# Surgeons' Perceptions about Removal of Orthopaedic Implants in Nigeria.

# Mue DD, Yongu WT, Elachi IC, Salihu MN<sup>\*</sup>.

(Department of surgery, Benue State University, Makurdi- Nigeria) \*(Department of clinical services, National Orthopaedic Hospital Dala, Kano-Nigeria)

**Abstract:** The routine removal of orthopaedic fixation devices after fracture healing is a common practice among surgeons; however, its benefits Vis-à-vis risks remainan issue of debate. Thisstudy evaluated surgeons' perceptions about the indications, priority of implants removal, effectiveness, and risks of removal of orthopaedic implants in Nigeria. A 44-item questionnaire was distributed to 110 attendees of the Annual General Meeting and Scientific Conference of the Nigerian Orthopaedic Association, Lokoja- 2013. Data was analysed using SPSS version 21. The response rate was 78/90 (86.7%), representing 70.9% ofattendees. Majority of surgeons did not agree that asymptomatic orthopaedic implants should be routinely removed for all patients (disagreement: 91.0%, agreement: 6.5%). The major indications for removals were breakage/mechanical failure, infected implants and allergic disposition with mean rating on a 5- point scale of  $4.56\pm0.948$ ,  $4.37\pm0.937$  and  $4.15\pm1.139$  respectively. Most surgeons accrued highest priority to removal of implants in children with a mean rating of  $4.14\pm0.954$ , followed by forearm rush nails  $3.82\pm1.079$ . Without a strict implant removal policy, a remarkable portion of the resources allocated for elective orthopaedic operations would be spent on routine hardware removal procedures. General recommendation for hardware removal is not justified; overall, implant removal should not be considered a routine procedure.

Keywords: Asymptomatic implants, Implant removal, Orthopaedic fixation devices

# I. Introduction

With expanding indications for operative fracture treatment in all age groups and fracture types, the prevalence of fixation devices has substantially increased during the last few decades [1]; consequently, removal of orthopaedic implants has become a frequent elective orthopaedic procedure in developing countries. The clinical indications for implant removal are not well established and there are no definitive guidelines. In a previous study by Bostman et al [2],implant removal contributed to almost 30% of all planned orthopaedic operations, and 15% of all elective surgical operations of the department and they inferred thatthe procedure itself may be quite challenging with substantial morbidity [3] and mayconsume considerable resources [4]. In a study based on 5,095 implant removals, 80% of all internal fixation devices were reported to be removed andit was concluded that without a strict implant removal policy, a remarkable portion of the resources allocated for elective orthopaedic operations would be spent on routine hardware removal procedures [3-4].

Controversy exists as to the need for routine implant removal and current literature does not support routine removal of implants [5]. Nevertheless, it is clear that in a situation where the implant has failed or is infected, it needs to be removed. In children, it may be necessary to remove implants early to avoid disturbances to the growing skeleton, to prevent their bony immuring making later removal technically difficult or impossible, and to allow for planned reconstructive surgery after skeletal maturation (e.g., in case of hip dysplasia). In adults, pain, soft tissue irritation, the resumption of strenuous activities or contact sports after fracture healing, and the patient's demand are typical indications for implant removal in clinical practice [6].

The operation for implant removal carries significant morbidity, with complications as high as 40% reported in certain publications [6,7].Implant removal requires a second surgical procedure in scarred tissue, and poses a risk for neurovascular damage and re-fractures [6], or recurrence of deformity and, it may be quite difficult, especially with deep seated implants that have been in place for a long time [8]. Pain may even worsen after implant removal. Gosling et al [9] a series of 109 femoral nail removals, reported an increase in pain and discomfort was noted in 4/58 (7%) of all patients with, and 10/51 (20%) of all patients without pre-operative symptoms [9].Loder et al [10]made similar observations in subjects who had undergone open reduction and internal fixation of ankle fractures [10].

A routine policy on removal of orthopaedic fixation devices after fracture healing remains an issue of debate as there is paucity of evidence-based guidelines available in literature[2], the clinical indications for implant removal are not well established and little is known on the attitudes of orthopedic surgeons towards implant removal[11]. This survey evaluates surgeons' perceptions about the indications, priority of implants removal, effectiveness, andrisks of removal of orthopaedic implants in Nigeria.

