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AlloMatrix Bone Graft in Distal Radial Fracture Model
A Prospective Randomized Controlled Clinical Trial
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Priscilla D’Agostino, MD.
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ABSTRACT

AlloMatrix Bone Graft in a Distal Radial Fracture Model.
A Prospective Randomized Controlled Clinical Trial

By D’Agostino P. and Barbier OJ.

Investigation performed at Orthopaedic Department, Catholic University of Louvain, Brussels, Belgium.

Background: The osteoinductive effect of Demineralized Bone Matrix (DBM) has been documented in animal studies. Nevertheless, the therapeutic efficacy of this bone graft has to be proven in humans.

Methods: The clinical properties of AlloMatrix, an injectable calcium-based demineralized bone matrix allograft, were studied by a prospective randomized study of fifty patients with an isolated unstable distal radial fracture treated by percutaneous fixation. Twenty-four patients were randomized to the Graft group and twenty-six to the No Graft group. One, three, six, nine weeks, six months and one year after surgery patients underwent range of motion, grip and pinch strength measurements, completed the Disabilities of Arm, Shoulder an Hand (DASH) questionnaire and underwent radiographic evaluations. Patients underwent at one, six weeks and one year after surgery bone mineral density evaluations of both wrists. All adverse events were recorded prospectively.

Results: No Statistical significant difference in wrist function and speed of recovery, rate and speed of union and bone mineral density was found between the two groups. The operating time was significantly (p=0.004) higher in the Graft group. There was a statistical difference in strength between the noninjured and injured side, significantly higher for pinch strength (p=0.01) at six weeks and grip strength (p=0.04) at nine weeks in the Graft group. There was no substantial difference in morbidity or surgical revisions. All deposits of AlloMatrix observed on radiographs disappeared after nine weeks.

Conclusion: The present study did not demonstrate a significant clinical effect of AlloMatrix DBM in this prospective randomized controlled trial.

Level of Evidence: Therapeutic Level I.
1. INTRODUCTION

1.1 Background and Literature Revue

Bone grafts are worldwide used in orthopaedic field and represent a growing industry within the orthopaedic marketplace. Implantation into bony defects that frequently arise after fracture reduction is one of their indications (De Long et al., 2007; Handoll and Watts 2008).

AlloMatrix™ Injectable Putty (Wright Medical Technology, Arlington, Tenn, USA) is a human cortical bone graft material consisting of Demineralized Bone Matrix (DBM) (86% by volume) with a binding medium of calcium sulfate hemihydrate (inert carrier to facilitate handling and graft containment) and carboxymethylcellulose.

Success of bone graft substitutes containing DBM has been assumed to be closely associated with osteoinductivity of DBM. Osteoinductive property of DBM is defined by its ability to induce bone formation in an extraskeletal site, such as in muscle (Urist 1965; Bauer 2007). All DBM lots that are incorporated into AlloMatrix putty are tested prior to use for osteoinductivity using a in vitro bio-assay that measures a direct effect of the DBM on human bone forming cells (Adkisson et al., 2000). Each lot of DBM is certified for inductive capability and comes with a Certificate of Osteoinductivity.

The demineralized bone matrix provides bone morphogenetic proteins (BMPs) that signal precursor cells and stimulate the formation of bone at a defect site (Reddi 1985). This bone graft functions both as an osteoinductive signal to activate the bone healing cascade as well as an osteoconductive scaffold (collagen network in DBM) for new bone formation.

Besides the BMPs, a number of growth factors in bone matrix may play a role in the formation and destruction of bone: TGF-β1 (transforming growth factor beta 1), IGF-1 (insulin-like growth factors-1), FGFs (fibroblast growth factors), PDGFs (platelet derived growth factors) (Blum et al., 2004; Wildemann et al., 2007).
AlloMatrix is a composite graft which combines the osteoinductive capacity of DBM with the proven clinical history of osteoconduction and controlled resorption of surgical grade calcium sulfate. Sodium carboxymethylcellulose (CMC) is a water soluble, nontoxic polymer that has been widely used as a pharmaceutical additive. The CMC in AlloMatrix acts as a plasticizing agent. It is biocompatible and facilitates bone growth (Kelly and Wilkins 2004; Watson 2004; Borrelli et al., 2003).

Fractures of the distal radius are frequently unstable (Fernandez eds 1996). The instability is defined as the inability of a fracture to resist displacement after it has been manipulated into an anatomic position (McMurtry and Jupiter 1992). A number of factors will interact to influence fracture stability. These include the extent of initial displacement, the presence and degree of metaphyseal comminution and the presence of localized osteoporosis (Lafontaine et al., 1989; Fernandez and Jupiter 1996; Hollevoet and Verdonk 2003). Age is found to be a statistically significant predictor of instability. Risk for displacement increase with increasing age (Nesbitt et al., 2004). Age of the patient, type of comminution, and the ulnar variance at presentation are proved to be important predictive factors of instability in distal radial fractures (Mackenney et al., 2006).

The position of the fracture at presentation influences fracture stability and there is a parallel between the quality of the anatomic result and the residual capacity of the wrist (McQueen and Caspers 1988; Hollevoet and Verdonk 2003), except in older, low demanding patients (Villar and March 1987; Young and Rayan 2000; Hollevoet and Verdonk 2003).

Injectable osteoconductive cements (calcium phosphates bone cements, hydroxyapatite bone cement, calcium sulfate injectable grafts) have been introduced to fill voids in metaphyseal bone. Previous biomechanical studies have shown that calcium phosphate cement alone is insufficient to withstand physiological flexion-extension wrist motion and that an additional fixation is necessary (Higgins et al., 2002). These injectable cements may provide a better stability around hardware in osteoporotic bone (McQueen and Caspers 1988), help maintain reduction of fracture fragments (Young and Rayan 2000; Zimmermann et al., 2003) and may allow for accelerated functional recovery (Kopylov et al., 1999; Sanchez-Sotelo et al., 2000; Larson and Bauer 2002 Cassidy et al., 2003, Zimmermann et al., 2003).
Nevertheless, a DBM allograft such as AlloMatrix could accelerate and improve bone healing and fracture stability by its osteoinductive properties (Borrelli et al., 2003; Kelly and Wilkins 2004; Watson 2004). Animal studies have documented the osteoinductive effects of DBM (Urist 1965; Einhorn et al., 1984; Bolander and Balian 1986; Han et al., 2003; Yoo et al., 2003; Edwards 2003; Atti et al., 2003; Peterson et al., 2004; Louis-Ugbo et al., 2004). Only few case reports, uncontrolled retrospective reviews and one unique controlled but not randomized and not prospective study evaluating the DBM efficacy in a human spine model (Schizas et al., 2008) have suggested potential therapeutic effects of DBM in humans. However, the role of demineralized bone matrix in bone healing and their clinical significance still have to be proven in randomized controlled study set-up. Randomized trials represent level-I evidence and remain the standard to which the evaluation of novel fracture-healing therapies must evolve.

1.2 Study Objectives

1.2.1 Primary Objective
In the present study, unstable distal wrist fractures are treated by percutaneous reduction and Kirschner wires (K-wires) fixation (Fernandez and Wolfe 2005). The control group treated by this standard protocol is compared with a group treated together with augmentation of the metaphysis with AlloMatrix™ Injectable Putty. The objective of the study is to investigate the capacity of AlloMatrix to accelerate or improve bone-healing by radiographic and densitometric assessments.

1.2.2 Secondary Objective
In view of the prognostic factors described above, a secondary objective of the study is to look at the possible differences between the two groups in term functional outcomes and complication rate. Does AlloMatrix Putty improve the wrist function and allow a earlier functional recovery?
2. MATERIAL and METHODS

2.1 Study Design

The study is designed as a randomized prospective study with concurrent control. This study is a clinical fracture-healing trial in phase IV and is registered in an international database established by the United States National Institute of Health (ClinicalTrials.gov Identifier: NCT00274378). The study protocol was also approved by the Ethical Committee of the Catholic University of Louvain (UCL) in Brussels, Belgium (Appendix A).

Between June 2005 and June 2008, a total of 50 patients were enrolled in one medical centre under the supervision of one Orthopaedic Hand and Upper extremity Surgeon (O.B, department of Orthopaedic Surgery and Traumatology, Cliniques Universitaires St-Luc (UCL), Brussels) and randomized into two groups. One group of patients of the study population had AlloMatrix™ Injectable Putty implanted. In a control group of patients no graft material was added.

Sequentially numbered randomization envelopes were provided by Wright USA. Once the surgical reduction and stabilization of the fracture was completed, the next sequentially numbered randomization envelope was opened at the end of the procedure and the patient received the treatment listed within the envelope. Each envelop contained one of the treatment arms according to a sequence determined by a computer random-number generator. The proposed treatment was AlloMatrix™ Injectable Putty or No Graft. Patients were randomly assigned to one of the two treatment arms.

This study design allows both groups to be representative for the population’s heterogeneity, balancing all prognostic factors know and unknow, and removing their confounding bias. This randomization allows to know that the estimated effects are due to the treatement and not to the mixing of effects from some other factor.

2.1.1 Blinding of Care Providers and Patients

Blinding surgeon to the treatment he had to give was possible during all surgical stabilization procedure, but was no more possible at the end of the surgical procedure by opening of the randomization envelope.
Blinding patients to the treatment received was not always possible. After the surgery and despite the protocol, some patients wanted to know if they received a graft or not.

2.1.2 Blinding of the Outcome Assessors
The study characteristics avoided blinding of the physician for the clinical assessment of fracture-healing and wrist function. Even if the examinator was not the surgeon, the obvious presence of the dorsal approach of the wrist, by which the graft material was introduced, was visible and detectable on physical examination.

For the radiographic assessments of fracture-healing and stability, blinding observer to graft material was considered to be possible. The BMD assessment was under the supervision of a blinded physician who was not involved in the patient’s care.

2.2 Fracture Model and Study Population

2.2.1 Patient Selection
The study is directed to potentially unstable distal radial fractures with a dorsal bending of the metaphysis associated or not with a fracture of the ulnar styloid (Figs 1a and 1b).

In this trial, distal radial fractures served as clinical model because they are the most common type of fracture seen and treated by orthopaedic surgeons (Court-Brown and Caesar 2006).

The study population was a group of young patients, because as it is currently admitted the functional outcome in older, low demanding patients is not significantly dependent of a precise reduction contrary to the outcome in younger, high demand patients (Kopylov et al., 2002).

Figs 1 Fracture Model.

Fig 1a (Left) Extra-articular distal radial fracture.

Fig 1b (Right) Dorsal bending of the metaphysis.
2.2.2 Inclusion Criteria

Absolute needed criteria for inclusion were:

- All distal radius fractures which fulfil the criteria of instability (Lafontaine et al., 1989), needing a combination of three or more of the following gravity factors:
  - dorsal tilt greater than 20 degrees
  - dorsal comminution
  - intra-articular radiocarpal fracture
  - associated ulnar fractures
  - age greater than 60 years
- High demand patient
- Patient younger than 70 years of age
- Product implanted according to labelling
- Patient is willing and able to come back for all post-operative visits
- Patient has signed Informed Consent (Appendix B)

2.2.3 Exclusion Criteria

Absolute refusal criteria checked by anamnesis and the patient file were:

- Bilateral distal radius fractures (in order to permit BMD measurement on the contralateral wrist)
- Other skeletal injury
- Active or latent infection at or about the surgical site
- Patients with severe vascular or neurological disease
- Uncontrolled diabetes
- Hypercalcemia
- Renal compromise or hepatic disease
- Pregnant women
- Drug and/or alcohol abuse
- Not willing and able to come back for all post-operative visits
- Not willing to sign an Informed Consent
2.3 Patient Evaluation

2.3.1 Evaluation Schedule

Each patient enrolled in the study was followed for evaluations according to the schedule below.

<table>
<thead>
<tr>
<th>Data Collection Schedule and Sequence</th>
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<tbody>
<tr>
<td>IC</td>
</tr>
<tr>
<td>Pre-Op</td>
</tr>
<tr>
<td>Surgery</td>
</tr>
<tr>
<td>1 W F-U</td>
</tr>
<tr>
<td>3 W F-U</td>
</tr>
<tr>
<td>6 W F-U</td>
</tr>
<tr>
<td>9 W F-U</td>
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<tr>
<td>6 M F-U</td>
</tr>
<tr>
<td>12 M F-U</td>
</tr>
</tbody>
</table>

W F-U = Weeks Follow-up; M F-U : Months Follow-up; IC = Informed Consent; BMDs = Bone Mineral Densitometry

The collected data were recorded onto Case Report Forms (CRFs) (Appendix C). To insure that data were poolable for analysis, the same definitions and techniques were strictly used to gather all the data.

