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The Use of Modular Distal Aiming Device (MODAD) System for Locked Intra-medullary Nailing for Fixation of Fractures in Nigeria: A Prospective Observational Study

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Author's contribution

The author made substantial contributions in the study design, implementation and write up.

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ABSTRACT

Locked intra medullary nailing has been accepted globally as the gold standard for treating fractures of the shaft of long bones. The method provides acceptable stabilisation of the fracture, controls alignment, axial translation and rotational deformity at the fracture. The challenges of closed locked intra medullary nailing of fractures include the availability of resources such as operation equipment, skilled manpower required for such practice as well as the risk of irradiation exposure from the use of Image intensifier for the procedure. To obviate these challenges, option to achieve locked intra medullary nailing of fractures using various devices have been developed including the modular distal aiming device.

Aim: The aim of this study is to evaluate the early experience with the use of the modular distal aiming device for locked intra medullary nailing in various hospitals across Nigeria.

Methods: Evaluation of prospectively collected data of patients with long bone diaphyseal fractures treated with Synthes modular distal aiming device between January 1, 2007 and May 15, 2014 in various hospitals across Nigeria. Data was analysed and results are presented and discussed.

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Results: During the period under study, 71 fractures were treated with the device in various hospitals across the country with the majority (54 {76%}) of the fractures treated at Teme Hospital Port Harcourt, Nigeria. Most of the fractures resulted from Road Traffic Crashes. The median total duration of surgery was 1 hour 54 minutes (IQR, 40 mins – 4 hour 10 mins) whereas the median time to locking distal holes was 47 mins (IQR, 25 – 2 hour 25 mins). The total average estimated intra-operative blood loss (including fracture haematoma) was 452 mls ±128 mls) requiring blood transfusion of 25 units of blood for all patients. The post operative infection rate was 5 (7%) including superficial infection, deep infection and overt chronic osteomyelitis.
Conclusion: Modular distal aiming device is a good tool for locked intra medullary nailing of long bone fractures. It obviate the huge cost of acquiring and maintaining C arm required for closed locked intra medullary nailing of fractures of the shaft of long bone. The results from the use of such distal aiming device compared favourably with those obtained from the use of C-arm from other centres and eliminated the exposure to irradiation associated with the use of C-arms.

Keywords: Long bone fractures; locked intramedullary nailing; modular distal aiming device; early experience.

1. INTRODUCTION

The use of locked intra medullary (IM) nails (locked IM nailing) is presently the gold standard for the treatment of long bone diaphyseal fractures [1,2]. It has been shown to be superior to other methods of fixation of such fractures. The Association for the Study of Internal Fixation (ASIF/AO) Group recommends its use for the treatment of diaphyseal fractures of long bones whenever it is possible [1]. Locked intra medullary nail does not only provides internal splinting of the fractured bone, it is a load sharing implant thereby reduces the axial load on the broken bone during the early healing phase of the fracture. Such systems also helps to restore the length, control proper axial alignment and most importantly axial rotational forces of the broken bone fragments when subjected to weight bearing [3]. While other implants used for internal fixation of fractures such as plates and screws can correct the longitudinal displacement and restore length, they are load shearing. Unlocked IM nails on its part despite being able to control alignment and bear some load, they have reduces ability to control axial translation, and rotational deformation especially of the distal fragment of the fractured bone [3].

Some of the challenges of locking during IM nailing especially of the distal holes of the nail include the need for the use of intra-operative imaging systems, availability of surgeons and operating room personnel (ORP) with the experience on the technique, the availability of the locked nailing instruments and system which are often comparatively expensive as such may not readily available in most hospitals the developing countries. Even when available the use of such systems may not be affordable to majority of the patients in most developing countries. The use of intra-operative imaging systems exposes the patient, the surgeons and other operating room (OR) personnel to doses of irradiation [4], prolonged operation time, associated with increased intra operative blood loss and the need for blood transfusion [5,6,7]. Safety regulation limits radiation exposure on professionals to 300–500 mSv per year as higher doses increases the risk of adverse consequences of irradiation [8].

