Acta Biomed 2022; Vol. 93, N. 2: e2022062 DOI 10.23750/abm.v93i2.11924

Original article

Preliminary report in treatment of proximal humeral fracture with closed reduction and DOS external fixation System: a multicentric study

Gabriele Scaravilli[1], Jacopo Mercurio[1], Antonella Grazioli[1], Carmine Gioia[1], Antonio D'Arienzo[2], Giuseppe Toro[3], Nicolò Galvano[4], Giuseppe Monteleone[5], Giuseppina Battaglini[5], Fabio Di Santo[6], Salvatore Sepe[7], Salvatore Pagliuca[8], Enrico Cesarano[1], Giuseppe Mastrobuono[1], Michele Italiano[1], Michele D'Arienzo[4], Pietro Maniscalco[9], Corrado Ciatti[9], Bruno Di Maggio[1]

[1]Orthopaedic and Trauma Unit, Piedimonte Matese Hospital, ASL CASERTA, Italy; [2]Department of Orthopaedic and Trauma Surgery, University of Pisa, Italy; [3]Orthopaedic and Trauma Unit, Sarno Martiri Di Villa Malta Hospital, ASL Salerno, Italy; [4]Department of Orthopaedic Surgery, University of Palermo (DiChirOnS), Palermo, Italy; [5]Orthopaedic and Trauma Unit, Napoli S. Paolo Hospital, ASL Napoli1 Centro, Italy; [6]Orthopaedic and Trauma Unit, AORN Cardarelli, Napoli, Italy; [7]Orthopaedic Clinic CTO, University of Florence, Florence, Italy; [8]Orthopaedic and Trauma Unit, Napoli S. Giovanni Bosco Hospital, ASL Napoli 1 Centro, Italy; [9]Department of Ortopedia and Traumatologia - Ospedale Civile "Guglielmo da Saliceto", Piacenza, Italy

Abstract. *Introduction:* Proximal humerus fractures are the seventh most frequent fracture in adults, and the third in patients over 65 years old, 5.7% of whole diagnosed fractures. Most of these fractures can be treated conservatively and achieve good results. However, more and more frequently we are confronted with dislocated and multifragmentary fractures, and with elderly and high functional demanding patients. In patients with osteoporosis and poor general conditions external fixation can be performed as rapid and mininvasive procedure with good outcome and low complication rates. The authors investigated the use of external fixation in the treatment of proximal humerus fractures. The objective is to demonstrate the effectiveness of this method as a valid alternative to other surgical techniques. *Materials and Methods:* A multicentre study was conducted at 7 hospitals in Italy from 2014 through 2018. We recruited all proximal humeral fractures (as classified with the Neer system) that are surgically treated with the same external fixator DOS, for a total of 110 patients, evaluated later with Oxford Shoulder Scale (OSS) and disability of the arm, shoulder and hand score (DASH) at 1, 2 and 6 months. *Results:* The patients have passed from a score of 75,37 in the first month to a score of 29,47in the sixth month at the DASH and from 47,02 to 27,71 at the OSS. The data further confirm the increased incidence of these fractures in women and in a mean age of about 65. *Conclusions:* Although it does not represent the golden standard in the treatment of fractures of the proximal humerus, in our experience the minimal osteosynthesis with external fixator turned out to be a very valid help especially for the simplicity and speed of the method, as well as for the exciting functional results. sometimes superior to other methods. The preliminary results from the different centers have confirmed this hypothesis. We hope this will be a good starting point for further in-depth studies**.** (www.actabiomedica.it)

Key words: Humeral fracture, External Fixation, Multicentric, Shoulder, Osteoporosis, DOS

