»High-performance materials need high-performance attention«

Biomechanist Prof. Dr. habil. Michael Morlock considers the current knowledge on hip prostheses – and draws conclusions
An eye on quality

Intermediate checking following the double verification principle ensures that a faultless item emerges from every finishing step. Here Hans-Dieter Flock and Mirko Herkules check whether the polished knee prosthesis has the required surface.
Dear Readers

Nothing so sustainably molds the reputation of a brand as the reliable high quality of its products. We need only to think of the story of the American parachutist, who lost his Leica 700 meters above the ground. Once landed, he dug it out of a field and continued cheerfully taking pictures.

The best material and the best workmanship we – focus on this at LINK. And this high quality requirement already begins in our company’s own precision casting foundry VACUCAST® in Berlin. The interview with the biomechanist Prof. Dr. habil. Michael Morlock also involves quality of materials and methods. Fortunately the quality of LINK products does not have to be tested by skydivers. However, where our prosthesis are concerned, in all certainty, every one of them would always land intact. I hope you enjoy reading the current issue of directLINK.

Sincerely

Helmut D. Link
Prof. Morlock, how can the development status for prosthetic materials be summarized?
Titanium has caught on as the material for cementless prostheses, there is no major argument any more in this field. This is different for tribological pairing. There are several options, and each has its pros and cons. And it’s precisely here where the difficulties begin.

Where exactly are they?
Nowadays in prosthetics we have superb materials. In hip prosthetics virtually all problems concerning materials have been solved. Yet our high-performance materials also need high-performance attention during fitting.

»When correctly implanted, ceramic/ceramic tribological pairing produces no detectable abrasion.«

High-performance attention during fitting?
Yes, because the prosthesis implantation conditions are extremely important for ceramics. When correctly implanted, ceramic/ceramic tribological pairing produces no detectable abrasion. In addition ceramic is so resistant to scratching that even residual bone cement would not roughen the head. Even if there were a few particles, this would not perturb the body. In contrast to metal and polyethylene, ceramic is biologically inert. However, if the prosthesis is not sitting one hundred percent correctly, just as serious and expensive problems can develop. With this, I mean joint sounds such as squeaking, which can unnerve the patient and lead to revision.

Then it is a materials problem?
No, because what is perceived as squeaking, is not the ceramic, but the vibrating stem in the bone. This only happens when the system runs dry and the components are subsequently in direct contact. Then particles break out of the ceramic, and the resultant increasing friction in the tribological pairing kick-starts the vibrating. However, if everything is implanted correctly, there is no problem.

How is the situation with polyethylene?
You mean the classic combination: hard head/soft cup? We know that the material of this tribological pairing lasts for 20 years and longer. Implantation is also less sensitive. If the cup gains a few degrees more in abduction, this barely matters. However, wear and tear occurs even with the highly cross-linked polyethylenes, thus they cannot last forever.

And with metal on metal?
Metal tribological pairings, which are not correctly positioned, can produce a very high
level of abrasion. And because cobalt, chrome and nickel are biologically very active, serious immunological responses can result. At the same time, metal on metal actually works well, we know this from car engines. Only metal on metal needs lubrication. Which brings us back to the topic »optimally implanted« components. For as soon as they are, for example, under increased edge stress, the lubricating film between the components gives way. And then there is literally tremendous friction and very high amounts of metal in the body.

Ceramic, polyethylene, metal – does the material then at all play a role in the lifetime of a prosthesis?
My personal answer is quite clearly: No. As a biomechanist I can indeed prove the advantage of a material in the simulator, but this cannot be shown in the patient. No registry in the world shows that lifetime is influenced by differences in materials.