Tasbas BA et al. [9] has shown that during locked IM nailing, the surgeon and the assistant surgeon receive various doses of irradiation. It was observed that following 107 consecutive operations over a 3-months period, the operating surgeon who is usually more than 90cm away from line of the radiation beam receives about 0.0375 mSv of irradiation in the outer gown dosimeter and 0mSv in the under gown dosimeter after each routine IM nailing procedure whereas the assistant who is often approximately 10 cm from the beam receives about 0.21 mSv and 0.05 mSv in the outer gown and under gown dosimeters respectively. This requires that the surgeon undertakes about 13,500 IM nailing and the assistant 2000 IM nailing in a year to reach the set safety limit of irradiation exposure by these personnel. Furthermore, various organs of the body receive various doses of irradiation during IM nailing with intra operative imaging. It has been observed that the eyes, thyroid and hands of the surgeon and the assistant receive 19.0 uSV, 34.5 uSV, 41.7 uSV doses of irradiation respectively during a routine locked IM nailing lasting for average of 2 hours using the C-Arm image intensifier [4]. Even operating room personnel within 30 inches from C-arm beam receive significant irradiation particularly to

unprotected areas such as the eyes, nail and hands [4].

In addition, because of the huge capital cost of acquiring and maintaining intra operative imaging systems, most hospitals in developing countries such as Nigeria do not have these systems. Most of the available ones are not operational due to lack of maintenance [2]. The use of such technology requires additional training of the surgeons to master the techniques of locking the nails especially the distal holes [10] or hiring of already trained personnel to operate the systems at additional costs. This increases the cost of care which is ultimately transferred to the patients and their family who are often already burdened by harsh economic challenges especially if the patient is the bread winner of the family which is often the case [11].

Because of challenges encountered during locking of distal holes in the nails even in presence of intra operative imaging, various devices have been produced to aid locking of IM nails and reduce the need and use for intra operative imaging. Such devices include the use of radiolucent drills [12], the use of distal targeting jigs [13], laser assisted devices [14], grid and flag devices [15], magnetic navigational aids [16] and the use of custom designed nails with special slots [17]. None of these has generally been accepted [18] as all of the mentioned devices have their challenges too. Most of the mechanical devices fail because of failure of the systems to take into account the deformational torque and rotational forces the nail undergoes during insertion [19]. However, the free hand technique with the use of C-arm remains the most popular method used globally.

The unavailability of the resources required for closed locked IM nailing such as functional intra operative imaging, huge capital cost required to acquire and maintain such equipment required for the technique and limited number of personnel with the requisite experience required for the technique limits the capacity to practice locked IM nailing in most centres in most developing countries including Nigeria. The introduction of aiming devices including the modular distal aiming device (MODAD) by Synthes@ was an attempt to obviate the challenges. The use of MODAD like other targeting devices used for locking IM nails particularly the distal holes of the nails is also associated with intra-operative challenges such as prolonged operation time as compared to the other conventional open reduction and internal fixation (ORIF) methods like unlocked IM nailing, use of plate and screws. This is attributable to the time required to assemble the locking device as well as the time required for locking of the holes in the nails especially the distal holes [20].

In Nigeria like in most other developing and resource scarce countries, the use of locked intra medullary nailing for fracture treatment still remain limited because of the reasons already adduced. Most centres resort to the use of available methods that obviates the use of intra-operative imaging. This study aims to showcase the experience with the use of MODAD for locked intra medullary nailing without intra operative imaging in various trauma centres in Nigeria.

2. METHODS

This is a prospective observational study reporting the experience of the use of Synthes MODAD system for locked IM nailing of long bone diaphyseal fractures treated by the same surgical team in various hospitals across Nigeria as expert visiting surgical team between January 1, 2007 and May 15, 2014. Appropriate ethical approvals were obtained from the relevant hospital authorities and informed consent was obtained from the patients according to Helsinki Declaration of 1975. The majority of the patients were treated at the Teme Hospital Port Harcourt a dedicated trauma centre in Nigeria.

The surgeries were undertaken by the same surgical team who had been previously trained on the use of the MODAD device. The team travelled to various hospitals and centres in Nigeria for the purposes of training other surgeons on the use of the system. The same surgical techniques and antibiotic protocol using intravenous cephtriaxone 30 minutes before incision which was repeated if surgery lasted beyond 4 hours and then daily for 2 days after surgery was used for all patients. All fractures were reduced using limited open method by short incision to ensure fracture reduction and passage of guide wire across the fracture into the distal fragment. Insertion and locking of the IM nails was done in conventional method using the MODAD.

