Original Article

Management of osteonecrosis of the femoral head
A novel technique

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Abstract

Background: Osteonecrosis of the femoral head (ONFH) is a debilitating disease in orthopedics, frequently progressing to femoral head collapse and osteoarthritis. It is thought to be a multifactorial disease. ONFH ultimately results in femoral head collapse in 75–85% of untreated patients. Total hip arthroplasty (THA) yields satisfactory results in the treatment of the end stage of the disease. However, disease typically affects males between the ages of 20 and 40 years and joint replacement is not the ideal option for younger patients. Recently, mesenchymal stem cells and platelet rich plasma (PRP) have been used as an adjunct to core decompression to improve clinical success in the treatment of precollapse hips.

Materials and Methods: A prospective study of 40 hips in 30 patients was done. There were 19 males and 11 females with a mean age 36.7 ± 6.93 years. The indication for the operation was restricted primarily to modified Ficat stages IIb and III. 16 hips (40%) had stage IIb and 24 hips (60%) had stage III ONFH. The period of follow up ranged between 36–50 months with a mean 41.4 ± 3.53 months. All patients were assessed clinically during pre- and post-operative period according to the Harris Hip Score (HHS), Visual Analog Score (VAS) and radiologically by X-rays. Magnetic resonance imaging (MRI) was done preoperatively to confirm the diagnosis and every 6 months postoperatively for assessment of healing. The operative procedure include removal of necrotic area with drilling then the cavity was filled with a composite of bone graft mixed with PRP.

Results: The mean HHS improved from 46.0 ± 7.8 preoperatively to 90.28 ± 19 at the end of followup ($P < 0.0001$). The mean values of VAS were 78 ± 21 and 35 ± 19 at preoperatively period and final followup, respectively, with an average reduction of 43 points.

Conclusion: We found that the use of PRP with collagen sheet can increase the reparable capacity after drilling of necrotic segment in stage IIb and III ONFH.

Key words: Collagen sheet, core decompression, osteonecrosis, platelet rich plasma
MeSH terms: Osteonecrosis, femur head, platelet-derived growth factor, visual analog pain scale

Introduction

Osteonecrosis of the femoral head (ONFH) is a debilitating disease.[1-3] The etiology of the disease is unknown.[4,5] However, it is thought to be multifactorial.[6-8] It results in femoral head collapse in 75–85% of untreated patients.[9-14] The current trend in the treatment of ONFH aims to preserve the joint in the initial stages and to delay the replacement surgery in advanced cases.[14-19] Recently, mesenchymal stem cells and PRP have been used as an adjunct to core decompression to improve clinical success in the treatment of precollapse hips.[20-23] PRP was first described by Whitman *et al*. in 1997,[24] it is an autologous preparation that concentrates platelets in a small volume of plasma. It contains multiple growth factors and has been shown to have positive effects on the stimulation of bones, blood vessels and the formation of chondrocytes.[24,25]

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This study describes early results of treatment ONFH by replacement of the necrotic segment after multiple drilling with bone graft and PRP covered by collagen sheet to augment healing process.

Materials and Methods

30 patients (40 hips) with modified Ficat stages IIb and III ONFH [Table 1].[26] underwent surgery between December 2009 and March 2014. There were 19 males and 11 females with a mean age 36.7 ± 6.93 years (range 20–48 years). The causes of osteonecrosis in this series were steroid intake (n = 15, 37.5%), post traumatic (n = 5, 12.5%), idiopathic (n = 20, 50%). In 10 patients, the procedure was performed bilaterally with average 3.5 months interval (2.8–4.6 months). 16 hips (40%) had stage IIb and 24 hips (60%) had stage III ONFH. The mean followup was 41.4 ± 3.53 months (range 36–50 months). All the patients were assessed clinically during pre- and postoperative period according to the HHS,[14] VAS[27] and radiologically by X-rays. MRI was done preoperatively to confirm the diagnosis and every 6 months postoperatively for assessment of healing. The inclusion criteria were: (1) Stage IIb or III ONFH as evidenced radiologically (2) age between 20 and 50 years (3) disabling pain that interfered with daily activity. The exclusion criteria were (1) active endocrine disorder (e.g. hypothyroidism) (2) active neurological disorder that might affect the patient's pain (e.g. peripheral neuropathy and multiple sclerosis) (3) any active disease requiring continuous use of corticosteroids (e.g., rheumatoid and systemic lupus erythematosis).

