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DEVELOPMENT OF A FULLY IMPLANTABLE DISTRACTION-DEVICE FOR OPERATIVE LEG-LENGTHENING

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SUMMARY

In cooperation with the orthopaedic hospital of the University of Munich a fully implantable distraction-device for operative leg-lengthening was developed which brings about a very smooth and precisely controllable automatic extension of congenital or traumatically caused femoral contractions. The device can be controlled and programmed transcutaneously by a small batteryoperated self-contained programming apparatus. The intrinsic implantable motor-unit containing the power supply, power transforming elements and the miniaturised electronic logic components is attached to the femur in such a way, that a high degree of stability for the whole system is achieved.
With several successful animal experiments and a likewise fully gratifying first clinical application the development is finished.

INTRODUCTION

The operative leg-lengthening has become an important therapeutic problem in the orthopaedic surgery since its introduction by CODEVILLA (1) in 1905. Although it is a relatively expensive therapy this method, carefully indicated, lends itself very well for curing severe handicaps caused by unequal leg lengths expecially with young patients. Moreover an ever increasing number of individuals injured by traffic accidents can be helped.

All operation techniques of leg-lengthening are based on extension or distraction of the bone with preceeding osteotomy, followed by homotransplantation of a bone segment or by filling the distraction gap with autoplastic bone material respectively and fixation by osteosynthesis.

As much as this therapeutic procedure is a rewarding and successful one, the risks are not immaterial. One essential problem is imposed by the often hampered adaption of the surrounding tissue to the increased lenght of its skeleton segment. Vascular irritations even palsy caused by stretching and expanding of main neuron branches may be among the complications.

For these reasons in collaboration with the orthopaedic hospital of the University of Munich a specific device was developed which makes possible an utmost smooth and precisely controlled extension of femoral contractions.

On the basis of an experimental design a functional model of the driving unit (Fig.1) was built, miniaturized and laboratory tested for working loads, maximum loads and different modes of operation (Forward, reverse, slow and fast). After the reliable proof of function of the power unit (distractor) a complete distraction system was conceived.

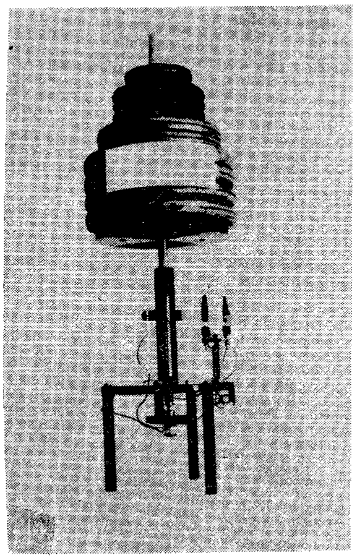


FIG. 1

DISTRACTION-DEVICE

EXPERIMENTAL MODEL

THE SYSTEM

The distraction device as such (Fig. 2) consists of the aforementioned power unit which generates the quasicontinous extension, and a telescopic guide plate built up of an outer plate and a linearly moveable inner part. This guide plate secures the required exercising stability of the proximal and distal diaphysis during the extension-process after osteotomy. The outer part of the guide ends proximally in a pertrochanter-plate by which the whole load flow is induced into the system. It is additionally fixed to the proximal end of the femur by two compacta-screws (Fig. 3). The inner plate is fixed to the distal diaphysis by two bone screws at its upper and lower ends. An important feature of the plate design is the fact that these ends of the relatively long inner plate of the telescopic guide show two joints which give an optimum adaption of the rigid guide to the anatomic shape of the femoral bone. By virtue of these flaps, bending moments will be avoided during and after fixation to the bone which in turn could cause jamming of the telescopic elements.

The system, telescopic guide with distractor is designed such, that the whole maximum load of approximately 0.3 body weight (25 kp) and the corresponding bending force is fed into the system by the pertrochanteric plate, flows through the assembly bridging the distraction gap and is led back into the distal diaphysis by the four bone screws mentioned above.

