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Original Research

Alternating Layers of Morselized Allograft and Injectable Ceramic Bone Graft Substitute in Acetabular Reconstruction: A Novel 'Sandwich' Technique

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ABSTRACT

Background: Impaction of morselized allograft is an appealing procedure for addressing the bone defects. However, concerns remain about its suitability for massive defects. We used a novel "sandwich" technique by impacting the morselized allograft in layers with an intervening layer of injectable bone graft substitute for restoring bone defects during acetabular reconstruction in total hip arthroplasties.
Methods: From August 2015 to June 2017, 17 revisions, 4 rerevisions, and 3 complex primary total hip arthroplasties were operated by this novel technique. Postoperatively, serial X-rays were evaluated at regular intervals. Clinical and functional outcomes were assessed by the Harris hip score. To examine if introducing an injectable bone substitute into allograft stock increased its load-bearing capability, simulated mechanical testing using Synbone samples was conducted in the laboratory.
Results: The mean Harris hip score significantly improved from 54.6 preoperatively to 86.8 at the latest follow-up. Graft incorporation was seen in all the cases. There was no evidence of component migration or loosening as compared to the X-rays at 3 weeks and 3 months in all the cases. With revision of component as end point, the survivorship was 100% at 82 months. The mechanical testing reported a higher capability of allograft samples when compared to those without bone substitutes.
Conclusions: Our data confirms that the use of the "sandwich" technique is a reliable option for major acetabular reconstruction. Early weight bearing is a significant value addition, and short-term results confirm good clinical and functional outcome. Longer follow-up is necessary to assess the status of the construct in the long term.

Introduction

Reconstruction of severe acetabular deficiency remains challenging for the orthopaedic surgeons [1]. Impaction grafting using allograft has remained a preferred technique for many surgeons to reconstruct these defects [2–4]. Impaction allografting has potential of integration and restores the bone stock. However, the allograft use has concerns about infection, antigenicity, stability, availability, cost, and aseptic loosening in the long term [5–7]. There is also a considerable delay in time to weight bearing when the allograft is used with revision shells or cages. These concerns

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have led to the use of bone graft substitutes mixed with the allograft to augment the volume as well as to improve the stability of the construct [1].

Noninjectable bone graft substitutes such as granules have been used with allografts for acetabular defects, mainly as allograft extenders [2,3]. The injectable biphasic bone graft substitute was introduced as a void filler for defects created after curettage of bone or due to fractures [4,5]. Several bone substitutes are commercially available for bone void filling[6]. However, they have been used for vertebroplasty, tibial, or radial fracture management [8–11]. The load-bearing capacity of such bone substitutes for acetabular defect reconstruction has not been investigated.

In this study, we used a novel "sandwich" technique by impacting the morselized allograft in layers with an intervening layer of injectable bone graft substitute for acetabular reconstruction in revision, rerevision, and complex primary THAs. We performed the biomechanical testing to compare the compressive load carrying capacity of such a construct with that of an impacted allograft. The purpose of this study was to validate this novel technique for reconstituting the bone stock of the acetabulum from a biomechanical perspective, assess the clinical and radiological outcomes, and ascertain survivorship.

Material and methods

Patients

From August 2015 to June 2017, a total of 24 patients (13 males and 11 females) operated by this novel technique were retrospectively reviewed. The mean age of the patients at surgery was 59.6 years (43 to 81 years). Study was approved by the institutional ethics committee. Written informed consents were obtained from all participants. Patients were followed at 3 weeks, 3 months, 6 months, and then annually.

Surgical technique

All the cases were performed by the first author (R.M.). A standard posterior approach in lateral position was utilized in all the cases. The femur was prepared first in primary arthroplasty or whenever femoral component revision was required. The last fitting femoral broach was left in situ, and the femur with broach was retracted anteriorly with a curved retractor. The acetabulum was further exposed by dividing the reflected head of rectus femoris and the gluteus minimus muscle to displace the proximal femur anteriorly. A Hohmann retractor was placed under the transverse acetabular ligament to delineate the inferior margin of the acetabulum. In case of revision surgery, the old implants and/or the cement spacer, the fibrous tissue, and membranes were removed, and multiple samples were sent for microbiological investigation. In primary as well as revision surgery, defects with an intact acetabular rim were considered for reconstruction using the "sandwich" technique; whenever the rim was deficient, it was reconstructed using trabecular metal augments. The peripheral reaming was done with the successive reamers to assess the acetabular shell size. Any sclerotic areas in the acetabular bed were drilled with multiple drill holes, and the floor was cleaned with pulsed lavage.

The irradiated femoral head allograft was thawed at room temperature in an antibiotic solution. The allograft chips of 3-5 mm were prepared and washed alternately with normal saline, hydrogen peroxide, and betadine solutions for at least 3 cycles. The allograft chips were dried and mixed with 2 gm of vancomycin powder. Injectable biphasic bone substitute (Cerament G, Bone Support AB, Sweden) of 10 ml was used in at least 2 layers with alternating layers of femoral head allograft chips to address the acetabular deficiency. For every 100 grams of allograft chips, 10 ml of bone substitute was used (ratio 10:1). The first layer of allograft chips was impacted on the acetabular bed, followed by injection of the bone graft substitute over it, deposition of another layer of allograft chips, and impaction with the acetabular impactor. Two or more layers of bone graft substitute were sandwiched in between the allograft layers, depending on the size of the bone defect (Fig. 1a-d). Acetabular reconstruction was completed by using either the modern porous metal shell (Regenerex multi hole acetabular system, Zimmer-Biomet, Warsaw, IN; Gription Pinnacle Revision Shell, Depuy, Warsaw, IN) or a Trabecular Metal Revision Shell (Zimmer-Biomet, Warsaw, IN) supplemented with multiple

