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EDITORIAL

## SAFETY AND PROBLEMS WITH METAL ON METAL HIP IMPLANTS

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Today metal-on-metal (MoM) implants used for hip resurfacing or replacement are at the heart of a heated discussion due to safety and problems related to the specific bearing surface (1).

Initially, failure was reported by Australian, English and Welsh registries regarding a specific device (ASR, Articular Surface Replacement). Later evidence emerged concerning the failure of largehead metal-on-metal implants (2-3).

Cobalt-chromium implants have been used successfully in orthopedic surgery for years. However with metal on metal hip implants clinicians have recorded patient reactions which have been divided into "Adverse Local Tissue Reactions" (ALTRs) or "Adverse Reaction to Metal Debris" (ARMD).

Many factors contribute to making this problem a complex one.

Firstly patients react to metal in different ways and it is very difficult to predict which patient will develop these complications (4).

A statistical analysis of the prosthesis outcome has not yet been conducted by the registries nor has it been published in other peer reviewed literature. The registries analyses were limited hence conclusions should be drawn cautiously. Furthermore, registry data alone are not a substitute for premarketing studies.

After a series of failures, device regulation is in need of radical change to improve patient health (5).

Measuring ion levels continues to be proposed to monitor MoM implants. However, there are many limitations to such methods as all patients with a MoM hip implant have a permanently raised level of chrome and cobalt metal in their blood.

The technical complications and lack of understanding of adverse reactions impose intellectual rigor to define the indications for Mo-Mo implants to guarantee patient safety and the efficacy of surgery (6).

The implant of these prostheses remains today the surgeon's decision however in the midst of much doubt satisfactory results can be obtained with the right indication and surgical skill.

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REVIEW ARTICLE

## SURGICAL TREATMENT OF OSTEOPOROTIC VERTEBRAL FRACTURES: STATE OF THE ART

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Osteoporotic vertebral fractures and the related surgical approaches are more frequent due to the increased lifespan. In most cases these fractures are atraumatic or associated with minimal trauma but high-energy trauma are increasing in patients with osteoporotic vertebrae. In addition to conservative treatment, several surgical procedures are available, but there is no defined therapeutic algorithm. The aim of this paper is to give a picture of the current state and new perspectives about the treatment of osteoporotic vertebral fractures.

**Narrative Review.** 

## Epidemiology

Current social and economic welfare has led to an increase in the elderly population subsequent to a growing life expectancy. The latest epidemiological projections show that in 2050 over 54% of the population will be over 65 years (1).

Osteoporosis is a systemic skeletal disease marked by low bone mass and the microarchitectural deterioration of bone tissue leading to increased fragility and a tendency to fractures, especially of the hip, spine and wrist.

Osteoporosis affects about 100 million people and is the most common metabolic disorder of the elderly. In Italy, about 3.5 million women and 1 million men suffer from it. Over 25% of post-menopausal women and about 33% males >75 years are involved.

The estimated prevalence of osteoporosis in women is approximately 15% for the 50-59 year group, 25% between 60-69 years, 40% between 70-79 years and even above 50% for the  $\geq$ 80 year group. Between 80% and 90% of vertebral fractures in the over 65 group are caused by osteoporosis but only

one third are clinically manifest (2).

Over 30% of patients affected by vertebral osteoporosis fractures need surgical treatment and 12% present complications requiring an invasive surgical approach. In most cases these are pathologic fractures, occurring spontaneously or associated with minimal trauma (3).

Today, there are more and more dynamic and active "elderly-fit". Vertebral fractures that occur in these patients could be specifically traumatic vertebral fractures.

These are not pathologic fractures, but only vertebral fractures that occur in a non physiological bone. This aspect must be considered when deciding surgical treatment.

#### **Biomechanics**

The vertebral body is formed by cancellous bone tissue biomechanically characterized by a high bone turnover (80%) and a lower calcified volume (20%). Therefore, this tissue withstands to dynamic stresses, deforming itself without breaking.

Key words: vertebral fractures, osteoporosis, fragility, trauma, spine surgery

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Degenerative disc disease and senile neuromotor and neurosensory decay, are associated with a progression in spinal kyphosis resulting in anterior translation of the gravitational axis, progressive posterior ligament distraction and anterior column compression.

In the case of osteoporosis, the trabecular thinning results in a reduction of vertebral body strength. In relation to the gravitational force, the fracture of the body induces a height soma reduction and spinal kyphosis progression, especially at the level of the anterior spinal column (4). The more involved vertebrae are T7 and T8, in the middle thoracic column and T12 and L1 in the thoracolumbar transition where there is a great flexion (Fig. 1). The thoracolumbar hinge undergoes the most stress as it is an area of different convex curve inversions. The kyphotic curve progression and the forward displacement of the gravitational axis lead to an increase in flexion, causing new fractures. In fact the risk of another vertebral fracture increases 5 fold after the first event ('domino-effect') (Fig 2).

These conditions must be taken into account when considering an open approach, especially in identifying the level of merger, the location and the surgical instruments, and the increased fixation failure risk (5).

#### DISCUSSION

#### Treatment options

The necessity of an algorithm for the treatment of painful osteoporotic fractures is based on the lack of consensus regarding proper surgical indications, timing, application and effectiveness of the percutaneous vertebral body augmentation techniques and the usefulness and indications for open surgery (6). Although vertebroplasty (VP) and kyphoplasty (KP) are currently widespread, their role is still controversial, specially if compared to conservative treatment (7). A review of the current literature reports mild and transient symptoms in the first month of conservative care. Vertebral body augmentation techniques should be done within 3 months from fracture to promote a good out come (8). Instead the vertebral body augmentation could be performed within a few days from trauma to encourage a good restoration of vertebral height (9).

One month is the minimum waiting time before considering surgery for fractures with a natural history due to the higher risk of cement leakage during that period (10). VP should be considered for persistent painful fractures with less than 30% of body height reduction if conservative treatment has failed. KP should be considered for vertebral body collapse  $\geq 30\%$  within the third month. Open decompression and stabilization techniques are necessary for the treatment of unstable fractures and/ or in patients presenting neurological impairment.

#### Non-operative treatment

The treatment of osteoporotic vertebral fracture is not possible without some drug therapy. By improving bone mass, pharmacological therapies effectively reduce the number of osteoporotic fractures. The availability of evidence-based data that show reductions in the incidence of fractures of 30– 50% during treatment has been a major step forward in the pharmacological prevention of fractures. New approaches (Hormones, Teriparatide, Human Immunoglobulin Monoclonal Antibody genetically engineered) to pharmacological treatment will include the further development of existing drugs, especially in regards to tolerance and frequency of dosing.

