TRENT INSTITUTE

University of Leicester
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for Health Services Research

WORKING GROUP ON ACUTE PURCHASING

Internal Fixation of Fractures of the Shaft of the Tibia and of the Distal Radius in Adults

April 1998

GUIDANCE NOTE FOR PURCHASERS 98/02

Series Editor: Nick Payne

InterDEC Report No. 2/1998

Trent Development and Evaluation Committee

The purpose of the Trent Development and Evaluation Committee is to help Health Authorities and other purchasers within the Trent Region by commenting on expert reports which evaluate changes in health service provision. The Committee is comprised of members appointed on the basis of their individual knowledge and expertise. It is chaired by Professor Sir David Hull.

The Committee recommends, on the basis of appropriate evidence, priorities for:

- the direct development of innovative services on a pilot basis;
- service developments to be secured by health authorities.

The statement that follows was produced by the Development and Evaluation Committee at its meeting on 21 April 1998 at which this Guidance Note for Purchasers (in a draft form) was considered.

INTERNAL FIXATION OF FRACTURES OF THE SHAFT OF THE TIBIA AND OF THE DISTAL RADIUS IN ADULTS

AUTHORS: Calvert N, Triffitt P, Johnstone S, Richards R G, Evans M. Sheffield: Trent Institute for Health Services Research, Universities of Leicester, Nottingham and Sheffield 1998. Guidance Note for Purchasers: 98/02.

EXPERT ADVISORS TO TRENT DEC: Dr N Calvert, Research Fellow, Health Economics, ScHARR; Dr R G Richards, Consultant in Public Health, North Nottinghamshire Health; Mr P Triffitt, Consultant Orthopaedic Surgeon, Glenfield General Hospital, Leicester.

DECISION: The Committee felt that there was insufficient evidence to support internal fixation as opposed to conventional treatment for fractures of the shaft of the tibia or the distal radius in adults. Clinical skill and judgement remains the basis for deciding which treatment should be used.

April 1998

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Conflict of Interest None of the authors of this document has any financial interests in the drug or product being evaluated here.

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ABOUT THE TRENT INSTITUTE FOR HEALTH SERVICES RESEARCH

The Trent Institute for Health Services Research is a collaborative venture between the Universities of Leicester, Nottingham and Sheffield with support from NHS Executive Trent.

The Trent Institute:

- undertakes Health Services Research (HSR), adding value to the research through the networks created by the Institute;
- provides advice and support to NHS staff on undertaking Health Services Research (HSR);
- provides a consultancy service to NHS bodies on service problems;
- provides training in HSR for career researchers and for health service professionals;
- provides educational support to NHS staff in the application of the results of research;
- disseminates the results of research to influence the provision of health care.

The Directors of the Institute are: Professor R L Akehurst (Sheffield);
Professor C E D Chilvers (Nottingham); and
Professor M Clarke (Leicester).

Professor Clarke currently undertakes the role of Institute Co-ordinator.

A Core Unit, which provides central administrative and co-ordinating services, is located in Regent Court within the University of Sheffield in conjunction with the School of Health and Related Research (ScHARR).

FOREWORD

The Trent Working Group on Acute Purchasing was set up to enable purchasers to share research knowledge about the effectiveness and cost-effectiveness of acute service interventions and determine collectively their purchasing policy. The Group is facilitated by The School of Health and Related Research (ScHARR), part of the Trent Institute for Health Services Research, the ScHARR Support Team being led by Professor Ron Akehurst and Dr Nick Payne, Consultant Senior Lecturer in Public Health Medicine.

The process employed operates as follows. A list of topics for consideration by the Group is recommended by the purchasing authorities in Trent and approved by the Purchasing Authorities Chief Executives (PACE) and the Trent Development and Evaluation Committee (DEC). A public health consultant from a purchasing authority leads on each topic assisted by a support team from ScHARR, which provides help including literature searching, health economics and modelling. A seminar is led by the public health consultant on the particular intervention where purchasers and provider clinicians consider research evidence and agree provisional recommendations on purchasing policy. The guidance emanating from the seminars is reflected in this series of Guidance Notes which have been reviewed by the Trent DEC, chaired by Professor Sir David Hull.

In order to share this work on reviewing the effectiveness and cost-effectiveness of clinical interventions, The Trent Institute's Working Group on Acute Purchasing has joined a wider collaboration, InterDEC, with units in other regions. These are: The Wessex Institute for Health Research and Development, The Scottish Health Purchasing Information Centre (SHPIC) and The University of Birmingham Institute for Public and Environmental Health.

Professor R L Akehurst,
Chairman, Trent Working Group on Acute Purchasing.

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EXECUTIVE SUMMARY

Fractures of the tibial shaft (shin bone) are typically high energy injuries in younger adults resulting mainly from road traffic accidents (RTAs) and sports injuries. Fractures of the distal radius (just before or at the wrist joint) are very common, particularly in elderly women.

There is evidence of variation across Trent districts in the numbers of the fractures treated by internal fixation, i.e. when metal devices are inserted into or onto the bone. This treatment requires longer in-patient admissions and more operating theatre time, and may include re-admission for removal in some cases. There has been concern in at least one Trent Health Authority that the number of internal fixations and subsequent requirement for the surgical removal of implants has risen significantly in recent years.

The alternatives to internal fixation are conservative management with plaster cast or external fixation in which an external bracing system holds the fracture by means of pins through the skin into the bone fragments. These require less in-patient care but more out-patient care.

Apart from one group of fractures of the tibial shaft (Gustilo Type IIIB) there is poor, or no evidence for or against the use of internal fixation (nail); conservative management provides acceptable outcomes for the majority. However, no study has properly assessed the broad economic issues raised by the alternative treatments.

There is no evidence for or against the use of internal fixation for the primary management of distal radius fractures. There was consensus that: fractures of the distal radius in the elderly should be managed conservatively in the vast majority of cases; Accident & Emergency (A&E) departments should have access to an appropriate anaesthetic service to avoid unnecessary admissions; some of these fractures in younger patients should be managed by external fixation.

More research is needed on fracture classification systems so that they can be used in routine practice. Research into economic issues needs to be central to further research to address unanswered questions.

It is recommended that the existing orthopaedic research network in the Trent Region should be enhanced with a view to establishing a national centre of excellence to research these neglected issues.

1. INTRODUCTION

This topic has been investigated because, in at least one district in the Trent Region, there has been a concern that the number of fracture fixations using internal fixation as opposed to more conservative management using plaster cast or external fixation, has risen considerably in the last few years. This trend may have significant resource implications in terms of theatre time, equipment, in-patient length of stay, the subsequent need to remove implants surgically, and increased risk of serious infections.

