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Antibiotic cement nails manufactured with threaded rods or cannulated intramedullary nails are better than those made with guidewires and do not debond

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Purpose: The purpose of this study was to comparatively evaluate cement debonding at the time of removal of antibiotic cemented coated nails (ABNs) with cores made with a guidewire ($120), a regular intramedullary nail ($1100) or a threaded rod from a circular frame external fixator set ($60).

Methods: A retrospective study was performed on 32 ABNs that had been implanted for long bone infections after intramedullary nailing. All ABNs were manufactured intraoperatively by the treating surgeon using 2 grams of vancomycin and single package of Tobramycin Simplex Cement (Stryker, Kalamazoo, MI). The powder, antibiotics, and polymer were mixed and then injected into an ABN cement mold (Bonesetter Holdings USA). Debonding was assessed at time of removal by the operating surgeon. Rates of cement debonding between the 3 groups were statistically compared.

Results: Debonding occurred in 0/12 of the cement nails manufactured with an intramedullary nail, 0/7 threaded rod ABNs, and 6/13 guidewire ABNs. There was a significant difference in the rate of debonding between the 3 groups ($P < 0.01$). Removal of the remnant cement was accomplished with thin osteotomes, long pituitary rongeurs, or reamers. The canal was visualized using an arthroscope to ensure complete removal of the cement.

Conclusion: ABNs fabricated with standard intramedullary nails or threaded rods did not lead to any debonding. Debonding of the cement from the inner core of an antibiotic nail often requires significant effort to remove the remnant cement. Given that threaded rods are often cheaper than guidewires, we recommend that ABNs be fabricated with either threaded rods or interlocking nails, but not guidewires, depending on the level of stability required.

Keywords: antibiotic nails, antibiotic rods, osteomyelitis, fracture-related infection, infected nonunion

1. Introduction

Infection after intramedullary nailing is a costly and challenging problem. It occurs in 1% to 2% of closed fractures and in higher rates with open fractures.[1–6] It is associated with impaired fracture healing leading to delay and subsequent nonunion. Both infection eradication and fracture stability are needed for treatment of these infections. Proponents of antibiotic nailing point to their unique ability to provide local antibiotic delivery in addition to fracture stabilization. Paley and Herzenberg[7] first described the use of a nonlocking antibiotic cement rod in the treatment of intramedullary osteomyelitis, demonstrating that such treatment could provide both stabilization and infection control. Variations of this technique were replicated in several studies with varying methods of fabrication. All of them use a core device either a guidewire from an intramedullary nailing set or more recently using an actual interlocking nail. These antibiotic cement nails (ABNs) are all fabricated during surgery with various tubes, either disposable or metal molds that help to apply the antibiotic laden polymethyl methacrylate over the core device.[5,8–17]

ABNs constructed out of polymethyl methacrylate mixed with antibiotics are believed to provide great elution profiles that can vary with adding a second antibiotic or changing the temperature when mixing the cement.[18,19] However, we have found debonding of the cement from the structural core can be a problem during removal of antibiotic devices which leaves cement, an unwanted fomite, in the medullary canal. Removing this cement can be a challenge, necessitating the use of reamers, osteotomes, and long pituitary rongeurs.[16,20,21]

In that context, the purpose of this study was to compare debonding at the time of removal of ABNs with cores made with a ball-tipped guidewire, a typical cannulated interlocking intramedullary nail, or a threaded rod from a circular frame external fixator set.

