BIOTECK

The science of bone tissue

BIOTECK GRAFTS & MEDICAL DEVICES FOR REGENERATIVE MEDICINE

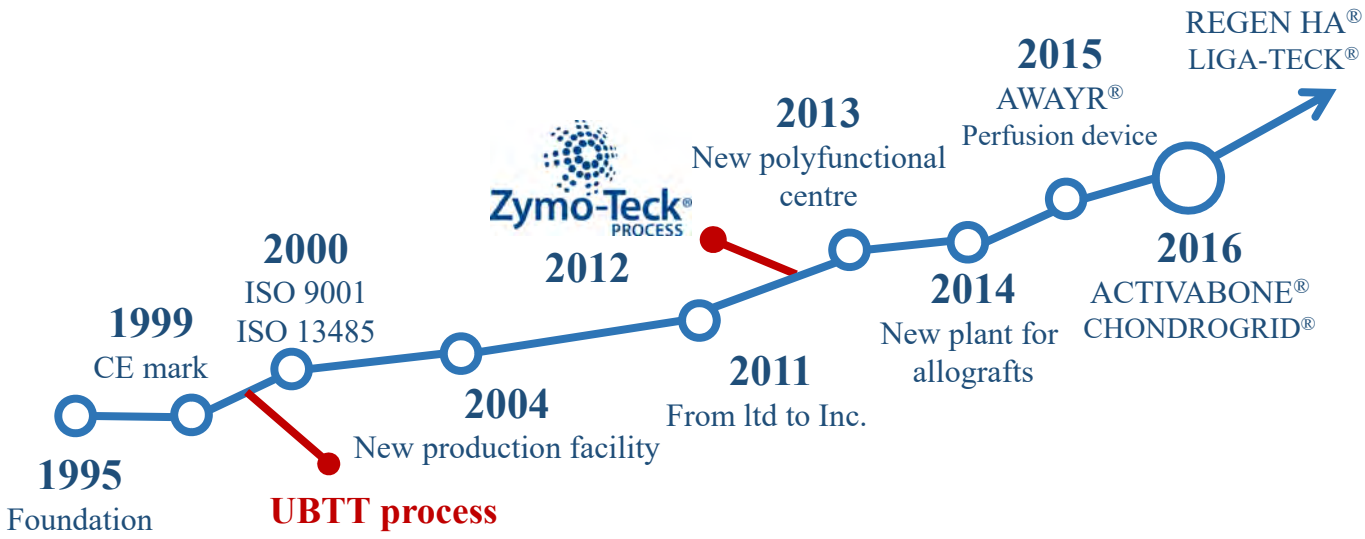
Fabrizio Raimondi
Business Development Manager

BIOTECK S.p.A.

BIOTECK is an Italian Company, manufacturing horse-derived substitutes for bone, cartilage and soft tissues reconstruction in Orthopaedics, Spine, General and Oral-Maxillofacial Surgery. Founded in 1995, it has developed Zymo-Teck®, a proprietary enzymatic de-antigenation process, which guarantees grafts with optimal biological and biomechanical properties, in a wide range of formats (chips, blocks, paste, putty, crunch, membranes).

OVER 20 YEARS OF TRUSTABILITY

Founded in 1995, it has developed Zymo-Teck®, a proprietary enzymatic de-antigenation process, which guarantees grafts with optimal biological and biomechanical properties, in a wide range of formats (chips, blocks, paste, putty, crunch, membranes).



Commercial headquarter in Vicenza

Production facility,
R&D and Customer Center

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PRESENCE IN FOREIGN MARKETS

ARGENTINA
CHILE
ECUADOR
COLOMBIA
BRASILE
PANAMA
COSTARICA
REPUBBLICA DOMINICANA
SAN SALVADOR
GUATEMALA
HONDURAS
MEXICO
SPAGNA
PORTOGALLO
FRANCIA
OLANDA
GRAN BRETAGNA
IRLANDA
DANIMARCA
GERMANIA
SVIZZERA
AUSTRIA
SLOVENIA

SERBIA
GRECIA
ALBANIA
KOSOVO
BULGARIA
ROMANIA
POLONIA
SLOVACCHIA
REPUBBLICA CECA
BIELORUSSIA
UNGHERIA
UCRAINA
RUSSIA
ESTONIA
LITUANIA
LETTONIA
ARMENIA
AZERBAIJAN
IRAN
TURCHIA
UAE
ARABIA SAUDITA
EGITTO

QATAR
BAHRAIN
SYRIA
KUWAIT
CIPRO
GEORGIA
LIBANO
GIORDANIA
PALESTINA
IRAQ
KIRGHIZISTAN
HONG KONG
INDIA
THAILANDIA
MALAYSIA
SINGAPORE
GEORGIA
AFGHANISTAN
PAKISTAN
LIBANO
GIORDANIA
GEORGIA
AFGHANISTAN

PAKISTAN
LIBANO
GIORDANIA
PALESTINA
IRAQ
KIRGHIZISTAN
HONG KONG
INDIA
THAILANDIA
MALAYSIA
SINGAPORE
SINGAPORE
INDONESIA
FILIPPINE
TAIWAN
KOREA DEL SUD
REUNION
POLINESIA
FRANCESE
SUDAFRICA
ALGERIA
SUDAN

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BIOTECK bone grafts unique features

Bone substitutes, manufactured by Bioteck SpA are natural grafts derived from heterologous equine bone tissue subjected to a proprietary patented cleaning process named Zymo-Teck®.

This tissue processing allows achieving fully biocompatible implants while preserving all their biological and biomechanical features for an optimal healing process after their implantation.

Zymo -Teck ® is a multi-step process that guarantees the removal of all potentially antigenic and/or immunogenic components from the treated bone, by specific enzyme mixtures effective against specific molecular targets such as lipoproteins, glycoproteins and collagen telopeptides.

Several baths in mixtures of glycolytic and lipolytic enzymes take place with pressurized washing cycles with osmotic water at low controlled temperature. All products are then treated through an oxidative phase using hydrogen peroxide for the removal of cellular debris and any other contaminants. Finally, grafts are freeze-dried, packed in double blister and sent to β -ray terminal sterilization at 25kGy.

This type of irradiation are more respectful of biological and bio-mechanical behaviors of grafts than the γ rays and is allowed only due to the very low bio- burden (level of contamination) of Bioteck substitutes at the end of the tissue processing.

The Zymo -Teck® process does not use high temperature and chemical solvents. This ensures the complete preservation without any even minimal alteration of bone collagen and mineral component, thus making them pure biological matrix acting as natural scaffold (optimal osteo-conduction capability) to newly-bone formation. The presence of bone collagen in its intact structure allows Bioteck grafts to properly interact with cellular elements involved in the healing process, favoring the formation of new living tissue in physiological time and manner.

Bone collagen in its native structure exerts all the effects ascribed to it and, in particular , interacts with the sub-units of the beta-1 integrin of osteoblast membrane enhancing cell adhesion to scaffold[1] ; It acts as a co- activator of morphogenic proteins increasing the stimulating action of local growth factors[2] ; it interacts with mesenchymal cells from bone marrow by inducing their adhesion, proliferation and osteoblastic differentiation[3] and finally, when implanted in a bone defect , exerts a pro - regenerative direct promoting the neo- osteogenesi[4] .

It is also important to consider that the preservation of endogenous collagen structure , not only gives important biological properties, but it also helps to make them more resilient and resistant with excellent strength and load-bearing properties, particularly required in many orthopedic indications.

Bioteck grafts must be rehydrated in saline solution according to the instructions, before implantation. It is highly recommended to use when possible AWAYR perfusion device for a complete saturation of Bioteck porous bone grafts with saline solution or patient own biological fluids, like bone marrow, peripheral blood, PRP, etc. in order to remove all the air inside grafts while forcing cells and growth factors inside its structure thus enhancing and speeding up bone integration and ingrowth.

Complete antigens removal and total compatibility profile of Bioteck bone substitutes make them the safest and most reliable options for bone defect repair or regeneration. Hundreds of thousands of implanted grafts worldwide, with no report of adverse events together to many clinical experiences and scientific studies demonstrate that Bioteck grafts are a suitable material in many surgical applications even in presence of severe bone defects.

References

1) Type I collagen in xenogenic bone material regulates attachment and spreading of osteoblasts over the Beta 1 integrin subunit
Baslè, Lesourd, Grizon, Pascaretti, Chappard
Orthopade 1988 Feb. 27 (2) 136-42

2) Dissociative extraction and reconstruction of extra-cellular matrix components involved in local bone differentiation
Sampath, Reddi
PNAS 1981 Dec; 78 (12) 7599-803

3) Effect of type 1 collagen on the adhesion, proliferation and osteoblastic gene espression of bone marrow derived mesenchymal stem cells
Liu, Hu, Zhao, Wu, Xiong, Lu
Chin J Traumatol. 2004 Dec. 7 (6) 358-62

4) Evaluation of the effect of heterologous type 1 collagen on healing of bone defects
Gungormus, Kaya
J Oral Maxillofacial Surg. May. 60 (5); 541 -S

COMPOSITION OF BONE TISSUE

70%

Inorganic phase

95%

- Ca Hydroxyapatite

5%

- Mg, Na, K, F, Cl.

30%

Organic phase

98%

- 95% Type I Collagen
- 5% Other proteins

Glycoproteins
Lipoproteins
Phosphoproteins

2%

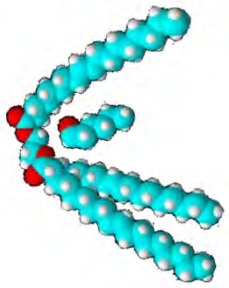
- Osteoblasts
- Osteoclasts
- Osteocytes

Proteins
Polysaccharides
Lipidis
Nucleic Acids

Antigens: Proteins, Polysaccharides, Glycoproteins, Lipoproteins and LPS
Antigenicity: interaction with an antibody
Immunogenicity: induction of an immune response

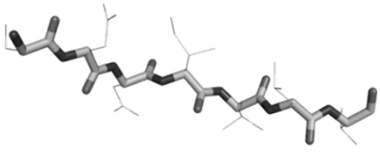
THE ZYMO-TECK® MOLECULAR TARGETS

Lipids



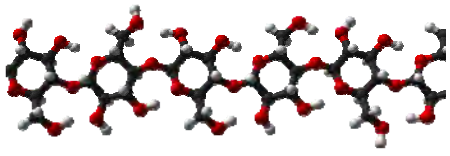
Type I Collagen Telopeptides

Antigenic



Polysaccharides

Immunogenic



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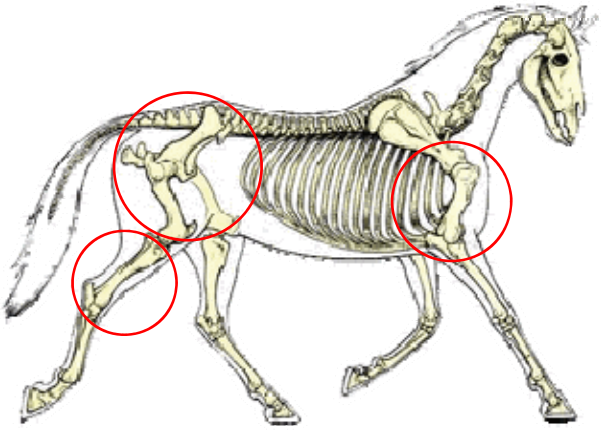
WHY EQUINE TISSUE



It is considered one of the safest animals.

No prions pathologies, non transmissable diseases.

Not included in 2003/32/EEC Directive

Bred in fence – good bone morphology

SAFETY VS QUALITY

In the production of biological grafts SAFETY and QUALITY are strictly connected and directly depending on the applied process.

Most of the time in the absence of a specific biotechnology, in order to guaranty the safety many biological features are sacrified.

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THE ZYMO-TECK® PROCESS STEPS

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5 - LYOPHILIZATION AND PACKAGING

Freeze dry Lyophilization

ISO 7 Clean Room
and ISO 5 Laminar Flow hood

Double blister packaging

Once packed in their final box, items are sent to terminal sterilization at 25kGy β rays.

QUALITY CONTROLS

Delipidation	• Lipids quantification • Fatty Acids Identification	Spectrophotometry Gas Chromatography
Deantigenation	• Glucids quantification • Glycans and Peptides Profiles • DNA quantification	Spectrophotometry HPLC Fluorimtry
Decollagenation	• Proteins quantification • Peptides Profiles	Spectrophotometry HPLC
Demineralization	• Ca^{2+} Quantification • pH	Atomic Absorption Spectrometry

ENVIRONMENTAL CONTROLS

Bioteck continuosly checks the *Microbiological Quality*

Working ambients Surfaces Products	Quantification Identification

Bioteck Microbiology Laboratory

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STANDARD GRAFTS

Bioteck offers a wide range of grafts with over 300 different available codes.

Standard grafts belong to the OSTEOPLANT® line, made of osteoconductive cancellous, cortical and cancellous-cortical grafts.

Load bearing capability for cancellous blocks have been tested higher than 360 kg/cm^2
(Mechanical tests performed by University of Padova)

Cancellous Chips

Cancellous Blocks

Cancellous-cortical Strips

Cortical Rod

Cancellous Dowels

Hemi-femoral Head

HTO Wedge for plate fixation

HTO Wedge

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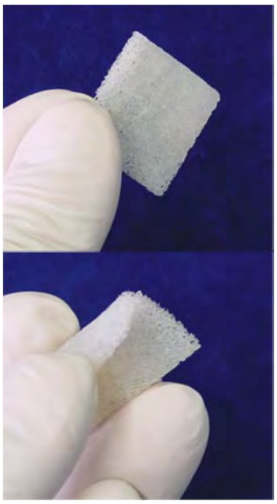
FLEXIBLE GRAFTS

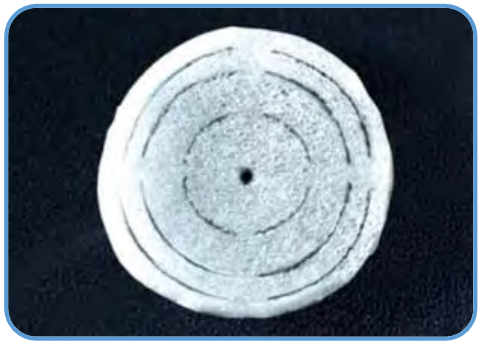


The OSTEOPLANT Flex grafts are partially deminera lized through a process of hydrolysis of calcium salts in acid environment that makes bone collagen more exposed compared to a standard graft.

For this reason, OSTEOPLANT® Flex grafts promote cell adhesion and reduces the time of incorporation and remodeling.

Osteoplant Cortical Flex Sheet

Osteoplant Cancellous Flex Sheet



Osteoplant Acetabular Mat

Osteoplant Cancellous Flex Disc

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XENO-DBM BONE PASTES

Cortical bone subjected to a treatment with selective enzymes and completely demineralized. Activagen contains the molecular signals typical of the extra-cellular matrix. These granules are the basis for our osteoproductive bone paste.

Osteplant Activagen Injectable Paste

Osteoplant Activagen Mouldable Paste.

Animal DBM works in human

Bone morphogenic proteins and growth factors have been highly conserved during the evolution. This translates into a very high level of correspondence between human BMPs and those of other mammals. Since many years there are in literature positive results on the effectiveness of DBM from different species.

BMPs are not species-specific. High level of identity of amino-acid sequence of BMP in different animal species (*Wozney JM, Cellular and Molecular Biology of Bone 1993)*

Evolution of the transforming growth factor-beta superfamily. - Burt DW, Law AS. Prog Growth Factor Res. 1994;5(1):99-118.

Homology of bone-inductive proteins from human, monkey, bovine, and rat extracellular matrix. Sampath TK, Reddi AH. Proc Natl Acad Sci U S A. 1983 Nov;80(21):6591-5

Implants of heterologous (bovine) demineralized bone matrix for induction of posterior spinal fusion in rats.Spine. Guizzardi S, Di Silvestre M, Scandroglio R, Ruggeri A, Savini R. 1992 Jun;17(6):701-7

Healing response to various forms of human demineralized bone matrix in athymic rat cranial defects. Chesmel KD, Branger J, Wertheim H, Scarborough N. J Oral Maxillofac Surg. 1998 Jul;56(7):857-63; discussion 864-5

ACTIVABONE® - NEXT GENERATION OF NATURAL BONE PASTE

ACTIVABONE® is the innovative line of heterologous bone pastes with high biological activity and superior handling properties, based on the new techonological platform of **Bioteck®** proprietary hydrogel with bio-modulated viscosity (Exur®).
This new carrier gives bone pastes better chemical-physical and rheological performances, allowing for suitable in situ stability with proper resistance to bleeding and irrigation.

The development of hydrogel-based injectable, mouldable and pre-formed **ACTIVABONE®** bone pastes has been foreseen as practical way to also enhance adaptability to defects of irregular geometry maintaining full contact with the live bone surrounding the defect area. The novel formulations guarantee longer maintainance of osteoconductive granules and osteoinductive DBM powders into defect and favour better attachment of osteogenic cells and growth factors to graft. These excellent biological and physical properties therefore translate into an optimal bone defect regeneration, by promoting and speeding-up early phases of tissue healing process with an improvement of the graft integration and remodeling.

This line of new bone pastes will be available on the market by the end of 2016.

EXUR ® Hydrogel Proprietary Technology

For the past three years, Bioteck® has been focusing its effort and attention to medical grade polymers commonly used in pharmaceutical applications, such as poly(ethylene glycol) - PEG, poly(ethylene oxide) – PEO and hydroxypropyl methyl cellulose – HPMC, and developed an innovative proprietary technology to control their sinergic polymerization.
The ability to regulate polymerization and cross-linking density of polymers avoids granules dispersion and loss during surgery, for assuring complete filling and direct contact with the tissue surrounding the defect and successful bone repair. HPMC, PEG and the chemically similar PEO hydrogels undergo a polymerization reaction by physical sterilization, which is modulated by introducing very limited amount of Vitamin C. This anti-oxidant molecule is able to limit intra- and inter-molecular rearrangement of PEG and HPMC polymeric chains, then specifically tailoring visco-elasticity of Exur®, the **Bioteck®** proprietary hydrogel carrier. The possibility to select specific polymers molecular weight and concentration, as well as finely tuned Vitamin C amounts, therefore allows **Bioteck®** to design unique bone fillers with different physical and handling properties, either injectable, mouldable or shapeable pre-formed bone substitutes.

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COLLAGEN FLEECES & MEMBRANES

Biocollagen Membrane & fleeces are medical devices mainly composed of type I collagen from equine achilles tendon. Flecees are used as graft extensor together to bone chips or for haemostatic use. Collagen membrane main indications are the protection of the grafted site or periostium substitute.

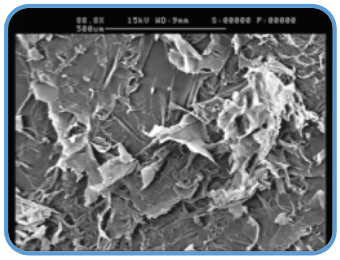
Biocollagen Fleece

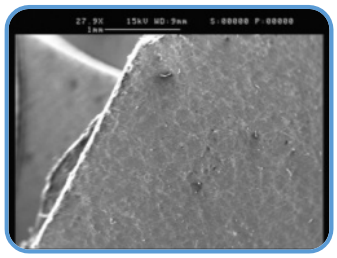
Biocollagen membrane

BIOCOLLAGEN MeRG

It is a particular membrane for cartilage treatment derived from Biocollagen. It is a dual side collagen membrane indicated in the treatment of chondral lesions with AMIC technique
(***A**utologous **M**embrane **I**nduced **C**hondrogenesis)*

The rough and the smooth side at the SEM





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MERG: DESCRIPTION

Re-absorbable membrane for guided tissue regeneration, (Biocollagen® MeRG).

Composition:
Mainly composed of Type I non-allergenic lyophilised collagen from equine Achilles' tendon (Type I >95%. See the following slides for specific instrumental analysis on contents.

Properties:
Microfibrillar collagen membrane. The peculiar arrangement of its fibers, given by the exclusive manufacturing process, gives the membrane resistance to torsion, pulling and tearing. The membrane features a smooth and a rough/fibrillar side.
The rough side improves adhesion, and allows for fixation with fibrin glue. Adhesion increases if blood is present. The collagen the membrane is made of is achieved from equine Achilles' tendons (one of the principal sources of type I collagen). Equines can not transmit encephalopathies.
Collagen shows the chemical and structural features of a glycoprotein, capable of interacting with the fibroblasts' and platelets' receptors. It activates actors XII and VIII and constitutes the structural basis of connective tissues. Its interactions with platelets is fundamental for coagulation, since its bonding with the platelets integrins leads to platelet degranulation and to release the factors that activate coagulation.
This creates the fibrin network that stops blood cells creating the clot. Finally fibroblasts migrate into the clot following chemotactic stimulation.

Therapeutic indications:
Chondral lesions treatment.

Contraindications:
Hypersensitivity to collagen.

Activity:
MeRG® carries out a "tent effect action" over mesenchymal cells, preventing their dispersion in the joint cavity. MeRG® is made of collagen fibres in a structure that favours cells adhesion. The three-dimensional structure of MeRG® enhances histological repair. In-vivo tests have shown that during the repair process, fibroblasts attach to the collagen fibrils, proliferate and orientate in order to reshape the damaged tissue. Collagen therefore supports tissue repair.

Degradation time:
MeRG® is physiologically degraded in 60/90 days. The fragments of collagen obtained by degradation are heat-sensitive and at a temperature of 37°C undergo a denaturation process, transforming into gelatine.

Product preparation:
Rehydrate the product with some drops of sterile physiological solution or with autologous bone marrow or PRP after shaping it.

MERG: COMPOSITION

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LABORATORIO R&D E ANALISI
10020 RIVA PRESSO CHIERI (TO) – Via G. Agnelli, 3 – Tel. +39 011 94 68 661 – Fax +39 011 94 64 036

ANALYSIS REPORT N.16219 – TA – 21/09/2016
RAPPORTO DI ANALISI N.16219 – TA – 21/09/2016

TITLE: BIOCOLLAGEN COMPOSITION
TITOLO: COMPOSIZIONE BIOCOLLAGEN

REFERENCE: ASTM F2212 - 11
RIFERIMENTO: ASTM F2212 - 11
INTERNAL PROCEDURE: ILL – 007, ILL – 008, ILL – 014, ILL - 023
RIFERIMENTO PROCEDURE INTERNE: ILL – 007, ILL – 008, ILL – 014, ILL – 023
TEST METHOD VALIDATION: NO
CONVALIDA METODO DI ANALISI: NO

REFERENCE DATA
DATI DI RIFERIMENTO
SAMPLES DESCRIPTION: BIOCOLLAGEN MEMBRANE (10 mg)
DESCRIZIONE CAMPIONI: MEMBRANA BIOCOLLAGEN (10 mg)
SAMPLES NUMBER: 3
N° CAMPIONI: 3
PRODUCTION BATCH: 14290132
LOTTO DI PRODUZIONE: 14290132

ANALYSIS PARAMETERS
PARAMETRI DI ANALISI
A) Proteins electrophoretic profile: No other bands than Collagen (As Type I Collagen Standard). B) GAGs spectrophotometric quantification (µg/100µg). C) % Moisture.

ASSAYS SAGGI ESEGUITI	*RESULTS* ESITI
SENSITIVITY SENSIBILITA'	A) 0.01 ng/100mg B) 0.01 µg/100µg C) 0.1 %
SAMPLES CAMPIONI	BIOCOLLAGEN 14290132 A) No other bands than Collagen are present.* B) 0.51 µg/100µg * C) 7.2 % (%M)

*Reference A and B instruments output attached.

