

# Identification and Consequences of Fine Wire and Half-pin Loosening for External Framing

## Abstract

This review article discusses the published methods of identification and consequences of fine wire and half-pin loosening. The evidence is reviewed and presented for the clinical, radiological, and histological analysis of the half-pin and fine wire to bone interface. **Materials and Methods:** A PRISMA compliant systematic review was conducted. Studies investigating the use of external fixators with descriptions on measurement of half-pin and fine wire loosening were included in this review. **Results:** Eight studies were eligible and included. No randomized controlled trials were identified. Torque measurement was most frequently used to quantify the half-pin-to-bone interface, histological analysis was performed by three studies, and radiographic analysis was performed by five papers including plain film and microcomputed tomography CT techniques. **Discussion:** The available evidence was of poor quality, with a lack of homogeneity in quantitative data for torque measurements and a prevalence of arbitrary figures for the definition of loosening. There was no mechanical analysis of fine wire loosening, and the most common clinical measure used for loosening was a scale validated for infection. Micro-CT was validated against torque figures and appears to be the most repeatable measure which could be applied clinically, however has only been used in canine studies. We recommend a study to compare the clinically relevant measurement of loosening against a standard model to provide a validated method of identification or prediction of half-pin and fine wire loosening.

**Keywords:** External fixation, fine wire, half-pin, loosening, systematic review

## Introduction

Fine wire and half-pin use are integral to the application of external fixators and frames for management of a number of different pathologies in orthopedic and limb reconstruction surgery.<sup>[1,2]</sup> The identification of fine wire and half-pin loosening during the use of such techniques is important to maintaining the efficacy of the construct. Failure to recognize and treat wire and pin loosening can increase the risk of infection and result in the failure of the construct.<sup>[2-5]</sup>

The bone-half-pin interface remains a weak link in the stability of an external fixation construct. Half-pin loosening and pin tract infection are intimately related, but the pathophysiology and relationship are not clearly understood. It has been hypothesized that loosening results in increased inflammatory change and fluid accumulation, which could increase the risk of pin tract infection.<sup>[6,7]</sup> However, other authors have shown that in the

absence of infection, there is a progressive reduction in the pin extraction torque over time.<sup>[8,9]</sup>

The recognition of fine wire and half-pin loosening within published literature includes clinical and radiographical findings; however, there appears to be no consensus on the best method to define or classify this. Due to a lack of homogeneity in the definitions of loosening, the clinical frequency of half-pin and wire loosening is hard to determine.

The aim of this study was to systematically review the current evidence describing the methods and techniques used for the identification of half-pin and fine wire loosening.

## Materials and Methods

A PRISMA compliant systematic review<sup>[10]</sup> was conducted to determine what extent is external fixator loosening present in the reported literature, and how it is identified and quantified.

**How to cite this article:** Nutt J, Sinclair L, Graham SM, Trompeter A. Identification and consequences of fine wire and half-pin loosening for external framing. *J Limb Lengthen Reconstr* 2022;8:138-43.

**James Nutt,**  
**Lucy Sinclair<sup>1</sup>,**  
**Simon Matthew**  
**Graham<sup>2,3</sup>,**  
**Alex Trompeter<sup>4</sup>**

*Department of Orthopaedics, Royal Surrey County Hospital Foundation Trust, <sup>1</sup>Brighton and Sussex NHS Library and Knowledge Services, University Hospitals Sussex NHS Foundation Trust, Brighton, <sup>2</sup>Oxford Trauma and Emergency Care, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, UK, <sup>3</sup>Liverpool Orthopaedic and Trauma Service, Department of Orthopaedic and Trauma Surgery, Liverpool University Hospital Foundation Trust, Liverpool, UK, <sup>4</sup>Department of Trauma and Orthopaedics, St George's Healthcare NHS Trust, London, United Kingdom*

**Submitted:** 18-Sep-2021

**Revised:** 16-Jan-2022

**Accepted:** 11-Aug-2022

**Published:** 29-Dec-2022

### Address for correspondence:

*Mr. James Nutt,  
Department of Orthopaedics,  
Royal Sussex County Hospital,  
Eastern Road, Brighton  
BN2 5BE, United Kingdom.  
E-mail: jnutt1@nhs.net*

