

Percutaneous balloon kyphoplasty for the correction of spinal deformity in painful vertebral body compression fractures

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Abstract

Vertebral body compression fractures can cause chronic pain and may result in progressive kyphosis. Although vertebroplasty has been used to treat pain, it does not attempt to restore vertebral body height and eliminate spinal deformity. Percutaneous balloon kyphoplasty is a novel technique, which involves the introduction of inflatable bone tamps into the fractured vertebral body for elevation of the endplates, prior to fixation of the fracture with bone cement. Our initial experience with this minimally invasive procedure indicates that percutaneous balloon kyphoplasty can be efficacious in the treatment of painful, osteoporotic vertebral compression fractures. © 2002 Elsevier Science Inc. All rights reserved.

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1. Introduction

In recent years, vertebroplasty, the percutaneous injection of polymethylmethacrylate (PMMA) bone cement into a vertebral body, has been applied to the treatment of aggressive hemangiomas, osteolytic neoplasms and osteoporotic compression fractures [1–3]. The goal of percutaneous vertebroplasty is to alleviate spinal pain by stabilizing the fracture through application of bone cement [4]. Although this procedure has proved safe and effective in the treatment of selected patients with painful osteoporotic vertebral compression fractures, it does not address the issues of vertebral height loss and kyphotic deformity. Residual kyphosis can cause continued pain and disability, as well as off-balancing of the patient who may be at risk of sustaining falls and developing new fractures or experience progression of spinal deformity [5,6]. In addition, spinal

deformity may cause restriction of respiratory function and further compromise quality of life [7].

Percutaneous balloon kyphoplasty, a recent modification of percutaneous vertebroplasty, entails inflation of a balloon into the collapsed vertebral body to restore vertebral height, prior to fracture stabilization with bone cement. We describe this new procedure and present our initial experience with percutaneous balloon kyphoplasty in patients with painful, osteoporotic vertebral body compression fractures.

2. Materials and methods

We performed percutaneous balloon kyphoplasty in 15 patients (11 women and 4 men; age range, 41–86 years; mean age, 75 years) who presented with painful vertebral compression fracture(s) refractory to conservative medical treatment. Twenty-four osteoporotic vertebral compression fractures (fracture age range, 2–48 weeks; mean, 14 weeks) were identified and treated. Multiple fractures were observed in seven patients. Eight patients (53%) had primary osteoporosis and seven patients (47%) had steroid-induced osteoporosis. We performed 14 (58%) thoracic

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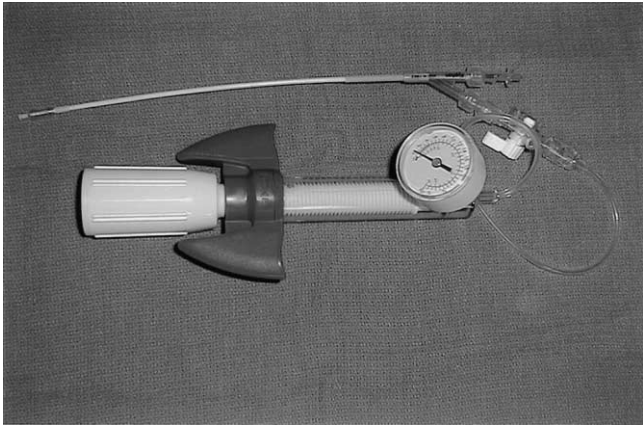


Fig. 1. Inflatable bone tamp with angioplasty inflation device.

and 10 (42%) lumbar procedures. All patients underwent careful physical examination and determination of the symptomatic level under fluoroscopic guidance. Imaging evaluation of fracture deformity was accomplished on radiographs and MR imaging studies of the spine. MR imaging studies were performed on a 1.5-T scanner (Signa; General Electric Medical Systems, Milwaukee, WI). Depiction of the

signal intensity characteristics of marrow edema on the T1-weighted spin echo (TR/TE, 500/15) and fluid sensitive T2-weighted fast spin echo (3600/85) MR images, or short tau inversion recovery (4595/60; inversion recovery time, 150 ms) images, was indicative of recent fracture.

