■ WRIST AND HAND

An investigation of the effect of AlloMatrix bone graft in distal radial fracture

A PROSPECTIVE RANDOMISED CONTROLLED CLINICAL TRIAL

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The osteoinductive properties of demineralised bone matrix have been demonstrated in animal studies. However, its therapeutic efficacy has yet to be proven in humans. The clinical properties of AlloMatrix, an injectable calcium-based demineralised bone matrix allograft, were studied in a prospective randomised study of 50 patients with an isolated unstable distal radial fracture treated by reduction and Kirschner (K-) wire fixation. A total of 24 patients were randomised to the graft group (13 men and 11 women, mean age 42.3 years (20 to 62)) and 26 to the no graft group (8 men and 18 women, mean age 45.0 years (17 to 69)).

At one, three, six and nine weeks, and six and 12 months post-operatively, patients underwent radiological evaluation, assessments for range of movement, grip and pinch strength, and also completed the Disabilities of Arm, Shoulder and Hand questionnaire. At one and six weeks and one year post-operatively, bone mineral density evaluations of both wrists were performed.

No significant difference in wrist function and speed of recovery, rate of union, complications or bone mineral density was found between the two groups. The operating time was significantly higher in the graft group (p = 0.004). Radiologically, the reduction parameters remained similar in the two groups and all AlloMatrix extraosseous leakages disappeared after nine weeks.

This prospective randomised controlled trial did not demonstrate a beneficial effect of AlloMatrix demineralised bone matrix in the treatment of this category of distal radial fractures treated by K-wire fixation.

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Fractures of the distal radius with dorsal displacement often result in a bony void after reduction,[1] which has been shown to diminish radiological and functional results, especially in patients aged < 65 years.[2,3] Dorsal comminution often predisposes to instability of the wrist.[4] The radiological appearance can be improved by bone grafting the metaphyseal defect. This can be achieved using autogenous bone graft, which is considered the reference technique,[5,6] but generally a general anaesthetic is required and the graft donor site is associated with significant morbidity.[1] Alternatively, allograft[7] and bone substitutes (including an injectable cement preparation[1]) can be used, with acrylics and ceramics being particularly attractive options. Polymethylmethacrylate is effective but it is not incorporated into the recipient bone and it cures by an exothermic reaction, which could impair fracture healing.[8] The ceramic cements are mainly composed of calcium phosphate,[9] which is brittle with little ability to withstand loads. However, they have been shown to enhance the performance of Kirschner (K-) wire fixation[10] and can be incorporated into the recipient bone.[1]

Cements with improved biological properties, such as AlloMatrix Injectable Putty (Wright Medical Technology, Arlington, Tennessee), are now available. This is a combination of surgical grade calcium sulphate and demineralised bone matrix (DBM) – a powder of cortical allograft that has been demineralised to expose bone morphogenetic proteins, which have osteoinductive properties.[6,11] DBM attracts mesenchymal stem cells and promotes endochondral ossification.[12]

We therefore designed a prospective randomised controlled trial to study the clinical, radiological and densitometric effects of AlloMatrix DBM injected into metaphyseal defects of extra-articular or simple intra-articular distal radial fractures in younger adults with radiological and clinical criteria of instability,[4,13] which had been managed by reduction and fixation with K-wires.

Our hypothesis was that the osteoinductive and osteoconductive properties of AlloMatrix