2.3.2 Functional Analysis

The function of the operated wrist was evaluated at each postoperative time interval as follows:

1. Active and passive range of motion in degrees of flexion, extension, radial and ulnar deviation and pro-supination (Solgaard et al., 1986).


3. DASH questionnaire (Hudak et al., 1996) (Appendix D).
2.3.3 Radiographic Analysis
At each follow-up time of the study, each patient sustained, both a posteroanterior and standard lateral view of the injured side wrist.
The immediate post-operative film also served as a baseline, against which the subsequent post-operative films were assessed for the operated wrist.

2.3.4 Bone Mineral Densitometry (BMDs)
At 1 week postoperatively, a BMDs was performed on the treated wrist and on the contralateral side. At the same time, a lumbar spine and hip BMDs were done.
A second BMDs at 6 weeks and then, a third at 1 year were performed on the both wrists.

2.3.5 Study Endpoints
Patients were followed from a pre-operative visit through a one-year visit.

Endpoints are:
- Radiographic and densitometric assessment of bone regeneration
- Comparison of time for fracture-healing
- Comparison of functional performance of operated wrist
- Complication rates (nerve or artery lesions, infection, drainage, hardware failure, wound dehiscence)
- Failure rates (Non-union, malunion, fracture instability, surgical revision)

2.3.6 Criteria for Success:
Success is determined by comparing trial treatment results to those of the control group.
Clinical success (Barbier et al., 2003) was assessed by objective assessment (range of motion - muscle strength), internationally accepted scores and the patient’s subjective assessment of his function and satisfaction (DASH questionnaire (Hudak et al., 1996)). Fracture healing - union and bone regeneration were assessed by radiographic and bone density measurements, and compared between the Graft and No Graft groups.
Union was assessed on the basis of a combination of clinical and radiographic criteria found in the literature. The most common criterion to define fracture union clinically is the absence of pain or tenderness at the fracture site during weight-bearing. The most common criterion to
define fracture union on plain radiographs is bridging of the fracture site (Morshed et al., 2008; Corrales et al., 2008). Bone density was assessed using the generally received standard values. Failure was defined as an instability of the fracture reduction, a lack of bony fusion or malunion on the study treatment side. Re-operation for removal or revision of the study implant was considered a failure. Removal of a patient from continued follow-up in the study due to death will not be considered a failure unless the event is directly caused by or attributable to the injection of AlloMatrix which is extremely unlikely.

2.4 Description of the Product

2.4.1 Product
AlloMatrix™ Injectable Putty comes in the form of a kit with premeasured powder, premeasured mixing solution, and the tools necessary to mix the components. After the powder is hydrated using all the mixing solution supplied in the kit, the resultant putty can be handled and placed in the appropriate bone sites.

2.4.2 General Indications
AlloMatrix is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. AlloMatrix is intended to be gently packed into bony voids or gaps of the skeletal system (i.e. the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

2.4.3 Contraindications
AlloMatrix™ Injectable Putty is contraindicated where it is intended as structural support in load-bearing bone and in articulating surfaces. Conditions representing relative contraindications include:
- Severe vascular or neurological disease, or renal impairment
- Uncontrolled diabetes
- Severe degenerative bone disease
- Active or latent infection in or about the surgical site
- Hypercalcemia
- Pregnancy
- Uncooperative patients who will or cannot follow post-operative instructions

2.5 Protocols

2.5.1 Enrollment Protocol

For each patient presenting as a candidate for the study, the inclusion and exclusion criteria listed above were reviewed. The patient received the information relative to the study and signed an Informed Consent. Pre-operative data were collected in the CRFs (see Appendix C) such as patient gender, date of birth, height in centimeters, weight in kilograms, side of fracture (Right/Left), type of fracture, hand dominance, medical history and medications taken by the patient.

Regular pre-operative data were collected to plan the surgery. The patient was usually operated within one week after the trauma. If there was a delay for surgery or an important displacement, fracture was previously and gently reduced by closed manipulation or using Japanese fingers traps directly in the emergency room and then a cast was applied (Fig 2).

![Fig 2](image)

Fig 2  Closed reduction using Japanese fingers traps.
2.5.2 Surgical Protocol

According to Fernandez (Fernandez and Jupiter, 1996; Fernandez and Wolfe, 2005), the dorsal bending fractures incorporated in this study were treated by pin fixation. We favored percutaneous pin fixation over open reduction and internal fixation. No significant clinical functional difference was noted between those two techniques in unstable fractures (Vasenius 2008; Koval et al., 2008; Henry 2008).

The surgical procedure was conducted under brachial plexus anesthesia. For both type of fracture, extra- or intra-articular fractures (Fernandez eds 1996), the reduction was obtained manually with image intensifier control and stabilized with two or three K-wires in a static mode. A distal to proximal pinning with one or two 1.8 mm K-wires entering through the radial styloid across to the proximal ulnar cortex of the metadiaphysis was used. These wires were placed using a power drill. An additional wire could be placed into the fracture fragment, inserted into the dorsoulnar corner of the radius between the fourth and fifth extensor compartments and directed from dorsoulnarly towards palmar radially in a distal to proximal direction (Fernandez and Jupiter 1996). The tips of the wires were bent and left under the skin, resorbable sutures (Vicryl 3/0) were used (Figs 3a and 3b).

The criteria for reduction were a radial inclination of 23°, a volar tilt of 11°, neutral ulnar variance and radial height of 12 mm (Friberg and Lundström, 1976). A radioscopic image of the contralateral wrist was taken in the operating room in the same prosupination conditions to serve as control (Gilula et al., 2002; Castaing 1964).

*Figs 3*  Percutaneous pin fixation.

*Fig 3a*  (Left) Static two K-wires stabilization.

*Fig 3b*  (Right) Static three K-wires stabilization.
At the end of the surgical reduction and stabilization of the fracture, the sequentially numbered randomization envelope was opened and the patient received the treatment listed within the envelope: either the AlloMatrix™ Injectable Putty or No additional Graft.

### 2.5.3 Preparation Protocol of ALLOMATRIX™ Injectable Putty

AlloMatrix™ Injectable Putty is supplied in a kit that contains the components and tools required to mix the components. The graft can be digitally placed or injected into bone sites.

#### Technique for preparing the putty:

1. Using sterile technique with gloves, empty the powder into the mixing bowl.

2. Empty the mixing solution into the bowl. If using the optional nozzle attachment and for easier injection, add extra fluids (saline, marrow, etc.) according to the following table below.

<table>
<thead>
<tr>
<th>Kit Size</th>
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<tr>
<td>5cc</td>
<td>1cc</td>
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<td>10cc</td>
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<tr>
<td>15.5cc</td>
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<tr>
<td>20cc</td>
<td>4cc</td>
</tr>
</tbody>
</table>

3. Mix with the spatula and knead the material against the side wall of the bowl until the desired consistency is achieved (approximately 30-60 seconds).

4. After achieving a putty-like consistency, the material can be handled digitally. The material maintains handling characteristics up to 10 minutes after mixing when left uncovered on the table. It can be held longer if covered with a damp towel to prevent drying out of the putty.

5. If injection through a syringe is desired, remove the plunger from the syringe, roll the putty into a cylinder-like shape and insert into the syringe barrel. (If additional diluent is added for nozzle injection a spatula may be used to fill the syringe). The nozzle can be attached to the syringe, if desired, but injection can be performed with or without nozzle attachment.

In this study, AlloMatrix™ Injectable Putty (5cc volume syringe) was injected percutaneously, by a dorsal approach of the wrist at the level of the fracture site, between the third and fourth extensor tendons compartments (Figs 4a and 4b).
2.5.4 Immobilisation Protocol

An open cast was applied immediately at the end of the surgical procedure. A removable thermo-plastic splint was applied two days later to allow radiographic and densitometric exams. Patients in both study arms were encouraged to perform early active and active-assisted digital and forearm motion exercises.

The K-wires were removed between 6 and 8 weeks. The patients then progressed through active and passive end range motion stretches and strengthening supervised by certified hand therapists.

2.5.5 Clinical Follow-up Protocol

Clinical follow-up including general status, wound status and functional recovery were assessed at each postoperative time interval (at 1, 3, 6, 9 weeks, at 6 months, and 1 year) by clinical objective evaluation of the range of motion, muscle strength and bone healing of the operated wrist. DASH Questionnaire was used for the subjective assessment.

Simple and reproducible methods were used for functional evaluation of the operated wrist (Solgaard et al., 1986) (Figs 5a to 5h).

Active range of motion in degrees of flexion, extension, radial and ulnar deviation and prosupination was evaluated with a goniometer. Flexion-extension mobility was measured by placing the goniometer on the palm for wrist extension, and along the dorsum of the hand for wrist flexion, over the axis of the third metacarpal bone, the elbow laying down on the table. Ulnar and radial inclinations, were measured with one arm of the goniometer along the axis of the third metacarpal, with the wrist in the neutral position of flexion or extension, the forearm laying down on the table. The Prosupination is tested with the elbow flexed and maintained against the chest along the body. The patient turn the palm up and down alternatively. The vertical arm of the goniometer was placed parallel to the axis of the humerus, and the horizontal arm on the dorsal
Figs 5  Range of motion and strength assessment.

Fig 5a  (Left) Flexion mobility.

Fig 5b  (Right) Extension mobility.

Fig 5c  Ulnar deviation.

Fig 5d  Radial deviation.

Fig 5e  (Left) Pronation.

Fig 5f  (Right) Supination.

Fig 5g  (Left) Grip strength (Jamar dynanometer).

Fig 5h  (Right) Key pinch (pinch gauge).
surface of the wrist, not over the hand to avoid the increase of prosupination mobility by the passive rotatory mobility of the carpus which may be as high as 40°.

For muscle strength, grip strength data were collected using a Jamar dynamometer and pinch strength (Key pinch) using a pinch gauge, both calibrated by the manufacturer. Jamar dynamometer and pinch gauge are considered an international reference for muscle strength measurement, they have a high calibration accuracy (Fess and Moran 1981; Mathiowetz et al., 1984).

Standardized procedures for subject position and instructions were used for hand strength evaluations. We used the standard strength testing position, as recommended by the American Society of Hand Therapists (ASHT), with subjects seated upright against the back of a chair with his shoulder adducted and neutrally rotated, elbow flexed at 90°, forearm in neutral position (Fess and Moran 1981), and wrist between 0° and 30° dorsiflexion and between 0° and 15° ulnar deviation (Hazelton et al., 1975; Pryce 1980).

Grip strength was tested first, followed by Key pinch. The Jamar dynamometers second (smallest) handle position was exclusively used for grip strength testing as recommended by ASHT. For measuring pinch strength, the gauge was placed between the thumb pad and the lateral aspect of the middle phalanx of index finger. After the individual was positioned properly, he had to squeeze as hard as he could and relax (Mathiowetz et al., 1984). The scores of three successive trials for each hand tested were recorded. The average score of the three trials were noted in kilograms. The same tools were used for all patients.

Bone union was assessed using clinical criteria and plain radiographic criteria of fracture-healing (Morshed et al., 2008, Corrales et al., 2008). The clinical criteria are the absence of pain or tenderness at the fracture site with weight-bearing or on palpation.

DASH questionnaire (Hudak et al., 1996) was used to assess patient subjective evolution at each post-operative time.

The DASH is scored in two components: the disability/symptom questions (30 items, scored 1-5) and the optional high performance sport/music or work section (4 items, scored 1-5). The assigned values for all completed responses were simply summed and averaged, producing a score out of 100 by the following procedure:

$$ \text{score} = \left( \frac{\text{sum of n responses}}{n} - 1 \right) \times 25 $$

The goal of the optional modules is to identify the specific difficulties that professional athletes/performing artists or other groups of workers might experience but which may not
affect their activities of daily living and consequently may go “undetected” in the 30-item portion of the DASH. This method allowed to obtain three DASH scores: general DASH score, sport DASH score and work DASH score at each postoperative time interval. The higher the score is, the greater the disability.

Finally, all per- and postoperative complications were recorded prospectively.

### 2.5.6 Radiographic Analysis Protocol

Distal radius morphology was assessed using the radiographic techniques described by Medoff (Medoff 2005). The following parameters were measured and followed at each pre- and post-operative time interval: radial inclinaison, radial height, ulnar variance on the postero-anterior (PA) incidence and volar tilt, tear drop angle on the lateral view (Figs 6a to 6c).

All radiographic parameters were measured using directly the longitudinal axis of the radius, or a plane perpendicular to this axis. To define the long axis of the radial shaft on PA view and lateral view, we used two reference points at 3 and 7 centimetres along the medial cortex of the radius on PA view, and along the volar cortex on lateral view.

