

EXPERT OPINION ON PUBLISHED ARTICLES

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Prognostic factors for predicting outcomes after intramedullary nailing of the tibia

Study to Prospectively Evaluate Reamed Intramedullary Nails in Patients with Tibial Fractures (SPRINT) investigators
J Bone Joint Surg Am. 2012;**94**:1786–93

'Never nail a tibia, stick to femurs!' remarked one of my first orthopaedic teachers. 'But a nail is a nail is a nail', I retorted. 'Stick to nailing femurs only and you will have a long and happy career' were his parting words, not wanting to be drawn into this topic.

Intramedullary nailing is the most common fixation method for tibial shaft fractures in many centres. It remains true however that to this day more mature orthopaedic surgeons in this country are still not comfortable with the idea of nailing a tibia. This may be due to previous unpleasant experiences with adverse outcomes. If we could identify predictive factors for a poor outcome then this may widen the appeal of tibial nails. The choice of reamed versus unreamed nails has remained controversial despite many studies showing higher re-operation rates with unreamed nails. The biggest criticisms of these studies were sample size and single-institution series reflecting usually the experience of one surgeon.

The commonest reasons for re-operations after tibia intramedullary nailing are non-union, malunion, knee pain, infection and broken implants.

This is the first large-scale, multicentre, multinational, blinded, standardised, randomised controlled trial of tibial shaft fracture fixation with the use of nails. This is a level II multi-centre randomised study of 1 226 patients in which the authors (using multivariable analysis) tried to answer the question of which characteristics are most predictive of risk of a negative outcome after tibial nailing.

Prognostic factors considered included age, sex, fracture morphology, injury mechanism, severity of soft-tissue damage, surgical delay, diabetes, vasculopathy, alcohol use, smoking, corticosteroids, antibiotics, anticoagulants, anticonvulsants, and anti-inflammatory medications.

These patients were part of the SPRINT trial (*JBJS Am* 2008) which suggested a benefit for reamed intramedullary nailing in closed tibia fractures and a potential advantage for unreamed nailing in open fractures.

There was an increased risk of negative events in the following group of patients:

- High energy mechanism of injury
- Stainless steel compared to a titanium nail
- Presence of a residual fracture gap
- Full weight-bearing soon after surgery

Other interesting findings were that there was no increased risk of an adverse event occurring with the use of NSAIDs, late or early time to surgery in open fractures, or smoking status (interestingly).

Patients who had wound management either without any additional procedures or with delayed primary closure had a decreased risk of adverse events compared to patients who had subsequent, more complex soft tissue reconstruction. All other variables proved non-predictive.

When faced with a patient who requires a tibia nail, surgeons should consider the predictors identified in this paper to inform their patients of expected outcomes.

Which characteristics are most predictive of risk of a negative outcome after tibial nailing?

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Use of a negative pressure incisional dressing after surgical treatment of calcaneal fractures

Mark J. Berkowitz, MD

Techniques in Foot and Ankle Surgery December 2013;**12**(4)

This article outlines the surgical approach, blood supply, suturing technique and application of a negative pressure incisional dressing.

Wound breakdown after open reduction and internal fixation (ORIF) of calcaneus fractures remains the most common post-operative complication.



Negative pressure wound therapy applied to a closed incision is a relatively new technique, appearing in the orthopaedic literature in 2006 for the first time.

In 2012 a prospective, randomised clinical trial compared incisional negative pressure wound therapy (NPWT) with traditional dressings in patients with lower limb fractures. The study demonstrated a significant decrease in wound complications with NPWT. Calcaneal fractures treated with NPWT developed over 50% fewer infections compared with traditional dressings.

The most commonly used surgical approach is the extended L-shape incision and flap over the lateral part of the heel. There are six angiosomes that supply arterial blood to the foot and ankle. The lateral hindfoot (elevated skin flap) is supplied by the lateral calcaneal branch of the peroneal artery. The skin posterior and plantar to the incision is supplied by the calcaneal branch of the posterior tibial artery. The surgical incision should be placed between the adjacent angiosomes to avoid jeopardising the blood supply to the skin in the watershed zones.

