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All stems subsided downward during the load periods but rose during the no load periods in a 1-day cycle, and a great deal of subsidence were seen by 200,000 cycles– after loading. For polished stems, more than 85% of the total subsidence occurred by 1 million loading cycles, and subsidence rates converged after that. Stem subsidence was not accompanied with cement subsidence. For rough stems, however, subsidence progressed linearly and was accompanied by cement subsidence.The convergence of stem subsidence and lack of synchronization with cement subsidence in polished stems indicated taper slip into cement without loosening. Early subsidence in rough stems leads to progressive subsidence.

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Strictly as per the compliance and regulations of:

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I. Introduction

According to fixation theory, femoral stems for cemented hip replacements are of two types: loaded tapered stems and composite-beam stems [9, 14]. In composite-beam stems, tight bonding of the stem and cement is necessary to achieve long-term stem stability. Stem surfaces are processed to be either matte or rough, with or without a pre-coating of polymethylmethacrylate. In contrast, loaded tapered stems slip in cement, and the taper operates like a wedge to transfer the weight load to the cement and bone.

Therefore, these stems are polished tapers without collars [9]. Lee et al. [12] noted that a polished tapered stem does not cause shear stress but that compressive force and hoop stress will occur because of taper slip at the stem–cement interface. In the rough stem, micromotion at the stem–cement interface does not occur; instead, the risk of subsidence exists when weak bonding at the cement–bone interface is broken by overload.

Researchers have demonstrated, using radiostereometric analysis, that polished tapered stems slip in vivo in cement [1, 2, 15, 16], and others have detected slight stem subsidence and retroversion even in composite-beam stems [1, 2, 16].

Most subsidence of polished tapered stems has been seen in the early postoperative phase, with some detected later in the clinical setting [15, 16]. However, there have been no reports of continuous observation of stem and cement movement even in experimental studies. Therefore, we conducted a study to observe consecutive subsidence for polished tapered stems, rough stems, and cement around stems in an ex vivo cemented total hip arthroplasty model designed to mimic the conditions of walking throughout the human life cycle.

II. Materials and Methods

a) Cemented Stem Model

For the polished stem, we used a collarless polished tapered stem (CPT stem, Zimmer, Warsaw, IN, USA) with a surface roughness of ≤ 0.1 μm and tapered in the coronal and sagittal planes. For the rough stem, we used a CPT stem processed to a rough finish with a roughness of 5.291 μm (SD, 1.100 μm) (Fig. 1). A centralizer dedicated to the CPT stem was attached to the stem tip. Two sizes (sizes 2 and 3) were used both for the polished stems and for the rough stems in this experiment. The proximal transverse diameter and offset for size 3 were larger than those for size 2 by 2.5 mm

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and 1 mm, respectively. A size 3 rasp was used for the preparation of implantation in all femurs.

Therefore, the cement mantle for the experiment using size 2 stems was thicker than that using size 3 stems. The experiment was performed four times: once each for the size 2 polished stem and the size 3 polished stem and once each for the size 2 rough stem and the size 3 rough stem.

We used composite femurs (composite femur 3303, Pacific Research Laboratories, Vashon, WA, USA) similar in shape, mechanical characteristics, and material to those of human femurs for this study [5, 8]. For stem insertion, we cut the composite femur neck obliquely at 20 mm distal to the greater trochanter top and cut the distal part of the femur at 230 mm from the greater trochanter top before its attachment to the fixator.

We created 16 holes, 8 on the proximal side and 8 on the distal side of the composite femur, each 6 mm in diameter, for tight fixation of composite bone to the fixator through rods. After the holes were created, the composite femurs were immersed in blended vegetable oil for 24 hours to simulate an environment of bone humidity. It has been reported that cement creep differs by both temperature and humidity [3].

