

**Evidence Summary: Published PRP Scientific Articles**

Cytomedix conducted a literature search of published articles wherein platelet gel was studied. Following is a List of the Scientific Articles for ease of identification and an Evidence Table with more complete details of the published studies. The articles referenced in the Evidence Table are available in the Scientific Articles Section.

The studies and articles have been grouped as either:  
 Randomized Controlled Trials (R)  
 Non-randomized Controlled Trials (C)  
 Additional Studies (A)

**List of Published Scientific Articles**

Ref. No.	Title	Author	Citation	Ref. No.
	<b>Randomized, Controlled Trials</b>			
<b>R-1</b>	A Prospective Randomized Control- led Trial of Autologous PRP Gel for the Treatment of Diabetic Ulcers	Driver VR, Hanft J, Fylling C, Beriou JM	<u>Ost Wd Mgmt</u> Jun 2006; 52(6):68-87	
<b>R-2</b>	A Controlled Study Of The Use Of Autologous Platelet Gel For The Treatment Of Diabetic Foot Ulcers.	Saldamacchia, G Lapice, v Cuomo, E De Feo, E D'Agostino et.al	<u>Nutr Metab Cardiovasc Dis</u> (2004) 14:395-396	
<b>R-3</b>	Autologous platelet gel application during cardiovascular surgery; effect on wound healing	Englert SJ, Estep TH, Ellis-Stoll CC.	<u>J Extra Corpor Technol.</u> 2005 Jun;37(2): 148-52	
<b>R-4</b>	A comparative study of bilateral sinus lifts performed with PRP alone vs. alloplastic graft material reconstituted with blood.	Steigmann M, Garg AK	<u>Implant Dent.</u> 2005 Sep;14(3):261-6	
<b>R-5</b>	Evaluation of the adjunctive benefits of PRP in subantral sinus augmentation	Kassolis JD, Reynolds MA	<u>J Craniofac Surg.</u> 2005 Mar;16(2):280-7	
<b>R-6</b>	Evaluation of bone healing enhancement by lyophilized bone grafts supplemented with platelet gel	Savarino L, Cenni E, Tarabusi C, Dallari D, et.al	<u>J Biomed Mater Res B</u> <u>Appl Biomater.</u> 2006 Feb; 76(2):364-72	

<b>Non-Randomized, Controlled Trials</b>			
<b>C-1</b>	The use of autologous platelet gel to treat difficult to heal wound	Mazzucco L, Medici D, Serra M Panizza R, Rivara, Orecchia S, Libener R, et.al	<u>Transfusion</u> . 2004 Jul;44(7):1013-8
<b>C-2</b>	Use of platelet gel (PG) and its effects on infection in cardiac surgery	Trowbridge CC, Stammers AH, Woods E, et.al.	<u>J Extra Corpor Technol</u> . 2005 Dec;37 (4):381-6
<b>C-3</b>	Healing effects of autologous platelet gel on acute human skin wounds	Hom DB, Linzie BM, Huang TC	<u>Arch Facial Plast Surg</u> 2007; 9:174-183
<b>C-4</b>	Platelet gel and fibrin sealant reduce allogeneic blood transfusion in TKA	Everts PA, Devilee RJ, Brown Mahoney C, et.al.	<u>Acta Anaesthesiol Scand</u> . 2006 May;50(5):593-9

