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Surgical Implant Generation Network (SIGN) implant follow-up: Assessment of Squat and Smile and fracture healing

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Abstract

Objectives: The aims of this study were to evaluate the reliability, sensitivity, and specificity of the Squat and Smile (S&S) test, a clinical photographic follow-up, in determination of fracture healing and to assess the extent of continued fracture healing beyond one-year post-operation.

Design: Retrospective review of the SIGN database.

Setting: The S&S test is utilized in low-resource settings where the SIGN intramedullary nail is used due to unavailability of intraoperative fluoroscopy.

Patients/Participants: 150 patients undergoing fracture fixation utilizing SIGN intramedullary nails with data available at least one year (9–16 months) post-surgery.

Intervention: None

Main Outcome Measurements: We extracted clinical data and calculated scores for the S&S photographs and radiographs at the one-year (9–16 months post-operative) follow-up and last follow-up available beyond that. We analyzed the sensitivity of S&S scoring, using radiograph assessment as the gold standard for fracture union.

Results: Of the 126 patients analyzed, 21% were found to have incomplete healing at one year, whereas 17% of the 64 patients with further follow-up past one year had incomplete healing. We found that both S&S and radiographic fracture healing scores had good inter-rater reliability ($k=0.73$ – 0.78 for S&S and 0.94 for radiographs). The S&S test had poor sensitivity (0.11) and specificity (0.85) in determining fracture healing at the one-year follow-up.

Conclusions: The S&S scoring method was reliable but neither sensitive nor specific for determining fracture healing at one year. Fractures deemed incompletely healed by radiographic evaluation at one year following SIGN implant may still have the potential to heal over time.

Introduction

Musculoskeletal trauma constitutes an enormous proportion of burden of disease in low resource countries.^{1–4} While this orthopaedic trauma disproportionately affects low- and

middle-income countries (LMICs), many of these countries do not currently have the imaging capacity, surgical implants, and necessary hospital equipment to perform surgical fixation.(1–3) In order to improve access to fracture care worldwide, the Surgical Implant Generation Network (SIGN) created intramedullary nails that do not require intraoperative fluoroscopy.(4–6) The implants are donated to facilities in LMICs with the stipulation that, for each implant utilized, follow-up with photographic evidence of a functional assessment of the patient's ability to squat must be uploaded to the SIGN database.

The Squat and Smile (S&S) test was developed to be utilized as a surrogate for assessing fracture healing in remote locations with limited radiographic imaging resources.(5, 7) Wu et al. demonstrated that depth of squat and use of support during the S&S can correlate with both EQ-5D index score and need for reoperation.(7) While surgeons utilize the S&S to help determine if a patient has failed to progress to union and requires additional surgery, no study has assessed the reliability of the S&S nor its ability to reflect the extent of fracture healing and predict further healing.

Even in well-resourced countries with access to standard post-operative imaging, no uniform assessment for determination of union exists. Many clinicians utilize a mixture of radiographic and clinical findings, including pain level and ability to bear weight, along with subjective time cut-offs as evidence for healing.(8) One method, the Radiographic Union Scale for Tibia fractures (RUST), has been used for assessment of fracture healing after intramedullary nailing for tibia and femur fractures.(8–10) The current study primarily aimed to assess the sensitivity and specificity of the S&S for predicting fracture healing, using the RUST score as the gold standard comparator. The secondary goals of this study were to assess the reliability of grading the S&S photographs and to assess the extent to which fractures may continue to heal beyond one year of follow-up.