Introduction

Proximal humerus fractures are the seventh most frequent fracture in adults, and the third in patients over 65 years old, 5.7% of whole diagnosed fractures. Humerus fractures have a seasonal pattern, that increase during the winter period (1). In young people, these fractures are observed in high-energy trauma (traffic accidents or sports injuries), while in elderly patients, with osteoporotic bone, they can be observed even in a low-energy trauma, like a trivial fall to the ground (2). Proximal humerus fractures are classified into 4 types based on Neer's classification, which is the most commonly used classification for the proximal humerus fracture. It includes greater tuberosity, surgical neck, 3-part, and 4-part fragment fractures. The greater tuberosity fracture represents the 1 fragment fracture, and the surgical neck fracture represent 1 displaced fragment. A 3-part fracture was defined as 2 displaced fragments, while a 4-part fracture was defined as having 3 or more displaced fragments from the proximal humerus (3). Most of these fractures can be treated conservatively and achieve good results. This is especially valid for compound fractures and for patients with low functional demands. (4) However, more and more frequently we are confronted with dislocated and multifragmentary fractures, and with elderly and high functional demanding patients. Obviously in these cases the treatment becomes surgical. In multi-fragment fractures, the most common treatment is open reduction and internal fixation. The commonly used solutions are represented by intramedullary nails and locking plates. The plates give a good result, but they are not free from risks and complications (5). Furthermore, trying to achieve an optimal reduction, it happens to devascularize small bone fragments, with high risk of non-union or retard in consolidation (6). On the other side, the intramedullary nails have undoubted biomechanical advantages, but they also present complications, such as not obtaining optimal reductions and occasional rotator cuff damage (7). Other kinds of surgical treatment include percutaneous k-wires, cannulate screws, Cage, External fixator, prosthetic replacement (8,9). The gold standard in treatment of displaced multifragmentary proximal humeral fractures in the elderly is still controversy. In literature are reported as many articles on the advantages of each single technique, as many articles on the complications of the same techniques (10). There is no consensus regarding which is the best treatment especially for three- or four-part fractures. Frequently, we observe three- or four-part fractures in elderly patients with osteoporosis. Osteoporosis itself becomes a primary problem, as it limits the tightness of screws in the bone (11). In patients with osteoporosis and poor general conditions external fixation can be performed as rapid and mininvasive procedure with good outcome and low complication rates (12). Overall, the trend has been to move away from the schemes of classification of fractures and to focus more on the characteristic and patient expectations. This preliminary report investigated the use of external fixation in the treatment of proximal humerus fractures using DOS by Gexfix, that was born as evolution of the TGF System (9). This preliminary study reports the results of the different centers in Italy that first began to use it and anticipates further studies that will follow this.

Materials and Methods

A total of 110 patients (74 women and 36 men) with a mean age of 65,17 years (range 40min.–86max years) with displaced proximal humeral fractures recruited in the study, from January 2014 to December 2018. 58 from Orthopaedic and Trauma Unit, Piedimonte Matese Hospital, 20 from Department of Orthopaedic Surgery, University of Palermo (DiChirOnS), 11 from Orthopaedic and Trauma Unit, Napoli S. Paolo Hospital, 6 from Orthopaedic and Trauma Unit, AORN Cardarelli, 6 from Orthopaedic and Trauma Unit, Nola Santa Maria della Pietà Hospital, 5 from Orthopaedic and Trauma Unit, Sarno Martiri Di Villa Malta Hospital, 4 from Orthopaedic and Trauma Unit, Napoli S. Giovanni Bosco Hospital. The inclusion criteria included all proximal humeral fractures (as classified with the Neer system) that are surgically treated with the same external fixator. The same external fixator and surgical technique was used to all patients. The mechanism of injury for all patients was irrelevant. A total of 66% of cases were two-part fractures and 34% were three-part fractures. The removal of the external fixator was performed with a mean of 41,92 days.