Conservative treatment is generally proposed for painful vertebral osteoporotic fractures. It consists of a period of bed rest and the application of a thoracolumbar extension orthosis.

Pain control and antiresorptive drugs are necessary to improve therapeutic compliance and prognosis in short and long-term.

Unfortunately nonoperative treatment does not restore the associated deformity, nor does it hinder the 'domino effect'. In the case of persisting pain, the only solution is surgery (Fig. 3).

#### Percutaneous surgical treatment

Percutaneous surgery with VP or KP (11) is necessary in case of pain persistence or contraindications to using an orthosis (e.g. intolerance, restrictive respiratory failure).

VP is recommended for patients with persistent pain and vertebral collapse < 30% until 1 month after the fracture or after 3 months.

KP is indicated for vertebral collapse and

persistent pain with high body reduction equal or higher than 30% (also in case of *vertebra plana*), between 1 and 3 months (12-13) (Fig. 3).

Only PMMA administration could be used for VP, allowing vertebral body reinforcement without direct body height being restored. KP provides a partial correction of vertebral body height by means of an "expandable balloon". KP is a more biomechanically valid process. This technique enables the stabilization of the fracture after reduction. In addition, the creation of an intrasomatic cavity filled with PMMA reduces the risk of cement leakage. (12,14-15).

Although the majority of PMMA leakages are asymptomatic, adverse effects of VP include localized bleeding, infection, mediastinitis, pain, neurological symptoms (neuropathic pain and paraplegia) and pulmonary embolism following the leakage of injected material (16-20).

PMMA leakage has been reported occurring in the venous plexus, the inferior vena cava, the epidural space in the spinal canal, in the neural foramina, intravertebral disk space, and paraspinal soft tissue. Adjacent vertebrae fracture is a possible complication due to the greater stiffness of the cement compared to the vertebrae. PMMA is contraindicated during infections. Hypotensive reactions may occur between 10 to 165 seconds from bone cement application. They could last from 30 seconds to 5 minutes or more, inducing cardiac arrest.

In short and medium term there are no significant benefits between VP and conservative treatment. Conservative treatment is recommended for fresh fractures. In the case of persistent pain for over 1 month, especially if there are risk factors (kyphosis and / or degenerative scoliosis), surgical treatment is indicated. In addition, KP allows recovery, although at times only partial, of the vertebral body height, thus combating the domino effect (21-22).

## Unipedicular approach

KP is performed using double balloons via the bilateral transpedicular approach for elevating the end plate. Recently, single balloon cross-midline expansion with a unipedicular approach has been performed to reduce surgery risks, operation time and radiation exposure (23-24). Zheng et al (25) used a particular probe to induce single balloon expansion to the opposite side via the unipedicular approach.

The balloon must be positioned cross-midline thus restoring the vertebral body height (26).

This method restores the vertebral body stiffness and strength reducing the lowering extent of failure loads (27).

## Vertebral Body Stenting (VBS)

VP has not an intrinsic capacity to restore vertebral height, but relies on patient positioning or bolsters used in the OR to induce lordosis. KP is able to directly restore vertebral height using a balloon tamp.

However, 34% of kyphoplasties do not result in an appreciable reduction in the kyphotic angle or height restoration (24) due to balloon deflation and consequent vertebral body height loss, prior to cement augmentation (28-29).

The uses of a specially designed cathetermounted stent (VBS - Vertebral Body Stenting), implanted and expanded inside the vertebral body can preserve the restored vertebrae height before cement introduction (30).

#### Alternatives for PMMA: Bone Expanders

PMMA is commonly used as a filler material but it could change normal spinal biomechanics leading to vertebral compression and subsequent fractures in the vertebra just above or below. Osteoconductive filler materials (CaP) might prevent subsequent vertebral compression and fractures because it is not as stiff as PMMA. CaP cement does not cause exothermic effects and it has osteoconductive activity (31-33).

However, CaP may not provide enough initial stiffness. Therefore, according to D. H. Heo et al. (34) recollapse may occur 1 year after in the CaP-augmented vertebrae (35).

Minimally invasive percutaneous vertebral augmentation with an intravertebral polyethylene mesh sac is a new filling used in the minimally invasive biological vertebral reconstruction procedures (36). It consists of a polyethylene mesh sac filled with morcelized bone allograft and introduced into the vertebral body. The bone graft is able to create a hyperdense pack, reducing the fracture and restoring vertebral height. Osteoconductive and osteoinductive properties allow a biological vertebral reconstruction. The adjacent vertebrae should be

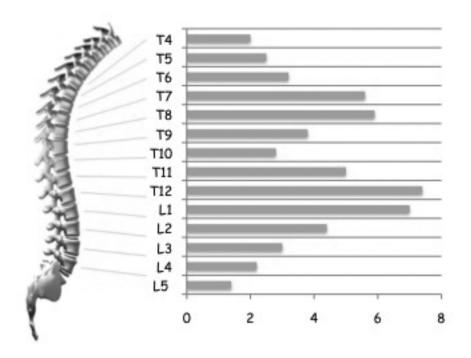


Fig. 1. Epidemiology of vertebral osteoporotic fractures.

better protected by a construct with similar elasticity and physical characteristics to the morcelized bone (37).

#### **Open procedures**

Most cases of osteoporotic thoracolumbar vertebral collapse can be managed conservatively, but neurological complications and kyphotic progression should be treated surgically. Neurological paraparesis (38) or complications that develop in an osteoporotic spine can happen establishing a durable surgical fixation. Osteoporotic vertebral injuries are divided into several types: (39-40) A) a wedgetype compression fracture exhibiting progressive kyphosis; B) a flat-type fracture with osteonecrosis or pseudarthrosis often exhibiting intravertebral cleft formations; C) a concave or H-shaped fracture associated with an anterior spur or sclerotic changes.

The best results are to be found in patients treated for wedge-type lesions. The presence of an anterior bone spur formation in H-shaped fractures may help to stabilize the collapsed vertebra. Therefore, a posterior approach could be the gold standard in cases of a concave or H-shaped fracture; in fact an anterior procedure could damage the anterior bone spur-derived stabilization. In addition, in cases of flat-type lesion with less severe kyphosis, the 'eggshell procedure' may be an excellent option (41-43).

