

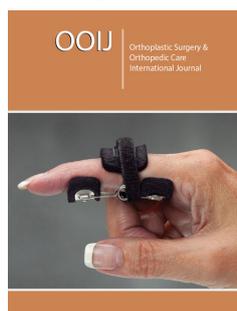
New Devices of Old Gold Ideas: Batbridge and DIF

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Background

The femur fractures of the elderly, in particular in the two varieties subtrochanteric and of the distal femur, remain nowadays one of the most important challenges in surgical fracture treatment as they are often complicated, with an oblique or a spiral shape, intra-articular and with a comminuted nature [1-4]. With the increasing of population age and increasing number of periprosthetic fractures, complex fractures of the distal or subtrochanteric femur are expected to increase, although they represent a low percentage of all femoral fractures [5-7].

Plate osteosynthesis and retrograde nailing are almost the unique options for the treatment of femur fractures indicated below. The use of plating technologies was intended to limit the disruption of the blood supply to the bones to improve healing, but locked plating can result in overly stiff constructs and thereby suppress interfragmentary motion preventing callus formation. Construct stiffness has been cited as a factor linked to non-unions [8-11]. Malunion and implant failure are relatively common in elderly due to the wide medullary canal and osteoporosis [12-14].

For an adequate bone healing one of crucial aspect is the maintenance of mechanical stimulus on the fracture site and to grant the right conditions under which healing can progress, such as the definition of interfragmentary strain beneficial for secondary bone healing. The use of Minimally Invasive Plate Osteosynthesis (MIPO), have further enhanced the biological capability for repair by minimizing trauma to the periosteum and surrounding soft tissues. Nowadays developments in locked plating surgical approach have addressed one main aspect for successful healing: the biology; but the resulting mechanical environment can vary substantially depending on the fracture structure and on the subsequent configuration of the implant [15].

Introduction

Looking at the history of the use of orthopaedic implants, many solutions have been sought to try to solve the problems related to bone healing. Only considering the aspect regarding stiffness of orthopaedic devices, many attempts have been made to solve the problem in other body districts or for other surgical solutions such as external fixators or intramedullary nails. With these devices it is possible to grant a first static phase of osteosynthesis, followed by a dynamic phase due to the modification of the implant itself, which should allow a better bone distribution of the strain forces on fractures to ensure reduction reduction of nonunion rate stimulating the bona callus fracture.

A simple technique that has found a wide use since the advent of surgical treatment of fractures is Cerclage wiring. In literature a lot of works have reported the use of various cerclage technologies with a wide range of results and clinical applications: in fact, it may have been the first internal fixation technique. There are four methods of cerclage wiring usage: tension band, cerclage, hemi-cerclage and interfragmentary wires [16].

Cerclage wire can be applied surgically in two different ways: as a temporarily device for reduction during surgery, which is removed when synthesis is obtained, and can be used long term as an implant. When cerclage wires are used as implants, they may be used

alone or in combination with another synthesis device (such as plates, nails, stems of prosthesis or a combination of thereof). The increasing numbers of periprosthetic fractures have led to a revival of interest for this simple technique so much to lead to the design of plates suitable for this specific purpose that had housings already prepared for the cerclage itself [17].

If we take a look at the solutions found in orthopedic surgery for the reduction and stabilization of complex fractures within the panorama of the plates, a particular type of plate stands out which has the possibility of performing a dual function: The Dynamic Internal Fixator (DIF). The DIF system is a plate with an angular stability which covers the principles of "internal fixator" and that can be modified to become dynamic if and when necessary, without having to remove it. In this way the most important limit of the internal fixators is overcome thanks to the possibility of allowing the compression at the fracture site by acting on the plate itself and allowing the patient to load during the healing process. Furthermore, the possibility of using a sliding plate, such as the DIF, reduce the potentially harmful angular bending forces by converting them into a sliding and axial compression movement at the fracture site [18-20].

The theory that different mechanical moments and variable mechanical stress during the healing process are necessary finds its basis in the fact that every single fracture has peculiar characteristics (such as fracture line, bone stock, number of fragments, comminution, etc.). Forces acting on the fracture site cause a biochemical reaction of the cells involved and a subsequent release of chemical mediators, growth factors, and hormones that work not only at the fracture site but also on a systemic level, as well as the alteration/deprivation of neuronal signals negatively affects the bone healing process. On the basis of these concepts there are many possible advantages in the complex process that leads to bone repair that can derive from a device of synthesis that can vary

from static to dynamic [21-24]. These devices showed in literature encouraging results in terms of surgical technique, operating time, safety, and functional outcomes, though the complications rate was comparable to that of other complex reconstructions [18].

