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Mechanical evaluation of a carbonated apatite cement in the fixation of unstable intertrochanteric fractures

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ABSTRACT – We created three-part unstable intertrochanteric fractures in 6 pairs of aged, osteopenic, human, cadaveric femora. Fractures were reduced and fixed with a Dynamic Hip Screw (DHS) (Synthes, Paoli, PA). Two test groups were evaluated: 1. Fixation with a DHS, and 2. Fixation with a DHS and calcium phosphate bone cement (Norian SRS (Skeletal Repair System)) augmentation of the fracture line and posteromedial calcar region of the proximal femur. Each femur was loaded to 1,650 N (2.5 body weight) for 10,000 cycles to simulate postoperative load transmission across the fracture construct during normal gait. The load was further increased successively by one body weight for another 10,000 cycles until failure. We evaluated fixation by measuring the amount of sliding of the lag screw of the DHS (shortening) and stiffness of the overall fracture construct (stability). SRS cement-augmented specimens had less shortening (1 mm versus 17 mm) and twice the initial construct stiffness compared to control specimens.

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Intertrochanteric fractures are usually fixated by a sliding hip screw device. Normal forces around the hip tend to cause impaction of the proximal and distal fragments by sliding of the lag screw within the barrel. Thus, the device provides controlled impaction across the fracture site resulting in a more stable construct. However, controlled impaction of unstable fractures can result in excessive shortening of the limb, sub-optimal hip mechanics, and altered gait. Unstable intertrochanteric fractures are usually associated with a fractured lesser trochanteric region. Despite the mechanical advantage of re-establishing the load-transferring ability of this region, this posteromedial fragment often cannot be reduced and stabilized surgically without extensive dissection and periosteal stripping.

Norian SRS is an injectable, biodegradable bone cement that cures at physiologic temperature and pH with high compressive strength, and crystallographic and chemical characteristics similar to the mineral phase of bone. We hypothesized that accurate reduction and fixation of intertrochanteric fractures using a sliding hip screw, augmented with Norian SRS cement injected into areas of comminution and compromised cancellous bone in the proximal femur, especially in the lesser trochanteric area, would provide a more stable mechanical environment then the sliding hip screw alone. We tested this hypothesis in a cadaveric mechanical study by measuring the sliding of the hip screw (shortening) and the stiffness (stability) of the fracture construct.

Material and methods

Material

Norian SRS cement Skeletal Repair System is an injectable, fast setting, high-strength, cancellous bone cement that cures in situ to form a

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carbonated apatite of low crystalline order and small grain size similar to the mineral phase of bone (Constantz et al. 1995). The cement paste is formed by mixing a phosphate-buffered solution with a powder consisting of calcium carbonate ($CaCO_3$), α-tricalcium phosphate ($Ca_3(PO_4)_2$), and monocalcium phosphate monohydrate ($Ca(H_2PO_4)_2.H_20$). Once implanted, the material equilibrates to body temperature, accelerating the formation of carbonated apatite. It hardens in about 10 minutes after implantation at body temperature. At 1 hour it acquires 50% of its ultimate compressive strength. Full compressive strength of 55 megapascals is attained about 12 hours after implantation (Constantz et al. 1995). It has been shown to remodel and to be replaced by host bone while maintaining structural integrity in the implanted region (Frankenburg et al. 1998).

Specimen selection

6 pairs of fresh frozen human adult cadaveric femora were prescreened with anteroposterior radiographs to exclude gross anatomical pathology. All femora were wrapped in saline soaked towels and stored in tightly sealed plastic bags at or below –20 °C. All specimens were defrosted for at least 8 hours at room temperature prior to radiographic assessment, bone density measurements, and creation of the intertrochanteric fracture. Screening anteroposterior and lateral radiographs of unfrozen specimens were taken as a baseline. Bone mineral density (BMD) of the intertrochanteric region was determined using Hologic 4500 (Hologic Inc., Waltham, MA) dual energy x-ray absorptiometry (DEXA).

Specimen preparation

Femora were cleaned of all soft tissue and transected 23 cm below the distal aspect of the lesser trochanter. The distal end of each specimen was potted with dental acrylic (PERM Reline and Repair Resin, Hygenic Corp., Akron, OH) in a 15 cm section of 6 cm diameter tubular aluminum tube stock. In addition, an acrylic acetabular cup was molded by using individual femoral heads as a template. These acrylic cups were used during testing to simulate in vivo loading conditions around the femoral head.