Operative procedure

Under general or regional anesthesia, the patient was placed on a standard operating table in a supine position with the buttock of the affected side sticks a few centimeters out of the border of the table. The skin incision began about 2 cm proximal to the tip of the greater trochanter and extended for 7–8 cm distally. The incision was angled about 25° with respect to the axis of the femoral shaft. After dissection of subcutaneous tissues, the fascia of the muscles was dissected in line of incision. The anterior margin of the gluteus medius was cut for about 4–5 cm at its insertion onto the greater trochanter. The gluteus minimus was then identified below the gluteal medius and was separately dissected, taking care to maintain about 0.5 cm of tissue distally to allow an easier reconstruction. Three Hohmann retractors were used to expose the hip capsule. Two were placed at 11 and 2 o'clock, while the third was placed at 9 o'clock for the right hip and at 3 o'clock for the left one. These retractors proximally and superiorly shifted the glutei and medially shift the rectus femoris and iliopsoas. The hip capsule was then tensioned by forcing the hip in flexion, adduction and external rotation and then a reversed T-shaped incision was performed. The hip was dislocated anteriorly, with care not to damage the posterior capsule [Figure 1].

Table 1: Modified Ficat classification

Stage	Findings on plain radiographs
0	Silent hip, normal radiograph
I	Normal or, at most, minor changes (subtle loss of clarity, blurring of trabecular pattern, slight patchy osteoporosis)
IIA	Diffuse or localized osteoporosis, sclerosis, or cysts of the femoral head
IIB	Crescentic subchondral line, segmental flattening of the femoral head (asymmetrical appearance)
III	Sequestrum, break in articular cartilage from one end of the affected area to the other, normal or increased joint space
IV	Decreased joint space, collapse of the femoral head, acetabular osteoarthritic changes

The necrotic area of the femoral head was identified and approached through the damaged articular surface, then curetted with the removal of all necrotic bone. Multiple drilling was done with a 4.5 mm drill bit for 1-5 cm depth. The cavity was filled with a composite of iliac bone graft mixed with PRP. The PRP must be used within 6 h of preparation. Finally, the cavity was covered with collagen sheet made of porcine collagen type I membrane. It consisted of 4.8 mg/ml rat tail collagen type I gel, the diameter of the samples was 9 mm with a height of 3 mm and stored at 4°C until implanted. (A Biocollagen MeRG® Collagen Membrane, Bioteck, Vicenza, Italy) and fixed with fibrin glue to the articular surface [Figure 2]. Gentle reduction was done and the anterior capsule was repaired.

The procedure for preparation of PRP consisted of 150-ml venous blood sample that was centrifuged twice for 10 and 15 min, respectively, to concentrate and produce 20 ml of PRP.[28]

Postoperatively, skin traction was applied for 3 days, with the functional training of the hip. Partial weight bearing with crutches was allowed after 6 weeks. Full weight bearing started at the beginning of the 3rd months and heavy physical activity up to 1 year postoperatively. All patients completed the followup till the end of the study. They were followed up at 6 weeks, 3 months, 6 months and at 1 year then every 6 months. At each followup, clinical evaluation was done according to VAS[27] and HHS.[14] In addition to radiological evaluation by X-rays (anteroposterior and lateral views), MRI study was done every 6 months. Each hip of patients with bilateral hip involvement was examined separately.

Statistical analysis

The following tests were used: (1) The nonparametric Wilcoxon test - To compare the average of the subjective

pain difference (difference between preoperative and postoperative followup as determined by the visual analog score [VAS]) and the joint function (as measured by HHS comparing preoperative function with function at followup). (2) The Kruskal–Wallis test - this test was used to study the difference between the subjective pain and HHS parameters based on the length of followup. Clinical success was defined as a good or excellent HHS score, improvement in VAS and no revision surgery.

