Zurich Cementless - a new concept in canine total hip replacement

Principles of anchorage, surgical technique and results after five years of clinical experience

P. M. Montavon, S. Tepic
School of Veterinary Medicine, University of Zurich
December, 1998

Note:

This document is intended for distribution to veterinary surgeons who have expressed interest in using Zurich Cementless canine prosthesis. It presents personal views of the authors on the history and the current status of canine total hip replacement; motivations for the development of this concept; scientific and technical basis for its implementation; surgical technique and clinical experience of five years; as well as an outline of the proposed program for a limited clinical introduction. The purpose of this document is to provide you with sufficient, at instances perhaps even superfluous information, which we hope will allow you to either confirm or deny your further interest in the collaboration. We would also hope that this lengthy presentation will stimulate an exchange of opinions which may well differ from our own and help us all learn a bit more about this topic of common interest.

1. Introduction
2. Anchorage of the femoral component
3. Anchorage of the acetabular component
4. Technical features of Zurich Cementless
4.1 Femoral component
4.2 Acetabular component
5. Surgical technique
5.1 Instruments
5.2 Implants
5.3 Surgical approach
5.4 Preparation of the proximal femur
5.5 Preparation of the acetabulum
5.6 Fixation of the acetabular cup
5.7 Fixation of the femoral component
6. Clinical experience
7. Concluding remarks

1. Introduction

In just over three decades, total hip replacement (THR) has changed the practice of orthopedic surgery, has created a whole new industry to support it and, most importantly, has improved quality of life of millions of patients to the extent unparalleled by any single procedure in the history of surgery. All of this was made possible with the advent of cemented THR. In human surgery, within the first decade following the pioneering work of Charnley, a broad base of trained surgeons, a highly motivated industry and compliant medical insurance policies have led to a world-wide acceptance of THR with an exponential growth in the number of procedures being done, currently about 400'000 annually in Europe alone.

This early period of unrestrained optimism was followed by a new wave of innovation, once the longer term results became available and the number of revisions (exchange or removal of one or both components of THR) started to climb as well. Most of the blame was placed on the bone cement, and efforts to eliminate it, by so-called cementless anchorage, dominated the next decade. But once again, the long term clinical outcomes forced a policy change -- cementless THR designs did not match the standard set by the cemented, Charnley-type hip prosthesis. The last NIH consensus conference on total hip replacement, held in 1994, resulted in a strong recommendation for the use of a cemented femoral component, paired with a cementless, porous-coated acetabular component.

In spite of the reasonably uniform medical training programs, and widely available and read professional literature, significant differences in attitudes controlling the practice of THR in different geographic regions persist until today and will probably continue to do so. There are countries where over 95% of THR procedures are cemented (e.g. Sweden), but also those where cementless have an edge (e.g. Germany, with about 2 out of 3 THR being cementless). Hybrid THR has also gained a strong following, especially in the U.S., usually with the acetabular component being cementless and the femoral stem cemented (interestingly enough, the opposite approach seems to have some supporters as well, and not without merit in view of some more recently published clinical outcomes).

The Swedish Hip Registry (and the more recently implemented registries in Norway and in Finland) has been instrumental in weeding out approaches that did poorly, but only a limited number of some 500 hip models currently on the world market will be used in Sweden, and in numbers large enough to draw any conclusions (some 250 designs did show up in Sweden). Many failures of innovation have also produced a very cautious surgical community, especially in Scandinavia. As the result of this practice of monitoring and control over selection of implants and surgical techniques, imposed by publishing the data from the Registry (including the performance of individual clinics), only one out of ten THR procedures currently done in Sweden is a revision. Less precise data suggests this to be one out of five in the U.S. and perhaps as much as one out of three or four in Germany. These overall numbers of revisions are in stark contrast to manufacturers' claims for the survival rates of their implants based on isolated studies, which have been edging ever higher and would not find their place on advertising pages if not being close to 99% for 10, or even 15 years.

Frequency of revision surgeries depends on many factors, but certainly one of them is the still superior performance of the cemented THR in comparison to cementless -- in the Swedish Registry, the overall rate of revisions of cementless is double that of cemented THR using modern cementing techniques. The debate has come to be dominated by the use of a single outcome parameter of THR -- one that the Swedish Registry is based on -- the survival rate. Since this is approximately 95% at ten years for a good prosthesis and a good cement properly used, it seems that there should be much less pressure for innovation than suggested by the 500 THR models present on the market and by the continuing efforts to improve cementless designs and cementing techniques. One of the reasons is that both the surgeons and the producers of implants need something new to wrestle for their respective shares of recognition and the market which is difficult to do in the flat field of cemented Charnleys. Price premiums for cementless THR are also very attractive, if difficult to maintain in face of pressures imposed by medical insurers.

Perhaps most important, in long term, is the fact that there are some real problems to solve,

in spite of the 95% ten-year survival of cemented THRs. The Swedish Registry has recently undertaken a project to estimate the performance of a smaller number of cases which have not been revised (and thus, until now, were not entering the Registry with an outcome) -- it is anticipated that some 15% patients will turn out to have a failed THR at 10 years, but are not being revised for various reasons, such as old age. In younger patients revision rates are higher, and cementless THRs currently available seem not to have made any positive impact.