Progressive neurological loss, severe unrelenting pain, and progressive kyphotic deformity are indications for surgical intervention in the setting of osteoporotic compression fractures. Neurologic deficit typically occurs with bone retropulsion fractures and severe deformity.

Anterior surgical approaches are used for decompression of the spinal canal and for releasing posterior structures, obtaining kyphosis correction; however, anterior instrumentation is associated with a high rate of failure when used alone (44-49). A combined anterior and posterior procedure may maximize the chances for successful fusion, especially with multiple points of spinal fixation and occasionally with PMMA augmentation (50-51). Vertebral body augmentation combined with stable anterior column constructs provides satisfactory long-

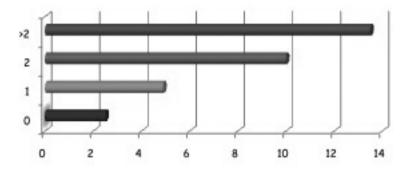


Fig. 2. Probability of new vertebral fractures within 12 months from the first.

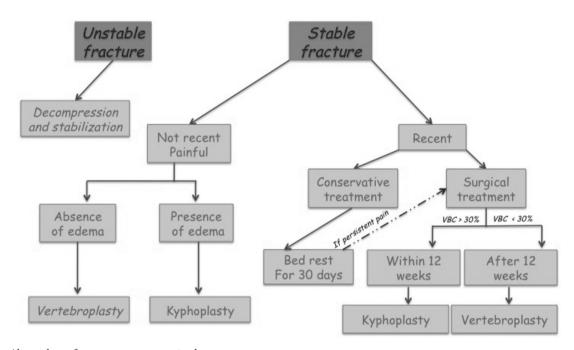


Fig. 3. Algorithm of percutaneous surgical treatment

term stability. Sublaminar hooks have been used for posterior instrumentation, although hook migration and laminar fracture may occur in osteoporotic bone. Pedicle screw fixation is a necessary alternative, allowing three-column fixation. Sublaminar hooks or wires can support load share with pedicle screws at the proximal or distal end of constructs.

Osteoporotic vertebral collapse issues include the loss of bone stock. Combination between the posterior instrumentation and the anterior support is recommended (52). A transpedicular posterolateral approach, a 360 circumferential approach, and a modified eggshell procedure, (41) with subsequent kyphosis correction and pedicle screw/ rod fixation, have been reported for the treatment of this fractures.

Anterior approach was not easy to achieve in elderly patients with more severe comorbid medical problems (45-46). Posterior approach allows a neural decompression and a stabilization of the spinal column restoring the normal alignment through the correction deformity (48). The posterior instrumentation, at least two vertebral bodies above and below the fracture, should be the first outcome (49).

This is an immediate but biomechanically indirect correction, acting directly on the posterior

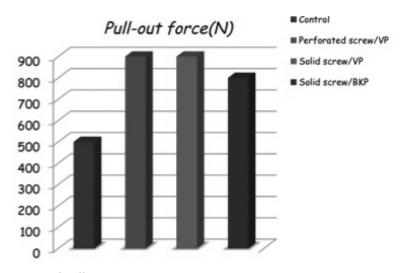


Fig. 4. Transpedicular screws and pull-out resistance.

**Table I.** Different characteristics of transpedicular screw fixation systems.

Group	CPS group	PMMA-PS group	EPS group
BMD (g/cm <sup>2</sup> )	0.68+/-0.06	0.71+/-0.08	0.66+/-0.007
F <sub>max</sub> (N)	751.50+/-251.37	1521.70+/-513.27	1175.20+/-396.51
E (J)	1.47+/-0.51	3.09+/-0.93	2.46+/-0.69

BMD, Fmax and E in CPS group, PMMA-PS group and EPS group

column and indirectly on the anterior column (52-53). Surgical complications include loss of correction and violation of the intact middle and posterior vertebral elements (48). The anterior approach is indicated in the case of anterior-column injury because the fracture can be treated without middle and posterior column alteration. For anterior reconstruction in osteoporosis, good bone stock must be restored in order to avoid non-union and bone graft implant collapse during the extensive correction of kyphotic deformity. In the case of a total collapse of the vertebral body in older fractures with kyphotic deformity or instability, posterior instrumentation with an anterior column support is required (50, 52-53). Anterior column injuries and progressive

kyphosis require a combined anterior decompression and fusion. The problem of each instrumentation is the difference between the hardness of the osteoporotic bone and the implant's stiffness. Pedicle screws may damage the bone, causing the screws to come loose. The endplates are the hardest part of the vertebral body and bear the cage. Therefore, the cage may sinter into the vertebral body; in fact it induces a progressive kyphotic deformity, and increases the forces on the screws leading to implant failure. The main complications are cement leakage into adjacent structures and fixation failure. Although the rate of clinically symptomatic leaks is low, severe complications can occur, mainly spinal cord or nerve root compression, pulmonary embolism, paraplegia, or death (54).

## Minimally invasive percutaneous approach

When conservative treatment is not possible and open posterior fusion might represent an overtreatment, the minimally invasive percutaneous approach is a good alternative (55). The minimally invasive approach is a tissue-sparing surgery, providing a reduction in blood loss and postoperative pain. Patients with osteoporotic vertebral fractures and candidates for surgery, are suffering from concomitant diseases and receiving multiple medications. Therefore, where possible, it would be advisable to use this approach, although careful patient selection is necessary in order to avoid needless and dangerous extended surgical time.

This technique involves, via mini-incisions, the insertion of pedicle screws with two external tubes and a targeting system. It is possible to insert a connection bar, synthesizing the upper and lower vertebrae. The minimally invasive approach is indicated for both vertebral fracture stabilization in polytrauma patients and in those needing immediate mobilization.

This technique offers great advantages: a quick, functional recovery, reduced blood loss and postoperative pain. Percutaneous posterior stabilization, used as an internal fixation system, should be reserved only for stable vertebral fractures (56).