What are your general recommendations for the choice of material?
The physician must know the advantages and disadvantages of the individual materials and weigh up the consequences with the patient. From the point of view of abrasion, ceramic on ceramic is the gold standard in the simulator. In the patient, the gold standard is ceramic on highly cross-linked polyethylene. Polyethylene neither squeaks nor breaks and probably means no problems for 15 years. Thus the consideration has to be: Do I want the lasting minimum abrasion, i.e. ceramic/ceramic? For this, will I take the risk of having a problem such as squeaking early on? Or do I take the more certain, but higher-abrasion route and decide, for example, for polyethylene?

What significance does the experience of the surgeon have?
Great significance, especially due to the enormous importance of correct implantation for many materials. There are also many studies, which show: Whoever does between 27 and 54 hips per year, attains a better quality of result. Therefore we do not recommend that anyone, who fits less than 100 prostheses per year, ventures on the implantation-sensitive high-tech materials.

What are the consequences of this for practice?
The future in endoprosthetics is not determined solely by the materials. It is also determined by correct use of these by the operators. As a biomechanist I can indeed build fits, which are so accurate, that they do not cause any more problems. But if nobody can continue this accuracy during implantation, it is not worth my while.
It follows in practice, that physicians have to be trained to implant these prostheses correctly. Then there are no problems.

»I would have a ceramic/ceramic implant.«

In which direction is materials management going in future?
We of course try to develop and test materials, which are durable, i.e. which, with the greatest possible certainty, last for the patient’s entire lifetime. Next on the testing list are polyurethane and polyether ether ketone, i.e. PEEK.

And what would be your material of choice today?
I would have a ceramic/ceramic implant. For I find it reassuring to have something in my body which is biologically inert. With metal I would have elevated levels of cobalt-chromium and nickel ions in my body, in this case something is always bound to happen. And with polyethylene I would have a macrophage reaction, something is also likely to happen there. But if, for example, I have a correctly implanted titanium prosthesis with ceramic in my body – then I really have the chance that everything will be all right.

Prof. Dr. Morlock, thank you for the discussion.
Periprosthetic infections are serious diseases, which can be life-threatening. But, from a microbiological point of view, there are clear criteria for their treatment. A discussion with the Hamburg microbiologist, Dr. Lars Frommelt.

**Dr. Frommelt, what causes periprosthetic infections?**
Within the first postoperative year, over 95 percent arise through intraoperative contamination. Good hygiene on the operating table is therefore the first step in avoiding periprosthetic infections.

**By this, do you mean »even more thorough handwashing«?**
No, the effectiveness of hygiene measures is growing exponentially and is approaching an intended success level – however, never to be attained without them. At some point then, even with the greatest care, hygiene can only be improved at the fractional digit level.

**What does the available data have to say on the current situation?**
In endoprosthetics, we have an average infection rate of one to two percent. However, the BQS data end with the hospital stay. Therefore we don’t actually know where we exactly stand.

**Then how can the topic of periprosthetic infections be purposefully addressed?**
The best avoidance strategy is a systematic quality improvement process under controlled conditions. We need systematic infection control, which everybody is involved in! In addition, I advocate a more analytical approach to the topic. It simply happens too often in everyday surgery, that the status of the literature is not sufficiently taken note of.

**What role do antibiotics play in the avoidance of periprosthetic infections?**
They must be used more sensibly. A patient with a chronic infection, who has neither fever nor signs of inflammation, does not need antibiotic therapy. With oral cephalosporin, for instance, we have an availability of six percent at the site of infection. This is negligible for the infection, however leads to resistance and side effects such as diarrhea. However, on no account should a patient simply be sent home with antibiotics.

**Can treatment principles then be set up for periprosthetic infections?**
The first question should be: Do I have to take immediate surgical action with a septicemic patient? Or do I still have time? If there is time, a puncture with cytology would be the next purposeful step. Afterwards it is certain whether or not there is an infection. If the diagnosis »periprosthetic infection« is certain, in principle only the question, whether exchange of the prosthesis should occur on one side or both sides, need be answered. But the surgeon should be able to decide that according to his competence. From the microbiological viewpoint the procedure in any case does not play a role.