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**DOI:** 10.4103/jllr.jllr\_26\_21

#### Quick Response Code:



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## Search strategy

We performed a systematic literature search on the July 9, 2021, to identify relevant articles. We conducted electronic searches for eligible studies within each of the following databases:

- Ovid MEDLINE® ALL <1946 to July 08, 2021 > date searched July 9, 2021
- Embase (OvidSP) <1974–2021 Week 26>, date searched July 9, 2021
- Cochrane Database of Systematic Reviews, Issue 7 of 12, July 2021, date searched July 9, 2021
- Cochrane Central Register of Controlled Trials, Issue 7 of 12, July, date searched July 9, 2021
- Cochrane Clinical Answers, date searched July 9, 2021.

We conducted electronic searches of the following grey literature database using search strategies adapted from the final MEDLINE search strategy:

- Google Scholar, date searched July 9, 2021

We searched trials register (NIH U. S. National Library of Medicine ClinicalTrials.gov (<https://clinicaltrials.gov/ct2/home>) to identify registered trials (up to July 9, 2021).

The search strategy is presented in Supplementary Table 1.

## Search eligibility

We aimed to identify randomized controlled trials (RCTs) and nonrandomized studies including prospective and

retrospective comparative cohort studies, case-control studies, lab-based studies including finite element analysis and cadaveric, animal, and mechanical analysis studies.

We included cross-sectional studies, case series, and case reports, as we did not expect to find a significant number of trials to have been conducted in this specific field of research.

Studies published in any language were included and papers were eligible irrespective of date of publication.

## Population

Included were studies examining adults, children and biomechanical studies, laboratory studies, and animal studies. Participants included patients undergoing deformity and acute fracture management of the lower limb with external fine wire and or half-pin framing and include pin to bar external fixators.

## Study identification

Two reviewers J. N and AT independently reviewed the title and abstract of each study. Full-text papers were ordered for those studies which met the eligibility criteria. Two reviewers J. N and AT then independently reviewed each full-text paper against the eligibility criteria and included those studies which met them. If a study eligibility was questioned or a disagreement arose between the reviewers, this was resolved with discussion between the two reviewers until a consensus was reached on its inclusion.

**Table 1: Selected study characteristics**

Author	Year published	Number of patients/pins	Methods listed to identify loosening	Consequences
Zheng <i>et al.</i> <sup>[11]</sup>	2011	24 dogs 96 half-pins	Extraction torque Radiological assessment two view X-ray Micro-CT Histological analysis	N/A <i>in vivo</i> Canine study
Aro <i>et al.</i> <sup>[7]</sup>	1993	57 dogs 342 half-pins	Torque-fixation index Radiological assessment two view X-ray Histological analysis	N/A
Pettine <i>et al.</i> <sup>[12]</sup>	1993	14 dogs 84 half-pins	Torque-fixation index Radiological assessment two view X-ray Histological analysis	Bone necrosis ( <i>n</i> =3)
Toksvig-Larsen and Aspenberg <sup>[13]</sup>	2013	20 patients	Torque insertion Checketts-Otterburn	Infection ( <i>n</i> =2 patients)
Gathen <i>et al.</i> <sup>[14]</sup>	2019	4 patients 4 cadavers	Torque-fixation index Checketts-Otterburn	Infection ( <i>n</i> =2 patients)
Pizà <i>et al.</i> <sup>[15]</sup>	2004	23 patients 161 half-pins	Torque-fixation index Checketts-Otterburn Radiological assessment two view X-ray	Infection ( <i>n</i> =13 pins) Cortical osteolysis ( <i>n</i> =72)
Placzek <i>et al.</i> <sup>[16]</sup>	2006	21 patients	Torque-fixation index Schmidt pin track infection classification	Skin necrosis ( <i>n</i> =26) Infection ( <i>n</i> =9)
Pieske <i>et al.</i> <sup>[17]</sup>	2010	38 patients 152 half-pins	Extraction torque Radiological assessment two view X-ray	Infection ( <i>n</i> =6)

N/A: Not available, CT: Computed tomography

## Data

Data were collected from each included paper by one reviewer J. N.

