Short-Term Clinical and Radiographic Follow-up of a Synthetic Calcium Sulfate and Beta-Tricalcium Phosphate Composite Bone Graft (genex®)

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INTRODUCTION: Synthetic bone grafts have gained popularity for addressing bone defects following trauma or curettage of bone lesions. While previous studies have investigated the use of calcium phosphate, calcium sulfate, or tricalcium phosphate alone for bone defect filling, limited data exists regarding the outcomes and associated radiographic resorption patterns of genex®, a synthetic calcium composite bone graft, in oncologic applications. Therefore, the purpose of this study is to evaluate the effectiveness of genex® in terms of graft resorption, incorporation, early clinical outcomes, and complications. We hypothesize that the graft will demonstrate progressive incorporation into the bone and controlled resorption over the course of one year, while being safe and efficacious in oncologic applications.

METHODS: A retrospective chart review of 14 consecutive patients' charts who underwent placement of a genex® graft was performed. Each patient had undergone open biopsy and defect grafting during 2020-2021. Initial graft dimensions were obtained from intra-operative notes. Graft resorption was assessed by measuring the proportion of remaining graft material on standard anteroposterior and lateral radiographs. Graft incorporation was determined by measuring the proportion of bone formation versus the initial defect size. Resorption and incorporation were both assessed at 6 weeks, 3 months, 6 months, and 1 year postoperatively. Additionally, the charts were thoroughly examined for any mentions of graft reactions or fractures.

RESULTS: Fourteen patients (mean age 18.5±13.6) were included in the analysis; one patient did not follow up after two weeks. On average, 65.9% ± 20.8 of graft material was resorbed at six weeks (n=13), increasing to 78.7%±28.3 by three months (n=10). Notably, four patients exhibited nearly complete resorption of graft material at three months. The average graft resorption at 6 months was 87.4%±15.9 (n=6), with three additional patients experiencing full resorption of graft material. At 1-year follow-up, the average graft resorption was 99.1%±1.8 (n=4), with three out of four additional patients experiencing complete resorption of the graft. The graft demonstrated 17.7%±26.8 incorporation at 6 weeks (n=13), 72.7%±105.7 incorporation at 3 months (n=10), 69.1%±23.6 incorporation at 6 months (n=4), and 99.2%±1.8 incorporation at 1 year (n=2). The most prevalent radiographic finding was a "halo" of sclerotic bone around the graft material, which was evident in 12 out of 13 patients at the six-week visit. The graft material was typically resorbed heterogeneously. Two post-operative fractures occurred through the graft site: one through a proximal femoral shaft unicameral cyst during baseball practice a year after curettage, and the second ten days after the curettage of a unicameral bone cyst in the humeral shaft following direct trauma. Additionally, two instances of local recurrence were observed: one in a unicameral bone cyst in the same patient who experienced the post-operative proximal femur fracture, and the other in an aneurysmal bone cyst in an additional patient. Importantly, no post-operative adverse local tissue graft reactions were noted.

DISCUSSION: Genex® exhibited rapid and effective resorption, with a mean resorption of over 65% at 6 weeks and essentially complete resorption at 1 year. Genex® also demonstrated effective incorporation as well, as indicated by almost complete incorporation at 1 year. Our study demonstrated this synthetic composite graft's capacity for osteo-regeneration and resorption, enabling the integration of native bone structure. The observed halo pattern of initially peripheral resorption signifies centripetal resorption progressing towards the center of the bone defect. While four complications in three patients were noted in this study, one of the two fractures occurred early post-op before any graft incorporation would be expected and another occurred in association with local lesional recurrence, suggesting a disease-related rather than graft-related etiology. However, for the patient with a late fracture in the absence of recurrence, the etiology is plausibly related to the lack of complete graft resorption and incorporation at that point. If this single case were considered a failure of the graft material, the success rate was 92.9%. Notably, there were found to be no instances of post-operative adverse local tissue graft reactions, including graft discharge, prolonged drainage, seroma formation, or infection/cellulitis, indicating the safety of this material. Larger studies are needed to investigate patient outcomes and complications.

SIGNIFICANCE: Genex® offers a promising solution for bone defect management after the resection of nonmalignant and low-grade malignant bone tumors, facilitating native bone regeneration through controlled resorption. These findings suggest it is a safe and effective option for use in orthopedic oncology applications.