ORIGINAL ARTICLE

Surgical treatment of multifragmentary segmental femur shaft fractures with ORIF and bone graft versus MIPO: a prospective control-group study

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ABSTRACT

Aim Multifragmentary segmental femoral shaft fracture is a high energy injury frequently associated with life-threatening conditions. The aim of this study was to compare the use of bio metallic open reduction internal fixation (ORIF) (plate with allograft bone strut) with minimally invasive plate osteosynthesis (MIPO) fixation for the treatment of multi-segmental femoral shaft fracture in terms of outcomes, bone healing and complications.

Methods Forty patients with segmental femoral shaft fractures were included and divided into two groups: 20 patients treated with ORIF+, 20 with MIPO. All fractures were classified according to AO (*Arbeitsgemeinschaft für Osteosynthesefragen*) and Winquist and Hansen Classification. Evaluation criteria were: duration of follow up and surgery, Non-Union Scoring System, Pain Visual Analogic Scale (VAS), objective quality of life and hip function, subjective quality of life and knee function, quality of life the Short Form-12 Survey Questionnaires (SF-12), bone healing and femoral alignment (radiographs), Radiographic Union Score for Hip (RUSH).

Results Better results of ORIF in terms of complication rate, RUSH, VAS, regression between RUSH and VAS, average correlation clinical-radiographic results and patients' outcomes (Cohen k) were obtained, and similar results for the length of follow up, surgery duration, perioperative blood transfusion, wound healing. No statistical difference for Harris Hip Score (HHS), Knee Society Score (KSS), quality of life (SF-12).

Conclusions The ORIF and bone strut allograft technique had better results compared to the MIPO technique with regards to complication rate, RUSH, VAS, regression between RUSH and VAS, and average correlation clinical-radiographic results and patients' outcomes (Cohen k) in the surgical treatment of multifragmentary segmental femoral shaft fractures.

Key words: allograft, bone strut, limb reconstruction, trauma, outcomes

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INTRODUCTION

Multifragmentary segmental femoral shaft fractures are high energy injuries frequently associated with life-threatening conditions (1). The common femoral shaft fracture incidence is 21/100,000 person/years (2). Non-operative treatment of femoral shaft fractures in adults is an exception (3). The concept of damage control in orthopaedics especially treating femoral fractures in polytraumatized patients is well established, but clear indicators of which patients benefit from this approach are missing (4).

Today intramedullary nailing of femoral shaft fractures is the gold standard of treatment. In a recent analysis comparing different treatment options in femoral shaft fractures, it could be clearly stated that intramedullary fixation was associated with the lowest complication rates and loss of reduction rates compared to external fixation or plating strategies (5). Plate osteosynthesis is particularly advantageous in certain situations where an intramedullary nail may be contraindicated or technically not feasible. These may include the polytrauma patient, ipsilateral femoral neck and shaft fractures, fracture in the proximal or distal shaft, paediatric femoral shaft fracture, or an excessively narrow intramedullary canal (6). Due to high complication rates with infection, refracture, delayed healing, non-union and soft-tissue problems, the concept of biological bridge plating (6) was developed with a minimally-invasive fixation technique (MIPO) in order to improve results and outcomes.

The aim of this study is to compare the use of biometallic fixation (plate with allograft bone strut) for the Open Reduction Internal Fixation (ORIF) with plate fixation with minimally invasive plate osteosynthesis (MIPO) for the treatment of multi-segmental femoral shaft fracture in terms of outcomes, bone healing and complications.

PATIENTS AND METHODS

Patients and study design

From a total of 120 femoral shaft fracture patients admitted and treated at five trauma centres (five Italian and one Spanish) from January 2016 to December 2019 we finally included in our study 40 patients with segmental femoral shaft fractures. Inclusion criteria were: patients admitted to our centre for surgical treatment of segmental femoral shaft fractures. Patients had to be fit for surgery, aged between 16 and 65 for males and 16 and 50 for females. Exclusion criteria were: haematological or oncological patients, acute or chronic infections, previous lower limb trauma, nerve injuries, segmental contralateral fracture, vessels injuries, non 3.2 type of fracture according to AO (*Arbeitsgemeinschaft für Osteosynthesefragen*) AO Classification (7), all Winquist and Hansen Classification's types, e. g. 0, I and II femoral shaft (8), age under 16 or over 65 for males and 50 years for females, amputee or subamputee lower limb, ipsilateral neck femoral injuries, intramedullary nailing or definitive external fixation treatment, bone metabolism diseases, skeletal immaturity, mental or neurologic disorder.