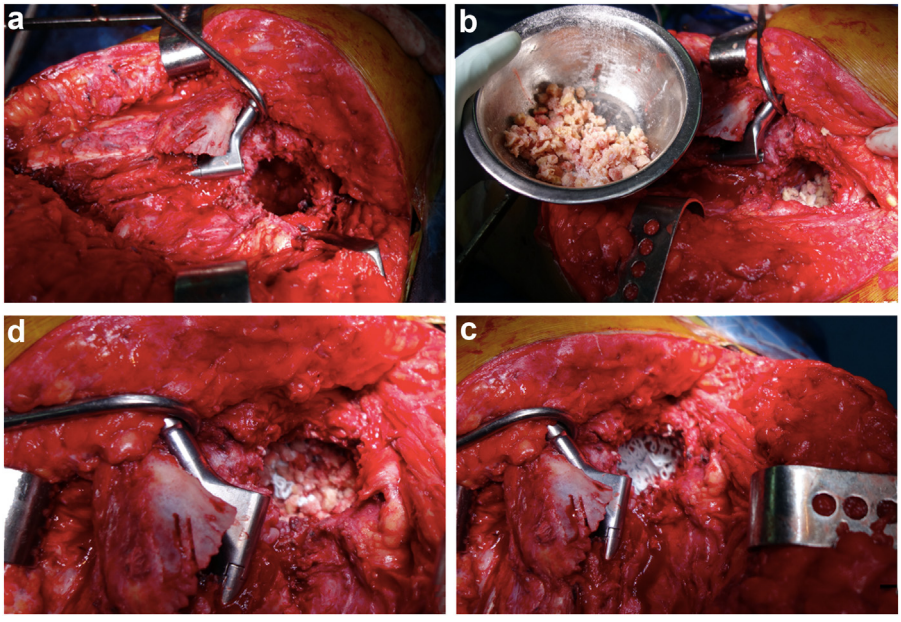


Figure 1. Intraoperative picture showing (a) Delineation of the acetabular bone defect (b) First layer of morselized allograft (c) Injection of Bone Graft Substitute, Cerament (d) Second Layer of morselized allograft (e), which is then impacted to disperse the bone graft substitute in the interstices of allograft chips.

Table 1
Summary of the demographics, implant details, and clinical presentation of the patients.

Case no.	Gender	Age	Diagnosis	Defect (paprosky type[a])	Surgery	Acetabular component (s)	Follow up (mo)	HHS (pre op)	HHS (final follow-up)
Patient 1	F	75	Failed left revision THA	3B	Left cup Cage rerevision and ORIF of fracture revision	Trabecular Metal Revision Shell 66 mm	82	58.8	74.8
Patient 2	M	47	Ankylosing spondylitis with failed right THA	2A	Right revision THA	Regenerex multi hole cup 62 mm	77	56.6	82.8
Patient 3	M	58	Failed left hip resurfacing	2A	Implant removal and left revision THA	Regenerex multi hole cup 62 mm	76	47.6	90.8
Patient 4	M	57	Ankylosing spondylitis with bilateral THA in situ with left failed THA	2A	Left revision THA	Regenerex multi hole cup 62 mm	76	58.8	87.8
Patient 5	M	81	Failed left THA	3B	Left revision THA	Trabecular Metal Revision Shell 70 mm	76	39.6	87.8
Patient 6	F	57	Follow up case of RA with failed left THA	3B	Left revision THA	Trabecular Metal Revision Shell 60 mm + BS cage 44 mm	74	40.6	90.6
Patient 7	M	62	Failed right THA	2C	Right cup revision	Regenerex multi hole cup 56 mm	74	58.6	88.6
Patient 8	F	76	Failed left THA	3B	Left rerevision THA	Trabecular Metal Revision Shell 72 mm + BS cage 56 mm	72	47.6	88.6
Patient 9	F	71	Failed osteosynthesis for complex acetabular fracture	2C	Complex primary left THA	Regenerex multi hole 56 mm	72	58.6	88.8
Patient 10	F	65	Post tubercular arthritis with large acetabular defect	2A	Complex primary Right THA	Regenerex multi hole 48 mm	72	58.6	90.8
Patient 11	M	70	Failed right THA	2C	Right cup revision	Pinnacle gription revision shell 64 mm	68	52.8	84.8
Patient 12	F	57	Failed right revision THA	2A	Rerevision Right THA	Regenerex multi hole cup 54 mm	68	48.6	88.8
Patient 13	M	58	Infection following acetabular fixation, postdebridement	3B	Complex primary right THA	Trabecular Metal Revision Shell 66 mm + BS cage 50 mm	67	56.6	90.8
Patient 14	M	52	Failed right THA with Charnley's hip prosthesis in situ	3B	Revision right THA	Regenerex multi hole acetabular system 64 mm	66	48.6	84.8
Patient 15	M	43	Ankylosing spondylitis with bilateral THA in situ with failed right THA	3B	Revision right THA	Regenerex multi hole cup 62 mm	66	39.8	88.6
Patient 16	M	65	Failed left THA acetabular cup loosening	2C	Cup Revision left	Regenerex multi hole cup 66 mm	65	58.6	90.6
Patient 17	M	45	Failed right THA	3B	Revision right THA	Trabecular Metal Revision Shell 72 mm + BS cage 56 mm	65	58.8	88.8
Patient 18	F	46	Failed left THA	2A	Left revision THA	Trabecular Metal Revision Shell 54 mm	63	58.6	84.8
Patient 19	F	62	Failed right hemiarthroplasty	2C	Right revision THA	Regenerex multi hole cup 54 mm	62	47.6	88.8
Patient 20	F	66	Failed left hemiarthroplasty	3B	Left revision THA	Trabecular Metal Revision Shell 72 mm	62	52.6	88.6
Patient 21	F	48	Failed left revision THA	3B	Rerevision left THA cup and head	Trabecular Metal Revision Shell 72 mm + BS cage 56 mm	61	40.6	90.8
Patient 22	M	54	Failed right THA	2C	Revision right THA cup and liner	Regenerex multi hole cup 64	61	58.6	88.8
Patient 23	M	62	Failed left THA	2C	Revision left THA	Trabecular Metal Revision Shell 72 mm	60	56.8	88.6
Patient 24	F	53	Failed left revision THA	3B	Rerevision left THA	Trabecular Metal Revision Shell 72 mm	60	58.8	84.8

THA, total hip arthroplasty; ORIF, open reduction and internal fixation; HHS, harris hip score; BS Cage, burch-schneider cage; mo, months.

