Osteosynthetic improvement of osteoporotic bone: prevention surgery

Sandro Giannini[1]
Deianira Luciani[1]
Eugenio Chiarello[1]
Matteo Cadossi[1]
Giuseppe Tedesco[1]
Martha Hoque[1]
Saverio Gnudi[2]

[1] II Orthopaedics and Trauma Clinic - Rizzoli Orthopaedic Institute - University of Bologna, Bologna, Italy
[2] Departmental Unit of General Medicine - Rizzoli Orthopaedic Institute - University of Bologna, Bologna, Italy

Address for correspondence:
Eugenio Chiarello, M.D.
II Orthopaedics and Trauma Clinic.
Rizzoli Orthopaedic Institute,
University of Bologna
Via G.C. Pupilli 1 - 40136 Bologna, Italy
Ph. +39 051 6366669 - Fax +39 051 334342
E-mail: eugenio.chiarello@yahoo.it

Summary

A prior osteoporotic femoral neck fracture (FNF) doubles the risk of a second, contralateral hip fracture. Pharmacological prevention of osteoporotic fractures is cost-effective but medication compliance and persistence rates are suboptimal. The aim of our study was to evaluate the safety and effectiveness of a device developed for the surgical prevention of an additional contralateral FNF in elderly osteoporotic patients. Only patients with a T score ≤ -2.5 were enrolled and randomized either to receive (Group A) or not receive (Group B) surgical prevention. Sixty-seven patients were enrolled. The mean follow-up was 16 months (range 1 to 22). To date, no contralateral FNF has been reported in either group. In Group A, no device-related complications were recorded. Twelve patients reported one or more falls and in four cases a non-femoral fragility fracture occurred.
The main problem with pharmacological prevention is therapy adherence and the extensive period needed for only a slight improvement in bone strength.
Surgical prevention is a potential solution for avoiding the occurrence of a second contralateral FNF. Nevertheless, a longer follow-up and a larger cohort of patients is necessary in order to verify the true effectiveness of the surgical prevention in elderly osteoporotic patients.

KEY WORDS: femoral neck fractures; osteoporosis; surgical prevention.

Introduction

Bone fragility leads to an increased susceptibility to fractures occurring after minor trauma, and is the clinical end point of this disease (1).

Among the fractures occurring in an osteoporotic patient, those affecting the hip are the most serious. As a matter of fact, hip fractures (HF) are associated with a 20% increase in mortality in the year following fracture (2) and up to 40% of patients do not survive beyond 1 year after fracture (3,4).
Furthermore, a prior femoral fragility fracture doubles the risk for a second, contralateral HF (5). In the literature, there are only a few studies which assess the risk of a second HF occurring in the contralateral hip and the incidence ranges from 7 to 12% (6-15). The risk of a second fragility fracture occurring, and in particular, a HF, appears to be under-recognized and undertreated (16). Thus, strategies for secondary HF prevention should be adopted.
Secondary HF prevention can be accomplished in three different ways: pharmacological prevention, non-pharmacological prevention and surgical prevention.
Pharmacological prevention of osteoporotic fractures is cost-effective in inhibiting the occurrence of future fractures (17-20). Unfortunately, compliance and persistence rates to medications are suboptimal (21).
Non pharmacological strategies include nutrition (22), modification of environmental hazards, and the use of hip protectors. The latter act to either reinforce the strength of the bone and muscles or to prevent falls. A recent review by Gillespie WJ et al. (23) which examined whether external hip protectors reduce the incidence of HF in older people following a fall did not demonstrate a clear effectiveness; although the protectors may reduce the rate of HF if applied to frail older people in nursing care, poor compliance has also been documented.
Surgical prevention is a new preventative strategy, but no clinical studies have been documented as of yet. Finite analysis and pre clinical studies (24-26) have demonstrated an effectiveness in preventing a second contralateral HF.
The aim of our study is to evaluate the safety and effectiveness of a new device for the surgical prevention of a new fracture in the contralateral hip in elderly osteoporotic patients with a femoral neck fracture (FNF). This device is a titanium tubular screw with a coated hydroxyapatite thread. We named it the Prevention Nail System (PNS).

