

Case Report

Volume 1 Issue 4 - November 2015

Ortho & Rheum Open Access J

Copyright © All rights are reserved by Rinaldo Giancola

Treating Osteonecrosis of the Femoral Head: SOIB Method - Core Decompression and Introduction of Mesenchymal Cells: Case Report

Rinaldo Giancola, Alessandra Savoia and Guido Antonini*

Ospedale San Carlo Borromeo, Italy

Submission: November 04, 2015; **Published:** November 23, 2015

***Corresponding author:** Guido Antonini, Ospedale San Carlo Borromeo, 20147 Milano, Italy, Tel: 39 3393929918; Email: md.guidantonini@gmail.com

Abstract

Osteonecrosis of the femoral head is a pathologic process with multifactorial origins, characterised by pain, alteration of the anatomy and biomechanics of the hip and increasing patient disability. The treatment method depends on the stage of the disease, the size and location of the lesions, whether the involvement is uni- or bilateral, the age of the patient, how active the patient is, their general health conditions and life expectancy. The unsatisfactory results obtained in saving the femoral head using the available methods have lead in recent years to renewed interest in this disease and seeking new methods and treatments aimed at arresting its development or even preventing its onset. We present a clinical case study of a new method involving core decompression combined with the introduction of mesenchymal cells through a specific titanium screw called "SOIB".

Keywords: head osteonecrosis; Mesenchymal cells; SOIB screw; Osteogenesis

Introduction

Osteonecrosis of the femoral head is a disease affecting adults aged between 40 and 50, more often male, which leads to the necrosis and collapse of the femoral head. This pathology has multifactorial origins and progressive evolution, leading patients to undergo arthroprosthetic implant as soon as diagnosed [1].

There are numerous systems to classify the stages of the disease. Radiographic classification influences the most appropriate treatment choice for the patient.

Surgical techniques previously used include core decompression, the trap-door procedure, derotational and valgus/varus osteotomy, vascularised bone grafts from the peroneum and iliac crest and total hip replacement. None of these has been identified as gold standard for the treatment of osteonecrosis yet. Core decompression appears to be the most appropriate treatment method in the early stages of the disease, but only recently, focal decompression has been combined with the introduction of mesenchymal cells. Autologous cancellous bone is today considered the gold standard in the event of bone grafts. Cancellous bone contains mesenchymal cells able to differentiate into osteoblasts, fibroblasts, chondrocytes, adipocytes and other types of cells present in connective tissue.

The importance of the use of aspirated bone marrow in bone regeneration depends precisely on the presence of these stem cells that under appropriate stimulation can differentiate into osteoblasts and thus form new bone.

In this paper we report the case study of a patient with osteonecrosis of the femoral head treated with decompression of the necrotic focus and the introduction of mesenchymal cells through the "SOIB" device (Figure 1).



Figure 1: "SOIB" device: titanium cannulated screw with plug.

Clinical Case Study

49-year-old female patient with osteonecrosis of the right femoral head classified as Arlet and Ficat stage III (Figures 2 & 3) with a 260° Kerboul angle [2]. Medical history: alcohol abuse, surgery for lumbar disc hernia, right inguinal hernioplasty, appendectomy, previous left total hip replacement due to osteonecrosis, hypothyroidism treated with replacement therapy, chronic obstructive pulmonary disease.

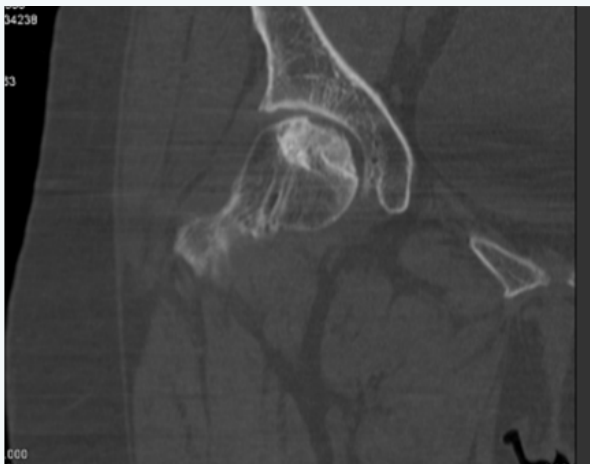


Figure 2: MRI of hip with osteonecrosis classified as Arlet and Ficat stage III.

