

Mid-term follow-up of acetabular reconstruction using bovine freeze-dried bone graft and reinforcement device

Acompanhamento a médio prazo da reconstrução acetabular com enxerto ósseo liofilizado bovino e dispositivo de reforço

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A B S T R A C T

Objective: To report clinical and radiographic graft incorporation capability of bovine freeze-dried bone grafts. **Methods:** Twenty five patients were enrolled. The mean follow-up was eight years. Grafts were purified and freeze-dried. Clinical analysis was based on the score of Merle d'Aubigné and Postel and an established score criteria for radiographic bone incorporation was used for radiographic analyses. **Results:** Good clinical and radiographic results were found in 80% and 72% of the cases, respectively. **Conclusion:** Bovine freeze-dried grafts can be safely and adequately used in acetabular revision in total hip arthroplasty.

Key words: Prostheses and Implants. Animals. Bones and bones. Freeze Drying. Acetabulum/surgery. Arthroplasty.

INTRODUCTION

Acetabular bone loss is one of the main problems in revision total hip arthroplasty¹. Treatment of type I and II deficiency¹ with impacted cancellous morselized bone has been shown to provide good results². Therefore, treatment of severe defects, type III and IV, is more challenging. A valuable option in those cases is the use of bulk allograft, but the rate of failure of structural grafts, not supported by a reinforcement device, has been shown to increase in the past years³. As an alternative, some authors have advocated the use of an acetabular reinforcement ring instead. This device seems to protect grafts from overstress, helping to settle the reconstructed acetabulum until graft is integrated^{4,5}.

However, choosing the reconstruction technique for an acetabular defect is not the only concern. The use of bone graft is essential too, and autografts are of limited amount to replace these losses. Moreover, tissue requirements are far greater than the real availability when considering the use of allografts⁶. This situation led us to search for an alternative tissue processing to submit the grafts to some method of disinfection and sterilization, as well as to attempt the use of xenografts from bovine source. For this reason, a lyophilization process was developed; and after initially confirmed by experimental studies in animals⁷

and followed by use in other general orthopedic procedures, this cohort was started.

Therefore, the aim of this study was to demonstrate clinical and radiographic bone integration capability of bovine freeze-dried bone grafts, produced at our Tissue Bank in Hospital de Clínicas de Porto Alegre University Hospital (HCPA, TBHCPA), in acetabular reconstruction procedures.

METHODS

From May 1997 to February 2005, 25 patients with severe acetabular defects, type III and IV of D'Antonio *et al.*¹ classification, were consecutively submitted to acetabular reconstruction in revision total hip arthroplasty (RTHA), by the same hip surgery team of the Orthopedic Department of the HCPA University Hospital. All patients were fully informed about the study, which was approved by the Ethics Committee of HCPA, and a written informed consent was obtained. Patients were followed up to January 2009. Grafts were from bovine source. The bovine bone is obtained from Brazilian cattle bone, and is thought to be completely free of Bovine Spongiform Encephalopathy (BSE) infection. All bone grafts were processed at the TBHCPA following our own processing protocol. This process allowed

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the production of bone grafts which kept the main characteristics (proteins and minerals) almost unchanged (Figure 1). The preparation method could not be fully disclosed to protect intellectual property. In the process, protein denaturation with 20% hydrogen peroxide is followed by alcohol extraction of lipids. The end product is composed of minerals (65%) and proteins (27%). It is definitively sterilized in autoclave. The failure of the arthroplasty was determined to be aseptic in all patients. The type and extent of the acetabular defects had been determined from preoperative radiographs and intraoperative assessments. The clinicopathologic characteristics of patients are shown in table 1.

All patients were operated on by the same team and same reconstruction technique. The posterior approach was performed in all cases.

Technique

The loose prosthesis was removed and all cement, debris, granulomata and fibrous membrane were completely cleared. Carefully reaming of the acetabulum cavity was performed in order to achieve the vascular bone bed, and then the acetabulum was reconstructed by cancellous morselized (chip size, approximately 8 mm³) freeze-dried

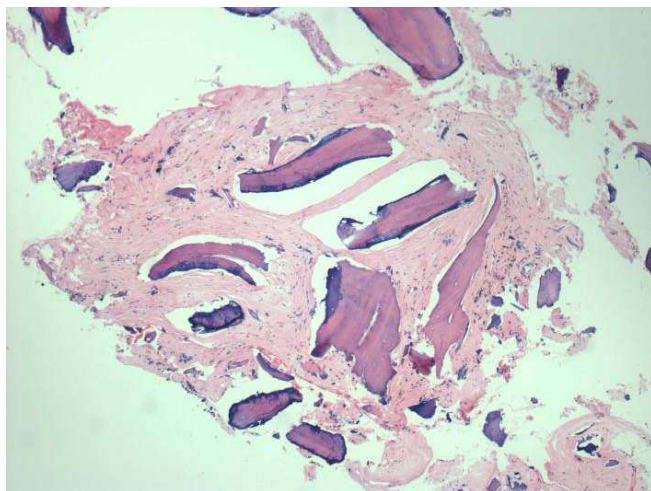


Figure 1 - Histology sample from a 2-year follow-up bovine graft showing areas of new bone formation and residual spicules from the graft material.

