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# New remote-controlled growing-rod spinal instrumentation possibly applicable for scoliosis in young children

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**Abstract:** Progressive scoliosis in young children has been treated with "spinal instrumentation without fusion" to avoid interference with spinal growth. Patients have to undergo a series of operations to have instruments exchanged for maintaining the correction. We have developed a newly designed remote-controlled growing-rod spinal instrumentation system proposed for the treatment of progressive scoliosis in young children. It can be used to stretch and correct the spinal deformities repeatedly and non-surgically, by means of a remote controller, after the first instrumentation operation. The purpose of this study is to describe the possible clinical application of this system for the treatment of progressive scoliosis in young children. To this end, we used the system in five beagle dogs with induced scoliotic deformities. The maximum distraction force of the instrument was 194N. Correction of 1 cm was performed non-surgically in awake animals 3 weeks after the instrumentation operation, and then correction of 1 cm was carried out again 6, 9, and 12 weeks after the operation. The average initial Cobb's angle of the induced scoliotic deformities was 25°; this was corrected to 20°, 15°, 8°, and 3°, after the distractions at 3, 6, 9, and 12 weeks, respectively, postoperatively. All corrections were performed non-surgically without apparent complications. By repetitive distractions with the use of our new system, we may be able to reduce the number of operations required in young scoliotic children.

**Key words:** scoliosis surgery, spinal instrumentation without fusion, growing-rod spinal instrumentation, scoliosis in young children, spinal growth

## Introduction

Surgery for spinal deformities in young children is a challenging field in spinal surgery because of the associated spinal growth disturbance. Progressive spinal deformities in young children have been treated with "spinal instrumentation without fusion" to avoid interference with spinal growth. However, to exchange the instruments for maintaining the correction, we need to perform a series of operations, which may increase the risk of instrumentation failures and infection. In an attempt to solve these problems, we have developed a new spinal instrumentation, consisting of a remote-controlled growing-rod system with a built-in motor. It can be used for repeated distraction of the spine and can be used to correct the deformity non-surgically after the instrumentation operation. In this article, we report our new system and the preliminary results in animal experiments.

## Design of the system

Figure 1 shows the schema of the whole system, which consits of the instrument, the remote control receiver box (the receiver box), and the remote controller (the controller). The instrument consists of four parts; the outer cylinder with a rod, the small motor with a gear head, the inner gear, and the growing-rod. Hooks are attached to the rod with conical sleeves, following the original Chiba Spinal System.[13]

The instrument is made of 316L implant steel. The receiver box is made of diecast alloy. It is connected to the instrument with a lead wire covered with silicon (Fig. 2). The motor with a gear head is a 13-mm-diameter coreless direct currect (DC) motor (Maxon DC motor; Interelectric AG, Brünigstrasse, Sachseln, Switzerland) with a super gear head (Fig. 3). The maximum force is 155N. When the controller is turned on, the torque generated by the motor is converted to distraction force by the inner gear, and therefore the growing-rod stretches without rotating.

The instrument and the receiver box are surgically implanted in the spine. The junctions of the lead to the

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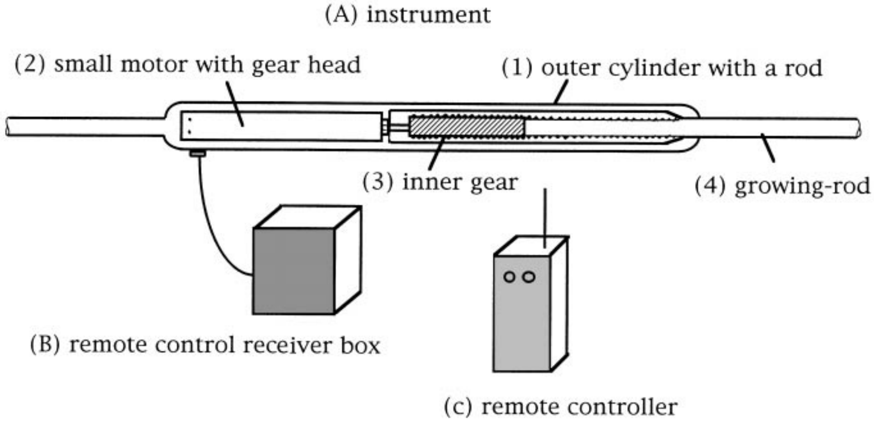



