

A CLINICAL STUDY ON INTRAMEDULLARY FIXATION UNDER DIFFERENT RIGIDITY CONDITIONS

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Abstract: *In the last decades there have been major changes in the management of lower and upper limb long-bone fractures. Intramedullary fixation is the treatment of choice for most diaphyseal fractures of the femur, tibia and humerus. Intramedullary nailing for fractures treatment is a minimally invasive technique which was reported to be an easy procedure with low complication rates, good cosmetic and functional results, restoration of bone length and fast return to daily activities. Differences in fractures healing rate depends on the biomechanical behavior, which is an important fact in biological healing, especially in fractures with additional biological needs, resulting from high energy trauma. We performed three prospective and one retrospective study of four groups of patients operated in The Department of Orthopaedics and Traumatology in Braşov County Hospital in the period 1997-2007 for limb fractures, with endomedullary fixation with different degree of strengthens, highlighting the complications. Dates from the studies were then statistically analyzed and compared with similar data from other studies in literature.*

Key words: *intramedullary fixation, strenght degree of internal fixation, internal nailing complications.*

1. Introduction

The treatment of humeral shaft fractures, femoral and tibial fractures are currently a very important topic in the orthopaedic literature. In modern traumatology the functional requirements are increasing and there is a general trend to a surgical treatment of fractures. The goal is to minimize the time required for complete recovery and social reintegration of patients as quickly as possible.

The surgical treatment in fractures is supported by the major companies producing orthopedic implants that have developed

experimental and research divisions in the field. The results were reflected in the emergence of materials and implants becoming more efficient and more resilient and a success rate that is becoming higher.

2. Clinical Studies of Intramedullary Osteosynthesis

Kempf, in 1985, concluded that the treatment with a blocked rod has many advantages compared to treatment with non-blocking rod. The risk of infection and nonunion is low, the incidence and severity of nonunion are reduced, the length of stay in the

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hospital is short and it allows early mobilization of the patient [Kempf, I. et al., 1985].

Wiss in 1986 extended the indications to use the locked intramedullary nailing for femur fractures. Infection and nonunion rate is remarkably lower. Immediate stabilization of the fracture allows immediate mobilization of the patient, early recovery of the limbs and a shorter stay in hospital [Wiss, D.A. et al., 1986].

Klemm & Börner highlighted the advantage for intramedullary osteosynthesis with a locked rod by the fact that after surgery it is allowed for the patient to have early and protected weight load on the operated member, and the rates of nonunion and infection are very small. There is a small risk of refracture after removal of implant [Klemm & Börner, 1986]. O'Brien concluded that the fixation with intramedullary nailing with reaming is an efficient alternative for the treatment of open femur fracture type I, II and type III associated with multiple trauma [O'Brien, P.J. et al., 1991], and the treatment of complex fractures, femoral shaft fractures with comminution or segmentation [Christie, I. et al., 1988].

Grosse, in 1993, in the treatment of 115 open fractures with intramedullary rods had good results and only 4 patients had delayed consolidation (they were successfully treated with bone graft) [Grosse, A. et al. 1993].

Nowotaraki in 1994 made a study on 39 patients with fractures of the femur following shooting and he recommends the use of intramedullary rods with good results [Nowotaraki, P. et al., 1993].

Court-Brown recommends the intramedullary blocked rod, and he reported from 125 patients with fractures of the tibia an incidence of 1.6% for infection, 40.8% for knee pain and 26.4% of patients required implant removal [Court-Brown, C.M. et al., 1990].

Alho in 1990 analyzed a total of 93 fractures of the tibia shaft operated with intramedullary blocked rod and he reports

10.7% with vicious consolidation and 3.2% with nonunion of the fracture [Aiho, A. et al., 1990]. Habemek has done a study on 109 patients with stem intramedullary blocked rod and he finds 14 infections and two vicious consolidation [Habemek, H. et al., 1992].

Firică, in a study in 2001 on a group of 23 patients treated by fixation with stable elastic osteosynthesis, recorded four failures, namely: 3 infections and one case of material migration [Firică, A. et al., 2001]. Gregory submits that intramedullary rod fixation became the method of choice in the treatment of unstable tibial fractures. This has advantages and disadvantages including bone necrosis, infection and compartment syndrome [Gregory, P., Sanders, R., 1995]. Gamal, after a study on 66 patients with elastic titanium rods, found a higher rate of complications particularly vicious consolidation and migration of the osteosynthesis material [Gamal EL-ADL et al. 2009].