On PA view, the positioning of the two points at 3 and 7 centimetres starts from the central reference point (CRP) described as the reference point midway the volar and dorsal ulnar corners to eliminate variation caused by dorsal angulation. Radiologic measurements are more accurate when defined with CRP (Medoff 2005) (Fig 7). On lateral view, the two points positioning starts from the tip of the volar rim of the lunate facet.

The two reference points positioned on the two different radiographs, a line is drawn linking each point to the opposite cortex (lateral cortex for PA view and dorsal cortex for lateral view). The axis of the radial shaft is considered as the line passing through the central point of the previous two lines.

*Figs 6*  Distal radius morphology assessment on PA and Lateral projections.

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*Fig 6a*  Radial inclination and ulnar variance.

*Fig 6b*  Radial height.

*Fig 6c*  Volar tilt and tear drop.
This method of measurement allows to establish a reproducible way of defining the long axis of the radial shaft on PA and standard lateral projections.

For each patient, at each time interval of the study follow-up, measurement of three radiographic parameters on PA view was achieved.

Radial inclination (RI) is considered to be the angle between the long axis of the radial shaft and a line connecting the tip of the styloid with the CRP (Medoff 2005). RI is recognized as a measurement of the radial slope in degrees on the PA projection (Van der Linden and Ericson 1981).

Radial height (RH) is the difference in millimetres in axial length between the tip of the radial styloid and the CRP. Ulnar variance (UV) is the difference in millimetres in axial length between the ulnar head and the CRP (Medoff 2005).

On lateral view, evaluation of the distal radius was achieved using two other radiographic parameters such as volar tilt and teardrop angle.

Volar tilt (VT) is measured in degrees as the angle formed between a perpendicular to the longitudinal axis of the radial shaft and a line formed by connecting the apex of the volar and dorsal rim. The teardrop represents the volar rim of the lunate facet. The teardrop angle (TD∢) is thus in degrees the angle formed between a parallel to the subchondral bone of the volar rim and a line extended from the central axis of the radial shaft (Medoff 2005).

The status of the graft and fracture-healing were qualitatively assessed (Castaing 1964; Fernandez and Wolfe 2005; Morshed 2008) for fracture lines and bony bridging, at each post-operative time.

Fracture union was assessed using clinical criteria (listed above) and plain radiographic criteria of fracture-healing (Morshed et al., 2008; Corrales et al., 2008). The radiographic criteria were obliteration of the fracture line and bridging of the fracture site.
Special attention was given to the occurrence of possible extraskeletal deposits of AlloMatrix. Their precise localizations and evolution were specified at each post-operative time of the study. The Kodak® Carestream PACS software (Eastman Kodak Company, 2005) was used for all radiographic assessments.

2.5.7 Bone Mineral Densitometry (BMDs) Protocol
At 1 week postoperatively, a BMDs was performed on the treated and on the contralateral wrist. At the same time, a lumbar spine and hip BMDs was done to compare bone density between both group.

Two others BMDs, at 6 weeks and 1 year, were used to assess resorption of the grafting material and bone regrowth at the operated site.

For both wrists, three interest zones were previously defined (R1 to R3) on the BMDs. R1 zone represent the fracture zone of the metaphyseal distal part of the radius. R2 zone is a projection of R1 zone on the ulnar head. R3 zone correspond to the radius and ulna diaphyseal shaft. To avoid metal interference in the fracture zone, all the measures (1w, 6w, 1y) at the level of the traumatized distal radius (R1) were performed at R1 with deduction of the zone corresponding to K-wires (Figs 8a and 8b).

Bone density of the hip, lumbar spine and both wrists was measured by the HOLOGIC® Dual Energy X-ray Absorptiometry Scan (DEXA scan).

_Figs 8_ Bone mineral densitometry protocol of the injured wrist.

_Fig 8a_ Three interest zones.

_Fig 8b_ Computerized extraction of K-wires zone in R1 at 1y.
2.6 Statistical Methods

Data extracted from patients files, X-rays and BMDs parameters values, DASH scores obtained at each study time interval were entered into data files using Excel (Microsoft Office). This database was used for statistical analysis with SigmaStat software from the Statistical Package for the Social Sciences 11.0 (SPSS Inc. Chicago, US) computer software and the JMP software from the SAS/STAT® statistical analysis software.

To confirm comparability of the two study arms after randomization, univariate analysis was performed with use of independent sample t-tests for numerical variables (age, height, weight, BMI, interval between injury and surgery) and with use of chi-square analysis for nominal variables (gender, injured side, dominance, fracture type, ulnar fracture).

A two-way repeated-measures mixed model analysis of variance was used to determine differences in the wrist mobility, strength, radiologic fracture stability, union and DASH scores at 1, 3, 6, 9 weeks, at 6 months, and 1 year follow-up evaluations. The same model analysis was used to determine differences in bone density at 1, 6 weeks and 1 year follow-up.

3. RESULTS

3.1 Data Statistical Analysis

3.1.1 Sample Characteristics

The study group included fifty patients (twenty-one men (42%) and twenty-nine women (58%)) with an average age of 43.7 years (range, 17 - 69 y).

The greatest number of fractures were extra-articular distal radius fractures in 80% of patients (38% in Graft group; 42% in No Graft group). An intra-articular extension was present in 20% of cases (10% in Graft group; 10% in No Graft group). 56% of the patients had an associated styloid fracture (26% in Graft group; 30% in No Graft group) and 4% an associated ulnar head fracture (two patients in the Graft group).
The right hand was affected in 23 patients (9 in Graft group; 14 in No Graft group) and the left side in 27 patients (15 in Graft group; 12 in No Graft group). The dominant hand was affected in 44% of cases (41.7% in Graft group; 46.2% in No Graft group).
The mean Body Mass Index (BMI) in the Graft group was of 24.02 kg/m2 and the BMI in the Graft group was of 23.58 kg/m2.
The mean interval between the injury and surgery was 1.92 days (range, 0 - 8 days). There was no statistical significant difference in interval between the injury and operation (p=0.7) between both groups (1.9 days (SD 1.8) for the Graft group and 2 days (SD 2.4) for the No Graft group).
Fractures of the distal part of the radius were stabilized by two static k-wires in 52% of the patients and three static K-wires in 44% of the patients. We found in one case (2%) a stabilization by four K-wires (three intrafocal K-wires using Kapandji’s pinning technique and one static K-wire). In an other case (2%), the synthesis was done using three K-wires, two static K-wires and one intramedullary elastic K-wire. The same patient sustained a neurolysis of the median nerve during the same surgery time.
Twenty-four times, the opening of the randomized envelope at the end of the surgery proposed to add a graft to the stabilization.
The twenty-four AlloMatrix™ Injectable Putty used in this study came from two different human cadaver donors. Twenty grafts (83.3%) from a young donor of twenty-eight year-old and the four remaining grafts (16.7%) from a donor of seventy-five year-old.
The mean volume of AlloMatrix injected were of 2.3 cc (range, 1-4 cc). The mean time of tourniquet inflation was 31.2 minutes (range, 0 - 65 min). The surgery duration was 36 minutes (range, 7-69 min). The operating time was significantly (p=0.004) higher in the Graft group (45 min against 30 min in the No Graft group).
The Graft group comprised twenty-four patients (48%) (thirty men (26%) and eleven women (22%)) with an average age of 42.25 years. The No Graft group comprised twenty-six patients (52%) (eight men (16%) and eighteen women (36%)) with an average age of 45 years.
The mean time to removal of the K-wires was 8.3 weeks (range, 4 - 17 w).
The two groups were comparable in terms of gender, age, BMI, fracture type, fracture side and dominant hand distribution (Table 1 and Fig 9).
### Table 1  Comparison of the Two Groups on Preoperative Data

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Graft Group</th>
<th>No Graft Group</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (sex) †</td>
<td>M = 13 (26 %)</td>
<td>M = 8 (16 %)</td>
<td>0,15</td>
</tr>
<tr>
<td></td>
<td>F = 11 (22 %)</td>
<td>F = 18 (36 %)</td>
<td></td>
</tr>
<tr>
<td>Age (years) *</td>
<td>42.25 (SD: 11,40)</td>
<td>45 (SD: 14,39)</td>
<td>0,46</td>
</tr>
<tr>
<td></td>
<td>20-62</td>
<td>17-69</td>
<td></td>
</tr>
<tr>
<td>Height (cm) *</td>
<td>171,6 (SD: 7,44)</td>
<td>168,6 (SD: 11,35)</td>
<td>0,28</td>
</tr>
<tr>
<td></td>
<td>158-182</td>
<td>151-200</td>
<td></td>
</tr>
<tr>
<td>Weight (Kg) *</td>
<td>70,8 (SD: 12,05)</td>
<td>67,3 (SD: 14,25)</td>
<td>0,19</td>
</tr>
<tr>
<td></td>
<td>49-98</td>
<td>47-90</td>
<td></td>
</tr>
<tr>
<td>BMI (Kg/m²) *</td>
<td>24,02 (SD: 3,60)</td>
<td>23,58 (SD: 3,96)</td>
<td>0,62</td>
</tr>
<tr>
<td></td>
<td>18,67-35,16</td>
<td>17,53-31,63</td>
<td></td>
</tr>
<tr>
<td>Injured side †</td>
<td>R = 9 (37,5 %)</td>
<td>R = 14 (53,8 %)</td>
<td>0,27</td>
</tr>
<tr>
<td></td>
<td>L = 15 (62,5 %)</td>
<td>L = 12 (46,2 %)</td>
<td></td>
</tr>
<tr>
<td>Dominance †</td>
<td>R = 19</td>
<td>R = 22</td>
<td></td>
</tr>
<tr>
<td></td>
<td>L = 4</td>
<td>L = 1</td>
<td>0,35</td>
</tr>
<tr>
<td></td>
<td>? = 3</td>
<td>? = 1</td>
<td></td>
</tr>
<tr>
<td>Fracture type †</td>
<td>E = 19 (38 %)</td>
<td>E = 21 (42 %)</td>
<td>1,00</td>
</tr>
<tr>
<td></td>
<td>I = 5 (10 %)</td>
<td>I = 5 (10 %)</td>
<td></td>
</tr>
<tr>
<td>Ulnar fracture †</td>
<td>Ulnar Styl. = 13 (26 %)</td>
<td>Ulnar Styl. = 15 (30 %)</td>
<td>0,68</td>
</tr>
<tr>
<td></td>
<td>Ulnar Head = 2 (4 %)</td>
<td>Ulnar Head = 0 (0 %)</td>
<td></td>
</tr>
<tr>
<td>Interval between injury-operation (days) *</td>
<td>1.9 (SD: 1,8)</td>
<td>2 (SD: 2,4)</td>
<td>0,70</td>
</tr>
</tbody>
</table>

M = Males; F = Females; R = Right; L = Left; E = Extra-articular; I = Intra-articular; Ulnar Styl. = Ulnar Styloid

* P Values obtained by a t-test
† P Values obtained by a chi-square test
Fig 9  Study randomized population.
3.1.2 Patient Flow

Among the fifty patients who enrolled in the study, forty-nine patients (98%; twenty-four grafted and twenty-five non grafted patients) completed the one-week clinical and radiological follow-up and forty-eight patients (96%; twenty-four grafted and twenty-four non grafted patients) had a BMDs. Forty-nine patients (98%; twenty-four grafted and twenty-five non grafted patients) completed the three-weeks clinical and radiological follow-up. Forty-seven patients (96%; twenty-four grafted and twenty-three non grafted patients) completed the six-weeks clinical and radiological follow-up and forty-three patients (86%; twenty-two grafted and twenty-one non grafted patients) had a BMDs. Forty-five patients (90%; twenty-two grafted and twenty-three non grafted patients) completed the nine-weeks clinical and radiological follow-up. Forty-two patients (84%; twenty grafted and twenty-two non grafted patients) completed the six-months clinical and radiological follow-up. Thirty-five patients (70%; eighteen grafted and seventeen non grafted patients) completed the twelve-months clinical and radiological follow-up and thirty-three patients (66%; sixteen grafted and seventeen non grafted patients) had a BMDs (Table 2 and figs 10a and 10b).

We planned to analyze the data on an intention-to-treat basis. The mean postoperative follow-up of this study is of 15 months (range, 3 weeks - 43 months).

There was no statistically significant difference in postoperative follow-up (p=0.9) between both groups (15 months (SD 11.4) for the Graft group and 14.2 months (SD 8.9) for the No Graft group)

**Fig 10a** Patient Flow: Clinical and Radiological Follow-up.
Fig 10b  Patient Flow : Bone Mineral Densitometry Follow-up.

Table 2  Patient Flow.

