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Continuous mandibular distraction osteogenesis using superelastic shape memory alloy (SMA)

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Distraction osteogenesis is a well-established method of endogenous tissue engineering. It is a biological process of bone neo-formation between segments subjected to tension. The concept of this study was to investigate the distraction osteogenesis with a device capable of creating a permanent and constant force during the whole process as if a very large number of small elongations were applied constantly.

The mechanical testing of the device used to produce the constant force and the *in vivo* analysis of the bone growth after it was implanted in rabbits are presented on this work. The device consists of a NiTi coil spring, superelastic at body temperature, in order to have a stress plateau during the austenitic retransformation during the unloading. The *in vivo* analysis was made on six female rabbits of 12 months old. A segmental mandibulectomy at the horizontal arm of the mandible and a corticotomy at 5 mm distant from the gap were made. Next, following a latency period of five days, the SMA springs were implanted to induce the bone neo-formation.

The displacement at the unloading plateau shows that it is necessary to have longer springs or to use several (available commercially) in series in order to fulfil the requirements of a human distraction. The temperature variations induced changes in the spring force. However, when the temperature returns to 37 °C the distraction force recovers near the initial level and does so completely when the distraction process continues. For the *in vivo* study, all six rabbits successfully completed the distraction. The radiographies showed the gap as distraction advanced. A continuity in the newly formed bone with similar transversal and horizontal dimensions than the original bone can be observed on the histologies.

In conclusion, the application of a constant force on distraction osteogenesis, using SMA springs, may be a successful alternative to the conventional gradual distraction.

1. Introduction

Can distraction osteogenesis be obtained through the application of a constant force? Studies on distraction osteogenesis investigate the optimum parameters to regenerate bone under a constant displacement. In this work, a mandibular distractor capable of applying a constant force during the distraction period is proposed.

Distraction osteogenesis is a well-established method of endogenous tissue engineering for bone lengthening [1, 10]. The procedure was initially described by Codivilla in 1905 [2], and the main issues and biological principles involved during this process were specified and studied by Ilizarov and Soybelman [3]. Distraction osteogenesis is a biological process of bone neo-formation between segments subjected to tension. It starts when the distraction force is applied to the callous that joins the two divided segments and continues while the traction is applied. The principal bone growth mechanism is the intramembranous ossification which means that there should be a good stabilisation of the bone segments. Another significant point is that the distraction forces generate a stimulus to the soft tissues surrounding the bones (e.g. gum, skin, fascia, muscle, cartilage, blood vessels and peripheral nerves). These tissues initiate an adapting sequence of changes called distraction histogenesis allowing larger bone distraction. In craniofacial surgery, distraction osteogenesis is aimed to correct deformities like the ones caused by malformation or resection of a tumour.

Several commercial mandibular distractors are

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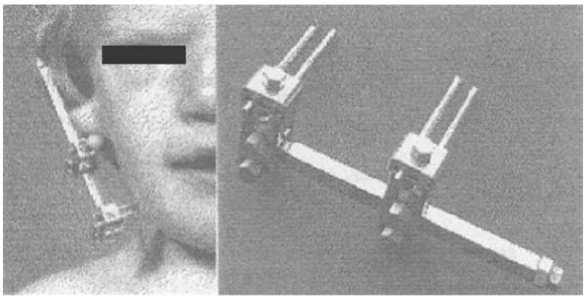

Figure 1 External and unidirectional distractor.

external and unidirectional which can induce complications such as infection and can present aesthetic drawbacks [4] (Fig. 1). Other devices are intraoral for which the disadvantages mentioned above are corrected [4, 5] (Fig. 2). Nonetheless, these two types of distractor work on the same principle, i.e. a screw produces a linear displacement of the resected bone segment. Then, the surgeon or the patient himself rotates the screw twice, three or four times a day to produce a linear displacement of the bone segment of 1 mm per day. For long bones, a better mineralised tissue is obtained for a larger number of small elongations instead of the traditional twice daily elongation [2]. In view of this result, the concept of this study was to investigate the distraction osteogenesis of a device creating a permanent and constant force during the whole distraction process as if a very large number of small elongations were applied constantly.