Table 1 - Clinicopathologic characteristics of the patients.

Features	Bovine Graft n = 25 (%)
Female	20 (80,0)
Male	5 (20,0)
Mean (SD) Age (years)	57,7 (12,3)
Mean (SD) follow-up (Mo)	96,1 (24,49)
Acetabular deficiency	
Type III	14 (56)
Type IV	11 (44)

sd= standard deviation.

bone. The chips were pressed into acetabulum defects and were carefully condensed. The flanges of the reinforcement device (MDTÔ, São Paulo, Brazil) were bent into shape to fit the specific anatomy of the acetabular region. The hook of the device was placed under the teardrop portion. The upper flange of the metal ring was screwed to the ilium. This should result in a stable composite (consisting of the load-bearing host bone, grafts and implant) with an impacted bone graft located beneath the ring. Afterwards, a polyethylene cup was cemented into the acetabular reinforcement device. The amount of bone graft used ranged from 40 g to 60 g in all cases.

Patient analysis was based on the clinical and radiographic evaluation. The clinical analysis was based on functional criteria established by Merle d'Aubigné and Postel⁸.

For the radiographic analyses, several subjectively established features such as radiolucency, density, trabecular bone formation and component migration were used. Thus, a radiographic analysis of bone integration, based on Conn's *et al.*⁹ criteria was developed to establish bone incorporation of the grafts in the two groups. Each criterion, except migration, received an independent score ranging from 0 to 2 for each of the three zones of De Lee and Chanrley¹⁰ in the acetabulum, where 0 was the worst and 2 the best result¹¹. The sum of the scores was then, multiplied by three for the acetabulum. For migration, a score of 2, 4 or 6 was established when there was more than 6 mm, 3 to 5 mm, or less than 3 mm of prosthesis displacement. Therefore, a total of 24 points could be achieved for acetabular assessment. Adequate results were considered those with a sum of 19 or greater.

RESULTS

No severe complication occurred in the early post-operative period. Only two deaths two and six years after the procedure were recorded and both were unrelated to RTHA. No more patients were lost to follow-up.

Overall, no minor events were clinically observed. However, a case of superficial infection (cellulites) occurred six months following the procedure and was successfully treated with antibiotics. Clinical and radiographic (Figures 2-4) outcomes are shown in tables 2 and 3, respectively.

DISCUSSION

The goals of reconstruction of severe acetabular defects in revision arthroplasty of the hip are to restore the bone stock, to repair the hip mechanics and to obtain stability, and the use of bone graft is imperative to achieve them. Autografts are excellent, but their amount is usually limited and thus allografts have been frequently used. Therefore, a bone bank under strict quality control is necessary to minimize the risk of disease transmission.



Figure 2 - Anteroposterior radiography of the acetabular loosening, type IV deficiency by D'Antonio et al.¹



Figure 3 - Immediate post-operative radiography showing the acetabular reconstruction with lyophilized bovine graft and reinforcement device.

Nevertheless, there is not one single technique that provides a solution to all deficiencies. Reconstruction with impacted cancellous morselized bone has been providing good results^{2,12}, but there is some skepticism about its use in hostile acetabula, especially those of type III and IV deficiencies^{1,4,5,13}. Additionally, reconstruction of structural allografts is still controversial³. Like others, these authors also consider that the occurrence of a severe acetabular defect is an indication for reconstruction by reinforcement device combined with bone grafts. This method provides initial stability, prevents grafts from mechanic stress until graft integration is achieved^{4,5}.