In human THR field it is generally expected that next several years will lead to consolidation in the industry (which seem to be confirmed by several recent acquisitions / mergers of the major orthopedic companies) and a continued struggle for the market share between the two dominant approaches -- cemented and cementless.

Presence of 500 THR models on the market may give an impression of great variety, but with only a few exceptions, there is not much to distinguish between different versions of a generic, Charnley type cemented stem, or slight modifications of a press-fit, porous-coated stem of the other group. Identity, if any, is built around appearance rather than substance.

In the veterinary field, THR has found its first broader clinical use in the mid-seventies in several clinics in the U.S., and has been slowly expanding, at a faster pace in the U.S. than in Europe. Many factors have limited the rate of expansion, not the least of which is the financial burden of the procedure on the owners. However, it appears now that a broad public awareness of the benefits which THR has brought to human patients, and a constant increase in financial commitments which owners seem to be making for the sake of their pets (including nutrition and medical care), have significantly reduced this particular obstacle to performing THR in dogs. The clinical need is certainly not a limiting factor with many popular breeds having over 50% incidence of hip arthrosis at mid life (most frequently due to hip dysplasia). In some countries, strict control and selection by breeders has helped reduce the incidence of dysplasia, but limits of these interventions have probably been approached and milder forms, which still lead to arthrosis, have reached a plateau.

Cemented THR presents special problems when used in veterinary practice. The high standards of asepsis available to human surgeons, are in general not available to veterinary surgeons. Published data from a leading veterinary center (Ohio State University, Columbus) suggest 5% incidence of infection in primary procedures and 25% in the first revisions. In smaller, less well equipped university or private clinics, infection rates may well be on the order of 25% in primary procedures (these are not published, but are mentioned in private by many disappointed veterinary surgeons). Thus the rates of infection, greatly reduced in human THR (in Sweden to well below 1%) with strict adherence to good aseptic practices and use of antibiotic-loaded cements, present a serious impediment to expansion of cemented dog THR outside several specialized clinics.

Proper placement of a cemented THR in dogs is also a major challenge, even for experienced surgeons, and with the best available instrumentation. These errors can easily lead to post operative dislocation of the hip, which only exceptionally can be treated without a revision. Large variations in size (18 to 70 kg) and anatomy of dogs in need of THR make the proper selection and placement of prosthetic components uniquely difficult. Reluctance of teaching schools to adopt programs in THR has also led to failure to produce a broad base of well trained surgeons.

In spite of all of these difficulties, THR has kept the attention of veterinary surgeons and there

are even signs of a surge in interest, as witnessed by days dedicated to THR issues at major international conferences on veterinary surgery. The need and the interest are there, but there has been very little in terms of innovation specifically addressing the problems of canine THR. Cementless designs based on porous coatings have generally failed to meet expectations in human THR -- in canine, the problems are multiplied on several fronts -- the range of shapes and sizes, and the cost of implants being essentially prohibitive for such approaches.

Limitations of conventional approaches to THR (both in human and canine) can probably be summarized, without much oversimplification, as follows:

- in cemented stems of reasonable design, most of the failures are due to limited fatigue endurance of the bone cement (leading to so called aseptic loosening);
- in cementless stems most of the failures are due to bone loss induced by movement at the stem-bone interface;
- in acetabular components, difficulty of matching the implant to highly compliant cancellous bone, with or without cement, leads to formation of soft tissue at the interface which may progress to gross instability

Zurich Cementless concept has been built around a practical solution to the problem of micromotion at the interface to the cortical bone of the femur. This was achieved in part by reducing the difficulty of the task by anchoring the stem to the medial cortex alone, and then by using bone screws locked into the stem as well as into the bone.

Acetabular component is also unique and has successfully addressed the challenges of interfacing to cancellous bone, by first providing a highly compliant titanium alloy shell to suspend the plastic insert of the cup, and then by promoting the bone ingrowth into this shell by leaving it hydraulically open, thus allowing convective mechanisms of mass transport to play their important role in bone formation.

There is ample evidence in some hundred THR procedures performed in dogs until now that the concepts of Zurich Cementless are valid and will withstand the challenges of expansion into broad clinical practice. This may help establishing a role for THR in veterinary surgery comparable to that it has taken in human surgery.

2. Anchorage of the femoral component

Basic mechanical principles of anchoring a hip prosthesis stem into the proximal femur are reasonably well understood even if frequent debates about the various issues involved suggest the contrary. Some of these debates are due to the interdisciplinary nature of the subject, where communication tends to be more difficult because of both the substance and the terminology; others due to relatively complex nature of the problem.

The clinical field is overwhelmingly dominated by intramedullary stem designs -- an intuitive approach to fixing a prosthetic component to a tubular bone structure. When a stem is inserted into a prepared medullary cavity, it must satisfy its basic mechanical role -- transfer of the joint force onto (into) the rest of the femur. Ideally, all other but hip joint forces, would remain substantially unchanged by the THR procedure. Over two dozen muscles span the hip joint -- forces exerted on the femur by their tendons as well as the joint forces at the knee, should remain quite normal. Of course, the diseased hip joint leads to a deteriorated muscular function, altered in pattern and magnitude of activity of individual muscles and major muscle

groups. The hope is that a properly executed THR will lead not only to elimination of pain, but also to restoration of the normal hip function, involving basically all of the leg muscles.

