Reliability of Radiographic Union Scale for Tibial Fractures (RUST) when used in determining Bone Healing in Femoral Fractures treated with Interlocked Intramedullary SIGN Nailing

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***Abstract*:** Non-union is still one of the most common complications in orthopaedic practice. One major problem with the diagnostic management of fracture non-union is the definition or the criteria of non-union. The objective of this study is to determine the reliability of the Radiographic Union Scale for Tibial Fractures (RUST) score when used to assess bone healing in patients with femoral fractures treated with intramedullary SIGN nailing. Six observers were employed randomly, namely, three fellow orthopaedic consultants from a pool of six consultants and three orthopaedic residents in a tertiary government hospital, to assess the femur radiographs treated with intramedullary SIGN nailing using the RUST. Two sets of radiographs in the Anteroposterior (AP) and Lateral Views for each follow-up period, One hundred five (105) sets in total, were randomly selected and assigned a specific number from the pool of one hundred and forty-four (144) available radiographs. These radiographs were initially assessed within the 3rd week of June 2018 in a specific order and another assessment was done on the 3rd week of July 2018. Assessments of one hundred five (105) radiographs totaled into an ICC of 0.94 *(0.92-0.94)* which can be interpreted as "excellent" according to Fleiss' (1986) standards and as "acceptable as clinical measure" according to Portney et. al (2009). Results of this study showed that the use of RUST can also be used clinically as a scoring tool for assessment of bone healing in femoral shaft fractures treated with intramedullary nailing with high reliability and reproducibility

Index Terms- RUST Score, Interobserver reliability, Intraobserver reliability, femoral fractures, intramedullary nailing, SIGN nails, Reliability

I. INTRODUCTION

Non-union is still one of the most common complications in orthopaedic practice. Its treatment curtails various options or strategies that are still largely controversial. However, one major problem with the diagnostic management of fracture non-union is the definition or the criteria of non-union. Various researches have been proposed for the radiographic union scoring for several bones, namely the hip or proximal femur and the tibia with the Radiographic Union Score for Hip Fractures (RUSH) and the Radiographic Union score for Tibial Fractures (RUST), respectively. Despite the availability of these radiographic union scoring systems, majority of the other bones still do not have an existing radiographic union scoring system for them to be utilized and thus standardize the language of union and non-union for each bone.

Two types of fracture union assessment has been formulated from the University of Toronto and McMaster University namely the RUST and RUSH (Radiographic Union Score for Tibial Fractures and Radiographic Union Score for Tibial Fractures) and was generated to increase the reliability of fracture assessment between observers but still currently needs further verification since there is no gold standard scoring system established for these types of fractures [1]. The RUST has been used mostly in assessment of tibial shaft fractures and sparsely used in determining fracture healing in femoral shaft fractures even though they are similarly long bones of the lower extremities.

With advances in trauma patient management, determination of whether fracture has united or not remains subjective. Precise assessment is needed to make a universal language for determination union or nonunion. In actual practice, fracture-healing is usually assessed by factors such as pain on bearing weight, or palpation of the fracture area in association with radiographic images [2]

II. REVIEW OF LITERATURE

A. Intramedullary Nailing of the femur

The gold standard for the treatment for femoral shaft fractures is Closed Antegrade Interlocked Intramedullary Nailing. Antegrade femoral nailing can be one of the most predictable procedures in orthopedic traumatology. It is the most common treatment for femoral shaft fractures in adults, and virtually all orthopedic surgeons have had some exposure and experience with the techniques necessary to successfully perform a femoral nailing [3]. The most commonly used implants for femoral shaft fracture fixation today are interlocking intramedullary nails—through which transverse or oblique transfixing screws can be inserted to control the major proximal

and distal fragments [1]. Currently, statically locked femoral nailing with limited reaming is the standard of care [4].

B. Fracture Healing

When motion occurs within certain limits at a fracture site, fracture callus progressively stabilizes the bone fragments, and remodeling of the fracture callus eventually produces lamellar bone. When the fracture surfaces are rigidly held in contact, fracture healing can occur without grossly visible callus in either cancellous or cortical bone. Some surgeons refer to this type of fracture healing as primary bone healing, indicating that it occurs without the formation and replacement of visible fracture callus. In most fractures that are rigidly stabilized with the bone ends directly apposed, the bone ends are in contact in some regions of the fracture line and other areas where there are small gaps. There are three stages in bone healing. Namely, they are, 1) Inflammation, 2) Repair or Callus Formation and 3) Remodeling [5].