[a] Classification of acetabular defects as described by Paprosky et al. Paprosky WG, Perona PG, Lawrence JM. Acetabular defect classification and surgical reconstruction in revision arthroplasty: a 6-year follow-up evaluation. J Arthroplasty. 1994;9:33–44.

screws. Ultimately, the technique ensured that the bone graft substitute was embedded in the interstices of the allograft chips, unitizing the construct while setting. Postoperatively, all patients were encouraged to walk with partial weight bearing by the next day of surgery and full weight bearing by 3 weeks, irrespective of the indication for surgery.

Outcome assessments

Clinical and radiological: The preoperative Harris hip score was obtained from the medical record in the service arthroplasty register. The change in postoperative Harris hip score was recorded. The radiological assessment was done by ascertaining the radiolucent lines in the zone of DeLee and Charnley, local resorption of the graft, or a change in the position of the acetabular component [7].

Mechanical properties of the reconstruction and testing of the samples

A uniaxial compression test was performed to assess the load-bearing capacity of acetabular reconstruction using Cerament bone void filler. Two sets of experiments were designed; in the first set of experiments, uniaxial compression tests on the cylindrical samples were performed to estimate the homogenized linear elastic material properties of the reconstruct (Supplementary Fig. 1a-e). In the second set of experiments, spheroid cavities, created in solid polyurethane foam blocks (Synbone, Johar Bahru, Malaysia), were filled with bone grafts and bone substitutes and subjected to compression loading mimicking the physiological loading condition (Supplementary Fig. 1f and g). In each set of experiments, 2 sample groups were prepared: the control group (BG, $n = 3$) where only allografts were used, and the experimental group (cerament with bone graft [CBG], $n = 3$) where a combination of allografts and Cerament was used. The details of the sample preparation technique are presented in the Supplementary Information 1. Uniaxial compressive loading was applied to the cylindrical and foam block samples using the universal testing machine (Shimadzu UTM AGX-10KN Plus). A preload of 20 N was applied to all the samples. Displacement-controlled compression loading (1 mm/min) was maintained along with a data acquisition (Trapezium X software) rate of 100 Hz. For both the cylindrical and foam block samples, the compressive loading was gradually increased until the specimen failed or 8 kN, whichever was earlier.

Statistical methods

The raw load-displacement data was analyzed in Matlab (vR2020b; The MathWorks, Inc., Natick, MA, USA) for all the samples. For cylindrical samples, the load-displacement data were first converted to engineering stress-strain data and approximated as a bilinear curve, and the parameters were estimated using a nonlinear least square error optimization algorithm [12]. The second slope of the bilinear curve was considered the Young's modulus of the sample [13]. For the foam block samples, the samples were scanned on the micro computed tomogram machine. Sample section images from 1 sample from each group are presented (Supplementary Fig. 1h-j) to help compare the porosity and amount of material in the filler stock. A linear regression analysis was performed between the recorded load and displacement data to estimate the overall stiffness of the reconstructed samples. One way analysis of variance (ANOVA) was performed within the samples of each group for both experiments. Two tailed independent Student's t-test was conducted to compare the CBG and BG groups of both experiments. The level of significance was 0.05.

Results

The cohort consisted of 17 revisions, 4 rerevisions, and 3 complex primary THAs. All patients were available for the latest follow-up, which varied between 60 and 82 months. The patient demographics, indication for surgery, and the implants used in reconstruction are depicted in Table 1. Six patients underwent cup only revision with retention of the femoral component. In 3 patients with failed cemented hip arthroplasty, cement-in-cement revision was done on the femoral side using CPT Stems (Zimmer Biomet, Warsaw, IN). The consolidation of the bone graft was seen in all the 24 cases within a range of 96 to 165 days. Graft incorporation was seen in all cases (Figs. 2-4). With revision of the component as end point, the survivorship was 100% at 82 months.

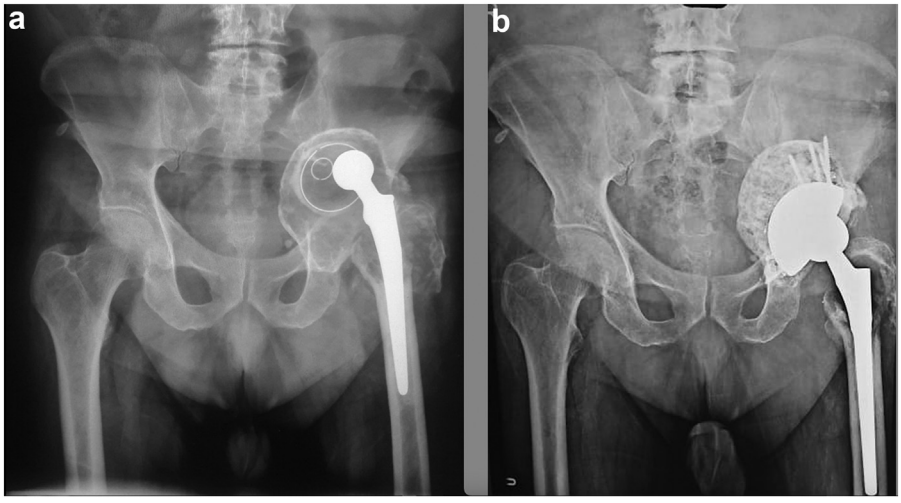


Figure 2. Sandwich technique in revision scenario: (a) Pre-operative radiograph of pelvis with both hips in Antero-posterior view showing failed THA on left side. Note the severe acetabular bone defect. Revision surgery was performed with acetabular reconstruction using the sandwich technique (b) Latest follow-up radiograph of pelvis with both hips in Antero-posterior view showing full incorporation of the allograft.

