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Case Report

How safe are intramedullary stainless-steel nails for long bone fractures?

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ABSTRACT

Femoral and tibial fractures are usually the result of high-energy trauma such as road traffic accidents, fall from heights and trauma in high-speed contact sports. Most femoral and tibial shaft fractures are treated surgically. Several studies have shown that early surgical stabilization is associated with reduction of complications and mortality. An intramedullary nail is a metal rod that is inserted into the medullary cavity of a bone and across the fracture in order to provide a solid support for the fractured bone. Intramedullary nailing is currently considered the "gold standard" for treatment of femoral and tibial shaft fractures. Proposed advantages of intramedullary nailing include short hospital stay, rapid union of the fracture and early functional use of the limb. Intramedullary nailing aims to preserve the anatomical structure of fracture site and to provide a proper environment for fracture healing. The present case report further enlightens the safe use of Intramedullary nailing for long bone fracture.

Keywords: *long bone fractures, intramedullary stainless-steel nails*

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INTRODUCTION

Beginning with the use of wooden sticks and later in mid-1800's through the decades of 1900's, the introduction of ivory pegs for intramedullary nailing for nonunion fractures further led to the use of metallic rods during the first world war. The introduction of metallic rods was associated with high infection rate and was not universally accepted. In 1931 Smith Petersen reported successful use of stainless-steel nails for the treatment of femoral shaft fractures.[1] As a result of failure and success for over 50 years, the modern interlocking nails offer universally accepted treatment methodology for long bone fractures of the limbs. Thereafter, several changes in the shape of device, method of administration and precautions were made. The modern locking nails offer additional strength and torsional control of the fractures for better union rates and overall results. Several studies have shown that early surgical stabilization is associated with reduction of complications and mortality (Fakhry 1994).[2] Intramedullary nailing is currently considered the "gold standard" for treatment of femoral and tibial shaft fractures (Rudolf 2009).[3] Proposed advantages of intramedullary nailing include short hospital stay, rapid union of the fracture and early functional use of the limb (Winquist 1984).[4]

CASE STUDY

A middle-aged male visited our hospital with pain and swelling in the right thigh secondary to trauma, which he had sustained

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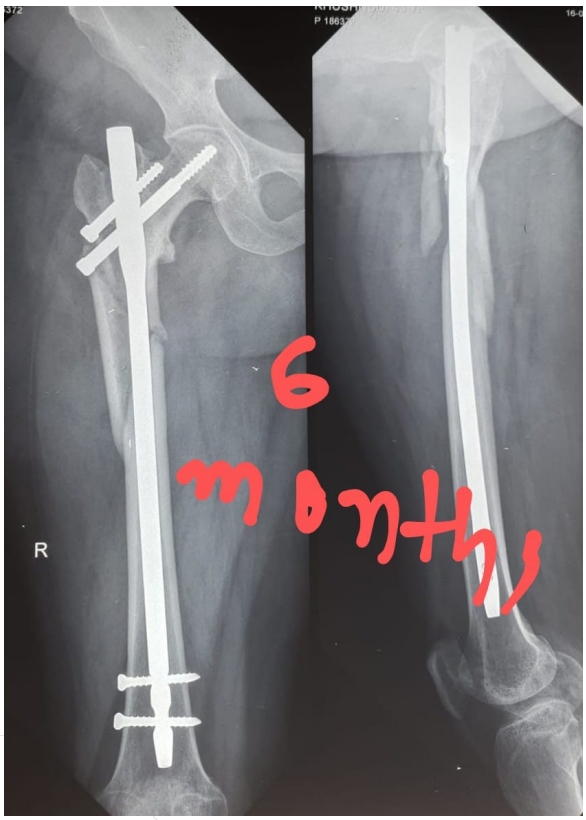
following a road traffic accident on 05/11/2016. X-ray of the right thigh revealed sub-trochanteric fracture right femur. He was advised to admit to the hospital and was operated and Recon intramedullary nail was implanted in the right femur. The patient was discharged on 7/11/2016. Patient visited hospital for follow-up on 20/11/2016. Progress was satisfactory, stitches were removed, and patient was advised to walk non weight bearing on the right lower limb with the help of a walker. X-ray revealed that progress was satisfactory, and the patient was advised to do physiotherapy of right hip and knee joints at home. After six months on 19/05/2017 patient was X rayed and as callus at fracture site of right femur was evident, he was advised stationary cycling and full weight bearing walk with the help of a walker. On 24/4/2018 i.e. after 2 years he came for follow-up with a broken right femoral nail. He said that he slipped while visiting field in the village. The patient attributed this to low quality of implant.