Surgical Technique

The operation is performed in General Anaesthesia. The patient is placed on the operating table in a "beach chair" position at 30° with flexed knees. The shoulder in in retropositioning in order to better externalize the surface of the humeral head. Fluoroscopy is positioned so as not to hinder the reductive and osteosynthesis manoeuvres. The reduction of the fracture is obtained by pulling and intra or extra rotate the arm. If that is not enough, it can be used a K-wire and/or a small access for introducing instruments. Placement of the first Kirschner wire is anterior to the Acromion and laterally to the throchite, so as to pass the wire more centrally to the fragment of the head. The second Kirschner wire must cross the first forming a sort of "X" in the Diaphyseal channel. It can be eventually used a third or more wires according to the needs to better reduce the fracture. Then, with the hand drill it can be inserted the first self-drilling self-tapping pin on the humeral diaphysis. The second pin take place distally on the humeral shaft at a distance of 3 or 4 centimetres from the first. Now it can be connected the DOS. It consists of a telescopic carbon bar, which connects the wires and the pins. The carbon telescopic bar is the basic element. The system is formed by a long arm of 18 cm, short arm of 11 cm on which a small bar of 9 cm is inserted forming a T (adjustable), on which the K-wires are fixed. The short bar is inserted into holes present on the top of the telescopic bar oriented to 125/130° (depending on the thickness of the patient's shoulder) The bar is adjustable by a central cursor, which can be rotated favouring the compaction or distraction, in order of 1.4 cm more or less, representing an advantage for the orthopaedic who, after stabilizing the fracture under radioscopic control, can further refine the reduction.

Postoperative care and Follow Up

Patients performed a radiographic examination immediately after the surgical procedure. Wound dressings of the skin passages of wires and pins were

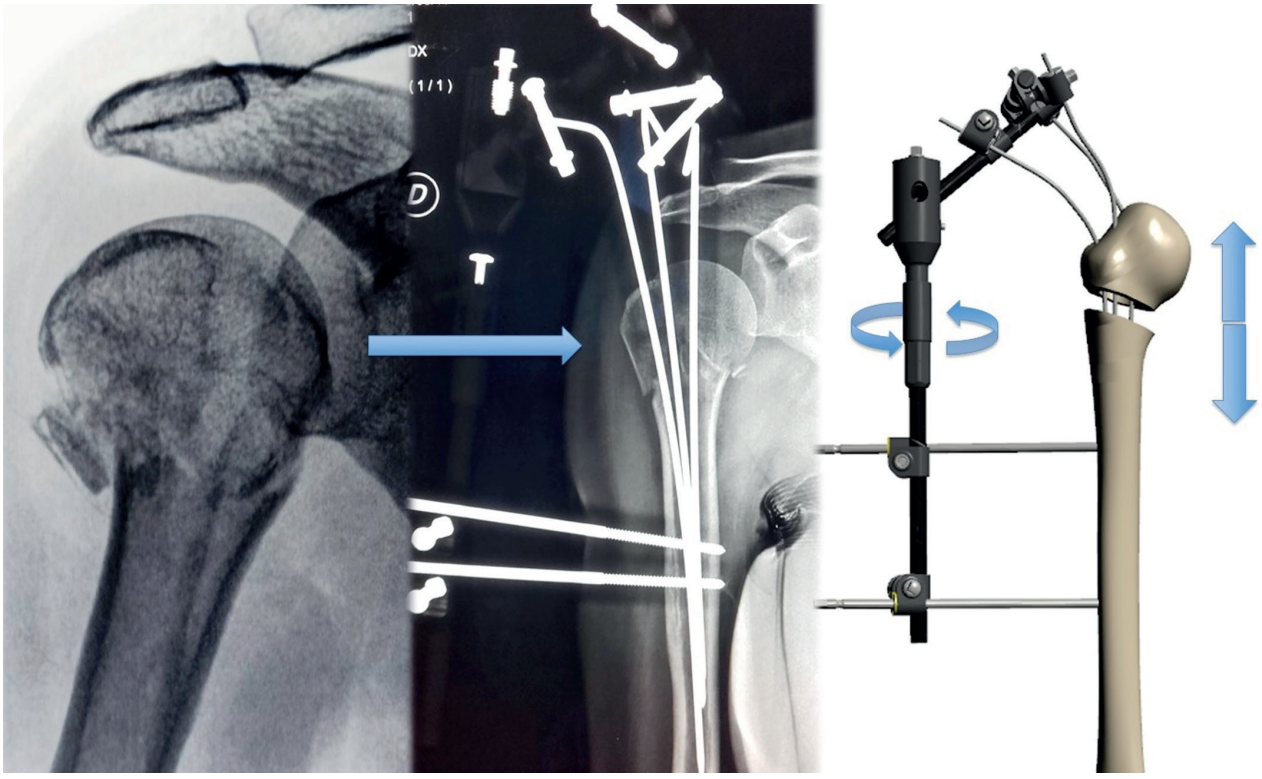

Figure 1.