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Table I. Pre-operative data

Parameter	Graft group (n = 24)	No graft group (n = 26)	p-value
Demographic details			
Male gender (n, %)	13 (*54*)	8 (*31*)	0.15*
Mean age (yrs) (SD; range)	42.3 (11.4; 20 to 62)	45.0 (14.4; 17 to 69)	0.46†
Mean height (cm) (SD; range)	171.6 (7.4; 158 to 182)	168.6 (11.4; 151 to 200)	0.28†
Mean weight (kg) (SD; range)	70.8 (12.1; 49 to 98)	67.3 (14.3; 47 to 90)	0.19†
Mean body mass index (kg/m^2) (SD; range)	24.0 (3.6; 18.7 to 35.2)	23.4 (4.0; 17.5 to 31.6)	0.62†
Right side injured (n, %)	9 (*38*)	14 (*54*)	0.27*
Dominance (n, %)			0.35*
Right	19 (*79*)	22 (*85*)	
Left	4 (*17*)	1 (*4*)	
Ambidextrous	1 (*4*)	3 (*12*)	
Fracture type (n, %)			1.0*
Extra-articular (class A)	19 (*79*)	21 (*81*)	
Intra-articular (class C)	5 (*21*)	5 (*19*)	
Ulnar fracture (n, %)			0.68*
Ulnar styloid	13 (*54*)	15 (*58*)	
Ulnar head	2 (*8*)	0 (*0*)	
Mean (SD) interval from injury to operation (days)	1.9 (1.8)	2.0 (2.4)	0.70†
Radiological details			
Mean (SD) posteroanterior parameter			
Radial inclination (°)	13.0 (5.9)	15.4 (6.3)	0.19‡
Ulnar variance (mm)	0.8 (2.0)	1.1 (1.8)	0.63‡
Radial height (mm)	7.5 (3.6)	6.4 (3.3)	0.27‡
Mean (SD) lateral parameter			
Volar tilt (°)	-23.1 (6.7)	-25.0 (10.2)	0.46‡
Tear drop angle (°)	41.8 (11.7)	39.1 (12.6)	0.46‡

* chi-squared test
† *t*-test
‡ two-way repeated measures (Fisher's test) mixed model analysis of variance

would improve the Disabilities of Arm Shoulder and Hand (DASH) score[14] and clinical function by improving bone formation reflected in a higher bone mineral density (BMD) at the fracture site. It was expected that secondary fracture displacement[15] would be avoided and a better radiological appearance would be achieved, including in particular the palmar tilt.[5]

Patients and Methods

The study was designed as a randomised prospective study with concurrent controls and was approved by the Ethical Committee of our University. It was a phase IV clinical fracture-healing trial registered in a public trial registry.[1]

Between June 2005 and June 2008, after providing informed consent, a total of 50 patients who satisfied the inclusion criteria were enrolled and randomised into two groups. The inclusion criterion for patients were: 1) age between 18 and 70 years; 2) significant (> 20°) dorsal bending fracture of the distal part of the radius without significant (< 2 mm) articular displacement or other skeletal injury (except ulnar fracture); and 3) eligible for operative treatment of their fracture by percutaneous pin fixation using K-wires in a static mode (bicortical fixation).[16] Patients were excluded if they had any of the following comorbidities: active or latent infection at or about the surgical site, severe vascular or neurological disease, uncontrolled diabetes, hypercalcaemia, renal or hepatic disease, a history of drug and/or alcohol abuse, or were pregnant. Sequentially numbered randomisation envelopes containing one of the treatment arms according to a sequence determined by a computer random-number generator were opened before completion of the procedure but after K-wire fixation.

The proposed treatment was either AlloMatrix Injectable Putty from one human cadaver donor lot (graft group) or no graft. The graft group comprised 24 patients (13 men and 11 women, mean age 42 years (20 to 62)). The no graft group comprised 26 patients (8 men and 18 women, mean age 45 years (17 to 69)).

The two groups were comparable in terms of age, body mass index (BMI), fracture type, fracture side and dominant hand distribution (Table I).

We included potentially unstable[4,13] distal radial fractures with dorsal bending (> 20°) of the metaphysis with or without an associated fracture of the ulnar styloid or ulnar head (Fig. 1). There were no statistical differences in criteria of pre-operative instability and potential risk of malunion[4] between the two groups (Table I). According to the

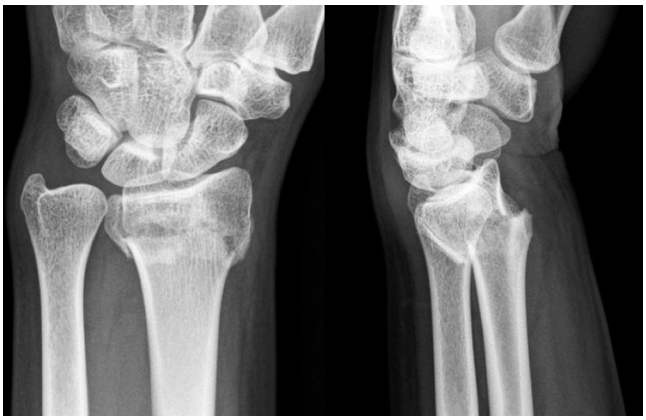

Fig. 1

Pre-operative radiographs of a displaced wrist fracture fulfilling the criteria for inclusion.