## New perspectives for screw fixation

Biomechanically, the pedicle provides the strongest screw fixation in healthy bone, but in osteoporotic vertebra, trabecular and cortical pedicular bone can be reduced by up to 50% (56). The instrumentation of the osteoporotic spine, especially in posterior stabilization, results in failure in 12% of the cases, due to conventional pedicle screw loosening or pull-out (57-61) together with a poor rigidity of the bone-screw contact. A correction failure or nonunion may make surgical revision necessary. Therefore different screw designs and screw augmentation methods should be available (62). Various methods were developed to increase the screw fixation strength in the case of bone deficiency. Perforated screw with vertebroplasty augmentation, solid screw with vertebroplasty augmentation and solid screw with balloon kyphoplasty augmentation are currently used (Fig. 4, Table I). Alternatively, it is possible to combine sublaminar hooks, wires, conical screws, iliac screws or expandable screws (54, 63), but with higher strength and higher risks (58, 64). Brantley et al. (65) suggested that there is an interaction between the increase in diameter and the increase in length. Polly et al. (66) reported that increasing the length of the screw alone or increasing the diameter of the screw by less than 2 mm does not improve screw stability. Screw insertion depth plays a significant role. Screws implanted over 50% deeper into the vertebral body or bicortical screws perforating anterior vertebral cortex, enhance the bone anchorage (67-68). However, bicortical fixation is avoided because of the anterior leakage risk. Cement augmentation is regarded as an efficient system to enhance screw strength in osteoporotic bones, transferring the biomechanical load anteriorly from the pedicle to the vertebral body (56). A greater strength of screw fixation can be obtained with a larger amount of injected cement. There could be potential problems, such as the risk of cement leakage and the difficulty in removing screws. Cook et al. (69) reported that PMMA injection through the expanded screw increased the pullout strength by 250% when compared with the non-cemented expandable screw (70). In both techniques, cement is injected prior to screw insertion. Researchers designed an expandable pedicle screw (EPS) able to improve screw stability without harming the pedicle, avoiding the risk of vertebral pedicle fracture, vascular and visceral injuries which may be caused by larger or longer screws. Many biomechanical studies have demonstrated that pedicle screw fixation is highly correlated with BMD (70). The mechanical load influences bone tissue structure according to Wolff's law (71). As a result, the bone tissue surrounding the expandable portions of the EPS has a high bone density. The expansion of the EPS should also improve fixation strength by allowing a greater bone contact, without an increase in the diameter of the pedicle insertion or screw length. EPS enhances screw fixation strength like the traditional method of PMMA screw augmentation (72). In conclusion, the expandable pedicle screw is an effective, safe and easy method and is indicated for osteoporosis screw stability augmentation.

## CONCLUSION

Osteoporotic vertebral fractures and related surgical approaches are more frequent due to the increase in the average life span. The osteoporotic vertebral fractures occur spontaneously or after trauma. Therefore, understanding the different treatments enhances the implementation of a specific patient care. Conservative treatment is no longer the only solution. Now, many surgical techniques are used (from percutaneous to open combined approaches), allowing a more rapid functional recovery and a biomechanically stable correction. Given the particular characteristics of the osteoporotic spine and patient comorbidity, the treatment must be done according to the guidelines for "early total care", "tissue sparing surgery" and "damage control orthopedic surgery".

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## RECURRING DESMOID TUMOR OF THE MIDFOOT: A CASE REPORT OF INTEGRATED SURGERY AND INTERFERON TREATMENT

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Aggressive fibromatosis (AF), known as desmoid tumor, is a broad group of benign fibrous tissue proliferations, similar in appearance but intermediate in their biological behavior between benign fibrous tissues and fibrosarcomas, for this reason they are classified as semi-malignant although they tend not to metastasize. A 43-year-old caucasian male, affected by Gardner's syndrome, developed over a few months a large mass on the left midfoot, adhering to the surrounding structures. After the first surgical excision, the mass grew again, hence it required a new wide excision and systemic long-term immunointervention with pegylated interferon alfa-2b. After 10 months of this therapy no signs of recurrence was evident. Despite a negative resection margin, a significant number of patients still develop local recurrency of desmoid tumors after excision within the first 2 years of their primary resection. Therefore destructive excision is not the best treatment, which instead should be an integration of surgical and pharmacological treatment.

Case Report: Evidence Level IV.

Aggressive fibromatosis (AF) known as desmoid tumors (from the Greek word desmos for band of tendons and first used by Muller in 1838) is relatively rare, representing 0.03% of all neoplasms (1), <3% of all soft tissue tumors with a reported annual incidence of 0.2–0.5 per 100 (2-3).

AF is a broad group of benign fibrous tissue proliferations similar in appearance but intermediate in their biological behavior between benign fibrous tissues and fibrosarcomas (4). AF tumors express genes and cell surface markers typical of mesenchymal stem cells (5).

The most frequently affected sites are the abdominal wall or within the abdomen but they may also occur in the extremities.

In a 60 patient-series Lee described that the

female-to-male ratio was 1.2:1 with an average age at diagnosis of 41.3 years (6).

An association of AF and Gardner's syndrome or familial adenomatous polyposis (FAP) has been identified. In patients with familial polyposis of the colon, the prevalence of desmoid tumors is as high as 10-13% (7-8). AF is characterized by low mitotic activity and a strong infiltrative growth pattern along tissue planes with an ability to invade adjacent tissues (9-10).

In the foot, Desmoid-type fibromatoses are destructively growing soft tissue tumors with high infiltrative pontentiality. A monoclonal proliferation of fibroblasts originates from the musculoaponeurotic structures, infiltrating the surrounding tissues, with a high potential for recurrence after treatment,

Key words: aggressive fibromatosis, desmoid tumor, surgery, interferon therapy

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Fig. 1. Large desmoid tumor mass on the dorsal and plantar foot surface.

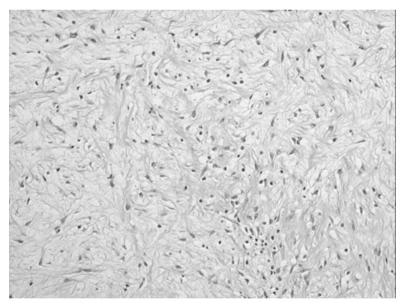


Fig. 2. Aggressive Fibromatosis (AF) with E.E.

resulting in local recurrence rates ranging from 24% to 77% in reported series (11-12). For this reason they are classified as semi-malignant although they tend not to metastasize.

Genetic, hormonal and traumatic factors are implicated in the pathogenesis even if the majority of cases are sporadic (13).

Differential diagnosis of desmoid-type

fibromatosis/aggressive fibromatosis in adulthood includes various fibroblastic/myofibroblastic soft tissue tumors such as nodular fasciitis, fibrosarcoma, low-grade fibromyxoid sarcoma, myofibroblastic sarcoma as well as leiomyosarcoma and soft tissue leiomyoma (14).

