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Case Report

Refractory humeral non-union: treatment with photodynamic intramedullary implant IlluminOss® and internal fixation

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Abstract. Surgically treated humeral shaft fractures can develop into pseudoarthrosis (PSA). Even if PSA is treated according to the proposed literature, refractory non-union of the humerus can be determined. Due to the rarity of this condition, we report our experience in the management of refractory pseudarthrosis of the humerus at the IRCCS Galeazzi Orthopedic Institute (Milan, Italy). We used internal fixation with plate and screws associated with the implant of the IlluminOss® Photodynamic Bone Stabilization System to increase bone stability and improve anchoring of the implant medium. This combined treatment allowed the consolidation of the complex fracture despite the bone loss, ensuring excellent stability of the fracture stumps and constituting a flexible and stable system with the most favourable biomechanical conditions. An increase in refractory PSA cases is likely in the future, due to a higher incidence of surgically treated humeral shaft fractures than in the past. Further studies on the effectiveness of the combined use of plate and screw and the IlluminOss® system will be indispensable. (www.actabiomedica.it)

Key words: non-union, intramedullary implant, refractory humeral non-union, pseudoarthrosis, IlluminOss®, humeral shaft fractures.

Introduction

Humeral shaft fractures represent 3% of all fractures and occur with an incidence of 13 per 100,000 per year (1).

The treatment options available for the management of humerus fractures include simple immobilization, placement of percutaneous Kirschner wires, stabilization with intramedullary nail and open reduction and internal fixation with plate and screws.

The choice of treatment is based on the severity of the fracture, the degree of comminution and bone loss, the patient's age, and functional requirements.

Complications of humeral shaft fractures includenon-union, paralysis of the radial nerve, postoperative infection, mobilization and breaking of surgical implants (2).

Pseudarthrosis (PSA) occurs when reparative phenomena do not occur correctly in a fractured bone due to lack of blood supply, described as atrophic PSA, or due to lack of adequate stability between the fracture stumps, forming hypertrophic pseudarthrosis (3,4).

The Food and Drug Administration (FDA) defines nonunion as a fracture of at least 9 months that has shown no radiological signs of healing for 3 consecutive months (3).

Non-union rate of humeral shaft fractures after surgery has a variable incidence between 2.5 and 13% (5,6).

There are many scientific articles on the different methods of managing non-union in humeral shaft fractures after a failed first surgical treatment (7-9). However, there are few studies on the treatment of refractory nonunion, which occurs after the failure of more than one surgery.

We report our experience atthe IRCCS Orthopaedic Institute Galeazzi (Milan, Italy), in the management of a patient with refractory humeral non-union after the failure of several surgical procedures. Our treatment choice was to use internal fixation with plate and screws associated to the implantation of the IlluminOss® Photodynamic Bone Stabilization (PBS) system (IlluminOss Medical INC, East Providence, Rhode Island, USA) to increase bone stability bone and improve the anchoring of theimplantation media.

Case report

A 60-year-old patient suffering from hypercholesterolemia and arterial hypertension, after an accidental fall with direct trauma to the left arm, went to the emergency room of a first hospital. After appropriate clinical-instrumental examinations, a fracture of the humeral shaft was diagnosed, in the absence of peripheral vascular-nerve deficits. The patient was surgically treated with an intramedullary nail to reduce and stabilize the fracture. However, the synthesis performed did not achieve adequate stability to the fracture fragments and a gradual evolution into atrophic pseudarthrosis occurred. A second surgical step was then opted at the same hospital, the intramedullary nail was removed, and a new fixation was performed with Kirchner wires and metal cerclages. However, also this operation failed, the consolidation of the fracture did not occur with a further evolution towards an atrophic pseudarthrosis, and painful-dysfunctional symptoms persisted.

The patient arrived atthe IRCCS Orthopaedic Institute Galeazzi 16 months after the trauma and in the middle of the Sars-CoV-2 pandemic. The semeiological findings consist of an alteration of the anatomical profile of the arm, with evident signs of preternatural motility at the level of pseudarthrosis, conspicuous scars due to previous surgeries, and the absence of peripheral vascular and nervous deficits. The patient reported a reduction in quality of life quantified with Disability of the Arm, Shoulder and Hand (DASH) score of 81.7 / 100. Radiographic investigations were performed which revealed loosening of the cerclage, mobilization of the Kirschner wires and angulation of the fracture stumps (Figure. 1).

The loosening of the implants and the displacement of fracture stumps were further defined by CT investigation. This exam also revealed diffuse areas of osteolysis on the bone fragments with the presence of nonuniform peri-skeletal tissues (Figure. 2).

After the evaluation of preoperative imaging, considering the functional needs of the patient, the anatomical situation, the poor quality of the bone tissues, the loss of bone substance at the fracture site able to compromise the stability of the synthesis, it was decided to combine an extramedullary device as plate and

Figure 1. X-ray in antero-posterior projection of the left humerus with evident axial displacement of the diaphyseal fracture abutments, with mobilization of osteosynthesis implants.

Figure 2. Coronal CT- scan of left arm showing the mobilization of the Kirschner wires and the areas of osteolysis (arrows).

