Biological Result of platelet rich plasma obtained from T-LAB Medical Devices

Objective: To obtain biological data on PRP obtained with medical devices from the company T-LAB whose distribution in France is ensured by the company 2F Surgical for a clinical application in pathologies of the musculoskeletal system.

Materials and Methods:

This study was carried out in collaboration with the company REMEDEX whose premises, tools and services were used for the preparation and qualification of the obtained PRPs. Blood samples were obtained from the blood of 3 healthy volunteers who gave their oral consent.

T-LAB PRP Kit Device:

Each blood sample was taken using the 21G sampling needle and the 2 tubes vacuum containing anticoagulant (0.8 to 0.9 mL) and supplied in the device. Volume total blood and anticoagulant is 9 mL / tube at the end of the sample (after email from Fabrice Fonseca of October 29).

A 0.5 mL blood sample was taken with a syringe from product in Microvette EDTA 500K2E tubes (Sarstedt, Numbrecht, Germany) following the existing guideline (Graiet el al) for carrying out cellular quantification of the initial blood samples.

Next PRP Syringe:

Each blood sample was taken using a 21G butterfly needle (not provided with the device) connected to the Next PRP syringe. **No anticogulant has been added**. The total volume of blood drawn is 10 mL.

A 0.5 mL blood sample was taken from each product and transferred in tubes Microvette EDTA 500K2E (Sarstedt, Numbrecht, Germany) according to existing recommendations (Graiet el al) for carrying out the cellular quantification of the initial blood samples.

A series of 2 half-days of manipulations were thus carried out by following the protocols recommended by T-LAB in the email sent to Fabrice Fonseca on October 29.

The table below summarizes the different series of manipulation as follows:

	Device Tested	Spin/Duration	Number of Unit
TRIAL 1	T-LAB PRP KIT	830g 4 min	2
TRIAL 1	NEXT PRP	1500 G 4 min	1
TRIAL 2	T-LAB PRP KIT	830G 4 min	1

TRIAL 2	NEXT PRP	1500G 4 min	2

0.5 mL of each of the PRPs obtained were sampled in EDTA Microvette tubes according to the existing recommendations for carrying out the cellular quantification of the PRPs obtained.

Cell count:

The cell count (concentration of platelets, red blood cells and leukocytes) was taken on whole blood and PRP using a MICROS ES60 automatic hematology machine (Horiba, Montpellier,France) by applying the instructions published by Graiet et al.

By comparing the concentrations of platelets, red blood cells, and leukocytes associated with the volumes of blood collected and PRP obtained, calculations were carried out and allowed to assess:

- The dose of platelets, red blood cells, and leukocytes present in PRP and deduce the relative composition of PRP
- The Platelet Recovery Rate
- The Depletion rate of WBC and RBC.
- The concentration of platelets and leukocytes

The following benchmarks have been arbitrarily set based on our experience in this domain to define the conformity of certain parameters:

Parameters	Benchmark
Volume (mL)	>10
Platelet concentration rate	>1
Leukocyte concentration rate	< 1
Recovery rate	>50
Purity	>90
Percentage of the Platelet activated	<10

Comparison against current devices

Based on an analysis of independent biological data available on the others PRP extraction systems, the volume of PRP obtained, the platelet concentration factors and leukocytes, the purity and platelet yield obtained with the T LAB devices were able to be compared and ranked against the average values of 36 PRP productions.

Results

The raw results of the biological characteristics of the PRPs obtained with each of the devices are shown in Table 1.

Cell Count and Performance indicators

The analysis of the compliance of key biological parameters is presented in the table below for each of PRP's productions. C: Compliant / NC: Non Compliant

Parameter	Benchmark	T-LAB PRP KIT			NEXT SYRINGE		
		#1	#2	#3	#4	#5	#6
Volume (mL)	>10	NC	NC	NC	NC	NC	NC
PLT Increase Factor	>1	C	C	C	C	C	C
Leukocyte Increase Factor	<1	C	C	C	C	C	C
Recovery Rate (%)	>50	C	C	C	C	C	C
Purity (%)	>90	C	C	NC	C	C	C

It can be seen that the use of the 2 T LAB devices under centrifugation conditions recommended by the manufacturer make it possible to obtain a PRP whose compliance criteria are all achieved, except a purity of less than 90% for production with the T LAB PRP device kit and a large volume (> 10 mL) which is never reached for either of the 2 devices.

