One of the main goals in fracture treatment is preservation of both intramedular and periosteal vascularisation. The aim of this paper is to show a new method of internal fixation which accomplishes these goals. The paper presents the results of clinical application of Mitkovic Internal Fixator, new self-dynamisable device, which provides fixation of the femur using minimally invasive technique. This device has been investigated experimentally on 60 animals. It has been applied to 267 patients. Here is presented a series of 92 fixations of femoral diaphyses after fresh fractures and after unsuccessful treatment using other methods. Follow-up was 3.1 years (2 to 7 years). Bone healing was achieved in all patients within 3.5 months (2.7-9 months) with big amount of periosteal callus formation. There were no complications in all patients seen. It can be concluded that this method and device meet biological and biomechanical requirements for safe fracture treatment.

Key words: femur, fracture, internal fixation, Mitkovic device, dynamisation

INTRODUCTION

Femoral fractures are a common problem in orthopaedic trauma. For decades, nail, plate and external fixator have been the most frequently used aids and are still present today. Using ordinary plate relates to vascular damage and dead space under the plate, which leads to bone loss and possible infection. Vascular damage is even more seen after nailing. External fixator using extrafocal concept does not interfere with vascular damage in fracture area and, when it is used, balanced three dimensional stability frame provides excellent biomechanical conditions. Fracture healing is undisturbed and additional dynamisation can further improve callus formation. But external fixator has disadvantages as pin tract infection, pin loosening, knee stiffens etc. During the past several years First author have tried to design one internal fixator as a substitute for an external dynamisable fixator, which will decrease the number of complications. The new internal fixator seems to be a treatment alternative to femoral fractures, especially complex fractures such as comminutive and segmental - including upper and lower end involvement.

MATERIAL

Internal fixator, designed by Mitkovic 1997, consists of one bar, 2-4 clamps and 4-6 screws (Figure 1). Bar has two holes on each end on the same plane: one ordinary hole and another hole like a slot along the long axis of the bone (Figure 2). The bar is available in different diameters and lengths. For trochanteric or condylar involvement it is available specially designed. Telescopic bar is also available. Clamps are simple. When pressed by the screw onto the bone cortex, the clamp is fixed to the bar. One screw is for each hole on the bar and one for each clamp. Device is produced in Ortokon Ltd., Nis. Within 4-6 weeks after application of internal fixator, spontaneous loosening of the clamps occurs, which provides telescopic of the internal fixator and self-dynamisation. Because of this feature, Mitkovic internal fixator can be regard as "intelligent implant" (Fig. 2). Rotation of the bar and angulation of the bone fragments, are prevented by two screws into the bar. Ninety-two fractures of the femoral diaphysis were treated (57 fresh, 18 after temporarily fixed femur in polytraumatised and other patients, 1 refracture after external fixation, 11 disintegrations or non-unions after plating, 4 nonunions or implant failures after Kuntscher nailing and 1 nonunion after interlocking IM nailing). There were sixty-one men and thirty-one women. The age of the patients ranged from 16 to 84 (mean 42.3). Twenty-nine fractures involved right and nine left femur. All fractures were closed. Follow up was 3.1 year (2 to 7 years).
METHOD

The technique used for application of the apparatus, consists of closed fracture reduction by special reduction device, and introduction of the bar and clamps through two, 5-8 cm long incisions, one proximally and another distally. The bar is introduced first, through one of the incisions and is pushed above the periosteal layer of the lateral parts of quadriceps muscle while one or two clamps are on the bar. Pushing of the bar is performed by means of a special handle temporarily connected to one of the two ends. The bar has special shapes on both ends. After reaching the second incision another 1-2 clamps are introduced onto the bar and the bar is pushed further until reaching the desired position along the lateral site of the femur. The handle is removed then, and pre-drilling and screwing of the bar and clamps is performed. During the pre-drilling of telescoping screw, care should be taken that this screw should be placed on the distal end of the hole in relation to the fracture area. After that, each clamp is tightened by one screw. Position of the clamps, if two clamps are used for each main fragment, is recommended to be in convergent orientation. This configuration provides balanced three-dimensional stability. If one clamp is used for each main fragment, it is then recommended that the clamp be applied from the anterior side of the bar. After that, wounds are closed. In the beginning, internal fixator was applied using open fracture reduction, but closed reduction was used later instead. Closed fracture reduction is achieved by a specially designed reduction device. The position of the fragments is checked by the use of image intensifier. Operation with reduction device is performed on an ordinary operation table (without traction tools). Postoperatively, patients are allowed to walk without weight bearing (but with touching the ground with the weight of the leg) during the first three weeks and after that, progressive increase in the weight bearing is introduced until full weight bearing is achieved after 8 weeks. Physiotherapy and rehabilitation begin 2 days after operation.