Table II. Complications

Complication (n)	Graft	No graft
Radial artery lesion (intra-operative)	0	2
Infection*	1	2
Flow of graft	1	0
Complex regional pain syndrome	3	1
Neurosensitive complaints	4	6
Tenderness on Kirschner wires	3	1
Tendon rupture*	0	2
Trigger fingers	0	1
Dupuytren's disease	0	1
Wrist synovial cyst	1	0
Symptomatic malunion*	1	1

* leading to surgical revision

classification of the Orthopaedic Trauma Association,[17] they included class A3 (extra-articular with comminution), class C1 (simple intra-articular and metaphyseal fracture) and class C2 (simple intra-articular with a multifragmented metaphysis).

All the fractures were treated within one week of the accident by percutaneous pin fixation.[9,18] As previous studies have failed to show a difference in clinical results between percutaneous pin fixation or plate fixation, we choose percutaneous K-wire fixation to allow the analysis of bone mineral density.[19,20]

Under brachial plexus anaesthesia, the tourniquet was inflated and the reduction was obtained manually and stabilised with two or three K-wires in a static mode inserted using a power drill.[18] A radioscopic image of the contralateral wrist was taken in the same pronation and supination positions to serve as control. The tips of the wires were bent and left under the skin. Resorbable 3-0 Vicryl sutures (Ethicon, Diegem, Belgium) were used to close the skin.

The sequentially numbered randomisation envelope was then opened. AlloMatrix Injectable Putty was prepared by mixing the diluent (saline solution) and the powder to fill a 5 ml syringe. As described previously,[9] the void secondary to disimpaction of the fracture was prepared through a small dorsal skin incision between the third and fourth extensor compartments by evacuating the fracture haematoma and impacting the crushed metaphyseal bone to a stable rim with a small tamp. The cement was then injected under fluoroscopic control and excess cement was removed. The skin was closed and the tourniquet then released.

The mean volume of AlloMatrix injected was 2.3 ml (1 to 4). This was slightly greater than the volume of the metaphyseal cavity as there were frequent small extra-osseous deposits. The mean time of tourniquet inflation was 31.2 minutes (0 to 65). In all patients the AlloMatrix came from the same 28 year-old male donor.

A circular removable thermoplastic splint supported the wrist post-operatively. The K-wires were removed after six to eight weeks. The patients then progressed through active and passive range of movement with stretching and strengthening exercises undertaken with the supervision of certified hand therapists.

Blinding the surgeon to the treatment was possible during all surgical stabilisation procedures, but was not possible at the end of the surgery when the randomisation envelope was opened. Patients were blinded to the treatment. They were aware that they would receive several small incisions around the wrist but the specific purpose of these was not detailed. At the end of the study (> one year), patients could be informed about their treatment group.

For the radiological assessments of fracture-healing and stability, blinding observer to graft material was considered possible (i.e., the observer of the radiographs does not know if patients were grafted or not at the time of analysis). The BMD assessment was performed under the supervision of a rheumatologist who was not involved in the patient's care.

The DASH questionnaire[13] was used for the subjective assessment at each post-operative time point (one, three, six and nine weeks, six months and one year). Active range of movement was evaluated with a goniometer.[21] For muscle strength, grip strength data were collected using a Jamar dynamometer (Sammons Preton Rolyan, Bolingbrook, Illinois) and pinch strength (key pinch) was determined using a pinch gauge, which were both calibrated by the manufacturer.[22,23] Bone union was assessed using clinical criteria and plain radiological criteria of fracture healing.[24] Clinical criteria were the absence of pain or tenderness at the fracture site with weight-bearing or on palpation. All peri- and post-operative complications were recorded.

Distal radius morphology was assessed using the radiological techniques described by Medoff[25] and with the help of Kodak Carestream PACS software (Eastman Kodak Company; Rochester, New York). The following parameters were measured at each pre- and post-operative time interval: radial inclination, radial height, ulnar variance on the posteroanterior (PA) radiograph, and volar tilt and the tear drop angle on the lateral view. Fracture union was