Comparison with current devices

Figures 2A and 2B classify the devices studied in decreasing order on 5 parameters among data from the literature on 36 PRP productions. It is thus understood that the device T LAB PRP kit makes it possible to obtain an above-average volume (6.5 mL) of PRP by comparison to other devices while the Next PRP syringe is average on this parameter (4.5 mL). The platelet and leukocyte concentration factors are among the lowest values in comparison to existing data in the literature justifying a classification of PRP poor in leukocytes. Platelet purity is excellent since the 2 T LAB devices achieve> 90% purity, which is only described in 7/36 preparations in the existing literature. Regarding the platelet recovery, it is excellent for the Next PRP Syringe (only 4 preparations have a higher yield) and quite acceptable with 12/36 productions higher for the T LAB PRP kit.

		T-LAB PRP KIT			NEXT PRP SYRINGE		
		HORIBA	HORIBA	HORIBA	HORIBA	HORIBA	HORIBA
		#1	#2	#3	#1	#2	#3
		31.10.2020	31.10.2020	11.11.2020	31.10.2020	11.11.2020	11.11.2020
	Hematocrit	40,00%	41,80%	40,40%	43,60%	45,90%	42,50%
WHOLEBLOOD	Volume of blood	17,5	17,5	17,5	10	10	10
	Volume of Anticoagulant	1,7	1,7	1,7			
Concentration	Platelet concentration [10^6/mL]	281	252	106	279	276	256
	Red Blood Cell concentration [10^9/mL]	4,38	4,75	4,54	4,99	5,23	4,65
	Leukocyte concentration [10^6/mL]	4	7,3	3,3	7,9	8,2	3,6
Quantity	Platelet [10^6]	4917,5	4410	1855	2790	2760	2560
	Red Blood Cells [10^6]	76650	83125	79450	49900	52300	46500
	Leukocytes [10^6]	70	127,75	57,75	79	82	36
PRP	Volume [ml]	6,5	6	7	4,2	4,4	5
Concentration	Platelet concentration [10^6/mL]	487	578	165	496	504	453
	Red Blood Cell concentration [10^9/mL]	0,01	0,02	0,03	0,01	0,01	0,01
	Leukocyte concentration [10^6/mL]	0,9	2,5	1,9	0,9	2,4	1,3
Quantity	Platelet [10^6]	3165,5	3468	1155	2083,2	2217,6	2265
	Red Blood Cells [10^6]	65	120	210	42	44	50
	Leukocytes [10^6]	5,85	15	13,3	3,78	10,56	6,5
Increase Factor	Platelets	1,73	2,29	1,56	1,78	1,83	1,77
	Leukocytes	0,23	0,34	0,58	0,11	0,29	0,36
Recovery/Depletion	Platelet recovery rate (%)	64,4	78,6	62,3	74,7	80,3	88,5
	Red Blood Cell Depletion (%)	99,92	99,86	99,74	99,92	99,92	99,89
	Leukocytes depletion (%)	91,64	88,26	76,97	95,22	87,12	81,94
Composition	Platelets (%)	97,81	96,25	83,8	97,85	97,6	97,57
	Red Blood Cells (%)	2,01	3,33	15,24	1,97	1,94	2,15
	Leukocytes (%)	0,18	0,42	0,96	0,18	0,46	0,28