3. Materials and Method

Intramedullary fixation methods allow the emergence of micro movements leading to healing and callus formation indirectly. But due to different degree of elastic behavior, as mechanical structure and in the fractured bone, we formed three groups and compared statistically the intramedullary fixation: elastic (E) - Ender rods type, the relative elasticity (RE) - locked calibrated rods, and relatively rigid (R) - calibrated rods (Kuntscher rods). We evaluated data from 4 clinical trials conducted in the Orthopaedic Department in Braşov County Emergency Hospital. Radiological and functional evolution with complications such as (nonunion, chronic infections, vicious consolidation, migration of the osteosynthesis material) were assessed by parameters included in a document type that was completed for each case in conjunction with the treatment applied (Annexed "clinical sheet"). Data

was recorded during the hospitalization and at surgery, and during postoperative controls to healing period, or in some cases to a diagnosis and chronic complications. The first group included 45 patients prospectively in the period 2004-2005, 28 women (60%) and 17 men (40%), aged 19-85 years, 9 femur fractures (18%), 30 leg fractures (67%) and 6 humerus fractures (15%). The method of fixing was with elastic intramedullary osteosynthesis (subgroup E1). The complications were 9 cases of migration of the osteosynthesis material that required reintervention (20%), 7 cases of vicious consolidation (16%), four nonunion (9%) and 2 immediate infections. The second prospective study to follow up was with patients who underwent internal fixation with intramedullary Kuntscher type rods - relatively rigid fixation "R". The study was conducted during 2004 - 2005 on a group of 50 patients. Some of them could not be followed in evolution (19 patients) because they refused further cooperation, only 31 patients remained in follow-up with closed fractures (subgroup R1). In this subgroup - 26 men (83.9%) and 5 women (16.1%) - there were 21 fractures of the tibia (68%), six fractures of the femur (19%) and 4 fractures of the humerus (13%). Complications arising from the treatment in the 31 patients were: delay in the consolidation occurred in 3 patients (10%), vicious consolidation for 2 patients (6%), nonunion in three patients (10%) of which 2 with septic complications (6%) and 2 patients (6%) with osteitis. The third group included 68 patients and they have been treated prospectively in the period 2005-2007. We excluded from the study 8 patients and in the end remained 60 patients: 19 women (31%) and 41 men (69%), aged 23-85 years. The method of fixing was with intramedullary rods that have been blocked (RE group). There have been two fractures of the humerus (4%), 23 fractures of the femur (38%) and 35 leg fractures (58%). The results were good and very good in 58 cases (96.67%) and functional recovery was not obtained in 2 cases (3.33%) of patients. The

only complication we encountered have been hospital wound infection in 5 cases (8%) - cured during hospitalization. Only one patient experienced this complication after discharge, requiring surgical reintervention to extract the fixation material. Osteosynthesis material damage occurred in 5 patients (8%), especially breaking or bending the lock bolt. One case was presented after 14 months with nonunion. To this data, we added data obtained by a previous study covering also the open fractures. In terms of the hypothesis of the study we considered open fractures all type III fractures according to Gustilo classification (1984). This study was the first chronologically study, and the selected cases have been operated in the period 1997-2004, for which we had complete data tracking. In the context of the study design we included in the study two groups of patients: 23 cases (33%) treated by elastic type osteosynthesis (subgroup EII) and 46 cases (67%) were fixed with Kuntscher rods (RII subgroup). In the EII subgroup there were six nonunion (26%), 3 infected (13%) from a total of 6 infections (26%). In the subgroup RII we recorded seven nonunion (15%), of which 5 infected (11%) from a total of 6 infections (13%).

4. Results

The group with elastic fixations (E) included in the final number of 68 fractures treated with elastic fixing, 55 closed fractures (81%) and 13 open fractures (19%). These results were obtained regarding the complications: vicious consolidation in 7 cases (10.3%), immediately infection in 2 cases (2.9%), migration of the osteosynthesis material which required reintervention in 9 cases (13.2%), nonunion in 10 cases (14.7%) and chronic septic evolution in 6 cases (8.8%).

The group with relatively rigid fixation (R) with Kuntscher rods had 77 fractures, 65 closed (84%) and 12 open (16%) and there were recorded the following complications: 2 cases with vicious

consolidation (2.6%), 3 cases with delay in the consolidation (3.9%), 10 nonunion cases (13%) and 10 cases of chronic septic evolution (13%).

The group with relatively elastic fixations (RE), had 60 closed fractures by fixation with blocked rods and showed healing in 58 patients (97%). The incidence of complications was with 5 cases submitted to immediate infections (8%), 1 case of nonunion (1.7%) and 1 case of osteitis (1.7%) which required early removal of the rod. In all these cases there was a late developing callus, but it has evolved into consolidation after activation. The exception was one case, where the patient returned after 14 months with a damaged lock bolt and nonunion. In

terms of late complications we need some clarification. Pseudoarthrosis was recorded in 50% of patients that have opened fractures fixed with relatively rigid rods, and 33% for the elastic rods. On the other hand in the group with closed fractures, the proportion is reversed, and the unstable fractures required surgical opening of the fracture. In contrast, the group fixed with blocked elastic rod has had no recorded case of nonunion.