Informed consent was obtained from all patients. The balloon kyphoplasty procedure was performed under local anesthesia (lidocaine hydrochloride; Astra, Nanterre, France) with conscious sedation (midazolam hydrochloride; Roche, Nutley, NJ; fentanyl citrate; Abbott Laboratories, North Chicago, IL) using the recently developed inflatable bone tamp (KyphX; Kyphon, Santa Clara, CA; Fig. 1). With the patient lying in the prone position, an 11- or 13-G bone biopsy needle was directed under aseptic conditions and fluoroscopic guidance to enter the bone via the transpedicular approach. A guide pin (K-wire) and blunt dissector were inserted into the fractured vertebral body directed into the posterior third of the vertebral body. A 3-mm working cannula was then placed over the dissector into the posterior aspect of the vertebral body. The dissector was removed and a 3-mm drill was passed to within 3–4 mm posterior to the anterior cortical margin of the vertebral body (Fig. 2A and B). Drilling of bone created a narrow

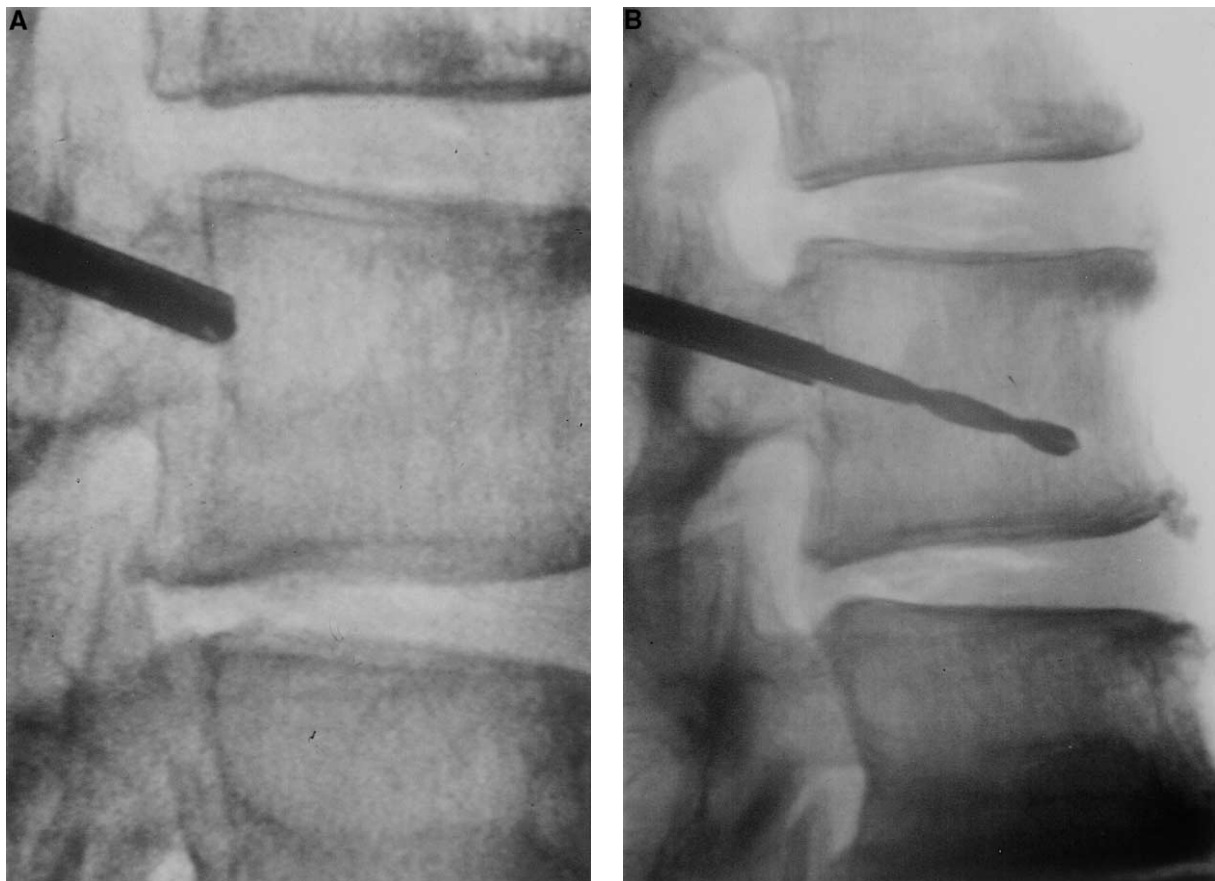


Fig. 2. Percutaneous balloon kyphoplasty: transpedicular approach. (A) Lateral view of lumbar spine at L3–4 level shows working cannula placed into posterior third of vertebral body. (B) 3-ml drill is placed through working cannula and creates cavity extending into anterior third of vertebral body. (C) Inflatable bone tamp is placed within cavity created by drill. Arrows on two fiducials denote proximal and distal extents of balloon.