1.1 Basic Epidemiology, Pathology, Treatment and Prognosis

Fractures of the Tibial Shaft

Tibial shaft fractures are less common than wrist fractures, but often occur in younger adults. The socio-economic impact is greater because of the propensity of these fractures to heal slowly. Intramedullary nailing, which gives reliable fixation and appears to accelerate functional recovery, is increasingly used as primary treatment in place of a plaster cast. The nail is usually removed at a second procedure once the fracture has healed. Conservative management in plaster may include the use of special casts that permit early weight-bearing.

Compound (open) fractures of the wrist and tibia have been routinely treated operatively for many years. Their incidence will vary with conditions on the roads and the nature of local employment.

Fractures of the Distal Radius

Fractures of the distal radius just above the wrist are particularly common and occur in three principal groups of patients:

- children;
- young adults sustaining higher energy injuries which are often severe, in RTAs or during sporting activity;
- elderly adults, usually women with osteoporosis.

In the first group, treatment is almost always by closed means. In the second, difficulties in holding an acceptable reduction have led to the increasing use of external fixation, using pins inserted into the bones of the hand and held together by an external frame. This may be combined with limited internal fixation. A large amount of research has given conflicting evidence as to the most appropriate management for the third group. Most patients are still managed by closed methods. However, stricter guidelines concerning the use of intravenous regional anaesthesia may lead to the admission to hospital of more of these patients than formerly.

1.2 Decision-making in the Primary Treatment of Fractures

The primary aim of fracture treatment is the restoration of function, to the fullest degree and in the shortest period possible. A secondary aim is the prevention of late complications from residual deformity. Achieving these aims rests upon the making of decisions regarding fracture reduction, fixation, and the rehabilitation both in respect of local soft tissue healing and of the patient as a whole.

Reduction of the fracture, that is restoring the bone to its anatomical shape, may not be mandatory. In children, residual deformities can remodel. In adults, the degree to which deformity affects function and late complications varies with the bone involved and the site of the fracture within the bone. In most cases there are no good data demonstrating how much deformity can be accepted in individual fracture types.

Reduction may be achieved by open or closed means. In the former, the fracture site is exposed surgically and in the latter it is not, reduction being achieved by manipulation or by traction. Open methods will be used when closed reduction proves impossible, when exposure is required to deal with neurovascular injuries, or in cases where internal fixation is to be used.

Fixation of a fracture will be required if it is unstable, that is the fracture fragments do not remain in the intended position either before or after reduction. Fixation may be by external means, such as by a plaster cast, traction or external fixation, or by internal means such as by plate fixation or intramedullary nailing. The use of fixation will depend upon decisions regarding the degree of instability of the fracture and the necessity for reduction. The type of fixation used will depend on decisions regarding the likely success of the method in holding the reduction, encouraging union, and in allowing appropriate rehabilitation, and regarding the likely complications. The general health of the patient may also influence these decisions.

1.3 The Rise of Internal Fixation

In the United Kingdom fractures have been treated traditionally by closed means. This may have arisen for a number of reasons. Firstly, exposure of fractures was considered dangerous in the pre-antibiotic era. Secondly, much orthopaedic work in district general hospitals was carried out by general surgeons. Thirdly, in the 1930s and during the Second World War the success of skilled closed management was championed by very influential surgeons such as Bohler[1] and Watson-Jones,[2] whose textbooks received wide readership. Fourthly, the methods of internal fixation available had limitations, and their application by those without appropriate training could lead to disastrous results.

Internal fixation became increasingly popular through the work of the AO/ASIF (Association for the Study of Internal Fixation) group in Switzerland which developed and popularised technically sound methods with a clear basis for their application. An important tenet of this group is that internal fixation is superior to closed methods through allowing earlier movement of injured joints or joints at the ends of injured bones, thus allowing quicker and more complete rehabilitation. This is widely accepted, although there appears to be little direct evidence. Rapid mobilisation may have been of particular concern in dealing with the large numbers of fractures endemic to this skiing holiday destination.

With the availability of sound methods, British surgeons began to use internal fixation more frequently. Primary fixation was used particularly for more severe joint injuries and fractures of the forearm in adults, where reduction and mobilisation were thought to improve functional outcome, and in the multiply-injured patient. Secondary fixation was used if closed means had failed to hold a reduction. The use of primary fixation increased as it became clear that long periods in traction could be avoided, fewer clinic visits were required, rates of union appeared better in some cases, and patients were pleased to avoid plasters. With skilled use of sound implants, major complications, particularly infection, were unusual. The superiority of internal fixation of the shaft of femur (thigh: in young men) and neck of femur (hip: in elderly women) over the alternative months of traction in bed is so clear as to need no further assessment.

1.4 Changes in the Management of Two Common Fractures:- The Tibial Shaft and the Distal Radius

Factors to be considered in reviewing changing practice include the following:

- requirement for hospital admission;
- use of an operating theatre;
- cost of implants;
- later removal of implants;
- number of clinic visits and radiographs;
- number of physiotherapy sessions;
- timing and degree of return to work and/or to independence in own home;
- level of complications such as infection, non-union, malunion, joint stiffness, and late secondary osteoarthrosis;
- acceptability to a patient population with ever higher expectations.

The measurement of outcome after fracture treatment is not straightforward in view of the number of variables involved, many of which are not readily measured. As a simple example, the time taken for a patient to return to work depends not only on the nature of the job, but on the patient's motivation. Other factors include age, gender, the level of physical and mental fitness before the accident, the nature of the accident, the location and type of injury, the involvement of other body systems, bone quality and so on. In particular, injuries to surrounding soft tissues may be a major determinant of speed of recovery and final outcome.

1.5 Outcomes, Casemix and Classification of Severity of Injury

As with all areas of health care, there are a number of outcome measures, with an emphasis on intermediary measures. These include technical measures such as fracture union (although orthopaedic professionals have no universally accepted definition of 'union') and angulation, but also mobilisation, weight-bearing, return to function and activities of daily living.

With outcomes so dependent on the severity of the injury, any research into outcomes of interventions must address casemix, including age of patient, whether the injury was caused by high or low energy trauma and the nature of bone and soft tissue injury. Classification systems have been developed which range from the complex, valid and impractical, to those which are simple and easy to use, but invalid (see Appendix A for examples of fracture classification systems). However, if research is to deliver answers to questions of best practice that can be applied to everyday clinical environments, a valid classification that is simple and workable must be developed. This must be a two stage process: an initial very detailed system which will permit analysis by treatments and outcomes (i.e. a multivariate analysis); the findings could then be used to produce a simpler clinical system, valid in terms of guiding practice and predicting outcomes.

1.6 Scale of the Problem in a 'Typical District'

A data analysis was undertaken using Trent in-patient data for 1994/95 in order to get an idea about the 'size of the problem' in terms of the number and type of fixation undertaken, and the resource usage by district health authority. By analysing the in-patient data on a district of residence basis, it should be possible to gain an understanding of the different treatment regimes for the treatment of fractures within Trent.

