Original article

Medial neck femoral fractures: algorithm of treatment and the use of F.G.L.™ memory shape stem

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Abstract. *Background and aim of the work:* We treat undisplaced or minimally displaced medial neck femoral fractures with screws in both young and elderly patients with good activity of daily living, without severe comorbidity. Total hip replacement is preferred in middle-advanced age, with good level of functional activity. Bipolar hemiarthroplasty is performed on patients who may require early mobilization to avoid deterioration due to existing comorbidities. Bipolar hemiarthroplasty with memory shape stem (F.G.L.™) is our preferred mode of surgery for high risk patients (ASA classification). In fact, higher perioperative mortality from cardiopulmonary complications has been attributed to the use of cement during arthroplasty. This stem in its metaphyseal region has 10 tabs, made of a Nitinol™ alloy, that facilitate the restoration of the implant to its original enlarged shape at physiological temperature. This enables a strong fit in the metaphyseal region. *Methods:* We report the clinical and radiological results of 24 patients (mean follow-up: 14 months) who underwent surgical procedure of bipolar hemiarthroplasty with F.G.L.™ stem in our department between March 2008 and December 2009. *Results:* No perioperative complications were observed and the results were comparable to those of patients who underwent standard cemented bipolar hemiarthroplasty. *Conclusions:* A significant advantage to the use of F.G.L.™ stem is that it allows immediate primary stability without using cement. A limiting consideration is the higher cost associated with the implant & procedure in comparison with standard cemented bipolar hemiarthroplasty. This implant may thus be most suitable for patients with pre-existing cardio-pulmonary complications for whom the use of cement is a major risk factor. (www.actabiomedica.it)

Key words: Hemiarthroplasty; F.G.L.; Memory shape; Stem; Proximal femoral fractures.

Introduction

Femoral neck fractures remain a vexing clinical problem for orthopaedic surgeons especially due to the high rate of postoperative complications (1-12). The management of this type of trauma requires a careful preoperative planning to determine the most appropriate type of treatment. Surgical options are internal fixation of the femoral neck, hemiarthroplasty and total hip arthroplasty (1, 3, 4, 11, 13-20). The treatment algorithm depends on the age and level of activity of the patient, the severity of fracture displacement, the bone stock and the presence of medical comorbidities (1, 3, 13, 15, 16, 18-20). Placement of multiple screws across the femoral neck is the treatment of choice for undisplaced or minimally displaced fractures in healthy and active patients without severe comorbidity (1, 3, 13, 16, 18-20). Inactive and chronically ill patients may be also treated by internal fixation in order to reduce pain and to avoid the prosthetic replacement that could be useless or potentially fatal, bearing in mind their critical clinical conditions. Total hip replacement provides the best results of any form of prosthetic replacement for displaced femoral neck fractures and this choice should be reserved for high-demand patients (1, 3, 13, 15, 16, 18-21). At last

in older and less active patients, but those who are still able to walk, hemiarthroplasty seems to be the best management because it allows early mobilization, avoiding the possible worsening of pre – existing comorbidities (1, 3, 13, 15, 16, 18-20). In case of hemiarthroplasty the choice for primary fixation of the stem is still widely varied between the use of cemented or uncemented devices (22-35).

Uncemented fixation is preferred in patients with adequate bone stock (32, 36-42). Initial mechanical fixation is obtained by a press-fit between the porous surface of the stem and the cortical bone. Afterwards a biological fixation is achieved through specific features of the stem such as texture created using plasma-spray, hydroxyapatite and/or porous coating methods. However the requirement of a tight metaphyseal fit increases the risk for femoral fractures during implantation.

Many authors advocate the use of cemented femoral stems in older patients with osteoporosis (23, 28, 31). In fact in this technique an optimal stem fixation is obtained by avoiding the risk of intraoperative femoral fractures. Moreover early rehabilitation is possible, and the cost of the treatment is reduced. On the other hand cemented hemiarthroplasties need longer surgical time (22, 23, 26, 30, 33) and are characterized by greater perioperative mortality (27, 29). The use of bipolar hemiarthroplasty with memory shape stem F.G.L.™ (Form Gedächtnis Legierung) (43) is our choice when the high preoperative risk (ASA classification) makes the use of cement critical in patients with osteoporosis who need early rehabilitation in order to avoid the worsening of their critical clinical conditions.

In this study we report clinical and radiological results of 24 patients treated by bipolar hemiarthroplasty with F.G.L.™ stem in order to assess the effectiveness, the security and the reproducibility of this technique.