performed on alternate days. Four hours after surgery, the patient began the initial rehabilitation program. Visual clinical control was performed every 7 days, including the assessment of pain. A new radiographic control was performed after 30 days. After 6 weeks (with a range between 5-8) the fixator, wires and pins were removed without anaesthesia with an outpatient procedure and was performed a radiographic examination. After removal, an additional dressing of the skin passages was performed at 7 days. Patients were assessed with the disability of the arm, shoulder and hand (DASH) score and Oxford Shoulder Scale (OSS) at 1 month, 2 months and 6 months after surgery (13,14). The union, documented with radiographic follow ups, was obtained in all cases, even if the reduction was not optimal in some of them.

Results

As shown in Table 1, the results obtained, assessed with the DASH and the OSS have been satisfactory, from the first month, with an improvement trend up to sixth month. Moreover, the data are comparable between the two evaluation scales.

The patients have passed from a score of 75,37 in the first month to a score of 29,47 in the sixth month at the DASH and from 47,02 to 27,71 at the OSS. No cases of bone infection and/or non-union have been reported. The pain remained always at acceptable levels, however controllable with over-the-counter analgesic drugs. These results indicate a good functional recovery of the joint. Almost all patients are satisfied with the result. Being able to see the limb moving right after the operation is a great help for the patient who begins the rehabilitation with more optimism. The data further confirm the increased incidence of these fractures in women and in a mean age of about 65.

Discussion

Even if hemiarthroplasty is accepted as the treatment of choice for 4-part fractures, especially in elderly patients, different techniques are currently performed for the treatment of 2- and 3-fragment fracture (15). The use of external fixation in 3 or 4-fragment fractures allowed us to perform a minimal surgical osteosynthesis procedure in patients often suffering from comorbidities that contraindicated invasive surgical operations. For example, it was possible to treat patients with severe cardiac or systemic diseases who were usually treated conservatively due to the increased risk of mortality due to open surgery, regardless of the

Table 1. Data collected from 7 surgical centers in Italy

Surgical Center	Patients	Left	Right	Male	Female	Mean Age (Min-Max)	Removal Day	DASH 1M	DASH 2M	DASH 6M	OSS 1M	OSS 2M	OSS 6M
Piedimonte Matese Ave Gratia Plena	58	28	30	15	43	66,16 (40-86)	43,05	65,45	48,12	31,83	41,82	32,96	20,73
University of Palermo	20	8	12	7	13	69,15 (44-82)	43,6	77,81	56,81	35,9	43,5	29,7	24,3
Napoli S. Paolo Hospital	11	6	5	7	4	63,09 (52-85)	41,45	78,65	57,32	34,76	48,45	37,54	22,45
Napoli AORN Cardarelli	6	4	2	1	5	65 (54-74)	41	74,58	52,24	29,74	48,6	37,6	20,16
Nola Santa Maria della Pietà Hospital	6	4	2	2	4	62,1 (59-81)	41,83	75,95	60,49	31,58	48,83	36,83	21
Sarno Martiri Di Villa Malta Hospital	5	3	2	2	3	66 (55-74)	41,25	77,56	23,9	7,68	48,45	37,54	24,3
Napoli S. Giovanni Bosco Hospital	4	2	2	2	2	64,75 (64-72)	41,25	77,56	59,16	34,78	49,5	35,75	19,05
Cumulative of the study	**110**	**55**	**55**	**36**	**74**	**65,17 (40-86)**	**41,92**	**75,37**	**51,15**	**29,47**	**47,02**	**35,42**	**21,71**

functional outcome. The management of displaced proximal humeral fractures in the elderly remains controversial. Before surgery, it is useful to perform a CT Scan exam (16). Often the only x-ray, although in most projections, are not able to clarify the true nature of the fracture and the position of all the fragments.