The analysis was constrained by the type of data fields presented in the in-patient Patient Information System (PIS) database. The most time-consuming part of the analysis was to define the sample dataset using diagnosis codes, operation procedures and bone codes. This process enabled in-patient Finished Consultant Episodes (FCEs) to be classified to wrist, lower leg, and multiple fractures, (arm and leg). Each FCE was then allocated to a treatment group, including 'internal fixations'. It is important to note that the PIS is an in-patient database and, therefore, excludes patients treated in A&E departments, unless they are subsequently admitted as in-patients or daycases.

Ideally, time trend data would have been analysed to help indicate trends in usage of internal and other types of fixation. Unfortunately, the Trent in-patient archive database, 'the archive', was not available at the time of the analysis and, thus, precluded the possibility of any time trend analysis.

Table 1 indicates that for Trent residents treated anywhere in the UK, and for anyone treated in Trent Trusts irrespective of district of residence, there were 7,723 in-patient FCEs in 1994/95 classified as fractures of the wrist and/or lower leg.

Table 1 FCE and Bed day Analysis by Limb 1994/95

Limb	FCEs	%	Bed days	%
Lower Leg	2,087	27%	18,422	46%
Wrist	5,353	69%	18,619	47%
Both	283	4%	2,986	7%

TOTAL	**7,723**		**40,027**	

Wrist fractures accounted for 69% of the FCEs captured by PIS, and 27% were classified as lower leg fractures. In terms of bed days, however, the wrist to leg ratio was about 50:50, illustrating the more complex nature of leg fracture treatment and rehabilitation. Around 86% of FCEs were classified as 'non-elective in-patients'; and some 62% of patients were aged 15 or over. Table 2 illustrates the classification of the FCEs to treatment groups.

Table 2 FCEs and Bed days by Type of Operation 1994/95

Operation Type	FCEs	%	Bed days	%
No Fixation	2,927	38%	8,223	21%
Other	2,324	30%	12,732	32%
No Operation Code	1,053	14%	7,334	18%
Internal Fixation	**997**	**13%**	**8,330**	**21%**
Removal of Implant	200	3%	921	2%
External Fixation	184	2%	1,929	5%
Internal & External Fix	30	0%	501	1%
Autograft of Bone	8	0%	57	0%
TOTAL	**7,723**		**40,027**	

The largest group in terms of number of FCEs is the 'no fixation group' (38%), although this group accounts for only 21% of bed days. 95% of the FCEs in this group have primary operation codes of 'manipulation of fracture'. Debridement is the second most common primary operation code for the 'No Fixation' group. The largest group in terms of occupied bed days (a better indicator of resource usage) is the 'Others' group. 26% of this group's FCEs comprise 'application of plaster cast' and 'remanipulations of fracture not elsewhere classified (NEC)'. The 'Others' group also includes non-specified types of internal and external fixations.

Internal fixations account for 13% of total FCEs and 21% of bed days. Removal of fixation devices (internal and external) accounts for only 3% of FCEs and 2% of bed days. 14% of FCEs had no operation codes present and are largely accounted for by high rates for Sheffield and Lincolnshire providers.

Lower Leg Fractures

The FCE rate for internal fixation of leg fractures varies from 0.34 per 10,000 residents in Doncaster to 1.11 in Nottingham. The Trent average is 0.7 FCEs per 10,000 residents. For a typical district of 500,000 adult residents, this equates to an average of 35 internal fixations of the lower leg per annum, ranging from 17 to 56. In terms of lower leg fracture workload for this group of patients, the proportion of workload classified to internal fixation ranges from 13.8% in Doncaster to 27.4% in Nottingham. Performing a chi-square independence test to test the null hypothesis that the rate of internal fixations performed does not vary across Trent districts, leads to a rejection of the Null Hypothesis at the 1% level. In other words, there is strong statistical evidence that the rate of internal fixations for lower leg fractures varies across the Region. Whilst casemix could be an issue, there is no reason to believe that the casemix of fractures should vary greatly between Districts other than for age and occupational factors.

Table 3 also indicates that North Nottinghamshire undertakes a disproportionately large number of fixation removals from the leg as emergency workload - 0.19 FCEs per 10,000 residents, (5.1% of total workload). Table 4 presents the same information as Table 3 but in terms of bed days per 10,000 residents. The Trent average is nine days per 10,000 residents, ranging from 5.5 days in Leicestershire to 16.7 days in Barnsley. Translated for a typical district of 500,000 adult residents, this implies an average of 450 bed days per annum ranging from 275 to 835. Using the average cost per in-patient day of £195 for generic services quoted in Netten and Dennett,[3] these figures represent an in-patient cost ranging from £53,600 to £163,000 and an average cost of £88,000 per annum.

Wrist Fractures

Table 5 indicates that the FCE rate for internal fixation of wrist fractures varies from 0.55 per 10,000 residents in Barnsley to 1.52 in Southern Derbyshire, with a Trent average of 1.08 FCEs per 10,000 adult residents. Thus, for a typical district of 500,000 adults, these figures indicate an average of 54 internal fixations per annum with a range from 28 to 76. This is almost a 3-fold difference. The chi-square independence test indicates that the number of wrist fracture internal fixations per head of resident population varies across the districts of Trent, ($p<0.01$). Examining the proportion of FCEs classified as internal fixation by District, there is a 5-fold difference from as low as 6% in Barnsley to 31% in Southern Derbyshire.

Table 3 Non-Elective FCEs per 10,000 Population by District of Residence and Operation Type For Patients aged 15 and over: Lower Leg Fracture

	Operation Type								
DHA of Residence	External	**Internal**	Both Ext. & Int.	Autograft	No Fixation	No Op.	Other	Removal	**Total**
N Derbyshire	0.07	**0.69**	0.10	0.00	0.66	1.42	0.53	0.03	**3.49**
S Derbyshire	0.11	**0.72**	0.02	0.00	0.31	1.01	1.03	0.00	**3.21**
Leicestershire	0.04	**0.45**	0.00	0.00	0.34	0.78	0.61	0.04	**2.26**
Lincolnshire	0.18	**0.52**	0.04	0.02	0.38	0.65	0.79	0.02	**2.60**
N Nottinghamshire	0.06	**0.53**	0.03	0.03	0.56	0.81	1.44	0.19	**3.66**
Nottingham	0.16	**1.11**	0.04	0.00	0.21	0.49	2.03	0.02	**4.05**
Barnsley	0.22	**0.99**	0.00	0.00	0.49	0.33	1.54	0.05	**3.62**
Doncaster	0.04	**0.34**	0.00	0.00	0.39	0.34	1.38	0.00	**2.49**
Rotherham	0.15	**0.83**	0.00	0.00	0.15	0.49	1.22	0.00	**2.84**
Sheffield	0.05	**0.92**	0.05	0.00	0.21	1.90	0.94	0.00	**4.06**
Trent	**0.10**	**0.70**	**0.03**	**0.01**	**0.35**	**0.87**	**1.09**	**0.03**	**3.18**