Cerclage

Femoral fractures, mostly spiral fractures or those occurring after total hip or knee replacement, often need cerclage wire fixation to optimize the reduction. These devices could be placed percutaneously, with mini-open or through widely open approaches. In literature is reported that cerclage wiring is an effective extramedullary instrument that provides circumferential force across the fracture surfaces when tension is applied allowing a good reduction and fixation when used alone in combination with other implants [25].

Subtrochanteric or distal femur fractures, in the presence of a long oblique or a complex multifragmentary rim of fracture, can be hardly cannulated with a guidewire without an open reduction. The use of cerclage wires as a first approach to reducing the fracture allows to immediately obtain the reconstitution of the normal anatomical profile, to have a reference for the reconstruction of the length and sometimes also to restore the correct rotational axis of the bone segment prior to nailing, making the intramedullary cannulation easier and faster [26-28].

Periprosthetic femoral fracture is one potential complication of total hip arthroplasty (THA). Modern osteosynthesis techniques are facing the treatment of these fractures also developing increasingly interesting devices. Nevertheless, a combination of locking plate and cerclage is considered by some authors as the more suitable strategy of treatment, eventually with the addition of strut allografts which should allow for better healing and fewer complications [29-34] (Figure 1).



Figure 1

Locking plate technology offers by its nature increased angular stability and, theoretically, better fixation in osteoporotic bone, even if for the correct positioning, which must not be too rigid, the skill of the surgeon remains crucial, and the sacrifice of soft tissues is still high. On the other hand, the evolution of percutaneous cerclage wiring and MIPO techniques have allowed to reduce the complications associated with extensive exposures [8]. In a 2016 study were reported the results of a cerclage wiring elevated from the bone surface with protrusions or spheres than cables or conventional wires, a low contact version (Batbridge), and was demonstrated used in four periprosthetic fractures as an exclusive

implant for reduction and fixation, whereas in 50 other cases it was combined with internal devices (hip stem of THA, intramedullary nail, DIF, antibiotic spacers). The results show non-union and delayed union which appear to be less than the complication rate seen with conventional open reduction and internal fixation. The average time to union (3 months) was comparable to other method of indirect reduction or mini-open reduction and fixation for such difficult fractures. The limitation of the cerclage is that it can be used in the most long oblique fracture, spiral fracture, and some wedge fractures, whereas it should be avoided for transverse or short oblique fractures [35] (Figure 2).

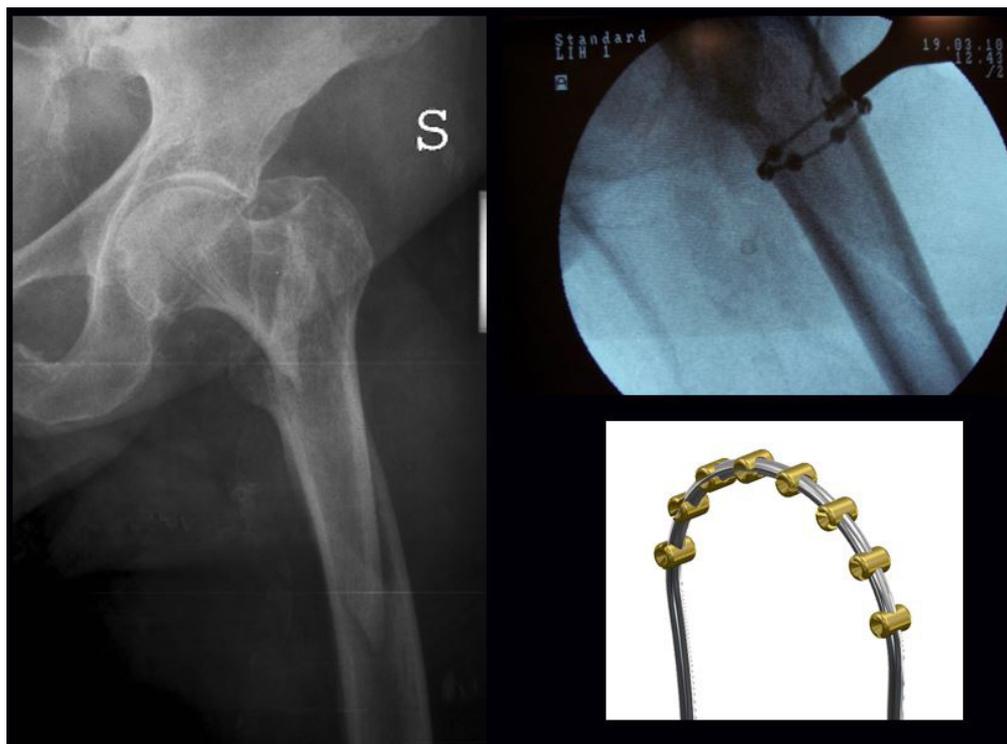


Figure 2

The use of cerclage wiring was recommended in these cases for the advantages of minimally invasive reduction and fixation technique, low costs, soft tissue sparing especially with percutaneous approach with almost the same or better outcomes in the management for displaced subtrochanteric fractures, fractures of the distal femur and peri-prosthetic fractures [25,35]. Traditionally, the use of cerclages in fracture has been considered potentially dangerous because there was a theory that these devices led to a strangulation of periosteal vascularization which can led to bone necrosis and non-union. Some evidence in literature have shown that the blood flow of the bone cortex is constituted by centrifugal, circumferential way, and in addition large longitudinal vessels, not only in the periosteum but also in the medullary canal, which are not destroyed using the cerclage wires [16,29,35,36].

