NiTi and TiNiCo shape memory alloys,
superelastic wiresNiTi springs,
mandibular distraction

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SUPERELASTIC AND SHAPE MEMORY NITI EXTENSION SPRINGS FOR MANDIBULAR DISTRACTION

The article presents studies of the superelastic NiTi and shape memory TiNiCo devices for the experimental distraction of mandibular bones in young pigs. The new method of gradual bone lengthening has two variants. In the first one distraction devices make use of two U-shaped NiTi superelastic springs that are extend, with constant force, the corpus of the mandible enfeebled by the decortication. The other variant uses double Ω-shaped springs that use the shape memory effect during gradual heating by the electric current in the temperature range 40-55°C drawing the bone fragments after osteotomy. On the basis of the X-ray phase analysis and the DSC analysis the wires which after special treatment show superelasticity in ambient temperature and shape memory in the desirable temperature range of about 40 to 55°C were chosen. Prototypes of the distractors were fabricated, suitable shapes and dimensions were selected, and different ways to fix them to the bones were tested on the models. Forces of the superelastic arches generated during stretching and unloading and distraction forces of the shape memory distractors generated during the process to regain the shape while being heated by the electric current were measured. In animal experiments the operations were performed on two pigs where NiTi superelastic distraction devices and TiNiCo shape memory distractors were used and placed subcutaneously, immediately on the bone under the periosteum. As a result of animal experiments about 10 mm lengthening of the pig mandible was obtained with the use of superelastic distraction devices.

1. INTRODUCTION

Memory and superelastic NiTi alloys have good mechanical properties, high corrosion resistance and are well tolerated by the human body. They are a unique material for the production of medical implants [1, 2]. Surgery and orthopaedics use clips, clasps, pins, sutures and other shape memory elements to connect discontinued soft tissues and to connect and stabilize bone fragments. Endosurgical NiTi stents restore the patency of blood vessels, bile tracts or ureters. Superelastic or thermally activated NiTi arches are widely used in the constructions of immovable correction devices used in orthodontics [3].

The phenomenon of superelasticity can be observed in alloys characterized by martensite transformation when the material undergoes deformation in the parent phase in the vicinity of the

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temperature A_f. The stress martensite that is formed during the process of elastic deformation disappears when the loading is removed and the material goes back to its original shape in an elastic way. The stress-deformation curve shows a characteristic hysteresis loop where during formation or disapparance of stress martensite constant stress of a wide deformity range can be observed.

Where the effect of shape memory is used, the element deformed in the martensite state below the M_f temperature goes back by itself to its original shape by heating in the temperature range of the reversible process from temperature A_s to temperature A_f.

In the II Faculty and Clinic of Maxillofacial Surgery in Katowice after positive results of mandibular bone fracture treatment using shape memory clips attempts to use distractors made from NiTi alloys showing properties of superelasticity and shape memory for mandible bone lengthening in animal experiments were started [4, 5].

Where superelastic distractors were applied it was important to check the possibilities of mandibular lengthening with the influence of extension constant stress exerted between the points of application of the distractors where the bone had been weakened by decortication. While using shape memory distractors it was important to check whether gradual, with a few days' breaks, mandibular lengthening after osteotomy with shape memory actuator heated by impulses by direct current was possible. In both variants the distractors were placed intraorally, directly on the bone, under the periosteum, on the external side of both shafts of the mandible.

Ilizarov inaugurated the method of bone lengthening by gradual distraction in 1950s who subsequently worked out the precise treatment procedures and introduced this method widely into the orthopaedic surgery [6]. Modified and modernized screw distraction devices based on pins screwed onto the bone near the transverse osteotomy make it possible to precisely displace the fragments at the rate of 1 mm per day. Recently an American company Autogenesis, Inc. has assured precise compression or distraction of limbs at the rate of 0.5 to 4 mm per day.

The attempts to use osteodistraction in maxillofacial surgery were started in the 1970s. Based on experimental studies (Snyder, 1973; Michieli and Miotti, 1977; Karp, 1990) McCarthy in 1992 publicized the first successful operations of lengthening the human mandible by using the extraoral device [7]. The construction of distraction devices was modified a few times to adjust them to different types of defects. In recent years Molina and Monasterio; 1995, Cohen, Simms and Burnstein; 1998 have achieved good results in lengthening and remodeling the human mandible by using the external screw distraction devices fixed on single or double pin holders drilled percutaneously into the bone, nearby the decortication zone in mandibular asymmetric or bilateral hypoplasia. Carls and Sailer [8] applied successful mandibular distraction in children by extraoral and intraoral distraction devices. Miniature internal screw distractors are more and more often used in mandibular distraction [9]. In some cases intraoral screw distractors, which rest on teeth implants, are effective [10].