Table 4 **Non-Elective Bed days per 10,000 Population by District of Residence and Operation Type for Patients aged 15 and over: Lower Leg Fracture**

	Operation Type								
DHA of Residence	External	**Internal**	Both Ext. & Int.	Autograft	No Fixation	No Op.	Other	Removal	**Total**
N Derbyshire	0.63	**7.05**	1.81	0.00	5.90	12.39	8.73	0.46	**36.96**
S Derbyshire	2.11	**7.40**	1.21	0.00	3.39	8.05	11.93	0.00	**34.08**
Leicestershire	0.71	**5.45**	0.00	0.00	2.82	8.06	5.57	0.27	**22.88**
Lincolnshire	5.06	**7.87**	1.86	0.40	4.84	7.16	8.47	0.00	**35.67**
N Nottinghamshire	0.44	**9.52**	0.47	0.22	4.01	4.88	13.05	4.63	**37.22**
Nottingham	2.65	**12.88**	0.82	0.00	0.94	2.84	17.78	0.16	**38.06**
Barnsley	3.73	**16.69**	0.00	0.00	8.18	3.68	14.98	0.55	**47.81**
Doncaster	0.04	**7.14**	0.00	0.00	5.12	0.60	14.14	0.00	**27.04**
Rotherham	2.35	**9.50**	0.00	0.00	0.54	8.62	7.54	0.00	**28.56**
Sheffield	0.94	**11.70**	1.03	0.00	1.93	20.90	11.98	0.00	**48.48**
Trent	**1.87**	**8.98**	**0.78**	**0.07**	**3.40**	**8.15**	**10.95**	**0.52**	**34.73**

Table 5 **Non-Elective FCEs per 10,000 Population by District of Residence and Operation Type for Patients aged 15 and over: Wrist Fracture.**

	Operation Type								
DHA of Residence	External	**Internal**	Both Ext. & Int.	Autograft	No Fixation	No Op.	Other	Removal	**Total**
N Derbyshire	0.23	**1.05**	0.03	0.03	3.79	1.02	1.42	0.03	**7.61**
S Derbyshire	0.16	**1.52**	0.02	0.00	0.99	0.45	1.70	0.09	**4.93**
Leicestershire	0.04	**1.14**	0.00	0.00	3.08	0.76	1.72	0.07	**6.81**
Lincolnshire	0.20	**0.69**	0.04	0.00	1.80	0.83	1.33	0.00	**4.88**
N Nottinghamshire	0.47	**1.35**	0.03	0.00	2.03	0.85	2.28	0.03	**7.04**
Nottingham	0.43	**1.19**	0.12	0.02	0.45	0.64	1.93	0.00	**4.77**
Barnsley	0.22	**0.55**	0.00	0.00	4.94	0.55	2.96	0.00	**9.22**
Doncaster	0.04	**1.29**	0.00	0.00	2.67	0.43	1.42	0.09	**5.93**
Rotherham	0.10	**0.98**	0.00	0.00	1.37	0.20	1.57	0.00	**4.21**
Sheffield	0.11	**0.80**	0.00	0.00	1.56	2.23	4.06	0.07	**8.83**
Trent	**0.20**	**1.08**	**0.03**	**0.01**	**2.09**	**0.85**	**2.01**	**0.04**	**6.31**

Table 6 Non-Elective Bed days per 10,000 Population by District of Residence and Operation Type for Patients aged 15 and over: Wrist Fracture

	Operation Type								
DHA of Residence	External	**Internal**	Both Ext. & Int.	Autograft	No Fixation	No Op.	Other	Removal	**Total**
N Derbyshire	0.89	**6.46**	0.07	0.16	12.62	5.86	5.40	0.10	**31.56**
S Derbyshire	0.63	**9.24**	0.09	0.00	4.86	1.64	8.34	0.47	**25.26**
Leicestershire	0.31	**6.26**	0.00	0.00	12.15	7.76	9.26	1.14	**36.89**
Lincolnshire	1.17	**4.44**	1.29	0.00	6.21	5.65	9.58	0.00	**28.35**
N Nottinghamshire	1.00	**8.55**	0.13	0.00	5.92	5.45	11.52	0.22	**32.77**
Nottingham	3.66	**8.30**	1.11	0.14	2.40	3.25	10.32	0.00	**29.18**
Barnsley	0.49	**4.56**	0.00	0.00	19.37	6.86	19.54	0.00	**50.82**
Doncaster	0.00	**4.21**	0.00	0.00	11.56	5.93	8.21	0.30	**30.22**
Rotherham	0.15	**8.08**	0.00	0.00	3.77	1.37	7.89	0.00	**21.26**
Sheffield	0.25	**5.37**	0.00	0.00	9.06	10.14	25.54	0.14	**50.50**
Trent	0.98	6.64	0.34	0.03	8.29	5.62	11.40	0.33	**33.64**

The bed day data presented in Table 6 indicates an average of 6.6 days per 10,000 residents for Trent in 1994, with a range from 4.21 days in Doncaster to 9.24 days in Southern Derbyshire. For a district of 500,000 adult residents, this implies expected bed days of 330, with a range from 211 to 462. Using an average cost per bed day of £195, these figures imply annual in-patient bed day costs of £64,000 (£41,000 to £90,000).

Summary of Data Analysis

The above has summarised the results of analysing in-patient databases from the Trent Region. Any analysis is constrained by the ability of the existing Trent in-patient PIS database to facilitate the classification of fractures of the wrist and lower leg, and to allocate FCEs to the various treatment groups examined. Treatment given during an A&E attendance is explicitly excluded from the analyses.

The analysis indicated average annual expenditure on internal fixation in-patient stays of the wrist and lower leg to be in the region of £152,000 for a typical district of 500,000 adults. This cost is split roughly 60:40 in favour of leg fractures.

Statistical analyses indicated that the number of internal fixation procedures per head of population varies across the districts of Trent for both wrist and lower leg fractures.

2. INTERNAL FIXATION OF FRACTURES OF THE SHAFT OF THE TIBIA AND OF THE DISTAL RADIUS IN ADULTS: SUMMARY OF EVIDENCE OF EFFECTIVENESS

2.1 Tibial Shaft Fractures

A critical appraisal of the large number of published articles has been problematic for a number of reasons:

- the variety of classification systems used;
- the different grades of injuries studied even when the same classification has been used;
- the small numbers of patients in most studies (especially problematic in addressing the implications of relatively uncommon complications such as deep infection);
- differences in treatment comparisons:
  internal fixation; reamed or unreamed, locked or static;
  conservative (plaster cast); with or without early weight-bearing;
  external fixation;
- the rarity of randomised controlled trials (RCTs) and the frequency of uncontrolled case series.