Table 1: Biological characteristics of PRP obtained with T-LAB Devices

Table 1

Company	PRP Commercial System	Study	n	PRP Volume obtained (mL)
Harvest	SmartPReP 2	Leitner 2006 (comparison)	3	10,0
Fidia	Hy-tissue 20	Guillibert, 2019 (clinical)	57	8,8
3i	PCCS	Leitner 2006 (comparison)	3	8,5
MTF	Cascade	Castillo, 2011 (comparison)	5	7,5
Harvest	SmartPReP APC+	Degen, 2017 (comparison)	7	7,0
EmCyte	GS60-PurePRP II	Mandle, 2016 (comparison)	4	7,0
Arteriocyte	Magellan	Mandle, 2016 (comparison)	4	7,0
	T LAB PRP KIT	Test Remedex	3	6,5
Arthrex	ACP	Fitzpatrick, 2017 (comparison)	3	6,5
Arteriocyte	Magellan	Fitzpatrick, 2017 (comparison)	3	6,5
Harvest	SmartPReP 2	Fitzpatrick, 2017 (comparison)	3	6,5
Biomet	GPS III	Fitzpatrick, 2017 (comparison)	3	6,5
Biomet	GPS III	Degen, 2017 (comparison)	7	6,1
Biomet	GPS	Eppley, 2004 (characterization)	10	6,0
Biomet	GPS III	Oh, 2015 (comparison)	14	6,0
Arteryocyte	Magelan	Castillo, 2011 (comparison)	5	6,0
EmCyte	Genesis CS	Degen, 2017 (comparison)	7	6,0
RegenLab	Regen device	Mandle, 2016 (comparison)	4	6,0
Aesthetics	Eclipse PRP	Mandle, 2016 (comparison)	4	6,0
Biomet	GPS II	Kaux, 2011 (comparison)	5	6,0
Biomet	GPS III	Castillo, 2011 (comparison)	5	6,0
Arteriocyte	Magellan	Degen, 2017 (comparison)	7	5,3
	NEXT PRP SERINGUE	Test Remedex	3	4,5
Selphyl	Selphyl	Magalon, 2014 (comparison)	10	4,1
RegenLab	Regen device	Atashi, 2015 (preclinical)	14	4,0
EmCyte	GS30-PurePRP II	Mandle, 2016 (comparison)	4	4,0
Arthrex	ACP	Magalon, 2014 (comparison)	10	4,0
Arthrex	Angel 7% HCT	Degen, 2017 (comparison)	7	3,5
Biomet	Mini GPS III	Magalon, 2014 (comparison)	10	3,2
RegenLab	Regen device	Kaux, 2011 (comparison)	5	3,1
RegenLab	Regen device	Magalon, 2014 (comparison)	10	3,1
Arthrex	ACP	Mazzocca, 2012 (comparison)	8	3,0
Biomet	GPS III	Mazzocca, 2012 (comparison)	8	3,0
Arthrex	ACP	Oh, 2015 (comparison)	14	3,0
Prodizen	Prosys	Oh, 2015 (comparison)	14	3,0
Arthrex	Angel 2% HCT	Degen, 2017 (comparison)	7	2,9
Curasan	Curasan	Kaux, 2011 (comparison)	5	1,0
Plateltex	Plateltex	Kaux, 2011 (comparison)	5	0,3