All patients were informed in a clear and comprehensive way of the two type of treatments and other possible surgical and conservative alternatives. Patients were treated according to the Ethical Standards of the Helsinki Declaration, and were invited to read, understand, and sign the informed consent form.

Azienda Sanitaria Locale (ASL) Lecce/Italy Ethical Committee approved this research.

Methods

All fractures were classified according to AO Classification (7) and Winquist and Hansen Classification (8). Forty patients were divided in two groups: 20 patients treated with ORIF plus tibial bone strut allograft (ORIF+) and 20 patients treated with MIPO technique (Table 1, Table 2).

All patients underwent the same rehabilitation protocol (see rehabilitation protocol). To study the bone healing on radiographs, the Non-Union Scoring System (NUSS) in retrospective mode was used (9) (Table 1).

The criteria to evaluate the patient groups during the follow-up were: the mean follow up, duration of surgery, Pain Visual Analogic Score (VAS) collected the same day that the X-rays were taken (10), objective quality of life and hip function measured by the Harris Hip Score (HHS) (11), subjective quality of life and knee function measured by Knee Society Score (KSS) (12), the Radiographic Union Score for Hip (RUSH), quality of life measured by the Short Form Survey (SF-12) questionnaires (11). The bone healing and

Table 1. Description of the patients with open reduction internal fixation plus bone graft (ORIF+) and patients with plate fixation with minimally invasive plate osteosynthesis (MIPO)

Characteristic	ORIF+ (n=20)	MIPO (n=20)
Average age, years (standard deviation, SD)	39.67 (±12.34)	39.56 (±11.87)
Age range (years)	16-65	16-65
Gender ratio (No) (male:female)	9 (18:2)	9 (18:2)
Previous type of accident (No, %)		
Fall from height	5 (25)	4 (20)
Car accident	4 (20)	5 (25)
Motorcycle accident	4 (20)	5 (25)
Work accident	6 (30)	5 (25)
Agricultural accident	1 (5)	1 (5)
Previous type of femoral shaft fractures according AO (7) (No, %)		
Proximal 1/3 intact segment	1(5)	1(5)
Proximal 1/3 fragmentary segmental	1 (5)	1(5)
Middle 1/3 intact segment	6 (30)	6 (30)
Middle 1/3 fragmentary segmental	6 (30)	5 (25)
Distal 1/3 intact segment	3 (15)	4 (20)
Distal 1/3 fragmentary segmental	3 (15)	3 (25)
Winquist and Hansen Classification's femoral shaft type (No, %)		
III	11(55)	12 (60)
IV	9 (45)	8 (40)
Type of Fracture (No, %)		
Closed	14 (70)	15 (75)
Open	6 (30)	5(25)
Open fracture according Gustilo Anderson Classification (14) (No, %)		
Type II:	10 (50)	10 (50)
Type IIIA	5 (25)	6 (30)
TypeIIIB	5 (25)	4 (20)
Orthopaedic device used in the surgery for the damage control (No, %)		
Skeletal traction	4 (20)	3 (15)
External fixation	16 (80)	17 (85)
Work occupation (No, %)		
Agricultural industry	6 (30)	7 (35)
Industrial sector	10 (50)	9 (45)
Tertiary industry	4 (20)	4 (20)
Injured lower limb side (No, %)		
Right	8 (40)	7 (35)
Left	12 (60)	13 (65)
Average Non Union Scoring System (SD)	50.89 (±18.33)	50.74 (±18.47)
Range Non Union Scoring system	21-75	21-75

Table 2. Description of associated injures in the patients with open reduction internal fixation plus bone graft (ORIF+) and patients with plate fixation with minimally invasive plate osteosynthesis (MIPO)

