RIGENERA™

Micrografts Applications in ORAL & MAXILLO-FACIAL SURGERY

Editors: **Dr. Graziano A. , Dr. D'Aquino R.**



A UNIQUE SINERGY OF
SCIENCE & INNOVATION
IN REGENERATIVE MEDICINE

REMEDI

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RIGENERA®TECHNOLOGY

The Rigenera® Technology consists of disposable devices named Rigeneracons in combination with different activators, such as the Sicurdrill device or the N4SA Machine.
This technology has obtained CE, and FMA certification moreover it is FDA listed. The Rigeneracons disposable devices is a mechanical disruptors of biological tissues (skin) that allow to obtain micrografts in an autologous, homologous, and minimally invasive manner. The main feature of the Rigeneracons device is the ability to disaggregate different tissue types (dermis, cartilage and bone) and the obtained volume of micrograft suspensions.

The Rigenera® Technology is currently applied in Aesthetic Medicine and Dermatology, Orthopedics and Rehabilitation, Wound care and Plastic surgery, Oral & Maxillo-facial Surgery. More specifically, the use of Rigenera® in Oral & Maxillo-facial Surgery refers to the use of micrografts for: (1) Socket preservation or Implant Surgery, (2) Sinus lift augmentation, (3) Periodontal regeneration, (4) Mucogingival application and (5) Osteonecrosis.

Recent evidence suggests its use also in the field of cardiac regeneration, such application is still at the R&D stage. The Rigeneracons device consist of a grid with 100 hexagonal holes, each hole is 80 Microns in size and equipped with six microblades, responsible for the tissue disaggregation.

The surgical the surgical motor, with 80 rpm with a torque of 15 [N*m] for 3 minutes, activates the Rigeneracons by gently pressing the tissue onto the micro-blade. Lastly while the sample is processed, the calibrated holes act as a filter by selecting only the particles and cells smaller than 80 microns in a reservoir and later collected by the doctors as a Micrografts. The entire procedure (disaggregation and grafting) occurs in one surgical time, that lasts about 30 minutes and the patient is both donor and acceptor of the tissue.

Scientific studies have shown that the cellular population obtained after the mechanical disaggregation is positive for mesenchymal stem cells markers identifying those cells as Progenitor Cells (PC) and have shown a viability ranging between 70-90% (Trovato L, et al. J Cell Physiol. 2015). Moreover, subsequent analysis displays that micrografts contain a high percentage of Stromal Vascular Fraction Cell (SVF) and Progenitor Cells which play a key role in tissue regeneration by promoting revascularization and regrowth.

The Rigenera® technology does not present any type of risk to the patient, as it is minimally invasive. Likewise, there are no risks for the personnel, as the use is simple and possible even in private practice.

MICROGRAFTS THEORY

Rigenera® Technology is based on two fundamental pillars of regenerative biology:

- **Principle 1: The side population.**

Numerous scientific papers have demonstrated that progenitor cells (PC) reside within the adult tissue but have determined morphological features. The main features of these cells are: (1) the size, and (2) a significantly higher stem cell marker expression.

- **Principle 2: The niche concept.**

Preserving the extracellular matrix (ECM) allows the cells to maintain their physiological niche. This specific environment not only improves cell viability, but also gives the progenitor cells the appropriate growth factors that support their role in the regenerative process.





RIGENERA HBW

PROTOCOLS



MICROGRAFTS WITH RIGENERACONS FOR SOCKET PRESERVATION OR IMPLANT SURGERY

PROCEDURE:

A.Harvest the tissue sample:
The Periosteum can be taken, after making a partial thickness flap from the deep palatal mucosa or from the alveolar periosteum, with a scalpel or a punch biopsy.

B. Add 0.8ml of sterile saline solution, using a syringe through the hole on the edge of the device.

C. Place the harvested tissue sample on the grid (not on the helix) inside the Rigeneracons. Manually turn the device helix in order to cover the tissue sample.

D.Connect the Rigeneracons, with the adapter, to the the Surgical Motor, connect the Rigeneracons with the specific Adacons adapter and use the machine at 80 RPM for 3 min.