2. Methods

A retrospective study was performed on ABNs fabricated with either an intramedullary nail, guidewire, or threaded rod that had been implanted for tibial, femoral, hindfoot nails, and humeral infections after intramedullary nailing using our standard protocol. One patient was excluded because they had an ABN that was fabricated with an alternative technique using a combined

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TABLE 1

A Description of all Antibiotic Cement Constructs That Were Included in This Study

Patient	Nail	Indication	Reason for Removal	Implant Length Weeks
1	Guide rod	Infected tibia nail	Exchange	6
2	Guide rod	Infected tibia nail	Exchange	12
2	Guide rod	Infected tibia nail	Patient wanted it out	52
3	Guide rod	Infected tibia nail	Exchange	6
4	Guide rod	Infected tibia nail	Exchange	24
4	Guide rod	Infected tibia nail	Knee pain	52
5	Guide rod	Infected femoral nail	Exchange	8
5	Guide rod	Infected femoral nail	Exchange	52
6	Guide rod	Infected tibia nail	Knee pain	24
7	Guide rod	Infected tibia nail	Knee pain	24
8	Guide rod	Infected tibia nail	Exchange	12
8	Guide rod	Infected tibia nail	Patient wanted it out	52
9	Guide rod	Infected tibia nail	Exchange	12
1	LIMN	Infected tibia nail	Exchange	6
10	LIMN	Infected tibia nail	Exchange	6
10	LIMN	Infected tibia nail	Exchange	10
11	LIMN	Infected humeral nail	Exchange	6
11	LIMN	Infected humeral nail	Exchange	24
12	LIMN	Infected tibia nail	Knee pain	52
13	LIMN	Infected femoral nail	Patient wanted it out	24
14	LIMN	Infected tibia nail	Exchange	12
14	LIMN	Infected tibia nail	Patient wanted it out	52
15	LIMN	Infected tibia nail	Patient wanted it out	40
16	LIMN	Infected tibia nail	Patient wanted it out	32
17	LIMN	Infected tibia nail	Exchange	12
18	Threaded rod	Infected hind foot nail	Exchange	4
19	Threaded rod	Infected hind foot nail	Exchange	6
19	Threaded rod	Infected tibia nail	Exchange	6
20	Threaded rod	Infected tibia nail	Exchange	12
21	Threaded rod	Infected tibia nail	Patient wanted it out	52
22	Threaded rod	Infected hind foot nail	Patient wanted it out	6
23	Threaded rod	Infected femoral mail	Exchange	32

guidewire and interlocking nail. We hence analyzed 32 ABNs for debonding. These infections occurred in 23 patients because 9 patients had more than one nail device implanted (Table 1). All surgeries were performed at a single institution which included 4 surgeons. All ABNs were manufactured intraoperatively by the treating surgeon using 2 grams of vancomycin and a single package of Tobramycin Simplex Cement (Stryker, Kalamazoo, MI). We removed a tablespoon of the powder from a single bag of the cement and mixed the rest with the vancomycin. Once the 2 powders were well-mixed, we added the polymer and mixed it in the mixing canister (Stryker, Kalamazoo, MI). Once the cement was of appropriate liquid consistency, we filled the cement gun and then injected it into an ABN cement mold (Bonesetter Holdings USA). Each mold was 11 mm in diameter. The core device was then inserted, and the mold ripped off with the tabs once the cement had completely cured. Figures 1–5 detail the method of ABN fabrication.

There were 12 statically locked intramedullary nails (Depuy Synthes, Johnson and Johnson, Paoli, PA or Smith and Nephew, Memphis, TN), all of which were 7 to 9 mm in size, 7 threaded rods from the Distraction Osteogenesis Ring System (Depuy Synthes Johnson and Johnson), and 13 ball-tipped guidewires (Depuy Synthes, Johnson and Johnson or Smith and Nephew). Figures 6–8 detail radiographic and clinical images of retrieved constructs. The cost of each implant is as follows—statically locked intramedullary nail: $1100 plus $180.18 for each interlocking screw; threaded rod: $60; and ball-tipped guidewire: $120. The cost of the Tobramycin Simplex Cement was $250.

The nails were imbedded from 4 weeks to 12 months. At the time of removal, the nails were assessed for cement debonding (Table 1).

