

Original Research Article

The Use of Synthes Modular Distal Aiming Device (MODAD) System for Locked Intra-Medullary nailing for fixation of fractures in Nigeria. A Prospective Observational Study.

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 MODAD by Synthes.

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

Method: 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.

Result: During the period under study, 71 fractures were treated in the 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 mins (IQR, 40mins – 4hour 10 mins) whereas the median time to locking distal holes was 47 mins (IQR, 25 – 2hour 25 mins). The total average estimated intra-operative blood loss (including fracture haematoma) was 452 mls $\pm$ 128mls) requiring blood transfusion of 25 units of blood for all patients. The Post operative infection 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 od MODAD is comparable with those obtained from the use of C-arm and it eliminated the exposure to irradiation associated with the use of C-arms.

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 nails do not only provides internal splinting of the fractured bone, it is a load bearing 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 alignment and most importantly axial rotational forces of the broken bone fragment 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].

The challenges of the process of locking during IM nailing especially 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 system which are often quite expensive as such may not readily available in most hospitals and affordable to most patients in the developing countries. The use of intra-operative imaging systems exposes both the patient, the surgeons and other operating room (OR) personnel to doses of irradiation [4], prolonged operation time, increased 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].

60 Tasbas BA et al has shown that during locked IM nailing, the surgeon and the assistant
 61 surgeon receive various doses of irradiation. It was observed that following 107 consecutive
 62 operations over a 3-months period,, the operating surgeon who is usually more than 90cm
 63 away from line of the beam receives about 0,0375mSv of irradiation in the outer gown
 64 dosimeter and 0mSv in the under gown dosimeter after each routine IM nailing procedure
 65 while the assistant who is usually approximately 10cm from the beam receives about 0.21mSv
 66 and 0.05mSv in the outer gown and under gown dosimeters respectively [9]. This requires
 67 that the surgeon undertakes about 13,500 IM nailing while the assistant 2000 IM nailing in a
 68 year to reach the set safety limit of irradiation exposure by these personnel. Furthermore,
 69 various organs of the body receive various doses of irradiation during IM nailing with intra
 70 operative imaging. It has been observed that the eyes, thyroid and hands of the surgeon and
 71 the assistant receive the following doses of irradiation (19.0 uSV, 34.5uSV, 41.7uSV)
 72 respectively during a routine locked IM nailing lasting for average of 2 hours using the C-
 73 Arm image intensifier[4] Even operating room personnel within 30 inches from C-arm beam
 74 receive significant irradiation particularly to unprotected areas such as the eyes, nail, hands
 75 [4]

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

85

86 Because of challenges_of locking of distal holes even in presence of intra operative imaging,
 87 various devices have been produced to aid locking of IM nails and tried to reduce the need
 88 and use for intra operative imaging. Such devices include the use of radiolucent drills [12],
 89 the use of distal targeting Jigs [13], laser assisted devices [14], grid and flag devices [15],
 90 magnetic navigational aids [16] and the use of custom designed nails with special slots [17].

91 None of these has generally been accepted [18] as all of the mentioned devices have their
92 challenges too. Most of the mechanical devices fail because of failure of the systems to
93 account for the deformational torque and rotational forces the nail undergoes on insertion
94 [19]. Free hand technique with the use of C arm remains the most popular method used
95 globally.

96 The unavailability of the resources required for the practice of closed locked IM nailing such
97 as functional intra operative imaging, huge capital cost required to acquire and maintain such
98 equipment required for the technique and non availability of personnel with the requisite
99 experience required for the technique limits the capacity to practice locked IM nailing in most
100 centres in the developing countries including Nigeria. The introduction of aiming devices
101 including the MODAD by Synthes was an attempt to obviate the challenges. The use of the
102 MODAD like other targeting devices used for the locking the IM nails particularly the distal
103 holes of the nails is associated with intra operative challenges such as prolonged operation
104 time as compared to the other conventional ORIF methods like unlocked IM nailing, use of
105 plate and screws. This is attributable to the time required to assemble the locking device as
106 well as the time required for the locking of the holes in the nails especially the distal holes
107 [20].

108

109 In Nigeria like in most other developing and resource scarce countries, the use of locked intra
110 medullary nailing for fracture treatment still remain limited because of the reasons already
111 adduced. Most centres resort to the use of available methods that obviates the use of intra-
112 operative imaging. This study aims to showcase the experience with the use of
113 Synthes/Modular Aiming Device (MODAD) for locked intra medullary nailing without intra
114 operative imaging in a trauma centre in Nigeria.