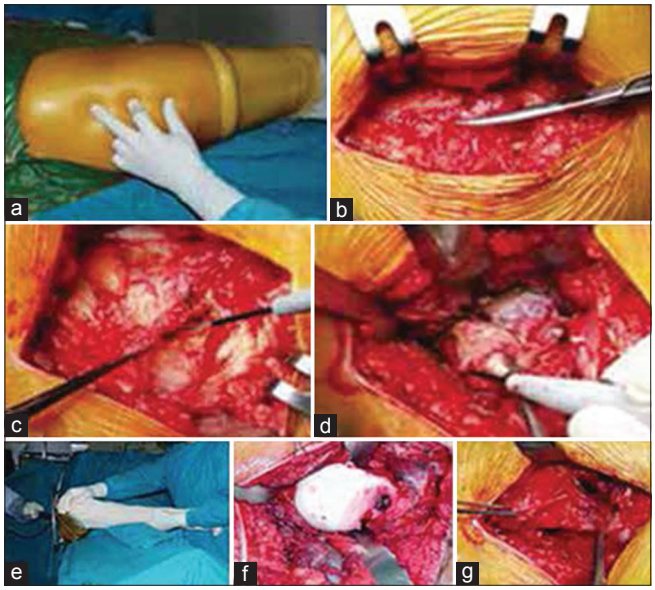

Figure 1: Surgical approach, (a) patient positioning, (b) iliotibial band incision, (c and d) incision of anterior fibers of gluteus medius, minimus and capsule, (e and f) anterior dislocation of the hip joint, (g) repair of the gluteus medius and minimus at the end of the procedure

Results

There were no significant complications in any patient who underwent this procedure. Two patients were noted to have postoperative trochanteric bursitis at immediate followup and one case of deep venous thrombosis, however, these were managed nonoperatively.

The average values of VAS were 78 ± 21 and 35 ± 19 at preoperative and final followup, respectively, with an average reduction of 43 points. This difference was statistically significant ($P < 0.0001$). Significant pain relief was reported in 34 hips (85%), while the rest of patients reported little or no pain relief. As regards improvement in VAS, there was no significant difference between stage IIb and III ONFH, risk factors, age, gender, or bilateral treatment. HHS improved from 46.0 ± 7.8 preoperatively to 90.28 ± 19 at the end of followup. The comparison between average scores showed statistical significant difference ($P < 0.0001$) [Figures 3 and 4].

Twenty seven hips (67.5%) had excellent results and nine hips (22.5%) had a good result. Four hips (10%) had fair results. These patients walked with a painful limp and were prepared for THA. Patients with stage IIb has better improvement in HHS than stage III, but this was statistically insignificant.

