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Outcome of Synthetic Bone Graft Substitute Hydroxyapatite in the Different Orthopedic Conditions

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Abstract: *A randomized study was conducted to know the efficacy of use of Hydroxyapatite as a bone graft substitute in union of fractures and other bone defects. Ofsurgeons and periodontists need to fill defects in the bone or augment deficient bone. Bone harvested from donor sit the 37 defects in 33 patients, union was seen in 29 patients. Average follow-up was 7.9 months of the available 29 patients for follow up, ranging from 1.5 to 21 months. The mean defect size was 4.9 cu.cm. Non union and tumor recurrence were seen in 1 patient each. Minor complications such as soft tissue infiltration of hydroxyapatite, superficial infection and wound gaping causing nodule formation and pain were noted in few patients. Superficial infection responded adequately to regular dressings and proper antibiotics and pain following the nodule formation gradually subsided over a period of 5-6 months.*

Conclusion *This study concludes that hydroxyapatite can be a useful bone graft substitute with avoidance of donor site morbidity. Complications arising by use of hydroxyapatite per se, are readily manageable*.

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I. Introduction

With the exception of blood, bone is the most frequently transplanted tissue in humans. Virtually every operative day, orthopaedic surgeons, neurosurgeons, craniofacial es is the gold standard for grafting procedure. Although autograft is the standard that all bone graft substitutes must meet or exceed, autograft has significant limitations, including donor site morbidity, inadequate amount or inappropriate quality (osteoporotic). Thus, there is an obvious need for a bone graft substitute to serve as an off the shelf alternative to autograft

II. Material And Methods

Study Design: Prospective study
Study Location: This was a tertiary care teaching hospital-based study done in Department of orthopedics in Narayana Medical College and Hospital, Nellore
Study Duration: between December 2017 and June 2018
Sample size: 33 patients.
Subjects & selection method: By follow up at intervals 1st, 3rd, 6th months, respectively, and 1-year post Operatively. The cases at follow up were analyzed both clinically and radiologically, and
Protocols were filled

Inclusion Criteria
Fractures of long bonesnon union and delayed union after trauma,
Age >20 years to < 60 years
Spinal deformity
Skeletal deformities requiring surgical correction

Exclusion criteria:
Osteomyelitis of the involved limb.
Concurrent use of corticosteroids or immunosuppressive agents.
Pathological fractures.
Pre-existing vascular disease.
Co-existing degenerative / metabolic bone disease.
Expectation of non-compliance because of mental illness or alcoholism.
Fractures or bone defects requiring more than 30 cc graft material.
Open fracture with type III B / III C wounds.

Procedure methodology
Hydroxyapatite was made available in a sterile packet of 10 cc granules / blocks / dowels.
In the routine operation theatre, under suitable anaesthesia, with or without radiological control the necessary procedure was performed. The size of bone defect was then assessed. The site was then washed with Normal saline and dried completely of blood. Any active bleeding in the vicinity of the grafting site was controlled. The sterile hydroxyapatite implant was taken in a dry bowl. After assuring that the site was completely dry, hydroxyapatite was inserted into the bone defect. Care was exercised while inserting this hydroxyapatite implant that it did not spill into the soft tissues. This was made easier when a bone gouge was used for inserting the hydroxyapatite implant. Before closure it was checked that the defect was filled completely with hydroxyapatite. Wound closure was done with soft tissue coverage over the grafted site. Negative suction drain, if needed, was then placed over this layer. This was done so as to prevent the hydroxyapatite granules from coming out through the negative suction drain. Splint was then applied as needed.
Wound examination was done primarily on the third or fourth post operative day and subsequently on the 10th – 12th post operative day when the sutures were removed and the patient discharged if the wound was healthy. In cases where wound was not healthy, wound swabs were taken and sent for culture, broad spectrum antibiotics were continued till the reports were available and then the antibiotics were changed accordingly, if needed. Regular dressings were done till the wound healed completely and then the patient was discharged.

Follow-up:
Follow-up of the patients was done at 6 weeks, 3 months, 9 months, 12 months and at the end of study. At each follow-up the patients were evaluated clinically and radiologically. Clinical assessment of wound and assessment of the activities of daily living were done. Radiographs were taken to assess -

- the fracture union or filling of bone defect.
- any complications such as loss of fixation, delayed union, non-union or implant failure.