115

116 **Method:**

117 This is a prospective observational study reporting the experience of the use of Synthes
118 MODAD system for locked IM nailing of long bone diaphyseal fractures treated by the
119 author in various hospitals across Nigeria as an expert visiting surgeon between January 1,
120 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 surgery was undertaken by the author of this study who had been trained on the technique of use of the MODAD device and travelled to various hospitals and centres in Nigeria 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 fracture 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 assessed by the duration of post operative wound healing, clinical and radiological fracture union, post operative wound infection and occurrence of post operative osteomyelitis.

Data relating to patients demographics, indication for locked IM nailing, intra operation time, intra operation blood loss and post operative outcome estimated by the length of hospital stay, post operative infections and duration of early fracture healing as assessed by early radiological union were collated. The data was analyzed using statistical package for windows version 20 (IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp.). Descriptive statistics was generated and presented with means with standard deviation (SD) and median with inter quartile ranges (IQR) for numerical variables while categorical variables are presented as proportions and percentages. Chi Square X2 was used to test for observed differences among categorical variables whereas differences between means were tested by student's t test. Results are presented with descriptive statistics as considered appropriate and inferential statistics when necessary. P values less than 0.05 are accepted as statistical significant.

151 **Results:**

152 Between January 1 2007 and May 15, 2014, 71 cases of locked intramedullary nailing of the
 153 fractures of the shaft of long bones were undertaken by the author across various hospitals in
 154 Nigeria. Most 54 (76%) of the operations were undertaken at the Teme hospital Port
 155 Harcourt. The patients and the hospitals are distributed in table 1.

156

157 **1. Table 1 showing Patients and the Hospitals where procedure was undertaken.**

158	<u>Centre</u>	<u>No of cases</u>
159	Teme Trauma Centre Port Harcourt	54
160	Other Private Hospitals in Port Harcourt	10
161	University of Port Harcourt Teaching Hospital	2
162	National Orthopaedic Hospital Igbobi Lagos	1
163	National Orthopaedic Hospital Enugu	1
164	National Orthopaedic Hospital Dala Kano	2
165	Federal Medical Centre Gombe	1
166	Total	71

167 **2. Age distribution of the patients:**

168 **Table 2, Age distribution of the patients.**

Age in years	No	%
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

169

170 3. Gender distribution

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

172

173 3. Cause of Injury

174 Table 3, Distribution of cause of injury

Cause of injury	Nos	%
Road Traffic Injury	58	81.7
Gunshot Wounds	3	4.2
Sports Injuries	4	5.6
Falls	6	8.5
Total	71	100

175 $\chi^2 = 46.67$, $P < 0.00001$

176

177 4. Types of fracture and bones involved

178 Most of the fractures treated using MODAD were closed (n=68, {95.8%}) whereas 3 (4.2%)
 179 of the fractures were open. Forty eight (67.6%) of fractures involved the femur while 23
 180 (33.4%) were tibial fractures.

181

182

5. Average Duration of surgery

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

6. Estimated blood loss from the procedure

Average estimated intra-operative blood loss (including fracture haematoma) was 452 mls $\pm$ 128 mls)

Total units of blood transfusion for all patients 25 units
Intra-op transfusion 10 units
Post - op blood transfusion 15 units

Number of Units of Blood transfusion per patient.

A total of 58 patients (81.7%) did not require blood transfusion, 11 patients has between 1 and 3 units of blood while only 1 patient had more than 5 units of blood.

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

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

$\chi^2 = 50.7528$ $P < 0.00001$

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%

$\chi^2 = 44.0907$ $P < 0.00001$

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 while only 1 patient stayed beyond 28 days after surgery.

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

$\chi^2 = 43.3174$, $P < 0.00001$

Median duration of Post Op hospitalization = 2 days, IQR (2 – 42days)

9. Average duration to early 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 fractures (8.4%) of the fractures was yet to show evidence of healing at 6 months. State of healing of 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 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

The median duration to early radiological union = 15 weeks, IQR (6 – 42) weeks

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 patient developed overt post operative chronic osteomyelitis 3 months after the surgery. The number of persons that developed chronic osteomyelitis among the 8 patients that defaulted follow up could not be ascertained.

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

DISCUSSION:

Long bone diaphyseal fractures 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 premorbid condition. These remain the goal of treatment.