C. Nonunion

Nonunion occurs when a fracture has failed to heal in the expected time and is not likely to heal without new intervention. Delayed union occurs when a fracture has not completely healed in the time expected, but still has the potential to heal without further intervention. Establishment of a nonunion can also be defined based on a lack of complete bone healing in a specified time frame, commonly 6 to 8 months, but this is arbitrary [3]. Nonunion, while often obvious in retrospect, is often difficult to define and diagnose in real time. For example, in the tibia the time for a metaphyseal fracture to be considered nonunited will be different than for a fracture in the diaphysis. Both clinical and radiographic findings are necessary for the diagnosis of nonunion. However, such signs may be elusive as primary and secondary healing may be occurring simultaneously. On a cellular level, nonunion occurs when there is cessation of a reparative process antecedent to bony union.

D. Radiographic Union Score for Tibial Fractures (RUST)

In a study by Whelan et.al. (2010) they assessed the Radiographic Union Score for Tibial fractures (RUST). They reviewed 45 sets of tibial shaft fractures treated with intramedullary fixation. Seven orthopedic reviewers independently scored bony union using RUST. Intraclass correlation coefficients (ICC) with 95% confidence intervals (CI) measured agreement. Overall agreement was substantial (ICC, 0.86; 95% CI, 0.79-0.91). There was improved reliability among traumatologists and overall intraobserver reliability was also substantial (ICC, 0.88; 95% CI, 0.80-0.96). However, since there is currently no gold standard to compare the RUST to, they concluded that further research is required to fully validate this scoring system as a clinical tool. The RUST is based on callus formation and visibility of fracture line at 4 cortices observed on AP and lateral radiographs. Minimum score of 4 indicates no healing and maximum of 12 indicates a healed fracture [6].

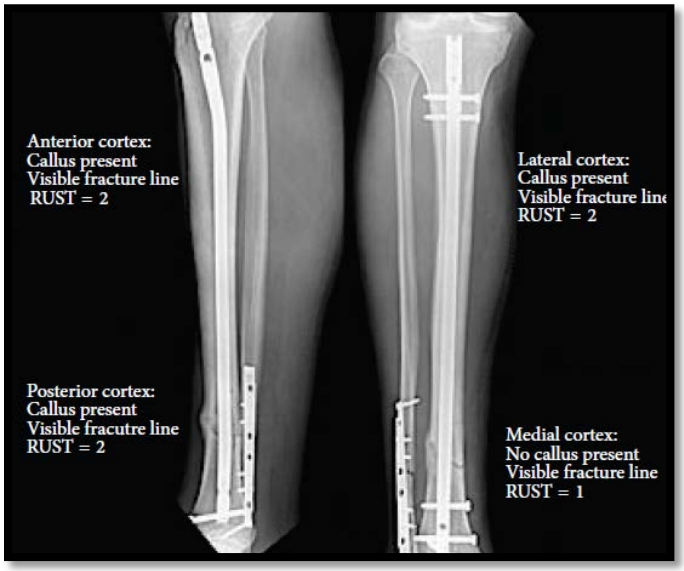

Figure 1: Assignment of the RUST in a patient with distal tibial shaft fracture at 3 months postoperatively. Overall RUST = 7. *Copied from Whelan et. al. (2010)*

III. MATERIALS AND METHODS

This study was designed to determine the reliability of Radiographic Union Score for Tibia Fractures (RUST) when used in randomly selected patients who have undergone intramedullary SIGN Nailing of the femur from January 2011 to December 2017 at Western Visayas Medical Center. This is a descriptive cross-sectional study done at Western Visayas Medical Center at Iloilo City, Philippines and was conducted from May to July 2018.

