Results after Using Bioactive Glass S53P4 in Reconstructive Orthopaedic Surgery - A 36 - Month Follow-up Clinical Study

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Osteocartilaginous tissue normally has the capability of regeneration, which means that many osteoarticular problems or bony defects will heal spontaneously, not needing important interventions. Although the high regenerative capacity of this tissue, large osseous defects encountered difficulties in optimal healing process and remain a clinical challenge, demanding surgical procedures. This aim of this study was to evaluate clinical and radiological outcomes using bioactive glass S53P4 (BonAlive®) as a synthetic bone substitute material in some specific orthopedic pathologies like prosthesis revision surgery, and pseudarthrosis.

Keywords: Bioactive Glass, osteostimulation, osteoconductive materials

BonAlive® is a 100% synthetic bioactive bone graft substitute which promotes new bone formation [1-3]. It is well known that BonAlive glass has some good abilities which improve the growth of bone cells and the connections between soft tissues and bones. BonAlive® granules offers important osteoconductive properties providing a supportive material for the osteoblast cells during bone formation. As a result of the osteoconductive process, bone grows onto and between the bioactive glass granules. Furthermore, the bioactive glass has been proven to activate a biological process that stimulates bone regeneration in a superior way than other osteoconductive materials [3-8]. After implantation the chemical reactions starts with appearance of an amalgam of amorphous calcium phosphate or crystallin hydroxyapatite covering the glass particles [9].

An important number of cases with bones injuries or chronic pathologies which involve a lack of bone tissue the bone regeneration can be unsuccessful. These cases, for example tibial fractures, predisposed to delayed union or pseudarthrosis or bone defects encountered in revision arthroplasty, a large quantity of bone tissue is needed. The regeneration is not possible in these cases due to amount of bone loss which disrupts the potential of self-healing [10,11].

In those situations, we have to use scaffolds for bone regeneration known as polymer, glass and ceramic materials. The best scaffold required for bone regeneration should encountered some specific qualities such as biocompatibility, osteoinductivity and good osteogenic response [12,13].

Experimental part

Between June 2010 and August 2014, we designed a prospective, clinical and radiological study. 36 months follow-up consisting of 75 patients treated surgically on which we use bioactive glass to fulfill bone defects. The patients were included in three groups regarding the site of bone defects. The first group included the upper extremity, the second group contain lower extremity and the third group with acetabular defects after hip arthroplasty. A number of 75 patients were included in this study divided in 32 females, 42 males, mean age 57 years (range 25-82). All patients were operated by the same surgical team. In 15 cases the patients complain about gastric pain and have been investigated in the Gastroenterological department and they have been diagnosticated with helicobacter Pylori and receive specific medication.

All patients were treated with BonAlive® scaffold used as the substitute material for the bone defects.

The first group of 22 patients were treated for upper limb pseudarthrosis (14 humerus and 8 forearm) with intramedullary nail and plate with screws.

The second group of 32 patients with lower limb pseudarthrosis (22 femur and 10 tibia) with intramedullary nail and plate with screws.

The third group of 21 cases with different type of acetabular defects (table 2) described by [14] underwent revision hip arthroplasty.

Table 1

Type	Sex	Patients
Type 2 A	Male 6, female 5	11
Type 2 B	Male 4, female 2	6
Type 2 C	Male 3, female 1	4

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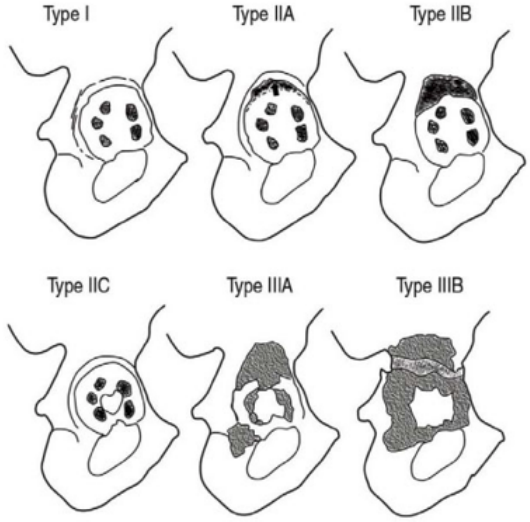

Fig.1.AAOS acetabular defects classification

Bone defect location	BonALive Granules size	Type of procedures
Humerus	Medium	intramedullary nail 6 cases plate and screws 8 cases
Forearm	Medium	Plate and screws 8 cases
Femur	Large	intramedullary nail 12 cases plate screws 10 cases
Tibia	Large	intramedullary nail 10 cases
Acetabulum	Large	uncemented prosthesis 13 cases cemented revision prosthesis 8 cases

Table 2
ACETABULAR DEFECTS TYPE

All these procedures are contained in table 1.

