Transport Distraction Osteogenesis Using Nitinol Spring: An Exploration in Canine Mandible

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Some experiments in rabbits have presented the potential feasibility of using shape memory alloy spring for continuous distraction osteogenesis. To confirm the effectiveness of such method, we established canine models for the exploratory experiments of transport distraction osteogenesis using nitinol springs. Simple devices, including an internal 60-mm long sinusoid-shaped nitinol springs were used in the study. All dogs needed only one operation. In the operation, osteotomy was performed to create a 40-mm unilateral segmental mandibular body defect and a tooth-bearing transport bone disc. After reconstructive fixation of the remnant mandible, the spring was constricted and anchored across the distraction gap to activate transport distraction immediately. At the second experimental stage, an ePTFE sheet was further fixed to protect the defect and distraction gap before closing the incision. Control dogs underwent the same operation except for anchoring of the spring to examine the spontaneous bone regeneration. Automatic bone transportation, as a gradual slowdown process, was observed under the effect of the spring. The transport disc could get to the opposite side of the defect, or stopped halfway when ePTFE sheet intervened. Mandibular reconstruction was achieved in all these dogs and better in dogs with sheet protection. No integrated bone mass was found in the defect of control dogs. The study further proves that continuous distraction osteogenesis using nitinol springs is a practical technique, although the devices need more improvement for better control of the process of distraction and the quality of regenerated bone.

Key Words: Mandible, transport distraction osteogenesis, canine model, nitinol spring

Superelastic shape memory alloy (SMA) has been used in some experiments to make new device for continuous distraction osteogenesis in recent years.1,2 These attempts showed that application of a constant force on distraction osteogenesis using SMA springs might be a successful alternative to the conventional gradual distraction. At almost the same time, we carried out our preliminary research to make an internal automatic distractor using nitinol, a typical SMA named after its discoverer (Nickel-Titanium Naval Ordnance Laboratory).3 The experiment was designed basically according to previous protocol,4 but two important procedures in conventional distraction technique were not scheduled, including the latency period after osteotomy and the strict control of distraction rate. These modifications, which were even different from the methods of other SMA-mediated distraction experiments, generated a controversial rapid process of bone transportation. Fibrous union or non-union has been proved to be the usual outcome of immediate acute bone distraction like this,5-7 so we think further confirmation of the feasibility and effectiveness of such pattern of spring activation is necessary.

Limited to the size and structure of the rabbit mandible, the rapid lengthening of mandibular ramus in our experiment might be considered as a similar process of spontaneous bone regeneration, but not distraction osteogenesis. For better observation and understanding of this special course of spring activation, we hoped that experiments in accepted large animal model would prove useful and conclusive. Dogs have been used frequently in the past history of distraction osteogenesis research,8 and segmental...
Mandibular reconstruction by bone transportation has been one important experimental model. Generally, 20–30-mm unilateral segmental mandibular body defects were created in these experiments and judged to be over critical size of spontaneous bone healing. But the remarkable ability of bone regeneration of dogs even in critical-sized mandibular defects should be reconsidered, as shown by Lemperle. Thus we created a larger defect of 40 mm in our canine model to examine the feasibility of using nitinol spring to activate bone transportation and regeneration.

**MATERIALS AND METHODS**

The Nitinol Spring

A sinusoid-shaped spring was made from a 1.3-mm Nitinol wire, and its two free ends were bent as perpendicular underprops. The length of the spring (distance between the two underprops) was 60 mm and the width was 15 mm (Fig 1). For mechanical testing, the spring was constricted to 15 mm long and put in 37°C water. Then the tensile force between the two parallel underprops on unloading of the spring in a controlled rate of 1.0 mm every 2 min were measured by the machine MTS 858 MiNi Bionix II. On the basis of the data, the scatter-plot-smoother unloading curve of the Nitinol spring were drawn by the statistical software SPSS. Besides, repeated constriction and recovery of the spring was tested to ensure its superelasticity.

Surgical Treatments

A total of ten healthy hybrid dogs, 3 years old, weighing 20–25 kg were used in the experiments. The canine model was established theoretically in accordance with classic bifocal distraction osteogenesis. No tooth extraction was performed in advance, and all the surgical works were accomplished in single operation.

