

Follow up of biocompatibility of new total hip joint endoprosthesis in a canine model

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ABSTRACT

Purpose: of this paper was the follow up of biologic compatibility and functional use of new type endoprosthesis in a canine model.

Design/methodology/approach: Prospective animal study with evaluation of new type ZRM of titanium alloy cementless total hip replacement (THR) in dogs in 2007. We used congruent ceramic head and polyethylene acetabular inlay. That is the gold standard in THR. The methods of X ray imaging evaluation after implantation and overgrowth evaluation were employed. We evaluated loading and use of the leg during walking and running. Total hip joint replacements were implanted in 6 dogs – German Shepards under general anesthesia. The follow up time was 6 months. We compared X ray findings after the operation and after 6 months, wound healing, use of THR during leg loading and biocompatibility of THR in femur and pelvis.

Findings: The femoral and acetabular components were anchored using a press-fit technique. We found good biocompatibility in 5 dogs with good loading during walking and running, one complication with femoral fracture and wound abscess. At six months, there was good bony ongrowth of the THR in 5 dogs and small overgrowth on the surface of THR in one dog, deemed as complication. In the same animal, explanation of the THR was performed, due to fracture.

Research limitations/implications: This study was not monitored. In the future, we would like to perform a randomized study design with a control group.

Practical implications: The new THR developed by authors can restore function in canine model of damaged hip joint. The press fit anchorage of the cup allowed firm adhesion of the cup surface to the pelvic bone and likewise, the femoral component demonstrated firm fixation in the proximal femur.

Originality/value: This paper is original by presenting the first results of new THR in canine model. The value of this paper is in laying groundwork for human study in the future.

Keywords: THR; Canine model; Biocompatibility

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1. Introduction

Total hip replacement (THR) is the treatment of choice for hip joint damaged by dysplasia, osteoarthritis, avascular necrosis and trauma. In 1997-2006 we developed a new total hip replacement (ZRM). In a previous study we developed a new design of femoral component with vertical and horizontal anchorage ribs, press fit technique of implantation of femoral and acetabular component. The cup of the acetabular component is of spherical-conical shape with special self-tapered thread on the surface. Upon the conclusion of the development of this new ZRM prototype we decided to test implantation and biocompatibility of this new implant in a canine model. Then we have made proposal of this 6-month canine study model with testing of technique of implantation, biocompatibility, X-ray evaluation of ongrowth and complications.

2. Material and methods

After a pilot study on model of canine pelvis and femur, where we compared sizes of proximal femoral cavity and acetabular cavity with cup and femoral stem sizes and we experimentally implanted this new type of ZMR total endoprosthesis of the hip joint under in vitro conditions.

All hips were implanted under general anesthesia in 6 German Shepards (5 male and 1 female). The selected implant was the new total hip replacement (ZRM) with special anchoring elements and new-shaped femoral and acetabular components.

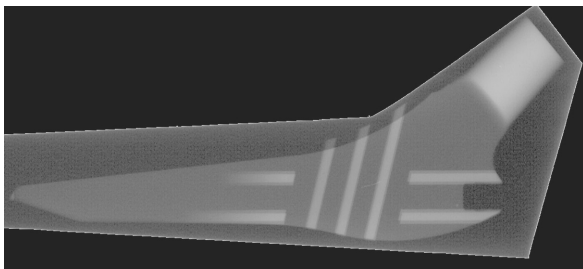


Fig. 1. X-ray picture of 1st version of canine model



Fig. 2. The 1st version of total hip replacement - canine model - potential - ZMR, after some modification was created model as in Fig. 3

In 2007 year from January to June we have implanted 6 THR type ZMR in our experiments in German Shepards.

These experimental animals were kept in standard conditions according international ISO standards. During the follow-up we evaluated surgical technique, press fit implantation, X ray imaging and biocompatibility immediately post-operatively and after six months after implantation. We have evaluated the condition of the animals after surgery, general anesthesia, complications, breeding, and wound healing, walking and running with implanted THR.

In the Fig. 1 is X-ray picture after cyclic test - N=1 mil. cycle by frequency $f=99$ Hz and by loading $F_n=0.5kN$, $F_h=2.5kN$, than N=5 mil. cycle by frequency $f=108Hz$, and by loading $F_n = 0.7kN$, $F_h=3.5kN$, Welding institute Bratislava, on 21.4.1999 (Fig. 2).