Materials and Methods

Study Design

This study was a retrospective cohort study of patients having undergone intramedullary nailing of the tibia or femur with the SIGN intramedullary nail. Utilizing the SIGN database, 150 patients who underwent SIGN intramedullary nail treatment for a femur or tibia fracture between January 2010 and July 2015 and who had a recorded post-operative follow-up of at least 9 months were randomly selected for retrospective review. To be included in the analysis, patients must have had only one fractured long bone (tibia or femur), must have had both S&S and radiograph (anteriorposterior and lateral) results recorded at the one-year (9 – 16 months) follow-up, and must have not needed revision surgery for non-union before their one year follow-up. Of the 150 patients randomly selected, 128 met inclusion criteria. If patients received surgical intervention for non-union between initial surgery and the follow-up being evaluated, they were considered to have failure to unite and were included in initial analysis of percentage of patients not fully healed, but they were removed from further S&S and radiographic assessment.

Data Collection Procedures

We created an individual entry for each included patient in a REDCap database for demographic data, S&S assessment, and radiographic assessment. Study personnel assessed both S&S photographs and radiographs at one year of follow-up, which we defined as the follow-up visit closest to 12 months within 9-to-16 months following surgery. We also assessed radiographs from the last available follow-up visit for patients with additional follow-up after the one-year time point.

For assessment of the S&S, we graded photographs from the one-year follow-up. The grading was conducted via visual assessment of the photograph. The assessment included three questions: (1) if the subject was smiling (yes, no, unsure), (2) if the subject's squat broke 90° of knee flexion, and (3) if the subject required an assistive device (i.e., holding onto an object such as a cane, crutch, chair, or person for assistance in squatting). As the majority of smile ratings were unsure or discordant between readers, we decided not to utilize them in assigning a grade. We then assigned grades on a 0 to 2 scale. If the subject's squat did not break 90° flexion, the score was 0. If the subject's squat did break 90° flexion but an assistive device was used, the score was 1. If the subject's squat did break 90° flexion and an assistive device was not used, the score was 2. Two assessors conducted the photographic evaluation, and one assessor ("Reader 1") performed the grading twice, six months apart. These data were used to evaluate intra- and inter-reader reliability.

Study personnel also assessed radiographs of each subject's fractured bone at the one-year follow-up, as well as at the last follow-up for those with available radiographs. Two surgeons assessed each radiograph for visibility of fracture line and for presence or absence of callus anteriorly, posteriorly, medially, and laterally. We calculated RUST scores from these assessments. Each of these surfaces was rated 1 to 3 with 1 = fracture line visible and no callus present, 2 = fracture line visible but callus present, 3 = no fracture line visible. The four scores were summed to yield a RUST score with a possible range of 4 to 12.(9) We evaluated inter-reader reliability for the assessments made by these two surgeons. After reliability testing, the assessors reviewed and resolved any discrepancies in scores.

Data Analysis

We used weighted kappa analysis to assess inter-reader and intra-reader reliability in the S&S assessment. We conducted a pairwise comparison of three readings: Reader 1's first reading (Reader 1a) with Reader 2's reading; Reader 1's second reading (Reader 1b) with Reader 2's reading; and Reader 1's first reading (Reader 1a) with Reader 1's second reading (Reader 1b). We also used weighted kappa analysis to assess inter-reader reliability in the radiographic assessment of presence of fracture line and callus.

Functional scores from the S&S were assessed and dichotomized, with a score of 2 classified as normal function and <2 classified as abnormal function. The radiographic score was dichotomized as healed (RUST score of ≥9) and not healed (RUST score of <9).(8) We analyzed the sensitivity and specificity of the S&S score for detecting fractures that are not healed, using RUST scores as the gold standard. We defined sensitivity as (number of participants with abnormal S&S and not healed RUST score / total number not healed based

on RUST score) and specificity as (number of participants with normal S&S and healed based on RUST score / total number healed on RUST score) and provided exact confidence intervals. Patients included in these assessments were only those that had not required surgery for non-union between the original surgery and the one-year follow-up date assessed. In addition, we compared RUST scores between the one-year follow-up and last follow-up available in order to evaluate progression of healing for patients with follow-up beyond one year.