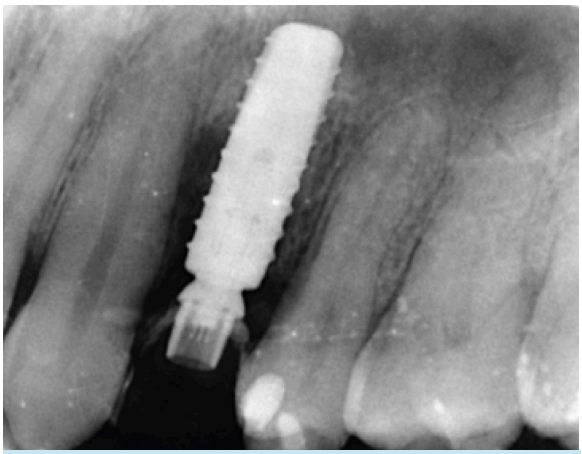
E.Collect the micrografts suspension with a syringe from the same hole in which the saline solution was previously injected.

F.Inject the obtained micrografts solution with the selected scaffold (collagen or different) and place it onto the surgical defect.

Dr. D'Aquino R.



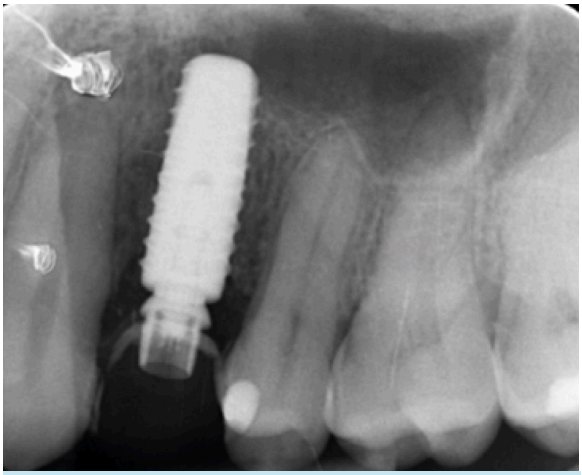
BEFORE



AFTER



30 DAYS AFTER



90 DAYS AFTER

Journal of Translational Science

Research Article ISSN: 2059-268X

Periosteum-derived micro-grafts for tissue regeneration of human maxillary bone

Riccardo d'Aquino[1,2], Letizia Trovato[2]*, Antonio Graziano[2], Gabriele Ceccarelli[3], Gabriella Cusella de Angelis[3], Angelo Marangini[4], Alessandro Nisio[5], Massimo Galli[6], Massimo Pasi[7], Marco Finotti[8], Saturnino M Lupi[9], Silvana Rizzo[9] and Ruggero Rodriguez Y Baena[9]

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[3]Department of Public Health, Experimental Medicine and Forensics, University of Pavia, Pavia, Italy [4]Oral Surgeon,Naples, Italy

[5]Oral Surgeon, Bari, Italy

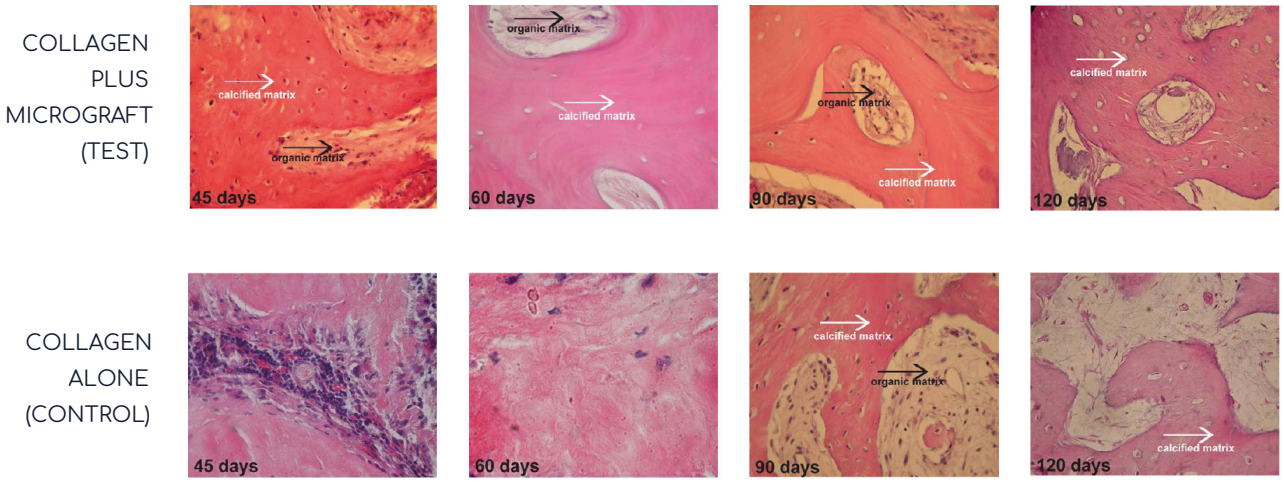
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Abstract