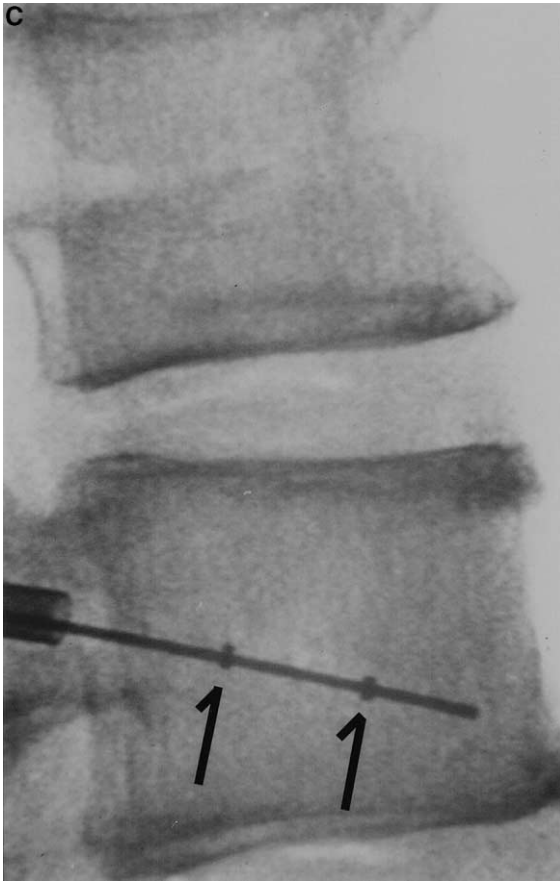


Fig. 2. (continued)

channel for insertion of the inflatable bone tamp. Multiplanar fluoroscopy was used regularly to verify positioning and orientation of the tools over the procedure.

The inflatable bone tamp was prepared with 60% dilute iodine contrast medium, and an angioplasty injection device equipped with a pressure monitor was utilized for the inflation of the bone tamp (Fig. 1). The drill was removed and the inflatable bone tamp was inserted and directed to the anterior most extent of the vertebral body that had been predrilled (Fig. 2C). Inflation of the bone tamp was started by raising the pressure to approximately 50 psi; bone tamp was progressively inflated in 0.5-ml increments until an inflation endpoint was reached (maximum achievable pressure, 220 psi; Fig. 3A and B). During inflation, the decay of pressure in the bone tamp owing to compaction of bone was monitored. The end point of inflation was indicated by

restoration of vertebral body height to normal prefracture height, flattening of the inflatable balloon tamp against any of the vertebral body cortical margins, inflation with no