The operation was performed under pentobarbital anesthesia (30 mg/kg IV). Dogs breathed air by assisted respiration, and accepted intravenous drip of Penicillin (1.6 million units in 100 mL normal saline) and then lactated Ringer solution throughout the surgical treatment. The lateral side of the left mandibular body was exposed through submandibular incision. Attention was paid that the attached gingiva and medial periosteum should not be detached from the bone. A mandibular segment containing the fourth premolar and the first molar was removed by osteotomy to create a 40-mm segmental defect. Another osteotomy was then carefully performed between the second and third premolar to create a tooth-bearing (the third premolar) transport bone disc. A Kirschner pin was inserted through the mandibular canal of the transport disc for stabilization.
and guidance of the bone transportation, and a reconstructive plate was fixed to keep the size of the defect. Two holes 15 mm apart were drilled respectively beneath the roots of the second and third premolar to anchor the underprops of the constricted Nitinol spring (Fig 2). Thus bone transportation was activated immediately by the elasticity of the spring. At the primary stage of the experiments, the gingiva wound and the submandibular incision were then directly closed. After the explorations in four dogs, simple ameliorations were made in following operations at the second stage. As shown in Fig 3, a piece of ePTFE (expanded polytetrafluoroethylene) sheet was covered on the exposed lateral side of the mandible to protect the defect and the distraction gap from soft tissue interference. A total of four dogs accepted such sheet protection before closing the incision.

**Fig 3** Photographs of the experiment at the second stage. The upper shows altered fixation of the reconstructive plate. The lower shows placement of the ePTFE membrane and Nitinol spring.

Furthermore, another two dogs were involved in a control experiment. They underwent same osteotomy and reconstructive fixation surgery, but accepted only defect protection. No spring was anchored to activate bone transportation.

**Fig 4** The unloading curve of the Nitinol spring.

**Fig 5** The process of the bone transportation indicated by the movement of the third mandibular premolar. (A) The general track at the primary experimental stage. (B) The track at the second stage.
Postoperative Treatments
Penicillin (0.8 million units) was intramuscularly injected twice per day for five days. The distance between the second and third mandibular premolar was measured daily to record the transportation rate. These works could be accomplished without anesthesia. The experimental dogs were killed 12 weeks (consolidation period) after the third mandibular premolar arrived at the opposite side of the defect, or got to a halt on its way of transportation. And the control dogs were killed 16 weeks after the operation. Mandibles were harvested for morphological and radiographic examinations. The bone samples were then fixed in 10% neutral buffered formalin, decalcified in 0.5 mol/L ethylene-diaminetetraacetic-acid (EDTA), and subsequently embedded in paraffin. Thickness sections of 5-mm were cut and stained with hematoxylin and eosin for histologic microscopy.

RESULTS
All dogs survived the operation and convalesced nicely about one week after the operation. Because all equipment was totally embedded within tissue, the dogs could eat semi-liquid food and move freely. At the primary stage of experiments, two dogs had a part of reconstructive plate exposed about two weeks after the operation. But the dogs were still able to maintain the reconstruction without infection or severe wound rupture until the end of the experiments. At the second experimental stage, two dogs presented longitudinal gingival avulsion on the top of the lengthening alveolar ridge between the second and third premolar. No special treatment was taken and self-healing of the wound occurred after the bone transportation stopped.

The unloading curve of the Nitinol spring showed extensive course of stable discharge, usually called unloading plateau (Fig 4). Such slow attenuation of the elasticity theoretically offered the spring a function distance over 40 mm. Under the effect of spring’s elastic tensile force, gradual movement of the third premolar was observed after the operation, but the moving rate was not rigorous constant. The graph was drawn on the basis of daily measurement of the distance between the second and third premolar (Fig 5). It showed that spring-activated bone transportation was...
generally a decelerated course with an acute beginning (about 3 mm per day) and comparatively stable mid-stage (about 1–1.5 mm per day). The third premolar could finally get adjacent to the second molar on the opposite side of the defect, or gradually stopped halfway when sheet protection was supplemented. Correspondingly, the transportation phase lasted about 4 weeks in primary experiments, and was reduced to about 2.5 weeks at the second experimental stage.