Characteristic	ORIF+	MIPO	p
Injuries associated with the segmental shaft fracture (No, %)			
Brain Injury/ Cerebral concussion	9 (45)	10 (50)	>0.05
Fat Embolism	1 (5)	1 (5)	1.00
Hemopneumothorax	4 (20)	3 (15)	>0.05
Liver injuries	7 (35)	6 (30)	>0.05
Spleen injuries	2 (10)	2 (10)	1.00
Bowel injuries	5 (25)	6 (30)	P>0.05
Ipsilateral tibial injuries	4 (20)	5 (25)	P>0.05
Contralateral femoral injuries	4 (20)	3 (15)	P>0.05
Contralateral tibial injuries	3 (15)	4 (20)	P>0.05
Rib fractures	15 (75)	16 (80)	P>0.05
Clavicle fractures	4 (20)	5 (25)	P>0.05
Humerus fractures	3 (15)	4 (20)	P>0.05
Forearm fractures	5 (25)	4 (20)	P>0.05
Metatarsal fractures	6 (30)	5 (25)	P>0.05
Patella fractures	2 (10)	2 (10)	1.00
Acetabulum fractures	2 (10)	2 (1)	P>0.05
Pelvic injury	1 (5)	1 (1)	P>0.05
Spine fractures	6 (30)	5 (25)	P>0.05
Total	83 (100)	84 (100)	P>0.05
Associate knee's injuries type II: (No, %)			
Lateral meniscus	6 (30)	5 (25)	P>0.05
Medial meniscus	12 (60)	13 (65)	P>0.05
Posterior cruciate	3 (15)	2 (10)	P>0.05
Anterior cruciate	11 (55)	10 (50)	P>0.05
Medial collateral ligament	5 (25)	4 (20)	P>0.05
Lateral collateral ligament	8 (40)	9 (45)	P>0.05
ISS average (SD; range)	26.1 (±4.77;12-52)	25.7 (±4.86;12-53)	P>0.05
GCS average (SD; range)	11.8 (±1.64;8-15)	11.9 (±1.66;8-15)	P>0.05
Orthopaedic device – plate used in the definitive surgery (No, %)			
Straight	4 (20)	5 (25)	P>0.05
Curved	5 (25)	5 (25)	P>0.05
Condylar	11 (55)	10 (25)	P>0.05

ISS, injury severity Score; GCS, Glasgow Coma Score;

femoral alignment were measured using plain radiographs films. The evaluation endpoint was set at 12 months after surgery. Bone union was measured using the radiographic union score as described by Litrenta et al. (13).

ORIF + bone strut allograft technique. The patient was placed in a supine position on the radiolucent operating table. A supporting pad was placed under the knee in 20 degrees of flexion with the patella pointed upward. The limb was draped free from the iliac crest to the foot to allow intraoperative assessment of length and rotation. In segmental multifragmentary fractures or long spiral fractures, the opposite uninjured limb was also prepared to allow intraoperative comparison with the fracture side. The image intensifier was positioned on the opposite site of the operating table. The 4.5-mm broad locking compression plate system (LCP, DePuySynthes, Oberdorf, Switzerland) was used for all cases. The plates chosen were short or long, depending on the fracture location and configuration. As a general rule, the plate should be long enough to allow the insertion of at least three screws each into the proximal and distal main fragments. The modification of the surgical access consisted of saving the vastus lateralis and perforating arteries. After exposing the fracture site, the fracture site was bloodied and the tibial shaft allogeneic bone strut was prepared on a separate table after performing tampon dye tests for the risk of infection. The modelling of the tibial bone strut always measured two and a half times the extent of the fracture site. The distal portion of the strut was modelled to "flame" to be as congruent as possible to the anatomical shape of the metaphyseal passage to the medial femoral condyle, when we needed to use the bone strut to fix the distal segmental shaft fracture. The margins of the fracture site were modelled in such a way to create a wide surface for a compression osteosynthesis. The hardware for osteosynthesis used in all cases was an anatomically pre-contoured low profile plate LCP or the condylar plate LISS (DepuySynthes, Oberdorf, Switzerland). Longitudinal traction or with external fixation or great distractor was applied to restore the length and rotation alignment of the femur. The alignment was checked with the image intensifier in both anteroposterior (AP) and lateral views. The compression cortical screws were also applied to stabilize the strut bone, and placed to reinforce the medial wall of the diaphysis or distal metaphysic too. Furthermore, the free space between the splint and bone was filled in with morcelized bone and bone paste. At this step, the hip rotation test was done by flexion of the hip and knee to 90 degrees, and internal and external rotation of the hip was performed. Finally, the soft tissues and skin were sutured.

MIPO technique. The patient was placed in a supine position on the radiolucent operating table. A supporting pad was placed under the knee in 20 degrees of flexion with the patella pointed upward. The limb was draped free from the iliac crest to the foot to allow intraoperative assessment of length and rotation. In segmental multifragmentary fractures or long spiral fractures, the opposite uninjured limb was also prepared to allow intraoperative comparison with the fracture side. The image intensifier was positioned on the opposite site of the operating table. The 4.5-mm broad locking compression plate (LCP) system or the condylar plate LISS (DepuySynthes, Oberdorf, Switzerland) was used for all cases. The plates chosen were short or long, depending on the fracture location and configuration. As a general rule, the plate should be long enough to allow the insertion of at least three screws each into the proximal and distal main fragments.