**Fig. 1.** Schema of the whole system, which consists of *A* the instrument, *B* the remote control receiver box (the receiver box), and *C* the remote controller (the controller). The instrument is composed of *1* the outer cylinder with a rod, *2* the small motor with a gear head, *3* the inner gear, and *4* the growing-rod

instrument and to the box are strictly shielded with silicon. The outlet of the growing rod is also shielded. The receiver box contains a radio-control receiver and a 9-volt battery (Fig. 4).

Prior to the animal experiments, the system was applied to a scoliosis model composed of plastic vertebrae with polyurethane intervertebral discs. Smooth correction was obtained using the remote controller (Fig. 5).

The distraction force of the instrument was measured using a load cell. The maximum distraction force of the instrument was 194 N.

## Animal experiments: Materials and methods

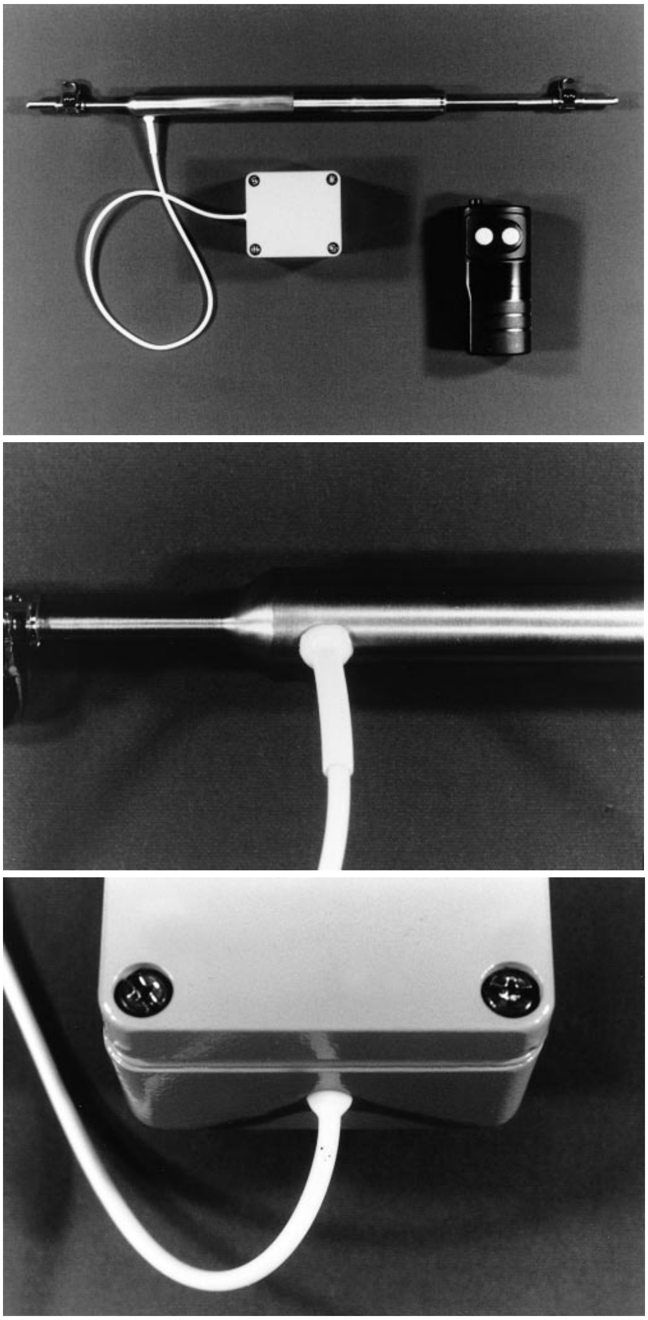
Five beagles, weighing 9.3–10.4 kg, were anesthetized with an intramuscular injection of 20 mg/kg body weight of Ketalar (ketamine 50 mg/ml, Sankyo, Tokyo, Japan). Anesthesia was maintained by additional intravenous injections of Ketalar. After the lengthened instrument was applied to the beagle spine without fusion, the instrument was shortened and a long C-curve scoliosis was made. The instrument was placed in subcutaneous tissue and the receiver box was placed in the abdominal cavity. After the instrument was confirmed to be secured to the spine, the wounds were closed. Intraoperative and postoperative antibiotic (1 g cefazolin sodium) was administered intravenously, and analgesic was administered orally (phenylbutazone). The beagles were housed one per cage and allowed food ad libitum. They were monitored daily for general health and neurologic function. Correction was performed non-surgically in awake animals, by 1 cm 3 weeks after the instrumentation operation, and then by 1 cm at 6, 9, and 12 weeks after that operation. Antero-posterior radiographs were taken after each correction and Cobb's angles were measured. This animal experiment was approved by the Animal Care Committee at Chiba University.

