POST-STABILIZATION INFECTION OF LOWER LIMBS' SHAFT FRACTURES: A TREATMENT PROTOCOL

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SUMMARY

Treatment of infection following intramedullary nailing of lower limbs present a large variety of options, that goes from debridement and maintenance of the nail up to the its removal and external fixation of the limb. The cement rod is an unusual technique employed for treating this kind of infection, although little is found in literature about its application. At the IOT HC-FMUSP, this technique has been increasingly employed and the purpose of this article is to describe the treatment protocol used in our institution. The protocol consists in intravenous antibiotic therapy, removal of the nail, intramedullary debridement and insertion of an antibiotic cement rod. We analyzed the history of 11 patients presenting with 13 fractures, being five femurs and eight tibias. The patients were submitted to the surgical technique described above. The time of follow up ranged from 6 to 36 months (average: 14.27 months). Satisfactory results were found in 10 of the 13 studied fractures, representing a good outcome rate (76.93%). We concluded that this method represents a good alternative to treatment in these cases, however further comparative studies are required in order to establish its advantages and to popularize the use of the method.

Keywords: *Infection; Fracture fixation, Intramedullary; Femoral fractures; Tibia.*

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INTRODUCTION

Femoral and tibial shaft fractures deserve a special remark on orthopaedic trauma due to their high incidence rates and socioeconomical impact. Although well standardized criteria exist for non-surgical treatment indications, surgical methods are recommended because of their better functional results and to the shorter rehabilitation period. Blocked intramedullary nails – BIMN – are the therapeutic alternative of choice for many authors because they require a simple, standardized and reproducible surgical technique, and they do not cause further damages to soft tissues, and also allow early load(1).

One of the most feared complications of a surgical treatment is postoperative infection, significantly raising costs and treatment time and causing damages to functional outcomes and to long-term rehabilitation, thus representing a challenge to orthopaedic surgeons. The main risk factors for postoperative infection of fractures are(2):

1. Trauma energy degree.
2. Soft parts injury degree.
3. Local contamination degree.
4. Surgical time for osteosynthesis.
5. Patient's immunologic status.

When facing a postoperative infection case in a shaft fracture fixated with BIMN, an orthopaedic surgeon has some challenges, such as resolving the infectious process, the dead space associated to spinal canal created after a nail is removed, and the maintenance of fracture reduction and stabilization. Frequently, the infectious process is established before the fracture is united, which brings further difficulties to treatment(3). Several methods are employed and studied for treating these infections, which shows how difficult it is to handle them(4,5).

The purpose of this study is to assess the Treatment Protocol for post-stabilization infection with BIMN of lower limbs' shaft fractures used at IOT-HC-FMUSP.

MATERIALS AND METHODS

Treatment Protocol

Treatment Protocol for postoperative infections of femoral and tibial shaft fractures treated with BIMN is as follows:

1. Synthesis material removal.
2. Surgical debridement of the spinal canal.
3. Application of a cement + antibiotics shaft retractor.
4. Empirical endovenous antibiotic therapy, modified according to bacteria cultures and antibiograms obtained.

The retractor employed is manually made with an Ender nail or Steinmann's wire. This is wrapped by orthopaedic cement mixed with bactericidal antibiotics, with active properties in contact with the cement. Two cement units (80 g) are used, which are mixed with Vancomicyn 1g and methylene blue (5 ml, 1%) for achieving a bluish color, aiming to differentiate it from bone tissue.

Following preparation, the cement is manually molded around the Ender's nail using the outer diameter of the removed nail as a reference. We try to achieve a good homogeneity on the surface of the retractor and a little narrower diameter than the nail's in order to provide an easier introduction of the retractor. Another care to be taken is regarding the maintenance of a loop on the proximal end of the system that could enable the use of a hook for subsequent removal. Cement is allowed to dry and harden for the introduction into spinal canal, otherwise union may occur between cement and bone, making impossible to remove it as usual, which could even require osteotomy in cases when removal is imperative.

