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Technical note

Evaluation of the SMALL nail: Drive technology and behavior *in situ*

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ABSTRACT

Although clear advances have been made during the last 5 years, practical difficulties persist for patients and surgeons in procedures for intramedullary lengthening of long bones. In particular, precise adjustment of the desired amount of lengthening and technically reliable checking of the length actually achieved are problematic. An intramedullary nail with a new type of drive that exploits the shape memory effect has been constructed. The drive technology and the behavior of the intramedullary nail *in situ* were evaluated in a cadaver experiment. Three shape memory alloy limb lengthening (SMALL) nails were implanted in a body donor. The SMALL nail contains a spring coupled to a shape memory element consisting of a nickel–titanium alloy. This shape memory element "remembers" its initial state before the lengthening through the spring and can return to it when it is warmed. A cartridge heater inside the lengthening nail is warmed using transcutaneous induction with high-frequency energy *via* a subcutaneously implanted coil. For evaluation, two SMALL nails were implanted into the femora (antegrade on the left and retrograde on the right) and one SMALL nail was implanted into the left tibia. Lengthening by 50 mm was attempted using repeated activation of the drive mechanism. At the same time, test parameters for temperature increases and cooling periods were continually monitored and the data were subsequently analyzed. The nail's mechanism worked in principle, but was inadequate in view of success rates (number of lengthening steps attempted versus number of lengthening steps achieved) of 21% for the SMALL nail in the tibia and left femur and 14% for the nail in the right femur. The temperature values measured during the distraction experiments show that high-frequency energy induction in the SMALL nail gives no cause for concern for patients.

1. Background

The possibility of limb lengthening was a big step forward in the treatment of extremity length discrepancies with the aim to correct skeletal imbalance and for cosmetical reasons. A length difference can be congenital, posttraumatic or postinfective. Up to the end of the 1990's, lengthening of the extremities was a sphere reserved for external fixation. Research on the principles involved had been carried out in Ilizarov's time [1], and information about this had been available in Western countries since around 1980 [2,3]. Detailed reports on the range of complications occurring in external bone lengthening – with frequent pin tract infections – were published in the literature [4,5]. The use of intramedullary systems eliminated sources of infection by dispensing with transcutaneous screws and wires [6,7]. However, other difficulties with lengthening of the extremities that are not immanent to the system persist. This type of intramedullary lengthening of long bones is achieved using mechanical systems such as the Albizzia nail, the Intramedullary Skeletal Kinetic Distractor (ISKD), the Fitbone nail with an electromechanical drive, and the electromagnetically controlled PRECICE system. In all of these intramedullary nails, the external structure involves a telescopic system, and their performance is also comparable with regard to the resetting forces acting and the ability to control the amount of lengthening. In the Albizzia and the ISKD nail, lengthening is achieved using a mechanical rotation system [6,8,9]. Despite the facility for monitoring, precise control of the distraction rate is not always ensured with the ISKD nail [7,10,11]. Manual rotation of the external segment often causes pain, both with the Albizzia system and also the ISKD system [7,9]. The Fitbone nail, with an electromechanical drive, is only available to a few hospitals for evaluation, in the framework of a

Abbreviations: AE, adverse event; ISKD, Intramedullary Skeletal Kinetic Distractor; HTWG, Hochschule Konstanz University of Applied Sciences; SAE, Severe adverse event; SMA, shape memory alloy; SMALL, shape memory alloy limb lengthening.

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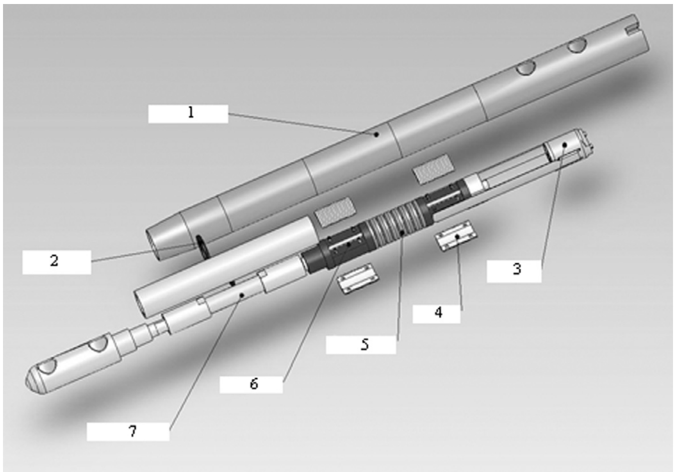

Fig. 1. The shape memory alloy limb lengthening (SMALL) nail. (1) External tube, (2) seals, (3) switch, (4) catches, (5) spring cartridge, (6) thrust, (7) NiTi tube.