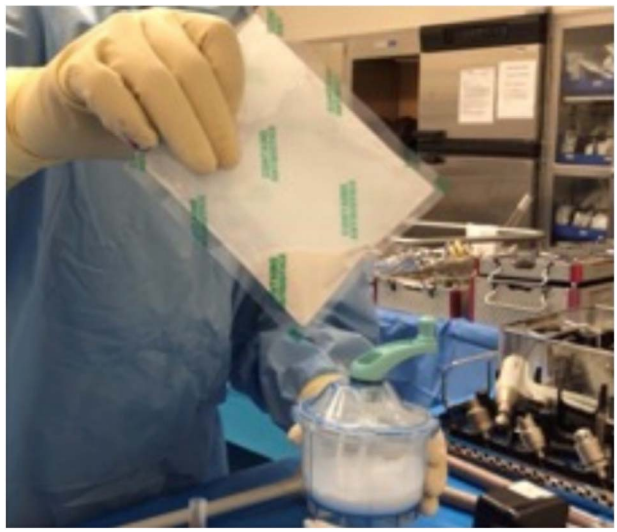

Figure 1. One to two grams of vancomycin powder is added to 1 package of antibiotic bone cement containing tobramycin. One tablespoon of the antibiotic bone cement is removed before adding the vancomycin.

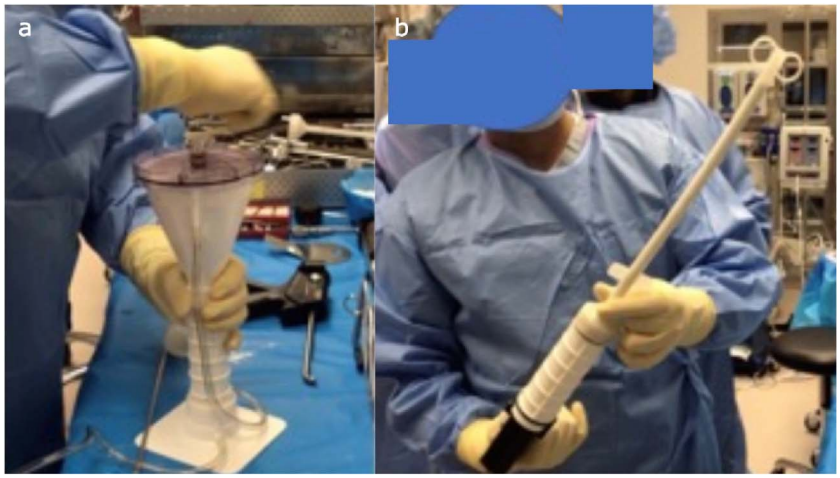

Figure 2. The cement is mixed without vacuum to maintain porosity (A) and then injected into the ABC nail tube while in a liquid phase (B).

The statically locked intramedullary nails were coated using the 11-mm ABN tube and inserted with the regular insertion device from the nail manufacturer. Locking was performed through the cement mantel when the ABN was in the tibia (no predrilling is necessary). The ball-tip guidewire ABNs were impacted in with a mallet and bone tamp and were not locked. The threaded rod ABNs were screwed into the gold connector and a second threaded rod with an outrigger and impacted in with a mallet; these were also not locked. The second rod and sometimes the gold connector were then removed.

At the time of removal, the interlocking nail ABNs were removed using standard nail removal techniques. The guidewire ABNs had loops so that they could be extracted with a bone hook or pliers. The threaded rod ABNs were removed with the same gold threaded connector device as used for insertion. At the time of removal, all ABNs were assessed for cement debonding. This was a qualitative, binary assessment that was performed using direct visualization of the nail by the operating surgeon. If any cement was left behind in the canal, a variety of instruments were used to remove the remnants, which we report below. A Fischer exact test was used to compare cement debonding rates between the 3 groups. Significance was set at a *P*-value threshold of less than 0.05.