Canal debridement is provided soon after BIMN removal, while the retractor is prepared by other surgeon, in an ancillary table. At first, drilling is made, preferably with a larger diameter than the removed

Study developed at the Institute of Orthopaedics and Traumatology, HC-FMUSP.
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nail's intending to remove the contaminated endoosteum. Long curettes can also be used for additional debridement. Then, a bone window of ± 1cm² is opened at the opposite end to the nail introduction, and then thorough irrigation with saline solution. This step is designed to promote a cleaning irrigation with a single-direction flow on the spinal canal, allowing debris removal together with the solution employed, avoiding the accumulation of contaminated tissue within the canal. Finally, after an appropriate debridement of the canal, the retractor is introduced, usually easily, when all the steps described are appropriately followed.

Treatment is implemented as soon as postoperative infection signs are noticed, such as surgical wound leakage, fistula, hyperemia, and the presence or absence of fever. Laboratory changes on VHS, PCR and leukogram may be associated. In some cases in which the infection is regarded as superficial, measures are provided in order to spare the nail, such as local surgical cleaning and bacterial culture for a targeted antibiotic therapy. In most cases, however, infection is regarded as contiguous with deep planes. The indication for nail removal and retractor use is promptly made.

The time of retractor use and the number of replacements are guided by the infectious picture evolution. Cases in which a good evolution occurs, the retractor replacement for a new nail is provided within 21 days. In cases where the infectious process remains, longer periods of retractor use are required, which may last for several months. The number of retractor replacements is influenced by the evolution of the infection, as well as by patient's surgical status and, even, by logistic factors in the service, so that a scheduled replacement may not be provided due to the influence of any of these factors.

Fracture stability and union are important issues in cases of postoperative infection. The retractor is usually inserted after more than some weeks using the BIMN. This, many times, allows for some degree of early stability at fracture core, both angular and rotational, enabling that the lower stabilization given by the retractor plays the role of maintaining the initial position, achieved with BIMN placement, without requiring additional immobilization. In the cases where we found a good evolution of the infection and a good union progress, this many times occurs when a retractor is being used, which, in general, is easily achieved. We have experienced some cases in which, despite of the appropriate technique employed for placing the retractor, union occurred between bone tissue and the cement on retractor. In these, the attempt to remove it by traditional methods was shown to be unfeasible, with Ender's nail extraction alone and with the cement remaining within spinal canal. Cases such this, in which the patient is asymptomatic concerning the presence of retractor and with a resolved infectious process, we select the expecting approach and periodic follow-up, with removal being indicated should any symptomatic event related to the retractor occurs.

CASE SERIES

Eleven patients with thirteen LLLL shaft fractures (eight tibias and five femurs), occurred between August 2004 and January 2007, treated according to the protocol described above, had their medical files assessed to collect data for analysis. The population was comprised of nine male patients (81.82%) and two female patients, with ages ranging from 20 to 58 years (average: 31.2; median 29 years). All patients suffered traffic accidents involving motorcycles. Of the thirteen fractures, nine were open (63.23%), with two Gustilo I type (22.22%), one type II (11.11%), five type III A (55.56%) and one type III B (11.11%); four fractures were closed. Of the eleven patients, seven had injuries on other limbs – trunk or TCE, being regarded as multiple-trauma patients (63.64%); four patients had injuries only on fractured limbs (Table 1). Nine patients had positive cultures at some moment (81.82%), collected from the bone where the retractor was used, with S. aureus present in all cases, except for one in which the culture was positive to Pseudomonas aeruginosa. The Gram-negative bacterium enterobacter was present in association with S. aureus in two cases, while the Gram-negative acinetobacter was present in other two cases (Table 2); both had their endovenous antibiotic therapy changed to specific coverage. Even in these cases when any Gram-negative germ was associated, the retractor was made only with Vancomicyn, targeting S.aureus action, leaving endovenous antibiotic therapy responsible for additional coverage. Two cases showed negative culture in all surgical debridement performed, although they presented evidences of postoperative infection, outlining that both were using endovenous antibiotic therapy.

Table 1 *– Patients' data*

Patient	Gender	Age	Fracture	Open?	Type	Associated injuries
1	M	32	Tibia R	No		Yes
2	M	22	Tibia L	Yes	I	Yes
			Femur L	No		
3	M	29	Tibia L	Yes	III B	No
4	M	40	Tibia L	Yes	I	No
5	F	24	Femur R	Yes	III A	Yes
			Tibia R	Yes	III A	
6	M	58	Femur R	No		Yes
7	M	29	Tibia L	Yes	III A	Yes
8	M	35	Tibia L	Yes	III A	No
9	M	23	Femur R	Yes	III A	No
10	M	20	Femur L	No		Yes
11	M	31	Tibia R	Yes	II	Yes