Materials and Methods

This prospective randomized clinical trial was approved by the local ethical review board and we obtained special permission from the Italian Ministry of Health to use this new medical device in clinical practice.
All patients were admitted to our ward with a radiographic diagnosis of FNF.
The inclusion criteria were: low-energy trauma or fall from a standing height, 65 years of age or older, a dual-energy X-ray absorptiometry (DXA) diagnosis of osteoporosis (T-score ≤ 2.5 SD), ability to understand the aim of our study and willingness to sign the informed consent form.
The exclusion criteria were: pathological fractures, trochanteric fractures, non-cooperative patients and a prior FNF.
Before surgery, a DXA scan (Norland XR-36. CooperSurgical, Inc. 95 Corporate Drive Trumbull, CT 06611 USA) on the non-injured hip was performed and only patients with a T score ≤ -2.5 were enrolled.

The injured hip received the standard of care (SOC), which consisted of either bipolar hemiarthroplasty, total hip replacement or internal fixation with cannulated hip screws. The non-injured hip was randomized either to receive (Group A) or not receive (Group B) surgical reinforcement with the PNS.
The American Society of Anaesthesiologists (ASA) score, surgical time and length of hospital stay were recorded (Table 1).
Additional DXA scans were scheduled at 3 and 12 months after surgery. An X-ray computed tomography (CT) scan and X-rays of the pelvis in 2 planes were also taken at these time-points. Furthermore, at each follow-up (FU), walking ability (Table 2) and the Harris Hip Score (HHS) of the treated hip were evaluated. Patients were investigated if further falls occurred. The radiographic analyses were all performed at our Institute and evaluated by a radiologist.

Surgical technique

The patient is placed supine on a fracture table with the unaffected leg flexed at the hip and knee, and then abducted and slightly internally rotated.
A longitudinal incision of 2-3 cm is made below the greater trochanter.
Using the image intensifier guide wire is positioned with a shaft neck angle of 130°-140°, while protecting the soft tissue.
The guide wire is drilled down towards the apex of the femoral head until the subchondral bone is reached. It is important to ensure that the pin is parallel to and in the centre of the femoral neck. The position should be checked with the image intensifier. When the guide wire is adequately positioned in the femoral head, the percutaneous direct measuring gauge should be used. By subtracting 10 mm from the established length, the appropriate PNS length and reaming distance can be determined; a barrel is introduced through the guide wire, towards the cortex. Reaming is then performed in order to obtain the established length. The reamer is removed, leaving the guide wire. The T handle screwdriver is attached to the PNS.
The PNS is screwed in until it is completely inserted. The T handle screwdriver and the guide wire are removed. The compression screw which covers the internal thread of the screw is then removed. One resorbable 0 stitch is used for the fascia, 2 resorbable 2-0 stitches are used for the subcutaneous tissue and three metallic staples are used for the skin.

Statistical analysis

All continuous data were expressed in terms of the mean and the standard deviation of the mean. Grouping variables were expressed in frequency and percentage. One Way ANOVA was performed to test differences between means of different groups if the Levene test for homogeneity of variances was not significant ($p<0.05$); in all other cases, the Mann Whitney test was used. Pearson's Chi square test, calculated with the Montecarlo Method for small samples was performed to investigate the relationships between grouping variables. The Fisher exact test was performed to investigate the relationships between dichotomic variables. Kendall Tau correlation was used to assess the influence of ASA over walking ability. Spearman rank correlation was performed to assess the influence of continuous variables over walking ability. For all tests, $p<0.05$ was considered significant.
Statistical Analysis was carried out by means of the Statistical Package for the Social Sciences (SPSS) software version 15.0 (SPSS Inc., Chicago, USA).

Results

Since September 2008, we have enrolled 67 patients in our trial (49 females and 18 males, mean age of 84, range 68 to 97). Fifteen patients with an osteopenic DXA T-score were excluded. Group A consisted of 34 patients: 15 have reached the 12 months FU, 15 have reached the three months FU, and 4 the one month FU. Five patients did not return for FU but they were contacted by phone.
The mean DXA T-score was -3.21 (SD±0.68);
Group B consisted of 33 patients: 17 have reached the 12 months FU, 11 have reached the three months FU, and five the one month FU. Four patients in Group B died and were therefore excluded from our analysis;
The mean T-score was -3.47 (SD±0.72);
The surgical time in Group A was longer by an average of 20 minutes (SD±5 min).
To date, the mean FU is 16 months (range 1 to 22); No contralateral FNF occurred in either group. In Group A, no device-related complications were recorded.
Twelve patients reported one or more falls and in four cases a new non-femoral fragility fracture occurred: two in Group A (one wrist and one vertebral) and two in Group B (2 vertebral fractures). The ASA scores recorded ranged from 1 to 4 and the median was 3 in both groups.
CT scans of the reinforced hips performed at 3 and 12 months FU were analyzed in axial, coronal, and sagittal planes and showed no radiolucencies or PNS loosening. X-rays were analyzed to check for atrophy or hypertrophy around the hydroxyapatite-coated thread. No differences were found at the various FU time-points (Figure 1).