Demographics of the patients whose fracture were treated with MODAD system, injury characteristics, interval to fracture fixation form initial injury, surgical time, intra operative

bleeding, transfusion requirements and post operative outcome were determined. Outcome was assessed by the duration of post operative wound healing, clinical and radiological fracture union, post operative wound infection and occurrence of post operative osteomyelitis.

Obtained data was analyzed using statistical package for windows version 20 (IBM SPSS Statistics for Windows, Version 20.0. IBM Corp. Armonk, NY:). Descriptive statistics was generated and presented with means and standard deviation (SD) and median with inter quartile ranges (IQR) for numerical variables while categorical variables are presented as proportions and percentages. Chi Square X^2 was used to test for observed differences among categorical variables whereas differences between means were tested with student's t test. P values less than 0.05 are accepted as statistical significant. Results are presented with descriptive statistics as considered appropriate and inferential statistics when necessary.

3. RESULTS

Between January 1 2007 and May 15, 2014, 71 cases of locked intramedullary nailing of fractures of shaft of long bones were undertaken across various hospitals in Nigeria. Most 54 (76.1%) of the operations were undertaken at the Teme hospital Port Harcourt. The patients and the hospitals are distributed in Table 1.

Table 1. Showing patients and the hospitals where procedure was undertaken

Centre	No of cases	%
Teme Trauma Centre Port Harcourt	54	76.1
Other Private Hospitals in Port Harcourt	10	14.1
University of Port Harcourt Teaching Hospital	2	2.8
Various National Orthopaedic Hospitals	4	5.6
Other Federal Medical Centre	1	1.4
Total	71	100

3.1 Age Distribution of the Patients

Majority of the patients were within the age group between 20 years and 49 years (n= 55 {77.5%}) while patients within the age group of 50 years and above constituted 14% (n=10).

Table 2. Age distribution of the patients

Age in years	Nos	%
0 – 9	Nil	Nil
10 – 19	6	8.5
20 – 29	20	28.2
30 – 39	23	32.4
40 – 49	12	16.9
50 and above	10	14.0
Total	71	100

3.2 Gender Distribution

There were 54 males and 17 females giving a male to female ratio of 3.2:1.

3.3 Cause of Injury

The commonest cause of injuries among the patients treated with MODAD was Road Traffic Crashes (RTC). Gunshot wounds contributed the least type of injury amongst these groups.

Table 3. Distribution of cause of injury

Cause of injury	Nos	%
Road traffic crashes	58	81.7
Gunshot wounds	3	4.2
Sports injuries	4	5.6
Falls	6	8.5
Total	71	100

X^2= 46.67; P < 0.00001

3.4 Types of Fracture and Bones Involved

Most of the fractures treated using MODAD were closed (n=68, {95.8%}) whereas 3 (4.2%) of the fractures were open. Forty eight (67.6%) of fractures involved the femur while 23 (33.4%) were tibial fractures.

3.5 Average Duration of Surgery

Median total duration of surgery	1 hour 54 mins IQR (40 mins–4 hour 10 mins)
Median time to locking distal holes	47 mins IQR (25 – 2 hour 25 mins)

The longest duration of surgery which was directly related to the time required for distal locking of the distal holes in the nails was observed in the third surgery performed using this system. This time improved with subsequent surgeries as the experience of the surgical team improved.

3.6 Estimated Blood Loss from the Procedure

The average estimated intra-operative blood loss (including fracture haematoma) was 452 mls ±128mls) necessitating transfusion of 25 units of blood in all patients. Ten of such blood transfusions were given intra operatively while 15 units were given post operation.

Evaluation of the distribution of frequency of blood transfusion per patient showed that a total of 58 patients (81.7%) did not require blood transfusion, 11 patients has between 1unit and 3 units of blood while only 1 patient received more than 5 units of blood.

Table 4. Distribution of the frequency of blood transfusion among the patients

Transfusion rates	Frequency	%
Nil	58	81.7
1 – 3 units	11	15.5
4 – 5 units	2	2.8
Above 5 units	1	1.5

X^2 = 50.7528; P < 0.00001

3.7 Target Hit of Distal Holes Successfully Locked

There were 142 distal holes in the 71 IM nails. Distal locking was only attempted for 102 slots based the geometry of the fracture pattern. Ninety four (92.2%) target hits were achieved out of the 102 attempted locking of distal holes.