Table 2 *– Bacteria culture*

Patient	Culture
1	*s. aureus*
2	*s. aureus*
3	*s. aureus + enterobacter*
4	negative
5	*s. aureus + enterobacter*
6	negative
7	*s. aureus + acinetobacter*
8	*s. aureus*
9	*s. aureus + acinetobacter*
10	*pseudomonas*
11	*s. aureus*

Concerning the time elapsed from the moment of trauma until BIMN placement, of the thirteen fractures, three had the nail placed at once (on the day of trauma); in nine, a delay occurred ranging from 2 to 20 days, and, in one case, the nail was placed after a period of 260 days (median: 10 days). In cases of non-immediate placement, the early stabilization was provided by using an external fixator and in only one case – a closed tibial fracture – an inguinopodalic casted splint was employed. The BIMN use time until its replacement by the retractor was quite variable, with a median of 6 weeks. Four patients had a prolonged nail use until its removal, with the late emergence of infection signs. In these, the nail was used for a period of 21 to 64 weeks, after which they have been replaced by a retractor. Other seven patients showed an earlier infectious picture and remained for a period of 1-7 weeks with the BIMN until its replacement (Table 3).

The time of retractor use has also showed great variability, with an average of 10.7 weeks, ranging from 2 to 35 weeks (Table 4). Two fractures, occurred in the same patient (ipsilateral femur and tibia), united during the use of retractors, remained with the retractors as definitive synthesis after attempting to remove it unsuccessfully, after 21 weeks of use. This patient shows good evolution, with no infection signs, with 13 months of follow-up from the time the retractors were placed.

Table 3 *– Treatment provided previously to retractor insertion*

Patient	Previous treatm.	Delay - IMN	Duration - IMN
		(days)	(weeks)
1	Casted splint	2	3.5
2	External fixator	17	64
	External fixator	17	64
3	External fixator	260	6
4	External fixator	5	47
5	External fixator	10	1
	External fixator	10	1
6	IMN	immediate	21
7	External fixator	8	3
8	IMN	immediate	41
9	IMN	immediate	7
10	External fixator	20	2.5
11	External fixator	15	2.5

Table 4 *– Retractor use characteristics.*

Patient	Duration - Retractor	Replacement	New IMN
	(weeks)		
1	3	No	Yes
2	permanent	No	No
	permanent	No	No
3	35	4	No
4	8	1	No
5	17	1	No
	17	No	No
6	8.5 *	No	No
7	12	1	No
8	2 *	1	No
9	15.5	6	No
10	6	1	Yes
11	4	1	Yes

RESULTS

Of the thirteen fractures in this study, ten showed a satisfactory evolution regarding the infectious process resolution and the union, representing an effectiveness rate of 76.93%, with a mean follow-up of 14.27 months, ranging from 6 to 36 months, since the retractor insertion until the last follow-up visit. Three fractures, after using a retractor for an average time of 16 weeks, had their treatment modified due to persisting infection signs. In one of these cases, the retractor was removed and replaced by fixation with Ilizarov. In the remaining two fractures, ipsilateral femur and tibia, occurred in the same patient, immobilization with casted splint was kept on tibia and a new retractor was placed on the femur. Both were still under treatment, without infection process resolution and no union signs at the time this paper was written.

Replacement of a retractor by a new BIMN was provided in only three fractures (23.08%) (Table 4). Of these, one presented relapsed infection after a new BIMN was inserted, which was again replaced by a retractor, kept for additional four weeks, evolving with fracture union and infection resolution; the other two cases showed a good evolution, with union and infection resolution, keeping the new BIMN in use at the time of our last follow-up visit. In the remaining 10 fractures in this study, no new BIMN was inserted. Of these, seven showed fracture union during the use of the retractor, five of them being removed and two maintained after unsuccessful attempt to remove it. The other three fractures correspond to failure cases previously mentioned (Table 5).