To date, the best treatment is a wide surgical excision of the mass. There is also growing evidence



Fig.3. Plantar surgical approach to perform the wide excision of the mass.

in literature that chemotherapy is an effective adjuvant therapy against AF with almost one in two patients being likely to respond (12). Radiation therapy has also been shown to improve local control of desmoid tumors in both the adjuvant and the primary setting (15-16).

## CASE REPORT

A 43-year-old caucasian male, suffering from Gardner's syndrome with genetic alterations on chromosome 5 (17) developed, over a period of a few months, a large mass on the left midfoot adhering to the surrounding structures, that rapidly grew extrinsically on the dorsum and plantar surface (Fig.1) (18). Previously, in the period between 1991-2008, he had undergone 4 colonscopies and one gastroscopy revealing severe polyposis which histological studies confirmed as Gardener's syndrome.

At onset the mass was confined to the dorsum of the foot originating in the space between the divaricated first and second metatarsal heads. There were no signs on the plantar surface and the mass, 4 cm in diameter and 3 cm in height, completely adhered to the subcutaneous derma and was associated with pain and functional impairment.

After a careful clinical examination and evaluation

of the X-ray and MRI images (19-20) we decided to perform a needle-biopsy in order to define a precise treatment protocol.

The histological diagnosis was for desmoid tumour (aggressive fibromatosis) (Fig. 2).

We decide to perform a wide excision of the mass immediately, paying particular attention to performing a radical excision of the infiltrated margins (21) (Fig.3). We removed a mass weighing 46 gr and measuring 50 mm in diameter. The intraoperative biopsy confirmed the pre-operative diagnosis of desmoid tumor.

After 2 months of quiescent, the mass grew again on the dorsal surface, and after 11 months a MRI showed a mass of 8.5 cm in diameter, confined to the midfoot with no local infiltrated margins. We decided to re-operate the patient. We performed a second surgery (Fig. 4) with a more aggressive excision of the mass, paying attention to avoid metatarsal and tarsal bone damage. It measured 7x4x2.5 cm and was of a hard consistency. The histological examination re-confirmed the diagnosis of desmoid tumor (Fig. 5).

In collaboration with the Oncology Department in our hospital, we started long-term systemic immunotherapy with pegylated interferon alfa-2b ( 22).

After 10 months of treatment the mass grew back



Fig.4. Recurrency on the dorsal midfoot surface.

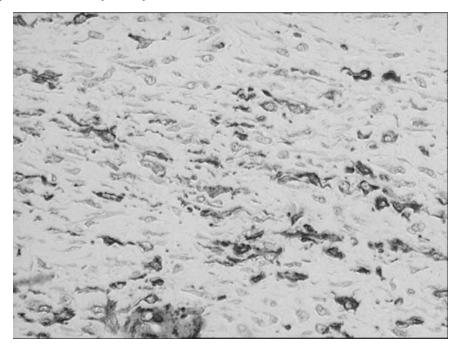


Fig. 5. Aggressive Fibromatosis (AF) with actina.

again. The MRI showed it to have a diameter of 7mm, therefore we performed a new wide excision. It was impossible to achieve skin closure, so we performed a weekly toilette of the open wound in order to facilitate soft tissue and skin regeneration.

The treatment with interferon was continued for 10 months, after 5 months the skin was completely closed without any sign of tumor recurrency (Fig.6).

We evaluated the foot condition by MRI and there was no evidence of a desmoid mass.



Fig.6A) and B). Final appearance after surgical and interferon treatment

No interferon related side effects were reported by the patient and at the end of therapy he achieved complete recovery of the foot and ankle function.

## DISCUSSION

Local recurrence is more common in desmoid tumours arising in extra-abdominal sites (23). Although our patient was 43 yrs old at the onset of the tumor, in literature it is a younger age group (<30 years) that is a significant risk factor for local recurrence (P < 0.05). Tumor size, surgical margin and previous surgical history were not always associated with a higher rate of local recurrence (24).

It is evident that despite a negative resection margin, a significant number of patients still develop local recurrency of their tumors within the first 2 years of their primary resection (25-26). Attempts to achieve a negative resection margin does not always reduce the risk of recurrency and may result in unnecessary morbidity due to mutilating surgery. For this reason adjuvant pharmacologic therapy, in our experience, is the best method to control the recurrency rate. In our case, long-term immunotherapy with pegylated interferon alfa-2b led to a marked clinical improvement and stabilization of the disease (14).

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## ALLOGRAFT FOR THE TREATMENT OF MASSIVE BONE LOSS IN OPEN AND INFECTED IIIA FRACTURE OF THE DISTAL FEMUR

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Infection and bone loss following local debridement in high grade open fractures are two difficult issues. The treatment of bone infection needs radical "oncological" debridement that leaves a segmental bone defect. Once the infection is eradicated, the defect may be treated with different surgical techniques: bone graft, bone transport, Masquelet's two stage reconstructions, allograft or vascularized fibular transplant. In literature these options are described only for bone loss less than 15 cm. We describe the case of a female with an open IIIA fracture of the right distal femur with 25 cm of infected bone loss, treated with radical multi-staged debridement, the Masquelet technique and ORIF with massive allograft and autologous bone graft. This case offers us the opportunity to discuss the following principles: radical debridement, the biological chamber, two stage reconstruction and internal stable fixation in infected bone.

## **Case Report: Evidence Level IV.**

Severe contaminated open fractures present three main problems: infection, bone loss and fragment fixation s.

Infection usually requires a combination of surgery and antibiotics (1-5).

The aim of surgery is the radical excision of infected tissues (either bone fragments or soft tissues) and the fixation of the bone fragments with external fixation (6). The modern suggestions described in literature (1) are to leave the debrided wound open and to add vacuum therapy in order to achieve a long lasting effect of the debridement on the infected soft tissues. The local examination of the microbiological environment gives the correct antibiotic for the general treatment.

Repeated debridement usually leads to bone loss.

Therefore, once the infection is under control, the main problem becomes how to treat and fix the bone loss in order to ensure that the length of the limb is restored, that the fracture will heal and that the limb will be ready for full weight bearing.

In literature there are various methods to solve these problem (7-10).

The Masquelet procedure (11) consists of radical debridement of the infected bone and soft tissues and the implant of a self-made cement spacer until the infection is resolved. When the clinical and microbiological parameters are at normal levels it will be possible to remove the spacer, put the bone graft inside to fill the defect and make the open reduction and internal fixation. However this technique is indicated for the tibia and for <6 cm bone loss in the femoral shaft.

