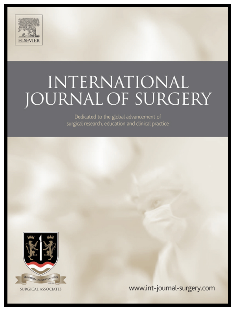
Accepted Manuscript



The Implants used for Intramedullary Fixation of Distal Fibula Fractures: A Review of Literature

Haroon Rehman, William T. Gardner, Iain Rankin, Alan J. Johnstone

PII: S1743-9191(18)31512-7

DOI: 10.1016/j.ijsu.2018.06.019

Reference: IJSU 4697

To appear in: *International Journal of Surgery*

Received Date: 23 February 2018

Revised Date: 22 May 2018

Accepted Date: 11 June 2018

The Implants used for Intramedullary Fixation of Distal Fibula Fractures: A Review of Literature.

Mr Haroon Rehman MBChB, MRCS, MSc[1†]

Mr William T Gardner[2]

Mr Iain Rankin MBChB, MRCS

Professor Alan J Johnstone FRCS (T&O)[1]

[1]Aberdeen Royal Infirmary, Foresterhill, Aberdeen, AB25 2ZN

[2]University of Aberdeen

[†]Corresponding Author

haroon.rehman.06@aberdeen.ac.uk

No sources of financial support were required for the production of this article

Key words: Intramedullary, nail, fibula, lateral malleolus, fracture

The Implants used for Intra-medullary Fixation of the Distal Fibula.

Abstract

Background

Ankle fractures are amongst the most common surgically treated musculoskeletal injuries. Intramedullary (IM) fixation of the lateral malleolus had been attempted as early as the 1990s. In recent years, dedicated implants have emerged. This review evaluates the design characteristics of the technology used to perform IM fixation of distal fibular fractures.

Materials and methods

A search of electronic databases was performed. Medical subject headings (MeSH) and free-text terms were used to optimise search sensitivity and specificity.

Results

We identified 10 different surgical technologies for IM fixation of lateral malleolar fractures reported across 12 articles, including both improvised and custom-designed Orthopaedic implants. Most implants were inserted through percutaneous surgical techniques.

Conclusion

Advances in technology have improved the feasibility of intramedullary fixation as a treatment option for lateral malleolus fractures. The implants we reviewed had very diverse morphological and mechanical properties. Intra-medullary fixation may outperform extra-medullary fixation of the lateral malleolus, particularly in patients at high risk of soft tissue complications. Robust scientific evidence is awaited.

Level of evidence Level IV evidence.

Key words: Intramedullary, nail, fibula, lateral malleolus, fracture

Introduction

The use of intramedullary (IM) devices has expanded in recent years to include the distal fibula, in tandem with the move towards minimally invasive surgical approaches in other areas of orthopaedic surgery. Ankle fractures are amongst the most common musculoskeletal injuries treated with an operation.[1-3] Conventional surgical treatment is open reduction followed by internal fixation using plates and screws as described by the AO group[4]. However soft tissue fragility, swelling or compromise can pose significant challenges for surgeons. Minimally invasive plate osteosynthesis (MIPO) has been developed to address such cases although these techniques involve deep tissue dissection.[5]

Intramedullary devices for ankle fractures are a continually evolving technology. Implants range from screws and rod-like spikes to modern, bespoke IM fibular nails. Intramedullary fixation may potentially reduce wound complications, symptomatic metalwork and improved recovery times. The biomechanical advantages of IM over traditional plate fixation have been extensively described. Nails are load-sharing implants, whereas plates are load bearing implants. There is usually less stress shielding, reduced risk of peri-implant fractures, and the injured limb can be loaded earlier. IM devices can be inserted through minimal dissection. The weak evidence base and variety of implants does however create dubiety over the effectiveness of this technology in clinical practice and may subsequently hinder uptake.

The primary aims of this review are to evaluate the surgical devices that have been used to treat distal fibular fractures with IM fixation. We provide discussion on the design and biomechanical strengths and weaknesses.