In order to test this concept a shape memory alloy (SMA) spring coil was used. SMA spring coils made of NiTi alloy present a specific property; a solid–solid reversible transformation austenite–martensite occurs when a tension is applied. This transformation results in a large deformation under a constant force represented by a plateau in the stress–strain curve (Fig. 3). In this study, it is aimed to use this discharge plateau as the constant distraction force. However, since no study has been found in the literature on the behaviour of SMA spring coils under mouth conditions, it is first aimed to perform a mechanical analysis of its behaviour under various loading and environmental conditions. The results of such a study will indicate the possible application of SMA spring coils for distraction osteogenesis.

Thus, the objective of this study was to test the use of a mandibular distractor based on a constant force displacement to induce a better mineralised distraction osteogenesis. For this, two steps need to be taken; first, the mechanical testing of the device used to produce the constant force in order to analyse how the device works under different conditions, and second, the *in vivo* analysis of the bone growth after implanting the novel distractor on rabbits, where the quality of the neo-formed bone will be analysed through X-rays and histologies.

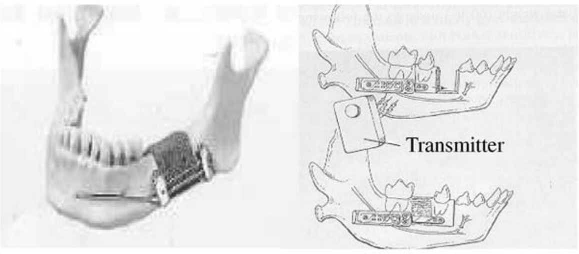

Figure 2 Intraoral distractor. Left: A conventional distractor commercially available. Right: Distractor being developed by Kremer *et al*. [5].

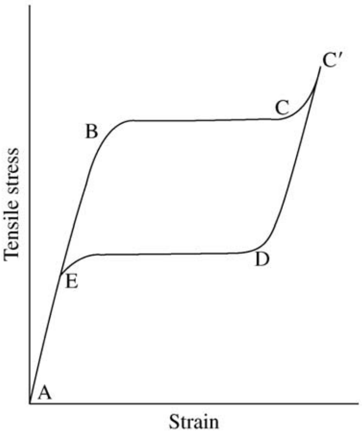

Figure 3 Theoretical stress–strain curve of a SMA. AB: Elastic austenite, BC: Loading plateau – transformation from austenite to force induced martensite, CD: Elasticity of the martensite, DE: Unloading plateau – retransformation martensite austenite, EA: Elasticity of austenite.

2. Materials and methods

2.1. Design

NiTi spring coils were used to obtain large deformation under a constant force. They have the advantage of occupying a small volume and having its length easily modifiable for different distraction cases. The device is simple and consists of a NiTi spring that is commercially available for orthodontic applications (GAC-Orthospain). The spring is fixed at one end to the distal bone and at the other end to the moving bone segment. In order to have a good stabilisation of the mandible and promote the intramembranous ossification, two titanium bone plates were screwed to the distal and proximal bone to fix the mandible (Fig. 4). This is known to be one of the basic principles for successful osteogenesis distraction [6].

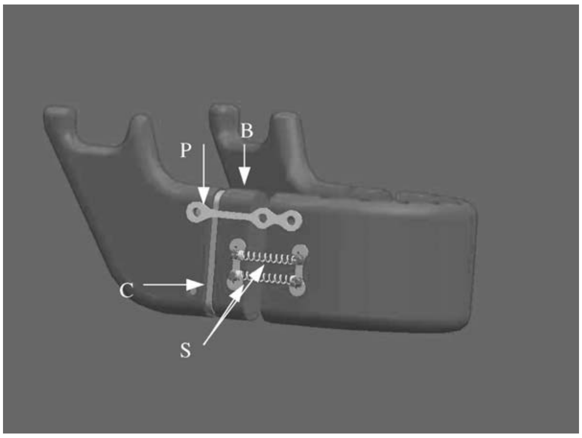

Figure 4 Novel superelastic SMA distractor proposed. S: SMA Springs, P: Bone plates to fix the mandible not allowing movements, D: Segment that is going to be displaced forward, C: Neo-formed bone.