A prototype of apparatus activated by shape memory metal wire, used together with a double latch mechanism which can function as a remote-controlled gradual distraction device for bone or soft tissue distraction was constructed by Besselink and Sachdeva [11, 12]. Another distraction device placed in the marrow cavity in the form of a telescope pin that is lengthened by a linear NiTi microactivator with two-way shape memory used for lengthening limb bones was presented in the study [13]. Recently, Gil and Raspall in Barcelona have proposed an intraoral mandibular distractor, which has been designed using shape memory alloys. Ngan and Ciambotti applied NiTi shape memory palatal expander of Arndt that rested on teeth in maxilar expansion.

In all methods of bone lengthening that have been described a certain force that must be exerted on the bone to stimulate its growth is of a fundamental importance. The disadvantage of those methods lies in the fact that if one wants to obtain that force the application of complicated constructions is necessary.

The study presents a process of preparing devices for experimental mandible distraction using extension springs from superelastic or shape memory wires, which were obtained from nickel-titanium and titanium-nickel-cobalt alloys. It also presents an attempt to use superelastic or shape memory distraction devices made of the above mentioned alloys to lengthen mandibular bones in young pigs. The distractors were placed subcutaneously, immediately on the bone, under the periosteum.

The purpose of the study was:

a) to obtain needed superelastic and shape memory NiTi alloys and to select suitable working and thermomechanical treatment for preparing superelastic wires affected above room temperature and shape memory wires with temperature shape recovery range exactly from 42 to 55°C,
b) to produce prototype devices from superelastic NiTi and shape memory TiNiCo wires which have desirable force properties for experimental mandibular distraction,
c) to make an attempt to use distractors with superelastic and shape memory properties for lengthening mandibular bones in young pigs.

2. MATERIAL AND EXPERIMENTS

The research uses superelastic wires with diameters 0.8 mm, 1.0 mm and 1.2 mm made from two-component NiTi alloy bought from the Belgian company SMATEC and our own three-component alloy with the chemical composition Ti-48.7%at.Ni-1.3%at.Co smelted and cast in a vacuous induction heater. Metals of high purity were used as burden material. The ingot after the homogenizing treatment was processed by hot profiling into rods where after rotary forging and hot pull broaching through wire drawing dies the sinter was converted into wires with diameters from 2 to 1 mm. In the final phase some of the wires underwent cold pull broaching. Quenching from the temperatures 800-700°C and the annealing in the temperature range 200-600°C were carried out in a resistance furnace, in the argon atmosphere. The temperature and angle of shape recovery were measured in bending tests. After heat treatment the wires were dipped in ethanol cooled to about -60°C, they were bent out to the angle of about 90°, and then they were heated up to 70°C while the shape recovery angle and the temperature were taken. Conditions for heat treatment were chosen and the wires were prepared with the temperature range of shape recovery from 40 to 55°C. Cyclic stretching of superelastic wires with different diameters was done in an Instron strength machine. Interaction forces of the prototype distractors during cyclic bending and heating with current were measured at a specially constructed measuring point, equipped with an extensometer Hottinger force converter, Peltron transformer linear displacement indicator and a digital temperature indicator with an MC 201 recorder able to visualize the measurements taken and data transmission to a computer.

X-ray diffraction phase analysis of wires intended for distractors was carried out using X-Pert Philips diffractometer equipped with a graphite monochromator. CuK_α radiation was applied. Diffraction patterns were recorded at room temperature at an angle range from 7 to 154° (2θ) and at an angle from 37 to 47° C (2θ). The courses and characteristic temperatures of transitions by the DSC method were determined. Measurements during cooling and heating with the rate of 10 deg/min over the temperature range from –100 to +100°C were taken using TA 2100 calorimeter.

3. RESULTS AND DISCUSSION

3.1. DESCRIPTION OF ALLOYS DESIGNED FOR DISTRACTORS

In room temperature superelastic NiTi wires had the structure of the original phase B2, while TiNiCo wires after proper heat treatment showed the martensite structure (Fig. 1).

