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Percutaneous strain reduction screws are a reproducible minimally invasive method to treat long bone nonunion

Matthew Bence MA MRCS[1], Alpesh Kothari MSc DPhil FRCS (Tr & Orth)[2], Andrew Riddick FRCSEd (Tr & Orth)[3], William Eardley MSc MD FRCSEd (Tr & Orth)[4], Robert Handley FRCSEd (Tr & Orth)[2], Alex Trompeter FRCS (Tr & Orth)[1]

[1]St George's Hospital, London, UK.

[2]John Radcliffe Hospital, Oxford, UK.

[3]Southmead Hospital, Bristol, UK.

[4]James Cook University Hospital, Middlesbrough, UK.

Corresponding Author: Matthew Bence, Trauma & Orthopaedic Department, St George's Hospital, Blackshaw Rd, London, SW17 0QT, UK matthewbence@me.com

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Abstract

Objectives: (1) Evaluate whether initial results from percutaneous treatment of nonunion are reproducible (2) Estimate the relative cost of percutaneous treatment of nonunion versus traditional methods.

Design: Retrospective multicentre case series

Setting: Four Level 1 trauma centers

Patients/Participants: 51 patients (34 men and 17 women) with a median age of 51 years (range 14 – 81) were treated for nonunion at a median of 10 months (range 4 – 212) from injury.

Intervention: Percutaneous strain reduction screws (PSRS)

Main Outcome Measured: Union rates and time to union were compared for patients treated in the developing institution versus independent units as well as with previously published results.

Results: 45 (88%) of patients achieved union at a median time of 5.2 months (range 1.0 – 24.7) confirming the previously published results for this technique. Comparable results were seen between the developing institution and independent units. No patients experienced adverse events beyond failure to achieve union. PSRS appears to offer savings of between £3,177 ($4,416) to £11,352 ($15,780) per case compared with traditional methods of nonunion surgery.

Conclusions: PSRS is a safe, efficacious treatment for long bone nonunion and may be more cost-effective than traditional non-union treatment methods. The promising initial results of this technique have now been replicated outside of the developing institution.

Levels of Evidence: Therapeutic Level III. See Instructions for Authors for a complete description of levels of evidence.

Keywords: Nonunion; Minimally Invasive Surgery; Long Bone Fracture; Strain; Clinical Outcomes; Cost Effectiveness

Introduction

Long bone fracture nonunion presents a clinical and socioeconomic challenge, causing a significant impact on health-related quality of life[1]. It complicates the treatment of around 2% of fractures, with the highest rate of nonunion affecting fractures of the tibia[2].

Nonunion is challenging to define, as evidenced by a multitude of diagnostic approaches and variability in time of diagnosis[3, 4]. To add objectivity to the assessment of union, the Radiographic Union Score for Tibial Fractures (RUST) and modified RUST (mRUST) scoring systems were developed for quantifying the radiological changes associated with fracture healing[5, 6].

Two key aetiologies are recognised in the development of nonunion, a failure of the biological processes of fracture healing and inadequate fracture stability[7, 8]. In the majority of patients, excess strain at fracture sites is the predominant driver of nonunion[9, 10].

Traditional treatments for nonunion modify the strain environment by revising to a fixation with greater stability. Techniques described include: exchange nailing to larger diameter, and therefore stiffer intramedullary (IM) devices; plate osteosynthesis; and ring fixation. Treatment can be protracted, expensive and invasive[11-13].

It is increasingly apparent that oblique nonunion planes arise as a result of shear forces at fracture sites[10, 14]. For nonunion occurring as a result of excess shear, modifying the strain environment may facilitate fracture healing. Percutaneous strain reduction screw (PSRS) insertion is a minimally invasive technique, which counteracts shear forces by the insertion of screws perpendicular to the nonunion plane[15].

A single centre published case series presented promising results, with high union rates and short times to union[15].

It is not uncommon for data arising from intuitions who develop a technique, to report better outcomes than independent groups or registry data[16]. To assess the reproducibility of this technique, a multi-centre retrospective case series was analysed, including further cases from the developer institution as well as from independent institutions for comparison.

The aim of this study was to investigate the clinical and radiological outcomes of PSRS from multiple centres, confirming reproducibility outside the developer institution. It was hypothesised that PSRS would have similar outcomes in achieving union whether undertaken within or outside of the developing organisation, and that outcomes would also be comparable to the initial case series.

PSRS has the potential for large cost savings compared with established surgical procedures for nonunion. A comparative cost analysis was performed for PSRS against traditional methods of nonunion surgery, to give an indication of the magnitude of savings available.

