

**Clinical data on “Zurich Cementless”
– Internal report**

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“Zurich Cementless” canine THR, commercialized by Kyon AG, Zurich, was introduced to broad clinical use in February 1999, after 6 years of development (and 160 clinical cases) by Tepic and Montavon at the School of Veterinary Medicine, University of Zurich. Total number of prosthesis implanted until the autumn of 2004, is about 3'000, by over 100 surgeons.

For this document six sets of follow-up data on “Zurich Cementless” canine THR will be presented:

- (1) Multi center clinical trial (with about 800 cases collated by 14 surgeons from the US, Europe and Japan); publication of this data is not expected before approx. two years from now. Study coordinator, Prof. Dr. Randy Boudrieau, of Tufts University, has presented intermediate results at several occasions – for this discussion, data (on 356 cases) he has presented at the 13th annual symposium of the American College of Veterinary Surgeons (ACVS), Washington DC, 2003, will be used;
- (2) 100 consecutive cases operated by Prof. Dr. Pierre M. Montavon at the University of Zurich, reported on at the ESVOT meeting in Munich, September 2004;
- (3) 125 cases operated by the surgeons being introduced to Kyon canine THR by Slobodan Tepic, Dr.Sci. (Kyon requires all its clients to perform at least 2 supervised surgeries, before purchasing any implants/instruments);
- (4) Short term follow up on 224 cases contributed by 16 US surgeons within one year from them completing an instructional course from Kyon;
- (5) Long-term (4 year) follow up by Dr. Jeffrey Peck, Orlando, USA, on the first 90 of his cases (now about 160);
- (6) Long-term follow up by Dr. Aldo Vezzoni, Cremona, Italy, on his first 100 cases.

These data sets will be compared to (generally acknowledged) the best, most objective reports on the cemented canine THR of Biomedtrix, Allendale, N.J., USA, by Dr. William Liska, USA, presented at (among others) Orlando Symposium on the Contemporary Issues in Canine Hip Replacement, 2001 (400 cases).

Data in the Table 1 summarizes information on the main complications documented in these reports. Of relevance are the complications of femur fracture, infection, loosening of the stem, implant failure, death from surgery; failure of the procedure and luxation (dislocation) of the hip. It must be emphasized that loosening of the stem in this context is poorly defined since in the case of Kyon hip the follow-up period (from the groups presented here) is too short and the data from Liska relates to the cases which actually had a revision surgery for a **recognized** loose component. In a later comparison, with

different sources of data, we will address the issues of aseptic loosening by comparing **unrecognized** loose implants.

	MC	PM	ST	USA	Kyon	WL	WL-2
Nr. of cases	356	100	125	224	805	400	568
Femur fracture	1.4%	1.0%	0.8%	2.7%	1.6%	2.5%	2.9%
Acetabulum fracture	0.6%	0.0%	0.0%	0.0%	0.2%	0.0%	
Infection	0.6%	2.0%	3.2%	0.4%	1.1%	1.2%	
Cup avulsion	0.3%	0.0%	0.8%	0.4%	0.4%	0.0%	
Luxation	4.5%	3.0%	4.0%	3.6%	4.0%	4.5%	
Stem loosening	0.3%	0.0%	0.0%	0.4%	0.2%	2.2%	
Cup loosening	2.0%	2.0%	0.8%	0.4%	1.3%		
Implant failure	0.6%	0.0%	0.0%	0.0%	0.2%	0.0%	
Death at surgery	0.0%	0.0%	0.0%	0.0%	0.0%	0.2%	
Failure of procedure	2.0%	2.0%	1.6%	0.4%	1.5%	4.0%	

Table 1 Columns in the table correspond to different groups: MC – multi-center study with Kyon THR (group 1); PM – consecutive cases with Kyon THR from P.M. Montavon (group 2); ST – cases with Kyon THR supervised by S. Tepic; USA – Kyon THR cases from 16 newly trained surgeons in the US; Kyon – average of different Kyon groups; WL – cemented (Biomedtrix) THR cases reported on by W. Liska; WL-2 – cemented (Biomedtrix) THR cases from the published report focusing on the femur fracture incidence.

