directLINK®

Magazine for Arthroplasty

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»The new LINK Embrace Shoulder System works great«

Dr. Pablo Cañete, Head of Orthopedic Surgery and Traumatology Service at Manises Hospital in Valencia, Spain

MDR legislation
LINK Managing Director Norbert Ostwald on successful certification under the new Medical Device Regulation (MDR)

LINK FlexiCones
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Orthogeriatrics
PD Dr. Hendrik Kohlhof on implant selection in arthroplasty specifically for the elderly

LINK Embrace
Shoulder System

DESIGNED TO EMBRACE YOUR RANGE OF MOTION

The Reverse Glenoid Baseplate of the new LINK Embrace Shoulder System is anchored in the bony glenoid by means of a central press fit pin and up to four peripheral screws, and can optionally accommodate a central screw. Surgeons can choose between angle-stable, polyaxial angle-stable and screw fixation for cancellous and cortical bone, respectively. The Reverse Glenoid Baseplate is manufactured from Tilastan in an additive process; it bears the three-dimensional TrabecuLink structure on its bone-facing surface for optimal bone bonding. Read more about the LINK Embrace Shoulder System starting on page 2.

Dear readers!

»If I have seen further, it is by standing on the shoulders of giants« Sir Isaac Newton (1642–1727) is said to have once written in a letter to a colleague. With Newton's axioms, he formulated the basic laws of motion in 1687. The axioms are still the foundation of classical mechanics.

When our new LINK Embrace Shoulder System bears the motto »Designed to Embrace Your Range of Motion«, we are literally standing on the shoulders of this British research giant. The most important facts about Embrace at a glance as well as interviews with the first users Dr. Pablo Cañete and Dr. Jörg Löwe can be found on the following pages.

The new Medical Device Regulation (MDR) legislation is weighing heavily on the shoulders of implant manufacturers. LINK has mastered the challenge with great effort and has been certified according to MDR since last fall. Nevertheless, we are still very critical of the new legislation. Managing Director Norbert Ostwald talks about the core of the problem and why MDR is also at the expense of patients in an interview starting on page 22.

We hope you enjoy reading about these and many other topics in direct**LINK**.

Yours,

Helmut D. Link

Imprint

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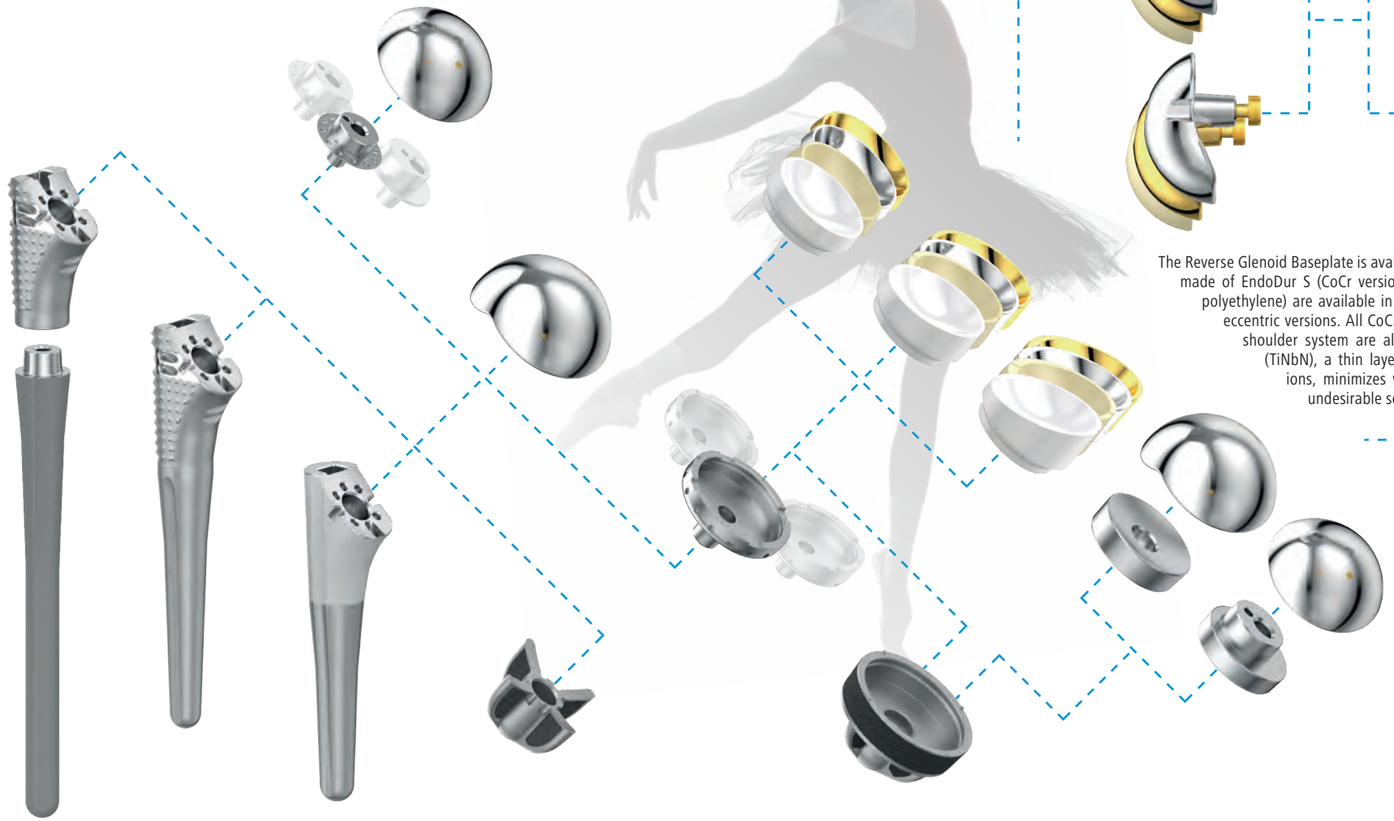
LINK Embrace
Shoulder System

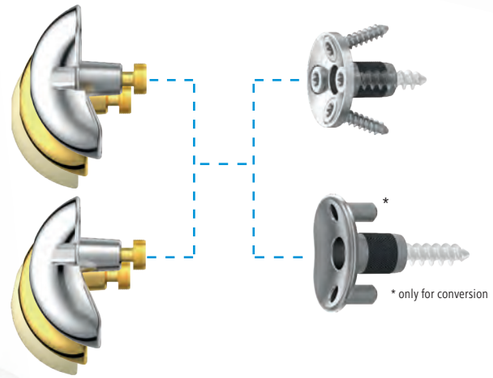
Designed as a platform, the new LINK Embrace Shoulder System covers a wide range of indications. It ranges from anatomical elective procedures to fracture and reverse treatment to conversion scenarios from anatomical to reverse (and back) and revision cases. The design took into account many years of experience with successful implant systems and fixation concepts as well as the latest material and coating technologies.

LINK EMBRACE – HUMERAL OPTIONS



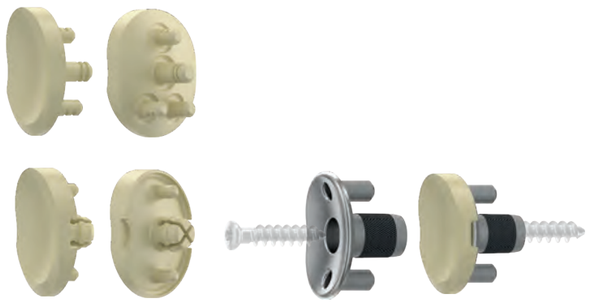
LINK Embrace humeral stems are available in monobloc and modular versions and thus offer effective, individually adaptable and quickly feasible treatment options in anatomical and reverse configurations. Stemless Cages for primary anatomical treatments and Stemless Ring Cages for primary reverse treatments are available for particularly bone-saving treatments. They are designed to directly accommodate a reverse insert made of UHMWPE or CoCr. All Stemless components of the Embrace system are convertible from anatomic to reverse (and back). The modular head adapters with different offsets, as well as a wide range of humeral heads with different diameters and lengths, allow physiological morphology to be restored in an appropriate way. Reverse trays in neutral, inclined and in offset design in combination with reverse inserts allow the surgeon to adjust the mechanical parameters in sagittal and in coronal planes independently.