Therefore, we used vegetable oil to allow adequate cement movement in this study [11]. An aluminum plate for observation of cement subsidence was inserted through one of the holes that we had created in the posterior side of the femur at 22 mm distal to the cutting plane of the femoral neck. The other 15 holes were used for fixation of the composite femur by inserting rods from outside a fixator to the cement–bone interface.

We used a fixator for securing the composite femur using machine-structural-use carbon steel and epoxy resin [11]. The exterior of the fixator was made of carbon steel; the interior's epoxy resin was formed to the contours of the composite femur (Fig. 2A). A composite femur was fixed completely with surrounding epoxy resin and 15 rods inserted from the exterior of the fixator to the cement–bone interface through the epoxy resin (Fig. 2B). The bottom of the fixator was also attached to the basal table of the fatigue tester. We injected vacuum-mixed cement (Osteobond; Zimmer, Warsaw, IN, USA) with a cement gun into the composite femur. The medullary canal was plugged distally, and the stem was fixed into pressurized cement using two thumbs. This composite femur had both a cortex and cancellous bone, and a stem was fixed into the cancellous bone with cement after rasping. After we implanted the stem in the composite femur, we kept the temperature of the femur and cement at 37°C by using a heater (G6A92 240V250W, Takigen Mfg., Tokyo, Japan) and attaching a temperature sensor (T-35 thermocouple, Takigen) to the epoxy resin.

b) Load

A dynamic sine-wave load of 3,000 N was applied 2 million times at a frequency of 1 119 Hz to the metal head, which was fixed to the stem at 15° in the coronal plane [4] using a hydraulic controlled fatigue tester (type 1331, Instron Japan, Kanagawa, Japan). In actual practice, the fixator was inclined 15° horizontally in the coronal plane and the load was applied vertically. The 3,000-N load is equivalent to the load applied to the hip joint when a person weighing 70 kg stands on one leg, and 2 million applications of load correspond to 2 years of walking [6, 19].

The tester cannot perform complex motions such as walking; therefore, we tested only single-stance equivalent load in this study. Assuming sleep time, we provided a no-load period of 8 hours between 16-hour periods of load application. Therefore, 38 days were required for one composite femur experiment.

c) Data Measurement

We measured stem subsidence and strain on the aluminum plate inserted in cement. CPT stems have a screw hole on the upper lateral portion. For stem subsidence, a digital displacement gauge (5-mm DTH-A-5, Kyowa Electronic Instruments, Tokyo, Japan) was applied to the attachment screwed into the screw hole of the stem, and stem motion was recorded as the digital data of displacement, with a downward direction being expressed as a positive value (Fig. 2C). Because of complete fixation of the composite femur with a fixator, the data from the digital displacement gauge was considered to represent stem subsidence. The displacement gauge was able to measure upward-direction values because the gauge could move up and down smoothly.

We measured stem subsidence over time; the data were automatically entered into a personal computer via software for measurement collection and analysis (sensor interface PCD-300A, Kyowa Electronic Instruments). The load and no-load periods in a day were classified into early, middle, and late phase at each period. In each phase, 10,000 data sets corresponding to approximately 8 minutes were stored as one file per 30 minutes; we collected a total of 912 files. The obtained data were corrected and converted to distance units. Stem subsidence in each period was defined as the mean of the collected values in the two consecutive files (20,000 data sets) after the start of each phase.

Before the cement hardened, we inserted a 1-mm-thick metal plate into the cement through the posterior-side hole in the composite femur. After the cement had hardened, we exchanged the metal plate for an aluminum plate with a strain gauge pasted onto it (Fig. 3). The deformity of the aluminum plate represented the longitudinal displacement of cement. The data from the strain gauge reflected cement subsidence or force to the cement around the aluminum plate.

Continuous strain data were automatically recorded by a computer. Using lateral radiographs before loading, we confirmed that the aluminum plate was positioned in the cement and was not in contact with the femoral stem. Deformity of the aluminum plate was confirmed by radiographs obtained after the experiment.