It is thus important to consider the issues of prosthesis anchorage in the global context of musculo-skeletal function instead of relying on a simplistic, and false, perception that the problem can be reduced to fixing a metal prosthesis stem (rod) into a tubular bone in order to resist forces applied to the prosthesis head. While anchorage abstracted to that level is still frequently used in both analytical and experimental studies, it is unlikely to lead to a solution for a proper in vivo function.

Compliance (inverse of stiffness) of the bone is higher than that of solid metal prostheses. The burden placed on the interface which is to remain stable, i.e. free of any micromotion (a poorly defined term, probably meant to indicate any motion), is rather serious -- under loading imposed on both the prosthesis (from the joint) and the bone (from the muscles), the implant will tend to move with respect to the bone, mostly in a gliding (shear) fashion. Perhaps one should think of the viscoelastic bone being moved (deformed) over the implant, especially when considering the lateral aspect of the femur (greater trochanter) and the large forces being exerted on it by the leg musculature. Should any of this motion occur before the interface is secured by bone adaptation (by interlocking) to the implant, true anchorage of the prosthesis will fail and this will eventually lead to a functional failure of the THR procedure. In principle, as has been shown by finite element (FE) analyses, it is impossible to achieve a fully stable interface by relying on a press-fit and friction -- proximal femur will split before sufficient pre-load can be applied to keep the interface of the canal-filling stem stable in functional use. Preparation of the medullary canal for implantation kills about two thirds of the cortex with the endosteal (inner wall) blood supply to the bone totally destroyed. About 10 to 12 weeks after surgery, remodeling of this dead bone will lead to its peak porosity. Presence of the canal filling stem does not allow for much activity from the inner (endosteal) side, so all of the bone removal and replacement happens from the outer (periosteal), living bone, towards the inner (endosteal) . During this period, and then longer still to allow for the bone to refill and gain some strength (another 10 to 12 weeks), patients are advised to protect the hip from (over)loading. This is at best difficult, and in most cases impossible. It has been measured with instrumented hip implants that a very simple action, such as turning over in the bed, can load the joint with co-contraction in excess of a body weight. As a consequence, most, if not all, of press-fit implants get loose at some stage and are then subjected to a chancy process of bone remodeling which may eventually form a stable interface at some areas, with soft connective tissue covering most of the implant. Very common, in perhaps half of the cases, is a transient (a year or longer) thigh pain, which may also become chronic. Instability, with a soft tissue, rather than bony interface, is almost certainly to blame for this serious and frequent complication of cementless THR. For a typical patient who has decided to undergo the surgery exactly because of the pain, this may be a very disappointing outcome. For older patients a prolonged lack of activity (bed rest) can quickly lead to life-threatening complications.

Most of the biomechanical literature on the subject blames the bone remodeling on the effects of so-called stress shielding. While it would be silly to deny the ability of bone to respond to changing patterns (spatial and temporal) of physiological loading, it is just as distressing that basic facts of bone biology have been left out by most so-called bio-mechanical analysis done on THR. Assigning some homeostatic (mostly black box type) properties to bone and performing iterative FE analysis of the prosthesis-bone construct in order to predict the response of bone, does not in any way address the problem of dead bone (due to cavity

preparation) surrounding the implant, and the biological limitations thus imposed on the process of integration.

Authors' preoccupations with similar problems associated with plating of fractured bones have provided crucial insights which led to the development of Zurich Cementless. In several years of research and development of so-called PC-Fix plating system (led by Tepic during his 14 years tenure at the AO Research Institute, Davos, Switzerland), some 250 tibia fractures in sheep have been treated under different gap and fixation conditions, mechanically tested post mortem at time intervals from 3 months to 2 years, and histologically analyzed. About a third of the fractures were treated with conventional plates; the rest with PC-Fix. Fractures treated with PC-Fix healed much faster and with less complications than those treated with conventional plates; after only three months, when plates were removed and bones broken to test the union, there were no refractures (through the original fracture) with PC-Fix, whilst all of the conventionally plated bones refractured (6 animals per group). In fact, refractures (in strength tests) in conventionally plated bones persisted up to 1 year.

Resistance to infection was studied in some 400 rabbits at Karolinska, Sweden, with systemic infection challenge, and in Davos with local challenge. Intact tibiae were plated with conventional stainless steel or titanium plates, or with titanium PC-Fix. PC-Fix demonstrated a clear advantage in resistance to infection in both studies. In the local challenge model, the number of colony forming bacteria required to cause bone infection (in 50% of animals in a given group) with PC-Fix was 100 times higher than with a conventional stainless steel plate, and 10 times higher than with a conventional titanium plate. In fact, local infection with PC-Fix was so difficult to achieve that a number of animals injected with the doses required to establish a local infection, developed sepsis. Increased resistance to infection, achieved by minimizing the amount of bone killed by vascular disruption, was the prime motivation of PC-Fix development.

Clinical testing of PC-Fix done in dogs (by Montavon) and in a large multicentric study in humans, with now some 1500 cases treated, has met expectations -- incidence of infection in closed fractures is below 1% and in open fractures below 2% -- reduced several fold in comparison to major published studies.

