ORIGINAL ARTICLE

Our Short-term Experience with the Use of S53p4 (BonAlive®) Bioactive Glass as a Bone Graft Substitute

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Objective: To analyze the results of using S53P4 as a bone graft substitute in a series of orthopaedic procedures.
Methods: We included a number of 9 patients in our study between July 2010 and March 2011. There were 4 cases of cystic or tumoral lesions, 2 revision total hip replacements, 1 primary hip replacement, 1 calcaneus fracture and 1 case on femoral supracondylar non-union. All were treated using bioactive glass as a bone substitute alone, or in conjunction with morselized allografts and autogenous bone grafts. Patients were evaluated clinically and radiologically at 1, 3 and 6 months after surgery.
Results: We found good results on clinical evaluation and radiological evaluation showed signs of graft osteo-integration and incorporation of the synthetic bone substitute in all cases.
Conclusions: Our preliminary results have shown that bioactive glass (S53P4) can be successfully used as a bone substitute material in all of the presented pathological conditions. We believe that this type of synthetic bone substitute will become more popular in the future, due to its special properties.

Keywords: bioactive, glass, bone, graft, substitute

Introduction

A number of approximately 2.2 million bone grafting procedures are performed worldwide every year. These are used for the treatment of bone tumours, osteomyelitis, fractures, revision arthroplasties, spine fusion, etc. This has led to an increase in the need for auto- and allografts, but both of these options come with side effects (e.g. local complications and donor site morbidity). In addition, the amount of autogenous bonegraft available may be the limiting factor for many procedures.

Thus the use of bone graft substitutes has become a viable, effective and safe option, and it seems that synthetic bone graft substitutes are replacing the traditional golden standard of autogenous bone grafts and allografts. In 2007, the number of orthopaedic procedures performed in the USA with bone graft substitutes exceeded for the first time the number of those using autologous bone.

From the many variants of bone graft substitutes, the group of bioactive glasses offer a great number of possibilities, because the properties of the material can be changed by altering the glass composition. Additionally, bioactive glasses have been proven to be antibacterial. S53P4 is composed of of 53% SiO_2, 23% Na_2O, 20% CaO, and 4% P_2O_5 given as weight percentages. Experimental studies on animal models have shown good results of its use in maxilla-facial, oral and bone tumour surgery [1].

We intended to analyze the results of using S53P4 as a bone graft substitute in a variety of orthopaedic surgical procedures, alone or in conjunction with autogenous bone grafts and allografts.

Methods

Between July 2010 and March 2011, we included a number of 9 patients in our study. The patients have been diagnosed with different pathological conditions that implied treatment based on surgical procedures using bone grafting techniques. Table I shows the list of patients, the main diagnosis and the procedure performed.

Routine antibiotic and antithromboembolic prophylaxis were used in all cases. The bioactive glass granules were moisturised with saline before use according to the instructions on the package, and the granule sizes were chosen based on the bony defect to be filled. In some cases the bioactive glass was used in conjunction with morselized bone grafts, while in others it was utilised alone to fill out the cavities.

We had 4 cases of cystic or tumoral lesions (3 affecting the proximal tibia and one in the lateral humeral condyle). These were treated by curettage and filling the defect with either bioactive glass alone or a mixture of bioactive glass and bone allografts, the curetted material being sent for histological examination. Intraoperative images of one of these interventions can be seen in Figure 1.

There were two cases of revision arthroplasty of the hip after a total cemented arthroplasty and after an uncementedarthroplasty, with loosening of the femoral component and both prosthetic components respectively. These cases were solved by revision hip arthroplasties. For the femoral part loosening, a revision Stryker long stem was implanted, and femoral osteoplasty was performed with the use of a combination of morselized bone grafts and synthetic bone substitute, reinforced with a metallic net and 3 cables. The loosening of both components after uncementedarthroplasty was treated by revision total hip replacement with a Stryker cemented system, and acetabuloplasty with a mixture of morselized bone grafts and synthetic bone substitute, and the use of a reinforcement ring. Figure 2 shows intraoperative images of this procedure.

