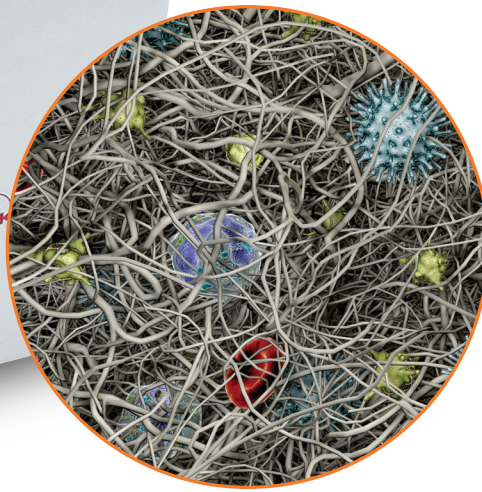




INTRASPIN[®]

brochure



the **FDA-cleared and CE-marked** medical device for the production of L-PRF[®]

BIOHORIZONS[®]
SCIENCE • INNOVATION • SERVICE

don't be fooled.

choose a medical device that is **FDA-cleared and CE-marked** for the production of Leukocyte- and Platelet-Rich Fibrin.

- simple & economical¹
- quality guarantee
- quick, three-step processing protocol
- up to 80% reduction in undesirable vibrations²
- high-quality, German engineering and manufacturing

no anticoagulant, heating,
pipetting, second spin, chemical
additives or expensive consumables



benefits of L-PRF[®] in surgical procedures



SAFE. L-PRF is a 3D, autogenous, platelet-rich fibrin derived from the patient's own blood which reduces the risk of disease transmission, allergic reaction or rejection.¹

COST-EFFECTIVE. L-PRF is a chairside procedure with a low per patient cost that enhances your surgical procedures naturally.¹

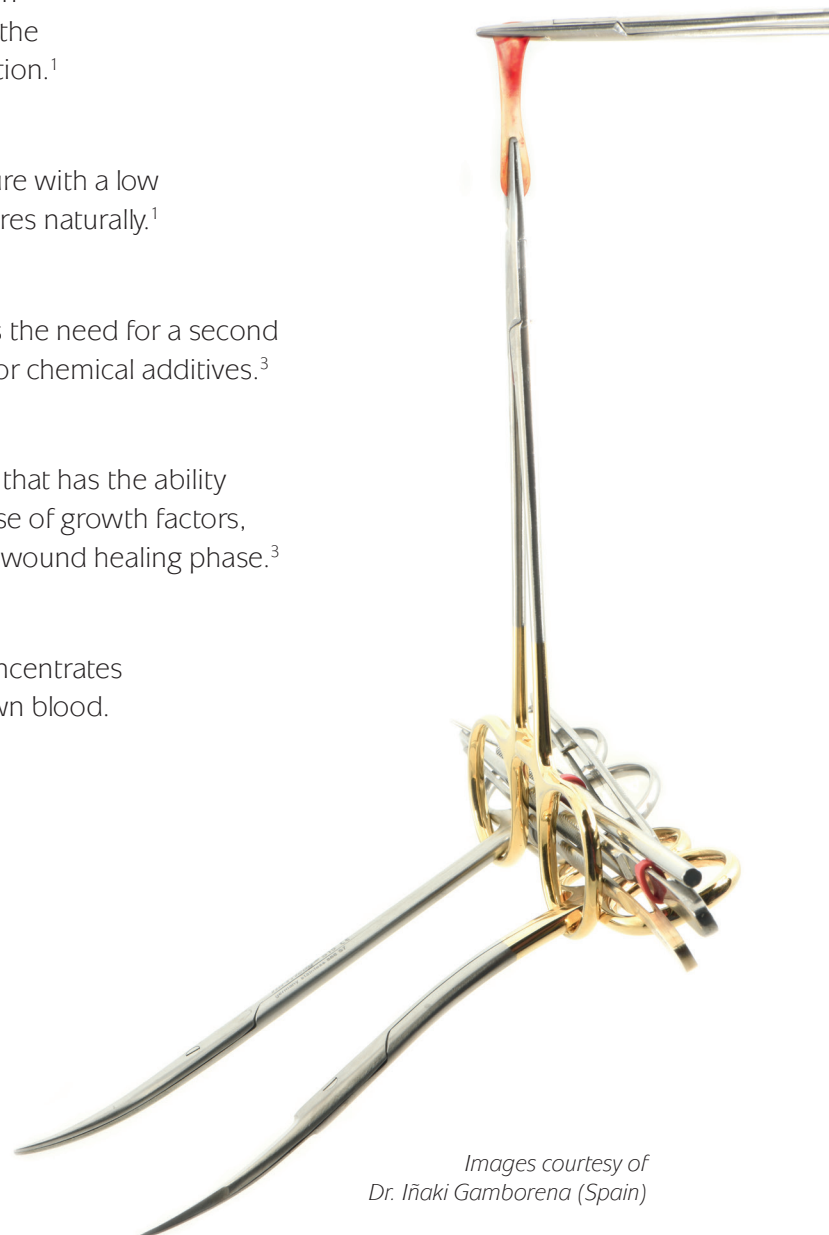
SIMPLE. L-PRF is a simple protocol that eliminates the need for a second spin, heating, pipetting, or the use of anticoagulants or chemical additives.³

