CONCEPTS OF ZURICH CEMENTLESS PROSTHESIS

S. Tepic, Dr.Sci., P.M. Montavon, Prof., DVM
School of Veterinary Medicine, U. of Zurich, Zurich, Switzerland

E.S.V.O.T. September 2004, Munich

Zurich Cementless provides for an immediate and indefinitely stable anchorage of the prosthetic components by resolving two, partially coupled problems: (i) load-induced movement at bone-implant interfaces; (ii) stress shielding of the bone, particularly by conventional, stemmed, femoral components. Bone cement in a Charnley-type Total Hip Replacement (THR) accomplishes both: stability of the interface by an in situ polymerized interlock; and well defined load distribution through a compliant cement mantle. All of this is fine on short, but less satisfactory on long term basis - aseptic loosening is the most common reason for long term failure of THR. The best efforts at analysis, as well as careful observation, suggest that fatigue failure of the cement mantle is a common and important component of the process leading to aseptic loosening, the main mode of THR failure in both people[1] and in dogs[2]. This has been the main driving force behind development of cementless THR, but clinical performance of all of the different types tested broadly enough and with sufficient follow-up, is still inferior to that of a well-designed, well-cemented THR[1]. In most cases, cementless prostheses have replaced the soft cement mantle by more of a stiff metal added to an already stiff core element. This exacerbates both problems: a higher mismatch in stiffness leads to more pronounced stress shielding, but also to higher shear loads at interfaces and hence increased risk of micromotion. The femoral and acetabular components of Zurich Cementless reflect different, both novel, approaches to these objectives.

Anchorage of the femoral component: Compliance of the femur is higher than that of a solid, canal-filling metal prosthesis. The burden placed on the interface, which is to remain stable, is serious - physiological loading generates high interface shear stresses, which, initially, can be resisted by friction alone. It has been shown by theoretical analysis that canal-filling, press-fitted, metal stems cannot be stable at all contact areas to the femur under physiological-level loading. Should any of this motion occur before the interface is secured by bone adaptation to the implant (by ongrowth and/or ingrowth), true, solid anchorage of the prosthesis will fail.

Preparation of the medullary canal for implantation kills about two thirds of the cortex with the endosteal (inner wall) blood supply to the bone inevitably 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 remodeling activity from the endosteal side, so all of the bone removal and replacement happens from the periosteal, living bone. During this period, and then longer still to allow for the bone to refill and gain some strength (another 10 to 12 weeks) the hip should be protected from (over)loading. This is at best difficult, and in most cases impossible. 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.

In departure from the press-fit / bony ingrowth concept, Zurich Cementless THR deploys a screw-based 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 in a manner similar to that of interlocked nails. If the screws are not locked in the stem, as with conventional plates, remodeling around the screws will lead to loss of stability of the whole implant. But with screws safely locked in the stem, by analogy to the extensively researched PcFix plating system of AO/ASIF[3], 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, the stem is permanently anchored in the bone. Zurich Cementless THR is fixed by mono-cortical screws to the medial cortex only. Screws are passed through the access holes in the lateral cortex, all of the drilling and fixation performed with the aid of a drilling guide attached to the stem. Medial cortex 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. Medullary cavity is spared some damage and stem size selection is greatly simplified. Avoiding coupling between the medial and lateral cortices is the most important, distinguishing characteristic of Zurich Cementless THR.

If any bone is to eventually bridge the gap and grow to direct apposition with the implant, it may do so under ideal conditions of stability. To facilitate the process of integration, the most recent version of the stem is plasma coated by pure titanium.

Strength of the prosthesis, and of anchor screws in particular, is subject to a rational design process, with a serious shortcoming in our ignorance about functional loading of canine THR. Our empirical approach resulted in screw failures in the early versions of the stem when used in larger dogs. The problem has been rectified by modifications of the screw's geometry, the material and the manufacturing process, as well as in the number of screws used -- four for small dogs and five for larger (the early versions used only three screws).

Anchorage of the acetabular component: Anchoring an acetabular cup into pelvic bones presents a very different problem than that of the femoral component. Pelvic bones form a compliant support structure for the acetabulum, whereby the cartilage layer covers a shell of hard, subchondral bone, backed by soft cancellous bone.