**Dr. Frommelt, thank you for the discussion.**
Dr. Gianfranco Fraschini, what are your general experiences with the C.F.P.® hip prosthesis stems?
We have been using the C.F.P.® system for the past eleven years. It suits our expectations of tissue-sparing surgery, also concerning biomechanics. In the past six years we used 300 total hip prostheses with C.F.P.® stems and T.O.P.® and BetaCup® cups and only had one problem case. The reason for this was septic stem loosening associated with rheumatoid arthritis and steroid therapy.

Which patient group do you mainly provide with the C.F.P.® System?
Usually we implant the system C.F.P.® into moderately young patients with good bone quality. A further criterion is the absence of notable morphological hip deformities.

What advantages are fundamentally offered by short stems in combination with ceramic/ceramic tribological pairing?
Short stems generally have advantages affecting preservation of the metaphyseal and diaphyseal bone. It is simply very important to conserve as much femur as possible during the primary intervention, so that a later revision can be carried out better and more easily. However, concerning ceramic/ceramic tribological pairing, the survival rate of the implants is markedly increased.

How would you summarize the advantages of the C.F.P.® System?
With the C.F.P.® system it is possible to preserve both bone substance and the biomechanics of the hip. With this, I mean especially the offset and the anteversion angle of the femoral neck. However, preserving the offset is also linked to the ability of the surgeon, both in preserving enough femoral neck and in selecting the optimal stem curvature.

What route of access do you give priority to for implantations?
With the C.F.P.® system we choose the lateral
access with minimal dissection of the gluteus medius tendon at the large femoral tuberosity. In this way both a minimally invasive and a tissue-sparing surgical procedure is possible. To date we have had no dislocations with this route of access and the C.F.P.® system. All patients recovered quickly with an average Harris Hip Score value of 95 three months post surgery.

The C.F.P.® system is considered simple and quick to implant. What is your opinion on this? The C.F.P.® system is really quick to implant, if you only consider the surgery time. However more time should be invested in preoperative planning. It is very important for optimal positioning of the femur and the cup components. For besides optimal planning, preserving the femoral neck means a reduced potential for modification of anteversion of the prosthesis stem.

Currently there is a trend towards shorter and shorter stems. How do you evaluate this development? We believe this development could have two effects. Positive would be greater preservation of thigh bone. Negative might however be the reduced osteointegrative surface associated with very short stems. The long-term follow-up will show whether the very short stems really have enough osteointegrative capacity and sufficient durability.

What are your experiences in this regard with the C.F.P.® stems? Our unpublished data on osteointegration with C.F.P.® stems show that periprosthetic bone loss is very low after implantation. This indicates high osteointegrative capacity and high durability of this type of prosthesis stem.

Dr. Fraschini, thank you for the discussion.

The LINK® C.F.P.® hip prosthesis stems were specially developed for biologically young, active patients, who, because of their long life expectancy, have to expect a higher than average rate of aseptic loosening with a conventional hip prosthesis.
Prof. Tokgözoglu, Prof. Dabak, the LINK User meeting has just finished. What are your impressions?

Prof. Dabak: It was a very good meeting for us. We had the opportunity to discuss new ideas with other users of the Megasystem-C® and exchange a few experiences, which make life as a surgeon easier. We recently started using the Megasystem-C® more frequently. Therefore it is helpful to discuss with colleagues the little “hic-ups”, which a new system brings along with it.

Are there specific problems then with patients in Turkey concerning revisions?

Prof. Tokgözoglu: Yes, for example, we have many patients with early osteoarthritis. These patients need a hip joint replacement in younger years. But since they are young and generally active people, their hip joints are often in a disastrous condition when they come to us. It is then good to know that we can use the Megasystem-C® for their revisions. We also have many knee prosthesis cases, which are not easily mounted because the patients likewise come in very advanced stages. Thus we have begun to use the modular LINK Endo Model® joint components for this, which are part of the Megasystem-C®.

To date you have used the Megasystem-C® in around 80 cases. What are your general experiences with this system?