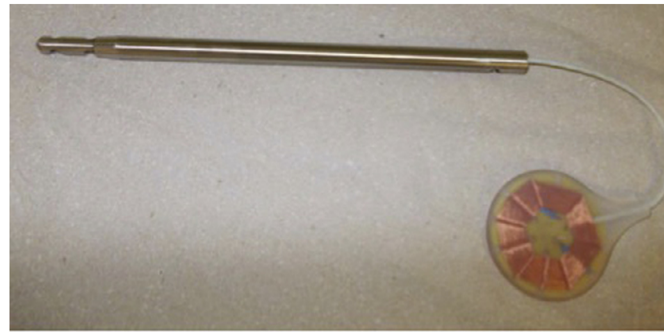

Fig. 2. A shape memory alloy limb lengthening (SMALL) nail, connected by an insulated cable to the coil that is implanted subcutaneously.

Fig. 3. Anteroposterior radiograph of the right femur.

licensing procedure [12,13]. With an electromagnetically drive system the PRECICE nail achieves satisfactory accuracy and precision in the lengthening procedure [14] and leads to fewer complications in comparison with mechanical nails [14,15] – particularly through reduced pain [14–16]. However, the rate of material breakages (4%) is worth mentioning. [14] Despite clear advances, the outcome of these developments shows that reducing the still high rate of complications and reducing the pain component continue to be major challenges in the development of new systems. To reduce the risk of infection, a completely internal system is probably the method of choice. Maintaining the exact distraction length requires a high-precision system, preferably with a specifically measurable slip-free holding system that can reliably trigger small-step lengthening based on the all-or-nothing principle (no lengthening versus completed lengthening as intended). The aim of the present study was to test a fully implantable intramedullary lengthening nail incorporating a shape memory element, in a cadaver experiment. The focus was on evaluating the performance and analyzing the safety of the distraction mechanism, as well as on the technique of transcutaneous induction of high-frequency energy. The nail, which so far has been given the working name SMALL during testing in the university setting, allows precise distraction in 0.5-mm steps. Following the evaluation, the intention is to carry out further development of this new type of drive technology for orthopedic implants.

2. Methods

2.1. Small nail

The intramedullary nails implanted are lengthening nails featuring a shape memory alloy (SMA) element. The nails consist of a telescope system with an internal and external steel shaft (Fig. 1). The inner wall of the external shaft has a serrated profile with an increment of 0.5 mm into which segmental catches on the internal shaft engage. The SMA element is connected with these catches *via* various components and is preloaded with a spring in its low-temperature phase martensite. When it is warmed, the associated change in state can initiate a distraction. For this purpose, a heating element located in the internal shaft is activated with induced current *via* a receiver coil. When the SMA element is thermally activated beyond the transition temperature and enters its high-temperature phase austenite, it becomes shorter, returning to its original state, and thereby causes a notch thrust on the rear catch, which in turn leads to an increase in the preloading of the spring that is coupled to it. This step does not yet cause lengthening of the nail. A switch inside the SMALL device, which interrupts the current supply when the transition temperature is reached and the SMA element switches to the austenite state, is intended to prevent overheating. Cooling then causes a transformation back into the martensite state (the low-temperature phase), with renewed dilation of the SMA element *via* the preloaded spring. The thrust force in the spring that results from this dilation causes a second notch thrust in the direction of the first notch thrust – with movement in the opposite direction and any associated shortening being prevented by the serrated profile. The actual lengthening of the nail is achieved in this way, and at the same time the integrated switch described returns to its original state to allow repeat activation by induced current. The result is a "caterpillar-like" movement with a lengthening of 0.5 mm per cycle [17].

2.2. SMA element

Metals with shape memory effects are widely used in medical technology [18], and a nickel–titanium alloy is often used [19]. The shape memory element inside the SMALL nail also consists of this alloy. The biocompatibility of the alloy has been confirmed [18,19]. The SMA element in the SMALL device is characterized by a