The method of wire and half-pin loosening was identified, including clinical, radiological, and histological analysis. Where possible consequences as a result of half-pin loosening were captured. Any previously validated method of classification was identified and explored.

## Data analysis

No statistical analysis was performed due to the inhomogeneity between study population and indication for external fixation, including the type of pins/wires used and the lack of consistency in the definition of outcome measures. Therefore, a narrative review was deemed most appropriate and was undertaken to answer the research question.

## Results

5009 results were acquired using our search strategy. Eight studies were included in our review. The results of the search are presented in the PRISMA flowchart [Figure 1]. No RCTs were identified and there was significant data heterogeneity. Therefore, we present a narrative review of the included studies; the findings are summarized in Table 1.

### Determining half-pin site loosening

#### *Torque measurement*

The most common method of evaluating pin loosening in the studies reviewed was to measure the extraction torque of a pin with a digital or analogue torque wrench and compare it with the corresponding insertion torque. This was first described by Pettine *et al.* and subsequently by Moroni *et al.*<sup>[12,18,19]</sup> Using a torque meter [Figure 1], the authors were able to present reproducible results; however, we note that units presented varied between papers, from N mm, N cm, and N m.

Placzek *et al.* offered a new and more transferable index for measuring the difference between insertion and extraction torque.<sup>[16]</sup> The “Fixation Index” [Figure 2] is the quotient maximum extraction torque over maximum insertion torque.



Figure 1: A digital Torque Wrench. (Available at: <https://mecatechnic.twic.pics/img/photos/>)

The authors stated that this allows appreciation of the specific screw fixation strength and eliminates the influence of multiple variables including varying half-pin–bone contact, coating, roughness, diameter, cone size, thread depth, and the contact zone along the half-pin.

Finally, Pieske *et al.* used a similar digital torque wrench to ascertain the extraction strength; however, the authors formed their own group stratification split into four groups: (1) “strong” (>0.8 N m); (2) “good” (0.4–0.8 N m); (3) “low” (<0.4 N m but not “loose”); and (4) “loose” (the half-pin could be extracted manually because of complete loosening of the pin–bone interface).<sup>[17]</sup>

We were unable to tabulate and compare different torque figures and provide a definitive comparison chart for loose versus secure half-pins as described in our review papers, as there were too many unaccountable variables, including half-pin size, site, and duration of treatment.

### Radiological analysis

Five papers used plain film radiography as a measure of half-pin–bone loosening and one paper described the use of microcomputed tomography (CT).

Plain film radiography analysis was commonly performed using two different view radiographs taken at intervals during treatment. Pettine *et al.*<sup>[12]</sup> and Aro *et al.*<sup>[7]</sup> performed radiological analysis of the half-pin–bone interface at weekly intervals. Rarefaction of bone around a half-pin site was arbitrarily chosen by both authors at 0.5 mm or more; this was correlated with the torque value and histological analysis performed.

Pieske *et al.*<sup>[17]</sup> considered a half-pin as loose when a radiolucent line was present around the threaded half-pin and grouped the results into monocortical (“minor loosening”) and bicortical (“major loosening”).

Pettine *et al.* showed statistical significance when radiographic rarefaction exceeded 1 mm around the half-pin–bone interface; it was noted that no half-pins had rarefaction of the exit cortex without entry cortex rarefaction.

Micro-CT was utilized by Zheng *et al.* as a measure of bone quality at the half-pin–bone interface.<sup>[11]</sup> Scanned slices were reconstructed to show cutaway views of the implanted half-pins [Figure 3]. These cross-sectional images were perpendicular to the longitudinal axis of half-pin.