Methods

A retrospective analysis was conducted of all PSRS cases for treatment of long bone nonunions in 4 U.K. level 1 trauma centers (MTCs) from 2016 to 2020. The developing institution who originally described this technique, submitted 29 new previously unpublished patients' cases. Three further independent units submitted 22 cases for inclusion over the same study period.

To calculate union rate and time to union, patients were followed up until fracture union was achieved or further management was required. Data was collected on patients: demographics;

injuries; initial management; presence of associated infection; and OTA/AO fracture classification[17]. Clinical notes and radiology were reviewed, to determine whether patients had reached clinical and/or radiographic union, required further surgical intervention or experienced any complications of surgery.

This study was registered as a service evaluation at each institution after use of the UK National Health Service (NHS) Health Research Authority assessment tool. No patient identifiable data was shared.

Indications for Surgery

A diagnosis of nonunion was made following failure of progression on serial clinical and radiological examination. All treating surgeons were full time UK NHS consultants experienced in the treatment of long bone fracture nonunion.

For patients to be treated by PSRS, surgeons had to assess whether: further intervention was necessary for union to occur; excess strain was likely to be an impediment to nonunion healing; there was no suspicion of infection as defined by the fracture related infection criteria[18]; the fracture alignment was satisfactory; and the orientation of the nonunion plane and pre-existing fixation were amenable to supplementation with PSRS. Cases where the original implant was grossly unstable (peri-implant lysis, or implant fatigue) were not deemed suitable.

Pre-operative Workup

Pre-operatively all patients were planned for day-case surgery under general anaesthetic, with standard elective operating pre-assessment anaesthetic protocols. Workup for surgery included bloods (with inflammatory markers) as well as anteroposterior (AP) and lateral radiographs showing the absence of fracture healing and the plane of the nonunion. The majority of patients also required computed tomography (CT) scanning for surgical planning and further in-depth assessment of the presence of bridging callus. Where appropriate, full length leg views were also performed to ensure that alignment was satisfactory.

Surgical Technique

PSRS was performed under general anaesthetic with image intensifier guidance. One, two or three 3.5 or 4.5mm solid screws were placed through minimally invasive stab incisions.

Screws are typically inserted as positional rather than lag screws. Positional screws have threads engaged in bone on both sides of a nonunion with a short section of screw traversing the nonunion site between fragments. This gives them a shorter working length with which to resist shear strain compared with the much longer working length from the head of a lag screw to the threads engaged in the distal fragment. Rarely is it possible to reduce the fracture gap with a lag screw, therefore positional screws are preferred as they are technically simpler to insert and will act by resisting shear forces irrespective of compression at the site of the nonunion.

Post-Operative Care

Most patients were discharged on the day of surgery, with around a fifth of patients requiring a single night stay in hospital for post-operative pain management.

Patients were kept non-weight bearing on the affected limb for 6 weeks or rested in a sling for a similar duration for upper limb surgery. They were then repeatedly assessed both clinically and radiologically in the outpatients' department until union occurred or further management was required. Union after treatment, was a clinical and radiological diagnosis made by the operating surgeon at the time of post-operative review in the outpatients' department. To quantify healing on radiographs, the Modified Radiographic Union Score for Tibial fractures (mRUST score) at each follow-up was calculated[6]. Patients lost to follow up were excluded from analysis.

Cost analysis

To ascertain the relative financial impact of this intervention, a comparative cost analysis was performed for PSRS against traditional methods of nonunion treatment. Records for patients with aseptic tibial nonunion, treated with traditional surgical intervention in a single centre were identified. Intervention with circular frames, plating and exchange nailing were compared against those treated with PSRS. The mean length of stay, number of post-operative outpatient appointments and any post-operative radiology costs were recorded.

Industry representatives were consulted for the costs of implants and consumables used intra-operatively. Accepted tariffs and costings for NHS services for inpatient bed stays, post-operative radiology, outpatient appointments and the cost of the procedure to remove a circular frame were also used to formulate the cost analysis[19].

It was not possible to obtain accurate electronically tracked theatre timings for comparison of operative time between the different treatment modalities. To give an indication of the operative time taken for PSRS cases, it was felt that the start and finish time of the intra-operative fluoroscopy may provide a reasonable estimate. This is because x-ray is used throughout the case, there is no surgical time used for removal of prior fixation and only minimal time is taken for the surgical approach and closure.

Statistical Analysis

All statistics were calculated using R (Version 4.0.4)[20]. All continuous variables were found to have skewed, non-normal distributions, so were quoted as median values with a range and compared using the Mann-Whitney U test. Categorical variables were quoted as percentages and compared using the chi squared test.