Table 2

Company	PRP Commercial System	Study	n	Platelets Increase Factor
Arthrex	Angel 7% HCT	Degen, 2017 (comparison)	7	11,2
Arthrex	Angel 2% HCT	Degen, 2017 (comparison)	7	10,0
Arteriocyte	Magellan	Degen, 2017 (comparison)	7	9,7
Biomet	GPS	Eppley, 2004 (characterization)	10	8,0
Harvest	SmartPReP APC+	Degen, 2017 (comparison)	7	7,3
Biomet	GPS III	Oh, 2015 (comparison)	14	7,3
Biomet	GPS III	Degen, 2017 (comparison)	7	6,5
Biomet	GPS II	Mazzocca, 2012 (comparison)	8	6,1
EmCyte	GS60-PurePRP II	Mandle, 2016 (comparison)	4	5,8
EmCyte	Genesis CS	Degen, 2017 (comparison)	7	5,5
EmCyte	GS30-PurePRP II	Mandle, 2016 (comparison)	4	5,4
Arteriocyte	Magellan	Mandle, 2016 (comparison)	4	4,9
Arteriocyte	Magellan	Fitzpatrick, 2017 (comparison)	3	4,7
3i	PCCS	Leitner 2006 (comparison)	3	4,6
Harvest	SmartPReP 2	Fitzpatrick, 2017 (comparison)	3	4,6
Prodizen	Prosys	Oh, 2015 (comparison)	14	4,2
Biomet	Mini GPS III	Magalon, 2014 (comparison)	10	3,9
Harvest	SmartPReP 2	Leitner 2006 (comparison)	3	3,8
Biomet	GPS III	Fitzpatrick, 2017 (comparison)	3	3,6
Plateltex	Plateltex	Kaux, 2011 (comparison)	5	3,4
Arteryocyte	Magelan	Castillo, 2011 (comparison)	5	2,8
Curasan	Curasan	Kaux, 2011 (comparison)	5	2,8
Arthrex	ACP	Mazzocca, 2012 (comparison)	8	2,7
Arthrex	ACP	Oh, 2015 (comparison)	14	2,4
Biomet	GPS III	Castillo, 2011 (comparison)	5	2,1
	T LAB PRP KIT	Test Remedex	3	1,9
Biomet	GPS II	Kaux, 2011 (comparison)	5	1,9
	NEXT PRP SERINGUE	Test Remedex	3	1,8
RegenLab	Regen device	Atashi, 2015 (preclinical)	14	1,7
MTF	Cascade	Castillo, 2011 (comparison)	5	1,6
RegenLab	Regen device	Magalon, 2014 (comparison)	10	1,6
RegenLab	Regen device	Kaux, 2011 (comparison)	5	1,6
Arthrex	ACP	Fitzpatrick, 2017 (comparison)	3	1,5
Fidia	Hy-tissue 20	Guillibert, 2019 (clinical)	57	1,4
Arthrex	ACP	Magalon, 2014 (comparison)	10	1,3
Selphyl	Selphyl	Magalon, 2014 (comparison)	10	1,2
RegenLab	Regen device	Mandle, 2016 (comparison)	4	0,5
Aesthetics	Eclipse PRP	Mandle, 2016 (comparison)	4	0,4

Table 3

Company	PRP Commercial System	Study	n	Leukocytes Increase Factor
Biomet	GPS III	Castillo, 2011 (comparison)	5	5,4
Biomet	GPS	Eppley, 2004 (characterization)	10	5,4
Biomet	GPS III	Degen, 2017 (comparison)	7	5,3
Biomet	GPS III	Oh, 2015 (comparison)	14	5,1
Harvest	SmartPReP APC+	Degen, 2017 (comparison)	7	4,4
Biomet	Mini GPS III	Magalon, 2014 (comparison)	10	4,2
Biomet	GPS III	Fitzpatrick, 2017 (comparison)	3	4,1
EmCyte	Genesis CS	Degen, 2017 (comparison)	7	4,0
Arteriocyte	Magellan	Degen, 2017 (comparison)	7	3,8
Biomet	GPS III	Mazzocca, 2012 (comparison)	8	3,7
Arteriocyte	Magellan	Fitzpatrick, 2017 (comparison)	3	3,6
Arthrex	Angel 7% HCT	Degen, 2017 (comparison)	7	3,3
Harvest	SmartPReP 2	Fitzpatrick, 2017 (comparison)	3	2,8
Arteriocyte	Magellan	Mandle, 2016 (comparison)	4	2,5
Arthrex	Angel 2% HCT	Degen, 2017 (comparison)	7	2,1
Harvest	SmartPReP 2	Leitner 2006 (comparison)	3	2,1
3i	PCCS	Leitner 2006 (comparison)	3	2,0
EmCyte	GS60-PurePRP II	Mandle, 2016 (comparison)	4	2,0
Prodizen	Prosys	Oh, 2015 (comparison)	14	1,8
Arteryocyte	Magelan	Castillo, 2011 (comparison)	5	1,7
RegenLab	Regen device	Magalon, 2014 (comparison)	10	1,5
EmCyte	GS30-PurePRP II	Mandle, 2016 (comparison)	4	1,4
Biomet	GPS II	Kaux, 2011 (comparison)	5	1,2
Plateltex	Plateltex	Kaux, 2011 (comparison)	5	0,9
	T LAB PRP KIT	Test Remedex	3	0,4
	NEXT PRP SERINGUE	Test Remedex	3	0,3
Selphyl	Selphyl	Magalon, 2014 (comparison)	10	0,2
MTF	Cascade	Castillo, 2011 (comparison)	5	0,2
Arthrex	ACP	Fitzpatrick, 2017 (comparison)	3	0,1
RegenLab	Regen device	Atashi, 2015 (preclinical)	14	0,1
Arthrex	ACP	Mazzocca, 2012 (comparison)	8	0,1
RegenLab	Regen device	Mandle, 2016 (comparison)	4	0,1
Arthrex	ACP	Oh, 2015 (comparison)	14	0,1
Arthrex	ACP	Magalon, 2014 (comparison)	10	0,1
Curasan	Curasan	Kaux, 2011 (comparison)	5	0,0
Fidia	Hy-tissue 20	Guillibert, 2019 (clinical)	57	0,0
Aesthetics	Eclipse PRP	Mandle, 2016 (comparison)	4	0,0
RegenLab	Regen device	Kaux, 2011 (comparison)	5	0,0