In conventional plating, screws are used as anchors to pull the plate against the bone and allow for load transfer to and from the plate to be effected by friction. As the bone around the screws goes into remodeling, the pressure between the plate and the bone is lost and the plate starts to move underneath the screws' heads. At one year post-op, when plates may be removed from the healed bone, screws can easily be re-tightened by about 0.5 mm axial displacement (towards the bone). In spite of the screws being now well incorporated into the bone (due to remodeling of the bone killed by drilling), the load-carrying plate is not solidly fixed (connected) to the bone.

In contrast, with PC-Fix, where the screws are not pulling the plate against the bone, but are instead locked with their heads in the plate, at one year (or in fact at any time after implantation) there is no loosening of the plate with respect to the bone. While bone had certainly been damaged by screw insertion, and had remodeled around the screws, the construct bone-screws-plate remains absolutely stable. In the case of PC-Fix, there is an additional advantage due to preservation of the periosteal blood supply (only point contact, and thus PC in the name, between the plate and the bone).

These observations have led to our proposal for the primary fixation of the femoral component. The prosthesis is anchored by screws which are locked in the stem -- this in contrast to conventional screws, which have been used for hip prosthesis fixation in the fifties, and now in the Kent revision stem of Biomet. If the screws are not locked in the stem, as with conventional plates, remodeling around the screws will inevitably lead to a loss of stability of the whole implant. But with screws safely locked in the stem, remodeling can proceed without a major risk of loosening, less most of the bone around all of the screws got resorbed at the same time. Once the screws are re-embedded in the newly formed bone, which also leads to a reduction of stress concentration factors, the stem is permanently anchored in the bone. Zurich Cementless is fixed by monocortical screws to the medial cortex only. This is where most of the joint force is transferred to in a natural joint -- lateral cortex is loaded most directly by the muscle forces. Keeping the stem in contact with only the medial cortex greatly simplifies the task of anchoring -- since the stem does not need to touch the lateral cortex in order to transfer any load to it, it may freely move with respect to it without causing bone resorption. Avoiding coupling between the medial and lateral cortices, brought about by the concept of canal-filling, press-fit stem, is the most important, distinguishing characteristic of Zurich Cementless. The need to avoid coupling of cortices by the stem is perhaps most easily appreciated for the frontal plane, but this of course is also valid for the sagittal plane, i.e. for the cranial and caudal cortices.

Strength of the prosthesis, and of anchor screws in particular, is subject to a rational design process. Titanium alloys have a definite, well defined high-cycle fatigue strength (above 1 million cycles they will sustain about 1/2 of their static strength). International standards for implant testing call for establishing load carrying capacity for 5 million cycles -- if implants do not fail at that many cycles, they are expected to last indefinitely.

The main limitation on rational design is our ignorance about loading of the THR in vivo. This is the case even for human prosthesis, and to a much bigger extent, for canine. Screw failures have necessitated many of our revisions as we broadened indications of the original design, with only three anchor screws, to larger dogs. The problem has been fully rectified by modifications of screws, in the material, the geometry and the manufacturing process, as well as in the number of screws used -- three for small dogs and up to five for the largest (until now, a 65 kg Rottweiler).

3. Anchorage of the acetabular component

Anchoring an acetabular cup into pelvic bones presents a very different problem than that of the femoral component, and Zurich Cementless offers a unique solution here as well. Pelvic bones form a fairly compliant support structure for the acetabulum, whereby the cartilage layer covers a shell of hard, subchondral bone which is backed by very soft cancellous bone.

In cemented acetabular components, the standard practice calls for removal of the cartilage and a minimal amount of the subchondral bone, which is then drilled by a plurality of holes allowing the cement to penetrate behind the subchondral shell and thus to better anchor the cup. Cups are either all polymer (ultra high molecular weight polyethylene - UHMWPE) or metal backed polymer. Recently, there has been renewed interest in metal-metal articulations, where a typical construction calls for an additional metal liner for the articular surface (polymer insert has been retained with an idea to provide some compliance to the construct).

In cementless acetabular components, the subchondral shell is either completely removed in

designs aiming for bone ingrowth, or partially retained in various threaded-type designs. In a great majority of cementless cups, the metal backing component is a very stiff structure leading to a huge mismatch in compliance and seriously reducing the chances of a bony integration. Wire mesh-backed polymer acetabular cups developed by Sulzer Orthopaedics are probably the least stiff of the currently available cementless components. New developments with metal foam backing are still experimental.

In all cases, metal backing presents to the bone a textured surface, sometimes with interconnected pores running some depth into the implant (e.g. in bead or plasma coated cups; in wire mesh coated cups; in laser-drilled solid metal backings), but invariably ending in closed, dead-end holes. Our preoccupation with the role of convective transports in bone growth and remodeling, has led us to propose the concept of hydraulically open implants -- the acetabular component of Zurich Cementless is the first embodiment of this concept.