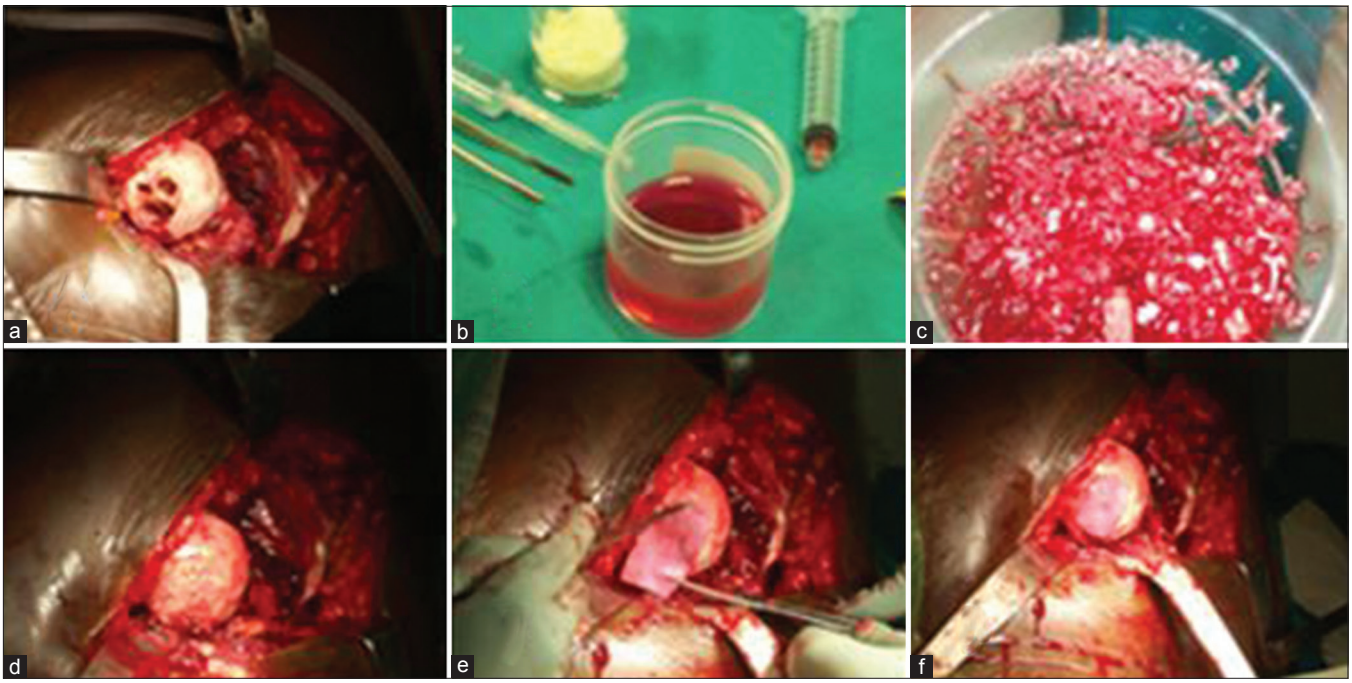

Figure 2: Operative technique, (a) stage III osteonecrosis of the femoral head after curettage and multiple drilling, (b) platelet rich plasma (c) composite of platelet rich plasma and bone graft (d) femoral head after impaction of bone graft and platelet rich plasma (e and f) coverage with collagen sheet

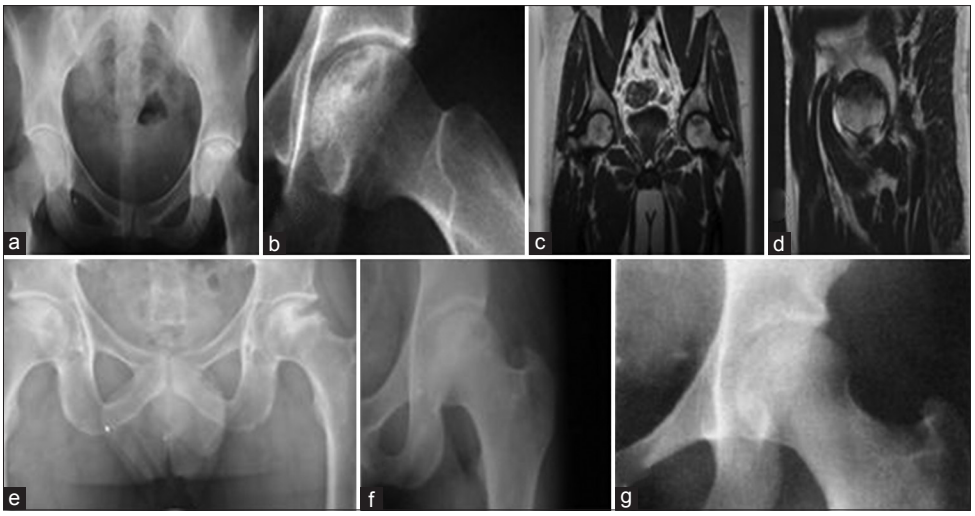

Figure 3: Stage IIb (a and b) subchondral collapse is indicated by the appearance of a crescent sign without flattening of the femoral head. The lateral radiograph shows a typical crescent sign, (c and d) preoperative magnetic resonance imaging showing avascular necrosis changes (e) immediate postoperative X-ray showing adequate curettage and filling with composite of platelet rich plasma and bone graft, (f) 6 months followup postoperative x-ray showing healing (g) 25 months followup postoperative x-ray showing healing of lesion