Table 1 - Characteristics of the patients randomized in the two groups. In group A, patients received surgical reinforcement; In group B, patients did not receive surgical reinforcement.

	Group A (PNS)	Group B (control)	p
Age at surgery[1]	83.6 (97- 68) years old	83.2 (93-73) years old	ns p = 0.8
Sex	10 M; 24 F	8 M; 25 F	
DXA T-Score[1]	-3.21 (SD±0.68)	-3.47 (SD±0.72)	ns p = 0.62
Hospital Stay[1]	11.6 ± 3.4 days	12.4 ± 4.7 days	ns p = 0.44
HHS	76±13.8	71±12.5	ns p = 0.23
VAS[1]	0.29	0.53	ns p = 0.66
ASA score	3 (Median)	3 (Median)	
Falls[2]	8	4	ns p = 0.87
Second Hip Fracture	0	0	
Second Non Hip Fracture	1 wrist, 1 vertebral	2 vertebrals	

1 = One Way Anova; 2 = Pearson's chi-square test

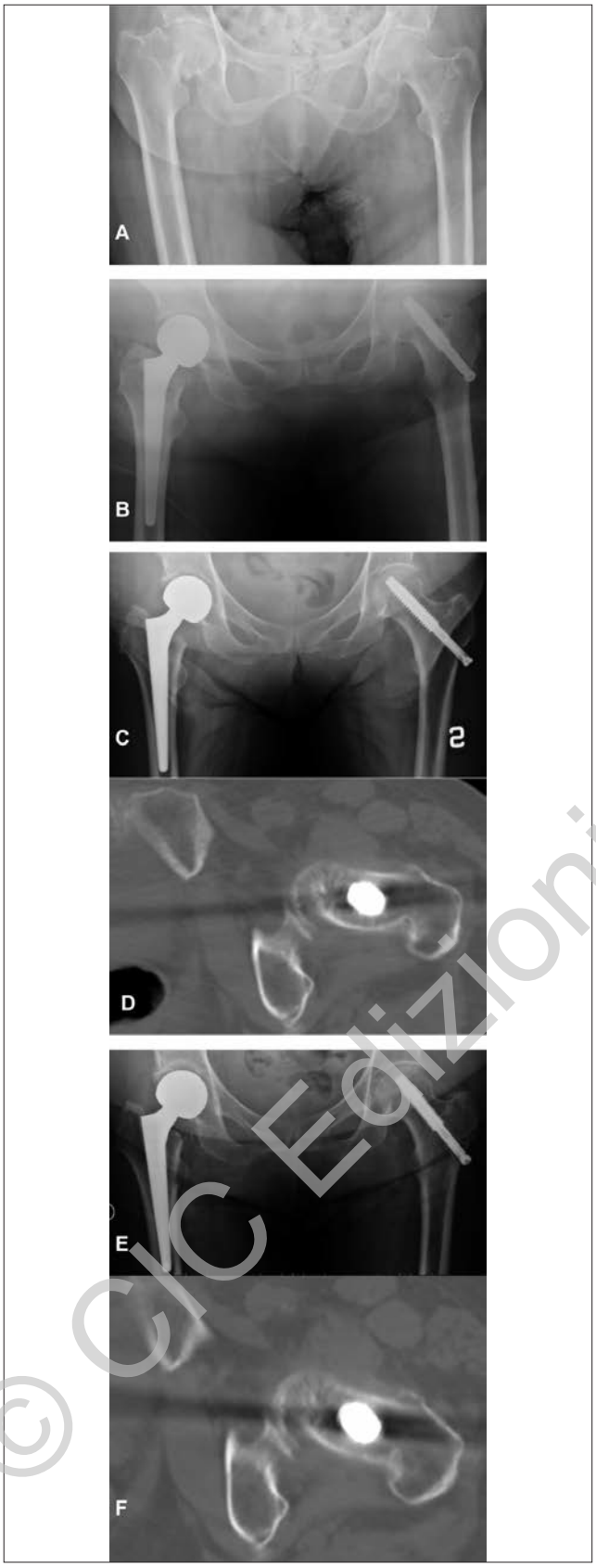

Figure 1 - **A:** X rays of an 83 year old female with a right FNF; **B:** Post operative X rays; in the injured hip, a hemiarthroplasty was performed while a PNS was used in the contralateral hip. **C:** 3 months FU X-rays. **D:** 3 months CT scan of the reinforced hip shows good osteointegration. **E:** 12 months FU X-rays. **F:** The CT scan performed at 12 months confirms the osteointegration.