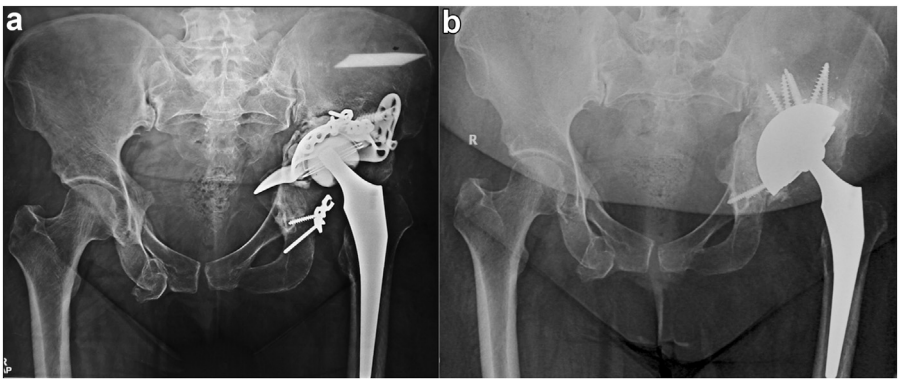


Figure 3. Sandwich technique in re-revision scenario: (a) Pre-operative radiograph of pelvis with both hips in Antero-posterior view showing failed revision THA on left side. Note the severe acetabular bone defect. Re-revision surgery was performed with acetabular reconstruction using the sandwich technique (b) Latest follow-up radiograph of pelvis with both hips in Antero-posterior view showing incorporation of the allograft.

Clinical and radiological outcomes

The mean Harris hip score significantly improved from 54.6 preoperatively to 86.8 at the latest follow-up ($P < .05$). The patients were satisfied, particularly with regard to pain relief and early full weight bearing. One case in the revision group showed radiolucent line in DeLee and Charnley zones 2 and 3 at 1 year but there was no progression at the latest follow-up radiographs. The patient was neither symptomatic nor warranted any revision after work-up to rule out any subclinical infection. There was no evidence of component migration or loosening as compared to the X-rays at 3 weeks and 3 months in any patient.

Mechanical assessment of the cylindrical and foam block samples

The density of CBG samples (=1.015 gm/cc) was higher than that of bone graft alone (=0.925 gm/cc).

The stress-strain curves generated during uniaxial loading of cylindrical samples of the BG and CBG are shown in Figure 5. The CBG exhibited a higher Young's modulus (12.13 MPa) as compared to the BG (3.15 MPa). Similarly, the compressive strengths of the CBG and BG samples were 1.02 MPa and 0.225 MPa, respectively. The BG samples exhibited higher deformation at any given load as compared to the CBG samples, indicating higher deformations developed within the BG samples under similar loading conditions. Statistical results showed no significant difference between samples of each group (ANOVA p-value = 0.37 BG and 0.42 CBG). However, the difference was significant among the groups (t-test p-value <0.01).

The images of the scanned block samples are shown in Supplementary Figure 1h-j. Images clearly show more space inside the filler material of the BG than the CBG. Moreover, in the CBG, due to the Cerament layer between allograft layers, the material is more compared to the BG. The computer-aided design model of filler material developed using image segmentation gave an average porosity of 55.2% and 17% for the BG and CBG, respectively. The force-displacement curves (mean ± SE) of both groups have been given in Figure 6. The corridor of the CBG (ie, ±SE) is much thinner than the BG. This shows that the CBG samples would have a smaller variation in deformations under these loading conditions. No significant difference was noticed within samples of each group (ANOVA p-value = 0.23 BG and 0.57 CBG). The mean difference among the groups was significant (p-value = 0.012).

Difference in deformation between the samples was also computed. At each load step, the deformation in the BG was higher than in the CBG samples. The average value of the slope of the load-displacement curve (generated by fitting a linear line in an elastic region) (Fig. 6) in the CBG was 2.106 kN/mm. This value is higher than the average value of the slope of the BG (1.696 kN/mm). Thus, the CBG samples exhibited an 18-21% lower deformation at loads between 1-4 kN during loading. The percentage by which CBG samples showed lower deformation compared to allograft samples increased to 47% at 8 kN load, thereby indicating a more stable construct.

Complications

One patient in rerevision group presented with dislocation at 3 weeks and was treated with closed reduction. She continued

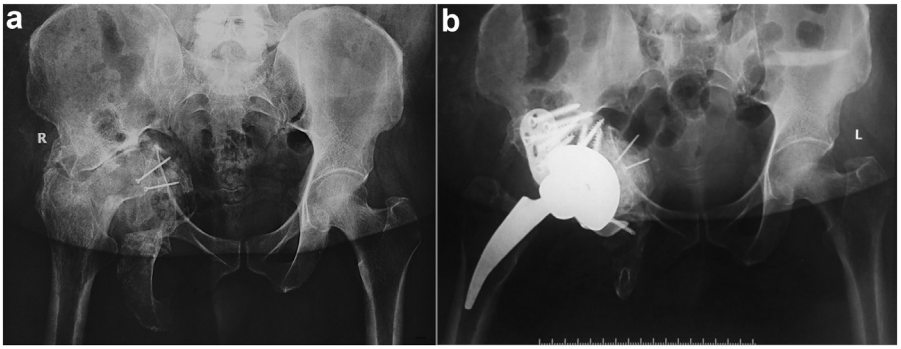


Figure 4. Sandwich technique in complex primary scenario: (a) Pre-operative radiograph of pelvis with both hips in Antero-posterior view showing severe arthritis with protrusio right hip in a case of failed fixation for acetabular fracture. Note the severe acetabular bone defect and the remaining femoral head. Primary THA was performed with acetabular reconstruction using the sandwich technique (b) Radiograph of pelvis with both hips in Antero-posterior following reconstruction.

