A Fully Implantable, Programmable Distraction Nail (Fitbone) – New Perspectives for Corrective and Reconstructive Limb Surgery

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Systems for Callus Distraction – Overview

Within the last few years distraction osteogenesis has become an established method for limb lengthening and for the treatment of large bone defects. Besides the original technique by Ilizarov [7] based on ring-fixators, monolateral fixators with special lengthening devices [10] are being used, especially at the femur. During the last few years intramedullary systems have gained increasing significance [1, 2, 4, 6].

Table 4.11.1 gives an overview of different systems for distraction osteogenesis at the lower limb. For the classical fixator devices, external fixation is necessary for the complete duration of treatment, i.e. for the time of distraction as well as for the whole consolidation period. Its advantages are relatively small surgical procedures and simple approachability concerning corrections. Especially at the thigh, ring-fixators are extremely incriminating. Monolateral fixators with special modulars provide almost the same corrective options and are therefore regarded to be more advantageous. However, due to pin-track infections, pain and poor cosmetic results [8], external corrective systems barely seem to be justified for adults. There are considerably advantageous alternatives.

In order to reduce the time of external fixation, the fixator can be combined with an intramedullary nail. Thus the intramedullary nail provides internal stabilisation, both during the lengthening and consolidation period. The fixator itself is only necessary for lengthening and can be removed afterwards, when the nail is locked. This method is known as the lengthening over nail (LON) technique [9] and can be considered as a first important step on the way to fully implantable distraction systems. At the lower leg the LON technique appears to be justified for short distraction distances (<2 cm). For longer distraction distances and generally at the thigh, this technique is only a procedure of second choice.

Among the fully implantable systems, mechanical nails have to be distinguished from motorised distraction nails.

The Albizzia Intramedullary Nail

With this device, lengthening takes place mechanically by the patient himself or another person. A ratcheting mechanism is activated 15 times a day by internal and external rotation of 20° each at a time, causing a distraction of 1 mm per day [5, 6]. This procedure is regarded to be very painful, especially at the early stages of distraction, but often during the entire process. Often it cannot be tolerated without anaesthesia, which obviously decreases its acceptability. Preoperative planning was often reduced to the implantability of the nail into the bone without consideration of required corrections. Especially axis corrections can hardly be performed. The Albizzia intramedullary nail is only available for the femur with a starting length between 240 and 320 mm and diameters of 11, 13 and 15 mm. Lengthenings up to 100 mm are technically possible. In consideration

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<th>Table 4.11.1. Systems to perform distraction osteogenesis at the lower limb</th>
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<th>External systems</th>
<th>Fully implantable systems</th>
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<td>Without intramedullary nail</td>
<td>With intramedullary nail</td>
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<td>Ring fixator</td>
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of today’s standards for corrective limb surgery with the demand to correct all deformities, this system does not bear quality control in the majority of cases. It can only be recommended for limb lengthening if there is no need for axis corrections and if the mentioned disadvantages are accepted.

The Intramedullary Skeletal Kinetic Distractor Nail

The intramedullary skeletal kinetic distractor (ISKD) works similar to an automatic clock. Internal and external rotations of about 6° are sufficient for activation of the installed mechanism [4]. Therefore, manual manipulation is no longer necessary. Referring to the manufacturer’s instructions, “activities of everyday life combined with controlled ambulation and partial weight bearing” should be adequate to produce a rate of lengthening of 1 mm per day. As expected, this is not a very regular and continuous mechanism, leading to both rapid lengthenings of up to several millimetres per day (nickname: “run-away train”) and standstills in distraction. An installed stick magnet and an external detector help control the achieved lengthening. For the thigh, the ISKD intramedullary nail is available as a straight model with diameters from 12.5 to 14.5 mm and a starting length of 255 mm. For the lower leg, ISKD nails with a Herzog bending are available in diameters from 12.5 to 13.5 mm and a starting length of 215 mm. Distractions up to 80 mm are technically possible. Apart from the poor control of the distraction rate, this implant again offers insufficient options for axis and torsion corrections.

The Fitbone System

In contrast to mechanical distraction nails, the Fitbone system enables lengthening through an integrated, hermetically encapsulated motorised drive. The power of the system reaches peak values of more than 2000 N. The required energy is sent from an external control unit via a transmitter to a subcutaneously placed receiver. Thus there is no direct connection from the implanted material to the outside. The skin can be closed completely after surgery (Fig. 4.11.1). The energy supply is provided by positioning the transmitter next to the skin opposite the subcutaneous receiver. Energy can be supplied either three to four times a day (90 s at a time) or continuously at night while the patient is sleeping. For the nighttime distraction, the transmitter is fastened onto the skin similar to an electrocardiographic electrode.

Two different types of Fitbone nails are available: the Fitbone slide active actuator (SAA) nail and the Fitbone telescope active actuator (TAA) nail.

The Fitbone SAA Nail

The SAA intramedullary nail has a longitudinal hole in its middle part and is currently only applicable to the thigh, due to its straight construction (Fig. 4.11.2). The modular conception facilitates implantation of the intramedullary nail first and bringing in the hermetically encapsulated drive afterwards at the end of surgery. According to this procedure, the drive and its complex technology can be removed separately after lengthening. The intramedullary nail has a diameter of 13 mm and is available in lengths between 260 and 520 mm. Extensions up to 85 mm as well as bone transport up to 200 mm are possible. The SAA intramedullary nail is almost exclusively implanted through an antegrade approach, although a retrograde approach is likewise possible.