Once the infected bone has been removed, bone transport (7-8), uses bone regeneration, to fill the defect, killing the remaining infection. It needs a very long period of distraction, an estimated 35.7 days for each cm of bone loss.

Key words: infection, open fracture, bone loss, femur, allograft.

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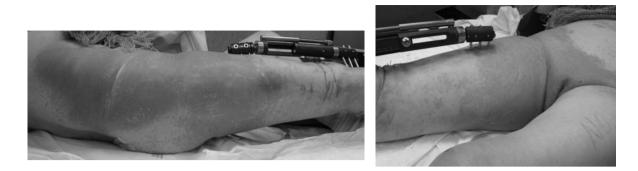
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#### Fig. 1.

The microvascular double barrel vascularized fibula transplant (7) has the problem of the length and the size of the transported bone and of the residual vascularity of the injured site where the anastomosis should be. It is indicated only for defects <15 cm.

The autologous bone graft, when the defect >5-7 cm, has a great number of non unions (17-50%), refractures (17-30%) and infection (10-15%).

The allograft is another option, but the history of infection and the quality and vascularization of the surrounding altered soft tissues may interfere with new bone apposition.

The bone transport with the circular frame has an intrinsic stability, the fixation in the other techniques each case should be discussed individually (12-13).

We present this case of an open infected fracture of the distal femur in order to illustrate and discuss a possible solution to these cases, applying different principles: radical debridement, biological chamber, two stage reconstruction, internal stable fixation in infected bone (14).

## Case Description

In October 2010, a 74 -year-old woman, after a fall at a farm, suffered an open III A fracture of the distal right femur. She was originally stabilized with an external fixator in another hospital, treated with prophylactic antibiotic therapy (amoxicillin+clavulanic acid three times a day) and, after 5 days, was admitted to our institute with severe infection (Fig. 1).

There was an extensive skin reaction and reddening of the whole thigh, extending to the lumbar and dorsal side and the breast. The knee was painful and swollen. There were also purulent secretions from the proximal screws of the fixator. The skin at the level of the exposure of the fracture was sutured. The internal temperature was 39° C.

The fracture pattern (Fig.2) was 33-C2 based on AO classification and type III A based on Gustilo open fracture classification. There was diaphyseal comminution with articular extension.

At admission, laboratory assessments such as erythrocyte sedimentation rate, C-reactive protein, and white blood cell counts demonstrated evidence of infection.

A CT-scan (Fig. 3) demonstrated the presence of free air in intra-muscular spaces.

We performed immediate surgical debridement of the fractured wound and thigh fasciotomies. We put



Fig. 2.



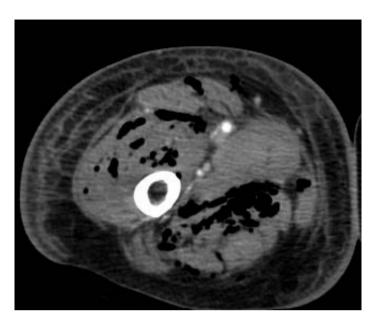


Fig. 3.

a gentamicin impregnated polymethymethacrylate bead at the open fracture level and administered vacuum therapy at the fasciotomy sites. We also debrided the screw sites of the previous fixator that was changed, maintaining the spanning configuration. We also put a double way lavage system with betadine (1:5) that lasted 2 days.

Colliquated material was collected for a bacteriological examination. We started a new antibiotic therapy with vancomycin 1 gr/die.

The patient was debrided daily and hyperbaric oxygen therapy was started at the same time.

The microbiological results were positive for escherichia coli, enterobacter and clostridium perfringens, and the antibiotic therapy was adjusted accordingly.

After 5 days the patient reported pain and she had severe anemia; hence we performed an angiography that showed bleeding from the superficial femoral artery that had embolised.

After 3 weeks, the laboratory indicators of infection, in particular the C-reactive protein, were still elevated, but a CT scan revealed no more air in the muscle compartments so we closed the fasciotomies.

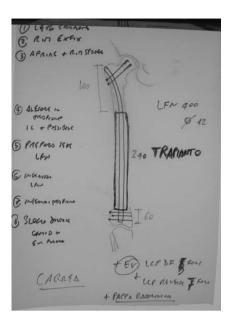




However after a few days she still had a fever (39°C) accompanied by pus secretions from the proximal screws of the fixator.

We performed another surgical debridement

#### M. BERLUSCONI ET AL.



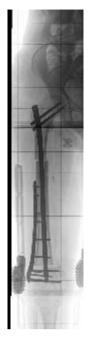


Fig. 5.

(December 2010). We found a deep infection involving the bone that was avascular and severely contaminated. Abbundant purulent secretions came from the holes of the pre-existing screws of the external fixator.

We removed the bead chains and all the infected necrotic bone (24 cm of the femoral shaft) and put a gentamicin cement spacer of the same length and a new external fixator with screws also in the distal femur in order to give more stability, considering that at this point the articular fracture line would be partially consolidated (Fig.4).

Systemic antibiotic therapy was continued.

The C-reactive protein value decreased progressively.

She was discharged to a rehabilitation hospital.

At 4 months from the injury (February 2011), once the laboratory infection markers (i.e. erythrocyte sedimentation rate, C-reactive protein and white blood cell counts) swere within the normal range, we decided to treat the bone loss.

Massive bone allograft was preferred because it would allow rapid weight bearing in an elderly woman who was getting depressed due to the injury and its complications (Fig.5).

The program was to review the fragments (eventually cutting the possibly still contaminated edges) and to reinforce the allograft with a nail and a plate if the distal locking was weak. Bone graft from the iliac wing and platelet factors were supposed to be useful at the "docking" sites.

On a traction table used to maintain the length, we removed the external fixator and performed a lateral approach to the femur.

No visible signs of infection were found during surgery.

After removing the cement spacer we found a complete pseudomembrane that enclosed either the spacer or the proximal and distal femur (the biological chamber of Masquelet).

We cut 5mm of the edges of the fragments and prepared the site for a recon nail (LFN 400x12 mm Synthes Co.) as planned.

We prepared the allograft, reaming it to 13.5mm and assembling it inside the thigh.

We distally locked the nail trying to ensure good contact between the allograft and the fragment. We pulled the nail back to have a good contact









proximally and locked it with femoral neck screws. The proximal locking was stable, the distal locking was quite weak either because of bone porosis or the previous screws of the external fixator, so we added a lateral plate (LCPDF Synthes Co.).