Histological examination of our first THR procedure in an experimental dog has revealed a very fast outgrowth of cancellous bone, which by week 8 seemed to have been arrested at a distance of several hundred micrometers to about a millimeter away from the solid implant surfaces (stem in the proximal femur and, at that time, a solid, metal-backed acetabular cup). Why would bone suddenly "change its mind" ? In that case we have used c.p. titanium, which should have caused no inhibitory chemical signals (in absence of fretting, titanium is essentially inert, body fluids being naturally saturated with its very poorly soluble salts). We proposed that a large, impermeable surface of the implant was responsible for the inhibition of the convective currents set in motion by the cyclic pressure gradients. These gradients are caused by the physiological loading of the bone; possibly by the blood pulsation. If inhibition of convective mass transport was responsible for slowing down bone outgrowth, the solution could be in the application of permeable, or hydraulically open implants. Of course, only if allowed by the functional and mechanical constraints (strength) imposed on the implant design.

In a pilot experiment performed in two dogs we have addressed this issue and are quite comfortable with a statement that our hypothesis seems correct. An intramedullary nail in the form of a tube was inserted in a retrograde fashion into an intact femur and interlocked proximally and distally with transcortical screws (threads of the screws engaged in the nail as well as in the bone, preventing any larger movement of the nail within the bone). One half (distal) of the nail was a solid tube, the other was perforated by closely spaced holes.

At locations where a large (several millimeters in lateral extent) surface faced the front of the newly growing bone, the growth was arrested and no contact between the bone and the implant was formed up to eight weeks. In contrast, perforated nail sections allowed bone trabeculi to cross the wall of the implant. Sounds reasonable ? We thought so -- hence the metal shell of our acetabular component. Polyethylene (UHMWPE) insert is suspended within a densely perforated shell leaving about 1 millimeter free space between the inner wall of the metal shell and the outer wall of the insert, i.e. bone is free to grow past the shell into this space. Moreover, elasticity of the construction will lead to pumping of the fluid in and out of the bony bed and in and out of the perforated shell under dynamic loading of the hip.

This is perhaps the main functional distinction over the perforated, cylindrical implants developed by F. Sutter (who has also supported our early efforts) of the Straumann Institute, Waldenburg, mostly for dental, but also for orthopedic applications.

A couple of acetabular component revisions we have performed at some weeks to months after implantation, required use of extreme forces (hammering) for removal of the cups from their bony bed. Histological evaluation still pending, it appears that bone ingrowth into our perforated shell is very rapid and provides for a solid, stable anchorage of the acetabular component.

4. Technical features of Zurich Cementless

All metal components of Zurich Cementless are manufactured from TiAl6V4, which is the most widely approved and used titanium alloy for orthopedic implants. The main clinical concerns over the wear debris of TiAl6V4 we believe should be greatly reduced due to an essential lack of micromotion between the primarily stabilized THR and bone, as well as between the various components of the prosthesis.

All components are supplied sterile packaged. Metal parts can of course be steam re-sterilized, but acetabular cup must not be steam re-sterilized.

4.1. Femoral component

A femoral component comprises:

- stem of three sizes (small, medium and large);
- bone screws; 3 for the small stem; up to 5 for medium and large (use of 5 screws is recommended for both medium and large stems, but leaving the second most distal hole in the medium stem empty is an option);
- head-neck of three sizes (small, medium and large in 4 mm length increments); head diameter is 16 mm in all cases.

Stem-to-neck connection is via a standard cone with a 1:10 taper. Surface of the stem which is placed within the femoral cavity is rough blasted and passivated, a standard procedure for many cementless titanium alloy stems. With the primary fixation with screws, bone ongrowth and possible interlock at these rough surfaces is welcome, but optional.

Screws are self-taping with a special thread shape optimized for the strength of the screw. The core diameter of the screws is 3 mm; the outside diameter is 3.4 mm. These shallow threads provide sufficient pull-out strength in the cortical bone to guarantee a safe locking of the conical head of the screw in the stem, even with a thin, 1 mm cortex. Once the conical head of the screw (1:10 taper) is locked in the matched hole of the stem, most of the loading on the screws is in shear for which the screw thread profile has a very favorable geometry. Presence of the properly inserted screw heads in the stem is important for the strength of the stem. To minimize the risk of stem failure all screws should be used, with a possible exception of the second most distal screw in the medium stem. Self-taping function is superior to any bone screws we have experience with, resulting in a smooth insertion and a minimal risk of bone delamination. Screw driver recess is hexagonal for the 2.5 mm screwdriver (small AO screw-driver, but with a special screw holder sleeve).

The head of the prosthesis is polished, TiN coated and polished again. This provides a very hard, ceramic surface for articulation against polyethylene. Laboratory tests of this treatment have shown excellent results in comparison to untreated titanium, stainless steel, or even chrome/cobalt based alloys, but the limited clinical experience has been less positive. The risk,

as with any articulation pair, is the third body damage, particularly with hard particles of zirconium dioxide used as a contrast additive in bone cements. In the case of primarily fixed, cementless prosthesis, the risk of a third body damage should be eliminated, and we anticipate the long term performance of our TiN coated head to meet the positive expectations from the laboratory tests.

4.2. Acetabular component

Acetabular cup is a single, pre-assembled component with an UHMWPE insert suspended within a TiAl6V4 thin, perforated shell. Articulating surface is a full hemisphere. A single, central ("polar") hole receives an anchor screw, a standard AO 4 mm titanium cancellous screw. Construction of the neck of the prosthesis allows for 120º of angulation, which exceeds the natural range of motion in a dog hip joint.