## Results

The average initial Cobb's angle of the induced scoliotic deformities was 25°(range, 23°–28°), which was corrected to 20° (range, 18°–24°), 15° (range, 11°–18°), 8° (range, 5°–10°), and 3° (range, 0°–5°), after each distraction at 3, 6, 9, and 12 weeks, respectively, postoperatively (Table 1). An illustrative case is shown in Fig. 6. All corrections were performed non-surgically without apparent complications, including instrumentation failures or infection.

## Discussion

Spinal fusion with instruments is a method of last resort to control spinal curvature that does not respond to conservative treatment. However, spinal fusion in young children before the growth spurt can interfere with posterior spinal growth. The remaining anterior spinal growth causes vertebral body rotation towards the convexity, giving rise to a loss of correction and deterioration of the rib hump.[2,3] Spinal instrumentation without fusion has been recommended for scoliosis in young children to avoid interference with spinal growth.[1,4,6–10,13,14] The procedure was first described by Harrington,[1] who intended to use the method without an external support. Moe et al.[10] indicated the risk of spontaneous bony fusion or at least soft-tissue scarring, due to subperiosteal exposure required for placing the rod on the concave side. In addition, instrumentation failures could occur without an external support, including hook dislodgement and rod breakage. Moe et al.[11] described preliminary surgical results with a subcutaneous Harrington rod to control severe spinal curvature in young children in 1979. The rod was placed in the subcutaneous tissue, and only the laminae to which the hooks were inserted were exposed subperiosteally. The Milwaukee brace was applied as an external support.



a

b

c

**Fig. 2.** **a** The whole system. The instrument is made of 316L implant steel. The receiver box is made of diecast alloy. **b,c** The receiver box is connected to the instrument with a lead wire covered with silicon

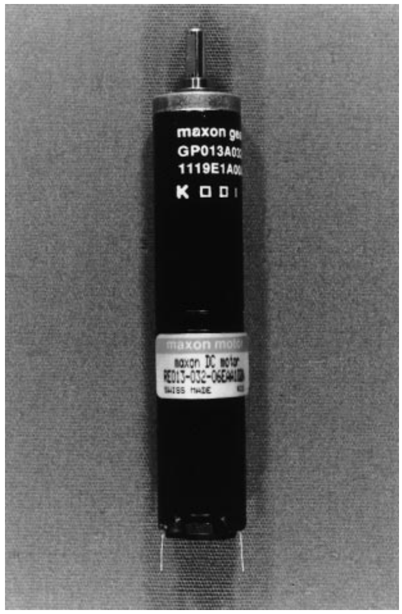


**Fig. 3.** Motor with gear head. The motor is a 13-mm-diameter coreless direct current (DC) motor (Maxon DC motor) with a super gear head