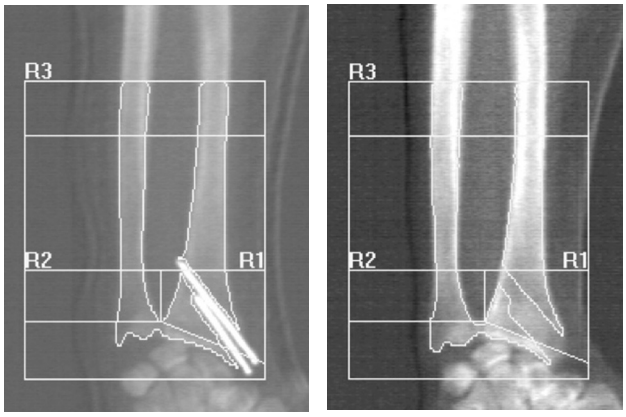

Fig. 2a

Fig. 2b

Radiographs showing a) the three zones of interest in the bone mineral densitometry protocol of the injured wrist post-operatively and b) the computerised extraction of Kirschner-wires zone in R1 at one year post-operatively.

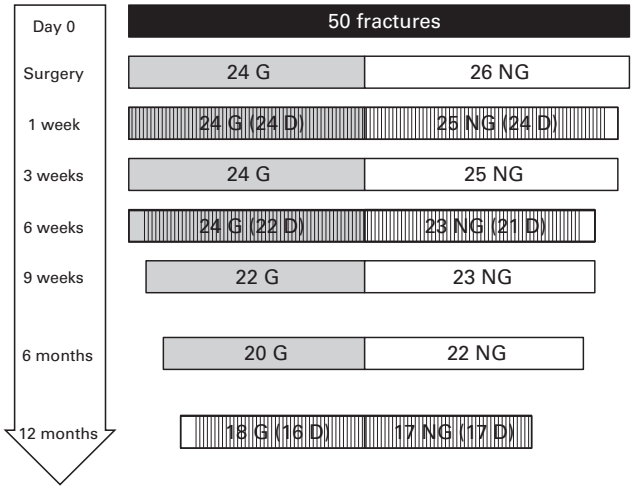

Fig. 3

Flow-diagram showing the flow of patients in the grafting (G) and non-grafting (NG) groups. Hatching denotes the proportion of patients who underwent densitometry analysis (D).

assessed radiologically, inspecting for obliteration of the fracture line and bridging of the fracture site using the criteria mentioned above. Special attention was given to the occurrence of possible AlloMatrix extraskeletal leakage.

BMD was measured by a Dual Energy X-ray Absorptiometry Scan (Discovery QDR series, Hologic Inc., Bedford, Massachusetts). In order to evaluate patients' bone status and the adequate random distribution in two similar groups for this important parameter of stability,[15] a densitometry measurement was performed within one week of the fracture treatment with common criteria (BMD of the spine and the hip) and specific analysis (BMD of both distal forearms).

Two other BMDs, performed at six weeks and one year, were used to assess the operated site. On forearm BMDs, three zones of interest were defined (R1 to R3). The R1 zone represents the fracture zone of the distal metaphysis of the radius. The R2 zone is a projection of the R1 zone over the ulnar head. The R3 zone corresponds to the radius and ulnar diaphysis. In order to avoid metal interference, measurements by a specific technique were performed on the fractured wrist (R1 zone) with subtraction of the density of the K-wires. This technique comprises a computed substraction of the density of the zone of the K-wires, with the outlines of the K-wires drawn manually on a high-resolution screen. This specific analysis was intended to evaluate the initial augmentation of local density by the calcium sulphate in the graft, then the osteoconductive properties of the graft and finally the ability of this DBM to limit the usual mineral resorption of a fractured wrist by expression of osteoinductor factors (Fig. 2).

The primary outcome of this study was the disability of the patient evaluated by the DASH questionnaire.[17] On the basis of previous studies,[26,27] a meaningful difference in the DASH score was estimated to be at least ten points. This minimal value, supported by recent literature,[16,28] was used to perform an *a priori* sample size analysis. Additionally, several studies on the treatment of distal radial fractures[29,30] showed that the standard deviation (SD) of DASH scores ranged from five to ten points. We then estimated that at least 17 patients were required for each branch of the study with a SD of ten points to detect a difference of ten points in DASH scores with 80% power.[31]

We planned to analyse the data on an intention-to-treat basis (Fig. 3). The mean duration of post-operative follow-up was 15 months (0.75 to 43). There was no statistically significant difference in terms of post-operative follow-up ($p = 0.9$, Mann–Whitney test) between both groups: 15 months (SD 11.4; 1 to 43) for the graft group and 14.2 months (SD 8.9; 1 to 38) for the no graft group.

