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MiniMAX anatomical stem

5 Years Clinical Outcomes

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MiniMAX anatomical stem

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ABSTRACT

The purpose of this clinical study is to assess prospectively, in a homogeneous and continual series of patients, the clinical and radiological outcomes of the anatomical shaped, cementless HA coated MiniMAX stem at mean of 5-year follow-up. The series includes 166 stems (159 patients) implanted between 2007 and 2010. According to the Kaplan-Meier method, 5-year stem survival rate is 100% considering aseptic loosening and 98.2% considering stem revision for any reason as endpoint. 100% of the patients declared an excellent or good satisfaction at the last follow-up. The Harris Hip Score significantly improved from preoperative evaluation: increasing from 40.7 to 97 points at the last evaluation. Radiographically all implants are stable, well fixed and osteointegrated without critical radiolucencies (>2mm).

INTRODUCTION

Aseptic loosening of the femoral component in the longterm follow-up of cemented hip arthroplasty is one of the main complications.

In order to avoid the disadvantage of bone cement and make implantation easier, cementless femoral components with biological fixation were introduced and used more and more frequently.

The philosophy of an anatomical stem was introduced into the market in 1980 with the aim of obtaining the best press-fit in the metaphyseal femur using a design which follows the natural geometry of the proximal femur^[1]. Noble et al. demonstrated that the femoral cavity has no uniform shape and described the great variability of femoral endosteal anatomy^[2].

An ideal cementless stem should transfer the loads to the bone on an area large enough to minimize local stress and stem-bone motion.

An anatomically shaped femoral component with a good proximal fit allows good maintenance of bone around the femoral component, good bone remodeling and bone ingrowth, good initial stability, no bone resorption or stress shielding, and therefore a load transmission closely resembling the physiological one is possible.

The MiniMAX (Medacta International SA, Castel San Pietro) is an anatomical cementless stem, Hydroxyapatite (HA) coated, developed by an international group of surgeons and introduced to the market in 2007, for use in total or partial hip arthroplasty for primary or revision surgery with the same indications and contraindications as for the traditional stem.

The length of the stem and the shape have been studied size by size to measure bone and to provide good mechanical stability.

The macrostructure methaphyseal area is designed according to the "fit and fill" principle to restore physiological loads and guarantees a good rotational stability.

The stem is coated by Mectagrip-HA on the proximal two thirds of the shaft to enhance primary stability and by HA distally to accelerate osteointegration.

Finally, the curved design of the tip is optimized.

The aim of the current clinical study is to evaluate the performance and the safety of MiniMAX stem.



Figure 1. MiniMAX anatomical stem

MATERIALS AND METHODS

Between October 2007 and December 2010, a consecutive series of 159 patients (with a total of 166 procedures) underwent a primary total hip arthroplasty using a cementless MiniMAX stem coupled with cementless acetabular shell Versafitcup CC (Medacta International SA, Castel San Pietro).

All operations were performed by two surgeons (P.G.V., R.R. and supervised by P.P.) in the same hospital (Ospedale Mazzolani Vandini, Argenta - Italy).

Patients' demographic data are shown in Table 1. It has to be noted that there is a higher percentage of right implants than left ones, because during the trial period it was decided to start with the right side.

Nr. of patients/Nr of hips	159/166
Age (years)	67 (28-86)
Gender (female/male)	115/44
Side (right/left)	119/47
BMI (kg/m^2)	27.2 (19.5 to 44.1)
Indications (%)	
Primary osteoarthritis	82
Secondary osteoarthritis	9
Rheumatoid arthritis	1
Femoral neck fracture	5
Femoral head necrosis	2
Failed arthroplasty	1

Table 1. Patient demographics

The majority of surgeries (92%) were performed using the AMIS technique (Anterior Minimally Invasive Surgery, Medacta Interational SA) with the aid of the AMIS Mobile Leg Positioner, 1% of the patients with minimally invasive technique, posterolateral approach, and the remaining 7% were performed with conventional approaches.

At the last evaluation 7 patients had died of causes unrelated to the prosthetic system and 5 patients underwent additional surgery: in 4 cases the stem was exchanged (2 infections, 2 traumatic bone fractures).

As to acetabular cup revisions, one cup was exchanged for ceramic liner fracture (traumatic case) and one cup and head were exchanged for local infection leaving the stem in situ.

In this study report we present the clinical and radiological outcomes at different time-points:

• at a mean of 2 ± 0.7 years, 124 patients (129 implants) attended an intermediate follow-up;

• at mean of 4.9 ± 0.9 years, we report the results for 140 patients (147 procedures), 7 patients were lost to follow-up.

The parameters taken into consideration, to record the clinical/functional outcome, are both subjective and physical such as the Harris Hip Score (HHS), the range of motion and patient satisfaction.

From a radiological point of view, particular attention has been paid to the osteointegration of the stem, incidence of greater trochanter fractures and the presence of radiolucencies.

The area around the stem has been divided into 7 different zones on the lateral view as described by Gruen et al.^[3, 4] (figure 2), and also an additional 7 zones (from 8 to 14) on the antero-posterior view because of the anatomic shape of the stem (figure 2).