III. Results

Subsidence in both sizes of polished stems was rapid by 200,000 loading cycles and then decreased slowly (Table 1, Fig. 4). The final amount of subsidence was 1.229 mm for the size-2 stem and 0.680 mm for the size-3 stem, respectively. By 1 million loading 163 cycles (early loading cycles), 85.8% and 92.5% of total subsidence had occurred for the size-2 stem and the size-3 stem, respectively.

Polished stems subsided during the load periods but rose during the no load periods in a 1-day cycle (Fig. 5). The average ratio of stem subsidence to stem rising in 1 day, determing by the equation

$$\frac{\text{stem rising}}{\text{stem subsidence}} \times 100\ (\%)$$

was 85.1% in the size-2 stem and 91.6% in the size-3 stem by the early loading cycles and was 96.3% in the size-2 stem and 97.2% in the size-3 stem at a point between 1 million and 2 million loading cycles (late loading cycles). The ratio for stem rising was greater in the late loading cycles of the experiment than in the early loading cycles, and significantly, stems returned to close to their original position before any subsidence ($P < 0.001$; unpaired t-test).

In both sizes of the rough stems, there was a great deal of subsidence early on in loading and then it progressed (Table 1, Fig. 4). The amount subsidence after 2 million loading cycles was 2.715 mm for the size-2 rough stem and 1.971 mm for the size-3 rough stem, respectively, and was greater than that for the polished stems. The amount of subsidence was 1.892 mm for the size-2 rough stem and 1.255 mm for the size-3 rough stem by early loading cycles and was 0.823 mm for the size-2 rough stem and 0.761 mm for the size-3 stem after that.

We analyzed the values only in the size-3 polished and rough stems for the strain of the aluminum plate. Because a setting error occurred in the strain gauges in the size-2 polished stems, making the difference between the data in those stems and the data in the size-2 rough stems much larger than the measurable range. The experiment revealed that there was less deformity of the aluminum plates in the size-3 polished stem than in the size-3 rough stem (Fig. 6A). For the polished stem, the strain of the aluminum plate was not synchronized with stem subsidence. but recovered sometimes independently of stem subsidence (Fig. 7A). Neither stem loosening nor cement cracking were seen in radiographs obtained after the experiment. This demonstrated that the polished tapered stems slipped into cement without cement subsidence.

In contrats the aluminum plate in size-3 rough bent stem was distally (Fig. 6B), and the strain of the plate was synchronized with stem subsidence in the stem (Fig. 7B). This stem subsidence was accompanied with cement subsidence. The aluminum plate in size-2 rough stems was also bent distally. However, the extent of debonding and loosening at the stem–cement interface could not be determined after the experiment in rough stems of either size. Therefore, rough stems failed at the cement–bone interface in the early stage of our experiment and were considered to represent models of loosening cemented stems.

IV. Discussion

Researchers have demonstrated, using radiostereometric analysis, that polished tapered stems slip in vivo into cement [1, 2, 15, 16]. However, it is difficult to observe stem slip continuously in vivo.

Continuous stem subsidence and strain on the aluminum plate inserted into cement were observed for this study. Polished tapered stems subsided, yet the aluminum plates in them did not bend distally, and stem subsidence did not synchronize the strain on aluminum plates. This fact demonstrated that stems slipped into the cement without cement subsidence.

In this study, stem subsidence did not progress linearly but converged slowly after the initial subsidence. The slow subsidence after the initial large amount of subsidence in polished tapered stems is similar to the pattern found in clinical studies using roentgen stereo photogrammetric analysis [1, 15, 16]. Our findings of a lack of stem loosening and a lack of cement cracking were also similar to the findings of clinical studies [9, 10, 18].