Fracture creation

A three-part intertrochanteric fracture was created by making 1.5 mm drill holes 2–3 mm apart in the cortex of the proximal femur along the intertrochanteric line anteriorly, through the superior aspect of the greater trochanter, and along the intertrochanteric crest posteriorly. The drill holes were continued above and below the lesser trochanter to define the posteromedial fragment of the fracture. The specimen was then mounted on an MTS servohydraulic machine and loaded axially to create a three-part intertrochanteric fracture. If the lesser trochanteric fragment did not form, an osteotome was used to displace the lesser trochanter from the femur.

Fracture fixation

1 specimen from each pair was randomly assigned to be the experimental side with internal fixation using a sliding hip screw augmented with Norian SRS cement, and the contralateral side was assigned to be a control specimen with the sliding hip screw alone. The standard surgical technique for implanting a sliding hip screw and four hole sideplate (Dynamic Hip Screw, Synthes, Paoli, PA) was carried out on the fractured femur by an experienced orthopedic surgeon. After placement of a guide pin, drilling, reaming, and tapping for the lag screw were carried out. After inserting the lag screw and 135° four hole sideplate, 4.5 mm sideplate screws were placed.

In the experimental group, before placement of the sideplate, loose cancellous bone in the intertrochanteric region was impacted using a tamp through the lag screw hole. SRS cement was then injected along the shaft of the lag screw into the intertrochanteric region with either a straight 2.7 mm or 2.0 mm needle under image intensification. The sideplate was immediately guided over the lag screw and secured to the lateral aspect of the femur with a self-tapping 4.5 mm cortical screw through the second most proximal screw hole in the sideplate. All remaining sideplate screws, except the most proximal, were inserted in the sideplate. A 4.5 mm drill was then used to direct a hole through the proximal screw hole of the plate towards the lesser trochanter area. A curved probe was used through this hole to create a pathway to the lesser trochanter region while visualizing