Table 5. Precision of distal hole locking using MODAD

No of locking slots	Nos	%
Total nos. of distal locking slots in nails	142	
Total distal holes locking attempted	102	100
Distal hole target hit	94	92.2%
Distal hole target misses	8	7.8%

X^2= 44.0907; P < 0.00001

3.8 Duration of Post Op Hospitalization

Fifty four (76.1%) of the patients stayed between 1 day to seven days in the hospital after surgery (post OP hospitalization) while only 1 patient stayed beyond 28 days after surgery.

3.9 Average Duration to Radiological Union of Fractures

More than 83% of the fractures had reached advanced stages of healing as evidenced by good callus formation at 6 months after surgery while 6 (8.4%) of the fractures was yet to show evidence of healing at 6 months. The extent of healing of fractures in 8 patients who were lost to follow up could not be ascertained. There was a statistically significant difference between the number of fractures with evidence of radiological union as at 6 months and the fractures that united after 6 months (X^2 = 24.805, P < 0.00001).

Table 6. Distribution of post operative hospitalization among the patients

Post Op hospitalization in days	Nos	%
1 – 7	54	76.1
8 – 14	12	16.9
15 – 28	4	5.6
Above 28 days	1	1.4
Total	71	100

X^2 = 43.3174, P < 0.00001
Median duration of post Op hospitalization = 2 days, IQR (2 – 42 days)

Table 7. Duration to early radiological union of the fractures

Duration to radiological union in weeks	Nos	%
6 – 12	24	33.8
13 – 18	20	28.2
19 – 24	13	18.3
Above 24 weeks	6	8.4
Lost to follow up	8	11.3
Total	71	100

X^2 = 24.805, P < 0.00001.
The median duration to early radiological union = 15 weeks, IQR (6 – 42) weeks

3.10 Post-operative Infections

A total of 5 patients (7%) developed infection. Three (4.2%) out of the four (5.6%) patients with superficial infection progressed to deep wound infection, of which 1 case developed overt post operative chronic osteomyelitis. One other patient developed overt post operative chronic osteomyelitis 3 months after surgery. The number of persons that developed chronic osteomyelitis among the 8 patients that defaulted follow up could not be ascertained.

4. DISCUSSION

Long bone diaphyseal fracture often results from high energy injuries especially in young fit adults. These injuries may involve multiple long bones such as the humerus, femur and tibia. When such fractures occur, early fixation of the fractures is required to enable early mobilization of the patients and early return of the patients to pre-morbid condition. These remain the goal of treatment.

Table 8. Distribution of post operative infections

Type of post op infection	Nos	%
Superficial wound infection	4	5.6
Deep wound infection	3	4.2
Chronic Osteomyelitis	2	2.8
Total pts with infection	5	7

The age and gender distributions of the patients in this study (Table 2) buttress the fact that these injuries are commoner among the young active males who are often the economic livewire of their various families, community and the wider society [10]. The reasons for this may include the fact that the group are more exposed to risks and have a higher tendency to risk taking in their daily activities especially when they are the bread winners of their family.

Most of the fractures treated in this study resulted from road traffic crashes (RTC) (n= 58 {81.7%}). This is a common finding in other studies across the globe [21,22]. This is not surprising because such injuries from RTC often produce closed fractures resulting from blunt mechanism of injury. Penetrating injuries from gunshot wounds (GSW) and stab injuries often will result in open fractures which are not commonly treated by internal fixation especially when they are heavily contaminated for fear of post operative infection. In this series, only 3 of the fractures of Gustilo and Anderson types 1 and 2 open fracture [23] resulting from GSW was treated by locked IM nailing using the MODAD. This has been the tradition among most orthopaedic surgeons but of recent, some surgeons are beginning to apply internal fixation for open fractures even in cases of Gustilo and Anderson grade 3a with reported good results [24]. Internal fixation in open fracture requires the application of principles of early and appropriate wound care, stable internal fixation followed by immediate wound cover and appropriate antibiotics administration. This is exemplified in the principles of “fix and flap” advocated jointly by the British Orthopaedic Association and the British Association of Plastic Surgeons [25].