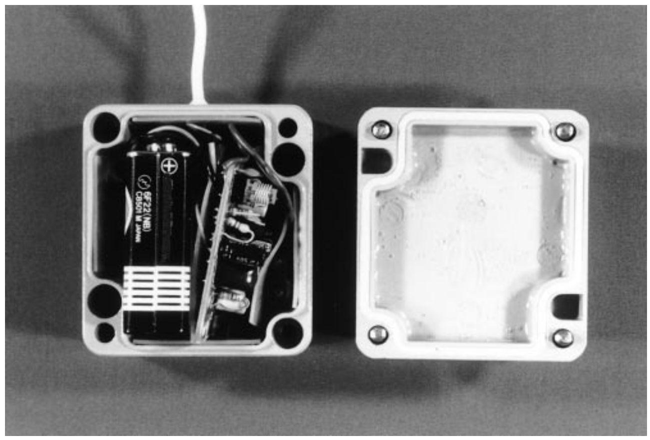


**Fig. 4.** Remote control receiver box. It contains a radio-control receiver and a 9-volt battery

In that series, the rod was lengthened periodically. Marchetti and Faldini[5] reported patients treated over a period of 7 years for severe infantile or early adolescent scoliosis by subcutaneous Harrington instrumentation. In their series, there was a high rate of instrumentation failures, and the patients required frequent operations to restore tension in the distraction rods. These conventional methods require a series of operations to exchange the spinal instruments according to the patients' growth. Our new instrumentation system can be used to stretch the spine repeatedly and correct the deformity non-surgically after the instrumentation operation. With this system, additional operations for exchange to longer instruments (elongation of instruments) can be avoided.

The distraction force generated by the Harrington rod is reported to be about 100–200 N.[11] The maximum distraction force of our instrument is 194 N, similar to the usual distraction force of the Harrington rod.

Moe et al.[10] described two main factors causing hook dislocation; rod loosening, which causes hook rotation and subluxation, and lamina fracture. In addition to

