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ORIGINAL ARTICLE

STUDY OF AN ASSESSMENT OF THE FATE OF CALCIUM HYDROXY APATITE BLOCK WITH CORTICO CANCELLOUS BONE GRAFT USED IN COMMUNITED FRACTURES OF LONG BONE OF LOWER LIMB

Ahmad Ayaz[1], K. K. Pruthi[2], R. K. Goyal[3], Syed Esam Mahmood[4]

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ABSTRACT: INTRODUCTION: In recent years there has been an increasing interest in biologically active calcium phosphate ceramic materials for orthopaedic application. A number of materials from human, animal or non-biological sources have been used to fill defects with or without additional autogenus bone. It would be ideal to have bone substitute which is easily fabricated and preserved, is biocompatible with bone, and is biodegradable. The calcium phosphate system, and in particular hydroxyappatite (HA), has long been the subject of intensive investigation. **MATERIAL AND METHODS:** This observational two year study was undertaken at S.N. Medical College and Hospital, Agra (U.P.). The patients having the comminuted fracture of the long bone of lower limbs were treated with autogenus bone graft and calcium hydroxy Apatite bone block. Functional results were presented according to Klemm and Borner (1986) criteria. **RESULTS:** The total cases studied were 25 out of which 21 cases had fracture of both bones of leg and 4 were of fracture femur. The patients were aged between 15 to 70 years. Most of the patients were males and the common mode of injury was road traffic accident. An excellent result were seen in the majority 9(36%) of patients while 8(32%) patients showed a good result and 6(24%) showed a fair result. 17(68%) patients had compound fracture while 8(32%) patients were having closed fracture. **CONCLUSION:** Calcium Hydroxy Apatite is a suitable alternative to bone graft. There was no evidence of any foreign body reaction and infection at the Calcium Hydroxy Apatite implanted site. There was satisfactory healing of all the comminuted fractures. The movement of adjacent joints was nearly normal. No refracture was observed on follow up.

KEYWORDS: Calcium Hydroxy Apatite, graft, comminuted fractures.

INTRODUCTION: Bone Graft is a piece of bone generally taken from one site and inserted elsewhere in the body to replace another osseous structure. Requirement of bone graft is a basic old and important need in orthopaedics surgery. The main indications for bone grafting are in the treatment of non-union of fractures, for filling cavities of bone, or bridging gaps in the shaft of bones caused by trauma and in surgical fusion (arthrodesis) of joints. The 4 main types of grafts used defined on the basis of their origin are autograft, isograft, allograft and xenograft.

The incorporation of a bone graft is defined as the "process of envelopment and interdigitation of the donor bone tissue with new bone deposited by the recipient". The process follows a typical multistep cascade. The sequence of events at the site of graft involves hemorrhage, inflammation, revascularization and finally substitution and remodeling of the graft.

The ideal graft would possess an osteoconductive matrix, osteoinductive factors, osteogenic cells and structural integrity.

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In recent years there has been an increasing interest in biologically active calcium phosphate ceramic materials for orthopaedic application. A number of materials from human, animal or non-biological sources have been used to fill defects with or without additional autogenus bone. It would be ideal to have bone substitute which is easily fabricated and preserved, is biocompatible with bone, and is biodegradable.

The calcium phosphate system, and in particular hydroxyappatite (HA), has long been the subject of intensive investigation. It is from this system that vertebrate tooth and bone mineral are derived. The precipitation and dissolution of HA in aqueous media continues to be studied in detail in order to gain insight into in vivo mineralization processes. Innovations that have emerged from such studies include preventive fluoridation and the development of the diphosphonates used in the treatment of Paget's disease.

Two major types of coralline implants have been extensively investigated, each derived from a different genus of reef-building coral. The coralline hydroxy apatite replicated from the exoskeleton of porites [Coralline Hydroxy Apatite Porites (CHAP)] consists of 230-□m-diameter, parallel channels interconnected by 190-□m diameter fenestrations and has a void volume of 66%. It exhibits only 2.2% of the ultimate strength of human femoral cortical bone. Bone substitute implants of CHAP similar in configuration to autogenous graft strips have been most frequently used as cortical onlay graft material in the treatment of comminuted diaphyseal fractures, combined with internal fixation hardware.