# II. Materials And Method

This cross sectional descriptive study was conducted on 78 attendees of the Annual General Meeting and Scientific Conference of The Nigerian Orthopaedic Association Lokoja- Nigeria, 2013. The survey was conducted during the first of the three day conference through aself-administered two-page questionnaire with 44 items to determine surgeons' opinions and concerns about implant removal.

The proforma contained four parts: 1) demographic information (including age, gender, level of training and specialization, current affiliation, and origin), 2) General knowledge and beliefs about potential benefits and harms of retained material and removal surgery, 3) priority of removal of various orthopaedic implants, and 4) Reasons for removing implants (e.g., type of implant, clinical conditions demanding removal). General knowledge and beliefs were polled by 5-point Likert-scales. Answer options included "I strongly agree," "I strongly disagree," "I don't know," "I disagree," and "I strongly disagree." For all other questions, ratings were made on 5- point scales ranging from "1 = never" to "5 = always."Permission to conduct the survey was obtained from the local organizing committee and the participants were informed that, by filling out the questionnaire, they consented in using the anonymously gathered data for research and publication.

The data was analysed for frequencies of various variables using the Statistical Program for Social Science (SPSS) version 21.According to the quality of data, results are presented as proportions, means, or medians and standard deviations. To ease reading and data interpretation, the results from queries on general knowledge and opinions about implant removal are expressed as proportions of disagreement (including "I strongly disagree" and "I disagree") and agreement (including "I strongly agree" and "I agree").

# III. Results

Of 90 distributed questionnaires, 78 (86.7%) were completed. This represented 70.9% of all 110 attendees of the Annual General Meeting and Scientific Conference of The Nigerian Orthopaedic Association Lokoja- 2013.Surgeonsfrom 24 of the 36 states of Nigeria and 5 countries with a mean age of  $45 \pm 8.8$  years(range; 30 - 65 years) took part in the survey. There were74 males and 4 females with a male female ratio of 18.5:1. The demographic profile issummarized in TABLE 1.

TABLE 2 summarizes the distribution of answers to questionsabout general opinions and attitudes. Majority of surgeons did not agree that asymptomatic orthopaedic implants should be routinely removed for all patients (disagreement: 91.0%, agreement: 6.5%) similarly, many surgeonsdid not agree that orthopedic implants need to beroutinely removed in younger, asymptomatic patients(disagreement: 74.3%, agreement: 23.0%). Also, manyparticipants did not believe that indwelling implants posean excess risk for fractures (disagreement: 52.1%, agreement: 43.9%) and allergy or malignancy (disagreement: 53.3%, agreement: 30.7%). Titanium was considered afer to be retained than stainless steel material (agreement: 63.2%, disagreement: 14.4 %). In contrast to the overall tendency against routine metal removal, 57.3% of all respondents agreed that it therapeutic option in case of otherwise unexplained pain and functional deficits representsa (disagreement:34.6%).Most participants disagreed- that implant removal causes additional soft tissue damage(disagreement: 65.3%, agreement: 28.0%). Most respondents disagreed that implant removal is a procedure that drains valuable hospital resources (disagreement: 63.3%, agreement: 33.8%). About half of all surgeons (50.7%) could not decidewhether implant removal is adequately reimbursed byhealth care insurance carriers, and 40.0% and 9.7% agreed and disagreed that payments are inadequate for the procedure. However, most surgeons want patients to take responsibility for incurring cost of implant removal (agreement: 71.0%, disagreement: 21.0%) most surgeons willadequately charge patients to pay for implant removal by themselves (agreement: 93.4%, disagreement: 6.6%).

Most surgeons would recommend the regular removal implants in children with a mean rating on a 5-point scale of 4.14 $\pm$ 0.954, followed by forearm rush nails 3.82 $\pm$ 1.079, ankle plate 3.72 $\pm$ 0.826, tibial plate 3.66 $\pm$ 0.768,cerclage wires patella 3.61 $\pm$ 0.987. Spinal implants, Dynamic hip screw, clavicular plate and humeral shaftplate wereassigned the lowest priority for removal (mean rating 2.03 $\pm$ 0.944, 2.84 $\pm$ 0.911, 3.06 $\pm$ 1.145 and 3.14 $\pm$ 0.890 respectively) Findings are illustrated in Fig. 1.

