Medical Engineering and Physics 000 (2017) 1–9

Contents lists available at ScienceDirect

Medical Engineering and Physics

journal homepage: www.elsevier.com/locate/medengphy

Characterization of an innovative intramedullary nail for diaphyseal fractures of long bones

V. Filardi

CARECI—University of Messina, Via C. del Mare, 41-98121 Messina, Italy

ARTICLE INFO

Article history:
Received 9 January 2017
Revised 27 June 2017
Accepted 7 August 2017
Available online xxx

Keywords:
Intramedullar nail
Tibia
CAD simulation
FE analysis
Energy methods

ABSTRACT

In this paper, an innovative design of nail for fractures occurring on long bones has been investigated. Its functioning is based essentially on sliding of conical surfaces, located in a spindle and in holding pins. Spindle and holding pins are connected together by a sleeve. The sliding transforms the rotational and translational motion of the spindle to a radial expansion of the holding pins, protruding inside the intramedullary canal. In order to evaluate mechanical behavior of the prosthesis different benchmarks and tests were numerically performed by an FE code. Results confirm good performances in terms of strength, under compression, bending and torque loading. Moreover, a complete model of the nail implanted on a tibia, has been developed and tested evaluating two loading configurations. Results confirmed a satisfactory behavior of the nail in terms of stress and strain shielding, comparable to the others traditional systems of prosthesis. In conclusion, this kind of nail appears to offer a good solution for elderly patients, which could not endure complications due to a complex surgery, as distal or medial screws are not necessary.

1. Introduction

In most cases, fractures are treated with a conservative approach that involves the immobilization of the limb by cast bandage. However, in some circumstances, it is necessary to stabilize the skeletal segments employing mechanical devices, applied by surgical interventions. Osteosynthesis is employed in the following cases:

- Whenever there is certainty of obtaining an unsatisfactory result with a conservative approach;
- When the fracture is complicated by an injury that requires immediate surgical repair (major vascular injury or major damage of the soft parts);
- When the healing cast bandage treatment appears to be too long and the blocking of one or more joints, for an excessive period, could cause degeneration (especially in the elderly);
- When the cast bandage could limit autonomy or self-management of the patient.

Pseudarthrosis is defined as the non-union of a fracture within about 6 months after the traumatic event. It is more common in those areas where bony vascularization is lacking, or when the entity of the trauma prevents the correct blood supply of fragments, but it may occur even in a well-watered district. Some bones in fact, such as the feet, have good intrinsic stability and good blood supply and can be restored with a minimum treatment. Other bones such as the proximal femur and the small bones of the wrist (in ex. scaphoid), have a rather precarious circulation, thus blood supply can be easily interrupted by traumatic events [1]. The bones, such as the tibia, have a discrete blood supply, but they are covered by a small thickness of soft tissue that can be easily damaged in case of severe trauma. Trauma can comprise both the internal vascularization of bone marrow (endosteal, vessels), and the external one (periosteal), coming mostly with branches piercing the overlying muscles [2]. Moreover, some fractures do not heal even when the treatment is appropriate, showing that not all the physiological mechanisms of pseudarthrosis are well known.

1.1. The intramedullary nailing

The traditional intramedullary prosthesis generally consists of a particular nail adapted to be inserted inside the bone, and subsequently fixed by means of proximal and distal threaded screws. In order to guarantee the correct positioning of screws, it is necessary to identify the insertion points, by means of X-rays. Successively fleshy tissue and bone must be drilled, and all the screws inserted, with considerable increasing of timing and possible complications. Several cases have shown how an erroneous positioning of the stabilizing screws can determine the necessity of a further intervention to make the proper reinsertion of the prosthesis, since

E-mail address: vfilardi@unime.it

http://dx.doi.org/10.1016/j.medengphy.2017.08.002
1350-4533/

pathological states caused by infections and wounds could rise up. The Kuntscher nail in 1940 has enabled the early mobilization of a large number of diaphyseal fractures (initially only in the femur), by using the intramedullary nailing technique, and an open section nail shaped as a clover. The nail shape allows, after an appropriate reaming of the medullar canal, good internal adhesion ensuring excellent stability in flexion, while less stability is guaranteed for rotation and translation. The intramedullary nailing provides some significant advantages such as:

- Limited and economic instrumental equipment;
- Relatively low cost;
- Simple and fast surgical intervention;
- Easy removal and minimally invasive.

This technique is generally adopted to stabilize the fractures occurred on long skeletal segments. On the other hand some compliance can arise, such as:

- Obstacle to the medullary vasculature;
- Mobilization / migration of the nail inside the bone;
- Need of auxiliary fixation devices (cerclage wires, screws, etc.);
- The nail shows its best performances for bending solicitations.

