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# Transarticular tibiotalocalcaneal nailing versus open reduction and internal fixation for treatment of the elderly ankle fracture: protocol for a multicentre, prospective, randomised controlled trial

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## ABSTRACT

**Introduction** Ankle fractures are common in the elderly population. Surgical fixation is technically challenging and often results in complications due to high rates of osteoporosis and vascular disease. Open reduction and internal fixation (ORIF) often requires prolonged periods of non-weight bearing increasing the risks of complications. Tibiotalocalcaneal (TTC) nailing has been suggested as an alternative to ORIF which allows immediate weight bearing, and is suggested to result in fewer complications. This study aims to compare the two surgical techniques in the elderly population with ankle fractures.

**Methods and analysis** The study will be a multicentre, prospective, randomised controlled trial comparing ORIF to TTC nailing in 110 patients with ankle fractures aged 50 or above with a Charlson Comorbidity Index of greater than or equal to four. Participants and assessors will not be blinded to intervention. The primary outcome measure will be overall complication rate. Secondary outcomes include length of hospital stay, mobility at discharge, discharge destination, the American Orthopaedic Foot and Ankle Society Ankle-Hindfoot score, the Olerud-Molander Ankle Score, mortality rate, rate of secondary surgical interventions and number of blood transfusions required postoperatively. Our null hypothesis is that there is no clinically significant difference in the primary outcome measure between the two treatment groups.

**Ethics and dissemination** The study has been approved by Metro South Hospital and Health Services Human Research Ethics Committee (EC00167) (reference number HREC/17/QPAH/351).

**Discussion** Completion of this trial will provide evidence on the effectiveness of TTC nailing versus ORIF in treatment of the elderly ankle fracture. If TTC nailing is found to result in superior outcomes, this trial has the capacity to change current clinical practice.

## Strengths and limitations of this study

- ► Tibiotalocalcaneal nailing is a novel intervention for management of ankle fractures, which if proven to result in superior outcomes than open reduction and internal fixation may change clinical practice.
- ► Randomisation minimises the risk of selection bias.
- ► Multicentre study design will increase generalisability.
- ► Lack of blinding of surgeons, participants and assessors may result in bias.

**Trial registration number** ACTRN12617001588381;Pre-results andU1111-1203-1704.

## BACKGROUND

Ankle fractures in the elderly population are common and comprise the third most common extremity fracture in this demographic.[1–4] Like fragility fractures of the hip, elderly ankle fractures occur frequently in osteoporotic patients following low energy trauma, most commonly a fall from standing height.[5] Ankle fractures in this population are associated with significant morbidity and mortality, with 12-month mortality rates described as between 11.9% and 27%.[6–8] With an ageing population worldwide, the incidence of elderly ankle fractures and their impact on healthcare systems and society is expected to become greater with time.[9–12]

The mainstay of treatment for unstable ankle fracture patterns is open reduction and internal fixation (ORIF), which results in improved fracture reduction, higher rates of union and superior patient outcomes

when compared with non-operative management.[4 8 12–18] However, a high prevalence of osteoporosis makes fracture fixation technically challenging and increases the rate of failure.[12 19 20] Tenuous fixation often requires a prolonged period of non-weight bearing, putting the elderly patient at risk of pressure sores, pneumonia and venous-thromboembolic events.[12 21–23] Furthermore, elderly patient's poor soft tissue and compromised vasculature increase local wound complications.[21 24 25]

Tibiotalocalcaneal (TTC) nailing has been suggested as an alternative to ORIF in the management of ankle fractures in the elderly patients. The technique is minimally invasive and allows for immediate weight bearing, with reports in the literature suggesting a lower complication rate than ORIF.[19 21 26 27] Trials have shown a high return to premorbid level of mobility and patient satisfaction following TTC nailing. However, there is a paucity of comparative trials, with the majority of the literature concerning TTC nailing in elderly ankle fractures being limited to a small number of case series.[19 21 26 27]

One randomised controlled trial (RCT) has directly compared TTC nailing with ORIF.[28] In 2017, an RCT of 87 participants aged 70 years and older found a reduction in postoperative complications, hospital length of stay and mortality in patients treated with TTC nailing when compared with ORIF.[28] However, the study suffered from poor reporting—there was no reporting of scientific methods for the primary outcome measure, the sample size nor the method of randomisation. It was reported that there were 43 participants in the TTC nailing group and 44 participants in the ORIF group. However, the results of the trial are calculated on groups of 37 and 36 respectively without clear explanation to the change in numbers. These shortcoming results of this trial must be interpreted with caution, and further robust RCTs are needed to substantiate TTC as a valid technique in the elderly ankle fracture patient.