The recorded median total operation time of 1 hour 54 minutes (mins) which ranged from 40 mins to 4 hour 10 mins) can be attributed to limited experience on the use of the device especially in the early stages of commencement of the use of MODAD. The operation time improved over the period with improvement in the learning curve. Other intra operative challenges observed in this study, was the number of target misses while inserting the locking screws in the IM nails especially the distal ones. The precision of insertion of the locking screws also improved with experience of the surgeon. The recorded 8 misses of target hole (7.8%) from this study confirmed a high precision of the use MODAD system. Other authors had published comparable target hole misses [18,20] and even with the use of C-arm [12].

The average blood loss recorded (452 ± 168 mls) during surgery with the use of MODAD was relatively much less when compared to that from reported from open nailing [26] but much higher than the 119 mls recorded by Chaudhary et al. [27] from closed reduction and intra medullary nailing of femoral fractures. This is due to the fact that the fracture site still required to be opened when using MODAD to enable reduction of the fracture fragments. Opening the fracture site usually results in bleeding, loss of the fracture haematoma and exposes both the fracture site and the fracture haematoma to the exterior. Some authors have argued that this action converts the closed fracture to an open fracture with attendant higher risk of infection, delayed and non-union [28,29]. The average amount of blood loss recorded from this study is however lower than that reported during open reduction and internal fixation (ORIF) using plates and screws (plating) [29] especially in cases of fractures of the femur and humerus. This quantity of blood loss did not require blood transfusion in most cases. The observed total infection rate of 7% (n = 5) is comparable to that recorded by Young et al. [30] but higher than 1% to 2% reported by Duan et al. [31]. The reason for the observed differences may be related to other factors rather than the choice of instruments of surgery such as differences in the conditions of the operating rooms (OR) behaviour of the operating room conditions from the different studies. However, the reported post operative

infection rate from this study is far lower than that reported by various authors for higher grade open fracture which may exceed 30% in some cases [32,33]. The observed infection rate from this study is not unusual as the fracture site had to be opened for reduction of the fractures fragments before fixation using this method, thus converting closed fractures to open fractures in most instances. This is however the usual practice when plates and screws is used for the fixation of fractures.

The observed median duration of post operative hospitalization of 2 days ensured appreciable reduction in the cost of hospitalization and lower risk of acquiring hospital associated infections which contributes to increased cost of care to hospitalized patients [34]. In addition, the early mobilization and early weight bearing of the patients on the affected limbs reduced the rate of complications associated with prolonged immobilization such as development of deep venous thrombosis, orthostatic pneumonia and decubitus ulcers [35].

The observed median duration to radiological healing (union) of the fractures of 15 weeks, IQR (6 – 42) weeks for the fractures is comparable to the 16 weeks reported by Babalola et al. in which fractures were fixed by locked IM nailing after open reduction. The reported healing time in this study, compared better than the 19.36±6.1 weeks reported by Sadic et al. [36]. This may be related to the minimal tampering of the fracture haematoma and fracture biology despite that the fracture reduction was done by open method thus ensuring optimal fracture biology during the process of the fracture fixation. In addition, the early weight bearing on the affected limb because of the load sharing nature of the implant also stimulates fracture healing [37]. These reasons may increase patients' acceptance of this method of treatment as compared to traditional plating and non-locked IM nailing which often require longer duration to bearing and of fracture union.

5. CONCLUSION

Methods of treatment of fractures continue to evolve over the years. Trends toward minimally invasive techniques with minimal tampering of the fracture site and haematoma but providing adequate stabilization of the fracture are encouraged. These allow early mobilization of the fractured limb and the injured patient as well as early fracture healing with minimal complications. The use of this system resulted in shortened post operative hospitalisation, early mobilization of patients, early weight bearing on the fractured limb, early fracture union and acceptable infection rates in the treatment of fractures of the shaft of long bones. The use of MODAD in the treatment of fractures of the shaft of long bone is a good method especially in a developing country like Nigeria where the resources required for optimal fracture care like closed IM nailing such as intra operative imaging and experienced human resources may not be readily available.

CONSENT

As per international standard or university standard, patient's written consent has been collected and preserved by the author.

ETHICAL APPROVAL

As per international standard or university standard, written approval of Ethics committee has been collected and preserved by the author.

COMPETING INTERESTS

Author has declared that no competing interests exist.

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