Power analysis prior to the study demonstrated that a sample of 100 patients was necessary to yield an acceptable level of precision around the estimates of sensitivity and specificity. In order to ensure that 100 patients were included, we randomly selected 150 patients from the SIGN database.

Results

A review of 150 patients in the SIGN database resulted in 128 patients meeting inclusion criteria for the study. The cohort was predominantly from Asia and Africa, had a mean age of 31, and was 81% male (Table 1). Included patients had a nearly even mix of tibia or femur fractures, 84% of which were closed injuries, and other injuries, including head and abdominal injuries, were present in 9% of the cohort. The cohort was followed for a median length of 1.3 years, with a mean length of follow-up of 1.7 years.

SIGN Outcomes

Of the 128 patients included, 66 had follow-up records past the one-year follow-up necessary for inclusion. Painless weight-bearing was present in 87% of the total cohort at one-year follow-up and in 91% of patients with the final follow-up data (Table 2). Complications included infection (7 patients) and need for further surgery for non-union (7 patients). An additional 23 patients elected to have implant removal. Of the 7 patients requiring further surgery, 2 had the procedure before their one-year follow-up and 5 before their final follow-up. The 2 patients who had surgery for non-union before the one-year follow-up were removed from S&S and radiographic analysis. Consequently, the number of subjects included in the one year analysis is 126. Seventy-nine percent and 83% of patients in this analytic sample demonstrated full fracture healing, defined by a RUST score 9, at one-year follow-up and final follow-up, respectively. Further analysis of potential factors contributing to failure to unite demonstrated that femur fractures were statistically significantly more likely than tibia fractures to not fully heal at one-year post-operation (34.8% vs 5.3% respectively, $p<0.05$).

Of the 64 patients with follow-up longer than one year and no intervening surgery for non-union, an assessment of fracture healing between the one-year follow-up visit and the last available follow-up demonstrated healing progression (Table 3). Five of the 11 patients who at one year had a RUST score <9 and had follow-up available beyond one year, indicating that fractures were not fully healed, had a RUST score 9 at their last follow-up.

Reliability of Squat and Smile Test Assessment and Radiograph RUST Scores

The S&S scoring system, as described in Materials & Methods, had good intra-reader reliability, $k=0.75$, and good inter-rater reliability, $k=0.73-0.78$ (Table 4a).

126 radiograph images were assessed in the AP and lateral views by the two reviewers at one-year follow-up, and 64 radiographs were assessed at final follow-up. RUST scoring of the radiographs from the one-year and final follow-up had high inter-rater reliability ($k=0.94$) (Table 4b).

Sensitivity Analysis of S&S Test

At the one-year follow-up, the S&S was found to have a sensitivity of 11% (95% CI 2–29%) and specificity of 85% (95% CI 76–91%), as compared to RUST scores as the gold standard for determining union. For the subset of 64 patients with final follow-up data, the S&S was found to have a sensitivity of 17% (95% CI 0.4–64%) and a specificity of 91% (95% CI 81–97%). Additional details are included in Tables 5–6.

Discussion

This retrospective review of patients with fracture fixation utilizing SIGN intramedullary implants demonstrates that the S&S test is reliable but is neither sensitive nor specific in determining fracture healing.

Our reliability findings are similar to the results of Wu et al.(7), who demonstrated that squat depth and support needed were assessed reliably by the S&S. Our findings also corroborate Wu et al.'s finding that facial expression in the S&S was not a reliable measure of fracture healing.(7) These authors additionally correlated squat depth and need for support with participants' EQ-5D scores and need for reoperation.(7)

While the S&S test has been shown to be reliable, we find that it has both a low sensitivity and specificity (11% and 85%, respectively, at one-year follow-up), and thus does not describe radiographic healing. Further data, including clinical findings such as infection, pain, and ability to bear weight and/or radiographic findings, would be necessary for making clinical decisions regarding the status of fracture healing.