Methods

A search of the following electronic databases was performed: Cochrane Central Register of Controlled Clinical Trials (CENTRAL); MEDLINE (OvidSP); Embase (OvidSP) and WHO international trial register. Medical subject headings (MeSH) and free-text terms were used to optimise search sensitivity and specificity: unstable, ankle/fibula fracture, nail, pin, rod and intramedullary fixation. Bibliographies of papers were hand searched for any additional studies not obtained through electronic search. Images and user manuals were reviewed where possible. Inclusion/Exclusion Criteria are listed in Table 1.

Primary data extraction

Technical descriptions of fracture fixation and descriptions of the technology used.

Secondary data extraction

Outcomes were extracted if standardised data was presented on union rates, complication rates, functional scores and radiological scores were recorded.

Results

Our literature search identified 10 different surgical technologies for IM fixation of lateral malleolar fractures reported across 12 articles. The number of patients described in the articles ranged from 9 to 194. Only 3 techniques were evaluated by Randomised Controlled

Trial,[6-8] and 7 techniques in 9 case series alone.[9-18] Some techniques were reported in multiple publications.

Secondary outcome measures

Functional Scoring was undertaken in 6 studies using the method devised by Olerud and Molander[19] in 1984. Standardised radiological scoring of reduction was reported in 7 studies. A good reduction was defined as no fibular shortening, a posterior displacement of less than 2mm and a 1mm increase in medial clear space. A fair reduction represented fibular shortening of 2mm, posterior displacement of 2-4mm and a 1-3mm increase in medial clear space. A poor reduction was defined as a fibular shortening in excess of 2mm, posterior displacement of over 4mm and greater than 3 mm increase in medial clear space.

Study characteristics and secondary outcome data is presented in Table 2.

Surgical Techniques & Implants

Preparation and approach to the fibula

Patients were operated on in the supine position or lateral decubitus position depending on surgeon preference. No tourniquet was used in the majority of cases. Generally, all authors describe a *percutaneous* approach to the fibula.

Fluoroscopy was used in every case. Where present, medial malleolar fractures were treated based on the fracture characteristics and surgeon preference. In most cases using partially threaded lag screws or tension band wiring constructs were used. Less frequently a small plate and screws.

Rush Rods (Berivon, Meridian, MS, USA)

Pritchett[7] described treatment of unstable ankle fractures using percutaneously inserted 3.2mm Rush Rods. Rush rods are steel rods with a chisel-like tip that can be inserted into the intramedullary space without reaming. After pre-contouring, the Rush rods were inserted through a drill hole made at the tip of the fibula. Patients were allowed to weight-bear as tolerated with aids; the use of cast immobilisation was unclear from the authors' technical description.

Knowles Pins (Zimmer, Warsaw, IL)

The Knowles pin was used to stabilise fibular fractures in a 45 patient cases series.[14,20] Knowles pins are collared pins that are partially threaded from tip to midshaft, made from stainless steel. The authors describe an extensile approach in their article, making an incision from the tip of the fibula extended 1 cm proximal to the fracture to facilitate direct fracture reduction using a bone holding forceps. The entry drill hole was made 2mm medial to the tip of the fibula.

ANK Nail (manufacturer unspecified)

The ANK Nail was a steel rod with a curved anterior limb and distal loop for additional fixation to the tibia conferring "stability" to the syndesmosis[10] (Figure 1). The device was not fixed proximally. The authors approached the fibula using a linear incision placed along the lateral malleolus, curved anteriorly (reverse 'J' incision) to expose the anterior tibio-fibular junction. This incision facilitated fixation of the implant to the tibia distally. Fracture reduction was achieved under direct vision and maintained with a bone-holding forceps. The nail was inserted over a standard K-wire.

Inyo Nail (Richards Medial Company, Memphis, Tennessee, USA)

The Inyo Nail was trialled by McLennan et al.[9,21] This device relied on its wedge design for improved bone contact within the metaphyseal bone. It was a 90mm v-shape, tapered nail made from malleable stainless steel (ATSM F138), with holes present in the broadened distal end to facilitate removal should this be required (Figure 2). To allow implantation the distal ridge of the lateral malleolus was osteotomised via a linear 2-3cm incision. The Intramedullary canal was then prepared with a 2.3mm dental burr prior to nail insertion over a Steinmann Pin (Zimmer, Warsaw, Indiana).