The age and gender distributions of the patients in this study 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 RTC (n= 58 {81.7 %}). This is a common finding in other studies across the globe (Refs). This is not surprising because such injuries from RTC often 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 often not commonly treated by internal fixation especially when they are heavily contaminated for reasons of fear of post operative infection. In this series, only 3 of the fractures which were of Gustilo and Anderson types 1 and 2 open fracture [21] resulting

from GSW was treated by locked IM nailing using the MODAD. This has been the tradition among most orthopaedic surgeons but in the recent times some surgeons are beginning to apply internal fixation for open fractures even up to Gustilo and Anderson grade 3a with reported good results [22]. 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 such as in the principles of “fix and flap” advocated jointly by the British Orthopaedic Association and the British Association of Plastic Surgeons[23].

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

The average blood loss recorded (452 ± 168 mls) from the use of this method was relatively much less when compared to that from reported from open nailing [24] but much higher than the 119 mls recorded by Chaudhary et al for closed reduction and intra medullary nailing of femoral fractures [25] (Ref). This is so because the fracture site still had to be opened when using MODAD to enable proper reduction of the fracture fragments. This usually results in bleeding, loss of the fracture haematoma and exposure of both the fracture site and the fracture haematoma to the exterior. This average amount of blood loss recorded from this study is however lower than that reported during ORIF using plates and screws (plating) [26] especially in cases of fractures of the femur. This quantity of blood did not require the blood transfusion in most cases. 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 [26] [27].

The observed total infection rate of ($n = 5$, {7%}) is comparable to the that recorded by Young et al [28] but higher than 1% to 2% reported by Duan et al [29] The reason for the observed differences may be related to the differences in the operating room (OR) conditions especially as it relates to the OR design, facilities available, and differences in the observation of aseptic measures by the OR personnel between the different centres. However, the reported post operative infection rate from this study is far lower than that reported by various authors for open fracture which may exceed 30% [30] [31]. Especially as the fracture site was opened for reduction of the fractures before fixation thus converting the closed fracture to open fracture in most instances. This is 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 that patients left the hospital early thus ensuring 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 [32] 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 [33].

The median duration to early radiological healing (union) of the fracture of (15weeks, IQR (6 – 42)weeks for most of the fractures is comparable to the 16 weeks reported by Babalola et al 2016 in which fractures were fixed by locked IM nailing after open reduction of the fractures. The healing time compared better than the $19,36 \pm 6,1$ weeks reported by Sadic et al [34]. . This may be related to the minimal tampering of the fracture haematoma and fracture environment despite that the fracture reduction was by open method thus ensuring optimal fracture biology during the process of the fracture fixation and the early weight bearing on the affected limb because of the load bearing nature of the implant which also stimulates fracture healing [35] These reasons contributed to increased patients' satisfaction and 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.

313 **CONCLUSION**

314 Methods of treatment of fractures continue to evolve over the years. Trends toward
 315 minimally invasive techniques with minimal tampering of the fracture site and haematoma
 316 but providing adequate stabilization of the fracture are encouraged. These allow early
 317 mobilization of the fractured limb and the injured patient as well as early fracture healing
 318 with minimal complications. The use of MODAD obviated the need for the expensive C-arm
 319 with its attendant intra operative exposure to irradiation and high skills required for closed IM
 320 nailing of long bone fractures. The use of MODAD however is not without associated
 321 challenges especially during the early period of commencement of the use of such system.
 322 These challenges include prolonged operation time, relatively higher blood loss, distal hole
 323 misses and time required to mastering the technique. These intra operative challenges
 324 improved with experience in the use of the MODAD. The use of this system resulted in
 325 shortened post operative hospitalisation, early mobilization of patients, early weight bearing
 326 on the fractured limb, early fracture union and acceptable infection rates in the treatment of
 327 fractures of the shaft of long bones. The use of MODAD in the treatment of fractures of the
 328 shaft of long bone is a good method especially in a developing country like Nigeria where the
 329 resources required for optimal fracture care like closed IM nailing such as intra operative
 330 imaging and experienced human resources may not be readily available.

331 **DECLARATIONS:**

332 The authors wish to categorically state that this manuscript, including related data, figures
 333 and tables has not been previously published and the manuscript is not under consideration
 334 elsewhere.

335 All the information contained in this manuscript are original except otherwise clearly stated
 336 and duly acknowledged.

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338 **Consent for Publication: Not applicable**

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