LINK EMBRACE – REVERSE GLENOIDS AND GLENOSPHERES



The Reverse Glenoid Baseplate is available in various designs. Glenospheres made of EndoDur S (CoCr version) and alternatively E-Dur (vitamin E polyethylene) are available in several diameters and in neutral and eccentric versions. All CoCrMo components of the LINK Embrace shoulder system are also available with PorEx modification (TiNbN), a thin layer that reduces the diffusion of nickel ions, minimizes wear and helps to reduce the risk of undesirable soft tissue reactions.

LINK EMBRACE – ANATOMICAL GLENOIDS



Cemented all-poly glenoids in the proven peg design (top) and cementless metal-backed glenoids with conversion option (bottom) offer surgeons different treatment options. The convertible glenoid, implanted primarily in an anatomic configuration, can be fitted with a glenosphere for reverse treatment at a later revision. The Metal-Back is manufactured from Tilastan in an additive manufacturing process and carries a TrabecuLink structure on the bone-facing surface for high primary and secondary stability.

Scan this QR code for more information about the LINK Embrace Shoulder System.

»The new LINK Embrace Shoulder System works great«

Dr. Pablo Cañete specializes in shoulder arthroplasty. In this interview, he talks about his experience with the new LINK Embrace Shoulder System and his role in the development of Embrace.

Dr. Cañete, you are a member of the development group for the new LINK Embrace shoulder system. What made you want to be part of it?

About two and a half years ago, LINK asked for my opinion on the initial project designs of the Embrace Shoulder System and its associated instruments. Being part of the development group was a fascinating opportunity for me to be involved in developing a new shoulder system from the very beginning and working together with the engineers.

ABOUT

Dr. Pablo Cañete is Head of Orthopedic Surgery and Traumatology Service at Manises Hospital in Valencia, Spain. He specializes in the field of shoulder arthroplasty. Dr. Cañete is a member of the developmemnt group for the new LINK Embrace Shoulder System.

You are also one of the first adopters of the Embrace Shoulder System. For which indications do you use Embrace?

My main indications are the rotator cuff arthropathy and fractures in older patients. Functional outcomes have improved greatly since we started using the reverse prosthesis instead of hemiarthroplasty. With the reverse prosthesis, we can achieve excellent results after shoulder fractures. Another indication is for patients with fracture sequelae who have been treated without surgery or operated on with osteosynthesis. They often have severe pain and very poor shoulder function. With Embrace, we can achieve a good result for them: no pain, better function and better quality of life. Primary shoulder osteoarthritis is also an indication we see frequently in our clinic. In these elective cases, we use the anatomic prosthesis unless the patient has a rotator cuff or subscapularis muscle tear or a degenerative glenoid with severe posterior wear; in these cases, I also use the reverse prosthesis.

What are the strengths of the Embrace Shoulder System?

In my opinion, Embrace is a complete and very versatile shoulder system with high modularity. It gives me many options to treat different shoulder problems and even the possibility to personalize the implant precisely for each patient's situation. For example, whether I want to have a CCD angle of e.g. 145 to adapt the implant to the patient's individual needs, whether I want more or less offset, or whether I need to change the polyethylene glenosphere and metal inlay to address glenoid impingement, Embrace gives me all the options I need to ensure the best possible outcome for the patient.

What is your opinion of Embrace's instruments?

During development, the LINK engineers emphasized optimizing the Embrace instrument set with surgeons in mind, and I too played my part. I think when you work with the instrument set, you realize that they listened closely to us surgeons because, in my opinion, it is the best instrument set on the market. Not only is it very intuitive and easy to use, but it's also very versatile, which reduces the number of instruments and the number of trays. All of this makes the work very comfortable for me as a surgeon and for the OR staff. I am very satisfied with the instruments.

How important is it for your work that Embrace allows the use of cementless stems?

I used Embrace cementless stems for fractures in patients over 80, with very good results, and love the mini stem, it is my favorite for degenerative cases. The fracture stem is also fantastic. It's very important to me to have these options because operating less invasively leads to significant bone preservation potential. Thanks to Embrace, fractures can be treated with cementless stems in most cases. I have not had to cement a case yet. Another advantage is that when you insert the base plate into the glenoid, you can feel that it fixes very well. The different types of screws for the base plate are also great. We can also use glenoid spheres made of polyethylene or metal. With Embrace, you simply have a lot of options.

»My first impression of Embrace was that although it looks new, it feels like it is mature and complete. The design and the instruments are just great. Embrace will definitely help my patients.«

Dr. Miguel Angel Ruiz Ibán, Hospital Universitario Ramón y Cajal in Madrid, Spain. Dr. Ruiz is a member of the development group for the LINK Embrace Shoulder System.

How many Embrace Shoulder Systems do you implant per month?

In our clinic's shoulder-elbow unit, we implant up to ten shoulder systems per month in an average year. At the moment, it's a little less because of the coronavirus pandemic, but we have a very long waiting list. About 90 percent of the cases are reverse shoulder arthroplasties and 10 percent are anatomic arthroplasties. For the treatment of fractures, most experienced surgeons in our clinic now use reverse treatment. We also use reverse treatment for primary osteoarthritis of the shoulder. But in addition to elective shoulder arthroplasty, we take care of many shoulder fractures as well. I do shoulder arthroscopies, care for shoulder fractures, and implant shoulder arthroplasties, so I have an excellent overall view of the shoulder pathology and treatment options. This has given me a lot of experience over time in judging whether the best treatment for the patient would be arthroscopy or implanting a prosthesis. That makes it easier to ensure that surgery is the right option. One of the keys to getting a good result in shoulder arthroplasty is a good indication. Also, it is very important to have a good rehabilitation team because shoulder surgery requires good physical therapy before and after to fully restore the mobility of the shoulder joint.

The shoulder joint can be a challenge from a surgical perspective. Why is that?

Unlike joints such as the hip, the soft tissues are crucial in the shoulder: the rotator cuff, the deltoid muscle, the periscapular muscles. It is a very mobile joint and mobility and stability depend mainly on the soft tissues. When the rotator cuff fails, the reverse prosthesis, by its design, enables the patient to improve the function of the deltoid muscle and thus restore the mobility of the shoulder. Good management of the soft tissues in shoulder surgery is key to achieving a good outcome. It is a technically challenging surgery that comes with a learning curve.

What do you recommend to young doctors who want to become shoulder surgeons?

It takes about five years to learn enough about the shoulder so that you can independently establish a conclusive surgical indication and perform the surgery successfully. I did shoulder arthroscopies at the

LINK Embrace
Shoulder System

A wide range of stems in different configurations allows for cemented and cementless fixation. Modular options provide a wide range of possibilities for adaptation.

Different types of Stemless Cages offer less invasive options with considerable bone preservation potential.

The glenoid components were designed specifically to address various treatment options depending on surgeons' choice. This facilitates the right treatment for each individual indication by appropriate adaption fixation, size, offset, version and joint tension.

In the LINK Embrace Shoulder System, Humeral Short Stems as well as Stemless Cages help to save valuable bone stock for possible future treatments and revisions.

The LINK Embrace Shoulder System follows the onlay concept in which all meta- and epiphyseal parts are fixed on top of the humeral, intramedullary components.

beginning, then shoulder fractures, and finally implanted shoulder replacements. I think if you want to treat shoulder problems, you have to be a global shoulder surgeon. I recommend finding a clinic with good shoulder surgeons, learning from them, and working with them on as many different shoulder problems as possible. I was fortunate that the hospital where I did my residency had excellent shoulder surgeons who taught me a lot. After that, I went to the U.S. and did a great deal of surgery myself and optimized my handling of possible complications.

You implanted the first LINK Embrace Shoulder System in Spain and have since treated several dozen patients with it. How are the patients doing?

My patients are doing very well. I'm very happy with the results so far, and we haven't seen any complications. I operated on the first patient in the middle of September last year, so it's too soon to say any more. But it's safe to say that the new Embrace Shoulder System from LINK works great.

Dr. Cañete, thank you for the interview.

»The new LINK Embrace shoulder system is easy to use and covers very many requirements in everyday life. In particular, components with TrabecuLink structure are excellent.«

PD Dr. Jörn Kircher, Head of the Shoulder and Elbow Surgery Section of the ATOS Klinik Fleetinsel in Hamburg, Germany. Dr. Kircher is a member of the development group for the LINK Embrace Shoulder System.