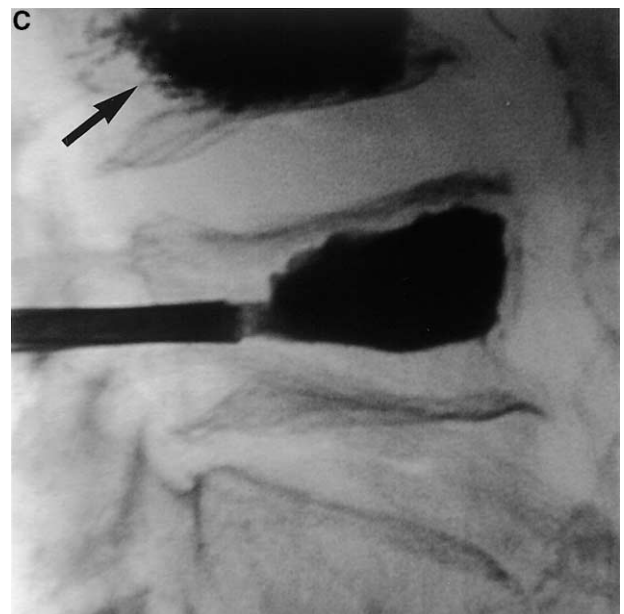
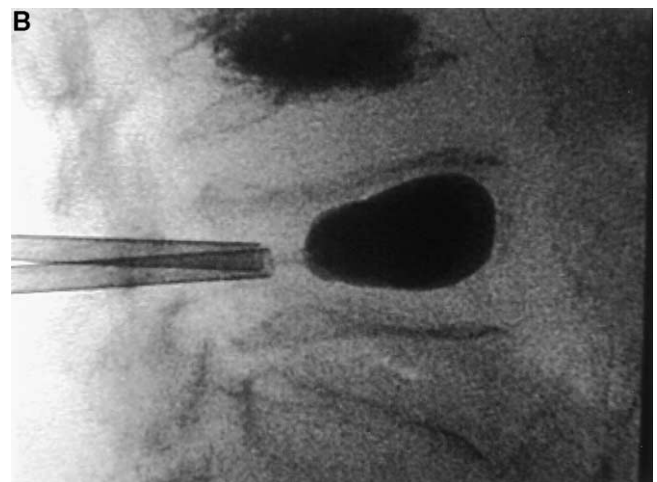
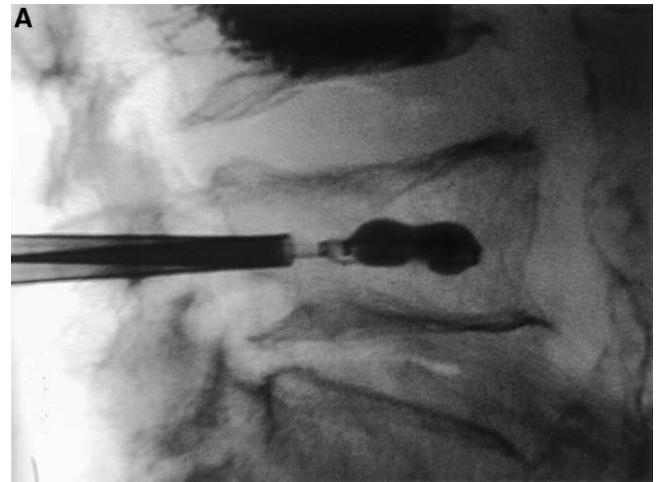


Fig. 3. Percutaneous balloon kyphoplasty: balloon inflation and application of bone cement into vertebral body. (A) Lateral view of spine at L4–5 level shows initial balloon inflation. (B) Bone tamp is now fully deployed with superior margin of balloon flattened against elevated endplate. Further balloon expansion at this time would likely breach superior endplate. (C) Cement application through working cannula with bone cement filler tube. Note smooth margins of low-pressure cement application within cavity created by inflatable bone tamp. Vertebral body at L3–4 level shows more feathered margins (arrow) from previous vertebroplasty.

further pressure decay or attainment of the maximum volume of the balloon.

Polymethylmethacrylate (Simplex P; Howmedica, Rutherford, NJ) bone cement was used for stabilizing the fracture. The monomer was processed after being prechilled in the refrigerator at 0–4 °C for 24 h before use, so that the rate of polymerization would slow, thus increasing its working time. The acrylic cement was prepared by mixing 40 ml of methyl methacrylate polymer powder with a radiopaque agent comprised of either 6 g of sterile barium sulfate powder (Bryan, Woburn, MA) or 2 g of tungsten or tantalum powder (Nycomed, Princeton, NJ), 1 g of powdered antibiotic (cefazolin, Apothecon, Bristol, Myers, Squibb, Princeton, NJ or tobramycin, Nebcin, Eli Lilly, Indianapolis, IN) and 10 ml of the liquid methyl methacrylate monomer until a very doughy and cohesive consistency was achieved. As a preventive measure against infection, intravenous antibiotics were also administered (cefazolin, Apothecon, Bristol, Myers, Squibb or tobramycin, Nebcin, Eli Lilly). Because percutaneous balloon kyphoplasty entails the injection of bone cement under low pressure, the cement can be cured for about 4 min (range, 3–7 min) until a very doughy and thick consistency is reached. The cement was loaded into 3-mm bone cement filler devices and then was slowly applied to the cavity created by the inflatable bone tamp under direct fluoroscopic visualization (Fig. 3C). Once bone cement application was complete, as confirmed by biplanar fluoroscopy, tools were removed promptly, and hemostasis was obtained at the incisional site. For bilateral transpedicular or extrapedicular approaches, the same sequence of events was performed on the contralateral side. Performance time for kyphoplasty was typically 30–45 min per spinal level.