Implant breakage/mechanical failure, infected implants, allergic dispositionand Painful implants were considered the mainindication for metal removal (mean rating of  $4.56\pm0.948$ ,  $4.37\pm0.937$ ,  $4.15\pm1.139$  and  $3.92\pm0.897$  respectively), whereas the patient's demand and reducing artifact for planned CT/MRI ranked lowest onthe list of potential indications (mean rating  $3.2\pm1.127$  and  $2.61\pm1.273$  respectively). Results are depicted in Fig. 2.

Characteristic		N(Percentage)		
Age(years)	Range	30-65		
	Mean	45±8.8		
Gender	Male	73(93.6%)		
	Female	4 (5.1%)		
Professional background	Orthopaedic surgeon	69(88.5%)		
	General surgeon	1 (1.3%)		
	Trainee	5 (6.4%)		
	Other	3 (3.8%)		
Current Position	Professor	9 (11.4%)		
	Consultant	57(73.1%)		
	Intern/resident	7 (9.0%)		
	other	5 (6.4%)		
Affiliation	University hospital	35(44.9%)		
	Public, Non-university hospital	32(41.0%)		
	Private hospital	8 (10.3%)		
	Other	2 (2.6%)		

#### Table 1. De nhia file of ondo ----

Table 2: Proportions of agreement and disagreement in statements about general attitude towards implant removal.

Temoval.		Letrongly	I Disagree	I don't		Letrongly
Statement	N(Valid)	disagree(1)	(2)	know (3)	Agree (4)	Agree (5)
Asymptomatic Orthopedic Implants must be removed for all patients	77	21(26.9%)	49(62.8%)	2(2.6)	4(5.1%)	1(1.3%)
Orthopedic Implants must be removed in younger patients (<40yrs of age) even if they cause no problems	74	8(10.3%)	47(60.3%)	2(2.6%)	11(14.1)	6(7.7%)
Not every patients should have implants removed	76	2(2.6%)	-	-	44(56.4%)	30(38.5%)
Leaving implants in-situ poses a risk for later fractures	73	7(9.0%)	31(39.7%)	3(3.8%)	28(35.9%)	4(5.1%)
Titanium implants are safer to be kept in-situ than devices made from stainless steel	76	2(2.6%)	9(11.5%)	17(21.8)	36(46.2)	12(15.4)
In case of otherwise unexplained pain and functional deficits, implants removal is a good option to improve the physical status	75	4(5.1%)	22(28.2%)	6(7.7%)	33(42.3%)	10(12.8%)
Leaving implants in-situ increase the life-time risk for chronic infections,	75	10(12.8%)	30(38.5%)	12(15.4%)	20(25.6%)	3(3.8%)
allergy, and cancer Removing implants is a surgical procedure which drains valuable hospital resources	77	4(5.1%)	44(56.4%)	3(3.8%)	22(28.2%)	4(5.1%)
Removing implants damages healed soft tissue, and is riskier than	75	6(7.7%)	43(55.1%)	5(6.4%)	19(24.4%)	2((2.6%)
retaining the device Given the time and efforts required for implant removal, this procedure is not adequately reimbursed by insurance carriers.	75	-	7(9.0%)	38(48.7%)	27(34.6%)	3(3.8%)
Patients should take responsibility for the incurring costs of implant removal	76	2(2.6%)	14(14.9%)	6(7.7%)	47(60.3%)	7(9.0%)
I will adequately charge patients for the procedure	76	1(1.3%)	4(1.3%)	-	60(76.9%)	11(14.1%)
Biodegradable implants preferred whenever feasible	77	1(1.3%)	7(9.0%)	3(3.8%)	32(41.0%)	34(43.6%)



# IV. Discussion

The findings from this survey indicate that majority (91.0%) of surgeons do not agree in a routine removal policy in asymptomatic subjects. This is in keeping with previous studies by Kahle et al [12] on a case against routine metal removalwhich reported that routine removal of orthopaedic implants in asymptomatic patients is notrecommended andSyed et al [13] in their study on Outcome of painful implant removal after fracture union, which reported that a general recommendation for hardware moval is not justified, overall, implant removal should not be considered aroutine procedure.