Table I. The characteristics of the resolved cases (patient data, diagnosis, intervention, grafts used)

No.	Patient initials	Sex	Age (yrs)	Diagnosis	Surgical procedure	Grafting
1	M.V.	Male	50	Calcaneus fracture – joint depression type	– open reduction and elevation of the depressed fragment – bone defect filled with bone grafts – immobilization in a plaster cast	– structural allograft – morselized bone grafts – synthetic bone substitute (BonAlive®, 12 mm granules, 10 cc)
2	F.I.	Female	71	Loosening of the femoral component after THR with cemented endo-prosthesis	– replacement of femoral stem with a Stryker revision stem (stem: Omnifit #5/300MM, head: CTaper: 28 mm/+10) – femoral osteoplasty with grafts – internal fixation/ reinforcement with metallic net and 3 cables	– morselized bone grafts – synthetic bone substitute (BonAlive®)
3	S.M.	Male	60	Femoral supracondylar non-union	– open reduction and internal fixation – osteoplasty with bone grafts and synthetic substitute – knee arthrodesis – immobilisation in a plaster cast	– morselized bone grafts – synthetic bone substitute (BonAlive®, 20 cc)
4	A.A.	Female	69	Tumoral lesion proximal tibial epiphysis	– curettage – filling the defect with synthetic bone substitute – histological exam	– synthetic bone substitute (BonAlive®)
5	B.E.	Female	16	Cystic lesion lateral humeral condyle	– curettage – filling the defect with bone grafts and synthetic bone substitute – histological exam	– morselized bone grafts – synthetic bone substitute (BonAlive®, 1.0–2.0 mm granules, 10 cc)
6	B.M.	Female	60	Hip arthrosis secondary to acetabular protrusion	– HR with a reverse hybrid Biotechniendo-prosthesis (50 mm cup, #11 Filler stem, Surgival 28 mm/3,5 head)	– synthetic bone substitute (BonAlive®)
7	S.M.	Male	28	Relapsed osteoclastoma proximal tibial epiphysis	– curettage – filling the defect with bone grafts and synthetic bone substitute – histological exam	– morselized bone grafts – synthetic bone substitute (BonAlive®, 1.0–2.0 mm granules, 3 x 10 cc)
8	T.E.	Female	41	Loosening of both endo-prosthetic components after cementless THR. Acetabular protrusion	– revision THR with a Stryker cemented prosthesis (46 mm cup, #9Omnifit stem, CTaper CoCr 28 mm/+0 head) – acetabuloplasty with bone grafts and synthetic bone substitute and reinforcement ring	– morselized bone grafts – synthetic bone substitute (BonAlive®, 1.0–2.0 mm granules, 10 cc)
9	V.L.	Male	32	Cystic lesion proximal tibial epiphysis	– curettage – filling the defect with synthetic bone substitute – histological exam	– synthetic bone substitute (BonAlive®)

A patient with primary total hip replacement for coxarthrosis secondary to acetabular protrusion also benefited from the use of synthetic bone substitute for acetabuloplasty prior to the implantation of a reverse hybrid hip system.

We treated a patient with a calcaneus fracture – the joint depression type – by open reduction and elevation of the depressed fragment, the remaining defect being filled with a combination of structural allograft, morselized bone grafts and bioactive glass as a synthetic bone substitute.

Our remaining case was a femoral supracondylar non-union, for which a complex surgical intervention was performed, with open reduction and internal fixation of the non-union, femoral osteoplasty with both morselized bone grafts and synthetic bone substitute and knee arthrodesis with the use of synthetic bone graft for filling the bone defects.

Patients were evaluated clinically and radiologically. 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 and 6 months. Incorporation of the bioactive glass granules was evaluated visually, by assessing morphological changes of the granules – mostly their outlines definition.

Results

Postoperative evolution and the wound healing were normal. Clinical evaluation showed good results after all interventions at the mentioned follow-up terms (1, 3 and 6 months post-operative).