Statistical analysis. In order to confirm the comparability of the two study arms after randomisation, univariate analysis was performed with the use of independent sample *t*-tests (or Mann–Whitney U tests on non-normal distributions) for numerical variables (age, height, weight, BMI, interval between injury and surgery) and with chi-squared analysis for nominal variables (gender, injured side, dominance, fracture type and ulnar fracture).

A two-way repeated measures mixed model analysis of variance (MANOVA) was used to determine differences in wrist mobility, strength, radiological fracture stability, union and DASH scores at one, three, six, nine weeks, six months and one year follow-up evaluations. The same model analysis was used to determine differences in bone density at one, six weeks and one year of follow-up. A p-value ≤ 0.05 was considered statistically significant.

Results

The mean duration of surgery was 36 minutes (7 to 69). Operating time was significantly longer in the graft group at a mean of 45 minutes (15 to 69)) than in the no graft group at a mean of 30 minutes (7 to 58) ($p = 0.004$, *t*-test).

Table III. Primary outcome: Disabilities of the Arm, Shoulder and Hand (DASH) scores

	Nine weeks			Six months			12 months		
Mean (SD) outcome*	**Graft**	**No graft**	**p-value†**	**Graft**	**No graft**	**p-value†**	**Graft**	**No graft**	**p-value†**
DASH general	25.4 (21.7)	25.6 (22.5)	0.81	15.2 (15.7)	13.2 (18.7)	0.79	7.5 (13.2)	13.3 (19.3)	0.41
DASH sport	44.8 (32.4)	46.9 (42.7)	0.73	26.6 (36.6)	27.5 (40.1)	0.6	10.4 (28.7)	5.6 (10.4)	0.92
DASH work	36.7 (38.6)	48.8 (45.8)	0.26	27.1 (37.8)	19.4 (32.9)	0.42	21.1 (36.9)	10.6 (19.0)	0.29

* DASH scores in general, specifically for sport activities and in relation with work (0 to 100 (maximum disability) for each subscale)
† two-way repeated measures (Fisher's test) mixed model analysis of variance

Table IV. Secondary outcome: range of movement (ROM) and strength of the injured side after Kirschner-wire removal

	Nine weeks			Six months			12 months		
Mean (SD) outcome	**Graft**	**No graft**	**p-value***	**Graft**	**No graft**	**p-value***	**Graft**	**No graft**	**p-value***
ROM (°)									
Flexion	38.7 (19.7)	39.6 (10.6)	0.88	54.7 (21.9)	61.9 (13.6)	0.16	59.1 (20.3)	69.4 (15.4)	0.03
Extension	37.4 (17.6)	38.9 (15.1)	0.96	56.7 (14.4)	54.8 (21.9)	0.47	65.3 (12.2)	65.0 (21.7)	0.99
Ulnar deviation	20.8 (11.7)	30.8 (10.2)	0.25	35.0 (11.3)	36.9 (17.0)	0.77	38.9 (14.4)	38.8 (17.5)	0.93
Radial deviation	14.2 (11.7)	14.0 (14.1)	0.86	17.9 (8.9)	20.8 (9.3)	0.44	25.0 (10.9)	25.8 (9.8)	0.70
Pronation	73.2 (19.0)	75.9 (15.6)	0.64	77.8 (19.9)	77.2 (16.2)	0.89	82.8 (12.4)	80.0 (13.2)	0.95
Supination	55.0 (26.8)	62.1 (23.0)	0.36	72.5 (23.0)	78.7 (13.2)	0.30	83.4 (9.8)	81.2 (14.0)	0.84
Strength (kg)									
Grip	18.2 (7.7)	21.4 (8.6)	0.50	30.1 (12.2)	30.3 (15.2)	0.98	34.5 (9.6)	31.0 (16.2)	0.60
Pinch	6.6 (2.1)	6.8 (2.0)	0.72	8.7 (2.8)	8.1 (3.0)	0.40	9.5 (2.1)	8.3 (3.1)	0.23