Many surgeons doubt clinically significant adverse effects of indwelling metal like stress shielding or an allergic or even carcinogenic potential. Most surgeons agreed that titanium implants are safer to be kept insitu than devices made from stainless steel and that they would prefer biodegradable implants whenever feasible. Although corrosion, systemic release of nickel, chromium, and cobalt, and its presumed toxic, allergic, and even carcinogenic potential have been linked to stainless steel implants, titanium and aluminum had been traced in serum and hair of 16 of 46 patients after spinal instrumentation[14] none of these adverse effects had convincingly been confirmed in the clinical setting<sup>15</sup> and current literature does not support routine removal of implants to protect against allergy, carcinogenesis or metal detection[5]. Nevertheless, it is clear that in a situation where the implant has failed or is infected, it needs to be removed. Orthopedic fixation devices made from titanium alloy are considered less susceptible to degradation and safe to be retained in situ[16]. This knowledgemight be important for counseling of patients whenplanning implant fixation.

Implant breakage/mechanical failure, infected implants, allergic disposition, Painful implants and palpable irritating implant were considered the major indications for metal removal as illustrated in fig. 1, whereas the patient's demand and reducing artifact for planned CT/MRI ranked lowest on the list of potential indications hence are regarded relative indications to take out implant[17]. Within the literature, previously listed criteriafor implant removal include symptomatic hardware,skeletally immature patients, broken hardware,compromised skin, revision fracture surgery for nonunion, malunion,infection, fear of carcinogenesis, peri-implantfracture, prevention of post union stress-shielding, prevention of future bacterial colonization, avoidance of difficult surgery owing to the potential for refracture or implant failure and the possibility that removal will improve functional outcome<sup>18</sup>. The current knowledge base on indications for hardware removal is still limited and would benefit from further exploration [18].

Implants in children ranked first among implants to be considered for routine removal. This information may add to results from a previous survey by Loder et al [11] of 273 pediatric and 99 non-pediatric specialists regarding implant removal in children [11]; While 64% and 50% of all respondents recommended removing DCPs after upper extremity fractures and interlocking nails after femoral shaft fractures, some authors admitted their inclination to remove flexible nails in children despite the lack of scientific evidence and the potential risk for refractures[19]. In children, it may be necessary to remove implants early to avoid disturbances to the growing skeleton, to prevent their bony immuring making later removal technically difficult or impossible, and to allow for planned reconstructive surgery after skeletal maturation (e.g., in case of hip dysplasia)

Most surgeons accrued highest priority to regular removalof forearm rush nails, followed by ankle plate, tibial plate and cerclage wires patella in that order. This may be attributed to palpable irritating effects of (forearm rush nails, ankle plate, tibialplate, cerclage wires patella), unexplained pain (ankle plate), restricted range of joint motion (forearm rush nails) and apparently quick and safe removal procedure of these implants. Spinal implants, Dynamic hip screw, clavicular plate and humeral shaft plate were assigned the lowest priority for removal which may be attributed to the potential risk of the removal operation [9,15]

In case of otherwise unexplained pain and functional deficits, majority of surgeons agreed that implant removal is a good option to improve physical status. According to eight retrospective studies [17] enrolling 346 symptomatic patients, the weighted success rate (i.e., a complete or marked reduction of pain) of implant removal can be estimated at 78%. On the other hand, the weighted failure rate (including subjects with worsening pain) is 22%, or about 1 in 5 patients. Minkowitz et al [20] in their prospective study of 60 patients, mean pain scale, Short Musculoskeletal Function Assessment (SMFA), and Short Form36 Physical Component Scores (SF36-PCS) significantly improved over one year after removal of painful implants [20]. The lack of a head-to-head comparison in available studies does not justify conclusive inferences about a causal relationship between implant removal and symptom control [17].