Epiphysa fibular nail (manufacturer unspecified)

The Epiphysa fibular nail is described by Francois et al [15] for in a 39 patient case series. The device is a smooth straight rod with a round profile and threaded head that was available in three different lengths. The head engages the metaphysis but the device is not fixed proximally. The exact surgical technique is unclear from the article.

Epifisa®Nail (FH Orthopaedics Inc, New York, USA)

Asloum et al[8] trialled a contemporary nail which combines a curved shaft with a self-tapping threaded head (Figure 3). It is available in four lengths, ranging from 70 to 130mm. The authors described a percutaneous approach but there is lack of clarity concerning the techniques used to reduce the fracture, maintain alignment, and prepare the intramedullary canal. All patients were immobilised in a cast post-operatively, but were permitted progressive weight-bearing once the wound had healed.

Acumed Fibular Rod ((Hillsboro, Oregon, USA)

This nail is made of solid titanium and comes in two diameters (3mm and 3.6mm) and three lengths (110mm, 145mm and 180mm). It was designed specifically for percutaneous fixation of the lateral malleolus [6] (Figure 4). Insertion involves a number of stages. The tip of the fibula is used as an entry point. A cannulated drill is passed over a 1.6mm guide wire to prepare the distal metaphysis. The diaphysis can be further hand-reamed prior to nail insertion. The device allows distal anterio-posterior locking screws, and lateral to medial trans-implant tibial / 'syndesmosis' screw. In initial reports it was recommended a proximal blocking screw be inserted to prevent shortening but this practice has since been discontinued[22]

XS Nail (Intraplant, Endocare, Germany)

The XS nail is a cylindrical implant with uniform diameters of 4.5mm or 3.5mm.[13] Lengths range from 197mm to 272mm and it has between 4 to 11 locking holes that are 9mm apart. Proximally, screws can be inserted across the fibula and into the tibia to provide additional stability. This implant is cannulated and is inserted over a central guidewire pre-positioned within the intramedullary canal. A radiolucent aiming device is used to facilitate cross-locking screw insertion. Compression of the fracture can be achieved through one of two oblong compression holes, either side of the implants centre-point.

SST® (Stainless Steel Taper) Nail (Biomet, Warsaw, IN, USA)

The SST Nail is a slender, tapered, cannulated rod made of stainless steel, with screw holes that permit distal locking. It is described in two case series.[16,17] Both groups used the interlocking feature of the implant and allowed progressive weight-bearing over a period of 4 to 6 weeks after the wound had healed.

Acutrak Plus Compression Screw (Acumed Inc., Beaverton, OR, USA)

The Acutrak plus compression screw is a fully-threaded, cannulated, tapered, headless screw with a variable pitch measuring 5mm at its tip, and expanding to 6.5mm at its tail. The screw is inserted over a guide pin. Fixation using this implant is described by Lee et al.[18] In their study, the authors exposed both the tip of the fibula and the fracture site to permit accurate fracture reduction with bone holding forceps while the screw was being inserted.

Percutaneous Screw Fixation

Fixation using stainless steel screws has been described in two papers, Ray et al[12] and Smith et al.[11]

Smith et al used closed reduction of the fracture and direct digital pressure over the fracture to maintain reduction. Through a 1cm inline incision made approximately 1.5cm distal to the tip of the fibula, a 2.5mm drill was used to open the distal 1.5 cm of the fibula permitting the insertion of a fully threaded 100mm long, 4mm cancellous screw. The authors aimed to implant the screw such that the thread would engage the inner aspect of the diaphyseal canal proximally. The tensile properties of the screw reduce the tendency for talar shift. Ray et al[12] also used a 4.2mm fully threaded, self-tapping screw (Woodruff, Zimmer, Warsaw, IN) measuring between 2.5 and 4 inches long, though the thread pitch is unclear.