»We chose the new LINK Embrace Shoulder System because it offers options in terms of fixation and biomechanics with extensive component modularity. There have been no complications in our patients so far and the functional outcome is good.«

Dr. Enrico Guerra, Istituto Ortopedico Rizzoli di Bologna, Italy.

LINK Embrace
Shoulder System

»The LINK Embrace Shoulder System optimally supports the global trend towards reverse shoulder arthroplasty«

Dr. Löwe, how has shoulder arthroplasty developed in recent decades?

The number of cases has increased dramatically. The reasons are the experience gained in primary arthroplasty in recent years, but above all the growing number of options for the treatment of proximal humerus fractures by means of using modular reverse shoulder implant systems. Because the results of prosthetic treatment of humeral fractures have often failed to meet the needs of patients and surgeons, and these fractures have often been treated osteosynthetically or left in place conservatively. The possibility of gently converting a primarily anatomic prosthesis to a reverse configuration, if required, justifies an anatomic reconstruction attempt and, in the case of a primarily reverse treatment, leads to predominantly good clinical results in terms of function and pain reduction.

What are the advantages of the new LINK Embrace shoulder system in this context?

One of the great strengths of Embrace are the components provided with TrabecuLink surface structure, which thus achieve very good primary and secondary stability. This is a great advantage, especially in shoulder arthroplasty, where the bony situation is often precarious.

From an arthroplasty point of view, the shoulder is different from the hip or knee joint. Why?

The success of shoulder arthroplasty depends to a large extent on the quality of the interarticular musculature. In the case of an insufficient rotator cuff, the principle of the reverse shoulder prosthesis offers the possibility of compensating for the limited functions by increasing the efficiency of the deltoid muscle through a targeted change in the biomechanics. This is a special feature in the shoulder that does not exist in this form in the hip and knee.

What demands does shoulder arthroplasty place on surgeons?

Historically, due to the lower number of cases compared to the knee and hip, the development of expertise in the shoulder area was more protracted. This phenomenon has become less important due to the recent increase in case numbers. Nevertheless, especially the treatment of dysplasia as well as revisions of the shoulder are often challenging. Complications such as periprosthetic fractures, which can be managed well at the knee and hip joints, are often challenging due to the more delicate bony situation at the glenoid and humerus. In these situations, surgeons benefit from experience that can be gained most effectively in a center with appropriate case numbers.

What should the future hold for shoulder arthroplasty?

For me, the future is what I see on the horizon at Embrace: the connection with a MEGASYSTEM-C for the upper extremity for all situations. Because if shoulder arthroplasty continues to track knee and hip arthroplasty, then loosening, infection and loss of bone and soft tissue will also increase dramatically. For the lower extremity, LINK has offered the proven MEGASYSTEM-C for many years, which now has its Embrace compatible equivalent for the upper extremity in the form of the MEGA-C Upper Limb system.

Dr. Löwe, thank you for the interview.

ABOUT

Dr. Jörg Löwe is Senior Principal Surgeon of the EndoProthetikZentrum der Maximalversorgung at the Lubinus Clinicum in Kiel. He implanted the world's first LINK Embrace Shoulder System.

You can find the webinar on this topic at

LINKADEMY.TV

»Once you start with the DAA, there is no way back«

In an interview with this magazine four years ago, Dr. Pawel Skowronek predicted a bright future for the Direct Anterior Approach (DAA) as a surgical technique in hip replacement surgery. In this interview, he reports what has changed since then.

Dr. Skowronek, has the DAA become as widely accepted in hip replacement surgery as you predicted in our last interview?
Well, the DAA cannot win 100 percent of all orthopedic surgeons ad hoc, of course. Today, some very experienced colleagues use different approaches for hip replacement surgery. But there are more and more surgeons who are interested in the DAA. For example, I meet many young physicians who want to learn about the DAA during their residency. In my home country, Poland, more than 20 hospitals have started using the DAA in the last two years, most of them after attending my courses. During the previous two years, more than 100 training courses, roadshows, and cadaver labs for teaching the DAA were held in Europe and worldwide. These have had to be replaced by webinars at the present time due to the COVID-19 pandemic.

In 2017, your patients stayed in the hospital for around 2.6 days after hip replacement surgery using the DAA, instead of an average of 5.5 days with other approaches. Has the length of stay decreased further since then?
Further reducing the length of stay is one of our goals. Currently, the average length of stay at my three hospitals is 2.2 days. For example, we start gait rehabilitation for patients operated on in the morning on the same day as the surgery. We are also optimizing our local anesthesia technique, which also influences the length of stay.

What are the cost advantages of the DAA?
The costs for a total hip replacement without implants are almost one-third lower at our hospitals than other hospitals, where they mainly use different approaches. This is due to the shorter hospital stay, the lower consumption of painkillers and blood products, and the 30% shorter operating time than with the posterolateral approach. By default, we do not use drainage either. We also use only standard retractors and instruments and standard operating tables. The instrument set for DAA could, of course, be expanded to include automatic hooks or a traction table. But the technique we use and teach can be applied in all hospitals and on all operating tables worldwide.

ABOUT

Dr. Pawel Skowronek is Chief Surgeon at Orthopedic Clinics in Kielce and Warsaw, Poland.

In 2017, you had performed around 600 implantations with the DAA. What figure do you arrive at today?
Last year, we performed about 1200 surgeries in my surgical team of three surgeons. The numbers of hip replacement surgeries with the DAA are increasing. We have increasingly long waiting lists, and even more patients are choosing one of our locations because we use the DAA.

You use your own surgical technique in the DAA. How does it differ from the standard technique?
The basic idea is almost the same, but we have changed crucial details. To promote better wound healing, we have modified the skin incision, the number of retractors we use, and the femoral release technique. We always release only as much tissue as necessary, never more. We have also modified the position of the incision to best protect the nervus cutaneus femoralis lateralis. Since every case of hip arthroplasty is a new experience, we have also developed new techniques for fascial opening, more comfortable control of the acetabular versions, and the femoral release in obese and muscular patients.

You have been implanting the SP-CL and the LCU from LINK for several years. What are the advantages of these implants in terms of the DAA?
LINK has very user-friendly instruments for the DAA, especially a good design of the handles permitting them to be used with the right or left hand. I also find the stems well-designed, especially with the SP-CL. With this anatomical stem, bone compression in the femur is very simple.

The DAA seems to be particularly interesting for young surgeons. Why?
I think it's because young surgeons want to learn about all approaches and techniques in hip arthroplasty and then choose the safest, most straightforward, and most reproducible approach. They value not only the surgical technique but also the simplicity and brevity of rehabilitation, as well as the economic benefits to the hospital. Especially for patients who want to get active again after hip replacement, play sports, and live life without the feeling of having a prosthesis, the DAA is often best suited. We have produced two papers comparing the DAA and PLA in terms of surgical and economic benefits. The DAA performs better.

What is your philosophy when teaching the DAA in your workshops and BioLabs to colleagues?
First of all, the DAA is not magic; it is a simple technique, supplemented with some tricks that work for all primary hip patients and almost all anatomical situations. It takes some time to master the DAA, but it is not rocket science.

Are most of your young colleagues adopting the DAA in their repertoire?
In all the clinics where I work, more than 98% of cases of primary implantations are performed using the DAA. All of my residents also use the DAA for primary hip replacement. This approach is their first choice.

Which implant from LINK should inexperienced surgeons start with when using the DAA: the SP-CL or the LCU?
The SP-CL has a very user-friendly design, but it is a challenging stem for beginners. It's like a sports car – you need to know how to drive it before starting the engine. The LCU is like a good Volkswagen, suitable for most cases and most patients. If you want to start with primary implantations using the DAA, you should choose the LCU. If you have some hip arthroplasty experience and a feeling for a more delicate technique, then take the SP-CL. One thing is for sure: once you start with the DAA, there is no way back.

Dr. Skowronek, thank you for the interview.