Most participants disagreed- that implant removal causes additional soft tissue damage. This is at variance withprevious studies investigating implant removal and problems encountered in doing so as relatively high complication rate have been reported[3,6,21] including infection, damage to neurovascular structures and wound healing. Sanderson et al [21] reported an overall complication rate of 20% in a series of 188 patients who had implants removed. In this series, the highest complication rate (42%) was seen in forearm implant removals with the main complications being infection and nerve palsy. Beaupre et al [6] reported refracture rates of up to 21% following removal of 459 plates from the forearm. In a review of 14 studies [17] enrolling 635 patients who underwent removal of forearm plates, the overall incidence of complications ranged from 12 to 40% [22]. Iatrogenic nerve injuries were noted in 2 to 29% refractures in 2 to 26%, and wound infections in 5 to 12% of all studies. An anatomical study performed on cadavers concluded that there was a significant risk to the superficial peroneal nerve when using the distal 3 holes on a 13-hole distal tibial LISS plate [23]. This danger was further exposed by Langkamer and Ackroyd[3]. They described a 40% complication rate following implant removal with 16 out of 22 of these complications being sensory losses secondary to nerve damage. They concluded that unless absolutely necessary, implant removal should not be undertaken.

About half of all surgeons (50.7%) could not decide whether implant removal is adequately reimbursed by health care insurance carriers, and 40.0% and 9.7% agreed and disagreed that payments are inadequate for the procedure. However, most surgeons want patients to take responsibility for the incurring cost of implant removal and most surgeons will adequately charge patients to pay for implant removal by themselves. In a study based on 5,095 implant removals, 80% of all internal fixation devices were reported to be removed [4]. It was concluded that without a strict implant removal policy, a remarkable portion of the resources allocated for elective orthopaedic operations (29% in this series) was spent on routine hardware removal procedures. Furthermore, Bostmanet al [2] in theirstudies on the removal of all implants after fracture healing reported it is not cost-effective and acknowledges the burden of implant removal to hospital resources.

There is currently no controlled trial that would allow for comparism between the benefits and risk of implant removal that might inform scientifically grounded counseling of patients. In addition to the possibility of retained material (broken screws, failed removal) and another period of sick leave and restricted weight bearing, patients must be informed about potential risks of the removal operation[9,15] and about the expected level of success when planning the removal of implant. Several limitations of this investigation desire attention. As a survey, it can only describe opinions and practice patterns, and does not allow for determining the actual effectivenessof implant removal. Questionnaire surveys are prone to multiple sources of bias [24] and answers of the respondents may not reflect their true daily behavior. In addition, recalled numbers may be incorrect and may also have been introduced by remembering a recent successful or unsuccessful case. The proformamay have missed certain scenarios, and some of the questions may be ambiguous.

# V. Conclusion

Implant breaking/mechanical failure, infected implant and palpable irritating implants was agreeable by most surgeons as the commonest indications for removal. Implants in children, condylar plates, and forearm shaft rush nails and tension band wiring of patella were accrued the highest priority for removal by most surgeons. Most surgeons did not know if it is adequately reimbursed by insurance carriers but agreed that patient should be made to adequately pay for the incurring cost. Most surgeons do not agree in a routine removal policy in asymptomatic subjects as this may pose risk to soft tissue and drain valuable hospital resources. Without a strict implant removal policy, a remarkable portion of the resources allocated for elective orthopaedic operations would be spent on routine hardware removal procedures. General recommendation for hardware removal is not justified; overall, implant removal should not be considered a routine procedure. A controlled trial that compares removal to retention is warranted which may identify biological mechanisms and clinical determinants of symptomatic implants, and help to develop clinical decision that may allow for identifying patients who will benefit most from implant removal.

## Acknowledgement

We wish to appreciate the Local organizing committee of Annual General Meeting and Scientific Conference of The Nigerian Orthopaedic Association, Lokoja - 2013 for their support towards data acquisition.