On radiological evaluation, we found signs of graft osteointegration in all cases, and signs of the incorporation of the synthetic bone substitute with the surrounding bone on the radiographs taken at 1 and 3 months postoperatively. The remodelation of the grafted zone was visible as the disappearance of the sharp boundaries of the granules and appeared on the 6 month postoperative images (Figures 3 and 4).

Discussion

We found that bioactive glass granules were suitable bone substitute materials in all the cases we studied, showing good results on both clinical and radiologic evaluation. Similar good results have been published beforehand [2,3,4,5].

The cases we presented can benefit from the use of autogenous bone grafts, allografts and synthetic bone as well. The golden standard remains the use of autogenous bone grafts. However, this is not a material that is readily available and the harvesting of these grafts can produce significant complications and comorbidities.

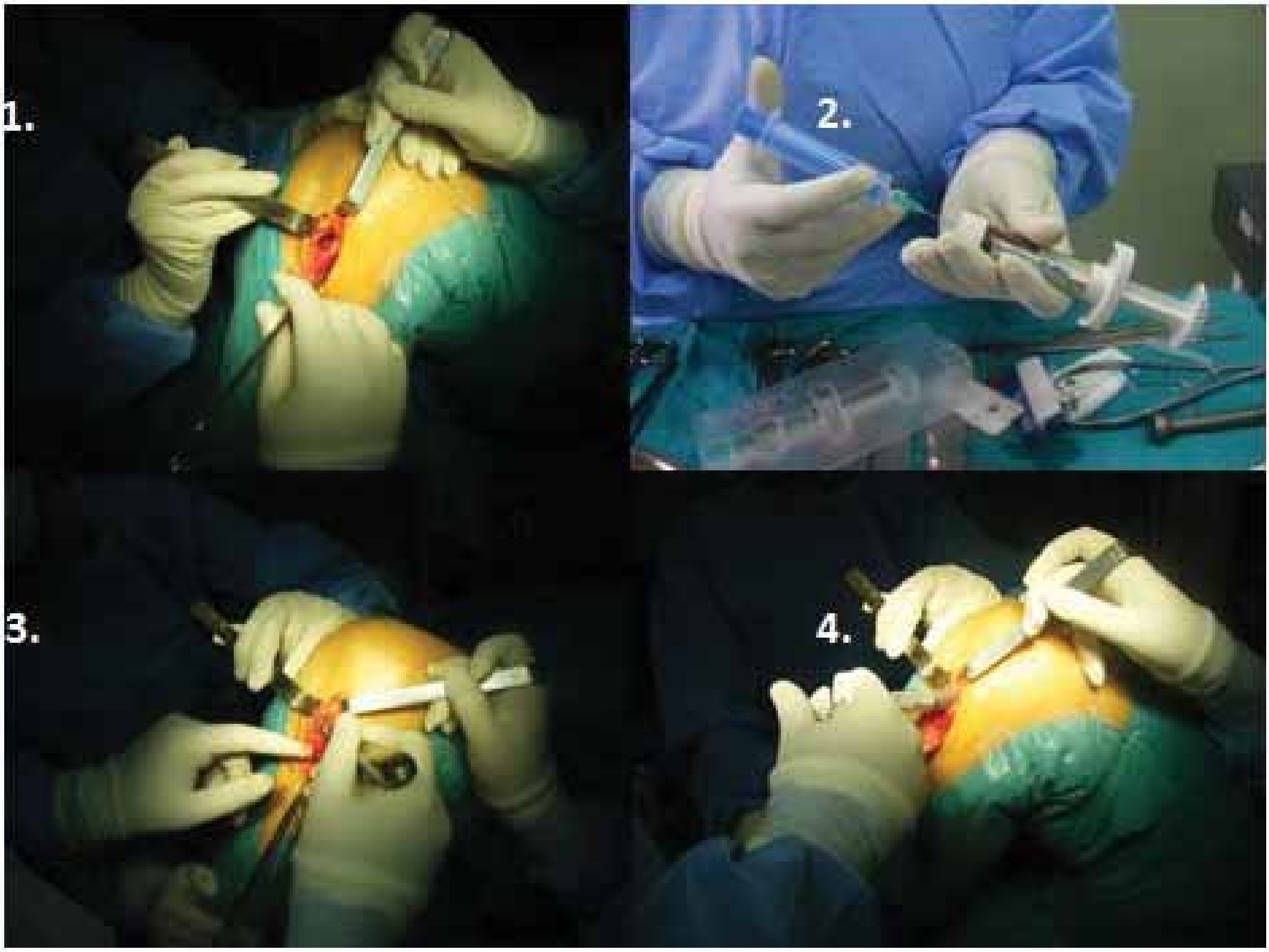

Fig. 1. Case no. 4 intraoperative images – a tumoral lesion of the proximal tibial epiphysis. (1. – Exposing the lesion and a bony window created. 2. – Preparation of the bioactive glass – moisturising with saline. 3, 4. – Filling the defect).

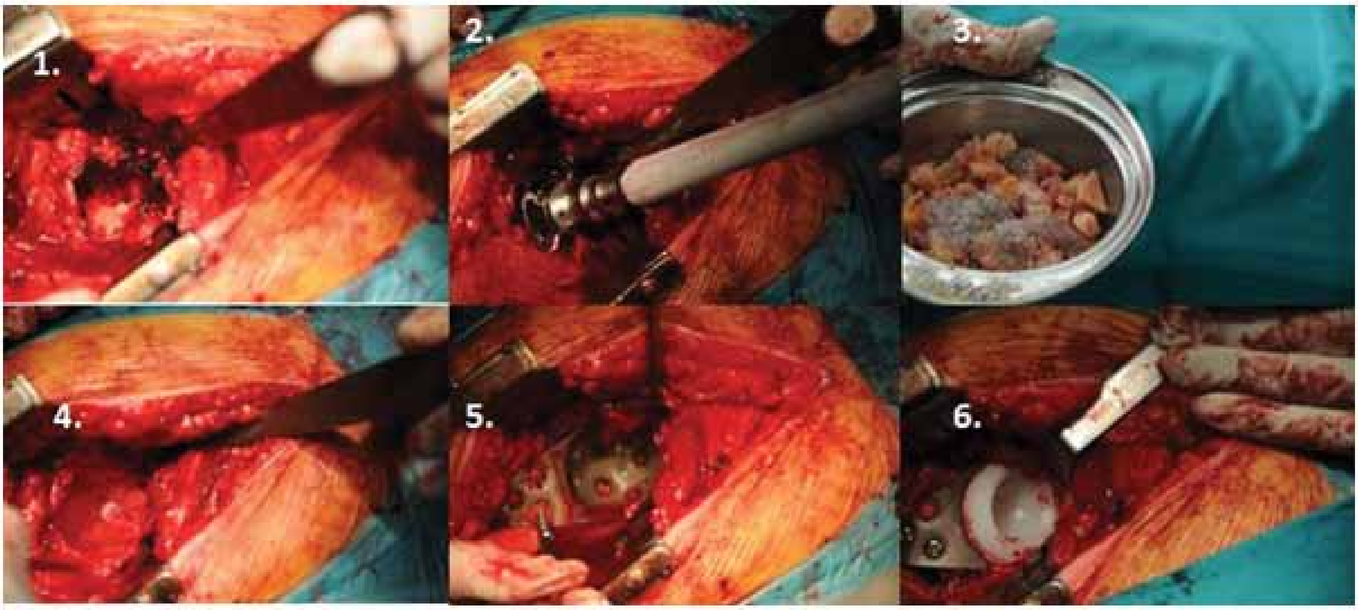

Fig. 2. Case no. 8 intraoperative images – loosening of both endo-prosthetic components after cementless THR.Acetabular protrusion (1. – Exposing the acetabular defect. 2. – Preparation of the acetabulum with reamers. 3. – Preparing the mixture of morselised bone grafts and bioactive glass moisture with saline. 4. – Filling the acetabular defect. 5. – Placing the reinforcement ring. 6. – Cementing the acetabular component)

Fig. 3. Case no. 4 preoperative and postoperative radiographs. (1. – AP preoperative radiograph. 2. – AP postoperative radiograph at 3 months. 3. – LL preoperative radiograph. 4. – LLpostoperative radiograph at 3 months.)