»My advice for beginners with the DAA is to start with the LCU straight stem (above) and then quickly switch to the SP-CL (left).«
Dr. Pawel Skowronek

»The primary stability of the LINK FlexiCones is fantastic«

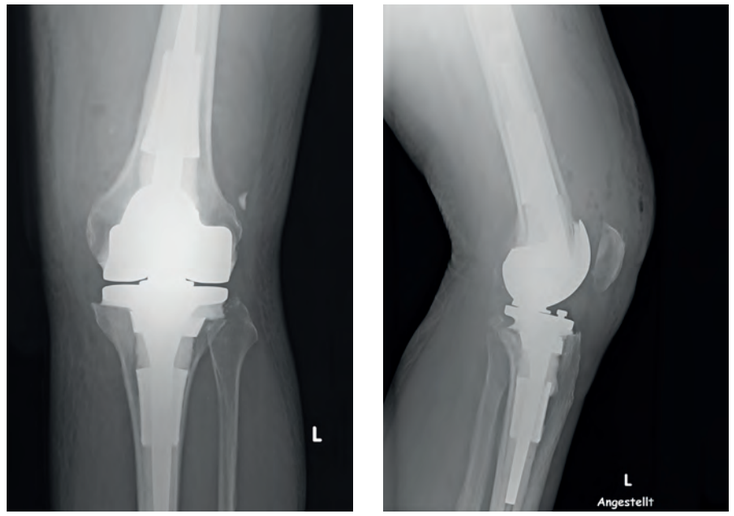
LINK TrabecuLink Femoral and Tibial Cones provide solid anchorage in at least two of three zones,* serving to reinforce meta- and diaphyseal bone defects or bone loss and thus stabilize in the distal femur and proximal tibia. Dr. Thomas Kreibich talks about his experience with the use of FlexiCones in practice in this interview.

Dr. Kreibich, you have been using LINK FlexiCones for complex knee revisions since the beginning of 2020. Why?
If you reduce large defect zones in the meta- and diaphyseal area with bone graft, this usually does not lead to good results in the long term. This is due to reduced rotational stability and the fact that the prosthesis cannot be securely anchored in the newly created bone bed. With the FlexiCones, we reduce the defect zone in both the dia- and metaphysis and thus increase the degree of coupling. Because of this form-fit, the femoral component is well grasped by the FlexiCones.

Do you ever use several FlexiCones at the same time?
If the defect in the different levels is very pronounced, I place two FlexiCones on top of each other to increase the anchoring potential for the new prosthesis to be cemented.

For which indications have you used the FlexiCones so far?
They were large knee revisions with multiple previous surgeries, especially in patients who already had a knee revision once due to sepsis and in whom the femur was significantly altered due to type II and type III bone defects.

What do you think is special about the FlexiCones from LINK?
Firstly, it is very good that the 3-zone FlexiCones are precisely tailored to LINK implants. This results in a high form-fit



Septic replacement of a knee prosthesis: restoration with LINK Endo-Model and LINK FlexiCones: 2-zone TrabecuLink Femoral Cone (femoral), half TrabecuLink Tibial and proximal Femoral Cone (tibial).

right from the start. What I particularly like about LINK FlexiCones is that they can be adapted to the defects better than the somewhat rigid, thicker-walled models that we have mainly used up to now.

Do you see a difference between a stem that is precisely adapted to the medullary canal and a FlexiCone that is anchored without cement but contains cement inside to fix the standard stem?
Absolutely. The interface between the cone and the bone makes the defect smaller. But in the same way, the FlexiCone improves the cement anchorage with the stem-anchored knee prosthesis on its inside. I see an advantage in the fact that with relatively conventional, stem-anchored LINK implants and the FlexiCones, a good result can be achieved. This shortens the operating time and is good for the patients.

ABOUT

Dr. Thomas Kreibich is Head of the ENDO-Klinik location in Wuppertal, Germany.

The LINK FlexiCones are elastic. How do you rate this aspect?
I see the flexibility due to the thin-walled design as an advantage because, on the one hand, it significantly reduces the risk of fracture or fissure during implantation in the remaining femur. On the other hand, the FlexiCones adapt better to the defect situation than rigid models. It is then no longer necessary to trim the bone in order to place a rigid cone.

You are planning a FlexiCones study with ten patients. What is it about?
We will follow the patients we have operated on with this procedure for two to three years, take regular X-ray diagnostics and compare the images with the postoperative images to assess the stability of the FlexiCones.

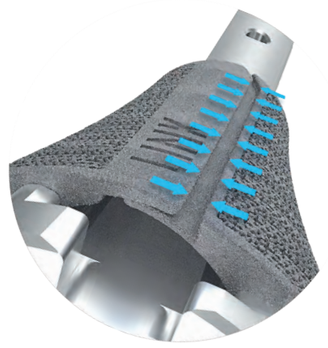
You use the FlexiCones for revision surgeries with larger bone defects. Are they also suitable for primary implantations?
That is certainly possible. We had an elderly lady with very pronounced osteopenia who initially required a stem-anchored implant due to bone density reduction. In this case we did additional reinforcement with a FlexiCone.

How do you proceed with a revision if the bone no longer contains any cancellous bone?
In such bone glades, we remove the loosening membrane, practically just cleaning out soft layers from the inside bone. Then we drive the FlexiCone into this corticated bone. Since there are no large stress peaks as with rigid cones, there is also no great risk of fissure.

The intention in the development of the FlexiCones was that the force is applied in the meta- and diaphyseal area, so that no more loosening occurs. How do you rate this aspect?
What we can already say is that the primary stability of the cones in the bone is fantastic and we have much higher primary stability in the cement anchorage due to the internal structure of the cones. These two points are extreme advantages, especially in burnt-out knee revisions. After all, we know that even with scarfed prostheses after septic revisions, the femoral and tibial components of the stem often show signs of loosening after only a few years. I hope to see no more of these effects, because the FlexiCones from LINK are a big step forward for advanced revision arthroplasty.

Dr. Kreibich, thank you for the interview.

Stable anchorage: TrabecuLink FlexiCones stabilize prosthesis anchorage in meta- and diaphyseal bone defects; they are compatible with the entire LINK Endo-Model Knee Family.



Elastic design: TrabecuLink FlexiCones with spring effect ensure easy intrasurgical positioning and high primary stability.

* R. Morgan-Jones, S. I. S. Oussedik, H. Graichen, F. S. Haddad: Zonal fixation in revision total knee arthroplasty, The Bone & Joint Journal, Vol. 97-B, No. 2, February 2015

»Orthogeriatrics will become established in Germany«

Geriatric patients are not simply old adults, but a patient collective of their own. What this means for the choice of implants in hip arthroplasty and why Germany now needs orthogeriatrics is explained by PD Dr. Hendrik Kohlhof in this interview.

Dr. Kohlhof, you propagate the term orthogeriatrics. Why?

We see that there is considerable need for improvement in the arthroplasty care of geriatric patients. These patients are not simply old adults, but a separate collective. This results in a separate field, which we call orthogeriatrics – analogous to geriatric traumatology. There, the positive effects of treating geriatric patients separately have been very well studied scientifically over the last 20 years.

What do these data tell us?

Geriatric patients have a significantly higher survival rate if they are treated as a separate group. During major surgery such as hip revision, these patients develop delirium in more than 70 percent of cases, which extremely increases the risk of mortality. This is compounded by the fourfold higher cardiovascular risks associated with major surgery in this patient population. Compared to younger patients, the survival rate of revision implants is also shorter in patients over 70 years of age.

What do these circumstances mean for implant selection?

To date, we have preferred to use a cemented cup with a cemented stem in the context of primary hip replacement in geriatric patients; for example, the Lubinus SP II from LINK. The SP II is among the stems with the best survival rates overall in the Swedish Hip Arthroplasty Register.[1]

What about a cementless treatment?

The international registry data[3] show that you can achieve just as good – if not better – results with a hybrid fitting in geriatric patients. However, according to one study,[2] they can also be implanted with cementless stems, and very good results can even be achieved with short stems. This is also true for follow-ups of ten years. Whether the improvement of implants can lead to a completely cementless treatment must be proven by further research. The regular treatment using cemented stems in patients with reduced bone quality remains undisputed.

What purpose would this serve if sufficiently long implant survival rates were achieved with cemented implants?