Stem subsidence occurred in the loading periods, but stems rose slightly in the no load periods in both types of stems. We think that the rising of the stem was caused by stress relaxation in the cement. Stress relaxation is a characteristic of cement in which stress stored in the cement during loading is released in the no load periods. The role of stress relaxation has been shown to be self-protection from cement breakage [7, 12]. In our study, stress relaxation tended to occur in the polished tapered stems. The strain gauge, which indicated cement movement or force to the cement, produced higher and lower values also in the polished tapered stem. It also might indicate stress relaxation of cement against a stick-slip phenomenon. Verdonschot

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et al. [17] noted that the subsidence pattern was stepwise and that cement creep was related to this phenomenon. The change in strain on the aluminum plate was thought to reveal the change in force in the cement. Therefore, decreasing force, instead of subsidence, might have been caused by stress relaxation.

In the rough stems in our study, most subsidence occurred on the first day of the experiment, and then it decreased linearly. Stem subsidence was accompanied by cement subsidence, which was confirmed by strain gauges. The rough stems became models of loosening in our study.

It was unclear why the bone–cement interface of rough stems broke so quickly in our study. We surmised that the stems could not slip in the cement because of their roughness and because the bonding composite of stem and cement caused shear stress at the bone–cement interface. The artificially processed tapered stems with no collar that were made for this study did not work as a composite beam, and thus they might have led to early deboning at the cement–bone interface.

Subsidence of the size-2 polished tapered stem with a thick cement mantle was greater than that of the size-3 stem with a relatively thin cement mantle. It has been hypothesized that a thin cement mantle can more easily be restricted by bone because the volume of cement is smaller than in thicker mantles [13].

Results were very different by surface roughness in our study. Though stem subsidence occurred in both stem types, subsidence rates converged for polished stems and the use of rough stems led to stem loosening. The early subsidence of rough stems of the composite-beam type must be carefully observed to detect loosening.

V. Acknowledgments

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Table 1 : The amount and rate of stem subsidence

	Polished size 2		Polished size 3		Rough size 2		Rough size 3	
Day	**Subsidence in mm (SD)**	**Rate**	**Subsidence in mm (SD)**	**Rate**	**Subsidence in mm (SD)**	**Rate**	**Subsidence in mm (SD)**	**Rate**
1–5	0.773 (0.004)	62.9	0.518 (0.008)	76.2	1.094 (0.009)	38.6	0.887 (0.019)	45.0
6–10	0.17 (0.007)	13.8	0.062 (0.004)	9.1	0.355 (0.011)	13.1	0.156 (0.013)	7.9
11–15	0.071 (0.008)	5.8	0.028 (0.006)	4.2	0.302 (0.013)	11.1	0.109 (0.013)	5.5
16–20	0.057 (0.006)	4.6	0.028 (0.008)	4.2	0.279 (0.012)	10.3	0.202 (0.013)	10.2
21–25	0.046 (0.008)	3.7	0.016 (0.007)	2.4	0.247 (0.007)	9.1	0.182 (0.018)	9.2
26–30	0.046 (0.008)	3.7	0.011 (0.005)	1.7	0.200 (0.007)	7.4	0.174 (0.009)	8.8
31–35	0.040 (0.006)	3.2	0.014 (0.006)	2.1	0.172 (0.006)	6.3	0.182 (0.052)	9.2
36–38	0.027 (0.004)	2.2	0.002 (0.006)	0.3	0.110 (0.007)	4.1	0.079 (0.027)	4.0
Totals	**1.229 (0.004)**	**100.0**	**0.680 (0.006)**	**100.0**	**2.715 (0.007)**	**100.0**	**1.971 (0.027)**	**100.0**

Subsidence values are shown as average millimeters (standard deviation) during each period; rates are the percentages for each stem group, obtained by dividing each group's subsidence by the total subsidence for type of stem.