The purpose of this study is to directly compare TTC nailing with ORIF in the management of unstable ankle fractures in the elderly via an RCT study design. The primary hypothesis is that TTC nailing results in fewer complications when compared with ORIF.

## METHODS

### Study design

The following protocol has been developed per Standard Protocol Items: Recommendations for Interventional Trials guidelines.[29] This study will be a multicentre, prospective, RCT comparing the outcome following either TTC or ORIF in elderly patients with unstable ankle fractures. The trial will be conducted in three tertiary hospitals in Queensland, Australia with more centres expected to be recruited over the duration of the trial. Study sites are included in the online supplementary appendices of this protocol.

Blinding is inherently difficult in surgical trials, and neither surgeons nor participants will be blinded to treatment allocation. An independent statistician performing statistical analysis will be blinded to allocation groups.

### Recruitment and consent

The study population will be individuals aged 50 years or over presenting to participating institutions with an isolated, displaced and closed ankle fracture. Individuals must have a Charlson Comorbidity Index (CCI) of four or greater to be eligible to participate. The CCI predicts 10-year mortality, with stepwise increases in cumulative mortality with each level of the index.[30] It has been shown in orthopaedics trials to correlate significantly with complications and mortality rate.[31 32]

Eligible individuals will be invited to take part in the trial. Written information along with a detailed explanation of the trial will be given by a member of the research team. Consenting patients meeting all inclusion criteria and none of the exclusion criteria will be enrolled in the study.

### Study participants

#### Inclusion criteria

- Isolated, displaced and closed ankle fracture.
- Age greater than or equal to 50.
- CCI greater than or equal to four.
- Unstable fracture or fracture dislocation determined by treating team to require operative intervention.

#### Exclusion criteria

- Periprosthetic fractures.
- Open fractures.
- Patient medically not fit for surgery.
- Requirement of removal of previous metalwork.
- Cognitive impairment limiting ability to give informed consent.
- Significant language barrier limiting ability to give informed consent.

### Baseline measures

The following will be collected from all participants preoperatively:

1. Age.
2. Sex.
3. CCI.
4. Residence.
5. Mechanism of injury.
6. Classification of injury (AO/OTA classification[33]).
7. Associated injuries.
8. Olerud-Molander Ankle Score (OMAS).

### Treatment allocation

Individuals consenting to participate in the trial will be randomised to surgery either by TTC or by conventional ORIF. A 24-hour randomisation service will be provided by Sealed Envelope. The sequence will be stratified by study centre and age (<80 or >80), and allocated in random blocks of four, six and eight. Age over 80 has been shown to be a major risk of complications

following ankle fracture.[34] Stratified randomisation has been recommended for clinical trials with less than 200 participants per treatment arm.[35]

## Intervention

All operations are to be performed by consultants or their trainees under direct supervision. Level of seniority of surgeon will be recorded. Patients are positioned supine on a radiolucent table with a sandbag under the ipsilateral hip. All patients will receive intravenous antibiotics. A tourniquet will be used for all operations.

TTC nailing will be performed using the Styker T2 Ankle Arthrodesis Nail. The patient's foot is positioned in neutral dorsoplantar flexion, 5°–10° of external rotation and 5° of hindfoot valgus. Closed reduction of the fracture is performed under image intensifier (II) guidance. The longitudinal axis of the calcaneus and tibia are marked on the patient using a Kirschner wire (K-wire) and a marking pen. A 2–3 cm longitudinal incision is made at the intersection of the marked lines, followed by soft tissue dissection to gain access to the plantar aspect of the calcaneus. A K-wire is then inserted through the incision, and after confirmation of positioning with II, it is progressed through the calcaneus, across the subtalar and talocrural joints and into the tibial medullary canal. A rigid reamer is used over the wire and reamed until it reaches the medullary canal of the tibia.