Table 2 - Walking ability at the latest FU expressed as a percentage of the total number of patients in each group.

WALKING ABILITY	Group A % (PNS)	Group B % (control)
Without aids	25.7	21.1
One cane	14.3	15.8
One crutch	5.7	26.3
Two crutches	5.7	0
Walking frame	14.3	21.1
Walking with a Caregiver	20	15.8
Bed only	14.3	0

Clinically, in Group A, only one patient reported slight pain in the reinforced hip, with a score of 10mm on the Visual Analogue Scale (VAS) (range 0 to 100 mm). Comparing the HHS. In patients with the reinforced hips (Group A) or the intact hips (Group B), no statistical difference (p = 0.08) was found: (mean HHS: Group A = 76±13.8; Group B = 71±12.5). The average hospital stay was 11.6 days ± 3.4 in Group A and 12.4 ± 4.7 in Group B with no statistically significant difference (p = 0.1).

Discussion

Reducing a future fracture in frail elderly patients requires a sequence of interventions, including the identification of risk factors for falls, bone density measurements, and the initiation of pharmacological therapies for osteoporosis. Unfortunately, pharmacological and non pharmacological strategies are very difficult to achieve. The main problem with pharmacological prevention is therapy adherence (27) and the long period needed for only a slight improvement in bone strength.

Surgical prevention is a possible solution to prevent a second contralateral hip fracture in elderly osteoporotic patients.

In the present study, which is still ongoing, we analyzed a device developed for the secondary surgical prevention of hip fractures. The PNS was well tolerated by patients; only one patient in Group A had a VAS of 10/100 and was affected by osteoarthritis, which was radiographically evident on the X- rays performed on the reinforced hip.

The PNS is a safe device exhibiting good osteointegration. Osteointegration was radiographically confirmed, even at 3 months postoperatively. The surgical technique is simple and fast (only an additional 20 minutes of surgical time was needed for the procedure). The rehabilitation protocol was the same in the two groups, with total weight bearing on the non-fractured hip from the second day after surgery.

No further hospitalization was necessary for the PNS group.

No contralateral FNFs occurred in either group. Nevertheless, only 31% of patients returned to their pre-injury walking ability. 69% percent of patients lost their self-sufficiency and were impaired in one or more of their daily activities. 10% of these patients completely lost their walking ability.

We believe that a longer FU and a larger cohort of patients is necessary in order to verify the real effectiveness of the PNS in preventing FNFs in elderly osteoporotic patients.

In the future we aim to identify the patient population which could truly benefit from the surgical prevention of FNF, in order to focus on this specific, high risk group of patients. Considering the high mortality and morbidity rate of FNF in elderly patients, we may surgically prevent hip fractures even before the first fracture has occurred.