3. Results

There were 32 ABN retrievals. Nine patients had exchange nailing. The debonding occurred in none (0/12) of the ABNs manufactured with an intramedullary nail with the recommended technique, none (0/7) of the threaded rod ABNs, and nearly half (6/13) of the guidewire ABNs. There was a significant difference in the rates of debonding between the 3 groups ($P < 0.01$). The average time to removal was 22.8 ± 18 weeks (range 4–52 weeks). ABN removal was performed for persistent infection and exchange antibiotic nailing in 20 instances, removal for discomfort, or patient desire for hardware removal after the infection was controlled in 12 instances (Table 1).

4. Discussion

Long bone infection after intramedullary nailing is a difficult problem to treat; an infected nonunion is even more troublesome. ABNs are powerful tools to combat these problems.[5,9–12,16–19,22] Debonding of the cement from the ABN is common when using guidewires for the inner core. Debonding of the cement from the inner core of an antibiotic nail often requires significant effort and time to remove the remnant cement. Multiple studies have been published describing various techniques to remove the remaining

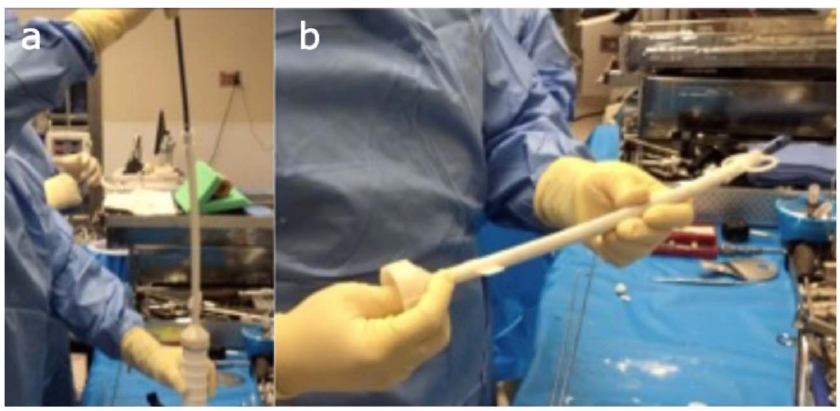

Figure 3. The nail, threaded rod, or wire is inserted into the cement-filled tube (A), and the cement is then allowed to completely harden (B).

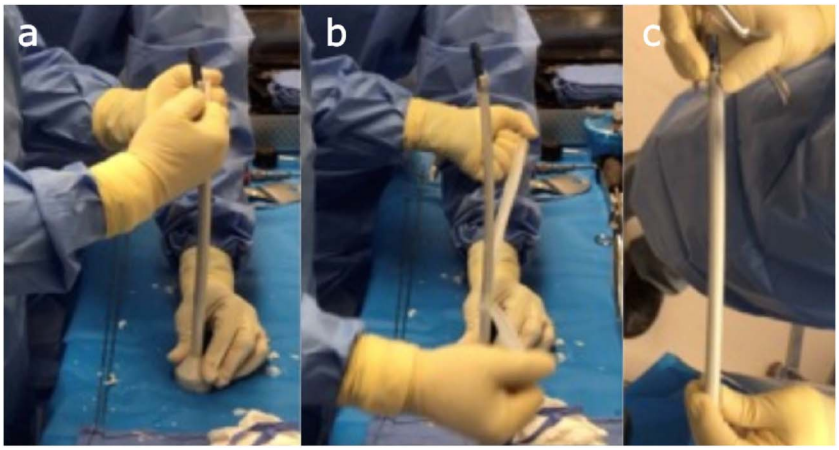

Figure 4. The mold tube is grasped by the handles (A) and ripped off (B), resulting in an 11 or 13 mm nail (C), depending on the tube used.

cement mantle that can act as a fomite for continued infection. A chiseling system that uses endoscopy for visualization was developed; another group of surgeons used the Reamer Irrigator Aspirator system (Synthes, Paoli, PA) to remove the left behind cement.[20,21] Other techniques for cement removal including corticotomies have been described.[13]

This study shows that using a threaded rod or a standard cannulated nail can decrease the likelihood, if not eliminate, the problem of debonded remnant cement in the intramedullary canal. Furthermore, the use of a standard intramedullary nail coated with antibiotic cement allows static locking in cases of nonunion associated with infection. In united infected long bones, the choice of an ABN manufactured with a threaded rod is cheaper at $60 versus the $120 cost of a ball-tip guidewire and does not suffer from debonding. Threaded rods or standard cannulated nails have devices that can be screwed onto the construct which makes removal and insertion significantly easier. With regard to choosing antibiotic threaded rods versus interlocking nails, interlocking nails have the advantage of providing additional rotational and axial stability, while threaded nails have the advantage of being cheaper.