<b>Additional Published Studies</b>			
<b>A-1</b>	Maxillary sinus augmentation with anorganic bovine bone (Bio-Oss) and autologous PRP	Maiorana C, Sommariva L, Brivio P, Sigurta D, Santoro F.	<u>Int J Periodontics Restorative Dent.</u> 2003 Jun;23(3):227-35.
<b>A-2</b>	PRP (platelet gel) in secondary alveoloplasty in cleft patients {Spanish}	Mendez R, Lopez-Cedrun J, Patino B, et.al.	<u>Cir Pediatr</u> 2006 Jan;19(1):23-6
<b>A-3</b>	Platelet gel for endoscopic sinus surgery	Pomerantz J, Dutton JM.	<u>Ann Otol Rhinol Laryngol.</u> 2005 Sep;114(9):699-704
<b>A-4</b>	Platelet gel (AGF) fails to increase fusion rates in instrumented posterolateral fusions	Carreon LY, Glassman SD, et.al.	<u>Spine</u> 2005 May 1; 30(9):E243-6
<b>A-5</b>	Role of activated growth factors in lumbar spinal fusions	Castro, FP	<u>J Spinal Disord Tech.</u> 2004 Oct; 17(5):380-84
<b>A-6</b>	A prospective study of autologous growth factors (AGF) in lumbar interbody fusion	Jenis LG, Banco RJ, Kwon B.	<u>Spine J.</u> 2006 Jan-Feb; 6(1):14-20. Epub 2005 Dec 6.
<b>A-7</b>	Efficacy of platelet gel in reconstructive bone surgery	Franchini M, Dupplicato P, Ferro I, De Gironcoli M, Aldegheri R.	<u>Orthopedics.</u> 2005 Feb;28(2):161-3
<b>A-8</b>	The efficacy of autologous platelet gel (APG) in pain control and blood loss in TKA	Gardner MJ, Demetropoulos, D	<u>Intl Ortho</u> 2006 Apr27;

The following Evidence Table summarizes the details of each study which is in the Scientific Articles Section:

<i>Randomized Controlled Trials</i>											
Type of Study / Tissue (Ref #)	Title	Author	Citation	Study Design	Patient Sample Size	Sample Characteristics	Endpoints	Results	Stat. Sig.	Conclusions	Co./ Centri-fuge
<i>CHRW / Diab. Foot Ulcer (R-1)</i>	A Prospective Randomized Controlled Trial of Autologous PRP Gel for the Treatment of Diabetic Ulcers	Driver VR, Hanft J, Fylling C, Beriou JM	<u>Ost Wd Mgmt</u> Jun 2006; 52(6):68-87	Prospective randomized controlled, double-blinded trial	N = 40	Patients had non-healing diabetic ulcers between 0.5 and 20 cm <sup>2</sup> . Age (mean) PRP- 56.4 SD 10.2 years Control- 57.5 SD 9.1 years Autologous PRP used.	Wound closure in 12 weeks	ITT: 72 patients Per Protocol: 40 patients Wounds healed: AutoloGel- 13 of 19 (68.4%) Control – 9 of 21 (42.9%) Majority wounds: 35 {size <= 7.0 cm <sup>2</sup> in area and <= 2 cm <sup>3</sup> in volume} AutoloGel- 13 of 16 (81/3%) Control – 8 of 19 (42.1%)	Per Protocol wounds: p = 0.125 (Fisher's Exact test)  Majority size wounds : p = 0.036 (Fisher's Exact test)	PRP gel is safe for treatment of non-healing diabetic foot ulcers. Common size (<= 7.0 cm <sup>2</sup> in area and <= 2 cm <sup>3</sup> in volume) wounds were significantly more likely to heal than the control saline gel.	Cyto-medix / Autolo-Gel System

**Randomized Controlled Trials**

Type of Study / Tissue (Ref #)	Title	Author	Citation	Study Design	Patient Sample Size	Sample Characteristics	Endpoints	Results	Stat. Sig.	Conclusions	Co./ Centrifuge
<i>CHRW / Diab. Foot Ulcer (R-2)</i>	A Controlled Study Of The Use Of Autologous Platelet Gel For The Treatment Of Diabetic Foot Ulcers.	Saldalamicchia, G Lapice, v Cuomo, E De Feo, E D'Agostino et.al	<u>Nutr Metab Cardiovasc Dis</u> (2004) 14:395-396	Randomized, controlled, blinded clinical trial	N = 14	Patients with grade II / III (Wagner) ulcers lasting for 8 wks or more and no infection. Age: PG- 61 ± 9.4 years CTL- 58 ± 7.8 yr Autologous PRP used.	Assessment of wound area size and reduction (%) rate after 5weeks of treatment. Complete healing or reduction of at least 50%	Proportion of complete healing or >= 50% reduction was 71% for study wounds vs. 29% for control and not statistic significant. Proportion of reduction rate was 71.9% for study group vs. 9.2% for control	p = 0.29  p = 0.039	Study results strongly support safety and effectiveness of platelet gel in addition to standard care as a means for accelerating the healing process.	