References

1. J.-Y. Reginster; N. Sarlet; M.-P. Lecart. Fractures in osteoporosis. the challenge for the new millennium. Osteoporos Int 2005; 16: S1-S3, DOI 10.1007/s00198-004-1752-9.
2. Siris ES, Miller PD, Barrett-Connor E, et al. Identification and fracture outcomes of undiagnosed low bone mineral density in postmenopausal women: results from the National Osteoporosis Risk Assessment. JAMA 2001;286:2815-22.
3. Cobey JC, Cobey JH, Conant L, Weil UH, Greenwald WF, Southwick WO. Indicators of recovery from fractures of the hip. Clin Orthop Relat Res 1976:258-62.
4. Ira P, Scott DL, O'Neill TW, Pritchard C,Woolf AD, Davis MJ. Quality of life, morbidity and mortality after low trauma hip fracture in men. Ann Rheum Dis 2005.
5. Ryg J, Rejnmark L, Overgaard S, Brixen K, Vestergaard P. Hip fracture patients at risk of second hip fracture: a nationwide population-based cohort study of 169,145 cases during 1977-2001. J Bone Miner Res 2009; 24:1299-1307.
6. Rodaro E, Pasqualini M, Iona LG, Di Benedetto P. Functional recovery following a second hip fracture. Eura Medicophys. 2004;40(3):179-83.
7. Boston DA. Bilateral fractures of the femoral neck. Injury 1982; 14:207-210.
8. Dretakis KE, Dretakis EK, Papakitsou EF, Psarakis S, Steriopoulos K. Possible predisposing factors for the second hip fracture. Calcif Tissue Int 1998; 62:366-369.
9. Dinah AF. Sequential hip fractures in elderly patients. Injury 2002;33:393-394.
10. Shabat S, Gepstein R, Mann G, Kish B, Fredman B, Nyska M. The second hip fracture--an analysis of 84 elderly patients. J Orthop Trauma 2003;17:613-617.
11. Melton LJ, 3rd, Ilstrup DM, Beckenbaugh RD, Riggs BL. Hip fracture recurrence. A population-based study. Clin Orthop Relat Res 1982;131-138.
12. Berry SD, Samelson EJ, Hannan MT, McLean RR, Lu M, Cupples LA, Shaffer ML, Beiser AL, Kelly-Hayes M, Kiel DP. Second hip fracture in older men and women: the Framingham Study. Archives of Internal Medicine 2007;167:1971-1976.
13. Ryg J, Rejnmark L, Overgaard S, Brixen K, Vestergaard P. Hip fracture patients at risk of second hip fracture: a nationwide population-based cohort study of 169,145 cases during 1977-2001. J Bone Miner Res 2009;24:1299-1307.
14. Lonnroos E, Kautiainen H, Karppi P, Hartikainen S, Kiviranta I, Sulkava R. Incidence of second hip fractures. A population-based study. Osteoporos Int 2007;18:1279-1285.
15. Yamanashi A, Yamazaki K, Kanamori M, Mochizuki K, Okamoto S, Koide Y, Kin K, Nagano A. Assessment of risk factors for second hip fractures in Japanese elderly. Osteoporos Int 2005;16:1239-1246.
16. Gehlbach SH, Avrunin JS, Puleo E, Spaeth R. Fracture risk and antiresorptive medication use in older women in the USA. Osteoporos Int. 2007;18(6):805-10. Epub 2007 Jan 6.
17. Johnell O, Jönsson B, Jönsson L, Black D. Cost effectiveness of alendronate (Fosamax) for the treatment of osteoporosis and prevention of fractures. Pharmacoeconomics 2003;21:305-314.
18. Levis S, Quandt SA, Thompson D, Scott J, Schneider DL, Ross PD, Black D, Suryawanshi S, Hochberg M, Yates J. Alendronate reduces the risk of multiple symptomatic fractures: results from the fracture intervention trial. J Am Geriatr Soc 2002;50:409-415.
19. Chrischilles EA, Dasbach EJ, Rubenstein LM, Cook JR, Tabor HK, Black DM. The effect of alendronate on fracture-related healthcare utilization and costs: the fracture intervention trial. Osteoporos Int 2001;12:654-660.
20. Black DM, Thompson DE, Bauer DC, Ensrud K, Musliner T, Hochberg MC, Nevitt MC, Suryawanshi S, Cummings SR. Fracture risk reduction with alendronate in women with osteoporosis: the fracture intervention trial. FIT research group. J Clin Endocrinol Metab 2000;85:4118-4124.
21. Cramer JA, Gold DT, Silverman SL, Lewiecki EM. A systematic review of persistence and compliance with bisphosphonates for osteoporosis. Osteoporos Int 2007;18:1023-1031.
22. Tucker K. Osteoporosis prevention and nutrition. Curr Osteoporos Rep. 2009 Dec;7(4):111-7.
23. Gillespie WJ, Gillespie LD, Parker MJ. Hip protectors for preventing hip fractures in older people. Cochrane Database Syst Rev. 2010;6 (10):CD001255.
24. De Bakker PM, Guy P, Fernlund G, Oxland TR; Prophylactic augmentation of the contralateral femur: A finite element study Osteoporos Int 2006;17 (Suppl 2).
25. Beckmanna J, Ferguson SJ, Gebauer M, Luering C, Gasser B., Heini P. Femoroplasty - augmentation of the proximal femur with a composite bone cement - feasibility, biomechanical properties and osteosynthesis potential Medical Engineering & Physics 2007;29: 755-764.
26. Heini PF, Franz T, Fankhauser C, Gasser B, Ganz R. Femoroplasty-augmentation of mechanical properties in the osteoporotic proximal femur: a biomechanical investigation of PMMA reinforcement in cadaver bones Clinical Biomechanics 2004;19:506-512.
27. Briesacher BA, Andrade SE, Harrold LR, Fouayzi H, Yood RA. Adherence and occurrence of fractures after switching to once-monthly oral bisphosphonates. Pharmacoepidemiol Drug Saf. 2010;19(12):1233-40.