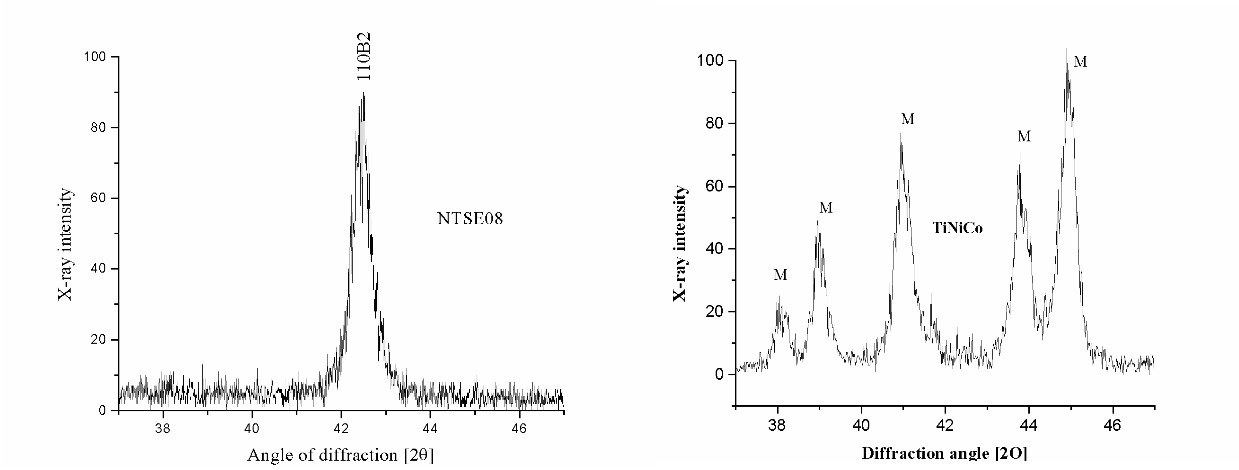

Fig.1. Diffraction patterns recorded at room temperature by X-Pert Philips diffractometer
(on the left) - NiTi superelastic wire with the diameter of 0.8 mm
(on the right) – TiNiCo shape memory wire in the martensitic state

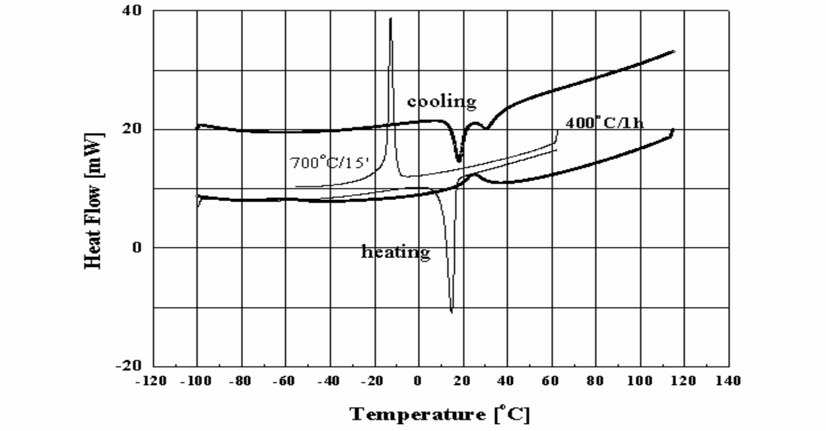

Fig.2. Courses of phase transformations during cooling and heating of TiNiCo samples after quenching from 700°C and annealing at 400°C/1h recorded by Perkin Elmer's calorimeter.

In TiNiCo alloy after quenching from 700°C the reverse process during heating took place below room temperature. A slight increase in the temperatures of the processes occurred after additional annealing at the temperature of 400°C (Fig. 2). Shift of the temperature range of the reverse change over the temperature of 40^{o}C for the wires needed to make distraction devices activated by the heat was achieved after annealing in higher temperatures and annealing in the temperature of 300^{o}C after cool pull broaching (Fig. 3, 4).

The diagrams below present histeresis loops $\sigma(\varepsilon)$ of superelastic wires recorded during cyclic stretching and forces measured during stretching and unloading of the superelastic arch distraction devices of the same length made of wires with different diameters (Fig. 5, 6).

