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Stefano Lepore
Nicola Capuano
Luciano Lepore
Gaetano Romano

Preliminary clinical and radiographic results with the Fixion intramedullary nail: an inflatable self-locking system for long bone fractures

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S. Lepore (✉) • N. Capuano • G. Romano
Second Orthopedics Division,
A. Cardarelli National Hospital,
Via Cardarelli 9, I-80131 Naples, Italy
Tel.: +39-081-7473812
Fax: +39-081-7473811
E-mail: ortopedia2cardarelli@yahoo.it

L. Lepore
First Orthopedics Division,
ASL Naples I,
Orthopedic Trauma Center, Naples, Italy

Abstract We present a new inflatable self-locking intramedullary nailing system for the treatment of long bone fractures. The features of this system and the advantages of the technique include: fixation along the entire length of the nail, lack of proximal or distal interlocking screws, optional reaming, reduced exposure of the surgeon to X-ray and reduced operating room time. First preliminary clinical and radiographic results are reported. Out of 41 patients who received implants for closed fractures, 29 were available for follow-up. We observed fracture consolidation in all 29 cases (100%), with absence of nonunions, infections or rotational malalignments. Only in 2 (6.9%) cases were complication reported, consisting in the opening of the fracture after inflation of the nail. Good stability of the nail, however, assured a complete callus formation. We conclude that the use of this intramedullary nail is an innovative, effective, simple and minimally invasive treatment for long bone shaft fractures.

Key words Intramedullary nail • Expandable • Self-locking • Unreamed

Introduction

Intramedullary nailing has become a standard procedure for the treatment of long-bone closed fractures. The Fixion system consists in an expandable, stainless steel cylindrical tube, with a conical distal end. This stainless steel nail is designed to be inserted in the medullary canal directly, without reaming and without any guide wire; then it is inflated with high-pressure saline (Fig. 1). With expansion, the nail increases its diameter by approximately 175% and locks into an anatomical fit into the bone (Fig. 2). The expansion of the nail is carried out under controlled pressure up to 70 atmospheres, and does not raise any safety concerns. This expansion process, by utilizing an incompressible fluid, ensures that any minimal fluid leakage will cause immediate pressure loss without any risk to the patient.

The nail is folded longitudinally in a specially designed press. This tubular structure is sealed distally with a cone-shaped cap and proximally with a one-way valve. The cross section of the nail is circular with four reinforcement bars: after expansion, abutment of the longitudinal bars to the

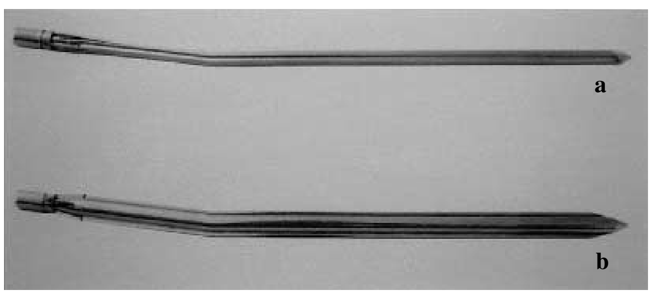

Fig. 1a,b The Fixion nail before (**a**) and after expansion (**b**) with saline

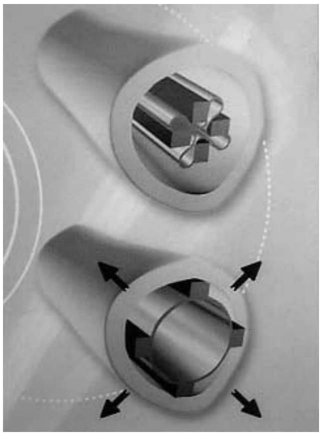

Fig. 2 Cross-section of the nail. After expansion, the diameter increases by approximately 175%

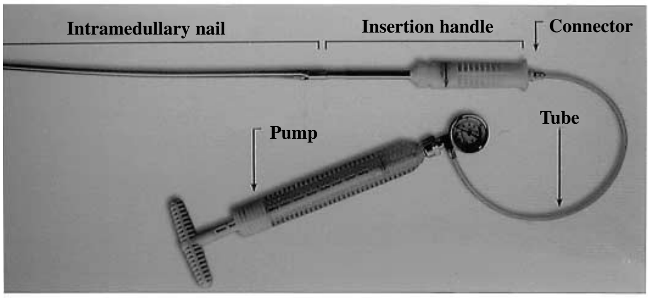

Fig. 3 The Fixion system: the nail with the insertion handle and the inflation device

inner surface of the canal along its entire length provides fixation of the nail to the bone ensuring no risk of migration, rotatory stability, fragment alignment and length of the fragments, excluding the need for interlocking screws.

The inflation device is a single-use manual plastic "pump", similar to a PTCA (percutaneous coronary angioplasty) inflation pump. A pressure gauge is located at the distal end of the pump, enabling continuous monitoring of the pressure in the system. An outlet tube at the distal end of the pump has a quick connect couple to the insertion handle. The insertion handle is a cylinder with a plastic handle, connected to the nail implant's proximal end, which is used for the nail insertion, location and adjustment in the intramedullary canal (Fig. 3).