Figure 2A: Comparison of volume, mean platelet and leukocyte concentration factor of PRPs obtained with T LAB devices compared to data available in the literature on other PRP preparation systems

Company	PRP Commercial System	Study	n	Relative content in platelets (%)
Aesthetics	Eclipse PRP	Mandle, 2016 (comparison)	4	99,6
RegenLab	Regen device	Mandle, 2016 (comparison)	4	99,2
Curasan	Curasan	Kaux, 2011 (comparison)	5	97,7
	NEXT PRP SERINGUE	Test Remedex	3	97,7
RegenLab	Regen device	Kaux, 2011 (comparison)	5	97,5
Fidia	Hy-tissue 20	Guillibert, 2019 (clinical)	57	96,6
	T LAB PRP KIT	Test Remedex	3	92,6
Arthrex	ACP	Fitzpatrick, 2017 (comparison)	3	92,3
Arthrex	Angel 2% HCT	Degen, 2017 (comparison)	7	90,7
RegenLab	Regen device	Atashi, 2015 (preclinical)	14	88,7
Arthrex	ACP	Oh, 2015 (comparison)	14	87,7
Plateltex	Plateltex	Kaux, 2011 (comparison)	5	87,5
MTF	Cascade	Castillo, 2011 (comparison)	5	81,4
Arthrex	ACP	Magalon, 2014 (comparison)	10	81,0
Prodizen	Prosys	Oh, 2015 (comparison)	14	79,2
Selphyl	Selphyl	Magalon, 2014 (comparison)	10	73,9
Arthrex	Angel 7% HCT	Degen, 2017 (comparison)	7	69,4
Arthrex	ACP	Mazzocca, 2012 (comparison)	8	65,3
Arteriocyte	Magellan	Degen, 2017 (comparison)	7	64,0
EmCyte	GS30-PurePRP II	Mandle, 2016 (comparison)	4	63,9
Arteryocyte	Magelan	Castillo, 2011 (comparison)	5	60,4
Biomet	GPS II	Degen, 2017 (comparison)	7	56,7
3i	PCCS	Leitner 2006 (comparison)	3	55,8
Arteriocyte	Magellan	Fitzpatrick, 2017 (comparison)	3	54,4
Biomet	GPS	Eppley, 2004 (characterization)	10	52,8
Biomet	Mini GPS III	Magalon, 2014 (comparison)	10	51,8
Arteriocyte	Magellan	Mandle, 2016 (comparison)	4	51,6
Biomet	GPS III	Oh, 2015 (comparison)	14	51,0
Biomet	GPS III	Fitzpatrick, 2017 (comparison)	3	47,5
Harvest	SmartPReP 2	Leitner 2006 (comparison)	3	46,3
Biomet	GPS III	Mazzocca, 2012 (comparison)	8	46,1
RegenLab	Regen device	Magalon, 2014 (comparison)	10	46,0
Harvest	SmartPReP 2	Fitzpatrick, 2017 (comparison)	3	45,7
EmCyte	GS60-PurePRP II	Mandle, 2016 (comparison)	4	37,8
Harvest	SmartPReP APC+	Degen, 2017 (comparison)	7	31,9
Biomet	GPS III	Castillo, 2011 (comparison)	5	27,0
EmCyte	Genesis CS	Degen, 2017 (comparison)	7	26,6
Biomet	GPS II	Kaux, 2011 (comparison)	5	6,0