HEAD OF BIOCHEMISTRY LABORATORY
Responsabile del Laboratorio Biochimico
Dott. Paolo Fattori

MERG: GAGs QUANTIFICATION

```
Metodo:                 GAGs_QUANT_140916.mqa    (520 nm)
Modificati il:          14/09/2016 10:52:53 AM daWSSPECTRA\VERITON (SPECTRA)
Spettrofotometro:       GENESYS 6
Numero di serie:        2M8F197001
Insieme di..centrale :1.120
Auto Zero:              14/09/2016 10:51:12 AM
Misurato:               14/09/2016 10:54:14 AM daWSSPECTRA\VERITON (SPECTRA)
Nome del f..risultati:BIOCOLLAGEN_GAGs.rqa
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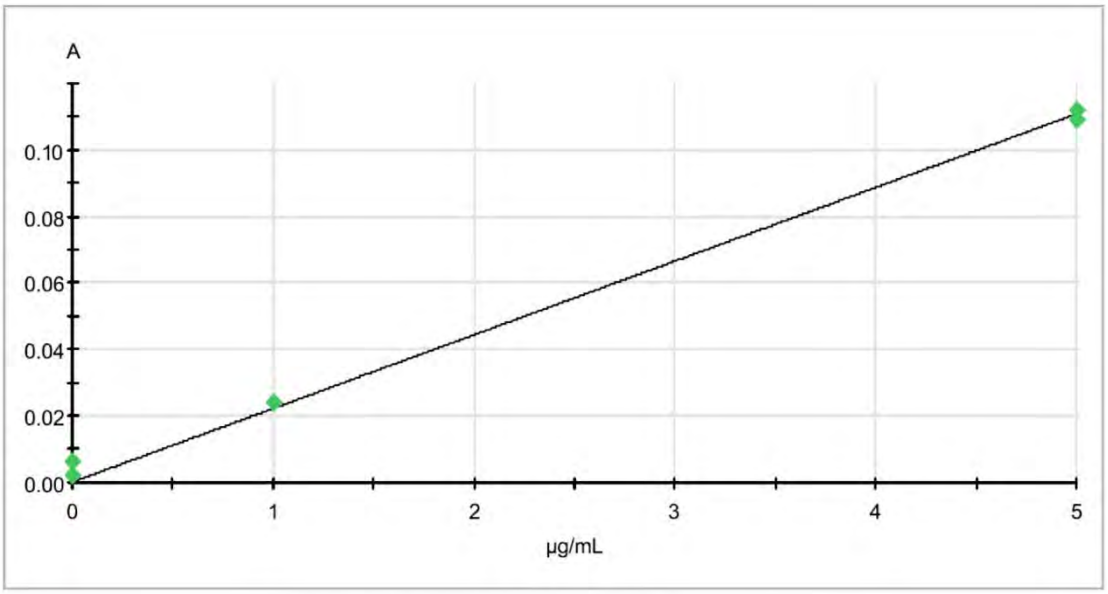

Parametri della curva: y = 2.217308E-02 x
Errore residuo: 0.0032 Coefficiente di correlazione: 0.99799
Data: 14/09/2016 10:52:27 AM

Standard

Numero	Concentrazione [µg/mL]	Ordinata [A]	Errore [A]	Già
1	0.00	0.006	0.006	Si
2	0.00	0.002	0.002	Si
3	1.00	0.024	0.002	Si
4	1.00	0.024	0.002	Si
5	5.00	0.112	0.001	Si
6	5.00	0.109	-0.002	Si

Campione	Diluizione Fattore	Ordinata [A]	Concentrazione [µg/mL]
SAMPLE 1	1	0.342	15.42
SAMPLE 2	20	0.057	51.41

MERG: PHYSIOCHEMICAL CHARACTERIZATION

Characteristic	Specification	Method	Unit
Chemical analysis			
Ashes (500-600° C)	< 5.0		%w
C	40.0-50.0	GC	%w
H	5.0-7.0	GC	%w
N	15.0-17.0	GC	%w
P	<1.0	GC	mg/g
Ca	<1.0	ICP-OES	mg/g
Mg	<0.5	ICP-OES	mg/g
Fe	<0.15	ICP	mg/g
Zn	<0.10	ICP	mg/g
Mn	<0.10	ICP	mg/g
Cu	<0.10	ICP	mg/g
Pb	<0.10	ICP	mg/g
As	<0.10	ICP	mg/g
Ca/P	Not appl.	Calculation	%
Cations and Anions			
Calcium ($Ca^{2+)}$	0.40-0.60	IC	mg/g
Magnesium ($Mg^{2+)}$	0.05-0.10	IC	mg/g
Sodium ($Na^{+)}$	0.30-0.70	IC	mg/g
Potassium (K^{+})	<0.10	IC	mg/g
Ammonium (NH_4^{+})	<0.20	IC	mg/g
Chloride (Cl^{-})	<1.50	IC	mg/g
Nitrate (NO_3^{-})	<0.10	IC	mg/g
Sulfate (SO_4^{2-})	<0.30	IC	mg/g
Phosphate (PO_4^{3-})	<0.05	IC	mg/g
Solution pH	5.0-6.0	IC	mg/g
Fat content	<0.01	GC/MS	%w
Collagen Characterization			
Purity of soluble collagen	No difference between bands of membrane derived collagen and standard	SDS-PAGE	
Elastin Assay	No elastin present	Western Blot	
Trypsin susceptibility		HPLC	
Amino acid analysis	Hydroxyproline >10.0 Tyrosine = 0.5 % Tryptophan = 0.5 %	HPLC	%w
Denatured collagen	=0.50%	HPLC	%w

Characteristic	***Laboratory***
Chemical analysis	Chemical Sciences Department
Cations and Anions	Instrumental Analysis Laboratory
Fat content	University of Padua – Padua - Italy
Collagen Characterization	Chelab S.r.l. – Resana (Treviso) – Italy

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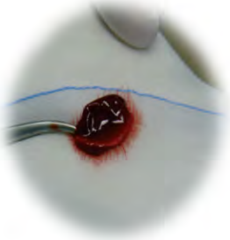
MERG CLINICAL WORK

Use of human mesenchymal stem cells (MSCs) combined to collagen-based scaffolds for cartilage and meniscus regeneration

Bighetti G, Sorbilli L, Faccini R., U.O. Ortopedia e Traumatologia Ospedale del Delta, Lagosanto, Ferrara, Italy

6 patients affected by intra-articular defects in the knee underwent cartilage reconstruction by implantation of MeRG® combined to autologous Bone Marrow Concentrate collected from the iliac crest.
At 6 and 12 months post-op, patients were evaluated from a clinical point of view, by using several scores (VAS, IKDC, Tegner/Lysholm); moreover, MRI analysis was also performed.

Bighetti G, Sorbilli L, Faccini R. Utilizzo di cellule mesenchimali autologhe associate a scaffold per la rigenerazione cartilaginea e meniscale. *OrthoAcademy, Tabloid Ortopedia, 2010; 17-18.*



MeRG membrane combined to BMC and autologous thrombin

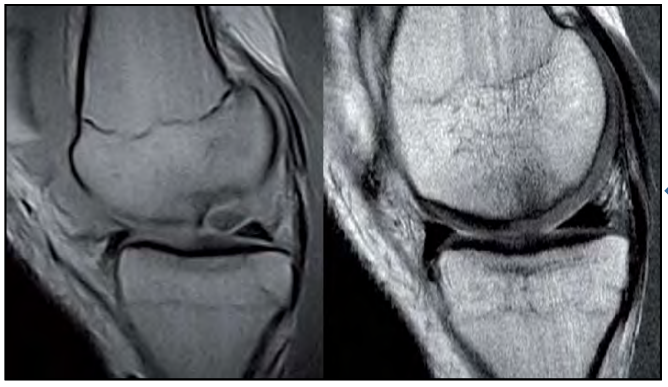
Clinical evaluation

At 12 months follow-up, any symptom affected the knee joint was nearly absent (VAS, IKDC and Tegner/Lysholm), patients began sports activity again, at levels comparable to pre-lesion condition.

MRI evaluation

From 6 to 12 months follow-up, defects were progressively filled with cartilaginous tissue showing structure comparable to healthy surrounding tissues; between cartilage and sub-chondral bone tissues a tide-mark like line was clearly visible.

Osteochondritis disseccans (OCD) of femoral condyle



12 month post-op MRI evaluation of cartilage defect

Bighetti G, Sorbilli L, Faccini R. Utilizzo di cellule mesenchimali autologhe associate a scaffold per la rigenerazione cartilaginea e meniscale. *OrthoAcademy, Tabloid Ortopedia, 2010; 17-18.*

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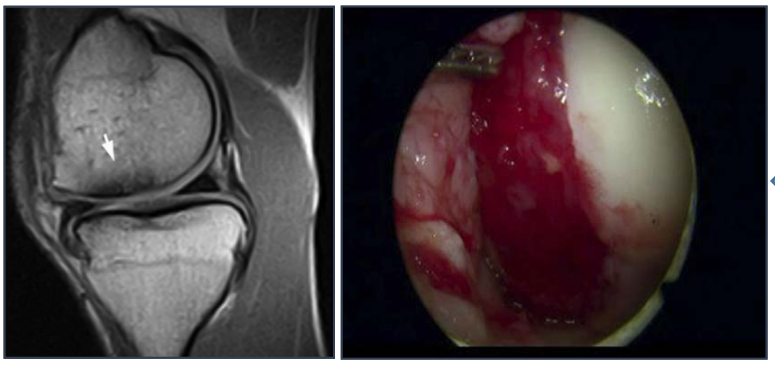
CLINICAL CASE REPORT

Arthroscopic Knee Cartilage Repair With Covered Microfracture and Bone Marrow Concentrate

Gigante A, Cecconi S, Ramazzotti D, Busilacchi A, Enea D. Polytechnic University of Marche, Orthopedics, Ancona, Italy
Calcagno S , Department of Orthopaedics, Sestri Levante Hospital (S. Calcagno), Sestri Levante, Italy.

37-yrs old man with medial joint-line pain in the left knee, MRI showed 3 cm^2 cartilage lesion on the medial femoral condyle. Cartilage defect was debrided, microfactures holes created, MeRG was combined to BM Concentrate, implanted and fixed in place with a mixture of fibrin glue and BMC. At 12 months post-op an MRI analysis was performed.