Designated regions of interest 6 mm in size were defined; these included the central area of implanted half-pins and surrounding bone tissues and were subsequently compared with histomorphometry parameters discussed in the basic science analysis section below.

$$\text{Fixation Index} = \frac{\text{Maximum extraction torque}}{\text{Maximum insertion torque}}$$

The fixation index: The quotient maximum extraction torque over maximum insertion torque allows to appreciate the specific screw fixation strength because of elimination of the influence of the varying pin–bone contact.

Figure 2: The fixation index equation

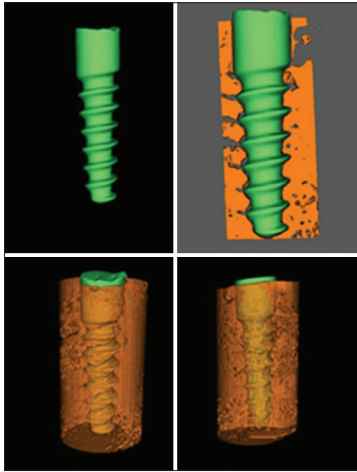


Figure 3: Micro CT analysis

### Determining fine wire site loosening

No papers provided a discernible measure of mechanical loosening of fine wire external fixation; however, three papers<sup>[13-15]</sup> made reference to the Checketts and Ottenburn classification used for the prevention and management of external fixator pin track sepsis.<sup>[20]</sup>

Described in 2000, this system classifies pin site infections into two groups and makes assumptions on the pin to bone interface through clinical findings; it is therefore used as a proxy measure for loosening. The two groups are minor (Grades 1–3) and major (Grades 4–6); major infections are deemed at risk of sepsis and osteomyelitis and also deemed loose, and were used in all three papers as a proxy measure of wire and pin site loosening.

### Basic science

Three papers were identified with a basic science theme.

Pettine *et al.* and Aro *et al.* performed a clinical, radiological, and histological analysis of the half-pin–bone interface using *in vivo* loading conditions on canine subjects.<sup>[7,12]</sup> Pettine *et al.* used 5-mm titanium self-tapping threaded half-pins in predrilled (3.5 mm diameter) tibia. Aro *et al.* used 6-mm stainless steel half-pins which were predrilled to 3.2 mm.

Both papers conducted a clinical evaluation using the previously described torque wrench method to measure the maximum insertional torque of half-pins. Pettine *et al.* found that of 168 half-pins inserted, 69% with an

initial torque resistance of <67.8 Ncm developed gross clinical loosening, whereas only 9% with an initial torque resistance >67.8 Ncm became grossly loose.

Histological analysis of the half-pin–bone interface was performed after termination of both experiments, this was performed using combined tetracycline labeling and microradiography, and the results compared with the torque values for each pin. The method of tetracycline labeling was first described by Vanderhoeft *et al.*<sup>[21]</sup> and enables clear identification of new bone formed. Pettine *et al.* used the method to identify where bone had formed or resorbed around the half-pin threads in 6 different zones along the treaded half-pin. Statistically significant results were found in the histology of bony “thread triangles” between the grossly loose and tight half-pins. It was also noted that the “entry cortex” sample zone showed more bone resorption when compared with the “exit cortex” zone.

Zheng *et al.* also used canine subjects but performed a different form of histological analysis, using a combination of decalcified and undecalcified preparation with toluidine blue staining.<sup>[11]</sup> Three blinded individuals then performed histological analysis reporting on bone mineral content, bone mineral density, tissue mineral density, tissue mineral content, and bone volume/tissue volume.

Pieske *et al.*<sup>[17]</sup> performed a comparative study between two half-pin material types, within their analysis patient’s age found to correlate to an increase in the rate of loose half-pins ( $P = 0.018$ ). Other demographic data including gender and ASA score incidence of open fracture were not correlated to loosening ( $P \geq 0.05$ ).

### Consequences of half-pin and fine wire loosening

Of the 8 studies included, 7 detailed consequences of pin site loosening. These including bone necrosis, infection, skin necrosis, and cortical osteolysis were all directly implicated following pin loosening.<sup>[12,15]</sup> However, all papers detailed in their discussion that there is no consensus as to which forms first infection or half-pin loosening and that rarely does one exist without the other.