Fig. 3. New type of total hip replacement – version - canine model

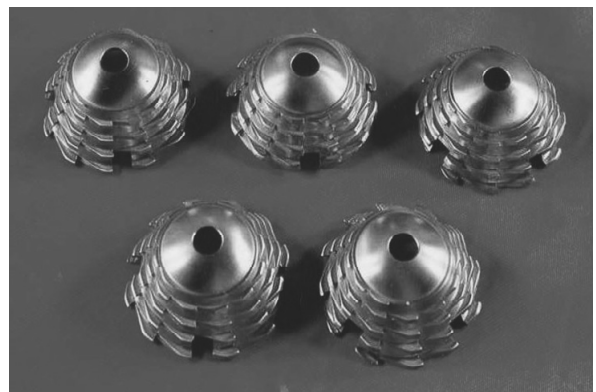


Fig. 4. Pilot -in vitro study of implantation of new ZMR total hip joint replacement

Table 1. Experimental dogs with THR implanted in left hip joint (sex, age, weight)

Dog No:	sex	Age in months	Weight
1	M	27	34
2	M	38	35
3	M	16	27
4	M	30	32
5	M	36	35
6	F	42	25

Pictures of pilot-in vitro study of implantation of new 1st canine model of the total hip joint replacement, canine models prepared for implantation and Pilot -in vitro study of implantation of new ZMR total hip joint replacement are shown in Figs. 4-6.



Fig. 5. Pilot-in vitro study of implantation of new 1st canine model of the total hip joint replacement



Fig. 6. The canine models prepared for implantation

3. Results

Our study was prospective with a small group of dogs but according to a sample size analysis, with sufficient statistical power.

Six German Sheppards (see Table 1) had surgically implanted total hip replacement of their left hip joint (Fig. 7). Implantations were performed without complications, only in one dog there was infraction of proximal femur followed by loosening of the femoral component. In addition, the operative wound in this animal was complicated by abscess formation. Condition of all implanted dogs after surgery was good. Their feeding, standing, walking and running was improving up to 7 days post-operatively (Fig. 8). All animals had antibiotics administered within first 3 days.

Immediately after the surgery, X-ray was taken (Fig. 9) and at the end of experiments and after 6 months (Fig. 10). We found good condition of the operated animals, early walking and loading of the operated hip joint and after 14 days of running during outside stay. In all 6 animals, incorporation of the new type of femoral component on X ray images was good as was overgrowth of the surface of the implanted cup.

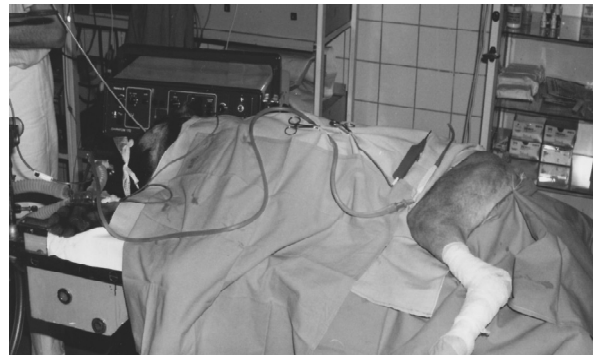


Fig. 7. The patient is very charily prepared for implantation



Fig. 8. The patient third day after implantation



Fig. 9. X-ray of left hip implanted THR in dog

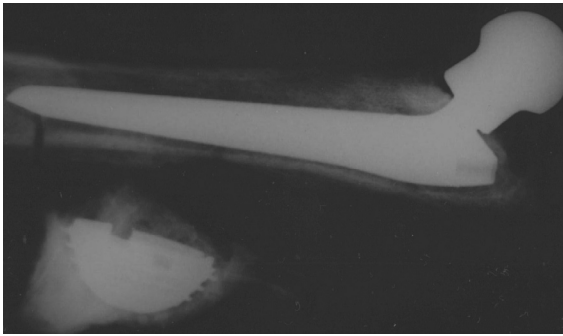


Fig. 10. X-ray picture in skeleton of dog after 6 month of implantation

In our study, we followed 3 complications in one dog. In this animal, we found infraction of proximal femur and development of large hematoma and abscess in the wound.

We had to perform explantation of the THR, abscess drainage. Healing followed with chronic inflammation and subsequent leg shortening. The possibility of THR re-implantation in this animal was thus excluded.

4. Conclusions

This study showed that a canine model of total hip replacement is good for preclinical testing before human trials. After this study, it was demonstrated that the new THR type ZMR) is an appropriate implant for surgical THR in humans and

has confirmed good biocompatibility, ongrowth of femoral stem and acetabular cup.

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