Figure 1A–B : Collarless double-taper stems: (A) a rough surface stem; (B) a polished stem

A **B**

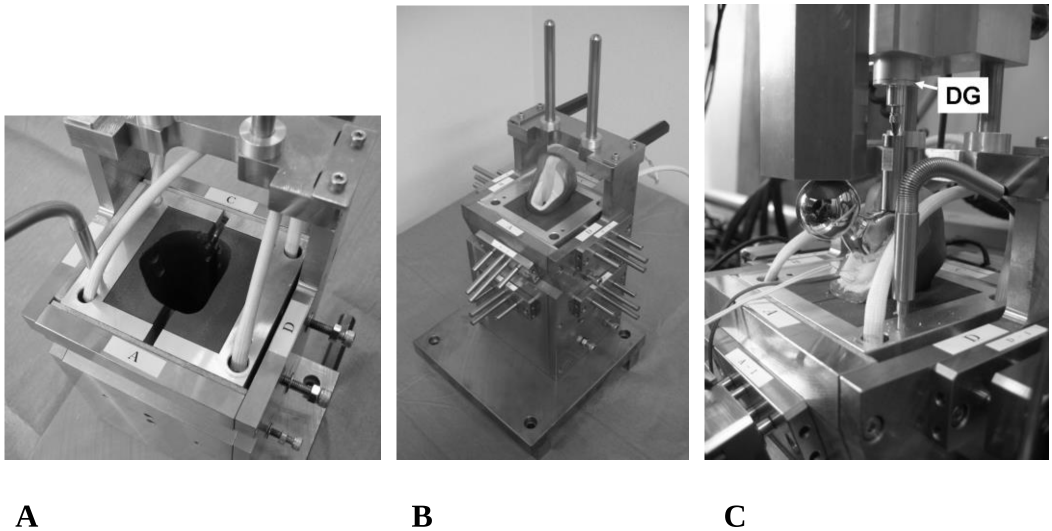

Fig. 2A–C (A) The fixator. The exterior of the fixator was made of carbon steel; the interior's epoxy resin was formed to the contours of the composite femur. (B) A composite femur was fixed completely with surrounding epoxy resin and rods inserted from the exterior of the metal fixator through the epoxy resin. (C) Measurement of stem subsidence. A digital displacement gauge (DG) was applied to the attachment screwed into the proximal lateral side of the stem to measure the amount of displacement.

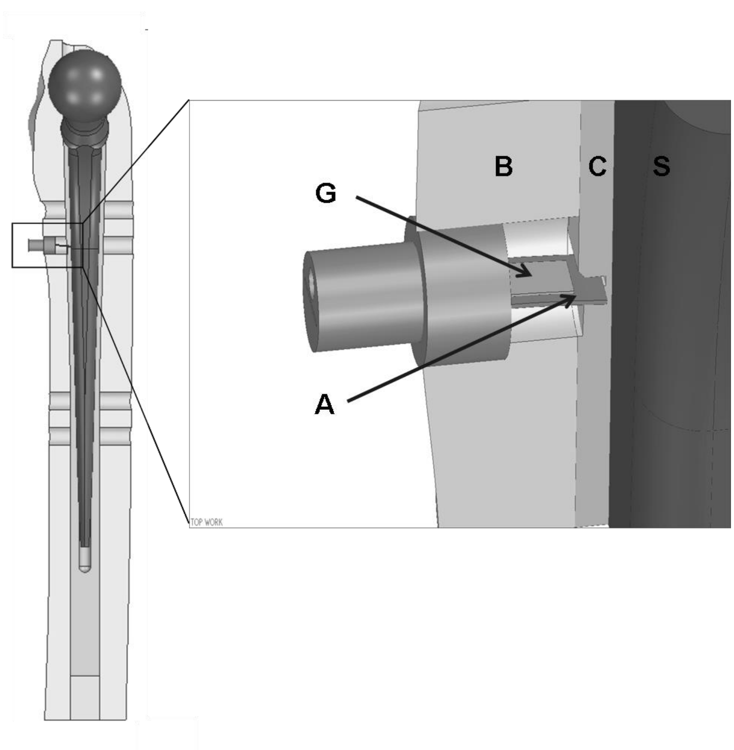

Fig. 3 Strain gauge. The aluminum plate onto which the strain gauge was pasted was inserted in the cement through the proximal posterior hole in the composite femur. The displacement of the aluminum plate represented the longitudinal displacement on the cement. A, aluminum plate; B, composite femur; C, cement; G, strain gauge; S, stem.