Due to increasing life expectancy, more and more geriatric patients require a revision. In this case, a cementless implant is a great advantage, because the operating time – one of the most important factors for the development of delirium in geriatric patients – is significantly shorter in these surgeries. Accordingly, the risk of delirium is also reduced. If I can implant a cementless primary cup, I significantly shorten the operating time.

Which cementless LINK products do you use in hip arthroplasty?

As a cementless acetabular implant, I use the MobileLink Acetabular System with the different surface coatings for better bony integration. The MobileLink also allows for augmenting small bony defects and inserting different inlays.

How do you rate the Face Changer options with the MobileLink?

With the Face Changers I can correct the offset and the acetabular entry angle. To make a dual mobility system out of the MobileLink, I use a dual mobility insert, which makes it possible to use a BiMobile liner. Data from the U.S. and France show that this approach is also beneficial in geriatric patients during primary implantation of a hip arthroplasty because it reduces the risk of dislocation.

What is the rehabilitation of geriatric patients like?

We mobilize our geriatric patients as soon as possible after implantation of a hip prosthesis. In the 1970s to 1990s, studies of young men in the U.S. showed that they lose up to 300 grams of muscle mass in the lower leg within six weeks. Add in the age factor, and geriatric hip patients lose up to 600 grams of muscle mass per six weeks – if they are not mobilized. So if we don't get geriatric patients out of bed as early as possible, they become so muscularly weak that it has a negative impact on surgical outcomes.

How will the field of orthogeriatrics evolve?

Orthogeriatrics deals with all orthopedically related diseases of the elderly, analogous to geriatric traumatology for accident surgery causes. In the field of arthroplasty, one of the goals would be to bring the surgical results into line with those of younger patients. For this, we need to treat geriatric patients separately. Orthogeriatrics will prevail in Germany not only in the case of arthroplasty, I am firmly convinced of that.

Dr. Kohlhof, thank you for the interview.

ABOUT

PD Dr. Hendrik Kohlhof, MHBA, is a Senior Physician in the Section of Joint and Rheumatoid Orthopedics and Section Head of Joint Surgery of the Clinic and Polyclinic at the University Hospital Bonn, Germany.

Five times lower PPF hazard ratio compared to Exeter stem: anatomically shaped SP II stem with Lubinus Cup.*

MobileLink Acetabular System with TiCaP double coating or TrabecuLink surface, triple secured inserts, secure Face Changer fixation.

BiMobile Dual Mobility System; proven EndoDur cobalt-chromium alloy, self-centering UHWMPE inlay

[1] Swedish Hip Arthroplasty Register, https://shpr.registercentrum.se

[2] Thien TM et al.: Periprosthetic femoral fracture within two years after total hip replacement: analysis of 437,629 operations in the Nordic Arthroplasty Register Association Database; J Bone Joint Surg Am. 2014 Oct 1;96(19):e167. doi: 10.2106/BJS.M.00643

[3] Gkagkalis G, Goetti P, Mai S, Meinecke I, Helmy N, Bosson D, Kutzner KP: Cementless short-stem total hip arthroplasty in the elderly patient – is it a safe option? A prospective multicentre observational study. BMC Geriatr. 2019 Apr 17;19(1):112. doi: 10.1186/s12877-019-1123-1. PMID: 30995903; PMCID: PMC6472082

»What is immobilized with the finger splints from LINK, remains immobilized«

The LINK Finger Splints Stack Type provide a high level of comfort and thus increase the wearing compliance. The automatic positioning of the distal finger joint in the extension position accelerates the therapeutic success in the case of extensor tendon rupture and protects against fingertip and nail bed injuries. Hand surgeon PD Dr. Felix Stang describes the practical use of the LINK Finger Splints in this interview.

Dr. Stang, how long have you been using LINK Finger Splints?

The Stack type splint and the buttonhole splint from LINK are elementary components of hand surgery. I have been using these splints almost daily since I started 13 years ago.

For which indications?

Stack's splint is the most frequently used splint of all. We use it mainly for injuries to the distal phalanx: These can be fractures or a bony or subcutaneous extensor tendon tear. We use the buttonhole splint to treat patients with injuries to the middle joint, where the extensor tendons and collateral ligaments are most commonly affected.

In which sports do such injuries occur?

Mainly in ball sports such as basketball, volleyball and handball. Often the patients are recreational athletes or come from school sports. In professionals, such injuries occur less frequently because they tape their finger joints before games. However, degenerative extensor tendon ruptures are also common: If tendons are pre-injured or have degenerative changes, they can tear even with trivial trauma, such as when the person in question puts on stockings.

What about occupational injuries?

Craftsmen such as bricklayers, carpenters and joiners often come to us with end phalanx fractures or soft tissue wounds to the end phalanges of their fingers. These injuries also require immobilization. However, not every finger fits into a prefabricated splint. That's why it's good that LINK's thermoplastic moldable splints can still be adjusted.

Is there a typical finger injury pattern in children?

Children have fewer tendon ruptures, but more fractures. Many fractures can be treated conservatively with the splints. Of course, the children have to be willing to go through this. But it works quite well for 12- or 13-year-olds.

Could pediatricians or family doctors also apply the finger splints?

The application of Stack's splints is not complicated. Assuming a correct diagnosis, young patients can also be fitted with them by an experienced pediatrician or family doctor.

What do the patients have to pay attention to?

It is essential that the patient is thoroughly instructed about the treatment. Many injuries treated with a splint must be immobilized for eight to twelve weeks. The finger must remain extended when the splint is first removed for cleaning and then correctly reapplied. If the patient masters the use of the splint, the treatment results are very good. However, if he checks after only three weeks to see if the torn extensor tendon is working again, those three weeks were in vain.

How do patients cope with the splint?

Of course it is annoying to have to wear a splint on your finger for many weeks. But I think the acceptance is still there, and the handling is not a big problem for the patients. Our claim in hand surgery is: Only the necessary part is immobilized, everything else is to be kept moving. LINK's Stack splint fulfills its purpose here: What is immobilized remains immobilized – even if the patient uses the affected hand a lot.

Dr. Stang, thank you for the interview.

Recommended reading
L. Hölscher, T. Lötgers: Verletzungen des Strecksehnenapparates in der Zone I; Der Unfallchirurg 4/2021

The LINK Finger Splints Stack type have fulfilled the »Made in Germany« quality standard for decades. They are available in skin-colored and transparent (thermoplastic moldable), in standard or Stactip design with tactile distal windowing, individually or in an assortment, with or without Velcro strips, in sizes 00 to 7 (Stactip 1 to 7).

ABOUT

PD Dr. Felix Stang is Senior Consultant at the Clinic for Plastic Surgery at the University Hospital Schleswig-Holstein (UKSH) in Lübeck, Germany.

Repositioning osteotomy after conservative fracture healing with MP Monoblock from LINK

A 62-year-old male patient presented to the Department of Trauma and Reconstructive Surgery at Bayreuth Hospital with right coxarthrosis secondary to a proximal femur fracture treated conservatively 40 years ago. Clinical and whole-leg X-rays showed a right leg shortening of 4 cm and an anteriorly displaced trochanteric mass about the width of the stem; a CT confirmed these findings.

The surgical plan was to achieve a leg length compensation of 4 cm. Of this, 2 cm each was to be achieved by a corrective step osteotomy of the proximal femur and by the appropriate positioning of a hip prosthesis (Figure 3). The implant of choice for this approach was the MP Monoblock from LINK.

In addition to its ease of use, the slender proximal design and diaphyseal anchorage were factors in favor of this implant given the patient's young age. The fact that the MP Monoblock by LINK is not expected to have any problems with a docking site, as is the case with some other modular systems on the market, also contributed to the decision in favor of this implant.

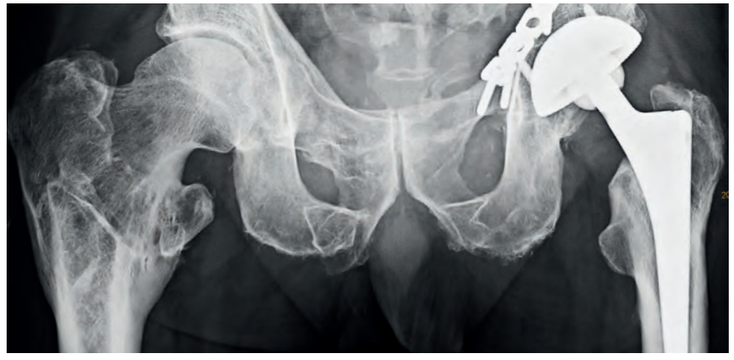
The surgery at the end of July 2020 proceeded without complications. After Gibson access with exposure of the proximal femur and K-wire marking of the coronary ascending limb of the z-shaped osteotomy, sagittal splitting of the proximal fragment in terms of an extended trochanteric flip osteotomy and exposure of the cup for implantation was performed.