The bone regeneration is one of the most important challenges for regenerative medicine. In maxillo-facial area, bone resorption of the alveolar crest occurs after tooth extraction and leads to several risks for rehabilitation treatments, including dental implants procedures. Goal of our study was to demonstrate the efficacy of an innovative clinical protocol of bone tissue engineering called Rigenera protocol, aimed to create and optimize bio-complexes constituted by collagen biomaterial and human autologous periosteum-derived micro-grafts. We assessed the capacity of these bio-complexes to prevent the bone resorption in the alveolar crest with respect to simple collagen performing histological evaluations of neo-formed osseous tissue. We demonstrated that autologous bio-complexes significantly reduced the bone resorption of both horizontal and vertical dimension of alveolar crest when compared to collagen alone. We also showed that these bio-complexes accelerate the ossification process triggering the formation of new osseous tissue after 45 days from treatment and increasing the calcified matrix after 60 days and until to 120 days with respect to collagen alone. Taken together, these data showed the efficacy of bio-complexes composed by periosteum-derived micro-grafts and collagen in the alveolar ridge preservation through a reduction of bone resorption and an enhancement of new osseous tissue formation.



Histological evaluation of core bone sections collected from Test and Control sites after 45, 60, 90 and 120 days from treatment. The sections were stained with Hematoxylin and Eosin as indicated in the appropriate section of patients and methods. The white arrows indicate the calcified matrix, while the black arrows indicate the organic matrix. The comparison of the samples treated with collagen alone (control) and collagen with periosteum-derived micro-grafts (test) showed that the ossification process is much faster in the Test group than Control group at each point.

Periosteum-derived micro-grafts for tissue regeneration of human maxillary bone D'Aquino R, Trovato L, Graziano A, Ceccarelli G, Cusella de Angelis G, Marangini A, Nisio A, Galli M, Pasi M, Finotti M, Lupi S, Rizzo S and Rodriguez Y Baena R J Transl Sci, 2016 doi: 10.15761/JTS.1000128

MICROGRAFTS WITH RIGENERACONS FOR SINUS LIFT AUGMENTATION

PROCEDURE:

A.Harvest the tissue sample:

The Periosteum can be taken, after making a partial thickness flap from the deep palatal mucosa or from the alveolar periosteum, with a scalpel or a punch biopsy.

B. Add 0.8ml of sterile saline solution, using a syringe through the hole on the edge of the device.

C. Place the harvested tissue sample on the grid (not on the helix) inside the Rigeneracons. Manually turn the device helix in order to cover the tissue sample.

D.Connect the Rigeneracons, with the adapter, to the Surgical Motor, connect the Rigeneracons with the specific Adacons adapter and use the machine at 80 RPM for 3 min.

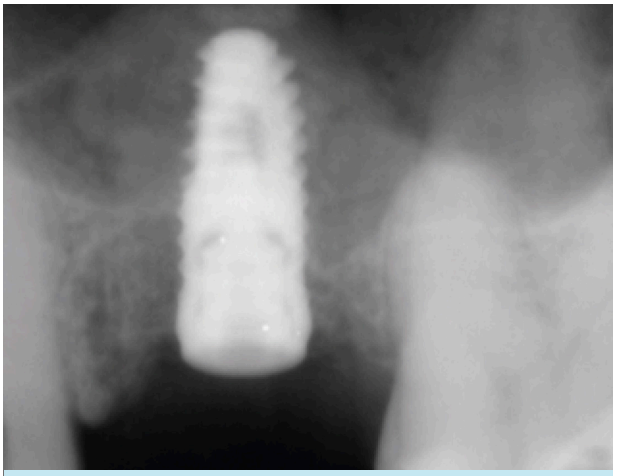
E.Collect the micrografts suspension with a syringe from the same hole in which the saline solution was previously injected.