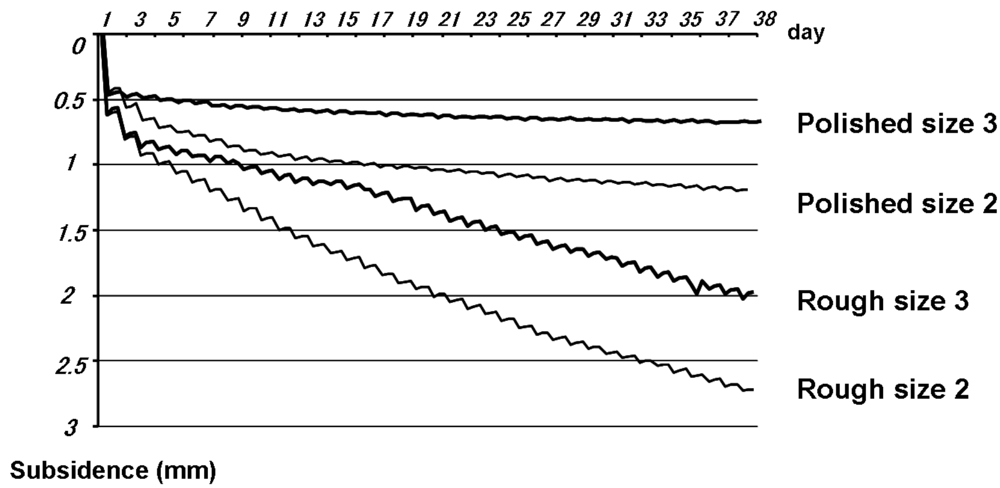

Fig. 4 Stem subsidence. All stems had subsided rapidly by 200,000 loading cycles. Afterward, subsidence for the polished stems converged slowly. However, subsidence after the early period was linearly progressive in the rough stems. The total amount of subsidence in the rough stems was more than two times that for the polished stems of the same size.

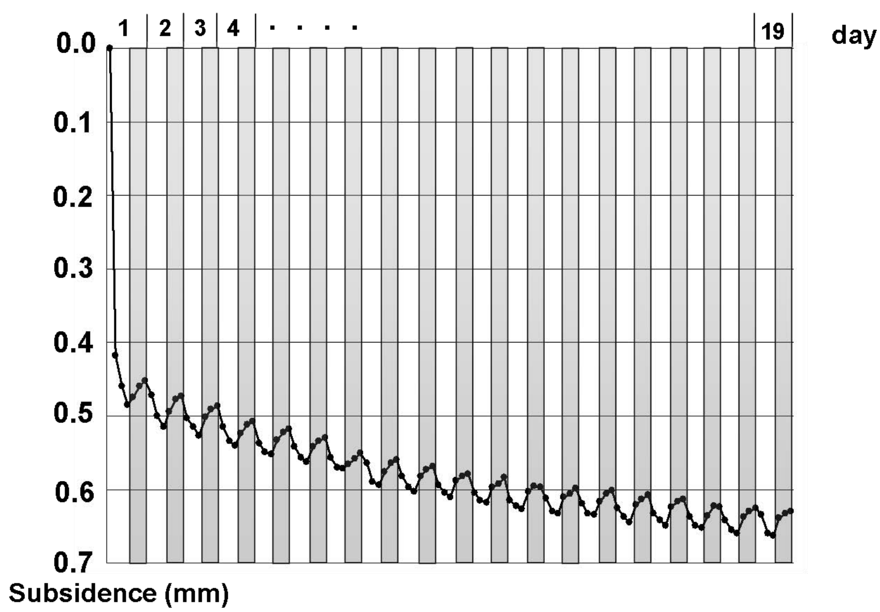

Fig. 5 Enlargement of stem motion during load and nonload in size-3 polished stems: displacement from original position between day 1 and day 19. The stem subsided during the load periods but rose up during the nonload periods. Other stems were also seen to have a similar zigzag motion, seen in Fig. 4