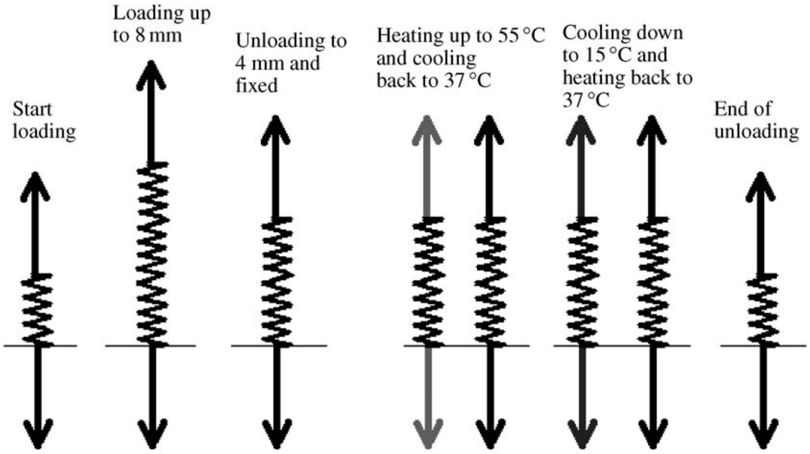

Figure 5 Temperature test protocol to simulate the conditions a hot/cold ingestion on the distraction process.

2.2. Spring tests

Twenty NiTi closed 300 g coil springs were obtained by GAC-Orthospain (reference 10-000-20). The springs have an external diameter of 1.1 mm, a wire diameter of 0.3 mm, a working length of 2.7 mm (nine coils), and a theoretical discharge force of 300 g (this is the force in which the unloading plateau should occur).

The springs were subjected to a tensile force with an universal testing machine MTS-Adamel (100-N load cell). All tests were performed in water maintained at 37 °C unless specified. The following tensile test was performed: a traction force was applied at a strain rate of 2 mm/min up to 8 mm (3.9 times the original length) followed by a complete unloading at 1 mm/min. The loading–unloading cycle was repeated four times to evaluate the elastic behaviour of the springs for several cycles. The influence of the loading rate was investigated by testing the springs at a velocity of 0.1, 1 and 10 mm/min. In another test, two springs were put in series to obtain a longer resulting plateau length.

To simulate the change of temperature when ingesting food or drinks, the bath temperature was changed during the unloading period. Springs were first loaded at 2 mm/min and unloaded at 1 mm/min. However, during unloading the displacement was stopped and fixed at 4 mm. At this position, the temperature of the bath was changed to either 55 °C or 15 °C to simulate respectively the ingestion of a hot or cold beverage [7]. Subsequently, the temperature was returned to 37 °C, and the unloading of the spring continued (Fig. 5).

2.3. *In vivo* analysis

The distractor shown in Fig. 4 was used in an *in vivo* analysis on six female rabbits of 12 months old (2.9–3.4 kg). A segmental mandibulectomy at the horizontal arm of the mandible of approximately 8 mm lengh and a corticotomy at 5 mm distant from the gap were made. Next, following a latency period of five days, the SMA springs were implanted to induce the bone neo-formation (Fig. 6). The process was monitored by X-rays at day seven and day 21 after the beginning of distraction. The animals were sacrificed two months after the surgery. Histology of horizontal and transversal cuts of the newly formed bone were compared with the cuts taken from the other side of the mandible not subjected to distraction.

Figure 6 Mandibular distraction osteogenesis on a rabbit. After the latency period the spring is connected to start the distraction period followed by the consolidation of bone. C: corticotomy, M: mandibulectomy, S: NiTi Spring coil.

3. Results

3.1. Spring test

Tensile tests showed that a typical behaviour of a superelastic SMA (compare Figs. 3 and 7). First, the elasticity of the austenite can be observed (AB). Then, the loading plateau that corresponds to the transformation to force-induced martensite can be seen with an elongation up to 8 mm (BC). Subsequently, the elasticity of the martensite is observed (CD) followed by the unloading plateau. The unloading plateau is the segment that needs to be used during distraction and goes approximately from 7 to 0.5 mm (DE). Finally, the elasticity of the re-transformed austenite can be observed (EA). This 6.5 mm unloading plateau may be insufficient for a human distraction (up to 20 mm of new bone may be needed). To solve this problem, springs in series are an alternative since the same behaviour is observed but with a longer unloading plateau, for example, 19 mm was obtain for two springs in series (Fig. 8).

The variation of the elongation rate while loading did not affect significantly the shape nor the value of the unloading plateau (Fig. 9). Moreover, the repetition of

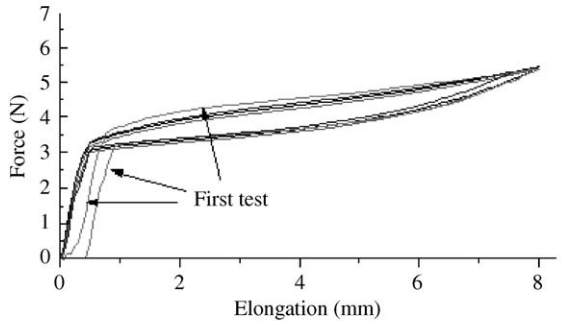

Figure 7 Several tests made on the same spring to evaluate the influence of cycling on the unloading plateau.

