINK was still able to provide the surgeon with all the data and measurements for this custom-made implant. Six months after this operation, the last to date, the patient is able to put full weight on his leg. He cycles and drives, swims and is almost pain-free. He can go hiking for up to three hours using walking aids, and that time limit is only because of the pressure on the hands caused by the walking aids.

Integration of a partial replacement into the pelvis should be as elastic as possible

Even though this patient's partial pelvis replacement is still functioning reliably after 35 years, LINK continues to incorporate new design features into today's custom-made implants. »The modulus of elasticity of the cortical bone of the pelvic ring is only 1/5 to 1/3 of the femoral cortical bone, and considerable mobility is possible in the symphysis and iliosacral joint. This means that the implant should be integrated elastically«, explains LINK proprietor Helmut D. Link. The migrated screws also confirm that a relatively large endoprosthetic replacement in the pelvic ring requires elastic placement, as a sort of spacer. A spacer with high surface support for the residual bone can act as an elastic connection in the pelvic ring. As Helmut D. Link puts it, »The pelvis has stability and elasticity at the same time because the partial replacement becomes lined with a connective tissue sac«.



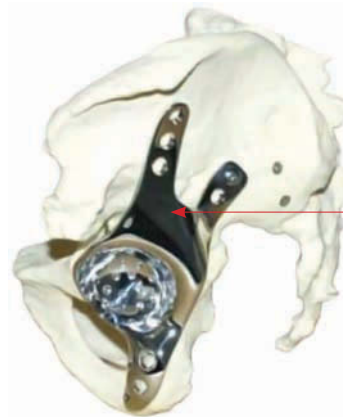
The patient on a mountain hike in 2006



Custom-made partial pelvis replacement from LINK, 1978



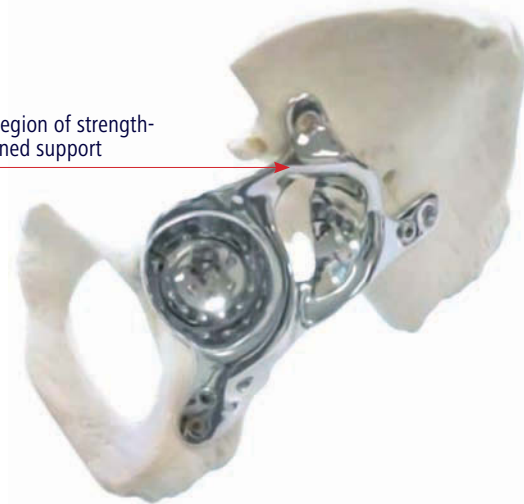
Partial pelvis replacement of 1978 in situ, X-ray from 2010



Strengthened support:
The decisive factors for stability of the pelvis with a partial replacement are elastic integration and support on the residual bone

Custom-made partial pelvis replacement from LINK, 2014;
top: ventral view; bottom: lateral view

Region of strengthened support



LINK Twin Sphere partial pelvis replacement, lateral view

Successful entry into the primary arthroplasty market for LINK India

In May 2011, LINK became established in the south of India. »LINK has a reputation for excellent quality, and is therefore highly regarded in India, as elsewhere«, says Aravindan Arumugam, Managing Director of LINK India, based in Chennai. His team of ten look after the requirements of more than 55 surgeons. Among the most successful LINK products in India are the LINK® Endo-Model® Rotational Knee for primary and revision surgery and the LINK® Lubinus Classic Plus® Hip Prosthesis System.

»In 2013 LINK successfully entered the primary arthroplasty market in India, and in 2014 we are aiming to build on this success by focusing on market leadership in the knee revision market«, explains Aravindan Arumugam. There is good reason to expect that this objective will be achieved: »In India there are many patients with complex knee problems and joint deformities. Furthermore,

the number of revisions is increasing.« The Managing Director of LINK India is delighted that more and more surgeons in India are insisting on high quality when it comes to joint prostheses: »In India too, our role is to support the surgeons by providing solutions.«



»In India too, our role is to support the surgeons by providing solutions« – The staff of LINK India:

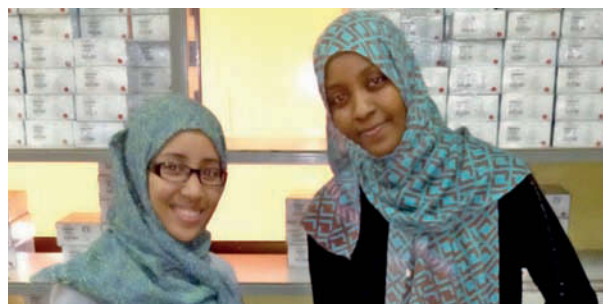
M. Sundaram, S. Kannan, M. Vadivelu, K. Ramaraj and S. Janarthanan (l. to r.), together with **LINK Managing Director Peter Willenborg** (center) and **Export Manager Matthias Grebien** (2nd from l.)

LINK quality in demand in Sudan

LINK is the first manufacturer of high-quality joint prostheses to become established in the Republic of Sudan. LINK currently has a 30 percent share of the market for imported implants in this North African state, and is the only supplier in the field of revision arthroplasty in a market otherwise dominated by low-price competitors. At present, around 2,000 knees and 2,000 hips are being implanted each year. Together with its local partner, the Best Care Hospital in the capital Khartoum, LINK markets joint prostheses such as the LINK® SP II® Hip

Prosthesis Stem and the GEMINI® SL® Total Knee Replacement.

The Republic of Sudan, with its population of 38 million, is the third largest African country by land area, and five times bigger than Germany. In the past ten years, orthopedic treatment in the country has been greatly improved. Thus, the number of orthopedic surgeons – represented by the Sudanese Orthopaedic Surgeons Association SOSA – has grown from 30 to 150.



Friendly people and a very dedicated orthopedic association in the Republic of Sudan



»Berlin Declaration at the DKOU 2013« – Orthopedic surgeons and traumatologists from China and Germany agree on close scientific exchange

Scientific exchange with China is on the increase

As an arthroplasty pioneer, LINK is also actively involved in countries with up-and-coming orthopedic associations – with success: 2013 saw China participate in the scientific program of the German Congress of Orthopedics and Trauma Surgery (DKOU) for the first time. That has given increased impetus to the academic transfer of knowledge.

LINK started up the transfer between German and Chinese surgeons back in the mid 1990s. Today, LINK promotes the exchange of knowledge through several arthroplasty events each year. The »LINK® Academic Sino-German Friendship Symposium« is being held for the fifteenth time in 2014. As a counterpart, German surgeons are taking their expertise to Chinese hospitals in an arrangement facilitated by LINK.

So it is all the more pleasing that, in 2013, the Chinese Orthopedic Association (COA) and the World Orthopedic Alliance (WOA) took part for the first time in the DKOU's scientific program, in Berlin. On this occasion, the »Berlin Declaration« laid the foundation for even closer German-Chinese cooperation, thereby adding momentum to the academic transfer of knowledge in this field. »In the last two decades, the number of orthopedic disorders around the world has increased by almost 100 percent«, says Prof. Yan Wang, member of the WOA Steering Committee. »Good orthopedic and trau-

matology training is of decisive importance in meeting these challenges. The WOA therefore has the goal of raising the level of arthroplasty expertise worldwide.« Professor Wang and 80 colleagues participated in the DKOU 2013 in Berlin at LINK's invitation.

WOA as a platform for the exchange of training course content

The WOA is to act as a platform for advancing the exchange of training course content. The focus is principally on developing countries, and the primary objective is to improve knowledge and surgical capabilities in the fields of orthopedics and traumatology. »It is essential to raise the level of expertise in arthroplasty around the world if patients in all countries are to receive the best possible treatment«, says Prof. Wang. Against this background, LINK is involved in emerging markets. Proprietor Helmut D. Link is a member of the WOA Advisory Committee.



»The WOA aims to advance international arthroplasty training« – **Professor Yan Wang** is a member of the WOA Steering Committee



Obesity: Standard joint prosthesis or customized solution?