Cartilage defect and marrow edema of femoral condyle



Implant of MeRG combined with BMC

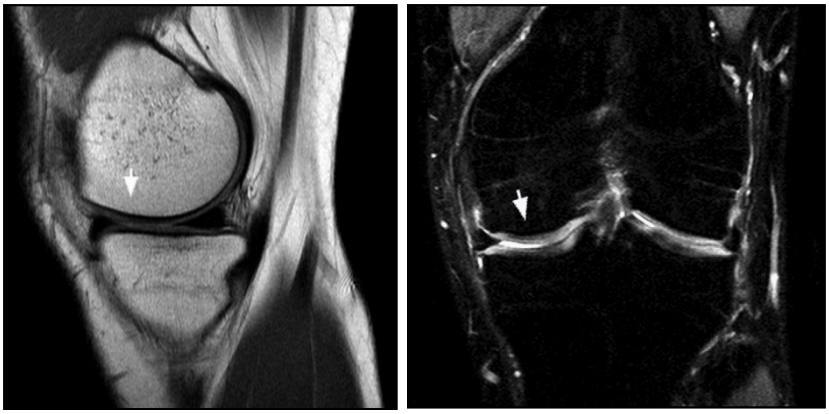
Clinical evaluation

At 12 months follow-up, any symptom affected the knee joint was absent. At 24 months, the patient was still asymptomatic.

MRI evaluation

MRI scan at 12 months showed good defect filling with a tissue signal very similar to that of surrounding tissue, as well as no signs of bone marrow edema.

12 months MRI of left knee, T1 sagittal section



12 months MRI, T2 coronal section

Gigante A, Cecconi S, Calcagno S, Ramazzotti D, Busilacchi A, Enea D. Arthroscopic knee cartilage repair with covered microfracture and bone marrow concentrate. *Arthroscopy Techniques, Vol 1, No 2 (December), 2012: pp e175-e180.*

CLINICAL STUDY

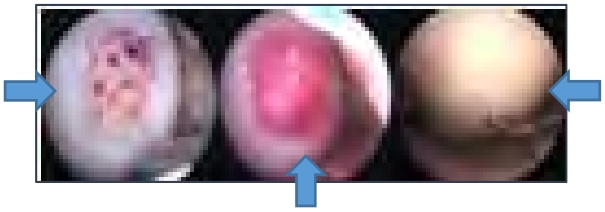
Membrane-guided regeneration (MeRG) augmented with bone marrow concentrate (BMC) for cartilage repair in the knee. Histological results.

Enea D.[1], Calcagno S.[2], Alberto B.[1], Cecconi S.[1], Manzotti S.[1], Gigante A.[1]

[1]Polytechnic University of Marche, Orthopedics, Ancona, Italy, [2]Rapallo Hospital, Orthopedics, Rapallo, Italy

5 consecutive patients affected by a focal isolated cartilage lesion in the knee underwent arthroscopic microfractures and the implant of MeRG® augmented with autologous BMC obtained from the iliac crest.

the debrided chondral lesion with microfractures



second-look arthroscopy after 12 months

the collagen membrane soaked in the bone marrow concentrate once implanted

Arthroscopic evaluation

4 implants appeared nearly normal

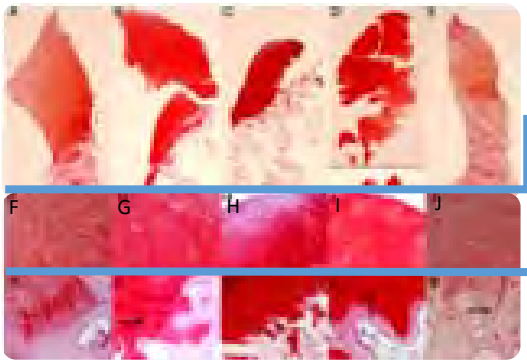
1 implant appeared abnormal according the ICRS Cartilage Repair Assessment (CRA).

Results at the hystological evaluation

1 biopsy presented hyaline matrix (picture I)

1 biopsy presented a mixture of hyaline/fibrocartilage (picture J)

3 biopsies showed fibrocartilage (pictures F, G, H)



Each column represents a single patient.

Osteochondral bioptic cylinders at 1x magnification.

Osteochondral bioptic cylinders at 20x magnification representative of chondral matrix.

20x magnification representative of osteochondral integration.

Gigante A, Calcagno S, Cecconi S, Ramazzotti D, Manzotti S, Enea D. Use of collagen scaffold and autologous bone marrow concentrate as a one-step cartilage repair in the knee: Histological results of second-look biopsies at 1 year follow-up. *Int J Immunopathol Pharmacol 2011;24:69-72.*

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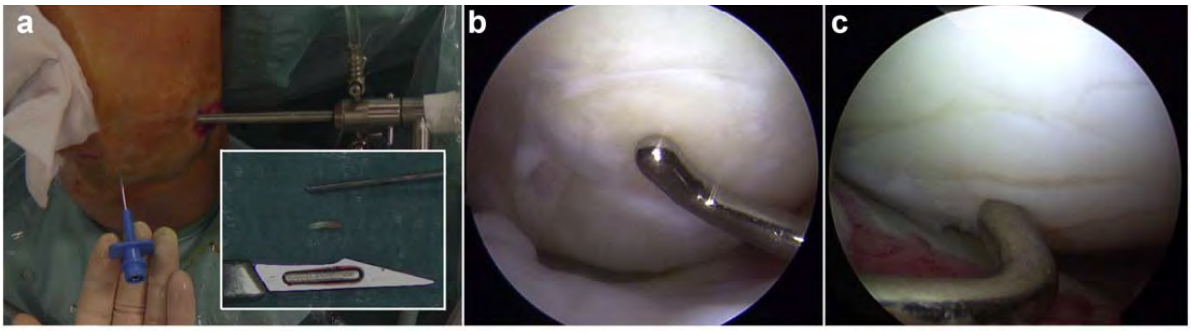
The science of bone tissue

CLINICAL STUDY

One-step cartilage repair in the knee: Collagen-covered microfracture and autologous bone marrow concentrate. A pilot study.

D. Enea [a],⍰, S. Cecconi [a], S. Calcagno [b], A. Busilacchi [a], S.Manzotti [a], A. Gigante [a]
(a) Department of Orthopedics, Polytechnic University of Marche, Via Tronto 10/A, 60020 Ancona, Italy
(b) Sestri Levante Hospital, Sestri Levante, GE, Italy

Nine patients with focal lesions of the condylar articular cartilage were consecutively treated with arthroscopic microfractures (MFX) covered with MeRG ® membrane immersed in autologous bone marrow concentrate (BMC) from the iliac crest.

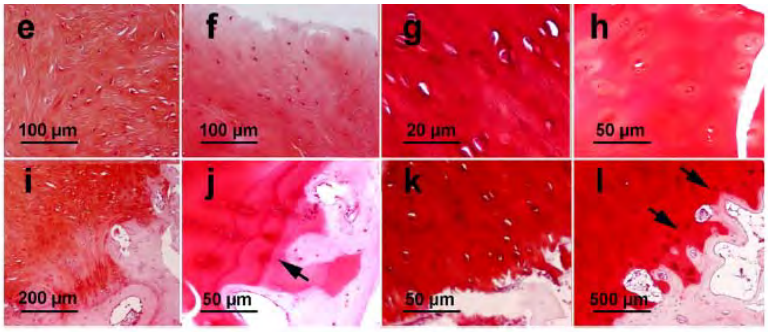


2nd look arthroscopy @ 1 year post-implant

Patients were retrospectively assessed using several standardized outcome assessment tools and MRI scans. Four patients consented to undergo second look arthroscopy and biopsy harvest.

Results at the hystological evaluation

Cartilage macroscopic assessment at 12 months revealed that all the repairs appeared almost normal. Histological analysis showed a hyaline-like cartilage repair in one lesion, a fibrocartilaginous repair in two lesions and a mixture
of both in one lesion



Biopsies stained with Safranin-O.
Each column represents a single biopsy; lines e–h represent the chondral matrix; and lines i–l represent the osteochondral junction.

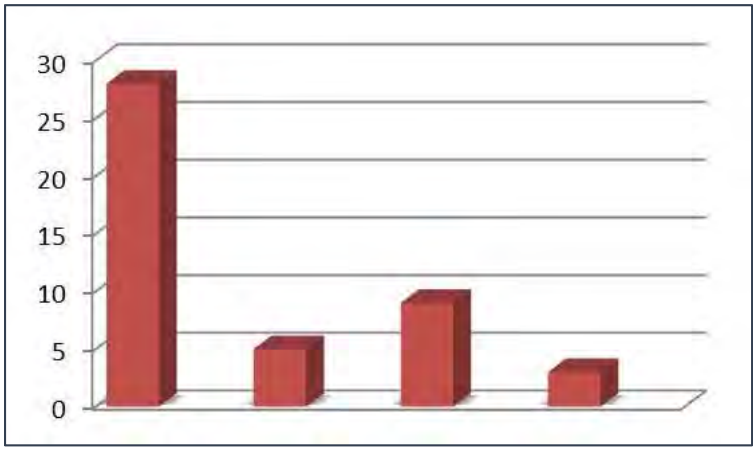
D. Enea, S. Cecconi, S. Calcagno, A. Busilacchi, S.Manzotti , A. Gigante. One-step cartilage repair in the knee: Collagen-covered microfracture and autologous bone marrow concentrate. A pilot study. *The Knee, 2015;22:30–35.*

CLINICAL EXPERIENCES *(P. Tessari, MD- Verona)*

2008-2013

45 patients (65% male, 35% female, 43 years mean age)

Knee	*medial compartment*	28	94%
	lateral compartment	5	
	patella		
Tibio-tarsal (talar area)		3	6%



MeRG
Implantation sites

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FOLLOW-UP AND RESULTS

Follow-up, 6 months post-op (45 patients - 100%)

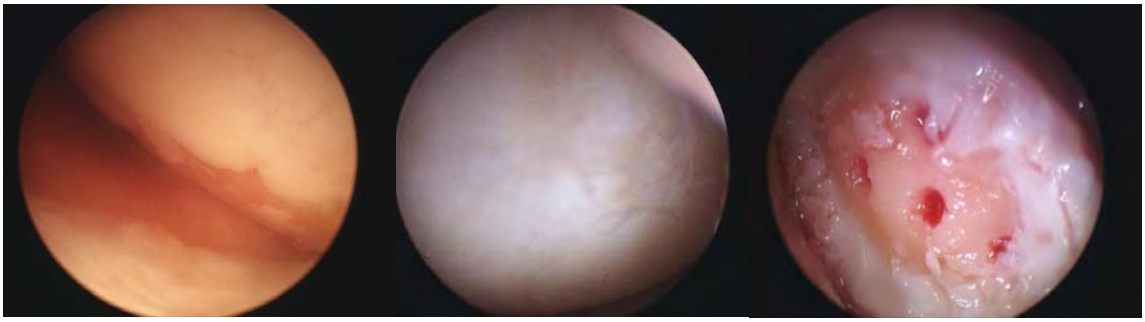
Excellent		35	78%	Satisfying 90%
Good		5	12%	
Fairly good	4	8%	2%	Unsatisfying 10%
Bad		1		

Follow-up, 2 years post-op (42 patients - 94%)

Excellent		26	58%	Satisfying 83%
Good		11	25%	
Fairly good	5	11%	6%	Unsatisfying 13%
Bad		3		

CLINICAL IMAGES OF DEFECTS

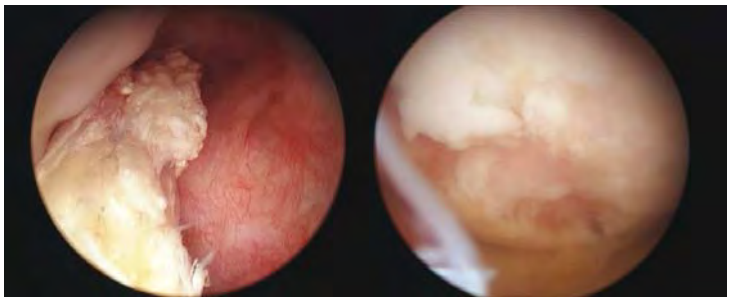