Statistical analysis
Statistical software used: SPSS 16 versions were used for the analysis of the data.
Statistical tests used:
Descriptive statistics like mean, percentage, and standard deviations were used.
Chi-Square test of significance for proportions.

III. Results

Patient characteristics:
33 patients were included in the study of which 27 were males & 6 were females. Age of patients ranged from 5-85 years; mean being 39.69 years. Of the patients studied, three patients had previous surgeries with implant failure. There were three patients of non-union and two patients of delayed / mal -union who were previously treated conservatively.

Fracture/Defect characteristics:
Of the 37 defects implanted with hydroxyapatite, 17 [45.9 %]were in femur, 2[5.4%] in tibia,6[16.2%] in humerus,7[18.9%] in radius,3[8.1%]in ulna and 2[5.4%]in spine. Diaphyseal bone defect was in 22 fractures/lesion [59.4%], metaphyseal in 13 fractures/lesions [35.1%]and in one patient both diaphyseal and metaphyseal defect were implanted with hydroxyapatite in the same sitting.

Distribution by type:
In our study 22 fractures [59 %]of 37 defects were comminuted, old were 4[10.8 %], non-union was in 6 fractures [16.2 %]. There were two patients [5.4 %] each of spine and implant failure.

Operative characteristics:
In 33 patients 34 surgical procedures were performed and 37 defects were implanted with hydroxyapatite. 18[52.9%] under general anaesthesia.

Duration of surgery:
Average duration of surgery was 99 minutes, ranging from 60 to 180 minutes. Rigid fixation was achieved in most i.e. 28 [75.6 %] fractures.

Defect:
Average size of defect filled with hydroxyapatite was 4.9 cu.cm.; ranging from 0.75 cu.cm. to 12 cu.cm.

Clinical assessment:
- Wound healing:

In most patients, wound healing was normal. Sterile effusions were seen in two patients and partial wound gaping following superficial infection in one patient.
- Range of movements:
On fracture healing the range of movements was almost normal in most patients after adequate physiotherapy. No significant restriction of movements was noted, and most patients were able to return to work or could perform activities of daily living.

Complications:

Soft tissue infiltration of hydroxyapatite implant was seen in three cases of the study. This resulted in pain & nodule formation in the subcutaneous portions of the forearms of two patients. Pain gradually subsided by the end of 6 months. Superficial infection and wound gaping was noted in 1 patient. Non union was seen in 1[4.2%] patient, and recurrence of tumor occurred in one.

IV. Discussion

Of the 37 defects in 33 patients in the study, 31 [83.7%] were followed up at least till their expected time of union. Of these 29 [93.5%] were found clinically and radiologically united. Two patients lost to follow-up-one male [subtrochanteric fracture] and one female intertrochanteric fracture]. Two patients were operated upon recently and hence even their minimum follow up was not possible. Average follow-up was 7.9 months of the available 29 patients for follow up, ranging from 1.5 to 21 months.

Humerus:

Of the 6 humeral fractures 4 were followed up at least till their expected time of union [follow up range - 5 months - 1 year]. All 4 united at an average duration of 5 months. Two patients with fracture humerus reported for follow up till 3 months post operatively. Till this period both patients had no complications and were progressing towards union.

Forearm bones:
Of the 10 forearm bone fractures in 7 patients, 7 were in radius and 3 in ulna. All 10 [100 %] fractures united at an average of 3.9 months follow up [follow up ranging from 4 months - 21 months].

Femur:

Of the 17 femoral fractures (in 16 patients), 13 were followed up till or more than the usual time required for their union. Union was seen in all these 13 fractures at an average of 5.9 months [100% union].Two femoral fractures were operated recently (then) and hence their follow up wasn't possible. Two patients, one each of subtrochanteric and intertrochanteric fracture were lost to follow up.

Tibia:

Two patients with tibial defects were implanted with hydroxyapatite. One patient with non union of tibial diaphysis was treated by open reduction and internal fixation with 8 holed Dynamic compression plate and screws. Patient was lost to follow up till one year post operatively. At one year post operatively, he presented with implant failure and infection.

A child with polyostotic fibrous dysplasia was implanted with hydroxyapatite in tibial lesion after curettage. Recurrence was seen after three years.