Our radiographic assessment of femoral and tibial fractures treated with SIGN intramedullary nails demonstrates reliable scoring with the RUST method. A standardized assessment of fracture healing is essential to enable comparison of results across trials, as many previous studies have relied on a variety of clinical findings to differentiate union, delayed union, and non-union. Prior studies have demonstrated the reliability of the RUST score, but these studies have not included SIGN nail implants.(8–10) Our data further demonstrate the ability of RUST scoring to be reliable and applicable to fractures treated with other modalities.

Using a RUST score threshold 9 for union, we found that 21% and 17% percent of patients had not healed by the one-year and final follow-up points, respectively. In addition, complications included infection (5%), and repeated surgery for failure of union (5%). A

recent literature review of SIGN intramedullary nail placement demonstrates a paucity of long-term studies to define outcomes, as the average follow-up for the included studies was 6 months (ranging from 1–22 months).(2) Prior studies of SIGN intramedullary nails for long bone fractures have found union, whether defined clinically or radiographically, in 69–99% of patients.(2, 11–22) Complications found by prior studies have included delayed union in 4–34% of patients, and infection in 1–11%, implant failure in 3–4%.(2, 11–22) Despite their use of heterogeneous outcome measurements, these SIGN nail results have been found to be comparable to those from other studies that evaluated more traditional cannulated interlocking intramedullary nails.(2, 12)

There are several limitations of the current study. The SIGN database we used has the potential for lack of input standardization and quality control, given that data is entered by surgeons around the world. Surgeons inputting data from a breadth of countries may interpret or enter data differently, leading to potential inaccuracies. In addition, the variable quality of photographs and radiographs may have led to potentially inaccurate assessments by our reviewers. However, despite varying quality of the photographs, our study demonstrated good reliability of assessment of the photographs and radiographs.

Importantly, we only reviewed patients from the SIGN database with post-operative follow-up of at least one year. This constraint may have created a bias wherein patients who were asymptomatic and functioning well did not return for a one-year follow-up, whereas symptomatic or functionally impaired patients were more likely to return to evaluation. The latter group would be more likely to have incompletely healed fractures. Lastly, the study utilized a S&S scoring methodology created during a pilot study we performed, in which only squat depth and use of assistive device were graded, excluding assessment of facial expression. However, the reliability resulting from our developed S&S scoring method is supported by recently published results from Wu et al.(7)

The significance of the S&S test may lie outside of clinical assessment of fracture healing. As follow-up visits and documentation are required to receive free SIGN nails, physicians in resource-limited countries have begun following patients post-operatively and maintaining documentation, neither of which were previously traditional practices. Such lack of follow-up in low resource countries initially led the SIGN program to implement these guidelines, which have now resulted in a global trauma database.(23) The policy of linking provision of implants to mandatory follow-up assessment encourages continuous quality-improvement. While it is conceivable that the S&S is a good marker for functional limitation and pain following fracture repair, our data suggest it is not a valid proxy for radiographic healing.

The S&S test, which is required at follow-up for patients who have received the SIGN intramedullary nail procedure for surgical fixation of their long bone fractures, is reliable under our scoring method. However, it is neither a sensitive nor specific test for determining fracture healing and thus should not be used in isolation when making decisions about clinical management. Additional benefits of the increased follow-up, documentation, and surgeon assessment inherent in the S&S test will require further assessment.

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Table 1.

Cohort characteristics

Mean age, years (SD)	31 (14.66)
Sex	
Female	24 (18.75)
Male	104 (81.25)
Geographic region	
Asia	99 (77.34)
Africa	20 (15.63)
South America	2 (1.56)
Central America	1 (0.78)
Caribbean	6 (4.69)
Bone	
Femur	71 (55.47)
Tibia	57 (44.53)
Open/Closed	
Open	21 (16.41)
Closed	107 (83.59)
Antibiotics given	
Yes	86 (67.19)
No	42 (32.81)
Other injuries present (%)	8.59
Median time to surgery (days)	7.5
Median length of follow-up (years)	1.25

Table 2.