A deep suction drain should be inserted to prevent a haematoma formation beneath the surgical flap.

The skin is closed using the Allgower modification of the Donati vertical mattress suture. This technique does not violate the epidermis on the flap side of the incision.

Application of the negative pressure dressing is as follows:

- Prepare skin with adhesive to ensure an effective seal.
- Apply plastic strips along the periphery of the incision to protect the surrounding skin from maceration.
- Cut petroleum gauze into strips to cover the suture line.
- Cut the black sponge slightly smaller than the petroleum gauze (it does not have direct contact with the skin).
- Cover the sponge with adhesive plastic to create an airtight seal.
- Apply continuous pressure of 75–100 mmHg.
- Remove the negative pressure dressing after 72 hours and apply a dry dressing.

Wound breakdown will never be completely eliminated. NPWT is a technique that can be used to help prevent this troublesome complication.

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Long term functional outcomes of resected tarsal coalitions

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This is a study with one of the longest follow-up reports published on the results of resection of tarsal coalitions (both talo-calcaneal as well as calcaneo-navicular coalitions).

They reported on 24 patients with 32 tarsal coalition resections, (19 CN and 13 TC feet) with a mean follow-up of 13.4 years after surgery. Calcaneo-navicular (CN) and talo-calcaneal (TC) bars are the two most common types of tarsal coalitions, accounting for 90% of all coalitions. It is estimated that only approximately 25% of patients are symptomatic. The goal of treatment is pain relief and improvement of function. The indication for resection as primary treatment is still controversial.



Primary arthrodesis, either subtalar or triple, has been advocated for TC coalitions with a surface area greater than 50% which is calculated as a percentage of the total cross-sectional area of the coalition against the area of the posterior facet. It has also been accepted that CN bar resections have better outcomes than TC bar resections. They compared the outcome following resections of both CN and TC bars and also evaluated the functional outcomes of patients with TC bars greater than 50% in relation to the area of the posterior facet.

The average size of TC bars with respect to the posterior facet was 57.6% with four bars less than 50% and five bars equal to or greater than 50%. In the CN bar resections they used mainly extensor digitorum brevis as interpositional graft. In the TC bar resections they used fat or wax as interpositional material in seven of the 13 cases; in four they used flexor digitorum longus; and in one FHL. In one they did not use any material. Both the CN and TC groups had one calcaneal osteotomy included. For follow-up evaluation they used the AAOS Foot and Ankle module and the Foot Function Index. No correlation was noted between the outcome scores and size of the TC coalitions. There was also no difference in the outcome scores between the TC and CN groups. The TC coalitions with hind foot valgus less or equal to 16° had comparable outcomes to those greater than 16°. The study demonstrated that for young adults after surgical resection, the majority of patients had relatively little pain and few functional limitations. The number of patients who ultimately quit their sport was much higher in the non-operative group compared with the operative group.

The results in this article differ from the previous accepted treatment based on the article by PH Wilde which reported much worse results if the coalition area was greater than 50% of the size of the posterior facet. Wilde had a much shorter follow-up than in the present article. An aspect that was not mentioned in this report but discussed in the article of Wilde is that talar beaking, which was present in 70% of their cases, is a traction spur rather than an osteoarthritic osteophyte and is not an indication for an arthrodesis, but can be ignored. Narrowing of the posterior facet of the subtalar joint is a sign of degeneration of the subtalar joint and is an indication for an arthrodesis. Although they did not find worse results in feet with valgus of the hind foot of more than 16° it is advisable to address excessive hind foot valgus with a medial displacement calcaneal osteotomy for instance, or an arthroereisis procedure when resecting the coalition. In the light of the good long-term results one should consider resection of a bar first and not opt for a primary arthrodesis in a child or young adult. Resection when performed as an initial procedure does not exclude the possibility of a future arthrodesis, if needed.

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Complications and re-operations after Bristow-Latarjet shoulder stabilization: a systematic review

Michael J. Griesser, Joshua D. Harris, Brett W. McCoy, Waqas M. Hussain, Morgan H. Jones, Julie Y. Bishop, Anthony Miniaci
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Bristow-Latarjet surgery for shoulder instability has undoubtedly become more popular for those patients with recurrent instability and associated significant bone loss. This systematic review by Miniaci *et al* provided some very interesting findings and conclusions. Such a potentially high impact factor study deserves a degree of scrutiny to best interpret its results, certainly with its conclusion suggesting an overall complication rate of up to 30%.