A.W. - Male, 55 yrs



Medial femoral condyle

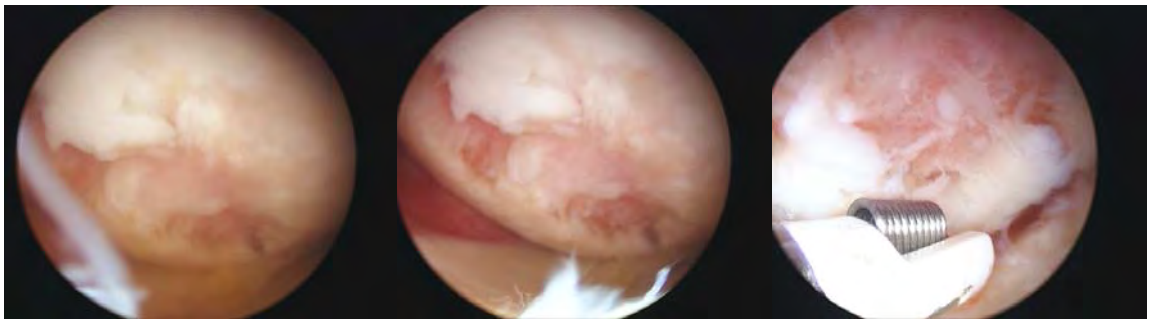
Defect with micro-fractures

A.C. - Male, 28 yrs
Footbal player

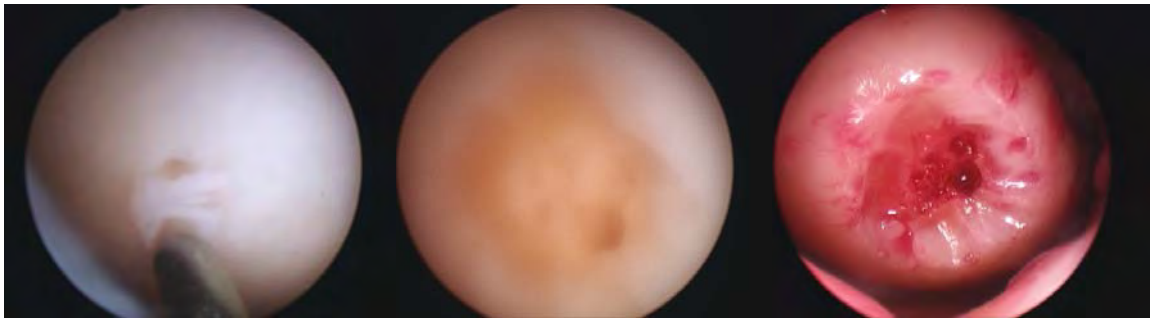


Iatrogenic calcinosis
of ligament

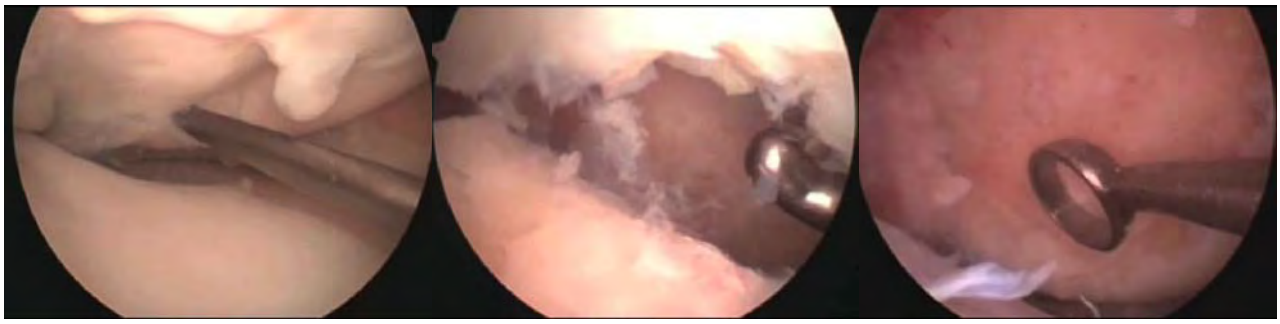
S.R. - Male, 57 yrs



B.R. - Female, 30 yrs, Tennis player

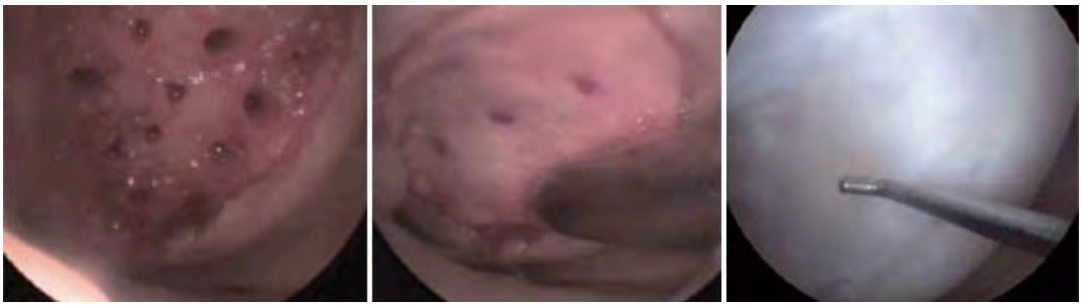


CLINICAL CASE - SECOND LOOK



Chondral lesion

Debridment of ill cartilage



Microfractures

MeRG positioning in CO_2

Second look at 7 months

CONSIDERATIONS

Dr. Tessari reported just 1 bad result (hyperemic reactive synovitis), assessed and arthroscopically treated .
At 2 years follow-up, he reported 3 bad results, just because 3 patients did not come back to controls.

However, results are aligned to what is reported in literature.

J. Gille, P. Behrens, P. Volpi, L. de Girolamo, E. Reiss, W. Zoch, and S. Anders. Outcome of Autologous Matrix Induced Chondrogenesis (AMIC) in cartilage knee surgery: data of the AMIC Registry. *Arch Orthop Trauma Surg. 2013 January; 133(1): 87–93.*

CONCLUSIONS

This 6 years-long experience with MeRG membrane has showed satisfying clinical outcomes in 83% of cases after 2 years.
All these cases had a complete pain resolution (VAS 0-2) and nearly complete joint recovery (ROM >95%).

Unsatisfying results were about 13% (6% just because referred to non controlled patients).
All these patients had a story of soreness in the treated area and a subjective functional recovery that did not meet their expectations.

There was no case of infection. 4 synovitis, pharmacologically treated and in 2 cases arthroscopic revision and synovectomy were performed.

AMIC technique with MeRG membrane represents a *good and reproducible* surgical technique, in terms of timing and method.

The learning curve is quite fast before to easily manage the surgical procedure.

It is very important to strictly follow the indications, avoiding to extend the method to bigger defects or to cases associated with alteration of the loading axis and joint stability (ligament injuries).

Critical issues are micro-fractures of the sub-chondral bone which result in a very low supply of mesenchymal cells.

For this reason, we are thinking to improve the quality of the regenerated tissue performing specific micro-perforations.

NEW FINDINGS AND FUTURE TRENDS FOR MERG-BASED GCR (1/2)

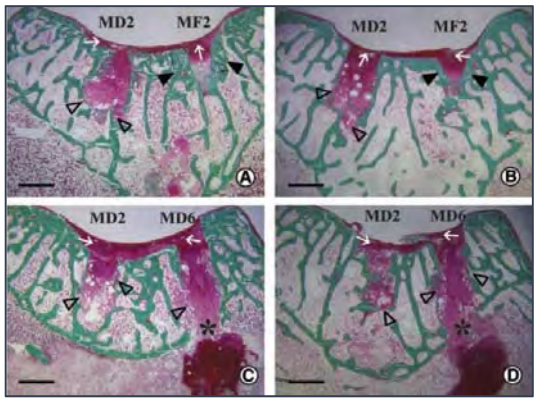
Drilling and Microfracture Lead to Different Bone Structure and Necrosis during Bone-Marrow Stimulation for Cartilage Repair

Hongmei Chen,[1] Jun Sun,[2] Caroline D. Hoemann,[1] Viorica Lascau-Coman,[1] Wei Ouyang,[1] Marc D. McKee,[3] Matthew S. Shive,[2] Michael D. Buschmann[1]

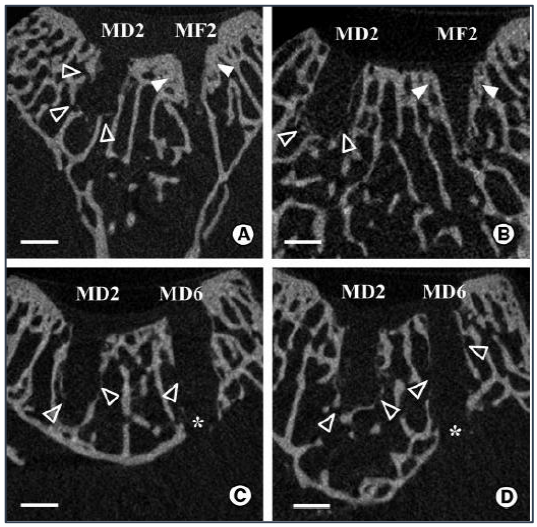
[1]Department of Chemical Engineering and Institute of Biomedical Engineering, Ecole Polytechnique de Montreal, P.O. 6079 Station Centre-ville, Montreal, QC, Canada H3C 3A7, [2]BioSyntech Canada, Inc., Laval, Canada, [3]Faculty of Dentistry, McGill University, Montreal, Canada


Drilling and Microfracture Lead to Different Bone Structure and Necrosis during Bone-Marrow Stimulation for Cartilage Repair

This study reveals “significant differences between Microfracture (MF) and Microdrilling (MD), which could potentially influence subsequent repair responses and longer term cartilage repair properties”.



“Microfracture with an awl induced fracturing and bone compaction around holes that were largely sealed-off from adjacent bone marrow, in contrast to drilling which cleanly removed bone debris and left channels that communicate between the hole and marrow. Microfracture also produced a high level of osteocyte necrosis in adjacent bone, in contrast to our drilling method which included cooled irrigation and did not cause apparent thermal necrosis.”



MD 6mm >> MD 2mm > MF 2mm

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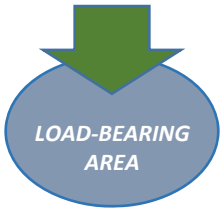
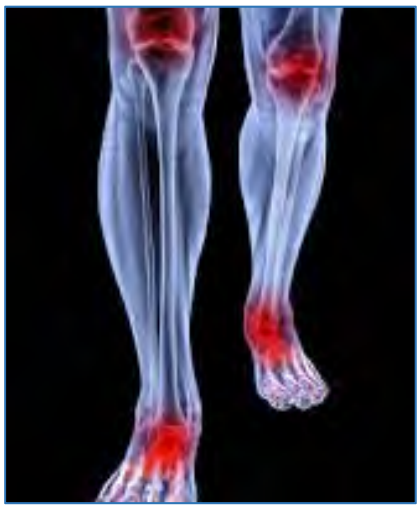
MERG REHABILITATION PROTOCOL

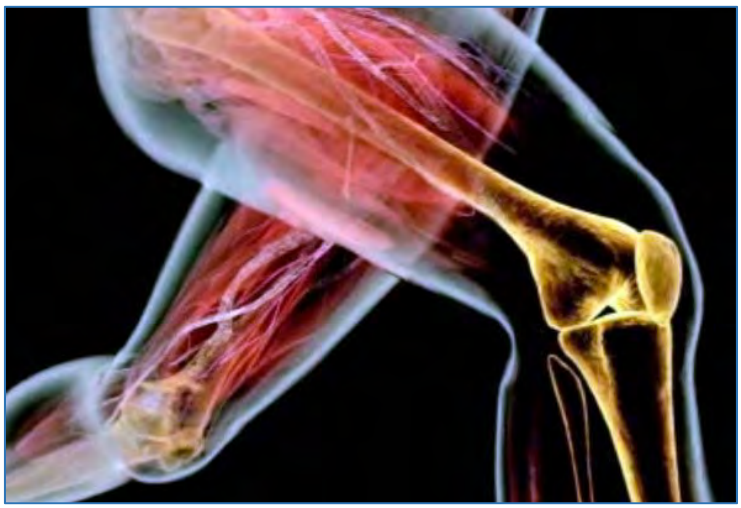
- Immobilization with brace and unloading for 10 days
- Passive motion with articulated brace and unloading for 10 days
- Progressive loading with use of crutches for 10 days, associated to active joint mobilization
- Complete loading and joint exercises to achieve full ROM, for 3 weeks
- Restarting of sports activity, 3 months after surgery



- Immobilization with fixed brace and unloading for 1 week
- Mobilization with articulated brace and progressive load with crutches for 2 weeks
- Complete loading with muscle strengthening exercises, achieving full ROM in 1 week
- Return to normal activity after 1 month (no sports activity)
- Return to sports activity, after 2 months

This protocol is indicated for non load-bearing areas, as well as for regions of indirect loading (e.g. patella)





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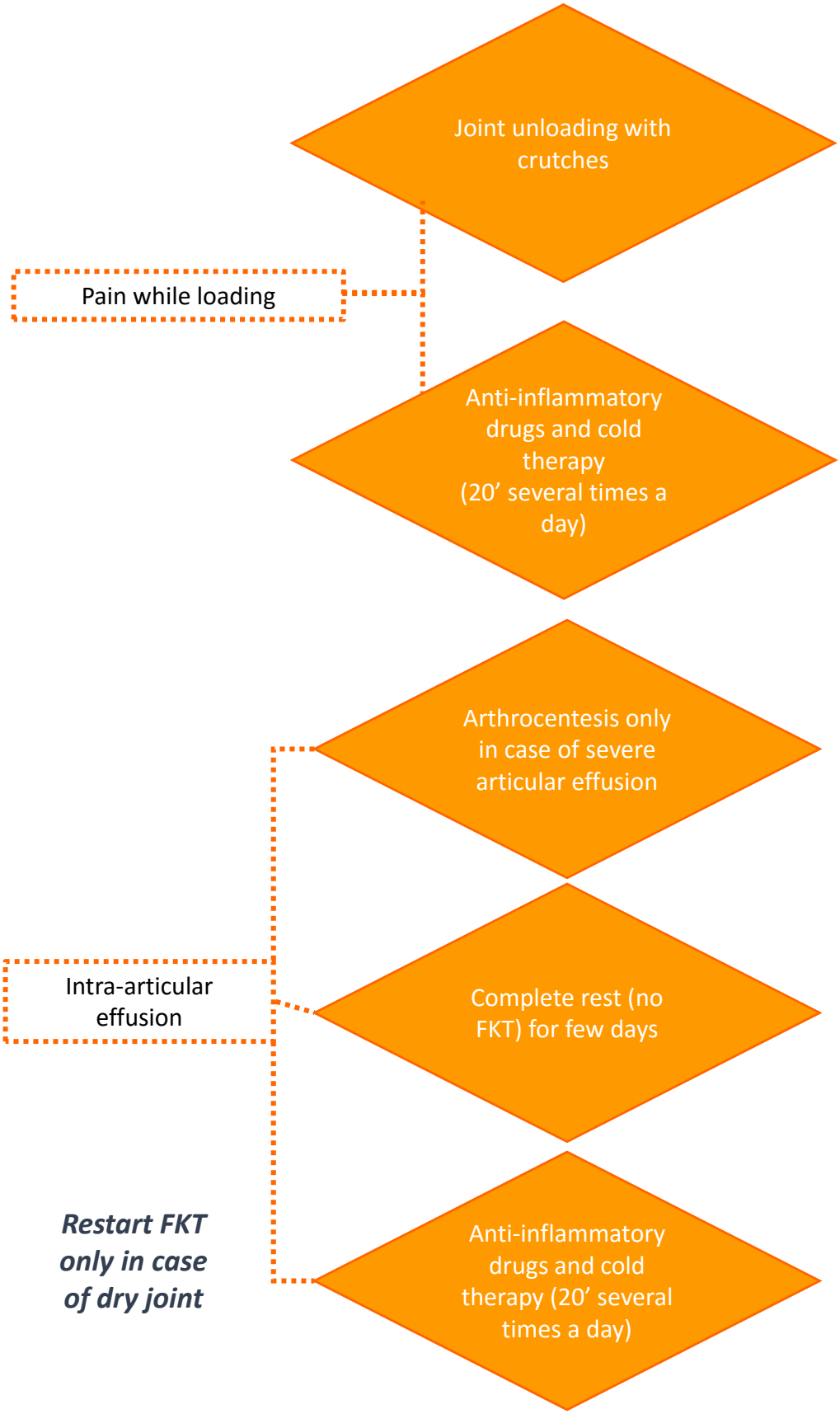
MERG: CRITICAL ISSUES IN REHAB