<table>
<thead>
<tr>
<th>FOLLOW-UP</th>
<th>BONE MINERAL DENSITOMETRY</th>
</tr>
</thead>
<tbody>
<tr>
<td>α</td>
<td></td>
</tr>
<tr>
<td>n = 50</td>
<td>G = 24 (48%)</td>
</tr>
<tr>
<td></td>
<td>NG = 26 (52%)</td>
</tr>
<tr>
<td>1W</td>
<td></td>
</tr>
<tr>
<td>n = 49</td>
<td>G = 24 (48%)</td>
</tr>
<tr>
<td></td>
<td>NG = 25 (50%)</td>
</tr>
<tr>
<td></td>
<td>- 1 : absent</td>
</tr>
<tr>
<td></td>
<td>- 1 : surg.revision</td>
</tr>
<tr>
<td>3W</td>
<td></td>
</tr>
<tr>
<td>n = 49</td>
<td>G = 24 (48%)</td>
</tr>
<tr>
<td></td>
<td>NG = 25 (50%)</td>
</tr>
<tr>
<td></td>
<td>- 1 : surg.revision</td>
</tr>
<tr>
<td>6W</td>
<td></td>
</tr>
<tr>
<td>n = 47</td>
<td>G = 24 (48%)</td>
</tr>
<tr>
<td></td>
<td>NG = 23 (46%)</td>
</tr>
<tr>
<td></td>
<td>- 2 : absent</td>
</tr>
<tr>
<td></td>
<td>- 1 : surg.revision</td>
</tr>
<tr>
<td>9W</td>
<td></td>
</tr>
<tr>
<td>n = 45</td>
<td>G = 22 (44%)</td>
</tr>
<tr>
<td></td>
<td>NG = 23 (46%)</td>
</tr>
<tr>
<td></td>
<td>- 2 : absent</td>
</tr>
<tr>
<td></td>
<td>- 1 : surg.revision</td>
</tr>
<tr>
<td>6M</td>
<td></td>
</tr>
<tr>
<td>n = 42</td>
<td>G = 20 (40%)</td>
</tr>
<tr>
<td></td>
<td>NG = 22 (44%)</td>
</tr>
<tr>
<td></td>
<td>- 3 : absent</td>
</tr>
<tr>
<td></td>
<td>- 1 : moved</td>
</tr>
<tr>
<td></td>
<td>- 1 : surg.revision</td>
</tr>
<tr>
<td>12M</td>
<td></td>
</tr>
<tr>
<td>n = 35</td>
<td>G = 18 (36%)</td>
</tr>
<tr>
<td></td>
<td>NG = 17 (34%)</td>
</tr>
<tr>
<td></td>
<td>- 4 : absent</td>
</tr>
<tr>
<td></td>
<td>- 2 : surg.revision</td>
</tr>
<tr>
<td></td>
<td>- 1 : pregnant</td>
</tr>
<tr>
<td></td>
<td>- 1 : hospitalized</td>
</tr>
<tr>
<td></td>
<td>- 1 : moved</td>
</tr>
<tr>
<td></td>
<td>- 1 : hospitalized</td>
</tr>
<tr>
<td></td>
<td>- 1 : moved</td>
</tr>
</tbody>
</table>

G = Graft group; NG = No Graft group
3.1.3 Preoperative Morphological Radiographic Evaluation

Distal radial deformity was evaluated using standard radiographic measurements on the initial post-injury (pre-reduction) radiographs. The studied radiographic parameters in both groups were RI, UV, and RH on PA projection, VT and TD on lateral projection.

The results demonstrated no statistical difference in preoperative instability of fractures between the Graft and No Graft groups (Table 3).

<table>
<thead>
<tr>
<th>PA projection parameters</th>
<th>Graft group *</th>
<th>No Graft group *</th>
<th>P Value **</th>
</tr>
</thead>
<tbody>
<tr>
<td>RI (˚)</td>
<td>13 (SD: 5.94)</td>
<td>15.4 (SD: 6.32)</td>
<td>0.19</td>
</tr>
<tr>
<td>UV (mm)</td>
<td>0.8 (SD: 1.97)</td>
<td>1.1 (SD: 1.82)</td>
<td>0.63</td>
</tr>
<tr>
<td>RH (mm)</td>
<td>7.5 (SD: 3.60)</td>
<td>6.4 (SD: 3.30)</td>
<td>0.27</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Standard lateral projection parameters</th>
<th>Graft group *</th>
<th>No Graft group *</th>
<th>P Value **</th>
</tr>
</thead>
<tbody>
<tr>
<td>VT (˚)</td>
<td>23.1 (SD: 6.67)</td>
<td>25 (SD: 10.24)</td>
<td>0.46</td>
</tr>
<tr>
<td>TD (˚)</td>
<td>41.8 (SD: 11.7)</td>
<td>39.1 (SD: 12.56)</td>
<td>0.46</td>
</tr>
</tbody>
</table>

* The values are given as the mean, with the standard deviation in parentheses.
** The p values pertain to the difference between the Graft group and the No Graft group on the injured side.

3.1.4 Functional Recovery: Objective and Subjective Outcomes

At 1-3-6-9 weeks, 6 and 12 months postoperatively, there were no statistically significant differences between the groups with regard to wrist motion, grip and pinch strength on the injured side and DASH scores (Tables 4 and 5).

The results showed a statistical difference in strength between the noninjured and injured side, significantly higher for pinch strength (p=0.01) at six weeks and grip strength (p=0.04) at nine weeks in the Graft group. This significant difference in strength between both wrists disappeared after nine weeks.

3.1.5 Postoperative Morphological Radiographic Evaluation

At each postoperative time, there were no significant differences between the groups with regard to radiographic measurements.
The results demonstrate no statistical difference in postoperative stability of fractures between the Graft and No Graft groups (Table 6).

3.1.6 Union Rate
At each postoperative time, there were no significant differences between groups with regard to plain radiographic criteria of fracture union.
The complete bridging of the fracture gap was obtained at nine weeks in both groups. There was no statistical difference in union rate and speed of union between both groups (Table 7).

3.1.7 Bone Mineral Density
There was no statistical significant difference between the groups in bone density on the non-injured side, on hip and lumbar spine (Tables 8 and 9).
One week postoperatively, there were no significant differences between the groups with regard to bone density in R2, R3 zones and with regard to the global bone mineral density on the injured side. Nevertheless, at the same postoperative time, there was a statistical significant difference between the groups in bone density in R1 zone (p=0.05) on the injured side with a bone density higher in the Graft group.
At six weeks and one year post-op, there were no more significant differences between the groups and for both wrists (Table 10).

3.1.8 Improvement Between one week and one year Within Groups.
Between the one week and one year assessments, there were significant improvement in the range of motion, strength, fracture-healing and bone density on the injured side (p<0.001 for all) in both Graft and No Graft groups. DASH scores (general, sport and work) also improved significantly in each group between the one week and one year evaluations (p<0.001 for all).
There were no significant changes in the radiographic measurements for RI (p=0.4), RH (p=0.6) and VT (p=0.2) within groups between one week and twelve months after surgery. On the contrary, there were significant changes for UV (p<0.001) and TD (p=0.04) in time.
An increase of the UV was observed in both groups and a slight decrease of the TD in the Graft group. The modification of these two parameters signed the existence of a progressive radial crush during the one year follow-up in both groups.
Table 4  Range of Motion and Strength of the Injured Side at Each Postoperative Time

<table>
<thead>
<tr>
<th>Motion</th>
<th>1 Week</th>
<th>3 Weeks</th>
<th>6 Weeks</th>
<th>9 Weeks</th>
<th>6 Months</th>
<th>12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>G *</td>
<td>NG *</td>
<td>P **</td>
<td>G *</td>
<td>NG *</td>
<td>P **</td>
</tr>
<tr>
<td>Flex (°)</td>
<td>25.7 (SD: 12.7)</td>
<td>35.8 (SD: 12.4)</td>
<td>0.14</td>
<td>24.3 (SD: 12)</td>
<td>36.1 (SD: 11)</td>
<td>0.90</td>
</tr>
<tr>
<td>Ext (°)</td>
<td>12.1 (SD: 12.5)</td>
<td>16.7 (SD: 11.7)</td>
<td>0.79</td>
<td>18.1 (SD: 13.7)</td>
<td>23.7 (SD: 15.9)</td>
<td>0.40</td>
</tr>
<tr>
<td>UD (°)</td>
<td>10 (SD: 9.8)</td>
<td>25 (SD: 19)</td>
<td>0.33</td>
<td>15.6 (SD: 8.4)</td>
<td>24.7 (SD: 15)</td>
<td>0.43</td>
</tr>
<tr>
<td>RD (°)</td>
<td>8.3 (SD: 6.8)</td>
<td>4.5 (SD: 6.4)</td>
<td>0.29</td>
<td>12.1 (SD: 7.7)</td>
<td>10 (SD: 3.5)</td>
<td>0.38</td>
</tr>
<tr>
<td>Pro (°)</td>
<td>52.9 (SD: 37.8)</td>
<td>75.7 (SD: 21.3)</td>
<td>0.01</td>
<td>66.9 (SD: 23.9)</td>
<td>75.9 (SD: 21)</td>
<td>0.18</td>
</tr>
<tr>
<td>Sup (°)</td>
<td>10 (SD: 26.4)</td>
<td>28.2 (SD: 32.2)</td>
<td>0.13</td>
<td>27.3 (SD: 25)</td>
<td>38.2 (SD: 32.6)</td>
<td>0.26</td>
</tr>
</tbody>
</table>

Table 5  DASH Scores at Each Postoperative Time

<table>
<thead>
<tr>
<th>Parameters</th>
<th>1 Week</th>
<th>3 Weeks</th>
<th>6 Weeks</th>
<th>9 Weeks</th>
<th>6 Months</th>
<th>12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>G *</td>
<td>NG *</td>
<td>P **</td>
<td>G *</td>
<td>NG *</td>
<td>P **</td>
</tr>
<tr>
<td>DASH general</td>
<td>53.1 (SD: 17.7)</td>
<td>44 (SD: 14.5)</td>
<td>0.43</td>
<td>44.8 (SD: 16.3)</td>
<td>45.1 (SD: 18)</td>
<td>0.88</td>
</tr>
<tr>
<td>DASH sport</td>
<td>77.5 (SD: 37.9)</td>
<td>79.2 (SD: 35.9)</td>
<td>0.69</td>
<td>91 (SD: 11.3)</td>
<td>80.2 (SD: 33.6)</td>
<td>0.55</td>
</tr>
<tr>
<td>DASH work</td>
<td>79.6 (SD: 38.6)</td>
<td>91.7 (SD: 20.4)</td>
<td>0.05</td>
<td>77.4 (SD: 33)</td>
<td>78.6 (SD: 36.8)</td>
<td>0.49</td>
</tr>
</tbody>
</table>

* The values are given as the mean, with the standard deviation in parentheses
** The p values pertain to the difference between the Graft group and the No Graft group on the injured side
### Table 6  Postoperative Morphological Radiographic Evaluation

**| 1 Week | 3 Weeks | 6 Weeks | 9 Weeks | 6 Months | 12 Months |
---|--------|---------|---------|---------|---------|---------|
**PA project**: | | | | | | |
G | 21.2 (SD: 4.4) | 20.7 (SD: 5.2) | 21.2 (SD: 5.1) | 20.3 (SD: 6.4) | 21.4 (SD: 4.3) | 20.6 (SD: 6.3) |
NG | 20.4 (SD: 4.1) | 19.9 (SD: 5.1) | 20.6 (SD: 4.3) | 21.9 (SD: 4.7) | 21.5 (SD: 4.6) | 21.3 (SD: 5.4) |
P | 0.48 | 0.63 | 0.44 | 0.48 | 0.95 | 0.86 |
**UV (mm)**: | | | | | | |
G | -0.4 (SD: 1.4) | 0.06 (SD: 1.6) | 0.4 (SD: 1.6) | 0.5 (SD: 1.9) | 0.07 (SD: 1.5) | 0.2 (SD: 2.1) |
NG | 0.04 (SD: 1.8) | 0.7 (SD: 1.8) | 0.6 (SD: 2.2) | 0.9 (SD: 2.1) | 0.9 (SD: 2) | 1.2 (SD: 2.2) |
P | 0.41 | 0.26 | 0.50 | 0.85 | 0.43 | 0.26 |
**RH (mm)**: | | | | | | |
G | 11 (SD: 2.5) | 10.5 (SD: 2.6) | 10.9 (SD: 2.4) | 10.3 (SD: 3.3) | 10.9 (SD: 2.1) | 10.4 (SD: 3.2) |
NG | 10.1 (SD: 2.5) | 9.7 (SD: 2.8) | 10 (SD: 2.1) | 10.7 (SD: 2.8) | 10.5 (SD: 2.3) | 10.6 (SD: 3) |
P | 0.20 | 0.33 | 0.15 | 0.86 | 0.35 | 0.50 |

* The values are given as the mean, with the standard deviation in parentheses.
** The p values pertain to the difference between the Graft group and the No Graft group on the injured side.

