

Bone-conserving radiation-free intramedullary nail removal technique: A prospective surgical study on 108 patients with healed tibia fractures



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Submission: 12-02-2023

Revision: 02-04-2023

Publication: 01-05-2023

ABSTRACT

Background: While attempting hardware removal, intraoperative challenges and hardware removal strategy vary in each case. Only a few nail removal techniques are reported in the literature. Surgeon's understanding and resolution of these rather challenging situations improve with experience and exposure. Patients having healed tibia fracture with *in-situ* intramedullary nail were subjected to intramedullary nail removal. **Aims and Objectives:** The aim of this study was to assess the performance of novel bone-conserving C-arm-free technique of intramedullary nail removal and describe trends such as surgical timing, complications, hardware removal ratio, intraoperative fluoroscopy requirement, comorbidities, and time since the first surgery in patients undergoing the surgical procedure. **Materials and Methods:** This was a prospective therapeutic observational study conducted from July 2017 to December 2021. Patients having healed tibia fracture with *in-situ* intramedullary nail were subjected to hardware removal using a novel bone-conserving radiation-free technique. **Results:** Among 108 patients, 49.72 (%) were men and 50.28 (%) were women. Patient demographics: age-45 years (mean); range-18–75 years. The overall surgical timing was 117.5 ± 2.1 min (mean/S.D). Hypertension was the most common comorbidity overall with the incidence of 32.40% (35/108 patients); maximum 50% in the age group of 46–60 years (12/24 patients). Nail retrieval was possible in all cases with a 100% hardware removal ratio. The most common complication encountered was DVT/Thrombii (7.40%, 8/108 patients), followed by surgical site infection (5.55%, 6/108 patients) and fractures (2.77, 3/108 patients), with maximum complications in the age group of 61–75 years (63.63%, 7/11 patients). Patients presented 3.8 ± 1.1 years (mean/SD) after the first surgery for nail removal. **Conclusion:** In complicated situations, an extra bony window over interlocking bolt slots can be used to maneuver the nail, thus facilitating tibial or femoral nail delivery.

Key words: Bone; Bone nails; Fractures; India; Orthopedics; Operative

INTRODUCTION

Hardware removal is usually offered to and attempted in patients of younger age groups, broken hardware, or symptomatic implants like prominence, pain, mechanical obstruction, etc. Surgeons face difficulties during nail

extraction such as nail extractor mismatch or broken nail and impacted extractor fragments. Nail removal becomes difficult when dealing with a broken nail, damaged proximal nail threads, nail extractor mismatch, impacted endcaps, and incarcerated nails. Osteoporotic patients present a major challenge due to high fracture risk and patients operated

Access this article online

Website:

<http://nepjol.info/index.php/AJMS>

DOI: 10.3126/ajms.v14i5.52398

E-ISSN: 2091-0576

P-ISSN: 2467-9100

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elsewhere with missing hardware details and cold-welded implants.

Some of known hardware removal indications include pain around implant site, infected implants, broken implants, and adjacent vital structures.^{1,2} Few Implants like Hook Plate, Kirschner Wire, Elastic Nails and Plates in Children require early hardware removal. Patients themselves desire a hardware removal on a few occasions.^{3,4}

Hardware removal is riskier than leaving the implant *in situ*; probably due to numerous complications which can occur during and after operative implant removal.^{4,5}

Due to less indications of hardware removal and lack of published literature,⁶ bail-out options and useful experiences are not known widely. Recently published nail removal techniques described the use of a carbide drill bit (Midas Rex©) to drill a hole in nail, but the bit is costly and not commonly available; heat necrosis and metal debris are potential risks with this approach.⁷ A few techniques describe the creation of variable length longitudinal bony slots; however, the chances of fracture are high. Another technique utilizes a hook to fish out the nail portion; however, this approach is dependent on intraoperative fluoroscopy for successful hardware removal and is primarily reserved for broken and hollow nails.⁸ One technique describes drilling a slot distal to nail, putting guide wire retrograde, and pushing out the nail against a reamer; this needs intraoperative fluoroscopy with associated bone fracture risk.⁹

An innovative bone-conserving and fluoroscopy-free surgical technique is described that helps deliver intact or broken intramedullary nails (solid or hollow) even in setting of nail extractor mismatch or jammed nail extractor. It does not need any special instrumentation.

Aims and objectives

The aims of this study were 2-fold, first to assess the performance of bone-conserving intramedullary nail removal technique and second to describe trends such as surgical timing, complications, hardware removal ratio, intraoperative fluoroscopy requirement, comorbidities, and time since the first surgery in patients undergoing the surgical procedure.