Patients were not allowed to weight bear for 6 weeks post-operatively in either of the studies.

Discussion

The increasing incidence of low-energy, unstable ankle fractures in elderly patients with poor soft tissue and bone quality challenges contemporary trauma surgeons.[3,23] Demand for safe and reliable fixation techniques has encouraged surgeon scientists and innovators to advance minimally invasive techniques. Intramedullary fixation is a conceptually straightforward technique relying on well-established principles, already applied in current practice. It does not require substantial training or education.

The procedure can be unforgiving due to the limited ‘inline’ single axis the implant must follow proximally into the diaphysis. Off-axis positioning of rigid implants and reamers in ‘soft’ bone can result in fracture malalignment, or iatrogenic fracture. Care should be taken to achieve a good entry point, which ideally should be screened intra-operatively with both antero-posterior and lateral views using image intensifier. Obese patients or particularly swollen ankles add further complexity to the procedure. At the beginning of the learning curve, patient selection is essential to avoid conversions, lengthy operating times and further compromise to the soft tissue envelope. The reduced number of steps in IM nailing should reduce operating time. However, achieving and maintaining closed reduction in highly comminuted or displaced fractures can be technically challenging and consume more time than expected initially.

The majority of authors describe closed reduction and a percutaneous approach to the fibula for introduction of their specific implant. Generally, the rate of wound complications reported was higher for the plate group in studies using a comparator.[7,8,14] This may reflect the longer skin incisions for traditional ORIF, compared to the 1-2 cm incisions required for nails. Modern implants do not require extensive dissection. Preventing exposure of the fracture to the external environment and thus preserving fracture 'biology', non-union and deep infection rates should be lower. Extensive dissection and direct visualisation of the fracture negates the benefits of smaller incisions for nails, especially in cases of swelling.

An additional benefit of intra-medullary implants is reduced potential for symptomatic metalwork. Brown et al have reported that as much as 31% (n=126 patients) experienced pain in the skin overlying hardware.[24] Where AP cross-locking screws options are available the screws must not be too long, to prevent peroneal tendon injury.

The mechanical advantages of intramedullary devices are conferred by way of lying on the central longitudinal bony axis and therefore implants are not subject to the same cantilever forces as plates lying on one side of bone. Smith et al[25] studied the mechanics of the fibular nail in fresh frozen cadaveric legs with oblique Weber[26,27] A fractures *but no medial lesion*. The limbs were then mounted on a Zwick tensile biomechanical testing apparatus and stressed to failure using an external rotation force. The study demonstrated a higher load to failure for the limbs stabilised with a fibular nail compared to a standard AO lag-screw and plate construct which sits "off-axis".

There is much heterogeneity between implant designs. Intramedullary fixation of metaphyseal bone is dissimilar to diaphyseal fixation due to reduced implant-bone contact at the metaphysis. Compared to slender implants such as screws, Rush rods or Knowles pin, tapered and or morphologically contoured devices should give improved reduction and stability through greater load sharing and working length. However, an implant which is not fixed to bone at two or more points creates an inherently unstable biomechanical construct which will fail to resist shortening and rotation. Although tapered implants are certainly one solution, metalwork migration may still be a problem. Ten percent of patients treated with the Inyo nail required removal of the implant due to hardware prominence or proximal migration. There was also a high rate of malunion with the wedge fit implant, presumably as fracture were fixed with malalignment, or displacing during implantation or loading. Exceptions may apply to devices with variable, cross-locking features. Cross locking proximally through tapered, modern implants is often not possible due to the narrowness of the fibula's diaphysis. The XS nail does offer proximal locking but at the expense of width. A uniform diameter may result in these implants being too large for the fibular diaphysis.

Bugler et al initially used a proximal "blocking" screw as the solution to shortening with the Acumed Fibular Rod, although this practice was later discontinued due to the risk of fracture. A relatively robust construct with Acumed nail can be achieved by routinely filling the syndesmosis screw hole.