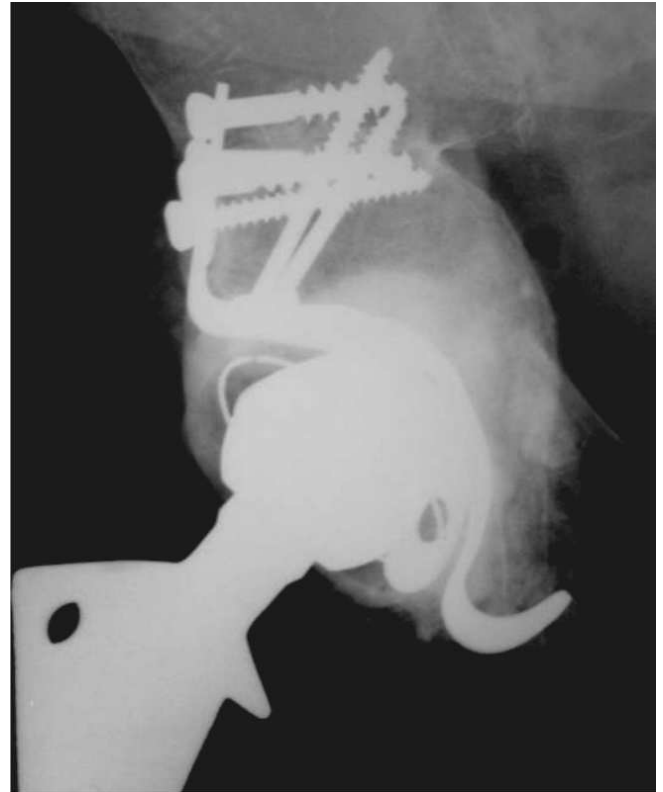


Figure 4 - Anteroposterior radiography of the reconstruction with lyophilized bovine graft and reinforcement device (3-year follow-up) showing suggestive signs of bone incorporation, as it can be seen by the regularity of medium wall, graft density and no radiolucent lines.

For hip procedure, it's believed that the most suitable graft would be the one slightly changed by any process. In the physical and chemistry analyses, the freeze-dried bones produced at TBHCPA kept most of the mineral and protein characteristics virtually unchanged and both grafts from bovine and human sources are strongly alike, though not keeping the same texture and malleability as their deep-frozen counterparts¹⁴. This enabled proper handling of freeze-dried bones, both from a technical and mechanical viewpoint, after re-hydration¹⁵.

By the Merle d'Aubigné and Postel⁸ criteria, the average results obtained for bovine grafts were considered good and very good in 80% of the cases. Although the follow-up may be considered not long enough for a more reliable clinical evaluation, it is indicative that the use of bovine freeze-dried grafts during that period did not cause any harm to the patients or significant differences between both. By comparing these results with those in the literature with similar follow-up - but using allogeneic deep-frozen grafts instead -, no considerable differences that could be attributed to the use of freeze-dried bovine grafts were observed^{4,5,13}.

Several studies have clinically and radiographically evaluated, in a number of bone diseases, the use of human and bovine freeze-dried grafts demonstrating very good results. However, few indexed articles concerning the use

Table 2 - Clinical outcomes.

Clinical Evaluation Merle d'Aubigné and Postel	Bovine Graft (n=25) n (%)
Very good and good	
12	8 (20)
11	9 (35)
10	2 (12)
Total	19 (76)
Medium, fair and poor	
9	3 (12)
8	1 (4)
7 or < 7	2 (8)
Total	6 (24)

Table 3 - Radiograph results.

Radiograph Evaluation Scores (%)	Bovine Graft (n=25)
Very good and good	
24 – 22	15 (60)
21 – 19	3 (12)
Total	18 (72)
Medium, fair and poor	
18 – 16	2 (8)
15 – 13	2 (8)
< 13	3 (12)
Total	7 (28)

of human or bovine freeze-dried grafts in RTHA have been reported. This reluctance of hip surgeons to use freeze-dried grafts may be partially related to a number of available grafts with different steps in the production process for distinct purposes and indications as well. As a result, different mechanical and biological responses may be obtained, leading to an unjustified concern to use this type of graft¹⁶. Levai and Boisgard¹⁴ reported thirty revision cases performed on loose total hip replacements with a specific technique for acetabular reconstruction combining the use of a bovine bone substitute and a support ring. No migration of the acetabular implant or osteolysis of the heterograft was seen in 27 (90%) cases within three years after procedure. Radiologically, the heterograft gradually condensed, and its appearance was similar to that observed with allografts. In that series, the two failures with implant migration and heterograft osteolysis were considered as technical bias related to the use of the Muller ring, and in both cases, it was supported by the cancellous heterograft and not by the host bone¹⁴. De Roeck and Drabu¹⁷ reported on 32 patients who underwent RTHA using cemented components and allograft impaction of processed freeze-dried bones. The overall endurance with this type of graft at a mean follow-up of four years was 91%. There were no femoral component failures, although revision was required in three