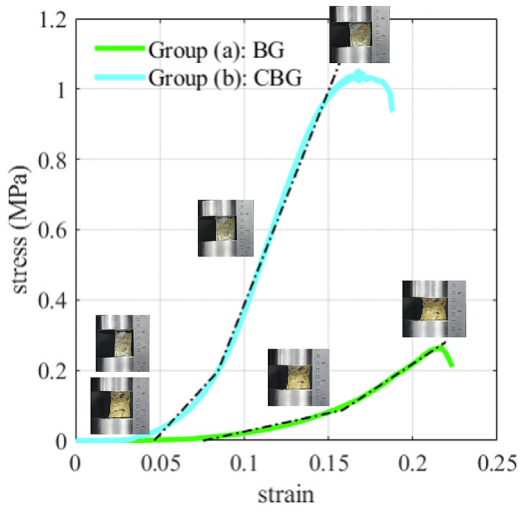


Figure 5. Stress-strain plots of cylindrical samples developed from bone allograft chips and bone allograft chips with Cerament.

walking with hip abduction brace for 6 weeks. There was no recurrence. One patient with revision for a failed bipolar femoral prosthesis had prolonged soakage after the surgery and was managed with debridement and antibiotics for 6 weeks. The patient continued to do well thereafter.

Discussion

A stable construct with restoration of bone stock remains the primary goal in acetabular reconstruction with large defects. Autograft harvesting increases the risk of blood loss, surgical time, and donor site morbidity [1]. However, impaction allografting is technique-intensive and prone to failure when improperly performed [14]. Prolonged protected weight bearing until consolidation of graft is recommended.

Use of bone substitutes in the granular form with allograft in acetabular reconstruction has been reported with satisfactory clinical and functional results, but the radiological outcomes were

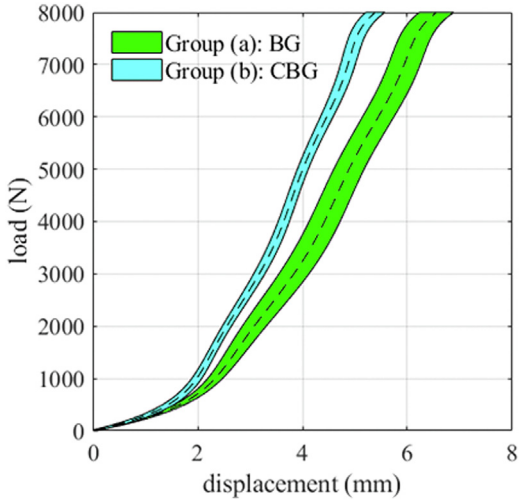


Figure 6. A pictorial presentation of load-displacement curve generated after mechanical testing of Synbone samples filled with impacted morsellised bone allograft (Group a: BG) or Cerament sandwiched between layers of impacted morsellised allografts (Group b: CBG) (Mean ± SE)..

Table 2
Summary of similar other studies.

Author	Number of subjects	Diagnoses	Material used	Follow-up	Clinical result	Functional result	Radiological result	Survivorship
Abdullah et al. (2017)	47 patients	10 primary and 37 revision THA with large uncontained acetabular defects	50:50 mixture of freeze-dried bone allograft and HA	Mean 10 years	HHS for pain primary – 9 to 39 revision – 17 to 41	HHS primary – 20 to 32 revision – 19 to 32	Lysis in 8 patient and migration in 4 cases	100%
Whitehouse et al. (2013)	43 patients	Contained acetabular defects	50:50 mixture of femoral head allograft and BoneSave (biphasic porous ceramic bone graft substitute)	7 years	OHS - 31	SF 12 – PCS – 38MCS - 55	Graft material incorporation in all except 1 with aseptic loosening	94%
Sudo et al. (2007)	17 patients	Acetabular bone defects	Porous hydroxyapatite (HA) granules	5.6 years	-	Merle d'Aubigne functional hip score 11.6 to 15.6	4 cases – superior migration but without any detrimental effect	-
Oonishi et al. (1997)	40 patients	Revision THA with massive bone deficiencies	Hydroxyapatite (HA) granules 100 to 300 micron, 0.9 to 1.2 mm and 3 to 5 mm were mixed in ratio of 10:45:45	7.9 years	Hip pain alleviated in all the patients	Walking ability and range of motion markedly improved	3 cases – socket migration seen	-
Our study	24 patients	Complex primary THA (3) revision THA (17) Rerevision THA (4)	2-3 layers of injectable ceramic bone graft substitute	60-82 months	HHS = 86.8	Full weight bearing by 3 weeks	Nonprogressive radiolucent line in 1 case	100%

HHS, harris hip score; OHS, oxford hip score; MCS, mental component score; PCS, physical component score.

Table 3
Comparison of biomechanical properties of different bone graft substitutes used in acetabular reconstruction.

Bone graft substitute	Composition	Porosity	Available form
BoneSave (Stryker, Newbury, UK)	80% tricalcium phosphate 20% hydroxyapatite	50% by volume pore size 300-500 μm	Granules 2-8 mm
ApaPore 60 (ApaTech Ltd., Elstree, UK)	Synthetic hydroxyapatite	60% by volume	Granules 2-5 mm
Cerament (BoneSupport AB, Sweden)	60% calcium sulfate hemihydrate 40% hydroxyapatite	20-40% by volume pore size 1 μm	Powder that can be mixed with the liquid to form a paste

suboptimal and the failures at long term were predicted [2,3,15–17]. The results of the relevant studies are summarized in Table 2. The injectable ceramic bone graft substitute has been shown to be biocompatible, bioactive, and osteoconductive. Voor et al. demonstrated more bone formation in the Cerament filled defects compared to unfilled defects [18]. Unlike other bone substitutes, Cerament facilitates accelerated but balanced bone ingrowth based on its micro- and macro-porosity, resulting in multiple sites of new bone formation throughout the implant surface [19]. The alcium sulfate in the substitute acts as a complement to the osteoconductive characteristics of hydroxyapatite and guides the hydroxyapatite particles for bone ingrowth and ultimate incorporation into the newly formed bony trabeculae [20,21]. The biomechanical properties of different bone graft substitutes used in the other studies are compared in Table 3.