We are aware of one device, the Fibulock nail (Sonoma Orthopaedic Products Inc), which is unpublished in medical literature that utilises expanding fins proximally to offer better stability. Despite the design properties, such implants are again often wider than their counterparts due to the internal mechanisms. Caution should be taken in using 'wide', non-tapered implants as they pose high risk of iatrogenic fracture. Similarly, surgeons should avoid over-dilating the intramedullary canal during the reaming process.

Screw fixation is a reasonable and inexpensive improvisation for intramedullary fixation. Screws and nails have different mechanical properties. Bone purchase through the threads of an adequately sized screw should prevent shortening. Such a feature also theoretically allows a bridging type fixation of slightly comminuted bone. A well positioned screw should also function as internal buttress, maintaining talar reduction by exerting medially directed forces against the internal medial cortex through 'elastic recoil'. Although all screws can be applied in compression mode, the variable pitch on an Acturak is probably more effective in doing so. Despite the absence of a cross-locking option with screws, Banskton et al[28] have demonstrated rotational stability equal to plate and lag screw fixation in cadavers with experimentally produced Weber B fractures (n=16). Specimens were placed under torsional load to failure. This rotational stability presumably arises from the fracture ends interlocking and opposing each other and would not apply to situations where there is a high degree of comminution.

It is unclear from the literature whether the proposed advantages of intramedullary nails are outweighed by implant costs. The reduced complications and early return to activity on a weight-bearing construct may make the technique more cost-effective. Methods using 'improvised' intramedullary implants such as fixation with percutaneous screws are inexpensive and viable alternatives to commercial products.

The poor level of evidence and range of implants can plunge one into a mire of uncertainty, in selecting an intramedullary technique. It is important to focus on the physiological insult the approach will deliver, and mechanical stability the implant offers. Based on past trends it is likely future technology will remain morphologically contoured. This region of the human body does not accommodate a 'one size fits all' implant. Although a range of sizes in commercial products are available, a potential development may be patient-specific intra-medullary nails. Such devices could be made intra-operatively using materials such as resin or cement if a kit were available.

Limitations

Much of the current literature exists in the form of commentary and small case series. Although reasonable attempts at systematic review and meta-analysis have been made,[29,30] lack of standardised outcome measures and adequately powered randomised controlled trials limits meaningful conclusions. Many of the early implants are no longer commercially available. Then trend in both literature and technology would suggest that for high-risk patients, intramedullary distal fibula fixation is becoming an accepted, ‘emergency’ procedure within the surgical community. However, the individual studies do have potential for selection bias because the primary aim of the authors is to present their technique or implant, with subsequent favourable patient selection for cases in the experimental arm. Authors used broadly similar inclusion criteria, elderly patients with unstable ankle fractures avoiding cases in which there was a serious soft tissue insult. Our paper has focused on techniques rather than reported outcomes.

Conclusion

Nails may outperform plate and screws for fixation of the lateral malleolus in elderly patients at high risk of soft tissue complications. Robust scientific evidence is awaited. This study evaluates and summarises the design aspects of implants used for intramedullary fixation of the fibula. Future research must address cost effectiveness, scientifically assess mechanical differences between implant designs and demonstrate superior health and quality of life outcomes. The implants at the moment remain user dependant. Surgeons should use an implant with characteristics that meet their individual case requirements.

Reference List

[1] C.M. Court-Brown, J. McBirnie, G. Wilson, Adult ankle fractures-an increasing problem? Acta Orthopaedica. 69 (1998) 43-47.

[2] P. Kannus, J. Parkkari, S. Niemi, M. Palvanen, Epidemiology of osteoporotic ankle fractures in elderly persons in Finland, Ann. Intern. Med. 125 (1996) 975-978.

[3] P. Kannus, M. Palvanen, S. Niemi, J. Parkkari, M. Jrvinen, Increasing number and incidence of low-trauma ankle fractures in elderly people: Finnish statistics during 1970–2000 and projections for the future, Bone. 31 (2002) 430-433.

[4] M. Muller, Manual of internal fixation techniques recommended by the AO-ASIF group, (1991).