Titanium shell is rough blasted and passivated prior to assembly with the polyethylene insert. A very substantial snap-fit of the insert into the shell guarantees safe, motion free interface between the two components, which in a number of metal backed cups assembled in surgery has been identified as a major source of polyethylene debris. In fact, our production calls for assembly prior to machining of the articulating surface of the insert, which thus can be made to the final tolerances.

5. Surgical technique

5.1. Instruments

Standard set, hip prosthesis implantation set, AO / ASIF drill machine, oscillating device, rongeurs, different sizes retractors (Army Navy, Meyerding, Hohmann), periosteal elevators, surgical suction, cautery, suture materials.

5.2. Implants

- femoral head-neck (3 sizes)
- emoral stem (3 sizes)
- 3 to 5 screws for stem fixation
- acetabular cup (4 sizes: 23, 26, 29 and 32 mm outer diameter)
- an AO / ASIF cancellous bone screw (titanium; 4 mm; 12 to 20 mm long, in 2 mm increments)

5.3. Surgical approach

The dog is anesthetized, administrated perioperative antibiotics, prepared aseptically for the orthopedic procedure and positioned in lateral recumbency on the surgical table.

Through a craniolateral approach the cranial aspect of the neck is exposed by elevation of the vastus lateralis and the joint capsule is freed from the attachment of the vastus intermedius to its ventral extent. A T-shaped capsulotomy is made along and at the dorsal and ventral base of the femoral neck. If necessary, the round ligament is transected to allow luxation of the femoral head.

5.4. Preparation of the proximal femur

The bony ridge between the femoral neck and the greater trochanter is removed as close as possible to the greater trochanter in a ventral direction down to 5 to 10 mm above the level of the lesser trochanter. The osteotomy of the femoral head and neck is completed with a Gigli wire placed in the created grove and below the femoral head, cutting into the direction of the lesser trochanter. Osteotomy can alternatively be performed with an oscillating saw or with a burr. A Hohmann retractor is placed under the proximal femur from proximally, in order to raise the femur and protect the gluteal musculature during the preparation. With the surgeon facing the side of the back of the patient, a 6 mm drill, mounted on a T-handle, is introduced into the caudolateral aspect of the osteotomized femoral neck and carefully advanced into the medullary cavity of the femur. The size of the created canal is enlarged with the help of an 8 mm reamer. This diameter allows insertion of the smallest size femoral stem.

If a larger stem is needed, a corresponding file is introduced in an appropriate angle of anteversion for positioning of the femoral component (35°). The grooves for the lateral ribs of the stem are cut toward the lateral cortex of the proximal femur, until the desired depth is reached, the file acting as a template, granting later insertion of the femoral stem.

5.5. Preparation of the acetabulum

With the limb positioned parallel to the body of the animal, the femur is distracted caudodistally with the help of a Mayo retractor, with the tip placed through the capsule in the caudoventral area of the caudal rim of the acetabulum. The insertion of the capsule is elevated around the rim of the acetabulum over a distance of 2 to 4 mm, as proposed by De Young, and retracted with finger Meyerding retractors. The cavity is cleaned of soft tissue remnants. A pilot hole is drilled into the most medial area of the surface of the acetabulum, located slightly cranial to the fossa, with a 2,5 mm three-lipped drill and an oscillating attachment. The oscillating movement of the drill reduces the tendency of the drill to slip and deviate from the axis, and most importantly, it offers protection of soft tissues which cannot wrap around the drill. With the use of the oscillating attachment, injury of the pelvic and sciatic nerves is very unlikely. Repeated measurements of the remaining bone thickness, obtained by passing a depth gauge through this pilot hole, are used to control progression of the reaming.

The acetabulum is now prepared using first a reamer one size smaller than the best pre-operative estimate, directed into medial direction, until the cortical bottom of the fossa is reached. This usually leaves about 3 to 5 mm of bone thickness at the pilot hole. The caudal rim of the acetabulum should be closely monitored to avoid its excessive reaming. The next larger size reamer is then used to finalize preparation of the acetabulum, unless all of the subchondral bone was removed in the first step. Osteostyxis limited to the depth of 2 to 3 mm is performed into the sclerotic areas with a 2,5 mm drill mounted on the oscillating attachment.

5.6. Fixation of the acetabular cup

A cup of corresponding size is digitally inserted to an approximate position and making certain there is no tissue interposition. The impactor is assembled according to the right or left side and positioned into the cup. The cup is hammered down until the impactor's orientation pins matching the long axis of the pelvis and the complementary angle of inclination of the

prosthesis come into the horizontal plane. Tilting of pelvis during this phase should be avoided.

A 2.5 mm hole is drilled with the oscillating attachment through the hemipelvis, using a drill sleeve positioned into the central hole of the acetabular cup. A titanium 4 mm cancellous bone screw of pre-measured length is then inserted in self tapping fashion for the fixation of the cup.

Presence and size of osteophytes is determined using digital palpation. Any osteophytes above the rim of the cup at any location are removed with rongeurs or osteotomes.