According to the statistics issued by the German Federal Institute for Drugs and Medical Devices (BfArM), 2,695¹ cases of material-related implant failure were reported in 2012. Obesity-related implant fractures are not listed separately, and the BfArM does not supply detailed information on request. But a retrospective Italian study from 2011, with 27,571 patients, compares the influence of patient weight and BMI on the long-term survival of total hip prostheses over a period of ten years. This study reports 73 implant fractures due to patients being overweight and obese.² Further research

produced just a single limit value for the weight threshold, and this figure is presumably a rough estimate: Fractures due to obesity in the case of implants made of titanium are stated as occurring only in patients who are overweight by 100 kilos or more.³

A quarter of the German population is obese.

While the facts concerning »obesity-related implant fractures« are rather sparse, the problem could quickly grow in importance. According to the survey of adult health in Germany conducted

by the Robert Koch Institute and known as the DEGS study⁴, around 23 percent of men and just under 24 percent of women in Germany were obese in 2011. The largest increase in obesity was seen in the age group of 25 to 34-year-olds. Consequently, at the annual conference of the German Adiposity Society (DAG) in 2013, experts called for obesity to be recognized as an illness. And with good reason. In the USA, the number of obese people has risen sharply in the last 30 years. Almost two thirds of Americans are already overweight today, and some 30 percent are obese.⁵

Customized solution instead of standard prosthesis

This trend could manifest soon enough in Germany, too. So is this reason enough to optimize the material used in the weight-critical regions of knee and hip prostheses, such as the stem and neck? »Unlike some of our competitors' products, the joint prostheses from LINK have no weight limitations«, explains Helmut D. Link. »We do, however, recommend our customers not to implant standard prostheses in patients who are considerably overweight, but instead to use custom-made solutions for safety.«

Greater fracture resistance with BIODUR-S® axis in the LINK® Endo-Model® SL® Rotational Knee

For such cases, the LINK product portfolio includes, for example, the MP® Reconstruction Protheses⁶ for the hip with strengthened stem, namely the MP Super BIODUR® prostheses for heavy-duty use.⁷ A similar purpose is fulfilled by the BIODUR-S® forged axis made of CrCrMo alloy in the case of the LINK® Endo-Model® SL® Rotational Knee Prosthesis. »The increased fracture resistance of the CoCrMo is achieved by means of a special forging process«, says Helmut D. Link. »This means that the material used in the component has approximately 30 percent higher tensile strength and hardness.«

Standard material tests are only designed for 70 kilograms.

In spite of the efforts to create joint prostheses with greater fracture resistance for obese patients, a fundamental problem remains. In the conventional tests for joint prosthesis materials, 5–10 million load cycles are applied, which corresponds to an assumed number of years in situ – but the tests are not designed for obese patients. »Without prior tests under appropriate conditions, it is not possible to state with certainty how a significantly higher body weight and greater patient activity will affect the prosthesis«, according to Helmut D. Link. »So in case of doubt, it is advisable to speak to us because we also develop joint prosthesis solutions for very obese patients.«

¹ Source: Risk warnings for non-active implants, www.bfarm.de, accessed on 10 February 2014.

² Patient weight more than body mass index influences total hip arthroplasty long term survival. Francesco Traina, Barbara Bordini, Marcello De Fine, Aldo Toni; Prosthetic Hip and Knee Surgery, Rizzoli Orthopaedic Institute, Bologna, Italy. Hip international: the journal of clinical and experimental research on hip pathology and therapy. 12/2011; 21(6):694-9. DOI:10.5301/HIP.2011.8879.