RESULTS

All wounds healed within 12 days after operation. Sufficient radiological healing has ordinary been registered at three months after operation (Figure 3). All fractures healed within 2.7 to 9 months (average 3.5 months) Patients returned to their full activities after four to ten months (average 5.3 months). Normal function of the knee and hip joint, normal gait, normal femur length and fragments alignment were observed in most of the patients. In 21 patients (22.8%) a shortening of 3mm to 18mm (average 7mm), due to dynamisation, was observed radiologically or clinically. A big amount of periosteal callus formation equally distributed in AP and LL position was registered. In 13 patients, a big amount of callus formation was seen, even around the distal end of the internal fixator where telescopic movements of the bar occurs and around the clamps. Self-dynamisation effect and telescoping was observed in 35 patients (38.1%).

FIGURE 1
DRAWING OF MITKOVIC INTERNAL FIXATOR WITH 2 SCREWS THROUGH THE HOLES NEAR TO PROXIMAL AND DISTAL END IN LATERO-MEDIAL DIRECTION AND 2 SCREWS THROUGH EACH OF 2 CLAMPS IN MORE ANTERO-POSTERIOR DIRECTION. ROD DOESN’T TOUCH THE FRAGMENTS IN THE FRACTURE AREA.

FIGURE 2
DRAWING SHOWING SPONTANEOUS DYNAMISATION OF THE MITKOVIC INTERNAL FIXATOR: A) BEFORE AND B) AFTER AXIAL DYNAMISATION.
were no complications as infection, neurovascular damage, joint stiffness, pain, fragment misalignment or gait alteration.

**DISCUSSION**

The aim of this study was to analyse the feasibility of new internal fixator as one of methods for femoral fracture treatment. Conventional internal fixation using intramedullary nail or plate is well established and improved in recent years, especially in minimal invasive ideas. One of the pre-requests for new internal fixator is to provide preservation of both intramedullary and periosteal vascularisation and to decrease intraoperative and postoperative complications on minimally invasive method. Implantation of Mitkovic internal fixator is relatively simple and can be realised using minimal invasive method through small incisions, without opening the fracture area. Construction of the apparatus provides fixation of the main fragments without contact between the implant and bone fragments in fracture area so that the implant does not interfere with periosteal or medullar blood circulation in the fracture area. Use of the bar excludes dead space on the fracture area. From a biomechanical point of view, this internal fixator provides balanced three-dimensional stability on fracture area, which is confirmed by wide biomechanical investigations. From a biological point of view, this internal fixator preserves periosteal and intramedullary blood circulation and big amount of callus formation equally distributed around the fracture area (in AP and LL view). It has been confirmed experimentally on 60 animals in comparison to intramedullary and plate fixation. The system is sufficiently elastic to stimulate production of big amount of bone callus. Construction provides also the effect of spontaneous dynamisation of the fixator during the time, when screws on clamps become a little looser. This effect has been confirmed radiologically. This effect can bee especially important if there is delayed union, when telescoping movements along the long axis of the bone can provide pressure on the fracture area and stimulate ossification of the cartilage. It is believed that it will decrease the overall rate of delayed union and non-union. Because of this spontaneous dynamisation feature, this internal fixator can be regarded as an "intelligent implant". This implant is suitable for minimal invasive surgery.

**CONCLUSION**

According to the clinical results obtained during 7 years of use of the new internal fixator, it can be concluded that this implant provides good biological and biomechanical environments for femoral fracture healing. It is especially suitable for complex fracture treatment, as comminuted fractures, segmental fractures with involvement of trochanteric or condylar area. Its application is relatively simple and this implant is suitable for routine use.
REZIME

NOVA BIOLOŠKA METODA UNUTRAŠNJE FIKSANCIJE FEMURA


Ključne reči: femur, unutrašnja fiksacija, Mitković unutrašnji fiksator, dinamizacija

REFERENCES


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