5.7. Fixation of the femoral component

The femoral stem is fixed onto the guide. Both are positioned into the anteversion angle given during the preparation of the proximal femur and the stem is introduced into the medullary cavity. The bony contour of the basis of the neck may need some adjustment to the stem, using rongeur. The vastus lateralis muscle is retracted cranially over the area of the linea aspera of the femur and an access hole is drilled over the middle hole of the stem, using a guided, 4,5 mm three-lipped drill, mounted on the oscillating attachment, using copious tissue irrigation. A drill sleeve is introduced blindly into the hole of the prosthesis and a hole is drilled into the medial cortex with a 3,0 mm drill, pressing the stem against the medial cortex, preferably in valgus position. A self tapping screw with a conical head is then inserted and locked into the hole of the femoral stem. Distal and proximal screws are then inserted in the same fashion. The screws are controlled for tightness and the guide is then removed. The cancellous screw used for fixation of the acetabulum is now re-tightened. The femur is then moved in a physiological fashion and the distance between the femoral and the acetabular components is estimated. Femoral head-neck components exist in three sizes with a 4 mm increment in neck lengths. The head-neck component of the minimal estimated length is placed and hammered onto the conical peg of the femoral stem already in place. The prosthetic joint is reduced manually or with the help of a special retractor.

Three positions are tested for impingement and possibility of luxation within the physiological range of motion:

- abduction to test the clearance between medial greater trochanter and the dorsal edge of the cup;
- outward rotation of the hip with flexed stifle at 90º for craniodorsal luxation of the prosthesis; and
- full flexion and inward rotation of the hip for caudoventral luxation of the prosthesis.

The construction of the neck and the cup allows for the motion range of 120º in all directions, i.e. more than a natural hip joint. With positioning errors not exceeding 15 degrees, the joint replacement components should not cause an impingement. This does not exclude the possibility of skeletal structures impinging on themselves, or the joint replacement. If tendency to, or an actual luxation, occurs in any of the three tests, the prosthesis has to be tested with the next longer neck, until the joint is judged stable. If present, impingement of the caudal fibrous joint capsule may be carefully resolved with a rongeur (cave: sciatic nerve). If instability of the prosthesis persists, the acetabular screw can be removed and the cup repositioned in order to cover the area of luxation.

After copious flushing, the joint capsule is closed with 2 for 3 far-near-far-near stitches, with synthetic resorbable material (size 2-0). Fasciae, subcutaneous layers and skin are closed in

appositional fashion.

6. Clinical experience

The first implantation of the Zurich Cementless hip prosthesis was performed on an active, 3 years old German shepherd, with 32 kg body weight, in December 1993. The dog had bilateral coxarthrosis and sustained a traumatic hip luxation after being hit by a car. A revision because of the broken neck of the prosthesis (then a simple, adjustable screw, made in c.p. titanium) was needed after a year. The neck was replaced with a stronger titanium alloy component without removal of the stem. Since then the dog has been regularly clinically and radiographically controlled, and the prosthesis is still fully functional today.

In 1994, five further prosthesis of this generation were implanted in clinical cases. After an observation time of one and a half years, a second generation of prosthesis was developed and regularly used in clinical cases, starting in June 1996. In the course of next two years several clinical problems and implant deficiencies became apparent. These were analyzed and whenever possible, corrected. The last modification in implants was made in June of 1998 (stronger screws).

The surgery time averages 1 hour and 40 minutes with a surgeon and two assistants. The technique proved to be reproducible, with now eight surgeons having performed the surgery with the help of the authors.

A total of 95 prosthesis have been implanted in 89 dogs of many different breeds and a wide age span (10 months to 11 years). Four dogs were less than one year old. Most of the patients were family dogs, among them several working dogs. Three dogs were active in agility trials. Two revisions of failed cemented prosthesis (an aseptic loosening and a prosthesis neck fracture) were also successfully performed.

Nineteen cases (20 percent) required one, and 6 cases (6 percent) required two surgical revisions. All patients still alive have been controlled at six weeks and one year after the surgical implantation. At this time, all patients are fully functional, and show no lameness or gait anomaly of the operated limb.

Complications requiring surgical revisions were caused by three major categories of problems. Luxation of the prosthesis in 7 cases (7 percent) was the first significant problem encountered. A subsequently developed acetabular impactor, combined with the consequent performance of intraoperative tests to evaluate the stability of the prosthesis, has solved this problem. No luxation has occurred in the last 19 cases.

The second category was loosening of the acetabular cup, a problem encountered in 10 cases (10,5 percent). The positioning of the bone screw used for fixation of the cup into the pelvis was optimized and standardized with the help of the acetabular impactor defining the ideal position for the screw. Reaming of the acetabulum with depth control was also increased towards the medial cortex, placing the cup deeper into the hemipelvis. Additionally, a careful pre-operative selection of the size of the cup led to use of generally smaller cups with the improved dorsal bony converge. These three measures combined appear to have resolved the problem of cup loosening. There was no case for cup revision in the last 25 patients.