A ball-tipped guide is then passed into the tibia with sequential reaming over the wire to 1–1.5 mm greater than the nail diameter previously selected. A long (300-mm) nail will be used, as shorter nails are associated with a higher rate of anterior tibial pain and periprosthetic fracture.[19] The nail is then locked with one screw proximally through the dynamic hole of the nail tibial shaft, and two distally in the calcaneus in orthogonal planes. Skin will be closed with 3.0 nylon interrupted sutures. Patients will be placed in a cam walker and allowed to full weight bear day 1 postoperatively.

ORIF will be performed using AO principles via a medial and lateral approach. Fibular fixation will be performed either using dynamic compression plating (DCP) (1/3 tubular plate with 3.5 mm screws), or with locking compression plates (LCP). The choice of DCP or LCP will be left to the discretion of the orthopaedic consultant in charge of the case. Medial malleolus fixation and posterior malleolus fracture fixation, if required, will be carried out. Closure of the wounds will be in layers with 2.0 vicryl to deeper layers, and 3.0 nylon interrupted sutures to skin. A below knee plaster of paris back slab will be applied.

In both groups, II will be used to assess quality of reduction intraoperatively and saved to the local Picture Archiving and Communication System. If any concern arises regarding the quality of images from II during surgery, day 1 postoperative X-rays will be obtained.

## Postoperative management

Participants in the TTC nailing group will have no weight-bearing restrictions and will mobilise as tolerated day 1 postoperatively under the guidance of a physiotherapist.

Participants in the ORIF group will be non-weight bearing for 2 weeks in a plaster cast. At 2 weeks, the cast will be exchanged for a controlled ankle motion (CAM) walking boot. Participants will remain non-weight bearing for a further 4 weeks, but will be allowed to remove the boot for simple range of motion exercises. If clinical assessment and radiographs performed 6 weeks postoperative are satisfactory, all patients will be allowed to weight bear as tolerated in a CAM walking boot.

## Outcome measures

The primary outcome measure will be overall complication rate, which will be a composite score of the following:

- Superficial wound infection.
- Deep surgical infection.
- Wound dehiscence
- Failure of metalwork.
- Iatrogenic fracture.
- Periprosthetic fracture.

Secondary outcome measures include the following:

1. Length of stay.
   a. Acute hospital length of stay.
   b. Total hospital length of stay.
2. Non-union.
3. Blood transfusions.
4. Medical complications.
5. Mobility at discharge.
6. Discharge destination.
7. The American Orthopaedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot score at 3, 6, 12 and 24 months postoperatively.
8. The OMAS at 3, 6, 12 and 24 months postoperatively.
9. Rate of secondary interventions.
10. Mortality rate.
11. EuroQol 5 Dimensions (EQ-5D) quality of life outcome measure.

Surgical complications include wound infection, wound dehiscence, deep surgical infection, intraoperative fracture and periprosthetic fractures. A composite score of surgical complications will be the primary outcome measure. The requirement for blood transfusions will be determined from participant's electronic health record over the intraoperative and postoperative period. All medical complications will be recorded, including deep vein thrombosis and pulmonary embolus.

Length of hospital stay will include both acute hospital length of stay, and total length of stay in the cases of patients discharged to a rehabilitation facility. Complications will be recorded from medical records.

Non-union will be assessed at 9 months postoperatively, and is defined as failure of fracture to unite in three of four cortices on two radiographs taken in perpendicular planes, with the absence of progressive signs of healing over the course of 3 consecutive months.[36]

At discharge from hospital, mobility and destination will be recorded. Mobility status at discharge will be assessed by a qualified physiotherapist, and categorised as follows:

1. Independent with no additional assistance.
2. Single point stick/walking stick.
3. Crutches.
4. Four-wheeled walker.
5. Hopper frame.
6. Wheelchair users.
7. Bed bound.

Destination will be categorised as participant's normal residence, supported accommodation, rehabilitation facility or nursing home.

The AOFAS Ankle-Hindfoot scale combines subjective patient reported outcomes with objective, clinician measured outcomes to form a 100-point scale.[37] The maximal combined score is 100 points which indicates that the participant has no pain nor functional deficit. The clinician measured that part of the scale has been validated and shown to be reliable.[38]

The OMAS is self-administered questionnaire used to determine functional outcomes following ankle fracture,[39] and has been shown to be a valid and reliable measurement tool for ankle fractures.[40] It would be expected that the TTC nailing group will have poor stiffness scores; however, the measure has been included due to use in previous studies of TTC nailing thereby allowing results to be collated in future meta-analyses.[19 26 28]

Secondary intervention required for infection, implant failure, metalwork failure, to relieve pain or improve function will be recorded from medical records. This will be followed for the entirety of the study duration.