Outcomes of Surgical Implant Generation Network (SIGN) nail

Painless weight-bearing	
1-year follow-up (<i>n</i> = 128)	
Yes	111 (86.72)
No	17 (13.28)
Final follow-up available (<i>n</i> = 66)	
Yes	60 (90.91)
No	6 (9.09)
Healed (Healing determined as RUST score >=9)	
12-month follow-up (<i>n</i> = 126)	
Healed	99 (78.57)
Not fully healed	27 (21.43)
Last follow-up available (<i>n</i> = 64)	
Healed	53 (82.81)
Not fully healed	11 (17.19)
Complications	
Infection	
Yes	7 (5.47)
No	121 (94.53)
Surgical intervention for non-union	
Yes	7 (5.47)
No	121 (94.53)

Table 3.

Progression of healing between 12-month follow-up and last follow-up

12-month follow-up x-ray score (Frequency, percent)	Last follow-up x-ray score (Frequency, percent)					
	RUST 4	RUST 5–6	RUST 7–8	RUST 9–11	RUST 12	Total
RUST 4	2 3.13	1 1.56	0 0.00	1 1.56	0 0.00	4 6.25
RUST 5–6	0 0.00	1 1.56	0 0.00	0 0.00	0 0.00	1 1.56
RUST 7–8	0 0.00	0 0.00	2 3.13	0 0.00	4 6.25	6 9.38
RUST 9–11	0 0.00	0 0.00	0 0.00	8 12.50	15 23.44	23 35.94
RUST 12	0 0.00	0 0.00	0 0.00	0 0.00	30 46.88	30 46.88
Total	2 3.13	2 3.13	2 3.13	9 14.06	49 76.56	64 100.00

RUST = Radiographic Union Scale for Tibia.

Table 4a.

Inter-reader and intra-reader reliability for symptomatic assessment variables: Weighted kappa (95% confidence interval; percent agreement)

Variable	Comparison	Rater 1a	Rater 1b	Rater 2
Squat and Smile	Rater 1a	1.00 (1,1; 100%)	0.75 (0.60, 0.89; 90%)	0.78 (0.65, 0.92; 92%)
	Rater 1b	-	1.00 (1,1; 100%)	0.73 (0.59, 0.88; 90%)
	Rater 2	-	-	1 (1,1; 100%)

Table 4b.

Inter-reader reliability for radiographic assessment variables

Variable	Weighted kappa	95% Confidence Interval	Percent agreement
Baseline	0.94	0.90, 0.98	89%
Follow-up	0.93	0.84, 1	95%

Table 5.

X-ray score by Squat and Smile score at 12-month follow-up

Squat and Smile Score (Frequency, percent)	X-ray score (Frequency, percent)		
	Not healed	Healed	Total
Abnormal	3 2.38	15 11.90	18 14.29
Normal	24 19.05	84 66.67	108 85.71
Total	27 21.43	99 78.57	126 100.00

Normal Squat and Smile score = breaking 90° flexion without assistive device; abnormal = not breaking 90° flexion or breaking 90° with an assistive device. Healed X-ray score = RUST score ≥ 9; not healed = RUST score < 9. RUST = Radiographic Union Scale for Tibia.

Table 6.

X-ray score by Squat and Smile score at last follow-up

Squat and Smile Score (Frequency, percent of total)	X-ray score (Frequency, percent of total)		
	Not healed	Healed	Total
Abnormal	1 1.56	5 7.81	6 9.38
Normal	5 7.81	53 82.81	58 90.63
Total	6 9.38	58 90.63	64 100.00

Normal Squat and Smile score = breaking 90° flexion without assistive device; abnormal = not breaking 90° flexion or breaking 90° with an assistive device. Healed X-ray score = RUST score ≥ 9; not healed = RUST score < 9. RUST = Radiographic Union Scale for Tibia.