[5] F. Hess, C. Sommer, Minimally invasive plate osteosynthesis of the distal fibula with the locking compression plate: first experience of 20 cases, J. Orthop. Trauma. 25 (2011) 110-115.

[6] K. Bugler, T. White, P. Appleton, M. McQueen, A Prospective, Randomised Controlled Trial of a Fibular Nail versus Standard Open Reduction and Internal Fixation for Fixation of Ankle Fractures in Elderly Patient, Bone & Joint Journal Orthopaedic Proceedings Supplement. 95 (2013) 8-8.

[7] J.W. Pritchett, Rush rods versus plate osteosyntheses for unstable ankle fractures in the elderly, Orthop. Rev. 22 (1993) 691-696.

[8] Y. Asloum, B. Bedin, T. Roger, J. Charissoux, J. Arnaud, C. Mabit, Internal fixation of the fibula in ankle fractures. A prospective, randomized and comparative study: plating versus nailing, Orthopaedics & Traumatology: Surgery & Research. 100 (2014) S255-S259.

[9] J.G. McLennan, J.A. Ungersma, A new approach to the treatment of ankle fractures: the Inyo nail, Clin. Orthop. 213 (1986) 125-136.

[10] A.N. Kara, C.Z. Esenyel, B.T. Sener, E. Merih, A different approach to the treatment of the lateral malleolar fractures with syndesmosis injury: the ANK nail, The Journal of foot and ankle surgery. 38 (1999) 394-402.

[11] M. Smith, G. Medlock, A.J. Johnstone, Percutaneous screw fixation of unstable ankle fractures in patients with poor soft tissues and significant co-morbidities, Foot and Ankle Surgery. (2015).

[12] T.D. Ray, P. Nimityongskul, L.D. Anderson, Percutaneous intramedullary fixation of lateral malleolus fractures: technique and report of early results, Journal of Trauma-Injury, Infection, and Critical Care. 36 (1994) 669-675.

[13] J. Gehr, W. Neber, F. Hilsenbeck, W. Friedl, New concepts in the treatment of ankle joint fractures, Arch. Orthop. Trauma Surg. 124 (2004) 96-103.

[14] Y. Lee, H. Huang, T. Lo, C. Huang, Lateral fixation of AO type-B2 ankle fractures in the elderly: the Knowles pin versus the plate, Int. Orthop. 31 (2007) 817-821.

[15] M. François, N. Inal, E. Nassar, A. Benrahho, B. Moujawaz, The "epiphysa" fibular nail-45 Cases during 30 months, European Journal of Orthopaedic Surgery & Traumatology. 8 (1998) 81-83.

[16] A. Rajeev, S. Senevirathna, S. Radha, N. Kashayap, Functional outcomes after fibula locking nail for fragility fractures of the ankle, The Journal of Foot and Ankle Surgery. 50 (2011) 547-550.

[17] P. Ramasamy, P. Sherry, The role of a fibular nail in the management of Weber type B ankle fractures in elderly patients with osteoporotic bone—a preliminary report, Injury. 32 (2001) 477-485.

[18] Y. Lee, T. Hsu, C. Huang, S. Chen, Lateral fixation of AO type-B2 ankle fractures: the Acutrak plus compression screw technique, Int. Orthop. 34 (2010) 903-907.

[19] C. Olerud, H. Molander, A scoring scale for symptom evaluation after ankle fracture, Arch. Orthop. Trauma Surg. 103 (1984) 190-194.

[20] Y. Lee, C. Huang, C. Chen, C. Lin, Operative treatment of displaced lateral malleolar fractures: the Knowles pin technique, J. Orthop. Trauma. 19 (2005) 192-197.

[21] J.G. McLennan, J. Ungersma, Evaluation of the treatment of ankle fractures with the Inyo nail, J. Orthop. Trauma. 2 (1988) 272-276.

[22] K. Bugler, C. Watson, A. Hardie, P. Appleton, M. McQueen, T. White, The treatment of unstable fractures of the ankle using the Acumed fibular nail Development of a technique, Journal of Bone & Joint Surgery, British Volume. 94 (2012) 1107-1112.