Materials and methods

We reviewed twenty-four patients [16 male, 8 female; age: mean 82 years (range: 65-92 years)] with displaced femoral neck fracture treated with bipolar hemiarthroplasty with F.G.L. stem in our department from March 2008 to December 2009. Anteroposterior (AP) and lateral radiographs of the pelvis were obtained in the operating theatre and during the follow up for analysis. "Harris Hip Score" questionnaire was used to evaluate the outcomes and quality of life of the patients during the 14 months follow up. Of the ten factors in the questionnaire, eight were rated by the patient for pain, distance walked, activities, public transportation, support, limp, stairs and sitting. Absence of deformity and range of motion were assessed by the physician based on physical examination of the patient. Scores were assigned a range between 0 to and 100. A result was considered excellent if the score was greater than 90, good if it was between 80 and 89, fair between 70 and 79 and poor between 60 and 69. For results lower than 60 the hemiarthroplasty procedure was deemed failed (44-46).

s Features of FGL Memory Shape Stem

The F.G.L.™ memory shape stem is made of a Ti-Al alloy with a porous-coated surface in the proximal third. (Fig.1) This stem in its metaphyseal region has 10 tabs (5 for each side) made of a Nitinol™ alloy (Ni-Ti). This is a shape memory alloy and exists in a martensitic state below a first temperature and an austenitic state above a second temperature. (Fig.2) As the different states (martensitic and austenitic) have different geometries, a temperature shift can lead to a change in shape of an object made of shape memory material. For this reasons the Nitinol™ tabs serve as

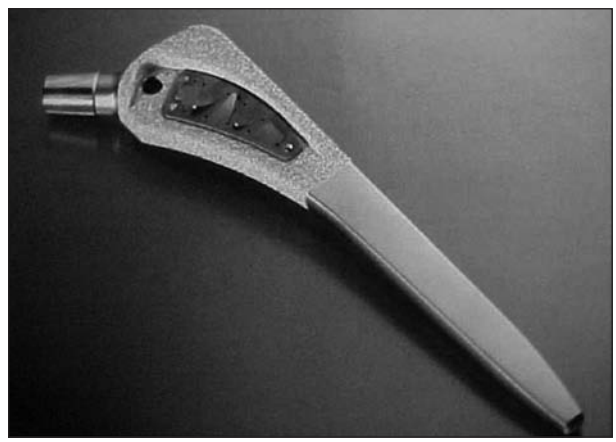

Figure 1. The F.G.L.™ memory shape stem.

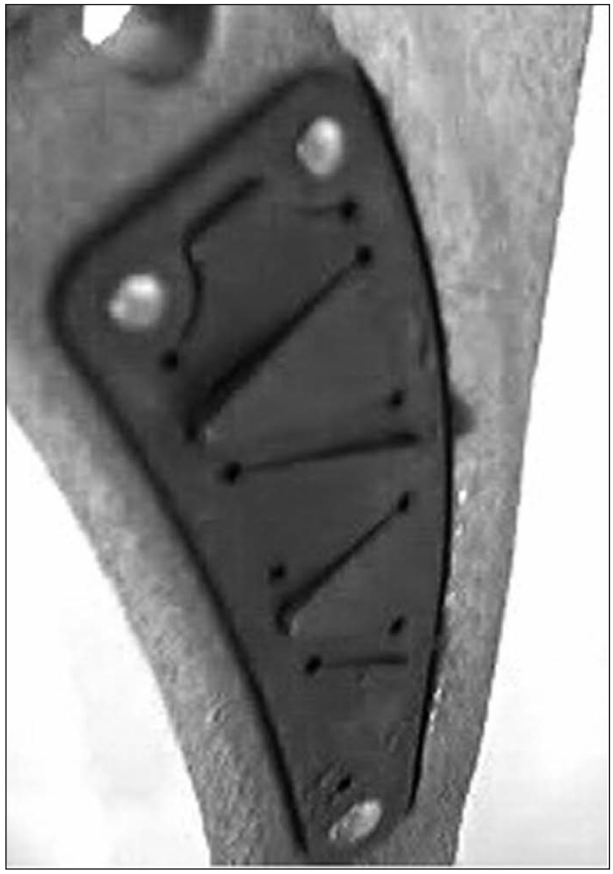

Figure 2. Tabs made of a Nitinol™ alloy (Ni-Ti).

an expandable bone-locking portion having a contracted state (martensitic state) and an expanded state (austenitic state) and expansion of the shape-memory tabs produces a locking force. In fact when F.G.L. stem is maintained into the refrigerator at 4° - 7° the Nitinol™ tabs are in the contracted (martensitic) state. Immediately prior to implantation during surgery, the stem is taken out of the refrigerator and inserted into the femoral diaphysis. The temperature increase causes a change from the "restricted" configuration (martensitic) to the expanded (austenitic) state of the Nitinol™ portions of the stem. Therefore at corporeal temperature, the Nitinol™ tabs change to an enlarged shape compressing the metaphyseal cancellous femoral region. (Fig.3)

This compression gives the stem strong and immediate primary mechanical fixation. (Fig.4)

In fact the laboratory results showed that the pressure of the shape memory alloy of the stem against