Only radiolucencies bigger than 2 mm have been considered as critical as this is considered by many authors to be a sign of probable loosening in the future^[4, 5].

Moreover the heterotopic bone formation according to Brooker classification has been evaluated^[6].

Most authors agree that the grade of heterotopic ossification and excessive bone formation negatively affects hip function after total hip arthroplasty.

In particular Brooker class I, II or III don't alter significantly the result obtained with the total hip replacement.



Figure 2. Areas with possible radiolucency around the stem

The survival rate of the stem has been computed according to Kaplan-Meier method considering stem replacements for all reasons and for aseptic loosening.

The collected data allow evaluation of the patient's ability and capacity to use the prosthetic joint in normal daily activities.

STATISTICAL ANALYSIS

Descriptive analysis was performed with the use of univariate statistics for the continuous variables and frequency distribution for the categorical variables. Results are reported as means and standard deviations.

The survival rate was calculated on the basis of the Kaplan-Meier method^[7].

In order to evaluate the difference between the preoperative and postoperative group, paired Student's t-tests were performed.

The results of these comparisons are reported as p-value (<0.05).

RESULTS

Only 2 patients had intraoperative trochanter fracture, both treated with cerclage.

The immediate post-operative local and systemic complications reported are: hematoma (2), femoral nerve palsy (1), superficial sepsis (1), urological (2) central nervous system (1), all solved without sequel.

Clinical results

The analysis of clinical data revealed a significant improvement from pre-operative evaluation.

The mean HHS was initially 40.7 (\pm 13.5) points that significantly increased at 95.6 \pm 7.7 points and at 97.4 \pm 5.4 points (p<0.001) at a mean of 2 and 5 years respectively. At the last follow-up, the 93.9% of patients (138 procedures) reported an excellent score (>90 points), the remaining 6.1% (range 62 \pm 90 points, 9 procedures) is represented by patients with concomitant articular or other problems that can affect clinical evaluation and results.

100 % of patients declared an excellent (76%) or good (24%) satisfaction.

Radiological results

One patient presented a possible stem loosening at 2-year evaluation, resolved at 6 year follow-up.

All remaining cases are stable, well fixed and osteointegrated, as shown, for example, in figure 3, representing a 75-year-old woman affected by coxarthrosis.

Figure 3A shows the preoperative status and 3B shows radiological follow-up at 2 years.

At the last follow-up, no patients showed radiolucencies larger than 2 mm on either lateral or anteroposterior view. 5 patients underwent revision: 1 patient was revised for suspected infection 1 month after the first surgery, following a hematoma.

The stem was revised with another MiniMAX stem but has been excluded from further follow-up.

A second case for definitive infection occurred 1 year post-surgery; the stem was substituted by a cemented spacer for two months, and then by a revision stem.

Two cases of revision were due to a trauma which caused a femoral periprosthetic fracture and one to a liner breakage.

The survival rate of the stem at 5 years after surgery is 100% considering aseptic loosening and 97.5% considering stem revisions as endpoint (figure 4)



Figure 3. X-ray images of a 75 years old woman, A) preoperative, B) postoperative 2-year follow-up

DISCUSSION

This report demonstrates the success obtained with the cementless, anatomical, femoral stem MiniMAX. All intraoperative complications reported were solved without sequel, showing a safe and reliable procedure, performed in 92% of cases through AMIS (Anterior Minimally Invasive Surgery).



loosening as endpoint

The curved design of the stem on both planes, sagittal and frontal, facilitates the insertion through a small incision. This approach follows a path both inter-muscular and inter-nervous and therefore reduces the risk of damaged periarticular structures^[8, 9].

In addition to a small skin incision, we reported many other advantages, such as a minimized need for soft-tissue dissection and decreased surgical exposure necessary to obtain accurate and reproducible acetabular and femoral preparation, decreased blood loss, decreased need for blood transfusion, decreased pain, shorter hospital stays, and faster rehabilitation^[10, 11, 12].

The design of this prosthesis has been a determinant in the results obtained.

No greater trochanteric fractures were reported in our series: the curved shape of the stem, both in the sagittal and in the frontal planes, its reduced and short thin tip with slight curvature helped to easily introduce the stem, especially for minimally invasive anterior approach but it has also proved to be versatile in the few cases performed by conventional approach.

Moreover minimal risk of impingement and fracture has been shown because of the lateral flare design. The clinical results of this study are promising, with the majority of patients reporting relief from pain and rapid restoration of the activities of daily living.

No patient reported thigh pain, a risk in cementless stems that is reported to range from 10% to 20%^[13].

From a radiographic point of view excellent fixation and stability were achieved with a stem that uses a methaphyseal fixation and proximal Mectagrip-HA coating.

No cases of severe heterotopic bone formation were reported and no patients showed critical radiolucencies bigger than 2 mm.

CONCLUSION

At 5 years 100% of patients declare an excellent or good rate of satisfaction. Clinically, at last follow-up, the mean HHS was 97.4 ± 5.4 points with a significant increment in comparison to preoperative data (40.7±13.5) (p<0.001). According to the data collected to date, the 5-year survival rate for MiniMAX is 97.5% considering stem replacements for any reason, and 100% considering revision for aseptic loosening as endpoints.

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