Papers published in the early 1980s tended to favour conservative management of tibial shaft fractures with early weight-bearing in patellar-tendon bearing casts. These papers made little reference to classification of the injuries though appear to cover the full range of injuries. As late as 1995 Shaw and Lawton[4] supported external fixation for closed and Gustilo[5] grades I and II compound unstable fractures on the basis of a case series of 44.

A meta-analysis by Dervin,[6] having identified problems with the validity of some of the classification systems, concentrated on Gustilo grade IIIB as inter-observer agreement was high for this grade of fracture. Two studies were finally selected for meta-analysis comparing internal against external fixation but with only 27 and 28 patients respectively in the two groups. Three outcomes were analysed: time to union; superficial sepsis; and malunion. Only time to union was statistically significantly better for internal fixation, though the trend for all was in favour of internal fixation; these findings are plausible and consistent with the non-RCT studies. Superficial sepsis is, however, a minor outcome of minimal clinical significance. Deep infections were too few to analyse, yet this relatively uncommon complication could be of great clinical significance with the trend of study results favouring external fixation or conservative management. Tu et al.[7] found deep sepsis to be a problem in their series of Gustilo grade IIIB fractures and concluded that internal fixation was not recommended for these fractures (this paper was not included in Dervin's review).

Just prior to publication of this paper, a paper undertaking a meta-analysis of closed fracture of the tibia, found 2,372 reports of comparative trials published between 1966 and 1993.[8] Treatment included, immobilisation with a cast, open reduction with internal fixation, and fixation with an intramedullary rod. The abstract reports that 'the studies that were reviewed generally had few subjects and were poorly designed'. The analysis indicated that infection rates were lower using plaster, but that union rates were higher at 20 weeks for open reduction and internal fixation. There were no other significant associations. The report concludes that there is insufficient evidence in the published literature on which to base medical decisions with regard to the treatment of closed fractures of the tibia.

2.2 Distal Radius Fractures

Fractures of the distal radius vary greatly from simple undisplaced fractures through to those involving the joint and other wrist bones. Again this leads to difficulties in interpreting published data.

An extensive review of 103 references in 1991 by Jupiter[9] discussed these problems and, whilst concluding that the majority of these fractures should be treated conservatively, it ended with: 'The recognition of the role of anatomical restoration in functional recovery has led to greater interest in osteotomy of malunited fractures of the distal end of radius'. This appears to ignore one of the papers reviewed[10] and is contrary to a paper published in the same month: 'We found no correlation between final anatomical and functional outcome'.[11] An RCT of external fixation versus plaster cast did show a relationship, but was only statistically significant for patients under 50 years of age. Jupiter[9] concluded that for internal fixation 'serious complications .... can occur even when the surgeon is experienced'.

A Cochrane Collaboration Review by Murphy et al.[12] has been significantly delayed because of the problems created by the numerous classifications, classification systems, and other complexities of this topic. Its last expected date for publication completion was 15 February 1998, but it is still unavailable at the time of writing (April 1998).

2.3 Summary

The general direction of the evidence for the management of tibial fractures (which is generally of poor quality) is only clear in respect of recommending the use of internal fixation for Gustilo grade IIIB fractures, but with the proviso that careful audit is needed to check on deep sepsis rates. Significantly high rates should lead to a reassessment of policy. The quality of the available evidence for the management of wrist fractures is also poor and neither supports nor rejects the use of internal fixation in the primary management of distal radius fractures. Generally, fractures in the elderly should be managed conservatively. Complex fractures in the young will probably benefit from external fixation techniques. The expected more detailed review by Murphy[12] may add to our understanding of the management of fractures of the distal radius.

3. COST AND BENEFIT IMPLICATIONS OF ADOPTING INTERVENTION

3.1 Overview

The evidence for the cost-effectiveness of internal fixation compared to alternative treatment is even less good than the evidence for clinical effectiveness. Many of the published articles which compare clinical effectiveness make no reference to the comparative costs of treatment. Having said this, a number of the papers do provide information on comparative resource usage which could be used as a basis for a costings analysis. Those papers which do report costing information are concerned with direct treatment costs to the NHS. The direct costs to patients and families and the indirect costs of patients not being able to work, and thereby contribute to the wider economy, are not addressed. Many economists would argue that these indirect costs should be included in an economic analysis of this type where the time taken to return to work could vary significantly between the alternative forms of conservative and surgical interventions. In the context of work for the Trent Working Group on Acute Purchasing (WGAP), the group has taken a policy decision to summate only the costs of interventions to the NHS. Direct and indirect patient savings or costs are to be considered as benefits or disbenefits of intervention.

Of the relatively small number of papers which concern themselves with comparisons of effectiveness of fracture treatments, two purport to address economics, (Shaw 1995[4] and Pritchett 1995[14]). Another indicates some form of economic content, (Cannon 1985[13]), although the paper only claims that external fixation is cost-effective without presenting any costing analysis to support this assertion. Another paper by Hooper[15] presents some reasonable resource usage information without explicitly addressing costing. Pritchett[14] is the only author to address the issue of comparative cost-effectiveness of treatments for distal radius fractures.

As already alluded to in this paper, there are numerous classifications and classification systems for wrist and lower leg long bone fractures. This complicates the issue of effectiveness and cost-effectiveness and the conclusions about the effectiveness and cost-effectiveness of the various forms of treatment are likely to differ for each location and classification of fracture.

3.2 Tibial Shaft Fractures

Of the papers identified, the Shaw[4] paper is the most informative about issues of cost-effectiveness. The paper aims to compare the cost-effectiveness of the Orthofix external fixator, with three forms of internal (plate or nailing) fixation in the management of closed and Gustilo grade I and II compound fractures. Results from other published papers were used to derive cost estimates for plating and nailing methods of treatment.

All fractures in the Shaw[4] paper were classified as unstable, in that a stable reduction could not be achieved or maintained through manipulation and plaster cast treatment. The authors openly acknowledge that there is no general agreement amongst orthopaedic professionals about the most appropriate form of treatment for these fractures. All forms of treatment are said to have their proponents.

Amongst other things, the study recorded the median time to union and the number of days in hospital for both compound (open) and closed fractures. The details presented about the costing methodology are insufficient to allow detailed comments here. Although Shaw et al.[4] make a good attempt to describe the costing methodology, the figures are not presented in any depth. There would appear to be some confusion over the concept of fixed and variable costs given that the authors describe implants as fixed costs when they are clearly a variable component. Costs for first and second admissions have both been calculated at an average £120 per day (irrespective of whether the re-admission was for complications or for removal of implants). No sensitivities around these figures were presented in the paper. The results of the costing exercise were a cost per patient of £1,686 for the external fixator compared with £2,358 for nailing, and £2,022 and £3,412 for the two studies looking at plating. The results imply the relative cost-effectiveness of external fixation compared with the various forms of internal fixation. These results are dominated by the length of hospital stay costs and, as such, highlight the need for more precise attempts to model the marginal costs for hospital stays.