We added bone graft from the iliac wing in both the "docking sites" with platelet factors.

After surgery we could examine the knee and found an instability, so we used a brace for 2 weeks

in extension, than with a progressive flexion for 8 weeks and with partial weight bearing with crutches (20kg toe-touch).

At 3 months the patient was able to climb the stairs (Fig. 6)and at 1 year (October 2011) she was declared healed (Fig.7).

## DISCUSSION

In literature there are few papers on open distal femoral fractures. None on severe contamination with subsequent extensive bone loss.

We treated this case following the principle guidelines for open fractures (multi-staged extensive debridement and antibiotic prophylaxis); for infection (removal of all infected, contaminated and avascular fragments) and for osteosynthesis (stable fixation resistant to infection which permits the fracture to heal).

We have experimented the allograft to fill bone loss in the presence of a history of infection as it looked like the best way to give immediate weight bearing, in consideration of the biological and mechanical properties of the other possible solutions (bone transport, bone graft and microvascular fibular transport).

We think that in good biological conditions (the biological chamber of Masquelet), this solution could be suggested in these rare and difficult cases.

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## SHORT TERM EVALUATION OF PERIPROSTHETIC BONE MINERAL DENSITY IN COLLUM FEMORIS PRESERVING (CFP) STEMS

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Periprosthetic bone resorption in total hip arthroplasty (THA) is one of the most important causes of long term implant failures. Recent studies show that the amount of periprosthetic bone mineral density (pBMD) is directly related to the longevity of the implant. Nowadays neck preserving stems are becoming more widely used in THA surgery to maintain a better femoral bone stock. We decided to study pBMD in Collum Femoris Preserving (CFP) stems because its design allows a more physiological load distribution along the femoral metaphysis. 18 patients who underwent THA using CFP stems were included in this study; pBMD were evaluated by DEXA scan (QDR HOLOGIC 4500) using a metal removal software at baseline and at 3 and 6 months after the implant. Gruen areas were used in the analysis of pBMD. Statistical analysis has been performed with the Student's T-Test. Data analysis has shown that global pBMD decreased by 4.5% and 5% after 3 and 6 months respectively. When the single Gruen areas were evaluated, the maximal loss in pBMD was reached in area 7 (-11.7% after 6 months). The minimal decrease in pBMD found after 6 months from surgery shows a highly adaptive capability of CFP stems in the proximal third of the femur. These findings could be indicative of the longevity of CFP stems. Case Series: Evidence Level IV.

Periprosthetic bone loosening in THA is one of the most significant problems in prosthetic failures (1). Femoral and acetabular bone loosening is due to osteoclast bone resorption around the metallic components. It is now possible to obtain interesting information about periprosthetic bone resorption (2-3), thanks to specific markers of osteoclastic and osteoblastic activity and to DEXA scan; the latter is able to evaluate bone mineral density (BMD) around the metal devices. It is well known that after 6 months from the prosthetic implant, BMD may decrease by up to 30%, independently of the final surgical result of the implant (4-9). This decrease in bone mass derives initially by trabecular destruction during surgery, and subsequently by the bone's biological adaptation to the metal structures. Prosthetic components are englobed in the bony tissue in different ways, depending on the biological reactivity of the bone and on the biocompatibility and physical surface of the prosthetic materials. This mechanism, defined as prosthetic integration, is considered one of the most important factors in determining the life span of the implant. Biological processes and prosthetic integration studies should offer indirect data on prosthetic longevity and on periprosthetic bone loosening genesis.

Considering the quick and highly relevant changes of periprosthetic bone around stems, we evaluated

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Key words: total hip arthroplasty, collum femoris preserving stem, bone mineral density

Mailing address: Dr. G. Potalivo via Giovan Battista Pontani 9 06128 Perugia, Italy Tel: ++ 39075 5058485 Fax: ++ 39075 5010921 e-mail: g.potalivo@libero.it periprosthetic bone mass density (pBMD) variations in a particular kind of collum femoris preserving stem (CFP). CFP stems offer great rotational stability thanks to the triplanar fixation on the lateral cortical of the femoral neck, that is preserved, and gives a better tolerance

to varus-valgus stresses. CFP stem has an excellent primary stability thanks to the preservation of the cortical bone of the femoral neck and the metaphyseal trabecular bone compression performed during femoral stem fitting (10). This leads to a more physiological distribution of the load along the trabecular system, with compression forces on the medial side and distraction forces on the lateral side, giving the bone-prosthetic system a physiologicallike elasticity in the proximal metaphyseal region. Considering these features, it is believed that CFP stem integration should occur in a short time with a minimal overall pBMD decrease at the site.

## MATERIALS AND METHODS

#### Population

From 2007 till 2008, every in-patient at our Orthopedic and Traumatology Unit that had to undergo to a THA with a CFP solution was anamnestically evaluated before surgery. Every subject with metabolic bone diseases (except for post-menopausal osteoporosis) or taking drugs able to interfere with mineral and bone metabolism or had neoplastic, hepatic or renal diseases were excluded from the study.

Eighteen of these subjects, 11 males and 7 females, were included in the study group. The mean age of the population was  $53\pm10$  years.

Every patient followed the same rehabilitation program: deambulation using two crutches with partial weight bearing on the operated limb from the second to the thirtieth postoperative day; complete load using one crutch on the contralateral side to the operated limb for the next 15 days. During this period each subject practiced daily exercises to strengthen gluteal and thigh muscles. Each patient underwent short-term antibiotic and antithrombotic prophylaxis (low molecular weight heparin) (35 days from surgery); the subjects wore an elastic sock while standing and performing physical exercises for one month after surgery.

All patients gave informed consent prior to being included in the study. The study was authorized by the local ethical committee and was performed in accordance with the Ethical standards of the 1964 Declaration of Helsinki, revised in 2000. The authors declare no conflict of interest.

#### DEXA study

The pBMD was studied with a DEXA scan in the first week after the prosthetic implant (T0). The following evaluations were done at 3 (T1) and 6 (T2) months after surgery. pBMD was measured using the QDR HOLOGIC 4500 system; pBMD analysis was performed with a metal removal software to exclude prosthetic components. All the DEXA scans and pBMD analyses were performed by the same operator in order to minimize operator-related error; the technique's precision, evaluated with 4 observations on the same hip in 3 different individuals, showed a CV equal to 1.43%. During the DEXA study, the lower limb was placed with the foot blocked at a 30° internal rotation using a Hologic prosthetic hip foot positioner (11).