Company	PRP Commercial System	Study	n	Recovery rate in platelets (%)
Harvest	SmartPReP APC+	Degen, 2017 (comparison)	7	94,0
Arteriocyte	Magellan	Degen, 2017 (comparison)	7	86,0
Biomet	GPS	Eppley, 2004 (characterization)	10	85,0
RegenLab	Regen device	Atashi, 2015 (preclinical)	14	83,7
	NEXT PRP SERINGUE	Test Remedex	3	81,2
EmCyte	GS30-PurePRP II	Mandle, 2016 (comparison)	4	81,0
Biomet	GPS III	Oh, 2015 (comparison)	14	80,9
RegenLab	Regen device	Kaux, 2011 (comparison)	5	80,2
Arthrex	ACP	Mazzocca, 2012 (comparison)	8	79,5
EmCyte	GS60-PurePRP II	Mandle, 2016 (comparison)	4	78,1
Arthrex	Angel 7% HCT	Degen, 2017 (comparison)	7	75,0
Biomet	GPS III	Degen, 2017 (comparison)	7	73,0
Harvest	SmartPReP 2	Leitner 2006 (comparison)	3	70,1
	T LAB PRP KIT	Test Remedex	3	68,4
Fidia	Hy-tissue 20	Guillibert, 2019 (clinical)	57	68,3
Biomet	GPS III	Mazzocca, 2012 (comparison)	8	68,0
MTF	Cascade	Castillo, 2011 (comparison)	5	67,6
3i	PCCS	Leitner 2006 (comparison)	3	67,0
Arthrex	ACP	Fitzpatrick, 2017 (comparison)	3	66,4
Arteryocyte	Magelan	Castillo, 2011 (comparison)	5	65,5
Arteriocyte	Magellan	Mandle, 2016 (comparison)	4	62,6
EmCyte	Genesis CS	Degen, 2017 (comparison)	7	61,0
Selphyl	Selphyl	Magalon, 2014 (comparison)	10	59,9
Arteriocyte	Magellan	Fitzpatrick, 2017 (comparison)	3	58,8
Harvest	SmartPReP 2	Fitzpatrick, 2017 (comparison)	3	56,9
Arthrex	Angel 2% HCT	Degen, 2017 (comparison)	7	56,0
RegenLab	Regen device	Magalon, 2014 (comparison)	10	55,3
Arthrex	ACP	Oh, 2015 (comparison)	14	48,7
Arthrex	ACP	Magalon, 2014 (comparison)	10	48,2
Biomet	Mini GPS III	Magalon, 2014 (comparison)	10	46,5
Biomet	GPS III	Fitzpatrick, 2017 (comparison)	3	44,8
Prodizen	Prosys	Oh, 2015 (comparison)	14	41,6
RegenLab	Regen device	Mandle, 2016 (comparison)	4	35,0
Curasan	Curasan	Kaux, 2011 (comparison)	5	32,4
Aesthetics	Eclipse PRP	Mandle, 2016 (comparison)	4	30,3
Biomet	GPS II	Kaux, 2011 (comparison)	5	22,7
Biomet	GPS III	Castillo, 2011 (comparison)	5	22,6
Plateltex	Plateltex	Kaux, 2011 (comparison)	5	17,2

Figure 2B: Comparison of mean platelet purity and platelet yield of PRPs obtained with T LAB devices compared to data available in the literature on other PRP preparation systems