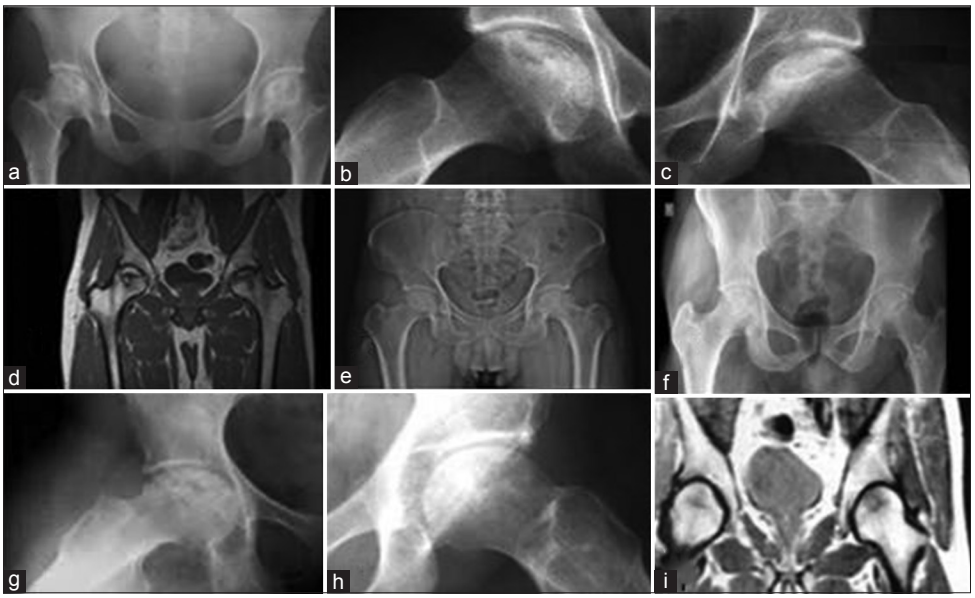

Figure 4: (a) Preoperative x-ray pelvis showing both hips anteroposterior view showing bilateral stage III osteonecrosis of the femoral head (b and c) preoperative frog lateral view of both hips showing bilateral avascular necrosis changes (d) preoperative magnetic resonance imaging showing avascular changes (e) immediate postoperative x-ray pelvis anteroposterior view showing curettage and filling with composite of platelet rich plasma, 30 months postoperative followup anteroposterior (f) and frog leg lateral views of (g,h) both hips showing healing changes (i) 30 months followup postoperative magnetic resonance imaging showing healing changes

Radiologically, one hip at stage IIb progressed to stage III and one hip at stage III progressed to stage IV. Unchanged radiological appearance over the followup period was observed in three hips (7.5%), but with improvement in functional score and patient satisfaction. All other hips showed evident radiological signs of regeneration and sound healing.

Discussion

Although options to halt the progression of ONFH are available (e.g. core decompression, osteotomy, vascularized fibular graft and medical treatments), the results have been disappointing, with up to 40% of patients progressing to THA. There is no agreement on the best surgical method for ONFH. Conceptually, the best option is removal of the necrotic bone from the femoral head and replacement with a viable and structurally-sound bone, thus restoring vitality to the femoral head, preventing collapse of the articular surface and delaying THA.[29,30] Of the various treatment options available to avoid THA, core decompression, as described originally by Ficat *et al*.[31] and later by Mont *et al*.[2] is one of the most commonly used surgical treatments for

ONFH.[2,31] Core decompression may be a suitable option for stage I or IIA but the main problem is with more advanced stages, especially in young active patients. Most literatures about management of ONFH try to preserve the hip joint in early stages of the disease, but there is a debate on the efficacy of this treatment in advanced stages, especially with articular damage.[32-34]

