Clinical Sheet

OSTEONECROSIS OF THE FEMORAL HEAD: A CLINICAL TRIAL

A bone substitute paste was successfully used in conjunction with autologous bone tissue in the treatment of 19 patients.

From the Bioteck Academy Editorial Office

Osteonecrosis of the femoral head is the result of a pathological process characterized by insufficient vascularization of the bone tissue, which generally affects adults aged between 20 and 50. The lack of hematic perfusion, in turn, may have various causes, traumatic and non. Left untreated, the condition may go as far as to induce the collapse of the femoral head and the degeneration of the whole joint.
The treatment of this condition presents one of the greatest challenges for the orthopedic surgeon: firstly, because the disease is mostly asymptomatic in the initial stages, when simpler and less invasive treatments would have been possible. In addition, since the condition usually affects young people, the functional needs of the patient are very high. In more advanced forms, i.e. following the collapse of the bone, or in the presence of arthrosis, the main surgical option is the replacement of the hip (*Total Hip Arthroplasty, THA*).
A type of procedure that may be performed even in advanced stages of the condition, and which does not involve total replacement with a prosthesis, is the FVFG technique (*Free Vascularized Fibular Grafting Technique*). The technique consists in the removal of the necrotic bone tissue and in the placement of a vascularized autologous graft obtained from the fibula, which may be accompanied by a further autologous and/or heterologous non-vascularized bone graft.

Materials

In this case, the patients were treated with a bone substitute paste (Osteoplant Activagen Injectable Paste, Bioteck), composed of demineralized bone matrix (DBM) obtained from equine cortical bone dispersed in a collagenic carrier. The graft is obtained thanks to an enzymatic process that eliminates antigens (Zymo-Teck process), followed by the complete demineralization of the equine bone tissue. This last step makes the bone collagen contained in the tissue immediately available, enhancing its biological benefits, such as the function as coactivator of endogenous growth factors[1] and as substrate for osteoblast cell adhesion[2].

Activagen Injectable is an injectable bone paste: its consistency allows it to be easily molded into the desired shape. Its collagen constituents further promote adhesion when they come into contact with blood.

The bone paste is used together with autologous cancellous bone obtained from the greater trochanter in combination with the vascularized fibula graft.

1. Regazzoni C, et al. Type I collagen induces expression of bone morphogenetic protein receptor type II. Biochem Biophys Res Commun, 283, (2), 316-322 (2001).
2. Liu G, et al. Effect of type I collagen on the adhesion, proliferation, and osteoblastic gene expression of bone marrow-derived mesenchymal stem cells. Chin J Traumatol, 7, (6), 358-362 (2004).

Fig. 1 *– The Osteoplant Activagen Injectable Bone Paste.*

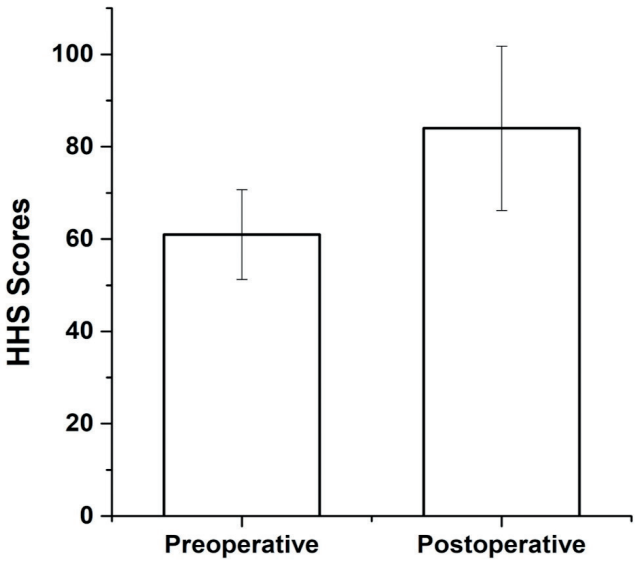

Fig. 2 *– The increase in postoperative functionality, measured on the HHS scale, is statistically significant.*

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Results

The sheet summarizes the results of a retrospective trial, published in 2016[3], in which 19 patients underwent the FVFG procedure (bi- or unilaterally, for a total of 26 hips). The patients presented with osteonecrosis of the femoral head at stage 2 or 3 of the FICAT scale. Following the procedure, X-rays of the patients were taken to observe the formation of new bone tissue. The functional outcomes were evaluated using the Harris Hip Scores (HHS) scale.

All patients were operated by a team of expert microsurgeons: the treatment involved the insertion of the fibular vascularized autologous graft and of the mixture composed of autologous bone tissue obtained from the greater trochanter and of the Bioteck bone graft paste.