Also, the procedures were made easier by the use of bone substitute material – for both the surgeon and the patient – and obviously postoperative pain is less intense and the mobilization can be done earlier this way.

Radiologic evaluation showed that the bioactive granules-host bone interface disappeared gradually on later follow-ups, the sharp contour of the granules became rounder – probably due to the formation of a surface reaction layer and the later bone formation on the granules. This has also been observed in animal studies [6,7]. Unfortunately radiologic evaluation alone is not the ideal tool to evaluate this process.

For future studies it is important to evaluate the costs of prolonged interventions in case of autogenous bone graft harvesting and compare them to the costs of the synthetic bone substitute. We feel that the bone substitutes will become more popular as long as the costs implied by their use shall be less than that caused by the additional operation theatre time. Furthermore, we must not forget that bone harvesting can cause pain, discomfort or complications for the patient.

Another aspect that must be taken into account is that an ideal bone substitute will not resorb faster than the new bone tissue is being formed, but it should nevertheless resorb in time. Previous studies have demonstrated that S53P4 is bioactive, osteoconductive and bone bonding, and that it does resorb slowly in human bone. It'sresorption time depends on the granule size and the amount used [8,9]. Furthermore, bioactive glass has a proven bacteriostatic property [10,11].

Fig. 4. Case no. 8 preoperative and postoperative radiographs. (1. – AP preoperative radiograph. 2. – AP postoperative radiograph at 6 months.)

Conclusions

Our preliminary results have shown that bioactive glass (S53P4) can be used as a bone substitute material in the types of cases presented. It is also our believe that synthetic bone substitutes such as the one studied by us will become more popular in the future, it's major advantages being the good bonding to bone, it's bacteriostatic properties and probable gradual complete resorption.

Acknowledgement

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References

1. Valimaki VV, Aro H – Molecular Basis for Action of Bioactive Glass as Bone Graft Substitute. Scandinavian Journal of Surgery 2006, 95 (2): 95–102.
2. Lindfors NC – Treatment of a recurrent aneurysmal bone cyst with bioactive glass in a child allows for good bone remodelling and growth. Bone 2009, 45(2): 398–400.
3. Lindfors NC, et al. – Bioactive glass S53P4 as bone graft substitute in treatment of osteomyelitis. Bone 2010, 47: 212–218.
4. Lindfors N, et al. – Bioactive glass and autogenous bone as bone graft substitutes in benign bone tumors. J Biomed Mater Res–Part B 2009, 90(1):131–136.
5. Peltola M, et al. – Bioactive glass S53P4 in frontal sinus obliteration: A long-term clinical experience. Head and Neck 2006, 28(9): 834–841.
6. Heikkila J, et al. – Bone formation in rabbit cancellous bone defects filled with bioactive glass granules. Acta Orthopaedica 1995, 66(5): 463–467.
7. Heikkila J, et al. – Long-term behaviour of bioactive glass cone and granules in rabbit bone. Bioceramics 1996, 9: 123–126.
8. Aho AJ, Suominen E, Alanen A, et al. – Remodelling of the tibia after grafting of a large cavity with particulate bioactive glass–hydroxylapatite-case report on treatment of fibrous dysplasia with 13 years follow-up. Acta Orthop Scand 2003, 74(6): 766–70.
9. Lindfors N – Granule size and composition of bioactive glass affect osteoconduction in rabbit. J Mat Sci: Mat Med 2003, 14: 265–372.
10. Munukka E, et al. – Bactericidal effects of bioactive glasses on clinically important aerobic bacteria. Journal of Materials Science: Materials in Medicine 2008, 19(1): 27–32.
11. Lepparanta O, et al. – Antibacterial effect of bioactive glasses on clinically important anaerobic bacteria in vitro. Journal of Materials Science. Materials in Medicine 2007, 19(1): 27–32.