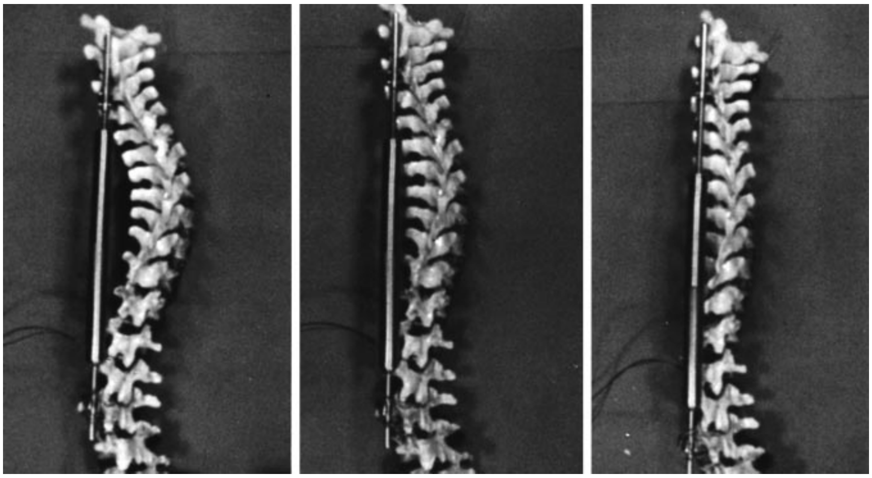


**Fig. 5.** The system was applied to a scoliosis model. Smooth correction was obtained using the remote controller

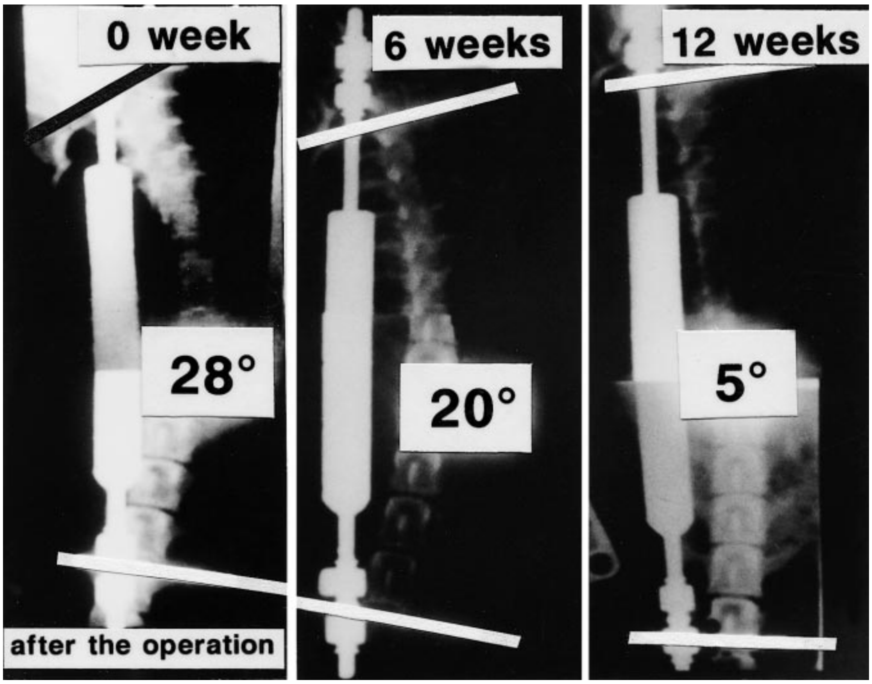



**Fig. 6.** An illustrative case showing results after use of the remote-controlled system in a beagle dog. The initial Cobb's angle was 28°. The scoliotic deformity was corrected non-surgically, using the remote controller, to 20° 6 weeks after the instrumentation operation and 5° 12 weeks after the operation

**Table 1.** Changes in Cobb's angle in spines of beagles with induced scoliosis treated with remote-controlled growing-rod spinal instrumentation system

| | 0 Week | 3 Weeks | 6 Weeks | 9 Weeks | 12 Weeks |
|---|---|---|---|---|---|
| Beagle No. | Cobb's angle | | | | |
| 1 | 25° | 19° | 16° | 9° | 5° |
| 2 | 28° | 20° | 15° | 7° | 3° |
| 3 | 28° | 24° | 18° | 10° | 5° |
| 4 | 22° | 18° | 11° | 5° | 0° |
| 5 | 23° | 19° | 14° | 7° | 3° |
| Average | 25° | 20° | 15° | 8° | 3° |

these two factors, there is loosening between the vertebra and the hook associated with spinal growth. With our system, if the rod is elongated repeatedly within a short period, an effective distraction force can be continuously applied to the spine, and dislodgement of the hook can be avoided, even during the rapid spinal growth period.

Our system also offers the possibility of continuous neurologic monitoring during awake correction.

The main problems with our system are the relatively large size of the instrument (the outer cylinder is 16 mm in diameter), and selection of body site at which to place the remote control receiver box. The size of the outer cylinder depends on the size of the motor. If a small powerful motor is developed, we could reduce the size of the outer cylinder. In the present experiment, we placed the receiver box in the abdominal cavity, and we had to make another incision to place it. If we could make the receiver box smaller, the ideal site would be on the back, near the instrument.

With the use of our new system, allowing repetitive spinal distraction, it could be possible to reduce the number of operations required in young scoliotic children. The method may also reduce the risk of instrumentation loosening associated with spinal growth. Although the present system is preliminary, we hope it will open a new horizon in the treatment of progressive scoliosis in young children before the growth spurt.

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