UNIQUE. L-PRF offers a unique biologic signature that has the ability to enhance your surgical outcomes with a slow release of growth factors, proteins, leukocytes and cytokines during the critical wound healing phase.³

100% NATURAL. L-PRF is 100% natural and concentrates the growth factors that are present in the patient's own blood. L-PRF helps the patient's body heal itself naturally.³

"L-PRF, A human living tissue that challenges the paradigm of osseointegration and tissue regeneration. What we thought impossible yesterday, could be routine tomorrow with L-PRF and Natural Guided Regeneration-Therapy."

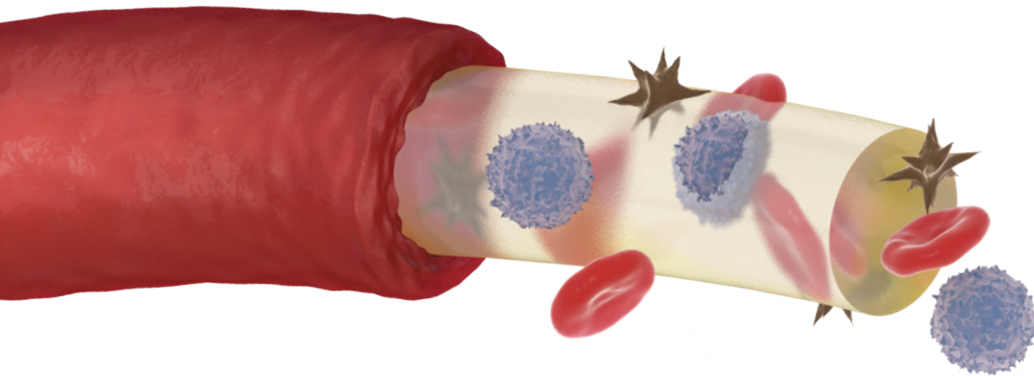
Dr. Nelson Pinto



*Images courtesy of
Dr. Iñaki Gamborena (Spain)*

what is Leukocyte- and Platelet-Rich Fibrin (L-PRF)?

L-PRF is a 3D autogenous combination of platelets, growth factors, proteins, leukocytes and cytokines incorporated into a natural fibrin network derived from the patient's blood.¹



A simplified chairside procedure results in the production of a thin, compressed layer of Leukocyte- and Platelet-Rich Fibrin that is strong, pliable and suitable for suturing. Clinically, L-PRF displays excellent working properties including the ability to be cut to size and supple enough to adapt to many anatomical areas.

The unique biologic signature of L-PRF has demonstrated twice the strength, larger clots/membranes and a more intense release of growth factors when compared to A-PRF. L-PRF offers a slow release of growth factors for more than 7 days during the critical wound healing phase².

INTRASPIN[®]

The IntraSpin[®] System is intended to be used for the safe and rapid preparation of autologous Leukocyte-and Platelet Rich Fibrin (L-PRF) from a small sample of blood taken chairside. The IntraSpin System:

- Offers high-quality, German engineering and manufacturing with a set of proprietary parameters critical for the precise preparation of L-PRF.
- Features an optimized protocol that was scientifically developed and clinically proven from over 200 studies over 10+ years which ensures predictable results.

A simple, three-step, processing protocol includes drawing blood, spinning blood and forming a thin, compressed layer of L-PRF in the Xpression[®] box. The Intraspin system features specialized instruments designed for completing this processing protocol.

ordering information

The IntraSpin system components are **FDA-cleared and CE-marked** and are optimized to ensure proper material biocompatibility and clinical performance.



IntraSpin® Centrifuge

The IntraSpin Centrifuge has a specific configuration and proprietary set of parameters. It has been calibrated and tested to ensure consistent separation of the blood into its proper segments for L-PRF.

ISS110	IntraSpin System, 110 volts
	Includes centrifuge, Tissue Regeneration Kit and blood collection system

Tissue Regeneration Kit

The Tissue Regeneration Kit includes the Xpression® box which is engineered to optimize the final step in the fabrication of Leukocyte- and Platelet-Rich Fibrin. The weighted press is designed to express serum from the fibrin clot in a controlled manner and to form a thin compressed layer of L-PRF of a consistent thickness. A piston and cylinder assembly is used for the creation of L-PRF plugs. The instrumentation is also designed for mixing graft material into the L-PRF matrix.