In the case of 3 patients, the procedure was not sufficient to halt the progression of the condition: they subsequently underwent the THA procedure. The remaining 16 patients, however, did not suffer any intra- or postoperative complication; in all cases, there was a statistically significant increase in the functional scores measured on the HHS scale (from 61 ± 9.7 to 84 ± 17.8). X-rays showed the formation of new cancellous bone tissue on the point of the fibular bone graft in all patients.

The results of this trial showed that the use of the Bioteck bone graft completely filled the cavity resulting from the removal of the necrotic bone tissue. Not only would the autologous bone graft obtained from the greater trochanter not have been sufficient for this purpose, but the removal of an excessive quantity would have increased the risks of a femoral fracture. The authors confirm, instead, that the high survival rate, also in cases of extensive lesions, may be linked to the use of the bone substitute.

3.Unal MB, et al. Treatment of osteonecrosis of the femoral head with free vascularized fibular grafting: Results of 7.6-year follow-up. Acta Orthop Traumatol Turc, 50, (5), 501-506 (2016).

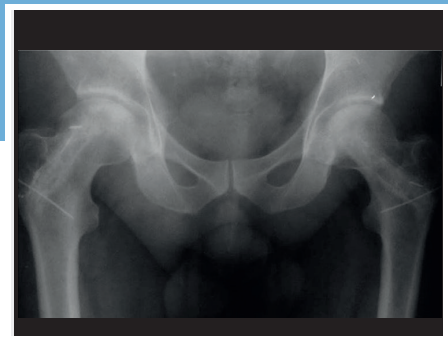

Fig. 3 *– X-ray in the sixth year of follow-up of a patient who was operated at stage 2 of the condition.*

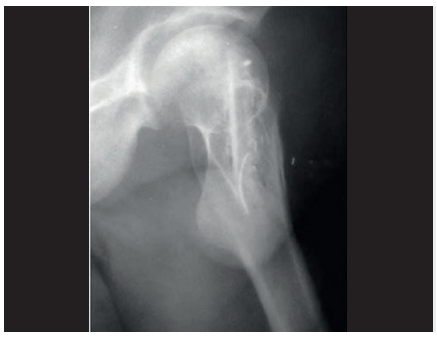

Fig. 4 *– X-ray in the sixth year of follow-up of a patient who was operated at stage 2 of the condition.*

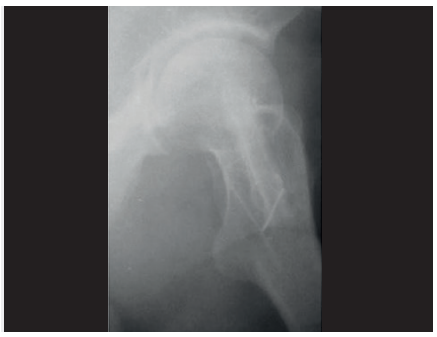

Fig. 5 *– X-ray in the sixth year of follow-up of a patient who was operated at stage 2 of the condition.*

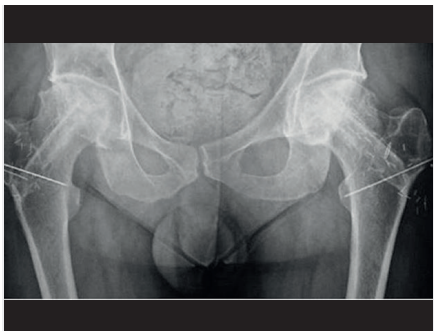

Fig. 6 *– X-ray in the seventh year of follow-up of a patient who was operated at stage 3 of the condition.*

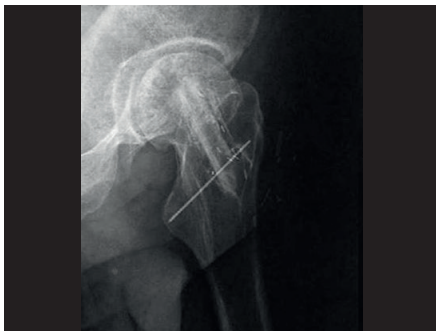

Fig. 7 *– X-ray in the eighth year of follow-up of a patient operated at stage 3 of the condition.*

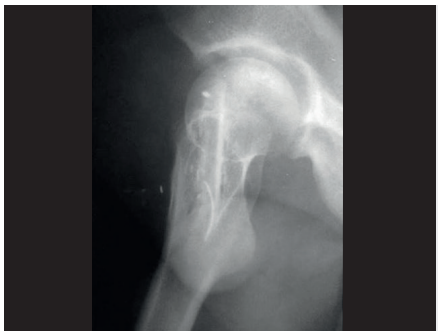

Fig. 8 *– X-ray in the eighth year of follow-up of a patient operated at stage 3 of the condition.*

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