Results

51 patients were treated with PSRS at 4 U.K. MTCs between 2016 and 2020. 29 patients were treated at the developer institution and 22 were treated within the 3 independent institutions. The mean age of patients treated was 46.6 years old and 34 (66.7%) were male. 35 patients had nonunions of the tibia, 14 of the femur, 1 of the humerus and 1 of the fibula. 21 patients had open fractures and 15 sustained polytrauma at time of initial injury. 29 patients were initially treated with IM nails, 12 with plate fixation, 8 with ring fixation and 2 with conservative management. 28 patients were treated for hypertrophic, 15 for oligotrophic and 8 for atrophic nonunions. The median time from initial injury to PSRS was 10.4 months. The median surgical time for PSRS was 28 minutes (range 7 – 91mins). 45 (88%) patients achieved union at a median time of 5.2 months (range 1.0 – 24.7).

The baseline characteristics of the patients treated in the developer and independent institutions are summarised in Table 1. They were similar except that the developer institution appeared to treat patients with PSRS on average 10 months earlier than the other institutions. The outcomes summarised in Table 2, were similar between the developer and independent institutions. No patients developed post-operative infections or any other significant adverse event.

Median mRUST increased with time from PSRS Surgery. Scores of patients who eventually reached union appear to diverge from those with persistent nonunion at around 3 months post-operatively. The difference in the mRUST scores between the two groups was statistically significant at 18 weeks post-operatively. For those patients who did unite, the median mRUST score at the point of union was 14.

6 patients did not achieve union and required further treatment. 3 patients underwent formal revision surgery at 6, 13 and 35 months post PSRS. 1 patient with a closed tibial fracture treated with IM nailing before PSRS, had a fibular osteotomy and plate augmention of tibial fixation. 2 patients underwent exchange nailing, 1 with a Gustilo-Anderson IIIB tibial fracture and another with multi-system injuries including a closed femoral fracture.

Significant operative delays from the ongoing worldwide COVID-19 pandemic, meant that at the time of writing 3 further patients are still awaiting revision surgery at 13, 14 and 25 months since PSRS.

Nonunion causes long standing pain and disability and is treated in regional specialist centers. As a result, patients are highly likely to reattend the treating institution in the event of persistent nonunion. 2 patients were making good clinical progress before being lost to follow up and are therefore presumed to have united, but have been excluded from analysis.

Comparative cost analysis shows possible savings of between £3,177 to £11,352 when treating a nonunion with PSRS instead of traditional methods of nonunion surgery. The individual components contributing to the cost differential between different treatments is shown in Table 3.

Discussion

The outcomes in this multicentre case series are very similar to those quoted in the original case series (90% union at median time of 4 months) showing that the initial results can be replicated. The developer and independent institutions showed similar results, indicating that PSRS is a transferrable technique to other centres performing nonunion surgery.

No complications were reported beyond ongoing pain and failure to achieve union. Significantly, there was a 0% infection rate achieved in combination with 88% union rate highlighting the advantageous risk profile of this efficacious treatment.

There was an absolute difference in union rate of 13% in favour of the developing institution. Whilst this is within the limits of expected statistical variability, this modest difference could also be as a result of the more expedient treatment with PSRS in the developing unit or other unmeasured confounding factors.

6 patients required further intervention after failing to reach union. For them PSRS was a low cost, low risk venture which did not add to the complexity of subsequent surgery, but did delay definitive revision fixation.

Fracture nonunion is a well-recognised consequence of high-energy injury. What may have been appropriate initial management to commence fracture healing, may not confer the required stability to complete it[21]. This is demonstrated in the low strain environments seen in multi-fragmentary fractures, where displacement is shared across multiple different fractures[9]. As multiple fractures heal, a single fracture line may persist, at which any strain is concentrated arresting healing to form a single plane nonunion[10]. The PSRS technique supplements primary fixation, to reduce strain specifically at the site of nonunion, allowing fracture healing to recommence. The flexibility of this technique to supplement pre-existing fixation without removal, can be demonstrated by the radiographs of treated patients (see Figures Supplemental Digital Content 1 – 4, http://links.lww.com/JOT/B698, http://links.lww.com/JOT/B699, http://links.lww.com/JOT/B700, http://links.lww.com/JOT/B701).

Subgroups

Neither category of nonunion, nor mode of initial fixation appeared to grossly affect results. These data are summarised in Table 4. With such small subgroups, this study is under-powered to detect anything but very large differences in these outcomes. Identifying cohorts of patients who respond particularly well or poorly to PSRS will be an important focus of future work.