After exposure of the proximal femur, stem implantation with diaphyseal anchorage was performed. Both intrasurgical and postoperative X-rays showed a proper fit of the implant and a successful leg length compensation of 4 cm in total.

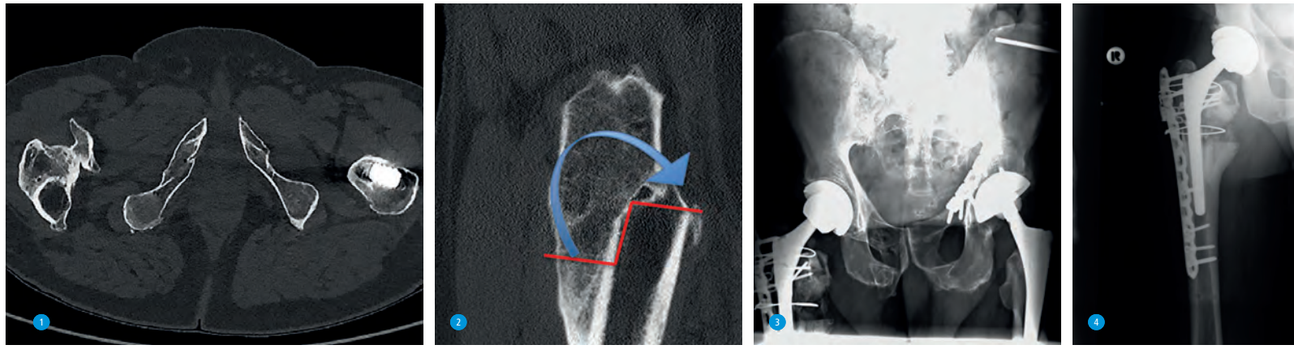
In the course, there was a delayed healing of the osteotomy site as well as regressive residual symptoms.

ABOUT

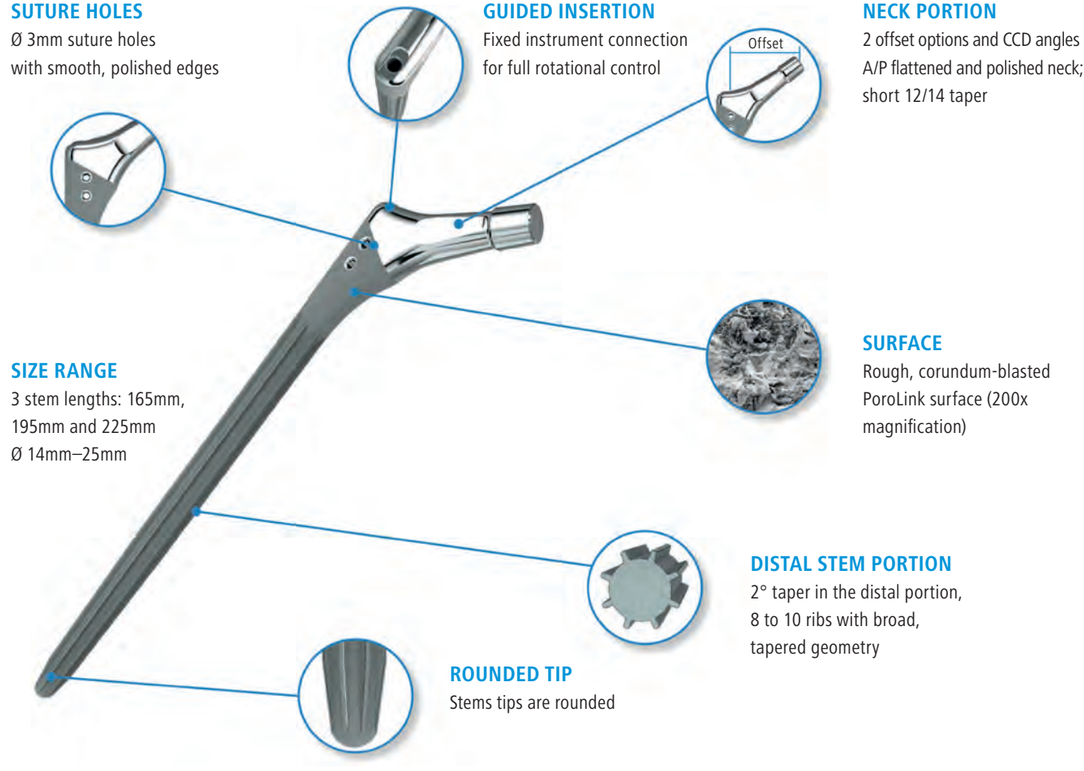
Prof. Dr. med. Michael Müller is Head of the Clinic for Trauma and Reconstructive Surgery at Bayreuth Hospital, Germany.



The preoperative pelvic overview X-ray shows coxarthrosis on the right as a result of a proximal femur fracture treated conservatively 40 years ago; the right trochanteric mass is displaced approximately stem-wide anteriorly.



Top: The preoperative CT images (1, 2) show the stem-wide displaced trochanteric massif and a shortening of the leg; the surgery planning is drawn in. The postoperative pelvic overview image (3) and the A.-p. image (4) show the proper fit of the MP Monoblock.
Bottom: LINK's new MP Monobloc Hip System is based on the proven design features of the MP Reconstruction System; it was developed to meet the requirements of modern revision surgery and to make the MP family even more flexible.



Ultimate modularity for maximum mobility with the MEGASYSTEM-C from LINK

A 39-year-old patient presented for the first time to the Clinic and Polyclinic for Orthopedics at Rostock University Medical Center in December 2018: As a result of a 20-year-old diaphyseal resection of the left femur after bone sarcoma in a Moscow hospital, his left leg was nonfunctional and unstable. The patient, who was in a wheelchair, stated that he had lost his ability to walk and stand as a result of the surgery and could only walk short distances on two crutches. The father of an 11-year-old girl expressed the wish to be able to stand on two legs in front of his daughter.

Clinical examination revealed essentially a completely nonfunctional, unstable left leg with a leg shortening of 23 cm, as well as a stiff left hip and knee joint and an unstable defect in the mid-thigh. Anamnestic diaphyseal reconstruction using allograft had been performed at the age of 25. One and a half years later, the allograft became infected and was removed. After several follow-up surgeries, the patient had initially accepted the loss of his ability to walk and stand.

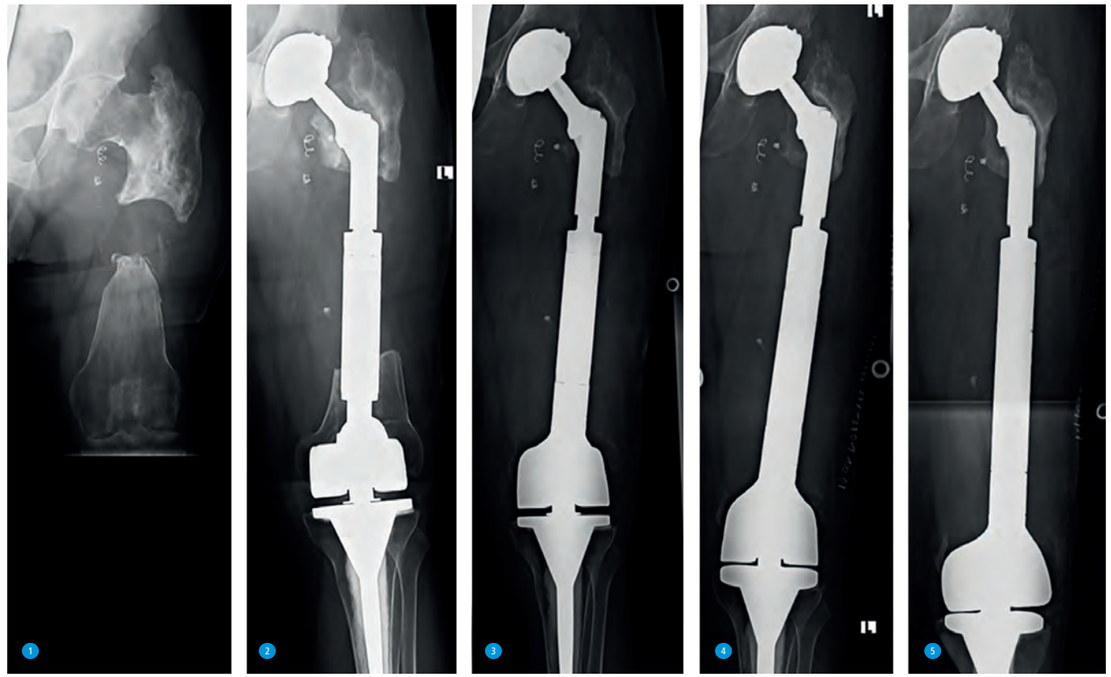
Starting in January 2019, reconstruction of the function of the hip and knee joints was performed in four steps at the clinic using the modular MEGASYSTEM-C tumor and revision system from LINK. At the end of 2020, the residual leg length difference was 7 cm; it is compensated with a shoe sole elevation.