Small (4–5 cm) proximal and distal incisions were made over the lateral aspect of the femur with deep dissection down through the ilio-tibial tract and vastus lateralis muscle in line with their fibres to the plane between the periosteum and the vastus lateralis muscle. The lateral cortex of the femur was exposed using two Hohmann retractors—one ventral and one dorsal on both incisions. A tunnelling instrument was then tunnelled from the proximal incision toward the distal incision between both Hohmann retractors to create a submuscular, extraperiosteal tunnel. One end of the plate was tied to the hole at the tip of the tunnelling instrument by means of a suture. The tunnelling instrument was then withdrawn, pulling the attached plate along the prepared tunnel.

Once the plate was fully advanced into the tunnel, the image intensifier was used to check the correct position of the plate. Longitudinal traction or with external fixation or great distractor was applied to restore the length and rotation alignment of the femur. The alignment was checked with the image intensifier in both anteroposterior (AP) and lateral views. The length and angulation were re-checked. If reduction was satisfactory, we did the fixation with two compression screws near the fracture side (one distal and one proximal). After we completed the insertion of screws, the hip rotation test was done by flexion of the hip and knee to 90 degrees, and internal and external rotation of the hip was performed. If alignment was achieved, the fixation was completed using at least three bicortical screws on each main fragment; these screws could require longer or separate incisions for other screws insertion or percutaneous screws. Screw placement was done by different techniques depending on surgeon’s preference.

Rehabilitation protocol. The aim of our protocol was to provide the clinician an orientation of postoperative rehabilitation course, and to standardize and direct the whole patient population to follow a single physio-kinesiotherapy program to reduce the bias. From the post-operative up to the third week all patients wore a long leg splint plaster with a flexed knee at 20°.

Phase I (from 3 to 6 weeks). Target: protect the fixation and early bone healing avoiding weight bearing if instructed to do so, ensure wound healing, attain and maintain full hip and knee extension, gain hip and knee flexion to 90 degrees, decrease hip and knee and leg swelling, promote quad muscle strength and control. Precautions: weight bearing as ordered by surgeon, no resisted closed chain exercises x 6 weeks, no resisted open chain exercises x 6 weeks, limit knee flexion with strengthening to 45 degrees, avoid loading knee at deep flexion angles.

Phase II – intermediate phase (from 6 to 12 weeks). Target: no effusion, full hip and knee extension, single leg stand control, normalize gait, regain full motion, regain full muscle strength, good control and no pain with functional movements (including step up/down, walking in flat floor, partial lunge) (staying less than 60° of knee flexion). Precautions: limit knee flexion with strengthening to 45 degrees, avoid loading knee at deep flexion angles, post-activity swelling, stair stepper, deep knee bends and squats.

Phase III (week 12+). Target: regain full muscle strength, no thigh atrophy, gradual return to full activity, walk without pain for 2 kilometres. Precautions: avoid pain along skin wounded and all lower limb, build up resistance and repetitions gradually, perform exercises slowly avoiding quick direction changes and impact loading, exercise frequency should be 4-6 times per week to build strength, be consistent and regular with the exercise schedule, do not do knee extension weights with machine (running, jumping, pivoting or cutting, lunges, stairmaster, step exercise with impact).

Statistical analysis

Descriptive statistics were used to summarize the characteristics of the study group and subgroups, including mean and standard deviation of all continuous variables. The t-test was used to compare continuous outcomes. The $\chi 2$ test or Fisher's exact test (in subgroups smaller than 10 patients) were used to compare categorical variables. The statistical significance was defined as $p<0.05$. Pearson correlation coefficient (r) was used to compare the predictive score of outcomes and quality of life. Mean age (and the range) of the patients was rounded at the closest year. The predictive score of outcome and quality of life and the range were approximated at the first decimal, while the Pearson correlation coefficient (r) was approximated at the second decimal.

Cohen's kappa coefficient (κ) used to measure inter-rater agreement for qualitative (categorical) items; through this parameter we calculated the concordance between different qualitative values of the outcomes and the bone healing, the anatomical and biomechanical axis of the humerus from the radiological point of view.

RESULTS

There were no statistically significant differences between the two populations according to age, gender, type of fracture, NUSS, etc. (Table 1).

All patients were polytraumatized patients, in the ORIF Group there were 83 associated lesions and eight in the MIPO group ($p>0.05$) (Table.2).

The most present associated knee injury was the medial meniscus injury in both the ORIF + and MIPO group ($p>0.05$) (Table.2).

There was no statistically significant difference ($p>0.05$) between the two groups for Injury Severity Score, the Glasgow Coma Scale and the plates used for osteosynthesis (Table 2).

The average time from trauma to definitive care was 16.16 (±13.19; range 0-42) days in ORIF+, while in MIPO it was 13.8 (±11.86; range 0-36) days ($p>0.05$).