When making comparisons, one should also consider the fact that all, with the exception of P.M. Montavon, surgeons using Kyon canine THR were at the beginning of the learning curve and that their average case load of one THR per month was much lower than that of W. Liska with an average case load of about one THR per week.

For the purpose of further analyses, only the complications of special interest were extracted from Table 1, and then only for the average of Kyon groups and WL. An obvious statistical deviation is the occurrence of four infections in the ST group – those were all from one clinic in Europe and were ultimately blamed on a faulty sterilizer. While there is no definitive information to support this claim, it may be noticed that veterinary clinics in Europe have not as of now reached the level of the leading ones (strictly referral clinics) in the US with respect to enforcement of strict antiseptic measures. Thus, for the comparison of the infection rates another datum was added to the Table 2 – infection rate (0.5%) of Kyon cases in the US alone (580 cases).

	Kyon	Kyon USA	WL	WL-2
Nr. of cases	805	580	400	568
Femur fracture	1.6%		2.5%	2.9%
Infection	1.1%	0.5%	1.2%	
Stem loosening	0.2%		2.2%	
Implant failure	0.2%		0.0%	
Death at surgery	0.0%		0.2%	
Failure of the procedure	1.5%		4.0%	

Table 2 A subset of data from Table 1 of particular relevance to clinical stem performance.

Comparisons

Femur fracture: Kyon incidence is lower than WL-2, but even with the 805 cases of Kyon and 568 of WL-2, the **chi-square** (χ^2) test does not reach the level of significance (in this case $p=0.14$; *for significance, we will use the usually required level of $p=0.05$*).

Infection: Kyon USA incidence is lower than WL, but, again the χ^2 statistic does not reach the required level of significance ($p=0.22$).

Stem loosening: Kyon incidence is lower and the difference is statistically significant ($p<0.005$). Again, in both cases, these are the cases **recognized** as being loose (by clinical signs) and revised for that purpose. We will return to address the issue of unrecognized loose stems.

Implant failure: There were two failures of Kyon stems, both in very large dogs and with long or x-long necks. Both occurred before the process of micro peening was added in the production process. No stem failed after that (about 1800 cases). There is no statistical significance to the difference between Kyon and WL ($p=0.75$).

Death at surgery: As with implant failure, the incidence is low and the difference is not significant ($p=0.75$).

Failure of the procedure (removed implants or euthanasia): Kyon procedure failure rate is lower than WL and the difference is significant ($p<0.01$).

Thus, Kyon incidence of main complications was lower than WL in all categories except in implant failure, where the incidence was very low and not statistically significant (χ^2 test was used in all comparisons). In Stem loosening and Procedure failure, the difference was statistically significant.

Unrecognized, long-term loosening of the femoral stem – Kyon vs. cemented

	Skurla, James	JP	AV	JP +AV
Nr. of cases	38	90	130	220
Loose stem	63%	1.1%	2.3% *	1.8%

* Vezzoni has reported on 2 stems getting loose secondarily to loosening of the cup and due to particle-mediated osteolysis; 1 additional stem failed to get any bony ongrowth, which has resulted in the failure of the screws (twice, twice revised).

Table 3 Unrecognized loose THR components: Skurla and James data is from a post mortem study of cemented canine THR's, which had no record of clinical problem at the time of death; JP is personal communication from Dr. Jeff Peck on the 90 cases of Kyon THR called in for another purpose, but then clinically and radiologically examined for THR – these cases were operated between 1999 and 2001, and examined from 2003 until 2004, i.e. about 4 years post op; AV is based on the personal communication from Dr. Aldo Vezzoni, who sees about 75% of his cases for regular **yearly** exams; last column combines JP and AV data on **unrecognized** loosening of Kyon THR.

Comparison

Unrecognized loosening of the Kyon femoral stem is relevantly and statistically significantly ($p < 0.005$) lower than the cemented canine stems from, which include two generations of Biomedtrix and a Richards cemented stem. It should also be noted that radiological examination of 38 post mortem canine femoral components of THR in Skurla and James showed 100% signs of loosening (whereby mechanical testing confirmed 63% of those as being actually loose). Kyon THR's were diagnosed as loose by radiological exam as well, but that has left no doubt that the stems were in fact loose (even though the owners of one dog were satisfied with their dog's performance and have refused revision surgery).