In December 2020, 14 days postoperatively, the left leg showed good function and a problem-free single-leg stance on the operated leg. The patient is now able to walk without crutches, even for longer distances. He no longer needs a wheelchair or crutches three months after surgery.

14 days after the last surgery, the patient can stand on his operated leg without crutches and is able to walk for longer distances.

ABOUT

PD Dr. med. Martin Ellenrieder is Senior Physician and Deputy Clinic Director of the Orthopedic Clinic and Polyclinic at the University Medical Center Rostock, Germany.



The X-ray on admission shows an unstable defect in the left mid-thigh with ankylosed hip and knee joint (1). Reconstruction of the joint function of the hip and knee in four steps with the modular MEGASYSTEM-C from LINK (2-5).

LINK Products in the current scientific literature

Silver-coated megaprosthesis in prevention and treatment of peri-prosthetic infections: a systematic review and meta-analysis about efficacy and toxicity in primary and revision surgery
Michele Fiore, Andrea Sambri, Riccardo Zucchini, Claudia Giannini, Davide Maria Donati, Massimiliano De Paolis;
European Journal of Orthopaedic Surgery & Traumatology; https:/ /doi.org/10.1007 /s00590-020-02779-z

Gait analysis: Comparative evaluation of conventional total knee replacement and modular distal femoral megaprosthesis
Pietro Pellegrino, Andrea Conti, Andrea Pautasso, Michele Boffano, Nicola Ratto, Marina Carlone, Chiara Beltramo, Giuseppe Massazza, Raimondo Piana;
J The Knee 27 (2020) 1567- 576

The knee prosthesis constraint dilemma: Biomechanical comparison between varus-valgus constrained implants and rotating hinge prosthesis. A cadaver study.
Victor-Estuardo L-R, David G-M, Irene Isabel L-T, et al.;
J Orthop Res. 2020;1-7. https do1.org 10 1002/jor 24844

»In the LINKademy courses you really learn something new«

In order to familiarize himself with the Direct Anterior Approach (DAA) in hip arthroplasty, Dr. Mahmoud Otabashi completed two DAA courses from the LINKademy (Level I and II) within six months and acquired the relevant technique through two clinical observerships. In this interview, he reports on his experiences.

Dr. Otabashi, you were particularly interested in the Direct Anterior Approach (DAA). Why?
Like any surgeon, we want to ensure that our patients receive the best possible treatment. In addition to a good surgical result, this also includes rapid mobilization, and of course as few complications as possible should occur. All this can be achieved with the DAA access.

How extensive was your experience with the DAA before you took the LINKademy courses?
I had learned during my first observership how the DAA works intrasurgically and and how the procedures from anesthesia to postoperative care function. After that, I was convinced by the DAA and we decided to implement this access in our clinic.

ABOUT

Dr. Mahmoud Otabashi is Head Physician of the Department of Orthopedics of the Endoprothetik-Zentrum at the Zentralklinik Bad Berka, Germany.

What were the highlights of the observership?
What impressed me most was how well the team worked together. Patients came to the clinic on the day of surgery and were taken directly to the OR, where colleagues already had all the important information about the person and the surgery. The implantation via the DAA went quickly and smoothly, so there was no loss of time. Only two hours after the surgery, the patients were already mobilized.

After your first observership, you completed the Level I and Level II courses of the LINKademy at intervals of five months. What did you learn?
First, we discussed how the DAA works and what problems can arise. We had great speakers. After the Level I course, I already felt very familiar with the DAA. In the Level II course, I was then able to deepen my knowledge and skills. During an internship with Dr. Pawel Skowronek in Warsaw, Poland, a colleague and I accompanied several surgeries and thus gained our first practical experience with the DAA. After that, we felt confident enough to start performing hip replacement surgeries in our clinic using the DAA.

How many surgeries do you now perform with the DAA per month?
The standard in our clinic is still the lateral approach. I am currently the only one operating via the DAA. From February to December 2020, I operated on a total of around 200 patients, 26 of them via the DAA. So far, no complications have occurred. Our goal is therefore to establish the DAA as the standard approach for hip replacement surgery in 2021.

Does your hospital use the DAA for marketing purposes?
Yes, we do. We have printed information flyers and sent them to colleagues in private practice. We have also noticed that many patients have already heard about the DAA and its advantages – for example, the small skin incision, little blood loss, fast mobilization.

How do you like the LINKademy concept overall?
I have been attending LINKademy courses since 2015. I am still fascinated by how well everything is organized and how structured the speakers are. You really learn something new in the LINKademy courses.

Will you attend more courses?
Of course. In order to establish the DAA as a standard approach at our hospital, I will also send my colleagues to the LINKademy courses.

Dr. Otabashi, thank you for the interview.

»We are proud of our MDR certification«

Mr. Ostwald, LINK has recently been certified in accordance with the new MDR[1] legislation. What advantages does that bring to customers?
None, because high-quality products do not become even better as a result. MDR certification is mandatory. All products that implant manufacturers want to recertify or launch on the market after 2020 must meet the requirements of the MDR.

LINK is critical of the MDR legislation. For what reason?
Essentially, the new MDR legislation has resulted in considerable additional bureaucracy and costly extra work, without resulting in greater patient safety. On the contrary: because of the MDR, manufacturers will have to withdraw certain other rarely sold but proven implants from the market.

Why?
In contrast to the MDD,[2] the MDR describes in much greater detail the requirements for documenting data on devices. One key area is clinical evaluation, where there are some of the most extensive changes compared to the MDD. For products that we have had successfully on the market for 30 years, MDR certification can only be realized with a very large amount of effort for the collection of the required clinical data. It does not matter how the implant has proven itself or how important it is for medical care.

What are the consequences of the MDR legislation for manufacturers?
Some smaller manufacturers have already given up because of the MDR requirements, and others will follow. Recertification of products will be much more expensive in the future because corresponding studies are more costly than studies for products already on the market.

How will LINK generate the clinical data for legacy products in the future in order to be able to certify them according to MDR?
For primary products, which we sell in large quantities, the data from the registries are ideal. From the EPRD,[3] for example, we receive data with the annual report that clearly prove the high quality of our products. In addition, LINK naturally has a complaints management system. Problems, if they occur, are reported back to us.

What is the situation like with revision products?
Definitely more difficult, because with revision products, which are used for reconstruction, we don't have the required number of cases or the necessary range of indications. I therefore see the situation as critical with products that we do not sell in large quantities. Even with standard products that are about to be certified, we are not allowed to manufacture them as custom products and give them out to physicians. This is particularly problematic because obtaining MDR approval currently takes more than twelve months, more than twice as long as before.

If manufacturers have to take proven implants off the market for cost reasons, and are not allowed to sell them individually even as custom-made products, this sounds like a legal loophole that could have a detrimental effect on patients. What should happen in this regard?
In the U.S., a physician can apply to the FDA[4] for an unapproved product to still be allowed to be used. This approval, called compassionate use, then applies to all physicians. In Denmark, it is possible to obtain approval for custom-made products, which means that they can be ordered more than once. So there are ways to close the loophole in the law.