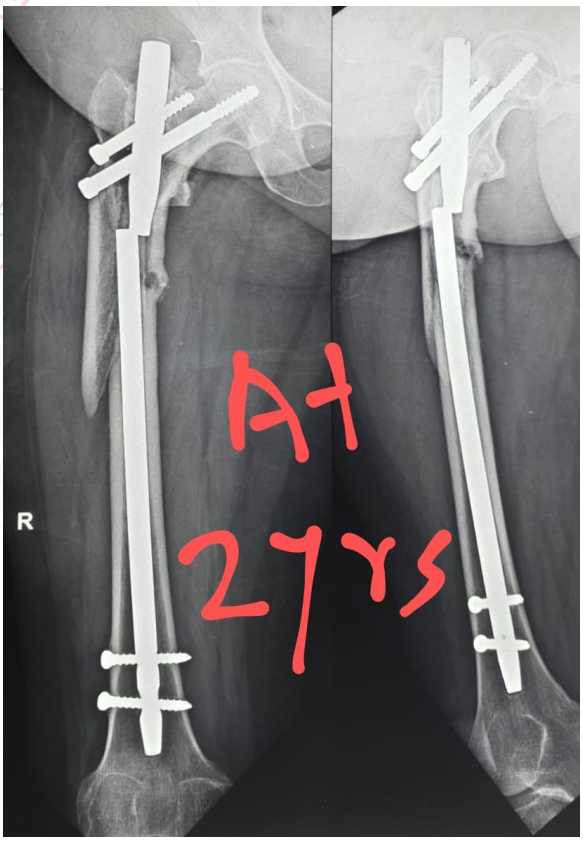
The same case was reported to nearby "Materiovigilance Centre" under the Materiovigilance Programme of India (MvPI). Following additional information was provided with case report.

(A)

(B)



(C)



(D)

Figure 1 (A,B,C,D): Photographs of the same patient in proper order

Intramedullary nail – quality and composition

The femoral nail implanted in the patient was supplied by M/S R N S Surgicals, who is a manufacturer of orthopedic implants, approved supplier of government hospitals and is also exporter of implants. R N S Surgicals is registered against provisions of ISO 9001:2008 (International standard) with registration no.

7224225121-8 and licensed by Government of NCT of New-Delhi, drug control Department vide license no. 10 (1821). SS 316L is an austenitic Chromium-Nickel stainless steel with superior corrosion resistance. The low carbon content reduces susceptibility to carbide precipitation during welding. This permits usage in severe corrosive environments such as isolator diaphragms.

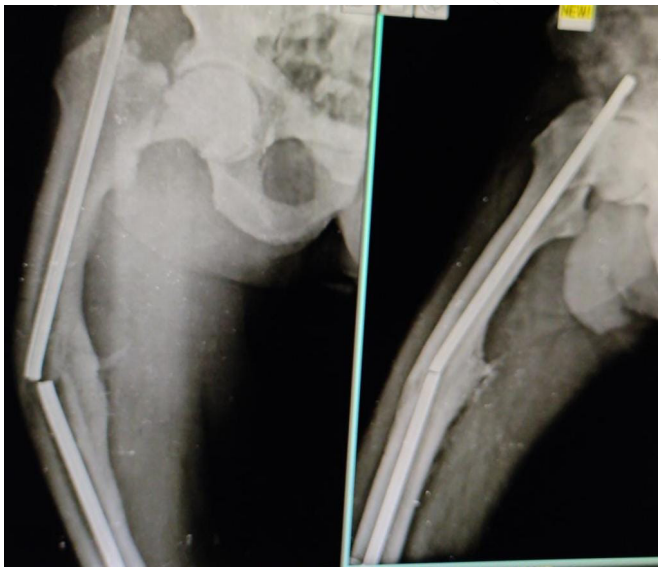
NOMINAL COMPOSITION

Chromium	17.2%	Manganese	1.6%
Nickel	10.9%	Carbon	.02%
Molybdenum	2.1%	Iron	Balance

TYPICAL MECHANICAL PROPERTIES

	ANNNEALED	COLD ROLLED
Ultimate Tensile Strength	90,000 PSI	180,000 PSI
Yield Strength (0.2% Offset)	42,000 PSI	160,000 PSI
Elongation in 2”*	40%	2%
Modulus of Elasticity (Tension)	28 X 10^6 PSI	
Poisson’s Ratio	0.25	

* The measured elongation will be less as thickness decreases to 0.002” and less.