[23] K.J. Koval, J. Lurie, W. Zhou, M.B. Sparks, R.V. Cantu, S.M. Sporer, J. Weinstein, Ankle fractures in the elderly: what you get depends on where you live and who you see, J. Orthop. Trauma. 19 (2005) 635-639.

[24] O.L. Brown, D.R. Dirschl, W.T. Obremskey, Incidence of hardware-related pain and its effect on functional outcomes after open reduction and internal fixation of ankle fractures, J. Orthop. Trauma. 15 (2001) 271-274.

[25] Smith G, Wallace R, Findlater G, White T., The fibular nail: a biomechanical study [abstract].
, Procs Seventh SICOT/SIROT Anuual International Conference, Gothenburg,. (2010).

[26] B.G. Weber, Die Verletzungen Des Oberen Sprunggelenkes, Huber, 1966.

[27] R. Danis, Les fractures malleolaires, Theorie et pratique de l'osteosynthese.Paris: Masson. (1949) 133-165.

[28] A.B. Bankston, L.D. Anderson, P. Nimityongskul, Intramedullary screw fixation of lateral malleolus fractures, Foot & Ankle International. 15 (1994) 599-607.

[29] S. Jain, B.A. Haughton, C. Brew, Intramedullary fixation of distal fibular fractures: a systematic review of clinical and functional outcomes, Journal of Orthopaedics and Traumatology. 15 (2014) 245-254.

[30] H. Rehman, T. McMillan, S. Rehman, A. Clement, D. Finlayson, Intrmedullary versus extramedullary fixation of lateral malleolus fractures, International Journal of Surgery. 22 (2015) 54-61.

Inclusion Criteria	Exclusion Criteria
• All study designs • All studies in humans of any age • Original Studies, Biomechanical studies, case reports, review articles • All patients had been diagnosed preoperatively by imaging techniques including x-rays and CT. • Studies conducted on patients with unstable fracture of the distal fibula (lateral malleolus).	• Experimental studies • Insufficient data to allow analysis • Studies with Duplicate Techniques by a single group of authors • Intramedullary devices described for use in the tibia • Intramedullary devices described for proximal fibula/diaphysis • Commentary • Letters

Table 1 – Inclusion/ Exclusion Criteria

Implant/ authors	Study type	Participants	Secondary outcomes	Current commercial availability
rush rod • Pritchett eta al	RCT	n=25	Infection (n=0); non-union(n=25) "poor" radiological result (n=5)	Available
Knowles Pin • Lee et al	Case series	n=45	"Good" fracture reduction (95%); average operating time (22min); complications (n=0); symptomatic hardware (n=0)	Available
Inyo nail • McLennan et al	Case Series	n=75	non-union (0); infection (0); malunion (7%); removal metalwork (10%); Good radiological result (80%); good functional outcome (85%) (return to previous activity level with no pain or stiffness);	Not available
Fibular nail • Bugler et al	RCT	n=100	Infection (0); wound problems (0)	Available
Ank nail • Kara et al	Case series	n=139	Fibular shortening (11)	Not available. Customised implant
Accutrak Screw • Lee et al	Case Series	n=23	"Good" reduction (95.7%); mean operating time (25.3min); superficial wound infection (1); At long-term follow-up, 91.3% (21) patients reported good or excellent results	Not avialbe
Cortical screw • Smith et al • Ray et al	Case series Case series	n=24	Infection (0); symptomatic hardware (1) – metalwork removed; "Good" reduction (21); "good/ excellent" function (16)	Available
Epiphysa nail • Francois et al	Case series	n=39		Not available
Epifisa Nail • Asloum et al	RCT	n=28	All patients rated their function as "excellent" despite there being a 7% post-operative complication rate.	Available
XS nail • Gehr et al	Case series	n=194	Superifical haematoma (2); superficial infection (1); metalwork migration (2); "good" or "excellent" outcomes (91.5%)	Available
SST Nail • Ramansay et al • Rajeev et al	Case Series Case Series	n=9 n=24	"Excellent/ good" outcome (88%); "poor" radiologic result (2) Complication (0); Olerud and Molander score at 1 year (58.125 +/- 6.00, fair outcome)	Available

Table 2: Study characteristics and secondary outcome data.