The comparison treatment groups were problematic in that one study included some stable fractures, and various assumptions had to be made about length of stay for complications and apportionment of capital costs. It is not clear whether Shaw's[4] costing analysis allows for inflationary differences for equipment costs. The paper assumes the costs of out-patient care to be the same for all types of intervention. Shaw implies that the costs of internal fixations may be under-estimated in their analysis because no allowance is made for possible long-term care required for treatment of post-operative complications.

Having implied that treatment using plaster cast was not effective for this class of unstable fracture, Shaw goes on to indicate that plaster is the cheapest form of intervention for these fractures, but possibly resulting in a high rate of angular deformity and the preclusion of immediate mobilisation.

Shaw concludes that the use of external fixators for the treatment of unstable tibial fractures is both clinically justified and cost-effective. Whilst one of the better attempts at an economic appraisal, there are a number of potential flaws in the analysis which leave a question mark over the conclusions drawn.

A paper by Hooper et al.[15] reports the results of a New Zealand study using prospective randomisation of 62 tibial shaft fractures, (Gustilo grade II and III compound fractures excluded). Without addressing costs explicitly, the paper presents good resource use information, including the time off work for the patient. The comparative treatments were conservative treatment with plaster and 'closed' intramedullary nailing with either dynamic or static locking. The statistical analysis indicated significantly shorter times to union, time off work (13.5 versus 23 days), number of out-patient visits and radiographs for the internal fixation group. However, the time in hospital was significantly longer statistically (11.7 versus 8.1 days).

The Hooper paper highlights the issue surrounding the complexity of fracture classification. Despite the fact that the paper only deals with Gustilo grade I fractures, sub-classifications of fractures are identified as transverse, oblique, spiral, and segmental, and can be located in proximal, middle, or distal positions along the tibial shaft. Although the treatment groups were well matched across these classifications, it is unclear whether cost-effectiveness is likely to differ across these various sub-classifications. Like the Shaw paper, the results of the Hooper study imply relatively long lengths of stay for internal fixation patients. On the other hand, the Hooper paper indicates cost advantage for out-patient visits and radiographs, and most significantly for the indirect costs of patients being off work. Operation costs are not included, but the authors state their belief that these will not offset the significant cost advantages of the nailing method.

In terms of various effectiveness criteria presented by Hooper et al.,[15] the results of the internal fixation group compare favourably with the conservative group. The authors were so convinced by the early results of their study that they concluded that it was unethical to continue with conservative management for the fractures concerned purely to increase the sample size for their study. None of their 29 internal fixation patients had significant infections, a result repeated for the 15 such patients in Tornetta III et al.'s[16] randomised trial. However, Tu et al.[6] had higher infection rates in their 18 internal fixation patients, and recommended that internal fixation be avoided for type IIIB fractures.

The problems resulting from deep infections are potentially very serious and can impact significantly on hospital resources and time off work for the patient. Hooper's study was small and, although no serious adverse events occurred in their sample the study was under-powered to detect them. The presence of any infections in their sample could have significantly altered the results and conclusions of the study.

3.3 Distal Radius Fractures

The quality and quantity of evidence for the cost-effectiveness of treatment for distal radius fractures is even poorer than for tibial fractures. The Pritchett paper[14] concerns itself with complex fractures of the distal radius (Colles' fracture) and is the only paper found which addresses comparative costing issues. All patients had Frykman[17] Type viii fractures and the treatments compared were primary external fixation or closed medullary pinning. Patients were allocated randomly to the two treatment groups.

The paper presents a range of performance results for which the internal fixation does relatively well. Some summary statistics are presented relating to resource usage. Mean operating theatre time was recorded as 41 minutes for the medullary pinning group, compared to 64 minutes for the external fixation group. The information presented also implies more out-patient visits, more drug consumption, and higher complication costs for the external fixation group. Other than this, no more information is presented for costings except that the authors say that the costs of external fixation are twice those of medullary pinning. There is no indication that costs other than those to the provider are included. There is no indication that patient or indirect costs have been included. No further critique of the costing methodology can be made given the information presented in the paper.

3.4 Summary of Evidence of Cost-effectiveness

The evidence for the cost-effectiveness in respect of any form of treatment of tibial and distal radius fractures is poor both in term of quantity and quality of evidence. A number of studies have presented some information which may help to identify hospital resource usage. The costs to patients, their families, and the wider economy have not been calculated in any of the papers researched. This is unfortunate given that a key effectiveness criterion is to return the patient to full functionality. Very few papers have indicated any intention to analyse cost-effectiveness, even though the additional costs to the studies of including an economic analysis would have been relatively small.

The issue of cost-effectiveness is further complicated by the number of classifications and sub-classification of tibial and radius fractures. The evidence for effectiveness suggests that the relative effectiveness of internal fixation will vary by type of fracture. The same is likely to be true for cost-effectiveness. However, we cannot know with any degree of certainty until the research evidence is improved. A table summarising the key publications purporting to address comparative and/or economic analysis is presented in Appendix B.

3.5 Recommendations for Future Studies

In terms of analysing the cost-effectiveness of internal fixations for fractures of the tibial shaft and the distal radius, interested parties (purchasers, providers, researchers, etc.) need to identify for which sub-classifications of fractures the cost-effectiveness of internal fixation is a potential issue. Having done this, it then needs to be determined whether or not the issue is important enough, in terms of comparative resource usage, to warrant more detailed cost-effectiveness research.

More generally, it would appear that there is a need for the orthopaedic research community to improve the application of economic analysis in its Health Technology Assessment (HTA) research. Ideally, health economists should be involved in the design phase of any research proposals in order to ensure that the research proposed will enable the collation of pertinent economic data. As referred to above, the involvement of the economist is unlikely to add significant research costs. Based upon the literature found for this paper, there would appear to be an issue of improving the details about the costing information presented in many orthopaedic research papers. Significantly, the need to consider the costs falling upon patients and the wider economy has been noted.

4. OPTIONS FOR PURCHASERS AND PROVIDERS

The findings of this review do not readily deliver a series of options, but rather suggestions for action: these are covered in Section 5.

5. DISCUSSION AND CONCLUSIONS

Discussion at a meeting of the Trent Working Group on Acute Purchasing showed near unanimity rather than mere consensus on distal radius fractures, although tibial shaft fractures were less explicitly addressed. There is a clear view that research has so far answered few questions. It was felt that the Trent orthopaedic network and the data it collects could contribute greatly to the debate, especially if it were supported better.