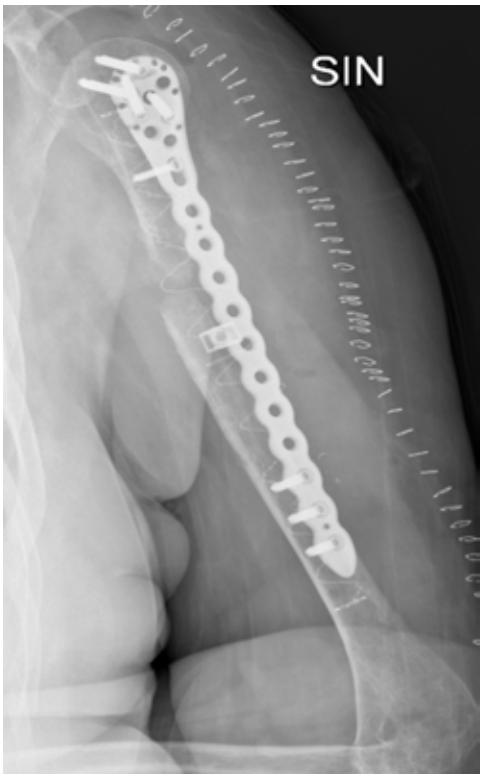

Figure 3. X-ray of the left humerus after implantation of the plate and screw and the IlluminOss® system.

screws with IlluminOss®PBS system a photodynamic intramedullary implant to increase bone stability and improve plate anchoring.

A trans-deltoid surgical approach distally extended with a trans-bicipital approach was performed. The dissection of the soft tissues was performed until reaching the bone plane, where the implants previously used were identified at the level of the pseudarthrosis and then removed. Intraoperatively, reduced callus formation was found in the PSA focus. The presence of thin shoots of loose fibrous tissue in the interfragmentary space was associated with the loss of bone substance of the fracture stumps which also appeared sclerotic.

The IlluminOss® guide wire was positioned inside the medullary canal through the humeral head and reamedto prepare a pathway for the implant. After determining the canal diameter and length of the balloon catheter size, the definitive IlluminOss® catheter (8mm × 160 mm) was insert, pressure-filled with photodynamic monomer according to the product technique, and its photopolymerization was performed using the Photodynamic Curing System.After completion of the curing cycle for the IlluminOss® implant, supplemental fixation has been performed with the use of cross-locking cortical screws through the IlluminOss® implant.Then a 12-hole Axsos3® Proximal Humeruslong plate with screws (Stryker Corporation, Kalamazoo, Michigan, USA) and Ortholox® UHMWPE Cerclage Band System (Ortolog Medikal Sanayi ve Ticaret A.S., Ankara, Turkey)were applied (Figure. 3).

At the post-operative follow-up (FU), forty days after surgery, the patient reported an improvement in quality of life calculated with a DASH score of 70/100 and a significant reduction in pain. Clinically, the patient presented a eutrophic scar with limited range of motion (ROM) of the shoulder in internal rotation and at maximum degrees of flexion and abduction, in the absence of objective peripheral vascular and nervous deficits. The subsequent medical visits were performed during the pandemic period that has passed

up to 1 year of FU, through telemedicine, which was proved to be a valid tool suitable for reducing the risk of SARS- CoV-2 infection and septic complications, simplifying the patient's care relationship (10,11).

Informed consent to participate in the study was granted by the patient, pursuant to an agreement to publish all the necessary information.

Discussion

The most common cause of failure in humeral shaft fractures surgical treatment is the inadequate internal fixation, lacking sufficient stability of the fracture stumps (12,13). For this reason, we believe that the type of synthesis chosen in the second surgery is inadequate. For the treatment of PSA, we believe that the most appropriate treatment is the complete removal of the interposed necrotic tissue, the remodelling of the bone fragments and the restoration of the stability of the fracture site by osteosynthesis with plate and screws associated with cortico-cancellous grafts to increase mechanical stability of the synthesis.

Surgical treatment of refractory PSA of these fractures is a complex condition due to its complicationsand the risk of surgical failure. In the literature there are several treatments proposed for the treatment of PSA, although there is no consensus in the literature regarding the most effective treatment (14-19).

In a meta-analysis by Peters et al. it is noted that plate and screw fixation combined with autologous bone graft appears to achieve the highest union rates combined with a relatively low complication rate. However, also external fixation has been shown to lead to high union rates (20). Several articles have focused on complex surgical techniques for managing persistent nonunion after two or more surgeries. Hornicek et al. described the combined use of cortical bone plates and bone grafts to achieve healing in six patients with diffuse osteopenia and refractory nonunion following two failed surgical procedures (21). Patel, instead, used Ilizarov circular external fixator on 16 patients, with an average of 2.6 previous surgeries, with fracture consolidation achieved in 15 of 16 cases (22).

A study by Gaillard et al. conducted on 15 patients with refractory PSA, treated with induced membrane technique, documented the pseudarthrosis healing in all patients (23).

There have been no scientific articles in the literature describing refractory pseudarthrosis of the humerus, treated with IlluminOss® photodynamic intramedullary implant and internal fixation with plate and screws. Plate and screws fixation can be used together the photodynamic nail, increasing the stability of the fracture and fixation.

In our opinion, this combined treatment offers many benefits. It made possible to obtain the consolidation of complex fracture of the humeral shaft which have been evolved into PSA, despite the great bone loss present, ensuring excellent stability to the fracture stumps, constituting a flexible and stable system, in presence of the most favourable biomechanical conditions for PSA focus consolidating.

In conclusion, the combined use of plate and screws and a photodynamic intramedullary implant IlluminOss® represents a good treatment in cases of refractory pseudoarthrosis of humeral shaft after failure of other surgical procedures.

The main advantages of this method are the reduction of morbidity, a flexible stabilization but enough rigid to guarantee a correct stability of the fracture stumps, allowing adequate healing.

The possible risk of iatrogenic radial nerve injury should be considered during the procedure, recommending any appropriate and careful prevention strategy.

An increase in refractory PSA cases is likely in the future, due to a higher incidence of surgically treated humeral shaft fractures than in the past. Further studies on the effectiveness of the combined use of plate and screw and the IlluminOss® system will be indispensable.

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