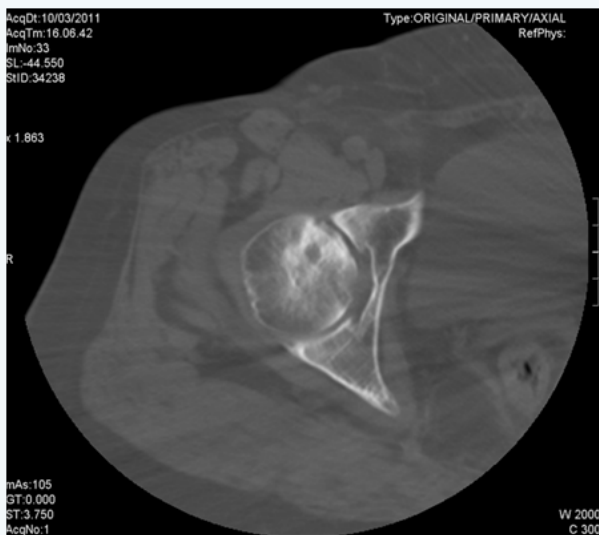


Figure 3: MRI of hip with osteonecrosis classified as Arlet and Ficat stage III.

The pre-operative physical examination assessed the following aspects:

- Inspection and ambulation: lower limbs normal in appearance, no different length in limb, bilateral muscular hypotonic atrophy of the gluteus and quadriceps, no bilateral neurological defects, right

limping, walk with the assistance of crutches

- Right hip range of motion: passive flexion-extension: 110°-10°, passive abduction-adduction: 45°-5°, passive internal-external rotation: 15°-30°.

In a single surgery session the patient underwent bone marrow concentrate harvest from the iliac crest, core decompression of the osteonecrotic focus and the subsequent introduction of mesenchymal cells through a special titanium cannulated "SOIB" screw equipped with holes along the whole screw.

Surgery Phase I

A 2-3cm incision was made at the ipsilateral iliac crest to access the bone. A specific disposable kit with a trocar was used to harvest 60 ml of marrow aspirate, which was then centrifuged for 15 minutes in a bone marrow concentrator containing ACD-A anticoagulant which separates the components of the autologous bone marrow according to density to obtain about 6 – 10 ml of mesenchymal cell concentrate.

Surgery Phase II

A lateral cutaneous incision of about 1.5 – 2 cm was made to the greater trochanter area of the femur; dieresis of the muscular layers, fasciotomy and exposure of the bone; a guide wire was then positioned under screen intensifier guidance at the necrotic focus, which was drilled to encourage bleeding in the necrotic area. The SOIB screw was positioned along the guide wire (8.5 by 90mm) (Figures 4 & 5).



Figure 4: Antero-posterior radiography of hip with osteonecrosis after treatment through SOIB device.

The centrifugate from the iliac crest containing the mesenchymal cells was selectively injected into the necrotic site through the device. Finally a plug was positioned to ensure greater mechanical resistance of the screw and its perviousness

in the event of further procedures.



Figure 5: Axial radiography of hip with osteonecrosis after treatment through SOIB device.

On the second day after the operation the patient began progressive weight-bearing with the use of two crutches, which were then abandoned on post-operative day seven.

Unlike traditional core decompression, the presence of the screw enables earlier weight-bearing and less bleeding at the site of the intervention. The patient underwent MRI scans and clinical assessments at 3, 6, 12 and 24 months. Pain disappeared in the first few days after the operation with an improvement in the Harris Hip Score (HHS) after just 45 days.