Study design

The design of the review is of interest. The systematic review had a broad remit of analysing any studies published regarding primary Bristow or Latarjet procedures.

The inclusion criteria were very broad and there was no direct effort to assess whether the patients who underwent Bristow or Latarjet surgery had comparable indications or glenohumeral bony changes. No mention was given to the demands of the patient population. Elite athletes and patients in the general population may present with similar pathology; however, they have markedly different needs and expectations.

No discrimination was made regarding the expertise or experience of the surgeon performing the operation. Latarjet surgery is a demanding procedure requiring a diligent surgical approach and dissection, bone and bed preparation and screw placement.

There was a lack of information in the analysis regarding the specific technicalities of the surgery performed. Critical analysis of the steps of the surgical approach was not performed. This meant that details were missed regarding coracoid preparation, musculocutaneous nerve dissection, the number of coracoid screws used and whether these were uni- or bicortical. Also not discussed in the analysis of the individual studies was whether subscapularis was taken down or split or whether the capsule was taken or discarded.

These are all important considerations as they significantly alter the efficacy of the procedure and in turn change the potential complication profile of it. Another important consideration was the method of surgery – open or arthroscopic. Currently only two centres, Boileau and LaFosse, are able to offer meaningful results regarding their experience with this. The conclusion that arthroscopic Latarjet offered fewer complications is potentially confusing. This is because these accepted centres of excellence do not represent the experience or abilities of the average shoulder surgeon. The patient age range is also wide, from 8–69 years. This provides significant heterogeneity to the study population, and performing Latarjet surgery on skeletally immature shoulders is not something practised or advocated by the senior author.

Rehabilitation is of crucial importance to patients following this surgery but is known to be diverse in its timescale and structure. This in turn provides problems with comparing results between the different studies and this is not addressed by the systematic review.

Consideration of individual complications

The study quoted an overall summative risk of 30% regarding Bristow-Latarjet surgery. The study did not stratify the complications but gave each equal weighting irrelevant of the rarity or relevance to the patients’ return to activity. These complications will be discussed in turn with respect to the senior author’s experience.

Some of the documented risks were in keeping with what is seen globally. This includes the documented low infection and haematoma risk. The senior author routinely uses a drain in an attempt to attenuate haematoma formation. Other complications discussed were of greater interest. The quoted fibrous and non-union rates were higher than expected. It is felt that optimising block and bed preparation for good surface apposition along with the use of two bicortical screws help mitigate these concerns along with coracoid lysis. The senior author routinely uses two bicortical screws and has found this sufficient even in the higher demand elite athletes.

Neurovascular injury is always a consideration for all surgeons and so must be respected. The rates quoted by the review are out of character for the procedure in the senior author’s experience. In his practice the musculocutaneous nerve is always dissected and simulated to ensure its integrity during coracoid harvest and mobilisation. The axillary nerve is not routinely seen but lies approximately only 1.5 cm away from the glenoid so careful retraction is advised. Suprascapular nerve injury is unusual but is possible at the spinoglenoid notch with inadvertent drill or screw placement. Brachial plexus injury is very unusual. The thought here is that the surgeon is generally safe with regard to the plexus when the coracoid is still attached; the danger time is post detaching the glenoid block and as such judicious use of traction at this point is crucial. Post-operative subscapularis rupture should be rare especially if the subscapularis is split. A rupture of the tendon implies rupture secondary to detachment post repair. The senior author’s technique is to therefore split the tendon to facilitate coracoid mobilisation. The review does not include osteoarthritis as a complication. This is of interest as this is an accepted risk in this population and would be of interest to see what rates are seen in these study populations. Other rare events such as death and ventricular tachycardia are not generally regarded as orthopaedic-related events and as such are not felt to be of note in discussing with the patient. As the majority of the patients requiring Latarjet are young and many are active sportsmen and women it is of relevance if they failed to return to sports. This could be considered as a more practical and meaningful complication to both the surgeon and patient. This was not considered though in the systematic review.