### Table 7  Bone Healing and Fracture Union at Each Postoperative Time

**| 1 Week | 3 Weeks | 6 Weeks | 9 Weeks | 6 Months | 12 Months |
---|--------|---------|---------|---------|---------|---------|
**Bridging cortices**: | | | | | | |
G | 4.6 (SD: 3.9) | 3.9 (SD: 10.8) | 3 (SD: 11.3) | 2 (SD: 12.2) | 5 (SD: 8.7) | 2.5 (SD: 11.6) |
NG | 3.9 (SD: 10.9) | 3.9 (SD: 9.8) | 3.9 (SD: 10.5) | 1.8 (SD: 11.3) | 1.3 (SD: 12.2) | 3.5 (SD: 11.7) |
P | 0.95 | 0.96 | 0.68 | 0.54 | 0.99 | 0.94 |
**TD < (°)**: | | | | | | |
G | 65 (SD: 9) | 66.6 (SD: 9.5) | 64.4 (SD: 10.6) | 61.9 (SD: 10.7) | 66.8 (SD: 9.3) | 64.9 (SD: 10.8) |
NG | 66.6 (SD: 9.5) | 66.7 (SD: 10.1) | 66.7 (SD: 10.8) | 65.8 (SD: 10.8) | 64.2 (SD: 12) | 65 (SD: 11.1) |
P | 0.46 | 0.38 | 0.12 | 0.70 | 0.65 | 0.87 |

* The values are given as the mean, with the standard deviation in parentheses.
** The p values pertain to the difference between the Graft group and the No Graft group on the injured side.

### Table 7  Bone Healing and Fracture Union at Each Postoperative Time

**| 1 Week | 3 Weeks | 6 Weeks | 9 Weeks | 6 Months | 12 Months |
---|--------|---------|---------|---------|---------|---------|
**Obliteration # line**: | | | | | | |
G | 0.04 (SD: 0.2) | 3 (SD: 0.82) | 3.3 (SD: 0.86) | 3.9 (SD: 0.89) | 4 (SD: 0) | 4 (SD: 0) |
NG | 0 (SD: 0) | 0.71 (SD: 0.93) | 3.6 (SD: 0.73) | 4 (SD: 0) | 4 (SD: 0) | 4 (SD: 0) |
P | 0.82 | 0.37 | 0.64 | 0.99 | 0.99 | 0.99 |

* The values are given as the mean, with the standard deviation in parentheses.
** The p values pertain to the difference between the Graft group and the No Graft group on the injured side. P values obtained by a Mann-Whitney test.
### Table 8  Bone Mineral Density of the Non-Injured Side Between Both Groups

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Graft Group *</th>
<th>Non Graft Group *</th>
<th>P Value**</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMD global (g/cm³)</td>
<td>0.59 (SD: 0.08)</td>
<td>0.55 (SD: 0.09)</td>
<td>0.12</td>
</tr>
<tr>
<td>BMD R1 (g/cm³)</td>
<td>0.42 (SD: 0.06)</td>
<td>0.40 (SD: 0.07)</td>
<td>0.20</td>
</tr>
<tr>
<td>BMD R2 (g/cm³)</td>
<td>0.34 (SD: 0.08)</td>
<td>0.23 (SD: 0.09)</td>
<td>0.10</td>
</tr>
<tr>
<td>BMD R3 (g/cm³)</td>
<td>0.82 (SD: 0.10)</td>
<td>0.78 (SD: 0.11)</td>
<td>0.16</td>
</tr>
<tr>
<td>BMD Net (g/cm³)</td>
<td>0.55 (SD: 0.07)</td>
<td>0.51 (SD: 0.08)</td>
<td>0.11</td>
</tr>
</tbody>
</table>

* The values are given as the mean, with the standard deviation in parentheses
** The p values pertain to the difference between the Graft group and the No Graft group on the injured side

### Table 9  Bone Mineral Density in Hip and Lumbar Spine

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Graft Group *</th>
<th>Non Graft Group *</th>
<th>P Value**</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMD Neck (g/cm³)</td>
<td>0.76 (SD: 0.11)</td>
<td>0.74 (SD: 0.11)</td>
<td>0.58</td>
</tr>
<tr>
<td>BMD Trock (g/cm³)</td>
<td>0.67 (SD: 0.11)</td>
<td>0.62 (SD: 0.08)</td>
<td>0.08</td>
</tr>
<tr>
<td>BMD Total (g/cm³)</td>
<td>0.89 (SD: 0.15)</td>
<td>0.83 (SD: 0.11)</td>
<td>0.13</td>
</tr>
<tr>
<td>BMD Ward’s (g/cm³)</td>
<td>0.60 (SD: 0.13)</td>
<td>0.57 (SD: 0.13)</td>
<td>0.43</td>
</tr>
<tr>
<td>BMD L1-4 (g/cm³)</td>
<td>0.96 (SD: 0.13)</td>
<td>0.89 (SD: 0.08)</td>
<td>0.02</td>
</tr>
</tbody>
</table>

* The values are given as the mean, with the standard deviation in parentheses
** The p values pertain to the difference between the Graft group and the No Graft group on the injured side

### Table 10  Bone Mineral Density of the Injured Side Between Both Groups

<table>
<thead>
<tr>
<th>Parameters</th>
<th>1 Week</th>
<th>6 Weeks</th>
<th>12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>G *</td>
<td>NG *</td>
<td>P **</td>
</tr>
<tr>
<td>BMD global (g/cm³)</td>
<td>0.62 (SD: 0.06)</td>
<td>0.60 (SD: 0.08)</td>
<td>0.41</td>
</tr>
<tr>
<td>BMD R1 (g/cm³)</td>
<td>3.53 (SD: 0.06)</td>
<td>0.45 (SD: 0.06)</td>
<td>0.05</td>
</tr>
<tr>
<td>BMD R2 (g/cm³)</td>
<td>3.33 (SD: 0.07)</td>
<td>0.31 (SD: 0.07)</td>
<td>0.45</td>
</tr>
<tr>
<td>BMD R3 (g/cm³)</td>
<td>3.82 (SD: 0.08)</td>
<td>0.80 (SD: 0.11)</td>
<td>0.54</td>
</tr>
<tr>
<td>BMD Net (g/cm³)</td>
<td>3.60 (SD: 0.06)</td>
<td>0.58 (SD: 0.08)</td>
<td>0.30</td>
</tr>
</tbody>
</table>

* The values are given as the mean, with the standard deviation in parentheses
** The p values pertain to the difference between the Graft group and the No Graft group on the injured side
3.1.9 Complication and Failure Rates

In this series, one peroperative complication was observed. Two non grafted patients sustained a radial artery lesion during positioning of K-wires in the radial styloid, treated by a micro-surgical suture.

Postoperative complications are divided into distinct groups: infection, flow of graft, Complex Regional Pain Syndrom type I (CRPS I), neuro-sensitive complaints, local tenderness on K-wires, trigger fingers, Dupuytren’s disease, wrist synovial cyst and symptomatic malunion.

Three patients presented a pin tract infection with a Staphylococcus aureus. In one non grafted patient, the infection appeared one week post-operatively, treated by removal of the pins, soft tissues debridement and wrist immobilization. The radiological follow-up of this patient showed the occurrence of a distal radius osteolysis one month later, the patient sustained an osseous debridement with filling of the void with a cement spacer. Two months later, the treatment option for radius reconstruction used by the team in charge of the patient was an allograft stabilized by plates with additional iliac crest autograft associated to a radial flap. Nineteen months later, this patient presents a complete palmar painful dislocation of this wrist. The treatment proposed to the patient in confront of this present situation is a wrist arthrodesis. Unfortunately, this patient appeared during the follow-up to be psychologically unstable with tendencies to self-mutilation. Actually, the local skin state prevents all type of surgery (Figs 11a to 11f).

*Figs 11*  Pin tract infection leading to surgical revision.

*Figs 11a*  Removal of the pins one week post-op.

*Figs 11b*  Distal radius osteolysis one month post-op.

*Figs 11c*  Osseous debridement and cement spacer.
At three weeks follow-up, two other cases of pin tract infection were discovered (one grafted patient and one non grafted patient). The infection led to a simple removal of the pins in the grafted patient.

A flow of AlloMatrix graft (0.5 cc) through the dorsal approach of the wrist was observed in one patient at one week follow-up. The volume of graft injected during surgery was 3 cc. In this patient, the skin healing achieved without other complication.

Four patients developed a CRPS I (three Graft patients and one No Graft patient). This CRPS I spontaneously resolved without sequelae in one grafted and non grafted patient. In the two remaining grafted patients, the CRPS I conducted to a painful wrist stiffness and a stiffness in flexion of the three most ulnar fingers.

Ten patients complained about neuro-sensitive disturbances. Six are non grafted patients and four belong to the Graft group. Patients complaints were paresthesia or hypoesthesia of the

Figs 11d  Radius reconstruction.  
Figs 11e  Complete palmar dislocation of the wrist.  
Figs 11f  Skin lesions of self mutilation.
first web space and/or the dorsal aspect of the thumb, thumb pad hypoesthesia, lateral border of the thumb hypoesthesia. These symptoms spontaneously resolved in seven patients. At one year, two grafted patients remained with an hypoesthesia of the lateral border of the thumb and one non grafted patient developed a carpal tunnel syndrome, actually medically treated.

At six weeks follow-up, four patients complained of local tenderness due to the presence of the pins just under the skin. Three are grafted patients and one non grafted patient. At the same time follow-up and at nine weeks follow-up, two non grafted patients presented a clinical rupture of tendons leading to a surgical revision. In the first case, there was a complete rupture of the EPL, reconstructed using a Palmaris longus and in the second case, there was a complete rupture of the tendon extensor communis of the fourth and fifth fingers. They were sutured laterally to the extensor communis of the third digit.

At six months follow-up, one non grafted patient developed trigger fingers of the third and fourth rays which completely resolved at one year.

One non grafted patient developed, at one year follow-up, a Dupuytren’s disease in the axis of the fourth ray. The lesion is a palmar nodule without contracture of the ring finger, corresponding to a stage NP in Tubiana Staging System.

At one year follow-up, one grafted patient presented a dorsal wrist ganglion cyst (scapholunate junction). Actually, this cyst remains asymptomatic.

Two cases of symptomatic malunion leading to a surgical revision were deplored. The first case was an ulnocarpal impingement syndrome appeared after a progressive distal radius cruch in a non grafted patient. The second case was a malunion of the distal radius caused by an over-reduction of the fracture in palmar flexion associated with a DRUJ instability in a grafted patient. Both patients sustained a distal radius corrective osteotomy and iliac crest bone grafting at ten months post-op for the first patient and at seven months post-op for the second case (Figs 12a and 12b).

The results showed no statistically significant differences in complications and surgical revisions between the two groups (Table 1). During the follow-up, two patients sustained a distal radius fracture on the contralateral side. The first one at seven months post-op, treated by a volar plate (Synthes® titanium) and the second one at ten months post-op, treated by three Kirschner wires (18/10) in a static mode. One patient sustained a proximal humeral fracture on the ipsilateral side at eleven months post-op, treated conservatively.
Figs 12  Symptomatic malunions leading to surgical revision.

Figs 12a  Distal radius crush and ulnocarpal impingement syndrome.

Figs 12b  Over-reduction in palmar flexion and DRUJ instability.

Table 11  Complications in Both Groups

<table>
<thead>
<tr>
<th></th>
<th>Graft group</th>
<th>No Graft group</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Peroperative</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radial artery lesion</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td><strong>Postoperative</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infection *</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Flow of graft</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>CRPS I</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Neurosensitive complaints</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>Tenderness on K-wires</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Tendons rupture *</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Trigger fingers</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Dupuytren’s disease</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Wrist synovial cyst</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Symptomatic malunion *</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

* Complications leading to surgical revision
3.1.10 Extraosseous AlloMatrix Deposits

Soft-tissue extrusion was present on X-rays in nineteen patients, all belong to the Graft group (79% of Graft group). In the others five grafted patients any sign of graft material was not visible in soft-tissue. Calcifications were observed along the extensor or flexor tendons and muscles, at the level of the inter-osseous space between the radius and ulna or simply in direct contact with cortices at fracture site without any extension in soft-tissues. These localizations may be combined within the same patient. The radiological follow-up showed a complete disappearance of all soft-tissue deposits of AlloMatrix after nine weeks (Figs 13a and 13b).