F.Inject the obtained micrografts solution with the selected scaffold (collagen or different) and place it onto the surgical defect.

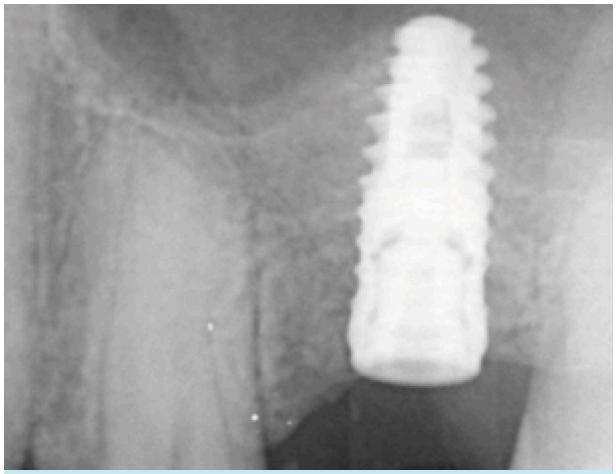
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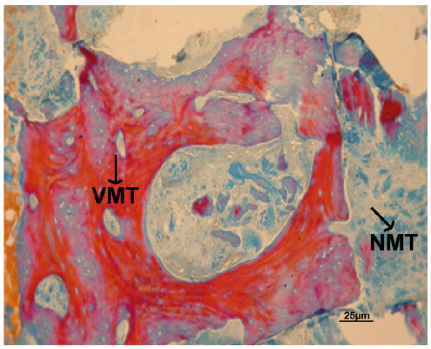
BEFORE



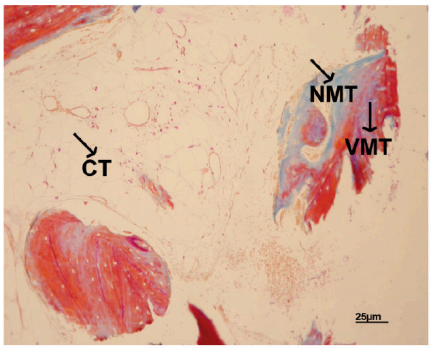
AFTER



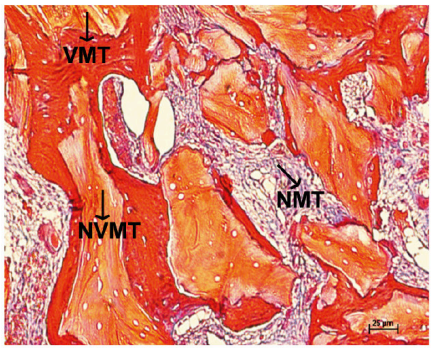
60 DAYS AFTER



Alos + micrografts (group A)

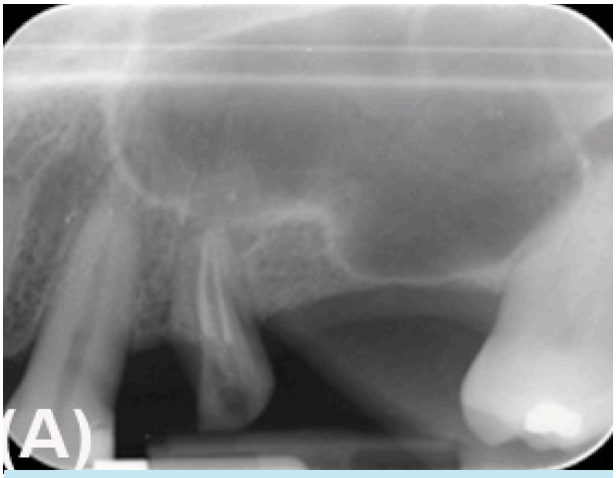


Alos alone (group B)