It is recommended that:

Gustilo grade IIIB tibial fractures should be treated by internal fixation (nail), but these cases should be audited to establish deep infection rates; further research will need to establish the best type of internal fixation.

The literature provides little or no evidence to indicate the relative benefits of internal fixation versus other treatments for other classifications of tibial shaft fractures. The potential for economic benefits has been particularly poorly addressed. However, the greater use of in-patient beds for internal fixations could impact on the availability of beds for cost-effective orthopaedic surgery such as knee and hip replacements, thus increasing waiting lists.

The literature provides little or no evidence to indicate the relative benefits of primary internal fixation versus other treatments for fractures of the distal radius.

There was some consensus amongst clinicians involved in discussing this paper:

Distal radius fractures should be managed conservatively in the vast majority of elderly patients; A&E departments should have access to an appropriate anaesthetic service to ensure that such patients can be managed without recourse to admission (with subsequent discharge problems). This should have some impact on ‘winter pressures’. Some more complex fractures, such as displaced comminuted fractures, may best be treated by external fixation, especially in the under 50 age group.

More research is needed, directed at the broad economic implications of the treatment options. In the small number of papers which did attempt some form of economic analysis, the quality of the analysis could have been improved significantly. In particular, the direct and indirect costs to patients and society were not analysed sufficiently.

Classification systems need to be developed further for routine clinical use which can predict outcomes and guide treatment choice.

Given the orthopaedic research network already established in Trent and the contribution it makes to the literature, serious thought should be given to Regional Research and Development (R&D) funding being directed at enhancing that network. The way in which the Trent Institute for Health Services Research was established could be used as a model (i.e. for a Trent Institute for Orthopaedic Research).

A review of the management of distal forearm fractures is awaited from the Cochrane Collaboration, but has been delayed significantly by the complexities of the topic. A meta-analysis of three methods of treatment for closed fractures of the tibia, including internal fixation, and published after this paper was first written, also concluded that the available research evidence was poor and of little use for decision making.

APPENDIX A

FRACTURE CLASSIFICATIONS

Fracture classifications are developed with a view to guiding both treatment and prognosis, and, as such, they also assist in comparison of clinical studies.

1. Tibial Shaft Fracture Classifications

Tibial shaft fractures have traditionally been classified according to the site of the fracture along the shaft and its configuration (transverse, oblique, spiral, etc.). Displacement has been described in terms of angular deformity and shift, normalised to the width of the shaft. Clinical studies have, however, suggested that outcome is related most closely to the degree of force involved in the injury, and the degree of soft tissue injury. The almost universally used system for the classification of open fractures is that of Gustilo and Anderson.[5] In Type I injuries, the wound is clean and less than 1cm in length. In Type II, the wound is longer than 1cm but without extensive damage, flaps or avulsions. In Type III, soft tissue damage is extensive, or the underlying fracture is segmental. In 1984, Type III injuries were further classified as IIIa, with adequate soft tissue coverage, or lesser degrees of compounding but with high-energy trauma; IIIb, with extensive periosteal stripping and bone exposure, usually with severe contamination; and IIIc, an open fracture associated with arterial injury requiring repair. As can be imagined, there is scope for interobserver variation with such a clinical system, but outcomes in most studies are found to be related to the Gustilo grade.

Gustilo Classification of Open Tibial Fractures:

- Gustilo classification describes soft tissue injury, but does not necessarily describe fracture comminution;

- Grade I:
  - wound less than 1 cm with minimal soft tissue injury;
  - wound bed is clean;
  - bone injury is simple with minimal comminution;
  - with intramedullary nailing, average time to union is 21-28 weeks*.

- Grade II:
  - wound is greater than 1 cm with moderate soft tissue injury;
  - wound bed is moderately contaminated;
  - fracture contains moderate comminution;
  - with intramedullary nailing, average time to union is 26-28 weeks*.

- Grade III:
  - following fracture automatically results in classification as type III:
    - segmental fracture with displacement;
    - fracture with diaphyseal segmental loss;
    - fracture with associated vascular injury requiring repair;
    - farmyard injuries or highly contaminated wounds;
    - high velocity gun shot wound;
    - fracture caused by crushing force from fast moving vehicle.

  - Grade III a fracture:
    - wound greater than 10 cm with crushed tissue and contamination;
    - soft tissue coverage of bone is usually possible;
    - with intramedullary nailing, average time to union is 30-35 weeks*.

  - Grade III b fracture:
    - wound greater than 10 cm with crushed tissue and contamination;
    - soft tissue is inadequate and requires regional or free flap;
    - with intramedullary nailing, average time to union is 30-35 weeks*.

  - Grade III c fracture:
    - a fracture in which there is a major vascular injury requiring repair for limb salvage;
    - fractures can be classified using the mangled extremity severity score (MESS);
    - in some cases it will be necessary to consider below knee amputation following tibial fracture.

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*'Times to Union' quoted in this appendix should only be viewed as approximate figures due to subjectivity surrounding the definition of the term 'union'.

2. Distal Radius

Many such systems have been devised, but for the common Colles' fracture of the distal radius the most commonly used are probably variants of the Gartland and Werley[18] system and the Frykman[17] method. In the former, fractures are divided into intra- and extra-articular groups, which are further divided according to the presence of displacement and stability. In the latter, fractures are divided according to the involvement of the radiocarpal joint, the distal radio-ulnar joint, both, or neither, and further subdivided according to the presence or absence of a concurrent ulnar fracture. Fractures of the distal radius other than the Colles' type are uncommon: in a Smith's fracture the angulation is volar rather than dorsal, and in a Barton's fracture the volar lip of the distal radial articular surface is displaced proximally.

Frykman Classification of Distal Radius Fracture:

Fracture	**Distal Ulnar Fracture:**	
	Absent	**Present**
Extra articular	I	II
Intra articular involving radiocarpal joint	III	IV
Intra articular involving distal RU joint	V	VI
Intra articular involving both radiocarpal & distal radioulnar joints	VII	VIII

Discussion:

- Frykman classification considers involvement of radiocarpal & radioulnar joint, in addition to presence or absence of fracture of ulnar styloid process;
- classification does not include extent or direction of initial displacement, dorsal comminution, or shortening of the distal fragment; hence, it is less useful in evaluating outcome of treatment.

Universal Classification of Dorsal Displaced Radius Fractures;

- Type I: extra articular, undisplaced;
- Type II: extra articular, displaced;
- Type III intra articular, undisplaced;
- Type IV: intra articular, displaced.

Melone Classification for Distal Radius Fractures:

- Components: Shaft, Radial Styloid, and Dorsal Medial and Palmar Medial Parts;

- Type I:
    - Colles' fracture equivalent: undisplaced and minimally comminuted.