Two years after the surgery, on the basis of radiographic and clinical assessments it was decided to remove the SOIB device without proceeding with hip replacement. There was a stop in the evolution of the pathology treated and the lack of any symptoms of pain experienced by the patient (Figures 6 & 7).



Figure 6: Antero-posterior radiography of pelvis with osteonecrosis after removal of SOIB device.



Figure 7: MRI of pelvis with osteonecrosis after removal of SOIB device.

At the 4-year follow-up, the patient had not undergone any further orthopaedic surgical procedures, did not require any support during walk, had, only occasional, mild pain of the right hip and had not in any way modified her daily life. There were no substantial changes to the articulation compared to the pre-operative assessments.

Discussion

Osteonecrosis of the femoral head has multifactorial origins and mainly affects relatively young adults with an active lifestyle. Pain, changes to the anatomy and biomechanics of the hip and increasing disability are the natural developments of this disease. Osteonecrosis of the femoral head is also known as “avascular or ischemic necrosis” (indicating a possible lack of blood supply) or “aseptic necrosis” (to distinguish this condition from the bone sequestrum that can develop in osteomyelitis). It is a degenerative, progressive disease involving necrosis of the osteocytes, osteoblasts and osteoclasts that populate a variously delimited area of the femoral head [3].

Osteonecrosis affects relatively young subjects in their forties and fifties with a 4:1 rate of men compared to women. In 50% of cases both hips are affected and in 10% of cases it can also involve other joints such as the knee, shoulder and temporomandibular joint.

Diagnosing osteonecrosis is often difficult and requires a high degree of experience. Patients often only suffer from modest pain in the inguinal area, at other times the pain may be acute and affect both the inguinal region and the anteromedial fascia of the thigh. This pain is aggravated by weight-bearing and walking. As the disease progresses, however, the pain can also appear at rest. Patients may experience symptoms for over a year before the disease is diagnosed.

The link between the appearance of symptoms and radiographic findings is not always proportional: many patients can be asymptomatic despite clear radiographic findings of very advanced stages of the disease or, vice versa, the pain can be invalidating in the early stages of the disease. Magnetic Resonance is the best method to diagnose osteonecrosis of the femoral head, particularly in the event of negative or unclear radiograph results, since it has 99% sensitivity and 98% specificity for the disease [4-5].

At the physical examination the patient may have a limp on the affected side with a reduction in the range of motion above all on flexion and intra-rotation with extreme degrees of movement causing pain.

Despite the numerous theories put forward, there remains uncertainty as to the actual aetiology of the disease. Many factors have been associated with osteonecrosis of the femoral head. The interaction between these factors and genetic predisposition may trigger the series of events that leads to the disease developing. There are numerous causes that can be subdivided into traumatic and atraumatic [6-7]. Traumatic causes can include hip dislocation, subcapital hip fractures and osteosynthesis of fractures with intramedullary screws that damage the blood supply to the femoral head. The risk factors for atraumatic causes can be direct and indirect. Direct factors include: radiation, sickle-cell anaemia, myeloproliferative diseases, decompression sickness, Gaucher's disease, pregnancy, chemotherapy, organ transplant, thrombophilia, hypofibrinolysis, thalassemia, hepatic diseases and gastric malabsorption syndromes. Some of the main indirect factors are: corticosteroid use, alcohol abuse, HIV, LES, smoking and genetic predisposition. Around 15% of osteonecrosis cases are idiopathic as no clear cause is found in the patients affected.

Although the physiopathology of osteonecrosis remains undetermined, it seems that more than 90% of patients suffering from osteonecrosis have inadequate bone repair and regeneration processes with consequent progression of the disease. The development of the disease appears, in all cases, to be the outcome of reduced blood supply to the femoral head [8].

Various classification systems developed are based on the severity of the symptoms and the radiographic findings. The introduction of new imaging techniques has facilitated early diagnosis of the disease and an improvement in assessing the treatment outcome. In femoral head osteonecrosis, the optimal treatment is identified by determining the degree of involvement of the head. Staging also makes it possible to compare the long-term results of the various treatment methods in terms of morbidity. More than 20 systems are used to classify osteonecrosis. The first and most widely used is the one described by Ficat and Arlet in 1960.

