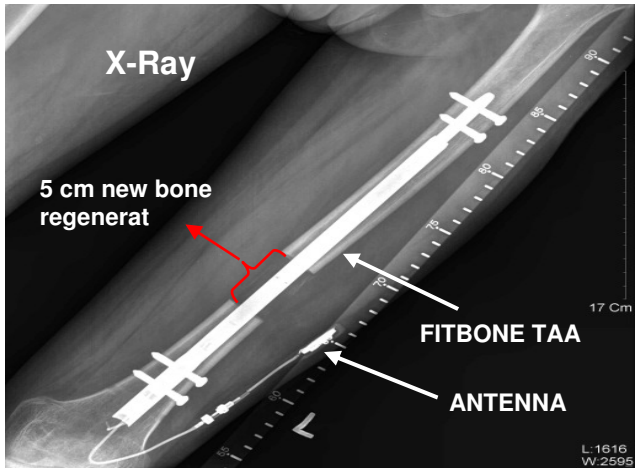

Aside from the comfort in treatment, the excellent cosmetic result and the elimination of infection risks FITBONE® patients appreciate a reduction of their hospitalization to the extent of only 1/5th -1/10th as compared to external methods. The structural strength of the FITBONE® implant permits an increase of weight bearing on the operated leg already in the early stage of the treatment. Depending on the speed of bone mass formation (Osteogenesis), full weight bearing can be gradually achieved already towards the end of the distraction period. Consequently, early re-integration into regular life becomes feasible.
Only the internal method is a realistic option for simultaneous lengthening of upper- and lower leg, i.e. a kind of treatment which is increasingly popular in cosmetic lengthening. Since both implants can be inserted through the same incision, the surgery is minimal invasive and permits very good cosmetic results.

before

after

Thanks to FITBONE® specific surgical methods, total operating time and damage to blood vessels in lengthening operations have been reduced to a safe and acceptable level.

Metal removal is performed approximately 1,5 or 2 years after completion of the lengthening.
A hospitalization of 3 - 4 days should be considered for that purpose.

Shortly summarized, the FITBONE® method offers a synergy of the following features:

- Minimal risk of infection
- Minimal pain
- User-friendly, permanently monitored process
- Best cosmetic result
- Time-saving through simultaneous lengthening option
- Reduced surgical risk
- Reduced theatre time
- Short hospitalization
- Early re-integration

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WITTENSTEIN intens

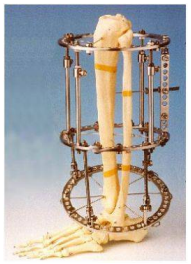
Medical Technology

Innovation in Bone Lengthening Concepts

Bone reproduction and leg lengthening through a fully implantable, computer-controlled distraction device

For this purpose, the WITTENSTEIN intens® company has developed a fully implantable distraction system which gradually increases the distance between two bone segments through a telescope - like device. This miniaturized mechatronic actuator which carries the designation „FITBONE®“, also stabilizes the two bone segments after the bone has been separated to create a reproduction (or „growth“) zone.

The internal drive system consists of an electromechanical segment and an integrated electronic module which receives electric power through high frequency transmission from outside. There is no connection between the implant and the surface of the human body. This completely internal feature allows, compared to the commonly used „external“ systems, a comfortable painless treatment in which the risk of infection is virtually eliminated and reduces the formation of scar tissue significantly.
External fixation systems stabilize the bone segments through steel pins which penetrate through skin, muscle tissue and bone from one side of the leg to the other (see illustration) and therefore, expose the pin-tracts and their openings to a serious infection hazard which increases dramatically over the number of month during which the external fixation device has to be carried. Through the pin tracts, dangerous infections can be transferred also into the bone, which can have the ultimate consequence of losing one‘s leg.