Periosteal devascularization may occurs in the surgical dissection due to stripping to expose and reduce the fracture, causing potentially bone necrosis and other complications. A

possible disastrous complication is neurovascular injury, such as charge of the superficial femoral artery and sciatic nerve, because it travels from the femur midshaft to the distal third often close to the fractures site or near the surgical site of cerclages [37-39].

DIF

In literature could be find many studies that have dealt with the issue of fracture fixation by internal or external fixation in an increasingly innovative way. Many factors have significantly influence in bone healing (biology, macro and microscopic loading forces, implant-bone interface, force loading and unloading axes) and often they are not exactly predictable variables in the preoperative phase, so it makes extremely difficult to formulate an exact prognosis or predict the evolution of a certain fracture after surgical treatment [40].

This problem has been tackled over time first with static systems that guarantee a high stiffness to the construct set up

for fracture treatment. Subsequently, the approach was modified (ex. intramedullary nailing) introducing technical measures that guarantee not only stability of the construct, but also the possibility of stimulating bone regeneration through the application of the forces necessary to stimulate the biology of the bone itself through the normal anatomical axis [41]. Consolidation delays, non-union and implants ruptures are often caused by the rigidity of the implants that do not allow a correct load transfer on the fractures fragments. Another described problem was the asymmetric formation of the bone callus often due to the total stiffness in the bone segments underlying the plate. The use of a longer plate that correctly cover the site of the fracture optimizes the distribution of mechanical stress, but only the possibility of changing the

load vector forces on the fracture and on the plate from static to dynamic can allow the protection of the reliability of the plate and the stabilization in compression of the fracture with lesser bending and non-axial loads [18,42].

In literature is described an interesting solution with these characteristics: The Dynamic Internal Fixator. The theory underlying the development of the Dynamic Internal Fixator (DIF) plate: it is a plate with angular stability with the possibility of ongoing dynamization, as already possible, without needing to remove it. Unlocking the sliding movement, the distalization of the fulcrum modified the bending forces into translatory ones, compressing the fracture ends and shifting resistances from the plate to the bone itself [18] (Figure 3).

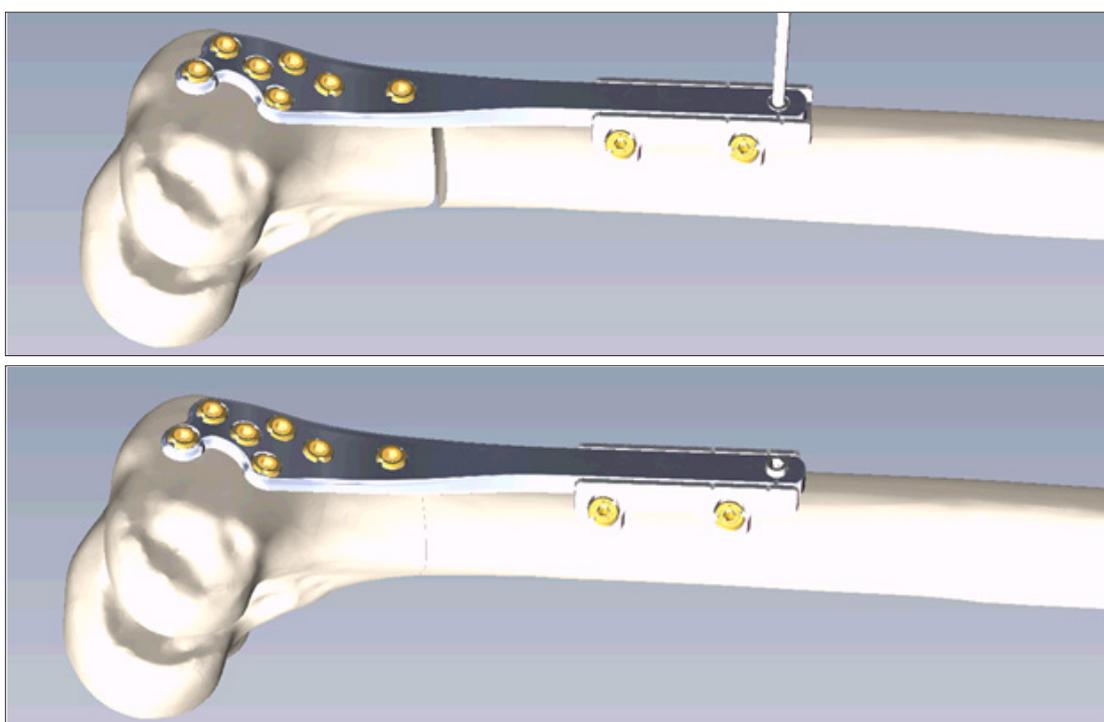


Figure 3: The DIF system.