The surgical procedure was often performed in emergency in polytrauma, to allow a rapid and effective temporary stabilization of the fracture with nerve vascular compression, in order not to interfere with the execution of further emergency surgical procedures. This stabilization, born as a temporary one, often turned into a definitive one, leading to the healing of the fracture without the need for further surgery.

Two operators are sufficient for the surgical technique. One to maintain the reduction obtained and one to introduce the K-wires. It is a percutaneous procedure that adopts surgical accesses with minor risks. It does not imply significant blood loss. The learning curve is relatively short. It is possible to customize the technique to the type of fracture using additional k wires, all of which can be connected to the DOS system. The presence of a cursor on the main bar allows to improve the reduction in distraction, avoiding the phenomenon of impaction of the head on the remaining distal humerus, an occurrence that often undermines the correct reduction. The system used in our study is composed of a proximal part that blocks the K wires and a distal part that connects to the fiches. In this way, elastic osteosynthesis is coupled to a rigid one, becoming a hybrid system. This system combines the rigid osteosynthesis that keeps the fracture stable, to the elasticity that allows those micro-movements that stimulate the healing of the fracture (17).

Mobilization starts practically immediately after surgery, with pendular movements of the humerus and with active and passive mobilization of the other joints of the upper limb in order to avoid muscle-tendon retractions which would lead to a longer functional recovery. In this way, the patient can immediately notice the progressive functional recovery. Pain is always no more than 5/6 according to the Numeric rating Scale (NRS) in the post-operative period, to become 2/3 after 48 hours of surgery.

The patient is discharged with prescription of frequent outpatient checks in the first 15 days. An external fixator management manual is also given, explaining what to do and how to behave in multiple situations. It is often explained to the patient not to be alarmed by the presence of secretion coming from the passage of the K wires. Frequently, leakage of a serious or serum-ematic fluid occurs which alarms the patient for fear of infection. This liquid comes from the subacromial bursa which is obviously the object of crossing by the K-wires (18). In this case it is advisable to perform dressings more frequently.

The radiographic controls are performed immediately after surgery, between the seventh and fourteenth day to verify the maintenance of the reduction. Subsequently, a check is performed between the thirtieth and the fortieth day, before removal. The results of this method were beyond expectations. If you could not always get exciting radiographic results and the reductions were not optimal, however the functional result has always been great, even compared to other surgical methods.

After removal, the patient is invited to intensify the physiotherapy program, adding elevation exercises. Evaluation scales have shown a steady growth over six months. In addition, the patients were increasingly motivated to perform physiokinesitherapy for the tangible improvement they experienced day after day (19). Removal is performed on an outpatient basis and often does not require important anaesthetic procedures.

The results showed that the use of external fixation is important in allowing early mobilization. It allows early counteract muscle retraction, with sometimes better functional outcomes compared with other surgical methods. The results confirm that the improvement is observed as early as one month after the removal of the fixator. Improvements continue from month to month, with excellent results 6 months after removal. In terms of pain, the patient observes an improvement already a few days after the operation. Other techniques of operative fixation can cause soft tissue disruption or accidental lesions of axillary nerve (20,21). It can increase the risk of avascular necrosis and non-union of the humeral head. Percutaneous fixation significantly reduces these risks. Minimal surgical dissection may allow for improved rehabilitation and range of motion. The main indication of the DOS system is three and four-part fractures. In some

cases, percutaneous screw can be used on the great tuberosity. Another important vantage of the external fixation. Additional indisputable advantage of the system is that it can be subsequently replaced by other surgical techniques. In fact, the temporary stabilization in emergency with the DOS does not preclude the possibility to implant a plate later. Similarly, the synthesis with the DOS does not preclude the future possibility of implanting a prosthesis. The system is extremely customizable.

An important limitation of this study consists in not comparing the results with those of patients undergoing other types of surgical treatments. From a first analysis the functional results of DOS would sometimes seem superior to other methods.