Fig 13a  Evolution of Extraskeletal Soft-Tissue Deposits of AlloMatrix.
Figs 13b  Case illustration of calcifications evolution.

1 week

3 weeks

6 weeks

9 weeks
4. DISCUSSION

The results of this clinical trial demonstrated that augmentation of the metaphyseal distal part of the radius with a DBM such as AlloMatrix was feasible but without enhancement of functional recovery, fracture-healing, fracture stability and bone density, and without substantial increase in morbidity and surgical revisions.

AlloMatrix injectable graft and Safety

The unique peroperative complication in the study (radial artery lesion), was observed in two non grafted patients. During fracture reduction and stabilization, there was no possible influence of the surgeon as the randomization envelope was opened at the end of the surgical procedure. This complication is surgeon and technique related without direct relation with grafting.

The infection rate was not higher in the Graft group and the only case who needed an extensive surgical revision belong to the No Graft group. We never observed infection at the graft injection site.

Symptomatic malunion were not caused by grafting at the fracture site. Radiographic analysis showed a progressive secondary displacement of bone fragment and bone crush in one non grafted patient and an over-reduction of the fracture in palmar flexion in a grafted patient.

Others were common complications linked to the presence of pins (neuro-sensitive complains, tenderness on K-wires, tendon ruptures) or described complications occuring after such trauma (trigger digits, Dupuytren’s disease, carpal tunnel syndrome and synovial cyst). Their incidence in the Graft group was not higher. To be noted is that the unique case of dorsal wrist synovial cyst occurred in one grafted patient and could be in relation to an induced weakness of the dorsal capsular joint by the dorsal approach use for grafting.

No adverse events related to the use of AlloMatrix DBM were observed.
Handling of AlloMatrix injectable putty

The use of this injectable DBM requires a supplementary dorsal approach of the wrist. The preparation of the product and surgical approach needed to inject the product led to a significant increase of the surgical procedure time. The radiologic observation of extraskeletal deposits (tendons and muscles) of AlloMatrix demonstrates the important difficulty encountered by the surgeon in handling of this kind of injectable DBM graft. This surgical approach might be incriminated in the statistical significant difference in strength between the noninjured and injured side observed in the Graft group at six and nine weeks. Passing through the extensor compartments might create a certain degree of extensor tendinitis and weaken the power hand strength. This inflammatory state might be increased by the postoperative graft resorption phenomenon, worsening the weakness of the affected hand.

Graft Resorption

The calcium sulfate carrier contains in AlloMatrix is known to resorb in time. This study showed a radiologic complete disappearance of the soft-tissue deposits after nine weeks. Bone formation in these extraskeletal sites (tendons and muscles) was not observed. Moreover, bone density in R1 zone is significantly higher in the Graft group at one week post-op. At six weeks follow-up, there was no more significant difference between both groups. The significant difference at one week is probably due to the presence of sulfate calcium at the level of fracture site (R1 zone). Later, it as been resorbed. Those results demonstrated the carrier resorption on BMDs at six weeks and on radiographs after nine weeks but without enhancement of the bone healing and bone density, and without radiologic bone formation in extraskeletal sites in the Graft group. The inability of this DBM to form bone in an nonosseous site might argue against its osteoinductive activity and against its osteogenic property in humans. As far as we know, DBM induced bone formation within tendon and intermuscular spaces has not yet been reported neither in animals or humans.
Variability in Osteoinductivity of AlloMatrix

Several factors influence the osteoinductivity of a DBM product and may influence the results. In DBM particles, osteoinductive properties come from BMPs. Logically, the greater the amount of DBM a product contains, the greater the bone formation potential. Animal studies support this concept referred as Proportional Osteoinduction (Han et al., 2003; Yoo et al., 2003; Edwards 2003; Atti et al., 2003; Peterson et al., 2004). AlloMatrix is a DBM product of the first generation and its corresponding percentage of DBM content is 40% by weight.

In addition, DBM preparation and storage methods induce variability in osteoinductivity of DBM products. Studies demonstrated that the existence of different demineralization process (Zhang at al., 1997), carrier-DBM (Han et al., 2005), sterilization process (Ferreira et al., 2001; Alanay et al., 2008; Qiu and Connor 2008) and storage (Pinholt and Solheim 1994; Han et al., 2005) are factors which may deeply modify the osteoinductive potential of the various DBM products. There is an intervariability of BMPs in DBM grafts (Bae et al., 2006; Boyan et al., 2006; Wang et al., 2007).

The variability in BMPs osteoinductivity between individual donors might intervene in the bone formation potential of a DBM product.

In this trial, two different lots of AlloMatrix have been used from two human cadaver donors of distinct ages (twenty-eight and seventy-five year-old donors) and same gender. This might lead to a variability in the osteoinductive potency of BMPs within the two lots of the same DBM product and may bias results.

There is continued debate over the acceptable age range of donors for bone. Some studies suggested that the osteoinductive response of demineralized bone for clinical use could be enhanced by using young donors. In the present study a minority of grafted patients (4/24; 16.7% of the Graft group) sustained a grafting of the fracture site with the second lot of AlloMatrix (oldest human donor). This argument alone fails to explain the total absence of a faster bone healing in all grafted patients. Results of several studies do not support the contention that young donors of demineralized bone are preferable to adult donors. An animal study demonstrated that the osteoinductive response increased significantly with increasing donor rat age (Pinholt and Solheim 1998). An other recent animal study using DBM prepared from human donors demonstrated
that there was no significant statistical association of osteoinductivity with age, gender and their interaction, concluding that demineralized bone from donors through at least 85 years of age is a viable grafting material (Traianedes et al., 2004).

Nevertheless, without taking into account the donor age factor, a more recent study demonstrated the highest intravariability in concentration of BMPs among different lots of the same DBM formulation than among different DBM formulations (Bae et al., 2006).

In this study, the proportional amount of BMPs in AlloMatrix product and thus, the osteoinductivity potency of AlloMatrix seems to be insufficient to enhance bone formation and enhance bone union at fracture site.

Recently, studies have demonstrated that PDGF (platelet derived growth factor) present in blood and platelet-rich plasma decrease the osteoinductivity of DBM in animal model (Ranly et al., 2005 and 2007).

In our study, patients blood was never adjuncted or mixed to AlloMatrix but the product had always been in direct contact with patient’s blood while injecting the graft in the fracture site.

According to the authors, the negative effects of PDGF are dose-sensitive.

**Sample size**

Finally, the small number of patients studied in this prospective randomized trial is a factor that might limite the power of the analysis.
5. CONCLUSIONS

The present study did not demonstrate a significant clinical effect of AlloMatrix DBM graft in this human model.

Additional trials are needed to evaluate the utility and potential benefits of demineralized bone matrix grafts such as AlloMatrix in humans and to confirm our observations.
REFERENCES


APPENDICES

Université Catholique de Louvain
Faculté de Médecine

Commission d’Ethique Biomédicale
Hospitio-Pascaute

Bruxelles, le 21 février 2005

Monsieur le Docteur Olivier BARRIER
Chirurgie orthopédique
Cliniques Universitaires Saint-Luc
1200 BRUXELLES

Cher Collègue,

Concernant : Réf. 2004/29/JUILLET/139 (à rappeler dans toute correspondance concernant ce projet

Intitulé : AlloMatrix™ injectable putty in distal radius fractures. Randomised, controlled clinical study in unstable dorsal bending fractures of the distal radius.

La Commission d’Ethique Biomédicale a bien reçu les modifications apportées concernant le protocole susmentionné.

La Commission donne un avis favorable définitif à ce projet et estime que l’expérimentation prévue peut être entreprise.

Nous vous prions d’agréer, cher Collègue, l’expression de nos sentiments les meilleurs.

Professeur J. MASSON
Curate

Professeur M.F. van den HOVE
Secrétaire

Professeur J.-M. MALOTTAUX
Président

avenue Hippocrate 55, 14
Touche, avenue B
1200 Bruxelles

Tél. : 02/704.55.14
Fax : 02/704.55.13
E-mail : commission.ethique@medoslac.be

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Appendix A: Approval of the Ethical Committee of the Catholic University of Louvain (UCL) Brussels, Belgium.
Appendix B : Inform Consent

Je confirme que j'ai expliqué la nature, le but et les effets prévisibles de l'étude au volontaire/patient mentionné ci-dessus.
Le volontaire/patient confirme son accord de participation par sa signature personnellement datée.

_________________________                  __________________________
Signature de la personne qui procure l'information                  Date (jour/mois/année)

_________________________
Nom en lettres capitales de la personne qui procure l'information

Confidentiel                  Paraphe du patient

5
# Appendix C: Case Report Form

## Preoperative Information

**Patient Code:**

**Preoperative Evaluation Date:** / / 

**Primary diagnosis**
- [ ] Trauma - closed fracture
- [ ] Trauma - open fracture
- [ ] Pathologic fracture:
  - [ ] Bone cyst
  - [ ] Benign tumor
- [ ] Known osteoporosis
  - [ ] NO: see medication list
  - [ ] YES: see medication list

**Date of fracture:** / / 

**Side of fracture:**
- [ ] Right wrist
- [ ] Left wrist

**Previous treatment:**
- [ ] YES
- [ ] NO

**Specify:**
- [ ] CAST
- [ ] K-Wires
- [ ] ORIF

**Medical History: concomitant diagnoses: specify:**

**List of medication taken by patient:**

**Osteoporosis treatment: specify:**

**Other medications:**

**Systemic or local factors that affect immune surveillance, metabolism, and local vascularity**

### Systemic
- Malnutrition
- Renal, liver failure
- Alcohol abuse
- Immune deficiency
- Chronic hypoxia
- Diabetes mellitus
- Steroid therapy

### Local
- Tobacco abuse
- Chronic lymphedema
- Venous stasis
- Major vessel compromise
- Arthritis
- Extensive scarring
- Radiation fibrosis

---

## Patient Data

**Gender**
- [ ] Male
- [ ] Female

**Date of Birth:** / / DD MM YY

**Height:**

**Weight:**

---

## Fracture: Classification of distal radius fracture (Fernandez):

- [ ] Type I = Bending fracture of metaphysis
- [ ] Type II = Shearing fracture of joint surface
- [ ] Type III = Compression fracture of joint surface
- [ ] Type IV = Avulsion fracture-radiocarpal fracture-dislocation
- [ ] Type V = Combined fractures – high velocity injury

## Associated lesions of the distal radioulnar joint (DRUJ):

- [ ] Type 1 = Stable following reduction of the radius the DRUJ is congruous and stable
- [ ] Type 2 = Unstable subluxation or dislocation of the ulnar head
- [ ] Type 3 = Potentially unstable subluxation possible

## Laboratory Data

**Insert laboratory data sheet containing:**

**Peripheral Blood Cell Counts and formula Coagulation**
- Ions: specify: 
  - Calcium: ______ mg/dl

**Renal function**

**Hepatic function**

**HCG (only in case of possible pregnancy)**

---

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<table>
<thead>
<tr>
<th>Surgery Information</th>
<th>ALLOMATRIX® study UCL Belgium</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Patient Code:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Surgery: <strong>/</strong>/__</td>
<td></td>
</tr>
</tbody>
</table>

**Procedure(s)**
- Percutaneous K-Wires: n = ........
- ALLOMATRIX®:
  - YES
  - NO
- additional procedure: ...........................................
- open cast

**Intraoperative Fluoroscopy of both wrists**

**Operated wrist**
- Ulnar inclination: ...............°
- Palmar inclination: ...............°
- Radial length: .................mm
- Ulnar variance: .................mm
  - When compared to contralateral wrist:
    - neutral
    - not neutral
- Radial width: .................mm

**Contralateral wrist (control)**
- Ulnar inclination: ...............°
- Palmar inclination: ...............°
- Radial length: .................mm
- Ulnar variance: .................mm
- Radial width: .................mm

**Remarks:**
- ............................................................................
- ............................................................................