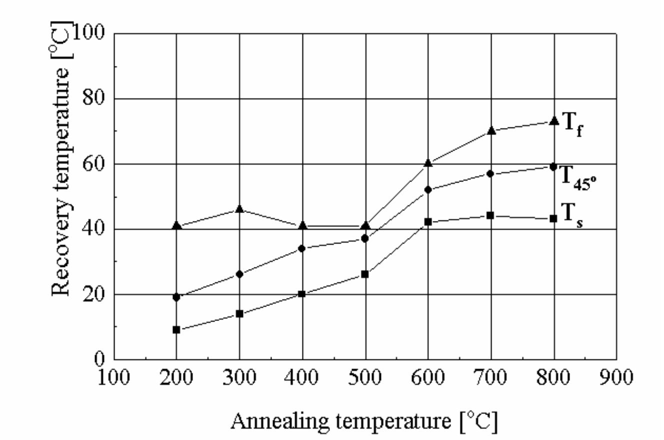

Fig.3. Influence of annealing temperature on the shape recovery temperature (T_s, T_f - temperatures of start at and finish of shape recovery, T_{45} - temperature measured recovery angle 45^o)

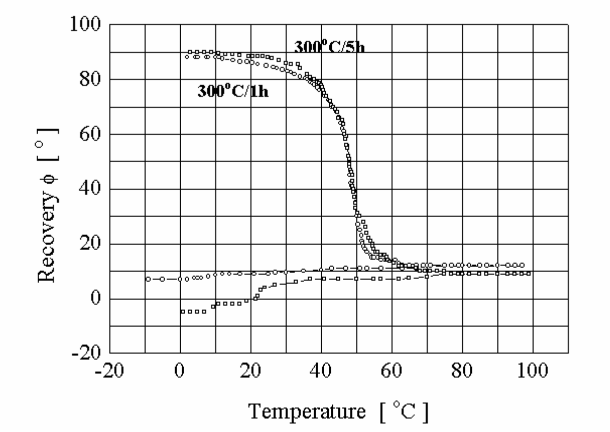

Fig.4. Selection of heat treatment for obtaining wires with recovery temperature above body temperature

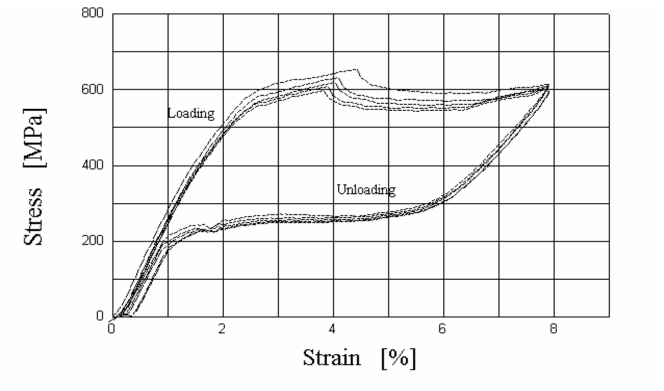

Fig.5. Stress changes during cyclic deformation of NiTi superelastic wire with the diameter of about 0.8 mm

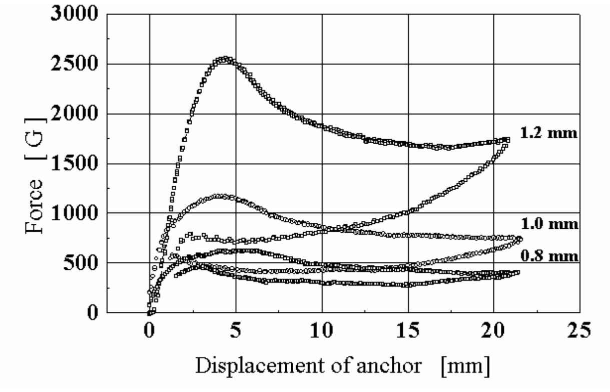

Fig.6. Force-deflection curves for distractors with the same length of about 35 mm which were obtained from superelastic NiTi wires with various diameters

3.2. PREPARATION OF PROTOTYPES SHAPE MEMORY AND SUPERELASTIC DISTRACTORS FOR BONE ELONGATION

On ends of short pieces of wire with the diameter of 1.5 mm and the length of 45 mm loops with the diameter of 2 mm were formed in the flame of a gas burner using pliers. These loops were needed to screw the distractors to the margins of the bone after osteotomy with titanium screws. The elements prepared in this way were cooled down in liquid nitrogen and then they were mechanically deformed to form the omega letter. Two Ω-shaped moulders juxtaposed together in an opposite way and with titanium screws in the loops constituted a single distractor. During deformation this distractor guaranteed directional functioning of the forces stretching along the straight line connecting the points of placement, which when the distractors were properly attached to the mandible on its both sides resulted in pushing the detached part of the mandible forward. Osteotomy was performed between the points where the distractors were screwed down. Moulders screwed down to the detached parts of the bone were at the same time the spans stabilizing bone chips, counteracting the mobility of the detached part during the process of mandibular lengthening. The distance between the points where the distractor was placed in the martensitic state, in ambient temperature, was about 15 mm. After attaching the electrodes to the screw heads and gradual impulse heating with the electric current of the distractors assembled in this way it was possible to obtain a 35 mm distance between the attachment points. The shape and size of the shape memory distractors before heating and after shape recovery are presented in the photograph (Fig. 7).

