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NEW BIOLOGICAL METHOD OF INTERNAL FIXATION OF THE FEMUR

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Summary. *Femoral fractures are common problem in Orthopaedic Traumatology. Preservation of intramedular and periosteal vascularisation is very important in the surgical treatment of these fractures. It is shown new internal fixator that provides fixation while application can be performed by minimally invasive method with no contact between the implant and bone fragment in fracture area. The device is selfdynamisible. It has been applied to 38 patients. In the beginning application has been performed using open method on the fracture area, while later, after author has developed new, selfnavigatible reduction device, application of internal fixator has been performed by minimally invasive surgery, after closed reduction has been achieved. Follow up was 2.1 year (4 months to 3.5 years). Bone healing was achieved in all patients within 3.6 months (3-5 months) with big amount of periosteal callus formation equally distributed around the fracture area. Self-dynamisation of the implant has been proven radiologicaly. There was no any complication in all patients treated.*

Key words: *Femur, Fracture, internal fixation, reduction device, dynamisation*

Introduction

Femoral fractures are common problem in orthopaedic trauma. Nail, plate and external fixator are since decades the most frequently used and they are still present today (1). Using ordinary plate relates to vascular damage (2) and dead space under the plate (3), which leads to bone loss and possible infection. Vascular damage is even more seen after nailing (4). External fixator using extrafocal concept doesn't interfere with vascular damage in fracture area and, when it is used balanced three dimensional stability frame, provides excellent biomechanical conditions (5-7). 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 we have tried to make one internal fixator as an substitute for an external dynamisable fixator.

The new internal fixator seems to be a treatment alternative to femoral fracture especially complex fractures as comminutive and segmental including upper and lower end involvement.

Device

Internal fixator consists of one bar, 2-4 clamps and 4-6 screws (Fig. 1). Bar has two holes on each end on the same plane: one ordinary hole and another hole like slot along the long axis of the bone (Fig. 2). Diameter of the bar is 10 mm and length 250-300 mm. For trochanteric or condylar involvement it is available specially designed bar on one of end. Also telescopic bar is available. Clams 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.

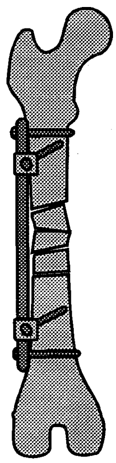

Fig. 1. Internal fixator with 2 screws through the holes near to proximal and distal end in latero-medial direction and 2 screws through each of 2 clamps in more antero-posterior direction. Rod doesn't touch the fragments in the fracture area.

During the time after application of internal fixator, bone loss around the screws leads to slight loosening of the clamps, which make possible telescopic sliding of the bar along the long axis of the bone. It provides self-dynamisation of the implant (Fig. 2). Rotation of the bar and angulation of the bone fragments, are prevented by two screws into the bar.

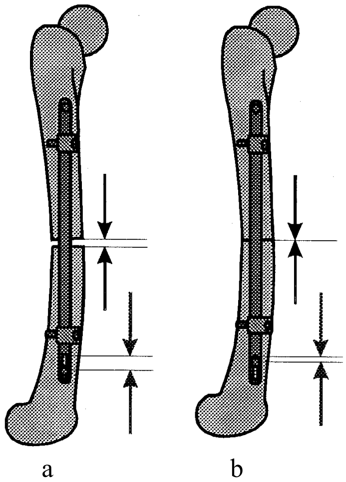

Fig. 2. Axial self-dynamisation of the internal fixator after spontaneous slight loosening of the screws: a) before and b) after axial dynamisation/

Patients

Thirty-eight femoral fractures were treated (30 fresh, 1 refracture after external fixation, 3 after disintegration after plating and 4 non unions).

There were twenty-four men and fourteen women. The age of the patients ranged from 18 to 74 (mean 42.3). Twenty-nine fractures involved right and nine left femur. All fractures were closed. Follow up was 2.1 year (4 months to 3.5 years).