### *Randomized Controlled Trials*

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<b><i>SURG CV / Open Cutaneous (R-3)</i></b>	Autologous platelet gel application during cardiovascular surgery; effect on wound healing	Englert SJ, Estep TH, Ellis-Stoll CC.	<u>J Extra Corpor Technol.</u> 2005 Jun;37(2): 148-52	Prospective randomized control (pilot) trial	N = 30	Patients who underwent cardiopulmonary bypass with a sternal incision. Age: 30 – 85 years Autologous PRP used.	Subject reports of chest and leg pain, the amount of measurable bruising and platelet indices for 30 days postoperatively	Overall the experimental APG group reported less chest and leg pain than control during all measurement times.	NS	Study found support that chest and leg pain were decreased in experimental group and had less bruising, though not statistically substantiated	Med-tronic / Magellan APSS
<b><i>SURG MAXFA / Soft &amp; Bone (R-4)</i></b>	A comparative study of bilateral sinus lifts performed with PRP alone vs. alloplastic graft material reconstituted with blood.	Steigmann M, Garg AK	<u>Implant Dent.</u> 2005 Sep;14(3):26 1-6	Randomized controlled trial	N = 20	Patients requiring sinus augmentation with crestal bone height of 7 - 9 mm.  Autologous PRP used.	Radiographic comparison of alveolar bone growth at 6 month post-operatively.	Results indicate that using PRP alone in cases with > 7mm residual crest can produce bone growth.  The results seem to indicate that a higher percent of new bone formation occurs where only PRP was used because no resorption of graft material is required.		The use of PRP alone in appropriate sinus lift cases can produce bone growth and minimize the potential for residual graft material	Harvest Tech / Smart Prep

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Type of Study / Tissue (Ref #)	Title	Author	Citation	Study Design	Patient Sample Size	Sample Characteristics	Endpoints	Results	Stat. Sig.	Conclusions	Co./ Centri-fuge
<b>SURG MAXFA Soft &amp; Bone (R-5)</b>	Evaluation of the adjunctive benefits of PRP in subantral sinus augmentation	Kassolis JD, Reynolds MA	<u>J Craniofac Surg.</u> 2005 Mar;16(2):280-7	Randomized, control clinical trial	N = 10	Patients indicated for bilateral sinus augmentation treated with freeze-dried bone (FDBA) or FDBA plus PRP.  Autologous PRP used.	Histomorphometry of bone formation after 4.5 to 6 months post grafting procedure	Percentage (78.8%) of vital tissue (bone and connective) after treatment with FDBA and PRP was significantly higher.  The percentage (33.3%) of vital bone formation with PRP was non-significantly higher than FDBA alone.	p = 0.01  p < 0.10	Study results suggest that combination of FDBA and PRP enhances the rate of bone formation compared to FDBA and membrane for antral sinus augmentation	Harvest Tech / Smart-Prep

***Randomized Controlled Trials***

<b>Type of Study / Tissue (Ref #)</b>	<b>Title</b>	<b>Author</b>	<b>Citation</b>	<b>Study Design</b>	<b>Patient Sample Size</b>	<b>Sample Characteristics</b>	<b>Endpoints</b>	<b>Results</b>	<b>Stat. Sig.</b>	<b>Conclusions</b>	<b>Co./ Centri-fuge</b>
<b><i>SURG ORTHO Soft &amp; Bone (R-6)</i></b>	Evaluation of bone healing enhancement by lyophilized bone grafts supplemented with platelet gel	Savarino L, Cenni E, Tarabusi C, Dallari D, et.al	<u>J Biomed Mater Res B Appl Biomater.</u> 2006 Feb; 76(2):364-72	Randomized control trial to standardize in vivo model and lab methodology	N = 10	Patients undergoing high tibial osteotomy for genu valgus. Age: 25 – 61 years Autologous PRP used.	Semi-quantitative evaluation of osteogenic and angiogenic processes after 6 weeks post-operative to knee surgery	Microradiography- Study group reached a degree of mineralization similar to that of host bone. Histomorphometric- Study group results demonstrated an active osteogenetic process in comparison to control group.	p < 0.05	Lyophilized bone with platelet gel seems to accelerate the healing process as shown by deposition of newly formed bone	