The effectiveness of core decompression alone in preventing collapse in ONFH has been a major source of controversy.[35-39] A wide range of success rates has been reported for core decompression according to Mont *et al*.[40] 63.5% of 1166 hips achieved a satisfactory clinical result after core decompression.[40] A retrospective review described a technique that utilized a trephine approach to enter the area of necrosis under fluoroscopy and then inject concentrated bone-marrow directly into this area. It found excellent results in patients who were precollapse (stage I or II). However, in patients who had already collapsed (stage III or IV), 25 out of 44 hips required a THA.[23] Keizer *et al*.[41] described the long term results of core decompression and placement of a nonvascularized bone graft with 44% revision rate at a mean of 4 years.[41] These results were less satisfactory compared to the results of our technique who reported good to excellent results in 90% with a revision rate of 10% (four hips). On the other hand, our results may be comparable to some reported results with the use of vascularized fibular graft as reported by Zhao *et al*.[34] The procedure was successful in 90% at Ficat III. He also described a modified technique of tantalum rod implantation combined with vascularized iliac grafting for the treatment of ONFH stage II–IV. Their overall success rate of the entire group was 87.5%.[34] However, contrast of the others, Chen *et al*.[42] reported that the use of vascularized iliac bone grafting may not be as promising as originally suggested resulting 76% required THA.[42]

Since progenitor cells may be lacking in the lesion area, newer treatment modalities have been developed to introduce biologically active cells to the areas of necrosis in an attempt to prevent fracture and collapse by restoring the architecture of the femoral head. Hernigou and Beaujean[23] first described a technique for injecting mesenchymal stem cells combined with standard core decompression to introduce biological active cells into an area of necrosis, 23 patients with early (precollapse) disease had excellent results, only nine of 145 hips requiring THA. However, among patients who had stage III or greater (25 of 44) hips required THA.[23] This may clarify better results we obtained because of direct attacking of the pathology and removal of all necrotic segment as it has been demonstrated that biologically active cells may not be able to survive in the necrotic lesions, in addition to the use of collagen sheet as a scaffold that may increase the repairable capacity of PRP. Gangji *et al*.[20] reported that the addition of mesenchymal stem cell to core decompression was found to improve its results; he observed that the level of pain was significantly decreased from 37.8 ± 8.4 to 18.5 ± 6.2. This was comparable to our work, in which the average values were 78 ± 21 and 35 ± 19 at preoperative and final followup, respectively, with an average reduction of 43 points. Daltro *et al*.[43] assessed the efficacy and safety of autologous bone-marrow mononuclear cells implantation in necrotic lesions with a significant postoperative increase in the HHS (98.3 ± 2.5 points) compared to preoperative HHS (78.5 ± 6.2 points) ($P < 0.001$).[43] Our results found significant improvement in hip function with success rate 90% [27 hips (67.5%) had excellent results and nine hips (22.5%) had a good result] with improvement of HHS from 46.0 ± 7.8 preoperatively to 90.28 ± 19 postoperatively after 4 years followup.

A thorough review of the literatures, we found an old technique of treatment that may be similar to ours done by Merle D'Aubigné *et al*.[10] who used cancellous bone graft harvested from the iliac crest, have been used to fill the defect in the femoral head after complete evacuation of the necrotic bone.[10] These bone graft can be introduced through a cortical window in the femoral neck or via a "trapdoor" through the articular cartilage of the femoral head, after dislocating the femur head and exposing the flap from the chondral surface of the femur head. The necrotic segment is removed with curette and burr. The void is then filled with iliac crest bone graft. This was first performed in conjunction with an osteotomy by Ganz and Büchler.[44] Mont *et al*.[45] had reported their observations with this procedure in 24 Ficat stage III and six stage IV hips. With an average followup of 56 months, 73% their patients had good to excellent results.[45] Our results were much better than that recorded by Mont *et al*.,[45] although the similarity of both techniques that can be explained by the improvement of healing and positive reparable effect of PRP with collagen sheet scaffold that was used in our research.

There are some limitations to our study including small sample size and short term of followup. Accordingly, prospective, randomized, controlled studies with large sample size are necessary to verify the therapeutic effects of PRP. However, according to our present results, we are optimistic that this novel approach may lead to a successful outcome in the treatment of advanced stages of ONFH.

To conclude, in young active adult, the use of PRP with collagen sheet scaffold can increase the reparable capacity after adequate curettage and drilling of necrotic segment with the addition of bone graft in stage IIb and III ONFH.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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