The main aim of treatment of osteonecrosis of the femoral head is timely intervention in order to avoid or delay prosthetic

hip replacement, given that the patients affected are relatively young and active and therefore likely to undergo subsequent prosthetic revision surgery.

The treatment methods depend on the stage of the disease, the size and location of the lesion, whether involvement is uni- or bilateral and the patient's age, degree of activity, general health conditions and life expectancy. The choice of treatment must be based initially on the stage of the disease: the sooner it is diagnosed, the better the prognosis after treatment will be. The current treatment options for osteonecrosis of the femoral head tend towards surgery.

Conservative treatments have been implemented in early stages of the disease (generally stages I and II) but with limited success. Various conservative treatments have been tried over the years, such as:

- a) Unweighted walking on the affected limb: a reduction in weight-bearing on the affected limb does not stop the progression of the disease and this treatment is currently indicated solely for those patients who are not suitable for either medical or surgical treatment [9];
- b) Shockwave and magnetic therapy: these may be considered adjuvant therapies combined with surgery since they temporarily reduce pain and inflammation but do not prevent the disease from progressing to the point of collapse of the femoral head [10];
- c) Pharmacological treatment with anticoagulants, statins, vasodilators, low molecular weight heparin, bisphosphonates and parathormone. There has been particular interest in the bisphosphonate alendronate since it inhibits osteoclast activity and influences bone turnover and remodelling. No randomised trials with long-term follow-up are as yet available to establish the efficacy of any of these therapies and their application is consequently limited [11-13];
- d) Hyperbaric oxygen therapy: this enhances oxygenation of the hypoxic tissues thus reducing oedema of the cancellous bone through a high concentration of free oxygen in the extracellular portion and may therefore give good results if associated with other conservative or surgical treatments [14].

Surgery can be divided into procedures that save the femoral head and procedures that sacrifice the femoral head. Procedures that save the femoral head include:

- A. Core decompression: this was introduced for the first time by Ficat in 1962 to treat osteonecrosis. It decreases intra-bone pressure thus allowing increased blood supply which in turn promotes neovascularization and the formation of new bone growth. During core decompression single or multiple holes are drilled in

the necrotic area of the head through the femoral neck [15];

- B. Trapdoor procedure: this is an invasive procedure in which the femoral head is surgically dislocated and spongy and cortical bone are grafted through a “trapdoor” created in the femoral head cartilage. The procedure aims to reintegrate bone content in the necrotic area [16];
- C. Vascularised bone grafts from the peroneum or iliac crest used to bring vital vascularised bone to the necrotic zone [16];
- D. Osteotomies: these can be derotational, valgus, varus. The purpose of osteotomy is to displace the necrotic area from weight-bearing to avoid putting it under strain leading to its collapse [17];
- E. Tantalum implants: positioned in the femoral neck without debridement of the necrotic tissue or regenerative supply to the focus in order to stimulate osteoclasts and osteoblasts towards bone remodelling [18].

The last resort in treating osteonecrosis is the sacrifice of the femoral head and prosthetic hip replacement. This treatment should be reserved for patients in an advanced stage of osteonecrosis at diagnosis, where the joint surface is extensively degenerated and other treatment options are no longer viable.

The unsatisfactory results obtained with the methods so far available to save the femoral head have led in recent years to renewed interest in the disease in search of new methods and treatments that can stop its progression or even prevent it from occurring.

Osteonecrosis of the femoral head is a major cause of disability in relatively young subjects with the tendency to progress to the point of complete loss of hip functionality. It is a disease that is difficult to treat in the early phases. In the initial stages, when the necrotic lesions are evident without mechanical weakening of the head, there are various surgical and non-surgical approaches. The goal in treating this disease should be effective interventions that slow down or prevent the collapse of the femoral head and preserve the range of motion of the hip.

In a paper by Hernigou et al. the percentage success of the combination of core decompression and mesenchymal cells was 94% out of 145 operated hips [19-20].