***Non-Randomized Controlled Studies***

Type of Study / Tissue (Ref #)	Title	Author	Citation	Study Design	Patient Sample Size	Sample Characteristics	Endpoints	Results	Stat. Sig.	Conclusions	Co./ Centri-fuge
<b><i>CHRW / Chronic Wound (C-1)</i></b>	The use of autologous platelet gel to treat difficult to heal wound	Mazzucco L, Medici D, Serra M Panizza R, Rivara, Orecchia S, Libener R, et.al	<u>Transfusion.</u> 2004 Jul;44(7):101 3-8	Non-randomized controlled trial	N = 53 Dehiscence sternal wound- (22) Necrotic skin ulcers (Stage III & IV venous, arteriopathic & pressure ulcers (31)	Patients with dehiscent sternal wounds and necrotic skin ulcers presenting between Jan and Dec 2002. Retrospective comparison to patients with conventional treatment. Age (mean): 64 ± 8 years – PG 66 ± 5 years - Control Autologous PRP used.	Sternal wounds: time required for complete healing and total hospital length of stay Severe necrotic wounds: time required to have surgery from the beginning of treatment	Dehiscence sternal wound: healing rate- 3.5 vs. 6.0 week Hospital stay- 31.5 vs. 52.5 day Necrotic skin ulcers: time to surgery- 15.0 vs. 35.5 weeks	p = 0.0002 p < 0.0001  p < 0.0001	Patients with chronic unhealing wounds showed substantial improvement when treated with platelet gel lesion dressings.	

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<b><i>SURG/CV / Open Cutaneous C-2)</i></b>	Use of platelet gel (PG) and its effects on infection in cardiac surgery	Trowbridge CC, Stammers AH, Woods E, et.al.	<u>J Extra Corpor Technol.</u> 2005 Dec;37 (4):381-6	Non randomized controlled trial	N = 2259 (PG 382, HC 929, NoPG 948)	Patients (> 19 yrs) under going cardiac surgery from Oct 2002 to Jun 2005. Comparison to historical control (HC). Sternal incisions/harvest sites  Age (mean): HC- 65 years PG- 64 years NoPG- 64 years  Autologous PRP used.	Incidence of superficial and deep sternal wound infections	Superficial wd-PG-0.3%, NoPG-1.8%, HC- 1.5% Deep sternal wd-PG-0.0%, NoPG-1.5%, HC- 1.7%	p < 0.05  p < 0.029	Application of PG seems to confer a level of protection against infection	Smart Prep II-Harvest Angel PSD-Cobe, CATS-Terumo

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<b><i>OPCUT</i></b> <b><i>Normal tissue-Full thickness Punch Wds</i></b>  ( C-3 )	Healing effects of autologous platelet gel on acute human skin wounds	Hom DB, Linzie BM, Huang TC	Arch Facial Plast Surg 2007; 9:174-183	Prospective, single-blind, pilot study	N = 80 wounds	Healthy subjects (8)	Healing of wound, time for complete wound closure up to 42 days post-acute punch wound and endothelial cell proliferation.	Over a 42-day period, APG-treated sites and increased wound closure compared to control.  APG wound closure velocity was significantly higher than for the controls.  Supplemental APG showed increased endothelial cell proliferation compared with controls.	( p ≤ 0.02)  (P = 0.001)  (P < 0.04)	Pilot study provides prelim evidence that topical APG may hasten wound closure	Medtronic / Magellan APS

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<b><i>SURG ORTHO / Soft Tissue (C-4)</i></b>	Platelet gel and fibrin sealant reduce allogeneic blood transfusion in TKA	Everts PA, Devilee RJ, Brown Mahoney C, et.al.	<u>Acta Anaesthesiol Scand</u> , 2006 May;50(5):59 3-9	Non randomized control study to evaluate the hemostatic efficacy of sealing tissues, vessels and lymphatics.	N = 165 (Study 85, Control - 80)	Patients with osteoarthritis of the knee scheduled for primary unilateral total knee surgery.  Age: PG- 69.4 ± 9.1 years Control- 67.4 ± 9.9 years Autologous PRP used.	Mean hemoglobin values pre-op through day 4 post-op. Incidence of wound leakage & wound healing disturbances Length of stay	Patients in study group had significantly higher post-op hemoglobin level and a decreased need for allogeneic blood products than those of the control group. Incidence of wound leakage & wound healing disturbances were significantly less in study group. Hospital stay decreased by 1.4 +/- 1.5 days in the treatment group.	p < 0.001  p < 0.001	Peri-operatively applied platelet gel and fibrin sealant may reduce the incident of allogeneic blood transfusions and complications associated with TKA	Sorin Group / Electa