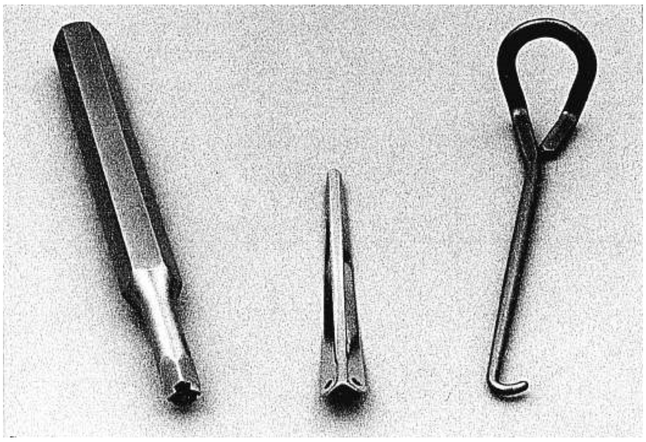



Figure 1 – Inyo Nail. Introducer, Nail and extractor (left to right).

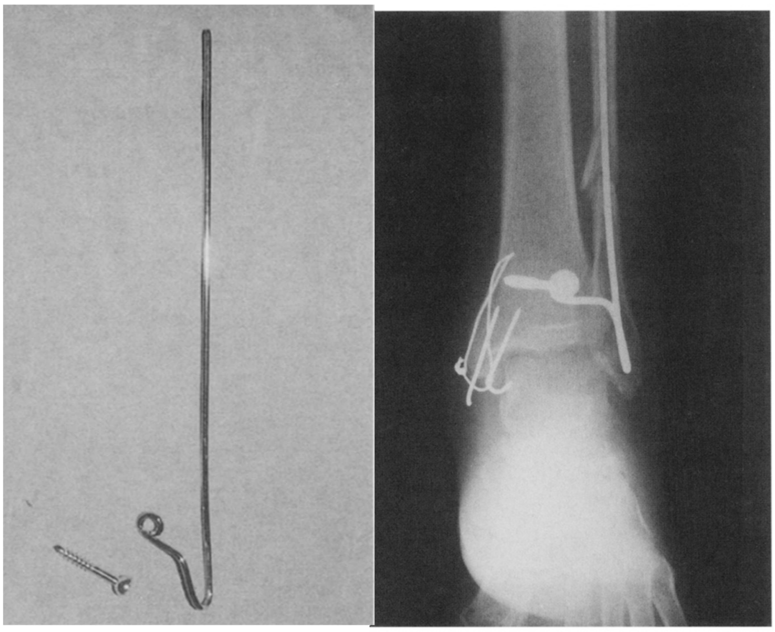


Figure 2 – ANK nail

Figure 3 – Epifisa Nail

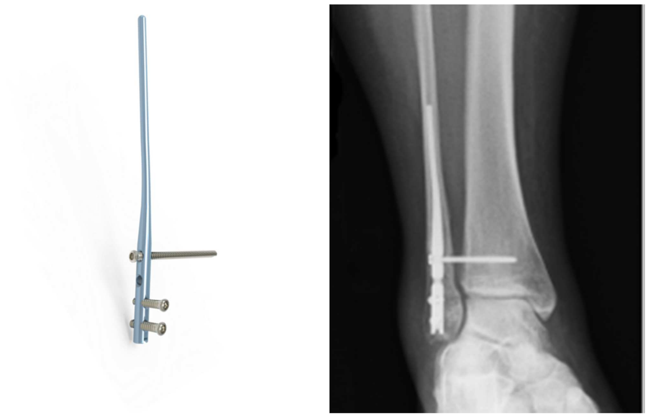


Figure 4 – Accumed Fibular rod

- The design failure of some of the older devices has resulted in them being phased out
- Most devices can be inserted percutaneously
- Modern device control for rotation with cross locking screws or taper fit
- There is a need for adequately powered, scientific trials and biomechanical studies.