### Discussion

Identification of fine wire and half-pin loosening is an important part of the management of patients undergoing treatment with external circular frame and hexapod frames. A consensus agreement on what defines a loose wire



or half-pin remains elusive. Defined criteria, clinically, radiologically, or biomechanically, would serve to allow more homogeneity in reporting outcomes in published data.

Almost all studies identified as suitable for this review, included fine wire or half-pin loosening as a secondary measure, few listed rationale for their chosen method, and almost none provided peer reviewed data on why one method was chosen over another. We found no studies which provided meaningful analysis or measurement of fine wire loosening. Historical references occurred frequently, with little modification or update on historic techniques for defining half-pin or wire loosening.

There was no comparative trial between two types of measurement using the same half-pin or fine wire to bone interface.

Technological advances including the use of digital torque meters or micro-CT were not compared with existing technology; only correlations were drawn between the results of such measures with broader definitions of loosening.

Our search strategy produced results most often surrounding the *in vivo* comparison of two half-pin types, either the material, mechanics, or coating. Measurement of insertion versus extraction torque was the most cited method of defining loosening, but again arbitrary values for loosening were regularly chosen, mostly due to the study design being a comparison between two cohorts and detecting a significant difference between groups was the main outcome measure, rather than reaching a lower set threshold for what would be considered loose.

The torque index was a measure used in five papers, displayed as a ratio of insertion versus extraction torque. This could only be calculated and measured after removal of the half-pin, and so would have little clinical benefit in ascertaining if a half-pin was loose prior to removal, or in the decision-making process for replacing a suspected loose half-pin.

One study defined an absolute measure of torque insertion which was statistically significant in reducing the rate of ‘grossly loose half-pins’; this is not strictly identification of loose half-pins, but could go some way to mitigate the risk of half-pin loosening to the practicing clinician. Insertion torque of  $>68.7$  Ncm<sup>[12]</sup> into a tibia resulted in only 9% of half-pins becoming grossly loose ( $<5$  Ncm extraction torque) after 40 days *in vivo*.

The two papers which provided a histological analysis of half-pin sites after application of frames in canine models gave an in-depth analysis of the basic science surrounding half-pin site loosening.

Both papers compared the half-pin–bone interface between a stable fracture configuration and an unstable one, with each reporting that frames around an unstable fracture

pattern had the highest incidence of gross loosening. Within their results histological analysis was performed which showed that secure half-pin tracts were characterized by a lack of bone remodeling, whereas loose half-pin tracts displayed extensive bone resorption and inflammatory infiltrates.

With respect to clinical assessment of half-pin and fine wire loosening, the Checketts and Otterburn score was used in three papers. All three used this score as a primary measure for pin site infection, and made only assumptions that a pin site with a “major” infection (Grade 4–6) was at significant risk of being loose, noting that this score recommends that external fixation be abandoned with grade 4, 5 and 6 pin sites.

Radiological analysis was described with a two-view plain film radiograph. A reproducible measure of 0.5 mm of radiolucency around a half-pin–bone interface was set to define loosening. In particular, if radiolucency  $>0.5$  mm was seen around the far cortex of a half-pin–bone interface, this could be strongly correlated with a clinically loose half-pin. Micro CT analysis was performed in one study, this entailed the measurement of bony porosity. Assumptions were made on amount of bony absorption around a half pin based on the number of pores counted within a 6 mm sphere of the pin, this data was strongly correlated to a high torque index suggesting such analysis of bony porosity may be a reproducible and reliable proxy measure of half pin security.

The consequences of half-pin and fine wire site loosening included bone necrosis, cortical osteolysis, skin necrosis, and infection. Infection was listed most often; however, no definitive pathway was proposed by any of the studies as to which process occurred first. A loose pin is a recognized risk factor for infection of a pin tract, just as the pins that are subsequently removed from an infected pin tract are invariably loose.<sup>[7]</sup>

## Conclusion

It is clear that various methods of clinical, biomechanical, radiological, and histological analysis have been performed and described for half-pin loosening but without comparative studies to validate the process chosen.