***Additional Published Studies***

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<b><i>SURG MAXFA / Soft &amp; Bone (A-1)</i></b>	Maxillary sinus augmentation with anorganic bovine bone (Bio-Oss) and autologous PRP	Maiorana C, Sommariva L, Brivio P, Sigurta D, Santoro F.	<u>Int J Periodontics Restorative Dent.</u> 2003 Jun;23(3):227-35.	Consecutive case series-preliminary clinical and histologic evaluations	N = 10	Patients (mean age 52.5 yrs) with posterior maxillary bone atrophy, indicated for bone augmentation.  Autologous PRP used.	Patients' grafting procedure were evaluated clinically, histologically and by radiographs at 6 months post-op.	Histomorphometric results on two cases confirmed the proceeding bone regeneration process.  Radiographically the results indicated volumetric stability of the graft		Clinical and histologic results confirmed the effectiveness of the combination of PRP and Bio-Oss as a grafting material for sinus augmentation procedures.	JOUAN / KR 4-22

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<b><i>SURG MAXFA / Soft &amp; Bone (A-2)</i></b>	PRP (platelet gel) in secondary alveoloplasty in cleft patients {Spanish}	Mendez R, Lopez-Cedrun J, Patino B, et.al.	<u>Cir Pediatr</u> 2006 Jan;19(1):23-6	Consecutive case series	N = 14	Patients with congenital alveolar cleft and indicated for secondary alveoloplasty.  Age: 5 – 12 years Autologous PRP used.	Pain, edema, bleeding were evaluated at 3, 7 and 15 days post-op and radiographic bone density at 3 and 6 mo post-op.	The injury of the alveoloplasty healed more quickly in study patients than controls as well as less pain and edema in the 1 <sup>st</sup> days of post-op period.  At 3 mo, study patients had faster alveolar bony regeneration than controls, but similar at 6 months from intraoral radiographic evidence.	p > 0.001	Use of PRP is a valid protocol for reconstruction of congenital alveolar clefts.	

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<b><i>SURG MAXFA / Soft Tissue (A-3)</i></b>	Platelet gel for endoscopic sinus surgery	Pomerantz J, Dutton JM.	<u>Ann Otol Rhinol Laryngol.</u> 2005 Sep;114(9):699-704	Retrospective cohort study	N = 32 (Study-16, Ctl - - - 16 )	Endoscopic sinus surgery patients, between Oct 2002 and March 2003, received platelet gel for sinus packing. Age (mean): 43.7 years Autologous PRP used.	Changes to the pre-op and post-op scores of Quality of Life (QOL) surveys completed by patients.	Platelet gel group had improved QOL scores over the control group	Not statistically significant	Patient quality of life may be improved by the use of platelet gel packing. Platelet gel offers efficient hemostatic properties as well as growth factors to advance the healing process.	Medtronic / Magellan

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<b><i>SURG ORTHO / Soft &amp; Bone (A-4)</i></b>	Platelet gel (AGF) fails to increase fusion rates in instrumented posterolateral fusions	Carreon LY, Glassman SD, et.al.	<u>Spine</u> 2005 May 1; 30(9):E243-6	Retrospective, consecutive series	N = 152 (Study group- 76)	Consecutive patients (mean age of 50.6yrs) with degenerative conditions of the lumbar spine from Jan 2000 to Dec 2001. Age (mean): AGF- 50.6 years Control- 49.9 years Autologous PRP used.	Incidence of non-union based on radiographic evidence or surgical exploration.	AGF- 19 of 76 (25%) of nonunion  Control- 13 of 76 (17%) of nonunion	p = 0.18	Platelet gel failed to enhance fusion rate	Inter-pore Cross International /