In conventional cementless acetabular components, the subchondral shell is either completely removed in designs aiming for bone ingrowth, or partially retained in various threaded-type designs. The metal backing is usually a very stiff structure leading to a huge mismatch in compliance and seriously reducing the chances of a complete, long-lasting bony integration. Wire mesh-backed polymer acetabular cups developed by Sulzer Orthopaedics and Zimmer's metal foam backing (developed by Implex Corp.) are notable exceptions.

In most cases, metal backing presents to the bone a textured surface, sometimes with interconnected pores running some depth into the material, but 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 THR being the first embodiment of this concept.

Polyethylene (UHMWPE) insert is suspended within a densely perforated titanium 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. Its ingrowth is accelerated by the convective fluid currents set in motion by the cyclic pressure gradients caused by the physiological loading of the bone. 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 Franz Sutter (who has also supported our early efforts) of the Straumann Institute, Waldenburg, Switzerland, mostly for dental, but also for orthopedic applications[4]. Fluid convection is presumed to increase the mass transport of important bone growth promoting factors emanating from the extant cancellous bone surrounding the implant.

Surface of the titanium shell is also plasma, titanium coated for an additional micro-interlock. The early versions shells were a plain hemisphere - the last modification, aimed at improved press fit for the initial stabilization, incorporates small protrusions running circumferentially just bellow the "equator". The pole of the shell is slightly flattened to avoid the cups bottoming out at the pole without a full engagement at the "equator". A single central screw is used to maintain a pull on the cup into its bony bed during the bone ingrowth phase.

In the first version of the prosthesis the design objective for articulation was to give an impingement-free range of motion superior to that of an average normal dog hip. Angulation of 120 degrees was found to satisfy that requirement. The head coverage was 180 degrees. Some of the surgeons reported luxation incidence higher than for cemented prosthesis (from their own experience). The neck diameter was decreased once to give 130, and then again to give over 145 degrees of total angulation, without a clear sign of improvement in the luxation rate (estimates complicated by the concomitant process of learning). Finally, the cover of the head was increased to approximately 200 degrees, which, combined with the new necks, still provides over 120 degrees of impingement-free angulation. These steps have lowered luxation rate to a seemingly accepted rate of less than 5 percent. Perhaps the current balance of impingement-free motion vs. head coverage is close to some optimum. In retrospect, the design objective could be restated as: maximize the range of impingement-free motion by minimizing the neck diameter, and then cover the head maximally, still to avoid impingement in a well placed THR. We have found a new challenge in meeting these criteria in very young dysplastic dogs, which typically show a great range of motion, and therefore an increased risk of luxation. A series of intra-operative stability tests, and appropriate corrective measures, if any lack of stability is detected, seem to provide a strong guarantee against postoperative luxation.

With about 3000 dogs treated with Zurich Cementless THR by about 100 surgeons, and with over 10 years of follow-up, almost five of those in broad clinical use, it seems that the goal of providing an immediately and indefinitely stable THR, with a clinically acceptable surgical procedure, is within reach. However, some of the improvements are still recent (3 years out), and need to be carefully followed-up for a few years.

References:

1. Annual Report 2002, The Swedish National Hip Arthroplasty Register, Department of Orthopaedics, Sahlgrenska University Hospital, April 2003, www.jru.orthop.gu.se

2. Skurla CP, James SP, Postmortem retrieved canine THR: femoral and acetabular component interaction, Biomed Sci Instrum 40:255-60, 2004

3. Tepic S, Remiger AR, et al., Strength Recovery in Fractured Sheep Tibia Treated with a Plate or an Internal Fixator: An Experimental Study with a Two-Year Follow-up, J Orthop

Trauma 11(1):14-23, 1997

4. Vuillemin T, Raveh J, Sutter F, Mandibular Reconstruction with the Titanium Hollow Screw Reconstruction Plate (THORP) Sytem: Evaluation of 62 Cases, Plast Reconstr Surg 82(5):804-14, 1988