The mean of follow-up was 18.36 (±1.12; range 12–48) months for ORIF+ and 18.48 (±1.18; range 12–48) months for MIPO ($p>0.05$).

The surgery lasted for an average of 92.9 (±21.6; range 73-123) minutes in ORIF+, while 88.7 (±20.8; range 67-118) minutes for MIPO ($p>0.05$).

The RBC (red blood cell) of perioperative transfusions was on average 4.2 (±1.42; range 1-9) in ORIF+, while 4.1 (±1.25; range 1-8) for MIPO ($p>0.05$).

In both groups, patients demonstrated appropriate wound healing within 25 days.

During the follow up no complications were noticed in ORIF+ group; instead there were two breakage of plate cases and one plating bending case ($p<0.05$) for MIPO. The time of plate breakage with respect to surgery was: 110 days in one case and 87 days in the second case. The bending plate case was recorded 67 days after the surgery.

All three MIPO cases were re-operated using lateral compression locking plate screws and medial anterior bone strut allograft. All these surgeries were successfully performed and were uneventful.

The average time of bone healing was 145.4 (±24.8; 108 -173) days after the surgery in ORIF+, while it was 154.7 (±25.3; 106 -187)

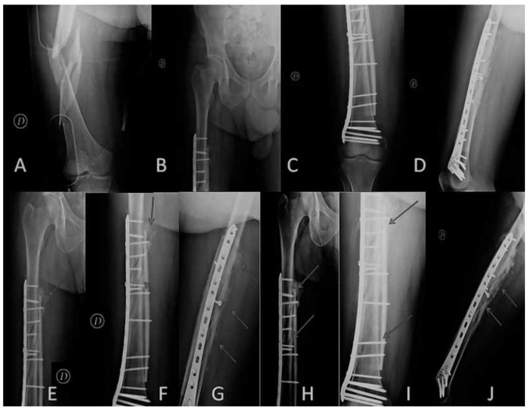

Figure 1. A 47-year-old male patient, closed trauma of right femur after car accident. A) 1/3 middle multi fragmentary fracture according to the new AO's Classification while 32.C3 according to the old AO's Classification; B-D) after trans-skeletal traction, the fractures were treated for 7 days after the trauma with ORIF technique; E-G) at 3 months from the surgery formation of exuberant callus bone already present (arrows); H-J) at one year from the surgery X-rays show complete fusion of the medial bone splint (Rollo G, 2016)

days for MIPO ($p>0.05$). The average time of bone healing in reoperated MIPO cases was 138.2 (±21.4; 102 -168) days.

At average day of the bone healing the RUSH was of 29.4 (±0.2; range 27.9-30) points in ORIF+ while 27.8 (±0.8; range 26.4-30) in MIPO ($p<0.05$). At the last X-rays control before the breakage of the plates the RUSH was of 14.6 points in one case and 13.9 in the other case, while in bending plate case it was 16.8 points. At average day of the bone healing in the MIPO reoperated group, the RUSH was of 27.73 (±0.75; range 27.4-28.2).

In the average day of the bone healing the VAS was 1.7 (±0.7; range 0-3) point in ORIF+ while it was 2.8 (±0.9; range 0-4) in MIPO ($p<0.05$). At the last follow up review before the breakage of the plates, the VAS was 4.7 points in one case and 3.9 in the other case, while in bending plate case it was 3.7 points. At average day of the bone healing in the MIPO reoperated group, the VAS was 2.3 (±0.57; range 2-3).

We found that on average day of bone healing the regression between RUSH and VAS scores showed a $p= 0.042$ in ORIF+, while $p=0.072$ in MIPO ($p<0.05$). We found that at average day in MIPO reoperated group of bone healing the regression between RUSH and VAS scores showed a $p=0.051$.

The ORIF+'s objective functionality of the hip and quality of life before the trauma, measured by HHS, was about 87.8 points (±6.53; range 82.2-100). The quite same functionality of the hip and quality of life before the trauma,

Figure 2. A 46-year-old female patient, closed trauma of right femur after car accident; A-C) 1/3 middle multi fragmentary fracture according to the new AO Classification while 32.C3 according to the old AO Classification (7). D-F) After trans-skeletal traction, the fractures were treated for 5 days after the trauma according to MIPO technique; G-I) After 20 months from the surgery plate and screws were removed (G,H,I) and the patient experienced pain during weight bearing; J-L) After 20 days from onset of symptoms no pain during weight bearing was experienced and there was radiological proof of definitive bone healing (Bonura EM, 2017)