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<b><i>SURG ORTHO / Soft &amp; Bone (A-5)</i></b>	Role of activated growth factors in lumbar spinal fusions	Castro, FP	<u>J Spinal Disord Tech</u> , 2004 Oct; 17(5):380-84	Retrospective, consecutive case series	N = 84 (Study group-22)	Patients indicated for transforaminal lumbar interbody fusion. Age: PG- 47 ± 2 years Control- 49 ± 1 years Autologous PRP used.	Rate of pseudoarthrosis based on radiographic exam and length of hospitalization	The pseudoarthrosis rate of the study group (64%) was not significantly different compared to the control group (45%). Length of hospitalization was equivalent between the study and control group.	p = 0.12  p = 0.78	Benefits of activated growth factors were <u>not</u> clinically appreciated	Inter-pore Cross / Ultra Concentra-tor

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<b><i>SURG ORTHO / Soft &amp; Bone (A-6)</i></b>	A prospective study of autologous growth factors (AGF) in lumbar interbody fusion	Jenis LG, Banco RJ, Kwon B.	<u>Spine J.</u> 2006 Jan-Feb; 6(1):14-20. Epub 2005 Dec 6.	Prospective cohort study	N = 37 (study group – 15)	Patients indicated for standard anterior-posterior lumbar fusion. Age: AGF- 40.3 ± 7.5 years Control- 41.4 ± 8 years Autologous PRP used.	Radiographic (CT scan at 6 mo and radiographs at 24 months) evidence and clinical outcomes, i.e., back pain.	Pain reduction ratios were similar between AGF (0.38) and control (0.36) patients. No significant differences between groups of pain relief of functional outcome.  Radiographic evaluation: AGF- 89% vs. control 85%	p > 0.05          p > 0.05	AGF combined with an allograft carrier is equivalent in radiographic and clinical outcomes to autograft in lumbar interbody fusion and eliminates iliac crest bone graft harvesting.	Inter-pore / AGF

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<b><i>SURG ORTHO / Soft &amp; Bone (A-7)</i></b>	Efficacy of platelet gel in reconstructive bone surgery	Franchini M, Dupplicato P, Ferro I, De Gironcoli M, Aldegheri R.	<u>Orthopedics.</u> 2005 Feb;28(2):161-3	Prospective, consecutive case series	N = 19	Patients (age, 15-69 yrs) undergoing reconstructive bone surgical procedures or treatment for impaired fracture repair. Age (mean): 36.3 years Autologous PRP used.	Assess the osteo-inductive effect of platelet gel based on radiographic and clinical examinations every 3 months.	Radiographs showed improved osteoblastic reaction and reconstruction. Clinical results were good with no complications. By 3-month follow-up evaluation, patients had recovered full load bearing on the operated limb.		Results demonstrate efficacy of platelet gel and cryo-precipitate in stimulating bone regeneration following reconstructive surgery.	



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<b>SURG ORTHO / Soft Tissue (A-8)</b>	The efficacy of autologous platelet gel (APG) in pain control and blood loss in TKA	Gardner MJ, Demetrikopoulos, D	<u>Intl Ortho</u> 2006 Apr27;	Retrospective cohort study	N = 98 (APG- 61 CTL- 37)	Patients who underwent TKA for end-stage osteoarthritis and consecutively treated with and without APG. Age (average): APG- 73.3years Control- 72.9 years Autologous PRP used.	Evaluation of clinical parameters: discharge ROM, hemoglobin at day 3 post op, quantity of pain medication and length of hospital stay	<p>Patients receiving APG had a smaller decrease (2.68 vs. 3.16 g/dl) in post-op hemoglobin. Functional ROM achieved at discharge was greater (78.2% vs. 71.9) in APG-treated patient.</p> <p>Patients with APG were discharged earlier (4.04 vs. 5.29 days) than control.</p> <p>The platelet gel group required less intravenous (17.0 vs. 36.3 mg/da) and oral (1.84 vs. 2.75 tabs/da.) medications.</p>	<p>p = 0.026</p> <p>p = 0.052</p> <p>p = 0.002</p> <p>p = 0.024</p> <p>p = 0.063</p>	Application of APG may have substantial benefits in patients undergoing TKA	Medtronic / Sequestra 100 Auto-transfusion