The scleractinian coral genus Goniopara, which possesses a microstructure resembling that of cancellous bone, has been converted to hydroxy apatite [Coralline Hydroxy Apatite Goniopora (CHAG)], chiefly for use as an alternative to autogenous grafting in the management of residual subchondral osseous defects following elevation of depressed articular fragments of epiphyseal-metaphyseal long bone fractures. Although coralline hydroxy apatite is not inherently as strong as trabecular bone and does not exhibit plastic properties owing to the absence of a collagen matrix, with subsequent ingrowth of native bone, it has been shown to become stronger but less stiff than autogenous graft material. This combination of material properties is considered preferable since greater structural support with fewer propensities for damage to the overlying articular cartilage is expected.

Two most widely evaluated material are hydroxy apatite and tricalcium phosphate [$Ca_3(PO_4)_2$]. Calcium hydroxy apatite ceramics are non-toxic substances which provoke little reaction from tissues and have many properties both chemical and physical that make them suitable alternatives to bone grafts. In animal experiments the biological compatibility of CHA to bone & bone marrow has been demonstrated by many investigators.[1-6]

Hydroxy apatite crystals are in shape of needles and plates 27A° – 75A° thick, 44A° – 75A° wide and 50A° – 400A° long. Each crystal consist of lattice composed of thousands of polyhedral units, with some of the positions on the lattice available for substitution by molecules containing Sodium, Potassium, Magnesium, Carbonate, Citrate, Fluoride and other trace elements. The individual apatite crystals are extremely small.

The biological compatibility of calcium hydroxy apatite to bone and bone marrow has been adequately demonstrated. In recent years, therefore hydroxy apatite has become accepted as a suitable material for the repair and filling of bone defects.

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This study was conducted with following aims & objectives:

1. To assess the fate of cortico-cancellous bone graft and calcium hydroxyapatite blocks used in comminuted fracture of long bone of lower limb.
2. To see the merits and demerits of the procedures.
3. The assessment of the complications of the procedures and calcium hydroxyl apatite blocks used in comminuted fracture of long bone of lower limb.

MATERIAL & METHODS: The present two year observational study was conducted amongst the patients admitted in the emergency ward and outdoor patient department of Orthopaedics in S.N. Medical College and Hospital, Agra after taking permission from institution ethical committee. Informed consent was obtained from all the patients. Twenty five patients of either sex having the comminuted fracture of either femur or tibia were managed by primary bone grafting with cortico-cancellus autograft and Calcium Hydroxy Apatite blocks.

CRITERIA FOR SELECTION:

1. Patients above 10 years of age.
2. Patients with defect due to comminuted fracture in long bone of lower limb.
3. The patients with compound fracture in which first management of the wound was done either by primary closure or by dressing and later on skin grafting or flap rotation was done to convert the open fracture into a close fracture and further operated for bone grafting.
4. Patients with skeletal disease or previous osteomyelitis of the affected lower limb were excluded.

General condition of the patient was assessed with regard to hypovolemia associated to orthopaedics or systemic injury and resuscitative measures were taken accordingly.

After immobilizing the limb by just putting the limb on Thomas or B.B. splint as a first aid-measure a thorough clinical examination was done including detail history regarding to age, sex and mode of injury.

After splinting the fracture site patient was shifted for radiological assessment to know the type of fracture and its degree of comminution.

X-rays of the fractured limb were taken in both Antero-posterior and lateral view. Routine investigation and Electrocardiography was done.

INDICATION: In bone defect created by comminuted fracture of long bone of lower limb, metaphysial fracture of femur, diaphysial fracture of femur, metaphysio diaphysial fracture of femur, metaphysial fracture of tibia, metaphysio diaphysial fracture Tibia and diaphysial fracture of tibia.

CONTRAINDICATION: In fracture with vascular impairment proximal to graft site, for the fracture of epiphyseal plate, presence of metabolic and systemic bone disorder and where soft tissue coverage in not possible at graft site.

INSTRUMENTS USED: General orthopaedics instruments, osteotome, currette, bone nibbler and bone gouge.

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IMPLANTS: Calcium hydroxy appatite blocks**.** Out of 25 cases in two cases flexible medullary nail was also used.

ANESTHESIA: Generally spinal or epiduaral anaesthesia were given to the patients.

POST-OPERATIVE MANAGEMENT WAS DONE: The follow up of patient was done on regular basis in OPD which included clinical examination of the patient and radiological evaluation of involved limb.

Functional results were presented according to Klemm and Borner (1986) criteria[7]:

Muscle Atrophy: None, <2 cm, >2 cm.