The bioactive glass granules were moistened with saline solution before implantation according to the instructions, and the size wes chosen based on the defect largeness.

Patient follow-up extended up to 36 months, were clinically and radiological evaluated. Clinical evaluation was done according to the specific area of surgery. Radiologic evaluation was based on comparing the preoperative radiographs with the postoperative ones, obtained immediately after surgery, at 1, 3, 6,12,24 and 36 months.

Integration of the bioactive glass granules was observed on Rx images.

All the patients received the same antibiotheraphy and tromboprophilaxy (for the lower limb) medication and rehabilitation protocol for the affected area.

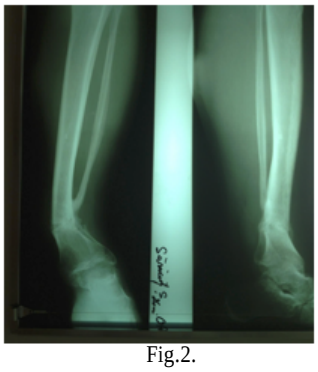

Fig.2.

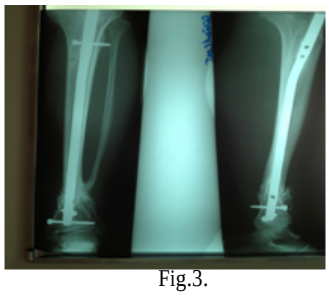

Fig.3.

Results and discussions

Clinical and radiological examination of the patients were performed at 1, 3, 6, 12, 24 and 36 months, and also the patient satisfaction level and functional performance were evaluated. Radiological analysis was performed preoperatively, immediately postoperatively and at 1, 3, 6,12,24 and 36 months. We used the Visual Analog Scale to evaluate the results(d.). 94 % of the patients were very satisfied with the results and 6% were satisfied. The radiological results were excellent in all cases showing that BonAlive® granules were very well integrated and helped for the defects fulfilling preventing bone collapse. No signs of osteolysis or implant rejection were observed on the X-rays. In hip revision surgery due to local bone loss, BonAlive® can be successfully used to fill the dead space above the acetabular component (fig. 2-6).

From the number of satisfied patients 8 cases suffered complication, 6 cases presented local seroma which was drained and solved and in 2 cases the patients suffered traumatic accidents and presents a hematoma which was treated properly.

This bioactive glass compounds a lot of important properties such as osteoconductive and osteoinductive useful for new bone growth at the board with the surrounding tissue; it increases from boarder to center also from the implant center to the bone-implant face. The sodium and calcium ions and soluble silica are responsible for the osteogenic induction. The approbative effects of bioactive glasses implants are not limited to osseous regeneration, as it was shown that they induce an increased vascularity in bone lesions of earlier irradiated calvaria [16].

Fig.4.

Fig.5.

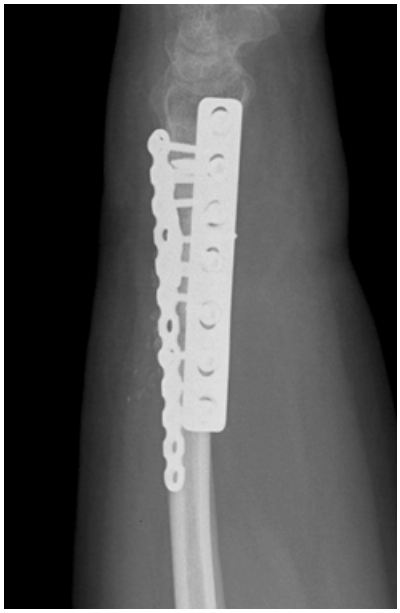

Fig.6.

Bioactive Glass seems to be a very good solution for treating osteomyelitis, traumatic pseudarthrosis, revision prosthesis interventions or other pathologies involving bone tissue resorbtion or bone defects [18, 25-29]. This scaffold seems to be a proper substitute for other treatment in hip revision arthroplasty [23,24].

It shows important anti-microbial, osteoconductive and angiogenic properties useful for bone defects treatment [17,18]. Moisture with body fluids bioactive glass provides ions (Na, Ca, Si and P ions) providing an alkaline environment (high *p* H) and increased osmotic pressure needful to inhibit bacterial growth.

The resorption period depends on the size of the granules and the amount used [19,20].

Furthermore, bioactive glass has a proven bacteriostatic property [21,22].

Conclusions

Due to its osteostimulative nature and packing properties, BonAlive® may be effectively used in demanding cases such as pseudarthrosis and revision surgery.

In this study, all patients were successfully treated and recovered, showing excellent results.

Previous studies and this study have demonstrated that S53P4 is bioactive, osteoconductive and bone bonding, and that it does resorb slowly in bone tissue.

We conclude that bioactive glass S53P4 (BonAlive®) granules can be clinically used, with success as a bone substitute material providing a good alternative for bone defects treatment.

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