Spine:

A patient of Pott's spine [L5 - S1] was operated upon by an anterior approach for curettage and fusion. Defect was then filled with hydroxyapatite [intraoperative decision]. Patient improved clinically but radiological fusion was not seen at 6 months follow up. Incorporation of hydroxyapatite implant was present. In a patient of spondylolisthesis with Intervertebral disc prolapse with neurodeficit, fusion was not evident at 3 month of follow up.

Autogenous graft has three overlapping clinical roles: it can provide immediate structural support, it can provide an osteoconductive scaffold for the filling of a defect and it can provide an osteogenic stimulus from both cells & growth factors. But the demand of autografts fairly exceeds the supply. Another major drawback is that postoperatively the patients very often suffer pain at donor site. With autograft harvesting procedure the operation time is prolonged considerably with increased costs and risks for the patient.

The synthetic Hydroxyapatite implant is osteoconductive. As it is brittle with little strength, its use is recommended with rigid internal fixation using implants such as plates and screws so as to prevent the hydroxyapatite implant from loading.

Histologically, it has been shown that the osteons contained with the Hydroxyapatite pores after bony investment are not initially arranged along load - bearing forces, [Sandhu and Boden, 1998]. In the present study good incorporation of hydroxyapatite was seen in all the fractures that united or were uniting. Bone ingrowth was seen radiologically as traversing of trabeculae across the fracture or lesion site at last follow up.

The average duration of surgery was 99 minutes. This would have definitely been more had autogenous bone grafting been done as a separate surgical procedure.

Duration of anaesthesia required was also reduced as the need for second surgery for harvesting a graft was eliminated. This prevented intra-operative and postoperative complications due to prolonged anaesthesia especially in old patients which were in a significant number [9 patients were > 50 years] in our study.

Spinal fusion is difficult to visualize early [Thalgott et al,1999]. But symptomatic improvement in these patients and incorporation of hydroxyapatite without its displacement would suggest that fusion would result at later follow up.

In the present study, in 4 out of 33 cases , two that lost to follow up and the two in whom even a minimum follow up wasn't possible due to their recent surgery, no wound complications such as effusion or wound infection were seen.

In the case of infective non-union of tibia the patient didn't appear for regular follow up. Also, the patient was non-compliant. In such circumstances complications can be expected and the role of hydroxyapatite implant in its causation is difficult to ascertain. Also, infection and non union per se, are major problems in Tibialdiaphysial fractures fixed with Dynamic compression plate and screws.

There is potentially an unlimited supply of this implant. In case of Fibrous dysplasia in 5 year child, the availability of adequate amount of autogenous donor bone for grafting is limited. Recurrence was seen after three years follow-up which is comparable with studies of Uchida et al, 1990 and of Gouin et al, 1995.

The dense radiographic image of Hydroxyapatite presented difficulty on quantification of bone ingrowth due to radio-opaque nature of hydroxyapatite and fixation device itself. In most cases of fractures, the adjacent trabeculae blended into the sides of implant without evidences of radiolucent lines at interface. In a case of benign bone tumour curettage incorporation of hydroxyapatite and union was judged according to the criteria given by Uchida et al, 1990 viz -change in radiolucent line or halo around hydroxyapatite implant, increase in density of radiographic image ,and lack of displacement or dislocation of hydroxyapatite implant.

Soft tissue infiltration of hydroxyapatite implant was seen in the initial three cases of the study. This resulted in pain & nodule formation in the subcutaneous portions of the forearms of two patients. Pain gradually subsided by the end of 6 months. Similar observation was seen in the study by Yamamoto et al, 2000.

Other known complications associated with use of Hydroxyapatite, fracture of hydroxyapatite implant itself and erythema around operation site, were not seen in any case.

Biodegradability of hydroxyapatite is slow [Khan et al, 2000] and according to previous studies it has been seen to persist on radiographs for about 10 years. Conforming to this no evidence of biodegradation was seen in any of our cases studied.