We combined allograft with an injectable bone graft substitute to restore the bone stock in hip arthroplasty by a novel sandwich technique to address the concerns associated with previous techniques involving impaction allografting. Significant improvement was observed in both clinical and functional scores in our patients, confirming that our conceptualized “sandwich” technique offers a good option for acetabular reconstruction in the presence of major acetabular defects. In addition, this technique, being biological, retains the potential for osteointegration and restoration of bone stock in case the patient requires a revision surgery in future.

In our mechanical-based analysis, the cylindrical samples of both BG and CBGs showed increased resistance to deformation with increased load. The mechanical testing demonstrated that when Cerament is present between allograft layers, the weight-bearing capacity of the construct is improved (ie, higher energy is required to deform the samples). These results are consistent with previously published articles on the use of Cerament and other hydroxyapatite-based filler materials for various applications. McNamara et al. have shown that the addition of hydroxyapatite to the morselized bone grafts improves the mechanical strength of the reconstruction [9]. Kok et al. injected Cerament before total hip replacement in the femoral neck of the patients and reported enhanced compressive strength with an increased volume (from 5 to 20 ml) of the injected Cerament [22]. Similarly, Masala et al. reported enhanced vertebral fracture reconstruction stability in patients with osteoporosis when Cerament is injected into bones before surgery [11]. The current work reports a novel technique for use in total hip replacement and a scientific analysis of the mechanical behavior of the Cerament–allograft construct. These corroborations with previously published articles provide confidence in the present study.

The μCT images of Synbone samples showed the presence of higher porosity in the BG samples (55%) as compared to the CBG group (17%). These values are close to those reported by Nilsson et al. and Yono et al [10,23]. Literature suggests that the failure strength of the filler material increases with a reduction of its porosity [24]. A similar trend was also observed during the mechanical testing of the foam blocks, wherein higher stiffness and lower porosity were exhibited by the experimental group compared to the BG. Moreover, the deformation in experimental group reconstruction showed less variation than the BG (ie, a smaller corridor of load-displacement curves). Arts et al. also reported improved stability of femoral head morselized bone graft under shear loading when used with BoneSave (Stryker Orthopaedics) granules [25].

Blom et al. used BoneSave (Stryker Orthopaedics) along with allograft chips in 50:50 ratio in a series of 43 patients with acetabular defects. At a mean follow-up of 2 years, there were no revisions or impending revisions in any of the cases. The mean Oxford hip score was 26.9, and the overall satisfaction score was 75, ranging from 17 to 100 [2]. Abdullah et al. reported the results of reconstruction of acetabular bone deficiencies in 47 total hip arthroplasties using allograft and ApaPore 60 (ApaTech Ltd., Elstree, UK) in the ratio of 1:1 and found that the clinical outcome was excellent pertaining to function and pain at 11 years follow up. However, there was radiological lysis in 8 and migration in 4 cases, which were of concern [3]. We report the first human cohort study using the injectable Cerament and allograft mixture to address the acetabular bone defects. There was a significant improvement in the clinical score, and the main advantage was early weight bearing. Unlike the techniques used by Blom et al. and Abdullah et al., where the ceramic bone substitutes were in granular form, our technique is an improvement over these 2 because of the use of ceramic bone graft substitute in injectable form, where the viscous bone graft substitute fills up the interstices between the allograft chips and solidifies the construct to make it a single unit in the acetabular bed. This unitization of the construct helps in early weight bearing and consolidation, as seen in our patients, and can alleviate suboptimal impaction technique. The provision of mixing antibiotic in the liquid part of the bone graft substitute reduces the risk of infection. In our institution, allograft is readily available and provided free of cost to the patient and therefore preferred over costly metal augments. Our study also confirms that porous-coated uncemented cups are equally suitable for impaction allografting, which is often reserved for use with cemented cups [26].

Limitations

Our cohort includes subset of patients with heterogeneous indications, including complex primary hip, revision, and rerevision arthroplasties. The sample size is relatively small for mechanical testing. Also, it is not a randomized study, which is hardly possible given the various shapes and sizes of acetabular defects. However, a comparative study with other techniques of noninjectable bone graft substitute may be warranted in the future. Bone substitutes have conventionally been used as bone expanders because of the limited availability of bone allografts. However, in our institute, the allograft is freely available hence reducing the cost of metal augments where required. It was obvious that the cost of the bone substitute is less than the cost of porous metal augment in our setup, and the use of bone augments incurs the additional cost of bone cement to unitize the augment with the acetabular component. However, since the comparison group was not available, the cost-effectiveness was not assessed.

Conclusions

The morselized allograft with an intervening injectable ceramic bone graft substitute is an improvement over the conventional impaction of allograft alone. The mechanical tests conducted confirm the higher stiffness and load-carrying capacity of allograft layers mixed with bone substitute. The technique showed good clinical and functional outcomes and an excellent clinical survivorship while augmenting bone stock for future revisions. However, a longer follow-up is necessary to assess its long-term survivorship and status of the construct in revisions.

Conflicts of interest

The authors declare there are no conflicts of interest.

For full disclosure statements refer to https://doi.org/10.1016/j.artd.2023.101150.