Radiographic Alignment: Normal, angular deformity less than 5 degree, angular deformity 5 – 10 degree and angular deformity greater than 10 degree.

Knee and ankle movement: Full, < 25% loss of knee/ ankle movement and > 25% loss of knee and ankle movement.

Shortening: Non – significant 0.5 – 2 cm and significant >2 cm.

Union time: Normal (16 weeks – 24 weeks) and Accelerated (<16 weeks).

The ultimate goal of the comminuted fracture of the long bone of the lower limb was to attain an anatomical, functional limb and to return the patients nearly to his pre injury level of function as early as possible.

Data was analysed using SPSS software.

RESULTS:

Gender	**No. of Patients**	**Percentage**
Male	23	92
Female	2	8
Total	**25**	**100**
Age Group (Years)	**No. of Patients**	**Percentage**
Up to – 20	2	8
21 – 30	8	32
31 – 40	7	28
41 – 50	5	20
51 – 60	2	8
61 – 70	1	4
Total	**25**	**100**

Table 1: Gender and Age wise distribution of patients

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Out of 25 cases, 23 patients were males (92%) and 2 were females (8%). The highest number of patients was in 3rd and 4th decade. (Table 1)

Site	No. of Patients	Percentage
Proximal Tibia	7	28
Mid Shaft Tibia	4	16
Distal Tibia	10	40
Proximal Femur	1	4
Mid Shaft Femur	2	8
Distal Femur	1	4
Total	**25**	**100**

Table 2: Percentage of Site of Fracture of Involved Bone

Leg was more commonly fractured bone than femur required bone grafting. There were more cases of lower end of tibia in which bone grafting were done than upper or middle end. (Table 2)

Mode of Injury	No. of Patients	Percentage
RTA	21	84
Others	4	16
Total	**25**	**100**
Type of Fracture	**No. of Patients**	**Percentage**
Patients with open fracture	17	68
Patients with closed fracture	8	32
Total	**25**	**100**

Table 3: Mode of Injury and type of fracture among patients

In majority of cases the mode of injury was road traffic accident (84%) and rest (16%) injuries was either by physical assault, fall from height or gun-shot injury. 17(68%) patients had compound fracture while 8(32%) patients were having closed fracture. (Table 3)

Functional Results		No. of Patients	Percentage
Excellent	Full knee and ankle motion, nomuscle atrophy, normal radiographic alignment	9	36
Good	Slight loss of knee and ankle motion (< 25%), < 2 cm of muscle atrophy, angular deformity < 5^0	8	32
Fair	Moderate (> 25%) loss of knee and ankle motion, > 2 cm muscle atrophy, angulation 5-10^0	6	24

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Poor	Marked loss of knee or ankle motion, marked muscle atrophy, angular deformity > 10^0	2	8
Total		**25**	**100**

Table 4: Function Results using Klemm and Borner criteria (1986)

An excellent result were seen in the majority 9(36%) of patients, 8(32%) patients showed a good result and 6(24%) showed a fair result. (Table 4)

DISCUSSION: The youngest patient was of 15 years of age and oldest was of 68 years in this study. The maximum number of the cases belonged to 3rd and 4th decade and were males. This can be attributed to their active life style. Males who do most of the outdoor activities and driving in India are more prone to injury.

In our study group in which bone grafting was done comprises 84% patients with fracture of tibia, and 16% with fracture femur. The common fracture in which bone grafting were done were at on either end of tibia comprising, 40% and 28% on distal third and proximal third respectively and third common site was mid shaft tibia. This was probably because of the fracture of leg much more common than that of femur which undergo comminution as a result of which defects are created and require bone grafting for the stability and union of the fracture.

In today's scenario high velocity trauma is commonly responsible for most of the fracture of the long bone of lower limb particularly the tibial shaft fracture which is the commonest one. These high energy trauma are responsible for the comminution and soft tissue damage. More over poor blood supply, comminution and soft tissue damage particularly in the tibial fracture are associated with a higher incidence of delayed union and non-union as compared to the other long bones.

Therefore the bone defects caused by comminuted fracture should be filled with autogenus bone graft and bone substitute to achieve early union and obtain mechanical strength as soon as possible by the stimulation of osteogenesis, osteoinduction and osteoconduction.

Porous or granular Calcium Hydroxy Apatite implanted into bone defects can produce a suitable frame work for human osteogenesis and is comparable and comfortable well with other bone substitutes such as allografts and xenografts.

