A Novel Internal Callus Distraction System

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Introduction

Leg-length discrepancies in the lower extremities have a static and dynamic effect on the entire postural and musculoskeletal system. Affected people often find that the associated cosmetic problem is just as debilitating as the functional limitations. It is hardly surprising then that, ever since the mid-1800s, attempts to lengthen pathologically shortened extremities have been made and described in detail. The causes of such differences in the length of the extremities can be congenital, enchondral, or deformities affecting either both sides or just one side of the body. Furthermore, the consequential resection of tumour tissue, performed within the accepted practice of tumour surgery, frequently calls for the removal of large sections of bone and soft tissue. More commonly today, however, differences in leg length arise because of a high-energy trauma with extensive loss of bone and soft tissue.

Conservative measures, such as shoe augmentations and orthotics to correct length, are clearly visible and are, therefore, mostly refused because they tarnish the external appearance. The option of surgically correcting the length of a leg by shortening osteotomy is likewise rarely accepted, despite the low risk involved, compared with surgery to lengthen limbs. The present-day ideal in the human mind as to what is aesthetically pleasing, which is associated with height as well as dominance and superiority, is often in direct contrast to this procedure. Spontaneous bridging of an extensive bone defect is a possibility [13], but this is seldom performed and is certainly not a routine therapeutic consideration.

Particular attention is thus paid to surgical techniques to lengthen the extremities or to bridge bone defects. In this respect, the contribution made by Ilizarov [14, 15] is undisputed. Through systematic basic research and extensive clinical application, taking into account all of the information available at the time, he introduced what he referred to as distraction osteogenesis as a standard technique.

To achieve the benefits of the generation of a load-bearing, autogenous and tube-shaped bone, by the methodical distraction of a self-forming callus, remains a challenging task, despite improved understanding of the biology of callus distraction and the availability of numerous technical devices and implants to carry out this procedure.

The main complications associated with callus distraction, such as infection, joint stiffening, soft tissue contraction, axial deviation and extensive scar formation, are due to the regularly used external components of the callus distraction systems (CDS) [16]. The few systems that are entirely implantable at the present time are not widely used because they are too limited in terms of function, are prone to complications and are difficult to finance, due to the complicated, time-consuming procedure involved. Furthermore, they are beset by more specific complications that prohibit wider application [3, 4, 8].

The aim to develop a device that is entirely implantable, without access via the skin during the distraction phase, was first achieved by a large, interdisciplinary working group at the orthopaedic clinic and outpatient department at the University of Munich, in conjunction with Messerschmitt-Bölkow-Blohm GmbH. They took up the idea of Schöllner’s gliding splint, angular plate [18] and, using a great deal of technical expertise, constructed a drive unit, which the plate sits on and distracts. The drive unit comprises mechanical components, a battery and the corresponding electronics, and is small enough to be implanted beneath the lateral, femoral extensor muscles. The unit is operated externally by a transmitting device for wireless impulse transmission. The device is suitable only for lengthening the femur through callus distraction and was successfully implemented in 1978, in a 14-year-old female patient with a post-traumatic femoral shortening of 7 cm [19]. Twelve years later, an interdisciplinary working group from the surgical clinic and outpatient department of Maximilian University, Munich, reviewed the previously published ideas of Bau-
mann and Harms [1] and Witt et al. [19]. At great technical and personal expense, as well as with the financial support of the Dr. Johannes Heidenhain foundation, they designed a medullary pin with a programmable drive for lengthening the femur. On the one hand, this system comprises an extracorporeal, telemetric transmitter to guide the receiver implanted in the subcutaneous tissue, together with a control unit and battery pack. On the other hand, a telescopic medullary pin stabilises and distracts the femur as a tube-in-tube design with an interior electric motor, gears and spindle mechanism, including transverse interlocking screws. In a subsequent version of this nail, the battery pack is superfluous, since the necessary energy is transmitted by means of an extracorporeal energy supply and control unit via high-frequency energy connection to a subcutaneously positioned energy receiver. This skilful solution to the energy problem in the specialist technical field must be viewed as an actual innovation regarding the nailing systems [2–4].

A design innovation was presented by Grammont and Guichet in 1995 with the “Albizzia nail”. This telescopic nail is suitable only for lengthening the femur and works according to a straightforward, exclusively mechanical mode of action.

Both tubes of the telescopic nail, which are inserted one inside the other, allow step-by-step distraction via an interior ratchet by rotating the tubes against each other. The respective proximal and distal tube are fixed to the femoral bone with transverse interlocking screws such that the corticotomy position of the interlocking screws is incorporated. The ratchet mechanism can be activated externally by rotating the proximal section of the femur against the distal section. This manual twisting of the femur triggers the force required for the ratcheting manoeuvre involved [7]. Tests carried out to determine the material properties and the first clinical results have shown that the lengthening nail works convincingly in the femur to the extent that, up to 1999, over 150 of these nails were implanted by Guichet [8]. A theoretical further development of this nail also uses the ratchet mechanism for segmental transport, but there are no reports as to whether or not this modification has been tested [17].

Outside Russian-speaking areas, a femoral lengthening nail first came to the fore in 1997. Its design uses the active and passive movement of the hip joint to exert force onto an interior mechanical system. A telescopic lever arm, connected mechanically to the joint at the proximal end of the implanted lengthening nail, is passed through the gluteal muscle at the anterior iliac crest and fixed in position there with a screw. Via internal and external rotation of the hip joint, the femur is turned with the inlaying nail against the lever arm. This manoeuvre triggers the mechanism and, thus, the distraction of the lengthening nail. Over 174 femoral lengthening procedures using this device were reported between 1983 and 1995 at the Simferopol University Medical Centre, Ukraine [5, 6].

A new implant for callus distraction [9–11] is presented below, which overcomes many of the disadvantages of existing systems and helps to prevent the well-known complications. One essential feature of the CDS is that no external components are required and the system can be fully implanted. The problem of energy generation, which is essential for callus distraction, is solved with the CDS, without external components.

Given the particular biomechanical position of the lower extremity, the CDS has initially been developed for use in the femur and tibia. However, the indication for use can, in principal, be expanded to the upper extremities.

**Design of the CDS as a Three-Component Implant**

**Solution Concept**

The concept is presented only for segmental transport in the femur, although it can also be applied to the tibia or humerus. Basically, this concept can also serve to lengthen the long tubular bone through callus distraction by using the existing telescope system as a tube-within-a-tube implant via wire-pulling mechanics.

The CDS is made up of three individual components:

1. A locking intramedullary nail
2. A traction wire
3. The mechanism.

The interlocking intramedullary nail (2 in Fig. 4.12.1) is introduced in a retrograde fashion into the femur. It stabilises the femoral fragments in terms of axis and rotation and holds the defective area open. At the distal end of the nail, a wire (1) is inserted before the momentary fulcrum of the knee joint. This wire, which passes through the lumen of the nail, provides the necessary strength for segment transport. The mechanism, once set in motion inside the nail's lumen (3), converts the force introduced via a threaded rod (4) and a bone segment connection (5) into segment trans-