However, this data would require a greater in-depth analysis with a higher follow-up and with a comparison between fractures of the same classification. Analysing the data coming from several surgery centers, it is often possible to observe differences in the cataloguing of fractures, in the implementation of surgical technique and in follow-up. These differences can lead to errors collecting data and, finally, in the study. At the same time, it can represent a point of strength because forces us to constant comparison and collaboration with colleagues. We believe that a constant increase of cases, a refinement of the surgical technique, a follow-up longer and the comparison with standardized results in other surgical techniques can offer a better understanding of the validity and reliability of this method. It can be useful in future to compare a longer follow-up using external fixator with follow-ups relative to other technique.

Conclusions

Proximal humerus fractures are extremely common injuries. Although it does not represent the golden standard in the treatment of fractures of the proximal humerus, in our experience the minimal osteosynthesis with external fixator turned out to be a very valid help, especially for the simplicity and speed of the method, as well as from the exciting functional result, sometimes superior to other methods. Given the results obtained, we consider minimal osteosynthesis with the DOS fixator a surgical possibility, not alternative to the others, but like the others, very valid tool for the osteosynthesis, temporary or definitive, of proximal humerus fractures, especially at 2, 3 or more fragments.

Conflict of Interest: Each author declares that he has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article.

References

1. Horak J, Nilsson BE. Epidemiology of fracture of the upper end of the humerus. Clin Orthop Relat Res. 1975;(112):250–3. (PubMed)
2. Lind T, Kroner K, Jensen J. The epidemiology of fractures of the proximal humerus. Arch Orthop Trauma Surg. 1989;108(5):285–7. doi: 10.1007/BF00932316. (PubMed) (Cross Ref)
3. Neer CS 2nd. Displaced proximal humeral fractures. I. Classification and evaluation. J Bone Joint Surg Am. 1970 Sep;52(6):1077-89. PubMed PMID: 5455339.
4. Li Y, Zhao L, Zhu L, Li J, Chen A. Internal fixation versus nonoperative treatment for displaced 3-part or 4-part proximal humeral fractures in elderly patients: a meta-analysis of randomized controlled trials. PLoS One. 2013;8(9):e75464. (PMC free article) (PubMed)
5. Thanasas C, Kontakis G, Angoules A, Limb D, Giannoudis P. Treatment of proximal humerus fractures with locking plates: a systematic review. J Shoulder Elbow Surg. 2009;18(6):837–844. (PubMed)
6. Greiner S, Kääb MJ, Haas NP, Bail HJ. Humeral head necrosis rate at mid-term follow-up after open reduction and angular stable plate fixation for proximal humeral fractures. Injury. 2009 Feb;40(2):186-91.
7. Füchtmeier B, May R, Hente R, et al. Proximal humerus fractures: a comparative biomechanical analysis of intra and extramedullary implants. Arch Orthop Trauma Surg. 2007;127(6):441–447
8. Yoon RS, Dziadosz D, Porter DA, Frank MA, Smith WR, Liporace FA. A comprehensive update on current fixation options for two-part proximal humerus fractures: a biomechanical investigation. Injury. 2014 Mar;45(3):510-4. doi: 10.1016/j.injury.2013.08.024. Epub 2013 Sep 7. PubMed PMID: 24168862.
9. Parlato A, D'Arienzo A, Ferruzza M, Galvano N, D'Arienzo M. Indications and limitations of the fixator TGF "GexFix" in proximal end humeral fractures. Injury. 2014 Dec;45 Suppl 6:S49-52. doi: 10.1016/j.injury.2014.10.023. Epub 2014 Nov 18. PubMed PMID: 25457319.
10. Kavuri V, Bowden B, Kumar N, Cerynik D. Complications Associated with Locking Plate of Proximal Humerus