Once the nail is inserted, a clinical stability torsional test is performed under X-ray visualization to verify the stability of the reduction.

Materials and methods

In the period February 2000 to July 2000, we implanted 50 Fixion intramedullary nails (Disc-o-Tech, Herzliya, Israel): 16 were implanted in the femur, 23 in the tibia and 11 in the humerus. A total of 41 nails were implanted for closed shaft fractures, 1 for open fracture stage II of Gustilo, 6 for non-union, 1 for a fracture of a plate and 1 for a pathological fracture. All operations were performed under peripheral anesthesia. Antibiotics were always used for short-term prophylaxis 15 min before operation. All patients received low-molecular weight heparin therapy at the time of hospitalization, prolonged for four weeks after surgery.

For the humerus we always utilized the retrograde approach, the classic trochanteric approach for the femur, and the medial para-tendinous approach for the tibia.

The traumatic series involved 32 men and 9 women having 13 femoral fractures, 18 leg fractures and 10 humeral fractures. The A.O. (Arbeitsgemeinschaft für Osteosynthesefragen) classification was used [1]: 33 fractures (80.5%) were type X2.A (spiral, short oblique and transverse), 7 (17%) were type X2.B (wedge) and 1 (2.5%) was type X2.C2.1 (bifocal with one fragment).

The patients were reviewed after surgery with an X-ray at 10 and 30 days and every 3 weeks until consolidation.

Results

Out of 41 patients who received implants, 29 were available for follow-up: 9 with fracture of the femur (8 type 32.A and 1 type 32.C2.1), 13 with fracture of the leg (12 type 42.A, 1 type 42.B) and 7 with fracture of the humerus (5 type 12.A and 2 type 12.B).

Reaming was performed only in 40% of the cases to enlarge by 1-2 mm the isthmus in the tibia and in the femur. In the humerus, because of the retrograde insertion, it was always performed in the distal fragment to avoid damaging the tip of the nail.

In 32.A and 42.A fractures, weight bearing was allowed after 10 days at 50%, full weight, in absence of pain, after 2-3 weeks. In some cases, full weight bearing was delayed for the presence of pain. In no cases, however, did we wait for complete callus formation to be seen on X-rays.

We observed fracture consolidation in all 29 cases (100%). Mean time of consolidation for type X2.A fractures was 12 weeks for the humerus, 9.5 weeks for the femur (Fig. 4) and 10 weeks for the tibia (Fig. 5). Criteria for evaluation were presence of pain with weight bearing, muscle power according to Constant score for the humerus, and callus formation on the X-ray.

We did not observe differences in the time of consolidation in the reamed group. We did not reported non-unions, infections, rotational malalignments, limb shortening or fat embolism.

Only 2 (6.9%) cases had complications, consisting in the opening of the fracture after inflation of the nail. We removed 4 nails, 3 from the tibia and 1 from the humerus, always without problems.