* two-way repeated measures (Fisher's test) mixed model analysis of variance

Table V. Secondary outcome: radiological assessment

	One week			12 months		
Mean (SD) outcome	**Graft**	**No graft**	**p-value***	**Graft**	**No graft**	**p-value***
Posteroanterior						
Radial inclination (°)	21.2 (4.4)	20.4 (4.1)	0.48	20.6 (6.3)	21.3 (5.4)	0.88
Ulnar variance (mm)	-0.4 (1.4)	0.04 (1.8)	0.41	0.2 (2.1)	1.2 (2.2)	0.26
Radial height (mm)	11 (2.5)	10.1 (2.5)	0.2	10.4 (3.2)	10.6 (3.0)	0.50
Lateral						
Volar tilt (°)	4.6 (9.3)	3.9 (10.8)	0.95	2.5 (11.6)	3.5 (11.7)	0.94
Tear drop angle (°)	65.0 (9.0)	66.6 (9.5)	0.46	64.9 (10.8)	65.0 (11.1)	0.87

* two-way repeated measures (Fisher's test) mixed model analysis of variance

There was no difference in complications or the need for revision surgery in the graft group compared with the no graft group (Table II).

Between the assessments at one week and one year, there were significant improvements in range of movement, strength, DASH scores (general, sport and work), fracture-healing and bone density on the injured side in both the graft and the no graft groups ($p < 0.001$ for all, Fisher's test MANOVA). However, at one, three, six and nine weeks, six months and one year post-operatively, there were no statistically significant differences between the groups with regards to DASH scores (Table III), wrist movement or grip and pinch strength (Table IV) on the injured side, with the exception of a better flexion in the no graft group at one year ($p = 0.03$, Fisher's test MANOVA).

For each post-operative time point, there were no significant differences between the two groups. This demonstrates no significant difference in the post-operative stability of the fractures (Table V).

There were no significant changes in the radiological measurements for radial inclination ($p = 0.4$), radial height ($p = 0.6$) and volar tilt ($p = 0.2$) within groups between one week and one year after surgery. On the contrary, there were significant increases for UV ($p < 0.001$, all Fisher's test MANOVA) in both groups indicating the existence of a progressive radial crush during the one year follow-up period.

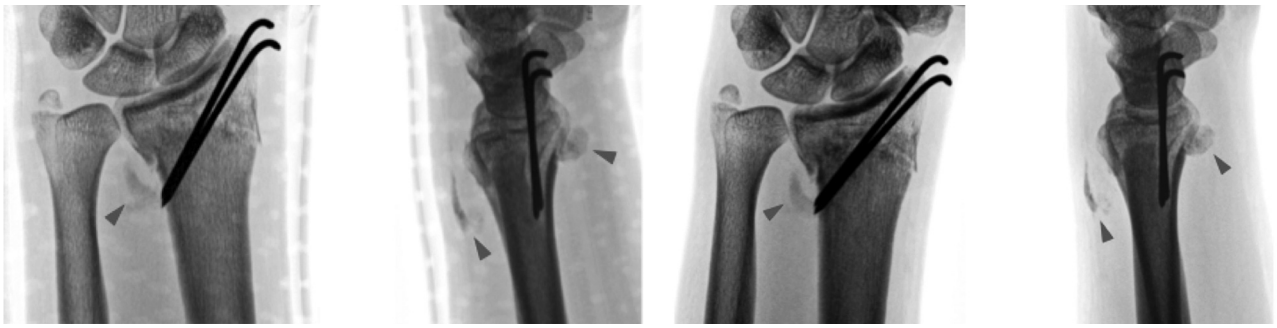

Fig. 4a

Fig. 4b

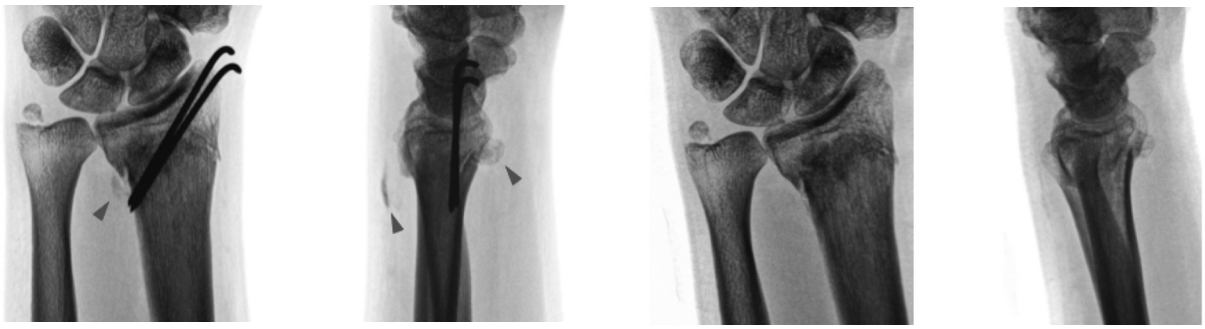

Fig. 4c

Fig. 4d

Radiographs showing a case illustration of the calcification evolution in a 24-year-old male patient, a) at one week, b) at three weeks, c) at six weeks and d) at nine weeks post-operatively. The arrows point the AlloMatrix extraskeletal leakage.