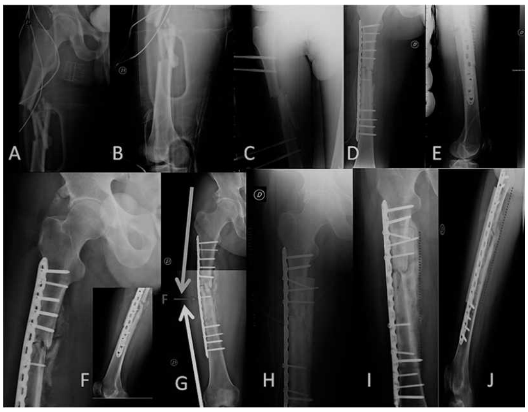

Figure 3. A-B) A 41-year-old, fell from a height, polytrauma, open fracture of the right femur; 1/3 middle multi segmental fracture according to the new AO Classification while 32.C3 according to tttt old AO Classification; B) Associated injury: brain injury. The patient was provided with damage control procedure with external fixation; D-E) At the 25th post-operative day, definitive fracture reduction and fixation with MIPO technique; F) At 30 days from the surgery with MIPO, the radiographs showed a fracture's breakdown despite a formation of bone callus; G) On the 67th postoperative day the patient presented limb shortening; the radiographs show the bending effect (top arrow and bottom arrow pointing to the inter-fragmentary screw indicated by the letter; F) of the plate; H) The X-rays show the surgical revision with ORIF + technique; I-J) The X-rays show the X-ray result at 12 months from the surgical revision. The line shows the reconstruction of the medial wall femoral (Rollo G, 2016)

measured by HHS, was about 88.1 points (±6.51; range 68.8-100) in MIPO (p>0.05). At the moment of trauma, the HHS was 22.4 points (±3.27; range 11.8-42.7) as at the moment of subtrochanteric fracture in MIPO, the HHS was 22.6 (±3.22; range 11.8-42.8) (p>0.05). There was no statistical significance (p>0.05) between the two groups at 1 month of follow up after the surgery. Also in the scoring of HHS there was a statistically significant difference after the third month after the surgery in favour of the ORIF+ group as the breaking of the fixation hardware prevented the injured lower limb function, and therefore, the patient's life quality, as well as the sixth month of follow-up. In ORIF+ group, at the twelve month follow up, the HHS score was 84.2 (±8.95; range 77.6-100) points while in MIPO’s 17 cases the HHS was 83.9 (±8.78; range 77.2-100) (p>0.05).

Twelve months after the revision surgery we had the same results in MIPO’s reoperated group, according to HHS. The results were: 88.2 points in the first case of breakage while 87.6 in the second case, in the bending plate case it was 90.4.

The ORIF+’s objective functionality of the knee and quality of life before the trauma, measured by KSS, was about 92.4 points (±4.42; range 86.6-100). Quite the same functionality of the hip and quality of life before the trauma, measured by KSS, was about 92.2 points (range 86.4.8-100) in MIPO, (p>0.05). At the moment of trauma, the KSS was 19.4 points (±6.53; range 11.8-36.7) as at the moment of subtrochanteric fracture in MIPO, the KSS was 19.6 (±6.47; range 11.8-36.7) (p>0.05). There was no statistical significance (p>0.05) between the two groups, ORIF+ at 1 month of follow up after the surgery. Also in the scoring of the KSS there was a statistically significant difference after the third month after the surgery in favour of the ORIF+ group as the breaking of the fixation hardware prevented the injured lower limb function and therefore the patient's life quality, as well as the sixth month of follow-up. In ORIF+ group, at twelve month follow up, the KSS score was 81.6 (±5.89; range 74.2-100) points while in MIPO’s 17 cases the KSS was 81.2 (±5.72; range 73.8-100) (p>0.05).

Twelve months after the revision surgery we had the same results in MIPO’s reoperated group, according to HHS. The results were: 82.6 points in the first case of breakage while 80.8 in the second case, in the bending plate case it was 86.8.

The quality of ORIF+’s life before the trauma, measured by SF-12, was about 94.6 points (range 86.4-100), while the quality of life before the trauma, measured by S-F12, was about 94.2 points (range 88.2-100) in MIPO (p>0.05). At the moment of trauma, in ORIF+ group the SF-12 was 34.8 (±6.47; range 16.4-46.6) as at the moment of subtrochanteric fracture in MIPO, HHS was 35.2 (±6.39; range 16.2-45.8) (p>0.05). There was no statistical significance (p>0.05) between the two group ORIF+ at 1 month of follow up after the surgery. After the third month after the surgery, there was a statistically significant difference at three months after the surgery in favour of the ORIF+ group as the breaking of the fixation hardware prevented the patient's quality life measured by SF-12, as well as the sixth month of follow-up. In ORIF+ group, at twelve months after the surgery, the SF-12 score was 90.4 (±12.77; range 76.8-100) points, while in MIPO’s 17 cases the SF-12 score was 89.6.4 (range 76.6-100) (p>0.05).