Mortality data will be recorded for intrahospital deaths. Out of hospital deaths will be confirmed by Australia's Births, Deaths and Marriages registry. The 30-day, 90-day, 1-year and 2-year mortality rates will be recorded.

The EQ-5D is a questionnaire validated for measuring health-related quality of life. The EQ-5D-3L has been validated for use in chronic pain, and has been shown to have good test–retest reliability.[41 42] The EQ-5D-3L will be administered preoperatively, and at 3, 6 and 12 months postoperatively.

A timeline of the study period may be seen in online supplementary table 1.

## Follow-up

All participants will be reviewed as per standard of care at our hospital for the targeted patient group, with reviews at 2 weeks, 6 weeks, 3 months, 6 months, 12 months and 24 months. Anteroposterior and lateral X-rays will be taken at all reviews except for the initial 2-week wound review. A member of the research team will review participant secondary outcome measures at each appointment.

## Sample size calculation

One RCT has previously compared ORIF with TTC nailing, reporting complication rates of 33% and 8%, respectively.[28] To reject the null hypothesis that complications rates are equal between groups, 40 subjects are needed per group with power set at 80%. The Type I error probability associated with this test of this null hypothesis is 5%. We will use an uncorrected $\chi^2$ statistic to evaluate this null hypothesis. Previous studies have indicated a mortality rate in similar cohorts of 10%–20%.[6–8 28] With an expected 10% loss to follow-up and 20% mortality rate gives 53 participants in each group which has been rounded to 110 participants total.

Prior analysis of incidence at the primary institute has indicated the requirement of additional centres to achieve recommended sample size. If recruitment numbers remain low, additional institutes will be invited to participate to reach the target sample size.

## Data collection and management

Data collection will be primarily electronically based. Data collected by local site investigators will be sent securely to principle investigator at the primary institution. All data will be deidentified prior to sending. Data will be stored on a password protected computer in a locked office in the primary institution. Personal information collected at recruitment will be kept in paper format at the local institution in a locked filing cabinet. Five years following the conclusion of the trial, all paper copies of personal information will be destroyed.

An attempt will be made to minimise missing data. Multiple contact details will be taken at recruitment including telephone numbers, mobile telephone numbers, addresses and email addresses. A system of reminders will be used to ensure participant return to clinic is as complete as possible. Phone contact and written letter with appointment details will be sent prior to appointments. Participants who do not attend clinic will be contacted via phone, email and written letter. This will be repeated twice at 2 weekly intervals. Failure to respond after third attempt at contact will result in a participant being deemed as lost to follow-up.

## Data analysis

All data will be entered into a password protected excel database. Statistical analyses will be conducted using SPSS or Stata. Data will be reported on following CONsolidated Standards Of Reporting Trials (CONSORT) guidelines.[43]

The characteristics of the sample allocated to each arm of the trial will be described and any differences between groups in potential confounding variables (eg, clinical characteristics) will be examined using appropriate inferential statistics for between group comparisons (eg, Fisher's exact test) using baseline data. Data related to potential benefit of TTC nailing versus ORIF will be analysed using 'intention-to-treat' principle, defined as participants being analysed according to their randomly allocated study group regardless of treatment received, who completed follow-up data collection and who received the recommended length of interventions. To examine the potential effect of TTC nailing versus ORIF, potential between group differences in

primary and secondary outcomes will be examined using generalised linear mixed models (using appropriate family functions and transformations where necessary, dependent on the characteristics of observed data). For variables collected at multiple assessment points, all time-points will be included to allow non-biased estimates of treatment effect in the presence of any potential missing cases, providing data are missing at random. However, a sensitivity analysis to missing data will also be carried out using multiple imputation if >10% of data are missing to ensure that there are no unexpected biases. This approach also permits adjustment for any between group differences in potential confounders at baseline (eg, age, sex and body mass index). Significance will be set at less than 0.05. An attempt will be made to minimise missing data by ensuring adherence to follow-up. This will include recording multiple contact details for participants where possible at the time of recruitment to maximise ability to contact participants who fail to attend a scheduled follow-up appointment.