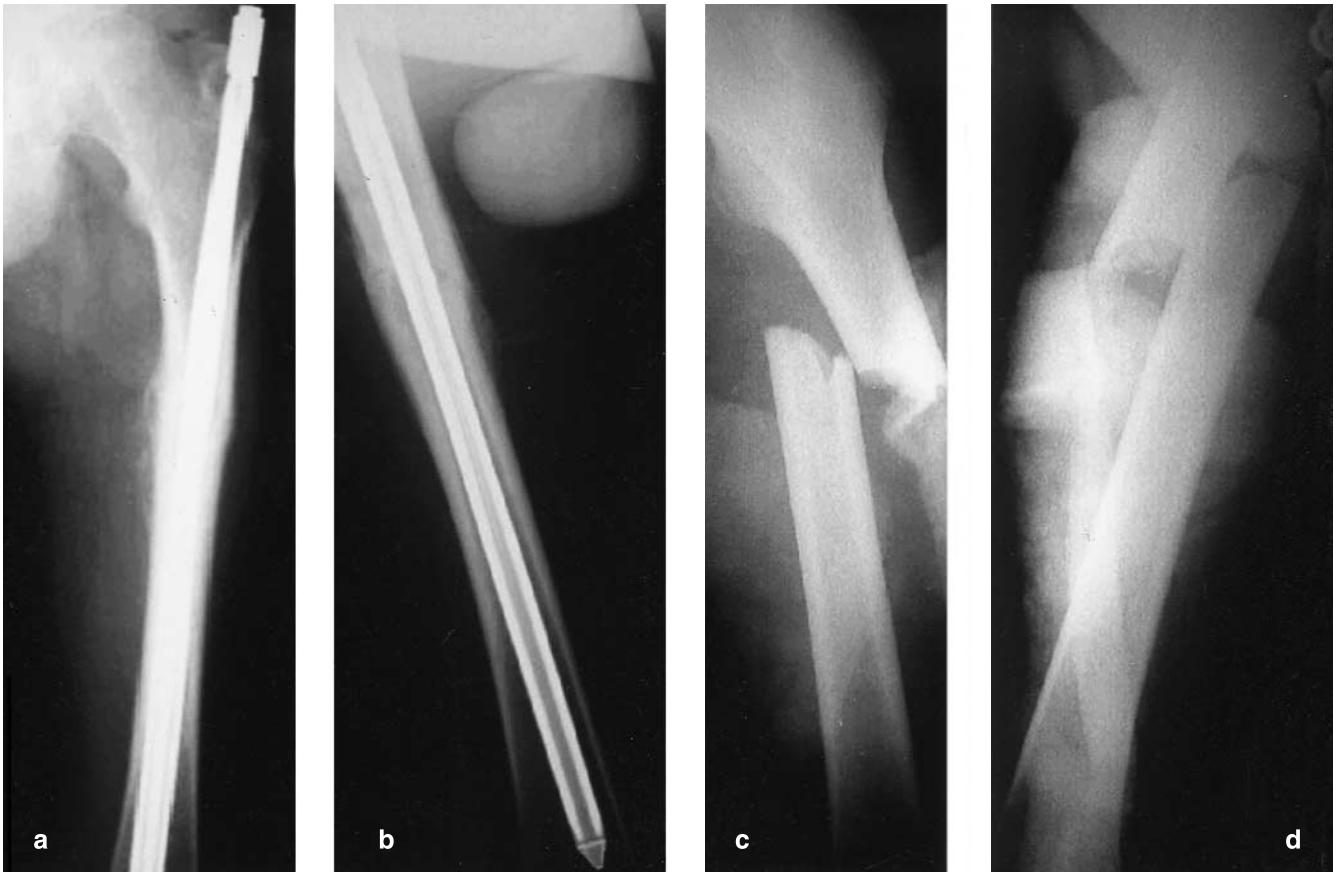

Fig. 4a-d *Femoral shaft fractures (type 32A2.1).* **a, b** Preoperative views of two patients. **c, d** X-rays at 9 weeks with complete consolidation

Discussion

The intramedullary interlocking nailing has become the gold standard in the treatment of closed diaphyseal fractures of the long bones [2, 3]. Being closer to the weight-bearing axis, an intramedullary nail has mechanical advantages over other fracture stabilization devices such as plates, external fixators, casts, etc.

Many articles have compared reamed interlocked intramedullary nailing with unreamed interlocked intramedullary nailing in the management of open and closed fractures. Reaming allows the insertion of a nail with a larger diameter that provides better stability, but some authors consider reaming to be a significant factor in delaying fracture union by damaging the intramedullary blood supply [4-6], affirming also that the degree of destruction is proportional to the amount of endosteal reaming [7]. Reaming also increases the intramedullary pressure inducing fat and medullary debris into the circulation, which can lead to pulmonary and cardiac complications [8, 9]. Proponents of unreamed nailing also believe that the risk of infection increases with reaming, especially in the treatment of open fractures [10-16].

Partisans of reaming nails have reported that reaming produces an internal bone graft locally which appears to stimulate fracture union and reduces the need for bone grafting [17]. Anglen and Blue [18] also reported faster healing times in fractures treated with reamed nails. Finkemeier et al. [19], Court-Brown et al. [20] and Wiss and Stetson [21] have found that reaming promotes fracture healing in nonunions compared with the insertion of unreamed nails.

In our fracture cases, we did not observe any differences in time of callus formation in the reamed and the unreamed group. We believe that this result is a function of the peculiar biomechanical behavior of the Fixion nail. In fact, the Fixion nail anchors with its longitudinal bars all along the endosteal wall, so that bearing forces are homogeneously shared along the entire diaphysis, unlike the common interlocking nails which have three points of grip.

Reaming is necessary to enlarge the humeral distal entrance of the nail, to avoid damaging the tip of the nail

Fig. 5a-d *Tibial shaft fractures (type 42.A1.1).* **a, b** Preoperative views of two patients. **c, d** X-rays at 10 weeks with complete consolidation

and to prevent fluid leakage. Moreover, we prefer to ream in young patients when time of surgery is delayed from the accident.

The advantages in using the Fixion system are:

- It is a minimally invasive and simple technique for nail insertion and removal, as interlocking screw dissection is not required.
- It saves time for surgery.
- It reduces X-ray exposure.
- It reduces intra- and postoperative blood loss.
- It reduces risk of fat embolism.
- It reduces risk of infection.

We report as the only complication the opening of the fracture in 2 cases after expansion of the nail. We believe that this can be avoided by inflating the system "step by step". When the surgeon feels a resistance in the screw mechanism of the pump he must stop inflating, with no need to reach the pression of 70 atmospheres. However, the torsional test performed under X-ray guidance showed in these cases the complete filling of the canal with a good stability and no movement of the fracture. Full weight bearing was allowed after 6 weeks, with complete callus formation.

The results in our experience with monofocal and simple bifocal fractures are encouraging. More experience and clinical evaluation are needed to evaluate other indications such as nonunion, osteotomy, long bone reconstruction following tumor resection, prophylactic nailing of impending pathological fractures, and revision procedures when other devices have failed.

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