Table 5 *– Outcomes and follow-up time.*

Patient	Fracture	Outcome	Follow-up
			(months)
1	Tibia R	Union, no infection	36
2	Tibia L	Union, no infection	13
	Femur L	Union, no infection	
3	Tibia L	Union, no infection	14
4	Tibia L	Union, no infection	13
5	Femur R	pseudoarthrosis	19
	Tibia R	pseudoarthrosis	
6	Femur R	Union, no infection	15
7	Tibia L	Union, no infection	16
8	Tibia L	Union, no infection	6
9	Femur R	pseudoarthrosis	10
10	Femur L	Union, no infection	9
11	Tibia R	Union, no infection	6

DISCUSSION

The use of blocked intramedullary nails was first reported in the 1980's, with the evolution of Küntscher's nails, showing a strong growth in the subsequent years, becoming the method of choice for most of the authors when treating lower limbs' shaft fractures[6,7]. In conjunction with its increased use, the first postoperative infection cases presented a new scenario in terms of how to handle these fractures, despite of its significantly low incidence rate.

Big series show infection rates below 1% for closed fractures and between 2.4 and 4.8% for open fractures[8,9]. Studies with intramedullary fixation for open fractures indicated that the infection rate for Gustilo I and II open fractures treated with early nail insertion is similar to that for closed fractures[10-12]. In contrast, the fixation with BIMN of III-type open fractures of the femoral shaft shows a significantly higher infection rate (4 - 5%)[13]. The use of any BIMN after external fixation used for more than a few days seems to impose an increased risk of intramedullary infection. In the infection occurs during external fixation, even when successful, its recurrence after definitive fixation with BIMN should constitute a real concern. Although over several weeks delays between fixator removal and nail insertion may somehow reduce the risk of infection, this remains high when compared to that in a fracture in which infection did not occur[14,15].

Different approaches are used and continuously studied for treating intramedullary post-stabilization infections. Maintaining the nail and performing serial surgical debridement conjunctively with antibiotic therapy is an alternative employed by many authors[1,2,16,17]. These recommend that the nail is maintained until fracture shows some stability degree with bone callus formation, and only then synthesis should be removed and the canal cleared. Chen et al[18] compared a group treated with nail maintenance and surgical debridement to another group in which the nails were removed and the fractures were stabilized with an external fixator. All fractures in the first group showed union, while a higher number of complications were found on the group treated with external fixator. They conclude by indicating nail maintenance in cases where the fixation device remains stable and the infection is under control. The external fixator is indicated for uncontrollable osteomyelitis cases or infectious pseudoarthrosis. Fracture stabilization is an important factor for infection process resolution, and should always be targeted during infection treatment[19-21].

Orthopaedic cement (PMMA) impregnated with antibiotic agents employed as a retractor was first used in infected hip arthroplasties[22]. Subsequently, the use of antibiotic pearls necklace became popular and started being used as an important alternative for chronic osteomyelitis treatment and as a prophylactic method in open fractures[23,24]. However, this method presents the disadvantage of lacking a structural support to the fracture and of bone growth around the spheres, which makes its removal after 2 or 3 weeks very difficult[16,25]. The use of cement as shaft retractor is a technique that is still under development, and little employed in orthopaedic practice, counting on few literature reports[26-28]. Its major advantage would be the correlation between local antibiotic-release effect, such as with the pearl necklace, and the structural support provided by the nail used on inner retractor. If its theoretical advantages are confirmed, this method can become an important alternative to the strategies currently employed, such as the maintenance of BIMN, which, in general, presents challenges in resolving an infectious process or external fixation. Pailey and Herzenberg[26] successfully treated 9 post-stabilization infection cases with nails by using shaft retractors. In their study, six femurs, two tibias and one humerus were treated, with eight cases using BIMN for stretching or fixation of corrective osteotomy, and in only one case for fracture fixation. All cases evolved with osteotomy or fracture union and none showed infection recurrence after a mean follow-up of 40.9 months. The advantages of temporary fracture fixation and the low cost of the method have been mentioned. In our study, the purpose was to present the technique employed in our institution and to analyze our initial case series together with their preliminary results. All data were retrospectively collected by means of medical files analysis, and, different methods have never been compared for providing an absolute indication of any of the treatment types. The development of randomized prospective trials is still warranted, and the determination of the actual advantages of this technique and its major indications deserve new study results so that its use may become broader and further supported.

CONCLUSION

Shaft retractors constitute a technique that is being developed for treating post- intramedullary stabilization infection of lower limbs'shaft fractures. The local release of antibiotic agents associated to the temporary stabilization of fractures and its low cost represent the major advantages of the method. Future studies are required to determine the main indications of this therapy and to compare it to currently employed methods in orthopaedic practice.

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