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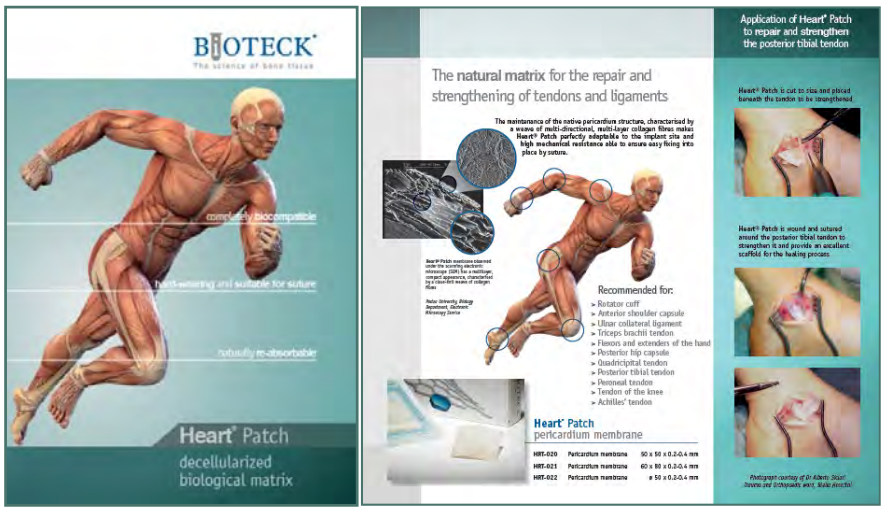
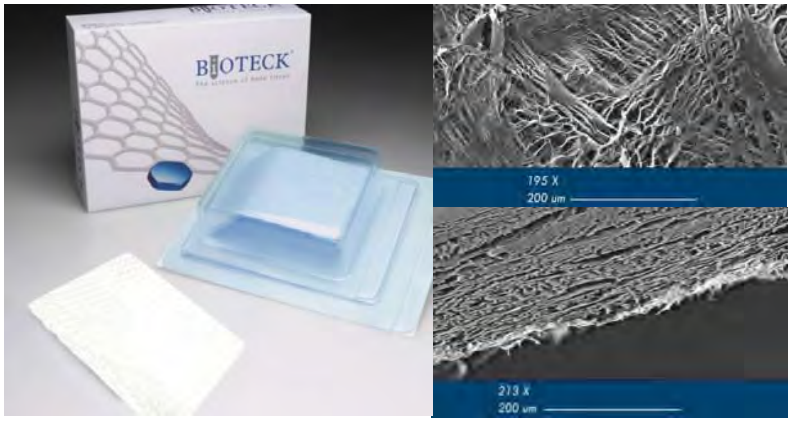
PERICARDIUM MEMBRANES



Heart Patch

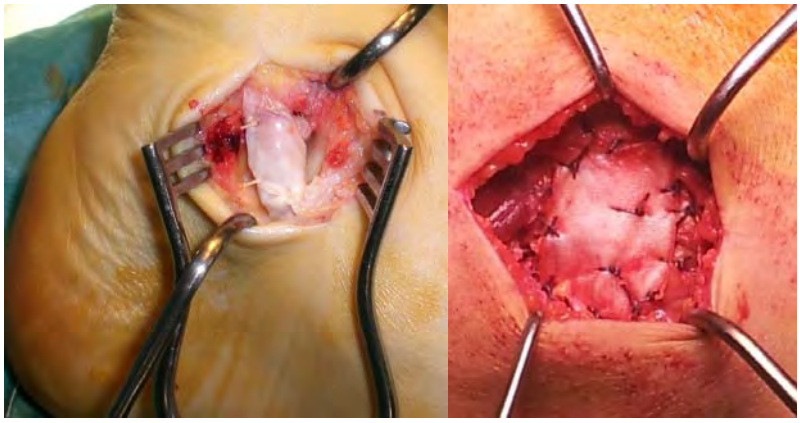
Acellular native collagen patch from equine pericardium.

Soft, strong and elastic due to its structure of the fibers oriented in all directions.



SEM pictures show the compact multi-layer structure and the dense network of collagen fibers.

SEM pictures by Dept. Of Biology, University of Padova, Italy



The use of Heart Patch in the reinforcement of the posterior tibialis tendon.

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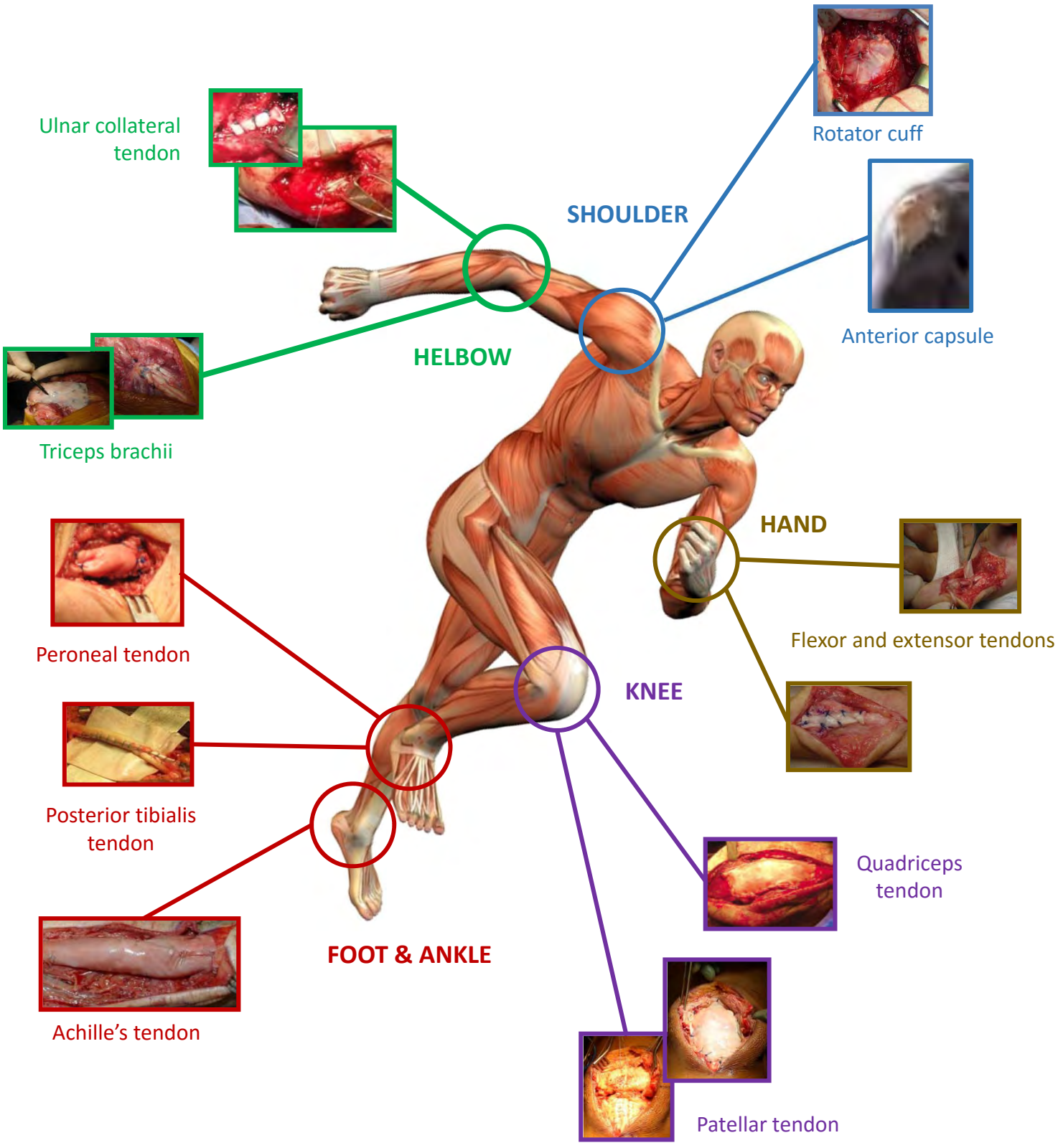
HEART® PATCH INDICATION



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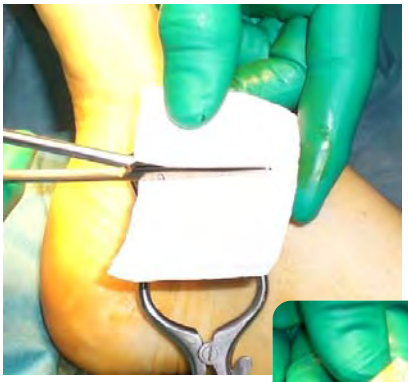
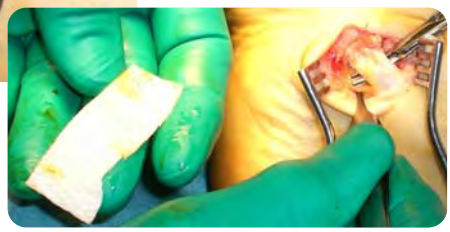
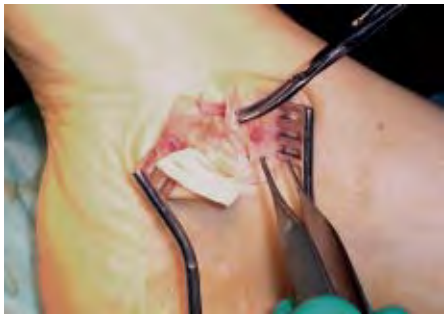
HEART PATCH
IN POSTERIOR TIBIALIS TENDON REPAIR

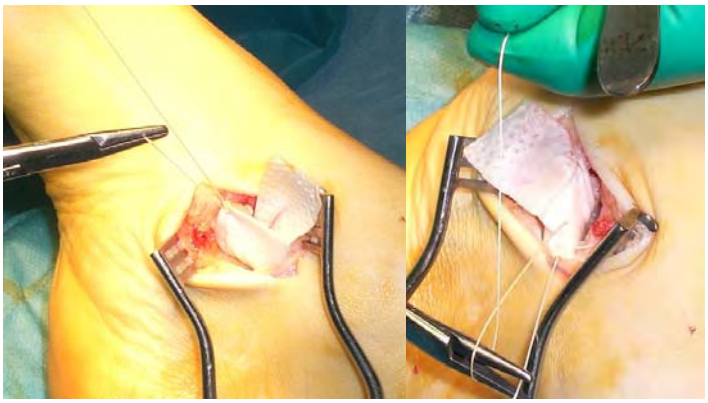




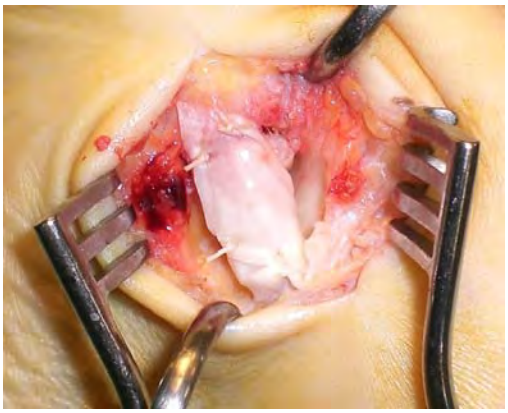
The patch is cut to the needed size, before rehydration



The pericardium strip is passed under the tendon



The pericardium strip is sutured and the excess is then trimmed



The tendon is completely wrapped by the pericardium strip

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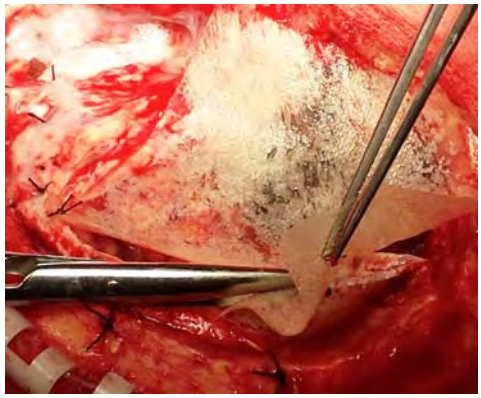
HEAD AND NECK GRAFT LINE

Osteoplant Spine
A complete line of grafts for Spine surgery

Heart DM
Equine Pericardium membrane for dura substitution and repair

Heart DM
Available in 5 different size from 30x20mm to 120 mmx x160



Heart DM as dura substitute in a meningioma case

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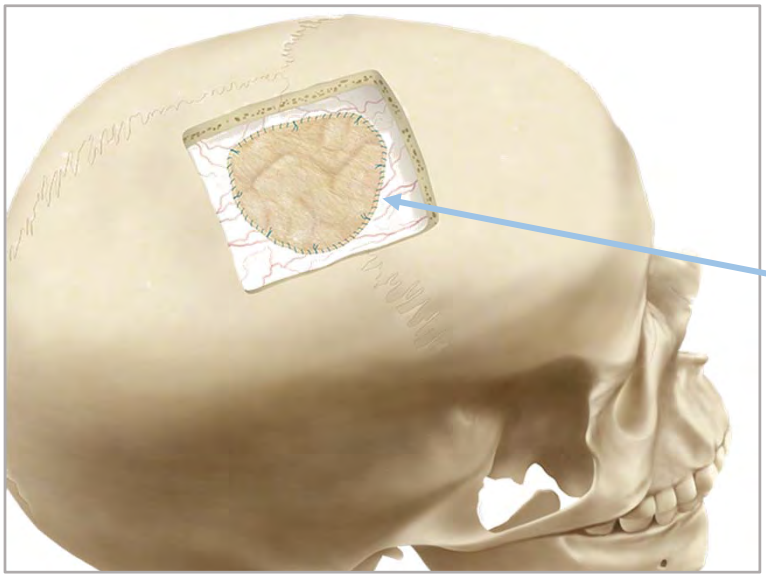
HEART DM INDICATIONS



CODE AND AVAILABLE SIZES

Code	Description
HRT-40DM	*HEART® PERICARDIUM MEMBRANE 25 X30 mm*
HRT-41DM	*HEART® PERICARDIUM MEMBRANE 50 X 50 mm*
HRT-42DM	*HEART® PERICARDIUM MEMBRANE 60 X 80 mm*
HRT-43DM	*HEART® PERICARDIUM MEMBRANE 80 X 140 mm*
HRT-44DM	*HEART® PERICARDIUM MEMBRANE 120 X 160 mm*

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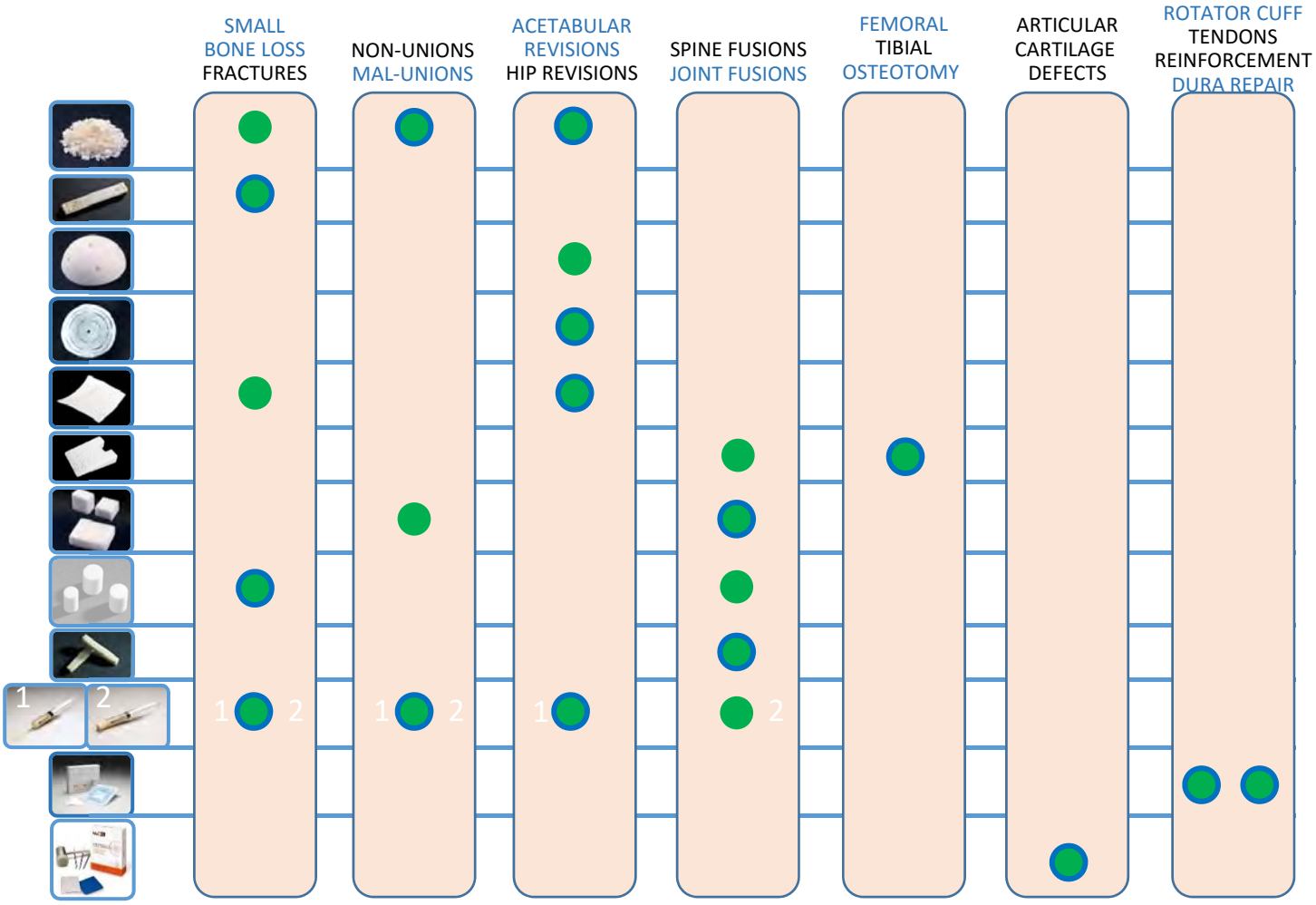
TABLE OF MAIN INDICATIONS



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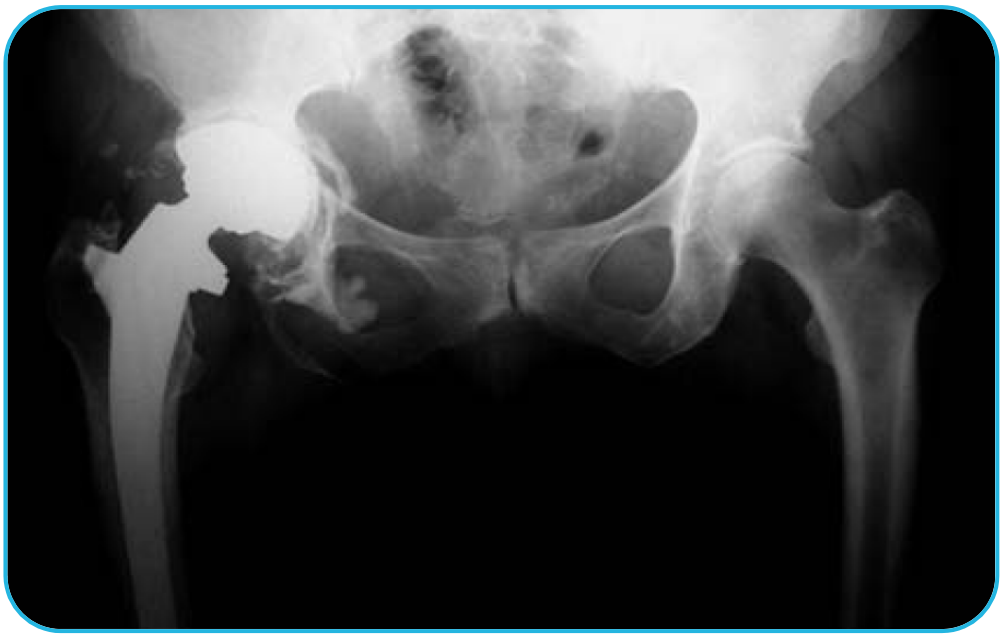
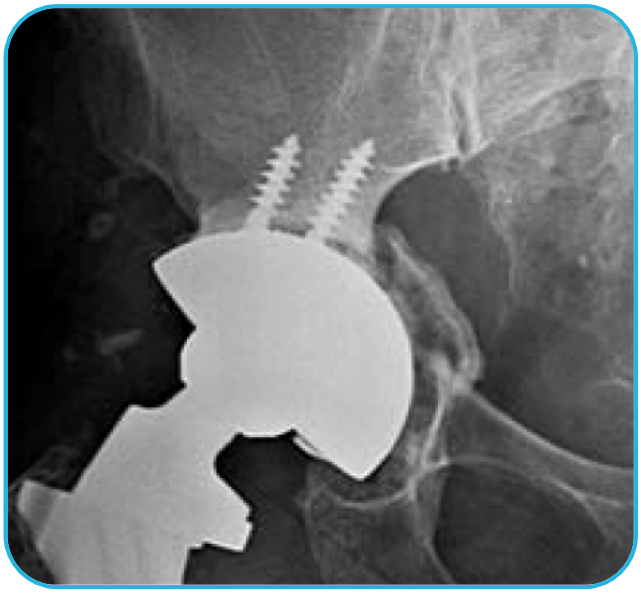
CLINICAL CASES 1
BONE SUBSTITUTES IN ACETABULAR REVISION

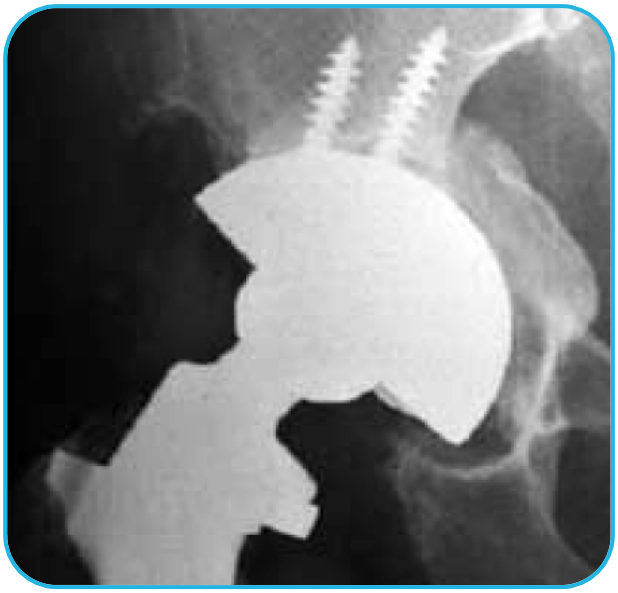
Courtesy of prof. Roberto Sessa, MD. – Catania, Italy



Acetabular cup revision in a 74 years old female – RX pre-op.



Osteoplant cancellous chips .
RX 3 months post-op.



Osteoplant cancellous chips .
RX 18 months post-op.

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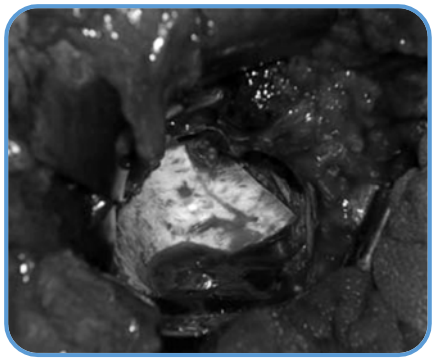
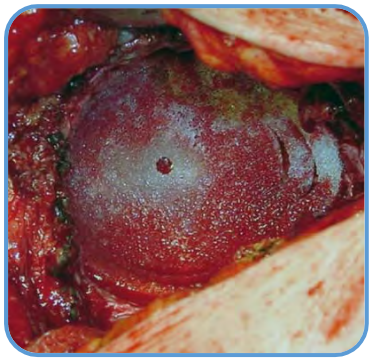
CLINICAL CASES 2
BONE SUBSTITUTES IN ACETABULAR REVISION

Courtesy of prof. Roberto Sessa, MD. – Catania, Italy

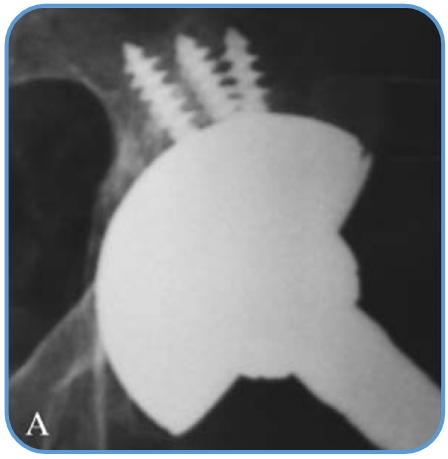


OTC-C8 Flex Cortical Sheet.

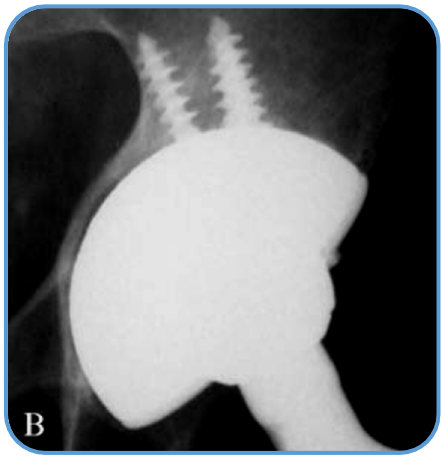


OSP-070 Flex Acetabular Mat

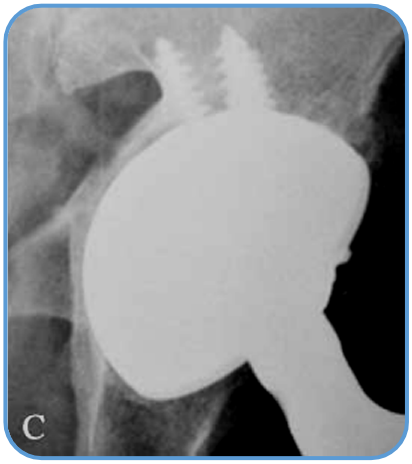
In presence of acetabular protusio, flex cortical sheet is used as a new acetabular wall associated to the acetabular mat for filling the defect



RX 2 months post-op.



RX 8 months post-op.



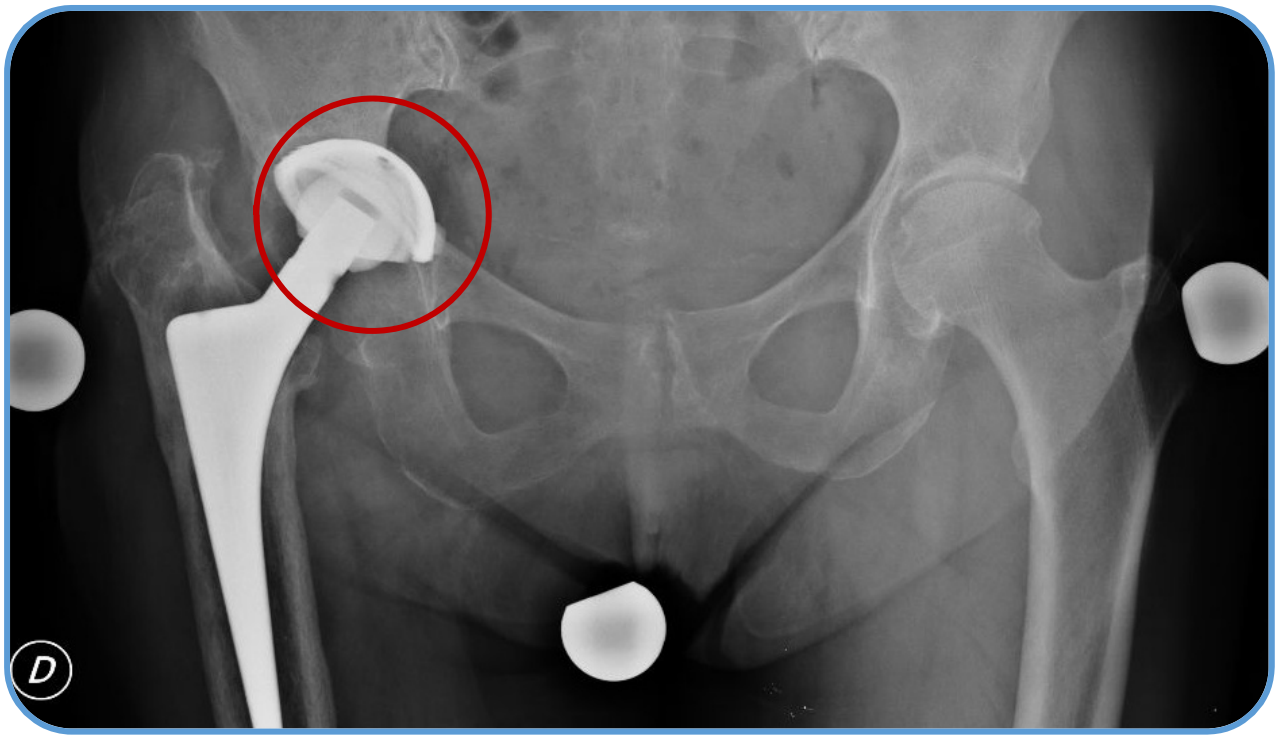
RX 16 months post-op.

G. Sessa et al.: *Equine bone tissue in acetabular revision: our experience*
MINERVA ORTOP TRAUMATOL 2010;61:469-76)

BIOTECK
The science of bone tissue

CLINICAL SERIE
BONE SUBSTITUTES IN ACETABULAR REVISION

Courtesy of Prof. Massimiliano Marcucci
Director of C.E.S.A.T. Centro Eccellenza Sostituzioni Articolari Fucecchio (FI) - Italy



RX pre-op

*Bone regeneration in revision hip arthroplasty using equine-derived bone grafts: a retrospective study

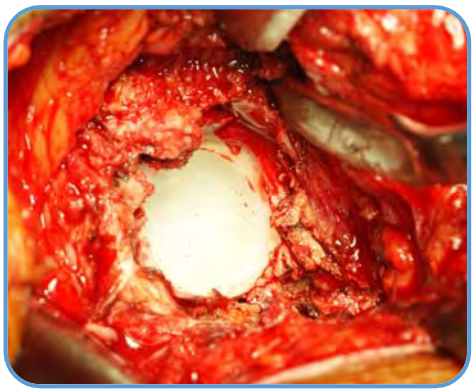
Massimiliano Marcucci[1], Angelo Graceffa[1], Nicola Piolanti[1], Pier Francesco Indelli[2] and Leonardo Latella[1]

[1]Articular Replacements Excellence Center (CESAT) - Fondazione Onlus "...In Cammino...", Fucecchio, Italy
[2]Stanford University, San Jose, California, USA

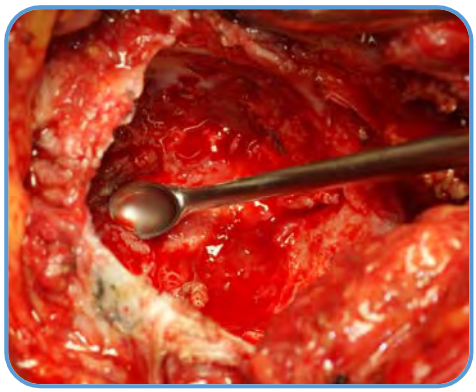
Paper submitted for pubblication

Abstract

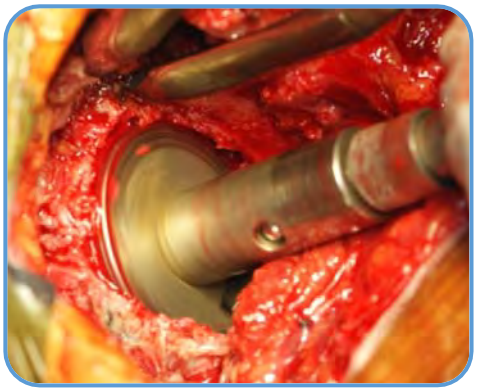
Background: During the last decade, total hip arthroplasty has become a common procedure performed in younger patients, as well as elderly ones. This has led to an increase in total hip arthroplasty revisions. Loosening of primary components with associated bone loss represents the major cause of total hip arthroplasty revision. This study evaluates the safety and performance of an enzyme-deantigenic equine-derived bone graft material when used as an alternative to bone autografts and/or allografts in acetabular defect reconstruction. **Methods:** Records of 55 patients who were treated for Paprosky Type II or III acetabular bone defects with arthroplasty revisions using equine-derived bone and followed for an average of 18 months (range 6—48 months) were analyzed. **Results:** Of the 59 revisions, 53 (89.8%) were regarded as successful, with evidence of incorporation of the equine bone graft. Failures included one infection (1.7% of revisions) and five cases of aseptic loosening of the acetabular prosthesis (8.5% of revisions). These results are consistent with those of studies having a similar follow-up period for allografts used in combination with trabecular metal components. **Conclusion:** Results of the present study suggest that enzyme-treated equine-derived bone grafts may be a valid alternative to autogenous and homologous bone grafts in total hip arthroplasty revision.