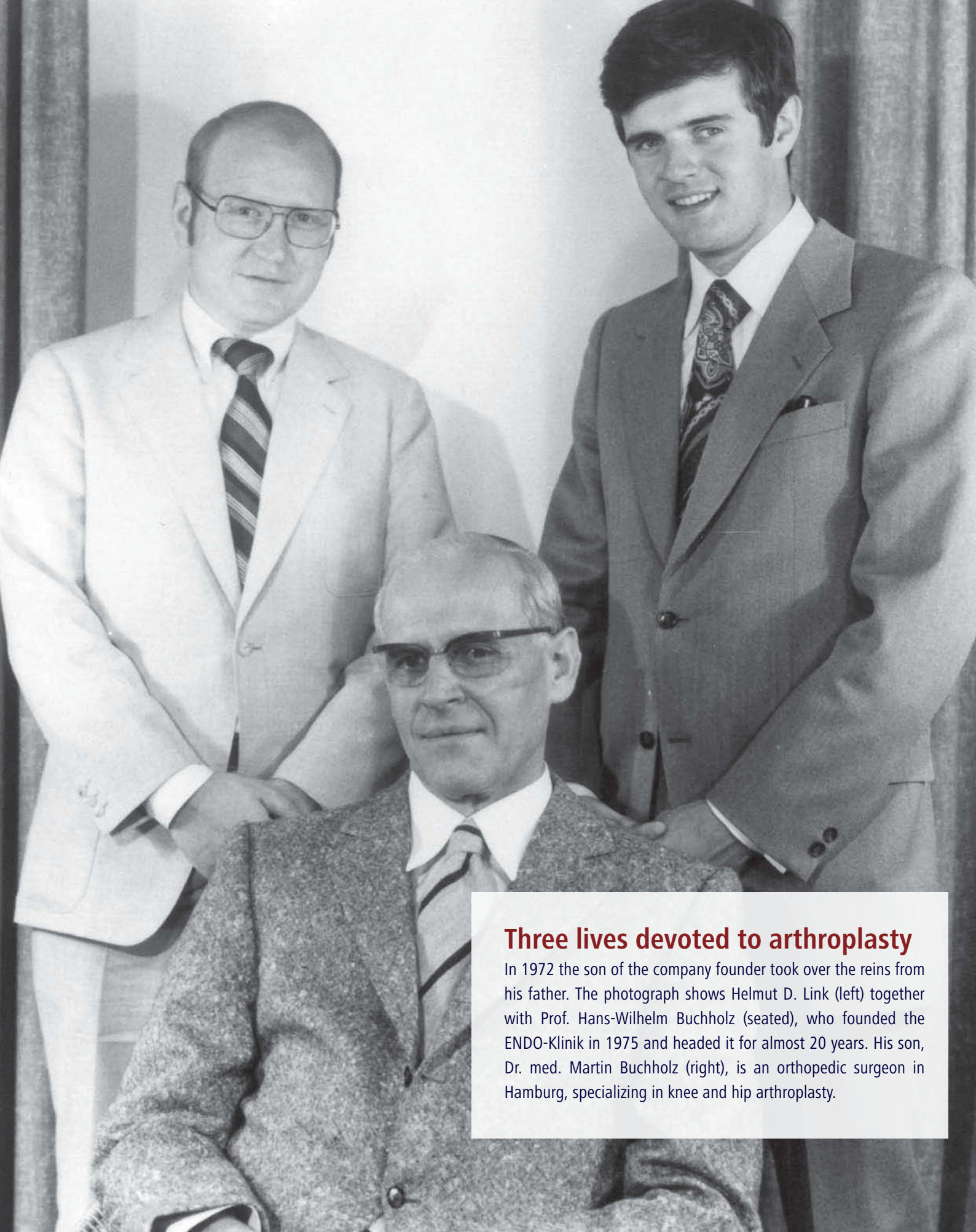
³ www.main-netz.de/nachrichten/serien/gelenk-gesundheit/art11674,304968

⁴ Source: www.degs-studie.de.

⁵ Source: National Health and Nutrition Examination Survey (NHANES 2008); www.cdc.gov/nchs/nhanes.htm.

⁶ Available in cementless and cemented versions.

⁷ Available as custom-made implants.



Three lives devoted to arthroplasty

In 1972 the son of the company founder took over the reins from his father. The photograph shows Helmut D. Link (left) together with Prof. Hans-Wilhelm Buchholz (seated), who founded the ENDO-Klinik in 1975 and headed it for almost 20 years. His son, Dr. med. Martin Buchholz (right), is an orthopedic surgeon in Hamburg, specializing in knee and hip arthroplasty.