patients due to failure of the acetabulum. Freeze-dried graft can require longer re-hydration for adequate impaction. The results of impaction bone grafting with freeze-dried bone alone have been satisfactory, although these authors do not feel entirely secure with its use alone in cases of hostile acetabulum¹⁷. Thien et al.¹⁸ reported an overall survival rate for acetabular reconstructions of 86% in seven cases using impacted freeze-dried cancellous bone chips and a cemented cup, with a follow-up average of 7 years (range, 5-9 years). At this median follow-up period, no aseptic loosening was observed and the results for freeze-dried allograft bone chips were acceptable. Charalambides et al.¹⁹ published a paper addressing their poor results in 27 RTHA cases, followed up for an average of 2.5 years, after the use of autograft and xenograft (Surgibone) bones combined. Seventeen (62%) out of the 27 patients showed apparent bone incorporation within three months. In three (11%) patients, however, there was no incorporation. Three other cases (11%) appeared to have what they considered a pseudoinfection (with no agent identified); and one patient, who had the revision procedure revised again has suffered from deep MRSA infection. Disregarding the case of unequivocal infection, unrelated to graft, and, even considering the three cases of pseudoinfection, that may not be related to the grafts, one finds 77% of good results, which is similar to those obtained by other methods, and therefore, their poor results may be argued. Moreover, the authors also showed a histologic sample from that patient who required, despite apparently radiographic incorporation, revision of the replacement due to acetabular loosening. New bone formation from the grafted area and residual necrotic bony spicules from the graft material were observed, which clearly demonstrates graft incorporation²⁰.

Considering the radiographic criteria, despite biases, the results obtained with bovine freeze-dried bone grafts from TBHCPA, in this series, were comparable to each other and to those reported in the literature, even with those reports of the use of deep-frozen allografts. Using a similar technique of impacting deep-frozen graft and cement, and with a similar follow-up, Kerboull et al.⁴ reported a similar rate of 92% of graft incorporation. Therefore, the achievements obtained in RTHA seem to be more related to surgeon skills, inherent limitations of the techniques and the severity of the case rather than to the type of graft used.

The use of freeze-dried bone grafts provides a decrease in the risk of transmission of infectious diseases and tumors, since chemical reagents are used in its process to inactivate bacteria, viruses and, probably, prions due to exposure to sodium hypochloride²¹. After the whole process, the bone is also submitted to some kind of sterilization^{22,23} that in our tissue bank virtually achieves 100% of effectiveness. This way, concerns related to prion transmission (EEB), attributed to the use of freeze-dried bovine bone graft seems to be inappropriate. Also, careful selection and country of origin of herd, especially Brazil, that has been always a risk-free country for EEB, should be considered²⁴.

From the mechanical point of view, some studies that use non-decalcified freeze-dried bone concluded that there is no mechanical difference between freeze-dried and deep-frozen bone, and if there is one, this favors the freeze-dried ones, since they lack fat, blood and marrow cells^{15,25}.

Although there is a shortage of data regarding xenograft use in RTHA, clinical complications have not been observed, except for those complications expected with the

use of allografts or xenografts in general, since physical and chemistry characterizations have confirmed both bones are alike^{26,27}. The obtained results, therefore, have shown that the use of freeze-dried bovine bone grafts does not cause adverse reactions of any kind, further supporting their safety.

In conclusion, the lyophilization process of bones from bovine, accomplished in tissue bank, is of suitable quality to be used in RTHA.

R E S U M O

Objetivo: Relatar a capacidade clínica e radiográfica de integração de enxertos ósseos liofilizados bovinos. **Método:** Vinte e cinco pacientes foram incluídos. O período médio de seguimento foi de oito anos. Os enxertos foram purificados e liofilizados. O tipo e extensão dos defeitos acetabulares foram determinados por estudo radiográfico pré-operatório e visualização per-operatória. A análise clínica baseou-se no score de Merle d'Aubigné e Postel, e critérios de pontuação estabelecidos para a osteointegração radiográfica foram usados para as análises radiográficas. **Resultados:** Não houve complicações no pós-operatório imediato. Duas mortes ocorreram em dois e seis anos depois do procedimento não relacionadas ao processo cirúrgico. Os resultados clínicos e radiográficos foram considerados como bons em 80% e 72% dos casos, respectivamente. **Conclusão:** Enxertos liofilizados bovinos podem ser usados com segurança na revisão acetabular da artroplastia total de quadril e o processo de liofilização de ossos bovinos é adequado para uso cirúrgico.

Descritores: Próteses e Implantes. Animais. Ossos e ossos. Liofilização. Acetábulo/cirurgia. Artroplastia.

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