Radiographic Assessment of Union

Median mRUST at union was 14. This was slightly higher than the previously published mean mRUST score at union of 11.4 in a study which assessed the purely radiographic progress of fracture healing post fracture[6]. Union in this study was diagnosed after both clinical and radiological assessment of patients, so it is possible that clinical signs such as fracture site tenderness or pain on weight bearing delayed the diagnosis of union.

Because radiographic progress towards union could not be accounted for in between clinic visits, or after discharge from the service, our analysis underestimated the median mRUST at each time point.

Figure 1 shows that plain radiographs indicated divergence of the clinical course of patients at around the 3 month mark. In future, it is possible that strategies such as routine post-operative CT scanning could delineate those patients likely to need further surgery sooner. This would therefore minimize the main downside of PSRS, which is delay to definitive revision surgery.

Although mRUST is only validated for fractures of the tibia and femur, because other long bones heal in the same way, it was felt that the use of the score could be justified for the humeral and fibular fractures in this study.

Cost Analysis

Absolute cost estimates for traditional nonunion treatment have already been published and range from £7,000 to £79,000 ($9,730 to $109,810) per case[11-13]. The cost analysis described was designed to allow basic comparison between different treatment modalities rather than an absolute estimate of treatment cost. It was not practical to compare large cohorts of matched patients and instead used small numbers of unmatched patients treated for similar pathology. It does not account for physiotherapy or any treatments received outside of the hospital due to the added complexity of accounting.

Nearly all of the patients treated with PSRS went home on the same day of surgery. This lack of requirement for inpatient treatment was a large component of the apparent cost saving associated with PSRS. The other major contribution to the relative cost saving in this analysis was the use of cheap generic screws, rather than proprietary implant systems used in traditional nonunion treatment.

Two significant sources of under-estimate of the cost-benefit of PSRS were identified. There was no calculation of the comparative amount of time spent in theatre; a major additional cost estimated to be at around £600 ($834)/hour[22]. This was not included, because using retrospective data, no sufficiently accurate electronically recorded theatres timings were available for the procedures studied. PSRS took a median of 28 minutes, compared with an expected duration in the region of 90-120 minutes for exchange nailing or ring fixation.

Of the small number of patients selected for cost analysis comparison with PSRS, none experienced a major post-surgical adverse event. A complication would greatly increase the cost estimate for a treatment modality and is anticipated to be much more likely with traditional techniques than with PSRS.

Cost in this study was deemed to be money paid by the U.K. taxpayer to hospitals for medical treatment, but does not account for loss of earnings, care or the wider costs to society.

Limitations of this study include the retrospective nature and the variance in practice between multiple treating institutions. There was no standardisation of the number or frequency of follow up appointments and x-rays. From inception this study was designed to confirm that PSRS could be employed to treat nonunions outside of the developer unit; which it showed. It may now be possible to justify funding a prospective randomised trial.

Conclusion

PSRS is a simple and elegant way to manage nonunion, with good healing rates and potentially reduced cost and operative time compared with traditional management methods. Promising results from the initial case series have been confirmed both within and outside of the initial centre. No adverse events occurred aside from a delay to definitive fixation for those whose fractures did not unite. With no reported infections and no added complexity for further revision surgery if nonunion persists, PSRS is an attractive treatment option for treating long bone fracture nonunion.

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Figure 1 Legend:

Divergence of mRUST scores of patients achieving union versus those with persistent nonunion

Table 1. PSRS patient baseline characteristics

	Developer Institution	Independent Institutions	p value
n=	29	22	
Median Age at PSRS	51 (range 14 – 81)	42 (range 15 – 72)	0.464*
Male	66%	68%	0.842**
Involved Bone:			
Tibia	20 (69%)	15 (68%)	
Femur	9 (31%)	5 (23%)	
Humerus	0	1 (5%)	
Fibula	0	1 (5%)	0.399**
Open Injury at Presentation	13 (45%)	8 (36%)	0.543**
Polytrauma at Presentation	8 (28%)	7 (32%)	0.503**
Initial Fixation:			
IM nail	19 (66%)	10 (45%)	
Ring Fixator	4 (14%)	4 (18%)	
Plating	5 (17%)	7 (32%)	
Conservative	1 (3%)	1 (5%)	0.531**
Nonunion Type:			
Hypertrophic	16 (55%)	12 (55%)	
Oligotrophic	6 (21%)	9 (41%)	
Atrophic	7 (24%)	1 (5%)	0.091**
Median mRUST Pre-PSRS	7 (range 4 – 9)	8 (range 4 – 11)	0.115*
Median months from Injury to PSRS	9 (range 4 – 33)	19 (range 5 – 212)	**0.011***