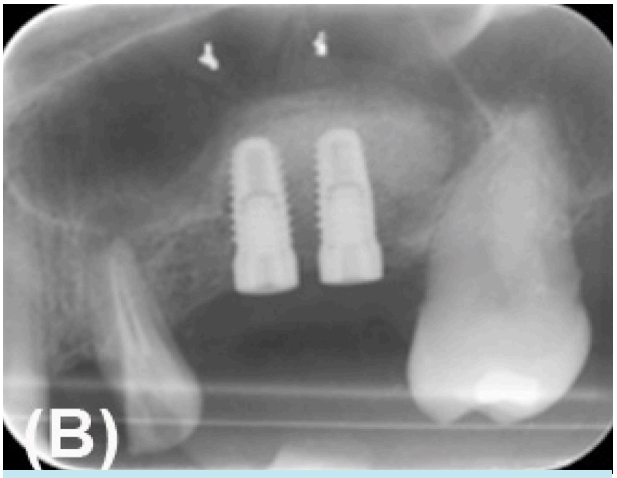


Bio-Oss alone (group C)

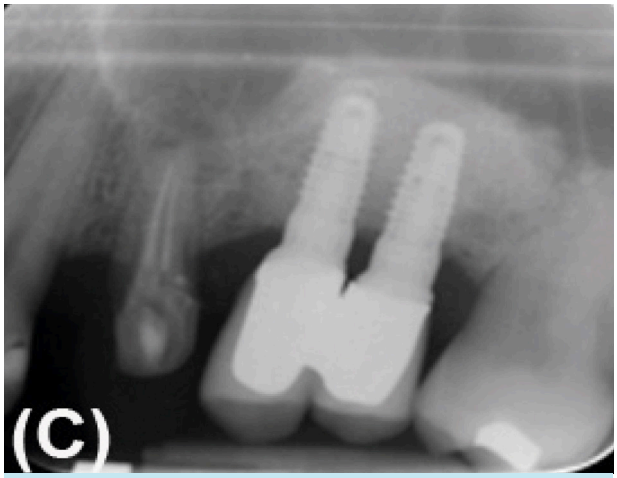
Histological evaluation after 4 months from micrografts application. The biopsies sections for each group of study were stained with Mallory's tricome technique as reported in the text. NVMT, nonvital mineralized tissue (orange); VMT, vital mineralized tissue (red); NMT non mineralized tissue (blue), CT connective tissue (magnification 40X; scale bar 25µm).



A



B



C

Radiography control after six months of micrografts application in patients treated with PLGA/HA + periosteum- derived micrografts. (A) Pre- surgical Rx. (B) Implant surgery Rx after 4 months and Rx after 2 years (C).

D'Aquino R, Trovato L, Graziano A, Ceccarelli G, Cusella de Angelis G, Marangini A, Nisio A, Galli M, Pasi M, Finotti M, Lupi SM, Rizzo S, Rodriguez Y Baena R. Periosteum-derived micro-grafts for tissue regeneration of human maxillary bone. Journal of Translational Science 2016, 2(2) 125-29 doi: 10.15761/ JTS.1000128

frontiers in Cell and Developmental Biology

ORIGINAL RESEARCH
published: 27 September 2017
doi: 10.3389/fcell.2017.00087

Autologous Periosteum-Derived Micrografts and PLGA/HA Enhance the Bone Formation in Sinus Lift Augmentation

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OPEN ACCESS

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Specialty section:
This article was submitted to Stem Cell Research, a section of the journal Frontiers in Cell and Developmental Biology

Received: 20 June 2017
Accepted: 12 September 2017
Published: 27 September 2017

Citation:
Rodriguez y Baena R, D'Aquino R, Graziano A, Trovato L, Aloise AC, Ceccarelli G, Cusella G, Pelegrine AA and Lupi SM (2017) Autologous Periosteum-Derived Micrografts and PLGA/HA Enhance the Bone Formation in Sinus Lift Augmentation. Front. Cell Dev. Biol. 5:87. doi: 10.3389/fcell.2017.00087