Standard Ilizarov technique

fully implantable intramedullary FITBONE®

Previous FITBONE® experiences have shown that the fully internal distraction method reduces the hospitalization period after surgery significantly, so that re-integration into the regular working-, household- or school life is possible at early stage. This is evident from the typical FITBONE® treatment schedule:

At the day of surgery the bone is separated into two segments to create the growth zone. This is done from inside, i.e. from the internal channel which is typical for the bones of the upper and lower extremities. A special internal type of surgical saw is used for that purpose. After that the two bone segments are stabilized through the insertion of the FITBONE® distraction device. The patient remains hospitalized for a recovery period of 5 - 7 days during which the FITBONE® implant is not yet activated. This period is necessary to let the incisions heal. After that, the patient is released from the hospital and can resume his normal life and his rehabilitation regime, walking on crutches to ensure that the operated leg is only partly loaded.

Distraction, i.e. the process of lengthening, is started already during the period of hospitalization, usually at the fifth day of the treatment. The FITBONE® implant is activated through a computerized control unit and moves the bone segments apart at a rate of approximately one millimeter per day. This is done in several steps, in accordance with the computerized control program and continued until the desired bone lengthening distance has been achieved.

After the lengthening, the next stage is the period of consolidation, during which the newly built bone mass solidifies. Depending on the extent of lengthening and the volume of regenerated bone mass, this phase can take approx. 4 up to 9 month.

In case of the traditional treatment with external fixation rings according to Ilizarov, a leg lengthening result of 40 - 50 mm would require that the external fixation rings and their fixation pins are carried for a period of 9 up to 18 month. In more than 50% of these cases, pin tract infections will make additional surgeries for the exchange of pins and fasteners inevitable. This is particularly valid in case of the upper leg (Femur), because that bone is surrounded by a large volume of soft tissue. There is always the danger that germs and infections penetrate into the pin tracts, which are in a permanent state of mechanical irritation and finally infect the bone what can have serious consequences (Ostitis).
Such complications, which happen in 30 - 60% of all lengthening cases (Rüter and Brutscher 1988, Paley 1990, Ilizarov 1990), require a much extended stay in the hospital.

Typical fields of application for FITBONE®:

Classic indications:

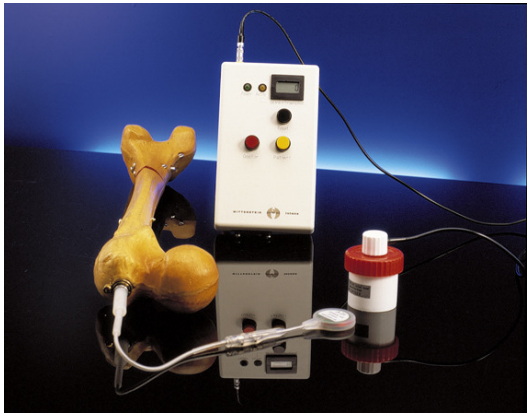
- Length difference between both legs
  - congenital differences
  - after Trauma / accident
- One-sided impaired growth
- One-sided abnormal growth
- Poliomyelitis
- Bone Tumors
- Pseudarthrosis

Special indications:

- Bone stump extension after amputation
- Impaired growth
- Bone segment transport after tumor resection
- Cosmetic lengthening

There have been no infection-related complications whatsoever in FITBONE® treatments up to date.

From the biomechanical point of view, the internal distraction method has the important advantage that all muscle- and tension forces are accommodated in the center of the bone, which means that the two bone segments remain perfectly aligned. In case of the monolateral, external fixation method, mis-alignement of the bone segments due to flexible deformation of the fixation device is very common.
This problem is frequently encountered in the course of upper leg lengthening, as Ilizarov-style fixation rings would be too cumbersome at that location and thus, cannot be applied there.



Fitbone® with control unit

The FITBONE® system is a modular concept which consists of the FITBONE® distraction device (which can be customized to meet the patient's condition), an implanted antenna for the wireless power supply and the computerized control unit. High frequency modulated electric energy is sent from the transmitter head of the control unit, through skin and soft tissue, to the antenna which is implanted beneath the skin. This controls the lengthening process.

In Germany the social insurance system finances the cost of a FITBONE® treatment in medically indicated cases. The system price also includes the leasing rate for the control unit and a tool set, which have to be returned after completion of the treatment.