- Type II:
    - die punch fracture: unstable with moderate to severe displacement;
    - similar to Mayo class II: displaced fracture involving radioscaphoid joint;
    - radioscaphoid joint fracture: involves more than radial styloid (Chauffeur fracture) and has significant dorsal angulation and radial shortening;
    - may require stabilisation provided by external fixators, along with percutaneous pins, to maintain an accurate reduction.

- Type IIb (irreducible):
    - this is a double die punch fracture which is an irreducible injury;
        - dorsal medial component fragmentation;
        - persistent radiocarpal incongruity > than 2 mm;
        - radial shortening > 3 - 5 mm;
        - dorsal tilting & displacement > of 10 degrees
        - radiocarpal step off > 5 mm (on a lateral view);
    - may require open treatment for restoration of articular congruity;
    - may require open reduction and internal fixation (ORIF) of radiocarpal articular surface, supplementary external fixation and iliac bone grafting.

- Type III:
    - is die punch or lunate load fracture, and is often irreducible by traction alone;
    - involves additional fracture from shaft of radius that projects into flexor compartment;
    - Mayo equivalent: are displaced involving the radiolunate joint;
    - may require fixation with small screws or wires in conjunction with closed or limited open articular surgery.

- Type IV:
    - transverse split of articular surfaces with rotational displacement;
    - Mayo equivalent is a displaced fracture involving both radioscaphoid and lunate joints, and the sigmoid fossa of the distal radius;
    - is often a more comminuted fracture involving all of major joint articular surfaces, and almost always includes fracture component into distal radioulnar joint.

APPENDIX B Summary of Publications Purporting to Undertake Comparative or Economic Analysis

Author	Journal	Year	Bone	Open V Closed Fractures	Stable/ Unstable	Class	Economics	Patients	Type of Article/Trial	Interventions	Paper's Recommendations	Our Comments
Murphy NM et al.[12]	Cochrane	1997	Distal radius	All	All	All	No	Adults	Review	All		Having great difficulty due to wide range of procedures and quality of papers
Pritchett[14]	J Bone & Joint Surg	1995	Wrist (colles)	Open	Unstable	Frykman type viii	Yes	Adults	Randomised	External fixation versus closed medullary pinning	Medullary pinning should be the treatment of choice	Similar results, but pinning was cheaper and greater patient satisfaction. Costing not explained. No societal costs.
Mcqueen MM[19]	J Bone & Joint Surg	1995	Distal radius		Unstable	A3.2 to C3.2	No	>15 years	Prospective Randomised Trial	External fixation w & w/o mobilisation, open reduction and bone graft, remanip. and plaster.	Dilemma of how best to treat remains	Quotes many references. No clear story emerges. Numerous statistical analyses.
Frykman GK[20]	Hand Clin	1993	Wrist		Unstable				Comparative	External fixation	Vague	Descriptive comparison of fixators
Mennen U[21]	S Afr J of Surg	1993	Distal radius;-comminuted intra-articular	Both		Frykman 8,2,4,5,6,7.	No	Adults	Descriptive	External fixator with plaster	Only for well motivated patients with good bone stock	Small sample of 27. No indication of how it compares with other methods.
Antich-Adrover P[22]	J Bone Joint Surg Br	1997	Tibia	Open		Gustilo II IIIa and IIIb	No, but some resource usage info		Prospective randomised trial	External followed by secondary cast or nailing	Recommend secondary nailing	Authors say that nailing is also more efficient, but the evidence they present could contradict this.
Dervin GF[6]	Clin Orth and Rel Res	1996	Tibia	Open		Grade IIIb	No, but some useful resource use information	Adults	Meta-analysis using randomised studies	External fixation versus unreamed intramedullary nailing	Not enough evidence to choose between them. Need for more well designed randomised trials	2 randomised trials reported. (Tornetta and Henley) Does not refer to TU paper results
Court_Brown CM[23]	J Bone Joint Surg Br	1996	Tibia	Closed		Tscherne C1	No, but time to return to work is indicated		Prospective randomised trial	Reamed versus unreamed nailing	Do not use unreamed nails for these fractures	Faster union times reported, but no difference in time taken to return to work. Small sample. Reduced need for 2nd operation.
Tu YK[7]	J Trauma	1995	Tibia	Open		Grade IIIa and IIIb	No, but some useful resource use info (key exclusions)	Adults >16 years	Prospective randomised study	External fixation versus inter-locking unreamed intramedullary nailing	Recommends internal fixation for IIIa but not for IIIb (infection rates)	Can this be appended to Dervin work? Small Sample
Shaw DL[4]	J R Coll Surg Edinb	1995	Tibial shaft	Closed and compound	Unstable	Closed, grade I and II compound	Yes, but only NHS costs	>17 years	Observational comparison	Orthofix external fixator compared with other treatments	The use of a dynamisable unilateral external fixator is both clinically justified and cost-effective	Costing was simple; no randomisation.
Tornetta P[6]	J Bone Joint Surg Br	1994	Tibia	Open		Grade IIIb	No, but some useful resource use info.	>19 years	Randomised prospective study	External fixation and non-reamed locked nails	Locked non-reamed nails is the treatment of choice for grade iiiB open tibial fractures	Small sample. Results in Dervin 1996. Controversy over grading of iiib fractures. Good summary of results from published papers.
Hooper GJ[15]	J Bone Joint Surg Br	1991	Tibial shaft	Both	Displaced	Grade II and III compound excluded	Some good resource use information	Skeletally Mature	Randomised prospective study	Conservative management versus closed IM nailing	IM nailing is the 'most efficient' treatment for these fractures.	Sample size better than most, no cost calculations, but information presented.
Den Outer AJ[24]	Clin Orthop	1990	Tibial Shaft	Closed and 1st degree open	Displaced	Noncomminuted, a1. a2 and a3	Some discussion but vague and no indirect costs.	>16 years	Retrospective comparative study	Conservative (mainly functional bracing) versus operative (mainly plate fixation)	Conservative management favoured because less discomfort and cost contained	Sample 170, but smaller once differences are allowed for. The costs comments do not appear to allow for patient and indirect costs to the economy.
Kay L[25]	Injury	1986	Tibia	Both		Oblique, Transverse and comminuted. NOT proximal or distal	No, but good info on time to healing.	All	Observational and comparative	Conservative treatment versus internal fixation	No recommendations. Indicates almost double the length of time in hospital and time to full weight-bearing for conservative patients	Much potentially useful information, but the classification is different from that encountered in most other papers
Cannon SR[13]	Injury	1985	Mainly Tibia and Fibula	Both		Grade 2 and 3	Yes, but no supporting evidence.		Case studies	External fixation	External fixation for initial treatment of grade 2 and 3 open fractures. Also on closed unstable fractures.	Descriptive only
Lourie JA[26]	PNG Med J	1983	Tibia	Compound	Unstable		No		Case study			Very early and basic.

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