Fractures. Indian J Orthop. 2018 Mar-Apr;52(2):108-116. doi: 10.4103/ortho.IJOrtho_243_17. Review. PubMed PMID: 29576637; PubMed Central PMCID: PMC5858203.
11. Sun Q, Ge W, Li G, Wu J, Lu G, Cai M, Li S. Locking plates versus intramedullary nails in the management of displaced proximal humeral fractures: a systematic review and meta-analysis. Int Orthop. 2018 Mar;42(3):641-650. doi: 10.1007/s00264-017-3683-z. Epub 2017 Nov 9. Review. PubMed PMID: 29119298.
12. Meselhy MA, Singer MS. Management of proximal humeral fractures by the Ilizarov external fixator. Arch Orthop Trauma Surg. 2017 Sep;137(9):1279-1284. doi: 10.1007/s00402-017-2749-0. Epub 2017 Jul 14. PubMed PMID: 28710670.
13. Booker S, Alfahad N, Scott M, Gooding B, Wallace WA. Use of scoring systems for assessing and reporting the outcome results from shoulder surgery and arthroplasty. World J Orthop. 2015 Mar 18;6(2):244-51. doi: 10.5312/wjo.v6.i2.244. eCollection 2015 Mar 18. Review. PubMed PMID: 25793164; PubMed Central PMCID: PMC4363806.
14. Dawson J, Rogers K, Fitzpatrick R, Carr A. The Oxford shoulder score revisited. Arch Orthop Trauma Surg. 2009 Jan;129(1):119-23. doi: 10.1007/s00402-007-0549-7. Epub 2008 Jan 9. PubMed PMID: 18183410.
15. Martin C, Guillen M, Lopez G. Treatment of 2- and 3-part fractures of the proximal humerus using external fixation: a retrospective evaluation of 62 patients. Acta Orthop. 2006 Apr;77(2):275-8. PubMed PMID: 16752290
16. Fisher ND, Barger JM, Driesman AS, Belayneh R, Konda SR, Egol KA. Fracture Severity Based on Classification Does Not Predict Outcome Following Proximal Humerus Fracture. Orthopedics. 2017 Nov 1;40(6):368-374. doi: 10.3928/01477447-20170925-04. Epub 2017 Oct 3. PubMed PMID: 28968473.
17. Hart NH, Nimphius S, Rantalainen T, Ireland A, Siafarikas A, Newton RU. Mechanical basis of bone strength: influence of bone material, bone structure and muscle action. J Musculoskelet Neuronal Interact. 2017 Sep 1;17(3):114-139. PMID: 28860414; PMCID: PMC5601257.
18. Kennedy MS, Nicholson HD, Woodley SJ. Clinical anatomy of the subacromial and related shoulder bursae: A review of the literature. Clin Anat. 2017 Mar;30(2):213-226. doi: 10.1002/ca.22823. Epub 2017 Feb 9. Review. PubMed PMID:28033656.
19. Aguado HJ, Ariño B, Moreno-Mateo F, Bustinza EY, Simón-Pérez C, Martínez-Zarzuela M, García-Virto V, Ventura PS, Martín-Ferrero MÁ. Does an early mobilization and immediate home-based self-therapy exercise program displace proximal humeral fractures in conservative treatment? Observational study. J Shoulder Elbow Surg. 2018 Nov;27(11):2021-2029. doi: 10.1016/j.jse.2018.04.001. Epub 2018 May 24. PubMed PMID: 29803503.
20. Hepp P, Theopold J, Voigt C, Engel T, Josten C, Lill H. The surgical approach for locking plate osteosynthesis of displaced proximal humeral fractures influences the functional outcome. J Shoulder Elbow Surg. 2008 Jan-Feb;17(1):21-8. Epub 2007 Nov 1. PubMed PMID: 17936024.
21. Khan LA, Robinson CM, Will E, Whittaker R. Assessment of axillary nerve function and functional outcome after fixation of complex proximal humeral fractures using the extended deltoid-splitting approach. Injury. 2009 Feb;40(2):181-5. doi: 10.1016/j.injury.2008.05.031. Epub 2008 Dec 18. PubMed PMID: 19100541.

Correspondence
Received: 21 June 2021
Accepted: 24 June 2021
Prof. Pietro Maniscalco
Department of Ortopedia and Traumatologia - Ospedale Civile "Guglielmo da Saliceto", Piacenza, Italy
E-mail: p.maniscalco@ausl.pc.it