Clinical trial on femoral head osteonecrosis: simple core decompression vs. core decompression and fibular allo-graft placement

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Abstract: Femoral head osteonecrosis is a progressive disease which affects the patients in the 3rd to 5th decades of their life. Improvement was reported in 50% to 80% of the patients after decompression and fibular graft placement. On the other hand, decompression success is in doubt by some surgeons reporting failure rate of 60% in pre-collapse and 100% in post-collapse stage. In this clinical trial study, patients with femoral head osteonecrosis Ficot stages of 1, 2 and 3 were included.15 patients in" simple decompression" group and 14 patients in "allograft" group. For decompression a single 8 mm track was drilled using an 8 mm trephine, for second group after decompression. In total, 29 patients with 44 hips were included in this study. Mean Harris hip score before trial was 47.5±7.1 in simple decompression group and 57.4±8.8 in fibular graft group. 3 months later it became 64.2±9.6 and 75.1±11.2 for these groups. At final follow-up Harris hip score reached to 77.1±11.8 for simple decompression and 89.3±12.9 for fibular allograft group.(p value= 0.0001). In the core compression group 13 hips (56.5%) showed no progression but in the fibular graft group 17 hips (80.9%) had no progression. With nonvascularized fibular allograft, there would be no donor site morbidity as well as simple and reproducible technique with shorter surgery time. In our study, improvement of more than 20 in Harris Hip Score (HHS) was considered as clinical improvement. Moreover, to the last follow up, 81% of the patients in fibular graft group remained constantly in a same stage as before surgery which is comparable to 56% of the patients in simple compression.

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1. Introduction

Femoral head osteonecrosis is a progressive disease which affects the patients in the 3rd to 5th decades of their life (1). Improvement was reported in 50% to 80% of the patients after decompression and fibular graft placement (2). Advancement in microsurgical technique facilitates vascularized fibular graft placement with more encouraging results which accounts for 80% to 91% success rate (3).

Based on the literature, lower stage of involvement shows more expectable response to decompression. A report on decompression surgery resulted in 100% satisfaction in stage 1, 19% in stage 2A and 0% in stage 2B and above. Moreover, Pawel et al reported 67% good to excellent results in Ficot stages 1 and 2 on 18 patients with high risk collagenvascular disease affected by steroid treatment (4). On the other hand, decompression success is in doubt by some surgeons reporting failure rate of 60% in pre-

collapse and 100% in post-collapse stage. According to Christine et al, decompression technique was failed in 12 out of 18 patients affected by Ficot stage 2B (5).

Reviewing the current literature, supports the central decompression for Ficot stages 1 and 2B and for small central lesions in young, non-obese patients who are not under steroid influence. For higher Ficot stages (2B and 3), the results of decompression are less predictable; therefore, alternative treatments should be considered (6). Successful treatment was reported in 50-80% of patients after cere decompression and fibular graft placement (7, 8). Keizer et al investigated on nonvascularized cortical graft; in their study on 85 hips, tibial cortical autograft in 18 hips and fibular allograft in 62 hips were tried. They reported comparable results of tibial autograft due to the better quality of bone suggesting a simple and extra-articular technique (9, 10). We aimed to evaluate the results of core decompression and fibular

graft placement in patients with femoral head osteonecrosis in different stages of the disease (Table 1).

Table 1. Gender of the patients

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Gender	Number (%)
Male	21 (81.9)
Female	8 (18.2)

Table 2. Head involvement in AVN of the femur.

Amount of femoral head involvement	Quantity (hips)
One quadrant	9 (20.5%)
Two quadrant	16 (36.4%)
Three quadrant	17 (38.6%)
Four quadrant	2 (4.5%)
Total	44 (100%)

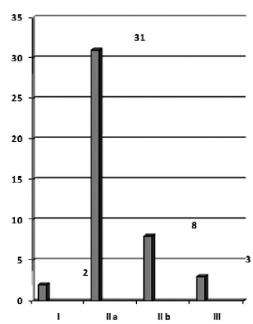


Diagram 1. frequency of patients according to Ficat classification system

2. Material and Methods

In this clinical trial study, patients with femoral head osteonecrosis referring to university hospitals from 2007 to 2010 were included. Clinical examination, plain x-ray and MRI were done for all of the patients to confirm the diagnosis. Ficot stages of 1, 2 and 3 were included. Patients with no chance of discontinuation of steroid treatment, traumatic osteonecrosis (due to hip fractures), patients who need arthroplasty for treatment were excluded as well as the patients who did not intend to participate in our study. In total, 29 patients with 44 hips were included. 15 patients in "simple decompression" group and 14 patients in "allograft" group. For decompression a

single 8 mm track was drilled using an 8 mm trephine, for second group after decompression. Surgical technique was explained for the patients and consent form was obtained. Our study was approved by IRB of our university. Patients had the opportunity to opt their treatment method. Patients were treated by either simple decompression or decompression and fibular alo-graft placement (Iranian tissue bank research and preparation center"ITB"®).

