

## Antibiotic Impregnated Cement Coated Nail for Infected Un-United Diaphyseal Fractures.



### Medical Science

**KEYWORDS :** infection, nonunion, antibiotic cemented nail.

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### ABSTRACT

*Intramedullary infection of long bones in the absence of fracture healing is one of the unsolved problems in Orthopaedics. Our aim was to study the effectiveness of an antibiotic loaded cement coated intramedullary nail in control of infection and fracture healing.*

*14 cases of frank intramedullary infection presenting after intramedullary nailing of fractures of the femur and tibia are presented. All cases were treated by thorough debridement followed by stabilization with an antibiotic coated cemented nail.*

*Of the 14 patients, one was lost to follow up. Of the remaining 13 patients, infection control was achieved in 11 patients and fracture healing in 12 patients.*

*Antibiotic cement nails are very useful in long bone infections, especially in those cases used to treat the twin problems of infection and instability.*

### Introduction

The control of established intramedullary infection in a long bone is difficult, especially if it occurs in a fracture that has been treated by intramedullary nailing.

The twin problems of infection and non-union of the fracture is one of the unsolved problems in Orthopaedics. Various treatment methods exist including repeated debrima, exchange nailing, skeletal traction, external fixator, Ilizarov external fixation with corticotomy and distraction, antibiotic impregnated cement beads...etc. (Ref 1-2) Most of the above methods have had some degree of success in control of infection and union of the fracture. Of these the Ilizarov fixator has had the best track record. However its use in the femur is cumbersome with poor patient compliance and a long learning curve.

We conducted a prospective study looking at the control of infection and stabilization of the fracture using an intramedullary nail, which is coated with antibiotic impregnated polymethyl methacrylate.(PMMA).

Literature reviews show that this method has been used successfully to treat infected nonunions. (ref 3 )

### Materials and methods:

#### Inclusion criteria:

All patients with intramedullary infection of the femur of tibia with an un-united fracture were included. None of the patients had more than 2cm of bone loss.

Patients with more than 2cm bone loss were excluded from the study.

14 consecutive patients with intramedullary infections of the femoral and tibial shaft were studied.

There were 10 infections of the femur and 4 involving the tibia.

12 patients had closed fractures initially and 2 patients had an open fracture.

Only one patient presented at 3 months with an acute abscess. All the other patients had a discharging sinus at the time of presentation, which averaged 8.4 months, with a range from 3 to 18 months.

Treatment consisted of the following steps:

- Deep wound cultures were taken from the sinus for culture and sensitivity tests.
- In cases where there was no discharging sinus, we did a technetium gallium scan to confirm infection. ( fig 1 here)
- The implant if any was removed and a thorough debridement of the fracture site was done. This included removal of any sequestrae.
- The canal was reamed using flexible reamers and a thorough lavage performed.
- The reamings were sent for repeat cultures to confirm bacteria isolated.
- An Antibiotic impregnated cemented nail which will impart stability to the bone, as well as release high local concentration of antibiotic into the surrounding tissue was then inserted. (fig 2 here)
- The antibiotic used was one to which the cultured organism was sensitive to as well as being heat stable
- Mobilization of the patient as per tolerance.

Depending on the control of infection, the nails were changed every 4-6 wks.

In cases where the infection was completely controlled and the fracture stable, the nail was left in situ till fracture union.

The antibiotic impregnated cement coated nail is prepared as follows:

A size 8/9mm diameter K/V nail of appropriate length for that particular patient is chosen.

40 grams of Gentamicin containing cement powder is taken in a sterile container. 4g of the appropriated antibiotic powder is added. 1<sup>st</sup> or second generation Cephalosporin/ Vancomycin is used in gram positive infections. If a gram negative infection is suspected, a 3<sup>rd</sup> or 4<sup>th</sup> generation Cephalosporin is used. The cement powder and antibiotic are manually mixed with a spoon for a period of 5 minutes to distribute it as uniformly as possible.

The cement dough is now uniformly applied to the nail and rolled, leaving the extraction slots free.

The coated nail, with the cement still in the doughy state, is now passed through a template so that it has a uniform diameter of 10-11mm.

Evidence of infection control was gauged mainly clinically and

sometimes thru lab studies.

#### Clinical criteria included

- Decreasing local pain, warmth, and tenderness.
- No discharging sinus.
- Fracture healing.

In cases in which there was incomplete infection control, the nail was exchanged for another cemented nail. A repeat debridement was done and another antibiotic impregnated cement coated nail inserted in similar fashion.

Two patients required 3 such nailings and 2 patients required two nailing for control of infection.

In most cases, the fracture united with the cemented nail in situ. In cases requiring a bone graft, the cemented nail was exchanged with a standard locking nail. (fig 3-5)

#### Results

Of the 14 patients treated, one was lost to follow up.

Of the remaining 13 patients, 12 fractures united, and 11 infections were completely controlled.

For the control of infection, 2 patients required three sequential cemented nailings and two patients required two nailings. All the other patients' infections were controlled with a single nailing.

For fracture union, 2 patients required exchange nailing with a standard interlocked nail and autologous bone graft. One was treated with a non-vascularized fibular graft and hip spica after control of infection with the cemented nail.