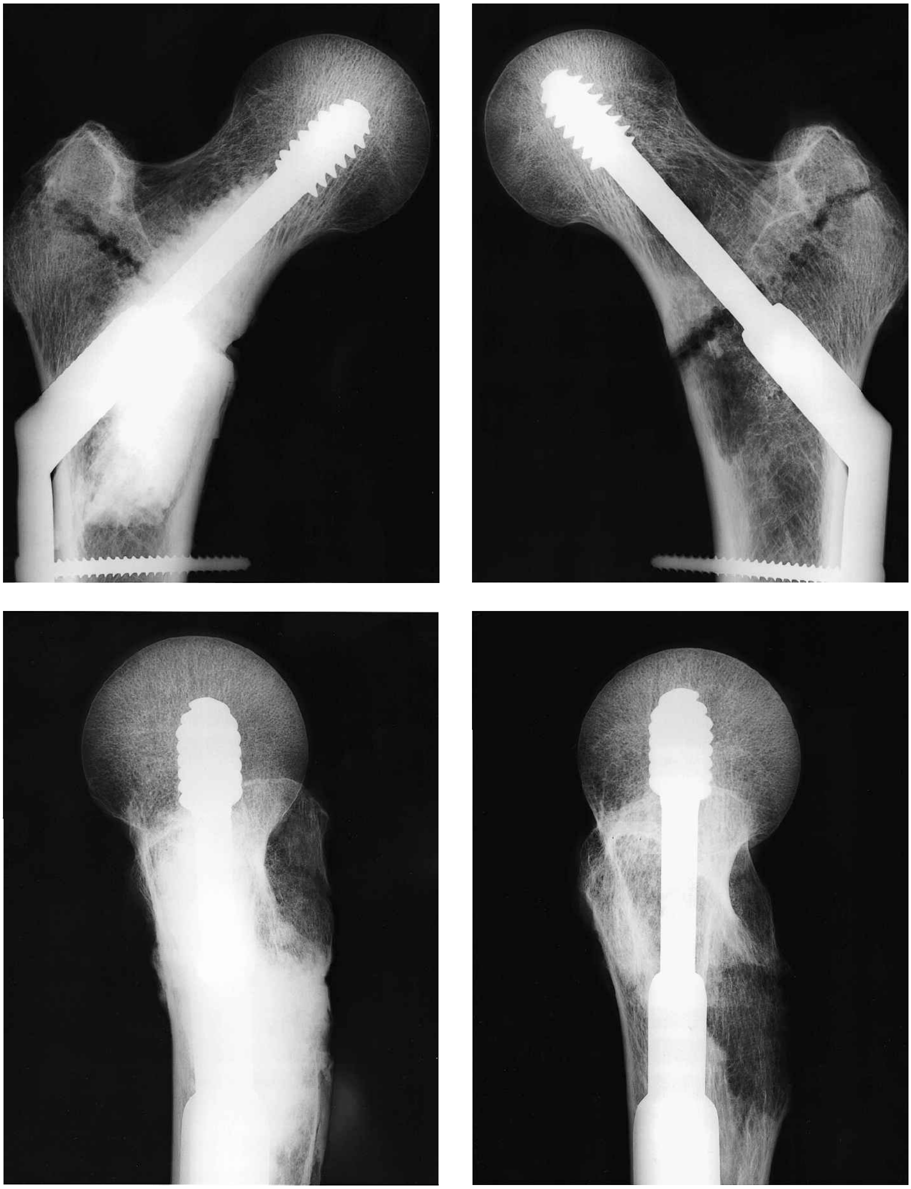

Figure 1. Anteroposterior and lateral radiographs of paired experimental (figures on the left) and control specimens (figures on the right). Note the posteromedial defect resulting from the displaced lesser trochanter on the figure at the right bottom and the same region filled with Norian SRS cement on the figure at the left bottom.

this area fluoroscopically. The pathway and the posteromedial region were cleared of debris using this probe and lavaged. The posteromedial defect in the area of the lesser trochanter was then filled with Norian SRS cement using a curved 2.7 mm needle inserted through the proximal screw hole in the plate oriented posteromedially. The medial cortex of the femur was drilled with a 3.2 mm drill and the proximal sideplate screw was quickly inserted to avoid disruption of the cement while setting. In both experimental and control groups, the posteromedial lesser trochanteric fragment was not replaced (Figure 1). Lateral-medial fluoroscopic images were essential to visualize adequately posteromedial void preparation and filling.

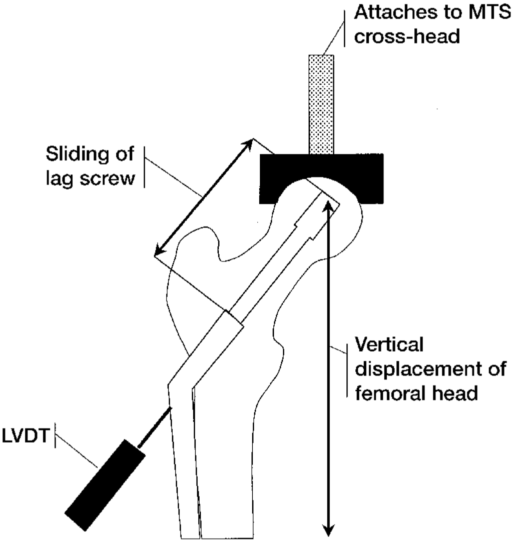

Figure 2. Graphic representation of sliding of the lag screw and vertical displacement of femoral head measurements.

All test femora were immersed in a container with 1 L phosphate-buffered solution at 37 degrees Celsius and placed in an incubator which maintains 100% relative humidity and 37 °C. The SRS cement was allowed to cure in the incubator for at least 12 hours. No specimen was refrozen after fixation.

Testing after fracture

After curing of the SRS cement, a linear variable differential transducer (LVDT) was attached to the sideplate using a custom fixture (Figure 2). The LVDT core was aligned with the protruding end of the lag screw to measure relative displacement between the sideplate and the lag screw. Specimens were mounted on an MTS table and inclined 15° from the vertical plane to simulate physiological loading. Each femur was loaded to 125 N 10 times at a loading (and unloading) rate of 250 N for preconditioning and immediately followed by 10,000 cycles of loading to a peak compressive force of 1650 N (2.5 body weight, load rate of 3,300 N/s). Then the load was increased by one body weight (660 N) at a load rate of 4,620 N/s (an increment of 1,320 N/s) and loaded for another 10,000 cycles. One body weight increments for an additional 10,000 cycles were added until the specimen failed. Failure was defined as either 40 mm cross-head displacement, 40 mm sliding of the lag screw, fracture of the femur and/or hardware failure. Beginning with the first cycle force, cross-head displacement and settling of the lag screw were sampled at 2 hertz.

