# THE EFFECTS OF SILVER COATED EXTERNAL FIXATION PINS

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## ABSTRACT

**We performed a randomized controlled trial in order to assess the effect silver coating of an external fixator pin has on pin infection. The experimental silver coated pins (SC) were compared to control stainless steel (SS) pins. A clamp design monolateral fixator was used, and pins were randomized to clamp position to allow side-by-side comparisons of pins in a similar environment. Nineteen patients and 33 clamps were entered and completed the study. There were no significant differences between the two types of pins in the rate of pin tract infection, clinical appearances of the pin sites, bacteriology of the pin tracts, torque to remove the pins, or radiographic lucency around the pin. We concluded that with the numbers available in this study, there were no detectable differences between the performance of SC and SS pins.**

## INTRODUCTION

Pin tract infection is the most significant complication associated with the use of external fixation and has been reported to occur in up to 63% of pins.[1-15] This high infection rate has been attributed to the conduit that the pins provide between the skin and underlying soft tissue and bone. Complications related to pin tract infection include need for pin change or removal, failure of fracture healing, septic arthritis, and osteomyelitis. A method to decrease the rate of pin infection, therefore, has tremendous clinical appeal.

Silver, with its potent, broad-spectrum antibacterial activity, has had many clinical uses.[16] Silver-based creams for wound care and silver coatings for catheters have decreased infection rates with minimal systemic effects.[17,18] Silver coating has been advocated for use on external fixation pins to decrease infection rate, and a small, animal study has demonstrated decreased infection and motion at the pin-bone interface.[19] Although silver coated pins are now commercially available, no clinical study has been performed to confirm their efficacy.

We designed and performed this prospective, randomized study to test the hypothesis that silver-coated pins decrease the pin infection rate and improve the pin-bone interface characteristics when compared to traditional stainless steel pins.

## METHODS

The study was approved by the institutional review board at the University of Iowa. Between June, 1998 and June, 1999 we enrolled 22 patients treated with a monolateral clamp design external fixator for fractures of the tibia into this prospective, randomized study. We excluded patients treated with temporary frames, as well as patients with obvious sources of infection, pathologic fractures, and immunosuppression. Also excluded were wire fixators and metaphyseal T-clamps. Three initially enrolled patients were excluded from analysis because their external fixator was removed and their fracture was internally fixed within two weeks of injury. The remaining nineteen patients included fifteen men and four women. Eight patients were smokers and eleven were non-smokers. Three patients had prior fractures of the tibia, two patients had crush injuries, and one patient each had psoriasis, a transient popliteal artery occlusion, and foot compartment syndrome. No patient had diabetes. Nine fractures occurred in the right tibia, nine in the left tibia, and one patient had bilateral tibia fractures. The average age of the patients was 43 years (range 18-65 years). Open fractures occurred in seven patients. There were six fractures of the tibial shaft, twelve distal tibia fractures, and two tibial plateau fractures (Table 1).

Since silver does not leach either locally or systemically from a coated pin, we used each external fixator clamp as an individual experiment to minimize patient and mechanical variability. The proximal and distal clamps of the fixator were each eligible for inclusion in the study. In each clamp, one silver-coated and one stainless steel pin was placed. Pins were randomized within each fixator clamp to allow a side-by-side comparison of each experimental (SC) and control (SS) pin. Randomization for each clamp was by position in the clamp as "closest to" or "farthest away" from the fracture site. If a patient had one clamp eligible for participation in the study, the two study pins (SC & SS) were randomized between "closest to" and "farthest away" using a random number table. If a patient had two clamps eligible for study participation, the randomization table was utilized for the proximal clamp, and the pins in the distal clamp were placed opposite to those in the proximal clamp. For example, if SS was placed "closest to" the fracture site and SC was placed "farthest away" from the fracture site in the proximal clamp (as determined by the ran-