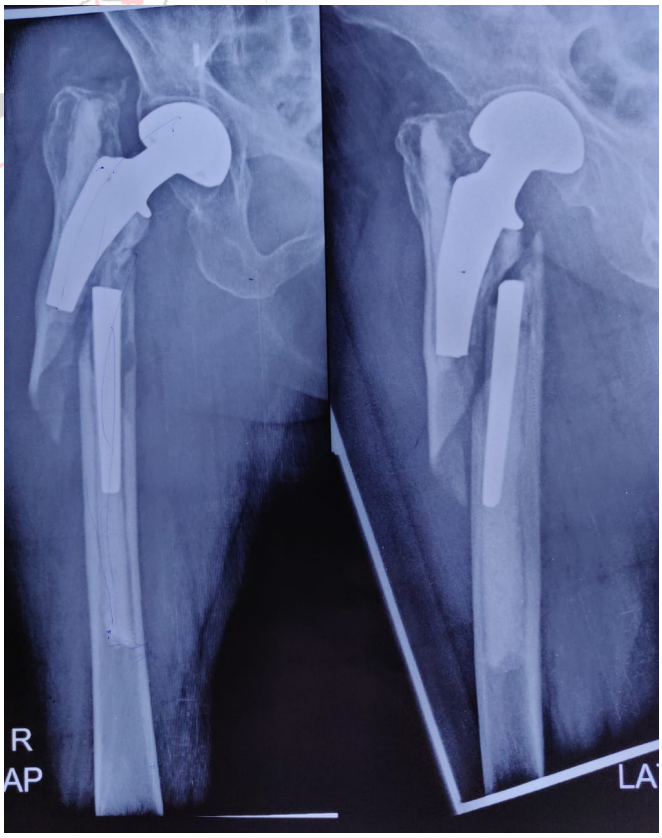


Figure 2: Some other implant failures photos

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DISCUSSION

Intramedullary nailing is a common treatment for proximal femoral fractures. Fracture of the nail is a rare but devastating complication that exposes often frail patients to complex revision surgery. A related study determined the patient-specific factors which contribute to and are associated with this form of implant failure. Study included 19 patients with 22 broken nails between 2004-13. There was one case of bilateral nail failure and two cases of recurrent ipsilateral breakage. Mean age was 70.4 years (range 55-88 Yrs.). In 18 cases failure was preceded by a fall (Johnson et.al 2017).[5]

Implant material is designed to minimize the adverse reactions associated with introduction of foreign material in body. The immune system will typically attack anything that has originated outside the body leading to inflammation. Elevated levels of particular metals in the blood stream can lead to various problems including cytotoxicity and carcinogenesis. It is crucial to choose materials that will have a minimum negative impact on the body. The danger arising from introducing an alien element into the body leads to working out some low regulations included in ISO 10993 defining the way of using the new material and implants made of them in order to make them suitable to be used in medicine. However, following the rules strictly, does not remove the danger of some complications (Budinger and Hertl 2000).[6] Chemical compounds present in metallic implants are as a rule well accepted by the body, however, they may have toxic and carcinogenic effects or cause allergy (Swierczynska-Machura et.al. 2004).[7] The implant surface is subjected to reaction from the tissue, as well as body liquids during the process of oxidation. As a result of metal corrosion tissues may be penetrated by the toxic ions like: vanadium, nickel and chromium. Moreover, an infection can be caused by the microorganisms, which suck the surface of the implant. The presence of bacteria and biofilm on the implant surface changes the immunological reactions (Swierczynska-Machura et.al. 2004).[7] The data concerning the influence of allergic reaction on the joint surface between the implant and the tissue does not give a definite answer to the question, whether; the sensitivity of the implant compounds is responsible for the post-operative complications (Kanerva and Forstrom 2001).[8] The research conducted on rabbits allergic to nickel which underwent inserting metallic wires to join the tibia bones showed decreased of bone endurance increasing their absorption, decreased number of osteocytes as well as weaker rebuilding of bone tissue (Brown, Devine and Merriti 1983).[9]