Thanks to the possibility of dynamization, the DIF plate allows the load to be transferred to the fracture site in a controlled manner during the healing process. Moreover, the characteristics of a plate “slide” system allows the bending movement to be converted into a sliding movement and then into axial compression. This system could be used for fixation of femoral fractures in the following cases:

- I. Fractures of the middle/distal diaphysis
- II. Supracondylar fractures
- III. Distal intra-articular fractures
- IV. Consolidation delays and non-union

- V. Growing bone segments (pediatrics)
- VI. Failure of implants.

Foreseen advantages include using of self-locking screws with a conical head that avoids the loss of reduction even in osteoporotic bones, the possibility of early functional load thanks to the correct transfer of forces on the fracture fragments, the reduction of failure rate or breakage of the implants and a potential reduction of functional healing times. Encouraging results were reported on 26 cases treated with this device. Fracture healing with complete bony consolidation and without secondary loss of reduction evaluated at 6 months from the first surgery was achieved in 96% [18] (Figures 4-6).

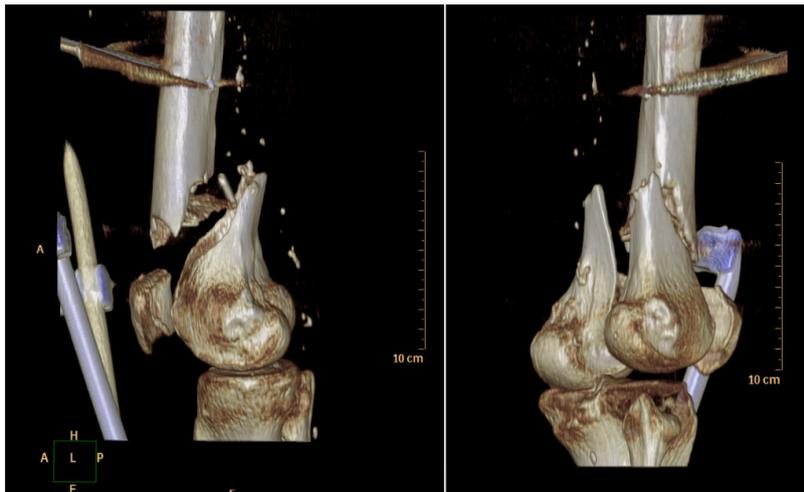


Figure 4: Fracture of the distal femur before treatment.

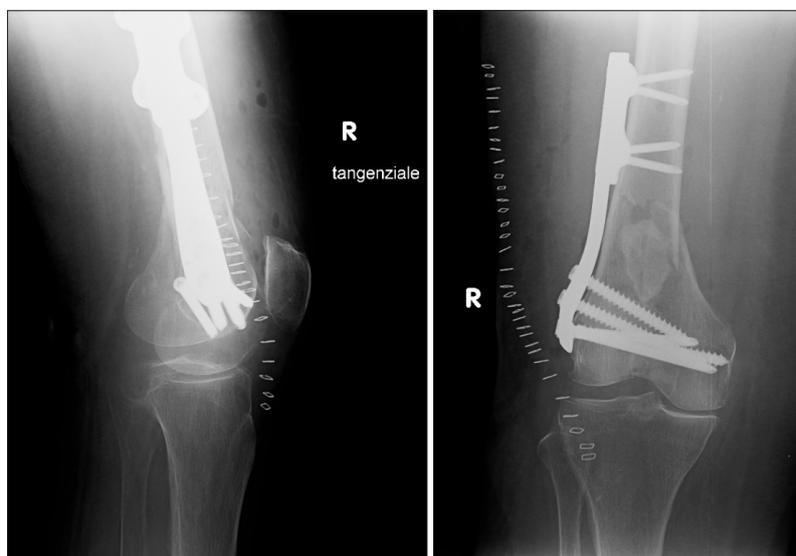


Figure 5: Fracture of the distal femur after treatment with DIF system.



Figure 6: Fracture of the distal femur (3 months dynamization) after a year from surgical treatment.

Conclusion

These simple techniques DIF and cerclage are still used and can represent solutions that are often little used or even misunderstood, but easy to apply, for a weighted approach between surgical risks and benefits for the patient for many of the cases described in literature.

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