Sinus lift augmentation is a procedure required for the placement of a dental implant, whose success can be limited by the quantity or quality of available bone. To this purpose, the first aim of the current study was to evaluate the ability of autologous periosteum-derived micrografts and Poly(lactic-co-glycolic acid) (PLGA) supplemented with hydroxyl apatite (HA) to induce bone augmentation in the sinus lift procedure. Secondly, we compared the micrograft's behavior with respect to biomaterial alone, including Bio-Oss® and PLGA/HA, commercially named Alos. Sinus lift procedure was performed on 24 patients who required dental implants and who, according to the study design and procedure performed, were divided into three groups: group A (Alos + periosteum-derived micrografts); group B (Alos alone); and group C (Bio-Oss® alone). Briefly, in group A, a small piece of periosteum was collected from each patient and mechanically disaggregated by Rigenera® protocol using the Rigeneracons medical device. This protocol allowed for the obtainment of autologous micrografts, which in turn were used to soak the Alos scaffold. At 6 months after the sinus lift procedure and before the installation of dental implants, histological and radiographic evaluations in all three groups were performed. In group A, where sinus lift augmentation was performed using periosteum-derived micrografts and Alos, the bone regeneration was much faster than in the control groups where it was performed with Alos or Bio-Oss® alone (groups B and C, respectively). In addition, the radiographic evaluation in the patients of group A showed a radio-opacity after 4 months, while after 6 months, the prosthetic rehabilitation was improved and was maintained after 2 years post-surgery. In summary, we report on the efficacy of periosteum-derived micrografts and Alos to augment sinus lift in patients requiring dental implants. This efficacy is supported by an increased percentage of vital mineralized tisssue in the group treated with both periosteum-derived micrografts and Alos, with respect to the control group of Alos or Bio-Oss® alone, as confirmed by histological analysis and radiographic evaluations at 6 months from treatment.

Keywords: micrografts, autologous, rigenera, biomaterial, sinus lift, bone augmentation

MICROGRAFTS WITH RIGENERACONS FOR PERIODONTAL REGENERATION

PROCEDURE:

A.Harvest the tissue sample:
The Periosteum can be taken, after making a partial thickness flap from the deep palatal mucosa or from the alveolar periosteum, with a scalpel or a punch biopsy.
B. Add 0.8ml of sterile saline solution, using a syringe through the hole on the edge of the device.
C. Place the harvested tissue sample on the grid (not on the helix) inside the Rigeneracons. Manually turn the device helix in order to cover the tissue sample.
D.Connect the Rigeneracons, with the adapter, to the Surgical Motor, connect the Rigeneracons with the specific Adacons adapter and use the machine at 80 RPM for 3 min.
E.Collect the micrografts suspension with a syringe from the same hole in which the saline solution was previously injected.
F.Inject the obtained micrografts solution with the selected scaffold (collagen or different) and place it onto the surgical defect.

Dr. D'Aquino R.



BEFORE



AFTER



BEFORE



AFTER



Test group site treated with minimally invasive surgical technique and autologous dental pulp/biocomplex collagen sponge micrografts (M.A. periodontal surgeon). Preoperative radiographic view of an intraosseous defect on the distal level of the maxillary first molar (a), flap elevation and probing of the intraosseous defect (b), intraoperative view of the defect before elevation of the interdental papilla (c), mechanical dissocation of the dental pulp (d), placement of a collagen sponge with dental pulp micrografts (e), suture (f), clinical (g) and radiographic (h) results at 12 months after treatment (h).



Control site treated with minimally invasive surgical technique and collagen sponge only. Preoperative (a) and clinical (b) radiographic views (a) of an intraosseous defect on the distal aspect of the mandibular fist premolar, flap elevation and debridement of the defect (c), suturing (d), radiographic (e) and clinical (f) results at 12 months after treatment.

Ferrarotti F, Romano F, Gamba MN, Quirico A, Giraudi M, Audagna M, Aimetti M. Human intrabony defect regeneration with micrografts containing dental pulp stem cells: A randomized controlled clinical trial. J Clin Periodontol. 2018 Jul;45(7):841-850. doi: 10.1111/jcpe.12931.

Received: 24 October 2017 | Revised: 18 April 2018 | Accepted: 13 May 2018
DOI: 10.1111/jcpe.12931

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RANDOMIZED CLINICAL TRIAL

WILEY Journal of Clinical Periodontology

Human intrabony defect regeneration with micrografts containing dental pulp stem cells: A randomized controlled clinical trial

Francesco Ferrarotti | Federica Romano | Mara Noemi Gamba | Andrea Quirico | Marta Giraudi | Martina Audagna | Mario Aimetti

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Funding information
The study was self-funded by the authors and their institution, but Human Brain Wave srl (Turin, Italy) provided free material to be used in this study.

Abstract

Aim: The goal of this study was to evaluate if dental pulp stem cells (DPSCs) delivered into intrabony defects in a collagen scaffold would enhance the clinical and radiographic parameters of periodontal regeneration.