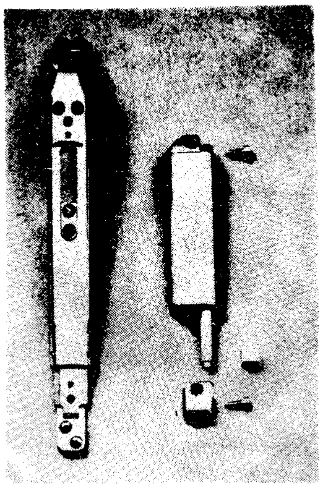


FIG. 2 DISTRACTION-DEVICE

GUIDE CARRIAGE AND DISTRACTOR

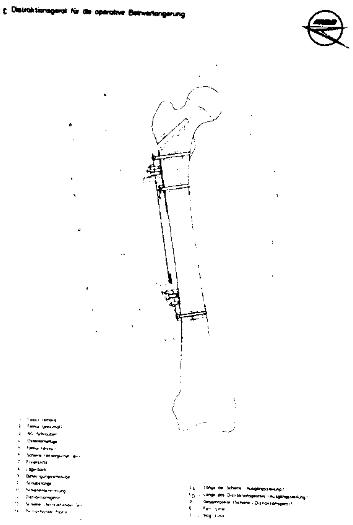


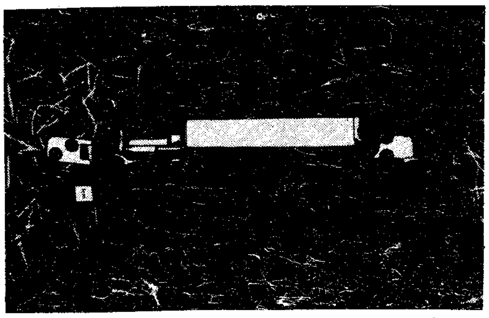
FIG. 3

APPLICATION SCHEME

The distractor is fastened to the telescopic plate by two bearing blocks (Fig. 4). Assembly and disassembly is readily done 'in situ' by putting in the two blocks in preformed adjusting holes and fixing them by one screw each. The extension rod of the power unit acting on the lower bearing block does not transmit any bending forces either for the reasons given before.

The distractor, in essence the power and control unit includes an electromotor (Fig. 5) with a multistage gear for power transformation, a screw spindle for the transformation of rotational movement into translation forces, the power supply and the miniaturized electronic control elements. An external programming unit (Fig. 6) enables the transcutaneous operation and control.

FIG. 4
DISTRACTION-DEVICE
ASSEMBLY



An adjustable rod-stabilizer (Fig. 7) which substitutes the distractor after the finished extension process and which is fastened to the telescopic plate in the same simple way, completes the system.

All parts to be implanted i.e. the telescopic guide plate and the distractor housing, extension rod included and the stabilizer are fabricated of a tissue-compatible chromium-nickel-molybdenum alloy according to the German Norm DIN 58800.

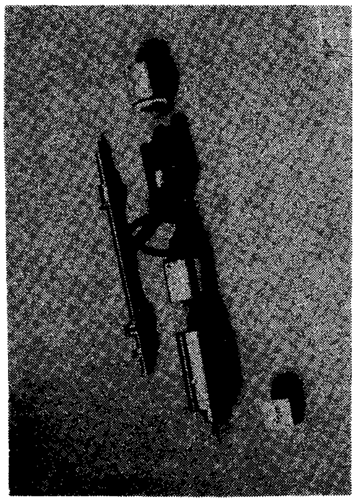


FIG. 5
DISTRACTOR COMPONENTS

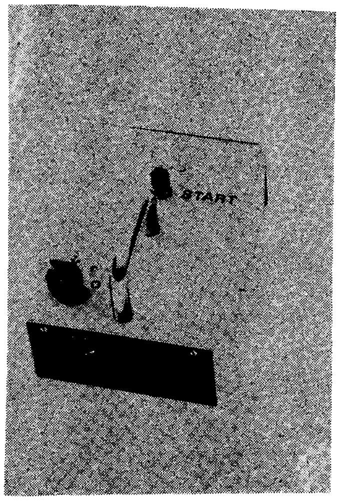


FIG. 6
PROGRAMME TRANSMITTER

FIG. 7 TELESCOPIC PLATE AND STABILIZER

ELECTRONIC CONTROL

The entire control configuration of the externally programmable distraction-device, which once beeing programmed, works automatically, consists of two basic electronic units. First, the external programming apparatus, already shown, and the internal receiving part (Fig. 8), which is built up in a sandwich structure, allowing high packaging densities. The cylindrically arranged components are totally embedded in epoxi resin. For obvious reasons the volume of the internal unit is only approx. 4 cm^3. As power supply a mercury battery is utilized, which is about the same size as the electronics block. Both components in turn have the same diameter of 16 mm as the micro-electromotor. The voltage of the battery is 1.35 V, its capacity 1 A h.

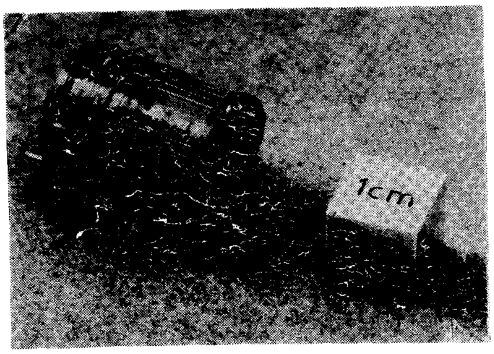
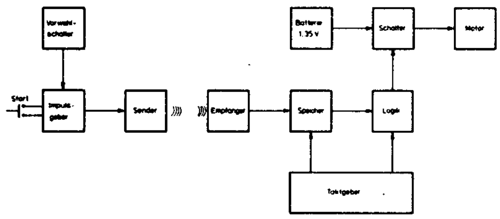


FIG. 8 INTERNAL CONTROL UNIT

A block diagram of the complete electronic subsystem is shown in Fig. 9. The left hand part depicts the programming block, which in essence operates as transmitter, giving the operation commands at the will of the physician. The right hand part shows the internal receiving unit, which decodes the transmitted signals and operates the electromotive drive.