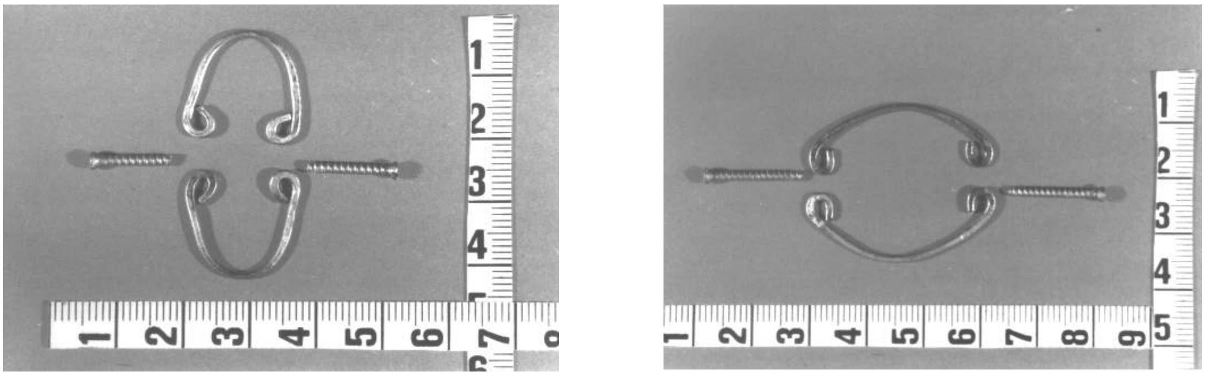

Fig.7. Photographs of TiNiCo shape memory distractor before heating (on the left) and after heating (on the right).

The next photograph (Fig. 8) shows the elements of NiTi superelastic distractors where on a stiff NiTi U-shaped span one can see two holders made of titanium microplates the ends of which have the shape of sleeves. It was possible for one of the holders to move freely by itself along both arms of the span. The two superelastic NiTi springs in the shape of straight wires with loops at their ends that can be seen lying side by side were juxtaposed on the holders opposite each other, they were shaped like a U letter, and then they were connected to the bone with titanium screws. The screws were introduced into the holes drilled previously on both sides of the bone-weakening zone through the loops of the springs and holes in the holders.

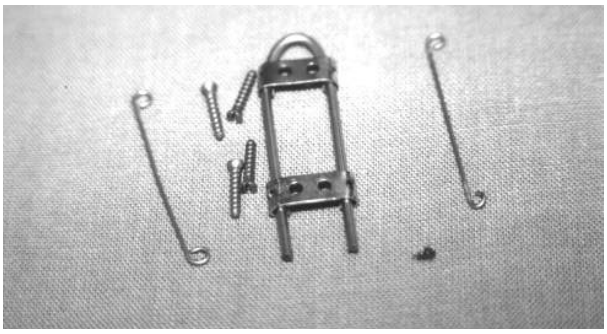

Fig.8. Parts of a slide distractor using the phenomenon of superelasticity.

Prototypes of shape memory and superelastic distractors for lengthening mandibular bones had to be designed, produced and checked on models. It was essential to arrive at proper shape and dimensions of the distraction devices and to determine the force that they generate during the process of expansion in the demanded range of deformation. Measurements of interaction forces of the distraction devices and the repeatability of the superelastic effect were taken. Depending on the diameter of the wire and the length of a span average forces measured during the expansion of double springs on superelastic slide distractors were between 200 G to about 4 kG. For impulse heating of the shape memory distractors using the electric current a controllable direct current feeder was used. It had an additional multirange time controller which makes it possible to switch on the electric feeder for periods from fractions of a second to a few minutes. To make gradual shape recovery and controlled displacement of the distractor's ends in a single series of impulses at the distance of about 2 mm possible - voltage, current and heating time were adjusted. To achieve total displacement of a shape memory distractor gradual heating with one series of about 10 impulses of the current with the intensity of about 3.5 A and constant supply voltage of 1.5 V was used.