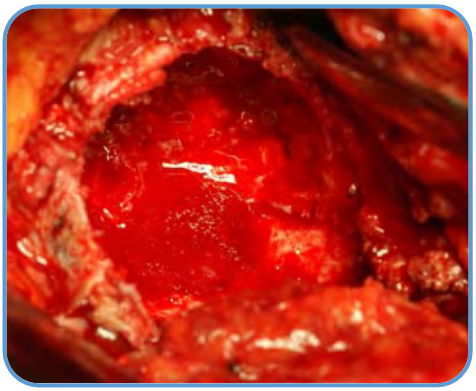
Acetabular prosthesis to revise



Curettage of the defect



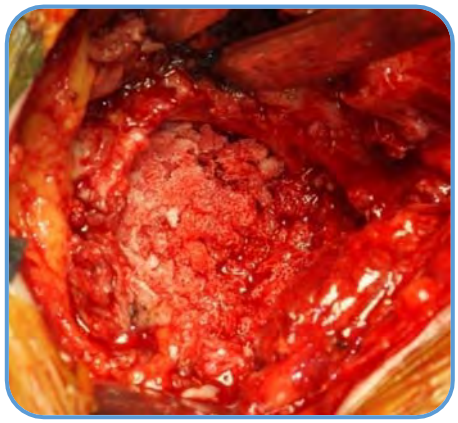
Reaming of the acetabulum



Acetabulum ready for grafting

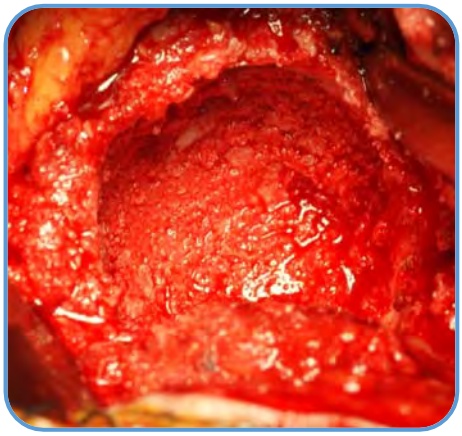
Activagen Injectable Paste mixed with Osteoplant chips

Filling of the acetabular defect

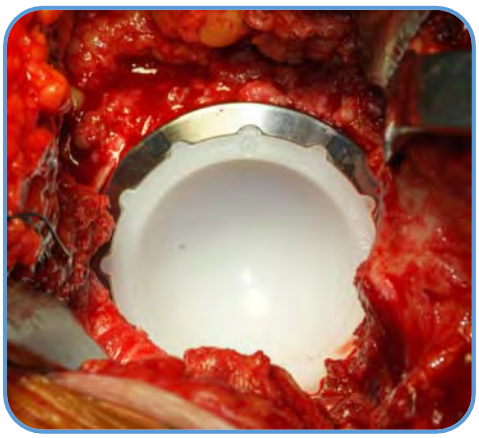


The defect is filled

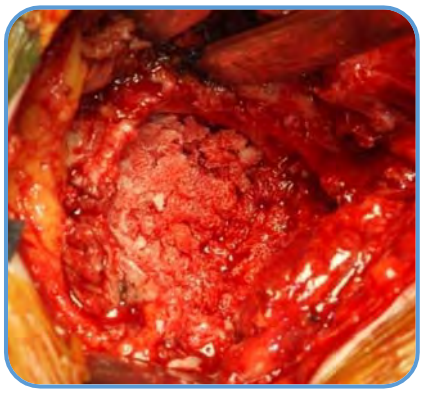
Chips are compacted by using the reamer with opposite rotation



Appearance of the reconstract acetabular cavity

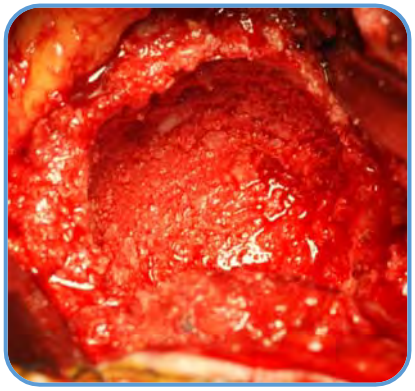


Acetabular prosthesis is placed

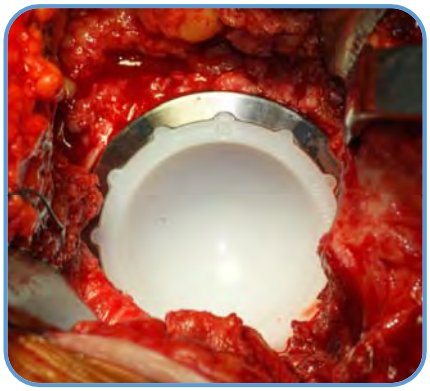


The defect is filled

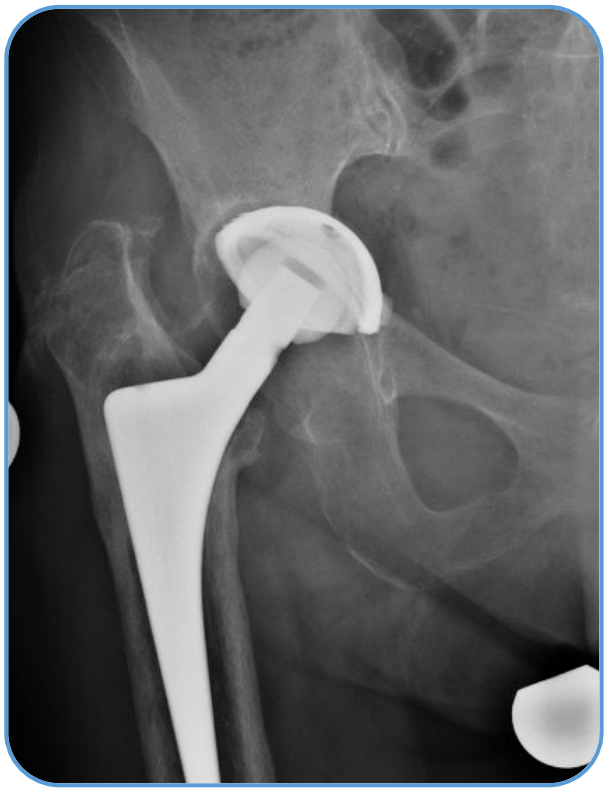
Chips are compacted by using the reamer with opposite rotation



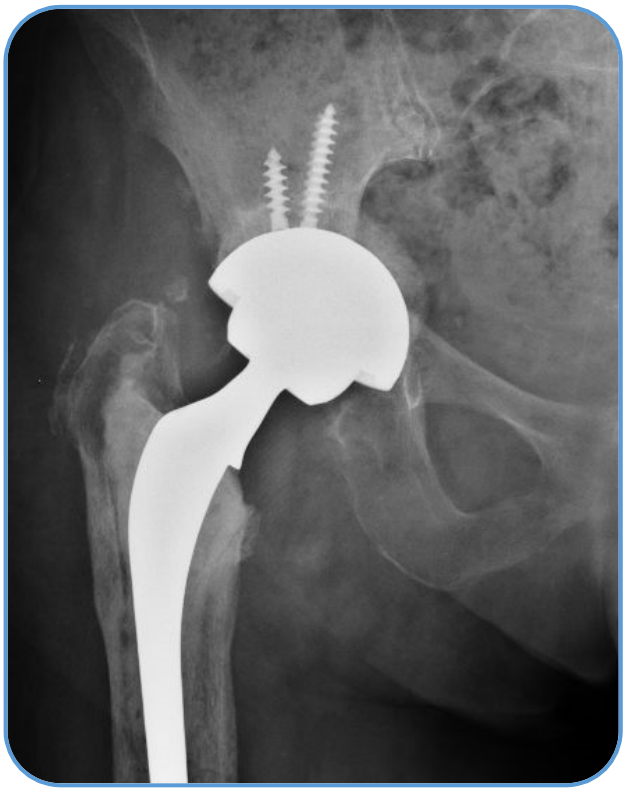
Appearance of the reconstract acetabular cavity



Acetabular prosthesis is placed



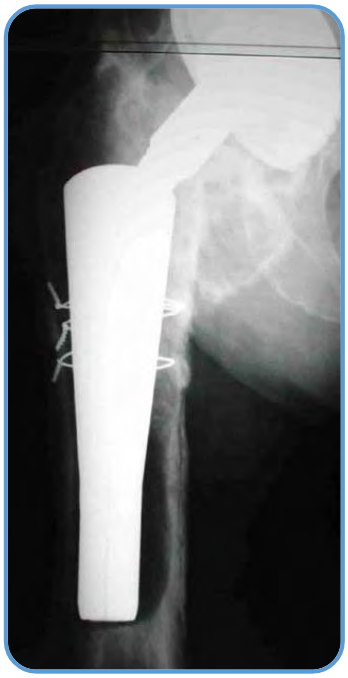
RX pre-op.



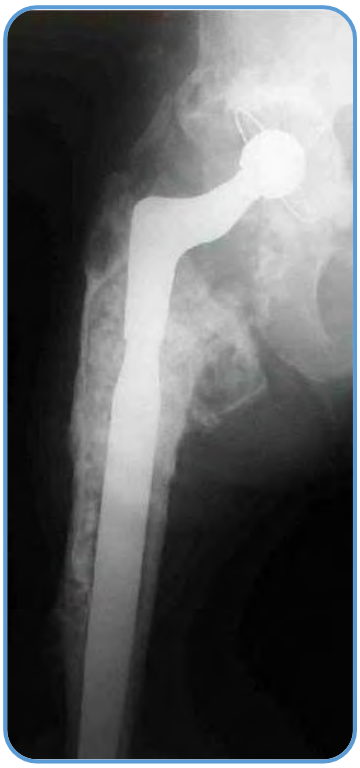
RX post-op.

CLINICAL CASES
BONE SUBSTITUTES IN HIP REVISION

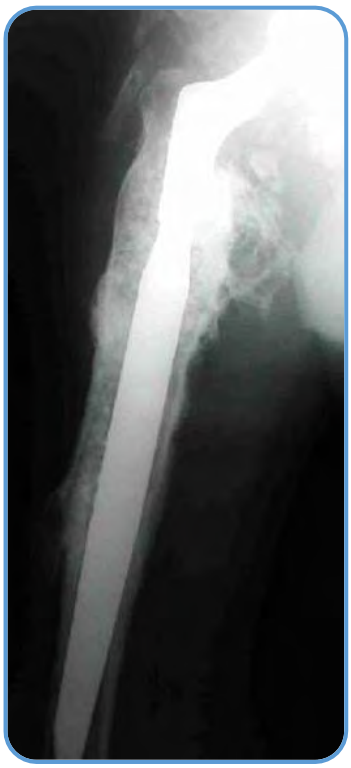
Courtesy of prof. Roberto Sessa, MD. – Catania, Italy



RX pre-op.



Impaction grafting - RX post-op.



RX 30 months post-op.

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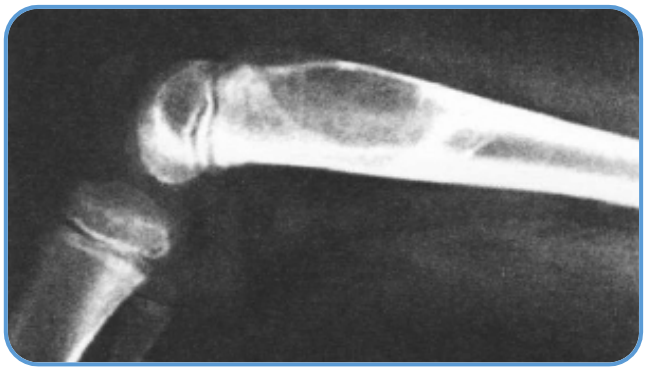
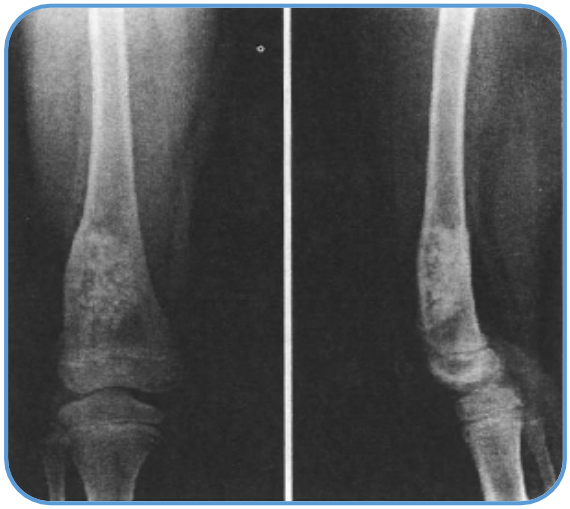
CLINICAL CASE
ANEURISMATIC BONE CYST IN A 9 Y. O. CHILD

Equine-derived bone substitute in orthopedics and traumatology: authors' experience

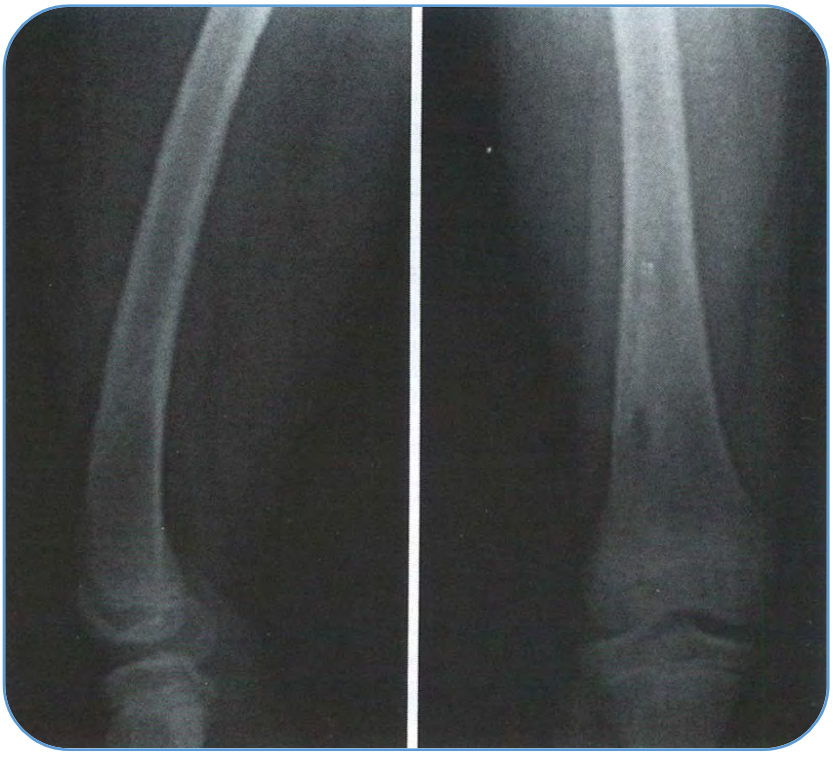
S. SANTINI. P. BARBERA. M, MODENA. R. SCHIAVON. M. BONATO



X-Ray pre-op.



Part of the graft is still visible
X-ray 6 months post-op.



Perfect integration of the graft.
RX 20 months post-op.

ORIGINAL ARTICLE

MINERVAC HIR2 011166,1

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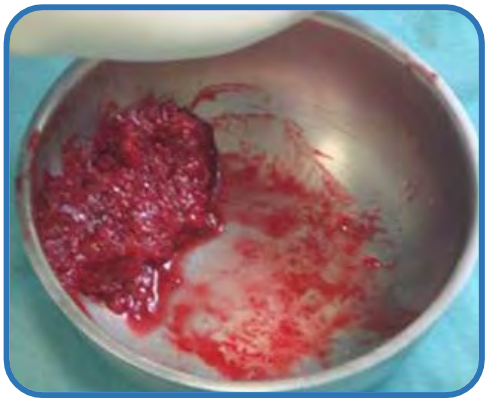
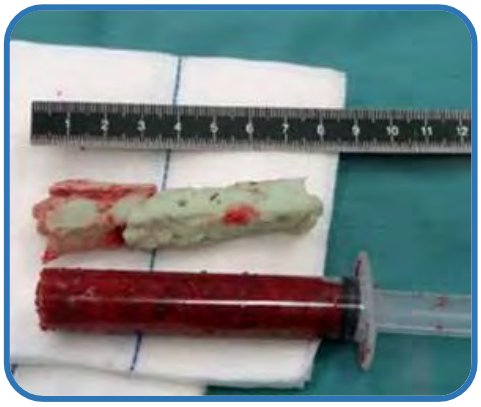
CLINICAL CASE
INFECTED SEVERE NON-UNION IN UPPER LIMB

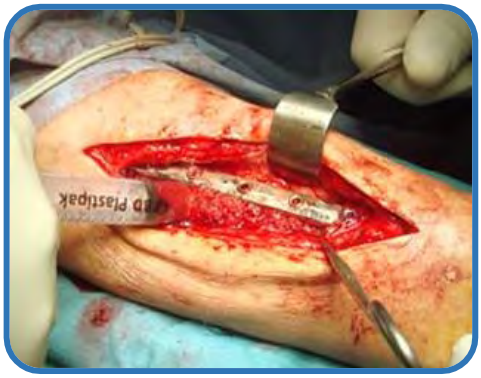
Pictures are courtesy of Dr. F. Da Rin - Codivilla Putti Hospital, Cortina d'Ampezzo (BL)

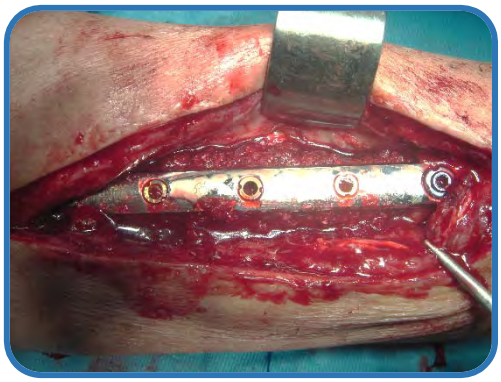




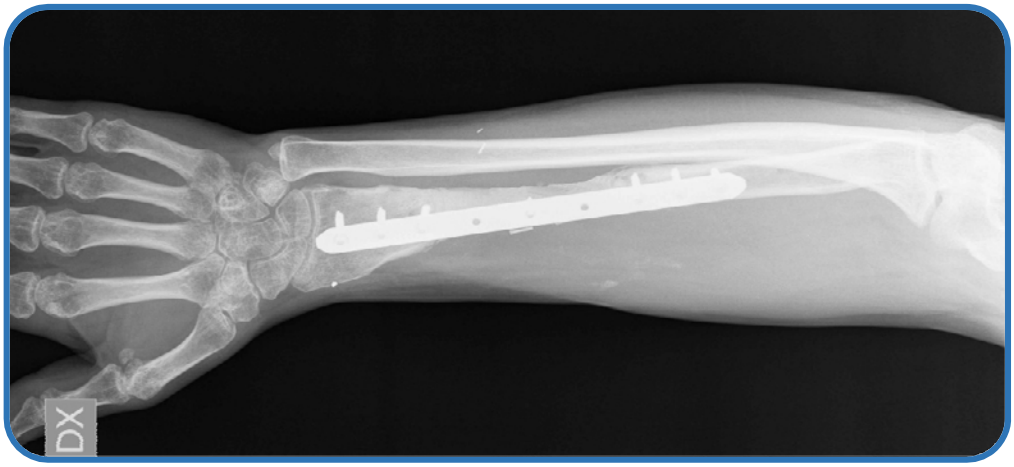
Antibiotic spacer is removed. The mixture have been put in a cut syringe for some minutes in order to get a more solid graft due to blood coagulation and then placed under the metal plate.

Bioteck chips mixed with autografts and bone marrow





Graft positioning



X-ray control 6 months post-op.

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CLINICAL SERIES
PROXIMAL HUMEROUS MULTI-FRAGMENTS FRACTURE

M. Trono, , G.Lucidi
U.O. Ortopedia e Traumatologia - Ospedale Infermi, Rimini

***Abstract**

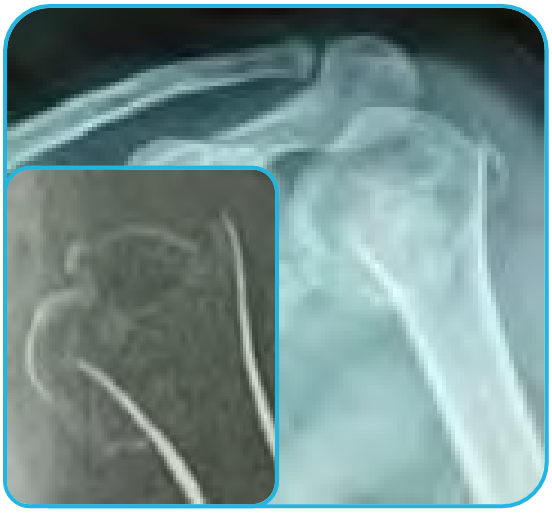
Background: This retrospective study aimed to evaluate the functional outcomes and incidence of complications in cases of proximal humeral fractures treated by open reduction and internal fixation with locking plates and concomitant equine-derived bone graft.

Methods: One hundred seventeen patients showing Neer 2-4 proximal humeral fractures were treated with locking plate fixation and concomitant grafting with an equine-derived bone substitute. Clinical and radiologic assessments were performed at the 1, 3, and 12-month follow-up appointments to evaluate fracture healing, alignment and reduction, and occurrence of complications. Functional recovery was assessed at the 12-month follow-up with the Constant-Murley scoring system.

Results: Radiologic and clinical bone healing was achieved in all patients. The overall complication rate was 5.1% and included nonunions, postoperative bleeding, and mobilization of the osteosynthesis devices. At the 12-month follow-up, the mean Constant score was 87.7 $\pm$ 8.5 and the mean Functional Recovery, in comparison with the contralateral unaffected arm, was 94.8% $\pm$ 4.2.

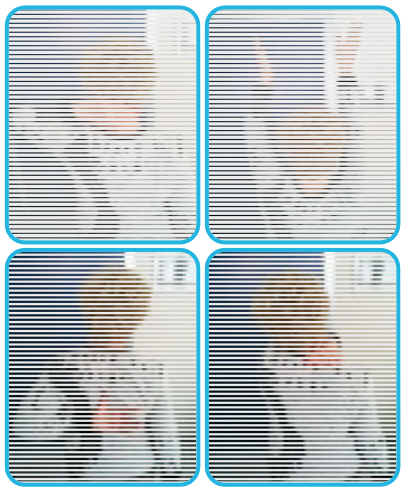
Conclusions: The use of equine bone blocks may be highly advisable in conjunction with locking plate fixation for the treatment of proximal humeral multipart fractures.

Level of Evidence: This work is a case series investigating the results of a treatment and corresponding to a Level IV of Evidence.



73 years old female - RX pre-op