Immediate infections have a multifactorial causation but the means of fixation do not play a role. Most cases and chronic infections (13%) occurred in the relatively rigid fixation group by unfavorable biological environment.

Table 1

The results of clinical studies involving Ender elastic rods (E), type Kuntscher relatively rigid rods (R), without relatively elastic (RE)

	Number of fractures	Closed fractures	Open fractures	Closed fractures (%)	Open fractures (%)	Vicious consolidation fractures (%)	Migration of the osteo-synthesis material (%)	Late consolidation (%)	Pseudoarthrosis (%)	Septic pseudoarthrosis (%)	Immediate infections (%)	Osteitis (%)
Group E	78	55	13	81	19	10,3	13,2	0,0	14,7	4,4	2,9	4,4
group R	77	65	12	84	16	2,6	0,0	3,9	13,0	9,1	0,0	3,9
group RE	60	60	0	100	0	0,0	0,0	0,0	1,7	0,0	8,3	1,7

Analyzing the evolution of the cases who underwent fixation with nonblocked rods the data does not show statistically significant differences compared with the results of the synthesis of the 16 published studies mentioned in the literature. Fixing with elastic rods differs only by development in the septic cases of the open fractures. There were some differences in the protocol. The primary external fixation followed by conversion to internal fixation

after stabilization led to a smaller number of septic nonunion and osteitis.

5. Centralizing the Statistically Significant Data

Elastic osteosynthesis

Fixation with elastic rods (E) represents a risk factor complications (rr. 3.44) and the presence of final instability (rr. 2.63) than other types of rods. In terms of the appearance of early callus

(4-6 weeks), E has a high probability of fixation than in the R and RE fixation to achieve this objective (rr. 1.46). In terms of development to the second control callus (7-12 weeks), fixation is also present at higher probability to R and RE fixation (rr. 1.08). Relative risk value close to 1 indicates that fixing with E is very close to the factor for the development of callus after 6 weeks.

Studies during the consolidation shows that the risk of losing the stability of osteosynthesis after charging is higher in E fixing than in other types of fixing regardless of the fracture type (rr. 3.74) and also in the closed fracture group (5.68).

Fixing with E is a risk factor for normal consolidation, regardless of the type of fracture. In the cases of closed fractures fixed with E the probability of developing a hypertrophic callus is higher compared to other types of fixation (rr. 2.27) and the probability to develop a hypotrophic callus is 0 compared to those with other types of fixing.

Rigid osteosynthesis

Relatively rigid fixation (R) has a probability of 0.58 not to develop callus until the first control, compared to other types of osteosynthesis. R type cases have a 0.89 probability not to develop callus until the second control, than other types of osteosynthesis.

R type osteosynthesis is a risk factor for callus formation in closed fractures compared with RE and E. The probability for R to form a hypotrophic callus after fixation is higher than in other types of osteosynthesis (rr. 5.3).

Relatively elastic fixation

Relatively elastic fixation (RE) is the protection factor for complications compared with other types of osteosynthesis. RE fixation is as protective factor for stability. The study shows that RE is a protection factor against chronic septic evolution compared with other types

of osteosynthesis. Stability study shows that the RE is a protective factor for stability after loading. The probability of periosteal callus consolidation is higher in RE osteosynthesis rather than other types of osteosynthesis (rr.1.3).

Conclusions

Classical elastic osteosynthesis was the best solutions especially in open fractures.

The major disadvantage is the limited stability conditions of this osteosynthesis.

Relatively rigid fixation had the highest rate of complications with increased risk for septic pseudoarthrosis especially in open fractures.

Intramedullary fixation with blocked rods has the best balance between satisfaction of the biological conditions and providing the desired mechanical stability.

References

1. Alho, A., Ekelund, A., Stromsoe, K., Folleras, G., Thoresen, B.O.: *Locked intramedullary nailing for displaced tibial shaft fractures*. In: J Bone Joint Surg, 1990, 72B: 805-9.
2. Barbu, D., Lupescu, O., Oprescu, S., Nagea, M., Propina, St., Niculescu, D.: *Tratamentul in urgenta al fracturilor diafizare de gamba la politraumatizati*. In: Revista de Ortopedie si Traumatologie, vol. 11, 2001, nr.1-2, p. 91-96.
3. Christie, I., Court-Brown, C., Kinninmonth, A.W.G., Howie, C.R.: *Intramedullary locking nails in the management of femoral shaft fractures*. In: J Bone Joint Surg., 1988, 70B: 206-10.
4. Court-Brown, C. M., Coll, J. R.: *The management of femoral and tibial diaphyseal fractures*. In: Surg. Edinb. 1988, 43, 374-380.