Contact radiographs and photographs of femora were obtained for each specimen (intact, after fracture, after fixation, and after loading—every 10,000 cycles or at failure).

Table 1. Comparison of survival of paired femoral specimens at 10,000 cyclic loading intervals with 2.5, 3.5, 4.5 and 5.5 body weights

Specimen #	DEXA (g/cm^2)	2.5 BW				3.5 BW		
		Comp. cycles	Sliding (mm)	Total sliding (mm)	Vertical sliding[a] (mm)	Comp. cycles	Sliding (mm)	Total sliding (mm)
SRS 1	0.97	10,000	2.1	2.1	3.0	10,000	0.7	2.8
Control 1	0.99	10,000	29	29	26	2,804	7.5	36
SRS 2	0.56	10,000	0.1	0.1	1.8	10,000	21	21
Control 2	0.57	3,808	43	43	56	N/A	N/A	N/A
SRS 3	0.86	10,000	1.0	1.0	4.9	10,000	0.5	1.5
Control 3	0.90	10,000	2.9	2.9	3.8	10,000	0.7	3.6
SRS 4	0.80	10,000	0.1	0.1	3.9	1,300	0.0	0.2
Control 4	0.68	10,000	4.8	4.8	7.2	10,000	7.1	12
SRS 5	0.58	10,000	0.1	0.1	1.2	10,000	0.0	0.1
Control 5	0.62	10,000	4.8	4.8	7.2	10,000	0.7	5.5
SRS 6	0.76	10,000	1.0	1.0	3.5	10,000	1.6	2.7
Control 6	0.76	10,000	28	28	26	N/A	N/A	N/A

[a] Vertical displacement only calculated for 2.5 BW testing.

Outcome parameters and statistical analysis

These included: 1. Sliding of the lag screw calculated as total DHS lag screw displacement from the beginning of the first cycle until the end of each 10,000 cycles. 2. Total sliding as calculated by adding individual sliding results as the load is increased by one body weight after each 10,000 cycle loading. 3. Total actuator displacement of MTS from the beginning of the first cycle until the end of each 10,000 cycles as the vertical displacement of the femoral head (Figure 2). 4. Stiffness of the construct was taken as the slope in the linear region of the force vs. displacement curve generated from each given period of 10,000 cycles. For this computation, displacement was taken as the MTS cross-head displacement and stiffness was then determined by averaging three consecutive loading cycles at predetermined time periods.

The data were examined for normality and equal variance. If they were found to be parametric, a student t-test was used. If they were found to be non-parametric, the Wilcoxon signed rank test was used. If they were found to be consistent with the normality assumption, but had an unequal variance, the unequal variance F-test was applied. One-way analysis of variance was used if there were more than two variables and Pearson chi-square test statistics were used for categorical variables. Finally, if no significant difference was found between the two groups in outcome parameters due to small sample size, type II error was calculated to show the probability that there really was a difference between the two groups although it was not detectable using the above-mentioned statistical analysis.

Results

The median and range for the bone mineral density of the intertrochanteric region of the control and SRS cement-treated specimens (n = 6) were similar, 0.72 (0.56–0.97) g/cm^2 and 0.78 (0.57–0.99) g/cm^2, respectively (p = 0.7) (Table 1). In evaluating the type II error for this analysis, the probability that there really was a difference between the two groups was 7%. The median sliding of the lag screw after the first 10,000 cycles was 0.6 (0.1–2.1) mm for the SRS cement-treated specimens and 17 (2.9–43.3) mm for the control specimens (p = 0.03). The median vertical displacement of the femoral head after the first 10,000 cycles was 3.2 (1.2–4.9) mm for the SRS cement-treated specimens and 21 (3.8–56) mm for the controls (p = 0.07). The type II error evaluation indicated 96% probability of a real difference. In the control specimens, the amount of settling was inversely