Of note, ABNs fabricated with interlocking nails or threaded rods using alternative techniques from that described in this study may still result in debonding. For example, one patient was excluded from our study because they had an ABN made with a standard interlocking nail that was not fabricated according to the protocol required for inclusion in this study. During fabricating the ABN for this patient, the operating surgeon placed a guidewire in the nail in an attempt to create a cannula to later use with another guidewire for insertion into the tibia. This procedure did not work well because some cement interdigitated between the guidewire and the nail when making the ABN, and then, the ABN had difficulty sliding over the guidewire when placing it in the tibia so that was abandoned. Later when the ABN was removed in an attempt to exchange it, debonding was present. We feel that having cement in the cannulated nail end is important to prevent debonding. In addition, one attempt was made in passing an ABN with a blocking screw placed previously for nailing. This also does not work and leads to debonding. We routinely remove these blocking screws and have found that the ABN still follows the right path because the position of the old nail in the tibia often remains in the secondary nailing situation.

When placing threaded rod ABNs in the femur, one has to make sure that a long enough threaded rod is available. If desired, they can also be stacked using a gold connector. In addition, removing a threaded rod from the tibia is not difficult if you use the gold connector, but trying to remove a threaded rod from the femur is considerably more difficult. In these instances, placing the gold outer connector is helpful in removing the implant. We suggest using an interlocking nail for ease of removal unless concern for cost is too much of a factor.

When removing retained cement, our algorithm is to try with long grasping forceps and with long curettes or osteotomes; if that does not work, we place a guidewire into the medullary canal and ream the cement with a series of reamers starting with the smallest end cutting reamer and then sequentially increasing the size. We then wash with the jet lavage with the exterior plastic removed and Yankauer plastic suction placed on its end. This usually gets most of the cement out. Sometimes using a long grasper after this is helpful as well. We have used an arthroscopy camera to look

Figure 5. The antibiotic cement nail is inserted and locked.

Figure 6. Radiographic and clinical photographs of a retrieved statically locked antibiotic cement intramedullary nail.

down the canal in cases of difficult removal to ensure the old cement is out and does not act as a nidus. On one occasion, a window was made in the distal tibia to remove the cement from the medial side.

Figure 7. Radiographic and clinical photographs of a retrieved antibiotic cement threaded rod from the Distraction Osteogenesis Ring System.

Figure 8. Radiographic and clinical photographs of a retrieved antibiotic cement ball-tip guide wire.

The limitations to this study are that it was limited to one institution, there are only 32 patients, and the study is retrospective. However, even with low numbers, we were able to eliminate the problem with debonding using ABNs fabricated with standard locked nails or a threaded rod. Using a threaded rod ($60) to implant an ABN provides a more economical option that is potentially quicker and safer to use than a traditional ball-tip guidewire ($120). There are limits to length of the threaded rods which may affect use in a long femur, and in these cases, it can be extended with a gold connector.

5. Conclusion

ABNs manufactured with interlocking intramedullary nails or threaded rods did not lead to any debonding in this study. Debonding of the cement from the inner core of an antibiotic nail often requires significant effort to remove the remnant cement. The use of ABNs fabricated with interlocking nails allows static locking in cases of nonunion associated with infection. In healed infected tibias, the choice of an ABN manufactured with a threaded rod is cheaper: $60 versus $120, leads to no debonding and can be inserted or removed with a threaded connector attachment.

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