The torque index appears to be used most frequently as a reliable and reproducible measurement; however, it fails as a clinically useful tool as it requires the extraction torque, therefore necessitates the removal of the half pin in question. Whereas simply recording the insertion torque may only provide a probability of loosening over a given time.

The ideal test would be one that provides a measurable value without sacrificing or risk damaging the pin–bone interface, the measure would be reproducible and easily performed while acceptable to the patient. Only one study appeared to use such a measure, the micro-CT scan, but the

authors failed to define a scale to represent loosening based on the number or volume of porosity around the pin–bone interface.

In the absence of a large multicenter trial of one method of measuring loosening versus another, further studies should be constructed to set out a standardized, evidence-based definition of loosening.

### Financial support and sponsorship

Nil.

### Conflicts of interest

There are no conflicts of interest.

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**Supplementary Table 1: Contd...**

**Search history results**

<b>Line number</b>	<b>Source</b>	<b>Criteria</b>	<b>Results</b>
12	Ovid MEDLINE (R) ALL	or/9-11	93,244
13	Ovid MEDLINE (R) ALL	Bone Wires/ae [Adverse Effects]	434
14	Ovid MEDLINE (R) ALL	((pin* or wire* or "kirschner wire*" or "bone wire*" or screw*) adj5 (loosen or loose or loosening or break* or remov*)).ti, ab, kf.	7570
15	Ovid MEDLINE (R) ALL	or/13-14	7922
16	Ovid MEDLINE (R) ALL	Reoperation/	90,421
17	Ovid MEDLINE (R) ALL	("return to theatre" or "joint revision" or "repeat surg*" or "surg* revision" or reoperation* or re?operation*).ti, ab, kf.	42,091
18	Ovid MEDLINE (R) ALL	((repeat or revision) adj1 (surgery or surgical or joint)).ti, ab, kf.	17,895
19	Ovid MEDLINE (R) ALL	or/16-18	123,073
20	Ovid MEDLINE (R) ALL	12 or 15 or 19	209,247
21	Ovid MEDLINE (R) ALL	8 and 20	3478
1	Embase	exp *lower limb/or leg fracture/or ankle fracture/or foot fracture/or knee fracture/or hip fracture/or tibia fracture/or fibula fracture/or femur fracture/	181,698
2	Embase	(("lower limb*" or "lower extremit*" or foot* or feet* or knee* or leg* or thigh* or hip* or buttock* or ankle or tibia or femur or femoral or fibula) adj3 (fracture* or trauma* or deform*)).ti, ab, kw.	83,484
3	Embase	or/1-2	219,546
4	Embase	exp *fracture external fixation/or exp *external fixator/or exp *fracture fixation/	41,027
5	Embase	("External fixation device*" or "External fixator*" or "External ring fixator*" or "External frame*" or "external orthopaedic fixation system*" or "external skeletal fixator*").ti, ab, kw.	6530
6	Embase	(Ilizarov adj2 (fixator* or frame* or apparatus or method or tech*)).ti, ab, kw.	2026
7	Embase	or/4-6	44,812
8	Embase	3 and 7	14,925
9	Embase	exp *device failure/	1242
10	Embase	((equipment or device or hardware) adj3 (defect* or failure* or malfunction* or misuse*)).ti, ab, kw.	8497
11	Embase	(regenerate adj3 collapse).ti, ab, kw.	6
12	Embase	or/9-11	9553
13	Embase	exp *bone wire/	1838
14	Embase	((pin* or wire* or "kirschner wire*" or "bone wire*" or screw*) adj5 (loosen or loose or loosening or break* or remov*)).ti, ab, kw.	9307
15	Embase	or/13-14	10,911
16	Embase	exp *reoperation/	6731
17	Embase	("return to theatre" or "joint revision" or "repeat surg*" or "surg* revision" or reoperation* or re?operation*).ti, ab, kw.	59,104
18	Embase	((repeat or revision) adj1 (surgery or surgical or joint)).ti, ab, kw.	24,023
19	Embase	or/16-18	76,814
20	Embase	12 or 15 or 19	95,898
21	Embase	8 and 20	1308