At twelve months after the revision surgery we had the same results in MIPO’s reoperated group, according to SF-12. He results were: 94.2 points in the first case of breakage while 96.6 in the second case, in the bending plate case was 96.4. The higher SF-12 score in this subgroup is due to the ORIF+ psychological aspect because all of 3 patients had a sense of more security and lesser anxiety.

The average correlation of clinical-radiographic results and patients outcomes was high according Cohen κ: 0.853±0.100 for ORIF+, while κ: 0.727±0.095 for MIPO (p<0.05).

DISCUSSION

Multifragmentary segmental femoral shaft fracture is not a very common pattern of injury. These types of fractures are usually associated with high energy injuries frequently associated with life-threatening conditions (1). Damage control is the strategy temporarily used in polytrauma patients (which is followed by definitive treatment when patients’ conditions allow so). Non-operative options are an exception and used only in very selected cases (very short life expectancy, other life-threatening injuries, etc.) (3,4)

Notoriously, the treatment of choice for diaphyseal femoral fractures is internal fixation with intramedullary nail (IMN) stabilization; it achieves correct alignment and high rate of bone healing with low complications rate and early limb mobility (15). In fact recent studies have proved that IMN stabilization allows the lowest possible complication rate and loss of reduction rate (5,16). Doubts rose on the possibility to perform reamed or unreamed nailing procedures, but several studies have shown that reamed intramedullary nailing is correlated with shorter time to union and lower rates of delayed-union, nonunion, and reoperation, and it should therefore be considered as the favourite option compared to undreamed IMN stabilization (15,17)

However, IMN stabilization is not always the treatment of choice, and plating techniques play an important role in treating such cases. Plate osteosynthesis is particularly advantageous in certain situations where an intramedullary nail may be contraindicated or technically not feasible. These may include the polytrauma patient, ipsilateral femoral neck and shaft fractures, fracture in the proximal or distal shaft, paediatric femoral shaft fracture, multifragmentary segmental shaft fractures or an excessively narrow intramedullary canal. Rigid locked plates and dynamic fixation with active locking plates are both studied options in this context with controversial results (6,18). Metal plates and the use of strut bone graft have become a very common strategy to treat femur shaft fractures, with the aim to correct as much as possible the lack of bone stock and to provide the highest grade of stability and allow good fracture union in the shorter period of time (19). These methods are however very invasive procedures and carry a relatively high risk rate of malunion, nonunion, infection, poor blood supply, refracture (20).

Therefore, minimally-invasive fixation technique (MIPO) have been studied and introduced in order to improve results and outcomes in specific selected cases, when a plate fixation is indicated. As a result of technical advancement, minimally invasive plate osteosynthesis (MIPO) has gained popularity in recent years and has achieved satisfactory clinical outcomes (6). Several authors claimed that MIPO, compared with the traditional approaches, decreases the union time by minimizing the disruption of the soft tissues (including periosteum), lowers the incidence of bone grafting as well as the rates of postoperative complications, and preserves vascular supply to the fracture site. This technique is considered worth further studies, but also considered to have proven to be a promising technique (20,21).

We present a control-group study including patients with sustained multifragmentary segmental femoral shaft fracture, treated either with ORIF+ and bone strut allograft or with MIPO. We wanted to compare results of the two techniques and compare our results with those present in the literature. We must say that our results are in contradiction with the authors supporting the MIPO option. Better results in terms of the complication rate, average day of proven bone healing (RUSH), VAS at the average day of bone healing, regression between RUSH and VAS at average day of bone healing and the average correlation clinical-radiographic results and patients outcomes (Cohen k) were obtained in the ORIF Group. Differently similar results were recorded for other clinical aspects, such as length of follow up, surgery duration, perioperative blood transfusion and wound healing.

We did not record any significant complication in the ORIF+ Group, while we recorded 3 complications for the MIPO Group: 2 metalwork breakages and 1 cases of metalwork bending. These 3 patients were all reoperated using lateral compression locking plate screws and medial anterior bone strut allograft; results were good with no further significant complications. We suspect that these complications have a biomechanical background causing a higher rate of failure of MIPO construct, but we do not have enough data to support this theory. But as a matter of fact, the complication rate of the MIPO group was significantly higher than that in the ORIF group.