3. Results

Percutaneous balloon kyphoplasty was successful in all 15 patients. After the completion of the procedure, measurements of vertebral body height restoration on radiographs of the thoracolumbar spine showed significant differences (Fig. 4A and B). The posttreatment mean vertebral body height \pm standard deviation (S.D.) was $91.5 \pm 11\%$ of the estimated original (prefracture) height, while the pretreatment mean vertebral body height \pm S.D. was $78.6 \pm 15.6\%$ of the estimated original height ($P = .000$, Student's paired t test). In particular, the mean height restorations \pm S.D. were anterior portion of the vertebral body $52 \pm 33.2\%$ (3.7 mm; $P < .0001$), midvertebral body $65.7 \pm 36.2\%$ (4.7 mm; $P < .0001$) and posterior portion of the vertebral body $53.4 \pm 49.1\%$ (1.5 mm; $P < .0001$; Student's paired t test; Fig. 5). Before balloon kyphoplasty, the mean kyphosis \pm S.D. was $25.5 \pm 10^\circ$. After the procedure, mean kyphosis \pm S.D. measured $15.6 \pm 6.7^\circ$ ($P = .000$, Student's paired t test). On average, balloon kyphoplasty improved kyphosis by $62.4 \pm 16.7\%$.

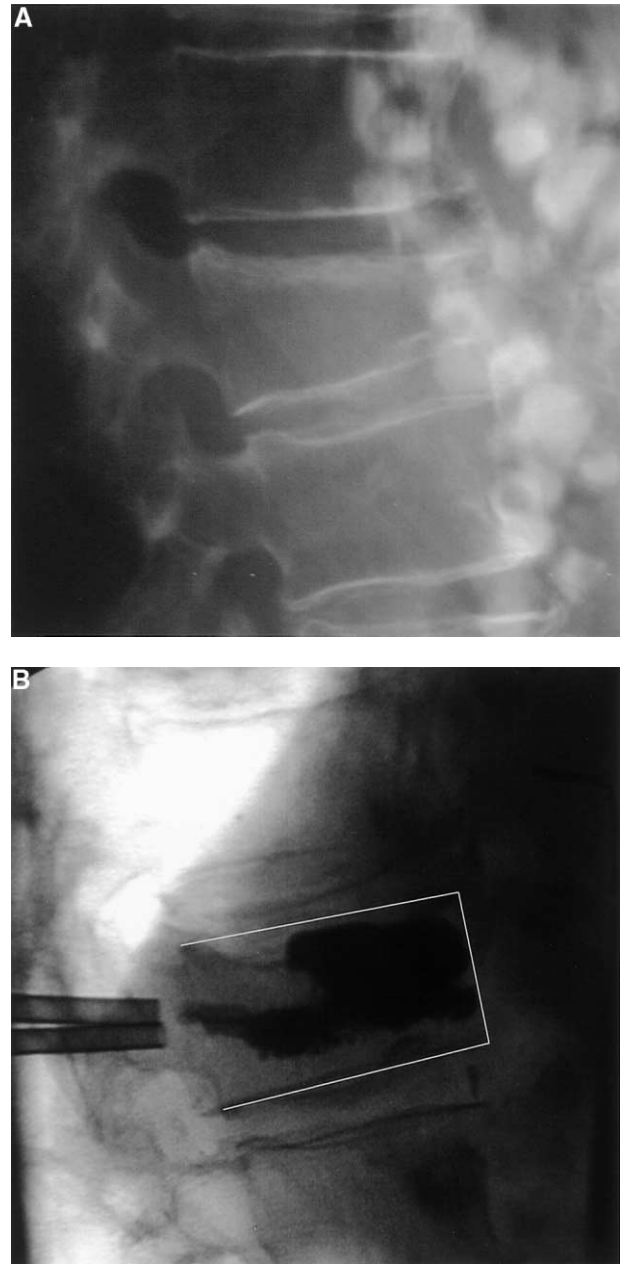


Fig. 4. A 69-year-old woman receiving steroid medications who presented with severe lumbar pain. (A) Lateral view of lumbar spine shows compression fracture of L3 vertebral body with associated anterior wedging deformity. (B) Following balloon kyphoplasty, significant height restoration especially of anterior superior portion of vertebral body can be appreciated.