In view of the results published in the literature [21-24], it was decided to combine core decompression with the application of mesenchymal cells harvested from the same patient selectively delivered through a cannulated SOIB screw. The presence of the screw means the mesenchymal cells can be delivered selectively, bleeding from drilling is limited, greater

mechanical strength of the femoral head/neck is ensured and weight-bearing can begin sooner.

Conclusion

The association of core decompression and mesenchymal cells transplant reduces internal bone pressure with removal of the necrotic component and provides a regenerative stimulus thanks to the mesenchymal cells. The mesenchymal cells provide the metabolic substrate which leads to neoformed bone deposits and the revascularization of the necrotic area. In the early stages an inadequate regenerative capacity, due to reduced osteogenesis caused by the decreased proliferation of bone progenitor cells, is one of the main causes of disease progression. The mesenchymal cells introduced into the necrotic area should therefore increase the potential for repair by differentiating in the bone progenitor cells that form new bone and should also stimulate vascularisation and oxygen supply thus accelerating the healing process [25].

Song et al. showed that from a histological point of view, new bone formation occurs 6 weeks after grafting the mesenchymal cells in the necrotic area [26].

The device used (Figure 7) allows the selective, directed introduction of the mesenchymal cells into the necrotic focus, provides structural support to the subchondral bone and also means the patient can immediately bear weight on the operated joint from the very first day after the operation guaranteeing structural and biomechanical stability to the femoral neck and head weakened by the core decompression holes.

References

1. M Takao, T Nishii, T Sakai, H Yoshikawa, N Sugano (2010) Repair in osteonecrosis of The Femoral Head: Mr Imaging Features At Long-Term Follow-Up. *Clin Rheumatol* 29(8): 841-848.
2. Kerboull M, Thomine J, Postel M, Merle d'Aubigne R (1974) The conservative surgical treatment of idiopathic aseptic necrosis of the femoral head. *J Bone Joint Surg* 56(2): 291.
3. Assouline-Dayana Y, Chang C, Greenspan A, Shoenfeld Y, Gershwin ME (2002) Pathogenesis and Natural History of Osteonecrosis. *Semin Arthritis Rheum* 32(2): 94-124.
4. LC Jones, AJ Johnson, MA. Mont, CR. Costa. Osteonecrosis of the Hip in Adults. *Clinic Rev Bone Miner Metab* (2011) 9:13-22.
5. Radke S, Kirschner S, Seipel V, Rader C, Eulert J (2004) Magnetic resonance imaging criteria of successful core decompression in avascular necrosis of the hip. *Skeletal Radiol* 33(9): 519-523.
6. Yamamoto S, Watanabe A, Nakamura J, Ohtori S, Harada Y, et al. (2011) Quantitative T2 Mapping Of Femoral Head Cartilage In Systemic Lupus Erythematosus Patients With Noncollapsed Osteonecrosis Of The Femoral Head Associated With Corticosteroid Therapy. *J Magn Reson Imaging* 34(5): 1151-1158.
7. Cooper C, Steinbuch M, Stevenson R, Miday R, Watts NB (2010) The Epidemiology Of Osteonecrosis: Findings From The GPRD And THIN Databases In The UK. *Osteoporos Int* 21(4): 569-577.
8. Séguin C, Kassis J, Busque L, Bestawros A, Theodoropoulos J, et al. (2008) Alonso, EJ Harvey. Non-Traumatic Necrosis Of Bone