### Patient and public involvement

TTC nailing is often used as a 'salvage operation' in elderly ankle fractures following failed fixation, but there is limited literature on its use as a primary treatment modality. The research question was developed to address this. Patients were not involved in the design of the study, the recruitment or conduct of the study. Results of this trial will be available through publication in a peer-reviewed journal, and at national orthopaedic scientific meetings. The burden of intervention will not be assessed by patients.

## ETHICS AND DISSEMINATION

### Safety

This trial compares a new surgical intervention with the current standard of care. A previous RCT has indicated a reduction in surgical and medical complications with use of this technique.[28] While serious adverse events with TTC nailing are not anticipated, an independent data safety monitoring board will be established at commencement of this trial. This board will meet at 6 months following the commencement of this trial for interim analysis.

Following conclusion of the trial, participant follow-up will follow local participating institute guidelines. Any detrimental medical effects on participants as a result of the trial will be managed at the local institution as appropriate for the individual case.

### Ethics

Any protocol modifications will be reported to the HREC, trial registry, publisher of protocol and individual trial participants. All adverse events will be reported the HREC committee.

Confidentiality of personal participant data will be managed as discussed previously in data collection and management.

### Dissemination

The results of the study will be presented at national orthopaedic scientific meetings such as the Australian Orthopaedic Association Annual Scientific Meeting. Results will be published in an orthopaedic or general medical journal following completion of the trial. Data will be reported on following CONSORT guidelines.[43]

Any protocol modifications or amendments will be communicated to the local HREC, trial registry and publishing journal.

## DISCUSSION

Unstable ankle fractures in the elderly pose a management dilemma due to poor bone and soft tissue quality and often numerous comorbidities of the patient. Operative management with TTC nailing is less invasive and allows for early mobilisation and would be expected to result in earlier recovery with less complications when compared with ORIF.

To date there have been four case series and one RCT on this subject. Lemon *et al* reported on a case series of 12 patients, with no cases of non-union nor delayed union, and all patients satisfied with outcome of treatment.[26] Amirfeyz *et al* found no intraoperative complications; however had one revision due to varus malalignment and one death due to postoperative bronchopneumonia in a case series of 13 participants with a mean age of 78.9[21]. All patients returned to preoperative mobility and had minimal pain at final follow-up.[21] Jonas *et al* reported on a number of surgical complications, including three periprosthetic fractures and two broken nails.[27] In a subsequent case series of 48 participants in 2014 by Al-Nammari *et al*, a long nail which crosses the isthmus of the tibia was recommended as it avoided the risk of periprosthetic fracture,[19] and it could be inferred that the complications reported by Jonas *et al* were due to use of a short TTC nail.

Georgiannos *et al* performed the only RCT to date comparing TTC nailing to ORIF, reporting a lower mortality rate (13.9% vs 18.1%) and a lower complication rate (8.1% vs 33.3%) in the TTC nailing group.[28] There was no significant difference between the groups with respect to hospital length of stay, return to premorbid mobility and functional outcome scores. However as outlined previously, there are a number of inconsistencies in the reporting of the study, and any recommendations for clinical practice using this literature should be interpreted with caution. The literature to date surrounding TTC nailing for the elderly ankle fracture is promising; however, there is currently no high quality, level I evidence to support its use.

It is clear that there is an important need for a definitive trial to guide practice, and if our study hypothesis is proven correct, this study has the capacity for a paradigm shift in elderly ankle fracture management. Strengths of this study include randomisation and the multicentre study design, which improves generalisability of results, along with the use of the CCI for inclusion criteria.

Additionally, leaving the choice of using LCP or DCP plates for the ORIF group up to surgeon discretion reflects current practice. Using a CCI of four or greater rather than a strict age criterion allows inclusion of younger patients with significant comorbidities that would be at risk of complications in ankle fracture surgery. Likewise, it excludes the healthy, active older individual for whom TTC nailing would limit ankle ROM and function.

Limitations of this study is the lack of blinding of participating surgeons, participants and assessors. Blinding was not used in this study—it is impossible to blind the participating surgeons to operative technique, and rigidity of the ankle joint post TTC nailing would be obvious to participants and assessors.

Inclusion of participants into the trial will commence in December 2017, with data collection expected to be complete by the end of 2019. With follow-up of 2 years, the data will be expected to be presented during the course of 2021.