MATERIALS AND METHODS

A prospective therapeutic observational study from July 2017 to December 2021 was performed at N.C. Medical College, Israna (Haryana) and Santosh Medical College, Ghaziabad (Uttar Pradesh). Mandatory clearances and

approval were sought from the Institutional Ethical Committee Board. [NCMH170712].

Inclusion criteria

Patients having healed tibia fracture with *in situ* intramedullary nail were subjected to hardware removal using a novel bone-conserving radiation-free technique. Male or female patients between 18 and 75 years of age having united tibia fracture (any etiology) with retained intramedullary nail, with or without infection, were included in the study group.

Exclusion criteria

Patients refusing consent and nonunions were excluded.

Surgical technique

All patients were operated under spinal anesthesia in supine position. The anteroposterior and lateral dimensions of the nail were marked on the leg using C-arm. Skin incision for proximal End (green) was 3–4 cm vertical incision centered over the proximal end in the anteroposterior view extending 2 cm either way from the proximal end of nail (Figure 1). The lateral window incision (yellow) incision was 4 cm incision centered over the proximal dynamic and static hole in the lateral view extending from the proximal limit of dynamic hole to the distal limit of the proximal static hole; this length can be limited to the proximal dynamic hole if only one screw is given proximally (Figure 1). Distal incisions (green) were 1 cm over distal locking bolts (Figure 1).

First, distal and proximal static bolts were exposed and removed in a minimally invasive fashion. Then, the proximal dynamic bolt was exposed, and then, the proximal end of the tibial nail was approached. The proximal nail end was exposed using standard slotting technique as the nail was incarcerated (Figure 2a). The universal nail extractor



Figure 1: Skin incision marking (proximal green incision is a 3–4 cm incision centered over the proximal end in AP are regular, Yellow incision is a 4 cm incision centered over proximal dynamic and static hole)

engaged in the proximal end firmly; thus, the proximal dynamic bolt was extracted.

While back-hammering, universal extractor tip broke (about 1 cm long) and got impacted within nail head, making it almost impossible to extract it traditionally using the threads at the proximal end (Figure 3). Nail could not be gripped and pulled out as it surrounded by bone at the proximal end.

Bony window

A technique in which the bony window (1.5–2 cm) was made using an osteotome over the proximal dynamic hole and the dynamic hole was exposed (Figure 2b). In the bony window, an impactor was engaged in dynamic slot and tapped proximally with multiple light blows (Figure 3).

The nail disimpacted and moved up one interlocking distance. The dynamic slot was further hit even when it went under the cortex using long curved osteotome/gauge. When the slot moved to the proximal part of the bony window and further up, a proximal static hole appeared in the distal part of the window; we used a Steinmann pin to engage this static hole and further advance the nail up.

As the nail was embedded deep inside bone (1.25 cm), the nail would normally slide under the patella in its natural course; leverage at the proximal end was provided, and nail directed upward using two heavy osteotomes and bone

spikes. Proximal migration of nail by one interlocking distance allows exit of nail's proximal end sufficient to be gripped and delivered out. As nail moves up, nail's static slot can further be used for impacting through same bony window.

The bone window site was finally washed and grafted with bone debris that was generated during the procedure. Ligamentum patellae and paratenon were repaired with absorbable sutures. Skin closure was done with surgical stapler.

Rehabilitation protocol

For all patients, toe walking with walker for 1 week, followed with flat foot partial weight bearing for 1 week and finally flat foot full weight bearing for the next 1 week. Patients leave walker at 3 weeks.

Medication and dressing protocol

The 1st post-operative dressing was done on the next day of surgery and then at 4 days interval till suture removal. Suture removal was performed between 14 and 16 days. Intravenous antibiotics were given for initial 24 h of surgery, followed by oral antibiotics, analgesics, and proteolytic enzyme preparations for 2 weeks.

Outcomes measured

Surgical timing, complications, hardware removal ratio, intraoperative fluoroscopy requirement, comorbidities, and time since the first surgery.

Statistical analysis

Data were tabulated using standard MS Office Tools (Microsoft Office 365 Apps-Word, PowerPoint, and Excel). The data were analyzed descriptively and organized in tables and graphs. $P < 0.05$ was considered statistically significant. The 95% confidence intervals were measured when appropriate. Standard deviation, mean, and range were calculated for continuous variables. Statistical analyses were performed using SPSS 13.0 (SPSS Inc, Chicago, IL, USA).

RESULTS

Among 108 patients, 49.72 (%) were men and 50.28 (%) were women. Patient demographics: age-45 years (mean); range-18–75 years. The mean follow-up was 12 months (range: 8–16 months and S.D-1.2 months). The overall surgical timing was 117.5 ± 2.1 min (mean/S.D) with a minimum time of 90 ± 1.8 min (mean/S.D) for the age group of 61–75 years ($P < 0.04$). Hypertension was the most common comorbidity overall with the incidence of 32.40% (35/108 patients); maximum 50% in the age group of 46–60 years (12/24 patients).