Procedure

The technique used for application of the apparatus, consists of closed fracture reduction by special reduction device, and introducing 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 through 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 the use of special handle temporarily connected on one of two ends. Bar is conical on both ends with no very sharp top. After reaching the second incision another 1-2 clamps are introduced onto the bar and bar is pushed further until reaching the desirable position along the lateral site of the femur. The handle is removed then, and pre-drilling and screwing of the bar and clamps is undertaken. First screw is introduced through the ordinary hole and second screw through the slot hole. During the pre-drilling of this second 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: one from anterior and other from posterior side of the bar. This configuration provides balanced three-dimensional stability. If one clamp is used for each main fragment, than it is recommended to be from anterior side of the bar. After that, wounds are closed.

Closed fracture reduction is achieved by specially designed reduction device. The position of the fragments is checked by the use of image intensifier. Operation with reduction device was performed on orthopaedic operating table but in four patients operations have been performed on ordinary operation table (without reduction extension tools). Postoperatively it has been allowed to patients to walk without weight bearing during the first three weeks and after that, progressive increasing of the weight bearing until full weight bearing after 8 weeks, has been encouraged. Physiotherapy and rehabilitation began 2 days after operation.

Results

All wounds healed within 12 days after operation. For the first two patients follow up was 3.5 years. Sufficient radiological healing has been registered at three months after operation. One of them (Fig. 3) came for checking in out patient clinic without any support (crutches or stick) 11 weeks after operation, in spite of suggested protocol, telling that he fills his leg reliable. Patients returned to their full activities after four to eight months (average 5,3 months). Normal function of the knee and hip joint, normal gate, normal femur length and fragments alignment were observed. It was registered big amount of periosteal callus formation equally distributed in AP and LL position. In one of the patients, it was seen big amount of callus formation even around the distal end of the internal fixator where telescopic movements of the bar occurred. In this patient it has been proven self-dynamisation effect and telescopic translation for about 4 mm.

There was no any complication as infection, neurovascular damage, joint stiffness, pain, fragment malalignment or gate alteration.

Discussion

The aim of this study was to analyse the feasibility of new internal fixator as one of method for femoral fracture treatment. Conventional internal fixation using intramedulary nail or plate is well established (8) and improved in recent years, especially in minimal invasive ideas. One of the pre-requests for new internal fixator using extramedulary nail is to provide equally well results under similar conditions.

Implantation of internal fixator using extramedullary nail (bar) is relatively simple and can be realised using minimal invasive method through small incisions, without opening of 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 implant doesn't interfere with periosteal or medullar blood circulation on fracture area. Using the bar excludes the dead space on the fracture area.

Fig. 3a x-ray of the first patient with slightly comminuted dyaphyseal fracture of the femur.

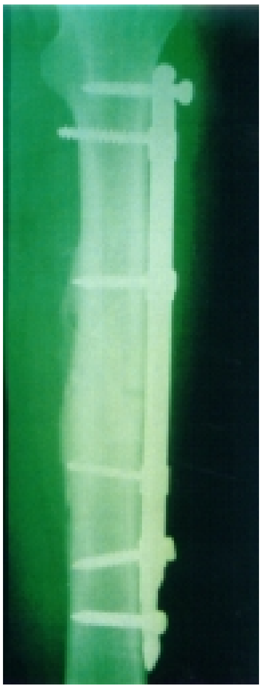

Fig. 3b x-ray seven months after operation.

From biomechanical point of view, this internal fixator provides balanced three-dimensional stability on fracture area, which is confirmed by equally distributed periosteal callus formation around the fracture area (in AP and LL view). The system is sufficiently elastic to stimulate production of big amount of bone callus. Construction provides also the effect of automatic dynamisation of the fixator during the time, when screws on clamps become a little looser. This effect has been confirmed radiologicaly. This effect can bee especially important if there is delay union, when telescoping movements along the long axis of the bone, can provide pressure on the fracture area and to stimulate ossification of the cartilage. It is believed that it will decrease the overall rate of delay union and non-union. Because of this automatic dynamisation feature, this internal fixator can be regarded as an intelligent implant. When, automatic dynamisation will occur, depends of two main thinks: one is the moment of force used during the tightening of the screws on the clamps and another is osteolysis around the screws. We don't know at this moment the influence and accurate dependence of these two circumstances.