When animals were sacrificed at the end of the experiments, the defect of the mandible was reconstructed in those that underwent bone transportation. While no integrated bone mass was found in the defect of control dogs. The pattern of mandibular reconstruction was different due to the supplement of ePTFE sheet. The transport disc adhered to the opposite side of the defect in the four primary dogs, and a consecutive bone segment was formed in the distraction area behind the disc. The length of the regenerated bone segment was up to 40 mm (Fig 6). When sheet protection was applied, segmental bone regeneration occurred on both distraction and compression sides of the transport disc and coagulated the disc on its half way through the defect (Fig 7). The junction of regenerated segments and common bone were smooth, especially in the parts of lingual cortex and alveolar ridge. Detachment of the lateral

Fig 8  Radiograph of the reconstructed mandible.

Fig 9  Histological examination of the regenerated bone. (A) Interface between the regenerated bone and common bone. (B) The regenerated bone of the primary experimental stage (distraction area). (C) The regenerated bone of the second stage (distraction area). (D) The regenerated bone of the second stage (compression area).
periosteum and fixation of a Kirschner pin and reconstructive plate influenced osteogenesis in parts of the inferior border and lateral cortex, which were improved by a supplement of an ePTFE sheet. Radiograph showed satisfied ossification of the regenerated bone (Fig 8). The histological examination found clear difference between common bone and regenerated bone (Fig 9A). The new bone trabeculae were organized longitudinally under distraction forces (Fig 9B, C) and crosswise under compression forces (Fig 9D). The density of the trabeculae was higher in dogs accepted ePTFE sheet protection (Fig 9C, D).

**DISCUSSION**

A fully implantable automatic device that can provide continuous distraction has been considered as a treatment of distraction osteogenesis. In fact, it has been point out in Ilizarov's basilic report that the greater the distraction frequency, the better the outcome. Later attempts to develop automatic distraction devices also confirm that the bone regeneration proceeded at a higher speed with the lower distraction forces in continuous osteodistraction, compared with non-continuous distraction. These findings actually give theoretic support to our exploration of continuous distraction using the Nitinol spring. Nitinol has specific superelasticity at body temperature, which refers to the ability to return to original shape upon unloading after a substantial deformation and maintain a constant pressure due to the unloading plateau. The properties enable a control of spring-activated bone distraction via elaborate mechanics design of the spring in advance. And this is proved by the study: the constricted Nitinol springs activated gradual bone transportation procedure generally matching their unloading curves. But there are two questions that might be controversial and need more discussion.

The first is how to control the rate and distance of the spring activation. In fact, this question cannot be answered perfectly by this feasibility research. Our preliminary opinion is that the rate of spring-activated bone transportation or distraction needs not to be strictly controlled. Many factors, like individual difference in tissue resistance and body temperature changes, can affect the spring expansion process. What we must learn is the physiological tolerance range of tissue elongation and regeneration, of course, by some larger sampled examinations. Better control of the distraction rate is definitely helpful to improve the new bone quality, but the rate might not be totally unshakable because of the higher speed of bone regeneration in continuous distraction. As to the distraction distance, it is basically decided by the unloading plateau of the spring. And more exact control of the distance could be achieved by amelioration of fixation devices.

The second question is the substance of spring-mediated bone regeneration and how to control its quality. The segmental defect of 40 mm is larger than the accepted critical size in literatures we know. Therefore, we do not think the defect can be restored by spontaneous bone regeneration and have confirmed that in control dogs. The radiograph and histological examination also indicate that the regenerated bone is the outcome of intramembranous ossification. Besides, the shortened bone transportation by segmental bone regeneration in compression area is just same as what have been described in Ayoub’s experiment of continuous distraction. There are several factors that might influenced the new bone quality in our experiment: We made osteotomy instead of corticotomy to form transport disc because we found it difficult to master the amount of corticotomy that is suitable for the distraction by spring; And we set no latency period before spring activation to simplify the surgical treatment; Furthermore, the Kirschner pin occupied the space of bone regeneration and blocked the mandibular vessels. To improve the new bone quality, we supplemented ePTFE sheet protection, and gained expected results like Klug’s and Elshahat’s experiments. It proves, by the way, that periosteum is the essential actor of spring activated continuous distraction. Guided bone regeneration (GBR) is a useful supplement to this technique. But further amelioration of the design and manufacture of the devices is surely necessary.

In conclusion, we think this study shows that continuous distraction osteogenesis using Nitinol spring is a practical technique, although the devices need more improvement for better control of the process of distraction and the quality of regenerated bone.

**REFERENCES**