#### Periprosthetic areas

The protocol for analysing the DEXA scans used the radiological zones described by Gruen et al. in 1979 (12); these Regions Of Interest (ROIs) were modified in order to adapt them to the small length of CFP stem. ROI 1 started from the top of the greater trochanter and ended distally at one third of the prosthetic stem. ROI 2 and 3

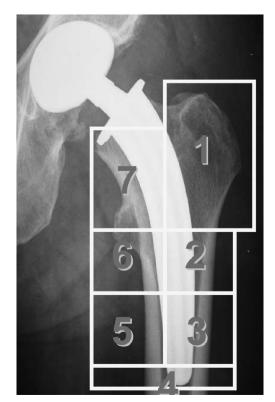


Fig. 1. Gruen ROI applied to CFP stem.

extended distally from ROI 1 on the lateral part of the femur, until the apex of the stem. ROI 4 included both the medial and the lateral sides of the femur, from the stem apex 15 pixels distally. ROI 5 was as big as ROI 3, but included the medial part of the bone. Proximal to ROI 5 was ROI 6, that had the same dimensions as ROI 2. ROI 7 included the small trochanter and the medial part of the femoral neck.

Due to the small dimensions of the CFP stem, compared to conventional ones, and in order to reduce the analytic method error, we decided to take lateral ROIs 5 and 6 together in a unique area, called ROI 5+6. We did the same procedure with areas 2 and 3, creating ROI 2+3 (Fig. 1).

Statistic analysis

We did statistic analysis using Student's T-Test for paired data. Significance value was considered as p<0.05

#### RESULTS

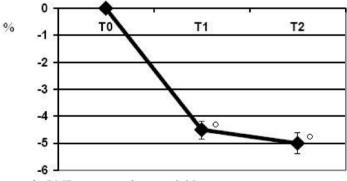
Fig. 2 shows time-related changes in pBMD in the

global ROI. At T1 from the surgical act a significant reduction of bone mineral density of 4.5% is seen (p<0.05). This value reaches -5% at T2 (p=<0.05).

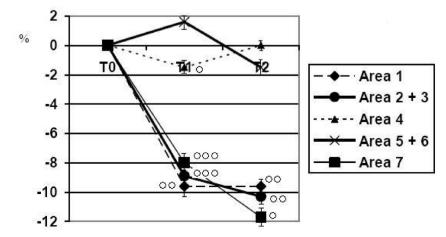
Figure 3 shows time-related changes in pBMD in each single analysed area. In ROI 1 pBMD significantly decreased by 9.6% at T1 (3 months, p<0.001), no further variation was found at T2 (6 months, p<0.01). In ROI 2+3 pBMD significantly decreased by 8.9% at T1 (p<0.001) and by 10.3% at T2 (0.001 < p<0.01). In ROI 4 pBMD significantly decreased by 1.5% at T1 (p<0.05) and reached the baseline value at T2. In ROI 5+6 pBMD did not significantly change after 3 and 6 months. In ROI 7 pBMD decreased significantly by 8% at T1 (0.001 < p<0.01) and by 11.7% at T2 (p<0.05).

## DISCUSSION

This study shows that in the first 6 months after Collum Femoris Preserving (CFP) stem



**Fig. 2.** *Mean global percentual pBMD variation*  $^{\circ} = p < 0.05$ 



**Fig. 3**. Mean percentual pBMD variation at T1 and T2;  $^{\circ} = p < 0.05$ ;  $^{\circ\circ} = 0.001 ; <math>^{\circ\circ\circ} = p < 0.001$ 

implantation, periprosthetic bone mineral density (pBMD) loss is generally low; our data show how overall pBMD decreased by 5% at 6 months. All the longitudinal studies that used DEXA scan to evaluate pBMD variation in THA showed that the maximum periprosthetic bone loss is reached at 6 months from the implant time; after this period no further pBMD loss is found in well-fixed stems (12-13). We can thus consider the first 6 postoperative months as the critical period that has to be studied to evaluate the quantitative femoral bone density variation to the prosthetic implant.

The decrease in femoral pBMD we found using CFP stems could be considered an important result if compared to data from scientific publications dating back to the early 1990's, that showed a pBMD loss that varied from 20 to 50% (14-24).

This leakage in bone mass density had to be ascribed to the poor tribologic characteristics of stems. When optimal tribologic and load spreading characteristics are joined in the same prosthetic component, pBMD loss can be even lower; in 2001 Venesmaa and others evaluated 22 subjects who had received a hydroxyapatite-covered stem implant; for the first time they noticed a global pBMD loss of 6.2%. This value confirmed the positive influence of design and tribologic features of the prosthetic stem on femoral bone behaviour (24).

The pBMD loss values in CFP prosthetised femurs that we observed in our study, showed an optimal conservation of periprosthetic bone mass density; no other stem showed similar results.

To give a qualitative estimation of femoral bone loss, other considerations have to be made; in the days following surgery for THA, the bone mass of skeletal parts distant from the hip show a decrease. In the heel, a trabecular bone structure, bone mass lessens about 14% after 3 months from the implant time; in the spine, where bones are made equally of cortical and trabecular bone, BMD reaches a 3% loss after 12 months (21). This bone loss is due to a decrease in patient activity and reduced weightbearing on the prosthetised limb, that is imposed in the first months after surgery.

Considering these observations, we think that part of the global decrease in pBMD of femurs prosthetised with CFP stems could be due to this postoperative inactivity; the final considerations on periprosthetic bone mass behaviour in CFP stems are much better than the bare values themselves, as if the pBMD decrease could be justified mainly by disuse rather than a reaction of the bone to the prosthetic stem.

Based on the previous considerations, we can assume that the pBMD loss we observed 6 months after surgery could be less relevant than it appears to be: the stem triplanar fixation and neck preservation seem to produce a more physiological spread of loads, leading to a better conservation of periprosthetic mineral content, according to Wolff's law.

This evaluation is further enforced by the analysis of ROI7. Venesmaa underlines how in this area bone loss is about 17.5% after 6 months from implant time (24); in our study of CFP stem, ROI7 had a bone loss of 10.5% after 3 months, and this value changed insignificantly after 6 months (-11.9%).

We can then conclude that the CFP stem leads to a very low alteration to the biomechanics of the hip, with a greater conservation of pBMD. Based on the fact that the stable fixation of the stem is inversely related to pBMD loss in the host bone (25), we can assume that the CFP stem could have great stability and subsequently a long life span.

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