*Mann-Whitney U test

**Chi Squared

Table 2. PSRS outcomes

	Developer Institution	Independent Institutions	p value
Achieved Union	27 / 29 (93%)	16 / 20 (80%)	0.169**
Median Time to Union (months)	4.0 (range 1.0 – 21.8)	5.8 (range 2.9 – 24.7)	0.105*
Median mRUST at Union	14 (range 11 – 16)	14 (range 12 – 16)	0.838*

*Mann-Whitney U test

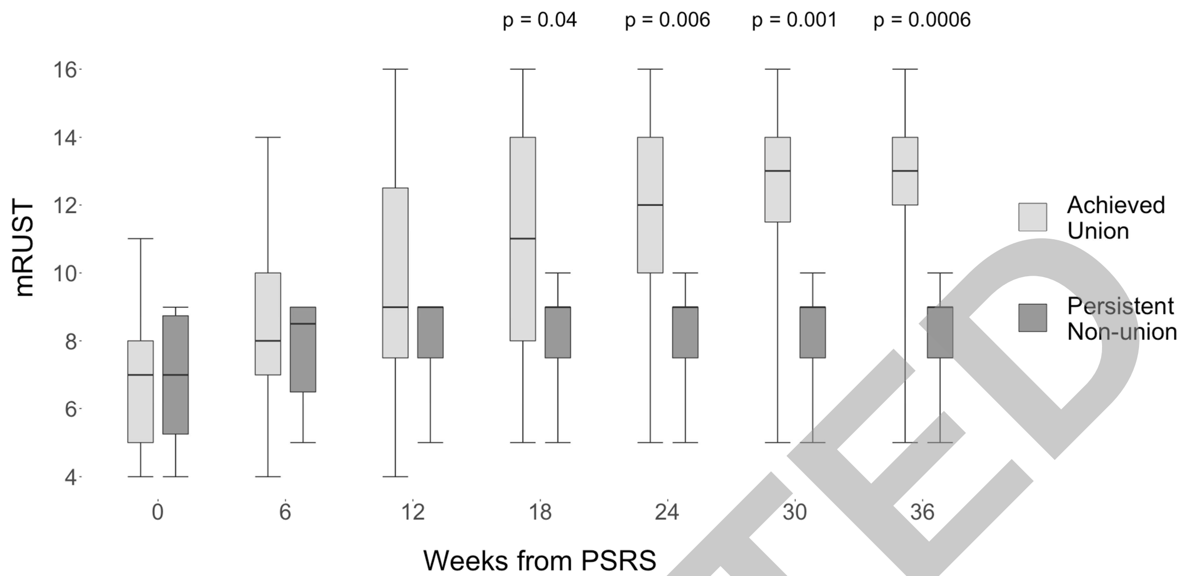
**Chi Squared

Table 3. Mean costs per patient by treatment modality for tibial non-union

	PSRS	Ring Fixator	Exchange Nailing	Plating
Outpatient Appointments	£242 / $336	£177 / $246	£177 / $246	£354 / £492
Post-operative Radiology	£378 / $526	£574 / $798	£549 / $763	£490 / $681
Implants and Consumables	£16 / $22	£7,847 / $10,907	£1,288 / $1,790	£4,108 / $5,710
Hospital Bed Stay	£69 / $96	£2,076 / $2,886	£1,868 / $2,597	£692 / $962
Frame Removal Procedure	n.a	£1,383 / $1,922	n.a.	n.a.
Total	**£705 / $980**	**£12,057 / $16,760**	**£3,882 / $5,396**	**£5,644 / $7,845**
Excess cost over PSRS	**n.a.**	**£11,352 / $15,780**	**£3,177 / $4,416**	**£4,939 / $6,865**

Table 4. Subgroup Analysis

	n=	Union Rate	Median time to Union (Months)
Nonunion Type:			
Hypertrophic	28	92.6%	4.9
Oligotrophic	15	71.4%	6.1
Atrophic	8	100%	5.8
Initial Fixation:			
IM Nail	29	82.1%	4.9
Ring Fixator	8	100%	3.5
Plating	12	91.7%	5.9
Conservative	2	100%	1.0


p = 0.04
p = 0.006
p = 0.001
p = 0.0006
mRUST
16
14
12
10
8
6
4
0
6
12
18
24
30
36
Weeks from PSRS
Achieved Union
Persistent Non-union