Coral is the constructed exoskeleton of marine invertebrates that extract calcium and carbonate from sea water. Specific, symmetrically oriented structures are produced by each unique species and because of their macroscopic architectural similarities to bone, they are suitable frameworks for human osteogenesis following chemical conversion. By a hydrothermal exchange method, the limestone or calcium carbonate of coral is replaced by pure hydroxy apatite without altering the structural characteristics.

We believe that Calcium Hydroxy Apatite has favourable clinical results because of less adverse effects, biocompatibility to tissue of the body, ease of manufacture production and shape adjustment. Therefore, it is strongly suggested as a useful bone substitute.

Radiographic observation after implantation shows evidence of abundant bone formation around Calcium Hydroxy Apatite with good incorporation into host bone. These radiographic results are generally consistent with those from other studies in fractures[8]. Because no quantitative

measurements are available for the evaluation of bone ingrowth into porous mineral it is impossible to compare exactly the ingrowth rates with that of other bone substitutes.

The currently available types of porous Calcium Hydroxy Apatite lack substantial mechanical integrity because of their brittle nature, which make them mechanically unsuitable for unstable segmental diaphyseal defects. However, where surrounding bone is intact or rigidly stabilized to shield the ceramic from loading during bone in growth a block of porous Calcium Hydroxy Apatite can provide better support that standard cancellous bone within months, the composite of Calcium Hydroxy Apatite and newly formed bone should have sufficient mechanical strength.[8,9]

To get good mechanical results, technical skill in tightly filling the defects is important for optimal bone ingrowth. In our series all the comminuted fractures healed and no refracture was seen in a follow up of two years. Post-operative radiographs also suggested that Calcium Hydroxy Apatite-implanted bone has sufficient mechanical strength because of early dense radiographic image of Calcium Hydroxy Apatite after operation. These findings should not misguide us, to let the patients mobilize early, so post-operative immobilization is important, particularly after treating the comminuted fracture of femur and tibia.

Based on Klemm and Borner's (1986) Criteria for functional assessment used in this study, 36% patients showed an excellent result, 32% patients showed a good result and 24% showed a fair result. Similar findings were observed in a study by Kumar et al (2013),[10] where out of 48 cases 20 (41.6%) showed excellent functional results, good results in 14 cases (29.1%), fair results in 12 cases (24.9%) poor results in 2 cases (4.1%) using Klemm and Borner's (1986) Criteria.

Judging from radiological findings the biodegradation of Calcium Hydroxy Apatite is likely to be very slight even after our follow up of two years.

In our limited experience with coralline hydroxy bone graft substitutes, we have encountered no significant complications related to implant themselves. The observed definite slight loss of intrinsic architecture and margins of the implants on follow up radiographs is presumably related to bone in growth and osteoclastic activity associated with normal incorporation, with the latter confined to the exposed surface of the material. This phenomenon should not be misinterpreted as graft infection, although the latter might be expected to produce similar finding. In two cases of superficial infections and only in one patient deep infection was observed which subsided uneventfully.

The aim of modern treatment is to get back the prediseased status as early as possible and to prevent refracture.

CONCLUSION: Calcium Hydroxy Apatite is a suitable alternative to bone graft. There was no evidence of any foreign body reaction and infection at the Calcium Hydroxy Apatite implanted site. There was satisfactory healing of all the comminuted fractures. The movement of adjacent joints was nearly normal. No refracture was observed on follow up.

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AUTHORS:

1. Ahmad Ayaz
2. K. K. Pruthi
3. R. K. Goyal
4. Syed Esam Mahmood

PARTICULARS OF CONTRIBUTORS:

1. Assistant Professor, Department of Orthopaedics, Government Medical College, Ambedkar Nagar, U. P.
2. Ex-Professor & Head, Department of Orthopaedics, S. N. Medical College, Agra, U. P.
3. Ex-Professor, Department of Orthopaedics, S. N. Medical College, Agra, U. P.
4. Assistant Professor, Department of Community Medicine, Government Medical College, Ambedkar Nagar, U. P.

NAME ADDRESS EMAIL ID OF THE CORRESPONDING AUTHOR:

Dr. Syed Esam Mahmood,
Assistant Professor,
Department of Community Medicine,
Government Medical College,
Ambedkar Nagar, U. P, India.
E-mail: semahmood@gmail.com

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