**TABLE 1**
**Classification of Fracture Types**

| Patient | Fracture Type (AO classification) |
|---|---|
| 1 | 41C3.3 |
| 2 | 43C3.2 |
| 3 | 41A2.1 |
| 4 - Left | 43C3.3 |
| 4 - Right | 43C3.3 |
| 5 | 43B3.2 |
| 6 | 42A2.3 |
| 7 | 43C3.2 |
| 8 | 43C2.1 |
| 9 | 42A2.3 |
| 10 | 43C3.2 |
| 11 | 43C3.2 |
| 12 | 43C1.1 |
| 13 | 42A3.3 |
| 14 | 41C3.2 |
| 15 | 43C3.2 |
| 16 | 43C1.3 |
| 17 | 42A2.3 |
| 18 | 43C2.1 |
| 19 | 42C1.1 |

domization table), then the SS pin was placed "farthest away" from the fracture site and the SC pin was placed "closest to" the fracture site in the distal clamp. This was done to maintain an appropriate balance of type of pin "closest to" and "farthest away" from the fracture site and to balance out the types of pins in metaphyseal and diaphyseal bone.

Standard pin insertion and external fixator placement technique was utilized. Bicortical purchase was obtained with each pin and was confirmed with fluoroscopy. An SC and SS pin were placed in each eligible clamp. The position of these pins was as far from each other in the clamp as possible to increase the rigidity of the construct, with the 1-5 position being preferred; however, the 1-4 and 2-5 positions were also accepted. The 1-3 and 3-5 position combinations were not acceptable for participation in the study since clustering of pins has been demonstrated to decrease the rigidity of the external fixation system.[20] Straight clamps and C-clamps for the hindfoot were eligible for placement of study pins.

Postoperative care was identical for each patient. Perioperative antibiotic treatment (intravenous Ancef) was given to all patients. Swab cleansing of the pin sites with normal saline two to three times a day followed by application of dry dressings was started on the second postoperative day and was continued until fixator removal. Hydrogen peroxide was not used because it increases the leaching rate of the silver approximately 1,000 fold.[21] All pin care was taught by the same clinical nurse. Each pin complication was treated at the discretion of the treating surgeon.

The performance of the SS and SC pins was measured in four ways: clinically, bacteriologically, radiographically, and mechanically. All clinical ratings were accomplished with use of a "1-10" visual (photo) analog scale that was developed prior to the study, (with "1" as the worst and "10" as the best pin site ever seen). Prior to commencement of the study, the investigators developed this standardized visual analog scale utilizing pin tract photos taken of non-study patients. A series of photos were chosen by the investigators from these pre-study photos and subsequently became the clinical guide for the study, i.e. the visual analog scale. A Likert Scale of 1-10 was used that assumed a continuous scale with equal intervals. Representative photos for each number on the scale were chosen for this guide. Issues addressed in the development of this visual scale included amount of inflammation, amount of erythema, and the amount and type of drainage.

The clinical performance of each pin was assessed at each visit, by at least one, and often two of the investigators (two staff surgeons, a nurse clinician and a resident). Data was recorded at the pre-determined observation times of 2 weeks, 4 weeks, 2 months, 3 months, time of fixator removal, and one month after fixator removal. In addition, photographs were used in a second way. Each of the study pin sites was photographed at the clinic visits (observation times) and these photos were subsequently used by all four investigators to rate each pin site. The aforementioned visual analog scale was used as a guide in rating the pin sites for both the direct clinical encounter and the subsequent photographic evaluation.

In addition to the Likert Scale, any pin tract complication that developed during treatment was classified into one of four types in order to directly compare our pin tract infection rate with other studies.[5-12] These four types included 1) those that resolved with oral or intravenous antibiotics, 2) those requiring pin change or removal, 3) those resulting in failure of the method and subsequent fixator removal, and 4) those resulting in osteomyelitis.

Bacteriologic data was obtained through gram stain and aerobic and anaerobic cultures of aseptically collected culture swab samples of each pin site at the time of fixator pin removal. This was accomplished by direct application of the culture swab tip into the tract left by each removed pin.

Radiographic evaluation of the pin sites was obtained at the time of fixator removal or one month after fixator removal. Periosteal reaction was documented as being absent or present. The area of radiographic lucency was measured for each pin tract by directly measuring the height and width of the pin tract and multiplying these two numbers. This was done in both the AP and lateral planes for each pin site.