BDTRK	Tissue Regeneration Kit
	Includes items below:
CTR	Xpression Box
BSTF	Surgical Tissue Forceps
BSCS	Surgical Curved Scissors
BDBC	Dual Biomaterial Carrier Spatula
BDBP	Dual Biomaterial Packer
BSSMT	Round Stainless-Steel Bowl
BRSSMT	Rectangular Stainless-Steel Bowl

BRACK	Test Tube Rack
--------------	----------------

Blood Collection System

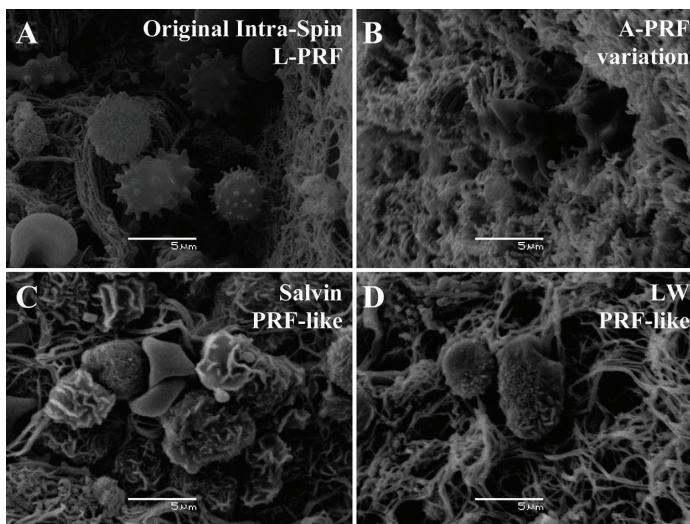
The blood sample collection system has been developed for proper biocompatibility, collection and maintenance of the blood sample.

455092	Red Cap 9ml Serum Clot Activator, pack of 50
455001	White Cap 9ml No Additive Blood Collection Tube, pack of 50
450160	Greiner Safety Blood Collection Set + Holder, 21G, box of 24
BAT	Medical Tourniquet, latex-free
450241	Holdex Single Use Holder, box of 100

key clinical study

The impact of the centrifuge characteristics and centrifugation protocols on the cells, growth factors, and fibrin architecture of a leukocyte- and platelet-rich fibrin (L-PRF) clot and membrane.

David M. Dohan Ehrenfest, Nelson R. Pinto, Andrea Pereda, Paula Jiménez, Marco Del Corso, Byung-Soo Kang, Mauricio Nally, Nicole Lanata, Hom-Lay Wang & Marc Quirynen

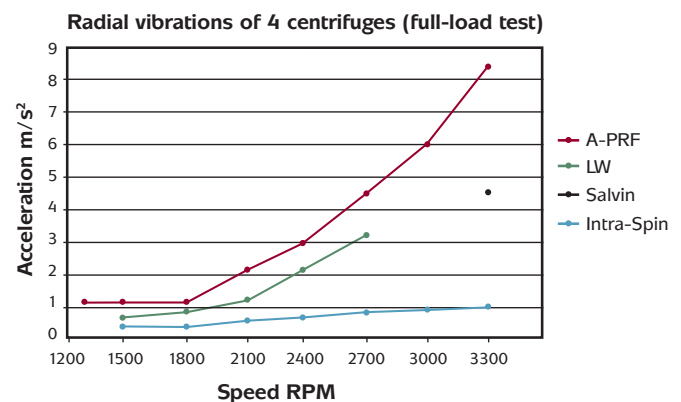


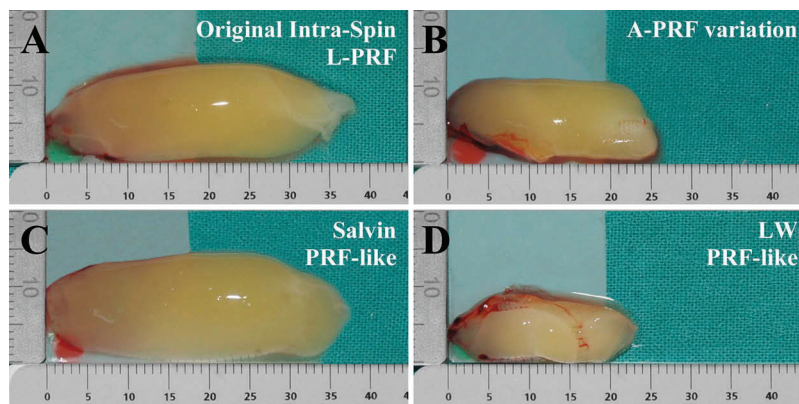
- IntraSpin was by far the most stable machine in all configurations and the level of undesirable vibrations was between 4.5 and 6 times lower than with other centrifuges.
- IntraSpin showed the lowest temperature of the tubes.
- IntraSpin produced the heaviest clot and quantity of exudate among the four techniques.
- IntraSpin L-PRF showed a strongly polymerized thick fibrin matrix and all cells appeared alive with a normal shape, including the textured surface aspect of activated lymphocytes.
- IntraSpin L-PRF membranes were significantly stronger (more than twice) and demonstrated a slow release of BMP2 during at least 7 days.