RX 6 months post-op



6 months clinical result

** Paper submitted for pubblications*

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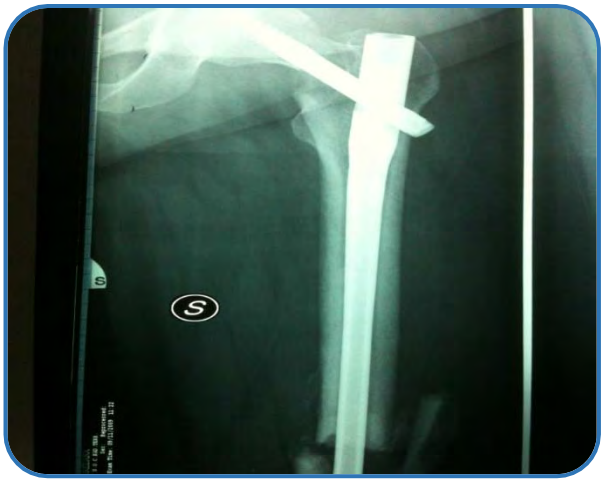
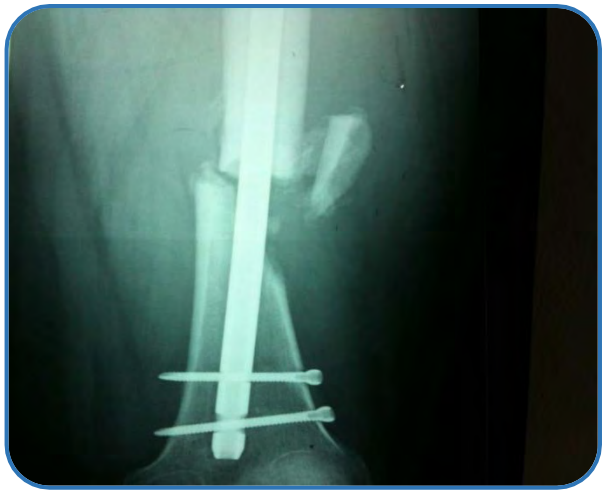
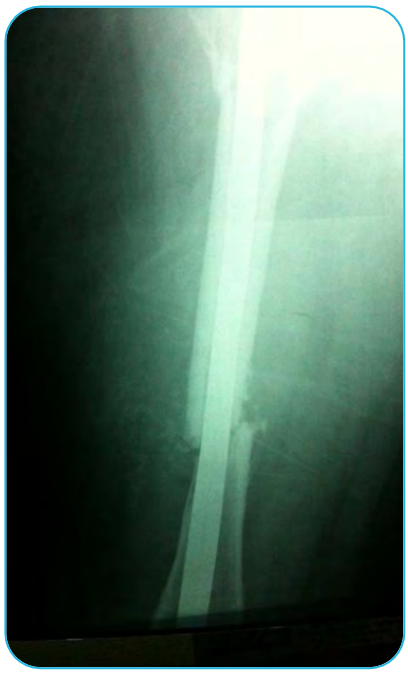
CLINICAL CASE 1
SEVERE NON-UNION IN LOWER LIMBS

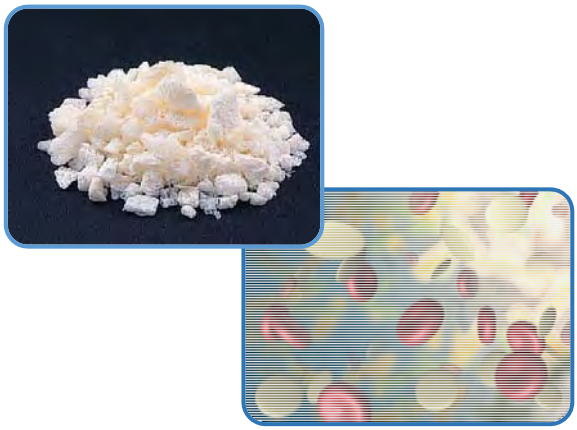
Courtesy of dr. Bruno Di Maggio, MD. – Piedimonte Matese (CE), Italy





Bifocal femur fracture in a 32 years old woman of 120 kgs.





Osteoplant chips + PRP

Previous treatment in an other hospital had no result after one year

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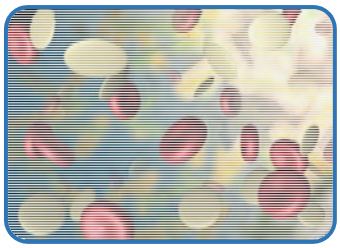
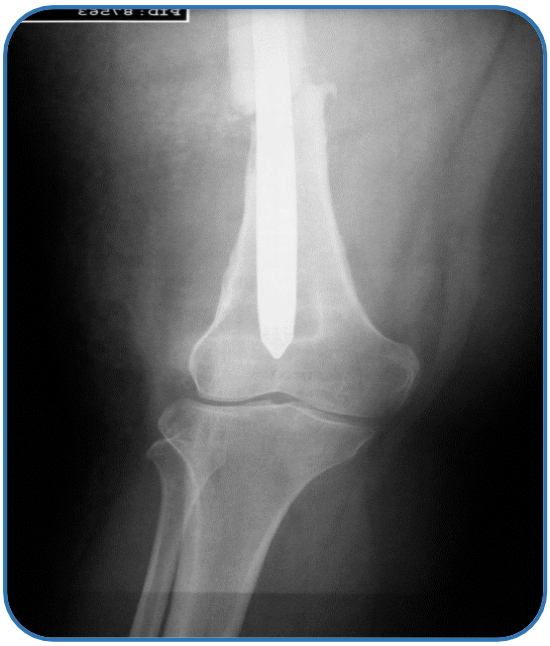
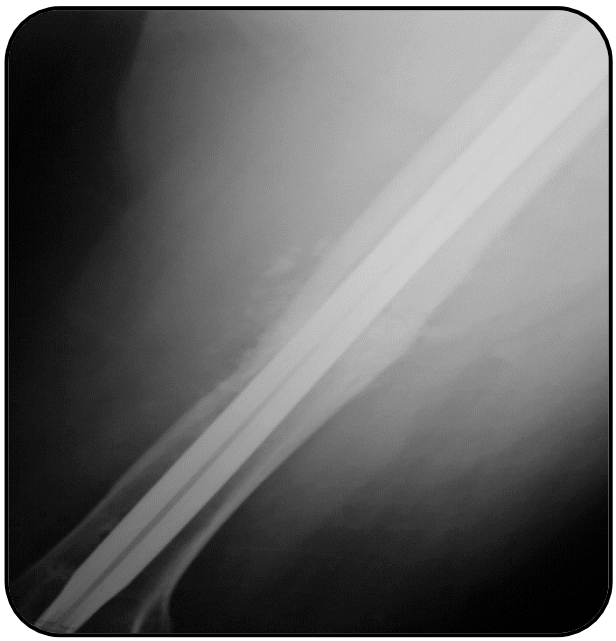


Implanted materials:
Osteoplant chips + autologousPRP

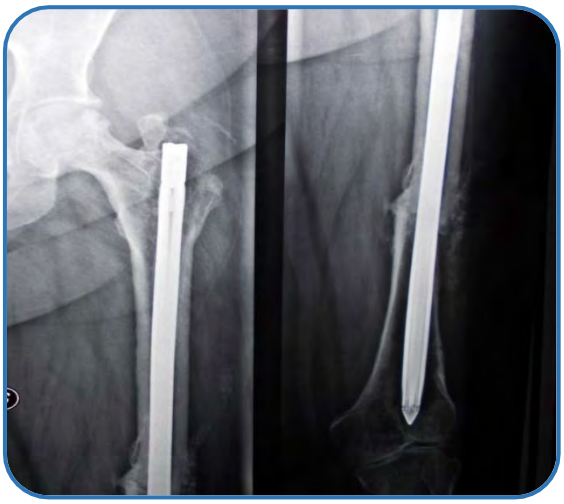


RX post-op



RX 4 months post-op

Clinical control 8 months post-op



RX 15 months post-op

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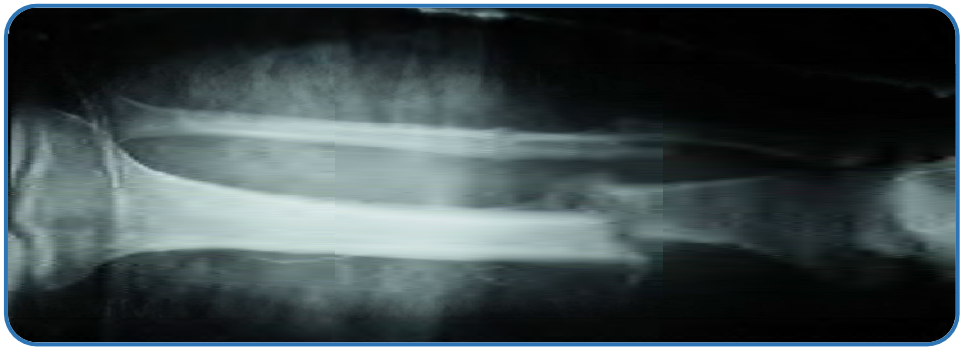
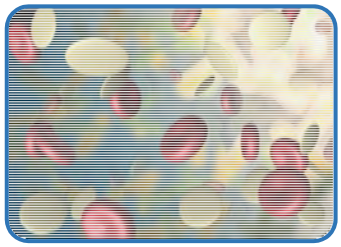
CLINICAL CASE 2
SEVERE NON-UNION IN LOWER LIMBS

Courtesy of dr. Bruno Di Maggio, MD. – Piedimonte Matese (CE), Italy



Double open leg fracture in a 20 years old woman.
External fixation in urgency, but signs of bone infection after 3 month



Implanted materials:
Osteoplant chips + autologousPRP

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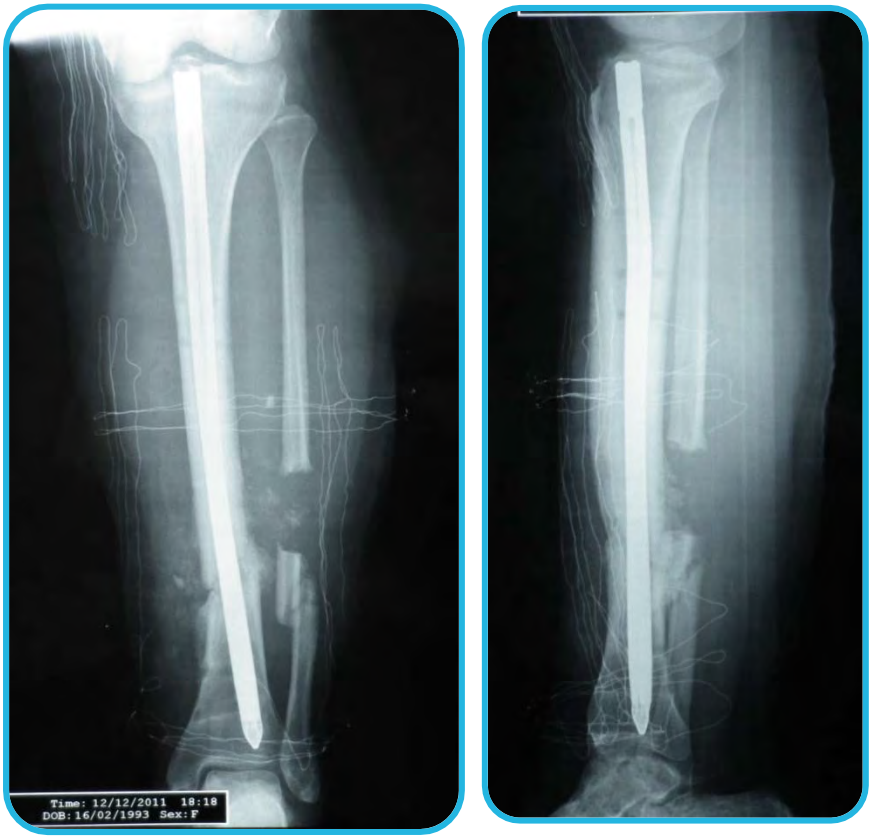
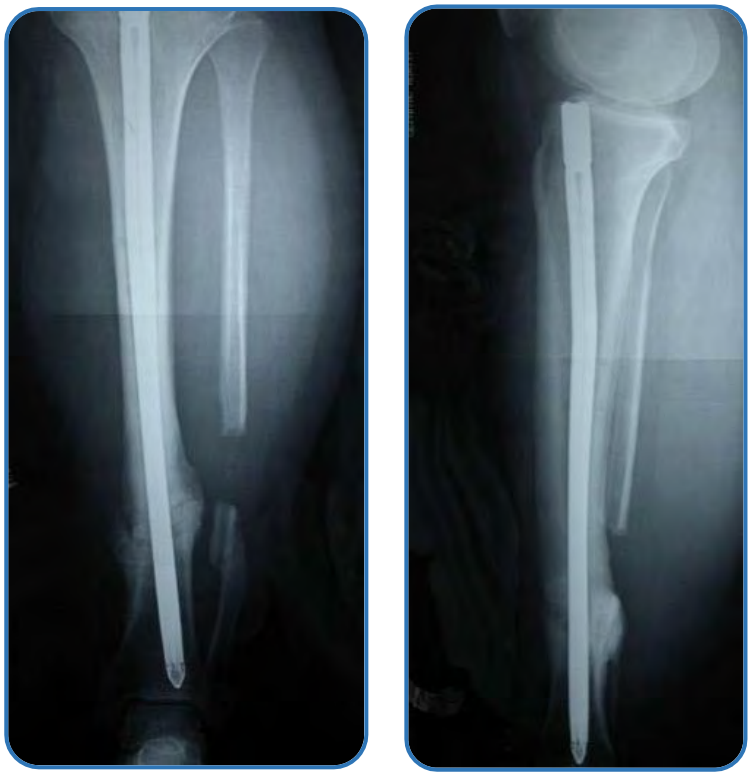
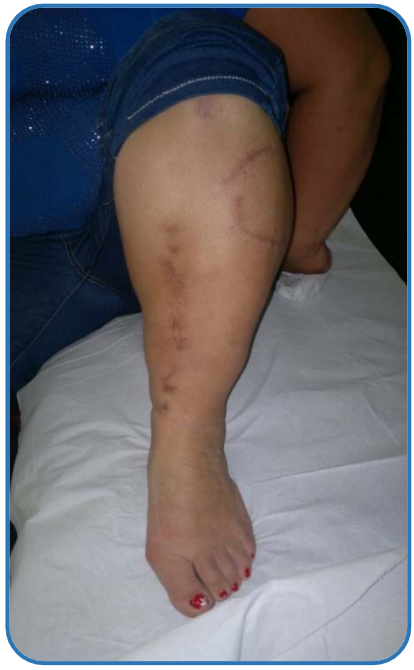


RX post-op



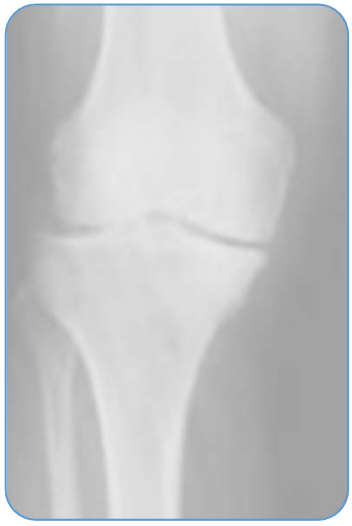
RX 3 months post-op



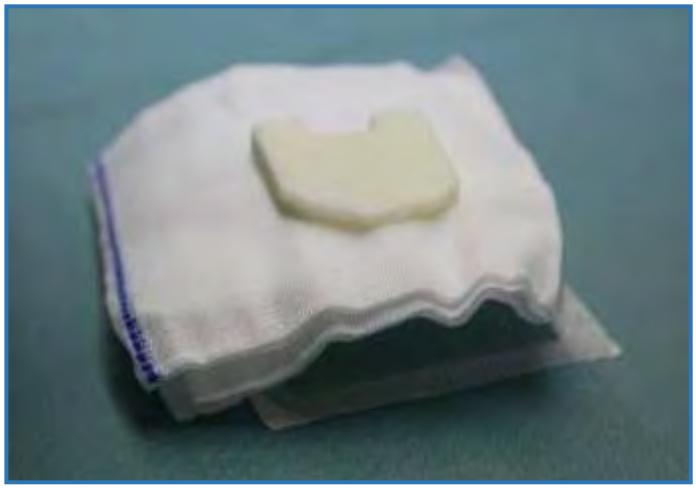
Clinical control 6 months post-op

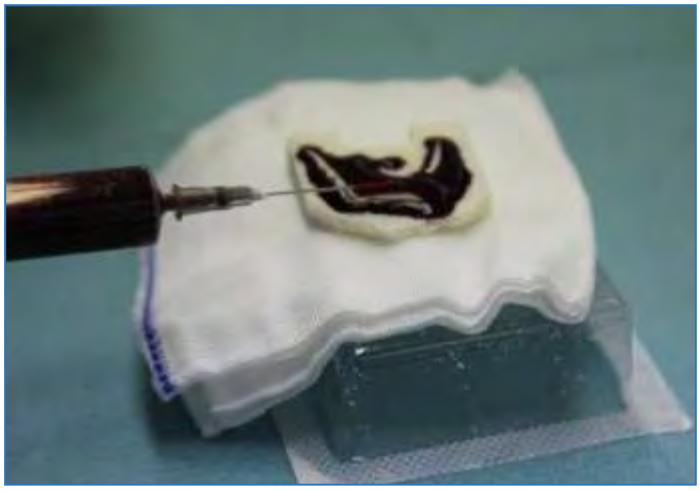
CLINICAL CASE
HTO WITH EQUINE BONE WEDGE

Courtesy of Rainero Del Din, MD. – SS.Antonio e Margherita Hospital, Tortona

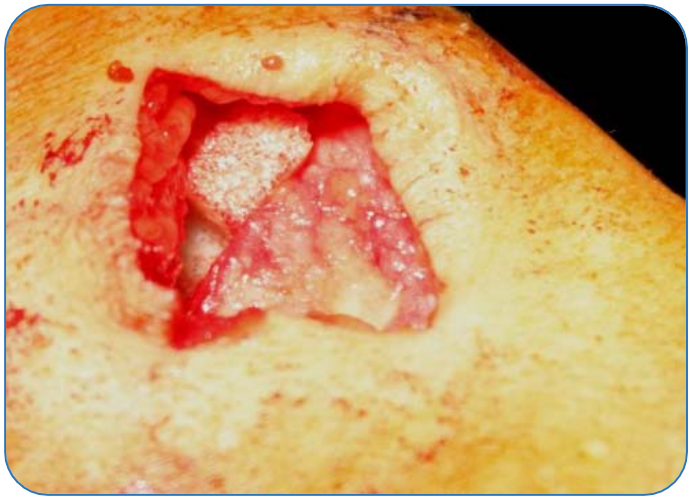


Pre-op RX





The wedge is adjust to final shape and size
Bone marrow concentrated cells are used to enrich it



The wedge is placed into the Tibial osteotomic lacuna

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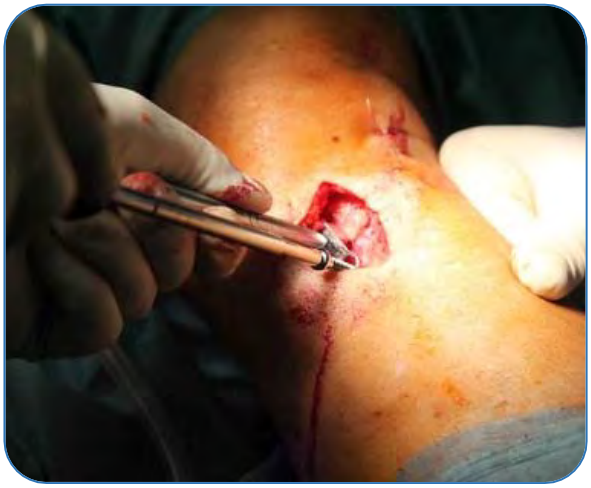
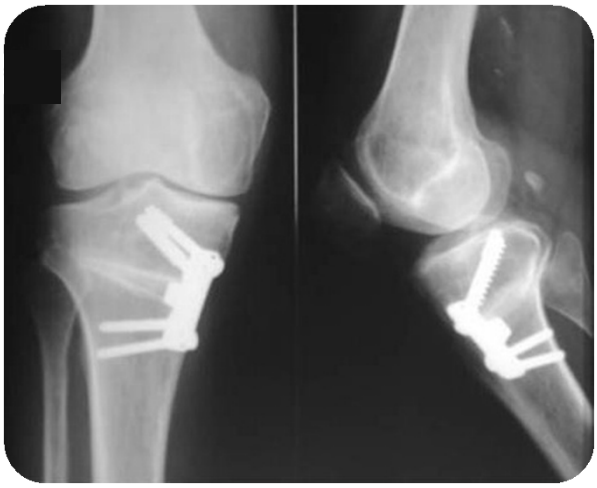
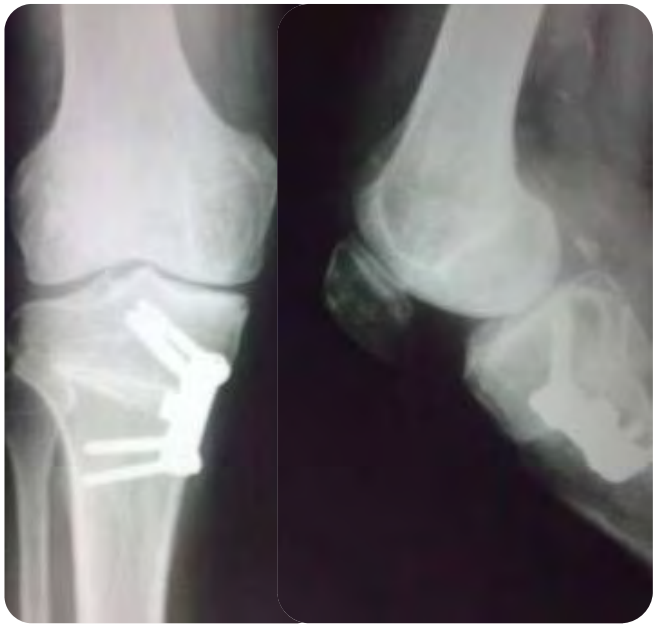


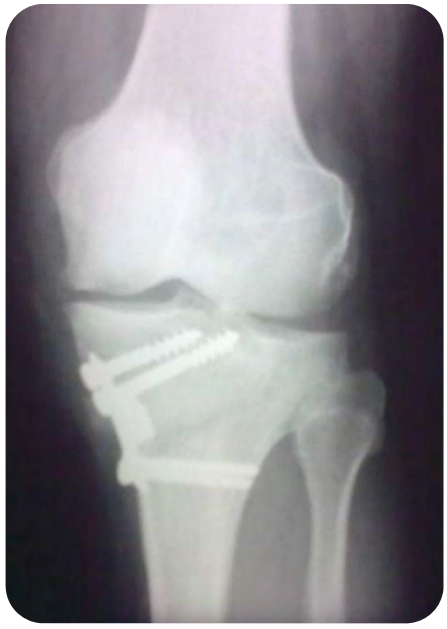
A metal plate is positioned and fixed with screws



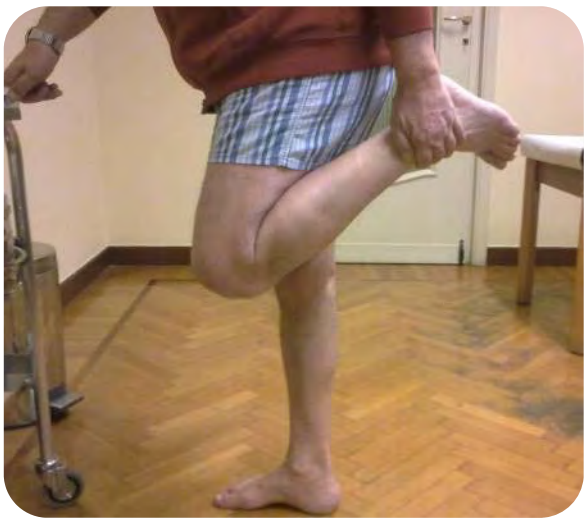
Post-op Xray



2 months post-op Xray



4 months post-op Xray



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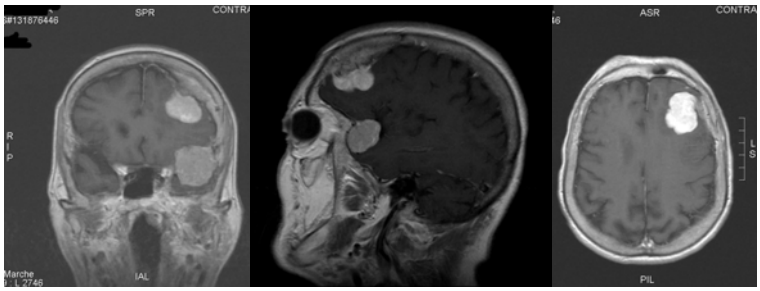
CLINICAL SERIES

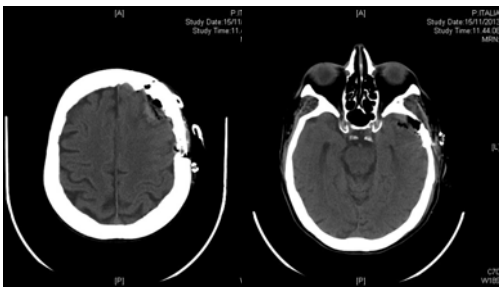
***A novel equine-derived pericardium membrane for dural repair: a preliminary, short-term investigation.**

Roberto Centonze MD, Emiliano Agostini MD, Samantha Massaccesi MD, Stefano Toninelli MD, Letterio Morabito MD
Division of Neurosurgery, Azienda Ospedaliera Marche Nord, Pesaro, Italy

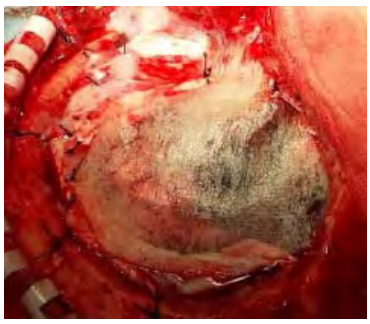
Background: A large variety of biological and artificial materials are employed in dural repair, each of them with major limitations: autologous grafts have limited availability and involves an additional incision and surgical time; cadaveric preparations and heterologous materials entail the risk of *iatrogenic transmission of prions* whereas synthetic substitutes have been reported to cause inflammatory reactions and graft rejection. An equine-derived pericardium membrane has been developed (Heart^{Ò} Bioteck, Vicenza, Italy) with mechanical and safety-related features that would make it suitable for neurosurgical application.
Aims: This preliminary study aimed to evaluate the short-term safety and efficacy of Heart^{Ò} membrane in dural repair procedures following meningioma surgeries.
Methods: The medical records of 8 patients surgically treated for an intracranial meningioma and undergoing duraplasty with the Heart membrane were reviewed retrospectively. Clinical and radiological assessments were performed on the 1st and 30th post-operative days. The occurrence of graft-related complications, such as cerebrospinal fluid (CSF) leakage, post-operative hematoma, wound infections, meningitis and neurological symptoms were analysed.
Results: A watertight closure was achieved in all the patients. Post-operatively, no patients exhibited CSF leak, cerebral contusion, haemorrhage or wound infections. The one-month follow-up revealed no evidence of pseudomeningocele, wound breakdown or meningitis. N*eurologic complications were observed in 3 patients but not directly imputable to the dural substitute or its application*
Conclusions: The pericardium membrane allowed to achieve watertight dural closure without graft-related adverse events in all the patients. Further investigations should be performed to assess medium- and long-term clinical outcomes in a larger set of patients.



TC pre-op



TC post-op



The membrane is sutured for covering the defect