During the use of this internal fixator there was doubt that it can produce pressure on the muscles and to be palpable beneath the skin and muscle layers. Actually the biggest thickness of the implant is on the place of the clamps where diameter is 11 mm. Clinically patients didn't have any complain in this regards, on regularly repeated our questions during each checking in out patient clinic.

This implant is suitable for minimal invasive surgery. In one patient it has been applied by percutan method with two small incisions without opening of the fracture area. Closed fracture reduction and fragment position holding, have been provided by specially designed reduction device. The position of the fragments has been checked by the use of image intensifier. In four patients, fracture area was opened because we didn't have reduction device available.

This implant is suitable for minimal invasive osteosynthesis using of motorised reduction device, previously developed by the author, and mechanical monitoring device, which is in development in collaboration with Professor Perren and Mr. Hehli in AO Development Institute in Davos. We believe that the using of these devices, fluoroscopy, ultrasound or any other imaging technique, can be avoided during closed fracture reduction.

According to the first clinical results received by the 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 involvements of trochanteric or condylar area. Its application is relatively simple and this implant is suitable for routine use. Further studies, however, are necessary to evaluate potential advantages or complications as compared to existing intramedulary and plate fracture fixation.

References

1. Krettek C, Schandelmaier P, Tscherne H. New developments in stabilisation of dia- and metaphyseal fractures of long tubular bones, Orthopade 1997; 26:408-21
2. Perren SM, Z'Brun P. Bone loss after plating ("stress protection"), Injury Suppl. 1991; 22:10-11
3. Stockenhuber N, Schweighofer F, Bratschitsch G, Szyszkowitz R. UFN system. A method of minimal invasive surgical management of femoral shaft fractures, Langenbecks Arch Chir 1996; 381: 267-74
4. Pfister U. Biomeschanische und histologische Untersuchungen nach Marknagelung der Tibia, Forttschr Med 1983; 101(37): 1652-9
5. Mitkovic M. New concept in external fixation, Prosveta, Nis, 1993.
6. Mitkovic M. Spoljna fiksacija u traumatologiji - Razvoj i primena aparata autora, Prosveta Nis, 1993.
7. Mitkovic M. Mitkovic type external fixator - biomechanical and experimental investigations and clinical results of 4.500 application, SICOT96, Amsterdam, Abstracts, 1996; P1.218
8. Muller ME, Allgover M, Schneider R, Willeneger H. Manual of Internal Fixation , 3rd edition, Springer Verlag, 1991.

NOVA BIOLOŠKA METODA UNUTRAŠNJE FIKSACIJE FEMURA

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Kratak sadržaj: *Prelomi femura su čest ortopedsko-traumatološki problem. Očuvanje intramedularne i perisostalne vaskularizacije igra vrlo važnu ulogu u lečenju svakog preloma duge kosti a naročito femura. U ovom radu, prikaziju se rezultati primene jedne nove, originalne metode kojom se postižu ciljevi očuvanja oba pomenuta vaskularna sistema duge kosti, što nije moguće ostvariti drugim metodama. Novi implantat je u zoni preloma odvojen od kosti, ne dolazeći u koliziju sa vaskularnim strukturama kosti, a istovremeno je i samodinamizirajući čime se ostvaruju optimalni biomehanički uslovi za zarastanje preloma. Do sada je primenjen na 38 pacijenata. U početku aplikacija novog implantata je bila ostvarivana otvorenim putem tj. otvaranjem mesta preloma a sada se izvodi minimalnom hiruškom intervencijom, kroz dva mala reza van mesta preloma. Prethodna repozicija preloma se ostvaruje pomoću samonavigacionog uredjaja za repoziciju kosti koga je takodje konstruisao autor. Dužina praćenja bolesnika posle operacije je u proseku 2,1 godinu (od 4 meseca do 3,5 godine). Do zarastanja je došlo kod svih pacijenata u proseku u roku od 3,6 meseci (3-5 meseci) us stvaranje velike količine periostalnog kalusa ujednačeno rasporedjenog celom cirkumferencijom oko preloma. Samodinamizirajući efekat je dokazan radiološki. Nije bilo ni jedne komplikacije.*

Ključne reči: *Femur, fractura, unutrašnja fiksacija, repozicioni uredjaj, dinamizacija*