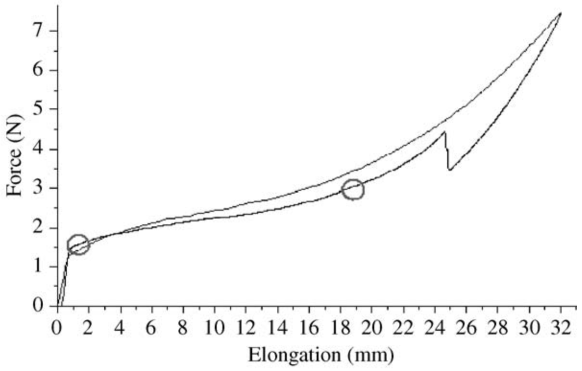

Figure 8 Two NiTi springs tested in series to have a longer unloading plateau. The test was made at room temperature and before the unloading plateau heated up to 37 °C to simulate a real surgery. The curve between the circles is considered as the unloading plateau.

the cycles indicated that there is no effect on the unloading plateau after several loading–unloading cycles (Fig. 7).

The increase in temperature (Fig. 10) of 18 °C induced an increase in the spring force of 30%. However, when the temperature returned to 37 °C the distraction force recovered near the initial level. After cooling down the spring to 15 °C, the force decreased by 46%. As observed for an increase of temperature, the spring force returns to the original value when the temperature goes back to 37 °C. In both cases it is important to note that, although the force does not return exactly to the original level when the temperature goes back to 37 °C, it does when the distraction process continues.

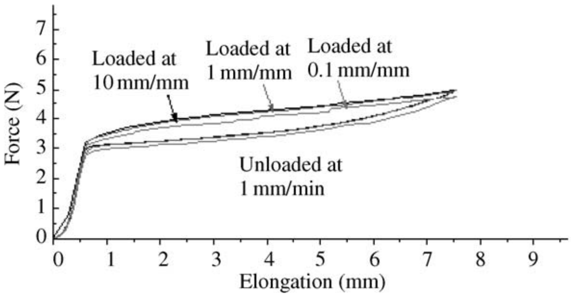

Figure 9 Different loading rates to evaluate the influence on the unloading plateau.

3.2. *In vivo* analysis

For the *in vivo* study, all six rabbits successfully completed the distraction. The radiographies showed that the gap was reduced by 2–5 mm at week one and 7–13 mm at week three (Table I).

After the animals were sacrificed, continuity in the newly formed bone was seen macroscopically in all of them, with similar transversal and horizontal dimensions than the original bone. Moreover, the trabeculaes were orientated longitudinally following the direction of the distraction force (Fig. 11).

The histological study showed a mesenchymous tissue with a large number of osteoblast cells starting to be surrounded by bone lacunas, with no sign of cartilaginous cells to appear. This is a typical intramembranous ossification and it is shown to be starting at both edges of the newly forming segment. At higher magnification of the distraction zone, the longitudinal disposition that the osseous trabeculae adopt can be observed, in contraposition to the mature bone with a harvesian typical disposition (Fig. 12).

TABLE I Measurements of spring length during the distraction process

Rabbit #	Initial gap (mm)	Gap at week 1 (mm)	Gap at week 3 (mm)
1	25	20	12
2	24	21	17
3	28	24	19
4	24	19	16
5	23	19	14
6	25	21	17

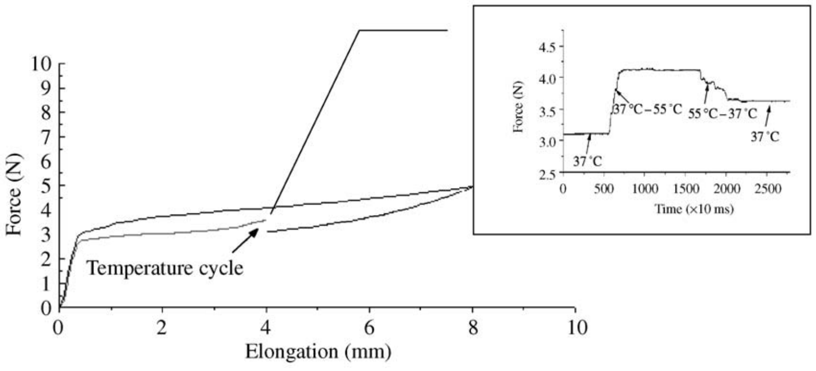

Figure 10 Mechanical test simulating a hot ingestion of food/beverage.