A stable nail, with the adequate caliber, allows the development of a correct intramedullary circulation. The main treatments, adopted in case of mid-diaphyseal fractures occurring in long bones, may be classified as follows:

- Closed-heart: when the prosthesis is implanted through a proximal access, without exposing the fracture site. This choice implies a preventive reduction of the fracture (or at least a good alignment). The principal osteosynthesis systems adopted in this case are: Gamma nail, Kuntscher nail, Elder nail, etc.
- Open-heart: when the nail is implanted with proximal access but the reduction and preventive stabilization of the fracture are surgically performed, accessing the fracture site. The principal osteosynthesis systems adopted in this case are: external fixators, screws, plaques, etc.
- With reaming: with the reaming of the medullary canal, by means of reamer tool. Reamed nailing affords greater stability of the nail inside the endomedullar canal.
- Without reaming: without any preparation of the medullary canal. Unreamed nailing preserves the endosteal blood supply and may therefore improve the fracture healing, decreasing risks of infection.

The Osteosynthesis involves overall several advantages such as stability of the fracture, early loading, rapid re-education of the neighboring joints, and rapid restoration of function. The disadvantages are associated to the longer anesthesia, possible risks of infection, and implant failure.

Generally, the nail is removed when it has fulfilled its function, but in some circumstances, the removal could cause many problems (older patients, etc.). In literature, there is no evidence of a direct relationship between complications and advantages involved by osteosynthesis, able to predict the necessity to remove or not a nail. Generally, the decision is taken evaluating case-by-case the determining factors, between complications and advantages, which can produce the restoration of function and minimize negative effects.

After the removal of the screws, holes remain in bone for many months. According to the natural process of bone remodeling, such holes are initially filled with fibrous tissue, without any mechanical seal. This fibrous tissue is replaced by bone tissue, mechanically performing, only after several months. Normally between 6 and 9 months, the holes are almost completely filled by bone tissue. A bone-screw hole causes stress concentration effects and weakens the bone, particularly in bending and torsion loading conditions [3]. For this reason during the first months, after the removal of the screws, fractures can occur in bones around the pierced areas. Aim of this paper is to study a new type of intramedullary nail, designed for fractures occurring on long bones. This new nail allows minimizing all of the disadvantages associated with traditional osteosynthesis devices [4]. Its peculiar geometry and functioning ensure a stable fixation of the bone stumps, reduce and simplify the nailing, and finally, it does not require any kind of screw to improve its stability. Its functioning is based essentially on the sliding between conical surfaces, located in a spindle and some holding pins. Spindle and holding pins are connected together by a sleeve. The sliding transforms the rotational and translational motion of the spindle to a radial expansion of the holding pins, protruding inside the intramedullary canal.

2. Materials and methods

2.1. The new endomedullar prosthesis

The intramedullary nail of new conception here proposed, is able to solve or minimize these surgical complications, being able to fix the broken bones with less invasive procedures that might lead to unwanted side effects. The nail consists of three principal parts: an outer longitudinal hollow sleeve, adapted to lodge a central spindle and some holding pins. When the spindle is screwed on the sleeve, the conical surfaces formed on it transform the rotational and translational motion to a radial motion of the holding pins, located inside the sleeve, and having the corresponding conical surfaces engaging on the previous ones, see Fig. 1. The cylindrical spindle is threaded at the top (M5*10), equipped with five radial conical surfaces obtained reducing its diameter, 79° angled, and longitudinally disposed at regular intervals of 48 mm. The conical surfaces engage ten holding pins, set up on the sleeve, and arranged in two rows diametrically opposed. In order to improve stability other two rows of pins located orthogonally to the first ones have been introduced. This configuration guarantees an excellent fastening of the nail inside the intramedullary canal, allowing the stabilization of the bone stumps. In conclusion, this new type of prosthesis achieves the same result of traditional implants, through the replacement of the medial and distal screws with the holding pins. The insertion procedure of this implant involves the following steps:

- Cutting of tissue and uncovering the upper bound of the bone;
- Drilling and reaming of the intramedullary canal, with support of RX;
- Implant insertion;
- Adjustment and stabilization of the system by screwing the upper end of the nail.

2.2. Forces and displacements calculation

The principal differences with traditional nails must be found in the functioning of the holding pins. In order to calculate forces and displacements, aging on them, the virtual work principle, with conservative forces systems hypothesis, can be used. This implies that the work carried out by a force depends only by the end point of the motion. In fact, by assuming that:

$\boldsymbol{F_T}$ *(screwing force)* = 100 *[N]*
$\boldsymbol{r}$ *(arm on which the force F acts)* = 3 *[mm]*
$\boldsymbol{p}$ *(pitch of the pin screw)* = 1.25 *[mm]* (fine pitch thread M10)
$\boldsymbol{d\theta}$ *(rotation angle imposed to the spindle)* = $k\ \pi$
$\boldsymbol{\beta}$ *(angle of conical surface)* = 79 *[°]*
$\boldsymbol{e}$ *(width of contact surface bone-holding pin)* = 2 *[mm]*
$\boldsymbol{f}$ *(length of contact surface bone-holding pin)* = 6 *[mm]*
$\boldsymbol{A}$ *(contact surface bone-holding pin)* = e*f = 12 *[mm²]*