A. Study Population

All patients admitted at Western Visayas Medical Center with fracture of the femoral shaft and have undergone intramedullary SIGN Nailing of the femur. In total, 108 patients were found to have undergone intramedullary SIGN nailing of the femur with adequately documented follow up-radiographs. Forty-four (44) radiographs were taken on the 3^{rd} to 6^{th} weeks, twenty (20) radiographs were taken on the 6^{th} to 8^{th} weeks, eighteen (18) radiographs were taken on the 8^{th} to 10^{th} weeks, nine (9) radiographs were taken on the 10^{th} to 12^{th} weeks, thirty-three (33) radiographs were taken on the 12^{th} to 52^{nd} weeks and twenty (20) radiographs were taken on more than 52 weeks. One hundred forty-four radiographs were available for viewing over-all.

B. Inclusion Criteria

Radiographs were also included if any of the following criteria are met: 1) Radiographic pictures are retrievable from the

online SIGN surgical database, 2) Patient was admitted in our institution (Western Visayas Medical Center) from January 2011 to December 2017.

C. Exclusion Criteria

Radiographs were excluded if any of the following criteria are met: 1) fractures not located on the femoral shaft (from five centimeters below the lesser trochanter and more proximally, and fractures six centimeter from the knee joint and distally), 2) patients having follow-up radiographs of fractures taken less than three weeks, 3) presence of a cast or brace on the thigh as seen on radiographs

D. Sample Size

A total of 144 radiographs of 108 patients will be employed in this study based on the computed sample size for frequency in a population using the OpenEpi Version 3, Open source calculator—SS Propor. To avoid errors, type I and type II, a 95% confidence level was set for the sampling size. An exacting degree of significance level was employed (set at 0.05) since the result of this study has important significance.

E. Description of the Study Procedure

Six observers were employed randomly using a simple randomization platform from an internet website "randomization.org", namely, three fellow orthopaedic consultants from a pool of six (6) consultants and three (3) orthopaedic residents of Western Visayas Medical Center from a pool of eleven (11) residents (one resident each from the 1st year, 2nd year and 3rd year), to assess the femur radiographs treated with intramedullary SIGN nailing using the Radiographic Union Scale for Tibial Fractures (RUST). Two sets of radiographs in the anteroposterior (AP) and lateral views for each follow-up period, one hundred five (105) sets in total, were randomly selected and assigned a specific number from the pool of one hundred and forty-four (144) available radiographs using a simple randomization tool from an internet website "randomizer.org". These one hundred five (105) sets of radiographs were initially assessed by the observers within the 3rd week of June 2018 in a specific order. Another assessment was done on the 3rd week of July 2018 by the same observers but with rearranged order and numbering of the previously selected and assessed radiographs. All the radiographs were evaluated in an office setting with minimal noise and ample lighting i.e. at the Orthopaedics office of Western Visayas Medical Center using one laptop with maximum brightness. Inter-observer and intra-observer agreement will be assessed by the statistical tool as follows.

F. Statistical Tool

Data were analyzed using SPSS Version 25. The RUST scores were analyzed with intra-class correlation coefficient to obtain the intra-observer and inter-observer reliability. 95% confidence interval was used. Portney LG & Watkins MP (2000) proposed a level of acceptability as clinical measure as shown on the table below (Table 1) with 0.90 to 0.99 as measure acceptable for clinical measures, good ICC at 0.75 to 0.89 and poor to moderate with 0.50 to 0.74 ICC.

ICC	Fleiss (1986)	P&W (2009)
0.99		
0.96		
0.94	Excellent	
0.89		
0.80		Good
0.75		
0.50-74	Good	Poor to moderate

Table 1: Level of acceptability as clinical measure by Portney LG & Watkins MP (2000)

G. Ethical Considerations

A letter of approval was given by the Institutional Review Board for the commencement of the study. The identity of all patients were kept strictly confidential and no information disclosing the identity of any individual was included in the final report.

IV. RESULTS

From the total number of 144 femur radiographs available, only 105 were included to be utilized for evaluation of consistency of RUST when used as a scoring tool for union in femoral shaft fractures treated with intramedullary SIGN nailing.