Overall this study has added more data to the topic of Latarjet surgery; however, the reported overall complication rate of 30% is high and must be interpreted carefully. Potentially use of stricter inclusion and exclusion criteria to more sharply define and limit the study population to open Latarjet procedures performed only by trained subspecialist shoulder surgeons could be of more merit. Despite this the study does provide evidence that such surgery should really only be performed by appropriately experienced subspecialty surgeons and is not one for the generalist.

Such a potentially high impact factor study deserves a degree of scrutiny to best interpret its results, certainly with its conclusion suggesting an overall complication rate of up to 30%

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Complications after open reduction and internal fixation of ankle fractures in the elderly

Michael J Lynde, Travis Sautter, Graham A Hamilton,
John M Schubert
Foot and Ankle Surgery, June 2012;18(2)

This is a retrospective study of 216 patients over the age of 60 years (mean age 70 years) who underwent an open reduction and internal fixation for an ankle fracture. Although it is a retrospective study with some limitations, it looks at three very relevant questions, namely:

1. Is there a higher risk of complications after open reduction and internal fixation of ankle fractures in the elderly because of the co-morbidities associated with advanced age, for instance osteoporosis (with possible resultant hardware failure)? They found that although the complication rates were higher with increased age (and with associated co-morbidities), it was only slight and not of statistical significance. The most common complication was wound dehiscence (9.9%) with the diabetic patients especially at risk.
2. Is it necessary to use a locking plate in the fixation of ankle fractures? They found the conventional non-locking plate to be adequate, with no higher risk of hardware failure compared with the locking plate in this series.
3. The third question they looked at was the risk of early weight bearing in this population (where non-weight bearing mobilisation is extremely difficult). They found that there was no higher incidence of hardware failure in the group that ambulated full weight bearing within the first 2 weeks post-operatively (45 cases). It must be said though, that they were all protected in a short leg walking cast. They also didn't mention the exact type of fracture in these cases.

Although there is some controversy about these fractures in the elderly, the article shows that the results of surgery can be relatively predictable with an acceptable complication rate, and that the use of conventional non-locking plates would be adequate.

The most common complication was wound dehiscence (9.9%) with the diabetic patients especially at risk

Conversion arthrodesis for failed first metatarsophalangeal joint hemiarthroplasty

David M Garras, Joel B Durinka, Michael Bercik,
Adam G Miller, Steven M Raikin
Foot & Ankle International, September 2013;34:1227

This article, reporting on work done in Philadelphia and surgery carried out by SM Raikin is a well-written article.

They looked at the problem of people who had replacement arthroplasties at the MP joints of the big toes for hallux rigidus and now had problems related to the implant. They confined the article only to patients who had had a replacement of the base of the proximal phalanx of the big toe. The reason for this was that the other types of implants caused even more bone loss and they wanted to have a group of patients that were reasonably homogenous to give a clearer picture.

They had 21 patients, all of which went on to fusion, and 18 were available for full follow-up.

The surgery required was always a bone graft but it could be with local cancellous bone or a tricortical graft from the pelvis where there was between 8 and 18 mm of shortening that had to be corrected.

Of interest is that they had patients who, in spite of the implant only being at the base of the proximal phalanx, had severe erosion of the metatarsal head with shortening of the ray.

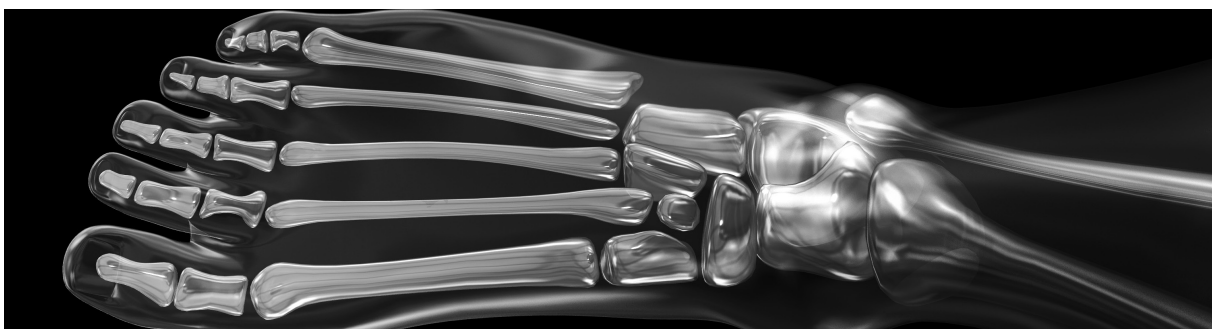
In the cases with severe shortening a plate was used and the time from the first operation to conversion was somewhere between 3 and 168 months, but 72% had failure of the hemiarthroplasties within the first three years.