Table 1. Continued

Specimen #	4.5 BW			5.5 BW			Failure mechanism
	Comp. cycles	Sliding (mm)	Total sliding (mm)	Comp. cycles	Sliding (mm)	Total sliding (mm)	
SRS 1	1,782	1.3	4.1	N/A	N/A	N/A	Implant
Control 1	N/A	N/A	N/A	N/A	N/A	N/A	Bone collapse
SRS 2	N/A	N/A	N/A	N/A	N/A	N/A	Bone collapse and screw cut-out
Control 2	N/A	N/A	N/A	N/A	N/A	N/A	Bone collapse
SRS 3	10,000	0.2	1.6	5,385	0.3	1.9	Implant
Control 3	10,000	0.5	4.1	4,516	0.6	4.7	Implant
SRS 4	N/A	N/A	N/A	N/A	N/A	N/A	Implant and screw cut-out
Control 4	2,803	20	32	N/A	N/A	N/A	Bone collapse and screw cut-out
SRS 5	8,488	0.0	0.1	N/A	N/A	N/A	Implant
Control 5	25	1.5	7.0	N/A	N/A	N/A	Implant and screw cut-out
SRS 6	3,701	1.7	4.4	N/A	N/A	N/A	Implant
Control 6	N/A	N/A	N/A	N/A	N/A	N/A	Bone collapse

Table 2. Comparison of stiffness of paired femoral specimens at various intervals during the first 10,000 cycles

Cycles	Stiffness (N/mm)						
Specimen	1–3	21–23	1998–2000	3998–4000	5998–6000	7998–8000	9998–10000
Control 1	604	632	1132	1242	1340	1371	1392
SRS 1	1180	1071	1051	1106	1175	1133	1169
Control 2 [a]	263	1130	2104	na	na	na	na
SRS 2	1543	1435	1549	1549	1501	1455	1442
Control 3	428	621	983	970	963	961	953
SRS 3	540	500	406	443	478	506	520
Control 4	494	661	766	771	758	755	753
SRS 4	862	1182	617	574	561	544	546
Control 5	412	538	821	823	857	868	871
SRS 5	1000	1915	2268	2376	2360	2470	2520
Control 6	334	668	377	520	1024	1242	1223
SRS 6	803	2047	1673	863	770	764	924
Control median	420	647	902	823	963	961	953
SRS median	931	1309	1300	985	973	949	1047
P-value	0.04	0.03	0.6	0.4	0.7	0.8	0.7

[a] na = not available due to fracture

correlated with the specimens' bone mineral density ($r^2 = 0.82$, $p = 0.01$). No significant correlation was found in the SRS cement group ($r^2 = 0.383$, $p = 0.19$).

We analyzed the stiffness results during the first 10,000 cycles (Table 2). First and 20th cycle stiffness were greater in the SRS cement specimens ($p = 0.04$ and $p = 0.03$, respectively). No other significant differences were observed between the two treatment groups at other times. When the type II error was evaluated for other times, the probability of finding a real difference between the two groups ranged between 7% and 8%. In both groups, average stiffness increased immediately in the first 20 cycles, representing initial settling of the fracture fragments. The individual data showed that 3 SRS cement specimens failed to increase immediately in the first 20 cycles. The increment in stiffness corresponded to the settling of the fracture construct and this phenomenon was most marked in the control specimens.

SRS cement-treated specimens bore more load than control specimens (Table 1). 3 SRS cement specimens fractured at higher load levels than control femora, while 2 pairs bore an equivalent load and 1 control specimen bore a greater load. This difference was not statistically significant with the number of specimens available ($p = 0.4$). In addition, SRS cement specimens settled less than controls. Even the 4th SRS specimen settled less than the control specimen. At lower load levels, specimens more often failed due to bone failures (excessive collapse). At high load levels, specimens more often failed due to implant failures (bending of the lag screw). Overall, most of the SRS cement specimens sustained more load than the control specimens, and the total amount of settling was significantly less in SRS cement specimens than in the controls: 3.0 (0.1–21) mm versus 30 (4.7–43) mm, respectively ($p = 0.03$).

Discussion

The sliding hip screw is assumed to create a more stable fracture construct by allowing impaction of the proximal fragment onto the distal fragment. However, union of intertrochanteric fractures is often achieved at the expense of shortening of the proximal femur, especially in unstable fractures. Mechanical studies have shown better stability of the fracture after fixation of large posteromedial fragments including the lesser trochanter (Chang et al. 1987, Apel et al. 1989).

Shortening of the proximal femur also reduces the length and moment arm of the hip abductor muscles, which lessens their efficiency (McGrory et al. 1995). Barnes (1984) analyzed functional outcomes in hip fracture patients and concluded that abductor muscle strength was positively associated with independence in ambulation.