- (Osteonecrosis) Is Associated With Endothelial Cell Activation But Not Thrombophilia. *Rheumatology (Oxford)* 47(8): 1151-1155.
9. Assouline-Dayane Y, Chang C, Greenspan A, Shoenfeld Y, Gershwin ME (2002) Pathogenesis and Natural History of Osteonecrosis. *Semin Arthritis Rheum* 32(2): 94-124.
 10. Hamilton TW, Goodman SM, Figgie M (2009) Sas Weekly Rounds: Avascular Necrosis. *HSSJ* 5(2): 99-113.
 11. Kang P, Pei F, Shen B, Zhou Z, Yang J (2012) Are The Results Of Multiple Drilling And Alendronate For Osteonecrosis Of The Femoral Head Better Than Those Of Multiple Drilling? A Pilot Study. *Joint Bone Spine* 79(1): 67-72.
 12. Agarwala S, Shah SB (2011) Ten-Year Follow-Up Of Avascular Necrosis Of Femoral head Treated With Alendronate For 3 years. *J Arthroplasty* 26(7): 1128-1134.
 13. Evans CH (2012) Gene Delivery To Bone. *Adv Drug Deliv Rev* 64(12): 1331-1340.
 14. Camporesi EM, Vezzani G, Bosco G, Mangar D, Bernasek TL (2010) Hyperbaric Oxygen Therapy in Femoral Head Necrosis. *J Arthroplasty* 25(6 Suppl): 118-123.
 15. Camp JF, Colwell CW (1986) Core Decompression of the Femoral Head for Osteonecrosis. *J Bone Joint Surg Am* 68(9): 1313-1319.
 16. R Merle d'Aubigne (1964) Idiopathic necrosis of the femoral head in adults. *Ann R Coll Surg Engl* 34: 143-160.
 17. Mont MA, Fairbank AC, Krackow KA, Hungerford DS (1996) Corrective osteotomy for osteonecrosis of the femoral head. *J Bone Joint Surg Am* 78(7): 1032-1038.
 18. Floerkemeier T, Lutz A, Nackenhorst U, Thorey F, Waizy H (2011) Core Decompression And Osteonecrosis Intervention Rod In Osteonecrosis Of The Femoral Head: Clinical Outcome And Finite Element Analysis. *Int Orthop* 35(10): 1461-1466.
 19. Hernigou P, Poignard A, Beaujean F, Rouard H (2005) Percutaneous autologous bone-marrow grafting for nonunions. *J Bone Joint Surg Am* 87(7): 1430-1437.
 20. Hernigou P, Beaujean F (2002) Treatment of osteonecrosis with autologous bone marrow grafting. *Clin Orthop Relat Res* (405): 14-23.
 21. Sen RK, Tripathy SK, Aggarwal S, Marwaha N, Sharma RR, et al. (2012) Early Results of Core Decompression and Autologous Bone Marrow Mononuclear Cells Instillation in Femoral Head Osteonecrosis. *J Arthroplasty* 27(5): 679-686.
 22. Zhao D, Cui D, Wang B, Tian F, Guo L, et al. (2012) Treatment Of Early Stage Osteonecrosis Of The Femoral Head With Autologous Implantation Of Bone Marrow-Derived And Cultured Mesenchymal Stem Cells. *Bone* 50(1): 325-330.
 23. Wang BL, Sun W, Shi ZC, Zhang NF, Yue DB, et al. (2010) Treatment Of Nontraumatic Osteonecrosis Of The Femoral Head With The Implantation Of Core Decompression And Concentrated Autologous Bone Marrow Containing Mononuclear Cells. *Arch Orthop Trauma Surg* 130(7): 859-865.
 24. Wang BL, Sun W, Shi ZC, Zhang NF, Yue DB, et al. (2010) Treatment on nontraumatic osteonecrosis of the femoral head with the implantation of core decompression and concentrated autologous bone marrow containing mononuclear cells. *Arch Orthop Trauma Surg* (2010) 130(7): 859-865.
 25. V Caretti, P Costa, M Mosconi, F Benazzo. Il trattamento della necrosi avascolare della testa femorale con core decompression e utilizzo di cellule staminali e fattori di crescita: l'esperienza della Clinica Ortopedica. *Bollettino della Società Medico Chirurgica di Pavia* 123(3): 579-590.
 26. Song S, Zhu S, Sun C (1998) Treatment of avascular necrosis of femoral head by periosteal cell transplantation : an experimental study. *Zhonghua Yi Xue ZaZhi* 78(1): 52-55.