3.3. EXPERIMENTAL LENGTHENING OF THE MANDIBLE IN PIGS.

Experiments were carried out in the Central Experimental Animal House of Silesian Medical Academy. Two 6-week old pigs that weighted about 10kg were used in the experiments. Operations were performed in intravenous general anesthesia. The shaft bone of the mandible was revealed after skin osteotomy on its lower margin. The bone between primary premolar teeth and molar teeth was weakened using deep decortication.

One pig had distractors based on the phenomenon of pseudoelasticity fixed on both sides of the mandible. Having drilled holes on both sides of the decorticated bone a stabilizing U-shaped span with sliding holders used to stabilize broken bone was fixed. On the slider there are two stretched superelastic arches that operate with constant resultant force in the desired direction of mandibular lengthening. Those arches and the slider were connected with titanium screws introduced into holes drilled previously in bone fragments (Fig. 9). Distraction devices fixed on both sides in this way forced the fragments of the bone, which was elongated to move in the direction of its long axle. The distractors were covered with detached tissues, and then the wound was closed in layers using catgut and nylon.

Since it was impossible to make roentgenograms, the only way to estimate the process of mandibular elongation was to observe how the mandibular incisors move in relation to the jaw incisors. Four days after the operation it was noticed that the mandibular incisors moved a few millimeters forward. This shift was becoming bigger and after 3 weeks it reached 10mm.

With the other pig shape memory distractors were used. After detaching the tissues and exposing the bone between premolar and molar teeth osteotomy was performed. Then the holes in bone fragments were drilled. Next, using long titanium screws two omega-like shape memory distractors made of TiNiCo wire were juxtaposed opposite each other (Fig. 9). The distractors were covered with tissues and the wounds were closed in layers.

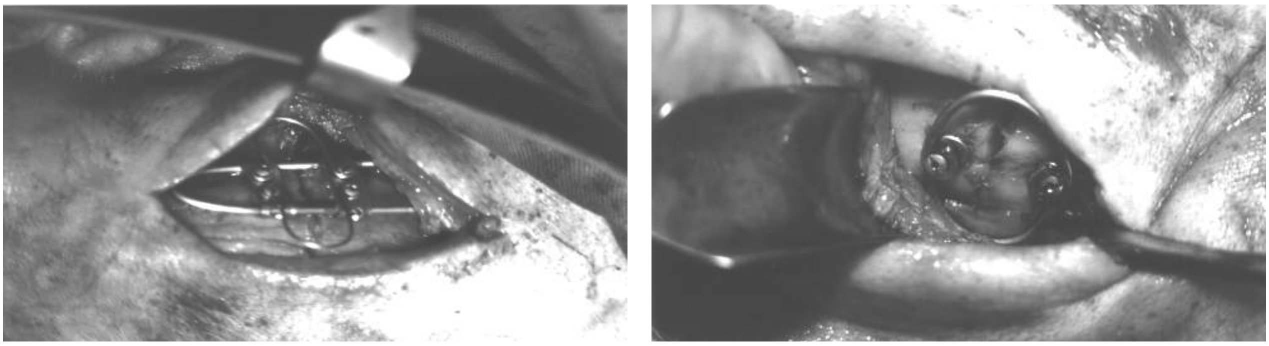

Fig.9 Photographs of distractors fixed on the mandible bones of young pigs
(on the left) – NiTi superelastic sliding distractor on the decorted mandible bone
(on the right) – TiNiCo shape memory distractor screwed onto the bone fragments after ostetomy

Six days later, at 4-day intervals, fragments on both sides were gradually separated using the effect of shape memory distractors heated by impulses with 1.5 V direct current. The electrodes also made of TiNiCo alloy were introduced percutaneously and connected to the end-pieces of the distractors. At each stage of the separation of the fragments mutual positioning of central mandibular incisors in relation to the jaw incisors was observed. During heating of distractors a visible displacement of lower incisors in relation to the upper ones was not observed.

Radiological research on elongated mandibular shafts after dissection as well as histopathological research on tissues from the zones of bone elongation are being continued.

4. CONCLUSSIONS

1. Depending on the diameter of the superelastic NiTi wires that were used and the length of a span it is possible obtain distraction devices with constant expansion force from 200G to 4kG.
2. By suitable processing and thermomechanical treatment it is possible to obtain distractors with desirable shape recovery exactly from about 40 to 55^{o} C.
3. The study proves that the mandible can be lengthened successfully using superelastic distractors.
4. Using shape memory distractors undergoing gradual deformation by impulse heating with electric current a desired effect of bone elongation was not produced. This technique needs more precise heating of the distractors.

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