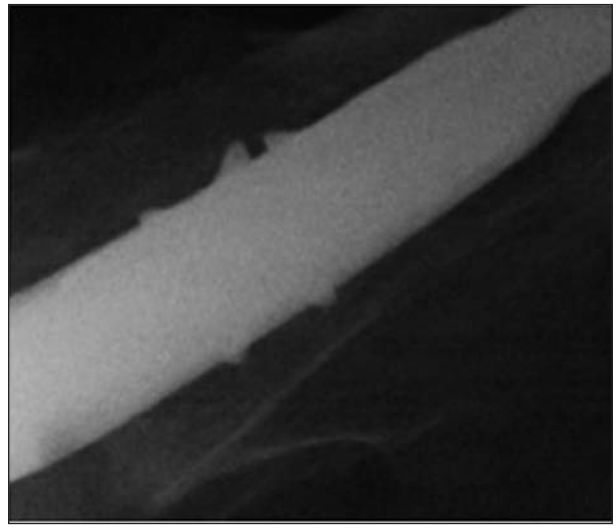

Figure 3. The Nitinol™ tabs have changed to an enlarged shape compressing the metaphyseal cancellous femoral region.

Figure 4. Strong and immediate primary mechanical fixation.

the cancellous bone is 80 N. Moreover the stability of the stem, evaluated as extraction force, increased from 6 N·m to 9.5 N·m with the use of this type of implants, while the rotational stability increased from 10.2 N·m· to 11 N·m (43).

Results

Our results are largely concurrent with the literature where patients underwent standard cemented or uncemented bipolar hemiarthroplasty (26, 47, 48).

No perioperative complications were observed. None of the prostheses failed and thus no revision surgery was required. During the 14 months of follow-up neither aseptic dislocation nor infection was observed. Postoperative radiograph analysis of the pelvis revealed that the stems were not dislodged and remained correctly *in situ* in all patients. (Fig.5) The evaluation of outcomes and quality of life of the patients made with the "Harris Hip Score" during the follow up are reported as follows: of the 24 patients evaluated, an excellent score was obtained from 3, good score from 10 and a fair score from 7. Four patients demonstrated poor results. These data are consistent with those reported for patients who underwent standard cemented or uncemented bipolar hemiarthroplasty (26, 47, 48). Importantly, the surgical times were significantly reduced (60 minutes for the F.G.L implant). In fact in our experience when cement is used surgical time is about 20 minutes longer.

Figure 5. Postoperative Antero-Posterior view radiograph of F.G.L.™ memory shape stem.

Discussion

The choice for the use of cement during hemiarthroplasty is widely in contradiction pertaining to the indications of the cemented and the uncemented device (22-35, 39). Cementless "press fit" fixation is usually reserved for patients with adequate bone stock (32, 36-42). The main disadvantage of this technique is the possibility that a femoral fracture may occur during implantation. The use of cement is preferred for patients with osteoporotic bone as it gives optimal primary stability, without press-fit thus preventing the possibility of intraoperative fractures. In this way early mobilization is permitted avoiding the possibility of worsening critical clinical conditions of patients. However, the use of cemented devices has its limitations; long surgical duration and higher perioperative mortality from cardiopulmonary complications due to the Bone Cement Implantation Syndrome (BCIS) (22, 23, 26, 27, 29, 30, 33, 49-53). BCIS is characterized by a number of clinical features that includes hypoxia, hypotension, cardiac arrhythmias, increased pulmonary vascular resistance and cardiovascular collapse requiring CPR that occurs during the peri-cementation period. The cause of BCIS has primarily been attributed to the formation of emboli due to high intramedullary pressures during cementation and prosthesis insertion (49). Some of the main risk fac-

tors in the occurrence of BCIS are poor pre-existing physical reserve, reduced cardiopulmonary function, pre-existing pulmonary hypertension, osteoporosis and bone metastases (49). In these patients the use of cemented bipolar hemiarthroplasty for the treatment of femoral neck fractures is contra-indicated. Our data enables us to speculate that the use of F.G.L.™ memory shape stem may facilitate optimal management for these patients. Our data demonstrates that this type of stem guarantees strong initial fixation avoiding both the risk linked to the use of cement and the risk of an intraoperative fracture associated with the use of press-fit systems. In fact in our experience we had no perioperative complication. Moreover during the 14 months follow up outcomes and quality of life of the patients treated with F.G.L.™ memory shape stem overlapped those of patients that underwent standard cemented bipolar hemiarthroplasty obtained from the scientific literature (26, 47, 48). While this approach has its advantages in that it has limited peri-operative complication and allows for improved quality of life, its primary limitation is the higher cost associated with the procedure in comparison with standard cemented bipolar hemiarthroplasty. Thus we recommend that the F.G.L.™ stem should be limited to those patients for whom surgical duration must be contained for severe comorbidity, or for patients susceptible to cardio-pulmonary complications possible with the use of cement. Although it must be noted at this time that techniques for the removal of the implant are poorly defined. In fact, the strong stability that characterizes this stem makes this operation difficult because the tabs expanding penetrate into the subcotical bone. However, considering the clinical conditions and the low life expectancy of the patients who these devices are being implanted, the occurrence of removing the implant is not common.

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