The third major problem has been fatigue failure of the screws used for fixation of the stem, which happened in 9 cases (9,5 percent). As we broadened indications and started operating on dogs over 35 kg using only three screws to fix the stem, fatigue failures of the screws, usually at over one million cycles started to generate revisions. Interestingly enough, in some cases only the proximal screws failed and in no case were there any signs of gross loosening with osteolysis around the stem. Radiographically, stems could be compared to conventional cementless ones. Yet with any screw broken the patients usually showed an immediate reduction in weight-bearing and were brought in for control. In response to these fatigue failures, the screw core diameter was increased (from 2.4 to 3.0 mm), as was the radius at

the root of the threads, thereby reducing the stress concentration. The production technology was also changed allowing for a gradual exit of the threads. Additionally, the number of screws was increased from 3 to 4 or 5 depending on the size of the dog. Positioning of the prosthesis was also modified to give the neck an anatomical anteversion of about 35º and thus to reduce the torsional moment of the propulsive forces. The last measure also resulted in an improvement of the range of motion of the reconstructed joint, with generally shorter necks being selected intraoperatively. No screw failure has occurred since those standards have been applied (last 29 cases).

There were also two failures of the early stem designs; one at the most proximal hole and one at the bottom of the stem cone. The stem and cone geometry have subsequently been modified and no stem failure has occurred since (last 84 cases).

Longitudinal fissures of the proximal femur appeared in 13 cases. These were caused by insufficient preparation of the proximal femur, but did not lead to any major recovery complications. The problem has been solved with a better stem file (broach) giving more freedom for insertion of the stem.

Three fractures of the femur (1 greater trochanter, 2 diaphyseal) occurred an middle aged to aged patients 1 to 3 days after the implantation. In both cases of revision of a previously cemented prosthesis, femurs had to be split in order to remove all of the cement. All these fractures were fixed internally and all have healed uneventfully.

Neuropraxy of the sciatic nerve occurred in 5 cases. Cadaver tests pointed to retraction of the gluteal musculature over crista ischiadica of the pelvis with an inappropriate Hohmann retractor as the cause of these injuries. All 5 patients recovered within 1 to 10 weeks.

Revisions, if not simple, were possible for any of the above mentioned complications, and all revised patients recovered uneventfully. Two owners elected euthanasia rather than revision surgery.

No case, primary or revised, showed clinical or radiological evidence of postoperative infection.

The referral case load at the Small Animal Hospital of the University of Zurich has been steadily increasing during the last three years and is currently about 45 cases per year.

7. Concluding remarks

In seven years Zurich Cementless THR has progressed from an idea to an extensively tested, revised and refined canine hip replacement system, comprising implants, instruments and the surgical technique. While no guarantee of success in broader clinical use can be given at this moment, we are fairly confident that complications most likely to occur have occurred, have been analyzed, and whenever possible, appropriate corrective measures have been taken.

Our intention now is to introduce the system into controlled clinical use at selected centers world-wide. We hope for a full cooperation in our effort to learn more about the clinical performance of Zurich Cementless, about its competitive advantages and disadvantages vs. conventional cemented THR systems. This knowledge will be essential if we are to meet our goal of making THR in dogs as successful a surgical intervention as it has become n humans. We are committed to respond to the relevant issues raised, problems identified, and constructive criticisms directed at any one of the parties involved in this process.

A new company, Kyon, has been incorporated in Switzerland with the mission to bring Zurich Cementless into the clinical use, to monitor its performance and to make every effort to correct any deficiencies the system may reveal in a critical clinical evaluation. Kyon has obtained from the AO/ASIF Foundation an exclusive license, limited to veterinary use, for the patents covering Zurich Cementless. Kyon is still considering various distribution options which will guarantee provision of the full support for the veterinary surgeons interested in adopting

Zurich Cementless, including training programs, instruction materials, an efficient organization for distribution of the instruments and implants and regular updates on the clinical performance of the system and any future modifications in technique and materiel.

This document is being distributed to about a dozen surgeons in the U.S., Canada and Mexico, and a dozen in Europe and Australia. With those who find our THR system interesting enough, we will plan the next steps to be initiated in late February of 1999. Briefly, we will plan to spend a day in each clinic using the first half of the day to present the material and perform a demonstration implantation on a dog femur and in a dog cadaver. In the afternoon we would like to assist the host surgeon in performing two procedures on his own patients. Those who decide to continue we will visit for the second time about a month later and assist with three additional surgeries (again within a day). We believe that experienced THR surgeons will manage Zurich Cementless implantation during 5 surgeries. Should anyone end up short of confidence after five procedures, we will try to help with more assistance, but this will call for some patience in scheduling further visits. An additional round of trips should be possible during the next summer and early autumn. An option we are willing to consider with anyone within the reach of Zurich is a visit with their own patients brought to Zurich for surgery.

Instruments and implants will be available at the time of the second visit. We hope that we will find sufficient interest to recruit 10 surgeons for a prospective follow-up study with Zurich Cementless. The goal is to enroll 200 cases in about a year. Evaluation of the results will be done by one of the centers, other than Zurich. As soon as the centers for the study are recruited, we will produce a draft of the protocol and circulate it to those involved for suggestions and approval.

Your comments to this document and our plans will be much appreciated. In order to schedule our first round which is to commence on February 14th, we would like to have your interest confirmed no later than mid January -- we shall contact you by phone during the second week of January.