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**Contributors** CM, MH and KT conceived the study. PT, MH, KT, JV and CM developed the current protocol. All authors read and approved the final manuscript.

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**Patient consent for publication** Not required.

**Ethics approval** This study was granted ethics approval by the Metro South Human Research Ethics Committee (EC00167) HREC/17/QPAH/351).

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## REFERENCES

1. Makwana NK, Bhowal B, Harper WM, *et al*. Conservative versus operative treatment for displaced ankle fractures in patients over 55 years of age. A prospective, randomised study. *J Bone Joint Surg Br* 2001;83:525–9.
2. Court-Brown CM, McBirnie J, Wilson G. Adult ankle fractures–an increasing problem? *Acta Orthop Scand* 1998;69:43–7.
3. Sporer SM, Weinstein JN, Koval KJ. The geographic incidence and treatment variation of common fractures of elderly patients. *J Am Acad Orthop Surg* 2006;14:246–55.
4. Kurar L. Clinical audit of ankle fracture management in the elderly. *Ann Med Surg* 2016;6:96–101.
5. Bugler KE, Clement ND, Duckworth AD, *et al*. Open ankle fractures: who gets them and why? *Arch Orthop Trauma Surg* 2015;135:297–303.
6. Hsu RY, Lee Y, Hayda R, *et al*. Morbidity and mortality associated with geriatric ankle fractures: a medicare part A claims database analysis. *J Bone Joint Surg Am* 2015;97:1748–55.
7. Toole WP, Elliott M, Hankins D, *et al*. Are low-energy open ankle fractures in the elderly the new geriatric hip fracture? *J Foot Ankle Surg* 2015;54:203–6.
8. Wijendra A, Alwe R, Lamyman M, *et al*. Low energy open ankle fractures in the elderly: Outcome and treatment algorithm. *Injury* 2017;48:763–9.
9. Kannus P, Palvanen M, Niemi S, *et al*. Increasing number and incidence of low-trauma ankle fractures in elderly people: Finnish statistics during 1970-2000 and projections for the future. *Bone* 2002;31:430–3.
10. Thur CK, Edgren G, Jansson KÅ, *et al*. Epidemiology of adult ankle fractures in Sweden between 1987 and 2004: a population-based study of 91,410 Swedish inpatients. *Acta Orthop* 2012;83:276–81.
11. Hoogervorst P, Bergen CV, Van den Bekerom M. Management of Osteoporotic and Neuropathic Ankle Fractures in the Elderly. *Curr Geriatr Rep* 2017;6:9–14.
12. Strauss EJ, Egol KA. The management of ankle fractures in the elderly. *Injury* 2007;38(Suppl 3):2–9.
13. Keene DJ, Mistry D, Nam J, *et al*. The Ankle Injury Management (AIM) trial: a pragmatic, multicentre, equivalence randomised controlled trial and economic evaluation comparing close contact casting with open surgical reduction and internal fixation in the treatment of unstable ankle fractures in patients aged over 60 years. *Health Technol Assess* 2016;20:1–158.
14. Ehrenfreund T, Haluzan D, Dobric I, *et al*. Operative management of unstable ankle fractures in the elderly: our institutional experience. *Injury* 2013;44(Suppl 3):S20–2.
15. Anand N, Klenerman L. Ankle fractures in the elderly: MUA versus ORIF. *Injury* 1993;24:116–20.
16. Ali MS, McLaren CA, Rouholamin E, *et al*. Ankle fractures in the elderly: nonoperative or operative treatment. *J Orthop Trauma* 1987;1:275–80.
17. Bariteau JT, Hsu RY, Mor V, *et al*. Operative versus nonoperative treatment of geriatric ankle fractures: a Medicare Part A claims database analysis. *Foot Ankle Int* 2015;36:648–55.
18. Phillips WA, Schwartz HS, Keller CS, *et al*. A prospective, randomized study of the management of severe ankle fractures. *J Bone Joint Surg Am* 1985;67:67–78.
19. Al-Nammari SS, Dawson-Bowling S, Amin A, *et al*. Fragility fractures of the ankle in the frail elderly patient: treatment with a long calcaneotalotibial nail. *Bone Joint J* 2014;96-B:817–22.
20. Olsen JR, Hunter J, Baumhauer JF. Osteoporotic ankle fractures. *Orthop Clin North Am* 2013;44:225–41.
21. Amirfeyz R, Bacon A, Ling J, *et al*. Fixation of ankle fragility fractures by tibiotalocalcaneal nail. *Arch Orthop Trauma Surg* 2008;128:423–8.
22. Teasell R, Dittmer DK. Complications of immobilization and bed rest. Part 2: Other complications. *Can Fam Physician* 1993;39:1440–6.
23. Prandoni P. Acquired risk factors for venous thromboembolism in medical patients. *Hematology Am Soc Hematol Educ Program* 2005:458–61.
24. Srinivasan CM, Moran CG. Internal fixation of ankle fractures in the very elderly. *Injury* 2001;32:559–63.
25. Buckingham RA, Hepple S, Winson IG. Outcome of ankle fractures in the elderly. *Foot and Ankle Surgery* 2000;6:175–8.
26. Lemon M, Somayaji HS, Khaleel A, *et al*. Fragility fractures of the ankle: stabilisation with an expandable calcaneotalotibial nail. *J Bone Joint Surg Br* 2005;87:809–13.
27. Jonas SC, Young AF, Curwen CH, *et al*. Functional outcome following tibio-talar-calcaneal nailing for unstable osteoporotic ankle fractures. *Injury* 2013;44:994–7.
28. Georgiannos D, Lampridis V, Bisbinas I. Fragility fractures of the ankle in the elderly: Open reduction and internal fixation versus tibio-talo-calcaneal nailing: Short-term results of a prospective randomized-controlled study. *Injury* 2017;48:519–24.
29. Chan AW, Tetzlaff JM, Altman DG, *et al*. SPIRIT 2013 Statement: defining standard protocol items for clinical trials. *Rev Panam Salud Publica* 2015;38:506–14.
30. Charlson ME, Pompei P, Ales KL, *et al*. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis* 1987;40:373–83.
31. Yian E, Zhou H, Schreiber A, *et al*. Early Hospital Readmission and Mortality Risk after Surgical Treatment of Proximal Humerus Fractures in a Community-Based Health Care Organization. *Perm J* 2016;20:47–52.