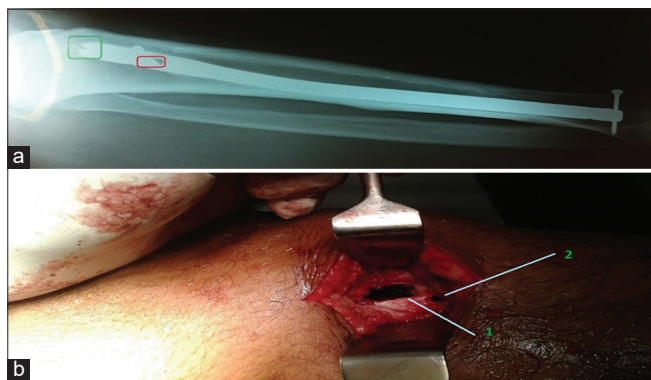


Figure 2: (a) Schematic bone window marking (Green window is the regular bone window at the proximal end; Red bony window is 1.5–2 cm centered over the proximal dynamic hole). (b) Intraoperative picture (1- Bony window over dynamic hole, 2- Static screw hole)

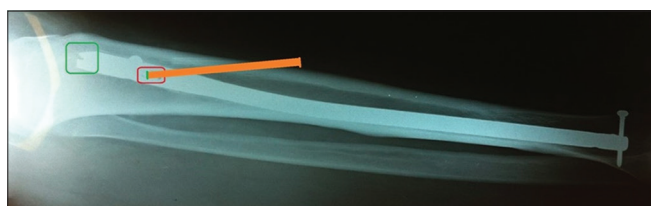


Figure 3: Schematic: Direction of hit in the dynamic hole. (Orange bar indicates the direction and site of engagement of impactor)

The most common complication encountered was DVT/Thrombii (7.40%, 8/108 patients), followed by surgical site infection (5.55%, 6/108 patients) and fractures (2.77, 3/108 patients); maximum complication in the age group of 61–75 years (63.63%, 7/11 patients).

Patients presented 3.8±1.1 years (overall mean/S.D) after the first surgery for nail removal (range- 1.4–8 years) (Table 1). The mean follow-up was 12±2 months (mean/S.D; range: 8–16 months).

Nail retrieval done in all cases with a 100% hardware removal ratio. None of the cases required intraoperative fluoroscopy for facilitating nail removal.

DISCUSSION

Hardware removal is often more difficult than primary implant fixation. Various reasons have been cited in the difficulty involved for the removal of intramedullary nail after bone union such as the incarceration, broken nail, unavailability of specific removal instrumentation, broken instrumentation, damaged threads, bony ingrowth or overgrowth (impacted nails),¹ or refracture. Nail removal is a minimally invasive procedure compared to other hardware removal procedures like a screw or plate in which direct visualization and hold of implant are possible.

Our experience presented with various difficulties. First, our patient was obese and abundant fatty tissue further increased our operating depth and also difficulty in positioning and manipulating the lower limb. Second, nailing was performed 3 years ago, and presently, the nail became incarcerated. Third, implant details were

unavailable, and thus appropriate instrumentation could not be arranged. Fourth, tip of universal nail extractor broke inside the proximal end of tibial nail and got impacted making nail delivery further difficult from the proximal end (Figure 4).

Lastly, the proximal end of nail was further posterior inside the bone; hence, if the nail would exit in its natural path, it would impinge against patellar articular surface.

Only a few techniques of nail removal in complicated cases are reported; in one technique, the tibia needs to be completely open by removing a one-third of circumference longitudinal bone window;¹ however, this is extensive, risky, highly demanding surgery to perform, and may cause fracture if not performed by experienced hands. In spite of the simplicity of this technique, care should be taken when making the bony window, because there is potential risk of a fracture around the window site. If required, intraoperative fluoroscopy can additionally be used to guide window placement.

Authors report a complication rate of 15.74%, whereas the literature report complication rates from 0% to 40% for surgical hardware removal.⁵⁻¹⁰ Authors have reported complications in 17 patients, namely, surgical site infection, fracture, and DVT/Thrombii, similar as reported by other authors.^{2,3,6} Other established complications after hardware removal are impaired wound healing, tissue and nerve damage, post-operative bleeding, or an incomplete removal.⁴ Incidences of injury to surgical team members, foreign body implantation, metal debris,⁷ thermal bone necrosis,⁷ and iatrogenic bony injury when using high speed burrs and drills are potential serious drawbacks of attempting a hardware removal.