The use of the sliding hip screw in intertrochanteric hip fractures leads to fracture impaction within days to weeks of fixation (Bendo et al. 1994). Movement of the fracture fragments in this unstable situation causes pain on ambulation which may increase morbidity and mortality. Bendo et al. (1994) found that 20/26 patients with moderate and severe shortening had considerable pain and poor function. Accoarding to Miller et al. (1978), early ambulation after surgery is important for survival of intertrochanteric hip fracture patients.

To address these clinical problems, polymethylmethacrylate bone cement has been used to increase the stability of intertrochanteric fractures. Lag screw augmentation in the femoral head (Witschger et al. 1991, Choueka et al. 1995, 1996, Claes et al. 1995) and augmentation of intertrochanteric fractures at the fracture site have also been studied (Harrington 1975, Muhr et al. 1979, Bartucci et al. 1985, Chow et al. 1987, Cheng et al. 1989). The early results were all reported to be good and few complications from the polymethylmethacrylate cement have occurred. Cheng et al. (1989) augmented the sliding hip screw by placing polymethylmethacrylate cement at the fracture site. However, after following the patients for 2–5 years, they reported late complications of up to 16%. They attributed this to the use of polymethylmethacrylate which is non-absorbable, exothermic, inhibits fracture healing, and may cause osteolysis and subsequent loosening.

Calcium phosphate cement has been used to increase the stability of several fractures in biomechanical and clinical studies (Constantz et al. 1995, Stankewich et al. 1996, Jupiter et al. 1997, Goodman et al. 1998, Yetkinler et al. 1999). Unlike polymethylmethacrylate, however, Norian SRS cement does not inhibit healing and it is replaced by the host bone while maintaining compressive strength in the region (Frankenburg et al. 1998). Elder et al. (2000) studied the augmentation of unstable intertrochanteric fractures with SRS cement in a similar biomechanical model. They found that load transfer on the medial side of the test femur was closer to the load levels seen in the intact femur as measured by strain gauges. However, in their experiment, specimens were loaded with only one body weight and for 1,000 cycles during cyclic loading. This inadequate loading method caused only 1.1 mm and 0.1 mm sliding of the lag screw in the control and experimental groups, respectively. In our study, we found sliding of the lag screw to be about 17 mm in control specimens. This clinically relevant sliding was achieved by 2.5 times body weight for 10,000 cycles. Sliding of the lag screw was less than 1 mm in the SRS cement-treated specimens. It was achieved by proper preparation and localization of the SRS cement, which provided a buttress or "neocalcar" on the medial aspect of the femur allowing for transfer of forces to the medial cortex (Elder et al. 2000).

Construct stiffness results indicated that, compared to the control specimens, SRS cement specimens were significantly stiffer than controls during the first 20 cycles. In the control group, stiffness gradually increased due to impaction of the bony fragments. Greater construct stiffness and stability are an indication that cement augmentation results in better load transmission and less movement of fragments.

In general, SRS cement-treated specimens failed at higher loads than control specimens. In the former specimens, we observed sliding of the hip screw with higher load levels, which suggests that the presence of cement did not inhibit the sliding mechanism, but simply prevented excessive impaction by improving the load transfer along the calcar femorale.

In our study, the results of vertical displacement were generally larger than those of sliding along the lag screw. This finding was surprising since we know that using a 135° plate vertical displacement should be roughly equal to sine 45° × sliding along the lag screw. We believe that the sliding hip screw results were more accurate, since measurements were taken directly from the sliding action of the lag screw. Vertical displacement results were obtained from the actuator of the MTS machine, which included sliding of the lag screw in the vertical direction, lag screw movement in the femoral head, and increased laxity of the specimen and the (whole) testing apparatus during repeated loading.

The initial clinical experience of using Norian SRS cement in hip fractures showed the safety of this product in intertrochanteric hip fracture patients; however, functional improvements were not fully evaluated since we had only a few cases and made continuous improvements in the surgical technique during the study (Goodman et al. 1998). These findings show clearly that functional outcomes may be improved further by better instrumentation and surgical techniques that optimize void preparation and filling with cement. The surgical technique used in this study is a further application of the method described in the preliminary clinical study.

One or more of the authors has received or will receive benefits for professional use as result of conducting the study.

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