The material used must have suitable properties to allow them to replace the natural tissue and to perform the same functions. The mechanical properties required are primarily to support the loads that are applied, and therefore the modules of the implant material are one of the main criteria. The iron-based implant is one of the non-biodegradable metals that have been proven safe as a fracture fixation device. Stainless steel has double the modulus of elasticity as titanium. So, titanium implant causes less stress shielding and also are less prone to fatigue (David et.al. 2010).[10] Stainless steel is cheaper, but it corrodes on long term and has higher rate of allergic reaction. Moreover, stainless steel has potential to cause toxicity on long term because of nickel and chromium content. Titanium implants offer advantage of less corrosion and allergic reaction and so no need to remove implant for fear of long-term toxicity and thus also reducing the chance of infection (Shah *et al.* 2018).[11] Design of an effective fracture fixation device requires attention to shape, mechanical and material properties. Mechanical properties of orthopedic implants depend upon several factors including stress and strain, isotropic and anisotropic behavior, viscoelasticity and wear resistance. In order to heal properly and maintain its normal strength, bone needs to be subjected to dynamic stresses. As stainless steel is significantly stiffer than bone (10 times stiffer), using stainless steel in rigid fixation devices can alter fracture remodeling and decrease bone density, leading to regional osteoporosis.

Nail failure has been reported in 0.5-3.3 % of cases with stainless steel reamed nail (Bucholz et.al 1987).[12] Distal locking holes are

the weakest points that are expected to fail because of stress concentration caused by the hole effect and slot effect. Nail breakage can also occur when weight bearing begins before the fracture regains 50% of its original stiffness. Protected weight bearing till clear radiographic union avoids loading the nail beyond its limit of endurance (Bhat et.al 2006).[13]

The risk of implant fatigue failure is highest in the young patients of good health. When the bone does not unite, stress is taken by the nail during weight bearing and over a certain period of time the nail will fail and break. When this happens, the broken nail has to be removed and a new one put in place, sometimes supplemented with bone grafting (Pan 2013).[14]

Another reason for nail breakage is the biomedical properties of nail, which may not be able to withstand cyclical loading stress imposed by walking if they are permitted to bear weight with caution.

Titanium flexible intramedullary nails have become more prevalent for stabilization of pediatric femur fractures in recent years, while steel may be expected to have superior fracture stability due to its higher elastic modules. Titanium alloy has experimentally demonstrated improved biomechanical stability, as measured by gap closure and nail slippage (Angel et.al 2008).[15]

Beginning with the conservative approach for the treatment of long bone fractures, which was earlier confined to providing external support and traction to prevent deformity and providing support to bone union. The advances in medical science led to the introduction of intramedullary nail, initially as iron rods, which rusted during the course of time and led to some complications including infection and breakage of the implant and was therefore, responsible for nail failure. With the introduction of stainless steel with strict quality control, the complications like rusting and reduction in the torsion strength of the nail could be avoided. However, the incorporation of chromium and nickel in the manufacture of stainless steel has been attributed to result in development of allergic reactions in some of the patients. The infection rate was very much reduced. At the same time stainless steel support resulted in better and early union of bone.

The allegation by some patients that low quality of nail has resulted in breaking/fracture of the implant appears far from reality. Stainless steel nails used in orthopedic practice under specific guidelines of regulating agencies are significantly stiffer than bone (10 times stiffer).

On the other hand, stainless steel in rigid fixation devices can alter fracture remodeling and decrease bone density, leading to osteoporosis. But this can affect the outcome only when the nail has been removed and the osteoporotic bone is not able to sustain the impact of normal movement and activity. The fracture/breaking of the nail can only occur with a high intensity blow to the affected limb such as during accident.

CONCLUSION

The patient needs to be made aware at the initial stage for not putting excess load or strain on the affected limb and at the same time instructions in unambiguous language be given informing that the implant is just a temporary support provided till the bone healing process is completed. We are required to give respect to nature and allow it to help in the process.

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