32. Lakomkin N, Goz V, Lajam CM, *et al*. Higher Modified Charlson Index Scores Are Associated With Increased Incidence of Complications, Transfusion Events, and Length of Stay Following Revision Hip Arthroplasty. *J Arthroplasty* 2017;32:1121–4.
33. Anon. Malleolar segment. *J Orthop Trauma* 2018;32(Suppl 1):S65–70.
34. Varenne Y, Curado J, Asloum Y, *et al*. Analysis of risk factors of the postoperative complications of surgical treatment of ankle fractures in the elderly: A series of 477 patients. *Orthop Traumatol Surg Res* 2016;102(4 Suppl):S245–8.
35. Kernan WN, Viscoli CM, Makuch RW, *et al*. Stratified randomization for clinical trials. *J Clin Epidemiol* 1999;52:19–26.
36. Bishop JA, Palanca AA, Bellino MJ, *et al*. Assessment of compromised fracture healing. *J Am Acad Orthop Surg* 2012;20:273–82.
37. Kitaoka HB, Alexander IJ, Adelaar RS, *et al*. Clinical rating systems for the ankle-hindfoot, midfoot, hallux, and lesser toes. *Foot Ankle Int* 1994;15:349–53.
38. Ibrahim T, Beiri A, Azzabi M, *et al*. Reliability and validity of the subjective component of the American Orthopaedic Foot and Ankle Society clinical rating scales. *J Foot Ankle Surg* 2007;46:65–74.
39. Wang R, Thur CK, Gutierrez-Farewik EM, *et al*. One year follow-up after operative ankle fractures: a prospective gait analysis study with a multi-segment foot model. *Gait Posture* 2010;31:234–40.
40. Nilsson GM, Eneroth M, Ekdahl CS. The Swedish version of OMAS is a reliable and valid outcome measure for patients with ankle fractures. *BMC Musculoskelet Disord* 2013;14:109.
41. Vartiainen P, Mäntyselkä P, Heiskanen T, *et al*. Validation of EQ-5D and 15D in the assessment of health-related quality of life in chronic pain. *Pain* 2017;158:1577–85.
42. Rabin R, de Charro F. EQ-5D: a measure of health status from the EuroQol Group. *Ann Med* 2001;33:337–43.
43. Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *Int J Surg* 2011;9:672–7.