Materials and Methods: In this randomized controlled trial, 29 chronic periodontitis patients presenting one deep intrabony defect and requiring extraction of one vital tooth were consecutively enrolled. Defects were randomly assigned to test or control treatments which both consisted of the use of minimally invasive surgical technique. The dental pulp of the extracted tooth was mechanically dissociated to obtain micrografts rich in autologous DPSCs. Test sites (n = 15) were filled with micrografts seeded onto collagen sponge, whereas control sites (n = 14) with collagen sponge alone. Clinical and radiographic parameters were recorded at baseline, 6 and 12 months postoperatively.

Results: Test sites exhibited significantly more probing depth (PD) reduction (4.9 mm versus 3.4 mm), clinical attachment level (CAL) gain (4.5 versus 2.9 mm) and bone defect fill (3.9 versus 1.6 mm) than controls. Moreover, residual PD < 5 mm (93% versus 50%) and CAL gain ≥4 mm (73% versus 29%) were significantly more frequent in the test group.

Conclusions: Application of DPSCs significantly improved clinical parameters of periodontal regeneration 1 year after treatment.

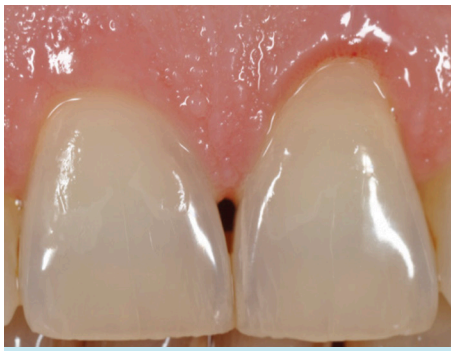
KEYWORDS
dental pulp, periodontal pocket, periodontal regeneration, randomized controlled trial, stem cells, tissue engineering

MICROGRAFTS WITH RIGENERACONS FOR MUCOGENGIVAL REGENERATION

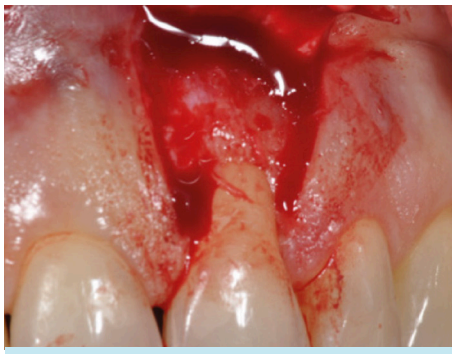
PROCEDURE:

A.Harvest the tissue sample:
The Periosteum can be taken, after making a partial thickness flap from the deep palatal mucosa or from the alveolar periosteum, with a scalpel or a punch biopsy.
B. Add 0.8ml of sterile saline solution, using a syringe through the hole on the edge of the device.
C. Place the harvested tissue sample on the grid (not on the helix) inside the Rigeneracons. Manually turn the device helix in order to cover the tissue sample.
D.Connect the Rigeneracons, with the adapter, to the Surgical Motor, connect the Rigeneracons with the specific Adacons adapter and use the machine at 80 RPM for 3 min.
E.Collect the micrografts suspension with a syringe from the same hole in which the saline solution was previously injected.
F.Inject the obtained micrografts solution with the selected scaffold (collagen or different) and place it onto the surgical defect.

Dr. D'Aquino R.



BEFORE



SURGERY



7 DAYS AFTER



3 MONTHS AFTER



3 YEARS AFTER

MICROGRAFTS WITH RIGENERACONS FOR OSTEONECROSIS

PROCEDURE:

A.Harvest the tissue sample:
The Periosteum can be taken, after making a partial thickness flap from the deep palatal mucosa or from the alveolar periosteum, with a scalpel or a punch biopsy.

B. Add 0.8ml of sterile saline solution, using a syringe through the hole on the edge of the device.

C. Place the harvested tissue sample on the grid (not on the helix) inside the Rigeneracons. Manually turn the device helix in order to cover the tissue sample.

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F.Inject the obtained micrografts solution with the selected scaffold (collagen or different) and place it onto the surgical defect.

Dr. D'Aquino R.