The external programmer is equipped with a selector switch for the functions 'FORWARD', 'STOP', 'REVERSE' or 'TEST' and with a 'START' - key. It consists basically of a variable pulse generator and a pulsed induction array. After having selected the proper function, according to the therapeutic requirements, the physician just brings the little box close to the leg of the patient and presses the said starting knob. At this instant the information is transmitted transcutaneously to the implanted device. The maximum distance for effective programming is about 7 to 8 cm.

Receiving and decoding within the internal control unit is done by a reedswitch in combination with a clock, shift register and usual logic circuitry. The output of the latter finally gives the motor command 'FORWARD', 'STOP', 'REVERSE' or 'TEST'.



Blockschaltbild der Steuerelektronik

FIG. 9 BLOCK DIAGRAM
ELECTRONIC CONTROL

It should be mentioned again that after beeing programmed the distraction or the reverse operation continues automatically in such a way, that approx. .12 mm per hour or 2.9 mm per day in forward operation and .56 mm/h or 13.4 mm per day in reverse operation can be achieved.

By strict miniaturization and making use of C-MOS technology the power consumption of the internal electronics stays below 40 μ A. As a result, even with a battery capacity of as low as 1 Ah, the decay after storing the device ready for implantation, is at most 10 per cent.

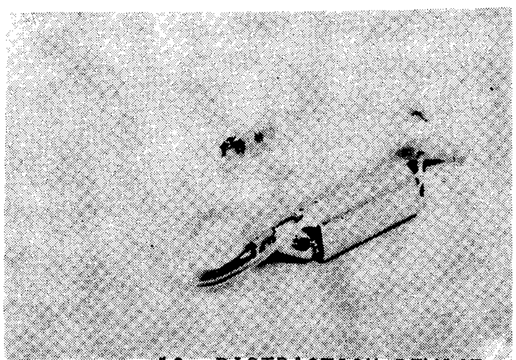


FIG. 10 DISTRACTION-DEVICE
ANIMAL TEST

ANIMAL EXPERIMENTS

After extensive investigation concerning the topologic conditions, the implantation feasibility and tissue compatibility via a geometry dummy in sheep, five functional experiments with the new distraction device were carried through.

For this purpose an adaptation of the instrument to the special size and anatomy of the sheep femur was to be done. Hence the telescopic plate had to be reduced in length and width, whereas the distractor was only shortened (Fig. 10). This had the advantage, that the complete drive mechanism of the original model could be kept. Only the battery and the internal control gadget was put into a Silicone bag, connected to the distractor by a thin silicon mantled lead, which than was implanted closely to the complete extension apparatus in a suitable interstitial muscle space.

Prior to implantation all components of the system were sterilized, that is, the distractor including its interior, by means of ethylenoxide gas, the other parts by usual heat sterilization.

The implantation, which can essentially be performed by known techniques of osteosynthesis did not cause any severe problemes. Wound healing followed with one exception per primam. At any given time, the distraction device was left in place until a distraction distance of ca. 20 mm was reached. After sacrificing the animal the instrument was withdrawn along with tissue samples. Fig. 11 shows a typical x-ray picture after extension of approx. 20 mm. The components of the device as well as the bone screws and a pertrochanteric bolt- another specific design feature for the animal experiments - can clearly be seen.

As main result among others these experiments prooved faultless function of the power and control units.

FIG. 11 ANIMAL TEST
DEVICE 'IN SITU'

FIG. 12
FIRST CLINICAL APPLICATION
X-RAY CONTROL

FIRST CLINICAL APPLICATION

The full procedure of the extension-osteotomy is carried out in three steps:

1. Fixation of the distraction device (telescopic plate with distractor) to the femur and osteotomy.

2. Withdrawal of the distractor only, after accomplished extension, subsequent filling up of the distraction gap with 'spongiosa' and fixation of the stabilization rod.
3. Detaching and removing of the guide plate including stabilizer after ossification of the distraction zone.

As first patient a 14 year old girl was selected, which in the age of 4 had a supracondylar fracture of the femur. The consequence of this was a shortening of about 65 mm of the respective leg. After detailed explanation of the new method to her and her parents, the first operation (osteotomy and fixation of plate and distractor) followed on August 2 nd, 1977.

The operative as well as the postoperative progress was without any complications. The patient enjoied primary wound-healing. During the first til fourth postoperative days, the device was programmed such, that a daily extension of 3 mm was achieved. Thereafter the quotidian distraction was reduced to 1 mm. Neither the slightest våscular nor neuromuscular irritations nor any alterations in perception of the patient's leg were observed. Beginning from the 2nd postoperative day, gymnastic exercises were carried out, thus maintaining full mobility of the hip-, knee- and ankle-joints.

Fig. 12 shows two x-ray control pictures in an early and final state of the extension procedure.

Thirty-six days after the implantation the distractor was removed, the stabilizing rod fixed to the plate and the gap filled up with spongy bone.

Three weeks later the patient was allowed to leave the hospital with the help of two crutches, beeing told before, to put only part of her body weight on the lengthened leg. Today she feels very well, x-ray control shows satisfactory ossification and withdrawel of the plate will presumably follow within the next two or three months.

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