### **References:**

- [1] Moore RM, Hamburger S, Jeng LL, Hamilton PM. Orthopedic implant devices: prevalence and sociodemographic findings from the 1988 National Health Interview Survey, J ApplBiomater, 2,1991,127-131
- [2] Bostman O, Pihlajamaki H, Routine implant removal after fracture surgery: a potentially reducible consumer of hospital resources in trauma units, J Trauma, 41, 1996, 846-849.
- [3] Langkamer VG, Ackroyd CE, Removal of forearm plates: A review of the complications, J Bone Joint Surg Br, 72, 1990, 601–604.
- [4] Davison BL, Refracture following plate removal in supracondylar-intercondylar femur fractures, Orthopedics 26,2003,157-159.
- [5] Hallab N, Merritt K, Jacobs JJ, Metal sensitivity in patients with orthopaedic implants, J Bone Joint Surg Am, 83,2001, 428–436.
- [6] Beaupre GS, Csongradi JJ, Refracture risk after plate removal in the forearm, J Orthop Trauma, 10, 1996, 87-92.
- [7] Brown RM, Wheelwright EF, Chalmers J, Removal of metal implants after fracture surgery: indications and complications, J R CollSurgEdinb, 38, 1993,96-100.
- [8] Busam ML, Esther RJ, Obremskey WT. Hardware removal: indications and expectations. J Am AcadOrthopSurg, 14, 2006,113-20.
- [9] Gösling T, Hüfner T, Hankemeier S, Zelle BA, Müller-Heine A, Krettek C, Femoral nail removal should be restricted in asymptomaticpatients, ClinOrthopRelat Res, 30, 2004, 222-226.
- [10] Brown OL, Dirschl DR, Obremskey WT, Incidence of hardware related pain and its effect on functional outcomes after open reduction and internal fixation of ankle fractures, J OrthopTrauma 15, 2001, 271-274.
- [11] Loder RT, Feinberg JR, Orthopaedic implants in children: survey results regarding routine removal by the pediatric and nonpediatric specialists, J PediatrOrthop, 26, 2006, 510-519.
- [12] Kahle WK: The case against routine metal removal, JPediatrOrthop, 14,1994,229-237.
- [13] Syed AR, Muhammad F U, Syed MA, Syed H M, Syed K A, Irfan AS, Outcome of painful implant removal after fracture union. Pak J Surg, 28(2), 2012, 114-117.
- [14] Kasai Y, Iida R, Uchida A: Metal concentrations in the serum and hair of patients with titanium alloy spinal implants, Spine, 28, 2003,1320-1326.
- [15] Bostman OM. Refracture after removal of a condylar plate from the distal third of the femur, J Bone Joint Surg Am, 72,1990, 1013-8.
- [16] Krischak GD, Gebhard F, Mohr W, Krivan V, Ignatius A, Beck A, Wachter NJ, Reuter P, Arand M, Kinzl L, Claes LE: Difference inmetallic wear distribution released from commercially puretitanium compared with stainless steel plates, ArchOrthopTrauma Surg, 124, 2004, 104-113.
- [17] Beate H, Chris VW, Dirk S. Surgeons' beliefs and perceptions about removal of orthopaedic implants, BMC Musculoskeletal Disorders 9,2008,71-77.
- [18] Muller ME, Allgower M, Schneider R et al. Manual of internal fixation: techniques recommended by the AO-ASIF Group, New York: Springer Verlag; 1979.
- [19] SimanovskyN,Tair MA, Simanovsky N, PoratS,Removal of flexible titanium nails in children,J PediatrOrthop26,2006, 188-192.
- [20] Minkowitz RB, Bhadsavle S, Walsh M, Egol KA: Removal of painful orthopaedic implants after fracture union, J Bone Joint Surg Am, 89,2007,1906-1912.
- [21] Sanderson PL, Ryan W, Turner PG, Complications of metalwork removal, Injury 23,1992, 29–30.
- [22] Evers B, Habelt R, GerngrossH,Indication, timing and complications of plate removal after forearm fractures: results of a metaanalysis including 635 cases,J Bone Joint Surg Br 86,2004, 289-294.
- [23] Raja S, Imbuldeniya AM, Groom G, Difficulties encountered removing locked plates, The annals, 94(7), 2012, 502-505.
- [24] TrelleS, Accuracy of responses from postal surveys about continuing medical education and information behavior: experiences from a survey among German diabetologists, BMC Health Serv Res, 2,2002,15-21.