Purpose:

The first objective of this study was to evaluate the mechanical vibrations appearing during centrifugation in four models of commercially available table-top centrifuges used to produce L-PRF and the impact of the centrifuge characteristics on the cell and fibrin architecture of a L-PRF clot and membrane.

The second objective of this study was to evaluate how changing some parameters of the L-PRF protocol may influence its biological signature, independently from the characteristics of the centrifuge.





Conclusions:

The centrifuge characteristics and centrifugation protocols impact significantly and dramatically the cells, growth factors and fibrin architecture of L-PRF.

- Each centrifuge has its clear own profile of vibrations depending on the rotational speed, and the centrifuge characteristics are directly impacting the architecture and cell content of a L-PRF clot.
- When using the same centrifuge, the original L-PRF protocol produced larger clots/membranes and a more intense release of growth factors (biological signature at least twice as strong) than the modified A-PRF protocol. Both protocols are therefore significantly different.

references

1. Dohan Ehrenfest DM, Del Corso M, Diss A, et al. Three-dimensional architecture and cell composition of a Choukroun's platelet-rich fibrin clot and membrane. *J Periodontol*. 2010. Apr; 81(4): 546-55.
2. Dohan Ehrenfest DM, Del Corso M, Kang B, Lanata N, Quiryren M, Wang HL, Pinto N. The impact of the centrifuge characteristics and centrifugation protocols on the cells, growth factors and fibrin architecture of a Leukocyte- and Platelet-Rich Fibrin (L-PRF) clot and membrane. Part 3: comparison of the growth factors content and slow release between the original L-PRF and the modified A-PRF (Advanced Platelet-Rich Fibrin) membranes. *POSEIDO*. 2014, June; 2(2): 155-66.
3. Michael Toffler, Nicholas Toscano, Dan Holtzclaw, DDS, et al. Introducing Choukroun's Platelet Rich Fibrin (PRF) to the reconstructive surgery Milieu. *J Implant & Adv Clin Dent*. 2009 Sept; 1(6): 21-32.

Direct Offices

BioHorizons USA
888-246-8338 or
205-967-7880

BioHorizons Canada
866-468-8338

BioHorizons Spain
+34 91 713 10 84

BioHorizons UK
+44 (0)1344 752560

BioHorizons Chile
+56 (2) 23619519

BioHorizons Italy
800-063-040

Distributors

For contact information in our 90 countries, visit www.biohorizons.com



BioHorizons®, Laser-Lok®, MinerOss®, AutoTac®, Mem-Lok® and TeethXpress® are registered trademarks of BioHorizons. Unigrip™ is a trademark of Nobel Biocare AB. Zimmer® Dental ScrewVent® and Tapered ScrewVent® are registered trademarks of Zimmer, Inc. AlloDerm™ and AlloDerm GBR™ are trademarks of LifeCell Corporation, an Allergan affiliate. Grafton® DBM is a registered trademark of Medtronic, Inc. Cytoplast® is a registered trademark of Osteogenics Biomedical, Inc. Puros Dermis is a registered trademark of Zimmer Biomet. Mucograft is a registered trademark of Ed. Geistlich Sogne Ag Fur Chemische Industrie. Symbios PerioDerm is a registered trademark of Dentsply Sirona. Spiralock® is a registered trademark of Spiralock Corporation. Pomalux® is a registered trademark of Westlake Plastics Co. Locator® is a registered trademark of Zest Anchors, Inc. Delrin® is a registered trademark of E.I. du Pont de Nemours and Company. Bio-Gide® is a registered trademark of Edward Geistlich Sohne AG Fur Chemische Industrie. BioMend® is a registered trademark of Zimmer Biomet Dental. IntraSpin®, L-PRF® and Xpression® are trademarks of Intra-Lock® International Inc. Not all products shown or described in this literature are available in all countries. As applicable, BioHorizons products are cleared for sale in the European Union under the EU Medical Device Directive 93/42/EEC and the tissues and cells Directive 2004/23/EC. We are proud to be registered to ISO 13485:2016, the international quality management system standard for medical devices, which supports and maintains our product licences with Health Canada and in other markets around the globe. Original language is English. ©BioHorizons. All Rights Reserved.



ML0333



REV A JUN 2019

shop online at
store.biohorizons.com