Prof. Tokgözoglu: What I really appreciate about this system is that it offers me unbelievably many options during the operation. Almost every combination is possible in order to finally find a solution for the respective patient problem. An additional good thing is: LINK is always very helpful if problems arise. They react very quickly to our questions and requests.

Prof. Dabak: Such a thorough service is very important for us. For, as surgeons, we depend on them. It makes a big difference if everything is correctly organized from the scalpel through to the prosthesis. I was very impressed that a company as large as LINK can react so flexibly to our needs. Our past experiences with other companies were different.

What should the next developmental step be for the Megasystem-C®?

Prof. Tokgözoglu: A suggestion for improvement was that we need trial implants – and they are now also being supplied by LINK. The technical information documents could still be supplemented through additional diagrams to explain the operation and the combination of options. This would be very helpful for surgeons and for surgery personnel alike.

Prof. Dabak: The conical milling cutter could have still better markings for precise insertion into the stem. But that would already be all for our suggestions of improvements.

As of recently, Turkey is a member of the Megasystem-C® reference group. What will your contribution be for this group?

Prof. Tokgözoglu: Bone tumors are not so frequent, we are just beginning to operate on a larger number of these cases. Our contribution will therefore be to make the data from our cases available to the Megasystem-C® reference group. And we of course hope that each case will increase the experience of the entire group.

LINK Discussion: Megasystem-C®

»We save time with Megasystem-C®«

Turkey is a growing market for revision systems. A good reason to talk to two of the most renowned trauma and tumor surgeons in the country about their experiences with the Megasystem-C®.
Prof. Dabak: I personally have undertaken several very interesting cases with different combinations of the Megastystem-C®. As it is a very modular system, each of these cases uniquely contributes to the intrinsic idea of the system. I am very pleased to be part of the project.

Prof. Tokgözoğlu: Yes, we are always need custom-made implants. But if you use such a modular system as the Megastystem-C®, and know that it works well, the need for customer-specific implants will presumably fall away in future. It is completely irrelevant, how well you plan a custom-made implant: In the actual operation things always go differently to the way they were planned. And it would be an enormous waste of money, time and effort, if a custom-made prosthesis were not used. Modularity, that is the way by which we should progress as far as possible. Prof. Dabak: In the future we will most certainly need custom-made designs. But another advantage of a modular system is timesaving. A custom-made solution requires time until the patient can be supplied with it. If, instead, you use the Megastystem-C®, you can certainly save a great deal of time.

Should the modularity of the Megastystem-C® be expanded?
Prof. Tokgözoğlu: No, not really. A great deal of problems can be solved with what we have. But there are other issues, which have to be addressed. For example, reducing the incidence of infection and maintaining the integrity of the implant over the years.

Prof. Tokgözoğlu, Prof. Dabak, thank you for the discussion.
Waldemar LINK GmbH & Co. KG opened on May 4, 2011 a new subsidiary in the Indian metropolis Chennai. The new subsidiary, currently comprising five employees, operates as a service company for sale of LINK products in India. A special focus lies both in LINK products for primary knee arthroplasty, revisions and tumor surgery. The number of employees is expected to grow to ten by the end of 2011.

Chennai is the capital city of the Indian Federal State of Tamil Nadu on the East coast of Southern India. Chennai is the fifth largest city in India with currently 4.7 million inhabitants. Under the name Madras, the city was an important center of the British Empire in India. The name was changed to Chennai in 1996.
Quality without compromise

**Before the final inspection** a product passes through up to 20 working steps. Each individual step is continuously examined and documented. Responsibility is assumed for the operation with a signature. If Thomas Säger does not recognize any defects under the microscope, it goes for final cleaning and packaging.
Tailor-made quality

Computer-guided 3D measuring instruments detect even the smallest deviations. The implant is only released for further processing when dimensions, shape and surface roughness of the metal carrier for the hip socket precisely correspond to specification.