Table 1: Patient age distribution, time since injury, comorbidities, and surgical timing with complications

| Patient age (years) | n/% | Years since primary implant fixation | | | Comorbidities* | | | Surgical timing (min) | | | Complications/Remarks* | | | |
|---------------------|-------|--------------------------------------|-----|---------|----------------|----|-------|-----------------------|-----|--------------|------------------------|-------|-------|--|
| | | Mean | SD | Range | Condition | n | %** | Mean | SD | Range | Condition | n | % | |
| 18–30 | 44/41 | 2.8 | 1.5 | 1.4–4.2 | Infection | 4 | 9.0 | 140 | 2.4 | 114–188 | SSI | 2 | 4.54 | |
| | | | | | Hypertension** | 8 | 18.1 | | | | | | | |
| | | | | | Diabetes** | 7 | 15.9 | | | | | | | |
| | | | | | | | | | | | | | | |
| 31–45 | 29/27 | 5 | 2 | 3–7 | Infection | 5 | 17.2 | 130 | 2 | 104–168 | SSI | 1 | 3.44 | |
| | | | | | Hypertension** | 10 | 34.5 | | | | | | | |
| | | | | | Diabetes** | 8 | 27.5 | | | | Fracture | - | | |
| | | | | | Cardiac Issues | 4 | 13.8 | | | | | | | |
| | | | | | | | | | | | | | | |
| 46–60 | 24/22 | 3.8 | 1.8 | 2–5.5 | Infection | 4 | 16.6 | 110 | 2.2 | 76–134 | SSI | 2 | 8.33 | |
| | | | | | Hypertension** | 12 | 50.0 | | | | | | | |
| | | | | | Diabetes** | 8 | 33.3 | | | | Fracture | 1 | 4.16 | |
| | | | | | Cardiac Issues | 6 | 25.0 | | | | | | | |
| | | | | | | | | | | | | | | |
| 61–75 | 11/10 | 7 | 1 | 6–8 | Infection | 2 | 18.18 | 90 | 1.8 | 72–114 | SSI | 1 | 9.09 | |
| | | | | | Hypertension** | 5 | 45.45 | | | | | | | |
| | | | | | Diabetes** | 2 | 18.18 | | | | Fracture | 2 | 18.18 | |
| | | | | | Cardiac Issues | 4 | 36.36 | | | | | | | |
| | | | | | | | | | | | | | | |
| | | | | | | | | | | Thrombii/DVT | 4 | 36.36 | | |

*Individual percentage in respective pool. **45/108 (41.6%) patients had overlapping comorbidities (2: 34/108 [31.48%]; 3: 8/108 [7.40%])



Figure 4: Broken instrumentation. (a) Extracted nail with 5 bolts, broken extractor with tip and broken Schanz pin. (b) Impacted extractor tip in the nail's proximal end. (c) Broken extractor and Schanz pin tip

Various indications warrant an implant removal, but the patient may not be aware of difficulties that can be encountered during nail removal and the fact that it may necessitate a major procedure followed by a prolonged recovery time. It is important to discuss all possible options and the possibility of procedure failure with patient during the consent. The procedure itself should be attempted at well-connected and specialized operation theaters, preferably involving a team of surgeons. Involving a team should help in exchange of ideas and skills, thereby improving the chances of a successful procedure. This technique can be employed even in incarcerated, or nails blocked with endcaps or broken assembly piece, damaged proximal threads, or when appropriate instrumentation is unavailable.

Being a surgical study not requiring fluoroscopy, prospective in nature and technique associated with minimal complications are its strength.

The surgical technique is nonfluoroscopy dependent, uses clinical markers for hardware removal and does not require creation of slots or splitting of bone (bone conserving), and allows hardware delivery for broken intramedullary nail or even when nail extractor mismatches or is jammed. This technique is reproducible and requires regular instrumentation, thereby increasing applicability and use.

Limitations of the study

Few Limitations are lack of comparative groups and nail removal from other bones like femur and humerus. Further research for curved long bones and other specialised nails will help gather more data and performance of the novel surgical technique.

CONCLUSION

In complicated situations, an extra bony window over the proximal dynamic oblong hole can be used to facilitate tibial or femoral nail removal. The novel technique does not rely on intraoperative fluoroscopy or special instrumentation, is bone conserving and reproducible, and can be easily performed even by younger surgeons.

ACKNOWLEDGMENT

The authors would like to thank all supporting staff involved in surgical procedures.

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Authors' Contributions:

NP- Study design, literature survey, data collection, manuscript preparation and revision, data analysis; **CM**- Study design, literature survey, data collection and data analysis; **AS**- Data collection, statistical analysis, literature survey, prepared first draft of manuscript; **GNC**- Implementation of study protocol, data collection and manuscript revision; **VM**- Data collection, manuscript preparation and editing; **RKG**- Data collection, figure preparation, statistical analysis and interpretation.

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Source of Funding: None, **Conflicts of Interest:** None.