V. Conclusion

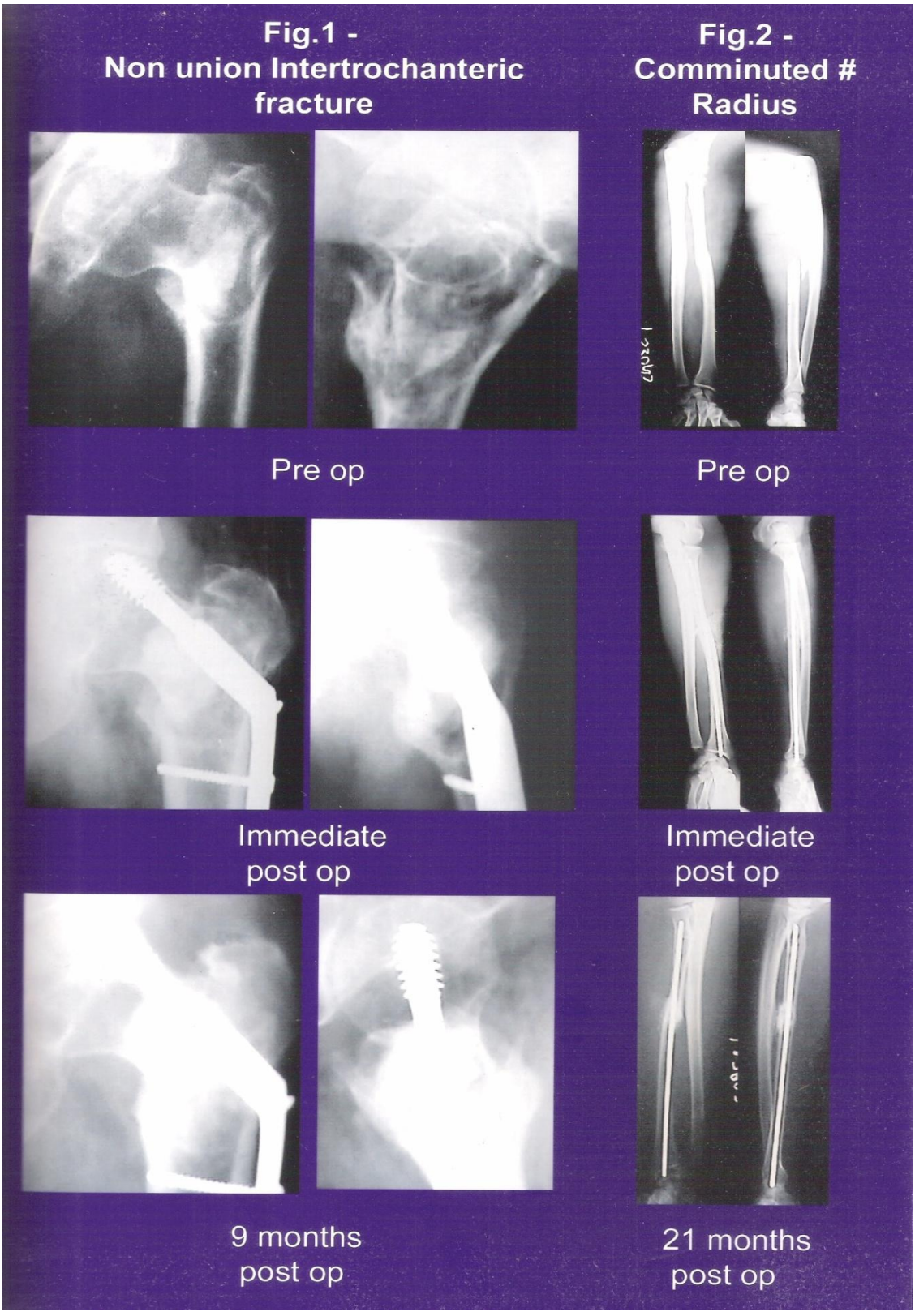
From the present study we conclude that use of Hydroxyapatite implant eliminates autogenous bone graft donor site morbidity, and effectively provides a scaffold for bone ingrowth and shows good incorporation within bony defects.

There are very few complications that occur, which can be easily managed. This use of hydroxyapatite implant is safe and effective procedure to autogenous bone grafting.

The use of synthetic bone graft substitutes is increasing rapidly, and it is hoped that transplantation of bone from donors will one day become obsolete.

Careful evaluation of various innovative materials is necessary to determine if they are safe and have the desired healing and mechanical characteristics. But the future holds good promise for the directed regeneration of bone, damaged by trauma, disease or degeneration.

Conflict of interest:
The authors declare that there is no conflict of interest.
Funding:
There is no sponsor for this study.
Ethical Approval:
Written informed and signed consent is obtained from the patient for publication of this case report.



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