**TABLE 2**
**Comparison between SC (experimental) and SS (control) Pins**

| | SC | SS |
|---|---|---|
| Percentage of pin infections | 30% | 21% |
| Average direct clinical score | 7.4 | 7.6 |
| Average indirect clinical score from photographs | 7.4 | 7.4 |
| Average removal torque | 4.8 | 5.9 |
| Average size of pin track lucency | 85 $mm^2$ | 64 $mm^2$ |

Mechanical integrity of the pin-bone interface was assessed at the time of pin removal. A torque wrench was mounted on each pin and the maximal torque required to begin removal of each pin was recorded.

Fracture type, clamp type, patient comorbidities, length of fixator placement, time to healing, time to weight-bearing, position in clamp, patient age, and patient sex were examined independently to determine each one's correlation with pin performance.

Statistically, the clinical and photographic ratings for SC and SS pins were compared using a mixed model, repeated measures analysis of variance. This model designated the pin type (SC vs. SS) as the fixed effect, and rater, patient, and clamp as the random effects. A p-value $<.05$ was considered significant when comparing the pin type mean scores.

**TABLE 3**
**Number of Pins Containing Each Species of Bacteriological Growth**

| Bacteria | No. of Pins |
|---|---|
| No growth | 6 |
| S. aureus | 28 |
| Coag Neg Staph | 20 |
| Mixed Flora | 14 |
| Gram positive rods | 7 |
| Beta Hemolytic Strep | 2 |
| Klebsiella/Enterobacter | 2 |
| Micrococcus | 2 |
| Pseudomonas | 1 |

**TABLE 4**
**Differences in Bacterial Growth between Paired Pins**

| Bacterial Differences | Less significant bacterial growth at SC pins | Less significant bacterial growth at SS pins |
|---|---|---|
| No difference (12) | | |
| Minor difference (5) | 2 | 3 |
| Moderate difference (8) | 8 | 0 |
| Major difference (4) | 2 | 2 |
| Cultures not taken (1) | | |

No difference—exact same amount and type of bacterial growth at each pin site within a clamp.
Minor difference—type of bacteria was the same; however, a smaller amount of bacteria was grown.
Moderate difference—both grew bacteria, but amounts and types varied.
Major difference—no bacterial growth at one pin site compared to presence of bacterial growth at other pin site.

## RESULTS

Average length of fixator placement was 16.7 weeks (range 8-31 weeks), and average time to weight bearing was 9.2 weeks (0 - 21 weeks). Eighteen of the 20 fractures healed, and average time to healing was 22.3 weeks (12 - 45 weeks). Four patients required intravenous and/or oral antibiotics to resolve infection related to their open fracture wound and not their pin sites. One patient required intravenous and oral antibiotics to treat a separate distal radius fracture external fixator pin site infection.

The major comparisons between the two pin types are displayed in Table 2. No difference between number of pin tract infections occurred; infections were seen in ten (30%) SC pins and seven (21%) SS pins. All ten SC pin tract infections resolved with oral antibiotics; whereas, five of the seven SS pin tract infections resolved with oral antibiotics. The remaining two SS pin tract infections were treated with intravenous antibiotics and resolved. No fixator pin infection required pin change, pin removal, or fixator removal. No pin tract infection led to the development of osteomyelitis.

No difference occurred between the average direct clinical score for SC pins (7.4) and that for SS pins (7.6). Similarly, no difference occurred between the average indirect photo score for SC pins (7.4) and that for SS pins (7.4).

A spectrum of bacteria was cultured; however, within each clamp little variation occurred (Tables 3 and 4). Twelve of the 33 clamps revealed no difference between the SC and SS pins in either the bacteria type or amount grown from the pin tract site. Five clamps revealed no difference in the type of bacteria grown, but a small difference in the amount of bacteria grown, i.e. few Staph. aureus grew from one pin site and rare Staph. aureus from the other pin site. Two clamps within this group grew a smaller amount of the same bacteria in the SC pin tract, and three clamps revealed a smaller amount of growth at the SS pin tract.