What positive aspects does LINK take away from the certification?
The MDR requirements for scientific product evaluations are much higher than those of the MDD. We have mastered the not inconsiderable challenge of the MDR and successfully achieved certification. This is a milestone, and we are proud of it.

Mr. Ostwald, thank you for the interview.

ABOUT

Norbert Ostwald is managing director of Waldemar Link GmbH & Co. KG, a member of the LINK Group, VACUCAST Feinguss GmbH & Co. Metall KG and the LINK development company DERU GmbH.

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herewith certifies that the company

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

SRN: not available

with locations listed in the appendix

has introduced, applies and maintains a quality management system for the medical devices/groups of medical devices listed in the appendix.

The compliance of this quality management system to the requirements of the **Regulation (EU) 2017/745 on medical devices** was verified by assessment according to:

Annex IX Chapter I

Any applicable limitations of this certification for certain medical devices are included in the appendix. This certification is subject to surveillance by MEDCERT.

Effective date:	**2021-02-26**
Expiry date:	**2025-09-30**
Final assessment report No.:	7402IA06F
Procedure No.:	QS – 7402
Certificate No.:	7402GB448210226A
Preceding certificate No.:	–
Preceding certificate date:	–
Identification of changes:	–

Hamburg, 2021-02-26

MEDCERT Certification Body
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BS-MDR-096

MEDCERT Identification Number: 0482

Form 820111 EN / Rev. 2 /

[1] MDR = Medical Device Regulation
[2] MDD = Medical Device Directive
[3] EPRD = German Implant Register
[4] FDA = U.S. Food and Drug Administration

After 22 years, only the tibial component of a tumor prosthesis from LINK needs to be replaced due to a periprosthetic fracture

An 89-year-old female patient was implanted with a custom-made proximal tibial partial replacement with UHMWPE replacement and long stem from LINK in 1998 due to a right chondrosarcoma. In October 2020, the patient sustained a periprosthetic fracture at the distal end of the stem. As the femoral component remained fixed, only the tibial component had to be replaced.

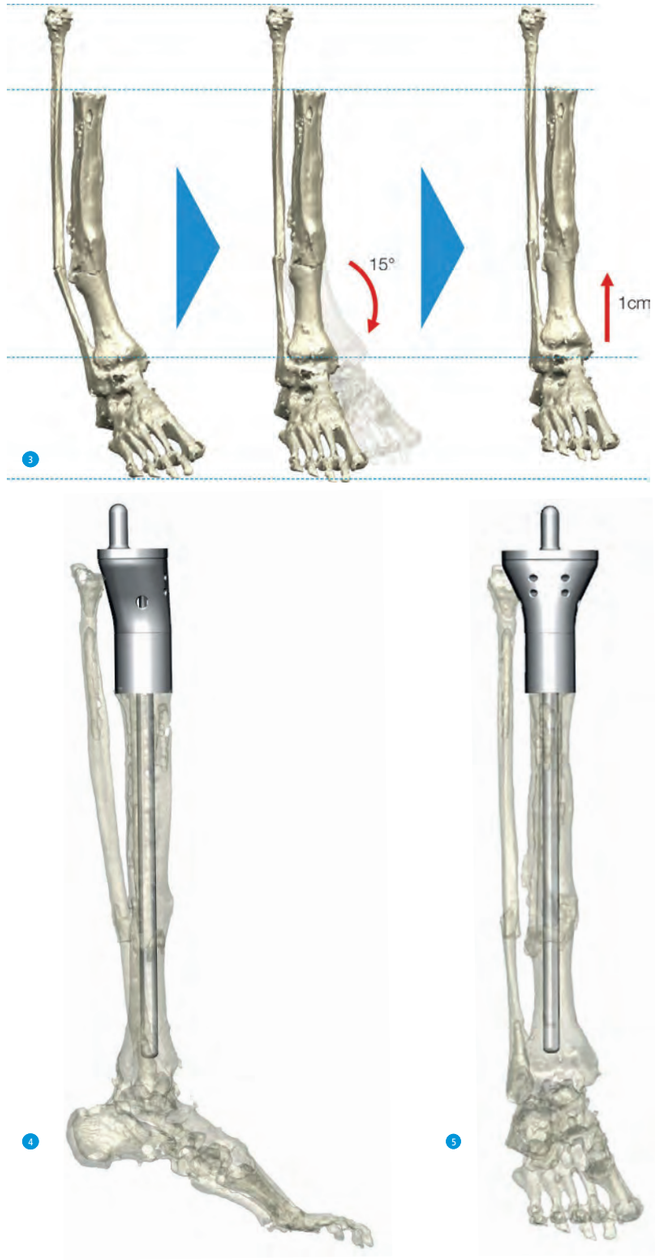
ABOUT

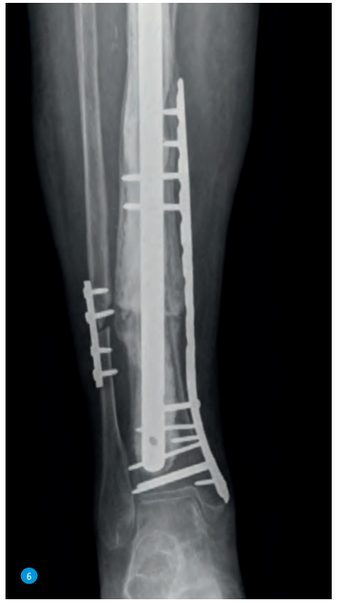
Dr. med. Ulrich Schietsch is a Senior Physician and Senior Main Surgeon at the Endoprothetikzentrum der Maximalversorgung as well as Department Head of Tumor Orthopedics at the Clinic and Polyclinic for Orthopedics and Orthopedic Surgery at Greifswald University Medical Center, Germany.

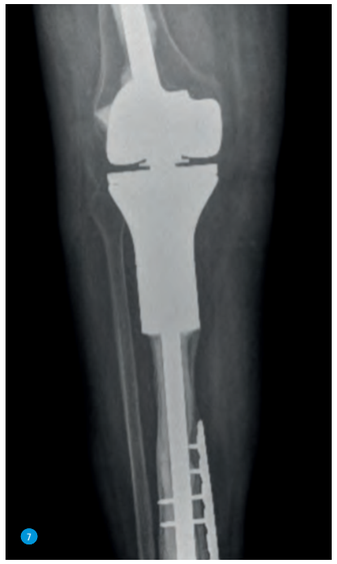
LINK fabricated a new tibial long stem component with a new proximal tibial partial replacement. The cemented stem is 330 mm long and has a diameter of 12 mm. The length of the proximal tibial segment, this time made of Tilastan (Ti6Al4V), is 65 mm; the length of the spacer, which complements the partial replacement and is also made of Tilastan, is 40 mm. According to the CT data, the tibial axis was shortened by one centimeter in the planning by removing the cartilage.

Intraoperatively, the old cemented LINK Endo-Model Rotational Knee Prosthesis was uncoupled by removing the inlay, and the loose-fitting tibial long-shaft implant was pulled out of the cement socket. After replacing the undamaged coupling socket on the femoral component and reaming the tibial stem to 14 mm, implantation of the cemented partial tibial replacement was performed. The osteotomies were secured tibially and fibularly with two angle-stable plates, then the inlay was inserted and fixed with the corresponding screw. Fluoroscopy showed an accurate fit of the implant and the osteosyntheses.

An X-ray from 2018 (1) shows the regular fit of the tumor prosthesis with tibial long stem, which was custom-made by LINK in 1998. In the preoperative image from 2020 (2), the periprosthetic fracture at the distal end of the tibial stem can be seen.







The preoperative CT images (3) demonstrate the need for correction of the tibial axis and tibial shortening by one centimeter. In the presence of varus lower leg deformity, this was achieved by transverse osteotomy of tibia and fibula, at fibula with lateral based wedge removal and simultaneous shortening by one centimeter. Figures 4 and 5 show the custom-made proximal tibial partial replacement with the spacer made of Tilastan (Ti6Al4V). Alternatively, it would have been possible to implant a custom-made UHMWPE spacer, also produced by customLINK, as in 1998. The postoperative X-rays (6 and 7) show the exact fit of the new partial tibial replacement and the osteosyntheses.

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