References

[1] Pierannunzii L, Zagra L. Bone grafts, bone graft extenders, substitutes and enhancers for acetabular reconstruction in revision total hip arthroplasty. EFORT Open Rev 2017;1:431–9.
[2] Blom AW, Wylde V, Livesey C, Whitehouse MR, Eastaugh-Waring S, Bannister GC, et al. Impaction bone grafting of the acetabulum at hip revision using a mix of bone chips and a biphasic porous ceramic bone graft substitute. Acta Orthop 2009;80:150–4.
[3] Abdullah KM, Hussain N, Parsons SJ, Porteous MJL, Atrey A. 11-Year mean follow-up of acetabular impaction grafting with a mixture of bone graft and hydroxyapatite porous synthetic bone substitute. J Arthroplasty 2018;33:1481–6.
[4] Kotrych D, Korecki S, Ziętek P, Kruk B, Kruk A, Wechmann M, et al. Preliminary results of highly injectable Bi-phasic bone substitute (CERAMENT) in the treatment of benign bone tumors and tumor-like lesions. Open Med (Wars) 2018;13:487–92.
[5] Yeo QY, Kee Kwek EB. Use of a biphasic cement bone substitute in the management of metaphyseal fractures. J Clin Orthop Trauma 2019;10:789–91.
[6] Heini PF, Berlemann U. Bone substitutes in vertebroplasty. Eur Spine J 2001;10(Suppl 2):S205–13.
[7] DeLee JG, Charnley J. Radiological demarcation of cemented sockets in total hip replacement. Clin Orthop Relat Res 1976;121:20–32.
[8] Brewster NT, Gillespie WJ, Howie CR, Madabhushi SP, Usmani AS, Fairbairn DR. Mechanical considerations in impaction bone grafting. J Bone Joint Surg Br 1999;81:118–24.
[9] McNamara I, Howard J, Rayment A, Schalk R, Brooks R, Best S, et al. Mechanical properties of morcellised bone graft with the addition of hydroxyapatite. J Mater Sci Mater Med 2014;25:321–7.
[10] Nilsson M, Zheng MH, Tägil M. The composite of hydroxyapatite and calcium sulphate: a review of preclinical evaluation and clinical applications. Expert Rev Med Devices 2013;10:675–84.
[11] Masala S, Nano G, Marcia S, Muto M, Fucci FP, Simonetti G. Osteoporotic vertebral compression fractures augmentation by injectable partly resorbable ceramic bone substitute (Cerament™|SPINE SUPPORT): a prospective non-randomized study. Neuroradiology 2012;54:589–96.
[12] Marquardt DW. An algorithm for least-squares estimation of nonlinear parameters. J Soc Ind Appl Mathematics 1963;11:431–41.
[13] Wan C, Hao Z, Wen S, Leng H. A quantitative study of the relationship between the distribution of different types of collagen and the mechanical behavior of rabbit medial collateral ligaments. PLoS One 2014;9:e103363.
[14] Dua A, Kiran K, Malhotra R, Bhan S. Acetabular reconstruction using fresh frozen bone allograft. Hip Int 2010;20:143–9.
[15] Whitehouse MR, Dacombe PJ, Webb JC, Blom AW. Impaction grafting of the acetabulum with ceramic bone graft substitute mixed with femoral head allograft: high survivorship in 43 patients with a median follow-up of 7 years: a follow-up report. Acta Orthop 2013;84:365–70.
[16] Oonishi H, Iwaki Y, Kin N, Kushitani S, Murata N, Wakitani S, et al. Hydroxyapatite in revision of total hip replacements with massive acetabular defects: 4- to 10-year clinical results. J Bone Joint Surg Br 1997;79:87–92.
[17] Sudo A, Hasegawa M, Fukuda A, Kawamura G, Muraki M, Uchida A. Acetabular reconstruction using a cementless cup and hydroxyapatite granules: 3- to 8-year clinical results. J Arthroplasty 2007;22:828–32.
[18] Voor M, Borden J, Burden R, Waddell SW. Cancellous bone defect healing with a novel calcium sulfate - hydroxyapatite composite injectable bone substitute. Proceedings of the orthopaedic research society 56th annual meeting; 2010. New Orleans, LA. Rosemont, IL: Orthopaedic Research Society; 2010.
[19] Lindberg F, Lidén E, Sandell V. Antibiotic elution and bone remodeling with a novel bone substitute impregnated with gentamicin. In: 31st annual meeting of the European bone and joint infection society. Montreux, Switzerland: European Bone and Joint Infection Society; 2012.
[20] Nilsson M, Wang JS, Wielanek L, Tanner KE, Lidgren L. Biodegradation and biocompatability of a calcium sulphate-hydroxyapatite bone substitute. J Bone Joint Surg Br 2004;86:120–5.
[21] Abramo A, Geijer M, Kopylov P, Tägil M. Osteotomy of distal radius fracture malunion using a fast remodeling bone substitute consisting of calcium sulphate and calcium phosphate. J Biomed Mater Res B Applbiomater 2010;92:281–6.
[22] Kok J, Širka A, Grassi L, Raina DB, Tarasevičius Š, Tägil M, et al. Fracture strength of the proximal femur injected with a calcium sulfate/hydroxyapatite bone substitute. Clin Biomech (Bristol, Avon) 2019;63:172–8.
[23] Ano H, Ohashi H, Kadoya Y, Kobayashi A, Yamano Y, Tanabe Y. Histologic and mechanical evaluation of impacted morcellized cancellous allografts in rabbits: comparison with hydroxyapatite granules. J Arthroplasty 2000 Aug;15:635–43.
[24] Barralet JE, Gaunt T, Wright AJ, Gibson IR, Knowles JC. Effect of porosity reduction by compaction on compressive strength and microstructure of calcium phosphate cement. J Biomed Mater Res 2002;63:1–9.
[25] Arts JJ, Schreurs BW, Buma P, Verdonschot N. Cemented cup stability during lever-out testing after acetabular bone impaction grafting with bone graft substitutes mixes containing morselized cancellous bone and tricalcium phosphate–hydroxyapatite granules. Proc Inst Mech Eng H 2005;219:257–63.
[26] Palm L, Jacobsson SA, Kvist J, Lindholm A, Ojersjö A, Ivarsson I. Acetabular revision with extensive allograft impaction and uncemented hydroxyapatite-coated implants. Results after 9 (7-11) years follow-up. J Arthroplasty 2007;22:1083–9.