A major difference occurred within four clamps, with two SC and two SS pin tracts exhibiting no growth while their counterpart pin tract had definite bacterial growth with a variety of organisms. The remaining eleven clamps revealed minor to moderate differences in flora, i.e. varied in amounts of two bacteria grown, or one pin tract grew two bacteria while the other grew one. Eight clamps within this group had either less growth or fewer numbers of types of bacteria at the SC pin tract compared to the SS tract, and three were equivocal. One clamp did not have cultures taken.

The average torque required to remove an SC pin was 4.8 Nm, and the average torque required to remove an SS pin was 5.9 Nm. This difference was not statistically significant. Eight clamps revealed a large difference (7) between the torque required to remove the two pins, with three being more secure within the SC pin tract, and five being more secure within the SS pin tract. Twenty-three clamps revealed minimal or no differences in removal torque between the two pin types.

Radiographic pin tract lucency averaged 85 $mm^2$ for SC pins and 64 $mm^2$ for SS pins and was not significantly different. The amount of radiographic lucency and the presence of periosteal reaction did not have any significant effect on the SC or SS clinical ratings. The presence of increased lucency did not correlate with need for oral or intravenous antibiotics (i.e. pin tract infection). Increased lucency significantly correlated with decreased torque required to remove pins.

The following variables had no statistically significant effect on the rating for the SC versus SS pin: patient sex, open versus closed fracture, smoking status, clamp position, time spent in fixator, time to healing, and time to weight-bearing. Increasing patient age was associated with an increase in rating for both SC and SS pins for both the clinical and photographic data.

There were 544 matched clinical and photographic pin ratings corresponding to 270 clamps with both SC and SS pins being rated. No statistical difference was noted between the clinical and photographic ratings for the same pin, i.e. the photographic rating was representative of the clinical rating.

## DISCUSSION

The most significant complication with external fixators is pin tract infection, which has been reported in up to 63% of patients.[1-15] At our own facility, pin tract complications have been reported in various studies at rates ranging from 19% to 63% of patients.[5-12]

Silver-coating external fixation pins has been proposed as one means to decrease the pin infection rate and subsequent pin tract complications. Bacteria colonize the surface of the pin and form a resistant biofilm of polysaccharides that serves as a barrier to antibiotics and the body's immune system. This film therefore serves as a conduit for bacteria to migrate from the surface of the skin via the pin to the bone. The silver coating provides an antimicrobial layer on the pin that prevents bacterial colonization and pin tract infections.[22]

The potential effectiveness of silver-coating external fixator pins has been supported by one animal study. Collinge, et al., demonstrated a decrease in infection rate (62% vs. 84%) after direct inoculation of pin tracts with *Staph. aureus* to 36 SC and 12 SS pins placed in the iliac crest of six sheep. The pin sites were examined for motion, inflammation, and bacterial growth at 2 1/2 weeks. Scanning electron microscopy revealed a decreased level of glycocalyx-protected colonization on the surface of the SC pins. The authors postulated that bacterial adherence to the surface of the SC pins was prevented by inhibition of the formation of a bacterial glycocalyx membrane on the pin itself, rather than silver leaching from the pins into the local environment.[19]

To determine if SC pins prevent pin infection in patients, we developed a study design that compared SC and SS pins side-by-side in a similar environment, i.e. the same clamp and same patient. This side-by-side comparison of the two pins in a similar environment eliminated some of the problems associated with comparative analysis of pin performance, such as differing mechanical and bacteriological environments in different patients. This design was justified since silver does not leach from the pin and, therefore, cannot affect a neighboring pin. The zone of inhibition of bacterial growth *(E. coli, P. aeruginosa, S. epi)*, has been found to be 4-6 mm around silver pellets and 0 mm around SC pins, eliminating any possibility of a local zone of inhibition.[21-23] Leaching rates have been studied to determine if systemic effects of silver from an SC pin would affect another pin's performance within the same patient and have been measured at 1.92 1.42 $mg/m^2 \cdot week$. At this leaching rate, it would take 50 years for all of the silver coating to come off. However, treatment with hydrogen peroxide would cause the leaching rate to increase 1,000 fold, and was prohibited in this study.[21,23] This provides strong evidence that the antibacterial effect of the SC pins would not affect the control SS pins within the same clamp or same patient.