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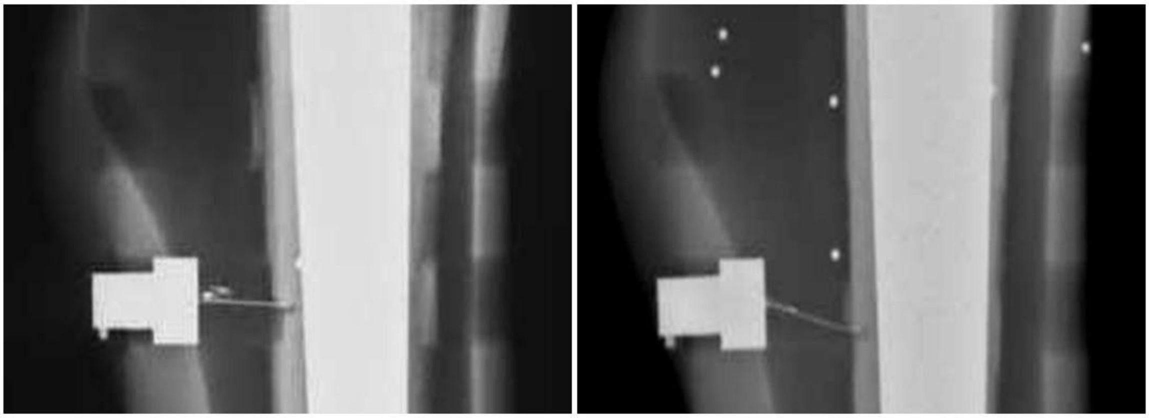
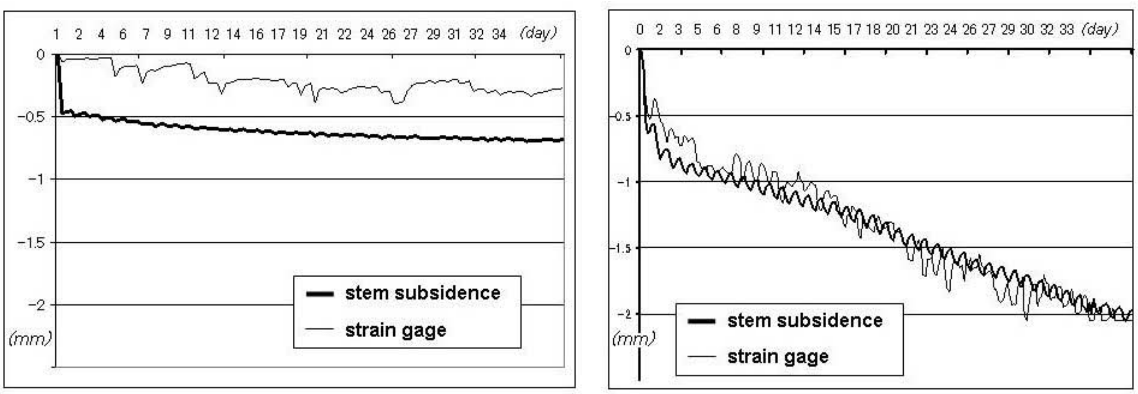


A B

Fig. 6A–B Radiographs of aluminum plates obtained after the experiment. (A) Polished stem. Less deformity of the aluminum plate was seen. (B) Rough stem. The aluminum plate was bent distally.



A B

Fig. 7A–B Stem subsidence and strain gage on the aluminum plate. (A) Polished stem. Cement movement was not synchronized with stem subsidence but recovered sometimes independently. (B) Rough stem. Cement subsidence was synchronized with stem subsidence.