BEFORE



AFTER



HEALING AT 21 DAYS



HEALING AT 90 DAYS

RIGENERA HBW

SAMPLE COLLECTION



MICROGRAFTS SAMPLE COLLECTION

The Periosteum can be taken, after making a partial thickness flap from the deep palatal mucosa or from the alveolar periosteum, with a scalpel or a punch biopsy. The periosteum samples size has to be at least 20 times smaller than the surgical defect.

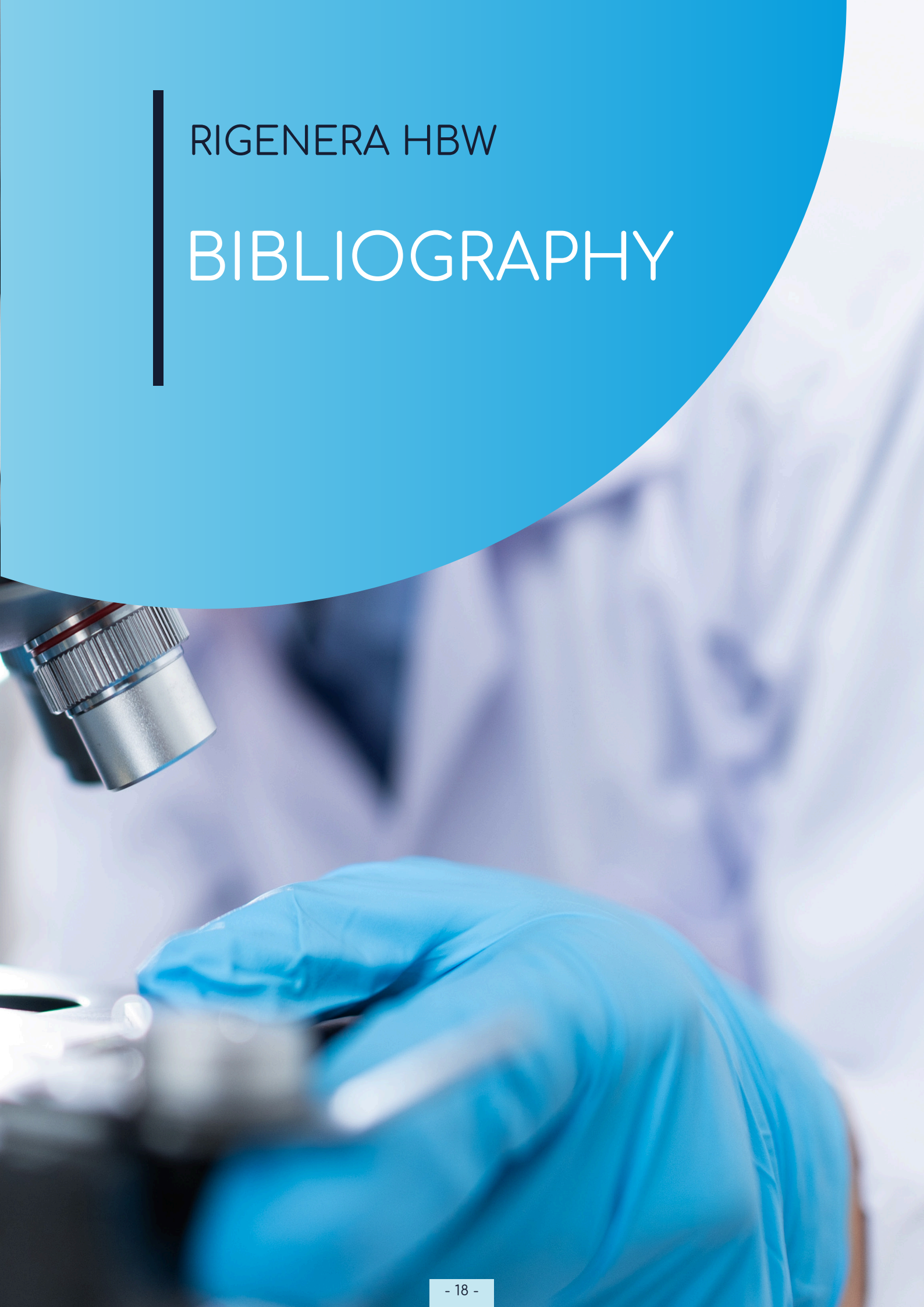






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