** Paper submitted for pubblications*

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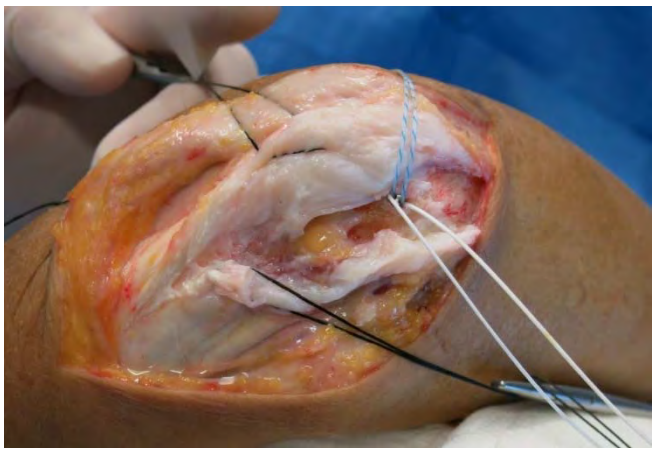
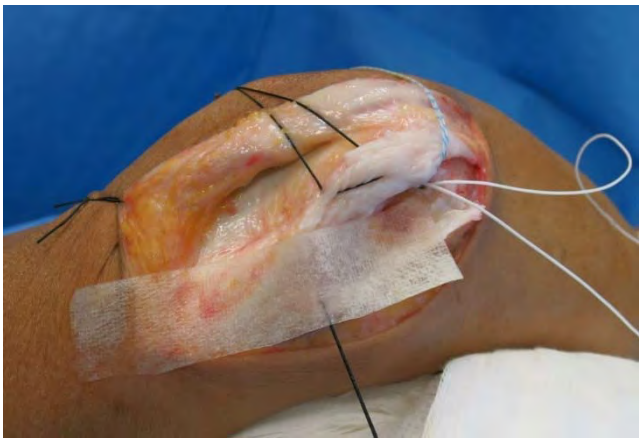
CLINICAL CASE HEART PATCH 1
AVULSION OF TRICEPS BRACHII

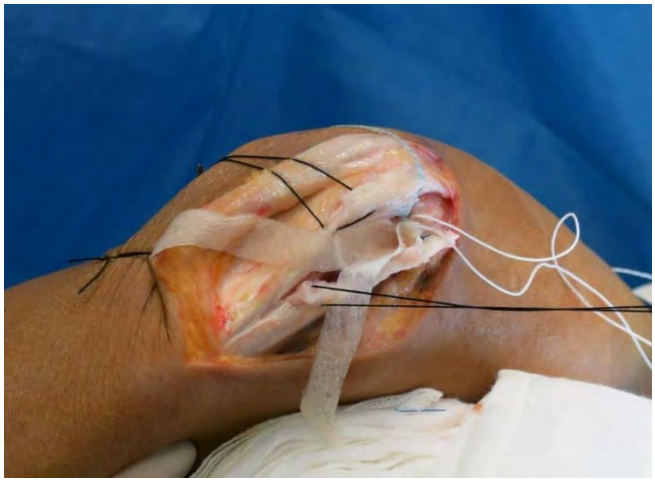
Courtesy of Andrea Atzei, MD. – Hand Surgeon, Treviso

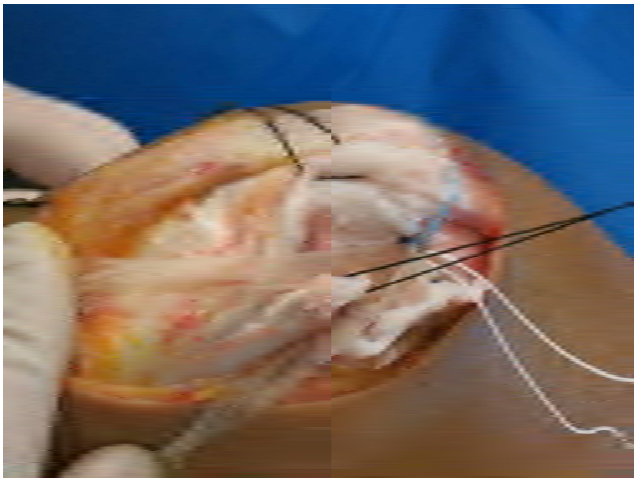


Bone Anchor fixation

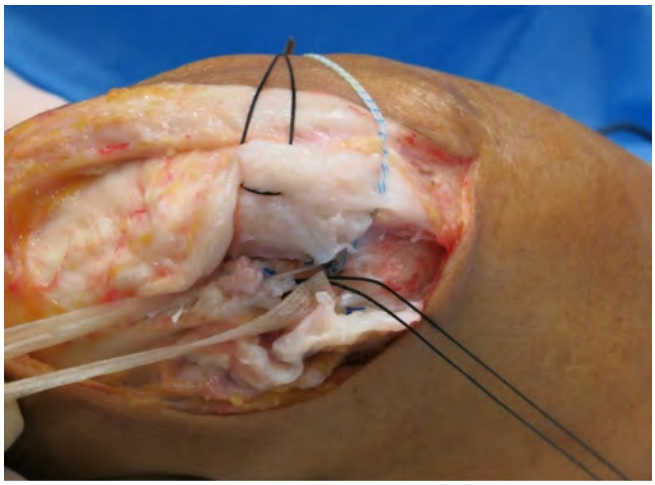


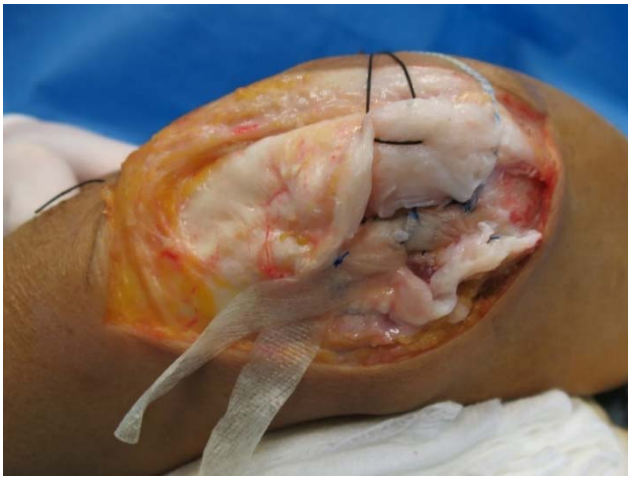
Heart® Patch to bridge the gap





Heart® Patch secured to Bone Anchor





Wrapping the Triceps Rafe Tendon

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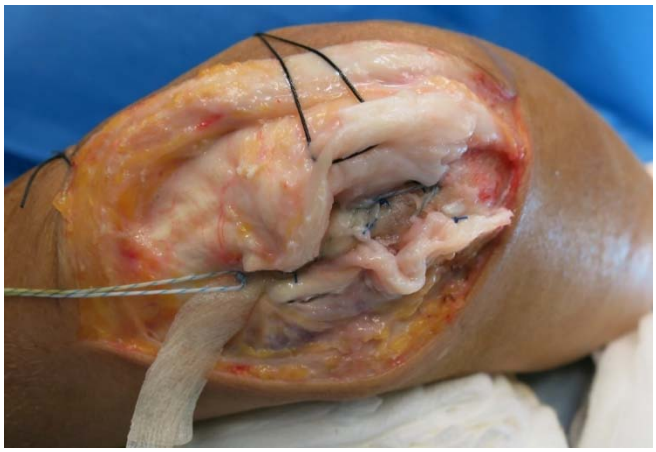
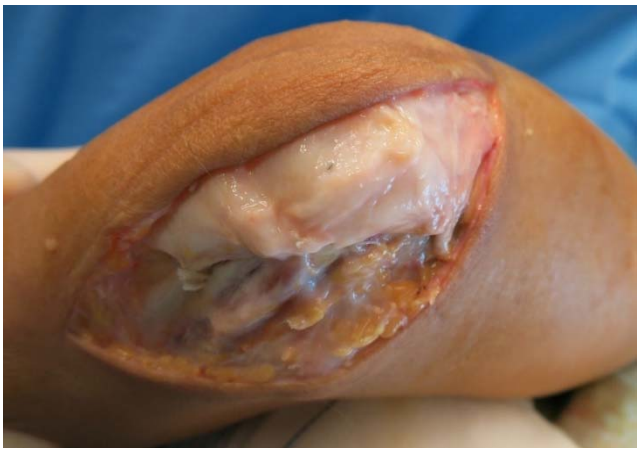


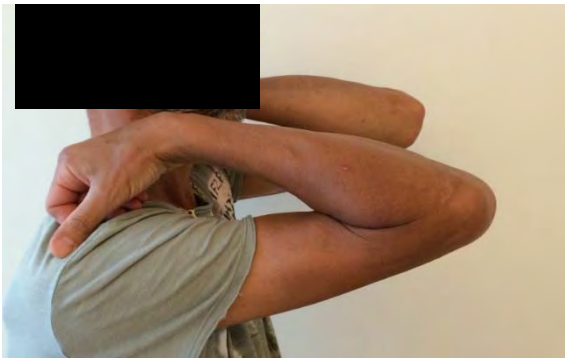
Core Sutures cross Heart® Patch

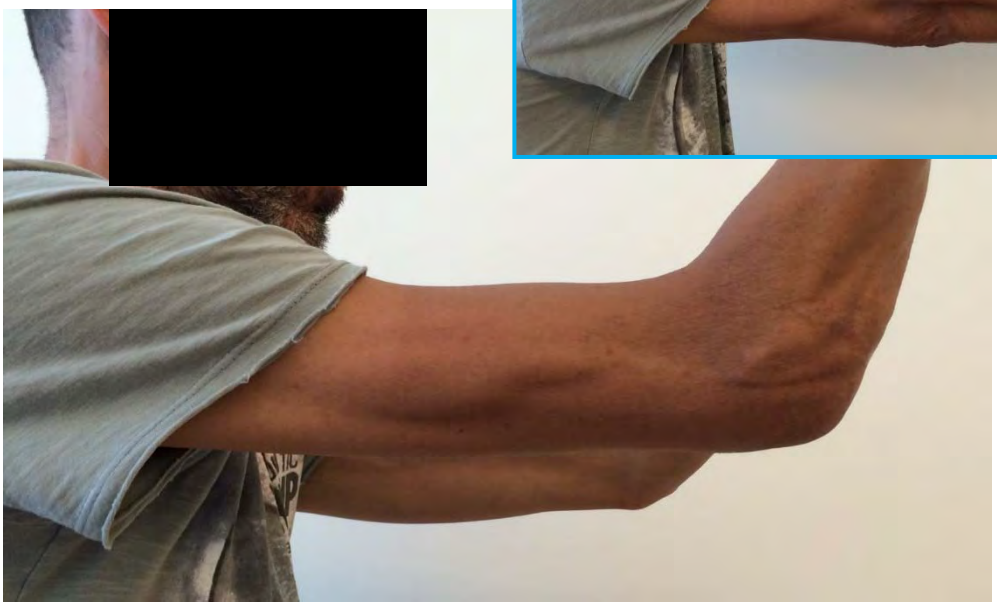


Soft tissue wrap around the Patch

<u>18 months P.O.</u>

Full ROM
90% strength





CLINICAL CASE HEART PATCH 2 AUGMENTATION OF CHRONIC RUPTURE DISTAL BICEPS TENDON

Courtesy of Andrea Atzei, MD. – Hand Surgeon, Treviso

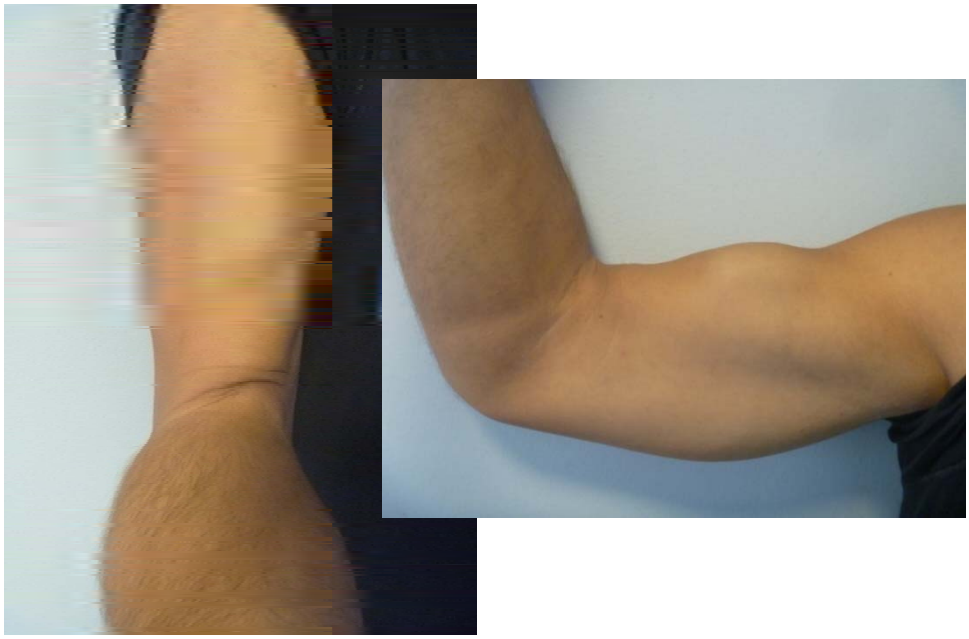
male - 28 yo heavy laborer

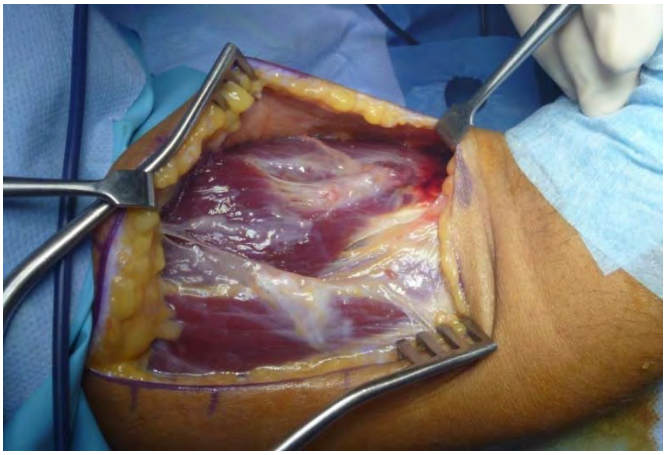
Closed injury palmar aspect right dominant elbow

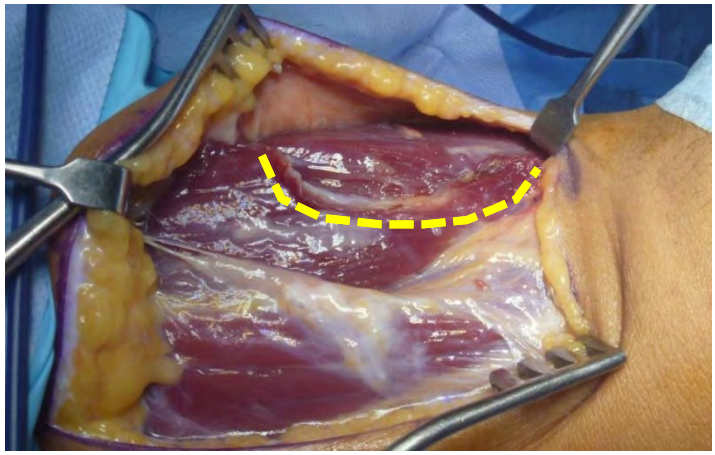
misdiagnosed as muscular “contusion” of the biceps brachii

left untreated.

After 2 months severe impairment of elbow flexion







Sub-total rupture of biceps brachii at teno-muscular junction 5 cm gap

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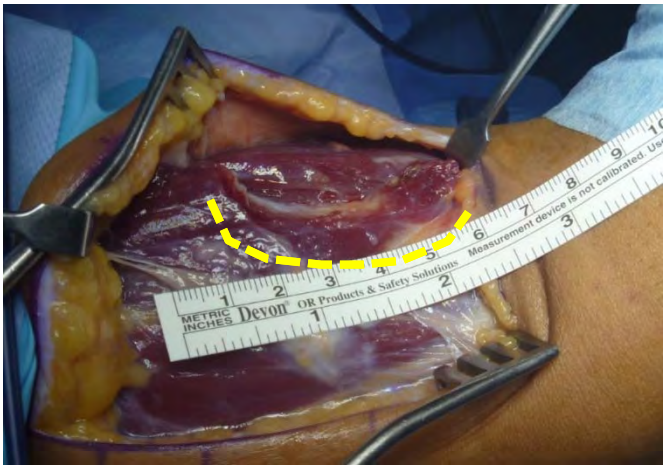
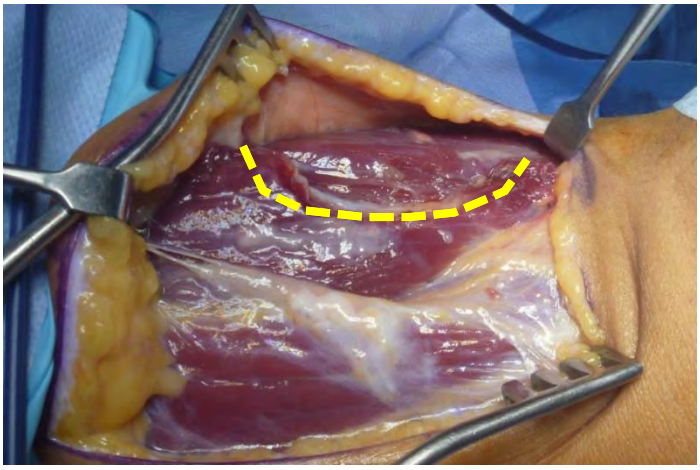
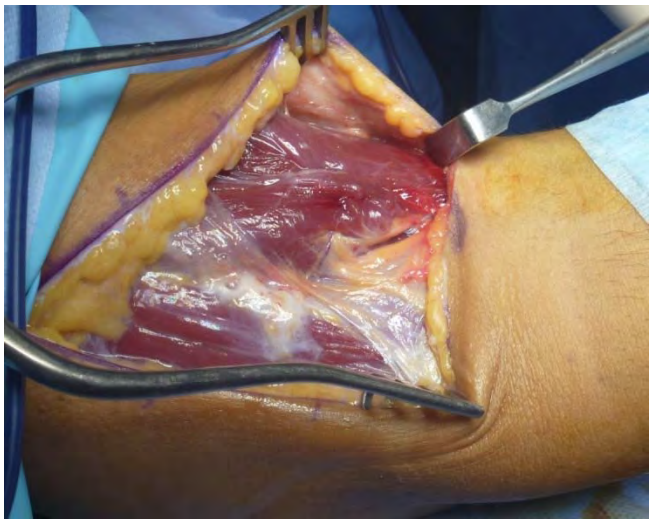
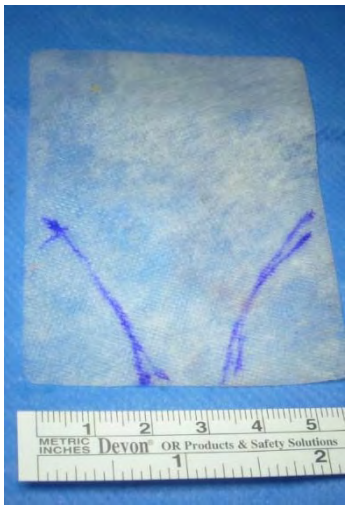
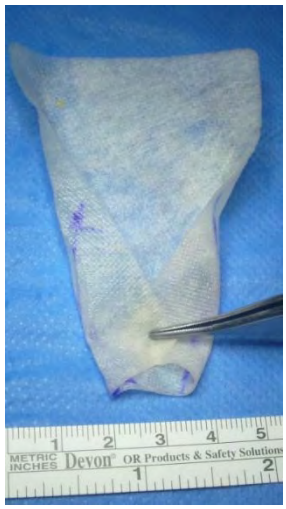




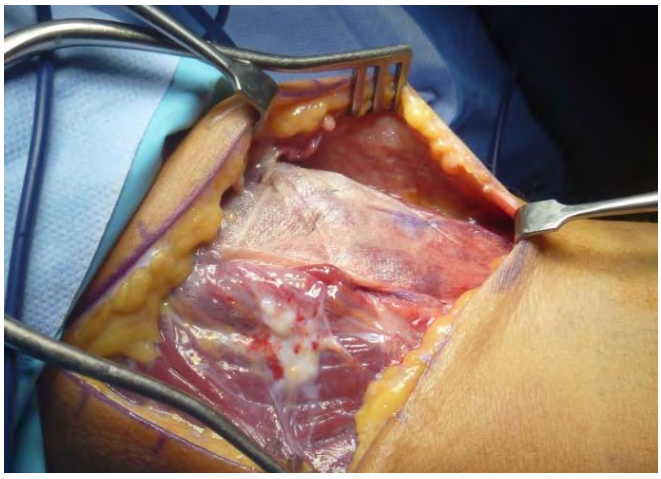


Two core sutures (Ethibond #2)

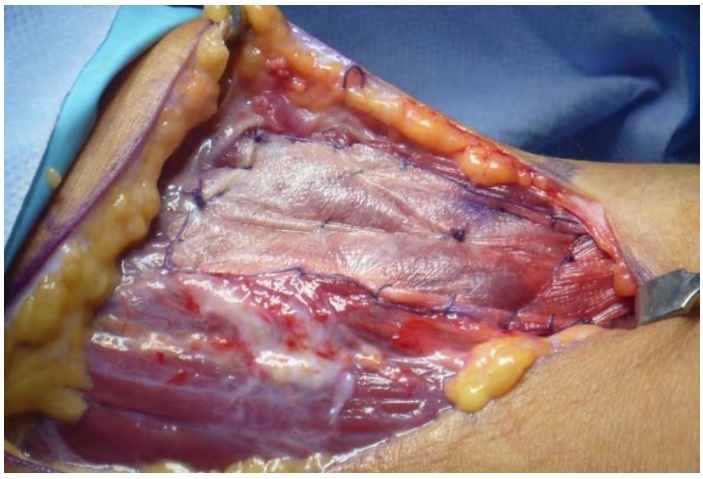




Preparation of the graft cutting Heart® Patch



Augmentation with Heart® Patch



Ethibond 2-0 interrupted sutures
at periphery and central

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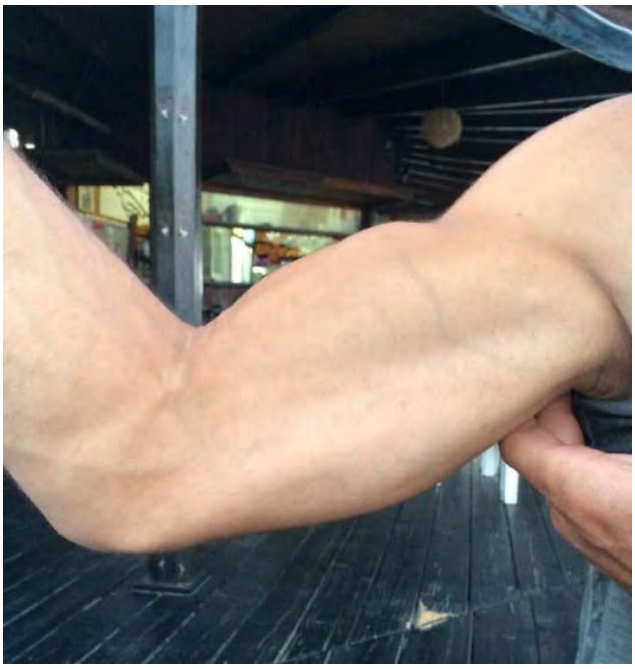

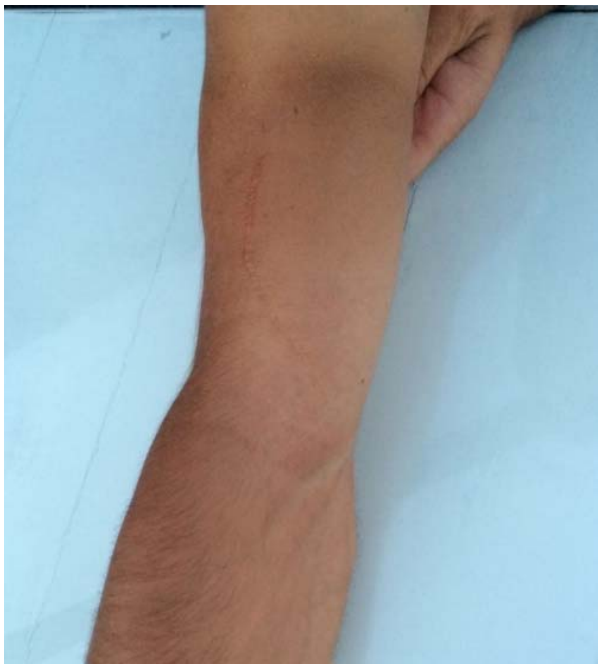

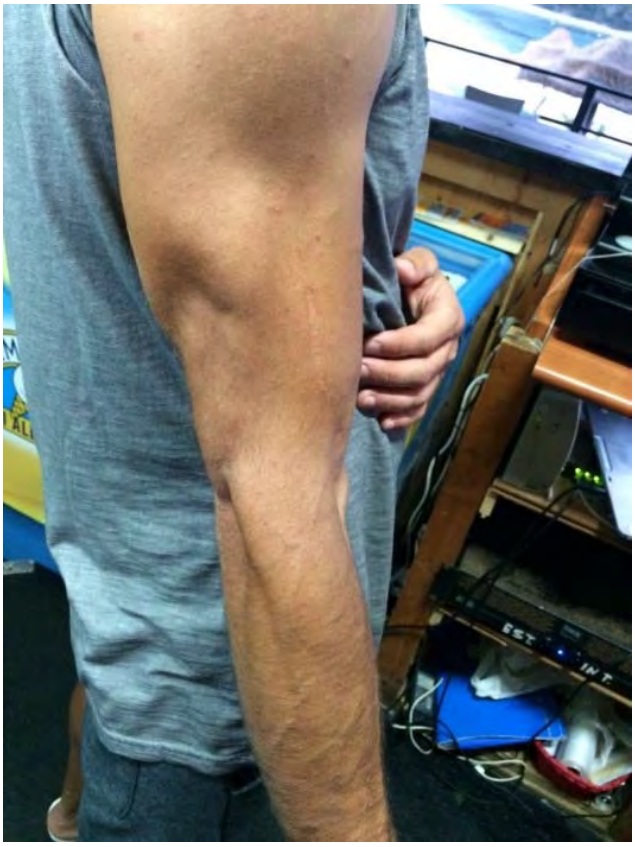

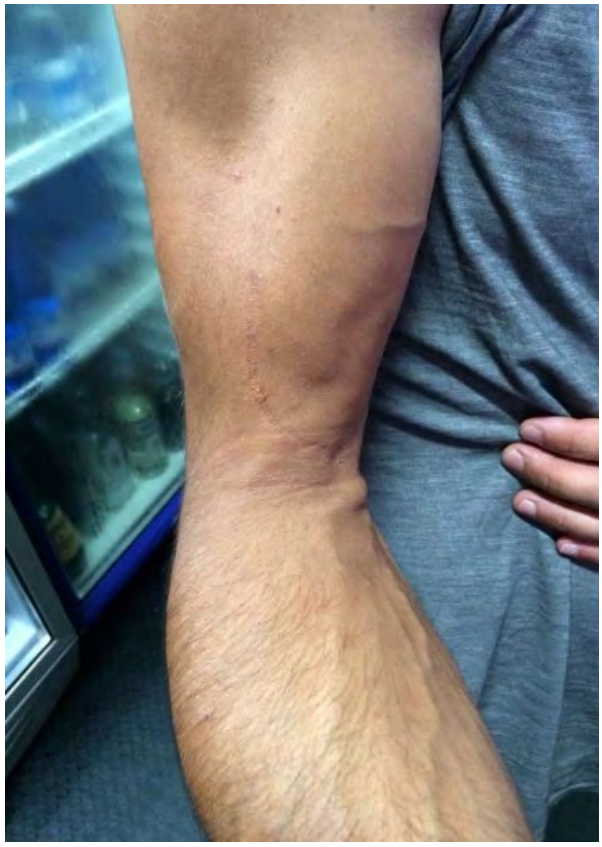

16 months P.O.

Full ROM
90% strength

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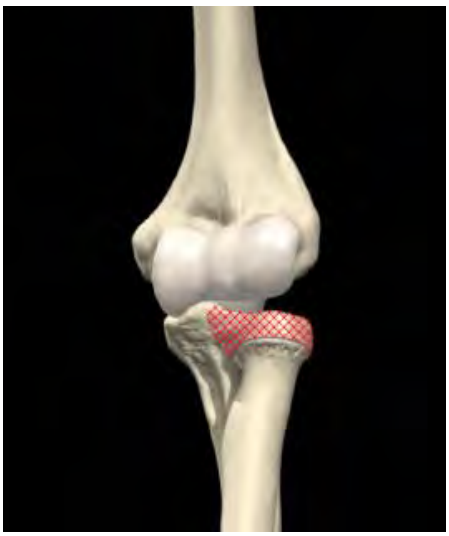
CLINICAL CASE HEART PATCH 3 AUGMENTATION OF ANULAR LIGAMENT RECOSTRUCTION

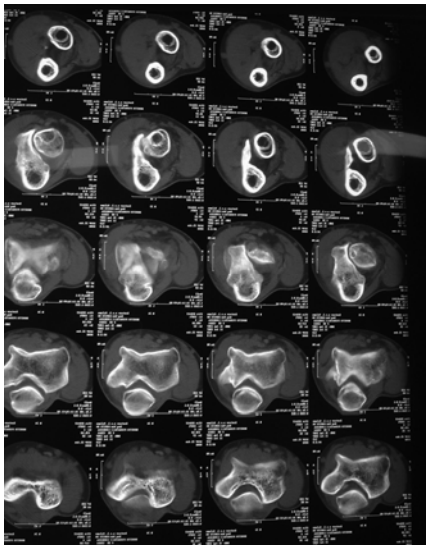
Courtesy of Andrea Atzei, MD. – Hand Surgeon, Treviso

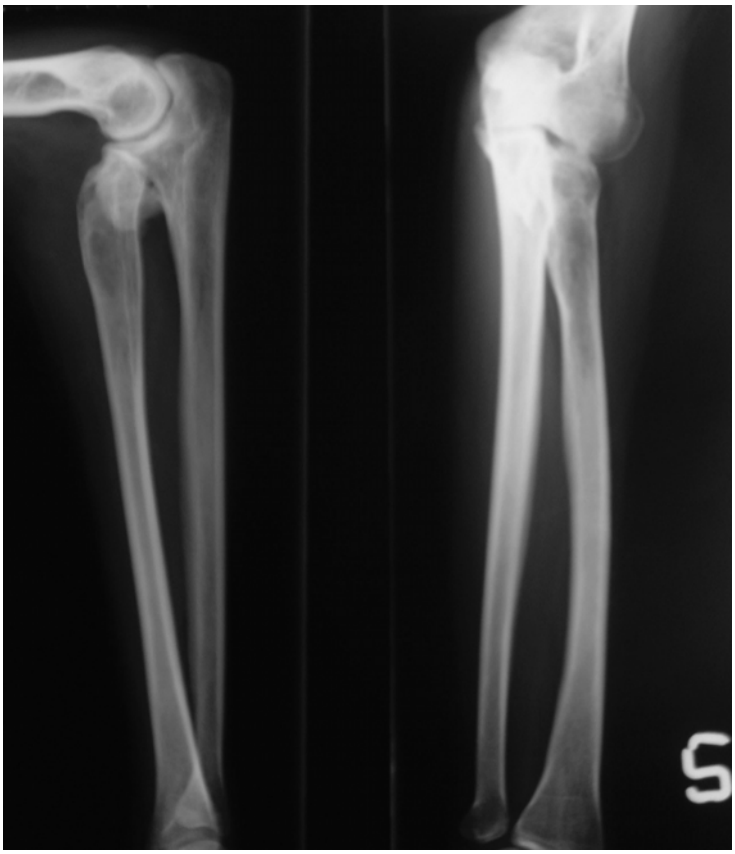
20 y-o female

13 years earlier post-traumatic isolated Proximal Radio-Ulnar Dislocation



Anular Ligament





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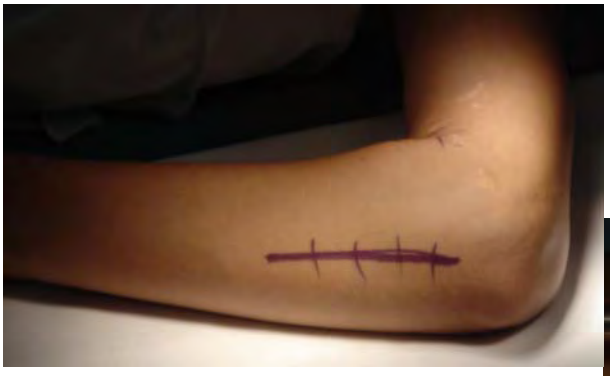
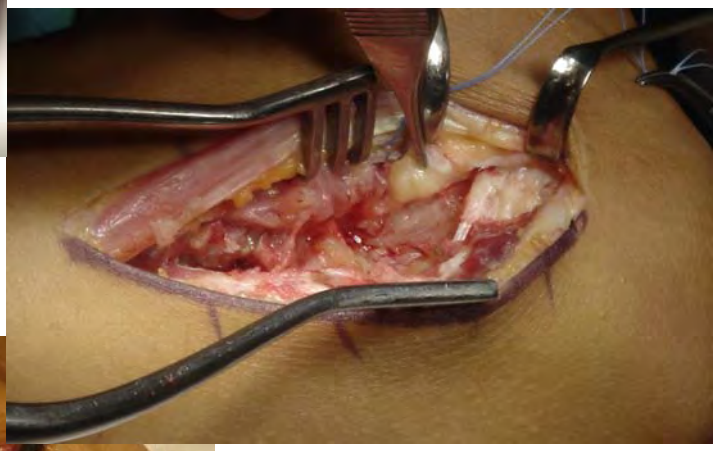
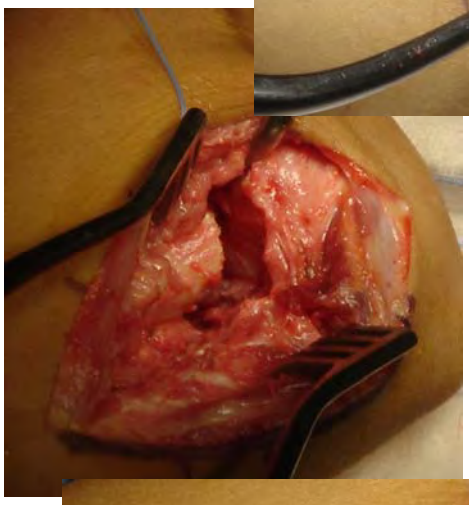
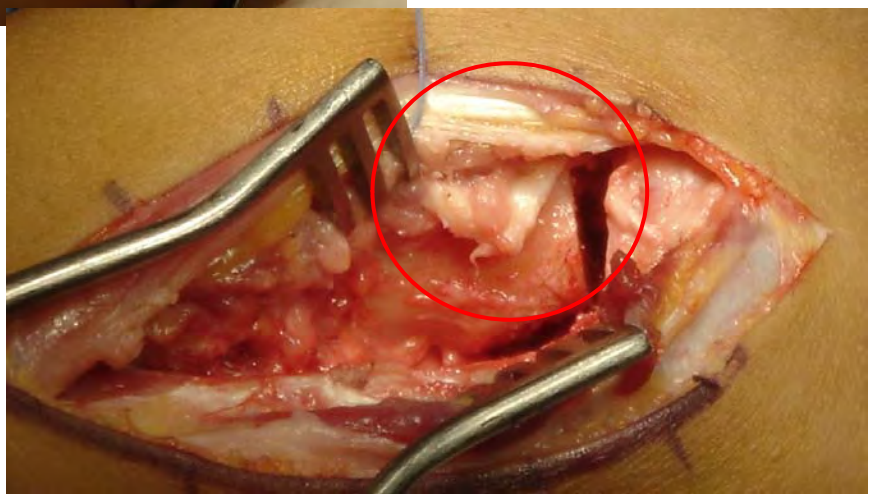




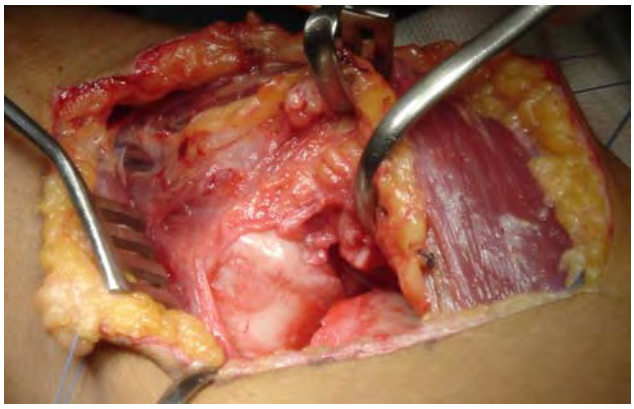
Lateral Approach
To PRU-j



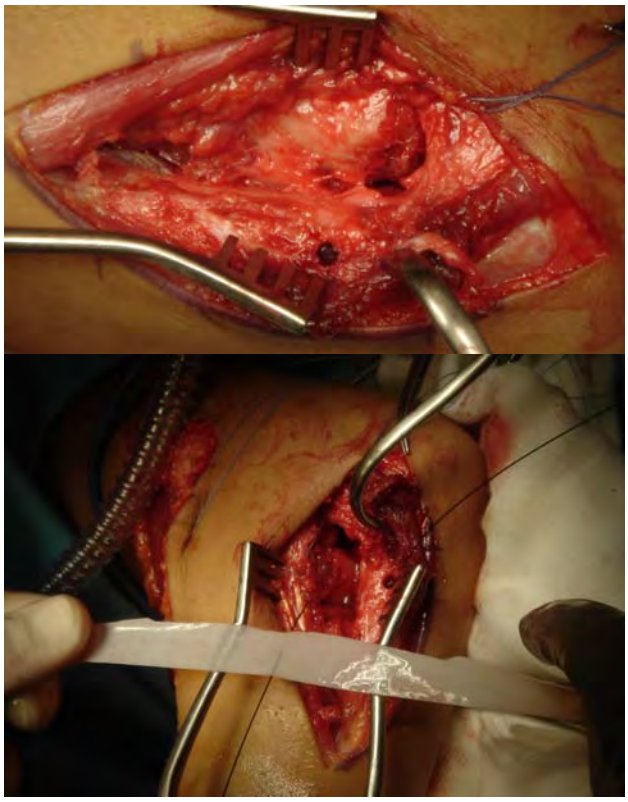


Radial Head
Resection & Reduction

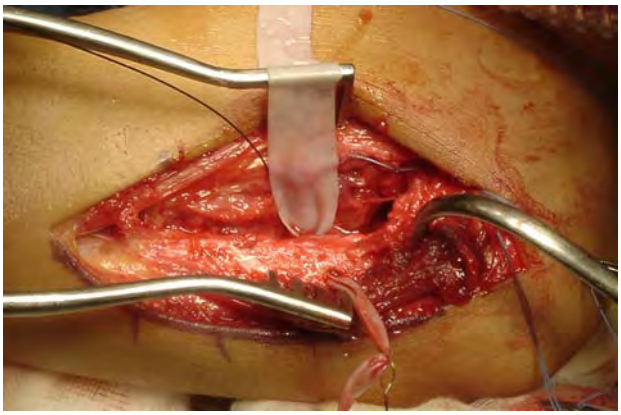
Ligament remnants



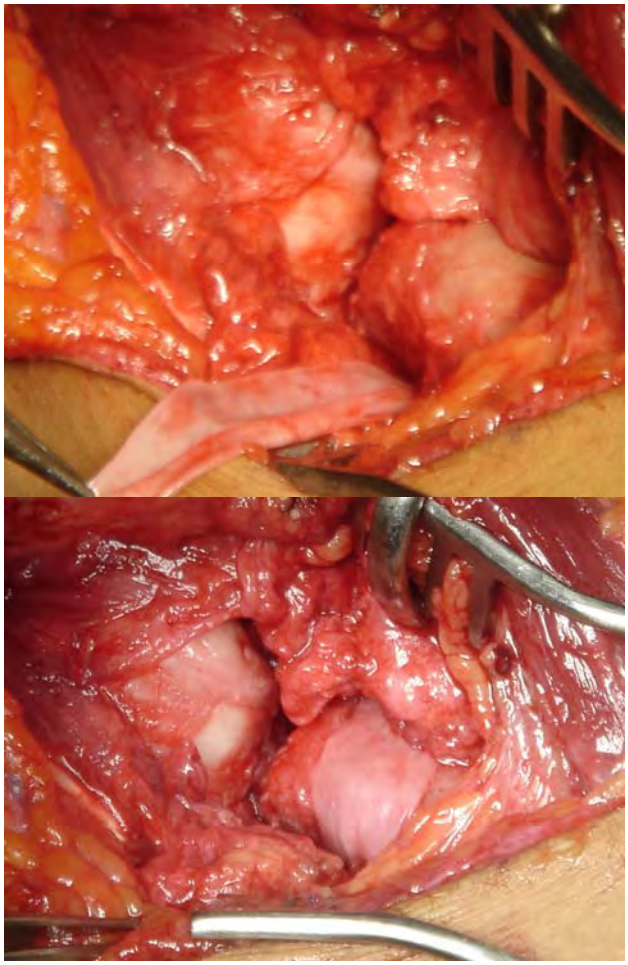
Anterior Approach to PRU-j

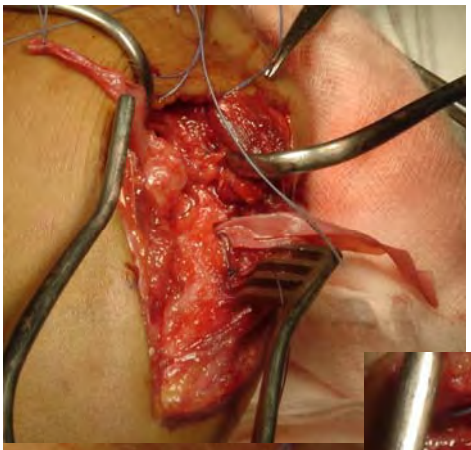


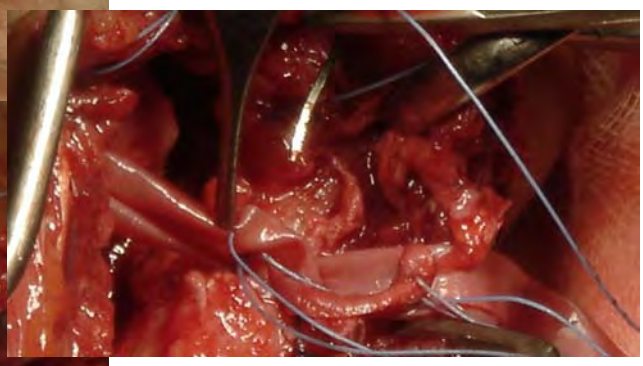
Harvesting bone tunnel
for Graft Fixation

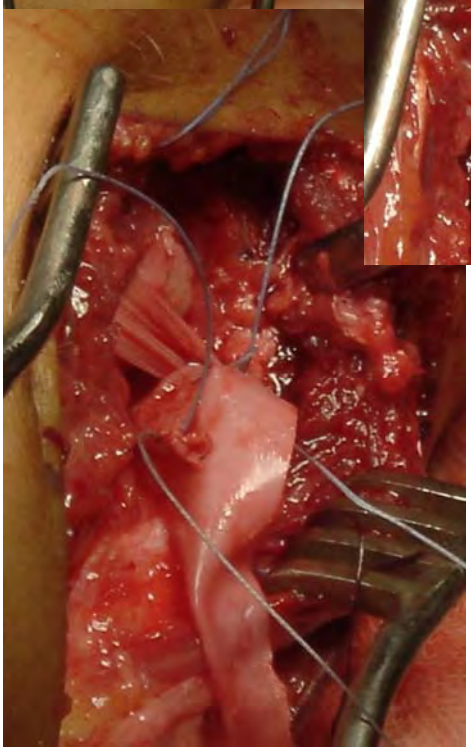


Positioning Graft around Radial Neck



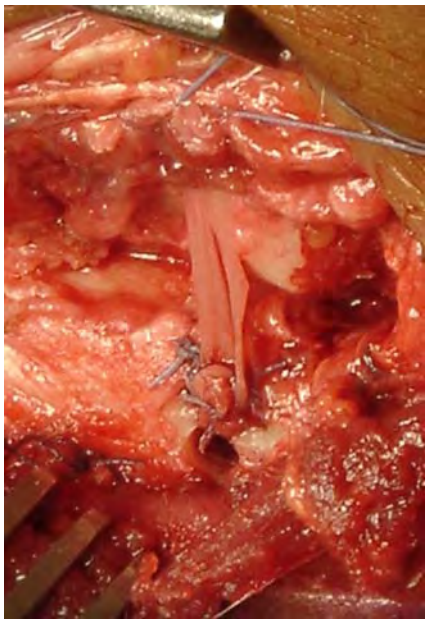


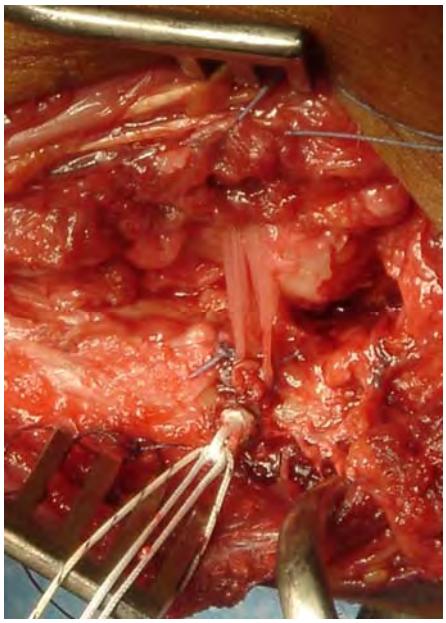




Suturing Graft To ligament remnants with interrupted sutures

Bone Anchor to fix Graft To the bone tunnel





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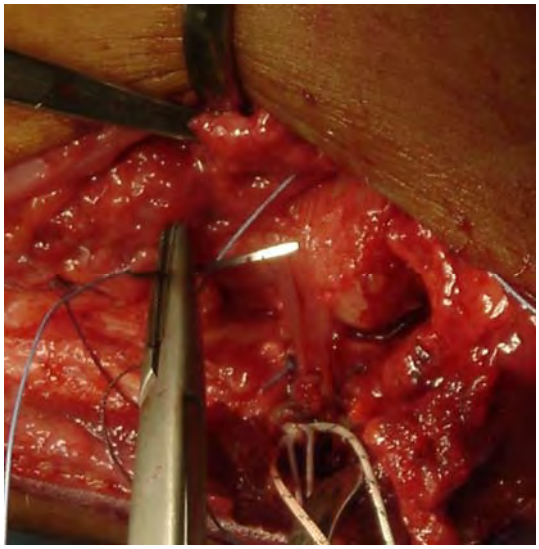
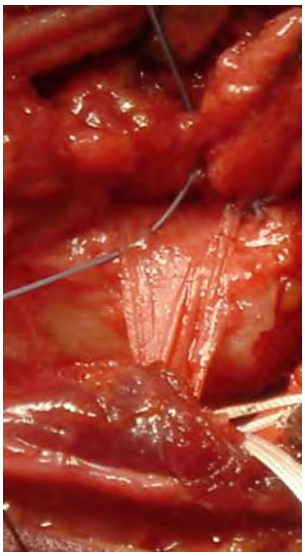
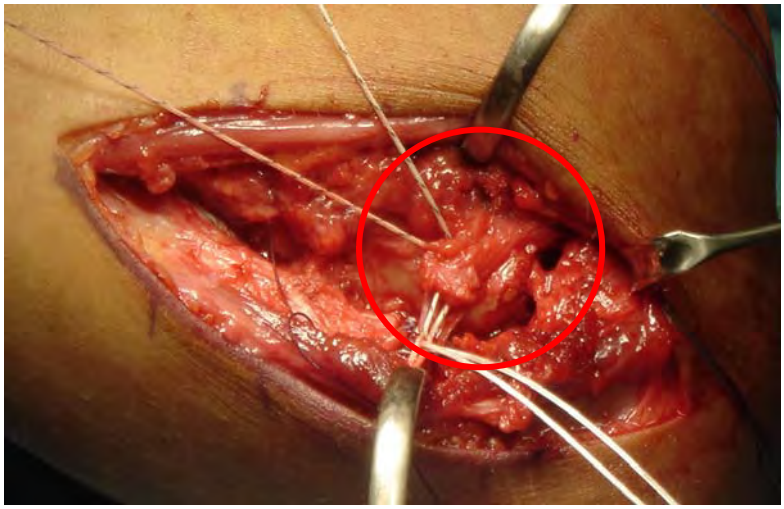
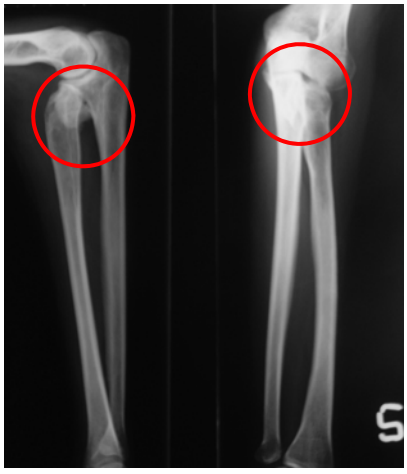


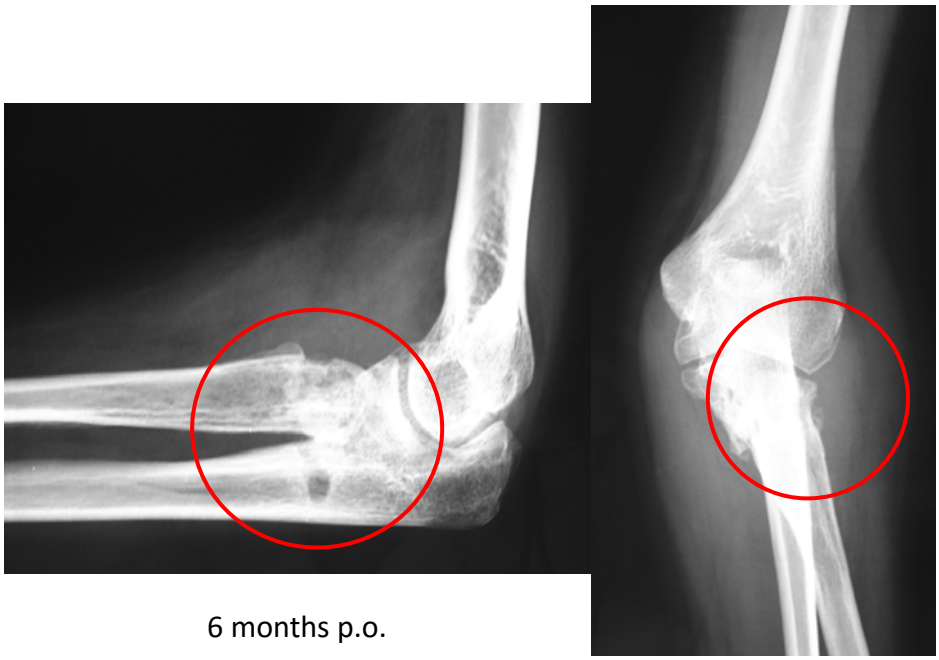


Suturing ligament
with Graft
And securing
with anchors sutures





Pre-op.



6 months p.o.

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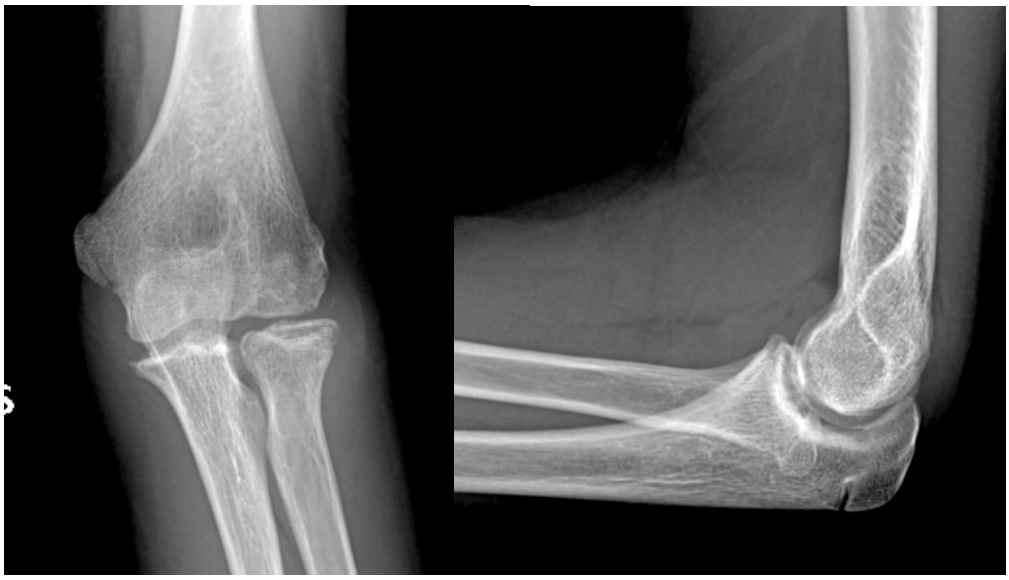
CLINICAL CASE HEART PATCH 4
INTERPOSITION ARTHROPLASTY POST-TRAUMATIC DISPLASTIC RADIAL HEAD RESECTION

Courtesy of Andrea Atzei, MD. – Hand Surgeon, Treviso

male - 16 yo
aerospatial student
(aircraft pilot)

Radial head fracture
left non-dominant elbow

early arthritis
of the
capitellum



Restricted elbow motion

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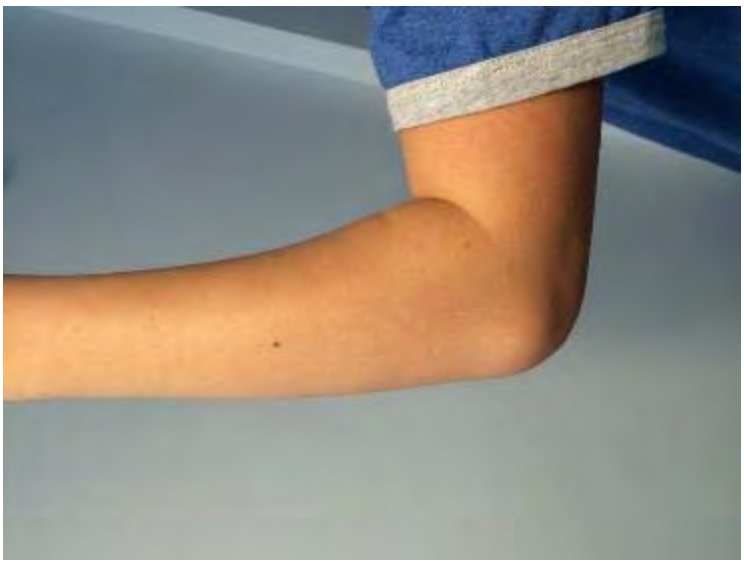
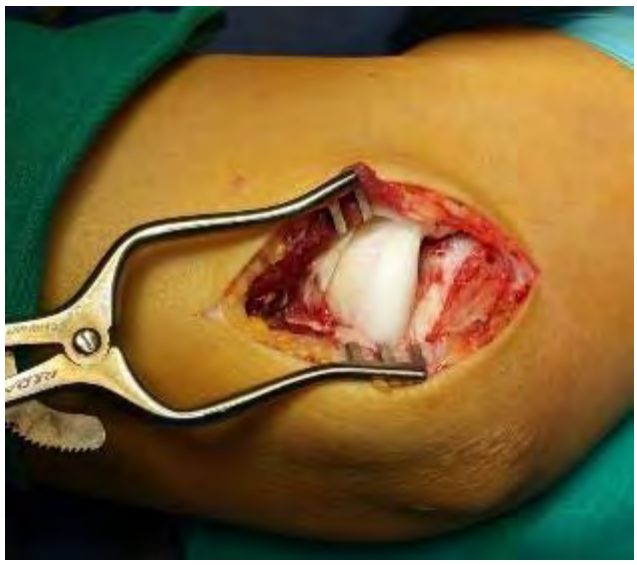
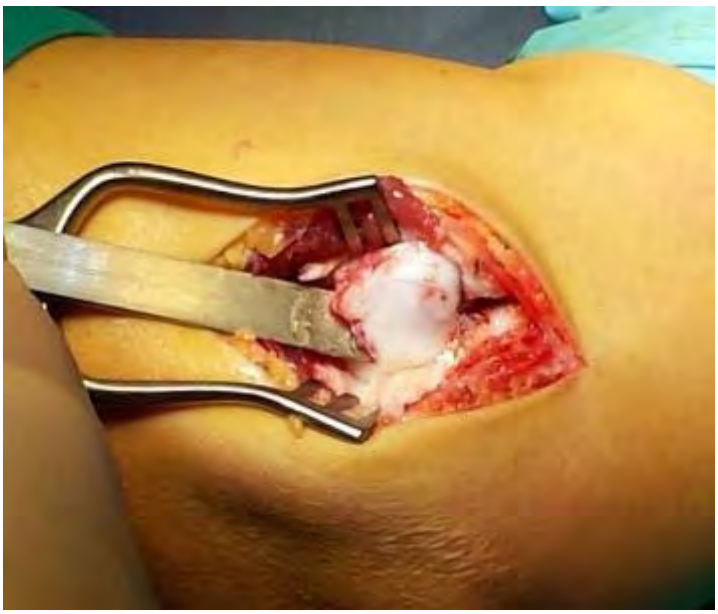
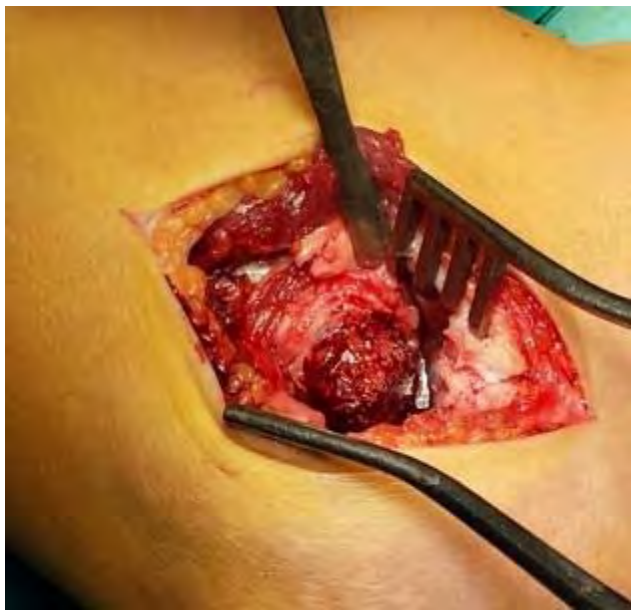
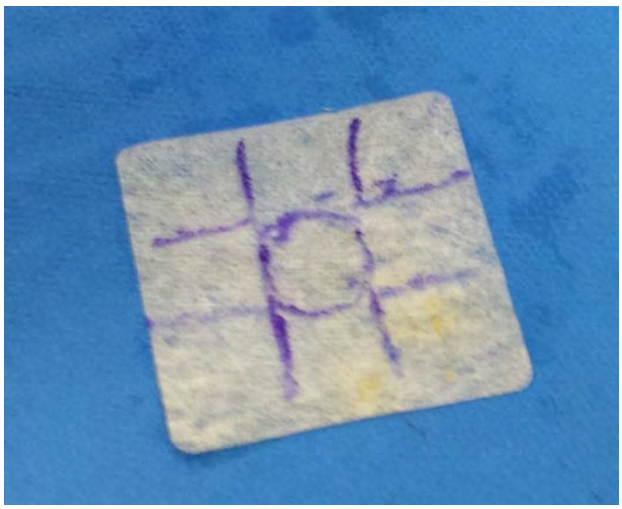


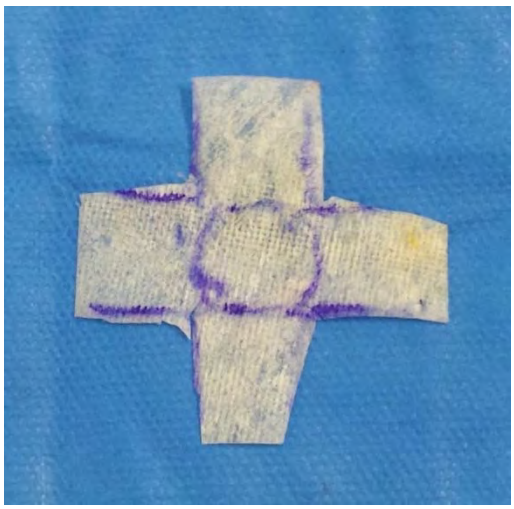


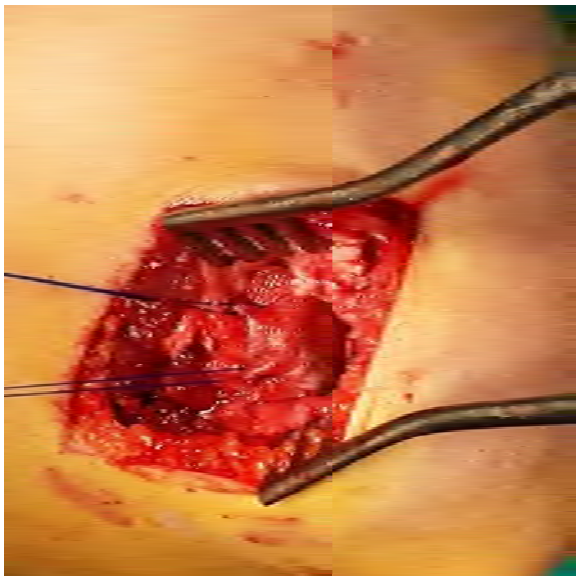


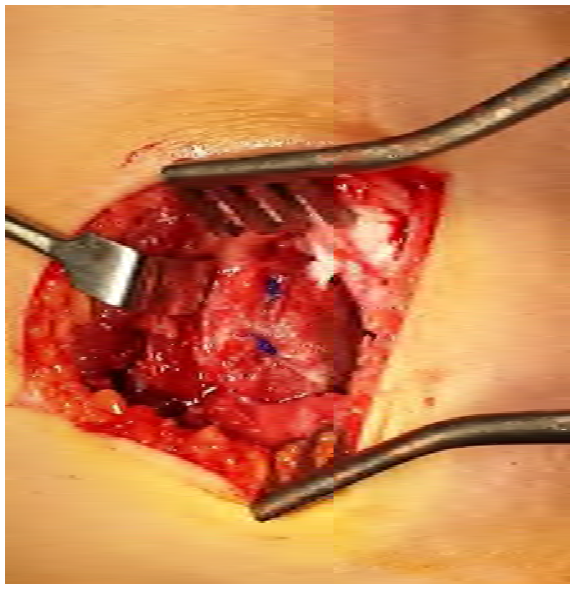


Radial head Resection









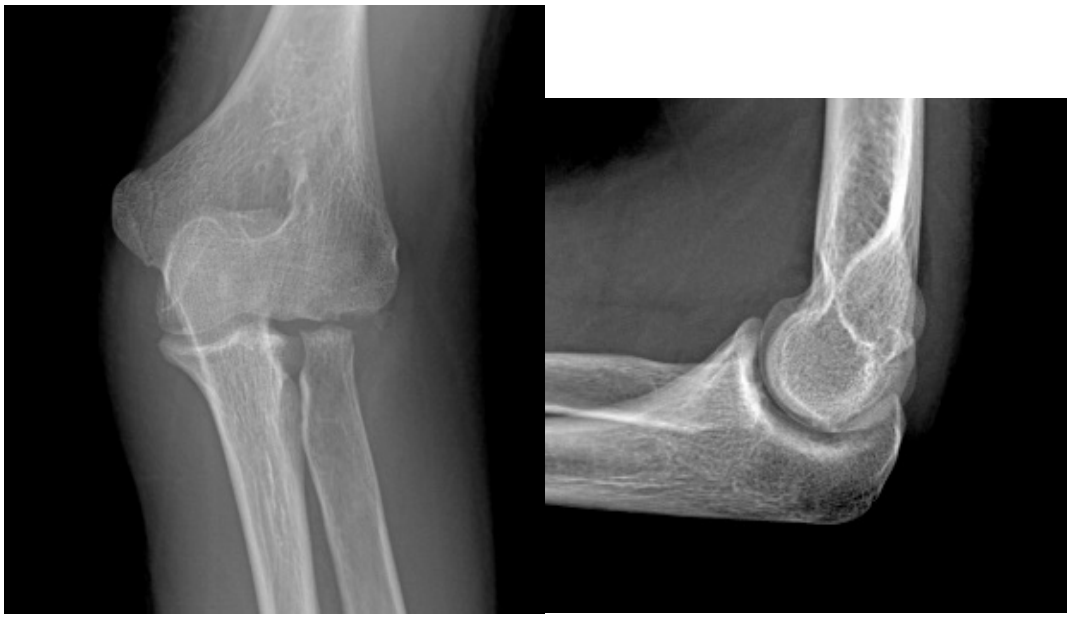
Resurfacing /interposition Arthroplasty

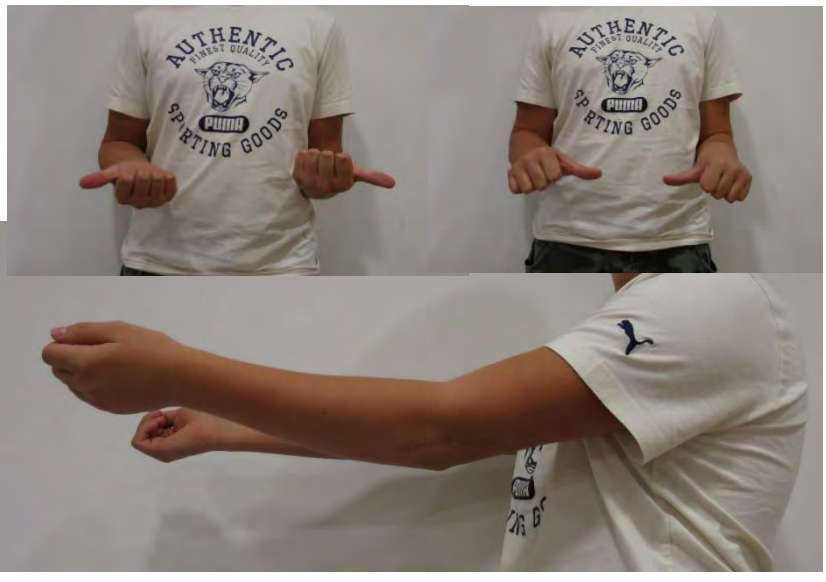
<u>18 months P.O.</u>

ROM 90%

90% strength

Stable PRUJ





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