**Randomization label:**
- Please stick the label found in the randomization envelope in this box

**VOLUME of ALLOMATRIX® implanted (ALLOMATRIX® group only)**
- ................. CC
**Postoperative Information**

### ALLOMATRIX® study
UCL Belgium

<table>
<thead>
<tr>
<th>Patient Code:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-op Evaluation Date:</td>
<td>/ / DDMYY</td>
</tr>
</tbody>
</table>

**Additional procedures at the operated wrist**
- ☐ Removable splint to be kept on when at rest
- ☐ Finger mobilisation

### CLINICAL SCORING: Score = ............... POINTS

<table>
<thead>
<tr>
<th>GRADE</th>
<th>POINTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain with rest</td>
<td>1</td>
</tr>
<tr>
<td>Mechanical Pain</td>
<td>2</td>
</tr>
<tr>
<td>Pain with palpation</td>
<td>3</td>
</tr>
<tr>
<td>Clinical healing</td>
<td>4</td>
</tr>
<tr>
<td>Normal function</td>
<td>5</td>
</tr>
</tbody>
</table>

### RANGE OF MOTION OF OPERATED WRIST

#### PASSIVE
- Flexion: .............°
- Extension: .........°
- Radial deviation: ..........°
- Ulnar deviation : ...........°
- Prosupination : ............°

#### ACTIVE
- Flexion: ..........°
- Extension: .........°
- Radial deviation: ..........°
- Ulnar deviation : ...........°
- Prosupination : ............°

### MUSCLE STRENGTH AT OPERATED WRIST

- Grip strength measured with dynamometer (Jamar):
  - Result: ............................................
  - ☐ Not performed

### QUANTITATIVE SENSORY EVALUATION

- Semmes-Weinstein Monofilament test :
  - Result: ............................................
  - ☐ Not performed

### ABIL Hand MANUAL ABILITY TEST

- SEE ATTACHED FORM

### 1 WEEK POSTOP

#### INVESTIGATOR'S LAST NAME:

#### DASH QUESTIONNAIRE

General upper extremity activities: ............. POINTS
Sports/music instrument: .................. POINTS
Work: ........................................ POINTS
Total SCORE: .................................. POINTS

#### RADIOGRAPHIC EVALUATION OF OPERATED WRIST

PLAIN X-rays Anteroposterior and Lateral views

#### DISTAL RADIUS MORPHOLOGY

- Ulnar inclination: ..........°
- Palmar inclination: ..........°
- Radial length: .......... mm
- Ulnar variance: .......... mm
- Neutral: ☐ Neutral
- Not neutral: ☐
- Radial width: .......... mm
- ☐ altered compared to index

#### GRAFT RESORPTION

- ☐ YES ☐ NO

#### HETEROTOPIC OSSIFICATION

#### FRACTURE HEALING: score = ............... POINTS

<table>
<thead>
<tr>
<th>GRADE</th>
<th>POINTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>No bone</td>
<td>1</td>
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<tr>
<td>Cortical contact</td>
<td>5</td>
</tr>
</tbody>
</table>

#### BONE MINERAL DENSITOMETRY AT 1 WEEK

#### SEE ATTACHED FORM

- Result: operated wrist: ....................................
- contralateral wrist: ....................................
- Remarks: ............................................
**Postoperative Information**

**ALLOMATRIX® study UCL Belgium**

<table>
<thead>
<tr>
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<td>Clinical healing</td>
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</tr>
<tr>
<td>Normal function</td>
<td>5</td>
</tr>
</tbody>
</table>

**SIDE EFFECTS:**

- Removable splint to be kept on when at rest
- Finger mobilisation

---

**3 WEEKS POSTOP**

**INVESTIGATOR'S LAST NAME:**

- Serum sample for Bone Angiogenesis Factor

**DASH QUESTIONNAIRE**

**SEE ATTACHED FORM**

General upper extremity activities: ………………………POINTS
Sports/music instrument: ………………………POINTS
Work: …………………………………………POINTS

Total SCORE: ……………………………… POINTS

**RADIOGRAPHIC EVALUATION OF OPERATED WRIST**

**PLAN X-rays Anteroposterior and Lateral views**

**DISTAL RADIUS MORPHOLOGY:**

- Change compared to index
- No

**Ulnar inclination:** ……………
- No

**Palmar inclination:** …………
- No

**Radial length:** ………….. mm
- No

**Ulnar variance:** ………….. mm
- No

- Neutral
- Not neutral

- Radial width: ………….. mm
- No

**GRAFT RESORPTION**: ………………. %

**HETEROTOPIC OSSIFICATION:**
- YES
- NO

**FRACTURE HEALING**: Score = ……………………… POINTS

**GRADE**

<table>
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</tr>
</tbody>
</table>

**BONE MINERAL DENSITOMETRY:** not at this point

**SEE ATTACHED FORM**

Result: operated wrist: ………………………
contralateral wrist: ………………………

Remarks: ………………………………………………

---

**AbilHand Manual Ability Test:**

**SEE ATTACHED FORM**

Score: ………………………… POINTS

---

**Diploma of Orthopaedic and Trauma Surgery - 2009**

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## Postoperative Information

**ALLOMATRIX®
study UCL Belgium**

**Diploma of Orthopaedic and Trauma Surgery - 2009**

| Post-op Evaluation Date: | / /  
|--------------------------|--------------------------
| DODMYY | 60 |

### Additional procedures at the operated wrist

- Removal of percutaneous K-wires
- Start of intensive mobilization and physiotherapy

### CLINICAL SCORING: Score = .................. POINTS

<table>
<thead>
<tr>
<th>GRADE</th>
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<tbody>
<tr>
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</table>

### RANGE OF MOTION OF OPERATED WRIST

- **PASSIVE**
  - Flexion: .............
  - Extension: .............
  - Radial deviation: .............
  - Ulnar deviation: .............
  - Prosupination: .............

- **ACTIVE**
  - Flexion: .............
  - Extension: .............
  - Radial deviation: .............
  - Ulnar deviation: .............
  - Prosupination: .............

### MUSCLE STRENGTH AT OPERATED WRIST

Grip strength measured with dynamometer (Jamar):

Result: 

- Not performed

### QUANTITATIVE SENSORY EVALUATION

Semmes-Weinstein Monofilament test:

Result: 

- Not performed

### ABILHAND MANUAL ABILITY TEST:

**SEE ATTACHED FORM**

Score: .................. POINTS

---

### 6 WEEKS POSTOP

**INVESTIGATOR’S LAST NAME:**

**SEE ATTACHED FORM**

### DASH QUESTIONNAIRE

- General upper extremity activities: .................. POINTS
- Sports/music instrument: .................. POINTS
- Work: .................................................. POINTS

Total SCORE: .................. POINTS

### RADIOGRAPHIC EVALUATION OF OPERATED WRIST

- PLAN X-rays Anteroposterior and Lateral views

- **DISTAL RADIUS MORPHOLOGY:**
  - Ulnar inclination: .............
  - Palmar inclination: .............
  - Radial length: ............. mm
  - Ulnar variance: ............. mm

- Neutral □ Neutral □ Not neutral

- Radial width: ............. mm

- GRAFT RESORPTION ................. %

- HETEROPTIC OSSIFICATION: □ YES □ NO

### FRACTURE HEALING: score = .................. POINTS

<table>
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</tr>
</tbody>
</table>

### BONE MINERAL DENSITOMETRY: AT 6 WEEKS

**SEE ATTACHED FORM**

Result: operated wrist: 

corporal wrist: 

Remarks: 


### Postoperative Information

**Patient Code:**

**Post-op Evaluation Date:** DDMYY

**Additional procedures at the operated wrist**
- [ ] Control after removal of percutaneous K-wires
- [ ] Intensive mobilization and physiotherapy stopped?

### CLINICAL SCORING: Score = .......... POINTS

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### RANGE OF MOTION OF OPERATED WRIST

**PASSIVE**
- Flexion:............
- Extension:.........
- Radial deviation:... 
- Ulnar deviation ...
- Prosupination : ....

**ACTIVE**
- Flexion:............
- Extension:.........
- Radial deviation:...
- Ulnar deviation :
- Prosupination :

### MUSCLE STRENGTH AT OPERATED WRIST

Grip strength measured with dynamometer (Jamar): Result: -------------------------
- [ ] Not performed

### QUANTITATIVE SENSORY EVALUATION

Semmes-Weinstein Monofilament test:
- Result: -------------------------
- [ ] Not performed

### ABILHAND MANUAL ABILITY TEST:

**SEE ATTACHED FORM**

Score: ......................... POINTS

---

### 9 WEEKS POSTOP

**INVESTIGATOR’S LAST NAME:**

**DASH QUESTIONNAIRE:**

**SEE ATTACHED FORM**

**GENERAL UPPER EXTREMITY ACTIVITIES:**................. POINTS

**SPORTS/NUISANCE INSTRUMENT:**................. POINTS

**WORK:** ........................................ POINTS

Total SCORE: ........................................ POINTS

**RADIOGRAPHIC EVALUATION OF OPERATED WRIST**

**PLAIN X-rays Anteroposterior and Lateral views**

**DISTAL RADIUS MORPHOLOGY**:
- [ ] Change compared to index

**ULNAR INCLINATION:**..............
- [ ] No

**PALMAR INCLINATION:**............
- [ ] No

**RADIAL LENGTH:**............. mm
- [ ] No

**ULNAR VARIANCE:**............. mm
- [ ] No

**NEUTRAL: Not neutral
- [ ] No

**RADIAL WIDTH:**............. mm
- [ ] No

**GRAFT RESORPTION:** ...............%

**HETEROTOPIC OSSIFICATION:** [ ] Yes [ ] No

**FRACTURE HEALING:** score = .......... POINTS

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**BONE MINERAL DENSITOMETRY:** not at this point

**SEE ATTACHED FORM**

Result: operated wrist: 
contralateral wrist: 
Remarks: 

---

**Diploma of Orthopaedic and Trauma Surgery - 2009**
### Postoperative Information

**ALLOMATRIX® study UCL Belgium**

### 6 MONTHS POSTOP

**INVESTIGATOR'S LAST NAME:**

**DASH QUESTIONNAIRE:**

**SEE ATTACHED FORM**

### CLINICAL SCORING: Score = .................. POINTS

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### RANGE OF MOTION OF OPERATED WRIST

**PASSIVE**
- Flexion: ................................
- Extension: ............................
- Radial deviation: ....................
- Ulnar deviation: ....................
- Prosupination: ........................

**ACTIVE**
- Flexion: ................................
- Extension: ............................
- Radial deviation: ....................
- Ulnar deviation: ....................
- Prosupination: ........................

### MUSCLE STRENGTH AT OPERATED WRIST

Grip strength measured with dynamometer (Jamar):
Result: ........................................

### QUANTITATIVE SENSORY EVALUATION

Semmes-Weinstein Monofilament test:
Result: ........................................

### ABIL HAND MANUAL ABILITY TEST:

**SEE ATTACHED FORM**

Score: .................................... POINTS

### RADIOPGRAPHIC EVALUATION OF OPERATED WRIST

PLAIN X-rays Anteroposterior and Lateral views

**DISTAL RADIUS MORPHOLOGY:**

<table>
<thead>
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</tr>
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<td>Ulnar inclination: ...........*</td>
</tr>
<tr>
<td>Palmar inclination: ...........*</td>
</tr>
<tr>
<td>Radial length: ...............mm</td>
</tr>
<tr>
<td>Ulnar variance: ...............mm</td>
</tr>
<tr>
<td>Neutral □ Not neutral</td>
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<tr>
<td>Radial width: ...............mm</td>
</tr>
</tbody>
</table>

**GRAFT RESORPTION ......................... %**

**HETEROTOPIC OSSIFICATION: □ YES □ NO**

**FRACTURE HEALING: score = .................. POINTS**

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</table>

**BONE MINERAL DENSITOMETRY: not at this point**

**SEE ATTACHED FORM**

Result: operated wrist: ................................
contralateral wrist: ................................

Remarks: ................................................................

---

**Diploma of Orthopaedic and Trauma Surgery - 2009**
### 12 MONTHS POSTOP

**INVESTIGATOR'S LAST NAME:**

**DASH QUESTIONNAIRE:**

General upper extremity activities: .................. POINTS
Sports/music instrument: ............................ POINTS
Work: .................................................... POINTS
Total SCORE: ......................................... POINTS

**RADIOGRAPHIC EVALUATION OF OPERATED WRIST**

PLAN X-rays Anteroposterior and Lateral views

**DISTAL RADIUS MORPHOLOGY:**

<table>
<thead>
<tr>
<th>Change compared to index</th>
<th>No</th>
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<tbody>
<tr>
<td>Ulnar inclination: ...........°</td>
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<tr>
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</tr>
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<td>No</td>
</tr>
<tr>
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<td>No</td>
</tr>
<tr>
<td>Radial width: ..............mm</td>
<td>No</td>
</tr>
</tbody>
</table>

**GRAFT RESORPTION ...................... %**

**HETEROTOPIC OSSIFICATION: □ YES □ NO**

**FRACTURE HEALING: score = .................. POINTS**

**GRADE**

<table>
<thead>
<tr>
<th>Points</th>
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</tbody>
</table>

**BONE MINERAL DENSITOMETRY: AT 12 MONTHS**

**SEE ATTACHED FORM**

Result: operated wrist: ........................................
contralateral wrist: ........................................
Remarks: .........................................................