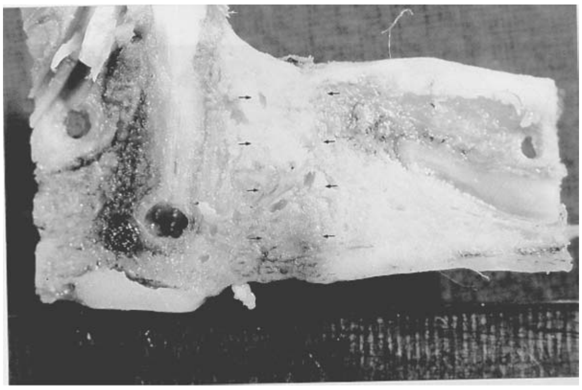

Figure 11 Longitudinal cut of the horizontal arm of the mandible subjected to tensile force.

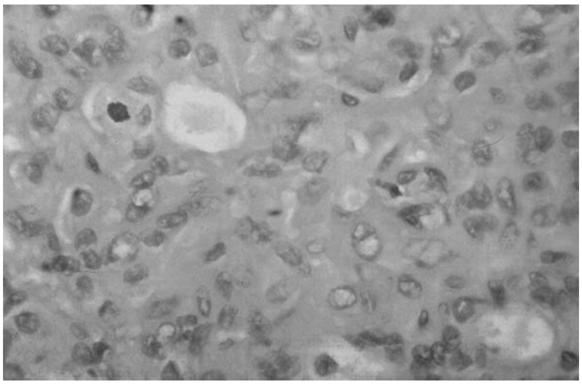

Figure 12 Mesenchimous tissue with a large number of osteoblast cells.

4. Discussion

This study shows that NiTi SMA springs can be used successfully to provide a constant force for an efficient distraction osteogenesis. The novel distractor presented in this study is easy to use for the surgeon and does not require intervention of the surgeon or the patient during the whole process. This new concept indicates promising advances in distraction osteogenesis but also in other maxilofacial applications.

However, as an initial study, this work presents various limitations. First, no study was made of the advance day by day of the gap reduction in order to be able to compare the results with conventional mechanisms. No direct data of the effect of applying different forces of distraction has been investigated, i.e. how did the elongation rate changed on the distraction period and if the mineralisation is affected on the consolidation period. This work also lacks a complete X-ray follow up to analyse the mineralisation of the callous [8].

An important parameter that was investigated in this study is the variation of temperature during distraction. When the temperature varies, the force applied by the device changes. When heating, the martensite transforms back to austenite. However, contrary to what has been reported for flexion forces on orthodontic wires, by Airoldi *et al.* [9] the force returns near the original level when the temperature returns to 37 °C. This indicates a re-transformation austenite–force-induced martensite. The cooling case is simpler, there is a higher percentage of martensite and this results in a force decrease. However, this phenomena is reversible when heating again. It is not clear though whether this increment on tissue stresses due to an increase of temperature can damage the tissues and cause a callous fracture. In such a case, the patient nutrition should be controlled to avoid warm food or beverage. If the stress increase does not damage the tissues, the distraction osteogenesis will continue as normal since the spring force returns to its original plateau.

One major advantage of this novel distractor is that the consolidation process occurs without the need for the surgeon to intervene. The consequence of this is an improvement in patient post-operative treatment in terms of comfort and social burden for the social welfare system. Moreover, the device is easy to handle and use. The springs can be extended several times during surgery to evaluate best positioning without any alteration of its properties. The springs can be easily attached at the end of the latency period. All these considerations make the surgery simpler and more reliable.

5. Conclusions

The application of a constant force on distraction osteogenesis using SMA springs may be a successful alternative to the conventional gradual distraction. This new concept has shown to induce a well mineralised neo-formed bone. Moreover, in order to apply this constant force, the use of NiTi superelastic springs has the advantage of being easy to use for the surgeon and the patient. Further *in vivo* studies and computational models are to be carried out to confirm these preliminary results.

Acknowledgments

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