A large number of the patients required further osteotomies of the lesser metatarsals for transfer metatarsalgia, caused by the relative shortening of the first ray.

The other interesting fact is that men had earlier breakdown of the arthroplasties but their recovery was quicker and they healed well. They also needed less bone grafting.

The article is well written and gives a good warning of the potential dangers of this procedure.

The authors make the point that when an arthroplasty has been performed and it appears to be showing signs of loosening or erosion, conversion of a fusion should be done earlier rather than later.



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Evaluation of oxidation and fatigue damage of retrieved Crossfire polyethylene acetabular cups

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Summary of the article

The purpose of this study was to evaluate retrieved Crossfire acetabular cups to determine whether they have oxidised *in vivo*, to what extent correlation was found with polyethylene degradation and the extent of expected clinical compromise. The study was particularly aimed at proving that more oxidation *in vivo* correlates statistically with a higher degree of polymer structural degradation and consequently higher expectancy for clinical failure.

The difference between Crossfire polyethylene crosslinking (CPC) and other methods (supposedly American) is pointed out in the paper. In the CPC process rod bar stock was gamma irradiated to 75 kGy and then annealed at 130 °C, after which the machining into acetabular cups was carried out. This was followed by gamma sterilisation to an additional 30 kGy. The polyethylene was thus exposed to a total absorbed radiation dose of 105 kGy – resulting in a polymer with a much higher degree of long-lived free radicals in the polymer compared to that of the gamma sterilisation process alone.

Appraisal

The authors did well with the first objective, proving a high oxidation level with the Crossfire technique; however, in respect of the ‘clinical performance’ no results were reported in the study – the latter being a purely engineering assessment.

We agree fully with the last remark of the authors that materials with a limited clinical history should be monitored carefully to ensure an effective performance in patients. The authors seem to be uncertain about the absorbed radiation dose administered – a critical factor in assessing the CPC technique of crosslinking. We agree that an absorbed gamma irradiation dose of only 105 kGy in the absence of any mediating crosslinking agent is not enough to ensure an effect of a ‘high’ degree of crosslinking in the polymer.

The study was particularly aimed at proving that more oxidation in vivo correlates statistically with a higher degree of polymer structural degradation and consequently higher expectancy for clinical failure

In addition, the CPC technique results in a serious problem – long-lived free radicals resulting in the oxidative degradation of the polymer and the ensuing clinical problems.

We have demonstrated as early as 1974 that the presence of a gaseous mediating agent during the gamma crosslinking eliminates both these obstacles. Furthermore, in the CPC technique, no indication is presented on the annealing process – a critical step. Should the gamma crosslinked bar stock be annealed in the presence of oxygen (air), the polymer will be oxidised even *before* the prosthesis is machined from it – especially on the surface!

Methods and materials

A total of 12 retrieved Crossfire cups were received from various surgeons and hips were revised from 1–5.3 years post operation – thus a mean of 2.3 years to failure.

Examination of the 12 cups was done for:

- Fatigue damage (structural degradation) – visual inspection by Nikon 10x dissecting microscope.
- Oxidation: Done by means of spectroscopic infrared analysis and the pattern of *in vivo* changes determined according to the relevant ASTM standard.
- Statistic evaluation: Employing the Spearman rho method – correlation between time *in vivo*, structural degradation (delamination, pitting and cracking). The wear measurement method is not mentioned.