---

### Postoperative Information

**ALLOMATRIX® study UCL Belgium**

**Post-op Evaluation Date:** ___/___/___

**DDMMYY**

**Additional procedures at the operated wrist**

**CLINICAL SCORING: Score = .................. POINTS**

<table>
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</table>

**RANGE OF MOTION OF OPERATED WRIST**

**PASSIVE**

- Flexion: ...........°
- Extension: ...........°
- Radial deviation: ...........°
- Ulnar deviation: ...........°
- Prosupination: ...........°

**ACTIVE**

- Flexion: ...........°
- Extension: ...........°
- Radial deviation: ...........°
- Ulnar deviation: ...........°
- Prosupination: ...........°

**MUSCLE STRENGTH AT OPERATED WRIST**

Grip strength measured with dynamometer (Jamar):
Result: ..................................................
□ Not performed

**QUANTITATIVE SENSORY EVALUATION**

Semmes-Weinstein Monofilament test:
Result: ..................................................
□ Not performed

**ABILHAND MANUAL ABILITY TEST:**

**SEE ATTACHED FORM**

Score: ................................. POINTS
### ALLOMATRIX® study UCL Belgium

#### Complications and adverse events

<table>
<thead>
<tr>
<th>Code</th>
<th>Date of Onset: <em>/__/</em></th>
<th>Date of Resolution: <em>/__/</em></th>
</tr>
</thead>
</table>

#### Complication Codes

<table>
<thead>
<tr>
<th>Systemic:</th>
<th>Local Complications:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Allergic reaction</td>
<td>13. Delayed union</td>
</tr>
<tr>
<td>2. Central line sepsis</td>
<td>14. Edema</td>
</tr>
<tr>
<td>3. Fat embolic syndrome</td>
<td>15. Fixation failure (graft, hardware, etc.)</td>
</tr>
<tr>
<td>5. Hematological (DIC, bleeding disorder, etc.)</td>
<td>17. Fracture (Site)</td>
</tr>
<tr>
<td>6. Metabolic (Renal, hepatic, etc.)</td>
<td>18. Graft lysis</td>
</tr>
<tr>
<td>7. Myocardial</td>
<td>19. Hematoma</td>
</tr>
<tr>
<td>8. Pulmonary embolism</td>
<td>20. Heterotopic ossification</td>
</tr>
<tr>
<td>10. Stroke</td>
<td>22. Infection, superficial</td>
</tr>
<tr>
<td>11. Thrombosis</td>
<td>23. Recurrence (Bone tumor)</td>
</tr>
<tr>
<td>12. Other (specify)……..</td>
<td>24. Recurrence (Infection site)</td>
</tr>
<tr>
<td></td>
<td>25. Wound dehiscence</td>
</tr>
<tr>
<td></td>
<td>26. Other (specify)………….</td>
</tr>
</tbody>
</table>

#### Action Taken

- None
- Referral
- Medication
- Other:________________________
- Surgery (see procedures operative data)

#### Relationship to ALLOMATRIX®

- None
- Possible
- Probable
- Definite

#### Final Outcome of Complication

- Full recovery
- Recovery with sequelae
- Death

If the outcome is a FAILURE:

**CLINICAL REASON OF FAILURE:**

Note in your own words:

______________________________

- non-union
- mal-union
- pain
- joint stiffness
- inflammation
- recurrent wound problem
- deep infection
- other: specify:__________________

Diploma of Orthopaedic and Trauma Surgery - 2009
QUESTIONNAIRE DASH- MEMBRE SUPERIEUR.

Développé par :

American Academy of Orthopedic Surgeons
Institute for Work and Health, Toronto
American Association for Hand Surgery
American Society for Surgery of The Hand
American Orthopaedic Society for Sports Medicine
American Shoulder and Elbow Surgeons
Arthroscopy Association of North America
American Society of Plastic and Reconstructive Surgeons.
La date d'aujourd'hui : / / 

Merci de compléter ce questionnaire !

Ce questionnaire va nous aider pour apprécier votre état de santé général et vos problèmes musculo-articulaires en particulier.

C'est à vous de remplir ce questionnaire. Ce n'est pas obligatoire, et les réponses resteront strictement confidentielles dans votre dossier médical.

Veuillez répondre à toutes les questions. Certaines se ressemblent, mais toutes sont différentes.

Il n'y a pas de réponses justes ou fausses. Si vous hésitez, donnez la réponse qui vous semble la plus adaptée. Vous pouvez faire des commentaires dans la marge. Nous lirons tous vos commentaires, aussi n'hésitez pas à en faire autant que vous le souhaitez.
Instructions

Ce questionnaire s’intéresse à ce que vous ressentez et à vos possibilités d’accomplir certaines activités. Veuillez répondre à toutes les questions en considérant vos possibilités au cours des 7 derniers jours. Si vous n’avez pas eu l’occasion de pratiquer certaines de ces activités au cours des 7 derniers jours, veuillez entourer la réponse qui vous semble la plus exacte si vous aviez dû faire cette tâche. Le côté n’a pas d’importance. Veuillez répondre en fonction du résultat final, sans tenir compte de la façon dont vous y arrivez.

Veuillez évaluer votre capacité à réaliser les activités suivantes au cours des 7 derniers jours.
(Entourez une seule réponse par ligne.)

<table>
<thead>
<tr>
<th>Question</th>
<th>Aucune difficulté</th>
<th>Difficulté légère</th>
<th>Difficulté moyenne</th>
<th>Difficulté importante</th>
<th>Impossible</th>
</tr>
</thead>
<tbody>
<tr>
<td>37. Dévisser un couvercle serré ou neuf</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>38. Ecrire</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>39. Touner une clé dans une serrure</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>40. Préparer un repas</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>41. Ouvrir un portail ou une lourde porte en la poussant</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>42. Placer un objet sur une étagère au-dessus de votre tête</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>43. Effectuer des tâches ménagères lourdes (nettoyage des sols ou des murs)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>44. Jardiner, s’occuper des plantes (fleurs et arbustes)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>45. Faire un lit</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>46. Porter des sacs de provisions ou une mallette</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>47. Porter un objet lourd (supérieur à 5 Kg)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>48. Changer une ampoule en hauteur</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>49. Se laver ou se sécher les cheveux</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>50. Se laver le dos</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>51. Enfiler un pull-over</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>52. Couper la nourriture avec un couteau</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>53. Activités de loisir sans gros effort (jouer aux cartes, tricoter, etc.)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>54. Activités de loisir nécessitant une certaine force ou avec des chocs au niveau de l’épaule du bras ou de la main, (natage, tennis, golf, etc.)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>55. Activités de loisir nécessitant toute la liberté de mouvement (badminton, lancer de balles, pêche, Frisbee, etc.)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>56. Déplacements (transports)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>57. Vie sexuelle</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>
Questionnaire DASH version 2.0  Traduction, version du 17 décembre 2000

58. **Pendant les 7 derniers jours**, à quel point votre épaule, votre bras ou votre main a-t-elle gêné vos relations avec votre famille, vos amis ou vos voisins ? (entourez une seule réponse)

<table>
<thead>
<tr>
<th></th>
<th>Aucune</th>
<th>légère</th>
<th>moyenne</th>
<th>importante</th>
<th>extrême</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Pas du tout</td>
<td>2 légèrement</td>
<td>3 moyennement</td>
<td>4 beaucoup</td>
<td>5 extrêmement</td>
<td></td>
</tr>
</tbody>
</table>

59. Avez-vous été limité dans votre travail ou une de vos activités quotidiennes habituelles du fait (en raison, par) de problèmes à votre épaule, votre bras ou votre main ? (entourez une seule réponse)

<table>
<thead>
<tr>
<th></th>
<th>Aucune</th>
<th>légère</th>
<th>moyenne</th>
<th>limité</th>
<th>Très limité</th>
<th>Incapable</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Pas du tout</td>
<td>2 Légèrement limité</td>
<td>3 moyennement limité</td>
<td>4 Très limité</td>
<td>5 Incapable</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Veuillez évaluer la sévérité des symptômes suivants durant **les 7 derniers jours**.
(entrez une réponse sur chacune des lignes)

60. Douleur de l’épaule, du bras ou de la main

<table>
<thead>
<tr>
<th></th>
<th>Aucune</th>
<th>légère</th>
<th>moyenne</th>
<th>importante</th>
<th>extrême</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

61. Douleur de l’épaule, ou bras ou de la main en pratiquant une activité particulière
Précisez cette activité : .................................. 

<table>
<thead>
<tr>
<th></th>
<th>Aucune</th>
<th>légère</th>
<th>moyenne</th>
<th>importante</th>
<th>extrême</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

62. Picotements ou fourmillements douloureux de l’épaule, du bras ou de la main

<table>
<thead>
<tr>
<th></th>
<th>Aucune</th>
<th>légère</th>
<th>moyenne</th>
<th>importante</th>
<th>extrême</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

63. Faiblesse du bras, de l’épaule ou de la main

<table>
<thead>
<tr>
<th></th>
<th>Aucune</th>
<th>légère</th>
<th>moyenne</th>
<th>importante</th>
<th>extrême</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

64. Raideur du bras, de l’épaule ou de la main

<table>
<thead>
<tr>
<th></th>
<th>Aucune</th>
<th>légère</th>
<th>moyenne</th>
<th>importante</th>
<th>extrême</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

65. **Pendant les 7 derniers jours**, votre sommeil a-t-il été perturbé par une douleur de votre épaule, de votre bras ou de votre main ? (entourez une seule réponse)

<table>
<thead>
<tr>
<th></th>
<th>Aucune</th>
<th>légère</th>
<th>moyenne</th>
<th>très perturbé</th>
<th>Insomnie complète</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Pas du tout</td>
<td>2 un peu</td>
<td>3 moyennement</td>
<td>4 très perturbé</td>
<td>5 Insomnie complète</td>
<td></td>
</tr>
</tbody>
</table>

66. “Je me sens moins capable, moins confiant ou moins utile à cause du problème de mon épaule, de mon bras, ou de ma main”

<table>
<thead>
<tr>
<th></th>
<th>Pas d’accord</th>
<th>Pas d’accord</th>
<th>ni d’accord</th>
<th>d’accord</th>
<th>tout à fait d’accord</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pas d’accord du tout</td>
<td>2 Pas d’accord</td>
<td>3 ni d’accord</td>
<td>4 d’accord</td>
<td>5 tout à fait d’accord</td>
</tr>
</tbody>
</table>

Questionnaire DASH
Questionnaire DASH version 2.0  Traduction, version du 17 décembre 2000

Les questions suivantes concernent la gêne occasionnée par votre épaule, votre bras ou votre main lorsque vous jouez d'un instrument ou que vous pratiquez un sport ou les deux. Si vous pratiquez plusieurs sports ou plusieurs instruments (ou les deux), vous êtes priés de répondre en fonction de l'activité qui est la plus importante pour vous.

Indiquez le sport ou l'instrument qui est le plus important pour vous :

Entourez 1 seule réponse par ligne, considérant vos possibilités durant les 7 derniers jours.

Avez-vous eu des difficultés :

<table>
<thead>
<tr>
<th></th>
<th>Aucune difficulté</th>
<th>Difficulté légère</th>
<th>Difficulté moyenne</th>
<th>Difficulté importante</th>
<th>Impossible</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pour pratiquer votre sport ou jouer de votre instrument avec votre technique habituelle</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Pour pratiquer votre sport ou jouer de votre instrument à cause des douleurs de votre épaule, de votre bras ou de votre main</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Pour pratiquer votre sport ou jouer de votre instrument aussi bien que vous le souhaitez</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Pour passer le temps habituel à pratiquer votre sport ou jouer de votre instrument</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

Les questions suivantes concernent la gêne occasionnée par votre épaule, votre bras ou votre main au cours de votre travail.

Entourez la réponse qui, sur chacune des lignes, décrit le plus précisément vos possibilités durant les 7 derniers jours.

Si vous n'avez pas pu travailler pendant cette période, considérez comme "impossible" les quatre propositions suivantes.

Avez-vous eu des difficultés :

<table>
<thead>
<tr>
<th></th>
<th>Aucune difficulté</th>
<th>Difficulté légère</th>
<th>Difficulté moyenne</th>
<th>Difficulté importante</th>
<th>Impossible</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pour travailler en utilisant votre technique habituelle</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Pour travailler comme d'habitude à cause de la douleur de votre épaule, de votre bras ou de votre main</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Pour travailler aussi bien que vous le souhaitez</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Pour passer le temps habituellement consacré à votre travail</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

Questionnaire DASH