No statistical difference was again recorded throughout the entire follow up with regards to objective functionality of the hip and quality of life before the trauma (measured by HHS), objective functionality of the knee and quality of life before the trauma (measured by KSS), quality of ORIF+'s life before the trauma (measured by SF-12).

Basing the discussion on our results, we would like to highlight that the ORIF+ and bone strut technique to treat multifragmentary segmental femoral shaft fractures could deserve prioritization against the MIPO technique. In fact the ORIF+

technique could allow a very good anatomical reduction of the fracture, together with an appropriate reconstruction of the medial wall. Our study suggests that ORIF+ can also provide better results in terms of fracture healing and VAS compared to MIPO. Despite the fact that several studies had highlighted that MIPO could reduce the risk of infection, complications and union time (mainly due to a better preservation of the vascular supply to the fracture site and minimization of soft tissue disruption, with consequent undisturbed rapid callus bone healing) (20,21), we did not record matching results in our study, which was composed of two good size control-groups if considering the incidence of multisegmentary segmental femoral shaft fractures.

A target of treatment of femur fractures should mainly be early functional recovery, avoidance of complications (bedsores, pulmonary complications, osteoporosis from disuse), restoration of axial alignment, good stabilization, early mobilization (to prevent stiffness and muscle atrophy), return to good quality of life (22,23). Compared to the data in the literature, the ORIF technique allows results in keeping with this accepted target. In fact we recorded a low complication rate, good fracture stabilization and healing, good clinical and functional final results which allowed very satisfactory ROMs (range of motion) and quality of life scores throughout the entire follow up.

Another advantage of ORIF+ against MIPO that we would like to stress is the possibility to use bone strut allograft. This is potentially able to reduce stress shielding, increase the percentage of probability of fracture consolidation, makes the system more stable, reduces complications, and improves patients' quality of life due to a shorter functional recovery. However, the customization of the transplant must be considered against the potential disadvantages of the lengthening of surgical time and the complexity of the surgery, the risk of infections, nonunion, mortality, and transmission of infectious diseases (22). Furthermore, the advantages of the use of bone graft have been reported in several studies for the treatment of femur fractures. This aspect was proved by reporting better results of patients treated with metal fixation and bone graft against patients treated with metal fixation alone. Advantages were recorded in terms of quality of life scores, functional scores, time of bone healing (Radiographic Union Score), complication rates and radiological imaging (plain radiographs and CT scans) (24,25).

Another allegedly positive aspect of the use of MIPO proposed in the literature is the fact the MIPO reduces the rate of cases needing bone graft if compared to conventional plating in complex femur fractures. The MIPO technique is thought to allow biological fracture healing by preserving the vascularity of all bone fragments, thus serving as a living bone graft. Therefore, primary bone graft could not be necessary. However, bone grafting is recommended in cases with no signs of callus on the radiographs at three months or cases with extreme destruction of vascularity by trauma, open fracture, or bone loss where healing takes more time (6,26,27). According to our experience we cannot confirm this aspect as we reported favourable results in the group where bone graft was used.

The analysis and discussion of our results seem to take the reader to favour the ORIF+ option against the MIPO option. Further studies with bigger cohorts and more powered studies are needed in order to finally validate or reject our hypothesis. As far as we know, we recommend the use of ORIF and bone graft for the treatment of multifragmentary segmental femur shaft fractures when IMN stabilization is not indicated. Specific indications that could favour MIPO have not been studied by the authors, but we encourage the development of research towards this aspect in order to have a more clear scenario on ORIF vs. MIPO indications and advantages/disadvantages. Most of the current data in literature are based on case series and other studies with a low level of evidence.

The use of the ORIF option should however be taken with caution, trying to provide an appropriate surgical technique and tissue handling, good haemostasis throughout the surgery, reduced surgery times, less possible invasive approach and exposure, satisfactory reduction and alignment, early mobilization. Good results are possible only if these aspects are taken into account as widely known.

The results of our study show that the ORIF and bone strut allograft technique has better results compared to the MIPO technique with regards to complication rate, average day of proven bone healing (RUSH), VAS, regression between

RUSH and VAS and average correlation of clinical-radiographic results and patients outcomes (Cohen k) in the surgical treatment of multifragmentary segmental femoral shaft fractures. Perhaps similar results are obtained in terms of length of follow up, surgery duration, perioperative blood transfusion and wound healing. Both techniques are indicated when IMN stabilization is not indicated to manage this pattern of femur fractures. However, ORIF+ offers advantages related to a better anatomical fracture reduction and reconstruction of the medial wall. We advocate for the need of a more powered study and bigger size cohorts in order to validate or reject our results and achieve consensus on ORIF+ vs MIPO.

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