Demographic data and physical examination data were collected. Different questionnaires measuring outcome namely WOMAC index and Harris Hip Score were collected prior to surgery and 3 months after surgery as well. Patients follow up time was between 6 and 38 month after surgery. Data were gathered and analyzed by SPSS software version 11.5 (SPSS Inc., Chicago, IL, USA). At first, nonnormality of the data was tested by Kolmogrov–Smirnov test. Univariate statistical analysis was done by Mann–Whitney and multivariate statistical analysis was done by binary logistic regression.

3. Results

In total, 29 patients with 44 hips were included in this study. The mean age was 35.3 years with the minimum and maximum age of 18 and 60, respectively. 20 patients had bilateral and 9 unilateral involvement. Based on Ficat classification system there were 31 in stage 2a. (Diagram 1). The mean time since starting point of symptoms to seeking treatment was 7.1 6.2 ranged between 1 and 27 month. The mean follow-up period was 17.03±9.6 months (range between 6 to 38months). 19 patients (65.5%) had history of steroid using, 4 patients (13.8%) were under steroid and immunosuppressive drugs and other 6 (20.7%) had no known etiologic factor. Based on the femoral head involvement, 63% of patients with 3 or 4 quadrants involvement eventually underwent arthroplasty. But only 23.3% of the patients with 1 or quadrants involvement progressed arthroplasty (Table 2).

Mean Harris hip score before trial was 47.5±7.1 in simple decompression group and 57.4±8.8 in fibular graft group. 3 months later it became 64.2±9.6 and 75.1±11.2 for these groups. At final follow-up Harris hip score reached to 77.1±11.8 for simple decompression and 89.3±12.9 for fibular allograft group.

According to Harris hip score in the last follow-up, 36 hips had more than 20 units improvement (81.8%) and 8 hips (18.2%) had less improvement. In allograft group 95% (20 hips) showed more than 20 unit's improvements, but in the other group (core decompression) only 60.9% (14 hips) showed more than 20 unite improvement and in 8 hips (18.2%) was less. In the core compression

group 13 hips (56.5%) showed no progression but in the fibular graft group 17 hips (80.9%) had no progression.

Statistical analysis of Harris hip score before, 3 months and in last follow-up using Analysis Repeated Measure showed significant difference (p value= 0.0001). This score was also significant. Statically analysis of Womack, before 3 months and in last follow-up using Analysis Repeated Measure was significantly difference (p value= 0.0001). Comparison of the Last score in harris hip score of both groups using t test showed no significant difference (p value=0.3), also the mean was higher in fibular graft group.

4. Discussions

Femoral head osteonecrosis is one of a debatable topics in orthopedic surgery, yet after describing the pathophysiology still there is no consensus on the standard care and it's an interesting field of research as before. Approximately 20,000 numbers of new cases of femoral head osteonecrosis are being diagnosed annually in the US (11). Hip replacement is being done for the nearly young and active population, and since identical complications and revision rate are expected for this age range, preservation of natural head is of most importance. Indeed, the art of treatment is to avoid collapse of the head (12).

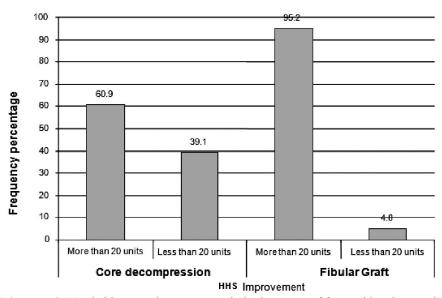


Diagram 2. Harris hip score improvement in both groups of femoral head necrosis

Ficot was done the first core decompression in 47 years ago which is still one of the most common surgeries for femoral head osteonecrosis. However, failure of treatment is not less common. In a study by Mount et al reporting the results of more than 1200 involved hips, success rate for Ficot stages 1 and 2 were 84% and 65%, respectively and even less with head collapse. In another study (8), Smith showed that success rate of core decompression would be declined significantly with the appearance of crescent sign (13). Steinburg also experienced less success in patients with collapsed femoral head rather than before collapse (7). On the other hand, combination of core decompression with the other surgical techniques such as osteotomies or graft placement showed promising results. Therefore, it seems that achieving better results in higher stages of involvement would be warranted by combining other techniques with core decompression (14, 15, and 16).

Vascularized fibular graft is an excellent option but accounting for 20% complication rate along with difficulty in microvascular technique and surgical time makes it less feasible. The largest cohort of patients with vascularized fibular graft were in Urbaniak's series with 103 patients which eventually 30% underwent total hip replacement (17, 18, 19, 20). For this reason, nonvascularized fibular graft is considered a simple substitute of vascularized one. This idea is also supported by studies that showed increased risk of collapse after simple core decompression which takes the support off of the superior subchondral bone. With nonvascularized fibular allograft; there would be no donor site morbidity as well as simple and reproducible technique with shorter surgery time. Moreover, better results would be obtained especially in stage 2b and some near collapse stage (21).

In our study, improvement of more than 20 in Harris Hip Score (HHS) was considered as clinical

improvement. In total 44 hips, we noticed 81% improvement by HHS; however, comparing two groups, we found a significant difference in which improvement was noticed in 95% of the fibular grafted patients rather than 60% in the simple core decompression. Moreover, to the last follow up, 81% of the patients in fibular graft group remained constantly in a same stage as before surgery which is comparable to 56% of the patients in simple compression (Diagram 2).

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