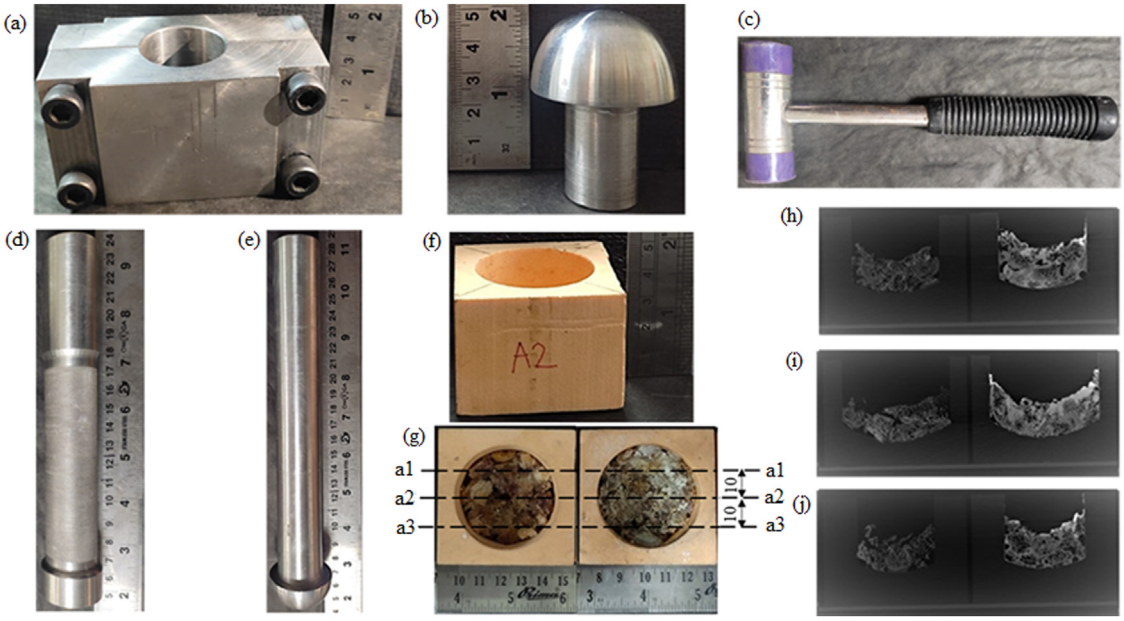
Appendix

Cylindrical sample preparation

A cylindrical chamber (Φ30 mm, length 50mm) was used to develop the cylindrical samples. First, a layer of allografts (approximately 10 bone chips) was spread uniformly at the bottom of the cylindrical cavity (Fig. 1a, Step 1). The allograft layer was impacted thrice by trained orthopaedic surgeons (S1 and S2) using a cylindrical punch and mallet (Fig. 1c and d). Care was taken to apply similar level of force that was used during acetabulum floor reconstruction surgery (Step 2). The 2 steps were repeated for 4 layers of allografts to prepare the BG samples. In the CBG samples, a layer of Cerament bone void filler was spread between each consecutive layer of allografts. Consequently, samples of the CBG had 4 layers of allografts and 3 layers of Cerament bone void filler. The mass and volume of the cylindrical samples were noted to calculate their density. The samples, once prepared, were kept for an hour at room temperature (~28°C) before testing.

Foam block sample preparation

For foam block sample preparation, a spheroid cavity (Fig. 1f) was created in solid polyurethane foam block (55 mm × 55 mm × 40mm; density: 30PCF; Synbone, Johar Bahru, Malaysia) to represent an acetabular cavity with a defect. Similar to the process of cylindrical sample preparation, in BG samples, a layer of allografts was first created at the base of the cavity. The layer was thereafter impacted thrice by the same trained orthopaedic surgeons (S1 and S2) using a cylindrical plunger with a hemispherical head (Fig. 1e). The process is repeated until 4 layers of allografts are placed in the spheroid cavity. The prepared samples are shown in Figure 1g. Thereafter, a custom-made plunger with a hemispherical head (Φ40; Fig. 1b) was fitted into the reconstructed cavity. For the CBG, a layer of Cerament bone void filler was placed between consecutive layers of bone grafts. Thus, there were 4 allograft layers and 3 Cerament layers in the samples of the CBG. The foam-block samples were scanned on the same day using high-resolution X-ray microcomputed tomography (XtremeCT II, Scanco medical CT equipment; resolution: 512 × 512; pixel size: 0.22 mm × 0.092 mm; slice thickness: 0.091 mm). A compression test was conducted as depicted, and biomedical image processing software (Mimics 23.0, Materialize, Leuven, Belgium 2021) was used to segment the cavity fillers (allograft in the BG, allograft and cerament in the CBG) and foam. The actual volume of the cavity fillers was estimated and compared with the designed volume of the cavity to calculate the overall porosity of the reconstruct.



Supplementary Figure 1. Mould, metallic punch, and Synbone blocks used for sample preparation. (a) mould used to prepare cylindrical samples, (b) punch used for transferring the load applied by load cell during mechanical testing in Synbone samples, (c) mallet used for manual impaction at the top of punches while preparing the layer of allograft, (d, e) punch used to prepare cylindrical and Synbone samples, (f) Synbone block representing an artificial pelvic bone, (g) top view of Synbone samples filled with bone substitutes (CBG left and BG right), and (h, i, and j) are the μCT images generated from samples given in (f) at section a1-a1, a2-a2, and a3-a3, respectively.