All 15 patients (100%) experienced dramatic pain relief often within hours after the procedure and expressed satisfaction with the treatment. Two (13%) patients with chronic obstructive lung disease also reported significant improvement in respiratory function. Three (20%) patients returned enthusiastically to undergo balloon kyphoplasty when they developed additional, new vertebral compression fractures. The procedure was well tolerated by the patients. No significant complications related to the procedure were

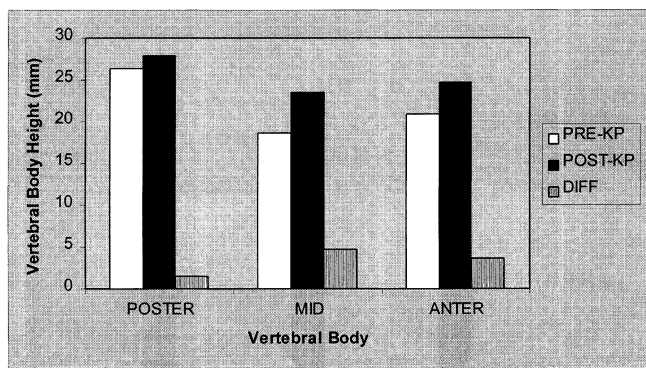


Fig. 5. Bar chart shows mean vertebral height restoration (mm) with balloon kyphoplasty (KP) according to expanded vertebral body portion. POSTER, posterior portion of vertebral body; MID, middle portion of vertebral body; ANTER, anterior portion of vertebral body.

encountered in any of our cases. At the follow-up period of 6–8 months postprocedure, one elderly patient had died because of a different underlying disease, but the remaining 14 patients continued free of pain.

4. Discussion

Vertebral compression fractures are a common and often debilitating complication of osteoporosis [6,8,9]. Patients with multiple vertebral body compression fractures may develop kyphosis, which can be associated with significant complications including pulmonary compromise and gastrointestinal tract dysfunction [6,7,9]. In addition, altered biomechanics in the spine, owing to the kyphotic deformity, may result in an increased risk of falls and development of new fractures or may impose overload on adjacent vertebrae causing them to fracture [5,6].

Percutaneous balloon kyphoplasty is a recent modification of the vertebroplasty procedure that attempts correction of the spinal deformity and restoration of vertebral body height, prior to fracture stabilization with bone cement. As with percutaneous vertebroplasty, balloon kyphoplasty provides stabilization and augmentation of the vertebral fracture that ameliorates pain and allows the patient to return to activities of daily living. Our initial experience with the procedure shows definite advantages of balloon kyphoplasty to reexpand the collapsed vertebra and correct the wedging deformity. Because the inflatable bone tamp creates a cavity in the vertebral body, however, bone cement can be injected under low pressure at the site of the fracture. In addition, large bone cement filler devices

used in balloon kyphoplasty allow for easy application of more cohesive and doughy bone cement that is unlikely to leak out of the fractured vertebral body. This appears to protect from the deleterious effects leakage of cement into adjacent tissues may have, thus allowing for increased safety of performance.

Percutaneous balloon kyphoplasty features the properties of percutaneous vertebroplasty and, in addition, may provide the patient with the multiple benefits of correction of the kyphotic deformity and relative restoration of normal spinal anatomy. Early experience in a relatively small group of patients suggests that the procedure can be performed safely in carefully selected patients who sustain recent vertebral body compression fractures. The procedure is performed on an outpatient basis, is well tolerated by patients and provides immediate pain relief in most cases. Based on our initial results, we believe that percutaneous balloon kyphoplasty will improve management of patients with painful vertebral body compression fractures refractory to current medical therapy. Further clinical studies are expected to establish the role of this innovative and minimally invasive spinal procedure to ameliorate pain and correct kyphosis.

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