Table VI. Evolution of the bone mineral density (BMD) of the injured side for the two groups

	One week			Six weeks			12 months		
Mean (SD) BMD(g/cm²)	Graft	No graft	p-value*	Graft	No graft	p-value*	Graft	No graft	p-value*
Global	0.62 (0.06)	0.60 (0.08)	0.41	0.58 (0.08)	0.56 (0.09)	0.30	0.58 (0.08)	0.55 (0.09)	0.18
R1	0.53 (0.06)	0.45 (0.06)	**0.05**	0.47 (0.07)	0.45 (0.08)	0.45	0.43 (0.07)	0.41 (0.07)	0.30
R2	0.33 (0.07)	0.31 (0.07)	0.45	0.23 (0.08)	0.24 (0.09)	0.10	0.29 0.07)	0.23 (0.08)	0.19
R3	0.82 (0.08)	0.80 (0.11)	0.54	0.79 (0.10)	0.78 (0.12)	0.33	0.78 0.10)	0.74 (0.12)	0.20
Net	0.60 (0.06)	0.58 (0.08)	0.30	0.56 (0.08)	0.54 (0.09)	0.31	0.55 0.07)	0.52 (0.08)	0.20

* two-way repeated measures (Fisher's test) mixed model analysis of variance

Extraskeletal leakages of AlloMatrix were observed in 79% of the graft group (19 of 24). All deposits disappeared after nine weeks without radiological bone formation in extraskeletal sites (Fig. 4). Complete bridging of the fracture gap was obtained by nine weeks in both groups.

At one week post-operatively, there was no statistical significant difference between the groups in bone density in the non-injured distal forearm, the hip and the lumbar spine (all $p \geq 0.08$), reflecting a good randomisation between the groups for this variable.[15]

There was a statistically significant difference between the groups in bone density in the R1 zone ($p = 0.05$, Fisher's test MANOVA) in the injured distal radius with a bone density higher in the graft group at one week post-operatively, probably due to the injected AlloMatrix containing calcium sulfate. At six weeks and one year post-operatively, there were no further significant differences of BMD between the groups and for both wrists (Table VI).

Discussion

Augmentation of the radial metaphysis with the AlloMatrix was technically straight forward, but did not lead to an enhancement of functional recovery, fracture stability or bone density.

The preparation of the product and the technique of injection led to a significant increase of surgical procedure time. The radiological observation of extraskeletal leakage of AlloMatrix, demonstrates the difficulty encountered by the surgeon in handling the material.

The calcium sulphate carrier in AlloMatrix is known to resorb over time. This study showed radiologically that there was complete disappearance of the soft-tissue

deposits nine weeks post-operatively without new bone formation in these extraskeletal sites. Bone density in the R1 zone was significantly higher in the graft group at one week post-operatively although at six weeks there was no significant difference between both groups. The significant difference at one week was likely to be due to the presence of calcium sulphate at the level of fracture site (R1 zone), which was then resorbed.

The osteoinductive capacity of DBM is characterised by its ability to form bone when implanted in various tissues such as subcutaneous fat, muscle and tendon.[32] The failure of extraskeletal AlloMatrix DBM deposits to form bone in non-osseous sites might argue against its osteoinductive activity and osteogenic properties in humans.

The osteoinductivity of AlloMatrix has been shown *in vitro*, but is known to be lower than bone morphogenetic protein-2.[6] In our study, the osteoinductivity potency of the AlloMatrix appeared to be insufficient to enhance bone formation at the fracture site. Previous studies have concluded that significant differences may exist between commercially available DBMs and between different batches.[11,33] Additional trials remain necessary to evaluate the utility of DBM in different clinical situations. This prospective randomised controlled trial did not demonstrate any difference to the radiological or clinical outcome when AlloMatrix was used as an adjuvant to K-wire fixation in common radial fractures in a group of young patients.

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No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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