5. Court-Brown, C.M., Christie, J., McQueen, M.M.: *Closed intramedullary tibial nailing: its use in closed and type I open fractures*. In: J Bone Joint Surg, 1990, 72B: 605-11.
6. Firică, A., Negruţoiu, M., Lăptoiu, D., Pârşu C., Malincenco, S., Firică, Adriana.: *Reabilitarea osteosintezei elastice. Osteosinteza elastică mixtă stabilizată a oaselor lungi*. In: Revista de Ortopedie si Traumatologie, 11, 2003, nr.3, p. 113-126.
7. Gamal, EL-ADL, Mostafa, Mohamed F., Khalil, Mohamed A., Enan, Ahmed: *Titanium elastic nail fixation for paediatric femoral and tibial fractures*. In: Acta Orthop. Belg. 75, 2009, 512-520.
8. Gregory, P., Sanders, R.: *The treatment of closed, unstable tibial shaft fractures with an unreamed interlocking intramedullary nail: preliminary results*. In: Clin. Orthop. Rel. Res., Vol. 315, 1995 : 48-55.
9. Grosse, A., Cluistie, J., Taglang, G., Court-Brown, C., McQueen, M.: *Open adult femoral shaft fracture treated by early intramedullary nailing*. In: J Bone Joint Surg, 1993, 75B: 562-5.
10. Habemek, H., Kwasny, O., Schmid, L., Ortner, F.: *Complication of interlocking nailing for lower leg fractures: a 3-year follow-up of 102 cases*. In: J Trauma 1992, 33: 863-9.
11. Hasenhuttl, K.: *The treatment of unstable fractures of the tibia and fibula with flexible medullary wires. A review of two hundred and thirty-five fractures*. In: J Bone Joint Surg Am. 1981, 63:921-931.
12. Kempf, I., Grosse, A., Beck, J.: *Closed locked intramedullary nailing: its application to comminuted fractures of the femur*. In: J Bone Joint Surg. 1985, 67A: 709-20.
13. Klemm, K., Borner, M.: *Interlocking nailing of complex fractures of the femur and tibia*. In: Clin. Orthop, 1986, 212: 89-100.
14. Mayer, L., Werbie, T., Schwab, J.P., Johnson, R.P.: *The use of Ender nails in fractures of the tibial shaft*. In: J Bone Joint Surg Am. 1985, 67:446-455.
15. Nowotaraki, P., Brumback, R.J.: *Immediate interlocking nailing of fractures of the femur caused by low-to mid-velocity gunshots*. In: J Orthop Trauma 1994, 8: 13441.
16. O'Brien, P.J., Meek, R.N., Powell, I.N., Blackat, P.A.: *Primary intramedullary nailing of open femoral shaft fractures*. In: J Trauma 1991, 31:113-6.
17. Purghele, Fl., Popescu, D., Hera, A., Ramona, B.: *Tehnica Dr.D.Galluccio de osteosinteza elastica aplicata la politraumatizati cu fracturi ale membrului superior*. In: Revista de Ortopedie si Traumatologie, vol. 6, 1996, nr.1-2, p. 43-46.
18. Sova, D., Filipescu, N., Nafornta, D., Popa, D.C., Neagu, I.: *Fractura deschisa de gamba – posibilitati de tratament*. In: Revista de Ortopedie si Traumatologie, vol. 15, 2005, nr.1-2, p. 107-111.
19. Şamotă, I.: *Fixarea endomedulară elastică în fractura deschisă de gambă*. Braşov. Editura C2 Design, 1999.
20. Tarnita, D.N., Grecu, D., Didu, S.: *Tratamentul fracturii diafizei humerusului, situate in 1/3 distala, prin osteosinteza cu tije elastice*. In: Revista de Ortopedie si Traumatologie, vol. 14, 2004, nr.1-2, p. 25-26.
21. Whittle, A.P., Russell, T.A., Taylor, J.C., Lavelle, D.G.: *Treatment of open fractures of the tibial shaft with the use of interlocking nailing without reaming*. The Journal of Bone and Joint Surgery, Vol. 74, 1992, Issue 8 : 1162-1171.
22. Wiss, D.A., Fleming, C.H., Mata, J.M., Clark, D.: *Comminuted and rotationally unstable fractures of the femur treated with an interlocking nail*. In: Clin Orthop. 1986, 212: 3547.