Our study results provide strong evidence that there is no difference between SC and SS pin performance overall. Clinically, both the direct clinical and indirect photographic scores revealed no differences between the performance of the SC and SS pins. Bacterial growth and radiographic appearance were similar between both groups. There was no difference in the mechanical performance, except for a small trend towards SC being less mechanically sound.

This study does not preclude the possibility of a difference in severe pin infection between the two types of pins because of the small number of patients entered and the relative rarity of these occurrences. A very large clinical trial would be required to detect this difference or exclude its absence. With the number of clamps we entered (33), we had a 90% power to detect a difference of 13% (a 1.0 difference on the Likert 1-10 scale) in the clinical grading if this difference had existed. Most assessments of clinical pin performance are made by visual

observation, which was the main outcome variable that we used in this study.

Although we found no statistically significant differences between the bacterial growth of the SC and SS pins, there was a trend for SC pins to have less bacterial growth. Twelve out of the thirty-two clamps cultured showed less significant growth at the SC pins compared to five clamps showing less significant growth at the SS pins. Additionally, no SC pins required intravenous antibiotics for treatment of infection; whereas, two SS pins did require intravenous antibiotics. Quantitative bacterial cultures taken at multiple times during treatment might have yielded more discerning results. Our clinically based study results differed from Collinge's animal-based laboratory experiment results. The biggest difference between the two studies occurred with the study design. A direct inoculation of bacteria was performed in Collinge's study, which is clearly different from the clinical setting in our study where pins were kept clean. It is possible that a direct inoculation of one type of bacteria would alter the development of the natural flora for both an SC and SS pin, thus altering the overall results of what would occur clinically. Other potential reasons for the differences between the two studies could have occurred secondary to fixator application technique, postoperative care, differences in control of environment, use of antibiotics, amount of time in fixator, and location of pins in metaphyseal versus diaphyseal bone. The data from our study indicates that factors other than local antibacterial coatings may have a bigger effect on pin performance. These include the mechanical environment of the pin, local bacterial flora, loading characteristics of the frame-bone composite, and perhaps other incompletely understood factors.

We used a novel method for clinical evaluation of pin site performance with the use of a Likert 1-10 photo scale, which allowed us to use a more continuous measure of pin performance rather than arbitrary categorical definitions of a pin classification. We did not assign any definitions to any number along the 1-10 scale guide, which enabled the investigators to utilize their own experience to rate a pin anywhere along the scale they felt was appropriate. This eliminated problems with failures of understanding or disagreements with categorizations, and produced a high inter-rater intra-class correlation (ICC) of .70 for these clinical ratings using the photo scale guide. This novel approach potentially provides a reliable and reproducible method of evaluating pin sites that may be used in future multi-center studies; however, further investigation is warranted.

Early in this study, we recognized that all four investigators would not be able to be present at every clinic visit, which introduced the possibility of variable assessments by different observers. To eliminate this potential problem, we augmented the direct clinical evaluation of a pin site by one or two investigators with photographs taken at the time of the clinic visit. These photos were subsequently evaluated and rated using the same 1-10 photo scale guide used in clinic by all four investigators. We compared the inter-observer reliability of the direct clinical assessment with the subsequent indirect photographic assessments, and found the observations to be reliable (clinical inter-rater ICC = .70, photo inter-rater ICC = .65).

In summary, we performed a prospective, randomized clinical trial testing the hypothesis that SC pins decrease clinical pin infection rate and improve mechanical integrity at the pin bone interface when compared to SS pins. In this study, each clamp offered a direct side-by-side comparison of an SC and SS pin existing in a similar environment, and a novel method of continuously ranking clinical pin infection was used. We found no statistically significant clinical, bacteriologic, mechanical, or radiographic differences between these two pin types. However, the small numbers of enrolled patients precludes us from eliminating the possibility of a difference in severe clinical infection.

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