All the other patients united with the cement nail in situ.

Of the two cases whose infection was not controlled, one was an HIV positive patient who initially grew MRSA and later had a mixed culture report. His is the fracture that has still not healed (15 months from onset of treatment and 24 months from the fracture).

The other patient was a grade 3B open fracture tibia initially treated with an external fixator and cross leg flap. She continues to have a discharging sinus even after fracture union. The cemented nail could not be removed and she is being treated with intermittent suppressive antibiotic therapy.

12 patients had complete control of infection and fracture healing.

#### Complications

There were two complications.

One patient needed an intraoperative femoral osteotomy because of impaction of the nail. This was a result of poor nail preparation resulting in a non-uniformity of the cement diameter. Subsequently because of poor infection control the nail was removed and the patient put in a Thomas' splint. The patient was given a treatment holiday but did not follow up.

The second complication was inability to remove the nail one year after fracture union. The patient requested implant removal because of prominence at the greater trochanter causing pain. Finally the prominent portion of the nail was sawn off and the nail left in situ.

#### Discussion

In our study we wanted to demonstrate that using an anti-

otic coated cemented nail is simple, cost effective, controls intramedullary infection and promotes fracture union and early mobilization of the patient.

Before the trial, we reconfirmed the high local bioavailability of antibiotics by doing elution studies of the antibiotic cement bead using the standard technique as described in the literature (ref 4 ). The microbiologic assay showed that the MIC was maintained till about 4 weeks after which it fell sharply.

Using the above data we allowed a maximum of four to six weeks for control of infection. If the infection was not controlled after 6 weeks the nail was removed and another nail inserted. (after fresh cultures and antibiotic sensitivity testing.)

The antibiotic used was one which was both heat stable and to which the organism was sensitive. These included the Cephalosporins, Aminoglycosides and Vancomycin.

We observed the following during our study:

1. The cemented nail, in addition to providing high local concentration of the antibiotic, also imparted good stability to the fracture. This also helped in infection control.

2. It is not very clear exactly how the nail imparts stability. One of the reasons is probably due to a three point pressure effect as demonstrated by a K-nail. The other reason may be due to a bone -cement interface bonding.

3. It is extremely difficult to remove a cemented nail after a period of 4-5 months. The 1<sup>st</sup> case we operated did not follow up early and we had to exchange the nail after a period of 5 months, at which time we faced considerable difficulty during extraction. A second patient, whose fracture had healed with the cemented nail in situ, came for implant removal a year after surgery, because of prominence at the greater trochanter. We were unable to remove the nail, and finally had to saw off the prominent portion of the nail.

4. Non-uniformity of the cement mantle in one case caused impaction of the nail necessitating a femoral osteotomy. Passing the coated nail through a template while the cement is still soft can ensure uniformity of the cement mantle. The other method is to place the nail in a plastic tube of uniform diameter and inject CMW 3 cement into it. We have also tried this technique. However in our hands it did not work well. Because of some perceived alteration in cement setting properties, the flow of cement is not liquid, and it became very tedious to do with some wastage of cement. Hence we are not currently using this technique.

5. During the procedure of removing the cement nail, either to exchange it with another such nail, or in order to insert an interlocked nail, we found that there was a considerable amount of bleeding from the endosteum. Perhaps this increased vascularity contributes to the infection control and bone healing.

6. regarding the number of nailings used to control infection:

The 1<sup>st</sup> patient's infection was completely controlled with the 1<sup>st</sup> cemented nail. However since this was our first case we erred on the side of caution and performed two cemented nailings.

a. Patient no. 11 needed three cemented nailings to control infection. He had an MSSA infection on repeat swabs and the reason for lack of control is still unclear. He eventually united in spite of continued infection and the nail was removed after complete union.

b. Patients no 9 and 10 had different cultures on initial swabs and subsequent reamings sent. So probably the initial antibiotic used was not appropriate.

c. It was more difficult to control gram negative and mixed infections. The reasons could be lack of appropriate heat stable antibiotics.

**Conclusion**

Based on our observations we have made the following recommendations while using this technique:

It may be used in cases of intramedullary infection with ununited fractures of the femur an tibia with less than 2 cm bone loss with good results.

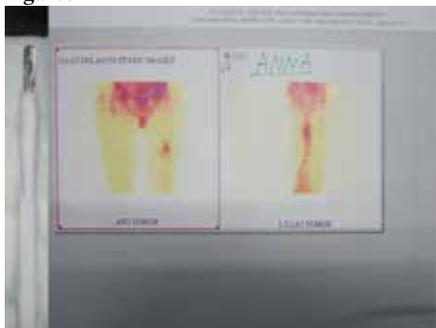
Treating gram positive infections gives better results

Ensure a uniform cement mantle in order to avoid nail impaction.

Exchange the cement nail by 12 weeks to avoid difficulty in extraction.

Keep blood available during exchange nailings.

**Figures**



**Fig 1. Technetium Gallium scan**



**Fig 2. Cemented nail.**



**Fig 3. Infected nail with discharging sinus**



**Fig 4. Cemented nail in situ**



**Fig 5. Fracture completely healed one year post exchange nailing and bone grafting.**

**References**

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