Appraisal

The authors are obviously qualified materials experts. There is no reason to doubt the accuracy and standards of their methods. The choice of statistical models is important and the Spearman rho correlation method was probably the right choice for a non-linear (monotonic) subject such as this study. It has to be pointed out, however, that the choice of our statistics department at the University of Pretoria remains the Pearsons’ and not the Spearman’s rho. (The Pearsons’ rho is particularly useful in smaller series, on condition that the correlation is linear, which, unfortunately, is not the case with the CPC study.)

Results

Six cases exhibited fatigue damage, five cases showed clear impingement, and five showed instability (two with signs of impingement). There was more evidence of oxidation in exposed parts of the cup, while oxidation was least obvious in the articular area – apparently protected by the femoral prosthesis head. The Spearman rho showed strong correlation between time *in vivo* and the structural degradation effects of oxidation.

Appraisal

- This is not a traditional series at all and no clinical evaluation is possible. The small cohort of 12 cases might have 12 from 100 (12%), which would imply extremely poor results with a very high failure rate and a 2.3 years life span. On the other hand, 12 from 1 000 (1.2%) would have been a much better result! Regrettably, we just haven’t got these figures and no clinical appraisal is possible.
- No comparisons could be made between the results from the Crossfire gamma crosslinked polyethylene cups and any other series. On the strength of this investigation there is simply no other comparable series in this study. There is thus a tendency to become anecdotal.
- The series was marred by the selection of an extremely unstable prosthesis. The cups are obviously very shallow, the heads are small and we don’t know the diameter of the neck (probably too thick). Almost 50% instability in only 3 years after surgery is unacceptable and should be withdrawn from the series. Subluxation and impingement can increase the polyethylene damage and confuse the issue.

- The results presented in *Table 1* show the worst results possible. Wear studies in polymer studies are most important in terms of osteolysis, loosening and pain. In this series none of these were seen, since these patients failed even before they had time to develop these complications!

Discussion

The chain of events leading to complications after substandard crosslinking methods are well known: Long-lived free radicals > oxidation > structural degradation > increased wear > polyethylene particle release > osteolysis > loosening > failure. To prevent this grave cascade of events it is imperative that wear should be minimised. The Gammalink® crosslinking technique that was developed and introduced in South Africa in 1974 entails the following fundamental differences with the series discussed in this paper:

- The polyethylene (UHMWPE) bar stock is machined into the final prosthesis before crosslinking. The gamma radiation crosslinking is carried out in the presence of an unsaturated mediating gas at an absorbed radiation dose of 100–140 kGy. Subsequent to the crosslinking process, the prosthesis is annealed for 8 hours at 80 °C in the presence of the mediating gas.
- The presence of the mediating gas is *fundamental* as it enhances the degree of crosslinking on the *surface* of the prosthesis and prevents any oxidation taking place during the annealing thereof by extinguishing all long-lived free radicals on the outer 300 micron of the device.
- The outer surface of the prosthesis thus becomes highly crosslinked and extremely wear and oxidation resistant, while the inner part thereof is less crosslinked, retaining the desirable visco-elastic properties of the prosthesis.

- The prosthesis is double sealed under high purity nitrogen prior to the gamma sterilisation thereof at a minimum absorbed dose of 25 kGy.
- Annual wear is thus reduced from the international figure of 0.1 mm/year to as low as a mean value of < 0.015 mm/year – a six-fold improvement.

Conclusions

Finally, the question remains: is this paper of any value to the arthroplastician? The answer is unequivocally *yes!* The following points should be borne in mind, however:

- Only on an individual cup basis can such a small series be significant.
- We cannot see any comparative clinical values.
- We appreciate the authors' conclusion that the Crossfire crosslinking method is not acceptable, *particularly due to the high levels of oxidation of the polymer and the resulting structural degradation thereof.*
- Perhaps the most important contribution is the proven correlation between (a) time related *in vivo* oxidation, (b) correlation with exposed surfaces of the cup, and (c) delamination is observed much less frequently than oxidation *per se*.

Lessons learned from this paper:

- A larger series is feasible.
- Better surgical skills and implant design are required.
- A much better and more scientifically based proven crosslinking method is important, and
- The American surgeons should begin to acknowledge research publications from outside the borders of the USA.