Table 2 summarizes all Intraclass Correlation Coefficients (ICC) with a 95% CI computed using SPSS Version 25. As shown in table 2 below, all twelve (12) assessments of one hundred five (105) radiographs totalled into an ICC of 0.94 *(0.92-0.94)* which can be interpreted as "excellent" according to Fleiss' (1986) standards and as "acceptable as clinical measure" according to Portney et. al (2009). This shows a significant correlation and agreement among the assessment of all observers. Total ICC of the orthopaedic consultants was slightly higher than the orthopaedic residents, 0.91 and 0.87 respectively. ICC of the second assessment as compared to the first assessment was noted to minimally improve to slightly improve respectively among the orthopaedic consultants and the orthopaedic residents, from 0.81 to 0.82 and from 0.71-0.78. Excellent intra-observer ICC were noted from two observers, namely Consultant 1 and Resident 3. Orthopaedic residents were noted to have marginally higher mean intraobserver ICC than the orthopaedic consultants at 0.84 and 0.82 respectively.

V. DISCUSSION

One of the common complications of long bone fractures is non-union. However, the criteria for its diagnosis has always been controversial and ambiguous. Criteria for union can be theoretically subdivided into two components, namely functional and radiologic. For the radiologic criteria, according to Court-Brown et, al (2015), in two orthogonal views of a fractured bone, three cortices out of four evidenced to have bridging callus

Table 2. Summary of all Intraclass Correlation Coefficients (95% Confidence Interval) for the entire study

Observer	Intra-Observer ICC 95% CI		First Assessment ICC 95% CI	Second Assessment ICC 95% CI	Total ICC 95% CI	
Consultant 1	0.91 *(0.87-0.91)*					
Consultant 2	0.71 *(0.57-0.80)*	0.82 (mean)	0.81 *(0.74-0.87)*	0.82 *(0.75-0.87)*	0.91 *(0.88-0.93)*	
Consultant 3	0.84 *(0.76-0.89)*					0.94 *(0.92-95)*
Resident 1	0.80 *(0.70-0.87)*					
Resident 2	0.81 *(0.71-0.87)*	0.84 (mean)	0.71 *(0.49-0.82)*	0.78 *(0.67-0.86)*	0.87 *(0.81-0.91)*	
Resident 3	0.91 *(0.87-0.91)*					

can be considered to have radiologic union [3]. This rule of thumb has been generally accepted among Orthopaedic surgeons though its use for research and clinical management has generally been vague and subdued. Several radiographic scoring tools were proposed, namely the Radiographic Union Scoring for Tibial Fractures. According to Whelan, overall agreement was substantial (ICC, 0.86; 95% CI, 0.79-0.91) for RUST when it was applied on Tibial Fractures and was noted to increase in relation to the raters' clinical experience.

In our institution, open reamed interlocked Intramedullary Nailing using SIGN implants have been made available since March 2011 with the sustenance of valuable implants especially the interlocking Nails for the long bones of the upper and lower extremities by the SIGN Fracture Care International Program. In this program, financially deprived patients are enrolled to have access to free and speedy treatment of their long bone fractures with the condition of having to come back for regularly scheduled follow ups for proper documentation and management postoperatively. All patients under this program are logged into an online SIGN Surgical database including their follow ups, squat and smile images and further relevant comments. With the help of an available online and properly documented surgical database, we are be able to review previous radiographs of trauma patients.

Currently there are no existing radiographic union scoring tools for femoral shaft fractures. In this study, we employed the RUST as a tool to evaluate bone healing in femoral shaft fractures treated with interlocked intramedullary SIGN nailing. With the availability of the SIGN surgical database, we were able to rate one hundred five follow up radiographs of patients who underwent Interlocked Intramedullary SIGN Nailing. After all assessments were done, an excellent absolute agreement between all observers was noted at 0.94 (95% CI; 0.92-0.94). According to Portney et. al. (2009), having an ICC of 0.90 to 0.99 can be acceptable for use as a clinical measure. This means that the usage of RUST scoring in femoral fractures treated with an intramedullary nail can be highly reliable and reproducible. Fleiss (1986) interpretation of total ICC in this study is excellent (0.75-0.99) [7]. Higher ICC was noted by Whelan et al (2010) among traumatologists versus residents which is also evident in this study however only up to a minimal extent [6].

Another notable result of this study is an increase in ICC upon second assessment which suggests that frequent use of this scoring tool improves inter-rater reliability and intra-rater reliability.

VI. CONCLUSION

Results of this study showed that the use of Radiographic Union Scale for Tibial Fractures is reliable when used clinically as a scoring tool for assessment of bone healing in femoral shaft fractures treated with intramedullary SIGN nailing.

VII. ACKNOWLEDGMENT

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